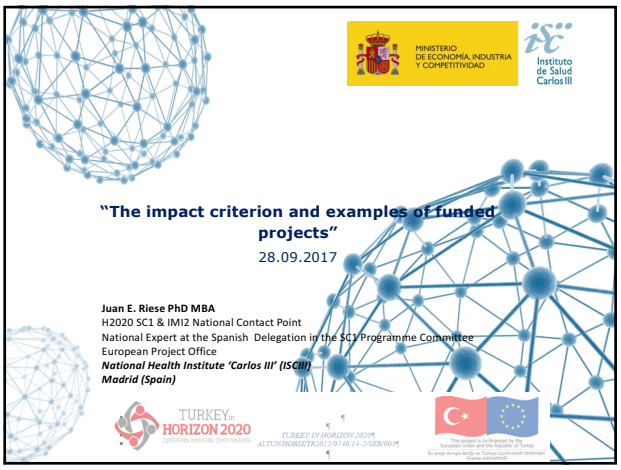
MINISTERIO DE ECONOMÍA, INDUSTRIA Y COMPETITIVIDAD
Instituto de Salud Carlos III
"The impact criterion and examples of funded projects"
28.09.2017
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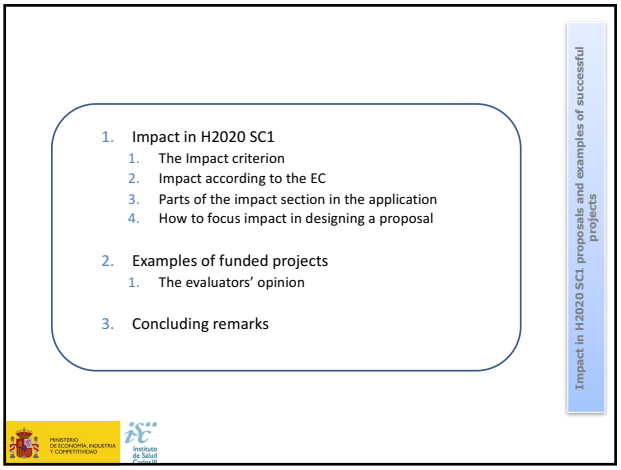
1. Impact in H2020 SC1
1. The Impact criterion
2. Impact according to the EC
3. Parts of the impact section in the application
4. How to focus impact in designing a proposal
2. Examples of funded projects
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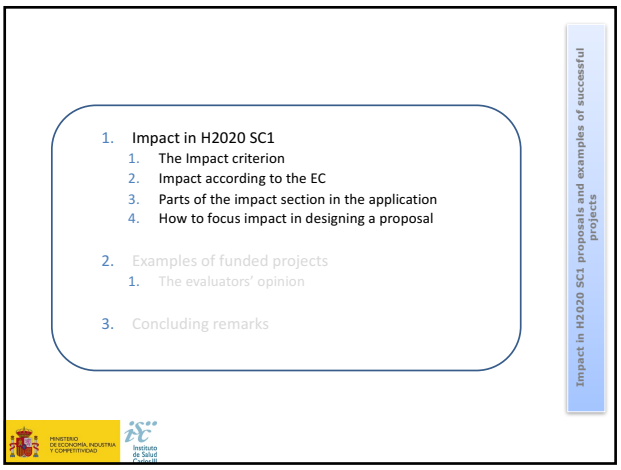
Impact in H2020 SC1 proposals and examples of successful projects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Evaluation criteria

Excellence

- Clarity and pertinence of the objectives
- Soundness of the concept, including trans-disciplinary considerations, where relevant
- Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art (e.g. ground-breaking objectives, novel concepts and approaches)
- Credibility of the proposed approach

Impact

- The expected impacts listed in the work programme under the relevant topic
- Enhancing innovation capacity and integration of new knowledge
- Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets
- Any other environmental and socially important impacts (not already covered above)
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant

Implementation

- Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks and resources
- Complementarity of the participants within the consortium (when relevant)
- Appropriateness of the management structures and procedures, including risk and innovation management

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Source: definitive draft (sept. 2017)

Standard scheme of a topic in WP SC1 2018-2019-2020

SC1-BHC-01-2019: Understanding causative mechanisms in co- and multimorbidities

Specific Challenge: The increasing number of individuals with co-and multimorbidities poses an urgent need to improve management of patients with multiple co-existing diseases. A better understanding of their causative mechanisms is needed to develop early diagnosis, efficient prevention and monitoring, and better treatments adapted to co- and multimorbid patients throughout their life course. Furthermore, there are many different etiological models of comorbid conditions (e.g., direct causation model or a consequence of treatment). In this context, capturing and measuring patient's complexity in the context of co- and multimorbidities is crucial for adequate management of these conditions and requires innovative approaches.

Scope: Proposals should identify and validate causative mechanisms (e.g. molecular, genetic, correlative, drug-drug interaction) combining mental and physical disorders through the integration of basic, pre-clinical and/or clinical research[1]. Applicants should prove the relevance of the identified mechanisms for its morbid development. Where pertinent, development of biomarkers and other technologies for diagnosis and monitoring of comorbid conditions in patients is encouraged. A purposeful exploitation of existing data, biobanks, registries and cohorts is expected[1], but does not exclude generation of new data. Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration. SME participation is strongly encouraged.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- New directions for clinical research to improve prevention, diagnosis, prognosis, therapy development, and management of co- and multimorbidities.
- Whenever relevant, identified biomarkers for more accurate and earlier diagnosis, prognosis as well as monitoring of patients' condition.

Type of Action: Research and Innovation action

The conditions related to this topic are provided at the end of this call and in the General Annexes.

DRAFT

[1] Clinical trials are excluded

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Source: definitive draft (sept. 2017)

Another example of Impact section in a topic from WP SC1 2018-2019-2020

SC1-BHC-19-2019: Implementation research for maternal and child health

- 'Implementation Research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on healthcare professional and organisational behavior.

- **Expected impact:**
  - Research-supported solutions to maternal and child health challenges.
  - Providing evidence of successful and/or innovative approaches for bridging the ''knowledge-do'' gap in improving maternal and child health.
  - Better understanding of scaling-up processes with regard to different contexts and resource requirements.
  - Contribution to the achievement of SDGs* 2 on improved nutrition (target 2), Goal 3 on health (targets 1 and 2 on maternal and child health) and Goal 5 on gender equality (targets 1 and 6) and Goal 10 (on reducing inequality within and between countries).

*: Sustainable Development Goals: http://www.un.org/sustainabledevelopment/health/

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Part B of a research project application

1. Excellence (science and technology)
2. Impact
3. Quality and Efficiency of the Implementation
4. Members of the Consortium
5. Ethics and Security Issues

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Expected impact on

- Related to the impact indication in the work programme
- Enabling and improving innovation capacities (new knowledge, knowledge transfer, evidence based policy making, policy innovations) EU-level!!!
- Barriers/obstacles/assumptions/risks (at market/society level, not at project level)

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Measures to maximize impact

- Dissemination and exploitation of R&D results
- Transfer of R&D results
- Sustainability of impact?
- Knowledge management strategy (data management, IPR?, open access!)

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Clarifying definitions

1. **Dissemination is the public disclosure of the results of the project in any medium.** Disclosure may sound passive, like a shop opening up, but it is an activity, like a shopkeeper attracting customers. It is a process of promotion and awareness-raising right from the beginning of a project. It makes research results known to various stakeholder groups (like research peers, industry and other commercial actors, professional organisations, policymakers) in a targeted way, to enable them to use the results in their own work. This process must be planned and organised at the beginning of each project, usually in a dissemination plan.

2. **Exploitation is the use of the results during and after the project's implementation.** It can be for commercial purposes but also for improving policies, and for tackling economic and societal problems.

3. **Communication** means taking strategic and targeted measures for promoting the action itself and its results **to a multitude of audiences**, including the media and the public, and possibly engaging in a two-way exchange. **The aim is to reach out to society as a whole** and in particular to some specific audiences while demonstrating how EU funding contributes to tackling societal challenges.

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Part B – Impact, of a research project application

Source: h2020-call-pt-ria-ia-2016-17_en_TEMPLATE

2. Impact

2.1 Expected impacts

Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, use quantified indicators and targets.

- Describe how your project will contribute to:
  - each of the expected impacts mentioned in the work programme, under the relevant topic;
  - any substantial impacts not mentioned in the work programme, that would enhance innovation capacity; create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits for society
- Describe any barriers/obstacles, and any framework conditions (such as regulation, standards, public acceptance, workforce considerations, financing of follow-up steps, cooperation of other links in the value chain), that may determine whether and to what extent the expected impacts will be achieved. (This should not include any risk factors concerning implementation, as covered in section 3.2.)

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

- Provide a draft '**plan for the dissemination and exploitation of the project's results**'. Please note that such a draft plan is an admissibility condition, unless the work programme topic explicitly states that such a plan is not required.

  Show how the proposed measures will help to achieve the expected impact of the project.

  The plan, should be proportionate to the scale of the project, and should contain measures to be implemented both during and after the end of the project. For innovation actions, in particular, please describe a credible path to deliver these innovations to the market.

Impact in H2020 SC1 proposals and examples of successful projects

Part B – Impact, of a research project application (II)

Source: h2020-call-pt-ria-ia-2016-17_en_TEMPLATE

Your plan for the dissemination and exploitation of the project's results is key to maximising their impact. This plan should describe, in a concrete and comprehensive manner, the area in which you expect to make an impact and who are the potential users of your results. Your plan should also describe how you intend to use the appropriate channels of dissemination and interaction with potential users.

Consider the full range of potential users and uses, including research, commercial, investment, social, environmental, policy-making, setting standards, skills and educational training where relevant.

Your plan should give due consideration to the possible follow-up of your project, once it is finished. Its exploitation could require additional investments, wider testing or scaling up. Its exploitation could also require other pre-conditions like regulation to be adopted, or value chains to adopt the results, or the public at large being receptive to your results.

- Include a business plan where relevant.
- As relevant, include information on how the participants will manage the research data generated and/or collected during the project, in particular addressing the following issues:
  - What types of data will the project generate/collect?
  - What standards will be used?
  - How will this data be exploited and/or shared/made accessible for verification and re-use? If data cannot be made available, explain why.
  - How will this data be curated and preserved?
  - How will the costs for data curation and preservation be covered?

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Part B – Impact, of a research project application (III)

Source: h2020-call-pt-ria-ia-2016-17_en_TEMPLATE

As of the Work Programme 2017 actions under Horizon 2020 participate in the 'Pilot on Open Research Data in Horizon 2020, except if indicated otherwise. Once the action has started (not at application stage) those beneficiaries which do not opt-out, will need to create a more detailed Data Management Plan for making their data findable, accessible, interoperable and reusable (FAIR).[2]

You will need an appropriate consortium agreement to manage (amongst other things) the ownership and access to key knowledge (IPR, research data etc.). Where relevant, these will allow you, collectively and individually, to pursue market opportunities arising from the project's results.

The appropriate structure of the consortium to support exploitation is addressed in section 3.3.

- Outline the strategy **for knowledge management and protection**. Include measures to provide **open access** (free on-line access, such as the 'green' or 'gold' model) to peer-reviewed scientific publications which might result from the project[3].

Open access publishing (also called 'gold' open access) means that an article is immediately provided in open access mode by the scientific publisher. The associated costs are usually shifted away from readers, and instead (for example) to the university or research institute to which the researcher is affiliated, or to the funding agency supporting the research. Gold open access costs are fully eligible as part of the grant. Note that if the gold route is chosen, a copy of the publication has to be deposited in a repository as well.

[2] Opting out of the Open Research Data Pilot is possible, both before and after the grant signature. For further guidance on open research data and data management, please refer to the H2020 Online Manual on the Participant Portal.

[3] Open access must be granted to all scientific publications resulting from Horizon 2020 actions (in particular scientific peer reviewed articles). Further guidance on open access is available in the H2020 Online Manual on the Participant Portal.

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Part B – Impact, of a research project application (and IV)

Source: h2020-call-pt-ria-ia-2016-17_en_TEMPLATE

Self-archiving (also called 'green' open access) means that the published article or the final peer-reviewed manuscript is archived by the researcher - or a representative - in an online repository before, after or alongside its publication. Access to this article is often - but not necessarily - delayed ('embargo period'), as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download/view fees during an exclusivity period

b) Communication activities[4]

- Describe the proposed communication measures for promoting the project and its findings during the period of the grant[5]. Measures should be proportionate to the scale of the project, with clear objectives. They should be tailored to the needs of different target audiences, including groups beyond the project's own community. Where relevant, include measures for public/societal engagement on issues related to the project.

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Writing an 'exploitation/business plan'

Include a business plan where relevant

Business Models:

Key partners: Think about the motivation of partnerships!

- Who are you key partners, key suppliers?
- Which resources do need from them?
- Which key activities will they perform?
- Which value do we deliver to the customer?
- Which of our customer's problems are we helping to solve?
- Which customer needs are we satisfying?

Please notice:
- Dissemination: Towards professionals
- Communication: Towards society

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About the 'Business Plan'

Due to space limitation and following the recommendations from the EC (Document "Clarification for NMP+B project proposers and evaluators on "Business Plan" and "Synergies with ESIF"), only key aspects of the business plan can be briefly presented and main projections could be focused on total potential market in Europe and other major markets.

It is also important to highlight that the full exploitation of results goes beyond economic and commercial value-making process, and also includes generation of inputs for future research, creation of novel norms and standards, innovative practices for the whole sector, etc..

Parts of the 'Business Plan' (be clear, support on facts and data, make well-based realistic projections, illustrate the evaluators with tables) 5-7 pages in part B

- Title: Outline of business plan
- Planned key exploitable results and their expected key areas of applications
- Description of the relevant market
- Business model: production/commercialisation by an involved SME? Direct selling? Licensing? Who will be in charge?
- Financial projections
- Commercialization roadmap
- Risk assessment
- Eventually: Alternative funding, sustainability

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2 examples of successfully evaluated projects (call H2020 SC1 2017)

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SC1-PM-10-2017:Comparing the effectiveness of existing healthcare interventions in the adult population (I)

Specific Challenge: Effective health care and prevention may be improved by additional evidence as to the most effective health interventions. Growing numbers of patients affected by chronic diseases also call for efficiently managing co-morbidities.

Scope: Proposals should compare the use of currently available preventative or therapeutic (pharmacological as well as non-pharmacological) healthcare interventions in adults[19]. While there is no restriction on the diseases or interventions to be the focus of proposals, preference will be given to proposals focusing on interventions with high public health relevance and socio-economic impact, i.e. interventions addressing conditions that are particularly frequent, may lead to co-morbidities, have a high negative impact on the quality of life of the individual and/or are associated with significant costs or where savings can be achieved. A cost effectiveness analysis must be included. Given the focus on existing interventions, proposals will aim to contribute to improve interventions, take decisions about the discontinuation of interventions that are less effective or less cost-effective than others, and make recommendations on the most effective and cost-effective approaches. A comprehensive array of clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health systems) for chosen populations should be assessed. Agreed core outcome sets (COS) should be used as endpoints in conditions where they already exist, in other cases efforts should be made to agree on such COS. Randomised controlled trials, pragmatic trials, observational studies, large scale databases and meta-analyses may be considered for this topic. Where relevant the study population should address gender as well as socio-economic differentials in health and/or any other factors that affect health equity.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

[19] Screening and / or the involvement of elderly populations are not excluded.

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SC1-PM-10-2017:Comparing the effectiveness of existing healthcare interventions in the adult population (II)

Expected Impact: This topic is to provide the required evidence base for:

- more effective and safer interventions at individual and population level;
- enhanced compliance with healthcare interventions in the adult population;
- the use of health technology assessment methodology in this target group.

In particular:

- Improvement of individual patient outcomes and health outcome predictability through tailoring of interventions.
- Improvement of guideline development for prevention or treatment of diseases and the management of comorbidities.
- Provision of more accurate information to patients, caregivers and prescribers.

Type of Action: Research and Innovation action

The conditions related to this topic are provided at the end of this call and in the General Annexes.

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SC1-PM-10-2017: Comparing the effectiveness of existing healthcare interventions in the adult population (II)

Expected Impact: This topic is to provide the required evidence base for:

- more effective and safer interventions at individual and population level;
- enhanced compliance with healthcare interventions in the adult population;
- the use of health technology assessment methodology in this target group.

In particular:

- Improvement of individual patient outcomes and health outcome predictability through tailoring of interventions.
- Improvement of guideline development for prevention or treatment of diseases and the management of comorbidities.
- Provision of more accurate information to patients, caregivers and prescribers.

Type of Action: Research and Innovation action

The conditions related to this topic are provided at the end of this call and in the General Annexes.

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Success Example 1 to Topic SC1-PM-10-2017
Proposal abstract

The present proposal aims to identify, compare, and rank the most effective and cost-effective self-management interventions (SMIs) for adults in Europe within four high-priority chronic conditions: type 2 diabetes, obesity, chronic obstructive pulmonary disease, and heart failure. This project addresses an important gap in current knowledge applying network meta-analysis, an extension of meta-analysis methodology that allows multiple (rather than pairwise) comparisons of intervention effectiveness, to randomised controlled trials (RCTs) that meet the study inclusion criteria. This centralised analysis of an estimated 4000 RCTs will substantially help to overcome current problems associated with the dispersion and duplication of evidence. The work will be based on a validated taxonomy of SMIs and will prioritise outcomes from the patients' perspective. In addition, a cost-effectiveness of the most effective SMIs will be estimated to provide insights into the economic consequences of adopting SMIs for societies, healthcare budgets, and patients. Contextual factors associated with successful interventions will also be studied. Drawing on our results, we will develop and pilot decision-making tools to facilitate access to evidence-based information on the most effective SMIs to key users through a user-friendly interactive platform. A multi-component strategy for exploitation of the research findings will lead to clear business cases for implementing it in different contexts within the heterogeneous EU health system. The end goal of the project is to have an impact in supporting policy-makers, guideline developers, researchers, industry, professionals and patients to make informed decisions on the identification and implementation of the most suitable SMIs, therefore contributing to the diffusion of the knowledge, healthcare sustainability and equity and promoting EU competitiveness in a globally emerging market

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ESR from proposal 1 – Call 2017 (First Criterion: Excellence)

Score: **4.50** (Threshold: 4/5.00 , Weight: -)

The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme:

- **Clarity and pertinence of the objectives**
- **Soundness of the concept, and credibility of the proposed methodology**
- **Extent that proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models)**
- **Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge**

The objectives are clear, well described and address a very important group of conditions with high public health relevance and socioeconomic impact as required by the call.

The concept is sound and the proposed work will go well beyond state of the art and open avenues for the application of improved approaches to utilisation of existing knowledge. The proposal lays the foundation for a standardised collection of evidence in a very structured and systematic way, covering the gaps of current knowledge and enabling advancement across all stages of the process. It is based on a holistic combination of research and involvement of the relevant stakeholders. Patients are actively involved, which is a strength.

There are some minor shortcomings. For example, the estimation that around n=4,000 RCTs would be retrieved is not sufficiently well supported. Some of the details of how the taxonomy will be modelled and built as a result of the analysis remain unclear. The same applies to the design of the decision support tool. The cost analysis is elaborated but lacks explanations how the benefits for the different stakeholders will be modelled.

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ESR from proposal 1 – Call 2017 (2nd Criterion: Impact)

Score: **4.50** (Threshold: 4/5.00 , Weight: -)

The following aspects will be taken into account:

The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic.

Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits for society.

Quality of the proposed measures to:

- **exploit and disseminate the project results (including management of IPR), and to manage research data where relevant**
- **communicate the project activities to different target audiences**

All call topic impacts are addressed very well and the proposal describes in a credible way how they will be reached. Key performance indicators for the measures to reach the impact are provided and achievable. The communication activities are original and appropriate, innovation management, preliminary business model, SWOT analysis and sustainability are also very well addressed. Overall, the plans for dissemination and exploitation are excellent.

Some minor shortcomings should be noted:

The results of the proposed work will also have to translate into behavioural changes of all stakeholders and there is insufficient information about how this is expected to happen.

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ESR from proposal 1 – Call 2017 (3rd Criterion: Implementation)

Score: **4.00** (Threshold: 3/5.00 , Weight: -)

The following aspects will be taken into account:

- **Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables**
- **Appropriateness of the management structures and procedures, including risk and innovation management**
- **Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise**
- **Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role**

The consortium composition and the responsibilities are adequately explained. The work plan is very complex and features series of analyses of data, with a logical flow between work packages. There is good complementarity between participating partners and the task allocation is appropriate. The IP issues receive appropriate attention in a dedicated task.

Some concerns about the implementation of the plan and its monitoring need to be mentioned:

There are multiple tasks for data mining activities, analysis, interpretation, and modelling of vast amounts of data and these tasks are highly interdependent. With this structure the risk of negative cascading effects seems high. The necessary monitoring of the smooth flow between tasks is not sufficiently addressed. The risks of delays appear underestimated and the contingency plans are not convincingly presented.

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SC1-PM-08-2017: New therapies for rare diseases (I)

SC1-PM-08–2017: New therapies for rare diseases

Specific Challenge: Rare diseases are diseases which affect not more than 5 per 10 000 persons in the European Union, as defined in the context of the EU legislation. A considerable amount of knowledge has been generated by biomedical research in recent years, yet most of the 6 000 to 8 000 rare diseases are lacking therapies despite many of these diseases being life-threatening or chronically debilitating.

Specific problems posed in therapy development for rare diseases include the small and dispersed patient populations and the nature of the therapies proposed, which are often highly specialised and novel. Amongst other challenges, this leads to the requirement for seeking early advice of regulatory authorities during development. In addition, despite the special incentives for the development of orphan medicinal products, and the often high prices of some of the developed therapies, the limited market for such therapies lead to a low commercial return, and/or limited access.

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SC1-PM-08-2017: New therapies for rare diseases (II)

Scope: Support will be provided to clinical trials on substances where orphan designation has been given by the European Commission, where the proposed clinical trial design takes into account recommendations from protocol assistance given by the European Medicines Agency, and where a clear patient recruitment strategy is presented. Clinical trials may focus on a range of interventions with an orphan designation, from small molecule to gene or cell therapy, may include novel interventions and/or repurposing of existing and known interventions. The intervention must have been granted the EU orphan designation at the latest on the date of the full proposal call closure. A concise feasibility assessment justified by available published and preliminary preclinical or clinical results and supporting data shall also be provided. Appropriate plans to engage with patient organisations, Member States health authorities and considerations of efficacy/potential clinical benefit as well as early indication on health economics should be integrated in the application. In addition to the clinical trial, proposals may also include limited elements of late stage preclinical research and/or experimental evaluation of potential risks which must be complementary/contribute to the clinical trial(s) carried out within the proposal. The centre of gravity must clearly be the clinical trial(s). The participation of SMEs is encouraged.

Selected proposals shall contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC (www.irdirc.org).

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

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SC1-PM-08-2017: New therapies for rare diseases (III)

Expected Impact: • In line with the objectives of the Union pharmaceutical legislation on orphan medicinal products, proposals shall contribute to advance the development of new therapeutic options with concrete benefits for patients living with rare diseases.

• Rapid progress in orphan drug development due to well-prepared clinical trials and a multinational multicentre clinical trial with an appropriate number of patients.

• Develop a preliminary assessment of the potential economic and public health aspects of the new therapeutic option.

• Contribute to growth of SMEs involved in drug development.

• In line with the Union's strategy for international cooperation in research and innovation, proposals shall contribute towards IRDiRC objectives.

Type of Action: Research and Innovation action

The conditions related to this topic are provided at the end of this call and in the General Annexes.

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Success Example 2. Topic SC1-PM-08-2017
Anonymised Proposal abstract

Disease X is a rare brain cancer with one of the highest mortality rates. It is considered an orphan disease due to its low prevalence (less than 0.5 cases per 10,000 inhabitants in the EU) and the lack of plausible therapies. Based on the discovery of the XXXXXXX the SME XYZ (leading this application) defined a novel anticancer drug target, molecule X. An innovative activator, DrugA , was designed and showed safety and efficacy in preclinical and preliminar clinical studies. A first-in-man clinical trial I/IIa (ClinicalTrials.gov identifier #) further demonstrated its safety and efficacy in humans. The European Medicines Agency (EMA) designated DrugA orphan drug for the treatment of this specific brain cancer and approximately half of the patients wsubmitted to >2 months of treatment showed positive response.

The present project aims to perform a clinical phase IIB study to demonstrate DrugA efficacy against brain cancer, in its most aggressive form. In this context, a written formal report from the EMA after scientific advice and protocol assistance (aaaaaa2014) indicates that DrugA would obtain Conditional Marketing Authorisation if this phase-IIB study further demonstrates statistically significant efficacy. In addition this project will further investigate DrugA safety, mechanism of action and biomarkers for diagnosis, prognosis and response to treatment. These studies will let us (i) know the molecular basis underlying the response to DruGA treatment, (ii) define new biomarkers, (iii) design more efficacious personalized treatments and (iv) investigate therapeutic alternatives in patients who do not respond to treatment.

Impact in H2020 SC1 proposals and examples of successful projects

MINISTERIO DE ECONOMÍA, INDUSTRIA Y COMPETITIVIDAD

Instituto de Salud Carlos III

ESR from proposal 2 – Call 2017 (First Criterion: Excellence)

Score: **4.00** (Threshold: 4/5.00 , Weight: -)
The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme:

- **Clarity and pertinence of the objectives**
- **Soundness of the concept, and credibility of the proposed methodology**
- **Extent that proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models)**
- **Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge**

1. The objectives of the proposal are clear and pertinent to the call.
2. The scientific concept seems sound and credible with relevant data provided that are supported by preclinical and an initial phase I/IIA clinical trial. The proposed methodology seems less credible, as a preclinical evaluation of the impact of the product formulation (which is not specified in detail) versus pure molecule (Ref. in , Biochim Biophys Acta. reports different activities of the R and S enantiomers on the proposed target) nor the pharmacokinetics of the 2 enantiomers has been discussed in the proposal. The project could be too ambitious as it aims to perform dose optimization, subpopulation identification, as well as biomarker determination.
3. The innovation potential is clear, with a new drug target discovered using an innovative therapeutic approach and a new mechanism of action.
4. The interdisciplinary content of the proposal is good and highlighted by a well-constructed network. The use of stakeholders' knowledge such as patient organizations is only mentioned in a generic manner.

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ESR from proposal 2 – Call 2017 (2nd Criterion: Impact)

Score: **4.50** (Threshold: 4/5.00 , Weight: -)
The following aspects will be taken into account:
The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic.
Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits for society.
Quality of the proposed measures to:

- **exploit and disseminate the project results (including management of IPR), and to manage research data where relevant**
- **communicate the project activities to different target audiences**

1. The outputs of the proposal would contribute to the expected impacts mentioned in the work program, although the benefit of the new drug for patients in terms of life expectancy and quality of life is not clearly described in the proposal. It will contribute to rapid progress in drug development, thus contributing to IRDiRC goals. Moreover, the proposal presents a preliminary assessment of the potential economic and public health aspects.
2. It will strengthen the innovation capacity and improve the growth prospect of the SMEs involved in the consortium, therefore generating a positive impact on their future development. The project might also have an important societal impact.
3. The dissemination plan and communication strategy seem appropriate, although it should have listed a more detailed and direct link between the communication channels and the communication aims targeted to various audiences.

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ESR from proposal 2 – Call 2017 (3rd Criterion: Implementation)

Score: **4.50** (Threshold: 4/5.00 , Weight: -)

The following aspects will be taken into account:

- **Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables**
- **Appropriateness of the management structures and procedures, including risk and innovation management**
- **Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise**
- **Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role**

1. The work plan is effective, with sufficient details broken down into work packages, individual tasks, detailed deliverables, and milestones, with two WP interfaces being central to the implementation of the project.
2. There is a good presentation of the project management structure with sufficiently described decision taking procedures, although it was somewhat felt that, given the complexity of the project and the clinical study design, a number of shortcomings were present in the discussion about risks with the proposed adaptive design, after regulatory feedback will have been obtained.
3. The consortium partners' expertise sufficiently complements each other in the project execution, having significant experience in different parts of the work plan.
4. All the participants seem to have a valid role in the project, being involved in most of its tasks, and the task allocation and the corresponding budget well justified.

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