

## **Bioavailability and bioequivalence trials**

Clinical drug trials have been carried out at the Military Medical Academy since 1973 according to the valid legal acts. Each year, the MMA Ethics Committee approves about 40 new clinical drug trials, along with the same number of performed trials at the MMA. Since 1995, about 100 trials of bioavailability/bioequivalence have been completed at the Military Medical Academy.

As a part of the Academy, Center for Clinical Pharmacology has been shown as a reliable partner for carrying out clinical trials in their 1<sup>st</sup> phase, here including also bioequivalence.

Center's expert team is comprised of qualified, well-educated and certified main researchers in a domain of good clinical practice, able to conduct a clinical trial of a drug which may completely satisfy the sponsor's demands. In addition, physicians as co-researchers, nurses and the other staff are licensed and qualified for clinical trials.

It boasts databases providing the information for recruiting healthy volunteers who are situated during the trial in a secure and appropriate area.

Clinical drugs are managed by pharmacists from the MMA Sector for Pharmacy. Biological samples are conserved and treated according to the rules of good clinical practice within the temperature range -20 °C up to -70 °C.

Center for Clinical Pharmacology assures good conditions for the visit and work of clinical trial monitors and audits.

Beside its own capacities, the Center relies on the capacities, staff and equipment of the nearby MMA clinics. It has on its disposal Biochemical Laboratory and Laboratory for Analytical Toxicology. The MMA units in its proximity are: Clinic for Anesthesiology and Critical Care, Clinic for Emergency Internal Medicine, Institute of Radiology, Institute of Blood Transfusion and Hemobiology, surgical clinics and the other necessary capacities.

### **Center for Clinical Pharmacology includes the following:**

- The area secured with a digital code at the entrance and video monitoring
- 12 beds for participants in trials
- Dining room and lounge with a TV and internet connection
- Bathrooms with the emergency calls
- Area suitable for monitoring activities with a internet connection
- Ambulatory
- Drug depot with a controlled temperature

- Fireproof closet for medicines and trial documentation
- Centralized kitchen and available diet meals

**Center's equipment:**

- Fireproof closet for medicines and trial documentation
- Centrifuge
- Freezer in the range -70°C and -20°C
- Digital 12 channel ECG machine
- Respirator
- Laryngoscope
- Chairs with the anti-shock therapy and defibrillator

**Center's services:**

- Complete performance of bioavailability/bioequivalence trials
- Trial design and examination protocols
- Pharmacokinetic analysis and estimations
- Final reports
- Database of healthy volunteers and patients- rapid participants inclusion into the trials