



Clinical Pharmacology Unit (CPU)

Optimum conditions for early-phase trials

Our CPU in the heart of Erfurt, the capital of Thuringia, was set up by us as early as in 2004. Since then we have continuously invested in maintenance and technical equipment depending on the needs of our clients and our own vision. The general set-up of the site is based on a modular system with highly flexible possibilities of adaptation to the respective phase-I or phase-II study design.

Our CPU is equipped with 58 beds. Depending on the safety level and the measures to be realised, this is the maximum number of subjects who can be hospitalised simultaneously. Of course, we often realise studies with higher sample sizes, then in a groupwise and staggered approach.

Our CPU is equipped with a central surveillance system, which has been established together with Siemens on the basis of Elpro measuring devices. Suppliers are qualified within our Quality Management System; software is validated following the requirements of US CFR 21 Part 11.

Freezers, refrigerators and the IMP storage area including safes for the storage of restricted drugs are under continuous surveillance and allow tracking of all critical steps.

Alarm runs on a 24/7 external emergency phone with qualified and trained background service for immediate intervention and a pre-specified emergency scenario.

Emergency calls run on the same central Siemens-based surveillance system and initiate a pre-specified emergency cascade documenting the call as well as the response. Emergencies are escalated via loudspeakers with specified and localised announcement as well as via internal emergency phones.

If a standardised temperature is necessary, e.g. for certain pharmacodynamic interventions, all relevant areas are air-conditioned.



Capacity

Temperature and humidity monitoring

Emergency system for subjects during hospitalisation

Air-conditioning



Our CPU - the all-in-one solution

- Centrally located with excellent public transport facilities for trial participants
- Located in close vicinity to a full-service hospital
- Perfect technical equipment
- Large geographical catchment area for healthy subjects of all ages
- Excellent patient access with a very low level of competitive trials
- Well-trained and experienced staff

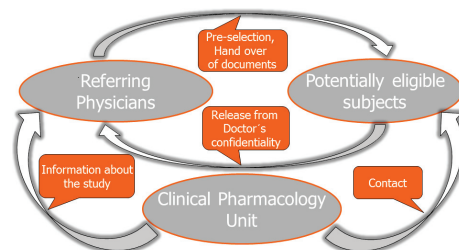


Subject availability

Our subject database contains more than 2,000 subjects including healthy subjects of both genders. The database is continuously maintained to ensure that the subjects are still active and available. We regularly organise public campaigns in print media and at universities to recruit new subjects. Furthermore, we have good access to a large number of postmenopausal women.

SocraTec R&D enjoys an excellent reputation in Erfurt and the surroundings, so that the feedback on recruitment campaigns for banal diseases allows even larger phase-III trials to be realised in a monocentric setting. For example, for the common cold and cough we are able to recruit 200 to 300 patients in one season (November to May).

Symptomatic patients are recruited via established referral systems all over Thuringia. In the field of oncology our network also includes the densely populated Rhine-Main area.



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