WHITEPAPER

# Why Biotech Sponsors Need Outside Support: IRB, IBC, DMCs and EACs

Emerging biotech companies must navigate the complexities of the development and approval process for drugs, biologics and devices — often with no previous experience.

Do they need an IBC? An EAC? Can they find partners who understand their therapeutic area? Sometimes the fate of the company, not just the product, hangs on the right answers to such questions. With limited pipelines and significant market pressures, these companies often have just one shot at a successful study. Most vendors lack the necessary therapeutic and scientific expertise to navigate the complex development landscape, so the selection of the right partner is critical. Without proper guidance, a biotech company faces significant risk to study and investor timelines.

WCG has the expertise, experience and technology to guide emerging biotechs through the journey. From oncology and CNS disorders to macular degeneration and autoimmune diseases, WCG understands the therapeutic areas, the technology, and the regulatory issues. We know the sites, and we know the subject matter experts.

You need a full-service partner to stand by your side. We'll provide the right mix of services and resources, and we'll stay with you the entire journey. A dedicated WCG team will work with you to ensure the best possible trial results, and you will have a single point of contact. You will always have access to our top professionals.

An important early step is Institutional Review Board (IRB) approval.

## DO YOU NEED AN IBC *AND* AN IRB?

Biotech sponsors working in gene transfer will likely need IRB review and Institutional Biosafety Committee (IBC) review. One IRB can review a protocol for multiple sites. However, each site needs an IBC.

IRBs protect the rights and welfare of research subjects. IBCs focus on protecting the staff, community and environment. IBCs review and approve research proposals involving recombinant DNA, synthetic nucleic acid molecules, and other potentially hazardous biological materials.

**Determining the need for an IBC**: The first important challenge is determining whether your study requires an IBC. National Institutions of Health guidelines spell out when IBC approval is required, but the applicability of these guidelines may not be immediately clear. Sponsors can be caught off-guard. For instance, a sponsor that assumes that the guidelines apply only to gene therapy may be unprepared to roll out an mRNA vaccine, an oncolytic virus or CAR-T cells. We help determine the type of review your product requires and make sure you are ready to meet all compliance issues.

**Ensuring a clean pharmacy manual:** Often, the operations team doesn't create the pharmacy manual until the last minute, creating a cascade of delays. The manuals also fail to consider the reality of administering the biologic product at a site. Equipment, storage facilities, and the site team's level of experience and training vary across sites. Thus, there's much more involved than writing a policy manual. Because each site is different, it's essential to prepare the site staff in advance.

We can help ensure that your pharmacy manual and product handling instructions are ready to deploy and quickly approvable, avoiding delays and ensuring compliance with guidelines.

**Assessing prospective site lists:** Studies requiring an IBC face an array of other site-related issues that WCG can support. We can evaluate your site list to ensure that you choose registered, well-equipped sites capable of rapid start-up, enabling you to meet your investors' expectations for patient enrollment.

- **Registration:** Does the site have an NIH-registered IBC? Sponsors need to develop timelines based on which sites are ready to go and which ones require registration. IBC registration can take several weeks.
- **Site readiness:** Do the sites have the necessary equipment and training in place for the specific agents involved

in your trial? You need to consider such factors as fire safety levels and risk groups. This requires specialized expertise, which WCG has.

- **Parallel review:** Large institutions with their own IRBs may have slower start-ups because they conduct IBC and IRB review sequentially. There's no reason to do this: We can help you find sites capable of conducting rapid parallel reviews. This allows you to initiate your trial promptly and then later approach larger academic centers. Another option is to choose a center that defers to WCG. Coordinating the reviews helps ensure efficient and thorough turnaround.

Working with a partner who can evaluate prospective sites and ensure they are registered and well-equipped can save time and resources and ensure that investors' expectations for patient enrollment are met. We can provide the necessary support to ensure you are well-equipped to navigate the approval process and meet your milestones. With our help, sponsors can identify registered, well-equipped sites capable of rapid start-up and ensure that investors' expectations for patient enrollment are met.

We can also help you determine the need for an Endpoint Adjudication Committee (EAC) and/or a Data Monitoring Committee (DMC).

## SCIENTIFIC REVIEW: EACs and DMCs

EACs and DMCs ensure the integrity and quality of clinical trials, assessing safety, and efficacy. Some studies require one or both; details are outlined in the FDA's guidance, "Establishment and Operation of Clinical Trial Data Monitoring Committees." Each is made up of independent experts charged with reviewing data, but the role and purpose are different and requires expert management and precision.

The primary role for an EAC is to determine if a clinical event meets pre-defined criteria. They look at patient-level clinical events or events of interest to provide an independent, consistent, objective and unbiased assessment throughout the trial. They often review unblinded data.

DMCs monitor the progress, safety and efficacy of ongoing clinical trials. They review interim unblinded data to determine whether the trial should continue, be modified or stopped early. Here, the right statistical and medical expertise is essential.

WCG can help biotech companies understand the complexities of clinical research and the critical oversight roles the EACs and DMCs play. We have the largest committee-dedicated staff in the industry, and we've been doing it longer than anyone else.

**Assessing the need for a committee**: Not all studies will need a DMC. Factors to consider when deciding to establish a DMC include the risk to trial participants, practicality given study timelines, the study design, and existence of a preplanned interim analysis for futility or efficacy. Similarly, not all studies require an EAC, because not all events need to be adjudicated. We can help you determine whether your study needs an EAC, DMC, or both.

**Expertise and guidance**: Partnering with an independent provider like WCG ensures access to a team of experts who can guide the process, from identifying committee members to setting up the committee and outlining the necessary steps. Finding the right specialists with the necessary expertise for their specific therapeutic area is not easy, but WCG has these experts at our fingertips. Our global network of more than 1,200 medical, safety and statistical experts across therapeutic areas is unmatched. We can look at a therapeutic area such as macular degeneration and assemble a committee tailored to that condition.

**Independent review**: Sponsors must keep an arms-length relationship with committees and committee members, which is why independent expertise is so important. You want to avoid unintentional bias and the perception of bias. Neither you nor your CRO has the distance to do this.

**Charter development**: A well-crafted charter, based on best practices for DMCs and EACs, is essential for a successful committee. WCG can provide charter templates that clearly outline processes, review criteria, and the handling of recommendations.

Committee Composition
(independent therapeutic experts)

Charter & Regulatory Grade Documentation

Event Identification Strategy

Aggregate Data (DMC) or Event packet compilation (EAC

Working backwards from critical study timelines

Technology Enabled Workflows

Data to Drive Results

## DMCs ALSO NEED

- **A way to manage blinded data**: Committee members need a secure, restricted virtual location to review data while keeping the sponsor blinded to the study. We provide this and equip committee members with easy-to-use technology and decision-support tools. We also help biotechs establish clear pathways and processes for receiving and acting on DMC recommendations. This helps maintain study integrity by preventing unblinded data from being prematurely shared with the study team.
- **Quality statistical support:** DMC members need a clear, informative and accurate statistical report. WCG is widely recognized by Sponsors and DMCs alike for the accuracy and clarity of our monitoring reports. We draw upon our history and expertise to efficiently create appropriate analyses and data presentations that allow DMCs to deftly make an informed decision.

All of this ensures streamlined, predictable scientific review.

## PULLING IT TOGETHER: SPEED, QUALITY, PREDICTABILITY AND RISK MITIGATION

Whether we're talking about EACs, DMCs, IRBs or IBCs, biotech sponsors need speed and predictability.

Delays in one area can ripple through the entire trial planning process. A full-service partner with a consultative approach can provide crucial support and ensure predictability. This allows emerging biotech sponsors to meet and minimize delays in start-up, patient enrollment and other key milestones.

Trust WCG to provide the necessary support throughout the approval process and help you navigate the challenges of clinical research.

WCG has the people, processes and technology to ensure that scientific review is done right. We're the only company that can make such a claim. Find out how.

**CONTACT WCG**