TOPIC : Actions in support of the International Consortium for Personalised Medicine

Topic identifier: SC1-HCO-01-2018-2019-2020

Publication date: 27 October 2017

Types of action: CSA Coordination and support action

DeadlineModel: single-stage

Planned opening date: 26 July 2018 **Deadline:** 16 April 2019 17:00:00

Types of action: CSA Coordination and support action

DeadlineModel: single-stage

Planned opening date: 07 November 2017 **Deadline:** 18 April 2018 17:00:00

Time Zone : (Brussels time)

Horizon 2020 H2020 webs

Pillar: Societal Challenges

Work Programme Year: H2020-2018-2020

Work Programme Part: Health, demographic change and wellbeing

Call : H2020-SC1-BHC-2018-2020 Call budget overvi

Topic Description - Less

Specific Challenge:

Personalised Medicine is a very broad and multifaceted area where success relies on a well-functioning collaboration between several disciplines and different actors. While great advances have been made in some fields of medicine, in particular in stratification of cancer patients and in addressing rare diseases, most of today's healthcare protocols do not include personalised approaches apart from occasional division into broad age groups (children/adults/elderly), sex or ethnicity. Furthermore the prevention aspect of personalised medicine, i.e. identifying individuals prone to develop certain diseases, is largely isolated from treatment options. As is the case for a relatively nascent field there is a need for standardisation of approaches, including for sampling, data storage, interpretation and data exchange and also for clinical trials design and reimbursement models. European countries with their social model of healthcare along with (in several cases) centralised cost reimbursement, are ideally placed to lead the way for an integrated health management system. Many needs for coordination and support activities have been identified by ICPerMed[1], which includes representatives from most EU countries along with several other European countries and Canada. Also the wider internationalisation of ICPerMed can be underpinned by coordinating networking activities with third countries.

Scope:

Each action should focus on *one* of the following fields:

1. International aspect: The action should focus on building links with third countries by analysing the potential and advantages of collaboration in personalised medicine (PM) with those countries, studying areas of interest for Europe in PM collaboration and promoting international standards in the field. In particular the uptake of personalised approaches in health systems and healthcare should be addressed, taking into account social and cultural aspects, health economy issues and equitable healthcare. For the 2018 call, the project should focus on CELAC[2] as a group of countries, and for the 2019 call on China. Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least

2. Regional aspect: The action should establish and support networking between regions and interregional cooperation in different European countries, in particular linking remote or sparsely populated regions with regions harbouring critical mass of medical and PM expertise while taking into account broader socio-economic and cultural aspects. The focus of the action can include aspects of genomic analysis, me-Health (mobile and electronic Health), telemedicine etc. but should aim at structuring PM application at regional level. Linkage to existing inter-regional projects (financed by INTERREG programmes) or interregional partnerships of Thematic Smart Specialisation Platforms will be actively encouraged. (2018 call).
3. Healthcare- and pharma-economic models for personalised medicine, interlinking European public health approaches with medical practice and financing. The action should carry out studies in support of research in and development of new health- and pharma economic models for PM, including prevention, to capture value and to develop relevant health financing models. Analysing mid- and long-term impacts of innovative products designated for sub-sets of patient populations on the patients themselves and on public health systems. Assessing the benefits of personalised medicine development for citizens and their broader social environment while ensuring patient safety, access, equity, solidarity, data safety and financial sustainability of public health systems in the EU. The action should involve different relevant stakeholders and take into account work being carried out by other EU funded initiatives, such as EUnetHTA[3]. SME participation is encouraged. Results of the studies and workshops should be actively disseminated to a wider audience, including relevant authorities, professionals and the wider public. (2018 call).
4. Standardisation for clinical study design. Establishment of innovative clinical trial design methodology for PM, including guidelines for research and reflection papers. The action should take into account sex/gender differences as well as the work done by relevant stakeholders and authorities such as EMA[4] and the HMA network[5], as well as the European legal framework[6]. SME participation is encouraged. The results of the studies and workshops should be actively disseminated to a wider audience, including, industry, researchers and other professionals. (2019 call).

For grants awarded under this topic for Coordination and Support Actions it is expected that results could contribute to European or international standards. Therefore, the respective option of Article 28.2 of the Model Grant Agreement will be applied.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1.5 and 2 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:

Contributing to the implementation and reach of the ICPerMed initiative; furthermore:

1. International aspect: Integrating the country/group of countries into ICPerMed activities. Support wider adoption of standards developed in Europe. Contribute towards the UN Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.
2. Regional aspect: Strengthened links between European regions setting up or planning personalised medicine healthcare approaches. Aligning research funding with ongoing and foreseen investments e.g. from Structural Funds. Recommendations on best practice in implementing PM at regional level.
3. Healthcare- and pharma-economic models: Increased understanding of personalised medicine perspectives on how to capture value, develop institutional support and design relevant payment models. Recommendations for faster translation from discovery to patients'/citizens' access. Contributing to understanding of trends and dynamics in the pharmaceutical markets in relation to increased emphasis of research and development efforts on PM. Suggestions on how savings through prevention can be included in payment and reward models and contribute to the sustainability of public health systems in the EU. Improved knowledge and understanding among healthcare professionals and the wider public of potential benefits of PM approaches.
4. Standardisation for clinical study design: Contribute to standardisation of PM clinical trial design. Demonstrate feasibility and importance of PM approaches. Underpin accelerated market uptake. Improved knowledge and understanding among healthcare professionals, regulatory authorities and industry how best to adapt clinical trials designs to stratified patient populations.

Delegation Exception Footnote:

Cross-cutting Priorities:

Socio-economic science and humanities
International cooperation
Gender

[1]International Consortium for Personalised Medicine; http://icpermed.eu

[2]Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Grenada, Guyana, Jamaica, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Lucia, Saint Kitts and Nevis, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay,Venezuela

[3]European Network for Health Technology Assessment: http://www.eunethta.eu/

[4]European Medicines Agency: www.ema.europa.eu

[5]Heads of Medicines Agencies: http://www.hma.eu/

[6]Especially the clinical trials regulation (EU) No 536/2014 and the data protection regulation (EU) 2016/679

Topic conditions and documents

- Less

1. Eligible countries: described in Annex A of the Work Programme.
A number of non-EU/non-Associated Countries that are not automatically eligible for funding have made specific provisions for making funding available for their participants in Horizon 2020 projects. See the information in the Online Manual.

2. Eligibility and admissibility conditions: described in Annex B and Annex C of the Work Programme.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals under 1. "International Aspect" shall include at least one participant from the international partner region CELAC or from China respectively.

Proposal page limits and layout: please refer to Part B of the proposal template in the submission system below.

3. Evaluation:

- **Evaluation criteria, scoring and threshold**s are described in Annex H of the Work Programme.
- **Submission and evaluation processes** are described in the Online Manual.

The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.
The same applies to the second stage of the two-stage call for topics SC1-BHC15-2018, SC1-BHC01-2019, SC1-BHC02-2019, SC1-BHC14-2019, SC1-BHC19-2019, SC1-BHC22-2019, SC1-BHC25-2019

4. Indicative time for evaluation and grant agreements:

Information on the outcome of evaluation (**single-stage** call): maximum 5 months from the deadline for submission.
Signature of grant agreements: maximum 8 months from the deadline for submission.

5. Proposal templates, evaluation forms and model grant agreements (MGA):

Coordination and Support Action:

Specific provisions and funding rates
Standard proposal template

General MGA - Multi-Beneficiary
Annotated Grant Agreement

Essential information for clinical studies

6. Additional provisions:

Horizon 2020 budget flexibility
Classified information
Technology readiness levels (TRL) – where a topic description refers to TRL, these definitions apply.

Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

7. Open access must be granted to all scientific publications resulting from Horizon 2020 actions.

Where relevant, proposals should also provide information on how the participants will manage the research data generated and/or collected during the project, such as details on what types of data the project will generate, whether and how this data will be exploited or made accessible for verification and re-use, and how it will be curated and preserved.

Open access to research data
The Open Research Data Pilot has been extended to cover all Horizon 2020 topics for which the submission is opened on 26 July 2016 or later. Projects funded under this topic will therefore by default provide open access to the research data they generate, except if they decide to opt-out under the conditions described in Annex L of the Work Programme. Projects can opt-out at any stage, that is both before and after the grant signature.

Note that the evaluation phase proposals will not be evaluated more favourably because they plan to open or share their data, and will not be penalised for opting out.

Open research data sharing applies to the data needed to validate the results presented in scientific publications. Additionally, projects can choose to make other data available open access and need to describe their approach in a Data Management Plan.

Projects need to create a Data Management Plan (DMP), except if they opt-out of making their research data open access. A first version of the DMP must be provided as an early deliverable within six months of the project and should be updated during the project as appropriate. The Commission already provides guidance documents, including a template for DMPs. See the Online Manual.

Eligibility of costs: costs related to data management and data sharing are eligible for reimbursement during the project duration.

The legal requirements for projects participating in this pilot are in the article 29.3 of the Model Grant Agreement.

8. Additional documents:

Introduction WP 2018-20
Health, demographic change and well-being WP 2018-20
General annexes to the Work Programme 2018-2020

Legal basis: Horizon 2020 Regulation of Establishment
Legal basis: Horizon 2020 Rules for Participation
Legal basis: Horizon 2020 Specific Programme

Submission Service

To access the Electronic Submission Service of the topic, please select the **type of action** that is most relevan

confirm your choice of the type of action and topic, as these cannot be changed in the submission system. Upon confirmation you will be linked to the correct entry point.

To access existing draft proposals for this topic, please login to the Participant Portal and select the My Proposals page of the My Area section.

Type of Action	**Coordination & support action [CSA]**	START SUBMISSION
Topic	Actions in support of the International Consortium for Personalised Medicine - SC1-HCO-01-2018-2019-2020	

Guidance on proposal submission: H2020 ONLINE MANUAL

IT Guidance: HOW TO

Get support - Less

H2020 Online Manual is your guide on the procedures from proposal submission to managing your grant.

Participant Portal FAQ – Submission of proposals.

National Contact Points (NCP) - contact your NCP for further assistance in your national language(s).

Research Enquiry Service – ask questions about any aspect of European research in general and the EU Research Framework Programmes in particular.

Enterprise Europe Network – contact your EEN national contact for advice to businesses with special focus on SMEs. The support includes guidance on the EU research funding.

IT Helpdesk - contact the Participant Portal IT helpdesk for questions such as forgotten passwords, access rights and roles, technical aspects of submission of proposals, etc.

Ethics – for compliance with ethical issues, see the Online Manual and Science and Society Portal

European IPR Helpdesk assists you on intellectual property issues

CEN and CENELEC, the **European Standards Organisations**, advise you how to tackle standardisation in your project proposal. Contact CEN-CENELEC Research Helpdesk at research@cencenelec.eu

The European Charter for Researchers and the Code of Conduct for their recruitment

Partner Search Services help you find a partner organisation for your proposal.