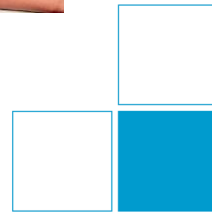


A European Metrology Network for Laboratory Medicine (case study 3)

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With support from
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Rationale

European In-vitro Diagnostic Device Regulation (EU) 2017/746:

*„**metrological traceability** of values assigned to **calibrators** and **control materials** shall be assured to certified reference materials or reference measurement procedures.“*

*“... reference laboratories **shall form a network** in order to **coordinate and harmonise** their working methods ...” (2017/746, Article 100)*

NMIs, DIs, Reference laboratories:

Have already established capabilities but **no single institute** is able to cover the full scope needed

European network of metrologists, PT providers, clinicians, regulators, ...

... shall be established to coordinate existing capabilities

... ensures sufficient redundancy but avoid unnecessary duplication of work

→ **More efficient and effective use of resources of European NMIs and DIs**



replaced IVD Directive 98/79/EC in May 2017

Background, Activities & Actors

CCQM – Consultative Committee for Amount of Substance

OAWG, IAWG, BAWG: Pilot studies & Key comparisons
CMCs for a number of relevant biomarkers

Germany, PTB (Physikalisch-Technische Bundesanstalt)			
Certificate of Comparison for Biological Fluids and reference for Germany (PDF file)			
Matrix of material	Analyte or component	Concentration range of measurement capability	Relative expanded uncertainty (k = 2, 95%) in %
Blood serum	cholesterol	3.0 to 9.0	0.5 to 1.1

IMERA+, EMRP, EMPIR projects

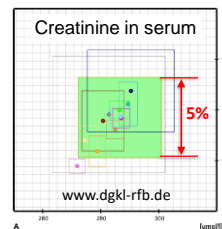
“TraceBioActivity”, „ClinBioTrace“, “Metallomics”, “ReMind”

Development of primary reference standards for some important and demanding measurands

External Quality Assurance (EQA) schemes

IFCC RELA: EQA for Reference Laboratories

Regular calibration service based on international recognized reference measurement procedures, e.g. ID-MS



Key actors:



- ← National medical associations
- ← Clinical partners (medical univ.)
- ← IVD manufacturers

Physikalisch-Technische Bundesanstalt ■ Braunschweig und Berlin

National Metrology Institute

WS on European Metrology Networks, 09.01.2018

3

Outputs

Services

- Provision of SI-traceable reference points for the most relevant analytes in laboratory medicine
- Provision of Proficiency Testing (PT) schemes for reference laboratories on a regular & sustainable basis (existing standards → new standards)
- Provision of support & training (capacity building: emerging NIMs)

Research & Development

- Identification of research needs (with input from clinical partners)
- Joint development of new standards (ref. procedures & materials)
- support development of assays (clinicians & IVD manufacturers)

Organizational matters

- Evaluation of a European legal framework for coordinated actions
- Establishment of a common quality infrastructure

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4

Impact

A European Metrology Network on Laboratory Medicine will

- Underpin the quality infrastructure in laboratory medicine as required by EU regulation 2017/746
- Provide European coherence by provision of harmonized, consistent services on a long-term, sustainable basis for any European stakeholder
- Establish a legal framework to decide on criteria for eligibility to participate in an EMN and to develop a contractual basis on which the commitment of each network partner shall be agreed

Calibration Hierarchy in Laboratory Medicine

