



Clinical Pharmacodynamics Services

September, 2007

Introduction

FOCUS Clinical Drug Development GmbH (FOCUS) is a leading company specialized in clinical pharmacology studies, explorative development, and drug development. **FOCUS** has the advantage that it has more than 25 yrs of clinical pharmacology experience in the conduct of phase I – III studies and is in the position that it can offer world wide experience as a contract research organisation (CRO) to the pharmaceutical and biotech industry.

FOCUS has clinics in Neuss (Germany), Moscow (Russia) and Jakarta (Indonesia).

All patient research carried out at **FOCUS** is conducted to the highest industry and scientific standards and are acceptable to all global authorities and their regulations.

Please visit our websites for more detailed information concerning our company.

Clinical Pharmacodynamics

Biomarkers and surrogate endpoints have become essential tools in exploring desired and undesired effects in exploratory clinical development studies.

The advantages of these measurements in exploratory development is that the data obtained may reflect at an early stage the mechanisms of wanted or unwanted effects, and may provide evidence about dose & time response. In general obtained data may improve the reliability and objectivity of clinical research, and may be used to accelerate the internal decision making processes in clinical drug development.

Biomarkers can be measured in our own Molecular Biology Laboratory, and target specific tissues, organs, and organ systems as well as diseases, disorders and syndromes, such as CNS, immune system, diabetes, cardiovascular & related conditions (www.focus-biomarker.de).

CRO's can play an important role in the development, use and qualification of biomarkers.

Our current models include:

Cardiovascular, e.g.:

- 12-lead ECG
- telemetry
- several blood pressure devices, e.g. ambulatory blood pressure monitoring
- exercise testing
- ECG-Holter monitoring
- coagulation and hemorrheology tests, e.g. bleeding time

CNS, e.g.:

- EEG
- psychometric/ neurocognitive tests, e.g. visual analog scales, test batteries
- pupillometry
- pain models (e.g. cold pressure test for Acute Pain)
- neuroendocrine challenge tests
- cerebrospinal fluid acquisition (and scientific cooperation with certified laboratory of the German Society for Neurochemistry)
- colour duplex and Doppler ultrasound (transcranial and extracranial, leg vessels)

Metabolic disorders, e.g.:

- oral glucose tolerance test
- glucose bedside/ ambulatory glucometer testing
- administration of cytochrome P450 probes

Respiratory, e.g.:

- lung function tests
- skin prick tests
- continuous monitoring of variables such as pulse oximetry

Through associations with external partners, **FOCUS** has access to the following technologies: abdomen ultrasonography, echocardiography, genetic tests, fMRI/ MRI, tests for detecting extrapyramidal and cerebellar effects (e.g. grasp force, 9-hole peg test), nuclear medicine (radioactive mass balance and microdose studies), and PET imaging.

In the past, we have partnered with different institutes in Germany and Russia on the conduct of studies related to special patient populations, and sample groups of treated and treatment-naïve patients.

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