

# ClinPharmCologne



Your high Care Phase I/IIa CRO

# Our Services



Do you need your trial to be conducted in an absolutely dependable and qualitatively excellent manner? Of course you rightly expect your trial to be extensively looked after during the entire process. You want to reduce your workload and depend on a high standard of quality, certainty in time planning and a clear cost structure.

We are at your service at all times during the entire process of the trial. Try our services, you will not want to do without our competence and support any more.

#### **Several reasons to decide in favour of ClinPharmCologne:**

- We have already conducted more than 100 Phase-I trials since CPC was established.
- You will receive medical/pharmacological consultation during every part of the trial.
- Our constantly updated and extended database contains over 4000 subjects.
- We select subjects according to sub-populations.
- When conducting trials in patients, we work together with external physicians and clinics.
- By working in cooperation with external partners we offer you a wide spectrum of additional services.
- From a single service to a complete package, you decide exactly what you require, thereby keeping your costs under control.



# Project Implementation



Can we provide active support for your project? If so, this is what you can expect from us:

## Order Acceptance

Your first phone call or meeting with us will involve a consultation with our experienced project management staff and will be swiftly followed by a written offer. Feasibility studies are available upon request.

## Preparation

Once the contract has been signed, your project is handed over to one of our study teams (project manager, trial physician, internal study monitor, and administrative and operative study nurses). The following steps are undertaken:

- Protocol writing/subject information and informed consent (collaboration between project manager and physician)
- Input of know-how; review of protocols and subject information and informed consent
- CRF creation/review
- Notification of regulatory authorities (Ethics committee, BfArM [German Federal Institute for Drugs and Medical Devices], RP [regional government offices], Bundesopiumstelle [German Federal Narcotics Control Board])
- Volunteer/patient recruitment

## Clinical Trials

- Outpatient and inpatient studies (long-term studies possible) for all indication areas e.g. bioavailability, bioequivalence, first in man, drug/drug interaction, drug/food interaction, dose escalation
- Manufacturing licence/ GMP area
- Application: p.o./s.c./i.m./i.v.
- Profound experience in testing of transdermal systems (TDS)
- Integration of external partners: lab, analysis, data management, specialist medical practitioners e.g. ENT, x-rays, gynaecological examinations
- Internal monitoring: 100 % source data verification (this drastically reduces your monitoring expenditure)
- Data documentation: paper CRF, eCRF, digital pen, etc

## Evaluation

We provide the following services, either in-house or in collaboration with external partners :

- Biometry
- Medical writing
- Analysis



# Methods & Expertise



Our range of services in the development of new medicines begins with the evaluation of pre-clinical results.

Our services cover the full range of tasks involved in Phase I studies for different indications, including administrative requirements.

We provide expert support for “proof of principle” in Phase IIa studies.



## Our Methods and Expertise

- Central Monitoring of vital parameters (heart rate, blood pressure, respiration, oxygen saturation, arrhythmia, body temperature)
- 12-channel ECG with automatic measurement
- Colour doppler ultrasound monitoring of heart and blood vessels
- Heart rate variability including spectral analysis
- Impedance cardiography
- Spirometry and bronchial provocation testing
- EEG including spectral analysis
- Pupillometry
- Psychometrics
- Tremor analysis
- 24-hour long-term blood pressure and ECG recording (including spectral analysis and non-linear analysis (risk predictors))
- Uroflowmetry

## We also provide expert support in the following areas:

- Monitoring
- Auditing
- Procurement of study nurses
- Medical writing
- Creation of development plans
- Evaluation of licensed products
- Biometric planning and evaluation (in cooperation with partners)
- Manufacturing and packaging (in accordance with GMP)

For tests which we do not perform in-house, such as bioanalytics and clinical lab tests, we have carefully selected cooperation partners who share our high standards of quality.

# Equipment



Personnel and equipment are the keys to successful professional operations. We provide both to ensure that you are in the best of hands.

## **Our Staff – Our Greatest Asset**

Our physicians have years of clinical experience in a variety of medical fields. Our study teams are extremely well-trained, motivated and experienced, and our everyday working atmosphere is characterised by teamwork and collaboration. This cooperative atmosphere ensures the professional realisation of your projects; after all, highly-qualified and motivated teams produce the best results – and you reap the benefits.

## **Our “Hardware” – an Essential Basis for Quality**

Built in 1994, the spacious ClinPharmCologne building provides 48 overnight places for inpatient volunteers, plus an additional 22 treatment places. Our modern study beds are equipped with sophisticated monitoring technology, and our separate outpatient unit provides additional flexibility. Our Quality Management department – which operates independently from our other departments – ensures the high quality of every process at all times. All you need to do is sit back and relax.

## **Our Equipment in Detail**

- A total of 70 treatment beds, including:
  - 24 monitored intensive care beds
  - 16 monitored treatment beds
  - 24 overnight stay beds (monitoring equipment available)
  - 6 outpatient treatment beds
- 1 centralised monitoring unit per floor
  - heart rate, blood pressure, body temperature, arrhythmia
  - oxygen saturation
  - respiration rate
- 24 hour medical and nursing care to ensure maximum safety for volunteers
- GMP area with manufacturing licence
- Mobile vital signs monitoring facilities
- Long-term blood pressure monitoring facilities
- ECG recording equipment
- Holter ECG recording equipment
- Ultrasound facilities
- Pupillometry equipment
- EEG recording equipment
- Psychometric testing facilities (e.g. Vienna test system)
- Lung function testing facilities
- Uroflowmetry equipment
- Cold pain testing facilities
- RigiScan equipment
- Private canteen providing customised catering options

# Quality Management



You want to be certain that your clinical trial is in the best of hands. We have therefore set ourselves extremely high quality standards.

- Our Quality Management department is based in-house and functions independent of the study team.
- Its core task is the continuous improvement of processes in accordance with national and global quality standards.

We use audits to constantly monitor our processes and performance.

#### Items checked:

- ICH GCP
- Regulatory requirements and norms
- Special arrangements with our customers
- Trial protocol
- SOPs
- ICH GMP

We provide the following quality assurance measures for your trials:

- Trial protocol audits
- Subject information/ informed consent audits
- On-site study audits
- Report audits
- Investigator files audits

#### We routinely carry out the following internal audits:

- Quarterly system audits
- Service provider audits
- Process audits as required by Senior Management

All audit results are evaluated and any room for improvement is incorporated into our optimisation process. Constant optimisation is assured by implementing corrective and preventive actions.

This in turn, gives you the assurance that you are in the best of hands.



#### ClinPharmCologne

Neurather Ring 1 · 51063 Köln · Tel.: +49 221 6472-324 · Fax: +49 221 6472-353  
info@clinpharmcologne.de · www.clinpharmcologne.com