Clinical research for the validation of biomarkers and/or diagnostic medical devices

Specific challenge: Biomarkers are used in clinical practice to describe both normal and pathological conditions. They can also have a prognostic or a predictive power. They are therefore increasingly used in medicine and many potential biomarkers are proposed every year.

Only a few of them are however validated for use in a clinical research setting. Such validation implies the demonstration of a link to a pertinent clinical endpoint or process, as well as a robust and appropriate analytical method.

The clinical validation of biomarkers will be increasingly important for the development of new diagnostics, and this is a research area where many small European companies are active.

Improved clinical decisions should lead to better health outcomes while contributing to the sustainability of the health care system.

Scope: The SME instrument consists of three separate phases and a coaching and mentoring service for beneficiaries. Participants may apply to phase 1 with a view to applying to phase 2 at a later date, or directly to phase 2.

Proposals submitted to phase 1 shall consist of a draft business plan and feasibility study verifying the technological/practical and economic viability of the clinical validation proposed. These may, for example, comprise risk assessment, market study, user involvement, intellectual property (IP) management, innovation strategy development, partner search, feasibility of concept etc. Proposals may analyse bottlenecks preventing advance of the applicant SME in this area and identify how a phase 2 proposal may contribute to attaining growth or sustainability.

The main outcome of the proposal should be a detailed business plan. Funding for phase 1 will be provided in the form of a lump sum of EUR 50.000 and proposals should have a duration of around 6 months.

In phase 2 proposals should address the specific challenge described, elaborated in the scope section above, and demonstrate high potential in terms of applicant's competitiveness and growth underpinned by a strategic business plan.

Proposals shall be based on a business plan developed either through phase 1 or another means. Particular attention must be paid to IP protection and ownership; applicants should provide evidence of the possibility of commercial exploitation (‘freedom to operate’).

The clinical validation of existing potential biomarkers (not the identification of new ones) is sought. This validation should provide evidence for: high analytical validity; appropriate sensitivity and specificity; clinical validity/ utility. Preference will be given to validation of biomarkers with high potential for short term uptake into clinical practice.

In addition, validation of the clinical performance of new diagnostic devices can be supported, either in combination with the biomarker validation, or against existing standards.

Both in vivo and in vitro potential biomarkers are eligible. Preference will be given to the validation of disease related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers)

Proposals shall contain a specification for the outcome of the project, including a first commercialisation plan, and criteria for success.

The Commission considers that phase 2 proposals requesting a contribution from the EU of between EUR 1 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Phase two projects should duly justify their duration making reference to obtaining patient samples, ensuring patient follow up, etc.

In addition, in phase 3, SMEs can benefit from indirect support measures and services as well as access to the financial facilities supported under Access to Risk Finance of this work programme.

Successful beneficiaries will be offered coaching and mentoring support during phase 1 and phase 2. This service will be accessible via the Enterprise Europe Network (EEN) and provided by a dedicated coach through consultation to the

beneficiaries. The coaches will be recruited from a database managed by the Commission and on the basis of their business experience and competencies. Throughout the three phases of the instrument, the EEN will complement coaching support by providing access to its innovation and internationalisation services. This may include, for example, depending on the needs of the SME, support in identifying growth potential, developing a growth plan and maximising it through internationalisation; strengthening the leadership and management skills of individuals in the senior management team and developing in-house coaching capacity; developing a marketing strategy or raising external finance.

Expected impact: This should provide:

Increased clinical availability and exploitation of biomarkers for the benefit of the patient.

New diagnostic devices.

Facilitation of entry of improved diagnostics in the clinic and the market.

Support for the implementation of the Commission proposal for a revised in vitro diagnostic devices regulation[1].

Enhancing profitability and growth performance of SMEs by combining and transferring new and existing knowledge into innovative, disruptive and competitive solutions seizing European and global business opportunities.

Contribution to the sustainability of health care systems.

Increased likelihood of market uptake and distribution of resulting innovations tackling the abovementioned specific challenge(s) in a sustainable way.

Leveraging of private investment in clinical validation as described above, notably leverage of private co-investor and/or follow-up investments.

Type of action: SME instrument (100% funding)

While all other instances of the use of the SME instrument in Horizon 2020 provide for reimbursement at 70%, the predominance of research type activities in clinical validation necessitate reimbursement at 100% in this case.

[1] Proposal for a regulation of the European Parliament and Council on in vitro diagnostic medical devices COM(2012)541 final

Última actualización: 16 Noviembre 2023

Permalink: https://cordis.europa.eu/programme/id/H2020_PHC-12-2014-1/es