

**GLOBAL EXPERTISE IN CLINICAL TRIAL SUBMISSIONS  
AND ESSENTIAL DOCUMENT COLLECTION**

The dedicated, project-specific teams who specialize in investigator document collection and submissions to international regulatory agencies and IRB / EC.



# CLINICAL TRIAL SUBMISSIONS

**MEDPACE**

THE ADVANTAGE OF **FOCUS**

# FOCUS: CLINICAL TRIAL SUBMISSIONS



## A collaborative approach

The Medpace Clinical Trial Submissions team delivers a well-coordinated, collaborative approach that is critical to every phase of global trials. Our unique team structure ensures each Sponsor benefits from our global expertise – from writing informed consents to translations, to working with regulatory authorities and ethics committees around the globe.

Working directly with the local Clinical Research Associates, as well as Regulatory, Safety, and Contract groups, a fully dedicated manager oversees all aspects of investigator essential document collection and submissions including:

- Regulatory Agency and Institutional Review Board (IRB) / Ethics Committee (EC) submissions throughout the life of the trial
- Collection, review, and approval of site essential documents

Medpace has extensive experience submitting clinical trial applications in over 30 countries and has strategic regional presence throughout Europe, Asia, Australia, South Africa, and the Americas.

## Proactive, strategic, and experienced

Working with our global standard operating procedures, our dedicated specialists and managers coordinate and oversee activities at trial start-up and throughout the trial. We rigorously maintain timelines for trial start-up, ensuring that your trial starts recruiting on time. We manage and regularly evaluate metrics on all trials.

Medpace creates a customized submissions plan for each trial. This plan includes, but is not limited to:

- Definition of roles and responsibilities for Medpace and Sponsor
- Translation procedures
- Review and approval processes of investigator essential document packages
- Escalation and due diligence plan

Our proactive and experienced team members are always ready to provide advice and guidance to Sponsors and investigative sites to ensure compliance with appropriate regulations and requirements. And because the Clinical Trial Submissions team works with documents every day, they are quick to recognize and flag any issues.

## A breadth of capabilities

The submissions group:

- Prepares, reviews, and files clinical trial applications to international regulatory agencies and ethics committees
- Interacts with central and local ethics committees and regulatory agencies
- Consults with the Medpace Medical Affairs group, including medical writers and regulatory experts, throughout the study
- Reviews pertinent regulations to develop proactive solutions to regulatory issues and challenges
- Prepares and negotiates informed consent forms (ICFs) for the study sites to ensure they meet local requirements
- Obtains local insurance policies when necessary
- Represents the Sponsor as a legal entity where required
- Collaborates with the Sponsor to ensure all drug labels meet local regulations
- Procures import / export license, as applicable
- Coordinates all translations and ensures the most accurate and cost-effective translated documents
- Collects, reviews, and approves investigator essential document packages for release of the investigational product

## The Medpace difference

Medpace is a global, research-based drug development company led by top therapeutic and regulatory experts who are driven to further the advancement of pharmaceutical agents for use in cardiology, metabolism, and oncology. Medpace has assembled the industry's most experienced and therapeutically-focused team to execute at all levels of our operations, providing complete and seamless drug development services.

Through specialized regulatory expertise and therapeutically-focused clinical operations, Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development – from program planning and execution to product approval. With clinical trial experience in over 40 countries, Medpace has the global reach and capability to successfully conduct studies and navigate regulatory requirements worldwide.

## Medpace group of companies

**Medpace**

**Imagepace**

**Medpace Bioanalytical Laboratories**

**Medpace Clinical Pharmacology**

**Medpace Reference Laboratories**