SPIDIA4P & BBMRI-ERIC: What Solutions can we provide to improve in vitro Diagnostics?

EU Parliament

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Deficiencies in Routine Healthcare and Research demand for Improvements

- Diagnostic errors cause about 10% of all patient deaths and about 17% of adverse events
  Institute of Medicine (IOM) Report Sept. 2015

- Pre-analytical phase accounts for 46% to 68% of clinical laboratory errors
  Medical Laboratory Observer, May 2014

- Irreproducible preclinical research exceeds 50%, US $28B / year spent on preclinical research that is not reproducible - in the US
An Analytical Test Result is the Result of an entire Workflow

Major Efforts for Improvements

- Technologies
- International CEN & ISO Standards
- External Quality Assessment (EQA) Schemes
- Implementation - healthcare, biobanking, research

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Molecular in-vitro diagnostic examinations - Specifications for **pre-examination processes** for

- **Blood** — Cellular RNA, gDNA, ccfDNA, ccfRNA
- **Blood** - Exosomes
- **Tumor Cells** in Blood – DNA, RNA, staining
- **Tissue** (FFPE & Frozen) — DNA, RNA, Proteins
- **Tissue** (FFPE) - staining
- **Fine Needle Aspirates** – DNA, RNA, Proteins
- **Saliva** – DNA
- **Urine & Body Fluids** – cfDNA
- **Metabolomics** – Urine, Serum, Plasma
- **Microbiome** – Stool, Saliva etc.
Role of Standards and Technologies

EU IVDR – In-vitro-Diagnostic Device Regulation

Pre-analytical workflow parameters

EN ISO & CEN Standards

SOPs

Technologies & Products
Pre-analytical Workflow - Same Standards for all Segments

- Biobanks
  - Source for high quality samples
  - BBMRI-ERIC plays a central role

- Biomedical & Translational Research
  - Academia
  - Pharma industry
  - Diagnostic Industry

- Diagnostics
  - High sample quality is the safe way
  - Analytical assay might tolerate lower quality or not ⇒ Validation studies
Future Perspective beyond SPIDIA4P

- Patients sample qualities stay key for healthcare & innovation
  - new diagnostic targets
  - new electronic patient data modelling & integration, electronic patient records, new links between applications by digitalization etc.

- Continue standards initiative

- Continue implementation

- Health economics

- Clinical demonstrations / trials
Questions?

www.spidia.eu - New website coming soon
Back Up Slides
SPIDIA’s Road to Standardization

- **2018**: Progressing to ISO/FDIS
- **2014**: 8 new projects for ISO Standards approved in ISO/TC 212 „Clinical laboratory testing and in vitro diagnostic test systems”
- **2015**: 9 CEN Technical Specifications published
- **2013**: 9 new projects approved in CEN/TC 140 „In vitro diagnostic medical devices“
- **2010**: Start of standardization work

Vienna Agreement 1991

1. Problem - Errors in Diagnostics
   - 19% Preanalytics
   - 68% Analytics
   - 13% Postanalytics

2. Technical Solutions
   - Resect & Gross
   - Fix
   - Stabilize
   - Process
   - Allows histomorphology and molecular testing from the same specimen

3. Ring-Trials – Blood RNA (l.) and DNA (r.)

[Graphs showing data and comparison]