CALYX™

CASE STUDY

Utilizing Medical Imaging Expertise to Support Melanoma PD1/PDL1 Breakthrough Trial

SITUATION

A client approached Calyx Medical Imaging for support with a PD1 / PDL1 trial aimed to treat patients with advanced or unresectable melanoma who were no longer responding to other drugs.

CHALLENGE

The FDA granted breakthrough therapy designation based on Calyx Imaging central review which demonstrated preliminary clinical evidence that the drug potentially offered a substantial improvement over available therapies. The study began as a Phase I and quickly moved to the design of an advanced Phase III.

Calyx fully supported the quick ramp-up required to bring a breakthrough designation through to approval.

SOLUTION

Calyx provided senior project management and industry leading scientific guidance to help meet the demands of a breakthrough therapy designation.

The trial was granted accelerated approval by the FDA. Calyx's Medical Imaging expertise proved to be a key contributor to achieving regulatory approval.

KEY HIGHLIGHTS

- **Enrollment Adjustment**: Planned enrolled patients increased from 30 to more than 1200 due to change in design. Calyx quickly provided additional staffing to facilitate patient onboarding.
- **Read Design**: Adjusted during the process from single review to double review with adjudication, plus clinical data evaluated by a central oncologist.
- **Technology**: Originally scoped as a simple excel database, Calyx coded and validated a full electronic analysis suite, including three criteria on a single comprehensive electronic case report form.
- **Streamlined Documentation**: The Imaging Review Charter and other associated documentation were expeditiously rewritten to account for multiple analysis criteria and regulatory rigor.
- **Reader Management**: Quickly selected, trained, and contracted with 9 additional radiologists and oncologists to meet the expedited review timelines.
- **Regulatory Support**: Calyx supported the client's FDA and EMA audits, FDA approval, and the EMA submission.

CALYX™

Reliably solving the complex.

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