Dr. (MD) Uwe Albrecht, FIBMS, MFPM, MICR (Dis.), CSci
Chief Executive Officer
contact@mediconomics.com

History and Mission

Mediconomics is a successful CRO and consultant for research and development projects of both Medicinal Products and Medical Devices. The core philosophy is to keep the company small enough to provide flexible, bespoke solutions but large enough to deal with complex situations. Since 1999, our systematic and tailor-made approach has earned us an excellent reputation, and we would be proud to be part of one of your projects.

Highlights

Headquartered in Hannover, Germany and with subsidiaries in Denmark, Switzerland, the UK and US, Mediconomics operates within an international network.

In compliance with national guidelines and the requirements of European and international standards, we consult and support our clients in all phases of the clinical and regulatory life-cycle of Medicinal Products and Medical Devices.

Overall, we performed more than 160 Clinical Research Projects with
- Medicinal Products,
- Medical Devices and
- development candidates

as both full and single-service.

Mediconomics GmbH
Misburger Straße 81B
D-30625 Hannover

Tel. +49 (0)511 560 998 0

BVMA Member since 2020
Audit passed in 2020

mediconomics®
manage · research · improve

www.mediconomics.com

Services

Clinical Research
Planning, management and conduct of:
- Clinical trials (Phase I-IV) across different therapeutic areas,
- Non-interventional studies (NIS)
- Post Authorisation Safety Studies (PASS)

Data Management
- eCRF and database design,
- Transfer and integration of external data (e.g. laboratory),
- Medical Coding,
- Data validation and cleaning

Regulatory Affairs
Clinical Trial Regulatory Affairs
- Regulatory consultancy and advice,
- Approval, amendments, notification and reporting with Competent Authorities and Ethics Committees

Drug Regulatory Affairs
- Regulatory consultancy and advice as well as scientific advice meetings,
- Management and submission of eCTDs,
- Preparation and conduct of authorisation procedures (Central Procedure, Decentralised Procedure, Mutual Recognition Procedure, National Procedure)

Pharmacovigilance
- AE / SAE Management,
- Periodic Safety Update Reports (PSURs)
- Development Safety Update Reports (DSURs)
- EU-conform electronic reporting XEVPRM, ICSR

Medical Writing
- Study designs and study related documents (e.g. study design/protocol, IMPD)
- Biological Evaluation Reports and Clinical Evaluation Reports (CER/BER)
- Toxicological assessments
- Expert Reports
- Manuscripts and management of publications