

F A C T S H E E T

INFECTIOUS DISEASES

YOUR COUNTRY

SCOPE International is an international and independent full-service contract research organization (CRO) known as a reliable and proven partner for many pharma, biotech and medical device companies. We have excellent expertise in delivering clinical trials for development programs in the field of infectious diseases. One of our major USPs is our close relationship with sites and a vast network of experts and key opinion leaders worldwide.

Augmented by the COVID-19-pandemic, infectious diseases with the potential to severely impact public health and economies have raised high interest for the development of new vaccines and cures. The need for clinical trial expert leadership is paramount to achieve fast bench-to-market timelines, especially when developing new drugs for unmet needs.

SCOPE provides this kind of expert leadership across the major markets – EUROPE and USA –that will make the difference for your clinical development programs and for the time to market, making new therapies available even faster for the benefit of public health and economies.

We work with in a network of fully operational local offices across Europe, Russia, Ukraine and the USA. Other areas are covered with well-established partners, all tailored to the need of your project and for the best performance of your trial.

KEY SUCCESS FACTORS IN INFECTIOUS DISEASE STUDY DESIGN & MANAGEMENT

- **Expertise**
- **Optimal recruitment strategies**
- **Stable & experienced project teams**
- **Telemedicine**
- **Excellent site management & support**
- **Efficiency on time and budget**
- **Consistent high quality**

Whether it's a clinical developmental trial in PHASE I-III, post-authorization study in PHASE IV or a study rescue, SCOPE has the expertise, know-how, and resources to guide you through all phases of development while meeting your objectives and expectations.

INDICATION-SPECIFIC EXPERTISE

SCOPE International's team has managed clinical trials (Phase I-IV) for:

- **Human immunodeficiency virus – HIV**
- **Community-acquired Pneumonia – CAP**
- **GI, intra-abdominal infections**
- **COVID-19**
- **Respiratory virus infection**

FROM STUDY DESIGN TO STUDY REPORT

SCOPE's full-service portfolio offers you the whole set of fully integrated services while working with one dedicated Project Manager and the PM's team. You will have the best team for the successful and efficient preparation and setup, submissions, conduct and close-out of your study.

SUCCESSFUL, PRAGMATIC AND PROVEN DURING COVID-19

The previous months have shown how dynamic the pandemic situation and the challenges for clinical research can be. With experience, flexibility and a pragmatic approach, SCOPE has established new, unique and regulatory sound processes to maintain recruitment in all clinical trials.

KEY FACTORS FOR SUCCESS DURING COVID-19

- **Assessment of local and national pandemic development**
- **Identification of ultimate risk factors for patients and study data, prioritization**
- **Continuous review and assessment of the latest national regulations and requirements**
- **Extensive collaboration and communication with national authorities and ethics committees**
- **Development of corporate strategy, even prior to official authority regulations and permanent study-specific adaption**
- **Supporting sites in implementing preventive measures to ensure patient's safety when visiting sites for patient visits, as well as for CRA onsite monitoring visits and implementing remote 'site' visits**

Our project teams have the specific clinical expertise in Infectious Diseases needed for the success of your studies and programs.

Our low employee turnover rate allows consistency and continuity across multiple studies in a development program or across different programs.

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EXPERIENCE IN INFECTIOUS DISEASES



STRATEGIC
DEVELOPMENT



MEDICAL
WRITING



BIOSTATISTICS AND
SAS® PROGRAMMING



QUALITY
MANAGEMENT



CLINICAL
OPERATIONS



CLINICAL DATA
MANAGEMENT



SAFETY
MANAGEMENT



REGULATORY
AFFAIRS

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