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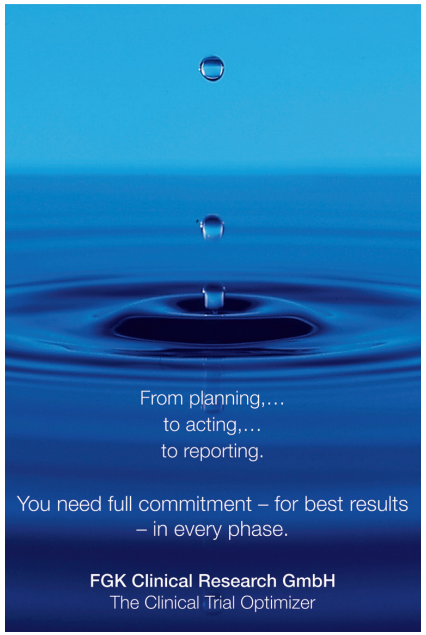
BVMA member since 2007
Audits passed in 2007, 2010, 2013 and 2016

FGK CLINICAL RESEARCH

HISTORY AND MISSION

FGK Clinical Research GmbH is a full service contract research organization based in Munich, providing its development, consulting and IT services all over Europe and the US. Over the span of the last 15 years, FGK has been closely cooperating on biotechnology, pharmaceutical and medical device projects with several international partners, and can thus provide future clients with its high-quality expertise and services – all controlled by our team of more than 100 professionals.



HIGHLIGHTS

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

Multicentre/Multicountry Trials:
- ▷ Experienced and well-trained staff
- ▷ Subsidiaries in the UK, 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 CT
- ▷ All major therapeutic areas

SERVICES

Regulatory Affairs
- ▷ Consulting on regulatory issues with respect to national Competent Authorities
- ▷ Review of study documents (e.g., protocol, informed consent form, labels)
- ▷ Authority submission, EC submission

Project Management and Monitoring
- ▷ Project and budget development, primary liaison for sponsor communication, status reports, web-based access to studies and eCRF/eTMF solutions
- ▷ Feasibility, contract negotiations, site visits and management, etc.

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

Data Management
- ▷ CRF design and review, clinical trial databases, eSolutions (EMT/eCRF)
- ▷ Data validation and cleaning, external data handling

Biostatistics and Programming
- ▷ Study design, sample size calculations, state-of-the-art software
- ▷ Statistical consultancy, analysis plan, programming and reporting

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

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