Phase I Study Start-up: Working within tight timelines

The Challenge:
A client presented with a compound ready for a Phase I "First-in-man" study. The client had a Board-imposed deadline to submit their Investigational New Drug (IND) Application within two months and needed a Phase I protocol written and finalized to submit with the IND. Additionally, the client needed at least one site up and running within 30 days of the IND clearing the FDA.

The Solution:
By using the TD2 template, TD2 was able to produce the first draft of the protocol within 30 days. By fast tracking the review period TD2 and its client were able to finalize the protocol within 45 days, which was well within the timeframe for the client's goal IND submission date.

Utilizing the TD2 RFP template, TD2 was able to get RFPs out to preferred clinical trial vendors utilizing the finalized synopsis in place of a final protocol so as not to delay the tight timeline. The TD2 project manager assigned to this project summarized the vendor bids within 24 hours of receipt and presented them to the client for final decision. Once the protocol was finalized the selected vendor was asked to finalize their project budget and plan. Due to the tight timeline TD2 engaged the selected vendor to begin work under a LOI, after which TD2 and the vendor worked together closely to manage timelines and get the project up and running on time.

By using the sites that TD2 has previous experience with, TD2 and its client selected a site that had a history of faster start-up timelines. TD2 worked closely with this site to finalize the budget, the Clinical Trial Agreement (CTA) and IRB review all in parallel to as to reduce the start-up timeline further.

The Result:
The final protocol was ready prior to the IND submission. The clinical vendor was able to complete the database and project plans and was ready to go by first-patient-on. The site was able to complete the contract, budget and IRB review within 30 days of the IND clearing the FDA. This site initiation visit was completed and the first patient on study was accomplished within the client's three-month timeframe.