IDDI

PASSION. SCIENCE. EXPERIENCE.

OVERCOMING THE CHALLENGES OF COLLABORATIVE GLOBAL TRIALS TO DELIVER HARMONIZED SAS SDTM DATABASE

IDDI CASE STUDY

STUDY DESCRIPTION

A Prospective, Randomized, Double-Blind, Phase III clinical trial in women with breast cancer to determine whether the addition of an anti-PD-L1 to chemotherapy improves pathologic complete response and survival.

INDICATION	PATIENT POPULATION	STUDY DURATION	REGIONS	NO. OF SITES:
Breast Cancer	1520 adult subjects	December 2017 – June 2024	North America and Europe	Up to 200

SITUATION

ONE STUDY, TWO SPONSORS, MULTIPLE SYSTEMS

This collaborative study is run by two cooperative groups, with financial support from a multinational healthcare company. The study protocol was slightly different for each Sponsor.

Due to the collaborative nature of the trial, the study set-up incorporates two electronic data capture (EDC) systems and three different Interactive Response Technology (IRT) systems (two for randomization and one for drug supply).

IDDI IS RESPONSIBLE FOR:

- The randomization list used for the IRT systems
- The Study Data Tabulation Model (SDTM) SAS programming for each EDC database
- Combining the databases into one final database used for the statistical analyses
- The statistical analysis of the whole trial
- Providing reports for Independent Data Monitoring Committee (IDMC)

CHALLENGES

✓ **COMPLEX SET-UP**	The cooperative model of this trial meant that multiple systems needed to be used, as each of the two cooperative groups preferred to use their own system. **Two separate EDC systems and three IRT systems (two for randomization and one for drug supply)** were required– the latter built and managed by an existing external vendor of the supplier of the study medication.
✓ **ONE SINGLE HARMONIZED SAS SDTM DATABASE**	IDDI was tasked with building **one SDTM SAS DATABASE out of two different EDC systems.** The data were handled in different EDC and IRT systems, making the harmonization of the two study case report forms (CRFs) complex, due to a non-fully CDASH compliant CRF imposed by Sponsors, and the slight CRF differences because of two slightly different protocols.
✓ **CONSISTENT PROGRAMMING**	As the data were entered into two separate EDC systems, IDDI **needed to program from two separate database extracts** and **ensure consistent SDTM SAS programming** at the end.
✓ **QUALITY CONTROL**	Data quality issues due to two different databases.
✓ **PROJECT COORDINATION**	The project entailed **intense communication** with Sponsors at different levels (Management and Operations), with each Sponsors individually and with both Sponsors together.
✓ **TRANSFER OF DATA**	Additional challenges were encountered around the transfer of data between the IRT systems. Although, the preferred option is to integrate systems via Web services, the Sponsor opted for transferring data through **sFTP protocol**, increasing the risk of transfer failures.

SOLUTIONS

IDDI has been working with one of the sponsors for over 10 years' and so they were confident that we would help them meet these challenges. We provided the client with an enhanced plan to address the study challenges. IDDI teams' extensive experience, flexibility and scientific background, combined with methodological and operational excellence, allowed to handle the complexity.

- IDDI put in place a comprehensive communication between all stakeholders and ensured expert oversight and responsive project management.
- Ensuring data equivalence within the final SAS database for operational and end-of-study analysis purposes was mission critical to all stakeholders. IDDI harmonized case report forms for both EDC systems and integrated all systems seamlessly.
- IDDI performed two sets of programs quality control on each separate database and One final QC after combining the two databases.
- IDDI built additional safeguards for sFTP data transfers.

RESULTS

- ✓ Thanks to IDDI's expertise, solutions-focused and adaptable approach, coherent submission-ready clinical data were delivered.
- ✓ IDDI's strategies helped the client to not only meet the challenges of this collaborative global trial, but also foster harmonized clinical data management

IDDI has successfully delivered

- One global harmonized SAS SDTM Database
- Several IDMC reports
- A sub-study for cardiac patients on a subset population
- Coding of medical terms for both databases

CONTACT US

For more information on IDDI's Trial Design - Randomization - Data Management and Biostatistics services for Pharmaceutical and Biotech companies:

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ABOUT IDDI

COMBINING PASSION, SCIENCE AND EXPERIENCE TO ENSURE YOUR CLINICAL DATA IS READY FOR SUBMISSION

International Drug Development Institute (IDDI) is an expert organization in biostatistical and integrated eClinical services that is committed to assisting pharmaceutical, biotech, medical devices, and Cooperative Groups in several disease areas, with a special focus on oncology and ophthalmology. IDDI optimises the clinical development of drugs, biologics and devices thanks to proven statistical expertise and operational excellence. Founded in 1991, IDDI has offices in Belgium, Boston (MA) and Raleigh (NC).