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Cycle de présentation des appels à projets
du programme de travail santé 2023-2024

# Les appels de la DESTINATION 6

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# Netiquette

- ✓ Éteignez votre microphone et vidéo pendant le webinaire pour ne pas bloquer la bande passante
- ✓ Posez vos questions dans le chat : à la fin de chaque topic ou à la fin du webinaire

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# Dans ce webinaire vous allez trouver:

- Qui sommes nous ?
- Planification stratégique 2021-2024
- Comment participer à un projet Horizon Europe en Santé
- Destination 6 et appels

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# PCN Santé – Qui sommes-nous ?

**Virginie Sivan, MESRI**
Coordination PCN et représentation au comité de programme Santé

horizon europepcn Santé

**Vania Rosas-Magallanes**

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Liste de diffusion

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# PCN Santé – Que fait-on ?

## INFORMER, SENSIBILISER, CONSEILLER LES ÉQUIPES SUR

- Les opportunités de financement de projets Horizon Europe en santé
- Les modalités de fonctionnement du programme
- Rencontre de porteurs de projets ou échange par mail et téléphone

https://www.horizon-europe.gouv.fr/cluster-1-sante

## FORMER la communauté scientifique et les personnels support

- Organisation de formations (dashboard, construire son réseau)

## ORIENTER

- Signaler l'existence et orienter vers d'autres sources de financement susceptibles de mieux répondre aux besoins des équipes

## CE QUE NOUS NE FAISONS PAS

- Le PCN ne fait pas de montage de projets
- Le PCN ne fait pas de relecture de propositions

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# Le Cluster Santé

**6 domaines d'intervention**


**Planification stratégique 2021-2024***

Priorités politiques de l'UE (Transition verte et numérique)
Orientations Stratégiques pour la R&I
"Expected impacts" – Destinations (Santé)

**Programme de travail Santé**

**Partenariats en santé**

**Mission Cancer**

* https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/3c6ffd74-8ac3-11eb-b85c-01aa75ed71a1

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# Participer au Cluster Santé

## Qu'est ce qu'un projet collaboratif ?

Consortium de partenaires réunis pour mener à bien un projet collaboratif et **multidisciplinaire** de recherche et développement, avec un **impact à la fois sociétal** au bénéfice du citoyen (et des patients) et **économique sur les systèmes de santé.**

## Financement d'un consortium

- **Coordinateur** : seul interlocuteur de la CE, assure le bon déroulé du projet et de ses livrables, et l'interaction entre les partenaires.
- **Partenaire (Bénéficiaire)** : responsable d'un *work-package* ou d'une activité

5 à 20 à partenaires

Budget 3 à 15M€

4 à 5 ans

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# Types d'action

- **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%**

- **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**
**100% pour les entités publiques - 70% pour les entités privées**

- **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%**

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# Règles de participation

- **Conditions d'éligibilité d'un consortium**

  Minimum 3 entités légales indépendantes et établies dans un Etat Membre ou Etat Associé différent, **dont au moins une établie dans un Etat Membre**

- **Condition de participation**

  Toute entité légale de tout pays peut participer (organisme de recherche, université, PME, associations, villes….)

- **Pays éligibles au financement**

  Etats Membres et états associés à Horizon Europe

  Certains pays tiers:

  - Pays à revenus faibles ou intermédiaires
  - Pays spécifiés dans les appels
  - **USA (pour le programme santé uniquement)**

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# Coopération internationale

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

## Contribution financière de la C.E pour le Cluster Santé

- 27 Etats-Membres
- Etats-Associés :
  - Albanie, Arménie, Bosnie-Herzegovine, Iles Féroé, Géorgie, Islande, Israël, Kosovo, Maroc, Moldavie, Monténégro, Macédoine du Nord, Norvège, Serbie, Tunisie, Turquie et Ukraine.

  ATTENTION : UK – association en cours - (possible de les associer à un projet en montage en attendant l'entrée en vigueur de l'association)
- Pays-Tiers : certains pays à faibles et moyens revenus sont automatiquement éligibles au financement (Programme Guide Horizon Europe)

## CAS PARTICULIER

USA : partenaires USA éligibles au financement par la CE uniquement pour le cluster Santé dans le cadre d'un accord de réciprocité avec le NIH → USA pas éligible au financement dans la mission Cancer

Suisse: pas d'accord d'association. Les institutions Suisses sont financées directement par leur agence nationale.

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# Structure d'un appel à projets

**Destination n°6 : Titre de la destination**

Description de la destination avec un état des lieux et des objectifs à atteindre

**Expected Impact** : → **Long terme**

Liste d'impacts en lien avec le plan stratégique que les propositions de l'ensemble des topics de cette destination doivent contribuer à atteindre.

**Topic 6.1 : Titre du topic**

- **Expected outcomes :** les résultats attendus des projets soumis en réponse à ce topic doivent y contribuer → **Court/moyen terme**
- Scope : périmètre d'action des propositions soumises dans le cadre de ce topic

**Topic 6.2 : Titre du topic**

- **Expected outcomes** : les résultats attendus des projets soumis en réponse à ce topic doivent y contribuer
- Scope : périmètre d'action des propositions soumises dans le cadre de ce topic

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# Cluster Santé : WP 23-24

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# Programme de travail 2023-2024

1- **Staying healthy** in a rapidly changing society

2- Living and working in a **health-promoting environment**

3- **Tackling diseases** and reducing disease burden

4- Ensuring **access to innovative, sustainable and high-quality health care**

5- Unlocking the full potential of **new tools, technologies and digital solutions** for a healthy society

6- Maintaining an innovative, sustainable and globally **competitive health-related industry**

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# Destination 6 :Maintaining an innovative, sustainable and globally competitive health-related industry

**Objectif** : L'industrie de la santé est un moteur essentiel de la croissance et a la capacité de fournir des technologies de santé au profit des patients et des prestataires de services de soins de santé. Il est nécessaire de mener des recherches et d'innover en intégrant les différentes parties prenantes afin de faciliter l'accès au marché des technologies de santé innovantes (technologies médicales, produits pharmaceutiques, biotechnologies, technologies de santé numériques)

**Contexte politique : transition verte (green deal) et transition numérique (Digital transformation of health and care)**

- Produire de composées pharmaceutiques compatibles avec le pacte vert
- Méthodologies, guidelines et standards adaptés aux solutions numériques
- Meilleurs méthodologies et approches interdisciplinaires pour soutenir les autorités publiques dans l'évaluation de nouvelles technologies de santé et interventions
- Développement de produits pharmaceutiques pour répondre aux besoins non pourvus

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# Destination 6 :Maintaining an innovative, sustainable and globally competitive health-related industry

## Expected impacts

**Health industry** in the EU: **more competitive and sustainable**, assuring **European leadership in breakthrough health technologies** and open strategic autonomy in essential medical supplies and digital technologies, contributing **to job creation and economic growth**, in particular with small- and medium-sized enterprises (SMEs).

**Health industry** is working more efficiently along **the value chain from the identification of needs to the scale-up and take-up of solutions** at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators ensuring suitability and acceptance of solutions.

European standards, including for operations involving health data, ensure **patient** safety and quality of **healthcare services** as well as effectiveness and interoperability of health innovation and productivity of innovators.

**Citizens**, **health care providers and health systems** benefit from a swift uptake of **innovative health technologies and services** offering significant improvements in health outcomes, while health industry in the EU benefits from decreased time-to-market.

**Health security** in the EU benefits from reliable **access to key manufacturing capacity**, including timely provision of essential medical supplies of particularly complex or critical supply and distribution chains, such as regards vaccines or medical radioisotopes

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# Destination 6 :Maintaining an innovative, sustainable and globally competitive health-related industry

| Topic | Date limite | Type | Budget par projet | Nbre projets financés |
|---|---|---|---|---|
| **Call - A competitive health-related industry (Single stage - 2023)** | | | | |
| 2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU | 13 Avr. 2023 | CSA | 5 M€ | 1 |
| 2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space | 13 Avr. 2023 | RIA | 3-5 M€ | 2 |
| 2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines | 13 Avr. 2023 | RIA | 4-6 M€ | 5 |
| 2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs) | 13 Avr. 2023 | CSA | 3 M€ | 1 |
| 2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe | 13 Avr. 2023 | RIA | 7-8 M€ | 2 |

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# Destination 6 :Maintaining an innovative, sustainable and globally competitive health-related industry

| Topic | Date limite | Type | Budget par projet | Nbre projets financés |
|---|---|---|---|---|
| **Call - A competitive health-related industry (Single stage - 2024)** | | | | |
| 2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs) | 11 Avr. 2024 | RIA | 8-10 M€ | 1 |
| 2024-IND-06-09: Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for EU regulators | 11 Avr. 2024 | CSA | 2 M€ | 1 |

# HORIZON-HLTH-2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

**Objectif du projet :** Mettre en œuvre des recommandations méthodologiques HTA et avancer l'expertise HTA en Europe via des programmes de formation.

Date limite de soumission
13 avril 2023

Budget total : 5 M€
Budget par projet : 5 M€
Type d'action : CSA

**« Expected outcomes »** Contribute to **all of** them

- **Identification of the most innovative HTA methods** developed by EU-funded projects, which respond to the needs of HTA bodies and are ready to be used in real-life settings. Endorsement by HTA bodies of such innovative methods would allow for advancing HTA methodology and improve evidence-based decision making, and patient access to novel health technologies
- **Dissemination among EU HTA bodies of robust innovative HTA** methods and tools developed by EU-funded projects.
- **Harmonisation of HTA expertise** across EU though the development of a training programme developed in collaboration with academia. The training should address HTA expertise in general, as wells as expertise in joint HTA to be carried out at EU level in accordance with Regulation (EU) 2021/2282, based on the methodological guidelines elaborated by the Coordination Group on HTA.
- **Contribution to a successful implementation of the HTA Regulation** as well as to building an EU methodological HTA framework fit for purpose and fit for the future.

# HORIZON-HLTH-2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

**Scope**

**Domaine** : Regulation, HTA methods, HTA bodies, harmonisation, standardisation, EU methodological framework, method of analysis, real-world data

**Stade développement** : building from existing EU funded projects

Les propositions devront traiter TOUS les aspects suivant :

- **Implementation of innovative HTA methods**: EU-funded research projects (e.g. COMED, IMPACT-HTA, HTx, GetReal, EHDEN) developed innovative methods aiming at addressing HTA bodies' needs.
- Identification of **innovative methods and tools**, in particular those developed in **EU-funded projects** able to address HTA bodies' needs (in different areas: relative effectiveness assessment, cost-effectiveness assessment, etc.)
- **Identifications of barriers** to the uptake of these methods (and potential associated tools, e.g. open-source software to run cost-effectiveness analyses)
- **Use cases** (based on the needs identified by HTA bodies) to facilitate the endorsement by HTA bodies of innovative methods
- Development of an implementation plan including **supporting tools and training modules** (by researchers, alone or in collaboration with HTA bodies, to be delivered to HTA bodies/agencies) across EU and Associated countries
- Recommendations for broader dissemination

# HORIZON-HLTH-2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

## Partenaires à inclure

- HTA bodies
- Health agencies
- Researchers
- Developers of HTA

# HORIZON-HLTH-2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

**Exemples de projets déjà financés (non exhaustive)**

**H2020**

**Topic: SC1-PM-20-2017- Methods research for improved health economic evaluation**

(3 projects funded on this topic)

-Project: IMPACT HTA: Improved Methods and Actionable Tools for Enhancing Health Technology Assessment

**Topic: SC1-BHC-26-2018 - HTA research to support evidence-based healthcare**

(1 project funded on this topic)

-Project: HTx: Next Generation Health Technology Assessment to support patient-centred, societally oriented, real-time decision-making on access and reimbursement for health technologies throughout Europe

**FP7**

**Topic: HEALTH.2012.3.2-2 - New methodologies for health technology assessment**

(4 projects funded on this topic)

-Project: INTEGRATE-HTA: Integrated health technology assessment for evaluating complex technologies

# HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

**Objectif du projet :** Recherche, développement et validation de formats d'interoperabilité harmonisés pour le partage de données

Date limite de soumission
13 avril 2023

Budget total : 8 M€
Budget par projet : 3-5 M€
Type d'action : RIA

**« Expected outcomes »** Contribute to **all of** them

- **European Health Record (EHR) stakeholders** (e.g. developers, suppliers, integrators, and operators) have at their disposal and use **fit-for-purpose standards, guidelines, and toolsets for prioritised health information domains** to address interoperability of EHRs in line with the principles set in the EEHRxF Recommendation, contributing also to security and privacy.
- **Stakeholders** have at their disposal **better quality and better integrated health datasets** within the European Health Data Space, to foster innovations in the health sector and Commission Recommendation on a European Electronic Health Record exchange Format (EEHRxF) (C(219)800) leverage the potential of new analytics solutions such as AI and big data, get new insights and detect trends from aggregated data, including for cross-border health threats.
- **Citizens** are provided with an **expanded access to their health data**, also across borders, and innovative digital services for high-quality health and care across the EU

# HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

**Scope**

**Domaine** : Bioinformatics, health data sharing, clinics, e-security

Les propositions devront traiter **TOUS** les aspects suivant :

- Research, develop and validate **harmonised interoperability formats** for sharing data in specific priority health information domains that should be selected with reference to the EU policies and priorities, in line with the EEHRxF recommendation
- Leverage and scale up the potential of EHR through **enhanced interoperability** to improve the quality, safety, and efficiency of patient care, enforce patients' right to data portability, enhance care coordination, guide crisis planning, reduce medical errors, and lower costs. Taking into account lessons learned from COVID-19
- Address semantic interoperability for prioritised information domains so that the transmitted health record contains **standardised coded data**.
- Maximise synergies with relevant initiatives, activities and programmes, building upon previous and linking to on-going actions

# HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

**Scope**

**Domaine** : Bioinformatics, health data sharing, clinics, cibersecurity

Les projets financés seront engagés dans des activités de réseautage:

- Prévoir un budget suffisant dans un WP dédié dans la proposition, même si les activités précises ne seront définies qu'au stade de préparation du grant si le projet est sélectionné.

# HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

## Partenaires à inclure

- Developers, suppliers, integrators, and operators (EHR)
- Healthcare professionals
- Healthcare industry (including SMEs)
- Cibersecurity and safety experts/AI experts
- Policymakers, legislators
- Ethics and regulation experts
- Citizens and patients

# HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

## Exemples de projets déjà financés (liste non exhaustive)

### H2020

**Topic: PHC-34-2014 - eHealth interoperability**

4 projets financés

**Topic: SC1-DTH-08-2018 - Prototyping a European interoperable Electronic Health Record (EHR) exchange**

2 projets financés

### Horizon Europe

**Topic: HORIZON-HLTH-2022-IND-13-05 - Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem**

Project: XpanDH- Expanding Digital Health through a pan-European EHRxF-based Ecosystem

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

**Objectif du projet :** Développement de méthodes diverses de modélisation et de simulation en tant qu'outils pour répondre aux besoins règlementaires dans le cycle de développement clinique de nouveaux produits pour maladies rares et pédiatriques.

Date limite de soumission
13 avril 2023

Budget total : 25 M€
Budget par projet : 4-6 M€
Type d'action : RIA

**« Expected outcomes »** Contribute to **all of** them

- **Developers and regulators** have access to **robust modelling and simulation tools** to accelerate the effective development of orphan and/or paediatric medicinal products.
- **Clinical researchers, developers and regulators** use **accurate computational models** to improve the statistical robustness in clinical trials intended for small populations and guide cost-effective clinical trial designs.
- **Clinical researchers and regulators** have access to **accurate in-silico tools** for assessing the actionable use of real-world data and for successfully estimating the risk-benefit effects in clinical trials for small populations.
- **Regulators** develop **guidance for the use of validated computational models** to support a robust extrapolation framework and facilitate the safety and efficacy assessment in the process of regulatory appraisal of orphan and/or paediatric medicinal products.

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

**Scope**

**Domaine**: Statistics, modelling, in-silico approaches, regulation

**Stade développement:** This topic is not intended to implement new preclinical/clinical studies but to use the existing knowledge/data for assessing and optimising the performance of mature in-silico models in the regulatory context with the goal of improving the clinical trial designs for small populations. Mature computational models

Les propositions devront traiter **TOUS** les aspects suivant :

- Establish a **multidisciplinary approach** for assessing the utility of **mature computational models**, as tools for supporting the optimal design of innovative clinical trials for small populations and as fit-for-purpose solutions for enabling the regulatory scientific advice and marketing authorisation assessment of orphan and/or paediatric medicines, including their pharmacovigilance follow-up.
- **Calibrate and optimise** mature computational models for enhancing their clinical performance, by using relevant sources of **patient data** (e.g. natural history and observational clinical studies, medical records, registries, pharmacovigilance and longitudinal studies etc.).

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

## Scope

**Domaine**: Statistics, modelling, in-silico approaches, regulation

**Stade développement:** This topic is not intended to implement new preclinical/clinical studies but to use the existing knowledge/data for assessing and optimising the performance of mature in-silico models in the regulatory context with the goal of improving the clinical trial designs for small populations. Mature computational models

Les propositions devront traiter **TOUS** les aspects suivant :

- **Assess validated in-silico models** for their capability to increase the statistical robustness, improve the risk/benefit assessment in small population clinical trials, and for their accuracy to predict and extrapolate the therapeutic and dose effects, taking into account the patient's genotypes/phenotypes, disease characteristics/stage variables and/or clinical/surrogate endpoints for delivering robust evidence of safety and efficacy of the orphan and paediatric medicines under study.
- **Benchmark** of diverse computational models by showcasing their simulation performance in virtual patient cohorts and by demonstrating that the models' synthetic data estimates match to actual clinical trial data.
- Set-up the criteria for the performance and **credibility assessment of** any relevant computational models for small population clinical trials to progress on their regulatory qualification and acceptability.

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

## Partenaires à inclure

- Regulatory agencies: National healthcare product regulatory bodies and EMA
- Patient associations
- SMEs is encouraged
- Statisticians
- Developers
- Bioinformaticians
- Clinical researchers
- Links to the EU RD platform, if possible

Les projets financés seront engagés dans des activités de réseautage:

- Prévoir un budget suffisant dans un WP dédié dans la proposition, même si les activités précises ne seront définies qu'au stade de préparation du grant si le projet est sélectionné

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

## Contexte politique européen

- Cité dans le texte de l'appel :
  - Regulatory Science Strategy 2025 to encourage innovation by building a more adaptive regulatory system for human and veterinary medicine
  - ISO-paper under development "Recommendations and requirements for predictive computational models in personalized medicine research — Part 1: Guidelines for constructing, verifying and validating models".
  - Proposals should be RGPD compliant (all)

# HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

## Exemples de projets déjà financés (liste non exhaustive)

### FP7

**Topic: HEALTH.2013.4.2-3 - New methodologies for clinical trials for small population groups**

**3 projets financés**

.

# HORIZON-HLTH-2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

**Objectif du projet :** Cartographier les besoins règlementaires, de sureté, d'évaluation de l'efficacité, de production, des besoins d'organisation et d'infrastructures pour améliorer la traduction des ATMPs du développement préclinique à l'utilisation clinique

Date limite de soumission
13 avril 2023

Budget total : 3 M€
Budget par projet : 3 M€
Type d'action : CSA

**« Expected outcomes »** Contribute to **all of** them

- Challenging aspects of regulation, policy, safety, efficacy, manufacturing, organisation, infrastructure, decision-making, and commercialisation are identified for **speeding up the equitable clinical applications of ATMPs.**
- **European regulatory frameworks** are **adapted to novel scientific progress**, especially those related to platform approaches, genome editing, interface with medical devices, artificial intelligence.
- **Competent authorities** in the Member States can propose **adapted pricing and reimbursement schemes** that allow European citizens to benefit from novel ATMPs.
- **Academic and SME developers and manufacturers of ATMPs** have an **increased knowledge of the regulatory aspects**.
- The **decentralised manufacturing of ATMPs** is consistent across health care centres.

# HORIZON-HLTH-2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

**Scope**

**Domaine** : Cell an Gene Therapies, regulation

Les propositions devront traiter **TOUS** les aspects suivant :

- **Map** the regulatory, safety and efficacy assessment, manufacturing, organisational and infrastructural needs to improve the translation of ATMPs from preclinical development to clinical use.
- **Address the gaps** and uncertainties in regulatory and policy aspects pertinent to complex innovative ATMPs.
- **Address predictivity of preclinical data for safety and efficacy testing of ATMPs**. Improved novel models could be proposed
- Tackle **decision-making processes relating to ATMPs,** such as for instance the assessment of their values, the demonstration of the long-term safety and effectiveness, or new pricing and reimbursement frameworks.
- Propose opportunities for an improved knowledge of the regulatory processes among academic ATMP developers.

# HORIZON-HLTH-2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

## Partenaires à inclure

- Regulatory authorities
- Health Technology Agencies (HTA)
- Clinicians
- Ethics Committees
- Patients
- SME developers and manufacturers

# HORIZON-HLTH-2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

## Exemples de projets déjà financés (liste non exhaustive)

### FP7

**Topic: HEALTH.2013.4.1-2 - Interactions between EU legislation and health research and/or innovation and the effects of its application and implementation on health research and/or innovation**

Project: EUCELLEX Cell-based regenerative medicine: new challenges for EU legislation and governance

.

# HORIZON-HLTH-2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

**Objectif du projet :** Développer et harmoniser les méthodologies pour évaluer les technologies numériques de santé (dont les applications mHealth et télésanté, ainsi que les technologies incluant l'IA) afin de faciliter l'évaluation de leur valeur ajoutée au niveau individuel, du système de santé et de la société et faciliter le déploiement transfrontalier de services de santé numérique en Europe

Date limite de soumission
13 avril 2023

Budget total : 15 M€
Budget par projet : 7-8 M€
Type d'action : RIA

**« Expected outcomes »** Contribute to **all of** them

- **Policymakers in the EU** have at their disposal a **methodological framework and standardised approaches** for assessing digital health technologies, that helps them make evidence-based decisions regarding the introduction of digital health technologies in their health and care systems with added value for patients and society.
- **Regulators** have access to **robust, scientifically underpinned evaluation methodologies**.
- **EU citizens** gain faster access to **safe and well-performing person-centred digital technologies** and are empowered through these tools.
- **Health technology developers** are better informed and dispose of **more guidance on the evidence needed** to demonstrate the added value of digital health technologies and have better insights on market predictability.
- **(Digital) Health Industry/digital health technology developers and HTA bodies** can contribute to the development of **EU harmonised Health Technology Assessment (HTA) rules** based on common principles.
- **Improved cross-border use and interoperability of digital health tools and services** throughout the EU and Associated Countries.
- **Increased trust in digital health technologies** and better integration of digital health tools and services in health and care systems.

# HORIZON-HLTH-2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

**Scope**

**Domaine** : Règlementation, développement de technologies appliquées à la santé de la chirurgie robotique à des applications mobiles pour les patients

Les propositions devront traiter **TOUS** les aspects suivant :

- Develop and/or expand a general **methodological framework** and standardised approaches to assess digital health technologies with a particular focus on criteria such as **privacy, cybersecurity, data quality, data storage and handling, interoperability** etc.;
- Comply with the relevant requirements proposed in the **European Health Data Space (EHDS)** legal provisions;
- Test the **robustness** of the developed methodologies on minimum 3 different digital health technology use cases;
- Pilot the development of common specifications to the **harmonisation of assessment frameworks** (pre-market and post market phases) throughout the EU and Associated Countries
- **Include end-users** of digital health technologies (be it professionals, care users or citizens), developers of digital health technologies, producers of health services, regulators and governments;
- Collect best practice for common approaches in methodology for digital health technology assessment and develop an open access **European repository for evaluation methods**, studies, results and evidence of digital health technologies and services
- Contribute to a framework to evaluate and monitor whether the uptake and use of digital health services contribute to the overall goals of the health and care system

# HORIZON-HLTH-2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

## Partenaires à inclure

- Devleoppeers of digital technologies
- Policymakers
- Regulators
- Citizens
- HTA bodies
- JRC pour leur expertise on of innovative health technologies (la CE fera le lien, mais n'oubliez pas de budgeetiser cette collaboration)

# HORIZON-HLTH-2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

## Contexte politique européen

➢ Cité dans le texte de l'appel :

- ASSESSING THE IMPACT OF DIGITAL TRANSFORMATION OF HEALTH SERVICES, Report of the Expert Panel on effective ways of investing in Health (EXPH) - https://ec.europa.eu/health/system/files/2019-11/022_digitaltransformation_en_0.pdf
- Existing frameworks such as (but not restricted to) 'Model for Assessment of Telemedicine' (MAST framework – Kidholm et al., 2012) and the results of previous EU-funded projects in particular (but not restricted to) COMED, project that already identified HTA challenges of telehealth and mhealth, and mHealth hub

# HORIZON-HLTH-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

**Objectif du projet :** Développement d'un cadre pour évaluer le cycle de vie entier de génération de preuves et d'évaluation de dispositifs médicaux et des dispositifs de diagnostic in vitro (IVD), en particulier ceux à haut risque.

Date limite de soumission
11 avril 2024

Budget total : 10 M€
Budget par projet : 8-10 M€
Type d'action : RIA

**« Expected outcomes »** Contribute to **all of** them

- **Patients** gain faster **access to innovative, safe and well-performing medical devices**;
- **Regulators** have access to **sound scientific resources for clinical/performance evaluation guidance** and development of common specifications as foreseen in Article 9 of the Medical Device Regulation (MDR);
- **Notified bodies**, by their direct participation to the production of documents, will have **a harmonised way of assessing the clinical evidence** in the pre-market and post-market phases; furthermore their network, will be enhanced;
- **Health technology developers** gain insight on the **evidence needed to demonstrate that their devices meet MDR clinical requirements** throughout their lifetime. They will also have more guidance on the use of real-world data for their clinical development strategies.

# HORIZON-HLTH-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

**Scope**

**Domaine** : Regulation for medical devices and in vitro diagnostic medical devices

Les propositions devront traiter **TOUS** les aspects suivant :

- Development of a framework for a life-cycle approach to evidence generation and evaluation of high-risk and innovative medical devices and IVDs.
- For medical devices, a pilot to support development of common specifications which would set the stage for a common specification ecosystem for medical devices in the EU
- Development of a general methodological approach to define, determine and update the state of the art for different device technologies.
- Possible use of registries and other sources of real-world data for demonstration of regulatory compliance both pre- and post-market
- Methodology for bridging studies for devices and IVDs with iterative development
- Identification of relevant quantitative and qualitative methodologies for integrating evidence derived from various data sources in the clinical evaluation/performance evaluation

# HORIZON-HLTH-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

## Partenaires à inclure

Build on EU funded initiatives:  2e.g. PARENT (PAtient REgistries iNiTiative) Joint Action, CORE-MD (Coordinating Research and Evidence for Medical Devices) H2020 research project, JAMS (Joint Action on Market Surveillance of Medical Devices) initiative

- Researchers
- Clinicians
- National competente authorities
- Notified bodies
- IVD laboratories
- HTA bodies
- Patients representatives

# HORIZON-HLTH-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

## Contexte politique européen

- Cité dans le texte de l'appel :
  - Medical Device Regulation
  - In vitro Diagnostic Regulation

# HORIZON-HLTH-2024-IND-06-09: Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators

**Objectif du projet :** Rassembler les développeurs et les utilisateurs de nouvelles approches méthodologiques (NAM) alternatives à l'utilisation d'animaux avec les responsables règlementaires européens pour l'utilisation des produits chimiques et pharmaceutiques pour informer sur les solutions NAM disponibles et encourager la construction d'un cadre sur l'utilisation des ces NAM

Date limite de soumission
11 avril 2024

Budget total : 2 M€
Budget par projet : 2 M€
Type d'action : CSA

**« Expected outcomes »** Contribute to **all of** them

- **Patients** gain faster **access to innovative, safe and well-performing medical devices**;
- **European regulators** gain **state-of-the-art knowledge** on different NAMs that are being proposed for the assessment of the safety and efficacy of chemicals and pharmaceuticals;
- **European regulators** understand better the **shortcomings of the current tools** based on animal procedures for the assessment of chemicals and pharmaceuticals;
- **European regulators collaborate on a framework on how to assess the safety** of chemicals based on NAM-data and how to classify the hazardous properties based on such data;
- **European regulators collaborate on a similar framework for assessment of safety and efficacy** of pharmaceuticals based on NAM-data;
- **Citizens** benefit from the supply and use of **chemicals** and pharmaceuticals that have been **assessed through NAMs** that are better predicting potential effects in humans than the current assessment methods;
- **Industry** has an **improved competitive position** with the availability of harmonised and standardised NAM-based assessment tools that are faster and more flexible;
- **European Commission and Member States regulators** are responding to the societal demand to **move away from animal testing.**

# HORIZON-HLTH-2024-IND-06-09: Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators

**Scope**

**Domaine** : Regulation, training on regulation, alternatives to animal testing

Les propositions devront traiter **TOUS** les aspects suivant :

- Develop technical and regulatory readiness criteria
- Reflect on how to provide mechanisms to support technology transfer, i.e. bringing promising NAMs to the market (including optimisation and transferability assessment)
- Discuss how to standardise NAMs and NAM-based strategies via OECD, CEN, ISO, ICH, VICH and other international organisations, as applicable
- Provide technical training for Contract Research Organisations (CROs) applying NAMs for regulatory purposes
- Promote dialogue (involving companies, regulatory bodies on EU level, including ECHA, EMA and EFSA and Member States authorities) on how to integrate and interpret data from NAMs and facilitate their uptake for safety and efficacy testing of chemicals (including pesticides) and pharmaceuticals, while addressing the lack of reliability and shortcomings of the current tools based on animal procedures
- Identify obstacles in EU legislation for the regulatory use of NAMs and propose options/changes in the EU regulatory framework which address these obstacles and facilitate the uptake and use of NAMs

# HORIZON-HLTH-2024-IND-06-09: Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators

## Partenaires à inclure

- Patients
- European regulators
- Citizens
- Researchers
- International organisations
- Ethics

Proposals should consider involving the JRC to take advantage of its expertise and relevant activities in bridging research and regulatory communities and facilitating uptake of NAMs for regulatory application. In that respect, the JRC is open to collaborate with any successful proposal after its approval.

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# Aide au montage

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# ANR : MRSEI
## Montage de Réseaux Scientifiques Européens ou Internationaux

Soutient **l'aide au montage et à l'animation** d'un réseau scientifique européen ou international **coordonné par une équipe Française** impliquant les membres du réseau qui sera déposé à un appel européen ou international.

Subvention: 35 k€ pour une durée maximale de 24 mois

Coût éligibles:

- ☑ communication, organisation et animation de rencontres, ateliers, symposium, etc…
- ☑ prestation de service à hauteur maximale de 10 000€ pour appuyer le coordinateur dans le montage du futur projet.

Prochaines dates de soumission :

- 3 avril 2023
- 1er juin 2023
- 9 octobre 2023

Toutes les infos : https://anr.fr/fr/detail/call/montage-de-reseaux-scientifiques-europeens-ou-internationaux-mrsei-2023/

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# Le diagnostic Partenariat pour le projets collaboratifs des entreprises

Le Diagnostic Partenariat Technologique International (Diag PTI) de Bpifrance vise à faciliter l'accès des entreprises françaises aux appels à projets collaboratifs de recherche, développement et innovation, au premier rang desquels Horizon Europe.

**En pratique, le Diag PTI comprend**


- une multitude de possibilités d'accompagnement sur toute la partie de montage du projet collaboratif : recherche de partenaires, négociation de l'accord de consortium, écriture de dossier, etc.
- une subvention qui couvre 50 % du montant TTC de la prestation d'un Expert Conseil
- une prestation adaptée aux besoins de l'entreprise : jusqu'à 25k€ HT si l'entreprise est cheffe de file, jusqu'à 5k€ HT si l'entreprise fait partie d'un consortium sans en être à la tête
- un dépôt au fil de l'eau, qui s'adapte à la timeline de l'entreprise
- une demande facilitée en ligne, sur le site de Bpifrance
- une réponse rapide sous 2 semaines

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# Devenez Expert Evaluateur

Toutes les informations et wébinaire de présentation :

https://www.horizon-europe.gouv.fr/devenez-expert-evaluateur-horizon-europe-aupres-de-la-commission-europeenne-24364

HORIZON 2020

## Pourquoi devenir expert ?

- S'approprier le mécanisme d'évaluation et affiner ses compétences en matière de rédaction de propositions ;
- Se faire connaître de la C.E. comme un expert du domaine ;
- Réaliser un état de l'art de la recherche européenne dans un secteur donné ;
- Développer un réseau de partenaires potentiels ;
- Mieux connaître les mécanismes européens ;
- Promouvoir sa perspective sur les enjeux de la recherche

## Qui peut être expert ?

Peuvent prétendre à devenir experts, les individus de toute nationalité, bénéficiant d'un haut niveau d'expertise dans un domaine relatif à une thématique d'Horizon 2020, qu'ils proviennent de la sphère académique, de la recherche ou de la sphère économique et commerciale.

**4 Critères de sélection des experts**

- Expertise : technique, et/ou gestion de projet, et/ou innovation, et/ou exploitation, et/ou dissémination, et/ou communication, et/ou "business development"
- Diversité géographique
- Parité
- Rotation/renouvellement : 30% par an

## En quoi consiste le travail d'évaluation ?

- Examiner et évaluer des propositions déposées dans le cadre des appels ;
- Travailler :
  - dans le cadre de sessions courtes d'une durée maximale de 10 jours par an ;
  - à distance et/ou à Bruxelles ou Luxembourg

*Le nombre de propositions à traiter est variable selon l'appel*

## Rémunération

Il s'agit d'une indemnité de 450 euros TTC/jour
Prise en charge des frais de mission

## Déplacements à prévoir

L'expert évaluateur doit prévoir 1 semaine de travail et de déplacement à Bruxelles ou Luxembourg par campagne d'évaluation.

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# A retenir

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**19 January : Info day CE santé (on line):** https://research-innovation-community.ec.europa.eu/events/2zRJQrIdbL7rCrilJbBN4l/overview

**20 January : Brokerage event santé CE (on line)**: https://www.horizon-europe.gouv.fr/cluster-sante-et-mission-cancer-horizon-europe-brokerage-event-appels-2023-34147

**25 January: Webinaire lump Sum par le PCN JurFin avec des temoignages et la CE:** https://www.horizon-europe.gouv.fr/webinaire-sur-le-financement-par-sommes-forfaitaires-34144

**09 February: Lump Sum Funding in Horizon Europe: How does it work? How to write a proposal?**
https://ec.europa.eu/research/participants/docs/h2020-funding-guide/other/event230209.html

**16 January: Appels Destination 6:** https://www.horizon-europe.gouv.fr/cluster1-16-01-2023

**https://www.horizon-europe.gouv.fr/les-shs-dans-le-programme-sante-34477**

**Contact your support services Europe**
**Contact the Health NCPs: pcn-sante@recherche.gouv.fr**

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