

CASE STUDY · MEDICAL DEVICE

Validation Study of a Gastrointestinal Motility Device With a Radiation-Sparing Protocol

Device validation study · Abdominal radiography, low-dose CT · Transit and motility endpoints

Challenge

A developer of an innovative device for evaluating gastrointestinal motility required a validation study comparing the device's output against an imaging reference standard. Conventional transit studies rely on serial radiographs or fluoroscopy, and a schedule dense enough to validate the device could expose healthy volunteers and patients to meaningful cumulative radiation.

The sponsor needed a protocol that produced an adequate reference standard while limiting radiation exposure, and a core lab able to design the imaging schedule, read the studies consistently and process the data on a timeline compatible with a device development program.

Intrinsic Imaging's Solution

Intrinsic Imaging's Chief Medical Officer co-authored the protocol design with the sponsor, structuring the imaging schedule to capture the transit timepoints needed for validation while limiting the number and dose of radiographic acquisitions. Low-dose techniques and defined collimation were specified in the charter, and sites were qualified and trained on the reduced-dose protocol.

Radiologists read the reference-standard imaging under a charter that defined marker counting, regional transit scoring and the handling of overlapping anatomy, with a second reader on a prespecified sample to establish reproducibility. Device output was compared against the imaging reference at matched timepoints.

Images and device data were processed through the company's cloud-based platform, linking each subject's imaging timepoints with the corresponding device measurements and delivering an analysis-ready dataset.

Intrinsic Imaging's Results

- Radiation-sparing imaging schedule reduced per-subject radiographic acquisitions by roughly 40% relative to a conventional transit protocol while preserving the reference standard
- 96 subjects imaged at 4 sites with all reference-standard timepoints evaluable
- Reader reproducibility of regional transit scoring established on a 20% double-read sample
- Imaging reference and device measurements delivered as a matched, analysis-ready dataset through the cloud-based processing platform

Read the full study online: <https://intrinsicimaging.com/case-studies/device-gi-motility>

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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