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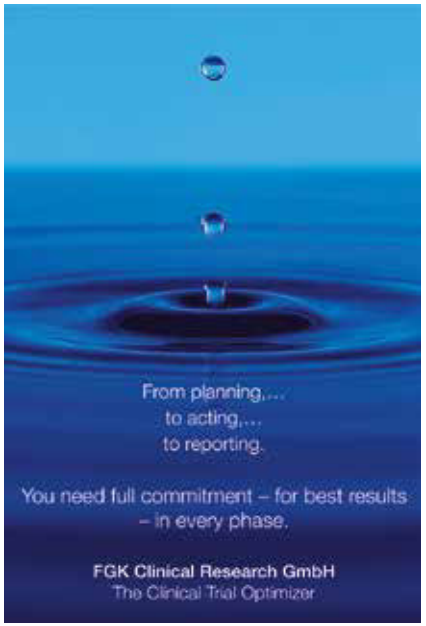
BVMA member since 2007
Audits passed in 2007, 2010 and 2013

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 US. Over the span of last twelve 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 in control of our 80-member team of professionals.



HIGHLIGHTS

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

Multicentre/Multicountry Trials:
- ▷ Experienced and well-trained personnel
- ▷ Subsidiaries in the UK, Poland, Hungary and Czech Republic
- ▷ Cooperation with partner CROs in Europe and US
- ▷ Legal representative for oversea clients – visit also www.fgk-rs.com

Focus:
- ▷ Small (start-up) & medium-size 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 or sponsor communication, status reports, web-based access to studies and eCRF
- ▷ Feasibility, contract negotiations, site visits and management, etc.

Medical Safety/Pharmacovigilance
- ▷ Adverse Event Management and their assessment/reporting
- ▷ Drug Safety, medical monitoring and adverse event coding
- ▷ Pharmacovigilance – visit also 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