PCSC | PRECLINICAL CLINICAL STUDY CENTRE

2018

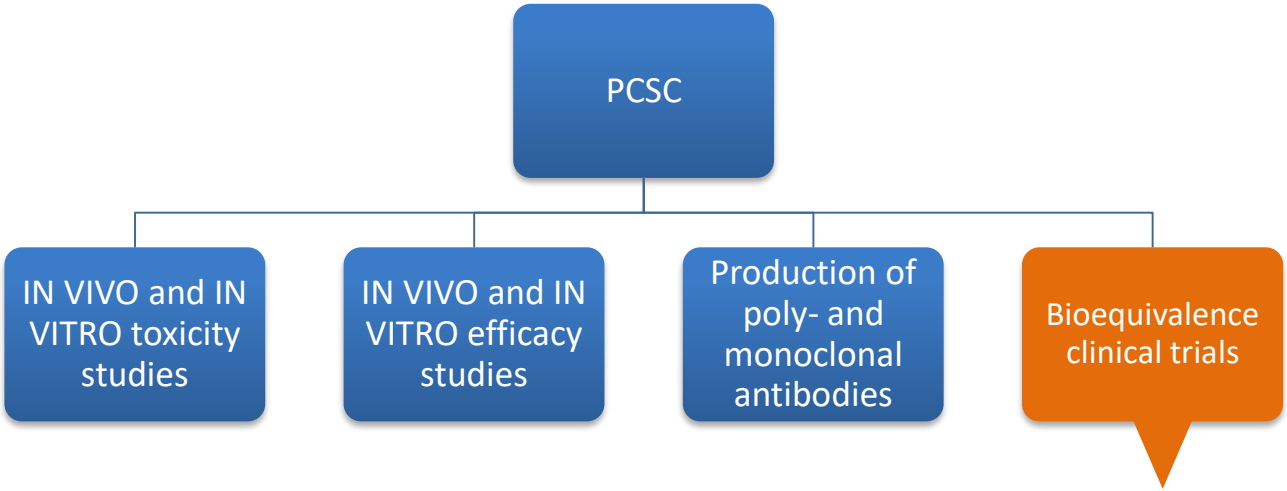
www.preclinical.ru

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE

Preclinical and clinical study centre

PCSC, LLC is a fast developing service contract organization specialized in a full cycle of pharmacological development, production, preclinical and clinical trials of biotechnological, biosimilar and generic drugs, medical materials and equipment, chemicals, pesticides, biocides, etc.



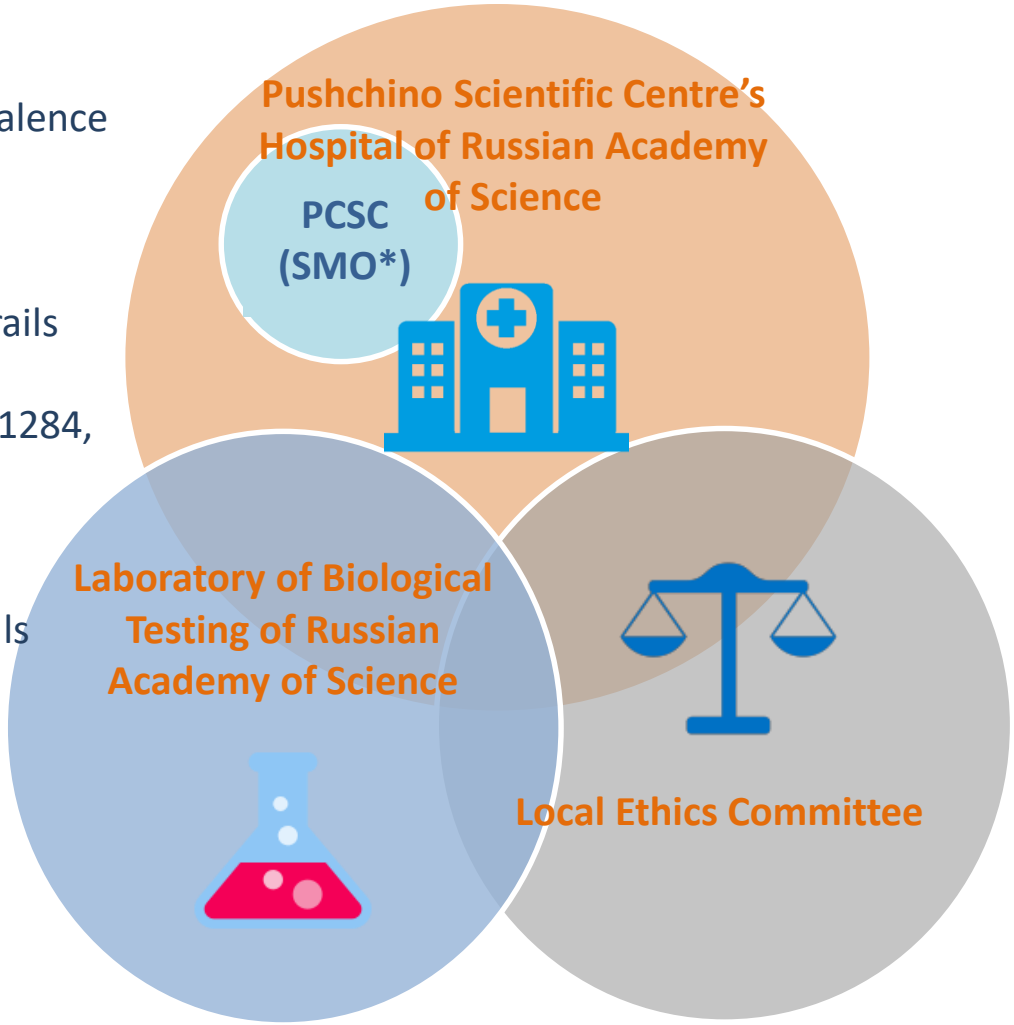
Department of bioequivalence clinical trials was established by PCSC in 2018

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE

Study Centre

- Organization of bioequivalence clinical trails
- Organization of clinical trails
  (Phase I-IV)
  (Local accreditation No 1284, 08.07.2016)
- 10 conducted clinical trials



* Site Management Organization

PCSC

PRECLINICAL and CLINICAL STUDY CENTRE

Technical capabilities

- Department with fully equipped wards for simultaneous hospitalization of up to 45 volunteers
- Intensive care unit
- Refrigerators for processing of samples, short-term and long –term storage
- Fully equipped rooms for drug and material storage, including “cold chain”
- Fully equipped archive for long-term storage of clinical trial documents
- Food unit and kitchen for volunteers
- Room for monitors, auditors and other representatives of the Sponsor

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE

Team

Principal Investigator

Ninel I. Kosyakova

Professor, Ph.D., M.D.

- Participates in clinical trials since 1999

CRC (PCSC)

Dmitry A. Bondarenko

Ph.D.

Senior Researcher

- Participates in clinical trials since 2017
- Participates in preclinical trials since 2015

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE

PCSC functions

- Attraction of the new trials to the research centre
- Organization of verification and signing of a contract with the research centre
- Organization of payments to the research centre staff and volunteers
- Involvement in the development and implementation of SOPs, as a part of the Quality Control System
- Organization and control of the recruitment of volunteers and research subjects. Database management
- Individual Registration Card filling
- Clinical trial forms filling and management of a Trial Master File
- Organization of the research centre's staff trainings
- Performing of administrative functions according to SOPs

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE

PCSC advantages

- Signing of a contract with the research centre as soon as possible
- Additional support and guarantee for the recruitment of the required number of volunteers and research subjects
- The presence of the CRC as a contact person for the Sponsor's representatives will allow to receive necessary information and answers for inquiries as soon as possible

- Additional control by the CRC and additional support for the PI and the research team through the administrative authority of the CRC
- Additional quality control and integrity of the obtained data
- Additional control by the CRC of the compliance of the clinical trial with the requirements of the Protocol, GCP and applicable legislation

+7 (916) 226-25-48

142290, Moscow region, Pushchino,
Prospekt nauki, 3
request@preclinical.ru

www.preclinical.ru

PCSC

PRECLINICAL and CLINICAL
STUDY CENTRE