Regulatory issues for AI and digital pathology

IVDR: a complex issue and a 'missed opportunity'

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In his lecture at the 8th Digital Pathology & AI Congress in London, BBMRI.at Director Professor Kurt Zatloukal (Med Uni Graz) raised concerns that many organizations in the field of digital pathology and AI might not yet be prepared for the European In-vitro Diagnostic Medical Device Regulation (IVDR).

The IVDR is in place since 2017 with a transition phase until May 2022 and requires new and about 80% of all diagnostics that are already on the market in Europe to provide additional data in order to comply with this new law. Also software – including AI-based analysis technology – is in its scope. The IVDR demands increased documentation on scientific evidence, analytical and clinical performance, including pre-analytical information about biological specimens (to be) used/analysed with the IVDs (e.g. software). Standards such as the ISO 20166-4 on pre-analytical requirements for tissue, which is typically used for digital pathology and computer-based analysis of tissue slides, are relevant and helpful in this context.

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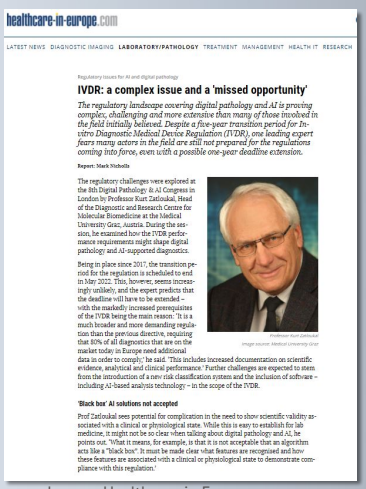
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Regulatory issues for AI and digital pathology

IVDR: a complex issue and a 'missed opportunity'

The regulatory landscape covering digital pathology and AI is growing complex, challenging and more extensive than many of those involved in the field initially believed. Despite a five-year transition period for In-vitro Diagnostic Medical Device Regulation (IVDR), one leading expert fears many actors in the field are still not prepared for the regulations coming into force, even with a possible one-year deadline extension.

Report: Mark Nicholls

The regulatory challenges were explored at the 8th Digital Pathology & AI Congress in London by Professor Kurt Zatloukal, Head of the Diagnostic and Research Centre for Molecular Biomedicine at the Medical University Graz, Austria. During the session, he examined how the IVDR performance requirements might shape digital pathology and AI-supported diagnostics.

Being in place since 2017, the transition period for the regulation is scheduled to end in May 2022. This, however, seems increasingly unlikely, and the expert predicts that the deadline will have to be extended – with the markedly increased prerequisites of the IVDR being the main reason: 'It is a much broader and more demanding regulation than the previous directive, requiring that 80% of all diagnostics that are on the market today in Europe need additional data in order to comply,' he said. 'This includes increased documentation on scientific evidence, analytical and clinical performance.' Further challenges are expected to stem from the introduction of a new risk classification system and the inclusion of software – including AI-based analysis technology – in the scope of the IVDR.

'Black box' AI solutions not accepted

Prof Zatloukal sees potential for complication in the need to show scientific validity associated with a clinical or physiological state. While this is easy to establish for lab medicine, it might not be so clear when talking about digital pathology and AI, he points out. 'What it means, for example, is that it is not acceptable that an algorithm acts like a "black box". It must be made clear what features are recognised and how these features are associated with a clinical or physiological state to demonstrate compliance with this regulation.'

Image: Healthcare in Europe

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