

TEF-Health Call #1

Action number: 101100700 Action Acronym: TEF-Health

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Testing and Experimentation Facility for Health AI and Robotics - hereby invites startups and SMEs to submit their applications to the TEF-Health Call #1

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Update: 1 April2024



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EF-Health call #1, published on February 1st was updated according to the following table:

Date of update	Details	Page
01 March 2024	New application link apply.eithealth.eu	6
	Amendment on name of the co-funding plan	3, 7
	from the Portuguese authority	
	Section 5a Eligibility Criteria:	5
	- "Be legally incorporated and established in one of	
	the EU member states." It was added to this	
	criterion a recommendation to upload the	
	official declarations in English or translated into	
	English by a certified translator.	
01 April 2024	- "Be an SME according to the EU definition (Commission Recommendation 2003/361/EC)." It was added to this criterion a recommendation to use the <i>Model declaration on the information relating to the qualification of an enterprise as an SME</i> available at the Official Journal of the European Union (2003/C 118/03)	
	Section 5b Selection Criteria: - Title changed from "Funding" to "SME investment capacity to acquire TEF-Health Services"	7
	New added FAQs	10











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1. Context of the Call

Under the Digital Europe Programme, the European Commission, in collaboration with Member States, is cofinancing a 5 years project, started from 2023 under the acronym "TEF-Health, <u>Testing and Experimentation</u> <u>Facility for Health AI and Robotics"</u> (Project: 101100700 — TEF-Health — DIGITAL-2022-CLOUD-AI-02).

TEF-Health is coordinated by Charité Universitätsmedizin Berlin, Germany and comprises partners from 9 European Union countries — each of which forms a so called "Node". TEF-Health is co-financed by national funding provided by these participating countries. In the particular case of TEF-Health Portugal "Node", TEF-Health is co-financed under the National Network Testbed (Project:189) by the RRP (Recovery and Resilience Plan), an initiative from the European Union to answer the economic downturn caused by COVID-19 pandemic. This project aims to support developers in the healthcare Artificial Intelligence (AI) Robotics sector, enabling them to bring trustworthy AI/robotic solutions to the market with increased efficiency, and fostering their widespread adoption across Europe.

One core element of this collaboration involves establishing a network of testing facilities. These facilities encompass a range of services, including physical infrastructure, data, and computational resources, living labs, and laboratory testing facilities. They provide healthcare innovators with the opportunity to conduct extensive tests and experiments on their Al and robotics solutions within large-scale and sustainable real or realistic environments.

2. The Services

TEF-Health is equipped to provide validation through services for AI and robotics-based solutions across various medical domains. This current Call is a gateway to identify the ideal partner for collaboratively designing and conducting a validation study for your groundbreaking healthcare product or service, rooted in AI or robotics technology.

Through this call, TEF-Health will connect your SME to the best Research Centers and Laboratories, Universities and Hospitals within Europe that can help you to test your solution with high-quality data, patients, clinicians, and medical staff, so you can get one step closer to go to market.

Selected Startups and Small and Medium Enterprises (SMEs) from European Union (EU) member states may receive state aid support in the form of discounts on the market price of validation services targeting their proposed solutions. Such discounts will vary based on the type and complexity of the service and relative demand for each offer. For the complete list of services offered, please refer to "tefhealth.eu". In this current Call, SMEs will gain access to the service catalogue offered by Portuguese TEF-Health partners. Specific requirements are further elaborated in this document. During the application process, applicants will be required to select a maximum of three services, ranked by order of preference.

To assure transparency and efficiency of the application process for selected SMEs and startups, the following process of application for TEF-Health is presented:











- Phase 1 Application to TEF-Health
- Phase 2 Eligibility Assessment according to section 5a below
- Phase 3 Evaluation according to section 5b below
- Phase 4 Application approval to gain access to the Portuguese TEF-Health services catalogue

3. Benefits for Selected Applicants

The following roadmap is offered to candidates that reach Phase 4 of the process of application (see Section 2 above):

- 1. Matchmaking phase(s) with Portuguese TEF-Health service providers;
- 2. Access to services that are not currently provided in the market;
- 3. Access to service quotations from Portuguese TEF-Health providers;
- 4. Signature of adhesion agreement (this signature will only take place if the service provider has the implementation capacity to provide the service in the period requested. If the TEF-Health services provider has several adhesion agreement requests for the same period and faces a low implementation capacity it will follow the first come first served rule to select the solution that will benefit from TEF-Health services);
- 5. TEF-Health services implementation process;
- 6. Product/Pilot evaluation report after service implementation;
- 7. A final product/pilot with TRL ranging between 5 and 9 depending on entry TRL.

The selected candidates that reach the signature of the adhesion agreement may benefit from:

- Access to AI and robotics experts from best-in-class organizations in Europe. Validation of AI and robotics-based innovation through qualified service offerings in tefhealth.eu;
- State aid as discount fees on the services, under the applicable conditions of:
 - Innovation aid for SMEs, under the dispositions set forth by Article 28 of GBER Regulations, not exceeding €200,000 per company over a period of 3 financial years. This type of state aid is applicable to companies legally incorporated in EU member states,

or











 De Minimis aid, as per Commission Regulation (EU) № 1407/2013, not exceeding €200,000 per company over a period of 3 financial years, for situations not fitted in (or regulated by) Article 28 of GBER Regulations.

4. Target Audience

Startups and SMEs from EU member states may benefit from state aid as discount services, if the applicable conditions are met (see Section 5 Eligibility & Selection Process).

5. Eligibility & Selection Process

To initiate the application process to the TEF-Health Call - Testing and Experimentation Facility for Health Al and Robotics please access the EIT Health Application Platform: apply.eithealth.eu
In case the applicant is new to the system, please follow the instructions document to complete the registration document properly. The document is available in tefhealth.eu: "SmartSimple Guide for applicants". For questions related to the application process, please contact tefhealth.eu. For all other questions related to TEF-Health, please contact info@tefhealth.eu.

To gain access to the service catalogue offered by Portuguese TEF-Health partners, SME applicants will be assessed based on the following eligibility and selection criteria:

a. Eligibility Criteria

- Be legally incorporated and established in one of the EU member states. Furthermore, the SME shareholding must be detained by any legal person incorporated or established in any of the EU member states or a country associated with the Digital Europe Programme¹. The complete fulfilment of this request shall be made with an official declaration issued by the authorities of the SME headquarters address, together with information about the ultimate beneficiaries of the SME shareholding, when applicable. It is recommended that this declaration is in English or translated into English by a certified translator.
- Be an SME according to the EU definition (<u>Commission Recommendation 2003/361/EC</u>). The fulfilment of this request shall be made with an official declaration issued by the national authorities of the SME headquarters address, or with the fulfilment of the *Model declaration on the information relating to the qualification of an enterprise as an SME*, available at the Official Journal of the European Union (2003/C 118/03)
- If the applicant wishes to gain access to services offered by Portuguese TEF-Health partners
 and be eligible to receive state aid support in the form of discounts on the market price of
 validation services under Article 28º of GBER Regulations, must present evidence that the SME
 has not received over 200,000 EUR in state aid support during the previous 3 fiscal years. The
 fulfilment of this request shall be made by self-declaration or a "declaration of honour" from
 the company.











¹https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/digital/guidance/list-3rd-country-participation_digital_en.pdf

- If the applicant wishes to gain access to services offered by Portuguese TEF-Health partners and be eligible to receive state aid support in the form of discounts on the market price of validation services under the EU Regulation nº1407/2013 (de-minimis) of the European Commission, must present evidence that the SME has not received over 200,000 EUR in state aid support during the previous 3 fiscal years. The fulfilment of this request shall be made with an official declaration issued by the Portuguese "Agência para o Desenvolvimento e Coesão (AD&C)" according to the Portuguese rules related to the "SircaMinimis" the central registration of minimis state aid.
- All and robotics solutions must be at a minimum Technology Readiness Level (TRL) of 4 (self-declared by the SME).
- Self-declared that the solution was not supported or is under support by another Portuguese testbed. More information about the National Network Testbed is available here.

b. Selection Criteria

To ensure a comprehensive and unbiased evaluation, expert evaluators will assess each application, using the criteria in the following table as the foundation for the selection process.

Criteria	Weight
Solution Description	40/100
(1) The applicant presents a novel solution that is innovative and promotes clear advancement beyond the current state of the art. The applicant presents a clear and feasible timeline for the solution.	15/100
(2) The solution addresses a significant unmet medical need.	10/100
(3) Soundness and consistency of the AI or robotics system and core	
technology used.	15/100
Fit to TEF-Health	45/100
(4) The applicant's needs may be supported by the service offerings provided in the current TEF-Health Service Catalogue.	15/100
(5) Service offerings in the TEF-Health service catalogue will actively facilitate and support the expansion of the company to new EU markets.	10/100
(6) The solution can increase TRL after implementation of TEF-Health Services within 6 months	20/100











SME investment capacity	15/100
(7) The applicant provides a budget availability that aligns with the prices of the current TEF-Health Service Catalogue and demonstrates having a solid financial track record with the capacity to cover the estimated expenses of acquiring the TEF-Health services	15/100

Each criterion will be scored from 1 to 7. Being: 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 in to promote clear results. An exception to this is criteria number 6: "The solution is able to increase TRL after implementation of TEF-Health Services within 6 months" which will be scored only with levels 1- Very Poor or 7- Very Good.

The evaluation will be calculated according to the following formula:

$$Evaluation = Weight(1) * Score(1) + \cdots + Weight(7) * Score(7)$$

Applications that meet the eligibility criteria and achieve the overall threshold of 5.0 in 7 will be selected and will gain access to services offered by Portuguese TEF-Health. The number of eligible applicants that may receive state aid support in the form of discounts on the market price of validation services will be determined by the available budget in the project: TEF-Health, Testing and Experimentation Facility for Health AI and Robotics (Project: 101100700 — TEF-Health — DIGITAL-2022-CLOUD-AI-02), and co-funded by the RRP(Recovery and Resilience Plan) under the National Network Testbed (Project:189).

6. Timeline

- The call will be open for application on 1 February 2024.
- The call will close when 100 products/pilots have been selected for implementation under the RRP (Recovery and Resilience Plan), National Network Testbed (Project:189), or on 30 of September 2025.
- Results of the application will be communicated up to 45 working days after submission.

7. Contact Information

• <u>tefhealth@eithealth.eu</u> and <u>info@tefhealth.eu</u>

8. FAOs











Q: How many solutions will be approved by the 30 of September 2025 to gain access to the TEF-Health service catalogue?

A: A maximum of 100 solutions will benefit from the TEF-Health services.

Q: What is a solution in TEF-Health?

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

Q: Can SMEs be beneficiary within this call by applying with multiple solutions?

A: There is no requirement for each SME to be associated with a specific number of solutions, which means that an SME may benefit from the services of TEF-Health for one or more solutions. For each solution, the SME should have an individual application.

Q: If I am not a Portuguese based organization, can I still apply to this call? Will I get discount as state aid from the services?

A: Yes. As long as the eligibility criteria from section 5.a are respected. Regarding the discount, if a company is not Portuguese-based, the company may receive state aid under Article 28 of GBER regulations, as long as all requirements are fulfilled.

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

A: The contract to be concluded between the TEF-Health service provider and the SMEs is governed by private law and will result from the terms decided between the two parties involved, and it must be ensured that access to the services provided is unrestricted, non-discriminatory and competitive. 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 the result of the will of the parties involved, and the will of both parties and the applicable legislation on the matter must be respected.

Q: How do the EU state aid rules apply if the company is registered in EU member state country, that is not Portugal?

A: The EU state aid rules apply uniformly across all EU member states. Therefore, if your company is registered in a different EU member state from the partners providing the services (all Portuguese for the present call), the rules still apply consistently, regardless of the specific member state where your company is registered. Please check the eligibility requirements from section 5a of this call.

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











A: Applicants can access the comprehensive list of services provided, on project website: tefhealth.eu

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

A: Your solution should have a minimum entry TRL of 4 and this should be self-assessed. Under the evaluation criteria the applicant will also be inquired if the submitted solution is able to increase TRL after implementation of TEF-Health Services. More details in section 5b. of this document.

- 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; and,
- TRL 9 Approved system in series production environment.

Q: What may be the benefits for the selected candidates that reach the signature of the adhesion agreement?

- Access to AI and robotics experts from best-in-class organizations in Europe. Validation of AI and robotics-based innovation through qualified service offerings in "tefhealth.eu".
- State aid as discount fees on the services, under the applicable conditions of:
 - Innovation aid for SMEs, Article 28 of GBER Regulations, not exceeding €200,000 per company over a period of 3 financial years. This type of state aid is applicable for companies from EU member states,

or

De Minimis aid, Commission Regulation (EU) № 1407/2013, not exceeding €200,000 per company over a period of 3 financial years, for situations not fitted in Article 28. Taking into account the Portuguese rules on SircaMinimis, the new Central Registry of de minimis aid managed by the Agency for Development and Cohesion (AD&C), in order for a non-Portuguese company to benefit from a discount on the services provided by the National Network Test











Bed, it would have to be registered, requiring a Portuguese value-added Tax Identification Number (VAT), meaning the registration of an establishment or branch in Portugal. The bureaucratic process involves a tax representative, with a national address, who can register the company, branch or non-resident legal person at a Portuguese Tax Authority office.

Q: In the service catalogue published within this call, the rates described are the indicative market price or after discounts on the market price?

A: The hourly rates described on the service catalog are the indicative market prices.

Q: The call description mentions that SMEs must self-declare if they haven't exceeded €200,000 under the de minimis scheme over a 3-year period, if they intend to request state aid support by this scheme. Will funding be provided for these services or will SMEs need to pay from their own resources?

A: The services available for this call have an indicative market price (catalogue available at https://tefhealth.eu/call/call-1). A discount may be applied on top of this market price, and this discount is provided to the company as state aid support. The discount as described above, will vary based on the type and complexity of the service and relative demand for each offer. If the discount does not cover the entirety of the service fees, the company will be responsible for paying the remaining balance.

Q: If a company has received more than the €200.000 for state aid, does that mean this company cannot participate, even if the company pays for the service fees?

A: The company can apply to TEF-Health Call #1 and benefit from the services available. In this case, the service fees will not be supported by state aid and the company would pay the full amount for the service.







