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

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. 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. Validation requires a reference that is informative at the times relevant to the device output, not simply a large collection of images. Reducing acquisition frequency creates a balance between limiting exposure and retaining temporal information. The imaging reference also has its own interpretive constraints, so agreement with it should be understood in relation to the transit measures actually observed.

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. The schedule links the radiation-sparing rationale to the scientific purpose of the study: capturing transit information suitable for comparison. Low-dose acquisition and collimation address exposure at the examination level, while the timing plan addresses how often imaging is needed. These choices are complementary, but fewer acquisitions should not be interpreted as equivalent to continuous observation of gastrointestinal transit.

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. Marker counting and regional scoring translate visible findings into reference measurements under explicit conventions. Rules for overlapping anatomy address ambiguity in assigning those findings to a region. Sampled additional reading evaluates interpretive reproducibility, whereas matching timepoints addresses temporal comparability; neither alone establishes the accuracy of device measurements outside the conditions represented by the validation dataset.

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. Linking each imaging timepoint to its corresponding device measurement preserves the pairing on which the comparison depends. An analysis-ready dataset supports evaluation of those paired observations without implying that processing resolves all disagreement between methods. The reported evaluability and reproducibility describe the imaging reference obtained in this study, not universal performance across other populations or acquisition schedules.

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

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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 50 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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com