Intrinsic Imaging ISO 13485 Medical Device Certification Leads to Award of Lung Cancer Clinical Trial

Imaging services and specialized radiologic review for an international trial of a medical device designed to treat lung cancer.

Bolton, MA / San Antonio, TX

Bolton, MA / San Antonio, TX — July 11, 2014 — Intrinsic Imaging, LLC, an FDA audited, ISO 13485, 9001 and 22301 certified medical imaging core lab specializing in providing imaging core lab services for clinical trials, announced today that the company has been awarded an international clinical trial for the evaluation of a medical device designed to treat lung cancer.

Intrinsic Imaging is the only ISO 13485 certified imaging core lab specifically certified to provide quality imaging core lab services for Medical Device clinical trials. Its certification is applicable across all therapeutic areas including, but not limited to Cardiovascular, Central Nervous System, GI & Genitourinary, Medical Device, Musculoskeletal, Respiratory and Oncology.

Throughout this lung cancer trial, Intrinsic Imaging will provide comprehensive medical imaging core lab services including protocol and charter development, site qualification, site training and management, image transfer, blinding and processing as well as the specialized radiologic review of images.

The Intrinsic Imaging Medical Device team is led by Dr. Amit Mehta, Intrinsic Imaging's Chief Medical Officer. Dr. Mehta completed his residency and fellowship training at Harvard Medical School and he is board certified in diagnostic radiology and specialty certified in vascular and interventional radiology.

Dr. Mehta, and his team of board certified, fellowship trained Interventional radiologists, are responsible for a broad range of assessments and evaluations of medical devices across the range of therapeutic areas several of which include filters, stents, angioplasty balloons, Interventional oncology including chemoembolization, RF ablation, microwave ablation as well as novel devices and biologics.

"Intrinsic Imaging's radiology team has experts in protocol design and in the selection and the utilization of imaging modalities that are best oriented towards the placement, assessment and evaluation of various medical devices," said Dr. Mehta. "By having a unique ability to guide the appropriate use of these imaging modalities, Sponsors achieve the optimal evaluation of their device, biologic, or technique utilized."

Intrinsic Imaging's medical device certification was granted by the British Standards Institution (BSI), one of the world's largest certification bodies. Intrinsic Imaging's ISO 13485 certification demonstrates Intrinsic Imaging's ability to provide quality imaging core lab services that consistently meet customer and regulatory requirements applicable specifically to medical devices.

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 750 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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