OCT Clinical Preparing Data Packages for proinnovera GmbH

OCT Clinical's biostatistics and statistical programming team successfully carried out interim statistical analysis for proinnovera GmbH.

OCT Clinical is the leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region.

ST. PETERSBURG, RUSSIA, March 5, 2021 /EINPresswire.com/ -- In March 2020, proinnovera GmbH, a dermatology-specialized European CRO, joined efforts with OCT Clinical's team to carry out interim statistical analysis in its study on 7 subjects and prepare necessary data packages. The database lock was performed in September, and by October OCT had successfully completed all assigned tasks and delivered all required data packages. The primary goal of the study is to evaluate the safety and pharmacokinetic profile of the active ingredients and their metabolites after application of the studied medical product.

OCT Clinical's biostatistics and statistical programming team was assigned to do the following: SDTM package (SDTM datasets programming and validation, annotated CRF, Study Data Reviewer's Guide, define.xml), ADaM package (ADaM datasets programming and validation, Analysis Data Reviewer's Guide, define.xml), Interim Statistical Analysis Plan, TFLs programming and validation, and Interim Statistical Analysis Report. Prior to the database lock a Data Review Meeting was organized to ensure the completeness and correctness of the data, as well as to review and assign ratings to protocol deviations and define analysis populations.

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> *Kristina Bondareva, Head of the Biostatistics Department at OCT Clinical*

A draft interim statistical report was written by the OCT biostatistics and statistical programming

team within 2 weeks of the meeting and database lock. All the minor comments were addressed effectively, which allowed for the statistical analysis report to be finalized within 3 weeks of the DBL.

Datasets and metadata were prepared in CDISC compliant format. The process of preparation of SDTM and ADaM packages was carried out in parallel with TFLs programming, so they were also delivered shortly after the interim statistical report. As per standard OCT practice, all analysis datasets and the majority of TFLs were QCed by double programming. SDRG/ADRG and define.xml also underwent rigorous review by a senior statistical programmer and a biostatistician.

Despite extremely tight deadlines and an extensive number of required deliverables, the OCT team was able to manage the workload and deadlines effectively and provide carefully designed data packages compliant with ICH guidelines, regulatory standards, and research objectives.

“One of the core principles at OCT Clinical is to focus on quality culture and regulatory compliance. To support this principle, we have been performing in-depth quality control and validation of statistical deliverables,” — commented Kristina Bondareva, Head of the Biostatistics Department at OCT Clinical.

Preparing data packages for successful submission is a significant part of OCT’s services portfolio. OCT Clinical’s experts offer flexible biostatistics solutions driven by every particular clinical research goal.

For more information on OCT Clinical’s CRO services, visit www.oct-clinicaltrials.com/services.

About OCT Clinical
OCT Clinical is the leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region. With a team of over 200 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT’s experienced team delivers both standalone services such as medical writing, consultancy, project management/monitoring, data management/biostatistics and turnkey service for clinical development. Since 2005, OCT Clinical Trials has worked on over 300 full-service and functional service projects in more than 20 therapeutic areas. OCT Clinical, a CRO operating in 12 countries, was selected as a principal CRO, responsible for the full range of activities for the vaccine trial in Russia, including regulatory and logistic support, project management, subject enrollment, site monitoring. Learn more at www.OCT-ClinicalTrials.com

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