



Clinical Research



www.istgmbh.com

History

IST was founded in 1990 as a privately-owned clinical research organization. Several specialists with long experience from work in pharmaceutical companies were recruited (MDs, statisticians, data managers, monitoring and drug safety specialists). We have been growing steadily and provide an excellent job environment with a low personnel turnover.

Vision

Our policy is to establish long-term business relationships and to develop in-depth knowledge of project specifics beyond the level of individual studies. We strongly believe that this makes our work more valuable to our sponsors enabling us to take over more responsible functions.

We are committed to high quality standards of service including, but not limited to, formal compliance with regulations and guidelines.

Adherence to timelines and budget control are important goals. Quick decisions and flexibility are warranted by a flat organizational structure.

Experience

Besides other therapeutic areas, we have worked in:

- Virology (hepatitis C and B, HIV)
- Oncology (gastro-enterological, hematological, dermatological, pulmonary malignancies, bone metastasis)
- Cardiovascular diseases (hypertension, cardiac disease)
- Bone metabolism disorders
- Rheumatology
- Renal insufficiency
- Anemia, transfusion avoidance
- Diabetes and dyslipidemia
- Stroke, other neurological and psychiatric indications
- Erectile dysfunction
- Pain
- Stem cell therapy
- Diagnostics

Personnel

There are presently about 50 people employed. 60% have more than 10 years of experience in research and 7 people more than 20 years. One out of three have experience from previous employment within the pharmaceutical industry. We employ 12 physicians, 4 biometricians and about 20 other academics.

Memberships

- DGGF
(German Society of Good Research Practice)
- BARQA
(British Association of Research Quality Assurance)
- DGPharmMed
(German Society of Pharmaceutical Medicine)
- DVMD
(German Society of Medical Documentation)
- DGK
(German Society of Cardiology)
- DGIM
(German Society of Internal Medicine)
- BraPP
(British Association of Pharmaceutical Physicians)
- FPM
(Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK)
- IBS
(International Biometric Society)
- ISOP
(International Society of Pharmacovigilance)

Software

- SAS
- ARISg
- Oracle
- Oracle Clinical experience
- nQuery 6.0 for sample size and power calculation
- TeleForm
- MSAccess
- MedDRA



Services

We provide services in the areas of:

- Phase II–IV clinical studies
- Post-marketing observations
- Medical writing
- Pharmacovigilance
- Study monitoring
- Data management
- Statistics
- International project management
- Documentation and presentation media



Medical Consulting

Medical Writing

- Study protocols and templates
- Study reports
- Expert reports
- Publications
- Scientific fact files
- Reviews
- Trainer's Manuals
- Investigator Brochures
- Presentations

Medical Management

- Feasibility Testing and Site Selection
- Medical management of study projects
- Science review
- Life-cycle concepts
- Publication planning and management
- Preparation and proceedings of symposia, medical-manager and advisory-board meetings
- Participation at drug safety monitoring boards
- Consulting
- Project-specific guidelines for investigators

International Project Management

Study Preparation

- Briefing of national management units
- Feasibility questionnaires
- Production and logistics of documentation material
- Project-specific SOPs and related documents
- Interaction of third parties (central laboratories, randomization centers, logistic centers, local CROs)
- Kick-off meetings and training of national units

- Training presentations
- Tracking tools and related documents

Project Management during the Study

- Correspondence with sponsor/national units
- Check of milestones and deadlines
- Telephone conferences, minutes, newsletters
- Risk management
- Logistics of interim analyses
- Process optimization
- Query management
- Logistics of essential study documents and management of trial master file
- Support of national units with audits and inspections

Monitoring

Study Preparation

- CRFs and user instructions
- Patient diaries
- Investigator files
- Study master files
- Plausibility and SDV checklists
- Feasibility questionnaires
- Site selection
- Prestudy visits
- Organization of investigator meetings
- Management of investigator contracts
- Submission of study documents to authorities and ethics committees

Onsite and In-house Monitoring

- Initiation visits
- Interim monitoring visits
- Telephone monitoring
- Support of study sites
- Study close-out visits
- AE reporting to sponsor
- Drug accountability management
- Query management
- Data coding

Project Management

- Project-specific SOPs
- Status reports
- News Letters
- Monitoring Guidelines/Plans
- Training of investigators
- Correspondence and meetings with sponsor
- Investigator honoraria and patient reimbursements
- Logistics of study material
- Preparation of audits

Pharmacovigilance

Safety Services in Clinical Trials

- AE management using ARISg
- Collection, documentation and follow up of Serious Adverse Events (SAEs)
- SAE processing in safety database
- Medical review of SAEs
- AE-data entry in clinical trial database
- Query generation
- Validation and analysis of AE data
- AE-listings (CIOMS II-listings, frequency tables)
- Data reconciliation of pharmacovigilance and clinical trial databases
- Science reviews
- Project-specific AE-guidelines
- Drug-safety specific training of study responsables in countries
- Safety surveillance and risk prevention
- Coding and thesaurus management

Post-authorization Safety Services

- Assessment and follow-up of spontaneous reports (SADRs)
- Evaluation of international specialized literature
- Medical evaluation and assessment of reported SADRs and literature cases
- ADR processing in pharmacovigilance database
- Surveillance of risk profiles
- Risk prevention and management strategies
- Drug safety consulting

Reporting to Authorities

- Generation of CIOMS I / MedWatch reports
- Case reports to authorities according to ICH-E2B format
- Management and dispatch of expedited reports

Safety-specific Medical Writing

- Periodic safety update reports (PSURs)
- Annual safety reports (ASRs)
- Risk analyses for authorities
- Safety analyses of studies and post-marketing observations
- Safety-specific parts of study protocols and other documents
- Study protocol templates for specific indications
- Narratives

Data Management

- CRF review
- Data management guidelines
- Database development and maintenance
- User interfaces for data entry and data management
- Data-entry manuals and training of personnel
- Handling of laboratory data
- Data validation plans and processing
- Query management
- Final data-quality check
- Integration/Updating of coding dictionaries
- Development/maintenance of project-specific coding thesauri
- EDC

Statistics

- Review of study protocols
- Biometrical study design and statistical methodology
- Sample size calculation
- Randomization, stratification and other methods to reduce bias, alpha-adjustment for multiple endpoints or interim analyses
- Review of CRFs, 'annotated' CRFs and data validation plans
- Statistical analysis plans with table shells
- Data analysis and biometrical reports
- Statistical parts of study reports and publications



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