DÉFI SOCIÉTAL SANTÉ, CHANGEMENT DÉMOGRAPHIQUE ET BIEN-ÊTRE

Wébinaire d'information
Appels à Projets 2020

Priorité 6-2 : Digital Transformation in Health and Care

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DT-TDS-04-2020: AI for Genomics and Personalised Medicine

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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 »

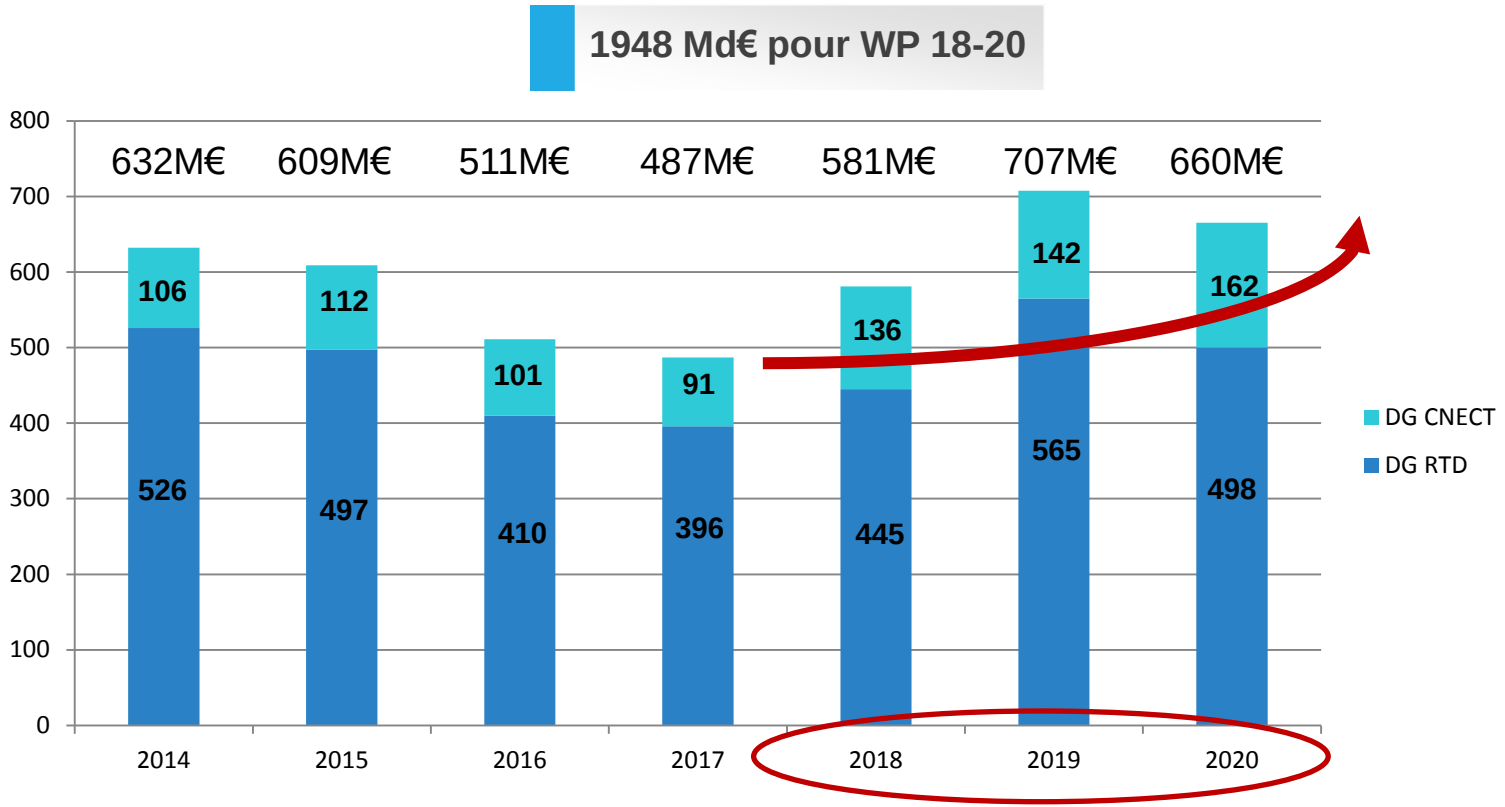
× Eligibilité des consortiums peut être remise en question (3 entités établies dans 3 Etats Membres ou Etats Associés différents)

× 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)

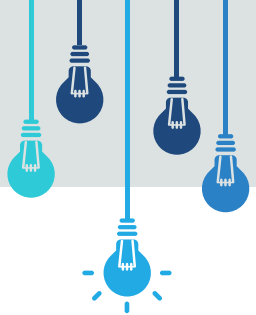
Budget 2020
92 M€

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

IA - Innovation Actions

→ prototypage, essais, démonstration ou pilotes, validation du produit à grande échelle, première commercialisation. Les projets peuvent inclure des activités limitées de recherche et de développement

Taux de financement européen 70% (sauf pour les entités à but non lucratif qui sont financées à 100% de leurs coûts totaux éligibles) et durée habituelle 30-36 mois

CSA - Coordination and Support Actions

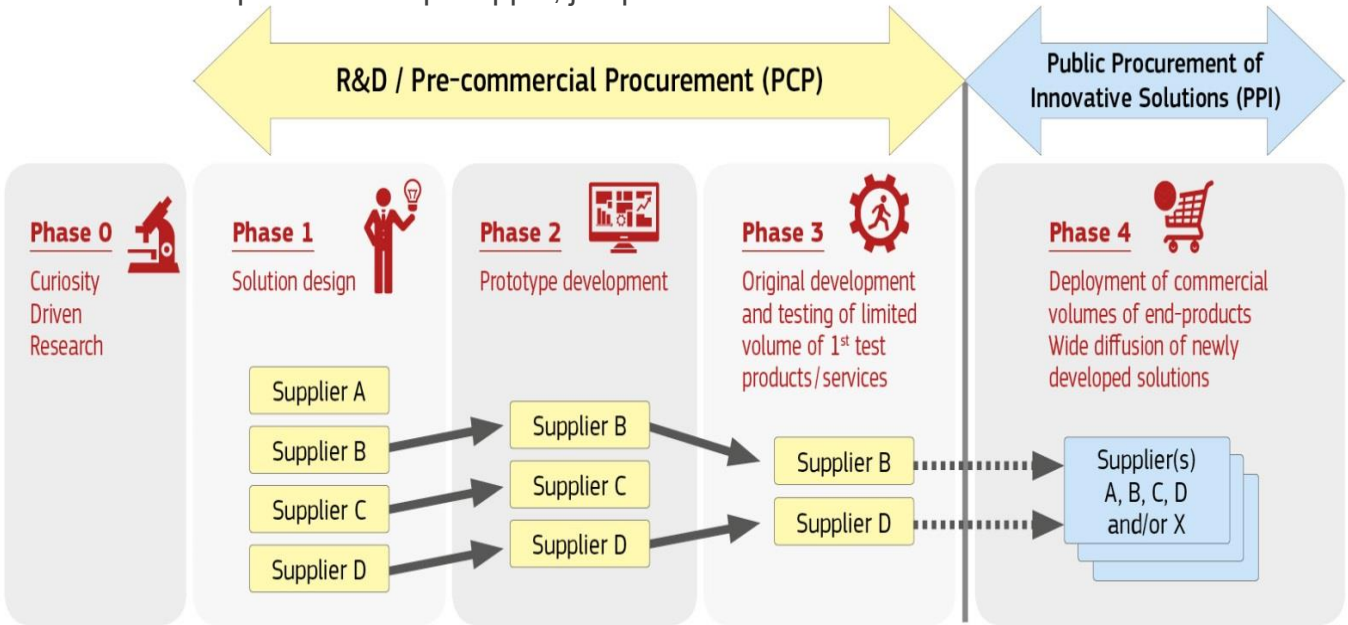
→ études de design pour de nouvelles infrastructures, activités complémentaires de planning stratégique, mise en réseau et la coordination entre programmes dans différents pays

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

Différents types d'actions

➢ **PCP**: développement d'une solution innovante, en collaboration avec les fournisseurs, répondant à un besoin qui ne peut pas être pourvu par le marché
Le Taux de financement dépend de chaque appel, jusqu'à 90% maximum

➢ **PPI**: achat de solution innovante déjà commercialisée
Le taux de financement dépend de chaque appel, jusqu'à 50% maximum



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 6: Digital transformation in Health and Care

DG RTD
DG CNECT

OBJECTIFS:
- Meilleur accès aux soins et durabilité des systèmes de soins et santé
- Faire participer les citoyens et faciliter la transformation des services de soins et de santé vers des modèles plus numérisés, centrés sur la personne et basé sur la communauté
- e-Health et m-Health
- TIC pour un vieillissement actif et en bonne santé

→ **Maximiser le potentiel de l'économie numérique dans les domaines du soin et de la santé**

CIBLES: Données sécurisées et interopérables, intelligence artificielle, « Big Data analytics »

CONTEXTE POLITIQUE:

Connected Digital Single Market

European Cloud Initiative

European Free Flow of Data initiative

Silver Economy initiative

Priority 6: Digital transformation in Health and Care

DG RTD
DG CNECT

DIGITAL SINGLE MARKET

La Commission Européenne a publié en 2015 sa stratégie politique pour la mise en œuvre d'un marché unique numérique européen.

- Adapter le marché unique de l'UE à l'ère numérique
- Faire tomber les barrières réglementaires et de transformer les 28 marchés nationaux en un marché unique.

TRANSFORMATION NUMÉRIQUE DES SOINS DE SANTÉ

En Avril 2018, publication d'une communication qui identifie 3 priorités concernant la santé dans le cadre du Digital Single Market. Cette communication propose également une série d'actions à mettre en œuvre pour atteindre les objectifs de ces priorités

1. Accès sécurisé et échange de données

Accès sécurisés des citoyens à leurs données de santé et la possibilité pour les personnels de santé de partager ces données avec d'autres Etats Membres

2. Données centralisées pour la recherche et la médecine personnalisée

Partager les ressources (données, infrastructures, expertises) pour une recherche, des diagnostics et des traitements mieux ciblés et plus rapides

3. Outils numériques et données pour l'autonomisation des citoyens et un système de soin centré sur la personne

Les citoyens peuvent surveiller leur santé, adapter leur style de vie et interagir avec leurs docteurs (recevoir et envoyer des inform
ations

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% agree To access their own health data (requiring interoperable and quality health data)

80% agree To share their health data (if privacy and security are ensured)

80% agree To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data

Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth @eHealth_EU @EU_Health

Updated 24/04/2018

DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions

Budget total: 41 M€

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

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- The number of **people with chronic illness is growing** and almost half of them have multiple chronic conditions. Patients with complex chronic conditions (CCCs) have chronic multi-morbidities or chronic disease complications that require the attention of multiple health care providers or facilities as well as home-based care. **Managing patients with complex chronic conditions therefore need s approaches that ensure multi-disciplinary, personalised** and well accepted by the patient ways of care and monitoring.

- The controlled randomised clinical trials on chronic diseases provide important information that can be translated in the daily clinical practice, but they often do **not comprise sufficient breadth and depth** commensurate to the complexity of diseases, and to the degree of personalisation of treat ment needed.

- **Real World Data** (referring specifically to any type of data not collected in a randomised clinical trial) can complement these to fill the knowledge gap between controlled clinical trials results and clinical practice needs in real environments. **They can provide new insights into disease patterns** and help improve the safety and effectiveness of health interventions.

- Tapping into this rich resource of 'real world data' issued from daily clinical practice, either collected on a permanent/regular basis by public bodies or through devices and mobile applications, and smartly assembled in combination with clinical studies, should boost both output and relevance of controlled clinical research results.

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7 avril 2020

Dépôt en 1 étape

SCOPE

- Clinical research integrating Real World Data from clinical practice or from patient's daily life and linking them with data collected with a research purpose if relevant.

- The research focus will be on the **use of real world data**, either newly acquired or from existing sources (such as data from clinical professional societies/associations, cohorts, registers, biobanks or collected through genome research initiatives) to **improve the clinical management of adults with complex chronic conditions**.

- The use of new technologies for data analytics and interpretation such as **artificial intelligence and computer modelling are encouraged**.

- Allow better treatment or monitoring of the person and thus changes in disease progression and/or therapy response.

- Quality of life, patient safety, psychosocial aspects and well-being are important determinants of complex health conditions and should be addressed whenever relevant

DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions

Budget total: 41 M€

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

7 avril 2020

Dépôt en 1 étape

SCOPE

- Assess the **potential and use of RWD for different health authorities** like regulators of safety and quality or health technology assessment bodies. Nevertheless, research has to take duly into account sex and gender differences.

- **Data protection, data privacy** and ethical issues have to be carefully considered as personal data from different sources are to be linked in the course of the proposed rese arch.

- Data sets assembled under the project, including the linkage to 'real world data' should be preserved in a sustainable and accessible way so as to enable future research on the targeted CCC, thus contributing to the **overall imperative of Open Science.**

- Research that focuses on self-management only is not in the scope of this topic. Research on rare and/or infectious diseases are supported through other sections of the programme and are excluded from the scope of this topic.

DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions

Budget total: 41 M€

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

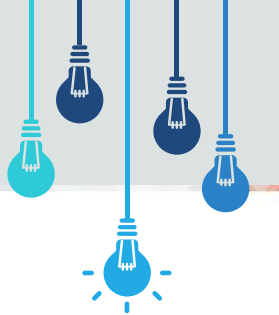
7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- Demonstrate the **potential of the use multi-disciplinary multi-source Real World Data** to advance clinical research on complex chronic conditions;
- Demonstrate potential and use of RWD, in particular RWD from disease-specific professional societies/associations, by health authorities to understand safety, quality and effectiveness of therapies;
- **Improve the clinical outcomes** as well as **quality of life** of patients living with CCCs
- Advance the **understanding of management of complex diseases** including the interdependence of co-morbidities, thus underpinning evidence based therapies and pro gnostic approaches;
- Further **development of new technological tools** and platforms for advanced data management;
- Contribution to the cross-border health data exchange and to the goals of the Digital Single Market

DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions



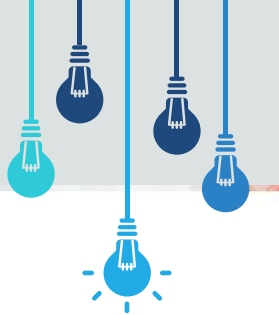
Analyse du PCN

COMMENTAIRES

➢ Pas de définition précise de « *Complex Chronic Condition* » de la part de la Commission Européenne. Ce terme fait référence majoritairement aux maladies chroniques avec des co- ou mutli-morbidités associées (comme décrit dans le specific challenge)

➢ Diversité de partenaires nécessaire au sein du consortium :
Cliniciens / Expert en éthique et sécurité des données / Expert en Intelligence Artificielle et/ou data analytics / Association de patients / Sciences humaines et sociales

DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions



EXEMPLES DE PROJETS DÉJÀ FINANCÉS

IMI Programme: *Big Data for better outcomes*

→ **ROADMAP** : Real World outcomes across the AD spectrum for better care

→ **HARMONY** : Big Data to enable better and faster treatment for Patients with Hematological Malignancies.

→ **BigData@Heart** : Big Data For Better Hearts

Analyse du PCN

HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research

Budget total: 3 M€

- 2 à 3 M€ par projet
- 1 projet financé
- Type d'action: CSA

7 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- Technological innovation has triggered an unprecedented increase in data production in health research and healthcare.
- The **need to make EU health research data FAIR** (i.e., Findable, Accessible, Interoperable and Re-usable) becomes more pressing than ever before if European health research is to reap the full benefits of this valuable resource.
- A wide range of challenges needs to be overcome before this vision becomes a reality. To be able to seamlessly integrate and analyse health data coming from different sources and different health sub-disciplines, individual research institutes and/or hospitals would need a potent IT infrastructure and interoperability solutions as well as powerful data analytics tools.
- Services in the Internet Cloud (i.e., Cloud Services) are a promising starting point to build these systems.
- Properly addressing the security and privacy of health research data, and the compliance with various levels of legislations, in particular the General Data Protection Regulation (GDPR) together with the applicable National legislations in the EU Member States/Associated Countries and with different jurisdictions is a critical step for the design of a Health Research and Innovation Cloud (HRIC).

HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research

Budget total: 3 M€

- 2 à 3 M€ par projet
- 1 projet financé
- Type d'action: CSA

7 avril 2020

Dépôt en 1 étape

SCOPE

- Bring together **data-intensive EU health research initiatives** to design an implementation **roadmap /strategic agenda for a one-stop shop**, a HRIC FAIR data portal respecting legal and ethics requirements.

- Define and promote, among research projects, **procedures to make data FAIR** as well as standard way of communicating such data, so that any IT-system can easily provide metadata to the portal. This portal would serve as catalogue of all relevant publicly-funded health research databases, registries and infrastructures (e.g., ESFRI) and allow access to high quality health research data.

- Build a Community (i.e., a wider forum) in order to align strategies and capitalise on the work done by relevant European and international initiatives.

- **Develop two use cases**, where all the aforementioned aspects will be integrated and analysed. The participation of **experts in ethics and law** as well as patient representatives is strongly recommended

- **Produce guidelines for researchers to contribute to the proper application of the GDPR regulation**, taking into account the specific features of processing personal data in the area of health. **The HRIC should contribute to the European Open Science Cloud**.

HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research

Budget total: 3 M€

- 2 à 3 M€ par projet
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- Type d'action: CSA

7 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- **A HRIC FAIR data portal** respecting legal and ethics requirements. This portal should serve as catalogue of all relevant publicly-funded health research databases, registries and infrastructures (e.g., ESFRI) and allow access to high quality health research data.

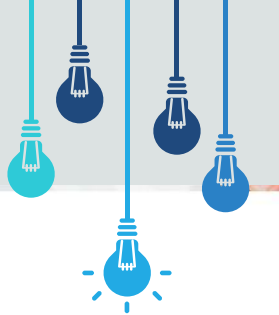
- **Through use cases**, demonstrate the added value of close collaboration of health researchers with healthcare providers and other actors in health care systems.

- **Guidelines on application of the GDPR** and the EU Member States and Associated Countries national legislations. The developed guidelines should cover the processing and further processing of health research data.

- Contribute to the setup of a **Health Research and Innovation Cloud**, the Health thematic cloud of the European Open Science Cloud.

- Contribute to the Digital Single Market through piloting IT health research solutions.

HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research



CONTEXTE POLITIQUE EUROPEEN

Initiative EOSC : European Open Science Cloud

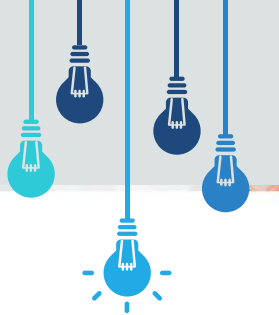
The EOSC will offer 1.7 million European researchers and 70 million professionals in science, technology, the humanities and social sciences a virtual environment with open and seamless services for storage, management, analysis and re-use of research data, across borders and scientific disciplines by federating existing scientific data infrastructures, currently dispersed across disciplines and the EU Member States

Analyse du PCN

EOSC : Strategic Implementation Plan (Juillet 2019)

Contact : Gavin Connor Fox, MESRI – Délégué français dans la gouvernance d'EOSC

HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research



EXEMPLES DE PROJETS DÉJÀ FINANCÉS

INFRAEOSC-04-2018 : Connecting ESFRI infrastructures through Cluster projects

→ **EOSC-Life** : Providing an open collaborative space for digital biology in Europe

INFRAEOSC-06-2019-2020: Enhancing the EOSC portal and connecting thematic clouds

Analyse du PCN

HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes

Budget total: 2 M€

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

22 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- **E-Health can contribute to better, more accessible and more efficient health and care services**, in particular to remote populations and underserved communities.

- E-Health and mHealth technologies can only be successful, if they are **supported by national governments**, who have established e-Health policies and strategies and demonstrate strong owner ship of the national e-Health programme.

- E-Health programmes will only achieve their objectives, if they are **adapted to country needs**, are citizen centered and sustainable through sound public finance management. These pre-requisites will impact on the quality and accessibility of such e-Health services and their sustainability, usability, data security and interoperability, privacy and ethics issues.

- Access to one's own health data and high-quality mHealth services in real-life environment are still a challenge because of a lack of government ownership, e-Health policies including enabling regulations, a sustainable and trustable infrastructure, and digital literacy.

- Coordination and support is needed for taking stock of and further developing strategic partnership on E-Health deployment together with low and middle income countries and regions in Africa with the aim to improve the health of the citizens.

HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes

Budget total: 2 M€

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

22 avril 2020

Dépôt en 1 étape

SCOPE

- Support the **coordination of a registry of relevant existing e-Health solutions** describing their services and potential for low and lower middle income African Countries or regions together with a **roadmap and strategic implementation plans** building on the requirements of end-user communities and policy makers in the target countries.

- Take into account national and regional policies and (best) practices regarding health and care services and health infrastructures and also include lessons learned from existing eHealth policies and programmes at all levels of the health system.

- Take into account the new **Africa-Europa Alliance for Sustainable investment and Jobs** as relevant. It should identify and build on and identify relevant existing and emerging initiatives and capacities in Europe and Africa which can form the basis for future cooperation and deployment.

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- 1,5 à 2M€ par projet
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22 avril 2020

Dépôt en 1 étape

SCOPE

- Make use of and contribute to standardisation as appropriate.

- Comply with and contribute to the development of the relevant legislation, in particular on ethics and data protection of health data. Socio-economic and gender issues should be addressed appropriately.

- Ensure that relevant stakeholders **including end-users** are engaged during the process through national, regional and international **workshops** and a set of communication and dissemination actions, aligned to national policies, to support the deployment of e-Health services in low and lower middle income countries in Africa.

- Provide an added value, to the facilitation of the cooperation between European and low and middle income countries in Africa for a better health for all.

HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes

Budget total: 2 M€

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

22 avril 2020

Dépôt en 1 étape

EXPECTED IMPACTS

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Higher level of **international cooperation and networking in eHealth programmes** and policies between European countries or regions and low and middle income African countries, focusing on areas that are beneficial to the target countries / regions and their citizens in eHealth;

- Increased **opportunities for e-health innovators**, patients, medical staff and health system stakeholders in Europe and Africa;

- Better **accessibility of eHealth Services**.

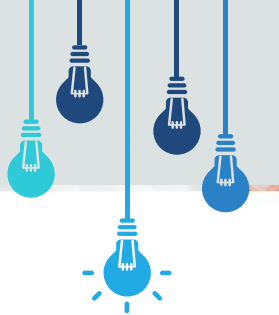
HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes

Analyse du PCN

COMMENTAIRES

- Proposer des solutions spécifiques aux pays ou à la région étudiée: adapter le projet en réponse aux besoins spécifiques des pays/régions cibles
- Le bénéfice doit être à la fois pour l'Afrique et l'Europe
- Très important de construire la feuille de route basée sur les besoins des utilisateurs finaux
- Important d'intégrer des experts concernant les aspects éthiques et légaux
- Une veritable collaboration entre l'Europe et l'Afrique est attendue

HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes



CONTEXTE POLITIQUE EUROPEEN

Africa-Europa Alliance for Sustainable investment and Jobs

Analyse du PCN

HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine

Budget total: 4 M€

- 4 M€ par projet
- 1 projet financé
- Type d'action: CSA

13 Novembre 2019

Dépôt en 1 étape

SPECIFIC CHALLENGE

- Personalised medicine uses data generated by new technologies to better understand the individual characteristics in order to deliver the right care to the right person at the right time.

- This approach has substantial potential for tackling major health challenges, such as cancer and rare diseases, helping to deliver better and more effective health outcomes.

- In order to seize this potential, there is a need **to support the large scale pooling of expertise and of genomic and other health data, as well as to identify common standards for the generation, analysis and sharing of this data.**

- CSA is needed **to develop cross-border solutions for sharing expertise and linking genomic and other health data**.

- This should be achieved by identifying relevant initiatives and projects, discerning best practice emerging from clinical implementation and engaging with relevant stakeholders. It is critical to identify common standards for data quality, security, interoperability, privacy, ethical guidelines and governance models underpinning the establishment of sustainable cross-border digital infrastructures and networks for genomics and personalised medicine in Europe

HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine

Budget total: 4 M€

- 4 M€ par projet
- 1 projet financé
- Type d'action: CSA

13 Novembre 2019

Dépôt en 1 étape

SCOPE

- This action should aim **to support the identification of common standards, cross-border digital infrastructures and coordination mechanisms to advance PM in Europe**.
- It should build on **existing initiatives, projects and resources at national, regional an Europe**an level
- This CSA should consolidate knowledge from existing initiatives and projects **to identify the most appropriate practices, standards and governance models for establishing cross-border digital infrastructures supporting genomics research and personalised medicine in Europe.**
- In a coordinated effort with national initiatives, Research & Innovation projects, and other stakeholders (among them national authorities, health institutions, standardisation bodies, ICT industry), the action should develop coordination mechanisms for **sharing expertise and for securely linking genomic and other health data** (eg electronic health records, registries, including rare disease registries etc), **respecting legal** (including but not limited to similarities and differences in EU Member states and associated countries, standardisation, type approval etc.) **and ethics requirements**.
- This CSA should identify and facilitate the exchange of best practices between relevant R&I project, initiatives and other stakeholders. It should provide an overview of relevant standards for data quality, security, interoperability, privacy and ethics.

HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine

Budget total: 4 M€

- 4 M€ par projet
- 1 projet financé
- Type d'action: CSA

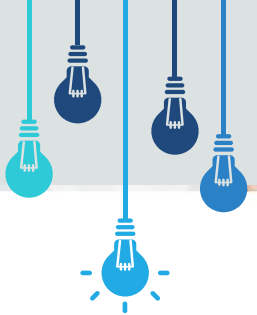
13 Novembre 2019

Dépôt en 1 étape

EXPECTED IMPACT

- The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas
- Agreed standards and mechanisms for the cross-border linking and analysis of genomic and other health data with potential for wide-spread adoption across Europe
- Adequate basis for developing a cross-border digital infrastructure for linking genomic and other health data in Europe
- Best possible and secure use of genomic and other health data for personalized medicine.
- Adequate basis for investment decisions in personalized medicine (both private and public) based on expected returns
- Support Europe's global leadership in personalized medicine

HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine



Analyse du PCN

COMMENTAIRES

- Develop coordination among stakeholders for sharing expertise and linking genomics and other type of data in order **to have a benefit for the patient**. Enable to **more informed decision** (area of cancer, prevention, etc)

- Should help the collaboration among stakeholders in different countries, would include **exchange of such data between the countries**

- Identified best practices and initiatives in other stakeholders **to avoid duplication**

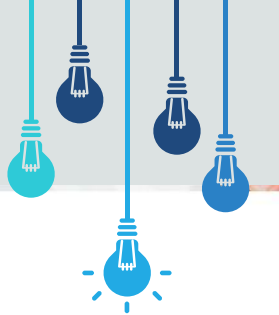
- Provide relevant standard in this fields (security, privacy, interoperability …)

- Identifies critical element to successfully exchange data

- Agree on such standards and **have an impact on practice not just guidelines**

- Not just a collection of several bilateral activities but a **wider European dimension**

HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine



CONTEXTE POLITIQUE EUROPEEN

- Plan France Medecine Genomique

- Elixir : Infrastructure that coordinates life science databases, software tools, training materials, cloud storage and supercomputers

- One million genome initiative:

Million European Genomes Alliance & Declaration : « Towards access to at least 1 million sequenced genomes in the European Union by 2022 » :

Analyse du PCN

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Budget total: 35 M€

- 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

22 avril 2020

Dépôt en 1 étape

SPECIFIC CHALLENGE

- Several national and regional initiatives already support the pooling of genomic and other health data to advance research and personalised medicine. **The next step is to make use of the existing infrastructures and initiatives for the successful exploitation of genomic data to facilitate personalised medicine.**

- The challenge is to **demonstrate the potential and benefits of AI technologies for identifying new knowledge, support clinical research and decision making by linking Europe's relevant genomic repositories,** while ensuring full compliance with data protection legislation and ethical principles.

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Budget total: 35 M€

- 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

22 avril 2020

Dépôt en 1 étape

SCOPE

- Demonstrate the potential and benefits of AI technologies for advancing research and personalised medicine through the linking of relevant genomics data and repositories, according to adequate organisational, regulatory, security, ethical and technical requirements.

- Develop and test AI solutions for linking genomics repositories across the EU, including banks of "-omics" and health related data, biobanks and other registries (including e.g. rare d isease registries), with the view of supporting clinical research and decision making.

- By combining sequenced genomic data and other medical data, physicians and researchers can understand better diseases at a personal level and can determine the most appropriate treatment for a particular person.

The focus should be:

- **to reduce the burden of diseases for which a treatment exists and to apply such tre atments in a more targeted way,**
- **to identify new evidences on the predictive value of the AI solutions**
- **to enhance the diagnostic capacity e.g. for rare or low prevalence and complex diseases.**

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Budget total: 35 M€

- 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

22 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- Supporting the development and testing of AI technologies on genomics and other linked –omics and health data repositories for identifying new knowledge, support clinical research and decision making, leading to more reliable and meaningful outcomes for advancing research and PM.

- Promoting the sharing of data and infrastructure for prevention and personalised medicine research, concretely a European network on genomics, seeking to link it with ongoing '-omics ' and human cell mapping initiatives.

- **Effectiveness of AI technologies for genomics and personalised medicine.**

- Measuring patient-based value healthcare outcomes for impact assessment on how genomics, personalised medicine and patient outcomes can help to implement value-based healthcare in Europe.

- Contributing to developing technical specifications for secure access and cross-border exchange of genomic and other –omics and health datasets in Europe for research purposes .

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Budget total: 35 M€

- 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

22 avril 2020

Dépôt en 1 étape

EXPECTED IMPACT

- Facilitating interoperability of relevant registries (including e.g. rare disease registries) and databases in support of genomics and personalised medicine research.

- Supporting the pooling of health data and resources across the EU, and demonstrate the benefits for advancing research, disease prevention and personalised medicine.

- **Contributing to standards for genomic data generation, analysis, privacy and sharing of genomic** and associated clinical and other phenotype data, including self-reported data, data from wearables, omics, and imaging.

- Contributing to the European Cloud Initiative, notably by providing open, reusable data for prevention, genomics and personalised medicine research.

- **Increasing the trust of users (healthcare professionals and patients**) and other stakeholders on AI solutions to process and link genomics data with other –omics and health related data for better decision-making and value-based patient health outcomes.

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Analyse du PCN

COMMENTAIRES

Knowledge and rolls needed to make a strong consortium

- Specialists of AI technologies on genomics and other linked –omics and health data repositories

- Owner/members of european network/data collection/repository of data and infrastructure for prevention and personalised medicine research

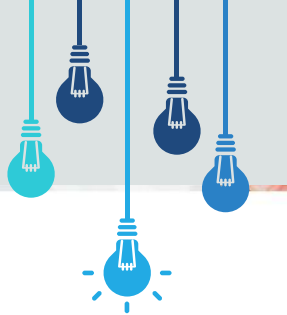
- To be able to link with ongoing '-omics' and human cell mapping initiatives.
- Clinicians/specialists of healthcare outcomes for impact assessment on how genomics, personalised medicine and patient outcomes can help to implement value-based healthcare in Europe.

- Specialists on technical specifications for secure access and cross-border exchange of genomic and other –omics and health datasets in Europe for research purposes. + on interoperability between registries/ biobanks

- Specialists on standards for genomic data generation, analysis, privacy and sharing of genomic and associated clinical and other phenotype data, including self-reported data, data from wearables, omics, and imaging.

- Links **with users** (healthcare professionals and patients) and stakeholders on AI solutions

DT-TDS-04-2020: AI for Genomics and Personalised Medicine



Analyse du PCN

COMMENTAIRES

Issues that should be taken into account

- **National and European initiatives**

- **Privacy, cybersecurity, ethical and legal rules + Sex and gender** aspects if appropriate

- Context of **European Open Science Cloud Initiative** (EOSC) to ease access of researchers to the newest data managing technologies, High Performance Computing facilities to process and analyse data and to a European Open Science Cloud list of ICT services while ensuring the appropriate data safety and protection.

- Proposals should address **technical specifications and standards for the secure access and exchange of cross-border genomic and other health data**.

- **Brokerage event : 16&17 septembre 2019, Oslo**

Le Research Council of Norway et l'Institut Français de Norvège organisent un évènement de partenariat ciblé sur les appels à projets du défi Santé, Changement Démographique et Bien-être et du programme Technologie de l'Information et la Communication (TIC) dédiés à l'**utilisation de l'intelligence artificielle en santé**

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

EXEMPLES DE PROJETS DÉJÀ FINANCÉS

Genomic:

EASI-Genomics - European Advanced infraStructure for Innovative Genomics

BeyondSeq - Genomic diagnostics beyond the sequence

IASIS - Integration and analysis of heterogeneous big data for precision medicine and suggested treatments for different types of patients

BD2Decide - Big Data and models for personalized Head and Neck Cancer Decision support_ MultipleMS - Multiple manifestations of genetic and non-genetic factors in Multiple Sclerosis disentangled with a multi-omics approach to accelerate personalised medicine

METASPACE - Bioinformatics for spatial metabolomics

MedBioinformatics - Creating medically-driven integrative bioinformatics applications focused on oncology, CNS disorders and their comorbidities (MedBioinformatics)

GenCoder - The first MPEG-G compliant software tools for efficient compression, storage, transport and analysis of genomic data enabling systems interoperability

AI

AI-MICADIS - Artificial Intelligence System for Multi-Cancer Detection Support

Analyse du PCN

DT-TDS-05-2020: AI for Health Imaging

Budget total: 35 M€

- 8 à 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

19 Novembre 2019

Dépôt en 1 étape

SPECIFIC CHALLENGE

- Artificial Intelligence (AI) offers substantial opportunities for healthcare, supporting better diagnosis, treatment, prevention and personalised care.

- **Analysis of health images is one of the most promising fields for applying AI in healthcare**, contributing to better prediction, diagnosis and treatment of diseases. In order to develop and test reliable AI applications in the field, access to large-volume of high- quality data is needed

DT-TDS-05-2020: AI for Health Imaging

Budget total: 35 M€

- 8 à 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

13 Novembre 2019

Dépôt en 1 étape

SCOPE

- This action should contribute to **testing and developing AI tools and analytics** focused on the prevention, prediction and treatment of the most common forms of cancer while providing solutions to securely share health images across Europe.

- Proposals should **set up and contribute to populate a large interoperable repository of health images**, enabling the development, testing and validation of AI–based health imaging solutions to improve diagnosis, disease prediction and follow-up of the most common forms of cancer.

- The repository should include high quality, interoperable, anonymised or pseudo-anonymised data sets of annotated cases, based on data donorship, and should comply with relevant ethics, security requirements and data protection legislation. Gender aspects should be considered appropriately.

The consortium should build on relevant national and EU activities and bring together:

1) expertise to set up the infrastructure, ensuring the appropriate sharing of data quality and interoperability,
2) AI developers/expertise to experiment its content while ensuring compliance with relevant legislations

DT-TDS-05-2020: AI for Health Imaging

Budget total: 35 M€

- 8 à 10 M€ par projet
- 3 à 4 projets financés
- Type d'action: RIA

13 Novembre 2019

Dépôt en 1 étape

EXPECTED IMPACTS

- Contributing towards the creation of a **EU-wide repository of health images** dedicated to the most common forms of cancer, enabling experimentation of AI-based solutions to improve diagnosis, treatment and follow-up and contribute to a more precise and personalised management of cancer.

- Contributing to **developing technical, organisational and ethical standards for AI for health imaging**

- Promoting access to anonymised health image data sets to be made more openly reusable across the EU for training AI applications.

- **Increasing trust in AI solutions among users** (healthcare professionals and patients), investors and stakeholders at industry and academia.

Liste des prochains webinaires et inscription

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

- 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 - Inscription

- 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 - Inscription

- 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