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History and Mission

CLINASSESS has been in business as independent CRO since 2000. You will find extensive professional expertise and high-quality services with us in all areas and phases of clinical trial processing and various indications (oncology, cardiovascular diseases, anti-infectives, central nervous system diseases). Based on two decades of experience, a highly motivated, competent, dedicated team, and close contact with opinion leaders and external specialists, we lead your projects to success.

Highlights

Staff: Interdisciplinary team experienced in successful processing of a broad spectrum of medical study projects. Excellent qualifications in Medicine, Project Management, Monitoring, Data Management, Biometrics, Drug Safety, Regulatory framework, QM/QA.
Competence: Comprehensive know-how in GCP-compliant conduct of clinical trials Phases I-IV and NIS.
Services: Range from takeover of individual components to realization of complete study projects. Management of an oncology network including numerous investigators and trial sites.
Facts & Figures: More than 300 studies with approx. 40.000 subjects. Intense cooperation with oncological professional societies, working communities and study groups.

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BVMA member since 2012
Audits passed in 2012, 2015, 2018 and 2022

www.CLINASSESS.de

Services

Project Management
- Our study project teams are guided by senior project managers with profound knowledge of study planning, development, coordination and administration.
- The project manager is primary contact for you and the trial sites, coordinating all project procedures in agreement with you.

Data Management
- Our data managers care for highest data quality levels (pCRF/eCRF studies). Close collaboration with our other departments ensures efficient data cleaning.
- Benefit e.g. from well-coordinated DM procedures, professional database development, DB/data validation, continuous data entry, status reports.

Medical Writing & Medical Consulting
- We have pooled our medical experts who support you with medical advice, evaluation and training in creating study-specific documents.
- All documents can also be prepared by our medical writers on your request.

Drug Safety / Pharmacovigilance
- We have established a highly skilled team of Drug Safety experts supporting your pharmacovigilance activities.
- Benefit e.g. from professional AE/SAE management, development of study-specific safety manuals, MedDRA coding, safety reporting.

Monitoring
- Our CRAs ensure controlled data collection quality and patient safety at sites.
- Intense initial and continued CRA training and qualification ensure best possible support of your trial centres.
- Onsite, remote, centralised, adaptive, risk-based Monitoring.

Biometrics
- Our well versed biometricians provide statistical services and consulting for the entire study process up to evaluation of results.
- Services include e.g.: Support in development of study protocols, calculation of power and sample size, generation of randomisation lists, SAPs, exploratory and confirmatory analyses, sub-group and interim analyses, statistical reports.