CASE STUDY

Clario supports accelerated FDA approval in non-small cell lung cancer study

Expert team and Clario reader network drive confidence in results

The challenge

Dealing with reader variability is a key challenge in oncology imaging trials. It occurs because:

- Characterizing tumors is difficult. Findings can be subtle and difficult to distinguish from normal variations. Responses to treatment can vary widely from patient to patient.
- Interpreting images is subjective. Radiologists can have varying opinions on the presence, extent or characteristics of tumors.
- Readers may be unfamiliar with imaging techniques and interpretation criteria.

Gaining agreement by experts on imaging reads is key to providing confidence in the results for regulators.

To do this, it is vital to partner with an endpoint data capture provider who has an extensive network of expert radiologists and can execute a well-constructed read paradigm.

Situation

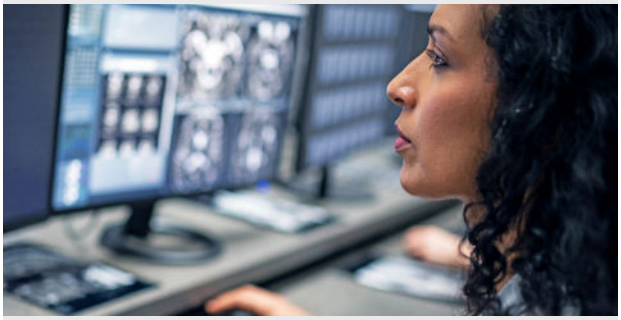
In 2017, a global pharmaceutical company began a Phase I non-small cell lung cancer (NSCLC) study in North America, the E.U., and APAC.

An alternative imaging vendor was engaged, but, by 2020, the sponsor was concerned with reader variability and delays that had accumulated.

In 2020, Clario was engaged to perform a rapid two-month retrospective image QC and analysis to meet accelerated FDA timelines.

Summary

- The sponsor engaged Clario to take over from the incumbent imaging vendor in a NSCLC study.
- Clario delivered retrospective image QC and analysis in two months.
- Clario also facilitated accelerated FDA approval and became the sponsor's trusted imaging partner.



Success factors

✓ **Deployment of expert team**
- Radiologists, oncologists, an external reader network, and project and data managers.

✓ **Reader harmonization**
- Onboarding, charter-specific training and regular reviews.

✓ **Smooth transition from prior vendor**
- Experience and process in place to rescue studies.

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Clario solution

To meet the timelines required for accelerated FDA approval, Clario was tasked with compensating for study delays.

This required an accelerated two-month project timeline. Partnering with the prior vendor to take over and reconcile the images was vital. The project involved:

- Retrospective QC and analysis of CT CAP images.
- A reader paradigm involving two radiologists, an adjudicator (if needed) and a clinical oncologist (if needed).
- Expert medical imaging support including advice on reader paradigm, fielding questions and support with the FDA submission.

Impact

Accelerated FDA approval

- The successful delivery of the project facilitated accelerated FDA approval.

Successful on-site FDA inspection

- Clario hosted a successful on-site FDA inspection in January 2021.

Trusted partner for NSCLC imaging

- The sponsor widened Clario's role to include full site-facing responsibilities and has subsequently awarded multiple other NSCLC studies.

Clario's success factors

Clario's expert-led approach has involved:

Deployment of expert team

- Team of radiologists, oncologists, and project and data managers.
- Highly approachable, consultative and responsive team to guide the sponsor throughout the study.

Clario external reader network

- 190+ expert readers in Clario's external reader network.
- Ability to quickly schedule expert multidisciplinary readers for imaging reads.

Reader harmonization and monitoring program

- On-boarding and charter-specific reader training to harmonize readers.
- Regular reviews of readers to ensure reader quality throughout the trial, with results provided to the sponsor.

Smooth transition from prior vendor

- Successful collaboration with prior endpoint data capture provider and sites.
- A clear process of dealing with image receipt and reconciliation from prior vendor.

Our team of experts is ready for your questions about your next oncology imaging clinical trial. To contact us, go to clario.com/solution/medical-imaging/ 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.