

CRS-Mannheim - The Largest Phase I/II Clinic for large-scale, long-term and challenging trials

Location

CRS-Mannheim is the largest of all CRS's clinics, originally established in 1977.

The CPU is located in Mannheim, in the centre of the Rhine-Neckar metropolitan region, and is populated by approx. 2.4 million citizens. With neighbouring major cities being Ludwigshafen, Frankfurt and Heidelberg, the region is one of Germany's driving economic forces, featuring global players in the chemical, software, automobile, financial and engineering industry. Moreover, the region is one of the most dynamic centres of bio-pharmaceutical research in Europe residing famous companies and research institutes such as the German Cancer Research Center (DKFZ) as well as the renowned university hospitals of Heidelberg and Mannheim.



Figure: CRS-Mannheim is located in the centre of the Rhine-Neckar metropolitan area (dark green) and in close distance to Frankfurt, Heidelberg as well as to the neighbouring areas Belgium and France.

Profile

Since 2004, the CRS clinic is located in the former building of the university hospital paediatric department which is in close proximity (500 m) to the university hospital campus. The floor space of 4,000 m² - surrounded by a garden of approx. 1,250 m² - comprises:

- ▶ Up to 102 beds, distributed over three levels and two wards
- ▶ Five large multifunctional labs for observational activities and special assessments
- ▶ An 800 m² outpatient area with a separate entrance that allows the performance of ambulatory trials with up to 200 volunteers/patients without interfering with in-house clinical trial activities and preventing contact to confined study participants
- ▶ Multifunctional labs are situated within the various wards. This enables a quick transfer and processing of samples
- ▶ Examination rooms can be individually equipped in order to meet specific study needs (e.g. PD models like lung function, pupillometry, exercise testing etc.)
- ▶ State of the art equipment e.g. digital spirometry and body plethysmography devices

Team

A highly dedicated team of ca. 46 clinic employees contributes to the successful conduct of the trials. The average team experience of eight years (mean employment time at CRS) supports the continuity throughout the study due to fix dedicated staff being in charge for the whole duration of a project. The team members cover diverse fields of expertise and form specialised working groups in order to meet the needs for the trial in the most efficient way.

Proficient project managers are acting as a central point of contact for the sponsor and subcontractors to ensure fast and efficient communication. The highly motivated team benefits from continuing education programs covering ICH/GCP, SOP and study specific trainings, handling of devices, external seminars, and regular emergency trainings for all medical staff. During long study conduct, additional staff is assigned to allow for more flexibility during the study.



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The CPU with Expertise in Respiratory Clinical Trials

Case Study

Respiratory research is one of the key competences of CRS-Mannheim. With more than 40 clinical trials conducted in healthy volunteers as well as asthma and COPD patients, CRS-Mannheim provides medical and technical expertise for realising all types of clinical trials such as PK, PD, BE and efficacy studies in this area. Extensive experience with inhalative substances and appropriate infrastructure allows minimising measurement variability. The following case study illustrates the clinic's outstanding capabilities in this therapeutic area.

Sponsor's expectations: In 2015, CRS-Mannheim conducted a large respiratory phase-I study with regard to sample size and duration of treatment periods.

The planned study consisted of a single-dose, 4-period, 4-sequence crossover design with a test and a reference inhalative product plus additional charcoal administration. 88 subjects had to be randomised.

The expected clinical duration per volunteer was approximately 13 weeks.

The logistical challenge already started during the screening visit when subjects were trained by the site staff on the correct usage of both inhalative devices and the air flow was determined via in-check DIAL device.

During the treatment duration, 80 blood samples with a total amount of approximately 600 mL were planned to be taken from each subject.

Outcome: CRS fulfilled all requests and was even able to exceed customer's expectations as follows:

- ▶ The actually performed screening ratio was 30% lower than initially committed.
- ▶ Best possible subject compliance was reached (91 subjects randomised, 89 treated and 81 subjects completed).
- ▶ 97% of blood samples could be analysed.
- ▶ The total clinical duration was only five months.
- ▶ Database lock was accomplished six weeks after last subject out.
- ▶ Only minor protocol deviations were observed. None of them led to the exclusion from any of the analysis sets.
- ▶ The final study report was provided within three months after the study completion.

One clinic - various opportunities

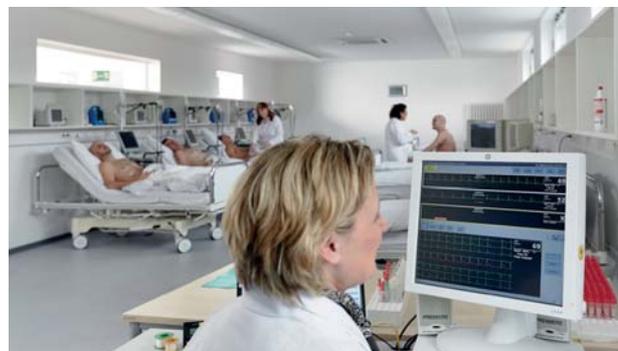
Large trials: The site is able to handle trials with large sample sizes and long-term confinements (e.g. 48 in-patient subjects / 180 outpatient subjects per day). Realisation of up to 40-50 studies per year is manageable.

Extended capabilities: Several trials can be conducted in parallel as the facility capacity can be subdivided into several separated wards.

Respiratory: A long track record of >40 successfully conducted trials supports CRS's extensive experience in this therapeutic area. Those studies include BA/BE, generics, biological & biosimilars.

Skin safety and dermal treatment: 20 years of experience in transdermal drug delivery (ca. 50 trials, 1500 enrolled subjects) dealing with PK/PD, irritation/sensitisation, phototoxicity, and photosensitisation.

Controlled substances: The site offers the appropriate infrastructure and experience in handling of narcotic drugs. Leading external university experts provide support in trials dealing with pain testing.



Recruitment: The unit has an enrolment rate of approx. 1000 subjects per year.

Special populations: Patients and healthy volunteers including special populations such as geriatric subjects, post-menopausal women, genotyped subjects, COPD/asthma, diabetic patients are included in CRS's database.

Strong cooperation: Multicentre trials within the CRS facilitate all trial related procedures by using standardised equipment, same quality standards and the same SOP system.