propharma

case study

Biostatistics and Programming – more than just Clinical Trials – a Powerful Engine for Data Insight Generation

Service Area: CRS - Biostatistics and Statistical Programming

Learn how ProPharma's Biostatisticians and Programmers enabled a biotech company to derive more meaningful and actionable insights from their legacy data.

A small biotech had previously conducted three studies for a dermatologic drug. The data they had collected for these three trials had been used to derive insights on the pre-planned endpoints and nothing more. After several years, the company wanted to know if there were any additional insights (new objectives, different analytical methods, etc.) that could be derived from their data.

The biotech called on ProPharma to ingest the legacy data and to review if any meaningful and actionable insights could be derived from the data.

ProPharma's Biostatisticians and programmers were able to ingest, clean, and explore the data and ultimately were able to provide the biotech with several interesting and actionable measures to look at from the legacy data which could eventually lead to the biotech submitting applications for the drug with new label claims and in new sub populations.

> "We were able to quickly and efficiently intake the client's data and evaluate what types of analyses may or may not have been doable, from there we spoke with the client and determined which analyses were worth persuing."
>
> Bobbie Rachford VP of Biostatistics and Programming, ProPharma

challenge

A biotech company with a dermatologic drug had previously conducted three studies, all looking at roughly the same primary endpoint.

The company found these original results promising but was interested to learn if there were any additional insights which could be gained from these legacy studies.

The issue was, the sponsor did not know which (if any) meaningful insights could be extracted from the three study's data.

Lacking the ability to determine this internally, and no longer in contact with the original CRO that conducted the three studies, the biotech company turned to outside help.

solution

The biotech company selected ProPharma's RCO model for our specific focus on strategic input into various projects. For this client, ProPharma was able to quickly load the legacy study data in to our GXP validated analytics server and begin the data evaluation process.

To start, ProPharma first evaluated all of the available data points, what they represented, how they were defined, and how clean the data was for that specific variable (proportion missing, number and magnitude of outliers, etc.).

From this assessment we were then able to put forward several viable analyses which could drive meaningful and actionable insights for the client (new sub populations to look at, new endpoints, new timepoints, etc.).

The client was then able to review and determine which of these proposed analyses ProPharma should complete.

results

In all, ProPharma identified over 21 additional analyses which had potential to be meaningful for the client and the client selected 7 of these to pursue to start.

ProPharma produced all 7 outputs (tables and figures) and provided these to the client for their review and approval. Upon review the client approved all 7 outputs and requested the remaining 14 analyses to be completed.

These outputs were then used by the client for publications and lead to the initiation of a new clinical development program.

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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

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