

SocraTec R&D: Clinical Trials in Ophthalmology

SocraTec R&D - a company profile

SocraTec R&D was founded in 1998 by Henning Blume and Barbara Schug. Both founders have far-reaching experience from many years in drug research and development, particularly in the fields of biopharmaceutics and Phase-I clinical studies. Meanwhile they have also expanded their activities to later stages of clinical development. SocraTec R&D operates from two locations in Germany: the Frankfurt/Main area and Erfurt, the capital of Thuringia. SocraTec R&D offers a service profile at the highest professional level.

Highly experienced CRO

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.

Quality Management

Phase-I Clinical Pharmacology Unit

Our Clinical Pharmacology Unit is located in the center of Erfurt. There are 60 beds available in a modern and functionally equipped clinical ward, the use of which can be varied according to study requirements. Even though study volunteers or patients and personnel are always close at hand the unit is also easily accessible to our clients. Here, with the help of a modular organisation principle, early phase trials with varying numbers of volunteers and patients and with various requirements are carried out under highly standardised conditions. Close cooperation with the circumjacent hospitals as well as networks of physicians ensure rapid recruitment of symptomatic patients when investigating specially selected populations. In this way the advantages of a classical CRO are combined with those of a SMO.

Early Phase Trials





Dedicated to the eye



Our highly engaged network of research-based ophthalmologists and optometrists, supported by SocraTec'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:

1. Diseases of the anterior segment of the eye:
 - Inflammatory disorders such as Dry Eye Syndrom, Allergies and Uveitis
2. Diseases of the posterior segment of eye:
 - Macular Degeneration
 - Macular Oedema
 - Vascular disorders
3. Glaucoma

The ocular tolerability, pharmacokinetics and dose-escalation will first be tested in healthy subjects.

Besides our clinical pharmacology expertise all routine ophthalmological exams are performed in our unit.

Technically more sophisticated investigations are also available:

1. Anterior segment of the eye:
 - Slit lamp microscopy
 - Gonioscopy
 - Topography and Aberrometry
 - Pentacam Scheimpflug Imaging
 - Anterior segment OCT
 - Osmolarity
 - Endothelial cell measurement
2. Posterior segment of the eye
 - Ophthalmoscopy
 - Optical coherence tomography (OCT)
 - Fluorescence angiography
 - Autofluorescence
 - Retinal vessel analysis

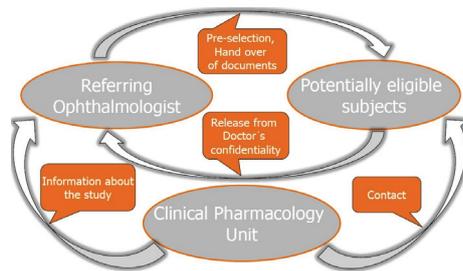
Further measurements like refractometry, tonometry, perimetry and biometry complete the tool of investigations.

Surgical facilities are also connected.



The Recruitment Concept

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.



Subjects or patients are recruited according to the requirements of the individual study protocol via referring ophthalmologists and they are then hospitalised in our Clinical Pharmacology Unit for study conduct. Alternatively they may also be treated in the competence centres under our supervision depending on the specific conditions of the trial.

Current Situation

Our Ophthalmological Network has been established with 2 cooperating competence centres and thus reaches about 50 local registered ophthalmologists working in private practice.

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.

In cases where the treatment demands direct surveillance of the competence centres our trained personnel supports the performance of the trial directly within the centre.

The Advantages

- Availability of a high number of patients with precise diagnosis
- Fast recruitment
- Highly standardised study conduct
- Comprehensive GCP-performance
- Audit- and inspection-ready processes, documentation and training



Reliability and Quality

Reliability counts

SocraTec R&D now has a workforce of more than 120 skilled employees with extensive experience. Combined with our network of ophthalmologic sites, competence centres and referring ophthalmologists, which provide reliable feasibility assessment, this is a unique setting ready for the conduct of complex clinical trials.

Quality matters

Our longstanding experience in all types of Phase-I-trials allows a high level of scientific and medical expertise, excellent standardisation and active contribution of all employees to appropriate and high-end study conduct. Further, our well-known quality level is reflected in the solid track record of our QA team in the management of high-level audits and inspections.



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