Global Clinical Trials, LLC (GCT) is a full-service regional CRO, established in 2001 and headquartered in Princeton (NJ), US with FDA/EMA/GCP compliant Phase I-IV/PK/BE clinical research operations in Central-Eastern Europe and Russia, with 15+ years experience in the industry.

GCT has solid experience in gynecology, obstetrics, and reproductive health (see some examples in the table below).

Nowadays the major players in clinical development in the area are Pfizer, Bayer, Merck, and Actavis. As per the recent CW data, at present the main indications in OB/GYN/RH investigated within international clinical research are breast cancer (47%), ovarian cancer (12%), urinary incontinence (7%), fallopian tube cancer (6%), endometriosis (7%), peritoneal cancer (5%), pregnancy (4%), uterine fibroids (3%), and others. However, there is still an unmet need in developing new drugs to treat public (like papilloma) and sexually transmissible infections (chlamydia trachomatis, gonorrhea, syphilis, candidiasis, genital herpes, HPV, AIDS, trichomoniasis, bacterial vaginosis, others), salpingitis, oophoritis, pediatric and adolescent gynecologic disorders (running up to 24% of morbidity in Russia and CEE region). Apart from obstetrics covering prenatal care and normal labor, there is a high demand in developing therapies to treat complication of pregnancy such as nausea, trauma, diabetes/herpes simplex virus of pregnant women, preterm labor, postdates pregnancy, pulmonary artery tromboembolia, pregnancy termination, etc.

Women of childbearing potential and pregnant women have been underrepresented in important clinical studies, especially in randomized controlled trials, due to the ethical issues and lack of experienced investigators and insufficient amount of specially equipped sites; at the same time the pharmacokinetics and pharmacodynamics of drugs used during pregnancy is absolutely different and unique, that leads to adverse effects on maternal health and fetal environment and health in the situation of prevalence of off-label medicines. Additionally, today new drugs and diagnostics in reproductive endocrinology, contraception and infertility as well as menopausal medicine, including osteoporosis are essential to be developed.

In the region with the total population around 220m and with the centralized healthcare system patients’ recruitment potential, including treatment-naive subjects, is enormous, that is especially actual for late-stage international clinical research projects. The quality of clinical research data coming...
from Russia and CEE region is comparatively high. For example, the percentage of FDA/EMA approved drugs studied within international clinical trials placed in part in Russia is increasing (21% in 2012, 66% in 2013, 56% in 2014, and 62% in 2015). As per the EMA report, Russia is among five top-enrolling countries in clinical research worldwide. Moreover, including Russia into your clinical study, you escape the need to conduct local registration clinical studies in future and save time and costs to launch to the Russian market!

Please contact our Business Development team at bd@gctrials.com now. We will perform thorough feasibility and provide full project cost estimate for free on provision of your study synopsis within one-two weeks!

Some statistics in OB/GYN/RH

Globally 40-50% of childbearing population suffers from gynecological disorders. The highest rate of complications is among pregnant women and ones in puerperium.

Inflammatory diseases of female genital organs occupy the first place (55-70 %) in the structure of gynecological diseases and may cause infertility, abdominal pregnancy, and persistent pain. Vulvit, Bartholinitis, colpitis, and cervicitis usually have an infectious origin. Arterial hypertension (AH) in pregnant in one of the most spread and dangerous conditions. In Russia AH is seen in 5-30% of pregnant and shares 12% in the structure of maternal mortality. Children of women with AH suffer from different metabolic, hormonal, cardio-vascular diseases. However, cesarean operation increases the risk of postpartum infectious complications in 5-20 times. Pulmonary artery thromboembolia remains one of the main direct causes of maternal mortality as well. Chronic stresses and poor nutrition result in pre-eclampsia which takes a leading place in the structure of maternal mortality.

The frequency of preterm birth globally is 5-10% and is not decreasing. The share of premature children accounts for 60 - 70% of cases of early neonatal mortality, 50% of neurological diseases, including cerebral spastic infantile paralysis, visual impairment (till blindness), hearing disorders (until deafness), and severe chronic lung diseases.

Region facts

In the region there is a number of specialized associations such as the Russian Society of Obstetricians-gynecologists (RSOG) joining more than 35,000 specialists in the country and being the member of the World Health Organization, European and World Associations of Obstetricians and Gynecologists, International Federation of Gynecology and Obstetrics (FIGO); the Association of Gynecologists-Endocrinologists in Russia; the Association of Obstetrician-Gynecologists of Ukraine, Romanian Society of Obstetric and Gynecology, and Bulgarian Society of Obstetrics and Gynecology which are the members of FIGO as well.

These associations make their reasonable contribution into training and education of the doctors in gynecology, obstetrics, and reproductive health, protecting the patients’ rights, development of medical standards, introduction of the state-of-the-art technologies into medical practice, organization of scientific and educational programs, seminars and conferences focused on gynecology, obstetrics, and reproductive, international scientific information exchange, etc.

For example, in Russia a number of federal clinical guidelines have been developed by the RSOG in the main indications such as abdominal delivery, hypertensive disorders, arterial hypertension in pregnant, iron deficiency, cesarean section, endometriosis, preterm delivery and many others.