

Reaching our goal together: Clinical trial centres and trial coordination unit

The Studienzentrum Bonn (SZB) is a union of all institutions and facilities of the university hospital Bonn (UKB) being concerned with conducting clinical trials.

The SZB comprises the various clinical trial centres of the respective hospitals, the trial coordination unit, the Phase-I unit, the study nurse pool and further administrative departments. The SZB aims at conducting high quality clinical trials in academic and methodical respects, hereby fulfilling GCP and internationally valid quality standards.

The SZB realizes investigator initiated trials (IIT) as well as industry initiated trials of all phases and all legislative contexts (drug and medicinal product studies). For achieving this demanding goal, it is necessary to combine academically medical expertise with specialized methodical knowledge of conducting clinical trials. At the SZB, this requirement is successfully ensured by the close contact and exchange between the clinical trial centres of the individual hospitals and the trial coordination unit. The committee for clinical trials merges both fields and creates in this way the basic conditions and an ideal environment for high quality conducting of clinical trials at the university hospital Bonn.

Clinical study centres

As a maximum care hospital, the university hospital Bonn has the full range of modern medicine at its disposal. By means of own clinical research projects or joint cooperations with external partner institutions (specialist companies, pharmaceutical industry, etc), new diagnostic procedures and therapies are tested and the causes of diseases are investigated. These research projects are conducted by the clinical trial centres at the respective hospitals.

Trial coordination unit

The trial coordination unit of the SZB consists of staff members of the institute for clinical chemistry and clinical pharmacology and the institute for medical biometry, information technology and epidemiology (IMBIE). Its currently 16 staff members support and coordinate the planning, preparation and conducting of research projects in the clinical trial centres at the individual departments. Besides planning of and consulting on study projects, further central services of the trial coordination unit of the SZB are project management of clinical trials, including coordination of all relevant tasks and all participating parties, biometric consulting, quality control through monitoring, quality and safety management as well as data collection and trial evaluation.

Quality at the SZB

A high level of quality is the basic requirement for successfully conducting clinical trials. Hence, quality management plays a decisive role at the SZB. The clinical trial centres as well as the trial coordination unit both work according to verified quality standards in the course of industry-initiated trials as well as investigator-initiated trials. The quality management department, which supports the dean as a sponsor of investigator-initiated trials, is based at the trial coordination unit and independently performs its tasks. If necessary, also clinical trials with industry sponsorships can benefit from the services offered by the clinical trial centres and the quality management department.

Phase I unit - from basic research to clinical development

The transfer of basic research knowledge into clinical research constitutes a main emphasis of the trial coordination unit. The unit gives advice to the clinical trial centres, basic researchers and industry partners on how research results can be transferred into clinical trials and how a Proof of Concept is most likely to succeed. The consulting comprises all critical work tasks of pre-clinical development. In addition, the trial coordination unit offers a trial respondent unit at the institute for clinical chemistry and clinical pharmacology in order to guarantee a specialized environment, in particular for conducting phase I/II trials. The trial respondent unit (Station Busch) is located amid the in-patient health care facilities of the most important clinical units. It has an overall capacity of twelve beds at its disposal of which six are equipped with technology enabling constant monitoring and long-term storage of telemetric 12-lead ECG, pulse oximetry and blood pressure data. The unit is suitable for all kinds of clinical trials which require either in-patient monitoring, also over long-term periods, or merely out-patient care. By integrating the phase I unit into the university hospital, a direct access to the adjoining intensive care unit as well as to diagnostic and therapeutical procedures and expertise of all medical areas is achieved. In order to support pre-clinical and clinical development, additional laboratory services and special immunological examinations can be offered thanks to the cooperation with the internal central laboratory and basic research laboratories. Hence, the SZB offers an ideal environment for implementing basic research insights in clinical practice.

Funding of clinical trials

The trial coordination unit supports scientists with application and funding of clinical trials. In this way, the unit has succeeded in acquiring public funds (e.g. BMBF, DFG) as well as industry sponsorships in order to realize local and national multi-center trials.

Furthermore, there are intra-faculty funding possibilities for science-initiated pilot studies. Through the research promotion programme BONFOR and the committee for clinical trials, the medical faculty provides the university of Bonn with funds and personnel in order to conduct pilot studies of excellent scientific standards. This creates special possibilities for realizing science-initiated clinical trials and successfully raising funds for follow-up studies on the basis of achieved results.

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