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CASE STUDY

From Drafts to First Patient in Record Time

Challenge

- Launching a full-scope global clinical study from the ground up posed a significant challenge, as the project began with only draft documents.
- Study setup started with a draft protocol in early January, while the final version was not received until March.
- Development of study-related documents, including ICFs, was impacted by working on these drafts.
- A global team needed to be established and over 10 key vendors coordinated, including a Sub-CRO for LATAM—entirely based on draft materials.
- The goal was to achieve First Patient In (FPI) in the US within just 3.5 months and to submit to regulatory authorities in Canada, UK, EU, AUS, and LATAM.

Solution

- The project management group maintained a clear focus on achieving FSA/FPI.
- Functional area heads were aligned on the goal, with PMs and team leads closely monitoring activities to avoid common errors associated with draft documents.
- A SmartSheet tool was developed to track progress across all functional areas and guide the next steps.
- Consistent internal communication and effective vendor coordination kept the project on track. Special attention was given to endpoint vendors and the LATAM Sub-CRO, which required additional onboarding, ProPharma trainings, and PM oversight.
- To meet US FPI timelines, fast-track sites were identified and supported by SSU and Clinical teams. For global submissions, daily communication among the Sponsor, SSU, and Regulatory teams ensured that all documents were proactively reviewed and finalized in a timely manner.

Results

- First Site was achieved exactly on schedule, as planned months in advance. First Patient In followed three weeks after site activation.
- Ambitious global submission timelines were met.
- The success demonstrated strong collaboration, effective planning, and focused execution.

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

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