Case Study

tranScrip

Leveraging Expertise in Clinical Translational Medicine

Challenge

A major pharmaceutical company faced a significant challenge in their nephrology drug development programme.

The company lacked sufficient internal resources and expertise in nephrology, a critical therapeutic area, to design a Proof-of-Concept (POC) study.

This knowledge gap threatened the timely and effective progression of their clinical development plans.

Solution

To address this challenge, the client engaged a tranScrip Subject Matter Expert (SME) in Clinical Translational Medicine, with a focus on nephrology, to join the client's project team.

The SME's involvement spanned the entire project lifecycle, providing comprehensive support in the following key areas:

Protocol and Statistical Design:

- The SME collaborated closely with the client's internal team to develop a robust study protocol. This included defining study objectives, endpoints, and methodology tailored to address specific clinical questions relevant to nephrology. The statistical design was meticulously crafted to ensure that the study could yield reliable and meaningful data.

Key Opinion Leader (KOL) Selection:

- Leveraging their extensive network and knowledge, the SME identified and engaged leading KOLs in nephrology. These experts provided invaluable insights into the disease area, patient populations, and study design considerations, enhancing the scientific validity and relevance of the study.

Site Selection:

- The SME played a pivotal role in selecting clinical trial sites. This included identifying sites with the necessary expertise, infrastructure, and patient access to ensure high-quality data collection and study execution.

Medical and Safety Oversight:

- Throughout the study, the SME provided continuous medical oversight, ensuring that clinical safety and efficacy data were accurately captured and analysed. This oversight was critical in maintaining the integrity and ethical standards of the study.

Study Reporting:

- Upon completion of the study, the tranScrip SME led the data analysis and reporting efforts. This included interpreting the study results and preparing comprehensive reports that were used to inform the client's decision-making process.

Outcome

The collaboration with tranScrip proved to be highly successful.

The expert's contributions were instrumental in revising and refining the study design, ensuring it met the project's scientific and operational needs.

The enhanced study design provided critical Go/No Go decision-making information, enabling the client's senior management to make informed strategic decisions about the future of the nephrology programme.

The study results offered valuable insights into the drug's potential efficacy and safety profile, supporting the decision to advance the development programme.

This outcome underscored the importance of having the right expertise at crucial stages of clinical development.

Conclusion

This case study highlights the impact of specialised expertise in Clinical Translational Medicine on the successful design and execution of a clinical trial.

By partnering with tranScrip, the client was able to fill a critical knowledge gap, optimise their study design, and obtain pivotal data that guided their strategic decision-making.

The collaboration not only addressed immediate project needs but also set a precedent for the value of external expertise in advancing complex therapeutic programmes.

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