SocraTec R&D - the Early Phase Specialists

Full service from bench to bedside – and beyond

You have our support and expertise from the very beginning. Our experienced team of clinical pharmacologists, pharmaceutical scientists and biostatisticians leads you through your scientific advice / Pre-IND meeting supported by a team of medical writers and an excellent network of pre-clinical specialists and modellers. We develop your first-in-human trial design, discuss it with authorities and help you realizing it within our clinical pharmacology unit. We provide everything you need: Project management, regulatory, pharmacovigilance, data management and biostatistics / PK.

Regulatory affairs and project management

Shortened approval timelines in Germany

A well CTIS-trained team of project managers and assistants realizes a smooth approval process supported by the shortened approval timelines for mono-national trials in Germany: guaranteed 26 days of authorities review-timeline foster clinical development and in the meantime significantly improve conditions for early phase trials in Germany.

Clinical Pharmacology Unit(s)

Excellent accessability for reliable recruitment

- Our main CPU with a total of 54 beds on 1,600 sqm is located in Erfurt close to the city center with a densely populated surrounding area
- Our brand-new intensive monitoring CPU is located directly on the grounds of Erfurt's university clinic and close to our main CPU, providing ideal conditions for First-in-Human trials and early phase trials in symptomatic patients with increased safety requirements

Data Management - SocraMetrics

- In 2007 SocraMetrics was founded from SocraTec's biometrical department, remaining under SocraTec's Quality Management System but with strong focus on IT and clinical data management
- All biometrical services at SocraMetrics are fully FDA compliant, follow the high standards of 21 CFR Part 11 and are set-up and validated in conformity with GAMP-5

Taking SocraTec and SocraMetrics together, we have more than 150 employees working on our projects, this means that we are big enough to handle complex trials, yet small enough to be highly dedicated to each individual trial. We are your partner in all matters. As a mid-sized company our employees identify with your projects as if they were our own!

Our Clinical Pharmacology Unit (CPU)

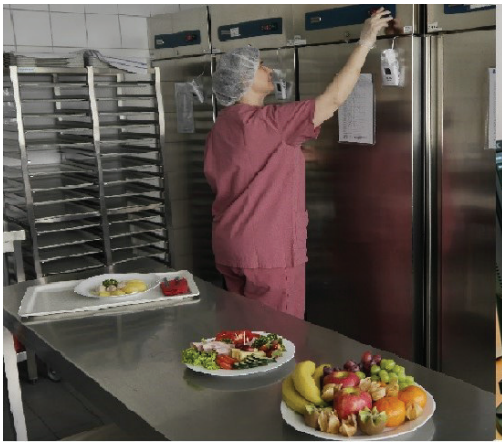
Optimum conditions for Phase I/II clinical trials

Our main CPU in the heart of Erfurt, the capital of Thuringia, was set up in this location in 2004. Since then we have continuously invested in maintenance and technical equipment, meeting our clients' needs and following our own visions.

The general set-up of the site is based on a modular system with highly flexible possibilities of adaptation to the respective phase-I or phase-II study design:

- The 1600 sqm unit is equipped with 54 beds
- A Tetronic (former Siemens) central surveillance system, on the basis of Vaisala measuring devices is our internal standard
- Freezers, refrigerators and the IMP storage area, including safes for the storage of restricted drugs, are under continuous surveillance with audit-trail-based tracking and an emergency system for immediate intervention
- Modern kitchen facilities and trained staff allow fully standardised food and beverages supply
- Long-term hospitalisation with urine and faeces sampling possible
- Special equipment e.g. for gynaecological and ophthalmological trials supports our early phase portfolio in both - healthy subjects and patients
- The unit is FDA and EU inspected, ANVISA certified and the software for all GCP-processes is validated and fully in line with requirements of US CFR 21 Part 11

Our experienced team of investigators, study nurses and technicians is successfully running PK and PD trials for 25 years, including bioequivalence trials. The cumulative expertise ensures quality in all details.



Our hospital-based Intensive Monitoring CPU

Excellent scientific and medical know-how under one roof

Our hospital-based intensive monitoring CPU is operated in cooperation with the university clinic in Erfurt and is located directly on the hospital grounds, a high-performance maximum care hospital with about 1.300 beds, covering almost every clinical speciality and providing ideal conditions.

Clinical expertise of a maximum care hospital

While SocraTec R&D's experienced scientists design and coordinate all projects, the hospital's clinical experts bring in their excellent in-depth knowledge in each of their areas of expertise, with highly experienced medical personnel in more than 30 different specialities.

With this outstanding combination of scientific and medical know-how we are not only able to conduct FIH-trials necessitating highest safety monitoring standards, but we also realise complex phase IIa/IIb studies with patient population.

The clinic regularly treats about 58.000 patients per year with various disease entities. The contractually-based co-operation between SocraTec R&D and the clinic allows direct patient access being supported by the hospital's clinical experts.

CSF sampling possible

We have direct access to the large intensive care unit of the hospital, their anaesthesiologists are trained in the new drugs' IBs of our trials. Within this collaborative setting we are also able to conduct cerebrospinal fluid (CSF) sampling, for the performance of trials evaluating drug substances with CNS action.

Separate and fully closed CPU within the hospital

SocraTec R&D's state-of-the-art, intensive monitoring unit is equipped with everything that is needed for highly professional and standardised study conduct, including temperature-controlled IMP- and sample storage, sample processing area, EDC system for sample tracking, continuous subject's surveillance system, kitchen and air conditioning.

Technical equipment and SOPs correspond to the ones of the main CPU so that our employees find identical conditions in both sites and subjects may also be transferred from one unit to the other whenever meaningful.

Study Volunteer Recruitment Potential

Excellent access to healthy volunteers and symptomatic patients

Well-maintained subjects' data base

Our subject database contains more than 2,000 volunteers, including healthy subjects of both sexes. The database is continuously maintained to ensure that the subjects are still active and available. We regularly organise public campaigns in social- as well as print-media and at universities to recruit new volunteers. Furthermore, we have good access to a large number of postmenopausal women and elderly subjects.

SocraTec R&D enjoys an excellent reputation in Erfurt and the surroundings, so that recruitment even during and after the pandemic stays continuously on a high and reliable level. This applies also to defined special populations.

Recruitment via referral networks

Symptomatic patients are recruited not only through our clinic but also via an established referral system for various indications all over Thuringia.

Over the years we have established several referral networks in different indications whenever recruitment is better via specialised medical offices. Due to the trust we enjoy in that region we are able to quickly set up new networks whenever needed. There are not many competitive trials in the region where we are located, so that we often provide the only access to clinical trials for patients as well as physicians.

Our advantages:

- Centrally located with excellent public transportation for trial participants
- Large geographical catchment area for healthy subjects of all ages
- Excellent patient access with a very low level of competitive trials
- Large subject's database of healthy subjects
- Established referral network for symptomatic patients
- Access to all medical-technical equipment of the maximum care hospital

Data Management & Pharmacokinetics

Clinical Data Management and Biometrics

SocraMetrics

For single- and multi- centre trials our Data Management Group at SocraMetrics is your professional partner with a highly motivated team with excellent academic background and a modern IT concept in line with requirements of CRF 21 Part 11. CDISC, SDTM and ADaM are fully established.

The very experienced software developers are responsible for the security of the IT system and tailored software programming. Our team of SAS programmers is responsible for statistical evaluation.

The Data Management group is experienced in early phase trials - keeping tight timelines during SAD / MAD trials is mandatory for us. Supported by well-designed eCRFs and pre-programmed evaluation strategies the schedules for interim evaluations (clinical data as well as PK) are reliably kept.

We offer data base service for your complete development program facilitating meta-analyses.

Pharmacokinetics

From First-In-Human to Bioequivalence

SocraTec R&D performs classical non-compartmental (NCA) pharmacokinetic (PK) analyses for pilot studies and pivotal trials used for approval in the EU and worldwide including US-FDA. From first-in-man to bioequivalence trials – our experience covers all relevant settings over decades of practical experience:

- Design development and sample size estimations
- Study performance in phase-I settings as well as later phases
- Statistical Analysis Plan development, evaluation and interpretation of study results
- "Probability of success" estimation based on in-vitro investigations

Evaluations are run by a team of experienced PK analysts, all of them with a university background. All evaluation steps are SOP-based and embedded in a comprehensive quality assurance system with internal quality control procedures for all potentially vulnerable steps, based on a systematic risk analysis. Our NCA evaluation is based on Phoenix WinNonlin and established in a validated IT environment.

Supportive Expertise: MW, QM and PV

Medical Writing Services

Our Medical Writers are highly qualified scientists (PhD or approbated pharmacists) and regularly extend their knowledge via the EMWA Professional Development Programme. They have excellent writing and communication skills and are experienced in preparing documents for any therapeutic indication. Our experience includes but is not limited to:

- Scientific Advice documents
- Study Protocols and statistical planning documents (SAP, DMP)
- Investigator's Brochures (IBs) and Patient Safety Narratives
- Patient information including Informed Consent and Patient Brochures
- ICH-GCP-compliant Clinical Study Reports (CSRs)

Our services are fully compliant with International Conference on Harmonisation (ICH) and Good Clinical Practice (GCP) regulations.

Quality Management

The quality management system is strongly influenced by GLP and GCP and follows a modern risk-based approach. All processes are compliant with current EMA and FDA requirements and embedded in a comprehensive Quality Management under the supervision of a very experienced QA-group. Frequent audits by all types of pharmaceutical companies, EU- and US-Authorities and ANVISA inspections ensure highest quality.

Pharmacovigilance for clinical trials

PV service for clinical trials but also MAA

We provide the worldwide PV management for sponsors of clinical trials on a worldwide level, handling all phases (I – IV). We will guide and support you from the first CTIS application until the pivotal phase III trials. Especially for start-ups and small companies we provide full PV service from the beginning.

Practical experience that matters

SocraTec R&D represents decades of experience in early phase trials. PK, BA/BE, DDI, PoC trials and all other special fields of early drug development are filled with practical experience.

What We Stand For

Our Claims

Following the principle "Success through Competence" we work out intelligent but pragmatic solutions to problems. With expertise and experience we provide professional and problem-orientated support for the developmental needs of our customers.

Our Principles

Clearly identifiable expertise, committed approach, customer-specific services and professionalism at the highest level are the key factors of our corporate philosophy. When it comes to competence and quality, we are not willing to make any compromises.

Our Visions

- To improve efficiency in pharmaceutical development and clinical research by bringing together excellent biopharmaceutical and medical expertise
- To work successfully and professionally as integral part of the sponsors' project team
- To advance drug therapy by adapting the biopharmaceutical properties of a formulation to the physiological conditions and clinical needs

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