ARRHYTHMIAS			
Protocol Identifier	**Subject Identifier** ☐☐☐☐☐☐		**Visit Description** **Treatment Period ABC** **Visit XYZ**

PAST MEDICAL HISTORY

Did subject have a prior history of the following:

Arrhythmia?	(Y) ☐ Yes	(N) ☐ No
Cardiomyopathy?	(Y) ☐ Yes	(N) ☐ No
Syncope with exercise?	(Y) ☐ Yes	(N) ☐ No
ECG abnormality?	(Y) ☐ Yes	(N) ☐ No
QT prolongation?	(Y) ☐ Yes	(N) ☐ No
Family hx for unexplained sudden death or QT prolongation?	(Y) ☐ Yes	(N) ☐ No

CLINICAL PRESENTATION

Date and time of arrhythmic event ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Did event include cardiac arrest? (Y) ☐ Yes (N) ☐ No

If yes, was CPR or shock delivered? (Y) ☐ Yes (N) ☐ No

What was heart rate at time nearest to event? ☐☐☐ beats/minute ___☐ not available

What was heart rate at time of presentation? ☐☐☐ beats/minute ___☐ not available

Symptoms (May want to add length of time for each symptom).

Chest pain	(Y) ☐ Yes	(N) ☐ No
Palpitations	(Y) ☐ Yes	(N) ☐ No
Lightheadedness	(Y) ☐ Yes	(N) ☐ No
Syncope	(Y) ☐ Yes	(N) ☐ No
Fatigue	(Y) ☐ Yes	(N) ☐ No
Heart failure If yes, complete Heart Failure eCRF	(Y) ☐ Yes	(N) ☐ No
Dyspnea	(Y) ☐ Yes	(N) ☐ No
Seizures	Y) ☐ Yes	(N) ☐ No
Other specify:	Y) ☐ Yes	(N) ☐ No

HOSPITALISATION

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Was subject hospitalized due to arrhythmias? (Y) ☐ Yes (N) ☐ No

If Yes, admission date and time ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Was subject seen by a cardiologist? (Y) ☐ Yes (N) ☐ No
If Yes, upload consult.

ECG STANDARD 12-LEAD

Was an ECG Performed? (Y) ☐ Yes (N) ☐ No

If Yes, date and time of ECG? ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Upload available ECGs.
Companies to consider adding ability to insert more ECGs as appropriate. If only one ECG slot available, insert ECG that best characterizes the arrhythmic event.

RHYTHM
✓ all that apply:

☐ heart rate _____ ☐☐☐ beats/minute ___☐ not available
☐ Marked bradycardia (heart rate less than 40 beats/minute
☐ Narrow QRS tachycardia (heart rate (heart rate greater than 120 beats/minute)

☐ First degree AV Block
☐ Type 2 second degree AV block
☐ Third degree AV block

☐ Atrial flutter
☐ Atrial fibrillation
_☐ acute
_☐ chronic

☐ Ventricular tachycardia, sustained
☐ Ventricular tachycardia, non-sustained
☐ Ventricular fibrillation, sustained
☐ Ventricular fibrillation, non-sustained

☐ Torsade de Pointes
☐ QTc greater than 500 msec

☐ Other abnormal rhythm,
Specify:___

If no ECG was performed, what was the clinical diagnosis of the arrhythmias? _____

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EVALUATION

If the response for any of the questions below is Yes and this event:
Is reported as an SAE, record details in _____Section of SAE. Or,
Has not been reported as an SAE, record details in the line below the date and time.

Is a rhythm / in-hospital telemetry strip available? (Y) ☐ Yes (N) ☐ No

If Yes, date and time of rhythm strip ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Is a pacemaker / ICD strip printout available? (Y) ☐ Yes (N)☐ No

If Yes, date and time of pacemaker/ICD strip ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Is a loop recorder printout available? (Y) ☐ Yes (N)☐ No

If Yes, date and time of loop recorder ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Is a Holter monitor report / printout available? (Y) ☐ Yes (N)☐ No

If Yes, date and time of Holter monitor ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

Is an Electrophysiology Study (EP) report available? (Y) ☐ Yes (N)☐ No

If Yes, date and time of Electrophysiology study ☐☐ ☐☐☐ ☐☐ ☐☐:☐☐
Day Month Year Hr:Min(00-00-23:59)

ECHOCARDIOGRAPHY

Was an Echocardiogram performed? [Y] ☐Yes [N] ☐N

If Yes, complete the following:

Date and time of Echocardiogram: ☐☐ ☐☐☐ ☐☐☐☐ ☐☐ ☐☐
Day Month Year Hrs:Mins (00:00-23:59)

Ejection Fraction Assessment (systolic function)? [Y] ☐Yes [N] ☐N

If Yes, record percentage ☐☐☐ **%**

Evidence of diastolic dysfunction? [Y] ☐Yes [N] ☐N

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Evidence of significant valvular disease? [Y] ☐Yes [N] ☐N

Evidence of cardiac dilatation? [Y] ☐Yes [N] ☐N
If Yes, indicate which chamber(s) [A] ☐Atrial [V] ☐Ventricular
Evidence of regional wall motion abnormality? [Y] ☐Yes [N] ☐N

Was a prior Echocardiogram performed? [Y] ☐Yes [N] ☐N

If Yes, complete the following:

Date and time of prior Echocardiogram:

☐☐	☐☐☐	☐☐	☐☐	☐☐
Day	Month	Year	Hrs:Mins (00:00-23:59)	

Prior Ejection Fraction Assessment (systolic function)? [Y] ☐Yes [N] ☐N

If Yes, record percentage ☐☐ **%**

Prior evidence of diastolic dysfunction? [Y] ☐Yes [N] ☐N

Evidence of significant valvular disease? [Y] ☐Yes [N] ☐N

Evidence of cardiac dilatation? [Y] ☐Yes [N] ☐N
If Yes, indicate which chamber(s) [A] ☐Atrial [V] ☐Ventricular
Evidence of regional wall motion abnormality? [Y] ☐Yes [N] ☐N

MUGA

Was a Multiple Gated Acquisition Scan (MUGA) performed? [Y] ☐Yes [N] ☐N

If Yes, complete the following:

Date and time of MUGA:

☐☐	☐☐☐	☐☐	☐☐	☐☐
Day	Month	Year	Hrs:Mins (00:00-23:59)	

Ejection Fraction Assessment?

☐☐ **%**

_ box for "not done"

Evidence of wall motion abnormalities? [Y] ☐Yes [N] ☐N

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Was a prior Multiple Gated Acquisition Scan (MUGA) performed? [Y] ☐ Yes [N] ☐ N

If Yes, complete the following:

Date and time of prior MUGA: ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐ ☐☐ Hrs:Mins (00:00-23:59)

Prior Ejection Fraction Assessment? [Y] ☐ Yes [N] ☐ N

If Yes, record percentage ☐☐ **%**

Evidence of wall motion abnormalities? [Y] ☐ Yes [N] ☐ N

Relevant chemistry labs within 24 hours of event (before or after event) (Y) ☐ Yes (N) ☐ No
If Yes, complete below:

LABORATORY RESULT DATA
Enter 'NR' if the laboratory results are not available to report or if a lab error occurred.

Laboratory Name_____ Lab ID

Address_____
_____

Date	Time	Test	Result	Normal Ranges		
				Low	High	Unit
Day Month Year	Hr: Min 00:00-23:59					
e.g. 01 JAN 2012	13:25	Serum Creatinine	83	62	115	umol/l
		Potassium				

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		Magnesium				

Calcium

		Glucose				

List all labs available. Add lines for serial values of the same lab as needed.

Are there recent TFTs available? (Within last year) (Y) ☐ Yes (N) ☐ No
If Yes, complete below:

LABORATORY RESULT DATA
Enter 'NR' if the laboratory results are not available to report or if a lab error occurred.

Laboratory Name_____ Address_____ ___ _____ ___	Lab ID

Date Day Month Year	Time Hr: Min 00:00-23:59	Test	Result	Normal Ranges		
				Low	High	Unit
e.g. 01 JAN 2012	13:25	Serum Creatinine	83	62	115	umol /l
		Serum TSH				
		Serum total T4 concentration				

Serum total T3 concentration

		Serum free T4 concentration				

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		Serum free T3 concentration				
		T3-resin uptake				
List all labs available. Add lines for serial values of the same lab as needed.						

CONCOMITANT MEDICATIONS

DIAGNOSIS

Was an underlying cause of the arrhythmia identified? (Y) ☐ Yes (N) ☐ No

If yes, specify_____

THERAPY

Was any of the following therapy administered?

Cardioversion (Y) ☐ Yes (N) ☐ No

☐ Pharmacological

Supplemental: consider listing specific classes, acute / chronic pharmacotherapy to treat the arrhythmia

☐ Electrical

Defibrillation (Y) ☐ Yes (N) ☐ No

Defibrillator/pacemaker insertion (Y) ☐ Yes (N) ☐ No

Radiofrequency ablation (Y) ☐ Yes (N) ☐ No

Surgery (e.g., MAZE procedure) (Y) ☐ Yes (N) ☐ No

Did the arrhythmia resolve? (Y) ☐ Yes (N) ☐ No

Is the arrhythmia ongoing? (Y) ☐ Yes (N) ☐ No

Any sequelae as a result of the arrhythmia? (Y) ☐ Yes (N) ☐ No

If Yes, specify_____

If the outcome was death, update the SAE form with outcome and fill out the Death form.