propharma

CASE STUDY

transfer and manage clinical data provided by multiple third-party vendors

challenge

- Tight timelines for database go-live.
- Complicated (non-CDISC) format of third-party smartphone application data.
- Large amount of data (some smartphone applications collected data continuously resulting in tens of thousands of records per subject).

solution

- ProPharma deployed a data management team consisting of a lead data manager, database developer, and a data programmer to build the EDC system and finalize data transfer specifications for the 10 third-party vendors.
- Our team quickly identified all variables requiring capture within the CRF to complete the EDC build. We brought in a biostatistician to evaluate and identify the necessary data points collected from the smartphone applications to create simplified data transfer specifications which were executed and completed on time, prior to the first data transfer.
- In addition, we were able to coordinate a test transfer from each of the third-party vendors to ensure specifications were followed and matched the sponsor requirements.

results

- We were able to create, test, and implement third-party transfer specifications prior to first transfer of data allowing for an on time and accurate interim analysis which was crucial for the client's manufacturing decisions.
- Our data management team was able to complete the EDC build on time for the first patient visit.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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