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COVER NOTE

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Subject:	COMMISSION STAFF WORKING DOCUMENT INTERIM EVALUATION of HORIZON 2020 ANNEX 2

Delegations will find attached document SWD(2017) 221 final - PART 14/16.

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PART 14/16

COMMISSION STAFF WORKING DOCUMENT

INTERIM EVALUATION
of
HORIZON 2020

ANNEX 2

{SWD(2017) 220 final}
{SWD(2017) 222 final}

J. HEALTH DEMOGRAPHIC CHANGE AND WELL-BEING

J.1. INTRODUCTION

J.1.1. Context

In this exercise, SC1 is assessed against the criteria of relevance, efficiency, efficacy, coherence and EU added-value. It makes use of the data available on the programme's implementation by 1 January 2017 (essentially input data extracted from the CORDA database) as well as the assessment by the staff implementing SC1 (management and project officers). It is also informed by preliminary results of a limited number of projects, opinions expressed by stakeholders and studies performed on Horizon 2020. It exploits, when relevant, evidence from past framework programmes. However, it cannot consider outputs and impacts given the early state of programme implementation.

In the impact assessment accompanying its Horizon 2020 proposal, the Commission underlined the insufficient contribution of research and innovation to tackling societal challenges and pointed to *still relatively weak coordinated response at a pan-European level* [to many major societal challenges] *in the field of science and innovation,* [underlining the] *danger of missing important opportunities for generating scale and interactions*[1]".

The Horizon 2020 decision listed the challenges to address (see section 4.1.1) and highlighted the need for excellence in research (with long-term and coordinated support for co-operation between excellent, multidisciplinary and multi-sector teams) and for a seamless and widespread translation of the resulting and existing knowledge into innovative, scalable, effective, accessible and safe products, strategies, interventions and services. It mentioned the demand for a European level response when addressing the need to understand the molecular basis of disease, identifying innovative therapeutic strategies and novel model systems, applying multidisciplinary knowledge, developing long-term cohorts, conducting clinical trials, using "-omics" (in clinical practice), systems biomedicine and developing e-health. Finally, it stressed that the requirements of specific populations are best addressed in an integrated manner, for example in the development of stratified and/or personalised medicine, in the treatment of rare diseases, and in providing assisted and independent living solutions.

J.1.2. Objectives and intervention logic

As best summarised in the Horizon 2020 Monitoring report 2015, *the main objective of the SC1 actions is to support health R&I from bench to bedside for translating science to benefit citizens and European healthcare sector; to ensure the rapid transfer of knowledge and innovative solutions into prevention, diagnosis, treatment modalities and healthcare in Europe and around the globe; and to promote healthy and active ageing. In doing so SC1 contributes to the broader objectives of ensuring better health for all and a more competitive health and care sector.* More precisely, as detailed in the Horizon 2020 decision, it aims at:

[1] *Commission Staff Working Paper, Impact Assessment accompanying the Communication from the Commission 'Horizon 2020 - The Framework Programme for Research and Innovation'.*
http://ec.europa.eu/research/horizon2020/pdf/proposals/horizon_2020_impact_assessment_report.pdf

- **Effective health promotion,** supported by a robust evidence base, to prevent disease and contribute to wellbeing and cost-effectiveness.
- **Successful efforts to prevent, detect early, manage, treat and cure disease, disability, frailty and reduced functionality**, underpinned by the fundamental understanding of their determinants and causes, processes and impacts, as well as factors underlying good health and wellbeing.
- **A comprehensive approach towards poverty-related and neglected diseases**, the need of which is underlined by the resurgence of old infectious diseases, including tuberculosis, and the increased prevalence of vaccine- preventable diseases. Likewise, the growing problem of AMR demands a similarly comprehensive approach.
- **Personalised medicine** (PM) to be developed, in order to suit preventive and therapeutic approaches to patient requirements, and underpinned by the early detection of disease.

To this aim, SC1 was broken down into the following broad lines of activities:

1. **Understanding health, wellbeing and disease** (1. Understanding the determinants of health, improving health promotion and disease prevention; 2. Understanding disease; 3. Improving surveillance and preparedness)
2. **Preventing disease** (1. Developing effective prevention and screening programmes and improving the assessment of disease susceptibility; 2. Improving diagnosis and prognosis; 3. Developing better preventive and therapeutic vaccines)
3. **Treating and managing disease** (1. Treating disease, including developing regenerative medicine; 2. Transferring knowledge to clinical practice and scalable innovation actions).
4. **Active ageing and self-management of health** (1. Active ageing and independent and assisted living; 2. Individual awareness and empowerment for self-management of health).
5. **Methods and data (**1.Improving health information and better use of health data; 2. Improving scientific tools and methods to support policy making and regulatory needs; 3. Using *in-silico* medicine for improving disease management and prediction)
6. **Health care provision and integrated care** (1. Promoting integrated care; 2. Optimising the efficiency and effectiveness of healthcare provision and reducing inequalities by evidence-based decision making and dissemination of best practice, and innovative technologies and approaches)

All of these activities are meant to provide support throughout the research and innovation cycle, strengthening the competitiveness of the Europe-based industries and the development of new market opportunities. Emphasis is placed on engaging all health stakeholders – including patients' and users' organisations, and health and care providers – in order to develop a research and innovation agenda that actively involves citizens and reflects their needs and expectations.

The Specific Programme added, notably, that *emerging epidemics, re- emerging infectious diseases as well as the threat of increasing anti-microbial resistance would be addressed,* [together with the development of PM] *in order to suit preventive and therapeutic approaches*

to patient requirements. In addition, *support* [would] *be given to translational approaches that integrate several steps of the innovation process in the health care industry*[2].

Accordingly, priorities in the **bi-annual WP's** 2014-2015 and 2016-2017 were structured in three broad lines of activities aiming at i) Personalising health and care; ii) Coordinating health activities at EU level and, iii) Providing targeted support to SMEs activities.

To address its objectives, SC1 relies on a comprehensive **set of instruments** covering the whole innovation cycle. SC1 supports multidisciplinary and translational approaches, aiming at the integration of new knowledge generated in pre-clinical, clinical and public health settings. It takes advantage of all Horizon 2020 instruments: RIA's, Innovation Actions (IA) and Coordination and Support Actions (CSA), Innovation Procurement (Pre-Commercial Procurement, PCP, and Public Procurement of Innovative Solutions, PPI), SME-instrument, public-public partnerships (ERA-NET Cofund, European Joint Programme Cofund, and Article 185 TFEU[3]), public-private partnerships (Article 187 TFEU), prizes and loans (InnovFin Infectious Diseases).

The SC1 specific objectives aim to contribute to the Horizon 2020 general objectives by increasing the effectiveness of research and innovation in responding to key societal challenges by supporting excellent research and innovation activities. Its activities, implemented along a challenge-based approach, bring together resources and knowledge across different fields, technologies and disciplines. Social sciences and humanities research is seen as an important element for addressing these challenges. The activities cover the full range of research and innovation, including innovation-related activities such as piloting, demonstration, test-beds, and support for public procurement, pre-normative research and standard-setting, and market uptake of innovations. The activities support directly the corresponding Health and Innovation policy competences at Union level, where appropriate. SC1 also aim to contribute to the overarching objective of sustainable development.

The objectives of SC1 have slightly evolved over time during its three first years. Although SC1 implementation has ensured the continuity of the core objectives of the challenge (e.g. PM, healthy ageing, etc.) the programme over time incorporated new areas where R&I was considered essential to inform urgent health policy needs/decisions. These includes public health emergencies for instance Ebola, ZIKA, migration and health, but also tobacco-smoking or maternal health. WP's and calls have also been taking into account specific challenges, opportunities or EU policy developments over time, such as the Juncker Package, the Digital Single Market, the Silver Economy and e-health policies. Collaboration with Members States and Associated Countries on setting research priorities was further strengthened and R&I collaboration deepened, in areas such as rare diseases or PM. New initiatives were launched to bring in new innovations such as the Infectious Disease Finance Facility and Inducement prizes.

The comparison with the objectives of FP7-Health, SC1's predecessor, shows a degree of continuity in targeting societal challenges, fostering the translational research aspect and the emphasis on close-to-market research and health outcomes as well as industry-driven research. No specific area of FP7-Health has been transferred to another area within Horizon 2020. The inclusion of innovation in addition to R&D stages provides for better continuity of

[2] https://erc.europa.eu/sites/default/files/document/file/Specific%20Programme%20Horizon%202020_council_decision_establishing_the_specific_programme_implementing_Horizon_2020.pdf
[3] Treaty on the Functioning of the European Union

support for the whole innovation cycle, including links with relevant EU policies (Health, Digital single market). Among several other examples of continuity, SC1 further tackles the reduction of health inequalities; it continues the work on rare diseases research and builds on the pioneer PM work of FP7 to take it to the next level. It also further capitalises on proven assets such as international collaborations with other funding agencies on global health issues.

As compared to FP7-Health, **some new areas emerged in Horizon 2020 SC1.**

1) In addition to the inclusion of **demographic change dimension**, and as opposed to FP7-Health, SC1 largely encompasses major health-related areas such as ***e-health*** and ***Environment & Health***[4], which were dealt with under other schemes in past Framework Programmes (FP's).
2) **The challenge-based approach** produces more diversity in submitted proposals. This approach, closer to a bottom-up one, with some very open, non-prescriptive, topics enables specific research ideas to stem from the research world, with an increased potential for innovation whereas some relevant areas could have been inadvertently overlooked in the past. Researchers from most disciplines have a chance to participate to a substantial number of topics.
3) **Stronger emphasis on major partnerships:** While, under the Health theme, a first Art. 185 initiatives was introduced with EDCTP under FP6, and a first Joint Undertaking, IMI under FP7, SC1 combines the renewal of both actions under Horizon 2020, both with a substantial budget increase, together with a renewed AAL Art 185, continuous support to the EIP on Active and Healthy Ageing and to the major international partnerships/consortia developed under FP7-Health. A much larger share of the EU funding is thus allocated to R&I themes developed with-and co-funded by- major partners and stakeholders.

From the start, SC1 presented a major focus on **Personalised medicine (PM)**, the development of which being such a broad challenge, in size and scope, that only the Commission could initiate it.

With the dismissal of the disease-centred approach (as Horizon 2020 was formulated in terms of challenges), **a more horizontal focus** was adopted, favouring multidisciplinary research and silos removal. In addition, the programme has reinforced clinical and public health research and added the implementation research component, which will facilitate the final uptake of R&I in clinical routine practice. The focused effort on **clinical trials** proof of concept and **comparative effectiveness studies**, with an accent on health economics is also a novelty. The march downstream – particularly to clinical research – is one of the main changes.

The addition of new **Innovation instruments** reflects the new dual nature of the FP**:** in addition to the SME-instrument and the fast-track to innovation, to which SC1 contributes, SC1 also introduced inducement prizes (see under section 5.4.2.3), building on a pilot tested at the end of FP7**.** Another major novelty is the contribution in 2016 of EUR 50 million to the Infectious Diseases Financing Facility scheme (InnovFin ID), following the successful initial pilot funding in 2015 by InnovFin FP7 surplus (EUR 100 million). This contribution will be continued in 2017.

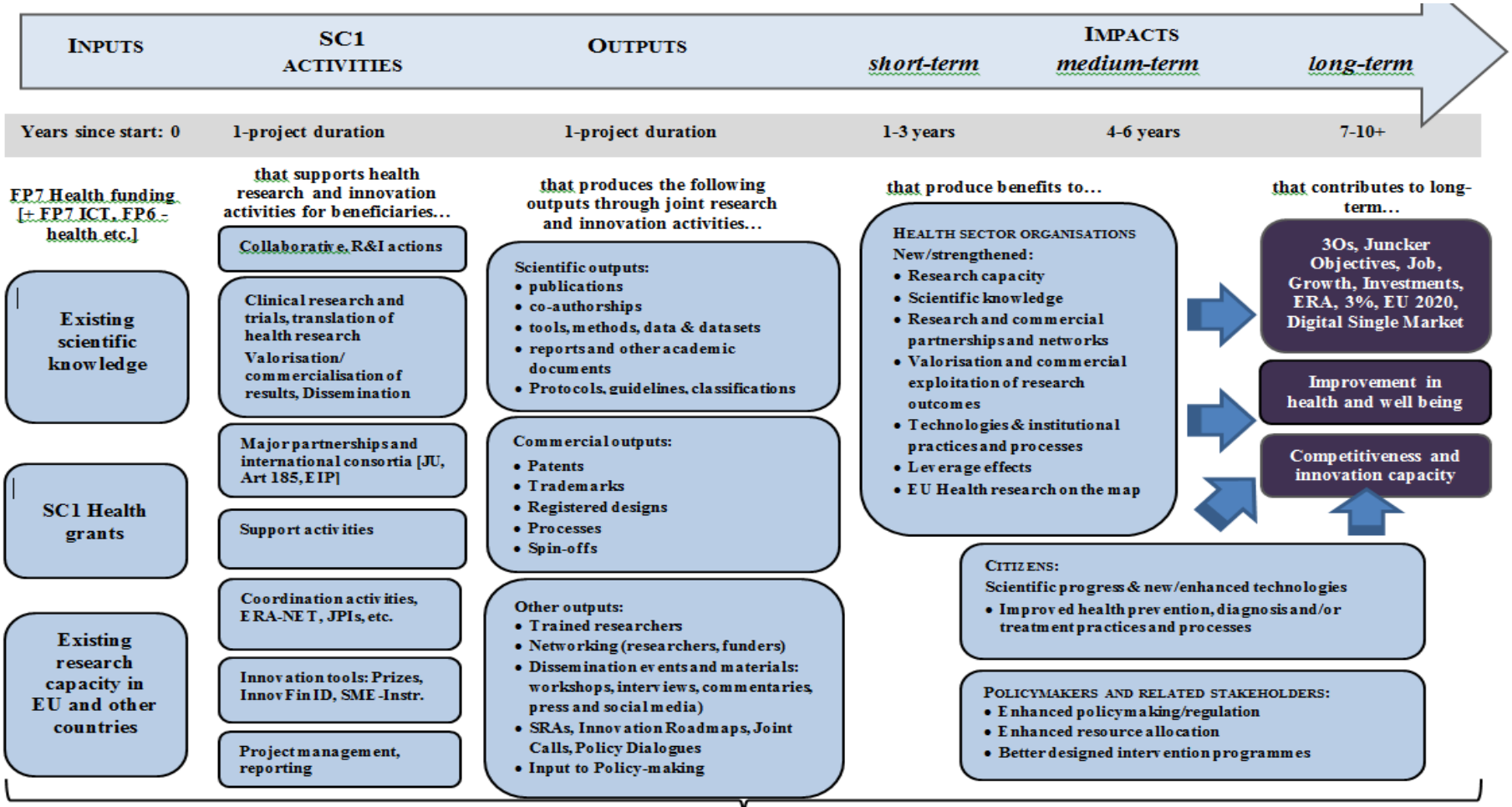
[4] *In line with the Expert group report recommendations on the future of health research in Europe, DG RTD, June 2011. http://ec.europa.eu/research/health/pdf/impact-assessment-of-health-research-projects-on-research-2002-2010_en.pdf*

The integration of **Social Sciences and Humanities**, which is no longer a dedicated scheme under Horizon 2020, requires the identification of the best topics with potential SSH integration.

To address the identified objectives, SC1 has adopted the **intervention logic** presented in Figure 1. As stated earlier, the overall objective of SC1 is to contribute to ensuring better health for all and a more competitive health and care sector. The figures that show the interrelationship between the strategic objectives of the Health theme and the inputs, outputs, impacts that lead to the realisation of these goals. The outlined inputs, outputs and impacts can be broadly described as follows:

- **Inputs** are defined as direct contributions of EU funding and existing knowledge base and infrastructure which lead to the realisation of R&I activities.
- **Outputs** are defined as direct products of the funded activities and relate to the operational objectives of health R&I projects. Outputs are differentiated into three categories, including scientific, commercial and other outputs.
- **Impacts** are defined as the extent to which SC1 R&I funding contributes to the observed changes: Improvement in health and wellbeing, Competitiveness and innovation capacity and other relevant policy objectives and strategies. Depending on the type of impact, the realisation of health R&I impacts can take place very shortly after the beginning of research activities (about 1-3 years), in the medium-term (about 4-6 years) or in the long-term (about 7-15+ years).

Figure 193 - Intervention logic of Horizon 2020 – SC1 Health, demographic change and well-being



Cross-cutting issues: child health, the health of ageing population, gender-related health issues, gender aspects in research, clinical research and innovative clinical trials, SME-relevant research, international cooperation, SSH, climate change, sustainable development
Externalities : Socio-economic conditions affecting the availability of funding at EU, national, regional, local level (public and private), Epidemics, MS policy, legislation and/or regulatory framework, International agreements (such as UN's 2030 Sustainable Development Goals)
Source: adapted from the intervention logic of FP7-Health as presented by PPMI.

J.2. IMPLEMENTATION STATE OF PLAY

The Commission services implement SC1, like the other Horizon 2020 Societal Challenges mainly through calls for proposals outlined in multiannual WP's (2014-2015, 2016-2017, and 2018-2020 in preparation). In addition, SC1 also contributes to the Innovative Medicines Initiative Joint Undertaking (IMI2), the EDCTP2 and AAL2 Art. 185 initiatives, the InnovFin ID scheme and the Human Frontier Science Programme.

J.2.1. Overview of programme inputs and activities

As of 1 January 2017, the state of play is the following:

The EC contribution allocated to the implementation of the calls included in WP's 2014-2016 has been EUR 1.55 billion, about 21% of total expected budget allocated to SC1 in Horizon 2020[5], which is EUR 7.472 billion for the period 2014-2020 (including roughly EUR 3 850 million for collaborative calls).

Through the Horizon 2020 WP's 2014-2017, each line of activity was allocated a share of the overall budget of SC1 in Horizon 2020, as indicated in table 1.

A part of this budget was allocated through calls implemented in the SME instrument WP's.

Table 118 - Activities and allocated share of budget dedicated to SC1 for the programming period 2014-2017

Activities in the legal basis	Allocated share of thematic budget [excluding IMI, EDCTP, AAL, the SME-Instrument, and project funding specific implementation aspects (ERA-NETs, CSA, etc.)
Understanding health, wellbeing and disease	16.5%
Preventing disease	16.5%
Treating and managing disease	40%
Active ageing and self-management of health	13%
Methods and data	7%
Health care provision and integrated care	7%

Source: SC1 work-programmes 2014 to 2017.

At the time of this interim evaluation, on 1 January 2017, no project is completed, 281 are ongoing, none are abandoned.[6] The programme has so far been implemented mainly through RIAs (237 projects, 90% of the funding), CSA's (29 projects, 2.5% of the funding), ERA-Net Co-funds (7 projects, 3% of the funding) and PCP / PPI CO-funds (4 projects, 0.4% of the funding).

[5] *This includes all 2014-2015 calls and part of the 2016 completed calls from the 2016-2017 WP.*
[6] *Excluding IMI and the SME instrument*

25% of the EC contribution is so far concentrated on projects addressing at least TRL7 (the TRL assessed being the one at the beginning of the project)[7].

Table 119 presents the success rate of the main calls (the ones for which over 100 proposals were received).[8]

Table 119 - Participation and success rates of SC1 calls

Proposal Call Id	Eligible Proposals	Quality Proposals	Retained Proposals	Success Rate Proposals
Horizon 2020-PHC-2014-single-stage	438	127	37	8.4%
Horizon 2020-PHC-2014-two-stage	605	182	62	10.2%
Horizon 2020-PHC-2015-single-stage	624	116	27	4.3%
Horizon 2020-PHC-2015-two-stage	484	171	49	10.1%
Horizon 2020-SC1-2016-CNECT	100	30	16	16%
Horizon 2020-SC1-2016-RTD	369	147	39	10.6%
Total [except JU's and SMEs)]	2 827	839	265	9.4%
Horizon 2020-SMEINST-1-2014	553	77	77	13.9%
Horizon 2020-SMEINST-1-2015	653	121	88	13.5%
Horizon 2020-SMEINST-1-2016-2017	1200	277	103	8.6%
Horizon 2020-SMEINST-2-2014	168	67	19	11.3%
Horizon 2020-SMEINST-2-2015	568	287	12	2.1%
Horizon 2020-SMEINST-2-2016-2017	480	250	24	5.1%
Total SME Instrument	3 622	1 079	323	8.9%
TOTAL OVERALL	6 449	1 918	588	9.1%

Source: CORDA data, 1 January 2017.

Table 120 details data on the number of projects and the funding provided by instruments.

[7] *Percentage estimated on a sample of 119 projects (52%) for which the project of the TRL Level at the beginning of the project was estimated by the project officer.*
[8] *Complete data is to be found under the Monitoring report 2015.*

Table 120 - Key data on signed grants per type of action (SME instrument & IMI excluded) for SC1: number, EC contribution

INSTRUMENT	Nr of Signed Grants	EC Contribution to Projects (€ million)	Participant Total Costs in Signed Grants	Average Project Costs in Signed Grants (€ million)	Average Project EC Contribution to Signed Grants (€ million) and % of total costs
COFUND-EJP	**1**	**49.9**	**74.1**	**74.1**	**49.9 (67%)**
COFUND-PCP	**6**	**22.2**	**26.4**	**4.4**	**3.7 [72 %]**
COFUND-PPI	**2**	**5.4**	**17**	**8.5**	**2.7 [32 %]**
CSA	**29**	**38.7**	**41.0**	**1.4**	**1.3 [94 %]**
ERANET-Cofund	**7**	**48.0**	**155.4**	**22.2**	**6.9 [31 %]**
IA	**4**	**13.6**	**15.2**	**3.8**	**3.4 [89 %]**
RIA	**237**	**1 380**	**1522**	**6.4**	**5.8 [91 %]**
TOTAL / average	**281**	**1 536**	**1820**	**6.5**	**5.5 [84 %]**

Source: CORDA, 1 January 2017.

The budget was allocated through 62 topics included in 13 closed calls for proposals on the date of 1 January 2017, all of which are covered by at least one contract.

Table 121 - Data on signed grants per type of action for SC1 (excl. SME-instr; & IMI): time-to-grant

INSTRUMENT	Nr of Signed Grants per € 10 million	Average TTG in Days	Nr of Grants within 8 months(total)	Share of Signed within Benchmark against all Selected
COFUND-PCP	3.6	231	6 (6)	100.0%
COFUND-PPI	12.5	232	2 (2)	100.0%
COFUND-EJP	0.2	240	1(1)	100.0%
CSA	7.2	223	24 (29)	100.0%
ERA-NET-Cofund	1.5	211	7(7)	100.0%
Innovation Actions	2.9	319	1 (4)	25.0%
R&I Action	1.7	239	223 (232)	96.1%
SME-1	200	107	238 (238)	100%
SME-2	3.4	188	40 (46)	87%
TOTAL	**3.33**	**241**	**542 (560)**	**96.8%**

Source: CORDA data, 1 January 2017, Selected Signed Grants by Type of Action.

Two-stage calls were launched in the case of SC1 calls in activity Personalised Health & Care in 2014 and 2015, with a success rate of respectively 8.4 % and 10.1 %.

J.2.2. Participation patterns

A total number of 285 projects have been selected by 1 January 2017. **Ethics screening** was performed for early detection of possible issues and problems.

In 2014-2016, the participation in the SC1 actions through the above calls resulted in **5644** eligible proposals, of which **2820** through the SME-instrument. The cumulative amount of EU contribution requested under these proposals was EUR **17 453 billion**, which represents more than ten times the SC1 budget estimated in the WPs. After evaluation, **1687** proposals (of which **845** from the SME instrument) scored above threshold.

Table 122 - Participation and success rates

Proposal Call Id	Eligible Proposals	Quality Proposals	Retained Proposals	EC Contribution requested by Eligible Proposals (€ million)	EC Contribution to Retained Proposals (€ million)	Success Rate Proposals	Success Rate Funding
Collaborative research calls [excluding IMI and SMEs]	2 827	839	265	14 518	1 451.8	9.4%	10.0%
SME Instrument calls	3622	1079	323	3361	212.4	8.9%	4.9%

Source: CORDA data, 1 January 2017.

The number of selected projects was **588** (of which 323 from the SME-instrument). By 1 January 2017, the number of grants signed was **542** (of which 278 for the SME-instrument) amounting to a budget allocation of **EUR 1 679 million** (including 147.9 million for the SME-instrument**)**. On average, the amount of EC budget allocated per signed grant under SC1 is **EUR 3.526 million**. This data is affected by the high number of small-scale SME instrument projects (average of EUR 521 000 for projects within the SME instrument). The average size of collaborative projects excluding the SME instrument is **EUR 5.55 million**.

Compared to the overall figures of Horizon 2020, the EU financial contribution allocated to successful projects in the SC1 actions represents 7.5 % of the Horizon 2020 budget allocated to calls closed in 2014-2016 (EUR 17 253 million). The number of SC1 signed contracts is 5.1 % of the Horizon 2020 total number of signed contracts (11108).

Participation trends in SC1 show that the EU-13/EU-28 participation rate is 1 to 10.2 (9.8 %), but only 1 EUR to 29 EUR only in terms of funding. Participation from Associated and Third countries is 6.3 % and 6.8 % respectively[9], while participation from private sector, including SMEs accounts to 43 % of the participations (25% of the funding, 35% of which in the SME-instrument).

However, Horizon 2020-SC1 is not only implemented through the standard collaborative research projects, but also via a portfolio of instruments better suited to some of its objectives. By 1 January 2017:

- EUR 189 million had been committed for the IMI2 JU (15 projects)
- EUR 51.5 million had been committed for the Ambient Assisted Living (AAL2) Art 185 partnership (52 projects)
- EUR 214.8 million had been committed for the European & Developing Countries Clinical Trials Partnership (EDCTP2) Art 185 initiative (19 grants signed)[10]
- EUR 50 million had been committed for the InnovFin ID scheme
- EUR 2 million had been committed for two inducement Prizes.
- 14.6 million had been committed for the Human Frontier Science Programme.

[9] Third Countries participation remained stable at 3.4% in 2014 and 2015 while it rose from1% to 1.7% in terms of budget.

[10] *https://ec.europa.eu/research/health/pdf/infoday_2015/edctp_european_developing_countries_clinical_trials_partnership.pdf*

J.2.2.1. Participation per type of organisation

The 276 selected proposals (excluding IMI2 and the SME instrument) represent a total of 3447 participations, mobilising 1686 distinct participants. **The success rate of proposals is 9.4%** (down from 20% under FP7-Health).

Higher or Secondary Education Establishments (mainly universities) currently hold the highest percentage of total participations in Horizon 2020-SC1 (almost 40%). Research organisations follow (25 %), then Companies (20%) while other public bodies and 'others', including bodies such as patients' and users' associations, make up for the remaining 15 % of the total.

While the success rate is small (the chance of success of an applicant in a collaborative research proposal is 11.2% for collaborative research, and 8.5% for the SME-Instrument), 31% of academic institution applying actually succeed in at least one proposal, and 15% of the SMEs for the SME-Instrument.

Table 123 - Applicants, applications (number and share) and success rates per type of participant [excl. SME-instrument and IMI2) with separate data for the SME-instrument in parenthesis

TYPE of Applicant	Nr of Applications in Eligible Proposals	Share of Applications in Eligible Proposals (in Programme Part)	Nr of Applicants in Eligible Proposals	Average Applications per Applicant	Nr of Applications in Retained Proposals	Nr of Applicants in Retained Proposals	Share of Applications in Retained Proposals (in % of Programme)	Success Rate per type of applicant (applicants succeeding within at least one proposal)	Success Rate of Applications
Higher or Secondary Education Establishments	12 327 (185)	42.1% (1.2%)	1 430 (53)	8.7 (3.5)	1 268 (16)	442 (6)	38.8% (1.9%)	30.9% (11.3%)	10.3% (8.6%)
Other	1 210 (277)	4.1% (3%)	628 (149)	1.9 (1.9)	164 (18)	141 (16)	5% (2.1%)	22.5% (10.7%)	13.6% (6.5%)
Private for Profit Entities (excluding HES)	8 129 (8398)	28.0% (90.4%)	4 898 (4383)	1.7 (1.9)	684 (758)	569 (674)	21.0% (90.7%)	11.6% (15.4%)	8.4% (9.0%)
Public bodies (excluding REC and HES)	1 631 (65)	5.6% (0.7%)	553 (42)	2.9 (1.5)	347 (1)	185 (1)	10.6% (0,1%)	33.5% (2.4%)	21.3% (1.5%)
Research organisation	5 954 (363)	20.4% (4%)	1 238 (138)	4.8 (2.6)	799 (43)	385 (30)	24.5% (5.1%)	31.1% (21.7%)	13.4% (11.8%)
Total	29 251 (9288)	100.0% (100%)	8 747 (4767)	3.3 (1.9)	3 262 (836)	1 722 (727)	100.0% (100.0 %)	19.7% (15.3%)	11.2% (9.0%)

Source: CORDA data, 1 January 2017 Participants and Participations by Legal Entity.

Roughly 20% of applicants succeeded in at least one of their collaborative research proposal to date. The success rate of the 'other' category is slightly higher than the average, which indicates that the added value of including non-research performing stakeholders is more an asset than a deterrent at proposal evaluation stage.

Table 124 - EC requested contribution, EC contribution and success rates (in terms of funding) per type of participant (excluding SME-instrument and IMI2

TYPE of Applicant	EC requested Contribution in Eligible Proposals (€ million)	EC Contribution in Retained Proposals (€ million)	Success Rate (Funding)	Average EC Contribution to Applications in Retained Proposals (€ million)
Higher or Secondary Education Establishments	6 801	675.2	10.0%	0.55
Other	393	46.1	11.1%	0.3
PRC: Private for Profit Entities (excluding HES)	6921	428.4	8.5%	0.4
Public bodies (excluding REC and HES)	669	113.1	20.6%	0.3
Research organisation	3032	338.4	13.2%	0.4
Total	17816	1601.2	10.7%	0.45

Source: CORDA data, 1 January 2017 Participants and Participations by Legal Entity.

On average, the academic world receives 11% of what it requests (roughly 8% for the private sector), and a successful academic participant receives an EU contribution of EUR 400 000 to 500 000.

Table 125 - Key data on participation per type of organisation for SC1: number of participants, of project coordinators, of newcomers, of participations, and EC contribution to participations (in EUR million)

Participant Type	Nr of Participants in Signed Grants	Nr of different Projects Coordinators in Signed Grants [an institution may coordinate several projects]	Nr of Participations in Signed Grants	Average number of Participations per Participant	EC Contribution in Signed Grants (€ million)
Higher or Secondary Education Establishments	**433**	**158**	**1 369**	**3.2**	**781.7**
Other	**137**	**4**	**169**	**1.2**	**47.1**
PRC: Private for Profit Entities (excluding HES)	**564**	**27**	**704**	**1.2**	**341.0**
PUB: Public bodies (excluding REC and HES)	**173**	**17**	**354**	**2.0**	**198.7**
REC: Research organisation	**379**	**75**	**851**	**2.2**	**451.5**
Total/average	**1 686**	**281**	**3447**	**2.0**	**1 820**

Source: CORDA data, 1 January 2017, Participants and Participations by Legal Entity.

J.2.2.2. Attraction of new participants / newcomers

There are 478 newcomers (28% of the participants) in SC1– excluding the SME instrument (where there are 207, 77% of the participants), "Newcomers" being defined as Horizon 2020 beneficiaries that did not participate in FP7.

Even in collaborative projects, enterprises make up for most of the newcomers (53%, 255 participants, roughly one enterprise out of two being a newcomer). 56% of the participants from the 'other' category are newcomers, which accounts for the openness of SC1 to non research performing stakeholders. In terms of geographical distribution, the higher proportion of new participants appears amongst Third countries (42 % of their participants are new to the FP) and amongst Associated and candidate countries (38%) and EU-13 MS (28%). For the EU-15 countries, the percentage is 22%.

J.2.2.3. Geographical participation patterns

A summary of the geographical participation in SC1 is presented below. Tables 8 and 9 present the key data on applications, success and participation in SC1 according to geographical distribution excluding the SME-Instrument and IM2.

Table 126 - Participation patterns (number and shares of participations, EU contribution, and rate of success, as % of proposals submitted, and as % of budget available) per group of country for SC1

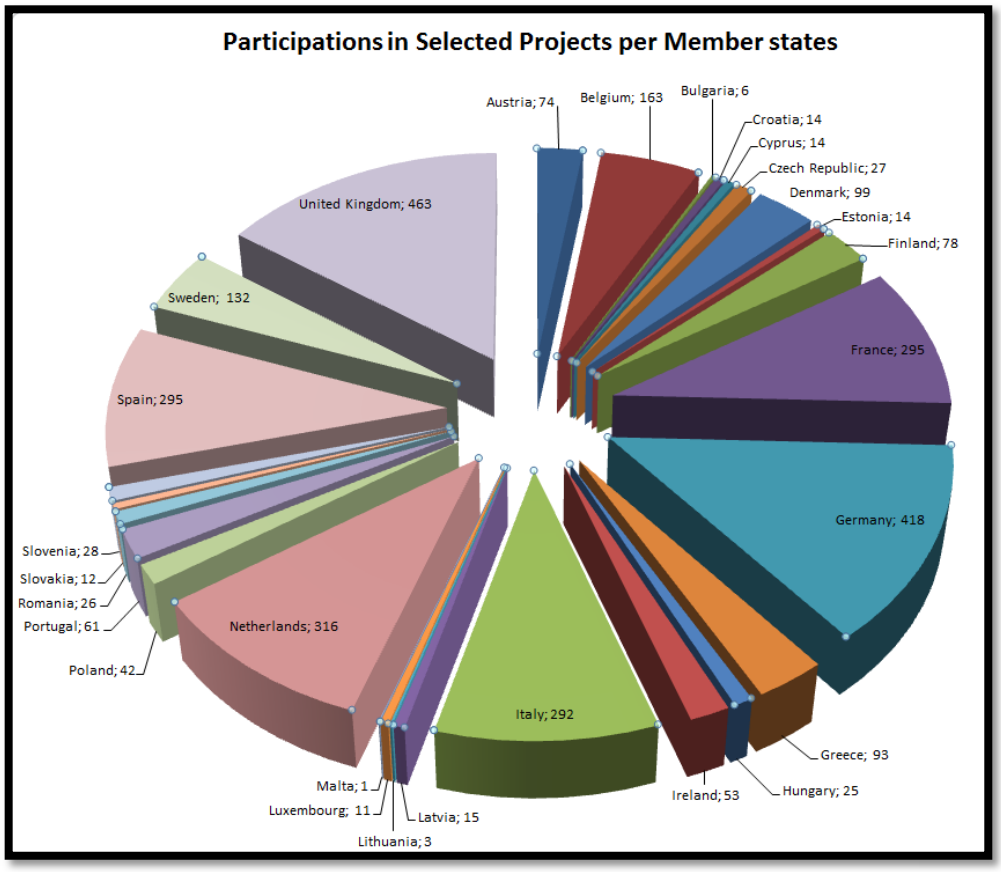
GROUP	Nr of Applications in Eligible Proposals (Nr of distinct Applicants)	Average number of Applications per Applicant	Share of Applications in Eligible Proposals	Nr of Applications in Retained Proposals (Share of Applications)	Success Rate of Applications (Success Rate of applicants)	EC Contribution requested in Eligible Proposals (€ million)	EC Contribution to applications in retained proposals in € million (Average contribution to applications)
EU-15	23 804 (6349)	3.7	81.4%	2 678 (82%)	11.3% (10.5%)	12 504.7	1 313.1 (0.5)
EU-13	2 319 (953)	2.4	7.9%	232 (7%)	10.0% (6.4%)	821.6	52.2 (0.2)
AC COUNTRIES	2 006 (705)	2.9	6.8%	199 (6%)	9.9% (5.5%)	762.3	49.4 (0.2)
THIRD COUNTRIES	1 122 (740)	1.5	3.8%	153 (5%)	13.6% (9.2%)	392.0	36.3 (0.2)
TOTAL	29 251 (8747)	3.3	100.0%	3 262 (100%)	11.2% (10%)	14 480.6	1 451.0 (0.4)

Source: CORDA data, 1 January 2017, Applicants and Applications by Country groups (excl. SME instrument and JUs).

The bulk of the EU funding goes to EU Member States (94 %) and more concretely to EU-15 countries (90.7% of the total EU contributions so far). EU-13, Associated countries and Third countries receive quite similar shares (3.2 %, 2.7 % and 2.8 % respectively).

The picture changes somewhat when the number of participations is taken as reference instead of the EU funding received. This indicator is not biased by economic factors such as the different living standards. There, one can observe that some MS are "punching above their weight", such as the Netherlands, with more participations than France, Italy or Spain.

Figure 194 - Participation in selected projects per Member States, Horizon 2020-SC1, as of 1 Jan. 2017



Source: CORDA data, 1 January 2017, Participants and Participations by Country group (excl. SME instrument and JUs).

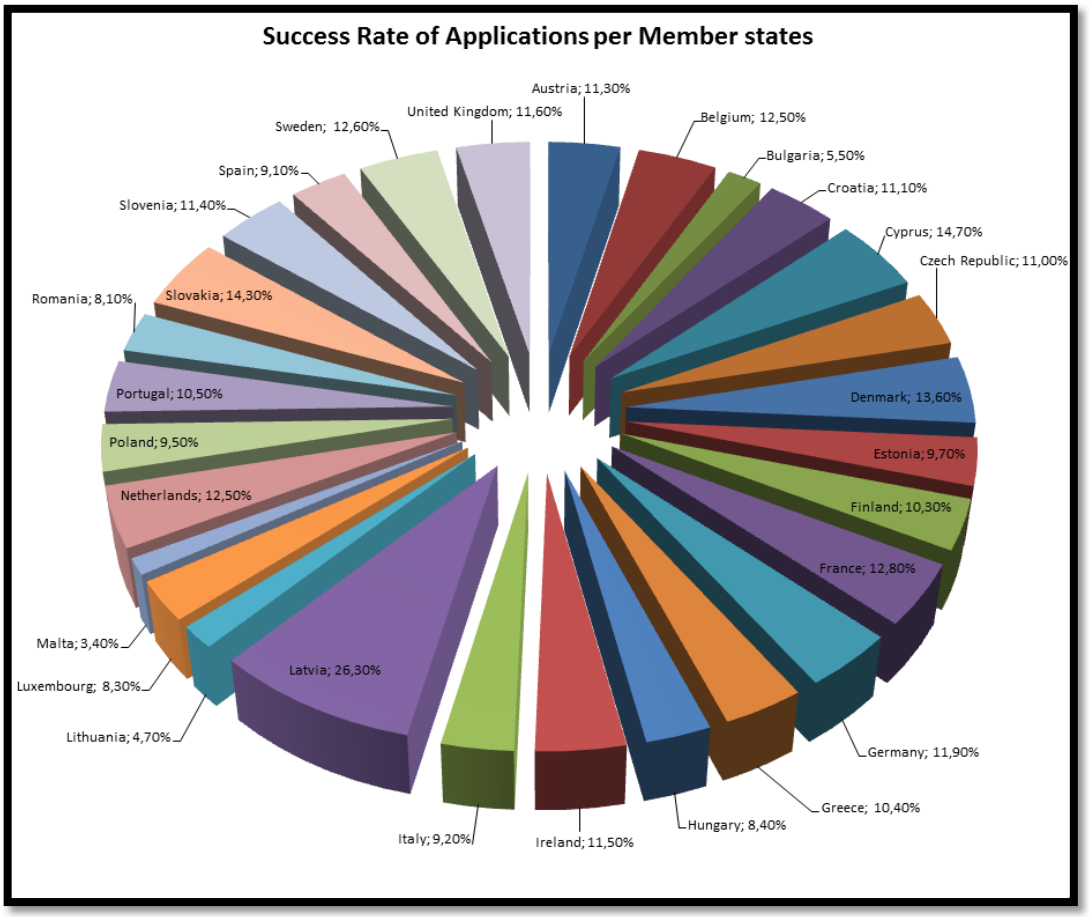
Table 127 - Geographical distribution of funding, participants and coordinators, and overall rates of success, EU-28, EU-13, EU-15, Associated countries, Third Countries

COUNTRY Group	Nr of Participants in Selected Projects	Nr of Projects Coordinators in Selected Projects	Nr of Newcomers in Selected Projects	Nr of Participations in Selected Projects [and respective %]	Average participations per Participant	EC Contribution to Participations in Selected Projects (€ million)
EU-28	1442	271	379	3051 [88.5%]	2.1	1447.8
EU-15	1289	268	338	2838[82%]	2.2	1399.6
EU-13	153	3	41	223[6.5%	1.5	48.2
ASSOC COUNTRIES	105	10	40	215 [6.3%]	2.0	46.9
THIRD COUNTRIES	139	0	59	171 [5.1%]	1.2	41.8
Total or average	**1686**	**281**	**478**	**3447 [100%]**	**2.0**	**1536.5**

Source: CORDA data, 1 January 2017, Participants and Participations by Country group (excl. SME instrument and JUs).

Table 127 shows that beneficiaries from EU-13 countries represent 6.5% of the total. This doubles their share of EC contributions (3.2 %). Similarly, the share of Associated countries and that of Third countries also increase along the same lines.

Figure 195 - Success Rate of Applications per Member States, Horizon 2020-SC1, as of 1 Oct. 2016



Source: CORDA data, 1 January 2017, Participants and Participations by Country group (excl. SME instrument and JUs).

Figure 195 depicting the success rates of applicants by Member states also reveals that teams from some EU-13 MS such as Latvia or Slovakia are actually very successful …when they apply.

J.2.2.4. International cooperation

A total of 740 distinct entities from Third countries applied to the programme, accounting for 1122 potential participations. Third countries are represented through 171 participations (15 % of these 1122) in the projects retained for funding, involving 147 distinct participants. As the percentage of Third country participants is higher in the successful proposals than in the overall proposal pool, one might conclude that the presence of this participant proved to be a decisive asset for a quarter of these proposals. The assessment of the current portfolio of projects by their respective project officers

shows that 19 % of projects and 19.5 % of the funding are considered relevant to cooperation with Third countries[11].

In line with the broadness of Horizon 2020 topics, SC1 chose to be as broad as possible also in terms of international cooperation. With Horizon 2020 being open to all Third countries, SC1 approach was not to designate specific countries in topics[12]. The approach in SC1 has been to indicate international cooperation or to make reference to specific multi-lateral cooperation initiatives, such as IRDiRC[13], GACD[14], and established entities, e.g. EDCTP2 and HFSP, which are international in nature. In the case of GACD, for instance (topics HCO 5 – 2014 and HCO 6 – 2015), eight projects were funded with a contribution of EUR 24 million. The participation from Third countries was 22.4%, with an overall EC contribution of EUR 4.8 million (20% of the overall contribution).

Among all topics funded in WP 2014-2015, twelve made reference to one of the multi-lateral initiatives and entities[15], while seven topics made reference to the importance of international cooperation[16]. In total, 32% of the topics fostered international cooperation.

From FP7-Health to SC1 (as of 1 January 2017), Associated states saw their share drop from 7.4 % to 2.7 % (215 participations, EUR 41.8 million), mainly because Switzerland lost this status. In parallel the participation of Third countries was reduced from 4.4% to 2.8% (171 participations, EUR 41.8 million). A large portion of this EU contribution is going to the USA (50 participations, EUR 15.7 million to date, 37 % of the Third country share). The contribution to Switzerland teams only accounts for EUR 4.2 million[17].

J.2.3. Cross-cutting issues

In SC1, EUR 501 million (39.2 % of EU contribution, i.e EUR 679.8 million) have been assessed as relevant for **sustainable development**. The target for Horizon 2020 is at least 60%. 3% of the funding (EUR 51.7million) is relevant to the climate change objective (the overall Horizon 2020 objective is 35%).

An assessment of the current SC1 projects portfolio by the projects officers indicates that 27.5 % of the projects, corresponding to 20.5 % of the funding contribute to the **Digital Agenda** for Europe[18].

As regards the promotion of **social sciences and humanities (SSH)** under SC1, in the period 2014-2017 there were 37 topics and other actions which have been classified as being relevant for SSH researchers. It can be observed that within the projects selected under these topics, 19% of partners indeed have an SSH background, receiving 14% of

[11] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[12] *The only exception was the recent ZIKA virus topic for which, given the prevalence of the disease in Brazil, the EC has decided to include Brazil in the topic and to fund exceptionally Brazilian organisations.*
[13] *http://www.irdirc.org/*
[14] www.gacd.org/
[15] *PCH-07, PCH-08, PCH-09, PCH-14, PCH-34, HCO-04, HCO-05, HCO-06, HCO-10, HCO-17, HOA-5 and HOA-5*
[16] *PHC-04, PHC-31, PHC-33, HCO-02, HCO-08, HCO-12 and HOA-9*
[17] *This data excludes IMI, SME-instrument and EDCTP projects.*
[18] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives. This data excludes IMI, SME-instrument and EDCTP projects.*

the EC contribution for these topics according to the SSH monitoring reports for projects in 2014 and 2015[19].

Looking at **gender issues,** 1555 women (46%) vs. 1818 men took part in the proposal evaluation sessions. In SC1 projects 35.4% of coordinators are women (33.4 % in Horizon 2020 overall and 31% of scientific coordinators in FP7-Health[20]), 50.7 % of women participate in the total workforce[21].

The assessment of the current portfolio of projects by their respective project officers indicates that 46.5 % of projects and 48 % of the funding are considered relevant to **interdisciplinary and cross-sectorial research and innovation**[22]. As to **areas relating to bridging from discovery to market application,** the assessment of the current portfolio by the SC1 project officers indicates that 22 % of projects (and funding) are considered relevant to this process, and that 34 % of projects and 34 % of the funding are considered relevant to innovation and broader private sector participation[23]. Support in this regard is provided via the following actions:

a) **Innovation actions:** they focus on demonstrations, tests and other activities close to applications. Only a few such topics were published as Innovation Action under SC1. This resulted in only five innovation actions being funded, all in the e-health, m-health and ICT for Active and Healthy Ageing areas.

b) **Support to SMEs:** As of 1 January 2017, SC1's total contribution to SMEs[24] amounted to EUR 346 million, corresponding to 21% of the EU funding.

c) **Pre-commercial procurement:** SC1 used the instruments of pre-commercial procurement and public procurement for innovation five times. Two selected *Pre-Commercial Procurement* terminated before signature due to the complexity of the instrument, in particular the difficulty to replace withdrawing partners acting as public procurers, which might endanger the compliance with the minimum eligibility criteria.

d) **Inducement prizes**: SC1 launched a EUR 1 million *Horizon Prize for Better Use of Antibiotics* on a rapid test to allow healthcare providers to decide which patients with upper airway infections can be spared from antibiotics. A second *Prize on Maternal and Child Health Research* was launched in 2016, with a EUR 1 million budget

J.3. RELEVANCE

This section aims to determine whether the original objectives of SC1 are still relevant and how well they still match the current needs and problems.

[19] *This information is based on projects already financed under calls closed in 2014 and 2015.*
[20] *Source: RESPIR.*
[21] *Workforce includes people actively participating in and paid by the EU project.*
[22] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[23] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[24] *Excluding IMI.*

J.3.1. Is SC1 tackling the right issues?

J.3.1.1. Relevance of SC1 given the challenges to address

The following points summarise both the context and the challenges to be addressed at the time Horizon 2020 was designed, based on the Impact Assessment (2011) and the Decision on Horizon 2020:

- rise of the cost of health and social care systems,
- ageing of the population,
- need to improve the lifelong health and wellbeing of all and to effectively prevention, treat and manage disease and disability, notably cardiovascular disease, cancer, diabetes, rheumatic and musculoskeletal conditions, rare diseases, brain disorders and neurodegenerative diseases,
- relevance of environmental, occupational, life-style and socio-economic factors,
- global concern regarding infectious diseases, notably poverty-related and neglected disease, emerging and re-emerging epidemics, as well as the threat of increasing AMR,
- high cost and lower effectiveness of today's drug and vaccine development processes,
- need for alternatives to classical safety and effectiveness testing,
- persistence of health inequalities,
- need for access to care for all,
- need to involve all relevant stakeholders.

Such health-related challenges do not disappear overnight. They are still relevant today, as underlined by the latest WHO reports[25] and G7 declarations[26]. SC1's objectives are therefore still relevant as they still correspond to the needs and problems identified.

With the exception of the Ebola and Zika outbreaks (see below), no major health challenge did emerge in the meantime. The intervention logic remains, therefore, as valid as at SC1's start.

However, it is difficult to fully address some important challenges with the available limited resources. All the more so since the European Fund for Strategic Investments (EFSI) required significant transfers from Horizon 2020 Programme for the provisioning of the guarantee fund over the period 2015-2020. This reduction affected the financial programming with an impact on the number of expenditure related outputs from 2015 onwards. As an example, SC1 is not fully able to continue contributing to the international initiatives that it has been involved and has contributed to launching (such as ICGC[27] or IHEC[28]) due to lack of funds. The two other cases presented below exemplify this issue:

- **Chronic non-communicable diseases** are on the rise worldwide in the context of co-morbidities and an ageing population. It would be important to ensure that the allocated budget is sufficient to ensure an appropriate impact level on this high burden of diseases area.

[25] *World Health Organisation, World Health Statistics 2015,* http://www.who.int/gho/publications/world_health_statistics/2015/en/
[26] *Kobe Communiqué, G7 Health Ministers' Meeting, 11-12 September 2016* http://www.mhlw.go.jp/seisakunitsuite/bunya/hokabunya/kokusai/g7kobe/KobeCommunique_en.pdf
[27] *http://icgc.org/*
[28] *http://ihec-epigenomes.org/*

- **Epidemics:** The original objectives of the Horizon 2020 SC1 referred to *Preparedness Research*. The public health emergencies (Ebola, Zika) of 2014-2016 demonstrated how relevant the initial objectives were as the area became one of the most important research field for public health in Europe and globally. By mobilising resources under SC1 on an *ad hoc* basis, it put the Commission firmly on the stage as a global player, but it lacks sufficient budget to really have an impact at international level. The Bill & Melinda Gates Foundation for instance spent over $1.1 billion on global health alone in 2014[29]; the Wellcome Trust contributed £166 million specifically to infectious disease and immuno-biology in the 2014-15 academic year, while SC1 could only dedicate less than EUR 200 million to infectious diseases for 2014-2015[30] (excluding the Ebola fund).

Cooperative research continues to be a highly successful tool to address the science behind societal challenges and solutions. In terms of flexibility, any other priority arising could be easily included in the Programme as has been done so far. The fact that SC1 has witnessed a high submission rates shows the pertinence of the proposed approach and the interest that the topics addressed have risen amongst the scientific community.

The Sustainable Development Goal (SDG) n°3 "Ensuring healthy lives and promoting the wellbeing for all at all ages" has the following targets:

A simple comparison of t**he Sustainable Development Goal** (SDG) n°3 "Ensuring healthy lives and promoting the wellbeing for all at all ages"[31] with the SC1 priorities exposed in section J.1.2 reveals that both general objective and specific targets and "measures of implementation" of SDG n°3 are of particular relevance to the ambitions of SC1. Several topics in the WP 2014-2015 made explicit reference to SDGs[32]; EDCTP2 contributes to the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, TB and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa. During the Ebola outbreak, the EC (via an *ad-hoc* call) and IMI (IMI 2 - Call 2 2014) invested more than EUR 240 million in calls targeting Ebola. During the recent ZIKA outbreak, the EC responded immediately after the declaration of the outbreak by publishing an urgent call and investing EUR 45 million.

The universality of the SDGs, addressing both developing and developed countries, is also a feature of SC1 as it responds to both the needs and concerns of EU citizens and promotes international partnerships on global health issues through its openness to the world and through financing fully any participation of developing countries. SC1's priority setting will continue to respond to the SDGs, both for infectious and non-communicable diseases.

Further efforts are still needed to **translate the results from research into application in health care systems and into society** more broadly[33]. This needs to happen, in

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[29] *http://www.gatesfoundation.org/Who-We-Are/Resources-and-Media/Annual-Reports/Annual-Report-2014*
[30] *https://wellcome.ac.uk/sites/default/files/wtp060206.pdf*
[31] *The full list of SDG n°3 targets is available on http://www.un.org/sustainabledevelopment/health/. SC1 actions are particularly relevant to objectives 3.1, 3.2, 3.3, 3.4, 3.8, 3.9, 3.b, 3.ds*
[32] *... such as topic PHC4–2015: Health promotion and disease prevention: improved inter-sector co-operation for environment and health based interventions.*
[33] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 144. This finding is also at the origin of the provision in the European trans-border healthcare directive to create European reference networks (ERNs). These ERNs have recently been selected and shall provide specialised care for rare diseases, serve as*

particular, for PM, where the healthcare systems need to adapt to this new approach[34]. This is also the case in e-health and m- health where the need for further support of the uptake of innovation and policy development beyond funding projects (such as support to the EIP-AHA, twinning, "Marie-Curie type of instrument" for Innovation) has been clearly identified by key stakeholders[35].

J.3.1.2. The relevance of SC1 to address European objectives

HORIZON 2020 and its SC1 were launched in the context of the **Europe 2020 Strategy** and in support of it. The approach to contribute to a smart, sustainable and inclusive growth through specific channels via a combination of instruments (renewal of IMI, SME instrument, Inducement prizes) is described under section J.4.4.2. Another illustration of SC1's support to the Europe 2020 Strategy is its sustained support to its flagship European (Public-Private) Innovation Partnership on Active and Healthy Ageing (EIP-AHA) launched in 2011, with the goal to coordinate the innovation opportunities for enhancing the quality of life as people age. EIP-AHA is a coordinated framework for definition and monitoring of actions in this area. Several FP and Horizon 2020 SC1 calls for proposals offered opportunities in areas of interest identified in its Strategic Implementation Plan and address some of its actions[36]. The Horizon 2020 SC1 coordination and support action PROEIPAHA aims at leveraging EUR 4 billion national funding committed through the EIP-AHA.

Given SC1's original design (encompassing the SME-instrument, e-health and m-health) and given the experience of past FP's (notably the pilot on SBIR-inspired SME projects or the FP7-Health-led multilateral initiatives and global consortia), the new **European Commission's priorities** from 2014[37] did not have a strong impact on SC1's design. The three most relevant priorities for SC1 are the following: 1) Boosting Jobs, Growth and Investment, 2) A Connected Digital Single Market, and 3) A stronger Global Actor.

1) Boosting Jobs, Growth and Investment: The objective to boost jobs and growth is already ingrained in the main objectives of the FP, as a consequence of the aim to increase the competitiveness of EU industries. The tools mobilised in support of EU 2020 therefore remain largely relevant. This is reflected in the assessment of the current portfolio of projects by their respective project officers. It shows that 53 % of projects and 53 % of the funding for collaborative projects are considered relevant to the Priority *Boosting Jobs, Growth and Investment*[38]. SC1 is also developing evidence-base and policy analysis to define the features of health R&I policy for an efficient and

research and knowledge centres and ensure availability of treatment facilities. SC1 is working with MS on bringing research and innovation investments together with the ERNs to provide a seamless pipeline from research to patient care and providing feedback from care to research.

[34] This has been recognised in the Advisory Group of SC1 recent report who recommends to pilot and implement PM in specific cases where PM approaches have already been taken in Europe (in addition to rare diseases, oncology and diabetes).

[35] Feedback from the key public and private stakeholders and the challenges in translating the digital innovation potential into scalable deployment has identified a clear need for a new type of action in the future FP, a Public-Private Partnership that can effectively bring together key demand side actors (such as regions/cities, as first movers in large scale innovation investments and procurements), and supply side stakeholders from Industry and SMEs, together with other partners committed to scale up innovative digital solutions for health and care across Europe (and globally)..

[36] Because the EIP-AHA is not a funding framework, it works in synergy with funding programmes to orientate the funding under the general banner of ageing research and public health actions. Structural Funds also provide funding possibilities to support research, innovation and other measures in active and healthy ageing.

[37] https://ec.europa.eu/priorities/index_en

[38] Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.

competitive European health sector, notably exploiting guidance reports from its Scientific Panel for Health (SPH).

Other channels are also mobilised to contribute to boosting jobs and growth, namely developing PM and contributing to the sustainability of health systems by providing evidence from research (e.g. on health workforce, Health Technology Assessment, health information) to ongoing health policy debates via workshops, conferences and presentation at EU Member States network meetings.

As opposed to instruments contributing to jobs and growth in the long term, investment instruments had, until now, not been used by predecessors of SC1. In support of the Juncker plan, in June 2015, a **new finance facility for infectious diseases, "InnovFin Infectious Diseases"**, was jointly launched by the Commission and the European Investment Bank (EIB) to facilitate the development of innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures in the field of infectious diseases. Following this successful initial pilot funding in 2015 by InnovFin FP7 surplus (EUR 100 million), SC1 contributed EUR 50 million in 2016 to the Infectious Diseases Financing Facility scheme. This contribution will be continued in 2017. The EFSI Investment Platform will be developed in order to scale up this InnovFin ID pilot.

Under SC1, a screening of EU legislation was performed (**Regulatory Fitness Screening for Innovation)** and innovators were invited to signal when they consider that extent regulations provides possible drivers or hurdles to innovation in health. This resulted in the inclusion of Health Technology Assessment (HTA)-related issues in a first set of case studies put forward in the *Better Regulation for innovation driven investment at EU level* Commission Staff working document[39]. Accordingly, the Commission Communication *Upgrading the Single Market: more opportunities for people and business* [40] identified HTA as an area deserving action.

***2) A Connected Digital Single Market (DSM)*:** The portfolio of projects addressing e-health, m-health, tele-health and -care, age-friendly smart homes, internet of things, large scale data gathering; contribution to human brain project; exploitation of big data; collaborations with health-related ESFRI, projects implementing the agenda of the international human epigenome consortium IHEC and International Cancer Genome Consortium ICGC, or projects implementing improved data analysis, modelling and simulation, all illustrate the drive and relevance of SC1 to contribute to establishing a connected DSM. This is confirmed by the assessment of the current portfolio of projects by their project officers that shows that 26% of projects and 19.5% of the funding are considered relevant to this EC Priority[41]. This drive also requires SC1, as requested by stakeholders such as Digital Europe, to define and implement health data sharing frameworks[42]. This is being developed in international consortia and in the context of Programme-Level international collaboration, especially in the field of brain research, in

[39] Better regulations for innovation-driven investment at EU level *Commission Staff Working Document, p. 17. https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf*

[40] *http://ec.europa.eu/DocsRoom/documents/14007?locale=en, November 2015*

[41] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*

[42] *Numerous data repositories exist. Immense quantities of high value information have been deposited and serve for the study of human health and disease. These repositories are scattered around the world but should ideally use the same data standards. There is a pressing need for better integration of public repositories and coordinated data sharing. Furthermore, the sustainability of the storage of high value data is a problem frequently reported by the scientific community. Apart from the hardware and maintenance costs, the cost of data curation can be significant while it is a necessary element to foster progress in biology and medicine.*

the context of the Human Brain Project (HBP), the International Initiative for Traumatic Brain Injury Research (InTBIR), the US Brain Initiative, and other actions.

3) ***A stronger Global Actor*****:** Given the global nature of many health issues addressed by SC1 and the portfolio of international consortia of funding agencies already developed under its predecessors, the EU, via the Commission, is already a strong global actor that compensates its comparatively low funding input by its drive to create partnerships with other major players, to influence common research priority-setting, alignment of R&I efforts and to foster leverage of funding to tackle pressing global health challenges. The assessment of the current portfolio of SC1 projects by their respective project officers shows that 38% of projects and 38.5% of the funding are considered relevant to the Juncker Priority *A stronger Global Actor* [43], but the initiatives below illustrate better SC1's drive to support this priority.

Examples of initiatives supporting the EC priority "*A stronger Global Actor*"

*Improving Global Health***.** The services implementing SC1 are developing a Commission Communication for late 2017 concerning an Action plan on Emerging and re-emerging infectious diseases research. Taking as issues the outbreaks of Zika and Ebola and focusing on the contribution of research on the rapid development of vaccines, it is preparing a co-fund initiative on emerging Infectious diseases. Through the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) international consortium, where funders come together to create a fast and efficient global research response to any new emerging infectious disease, it established a strong global coordination of Emerging infectious diseases research.

HIRO. In terms of agenda setting for health research at global level, the Director for SC1 features as a prominent member of the Heads of International Research Organizations (HIROs), an ad-hoc organization composed of directors of International Research Organizations that meets twice a year to discuss priorities in health research.

International consortia. The EU, via SC1 or its predecessor, has initiated or fostered several international initiatives that involve partnerships with funding agencies, MS and other stakeholders. These involve partners from USA, Canada, BRIC countries, Japan among others. These programmes are valued as platforms for research complementarity, protocol harmonization, data and findings integration into common databases and faster result generation with a lower use of resources. Some of the collaborations have already produced significant results[44]. For example, the International Mouse Phenotyping Consortium (IMPC) has started to generate mouse phenotype data and integrated it onto a single platform. As more data becomes available, the IMPC database will become an invaluable tool for researchers studying the genetic contributions of genes to human diseases. IRDiRC, the International Rare Diseases Research Consortium, ensures that funding from different organisations is coherent across the globe and provides for appropriate synergies to ensure the emergence of 200 new therapies and the means to diagnose most rare diseases by 2020. These international consortia are further supported under SC1.

EDCTP2. The European and Developing Countries Clinical Trials Partnership (EDCTP) created under FP6 and renewed under SC1 as EDCTP2 goes yet one step further. It has created a joint collaboration of European and African participating countries and the

[43] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[44] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 85*

Commission, which launches its own calls for clinical trials in poverty-related and neglected diseases in Sub-Saharan Africa to fight HIV/AIDS, malaria and tuberculosis. This public-public partnership brings together the strength of funding programmes and researchers in the North and South and gives researchers the opportunity to take new diagnostic or management strategies to the patients most in need. As a consequence of this co-ordination, the initiative is producing important and recognised results[45]. EDCTP can be considered a major example of how Europe can focus and coordinate its resources to address a grand societal challenge demonstrating global leadership and cooperation – as advocated by the Lund Declaration. Several political statements, e.g. by G7 ministers[46] or African health ministers[47], illustrate how the EDCTP has stepped up EU's status and how it is increasing its strength as a global player in health research.

SC1's main policy objectives were from the start in line with the Three O's main objectives, **Open Innovation, Open Science and Open to the World[48],** as will be shown below. A major pioneer initiative in open innovation had been developed under SC1's predecessor. As mentioned above, the international dimension of health challenges is fully ingrained in SC1, while the availability of health data -to the right users and only them- is a prerequisite for much of today's health research. No adaptation or reengineering of sorts was therefore required to align SC1 to this strategy.

1) Open Innovation: SC1's measures to support innovation have already been detailed above as they naturally support the *Boosting Jobs, Growth and Investment*, but SC1 is also no stranger to the specific *Open* nature of Open Innovation, where stakeholders agree to share more than they would be expected to in order to mutually increase their chances to innovate. The assessment of the current portfolio by the project officers suggests that 42 % of projects and 39 % of the funding are considered relevant to Open Innovation[49].

A typical example of such an open innovation project is **ICT4Life**[50] that will develop a modular health service platform to allow for the efficient provision of integrated care adapted to different end-user needs for patients suffering from dementia, Alzheimer's or Parkinson's disease. Breakthroughs in research and innovation on new services for integrated care will be achieved by developing a service-oriented ICT-based collaborative platform which exploits the latest advances in processing, communications and personalized human-machine interfaces. Addressing the priorities of the European

[45] *Examples of achievements include establishing the first African Networks of Excellence for clinical trials in central Africa; provision of new national ethics committees in many African countries; approval by US Food and Drug Administration (FDA) of an anti-retroviral formulation for HIV infected children in Africa, which was tested in an EDCTP project. Recent supporting references include G. Breugelmans et al.,* Bibliometric Assessment of European and Sub-Saharan African Research Output on Poverty-Related and Neglected Infectious Diseases from 2003 to 2011*, by PLOS Neglected Tropical Diseases, August 2015, http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0003997, that provides bibliometric evidence about the scientific impact/excellence of the EDCTP-funded research. The following EDCTP2-related scientific paper demonstrates the reach of EDCTP: Selidji T. Agnandji et al.,* Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe*, by., N Engl. J Med 2016; 374:1647-1660; April 28, 2016; DOI: 10.1056/NEJMoa1502924.*

[46] *Communiqué, Meeting of the G7 Ministers of Science, Berlin, 8-9 October 2015, https://www.bmbf.de/files/English_version.pdf*

[47] *See* A slim chance for South African medical research*: Incoming president of the nation's Medical Research Council, Salim Abdool Karim, talks about the challenges he faces, by Amy Maxmen, Nature, doi:10.1038/nature.2012.10789, 11 June 2012, http://www.nature.com/news/a-slim-chance-for-south-african-medical-research-1.10789*

[48] *https://ec.europa.eu/research/openvision/index.cfm*

[49] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*

[50] *http://www.ict4life.eu/*

Innovation Partnership on Active and Healthy Ageing (EIP-AHA), a multidisciplinary approach is proposed, integrating expertise and knowledge of medical doctors, nurses, social workers, psychologists, physiotherapists, social scientists, patients as well as programmers and interaction designers.

But another initiative, continued under SC1, has actually been a pioneer of open innovation in health, the **Innovative Medicines Initiative (IMI) Joint Undertaking**. IMI, the world's largest PPP in the health sector, has brought together partners from academia, SMEs, regulators, patient organisations and large industry, creating a new model for open innovation in the pharmaceutical research area, becoming a model for open innovation. In this new context, research actors and individual companies who used to work in silos now provide unprecedented access to each other's data and collaborate on solving problems of public health concern. IMI has proved that the different partners can be brought together in open innovation networks to participate along the long and risky biopharmaceutical innovation chain[51]. An evaluation performed by a panel of independent experts on IMI found that "*Europe has succeeded in establishing a new business model between public and private sectors, which unites research strengths across European pharmaceutical industry, academia and small and medium enterprises (SMEs)* […] *very important in developing open innovation in the health sector as it has enabled an unprecedented pooling of industrial research assets allowing scientific challenges to be tackled in a manner that could not be done otherwise* […] *In many respects IMI is an incubator for changing minds on how parties can work together across traditional boundaries and is therefore likely to have an important structuring effect in Europe, fully in line with the Innovation Union objectives*". Renewed under Horizon 2020 with an increased budget, IMI2 will take open innovation in health to a next level.

Another promising field where the EU is taking the lead requires as a prerequisite upstream collaboration of all relevant stakeholders, be they academic researcher, innovation providers, public authorities and patients' associations. This is the area of **Personalised Medicine** for which SC1, via its support to the International Consortium IC-Permed, but also via its collaborative projects and via IMI2, is providing the evidence base for developing PM, including the use of omics for personalised nutrition, mapping MS initiatives and mobilising resources, thus preparing an integrated approach to the accessibility and affordability of PM

2) Open Science: SC1 promotes better standardised and harmonised data, and at EU-level, agreement on standardisation and sharing and harmonisation of health data, with impact, among others, on clinical trials and PM. New international SC1-led health research international multi-funder initiatives incorporate data-sharing policy frameworks inspired by IRDIRC[52] and other international consortia, incorporating Data Protection Regulation, privacy and IPR aspects. With data from genomics and other -omics, clinical trials and cohort studies, health R&I has a lot to expect from progress in the processing of health 'Big Data' and notably prospects for a shift toward a more personalised medicine.

The assessment of the current portfolio of SC1 projects by the project officers indicates that 62.5 % of projects and 64.5 % of the funding are considered relevant to Open

[51] *Ex-Post Evaluation of the Seventh Framework Programme, Commission Staff Working Document, p. 114, https://ec.europa.eu/research/evaluations/pdf/archive/fp7-ex-post_evaluation/staff_working_document_annexes_part_2__en_autre_document_travail_service.pdf*

[52] *http://www.irdirc.org/, see above under section A stronger Global Actor.*

Science[53]. By mid-November 2016, roughly 80% of the published peer-reviewed articles resulting from SC1 projects were available in **open access**. Although these figures are based on a very small sample (ca. 0.4%) of the articles to be expected from SC1, one can observe that the push by Horizon 2020 to ensure publication in open access appears to be effective, resulting under SC1 in a percentage similar to that of the other societal Challenges, even though SC1 projects may actually decide to opt out of this scheme.

SC1's **Scientific Panel for Health** provides in all transparency guidance reports on crucial aspects of health research and innovation such as HTA, Training and Workforce, and Prospective.

3) Open to the World. Many of the actions in place that serve the 'Open to the world' objectives also contribute to the Juncker 'A stronger global Actor' objectives (see section J.3.1.2). The assessment of the current portfolio by the project officers shows that 45.5% of projects and 42% of the funding are found relevant to the Open to the World priority[54]. Actually, 56% of SC1 collaborative projects have at least one third or AC country team in their consortium[55].

Looking at the relevance of SC1 as regards **the Digital Single Market and Silver Economy, f**ollowing the emergence of these policy areas marked by Commission Communications on these issues, a greater focus than at the start of SC1 has been put on topics and instruments supporting the large scale implementation of innovative digital solutions for health and ageing. Example includes the Public Procurement of Innovation (PPI) of integrated care solutions, or large-scale pilots on IoT for Age-Friendly homes and living environments (which was identified as one of the areas with high social and economic potential by the EU background report on the Silver Economy).

J.3.2. Flexibility to adapt to new scientific and socio-economic developments

Successive Health programmes, including SC156, have always updated the ideas for topics and priorities to keep abreast of general progress in the relevant fields and to adapt to the new developments. Such adaptive measures can be traced back to the TSE outbreak of the 1990s and the H5N1 outbreaks of the 2000's57. Under SC1, this was notably achieved by adapting, sometimes in an extremely short time during infectious diseases outbreaks, WP's and calls (see sections J.3.1 and J.7.1 and below). These WP updates leave an inherent flexibility to react on new trends and opportunities. SC1 also responded timely to new socio-economic developments (economic crisis, availability of big data) and resulting strategic policy requirements.

The **outbreak of Ebola** in West Africa was one of the most serious **international health emergencies** of the past few years. SC1 promptly supported urgent research on Ebola, taking advantage of Horizon 2020's far-reaching administrative simplification and streamlined implementation by launching – for the first time – two fast-track procedures

[53] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[54] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[55] *Source: Corda.*
[56] *See section 2.2 for SC1.*
[57] *See PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 125.*

completed in an unprecedented short timeframe[58]. Thanks to these procedures, EUR 24.4 million from Horizon 2020 were mobilised despite not being foreseen in the Horizon 2020 WP. This procedure was planned during September 2014, with results announced and projects launched in October. In parallel, the Commission, together with the European Federation of Pharmaceutical Industries and Associations (EFPIA), started planning the IMI-Ebola+ call. It was launched on 6 November, with results announced mid-January 2015 – a procedure completed in record time taking into consideration the dual nature of IMI (a PPP between EU and EFPIA). This Horizon 2020 SC1 research response, very significant in scale, with a total of EUR 140 million, in turn, leveraged a further EUR 101 million from the pharmaceutical industry. These efforts are already delivering, with trials on the ground in West Africa already underway and with the first indication of results. These actions have placed the Commission second only to the US Government in terms of commitments made. However, no single player can alone overcome the research challenges surrounding this outbreak. Because of this, the Commission has also strived to coordinate other Ebola research funders.

Much work is being done to establish frameworks for cooperation to enable a swift and effective global research response in future outbreaks. SC1 has taken the lead in establishing the **Global Research Collaboration for Infectious Disease Preparedness** (GLOPID-r) that links together research funders, the scientific community, industry, patient groups and public health actors. Its goal is to mount an effective research response within 48 hours of an outbreak. It was soon tested with the Zika outbreak in Latin America in 2015, when the WP was updated to include in emergency a call on Zika research.

Another example of flexibility is the area of **implementation research** where evidence showed SC1's capacity to accelerate the uptake of interventions into clinical practice, matching the needs of the different geographical and socio-economic context. SC1 adapted by incorporating implementation research as the core theme of the Global Alliance against Chronic Diseases (GACD) initiative, to be implemented on an annual call basis.

At a slightly more anecdotal level, SC1 can also be flexible enough to seize opportunities at hand: the '**Maternal and child health research' prize**, initially planned for year 2017, was eventually launched in 2016, for a budget of EUR 1 million, since additional funding opportunities for the prize were available on that year (notably from the Bill & Melinda Gates Foundation) that might not have been at hand in 2017.

J.3.3. Addressing specific stakeholder needs

Like its predecessors, SC1 is allowing policy makers and civil society to actively contribute to activities and to be kept informed. Independently of Horizon 2020 participant's portal, the SC1 website receives an average of roughly 500 visits per month[59]. Consulting stakeholders has been an integral part of the programming process, a process that actually started as early as 2011, with two Advisory Workshops on the *Common Strategic Framework for EU R&I funding* preparation, dedicated to the *Health, Demographic Change and Wellbeing challenge,* with the objective to consult respectively a representative sample of the communities involved in this grand Challenge, and

[58] *while following all Horizon 2020 rules as the Financial Regulation foresees the possibility to award grants without a call for proposals in exceptional and duly substantiated emergencies*
[59] https://ec.europa.eu/research/health/.

representatives of the MS and Associated states to FP7, prior to the formal Commission proposal on Horizon 2020.

In order to develop its WPs, SC1 particularly considered the following inputs:

- **Targeted consultation of stakeholders** (August-September 2014). It triggered 260 replies from both European level associations and national level organisations such as individual companies, universities or research organisations. Amongst the contributions was a clear consensus on the need to consider ageing from cradle to grave, with a development approach; support for a main priority on PM and for the launch of an action on Human Bio-Monitoring. All these were taken into account in the successive SC1 WPs.
- **Advisory Group:** A large part of the input also came from the document *Advice for 2016/2017* of the Horizon 2020 Advisory Group for SC1, adopted on 25 July 2014[60]. It was followed in 2016 by a second report *Advice 2016 of the Horizon 2020 Advisory Group for Societal Challenge 1, Health, Demographic Change and Wellbeing*[61], that will be considered for the WP 2018-2020.
- A **Stakeholder Consultation on the Horizon 2020 WP 2018-2020 for SC1** was launched in June 2016, specifically targeted to e-health, m-health and ICT for active and healthy ageing aspects[62].

From 2014 to 2016, stakeholders were also invited to contribute to topics definition through specific **targeted workshops**, on topics such as rare diseases, big data, environment & human health, economic methods, mental health, maternal health, health technology assessment, patient empowerment, systems medicine, AMR, animal-free toxicity testing, type-1 diabetes research, PM, environmental epigenetics & the exposome, health enhancing physical activity, vaccines, etc. All these workshops contribute to the definition of call topics or of new actions by SC1. SC1 also carefully considers spontaneous contributions, such as **public position papers** of stakeholders from the public or private sectors[63].

A very positive feedback has been received from **national policy makers** as regards the value of coordinating national research activities (ERA-Net scheme and JPIs). The Programme Committee always approved the successive proposed WP's by a very large majority[64]. Many invitations were also received to present SC1, IMI2 and their achievements to date. Legislators, especially MEPs, take a keen interest in SC1, as reflected by the number of parliamentary questions addressed to the Commission that were related to health R&I (roughly 150 EP questions yearly).

Evidence from the SC1's predecessor points to a high potential for engagement with civil society actors or policy makers. According to the FP7-Health ex-post evaluation commissioned by DG RTD-Health (2016), "*Around half of finalized research projects reported on engagement with civil society actors or policy makers. Around 25% of these*

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[60] *http://www.eurida-research.com/downloads/ag_report-health.pdf*
[61] *Advice 2016 of the Horizon 2020 Advisory Group for Societal Challenge 1, "Health, Demographic Change and Wellbeing". http://ec.europa.eu/research/health/pdf/ag_advice_report_2018-2020.pdf*
[62] *https://ec.europa.eu/digital-single-market/en/news/stakeholder-consultation-Horizon 2020-work-programme-2018-2020-health- demographic-change-and-wellbeing*
[63] *For instance: Digital Europe,* Big data and B2B digital platforms: the next frontier for Europe's industry and enterprises, http://www.digitaleurope.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&entryID=2163&language=en-US&PortalId=0&TabId=353
[64] *6 consultations out of 6 with a positive vote, with no negative vote.*

were identified as having had an impact on EU policy[65]. Notable examples of evidence that has been/will be used in EU/national-level policymaking include several projects results under the SEURAT-1 initiative funded by FP7 Health with matching funds from the *Cosmetics Europe* industry association to develop a strategy to replace animal use in toxicity testing[66].

Patients associations, user organisations and similar types of stakeholder are directly involved and play a significant role in a large number of projects. SC1's major focus on the health and wellbeing of the EU citizens places **patients' and users' needs at the heart of the Programme**. For instance, in the projects in the e-health, m- health and active and healthy ageing areas, all projects must include end-user representatives to allow for verification of impact in real environments. The projects below, among many others, illustrate how stakeholders' involvement can take place in SC1 projects.

The VISION-DMD project[67] aims to advance clinical development of the orphan drug VBP15 as a new therapy to revolutionise care for Duchenne muscular dystrophy (DMD). *United Parent Projects Muscular Dystrophy* (UPPMD), one of the participants, is a worldwide organisation of parents of children with DMD, dedicated to finding a cure and viable treatments for DMD, to promoting good standards of care, and to informing parents around the globe. In the project, UPPMD provides advice and assistance on the design and execution of the clinical studies from a patient perspective, to help define the research priorities and develop trial ideas, and provide advice on tolerability of the schedule and intended outcomes. It also assists in the design of patient information sheets and consent forms. Using its worldwide network, UPPMD contributes to stakeholder identification, to engagement, communication and dissemination activities. It develops materials to encourage patient recruitment and presents the study and its potential benefits to the patient community.

The patient organisation *Stroke Alliance for Europe* (SAFE) is a partner in the Horizon 2020 project **SVDs-at-target**[68] focused on the comorbid conditions of stroke and dementia in the elderly. SAFE is composed of a network of organizations whose members are stroke survivors, carers, neurologists, researchers, therapists and campaigners. It is the only network of this type in Europe. Its role is the dissemination, exploitation and communication.

Overall there was no drop from FP7-Health in the involvement of the key academic research institutions, nor from major innovators in health. The response rate has been overwhelming. There is no evidence of complaints or negative feedback regarding the breakdown of activities or the use of instruments. Only for Public Procurement of Innovative Solutions did the response rate show a difficulty to trigger the interest of the relevant stakeholders, as explained in section J.2.3.

However, given the deliberate concentration on a limited number of topics, some disappointment was expressed, essentially regarding the absence of specific disease-centred calls. The absence of focus on diseases, and the reduced budget allocated to collaborative research have been identified by some research communities and learned societies as the cause of a decreased funding in some important medical areas[69], such as

[65] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 85*
[66] *SEURAT-1, http://www.seurat-1.eu/*
[67] *Research and Innovation action, EU contribution: € 6 000 000, duration: 2016-2019, http://vision-dmd.info/*
[68] *http://www.svds-at-target.eu/*
[69] *Similar statements as for diabetes were issues in areas such as brain disorders and cardiovascular diseases.*

diabetes. However, a closer look to the applications submitted showed that this decrease is related to a drop in the number of proposal received in this area, when compared to FP7-Health. Public health research advocates also complained about similar lack of opportunities[70]. However, very positive appreciations were also made public[71]. As already noted about the last phase of FP7-Health, the introduction of broad, bottom-up research topics ensured the consistency between planned versus funded research activities in the programme[72]. All 62 topics published triggered proposals and led to at least one selected project, which also confirms that the choice of instrument was deemed relevant for all topics. The appropriateness of the distribution was always endorsed by the MS. None of the six votes on the WP in 2014, 2015 and 2016 yielded any negative voice from any MS.

J.3.4. Relevance of the projects according to the objectives

The breakdown of the selected projects according to specific priorities is presented in section J.4.3. They are in line with the programme objectives.

J.3.5. Lessons learnt

SC1 is still relevant and still matches well the current needs and problems. It is proving well suited to the current challenges, which have not evolved significantly since the beginning of Horizon 2020. At the same time, just as FP7-Health proved reactive enough to include actions fostering the recovery from the economic crisis[73], SC1 has proven flexible enough to react to political, social and urgent public health developments.

The R&I topics funded under SC1 are fully consistent with the programme structure and target R&I activities foreseen under the legislative basis for Horizon 2020. The activities were planned via a participatory approach involving EU institutions and prominent stakeholders specialising in the health domain. Data shows that, as a result of the broad, bottom-up-like definition of R&I topics, all topics did receive funding under their initial calls for proposals.

SC1s priority setting is not only reactive to the current developments, it actually pilots the adaptation of EU R&I to some of the main new foreseeable features in the health landscape of tomorrow, such as the increased personalisation of medicine, taking advantage, notably, of both the evolution of -*omics* and the increased capacity to exploit big data. This has been well anticipated already from FP7-Health onwards[74], with an

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[70] *Kieran Walshe et al.,* Health systems and policy research in Europe: Horizon 2020*, The Lancet, March 2013, http://dx.doi.org/10.1016/S0140-6736(12)62195-3*

[71] *Alison Abbott,* Boon or burden: what has the EU ever done for science? *Nature, 15 June 2016. On IMI, see also: J. H. Rex,* ND4BB, Addressing the antimicrobial resistance crisis*, Nature Reviews Microbiology 12, pp 231–232 Year published:*
(2014)
DOI:
http://www.nature.com/nrmicro/journal/v12/n4/full/nrmicro3245.html

[72] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 80*

[73] *Commission Staff Working Document Ex-Post Evaluation of the Seventh Framework Programme, FP7-Health Annex, pp. 2-3.*

[74] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, pp. 106-107; "Analysis of the timeliness of the research performed yielded to key findings and conclusions. First, FP7 Health placed an overall strong emphasis on molecular cell biology and development of new databases and methods compared to other leading international research programmes, implying a timely shift towards personalised medicine approaches in the programme".*

increasing emphasis under Horizon 2020 that provides the EU with a strong leadership as to the definition of PM's features in the next decades.

Further efforts are still needed, however, to translate the results from research into application in health care systems, on the market, and into society more broadly.

J.4. EFFECTIVENESS

This section considers how successful the thematic activity/instrument has been in achieving or progressing towards its objectives.

J.4.1. Short-term outputs from the programme

No collaborative project was completed yet as of 1 January 2017, however, the elements presented below constitute anecdotal evidence that SC1 is delivering on its objectives.

As part of efforts to promote Responsible Research & Innovation (RRI) across Horizon 2020, SC1 fostered the **co-creation of scientific agendas and scientific contents**. In 15.2% of SC1's projects, citizens, Civil Society Organisations (CSOs) and other societal actors contribute to the co-creation of such agendas and contents[75] (Horizon 2020 average: 6.2%).

Regarding the gender dimension in research and innovation content, the percentage of projects taking into account the **gender dimension in R&I content** is 58.5 %, as compared to 24% overall for Horizon 2020. The assessment of the current projects portfolio by the respective project officers indicates that 36.5 % of projects and 33 % of the funding are considered relevant to responsible research and innovation, including gender[76].

Within the projects funded by SC1[77], 0.9 % of the EC contribution (4 projects for EUR 13.6 million) is allocated to innovation actions, all of them being **demonstration and first-of-a-kind activities**.

As of 1 January 2017, a few ongoing projects had reported **publications**. Table 10 present this data, as extracted from the CORDA database.

Table 128 - Ongoing Horizon 2020-SC1 projects publications, as reported in CORDA

Number of Peer-Reviewed Publications	Number of Chapters in books	Number of Publications in conference proceedings/ workshops	Number of Books/Monographs	Other publications	TOTAL Number of Publications
280	16	121	1	16	435

Source: Corda, data as of 1 January 2017.

[75] *(data provided by POs during GAP)*
[76] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives.*
[77] *excluding JUs and SME instrument*

Also, as of 1 January 2017, a few ongoing projects had reported filed **patents** (14 patents and one utility model). It is likely that these result from the SME-instrument that is both quite short-termed and downstream in terms of TRL. Looking at FP7, 37% of "hard science" FP7-Health projects produced patents applications. Around 9% of FP7-Health participants indicated that they were listed as an inventor on one or more patents arising from their project. Overall, some 750-800 patent applications will have been filed by the closure of the last FP7-Health project[78]. Experience from FP7 shows that the funded projects generate other types of outputs than just patents[79]: 85% of them led to new methodologies, 40% to new instruments, 38% to new prototypes and 33% to new demonstrators. 29% of the completed projects reported evidence of commercialisation activities[80]. The inclusion of e-health and m-health within SC1 will quite likely increase the latter four figures as it has slightly shifted the balance within the programme towards more technology-oriented solutions.

Looking at IMI more specifically it yielded 21 patent applications filed before 2016, mostly by public participants in IMI consortia. Also, 33% of finalised projects had created spin-off companies or foundations as a result of their IMI projects. The number of scientific advices and qualified opinions initiated by IMI projects at EMA and the US Food and Drug Administration (FDA) was 10 in 2014 and 8 in 2015. Considering these trends, it is reasonable to expect IMI2 to deliver significant progress towards its objectives.

With an estimated production of 1.65 patents per EUR 10 million under FP7-Health, SC1 RIA projects can be **expected to generate some 635 patents, plus at least 45 patents originating from IMI2**.

A number of projects can be identified that have already had an important effect so far, notably several projects launched under the Ebola calls.

The **EVIDENT** project[81] highlights the opportunity that Horizon 2020 provides in reacting to public health emergencies with appropriate and ad-hoc mobilisation of research funding. It addresses research gaps that emerged with the recent Ebola virus disease (EVD) epidemic in West Africa, studying samples collected from populations affected in order to provide urgently needed answers regarding the pathophysiology and transmissibility of the disease, and help better guide the planned clinical trials on vaccines and treatments. EVIDENT has successfully pursued objectives with immediate, mid-term and long-term impact to combat the recent and future EVD epidemics. It generated data that goes beyond the current knowledge and has implications for patient and outbreak management. It also has had a major impact in supporting operational research projects of other partners in the field. The consortium implemented its research programme under particularly trying field conditions, at the peak of the outbreak, facing hostile and fearful local communities and overwhelmed local administration. The scientific relevance and quality of its results is evident by the fact that the project in less than two years has already published several articles in high-impact journals (e.g. three already published and one under review in Nature), and more than 20 other articles already published or under preparation in well-known journals.

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[78] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 42, an estimate compatible with that of the services in 2014 (at least 650 patents), using Respir data [as of 15.09.2014]*

[79] FP7-Health Survey October 2014

[80] *Respir. [as of 01.01.2015]*

[81] *Research and Innovation action, EU contribution: € 1 759 325; duration : 2014-11-01* ***to*** *2016-10-31, http://evident-project.eu/about/institutions/bni/*

The Horizon 2020-funded clinical trials of convalescent plasma (project Ebola_Tx[82]) and the antiviral favipiravir (project REACTION[83]) provided critical evidence that these proposed treatments were not effective. An indicator of their success is that they were the only clinical trials of potential treatments that were completed by recruiting the predicted number of patients and produced valid results, while other clinical trials of potential treatments started later and had to stop recruitment or were underpowered due to the ebbing of the Ebola outbreak . Most significantly, in spite of the enormous challenges, the research was done with due respect to all Horizon 2020 and international ethical standards. The **Ebola MoDRAD**[84] project has developed rapid bedside inactivation vacuum tubes, which make it possible to inactivate Ebola virus directly during collection of samples from the patients. This can lead to safer handling of samples and their safe transportation from outbreak sites to reference labs in the EU.

In 2014, **Immunovia AB**[85], a Swedish health company from Lund, received an SC1 SME Instrument Phase 2 grant of EUR 4.2 million for a project on early diagnosis of pancreatic cancer. It has developed a method using a blood test to detect and diagnose pancreatic cancer earlier than competing methods, which increases chances to treat it. A world first in pancreatic cancer diagnostics, it could increase the overall 5-year survival rate from 3-4 % to approximately 59 %. Thanks to the SC1 EU-funding and new capital injection, the company will be able to commercialise it. In 2015, it had doubled its staff from 9 to 18 and developed enough to be accepted for trading on the Nasdaq First North in Stockholm. Before this, Immunovia carried out a promising share issue that was oversubscribed five times. It provided the company with SEK 60 million before issue costs and about 1 100 new shareholders, including many existing, new and international investors. The CEO, Mats Grahn**,** acknowledged that "*The SME instrument has been a decisive financial and confidence support to convince investors to subscribe to our share issue this year (2015) required to entry in the market in US and EU."*

The U-PGx project (2016-2020), supported with EUR 15 million EU contribution **is a true pilot for a personalised medicine approach in a real-life setting**. It conducts pre-emptive genotyping of multiple important pharmacogenes in large patients' cohorts in seven countries. The prospectively collected data will be embedded into the electronic records of patients and be available at the time of decision-making for a wide variety of common pharmaceuticals, in combination with data on the individual patient phenotype. Prescribers and pharmacists will be alerted through electronic clinical decision support systems when a drug is ordered or dispensed for a patient with an at-risk genotype. Being implemented at a large scale in seven existing European health care environments, the project will account for the diversity in health system organisations and settings. Feasibility, health outcome and cost-effectiveness will also be assessed.

J.4.2. Expected longer-term results from the programme

It is too early to assess the longer term results of Horizon 2020-SC1 actions. Only a few ongoing projects have reported publications (albeit some outstanding ones as for the Evident project) and patents. This section therefore mainly examines results from FP7-Health and attempts to extrapolate such results to Horizon 2020-SC1.

[82] *IMI project, IMI funding: € million 58, duration: 01/12/2014 to 30/11/2017, http://www.ebovac.org/*
[83] *IMI project, IMI funding: € million 20, duration: 01/12/2014 to 30/11/2017, http://www.ebovac.org/ebodac/*
[84] *IMI project, IMI funding: € million 4.3, duration: 01/02/2015 to 31/01/2017, http://www.ebolamodrad.eu/*
[85] *http://immunovia.com/*

Over and above its Key Performance Indicators[86], the main outputs that SC1 is expected to generate, as reflected in the intervention logic on fig. 1, are:

- **A. Scientific outputs** (publications, co-authorships, tools, methods, data & datasets, reports, protocols, guidelines, classifications);
- **B. Commercial outputs** (Patents, trademarks, processes, spin-offs, investments);
- **C. Other outputs** (trained researchers, networks of researchers and funders, dissemination events and materials, leverage effect, research agendas, roadmaps, joint calls, policy dialogues, Input to Policy-making).

A. As to **scientific output**, the same main academic institutions being present in both SC1 and FP7-Health, it is reasonably expected that, in terms of **high-ranking scientific publications**, their result will be of a very similar nature. According to the ex-post evaluation of FP7-Health, "[it] *achieved excellent results with respect to the production of scientific outputs [...] Data shows that an average finalised FP7-Health project produced more than 48 publications with an average SJR value of 3.8 and journal impact factor of 6.2* [an indicator of quality well above the European average of 2]. *It was estimated that by the end of all projects some 42.000 publications will have been published in FP7-Health. Some 1300 articles were published in top-ranking journals with an SJR value of at least 10, including Nature Genetics, Nature, Cell, Science, Neuron, Immunity and others*[87]. A different study concluded that 57% of the publications were published in high-impact journals[88]. 54% of project participants valued as one of the main reason for their participation that the projects *significantly expanded the research field beyond the initial state of the ar*t[89]. The average number of PubMed-listed publications generated with a member of a participant's group as first author, as estimated by the participants themselves, is about seven publications per project (with some 5% of participants publishing 15 papers or more). By extrapolation, the total number of PubMed-listed publications generated by Health research in FP6 and FP7 up to 2011 can be estimated at more than 70 000[90], a volume of RTD publications that reveals a very significant output of original and innovative knowledge in return for public funding.

Looking at IMI, it already delivered 1 678 scientific articles by the end of 2015, representing 62 publications per EUR 10 million of EU contribution reported and accepted. A large share of the publications is made of highly cited articles, and the citation impact is significantly above the EU and worldwide. IMI2 already delivered a few first significant papers.

Extrapolating PPMI's calculation of the productivity of FP7-Health in terms of publications[91], it can be expected that the SC1 collaborative projects alone (excluding IMI, the SME-instrument and the Art. 185 initiatives) will produce more than 46 000

[86] *SC1's Key Performance Indicators are the number of publications in peer-reviewed high-impact journals; the number of patent applications and patents awarded; the number of prototypes and testing activities and the number of joint public-private publications*

[87] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 129. In this evaluation journal impact factor was defined as average citations per document in a 2-year period.'*

[88] *Respir [as of 15.09.2014]. High impact journals are here defined to be the top 10% (in terms of SJR index) of all journals within their scientific category.*

[89] *FP7-Health Survey October 2014.*

[90] *Again, the time lag in this output needs to be kept in mind when estimating impact of research as according to respondents - 42% of scientific publications arose after the end of the project*

[91] *In terms of unit costs, each € 10 million spent by the EU contributed to over 120 publications*

scientific publications, to which one should add 10 000 publication to be produced by IMI2[92], adding up to a **minimum of 56 000 scientific publications from SC1-funded projects.**

B. The prospects regarding **commercial outputs,** based on FP7-Health results, are partly detailed under section J.4.1, notably with regard to the production of patents. In addition, FP7-Health impacts were particularly high for private industry organisations and SMEs. The ex-post evaluation of FP7-Health counted **37 spin-offs** as of October 2014, long before completion of most projects[93]. It is also expected that outside investments will be stimulated for companies winning the new generation of inducement prizes under SC1[94]. The potential power of innovation-supporting tools such as prizes capable of recognising an accomplishment and giving not only a monetary reward, but importantly, far wider recognition is amply demonstrated by the CureVac GmbH example. After it won the EUR 2 million vaccine prize in March 2014 for having developed prophylactic vaccines that can reach remote areas in the world without the need for cooling, the company's media coverage increased dramatically. Soon after, the Bill and Melinda Gates Foundation invested EUR 46 million in CureVac and started collaboration on novel therapeutic mRNA vaccines. The company also signed an exclusive license agreement with Sanofi Pasteur to develop and commercialize an mRNA-based Prophylactic Vaccine and secured up to EUR 150 million in one of the largest licensing deal of the sector that year with Sanofi Pasteur for exclusive global rights to develop and commercialise the jab against an undisclosed pathogen[95]. Table 129 shows the share of SC1 beneficiaries who sought additional or follow-up funding when developing their project and/or before being granted Horizon 2020 funding. SC1 participants tend to rely more on private/industrial sources for additional funding than the average Horizon 2020 participants.

Table 129 - Horizon 2020 SC1 beneficiaries seeking additional or follow-up funding (sample of 105 respondents)

	Own funding of project partners	Public national/regional schemes	Other EU programmes	Private/industrial sources
Share of SC1 beneficiaries who sought additional or follow-up funding when developing their project and before being granted Horizon 2020 funding (by funding source)	**60.8%**	**56.5%**	**23.3%**	**49.0%**
SC1 beneficiaries who expect to secure additional R&D funding for their projects in the future (by funding source)	**70.3%**	**74.7%**	**80.1%**	**68.0%**

Source. PPMI; Horizon 2020 European Added value Survey 2016.

Several avenues are used for the **exploitation of results.** 62% of completed FP7-Health projects referred to General advancement of knowledge as foreground results. 25% confirm the commercial exploitation of their results, while others mention other channels

[92] *Based on an estimate of 62 publication for each € 10 million observed for IMI.*
[93] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 44*
[94] *see section 5.4.2*
[95] *http://www.curevac.com/fileadmin/curevac.de/media/Content/Newsroom/20140701_CureVac_Press_Release_License_Agreement_Sanofi_Pasteur.pdf*

for exploitation of result such as social innovation (9%), EU policies (4%) or standards (1%). Evidence from the 2014 FP7-Health survey indicates that at least 65% of the patents had been licensed at this stage. Of the patents filed by SMEs, 47% had been granted by 2015, and 29% had been licensed already[96].

C. As to the **other categories of outputs**[97], under FP7-Health, **PhD and post-doctoral fellowships** were all generated through participation of a team in collaborative research. Around two thirds of participants claim that they had created new positions (in their organisation or in a start-up resulting from the programme) positions. Extrapolation indicates about 3 630 PhDs[98] and 3 130 post-docs positions created specifically under these FP7-Health projects[99], ensuring the education and advanced training of tomorrow's high potential innovators. Data from the 2010 survey of FP6 and FP7 Health participants indicate that, on average, the programme generated an estimated 5000 **jobs** per year during the 2002-2010 period.[100]. A 2015 study[101] estimated that the beneficiaries of FP7-Health hired more than 11 000 **additional researchers** from outside of the organisation. As there were just over 11 000 institutional beneficiaries in FP7-Health, an average of one researcher was additionally hired per team. The impact on team size was long-term: about 45% of the additionally hired researchers stayed in their teams after the project completion.

Data also shows that the **networking** resulting from FP7-Health funding reaches beyond the mere consortia but actually the whole community of EU-funded institutions in a given area (e.g. cardiovascular research). 2000 publications, or about 10% of the total scientific output produced, were co-funded by more than one FP7-Health project[102]. FP7-Health research produced **new, sustained, research partnerships** that represent a clear outcome of EU-funded health research. 60% of participants declare that their research network(s) formally continued to operate after the end of the project[103]. The *ex-post* study on FP7-Health exactly confirms this. It shows that for 43% of projects, previously existing collaborations were strengthened, while for 18%, new and sustained networks were created[104].

The programme also fosters a **sustained increase in the research capabilities of participants[105].** FP7-Health beneficiaries acknowledged that EU health research has a very significant impact on building the future research capacity of their organisations[106].

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[96] *FP7-Health Survey October 2014. Since two thirds of all respondents are involved in an on-going project that may not have reached yet its full potential in terms of knowledge generation, patents, publications, jobs or new products development, significantly increased figures can be expected once all project are completed. Comparison of data regarding the FP7-Health survey of October 2014 and the RESPIR database (the latter concerning only completed projects) hint at an increase of 70% of the figures regarding the number of filed patents.*

[97] Prospect or data regarding other outputs are discussed in other sections of this document: networking of funders (see sections 7.2.1.B, 4.1.2.3 and 7.2.2.A), dissemination events and materials (see section 6.2.1), research agendas and roadmaps (see sections 5.4.1, 7.2.1.B) policy dialogues and input to Policy-making (see sections 4.3 and 5.4.6)

[98] FP7-Health Survey October 2014 based on the project coordinators' replies. Data extrapolated from completed projects' reports indicate that some 9500 PhD students will have been involved on these FP7-Health projects (source: Respir).

[99] FP7-Health Survey October 2014 based on the project coordinators' replies.

[100] *Impact assessment of health research projects supported by DG Research and Innovation 2002-2010, Expert Group report recommendations on the future of health research in Europe, European Commission, 2011*

[101] *Idea Consult, PPMI and iFQ (2015), Study on assessing the contribution of the framework programmes to the development of human research capacity, European Commission, 2015.*

[102] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 136.*

[103] *FP7-Health Survey October 2014*

[104] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 91.*

[105] *FP7-Health Survey, October 2014*

Looking at **leveraging effect and matching funds,** in terms of direct crowding-in[107] of funding, SC1's projects are directly mobilising 0.09 EUR from the private sector and roughly 0.18 EUR from the public sector for each EUR of EU contribution. This reflects the maximum rate of reimbursement of eligible costs identified in the WP's 2014-17 which is 100 % for Research and Innovation Actions, and 70 % for Innovation Actions. With such funding rates, it is obvious that the leverage effect is not to be found in standard collaborative projects, but in Cofunds, with PPI's, and ERA-NET cofund, mobilising 4.9 EUR for 1 and 3.2 EUR for 1 respectively (see Table 120, in section J.2.1).

According to data from the FP7-Health 2014 survey of FP7 participants, around 56% of projects participants, regardless of their affiliation, indicated that EU funding helped them access other funding to expand or continue their research. Up to 64% of their current research funding was derived from this leverage effect[108]. As a further indicator of the importance of EU funding, 75% of participants acknowledge that EU funding represents up to 50% of their total research budget. The extra funding reported to have been obtained included national or regional sources (72% of respondents), other FP programmes (30%), private foundations and charities (24%), industry (19%) and international programmes & agencies (15%). By contrast, only 3% of all respondents who indicated leveraging by FP funding, reported business angel or venture capital sources. Unlike academic researchers, however, 14% of the SMEs with leveraged funds obtained these from business angels or venture capitalists.

Through EU R&I schemes, private companies can collaborate with foreign partners at a scale not possible at national level, in projects tested for excellence, which induces them to invest more than they would under national funding schemes. One example of this is IMI2: IMI2 JU already generated a large leverage effect on industrial R&D investment. In the reported costs at mid-October 2016, the total costs represent EUR 61.4 million of which EUR 14 million of EU contribution and EUR 47 million of certified in-kind contribution from EFPIA entities. The leverage effect for reported costs is thus 4.34.

According to the current evidence and to the experience of FP7-Health, which has attracted a very similar population of stakeholders, the outputs are in line with what SC1 aims to produce, and there is no sign that SC1 risks to underperform for any of these.

J.4.3. Progress towards attaining the specific objectives

Since its start, SC1 has implemented calls for proposals that were directly structured along its main specific objectives. With each topic published generating high quality proposals, all objectives have been addressed as detailed below (as of 1 January 2017):

- *Understanding health, wellbeing and disease* is being supported by 36 projects for EUR 137 million (corresponding to 15 % of the selected projects and 10.5 % of the funding)

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[106] Mialhe A, et al., *Profiles, motivations and expectations of participants to EC funded research in Health (2002–2010): A statistical analysis*. IRBM (2012), IRBM, Volume 33, Issue 3, June 2012, p. 208. http://www.sciencedirect.com/science/article/pii/S1959031812000632

[107] *The amount of funding contributed by the stakeholders to the Project, matching the EC contribution.*

[78] *FP7-Health Survey October 2014.*

- *Preventing disease* is being supported by 22 projects for EUR 126 million (corresponding to 9 % of the selected projects and 9.5 % of the funding)
- *Treating and managing disease* is being supported by 89 projects for EUR 565 million (corresponding to 37 % of the selected projects and 43 % of the funding)
- *Active ageing and self-management of health* is being supported by 34 projects for EUR 177 million (corresponding to 14 % of the selected projects and 13.5 % of the funding)
- *Methods and data* is being supported by 21 projects for EUR 92 million (corresponding to 9 % of the selected projects and 7 % of the funding)
- *Health care provision and integrated care* is being supported by 11 projects for EUR 45 million (corresponding to 5 % of the selected projects and 3.5 % of the funding)

All elements present in the Specific Programme have either been addressed by a topic, or the wording of the WP gave the opportunity to submit proposals addressing a point given in the Specific Programme. All priority areas indicated in the legal basis are already well covered. Every R&I topic stemming from these priorities yielded high quality proposals and, eventually, funded projects. This does not mean that all the sub-areas or elements mentioned in the Specific Programme are already fully covered. The depth and the range of coverage by the selected proposals will vary across topics, with some, such as clinical research for regenerative medicine, having been repeated in the 2014-15 and in the 2016-17 WP's.

The assessment of FP7-Health concluded that 98% of the projects achieved all or most of their objectives. The share of funded projects completely achieving the initially stated, peer reviewed project objectives was 42% while 56% achieved most of their objectives. Only 2% failed to achieve critical objectives[109]. As SC1 has managed to mobilise the same stakeholders overall, similar results can reasonably be expected under Horizon 2020.

The responses of a survey of SC1 project participants also point to a good overall coverage of the objectives but also to a strong expected impact within the next 10 years in many specific areas within the challenges with notably,

- 39 %, of projects expecting to have impact on *Combating European/global Health threats (pandemics or biological incidents, infectious diseases)*;
- 53 % of projects expecting to have impact on E-health & large-scale data gathering
- 16 % of projects expecting to have impact on AMR[110].

Looking at the IMI2 JU specifically it progressed well in terms of launching activities towards its objectives. As of October 2016, 9 calls for proposals had been launched representing EUR 451 million of EU contribution and EUR 419 Million of in-kind contribution from EFPIA entities and Associated Partners. As of October 2016, only 7 projects had already reported activities. It is thus premature to conclude about the outputs and impacts of IMI2. Nevertheless, IMI2 projects started delivering important results as

[109] Respir [as of 15.09.2014]. The percentage is 45% for *Biotechnology, generic tools and technologies*; 42% for *Translating research* and 36% for *Optimising the delivery of health care to European citizens*.
[110] PPMI: *Study on European Added Value in H020, overview of the survey results* (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016.

exemplified with the projects selected from the second call, addressing key objectives such as:

- *Increase the success rate in clinical trials of priority medicine*: EBOVAC1 and EBODAC (see section J.4.1) with the goal of rapidly testing new Ebola vaccines, have been perfecting their trial designs in response to the highly fluid situation regarding the number of Ebola cases reported.
- *Reduce the time to reach clinical proof of concept in medicine development*: The EBOMAN project, again launched to address Ebola disease, has manufactured and released sufficient vaccine for the clinical programme covered under EBOVAC 1 and 2, including any health authority submission packages.
- *Develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators*: The EbolaMoDRAD project has developed rapid bedside inactivation vacuum tubes, which make it possible to inactivate Ebola virus directly during collection of samples from the patients. This can lead to safer handling of samples and safe transportation of samples from outbreak sites to, for example, reference labs in Europe.

Pre-commercial Procurements of research in e-health have been launched with success, with a good response from the stakeholders and an equally good selection rate in 2016. A Public Procurement of Innovation action was also been launched in 2016 but only triggered a very limited response. The initial high interest in the PPI by potential applicants was hampered by difficulties in engaging the demand side procurement actors and implementing pan-European procurements due to the constraints of national co-funding, timing and legal issues in procurement rules.

No specific factors hindering progress towards the projects' objectives have been signalled or identified. The only area where some difficulties are met is that of **clinical trials**. The first 18-month reports are now reaching the services, and while some clinical research projects are moving largely ahead of schedule, other may have underestimated the undertaking required by major multi-partner international trials (cell manufacturing, distribution, protocol alignment, clinical trials approval procedure, patient recruitment, etc.) Indeed, regulatory issues, notably in terms of obtaining ethical approval, or of implementing some of these ethical requirements for multi-site clinical trials often prove problematic. In addition, many projects are confronted with an inappropriate patient recruitment rate that hampers the smooth running of the projects. However, as for FP7-Health, the main consequences are generally limited to delays in implementation that can often be solved with the extension of project' durations.

J.4.4. Progress towards the overall Horizon 2020 objectives

This section explains to what extent the current progress towards the achievement of the objectives allows contributing to Horizon 2020 specific objectives.

J.4.4.1. Fostering excellent science in scientific and technological research

Given the fierce competition witnessed for EU-funding by SC1, and the subsequent low success rate, it is expected that the projects retained are the cream of the crop, since only one in three high quality proposals was eventually funded.

The fostering of excellence is also illustrated by the following. Section J.4.2 shows the very high number and value of the publications expected for SC1 beneficiaries, on the

basis of FP7-Health results. More precisely, the preliminary estimates of a study based on a sample of 711 FP7-Health projects indicate that, on average, FP7-Health publications were cited around 22% more than the papers published by the same investigators but not related to FP7-Health funding[111] (the increase was 8 % for FP7 overall), while the average SJR value of the journal in which FP7-Health publications were published was 52% higher than the average SJR value of journals that published papers by the same investigators, but not related to their FP7-Health project during the same period (increase of 26 % for FP7 overall).

This also the case of papers produced by IMI-funded projects. A study published in July 2016 by Thomson-Reuters[112] noted that, by the end of 2015, IMI research has a citation impact of 1.93 - almost twice the world average (baseline of 1.0) and nearly twice the EU average (1.10). Around a quarter (23.5%) of IMI papers are 'highly cited', meaning they are in the top 10% of papers for that journal category and year, when ranked by number of citations received. On both measures, IMI research compares favourably to research funded by other well-established, high-profile medical research funding organisations like the Medical Research Council and the Wellcome Trust. IMI research is published in some of the most prestigious journals in the world, including the New England Journal of Medicine, Nature, and the Lancet. Nearly three-quarters (73.6%) of IMI papers were published in journals which rank in the top 25% according to their impact.

Box 15 - Contribution to the achievement and functioning of the ERA

To assess the expected structuring effect of actions under SC1, one might extrapolate findings for FP7-Health. The 2014 survey of FP7-Health beneficiaries points overwhelmingly to the perception that participation brings benefits in terms of ability to tackle more ambitious research objectives in cooperation than alone, to the value and sustainability of networking[113], access to expertise and infrastructures, sharing of data, and better coordination of research. The 2016 report on *ex-post* evaluation of FP7-Health claims: "*FP7-Health had **high structuring effect on the development of a single ERA** by creating a closely interconnected network of organisations and thereby facilitating knowledge flow in the ERA and beyond* […] *Several initiatives had a positive structuring effect on the ERA, including ERA-NETs and JPI's. In particular, European funding for neurodegenerative diseases such as dementia and Alzheimer's significantly expanded and became better coordinated as result of FP7 funding and funding leveraged by the JPI on Neurodegenerative Disease Research (JPND)".*

Optimal transnational co-operation by establishing collaborative networks of areas of particular EU added value. An example of the above is topic SC1-PM-04–2016: *Networking and optimising the use of population and patient cohorts at EU level*, specifically devised to enable networking of many European (and not only) cohorts with common scientific interests (e.g. across diseases, children, mothers, elderly, birth, gender, etc.) by taking advantage of new technologies (e.g. ICT, social platforms, etc.) and new type of data (e.g. geographical, genetic, e-health records, etc.). Based on those cohorts using a comprehensive integration strategy to facilitate hypothesis-driven research, data sharing, harmonization and analysis, the selected projects will provide

[111] *Finding based on analysis of OpenAIRE data, PPMI: Study on European Added Value in H020, overview of the survey results (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016,*
[112] http://www.imi.europa.eu/content/bibliometrics-2016, http://www.imi.europa.eu/sites/default/files/uploads/documents/Publications/BibliometricReport_2016.pdf
[113] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 70. "New, sustained research networks were created in about 20% of the finalised projects where no such networks existed prior to EU funding, implying a significant structuring effect of FP7 Health".*

expanded resources and knowledge on health and disease determinants, onset and course of diseases, clinical, public health and socio-economic research. Such an effort would be impossible if not for the integrative approach offered by SC1.

Optimal transnational co-operation by favouring the development of joint national research agendas in areas of common interest. Direct impact on ERA can be felt already at this early stage of SC1 implementation in areas where major coordination efforts are being pursued at EU or global level, such as IC Permed, the international consortium for the PM deployment roadmap; the EIP on AHA (continued from FP7); the European Human Biomonitoring Initiative (HBM4EU, see section J.4.4.6) to increase coordination of HBM activities in Europe, the Ambient Assisted Living 2 Art. 185 initiative[114], AMR where the coordination efforts at EU level, via the JPI, are being matched by a significant joint public-private effort via IMI2.

Improving the effectiveness of national research systems by tackling duplications and fostering alignment of priorities is at the heart of the ERA-NET concept. As an illustration, the E-RARE3[115] ERA-NET aims to develop and strengthen transnational cooperation of research funding on rare disease in Europe and beyond. Gathering 25 research funding organisations from 13 EU Member States and four non-EU countries, it launches annual Joint Transnational Calls. The EC topped up the first call in 2015 in which 19 collaborative projects covering a wide range of rare diseases aim at advancing understanding of disease mechanisms in order to develop new diagnostic tools and treatments. In the field of neuroscience, the NEURON-Cofund action, covering all brain diseases[116] has already implemented a first joint trans-national call on external insults to the nervous system. It will help to further structure the EU research landscape in neuroscience.

J.4.4.2. Boosting innovation, industrial leadership, growth, competitiveness and job creation

Direct overall impact on innovation cannot be estimated at this stage[117]. The SC1 approach for boosting innovation is based on four pillars: *public-private partnerships (PPP)*, *supporting the SME-instrument, boosting innovation through inducement prizes* and fostering investment: **1) Fostering public-private partnerships (PPP), the renewal of the IMI Joint Undertaking:** PPPs in health research respond better to the latest trends in R&I processes, including the changing business R&D strategies in the pharmaceutical industry such as open innovation or deeper collaboration with the academic sector. Under IMI2, the large industry invests own resources for its research, without receiving any EU-funding, and the EU matches this EUR 1.64 billion investment by funding the research of the other partners who benefits from the unique experience and expertise of these large companies. Companies' investments in areas of high public

[114] *AAL JP has contributed to the ERA by aligning and leveraging Member State funding in the area of digital solutions for active and healthy ageing. In addition it has helped more than 300 SMEs so far in participating in European cooperation with a view to bringing new products and solutions to the market*

[115] www.erare.eu

[116] *except neurodegenerative diseases, which are covered by the Cofund.*

[117] *However, one might extrapolate the findings regarding FP7-Health, the ex-post impact study of which concluded in 2016: Although innovation impacts are difficult to estimate and aggregate for the whole programme, available data point to very substantial commercialisation perspectives and outstanding examples of innovations created. Nearly 40% of FP7-Health projects belonging to pillars 1 and 2 (representing 85 % of its 4 pillars) contained evidence of realised or planned commercialisation activities. Small- and medium-scale projects with strong involvement of SMEs were most actively involved in the related activities, but large-scale projects with active participation of universities and public bodies from the EU-15 were also active in this area. High-throughput research, innovative therapeutic approaches and interventions, anti-microbial drug resistance, large-scale data gathering and detection, diagnosis and monitoring were the most active FP7 call topics.*

health need but low return on investment is difficult to stimulate. IMI has changed this dynamic, as evidenced by the collaboration to combat AMR. Only two new classes of antibiotics have been approved in the last 30 years. Thanks to IMI, a large European network of 261 clinical centres in 32 countries, has been created and several compounds are in various stages of clinical development. Taken as model for how to invigorate research and investment in this key growth industry, it is being copied across the globe. By supporting a better alignment of R&D strategies, it will in the long run increase the innovative capacity of the sector as a whole. IMI2 targets a SME participation (and funding) of at least 20%. As these were not reached during the starting phase, several measures were put in place to achieve this.

2) SME support: SC1 supports the key role of SMEs in the health innovation process to an unprecedented level. As of 1 January 2017, EUR 141 million were being invested under SC1 on the SMEs-instrument for 273 participations in the selected proposals. The huge response to the first calls illustrated not only that the instrument is adapted to the TRL stage when EU funding is most useful and needed but also that the open, bottom-up- calls, with short time-to-grant are well adapted to their needs.

Evidence from the 2014 survey of FP7 beneficiaries indicates that SMEs consider that, after "new or improved products", the second most important benefit from their participation to FP7-Health collaborative projects was "networking and/or coordination of science", underlining the very positive impact of the FP7-Health on their own industrial product development. This is confirmed by 77% of participating SMEs who state that *strengthening the competitiveness of European industry* is one of the most important impacts of their EU collaborative projects. This motivation elements to take part in collaborative research did not disappear under SC1, , and research-intensive SMEs were also attracted to the SC1's RIA's, with 498 participations for 394 distinct SMEs in 231 distinct projects for a total EU contribution of EUR 198.1 million[118]. These SMEs also claim that EU funding as brought about changes in their research behaviour: FP7-Health has encouraged them to be more involved in research activities. 74% of them stated that after having participated in FP7-Health, they will carry out research on a more regular basis. Also, 79% claim that it encouraged them to carry out research on a larger scale in the future[119].

As of 1 January 2017, SC1's total contribution to SMEs[120] amounted to EUR 346 million, corresponding to 21% of the EU funding (18.1% under FP7-Health).

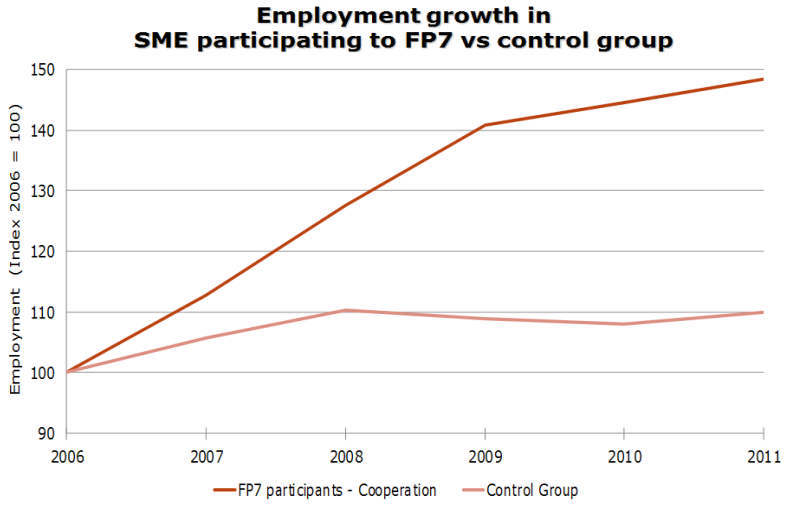
3) Inducement prizes set ambitious goals, but without detailing how each goal should be achieved or who should achieve it. They provide alternative opportunities to develop innovative solutions by offering a reward for completing a specific technological challenge. They are a prime exemple of 'value for money' as they are only awarded based on the delivery of the output i.e. upon the achievement of the target set, solving the challenge defined. SC1 launched a EUR 1 million *Horizon Prize for Better Use of Antibiotics* on a rapid test to allow healthcare providers to decide which patients with upper airway infections can be spared from antibiotics. A second *Prize on Maternal and Child Health Research* was launched in 2016, with the same budget.

[118] *See also the conclusions resulting from the statistical analysis and Social Network Analysis (SNA) performed on SME participation to FP7-Health: PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 56*
[119] *FP7-Health Survey October 2014*
[120] *Excluding IMI.*

4) The InnovFin Infectious Diseases (InnovFin ID) loan facility, launched in June 2015, operated with the EIB, and presented in section J.3.1.2 completes this portfolio of instruments offered to enterprises. It will facilitate the development of innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures in the field of infectious diseases. By 1 October 20016, 56 proposals had been received, 8 were rejected; 24 projects are on hold and can be re-activated; 21 projects are under further consideration and at various stages in the assessment process, while three deals have been concluded, with a total loan volume of EUR 45 million. The first loan went to the Swedish SME CAVIDI for the further development of a diagnostic device for HIV viral load testing[121]. The 2nd loan was secured with the French biopharmaceutical company Transgene SA to develop new treatments for hepatitis, HPV-induced cancer and tuberculosis[122]. The third loan will help a Finnish IVD SME (MOBIDIAG) to finalise and scale up their manufacturing, validation and commercialisation of a diagnostic tool for Infectious Diseases[123].

Assessing the impact of the programme on the **competitiveness at the firm level** is not straightforward[124] as SMEs in Health projects identify on average 2.9 different sources of funding. It is also important to bear in mind that the main exit strategy for biotech SMEs are mergers and acquisitions, which can also be positive for European industry competitiveness. Among the SMEs participants in the 2014 survey of FP7-Health beneficiaries, 5% of them had been acquired by another company. However, as of October 2014 (a stage when only 40% of the projects were completed), FP7-Health projects had already generated or were generating around 274 new SMEs[125] and an estimated 9 770 jobs.

Figure 196 - Job Creation under FP7, Employment growth of SMEs participating in EU projects



Source: Panteia, calculations based on eCORDA and ORBIS using PSM to construct control group.[126]

[121] http://ec.europa.eu/research/index.cfm?pg=newsalert&year=2015&na=na-130715
[122] http://ec.europa.eu/research/index.cfm?pg=newsalert&year=2016&na=na-280116-2
[123] http://www.eib.org/infocentre/press/releases/all/2016/2016-175-finland-innovfin-european-support-for-innovation-in-finland.htm
[124] *FP7-Health Survey 2014.*
[125] *FP7-Health Survey October 2014*
[126] *European Commission, Performance of SMEs within FP7 An Interim Evaluation of FP7 components, May 2014, p. 76, http://www.fteval.at/upload/Performance_of_SMEs_within_FP7_-_An_Interim_Evaluation_of_FP7_components.pdf*

Already 10% of these were considered to be long-term jobs, regardless of additional comparable positions that would emerge at later stage in the projects or of jobs linked to the creation of spin-offs.[127]. An average of 11% of the participants were involved in creating one or more SMEs in relation to their work in the project, 90% of which continued to operate after the end of the project[128]. There is no reason to expect that research funded under SC1 would not have a similar impact, all the more so since SC1 now mobilises the e-health and m-health sectors that offer an even richer opportunities for SME.

As noted on section J.2.3, the assessment of the current SC1 projects portfolio by the projects officers indicates that 27.5 % of the projects, corresponding to 20.5 % of the funding contribute to the **Digital Agenda for Europe**[129] and, hence, to the prospects that this sector offers in terms of boosting innovation, industrial leadership, growth, competitiveness and job creation. These projects are to be found in the areas of e-health, m-health, *Internet of Things* and other ICT solutions for active and healthy ageing**,** health big data, bioinformatics, data analysis, modelling and simulation in medicine.

Accordingly, based on the programme focus, the mix of instruments on offer, the early outputs and expected results from projects and participants selected so far, the programme appears to be on track to contribute addressing this Horizon 2020 specific objective.

J.4.4.3. Addressing the major societal challenges

The progress of SC1 towards addressing the challenge of *Health, Demographic Change and Wellbeing* has been analysed in previous sections. It is worth examining its impact on other major societal challenges. Contribution to the SDG is detailed under section J.3.1.1.

A 2016 survey to Horizon 2020 participants asked to assess whether they expected their projects to have impact on the societal challenges in the next 10 years[130]. The survey data indicates a relatively strong impact on SC6 - *Europe in a changing world - Inclusive, innovative and reflective societies* since 35% of SC1 respondents indicated an expected wider impact on SC6 in the next 10 years. Other Horizon 2020 societal challenges where perceived as being potentially less affected by the impact of SC1's projects. The main ones being SC2 : *Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy* with 10 %, and SC7, *Secure societies – Protecting freedom and security of Europe and its citizens*, with 10 %.

As to the climate change objective, the current level of contribution (EUR 17.4 million, 1.4% of the funding[131]) is limited (the overall Horizon 2020 objective is 35%). While the results of health R&I will understandably have little impact on climate change, it has a role to play in mitigating its impact on health. Climate change drives the impact on health through complex direct (e.g. temperature and sea level rise, melting of permafrost) and

[127] *FP7-Health Survey October 2014. Since two thirds of all respondents are involved in an on-going project that may not have reached yet its full potential in terms of knowledge generation, patents, publications, jobs or new products development, significantly increased figures can be expected once all projects are completed.*
[128] *FP7-Health Survey October 2014.*
[129] *Data resulting from the assessment by the POs of the relevance of their projects to cross-cutting and policy objectives. This data excludes IMI, SME-instrument and EDCTP projects.*
[130] PPMI: *Study on European Added Value in H020, overview of the survey results* (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016.
[131] *This data excludes IMI, SME-instrument and EDCTP projects.*

indirect (e.g. deforestation, urbanization, migration) mechanisms. Climate change and urbanisation are putting increasing strain on food production and health. This is evident in many developments across the world. The environment is affected by increased urbanisation, affecting the quality of air, water and soils, which can also have negative effects on human health. A wide range of infectious diseases are influenced by climate change, most importantly the waterborne and vector-borne diseases.

J.4.4.4. Spreading excellence and widening participation

While the proportion of the total health R&I budget granted to teams from newer MS has increased (from 2.5 % for EU-12 in FP7-Health to 3.2 % for EU-13 in SC1), their share remains small. EU-12 participation rate was 5.8% in FP7-Health [132] while the rate of EU-13 represents 6.5% under SC1. However, the trend is not as positive as it was, dropping from 7.6% in 2014 to 6% in 2015, and the figure were actually significantly better under FP6 when these countries were candidate countries. The success rate figures in SC1 reveal that the limited EU-13 presence is not a matter of rejection at proposal evaluation stage. The difference with EU-15 is not significant, and countries such as Latvia and Slovakia actually show the highest success rates of all EU-28. EU-13 teams are either reluctant to apply, or they are not invited into consortia.

The assessment of the current portfolio of projects by their respective project officers indicates that 19 % of projects and 17 % of the funding are considered relevant to widening participation across the Union in research and innovation and helping to close the research and innovation divide in Europe. Two projects actually aim to tackle these disparities in performance between regions[133]. The issue is hardly a problem of success rate at evaluation stage, as that of EU-13 teams is only marginally lower than that of EU-15 ones (10 % vs. 11.3 %). The matter is quite different in IM2, where EU-13 organisations represent 3.5% of all participants due to receive EU funding in selected projects from the first published calls, (EU-15 : 86.6%) while they represented 9% of all applicants. Thus, the rate of participation from EU-13 organisations to IMI2 JU calls is encouraging but they fare worse in the evaluation than other organisations.

J.4.4.5. Science with and for society

As indicated under section J. 4.1, as part of efforts to promote Responsible Research & Innovation (RRI) across Horizon 2020, SC1 fostered the co-creation of scientific agendas and scientific contents. In at least 17.4% of SC1's projects, citizens, Civil Society Organisations (CSOs) and other societal actors contribute to the co-creation of such agendas and contents[134] (Horizon 2020 average: 7.2%). They are representatives of patients or users who provide useful, sometimes crucial, information on the needs and expectations of important stakeholders, thereby influencing the project's design. Such organisations are heavily involved in the EIP-AHA initiative. They also play an active role in the definition of personalised medicine. Several examples of their involvement are also provided in the second half of section J.3.3.

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[132] *Respir [as of 15.09.2014]*

[133] Projects RegHealth-RI [Novel Approaches in Tackling the Health Innovation and Research Divide in the Danube and Baltic Sea Region, http://danubalt.eu/] and DanuBalt [The European Regions Network for Health Research & Innovation, aimed at analysing, discussing and improving the performance of health research & innovation across the different EU regions and countries. http://rhing-net.eu/reghealth-ri/] tackle the divide in health R&I performance in the EU by analysing the reasons for the disparities and will offer suggestions to improve the situation.

[134] *Data provided by POs during GAP.*

As regards the promotion of **social sciences and humanities (SSH)** under SC1, 19% of partners indeed have an SSH background, receiving 14% of the EC contribution for these topics according to the SSH monitoring reports for projects in 2014 and 2015[135].

Looking at the extent gender is addressed within projects, 61% of the projects take into account the **gender dimension in R&I content** (compared to 25% overall for Horizon 2020). It should be noted that such a high figure is not unexpected in health R&I, where gender differences play a clearer role than in, e.g. research on climate change or energy.

J.4.4.6. Science for policy

At European level SC1 played a pioneer role in launching the first European Joint Programme Cofund under Horizon 2020. The HBM4EU initiative represents a novel way of collaborating between several Commission services, EU agencies and national representatives, highlighting how research funding can build bridges between the research and policy worlds. A joint effort of 26 countries and the EC, its aims to coordinate and advance human biomonitoring in Europe and will thereby provide better evidence of the actual exposure of citizens to chemicals and the possible health effects to support policy making[136].

One of the key features of the EIP-AHA is the identification of centres of excellence (reference sites) where good practices for the management of all aspects of ageing are made available to the community, at Regional, National and European level. Several SC1 calls for proposals offered opportunities in areas of interest identified in EIP-AHA's Strategic Implementation Plan and address some of its actions. The Structural Funds also provide funding possibilities to support research, innovation and other measures in active and healthy ageing. EIP-AHA will also support the **standardisation** of care which will be essential for enhancing the quality of life as people age.

Supported by SC1, *hESCreg*, is another example of how SC1 can support standardisation and legislation. This Europe's unique human embryonic stem cell registry was set up to inform all stakeholders about technical details and availability of existing stem cell lines to avoid duplication of efforts and unnecessary derivation of new lines.

While it is too early to expect impact from SC1 projects on policy, a policy initiative on personalized medicine and another one on infectious diseases are being developed under the mandate of the European Commission, strongly based on the portfolio of projects funded under FP7 and Horizon 2020-SC1.

J.4.5. Early success stories

In addition to the Immunovia case as well as the Ebola-related project (see section J.4.1), the projects below illustrate how SC1 is making progress towards achieving its specific objectives.

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[135] *This information is based on projects already financed under calls closed in 2014 and 2015.*

[136] *This European Joint Programme Co-fund will get national biomonitoring programmes and Commission services working together. HBM4EU has the ambition to become the European counterpart of the other international human biomonitoring programmes such as NHANES in the USA by increasing coordination of HBM activities in Europe, advancing our understanding of the impact of chemical exposures in our daily life on our health and providing better evidence for policy making*

EUREST-PLUS, evaluating the impact of tobacco legislation on population[137]: Smoking and other forms of tobacco consumption are considered the single most important cause of preventable morbidity and premature mortality worldwide. Thanks to its Tobacco Products Directive (TPD), and to the ongoing implementation of the WHO Framework Convention on Tobacco Control (FCTC), the EU reduces the devastation of tobacco-related deaths and illness in Europe. EUREST-PLUS will monitor and evaluate the impact of the TPD legislation on the population. Areas addressed include tobacco products ingredients, additives, reporting, labelling, packaging, second-hand smoke exposure and e-cigarettes, all important for the EU Directive. This is done by creating a longitudinal cohort study of smokers in 6 MS (the ITC Europe Project) and compare psychosocial and behavioural impact of the EU Directive through cross country analysis across the participating MS and 16 other non-EU countries which are part of the WHO Framework Convention on Tobacco Control.

PRO-EIP AHA leveraging EUR 4 billion national funding committed through the EIP-AHA: EIP-AHA is the largest stakeholder group in Europe comprising the entire value chain of digital innovation for active and healthy ageing. As part of its strategy to support the creation of a Digital Single Market for health and care innovation, the Partnership has awarded Reference Site status to 74 European regions (regional ecosystems that include academia, public authorities, companies and civil society). Together these 74 regional organisations have committed to an investment of approximately EUR 4 billion in innovative digital solutions for health and care in the course of the years 2017-2020[138].

J.4.6. Lessons learnt and Areas for improvement

While is it too early to assess its real impact, SC1 is right on track to deliver on its objectives, with very good prospects for increasing the bulk of knowledge in the area (e.g., an expected 56 000 scientific publications stemming from SC1), achieving the large majority of the selected projects' objectives, fostering networking and sustained collaborations, leveraging investments in health R&I, stimulating innovation, the production of patents, the creation of jobs and spin-off companies, contributing to the achievement of ERA, influencing EU and national research policies, feeding into EU policy-making, and placing the EC on the map when it comes to tackling global health issues.

SC1 project participants expect strong longer term impacts within the next 10 years, notably as to *Combating European/global health threats*, *E-health & large-scale data gathering,* and *AMR*.

The relevance of the provisions allowing launching emergency calls in crisis situations (Ebola, Zika) was amply demonstrated.

Some difficulties are encountered for clinical trials, where regulatory and patient recruitment issues are causing delays and amendments linked to the revision of implementation plans.

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[137] *Research and Innovation action, EU contribution: € 2 325 545, Duration: 2016-01-01 to 2018-12-31, https://eurestplus.eu/*

[138] *More information can be found under: https://ec.europa.eu/digital-single-market/en/news/european-regions-bring-digital-single-market-active-and-healthy-ageing*

J.5. EFFICIENCY

SC1 is jointly implemented by DG RTD and DG CONNECT. The SME actions are implemented by the Executive Agency for SMEs (EASME).

J.5.1. Budgetary resources

As of 1 January 2017, the EC contribution allocated to the implementation of the calls included in WP's 2014-2016 has been EUR 1.55 billion, about 21% of total expected budget allocated to SC1 in Horizon 2020[139], which is EUR 7.472 billion for the period 2014-2020.

As mentioned under 4.1.1. The European Fund for Strategic Investments (EFSI) required significant transfers from Horizon 2020 Programme for the provisioning of the guarantee fund over the period 2015-2020. This reduction affected the financial programming of SC1 with an impact on the number of expenditure related outputs from 2015 onwards.

SC1 did not undergo any difficulty in terms of yearly budgetary execution, neither for commitments not for payments, thanks to a careful planning of the funding cycle and anticipation of potential difficulties.

The change in **funding rules** with 100% direct plus flat rate indirect costs for all legal entities from universities to SMEs is a clear simplification. It reduces the risk of errors and their consequences in the case of *ex-post* controls. This is globally acknowledged by the beneficiaries. The major bottleneck of FP7 (i.e. SME validated as SME or enterprise) is largely lifted. Beneficiaries have clarity from the proposal drafting stage as to how much funds they can plan/possibly receive from the EU[140].

Looking at the types of actions and their budget, the programme[141] has so far been implemented mainly through RIAs (232 projects, 90 % of the funding), CSA's (20 projects, 2.5 % of the funding) and ERA-Net Co-funds (7 projects, 3 % of the funding). Several major partnerships, including IMI2 and EDCTP2 are now implemented concurrently[142] and have grown in terms of budget. The yearly SC1 budget dedicated to the standard collaborative instruments is all the tighter compared to FP7-Health. Combined with the broader horizontal approach, this has resulted in an increased competition between proposals from different health research areas (which still exist in the real world as "specialities") and to reduced support, leaving important research areas uncovered due to budget limitations. The SC1 management had to be very selective in choosing the opportunities it could take up by publishing topics. This also required significant communication efforts. Another side-effect of the limited number of topics is that their broadness encourages very diverse proposals to be submitted for a call and leaves a large margin of interpretation (as to their relevance) to the evaluation experts. This can make the evaluation process (and final grades) difficult to harmonize between experts and groups of experts.

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[139] *This includes all 2014-2015 calls, and part of the 2016 completed calls from the 2016-2017 WP.*

[140] EC, Report on the Horizon 2020 Simplification Survey 24.09.2015 – 23.10.2015, http://ec.europa.eu/research/participants/data/ref/Horizon 2020/other/events/survey/Horizon 2020_simplification-survey_final-report_en.pdf

[141] *Excluding IMI2 and the SME instrument.*

[142] *EDCTP was previously mainly funded by the FP6 budget whereas IMI was implemented via the FP7-Health budget.*

Public Procurement of Innovative Solutions has struggled to attract a sufficient number of quality proposals. The two topics using PPI co-fund actions, *Public procurement of innovative e-health services*[143] and *PPI for deployment and scaling up of ICT solutions for active and healthy ageing*[144] yielded respectively only one and two proposal. From these latter two proposals, only one could be selected for funding and the allocated budget could not be absorbed. Through stakeholder consultation, SC1 identified the following elements leading to the adverse outcome[145]:

- The funding rate was too low to attract interest of procurers
- Without a prior PCP, procurers are reluctant to commit to large scale procurement of innovative solutions that they have no prior experience with
- Public procurers are not the usual "customers" of FP's, therefore, publicity of the calls towards these stakeholders needs to be properly channelled
- The topics were too narrow to fulfil interested parties' needs.

In terms of budget availability, it should be noted that EUR 3.23 billion more would have been necessary to fund all high quality proposals received under SC1 in 2014 and 2015.

J.5.2. Programme's attractiveness

J.5.2.1. Mobilisation of stakeholders

A novelty of Horizon 2020, including SC1 is that it places a stronger emphasis on impact, on multi-annual strategic programming. The two-year cycle for WPs works well, with strong focus on scoping papers, and overall a very high level of horizontal coordination of WP's. This provides for better predictability.

The scientific community is largely positive as regards the themes and problems addressed by SC1. This is reflected in a substantial response to each call, a strong interest in workshops and the conferences organized by the services and in the requests of a broad number of European learned societies for SC1 staff to participate to these.

The high interest for the chosen topics resulted in SC1's heavy **oversubscription**. Success rates (success rate of 11.5% in 2014, 7.9% in 2015[146]), are far lower than in previous FP's, about half of those of FP7-Health, as a result of the choice to publish broadly defined topics. EUR 3.23 billion more would have been necessary to fund all high quality proposals received under SC1 in 2014 and 2015. There is always a trade-off between enlarging the pool of applicants by defining large topics, thus stimulating a large response, and disappointing the R&I community with low success rates. In the long run, it might however discourage some excellent teams to apply, though this has not been

[143] *PHC 29 of WP 2014-2015*
[144] *PM-13 in WP 2016-2017*
[145] The report: European Commission DG Communications Networks, Content & Technology, *Quantifying the impact of Pre-Commercial Procurement (PCP) in Europe based on evidence from the ICT sector,* 2016, pp. 112-114., recommends targeted, aligned and synchronized open calls, dedicated to a specific type of contracting authorities, following preparatory consultation of public procurers all over Europe to ensure that calls match procurement needs for which concrete investments are planned in the yearly national procurement budget preparation cycles.
[146] *Source: 2015 Monitoring report: The success rates for the Health Societal Challenge are 7.9% in terms of eligible proposals and 7.2% in terms of EU funding requested (Horizon 2020 average: 10.7% and 10.9% respectively). The success rates of the SME Instrument are lower than the average of the Health Societal Challenge (8.19% vs 2.47%). The success rates are particularly low for call Horizon 2020-SMEINST-2-2015 (2.3% in terms of proposals)*

observed yet. The solution adopted at the start was **two-stage** submission and evaluation, with the automation of Stage 1, for the efficiency and speed of the process. This was not easily accepted by the Programme Committees, though the proportion of complaints, materialised by redress cases has not increased since the last calls of FP7 (2%, both at Stage 1 and at Stage 2)[147]. In order to make Stage 1 more selective and prevent widespread waste of resources used for drafting too many unsuccessful Stage 2 proposals, SC1 decided to raise the overall threshold at Stage 1 by ½ point (i.e. from 8 to 8.5) for the 2015 calls. This move contributed to eliminate more proposals, though less than expected since the experts adapted their marking pattern. A later option for limiting the number of proposals advancing to Stage 2 was to adopt a dynamic financial threshold, i.e. indicating in advance a multiple of the available budget combined with stronger requirement regarding measurable impact in the WP. While two-stage call processes are apparently preferred by many stakeholders, budgetary matters made it actually impossible to adopt it overall for the whole 2015. For some calls the single-stage submission and evaluation procedure was maintained because it was deemed more appropriate due to the nature of the topics.

Individual remote evaluation by independent experts was also considered an important element of a high-quality evaluation in SC1 even if SC1 services faced difficulties when attempting to communicate that there is a trade-off between a rapid evaluation process with reasonable investment in evaluator time and cost, and the level of detail in the feedback from the evaluation. The **horizontal, not disease-centric, approach,** of the programme however brings some degree of complexity to the review process due to the contrast between the broadness of the topics and the specificity of most submitted proposals which are still very much speciality-driven (which sometimes makes the selection of expert evaluators a complex process). The control in priority setting is also somewhat weaker than in the past: projects can be funded "accidentally" on certain issues due to the fact that topics are so wide open, which can be either positive or less so. In addition, apart from infectious diseases where focus has been maintained in SC1, IMI-2 and EDCTP2, the horizontal approach may complicate the development of a comprehensive research portfolio in any given area as it is not possible to anticipate which issues, technologies and medical subjects will be covered. Potential overlap between programmes (in particular with ERC) may be more pronounced than in FP7. Also, the evaluation criteria for RIAs may not sufficiently capture the element of ability to implement, leading to higher risk projects.

The **success rates** for SC1 collaborative research calls proposals is 9.6 % (Horizon 2020 average: 11.8 %). For the SME-instrument, it is similar: 9.0 %. It was particularly low for the calls Horizon 2020-PHC-2015-single-stage (Personalising Health Care) with 27 of 624 (4.3%) proposals being funded and Horizon 2020-SMEINST-2-2015, with 12 of 568 proposals (2 %) being selected for funding. The success rate of EU-13 applicants does not differ significantly from that of EU-15 (11.3% vs. 10%). The success rate of non-academic public bodies (21.3%) is higher than the 10% average. This might reflect the fact that they are largely present in ERA-NETs and similar coordination exercises where the success rate is much higher, or possibly that the presence in projects of bodies such as ministries was perceived as an added value by the evaluators. The success rate proved somewhat lower for private partners in collaborative projects (8.4%). It may be that, in the extremely competitive context of SC1 'classical' calls, very ‘conservative’ consortia

[147] Out of the 2041 rejected proposals for the 2014 and 2015 calls, 115 (5.6%) submitted a redress request, one of which was re-evaluated but eventually not funded. These rates illustrate the robustness of the proposal evaluation system, the quality, fairness and transparency of which was acknowledged by all successive independent observers.

have higher chances, and those are consortia of academics from the leading (medical) universities: a consortium including at least three universities of the EU top ten (according to the Leiden ranking) having 50% chances of succeeding[148].

As compared to FP7-Health, SC1 implements an increasing volume of budget being with a constantly decreasing number of staff, with increasingly shorter time-to-grant and time-to-pay. Based on monitoring data, the SC1 **Time-to-Grant** indicator is 97% (Horizon 2020 average: 91.6%, excluding ERC projects), with similar figures for projects financed through the SME Instrument (98.0%). This is largely in line with the Horizon 2020 target and a positive element for participating SMEs. The extensive negotiation phase both in scientific and administrative issues has been substantially shortened with few negative effects. The no-recommendations – no negotiation approach helps in weeding out non-focused projects. The timing is reasonable with 8 months in total between the call deadline to the **Grant Agreement** signature, though legal/financial validation of new project partners via REA can cause delays. For the largest consortia it can be very challenging to keep the consortium to short deadlines (e.g. European Joint Programme Co-fund). While shortness of Grant Agreement Preparation especially matters for SMEs for which competiveness issues require to quickly implement the selected projects, academic coordinators may not always be in a hurry since they need time to hire personnel (post-docs), once the funding is secured. Although this approach improves a "measure indicator" (time to grant), a rushed GAP may also sometimes result in the postponement of some structural problems that will appear later in the project, and will need to be solved via amendments (causing an increase in amendments numbers). **Validation of legal entities** is less of a problem than under FP7, but remains problematic in some cases, as is dealing with the consequences of financially weak or insufficient legal entities. Recurring implementation problems were noted, for example with co-funding, subcontracting and EU/national procurement requirements of PCP/PPI, where stronger external reliance on investments sometimes creates delays and complex contractual dependencies. **Ethics screening** is also performed for early detection of possible issues and problems.

Turning to **participation patterns** the main beneficiaries of EU health R&I funding in SC1 are academia and research organisations, which represent nearly two thirds of the participations and more than two-thirds of the funding. As under FP7-Health, SC1 highly mobilised the best EU research organisations in the field, both as coordinators and project participants. There is a clear continuity with FP7-Health in terms of academic players: the main participants under FP7-Health already secured a large number of participations to SC1[149]. 96% of the Higher or Secondary Education Establishments grant holders in SC1 were already funded under FP7.

The presence of nearly 5% of participants in the category "others", more than half being newcomers, suggests that Horizon 2020-SC1 is more open than its predecessors to new and more diversified categories of participants, notably patients associations involved in the clinical studies.

Industry participation has significantly increased from 20.7% under FP7-Health theme to 27 % under SC1 (with SME participation from 18 % to 21 %), notably thanks to e-health

[148] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Case Studies Interim Report, October 2016, p. 128.*

[149] *These include INSERM, University College London, Karolinska Institutet, Katholieke Universitet Leuven, Universities of Oxford & Cambridge, Academisch Ziekenhuis Leiden, Imperial College, Erasmus University Rotterdam, King's College London, Ludwig-Maximilians-Universität München, Vrije Universiteit Brussel, Fraunhofer Gesellschaft, Intituto de Salud Carlos III*

and m-health's increased presence, and as a result of introducing the SME instrument. Enterprises participate 1.2 times on average in the programme, i.e., less than academic institutions or other public bodies. The number of participations is a relevant indicator of a programmes' attractiveness: renewed participation suggest that previous or ongoing experiences are positive, and an incentive to further apply. In the case of *private for profit* entities, however, the rather low figure is not problematic, as the rate of newcomers is very high and also because smaller SMEs might not have the means to get involved in more than one EU project.

As to attracting EU innovative firms, while the same players remain present in the pharmaceutical sector, companies such as Philips or Empirica are now much more present under SC1 than in FP7-Health, as a result of the inclusion of e-health and m-health within the scope of SC1. Table 12 shows the attractiveness of SC1 for innovators in the health sector: 13 out the 16 largest EU serial innovators in health are largely involved[150].

Table 130 - Number of participations to SC1 (incl. IMI) of the TOP 16 European patent applicants in health

EU #	Country	Company or Institution	SC1	IMI2
1	NL	PHILIPS	13	
2	DE	SANOFI-AVENTIS	7	4
3	FR	CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE	10	
4	DE	BAYER PHARMA	2	1
6	DE	BOEHRINGER INGELHEIM INTERNATIONAL	3	3
7	FR	INSERM	52	
8	DK	NOVO NORDISK	2	2
9	DE	FRESENIUS MEDICAL CARE DEUTSCHLAND		
10	DE	MERCK	1	2
11	DE	BASF SE	1	
12	DE	AESCULAP & COMPANY		
13	FR	COMMISSARIAT A L'ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES	6	
14	BE	JANSSEN PHARMACEUTICA	9	7
15	DK	COLOPLAST		
16	DE	SIEMENS	2	

Source: Frietsch et al 2016 (EPO data and WIPO priority patents, companies of the same group regrouped into one), Corda

It should be noted that healthcare biotechnology involves costly R&D and a 10-20 year delay in generating product revenues. The high risk nature of early stage biotech research is not only supported through public funding but also through venture capital and about 20% of SMEs funded in FP7-Health were backed-up by Venture capitalists[151]. This is a good indicator of the very high quality of the SMEs supported and there is no evidence that this should be changing under SC1. This is also corroborated by the findings of the *ex-post* study on FP7-Health that notes *that around 30% of the participations involved*

[150] *The absence of Fresenius, Aesculap and Coloplast is explained by the concentration of Fresenius on the nephrology/ dialysis niche, and the position of Aesculap and Coloplast on relatively low-tech segments.*
[151] *Directorate RTD-E in collaboration with the EVCA (2014)*

SMEs with evidence of at least one patent in the EPO database, while almost 1 in 10 involved "serial innovators" with a track record of at least 10 patents[152]. It is understood that few of these SMEs will bring major breakthroughs to the market, will be acquired by- or merged with- bigger pharmaceutical and biotechnology companies, or will license out the next blockbuster drug. However, SC1 rewards risk takers and entrepreneurs by significantly improving their company's innovation potential. A look at the FP7-Health portfolio reveals that it has funded 10 of the 11 top spin-off European healthcare companies[153]. Under SC1, two of these companies are already funded as of October 2016: Galapagos and Immunovia. FP7-Heath and/or SC1 have notably attracted the only three so-called European 'unicorns': Oxford Nanopore, CureVac and Immunocore[154].

The best and main players are being attracted to IMI2 projects, both in terms of universities benefiting from EU funding, and industries contributing in-kind. In the first 15 signed grant agreements, more than half of the 63 universities participating in IMI2 JU are ranked amongst the first 200 according to the "*Shanghai Academic Ranking of World Universities 2016*", including 3 of the top 10 universities. Out of the 15 top world "Pharmaceuticals & Biotechnology" companies for R&D investments in the "*2015 EU Industrial R&D Investment Scoreboard*", all already participate in IMI2 JU projects. SMEs represent 9.8% of the EU beneficiaries, with 12.6% of the total EU funding.

SC1 has managed to attract a large number of stakeholders that were previously not involved: 28% of the participants to signed grants for collaborative research projects are **newcomers**. They come essentially from the following categories: private sector (45%), "other" (essentially patients' and users' association, 60%) and non-research public bodies (31%). The low number of newcomers in the academic area (5% in universities, 17% in research institution) may reflect the difficulty of smaller institutions to integrate existing networks, or the relatively small number of institutions that were not already present in a single FP7 project. The appeal of SC1 is particularly valid for the SME-instrument where 226 of the 289 participant are newcomers, the new instrument being well designed to suit their needs. IMI2 is open to newcomers through several modes. They may become Associated Partners, they may join EFPIA as members or as partners in research, or participate as beneficiaries in funded projects. There was no change in membership to IMI2 over its first two years. Participation of Associated Partners remains low, in spite of the notable and visible inclusion of the *Bill & Melinda Gates Foundation* as Associated Partners for the first grant agreements (with a cash contribution). Newcomers account for 50.4% of all EU-funded participants. A barrier for new organisations to join in IMI2 projects may be that consortia are typically quite large, (an average of 12 participants in the first 15 grant agreements). Entering into contact with large consortia may constitute a limiting factor especially for SMEs, smaller universities and EU-13 organisations, all being less well connected.

At this early stage, **dissemination, communication and outreach activities to effectively reach citizen** are not the SC1 projects' main priority. However the SC1 staff assists projects' efforts with press releases, drafting success stories and promoting EU-funded research on relevant occasions such as the World AIDS Day, or the Rare Diseases Day. Showcasing projects which are developed towards improving people's health and wellbeing is one of the priorities of the services implementing SC1. All SC1 events had a

[152] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 50.*
[153] *Source: Corda. These are Cellectis, Immunocore, Morphosys, Adaptimmune, Actelion, Galapagos,* ***Oxford Nanopore, Basilea,*** *Curevac, and Immunovia*
[154] ***Unicorns are private fast-growing companies valued more than a billion euro/dollars,*** *http://labiotech.eu/only-3-real-european-biotech-unicorns/*

social media presence and staff regularly participated to European and non-European conferences throughout the 2014-2016 years. This notably included:

- Horizon 2020 Information Days in Brussels, gathering funding applicants and multipliers, gathering 500 participants in 2014, 600+ in 2015 and 450+ in 2016, Horizon 2020 Info-Days in the MS (2014-16)
- The BIO International conventions (2014 to 2016)[155]
- The biannual regular Bad Gadstein Health Policy Forum[156] (ca. 600 health professionals)
- The EDCTP2 launch event (E1-E3), Cape Town, December 2014 (approx. 160 participants)
- The *European Summit on Digital Innovation for Active and Healthy Ageing*, March 2015, attracted a huge number of participants (1400+). It hosted 32 sessions, workshops, sandpits and the Pioneer Village with its 20 exhibition booths.
- *The eHealth Week*, May 2015.
- The AAL Forum, September 2015
- Major Conferences: *New Horizons for Vaccine Research and Innovation*, March 2014, attended by_200 international vaccine research and innovation experts; *Big data in health research: an EU action plan*, October 2015; *Together for the Next Generation, Research and Innovation for Maternal and New-born Health*, December 2015; *European Personalised Medicine*, June 2016, (500 participants, 2000 online)
- Workshops on numerous subjects were also occasions to keep information flowing to and from relevant stakeholders[157].

Efforts are underway to **track research results**, especially after the end of the project duration, by making use of publicly available information and thus being minimally invasive for beneficiaries. Reporting and programme evaluation can be hampered by unavailability of data that no longer belong to the project coordinators' reporting requirements (e.g. number of PhDs and post-doctoral positions created by projects, etc.), or by factors such as under-declaration of SME status: with the harmonised funding rate, apart for the SME instrument, there is no incentive for SMEs to have themselves qualified as such. With SME qualification being a cumbersome process, this may lead to underreporting of the EU contribution to SMEs. Access to data such as the unique registration number of every investigator involved may facilitate the extensive assessment of longer-term impacts of Horizon 2020 (does it boost scientific status, career development and citation index? etc.)

J.5.2.2. Geographical dimension

Country participation. EU-15 countries receive most of the EU contribution with a slight increase (from 86% in FP7-Health to 91%). The percentage of participations from EU-15 countries has also slightly decreased/increased, from 78% to 83%. Participation of Associated countries has dropped mainly because Switzerland is not associated anymore

[155] *BIO International Convention 2014, San Diego (14 000 participants); BIO-Europe Fall 2014 (Frankfurt, 3 000 participants), BIO-Europe 2015 Paris (2 300 participants), BIO-Europe 2015 Munich (3 500 participant), BIO US 2015 Philadelphia (15 000 participants); BIO-Europe Stockholm 2016 (2 400 participants), BIO-Europe Cologne 2016 (3 500 participants), BIO US, San Francisco (16 000 participants).*

[156] http://ec.europa.eu/research/health/policy-issues-pm-conferences-workshops_en.html

[157] see section 4.3 for examples of stakeholder workshops.

(before 2017). Participation of Third countries and EU-13 are discussed under sections on international collaboration (section J.2.2.4) and widening (section J.4.4.4) respectively. Noticeably SC1 is facing a decrease in numbers of participations of Third countries compared to FP7, which may lead to difficulties in coping with the objectives. However, this does not reflect the reality of international cooperation in health R&I between EU and Third countries. Counting of participations of Third country entities into SC1 projects is only a small part of the picture. Much more importance must be given to the portfolio of global strategic partnerships that initiated or joined by SC1 or its predecessor, and for which the EU is much more visible globally compared to previous FP's.

At EU level, as can be observed on fig.2 (in section J.2.2.3), the countries with the largest number of participants are, first by far, the UK (driven by the strong presence of University College London, Universities of Oxford & Cambridge, Imperial College, and King's College London), and Germany (with a significant presence of Ludwig-Maximilians-Universität München, and Fraunhofer Gesellschaft). As mentioned in section J.2.2.3, some MS are "punching above their weight", such as the Netherlands (led by Academisch Ziekenhuis Leiden, Erasmus University Rotterdam) -with more participations than France, Italy or Spain- or Belgium (driven by Katholieke Universitet Leuven and Vrije Universiteit Brussel).

The institutions mentioned above, together with other major participants such as INSERM (France), Karolinska Institutet (Sweden) and Instituto de Salud Carlos III (Spain), were also the top FP7-Health participant and coordinators[158], and they are widely recognised as belonging to the main research players in the EU. This can reasonably be expected from a very competitive programme, where the evaluation and election is based on excellence. But accordingly, it indicates that SC1 is rather reinforcing existing networks, although, as previously noted, it also provides for the integration of many newcomers (one out of four SC1 participants) into these pre-existing networks.

Country funding. The bulk of the EU funding goes to EU Member States (94 %) and more concretely to EU-15 countries (91.1% of the total EU contributions so far). EU-13, Associated countries and Third countries receive quite similar shares (3.2 %, 3.1 % and 2.5 % respectively). Compared with FP7-Health, the share of funding received by MS is increasing by 6.5 % (i.e. from 88.2 % to 94 %). EU-15 countries are increasing their FP7-Health share by 5.7% (i.e. from 85.8% to 90.7%). EU-12 participation was 2.5% in FP7-Health while EU-13 participation to SC1 is now 3.2% of SC1.

The situation of EU-13 MS merits further analysis. The share of EU-13 in the contribution to EU-28 (3.43%) looks *a priori* low, despite the increase compared with FP7-Health. However, this figure is in the same order of magnitude as that of EU-13's share of the EU's Gross Domestic Expenditure in R&D (GERD), namely 4%. As the FP's are based on excellence, MS that have attained a certain critical mass in terms of national R&D investment are in a better position to benefit from EU funding. It is worth noting, in the context of a possible activation of Art. 50 of TEU, that the UK is the first beneficiary of Horizon 2020-SC1 funding, with ca. 19 % of the total.

[158] *Commission Staff Working Document Ex-Post Evaluation of the Seventh Framework Programme, Health Annex, p. 4.*

From FP7-Health to SC1, Associated countries see their share reduced from 7.4 % to 2.7 % (EUR 41.4 million). However, a large part of this reduction can be attributed to Switzerland, which does not receive EU funding in SC1[159].

From FP7-Health to SC1, the funding to Third countries dropped from 4.4% to 2.5% (167 participations, EUR 41.3 million). This took place mainly because BRIC countries no longer receive EU contribution in Horizon 2020. A large portion of this contribution is going to the USA (50 participations, EUR 15.7 million to date, 37 % of the Third country share) largely due to the special reciprocity agreement between the EC and the National Institute of Health (NIH) that strongly benefits, in absolute terms, to the community of EU health researchers. The contribution to Switzerland teams only accounts for EUR 4.2 million[160].

The limited number of specific topics addressing areas of interest for developing countries (except in the context of specific initiatives such as GACD or other) has led to a reduced participation of LMIC scientific communities as compared to FP7-Health. However, SC1 fostered collaboration between European researchers and those in Third countries. Research actions in the area of infectious diseases involve in average around 20% of third country participation.

Another issue that emerged during the Ebola response is that **partners in low-resource countries** have difficulties keeping-up with the administrative burden required for them to be full-partners or even associated third parties. A solution found was that they were included as subcontractors.

There is no evidence that the current geographical distribution of projects, funds and participation could hamper the fulfilment of SC1's specific objectives.

J.5.2.3. Cross-cutting issues

While there is no sign that the situation of SC1 regarding cross-cutting issues could hamper the fulfilment of SC1's specific objectives, Horizon 2020 deals with so many cross-cutting issues (14 in total, including INCO, SSH, RRI, climate, etc.) that, in terms of priority-setting, it proves a challenge to draft topics that address adequately and concurrently the wide range of these, especially in the context of a very limited number of topics (significantly less than under FP7).

In SC1, 40.4 % of EU contribution has been assessed as relevant for **sustainable development**. The target for Horizon 2020 is at least 60% but SC1 is not expected to be a major contributor to it. 1.4% of the funding (EUR 17 million) is relevant to the climate change objective (the overall Horizon 2020 objective is 35%). While SC1 is, also there, not expected to be a major contributor to this KPI, this figure is limited and calls for remedial action as climate change has a significant direct and indirect impact on health (see section J.4.4.3).

In terms of promotion of **socio-economic sciences and humanities** (SSH) at least 17 % of projects are assessed by their project officers as SSH-relevant, adding up to a total EU contribution of EUR 310 million (see also section J.2.3 and J.4.4.5). This figure of 17% is more than twice the average percentage in Horizon 2020 and reflects a smooth embedding of SSH within SC1

[159] *Switzerland is considered an Associated country only for some parts of Horizon 2020.*
[160] *This data excludes IMI, SME-instrument and EDCTP projects.*

Looking at **gender issues,** SC1 is advised by an external Advisory Group, appointed by the Commission. A portion of its members have to be replaced after two years. SC1 has had so far two Advisory Group configurations (2014-2015 and 2016-2018). The first had 18 women and 13 men, and the second 17 women and 14 men. 1555 women (46%) vs. 1818 men took part in the proposal evaluation sessions. In SC1 projects 35.4% of coordinators are women (33.4 % in Horizon 2020 overall, and 31% of scientific coordinators in FP7-Health[161]), 50.7 % of women participate in the total workforce[162] (48% of the total work-force under FP7-Health[163], 40.3% in Horizon 2020 overall). The FP7-Health *ex-post* evaluation report noted that the efforts to improve the women's participation in projects by implementing various gender equality actions (GEA) but that the figures of women's participation with or without GEA were very similar[164].

As regards **areas relating to bridging from discovery to market application,** Horizon 2020 puts a specific focus on innovation under its second and third pillars (Industrial Leadership and Societal Challenges), which strongly rely on the use of new instruments/actions, namely innovation actions, innovation procurement and inducement prizes. Activities closer to the market and to end-users (e.g. prototyping, testing, demonstrating, piloting, large scale product validation and market replication, aiming at producing new or improved products or services) and support to demand-side approaches (such as pre-commercial procurement, procurement of innovative solutions, standardisation and other user-centred measures) would increase SC1's contribution in this respect, but the level of funding seems to be a deterrent, and a large majority of the topics published do not correspond to such TRLs. The Innovation Actions in ICT for Active and Healthy Ageing showed a well prepared landscape of stakeholders and applicants. Quality of proposals was high with good involvement of users through pilots in many countries. In future, additional emphasis on clear metrics for return of investment[165] may help to increase the visibility and impact of such projects. The joint innovation action of SC1-ICT LEIT in 2016 succeeded in bringing together demand and supply side with a selected large scale pilot funded by EUR 20 million covering nine pilot sites in seven countries with about 7000 users. This focus area call showed a reasonable success rate (14%).

The effect of actions in support of SMEs and innovation has been detailed under section J.4.4.2.

J.5.3. Cost-benefit analysis

Effective project monitoring and early follow-up of any performance issues are applied. So far all SC1 projects are delivering quality results in accordance with their obligations. No Horizon 2020 projects had to be stopped. No grant preparation process was stopped either, with the exception of two above-mentioned *Pre-Commercial Procurement* terminated before signature. The programme has moved to a more **digitalised and paperless environment** which is an efficiency gain in implementation. Though some of the initial difficulties are still present, especially for dealing with ethical assessments, the COMPASS/SYGMA system allows getting all the information from a project,

[161] *Source: RESPIR.*
[162] *Workforce includes people actively participating in and paid by the EU project.*
[163] *Source: RESPIR.*
[164] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 83*
[165] *e.g., through* ***Monitoring and Assessment Framework for the EIP on Active and Healthy Ageing (MAFEIP), http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=mafeip***

deliverables, reports, patents, publications etc., in the same application compared to different applications as it was under FP7.

Efforts are underway to track research results, especially after the end of the project duration by making use of publicly available information and thus being minimally invasive for beneficiaries. **Reporting and programme evaluation** can be hampered by unavailability of data that no longer belong to the project coordinators' reporting requirements (e.g. number of PhDs and post-doctoral positions created by projects, etc.), or by factors such as under-declaration of SME status: with the harmonised funding rate, apart for the SME instrument, there is no incentive for SMEs to have themselves qualified as such. SME qualification being a cumbersome process, this may lead to underreporting of the EU contribution to SMEs.

While it is obviously too early to provide cost-benefits ratios for SC1, reasonable estimates can be made using very recent data and observations from *ex-post* evaluation of FP7-Health: *In terms of unit costs, each EUR 10 million spent by the EU contributed to over 120 publications, implying an average cost of EUR 0.09 million per publication. Large-scale projects with budgets of EUR 9-11 million were particularly cost-effective in producing scientific output. Overall, these results appear to be similar to what was obtained in similar assignments analysing (United States) National Institutes of Health grants* [and other leading international research programmes[166]].

The capacity of SC1 to react quickly to launch emergency calls was amply demonstrated in the context of the Ebola and Zika calls.

While the simplification efforts are well appreciated by the stakeholders, it is considered that further **efficiency gains in financial reporting** could be obtained. Among the possible options (such as allowing a time allocation system for personnel costs, on the US model, or enforcing a structured encoding of costs declaration, including dropdown lists of items), the 'outcome-based financing' option will be tested in a pilot context in 2017-2018.

The current **IPR rules** are generally suitable to safeguard future commercial applications. Issues related to IPR arise mostly because of the difficulty to reach a consensus in large consortia, lack of agreement before the start of the project (which prevents controversial issues throughout the life of the projects), and the poor knowledge of IP within the scientific community who often deals with the Consortium Agreement. IMI2 has a tailor-made IPR policy that is both suitable to safeguard future commercial applications and to foster exploitation of results. It should be noted that the new provision in Horizon 2020 that beneficiaries can decide on how to assign ownership of jointly generated results only after the results have been generated[167] has created difficulties in the implementation of Horizon 2020. Initially meant to protect 'smaller players', it actually deters participants from bringing in valuable assets into Horizon 2020 projects or to even participate in projects. The latter situation applies in particular to venture-capital funded SMEs. Such difficulties have not been encountered for IMI's project participant, where IMI's specific IP provisions differ.

Large consortia can bring together a wide spectrum of competencies, skills and stakeholders. The FP7-Health *ex-post* assessment study has noted that "*Large-scale projects with budgets of EUR 9-11 million were particularly cost-effective in producing*

[166] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 38.*
[167] *See Article 41.2. of the Rules for Participation, Article 26 in the model grant agreement*

scientific output"[168]. However, they inherently create potential challenges in terms of efficient **project management**, a much higher frequency of amendments or delays in payments due to the complexity of work plans and involved partners, large size of budgets etc. More partners mean more "normal" events such as partners leaving, moving institution etc., hence more amendments. For coordinators, leadership and management of a large consortium can prove challenging. They need both commitment and an expert team for support For the Zika projects, with the very large consortia, especially with non-European partners, participants sometimes struggle to understand what is exactly needed in terms of administrative requirements, e.g. the validation process of partners is not always easy.

Inducement prizes remain a novelty to a large extent in Horizon 2020 in spite of the FP7-Health pilot experience, and while the experience is positive, it appears that the time needed for approval of the Rules of Contest should not be underestimated. That this may require several weeks should be taken into account when designing the timeline. A number of issues remain such as the possible co-funding of a Prize and the unambiguous definition of the award criteria.

J.5.4. Lessons learnt/Areas for improvement

The scientific community is vastly positive as to the themes and problems addressed by SC1, the long-term programming of which provides for better predictability. The high interest for the chosen topics and their broad definition resulted in SC1's heavy oversubscription. This oversubscription is made even more acute since yearly SC1 budgets dedicated to the traditional RTD collaborative instruments are tighter compared to FP7-Health, and since SC1's foreseen yearly budgets were cut as of 2015 to provision the EFSI guarantee funds. In such a context, only a two-stage selection process can limit the time and resource investment of the scientific community. To make Stage 1 selective enough, SC1 eventually opted for a dynamic financial threshold combined with stronger requirement regarding measurable impact in the WP.

High selectiveness -with a robust evaluation process - is a guarantee of excellence, and the continuing oversubscription shows that the scientific community does not turn away from SC1. However there are limits in the programme's capacity to deal with thousands of proposal. SC1 services faced difficulties when attempting to communicate that there is a trade-off between a rapid evaluation process carried out with reasonable investment in evaluator time and cost and the level of detail of comments in the feedback from the evaluation.

Increasing the overall budget of SC1 would obviously be the most effective remedial action to oversubscription: EUR 3.23 billion more would have been necessary to fund all high quality proposals received under SC1 in 2014 and 2015 only.

The main beneficiaries of EU health research funding in SC1 are academia and research organisations. SC1 highly mobilises the best EU academic research

[168] *More generally, in terms of cost-effectiveness, PPMI assessed by regression analysis the comparative cost-effectiveness of FP7-Health by taking into account a broad range of project characteristics and outputs produced. Following an extensive analysis, the evaluation team found that most FP7 projects were cost effective relative to their characteristics and output produced. Production of high quality publications and spin-off companies were strongly and positively associated with a larger share of own funds invested in the projects. However there was a trade-off in that these projects also tended to produce fewer open access publications, PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 119 & 164.*

organisations in the field but also attracts new and more diversified categories of participants, notably patients' and users' associations. Industry is more involved since FP7-Health, and SC1 still attracts the top innovators, both from large industry and from fast-growing spin-offs, thanks to its wide range of targeted instruments, though *Public Procurement of Innovative Solutions r*equire increased preparatory measures. SC1 also attracted a large number of newcomers (one out of four participants). The low participation of EU-13 teams that are essentially not attracted to Horizon 2020 calls for rapid corrective measures. Difficulties encountered by partners in low-resource third countries should be tackled.

Events, dissemination, communication and outreach activities are implemented by the programme and its projects in order to effectively reach stakeholders and citizens at large.

As compared to FP7-Health, **SC1 implements an increasing volume of budget with a constantly decreasing number of staff, and with increasingly shorter time-to-grant and time-to-pay**. The 97.0% Time-to-Grant indicator is largely above the Horizon 2020 target and a positive element for participating SMEs. The change in funding rules is well appreciated by stakeholders. The simplification of financial reporting should be further pursued.

A world-level scientific output to be expected. Evidence from FP7-Health suggests that the scientific output of EU-funded collaborative health research is similar to what is achieved by the US and other leading international research programmes, at the same cost. Research results and project data should be monitored in more detail. The programme should not refrain to include in the projects' reporting requirement the provision of data that is not easily accessible elsewhere but is necessary for assessing the programme and its impacts.

J.6. COHERENCE

J.6.1. Internal coherence

J.6.1.1. Internal coherence within SC1

The R&D objectives of SC1 are implemented mainly through RIA's in topics mainly labelled PHC and PM (232 projects, 89 % of the funding), while actions and studies in support of the programme and its policy objectives, are implemented via CSA's (24 projects, 2% of the funding) and ERA-Net Co-funds (7 projects, 3 % of the funding).

The portfolio of research activities and agendas of IM2, AAL, the JPI's and EDCTP2 are taken into account to avoid gaps or overlaps and ensure the best articulation with the SC1 WP. The presence in the services implementing SC1 of officers following-up these initiatives ensures coherence with the other RIA's. Typical examples are clinical studies on poverty-related disease or neglected infectious diseases, that are almost exclusively covered by EDCTP, or AMR clinical trials, that are covered by IMI and hence not in the 'core' part of the programme.

A mix of tools are on offer to promote innovation, from 'standard' collaborative development projects, innovation actions, innovation procurements and loan facilities to SME-instruments. Applicants can, therefore, choose what instrument serves best their objectives.

From the gap analysis of the current portfolio (see notably sections J.4.3), there is no significant omission, inconsistency or overlap. No complaint of stakeholders to that effect has been recorded either.

In short, no known coherence issue within SC1 is hampering it from delivering on its objectives.

J.6.1.2. Internal coherence with other Horizon 2020 intervention areas

From an implementation, managerial and administrative point of view, and with the exception that it is not implemented via an executive agency, SC1 follows the same processes as the other SCs and LEITs of Horizon 2020, in terms of type of content of WP, calls publication, evaluation rules, processes and criteria, adoption rules, funding instruments, use of corporate IT Tools, attention to cross-cutting issues, follow-up of projects, reporting instruments.

In terms of scope, SC1 now encompasses major health-related areas such as *e-health, m-health* and *Environment & Health*[169], which were dealt with under other schemes in past FP's. This is a noted progress towards the *One-Stop-Shop* for health research that was called for by an independent group of expert advising on the *Ex-ante Impact Assessment of FP8 for Health*[170].

However, in spite of this gain in coherence, a large number of health-related areas remain funded under other actions of Horizon 2020 : ERC & MSC grants, ESFRI Infrastructures (see Table 133), Nanomedicine and biomaterials development under LEIT NMPB, Health & Food interactions under SC2, the Human Brain Project under FET, EIT-KICs, etc. There is clearly more to EU-funded health research than the mere SC1.

This leads to an asymmetric situation where many actions contribute *de facto* to the objectives of SC1 at large, while SC1 does not contribute to the objectives of these actions. This is clearly reflected in the 2016 survey of Horizon 2020 participants on *wider impact of projects* where many beneficiaries of a large number of actions claim that they expect to have an impact on SC1 (see Table 131) whereas very few SC1 participants consider that they will have an impact on other Societal Challenges (see table 14)[171]. For SC6 (*Europe in a changing world - Inclusive, innovative and reflective societies)*, Research Infrastructures, LEIT NMPB and LEIT ICT, respectively 53.5 %, 52 %, 42.5 % and 52 % of respondents expected their project to have a wider impact on SC1 in the next 10 years[172].

Table 131 - Share of projects in other Horizon 2020 intervention areas which are expected to have a wider impact on SC1 in the next 10 years

Horizon 2020 specific objectives (n= number of replies)	SC1
Future and emerging technologies (n = 16)	33.3 %
Research Infrastructures (n = 27)	52.2 %
NMPB (n = 96)	42.4%

[169] *In line with the recommendation of the FP8 Health Assessment Panel Report, DG RTD, 18/04/2011.*
[170] *Expert group report recommendations on the future of health research in Europe, DG RTD, June 2011. http://ec.europa.eu/research/health/pdf/impact-assessment-of-health-research-projects-on-research-2002-2010_en.pdf*
[171] PPMI: *Study on European Added Value in Horizon 2020, overview of the survey results* (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016.
[172] *See also other relevant results of this survey under section 5.4.3*

Information and Communication Technologies (n = 177)	52.0%
Innovation in SMEs (n = 30)	24.4%
SC1 (n = 106)	98.1%
SC2 (n = 43)	49.2%
SC6 (n = 32)	53.6%
SC7 (n = 31)	38.6%
Spreading Excellence and Widening Participation (n = 24)	64 %
Science with and for Society (n = 10)	57.1 %
Fast Track to Innovation Pilot (n = 10)	66.7 %
Euratom (n = 3)	33.3 %
Total	46.9 %
Total number of valid responses	920

Source: PPMI: Study on European Added Value in Horizon 2020, overview of the survey results.

Table 132 - Share of SC1 projects which are expected to have a wider impact on the societal challenges in the next 10 years

Horizon 2020 Programme part	SC1	SC2	SC3	SC4	SC5	SC6	SC7
SC1 (n = 106)	98.1%	9.8%	1.7%	2.1%	5.3%	35.6%	9.6%

Source: PPMI: Study on European Added Value in Horizon 2020, overview of the survey results.

This widespread distribution of health research actions across many actions of Horizon 2020 requires a close monitoring of possible overlaps in border areas. This is easily done when the attribution of given topics to specific areas goes back to several FP's ago (e.g. *Health & Food*, with predecessors of SC2, or the development of biomaterials with the predecessor of LEIT NMP). On occasions, evolutions from programmes to their heirs lead to some of the border areas to fall between the stools (e.g., few projects have had funding opportunities in, say, computer-aided surgery since FP6), though generally, possibilities of overlap outweigh those of leaving thematic gaps.

As this interest for health issues from other areas are not a novelty, SC1's staff is already accustomed, to some extent, to ensure internal coherence through various mechanisms. This is confirmed by PPMI's assessment, regarding FP7-Health, that *the overarching conclusion is that FP7-Health and other FP7 programmes strongly complemented each other's activities through collaborative research and joint calls for proposals. At the project level, FP7-Health projects frequently carried out complementary research activities both within the programme and across FP7. Other FP7 programmes which where the largest number of projects targeted similar research topics included ERC, ICT, People, KBBE, Research Infrastructures and NMP. No concrete evidence of overlapping research activities between FP7-Health and other programmes was found*. As there is a very large continuity in terms of staff implementing SC1, main stakeholders and R&I themes, and since monitoring mechanisms are in place (as detailed below), there is no evidence that SC1 is not following the same path.

To ensure maximum coherence, both within the Horizon 2020 actions and with other EU actions, the governance of Horizon 2020 and the administrative processes have been organised in order to mitigate these overlap risks, using four main levels. Main principles and directions are collegially decided in regular Meetings of R&I Directorate Generals. The SC1 Horizon Group, where all services with an interest in SC1 are represented, meets regularly and provides input during the drafting of the WP. The Inter-service consultation on the WP, before formal adoption, provides further opportunities for relevant Directorate-Generals to comment and ask for amendments, while an *ex-post*

consultation on the lists of projects retained for funding enables a last search for double-funding. In addition, regular informal contacts at project officer level, together with contributions to interservice consultations and responses to parliamentary questions provide opportunities for SC1 staff to draw attention to the content of the programmes' project portfolios and ensure that the WPs of non-Horizon 2020 programmes will not overlap with SC1 actions. Focus Areas and gap analysis[173] are also example of measures undertaken to address coherence of Horizon 2020.

Table 133 - Participation (in grey) of health-related ESFRI infrastructure to calls of other parts of Horizon 2020

	Funded	Infra Funded	e-Infra Funded	Participation in Other Parts	Funded in Other Parts	Success rate in Other Parts
BBMRI-ERIC	11	6	3	20	**2**	**10%**
ECRIN	22	7		109	**15**	**14%**
EATRIS ERIC	4	4		13	**0**	**0%**
INFRAFRONTIER GMBH	6	5	1	4	**0**	**0%**
INSTRUCT	**7**	**5**	**2**	**2**	**0**	**0%**

Source: Corda Participation of the ESFRI health RIs in Horizon 2020 calls.

The inclusion of e-health and Environment & Health themes within the scope of SC1 have proved smooth and ensured further coherence for health-related R&I. A similar coherence could be noted within some predecessors of SC1 when health-related infrastructures, and projects related to ethical, legal or socio-economic aspects of health were also encompassed by the Programme.

J.6.1.3. Ensuring that every euro spent counts twice

SC1 contributed to Focus Areas of WP 2014 on *Personalising health and care* and on *Sustainable food security*[174]. In the 2016-2017 WP, topic *Smart living environments for ageing well*" will be jointly funded by LEIT-ICT (Leadership in enabling and industrial technologies Information and Communication Technologies) and SC1. Further contributions are considered to potential Focus Areas on *COP 21*, on *Digitisation*, and on *Security and Trust* in the 2018-2020 WP under preparation. Expected interdisciplinary solutions will thus cut across multiple specific objectives, ensuring both coherence and increased cost-efficiency.

With the four pillars supporting innovation presented under section J.4.4.2, SC1 can at the same time tackle societal challenges and give rise to new competitive businesses and industries.

J.6.1.4. Results of the Likert-Scale self-assessment

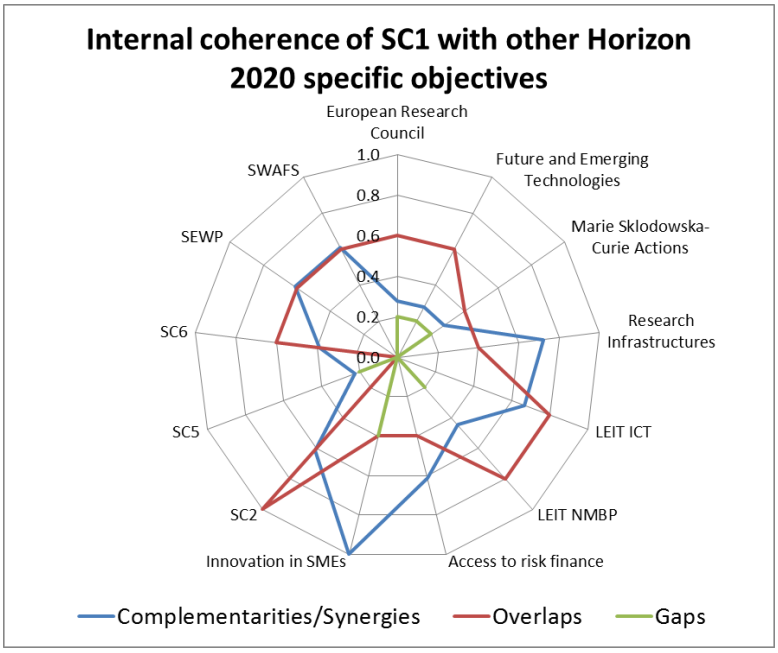
As indicated above, given the widespread distribution of health-related actions over Horizon 2020, the risks of overlap largely outweigh that of leaving thematic gaps. These higher risks are identified with SC2, LEIT NMBP and LEIT ICT, essentially because the

[173] *An extensive gap analysis exercise was performed in 2016 in view of WP 2018-2020.*
[174] *With SC2 contributing to SC1's topic Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens*

same range of instruments are on offer for the same clients in areas encompassing potential health content (e.g., Nanomedicine, Health and Food, etc.). This is compensated by a good level or articulation with these themes.

Complementarity and coherence also prove more difficult to ensure ex-ante with fully bottom-up, non-thematic actions (ERC, MSC actions, EASME/SME-instrument, Fast-track to Innovation) as one can never foresee what project will surface and be funded. SC1s staff tends to confirm that more feedback from-, or more dialogue with- these actions could be most useful.

Figure 197 - Internal Coherence of SC1 with other Horizon 2020 specific objectives



Source: Assessment by SC1 staff.

The highest 'gap' area, though still very limited, is with the Innovation in SMES that is actually partly funded via SC1. It reflects the very different instruments used, the different level of TRLs, the different population addressed and the different size of the contribution. This is compensated by a very high level of articulation.

With SC5, the low level of articulation reflects a very clear thematic delineation between the two challenges (the environment and health aspects being exclusively tackled within SC1) with little cross-references in the calls and WP's, as well as the fact that climate change has barely been tackled yet by SC1 call topics. The limits in articulation are not problematic as there are also no overlaps and very limited risks of gaps. The lower level of complementarity/synergies with SC6 reflects the bigger thematic distance with SC1.

Systematic tools, channels and processes to ensure access to internal on health research funding outside of SC1 are not yet available. They could further optimise the articulation of these actions with SC1. Complete knowledge of the portfolio content and achievements of all EU-funded health-related projects could allow the best possible exploitation and dissemination of EU-funded research results, notably in view of responding to policy objectives. The current corporate tools (Cordis and Corda) are not suited to that effect.

J.6.2. External coherence

J.6.2.1. Coherence with other major EU funding programmes

The funding programmes showing complementary to SC1 are essentially those of the European Structural and Investment Funds (ESI Funds), the European Fund for Strategic Investments (EFSI). Funding programmes supporting the Environment Policy (LIFE), Public Health Policy (Health for Growth), the Development policy, as well as the Competitiveness and SMEs policy (COSME) are dealt with in a subsequent section.

The **ESI Funds** can help build up the necessary health or R&I infrastructure in some regions, support the development of necessary human capital for R&I, support innovation in policy-making, notably through smart specialisation strategies. It is fundamentally complementary with Horizon 2020 as it never tackles RTD directly. There is, therefore, no problem of overlap with it. 22% of the FP7-Health participants claimed that they resorted to the use of EU regional funding mechanisms[175], though this contribution could not be achieved to bring matching funds to their specific FP7-Health project as the duty to avoid double funding prohibits such contributions. As modalities such as the Seal of excellence are difficult to apply for collaborative transnational project, SC1 did not develop articulation with Regional policy that could provide substantial complementary funding opportunities.

While, in theory, articulation could be developed with regions deciding to smartly specialise in health field, it should be kept in mind that the areas of specialisation might be very general and not specifically match the specific priority setting of SC1. Furthermore, the main hurdle to building bridges with ESIF is the difficulty to access useful, detailed, information on what regions intend to implement, and to determine the best modalities for collaboration/articulation. A pilot effort is ongoing, with SC1 services developing a map of health R&I priorities in smart specialisation strategies of EU regions, to be made publicly available by 2017 in order to facilitate the engagement of EU Regions into the implementation of the EU R&I framework for PM.

Looking at the articulation of SC1 with the **European Fund for Strategic Investments (EFSI),** EFSI essentially takes the form of a EUR 200 million provisioning of EFSI's guarantee fund. In addition SC1 service identified, in the list of the initial project proposals from the MS, which ones were relevant to health research. It should be mentioned that only four of the ca. 100 projects currently supported by EFSI by October 2016 are related to health or life sciences, only two of which include health research elements (the total EFSI contribution being ca. EUR 170 million). EFSI provides loans, which remain a relatively marginal feature in SC1. However, for these, it is envisaged to develop the EFSI Investment Platform in order to scale up the InnovFin ID pilot.

J.6.2.2. Coherence with other public support initiatives at regional, national and international level

A) Global and international Level

Most health-related issues are of a global nature and require a global solution. International cooperation is a fundamental and inherent component of SC1. Given the shared interest and the scale on which the issues arise, research in areas such as AMR, HIV, malaria, TB, ageing, health care costs, the personalisation of medicine, etc., are

[175] *FP7-Health Survey October 2014*

more effectively carried out at EU level, if not at global level with the EU as a major player. In a world of complexity and rapid pace, cooperation has to take place at a higher level than the local or national one, especially in health where constantly rising prices, changing disease patterns, and increasing use of sophisticated technology for diagnosis and treatment make it virtually impossible for single or small groups of organisations to provide the expected services to patients.

While closer coordination at the European level has been at the heart of EU research policy over the past years, international research has become a requisite to keep the pace of modern science and to adapt to the globalisation of markets. In addition, there is a trend at institutional level to commit into multilateral agreements rather than bilateral ones, in order to maximise the impact. In recent years, the EU has developed European and international research strategies that better integrate MS national policies and better reflect the globalisation of research. At international level, the EU has adapted its *modus operandi* in international cooperation to match the ever increasing globalisation of research by setting multilateral agreements with major international funders. This approach not only allows to commonly address global issues, but it also permits to drive future research trends and be on board with the most advanced and emerging countries in health research. These contribute to make of EU *a Stronger Global Actor*. Several of these initiatives and international consortia have already been presented under section J.3.1.2 (HIRO, International consortia, EDCTP). The two examples below are newer initiatives:

Global Action against Dementia SC1's emphasis on PM, active and healthy ageing as well as the specific topics on comparing the effectiveness of existing interventions for the elderly and the adult population are fully aligned with the global momentum on dementia, initiated by G7, and led by the Global Action against Dementia (GAAD). Indeed, the GAAD has set out priority areas where concerted action is needed to improve the lives of individuals with dementia. The autonomy of patients is also central and a series of SC1 topics have already provided support to ICT-enabled solutions for more autonomy of individuals with dementia and other neurodegenerative diseases

Articulation with the US in toxicology: EU-ToxRisk. With EU-ToxRisk, an Integrated European 'Flagship' Programme Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st century, SC1 is driving a paradigm shift in toxicology that is complementary to the approach followed in the US. Traditionally, the safety of chemicals for complex toxicological effects was assessed on animals, but the extrapolation of animal studies to humans is far from being optimal. The paradigm shift is based on the development of new test methods that are more relevant to human safety. EU-ToxRisk a successor of the FP7 SEURAT-1[176], with more emphasis on delivering solutions for regulatory acceptance of alternative methods, will move toxicological testing away from 'black box' animal testing. It will rely on a mechanistic understanding of the chain of events that link chemical exposure to toxic outcome. EU-ToxRisk will examine 100 chemical compounds along this chain of events to derive a comprehensive battery of tests that could be integrated to predict the toxicological effect. The consortium will provide proof of concept for such a mechanism-based testing strategy. The ultimate goal is to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals. Research supported by federal US agencies in human safety also follow the

[176] *EU-ToxRisk is a 6-year project that started on January 2016 with an EU contribution of €30 million. It is a collaboration of 40 institutions including regulatory authorities, universities, pharma and chemical industries, and SME. The major expected effect will be to progress towards the delivery of new regulatory-approved test methods that will replace animal testing for complex toxicity endpoints.*

same paradigm shift, but in slightly different way that is complementary to EU-ToxRisk. In the US, 10.000 compounds are being screened with different high-throughput "omics" technologies without necessarily trying to integrate all the data and link the results to the chain of events. That methodology allows prioritising the chemicals that would require further toxicology testing, including with more classical animal tests.

The following example also illustrates the impact of the EU teams within these international consortia: in November 2016, a coordinated package of 41 International Human Epigenome Consortium **(**IHEC) publications was released in *Cell* and *Cell Press* journals, plus individual ones in other journals, including *Science* and *Nature Biotech*. Out of these 41, 26 papers were contributed by FP7 BLUEPRINT *High-Impact project*[177], the EU component of the consortium.

B) National Level

Some 90 % of collaborative research in the EU is carried out in the context of Horizon 2020[178]. In this respect, there is no overlap to expect. SC1 is complementing national efforts in providing for the European and international collaborative dimension. Horizon 2020 provides access to expertise, resources and facilities that may not be available at national level.

Horizon 2020/SC1 does not duplicate national/regional funding. A survey of Horizon 2020 participants in 2016 indicates that 90% of Horizon 2020 projects saw no alternative funding for the type of activities funded. Lack of similar national or regional funds was the dominant reason why unsuccessful FP7 applicants were not able to implement their projects without EU funding[179]

On a thematic point of view, there is a clear asymmetry in terms of level of information, as SC1 lacks resources to monitor the priority-setting in MS, while, for their part, MS are fully aware of the SC1 priorities. Also, the EU has no specific vocation to develop bilateral articulation in health research with each and every MS. This happens indirectly, nevertheless, since several major national funding agencies are often involved, together with SC1, in global research consortia.

At national level, evidence has accumulated that health research is often fragmented and lacking coordination. This leads to unnecessary duplication of efforts. Through its ERA-NET and JPI schemes, aimed at aligning national research agendas and facilitating cross-fertilization, SC1 is substantially contributing to reinforce coordination and alignment of national research efforts, notably as regards Neurodegenerative diseases, AMR, cancer research, systems medicine, rare diseases, brain-related diseases and disorders, and the potential and challenges of demographic change [180]. Coordination efforts are also

[177] IHEC press release: http://ihec-epigenomes.org/news-events/coordinated-paper-release/; BLUEPRINT press release: http://www.blueprint-epigenome.eu/index.cfm?p=62AAF66A-F2A3-530B-B415B8D43F865FA5. Articles in Cell: http://www.cell.com/consortium/IHEC

[178] The figure is a*ctually 92% of all public collaborative research in the EU+EFTA countries, but it does not include the role of charities and foundations.* Information derived from http://ec.europa.eu/research/era/pdf/era_progress_report2014/era_facts&figures_2014.pdf, p. 17.

[179] *PPMI, Assessment of the economic impact and EAV of FP7 and Horizon 2020, preliminary results 15 November 2016.*

[180] Two examples of ERA-NET projects: TRANSCAN, (http://www.transcanfp7.eu) aimed at coordinating regional and national programmes on translational cancer research. With 25 partners from 19 MS and Associated countries, it has facilitated the establishment of a common research agenda in MS, who have already mobilised € 50 million to support calls. Similarly, the objectives and topics related to brain research have been identified as priorities and taken up at national level, as can be illustrated by the transnational calls issued under the umbrella of the Neuron ERA-Net (http://www.neuron-eranet.eu/). Neurodegeneration, mental disorders and cerebrovascular diseases were identified as requiring multinational, multidisciplinary approaches.

undertaken via two Art 185 initiatives and a European Joint Programme Co-funds, the first one of which, under Horizon 2020, is dedicated to Human Biomonitoring (HBM4EU, see section J.4.4.6). It will also ensure collaboration of national biomonitoring programmes, together with the Commission services.

Several tools may even be mobilised at the same time, e.g. for the coordination on ICT for active and healthy ageing with MS, through the Art. 185 AAL Joint Programme to help SMEs bring solutions to the market, the JPI *More Years Better Lives*, the EIP-AHA to scale up innovation in cooperation with regions, the EIT-KIC Health to help develop an entrepreneurial culture and stimulate investments, and structural funds (through twinning schemes with regions).

Several support actions were also funded to develop strategic European research agendas. An example is project PerMed[181] where MS research funders in PM came together with other stakeholders to develop a research agenda for their future co-investments. Now, under SC1, IC-PERMED is taking this endeavour to the next level.

The coordination sometimes takes place without (or before) formal channels being set up. The concept at the heart of such major coordination efforts is that of commonly defined *Strategic Research Agendas and Roadmaps*. The areas of *PM* and *active and healthy ageing* are excellent example of coordination and alignment of Europeans and national resources to tackle challenges that can only be addressed at EU level. However, it happens that EU-funding of a critical mass of projects naturally results in coherence of national programmes without recourse to any specific coordination instrument, as witnessed in the area of trans-national clinical trials for innovative therapies in the EU. SC1 is unique in adding the international dimension which is especially valuable for clinical research[182].

National level of investment in R&I remains an issue. There seems to be a significant correlation between the investments in R&D in a country and the capacity of its teams to take part to the FP. Under-investment (public or private) at national level will, therefore, most likely contribute to maintaining the divide between some of the EU-13 and the other MS.

Some other issues, such as **disparities in the regulatory landscape**, have been identified as a potential hurdle to innovation in the EU, Health Technology Assessment being a specific illustration, as pointed out below, in the 2016 Commission Staff Working Document *Better regulations for innovation-driven investment at EU level*[183] (see section

[181] www.icpermed.eu

[182] Initiatives of some MS, when disjointed from EU efforts, can sometimes prove counterproductive for themselves, as illustrated by the french *investissements d'avenir* case of 2010, when France borrowed € 35 billion to support, among others, research and innovation. French research teams were mobilised during a whole year applying to the national funding schemes and largely ceased to apply to FP7 calls, thereby significantly reducing the share of EU funding normally flowing to french research teams, and strongly undermining the foreseen positive effects of the *Grand Emprunt*. This episode led the french authorities to define a research strategy, *France-Europe 2020*, strongly aligned on priorities of Horizon 2020 in order to enable french researchers to apply more easily to both national and European schemes concurrently. While such an approach definitely fosters alignment of national R&I priorities on EU ones, it might, if others MS follow suit, dramatically increase overlaps in Europe, and cause an excessive concentration of resources on a limited set areas at the expenses of others. This is underlines the crucial role of integration of health RTD national policy/priority setting and funding programmes. The option not to require the full respect of all Rules for Participation as a condition for EU co-funding should be considered in the light of a potential increased response and impact.

[183] *Better regulations for innovation-driven investment at EU level* Commission Staff Working Document, 2016, p. 17. https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf

J.6.2). SC1, following funding to FP7-Health HTA-related projects, is fostering improved coordination between MS.

C) Regional level

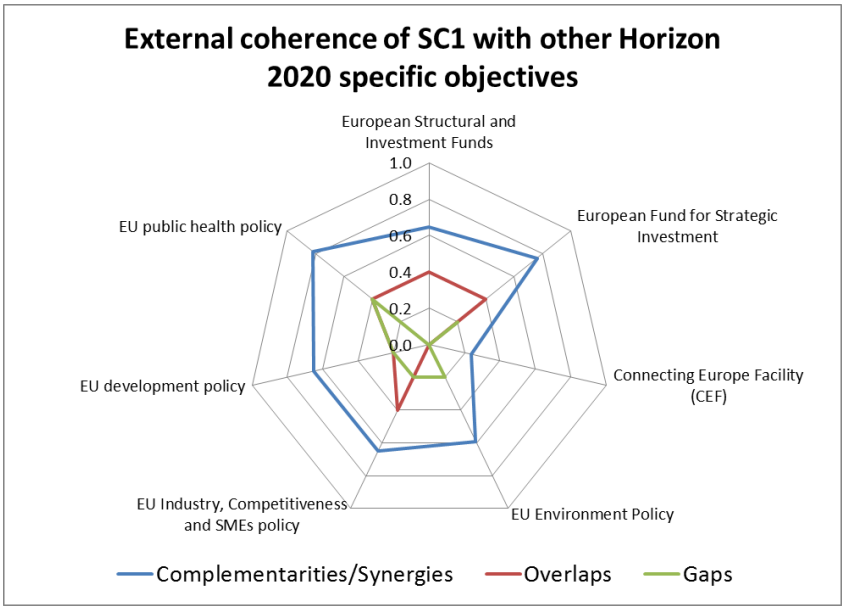
As indicated above **Horizon 2020 and SC1 do not duplicate regional funding**[184]**.** As it does to national funding, SC1 is complementing regional efforts in providing for the international collaborative dimension. Applicants to SC1 are seeking access to a network of expertise, resources and facilities that may not be available at local, regional, or national level. Occasionally, the coordination instruments proposed by SC1 have even included regional funding authorities. Regional agencies have taken part in some past ERA-NET projects such as TRANSCAN or EUROROCOURSE.

Systematic tools, channels and processes to ensure access to information on R&I spending and priorities at regional level, that would allow for an even better articulation with these, are not yet available[185].

J.6.2.3. External coherence of SC1 with other EU policies/programmes

The self-assessment graph below indicates a satisfactory degree of coordination of SC1 with other EU policies and programmes, with, understandably, less articulation with areas of more limited or more recent relevance to the Programme, such as the Connecting Europe Facility. Risks of leaving gaps appear clearly limited while overlaps essentially result from the fact that SC1 is open to a very large public that can also chose to apply to other EU instruments and programmes, though not necessarily for the same activities.

Figure 198 - External coherence of SC1 with other Horizon 2020 specific objectives



Source: assessment by SC1 staff, 2016.

[184] *PPMI, Assessment of the economic impact and EAV of FP7 and Horizon 2020, preliminary results 15 November 2016.*

[185] *The asymmetry in terms of level of information, underlined for the national level, is even more acute for the regional level. SC1 lacks resources to monitor the priority-setting in regions and to best exploit this information. This is also complicated by the different level of competence that regions may have from one MS to the other (some of them fund R&I, some do not), which prevents one-size-fits-all schemes.*

As to Environment Policy (and its LIFE programme), Public Health Policy (Health for Growth), Development policy (Development funds) and Competitiveness and SMEs policy (COSME) the services in charge of these policy-supporting funding action are involved in the governance of Horizon 2020 and SC1 through the mechanism described earlier in section J.6.1.1: 1) Meetings of R&I Directorate Generals; 2) The SC1 Horizon Group; 3) Inter-service consultation on the WP; 4) *ex-post* consultation on the lists of projects retained for funding. The risks of overlap are particularly limited since the Treaty reserve the funding of RTD to the FP. Coordination with these services is, therefore, much less a question of overlap, than a question of ensuring that R&I projects results will respond to the need for scientific evidence to back policy and legislative decisions.

Reciprocally, the internal process of inter-service consultation enabled SC1 services to ensure that SC1 efforts, and EU health R&I at large, might not be undermined by specific EU policies or regulations. This was notably the case, over the last years, for sensitive areas such as animal testing, clinical trials, data protection or endocrine disruptors.

SC1 and the EU policies, programmes and services of relevance to SC1 all therefore going in the same direction, with the occasional shared preparation of policy documents, e.g., on PM or AMR.

Analysing to what extent R&I projects has an actual impact on EU policies is an uncertain exercise, in particular because there is not any systematic monitoring system in place to measure how projects influence policy at EU, national or sub-national levels. Nevertheless, health research plays a pivotal role for providing data to support EU policies. SC1 is providing an important contribution to the development of evidence-based knowledge which will translate into policy making (legislation, guidelines, action plans, etc.).

Notable areas of SC1 support to EU or national-level policymaking include animal replacement in toxicity testing, PM, European Reference Networks on rare diseases, tobacco policy, clinical trial regulation, paediatric clinical trials, active and healthy ageing, HTA and AMR.

J.6.3. Lessons learnt/Areas for improvement.

No known coherence issue within SC1 is hampering it from delivering on its objectives. Robust mechanisms are in place to ensure proper consultation of interested services. No significant overlap with other European programmes or Horizon 2020 sub-programmes is reported. SC1 ensures that EU health R&I at large is not undermined by specific EU policies or regulations and contributes to the development of evidence-based knowledge that will translate into policy making in areas such as animal replacement in toxicity testing, PM, European Reference Networks on rare diseases, tobacco policy, clinical trial regulation, paediatric clinical trials, active and healthy ageing, HTA and AMR.

Complementarities are clearly illustrated by the SC1 involvement -and leadership- in many international consortia tackling global health challenges, thereby preventing duplication of efforts. The same is also valid for ERA-NET, JPI's and co-funding actions. The relevance of instruments such as IMI2, EDCTP2 or EIP AHA is notably illustrated by their capacity to leverage investments from third parties, be they regional or national governments, major global foundations (e.g., the Bill and Melinda Gates Foundation), or Third countries such as Canada.

SC1 is complementing national and regional efforts in providing for the European and international collaborative dimension. Currently, the requirement of full respect of all Rules for Participation as a condition for EU co-funding might be a deterrent to an increased response and impact.

Systematic tools, channels and processes to ensure access to internal (EU-funded health R&I outside of SC1) and external information (R&I spending and priorities at national and regional level) on health research funding and priority-setting, that would allow for an even better articulation with these, are not yet available. Complete knowledge, within SC1, of the portfolio content and achievements of all EU-funded health-related projects could allow the best possible exploitation and dissemination of EU-funded research results, notably in view of responding to policy objectives. The current corporate tools (Cordis and Corda) are not suited to that effect.

The involvement of regions remains limited. EIP AHA and Permed are encouraging examples of associating EU regional partners to the definition and implementation of Roadmaps and strategic agendas. However, expanding or generalising such efforts requires resources that are currently not available (e.g., translated regional policy documents, updated inventory of ongoing initiatives and access to reports, common set of standard keywords, data mining tools).

J.7. EU ADDED VALUE

J.7.1. Horizon 2020 projects demonstrating EU Added Value

In addition to major actions such as IMI2, the EU added-value of which has been extensively analysed and demonstrated during the legislative process, HBM4EU, implemented via the first joint programme cofund (see section J.4.4.6), or the ERA-Net projects such as E-RARE 3, detailed under section J.4.4.1, many other projects and actions such as the three presented below demonstrate a significant EU added value, in terms of effectiveness, efficiency and synergy.

J.7.1.1. SC1 for better effectiveness

SC1 provides for better effectiveness at EU level by tackling pan-European and global challenges via new types of collaboration[186], by coordinating national policies and structuring EU research[187] and by providing EU standards[188].

[186] As most of today's health-related issues call for global solutions, international cooperation is a fundamental and inherent component of the health research programme. Given the scale on which these issues arise, and the need to align efforts and define research agendas, R&D activities in areas such as PM, AMR, HIV, malaria, TB, ageing, the cost of health care, the personalisation of medicine, emerging and re-emerging epidemics (Ebola, Zika), chronic diseases, are more effectively carried out at EU level or even at global level, with the EU as a major player. In recent years, SC1 and its predecessor have engaged in different types of partnerships that allow tackling complex issues with a bigger impact. These have paved the way to new types of collaboration that occur at a highly strategic level, are embraced by key EU partners and reproduced worldwide. This approach has been pioneered by FP7-Health with the private sector and the MS, and is continued under SC1. One of these major initiatives, IMI demonstrated that partners who jointly invest and share risk can both be rewarded. Public-private partnerships' critical role improving the performance of health systems worldwide, by bringing together the best characteristics of the public and private sectors to improve efficiency, quality, innovation, and health impact of both private and public systems, is increasingly recognised. The added value of IMI2 JU is recognised worldwide. In February 2015, the US House of Representatives issued a white paper on the "21st Century Cures initiative". Launched by the House's Energy and Commerce Committee, it studied what steps can be taken to accelerate the discovery, development and delivery of cures. It recognises that what is missing in the USA is a public-private partnership that would bring together the various stakeholders and would need to be "*modelled after the Innovative Medicines Initiative*".

SC1 defines Strategic Research Agendas and Innovation Roadmaps for Europe for major challenges such as the development of PM or the need for EU to cope with its ageing population. It also fosters coordination of MS activities in most of the key health domains such as ageing, brain, cancer, rare diseases, system biology, AMR, neurodegenerative diseases, cardiovascular diseases, or ambient assisted-living to implement joint transnational research projects and set up international cooperations. And the EC has now developed a long-standing expertise is such endeavours. Studies have shown that already in FP7-Health, the areas of rare diseases, infectious diseases, AMR, ageing, systems biology, large-scale data gathering, chronic diseases, as well as projects and actions responding to EU policy needs demonstrated particularly high EAV[189].

EU-Thyroid Horizon 2020 project, started in June 2015, will establish a meta-platform for collaborative data collection and use National and regional registry data which will be collected in 17 national registries and up to 37 monitoring studies in 24 countries to gain an overview of prevalent and incident thyroid diseases and treatments in European nations. These data will then be collected in a centralised EUthyroid database to provide a valid European map of iodine status, subclinical and clinical thyroid disorders and will relate the iodine status of populations to thyroid-related outcomes for the evaluation of IDD prevention programmes. The EU added value of EUthyroid will be to evaluate IDD prevention across Europe. While fortification has to be done on a national or regional level, monitoring is ideally done on a more widespread and coordinated approach. Harmonised sampling, measurements and questionnaires to obtain high resolution map of iodine status in Europe could support reducing IDD. Whether monitoring is cost-effective, requires better evidence through outcome research to estimate costs and benefits. National awareness leads to prioritising at a national level based on assessed need.

J.7.1.2.SC1 for better Efficiency

SC1 provides for better efficiency **at EU level by pooling of resources, achieving critical mass and economies of scale and scope, and reducing research risk and commercial risk.** Some health research activities are of such a scale and complexity that no single MS can provide the necessary resources. They need to be carried out at EU level achieve the required critical mass. This occurs where a large research capacity is needed and resources must be pooled to be effective or where there is a strong requirement for complementary knowledge and skills. In Health research, pooling patient cohorts and constituting biobanks are a significant challenge at MS level. Recruiting sufficient numbers of patients is made easier by trans-European research co-operation.

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[187] *A significant effort has already been accomplished to coordinate MS activities by developing common strategic research agendas, aligning national plans, defining and implementing joint calls. This is proving very effective for catalysing MS activities (e.g. financial investments) to common areas, also outside Europe as shown by EDCTP. These activities are concrete examples of implementing ERA in terms of optimal co-operation and competition, optimal circulation and transfer of scientific knowledge, and more effective national research systems.*

[188] SC1 projects and initiatives also contribute to providing EU standards or common tools, such as the Large Scale Internet of Things Pilot on age-friendly living environments, a world-leading effort that will lead to establishing standards and guidelines in this field; or the EU-Japan cooperation on ICT for Ageing Well, building EU standards as baseline. Another example is the human biomonitoring joint programme cofund HBM4EU (see section 5.4.6) that ambitions to become the European counterpart of the other international human biomonitoring programmes such as NHANES in the USA. The initiative will reinforce collaboration between the national programmes and will establish common European guidelines and quality assurance/quality control systems for human biomonitoring data collection and analysis to obtain comparable data across Europe. The initiative will establish a common data repository (IPChem) and knowledge depository (the knowledge hub) accessible for the European research community.

[189] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 128.*

This is notably the case for rare diseases research, where patient cohorts need to be pooled from several MS to constitute statistically relevant sample groups. In addition to other merits previously exposed, EDCTP, the two JPIs as well as the ERA-NETs funded all provide significant, obvious, added-value in terms of pooling of resources. Added value is also conferred by the reduction of research or commercial risk: working in trans-national consortia, involving key EU industry players, helps firms to lower the risks, thus enabling certain research to take place. Further, it helps ensure that research results and solutions are applicable across Europe and beyond, enables the development of EU and world-wide standards and interoperable solutions, and offers the potential for exploitation in a market of 500 million people. The funding, via IMI, of the development of novel business models to boost the development of new antimicrobials is typical, among other *open innovation* features, of the reduction of research/commercial risks that EU funding can bring about. Without SC1 support, several clinical trials would never have been set up: EU-funded research in those areas requiring multinational input, such as clinical trials on medicines and devices for major chronic diseases, which have seen a decrease of industry input due to their complexity, definitely supported innovation and contributed lowering risk of later product development failure. It also helps reducing the risk for patients by providing crucial information on the potential adverse effects of otherwise useful medicines and medical devices. This is also valid for academic clinical trials, aiming at the comparative assessment of efficiency and cost-efficiency of given therapies. They can lead to discard expensive treatments, thereby strongly benefiting to national health systems. Industry may not be inclined to invest significant resources in such potentially unrewarding trials, hence the relevance of EU intervention.

EU-funded trials for Advanced Therapy Medicinal Products (ATMP) fostering the revival of gene therapy trials. Large scale publically funded trials with mesenchymal stem cells are unique in the world. The three most recent ATMP's to be authorized by EMA for marketing in Europe (Imlygic, Strimvelis and Zalmoxis) are gene therapy products and developers of the last two have been supported at some stage by EU research. Gene therapy clinical trials for treatment of severe combined immunodeficiency are being carried out by the recently approved Horizon 2020 SCIDNET project[190]. Large-scale clinical trials are testing the use of mesenchymal stem/stromal cells for treatment of graft versus host disease[191], heart repair[192] and osteoarthritis[193]. No other comparable large-scale studies of this nature have been reported in other parts of the world.

J.7.1.3.SC1 for Synergy: complementing and leveraging

While the **leverage effect** of SC1 has been extensively presented under section J.4.2, the EU added value of SC1 is also illustrated by its effect in improving S&T capabilities of participants, and getting them to achieve results and benefits that would not have been achieved if not for SC1. All SC1 projects contribute to the improvement of S&T capabilities of the participants: by participating in top trans-national teams, researchers can form world centres of excellence. This was clearly acknowledged and extremely valued by the 2014 survey of FP7-Health participants and s fully exportable to SC1 participants[194]. An example is the area of Cardiovascular research for which a recent study (Oct. 2016) on collaborative research from 1992 to 2012 notes: "... *over time, the*

[190] *scidnet.eu*
[191] *rethrim.eu*
[192] *stemcellscience.dk*
[193] *adipoa2.eu*
[194] *In the FP7-Health Survey conducted in October 2014, almost half of the participants ranked "New resources, including infrastructures" among the most important outputs of the project.*

EU-27 supra-national region has increased its participation above the USA. [... A] *number of European countries [...] have improved their absolute and relative citation impact above that of the USA by 2006–2012. Europe is a hub of cross-fertilization with strengthening collaborations and strong citation links.* [...] *All countries, but especially smaller, highly collaborative countries, have higher citation impact for their internationally collaborative research when compared with their domestic publications*[195]. This tends to be confirmed by the 2016 Thompson-Reuters study on IMI bibliometrics, which notes that publications with authors from multiple sectors or international co-authors have a higher citation impact than papers with authors from just one sector or one country respectively[196].

UM Cure 2020 aims to identify and validate at the preclinical level novel therapeutic approaches for the treatment of Uveal melanoma (UM) metastases. UM is a rare intraocular tumour with an incidence of 5 cases per million individuals per year. Up to 50% of UM patients develop metastases, most often in the liver, and these are invariably fatal. There is currently no therapy to either prevent or treat UM metastases. The UM Cure 2020 consortium brings together the major experts of UM in patient care and basic/translational/ clinical research, as well as patient representatives. The 13 participants are from 8 European MS (MS) including Poland. Four major referral hospitals for UM patients across Europe team-up with three other research institutions, two innovative SMEs in diagnostics and cancer therapeutics and a patient organisation. UM Cure 2020 represents a unique opportunity for these two SMEs to increase their research activities in UM and to provide innovative input with the development of a diagnostic array/therapeutic interventions leading to major impacts on UM patients. It will enable them to widen their access to European and global markets, thereby strengthening their competitiveness, and to enhance their connections with the EU biomedical and clinical community, as well as with patients associations.

J.7.2. Other issues related to EU Added Value

J.7.2.1. Counterfactual analysis.

The 2014 survey of FP7-Health beneficiaries found that the absolute majority of the projects (85%) would have been abandoned or only a small fraction of the activities would have been implemented without this funding. This implies a very strong additionally of the programme. This is also confirmed for SC1, where a recent survey of currently ongoing SC1 projects (105 respondents)[197] concerning the fate of the projects had they not been funded by Horizon 2020 produced the following conclusions:

The project would have gone ahead with none or minor modifications.	The project would have gone ahead with significant modifications.	The project would not have gone ahead.
12.3%	39.6%	48.0%

In projects which would have gone ahead without EU funding with significant modifications, the following aspects would have been affected.

[195] *D. Gal, W. Glänzel, K. R. Sipido, Mapping trans-national collaboration and communication in cardiovascular research from 1992 to 2012, European Heart Journal http://dx.doi.org/10.1093/eurheartj/ehw459, October 2016*
[196] http://www.imi.europa.eu/content/bibliometrics-2016, http://www.imi.europa.eu/sites/default/files/uploads/documents/Publications/BibliometricReport_2016.pdf
[197] PPMI: *Study on European Added Value in H020, overview of the survey results* (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016.

The scope of the project (i.e. the number of areas, subjects or the ambition of its objectives).	The timeframe of the project.	The number of partners involved.	The type of partners involved.
82.8%	80.7%	67.7%	63.3%

The most relevant reasons invoked for not going ahead with the project were

Not finding alternative sources of funding for the type of activities foreseen in your project	Not finding alternative sources of funding for the areas of research covered in your project.	Not being able to address pan-European issues in your project solely at national level.	Lack of access to necessary knowledge, expertise and skills in other countries without Horizon 2020.	Lack of access to necessary research infrastructure, databases and other tools in other countries without Horizon 2020.	The necessary amount of funding is larger than could be available funding from national/regional schemes.
89.2%	59.4%	61.3%	46.4%	40.5%	78.1%

Likely sources of funding for Horizon 2020 projects which would have gone ahead without EU funding

Own funds of project partners	Public national/regional schemes	Other EU programmes	Private/industrial sources external to the partners of your consortium
77.9%	76.5%	35.3%	69.7%

In the hypothesis that the project would have been funded by national/regional sources instead of SC1, the project participants considered that their capacities would have been negatively affected in several terms of research capacities, HR aspects and many other ways, as detailed below[198]:

research capacities					
Understanding and knowledge in existing areas	Understanding and knowledge in new areas	Scientific capabilities	Technological capabilities	Access to infrastructure and equipment	Planning and coordination of R&D to avoid duplication
46.1%	59.6%	45.3%	41.2%	45.8%	41.6%

human resources aspects				
Ability or capacity to provide training	Ability or capacity to attract researchers and other staff	Mobility of researchers	Career development of researchers	Relationships and networks
44.5%	63.4%	58.8%	50.8%	81.2%

commercial advantage aspects				
Competitive position nationally	Competitive position internationally	Market share in existing markets	Access to new markets	Revenue
42.2%	78.6%	44.8%	70.0%	55.6%

scientific/research outputs aspects				
Publications in refereed journals and books	Publications other than those in refereed journals and books	Scientific awards and prizes	Participations in scientific conferences, seminars or workshops	Specific outputs targeting policy making
44.2%	43.4%	50.7%	63.0%	64.3%

following research capacity outputs aspects						
Newly trained/ qualified personnel	Newly trained PhDs	Personnel temporarily exchanged with other	Additional research grants	The transfer of technology and knowledge	New collaboration partnerships with industry and business	New collaboration partnerships public administration and NGOs
36.1%	36.6%	52.4%	65.1%	55.2%	65.2%	50.6%

[198] PPMI: *Study on European Added Value in H020, overview of the survey results* (Framework contract 2012/S 144-240132) Overview of the survey results, September 2016.

J.7.3. Lessons learnt/Areas for improvement

The main added value of collaborative health research at EU level derives from transnational cooperation, the integration of relevant activities and participants, and the concentration of European effort on fewer, but most relevant priorities. Practically, EU health research:

- Removes barriers to research co-operation between countries, provides structures and incentives to establish multinational consortia and coordinates MS and Associated country national funding programmes.
- Provides structures and incentives for cooperation between different types of organisations and disciplines: governments, funding agencies, universities, research centres, hospitals, small and medium-sized enterprises (SME), large companies, foundations, patients' and users' organisations etc., and researchers, engineers, clinicians and industrialists, etc.
- Focuses efforts on issues with a scale which can only be tackled at a European (or global) level, or for which there is significant added value in acting in this manner.

Regarding the added value of FP7-Health, the ex-post evaluation of FP7-Health concluded that *the main mechanisms and drivers of European Added Value included the scale and scope of the activities funded; the transnational, inter-sectoral and interdisciplinary cooperation; the networks built; as well as the pooling of a critical mass of resources and research capacities. These effects were particularly driven by large-scale collaboration, high-impact research initiatives and integration of national and regional research programmes under ERA-NET*[199].

All these factors are equally present in SC1, which also plays a major role in positioning Europe on the global map of science and technology in health research thanks to its international consortia and other major initiatives.

J.8. SUCCESS STORIES FROM PREVIOUS FRAMEWORK PROGRAMMES

Among the many success stories from FP7 finished projects, the following three have been selected as having been particularly successful in tackling SC1, in inducing socio-economic impacts and in providing EU Added Value:

Influencing national practices: the ATOME project (*Access To Opioid Medication in Europe)* aimed at analysing the influential factors concerning inappropriate prescription of medicines and at developing policy recommendations for safe, effective and cost-effective use of medicines in Europe. The project included analysis of national policies and circumstances that affect the availability of opioid medicines, revisions of current law (proposing amendments) to better balance the need to prevent drug abuse while allowing patients access to such medicines, understanding the socio-cultural context of drug use and abuse. ATOME focused on 12 countries where statistical evidence shows very low morphine per capita consumption (Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Serbia and Turkey). The identified barriers were divided into different categories such as legislation, national policies, knowledge and societal attitudes, and economic aspects. They were presented in form of country reports and included concrete recommendations for legislative changes. These reports were presented to relevant ministries, national organisations and health-care professionals, and are expected to lead to the adoption of policies allowing for improved

[199] *PPMI, Ex-post Evaluation of the HEALTH Theme in FP7. Final report, November 2016, p. 28.*

access to pain medication and national action in the area of substitution therapy. Furthermore, ATOME also produced an update of WHO guidelines 'Ensuring Balance in National Policies on Controlled Substances' that provides an up-to-date and internationally agreed standard for policy and decision makers in Europe and other countries

A more secure liver surgery all over the world : PASSPORT (June 2008 - May 2011) developed a "virtual liver" that helps surgeons take critical decisions on whether to operate a patient or not. In 2013, the project coordinator IRCAD[200] launched Visible Patient[201], a start-up that developed further the two main results of the project: the patient-specific preoperative planning software and the 3D modelling service that can create 3D models of any part of the human body – the "virtual liver". Today the Patient Specific Modelling service and all associated software (modelling and surgical planning) are CE-marked, FDA approved as well as Canadian Health and Taiwan certified. This service, operating since April 2015 is used in more than 10 different countries with more than 200 clinical cases modelled during the last months. The main benefit is the possibility to optimize preoperative planning, significantly improved in more than 20% of clinical cases. Two open source frameworks developed during the project, FW4SPL and SOFA, allowing the development of the patient's specific surgical preoperative planning and real-time mechanical simulations for surgery or interventional radiology, are being industrially exploited by several companies as well as several research teams. Thanks to PASSPORT project, IRCAD, INRIA and Strasbourg University have developed a new industrial research program in a huge partnership with Karl Storz and Siemens Healthcare. This partnership was translated in a new private Foundation named Strasbourg IHU. Several industrial projects have been then initiated.

Attracting private funds: The project **NABATIVI** helped the small biotech company Polyphor to develop a promising new antibiotic compound. The compound was recently licensed to a large pharmaceutical company (Roche) in a deal worth hundreds of millions of Euros. EU-funding for NABATIVI thus reverses, for the first time, the trend of big pharma to leave this crucial area of drug development and will strengthen defences against resistant bacteria.

J.9. LESSONS LEARNT/CONCLUSIONS

In spite of the limitations inherent to health research evaluation at this stage of SC1[202], the evidence provided above point at significant prospects in terms of SC1 being smoothly implemented, despite difficulties resulting from the high response it has stimulated, producing durable collaborations, improving the research capabilities of its participants, the competitiveness of its industrial participants, contributing to training students and researchers, generating patents, creating jobs and SMEs, significantly adding to the stock of useful knowledge notably to inform national and European policy-

[200] *http://www.ircad.fr/*
[201] *https://www.visiblepatient.com/en/*
[202] There is no easy way to evaluate scientifically the impact of medical research (L. B. Allen, *The art of evaluating the impact of medical science*, WHO, 2010, vol. 88, p. 4), but studies do report exclusively positive impact of public funding for health research. A study on publically funded medical research in the UK between 1975 and 1992, focused specifically on mental health and cardiovascular medicine, concluded that the average time lag between research spending in these fields and health benefits was 17 years. But then, for every £1 of public or charitable funding, cardiovascular research produced benefits equivalent to 39 pence per year in perpetuity. The steadily increasing body of evidence suggests that, while impacts may not be immediately apparent, timely public investment in medical research in Europe will reap long-term dividends.

makers on public health issues and beyond, producing new methodologies, guidelines, new diagnostic and therapeutic tools, while supporting their market potential. SC1 also contributes to the achievement of ERA in health, structuring the EU RTD and innovation landscape, shaping Global, EU and national policies, while supporting standardisation and legislation. Accordingly, it is well on track to deliver on its short and longer term objectives. The limited weaknesses and bottlenecks identified in the previous sections are summarised below.

J.9.1. Relevance

KEY FINDINGS: SC1 is relevant, suited to current challenges and consistent with its legal basis.

THE STRENGTHS: SC1 is flexible enough to react to political, social and urgent public health developments.

THE WEAKNESSES: Some limitations are found in some areas in terms of translating research results into application in health care systems, on the market, and into society.

J.9.2. Effectiveness

KEY FINDINGS: SC1 is right on track to deliver on its objectives

THE STRENGTHS: The strengths lie in SC1 contribution to increasing knowledge with top scientific publications; to new and sustained collaborations; to leveraging research investments, stimulating innovation, production of patents, and creation of jobs and spin-off's; to influencing research policies, feeding into policy-making, and placing the EU a stronger global player in health R&Is.

THE WEAKNESSES: Some difficulties were encountered for clinical trials.

J.9.3. Efficiency

KEY FINDINGS: SC1 is a highly selective programme that implements an increasing budget with a constantly decreasing number of staff, and increasingly shorter time-to-grant and time-to-pay.

THE STRENGTHS: 1) The simplification is well appreciated. 2) The productivity in terms of scientific output is comparable to that of other leading international research programmes 3) SC1 mobilises top players in academia and industry.

THE BOTTLENECKS/WEAKNESSES: 1) Oversubscription triggers frustration in the scientific community 2) The participation of EU-13 teams is low 3) Research results and project data should be monitored in more detail.

J.9.4. Coherence

KEY FINDINGS: No known coherence issue is hampering SC1 from delivering on its objectives. It complements national and regional efforts in providing for the international collaborative dimension and fosters alignment and development of common research agendas.

THE STRENGTHS: SC1 provides leadership in international consortia, thereby preventing duplication of efforts on a global level.

THE BOTTLENECKS/WEAKNESSES: A bottleneck is the lack of streamlined access to user-friendly exploitable internal (EU-funded health R&I outside of SC1) and external information (R&I spending and priorities at national and regional level).

J.9.5. EU Added Value

KEY FINDINGS: The main added value of EU collaborative health R&I derives from transnational cooperation, the integration of relevant activities and participants, and the concentration of European effort on fewer, but most relevant priorities that can only (or better) be tackled at a European (or global) level.

THE STRENGTHS: SC1s assets are the scale and scope of the activities funded; the transnational, inter-sectoral and interdisciplinary cooperation; the integration of different types of organisations; the sustainable EU networks; the pooling of a critical mass of resources and research capacities; the coordination and/or integration of national and regional funding.

BOTTLENECKS/WEAKNESSES : There was no bottleneck or significant weakness identified.

K. FOOD SECURITY SUSTAINABLE AGRICULTURE AND FORESTRY MARINE MARITIME AND INLAND WATER RESEARCH AND THE BIOECONOMY

K.1. INTRODUCTION

This report is the Thematic Annex of Societal Challenge 2 (SC2) to the Interim Evaluation of Horizon 2020 and it is based on the final report of the Expert Group for SC2 Interim Evaluation. It critically examines the rationale, design and current state of implementation of the programme and presents the SC2 Expert Group's assessment of the relevance, effectiveness, efficiency, EU added-value and coherence of the programme. Although all of these evaluation criteria are covered by the evaluation, given the early stages of programme implementation and considering that limited evidence on actual outputs and results is available, this report focuses on design and implementation issues, relevance and coherence,. Moreover, it should be noted that this Report focuses on the projects funded through the main SC2 calls. This evaluation does not examine the SME instrument and the BBI-JU in detail as these topics are the subject of two, parallel, ongoing evaluations.

K.1.1. Evaluation methodology

The evaluation was designed to respond to a specific set of evaluation issues and questions. The overall design of the evaluation was based on a mixed methods approach comprising:

- *Desk research* which, inter alia, covered the legal base for Horizon 2020 and SC2, work programmes and documents produced as part of the Strategic Programming process, BBI Annual Work Plans, Annual Activity Reports, Calls for proposals, Project Deliverables, Project Periodic Reports (these were available for 10 projects at the time of writing this Report), Past evaluations and impact studies etc.;
- *Composition analysis* which entailed a quantitative analysis of CORDA data relating to SC2 proposals and projects such as the number and type of participants, EC contribution, cross cutting indicators etc.;
- *Semi-structured interviews with 11 key Commission and REA officials, 13 key informants/stakeholders and 20 project participants* to address programme level questions particularly those relating to its relevance, EU added value, alignment with national activities, main achievements and impacts;
- *An online survey of Horizon 2020 project participants* focusing on EU added value;
- *Mapping of (non-SME) projects characteristics* (such as their TRLs, expected outputs and contribution to 3Os, target users etc.) using a pre-defined template. Almost all non-SME projects that were approved by the end of January 2016 were mapped i.e. 111 out of 115 (including 13 BBI projects).
- *Mapping of SME project characteristics and expected impacts* using a predefined template. The scope of the exercise was as follows:
    - Phase I proposals and feasibility reports: all projects which were completed and for which feasibility study reports were available as of August 2016 (N=67);
    - Phase II proposals: projects approved by the end of January 2016 (N=26).

Further details on the methodology are available in Annex 1 of the Expert Group Report.

K.1.2. Context

The Societal Challenge pillar within Horizon 2020 seeks to find solutions to the major challenges facing Europe (as well as the world) as identified in the Europe 2020 Strategy and its flagship initiatives, while reflecting the concerns of Europe's citizens as well as demands to tackle these major challenges expressed by Member States and other public and private actors of the European Research Area. As articulated in the various Commission documents and policy statements, Societal Challenge 2 specifically addresses the following inter-related challenges and opportunities:

- *Feeding a growing world population*: the challenge is *not only to produce more, but also to produce safe and healthy food with fewer resources, less negative environmental impacts and in more difficult conditions*. Improving food security requires not only increasing food production, but also:
    - *Reducing food waste*
    - *Producing safe, healthy and high quality food that is accessible, nutritious, contains minimal or no allergens and chemical contaminants, and free of food-borne pathogens and toxins.*
    - *Reducing demand for animal protein*
    - *Taking account of the impact of urbanisation*
- *Harnessing the huge potential of Europe's oceans, seas and coasts for jobs and growth*
- *Reducing the EU's heavy dependence on seafood imports*
- *The need to shift to a bio based economy not only because of climate change, but also to reduce Europe's dependence on fossil resources and to create jobs and green growth.*
- *To get more feed, energy, and biological raw materials from forests while ensuring their sustainability*.

Addressing these challenges will require new knowledge and technology, and investment in R&I will be essential.

K.1.3. Objectives and intervention logic

K.1.3.1. Programme objectives and structure

With a budget allocation of EUR 3.85 billion over the period 2014-2020[203,204], SC2 aims "*to secure sufficient supplies of safe, healthy and high quality food and other bio-based products by developing productive, sustainable and resource-efficient primary production systems, fostering related ecosystem services and the recovery of biological diversity, alongside competitive and low-carbon supply, processing and marketing chains. This will accelerate the transition to a sustainable European bio economy, bridging the gap between new technologies and their implementation*".[205] Investments in R&I under SC2 are expected to contribute to food security; environmental sustainability; support the transition from a fossil fuel-based economy to a bio-based economy; and enable Europe to take a leading role in the

[203] *This budget represents 5% of the total budget allocated to Horizon 2020*
[204] *Of which EUR 800 million has been allocated to the BBI JU and EUR 3.05 billion to the rest of SC2. In accounting terms, the BBI has a separate budget line from SC2, although for practical purposes BBI JU is considered a part of the SC2 programme*
[205] *Horizon 2020 Regulation: Regulation (EU) No 1291/2013, Annex 1*

development of global agri-food industry and bio-based industries, including blue biotechnology.

In line with the above objectives, SC2 is structured around five activity lines, as specified and defined in the Council Decision of 3 December 2013 establishing the specific programme implementing Horizon 2020 (2014-2020).[206]

- *2.1 Sustainable agriculture and forestry:* developing knowledge, tools, services and innovations to support more productive, environmentally friendly resource-efficient and resilient agriculture and forestry systems that supply sufficient food, feed, biomass and other raw materials and deliver ecosystems services while at the same time protecting biodiversity and supporting the development of thriving rural livelihoods.
- 2*.2 Sustainable and competitive agri-food sector for a safe and healthy diet:* addressing food and feed security and safety, the competitiveness of the European agri-food industry and the sustainability of food production, processing and consumption. It covers the whole food chain and related services from primary production to consumption.
- *2.3 Unlocking the potential of aquatic living resources:* developing new insights, tools and models to improve understanding of what makes marine ecosystems healthy and productive and to assess, evaluate and mitigate the impact of fisheries on marine ecosystems (including deep sea); developing competitive and environment friendly aquaculture; developing new harvest strategies and technologies; boosting marine and maritime innovation through biotechnology.
- *2.4 Sustainable and competitive bio-based industries and supporting the development of a European bio economy:* research, innovation and networking actions focusing on the development of environmentally friendly bio-based products and processes, the development of integrated bio-refineries and the opening of new markets for bio-based products.
- *2.5 Cross-cutting marine and maritime research:* addressing cross-cutting marine and maritime scientific and technological challenges with a view to unlocking the potential of seas and oceans across the range of marine and maritime industries, while protecting the environment and adapting to climate change.

In addition, a general category consists of

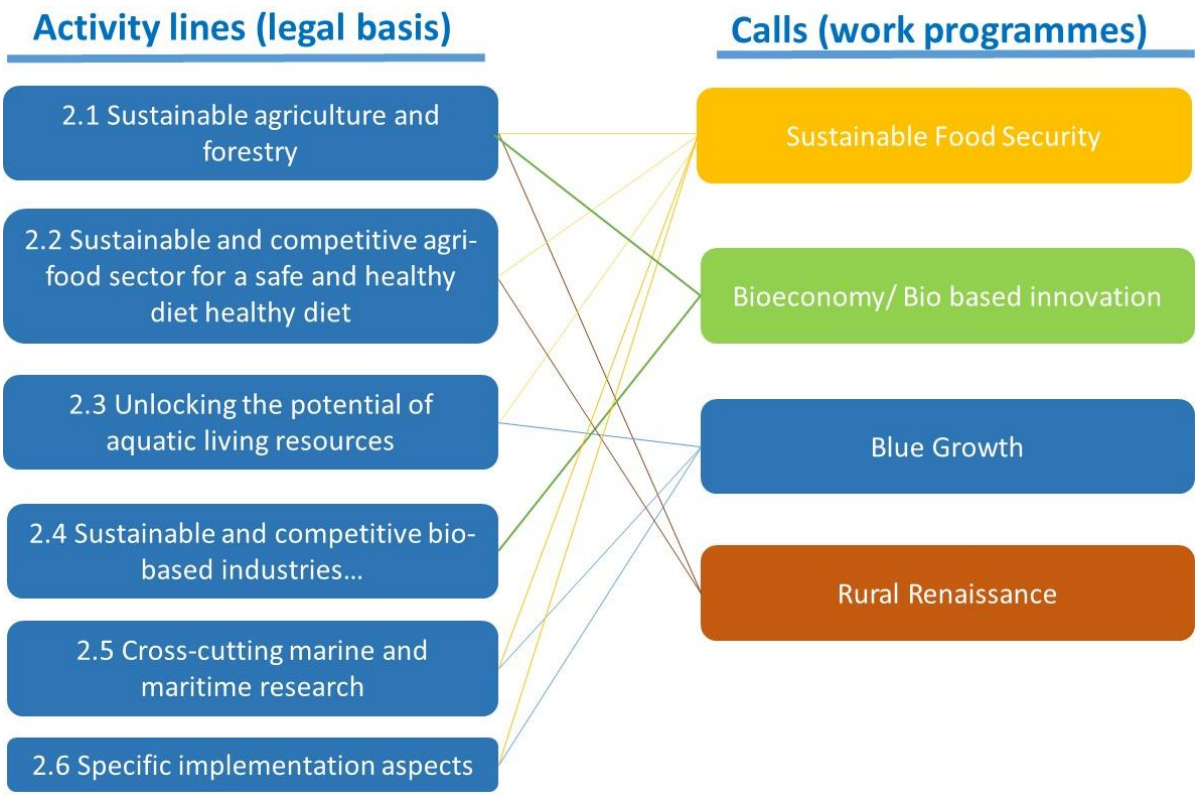
- *2.6 Specific implementation aspects:* supporting the implementation of the rest of the programme and including external advice, specific actions on communication, monitoring and evaluation, knowledge exchange and stakeholder involvement as well as pilot and demonstration activities.

The high level SC2 objectives and activities are implemented through biennial (or triennial) work programmes. The 2014-15 Work Programme comprised three calls: "Sustainable Food Security – SFS", "Blue Growth – BG" and "Innovative, Sustainable and Inclusive Bioeconomy – ISIB". The 2016-17 Work Programme continues SFS and BG, and adds a new call "Rural Renaissance - RUR". It also replaces the ISIB call with the "Bio-based innovation for sustainable goods and services - BB" call.

Figure 199 shows the links between activity lines set out in the legal basis and the call themes as defined in the work programmes.

[206] *Council Decision of 3 December 2013 L347/965*

Figure 199 - Relationships between Activity lines set out in the legal basis and call themes set out in the Work Programmes



NB: The definition of which activity line(s) (legal basis divisions) are covered by a particular call topic (and consequently a project) is carried out during work programme drafting.

Table 134 provides an overview of the two work programmes covering the first part of the programming period.

Table 134 - Objectives and scope of the first two SC2 Work Programmes

	2014-2015	*2016-2017*
Specific Objectives	• To develop competitive and resource-efficient aquatic and terrestrial food production systems • To harness the huge potential of Europe's oceans, seas and coasts for jobs and growth • To support sustainable agriculture and forestry management processes providing public goods and innovative products for sustainable growth • To foster innovation (including social innovation) in rural areas for inclusive growth • To enhance innovation in the bio-based industry for smart growth	• To ensure food and nutrition security, by fostering resilient and resource efficient primary production and industry as well as sustainable and healthy consumption • To demonstrate the innovative potential of the oceans, by bringing technology to market • To improve current European marine observing, surveying and monitoring capabilities • To foster innovation and business opportunities for rural and coastal areas, through new territorial approaches and business models • To re-industrialise Europe, through new bio-based value-chains, while securing sustainable biomass

	2014-2015	*2016-2017*
Scope	**Three Call Theme, 49 topics, EUR 482 million** • Sustainable food security EUR 251.5 million (52%) • Blue growth: unlocking the potential of Seas and Oceans EUR 144 million (30%) • Innovative, sustainable and inclusive bio economy EUR 86.5 million (18%)	**Four Call Themes, 86 topics, EUR 757 million** • Sustainable Food Security-Resilient and resource-efficient value chains EUR 461 million (61%) • Blue Growth – demonstrating an ocean of opportunities EUR 130 million (17%) • Rural Renaissance - Fostering innovation and business opportunities EUR 127 million (17%) • Bio-based innovation for sustainable goods and services - Supporting the development of a European Bioeconomy EUR 38.5 million (5%)
Budget appro-priations	SC2 budget allocated to above calls = EUR 422 million Allocation from another SC = EUR 60 million Allocation of SC2 budget to other SCs and other actions: EUR 46 million	SC2 budget allocated to above calls = EUR 679 million Allocation from another SC = EUR 78M Allocation of SC2 budget to other SCs: EUR 112 million

Source: SC2 work programmes and DG RTD data.

Table 134 does not include the Bio-based Industries Joint Undertaking (BBI JU) which accounts for a significant share of the SC2 budget: EUR 800 million or 20.8 % of the total SC2 budget.[207] The BBI JU implements a Joint Technology Initiative aimed at promoting investment in the development of a sustainable bio-based industry sector in Europe. Specifically, it will:

(i) Demonstrate technologies that enable new chemical building blocks, new materials, and new consumer products from European biomass which replace fossil- based inputs;

(ii) Develop business models that integrate economic actors along the whole value chain from supply of biomass to biorefinery plants to consumers of bio-based materials, chemicals and fuels, including by means of creating new cross-sector interconnections and supporting cross-industry clusters; and

(iii) Set up flagship biorefinery plants that deploy the technologies and business models for bio-based materials, chemicals and fuels and demonstrate cost and performance improvements to levels that are competitive with fossil-based alternatives.

The BBI JU is expected to leverage at least EUR 2.73 billion of private investment.

[207] *The BBI JU is a public-private partnership between the European Commission and the Bio-based Industry Consortium (BIC). It was established on 6 May 2014 by Council Regulation No 560/2014, entering into force on 27 June 2014. The total EU funding allocated to the BBI JU is EUR 975 million of which EUR 800 million comes from SC2 and EUR 175 million from the LEIT KET Biotechnology programme.*

Table 135 - Overview of BBI annual work programmes

*2014**	*2015**	*2016***
• One call • Budget = €50M + €1.5M EFTA appropriations • 16 topics (10 RIA, 5 DEMO and 1 Flagship)	• Two calls • Call 2015.1 dedicated to 3 Flagship topics (Budget= €100M) • Call 2015.2 dedicated to 7 DEMO topics, 10 RIA topics, and 2 CSAs (Budget= €106M)	• One call • Budget = €188M • 27 topics (12 RIA, 9 DEMO, 2 Flagship, 4 CSAs)

*Sources: *Annual Activity Reports for 2014 and 2015; **2016 Work Programme.*

K.1.3.2. Evolution from FP7 (2007-2013)

SC2 builds upon the following parts of FP7[208]:

- Cooperation Theme 2: Food, Agriculture and Fisheries, and Biotechnology (FAFB), also known as Knowledge Based Bio Economy (KBBE);
- "The Ocean of Tomorrow" call (31 projects, EUR 195 million) [209,210], an initiative launched in the second half of FP7 to promote cross-sectoral research to address sea related challenges.

In comparison with FP7-FAFB, the budget increased by two-fold in Horizon 2020. The overall budget earmarked for funding of the Cooperation Theme 2 for the period 2007 - 2013 was indeed EUR 1.9 billion.

Blue Growth has also emerged as a distinct cross-cutting 'Focus Area' under Horizon 2020. Building on the results from FP7 "The Ocean of Tomorrow" and blue biotechnology projects, it expands towards a variety of marine-related fields of knowledge and economy sectors that bear a high potential and thus deserve further development[211]. This is in line with SC2 responsibility of implementing activity 2.5, cross-cutting marine and maritime research.

SC2 also places significant emphasis on bio-based industries with the creation of a BBI-JU and the allocation of about a quarter of the SC2 budget to this. Within bio-based industries, the main focus area is on new integrated value chains. This is a major difference compared to FP7, which was more clearly separated between the different stages of the value chain (feedstock – processing – products). Also the role of demonstration projects and flagships is high in BBI-JU, which is a major change compared to FP7 and appears well justified

[208] *Details on the themes addressed within FP7-FAFB can be found in the ex-post evaluation of the rationale, implementation and impacts of EU Seventh Framework Programme (2007-2013) Cooperation Theme 2: food, agriculture and fisheries, and biotechnology: https://ec.europa.eu/research/evaluations/index_en.cfm?pg=fp7*

[209] *This cross-disciplinary call was launched under the Cooperation Themes: Food, Agriculture and Fisheries, and Biotechnology; Energy; Environment; Transport. "The Ocean of Tomorrow" call topics were designed to have a high technological impact by bringing together different scientific disciplines to deliver sustainable solutions for marine and maritime activities. Providing competitive advantage and leadership to European industry was an expected impact of this theme and to this end, the "The Ocean of Tomorrow" projects were implemented to deliver explicit commercial applications (novel automated system for in-situ monitoring; miniaturized immune-sensor) and boost marine technologies. Funded projects were also successful in achieving a high engagement of SMEs that are active technology developers and paved the way for the Blue Growth Focus Area within Horizon 2020.*

[210] *European Commission (2014) The Ocean of Tomorrow Projects (2010-2013)*

[211] *The recognition that marine biodiversity is largely unexploited and holds vast opportunities for new processes and products has made blue biotechnology part of the Blue Growth theme with specific calls in both WP implemented so far.*

considering that scale up and commercialisation typically are the main bottlenecks in new bio-based value chains.

There is also more emphasis on applied agricultural, fisheries and aquaculture systems research, value chain development, and increasing access to genetic resources; R&I along the food value chain; and more targeted international cooperation (in particular with African countries and China and South -East Asia) on issues such as food security. In particular, the EU-China flagship on Food, Agriculture and the Bioeconomy (FAB) has resulted in the flagging of several research topics that were of common interest for the EU and China. This resulted in increased collaboration and participation of Chinese actors in several research projects.

Under SC2, international cooperation is planned and implemented through strategic approaches of programme-level co-operation. For example, in the marine sector, a strategic approach was developed for international cooperation, based on the Atlantic Strategy and the then planned Ocean Governance Communication. In particular the Galway Statement establishing the Trans-Atlantic Research Cooperation was signed with the USA and Canada and the Bluemed Initiative was started. Currently, efforts to increase research cooperation in the South Atlantic are underway and preparations to extend the BLUEMED initiative to the Southern Mediterranean countries are progressing. These actions are facilitating coherent and structured approaches, aligning R&I agendas, and undertaking expensive explorations such as seafloor mapping. They are being supported with a number of projects which were launched in the WP2014-15, such as AORAC and AtlantOS.

Agriculture research in SC2 is linked to the recent reform of the Common Agricultural Policy. The second pillar of the new Common Agricultural policy includes a commitment to foster knowledge transfer and innovation in agriculture, forestry, and rural areas. Three significant programme changes have supported this:

1. Management of agriculture research within Horizon 2020 is shared between DG Research and Innovation (DG RTD) and DG Agriculture and Rural Development (DG AGRI).

2. Increased relevance of research to farmers and farm-related value chains is implicitly expected from the link to the Common Agricultural Policy through a number of mechanisms, most notably the development of the multi-actor approach in almost all projects under 'Agriculture' and a set of challenging and innovative research targets that complement other programmes and private sector investment.

3. The link to and support of the European Innovation Partnership 'Agricultural Productivity and Sustainability' ('EIP Agri'). The EIP Agri is a major element of efforts to include support for innovation in Pillar II of the Common Agricultural Policy, i.e., the Rural Development Policy. SC2 interacts with the EIP Agri in two major ways: in developing programme plans through the EIP Agri Focus Groups that bring stakeholders and sectoral experts together to discuss future R&I needs in specific areas of innovation activity; and the use of the EIP Agri to bring together and focus and deliver research results for specific groups of research users, especially farmers.

Overall across SC2, there is less focus on more basic / fundamental research as compared to FP7-FAFB which is in line with the philosophy of Horizon 2020. Basic research is substantially funded through the first pillar of Horizon 2020 (Excellent science – ERC grants and Marie Skłodowska-Curie actions), while at the same time the societal challenge pillar is expected to address higher TRL research and innovation.

In addition to the changes in programme focus and scope, there have been several general implementation changes from FP7 to SC2 – including: a strategic programming approach to the preparation of work programmes, allowing the identification of "focus areas" or calls, where R&I efforts should be focussed for maximum impact; broader call topics; a more joined up approach with the different DGs ('Horizon Group'); introduction of new instruments (e.g., the SME instrument, Innovation Actions); introduction of the multi-actor approach for agriculture and forestry projects; shared responsibility between RTD and AGRI for the development of SC2 programme; delegation of implementation management of calls to European Commission Executive Agencies (mainly REA, to a lesser extent INEA and EASME). These elements are discussed in-depth in subsequent sections.

K.1.3.3. Intervention logic

Figure 200 provides a simplified intervention logic for the Societal Challenge 2[212]. This logic informs and relates to a 'theory of change' i.e., the causal mechanisms through which the programme is expected to bring about the desired change(s). It consists of the following building blocks:

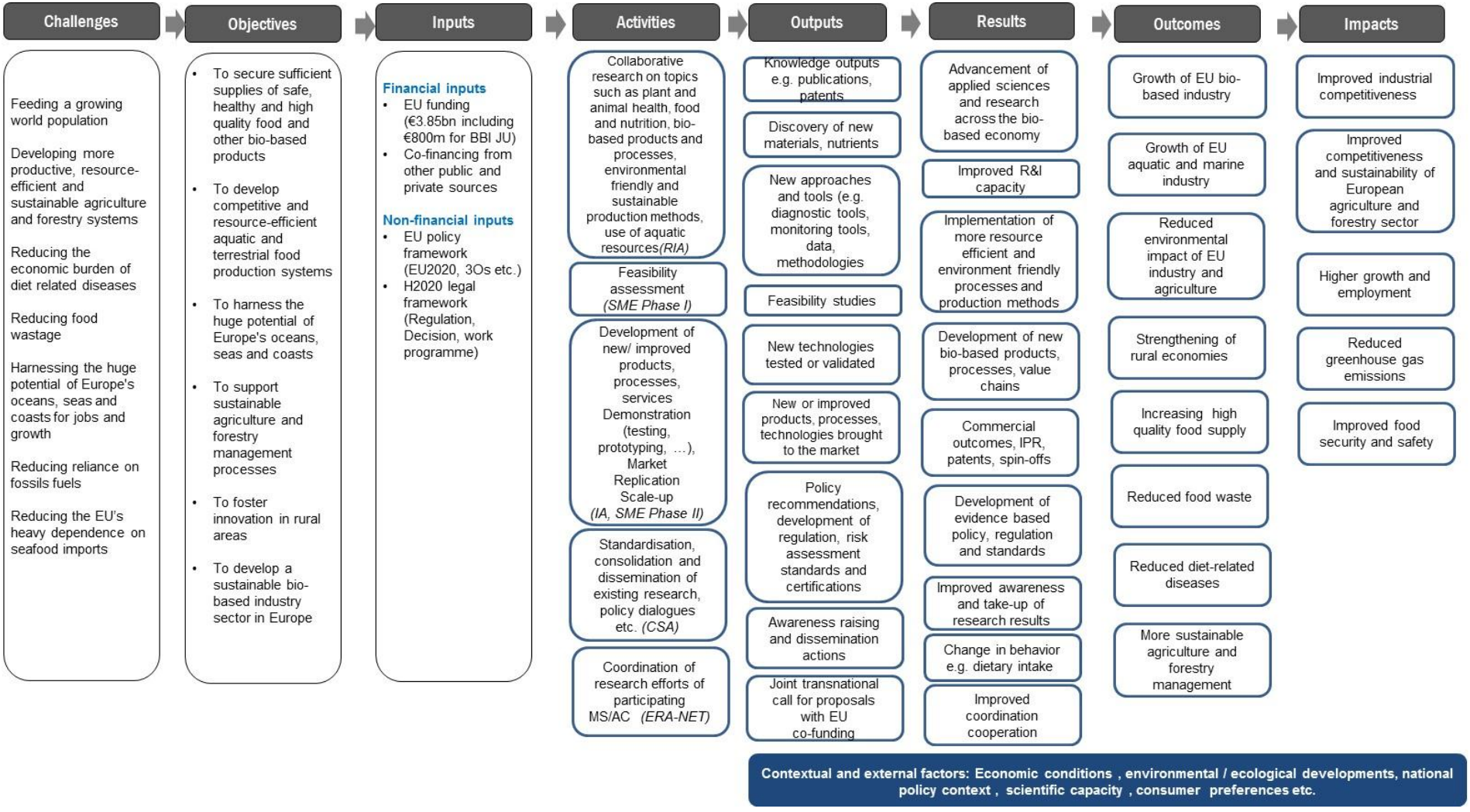
- The challenges or opportunities being addressed by SC2;
- The financial and non-financial inputs available under the programme which include EUR 3.85 billion of EU funding over the period 2014-2020 (including EUR 800 million allocated to the BBI JU), co-financing and contributions from other public and private sources (including at least EUR 2.73 billion of private investments expected to be leveraged by the BBI JU) as well as policy inputs provided by the Commission such as the legal basis, work programme etc.;
- The main programme activities, namely R&I activities as well as activities aiming to valorise existing research results;
- The main outputs generated by funded projects – which are both instrument and call topic specific - including generation of new knowledge; research outputs such as publications; development and/or validation of technologies, approaches, tools and methodologies; new products, processes, materials etc.; dissemination tools and awareness raising activities; as well as policy recommendations and policy evidence;
- Expected effects i.e. the results, outcomes and impacts reflecting the main objectives;
- The main external factors (confounding factors) that also influence the direction and scale of effects such as macroeconomic conditions, environmental factors, national R&I policy and capacity etc.

While an intervention logic is useful for setting out how the programme is expected to generate its impacts, these models are by the nature simplistic and linear, and in some ways not suited to the complexity of R&I and its inherent riskiness (the likelihood that outputs will not generate outcomes etc.). Indeed, there are a number of assumptions underpinning the relationship between activities/ outputs and effects in the intervention logic presented e.g.:

- That call topics are relevant;
- That the programme is successful in selecting suitable project ideas;
- That research results are disseminated and exploited to, *inter alia*, change consumer behaviour, inform policy and to develop new standards, processes, products etc.;
- That innovations are successful and ultimately scaled up.

[212] *Detailed intervention logics for each of the specific activity areas are provided in the Expert Group report.*

Figure 200 - Simplified intervention logic of Horizon 2020 Societal Challenge 2 (developed by the SC2 expert group)



K.2. IMPLEMENTATION STATE OF PLAY

K.2.1. Overview of programme inputs and activities

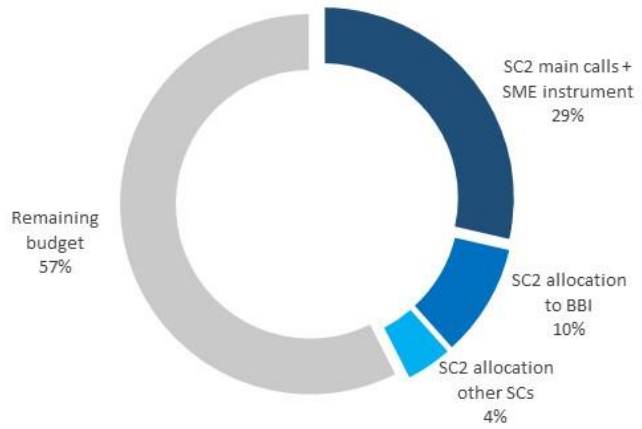
The data analysed by the expert group in this section reflects the situation as of 1 January 2017 concerning the portfolio of projects with which grant agreements were signed.

Project grants are allocated to individual projects via three mechanisms: (1) SC2 main calls; (2) dedicated Phase 1 and Phase 2 calls of the SME Instrument; and (3) the calls launched by the Bio-Based Joint Undertaking (BBI JU). Subsequent analysis of the state of play presents – apart from data at overall SC2 level – the first two implementation mechanisms separately, where feasible, but does not go into the details of the BBI JU calls as there is a separate analysis of the Joint Undertaking.

K.2.1.1. Budget allocation

The EC contribution allocated to the implementation of the calls included in Work Programme 2014-2015 and which have been closed at the date of *5 December 2015* was EUR *738* million (of which EUR 482 million were allocated to SC2 main calls and SME instrument and EUR 256 million were allocated to BBI calls). EUR 639.6 million came from SC2 budget, EUR 60 million were allocated from other SCs to SC2 work programme and EUR 38.4 million was allocated from LEIT to BBI. During the same period, EUR 46 million from SC2 budget was allocated to other SCs. Total EC contribution to 2016-2017 work programme amounts to EUR *945* million (of which EUR 752 million have been allocated to SC2 main calls and SME instrument and EUR 188 million were allocated to BBI calls[213]). EUR 838.8 million came from SC2 budget, EUR 78 million were allocated from other SCs to SC2 work programme, EUR 28.2 million was allocated from LEIT to BBI. During the same period, EUR 112 million from SC2 budget was allocated to other SCs. By the end of 2017, approximately 43% of the total SC2 budget would have been allocated (EUR 1.64 billion).[214]

Figure 201 - Allocation of the SC2 budget to Work Programmes 2014-2015 and 2016-2017



Source: Corda.

[213] *The figures for BBI JU do not cover the Work Programme for the year 2017.*
[214] *Apart from grant funding, the SC2 budget is also used to cover expert costs and to contribute to Horizon 2020 horizontal activities, which amounted to a total of EUR 7.14 million under the Work Programme 2014-2015.*

In the Work Programme 2014-2015, the most significant implementation mechanisms in terms of total budget were the *three main SC2 calls*: Sustainable Food Security (Horizon 2020-SFS-2014/2015), Blue Growth: Unlocking the potential of Seas and Oceans (Horizon 2020-BG-2014/2015), and Sustainable and Inclusive Bioeconomy (Horizon 2020-ISIB-2014/2015), with a combined budget of EUR 482 million.[215]

The SME Instrument (SMEInst) had a dedicated budget of EUR 36 million to fund related calls in the SC2 Work Programme 2014-2015, and the BBI JU was allocated a sum of EUR 256 million to fund their flagship, demonstration, and R&I calls.

Finally, a part of the SC2 budget (EUR 32 million) was allocated through calls implemented in the "SC1 - Health, demographic change and wellbeing" (PHC-07-2014 call topic) and "SC5 - Climate action, resource efficiency and raw materials" Work Programmes (WASTE-2-2014, WASTE-7-2015 and WATER-4b-2015 calls topics), as well as EUR 8.9 million within the framework of Horizon 2020-FTIPilot-2015 Fast Track to Innovation. The latter group of FTI Pilot projects is not included in subsequent analyses.

The specific challenges or research topics to be addressed by the proposals, as outlined in the Work Programmes, are grouped into *six* activity lines (referred to as level 5 topics in CORDA). Through the Horizon 2020 Work Programmes 2014-2017, each of these lines of activity was allocated a share of the overall budget of *SC2*, as indicated in the table below.

Table 136 - Activity lines and their allocated share of budget, *Work Programmes* 2014-2017

Activity lines	2014-15 WP	2016-2017 WP*	2014-2017 total
2.1 Sustainable agriculture & forestry	28%	35%	32%
2.2 Sustainable & competitive agri-food sector	8%	14%	12%
2.3 Unlocking the potential of aquatic living resources	7%	6%	7%
2.4 Sustainable & competitive bio-based industries	35%	23%	28%
2.5 Cross-cutting marine and maritime research	12%	12%	12%
2.6 Specific implementation aspects	9%	11%	10%
Total	**100%**	**100%**	**100%**

** Does not include BBI WP for 2017.*

K.2.1.2. Response to the calls and main calls

For the entire SC2, a total of 365 grant agreements were signed by 1 January 2017, the chosen cut-off date for the analysis (including those projects not directly managed by SC2, e.g. PHC, WASTE and WATER calls), selected from a total of 3,489 eligible proposals. At the time of the interim evaluation, 132 projects from the original portfolio – 130 SMEInst Phase 1 projects, 1 BG project and 1 CSA project – are completed and 233 are still ongoing.

The **main calls**, i.e. those excluding the SME Instrument and the calls managed by the BBI Joint Undertaking (as well as the WASTE, WATER and PHC calls which were co-financed from SC2 budget but which fall partly outside the remit of SC2), yielded a total of *127* projects with grant agreements signed before the cut-off date. This mainstream part of the

[215] *The EC contribution committed to projects under the Horizon 2020-BG-2014/2015 call came partly – in a total value of EUR 60 million – from the budget of other societal challenges (SC3 – Energy, SC4 – Transport, and SC5 – Climate).*

programme has so far been implemented mainly through Research and Innovation Actions (RIA) in terms of total EU contribution (67.1% of the funding), followed by Coordination and Support Actions (CSA, 15.2%). Innovation Actions (9.9%) and ERA-NET Cofund (7.7%) played only a smaller role. The total EC contribution committed to the 127 projects was EUR 564.2 million up to 1 January 2017. The average amount of EU funding committed to projects was higher for RIA (EUR 6.1 million) and lower for IA and CSA projects (EUR 4.0 million and EUR 2.0 million, respectively.

Table 137 - Number of projects, EC funding, share of total budget and average EC contribution per type of action for the main calls of SC2 (without SME instrument and Joint Undertakings

Type of action	Number of projects	Total EC funding (€ m)	Share of total budget	Average EC contribution (€ m)
RIA	62	378.7	67.1%	6.1
IA	14	56.1	9.9%	4.0
CSA	43	85.9	15.2%	2.0
ERA-NET Cofund	8	43.5	7.7%	5.4
Total	**127**	**564.2**	**100.0%**	**4.4**

Source: CORDA analysis.

The total EC contribution committed under the main calls (EUR 564.2 million) formed part of a total combined project budget of EUR 832.1 million (corresponding to a 67.8% average funding share).

The main calls were implemented either through one- or two-stage calls (whereas the SME Instrument and BBI JU calls were all one-stage calls).

The two-stage calls of SC2 were launched for call topics and yielded on aggregate 67 projects. Out of a total of 1,004 eligible proposals submitted, 500 did not meet the quality threshold in stage 1, leaving 504 proposals eligible for stage 2. The overall success rate for two-stage calls is 13.2%, when calculating the success rate only for the second stage – acknowledging the filtering effect of the first stage. The success rate of excellent proposals (which were above the quality threshold in stage 2) was 18.7% for the three main calls. Submitted eligible proposals oversubscribed the funding actually committed by a factor of 8.5 for the two-stage calls, when considering only proposals submitted to the second stage. The oversubscription of funds regarding excellent second-stage proposals was only 6.0.

The number of eligible proposals submitted to one-stage calls (without SME instrument and Joint Undertakings) amounted to 275 with 158 excellent proposals above the threshold. The number of related grant agreements signed was 60. The success rate of proposals was with 21.8% higher than for proposals submitted to two-stage calls (the second-stage part). The success rate of excellent proposals was 38.0%. Correspondingly, the oversubscription of funds was lower than for two-stage calls: 4.6 overall and 2.6 when looking only at excellent proposals.

Table 138 - Success rate and oversubscription for the main calls of SC2, one- and two-stage calls (without SME instrument and Joint Undertakings)

	SC2 One-stage calls	SC2 Two-stage calls (2nd stage)
Eligible proposals received	275	508
Proposals above threshold	158	359
Grant agreement signed	60	67
Success rate*	21.8%	13.2%
Success rate (excellent proposals)**	38.0%	18.7%
EC contribution requested by eligible proposals (€ m)	865.1	2,982.5
EC contribution requested by proposals above the threshold (€ m)	514.1	2,178.2
EC contribution granted (€ m)	200.4	527.7
Oversubscription	4.6	8.5
Oversubscription (excellent proposals)	2.6	6.0

** No. of grant agreements per eligible proposals. ** No. of grant agreements per proposals above threshold.*

K.2.1.3. SME Instrument

The **SME Instrument** funded in total 204 projects, of which 159 were Phase 1 (feasibility study phase) and 45 Phase 2 projects. A subset of Phase 2 projects was first funded by the programme under Phase 1 and progressed from there; another subset was submitted directly for Phase 2 calls. A total of EUR 69.6 million has been committed. Despite only funding 45 projects, the combined EC contribution committed to Phase 2 projects (EUR 61.6 million) accounted for 88.6% of the total EC contribution allocated to SME Instrument, considering that the standard funding given to Phase 1 projects was only EUR 50,000. The average EC contribution for the 45 Phase 2 projects was around EUR 1.4 million.

For the SME Instrument, a total of 2,484 eligible proposals were submitted (1,789 to Stage 1 and 695 to Stage 2). A large proportion, 75.6% (1,878) were below the quality threshold and rejected, and 402 proposals, equivalent to 16.2% of all proposals, passed the quality threshold, but were not selected due to lack of funds available.

The proportion of low quality proposals was higher for Phase 1 (19.7%) than for Phase 2 calls (36.5%). Although the overall success rate for the SME Instrument is very low at 8.2% (8.9% for Phase 1 and 6.5% for Phase 2), looking only at high-quality proposals that surpassed the quality threshold, the rates rise dramatically, to 33.7%. (45.2% for Stage 1 and 17.7% for Stage 2). Oversubscription rates in the SME Instrument were correspondingly high (12.2), although only 3.0 for above-threshold proposals.

Table 139 - Success rate and oversubscription for SC2 (SME Instrument)

	SC2 SME Instr. Phase 1	SC2 SME instr. Phase 2	Total SC2 SME instr.
Eligible proposals received	1,789	695	2,484
Proposals above threshold	352	254	606
Grant agreement signed	159	45	204
Success rate*	8.9%	6.5%	8.2%
Success rate (excellent proposals)**	45.2%	17.7%	33.7%
EC contribution requested by eligible proposals (€ m)	89.5	1,053.6	1,143.1
EC contribution requested by proposals above the threshold (€ m)	17.6	363.0	380.6
EC contribution granted (€ m)	8.0	61.6	69.6
Oversubscription	11.3	15.4	12.2
Oversubscription (excellent proposals)	2.2	5.6	3.0

** No. of grant agreements per eligible proposals. ** No. of grant agreements per proposals above threshold.*

K.2.2. Participation patterns

The selected proposals under *SC2* (excl. the SME instrument and Joint Undertakings) represent a total of *2,198* participations, mobilising *1,294* distinct participants, corresponding to an average of 1.70 participations per participant. A relative majority of the participants (437, i.e. 33.8%) were private for-profit entities; 23.7% were research organisations and 22.0% higher or secondary education establishments. Public bodies accounted for 7.9% of participants and the remaining 12.6% were other types of actors. In terms of total participations (beneficiary slots) the share of private for-profit entities falls to 21.7%, as a number of research organisations and higher or secondary educations establishments participate many times (their share in participations increases to 32.4% and 25.5%, respectively). Success rates by type of actors vary considerably: private for-profit entities will be funded only in 12.0% of all of their applications whilst public bodies in 35.8% of the cases.

Table 140 - Share of applicants, participants, coordinators, EC contribution, number of participations and rate of success by type of actor for SC2 (without SME instrument and Joint Undertakings)

Type of actor	Total applicants	Total applica-tions	Total partici-pants	Total partici-pations	Total coordi-nators	EC contri-bution (€ m)	Success rate (partici-pation / applications
Higher or Secondary Education Establishment	974	3,890	285	561	42	171.4	14.4%
Research Organisations	919	3,577	307	712	63	243.2	19.9%
Public bodies	320	692	102	248	5	50.1	35.8%
Private for-profit entities	3,060	3,960	437	476	13	102.9	12.0%
Other	575	961	163	201	4	29.8	20.9%
Total	**5,848**	**13,080**	**1,294**	**2,198**	**127**	**597.4**	**15.2%**

Source: CORDA analysis.

The SME Instrument typically involves single-beneficiary projects, the 204 projects have in total 232 participations by 219 participants (the difference reflects the projects that progress from Phase 1 to Phase 2 with the same participants). Due to the nature of the instrument, all participants are private for-profit entities, although there were other types of actors (public bodies, higher and secondary education establishments, other actors) among the applicants. The success rate for obtaining funding for a private for-profit applicant was 6.9%.

For the BBI JU, 318 individual participants combine a total of 388 participations among themselves. Most of the participants (64.5%) were private for-profit entities, whilst from the remainder, 17.3% were research organisations and 12.6% higher or secondary education establishments. The total participation number of private for-profit entities is somewhat lower, 62.1%, with research organisations and higher or secondary educations establishments increasing their share (to 20.6% and 12.1%, respectively), as they are more likely to have multiple occurrences in the programme. The success rates do not vary significantly between different types of actors, with the exception of higher or secondary education establishments and public bodies. They are considerably less likely to be funded than other actors (15.1% and 22.2% versus 30-35%).

K.2.2.1. Attraction of new participants / newcomers

There are *34.4*% (445 out of 1,294) 'newcomers' in SC2 among participants, defined here as those who did not participate in FP7 (excluding the SME instrument and Joint Undertakings). Most of those are coming from the private sector (254).and EU-15 countries (315).

In the SME Instrument, 82.6% (181 out of 219) of all distinct participants are newcomers which shows that the instrument has mobilised a large group of private enterprises that have not previously participated in FP7 projects.

K.2.2.2. Geographical participation patterns

A summary of the geographical participation in *SC2* is presented in the tables below. The country with the largest number of participations in the **main SC2 calls** is Spain, with a total of 238 participations. France and the UK have the largest number of coordinators (20 and 19). The countries following Spain are Italy (221 participations), the UK (218), France (191), Germany (185), the Netherlands (160) and Belgium (126). Associated Countries account for 7.9% of applications, for 8.1% of participations and 5.9% of the funding.

Table 141 - Participation patterns (number and shares of participations, of project coordinators, EU contribution, and rate of success) by country for SC2, without SME instrument and Joint Undertakings, EU-28 only

Country	Total applicants	Total applica-tions	Total partici-pants	Total partici-pations	Total coordi-nators	EC contri-bution (€ m)	Success rate (participation / applications
Austria	106	244	19	33	1	7.1	13.5%
Belgium	236	607	75	126	6	30.1	20.8%
Bulgaria	50	78	9	10		1.1	12.8%
Croatia	63	95	13	14		1.9	14.7%
Cyprus	28	61	6	7		1.4	11.5%
Czech Republic	54	121	15	19		2.7	15.7%
Denmark	119	407	20	64	6	22.3	15.7%
Estonia	24	52	9	14	1	2.3	26.9%
Finland	91	244	14	34	2	8.3	13.9%
France	402	954	98	191	20	59.6	20.0%
Germany	486	1 105	113	185	13	56.1	16.7%
Greece	170	464	35	61	2	15.6	13.1%
Hungary	98	198	24	32		5.4	16.2%
Ireland	81	238	26	65	6	18.1	27.3%
Italy	619	1 482	123	221	13	58.6	14.9%
Latvia	31	61	9	13		1.9	21.3%
Lithuania	29	52	7	12		1.5	23.1%
Luxembourg	6	10	1	1		0.1	10.0%
Malta	12	35	3	5		0.9	14.3%
Netherlands	289	801	76	160	14	53.8	20.0%
Poland	130	273	25	38	1	6.1	13.9%
Portugal	165	360	37	54	1	11.7	15.0%
Romania	105	166	17	27		3.8	16.3%
Slovakia	22	33	7	7	1	0.7	21.2%
Slovenia	48	115	12	16	1	1.9	13.9%
Spain	626	1 392	136	232	14	61.8	16.7%
Sweden	120	285	28	51	2	14.6	17.9%
United Kingdom	435	1,111	132	218	19	70.9	19.6%
Total	**4,645**	**11,044**	**1,089**	**1,910**	**123**	**520.2**	**17.3%**

Source: CORDA analysis.

The EU-28, and within that the EU-15, accounts for far the most participations and by far the most funding committed in SC2. EU-28 participants have a combined 1,910 participations (86.9%) and receive EC contribution worth EUR 520.2 million (92.2%). Within this group, EU-15 countries combined a total of 1696 participations (77.2%) and EUR 488.5 million funding (86.6%) – they also make up 93.7% of all the coordinators. EU-13 countries have a lower number of participations, 214 (9.7%) and an even lower share of funding received

(5.6%). Their success rate (16.0%) is slightly lower than the success rate of EU-15 applicants (15.5%).

Table 142 - Geographical distribution of funding, participants and coordinators, and overall rates of success by country group (EU-28, EU-13, EU-15, Associated countries, Third Countries) - without SME instrument and Joint Undertakings

Country	Total applicants	Total applica-tions	Total partici-pants	Total partici-pations	Total coordi-nators	EC contri-bution (€ m)	Success rate (participation / applications
EU-28	4645	11044	1089	1910	123	520.2	17.3%
EU-15	3951	9704	933	1696	119	488.5	17.5%
EU-13	694	1340	156	214	4	31.7	16.0%
Associated Countries	480	1016	106	177	4	37.1	17.4%
Third Countries	723	1020	99	111	-	7.0	10.9%
In percentage							
EU-28	82.4%	86.5%	84.2%	86.9%	96.9%	92.2%	-
EU-15	69.3%	75.3%	72.1%	77.2%	93.7%	86.6%	-
EU-13	13.2%	11.1%	12.1%	9.7%	3.1%	5.6%	-
Associated Countries	8.7%	7.9%	8.2%	8.1%	3.1%	6.6%	-
Third Countries	8.9%	5.6%	7.7%	5.1%		1.2%	-

Source: CORDA analysis.

In the SME Instrument, Spanish companies take the lead with 66 participations for a total of EUR 19.0 million funding. They are followed, with considerable gap, by Italian (32 participations, EUR 5.8 million), UK (19, EUR 4.5 million), French (12, EUR 3.6 million) and Irish participants (12, EUR 8.0 million). EU28 countries account for 89.7% of all participations, and 91.4% of the funding disbursed. Companies from the EU-15 take 79.7% of participations 86.9% of the funding, whilst the share of EU-13 companies is only 9.9% among all participants and 4.5% among the EC contribution committed. They are surpassed by Associated Countries in the latter, which account for 8.6% of all funding under the SME Instrument. The differences in success rates are considerable: EU-15 companies have a 8.7% chance of getting funded, EU-13 applicants only 4.7%, whilst companies from Associated Countries are close to the average with 8.0%.

K.2.2.3. International cooperation

Call topics which mention at least one third country or region were allocated 37.6% (EUR 287.0 million) of the budget in the Work Programmes 2014-2016.

Third Countries only account for a 5.6% share of all applications and 3.9% of all participations. Their share in funding is merely 0.8%, as most of them are ineligible to claim any EC contribution. A total of *736* entities from third countries applied to the programme (*1041* applications) with 111 successful third countries participants receiving EUR 7.0 million in funding.

K.2.3. Cross-cutting issues

In 2014-2016, *93.3*% (EUR 785.3 million) of the budget has been so far allocated to Sustainable development topics (the target for Horizon 2020 is at least 60%), an estimated *50.1*% (EUR 421.3 million) of the budget to Climate related topics (it should exceed 35% of the overall Horizon 2020 budget) and an estimated 29.9% (EUR 194.4 million) of the budget has been so far allocated to biodiversity. A share of *6.9* % (EUR 57.2 million) of the EC contribution is related to the Commission's Digital Agenda, notably ICT Research and Innovation.

More than a third, i.e. 14.5% of the *SC2* projects, is reported to have significant international cooperation aspects. As these are on average larger projects they account for 34.5% of the EC funding disbursed (EUR 287.0 million). An estimated 10.8% of the projects – calculated on projects for which the marker was filled in in the CORDA database – address the cross-cutting issue of gender equality, receiving an estimated 13.6% of the funding (EUR 112.8 million). Responsible Research and Innovation is a relevant cross-cutting issue for 18 out of 307 (5.9%) projects (with a marker), which receive an estimated 7.0% of EC funding (EUR 58.5 million). In terms of promotion of socio-economic sciences and humanities, it can be observed that *9.8*% of projects where information is availabl are SSH relevant, receiving an estimated *13.3*% of the EC contribution (EUR 110.5 million).

In SC2 projects, *40.7*% (388 out of 953) of project participants are women while *40.7*% (64 out of 234) of coordinators are women.

Within the 365 projects of *SC2* contracted before the cut-off date for this evaluation, *23.9*% (EUR 198.8 million) of EC contribution is allocated to innovation actions (a total of 27 projects), all of which include demonstration activities.

Table 143 - Breakdown of projects by their contribution to cross-cutting issues and calculated total budgets allocated to addressing these issues

Cross-cutting issues	Projects with marker available	Of which cross-cutting issue is:			Calculated EC contr. allocated to issue (€ m)	As % of total EC contr. (if marker available)
		Principal objective (100%)	Significant objective (40%)	Not targeted (0%)		
Sustainable development	365	263	100	2	763.3	91.7%
- Climate change	365	42	242	81	399.3	48.0%
- Biodiversity	365	63	90	212	194.4	29.9%
Digital Agenda	364	2	40	322	57.2	6.9%
Cross-cutting issues	**Projects with marker available**	**Projects relevant to addressing issue**	**Projects not relevant to addressing issue**		**EC contr. allocated to relevant projects (€ m)**	**As % of total EC contr. (if marker available)**
International cooperation	365	53	312		287.0	34.5%
Gender	323	35	288		112.8	13.6%
Responsible Research and Innovation	307	18	289		58.5	7.0%
Social Sciences and Humanities	325	32	293		110.5	13.3%

Source: CORDA.

Table 144 - Overview of cross-cutting indicators

Indicator	SC2	Horizon 2020 average
Percentage of publications in peer reviewed journals	68,8%	49,0%
Share of Signed Grants flagged as SSH-relevant (all projects)	9,8%	13,0%
Percentage of RRI projects where citizens, Civil Society Organisations (CSOs) and other societal actors contribute to the co-creation of scientific agendas and scientific contents	5,9%	11,0%
Percentage of women coordinators	27,4%	33,4%
Percentage of projects taking into account the gender dimension in R&I content	10,8%	36,4%
Percentage of budget of topics in the WP mentioning at least one third country or region	37,6%	23,3%
Percentage of EU financial contribution that is climate-related	48,0%	28,8%
Percentage of EU financial contribution that is sustainability-related	91,7%	53,3%
Percentage of EU financial contribution that is biodiversity-related	29,9%	4,0%
Share of EC contribution to Innovation Actions (IA) Signed Grants	23,9%	17,2%
Within IAs share of EC contribution focused on demonstration and piloting activities	59,0%	86,5%
Within IAs share of EC contribution focused on first market replication activities	26,9%	7,7%
Share of EC contribution to Digital Agenda (all projects)	6,9%	30,0%

Based on data provided by DG RTD (dated 01.09.2016).

K.3. RELEVANCE

K.3.1. Is Societal Challenge 2 tackling the right issues?

K.3.1.1. The relevance of SC2 given the challenges to address

At a high level, SC2 responds to a well-defined set of challenges and opportunities. As articulated in the various Commission documents and policy statements, Societal Challenge 2 specifically addresses the following inter-related challenges and opportunities:

Feeding a growing world population: the UN Food and Agriculture Organisation (FAO) estimates that farmers will have to produce 70% more food by 2050 to meet the needs of the world's estimated 9-billion population[216]. World population growth will therefore continue to put pressure on increasing agricultural and other types of food production on land and at sea. However*, the challenge not only to produce more, but also to produce safe and healthy food with fewer resources, less negative environmental impacts and in more difficult conditions*. Environmentally-harmful farming practices are causing soil degradation and water contamination, reduction in pollinators, loss of natural biological control of pests and diseases and of plant and animal genetic diversity. In addition, both agriculture and forestry are increasingly affected by the adverse effects of climate change. Climate change induced changes in temperatures, crop, water requirements and water availability and quality are negatively affecting both crop and livestock production systems in several parts of the world, thus putting pressure on the global agriculture system. The changing climate is also contributing to resource problems beyond food security, such as water scarcity, pollution and soil degradation. Not only would agriculture and forestry have to adapt to climate change, they will also have to contribute to climate change mitigation measures such as reduction in GHG emissions considering the impact that they have on the environment. For instance, agriculture accounts for about 10% of EU greenhouse gas (GHG) emissions including more

[216] *FAO (n.d.) How to Feed the World in 2050. Available at: http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf*

than half of the non-CO2 gases[217]. Globally, agriculture and forestry are the source of 24% of emissions, including through tropical deforestation[218]. Going forward, agriculture and forestry, food processing and consumption, environmental protection of natural resources and climate change will need to be considered in an integrated manner. Investment in R&I is essential to overcome these challenges and necessary to work towards an integrated food systems approach.

Improving food security requires not only increasing food production, but also:

- *Reducing food waste*: around 88 million tonnes of food are wasted annually in the EU, with associated costs estimated at EUR 143 billion.[219] Globally, food losses and waste are estimated at around 30% of all food produced[220];
- *Producing safe, healthy and high quality food* that is accessible, nutritious, contains minimal or no allergens and chemical contaminants, and free of food-borne pathogens and toxins. This is particularly important when considering the *economic burden of diet-related diseases*, not only on healthcare systems, but also on the workforce and in the face of an ageing population. For instance, cardio-vascular diseases are the cause of 52% of deaths in Europe and are estimated to cost the EU economy EUR 192 billion annually. Projections suggest that in 2020 3.4 million Europeans will develop cancer and over 2.1 million will die as a result of the disease.[221] It is estimated that 35 million adults had diabetes (both Type 1 and Type 2) in Europe in 2011. This is projected to increase by 23%, to 43 million in 2030. Furthermore, EUR 89 billion were spent on treating and managing diabetes and its related complications in 2011. The total cost of diabetes to society would be even higher if indirect costs such as productivity losses were taken into account.[222] The World Health Organisation (WHO) estimates that 80% of cardiovascular diseases, 90% of type 2 diabetes and 30% of all cancers could be prevented by a healthy diet.[223] However, producing safer and healthier food is one side of the equation. In parallel, behavioural change among consumers is also needed.
- *Reducing demand for animal protein:* protein intake has risen by 43 per cent in the daily diet, from an average of 355 calories a day in 1965 to 507 in 2014.[224] According to the FAO, demand for meat, fish and dairy products will peak in 2025. This will put an enormous pressure on natural resources in terms of the amount of feed and land use involved to meet this demand. Moreover, livestock produces 14.5 per cent of all greenhouse gas emissions, according to the UN. There is therefore, an urgent need or developing plant-based alternatives as a way of reducing demand for animals as food.
- *Taking account of the impact of urbanisation:* the worldwide trend towards more urbanisation is expected to continue over the next decades, creating a greater demand for higher quality and processed food. The challenge of providing habitants in cities

[217] *Global figures: IPCC "Climate change (2014) synthesis report". For the EU: Eurostat, Agriculture - greenhouse gas emission statistics.*
[218] *Fifth Assessment Report of the Intergovernmental Panel on Climate Change, agriculture and forestry contribute to GHG mainly and agricultural emissions from livestock, soil and nutrient management (CH4 and N2O emissions) and through deforestation. See: http://www.ipcc.ch/report/ar5/wg3/*
[219] *Europa website: http://ec.europa.eu/food/safety/food_waste/index_en.htm*
[220] *FAO (2013) Food wastage footprint, impact on natural resources, summary report*
[221] *EPHAC (n.d.) Towards a healthier, more sustainable CAP, European Public Health and Agriculture Consortium (EPHAC) position on "The Future of the Common Agricultural Policy*
[222] *OECD (n.d.) The diabetes epidemic and its impact on Europe*
[223] *World Health Organization (2008) 2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases, World Health Organization, Geneva*
[224] *Financial Times (2016) The appliance of agricultural science: Businesses are pushing futuristic schemes to help feed the world, 30 November 2016*

with sufficient, safe, and nutritious food is both urgent and complex and also depends on the regional, national or global position of the city. R&I on city-region food systems can contribute to overcome this challenge.

Harnessing the huge potential of Europe's oceans, seas and coasts for jobs and growth: oceans cover over 70% of planet Earth. They contain vast resources which can potentially be used for meeting human needs for food and energy, as well as producing a large variety of goods and services contributing to health and well-being. Additionally, the role of healthy seas and oceans in capturing greenhouse gas emissions is essential for all sectors of the global economy. Oceans and seas therefore, offer many great opportunities for growth and jobs in the EU which has the world's largest maritime territory, with the Exclusive Economic Zone of its Member States covering 25 million km2. The blue economy represents more than 5 million jobs and an added value of nearly EUR 500 billion per year.[225] The growth and job creating potential of European marine resources however, remains largely under-exploited[226]. Marine resources are under-exploited and under-explored due to a number of constraints include data access, financial constraints, human resource constraints, difficulties of coordination, legal and regulatory barriers to innovation. Public intervention – and particularly, support for R&I - is necessary to overcome these barriers.

Reducing the EU's heavy dependence on seafood imports: sea and ocean bio-resources provide 15% of the animal protein consumed globally. Approximately 60 % of total European seafood consumption depends on imports; the EU is the world's largest importer of fisheries products.[227] Fish stocks are increasingly overexploited, even if the aquaculture production is rising relentlessly. Thus, fisheries and aquaculture need sustained major investments in R&I to develop effective solutions to yield food and feed while coping with climate change and ecosystem sustainability challenges.

The need to shift to a bio based economy not only because of climate change, but also to reduce Europe's dependence on fossil resources and to create jobs and green growth. The transition from a fossil-based economy towards a bio based economy is however, a major challenge. The switch, inter alia, entails the transformation of conventional industrial processes and products into bio-based processes and products, the development of industrial biotechnologies, integrated bio-refineries and the opening of new markets for bio-based products. The growth potential for bio-based products depends on their capacity to substitute fossil-based products at competitive cost, with smaller ecological footprint and lower GHG emissions. Investment in R&I is essential to overcome these challenges and to accelerate Europe's transition to a bio based economy.

Forests as a renewable resource have the potential to play a key role in the emerging bio-based economy. A key challenge however, is *to get more feed, energy, and biological raw materials from forests while ensuring their sustainability*. Addressing these challenges will require new knowledge and technology, and investment in R&I will be essential.

The Expert Group's desk research and stakeholder interviews suggest that these challenges and opportunities continue to remain valid in the present context and that there is a clear scientific rationale for investing in R&I to address these. As such, the objectives of SC2 are highly pertinent to the challenges and opportunities facing Europe. However, the programme objectives as currently articulated in the legal basis are very broad and "all inclusive". They

[225] *European Commission (2012) COM(2012) 494 final*
[226] *Blue Growth opportunities for marine and maritime sustainable growth COM(2012)494*
[227] *Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020*

provide no indication of what success would look like on programme completion. As such, the current definition of objectives does not provide an adequate basis for programme priority setting, monitoring progress or evaluating programme performance.

The Expert Group observes that the translation of high level challenges and objectives into specific call topics might not be clear to external stakeholders. Several interviewees expressed the concern that the development of call topics within the work programmes is not transparent and that the inputs that they provide through various channels "go into a black box". The process through which the high-level challenges set out in the programming documentation (e.g. legal basis, public consultation documents) are translated into the specific challenges addressed by call topics is not set out in the work programmes and might not be clear to the 'outside world'. While the participatory nature of the Strategic Programming Process is greatly appreciated by stakeholders interviewed, the link between the scoping papers (which are not made publicly available) and the specific call topics is not always clear cut. There is little publicly documented evidence (a) explaining how the specific challenges (at call topic level) are identified and prioritised and (b) demonstrating that SC2 is funding the most critical or promising research topics to address the societal challenges identified.

Moreover, in certain areas, call topics are described in very broad terms in the opinion of several interviewed stakeholders (including project participants) – a view which is also shared by the Expert Group. While broadly defined call topics give applicants more room for creativity and developing different approaches/ solutions to a research topic, such an approach has the following potential disadvantages:

- *It makes it difficult for participants to respond to them appropriately* - individual topics sometimes list a broad range of requirements (e.g., SFS-7-2014/2015; ISIB-1-2014) which creates the dilemma if individual proposals should concentrate on only some of those requirements or if each project should address all of the requirements listed. This puts applicants and selection panels in a difficult position, especially where a large number of proposals to these broad call topics are made.
- Another outcome of broadly and imprecisely defined call topics is that in some cases *it has led to the funding of several projects in a related technical area with potentially little impact*. For example, resulting from the 2014-15 work programme, a significant research effort is devoted to the breeding or production of tomatoes: two projects on breeding tomatoes (TomGEN and TRADITOM) and two with a significant tomato component (G2P-SOL and EUCLID). There is no reason to question the merits of these projects, but this number of projects might make tomatoes the most researched crop species in this programme so far. It so happens that tomato is a good model plant for research such as analysing plant-pathogen interactions, genetics and genomics, but this was not a deliberate programming choice (rather, as explained above, an outcome of broadly and imprecisely defined call topics).
- *It might contribute to a high level of demand to some calls, particularly at stage 1 and potentially low quality proposals*. High demand translates into low success rates which also results in higher evaluation costs. The programme is attracting oversubscription and a worryingly high share of low-middle quality proposals (59.2% of the proposals were below the quality threshold for SC2 main calls, 80.3% were below threshold in case of the SME instrument and 54.2% of the proposals attracted by the BBI calls

were below the quality threshold). It is possible that this is somewhat related to the broadly defined call topics, at least as far as the main SC2 calls are concerned[228].

Whether call topics should be broadly or precisely defined is not an easy issue to resolve and it can be hard to please everybody. For instance, in the past, the Commission was criticised for developing top-down and overly prescriptive calls. In comparison to FP7, topics under Horizon 2020 therefore, have a broader introductory description but very precise impact expectations (reflecting the spirit of Horizon 2020 to fund impact driven research). Stakeholders debate the advantages and disadvantages of 'broad' versus 'narrow' topics, or 'prescriptive' versus 'non prescriptive' topics, and the same discussion has been led within the Commission. There may be a false dichotomy in this discussion and the real issue is the optimal degree of precision in topic texts in relation to the purpose of the topic.

K.3.1.2. The relevance of SC2 in addressing European objectives

European Commission's policy agenda

As demonstrated by the programme's intervention logic presented in section 1.3.2, SC2 (by design) is highly relevant to the European Commission's policy agenda:

- *A new boost for jobs, growth and investment:* by creating new bio-based value chains, commercialisation of new products, processes and technologies, supporting innovation within SMEs, SC2 is expected to stimulate investment, growth and jobs.
- *A deeper and fairer internal market with a strengthened industrial base:* a key objective of SC2 is to strengthen the European industrial base and particularly, the agri-food sector, bio-based industries and the fisheries, aquaculture and marine and maritime sectors.
- *A resilient EU with a forward looking climate change policy:* the programme seeks to support the transition from a fossil fuels based economy to a bio-based economy, support better management of forests, seas and oceans and reduce the environmental impact of food and feed production and consumption.

Moreover, a detailed mapping of 111 non-SME project proposals (out of 138 projects falling within the scope of the evaluation) shows that project activities are highly aligned with the Juncker Commission's policy agenda). Specifically, 72% of the non-SME projects mapped are expected to contribute to Europe's economic and industrial competitiveness. A mapping of SME projects suggests that Phase I SMEs are expected to generate additional EUR 1.5 billion of turnover and create 1,113 jobs during the next three years from commercialisation of products, processes and technologies being developed with support from the programme.[229] While the 26 SMEs that received Phase II funding are expected to generate additional EUR 1.03 billion of turnover and create 1,121 jobs during the next five years as a result of bringing their products to market.[230]

3Os: Open access, Open innovation and Open to the world

[228] *For the SME instrument, it is potentially a consequence of lack of understanding from new participants and for the BBI due to lack of good research ideas to match the opportunity described*

[229] *These figures do not include indirect job creation or destruction which the innovations lead to. Likewise, the effect of innovations on the turnover of other companies, which may either use the innovation or compete with it, are not taken into account in these estimates.*

[230] *The expected turnover and employment figures of Phase I and Phase II should not be added due to avoid double counting (several Phase II SME projects also received funding under Phase I).*

The following paragraphs assess the extent to which SC2 is aligned with the Commission's policy objectives with respect to 3Os. It should however, be noted that 3Os were introduced as a policy objective in 2015 i.e. after the first work programme had been published.

Open access[231] can apply to two broad types of research outputs:

- Peer-reviewed publications (these are published in academic journals);
- Scientific research data (data underlying publications and/or raw data).

The project mapping exercise reveals that open access issues are not systematically covered in project proposals (less than one in three projects share all their research outputs), the exceptions being CSA projects and projects addressing specific implementation aspects and horizontal issues (2.6) [232], see Table 30). Open access to data is a very ambitious goal set by the European Commission and the European Cloud Initiative launched in 2016 is expected to provide the infrastructure, rules and standards to push Europe to the forefront of Open Science. The realisation of the European Cloud roadmap is expected to have a bold impact on Open Science that will only be visible at the end of Horizon 2020 and beyond that. With few exceptions, the projects funded so far do not intend to take part in the European Cloud Initiative.

Table 145 - Envisaged use of four approaches to open access among SC2 projects (% of projects mapped)

	CSA	ERA-Net Cofund	IA	RIA	BI-IA	BBI-RIA	Overall
% of projects that envisage…							
Freely sharing **all** outputs (e.g. publications data blueprints prototypes...) - During project implementation	71%	0%	0%	25%	0%	0%	30%
Freely sharing **all** outputs (e.g. publications data blueprints prototypes...) - After project implementation	33%	0%	0%	18%	0%	0%	18%
Freely sharing the research outputs of the project on the European Open Science forum - During project implementation	10%	0%	0%	5%	0%	0%	5%
Freely sharing the research outputs of the project on the European Open Science forum - After project implementation	10%	0%	0%	3%	0%	0%	4%
Number of projects	27	3	7	61	6	7	111

	Activity level						
	2.1	**2.2**	**2.3**	**2.4**	**2.5**	**2.6**	**Overall**
% of projects that envisage…							
Freely sharing **all** outputs (e.g. publications data blueprints prototypes...) - During project implementation	30%	11%	30%	0%	46%	67%	30%
Freely sharing **all** outputs (e.g. publications data blueprints prototypes...) - After project	24%	11%	20%	0%	8%	33%	18%

[231] *Under FP7 projects could opt in for open access, whereas the general rule in Horizon 2020 is that projects are by default 'open access' for publications and need to justify a derogation from that rule if they wish to opt out.*
[232] *This makes sense as many of the horizontal marine issues are about international ocean cooperation and management*

	Activity level						
	2.1	**2.2**	**2.3**	**2.4**	**2.5**	**2.6**	**Overall**
implementation							
Freely sharing the research outputs of the project on the European Open Science forum - During project implementation	9%	0%	0%	0%	8%	0%	5%
Freely sharing the research outputs of the project on the European Open Science forum - After project implementation	5%	0%	0%	0%	17%	0%	4%
Number of projects	49	10	10	16	14	12	111

Source: project mapping by the expert group; N=111 projects.

Open innovation

Open Innovation is about opening up the innovation process to all active players so "that knowledge can circulate more freely and be transformed into products and services that create new markets, fostering a stronger culture of entrepreneurship"[233]. The Open Innovation 2.0 concept provides opportunities to realise the ambitious goals of Horizon 2020 in two fundamental ways. First, it emphasises the need to move from a researcher-centric to a user-centric innovation model, where the user is seen as the focal actor in the innovation process. This implies that users should be intensively involved throughout the whole process. The creation of Living Labs, the multi-actor approach (in Agriculture), and the adoption of rapid prototyping are seen as important tools to realise such close collaboration with users. Second, the Open Innovation 2.0 concept stresses that, in order to maximise societal impact, it is vital to move from mono-disciplinary collaborative clusters to multi-disciplinary ecosystems, in which a wide variety of different actors come together[234].

The expert group observes that:

- Open innovation is not a common approach in the projects funded so far, the exception being IA and multi-actor projects with a user-centric approach and envisaging a multi-disciplinary ecosystem approach.
- Open innovation is practiced more in activity lines 2.1 (sustainable and competitive agri-food sector) and 2.3 (unlocking the potential of aquatic living resources).
- Over half of the projects falling under activity line 2.5 (cross-cutting marine and maritime research) and four out of five projects in activity line 2.3 (unlocking the potential of aquatic living resources) envisage using open source tools and data. This could be explained by the fact that a large number of simulation models, management tools and modelling software are freely available.

[233] *European Commission (2015) Open Innovation Open Science Open to the World – a vision for Europe at* http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=16022

[234] *European Commission (2013). Open Innovation 2.0.:* ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=2118

European Commission (2015). Open Innovation 2.0 and Horizon2020: Opportunities and Challenges.: https://ec.europa.eu/digital-single-market/en/news/open-innovation-20-and-horizon2020-opportunities-and-challenges

Table 146 - Share of projects addressing open innovation issues by instrument and activity area

	CSA	ERA-Net Cofund	IA	RIA	BBI-IA	BBI-RIA	Overall
% of projects that envisage…							
…a user-centric innovation model approach	28%	0%	100%	37%	0%	0%	34%
…to follow a multi-disciplinary ecosystem	52%	0%	57%	47%	0%	0%	43%
… to make use of open innovation platforms	12%	0%	0%	13%	0%	14%	11%
… to make use of open source tools, software, data,...	24%	0%	14%	30%	0%	0%	24%
Number of projects	27	3	7	61	6	7	111

	Activity level						
	2.1	**2.2**	**2.3**	**2.4**	**2.5**	**2.6**	**Overall**
% of projects that envisage…							
…a user-centric innovation model approach	20%	90%	90%	0%	31%	42%	34%
…to follow a multi-disciplinary ecosystem	50%	60%	60%	6%	46%	33%	43%
… to make use of open innovation platforms	2%	0%	10%	6%	46%	25%	11%
… to make use of open source tools, software, data,...	11%	10%	80%	0%	54%	33%	24%
Number of projects	49	10	10	16	14	12	111

Source: project mapping by the expert group; N=111 projects.

Open to the world

Open to the world means striving to ensure that EU R&I has an impact at a global level, addressing global challenges, supporting international policy making and international collaboration.

SC2 has been carrying out a strategic international co-operation, with major programme – level co-operation activities, such as the Atlantic Ocean Research Alliance, the BLUEMED initiative, the EU-China Task Force and flagship in Food Agriculture and Bioeconomy, the Africa Partnership for food and nutrition. Consequently, a high number of call topics specifically encouraged cooperation with partners from third countries such as Africa, China and North America (Table 32).

This is however not fully reflected nor measurable merely in terms of third countries participation / EC contributions statistics, due to the nature of this type of international co-operation which often goes beyond direct participation in Horizon 2020 projects and rather imply mirroring activities by third countries' own programmes. Thus, third country participation appears quite low within SC2 – Figures 4 and 5 – despite the fact that substantial activities are on-going. In budgetary terms also, funding allocated to third country partners has decreased from 12% under FP7- KBBE to 8% under Horizon 2020 calls in the 2014-2015 period. However, these figures do not include: i) third country contribution to projects participants (several cases being third countries who do not have automatic right to EC funds), ii) third countries partners associated to the projects (but not being formal participants), and

iii) third country funding leveraged within the framework of major strategic international co-operation activities that have been implemented under SC2 through programme level co-operation with main partners worldwide.

For example, in Horizon 2020 there are 14 projects with 318 partners that support the implementation of the Galway Statement and run under the Atlantic Ocean Research Alliance. Within these projects, there are 10 project partners or participants through other arrangements from the United States, and there are 12 project partners or participants through other arrangements from Canada. Following the Communiqué of the G7 S&T Ministerial in May 2016, DG RTD is also working with its G7 partners on Ocean observations, ocean assessment and data sharing. Also in this case, third countries partners invest through mirroring own research programmes, supporting projects which interact with corresponding SC2-funded projects.

Table 147 - Call topics encouraging international cooperation with third countries

	2014-2015 Work Programme			2016-17 Work Programme		
	No. of call topics	**No. of call topics - Third country**	**% of call topics - Third country**	**No. of call topics**	**No. of call topics - Third country**	**% of call topics - Third country**
Sustainable Food Security	20	14	70%	48	21	44%
Blue Growth	16	6	38%	14	5	36%
Innovative, Sustainable and Inclusive Bio economy	13	2	15%			
Rural Renaissance				16	0	0%
Bio Based Industries				8	0	0%
Totals	**49**	**22**	**45%**	**86**	**26**	**30%**

Source: based on work programme mapping (Annex 1).

Figure 202 - Share of SC2 participations by region

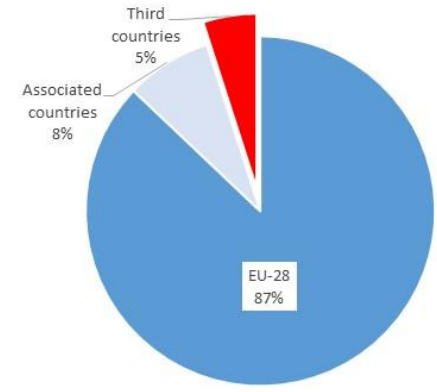
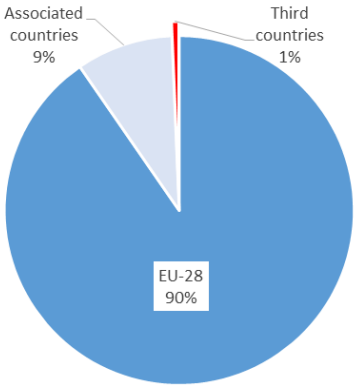


Figure 203 - Share of EC contribution by region



*Based on CORDA extracted in September 2016 (273 projects, EC contribution = EUR 783 million**; Total number of participations = 2,477). Figure 4 does not add to 100% due to rounding off. **There is a discrepancy between the total EC contribution that appears in the project level data and at participant level (of EUR 8 million). Third countries are all countries outside the member countries of the EU. Note: Associated third countries are IS, NO, AL, BA, MK, ME, RS, TR, IL, MD, CH, FO, UA, TN, GE*

The project mapping exercise further suggests that 42% of the projects mapped envisage dissemination and/ or knowledge sharing activities specifically targeting third country

participants (e.g. workshops, conferences etc.). However, only 23% of the projects mapped envisage cooperation or collaboration with third country actors.

Table 148 - Share of projects that are open to the world

	CSA	ERA-Net Cofund	IA	RIA	BBI-IA	BBI-RIA	Overall
Any dissemination and/ or knowledge sharing activities specifically targeting third countries	30%	33%	29%	59%	0%	0%	42%
Any cooperation or collaboration with actors from third countries?	19%	0%	0%	34%	0%	0%	23%
Number of projects	27	3	7	61	6	7	111
	Activity level						
	2.1	**2.2**	**2.3**	**2.4**	**2.5**	**2.6**	**Overall**
Any dissemination and/ or knowledge sharing activities specifically targeting third countries	53%	50%	40%	6%	43%	*42%*	*42%*
Any cooperation or collaboration with actors from third countries?	22%	40%	30%	6%	29%	*25%*	*23%*
Number of projects	49	10	10	16	14	12	111

Source: project mapping by the expert group; N= 111 projects.

Overall SC2 performs above Horizon 2020 average as far as international participation is concerned[235].

K.3.2. Flexibility to adapt to new scientific and socio-economic developments

Since the beginning of Horizon 2020, major political developments both in the EU and in the international arena relevant to SC2 included the Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change (2014), the Paris Agreement on Climate (2015), the UN Sustainable Development Goals (2015).

The Expert Group reported that desk research, stakeholder interviews and expert opinions suggest that there have not been any significant technological or scientific advances or wider socio-economic or political developments[236] since the initiation of Horizon 2020 that call for a substantive change in direction or shift of focus in the programme. Nevertheless, the programme has evolved to respond to new developments within specific thematic areas. As an example, in the 2014-2015 work programme, there were no topics directly addressing consumer research within SFS. The 2016-2017 work programme has however, included consumer science in its scope and this is reflected in at least three of its call topics. This change reflects new developments in the field that highlight the key role of consumers and citizens in achieving sustainable food and nutrition security. Likewise, the inclusion of the SFS-18 (CSA Food 2030)[237] in the 2016-17 work programme, strongly reflects current research policy needs identified in this field.

[235] *European Commission (2016) Performance Analysis of International Participation in Horizon 2020, A support study for the interim evaluation of Horizon 2020*
[236] *The implications of BREXIT are unknown at this stage*
[237] *Support to the development and implementation of FOOD 2030 - a European research and innovation policy framework for food and nutrition security*

Generally, stakeholders note that the needs to be addressed by SC2, the programme and its priorities are broadly defined covering implicitly or explicitly the essence of important research areas related to food security, agriculture and forestry, marine, maritime and inland water and the bioeconomy. Given the breadth and the loosely defined coverage, stakeholders generally consider the programme to be sufficiently flexible to adapt to new needs.

K.3.3. Addressing specific stakeholder needs

A series of initiatives have been implemented to ensure continuous interaction and engagement of stakeholders in the identification of R&I needed to address the challenges and opportunities described earlier. At an operational level, relevance is fostered through a bottom-up consultation of stakeholders to inform the drafting of the Work Programmes (via targeted and open public consultations[238]), expert advice (Advisory Group inputs, foresight exercises), inputs from working groups[239], and Member State inputs (via the SC2 Programme Committee and SCAR) while taking account of top-down considerations (EU policies, legal basis, strategies and road maps). The extensive use of the multi-actor approach (Table 28) and the creation of the BBI JU further supports relevance of the programme to the needs of stakeholder and end users.

These initiatives, independent or European Commission supported work to continuously identify stakeholder needs at all levels- national, regional, European - and deliver foresight papers and roadmaps. As an example for the bioeconomy, a EU Bioeconomy Stakeholders Panel has been established and a Bioeconomy Stakeholder's Manifesto was produced[240].

Table 149 - The use of multi-actor approach within SC2 during 2014-2015

	Total number of call topics	Call topics requiring multi-actor approach	No. of Multi-actor projects funded**	EU funds requested for €M*	EU funds allocated to multi-actor projects as % of call budget
Sustainable Food Security	20	8	17	89	36%
Blue Growth	16	-	-	-	-
Innovative, Sustainable and Inclusive Bio economy	13	2	11	24	28%
Totals	49	10	28	113	34%

** CORDA data provided to evaluators does not include the POnTE project. **The above list does not include 3 projects funded under WASTE and WATER calls (EU funds requested = EUR 18.6 million).*

[238] *For the WP2014-2015 there was no public consultation as it was adopted in December 2013 immediately after the adoption of the regulation. A public consultation has been organised for subsequent work programmes.*
[239] *For example, DG AGRI Research workshops, including EIP-Agri and DG RTD Thematic Workshops (e.g. on microbiomes): specific working sessions were organised to deepen the gap analysis and formulate research questions with key selected experts.*
[240] *4th Bioeconomy Stakeholders Conference, Utrecht April 2016*

Box 16 - Strategic Programming 2016 for WP2018-2020

- Open public consultation in 2016
- Stakeholders workshops - Conferences – Foresight : from Expo Milan onwards, at least 20 events have been organised : SCAR Conference and Foresight, Bioeconomy Investment Summit, Future of Agricultural Research, Bioeconomy Stakeholders Conference -Utrecht, Food 2030 High-Level Event, Lodz and Bratislava Bioeconomy for regions; thematic workshops on microbiomes, plant health protection …)
- Horizon Group: Inter-Service Group involving all the Commission services that have a stake in SC2. This includes all the other Horizon 2020 parts + JRC, DG SANTE, DG ENV, DG CLIMA, DG GROW, DG MARE, DG ENER, DG TRANSPORT, DG EAC, DG DEVCO, DG ECHO
- MS SCAR/PC workshops: 7 participatory workshops between EC, SCAR and PC dedicated to the strategic programming exercise (in addition to formal PCs and SCAR plenaries)

The approaches to user and societal engagement also mentioned above address some of the criticisms voiced in the past Framework Programmes: that the research agenda was driven primarily by the scientific community (and therefore not necessarily effective in meeting the needs of potential users and wider society) with the consequence of having a sometimes poor uptake of research results. The cross-cutting Horizon 2020 project CIMULACT[241] ('Citizen and Multi-Actor Consultation on Horizon 2020'), a three-year project that started in June 2015, represents one of the efforts to improve the engagement of citizens and to provide concrete input to the European Union's R&I agenda.

Overall, SC2 is highly valued and appreciated by stakeholders – as also evident from the high demand for programming funds. The introduction of the Strategic Programming Process has greatly improved the intelligence base underpinning programming choices and has helped better define the focus of the programme.

Box 17 - Stakeholder engagement within the Blue Growth theme

The European Marine Board (EMB) is a platform of leading European marine research performing and research funding organisations established to promote enhanced cooperation in marine science at a European level. EMB operates in association with the European Science Foundation (ESF) and contributes to the development of a more coordinated and integrated policy framework for marine science and ocean stewardship, addressing societal needs, through the creation of expert working groups, the publication of strategic publications, facilitation of major marine science-policy conferences (e.g. EurOCEAN conference series).
The Marine Board Expert Working Groups are the primary foresight and priority-setting tools of the Marine Board. Working groups are established on topics of strategic importance for marine sciences in Europe which are yet to be addressed properly or lacking visibility. The mode of operation of EMB ensures wide consultation of stakeholders group and close interaction with policy organisations in Europe and beyond. This systematic interaction led to the Rome Declaration in EuroOcean 2014 that sets a vision for seas and ocean science, identifies four important goals that have been clearly

[241] http://www.cimulact.eu/

considered in drafting the Horizon 2020 work programmes.
Another important tool used for stakeholder interaction is the Joint Programming Initiative Oceans, created to tackle Grand Societal Challenges that cannot be solved solely at the national level. Based on the principle of variable geometry, it allows Member States and Associated Countries to participate in joint initiatives most relevant to their national priorities. JPI Oceans currently includes 20 marine Member Countries, covers all European sea basins, and can provide an interface between European and international activities at global and regional levels, such as the Transatlantic Ocean Research Alliance and the Blue Growth Initiative for the Mediterranean Sea. The JPI Oceans Management Board have delivered the first iteration of the Strategic Research and Innovation Agenda (SRIA), presenting ten Strategic Areas, developed and agreed through an extensive consultation process through 60 stakeholder workshops. Building on the mapping and gap analysis and consultation process JPI Oceans has highlighted new research needs which the European Commission could consider for the Horizon 2020 work programmes. Additionally, the use of existing EC instruments such as public – public partnerships (ERA-NETs, ERA-NET Plus, ERA-NET COFUNDs or Article 185, infrastructures, mobility and training grants will enhance the ability of participants to work together in the implementation of the JPI Oceans Strategic Research and Innovation Agenda.
Horizon2020 work programmes directly reflect the strategic areas identified in foresight papers and SRIAs developed by the different initiatives, supporting at the same time the valorisation of distinct sea basins (BlueMed Initiative) and the interaction required by the lack of boundaries in the open seas and the oceans (Galway Alliance, Arctic dimension).

Table 36 presents the amounts of EU funding allocated to each type of participating organisation, for SC2. The largest category of beneficiary so far is the private sector receiving 38% of the EU funding allocated so far, with a particularly high share in BBI-JU (73%) due to the nature of this part of the programme. Compared to its predecessor programmes, Horizon 2020 SC2 represents a significant improvement in involvement and participation of industry (Figure 6). The BBI-JU, SME instrument, and the use of the multi-actor approach in Agriculture have greatly facilitated private sector participation within the programme. Expert opinion suggests that the needs of the farming sector and industry are well represented in most parts of the programme, with the exception being forestry projects (despite there being a huge forestry industry within the EU).

The Higher Education and research sectors are also well represented within SC2 projects. The public sector and other category of participants (e.g. CSOs) however, are less well represented.

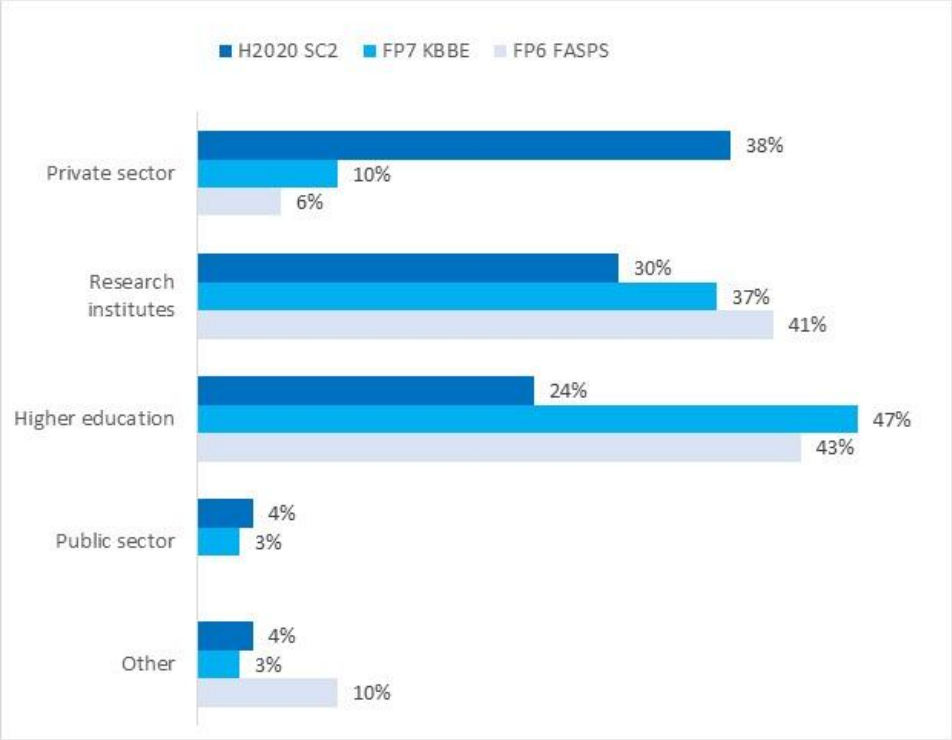
Table 150 - Share of EC contribution by type of organisation

	Share of EC contribution				EC contribution €M
Type	BBI projects (RIA, IA flagships, IA demo, CSA)	SME Instrument	SC2 projects under the EC's WPs (RIA, IA, CSA and Co-funds)	SC2 overall	
Higher education	8%		33%	24%	186.4
Other	3%		5%	4%	30.5
Private sector	73%	100%	17%	38%	300.8
Public sector	0%		6%	4%	32.4
Research	16%		39%	30%	233.0

institutes					
Total	232.8	44.9	505.4	783.1*	783.1*

*Based on CORDA data extracted in September 2016. (273 projects, *EC contribution = EUR 775 million). There is a discrepancy between the total EC contribution that appears in the project level data and at participant level (of EUR 8 million).*

Figure 204 - Share of EC contribution by type of organisation under FP6, FP7 and Horizon 2020



Horizon 2020 SC2 based on CORDA data extracted in September 2016. FP6 (Food quality and safety & Policy support actions) and FP7 KBBE sourced from ex-post evaluation of the rationale, implementation and impacts of EU Seventh Framework Programme (2007-2013) Cooperation Theme 2: food, agriculture and fisheries, and biotechnology.

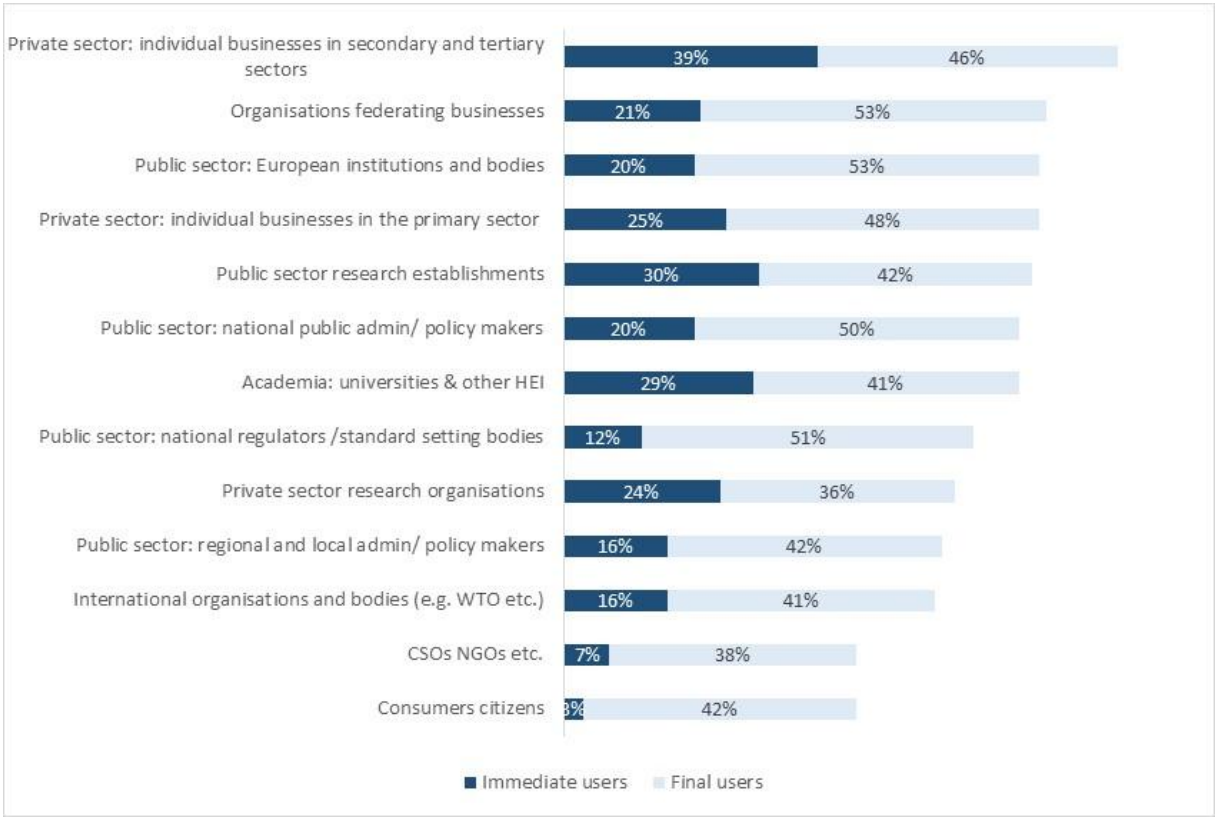
Dissemination and outreach activities – and reach of citizens

Dissemination and exploitation of research results are strongly encouraged in Horizon 2020. Project beneficiaries have an obligation to promote funded projects and their results, and communication forms part of the activities expected to generate project impact. To guide communication efforts, Horizon 2020 requires that projects develop and implement a communication plan, which goes beyond the project's own community to include "the media and the public"[242]. In addition to these general approaches, a large proportion of SC2 activity is relevant to the European Innovation Partnership for "Agricultural Productivity and Sustainability" which provides a mechanism to deliver research outputs to the farming sector.

The mapping of projects show that SC2 funded projects target a broad range of stakeholders as potential users of their outputs – Figure 7. As a result of the introduction of the multi-actor approach, it could be expected that new beneficiaries (farmers' organisations, advisory services etc.) will take part in SC2.

[242] *See for example, the Guidance for evaluators of Horizon 2020 proposals (2014): http://ec.europa.eu/research/participants/data/ref/Horizon 2020/grants_manual/pse/Horizon 2020-evaluation-faq_en.pdf*

Figure 205 - Share of projects targeting the different stakeholder categories as users



Source: project mapping by the expert group, n= 111 projects.

A review of the successful project proposals indicate that dissemination and communication efforts are largely targeting stakeholders which are expected to be "immediate users" of project results. Ensuring that potential users are aware of project developments and project outputs is generally the stated rationale for both dissemination and communication efforts. Target audiences are defined accordingly.

Many projects additionally aim at reaching out to citizens or consumers (and the media as an intermediary) as part of their communication efforts. This is in line with the requirement for Horizon 2020 communication which stipulates that "The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner."

Citizens however, are not an important target group, but rather a secondary or tertiary audience as can be expected. Low priority to citizens is illustrated by short or no objective descriptions for this audience and the communication approach presented by many project Consortia. Projects stating that they intend to target citizens typically mention websites, newsletters, publications social media channels and YouTube videos as means to reach the general public. Such tools require significant promotional efforts to generate public interest (i.e. communication to drive viewers to a website, make citizens follow a Facebook account etc.). However, only few project proposals reviewed, outline any strategy for generating public interest, suggesting that most projects are unlikely to generate any substantial citizen reach. It is only in cases where consumer engagement is a key for project success that proposals contain elements of a dedicated communication strategy targeting the general public. Illustratively, this is the case for the IA project EcoPROLIVE which includes specific communication activities targeting consumers with the aim of stimulating demand for the market uptake of olive end-products.

The fact that projects largely prioritise dissemination and communication efforts for a stakeholder community should be viewed positively. Projects are likely to be of variable public interest – with many projects unlikely to match core criteria for newsworthiness, especially at project start up and during project implementation (science content is more likely to be of interest if it is relevant for everyday life, tells something not known previously, is geographically linked to the audience, provide a political angle or are able to "touch" the audience[243]). The potential modest public interest may also be illustrated by the EC's own data on press coverage of projects which in a 1.5-month period identified 18 articles – half were identified media targeted professionals in the sector[244]. Furthermore, stakeholders consistently highlight the need to ensure adequate and focused communication to stakeholders and dissemination was mentioned as one of the main programme weakness in the 2011 study on *Impacts of EU Framework Programmes (2000-2010) and Prospects for Research and Innovation in FAFB*. Concentrating communication on actors which are key for ensuring programme impact is also in line with good communication practice[245]. This said, judging by the review of project applications, projects' attention to communication and dissemination – and the quality of approaches - varies across project types as discussed in section 6.

K.3.4. Other issues related to relevance

- Several interviewed stakeholders mentioned that it might be better to fund a larger number of smaller projects; rather than one big project under the call topics. According to them, the tendency to fund larger projects is resulting in larger consortia, but not necessarily better research. This approach is perceived as reducing diversity in R&I solutions proposed (and ultimately funded) in response to the specific challenges being addressed via the call topics.
- According to some stakeholders, the important role of forestry in tackling climate change, producing biomass and creating new jobs in relation to forest management, tourism, producing new products, value chains etc.) is not prominent within SC2. These stakeholders perhaps do not realise that these issues are covered by the BBI JU.
- Programme content analysis carried out by a DG RTD expert group reveals that the identified keywords from the EU and International priorities, the needs of the EU citizens and subsequent technological and scientific advances are to a high degree covered in both the SC2 legal basis as well as the 2014-2015 and the 2016-2017 work programmes[246].

K.3.5. Lessons learnt/Areas for improvement

- SC2 is addressing a well-defined and important set of societal challenges. There is a clear scientific rationale for investing in R&I in the activity areas covered by SC2. The programme is supporting R&I on important and pertinent issues. There is a strong

[243] *See "Survey of Researchers and Media Professionals" undertaken by The Evaluation Partnership and Deloitte for DG Research 2007 at https://ec.europa.eu/research/conferences/2007/bcn2007/executive_summary_en.pdf*

[244] e.g. Sheep Farmer; AgriLand.ie; Fleisch Magazin; Over the Counter; www.farmer.pl; Today's Farm and Fresh Produce Journal

[245] *which highlight the need to concentrate efforts on audiences which can generate the desired project or policy impact – as opposed to activities which aim at raising awareness as an end in itself. See for example A.Henningsen et all Measuring the European Commission's communication: Technical and Methodological Report study undertaken for the European Commission, DG COMM.*

[246] *European Commission (2016) Applying relevance-assessing methodologies to Horizon 2020*

justification (as well as strong stakeholder support) for a challenge based approach to EU funded R&I.

- The programme is highly valued and appreciated by stakeholders – as evident by the high demand for programming funds
- The policy relevance of SC2 is generally high. All SC2 activity lines are underpinned by an EU policy framework. It is well aligned with Juncker Commission's policy agenda. As far as 3O's is concerned:
    - Open access: is the norm for SC2 research publications. 90% of SC2 open access articles are expected to be published in peer- reviewed journals. However, only 30% of the mapped projects plan to share all their research outputs (presumably due to IPR issues especially among projects involving industry participation).
    - Open innovation: is not a common approach among funded projects. Nevertheless, 34% of mapped projects envisage a user-centric approach to innovation, 43% envisage following a multi-disciplinary eco-system, 11% envisage making using of open innovation platforms while 34% envisage using open source tools, software and data.
    - Open to the world: major strategic international cooperation established; 30-45% of call topics encourage cooperation with third countries. Overall SC2 performs better than Horizon 2020 on international cooperation.
- Significant improvements have been made to SC2 programme design and implementation arrangements (as compared to FP7-KBBE) to improve its relevance:
    - Development of Blue Growth as a distinct cross-cutting focus area;
    - Focus on Sustainable Food Security (40% of resources over 2014-17);
    - Creation of a BBI-JU, developing new integrated value-chains; and
- Introduction of the Strategic Programming Process has improved the intelligence base underpinning programming choices and helped better define the focus of the programme. However, the translation of high level challenges and objectives into specific call topics is not clear to external stakeholders.
- A stronger involvement of policy DGs, including co-management with DG AGRI and greater coordination with relevant policy DGs (e.g. DG MARE) has also been an important development.
- There are however some practical challenges in reconciling the perspectives of policy DGs with research perspectives. Specifically, the short to mid- term and specific legislative and policy making tasks of policy DGs can sometimes clash with the need for a long term and systemic view on research.
- Anecdotal evidence suggests that the tendency to fund larger projects in resulting in larger consortia (not necessarily better research) and excluding certain stakeholders (who lack the capacity to implement large projects) and excellent smaller-scale research. In certain areas, call topics are regarded as too broad making it difficult for participants to respond to them appropriately, resulting in funding of several projects in a technical area with potentially little impact, contributing to a high level of demand to some calls and potentially contributing to low quality proposals. The evaluation could not explore this issue in further detail due to time and data constraints.

K.4. EFFECTIVENESS

K.4.1. Short-term outputs from the programme

As indicated in section 3, 110 projects (109 SME Phase I projects and 1 CSA) have completed to date whereas 163 projects are ongoing. There is therefore, very limited evidence available on the effectiveness of the programme at this stage. Moreover, given the early stage of the programme, funded projects have reported a limited set of outputs so far.

Table 151 - Outputs reported by SC2 projects funded under the main calls (actuals)

Output Indicator	Value	Reported by:
Number of peer reviewed publications	95	11 projects
Number of patents/ trademarks/ registered designs applied for	9	7 projects
Number of patents/ trademarks/ registered designs awarded: of which *Patent* *Trademark* *Registered design*	5 *1* *3* *1*	4 projects

Data provided by DG RTD in August 2016.

Looking at the share of peer-reviewed publications provided in open access, SC2 records a 90% versus the 81% average of Horizon 2020.

Table 152 - Open access to publications under SC2

Nr of Signed Grants	Number of Publications in Peer-Reviewed Journals (expected)	Number of Open access articles published in peer-reviewed journals (expected)	% of Open access articles published in peer- reviewed journals
348	159	143	89.9%

Source: DG RTD. Based on CORDA data extracted 1 October 2016. Horizon 2020 average = 80.9%.

The table below provides the preliminary results of the KPIs for the first ten BBI projects (2014 call projects).

Table 153 - Estimated contribution of 10 projects (Call 2014) to BBI JU specific KPIs

KPI description	Estimates based on Grant Agreement data from 2014 Call projects	Target by 2020
KPI1 New cross-sector interconnections in bio-based economy clusters	> 8	36
KPI 2: New bio-based value chains	10	10
KPI 3: Cooperation projects	10	200
KPI 4: New building blocks based on biomass of European origin validated at demonstration scale	6-7	5
KPI 5: New bio-based materials	5-6	50
KPI 6: New demonstrated 'consumer' products based on bio-based chemicals and materials	4	30
KPI 7: Flagships resulting from BBI JU funded projects	1-2	5

Source: BBI Annual Activity Report – 2015.

Aside from the outputs and KPIs reported above, the mapping exercise carried out by the expert group suggests that funded projects are expected to deliver a much wider range of outputs.

Table 154 - Range of outputs envisaged by mapped (non-SME) projects

Output category	Number of projects	Share of projects
Non-academic publications (e.g.articles, workshop/conference proceedings, thesis, …)	92	83%
Models, methodologies and tools	85	77%
Knowledge transfer (transfer of existing or new knowledge)	80	72%
Dissemination of results to national/local gov./policy makers	73	66%
Dissemination of results to wider society	68	61%
Advanced or new knowledge	65	59%
Technological outputs	65	59%
Tested concepts, tested models, or tested products	65	59%
Dissemination of results to international organisations	65	59%
Training events and materials for non-project participants: students, researchers …	61	55%
Academic publications (peer reviewed)	60	54%
Training events and materials for project participants	54	49%
Evidence-based policy/ policy recommendations linked to (R&D) regional/national level	53	48%
Demonstrations	48	43%
New processes	47	42%
Protocols, technical manuals	46	41%
Prototypes	44	40%
New products	44	40%
Proofs of concept	42	38%
Best practices	42	38%
Research data	36	32%
Guidelines/standards	36	32%
Patents	36	32%
New non-research related partnerships (networks)	32	29%
Evidence-based policy/ policy recommendations linked to (R&D) international level	28	25%
New research partnerships (networks)	26	23%
Forward looking elements (scenario building, Delphi survey, forecast, roadmapping …)	24	22%
Evidence for new legislation	22	20%
Research capacity	18	16%
Organisational change	13	12%
Flagships	6	5%

Source: project mapping by the expert group

A mapping of SME projects suggests that at this stage of the programme implementation, crowding in effects on private funding seem low, as gleaned from SMEs' declared intended funding sources for the next stages of innovation development. It is important to better understand the reasons for the low declared intentions to use private capital. One possible explanation could be the nature of the innovation projects, for which private capital is difficult to attract, for example due to a high degree of risk. However, little evidence exists indicating that financed projects involve a high level of technological and/or commercial risk. A second possible explanation could be that projects do not apply for private funding because they are

not considered profitable enough by private investors. Expected profitability could not be identified as determining the intention to use private funding for developing innovation ideas. Another possible explanation is that SMEs intending to apply for Phase 2 funding – which is the case for the majority of Phase 1 projects – may have an incentive to under-report access to private funding. If that is the case, one important question is whether Phase 2 financing crowds out private funding de facto, or whether SMEs merely under report committed private funds before applying to Phase 2 grants. However, Phase 2 project proposals alone cannot reveal crowding in/out effects. Final reports and/or additional surveys addressing funding sources for the R&D projects are needed in order to complement the current analysis and examine whether supported projects attract or replace private funds.

K.4.2. Expected longer-term results from the programme

While it is too early to report on the longer term impacts of SC2, the programme is eventually expected to contribute to:

- The development of low-carbon, resource-efficient and competitive European agro-food and bio-based industries;
- Improved competitiveness and sustainability of European agriculture and forestry sector;
- Reduced greenhouse gas emissions;
- Improved food security and safety;
- Oceans observation and mapping; sustainable and smart use of marine resources;
- Higher growth and employment.

Notable examples of projects which are expected to contribute to the above impacts include:

- *Development of eco-friendly insecticides that target damaging insects while sparing beneficial ones* (nEUROSTRESSPEP). Considering that about 20% of global agricultural output is lost to insect attack, this project has the potential to significantly improve agricultural productivity and forest health.
- *Development of three novel food processing technologies* (i³-food): Pulsed Electric Field preservation which extends the shelf life of fruit and vegetable juices (e.g. from 7 to 21 days for orange juice); High pressure thermal sterilization HPTS which has the potential to deliver a comparable or even improved quality compared to the current heat pasteurisation technologies for e.g. chilled meals, which can be stored at ambient temperature without cooling; and Low shear extrusion of cold food products (ice cream) which has the potential to deliver significant energy savings (15-20%) and improve the quality of the ice cream in terms of creaminess and melting behaviour. These technologies will benefit both the European food and drink industry and the manufacturing industry.
- *Development of video technology to make underwater observation more accurate and less costly than is currently possible* (UTOFIA). Underwater video cameras are important tools for monitoring the marine environment, fish stocks and pollution. Other applications, including for the inspection of subsea installations, harbour surveillance and seabed mapping. Current commercially available cameras that provide the kind of resolution and clarity needed in turbid waters are often expensive – a barrier to their more widespread use. UTOFIA will thus fill a gap in the market and be commercialisation ready by 2018.

- *Exchange and transfer of innovative knowledge between European wine-growing regions on two important diseases in vineyard* (grapevine trunk diseases and Flavesence dorée) to increase the productivity and sustainability of the sector (WINETWORK).
- *Development of tools and adaptive strategies allowing fisheries and aquaculture sectors* and their governance to anticipate and prepare for adverse effects or future benefits of climate change (CERES)
- *Development of novel marine derived biomolecules to be used in prosthetic devices to treat biofilm infections* (NoMorFilm). The novel biomolecules will not only improve clinical effectiveness of prosthesis and quality of life for patients, but also reduce health system costs and surgical interventions.
- *Development of innovative, cost-effective and resource-efficient food crops that are high in protein* (PROTEIN2FOOD). Expected impacts include a 25% increase in protein production and shift in consumption of animal-based protein to plant-based protein in Europe.
- *Development of ICT-based platforms and tools to support new and existing solutions to reduce food waste as well as evidence based policy recommendations* (at EU/ national level) to help policy makers tackle food waste (REFRESH).
- *Development of evidence-based dietary and physical activity strategies to prevent malnutrition and support active and healthy ageing* as well as new food concepts, new food products and electronic support systems that fit within these newly developed dietary strategies (PROMISS). Expected economic benefits include lower healthcare costs and a strong EU market position in innovative and sustainable food products for older adults.

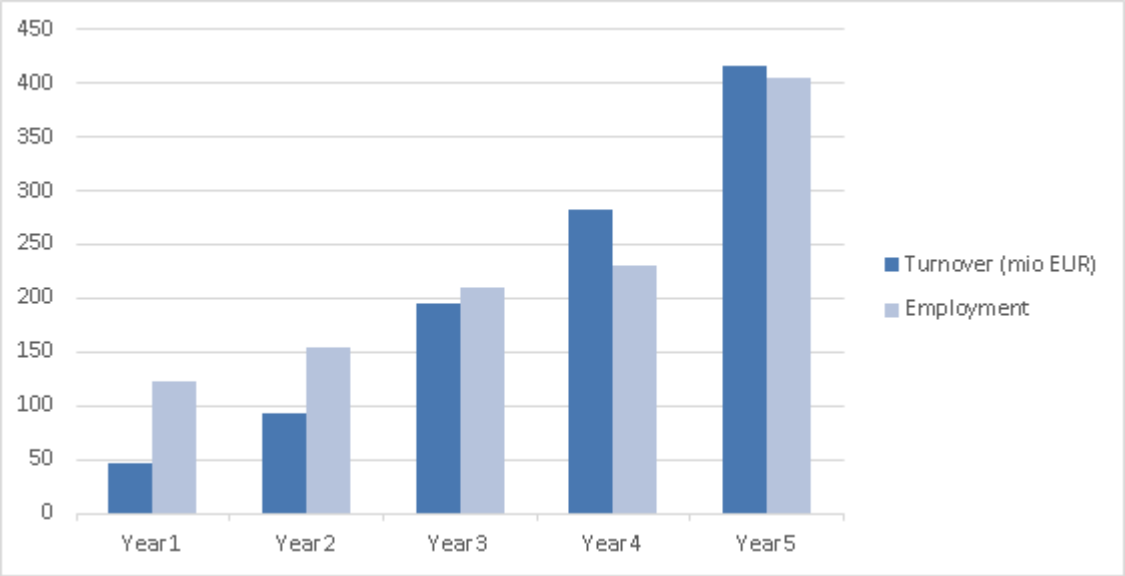
Some indications of the expected direct impact of SC2 on growth and jobs is available from completed SME Phase I projects and from Phase II proposal. The 55 projects for which this information was available are expected to generate an additional turnover of EUR 1.5 billion over the next three years. The innovations developed with support of SME Instrument Phase 2 funding (based on an analysis of 26 project proposals) are expected to produce a combined turnover of EUR 46 million in the first year of commercialisation, or an average of EUR 2.19 million per SME. The figures double for the second year to EUR 93 million and an average of EUR 4.44 million. The trend continues to year three, when the total expected turnover reaches EUR 194 million and an average of EUR 8.44 million, followed by EUR 282 million in total and EUR 12.81 million on average in the fourth year. Finally, by year five, SMEs expect to increase their turnover by EUR 19.8 million on average, for a total of EUR 416 million.

Regarding employment, the growth is more linear and less abrupt in the first four years, followed by a steep increase in year five. The average SME which benefited from Phase I funding expects to employ 10 extra personnel in the first year following commercialisation of the innovation, the number rising to 14 in year two, 19 by the third year, 25 and 46 in years four and five respectively. The 55 projects for which this information was available are expected to generate over 1,500 jobs over the next three years by bringing their innovations to market.[247]The total expected employment increase per year connected to Phase 2-funded projects starts at 123 employees in year one and rises constantly up to 230 in year four, peaking at 405 persons in the fifth year after commercialization (see Figure 8).[248] However,

[247] *Note: these figures are based on projected economic impact of the innovations, as indicated in project proposals and feasibility study reports by the beneficiary SMEs.*
[248] *This may suggest that beneficiaries of Phase II are selected among the projects with the highest expected impact on job creation.*

total figures need to be considered with caution, as less than half of the analysed Phase 2 projects provided yearly projections for employment growth.

Figure 206 - Expected total increase in employment and turnover attributed to projects funded in Phase 2



Source: Analysis by experts group SC2

Moreover, the principal expected outcome of BBI projects is the production of new bio-based materials (e.g. such as specialty fibres, plastics, composites and packaging solutions) which would eventually:

- Replace current materials such as high-cost petroleum-based carbon fibre with lignin-based carbon fibre (GREENLIGHT, SMARTLI, LIBRE), textile fibres with fibres derived from techno-economically feasible alkaline processes from reactive highcellulose pulps in connection to pulp mills (NEOCEL);
- Improve sustainability for example by valorizing residues and by-products from the agriculture and food processing industry to extract valuable biocompounds used to produce active ingredients, packaging and agricultural materials (AgriMax), or valorising agro-residues from mushroom industrial cultivation into bio-based functional additives and biopolymers (FUNGUSCHAIN), or residues of lignocellulosic biomass to extract molecules from hemicellulose and bio-polyesters (HYPERBIOCOAT);
- iImprove products for example by developing new plant-based protein ingredients in pasta, biscuit, cake and/or beverage production processes (PROMINENT), by optimizing moulded pulp for renewable packaging solutions (PULPACKTION) and so on.

BBI projects are also planning to develop bio-based chemicals for example with wood-based chemicals to replace fossil chemicals (VALCHEM, ZELCOR) and to create new value chains (from raw material to product) such as lignocellulosic value chains (BIOFOREVER), vegetable processing industry remnants value chain for functional proteins and other food ingredients (GREENPROTEIN), levulinic acid value chain for solvent and resin production from lignocellulosic biomass (GREENSOLRES), biorefinery technologies value chain for conversion of organic side-streams into multiple marketable products (INDIRECT) or for

refining sugar beet pulp (SBP) in order to produce microcellulose fibers, arabinose and galacturonic acid (PULP2VALUE), nutrient recovery bioprocesses value chain from waste streams and residues for manufacturing a new generation of bio-based fertilisers (NEWFERT).

Examples of new bio-based applications to consumer products being demonstrated are: final products packaging (AGRIMAX, PULPACKTION); food supplements, cleaning products, commercial masterbatches, commercial plasticizers and industrial films (FUNGUSCHAIN); detergents, personal care, (PULP2VALUE; VALCHEM), cosmetics (FIRST2RUN); biolubricants and bioplastics (FIRST2RUN).

The flagship projects will also create direct and indirect employment in some of the lagging regions of Europe. For example, the FIRST2RUN project (flagship demonstration of an integrated biorefinery) is expected to revitalise local economies across Europe by reconverting old industrial sites and the creation of skilled jobs: an estimated 60 new skilled jobs will be created for every kton of bioplastics produced, taking into account the whole value chain, from agriculture to the end life of the final products (i.e municipalities, composting plants).

As only SME-1 projects are completed at this stage there is very limited evidence available on the effectiveness of the programme. When considering the expected effects however, the following observations may be made.

Overall, projects associate added value especially with the programme scope and focus (coverage of transnational challenges addressing societal needs). When prompted on different attributes of potential added value compared to national or regional project funding "ability to address the needs of EU citizens and other final users", "tackling global challenges", "transfer of technology and knowledge", and "delivery of outputs targeting policy making" stand out (together with reputation and image) as the areas where the EU funding makes the biggest difference. Overall, more than 4 in 10 SC2 project coordinators surveyed report that Horizon 2020 (compared to national funding) significantly increased their projects' ability to address the needs of final users and to tackle global challenges and an additional third indicated that Horizon 2020 contributed hereto "slightly". Also, half of the projects note that they expect a significant, positive impact on the delivery of specific outputs targeting policy making.

These results are consistent with interview results, where interviewees highlight the transnational coverage/coverage of common priorities and challenges, a systemic approach to call topics (as opposed to a topical one); coverage of areas which may not be covered as part of national programmes and knowledge transfer as the main avenues in which the programme add, or has the potential to add, value.

Beyond this strategic level, project coordinators also report more R&I activities and output than what could have been achieved by national funding and improved commercial capacity. Areas where Horizon 2020 appears to have the potential to add significant value compared to national funding are undertakings of large scale demonstration projects and other testing/prototype activities and policy making. Horizon 2020 funding is also reported to generate more outputs, activities and other benefits (e.g. more publication in journals, non-academic publications; qualification of researchers; development of methods and technologies as well as commercial products and services; standards, business models, patents etc.). However, for most of these aspects the contribution of Horizon 2020 is reported to be small – with less than one in five reporting a significant impact. Furthermore, with the data available

it is not clear if the (potential) added value in these areas is generated from the quality of the project – or if it rather results from project/funding additionality.

Finally, more than two thirds of the commercially oriented projects consider Horizon 2020 to improve/has the potential to improve partners' competitive advance. The expected improvement mainly relates to access to new markets and the competitive position of partners internationally. In other areas, (competitive position nationally, market share in existing markets and revenue), most commercially oriented projects have either expectations of modest improvements, or no improvements.

K.4.3. Progress towards attaining the specific objectives

As stated in section 2.31, the specific objective of SC2 is "to secure sufficient supplies of safe, healthy and high quality food and other bio-based products by developing productive, sustainable and resource-efficient primary production systems, fostering related ecosystem services and the recovery of biological diversity, alongside competitive and low-carbon supply, processing and marketing chains. This will accelerate the transition to a sustainable European bio economy, bridging the gap between new technologies and their implementation". The highly ambitious and general nature of the stated objectives of the programme and the absence of pre-defined 'success indicators' makes it difficult to monitor and evaluate the programme's progress towards attaining its objectives. In general, the introduction of more KPIs for reporting, including specific ones for this part of the programme could help the monitoring and evaluation processes. However, some qualitative statements and evidence of expected impacts are provided in the preceding section.

Three quarters of the funded (non-SME) projects are expected to contribute to sustainable and resilient production and consumption systems and rural empowerment, 50% to food security and safety, 29% to empowering rural areas.

Table 155 - Intended (non-SME) project objectives by SC2 activity line - percentage of projects for which stated objectives were assessed as important, very important or extremely important objective

Objective	2.1	2.2	2.3	2.4	2.5	2.6	SC2 overall
Sustainable and resilient production and consumption systems	90%	70%	100%	56%	50%	50%	75%
Food security and safety (incl. improved diets)	69%	70%	40%	13%	36%	25%	50%
Empowering rural areas	53%	10%	0%	25%	0%	8%	29%
Number of projects	**49**	**10**	**10**	**16**	***14***	**12**	***111***

Source: project mapping by the expert group; N=111 projects.

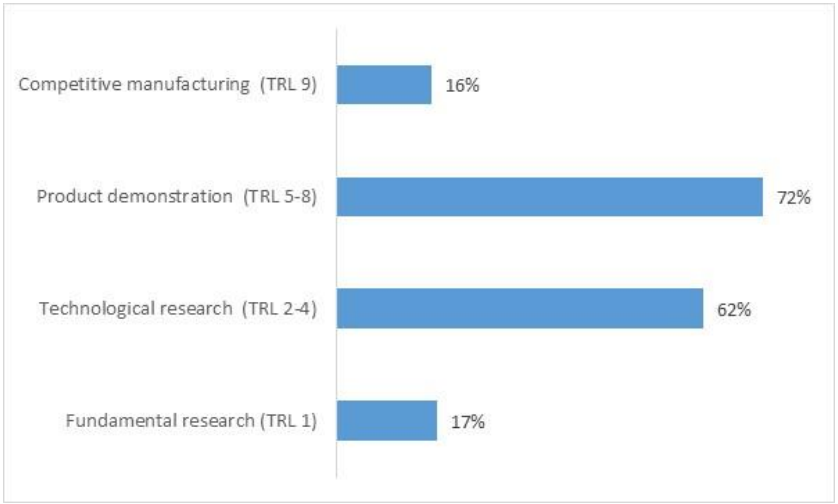
Additionally, the majority of SME phase I project proposals and reports mention several societal benefits the innovation is expected to bring, in addition to economic benefits for the applicant SME. Improved welfare for consumers or producers (which generally involve cost reductions and lower prices or higher product quality), improved food quality and food security, greater resource efficiency were the most frequently mentioned benefits. Examples of such benefits include improved fruit tree yields by 20%, reduced fertilizer and water use in agriculture, elimination of biological contamination in stored grains, 75% reduction of grain losses, improved health through consumption of iodine-rich seaweed, reduction of fruit waste, cultivation of vegetables in dense urban areas, reduction of costly food quarantines and

recalls, reduction in pesticide usage. The expert group also analysed the impact on society that the innovations undertaken in Phase 2 projects are expected to have if they are successfully commercialised. Most innovations are expected to improve food quality (15 out of 26 projects) and food safety (14), followed by reduction in air and soil pollution (12). Eleven projects envisage their innovations to help increase EU competitiveness in different areas, the same number expect to help increase society-wide water use efficiency. Improved energy efficiency is expected from 8 innovation projects, the same number tackling food waste along the value chain, while 4 expect to reduce food waste at the source. Food security is expected to improve as a result of 7 innovations receiving Phase 2 support. Five projects stated their expected positive effect on preserving wild aquatic (4) and land (1) fauna, the same number expecting to create added value from waste and by-products (3 from waste at source, 2 along the value chain), improve consumer welfare, and reduce water pollution. Animal welfare will be improved through the implementation of 4 innovation projects, while 3 expect to help improve work productivity. The results concerning expected societal benefits from SME projects should however, be treated with caution as in many cases, such predictions are probably difficult to undertake by the SMEs. Moreover, SMEs also have incentives to overstate such benefits in order to obtain public funding for developing their projects.

Additionally, the main achievements of SC2 can be summarised as follows:

- The BBI has been successfully established and secured industry buy-in.
- The programme has been successful in fostering huge technological advance (reflecting the spirit of Horizon 2020). Mapping data suggests that 88% of the projects are developing technologies which have been assessed at TRL 5 and above. Figure 9 shows the TRLs of mapped projects as assessed by the Expert Group.

Figure 207 - Share of non-SME projects by Technology Readiness Level (TRL)



Source: project mapping by the expert group, n= 90 projects. For remaining projects, TRLs could not be established.

- The programme has successfully set up strategic international cooperations. Several challenges that SC2 deals with are global by nature e.g. global warming and ocean acidification. In order to efficiently deal with global problems, international coordination and collaboration is necessary. Within Blue Growth focus area several such initiatives can be found such as the Atlantic Ocean Research Alliance, Joint Programming Initiative on Oceans, Arctic observation systems, Atlantic Ocean Research Alliance, the BLUEMED Initiative on marine and maritime R&I activities in

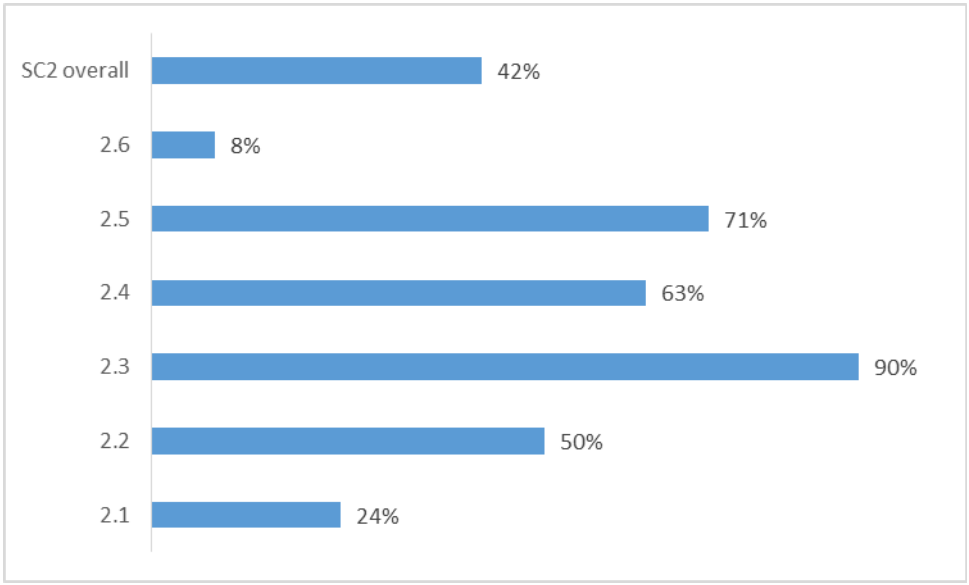
the Mediterranean area, the Joint Baltic Sea research and development programme-BONUS.

K.4.4. Progress towards the overall Horizon 2020 objectives

K.4.4.1. Fostering excellent science in scientific and technological research

Section 5.2 provided examples of SC2 projects fostering scientific excellence. Additionally, results of the project mapping exercise suggest that 42% of the funded projects are expected to contribute to research excellence i.e. breakthrough research.

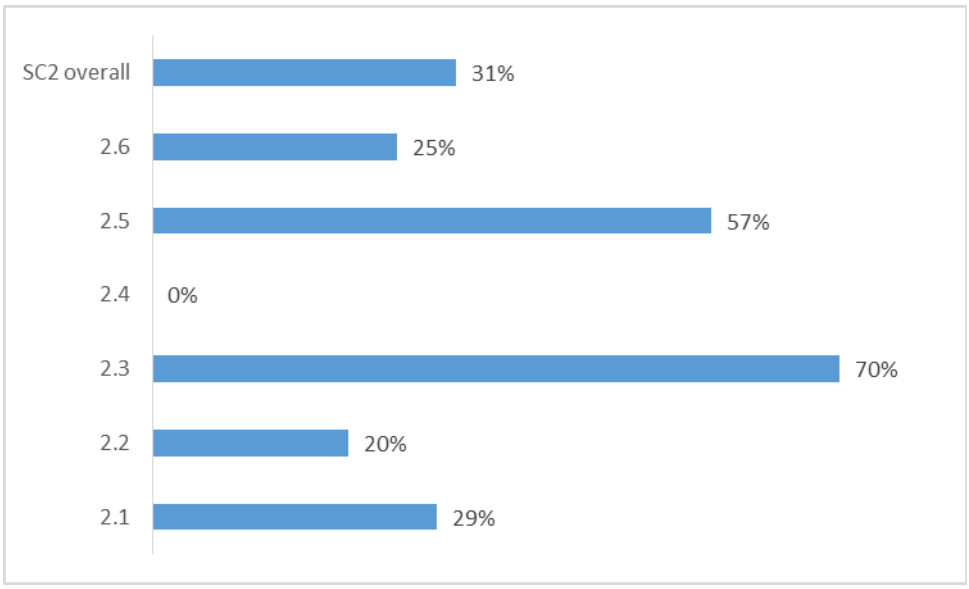
Figure 208 - Intended project objectives by SC2 activity line - percentage of projects for which "research excellence" was assessed as important, very important or extremely important objective



Source: project mapping by the expert group; N=111 projects.

Results of the project mapping exercise suggest that almost a third of the funded projects are expected to contribute to strengthening Europe's research skills base.

Figure 209 - Intended project objectives by SC2 activity line - percentage of projects for which "strengthening Europe's research skills base" was assessed as important, very important or extremely important objective



Source: project mapping by the expert group; N=111 projects.

K.4.4.2. Boosting innovation, industrial leadership, growth, competitiveness and job creation

Section 5.2 also describes how specific projects are boosting innovation and contributing to industrial leadership, jobs and growth.

K.4.4.3. Addressing the major societal challenges

Aside from addressing the societal challenges directly addressed by the programme (e.g. food security and safety, sustainable and resilient production and consumption systems and rural empowerment), more than half the funded (non-SME) projects are also expected to contribute to other societal challenges.

Table 156 - Intended (non-SME) project objectives by SC2 activity line - percentage of projects for which stated objectives were assessed as important, very important or extremely important objective

Objective	2.1	2.2	2.3	2.4	2.5	2.6	SC2 overall
Societal challenges outside SC2 (e.g. environment, health, transport, energy …)	45%	70%	100%	13%	93%	50%	54%
Number of projects	**49**	**10**	**10**	**16**	***14***	**12**	***111***

Source: project mapping by the expert group; N=111 projects.

Basic knowledge findings and product innovations resulting from marine research have the potential to contribute to societal challenges across the Horizon 2020 programme. They are expected to provide innovative solutions contributing to energy efficiency and sustainability (SC3), smart integrated transport (SC4), climate actions resource efficiency (SC5). Research infrastructure created with the purpose of supporting BG research may have spill-over effects on R&I in other sectors.

K.4.4.4. Spreading excellence and widening participation

The important steps taken by the programme to widen participation (through the use of multi-actor approach for example) and develop international cooperation have already previously been described.

K.4.5. Early success stories

HIPSTER: An ongoing Horizon 2020 Innovation Action project, HIPSTER, is focused on scaled-up development and full implementation of High Hydrostatic Pressure in combination with Temperature (HPT) technology to be used by the food industry in order to extend the shelf life of processed foods and improve their microbial safety while preserving the sensory qualities. To date, the work resulted in design and prototyping of the equipment (patented), initial establishment of the process parameters for treatment of foods, and determination of detailed inactivation kinetics of selected strains of both background (spoilage) microbiota and foodborne pathogen *Clostridium botulinum* in food model systems when exposed to HPT-treatment. In the next stage, the full-scale, industrial equipment will be produced and validated in the industrial setting. The project results will enable food producers to produce higher quality and safety foods with economic savings, reduce the carbon footprint through reduced food transport and wastes, improve own competitiveness, and better satisfy consumer's needs regarding nutritious and safe food.

COMPARE: COMPARE is a large EU project with the intention to speed up the detection of and response to disease outbreaks among humans and animals worldwide through the use of new genome technology (Next Generation Sequencing, Whole Genome Sequencing, Whole Community Sequencing). The COMPARE Consortium is receiving approximately EUR 20.8 million, and the project will run from 01 December 2014 through 30 November 2019. The partners (29) in this project form a multidisciplinary research network that is set up with the common vision to become: (a) the enabling analytical framework and globally linked data and information sharing platform system; (b) for the rapid identification, containment and mitigation of emerging infectious diseases and foodborne outbreaks. The system sets out to integrate state-of-the-art strategies, tools, technologies and methods for collecting, processing and analysing sequence-based pathogen data in combination with associated (clinical, epidemiological and other) data, for the generation of actionable information to relevant authorities and other users in the human health, animal health and food safety domains. Although there are rather high number of partners involved the project is well organised, and managed. This reflects in rather high number (49) of published peer review articles. In parallel to that, the project partners tends to established comprehensive database of protocols, information about reference genomes etc.

ATLAS project: ATLAS is a research project designed to provide the first coherent, integrated basin-scale assessment of Atlantic deep-water ecosystems and their potential to contribute to Blue Growth. ATLAS will unify research from physical oceanography through ecosystem function, biodiversity and connectivity as the foundation for unlocking the deep sea potential and making it a familiar ground for exploitation in Blue Growth activities. ATLAS aggregates a number of important international contributions through a network of Associate Partners and philanthropic funding to cover the substantial range of deep-water ecosystems in the North Atlantic and to take advantage of international ocean observation and prediction modelling initiatives, data collections and science for a. Furthermore, ATLAS will draw from a comprehensive knowledge and expertise base established by its partners in previous seabed mapping, spatial management, earth observation, climate change and human

impact FP6 and FP7 projects, and its enhanced and synchronous ocean observations link to AtlantOS, another Horizon 2020 project with aligned mission to support Blue Growth and strengthen trans-Atlantic co-operation through strong international partnership. Finally, to achieve the trans-Atlantic scale and incorporate the diversity of sensitive Atlantic deep-water ecosystems, ATLAS has assembled 12 Case Studies that follow the major Atlantic current patterns and are at proximity to Blue Growth activities (Biotechnology; Fisheries; Mining; Oil & Gas; Tourism). Integrating the wealth of expected outputs to policy-making across the Atlantic to support Blue Growth is the ultimate ambition of ATLAS.

K.4.6. Lessons learnt/Areas for improvement

- There is little evidence of outputs and effects at this early stage of programme implementation. Of the 273 projects falling within the scope of the evaluation 163 projects are still ongoing and although 110 projects have closed, 109 of these are SME phase I projects and 1 is a CSA. Only 10 out of the 163 ongoing projects had submitted periodic reports at the time of writing this report.
- Outputs reported so far include: 95 peer reviewed publications, 5 patents, 3 trademarks and 1 registered design.
- The evaluation however, found several examples of promising projects which can reasonably be expected to contribute to the following longer term impacts:
    - The development of low-carbon, resource-efficient and competitive European agro-food and bio-based industries;
    - Improved competitiveness and sustainability of European agriculture and forestry sector;
    - Higher growth and employment;
    - Reduced greenhouse gas emissions;
    - Improved food security and safety;
    - Oceans observation and mapping, sustainable and smart use of marine resources.
- Expected impacts of 55 closed SME Phase I projects that were mapped include:
    - EUR 1.5 billion of additional turnover over next three years
    - over 1,500 jobs over next three years
- Expected impacts of 26 SME Phase II projects include:
    - EUR 1.03 billion of additional turnover over next five years
    - 1,121 jobs over next five years
- Major achievements of the programme to date include:
    - Setting up of the BBI JU
    - development of strategic cooperations e.g. Trans-Atlantic Research Cooperation
    - Significant technological advance - 88% of the mapped SC2 projects are developing technologies which have been assessed at TRL 5 and above (reflecting the spirit of Horizon 2020)
- The programme could benefit from the use of more KPIs for evaluating and monitoring the programme's effectiveness towards attaining its specific objectives.

K.5. EFFICIENCY

K.5.1. Budgetary resources

The thematic allocation of funding is very close to what was envisaged in the work programme for 2014-15. Likewise the take up of budgetary instruments is as envisaged. This is not surprising considering that work programmes specify the budget and nature of instrument for each call topic.

Table 157 - Thematic allocation and absorption of programme resources (BBI not included)

	Work Programme budget		EC funds requested by approved projects	
	Amount €M	**As % of total**	**Amount €M**	**As % of total**
SFS	251.5	52%	265.3	53%
BG	144.0	30%	141.6	28%
ISIB	86.5	18%	91.7	18%
	482.0	100%	498.7	100%

Source: CORDA data. Based on 232 SME and non-SME projects. The above table does not include 5 projects selected under PHC, WASTE and WATER calls.

Table 158 - Allocation and absorption of programme resources by theme and instrument (BBI not included)

	Work programme					EC contribution requested by approved projects				
	SFS	**BG**	**ISIB**	**Total**	**As % total**	**SFS**	**BG**	**ISIB**	**Total**	**As % total**
RIA	211	112	35	358	74%	215.6	105.9	36.5	358.0	74%
IA	12	6		18	4%	12.2	6.0	-	18.2	4%
CSA	1.5	17	31.5	50	10%	1.5	20.8	35.5	57.8	12%
ERA-NET	0	0	20	20	4%	-	-	19.8	19.8	4%
SME	27	9		36	7%	36.0	8.9	-	44.9	9%
	251.5	144	86.5	482	100%	251.5	144.0	86.5	482.0	100%

Source: CORDA data. Based on 232 SME and non-SME projects. The above table does not include 5 projects selected under PHC, WASTE and WATER calls.

K.5.2. Programme's attractiveness

K.5.2.1. Mobilisation of stakeholders

Ensuring participation of newcomers, dissemination towards stakeholders and other potential users and uptake of project results, are areas which has been given enhanced attention with Horizon 2020 – and especially within SC2. A range of activities are implemented to inform

potential applicants, investors and stakeholders about the Work Programme, its policy lines and funding opportunities under SC2.

The programme has been quite successful in attracting newcomers. As previously reported:

- There are 21.6% (414) participations in SC2 from 'newcomers', defined here as those who did not participate in FP7 (excluding the SME instrument and Joint Undertakings).
- In the SME Instrument, 83.6% of all participations were by newcomers.
- 33.6% of the participations in the BBI JU represent newcomers.

The ECs SC2 info days/info week, organised jointly by REA, DG RTD and DG AGRI, is the main "flagship" activity to promote new funding opportunities. The info week provides information about the policy background of SC2 calls, the call implementation practicalities and guidance on the objectives of the WP topics. It also serves to showcase successful projects. The content of the events is in continuous development reflecting participants demands[249].

The 2016 info week attracted just above 400 participants (409), almost the double of 2015 (210) but identical to 2014. In addition, quite a number of people web stream the event or part of the event live[250]. The number of registrations usually reaches the maximum possible number. However, the share of "no show" appears significant. 2016 as much as 38% of those registered did not show. Most participants are Brussels based or from the six large and older Member States. About one fourth of showing participants (24%) are located in Belgium (representation offices largely). An additional 39% stem from six Member States (ES, FR, UK, DE, NL and IT). Participants from EU-12, Croatia and Greece represent only 8% of all participants. There is no data on the nature of the organisations represented.

Beyond the info week the EC implement a number of other communication and supporting activities to promote and generate Horizon 2020 participation organised around three main stages:

- *Launch of the WP:* Publication of the road map and release of communication material; press release/article on funding opportunities when the WP is published, info week and presentations of the WP at national Info-days;
- *During the opening of a call:* Promotion of the call and information sources at third party events, facilitation of partner search (through the EIP) and support to the RES;
- *After call evaluation closure:* Show and Tell events to show-case the projects portfolio as well a collection of data to communicate on the results of the calls (call statistics) and lessons learned.

Beyond the EC level, (Bio)NCPs play a key role in promoting SC2 funding opportunities. They undertake to this end various activities incl. national info days. BioNCPs receive support for their activities through a CSA project *Bio Horizon* which organises several communication and dissemination events in collaboration with the EC. There is no data available on the reach of these activities.

[249] *The the latest 2016 info week (June 2016) included a brokerage event to support networking; an NCP meeting; infoday incl. Q/A session; a dissemination event to showcase case results of FP7 and Horizon 2020 projects and a coordinators day for new project coordinators*

[250] *Ranging depending on session between some 150 to 880 viewers live viewing in the range of 20 to 40 minutes per day*

Some participants mentioned executive agencies are not accessible to address questions relating to calls (under FP7, applicants could informally contact the Commission to obtain clarifications). This is due to the new standard approach whereby Commission services cannot be contacted directly by prospective applicants (in order to ensure a fair treatment of all potential applicants). A network of trained National Contract Points (NCPs) has been set up to help project participants, but it is understood that the quality of service varies across the network.

With respect to the SME instrument, at this stage of the programme implementation, no evidence of tangible benefits of coaching services could be established.

Dissemination of SC2 project results is a joint responsibility of DG RTD, DG AGRI, the Executive Agencies and Horizon 2020 projects. DG RTD, DG AGRI and the EAs activities takes place within the framework of the EC's *Strategy for effective dissemination and exploitation of research results in Horizon 2020,* which set as objectives to improve the use of research project results contributing to commercial and social innovation as well as to ensure improve use in EU policy making when tackling the societal challenges. To this end the strategy foresees three lines of action: a) facilitating the dissemination of and access to the outputs and more targeted dissemination b) describing and facilitating a process for the feedback of results into policy making and c) supporting exploitation of research results. In SC2, DG AGRI and DG RTD operationalise the line of actions through exhibitions, publications and dissemination of success stories to external audiences, in addition to the dissemination activities which are organised horizontally for Horizon 2020[251]. Events include the bioeconomy village at the Bioeconomy Investment Summit and the Food village where successful projects display their results.

Dissemination of research results however, is far from limited to activities directly undertaken by the EC. Research projects themselves are expected to play a key role in the dissemination of results and are required to provide a plan for the exploitation and dissemination of results (as well as a communication plan as part of the project proposals). Effectiveness of the proposed measures to disseminate and otherwise promote uptake of the project results forms part of the assessment criteria. Furthermore, dissemination of research results is, in the framework of SC2, supported through:

- CSAs projects which explicitly aim at compiling, clustering and disseminating research EU funded research results from projects under FP7 and Horizon 2020/SC2: Columbus; CommBeBiz; Biolinks and ProBio)
- The thematic networks (CSAs) which are designed to identify and disseminate research on a specific agricultural area/theme (cover the identification and dissemination of research results and innovation practices of any relevant nature)
- EIP AGRI which among other provide formation about R&I projects

There are at this stage little evidence on the extent to which dissemination activities approaches have proven effective to support the dissemination of research results. However, the following observations may be made.

- The fact that funding is allocated specifically to dissemination projects and initiatives should be assessed positively given the dissemination challenges under the KBBE[252],

[251] *e.g. dissemination CORDIS, the EU Open Data Portal, OpenAIRE, and other public and commercial repositories – as well as activities which are intended to support EC dissemination internally for the purpose of policy uptake*
[252]

and the reported difficulties of research projects and researchers to be able to communicate results effectively in laymen terms.

- The first outputs of the CSAs projects which are to disseminate FP7 results are delivering promising first results (see Box 3)
- The multi-actor approach has a potential to address a traditional weakness in project dissemination because it requires the involvement of end-users' in all stages of the project design and implementation. As such it increases the likeliness that the projects dissemination efforts are better adapted and targeted to potential users of the research.
- Judging from the project proposals there is great heterogeneity in the approach, detail and quality of the dissemination and communication plans across projects. As it could be expected dissemination focused CSAs have better quality dissemination plans. The quality of the RIA proposals varies. Many SME -1 projects do not contain any plans to disseminate the results of the projects. This suggests that scientific excellence and other criteria are likely to prevail over dissemination in the selection process. Consequently, the plans to improve dissemination via additional guidance and a dissemination toolbox and the plans to raise appraisers focus on dissemination appear still relevant (as outlined in the Strategy for effective dissemination and exploitation of research results in Horizon 2020)
- Judging from the feedback from thematic network projects (CSAs) collaboration is well established with the EIP-AGRI providing the basis for subsequent dissemination.
- While REA has put in place mechanisms to ensure feedback on policy relevant research outputs there is concern regarding the potential effectiveness of such mechanisms. In view of the importance of the policy feedback close monitoring and assessment of these mechanisms will be necessary once projects start delivering results.

Box 18 - Dissemination via CSAs

COLUMBUS is CSA project tasked with ensuring that applicable knowledge generated through EC-funded science and technology research can be transferred effectively to advance the governance of the marine and maritime sectors while improving competitiveness of European companies and unlocking the potential of the oceans.

As the project passes its 18-month interim point (Sept 2016), results of the project already point to significant achievements including:

- The implementation of a replicable, efficient and systematic process to knowledge transfer covering four phases - collection, analysis, transfer and impact measurement: Nine partners from a variety of organisation types across Europe are applying this methodology to different sub-sectors including key blue growth areas;

- The piloting of aspects of the process by the EC and Member States: The EC have adapted the collection templates to gather 466 exploitable results from FP7 Oceans of Tomorrow projects and uploaded them to the EC 'Information Sharing Platform for marine and Maritime Research' and, the Irish Environmental Protection Agency will pilot the full process on nationally funded projects in 2017;

- The identification of 1,199 Knowledge Outputs from 111 FP7 marine projects submitted to a publicly accessible repository and

- Evidence based case studies of successful transfer of knowledge and measurable uptake, using the aforementioned methodology, by end-users in policy and industry

K.5.2.2. Geographical dimension

Some progress has been made in increasing participation from 'new' Member States in SC2 as compared to FP7-KBBE. Under FP7, the EU-13 accounted for 8% of participations while less than 1% of funding for coordinators went to partners based in the EU-13. Under SC2, the EU-13 accounts for 9% of the participations and 6% of the budget (including BBI JU). There is also a slightly larger share of project coordinators coming from EU-13 under SC2 as compared to FP7-KBBE.

Third countries account for 5% of SC2 participations, a slightly higher share than what is being achieved within Horizon 2020 as a whole (1.6%). Likewise, a slightly higher share of the programme budget goes to third country participants (1%) under SC2 as compared to Horizon 2020 overall (0.4%). As mentioned in section 4, the third-country participants are coming predominantly from *China* (30.9%), *Canada* (16.3%) and the *United States* (8.1%). More of half (60.2%) of third-country participants are either Higher or Secondary Education Establishments or Research Organisations, and 22% of them are private companies. Under FP7-KBBE, 71 third countries were involved and they accounted for 8% of all participations. China, Russia, the United States, South Africa, India, Brazil, Canada, Morocco, Australia, Tunisia, Argentina and Egypt were most common third country participants with more than 20 participations each in the FP7 KBBE projects. However, as previously mentioned SC2 has adopted a more targeted and strategic approach to the involvement of third countries.

K.5.2.3. Cross-cutting issues

On several cross-cutting indicators, SC2 performs better than Horizon 2020 overall. There are two areas where SC2 lags particularly behind: the percentage of projects where societal actors contribute to the co-creation of scientific agendas and content; and the percentage of projects taking into account the gender dimension in R&I content.

K.5.3. Cost-benefit analysis

A cost-benefit analysis cannot be performed at such an early stage of programme implementation, where very limited evidence is available on the effects. This section therefore, summarises the factors (both enabling as well as constraining) affecting efficiency.

According to the analysis from the Expert Group, the delegation of parts of SC2 implementation to REA took place smoothly at the end of the first year of the programme (2014). According to the Expert Group, efficient mechanisms have been put in place since then to ensure close interactions between the executive agency and the DGs, while issues such as feed-back loop to policy making and dissemination would still deserve further attention.

With respect to delegation of programme management to the executive agencies, there were some concerns expressed by Commission officials and stakeholders alike that this is creating distance between policy and projects and consequently, weakening the feedback loop. To address this issue several communication channels have been established between the RTD and REA / EAs:

- Each topic and project is assigned to a project officer (REA) and a policy officer (European Commission).
- There is a continuous communication between project and policy officers (e.g. selection and briefing of evaluators; participation to kick-off meetings and project review meetings).
- There are regular SC2 coordination meetings, both at middle (Head of Unit) and senior management (directors) level.
- SC2 encounters (internal meetings) are regularly organised with a focus on information exchange regarding policy framework and project implementation.

In addition to above, dedicated policy feedback mechanisms are planned to be established in 2017 (e.g. dedicated policy review meetings involving projects acting under one coherent research area). This was not done before because projects from the 2014 calls are just reaching now a stage where significant outputs are delivered.

A key assumption is that management has become simpler. However, the decentralisation of the programme requires much more coordination not only across the Commission services but also externally with the three executive agencies involved. For example, the cross-cutting nature of the Blue Growth focus areas implies that DG RTD needs to coordinate contributions (topics and budget) from other parts (such as Climate, Transport, Energy etc). In practice, this is a complex exercise, as it requires strong interactions with many other services, both during the programming phase as well as the implementation phase: this involved three executive agencies and various services. Despite the fact that SC2 succeeded in the first years, it is indeed a complex issue, and also quite a continuous challenge to receive contributions from other parts of the programme in order to reach a budget which meets the high and increasing political ambition of BG.

As regards the simplifications introduced within the programme, these have generally been positively received by project participants. Project participants specifically cited the following simplifications as examples of efficiency driving improvements: the removal of negotiation stage, simplified reporting; the participant portal, the electronic signatures for grants agreements, the single reimbursement rate, single flat rate for indirect costs.

Interviews with stakeholders and project partners suggests that the key added value of SC2 (in Horizon 2020 more broadly) lies in the pan-European coverage of research and research related activities. Undertaking activities beyond the boundaries of national priorities, focusing on common issues and/or areas which may be neglected at national level, involving a network of multi-national partners provides, given this wider scope, the basis for the identification of common solutions and a wider "European" application of research results – including via policy uptake at EU level. Given this wider scope for application of project outputs and results, projects are expected to provide better value for money.

Beyond this main line of expected added value, interviews and survey results furthermore suggest that the programme contributes to ensuring added value by:

- Supporting the development and deepening of collaboration between partners which would not have been possible without EU funding. More than the creation of new academic partnerships, funding allows for in depth collaboration between "best in category" around a specific theme of EU level priority. Furthermore, Horizon 2020 encourages new public and private partnerships and industry/business involvement.
- Developing research capacity. Judging by the added value survey results, SC2 funding contributes positively to understanding and knowledge of existing as well as new

areas, scientific capabilities, technological capabilities and access to infrastructure and equipment. Compared to other public sources, SC2 funding improves the three types research capabilities mentioned at project level. Impact is most widespread as regards development and understanding of new knowledge – with 74% of the SC2 projects indicating that their understanding and knowledge in new areas would had been smaller without Horizon 2020 funding. About half of the SC2 projects also indicate that Horizon 2020 funding, compared to national funding, impacted positively on planning and coordination of research and technological development (52%), scientific capabilities (49%) and understanding and knowledge in existing areas (46%). As it could be expected, the contribution is small, with most projects indicating that the difference in capability development is small between EU and nationally funded projects. However, half of the projects indicate that Horizon 2020 has had at least one significant impact on capabilities. Projects reporting a significant impact on capabilities are mostly RIA, CSA and ERA-nets. More than two thirds of the SME-1 and SME-2 projects (70%) did not consider that Horizon 2020 had any significant impact on research capacity.

- Supporting HR capacity. There is across SC2 projects a general agreement over the efficacy of Horizon 2020 funding in improving the staff capacity via projects. Participation in Horizon 2020, in a clear majority of the cases, had a positive impact on institutions' ability to attract researchers and other staff – as well as on development of relationships and networks (+70%). About half of the projects surveyed also note a positive impact on training capacity, researcher mobility and career development. The largest effect is identified in relation to relationship and network development (more than half of the respondents stating that EU funding has made a significant difference).
- Quicker delivery of project results. Judging by the added value survey results, participation in Horizon 2020 has also impacted positively on project delivery with 4 in 10 of the project coordinators of SC2 projects (41%) indicating that project delivery would have been slower had it been funded by national or regional public funds.
- Leverage of resources for follow up activities and/or spill over effects. According the added value survey results, a clear majority of project coordinators of SC2 s expect that participation in Horizon 2020 will impact positively on access to other public funding opportunities for similar activities, EU as well as national (Public national/regional schemes; other EU programmes and private/industrial sources). Importantly also, project funding appears to leverage additional "in house" R&D funding in the case of many non-SME projects. In contrast, judging by the final reports from SME Phase 1 projects, the crowding in /leverage effect of own sources is seemingly low (as previously reported). Some non-SME projects also mention other project spill-over effects, where partner interaction results in further partner and non-partner exchange and mutual learning.

K.5.4. Lessons learnt/Areas for improvement

The programme has a complex management arrangement involving coordination with multiple DGs; co-management with DG AGRI and delegation of parts of the programme across three executive agencies (REA, INEA, EASME). This has made coordination challenging and resource intensive. Further development of Standard operating procedures and clear division of tasks between different DGs and the executive agencies would help improve coordination.

At the same time several simplifications introduced under Horizon 2020 have contributed to improving efficiency: the removal of negotiation stage, simplified financial reporting; the participant portal, the electronic signatures for grants agreements, the single reimbursement rate, single flat rate for indirect costs.

K.6. COHERENCE

K.6.1. Internal coherence

K.6.1.1. Internal coherence of the actions

SC2 Work programmes 2014-2015 and 2016-2017 are designed as responses to the multi-faceted societal challenges facing Europe, EU and international policy issues and are aligned with the legal basis. The work programmes have put in place a wide array of instruments to address:

- Research and commercialisation of research outcomes: RIA, IA (including BBI-DEMO and BBI-FLAG) and SME instrument;
- Coordination, public-public partnerships and knowledge sharing: ERA-NET, CSA.

The above instruments represent a coherent response to the R&I needs that the programme seeks to meet and its stated objectives. Stakeholders have generally positively assessed the integration of instruments to support innovation alongside within the programme, and the coverage of the full spectrum of activities from fundamental research to technology roll out and innovation. Several stakeholders interviewed however, have argued that SC2 is focussed too much on innovation at the cost of more basic or fundamental research (that is a pre-requisite for innovation). This represents a lack of understanding among stakeholders as regards the new structure of Horizon 2020, wherein frontier research is supported under pillar 1 (Excellent science). The balance between R&I therefore, needs to be monitored across Horizon 2020 as a whole for specific themes (e.g. SFS, BG etc.). These data are not readily nor systematically available. RTD.F is however monitoring the implementation of BG through a co-ordination mechanism involving all services addressing marine and maritime research; these carry out joint portfolio analyses and monitoring of relevant activities throughout the programme.

Data are however, available for SC2 which shows that 62% of the funding allocated is dedicated to RIAs; 26% to IAs; 9% to CSAs; 6% to the SME instrument and 3% to ERA-NET – Figure 12. The use of instruments varies between activity lines (agriculture, aquaculture etc.). RIA is by far the most widely used instrument and is particularly strongly used in activity lines 2.1, 2.3 and 2.5 (Agriculture and Blue Growth). In contrast, the 'Food' thematic area makes high use of the Innovation Action and SME instrument. The SME instrument has also been used under Blue Growth.

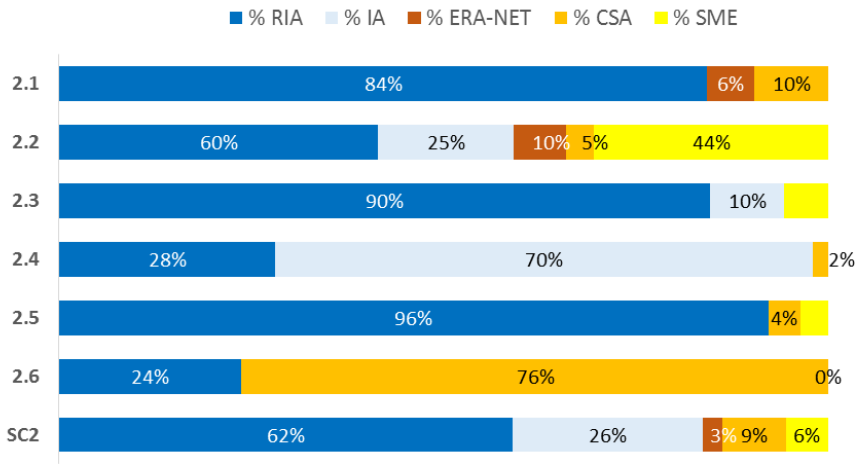
The structure of each work programme indicates a design that serves internal coherence; individual calls make use of different types of actions to deliver in a complementary manner. Illustrative examples include:

- In WP2014-2015, one sub-area within "Sustainable Food Security" is "*Safe Food and Healthy Diets*" that is tackled through four RIAs, one CSA and one IA to address food safety, sustainable and competitive food production.

- The focus area Blue Growth "*Boosting innovation for emerging Blue Growth activities*" in WP2016-2017 comprises three IAs, one CSA and one ERA-NET Cofund to address technologies required for multi-use of the ocean space.

This structural coherence is reinforced by the explicit requirement of the work programme for collaboration between certain projects that are funded to tackle relevant/ complementary issues.

Figure 210 - Distribution of EC contribution to SC2 projects by type, by activity line



Based on CORDA data extracted in September 2016 (273 projects, EC contribution = EUR 775 million). There is a discrepancy between the total EC contribution that appears in the project level data and at participant level (of EUR 8 million).

At project level synergy can especially be observed from CSAs and RIAs – whereas there the synergy effect generated from SME projects is less evident. CSAs in support of the JPIs (JPI HDHL 2.0 and FACCE-Evolve) ensure further implementation and durability of joint programming and actions, which were initiated under FP7. The CSA thematic networks, through the collection and dissemination of scientific knowledge and best practices from across Europe can be expected to contribute to leverage action at a European level. Likewise, across RIAs there are several examples of how projects are working in synergy – and building on - research activities funded by other sources.

K.6.1.2. Internal coherence with other Horizon 2020 intervention areas

Internal coherence with other areas of Horizon 2020 is ensured in a top-down manner (different scopes of intervention) as well as with a bottom-up approach via the coordination of funding and calls. This is also traceable and evident in both SC2 work programmes where justified links to other Horizon 2020 intervention areas are provided.

According to the analysis from the Expert Group, SC2 work programme actions are fundamental to a wider range of other Societal Challenges, especially SC1 "Health demographic change and wellbeing", SC3 "Secure, clean and efficient energy" and SC5 "Climate action, environment, resource efficiency and raw materials". EC officials have actively engaged with other services in order to link up and ensure complementarity between SC2 and other societal challenges – and associated calls. The complementarity is notably evidenced by 14% of the SC2 budget for 2014-2017 going to SC1 and SC5 Work Programmes. Likewise, 11% of the budget allocated to first two SC2 work programmes (WP2014-2015 and WP2016-2017) came from other SCs (see table 1 in section 2).

Considering the importance of the diet and food quality in human health, wellbeing and aging, SC2 will contribute to SC1 by supporting the development of food value chains that contribute to combating the challenging disorders and diseases of the aging European population. The SFS calls that cover issues in all areas of primary production, terrestrial and aquatic, are rich in projects that contribute to SC1 and in the BG calls, this endeavour extends to "Linking healthy oceans and seas with healthy people" by exploring how the interaction between humans and the oceans contributes to wellbeing and how to improve the availability, safety and dietary properties of seafood.

More evidently, SC2 is closely linked with SC5 with many complementary objectives and activities, i.e. achieving a resource – and water - efficient and climate change resilient economy and society; providing viable solutions of natural ecosystems; a sustainable supply and use of raw materials, in order to meet the needs of a growing global population within the sustainable limits of the planet's natural resources and eco-systems; Earth Observations - information on climate, energy, natural hazards and other societal challenge; systemic Eco-Innovation - Generating and sharing economic and environmental benefits.

From the analysis of the Expert Group, there are no direct explicit linkages between SC2 and other parts of Horizon 2020 (except for BBI which receives a contribution from Horizon 2020 LEIT). However, due to the multidisciplinary nature of marine and maritime research, close coordination and joint activities with other parts of Horizon 2020 is foreseen as part of the Horizon 2020 legal basis. Particular BG calls relevant to exploitation of marine biodiversity and blue biotechnology touch upon the goals served by the ESFRI project European Marine Biological Resource Centre (EMBRC), a distributed research infrastructure that supports both fundamental and applied research based on marine bioresources and marine ecosystems, aiming to drive forward the development of blue biotechnologies. Furthermore, the recent acceptance of the Svalbard Integrated Arctic Earth Observing System in the ESFRI roadmap brings ESFRI infrastructures closer to the objectives of BG theme. In addition, certain BG calls require explicitly the interaction with Copernicus and European Space Agency (ESA) programmes and infrastructure of the European Commission as well as the European Marine Observation and Data Network (EMODnet) and are driven by the aspiration to make EU the leader of the Global Observation Systems. To these higher goals BG projects make their own contribution implementing the commitment undertaken by the Commission. Also, under WP 2016-2017, the focus area Internet of Things (IoT) set up strong links between SC2 and DG CNECT activities.

No systematic action has been taken so far to connect ERC activities with the objectives of SC2, although interaction is sought through informal meetings between Commission officers of the relevant entities to avoid duplication of effort and to enhance cooperation. Being 'investigator-driven', or 'bottom-up', in nature, the ERC approach allows researchers to identify new opportunities and directions in any field of research, rather than being led by priorities set by the Commission as a funder. The ERC complements other funding activities in Europe such as those of the national research funding agencies, and is a flagship component of Horizon 2020. ERC projects are highly productive and many of those operate at the fore-front of scientific excellence. In the Domain of Life Sciences and Panel LS9 "Applied Life Sciences and non-medical Biotechnology" there is – according to the analysis form the Expert Group - a remarkable aggregation of projects with a big potential to contribute to the themes of SC2 such as genetic resources in primary production, bio-based industries and biotechnological applications to bring added-value to primary terrestrial and aquatic production systems.

Some sporadic links could be observed between SC2 and the European Institute of Innovation and Technology (EIT) which was set up in 2008 to enhance Europe's innovation capacity (information sessions to PC and NCP). EIT seeks to achieve its mission through a distributed network of thematically focussed Knowledge and Innovation Communities (KICs), which bring together higher education institutions, research organisations, industry and other stakeholders to create critical mass needed to stimulate innovation. The KICs are thematically aligned with the Horizon 2020 societal challenges. There following KICs appear to be particularly relevant to SC2:

- Climate-KIC: addressing climate change mitigation and adaptation
- EIT Health: addressing healthy living and active ageing; and
- EIT Raw Materials: addressing sustainable exploration, extraction, processing, recycling and substitution
- EIT Food in the field of sustainable supply chain i.e. from resources to consumers (2016).

While there are currently no plans for a knowledge and innovation community devoted specifically to the blue economy, it is understood that the Commission will examine whether its creation after 2020 could be of value.

SC2 has nevertheless taken actions to promote the bridging of activities related to this societal challenge throughout Horizon 2020, by calling a dedicated topics on *Bridging research and innovation efforts for a sustainable bioeconomy*[253] (three funded CSAs) and one on *Monitoring, dissemination and uptake of marine and maritime research*[254] (one funded CSA).

K.6.1.3. Ensuring that every euro spent counts twice

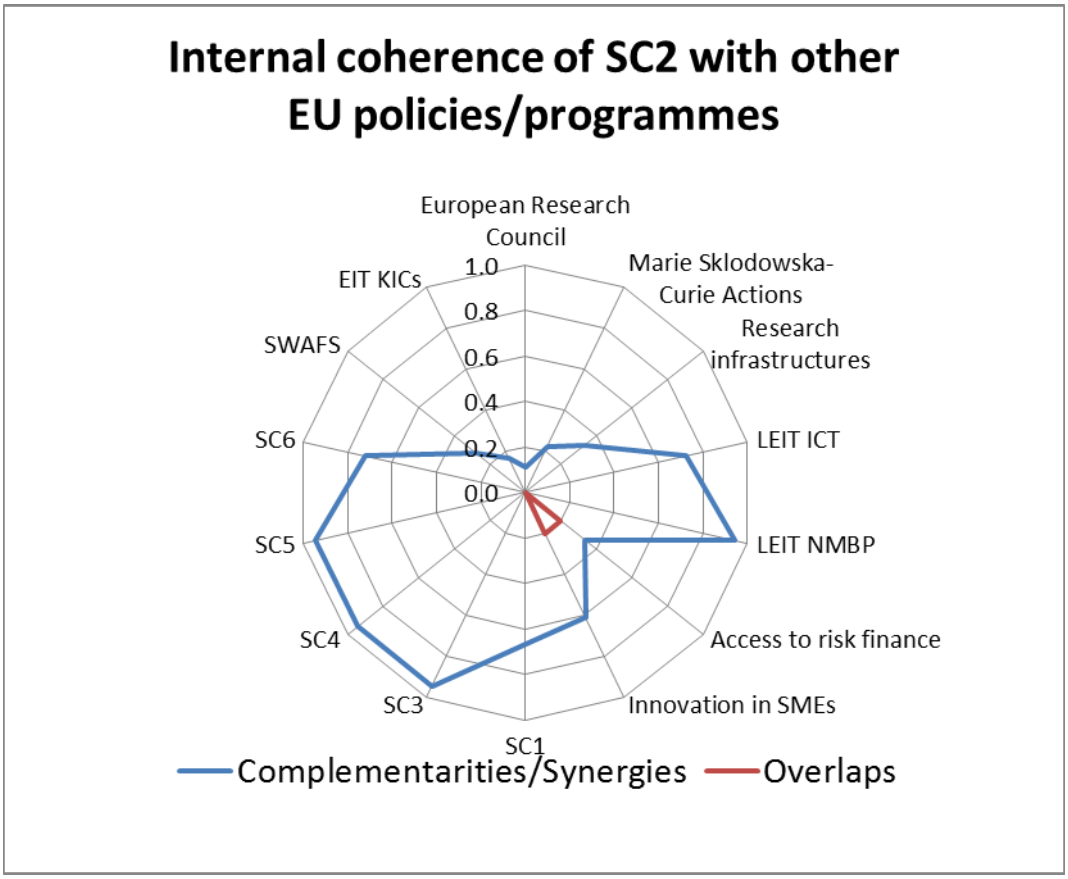
In particular cross-cutting projects such as those funded through Blue Growth calls have the potential to yield (i) interdisciplinary solutions which cut across multiple specific objectives of Horizon 2020 and (ii) to provide support to innovation in programming which is comprehensive and holistic so that it can at the same time tackle societal challenges and give rise to new competitive businesses and industries.

K.6.1.4. Results of the Likert scale

The figure below illustrates the level of coherence between Horizon 2020 Societal Challenge 2 and other EU interventions/policies, based on DG RTD's own assessment. As mentioned earlier, there are high levels of coherence between SC2 and certain other parts of Horizon 2020 namely, SC3, SC4, SC5 and LEIT NMBP.

[253] *ISIB-8-2014: Towards an innovative and responsible bioeconomy - B. Bridging research and innovation efforts for a sustainable bioeconomy*
Proposals should create links among various bioeconomy-related research and innovation activities carried out under different parts of Horizon 2020 and of the Seventh Framework Programme. This should foster knowledge transfer of best practice in sustainable process and technologies and facilitate the flow from discovery to further research and innovation (e.g. through twinning, networking, exchanges) and help discoveries to reach the market faster.
[254] *Topic BG-11-2014*

Figure 211 - Degree of internal coherence within Horizon 2020 according to the Likert scale assessment



Based on DG RTD's own assessment.

K.6.2. External coherence

K.6.2.1. Coherence with other EU funding programmes

Based on the analysis from the Expert Group, in broad policy terms, the 'Agriculture' activity line is coherent with other relevant EU interventions and especially the CAP (incl. the Rural Development Policy). Agriculture related research (Activity 2.1) is now managed jointly by DG Research and Innovation and DG AGRI. This provides a good basis for supporting policy development and delivery. There are also very close links to the European Innovation Partnership 'Agricultural Productivity and Sustainability. In addition to the general support from all farm-related research, the EIP is supported specifically by the Thematic Network CSAs in the agricultural sector which are intended to provide a clear pathway for impact on farm practice. In addition, the facilitation/mediation with Operational Groups funded under Rural Development Programmes also reinforces the coherence and strong link between Research and Rural Development Policy.

Similar high levels of coherence and policy added value is reported by experts with the Common Fisheries Policy and the Integrated Maritime Policy – albeit the management structure is different (DG RTD managed, in close interactions with DG MARE).

The Agricultural Thematic Area (2.1); the fishery and aquaculture area (2.3) bio-based industries (2.4) and Cross-cutting marine and maritime research (2.5) are all relevant to climate action, environment, resource efficiency and raw materials. Each activity line within SC2 is underpinned by an EU policy framework, namely Common Agricultural Policy,

Common Fisheries Policy, the Bioeconomy Strategy, Food Safety Policy, the Blue Growth Agenda, the EU Integrated Marine Policy, the Blue Energy Communication, the Blue Tourism Communication and the Blue Innovation Communication.

Certain SC2 issues are also subjects of funding by the "European Structural and Investment Funds" (ESIF), a common designation for five European funds: the European Regional Development Fund (ERDF), the European Social Fund (ESF), the Cohesion Fund (CF), the European Agricultural Fund for Rural Development (EAFRD) and the European Maritime and Fisheries Fund (EMFF). ESIF are set to respond to the needs of the real economy by supporting job creation and by getting the European economy growing again in a sustainable way. Although managed by different administration and no official procedures of interaction between SC2 work programmes and ESIF work programmes could be traced (apart from a workshop organised in 2014 to explore links between ESIF and bio-based industries[255]), evidence of complementarities is apparent in work programmes of ESIF funds. Also, the 2016 work programme of EMFF allocates funding to promote *inter alia* the Blue Economy in the Mediterranean Sea basin; Blue technology – innovative solutions for transfer to sea basin economies; Blue Labs: innovative solutions for maritime challenges; Maritime Spatial Planning. This alignment of scope provides ground for productive interaction between SC2 and ESIF that should not be overlooked.

Many actions were initiated to build and strengthen links with the EU Member States and regions and to enhance synergies and complementarities of Horizon 2020 programme / SC2 issues with the ESIF. A series of actions are presented below, *inter alia*:

1. Various events to support closer links with the EU regions and the ESIF, e.g.:
    - "*The role of regions in the European Bioeconomy*" high-level conference on 17/10/2016 in Bratislava,
    - The "*European Bioeconomy Congress EBCL 2016*" .
    - *Six Workshops under* the umbrella of the "Knowledge Exchange Platform (KEP)" in cooperation with the EU Committee of the Regions (CoR). *3rd High-level Black Sea Stakeholder Conference* in Odessa (14 June 2016) The *meeting of the Integrated Maritime Policy contact points in the Black Sea* on 27/10.2016 in Brussels.
    - *BLUEMED sessions* during the Ecomondo exposition, Rimini, November 2016
2. A study *"Mapping of EU Member States'/regions' Research and Innovation plans & Strategies for Smart Specialisation (RIS3) on Bioeconomy for 2014-2020"* (expected to be completed in Feb 2017, will map the EU Member States/regions' intentions and declared priorities, with regard to R&I and close-to-market plans (pilot, demos, commercial stages) on Bioeconomy in their Smart Specialisation Strategies (RIS3) and programmes supported by ESIF. The study will also identify and analyse the regions' commonalities and specificities and will focus on 22 regional case studies (focusing on EU-13), including inter alia successful regional R&I initiatives and good practices with a potential to be extrapolated to other regions, as well as bottlenecks and gaps on the deployment of the Bioeconomy;
3. A thematic smart specialisation platform on Agri-food has been launched on 1 June 2016 during the Smart Regions conference organised by DG REGIO, with the aim to facilitate

[255] *Workshop's report: Synergies between European Structural and Investment Funds (ESIF) and Horizon 2020 for research and innovation on bio-based industries. Brussels 18 March 2014. Available at: http://www.errin.eu/sites/default/files/publication/media/BBI-ESIF%20Workshop%20Report_18MARCH2014%20%285%29.pdf*

the creation of an investment pipeline of bankable projects in new growth areas in the domain on agro-food based on bottom-up interregional cooperation in the value chain.

4. Various Horizon 2020 funded projects are related to EU regions and EU-13, *inter alia*:
   - CSA in Horizon 2020 / SC2 Work Programme 2016 (EUR 1 million): A new CSA project BioREG [256] will create a Stakeholder platform of regional and local organisations (regional authorities or mandated agencies or clusters) interested to develop ambitious strategies in support of bio-based products/industries. Building on the "model demonstrator regions", successful case studies shall be shared and transposed to other interested European regions, among which also EU-13 with the aim to widen the participation of countries developing regional bio-based strategies.
   - BERST project created a "Bioeconomy Regional Strategy Toolkit" that assists the regions, also the EU-13 to identify their Bioeconomy potential and develop their regional bioeconomies. http://www.berst.eu/
   - The S2Biom project provides a tool to support sustainable delivery of non-food biomass feedstock at local, regional and pan European level through developing strategies, and roadmaps http://www.s2biom.eu/en/
5. Awareness raising / Guides – brochures "Synergies Horizon 2020– ESIF": The Bio-based Industries Consortium (BIC) who participates in the BBI JU, has published as a practical guide for decision-makers at regional level on how to effectively combine European structural funds with Horizon 2020 (and the BBI JU). The EC has also published general guidelines on how to exploit synergies between these different sources of funding, and practical examples of synergies as well and a brochure with examples for synergies, including examples related to SC2[257].

A recent, but relevant development has been EFSI, the European Fund for Strategic Investments, jointly launched by the European Commission and the European Investment Bank (EIB) in 2015. It also brings into focus the financial needs faced by SC2 R&D projects that have successfully finished at a high TRL level (at and above 7-8). In this context, a study to be published end of 2016, conducted by the EIB within the INNOVFIN advisory services and which focuses on bio-based and blue industries, has identified that these (new) industries are facing particular risks related to the regulatory environment but also to technological as well as market risks. While existing financial instruments such as INNOVFIN and EFSI are relevant to a number of projects, the large majority of projects is not served by existing instruments and there is also a lack of knowledge of these sectors among financial institutions, according to the Expert Group. The potential of specific financial instruments and platforms to boost investment to this sector will be further investigated in 2017 in order to tackle these problems. A study is also underway to investigate the financial needs of the agri-food sector with results expected for the end of 2017.

K.6.2.2. Coherence with other public support initiatives at regional, national and international level

Coherence with national research initiatives, ensuring EU additionality, is promoted via consultation with Member State authorities in the SC2 Programme Committee, as well as forums such as the Standing Committee for Agriculture Research (SCAR) and its dedicated Strategic Working Groups.

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[256] *Horizon 2020/SC2 CSA BioREG from topic BB-6-2016: Bio-based industries regional dimension*

[257] *"EU Funds working together for jobs and growth: Synergies between the R&I Framework Programmes and ESIF": https://ec.europa.eu/research/pdf/publications/ki-01-16-339-en-n.pdf*

In addition, Public-Public Partnerships are implemented via i) Art185 initiatives such as BONUS, the Joint Baltic Sea research and development programme[258], ii) Joint Programming Initiatives, such as Agriculture, Food Security and Climate Change (FACCE), Heatlhy Food and Healthy Diet (HDHL) and OCEAN, and iii) the ERA-Net cofund instrument, providing ground for the coordination of joint activities including common calls for research projects constituting clear mechanisms for integrating EU-funded and national research programmes. Furthermore, CSAs in support of the JPIs further support joint planning seeking to bring coherence and common purpose to national programmes across Europe.

Primary and secondary data collected in the framework of this study evidence that the programme raises standards across EU Member States, creates synergies and complements research efforts at different levels.

At a policy level SC2 provides structure and reference for the development of national research programmes, creating synergy and ensuring complementary in the research funding. This effect is illustrated by research approaches of key Member States such as France and Germany. In the case of France, the national research agenda *l'Agenda stratégique pour la recherche, le transfert et l'innovation "France Europe 2020"*[259] has explicitly been designed with the aim to ensure synergy and complementarity of research efforts. The research Agenda mirror the challenge based approach, with SC2 corresponding to "Defi 5 – Sécurité Alimentaire et Défi Démographique Ressources biologiques, exploitation durable des écosystèmes et Bioéconomie"[260].

At policy level also, SC2 funding supports directly transnational coordination with the ERA-Net cofunds designed to ensure alignment of national research programmes, generating a structuring effect and leverage action between EU and national research funding programmes. ERA-Net cofund actions are seen by stakeholders as well as the Expert Group to be potentially highly effective strategic investments in the European Research Area, generating a structuring effect and ensuring coherence between EU and national research funding programmes. The potential effect is likely to be particular strong in 'Agriculture' which is characterized by a wide range of regional, national, and European activities, in both the public and private sectors. Coordinators of past ERA-Net cofund actions furthermore highlight the role that these play to raise programing standards across all participating Member States. In view of these benefits, some stakeholders however also highlight the continued need for inclusiveness and cross European Member State representation in the ERA-Nets, which judging by the case of ERA-GAS appear not systematically ensured.

The BG theme calls relevant to marine environment observation systems and implementation of policies and alliances within Europe and internationally make explicit reference and align with the objectives of the following initiatives that EC is member of the board:

- Sustaining Arctic Observation Networks (SAON);
- Group of Earth Observations (GEO) and Global Earth Observation System of Systems (GEOSS) and Cold Region Initiative of the Group on Earth Observation in particular;
- WMO Programme Year of Polar Prediction.

[258] http://www.bonusportal.org/about_us
[259] http://www.enseignementsup-recherche.gouv.fr/cid71873/france-europe-2020-l-agenda-strategique-pour-la-recherche-le-transfert-et-l-innovation.html
[260] *See for example Agence Nationale de Recherche, Plan d'action 2017 at* http://www.agence-nationale-recherche.fr/fileadmin/aap/2017/ANR-plan-action-2017.pdf

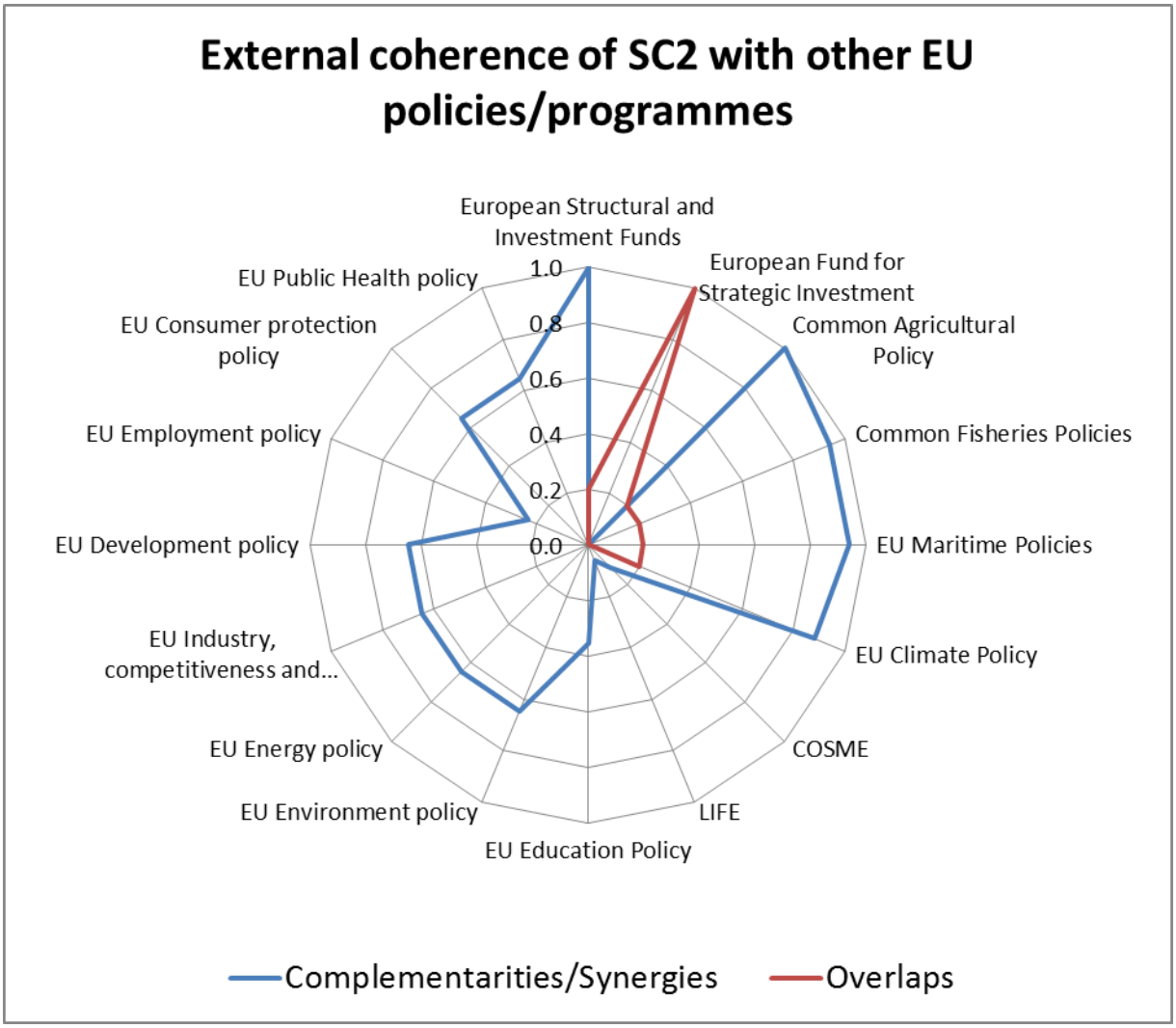
Horizon 2020 work programmes have taken into consideration the Commission's commitment and shared vision to support the activities of the above initiatives in the spirit of synergy with the other actors of the initiatives.

Overall, when considering capacity improvements, one fifth of the SC2 projects surveyed within the "added value Horizon 2020 project survey" (22%) noted that the capacity to plan and coordinate research to avoid duplication would have been much lower had project funding been provided by national or regional funds – and an additional 30% of SC2 projects indicated that the capacity to coordinate would have slightly decreased. If one considers only RIA, CSAs ERA-Nets, this effect is even more positive. 19 of the 20 RIA, CSAs ERA-Nets projects surveyed note a positive impact. Of these projects half of indicate that their capacity to plan and coordination of R&D to avoid duplication would have significantly decreased had project been funded by national sources.

K.6.2.3. Results of the Likert scale on external coherence

The figure below illustrates the level of coherence (as well as overlaps) between Horizon 2020 Societal Challenge 2 and other EU interventions/policies. As explained in detail in 7.1.1, the assessment by DG RTD found a high degree of coherence, complementarity and synergies in particular with the CAP, the CFP, maritime and climate policies, but also with environment, energy, industry and competitiveness, public health and consumer protection. There is a strong potential for complementarities in SC2 WPs of ESIF funds, e.g. actions targeting the development of new bio-based industries.

Figure 212 - Degree of external coherence within Horizon 2020 according to the Likert scale assessment



Based on DG RTD's own assessment.

K.6.3. Lessons learnt/Areas for improvement

The choice of funding instruments is coherent and complementary– although one of the issues raised by several stakeholders is that the programme is gravitating too much towards innovation at the expense of basic science. It appears that the stakeholders are not fully in tune with the new philosophy and structure of Horizon 2020, although the balance between R&I within each thematic area needs to be systematically monitored.

Thematic allocation of funding looks appropriate given the objectives of the programme.

There are clear links between SC2 and other SCs and LEIT, but no evidence of formal links with ERC or EIT (although interactions happen through meetings of the relevant entities to avoid duplication of effort and enhance cooperation).

Several actions have intensively supported the links with the EU Member States' / regions' plans and smart specialisation strategies using ESIF, for instance those targeting development of new bio-based industries. Although managed by different administrations and no official

procedures supporting interaction between SC2 WPs and ESIF WPs are set in place, there is strong potential for complementarities in SC2 WPs of ESIF funds which can be exploited.

ERA-Net cofund actions are potentially highly effective strategic investments in the European Research Area, generating a structuring effect and ensuring coherence between EU and national research funding programmes.

K.7. EU ADDED VALUE

Overall, the qualitative and quantitative data available provide strong evidence of added value of the SC2 programme. Project additionality is also strong. Furthermore, compared to national and regional funding the programme performs favourably increasing research capacities, commercial advantages and scientific and innovation outputs. However, these effects can mainly be observed for RIA, IA, CSAs and ERA-Net Cofunds, There is less evidence of the added value of the SME projects. This section considers the EU added value in terms of effectiveness, efficiency and synergy – as well as project added value.

SC2 has clear additionality, supporting projects which otherwise would not have been implemented or which would have been substantially modified and smaller in scale and aims. Judging by the results of the project participant survey conducted by *PPMI* within the framework of the assessment of the Union added value and the economic impact of the EU research framework programmes[261], 4 out of 10 (42%) of SC2 projects would not have gone ahead without EU funding. An additional 32% would have gone ahead in some form – but with significant modifications.

The share of SC2 projects which would not have been undertaken without Horizon 2020 is high and suggests that a discontinuation of funding would have serious negative impacts on the scale of research being undertaken in the areas covered by SC2. However, the share of SC2 projects which would not be undertaken is lower than the average for all the projects funded under Horizon 2020 (53%) and is lower than the equivalent numbers for other societal challenges (which vary between 43% and 64%). In total, one of four SC2 projects (26%) is estimated to be a "project deadweight" – i.e. projects which would have gone ahead with small or no modifications without Horizon 2020 funding. This number is significantly higher than average results for Horizon 2020 (14%) and for all of the other SCs (between 7 and 18%).

SC2 project additionality is highest for RIA and CSA projects with close to all surveyed projects stating that they would not have gone ahead without EU funding. In contrast it is low for SME projects. SC2 projects which would have gone ahead anyhow are nearly all SME-1 projects. Overall, every second SME 1 project (50%) would, according to the survey results have gone ahead with none or minor modifications without Horizon 2020 funding. Nearly all of the remaining SME 1 projects would also have gone ahead, but with significant modification - as would all of the SME-2 projects. Only 1 of the 23 surveyed SME projects would not have gone ahead at all. The share of SC2 SME "deadweight" projects is much higher that SME deadweight in Horizon 2020 in general (only 27% would have gone ahead anyhow, vs. 50% for SC2).

Project additionality of SC2 – understood as not being able to implement the project without SC2 or only with substantial modifications - is explained principally by three main factors:

[261] *The report by PPMI is not published at this point of time.*

inability to address pan-European issues via other funding mechanisms, non-availability of funding at the scale needed for the project and lack of alternatively funding sources for the type of activities undertaken by the project, with stakeholders and project partners generally highlighting the uniqueness of the research and/or research related activities at an EU level.

For projects which would have been subject to significant modifications – such modifications would principally have related to: the scope of the project (fewer areas, subjects or the ambition of its objectives) and the time frame (longer time frame).

K.7.1. Horizon 2020 projects demonstrating EU Added Value

The following three projects have clearly demonstrated a potential for providing significant EU Added Value:

ERA-HDHL is a ERA-NET Cofund in the field of nutrition and health supporting the JPI Healthy Diet for a Healthy Life (HDHL). The members of the JPI are working together to develop means to (1) motivate people to adopt healthier lifestyles (2) develop and produce healthy, high-quality, safe and sustainable foods and (3) prevent diet-related diseases. The project ensures EU added value by:

- **Synergy**: ERA-HDHL being dedicated to JPI HDHL, it will improve coordination and reduce the overlap between national and EU funding in relevant fields of research. Furthermore, coordination with the FACCE-JPI is planned and further activities to coordinate and seek synergies with other European initiatives are expected as part of the complementary project CSA project CSA JPI HDHL 2.0.
- **Efficiency**: The 19 public funding organisations participating in ERA-HDHL consortium have committed a total of EUR 12,51 million for the cofunded call. This commitment has doubled from 2014 when the first co-funded call on Biomarkers in Nutrition and health was launched.
- **Effectiveness**: ERA-HDHL aims to provide a robust platform for implementing Joint Funding Actions addressing the research challenges identified and described and agreed by the members of the JPI. As such ERA-HDHL will help ensuing critical mass and better use of limited resources.

CERES is a RIA project dedicated to advancing the understanding of how climate change influences important fish and shellfish resources in Europe and the economic activities depending on them. The project EU added value relate to:

- **Effectiveness**: CERES will provide industry tools and develop adaptive management strategies allowing fisheries and aquaculture sectors and their governance to anticipate and prepare for adverse changes or future benefits of climate change. A key innovative aspect is to assess where the adverse impacts of climate change can produce opportunities for new aquaculture production systems and profitable changes to fisheries.
- **Efficiency:** CERES focus on 32 commercially important species groups which collectively span the whole of the European territorial seas from the Mediterranean to the high Arctic and inland waters from Turkey/Romania to the north of Scotland and Norway.
- **Synergy:** CERES plan close collaboration with industry and policy stakeholders to provide regionally and industry relevant, future projections of key environmental variables for European marine and freshwater ecosystems; to assist in the adaptation of

aquatic food production industries, to apply innovative risk-assessment methodologies and to formulate policy guidelines and recommendations.

REFRESH is a RIA project focusing on the reduction of food waste and improved valorisation of food re-sources. The project ensures EU added value by:

- **Effectiveness:** building on research into the drivers of food waste the project takes an innovative, systemic approach to curbing food waste through practice oriented collaborative platforms and pilot projects. Knowledge from research are turned into actions – via reports, advising, and tools to encourage better decision-making.
- **Synergy:** the project will develop strategic agreements to reduce food waste with governments, business and local stakeholders in four pilot countries (ES, DE, HU and NL). Building on this experience the project will develop guidance and recommendations to EU and national legislators and policy makers to help support effective governance to tackle food waste and national implementation of food waste policy frameworks
- **Efficiency**: the project engages a multi-faceted consortium (universities, research institutes, businesses, governments, civil society etc.) allowing direct application of theory in practice.

K.7.2. Lessons learnt/Areas for improvement

Overall, there is strong qualitative and quantitative evidence of added value of the SC2 programme. Project additionality is strong.

The main elements of EU added value of SC2 are as follows:

- Supporting the development and deepening of collaboration between partners which would not have been possible without EU funding.
- Developing research capacity. SC2 project funding contributes positively to understanding and knowledge in existing as well as new areas, scientific capabilities, technological capabilities and access to infrastructure and equipment.
- Supporting HR capacity. Participation in Horizon 2020 SC2 seems to have a positive impact on institutions' ability to attract researchers and other staff – as well as on development of relationships and networks, training capacity, researcher mobility and career development.
- Quicker delivery of project results. 4 out of 10 SC2 project coordinators surveyed (41%) indicated that project delivery would have been slower had it been funded by national or regional public funds.
- Leverage of resources for follow up activities and/or spill over effects. A clear majority of SC2 project coordinators report that participation in Horizon 2020 will impact positively on access to other public funding opportunities for similar activities, EU as well as national (Public national/regional schemes; other EU programmes and private/industrial sources). Importantly also, project funding appears to leverage additional "in house" R&D funding from many Non SME projects.
- Overall, projects associate added value especially with the programme scope and focus (coverage of transnational challenges addressing societal needs). When prompted on different attributes of potential added value compared to national or regional project funding "ability to address the needs of EU citizens and other final users", "tackling global challenges", "transfer of technology and knowledge", and "delivery outputs

targeting policy making" stand out (together with reputation and image) as the areas where the EU funding makes the biggest difference.

- More than two thirds of the commercially oriented SC2 projects consider Horizon 2020 to improve/has the potential to improve the partners' competitive advantage. The expected improvement mainly relates to access to new markets and the competitive position of partners internationally.
- At a policy level, SC2 provides structure and reference for the development of national research programmes, creating synergy and ensuring complementary in the research funding.

However, these effects can mainly be observed for RIA, IA, CSAs and ERA-Net Cofunds, There is less evidence of the added value of the SME projects.

K.8. SUCCESS STORIES FROM PREVIOUS FRAMEWORK PROGRAMMES

The selected (collaborative) projects were chosen based on the mapping experience, and/or based on the analysis of their outcomes. For example, MultiHemp project was selected as it exhibits extremely versatile project teams with experiences from agriculture, pharmaceutical, construction … and they perform great in terms of the outcomes (Publication, web pages, dissemination). Similar criteria were used at other successful projects as well.

LipiDiDiet: Therapeutic and preventive impact of nutritional lipids on neuronal and cognitive performance in aging, Alzheimer's disease and vascular dementia (Budget: EUR 5,899,843.00; Project period: 08/2008 - 03/2015)

The FP7 funded project LipiDiDiet has researched and developed a nutrition-based approach to reducing the risks of dementia including Alzheimer's, slowing down the progression of the disease and stabilising cognitive performance in aging. This is a very relevant public health issue: around 47 million people live with dementia worldwide, which is projected to increase to over 131 million by 2050. The economic cost of dementia is estimated to increase from US$818 billion worldwide today to become a trillion dollar disease by 2018 (World Alzheimer Report 2016). Based on extensive multi- and inter-disciplinary research, the LIPIDIDIET project has led to comprehensive dietary guidance which addresses specific issues including dietary recommendations, novel foods, and modified foods, all contributing in a novel way to effective dementia management. The guidance includes specially targeted nutrition to help patients in nursing homes, clinics, and at home, as well as recommendations for healthy ageing and the well-being of the elderly in general. The impact is wide and varied. The project provides sound scientific data for the food industry and regulators for the assessment of health and nutrition claims, improving food quality/safety, and reducing socio-economic costs, and increasing Europe's competitiveness. In respect to commercialization of the results, a dietary product for human consumption has been made by an industrial partner (Danone) under the name „Souvenaid", which is effective in fighting pre-dementia Alzheimer's disease. The product has been used internationally, including outside of Europe, and it is expected that the use will further expand toward finding application for more disease stage or more disease over time.

LIFECYCLE: Building a biological knowledge-base on fish lifecycles for competitive, sustainable European aquaculture (Budget: EUR 5,995,801.00; Project period: 02/2009 - 07/2013)

LIFECYCLE researched the early development, growth and environmental adaptation of sea bass, sea bream, Atlantic salmon and rainbow trout. This addresses production problems

linked to abnormal larval development, skeletal deformities, poor growth and energy utilization, high mortality related to life stage transitions, poor environmental performance, and unwanted sexual maturation. The research resulted in a very large scientific impact with 106 academic papers, including many in high-impact general science journals that reach a wider academic audience. The project also provided a great example how aquaculture research can offer models in other areas of biological and medical sciences. LIFECYCLE supported the development of **Xelect Ltd** for the commercialisation of over 30 years of basic research made possible by continuous support from the UK Research Councils and the European Commission, the later through SEAFOODplus (FP6) and LIFECYCLE (FP7). Xelect has licensed genetic markers for superior meat yield in Atlantic salmon to SalmoBreed A/s and Landcatch Natural selection and several other license opportunities for this and other traits are currently under negotiation. An analytical method termed "**Smoltprobe**" has been established as a predictive tool in the assessment of smolt quality. The work has involved two of the major international salmon producing companies (Lerøy Seafood A/S and Marine Harvest A/S) and the Smoltprobe has been tested and evaluated in two commercial smolt producing operations. The Smoltprobe helps prediction of the correct timing of transfer to seawater, and to detect problems arising from poor freshwater quality and desmoltification (loss of smolt status).

MaCuMBA: Marine Microorganisms: Cultivation Methods for Improving their Biotechnological Applications (Budget: EUR 8,999,948.00; Project period: 08/2008 - 07/2016)

MaCuMBA has discovered marine microbes that can help in mitigating climate change, control disease and generate alternative energy sources. The project also solved problems in isolating and growing them. Besides the excellent scientific publication record, MaCuMBA: produced four major collections of key isolated strains; developed a Knowledge Management and Transfer Methodology (KMTM) based on a tried and tested Knowledge Management methodology developed by **MaCuMBA** partner AquaTT, which focuses on Knowledge Outputs (KOs), units of knowledge that have been generated out of a scientific project, all made publicly available through means of the EurOcean Marine Knowledge Gate, available at www.kg.eurocean.org; produced "*The Marine Microbiome: An Untapped Source of Biodiversity and Biotechnological Potential*" published by Springer; and organised the *Marine Microbiome Discovery & Innovation* event organized in Berlin in27-30 June 2016 represented the culmination of the MaCuMBA project. MaCuMBA actively explores synergies with the other EU projects, Micro B3 and PharmaSea.

MultiHemp: Multipurpose hemp for industrial bioproducts and biomass (Budget: EUR 5,999,999.00; Project period: 09/2012 - 02/2017)

MultiHemp is a good example of the multidisciplinary project teams that EU-funded research is so good at developing, comprising experts in biology, biotechnology, plant production, pharmaceutical industry, civil engineering, textile industry. Traditionally cultivated for the fibres, seeds and psychoactive substances, hemp is well suited to producing innovative biomaterials. Its production has a relatively low impact on the environment. Cutting-edge genomic approaches were used to support genetic improvement in line with end-users requirements. Knowledge in relevant areas of plant biology and metabolic pathways and utilisation of state of the art molecular tools was extended. A modular biorefinery was developed with long blast fibres extracted for high value textiles while short bast fibres extracted for injection moulded bio-composites and insulation products. The woody shives are used for low-carbon construction materials. Oil is used for health and personal care applications, protein for food and feed, and high added value chemicals such as phytosterols,

waxes and essential oils. In parallel, innovative applications was developed for the by-products and side-products from processing routes including: dust from fibre processing, retting liquor from fibre degumming, flour from oil extraction, and residues from seed harvesting.

Open-Bio: Opening Bio-based Markets Via Standards, Labelling and Procurement (Budget: EUR 5,996,597.00; Project period: 11/2013 - 10/2016)

Open-Bio focused on standardization and labelling as a way to stimulate the uptake of bio-based products. The aim is to support informed procurement decisions especially in public procurement. The project ended in October 2016. Open-Bio developed methods to assess bio-based products and prepared them for standardisation. These included the determination of the total bio-based content of a product, its likely biodegradation in sea water, compostability and the extent to which it can be recycled. Several of the developed methods have been submitted to the European Committee for Standardization (CEN) and the International Standardization Organisation (ISO). Two have already been adopted, and several more are being finalised in cooperation with these bodies. Eventually the standardized methods help manufacturers to substantiate their claims about bio-based products and their related properties. The project also looked at consumers' understanding of the term 'bio-based'. To some, it means eco-friendly, bio-degradable or compostable, whereas others assume that there was biotechnology involved. The consortium explored how the EU's Ecolabel system might convey information about the bio-based content and related aspects and developed a proposal for a manageable, user-friendly approach to implement this issue. A database to support public procurement decisions was also designed and piloted internally in the project. The database will be developed in another project launched in March 2015.

K.9. LESSONS LEARNT/CONCLUSIONS

Based on the Expert Group's observations, the main conclusions are the following:

K.9.1. Relevance

- There is a clear scientific rationale for investing in R&I in the activity areas covered by SC2 and a strong justification and stakeholder support for a challenge based approach.
- A high policy relevance of SC2 in line with the EU's Bioeconomy strategy, the European Commission's policy agenda and major polices such as the CAP and the CFP could be achieved.
- SC2 has so far performed above average with regard to Commissioner Moedas 3-Os-Strategy.
- A high degree of relevance has been achieved due to the new, extensive and increasingly participatory Strategic Programming process.
- Main challenges that have been identified are:
    - The translation of high level challenges and objectives into specific call topics is not always clear;
    - Finding the right balance on project size, coverage of topics and between R&I;
    - Reconciling the perspectives of short to mid- term legislative and specific policy making tasks of policy DGs with a long term and systemic view on R&I.
- Further significant developments and novelties that have been identified are:
    - The development of Blue Growth as a distinct focus area;

- The focus on Sustainable Food Security (40% of resources);
- The creation of the BBI-JU, developing new integrated value-chains;
- The new multi-actor approach, increasing users' involvement and uptake.

K.9.2. Effectiveness

- It is too early for significant evidence of outputs and effects (so far all RIA and IA projects are still on-going). However, there are several examples of promising projects with potential impacts on:
  - The development of low-carbon, resource-efficient and competitive European agri-food and bio-based industries;
  - Improved competitiveness, resilience and sustainability of European agriculture and forestry sector;
  - Reduced greenhouse gas emissions;
  - Improved food security and safety;
  - Oceans observation and mapping, sustainable and smart use of marine resources;
  - Higher growth and employment.
- The SME Instrument projects funded have shown the following prospective impacts:
  - 55 SME Phase I projects are expected to generate EUR 1.5 billion of additional turnover and over 1500 jobs over the next three years;
  - 26 SME Phase II projects are likely to deliver EUR 1 billion of additional turnover over next five years and over 1000 jobs over the next three years;
  - Positive, indirect impacts (supply chain and multiplier effects) may increase the economic impact further.
- Some of the most significant achievements of SC2 are the following:
  - Setting up of the BBI JU
  - Strategic international cooperation, e.g. Atlantic Ocean Research Alliance;
  - Very significant technological advances – Mainly higher Technology Readiness Levels (TRL) 5 and above
  - 42% of the funded projects are expected to contribute to research excellence i.e. breakthrough research
  - 1/3 of the projects are expected to contribute to strengthening Europe's research skill base.

K.9.3. Efficiency

- The thematic allocation of funding very close to what was envisaged.
- The programme has been efficient in attracting newcomers (22% in SC2 calls, 84% in SME topics, 34% in BBI). Although there is still room for further improvement in widening participation from new Member States.
- Programme management has shown to be efficient, albeit coordination arrangements with multiple DGs, co-management with DG AGRI and programme implementation across three executive agencies (REA, INEA, EASME) has been resource intensive.
- The delegation of programme management activities to REA has been smooth and included specific mechanisms for close interactions with the parent-DGs.
- The provision of feedback to policy making and dissemination might still deserve further attention.

- Horizon 2020 simplifications additionally improved efficiency and two-stage evaluation schemes helped to improve the overall success rate.

K.9.4. Coherence

- Strong internal coherence of SC2 has been achieved through:
    - a coherent and complementary choice of funding instruments;
    - an appropriate thematic allocation of funding and links between SC2 and other parts of the programme (particularly other SCs and LEIT).
- External coherence of SC2 is marked by a high degree of coherence, complementarity and synergies with other EU policies, particularly the CAP, the CFP, maritime and climate policies.
- The ERA-Net co-fund actions generate a structuring effect and ensure coherence between EU and national research funding programmes.

K.9.5. EU Added Value

- Overall, there has been strong qualitative and quantitative evidence of the added value of the SC2 programme. That includes:
    - High project additionality (42% of SC2 projects would not have gone ahead without EU funding while 32% would have gone ahead with significant modifications.);
    - The development of research capacities and the deepening of collaboration between partners which would not have been possible without EU funding.

The provision, at policy level, of structure and reference for the development of national research programmes, creating synergy and ensuring complementary in the research funding.