

CASE STUDY

Clario Medical Imaging contracted to rescue a global Phase III oncology study

Rapid engagement of Clario provided coordinated, high-quality services and data

The rescue challenge

Clinical studies are complex, costly and time consuming. To be successful, they require precise collection, analysis and collaboration between the sponsor and service providers. Unfortunately, this doesn't always take place as planned, and the difficult decision to replace your provider can even occur mid-study. However, the benefits of revitalizing the trial and having confidence in the quality of the data typically vastly outweigh the challenges faced to this point.

Situation

A global pharmaceutical sponsor conducted a Phase III oncology study for a complex indication requiring medical imaging to monitor the effectiveness of the investigational product.

The 60-month study took place at more than 200 sites across the United States, Europe and Asia. The imaging modalities include CT, MR and PET.

The imaging provider was contracted before the study started, but it became clear early in the study that the incumbent lacked the resources to support the trial, and the sites were not trained properly. The result was adjudication rates much higher than expected for the indication and what is considered acceptable by regulators, compromised data quality and an inability to meet timelines.

Summary

- A large, multiyear global oncology study used multiple imaging modalities.
- The sponsor sought an alternative medical imaging vendor to restore data quality and meet key analysis deadlines.
- Clario rapidly took over and implemented a robust project management plan.
- Cooperation with the previous imaging provider and better resourcing expedited the transfer of imaging responsibilities.



Impact

- ✓ Within 12 weeks from study award, a complex charter was finalized, the read system was developed, reader calibration training was completed and 3,000 images were QC'ed and read-ready.
- ✓ Quality data was restored, and tight study timelines were hit as a result of the rescue.

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Clario solution

The sponsor chose Clario to take over the imaging services, and our solution included the following:

- Accelerated setup was accomplished using a dedicated task force and resources.
- A team of 20+ members, including radiologists, oncologists and adjudicators, was established to cover the volume of work required.
- Site training was provided to increase the quality of the data.
- Clario hosted an in-person reader calibration training session with all study readers.
- The central read methodology consisted of 2 readers and an adjudicator, including clinical review by an oncologist.
- The project management plan and resourcing accounted for the planned interim analysis.

Clario's rescue approach

Sponsors and CROs trust Clario to assess, design and rescue trials, given Clario's track record of successfully turning around nearly 50 at-risk oncology studies.



Our team of experts is ready for your questions about Clario's Medical Imaging solutions. To learn more, go to clario.com or email info@clario.com.

Clario generates the richest clinical evidence. Fusing our deep scientific expertise and global scale into the broadest endpoint technology platform, we empower our partners to transform lives.

Clario's success factors

Clario's tailor-made solution was based on the following factors:



Accelerated processes

- Clario's experienced guidance and dedicated task force ensured timely development of the medical imaging charter.
- Proper resourcing enabled rapid, yet accurate, reads to put the study back on track.



Therapeutic area and regulatory expertise

- Appropriate adjudication management was established.
- Site training ensured collection of high-quality data and images.



Collaboration and support

- Input from the Clario Oncology Medical Affairs team provided assurance around the feasibility of meeting timelines and outcomes.
- The Clario team provided flexible solutions for image transfer from the previous imaging provider, to help meet timelines.