EMPIR Call 2016 – Energy, Environment, Normative and Research Potential

Selected Research Topic number: **SRT-r05**
Version: 1.0

Title: Developing research capabilities for traceable intraocular pressure measurements

Abstract

Medical metrology capability has developed unevenly across Europe and differences between western and central / eastern Europe still exist. The introduction of the Medical Devices Directive appeared in the times where the East-European NMIs suffered from the transition period. Hence, they still were not able to catch up the pace. Proposals in response to this SRT should address the development of the metrological research capabilities in the field of the intraocular pressure and other related quantities in ophthalmology (e.g. cornea thickness).

Keywords

Smart specialisation, medical metrology, traceability of medical devices, intraocular pressure, tonometry

Background to the Metrological Challenges

According to the World Health Organization (WHO) visual impairment affects 285 million people worldwide and would be avoidable in 80 % of the cases, with glaucoma the second leading cause of blindness and the main cause of irreversible blindness. Intraocular hypertension (high fluid pressure in the eye) is highly relevant and the only treatable risk factor for glaucoma. Tonometry (the process of determining the intraocular pressure (IOP)) is considered an indispensable measure in glaucoma diagnosis, hence legal requirements and clinical guidelines alike call for regular calibration of the measurement devices.

The introduction of the Medical Devices Directive (MDD) in the mid 1990s led to the deregulation of the European medical devices market. Traceability requirements for medical devices with a measuring function were left to the discretion of national legislators, and this together, with the subsequent accession of many new EU member states primarily from Central and Eastern Europe, resulted in a somewhat inhomogeneous situation across the EU. Until relatively recently, strong legal metrology regulation of the medical measuring instruments markets in eastern Central Europe led to good links between manufacturers and distributors and the NMIs/DIs, however these have largely disappeared due to changes in legislation and the high pace of technological progress resulting in the almost complete replacement of local manufacturers by international vendors.

The most common types of device used for IOP measurements are impression tonometers, applanation tonometers, and (non-contact) air-puff tonometers. OIML Recommendation ‘R 145 Ophthalmic Instruments – Impression and applanation tonometers’ and ISO 8612 ‘Ophthalmic Instruments – Tonometer’ specify safety and performance requirements for these devices, however only the OIML Recommendation, valid for impression and applanation tonometers, specifies the metrological requirements of the test equipment in detail. ISO 8612, which in practice is only valid for air puff tonometers, explains how to perform a clinical trial but has no detailed requirements on how to ensure the traceability of the measurement. Some EU countries, e.g. Austria, Czech Republic, Germany, have regulations for these devices to ensure the performance when in service by periodic metrological checks or (re-)verification. The equipment used to test impression and applanation tonometers following the OIML Recommendation is easily traceable to national standards, thus ensuring the correct performance of these eye tonometers. On the other hand, ISO 8612 does not include detailed requirements for the design of the test equipment for air puff tonometers, and hence different test setups have been developed in the past. Modern air puff tonometers are currently evolving into a new type of multi-purpose device which measure additional parameters of the eye, e.g. the thickness of the cornea, which is known to affect the accuracy of the intraocular pressure measurement but is not verified by the metrological checks at present. These technological advances mean that NMIs/DIs that have historically simply provided

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verifications of devices now face the problem that they need to implement a more extensive metrological framework for the more complex instruments that also measure other parameters.

Research capacity needs to be developed to provide modern metrological capabilities that will address these issues and support the national authorities and offices whose responsibility it is to establish, oversee and enforce the legal regulations associated with eye-related medical devices, healthcare professionals and the medical device industry, which needs a clear regulatory pathway to bring new products on the market. A common factor in Central European countries is that national laws require periodic metrological checks for measuring medical devices, and many of the NMIs/DIs in these countries lack either the resources, or the research know-how, or both to cope with new technical developments in the field of measuring medical devices in general and eye tonometry in particular. This makes this region a good starting point for developing a 'smart specialisation' solution addressing this challenge.

Objectives

Proposers should address the objectives stated below, which are based on the PRT 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 constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on the development of metrological capacity in traceable measurement of intraocular pressure and contribute to the establishment of a joint European metrology infrastructure in this field.

The specific objectives are

1. To develop measurement capabilities for traceable contact measurements of intraocular pressure in the physiological range of 10 mmHg – 80 mmHg in at least one NMI/DI and possibly at other NMIs/DIs seeking to establish research capabilities in this area
2. To develop measurement capabilities for traceable non-contact measurements of intraocular pressure in the physiological range of 10 mmHg – 80 mmHg in at least one NMI/DI and possibly at other NMIs/DIs seeking to establish research capabilities in this area.
3. To develop research capabilities to enable NMIs/DIs to identify other related ophthalmological measurands, both existing and those likely to be developed (e.g. cornea thickness), and to evaluate them with respect to their suitability as targets for metrological checks.
4. To engage with major regional stakeholders, including the responsible ministries and state authorities, calibration services and other governmental or non-governmental offices involved in ensuring that the legal metrology requirements in their countries are met, thus ascertaining that their needs are known and considered, and that they are aware of the project and encouraged to adopt the outcomes.
5. To develop and implement a concept for smart specialisation in the field of traceable intraocular pressure measurements. For each participant, to develop an individual strategy for the long-term operation of the capacity developed, including regulatory support, research collaborations, quality schemes and accreditation. They should also develop a strategy for offering calibration services from the established facilities to their own country and neighbouring countries. The individual strategies should be discussed within the consortium and with other EURAMET NMIs/DIs, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed for Europe as a whole and to develop an approach to extend this concept to other medical devices with a measurement function and beyond the Central European region.

Joint Research Proposals submitted against this SRT should identify

- the particular metrology needs of stakeholders in the region,
- the research capabilities that should be developed (as clear technical objectives),
- the impact this will have on the industrial competiveness and societal needs of the region,
- how the research capability will be sustained and further developed after the project ends.

The development of the research potential should be to a level that would enable participation in other TPs.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET has defined an upper limit of 500 k€ for the EU Contribution to any project in this TP, and a minimum of 100 k€.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 10 % of the total EU Contribution to the project.

Potential Impact

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

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Provide a lasting improvement in the European metrological capability and infrastructure beyond the lifetime of the project,
- Facilitate improved industrial capability or improved quality of life for European citizens in terms of personal health or protection of the environment,
- Transfer knowledge to the medical devices manufacturers, the healthcare sector, regulators and state authorities and the metrology community.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”

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
- organisations other than NMIs and DIs to be involved in the work

Time-scale

The project should be of up to 3 years duration.