DÉFI SOCIÉTAL SANTÉ, CHANGEMENT DÉMOGRAPHIQUE ET BIEN-ÊTRE

Wébinaire d'information
Appels à Projets 2020

Priorité 1.2 Innovative health and care industry
Priority 1.4 Innovative health and care systems - Integration of care

pcn-sante@recherche.gouv.fr

Sommaire

RAPPEL SUR LES REGLES DE PARTICIPATION

- Règles d'éligibilité
- Coopération Internationale
- Brexit
- Budget

PRESENTATION DES APPELS A PROJETS

Priority 1.2 Innovative health and care industry

SC1-BHC-08-2020 *: New interventions for Non Communicable Diseases (2 étapes)*
SC1-BHC-11-2020 : Advancing the safety assessment of chemicals without the use of animal testing
SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices
SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

Priority 1.4 Innovative health and care systems - Integration of care

SC1-BHC-24-2020 : *Healthcare interventions for the management of the elderly multimorbid patient (2 étapes)*
SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research
SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

Règles de participation

Consortium: Minimum 3 entités légales de 3 Etats-membres ou Etats associés différents

Toute entité légale peut participer

Entités légales financées : établies dans les Etats-membres ou Etats associés

A noter : Exception unique au défi santé : les entités des USA sont financées

Cas spécifique de la Grande-Bretagne

Pour les Etats tiers : Certains pays sont financés (voir liste) – ou leur participation est expressément prévue dans le programme de travail

Coopération Internationale : Politique de la CE

Toutes les lignes d'appel sont ouvertes à la coopération internationale

Contribution financière de la C.E pour le Défi Santé :

28 Etats-Membres, 16 Etats-Associés, 124 Pays-Tiers et USA

Pour les autres Pays-Tiers, pas de financement de la CE

→ **Mécanismes de co-financement existants pour certain pays:** Australie, Brésil, Canada, Chine, Honk-Kong&Macau, Inde, Japon, Corée, Mexique, Russie, Taiwan

Certaines lignes d'appel ciblent des pays spécifiques

Participation des pays tiers cités obligatoires pour que le projet soit éligibles

→ Stimuler la coopération dans un domaine spécifique qui représente un fardeau à la fois pour l'Union Européenne et le(s) pays ciblé(s)

→ Donner un « signe » visible de coopération (diplomatie scientifique)

BREXIT & H2020

Accord de retrait conclu au 31.10.19

✓« Business as usual »

✓UK pleinement éligible jusqu'à la fin d'H2020 (y compris pour les appels ouverts/clos après mars 2019)

✓Tous les projets H2020 financés jusqu'à leur terme

.

« No deal »

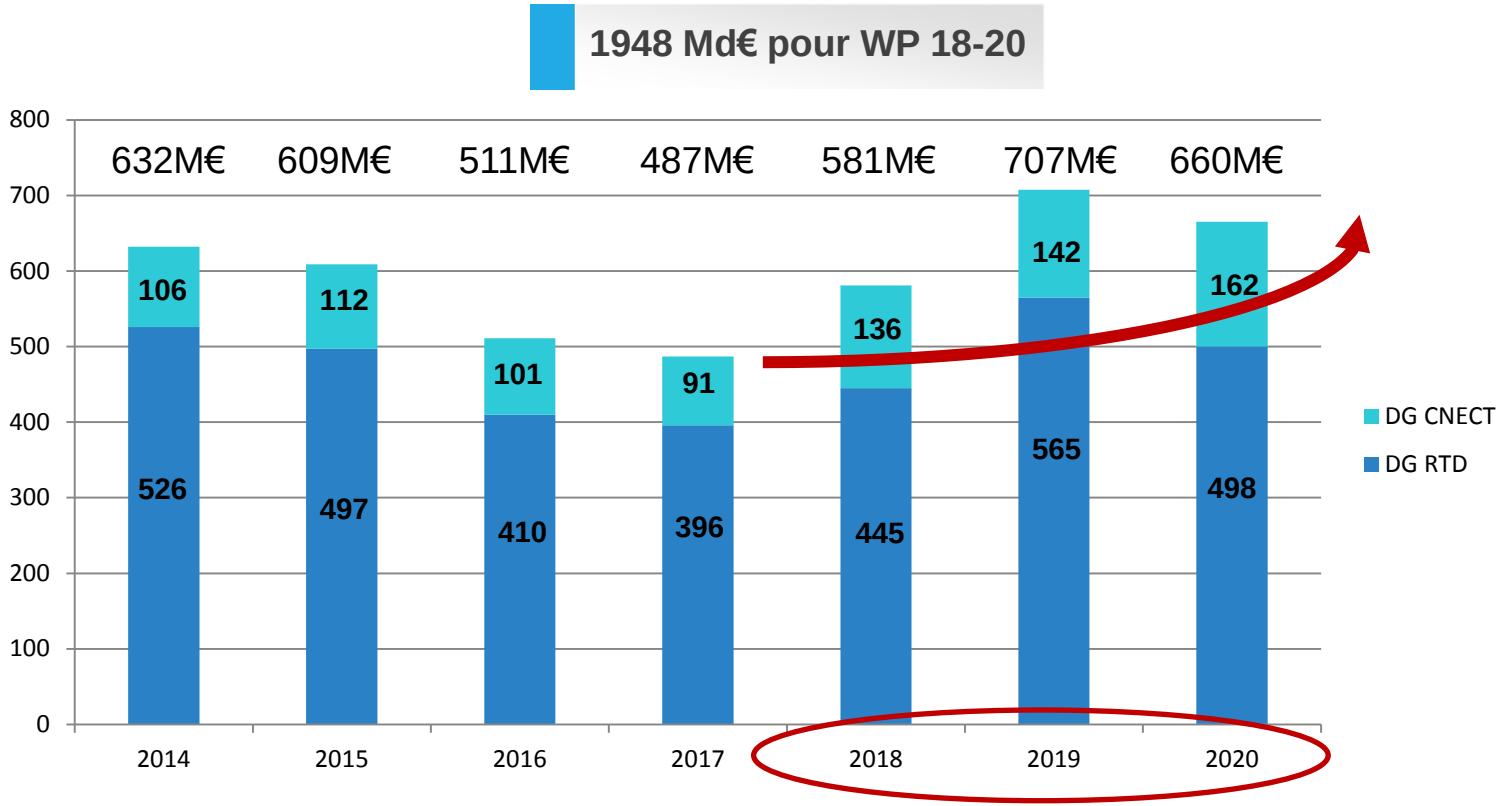
× Eligibilité des consortiums peut être remise en question (3 entités établies dans 3 Etats Membres ou Etats Associés différents)

× UK non éligible aux actions individuelles (ERC, EIC et certaines actions MSCA)

✓ Financement de la participation des entités britanniques au travers d'un fonds dédié

.

Défi Santé : Budget



Structure du programme de travail 2018-2020

Call 1. Better Health and care, economic growth and sustainable health systems, (13 RIA, 10 CSA, 1PCP, 1PPI)

Budget 2020
498 M€

1.1 Personalised medicine
1.2 Innovative health and care industry
1.3 Infectious diseases and improving global health
1.4. Innovative health and care systems - Integration of care
1.5 Decoding the role of the environment for health and well-being
1.6 Contribution to the Call on Digital transformation in Health and Care

DG RTD

Call 2. – Digital transformation in Health and Care (4 RIA, 4 CSA)

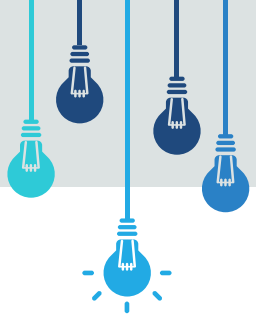
Budget 2020
92 M€

DG CNECT

Call 3. – Trusted digital solutions and Cyber security in Health and Care (2 RIA)

Budget 2020
70 M€

Différents types d’actions



RIA - Research and Innovation Actions

→ recherche fondamentale et appliquée, développement et l’intégration de technologie, essais et validation d’un prototype à petite échelle dans un laboratoire ou un environnement simulé

Taux de financement européen 100% et durée habituelle 36-60 mois

CSA - Coordination and Support Actions

→ études de design pour de nouvelles infrastructures, activités complémentaires de planning stratégique, mise en réseau et la coordination entre programmes dans différents pays

Taux de financement européen 100% et durée habituelle 12-30 mois

Structure du programme de travail 2018-2020

CALENDRIER 2019-2020

Derniers appels du programme cadre Horizon 2020
Publication officielle du programme de travail 2020 : **2 juillet 2019**

Dates limites de soumission des dossiers

DG RTD
- **24 Septembre 2019** : dépôt des dossiers de première étape (pour les appels en 2 étapes)
- **07 Avril 2020** : dépôt des projets complets pour les appels en 2 étapes et en 1 étape

DG CNECT : tous les appels sont en 1 seule étape
- **13 Novembre 2019**: 3 appels (HCC-06-2020, HCC-07-2020 et DT-TDS-05-2020)
- **22 avril 2020**: tous les autres appels

TYPES D'APPEL

- 16 RIA (Research and Innovation Action), dont 4 en deux étapes (**SC1-BHC-08-2020, SC1-BHC-24-2020, SC1-BHC-29-2020, SC1-DTH-13-2020**)
- 14 CSA (Coordination and Support Action), dont 3 ERA-NET

Part des CSA très importante dans ce Work Programme
→ préfiguration des prochains appels à projets ?
La France doit être impliquée dans ces activités

Priority 2 – Innovative health and care industry

DG RTD

OBJECTIFS

Transformer des connaissances et des technologies innovantes en application pratique au bénéfice des citoyens, du système de santé et des entreprises. Les PMEs sont une composante importante de cette priorité

Les actions au sein de cette priorité doivent démontrer:
- un potentiel d'exploitation très clair
- des bénéfices socio-économiques pour les patients et les systèmes de santé.

CIBLE

Diagnostique & Traitement, Médecine régénérative, « thérapies avancées », science règlementaire
Synergies avec les autres initiatives européennes (IMI, outils PME, FTI)

CONTEXTE POLITIQUE

Upgrading the single market

SC1-BHC-11-2020 : Advancing the safety assessment of chemicals without the use of animal testing

Budget total: 60 M€

- 10 à 20 M€ par projet
- 3 à 6 projets financés
- Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

Proposing and demonstrating scientifically valid means for comprehensive safety assessment of chemical substances without resorting to animal testing

SCOPE

- Consider integrative approaches, including in vitro/in silico tools, knowledge on human biology and toxicity pathways

- Exploitation of qualitative and quantitative information and knowhow from animal, clinical, epidemiological, exposure and biomonitoring studies is encouraged where appropriate to inform research strategies and to establish the scientific credibility of the approaches proposed.

- Link to Stake holders diversity, SMEs, International cooperation is encouraged

The JRC will consider interacting with any successful proposals
Proposal should describe how they will interact with the JRC but no need to take any contact before the selection

SC1-BHC-11-2020 : Advancing the safety assessment of chemicals without the use of animal testing

Budget total: 60 M€

- ❖ 10 à 20 M€ par projet
- ❖ 3 à 6 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACTS

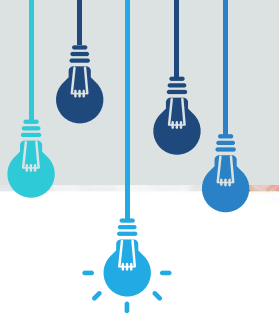
- Scientifically sound, practicably implementable non-animal solutions readily deployable to aid in meaningful safety assessment of chemicals.

- Recognition from regulatory bodies and their engagement to translate results, methods and solutions into safety assessment practice.

- Uptake and commercial exploitation of the developed safety assessment approaches, products and services.

- Contribution to the Three Rs (3Rs) principles ('Replacement', 'Reduction', 'Refinement'), with a particular emphasis on the 'Replacement' opportunities. → replacement in long term to be included

SC1-BHC-11-2020 : Advancing the safety assessment of chemicals without the use of animal testing



CONTEXTE POLITIQUE EUROPEEN

- **Three Rs**: Replacement, Reduction and Refinement

Animal welfare and the potential for pain and distress to be experienced by animals used in science have concerned the general public and thoughtful researchers for a long time.

- **REACH** is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitivenes s of the EU chemicals industry.

- **HBM4EU initiative**: a joint effort of 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020.

The initiative is coordinating and advancing human biomonitoring in Europe. HBM4EU is generating evidence of the actual **expos**ure of citizens to chemicals and the possible health effects in order to support policy making.

Analyse du PCN

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- ❖ 1 à 2 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- The **new Regulation (EU 2017/745)** reinforced rules for the generation of clinical evidence:
  - clinical investigations for high-risk devices will be **compulsory**
  - **More stringent requirements** regarding the clinical evaluation during the product lifetime

- **Medical devices particularities** makes the conduct of clinical investigations difficult :

→ a need for **methodologies** that enable to generate improved clinical evidence.

- New developments in **medical technologies such as mHealth,** artificial intelligence, and combination products, pose **additional challenges and opportunities** for developers to generate high-quality clinical evidence,

- **A need to raise awareness on new regulatory requirements** in terms of clinical evidence.

It is important to ensure a smooth transition from the former directive to the new regulatory frame work, especially with regard to clinical evidence, by **informing stakeholders involved** in the clinical evaluation of high-risk medical devices (e.g. academic researchers, clinicians, manufacturers, notified bodies, contract research organisations).

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- 1 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- Developing and promoting **methodological approaches**, including **alternative statistical** methodologies, adapted to the specificities of high-risk medical devices

- **Improve the robustness of clinical data needed** at different phases of the product's lifetime, such as conformity assessment, post-market clinical follow-up, continuous clinical evaluation, post-market surveillance, and potentially relative effectiveness assessment

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- 1 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SCOPE

Proposals should focus on

i) methods to generate **clinical data** both within the context of a clinical investigation and in daily practice (i.e. real-world data) so that robust clinical evidence is available for high-risk medical devices,

and

ii. Aggregation methods that will allow to **make optimal use of all available** data taking into account its heterogeneity (e.g. meta-analysis methods using different statistical approaches, methods to combine data from different types of sources)

and

iii) Promote **exchange of best-practices** and support **network activities** among developers.

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- ❖ 1 à 2 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SCOPE

- **Analyse the particularities** of high-risk medical devices and the potential resulting problems with regard to clinical evaluation,
- **Carry out a review** of the currently used clinical investigation designs for the evaluation of such devices,
- **Provide a hierarchy** of these approaches,
- Identify gaps to be filled (in particular in view of new developments like e.g. mHealth, artificial intelligence, and combined products) and
- **Derive recommendations** for the choice of clinical investigation methodology to obtain sufficient evidence.
- Contribute to the **exchange of best practices** among notified bodies with regard to the assessment of clinical data as provided by developers of high-risk medical devices.
- Support **networking activities** among developers and in particular academic centres with regard to **regulatory requirements** for assessing high-risk medical devices and foster a **pool of scientific expertise** on clinical evaluation of high-risk medical devices.

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- 1 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- **Higher quality and reliability of clinical data** needed for conformity assessment and continuous market access
- **Improved knowledge** of relevant legislative frameworks and regulatory requirements among **all stakeholders involved** in the development of high-risk medical devices
- **Improved evidence on safety and efficacy** of high-risk medical devices for the benefit of the patient and health systems

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Budget total: 2 M€

- ❖ 1 à 2 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

COMMENTAIRES

Consortia attendus

- ➢ **partners with relevant expertise** from e.g. academia, competent national authorities, centres of expertise for clinical research and care, scientific and medical learned societies.
- ➢ **relevant stakeholders** such as technology developers, healthcare providers, health technology assessment agencies and patients, with special regard to endpoints that are relevant for patients.
- ➢ **broad geographical** representation of European countries.
- ➢ **Sex and gender** aspects should be taken into account in carrying out the relevant activities.

NB . Implication of European Commission Joint Research Centre (JRC) : interfaçage en tre développeurs et agences réglementaires. Contribution à l'harmonisation international, Le JRC pourra travailler avec la proposition retenue.

SC1-HCO-18-2020 : Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

CONTEXTE POLITIQUE EUROPEEN

→ **Nouveau règlement EU 2017/745 (Mai 2017)** avec application au printemps 2020 :
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Analyse du PCN

Les initiatives autour de cette THÉMATIQUE

- **Joint Actions** in the field of medical devices evaluation (ex. PIP Action Plan) – 2012
- (CAMD) Competent Authorities for Medical Devices
- (MDCG) Medical Devices Coordination Group

CAMD
Competent Authorities for Medical Devices

SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

Budget total: 2 M€

- ❖ 1,5 à 2 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

Objective:

Propose strategies through website to convey reliable information on **cell and gene-based therapies**

- create a reliable, transparent, accessible resource for patients to make informed decisi ons and for citizens to have access to scientifically viable information on cell and gene-based therapies
- For the research community, provide a one-stop shop on where to seek further information and guidance relating to manufacturing guidelines, regulatory requirements , intellectual property rights, market acceptability and ethical matters

Specific Challenge:

- Difficulties reaching patients because inter alia the complexity and costs of product devel opment, regulatory hurdles and the non-harmonized procedures for reimbursements.
- Concerns over patient safety due to the use of unproven treatments

SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

Budget total: 2 M€

- ❖ 1,5 à 2 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SCOPE

- Well-structured and detailed strategies to convey accurate and up-to-date information on cell and gene-based therapies

- All communication material/information should be in English and proposals should provid a detailed strategy on the linguistic approach of dissemination in order to reach a large EU audience.

- Proposals should create a reliable, transparent, accessible resource **for patients** to make informed decisions and **for citizens** to have access to scientifically viable information on cell and gene-based therapies.

- **For the research community**, Proposals should provide a one-stop shop on where to seek further information and guidance relating to manufacturing guidelines, regulatory requirements, intellectual property rights, market acceptability and ethical matters.

- Proposals should provide a strategy on how they will liaise with regulatory agencies sustainability plan which explores how the ownership of the information will be structured, and propose a defined organisation to take responsibility, manage and administer the information

SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

Budget total: 2 M€

- 1,5 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- Communicate to patients and the public objectively, accurately and transparently, the latest developments and actual treatments available in the field in order to avoid misconceptions
- Provide the research community and patients with a high-quality information source for product development
- Ensure benefits for patients and healthcare systems
- Establish or reinforce the networking between advanced therapy-learned societies and the relevant EU national regulatory authorities
- Sustainability ensured for at least 5 years after the end of the project

SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

COMMENTAIRES

Knowledge and rolls needed to make a strong consortium

human stem cells, regenerative medicine, genome-editing and gene therapy, AND science communicators

Analyse du PCN

Partnership to realise impact

The consortium should consist of diverse actors and could include science communicators, patients' representatives, industry, SMEs, clinical and academic researchers as well as the major European learned societies in the field.

Agencies should be involved in a way even if not directly partners.

SC1-HCO-19-2020 : Reliable and accessible information on cell and gene-based therapies

CONTEXTE POLITIQUE EUROPEEN

EU-supported gene and cell therapy research: a long-lasting effort.

Activities and initiatives in advanced therapies, DG RTD power point presentation with the list of the 38 projects funded under H2020 on this thematic from 2014-2017

Analyse du PCN

Priority 4 – Innovative health and care systems – Integration of care

DG RTD

OBJECTIF

Développer des interventions de santé accessibles et durables ainsi que des systèmes de soins intégrés

- Meilleure coordination des soins primaires et des soins communautaires en fonction des besoins spécifiques des patients
- Cibler également les nouveaux financements et les modèles économiques avec la contribution des disciplines des sciences humaines et sociales

CIBLE

Santé mentale au travail, nouvelles approches pour les soins palliatifs, mise en œuvre de la médecine personnalisée, manage ment des maladies chroniques et de la promotion de la santé, HTA, innovation en soin et santé

CONTEXTE POLITIQUE

Upgrading the single market

Cross-border healthcare Directive

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

Budget total: 6 M€

- ❖ 4 à 6 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

LUMP SUM

SPECIFIC CHALLENGE

There is a need for new trial methodologies that address current challenges such as:

- Globalization of clinical research;
- Use of emerging health technologies
- Defining patient populations and patient enrolment strategies;
- Data management

New designs for clinical trials :

- reduce the operational **complexity,**
- assure **transparency** and build **trust,**
- meeting all **ethics standards** and protecting the individuals' personal identity and privacy

- **A need of a new methodology** that improves clinical trials legislative compliance and **en courage clinical trials conducted by non-commercial sponsors.**

NB. Non-commercial trials often show suboptimal performance as compared to large comm ercial trials in terms of data collection, management and processing, good clinical practice c ompliance, and pharmacovigilance

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

Budget total: 6 M€

- ❖ 4 à 6 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

LUMP SUM

SCOPE

- **Focus on methodology research and develop innovative solutions** to improve the design, conduct and analysis of clinical trials

- **identify and validate methods** that will improve the generalizability of evidence generated through differently designed trials, including personalized medicine approaches and combinatorial intervention

- In order to draw meaningful conclusions following state of the art of statistical analyses, applicants need **to demonstrate access to adequate clinical trial data sets** that will be included into the proposed research.

- The proposed methodology should allow sound extrapolation in various subgroups of disease of high public health burden as well as integration of RTC data and post-approval evidence generation.

- Furthermore, applicants should **identify best practices** to prevent bottlenecks in execution of clinical trial, including issues related to **patient recruitment, adherence** and **compliance, governance, ethics, sex and gender-based analysis** as well as **data sharing.**

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

Budget total: 6 M€

- ❖ 4 à 6 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

LUMP SUM

SCOPE

- The special attention should be put **on non-commercial trials**, including quantifiable indicators to the **qualitative improvement** in terms of trial **management, data processing,** and **reporting.**

- Whenever relevant, proposals should cover different aspects of **training exercises**, including hands-on trainings and closer monitoring of the scientific and technical staff involved in the conduct, management and analysis of the trial.

- All literature analyses to define the **current state of the art** in the clinical trial methodology research must be completed at the time of submission of the proposal.

- → Methodology research related to clinical studies exclusively on **medical devices is not in the scope** of this topic. (Voir SC1-HCO-18-2020 topic)

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

Budget total: 6 M€

- ❖ 4 à 6 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

LUMP SUM

EXPECTED IMPACTS

- **Improved relevance**, quality and efficiency of clinical trials conducted with public funding .
- Potential to establish a **novel clinical trial methodology** supported by regulatory authorities.

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

Budget total: 6 M€

- ❖ 4 à 6 M€ par projet
- ❖ 1 à 2 projets financés
- ❖ Type d'action : RIA

7 avril 2020

Dépôt en 1 étape

LUMP SUM

COMMENTAIRES

l'EMA (Europea Medicines Agency) soutiendra les consortia sélectionnés dans la mise en œ uvre de l'action

Collaboration attendue avec les CSA pertinentes dans le programme de travail pour échang er des informations, éviter les overlaps et créer des synergies → prévoir un **budget spécifi que** pour ces actions

Ex. STARS (HCO 2018) - *"Strengthening training of academia in regulatory sciences and su pporting regulatory scientific advice"; (825881) – CSA*

- Voir également le « European Centre for Disease Prevention and Control"

SC1-BHC-37-2020 : Towards the new generation of clinical trials – trials methodology research

CONTEXTE POLITIQUE EUROPEEN

→ Clinical Trial Regulation EU No. 536/2014
→ European Council Conclusion on personalised medicine for patients (2015/C 421/03)
→ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of n atural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)

NB. Dispositifs médicaux et recherche clinique : voir le call SC1-HCO-18-2020 topic: *"Developing an adaptive methodological framework for improved clinical investigation and evaluation of high-risk medical devices"*

LUMP SUM

SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

Budget total: 2 M€

- 1,5 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

Objective

Enhancing R&I from the ERN's
Achieve the goals of IRDIRC (International Rare Diseases Research Consortium) :
Bring new diagnostic tools to the patients
Methodologies to assess the impact of diagnoses and therapies on rare disease patients
Identify research priorities, relevant synergies, avoid overlaps

A completer

Tackle the lack of coordinating research in the network, identify clinical research priorities
- Create a big network system where all the actors can work together to establish faster research tran sfer for better diagnostics and treatments of the patient

SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

Budget total: 2 M€

- 1,5 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- European Reference Networks (ERNs) have been established under the Directive on Patients' rights in cross-border health care in view of tackling complex or rare diseases and conditions that require highly specialised diagnostic tools and treatments.

- ERNs in collaboration with other European initiatives will gain major research potential due to their network structure bringing **together highly specialised multidisciplinary expertise** across Europe and access to patient populations of rare diseases and complex conditions that require highly specialised treatments.

- Realisation of this potential requires highly organised coordination among the 24 ERNs, which operate in **26 countries**, over **300 hospitals** and more than **900 health care units**, and also with other Europe-led research collaborations beyond the networks, with all the other actors in the field of rare diseases research, especially the European Joint Programme on Rare Diseases.

- Support for coordination of the research aspects of ERNs is currently limited.

SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

Budget total: 2 M€

- 1,5 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

SCOPE

- This activity will aim at **enhancing research and innovation capacity** of the ERNs in view of achieving the goals of the International Rare Diseases Research Consortium (IRDiRC) for
  - **bringing new diagnostic tools and therapies more efficiently to the patients** and
  - for developing **methodologies to assess the impact of diagnoses and therapies** on rare disease patients, taking into account sex and gender differences where relevant.

- Support will be given **to identify research priorities and potential synergies** among ERNs and coordinate research and innovation activities to be tackled by ERNs.

- The project should address **fostering collaboration** in the field of clinical research among ERNs, ERN-independent clinical research collaborations and other stakeholders, such as research infrastructures, industry and patient organisations, as well as international collaboration with other clinical research networks.

- Close collaboration with the **European Joint Programme on Rare Diseases** will be necessary to ensure complementarity, to achieve relevant synergies and avoid overlaps

- To ensure **broad geographical representation** and participation across ERNs the proposals shall involve participants from several countries and aim at engaging all approved ERNs an **other relevant research networks in Europe**.

SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

Budget total: 2 M€

- 1,5 à 2 M€ par projet
- 1 à 2 projets financés
- Type d'action : CSA

7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACTS

- Along the IRDiRC vision to **enable all people living with a rare disease to receive an accurate diagnosis, care, and available therapy** within one year of coming to medical atte ntion by 2027.

- Contribute to the **development of a comprehensive European ecosystem for rare diseases** and conditions that require highly specialised treatments, which brings efficiently results of research and innovation to the benefit of the patients.

- Enhance synergy with the **Connecting Europe Facility Programme** and the EU Health Programme which provides support for the functioning of the ERNs and the development of patient registries for ERNs.

SC1-HCO-20-2020 : Coordination of clinical research activities of the European Reference Networks

CONTEXTE POLITIQUE EUROPEENS ET INITITATIVES EN COURS

NB. Ce Call est clairement ouvert à toutes les tructures, mêmes non désignées comme ERN

→ (IRDiRC) : International Rare Diseases Research Consortium

→ *ERN : European Reference Networks*

→ AAP Plateformes d'expertises Maladies rares / DGOS, cloture le 10 octobre 2019

→ EJP Maladies Rares
(Prochain call fin 2019, depot T1 2020)

Analyse du PCN

.

Listes des webinaires ciblés sur les AAP des différentes priorités

Appels à projets des priorités 1 et 5 - 6 Septembre 2019 à 10h - Présentation

- SC1-BHC-06-2020: Digital diagnostics – developing tools for supporting clinical decisions by integrating various diagnostic data
- SC1-HCO-01-2020: Actions in support of the International Consortium for Personalised Medicine
- SC1-HCO-03-2020: Bridging the divide in health research and innovation – boosting return on investment
- SC1-HCO-17-2020: Coordinating and supporting research on the human microbiome in Europe and Beyond
- SC1-BHC-36-2020: Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health

Appels à projets des priorités 2 et 4: 19 Septembre 2019 à 10h - Inscription

- SC1-BHC-11-2020: Advancing the safety assessment of chemicals without the use of animal testing
- SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices
- SC1-HCO-19-2020: Reliable and accessible information on cell and gene-based therapies
- SC1-BHC-37-2020: Towards the new generation of clinical trials – trials methodology research
- SC1-HCO-20-2020: Coordination of clinical research activities of the European Reference Networks

Appels à projets de la priorité 3: 4 Septembre à 14h - Présentation

- SC1-BHC-17-2020: Global Alliance for Chronic Diseases (GACD) – Prevention and/or early diagnosis of cancer
- SC1-BHC-20A-2020: Pre-Commercial Procurement for integrated care solutions
- SC1-BHC-20B-2020: Public Procurement of innovation solutions for diagnostics for infectious diseases
- SC1-BHC-33-2020: Addressing low vaccine uptake
- SC1-BHC-34-2020: New approaches for clinical management and prevention of resistant bacterial infections in high prevalence settings
- SC1-BHC-35-2020: Creation of a European wide sustainable network for harmonised large-scale clinical research studies for infectious disease

Appels à projets de la priorité 6- 1 (DG CNECT): 19 Septembre 2019 à 14h - Inscription

- SC1-DTH-02-2020: Personalised early risk prediction, prevention and intervention based on Artificial Intelligence and Big Data technologies
- SC1-DTH-04-2020: International cooperation in smart living environments for ageing people
- SC1-DTH-06-2020: Accelerating the uptake of computer simulations for testing medicines and medical devices
- SC1-DTH-14-2019-2020: Pre-commercial Procurement for Digital Health and Care Solutions
- SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment
- SC1-HCC-08-2020: Scaling up innovation for active and healthy ageing

Appels à projets de la priorité 6- 2 (DG CNECT): 10 Septembre 2019 à 10h - Présentation

- SC1-DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions
- SC1-HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes
- SC1-HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research
- SC1-HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities f or genomics and personalised medicine
- DT-TDS-04-2020: AI for Genomics and Personalised Medicine
- DT-TDS-05-2020: AI for Health Imaging

Ces webinaires seront consultables en ligne sur le site du PCN Santé

Toute l'information H2020 Santé sur le site du MESRI

Pour toute question, contacter le PCN Santé à l'adresse : pcn-sante@recherche.gouv.fr