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History and Mission

FGK Clinical Research GmbH is a full service contract research organization, offering a complete range of clinical development and consulting services all over Europe and the US. Over the span of about 20 years, FGK has been conducting a large number of national and international clinical trials for biotechnology, pharmaceutical and medical device companies and can thus provide all clients with its high-quality expertise and services – all controlled by a team of more than 180 professionals.

Highlights

Mid-sized CRO:
- Tailored customer approach
- Transparency of the clinical trial progress
- Quick reaction time to specific demands

Multicentre/International Trials:
- Experienced and well-trained staff
- Subsidiaries in Poland, Hungary and Czech Republic
- Cooperation with partner CROs in Europe and US
- Legal representative for non-EU clients – also visit www.fgk-rs.com

Focus:
- Small (start-up) & mid-sized biotech and medical device companies
- All phases of clinical trials
- All major therapeutic areas

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BVMA member since 2007
Audits passed in 2007, 2010, 2013, 2016, 2019 and 2022

FGK CLINICAL RESEARCH

www.fgk-cro.com

Services

Regulatory Affairs
- Consulting on regulatory topics
- Review of study documents (e.g. protocol, informed consent form, labels)
- CTA with submission to Authorities and ECs

Clinical Operations
- Project management, primary liaison for sponsor communication, status reports etc.
- Feasibility, contract negotiations, site management, monitoring etc.

Medical Safety/Pharmacovigilance
- Adverse Event Management and assessment/reporting
- Drug safety, medical monitoring and coding of medical terms
- Pharmacovigilance – also visit www.fgk-pv.com

Medical Writing
- Investigator's brochures, study protocols, ICF and subject information
- Clinical expert reports, clinical publications, IMP and submission dossiers

Data Management
- CRF design and review, clinical trial databases
- Data validation, processing and cleaning, external data handling
- CDISC SDTM

Biostatistics and Programming
- Study design, sample size calculations
- Statistical consultancy, analysis plan, programming and reporting
- CDISC ADaM

Quality Assurance
- Audits of investigator site, database and system audits, internal audits
- SOPs composition and implementation

eSolutions
- eCRF
- IWRS/Drug supply
- eTMF
- CTMS