Leading Artificial Intelligence Company Selects Intrinsic Imaging to Conduct Pivotal Clinical Trial to Support FDA Submission

Intrinsic Imaging's 15th AI clinical trial — pivotal MRMC study in support of an FDA submission.

Bolton, MA / San Antonio, TX

BOLTON, Mass. / SAN ANTONIO, Texas — January 11, 2018 — Intrinsic Imaging, a full-service medical imaging core lab providing comprehensive services in support of clinical trials for new drug applications and medical devices, announces today that it has been selected by a leading artificial intelligence company to conduct their pivotal multiple-reader multiple-case (MRMC) clinical trial in support of their upcoming submission to the Food and Drug Administration (FDA).

This is Intrinsic Imaging's fifteenth (15th) clinical trial it has been awarded to assess the clinical performance of artificial intelligence software in detecting pathologies from medical images.

"Intrinsic Imaging is the world leader in conducting multi-reader multi-case (MRMC) trials to assess the clinical performance of medical devices using artificial intelligence (AI), deep learning (DL) and computer assisted detection (CAD) algorithms," said Todd A. Joron, BSc. MBA, President & COO, Intrinsic Imaging. "We provide the most efficient means towards achieving FDA clearance of AI medical devices."

During this new study, Intrinsic Imaging will manage all aspects of the clinical trial including providing all resources to review and quality control over 14000 radiology reviews.

Intrinsic Imaging was selected due to its proven clinical performance that has led to multiple FDA clearances of AI software, its successful FDA inspection of an MRMC AI clinical trial with zero 483 observations, and its operational excellence and experience conducting large MRMC AI trials.

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging’s team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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