

OUR PRACTICE

Medical Research/Clinical Trials and Risk Management

Navigating the intricate landscape of clinical research requires experience in a myriad of legal and regulatory domains. From managing complex contracts to understanding global regulations, bringing innovative products to market demands seasoned guidance. Baker Donelson offers tailored support to pharmaceutical and life science entities, institutions, CROs, and SMOs. Our focus on compliance, coupled with our experience in navigating diverse regulatory frameworks, ensures seamless progress through each stage of the clinical trial journey.

Our seasoned health care team at Baker Donelson excels in managing the legal intricacies of clinical research for a diverse clientele, spanning startups to industry leaders. With extensive experience representing institutions and investigators across all major stages of clinical research, including Phase I safety evaluations to Phase IV post-marketing studies, our clients range from medical device and pharmaceutical companies to Principal Investigators (PIs), Clinical Research Organizations (CROs), Site Management Organizations (SMOs), Institutional Review Boards (IRBs), and service providers. We streamline contracting processes, negotiating agreements with stakeholders like clinical research sites, laboratories, sponsors, CROs, and vendors. We also advise on U.S. Food and Drug Administration (FDA) and U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) compliance requirements and provide comprehensive support for establishing and managing clinical trial programs.

With a pragmatic approach, we ensure trials stay on schedule from a legal and compliance perspective while safeguarding our clients against future liabilities. Offering advice on risk management and compliance to both in house departments and executives, we address areas such as insurance, indemnification, confidentiality, data privacy, and intellectual property.

Our Health Law Department comprises leaders who have built a multidisciplinary team with wide-ranging experience in law and business. We stay abreast of legal developments such as the Sunshine Act and business trends shaping the clinical research landscape, ensuring our clients remain competitive and compliant in an ever-evolving environment. Our experience spans a breadth of critical areas:

- Negotiating complex arrangements among biopharmaceutical companies, research sites, CROs, and vendors;
- Crafting and reviewing agreements, including master service agreements, clinical trial agreements, and informed consent forms;
- Partnering with pharmaceutical and life science companies across various research stages;
- Accelerating clinical site engagement and study subject enrollment in collaboration with in-house legal departments;
- Developing template agreements and playbooks for efficient negotiation of clinical trial agreements;
- Assuming legal functions for pharmaceutical companies and facilitating site enrollment processes;
- Navigating global privacy laws, including GDPR, for data transfer in marketing applications; and
- Assisting with negotiation and revision of indemnification obligations amidst geopolitical conflicts.

Baker Donelson is dedicated to supporting our clients through every phase of their clinical research endeavors. We are your trusted partner in achieving your clinical research objectives while mitigating risks and maximizing opportunities for success.

