REPUBLIC OF SERBIA
MINISTRY OF DEFENCE

MILITARY MEDICAL ACADEMY

CENTRE FOR CLINICAL PHARMACOLOGY

Military Medical Academy

Belgrade, Republic of Serbia

(CCP MMA)

- Clinical trials on new medicinal products have been conducted in the Military Medical Academy (MMA) since 1973, when the approval from the Yugoslav Federal Secretariat for Health and Social Policy was obtained;

- The Ethics Committee of the MMA (established in 1991) approved on average 50 studies per year before the Ethics Committee of Serbia took over that function in 2019

CCP

- Since 1995 to 2010 more than 100 bioavailability & bioequivalence studies (BA/BE) have been performed in the MMA;

- Centre for Clinical Pharmacology (CCP) was established in 2005 as a part of the Sector for Treatment of the MMA, according to the national rulebook on the internal organization of health care institutions in Serbia

CCP personnel

- Head of the CCP, Full Professor in Pharmacology and Toxicology, Clinical pharmacology specialist;
- Clinical pharmacology specialist; clinical assistant
- Medical Doctor with PhD diploma, Assistant Professor;
- Pharmacy Specialist in Pharmacoeconomy, Associate Professor;
- Biologist with a PhD diploma in genetics, Associate Research Professor
- Highly trained medical technician with GCP diploma;

- All other healthcare professionals, employees of the MMA clinics and laboratories can also be engaged during the study.

CCP Activity Regarding Clinical Trials

- Members of the CCP give expertise and regulatory support to the entire realization of the clinical trials in the MMA by participating in the activities of the Expert Team for Clinical Trials, Drug and Therapeutics Committee as well as Ethics Committee of the MMA and of the Medical Faculty of the Military Medical Academy University of Defence

CCP activity in BA/BE studies

- Study design and clinical trial protocol development;
- Conducting the clinical part of the study at the CCP;
- Laboratory for blood sample preparation in compliance with GLP standards and sending to GLP sertified laboratories
- Pharmacokinetic analyses (PK) and calculations;
- Production of final study report

Education, Licences

- All investigators and nurses have experience, working licences and GCP certificates;
- CRA Academy: ICH E6 GCP Training for Investigators and Site Personnel Version 1.0, Februar 2015.
- TAIEX Workshop on Challenges of Bioequivalence Assessment of Generic Medicinal Products, 2016, Belgrade, Reference code: INT MARKT 62596.

MMA Integrated Management System (IMS) of Quality

- Since 2008 CCP as an organizational unit of the MMA fulfills requirements and owns certificates for:

- Quality Management System(**QMS) - ISO 9001:2015,**
- Environment Managing System(**EMS) -ISO 14001,**
- Occupational Health and Safety Management System**-OHSAS18001,**
- Food Safety Management System**-ISO 22000**

"Detection and quantification of residual disease in patients with high-risk and advanced melanoma as a marker of therapy response and prognosis„ (ReDiMEL)

- From January 1st 2024, the ReDiMEL project is implemented at the Faculty of Medicine of the University of Defense under the PRIZMA call of the Science Fund of the Republic of Serbia. The project is financed through the SAIGE program of the EU and the World Bank.

Science Fund of the Republic of Serbia

#ЕУ ЗА ТЕБЕ

ReDiMEL

The ReDiMEL project is designed to answer the following questions:

(1) whether (and how) different variants of autophagy (one of the basic regulatory mechanisms of the cell) –related genes influence the response to immunotherapy;

(2) (2) whether a certain amount of circulating tumor DNA (so-called circulating tumor DNA) or its constant increase may indicate disease recurrence (before it is detected by standard diagnostic procedures);

(3) find the most suitable model for monitoring patients with melanoma, taking into account the patient's quality of life and economic sustainability for the health system.

CCP Standard operative procedures - SOPs:

No. 1 -Subject Informed Consent Form,

No. 2 -Maintaining study participant confidentiality,

No. 3-Document completion,

No. 4 -Source document library,

No. 5 -Recording source data in case report forms (CRF's),

No. 6 -Sample handling,

No. 7 -Patient safety and comfort,

No. 8 -Screening history and physical exam,

No. 9 -Obtaining vital signs,

No. 10 -Electrocardiogram Interpretation Guidelines,

No. 11 -Collection of blood samples,

No. 12 -Documentation and document handling,

No. 13 -Informed consent documentation,

No. 14 - Ethics Committee protocol approval

CCP Standard operative procedures - SOPs:

No. 15 -Storage, Distribution, and Accountability of Investigational Drugs,

No. 16 -Suspension or Premature Termination of a Study,

No. 17 -Clock synchronization,

No.18 - Admission and discharge from the hospital,

No. 19 - Biochemical evaluation of study participants,

No. 20 - Blood sample centrifugation,

No. 21 - Labelling tubes for blood sample collection,

No. 22 - Investigational product administration,

No. 23 - Monitoring of adverse events related to the application of the investigational medicinal product,

No. 24 -Food intake during a clinical study,

No. 25 -Frozen plasma/serum sample transport.

CCP ability and capacity for realization of I phase trials

- Fast recruitment of subjects
- Good working conditions for clinical trial monitors, audits and inspections.
- Using services and posibility of including staff from all institutes, clinics and laboratories in MMA.
- Clinic for Emergency Internal Medicine is positioned nearby CCP.
- Fast communication lines (internaly provided) with reanimation team from Clinic for Anaesthesiology

CCP ability and capacity for realization of I phase trials

- Separate department with digital entrance code
- Limited acces to trial documents.
- 12 beds for trial subjects
- Free-time activity space for trial subjects.
- Dining room with internet connection.
- Comfortable space for staff, including overnight stay.
- Computers with limited access (code).
- Kinetica 5® programme for PK parameters and SPSS for statistic data analysis.

CCP ability and capacity for realization of I phase trials

- Outpatient room.
- Drug storage room under controlled temperature conditions.
- Fireproof locker for keeping drugs.
- Blood sampling space.
- Centrifuge for sample preparation (-10°to+40°C).
- Freezer(-20°C and also the one available for sample storage at -80°C).
- Real time PCR system.
- Fluorometer for nucleic acids/proteins quantification.
- System for horisontal electrophoresis with transiluminator (analysis of nucleic acids).
- Digital PCR (in progress)

CCP ability and capacity for realisation of I phase trials

- Biological samples: processing and storage in compliance with GCP guidelines.
- Electrocardiograph.
- Laryngoscope.
- Cart with antishock therapy and defibrillator.
- Analytic scale.
- Height and weight scale

CCP ability and capacity for realization of I phase trials

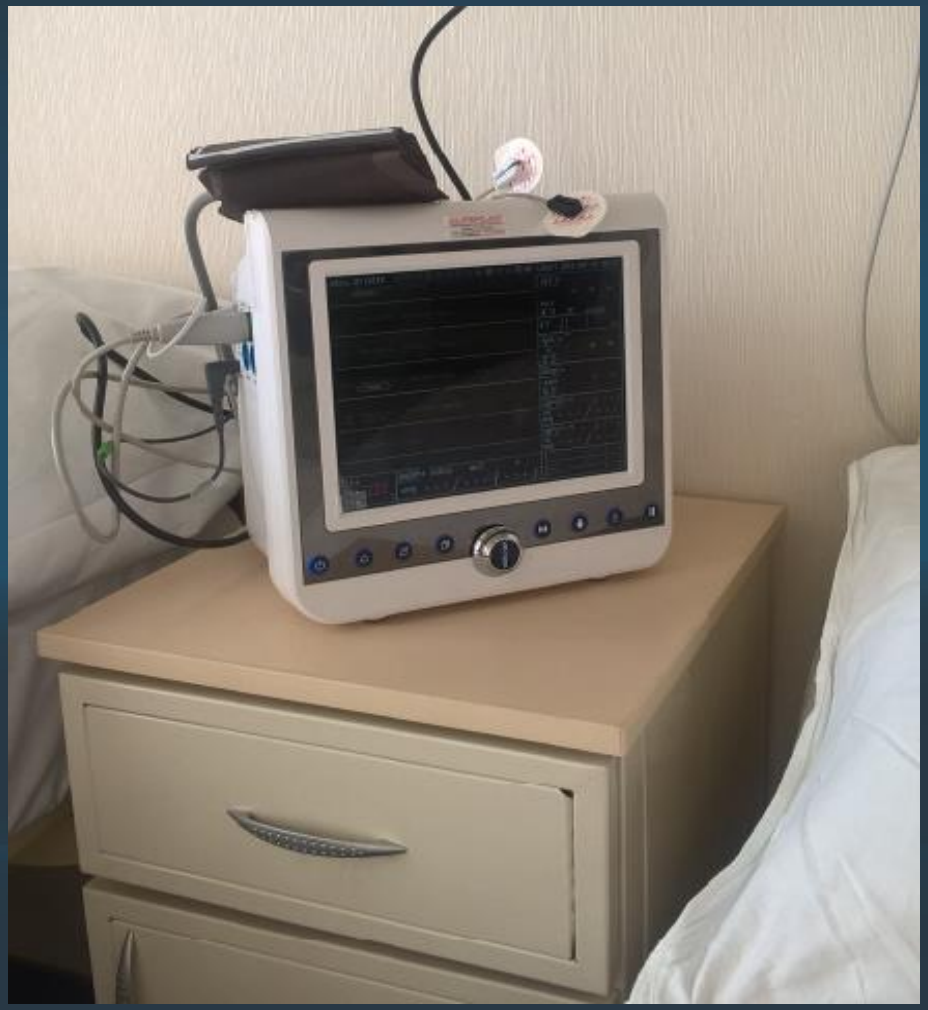
- Vital function monitors
- Equipment which enables subject emergency calls for medical staff in all facilities (rooms for volunteers, toilets)
- Detection of emergency calls within the space of the staff unit.
- Centralized kitchen.
- Possibility for preparing and distribution of specially prepared meals according to trial protocol.

Pristup u CKF ograničen šifrom

Sobe za ispitanike sa bolesničkom signalizacijom

Centralni prostor CKF

Monitori za praćenje vitalnih funkcija



Prostor za obedovanje i slobodne aktivnosti ispitanika

Digitalni satovi u prostorijama i pripremnoj laboratoriji

Laboratorija - centrifuga

Laboratorija - kolica sa defibrilatorom i EKG aparatom