European Commission

Horizon 2020 - societal challenge 1

Open Info Day

Funding Opportunities for SMEs

Horizon 2020 "Health, demographic change and wellbeing"

22 November2013
Brussels

Research & Innovation

Topic of the SME instrument

PHC 12 – 2014 and 2015: Clinical validation of biomarkers and/or diagnostic medical devices

Scope

- All existing potential biomarkers (prediction, diagnostic, prognostic, monitoring, toxicity, end-point, etc.).
- 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), but drug biomarkers are not excluded.
- Validation of the performance of new diagnostic devices (either in combination with the biomarker validation, or against existing standards).

Topic of the SME instrument

Background

- Global market for diagnostics is in expansion ($80 billion in 2013 worldwide), in particular for biomarkers (compound annual growth rate of 18.5%).
- 90% of the companies in the sector are SMEs.
- R&D bottleneck (around 25000 biomarkers identified each year that are in most cases not validated) and market failure with insufficient investments, as clinical validation is risky and valorisation of the diagnostic is poor (IVD is only 5% of medical product expenses).
- The Commission proposal for a regulation on *in vitro* diagnostic medical devices will change substantially the regulatory environment and will request clinical evidence.

Topic of the SME instrument

General Definitions

- A **biomarker** is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention (NHI Biomarkers Definitions Working Group; 2001)
- A **valid biomarker** is defined as "a biomarker that is measured in an analytical test system with well-established performance characteristics and for which there is an established scientific framework or body of evidence that elucidates the physiologic, toxicological, pharmacologic, or clinical significance of the test results (FDA. Guidance for industry - pharmacogenomic data submissions. 2005)

Topic of the SME instrument

Definitions (Regulation proposals)

- "**Performance of a device**" means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device.(IVD & medical device regulation proposals)
- "**Analytical performance**" means the ability of a device to correctly detect or measure a particular analyte. (IVD regulation proposal)
- "**Clinical performance**" means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user. (IVD regulation proposal)

Topic of the SME instrument

PHC 12 – 2014 and 2015: Clinical validation of biomarkers and/or diagnostic medical devices

Scope

- *All existing potential biomarkers are eligible.*
- *€ 50 000 and 6 months – Phase 1*
- *Between € 1 and 5 million – Phase 2 (up to 5 if properly justified)*
- *Between 12 and 24 months – Phase 2 (more if properly justified)*

Expected impact

- New validated biomarkers
- New "diagnostic" tools and methods
- Enhancing profitability and/or growth performance of SMEs
- Contribution to the sustainability of health care systems
- .....

Further information

- **European Commission**
  http://ec.europa.eu/index_en.htm
- **Health Directorate of DG RTD**
  http://ec.europa.eu/research/health/index_en.html
- ***In Vitro Diagnostic* Regulation**
  http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm
- ***Medical Device* Regulation**
  http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

Thank you very much for your attention

Jean-Luc SANNE, PhD
European Commission
DG for Research & Innovation
Directorate Health
Jean-luc.sanne@ec.europa.eu