CASE STUDY · ONCOLOGY

Fast-Track Rare Disease Oncology Trial

40 sites in 14 countries · Fewer than 3 patients per site · Priority Review program

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. Registration trials in rare diseases operate under severe recruitment and operational constraints. With fewer than three patients per site distributed across 40 sites in 14 countries, every imaging timepoint contributed materially to a limited dataset, and any delay in central review threatened enrollment momentum directly. The sponsor's expedited development and submission schedule required rapid core laboratory activation and responsive query resolution without compromising the methodological rigor or documentation of imaging assessments.

Geographic dispersion introduced practical difficulties of its own. Sites operated across time zones, regulatory environments and languages, and many had limited prior experience with central imaging review. Because each enrolled so few patients, opportunities to learn through repetition were scarce, and a single acquisition or submission error could compromise a meaningful share of the available data. The sponsor therefore required rapid activation, individualized site support and predictable central review turnaround within a controlled registration-trial framework, with acceleration achieved without transferring unresolved imaging issues to closeout.

Intrinsic Imaging’s Solution

Intrinsic Imaging completed the imaging charter in under three weeks, establishing the review framework while sites were still being activated. Electronic image submission with automated DICOM quality checks verified incoming studies immediately upon receipt, and rapid feedback allowed sites to correct problems before patients left their imaging visit windows. Our team developed concise, site-friendly imaging guidance and conducted training sessions scheduled around local working hours, so that centers with limited research staff could meet the protocol's requirements without extended preparation.

Central readers and adjudicators were scheduled to provide continuous coverage across all time zones, and the operational model was scaled to the trial's geographic distribution rather than to individual site volumes, so that a single-patient site received the same responsiveness as a high-enrolling center. Project managers monitored every outstanding timepoint and query, giving the sponsor current visibility into imaging status as the program advanced toward database lock.

Query management was designed for speed and clarity. Queries were written in specific, actionable language, routed directly to the appropriate site contact and tracked until resolution. Recurring issues were addressed through targeted guidance, reducing the incidence of similar queries as the study progressed and minimizing the burden on sites with limited research infrastructure. Early charter completion, a streamlined submission process and continuous operational coverage together allowed the expedited schedule to be met with the documentation expected of a registration trial.

Intrinsic Imaging’s Results

- 48 hours from acquisition to initial central image assessment, maintained across 40 sites in 14 countries despite fewer than three patients enrolled at each site
- 10 days from last patient out to database lock, a closeout interval made possible by tracking every query and outstanding timepoint continuously throughout the trial
- Approval granted under Priority Review, with the imaging component delivered on the expedited schedule the regulatory pathway required and documented to registration standards
- Imaging charter completed in under three weeks, establishing the full central review framework while site activation was still under way across the network

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Read the full study online: https://intrinsicimaging.com/case-studies/accelerated

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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