

MEDPACE BELGIUM

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Resources and Experience

- Office established in 2006
- Country Manager/Clinical Trial Manager – 9 years experience in international clinical research industry at sponsors and CROs
- Clinical Research Associates – average over 5 years experience in international clinical research industry at CROs
- Project Coordinators – average 3.5 years experience in international clinical research at CROs, audit, and data management experience
- Data Manager – 9.5 years experience in international clinical research industry at sponsors and CRO
- Data Coordinator – 3.5 years experience in international clinical research industry at sponsors and CRO

Therapeutic Expertise

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

- Phase II-IV
- Cardiovascular – device, acute MI, stroke, hypertension
- Metabolic disease – type I and II diabetes, dyslipidemia
- Oncology – gastric, pancreatic, liver, leukemia, non-small cell lung cancer
- Respiratory – asthma, COPD
- Infectious disease – HIV, intra-abdominal infection, streptococcal pharyngitis
- Neurological – adult ADHD, adult schizophrenia
- Musculoskeletal – osteoporosis
- Vaccines – rotavirus, human papilloma virus
- Gastro-enterology – gastro-oesophageal reflux, infantile colic
- Dermatology – seborrheic dermatitis

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

Data Management

- Develop and maintain DM-related documents
- Follow patient CRF and data query filing procedures
- Coordinate communication with external database providers for data transfers
- Coordinate clinical coding procedures and dictionary transfers
- Imaging

Why Belgium?

- Short regulatory timelines
- Experienced trial sites
- Short travels
- Many years of ICH GCP experience in clinical trials
- Follows EU directive
- ICH GCP compliant CA and CEC approval processes