Mastering complexity and deadlines: A case study on updating an investigator brochure for an investigational product in respiratory diseases

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BACKGROUND

Investigator brochures are pivotal in the field of clinical research. One of our clients, a global biotechnology company was facing challenges regarding the inclusion of the complex data from multiple ongoing studies in a stringent timeline.

BUSINESS CHALLENGE

Complexity of new data
The new data from recent studies introduced additional layers of complexity to the existing data. This data was in the form of Tables, Listings, and Figures (TLFs) and required a high level of expertise to be accurately interpreted and incorporated into the existing IB.

High stakes in accuracy
Given the drug's advanced phase, any error in the IB could have a cascading impact, including the possibility of delaying trials, adding costs, or even compromising patient safety.

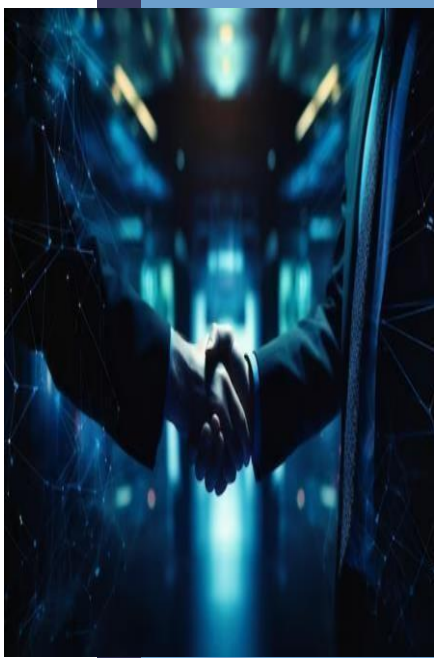
Resource constraints
Maintaining quality while adhering to strict timelines required specialized skill sets in medical writing, data analysis, and project management, which could stretch existing resources**.**

BUSINESS SOLUTION

Initial assessment and planning
Upon receiving the TLFs and the mandate to include additional cardiac and hepatic data, our Medical Writing (MW) team immediately organized an internal strategy meeting. They outlined an action plan, factoring in quality, regulatory compliance, and timelines.

Gap analysis and data integration
A comprehensive review revealed that while the existing TLFs contained a wealth of information, there were gaps in relation to the required cardiac and hepatic data. The client was alerted to these gaps and new tables meeting the criteria were recommended. Collaboration with client statisticians was initiated to guide them in generating new tables with the required data.

Process adaptation and execution
Additional medical writers with expertise in respiratory disease conditions were reassigned to the project. A dedicated reviewer provided ongoing checks to avoid last-minute delays. Two rounds of quality control ensured accuracy and compliance. Regular touchpoints with the client updated them on progress and resolved queries.



RESULTS

Timeliness
The IB was updated and submitted within the 45-day window.

Regulatory compliance
Health authorities approved the IB.

Client feedback
The client expressed satisfaction with the end product, process, transparency, and speed of execution.

Internal metrics and resource efficiency
The project remained within budget due to effective planning and execution.

CONCLUSION

The challenge of updating an Investigator Brochure (IB) for an advanced-phase neurology drug within a strict deadline required an adaptive, collaborative, and highly focused approach. This case serves as an example of how adept project management, subject matter expertise, effective stakeholder communication, and tactical use of technology can produce a high-quality document within stringent timelines. It sets a standard for future projects, showing that quality and timeliness need not be compromised, even under pressing conditions.

WHO WE ARE

Planning for a paradigm shift in the delivery of Pharmacovigilance services, AWINSA Life Sciences aims to provide end to end PV services including in its ambit both clinical trial and post marketing services. Manned by people with discernment and an eye for quality, we at AWINSA Life Sciences ensure astute analysis of safety reports so that clinical scenarios emerge in perspicuity.

Intricate and deep-rooted knowledge of the subject and the international regulations will ensure that you are delivered services of the highest order within the stringent timelines.

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