LEVERAGING EXPERTISE TO EXCEED IMMUNOTHERAPY CUSTOMER GOALS

IQVIA™ Biotech's creative approach speeds site initiation and database build

SITUATION

A private biologics company needed a specialized oncology CRO to manage its Phase I, multi-center study to evaluate the safety and pharmacokinetic (PK) profile of an immunotherapeutic drug in subjects with advanced solid tumors. The Senior Director of Clinical Operations was searching for an oncology-experienced clinical trial partner that could support protocol design and accelerate the start-up process to meet a quick First Patient In (FPI) milestone. Following a competitive review, the sponsor selected IQVIA Biotech based on our ability to deliver adaptive trial design, demonstrated extensive oncology expertise, flexibility and understanding of nuanced immunotherapy drug trials.

CHALLENGE

Every study has its unique set of challenges and, in this case, it was timing. The customer needed FPI of 60 days in order to meet an internal stakeholder commitment.

- Achieve FPI within 60 days.
- Complete and launch the database within four weeks so sites could begin enrolling subjects.
- A question from the FDA – and potential protocol amendment – occurred near the end of the 30 day review period creating a possible delay.
- The drug being evaluated was a PD-1 inhibitor, part of a new class of drugs that block PD-1 (programmed cell death protein 1) and activate the immune system to attack tumors. This complex compound and protocol called for specific expertise within the study team.

SOLUTION

The IQVIA Biotech Investigator Strategy and Site Coordination (ISSC) team created a comprehensive plan to manage the start-up process and meet the customer's expectations.

SITE INITIATION

IQVIA Biotech employed specific strategies in order to meet the goal:

- Site institutional review board (IRB) submissions were undertaken at risk. Based on an excellent working history with IQVIA Biotech, several Principal Investigators (PIs) were willing to identify potential subjects before the first site was open. IQVIA Biotech's established relationships with sites and investigators supported rapid site start-up, FPI and cohort enrollment.
- A strategic decision to utilize a mix of local and central IRBs dramatically sped up the process. The team selected some academic centers that could use a central IRB for the last review to save time.
- IQVIA Biotech leveraged excitement and interest around the immunotherapy drug to motivate investigators and increase commitment to the protocol.
- The ISSC team identified sites and PIs with working knowledge of complex PD-1 inhibitor compounds to ensure they could recruit appropriate patients.
- Changes from the FDA were very minor following submission of the final protocol. However, the sponsor received a question from the FDA near the end of the 30 day review period that could have required a

protocol amendment. A member of IQVIA Biotech's ISSC team was experienced in the specifics regarding adding serial ECGs to the study. IQVIA Biotech worked closely with the sponsor to find a solution and draft a response. The FDA was satisfied with the feedback and approved the original protocol, thereby avoiding delays.

> *"I was impressed by IQVIA Biotech's oncology expertise and knowledge of PD-1 inhibitors. IQVIA Biotech's data and ISSC managers provided invaluable counsel in constructing the study in a way that would meet our tight FPI goals. We were very pleased with the results."*
>
> *— Senior Director, Clinical Operations*

DATABASE BUILD

IQVIA Biotech's Data Operations team worked within a tight timeframe to launch the database in time for patient enrollment. The team's creativity and flexibility enabled IQVIA Biotech to work at risk and complete the database build within 30 days, as opposed to the typical 90 days.

- IQVIA Biotech's data manager made the decision to run a split deployment and began work on form development based on the draft protocol.
- The team collaborated with the sponsor to incorporate several unanticipated changes related to PK analysis, thereby avoiding delays.

RESULTS

- **FPI achieved ahead of schedule;** only eight weeks after the final protocol was signed. The first cohort enrolled three weeks later.
- **The database Go-Live occurred just 30 days** after the protocol was complete, allowing plenty of time to begin subject enrollment before the end of the year.
- **The sponsor's response to FDA comments was satisfactory and did not require protocol amendment** – a huge success for the sponsor.
- IQVIA Biotech's hands-on approach and **executive oversight** kept the study progressing.
- IQVIA Biotech developed a strong working relationship with the sponsor, facilitating timely reviews. The sponsor worked directly with the ISSC team to make decisions quickly, preventing unnecessary delays.

IQVIA Biotech devised two important strategies to speed study start-up including split deployment of the database build and utilizing a mix of local and central IRBs. The sponsor was thrilled to meet a critical FPI milestone before the year's end.

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