EP PerMed
European Partnership
for **Personalised Medicine**

EP PerMed Fast Track

Call for Proposals

10.12.2024

EIT Health

Co-funded by
the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101137129.

1 Change Log

The EP PerMed Fast Track Call was published on 10 December 2024. Any changes implemented after this date will be tracked below. If no information is included, it means no changes have been made since the launch of the Call.

ID	Date	Description of Change	Location in the document

2 Table of Contents

3 Introduction and aims of EP PerMed

Personalised Medicine (PM) represents a paradigm shift from a "one size fits all" approach to an optimised strategy for the prevention, diagnosis and treatment of disease for each individual, based on their unique characteristics, including biological features (e.g., phenotype, endotype, genotype), as well as lifestyle and environmental factors. Accordingly, PM puts the patient at the very centre of healthcare, aiming for optimised health promotion, treatments and management of disease or predisposition to disease. Today, the field of PM has been advancing rapidly and the range of technologies, methodologies and information utilised is much broader, supporting improved healthcare, diagnostics and tailormade treatments, including rehabilitation, and prevention strategies.

The European Partnership for Personalised Medicine, EP PerMed, is a platform for joint programming of national and European regional research and innovation (R&I) programmes putting into action "The Strategic Research & Innovation Agenda (SRIA) for Personalised Medicine (2023)"[1], SRIA for PM (2023), through dedicated research, development and innovation funding.

[1] *Strategic Research & Innovation Agenda for Personalised Medicine* (2024) *European Partnership for Personalised Medicine - EP PerMed*. Available at: https://www.eppermed.eu/action-areas/sria/ (Accessed: 05 December 2024).

Definition of Personalised Medicine

EP PerMed adheres to the definition stated in the PerMed SRIA: 'Shaping Europe's Vision for Personalised Medicine' (2015), adopted from the Horizon2020 Advisory Group:

"Personalised Medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."

Some additional information can be found in the 2018–2020 Advice of the Horizon 2020 Advisory Group for Societal Challenge 1, "Health, Demographic Change and Well-being":

"Different synonymous terms have been used alongside 'personalised medicine', most commonly 'precision medicine' and 'stratified medicine'. While there may be subtle differences in the literal meanings of these terms, they usually refer to the same concept when applied in practice. Stratified medicine (mainly used in the UK) is more treatment-dependent, while precision medicine (mostly used in US) has a relatively broad meaning as it refers to 4P (predictive, preventive, personalised and participatory) medicine. We use the term personalised medicine because this term best reflects the goal of effectively tailoring treatment based on an individual's 'personal profile', as determined by the individual's genotype and phenotype data. Based on individuals' profiles, PM aims to identify the optimal treatment regime by avoiding the treatment-failure approach commonly used in current evidence-based medicine."

4 Programme Timeline

Date	Event
10 December 2024	Opening of the Call for Proposals submission
13 March 2025	Deadline for Call submissions
14-18 March 2025	Eligibility check
19 March – 2 April 2025	Remote evaluation
11 April 2025	Remote review notification
11 June 2025	**Deadline for submission of validation plans**
20 June 2025	**Funding decision notification**
23 June – 31 December 2025	Validation studies
30 January 2026	Deadline for final report submission

5 Rationale of the Call

The EP PerMed Fast Track Validation Programme has been established to address a critical bottleneck in the development of PM solutions: the validation phase. Personalised medicine is a highly innovative and technology-driven field that holds immense potential for improving patient outcomes and optimising healthcare delivery. However, transforming groundbreaking innovations into market-ready products requires rigorous validation to ensure they meet the needs and expectations of end-users, including clinicians and patients.

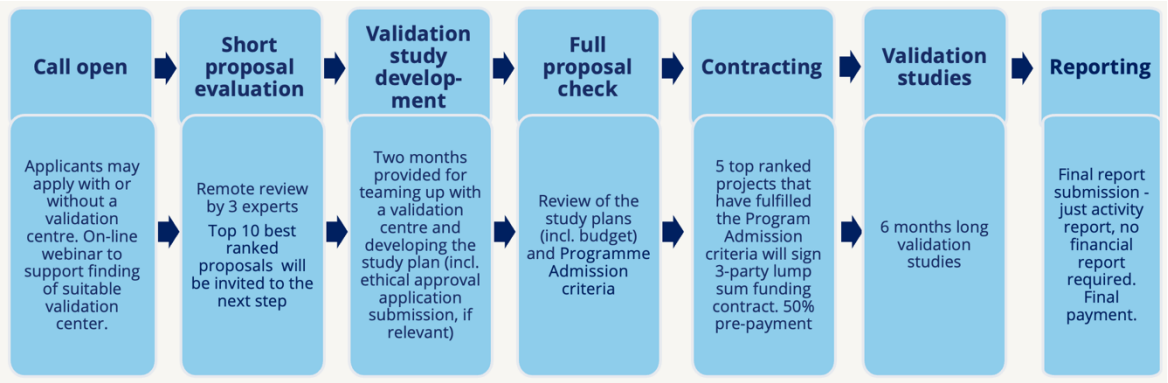
Validation is essential for achieving and maintaining product-market fit, a key determinant of commercial success. It involves a thorough assessment of whether a product or feature effectively addresses the identified needs and bottlenecks. This process is often conducted in specialised validation centres, which provide the

necessary infrastructure and expertise to test and validate innovations. Despite the availability of numerous validation centres across Europe, many innovators struggle to identify and access these resources, hindering the progress of their projects.

6 Programme overview

The Fast Track Validation Programme seeks to give support to overcome these challenges by providing a structured, accelerated pathway for PM innovators to validate their solutions. By leveraging a network of validation centres, the programme offers participants the opportunity to obtain critical evidence and feedback within a condensed timeframe of six months. This expedited process helps innovators swiftly advance their projects by at least one technology readiness level (TRL) and also enhances their readiness for market entry and commercialisation.

The programme supports start-ups and small teams and researchers at a pivotal stage of development, ensuring that promising PM innovations do not stall due to lack of validation resources and guidance. Through a combination of access to top-tier validation facilities, the Fast Track Validation Programme equips innovators with the tools and knowledge necessary to bring their solutions closer to clinical use and patient benefit.



The main steps in programme:

1. **Apply**: Applicants submit their proposals through the EIT Health Smart Simple application platform. Applicants may apply with or without a validation centre. During the on-line webinar, suggested validation centres will be introduced.
2. **Match**: Selected projects, that do not have validation centres will receive 2-3 suggestions as part of a positive funding note. Projects are free to find a match with the EP PerMed suggested centres or select other suitable validation centres based on individual needs as described in their application.
3. **Plan**: The applicant and their validation centre of choice formulate a detailed project plan on how they will work together during the programme. If ethical approval is required for the study, the approval application should be submitted before contracting.
4. **Funding Decision**: The final funding decision is made based on the project plan provided by the applicant together with the validation centre of choice.
5. **Validate**: A six-month long joint validation study is conducted.
6. **Final Report**: The applicant, together with the validation centre, will file a full report from the validation study at the end of the project.

Selected projects will receive funding of up to 80,000 EUR per project, which can be used to cover validation services and other eligible costs.

At least 70% of the budget should be allocated to user validation services. The funding will be provided through lump sum contracts, with 50% pre-payment and the remaining 50% disbursed upon approval of the final activity report.

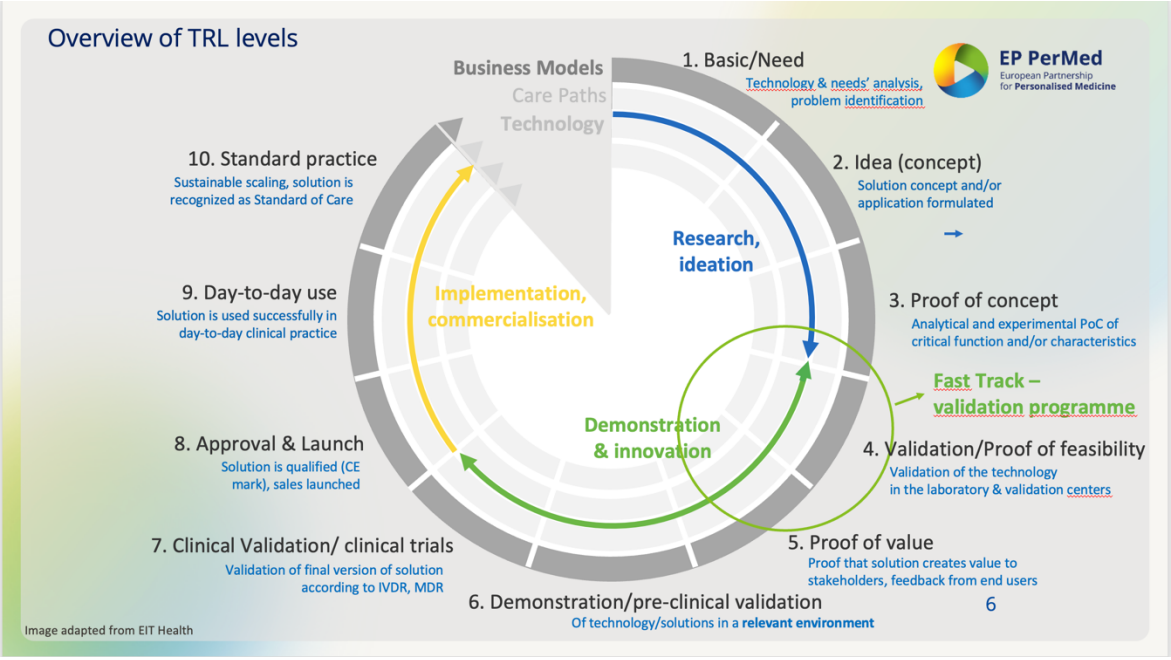
7 Aim of the Call

The Fast Track Validation Programme aims to accelerate the development and adoption of at least 5 innovative PM solutions in 2025, fostering advancements that can transform healthcare and improve patient outcomes. The programme

contributes to the overarching goal of Personalised Medicine: delivering tailored, effective, and efficient healthcare solutions that meet the unique needs of each patient.

8 Expected outcomes and impacts

Upon programme completion, participants will have rigorously tested and refined their innovations in realistic settings, elevating their projects by at least one TRL. This process ensures that solutions move to a higher level of technological and market readiness.



Please see **here** for more information on TRL levels.

The validation studies conducted in top-tier centres will provide essential evidence and, if applicable, user feedback, crucial for meeting regulatory requirements and demonstrating the efficacy and safety of the innovations. This rigorous validation process not only enhances the credibility of the projects but also reduces the time and risk associated with bringing new solutions to market.

By achieving higher TRLs, participants will be better equipped to attract investment and strategic partnerships, facilitating smoother transitions from

development to commercialisation. Ultimately, the programme aims to foster the development of Personalised Medicine innovations that are ready for clinical application, thereby accelerating the availability of advanced, patient-specific healthcare solutions and driving forward the field of Personalised Medicine.

9 Application

The EP PerMed Fast Track Validation Programme is open to start-ups, or small teams and researchers, seeking to incorporate into a start-up, who are looking to advance their PM innovations through rigorous validation studies. The programme targets solutions that are at least at the proof-of-concept stage (TRL3).

The application can be submitted with or without an already selected validation centre. When applying without a validation centre, the application must present a clear view on what kind of validation partner is needed for the project. This will help facilitate matching the application with an appropriate validation centre.

Applicants must submit their applications via EIT Health Application Platform: **https://apply.eithealth.eu/s_Login.jsp**. Please follow the instructions to complete account registration. If you have any questions, please see the "**Guide for applicants**" or contact **smartsimple@eithealth.eu**.

Registration Instructions:

For incorporated start-ups, make sure to register in the EIT Health Application Platform as a **representative of a start-up or independent team**. For Teams or researcher affiliated with an academic or healthcare research organization, please register as **a representative of an organization (excluding start-ups).**

10 Eligibility criteria

For an application to proceed to evaluation, it must meet all the below eligibility criteria. Each application will be reviewed for this eligibility criteria by EP PerMed Partners.

- Applicants must submit their applications via the application platform before the deadline on 13 March 2025 at 16:00 CET.
- Applications can be submitted by either a start-up or a team/researcher affiliated with an academic or healthcare research organization registered in an EU Member State or a Horizon Europe-associated country. - *If you are unsure about your eligibility, please do not hesitate to contact us using the information provided below* -
- Applications must be formulated in English.

10.1 Criteria for Validation Centres

- **Readiness to contribute**: The validation centre is ready to contribute to the project in the given time frame and fulfil the tasks in the given budget range.
- **Comprehensive Service Offering**: Provides a wide range of services that align with the specific needs of applicants, with flexibility to tailor support or customise services to meet unique project requirements.
- **Support for Early-Stage Innovations**: Demonstrates a successful track record in supporting start-ups or early-stage innovations, especially in validation.
- **Quality Management and Protocol Adherence**: Ensures strict adherence to quality management protocols in lab operations and clinical diagnosis, upholding high standards for reliability and accuracy.

10.2 Requirements for biobanks

The requirements of Biobanks as providers of samples and/or data for validation tests are as follow:

- Biobanks shall have readiness to provide samples and/or data, or other services and support for commercial purposes.

- Biobanks shall have broad consent for *retrospective* samples and/or data, that allows the samples and data to also be used for "commercial use".
- Biobanks complying to European and International Standards for preanalytical samples processing and/or ISO 21899:2020 (Biotechnology — Biobanking — General requirements for the validation and verification of processing methods for biological material in biobanks).
- Biobanks operations should be verified by complying to ISO 20387:2018 (Biotechnology – Biobanking – General requirements for biobanking) (accredited or quality labeled by BBMRI-ERIC).
- Biobanks that can support the applicant to obtain ethics clearance within max 1-3 months.

Biobanks associated with institutes at university/hospital level as potential validation centers:

Biobanks that operate under ISO 15189:2022 (Medical laboratories – Requirements for quality and competence) or ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories) or ISO 20658:2023 (Requirements for the collection and transport of samples for medical laboratory examinations).

11 Evaluation process and criteria

The selection process for this Call will involve a single proposal submission. Applicants will submit a single proposal through EIT Health's Smart Simple application platform. Applications will then be reviewed and evaluated by an independent panel of experts and scored according to a set of evaluation criteria on a scale of 1 to 5.

The evaluation criteria for admission into the EP PerMed Fast Track Validation Programme include:

- **Innovativeness of Idea:** The solution must present a novel approach that significantly advances the current state of Personalised Medicine.
  - Weight = 25%

- **Management Capacity:** The team should have the necessary skills and experience to successfully execute the project.
  - Weight = 25%
- **Market Opportunity and Impact:** The solution should address a clear market need with potential for substantial impact.
  - Weight = 20%
- **Co-creation and validation:** There must be a demonstrated need to refine and validate the solution.
  - Weight = 15%
- **Business Model and Development Strategy:** The applicant should have a clear and feasible plan for further development and commercialisation.
  - Weight = 15%

The evaluation will be calculated according to the following formula:

$$\text{Final score} = \text{Weight}(1)\times\text{Score}(1)+\cdots+\text{Weight}(5)\times\text{Score}(5)$$

Each proposal will be evaluated by 3 external programme evaluators. The final score will be the average of the aggregated scores of the evaluators.

As the programme uses lump sum funding, pre-selected projects should provide the detailed cost plan. In case of misbalance, suggestions will be provided and should be taken into account before signing the Financial Support Agreement.

12 Programme admission

Once projects receive the final scores from evaluators, they will then be ranked and the top 10 projects (rank one to ten) will be invited to the next step – creation of the study plan with validation centre of their choice. The TOP 5 ranked projects that meet all the funding criteria, will be funded.

To obtain access to the funding, the pre-selected projects should meet the following criteria:

- Both start-up and validation centers have signed the three-party-grant agreement (between EIT Health as funder, the validation centre, and the PM solution owner/applicant).
- Have provided a detailed validation plan, including detailed cost plan.
- If the cost plan anticipates changes, the amendments should be accepted.
- If the study plan foresees ethical approval, it must be submitted to the respective Ethical Board(s). A copy of the application should also be provided.

Based on previous experience, there may be a serious fallout from the funding list, therefore, we encourage the TOP 6-10 ranking teams to work on the study plan, as there is still high probability that some of the TOP 5 ranked will be not able to meet all the funding criteria.

Detailed validation plans must outline the scope, actions, timeline, and resources required for the validation activities and be presented no later than eight weeks following the selection notification.

Before a final granting decision is confirmed, these validation plans will be meticulously checked by EIT Health for completeness and accuracy. This review will focus on the feasibility and comprehensiveness of the plan, the suitability of the validation centre, the adequacy of resource allocation, and the readiness of the project team.

13 Funding and grant payout

Selected projects that successfully conclude a contract with a chosen validation centre will receive funding of up to 80,000 EUR per project. This funding is intended to cover validation services and eligible costs, with at least 70% of the budget allocated specifically to validation services. The funding will be provided

through a lump sum contract, structured to ensure efficient and effective use of resources.

The payment will be distributed in two instalments: an initial pre-payment of 50% of the total funding will be made at the start of the project, tied to the Financial Support Agreement signature, to facilitate the commencement of validation activities. The remaining 50% will be disbursed upon approval of the final activity report, which will verify the completion of the validation plan and the achievement of the project's objectives. This structured funding mechanism ensures that projects have the necessary resources to successfully complete the validation phase and progress towards market readiness.

Amount to be paid	Description	Payment tranche	Conditioned (All points must apply)
50 % of the Lump Sum Contribution	Validation Centre 35% of the total funding awarded. Start-Up 15% of the total funding awarded.	Pre-financing	Approval of the project plan by the programme management team - The approval process is outlined below – Signature of the Financial Support Agreement
50 % of the Lump Sum Contribution	Validation Centre 35% of the total funding awarded. Start-Up 15% of the total funding awarded.	Final payment	Completion of the task and the Project's objectives. Approval of all the tasks by the programme management team - The approval process is outlined below –

14 Data management and ethical compliance

EP PerMed expects proposals to meet the requirements of international state-of-the-art standards for data management (following the FAIR (Findable, Accessible, Interoperable and Reusable) principles[2], the General Data Protection Regulation

[2] H2020 programme guidelines on Fair Data Management in Horizon 2020. Available at: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf (Accessed: 05 December 2024).

(GDPR)[3]), and proposals are in accordance with Ethical principles[4] for data management.

Compliance with the requirements, must be reported in project final report.

15 Conflicts of interest (Evaluation panel)

The EP PerMed Fast Track Programme is committed to maintaining the highest standards of confidentiality and managing conflicts of interest throughout the admission process. All application materials and information provided by applicants will be treated as strictly confidential. EP PerMed Partners, EIT Health staff and independent evaluators are required to sign confidentiality agreements, ensuring that sensitive information is not disclosed to unauthorised parties.

To further safeguard the integrity of the evaluation process, EP PerMed implements rigorous conflict of interest policies. Evaluators and staff involved in the selection process are required to declare any potential conflicts of interest. Any evaluator with a conflict of interest will be recused from assessing the relevant application to ensure an unbiased review. This commitment to confidentiality and conflict of interest management guarantees a fair and transparent selection process, fostering trust and integrity within the programme.

16 Redress procedure

Applicants can appeal against the final award decision if they suspect a breach in the evaluation and selection procedures. This redress procedure only covers the procedural aspects of the Call. The redress will not call into question the scientific or technical judgement of experts/evaluators.

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[3] Legal text (2024) General Data Protection Regulation (GDPR). Available at: https://gdpr-info.eu/ (Accessed: 05 December 2024).

[4] Horizon 2020 programme guidance how to complete your ethics self-assessment. Available at: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf (Accessed: 05 December 2024) AND: Ethics and Data Protection - European Commission. Available at: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf (Accessed: 05 December 2024).

Applicants should submit their appeal to EIT Health via email (**appeals@eithealth.eu**) within seven calendar days following notification of the application outcome. The outcome notification email containing the results of the evaluation will give information on the appeals procedure, which is described below.

16.1 Admissibility of appeals

For an appeal to be admissible the following conditions must be met:

- The appeal must be submitted by the team to which the appeal relates;
- Only one appeal per proposal will be considered;
- The appeal must be submitted via email within seven calendar days of the outcome notification email. The appeal must contain the following minimum information:
  - The name of the Call for Proposals;
  - The proposal acronym;
  - The title of the proposal;
  - A description of the alleged shortcomings of the evaluation procedure.

The appeal must demonstrate a procedural irregularity, factual error, manifest error of assessment, misuse of powers, or a conflict of interests. Appeals that do not meet the above conditions, or do not deal with the evaluation of a specific proposal, or express mere disagreement with the result or the reasoning of the evaluation may be judged as not suitable for redress.

16.2 Procedure

Upon receipt of an appeal, an acknowledgement of receipt will be sent by EIT Health within seven calendar days. The acknowledgement shall report the redress process and the anticipated date by which a decision on the appeal will be communicated to the appellant.

All appeals received within the seven calendar days deadline will be processed together. The decision will be communicated to the appellant within 2 weeks from the deadline for submitting the appeals.

17 On-line webinar and call contact information

Join the on-line webinar for interested applicants of Fast Track call on **21 January 2025, 11am - 12pm CET. Register here.**

You can also register for our Q&A, before the Call closing date, on **4 March 2025, 11am - 12pm CET. Join us here.**

For further information:

- Please visit **https://www.eppermed.eu/funding-projects/calls/fast-track-call/**
- or contact: Mohammed Ilyass Rahmouni at **calls_eppermed@eithealth.eu**

18 Annex I: List of Validation Centres

The validation centers listed below are NOT official partners of this call. The provided links refer to publicly available sources. Applicants are encouraged to approach potential validation partners directly and provide more context on their needs and the scope of the call to help improve the call process.

1) TEF project: 83 virtual testing facilities and 93 physical testing facilities - **https://tefhealth.eu/**
2) EITH database of biobanks and health registers - **https://biobankshealthdata.eithealth.eu/**
3) Database of European biological and biomedical imaging - **https://www.eurobioimaging.eu/validation/**
4) HMA-EMA Catalogues of real-world data sources - **https://catalogues.ema.europa.eu/**
5) Catalogue of validation centers in European Network of Living Labs: **https://enoll.org/wp-content/uploads/2024/09/ENoLL_Member_catalogue_2024_web.pdf.**
6) BBMRI database of samples and data in biobanks - **https://directory.bbmri-eric.eu/ERIC/directory/#/catalogue.** Some biobanks that have given the confirmation to be part of Fast Track project in case of suitable match:
    a. Latvian National Biobank - Latvia: **https://www.genomadatubaze.lv/en/**
    b. Center of Excellence in Biobanking and Biomedical Research - Cyprus **biobank.cy**
    c. Integrierte BioBank Jena (IBBJ) – Germany **https://www.uniklinikum-jena.de/ikcl/ibbj.html**

d. Leipzig Medical Biobank, University Leipzig - Germany: **life.uni-leipzig.de**

e. Uppsala Biobank /Uppsala BioLab – Sweden: **www.uppsalabiobank.uu.se**

7) BBMRI-ERIC Expert Centers as potential validation centers in collaboration with biobanks:

   a. CNAG

   b. CBmed

   c. ATMA Platform