SocraTec R&D

# Your Partner for Consultancy & Medical Writing

We provide scientifically accurate, clear and concise medical and scientific documents – this is what our team stands for!

State-of-the-art medical communication – targeted to the audience – is key for interaction with medical experts, authorities and our clients and is therefore an essential pillar of our consultancy activities. Together with our dedicated scientific experts we support your development project – from the beginning until marketing authorisation, and even beyond.

## SocraTec R&D – a company profile

SocraTec R&D is a mid-sized full-service CRO founded in 1998. All key staff members have far-reaching experience from many years in drug research and development. Our expertise covers early phase clinical trials, conducted at our own clinical pharmacology units, and later stages of clinical development. In addition – and this is what makes us unique – we assist our clients in setting up their clinical development programme and accompany them through scientific advices with EU and US regulatory authorities.

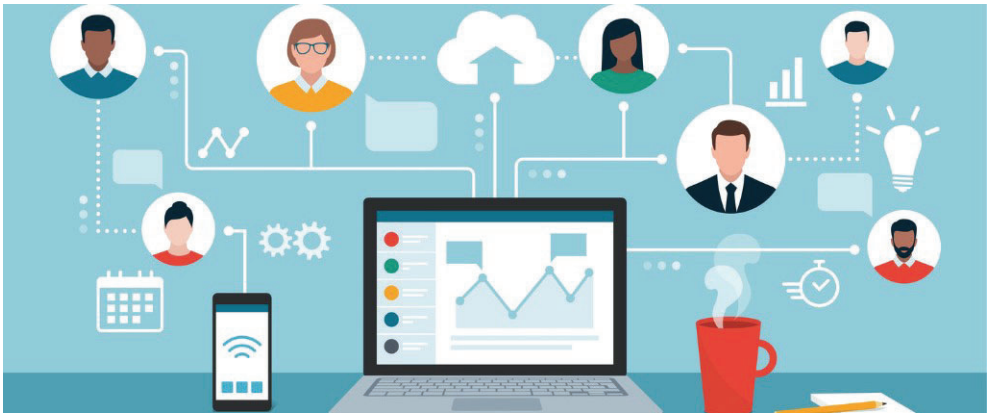

## The combination of experience and expertise is the key!

Our Medical Writers are highly qualified scientists and regularly extend their knowledge via training provided by the European Medical Writers Association. They have excellent writing and communication skills and are experienced in preparing clinical, regulatory and medical writing for any therapeutic indication. Our Medical Writers closely co-operate with our biopharmaceutical, clinical-pharmacological, statistical and regulatory specialists.

We timely deliver accurate and cost-effective documents with highest ethical and scientific standards!

Highly qualified and experienced Medical Writers ...

... connected to dedicated expert teams



SocraTec R&D

# Full Support for your Clinical Development

## Clinical Writing – everything around your trial

We provide you with ALL documents needed for each stage of your clinical development. Our broad expertise covers:

- Standard Operating Procedures (SOPs) covering all aspects of drug development including the design, conduct and reporting of clinical trials and the outsourcing of Sponsor responsibilities to a CRO
- Clinical Study Protocol and statistical planning documents (SAP, DMP)
- Investigator's Brochure (IB)
- Patient information including Informed Consent and Patient Brochures
- Investigational Medicinal Product Dossier (IMPD) including quality dossiers
- ICH-GCP-compliant Clinical Study Report (CSR): Phases I to IV and non-interventional studies, including CSR synopses for public disclosure
- Patient Safety Narratives
- Layperson / Plain Language Summary (PLS)
- Pharmacovigilance documents such as Periodic Safety Update Reports (PSURs) / Development Safety Update Reports (DSURs)
- Response documents to Deficiency Letters from authorities

## Regulatory Writing – support for your MAA

Our expertise covers the clinical and non-clinical documentation for your marketing authorisation application (MAA), including:

- Clinical Summary (CTD module 2.7) and Clinical Overview (CTD module 2.5)
- For EU and US regulatory authorities

# Full Support for your Clinical Development

## Consultancy – support for trial design and scientific advice

Our dedicated team of experienced biopharmaceutical, clinical-pharmacological, statistical and regulatory specialists supports you with any question you might have during your clinical development. In addition, our established network of external experts can provide further support. Our excellent Medical Writers bring it to paper – clear and concise:

- Planning of your drug development programme and approval pathway
- Planning of your clinical trials from Phases I to IV with our clinical-pharmacological and biopharmaceutical experts, including development of single- or multiple ascending dose study design
- Scientific advice meetings with EU or US authorities: including briefing book, study outline, meeting support and meeting minutes
- Expert statements

## Medical Communication – everything beyond your trial

Your clinical trial is completed or your marketing authorisation has been granted – what comes next? Our Medical Writers are experienced in publishing your clinical trial results, the results of your advisory board meeting or a review article on your defined scientific topic. Further, our Medical Writers have profound expertise in developing other kinds of medical communication materials – targeted to different audiences. Our professional medical communication support includes the following, but is not limited to:

Your first-class partner for medical communication targeted to different audiences

Check out our latest publications at PubMed or our company homepage!

- Full-service package for manuscripts: from journal selection to publication, including set-up of an EndNote literature library, management of author reviews, submission, revision and journal communication
- Conference materials: abstracts, posters, slide presentations
- Brochures, print inserts, e.g., Thieme Case Report
- Website content
- Technical illustrations for brochures, leaflets and package inserts

# Why SocraTec R&D?

## What we stand for

Our values

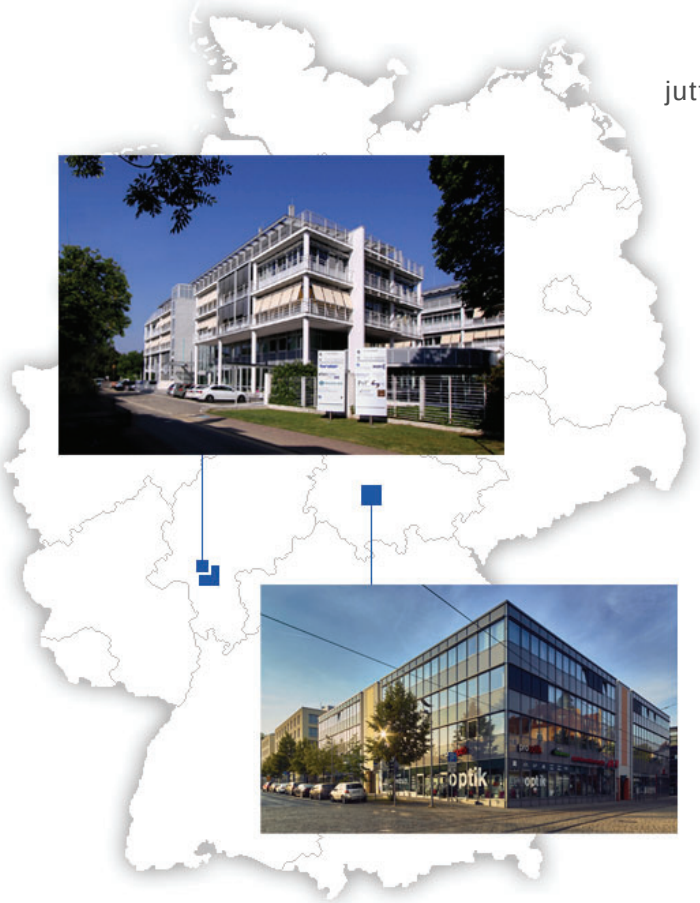
Clearly identifiable expertise, committed approach, customer-specific services and professionalism at the highest level are key for our corporate philosophy. When it comes to competence and quality, we do not make compromises!

## Why we are unique

Excellent teams have the best results

Our highly qualified and experienced team of Medical Writers is embedded in a full-service CRO with consultancy expertise from a dedicated team of biopharmaceutical, clinical-pharmacological, statistical and regulatory specialists. This enables us to incorporate the scientific knowledge from different disciplines into accurate and profound documents.

We provide excellent consultancy and medical writing services at each stage of your product development programme – during the planning phase, scientific advice procedures with authorities, clinical phase, marketing authorisation application, and even beyond.



Contact

Dr. Jutta Walstab
jutta.walstab@socratec-pharma.de
+49 (0)173 6269926

Address

SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel

Clinical Pharmacological Unit
Mainzerhofplatz 14
Eingang B
99084 Erfurt

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

© 2023