

CTSN AFIB DATA COLLECTION SCHEDULE

Assessment	Baseline	Procedure	Pre-Discharge	Weekly	3 Mos	6 Mos	9 Mos	12 Mos ¹	18/24 Mos	Event driven
General										
Pre-Screening Failure Form	X									
Informed Consent	X									
Release of Medical Information	X									
Demographics Form	X									
Medical History	X									
Medications	X		X		X	X	X	X	X	X
Physical Exam	X		X							
Laboratory Assessment	X									
Eligibility Criteria/Eligibility Evaluation Form	X	X ²								
Hospitalization	X									X
Surgical procedures ³		X								
Telephone Follow-up					X	X	X	X	X	
Cardiac										
Echocardiogram	X	X ⁴						X		X
ECG	X*	X ^Δ	X*							
Weekly TTM ⁵ /event recorder			X ⁶	X ⁷						X
72-hr Holter Monitoring						X		X		
Patient diary			X	X						X
Anti-arrhythmic interventions ⁸					X	X	X	X	X	X
Anti-arrhythmic drug termination					X					X
Biological Specimen Collection ⁹	X	X								
Quality of Life & Functional Status										
SF-12	X							X		
AFSS	X							X		
ELWAF	X							X		
NYHA Class	X							X		
Event Driven Data										
Adverse events			X		X	X	X	X	X	X
Follow-Up Surgical Procedure										X
Missed Phone / Visit Assessment										X
Mortality					X	X	X	X	X	X
Modified Rankin/NHSS										X
Study Completion/Early Termination									X	X
End of Study/Investigator's Statement										X
Cost										
UB-92 Forms & Hospital Bills ¹⁰					X	X	X	X		

¹Scheduled study visit: If in-person visit is not possible for 12-month assessment, then participating local cardiologist will perform echocardiogram, TTM will allow for a remote continuous 72-hour Holter assessment, and a telephone follow-up assessment by investigative center personnel will be performed.

²The Eligibility Evaluation Form will be completed in the OR following ECG and TEE.

³Surgical procedures include: primary procedure, operative parameters, device used for ablation, lesion sets created, and additional procedures performed at time of initial operation.

⁴Intra-operative trans-esophageal echocardiogram (TEE)

⁵Trans-telephonic monitoring (TTM)

⁶Patients receive a TTM device and are instructed in its use prior to discharge.

⁷Weekly and symptomatic arrhythmia driven TTM monitoring occurs between discharge and 12 months.

⁸Anti-arrhythmic interventions include: cardioversion, permanent pacemaker placement, and subsequent ablation.

⁹Biological specimen collection includes: blood, urine, and tissue collections.

¹⁰Investigative center coordinators must provide patient MR numbers to their center's financial administrators who then provide cost data to the Data Coordinating Center (DCC) directly.

* 12-Lead ECG

Δ Rhythm Strip