APCER LIFE SCIENCES
Together for better health

CASE STUDY

Accelerating product approval by handling complex and voluminous medical writing projects

Therapeutic area: All therapy areas

Product type: Drugs and devices

Geography: US

Product life cycle stage: Post-marketing

About the Client

A large pharmaceutical and life sciences company with a diversified portfolio across the therapeutic areas and business verticals such as pharma, consumer health, crop science and animal health. The pharma portfolio includes cardiology, women's healthcare, oncology, hematology, ophthalmology and radiology products.

Business Challenge

The company conducted a global multi-center Phase III clinical trial with more than 27,000 patients enrolled for a cardiovascular indication. As the primary endpoint for the study was met earlier than expected, it was required that they file for approval sooner than was originally planned. APCER supported the company by preparing a huge number of high-quality narratives in the least possible time. The project had its own set of challenges as mentioned below:

Resource management

- Resource allocation for the project in parallel to the ongoing projects.
- Requirement for a large number of authors and reviewers.

Overview-Narrative writing

Narratives are included within the clinical study report (CSR) or as an appendix to the CSR and are submitted to the regulatory agency as a part of the dossier. They aid in evaluating the safety profile of the investigational drug.

Some of the major challenges encountered while preparing narratives are as follows:

- Maintaining consistency in the narratives due to multiple resources working on the same project.
- Quick turnaround time with high quality of narratives.
- Different types of data sources.
- Changes in client review team during the project.
- Delays in review cycles by the client.

Thorough understanding of the therapeutic areas, study protocol, and data sources, template designing and reviewing the content for data accuracy and consistency is required.

A sponsor outsources narrative writing activities to leverage the expertise of service providers to produce high-quality deliverables within a quick turnaround time as a cost-effective solution.

Managing client SMEs

- More than 10 reviewers from the client study team.
- Different expectations in terms of data presentation.

Maintaining quality

- Ensuring quality and consistency across narratives authored and reviewed by multiple resources.

Managing timelines

- Delivering 350 narratives per week.

Solution

APCER Life Sciences created a project plan and designed a methodology to meet the expectations of the client within the agreed timelines. The methodology adopted is mentioned below:

Resource management

- Hiring and training the team.
- Optimizing resource utilization.
- Assigning seasoned project leads.

Managing client SMEs

Multiple calls and discussions for:

- Content harmonization.
- Quick query resolution.
- Bringing agreement and alignment within the client team.

Maintaining quality

- Conducting internal trainings.
- Customizing study-related checklists.
- Providing continuous feedback to authors on a real-time basis.

Managing timelines

- Efficient planning and tracking of the project.
- Efficient communication with the client for source data and query resolution to prevent time loss.

Outcome

The above-mentioned project plan helped in achieving the following:

- Preparation of **more than 3600 narratives** for the project.
- Updation of **more than 1500 narratives** within 5 weeks.
- Compilation of **CSR section 15 consisting of approximately 24,000 pages shared within a week.**
- **Timely delivery of high-quality** e-submission-ready document.

Our Medical Writing Capabilities

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

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

High-quality deliverables consistently exceeding expectations.

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

APCER LIFE SCIENCES | Together for better health
Part of APC Group

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.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

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