

A FOCUS Service to rapid & reliable Patient Recruitment

At the FOCUS of Clinical Research

There is a great need for new discoveries in medicine and safer and more effective new drugs. The success of clinical trials depends not only on the products to be tested, well-designed study protocols but most importantly on the rapid and reliable recruitment of eligible patients.

FOCUS is a provider of large numbers of high-quality patients to its sponsors due to its hospital-based patient-recruitment strategies.

The Clinical Research Units of FOCUS operate to the highest possible ethical and scientific standards. Our recruitment programmes are focusing on the individual subject (patients and healthy volunteers) first, and we spend significant time on the patient demographics and physician-patient relationship. At FOCUS we carefully select the pool of screened and enrolled subjects to ensure volunteer co-operation, high compliance and retention up to study completion.

FOCUS has conducted many patient studies and on the basis of our recruitment database we are able to provide realistic figures of patients recruited per month. As an example, please find in the Figure below some examples FOCUS patient recruitment rates.

FOCUS Patient Locations

Geographically FOCUS has positioned itself in Europe & Asia by having sites in Neuss (Germany), Düsseldorf (Germany), Moscow (Russia), Belgrade (Serbia), and Dubai (United Arab Emirates). It has further strengthened its position by having strategic co-operations with Investigators & Clinics in India.

Neuss (Germany)

FOCUS NEUSS has strong scientific and operational expertise. Its track record includes successful completion of > 80 First-in-Human studies in diverse therapy areas for NCE's and NBE's. We have collaborated with many clinical investigators in western and eastern Europe in the conduct of multi-center, multi-country clinical phase II & III trials.

Düsseldorf (Germany)

Our hospital-based ward in the University Medical Hospital is used for the conduct of (first-in-human) studies with small molecules, biologicals and vaccines, which may carry an increased risk according to the recently issued EMEA Guideline on strategies to identify and mitigate risks for First-in-Human clinical trials. In addition, we have an alliance with the Düsseldorf University Oncology Center for the conduct of First-in-Patients studies with new anti-cancer agents (see Figure below). For larger studies we collaborate with the University Clinical Hospitals in Aachen, Essen, Jülich, Köln and Freiburg in Germany.



- Oncology competence
- Access to various oncology disciplines and clinical/scientific experts
- Access to patients with various malignancies
- Recruitment of patients for clinical trials of major scientific interest
- Infrastructure of a large university hospital

- Clinical pharmacology competence
- Experienced personnel, in particular for the special requirements of phase-I-trials
- Fully functional phase-I unit in the UKD premises
- All operative units available for clinical trials (e.g. project management, data management, statistics, QA, medical writing)
- International pharmaceutical and biotechnology companies as longstanding customer and partners
- Business development and customer care

Synergies

to be harnessed for joint phase-I studies in oncology patients

Figure 01: Typical University Collaboration Model

Moscow (Russia)

Founded in 2003, FOCUS MOSCOW is working in a partnership with Prof. Dr. Arkady Vertkin's team of the Moscow State University of Medicine. We are recruiting patients in Hospitals 50 and 81 in Moscow (the home base of our partners) and other hospitals in Russia. We are performing study activities in our clinical wards with medical staff trained by FOCUS NEUSS in Germany and in Russia to ensure Global FOCUS clinical quality.

We have access to dynamic patient pools (including children) with various demographics to suit different types of indications and trial designs.

As an example, the following studies have been conducted in Moscow:

- First-in-Patient studies
- Exploratory and Confirmatory Phase IIa PoC studies
- Drug-Drug Interaction studies in Patients
- Phase IIb dose-response studies in target patient populations
- Therapeutic Bioequivalence studies in Patients (e.g., Asthma)
- Clinical pharmacology studies in Special Patient Populations with one or more diseases (e.g., Renally-Impaired studies, Hepatically-Impaired studies). These studies have been conducted according to the relevant FDA Guidance Documents.

Belgrade (Serbia)

Founded in 2007, FOCUS BELGRADE is working in a partnership with Prof. Dr. Petar Seferovic of the University Medical Center of Serbia. In Belgrade we have access to patients in different therapy areas (Cardiology, Neurology, Nephrology, Inflammatory Diseases, etc.) and each Principal Investigator can enroll up to 10 patients per month. In addition, we are recruiting patients in many different hospitals in Serbia. Study activities are performed in the clinical wards of our Principal Investigators with medical staff trained by FOCUS Neuss in Germany and in Serbia to ensure Global FOCUS clinical quality.

Within one year of inception in Serbia, FOCUS has conducted a number of studies namely Drug-Drug Interaction in Patients (see below), Renally-Impaired studies, and an Exploratory Phase IIa (PK/PD/biomarkers) study in patients with a cardiovascular disorder. In Belgrade FOCUS is able to conduct pediatric studies.

Case Study of a complicated Drug-Drug Interaction Study in patients with multiple sclerosis

An open-label, cross-over study to assess the interactions of **Compound A** with **Compound B** administered in subjects with multiple sclerosis (n=18 treatment-naïve or treatment-refractory patients)

FOCUS Belgrade
18 Multiple Sclerosis patients

FOCUS Neuss
2 Multiple Sclerosis patients

Successfully completed study

Study objectives: to investigate the influence of Compound A on the pharmacokinetics of Compound B, and to assess the incidence of TEAEs and clinical significant changes in laboratory safety tests, vital signs and physical examination findings due to co-administration.

Assessment schedule: 3 days in house (2 periods), study period 18-33 days

Recruitment rate: Belgrade (16pts in 3 months) and Neuss (2pts in 10 months)

Dubai (United Arab Emirates)

Regarding the Middle East and North Africa (MENA/region) FOCUS is conducting studies in Senegal (oncology patients, HIV), whereas the Middle East legal situation currently allows mostly only phase IV studies.

Via the FOCUS office in Dubai our industry experienced Indian staff performs clinical research in India with local medical centers and investigators known to us, thereby capitalizing on the low cost situation in India while maintaining global, international quality.

Some of these studies start as phase II/III studies in Europe and benefit from additional quick patient recruitment in India. FOCUS has local regulatory and monitoring forces to interact and secure quality and performance.

FOCUS Patient Recruitment Rates in 2009

Examples:

Therapeutic Indication	Moscow		Belgrade
	Patients per month		
	Phase II/III	Phase I	Phase II/III
Neuropathic pain	15	3-5	10
Rheumatoid Arthritis	15-20		8
Migraine	12-19		8
Multiple Sclerosis	12-15	4-5	5
Diabetes type 1	10		5
Diabetes type 2	15-25	6-8	20
Hepatically Impaired		8	-
Renally Impaired		6-8	8
Alzheimer	10-12	3-4	3

In addition, we have some recruitment rates in some other indications from Moscow:

Therapeutic Indication	Patients per month
Essential Hypertension	15
Pulmonary Arterial Hypertension	8-12
Heart Failure	10-11
COPD	15
Psoriasis	8-10
Major Depressive Disorder	12-15
Alzheimer	10-12

Showcase of a FOCUS Study package performed at different FOCUS Locations

FOCUS has developed an Efficiency Initiative to schedule a package of studies at different FOCUS Clinical Locations in order to expedite time lines, to cut costs and to ensure Global FOCUS clinical quality for our sponsors. An example is presented below:

1. Study/Neuss Phase I

Objectives: Investigate the safety and tolerability of single doses of compound in healthy male volunteers of Caucasian and Japanese origin (n=40).

2. Study/Neuss Phase I

Objectives: Investigate the safety and tolerability of repeated oral doses of compound in healthy male volunteers of Caucasian and Japanese origin (n=32).

3. Study/Moscow Phase I

Objectives: Investigate the safety and tolerability of single oral doses of compound in male Caucasian volunteer, treatment-naive patients and assess pharmacodynamic profile in patients after single dose of compound (n=18).

FOCUS: offering a full range of services:

FOCUS Clinical Drug Development GmbH (www.focus-cdd.de) is an independent full service drug development house. The unique combination of drug development and clinical pharmacology / exploratory drug development know-how, plus an in-house infrastructure to manage different population aspects of a program ensures fast results at a high standard of quality. We provide product consultancy, regulatory strategy and development planning for New Chemical/Biological entities, herbal products, biosimilars, generics plus and drug combinations (FDC). We also offer to support Japanese Pharmaceutical companies to develop their drugs according to EMEA & FDA guidelines for future filing and marketing in the EU and North America.

FOCUS Headquarters is located in Neuss / Düsseldorf, Germany with affiliates in Heidelberg, Belgrade, Moscow, Dubai and Jakarta. Since its inception in 1992, FOCUS has successfully grown to become an established provider of comprehensive NCE/NBE development services to global pharmaceutical and biotech companies.

We FOCUS on:

- Regulatory Path Finding and Development Planning
- Integrated Product Development Management with internationally accepted data package
- Global Phase I and rapid Clinical Proof of Concept Phase II studies
- Biomarker & PK-genotyping Laboratory
- Ethnicity Bridging Concepts
- Clinical Research Programs covering EUROPE - AFRICA - ASIA
- Study Experiences in numerous indications with novel drugs

For more information please contact us or visit our website www.focus-cdd.de!



Patient Opportunities

powered by FOCUS Clinical Drug Development



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Clinical Research Care for Patient Volunteers