



Publishable Summary for 20SCP02 CEFTON

Development of eye-tonometry in CEFTA countries

Overview

The Central Europe Free Trade Agreement (CEFTA) National Metrology Institutes (NMIs: IMBiH, INM, ME-BoM) need to be able to correctly implement intraocular-pressure (IOP) metrology regulations in line with a new harmonised approach (e.g. as specified in the Medical Device Regulation (MDR 2017/745)). However, these emerging NMIs have been unable to fulfil the needs of their national stakeholders in the field of eye-tonometry due a lack of relevant resources and experience. They required an experienced NMI partner to provide them with the necessary knowledge transfer. A Competence Centre for Intraocular pressure (IOP) metrology at CMI was used to provide the metrological know-how for this purpose and a smart specialisation concept, which had been previously designed for IOP metrology in the Central Europe region, was modified to meet the specific needs of the CEFTA countries (Bosnia and Herzegovina, Moldova and North Macedonia). Overall, the project was successful in the transfer of all the relevant knowledge and skills to the partners and in the establishment of cooperation within the extended smart specialisation concept. The partner NMIs are now ready to introduce IOP metrology in their region and to actively support the prospective legislative changes.

Need

Glaucoma is the world's second leading cause of blindness and it is the leading cause of irreversible blindness. Intraocular hypertension is the most relevant, and the only treatable, risk factor for this disease. Non-invasive IOP measurements, carried out using eye tonometers, are used to screen for intraocular hypertension. The correct measurement of the IOP is essential for the prevention of, and the fight against, glaucoma.

IOP metrology is unevenly developed across the EU. This developmental disparity has been even more marked when the CEFTA states were included and this caused a gap in the knowledge base of the European NMIs. The CEFTA NMIs needed to be able to correctly implement IOP metrology regulations in line with a new harmonised approach (Objectives 1 and 3). These emerging NMIs have not been able to fulfil the needs of their national stakeholders in the field of eye-tonometry due to the lack of relevant resources and experience. None of these emerging NMIs, nor any pertinent cooperation group of CEFTA NMIs, was able to quickly solve this problem to help the end users. An experienced NMI partner was needed to provide the know-how. A Competence Centre for IOP metrology at CMI can provide the metrological knowledge for this purpose (Objective 2) and the smart specialisation concept, which had been designed for IOP metrology in the Central European region, could be modified and extended to meet the specific needs of the CEFTA countries (Objective 3).

Objectives

The overall objective of this project was to develop a smart specialisation concept in traceable IOP metrology in CEFTA countries.

The specific objectives of the project were:

1. To closely engage with all (minimum 15) major regional legal IOP metrology stakeholders (including responsible state authorities, calibration service providers and other governmental or non-governmental offices), which ensure that legal IOP metrology requirements are met, thus ascertaining the existing and planned IOP metrology calibration services provided in the CEFTA countries as well as their requirements for new IOP metrology calibration services.
2. To provide advanced level metrological training courses at CMI, on IOP measurement, to the staff of IMBiH, INM and ME-BoM (minimum 4 trainees). In addition, to check and adapt the relevant IOP metrology guidelines for use in CEFTA countries.

3. To develop a smart specialisation concept in traceable IOP metrology in CEFTA countries based on an analysis of the legislation and of the possibilities for mutual cooperation amongst the CEFTA countries.

Results

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The project was originally focused on the CEFTA countries. However, it can be concluded now that the most active stakeholders and collaborators of the project were from the CEFTA countries plus Ukraine and Georgia. These countries are all now either Candidates negotiating, Candidates or Applicants for EU membership. In total, the consortium established contacts with 18 relevant IOP metrology stakeholders in the CEFTA countries (plus 3 from other Candidates/Applicants and 17 from the rest of Europe). Thus, an inventory of existing and planned metrology services in the field of IOP, as well as of needed and missing services, was collected and analysed. The stakeholders' need for support in achieving the correct metrological traceability for all types of eye-tonometers was obvious. Their feedback was used to steer the course of the project. Also, the "Working group eye tonometry" (which was founded for the EU region before the start of this project) was broadened significantly.

This objective was fully achieved by establishing a stimulating dialogue with a wide range of stakeholders and mapping their situation and needs.

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During this project, the CEFTA NMIs (IMBiH, INM, ME-BoM) obtained advanced theoretical and practical training on the metrology of impression (or indentation or Schiøtz), applanation (or Goldmann), contour, re-bound and non-contact (or air-puff) tonometers in January and in June 2022. All of the training utilised the training centre for IOP metrology in the premises of CMI in the city of Most. They were based on the "Good practice guidelines for traceable IOP metrology," which in turn reflect the relevant international standards, as well as the relevant German and Czech regulations. In total eight participants (originally anticipated 4-6) passed the training successfully and gained the necessary expertise. They are now prepared to be able to introduce such services in the CEFTA region. As far as the consortium knows, this training is unique in Europe. The partners also successfully finished their communication with the supervising bodies in the CEFTA countries. They also analysed the "Good practice guidelines for traceable IOP metrology" and compared it with relevant national legislation. The findings were presented at the stakeholder workshop in Prague in October 2022, and more information was sought during this workshop. Based on the feedback from the project stakeholders, we found neither legislative nor regulatory obstacle for the utilisation of the existing "guidelines" in the CEFTA countries. Now, there is a capacity ready to take part in the prospective legislation changes, especially in the context of the process of accession to the EU.

This objective was fully met, even a little surpassed, by providing the staff of the partner NMIs with advanced IOP metrology know-how, training and guidelines.

To develop a smart specialisation concept in traceable IOP metrology in CEFTA countries based on an analysis of the legislation and of the possibilities for mutual cooperation amongst the CEFTA countries.

The partners reached agreement from their supervising bodies concerning their proposed positions in the Smart Specialisation Concept in IOP metrology for the CEFTA NMIs. All the findings, the feedback of the stakeholders and an outline of the Concept were presented at the stakeholder workshop in Prague in October 2022. The partners evaluated the feedback from the workshop discussions for improving the proposal and for creating a mid- to long-term strategic plan for the CEFTA NMIs. Then, the Smart Specialisation Concept was finalised for the provision of calibration services for the basic types of eye-tonometers in the CEFTA region, reflecting the needs of the regional stakeholders. Now, the partner NMIs have the capacity to introduce and to establish the verification process for eye-tonometers in the CEFTA region. The services, the training and the expertise of the competence centre for IOP metrology at CMI and the networking support from all the partners

remain available to all the NMIs who are interested in using it to support their cohesion. The partners will continue their collaborations within the network both via “Working-group eye-tonometry” and bilaterally.

The eye-tonometer calibration service providers and test houses in CEFTA now have the NMI partners to turn to for metrological advice, but also as an entry point to feed back their valuable practical experiences with a Medical Device with a Measuring Function (MDMF) in the field. The legislators and regulatory authorities, e.g., Ministries of Trade and Industry, Ministries of Health and their subordinate supervision agencies, practitioners and professional organisations have the NMI partners to discuss the potential impact of new, extended or otherwise altered regulations. Finally, all CEFTA NMIs, which lack the resources, plans or capacity to build and maintain their own full traceability chains for eye-tonometry have a competent and reliable NMI partner, allowing them to provide some aspects of traceability in their country, e.g. verification of physical sensors, while more complex tasks can be relayed to the partners. Regional authorities, whose responsibility it is to meet existing and future regulatory requirements in their countries, will benefit from the new rigorous traceability chains, higher levels of regional cooperation and wider information exchange. Moreover, the manufacturers and distributors/service providers of eye-tonometers will deal with a more evenly developed market. Hence, the results and the smart specialisation cooperation network that were created, serve to support the enlargement of the EU with the CEFTA and other Candidate countries.

This objective was fully accomplished by extending the Smart Specialisation Concept in IOP metrology to the CEFTA NMIs. This concept was widely promoted and remains open to all European NMIs.

Impact

Early impact on user communities

In the context of the deregulation efforts in EU and CEFTA countries, a large number of private tonometer test and calibration offices were founded, providing a service which was formerly only supplied by governmental offices. However, these private companies rely on the official metrological system for the traceable recalibration of their equipment. The smart specialisation concept enables these small enterprises to have a reliable NMI partner to turn to. This will encourage a more secure and robust industry and it will help to make business more predictable for the serious test offices.

A major additional impact of the project has been the development of an effective communication and cooperation network between the participating NMIs which allows the metrological partners to stay in close contact with both their customers, public or private test and calibration offices, and legislators and regulatory authorities. This allows the metrologists to stay up-to-date with the latest developments.

Longer-term economic, social and environmental impacts

This project established the Smart Specialisation Concept for IOP metrology in CEFTA countries thus providing a natural starting point and a model strategy for thematically and geographically much wider follow-up projects. The participating NMIs will be able to further develop their expertise and strategies for establishing a sound metrological infrastructure for their MDMFs based on their specific needs. In the longer term, they will be able to transfer this newly acquired knowledge to their regional metrology partners, their stakeholders and into the specific metrology and quality infrastructure framework within their country. Understanding and sharing information on the needs of national stakeholders, such as industrial, healthcare, legislation and regulatory sectors, will create impact and it will be a great platform for future collaboration in the field of the IOP metrology.

More reliable, traceable and accurate calibration methods for eye-tonometers and tonometer test equipment will exist in CEFTA countries. This will improve the acceptance of metrological checks for eye-tonometers and this will provide CEFTA citizens with better, more reliable and less uncertain IOP measurements. As a result, screening for ocular hypertension will become more effective and the results will be more conclusive, thus reducing the misdiagnosis and non-diagnosis rate caused by erroneous eye-tonometry measurements. Hence, fewer healthy individuals will be subjected to unnecessary and potentially harmful treatment and fewer correctly diagnosed individuals will be denied the treatment they require. Thus, medical professionals will be able to treat one of the most important risk factors for glaucoma more effectively. This will improve the quality of life of CEFTA citizens and reduce the burden on their respective healthcare systems.

Project start date and duration:	01 September 2021, 18 months	
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