

Olga Marchenko, MS
Director, Biostatistics Consulting, Oncology, i3 Statprobe
Head of Adaptive Design Consulting Group

As Director, Biostatistics Consulting, Olga Marchenko is responsible for providing strategic leadership for the design and analysis of clinical trials, senior biostatistical oversight on projects, and biostatistical consulting services to clients. She serves as a resource for the department to provide integrity in the application of statistical methodology to clinical trials in a regulated environment. As head of the Adaptive Design Consulting Group, Olga is responsible for managing the group, keeping up with industry and academic research in the area, providing consultation and support to clients and statisticians working on trials utilizing adaptive design methodology, and providing training to the department in the area of adaptive designs and sequential methods.

Prior to joining i3, Olga Marchenko worked at the Ann Arbor, Michigan office of Pfizer. Prior to Pfizer, Olga was part of the biostatistical consulting department at Statprobe, Inc., where she provided full statistical support for over 100 clinical trials, five oncology programs, two cardiovascular programs, and several global regulatory submissions.

Olga received her master's degree in science mathematics from the Belarusian State University in Minsk (Belarus) and her master's degree in statistics from the Ohio State University in Columbus, Ohio. Currently, Olga is working on her PhD thesis in statistics at the University of Michigan, Ann Arbor. Olga made several presentations on adaptive designs in clinical trials at the University of Michigan, Ann Arbor, and at Pfizer. This summer, she presented a talk titled "Adaptive Design in Dose-ranging Studies Based on Both Efficacy and Safety Responses" at the 5th International Conference on Multiple Comparison Procedures in Vienna, Austria.

Corina Sirbu, PhD
Senior Biostatistician, i3 Statprobe
Member of Adaptive Design Consulting Group

As a Senior Biostatistician, Corina provides biostatistical support in the planning, design, analysis, and preparation of reports for clinical studies. She is responsible for writing statistical analysis and programming plans, and performing statistical design and sample size calculations, including options to design, monitor, and simulate adaptive trials. As a member of the Adaptive Design Consulting Group, Corina is the lead for the adaptive sequential methods and serves the department as a consultant on this topic.

Prior to joining i3, Corina worked for Boston Scientific Corporation as a Principal Statistician and for the School of Public Health, Boston University, as an Assistant Professor. Corina has been involved in many different therapeutic areas including cardiovascular, CNS, pain, oncology, endoscopy, urology, and gynecology.

Corina received her PhD degree in statistics and probability from Michigan State University in 2004. She holds a master's degree in stochastic processes and applied statistics (1999) and a bachelor's in mathematics (1997) from the University of Bucharest.

James Trammel, MS
Principal Biostatistician, i3 Statprobe
Member of Adaptive Design Consulting Group

As a Principal Biostatistician, James Trammel is responsible for assisting in protocol design, creating trial randomization, statistical analysis plan development, programming plan creation, results reporting, and senior statistical oversight. A member of the Adaptive Design Consulting Group, James is responsible for adaptive randomization and serves the department as a consultant on this topic.

Prior to joining i3, James spent 10 years at Red River Statistics as a Senior Statistician doing statistical consulting in the pharmaceutical business. He started his career at Boots Pharmaceuticals in 1989 and spent 6.5 years there. James has been involved in many different therapeutic areas including immunology, endocrinology, cardiovascular, and respiratory allergy. He has led both conventional and electronic submissions and been involved in many integrated summaries. He has experience with FDA interaction on various projects including both statistical and clinical reviewers.

James received his master's degree in statistics from the University of Southwestern Louisiana in 1989. He holds a bachelor's degree in mathematics from Northwestern State University in Louisiana (1987).