KRAKOWSKIE CENTRUM MEDYCZNE NZOZ

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INFORMATION ABOUT CLINICAL TRIALS FOR PHARMACEUTICAL COMPANIES

Krakowskie Centrum Medyczne is a private clinical trials centre of SMO type specialized in conducting the most difficult clinical trials' protocols of the Ist, IInd and IIIrd phase. The trials have been carried out since 1994. The director and owner of the centre is Prof. Edward Czerwinski former Head of Orthopaedic Clinic of Collegium Medicum Jagiellonian University and the author of 350 publications. So far, we have conducted 49 trials and we constantly start new trials. There are 84 persons of personnel including 18 doctors specialists with many years of experience in clinical trials, 3 nurses, 5 assistants and medical technicians. They all hold GCP certificates and fluently communicate in English.

We conducted trials of I-III phase in the following diseases: osteoporosis, osteoarthritis, rheumatoid arthritis, menopause, hypertension, diabetes, ulcerative enteritis, hypercholesterolemia, COPD, asthma, deep-vein thrombosis, acute pain. We are prepared to conduct advanced clinical protocols in the field of internal diseases, ophthalmology, gynaecology, laryngology and others. According to the requirements of a particular trial we are able to create a team of doctors of any specialist profile. In our previous trials participated about 600 patients.

The main investigators are specialists in applied field of medicine. Assigned to every trial coordinator and assistant ensure efficient screening, cooperation with the sponsor and CRO. Work of all teams is synchronized by a Trial Office. All procedures of the centre as well as the method of handling source documentation are described in detail in the internal SOPs, which are continuously improved.

Each patient included in the trial is under a medical care of the assigned to him/her doctor that is always available on a mobile phone. Long-term experience of the personnel and the modern equipment ensure high standard of provided services. The personnel of the centre conduct trials with the highest quality and devotion. The patients have twenty-four-hour access to medical care. We are known as one of the best centers in Europe and we cooperate with the companies from all over the world. We ensure fast and effective screening and the possibly highest retention of patients even in the long-term trials.
So far, the Centre has undergone 4 external audits. We always received very good assessment.

Patients' database
We possess a fully computerized database of 100,000 patients of our centre. At the recruitment we cooperate with 4 big multidisciplinary centers, 10 teams of primary medical care and 80 specialists in different fields. This creates another base of about 80,000 patients.

Equipment and premises
We have 4 fully equipped doctors' rooms, treatment room and offices for doctors and monitors (air conditioning). We have complete diagnostic equipment and premises for laboratory researches and modern medical equipment for bone densitometry, spine morphometry, USG (with a set of heads). We have the most modern ophthalmologic equipment, RTG, MRI, QCT and mammography (cooperation), (the list of equipment is attached). The centre is fully computerized with own server and fast internet connections.

Localization
Krakowskie Centrum Medyczne is situated in, known in Poland, Kopernika street, located among the departments of the University Hospital in Krakow, which enables us to offer our patients the highest quality of medical services. We are based within 7-minute walking distance from the Main Railway Station and famous Old Market Square. We have own car park and even garden.

KRAKOWSKIE CNTRUM MEDYCZNE
Cooperation

Pharmaceutical companies
ActivX Biosciencies Inc.
Amgen Inc.
Aventis Pharma Sp. z o.o.
Boeringer Ingelheim
Daiichi Sankyo
Danone Research
Eli Lilly & Company, Eli Lilly Polska
I.R.I.S.Servier France
Servier Polska Sp. z o.o.
Laboratoires SMB S.A.
Merck & Co. Inc.
Merck Serono International
Merck Sharp and Dohme Idea
MSD Polska Sp. z o.o.
Novartis Pharma
Organon Polska Sp. z o.o.
Pfizer Inc., Pfizer Polska Sp. z o.o.
Procter & Gamble
Proskelia Pharmaceuticals
Rigel Pharmaceuticals Inc.

Clinical Research Organization
Encorium Polska Sp. z o.o.
Grupa Sanofi-Aventis Sp. z o.o.
ICON Clinical Research
INC Research (dawniej MDS Pharma Services)
Kendle Branches Sp. z o. o.
Medpace Polska Sp. z o.o.
MSD Polska Sp. z o.o.
Novartis Pharma Poland Sp. z o.o.
Organon Polska Sp. z o.o.
Parexel Polska Sp. z o.o.
Pfizer Polska Sp. z o.o.
Pharmaceutical Research Associates Sp. z o.o.
Procter & Gamble Polska Sp. z o.o.
Servier Polska Sp. z o.o.
Smerud Medical Research Poland
Quintiles Polska Sp. z o.o.
Sanofi-Aventis
SantoSolve A/S
Smerud Medical Research Finland
Roche Holding AG

Central and local laboratories
Covance Central Laboratory
ICON Inc Central Laboratories
BARC Bioanalitycal Research Corporation
Esoterix Inc Clinical Trial Services
PPD Global Central Labs
Medpace Reference Laboratories
VirtualScopics Inc
Synarc

Previous audits
1. 17 – 21.06.2002, N.V. Organon, Molenstraat, The Netherlands
2. 7-8.12.2004, F. Hoffmann-La Roche Ltd Pharmaceuticals Division PDQ, Switzerland
3. 29-31.01.2009, Zur Wacht 2, D-61267 Neu-Anspach, Germany
4. 10-12.02.2009, International Centre for Therapeutic Research Poland
5. 11–12.05.10, KCR S.A. Poland
6. 27-28.07.2010, Amgen Limited, Cambridge CB4 0WD