Dear All,

We are Preclinical Study Centre, privately owned cross-bred Site Management and Contract Research / Manufacturing Organization specialized in full R&D support, preclinical, bioequivalence, early phase, observational and post marketing clinical studies and manufacture of pharmacological / biotechnological, biosimilar or generic human use medicines.

As a resident of the main Russian biotechnological cluster Preclinical Study Centre LLC, is involved in developing any kind of pharmacological/biotechnological innovative, biosimilar or generic human use medicines aimed to obtain Marketing Authorization (Russian MoH, FDA, EMA).

The main activities of the research platform include:

- Manufacture GMP API & drug product.
- Complete R&D MoA study, In vivo efficacy/PD model, mutagenicity, GLP-tox study.
- Over 200 healthy volunteers, 40+ bed in-patient clinic with SMO for phase I-III and BE studies.
- Full-featured analytical and clinical chemistry bio analytics.

The specific advantages are:

- Rapid access to multidisciplinary network of test sites including

- GMP process development and up-scaling — developmental biotechnology manufacture
- GLP Toxicology at laboratories (SPF`s, rodents, nHP)
- Analytical chemistry laboratories
- Mutagenicity and in vitro toxicology laboratories
- GCP-compliant Hospital

- Entire quality assurance and control division ensures permanent coordination of the study, quality, integrity and accuracy of data for each stage of the study.

- Study regulatory support: obtaining of a clinical trial regulatory approval, control of acceptance of the study results on each phase of development, and control of acceptance of the trial program results for marketing authorization.

- One point of contact for legal, contract, project management, medical writing, obtaining of regulatory and ethics approvals, vendor management, manufacture, logistics, pharmacovigilance, data management and biostatistics.

Looking forward hearing from you,

Kind regards,

Ilya Chistyakov MD, PhD,

CEO, managing Director

Preclinical Study Centre

of. 409, 4th floor, 3, Prospect Nauki, Pushchino, 142290, Russia

Cell: +7 (916) 226-25-48

E-mail: chistyakov@preclinical.ru / www.preclinical.ru