CASE STUDY · CARDIOVASCULAR & THORACIC

Imaging Data Transfer and Query Resolution Integrated With Sponsor EDC

140 sites · Echocardiography, cardiac CT · EDC-integrated transfers and query management

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. In a large cardiovascular outcomes trial, imaging is one data stream among many, and its value depends on how cleanly it joins the rest. This 140-site study collected echocardiography at four visits and cardiac CT in a sub-study, and the sponsor's data management team had to reconcile every central imaging result with the visit record in its electronic data capture system before each data safety monitoring board meeting and interim analysis.

Under the previous arrangement the reconciliation was manual. Imaging results arrived as periodic spreadsheets, visit identifiers did not always match the EDC convention, and discrepancies were resolved through a three-way exchange of emails among the site, the core laboratory and the sponsor's data manager. Query cycles averaged nearly three weeks, DSMB data cuts were delayed while mismatches were chased, and the sponsor had limited visibility into how many imaging timepoints were outstanding at any site. The sponsor required a transfer and query architecture agreed before the first transfer, validated on every release and transparent enough that monitoring effort could be directed to the sites that needed it.

Intrinsic Imaging’s Solution

Intrinsic Imaging worked with the sponsor's data management and biostatistics groups to write a data transfer specification before the first transfer. It defined the imaging variables, their formats and controlled terminology, subject and visit identifiers matching the EDC exactly, and a monthly transfer schedule with additional transfers ahead of each DSMB and interim cut. The specification was version-controlled and signed by both parties, and each transfer was validated against it before release.

Within our platform, we configured automated reconciliation of expected imaging timepoints against the visit schedule received from the sponsor's EDC, so that a missing or late examination generated a query to the site from the core laboratory rather than being discovered at reconciliation. Image-quality and protocol-deviation queries were routed to sites through the same tracked system, with status visible to the sponsor's monitors. Transfers were structured so the sponsor's programmers could map them to SDTM domains without restructuring, and the entire workflow ran in our validated, 21 CFR Part 11-compliant environment with a full audit trail.

A monthly imaging status report accompanied each transfer, listing by site the examinations expected, received, under query and complete, so that the sponsor's clinical operations team could direct monitoring effort to the sites falling behind. Changes to the specification, which arose twice when the protocol was amended, were handled through a controlled change process with a test transfer validated by both parties before production transfers resumed.

Intrinsic Imaging's Results

- 19 days to 8 days: the reduction in average imaging query cycle time after a tracked workflow replaced three-way email resolution among site, core laboratory and sponsor
- 0.3% of records with reconciliation discrepancies between imaging transfers and the EDC, each identified and resolved before the transfer was released
- 100% of DSMB and interim analysis data cuts delivered on schedule for the remainder of the study, with transfers mapped to SDTM domains without restructuring
- 140 sites monitored through a monthly imaging status report that allowed the sponsor to direct oversight to centers falling behind on expected timepoints

Read the full study online: https://intrinsicimaging.com/case-studies/cardiology-data-integration

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.

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