

MEDPACE BRAZIL

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Resources and Experience

- Office established in 2006
- Director of Clinical Operations – over 11 years experience, including project management
- Clinical Research Associates – over 3 years experience

Therapeutic Expertise

Medpace Brazil employees have collective experience in the following therapeutic areas and types of trials:

- Oncology
- Diabetes
- Cardiovascular
- Neurology
- Orphan drugs
- Urology
- Renal
- Endocrinology
- Gastroenterology

Services

Regulatory

- Submit regulatory packages and ongoing reports to authorities
- Interface and support answering regulatory queries
- Coordinate strategic and contingency planning for regulatory submissions
- Provide ongoing support and orientation for the importation and exportation of investigational products and biological samples
- Prepare, distribute, and track essential trial documents and master file

Project Management

- Provide reliable feasibility and ensure protocol compliance
- Perform site identification and evaluation
- Coordinate local investigator meeting, if applicable
- Negotiate and manage investigator agreements and payments
- Oversee clinical trial supply importation and distribution
- Manage audits
- Manage archival of trial materials

Medical Monitoring

- Provide medical management and expertise
- Contribute medical expertise to study reports, regulatory documents, and manuscripts
- Manage medical and safety components of clinical trials
- Assign feasibilities, design processes, and review and edit medical documents
- Follow specific research-related protocol and lead others in strict adherence to policies

Why Brazil?

- Fast recruitment in almost all therapeutic indications
- Experienced sites in GCP with proven track record of quality audited by FDA, EMEA, and sponsors
- Seasonal opportunities related to respiratory, allergy, and dermatology diseases