SocraTec R&D: Clinical Trials in Ophthalmology

SocraTec R&D - a company profile

SocraTec R&D, a mid-sized clinical CRO was founded in 1998. From the beginning the company was dedicated to early phase clinical 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.

Highly Experienced CRO

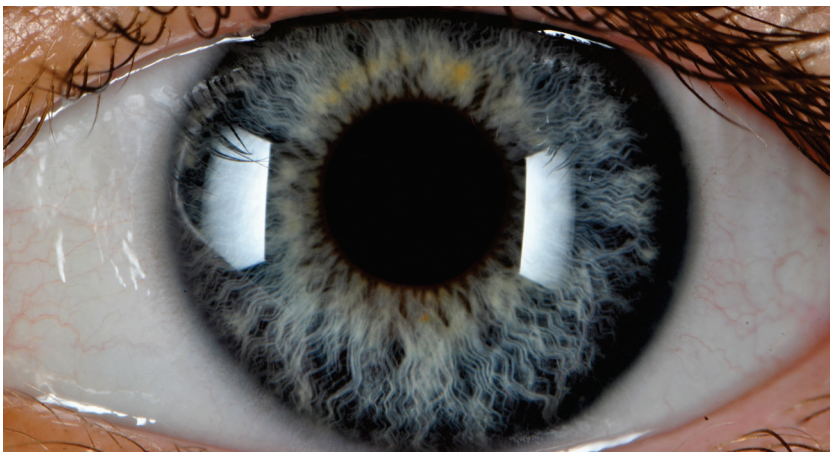
Quality Management

From the beginning SocraTec R&D was set-up with a modern quality management concept strongly influenced by GLP- and GCP-principles. All processes are embedded in a comprehensive Quality Management under the supervision of a highly experienced and independent QA-group. Biometric services follow the standards of 21 CFR Part 11. SocraTec R&D is frequently audited by all types of pharmaceutical companies and has been inspected by national EU-agencies, EMA and FDA as well as by ANVISA.

Phase-I Clinical Pharmacology Unit(s)

Early Phase Trials

- From the beginning we have been operating our own CPU near Weimar, focused on phase-I-activities
- Today's main CPU with a total of 54 beds on 1,600 sqm is located in Erfurt close to the city center
- An additional intensive monitoring CPU, is located directly on the grounds of Erfurt's maximum care hospital (former university clinic), providing ideal conditions for First-in-Human trials and early phase trials in symptomatic patients with increased safety requirements
- Close cooperation with the circumjacent hospitals, as well as networks of physicians ensure rapid recruitment of symptomatic patients when investigating specially selected populations.



SocraTec R&D

Our on site Intensive Monitoring CPU at Helios

Excellent scientific and medical know-how under one roof

Our specialised intensive monitoring CPU is operated in cooperation with the Helios Klinikum in Erfurt and is located directly on the hospital grounds. With Helios being a high-performance maximum care hospital with about 1.300 beds, covering almost every clinical speciality, this is an ideal constellation for FIH- and Early-Phase-Patient trials.

While SocraTec R&D's experienced scientists design and coordinate all projects, Helios' 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 knowledge we are not only able to conduct FIH-trials necessitating highest safety monitoring standards, but can also realise complex phase IIa/IIb studies with volunteers from the Helios patient population. Since Helios regularly treats about 58.000 patients per year, this cooperation provides excellent access to patient populations with various disease entities for your Early-Phase-Patients trials.

SocraTec R&D directly interacts with the maximum care hospital and therefore, has access to the ophthalmological patients of the hospital. As a lot of such patients are run on an ambulatory basis, we are operating with a network of referrals which is described later in the flyer.

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, and air conditioning.

Dedicated To The Eye

Our highly engaged network of research-based ophthalmologists and optometrists, supported by SocraTec R&D`s own phase-I-investigators, clinical pharmacologists and experienced team of study nurses offer a broad spectrum of eye-related investigations in healthy subjects and patients:

Indications

1. Diseases of the anterior segment:

- Inflammatory disorders, such as Dry Eye syndrome, also known as keratoconjunctivitis sicca and blepharitis, allergies, corneal ulcers, infections and uveitis

2. Diseases of the posterior segment:

- Macular Degeneration, Macular Oedema and Vascular disorders

3. Glaucoma

Patients may be enrolled in proof-of-concept and dose-finding trials in our site, but also First-in-Human studies may be realised.

Besides our clinical pharmacology expertise all routine ophthalmological exams are performed in our unit. Technically more sophisticated investigations are realized in the Helios hospital, where our intensive care unit is located. The technical equipment currently available is listed in the following, other methods may be established upon request:

Ophthalmological Methods

1. Anterior segment of the eye:

- Slit lamp microscopy, gonioscopy, topography and aberrometry, Pentacam Scheimpflug Imaging, anterior segment OCT, osmolarity and endothelial cell measurement

2. Posterior segment of the eye

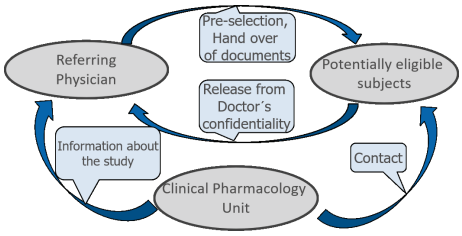
- Ophthalmoscopy, optical coherence tomography (OCT), fluorescence angiography, autofluorescence and retinal vessel analysis

Surgical facilities are also connected.

Further measurements like refractometry, tonometry, perimetry and biometry complete the toolbox of investigations.

Our Recruitment Concept via Referrals

Besides our access to the ophthalmological patients of the Helios hospital in Erfurt we recruit our patients from a network of centralised ophthalmological competence centres, where patients are referred to from locally practising ophthalmologists for optimised diagnose, surveillance and treatment and where competing trials are of minor relevance.



Healthy subjects come from our own data base. Patients are recruited according to the requirements of the individual study protocol via referring ophthalmologists and they are then hospitalised in our own Clinical Pharmacology Unit for study conduct.

Study participants may also be treated in the cooperating maximum care hospital under our supervision depending on the specificities of the trial protocol.

Current Situation

Our Ophthalmological Network has been established with cooperating competence centres and reaches several local registered ophthalmologists working in private practices.

This network covers a vast area in the middle and Western part of Thuringia, with significant numbers of patients and a marginal risk of potentially competing trials.

Professional Conduct

Recruited patients are hospitalised in our experienced Phase-I-unit for conduct of the clinical trial. There the patients undergo the Informed Consent Procedure and the study itself is run by our GCP-trained staff composed of investigators, study nurses and dieticians under supervision of the monitoring group and QAU of SocraTec R&D. This guarantees highly standardised processes and professional documentation. Our Quality Management System ensures highest quality standards.

In cases where the treatment demands direct surveillance of the competence centres or the maximum care hospital, our trained personnel supports the performance of the trial directly within these units.

What We Stand For

Practical Experience that Matters

SocraTec R&D represents decades of experience in early phase as well as late phase trials. PK, BA/BE, DDI, PoC trials and all other special fields of 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-solving oriented support for our customers' drug development needs.

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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