

# SS4-1 Navigating through the global regulatory AI jungle - A regulatory companion for clinicians, researchers, and developers.

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The rapid integration of artificial intelligence (AI) algorithms into the field of pathology has ignited a global conversation surrounding their regulatory oversight. Pathology, a crucial discipline in diagnosing diseases through tissue and cellular analysis, is being revolutionized by AI's potential to enhance accuracy and efficiency. However, this transformative power has prompted concerns about patient safety, data privacy, and the need for standardized regulations.

The regulatory landscape for AI algorithms in pathology varies significantly worldwide. Some regions have taken proactive steps to establish frameworks. The United States, for instance, relies on the Food and Drug Administration (FDA) to evaluate AI-based medical devices, including those used in pathology. In contrast, the European Union introduced the In Vitro Diagnostic Regulation (IVDR) to ensure the safety and efficacy of AI algorithms in medical diagnostics. Moreover, other countries also have their authorities to regulate the development and application of AI based algorithms in health, e.g. ANVISA (Brasil), CDSCO (India), MFDS & KMDICA (Korea), UKCA(United Kingdom), TGA (Australia), NMPA (China), PMDA (Japan), TFDA (Taiwan).

Despite these efforts, challenges persist. Striking a balance between fostering innovation and safeguarding patient welfare remains a complex task. Concerns include the transparency of algorithms, potential biases, and the need for robust clinical validation. Additionally, the pace of technological advancement often outstrips regulatory development.

We introduce a regulatory companion that consists of two arms – a) a query interface to commercially available AI algorithms in Pathology with information on their clearance for different markets and links to additional resources updated by vendors and b) a crawler to the 10 most relevant regulatory sites to learn about the situation in the different markets and stay up to date with any changes. These two resources are starting points for all health care professionals in pathology ranging from researchers to clinicians but also for algorithm developers.