

CRS-Berlin - The State-of-the-Art Phase I Unit located in the German Capital

Location

CRS Clinical Research Services Berlin GmbH is located in the heart of Berlin, only a few hundred metres from the central station and the Charité campuses Mitte and Virchow-Klinikum - easily accessible for study participants and customers from Berlin and outside.

With over 3.5 million inhabitants, Berlin is the largest city in Germany and it is a hotspot for clinical research and life sciences.

The phase I clinic was originally established in 1988 as a merger of different therapeutic area specific clinical pharmacology units (CPUs) at Bayer. In the 1990ies, the clinic moved to its current location with state-of-the-art facilities. Since July 2013, the unit continues its work as part of CRS and clients profit from the highly experienced staff and the modern phase 1 infrastructure.

Profile

CRS-Berlin is housed in the top floor of a modern building at the Bayer campus. A separate entrance, an automatic access control system and an independent technical infrastructure guarantee for a strict separation from the adjacent Bayer facilities. The floor space of 1500 m² - including a rooftop - comprises:

- ▶ 36 beds, including 20 intensive care beds, each equipped with an ECG, SpO₂, a vital signs monitoring system and a computerised ECG device as well as 8 convenient hotel double rooms
- ▶ Owing to the specialised floor plan, in-house and outpatient clinical trial activities can be spatially separated allowing the simultaneous conduct of several studies without interference
- ▶ Fully equipped gynaecological unit with two examination chairs incl. state-of-the-art ultrasound equipment
- ▶ Fully equipped laboratories for immediate blood and urine processing. Five large multifunctional labs for observational activities and special assessments
- ▶ Drug storage area with controlled access
- ▶ Dedicated facility for drug handling and drug reconstitution



Figure: CRS-Berlin is located centrally in the German Capital (dark green), close to the main station and the airport.

Team

A highly dedicated team of 25 qualified clinic employees contributes to the successful conduct of the trials. The team at CRS-Berlin has significant experience in the implementation of pharmacological trials such as First-in-Human (FIH), PK/PD studies and DDI/FDI trials involving e.g. cardiovascular or oncology drugs.

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 continuous education programs covering ICH/GCP, SOP and study-specific trainings (e.g. handling of devices), external seminars, and regular emergency trainings for all medical staff. During long study conduct additional staff is assigned to allow more flexibility.



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The Early Phase Clinical Pharmacological Unit with Focus on Gynaecological Trials

Case Study

The special expertise of CRS-Berlin is on the performance of Early Phase clinical trials in the area of Women's Healthcare with women of childbearing potential, surgically sterilised or post-menopausal women. This especially covers First-in-Human (FIH) and long-term outpatient studies with challenging PK/PD designs as well as early clinical trials with special populations such as tubal ligated women. Outpatient studies with women of childbearing potential can be conducted either cycle-dependent or with a synchronising cycle preceding the treatment phase leading to larger subgroups and efficient treatment schedules. The following case study gives an example of the great coordination of challenges the clinic can accomplish.

Challenges: The FIH study (SAD, MAD) dealt with a monoclonal antibody. Healthy post-menopausal women were the target population. A dose group size of 8 subjects (2 pilot subjects & 6 subjects one week later) was planned. The trial participants were recruited in a multi-centre competitive recruitment approach.

To that date no information was available about the tolerability in humans, but good tolerability in animals was proofed. The trial required a subcutaneous dosing, a detailed neurological examination of subjects, intensive safety monitoring and recording over 4 hours. The clinical duration from first to last subject dosed was 12 months (incl. interim analysis and safety meetings). The next higher dose level was only exposed when a thorough safety evaluation was made by the safety review board.

Logistics: The CPU put a lot of effort into a smooth realisation of the trial:

- ▶ Coordination of 2 sites (CRS-Mannheim & CRS-Berlin) with a tight time schedule for recruitment and clinical realisation
- ▶ Recruitment of 80 post-menopausal women (64 at CRS-Berlin)
- ▶ Long study duration (e.g. SAD part: 9 days confinement per subject, 12 ambulatory visits up to day 106)
- ▶ Due to stability reasons preparation of trial medication immediately prior to dosing
- ▶ Coordination of screening & FU visits with external neurologists
- ▶ Coordination of 11 ambulatory visits per subject after discharge
- ▶ Organisation of safety review board meetings



One Clinic - Various Opportunities

Early Phase Clinical Trials: The site's core business is the conduct of standard phase I/II trials with larger sample sizes as well as long-term confinements.

Gynaecological Expertise: Established gynaecological methods, e.g. standard gynaecological examinations, transvaginal ultrasound, vaginal cytology, endometrial biopsy, Insler and Hoogland score are applied by a board certified gynaecologists on-site.

Location: The unit is located in the German Capital with 3.5 million inhabitants and a cluster of biotech and pharmaceutical companies.

Special Populations: Patients and healthy volunteers including special populations such as post-menopausal or tubal ligated women are available in the database.

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