Tegra

REVEAL THE POWER IN YOUR DATA
Tegra Analytics
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FDA approves OraVerse® in pediatric dental patients

March 28, 2016

Columbia, SC. Tegra is pleased to announce the FDA approval a Phase IV, Multicenter, Randomized, Double-Blinded, Controlled Study of OraVerse® for Safety and Efficacy in Pediatric (Ages 3-5) Dental Patients Undergoing Mandibular and Maxillary Procedures (NDA 022159/S-011). The clinical trial spanning five years culminated in a letter of approval from the FDA. Tegra Analytics provided a comprehensive range of statistical services beginning with the design of the trial, collecting data from the case report forms and submitting statistical analyses to the FDA. The sponsor, Novocol Pharmaceutical of Canada, Inc., stated,

> *"OraVerse has been approved in the pediatric setting with no 483s, no supplemental TFLs, and within the review cycle. We had a successful FDA NDA submission with Tegra a few years ago with Articaine and history repeated itself with this OraVerse® study. Once again Tegra provided excellent study design, accurate statistics, and quality data.*
>
> *Tegra has been an invaluable addition to Novocol's pharmaceutical clinical study team. Their knowledgeable advice, keen attention to detail and ability to interact with all members of the team from President to lawyers to clinicians has made them an excellent choice as our statistical partners. In addition to the technical skills they brought to the project, their team is courteous, helpful, prompt in meeting deadlines, and equally comfortable offering suggestions or incorporating other ideas into the study design. I would not hesitate to recommend the services of Tegra for our next project."*

Tegra Analytics, LLC., located in Columbia, SC, and Doylestown, PA, offers custom, accurate and straight-forward analytical products and services. Tegra works with the physicians, Sponsor and FDA to design the statistical components of the protocols, create the statistical analysis plan (SAP), and analyze the clinical data to deliver a thorough FDA submission.

Tegra's Role

Throughout the design, analysis and approval process, Tegra provided the following services:

- Protocol review
- Research prior studies and submissions
- Construct optimal study designs
- Provide appropriate hypotheses and perform inferential statistical analyses
- Review safety considerations (primary)
- Develop efficacy criteria (secondary)
- Develop data collection procedures and data storage capabilities
- Provide patient selection randomization procedures, power calculations, cost considerations, sample size calculations, and statistical procedures
- Assist with data management, case report forms, provide all data entry, and QA
- Attend several meetings in Washington, DC with PI, Sponsor, FDA, and legal team
- Documentation of SAS data and procedures
- Statistical documentation for final clinical reports submitted to FDA
- Review documents and QA every number transcribed by Sponsor
- Assist with supplemental FDA requests during the approval process

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