

Wake Forest NCORP Research Base

Special Broadcast

May 20, 2019



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WF-97116 (Remember), Amendment 3

Guidelines for reconsenting patients on WF-97116 as a result of changes per Amendment #3:

- 1) All Patients:
 - a. All patients currently on study should be reconsented to make them aware of potential interactions of study drug and certain concurrently taken medications
 - b. All patients still receiving study drug will require an EKG to rule out unrecognized QTc prolongation or bradycardia
- 2) Patients currently taking the study drug and a moderate risk QTc prolongation medication (reference Appendix A)
 - a. Patients taking the study drug and a moderate risk QTc prolongation medication (reference Appendix A) should be notified of the new amendment requirements and reconsented immediately. These patients will receive an ECG and heart rate assessment at the time of consent as per 1b above.
 - i. Reconsented patients who have an **acceptable** QTc interval (< 500ms) on their ECG and who are **within the first 6 weeks** of study drug (Baseline – 6 Week) should refer to section 7.5 in the protocol for timing of additional ECG monitoring required in the amended protocol.
 - ii. Reconsented patients who have an **acceptable** QTc interval (< 500ms) on their ECG and who are **beyond the study drug dose increase time point** (6 Week) will not require any further cardiac monitoring
 - iii. Reconsented patients who have an **unacceptable** QTc interval (\geq 500ms) on their ECG and who are **within the first 6 weeks of study drug** (Baseline – 6 Week) should stop study drug and be followed as per protocol guidelines
 - iv. Reconsented patients who have an **unacceptable** QTc interval (\geq 500ms) on their ECG and who are **beyond the study drug dose increase time point** (6 Week) may have the dose of study drug reduced by half (i.e. back to initial dose level of study drug). Such a patient would then require repeat EKG testing in 3-7 days at which time they would be allowed to continue on reduced dose of study drug (if QTc is < 500ms) or be taken off the study drug and followed per protocol guidelines (if QTc \geq 500ms).

- 3) Patients currently taking the study drug and a moderate risk bradycardia-causing agent (reference Appendix B)
- a. Patients taking the study drug and a moderate risk bradycardia-causing agent (reference Appendix B) should be notified of the new amendment requirements and reconsented immediately. These patients should receive a heart rate assessment at the time of reconsent (use the EKG required as per 1b above).
- i. Reconsented patients who have an **acceptable** heart rate (≥ 60) and who are **within the first 6 weeks** of study drug (Baseline – 6 Week) should refer to section 7.5 in the protocol for timing of additional heart rate monitoring required in the amended protocol.
 - ii. Reconsented patients who have an **acceptable** heart rate (≥ 60) and who are **beyond the study drug dose increase time point** (6 Week) will not require any further heart rate monitoring
 - iii. Reconsented patients who have an **unacceptable** heart rate (< 60) and who are **within the first 6 weeks of study drug** (Baseline – 6 Week) should stop study drug and be followed as per protocol guidelines
 - iv. Reconsented patients who have an **unacceptable** heart rate (< 60) and who are **beyond the study drug dose increase time point** (6 Week) may have the dose of study drug reduced by half (i.e. back to initial dose level of study drug). Such a patient would then require repeat heart rate testing in 3-7 days at which time they would be allowed to continue on reduced dose of study drug (heart rate ≥ 60) or be taken off the study drug and followed per protocol guidelines (if heart rate < 60).

The results of these ECG and heart rate assessments, along with the date of the assessment, should be recorded on the Cardiac Monitoring Form at the most appropriate listed time point and submitted to the WF NCORP RB.