1. Date and time of ECG: yyyy/mm/dd  am  pm  24-hour clock
2. Ventricular rate / Heart rate: beats/min
3. PR interval\*: msec
4. QRS duration\*: msec
5. QT interval\*: msec
6. QTc interval: msec
7. QRS axis:
8. ECG results: (Choose one)

Normal

Abnormal, not clinically significant

Abnormal, clinically significant

Unable to evaluate

1. Heart rhythm:  Normal sinus rhythm

If not normal:

Sinus tachycardia

Sinus bradycardia

Atrial arrhythmia, specify type:  Atrial fibrillation  Atrial flutter  Other

Ventricular arrhythmia, specify type:  Ventricular fibrillation  Ventricular tachycardia  Other

Other, specify:

1. ST segment abnormality Absent  Present
2. T waves abnormality Absent  Present
3. Right ventricular hypertrophy: Absent  Present
4. Left ventricular hypertrophy: Absent  Present
5. Patterns of previous myocardial infarction: Absent  Present
6. Patterns of left bundle branch block: Absent  Present
7. Patterns of right bundle branch block: Absent  Present

## General Instructions

An electrocardiogram (ECG) is often used during the screening visit of a study to evaluate a participant’s/subject’s cardiac health and determine whether the participant/subject is eligible for the study. Follow up ECGs may be performed to continue to monitor the participant’s/subject’s heart rhythms over the course of the study.

Important note: The data elements with an asterisk (\*) included on this CRF Module are considered Supplemental – Highly Recommended (i.e., highly recommended and commonly collected in clinical research studies but whose relevance depends upon the study design or type of research involved). The remaining data elements (i.e., non Supplemental – Highly Recommended) are Supplemental and should only be collected if the research team considers them appropriate for their study.

## Specific Instructions

Please see the CDE Catalogue for definitions for each of the data elements included in this CRF Module.

No additional specific instructions

* Data and time ECG performed – Record the date (and time) the electrocardiogram (ECG) was performed. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Ventricular rate/ Heart rate – Record the ventricular rate/ heart rate in beats per minute.
* PR interval – Measure and record the PR interval in milliseconds (msec).
* QRS duration – Measure and record the QRS duration in milliseconds (msec).
* QT interval – Measure and record the QT interval in milliseconds (msec).
* QTc interval – Measure and record the QTc interval in milliseconds (msec).
* ECG results – Choose the response that best describes the overall ECG results.
* Heart rhythm – Choose all that apply. If 'Normal sinus rhythm' is chosen no other values can be chosen.
  + Atrial arrhythmia type – Choose all that apply.
  + Ventricular arrhythmia type – Choose all that apply.
* ST segment abnormality – Choose one.
* T wave abnormality – Choose one.
* Right ventricular hypertrophy – Choose one.
* Left ventricular hypertrophy – Choose one.
* Patterns of previous myocardial infarction – Choose one.
* Patterns of complete bundle branch block – Choose one.