COMPANY PROFILE

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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 180 Clinical Research Projects with
- Medicinal Products,
- Medical Devices and
- development candidates

as both full and single-service.

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BVMA Member since 2020
Audits passed in 2020 and 2023

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 and 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 CAs and ECs

Drug Regulatory Affairs
- Regulatory consultancy and advice as well as conduct of advice meetings,
- Management and submission of eCTDs,
- Preparation and conduct of authorisation procedures (CP/DCP/MRP/NP)

Pharmacovigilance
- AE / SAE Management,
- PSURs and DSURs,
- EU-conform electronic reporting (XEVPRM, ICSR)

Medical Writing
- Study designs and study related documents (e.g. study design/protocol, IMPD)
- Biological Evaluation Reports/Clinical Evaluation Reports (CER/BER)
- Toxicological assessment, Expert Reports and Publications

Monitoring
- In-house Lead CRA and CRAs
- Pre-Study Visits
- Initiation Visits
- Periodic Monitoring Visits
- Close-out Visits
- Site Management / Administration

Product Development
- Design performance and safety
- Business economics
- Risk Management
- Regulatory Requirements