

BIRTH COHORT 3 ELECTROCARDIOGRAM FORM

 Study ID B 3 - - / /

 Patient Initials:
 Last First

 Today's date: / /
 day month year

Electrocardiogram Form

Week 20 (tick one) <input type="checkbox"/> Day 0 done <input type="checkbox"/> Delivered <input type="checkbox"/> Withdrawn from study <input type="checkbox"/> Missed study drugs <input type="checkbox"/> Study drugs held for AE <input type="checkbox"/> Refused (if day 0 not done do not complete rest of this section)			
	Day 0 (before study drugs)	Day 2 (2-3 hours after 3 rd dose)	Follow-up ECGs (if grade \geq 3)
Date ECG done	/ /	/ / (leave blank if not done)	
If Day 2 ECG not done reason why: <input type="checkbox"/> Day 0 \geq 500 msec <input type="checkbox"/> Missed visit <input type="checkbox"/> Refused			
QT interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
RR interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
QTc interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
Change from baseline (day 2 – day 0)	<u> </u> <u> </u> <u> </u> msec		
	Grade* [<u> </u>]		
Week 28 (tick one) <input type="checkbox"/> Day 0 done <input type="checkbox"/> Delivered <input type="checkbox"/> Withdrawn from study <input type="checkbox"/> Missed study drugs <input type="checkbox"/> Study drugs held for AE <input type="checkbox"/> Refused (if day 0 not done do not complete rest of this section)			
	Day 0 (before study drugs)	Day 2 (2-3 hours after 3 rd dose)	Follow-up ECGs (if grade \geq 3)
Date ECG done	/ /	/ / (leave blank if not done)	
If Day 2 ECG not done reason why: <input type="checkbox"/> Day 0 \geq 500 msec <input type="checkbox"/> Missed visit <input type="checkbox"/> Refused			
QT interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
RR interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
QTc interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
Change from baseline (day 2 – day 0)	<u> </u> <u> </u> <u> </u> msec		
	Grade* [<u> </u>]		
Week 36 (tick one) <input type="checkbox"/> Day 0 done <input type="checkbox"/> Delivered <input type="checkbox"/> Withdrawn from study <input type="checkbox"/> Missed study drugs <input type="checkbox"/> Study drugs held for AE <input type="checkbox"/> Refused (if day 0 not done do not complete rest of this section)			
	Day 0 (before study drugs)	Day 2 (2-3 hours after 3 rd dose)	Follow-up ECGs (if grade \geq 3)
Date ECG done	/ /	/ / (leave blank if not done)	
If Day 2 ECG not done reason why: <input type="checkbox"/> Day 0 \geq 500 msec <input type="checkbox"/> Missed visit <input type="checkbox"/> Refused			
QT interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
RR interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
QTc interval	<u> </u> <u> </u> <u> </u> msec	<u> </u> <u> </u> <u> </u> msec	
Change from baseline (day 2 – day 0)	<u> </u> <u> </u> <u> </u> msec		
	Grade* [<u> </u>]		

***QTc AE grading:**
0: QTc <0.45 sec.

1: Asymptomatic, QTc 0.45 – 0.47 sec

2: Asymptomatic, QTc >0.47 – 0.50 sec

3: Asymptomatic, QTc >0.50 sec OR Increase in interval \geq 0.06 sec above baseline

4: Life threatening consequences e.g. Torsade de pointes or other associated serious ventricular dysrhythmia

Comments:
Initials: