CASE STUDY

BIOSTATISTICS AND MEDICAL WRITING PARTNERSHIP

BACKGROUND

In a successful rescue from a failed vendor, PPD entered into a six-year relationship to provide support for a large pharma client in biostatistics, programming and medical writing services across Phase I-IV in multiple protocols and therapeutic areas, including oncology, cardiovascular, respiratory and infectious diseases.

OBJECTIVE

The client required assistance for both global studies and China/Japan country-specific studies with all aspects of biostatistics, programming, clinical report writing and publishing to support clinical development and regulatory requirements.

CHALLENGES

In addition to the organizational and operational challenges of working on such a large book of business, a paradigm shift was required to bring together the PPD and client stakeholders. Challenges also arose as PPD integrated into the client's clinical development operating model, representing the analysis and reporting function on the clinical study teams. This integration included working closely with other vendors and the client's data management supplier, as well as other internal and external customers.

STRATEGY

With the goal of full transparency and visibility to our client, PPD brought together our biostatistics and medical writing expertise to deliver a unique model for this relationship. We collaborated closely with our client to conduct extensive training on the relationship, the clinical development philosophy, standard operation procedures (SOP), therapeutic standards/processes and created a clear project collaboration model through the Responsible, Accountable, Consulted and Informed (RACI) matrix and Project RACI to guide the team and processes. This collaboration model covered all activities associated with the clinical trial, up to delivery of a submission-ready clinical study report (CSR):

+ Statistical analysis plan (SAP) development
+ Study data tabulation method (SDTM) and analysis dataset model (ADAM) database production
+ Tables, figures and listings (TFL) production to support interim analyses and final analysis
+ Data safety monitoring board (DSMB) support
+ Safety narratives
+ Common technical document narrative provision
+ Produce International Conference of Harmonisation (ICH) and non-ICH clinical study reports
+ Food and Drug Administration Amendments Act (FDAAA) reporting

PPD also supported submissions and other interactions with regulatory authorities:

+ Submission data pooling and analysis
+ Common technical document deliverables
+ De-identification of clinical trial data
+ Briefing documents
+ Patient risk management plans
+ Periodic annual safety updates
+ Clinical expert statement/clinical overview addendum for license renewal in the European Union

RESULTS

This partnership resulted in more than 100 FTEs across North America, EMEA and APAC up in only nine months. PPD supported more than 50 studies, including a new drug application (NDA) and marketing authorization application (MAA) oncology submission, followed by the Japanese NDA submission. These represented a new client record for the shortest time from database lock to the submission of NDA and MAA. Across the 50 studies, PPD achieved 95 percent compliance on key quality and timeline metrics. In addition, PPD participates in the partner's process improvement initiatives and supports its standards group in the development of new data and reporting standards.

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