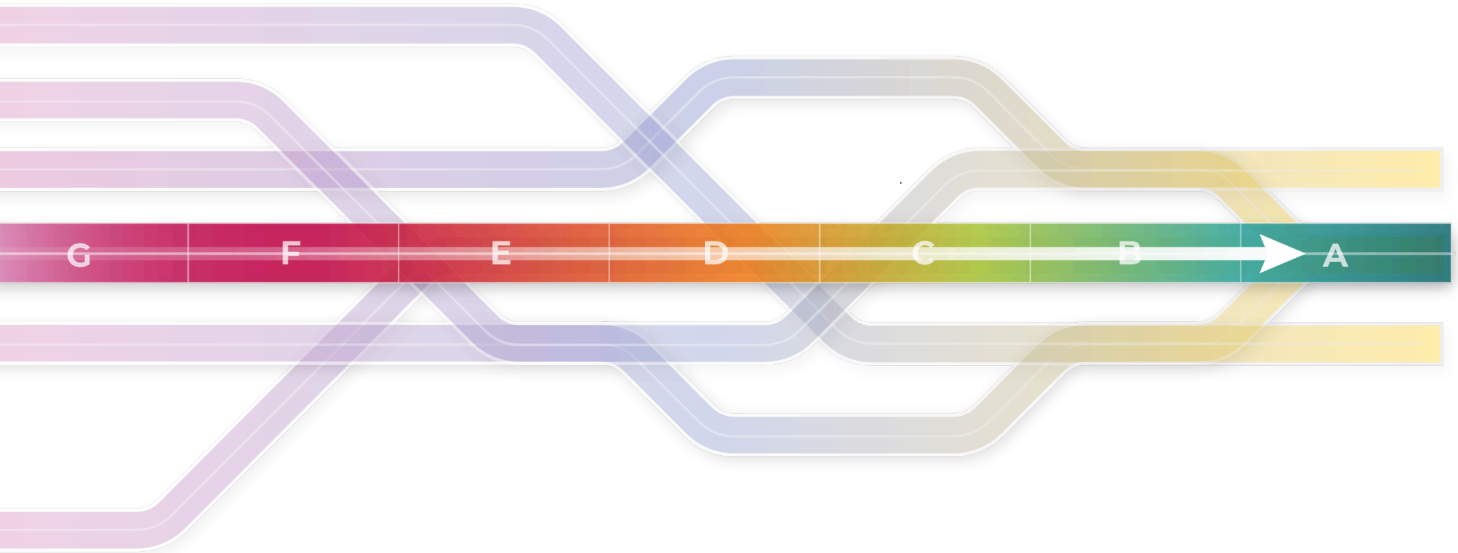
HEALTH DATA HUB

TEF-Health



TEF-Health Call #3

Action number: 101100700
Action Acronym: TEF-Health
Action title: Testing and Experimentation Facility for Health AI and Robotics
Author(s): Health Data Hub

Testing and Experimentation Facility for Health AI and Robotics hereby invites startups and Small and Medium Enterprises (SMEs) to submit their applications to the TEF-Health Call #3

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1. Context of the Call

1.1. Context

Under the Digital Europe Programme, the European Commission, in collaboration with several Member States, is co-financing a 5-year project, that started in January 2023 under the name "Testing and Experimentation Facility for Health AI and Robotics (TEF-Health; Project: 101100700 — TEF-Health — DIGITAL-2022-CLOUD-AI-02). TEF-Health is coordinated by Charité Universitätsmedizin Berlin, Germany and comprises 52 partners from 9 European Union countries – each of which forms a so-called "Node". TEF-Health is co-financed by national funding provided by the following participating countries: Belgium, France, Germany, Portugal, Slovakia and Sweden. TEF-Health establishes a network of testing facilities. These facilities offer a range of services, including access to physical and digital infrastructure, consulting, access to data, and computational resources, living labs, laboratory testing facilities and real-world testing environments. They provide healthcare innovators with the opportunity to conduct extensive tests and experiments on their AI and robotics solutions within real or realistic environments and to obtain support by experts for making their solutions compliant with the EU AI-Act and other regulations.

Via the call SMEs can access novel validation and experimentation services that are not yet established in the market at discounted prices.

1.2. Sponsor : the Health Data Hub (HDH)

The Health Data Hub, created on November 30th, 2019, is part of the French node of TEF-Health. It takes over the missions of the French Health Data Institute while expanding them. Its range of services for those seeking access to health data covers the following activities :

- A single gateway facilitating access to the necessary health data for projects contributing to public interest, while respecting patients' rights and ensuring transparency towards civil society.
- A documented data catalog, built up progressively to make priority data available to the community (historical SNDS, cohorts, registers, hospital data, etc.).
- A secure, state-of-the-art platform offering data storage, calculation, matching and analysis capabilities, enabling innovative projects sometimes considered impossible today.
- A range of tools to help bring together key actors within the ecosystem.

1.3. Objectives of the call

The objective of this call is to provide access to testing facilities that enable healthcare innovators to validate, and scale up their Artificial Intelligence (AI) and robotics solutions in realistic large-scale environments. These facilities aim to bridge the gap between innovation and market deployment by offering a safe, sustainable, and ethically supervised environment for testing new technologies.

2. The Services

TEF-Health is equipped to provide validation through services for AI and robotics-based solutions across various medical domains. The current Call, led by the Health Data Hub, is a gateway for SMEs to receive access to HDH services for designing and conducting validation studies at no cost to the beneficiary, with the corresponding value granted in compliance with the EU de-minimis state aid Regulation (EU) 2023/2831. These studies aim to support the development of innovative healthcare products or services using AI or robotics, ensuring they are ready for market access with the support of high-quality data. **SMEs from European Union (EU) and European Economic Area (EEA) member states are eligible for access to Health Data Hub services at a price reduced to 0 EUR, granted in compliance with the EU de-minimis state aid Regulation (EU) 2023/2831:**

1. **Support for simple use case including secure processing environment use** (without access and/or linkage to French National Healthcare Data System)
2. **Support for complex use case including secure processing environment use** (with access and/or linkage to French National Healthcare Data System)

These services include the following:

- **Project launch**: assistance in framing the project, particularly in identifying and implementing regulatory procedures; establishment of contacts with relevant stakeholders; support in collaborating with bodies in charge of health data, particularly with regards to contracting and meeting technical prerequisites for using such data;
- **Support towards institutional actors**, particularly when several data sources are involved and need to be combined or synchronized;
- **Data handling**: support for data custodians in extracting, structuring, qualifying, documenting, standardizing and/or transferring data involved as part of the project;
- **Support to research implementation**: provision of technological capabilities (dedicated project spaces with computing resources for 3 years, state of the art data management, analysis and visualization tools, alongside user onboarding and ongoing technical support), expert support (legal, data scientist, engineer, etc.), training and networking;
- **Results and project valorization**: communication events, networking within the ecosystem, etc.
- **Catalogue database fee**: manages the fees related to accessing and utilizing electronic health data for secondary use. The coverage is partial and depends on the chosen database, including standard access fees to database holders, potential compensation for a portion of the data collection costs, and a specific fee covering human and technical resources expended in enriching the electronic health data.
    - Examples of a non-exhaustive list of databases currently indexed in the Health Data Hub catalogue, with their medical domains and key features:

Database Acronym	Medical Domain(s)	Key Characteristics / Categories
TARPON	Emergency Medicine, Traumatology, Pharmaco-epidemiology	Provides data on emergency care episodes; relates to patient care pathways and professionals.
BNDMR	Rare Diseases	Focuses on rare disease populations, with data on patient follow-up, diagnosis, and care.

e-MUST	Cardiology, Emergency Medicine, Geriatrics, General Medicine	Data linked to management of acute myocardial infarction within SAMU/SMUR coverage in Île-de-France.
ATUc CBPC	Oncology (Small Cell Lung Cancer), Pulmonology	Cohort data for lung cancer (small cell), including clinical and environmental variables.
MEMENTO	Neurology, Geriatrics	Data on Alzheimer's disease and related disorders: progression, determinants, trajectories.
MDO	Infectious Diseases	Compulsory notification diseases, with data on incidence, patient profiles, and environmental contexts.
ESME CSM	Oncology (Metastatic Breast Cancer)	Real-world data on metastatic breast cancer, including epidemiology and therapeutic strategies.
UroCCR	Urology, Oncology (Kidney Cancer)	Multidisciplinary, multicenter clinico-biological database on kidney cancer.
APSOREN	Rehabilitation, Neurology, Traumatology	Focused on traumatic brain injury and recovery pathways, enriched with AI / neural network models.
SEDAAR	Ophthalmology, Neurology, Rare Diseases, Radiology	Eye disease screening via retinal imaging and automated analysis.

Additionally, in the scope of this call, SMEs from European Union (EU) and European Economic Area (EEA) member states are eligible for access to additional Health Data Hub services dedicated at enhancing the quality of the support received at a price reduced to 0 EUR, granted in compliance with the EU de-minimis state aid Regulation (EU) 2023/2831:

3. [extra] Protocol review

This service focuses on technical validation. It provides rigorous evaluation of experimental design, statistical power, reagent specificity, and controls to ensure methodological integrity and data reliability, identifying potential biases or flaws before study commencement.

4. [extra] Protocol writing

This service offers comprehensive scientific protocol authorship, generating detailed, technically sound protocols tailored to your research objectives. It encompasses experimental design, statistical considerations, precise methodological steps, and robust control measures, ensuring clarity and reproducibility for complex studies.

5. [extra] Analysis

This service provides in-depth data analysis expertise, specifically focusing on the exploitation of the French National Health Data System (SNDS) and, if applicable, its linkage with other datasets. Deliverables include commented R or Python programs for data processing and a detailed report presenting descriptive and analytical results, clear visualizations, conclusions, and recommendations, all to be completed within 60 days.

3. Roadmap for Applicants

The application process is divided in three phases:

Phase 1 – Application to TEF-Health through the current call coordinated by the HDH

Phase 2 – Eligibility Assessment according to section 5a below

Phase 3 – Selection of eligible projects : Upon closure of the application period, each submitted research proposal will be reviewed for eligibility against criteria listed in section 5.1. Eligible projects will then be reviewed by a jury as per selection criteria listed in section 5.2 Members of the jury will convene a selection committee to rank eligible projects. This list will be submitted to the management of the HDH for final decision.

4. Target Audience

SMEs from European Union (EU) and European Economic Area (EEA) member states may receive discounted services, if the applicable conditions are met (see section 5 Eligibility & Evaluation Process).

5. Eligibility & Evaluation Process

To apply for TEF-Health funding, please fill in the application webform on the TEF-Health Platform (https://tef.charite.de) as described here: https://tef.charite.de/docs/call/applicant/.

For questions related to the application process, please use the offered TEF-Health platform communication channels accessible upon registration (chatters, helpdesk) or contact info@tefhealth.eu.

Applications will be assessed according to the following eligibility (5.1) and evaluation (5.2) criteria:

5.1. Eligibility Criteria

SME is legally incorporated and established in one of the EU or EEA member states. The ownership or shares of the SME must not be held by individuals or entities outside the EU/EEA. The fulfilment of these requirements shall be confirmed through an official declaration issued by the legal representative of the SME.

Company is an SME according to the EU definition (Commission Recommendation 2003/361/EC). The fulfilment of this requirement shall be confirmed with an official declaration issued by the legal representative of the SME.

According to EU Regulation 2023/2831 (de-minimis) of the European Commission. The company must present evidence in the form of a formal declaration by the legal representative of the SME that the SME has not received over 300,000 EUR in state aid support during the previous 3 fiscal years.

AI and robotics solutions must be at a minimum Technology Readiness Level (TRL) of 5 (self-declared by the SME).

5.2. Evaluation schema

Expert evaluators will assess each application using the criteria in the following table.

Criteria	**Weight**
Expertise of project teams and project maturity	25/100
(1) The applicant presents a clear and feasible timeline for the solution	
(2) The applicant demonstrates prior experience with health data reuse projects	
(3) Alignment between project team composition and project's vision ;	
Solution	30/100
(4) The applicant presents a novel solution that is innovative and promotes clear advancement beyond the current state of the art.	
(5) The solution addresses a significant unmet medical need.	
(6) Soundness and consistency of the AI or robotics system and core technology used.	
Fit to TEF-Health	20/100
(7) The applicant's needs may be supported by the HDH service offerings provided in the current TEF-Health Service Catalogue.	
(8) The solution can increase TRL after implementation of the TEF-Health services.	
User centricity	15/100
(9) The applicant involves Medical Practitioners and/ or Patients in co-design, testing, or feedback activities.	
(10) The applicant ensures the solution is accessible and inclusive, addressing issues such as age, disability, digital literacy, and language.	
(11) The applicant demonstrates a plan to measure the impact of the solution on Medical Practitioners and/or Patients experience or satisfaction using relevant indicators.	
(12)The applicant ensures transparency and adherence to AI ethics, in compliance with the AI Act and/or MDR.	
Commitment & Resources	10/100
(13) The applicant demonstrates the necessary internal commitment, staffing, and resources to fully benefit from the Health Data Hub services.	

Each criterion will be scored from 1 to 7: 1- Very Poor; 2- Poor; 3 – Below expectations; 5- Above expectations; 6- Good; 7 – Very Good. Note that level 4 is not considered in the scale to promote clear results. The final evaluation score will be calculated according to the following formula:

$$Evaluation = Weight(1) * Score(1) + \cdots + Weight(13) * Score(13)$$

The number of eligible applicants that will receive state aid support in the form of discounts on the market price of services will be determined by capacity of the service providers.

6. Budget Requirements

No financial contribution is required from applicants, as access to Health Data Hub services will be provided at a price reduced to 0 EUR, granted in compliance with the EU de-minimis state aid Regulation (EU) 2023/2831. Applicants will not receive any direct funding or financial support for the development of their solution.

The budget will consist solely of the services selected from the TEF-Health platform.
However, applicants must ensure that they have sufficient internal resources and organisational capacity (e.g., staff availability, time allocation, technical readiness). These internal costs remain the responsibility of the applicant.

7. Timeline

The call stays open until the 30th of April 2026.

8. Contact Information

For questions related to the application process, please use the chatter function in TEF-Health Platform that you can access upon registration. For all other questions related to TEF-Health, please contact info@tefhealth.eu.

9. FAQs

Q: What is a solution in TEF-Health?

A: Solutions are digital products or services developed using AI and/or robotic technologies, which are to be subject to testing, experimentation and consulting services provided by TEF-Health.

Q: Can SMEs apply for multiple solutions in the same call?

A: SMEs may benefit from the services of TEF-Health for one or multiple solutions. For each solution, the SME should submit an individual application.

Q: If I am not an EU/EEA based SME, can I still apply to this call?

A: No, as indicated in section 5a. Eligibility Criteria, only SMEs legally incorporated and established in one of the EU/EEA member states are eligible to apply to this call and receive discounts due to state aid regulations.

Q: Does the Intellectual Property of the product remain with the SME, or is it shared with TEF-Health? Does the sole responsibility for commercialization lie with the SME or is it shared with TEF-Health?

A: The contract to be concluded between the HDH and the SMEs is governed by private law and will result from the terms decided between the two parties involved. The terms of the contractual and post-contractual relationship, as well as future rights over the solutions developed within the scope of the services provided by TEF-Health will be agreed by the parties in compliance with the applicable laws and regulations.

Q: How do the EU state aid rules apply if the SME is registered in an EU member state country, that is not the same as the EU member state of the Service Provider?

A: The EU state aid rules apply uniformly across all EU member states. Therefore, if the SME is registered in a different EU member state from the one where the service provider is registered, the rules still apply. Please check the eligibility requirements from section 5a of this call.

Q: Where can I find the complete list of services offered by HDH and their respective market prices, under this call?

A: Applicants can access the comprehensive list of services on the project website: tefhealth.eu where HDH's available services can be discovered.

Q: What is the required Technology Readiness Level (TRL) for my solution to be eligible for this Call?

A: Your solution should have a minimum entry TRL of 5. Please find here a short summary of each TRL level explanation**:**

- TRL 1 - Basic principles observed
- TRL 2 - Formulation of the technological concept
- TRL 3 - Experimental proof of concept
- TRL 4 - Validation of the technology in the laboratory
- TRL 5 - Validation of technology in a relevant environment (semi-industrial)
- TRL 6 - Demonstration of the technology in a relevant (semi-industrial) environment
- TRL 7 - Demonstration of the prototype system in an operational environment
- TRL 8 - Complete and qualified system
- TRL 9 - Approved system in series production environment