SocraTec R&D - your OTC specialist

Why are OTC studies so special?

OTC patient populations

OTC patient populations are usually not found at the general practitioner's office.

- The patients usually treat themselves and do not see the doctor.
- The choice of medication is made through advertising, friends and acquaintances. Often, the pharmacist also gives advice.
- Particularly in the case of banal infectious diseases, treatment must take place shortly after the onset of the disease in order to adequately prove efficacy in the study.

Normally, the clinical implementation of patient studies is done in a multi-centre study setting using the treating physicians - this concept often does not work well for OTC products - except for paediatric drugs. Experience shows that recruitment via pharmacies is also often not successful.

As a professional Phase I CPU, we specialize in OTC efficacy studies

our medical team

- Our medical team of qualified nurses and experienced, professional investigators ensures efficient recruitment, highly standardised collection of clinical parameters with excellent data quality and almost 100% data capture - missing data is almost only found in drop-outs.

our networks

- For patients who can be reached through institutions, we work with our local networks, which have been well cultivated over 25 years; examples are nursing homes for the acceptance testing of high-calorie liquid foods and sports clubs for the testing of analgesics and anti-inflammatory drugs.

SocraTec R&D - excellent recruitment

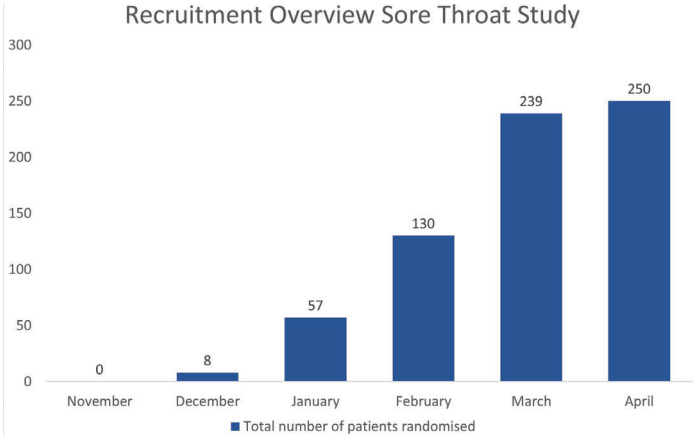
SocraTec R&D - Your full-service CRO

SocraTec R&D, a mid-sized clinical CRO was founded in 1998. From the beginning the company was set-up to provide full-service. Our team of project managers, clinical pharmacologists and medical writers supports with design and protocol development, realizes all regulatory aspects of the trial and coordinates the clinical part, which is monitored by our experienced monitoring team. The staff members in our CPU in the middle of Erfurt have far-reaching experience from many years in clinical drug development. Our team of data managers, biostatisticians and pharmacokineticists at SocraMetrics provides all biometrical services needed on an internationally accepted quality level.

sport injuries

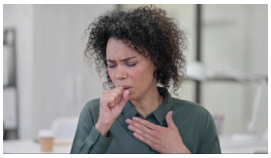
Excellent recruitment numbers speak for themselves

Depending on the indication, it is even possible to realise entire phase III studies in a monocentric setting. The following example of one of our sore throat studies, realised solely by our CPU in Erfurt, shows this impressively.



sore throat

- We develop indication-specific advertising concepts for our clients via newspapers, social media, flyers, banners, posters, and specific advertising campaigns in public transport and train stations.
- We use our very large pool of healthy test persons to initiate word-of-mouth advertising for individual studies on a regional basis.
- Our professional recruitment team conducts pre-selection based on specifically developed criteria through structured telephone interviews, to reduce the number of screening failures.
- In the case of seasonal diseases, we intensively focus on the period with the highest chances of recruitment.



cough

SocraTec R&D - What we stand for

Our creativity knows no limits!

Our team of project managers, experienced clinicians, pharmacologists, biostatisticians and recruitment specialists love to develop individual and tailor-made solutions. Every project is different and there is no "one-size-fits-all". We deal intensively with your project - if desired, our pharmacologists and design specialists also take over the development of the trial design and statistical concept. We design the optimal recruitment concept for you and closely coordinate the planning with you, so that you can also optimally contribute your experience with your product.

urinary tract infections

Taking SocraTec R&D and SocraMetrics - our biometrical company - together, 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.

What we stand for

Our company was set-up with a modern quality management concept, strongly influenced by GLP- and GCP-principles. 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 as well as EU- and US-Authorities and ANVISA inspections ensure highest quality standards.

constipation

SocraTec R&D represents 25 years of experience in the recruitment of various patient populations in Thuringia - we know how to get access to the population needed.

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 vision

- 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

OTC studies – perfect setting for virtual trials

Incorporation of digital health technologies into study design is an emerging trend in drug development. Virtual clinical trials offer the advantage that all or part of the study incorporates digital health technologies such as mobile devices, mobile apps, remote monitoring devices, and online social engagement platforms and enables remote participation outside of the traditional clinical trial site. For banal diseases visiting a doctor is not mandatory and patient-reported outcome is of high relevance for efficacy assessment. So, for trials with OTCs a partly or even full virtual approach is highly interesting:

video-based consultations

- Multiplication of patient accessibility via social media
- Monocentric setting with cross-regional recruitment improves cost-effectiveness
- Facilitated recruitment due to very low patient burden

The technical challenges are in good hands with us and our experienced team of programmers and software developers enable cost-effective, secure and creative solutions for your specific trial

Pre-defined processes ensuring GCP compliance, data protection and subject compliance

smooth interaction

- Video-based informed consent procedure and within-trial consultation with a certified provider for video consultation used also by general practitioners
- Strict cyber security policies ensure secure user accounts and data transfer - comprehensive and secure data back-up concept
- Validated ePRO/eDiary solutions with web-based access (“BYO Device concept”)
- Established processes for IMP shipment and device transfer to subjects observing data protection requirements in clinical trials
- IT-based reminder function-direct interaction with eCRF and pre-planned alarm function for staff in case of compliance issues
- Regular patient contact ensured by a highly qualified clinical team with full GCP background

Enter new territory with and we develop and realise your virtual trial!

SocraTec R&D - OTC paediatric studies

The world is a different place for children

Children are not small adults! Even though there are non-prescription drugs for many children's diseases, in most cases the involvement of a paediatrician is necessary and sensible when conducting clinical trials. We realise these OTC paediatric studies with paediatricians in private practice. In the meantime, this is even easier in Germany from an organisational point of view, because the new CT regulation has removed the requirement for a deputy. In the past, this was sometimes difficult in paediatric studies.

Interested?

Are you planning a phase II or III study with an OTC? Our team will be happy to advise you and develop suitable study concepts for you and with you. If the study should preferably be realised in several centres, we will gladly support you with our experience in the selection of further professionally operating institutions and take over the overall coordination of your project, also together with other sites. We realise your plans!

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