

## Executive Summary

Many pharmaceutical companies outsource the delivery of biostatistics activities to a third party company. The Sponsor's expectations are for all contracted deliverables to be accurate and to be delivered on time. However, as stated in ICH E6, although "...a Sponsor may transfer any or all of the Sponsor's trial-related duties and functions to a CRO, the ultimate responsibility for the quality and integrity of the trial data always resides with the Sponsor".

Sponsors may not always have the internal resources to oversee these outsourced deliveries and rely heavily on their vendors. This can lead to challenges for the Sponsor if quality concerns are raised and can be exacerbated if quality issues are raised across a number of projects with the same or multiple vendors.

The case study below summaries how Veramed statisticians have supported a Sponsor by operating as an extension to its own internal clinical team and provided statistical oversight of third party vendors.

## Challenges

The midsize pharmaceutical company had an established full service partnership with several large CROs. The number of compounds and studies that the small internal biostatistics team were being asked to support was escalating, covering design work for new studies and oversight of existing outsourced studies. The volume of work was simply too large for the internal team.

## Solution

Veramed initially identified a Lead Statistician who could work alongside the Sponsor's team to take responsibility for the oversight of some of the biometrics deliverables, including the review of the SAP and TFLs for quality issues and approving them on behalf of the Sponsor. Additional statisticians supported the Lead as the workload increased so that within a few years there was a team of Veramed statisticians supporting the Sponsor. The Veramed team all worked on the Sponsor's systems to their SOPs, based in Veramed offices but were available to visit the Sponsor offices and attend meetings as needed.

The Veramed Lead Statistician ensured that the team had the appropriate training and skills to support the demands of their role for the Sponsor. They had regular internal meetings to share learnings and effectively manage capacity. Learnings were also shared with the Sponsor to further inform future studies and planning. The benefit to the Sponsor was that the Veramed Lead Statistician managed the team and their workload so there was no additional burden in headcount or line management responsibilities.

## Outcome

Veramed was able to provide additional internal resource for the increasing amount of vendor oversight requirements without the added burden of line management and training.

The Veramed team were viewed by the Sponsor as an integrated and valued part of their internal statistical team. The work was varied and interesting; as the trust with Veramed developed, so did the remit, with Veramed statisticians working alongside the clinical teams contributing to study design and other strategic project activities. The added benefit was that the Veramed team felt valued and therefore contributed to a high retention of staff. This also ensured the continuity of quality and a rapid transfer of knowledge to new team members.

# Case Study

## Provision of vendor oversight for biostatistics deliverables for a midsize pharmaceutical company

### The Writer



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Biostatistics Director

Emma is responsible for enabling the Veramed Biostatistics team to achieve the highest levels of quality from consultancy to reporting. Emma has a wealth of experience in vendor oversight, statistical consultancy and of clinical statistical analysis gained from a variety of leading global pharmaceutical companies. She has knowledge in both technical and non-technical aspects of study design and statistical analysis across clinical studies from Phase I-III and multiple therapeutic areas, including oncology, respiratory and immunology.

### The client says

*"It's a great pleasure to work with Veramed. They're enthusiastic and well organised. I feel entirely comfortable delegating responsibilities to Veramed and trusting that they will make the right decisions and flag important issues to me."*