EMPIR Call 2018 – Networks

Selected Network Topic number: **SNT-w06**
Version: 1.0

Title: Support for a European Metrology Network on Traceability in Laboratory Medicine

Abstract

Metrologically-based quality assessment (QA) of clinical laboratory testing for *in vitro* diagnostic devices is no longer optional but is compulsory to meet European regulations such as (EU) 2017/746 which requests traceability of values assigned to calibrators and control materials. EURAMET intends to establish a collaborative network for Traceability in Laboratory Medicine involving metrology institutes, proficiency testing (PT) providers, clinicians, and regulators will be established to coordinate the provision of services, to identify stakeholder research needs, and to develop new standards. This long-term, sustainable coordination will comprehensively underpin a legally endorsed European QA infrastructure by providing consistent services to any European stakeholder.

This SNT is intended to support that EMN in their initial tasks.

Keywords

Laboratory Medicine, *In vitro* Diagnostic Medical Devices, European Reference Laboratories, Proficiency Testing Schemes, External Quality Assessment, Reference Measurement Procedures, Certified Reference Materials

Background

The reliability of measurement results in laboratory medicine has a major impact on decision making that directly impacts on the health of the European citizen. A large proportion of the measurands relevant to disease diagnostics in treatment procedures and in monitoring the health status are determined by means of *In vitro* diagnostic medical devices (IVD). Consequently, IVDs are an essential part of today's healthcare and their safety for operators (clinical laboratories) and end users (patients) is of critical importance which also includes acceptable clinical performance for their intended use.

These tests include HIV blood tests, pregnancy tests and blood sugar monitoring that are used to support crucial decisions ensuring the protection of public health and patient safety. To maintain a consistent level of safety and performance, IVDs are subject to regulation at the European level. In Europe, these requirements are laid down in the regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) replacing the former IVD directive (98/79/EC). IVDR significantly broadens the scope and sets out a new requirement "that metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures".

At present, neither the total number of measurands considered to be of highest priority is linked to the SI via reference measurement procedures (RMP) and certified reference materials (CRM), nor has a single national NMI/DI the capacity to provide the full scope of primary standards needed. With the aging society in Europe and the increasing number of biomarkers used in diagnostics, the requirements of the IVDR exceed the capacity of the NMIs/DIs and reference laboratories of a single member state to provide metrological traceability via RMPs and CRMs. Therefore, the setting up of a network of reference laboratories to coordinate and harmonise the working methods is explicitly encouraged in the IVDR.

The IVDR also emphasises post-market surveillance requirements that manufacturers must provide for their products on a long-term life-cycle basis. IVDs are subject to continuous performance and risk assessment and require reference measurement procedures and materials which remain stable and reliable for many years. It is the responsibility of the IVD manufacturers to ensure that the calibrators they provide are traceable to available and appropriate certified reference materials (CRMs) or reference measurement procedures (RMPs). However, such CRMs and RMPs of higher metrological order are best to be provided by National Metrology Institutes (NMIs) and Designated Institutes (DIs) to the manufacturers through the European reference

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The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States

laboratories (ERL) demanded in the IVDR. The tests performed in these ERL should “focus on analytical and diagnostic sensitivity using the best available reference materials”. However, such reference materials are scarcely available for many measurands of interest.

How and where NMIs should focus limited resources to obtain maximum impact for society urgently requires a strategic plan and significant coordination at the European level. No single NMI has the expertise or resource to tackle all or even a significant fraction of the most critical priorities without collaboration. Without coordination, there is a strong likelihood of unnecessary duplication, with NMIs (nationally and/or regionally) potentially independently choosing to focus efforts on the same challenge with consequential neglect of others. EURAMET intends to establish a European Metrology Network to coordinate the European NMI response, to establish close links to the stakeholder community, to develop and implement a strategic agenda and establish a knowledge, technology transfer and promotion plan, to ensure an effective response is put in place. This SNT is intended to support that network in their initial tasks.

Objectives

Proposers should address the objectives stated below, which are based on the PNT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical / legal / regulatory / market constraints, but the reasons for this should be clearly stated in the protocol.

The JNP shall focus on developing a long term ongoing dialogue between the metrology community and relevant stakeholders. This dialogue should support the take-up of research outputs from the metrology community and the collection of needs from industry to inform future research.

The specific objectives are:

1. To develop a plan for a joint sustainable European metrology infrastructure for traceability in laboratory medicine by stimulating smart specialisation of European NMI facilities and services. This should include processes to promote a constructive dialogue between NMIs/DIs and stakeholders such as clinicians, national medical associations, External Quality Assurance (EQA) providers, regulators and IVD manufacturers.
2. To create a coherent strategy for a joint European response to the need for traceability in laboratory medicine and IVD producers in this field, in accordance with the IVD Regulation (EU) 2017/746. This response should accommodate the need for sufficient redundancy while avoiding unnecessary duplication of work. A web portal serving as a single access point should direct customers’ requests for specific calibration services and reference materials to the service providers.
3. To develop a joint strategy with EQA providers for reference laboratories to identify and prioritise measurands for which SI traceability is required. Existing national priority lists should be utilised to identify a core set of measurands to start with. Reference points in proficiency testing schemes for SI-traceable measurements should be provided. With input from clinical research and national medical associations, the strategy should also propose additional candidate measurands for future EQA schemes.
4. To assess and report on the benefits of establishing a legal framework for coordinated action of the EMN, preferably underpinned by EURAMET as the legal body responsible for the collaboration of NMIs and DIs in Europe. To develop processes whereby regular consultation within the network on a long-term basis, can enable the EMN to work towards binding commitments among the members as well as to agree on a common quality infrastructure.
5. To set up a roadmap addressing the further development of the EMN both regarding timing and content of the activities and services offered. Broadening the scope of the activities may include but is not limited to engagement with (a) clinicians, to support the identification and quantification of novel biomarkers and the definition of more reliable clinical thresholds, (b) IVD manufacturers, to provide tools for the metrological validation of new assays in accordance with the new IVD Regulation (EU) 2017/746, (c) emerging European NMIs/DIs or even non-EU countries, to organize knowledge transfer by provision of support and training such as staff exchange and the organization of interlaboratory tests.

The proposed activities shall be justified by clear reference to the measurement needs within strategic documents published by the relevant stakeholders. Proposers should establish the current state of the coordination in this area, and explain how their proposed project goes beyond this.

The proposed activities should not include those essential for the establishment and operation of the EMN. EMNs will be established and operated by the EURAMET members using their own national resources

regardless of whether specific EMPIR proposals are funded. EMPIR funding is for specific tasks aimed at ensuring a planned EMN will progress quickly towards contributing to the objectives of the programme.

EURAMET expects the average EU Contribution for the selected JNPs in this TP to be 0.4 M€, and has defined an upper limit of 0.5 M€ for this project.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community, describing how the project partners and collaborators will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the sustainability of the organisation. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JNP results are going to:

- Address the SNT objectives and deliver solutions to the documented needs,
- Provide a lasting improvement to coordination in the European metrological community and communication with their stakeholders beyond the lifetime of the project,

You should detail other impacts of your proposed JNP.

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased

Time-scale

The project should be of up to 5 years duration.