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## Regional factors impairing multicentral clinical trial results

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The number of international multicentral clinical trials involving the range of investigational sites located in various regions throughout the world, including the Russian Federation, permanently grows. Data shows that clinical trials findings could vary from region to region regardless of whether the sample had been homogeneous or not. First of all statistic analysis of multiregional multicentral clinical trials often requires stratification, separate data processing or significant increase of sample size. Secondly, while planning a multicentral clinical trial one should take into consideration special regional factors (logistic and clinical, exterior and interior), which could impair study results. The main clinical factors that should be taken into account when working out study design are diagnostics and treatment differences and pharmacogenetic variance of participating regions. Some examples of multiregional clinical trials confirming the phenomenon include: PLATO, EVEREST, PURSUIT, BEST, CIBIC-II, COPERNICUS, MERIT-HF, and HERO. Recent observations present the following rough geographical division into regions that are likely to differ in world-wide clinical studies results: North America, South America, Western Europe, and Eastern Europe. However even countries-neighbors, which are located nearby and have similar conditions of clinical trials conduction *ex facte*, differ in some features that could affect final results of the study. Besides complications in international study results analyzing, the problem could be urgent in case of transmitting the foreign local clinical data to other regions and assessing the acceptability.

### Biography

Vladimir Popov, MD, PhD, Dr. MedSc is the Head of Clinical Pharmacology Department ("Scientific Medical Center", JSC "Russian Railways"), the leading researcher of Cardiology Department (Sechenov 1st Moscow State Medical University). He has published more than 140 papers, serves as an editorial board member of "Drug Development and Registration" journal (Russia) and is a member of Cardiovascular Pharmacology and Drug Therapy working group of European Society of Cardiology, Russian Society of Pharmacoeconomics and Outcome Research, Society of Specialists in Evidence-Based Medicine (Russia), a faculty of Cardiovascular Clinical Trials Forum (France), a governor of International Society of Cardiovascular Pharmacotherapy, and a scientific expert of Romualdo Del Bianco Foundation (Italy).

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