Prism Ideas

Case study

# Development of Patient Narratives to Aid Clinical Trial Reporting and New Drug Registration

## Background

A pharmaceutical company was investigating the efficacy and safety of a new chemotherapeutic agent, together with a novel administration procedure (peripheral hepatic perfusion, or PHP). Raw data from Phase I, II and III clinical trials were available.

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To obtain regulatory approval of this combination of a new chemotherapeutic agent plus PHP, the pharmaceutical company was asked to provide efficacy and safety data for each individual patient who participated in the trials (n=186). Although the patient data were available in a database format, a detailed narrative was required for each participant.

The narratives were intended to facilitate the preparation of clinical trial reports and the subsequent submission of findings to the relevant regulatory authorities. In addition, the narratives had to be provided within a limited time frame. Given its strong track record of clinical trial consulting and pharmacovigilance, Prism Ideas was selected to assist the client company with this pivotal project.

## Challenge

*With only 2 months in which to deliver a narrative draft for every patient, on schedule and on budget, it was essential to identify and address any data issues early.*

The clinical research organisation (CRO) involved in the conduct of the clinical trials provided Prism Ideas with the raw data for each of the 186 patients recruited. As the trials were conducted over a number of years, the type of information and level of detail recorded for each patient often varied between sites and clinical trial stage; in some cases, there were inconsistent or missing entries. With only 2 months in which to deliver a narrative draft for every patient, on schedule and on budget, it was essential to identify and address any data issues early.

## Solution

*Prism Ideas established a dedicated team of clinicians, medical writers and project managers with ample experience in oncology, drug development and pharmacovigilance.*

Prism Ideas established a dedicated team of clinicians, medical writers and project managers with ample experience in oncology, drug development and pharmacovigilance. The main tasks of the Prism Ideas editorial team were to review the raw data provided, identify and highlight any inconsistent or missing entries, and write up a narrative for each patient. The clinician's primary responsibility was to provide medical oversight across the whole project, ensuring that data entries were correct and made medical sense. In addition, the Prism Ideas clinician set up a meeting with the client to agree the format

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and specifications of the narratives. These included describing the patients' medical history, the treatment cycles received and the outcome after each drug administration. By working closely together, the editorial team guaranteed consistent, accurate data presentation in a customised template.

Given the nature of the source data and the complexity of the project, Prism Ideas also devised and implemented a set of internal procedures to brief and train each member of the team appropriately. This ensured that the narratives were written with excellent attention to detail, precision and adherence to the specified format.

## Conclusion

*Thanks to the strong teamwork and excellent communication and project management skills shown by the Prism Ideas team, all the requested patient narratives were delivered to the client company well ahead of schedule.*

Prism Ideas was chosen to deliver this crucial project due to its extensive therapy area knowledge and its unique ability to provide a comprehensive service, integrating both clinical and editorial expertise.

Thanks to the strong teamwork and excellent communication and project management skills shown by the Prism Ideas team, all the requested patient narratives were delivered to the client company well ahead of schedule.

This allowed the client company to identify and address any pending data issues before their submission to regulatory bodies. Any remaining data queries were clarified with the CRO and the patient database was updated. Once locked, the database was sent to Prism Ideas where the narratives were cross-checked against the final data and updated, as required.

By outsourcing this piece of work to Prism Ideas, the client company ensured the delivery of the required clinical trial documentation in a timely and accurate manner.