GOODWIN

Clinical Trial Services

As life sciences companies move from the research and discovery stages into clinical development, legal guidance is strongly encouraged. At Goodwin, we partner with clinical operations, regulatory and senior management teams to navigate clinic entry along with any hurdles that may arise.

Serving Your Industry

Getting Your Documentation in Order

- Study protocols, informed consent templates, and recruitment materials
- Clinical research standard operating procedures
- Clinical research organization agreements
- Clinical trial agreements, investigator-initiated trial agreements, and letters of indemnification
- Healthcare professional consulting and advisory arrangements
- Master services, supply, vendor and quality agreements, including for telehealth and remote nursing services
- Legal representative agreements
- Expanded access and right-to-try program agreements and policies
- Safety data exchange and pharmacovigilance agreements

Guiding Regulatory Compliance and Communications

- Interactions with and submissions to: FDA, IRBs, CROs, investigators, DSMBs and safety review committees
- Reporting of trial results and clinical developments
- Reporting of serious unexpected and/or suspected adverse reactions
- Good clinical practice (GCP) compliance and investigations
- ClinicalTrials.gov registration and compliance
- Special protocol assessment requests and negotiations
- Resolution of partial and full clinical holds
- FDA financial disclosure reporting obligations
- Shipment of clinical supplies

Representing Your Interests

Ensuring Privacy and Understanding Bioethics

- Data security and breach prevention
- Biobanking and use of patient samples and data, including biometric data
- Genetic privacy
- Reporting of incidental findings (ACMG)
- ICMJE data sharing and publication
- HIPAA
- Research data use agreements
- Donor and participant compensation
- GDPR (EU)
- GDPR and DPA 2018 (UK)
- California Consumer Privacy Act (CCPA)
- ePrivacy Directive and implementing legislation in the UK and EU member states

Addressing Liability and Navigating Insurance

- Subject injury claims and unblinding considerations
- Clinical trial insurance coverage
- Insurance claims and notifications
- Clinical article recalls and communications

Leading at Every Level

- ***U.S. News Best Lawyers:*** Recognized as Biotechnology Law Firm of the Year for seven out of the past eight years and nationally ranked FDA practice
- ***Chambers USA:*** Recognized practices in FDA, Healthcare, Medical/Pharmaceutical Products Regulatory, Life Sciences, Corporate/M&A, Venture Capital, Intellectual Property and Capital Markets
- ***LMG Life Sciences:*** Corporate Firm of the Year, U.S. Lifecyle Firm, and 13 lawyers recognized as Life Sciences and Regulatory Stars
- ***Chambers UK:*** Recognized for Life Sciences

Contact Us

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Meet us at the intersection of capital and innovation: goodwinlaw.com

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