Teams Come Together to Initiate a Study in Record Time

Dr. David Bernstein, a New York-based gastroenterologist, was attending an investigator meeting with his study coordinator. On the last day of the meeting on a Friday, representatives from the sponsor approached them to discuss a study that had a short turnaround. The participant recruitment window was closing soon.

Dr. Bernstein, who is a BRANY-certified investigator, and his coordinator were keenly interested in participating in the study. So they turned to BRANY for help. By the end of business that Friday, the BRANY team had a copy of the protocol and the regulatory package. On Monday the sponsor provided the remainder of the regulatory materials.

At BRANY, the entire team was alerted to the high priority of this project and they started processing the materials for BRANY's IRB, which meets twice a week. Using all available technologies, the BRANY team worked closely with the sponsor and the investigator to ensure all the pieces were in place for IRB review.

The IRB was notified of the urgency of the review and was able to include an addendum on its agenda. The IRB's main reviewer was able to contact all the parties in advance of the meeting to ensure they would be available to answer questions in real time during the meeting, rather than the traditional asynchronous methods of letters. The IRB issued a full approval of the protocol the same day as the meeting.

Divide and conquer

Concurrent to the efforts of the IRB review and regulatory processes, a BRANY team of financial analysts was working on the budget and the contract. With a motivated investigator and sponsor, the team was able to prepare a budget and secure approvals within one business day.

Because BRANY has prior relationships with both the investigator and the sponsor, much of the contractual legwork was easy. Rather than going through dozens of pages of legal documents, a master clinical trial agreement allowed the parties to develop a four-page contract addendum specific to the trial, which again allows for signing in a fraction of the time.

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The Biomedical Research Alliance of New York (BRANY) provides support services to sponsors and investigators in a wide variety of therapeutic areas, medical devices, biologic and diagnostic trials. Staffed by multi-disciplinary experts, BRANY is an AAHRPP-accredited "end-to-end solution" for clinical trials.

BRANY is able to offer turnkey solutions for:

- Site identification
- Expedited study startup
- Payor coverage analysis
- Central IRB
- Monitoring & auditing

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"The final rule is clear about institutions' responsibilities and accountability for oversight. Even fully staffed research offices may find the new regulations onerous."

Result

With the cooperation of the sponsor, the investigator and the IRB, BRANY's team was able to shepherd the entire study start-up in ten business days. This allowed the investigator and study coordinator to recruit participants within the window and to participate in the trial.

Keys to Success

A number of factors influenced the success of this effort.

- **Have a well-organized team with clear priorities.** The staff had clear direction that this study was a priority and they were able to focus their efforts throughout the process with minimal distractions. They were also able to keep the necessary tasks at the forefront. For example, rather than let a question or an issue linger for a business day, BRANY team members were able to follow-up every few hours until it was resolved.

- **Establish relationships in advance.** This includes having an investigator who had already undergone a rigorous pre-vetting process so all the necessary regulatory documentation about his qualifications and the research site's appropriateness for the protocol were already in place. This included having the investigator's curriculum vitae, as well as medical licensure and continuing education, updated in the database.

- **Work in a non-linear fashion.** Although there are specific processes in place to initiate a trial, the BRANY team was able to divide up the categories of work so various elements — regulatory, financial, and so on — could move forward in tandem.

- **Communicate expectations.** The investigator, the sponsor and the BRANY team were very clear about the timeline and expectations. This was essential to ensure rapid responses and resolutions to issues and questions.

- **Work lean.** Rather than long meetings in which everyone submitted their activities for the day, smaller teams met in "huddles" to discuss and work through streamlined agenda items. This ensured that meetings were relevant to all participants.

While a ten-day turnaround for the initiation of the trial is an extraordinary achievement, these lessons and processes can help organizations vastly improve their timelines.