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**GKM Gesellschaft für
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BVMA member since 2017
Audit passed in 2017



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HISTORY AND MISSION

GKM Gesellschaft für Therapieforschung mbH 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 highly experienced team consults and supports our clients throughout their national or international clinical projects deploying state-of-the-art technology and complying with the very latest standards.

HIGHLIGHTS

Key facts:

- ▷ over 800 completed clinical projects
- ▷ wealth of experience in a broad range of indications
- ▷ 74 in-house professionals
- ▷ outstanding personnel continuity
- ▷ high rate of academics and MDs

International coverage:

- ▷ DACH: 220 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

SERVICES

Concept & Design

- ▷ medical & statistical consulting
- ▷ feasibility analyses, sample size estimation
- ▷ definition of enrolment criteria, selection of adequate methods of measurement
- ▷ 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, journal management
- ▷ study registries publishing

