

Case Study

VEEDA ONCOLOGY SALVAGES DATA WHERE OTHER CROs FALL SHORT

Overall Problem: A phase I, 75 subject study in patients with various hematologic malignancies, was conducted at two different CRO's over several years. Data sets were provided to Veeda Oncology that were merged from the two previous vendors. Veeda Oncology was tasked with providing tables and listings from this study that accurately reflected the results and conduct of the trial. Upon receipt of the data it became clear that several issues needed to be addressed. Adverse Event terms were either miscoded or not coded at all. Visit identifiers in the data sets were different between the two vendors and a visit key could not be provided. Local lab normal data did not correlate with the patient data. Many lab adverse events were not assigned a Common Toxicity Criteria grade. Coding of the concomitant medications was incomplete. The annotated case report forms did not accurately reflect the data panel structures and the Statistical Analysis Plan was incomplete.

Solution: All adverse events were reviewed for coding appropriateness and coding recommendations were provided to and accepted by the sponsor. Protocol defined visits were derived algorithmically based on dosing and other visit information; illogical dates were identified and were factored into the visit designation. A unique key was developed to correctly merge reported laboratory data with the appropriate lab normal information so that shift tables and adverse event grading of lab events could be reported. At various points in the generation of the tables and listings, lack of clear information in the data set descriptions and CRF annotations required the team to explore the true relationships in the data.

Results: Data was salvaged and correlated that allowed for the generation of total of 113 tables and 36 listings. The final product was delivered to the sponsor in 5 weeks, allowing them to complete the study report in time to meet their regulatory timelines and requirements.