



Your Partner for Exploratory Clinical Drug Development

FOCUS is an established high-quality independent partner serving the Pharma and Biotech industry for more than 17 years. We are known for our competence in Clinical Pharmacology and in designing and executing integrated full-service Early Proof of Concept packages. Our locations in heavy populated areas like Düsseldorf/Essen (Germany), Moscow (Russia) and Belgrade (Serbia) ensure rapid enrolment of study subjects including difficult-to-recruit populations. Our clinical operations are experienced in performing a great variety of traditional, exploratory and complex phase I and phase IIa studies in both healthy and patient volunteers, including First-in-Human Studies, studies with Biologicals & Vaccines, Ethnic Bridging studies (e.g., Japanese, Chinese, black Africans) and Clinical Pharmacology Studies in Japanese subjects.

FOCUS - RECENT NEWS:

FOCUS Expertise in Thrombocyte Function Diagnostics

We are pleased to announce that our **FOCUS Clinical Laboratory** has extended its expertise to perform special thrombocyte diagnostics in-house.

Thrombocyte function tests are used to detect genetic or acquired disturbances of thrombocyte function and increased thrombocyte activity as well as drug-induced effects.

FOCUS implemented a method for measuring thrombocyte aggregation according to BORN using Mölab PAP 8 equipment in the FOCUS clinical laboratory and has since carried out several studies in this indication. This method is based on a turbidimetric measurement of the thrombocyte aggregation after stimulation of platelet-rich plasma by agonists such as ADP, arachidonic acid, epinephrine, collagen, U46619 or others. Testing is done on site, since only the processing of fresh samples ensures the quality of the analysis.

Thrombocyte function diagnostics can be used in therapeutic drug monitoring of thrombocyte aggregating inhibitors. In addition, this test may be used for mode-of-action analyses and for supporting dose recommendations for development compounds. Furthermore, thrombocyte aggregation testing offers a reliable method for the estimation of the tendency to bleed.

In summary, this test allows the early detection of desired or untoward haematological and cardiovascular effects during drug development.

The thrombocyte function diagnostics at FOCUS is perfectly complemented by a broad spectrum of haemolytic investigations and blood clotting analyses.

Expansion of the FOCUS hospital-based Unit at the University Clinic Düsseldorf

The FOCUS hospital-based unit was opened in 2007 at the University Clinic Düsseldorf for the conduct of clinical pharmacology studies in accordance with the guideline EMEA/CHMP/SWP/294648/2007 "On strategies to identify and mitigate risks for First-in-Human clinical trials with investigational medicinal products". In the meantime, several First-in-Human studies including Biologicals have been conducted in our hospital-based ward.

The unit has recently been expanded from 160 m² to 270 m² and the number of beds has been increased accordingly to cover the increased number of study requests.

The collaboration with the various University Clinics & Departments like Endocrinology, Gynaecology, Urology, Gastroenterology, Haematological Oncology, Paediatrics and Psychiatry, including specific pain research, has further been intensified and gives us direct access to patient pools and clinical expertise.

GLP-Qualification of the FOCUS Immunology & Biomarker Laboratory in Heidelberg

FOCUS is delighted to notify its sponsors that its **Immunology & Biomarker Laboratory** in Heidelberg has been GLP qualified by the combined Federal Authorities of North Rhine Westphalia and Baden-Württemberg on 17th February 2009.

This GLP qualification allows the conduct of in-vitro and ex-vivo / in-vitro pharmacological studies under certified highest quality standards. This is of specific importance for those studies requested by the EMEA/CHMP/SWP/294648/2007 "Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products" such as ex-vivo / in-vitro testing of human PBMs for cytokine release patterns in response to different modes of drug exposure etc. Hence, this testing facility for development candidates ideally complements and supports our hospital-based unit for first-in-human studies.

FOCUS Immunology has defined its offering to address important development aspects of new biological and chemical entities, such as immunogenicity testing, screening for immuno-modulatory activities, and immune-monitoring in clinical trials. Pertinent biomarker strategies have been developed and implemented to address these issues. In the past months several projects have been successfully completed in these areas.

Along these lines, FOCUS' experts have compiled a report on the use of biomarkers in exploratory clinical studies:

"Use of Biomarkers in Exploratory Clinical Drug Studies: Basic Considerations, Regulatory Background and Case Studies"

You may wish to down-load your personal copy under www.focus-ibl.com.

We believe that with the above mentioned new capabilities and our proven experience, FOCUS is well suited to be your reliable **Partner for Exploratory Clinical Drug Development**.

We are looking forward to receiving your response and will be glad to start more detailed discussions on your upcoming development projects.

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