



# CHILTERN

## Chiltern International Inc.

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**Website:** www.chiltern.com

**Number of Employees:** 1100

**Date founded:** 1982

### Therapeutic Areas of Expertise:

- Oncology
- Cardiovascular
- Infectious and Metabolic Diseases
- CNS
- Ophthalmology
- Gastroenterology
- Respiratory Diseases

## CHILTERN

Established in 1982, Chiltern is a leading global Contract Research Organization with extensive experience conducting and staffing international Phase I to Phase IV clinical trials across a broad therapeutic range for a wide variety of clients. Chiltern employs more than 1100 people with 20 offices across the United States, Europe and in India. Chiltern provides services including Early Phase, Global Clinical Development, Late Phase, Biometrics, Medical and Regulatory Affairs and Resourcing Solutions.

### EARLY PHASE:

The dedicated full-time team of physicians, registered nurses and scientists that make up Chiltern's Clinical Research Unit approach every study with four criteria in mind; safety, precision, quality and compliance. Specialists from project managers to physicians have input at every stage from planning through to study completion.

### GLOBAL CLINICAL DEVELOPMENT:

Chiltern's Global Clinical Monitoring personnel are located on four continents to ensure precise procedures and strict quality controls are practiced at all times. Dedicated local line managers recruit, train and manage clinical monitoring staff to global standards and monitor quality against Federal and ICH good clinical practice standards. Our emphasis on planning, clear communication and team cooperation across disciplines makes our added value evident from the day a project begins.

### LATE PHASE:

Our Global Late Phase Group of specialist project managers and experienced clinical development professionals are focused on providing specific services designed to support products from their launch through to market planning. Our expert teams provide Phase IIIb and IV, Non-Interventional, Observational, Epidemiology, Investigator-Initiated trials and Registry services, in both national and international markets.

### BIOMETRICS:

Chiltern Biometrics work alongside sponsors to optimize the value of our expertise to their study and objectives. Dedicated Electronic Data Capture (EDC) staff ensures the most beneficial fit between the sponsor and the investigator sites.

Full, ongoing statistical support is provided by our Biostatisticians and provided in electronic format for seamless incorporation in interim analyses for Data Monitoring Committees (DMC), clinical study reports and electronic submissions for regulatory filings. Our Medical Writing teams are fully experienced in reporting to the highest international guidelines.

### MEDICAL AND REGULATORY AFFAIRS:

Our Regulatory and Medical professionals keep track of and anticipate, developments globally. Their contribution to projects can range from the strategic planning of critical paths to applying for clinical trial and marketing authorizations. They are widely experienced in providing due diligence programs and full pharmacovigilance services for both licensed and unlicensed products.

The knowledge base within Chiltern's Regulatory and Medical Affairs Team ensures that studies always have high standards of scientific and medical representation, to meet the requirements of the relevant competent authorities.

### RESOURCING SOLUTIONS:

Years of recruiting talented people all over the world have led us to a unique position. We have a database of motivated and skillful people at all levels of experience in North America, Europe and India.

Using this resource we supply staff in a wide range of disciplines, on a contract basis, to the pharmaceutical industry around the world. In addition to short and long-term contracts we can also offer senior personnel on an interim basis, and are able to assist with all your permanent resourcing needs.