ONCOLOGY EXPERTISE FACILITATES ACCELERATED TIMELINE

IQVIA™ Biotech delivers database lock resulting in FDA approval three months ahead of schedule

SITUATION

IQVIA Biotech won a competitive bid for a pair of global Phase III prostate cancer trials from a small biopharmaceutical company. Eighteen months into the study the sponsor was acquired by a leading global pharmaceutical company. The acquisition greatly accelerated the trial timeline and created different points of emphasis for the study team which needed to be operationalized while continuing to aggressively move the study forward. In addition, patient and investigator excitement about the compound drove accrual much faster than anticipated, which created a hurdle not common to oncology trials.

CHALLENGE

IQVIA Biotech's new customer, the large pharmaceutical company, posed challenges to us 18 months into the study. With stringent data requirements and unique regulatory sensitivities, as well as exciting efficacy signals which could support an accelerated approval, the sponsor asked IQVIA Biotech to expedite the study timeline and submit data to the U.S. Food & Drug Administration (FDA) with an interim database lock. The pressure to accelerate was compounded by interest in the drug from regulatory agencies and advocacy groups following positive patient data reported out of the Phase II study.

SOLUTION

IQVIA Biotech collaborated with our customer, committed to meeting the accelerated timelines with the addition of resources and was flexible in our approach to the new requirements regarding data reporting, regulatory integrity and the demonstration of Good Clinical Practices (GCPs). IQVIA Biotech enhanced the study team, operationalized the necessary changes and ensured data and regulatory integrity despite the shortened timeline.

DEMONSTRATING PARTNERSHIP: THE DATABASE LOCK

The pressure to accelerate the study culminated with an interim database lock that historically takes 12 weeks; the sponsor needed it in four weeks.

IQVIA Biotech took advantage of a four-week planning window during which we developed and executed a plan focused on resourcing, training, data management and integrity and problem solving:

- Due to IQVIA Biotech's strong ability to secure highly specialized oncology Clinical Research Associates (CRA), we were able to recruit, train and deploy a large clinical monitoring SWAT team across 15 countries utilizing our staffing arm, IQVIA Recruiting & Staffing Solutions.
- We quickly allocated additional resources to our internal CRA monitoring team to ensure efficiency of on-site visits.
- Using custom reports around data currency and quality, the team was able to link up data entry status, on-site CRA work requirements and IMV scheduling to utilize our CRAs to ensure timely source verification.
- We proactively developed escalation strategies for non-responsive sites.

Perhaps most importantly, IQVIA Biotech appointed an internal group of senior executives across clinical and data operations to support the larger team, provide superior client communication and address challenges quickly and efficiently. This group met daily for the duration to ensure IQVIA Biotech was on track to meet the deadline while maintaining high quality data and regulatory compliance.

"On behalf of my colleagues, I want to congratulate IQVIA Biotech on our achievement. I am very proud of the cleanliness and consistency of the database we have achieved. I am deeply grateful for the opportunity to collaborate with you on this very important project."

— VP Clinical Research & Development, Large Pharmaceutical Company

RESULTS

By the end of the four-week database lock:

- 24,000 forms were entered and monitored and 14,000+ queries were issued, answered and closed.
- IQVIA Biotech's data management team delivered coding, aggregate data reviews and lab and vendor reconciliations.
- Our biostatistics, programming and QC team delivered a full TLF package to the independent data monitoring committee on time accommodating a 45% reduction in timeline.

The drug was approved by the FDA three months ahead of a six-month timeline. EU approval was granted shortly thereafter.

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