MINISTÈRE
CHARGÉ
DE L'ENSEIGNEMENT
SUPÉRIEUR
ET DE LA RECHERCHE

Liberté
Égalité
Fraternité

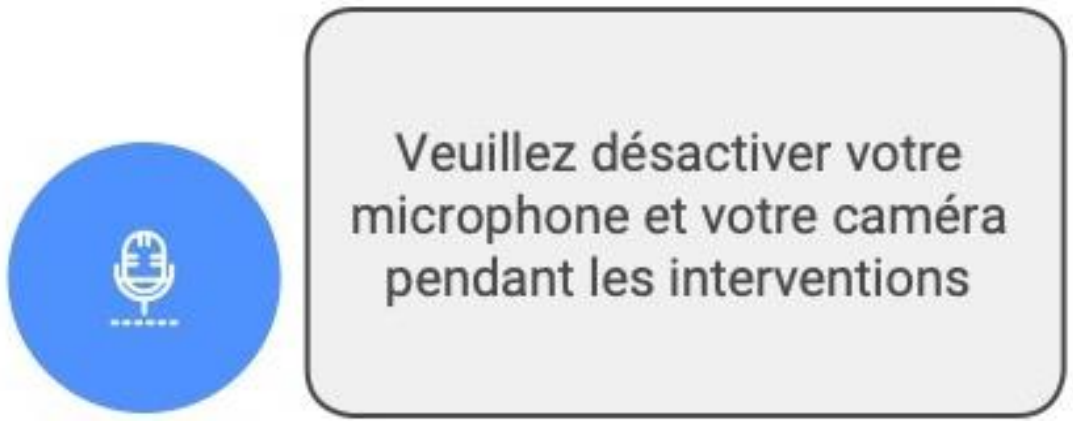
horizon europepcn

innovative health initiative

Session d'information du PCN Santé: IHI Calls 9 et 10

Avant de commencer…

Ce webinaire est enregistré pour mise en ligne ultérieure



Les questions se feront via le chat ou vous pouvez activer votre caméra pendant la session de questions-réponses

Session d'information sur les Ca

- **14h00-15h30**
  - Présentation des appels à projets des Call 9 et 10 par le PCN Santé (Roxane Brachet)
  - Conditions de participation et philosophie IHI, Patrick Boisseau, DG MedTech Europe
  - Témoignages
  - Nicolas Martelli, Pharmacien, MCU-PH, AP-HP, Hôpital européen Georges Pompidou
  - Cyril Guyard, Directeur Scientifique et Technologique, Bioaster
  - Questions-réponses

PCN Santé– Qui sommes-nous ?

Vania Rosas-Magallanes,
Coord. PCN Santé
Experte au Comité de Programme Santé- CE

Catherine Tostain-Desmares
PCN Santé

Roxane Brachet
PCN Santé

Kevin Plouchart
PCN Santé

Nous contacter: pcn-sante@recherche.gouv.fr
Nous suivre: LinkedIn
Liste de diffusion

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

Horizon Europe en bref

9e PCRI: 2021-2027

« Le programme de financement de la R&I le plus ambitieux jamais entrepris »

- Budget : 95,5 Md€
- Continuité avec Horizon 2020 : **« une évolution, pas une révolution »**
- Politique de Science ouverte
- Une plus grande ouverture sur l'international

- **NOUVEAUTÉS**
  - Conseil Européen de l'Innovation
  - Missions
  - Partenariats

La santé dans Horizon Europe

13,6 Md€ | **53,5 Md €** | **25 Md €**

Pilier 1
Science d'excellence

- Conseil européen de la recherche
- Actions Marie Skłodowska-Curie
- Infrastructures de recherche

Pilier 2
Problématiques mondiales et compétitivité industrielle et européenne

8,24Md€

- **Santé**
- Culture, créativité et société inclusive
- Sécurité civile pour la société
- Numérique, industrie et espace
- Climat, énergie et mobilité
- Alimentation, bioéconomie, ressources naturelles, agriculture et environnement
- Centre commun de recherche

Pilier 3
Europe plus innovante

- Conseil européen de l'innovation
- Écosystèmes européens d'innovation
- Institut européen d'innovation et de technologie

Élargir la participation et renforcer l'espace européen de la recherche

3,4 Md €

- Élargir la participation et développer l'excellence
- Réformer et consolider le système européen de R&I

Le Cluster Santé

6 domaines d'intervention

Planification stratégique
2021-2024
2025-2027

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

Innovative Health Initiative IHI

Partenariat institutionalisén entre EC et :

-Pharmaceutical companies (EFPIA)
-Radiological, electromedical, healthcare IT (COCIR)
-Medical technology companies (MedTechEurope)
-Biotechnology companies (EuropaBio)
-Vaccine companies (Vaccines Europe)

Objectifs :

- Transformer la recherche et l'innovation en matière de santé au bénéfice des patients et de la société

- Délivrer des innovations de santé qui couvrent **l'ensemble du spectre des soins** (de la prévention au diagnostic et au traitement), en particulier dans les domaines où il existe un **besoin de santé publique non pourvu**

- Rendre les **industries européennes de la santé compétitives** au niveau mondial.

- Recherche pré-compétitive ; consortia public-privé

Budget total: 2,4Md€

up to EUR **1.2 billion** provided by the European Union (**Horizon Europe Health Cluster**),
at least EUR **1 billion** provided by the member industry associations,
up to EUR **200 million** from Contributing Partners.

IHI call 9: des topics ouverts…

L'appel # 9 de l'IHI est un appel à projets en une étape, axé sur les candidats (applicant driven)

- Thème 1 : Stimuler l'innovation pour une meilleure compréhension des déterminants de la santé;
- Thème 2 : Stimuler l'innovation par une meilleure intégration des efforts fragmentés de R&I en santé;
- Thème 3 : Stimuler l'innovation pour des solutions de soins de santé intégrées axées sur les personnes;
- Thème 4 : Stimuler l'innovation par la numérisation et l'échange de données dans le secteur des soins de santé;
- Thème 5 : Stimuler l'innovation pour mieux évaluer la valeur ajoutée de solutions de soins de santé intégrés innovantes.

Attention: Les topics sont ouverts mais néanmoins alignés sur les objectifs spécifiques du programme stratégique de recherche et d'innovation de l'IHI (SRIA).

IHI call 9: des topics alignés avec objectifs spécifiques de l'agenda stratégique de l'IHI

Les objectifs spécifiques du SRIA IHI

1) Améliorer notre compréhension des facteurs qui influent sur notre santé et le développement et le traitement de certaines maladies.
2) Intégrer les efforts fragmentés de recherche et d'innovation en santé en réunissant les secteurs de l'industrie de la santé et d'autres parties prenantes ⇔ *développer des outils, des données, des plateformes, des technologies et des processus qui faciliteront la prévention, le diagnostic, le traitement et la gestion des maladies, en particulier dans les domaines où il existe un besoin non satisfait de santé publique.*
3) Démontrer la faisabilité de solutions intégrées en matière de soins de santé qui s'appuient sur diverses technologies provenant de différents secteurs et répondent aux besoins des usagers (patients ; professionnels de la santé).
4) Mieux utiliser les opportunités de recueillir des données de santé et de les utiliser dans la recherche et les soins, tout en respectant la législation pertinente sur la protection des renseignements personnels.
5) Développer des moyens d'évaluer la valeur de solutions innovantes et intégrées pour les patients, les soignants, les professionnels de santé et les organisations, ainsi que d'autres parties prenantes.

Consultez attentivement le SRIA

IHI call 9: topics alignés sur des objectifs spécifiques de l'agenda stratégique de l'IHI

Points importants pour les candidats:

- examiner attentivement quel objectif spécifique de l'agenda stratégique est le plus pertinent pour l'objectif principal de la proposition et la soumettre uniquement sous le thème du SRIA correspondant;
- justifier clairement l'alignement du projet avec le topic sélectionné/objectif spécifique du SRIA;
- les propositions peuvent également couvrir des aspects liés à d'autres objectifs spécifiques. Si oui, les candidats doivent également le souligner dans leur proposition;
- Les propositions doivent couvrir des activités à grande échelle qui favorisent la transformation en résultats concrets pour la santé;
- doivent répondre aux besoins non satisfaits en matière de santé publique.

IHI Call #9: topics, budget, calendrier

Calendrier
Lancement: 16 janvier 2025
Date limite de dépôt: 29 avril 2025, 17h00 heure de Bruxelles
Timelines to GA preparation: Maximum 5 months from the submission deadline
/ To GA signature: maximum 8 months from deadline

Type d'action : Recherche et innovation (RIA)
Appel en UNE étape ⇔ les partenaires privés sont identifiés et inclus en même temps que tout le consortium

Dépôts des projets sur le portail européen

Call ID: HORIZON-JU-IHI-2025-09-single-stage, RIA

Budget
Contribution maximum de l'IHI:
191 m€ pour les 5 topics du call #9

Apport de l'industrie/partenaires contributeurs*
pour chaque projet: **45%** minimum du budget total du projet
Il faut viser 50% du budget couvert par les CP

IHI call #10: two-stage, standard call

L'appel # 10 de l'IHI est en 2 étapes et porte sur les thèmes suivants:

- Thème 1: Le label numérique : une source d'information complète pour les produits de technologie médicale

- Thème 2: Permettre et sauvegarder l'innovation dans l'utilisation secondaire des données de santé dans l'espace européen de données sur la santé (EHDS)

- Thème 3: Substances perfluoroalkyliques et polyfluoroalkyliques (PFAS): exposition, émissions et gestion de fin de cycle dans le secteur des soins et de la santé

IHI call #10: topic 1

Topic 1: Digital label: one source of comprehensive information for medical technology products

Expected outcomes

1. **A consensus-based digital label** concept/framework for medical devices and in vitro diagnostic medical devices (IVDs) **is available to be used by manufacturers** that meets end **users' requirements** and addresses **regulators' demands**.

2. **Multiple valid and scalable digital label solutions** based on a standardised approach are available and they:
   a. **all work with the same enabler (label reader)** for all medical technology product labels (all medical devices and IVDs, all types, all classes).
   b. serve as an **up-to-date single point of access to all information** about the specific device;
   c. **are interoperable with other EU legislation** (such as digital product passport) and **national legislation** (e.g. language requirements);
   d. consider accepted international standards for data carriers;
   e. are acceptable after verification via user testing.

3. **Evidence-based recommendations are available** that may inform the European Commission's and the national competent authorities' policy recommendations.

4. **Training materials on digital labels are available to the end users** (healthcare professionals (HCPs) and patients), regulators (national competent authorities) and notified bodies in the EU Member States.

5. A basis towards future **international acceptance** is created via:
   • documentation gathered that would be needed to launch a proposal for a new digital label standard or adaptation of an existing standard under the International Organisation for Standardisation / International Electrotechnical Commission (ISO/IEC) – note that development of a standard itself is not planned during the lifetime of the project;
   • awareness raising with other international jurisdictions that consider digital label initiatives.

IHI call #10: topic 1

Topic 1: Digital label: one source of comprehensive information for medical technology products

Expected impacts

1. **Streamlined and 'green' delivery of information**

   a. Key information as well as additional information **is easily (and more) visible, accessible and identifiable to users (**HCProviders, patients) and health authorities equipped **with a simple smart device** (e.g., phone or tablet device);
   b. Significant reduction of carbon footprint and avoidance of over-labelling, hereby contributing to the European Green Deal.

2. **Improved accessibility of information for users** (HCPs and patients) and regulators. All the information that users might need is available **in one place in their language of choice**, thus increasing equal access of users to medical technologies.

   a. Targeted information based on user location: in the EU: summary of safety and clinical performance (SSCP), the European database for medical devices (EUDAMED) modules when available ; globally: electronic instructions for use (eIFU);
   b. Crucial information from the printed label is additionally visible upon scanning (e.g. expiry date);
   c. Connection to technical support in case of problems;
   d. Reducing risk of use errors;
   e. Real time updates;
   f. Avoidance of cluttered labels.

IHI call #10: topic 1

Topic 1: Digital label: one source of comprehensive information for medical technology products

Expected impacts

3. **Increased alignment between MD regulation and other EU and national legislations** and streamlined compliance for all. One digital carrier will directly link the user with the up-to-date information required by the Digital Product passport in multiple languages (EU Packaging and Packaging Waste Regulation EU Battery regulation, information on spare parts, etc.), hereby contributing to the European Green Deal.

4. **Increased competitiveness in the EU market** thanks to improved supply management and streamlined packaging and labelling operations.

5. **Driving acceptance through (voluntary) adoption of digital labels by medical device manufacturers and their use by end users,** notified bodies, national competent authorities in the European market, supported by the developed training material.
Digital label is considered an additional tool to requirements in current legislation (MDR, IVDR).

The pre-identified industry consortium : Arthrex (lead) • bioMérieux • Johnson & Johnson • Terumo • Thermo Fisher Scientific
For activities like : IT infrastructure provision and IT expertise; • expertise in labelling; regulatory affairs and intelligence; clinical research, marketing and communications, global supply chain management, project management etc.; • usability engineering.

Indicative budget and duration
• The maximum financial contribution from the IHI JU is up to EUR 3 806 900.
• The indicative in-kind contribution from industry beneficiaries is EUR 6 156 800.
Indicative duration: 36 months.

IHI call #10: topic 2

Topic 2 : Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Expected outcomes

- **comprehensive** frameworks, processes, policies and guidelines are available to **support the procedural and operational aspects of the EHDS from an innovation perspective;**

• **recommendations to inform EHDS governance are available to address the needs of a broad set of stakeholders**, including citizens, hospitals, public institutions and the healthcare industry. The right balance must be struck between the need for an EHDS that enables efficient data sharing for the secondary use of health data to promote research and innovation in healthcare, and the need for maintaining a strong Intellectual Property (IP) system while preserving confidential information within health research data;

• **recommendations are available for enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs) to address issues around innovation,** as well as dealing with IP, RDP, and Trade Secrets, utilising the EHDS and the operationalisation of the EHDS; and

• **materials, guidance, recommendations, training** and other support tools are available **to educate interested parties about innovation and data sharing under the EHDS.**

The target groups for all the outcomes are:
• those establishing the EHDS and the EHDS infrastructure, through which health data will be made available for secondary purposes;
• member state agencies involved with the establishment and functioning of HDABs;
• HDHs making IP, RDP and trade secret protected data, which may include sensitive and confidential data, available through the EHDS for secondary use;
• HDUs intending to access IP, RDP and trade secret protected data for secondary use.

IHI call #10: topic 2

Topic 2 : Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Expected impacts

The action under this topic is expected to achieve all of the following impacts:

• **Fostering data-driven research** and innovation advancing healthcare in the EU; • **A world-leading approach to IP** protection of data;
• Improved balance between data utilisation and access control rights; • **Best practices** for data sharing, data security and prevention of unauthorised disclosure; • **Recommendations** for legal and ethical standards; • Increased industry confidence in the EHDS.

The action will also contribute to several European policies/initiatives:

• The European Health Data Space; The European Commission's Pharmaceutical Strategy for Europe, specifically the pillar on competitiveness, innovation, and sustainability; • Related measures under the ongoing revision of the pharmaceutical legislation;
• The Trade Secret Directive; • The European Strategy for Data, (GDPR, Data Act, Data Governance Act, AI Ac)t;
• The Digital Strategy; • The Digital Single Market Strategy.

The pre-identified industry consortium : • AbbVie • Astra Zeneca • Bayer • bioMérieux • Boehringer Ingelheim • GSK • Johnson & Johnson (Lead) • Merck • MSD • Novartis • Novo Nordisk • Pfizer • Sanofi (Co-lead) • UCB
Pre-identified CP : Brightinsight • Clarivate

For activities as: Legal, paralegal experts and advisors/consultants specialised in IP & trade secrets protection in the digital and medical environments;
• Governmental affairs and policy experts; • ISRM (Information Security & Risk Management) experts;
• Data strategy and governance experts; • Communication expertise for webinars & workshops; • Data privacy experts; • Public affairs experts.

Indicative duration 36 months
Indicative budget
• The maximum financial contribution from the IHI JU is up to EUR 6 043 000.
• The indicative in-kind contribution from industry beneficiaries is EUR 5 772 500.
• The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500.

IHI call #10: topic 3

Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

Expected outcomes

- **replace PFAS:** new environmentally sustainable materials as alternatives to PFAS that maintain patient safety are developed for the benefit of the healthcare industry and the citizens;

• **reduce / re-use PFAS:** improved usage of PFAS materials and minimised exposure is achieved for the benefit of the environment and therefore citizens and society;

• **a mapping of the types and applications of PFAS** throughout the supply chain is available for healthcare technologies and products, including collaborating with upstream suppliers;

• **a database** of alternatives to PFAS is available;

• **new disposal processes of PFAS** are available for the benefit of the environment and therefore citizens and society.

IHI call #10: topic 3

Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

Expected impacts

1. contribute to IHI JU SRIA objectives, **driving cross-sectoral health innovation** for a competitive European health industry. Contribute to the objectives of the Industrial Strategy for Europe and Pharmaceutical Strategy for Europe;

2. **understanding human health and environmental risks from** PFAS in healthcare from a life cycle perspective, i.e. mapping where PFAS is introduced in the healthcare industry and removal, where possible;

3. **manage PFAS risks** with novel mitigation measures, including safe disposal, reuse, and recycling;

4. **develop methodologies and solutions for PFAS replacement** that meet regulatory requirements without compromising efficacy, quality, safety, or environmental performance;

5. **position the EU as a leader in safe, sustainable PFAS alternatives** through industry-academia collaboration; foster medicine supply in the EU, avoid non-EU dependencies, and keep R&D activities in Europe for active substances to address societal and political needs;

6. **strengthen stakeholder collaboration** to reduce emissions and exposure until alternatives are found;

7. **share industry knowledge and best practices** to inform future PFAS policy;

8. **improve business planning certainty** for medical technology manufacturers, ensuring longterm sustainability and patient access.

IHI call #10: topic 3

Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

Pre-identified industry partners:
•UCB (lead)
Abbott • Abbvie • AstraZeneca • Bayer • Biotronic • Boehringer Ingelheim • BSCI • Gilead • GSK • Johnson & Johnson • LabCorp • Edwards Lifesciences • Eli Lilly • Ion Beam Applications • Karl Storz • Merck KGaA • Novartis • Novo Nordisk • Olympus • Pfizer • Roche • Sanofi • Servier • Stryker • Terumo

For activities as: chemical synthesis and active pharmaceutical ingredient (AP)I/drug product manufacturing;
• medical device manufacturing and assembly, packaging, distribution, medical supply chain management and quality control;
• regulatory affairs topics, occupational safety; • standardised analytical methods and in process controls;
• use of process aids, their procurement and quality assurance aspects (e.g. qualification);
• management of chemical/biotechnology waste and decontamination of waste water; • circular economy expertise;
• safe and sustainable by design methodologies; • activities, results and insights from existing pilots and studies (may be historical data generated outside of the project timelines that will not constitute part of the in-kind contribution);
• publication support and data dissemination.

Indicative duration 60 months

Indicative budget

• The maximum financial contribution from the IHI JU is up to EUR 24 000 000.
• The indicative in-kind and financial contribution from industry beneficiaries is EUR 23 902 900.

The (additionnal) allocation of the EUR 567 500 financial contribution (committed) from industry beneficiaries will be decided by the full consortium at the second stage when preparing the full proposal.

IHI call #10: Budget, calendrier

Calendrier
Lancement: 16 janvier 2025

Date limite de dépôt **pré-proposition:**
23 avril 2025, 17h00 heure de Bruxelles

Date limite de dépôt **proposition complète:**
14 octobre 2025, 17h00 heure de Bruxelles

Contribution maximum de l'IHI: 33,9 m€

Contribution de l'industrie/partenaire contributeur: 35,9 m€

Dépôt des propositions sur le portail européen

Call ID: HORIZON-JU-IHI-2025-10-two-stage, RIA

Quelques liens importants

Call # 9 Information, SRA et call text https://www.ihi.europa.eu/apply-funding/ihi-call-9

Le brokerage event du call #9 en rediffusion ici https://www.ihi.europa.eu/news-events/events/brokerage-event-ihis-2025-calls

*Wébinaire du 30 janvier sur les partenaires contributeurs : https://www.ihi.europa.eu/news-events/events/everything-you-need-know-about-ihi-contributing-partners

Call # 10 Information et call text https://www.ihi.europa.eu/apply-funding/ihi-call-10

Les journées d'information de l'IHI du 7 au 16 janvier 2025 en rediffusion ici :

https://www.ihi.europa.eu/news-events/events/ihi-call-days-call-9-10

IHI calls 9 & 10: éligibilité et conditions de participation

>>>> Conditions de participation et philosophie du programme IHI,

Patrick Boisseau, DG MedTech Europe

Boosting innovation for a competitive European health ecosystem

IHI call 9 – topics 1 to 5

Patrick Boisseau, MedTech Europe

innovative health initiative

IHI Call 9

- IHI Call 9 comprises 5 topics, each focusing on one of the five IHI JU Specific Objectives (SOs)
- The call contains an introduction and general elements to be considered for all topics
- The overall aim is to fund pre-competitive research and innovation actions that are in line with the general objectives of IHI and address at least one of IHI SOs as set out in the IHI Strategic Research and Innovation Agenda (SRIA)

innovative health initiative

Introduction & general elements to be considered for all topics

Please read carefully the introduction to the Call and general elements to be considered for all topics

- Scope broad to **harness new science and technologies** that will foster the **development of health innovations** to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently, and that could ultimately **be integrated/implemented into the healthcare ecosystem** for the benefit of patients and society.
- Actions to be funded under this call:
  - are expected to **perform at scale activities** that drive concrete and transformational outcomes
  - should address **unmet public health needs**

innovative health initiative

Introduction & general elements to be considered for all topics

Please read carefully the introduction to the Call and general elements to be considered for all topics

- Most activities are expected to be **cross-sectoral**, reflecting the integrative nature of IHI as a public-private partnership, and to consider the different innovation cycles of the pharmaceutical and medical technology industries
- Proposals that aim to demonstrate the feasibility and/or scalability of integrating solutions into national or regional healthcare systems and/or of innovations are welcomed.

Research should remain at the **pre-competitive level**.

innovative health initiative

Introduction & general elements to be considered for all topics

Please read carefully the introduction to the Call and general elements to be considered for all topics

- Activities may cover the whole health innovation chain including but not limited to:
  - discovery of new molecules, mechanisms of action, processes, technologies;
  - development and testing of these discoveries;
  - development of methodologies for assessment of safety, health outcomes or health-economic evaluation;
  - standardisation activities;
  - contribution to regulatory science;
  - pilots/proofs of feasibility including in-silico trials.

innovative health initiative

Introduction & general elements to be considered for all topics

Read carefully the introduction to the Call and general elements to be considered for all topics

- To emphasise the people-driven mission and the inclusive objectives of the call, applicants are strongly encouraged to **provide open access to project-generated outputs** such as standards, GDPR compliant data sets and other research results.

- Proposals can only **be submitted under one topic**, so please consider which Specific Objective is the most relevant to the primary focus of your proposal and submit it only under the corresponding topic.

- Applicants must clearly justify the **alignment of the objectives of their proposed work with the Specific Objective select**ed. Considering the complementarity of the IHI JU Specific Objectives, proposals may also cover aspects related
to other Specific Objective(s). If so, applicants should also highlight this in their proposal

innovative health initiative

Scope

For each topic (T1 to T5)

- With a view to harnessing new science and technologies, fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases, and enable recovery more efficiently.

- Accordingly, **applicants must assemble a collaborative public-private partnership consortium** reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the selected IHI JU's Specific Objective and described in more detail in the IHI JU SRIA.

innovative health initiative

IHI Call 9 budget

Topic	Maximum EU contribution (EU funding envelope)	in-kind and cash contribution
1	25 million	25 million
2	100 million	100 million
3	30 million	30 million
4	24 million	24 million
5	12 million	12 million
	191 Million EU Funding Public funding (50 %)	**191 Million Private funding (50 %)**

50% matching is a target for Call 9
as 50% matching must be reached at overall Programme level

innovative health initiative

IHI Call 9 – budget per proposal

Topic	Maximum EU contribution (EU funding envelope)		in-kind and cash contribution		
1	8 million	+	8 million	=	16 million
2	15 million	+	15 million	=	30 Million
3	8 million	+	8 million	=	16 million
4	8 million	+	8 million	=	16 million
5	5 million	+	5 million	=	10 million

50% matching is a target for each proposal
as 50% matching must be reached at overall Programme level

Tips for applicants

- Read all the call-relevant material, especially **the introduction and the general elements to be considered for all topics** and the relevant **topic text**
  - www.ihi.europa.eu/apply-funding/future-opportunities
  - **FAQs on IHI call 9**
- Read carefully the Strategic Research and Innovation Agenda for the Specific objective selected
- Form your consortium **early**
  - Always think “public-private partnership“
  - Include partners bringing **in-kind contributions**
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results
- Updated proposal template Part B and evaluation form
- Call deadline 29 April 2025

innovative health initiative

Finding project partners

You'll need to build or join a consortium!

- Network via the **IHI Brokerage Platform:**
  - https://ihicalldays2024.converve.io/
- Use EU Funding & Tenders portal **partner search tool:**
  - https://europa.eu/!QU87Nx
- Get in touch with your **IHI national contact point**:
  - https://europa.eu/!D7jyMy
- Network on **social media**:
  - be.linkedin.com/company/innovative-health-initiative

innovative health initiative

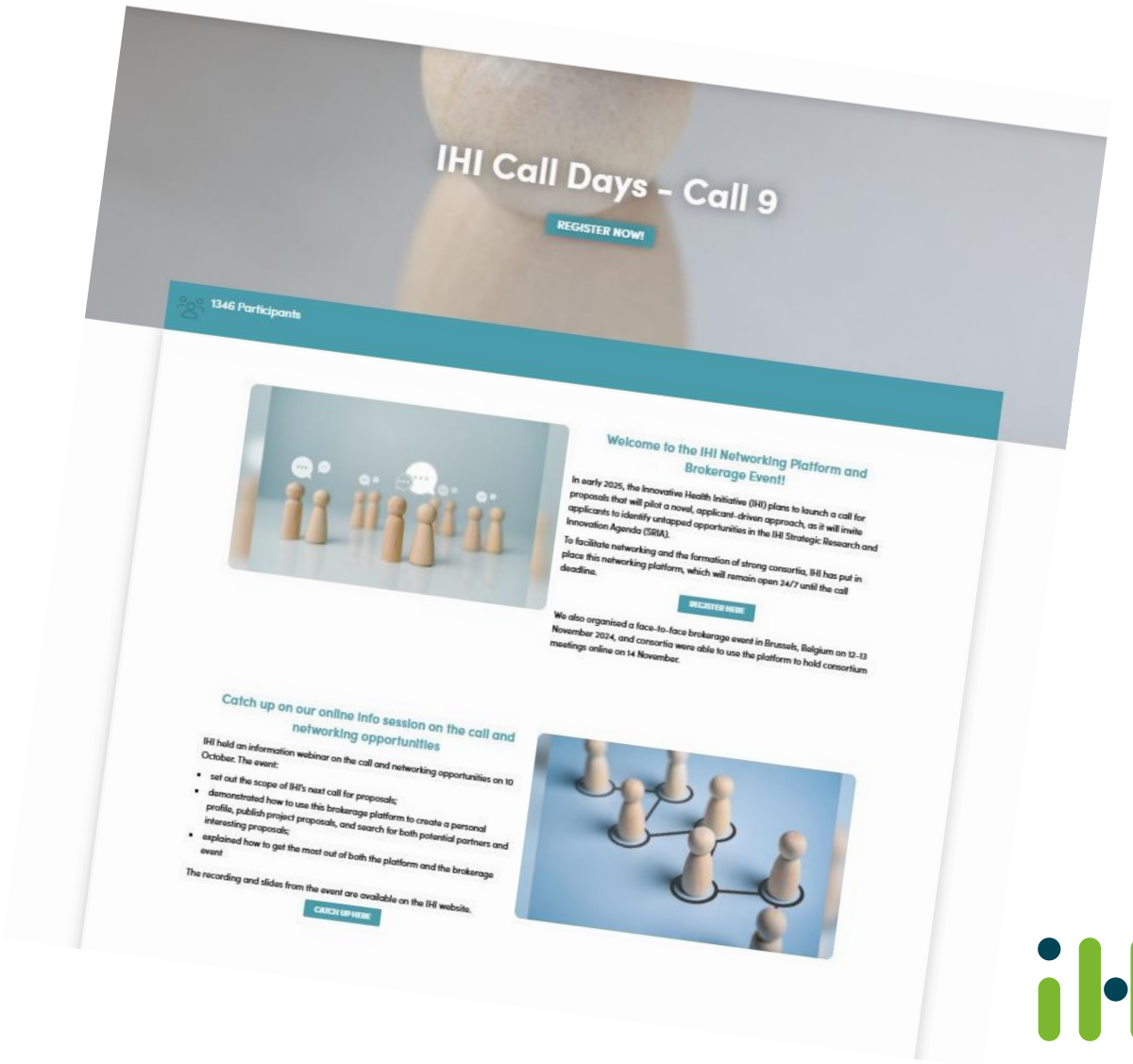
IHI Brokerage Platform

- **Share proposals ideas**
- **Networking opportunities**: making it easy to identify potential partners.
- **Interactive scheduling**: you can easily message other participants.
- **User-friendly interface**: designed with simplicity in mind, the platform ensures a smooth experience.

innovative health initiative

IHI Brokerage Platform

- **1357** Person Profiles.
- **1290** Companies Profiles
- **190** Proposals
- List of pitchers
- Presentation slides & recordings



innovative health initiative

IHI Brokerage Platform

How to get started?

Simply visit the platform at ihicalldays2024.converve.io

1. Create your person & company profile.
2. Share your proposal idea.
3. Start browsing and connecting with participants via messages.

innovative health initiative

#IHICallDays

innovative health initiative

Calls 9 & 10

15 Jan **10:30** Call 9: Rules & procedures

15 Jan **14:30** Call 10: Secondary use of data in the European Health Data Space

16 Jan **10:30** Call 10: Rules & procedures

Online event

COCIR Advancing Healthcare · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

HEU-EFS - Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union

Témoignage d’un partenaire d’un projet IHI

Infoday – IHI / PCN-Santé / 11 Février 2025

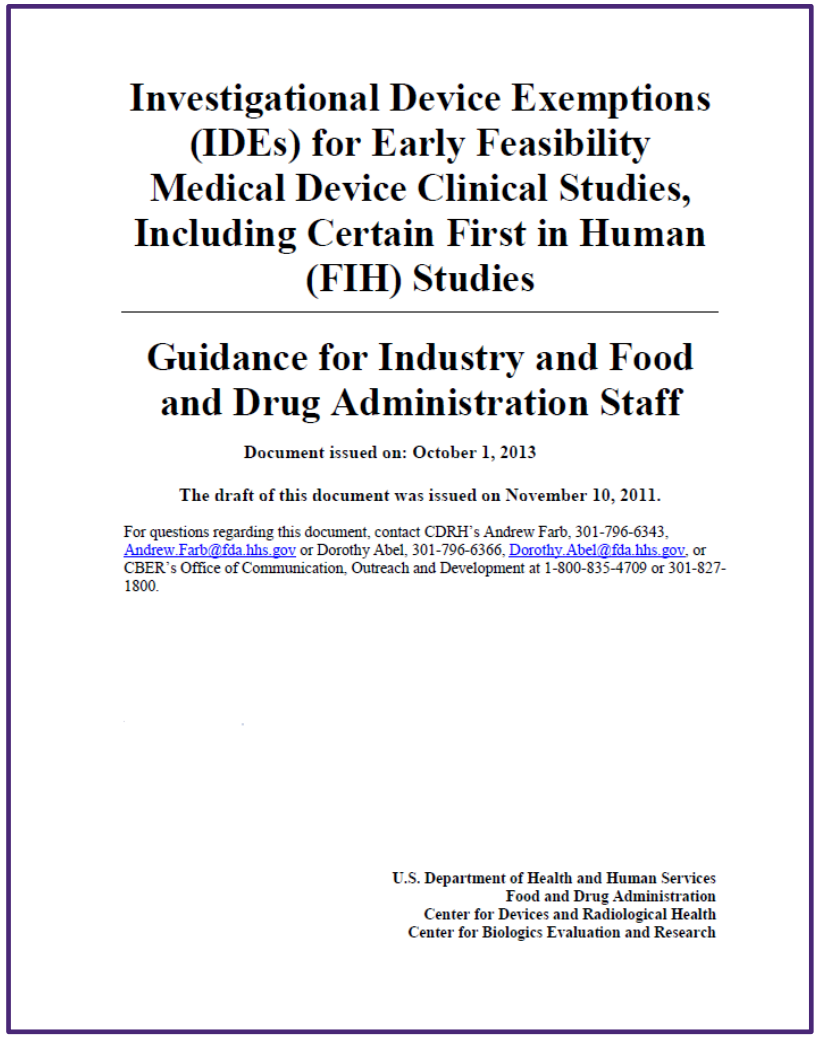
Dr Nicolas Martelli (Pharmacien, MCU-PH)

AP-HP, Hôpital européen Georges Pompidou

Université Paris-Saclay, Faculté de Pharmacie, GRADES

Disclaimer

Etude de faisabilité précoe (EFP)



Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 1, 2013

The draft of this document was issued on November 10, 2011.

For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Quoi ?

Une étude clinique limitée d'un dispositif un stade précoce de développement.

Quand ?

Généralement avant que la conception du dispositif ne soit finalisée, pour une indication spécifique (par exemple, dispositif innovant pour une nouvelle utilisation prévue).

Pourquoi ?

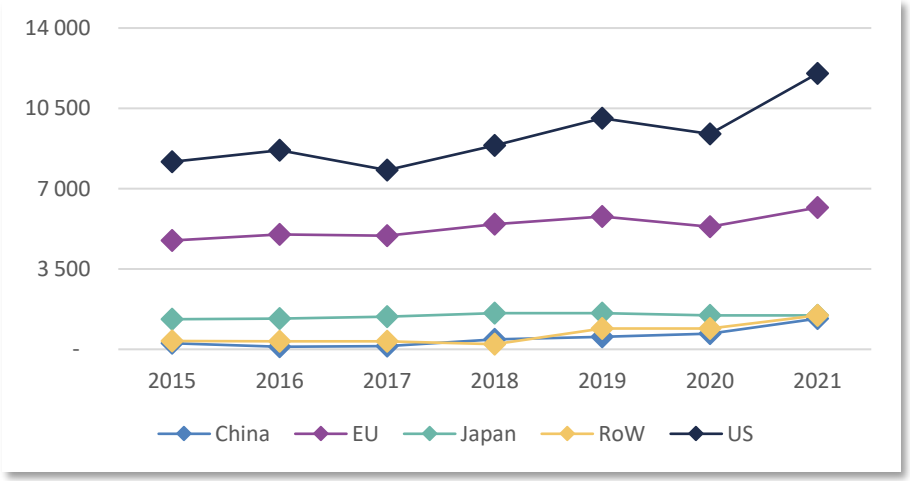
Elle peut être utilisée pour évaluer le concept général du dispositif en ce qui concerne sa sécurité clinique initiale et sa performance clinique ou l'efficacité du dispositif (si approprié) chez un petit nombre de sujets lorsque ces informations ne peuvent pas être fournies par des évaluations non cliniques supplémentaires ou lorsque des tests non cliniques appropriés ne sont pas disponibles. Les informations obtenues à partir d'une EFP peuvent orienter les modifications apportées au dispositif. Une EFP n'implique pas nécessairement la première utilisation clinique d'un dispositif.

Opportunité d'un programme d'EFP européen (II)

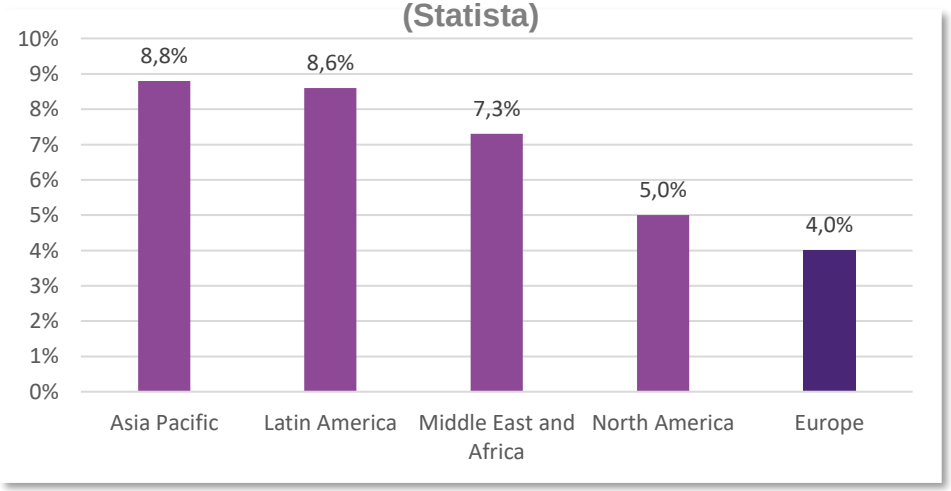
- Mais aucun cadre procédural standardisé, directives ou normes de référence communes pour mener des EFP dans l'UE.

- L'UE court le risque de perdre en compétitivité et en attractivité pour l'innovation et les investissements.

Investissements en R&D (millions d'euros) dans l'industrie des équipements et services de santé (Grassano et al. 2022)



Taux de croissance annuel composé (TCAC) attendu du marché mondial des technologies médicales 2017-2022 (Statista)



Impact et bénéfice des EFP

INDUSTRIE

- Améliorer l'efficacité et l'efficience dans le développement des technologies de santé.
- Maximiser la probabilité d'accès au marché.
- Maximiser la « probabilité de rémunération adéquate » pour l'innovation.

AUTORITE COMPETENTE

- Encourager l'accès à l'innovation tout en suivant des processus d'autorisation rigoureux et en préservant la sécurité des patients.
- Anticiper et faciliter les processus de prise de décision grâce à un échange précoce d'informations.
- Accroître le caractère innovant et la compétitivité du secteur.

PATIENTS

- Accès rapide aux technologies médicales innovantes pouvant répondre à des besoins cliniques non satisfaits et sans alternative de traitement.
- Accès contrôlé et sécurisé aux technologies médicales innovantes

HEU-EFS en quelques chiffres

- 22 partenaires publics et privés dans le consortium
- Projet de 4 ans
- Subvention de 19 millions d'euros de Innovative Health Initiative (IHI)
- Coordonné par l'Université Bocconi (Milan – Italie)
- Dirigé sur le plan industriel par Edwards Lifesciences

Motivations et identification des partenaires

- **Motivations** :
  - Développer mes activités de recherche sur les DM
  - Renforcer mes compétences en gestion de projet
  - M’initier à la collaboration interculturelle

- **Identification des partenaires :**
  - Sollicitation initiale par Bocconi (coordonnateur) – collaborations antérieures -> Co-leader d’un WP
  - Recrutement de spécialistes au sein de GHU (URC, PTI…)

Histoire du consortium

WP	Leader	Co-leader
WP 1 Recherche et analyse de l'état des lieux des programmes préalables au marché et des obstacles à la mise en œuvre de l'EFP	Bocconi	Johnson & Johnson
WP 2 Recherche et analyse sur le cadre réglementaire et l'organisation des programmes de génération de preuves cliniques dans l'UE	Trinity College Dublin	**Assistance Publique Hôpitaux de Paris**
WP 3 Développement méthodologique : justification, processus et procédure	Norwegian Institute of Public Health	Bocconi and Edwards Lifesciences
WP 4 Développement méthodologique : exigences en matière de preuves, données et outils statistiques	Meditrial	Abbott
WP 5 Développement méthodologique : système de suivi du programme EFP de l'UE	Bocconi	AGENAS
WP 6 Développement méthodologique : aspects éthiques et légaux	Bocconi	Edwards Lifesciences
WP 7 Test de la méthodologie : cas d'utilisation pilote	Edwards Lifesciences, Medtronic and Abbott	Fondazione Policlinico Agostino Gemelli
WP 8 Portail web, diffusion, exploitation et communication	Edwards Lifesciences	Bocconi
WP 9 Supervision scientifique et gestion de projet	Bocconi	

Premiers résultats en résumé

- **EFP possible dans le cadre européen,** mais pas explicitement facilité**.**
- **Dialogue comme pierre angulaire :** Communication régulière entre les développeurs et les régulateurs.
- **Orientations spécifiques aux EFP :** guidelines standardisées pour une conformité simplifiée des DM et des technologies de santé numériques.
- **Ressources institutionnelles :** Soutien pour une gestion efficace des EFP.

Bénéfices liés à notre participation

- **Visibilité et opportunités de collaboration :** Participer à un projet d'envergure européenne = reconnaissance professionnelle et opportunités de collaboration future avec des acteurs clés du secteur (publics et privés).

- **Accès à de nouvelles informations :** Participer à des discussions sur les tendances émergentes (DM, AI act,…).

- **Soutien institutionnel :** L'appui des structures AP-HP (DRCI) = bénéficier d'une expertise en interne (suivi du projet, aspects financiers) et de se concentrer sur la partie scientifique.

Défis rencontrés en début du projet

- **Définition claire des responsabilités :** Avoir des rôles et responsabilités bien définis.
- **Gouvernance efficace :** Avoir un coordinateur expérimenté (Bocconi).
- **Communiquer :** Savoir communiquer avec les bons partenaires et au bon moment.
- **Outils collaboratifs adaptés :** Utiliser des outils de gestion de projet adaptés (Teams, etc.) pour une coordination fluide entre les partenaires.

Quelques conseils

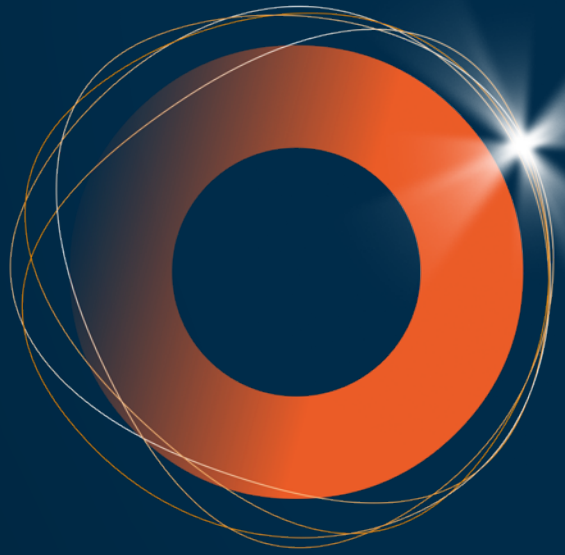
- **Bien anticiper** et calculer les **ressources nécessaires** (PM, matériel etc.)
- **Suivre avec précision** ses « dépenses » (PM notamment) pour éviter les dépassements budgétaires et s'assurer de la bonne allocation des fonds.
- **Bien TOUT documenter** (décisions, échanges et avancements pour faciliter les audits et la continuité du projet).
- **Bien anticiper la disponibilité** des équipes en fonction des pics d’activité pour éviter la surcharge de travail.

www.heuefs.eu @HEU-EFS @HEUEFS info@heuefs.eu

Merci à vous !

This project is supported by the Innovative Health Initiative Joint Undertaking (JU) under grant agreement No 101112185. The JU receives support from the European Union's Horizon Europe research and innovation programme and life science industries represented by MedTech Europe, COCIR, EFPIA, Vaccines Europe and EuropaBio.

innovative health initiative COCIR efpia EuropaBio MedTech Europe Vaccines Europe Co-funded by the European Union



IMI/IHI @ BIOASTER

Cyril Guyard
Directeur Scientifique

BIOASTER A NON FOR PROFIT INSTITUTE OF TECHNOLOGIES

BIOASTER

TECHNOLOGY INSTITUTE

BIOASTER is the only health-related Technology Research Institute (IRT) in France, based on a public/private partnership model.

Non-for-profit FOUNDATION

BIOASTER was established as a Foundation for Scientific Cooperation (FSC), a not-for-profit organization. It offers a novel approach to R&D, based on integration of major scientific and technological disciplines

Dedicated to MICROBIOLOGY & INFECTIOUS DISEASES

IMI (now IHI) projects @ BIOASTER

- VALUE-Dx

VALUE OF DIAGNOSTICS TO COMBAT ANTIMICROBIAL RESISTANCE & IMPROVE PATIENT OUTCOMES BY OPTIMISING ANTIBIOTIC USE, STARTING COMMUNITY-ACQUIRED ACUTE RESPIRATORY TRACT INFECTIONS

- GNA NOW

Novel Gram-negative antibiotic now

- ERA 4TB

EUROPEAN REGIMEN ACCELERATOR FOR **TUBERCULOSIS**
Part of IMI AMR Accelerator

Horizon2020
European Union Funding
for Research & Innovation

BIOASTER

ERA4TB : EUROPEAN REGIMEN ACCELERATOR FOR TUBERCULOSIS

Duration: 6 years (January 2020 – December 2025)

Partner : European consortium (31 partners)

8 WPs : Bioaster is involved in 2 WPs

Budget: 207,96 M€ - BIOASTER : 2.3 M€

Challenges/ needs

- Long duration treatment with side effects
- Multi-resistant and extensively-resistant strains
- **Antibiotic development is still complicated, long and extensive, with low investment return**

Idea

An European platform to enable a very efficient progression of new anti-TB compounds

→ effectively, a pipeline formed by a series of pre-clinical and clinical assays

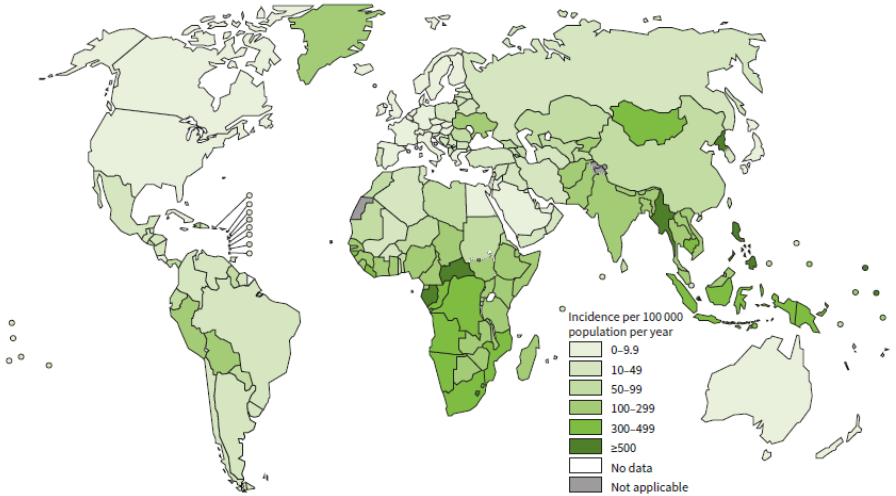
How it works

- EFPIA and associated partners: provide preclinical precandidate molecules
- **Academic laboratories, CRO and Bioaster: characterise these molecules (*in vitro, in vivo*, FITH) and generate results**
- Management and integration of the results with the ultimate goal to select the best antitubercular combination

→ Ultimate goal: Identification of new regimen ready for phase II

Tuberculosis: key facts

Estimated TB incidence rates in 2023



(From WHO TB report, 2024)

- Tuberculosis (TB) is an infectious disease mainly affecting the lungs and highly contagious when people are sick.
- Until the Covid 19 pandemic, TB was the leading cause of death from a single infectious agent.
- In 2023 :
  - 10.8 million people fell ill with TB
  - 1.25 million people died from TB
- *Mycobacterium tuberculosis (Mtb)* is the causative agent of TB and is transmitted through the air.
- A quarter of the population is thought to have been infected with *Mtb*, with 5-10% falling ill (active TB) and the rest remaining asymptomatic (latent TB).

(From https://www.who.int/news-room/fact-sheets/detail/tuberculosis)

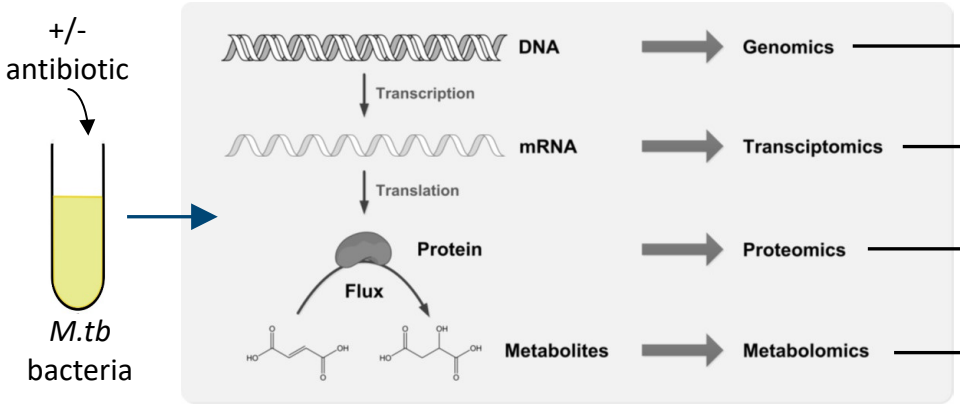
Collaborating Partners

The ERA4TB Consortium brings together a multi-disciplinary team with proven expertise and capabilities in TB drug development to profile and progress anti-TB compounds up to completion of Phase I.

- The project consortium integrates 31 organizations, namely seven prestigious academic institutions (**UC3M**, UNIZAR, UU, EPFL, UHC, UNIPD, UPV), four non-profit organizations (**IPP**, IPL, iM4TB, BAR), nine public research organizations (FZB, CNR, CEA, SERMAS, PHE, NICE, SCI, IOS, CIM – Sant Pau) and five highly skilled small-medium enterprises (SYNAPSE, C-Path, Aliri, QPS, GRIT), together with three **EFPIA members** (**GSK**, EVT, JANSSEN), and three IMI2 Associated Partners (BMGF, TBA, UNIVDUN).

WP2: Elucidation of anti-TB drugs mechanism of action (MoA)

Implementation of the Mtb model at Bioaster's BSL3 facilities and development of Omics techniques to decipher the MoA of preclinical candidates.



Transposon insertion sequencing → Unconclusive

RNA sequencing → Ready and used

LiP-MS (Limited proteolysis-coupled mass spectrometry) → Ongoing

Metabolomic/lipidomic profiling → Ready and used

- RNA sequencing: the developed protocol has been or is used to characterize 3 candidates from TB Alliance, Gates MRI foundation and GSK.
- Metabolomics/lipidomics: the developed protocols are being used to characterize 1 candidate from TB Alliance.

WP3 – Task 3.3. Biomarkers for anti-tuberculosis (TB) treatment efficacy assessment in *in vivo* pre-clinical models

BIOASTER

→ **Role of BIOASTER =** identification of biomarkers of TB treatment efficacy **in pre-clinical field**

↳ Correlation with **bacterial load** (gold standard) + Prediction of **relapse/treatment success**

Drug candidates

Dynamic analysis

***Mycobacterium tuberculosis* (*Mtb*) deactivation**

Performed at BIOASTER

Selection and validation of biomarkers

- Transcriptomics → Blood cell (host) RNA
- Immunoassays → Host serum proteins
- Targeted proteomics → *Mtb* proteins in serum
- Targeted lipidomics → *Mtb* lipids in serum

Bioinformatics and biostatistics

→ Correlation with CFU and other markers

→ Biomarkers signature identification

ERA 4TB
EUROPEAN REGIMEN ACCELERATOR FOR TUBERCULOSIS
Part of IMI AMR Accelerator

Data, metadata, result sharing

Novel Gram-negative antibiotic now

Problem

- Antimicrobial resistance (AMR) is a major threat to public health, causing 670,000 infections and over 33,000 deaths in Europe alone in 2015
- Gram negative bacteria are tough to treat, as the outer membrane effectively stops many antibiotics from entering the bacteria to kill it

Idea

- GNA NOW is part of the IMI AMR Accelerator Programme
- GNA NOW project aims to address the urgent need for new antibiotics to treat Gram-negative infections
- Four programmes in parallel, each focusing on a different drug candidate with an innovative mode of action

How it works

- EFPIA companies provided early preclinical candidate molecules
- Academic laboratories, CRO and Bioaster: characterised these molecules (*in vitro* & *in vivo*) and generated results
- Management and integration of the results with the ultimate goal to select the best Gram negative antibiotics

Goal: Identification of new antibiotics ready for human clinical trials

Horizon2020
European Union Funding
for Research & Innovation

BIOASTER

GNA NOW: NOVEL GRAM-NEGATIVE ANTIBIOTICS NOW

Duration: 6 years (July 2019 – December 2025)

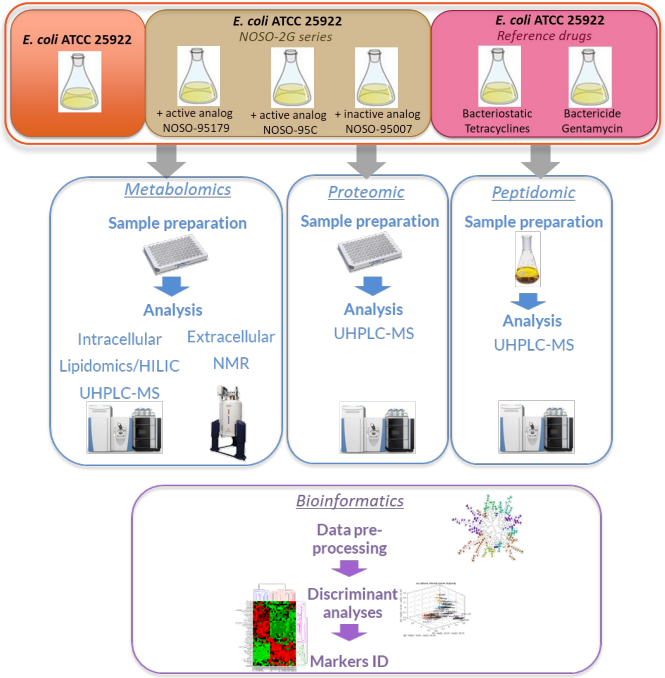
Partner : European consortium (11 partners)

7 WPs : Bioaster is/was involved in 6 WPs

Budget: 21,63 M€ - Bioaster: 0.441 M€

GNA-NOW Antibiotic candidate

- **Proteomics:** induces production of metabolites like those generated by aminoglycoside application
- **Lipidomics:** induces less production of phospholipids (PE, PG, PC, PS, PA) than tetracycline application. Other lipid classes are significantly impacted such as TGs and Ceramides
- **Metabolomics:** induces higher levels of amino acids (e.g. alanine, glycine, tyrosine, valine, methionine & isoleucine), consistent with inhibition of protein synthesis
- **Peptidomics:** Peptides produced following candidate application are different to those observed following aminoglycoside or tetracycline application
- **Pathway enrichment:** is involved in the rRNA and RNA binding pathways



Projets IHI/IMI @ BIOASTER

- **Ce qui vous a motivé à postuler à un appel IHI :**
  - Calls Public/Privés alignés avec le positionnement en innovation de BIOASTER

- **Comment vous avez identifié vos partenaires? :**
  - Réseaux académiques et industriels

  - Plateforme IHI/IMI : https://ihicalldays2024.converve.io/
  - Diffusion de profils et de propositions sur la plateforme de brokerage

- **Les principaux résultats ou bénéfices obtenus grâce aux projets :**
  - Contribution au développement de solutions diagnostics et thérapeutiques
  - Collaboration avec de grands centres académiques Européens et groupes industriels
  - Publications

Projets IHI/IMI @ BIOASTER

- **Les défis rencontrés lors de la mise en œuvre du projet et comment vous les avez surmontés :**
  - Réconcilier les besoins de la recherche académique et de la recherche industrielle
  - S'adapter aux évolutions de priorités des projets

- **Les leçons apprises et les conseils que vous donneriez aux futurs candidats:**
  - Contribuer aux consultations en amont concernant la construction des futurs appels à projet
  - Commencer à développer un réseau avant la publication des Calls
  - Être visible au plus tôt sur les plateformes de networking
  - Ne pas hésiter à contacter/poser des questions/proposer des solutions à l'IHI et aux partenaires porteurs de projets

www.bioaster.org