CASE STUDY

World's Largest CRO Leverages Partnership With Integrated Central IBC to Initiate Sites in COVID-19 Vaccine Research at Warp Speed

Executive Summary:

IQVIA understands what it takes to rapidly launch studies with genetically engineered therapeutics and vaccines. Advarra provides the world's leading integrated IRB and IBC research review service. Working together, the organizations partnered to advance Operation Warp Speed vaccine trials and deliver a concierge-level of service to sponsors and clinical research sites.

The result: Rapid advancement of life-saving, innovative COVID vaccines and other gene therapies.

About IQVIA:

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. Formed through the merger of IMS Health and Quintiles, IQVIA applies human data science—leveraging the analytic rigor and clarity of data science to the ever-expanding scope of human science—to enable companies to reimagine and develop new approaches to clinical development and commercialization, speed innovation and accelerate improvements in healthcare outcomes. Powered by the IQVIA CORE™, IQVIA delivers unique and actionable insights at the intersection of large-scale analytics, transformative technology and extensive domain expertise, as well as execution capabilities. With approximately 68,000 employees, IQVIA conducts operations in more than 100 countries.

Case Study: How Leading CRO Accelerated Vaccine Development to "Warp Speed"

The Challenge

IQVIA delivers world class site activation timelines, consistently achieving first patient/first visit performance for sponsors. The COVID-19 pandemic forced IQVIA to reimagine what was possible as it became clear traditional timelines would not be sufficient to move the new COVID vaccines through clinical trials and to the public at warp speed. As an added level of complexity, the research projects would involve a new class of vaccines involving genetically engineered compounds. U.S. NIH Office of Science Policy Guidelines on Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) and the requirement for institutional biosafety committee (IBC) review in addition to IRB would apply. A new level of collaboration between sponsor, CRO, sites, and oversight committees was needed to achieve desired results.

The Ask

Because of the accelerated approval timeline for a COVID vaccine, IQVIA had to move fast. Patients' lives and the country's economic livelihood depended on getting the vaccine candidate into clinical trials quickly. Sponsors expected approvals and turnaround times at warp speed without sacrificing safety, quality, and oversight so they could turn study data over to the Food and Drug Administration (FDA) as quickly as possible.

IQVIA needed to work with an IRB and IBC partner who could accelerate review times so the COVID vaccine trial sites could progress through site selection, IRB/IBC submission, approval, drug shipment, and complete site initiation visits in record time. Many sites were new to research using genetically engineered compounds, and needed education on the IBC process and product handling standard operating procedures (SOPs). The IRB and IBC partner also needed to work directly with the IQVIA site activation teams to coordinate all reviews, so first patient/first visit at each site could occur rapidly after the site initiation visit (SIV) was complete. This ask required a superior level of collaboration and performance between everyone.

Integrated IRB/IBC Service Delivered Exceptional Results:

First Patient/First Visit

7 days (global median across COVID vaccine trials) approval to SIV/patient enrolled

IBC Turnaround Time

Average 1.8 days from complete submission to approval

100% of Operation Warp Speed vaccine clinical trials supported by Advarra IRB/IBC

The Solution

IQVIA partnered with Advarra to provide integrated IRB and IBC review. Advarra offers the world's largest integrated IRB/IBC review service combined with the Gene Therapy Ready™ site network specifically designed to support research involving recombinant or synthetic nucleic acids, messenger RNA (mRNA), and other genetically engineered compounds. IQVIA worked directly with the IRB and IBC operations teams to lay out a schedule of site reviews along with expected deadlines for site initiation. Advarra supported the research sites who were new to this type of research in developing their site-level operating procedures for handling genetically engineered product. Sites were able to pre-stage their IRB and IBC applications by taking advantage of Advarra's Center for IRB Intelligence (CIRBI) Platform. Turnaround times were closely tracked by Advarra's dedicated client success partner working directly with IQVIA's site activation team. IRB and IBC approval documents were posted in real time with immediate notification to the sites and IQVIA team.

The Result

By partnering with Advarra, IQVIA reduced study startup timelines and delivered trial results to the sponsor quicker than expected. Together, Advarra and IQVIA moved the vaccine candidate through clinical trials at warp speed.

Advarra worked directly with sites and the IQVIA study activation teams to proactively prepare IRB and IBC materials. IBC approval timelines were reduced to under 2 working days. Study drug shipments, site initiation visit times, and IRB/IBC reviews were tightly coordinated with IQVIA. In many cases, IRB and IBC approval letters were posted during the SIV, and, through IQVIA's "White Glove" process, research sites could enroll an interested participant the same day the SIV concluded.

IQVIA's sites averaged 78% faster approval than non-COVID sites and activated sites to "ready to enroll" 71% faster than non-COVID sites, with patients enrolled the same day as site activation.

> **We were on an incredibly tight timeline and looking for a trusted partner with a one-stop solution for IRB and IBC. Advarra's IBC services provided the full-service piece of mind and integration with IRB I was looking for. From the dedicated client success partner to Sergio Armani (Vice President of Large Pharma and CRO Business Development) and James Riddle (Vice President of Research Services and Strategic Consulting) working behind the scenes to care of everything with thoughtful and frequent communication, our team truly felt supported, and we were able to deliver for our sponsor. For me, it was peace of mind knowing that IRB and IBC were handled so I could focus our team on activating sites and advancing research.**
>
> **Rick Fisher**
> *Global Head of Site Activation Managers*
> *R&D Solutions Operations*

To learn more, download our IBC and Consulting Services Info Sheet
or contact us at BusinessDevelopment@advarra.com

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