Standardisation and improvement of generic pre-analytical tools and procedures for in-vitro diagnostics (SPIDIA)

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Research Areas

- **Tool Development**
  Standard
- **Biomarker Research**
- **Product Development**

At a Glance

- Status: **Active Consortium**
- Year Launched: **2007**
- Initiating Organization: **European Commission Seventh Framework Programme (FP7)**
- Initiator Type: **Government**
- Location: **Europe**

Abstract

The Standardisation and improvement of generic pre-analytical tools and procedures for in-vitro diagnostics (SPIDIA) consortium aims to standardize the pre-analytical procedures used for in-vitro diagnostics. The proposed research and standardization activities cover all steps from creation of evidence-based guidelines to creation of tools for the pre-analytical phase to testing and optimization of these tools through the development of novel assays and biomarkers.

Mission

The SPIDIA consortium is a European Commission-funded effort, under the Seventh Framework Programme, to bring together clinicians, academics, and biobanks as well as in vitro pre-analytical diagnostic tool and assay developers. The aims of the consortium are:

Structure & Governance

The objectives of SPIDIA will be obtained by integrative research approaches and technologies, covered by the following activities, each consisting of different work packages:

Evidence-based, international guidelines and quality-assurance schemes

This activity consists of three key actions: (i) evaluation of solutions developed by the consortium by using ISO-certified analysis platforms and ring-trials, (ii) writing of proposed guidelines and quality assurance schemes for the pre-analytical phase of combined classical and molecular diagnostics, and (iii) discovery of quality assurance biomarkers to monitor the quality of biological samples easily and cost-effectively.

The results of the research carried out under this activity, will be provided to CEN/TC 140 In vitro diagnostic medical devices as an input and a potential basis for technical work on European Standards, Technical Specifications or Technical Reports in the field of pre-analytical procedures.

Research leading to pre-analytical tools for molecular in vitro diagnostics and classical pathology

This activity is dedicated to the discovery and integration of breakthrough technologies that strengthen weak links in the pre-analytical phase of in vitro diagnostics. The results will allow the association of classical and molecular diagnostics. The work varies from the discovery of stabilization technologies for tissues, blood, and non-invasive samples, such as swab samples, to the integration of multiple pre-analytical steps into an automated workflow. Furthermore, this activity will evaluate and provide feedback encouraging improvement and innovation of guidelines and tools used for the discovery and validation of biomarkers.

Management, ethics, and spreading of excellence

This activity will provide support and ethical rigor to the RTD and standardization activities in SPIDIA. It also aims to connect the outputs of SPIDIA to information channels for end users of the standards (Activity 1) and scientific and technological discoveries (Activity 2) as well as the general public. Internal training activities and seminars will be organized for SPIDIA members; other training activities will also be open for the research community. A wide dissemination of the research outcomes to a broader public beyond the research community will be supported through dissemination and knowledge transfer. Special attention will be given to the ethical, legal, and societal aspects associated

with the research with human biological samples.

Sponsors & Partners

EU FP7, Project reference: 222916
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EUR 13 823 601
EU contribution:
EUR 8 981 796

Homepage http://www.spidia.eu/
Qiagen GMBH
Medizinische Universitat Graz
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Magnetiche di Metalloproteine Paramagnetiche
Tataa Biocenter AB
Preanalytix GMBH
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