Worldwide Clinical Trials

Case Study

Advancing a Rare Bleeding Disorder to Phase III Through Precision Data Operations

A biotech company developing innovative first-in-class, best -in-class treatments for rare bleeding disorders ran a global Phase Ib study in adolescents and adults with von Willebrand disease. The multi-dose, open-label trial (up to four cohorts) aimed to determine the optimal dose for Phase III. A key challenge was ensuring an on-time database lock to support a planned End-of-Phase II FDA meeting, alongside managing complexity across multiple international sites.

Challenges

Worldwide Clinical Trials was selected as the operational partner for the Phase Ib study and successfully resolved 3 key challenges:

1. On-time source data verification, query resolution, and Prinicpal Investigator (PI) sign off of all data to stretch targets for on time DBL
2. Accelerating query resolution in response to a client request to advance the timeline by three days ahead of the originally agreed target
3. With 6 days remaining, compressing delivery of all PI sign offs to a 3-day time-frame to support a sponsor request

Study Type

- Phase Ib
- 4 dosing cohorts
- OLE

Study Population & Indication:

- Adults and adolescents with VWD

6 Locations:

- United States
- Canada
- Brazil
- India
- South Africa
- Australia

Solutions

- The Worldwide team worked backward from the sponsor's DBL deadline to create a detailed timeline.
- Worldwide aligned project and site teams to ensure sufficient resourcing, enabling CRAs to focus on DBL-critical activities.
- All sites received clear, urgent communication to support DBL timelines.
- CRAs leveraged strong site relationships to set data entry deadlines, prioritize monitoring visits, and ensure rapid query and protocol deviation resolution, typically within 24 hours.
- The CRAs ensured PIs or delegates had EDC access and were available to approve casebooks by the target date.

Outcomes

- Worldwide completed SDV, resolved all queries, reconciled all PDs, and achieved PI sign-off ahead of the original schedule as requested by the sponsor.
- Timely completion of DBL allowed the sponsor to prepare for their scheduled end of Phase II meeting and support discussions of the dose to be used in the Phase III study.
- The Worldwide team remained flexible and successfully met both requests, allowing the sponsor's vendor more time and ultimately resulting in DBL occurring a day ahead of schedule.

Let Worldwide Support Your Next Hematology Study

Worldwide Clinical Trials can support your study down to the smallest detail. We bring our client-centered ethos to every partnership, designing service solutions that fit your specific needs. Contact us for more information on our hematology experience or to discuss your upcoming drug development program.

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