Buchanan Ingersoll·Rooney

FDA AND BIOTECHNOLOGY

CLINICAL TRIALS TO SUPPORT DRUG, BIOLOGIC, AND MEDICAL DEVICE APPROVALS

Navigating One of the Most Critical Steps in Bringing FDA-Regulated Products to Market

Properly preparing for and conducting a clinical trial to test a new drug, biologic, or medical device is no easy task. From complying with FDA's regulations for Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications to managing complications that may arise during and after the clinical trial, the process can be daunting. Our life sciences team has decades of experience helping sponsors in the pharma and medical device industries get their products tested, approved, and on the market.

How We Can Help You

Securing FDA authorization of an IND or IDE to begin human clinical testing is not as simple as submitting a clinical trial protocol and hoping for FDA authorization. It requires a great deal of planning and working with experts. These experts are vital in assisting a sponsor during meetings with FDA, when preparing IND or IDE submissions, and when managing delays that might arise. Combine these efforts with the complexities of drafting a clinical trial protocol in the first place, and the need for regulatory and legal experts to move a clinical development program forward becomes even clearer.

IND and IDE Application Support

Our attorneys have extensive experience advising clients on a variety of FDA regulatory applications, including INDs and IDEs. This process requires that sponsors submit to FDA all of their existing pre-clinical data; information on the product's intended use, route of administration, and dosage; and proposed clinical trial protocols. Our attorneys work with sponsors to request FDA meetings to discuss an application, prepare INDs and IDEs, and assist with required annual updates to FDA.

Clinical Hold Assistance

Not every clinical trial goes exactly as planned. Difficulties can arise and, when they do, FDA may place a study on clinical hold until the FDA's questions are answered and any issues are addressed. Our team acts as the conduit between our clients and the FDA to resolve the regulators' concerns, get the clinical hold lifted, and keep the clinical trial process moving forward.

Managing Relationships between Sponsors and Clinical Trial Partners

Sponsors often outsource clinical trial management and oversight to a contract research organization (CRO). Even though the CRO may be working with clinical trial sites to conduct the trial, the sponsor remains responsible for how a clinical trial is conducted and any problems that may occur. Our attorneys can advise sponsors about how to select a CRO that meets the sponsors' needs and can help prepare contracts with these partners.

Informed Consent and Expanded Access / Compassionate Use

As part of the clinical trial process, sponsors must acquire informed consent from all participating study subjects. Our teams help to develop and review informed consent documents that meet FDA requirements to ensure that subjects are aware of the risks and benefits of participating in a clinical trial. Our attorneys have also worked with FDA to secure expanded access (i.e., compassionate use) authorization to provide a patient who is suffering from a life-threatening illness with access to an experimental drug if clinical trial participation is not feasible.

Decentralized Trial Structuring

Decentralized trials allow subjects to participate in trials from the convenience of their own homes rather than having to travel to a clinical trial site. Although not appropriate in all circumstances, decentralized clinical trials provide greater flexibility for participants with the goal of increasing enrollment numbers and increasing subject diversity. However, decentralized trials often require partnering with a CRO, which adds a different set of complexities from a traditional clinical trial model. Our teams work with sponsors to address whether this model may be right for the sponsor.

Cybersecurity and Data Privacy Protection

Cyberattacks and data privacy concerns have become one of the biggest threats to businesses of all types – and the pharmaceutical and medical device industries are no exception. In fact, FDA has issued a number of new guidance documents that address software cybersecurity issues for complex medical devices. From potential HIPAA violations to compromised data, ensuring clinical trial data is protected is critical. Our life sciences team works in conjunction with our cybersecurity attorneys to assess and improve your protocols, policies, and procedures for protecting access to subject information by bad actors.

Advancing Our Clients' Goals

Assessing International Data for FDA Use

Clinical trials have become a global enterprise, even if a sponsor is located in the U.S. We have worked with clients that have generated data from clinical trials conducted in Europe and Asia to help them determine what can be used with FDA approvals and what, if any, additional details or studies may be needed.

Helping Lift Clinical Holds

We have assisted clients with responding to clinical hold letters from FDA, helping them provide the information required to get the hold lifted and their trial back on track. Our life sciences team also includes government relations professionals who can work with members of Congress who serve on critical committees or subcommittees, or who represent the district where the client is located, to ask questions of FDA if the sponsor's efforts alone are not proving fruitful.

Untangling Complex Legal Issues

The life sciences team has been involved in a number of cutting-edge clinical trial issues, including working with the National Institutes of Health (NIH) when an NIH clinical researcher works with a private-sector company on a drug development program. In these cases, complex questions about data ownership and clinical trial oversight may arise that require experts who can untangle the many legal and regulatory issues that often ensue.

Preventing Fraud and Abuse

Enforcement in the life sciences space has ramped up in recent years, with the DOJ making it abundantly clear that fraud in the pharmaceutical industry, especially during the clinical trial process, will not be tolerated. By working with the right legal counsel, life sciences and healthcare companies, along with private equity firms, can head-off any issues before they turn into more serious investigations and other legal challenges.

OUR TEAM

BARBARA A. BINZAK BLUMENFELD, PH.D.
Life Sciences/FDA
Email: barbara.binzak@bipc.com
P: 202 452 7906

TINA HU-RODGERS
Life Sciences/FDA
Email: tina.hu@bipc.com
P: 202 452 7308

PAMELA E. HEPP
Healthcare, Cybersecurity & Data Privacy
Email: pamela.hepp@bipc.com
P: 412 562 1418

MICHELLE GARVEY BRENNFLECK
Healthcare
Email: michelle.brennfleck@bipc.com
P: 412 562 1822

ROBIN L. DIERBECK
Corporate
Email: robin.dierbeck@bipc.com
P: 202 452 5475

SUE C. FRIEDBERG
Cybersecurity & Data Privacy
Email: sue.friedberg@bipc.com
P: 412 562 8436