

**QT Prolongation Monitoring
(QT-1)**

Purpose: Document information collected from monitoring for QT prolongation.

When: At EN, F3, and as needed.

Completed by: CitAD certified personnel.

Information obtained from: ECG.

Instructions: Enter information documenting the ECG on this form. Attach a copy of the ECG blacking out all identifying information. Follow the **visit specific** instructions below:

At the EN visit: ECG must be performed and evaluated by a physician prior to randomization. Individuals with corrected QT (QTc) values greater than 450 milliseconds (ms) for men and greater than 470 ms for women are ineligible. Enter the date of the EN visit in item 4 and "EN" in item 5. Put the date of the ECG in item 8.

At the F3 visit: ECGs should be performed at the F3 visit. Enter the date of the F3 visit in item 4 and "F3" in item 5, and put the date of the ECG in item 8. If the ECG was not conducted at the F3 visit, use the visit date in item 4, enter "F3" in item 5, and check "no" in item 7 and conduct an ECG as soon as possible. QTc values greater than 450 ms for men and greater than 470 ms for women are considered prolonged and need review by the study cardiologist. See handbook for more information.

At the F6 or F9 visit: ECGs are performed at F6 and F9 visits as needed. Enter the date of the visit in item 4 and "F6" or "F9" in item 5. Put the date of the ECG in item 8.

At unscheduled visits: ECGs are performed at unscheduled visits as needed. Enter the date of the ECG in items 4 and 8 and "n" in item 5.

A. Clinic, patient, and visit identification

1. Clinic ID: _____

2. Patient ID: C _____

3. Patient four-letter code: _____

4. Date form completed:
 _____ - _____ - _____
 day month year

5. Visit ID: _____

6. Form revision date:
 2 7 - 0 c - 1 1
 day month year

10. ECG results reviewed by (*check all that apply*):

- a. Study physician ()
- b. Local cardiologist ()
- c. Study cardiologist ()
- d. Other (*specify*) ()

_____ specify
Note: QTc interval values greater than 450 ms for men and greater than 470 ms for women are considered prolonged. Patients with such QTc values at EN are considered ineligible; patients with such QTc values after EN visit require study cardiologist review.

B. ECG information

7. Was an ECG done for this visit:
 (Yes) (No)
 () ()

8. _____
If no, specify reason and then skip to 12.
 _____ specify

8. Date ECG was done:
 _____ - _____ - _____
 day month year

9. QTc interval: _____ ms

11. Actions taken as result of ECG review:

C. Administrative information

12. Date form reviewed by study coordinator:

 day month year

13. Study coordinator ID:

14. Study coordinator signature:

15. Date form reviewed by study physician:

 day month year

16. Study physician ID:

17. Study physician signature:
