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CLIFFORD'S NOTES

SMART DEVELOPMENT

AI is showing promise in creating medical device equipment

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Artificial intelligence is revolutionizing medical device development. It is providing innovative solutions to complex challenges on a global scale. With its ability to process incredible amounts of data and perform complex analysis, AI is transforming the way medical devices are designed, tested and optimized – but not without regulatory and ethical challenges that may impact medical malpractice lawsuits.

This globalization of medical knowledge and common goals shows promise of advancement in areas such as imaging that can help detect diseases and confirm accurate diagnoses earlier. For example, in breast cancer care, using AI reportedly is enabling the review of mammograms to be 30 times faster with 99% accuracy, reducing the need for unnecessary biopsies. AI also is being applied to oversee early-stage heart disease, allowing healthcare providers to discover potentially life-threatening problems at earlier and more treatable stages.

The Food and Drug Administration, charged with approving new medical devices, recently granted market clearance for U.K.-based AI company, Brainomix, for its 360 e-Lung system designed to detect a broad spectrum of more than 200 diseases including idiopathic pulmonary fibrosis (IPF). A rare chronic lung disease that causes lung tissue to thicken and stiffen, IPF leads to permanent lung tissue scarring and causes breathing problems. Brainomix teamed up with Nanoflex Robotics, a Swiss-based remote robotic surgical company, to deliver AI-assisted magnetic navigation systems for robotic surgical tools.

Ireland-based Trinity Biotech, a diagnostics and diabetes management company, has partnered with a Northern Ireland-based medical AI company, PulseAI, to enhance its continuous glucose monitor biosensor technology, using a platform that has needle-free insertion. The uses for AI seem to be endless.

One key area where AI is making a significant impact is in the design of medical devices. Traditionally, designing medical devices involves a lengthy and iterative process of trial and error. However, AI algorithms can generate and evaluate thousands of design options in a fraction of the time it would take a human designer. By using machine learning algorithms, AI can learn from existing designs, identify patterns and generate new concepts that meet specific requirements and constraints. AI can analyze vast amounts of patient data, including electronic health records, medical imaging and genomic data to simulate patient responses and identify potential issues. By leveraging AI, manufacturers can develop more robust testing protocols and ensure the safety and efficacy of their devices, but the data input must be accurate and unbiased.

The real question is: Can the FDA stay ahead of all of these new developments? In a March 2024 white paper, the federal agency stated it is collaborating with the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health and Office of Combination Products "to safeguard public health while fostering responsible and ethical innovation."

The agency also stated: "The FDA reviews medical devices through an appropriate premarket pathway, such as premarket clearance (510(k)), De Novo classification, or premarket approval. The FDA may also review and clear modifications to medical devices, including software as a medical device, depending on the significance or risk posed to patients of that modification." The 510(k) clearance process involves a comprehensive review of safety and performance data for the device, which may include scientific, non-clinical and clinical data to determine if a new device is substantially equivalent to a device that is already on the market.

The AI white paper also notes that FDA medical product centers intend to develop policies that will increase regulatory predictability and clarity as well as monitor trends in AI development. Additionally, the federal agency plans to support efforts to develop new methodologies for evaluating AI algorithms, including identification of bias in algorithm development and training.

On May 13, the FDA added 191 AI/ML (machine learning)-enabled devices to the list, bringing the total to 882. In line with prior trends, radiology once again accounted for the largest number of approvals (128 are radiology-focused).

Despite the benefits of AI in medical device development, numerous challenges need to be addressed. Ethical considerations, such as patient privacy and data security, must be carefully addressed to ensure the responsible use of AI in healthcare. There is also the issue of lawyers being technologically savvy enough to decipher when negligence has occurred and know how to utilize experts to figure out when something goes wrong.

AI is revolutionizing every aspect of healthcare and medical device development is no exception. By enabling faster design iterations, optimizing device performance and improving testing protocols, AI might lower healthcare costs. The integration of AI with medical device development also has the potential to significantly improve patient outcomes and advance the field of healthcare. Still, it is important to address regulatory and ethical challenges to ensure the responsible and effective use of AI in healthcare.

That simply may not yet be possible without human intervention. CL

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