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The role of explainable AI in regulatory practices

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Introduction: In the context of digital pathology and in-vitro diagnostics, Artificial Intelligence (AI) must empower (bio)medical professionals to take responsibility for their decision-making, raising the demand for explainable AI. The US Food and Drug Administration (FDA) and the European In-Vitro Diagnostics Regulation (IVDR) address explainability in their recommendations and documents. However, to achieve efficient and effective explanations in AI systems, it is essential to know who uses which type of AI-solution for what purpose and how the human-AI interface is designed.

Material and methods: We propose definitions for AI solutions in the field of digital pathology, including the classes of algorithms involved and how these may be applied. We identify the stakeholders using such applications,their aims and potential requirements. We define a taxonomy describing the interface between the AI solutions and their stakeholders, as well as varieties of explanations and metrics for their quality.

Results: Usability encompasses measurements for the quality of use, and causability encompasses measurements for the quality of explanations produced by explainable AI methods. We describe both concepts and give examples of how both are essential for demonstrating scientific validity, as well as analytical and clinical performance in digital pathology.

Conclusion: Explainable AI methods provide answers to important questions in scientific validation and the evaluation of analytical and clinical performance of AI solutions in digital pathology: “Why does an AI solution generate reliable results for an intended purpose?”, “Why did it produce a specific result?”, “Was the explanation satisfactory for the user?”.