goBalto™

casestudy

Smart Start-Up

Combining Streamlined Processes & Leading Edge Technology

the challenge

A leading global contract research organization was contracted to conduct a two phase global oncology trial on behalf of a mid-sized Pharma company. The study was comprised of both phase I (dose finding and dose confirmation) and phase II (dose expansion) components. The original goal was to activate 20-25 sites for the phase I component and an additional 55 sites to be on boarded for phase II. By the time the protocol was received, sites had been selected and the First Site Initiation Visit (FSIV) was targeted to occur in less than five months. The core regulatory pack was due for finalisation within 11 days of receipt of the protocol.

the solution

The CRO applied site related knowledge regarding approval processes and the timelines for contract, budget negotiation and the sites' internal processes such as Scientific Review Committees, to determine they would not be able to achieve the FSIV target date within the US. Instead, based on the same knowledge and reverse engineering their SSU Planning Tool, it was determined that France was best placed to achieve FSIV. The National Coordinating Investigator (NCI) site was targeted specifically based upon their previous performance.

goBalto's value add

Use of the goBalto Activate system ensured all parties had real time access to the status at a document, site, country and study level ensuring study success.

This combined with the expertise of the CRO's team ensured that we were able to effectively target the sites for rapid start up to achieve the sponsor's goals.

First site was initiated in France within 144 days of protocol receipt CRO detailed knowledge of the start-up site's cycle times for internal reviews, contracts and budgets enabled them to specifically target the PI and site to be the National Coordinating Investigator (NCI)

Using goBalto's Activate to guide the SSU workflow, document progress and milestone achievement, along with process rigor regarding the reuse of site related knowledge due focus was given to completing budget/contracts and essential document collection in parallel with the regulatory and ethical review process. As a result the Central Ethic Committee (CEC) submission was completed on the aggressive due date, with the Regulatory Authority (RA) submission being completed ahead of plan. Queries were received from both the RA and CEC with fast response times implemented in order to continue working towards the planned FSIV date.

> *"We selected France for FSIV and beat our French median cycle time by 53 days (approx. 36% faster than median cycle time for France) and the last patient visit by 4.5 months*
>
> Marie Keegan
> VP and Global Functional Head
> Study Startup | ICON

the outcome

Using goBalto's Activate system combined with process rigor regarding the reuse of site related knowledge the NCI site in France was initiated on schedule with a further three sites in France being initiated within the same month. As a result the First Subject First Visit (FSFV) milestone was achieved days ahead of the client goal and First Subject First Dose (FSFD) achieved three weeks ahead of target. From this point on, site activations and recruitment exceeded plans with the patient recruitment goal being completed 4.5 months ahead of schedule. Having a dedicated start-up team, the transparency of start-up progress within Activate and the Analyze reports enabled the project manager and the sponsor to have real time access to study start-up progress.