OUR PRACTICE

Medical Research/Clinical Trials and Risk Management

Fueling Innovation: Legal Excellence for the Life Sciences

At Baker Donelson, we go beyond conventional legal services. We are your trusted partner on the path to innovation, bringing unparalleled insight into the complex ecosystem of clinical research and development. From novel startup ventures to established industry leaders, our team adapts to meet the unique demands of each client with precision, dedication, and a forward-thinking approach.

Why Choose Baker Donelson?

Every clinical trial tells a story of potential breakthroughs, demanding meticulous legal and regulatory guidance. We do not just manage risks; we anticipate them, enabling our clients to focus on science and innovation. Our dedicated team handles everything from early-phase trials to post-market studies, ensuring your clinical research aligns with industry standards and exceeds them.

Innovative Contracting Solutions: Streamlined processes reduce delays and cut through complexity, setting a new standard in contracting. We bring efficiency to the table, with template agreements, playbooks, and pre-negotiated terms for quicker study site engagement.

Global Reach, Tailored Proficiency: Clinical research today is a global endeavor. Our team's proficiency in international regulatory frameworks, including the General Data Protection Regulation (GDPR) and other data privacy laws, allows your research to move forward confidently – wherever your trials lead.

Safeguarding Innovation: Compliance and protection are our watchwords. From managing FDA and HHS requirements to safeguarding your intellectual property, we ensure your investments are secure as your discoveries move from lab to market.

Holistic Support for Every Stakeholder

We understand the unique needs of each player in clinical research. Whether it's facilitating site enrollment, advising on indemnification, or building scalable compliance frameworks, our team serves as an extension of your own, collaborating with internal teams to keep trials on track and on budget.

The Baker Donelson Difference

We know that your intellectual property and data are among your most valuable assets, and we are dedicated to safeguarding them as your research advances. With a multidisciplinary approach, we stay ahead of trends impacting the life sciences industry, like real-world evidence and data, decentralized trials, and artificial intelligence (AI), so our clients remain compliant, competitive, and agile. We combine in-depth legal knowledge with a business-focused perspective, equipping you to navigate clinical research's evolving landscape with confidence. We are more than legal advisors; we are strategic partners committed to protecting your innovation pipeline.

Our experience spans a breadth of critical areas:

- **Formation of Clinical Research Enterprises:** We have years of experience assisting clients with the formation and growth of clinical research enterprises including dedicated clinical research sites, CROs, SMOs, and CMOs, and we can provide practical and real-world advice to executives on how

to navigate the many legal and business risks associated with operating in the industry.

- **Orchestrating Complex Partnerships**: We excel in negotiating intricate arrangements among biopharmaceutical companies, inventors, research sites, CROs, SMOs, CMOs, laboratories, and vendors, ensuring smooth collaboration that fuels clinical research and product development success.

- **Driving Ethical and Compliant AI in Research**: We guide clients in implementing AI-driven solutions that enhance efficiency in clinical research, ensuring that every use case aligns with ethical standards and complies with existing laws, from data protection to patient safety.

- **Guiding U.S. and Global Privacy Compliance**: Our team navigates HIPAA and the patchwork of U.S. state privacy laws as well as global privacy regulations, such as GDPR, ensuring your data is secure and can be moved where you need it, when you need it, in a compliant manner. Additionally, we assist and represent clients regarding the clinical research regulatory process and compliance requirements of the FDA and other Health Authorities, providing comprehensive support to ensure adherence to all relevant regulations.

- **Precision in Contract Design**: From master service agreements to clinical trial contracts and informed consent forms, we meticulously craft and review agreements to protect our clients' interests at every stage.

- **Supporting Every Step of Innovation**: As trusted partners, we work alongside pharmaceutical and life science companies from early-stage research through post-market studies, aligning legal strategy with scientific advancement.

- **Streamlining Site Engagement and Enrollment**: By collaborating closely with in-house legal departments, we accelerate clinical site activation and participant enrollment, optimizing timelines and reducing study delays.

- **Creating Efficiency with Templates and Playbooks**: We develop tailored template agreements and playbooks, empowering clients with efficient, consistent negotiation processes.

- **Fulfilling In-House Legal Roles for Pharma**: Acting as an extension of our clients' legal teams, we handle site enrollment processes and day-to-day legal functions, seamlessly supporting internal teams.

Let us help bring your clinical research vision to life with clarity, security, and purpose.