

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

The SME Instrument is a European funding programme and part of the Horizon 2020 framework, supporting innovative, internationally oriented SMEs

SMEInst-05-2016-2017-b

Deadlines: Phase 2 only, 18 Jan 2017

The SME instrument is a European funding programme intended for high-potential innovative, internationally oriented SMEs. The instrument is intended for SMEs that are close to bringing a breakthrough innovation to market. The project should be aligned to the business strategy, helping internal growth or targeting a transnational business opportunity.

Scope of the programme

Biomarkers are used in clinical practice to indicate both normal and pathological conditions. They are also used for predictive or prognostic purposes. They are being used increasingly in medicine and many potential new biomarkers are proposed every year. However, only a few of these have been validated for clinical use. To achieve validation a robust analytical method is required and a link to a pertinent clinical process or endpoint needs to be demonstrated.

This validation process should provide evidence for high analytical value, appropriate sensitivity and specificity, and clinical validity. Particular attention should be given to validation of biomarkers with potential for rapid uptake into clinical practice. Both in vivo and in vitro potential biomarkers are eligible. Priority is given to the validation of disease-related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers). Validation of the clinical performance of new diagnostic devices can also be supported, either in combination with the biomarker validation or against existing standards.

Benefits for companies

- External validation of your innovative idea/technology
- Non-dilutive funding

Conditions for SME instrument:

- For this call, funding is provided only for phase 2: demonstration and market replication.
- The call is intended for SMEs only. The SME may partner with other SMEs and subcontracting arrangements are possible. Academic parties may only take part as a third party partnering with an SME as main applicant.
- The SME Instrument supports the development of ideas for products, services or processes that are ready to face global market competition.
- Only one proposal may be submitted per SME per cut-off date, and only if no concurrent submission or implementation of another SME-Inst is currently ongoing.
- The SME instrument is not meant as a company creation vehicle/instrument, but start-ups without balance sheets are not excluded from participation.
- Proposals for phase 2 must include a first commercialisation plan
- In Phase 2: applicants will have to present convincing measures to ensure the possibility of commercial exploitation ("freedom to operate").

Indicative budget	EUR 45 million from the 2017 budget
Duration	No limitations, 2-4 years on average
Consortium	All beneficiaries need to be SME's, single applications possible.
Project size	100% funding rate. Maximum EUR 5M.
Indicative timetable for evaluation and grant agreement:	Deadline: 18 January 2017, 17:00u Brussels time Outcome of the evaluation: May/June 2017 Indicative date for the signing of grant agreements: October 2017