

Delivering timely data with a biomarker data management system



A Fortrea Functional Service Provider (FSP®) case study

Biomarker data management differs from clinical data management, requiring a high level of coordination and expertise. By designing and implementing customized processes for your biomarker data management system, we can help you power clear, confident decisions in your studies.

This case study shares our experience working with a large pharmaceutical company, as they initiated an effort to collect and analyze biomarker data from over 200 trials across three therapeutic areas. They sought the expertise of our Fortrea FSP team to help them support all aspects of data management and deliver clean, quality biomarker data in their standard format. This included setting up a new platform and processes to coordinate, transfer, map and deliver all of the biomarker study data, as well as continually support rapid turnaround and deliver timely reports to their biomarker scientists.

Understanding the unique challenge of biomarker data

Unlike clinical data, the analysis of the biomarker data is not centered around the clinical study report (CSR). Even after a trial is over, biomarker scientists may choose to analyze samples and generate data from samples in long-term storage. In addition, a sponsor may frequently partner with new vendors and request recently released tests, each of which may have its own standard data format. In this environment, rapid turnaround is essential; biomarker scientists need timely access to their data, so they can contribute to strategic clinical development decisions, as well as share their findings in symposia, conferences or publications.

In this particular Fortrea FSP partnership, the sponsor was working on over 200 studies with approximately 900 active vendor file transfers, spanning more than 136 vendors, many of which provided specialized or esoteric assays. Working with this large volume of disparate data required our team to implement a high level of coordination and organization.

KEY TAKEAWAYS

- Implemented a science-driven data management solution to enable rapid turnaround times
- Developed a responsive approach to handle and map disparate biomarker data
- Used an embedded employee model of FSP that allowed Fortrea to serve as a direct partner with the sponsor
- Met or exceeded every timeline from biomarker scientists' standard and ad hoc requests

Facilitating a productive partnership with the FSP embedded model

To set up the partnership, the sponsor opted to implement the embedded employee model of the FSP offering, wherein Fortrea employees are fully integrated with the sponsor's software, email and systems, while following the same training programs and standard operating procedures (SOPs) as their own internal employees.

Next, the sponsor set up a system in which all of the incoming biomarker data were directed to their own data repository. The sponsor then worked with our Laboratory FSP team to build a customized data review tool, which Fortrea helped test, providing input on how to best handle the biomarker data.

Setting up a responsive team to deliver biomarker data on-demand

Given that the Fortrea FSP team had to rapidly deliver clean biomarker data for all milestones—and often had little visibility into the sponsor's next request for biomarker data management—the team worked to develop a management structure called a “pod.” Each pod was designed to handle large volumes of clinical trials and external vendor files by assigning specialized roles to cover all aspects of the vendor interactions, as well as the needs for the study data. The team worked to set up well-defined processes to communicate with the sponsor's vendors, statistical programmers and biomarker study team representatives.



Manager

- Responsible for resource allocation
- Responsible for employee performance
- Ensures deliverables are on time



DMPL

- Main point of contact for sponsor
- Creates and manages timelines
- Coordinates pod assignments
- Communicates with sponsors and ensures timely delivery of data



EDS

- Creates data transfer specifications
- Ensures data meets sponsor standards
- Ensures data load successfully; matches specifications
- Communicates with vendors



CDA

- Responsible for data quality
- Creates data validation specifications
- Reviews data and issues queries to resolve discrepancies
- Communicates with programmers

Nurturing an ongoing, trusted partnership

Fortrea FSP has now been supporting this sponsor with the biomarker data management system for five years, using customized processes that align with the sponsor's mode of operation. These processes include transferring data, mapping specifications and cleaning data, as well as data validation and storage or delivery to the scientists and various study stakeholders.

From an employee management perspective, Fortrea FSP has assumed accountability and oversight of the deliverables and manages each employee's performance, so that the sponsor can maintain focus on the resulting data.

To ensure ongoing accountability and timely delivery, the sponsor and FSP team continue to hold quality reviews to oversee milestones, reinforce standards and review study documentation. Monthly project reviews are held to discuss milestones, review projected target dates and prepare for data delivery. Finally, metrics are generated at agreed-upon intervals to review status, highlight outstanding documentation and proactively research and address potential roadblocks.

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