Intrinsic Imaging Undergoes Extensive FDA BIMO Inspection — Receives Zero 483 Observations

5-day high-priority FDA inspection concludes with full compliance and zero observations.

Boston, MA

BOSTON, Feb. 26, 2019 — Intrinsic Imaging, a global medical imaging core lab for clinical trials, announces today that it recently underwent an extensive 5-day high priority Bioresearch Monitoring Program (BIMO) inspection by the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). This most recent inspection was related to a pivotal study of a new biologic license application (BLA) in patients with advanced epithelial cancers, including breast, glioblastoma multiforme, hepatocellular, lung, ovarian, prostate, and related cancers.

Similar to its prior inspections, Intrinsic Imaging was in complete compliance and received zero 483 observations from the FDA. During this successful inspection, the FDA audit included a review of all clinical trial documentation, standard operating procedures, site training and qualification records, image transmittal forms, radiologist RECIST determinations, case report forms, and adjudication determinations.

At the conclusion of the inspection, the FDA inspector highly praised Intrinsic Imaging's quality management system. In particular, the inspector highlighted the robustness of their quality control process to ensure the accurate data transfer of independent reviewer assessments to the sponsor.

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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