IVR Clinical Concepts

Case Study: The Making of a Successful Seasonal Allergic Rhinitis Study

How our ePRO applications created a successful Seasonal Allergic Rhinitis Therapeutic Equivalence Study

The Study

- 800 patients globally
- Initiated in South Africa, and rolled over to the Southern United States

What We Did

- Developed an ePRO application version of the Total Nasal Symptom Score (TNSS) and administered it as a twice daily survey.
- The scores were the primary efficacy determinant in this SAR therapeutic equivalence study comparing innovator's product, generic product and placebo.

How We Did It

- We initially deployed the ePRO application in South Africa, accommodating several local patient population languages.
- Patients were asked to report symptoms and dosing information two times daily for two weeks.
- The system calculated survey compliance based on Sponsor determination of the minimum number of completed diaries needed over the subject treatment period. We were able to help sites follow up with subjects to maintain high levels of diary compliance.
- We decided to roll-over the study to other active SAR season locations, assisted by IVRCC's global capabilities that allows rapid deployment to other world regions.

The Challenge

- To achieve a high level of diary compliance as quickly as possible in order to provide enough data that is statistically usable for efficacy evaluation despite the normal time limitations of regional SAR seasons.
- To be able to close enrollment when study just exceeds statistically required enrollment target that will produce adequate data points for analysis, and will maintain high level of efficiency.

How It Works

- The IVRCC application sent automated reminders to patients based on their morning and evening windows for patient reporting.
- With scheduled alerts, individualized emails and web-based reports, our automated systems notified sites, the CRO and other key study personnel of subject diary non-compliance on a daily basis giving them sufficient time to intervene and retrain the patients.
- Real-time enrollment and compliance reports were generated automatically by the system for virtually instant review by study managers, to allow for key cost and time saving decisions to be made, including for enrollment closure.

Success

- Diary compliance was increased to over 91%, higher than previous studies.
- Training, efficient engagement and re-in-servicing of subjects and site personnel with the benefits of our automated system helped make the trial a success.
- Date/time stamped data was collected from patients, satisfying the FDA's interest in and increasing requirement for immediacy, accuracy, relevance, and overall quality of subject reported information.

Results

- According to FDA review, the TNSS data from subjects showed superiority of both "actives" to placebo.
- The study also showed non-inferiority of the experimental drug, as compared to the control active standard thereby showing therapeutic equivalence.

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Want to learn more?

Put your study in our hands and we will deliver cost-effective and timely results.