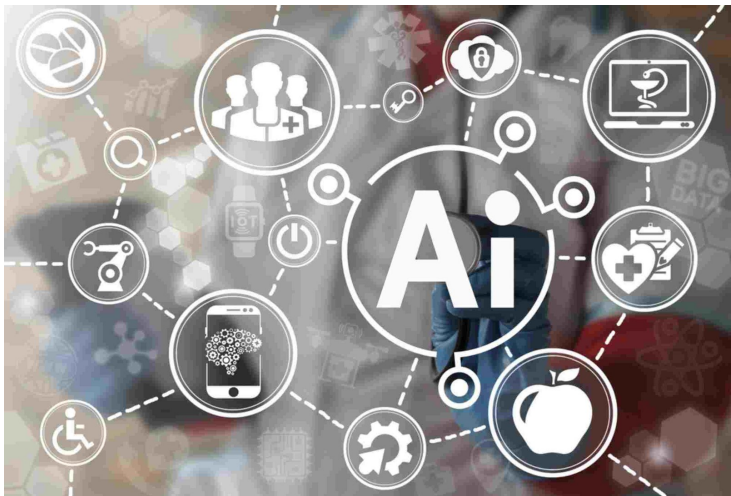


Bayer, Merck gets FDA breakthrough designation for CTEPH detection software

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This software analyzes image findings from cardiac, lung perfusion and pulmonary vessels in combination with the patient's clinical history



Bayer announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation to the Chronic Thromboembolic Pulmonary Hypertension (CTEPH) Artificial Intelligence (AI) Pattern Recognition Software, which Bayer is currently developing jointly with Merck, known as MSD outside the U.S. and Canada.

Being a rare disease, physicians may not always recognize CTEPH. Computed Tomography Pulmonary Angiography (CTPA), as well as a ventilation/perfusion scan (V/Q scan), is used to determine if the thromboembolic occlusion is causing pulmonary hypertension. Radiologists may have the first opportunity to identify CTEPH in a patient; therefore it's important they accurately detect CTEPH indicators on CTPA scans and images.

Development of the CTEPH Pattern Recognition AI Software will use deep learning methodology to support radiologists by identifying signs of CTEPH in CTPA scans. This software analyzes image findings from cardiac, lung perfusion and pulmonary vessels in combination with the patient's clinical history. If the development is successful, the software could be deployed via Bayer's Radimetrics software, an informatics technology platform that connects contrast medium, injector and scan information to provide important insights.

The FDA Breakthrough Device Program is intended to help patients have more timely access to devices and breakthrough technologies that provide for more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases by expediting their development, assessment, and review. While the FDA Breakthrough Device Designation is expected to expedite the software's assessment and review, its development remains complex given the nature of the disease and technology.