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1

Introduction

Koen Cobbaert, MSc, and Gert Bos, PhD, MSc, FRAPS

The current world, where almost all medical devices and in vitro diagnostic (IVD) devices are connected, is changing more rapidly than ever before, with the rapid onset of artificial intelligence (AI) in virtually all aspects of our modern-day society. The new horizon features AI-enhanced products, AI-supported assessment and decision tools, and various AI products that, in one way or another, support the healthcare system and providers, allowing, for example, longer periods of independent and assisted living. Soon after its global public launch, the fast-developing technology cannot be disconnected from our healthcare world as we enter the second quarter of the 21st century.

Today's connectivity of medical devices enables manufacturers to migrate essential and supporting functionality from the device's computing resources to personal computers, handheld devices, cloud servers, wearables, and other products in the Internet of Things. Those external computing platforms often offer more powerful capabilities and are easier to use, maintain, scale, and upgrade. Such medical device software enhances the original medical device's capabilities and performance. The onset of AI in computing and data analysis brings opportunities but also initially poses significant regulatory challenges, which the regulatory world is working hard to overcome.

As manufacturers have centralized almost everything that can be centralized, we are starting to see the opposite trend. As software gets more powerful and data-hungry, it clogs the data pipelines. At the same time, its connectivity may pose privacy, general, and cybersecurity challenges. Software manufacturers are now increasingly offloading functionality, computation, and data storage onto the spare computing resources of medical devices and wearables, close to where the raw data is generated. Such distributed computing is known as edge computing. Decentralized machine learning will further amplify this trend. The wider use of AI, beyond its subset of machine learning, is further accelerating the speed of change and innovation.

Manufacturers' flexibility in choosing where computing occurs and in how they bundle and sell software functionality or assign medical claims creates a certain degree of device fluidity. This trend will further intensify as continuous machine learning and broader AI support enhance the capabilities of medical devices. Alignment and further interpretative guidance are needed to help us all continue on our way to ensure such devices are safe and perform as intended. As data is getting central in the regulatory debate, AI-enabled devices ride on the crest of the wave of finding real world evidence, typically more pronounced after market launch. Postmarket is the new truth serum – where lifecycle management turns real-world data into a continuous evidence engine.

Postmarket is the new truth serum – where lifecycle management turns real-world data into a continuous evidence engine.

The International Medical Device Regulators Forum[1] created the term Software as a Medical Device (SaMD) for regulatory purposes. The IMDRF work intended to enable a uniform language, common definitions, and regulatory concepts. It has partially achieved those goals, prompting jurisdictions to adjust general concepts to SaMD's specific needs. Nevertheless, definitions vary somewhat, and some jurisdictions have added specific terminology. Also, of course, nowadays wearables take flight. In **Chapter 2**, Pat Baird, Koen Cobbaert, and Zhuo Li explain the foundations of SaMD, share their views on the modularization of medical device functionality, and discuss the regulatory status of wearables.

As software and, in particular, AI is eating the medical device world, the in-vitro diagnostics (IVD) arena follows

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