

BBMRI.at contribution

"Digital pathology & AI" and "standardisation of molecular pathology analyses in Europe" - Two topics at the annual congress of the European Society of Pathology (ESP)

Sep 2022

Over 4,000 participants with background or interest in pathology attended the 34th European Congress of Pathology (ECP) in Basel, CH, 3-7 September 2022.

In the context of the ECP, two topics were on the agenda on which BBMRI.at is working and which are highly relevant for modern pathology diagnostics and also for biobanking: "Digital Pathology & AI" and "Standardisation of molecular pathology analyses".

Digital Pathology and Artificial Intelligence (AI) Interaction Platform

The EU project BIGPICTURE invited to the launch event of their Digital Pathology and AI Interaction Platform. Aim of the project is to create a repository of digital copies of around 3 million slides. The interaction platform is intended to enable a dialogue between manufacturers, users and regulators in this rapidly evolving field of AI-based image analysis of clinical digital slides.

Participants from all over Europe from industry, universities, hospitals, regulatory and notified bodies, and from the professional society ESP attended this event.

The speakers reported about opportunities and challenges of digital pathology, requirements for clinical and non-clinical slides, and highlighted the need for quality control for whole slide imaging (WSI) and digital / computation pathology.

The presentation given by Prof Kurt Zatloukal (Med Uni Graz, BBMRI.at director and leader of BIGPICTURE WP5) is available for download: [Challenges and requirements for clinical slides \(by Kurt Zatloukal\)>](#)

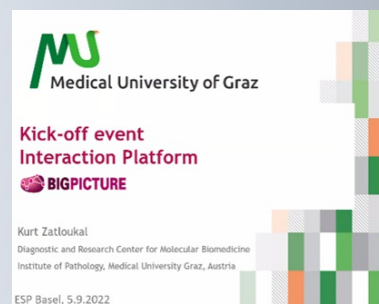
[More about the Innovative Medicine Initiative \(IMI\) EU project BIGPICTURE>](#)

Standardisation of molecular pathology analyses

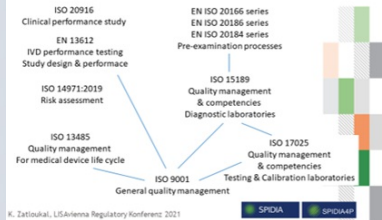
Recently a series of international ISO and European CEN standards relevant for molecular pathology was developed under the title "**Molecular in vitro diagnostics – specifications for pre-examination processes**". These standards were generated in the context of the EU project SPIDIA4P together with the standardization organizations ISO and CEN. BBMRI.at team members contributed to their development and led the development of standards for microbiome samples (CEN/TS 17626), FFPE tissue for in situ detection (ISO 20166-4) and for DNA analysis (ISO 20166-3), respectively.

In a session on "pre-analytics" Kurt Zatloukal explained the relevance of standardization and pre-analytics for obtaining reliable diagnostic and research test results and for meeting the demands of the In Vitro Diagnostic Regulation (IVDR). The IVDR is also relevant for Pathology Institutes offering diagnostic services using in house tests, so-called laboratory-developed tests (LDTs).

For download: The presentation given by Prof Kurt Zatloukal (Med Uni Graz, BBMRI.at director) [Challenges and requirements for clinical slides \(by Kurt Zatloukal\)>](#)



In vitro Diagnostics Standard Landscape



IVDs Manufactured by Industry and within Health Institutions



Implications of manufacture and use of devices within the same health institution ("in-house devices") "lab developed tests"

4. Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, shall be considered as having been put into service.

Final responsibility for IVDR compliance of the whole diagnostic workflow is with the user that makes the diagnosis