SocraTec R&D - the Bioequivalence Experts

Our BE expertise in a nutshell

SocraTec R&D, a mid-sized clinical CRO was founded in 1998. From the beginning the company was dedicated to BE, PK and PD trials in healthy volunteers, extending the activities towards patients and later phases during their history. The key staff members of the company have far-reaching experience from many years in drug research and development.

We have realised more than thousand bioequivalence trials of various types investigating different immediate release, orodispersible and modified release oral dosage forms but also all types of products with divergent routes of application like transdermal therapeutic systems and other dermally applied formulations, orally inhaled drug products, vaginally and rectally applied dosage forms, nasal sprays, intramuscular depot formulations, and ocular dosage forms.

We are ANVISA certified - in case your development program also includes Brazil we are your perfect partner and allow you to include the Brazilian reference product as additional arm of the trial.

ANVISA certified unit for Brazilian submissions

We have roughly 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 actively involved in development of BE standards worldwide and therefore, we are always a bit ahead of time.

We very often realise consultancy activities for our clients, a service which is useful for the client and at the same time extends our own expertise. And - we do help our clients avoiding unnecessary BE trials by full support of BCS-based biowaivers and strength waivers.

Consultancy support for biowaivers

SocraTec R&D - the full-service CRO

Sponsor’s representative in the EU / sponsorship

For our clients who are not located in the European Union, we take over the legal function as a sponsor’s representative within the European Union. Our Quality management System is adapted to full sponsorship, so that we may even take of this role if meaningful and needed.

Fully SOP-based sponsorship

Pharmacovigilance System

Our one-stop shop concept also covers the full PV system being needed for any type of clinical trials and for post marketing (pharmaco)vigilance services.

PV-services worldwide - not only for our own studies

The European Clinical Trial Regulation

For us CTIS is nothing magic. Our project management team is fully experienced in the new application procedures and covers all tasks and responsibilities. In the meantime, BfArM has adapted the approval processes so that we can achieve full clinical trial authorization within 31 days including ethic’s vote. Furthermore, in the sense of a “gentlemen’s agreement” BfArM reduced the deficiencies or so-called requests for information in favor of “approvals with conditions” and if possible provides approvals even a bit faster for BE trials with approved drug compounds – a lot of progress over the last months has been achieved!

Latest News: accelerated appoval times in Germany

Optimum clinical conditions for bioequivalence trials

Our 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.

SocraTec R&D

Fully equipped Clinical Pharmacology Unit

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 which allows us to run also trials with high number of subjects needed keeping the number of groups as small as possible.
- A Tetronic (former Siemens) central surveillance system, on the basis of Vaisala measuring devices is our internal standard; software is validated following the requirements of US CFR 21 Part 1. 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.

CFR 21 Part 11 compliant systems

- Standardised conditions in pharmacokinetic trials are ensured by temperature-controlled surrounding (AC) and modern kitchen facilities with trained staff and established processes for both high-fat, high-caloric as well as continental breakfast in fed studies. All our team members are very experienced in BE trials and are fully aware of the relevance of standardised application conditions.
- Special equipment e.g. for gynaecological and ophthalmological applications as well as standardised systems for assessment and photographic documentation of patch adhesion as well as skin irritation assessment for transdermal therapeutic systems is available and integrated in SOP-based routine processes ensuring highest level of standardisation also for sophisticated dosage forms.

Fully equipped CPU dedicated to the needs of phase-I studies

- We are experienced in developing tailor-made application procedures to optimise highly standardised topical applications for solutions, ointments and creams including a back-weighing process for the application device used ending in a fully controlled process. Including this in a success-controlled training system for the staff members who realise the application in the trial ensures optimum standardsation in critical studies.
- Other highly specific study designs like charcoal studies and studies for characterisation of influence on hypthalamic-pituitary axis for OIDPs are fully established.
- We are experts in opiod handling: Our unit is fully equipped with all protection equipment for storage of restricted drugs and we have already realised hundreds of BE trials with any type of narcotics - oral as well as transdermal and nasal.

Study Volunteer Recruitment Potential

Excellent access to healthy volunteers including postmenopausal women for hormone trials

Our subject database contains more than 6,000 volunteers, including roughly 4,000 healthy subjects of both genders. 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 also elderly subjects, if needed in certain settings. Our successful recruitment experience covers trials with significantly more than 100 subjects.

Biosimilar experience

For trials exceeding our capacities like biosimilar studies to be realised in a very short time we perform such trials as lead CRO with other German phase-I CROs. We recently completed the recruitment of a biosimilar study with 490 subjects within 4 months.

Bioanalytical services

EMA, FDA and ANVISA requirements are fulfilled

We care for the bioanalytical quantitation: we select the most appropriate bioanalytical laboratory for our clients. Whenever possible we work with our regularly audited preferred provider lab located in Germany, which offers excellent quality combined with a very reasonable price level and a very good inspection readiness. However, in those cases where other labs are preferred we support the selection process by an audit-based qualification. Longterm GLP-experience in our auditing group is here extremely useful.

Clinical Data Management and Medical Writing

Data Management and PK evaluations

Realised by our sister company 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 and IT-systems services at SocraMetrics are fully FDA compliant and follow the high standards of 21 CFR Part 11 and of GAMP-5.

Depending on the requirements of our sponsors we offer both, paper-based CRF and well as highly flexible eCRF services. Our paper-based CRF is still often attractive for short, monocentric BE trials, especially as we have a modern technology behind which allows the first data entry via scan process, and only the second one is done manually.

Experienced PK-experts in our teams

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 and ANVISA. 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 interpreation 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. Statistical analyses of PK parameters are either done in WinNonlin or SAS depending on the sponsor’s requirements.

SocraTec R&D

Reporting and publications

Medical Writing Services

Highly qualified and experienced Medical Writers ...

Excellent Medical Writing is essential for the presentation of clinical data as well as the communication of research results to different target audiences. This makes Medical Writing an important part of clinical research and this is why we take it seriously.

... connected to dedicated expert teams

Our Medical Writers are highly qualified scientists (PhD or approbated pharmacists) and regularly extend their knowledge via training at conferences held by the European Medical Writers Association (EMWA) and the EMWA Professional Development Programme. They have excellent writing and communication skills and are experienced in preparing documents for any therapeutic indication. Our Medical Writers closely co-operate with our biopharmaceutical, clinical-pharmacological, statistical and regulatory specialists.

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

What We Stand For

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.

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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