Opportunities for global convergence and prioritization of AI

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Disclaimer

These are my personal views and opinions. They do not necessarily represent the opinions of Hologic, Inc.

Setting the stage

Artificial Intelligence (AI) is a broad, umbrella term combining software and hardware in systems that are meant to approximate human reasoning.

AI exists along a continuum of dependency on human intervention from significant reliance on training and human-controlled updates to “self” learning and updating systems.

AI in healthcare, specifically medical devices (including IVDs), currently available for clinical use tends to rely on human intervention for updates and training.

AI as a priority

At present, only a few countries have issued regulatory guidance/statements on how they intend to regulate AI in medical devices. These guidance documents vary in the level of detail provided.

AI as a part of medical devices is not the only application though. Use to aid with clinical trials, submission reviews, manufacturing and post-market assessments are also areas where AI can be used.

AI as a priority for regulators is already or likely will become a priority topic. An example of this is the 2022 "*Advancing Regulatory Science at FDA: FOCUS AREAS OF REGULATORY SCIENCE (FARS)*" that highlights AI as a priority.

Global Convergence on regulating AI

While AI already seems to be a priority amongst several large markets, the detail of how AI will be regulated may not be consistent (or at least unclear of consistency).

Available guidance does not address all uses of AI in a regulated environment or in regulated devices (e.g., self-modifying AI). There does appear to be some convergence around ethical principles such as accountability, fairness and privacy.

Convergence on regulatory approaches to use of AI in regulated environments and products is crucial to streamline introduction of these technologies into healthcare systems. International standards are under development which could support this.