

CLINICAL TRIAL SERVICES

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

GETTING YOUR DOCUMENTATION IN ORDER

- Clinical research organization agreements
- Clinical trial agreements and investigator-initiated trial agreements
- Clinical trial supply agreements
- Healthcare professional consulting and advisory arrangements
- Master services, vendor and quality agreement negotiations, including for telehealth and remote nursing services
- Expanded access and right-to-try program agreements
- Safety data exchange and pharmacovigilance agreements

GUIDING REGULATORY COMPLIANCE + COMMUNICATIONS

- FDA IND and IDE interactions
- Protocol design and analyzing results
- Investment community and stock exchange disclosures of trial results and clinical developments
- Good clinical practice (GCP) compliance and investigations
- Patient-informed consents, recruitment materials and enrollment incentive programs
- ClinicalTrials.gov entries and compliance
- Special protocol assessment requests and negotiations
- Serious and/or adverse event reporting
- Resolution of partial and full clinical holds
- Investigator, IRB and CRO communications and interactions
- Trial subject engagement
- FDA financial disclosure reporting obligations
- DSMB and safety review committee interactions
- Expanded access and right to try programs
- Human factors testing
- Research misconduct

ENSURING PRIVACY + UNDERSTANDING BIOETHICS

- Data security and breach prevention
- Use of patient samples and data
- Genetic privacy
- Incidental Findings (ACMG)
- ICMJE data sharing and publication
- HIPAA
- Research Data Use Agreements
- Donor and participant compensation
- GDPR and DPA 2018 (UK)

ADDRESSING LIABILITY + NAVIGATING INSURANCE

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

LEADING AT EVERY LEVEL

Biotechnology Law Firm of the Year for six out of the past seven years and FDA practice nationally ranked by **U.S. News Best Lawyers**

Corporate Firm of the Year, U.S. Life Cycle Firm and 13 lawyers recognized as Life Sciences Stars and Regulatory Stars by **LMG Life Sciences**

Recognized by **Chambers UK 2021** for Life Sciences

100+ lawyers recognized by **Chambers USA 2020** across jurisdictions in 50 categories including Corporate/M+A, Private Equity Buyouts + Venture Capital, Life Sciences, Investment Funds, Intellectual Property and Litigation

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