APCER LIFE SCIENCES
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CASE STUDY

Compiling Large Volumes of Real World Data and Creating a Report with Appendices for a Global Client

Category: Real-World Evidence

Study type: Observational Study

Geography: United States

Product type: Drug

Therapeutic area: Cardiovascular

About the Client

The client is a global biopharmaceutical company committed to discovering, developing, and delivering innovative medicines to patients with serious ailments. The company has a diversified portfolio across a wide range of therapeutic areas, including cardiovascular, ophthalmology, and oncology.

Business Challenge

The client approached APCER to prepare a report for an observational study comparing the effectiveness and safety of treatment for a vascular condition in the United States. The client faced numerous complexities while preparing the report and appendices for the study, including:

- **Massive report size:** approximately 50,000 pages, including the report body and appendices.
- **Data inconsistencies:** discrepancies and missing information in Tables, Listings, and Figures (TLFs).
- **Evolving requirements:** new parameters added based on expert feedback, necessitating re-analysis and report updates.
- **Strict deadlines:** requirement to deliver a draft report within 2 weeks and revisions within 8 working days.
- **Multidisciplinary collaboration:** need for coordination with data scientists, statisticians, researchers, and epidemiologists

Overview – RWE Reports

An observational study is a type of research method where researchers observe and collect data from individuals or groups without intervening or manipulating variables. Real-world evidence (RWE) is derived from various observational studies that typically include a more diverse set of patients than randomized clinical trials. Ultimately, the RWE can improve patient outcomes by providing insights on compliance, adherence, and cost in a real-life environment. The RWE data are generated from real-world data sources such as electronic health records, claims databases, patient registries, and other sources of healthcare data.

The RWE reports are documents that present findings from studies or analyses based on data collected outside of traditional clinical trials. The RWE report contains clinical evidence about the usage of medical product and potential benefits or risks derived from real-world data analysis and provide insights into the effectiveness, safety, and value of medical interventions in the real-world clinical practice.

A sponsor may outsource RWE report preparation activities to leverage the expertise of service providers who specialize in producing high-quality content with a quick turnaround as a cost-effective solution.

Solution

To address the challenges in the preparation of reports and appendices, the APCER Medical Writing (MW) Team utilized a multidisciplinary approach, involving:

Early identification of issues: meticulously reviewed TLFs, uncovering data discrepancies, and missing data in the TLFs.

Proactive communication: swiftly communicating the identified issues to the relevant stakeholders, ensuring timely corrections, and preventing delays.

Efficient content creation: utilizing strong writing skills and knowledge of medical terminology, the writers quickly revised the Results section based on the updated TLFs. To minimize selection bias in the report, APCER helped the client in interpreting data on sensitivity analyses that impacted potential bias in the study findings.

The interpretation of data from subgroup and sensitivity analyses was prioritized to assess the robustness of the results and investigate potential variations in associations among different subpopulations. This improved the report's generalizability.

The team focused on supporting the client in the summarization of the results from propensity score matching and implemented a robust multistep QC process for data accuracy, consistency, and first-time quality despite a huge volume of data.

Collaboration and problem-solving: actively engaged with various specialists, including an integrated evidence generation researcher, a data scientist, a statistician, and a healthcare professional, who helped in clarifying uncertainties, resolving discrepancies, and incorporating new parameters seamlessly.

Project management: monitored the progress through a dedicated project-specific tracker and employed SharePoint for sharing, reviewing, and revision of report drafts in real time.

Appendix compilation support: assisted in organizing and compiling the extensive appendices (>50,000 pages), ensuring completeness and e-submission readiness.

Outcome

APCER's expertise and dedication were instrumental in navigating these challenges and delivering a high-quality report that met client's expectations.

High-quality report: despite the challenges, the APCER MW Team successfully delivered a comprehensive, accurate, and well-written RWE report adhering to the regulatory standards.

Meeting tight deadlines and surpassing expectations: the report and appendices were finalized within the tight deadlines, exceeding client expectations.

Effective collaboration: strong communication and teamwork across various disciplines facilitated a smooth and efficient workflow.

Our Medical Writing Capabilities

A team of 30+ members having rich experience across therapeutic areas and expertise in preparing regulatory documents and scientific communications.

Robust multi-step review process to ensure 100% quality control.

High-quality deliverables consistently exceeding client expectations.

Customized solutions fully compliant to the ever-changing regulatory landscape.

Trusted partner in navigating the complexities of RWE report preparation.

Successful completion of RWE studies by identifying early potential issues and taking proactive measures within expediting timelines.

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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