Hogan Lovells

Clinical Trials

Our clinical trials team helps clients bring new drugs, biotechnology products, and medical devices to market.

We provide specialized advice to companies big and small through their entire journey – from nascent proof-of- concept studies and process development to seeking regulatory approval and managing product life cycles. With a cross-disciplinary approach, a deep talent bench, and our knowledge of and contacts within U.S., European Union, and Asian government agencies, we ensure a comprehensive, integrated and risk-based strategy for issues that arise in drug and device development. We are here to help you achieve your long-term business objectives.

Representative experience

Multiple clients on the impact of COVID-19 on clinical trials, such as patient travel to clinical sites and potential force majeure claims from clinical trial vendors.

Coordinate the defense of a manufacturer of implantable class III medical devices against alleged liability in clinical trials after a voluntary worldwide product withdrawal.

Conduct regulatory due diligence on an acquisition target that helps drug companies and contract research organizations recruit subjects for clinical trials.

A large academic medical center in planning and overseeing a privileged audit of its global clinical trial

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Practices

Pharmaceuticals and Biotechnology Regulatory

Intellectual Property

Industries

Life Sciences and Health Care

network to evaluate compliance with FDA's Good Clinical Practice regulations.

Conduct research and practical advice to Amarin across 11 countries to address worldwide patient privacy and vital status concerns for its cardiovascular outcomes trial.

LabCorp on its US$1.2bn acquisition of Chiltern, a research organization focused on clinical services, and its US$371m purchase of Sequenom, a pioneer in noninvasive prenatal testing.

Biotech and pharma companies in evaluating and addressing significant data integrity and GCP compliance concerns raised in their clinical trials.

A leading European biotech company on the roll-out of a Phase III clinical trial throughout 21 countries.

Prepare and negotiate domestic and international clinical trial agreements and other sponsored research agreements.

Protect numerous pharma and biotechnology clients to prepare and negotiate domestic and international clinical trial agreements and other sponsored research agreements.

Latest thinking and events

News

MedTech 2023: Key takeaways from conversations on women's health, antitrust, and AI

News

Life Science Law Update – Key developments for pharma & device companies in EU

News

Informed consent duties for IRBs, investigators, and sponsors detailed in FDA final guidance

News

Regulatory considerations on artificial intelligence for health of the WHO

News

FDA broadens scope on communication about unapproved uses to HCPs

News

Post-COVID, FDA still permits changes to non-invasive remote monitoring devices without 510(k)