

Publication by BBMRI.at partner Med Uni Graz

AI-Supported Medical Image Analysis & IVDR

– how to demonstrate scientific validity as well as analytical and clinical performance for future AI-based IVDs

Authors from BBMRI.at partner Med Uni Graz published a paper on artificial (AI)-based analysis of whole slide images from digitized tissue slides in the context of the European In Vitro Diagnostic Regulation (IVDR).

AI-supported analysis is gaining interest for in vitro diagnostics and research purposes. This accounts also for the analysis of whole slide images digitized from tissue sections.

The IVDR poses major challenges for IVDs that involve Machine Learning algorithms for data analysis and decision support.

Trustworthy AI has to empower biomedical professionals to take responsibility for their decision-making, which clearly raises the need for explainable AI methods.

In this paper, the authors from BBMRI.at describe concepts and give examples of how explainability and causability are essential in order to demonstrate scientific validity as well as analytical and clinical performance for future AI-based IVDs

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[Müller H, Holzinger A, Plass M, Brcic L, Stumpfner C, Zatloukal K.](#)

Explainability and Causability for Artificial Intelligence-Supported Medical Image Analysis in the Context of the European In Vitro Diagnostic Regulation.

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