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Case study

Tight Timelines with Regulatory Responses

In a study rescue, a sponsor brought on PharPoint experts to make 1 SDTM and 1 ADaM dataset and corresponding documentation in **the timeline requested by the FDA—5 days.**

The FDA requested a sponsor's biotelemtry report data in an SDTM/ADaM format. Before PharPoint's involvement, the sponsor had elected not to send the data with their submission, and their source data was in multiple excel files.

While developing the SDTM dataset and performing reconciliation with the CRF data, PharPoint identified data issues with the source data and informed the sponsor of these potential data issues.

PharPoint resolved these data issues, which involved getting additional excel files from the sponsor.

PharPoint delivered the request within the 5 day timeline.