Accelerating Clinical Trial Excellence: A Seamless IRB & IBC Collaboration

For certain cell & gene therapy trials, the intersection of Institutional Review Boards (IRB) and Institutional Biosafety Committees (IBC) is critical for success. This case study illuminates the triumph of WCG in partnership with a Top 10 CRO to fast-track a large, complex clinical trial start-up. Together, they navigated the intricacies of a high-impact project – a groundbreaking vaccine study funded by Biomedical Advanced Research and Development Authority (BARDA).

BACKGROUND

WCG initially engaged in strategic discussions with the CRO's study start up team and together determined that this vaccine trial is Human Gene Transfer (HGT) research as defined by the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines), thus requiring biosafety committee oversight. WCG and the CRO therefore pursued a strategy to maximize efficiency of parallel IRB and IBC approvals. The project would cover 100 sites with ambitious timelines. Proactive initiatives and established relationships facilitated the initiation of this groundbreaking collaboration.

STRATEGIC APPROACH

Navigating the complexities of a large-scale clinical trial demands a strategic and forward-thinking approach. Aware of the project's multifaceted challenges, WCG adopted a series of strategic initiatives that laid the foundation for a robust collaboration with the CRO.

1 **Relationship Building Around Established Expertise**

Recognizing the importance of relationships, WCG engaged in strategic discussions with the CRO's study start-up team, fostering an environment of trust and collaboration. This relationship-driven approach was complemented by WCG's well-established expertise in IRB processes, setting the stage for a partnership based on competence and reliability.

2 **Proactive Site List Review**

Anticipating the need for comprehensive support even before the formal project award, WCG proposed an innovative site list review. This preemptive measure showcased WCG's foresight and served as an introduction to the power of their services. By dissecting the intricacies of potential sites, WCG was able to effectively demonstrate how their approach could streamline processes and enhance efficiency.

3 **Maintaining Adaptability**

Acknowledging the complexity of this trial, WCG recognized that success is dependent on the ability to remain flexible and agile. The ability to assimilate SOPs, coupled with a willingness to understand and accommodate the unique needs of each site, played a pivotal role in meeting aggressive milestones.

4 **Focused Communication and Transparency**

The strategic approach needed to extend beyond technical aspects to communication and transparency. WCG prioritized clear and concise communication channels, ensuring that all stakeholders were informed and engaged throughout the process. This level of transparency not only facilitated smoother interactions but also instilled confidence in the CRO regarding WCG's dedication to achieving mutual success.

ADAPTING TO SITE NETWORKS

An additional layer of complexity emerged as the CRO identified two site networks to participate in the trial. The key to success was integrated project management by WCG's IRB and IBC teams. This involved frequent enterprise-level communication between IRB and IBC project managers, as well as project leaders at the CRO and the site networks. Additionally, each clinical trial site was assigned a WCG Biosafety Analyst who provided individual site-level guidance and personal assistance through the approval process. Throughout this project, WCG enhanced transparency and understanding of site network needs and processes while increasing site comfort and familiarity with IBC reviews.

INNOVATIVE SOLUTIONS

WCG approached this project with innovative solutions, pushing the boundaries of conventional regulatory timelines. An inventive approach was implemented, resulting in a significant reduction in turnaround times. Central to this success was the deployment of a weekly IRB and IBC Site Tracker, which was shared weekly to provide progress of ongoing site activation. The Site Tracker not only streamlined communication but also addressed site-specific issues promptly. The coordination of parallel IRB and IBC reviews streamlined the operational processes, while white-glove service coupled with proactive site support ensured any issues that arose were quickly mitigated. These innovative approaches fostered a collaborative environment that ensured synchronized efforts between the IRB, IBC, and the CRO.

RESULTS AND IMPACT

The collaborative efforts of WCG's IRB and IBC teams set the standard for a commitment to accelerated workflows and the surpassing of critical milestones in clinical trial management. Achieving an average IRB review time of two days for the study level, and just one day for each site, showcased an unwavering commitment to efficiency. Notably, the teams secured approval for the first site well ahead of schedule, setting an ambitious tone for subsequent successes.

For the IBC teams, the focus shifted towards meeting stringent deadlines, notably the tight timelines associated with the BARDA grant. WCG's emphasis on agility and effectiveness was showcased by a remarkable achievement of securing approvals for 60 sites before the crucial deadline. This accelerated pace not only met the project's timelines but positioned WCG's IRB and IBC teams as reliable partners capable of navigating clinical trial complexities with exceptional proficiency.

Large clinical trials incorporating genetic transfer must consider the coordination of IRBs & IBCs for accelerated start up. Thankfully, WCG is the pioneer in centralizing these processes. For more information, please click below.

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