Hogan Lovells

# Clinical Trials

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

We handle the most challenging clinical research issues. We have resources to quickly and efficiently advise on global clinical studies, and we assist clients to structure and negotiate clinical agreements among physicians, medical centers, contract research organizations, and government bodies.

Our cross-disciplinary approach, our deep bench in virtually every discipline, and our knowledge of U.S., European, and Asian governments enable us to support clinical research globally and achieve the long-term objectives of clinical trials.

## Representative experience

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

Representing a global pharmaceutical company on several claims arising out of clinical trials in China.

Representing a leading research university in connection with a voluntary disclosure of irregularities in reimbursement of research patient care costs under NIH grants.

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

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

## Contacts

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Washington, D.C.

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Brussels

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## Practices

Pharmaceuticals and Biotechnology Regulatory

Medical Device and Technology Regulatory

Health Law

## Industries

Life Sciences and Health Care

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

Lawyers in 11 countries conducted research and offered practical advice to assist Amarin's efforts to address worldwide patient privacy and vital status concerns for its cardiovascular outcomes trial.

Advised 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.

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

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

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

Advising numerous pharmaceutical and biotechnology clients on protecting their IP rights and managing their exposure to liability.

Assisting numerous companies in understanding the ClinicalTrial.gov disclosure requirements under the 2016 final federal regulations.

Advising a U.S. company on new statutory requirements for holding clinical trials in Russia, including arrangements with the investigator and mandatory insurance of patients.

Assisting in a complex dispute relevant to interlocutory remedies sought by the claimant to obtain late enrollment in a pending clinical trial.

Advising a university on terminating an investigational new drug application over the objection of an employee / principal investigator.

Regularly counseling companies on their financial

arrangements with investigators and related disclosure obligations to FDA pursuant to the FDA financial disclosure regulations.

## Latest thinking and events

News
COVID-19: Daily Report for Life Sciences and Health Care Companies II

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News
Japan considers utilization of "compassionate use" exception to fast-track COVID-19 treatments

News
China takes a pragmatic approach to relaxing regulation of the life sciences sector during COVID-19

Insights
AFMPS issues guidance regarding the management of clinical trials during the COVID-19 epidemic

Webinar
How COVID-19 is changing the clinical trials landscape