Gynaecology: your market – our clinical expertise

SocraTec R&D – a company profile

Highly experienced CRO

SocraTec R&D, a mid-sized clinical CRO with strong niche expertise, was founded in 1998. The founders, Prof. Dr. Henning Blume and Dr. Barbara Schug, as well as all key staff of the company have far-reaching experience from many years in drug research and development. The expertise covers a broad range from early phase clinical trials up to later stages of clinical development. From the beginning SocraTec R&D was active in the medical field of gynaecology. This expertise is extended by a close cooperation with a strong network of local gynaecologists, a well-versed gynaecological advisor with active clinical background and – not least – by a co-operation with a niche CRO specialized in ovulation inhibition studies: Dinox (www.dinoxgroup.com).

Quality Management

From the beginning the company 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 supervision with a very experienced QA-group. Biometrical services follow the high standards of 21 CFR Part 11. SocraTec R&D is frequently audited by all types of pharmaceutical companies and has been inspected by EU- and US-authorities as well as by ANVISA.

Phase-I Clinical Pharmacology Unit

Early Phase Trials

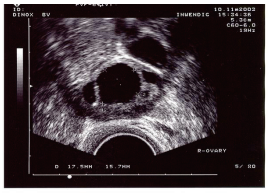
Our Clinical Pharmacology Unit is located in the centre of Erfurt. There are 60 beds available in modern and functionally equipped ward. Study volunteers and personnel are close at hand but the unit is also easily accessible to our customers. Here, early phase trials with varying numbers of volunteers as well as patients and differing requirements are carried out under highly standardised conditions. Close cooperation with the circumjacent hospitals as well as a network of physicians ensure rapid recruitment of symptomatic patients when investigating specially selected populations.

© wavebreakmedia/Shutterstock

SocraTec R&D

Hormonal contraceptives – the topic No. 1

Early phase trials



Our highly engaged group of phase-I-investigators & clinical pharmacologists together with our local gynaecologists supported by an skilled team of study nurses offers a broad spectrum of gynaecological investigations in healthy subjects and patients.

For early-phase clinical trials with new compounds our clinical pharmacology unit is excellently equipped: experienced staff, high-level medical supervision as well as a full-service hospital nearby allows first-in-(wo)man studies on an international level.

Bioavailability and bioequivalence trials are run with a well-trained team. Our subject data base of young healthy and postmenopausal women (for SHGB-bound compounds) guarantees quick and reliable recruitment.

Proof of concept

Female Health Research dinox

In case your product enters the next step, proof-of-concept and ovulation inhibition studies accepted by authorities worldwide can be realised on a high professional standard together with our partner Dinox. Dinox further contributes with an excellent background in characterization of haemostatic system as well as lipid metabolism. Dinox has accompanied a relevant number of hormonal contraceptives approved worldwide and is frequently and successfully FDA inspected.

Phase III

The next steps – characterization of bleeding pattern and assessment of Pearl Index – are realised by our project management team in national and international multi-centre trials. Our co-operations allow also quick recruitment by involving Eastern European countries.

From the early beginning – the biopharmaceutical characterisation up to late stage testing (phase IV) we are the experienced partner for your gynaecological development programme.

HRT / Vaginal Health – a growing market

Safety first for hormonal replacement

Reducing the hormonal load in HRT comes along with a series of highly-sophisticated galenical solutions. Not simply oral IR formulations, but transdermal gels, intravaginal tablets or devices for long-term application are under development. Our biopharmaceutical experts help you to optimise your clinical program.

Postmenopausal women for early phase trials in our clinical pharmacology unit are recruited via our data base and our network of local gynaecologists.

Gynaecologically relevant surrogate parameters for efficacy and safety, e.g. maturation value, vaginal pH, endometrial thickness and specific clinical laboratory parameters are determined by our experienced phase I team.

Your project may also profit from the endometrial biopsy experience of Dinox.

Clinical Datamanagement & statistics

For our national and international multi centre trials our Data Management Group at SocraMetrics is your professional partner:

- Sample Size Estimation
- Statistical Planning together with the medical team
- Data Management in accordance with CFR 21 Part 11 and – if requested - CDISC/SDTM/ADAM
- DMP-/ DVP-/ SAP-based data handling and evaluation on a high technical standard
- Validated statistical programming

Biopharmaceutical expertise

Besides IR formulations we also know how to develop locally applied hormonal products including hormone-releasing devices.

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

SocraTec R&D

Reliability and Quality

Reliability counts

SocraTec R&D now has a workforce of more than 120 skilled employees. Combined with our network of gynaecological sites, competence centres and referring gynaecologists, 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. Our unit is regularly inspected by national and European authorities. We are successfully FDA-inspected and have a valid ANVISA accreditation.

Address

SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel

Telefon +49 (0)6171 58571-0
Fax +49 (0)6171 5857-25

info@socratec-pharma.de
www.socratec-pharma.de

Managing Directors

Dr. Barbara Schug
André Warnke

Commercial Register

Bad Homburg v. d. Höhe
HRB 6590

VAT ID DE197498889