

MEDPACE SWITZERLAND

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Resources and Experience

- Office established in Zurich, 2008; moved to Basel after PharmaBrains AG acquisition in 2009
- General Manager/Vice President, Oncology – Over 20 years clinical experience in oncology and infectious diseases

Therapeutic Expertise

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

- Oncology (main focus)
- Cardiology
- Gastroenterology
- CNS – Alzheimers disease, psychiatry
- Medical Device
- Pediatrics

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

Quality Assurance

- Ensure GCP and ongoing protocol-related training of site staff
- Prepare sponsor audits

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

Safety

- Coordinate and track serious adverse event reporting
- Coordinate and track trial report narrative
- Report adverse events to the Eudravigilance/FDA (appropriate agencies in region), as appropriate
- Provide safety review of clinical trial documents, including protocols, study reports, and marketing application components

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 Switzerland?

- Europe, but non-EU country (i.e., does not fall under EU regulations)
- Very friendly towards Phase I and early development
- High quality and reputation; reliable
- Excellent track record in oncology
- Internationally recognized investigators
- Multicultural population
- Health care system has been repeatedly rated as the best in the world
- Easy geographical access