Standardization
in research and innovation projects

Success story: **health**

SPIDIA:

The SPIDIA project, funded by the FP7 (7th European Research Framework Programme) aimed for standardization and improvement of pre-analytical procedures for *in vitro* diagnostics by developing necessary guidelines, technologies and tools for practical applications in the area of health and medicine. SPIDIA enabled the development of several CEN/TS series. These Technical Specifications will answer the need to have standardized pre-analytical procedures for e.g. the sample collection, stabilization, transport, storage and processing integrated in one process. Processes will be sample-specific depending on the target for analysis (e.g. RNA, DNA, proteins) to secure dependable and reproducible analytical test results in the clinical/pathological laboratory.

www.spidia.eu

THE PROJECT

SPIDIA was a 54-month collaborative project which united public and private researchers to perform interdisciplinary translational research. SPIDIA addressed the objectives of the EU 7th Programme "HEALTH" priority 1 of the Cooperation programme and more precisely the "Detection, Diagnosis and Monitoring" topic dedicated to multidisciplinary research. SPIDIA fully met the expectations of the European Commission concerning the "Standardization and improvement of pre-analytical procedures for *in vitro* diagnostics".

SPIDIA contributed to the standardization and improvement of procedures and tools for pre analytical intervention. The individual steps, such as sample handling, stabilization and storage, were standardized and integrated in one holistic process combining classical and molecular diagnostics. Furthermore, new biological biomarkers were discovered and validated. Finally, SPIDIA aimed at developing and validating the necessary guidelines and tools to facilitate the production of new knowledge and its translation into practical applications in the area of health and medicine.

STANDARDS: A SOLUTION FOR MARKET UPTAKE

Molecular *in vitro* diagnostics has enabled a significant progress in medicine. Further progress is expected by new technologies analysing signatures of nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles of these molecules can change drastically during primary sample collection, transport, and storage thus making the outcome from diagnostics or research unreliable or even impossible, because the subsequent analytical assay will not determine the situation in the patient but an artificial profile generated during the pre-examination process. Therefore, the standardization of the entire process from sample collection to analyte measurement is needed. Studies have been undertaken to determine the important influencing factors in regards to blood, plasma, urine and tissue samples.

> "Standards are key enablers for new workflows, methods and technologies, and without them the implementation would lack behind in years."
>
> Dr. Oelmueller, SPIDIA Coordinator

HOW WAS THE STANDARD DEVELOPED?

Project partners, as well as representatives from a wider community of manufacturers, European and international research associations, users and researchers provided input to the content of the specifications. Thereby, CEN/TC 140 *'In vitro diagnostic medical devices'*, which is in close contact with ISO/TC 212 *'Clinical laboratory testing and in vitro diagnostic test systems'*, was able to target European and international needs in the field in respect to the preparation for future EN ISO Standards.

With the results from SPIDIA, there are currently three CEN/TS series under development by CEN/TC 140 totalling in eight CEN/TS. Based on sample specific differences, each specification series addresses the pre-analytic analyte-specific workflows (e.g., for RNA, DNA, proteins) of one sample type such as 'snap frozen tissue', 'blood' or 'formalin fixed and paraffin embedded (FFPE) tissue'. All documents will be published soon and are currently up for voting to become new work items for EN ISO Standards under ISO/TC 212. Also, there is a CEN/TS on metabolomics under development which will most likely be published in late 2015.

BENEFITS OF LINKING WITH STANDARDIZATION

Standardization within CEN/TC 140 was a key dissemination activity for the SPIDIA project, and is seen as fundamental for the potential long-term use and impact of project results. The further development of potential EN ISO Standards under ISO/TC 212 with a worldwide impact will be a big step towards the improvement of the health care system.

LONG-TERM EXPECTED IMPACT

Standardization activities in this field are very important for molecular *in vitro* diagnostic examinations (e.g. for *in vitro* diagnostic laboratories, laboratory customers, *in vitro* diagnostics developers and manufacturers, institutions and commercial organizations performing biomedical research, biobanks, and regulatory authorities) in terms of necessary handling procedures, documentation, quality controls as well as time and temperature regimes enabling optimized interpretation and comparability of analytical test results.

The CEN Technical Specifications are expected to be available to any interested stakeholder in early 2015. When the CEN Technical Specifications are published, the output by SPIDIA will be used to develop additional CEN Technical Specifications or even European Standards.

These specifications will enable the wide diffusion of the project results within Europe and beyond. Experts from American, Canadian and Japanese research institutes and industry are eager to establish International Standards based on these European specifications for their own applications.

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> Because analytical test results are depending on the quality of the tested sample, it is of utmost importance that the handling and documentation of the primary sample during the pre-analytic phase is done in a standardized manner. For this to be facilitated and widely spread, in order to enable the urgently needed improvement in the pre-analytic field, standardization is key.
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> Dr. Oelmueller, SPIDIA Coordinator

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Every project is different. The CEN-CENELEC Research Helpdesk can provide you with advice on how to include standardization in your project. Please feel free to contact us!

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Publisher : Andreea Gulacsi – © CEN & CENELEC - September 2014