STUDY START-UP AND ENROLLMENT

IQVIA™ Biotech's rapid start-up and enrollment sets course for successful oncology trial execution

SITUATION

IQVIA Biotech was approached by a clinical-stage biopharmaceutical company to run its Phase II prostate cancer drug trial in the U.S. The sponsor learned of our particular expertise in Genitourinary (GU) oncology, having supported the pivotal work for two prostate cancer drugs approved within the past three years, and received positive referrals from colleagues and clinics that had worked with IQVIA Biotech. The sponsor had expressed concerns regarding their experience with the previous Contract Research Organization (CRO) that was managing the ongoing Phase I study. The concerns were mainly centered on unsatisfactory attention from the project team, inadequate knowledge in the therapeutic area, frequent project team turnover, and lack of flexibility within a dynamic clinical environment. For the Phase II trial, the sponsor was searching for a CRO with an oncology-dedicated group, specific prostate cancer expertise, an ability to be flexible in implementation, and a willingness to provide transparency in the trial's execution. They valued the preliminary guidance and protocol input provided by IQVIA Biotech and selected us to begin work.

CHALLENGES

As with any clinical trial, there are always challenges to manage in order to meet sponsors' expectations.

- Multiple principal investigators from the Phase I trial wanted to influence Phase II protocol, sometimes with conflicting input.
- A challenging timeline to finalize the protocol, submit to the FDA and coordinate regulatory document versions.
- Most of the sites were academic, which are known to have lengthy negotiation histories.
- An aggressive First Patient In (FPI) goal of 10 weeks to get sites open, patients enrolled and a database live. This timeline was fixed by the sponsor to meet a corporate milestone tied to a funding event.
- An enrollment timeline of 12 months in an environment with many competitive trials.

SOLUTION

In order to meet the sponsor's compressed start-up timeline, our specialized oncology team worked to get enrollment started as soon as possible, holding the kick-off and data collection review meetings within a week of one another. The team provided input on the protocol to anticipate potential FDA concerns related to prostate cancer trials and guided the sponsor seamlessly through the start-up process.

SITE INITIATION

IQVIA Biotech's team applied its knowledge of key personnel, regulatory, contracts and budget processes at the selected sites in order to expedite FPI. The sponsor allowed our Site Contracts team to negotiate on its behalf, and provided fair negotiation parameters that minimized review cycles. Additionally, IQVIA Biotech

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>
> *— Director of Clinical Operations*

secured a waiver of on-site evaluation visits due to strong working relationships with several of the centers, thereby saving nearly three weeks.

IQVIA Biotech's clear understanding of the regulatory review process at each site enabled the sponsor to understand key priorities and milestones. Our Investigator Strategy & Site Coordination (ISSC) team impressed the sponsor with its ability to suggest mutually agreeable alternative language, and worked closely with the regulatory team to review and approve initial regulatory document packages, administrative letters and other IRB correspondence, shaving days off of expected timelines.

DATABASE BUILD

IQVIA Biotech held the online screen review of eCRF forms with the sponsor just one month after the kick-off meeting. From there, we created the initial Trial Design Document detailing all design specifications. The sponsor made one special request – they did not want to capture screen failures in the database and asked IQVIA Biotech to enroll each patient after the site entered the patient's information. The Data Management team created a unique CTM-PM enrollment user account to accommodate this request and was quick to create eCRF templates for the sponsor's approval.

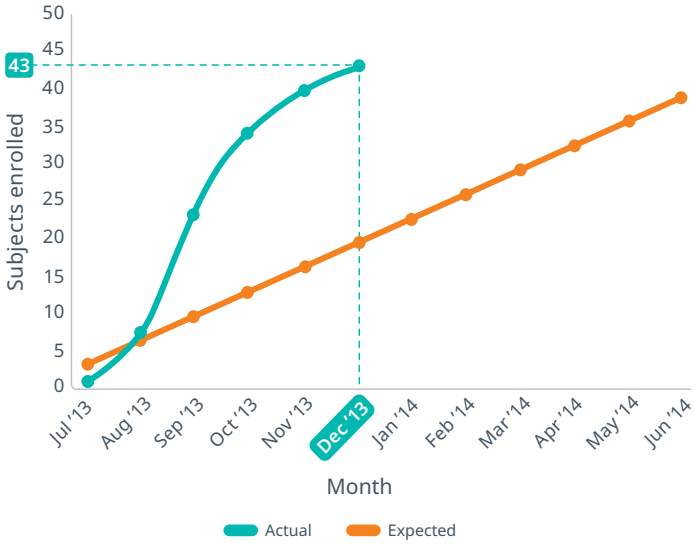
RESULTS

Not only were we able to meet the 10-week FPI goal along with a live database, but the sponsor was thrilled that patient enrollment was completed in four months as opposed to the one-year timeline originally projected.

- The Study Start-Up team had a solid understanding of running oncology trials and the specific nuances of a prostate cancer drug trial.
- The team was conscientious about working with academic sites to complete necessary documents for review and approval with a specific focus on a handful of "vanguard" sites we knew could initiate quickly to meet that corporate milestone.
- Additionally, the sponsor and IQVIA Biotech shared an excellent working relationship, collaborating to get the study off to a solid start and enroll patients quickly.
- Transparency existed throughout the entire process, including IQVIA Biotech's senior leadership. The teams trusted each other to meet goals set in the kick-off meeting, made adjustments as patient data came in faster than anticipated, and maintained continuity of the project team.

Interestingly, the sponsor was actively working with two other CROs, and given the overwhelmingly positive experience in comparison has chosen to work with IQVIA Biotech exclusively on a number of Phase II and Phase III trials.

Subject enrollment: Actual vs. expected



Patient enrollment completed in four months as opposed to the one-year timeline originally projected.
(Note: FPI on July 26; last patient consented on Dec. 12)

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