Open Innovation Test Beds for Safety Testing of Medical Technologies for Health (IA)

- Open Innovation Test Beds should upgrade or develop materials facilities and make available to industry and interested parties, including SMEs, services for the design, development, testing, safety assessment, and upscaling of new/existing medical devices in compliance with EU regulatory frameworks since the beginning of the development process;
- Test Beds could also contribute to develop methodologies to accelerate and simplify the subsequent pre-clinical and clinical testing in accordance with EU rules;
- Potential regulatory, economic, organisational and technical barriers should be identified and assessed. Where applicable, considerations regarding risk-assessment procedures that take into account potential gender differences should be considered;
- Open access at fair conditions and cost as well as outreach and dissemination across Europe, based on a distinct methodology;
- Quality control processes and tools should be validated to allow on-line quality controls;
- Medical devices should be demonstrated in relevant industrial environments.

Proposals submitted under this topic should include actions designed to facilitate cooperation, across Europe, with other projects; to enhance user involvement; and to ensure the accessibility and reusability of data produced in the course of the project.

Activities should start at TRL 4 and achieve TRL 7 at the end of the project.

The Commission considers that proposals requesting a contribution from the EU between EUR 7 and 15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The medical technology industry is an important economic and social player in Europe. The challenge is to provide companies and users in this sector access to affordable and advanced testing facilities and services to facilitate the development of new and safe medical technologies. The two new EU regulations[[Regulation (EU)

2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU]] governing medical technologies (medical devices and in-vitro diagnostics) are introducing a new set of rules to improve the safety of medical devices for the benefit of patients. To preserve timely access to innovative healthcare solutions and support the competitiveness of the European industry, testing facilities support services are needed to help industry and users develop and test medical devices in compliance with EU safety regulations. A bonus would be to define new methodologies for clinical testing, when relevant.

- Open and upgraded facilities at the EU level for the design, development, testing, safety assessment, and upscaling of new medical devices easily accessible to users across different regions of Europe;
- Attract a significant number of new SME users, with at least a 20% increase for existing test beds;
- Cost effective, innovative, and safe healthcare medical devices in compliance with EU safety regulations;
- Faster assessment of new medical devices' compliance with EU safety regulations;
- Reduced time to market of new medical devices (earlier determination of safety profile and facilitation of subsequent pre-clinical and clinical testing);
- Indirect substantial benefits for European citizens' safety and access to new and innovative medical products;
- New market opportunities for providing services to non-EU players interested in testing facilities to ensure compliance with EU regulatory frameworks for their export products to Europe.

Relevant indicators and metrics, with baseline values, should be clearly stated in the proposal.

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