

CEN and ISO Standards for Pre-analytical Processes in Industrial Development and Medical Diagnostics

The course organized by Institute of Pathology, SPIDIA4P, QIAGEN and BBMRI.at and held in Graz, Austria, raised awareness about the existence and relevance of the CEN Technical Specifications and ISO Standards and of standardizing pre-analytical processes in R&D and medical diagnostics.

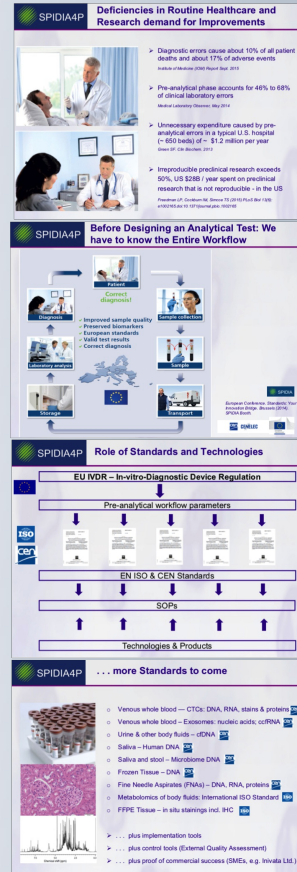
International participants learned about which CEN Technical Specifications (CEN/TS) "In-Vitro Diagnostic examinations - Specifications for Pre-examination Processes" have already been published and which pre-analytical CEN/TS and ISO Standards are under development.

The main focus of the course on May 16, 2018 was on demonstrating their relevance for medical diagnostics and research and development (R&D), particularly in the context of the new In-Vitro Diagnostic Regulation. The development process of standards was introduced and an overview on the structure and scope were given.

The major pre-analytical factors and their influence on analyses results in pathology and human genetic laboratories were addressed and examples of how to implement the standards were given. Participants also had the opportunity to test the BBMRI-ERIC online Self Assessment Tool. All participants rated the course 'excellent'.

Set of presentations given included:

- Dr. Uwe Oelmüller, QIAGEN GmbH, SPIDIA4P Coordinator, Germany: "New CEN and ISO Standards for Improving Diagnostics and Research"
 - How they are developed ...[view presentation](#)
 - What they mean for us ...[view presentation](#)
- Univ.-Prof. Dr. Kurt Zatloukal, BBMRI.at & Institute of Pathology, Medical University of Graz, Austria: "Pre-Analytical Errors" ... [view presentation](#)
- Mag. Cornelia Stumptner, BBMRI.at, Medical University of Graz, Austria:
 - "Meeting CEN and ISO Standards: BBMRI Self Assessment Survey Tool" ...[view presentation](#)



SPIDIA4P Deficiencies in Routine Healthcare and Research demand for Improvements

- Diagnostic errors cause about 10% of all patient deaths and about 17% of adverse events
Statista Infocenter 2016 Report April 2017
- Pre-analytical phase accounts for 46% to 68% of clinical laboratory errors
Medical Laboratory Observer Aug. 2014
- Unnecessary expenditure caused by pre-analytical errors in a typical U.S. hospital is 450 billion US\$ - \$1.2 million per year
Quest Diagnostics 2013
- Reproducible preclinical research exceeds 50% US \$205.1 year spent on preclinical research that is not reproducible - in the US
President of QIAGEN Dr. Uwe Oelmüller 10th International IVDR Summit

SPIDIA4P Before Designing an Analytical Test: We have to know the Entire Workflow

Improved sample quality
 Preserved biomarkers
 Consistent results
 Valid test results
 Correct diagnosis

SPIDIA4P Role of Standards and Technologies

EU IVDR - In-vitro-Diagnostic Device Regulation

Pre-analytical workflow parameters

EN ISO & CEN Standards

SOPs

Technologies & Products

SPIDIA4P ... more Standards to come

- Venous whole blood - cDNA, DNA, RNA, stems & proteins
- Venous whole blood - Electrolytes, nucleic acids, cytokines
- Urine & other body fluids - cDNA
- Saliva - Human DNA
- Saliva and stool - Microbiome DNA
- Frozen Tissue - DNA
- Fine Needle Aspirates (FNAs) - DNA, RNA, proteins
- Metabolomics of body fluids: International ISO Standard
- FFPE Tissue - in situ stainings incl. IHC

... plus implementation tools
 ... plus control tools (External Quality Assessment)
 ... plus proof of commercial success (SMEs, e.g. Sivalva Ltd.)