COMPANY PROFILE

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Chief Executive Officer
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History and Mission

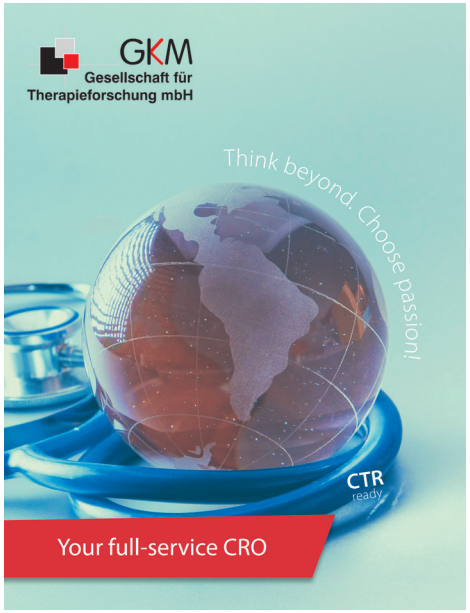
GKM is an independent, family-owned full-service CRO providing a comprehensive portfolio of clinical research services for the pharmaceutical industry, medical device manufacturers and academia since 1981. Our core competencies include studies with medicinal products, medical devices as well as early benefit assessment.
With 991 clinical research projects completed and ca. 1.6 million patients across various indications involved, our highly experienced team consults and supports our clients throughout their national or international clinical projects.

Highlights

Key facts:
- Over 1,100 clinical projects
- Wealth of experience in a broad range of indications
- 100 in-house professionals
- Outstanding personnel continuity
- High rate of academics and MDs

International coverage:
- DACH: 90 freelance CRAs
- World-wide: long term co-operations with our partner CROs

Competence:
- Clinical trials and non-interventional studies with pharmaceuticals
- Value dossier writing and consulting, health economic & outcome research
- Clinical and PMCF studies with medical devices



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BVMA member since 2017
Audits passed in 2017, 2020 and 2023

GKM
Gesellschaft für
Therapieforschung mbH

www.gkm-therapieforschung.de

Services

Concept & Design
- Medical & statistical consulting
- Feasibility analyses, sample size estimation
- Study design
- Definition of enrolment criteria, selection of adequate methods of measurement, patient-relevant endpoints
- Literature research, register searches

Preparation & Material
- Study protocol / observational plan
- (e)CRF concept, patient information, informed consent form
- Questionnaires and PROs (electronic or paper-based)
- Regulatory & ethics
- Site recruitment, selection & contracts

Realization & Support
- Data management & cleaning, query management
- EDC helpdesk
- Coding (performed by MDs)
- Interim analyses
- Clinical safety & medical surveillance (supervised by MDs)
- Monitoring, study-specific trainings
- Reimbursement management
- Vendor management
- Project & budget management

Completion & Publishing
- Statistical analysis
- Clinical study report and layman summaries
- Abstract, poster, presentation
- Peer-reviewed publication, publication management
- Study registries publishing

AMNOG Services
- Dossier strategy
- Development of consultation request
- Planing and writing of all modules
- Training/consulting for and participation in oral hearings