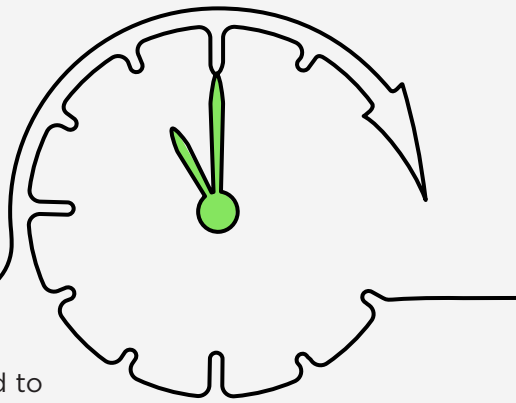
Worldwide Clinical Trials

Case Study

Accelerating Study Startup: A Case Study on Effective Site Activation in Oncology



A pharmaceutical company conducting a Phase III melanoma study aimed to achieve rapid timelines in a competitive indication. The company turned to Worldwide Clinical Trials, which leveraged its global network of sites, transparent communication, and proactive onboarding approach to expedite trial startup and site activation, delivering results beyond the sponsor's initial expectations.

Study Challenges

01 Short Timeline for Site Activation

The sponsor mapped out an aggressive timeline for their study. After initiating site feasibility in the third quarter, the sponsor asked for the first site to be active by the end of the year.

02 High Competition for the Same Population

Many trials, both ongoing and soon to start, were competing for the same sites and patient population. Worldwide needed to work closely with sites to secure interest and keep them engaged.

03 Unique Selection Criteria with High Site Burden

The study required patients to be observed overnight, severely limiting the potential pool of sites. Sites needed to have the facilities and personnel to support this protocol requirement.

Together, these factors initially suggested that no sites could meet the desired timelines due to the internal processes of the sites that were interested in participating. Worldwide would need to provide a carefully crafted, targeted site activation strategy to meet the sponsor's aggressive timelines.

Worldwide's Solutions

1

Leveraged Established Site Relationships

Worldwide began site feasibility in the third quarter and aimed to achieve the expectation of the first site activated in the fourth quarter. Through our understanding of the competitive arena for melanoma studies and a desire to avoid a lengthy activation process, Worldwide focused on "fast starter" sites with a previous history of successful partnerships. We strategically targeted two sites in Australia that could fulfill fast turnaround times due to fewer bureaucratic hurdles and more streamlined operations. Our strategic site selection process allowed for a shortened feasibility period with known sites; this adaptation was critical in meeting otherwise unattainable deadlines.

2

Worked Closely with the Sponsor and Maintained Transparent Communication

Worldwide established a dedicated escalation team of executive leaders to ensure timeliness and quality operations to meet the rapid timeline. It was critical to keep the sponsor updated about the requirements, risks, and progress of the study startup phase — at many points, communication took place daily.

This level of transparency ensured that all parties were aligned and could swiftly adjust to any changes or challenges. This synergy was crucial for effectively mitigating issues and maintaining the momentum toward achieving early site activation. It is reflective of our approach to collaboration and transparent communication.

3

Proactively Began SIVs and Other Work Ahead of Approvals

Worldwide adopted a proactive approach to onboarding. Our experts mapped out Site Initiation Visit (SIV) timing via planning in anticipation of upcoming approvals before finalizing all the documents. This "at-risk" practice considered the expected timeframe for each part of the activation process, allowing us to work ahead of standard regulatory approvals to ensure a seamless trial start without lost time.

Unlike traditional approaches, which create inherent slowdowns, we leveraged long-standing site relationships, beginning SIV and associated conversations in anticipation of standard approvals and agreements to streamline this sequence, significantly reducing the usual time required.

The Results

Fulfilling the aggressive expectations, Worldwide successfully activated not one but two unaffiliated sites the third week of December, despite beginning site feasibility only a few months before. This achievement outpaced typical site activation timelines and set a positive precedent for the rest of the study.

The early site activations exceeded the sponsor's expectations and contributed to a strong start to the study's operations. The study is currently recruiting patients and onboarding additional sites. Due to the highly collaborative approach and successes, the sponsor has contracted Worldwide for a second study, and conversations are underway for additional studies.

Worldwide Clinical Trials

Why Worldwide?

Worldwide is a leading full-service global CRO that offers innovative end-to-end customized solutions in partnership with biotechnology and pharmaceutical companies. Founded on an unwavering commitment to therapeutic excellence and personalized attention, we bring scientific expertise, a specialized and flexible oncology team, and a shared passion for advancing new medicines from discovery to reality.

Explore what an accelerated site activation could look like for your study by contacting us today.

Last Update: 06272024