

# MEDPACE CZECH REPUBLIC

Medpace Czech Republika s.r.o. | Rotavska 2656/2B | Prague 5 | 150 00 Czech Republic  
Tel: +420 251 551 466 | Fax: +420 251 510 801 | info.cz@medpace.com



## Resources and Experience

- Office established in 2007 (acquisition of local CRO, Monax)
- Medical Experts (CVS, infectious diseases)
- General Manager – 12 years experience within CRO business and the pharmaceutical industry in clinical management positions
- Clinical Trial Manager – over 20 years experience in the industry
- Clinical Research Associates – average 3 years experience
- Office-based staff

## Therapeutic Expertise

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

- Phase II-IV
- Cardiovascular
- Endocrinology
- Hematology
- Metabolism
- Oncology

## Services

### Site Monitoring

- Perform site evaluation, initiation, routine monitoring, and closeout visits
- Ensure drug accountability
- Collect and maintain essential documents
- Perform data and safety monitoring, including EDC and CRFs

### Regulatory

- Submit regulatory submissions and ongoing reports to authorities
- Correspond with ethics committee and central and local IRBs, as appropriate
- List and maintain trial details on National Research Register
- Export permit application and renewals for international material transfer
- Prepare, distribute, and track essential trial documents and master file

### Project Management

- Ensure feasibility and 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