# Second Stakeholder Workshop of EMP Project 22HLT05 MAIBAI *"Developing a metrological framework for assessment of image-based Artificial Intelligence systems for disease detection"*

## 14:30 – 14:45: Brief introduction to the workshop - Assessment of AI systems in the medical domain and real-world data gathering

**Alessandra Manzin (Istituto Nazionale di Ricerca Metrologica - INRiM, Italy)**

The exponential increase in healthcare data, as well as the fast-paced technology developments, have resulted in promising novel AI systems for disease detection and risk prediction. However, the adoption of AI in clinical settings remains limited, mostly due to the limited data quality and interoperability across heterogeneous clinical centres and electronic health records, the absence of robust validation procedures, and the distrust of predictions and decisions generated by AI systems.

Starting from the experience of the *European Metrology Partnership Project 22HLT05 MAIBAI*, this workshop aims at discussing the main strategies that can be adopted to face the above issues, with the design of a standardised and impartial framework for performance, generalisability and suitability assessment of AI systems in the clinical domain. Special attention will also be devoted to the development of large-scale and high-quality medical databases, the investigation of real-world data and the key standards relevant to AI-enabled medical devices.

## 14:45– 15:15: Independent assessment and real-world testing of radiology AI algorithms

**Nadia Smith, Rebecca Nutbrown and Elliot Ball (TÜV SÜD)**

The talk introduces TÜV SÜD and Royal Surrey's *"AI in Radiology – Independent Algorithm Assessment & Dataset Testing"* service*, designed to provide objective, third-party evaluation of radiology AI algorithms. It covers the clinical and regulatory motivations behind independent assessment, the technical framework for testing performance, bias, and generalisability, and how the service operates within AI development and procurement workflows. The approach supports benchmarking, transparency, and compliance with regulations, offering a scalable model for medical AI validation.

*https://www.tuvsud.com/en-gb/services/technical-advisory/medical-physics-data-science/radiology-ai-algorithm-auditing-and-dataset-testing

## 15:15 – 15:45: Robustness evaluation of deep learning models in biomedical imaging

**Evaristo Cisbani (Istituto Superiore di Sanità – ISS, Italy)**

Model observers based on Convolutional Neural Network have been developed to provide automated task-driven CT image quality assessment. Their robustness has been quantitatively investigated by Universal Adversarial Perturbations. Once the reliability has been consolidated, the model observer can be exploited for the optimal balance between diagnostic effectiveness and patient ionizing radiation exposure in CT protocols. Approach and preliminary results focused on robustness evaluation will be presented.

## 15:45 – 16:15: Understanding MDSW and AI in medical devices: MDR compliance and essential standards

**Martin Koval (Czech Metrology Institute – CMI, Czech Republic)**

The presentation will focus on how to understand Medical Device Software (MDSW) from the perspective of the Medical Device Regulation (MDR) and highlight the critical requirements. It will demonstrate how these requirements can be fulfilled using standards such as EN IEC 62304, including an overview of the structure of the standard, its links to related standards, and how they collectively support MDR compliance. The second part will focus on AI in medical devices, clarify the relationship between the AI Act and the MDR, and emphasize the key standards relevant to AI-enabled medical devices.

## 16:15 – 16:45: Breast Cancer Control: The Role of Screening

**Tanja Cufer (Medical Faculty, University of Ljubljana, Slovenia)**

Breast cancer is the most common cancer and the leading cause of death due to cancer among women worldwide. Although the incidence of breast cancer is increasing, there is good news that mortality has been decreasing in the developed world since the early 1990s. The decline in mortality is partly due to early diagnosis and screening and partly to advances in neo-/adjuvant therapies. This presentation will examine the benefits and potential harms of current breast cancer screening programmes, also considering the information provided by real-world data. Additionally, it will present new risk-stratified prevention initiatives that include both primary prevention and screening, and the importance.

## 16:45 – 17:15: The Slovenian translational platform GlioBank for brain tumor research: Identification of molecular signatures of glioblastoma progression

**Barbara Breznik (National Institute of Biology, Slovenia)**

Glioblastoma (GB) is considered incurable, and progress in identifying clinically relevant biomarkers and effective therapeutic options remains limited. However, with the rise and availability of omics and spatial biology technologies, new findings regarding the pathobiology and progression of GB are constantly emerging. Such studies require a large number of biological samples with associated clinical and molecular data. Data generated by large omics projects and smaller research groups should be stored in public repositories for future use. Biobanks with high-quality and well-annotated clinical samples are crucial for neuro-oncological research in the era of "precision" medicine. Biobanks of patient-derived tumour biopsies and cellular models, together with corresponding histopathological, molecular, and clinical data, have become an indispensable tool in translational cancer research.

We have established an academic disease-specific repository, named GlioBank, that will help accelerate the field of glioma research with an emphasis on GB and the subsequent translation into clinical practice. GlioBank is a database of different clinical and molecular tumour characteristics, together with corresponding tumour tissue samples and cellular models from glioma patients. GlioBank thus provides a disease-oriented biobank in Slovenia that can facilitate the development of new treatment approaches and the search for new biomarkers also thanks to the use of AI models, with the goal of improving outcomes for GB patients.

## 17:15 – 17:45: AI for cancer detection in mammography

**Sarah Verboom (Department of Radiology and Nuclear Medicine - Radboud University Medical Center & LRCB - Dutch Expert Centre for Screening, Netherlands)**

State-of-the-art AI models that can detect cancer in a mammogram currently have a performance equal to that of an average radiologist. The first prospective studies have shown their added benefit in breast cancer screening and in clinical practice. In this presentation, we will review the current status of the field and discuss the developments we can expect in the near future.