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## 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 are currently unable to fulfil the needs of their national stakeholders in the field of eye-tonometry due a lack of relevant resources and experience. They require an experienced NMI partner to provide them with the necessary knowledge transfer. A Competence Centre for Intraocular pressure (IOP) metrology at CMI will be used to provide the metrological know-how for this purpose and a smart specialisation concept, which was previously designed for IOP metrology in the Central Europe region, will be modified to meet the specific needs of the CEFTA countries (Bosnia and Herzegovina, Moldova and North Macedonia).

### 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 is even more marked when the CEFTA states are included and this causes a gap in the knowledge base of the European NMIs. The CEFTA NMIs need to be able to correctly implement IOP metrology regulations in line with a new harmonised approach (Objectives 1 and 3). At present, these emerging NMIs are not 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, are able to quickly solve this problem to help the end users. An experienced NMI partner is needed to provide the know-how. A Competence Centre for IOP metrology at CMI will provide the metrological knowledge for this purpose (Objective 2) and the smart specialisation concept, which was designed for IOP metrology in the Central European region, will be modified and extended to meet the specific needs of the CEFTA countries (Objective 3).

### Objectives

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

The specific objectives of the project are:

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

*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.*

The consortium will establish contacts with the relevant IOP metrology stakeholders in the CEFTA countries. Thus, an inventory of existing and planned metrology services in the field of IOP, as well as of needed and missing services, will be collected and analysed and used to steer the course of the project.

*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.*

During this project, the CEFTA NMIs (IMBiH, INM, ME-BoM) will obtain advanced training on the metrology of impression, applanation, contour and non-contact tonometers. This know-how, together with the respective testing procedures, will be adapted to the CEFTA NMIs local needs and legislature where necessary.

*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.*

Finally, a smart specialisation concept will be developed for the provision of calibration services for the basic types of eye-tonometers in the CEFTA region (it is expected that, at least in the short- to mid-term (3-5 years), CMI will provide advanced services for the CEFTA NMIs (e.g. traceability of uncommon eye tonometers and standards, verification, calibrations)), thus reflecting the needs of the stakeholders in the CEFTA countries. The eye-tonometer calibration service providers and test houses in Bosnia and Herzegovina, Moldova and North Macedonia will have an NMI partner 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 will have an NMI partner 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 will 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.

## 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 will create impact by enabling 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 will be the development of an effective communication and cooperation network between the participating NMIs which will allow 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 will allow the metrologists to stay up-to-date with the latest developments.

### *Longer-term economic, social and environmental impacts*

This project will establish a 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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2. IMBiH, Bosnia and Herzegovina		
3. INM, Moldova, Republic of		
4. ME-BoM, North Macedonia		