From Trial Design to CDISC Submission

Support from multi-disciplinary team

Background

- The sponsor is a virtually structured, specialty pharmaceutical company focused on the development and commercialization of novel therapies for the treatment of patients with musculoskeletal conditions.
- The company's lead product candidate is being investigated for its potential to provide improved analgesic therapy for a highly prevalent indication.
- At the time of contracting with Cytel, the company's lead candidate was entering Phase 2 of development.

The Challenge

Manage multiple, complex statistical analysis deliverables for a program of studies, CDISC compliant outputs, and data pooling for NDA submission to the FDA with minimal sponsor oversight.

The Cytel Advantage

As the world's leading biometrics CRO, all of Cytel's processes, talent and expertise are applied to maximizing the value of clinical data. A standardized approach to data collection and analysis ensures traceability and delivers operational efficiencies. Our specialist knowledge helps our customers to lower clinical trial risks, accelerate development and improve the probability of success. Whether you're a global pharmaceutical company or a virtual biotech, Cytel will provide a dedicated project team with the experience to ensure that work is done accurately, on time and on budget.

> **"They were flexible, diligent, and most importantly they communicated effortlessly"**

Cytel's global team worked around the clock to meet tight timelines

Cytel Solution

Bringing together statistical programming, statistics, data management, and medical writing expertise.

- Cytel Statistical Consulting team provided trial design for the company's Phase 2b study.
- Cytel provided statistical analysis and reporting support for a number of studies in the ongoing program, including pivotal Phase 2b and 3 studies.
- For the pivotal studies, Cytel provided CDISC compliant datasets as part of the in-line statistical reporting.
- In preparation for submission, Cytel CDISC experts prepared a gap analysis reviewing the SDTM compliance for legacy studies not reported by Cytel which were intended to form part of the ISS.
- Cytel provided SDTM conversion for the legacy studies for which CDISC compliant datasets were not originally produced.
- Cytel statisticians prepared the Statistical Analysis Plan for the ISS and assisted in preparing the SAP for the ISE.
- Where required, Cytel data coding experts up-versioned adverse events in MedDRA to 18.1 from earlier versions, ensuring standardization across studies for the ISS.
- Cytel statistics and statistical programming team performed the data pooling for the ISS/ISE from the individual study SDTMs to ADaMs.
- Reviewer's Guides, both for SDTM (cSDRG) and ADaM (ADRG), were prepared for the studies and the ISS/ISE.
- Cytel Medical Writers prepared the text for Section 2.7.4 (Summary of Clinical Safety) for the eCTD submission.

Success Factors

Communication

Close communication was established both within the Cytel project team and with the sponsor Lead Statistician.

Decision-making

A clear decision-making process was established between Cytel and the sponsor.

Expertise

A Cytel CDISC subject matter expert and experienced biostatistician were appointed as project leads to ensure effective coordination of the deliverables and adherence to the CDISC implementation guidelines.

Flexibility

Cytel had a global team available to work around the clock and meet tight delivery timelines.

Experience

This was a high visibility project for the sponsor and its investors. Cytel team members needed to proactively interact with sponsor's senior management and make recommendations where necessary.

Efficiency

A streamlined approach was created across study specific deliverables creating efficiencies, supporting delivery timelines and ensuring harmonization.

Outcomes

- The sponsor reported primary endpoint met in the Phase 3 pivotal trial.
- CDISC compliant filing was submitted on time to the agency. Cytel statistics and programming team are on hand to provide regulatory responses as required.
- Cytel continues to work with the sponsor on further clinical development projects.

References

"An FDA Submission Experience Using CDISC Standards - Angelo Tinazzi, Cytel" in • CDISC EU Interchange 2017, London 26-27 April 2017 • CDISC Italian User Network, Milan 21st October 2016