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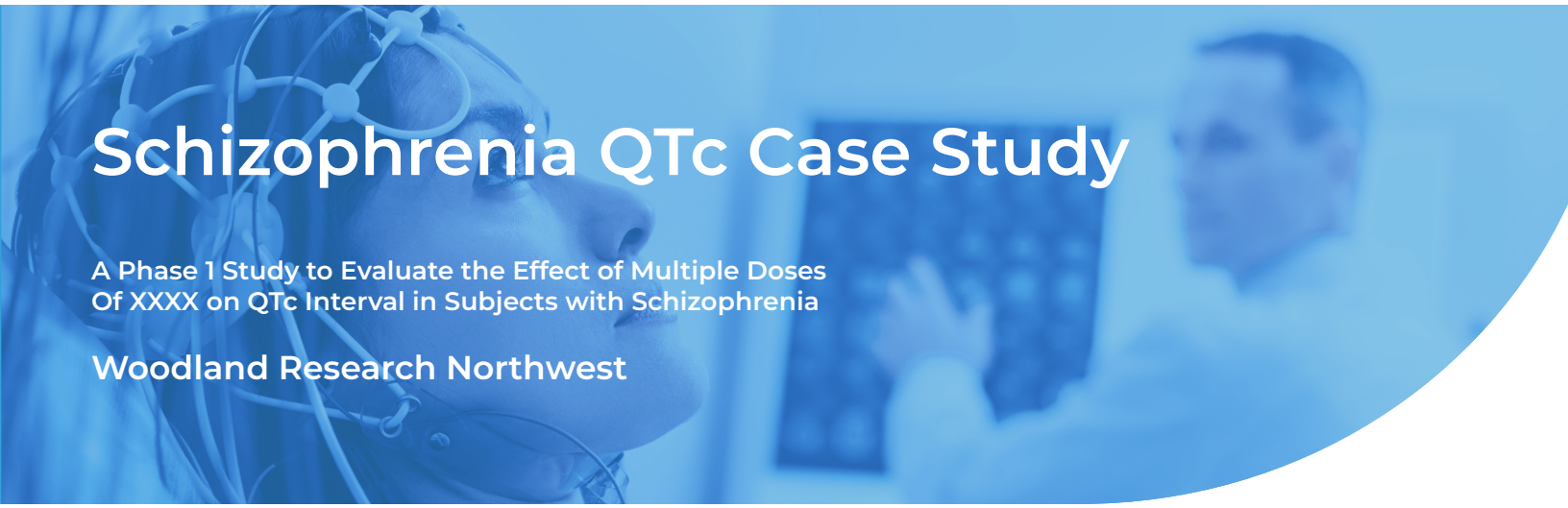

Schizophrenia QTc Case Study

A Phase 1 Study to Evaluate the Effect of Multiple Doses Of XXXX on QTc Interval in Subjects with Schizophrenia

Woodland Research Northwest

Phase: 1
Indication: Schizophrenia (Stable)
Individuals enrolled: Stable schizophrenics between 18 and 60 years of age which 30% are female
Study Duration: Approximately 10 weeks including 43 days for Screening, 17 days inpatient, and up to 15 days for safety follow-up
Enrollment period: 4.5 months
# of Study Subjects: 100
Method of Administration: Oral

Site Achievements:

- Top Enroller
- Randomized 35% of study
- 27% Screen Fail Rate
- 97% Completion Rate

OBJECTIVES

Primary

- To evaluate the effects of multiple therapeutic and supratherapeutic oral doses of XXXX on the heart ratecorrected QT (QTc) interval

Secondary

- To evaluate the effect of XXXX on other electrocardiogram (ECG) parameters; RR, PR, and
- QRS interval, and T-Wave morphology
- To demonstrate sensitivity of the study to detect a small QT effect using moxifloxacin as a positive control.
- To evaluate the safety and tolerability of XXXX
- To evaluate the PK/PD relationship between effect of XXXX on ECG and plasma concentrations of XXXX, XXXX, and its metabolites, XXXX and XXXX

ECGs – 36 per subject – 18 triplicate, 18 single

Lab Assessments
PK draws – 49 per subject
Vitals -29 per subject

Holter – 24-hour continuous ECG data recordings collected at baseline (Day -1) and on Days 1,4,8,13 and 14 for central read. Replicate 12-lead ECGs be extracted from continuous recording at 10 timepoints from pre-dose through 24 hours post dose on each day totaling 140 per subject

"The entire team at Woodland Research Northwest have been a pleasure to work with. The attention to detail in this complex clinical trial was critical to its successful execution. The identification of proper patients and the number randomized significantly contributed to meeting our study timelines. The site's overall performance provided us with a high level of confidence and we would not hesitate to work with them in the future." **- Clinical Trial Manager**