Case Study

Providing expert input into FDA submissions

Executive Summary

Detailed specifications are key to the success of a relationship between a CRO and a client. However, understanding of the requirements underlying those specifications is also important. Veramed has key staff with in-depth knowledge of FDA requirements in various Divisions, from CDISC through to complex statistical modelling to address issues around missing data. This has allowed Veramed to produce quality and reviewer-friendly input into NDA submissions, both at the study level and for Integrated Summaries of Safety or Efficacy, and to provide appropriate displays in a timely way in response to regulatory questions during the review process.

Challenges

It is difficult to provide comprehensive specifications for submission components without simply replicating FDA guidance. Following a specification without thought or with insufficient understanding can lead to errors and inconsistencies, and these can have a major impact if the deliverables are intended for FDA submission. Submission components that are difficult for a reviewer to negotiate may result in questions or delays. In addition, clarifying questions may arise from FDA review that are difficult to predict and need an answer in a very short time frame.

Solution

Veramed has a core of very experienced statisticians and programmers who have worked in the pharmaceutical industry for many years. Several staff members have experience of direct interaction with FDA at review meetings during product development and at an Advisory Committee meeting. All statisticians and programmers are encouraged to become familiar with regulatory guidelines, to think through the implications of what they are being asked to do, and to make things as clear as possible for a regulatory reviewer. No issues relating to data format, programming or statistical analyses have been raised in FDA submissions for which Veramed have provided these components. During the regulatory review process, Veramed's detailed knowledge of the data and expert statistical knowledge work together to allow completion of complex statistical analyses, such as tipping point analyses, to enable a client to respond to FDA questions within a short time frame.

Outcome

There is no substitute for experience and quality. This has enabled our clients to have the confidence in submission packages and FDA responses prepared by Veramed, with Veramed team members working collaboratively throughout.

The client says

"The thing I like most is the collaborative working engagement - it is not a chore but a pleasure to work with Veramed"

The Writer

Jean Brooks
Biostatistics Director

Jean has 30 years' experience as a statistician in the pharmaceutical industry, covering all phases of drug development, several therapeutic areas and work in global pharmaceutical companies as well as CROs.

Jean has acted as statistical representative at many regulatory meetings at various stages of drug development, including an FDA Advisory Committee and a CHMP Oral Explanation. She has experience of working in both the US and UK and has worked closely with teams in Japan and China.

Jean has an MSc in Statistics and Operational Research (Birkbeck College, University of London, 1991), a postgraduate Diploma in Statistics (University College London, 1988) and a BSc in Mathematics/Statistics (Leeds University, 1987).