SUPPLEMENTAL MATERIAL CIRCVOQ_2012_965368

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Appendix A: List of Participating Sites and Enrollment

HEALTH PLAN	NUMBER OF SUBJECTS	PERCENTAGE OF SUBJECTS
Henry Ford Health System	399	15.22
Kaiser Permanente Colorado	130	4.96
Kaiser Permanente Northern California	685	26.14
Kaiser Permanente Northwest	204	7.78
Kaiser Permanente Southern California	803	30.64
Marshfield Clinic	288	10.99
Meyers/Fallon Community Health Plan/U. Mass	112	4.27
TOTAL ENROLLMENT	2621	100

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Appendix B: Data Dictionary for NCDR ICD Registry

ICD Registry™

Implantable Cardioverter Defibrillators Registry v1.08

Data Dictionary - Definitions Only

A. Participant Administration

Field Name: Participant ID **Seq No:** 1000

Definition: Participant ID is a unique number assigned to each Participant by the ACC-NCDR. An ACC -NCDR Participant is defined as one entity that signs a Participation Agreement with the ACC, submits one data submission file to the harvest, and gets back one Outcomes Report on their data.

Each Participant's data if submitted to harvest must be in one data submission file. If one Participant keeps their data in more than one file (e.g. at two sites), then the data must be combined into a single data submission file for the harvest.

If two or more Participants share a single purchased software, and enter cases into one database, then the data must be exported into different data submisison files, one for each Participant ID.

Selections:

Field Name: Participant Name **Seq No:** 1010

Definition: The full official hospital name of the facility where the implant procedure was performed. Values should be full, official hospital names with no abbreviations or variations in spelling for a single hospital.

Selections:

Field Name: Medicare Provider Number **Seq No:** 1015

Definition: Indicate the medicare provider number of the facility at which the patient received the implant.

Selections:

Field Name: Participant NPI **Seq No:** 1016

Definition: Indicate the hospital's (N)ational (P)rovider (I)dentifier. NPIs, assigned by CMS, are used to uniquely identify hospitals for Medicare billing purposes.

Selections:

Field Name: Timeframe of Data Submission **Seq No:** 1020

Definition: Indicate the timeframe of data included in the data submission. Format: YYYYQQ. e.g. 2005Q4

Selections:

Field Name: Transmission Number **Seq No:** 1040

Definition: A unique number created and automatically inserted by the software. It identifies the number of times the software has created data submission files. The transmission number should be incremented by one every time the data submission files are exported. The transmission number should never be repeated.

Selections:

Field Name: Software Vendor Identifier **Seq No:** 1050

Definition: Software Vendor Identification (agreed upon by mutual selection between the vendor and the ACC) to identify software vendor. Vendors must use consistent name identification across sites. Changes to Vendor Name Identification must be approved by the ACC.

Selections:

Field Name: Vendor software version **Seq No:** 1060

Definition: Vendor's software product name and version number identifying the software which created this record (assigned by vendor). Vendor controls the value in this field. Version passing certification/harvest testing will be noted at the ACC.

Selections:

Field Name: Registry Identifier **Seq No:** 1070

Definition: The ACC-NCDR Registry Identifier describes which ACC data registry these records apply. It is implemented in the software at the time the data is collected and the records are created. This is entered into the schema automatically by software.

Selections:

Field Name: Registry Version **Seq No:** 1080

Definition: Registry Version describes the version number of the Data Specifications/Dictionary, to which each record conforms. It identifies which fields should have data, and what are the valid data for each field. It is the version implemented in the software at the time the data is collected and the records are created. This is entered into the schema automatically by software.

Selections:

Field Name: Patient Population **Seq No:** 1090

Definition: Indicate the population of patients that should be included in the data export and submitted to the registry.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	All Patients	All patients regardless of insurance payor and ICD Indication.
2	CMS Primary Prevention Patients	Patients with a Primary or Secondary insurance payor of "Medicare" and an ICD Indication of "Primary Prevention".

Field Name: Data Submission File Password **Seq No:** 1100

Definition: Indicates the ACC assigned password that should be applied to the data submission zip file.

Selections:

Field Name: Auxiliary 0 **Seq No:** 1110

Definition: Not for participant use. A 50 character text field that may be used to collect additional administrative information about the data submission.

Selections:

B. Demographics

Field Name: Patient Last Name **Seq No:** 2000

Definition: Indicate the patient's last name.

Selections:

Field Name: Patient First Name **Seq No:** 2010

Definition: Indicate the patient's first name.

Selections:

Field Name: Patient Middle Name **Seq No:** 2020

Definition: Indicate the patient's middle name or middle initial.

Selections:

Field Name: Patient SSN **Seq No:** 2030

Definition: Indicate the nine digit patient's United States Social Security Number (SSN). If the patient does not have a US assigned SSN, then leave the SSN blank.

Selections:

Field Name: Unique Patient ID **Seq No:** 2040

Definition: This is an arbitrary number (not a recognizable ID like SSN or Medical Record Number) that uniquely identifies each patient. Once assigned to a patient at a health care facility, this will never be changed or reassigned to a different patient. If a patient returns to the same hospital, or for follow-up, they will receive this same unique patient identifier.

Selections:

Field Name: Other ID **Seq No:** 2045

Definition: An additional 'optional' patient identifier, such as medical record number, that can be associated with the patient.

Selections:

Field Name: Patient DOB **Seq No:** 2050

Definition: Indicate the patient's date of birth.

Selections:

Field Name: Gender **Seq No:** 2060

Definition: Indicate the patient's gender at birth.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Male	
2	Female	

Field Name: Race **Seq No:** 2070

Definition: Indicate the patient's race as determined by the patient/family.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	White	
2	Black/African American	
4	Asian	
5	American Indian/Alaska Native	
6	Native Hawaiian	
7	Other	

Field Name: Hispanic Ethnicity **Seq No:** 2075

Definition: Indicate if the patient is of hispanic ethnicity.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Auxiliary 1 **Seq No:** 2080

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

Field Name: Auxiliary 2 **Seq No:** 2090

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

C. Admission

Field Name: Admission Date **Seq No:** 3000

Definition: Indicate the date on which the patient was admitted to the hospital for the current stay.

Selections:

Field Name: Date of Implant **Seq No:** 3010

Definition: Indicate the date of the ICD implant.

Note: In the event that multiple ICDs were implanted/explanted during a single admission, this is the date of the first/initial ICD implant. For clarification, see Sequence Numbers 3507, 3508.

Selections:

Field Name: Insurance Payor-Primary **Seq No:** 3020

Definition: Indicate the patient's primary insurance payor.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Government	Government refers to patients who are covered by government-reimbursed care. In the U.S. this includes, Medicare, Medicaid, (including all state/federal Medicaid-type programs), TriCare, the Veteran's Administration Health Plan, and Federal Employee's Insurance.
2	Commercial	Commercial refers to all indemnity (fee-for-service) carriers and Preferred Provider Organizations (PPOs) (e.g. Blue Cross/Blue Shield).
3	HMO	HMO refers to a Health Maintenance Organization (HMO) characterized by coverage that provides health services for members on a pre-paid basis.
4	Non-U.S. Insurance	Non-US Insurance refers to individuals who reside in and have health insurance in another country.
5	None/Self Pay	None/Self Pay refers to individuals with no or limited health insurance; thus, the individual is the payor regardless of ability to pay.

Field Name: Government Type-Primary **Seq No:** 3025

Definition: Indicate the type of insurance if the patient's primary insurance payor is Government.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Medicare	
2	Medicaid	
3	TriCare	
4	Veteran's Administration Health Plan	
5	Federal Employee Insurance	

Field Name: Insurance Payor-Secondary **Seq No:** 3027

Definition: Indicate the patient's secondary insurance payor.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Government	Government refers to patients who are covered by government-reimbursed care. In the U.S. this includes, Medicare, Medicaid, (including all state/federal Medicaid-type programs), TriCare, the Veteran's Administration Health Plan, and Federal Employee's Insurance.
2	Commercial	Commercial refers to all indemnity (fee-for-service) carriers and Preferred Provider Organizations (PPOs) (e.g. Blue Cross/Blue Shield).
3	HMO	HMO refers to a Health Maintenance Organization (HMO) characterized by coverage that provides health services for members on a pre-paid basis.
4	Non-U.S. Insurance	Non-US Insurance refers to individuals who reside in and have health insurance in another country.
5	None/Self Pay	None/Self Pay refers to individuals with no or limited health insurance; thus, the individual is the payor regardless of ability to pay.

Field Name: Government Type-Secondary **Seq No:** 3029

Definition: Indicate the type of insurance if the patient's secondary insurance payor is Government.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Medicare	
2	Medicaid	
3	TriCare	
4	Veteran's Administration Health Plan	
5	Federal Employee Insurance	

Field Name: Reason for Admission **Seq No:** 3030

Definition: Indicate the primary reason the patient was hospitalized for this admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Admitted for this Procedure	Admitted for ICD implantation.
2	Cardiac-CHF	Admitted for management of heart failure other than implantation of an ICD.
3	Cardiac-Other	Admitted for a cardiac reason other than heart failure or implantation of an ICD.
4	Non-Cardiac	Admitted for a non-cardiac reason other than implantation of an ICD.

Field Name: Auxiliary 3 **Seq No:** 3040

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

Field Name: Auxiliary 4 **Seq No:** 3050

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

D. History and Risk Factors

Field Name: Syncope **Seq No:** 3060

Definition: Indicate if the patient had a sudden loss of consciousness, including loss of postural tone (not related to anesthesia) with spontaneous recovery as reported by the patient or an observer. Patient may experience syncope when supine.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Family Hx Sudden Death **Seq No:** 3070

Definition: Indicate if the patient has a known family history (parent or sibling) of sudden cardiac death.

Sudden cardiac death is defined as a natural death due to cardiac causes heralded by abrupt loss of consciousness, occurring before 75 years of age. The time and mode of death are unexpected even though preexisting heart disease may have been known to be present. Traumatic death subsequently proven to be due to sudden loss of control due to a cardiac problem is included.
Coding Exception: If the patient is adopted, or the family history is unavailable, code "No".

Note: Patient history is defined as prior to the current admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: CHF **Seq No:** 3080

Definition: Indicate if the patient has a history of congestive heart failure (CHF), as documented in the medical record. Besides physician documentation of the CHF history, CHF can also be defined by one of the following:
1. Paroxysmal nocturnal dyspnea (PND);
2. Dyspnea on exertion (DOE) due to heart failure; or
3. Chest X-Ray (CXR) showing pulmonary congestion;
4. Pedal edema or dyspnea treated with medical therapy for heart failure.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: CHF Duration **Seq No:** 3090

Definition: Indicate the time since the initial CHF diagnosis.

Note: This includes any time prior to date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Within the past 3 months	
2	3 to 9 months	
3	Greater than 9 months	

Field Name: Prior CHF Hospitalization **Seq No:** 3095

Definition: Indicate if the patient has ever been hospitalized for CHF prior to this admission. Indicate the timeframe associated with that hospitalization.

Note: This timeframe does NOT include this admission. The intent of this field is to capture hospitalizations for CHF excluding the current admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	Not Hospitalized	
1	Yes-Within 6 months	
2	Yes-Greater than 6 months	

Field Name: NYHA Class - Current Status **Seq No:** 3100

Definition: Indicate the patient's New York Heart Association (NYHA) classification.

NOTE: For patients with no symptoms, code "Class 1".

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Class I	Patient has cardiac disease but without resulting limitations of ordinary physical activity. Ordinary physical activity (e.g., walking several blocks or climbing stairs) does not cause undue fatigue, palpitation, dyspnea, or anginal pain. Limiting symptoms may occur with marked exertion.
2	Class II	Patient has cardiac disease resulting in slight limitation of ordinary physical activity. Patient is comfortable at rest. Ordinary physical activity such as walking more than two blocks or climbing more than one flight of stairs results in limiting symptoms (e.g., fatigue, palpitation, dyspnea, or anginal pain).
3	Class III	Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. Less than ordinary physical activity (e.g., walking one to two level blocks or climbing one flight of stairs) causes fatigue, palpitation, dyspnea, or anginal pain.
4	Class IV	Patient has dyspnea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Field Name: Cardiac Arrest **Seq No:** 3110

Definition: Indicate if the patient experienced cardiac arrest due to arrhythmia.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No Arrest	
1	Brady Arrest	
2	Tachy Arrest	

Field Name: Brady Arrest Reason **Seq No:** 3111

Definition: Indicate the reason(s) for the Brady Arrest.

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Acute MI	
2	Severe Electrolyte Disturbance	
3	Drug Induced Arrhythmia	
4	Sinus Node Dysfunction/AV Block	
5	Unknown Etiology	

Field Name: Tachy Arrest Reason **Seq No:** 3112

Definition: Indicate the reason(s) for the Tachy Arrest.

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Acute MI	
2	Severe Electrolyte Disturbance	
3	Drug Induced Arrhythmia	
4	Primary VT/VF	
5	Unknown Etiology	

Field Name: Atrial Fibrillation/Atrial Flu **Seq No:** 3120

Definition: Indicate if the patient has a documented history of atrial fibrillation or flutter.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Ventricular Tachycardia **Seq No:** 3130

Definition: Indicate if the patient has a history of ventricular tachycardia (either spontaneous or induced) that led to the placement of the ICD. Ventricular tachycardia is defined as a cardiac arrhythmia of 3 or more consecutive complexes in duration emanating from the ventricles at a rate greater than 100 bpm (cycle length less than 600 msec).

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	No history of spontaneous ventricular tachycardia.
1	Yes-VT, Non-Sustained	Three or more consecutive beats of ventricular origin, terminating spontaneously in less than 30 seconds.
2	Yes-Monomorphic Sustained VT	VT greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
3	Yes-Polymorphic Sustained VT	VT with a constantly changing morphology lasting greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.

Field Name: Sinus Node Function **Seq No:** 3140

Definition: Indicate if the patient's sinus node function was normal or abnormal.

Note: Timeframe includes any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Normal	
2	Abnormal	Abnormal - History of any pause longer than 3 seconds OR Tachy/Brady Syndrome.

Field Name: Cardiac Transplant **Seq No:** 3150

Definition: Indicate if the patient had a history of cardiac transplant surgery.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Non-Ischemic Dilated Cardiomyopathy **Seq No:** 3160

Definition: Indicate if the patient has a history of non-ischemic dilated cardiomyopathy documented by heart failure and reduced systolic function.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Within the past 3 months	
2	Yes-3 to 9 months	
3	Yes-Greater than 9 months	

Field Name: Ischemic Heart Disease **Seq No:** 3180

Definition: Indicate if the patient shows evidence of ischemic heart disease as documented by any of the following conditions:
-At least one major epicardial artery with more than 70% obstruction by coronary angiography.
-Other Diagnostic Tests: History of myocardial infarction associated with wall motion abnormality as shown by echocardiography or other cardiac imaging. Stress testing diagnostic of coronary artery disease with or without imaging; ECG with evidence of MI; history of chest pain associated with cardiac enzyme abnormality.

Note:
1. Patient history is defined as any time prior to the date of implant.
2. At least one major epicardial artery with more than 70% obstruction by coronary angiography takes precedence over other diagnostic tests if ischemic heart disease has been documented.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-At Least 1 Epicardial artery greater than 70% Obstruction	At least one epicardial artery greater than 70% obstruction (Angiography).
2	Yes-Other Diagnostic Tests	History of myocardial infarction associated with wall motion abnormality as shown by echocardiography or other cardiac imaging. Stress testing diagnostic of coronary artery disease with or without imaging; ECG with evidence of MI; history of chest pain associated with cardiac enzyme abnormality.

Field Name: Previous MI **Seq No:** 3190

Definition: Indicate if the patient had a MI prior to the device implant.

The patient had at least one documented STEMI or NSTEMI. This can be coded based on physician documentation or history noted in the medical record.

Definitions: NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)

The patient was hospitalized for a myocardial infarction documented in the medical record.

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:
 a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.
2) CK-MB:
 a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event. OR
 b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.
3) Total CK:
 a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING:

1) Either ST segment depression or T wave abnormalities; or
2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include:
 a) unexplained nausea and vomiting; or
 b) persistent shortness of breath secondary to left ventricular failure; or
 c) unexplained weakness, dizziness, lightheadedness, or syncope.

ST ELEVATION MYOCARDIAL INFARCTION (STEMI)

Indicate whether the patient was hospitalized for an ST Elevation Myocardial Infarction (STEMI) documented in the medical record.

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:
 a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.
2) CK-MB:
 a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event; OR
 b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.
3) Total CK
 a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

Definition:

AND ONE OF THE FOLLOWING ECG CHANGES:

1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two or more continguous leads with the cut-off points >=0.2 mV in leads V1, V2, or V3, or >=0.1 mV in other leads; OR
2) Development of any Q wave in leads V1 through V3, or the development of a Q-wave > or = to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6. (Q wave changes must be present in any two continguous leads, and be > or = to 1mm in depth.)

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as < or = to 10%. Each individual laboratory should confirm the range of reference values in their specific setting.

Note: If more than one MI occurred, code the most recent event.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Within 40 Days of ICD Implant	
2	Yes-Greater than 40 Days prior to ICD Implant	
3	Yes-Both Within 40 days/Greater than 40 days	

Field Name: Previous CABG **Seq No:** 3200

Definition: Indicate if the patient had Coronary Bypass Graft Surgery by any approach.

Note: Patient history is defined as any time prior to the current admission. Timeframe does NOT include the current admission. CABGs performed during this admission should be coded within Sequence Number 3590: CABG During this Admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Previous CABG Date **Seq No:** 3210

Definition: Indicate the date of the most recent CABG. If month and/or day are not known enter 01.

Note: In the case of multiple CABGs prior to this admission, indicate the most recent.

Selections:

Field Name: Previous PCI **Seq No:** 3220

Definition: Indicate if the patient had a previous percutaneous coronary intervention (PCI) (even if unsuccessful) of any type (balloon angioplasty, stent or other), performed prior to the current admission.

Note: Timeframe does NOT include the current admission. PCIs performed during this admission should be coded within Sequence Number 3610: PCI During this Admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Within the past 3 months	
2	Yes-Greater than 3 months	

Field Name: Previous Valvular Surgery **Seq No:** 3230

Definition: Indicate if the patient had a previous surgical replacement and/or repair of a cardiac valve, by any approach.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Permanent Pacemaker **Seq No:** 3240

Definition: Indicate if the patient had a Pacemaker inserted prior to current ICD implant. If yes, indicate the type of pacemaker.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Atrial Chamber	
2	Yes-Ventricular Chamber	
3	Yes-Dual Chamber	Both atrial and ventricular chambers.
4	Yes-Biventricular	

Field Name: Previous ICD **Seq No:** 3250

Definition: Indicate if the patient had an ICD Implant procedure prior to this admission.

Note: Timeframe does NOT include the current admission. This device is coded within Sequence Number 3570: ICD Explant Device ID.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Single Chamber	
2	Yes-Dual Chamber	
3	Yes-Biventricular	

Field Name: Previous ICD Date **Seq No:** 3260

Definition: Indicate the date of the most recent previous ICD implant. If month and/or day are not known, enter 01.

Note: In the case of multiple implants prior to this admission, code the most recent.

Selections:

Field Name: Previous ICD Reason **Seq No:** 3280

Definition: Indicate the previous ICD indication (reason for ICD implant).

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Primary Prevention	Primary Prevention was the original indication for patients who were at risk for sudden death but had not suffered from a spontaneous life-threatening ventricular arrhythmia, syncope, or sudden cardiac death.
2	Syncope with Inducible VT	Syncope: Sudden loss of consciousness with loss of postural tone, not related to anesthesia. Inducible VT refers to performance of electrophysiological testing with resulting induction of VT.
3	Spontaneous Monomorphic Sustained VT	VT with a constant morphology greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
4	Spontaneous Polymorphic Sustained VT	VT with a constantly changing morphology lasting greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
5	Ventricular Fibrillation	Rapid, usually more than 300 bpm (cycle length 180 msec or less), grossly irregular ventricular rhythm with marked variability in cycle length, lack of discernible discreet QRS complex.
6	Cardiac Arrest/Arrhythmia - Etiology Unknown	Sudden loss of consciousness requiring cardioversion or defibrillation to restore hemodynamic stability.
7	Syncope and High Risk Characteristics	Syncope: Sudden loss of consciousness with loss of postural tone, not related to anesthesia, and High Risk Characteristics specific for non-ischemic dilated cardiomyopathy, or ischemic heart disease with significant ventricular dysfunction, hypertrophic cardiomyopathy, Brugada Syndrome, Long QT Syndrome.

Selections:

8	AFib	A cardiac arrythmia arising from the atrium with an atrial rate greater than 300 bpm and an irregular ventricular response in the presence of conduction. AF can be further characterized as: First detected AF Paroxysmal AF: AF is self-terminating within 7 days of recognized onset. Persistent AF: AF is not self-terminating within 7 days, or is terminated electrically or pharmacologically. Chronic AF: AF lasting more than 6 months.

Field Name: Previous ICD Implant Site **Seq No:** 3290

Definition: Indicate the previous ICD implant site.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Pectoral	
2	Abdominal	

Field Name: Cerebrovascular Disease **Seq No:** 3310

Definition: Indicate if the patient had cerebrovascular disease (CVD) prior to device implant, defined as any one of the following:
- Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 72 hours after onset.
- Reversible Ischemic Neurologic Deficit (RIND): Patient has a history of loss of neurological function with symptoms at least 24 hours after onset but with complete return of function within 72 hours.
- Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.
- Non-invasive/invasive carotid test with greater than 75% occlusion.
- Previous carotid artery surgery.This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.
Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Chronic Lung Disease **Seq No:** 3320

Definition: Indicate if the patient has a documented history of chronic lung disease prior to this admission (i.e. chronic obstructive pulmonary disease, emphysema, asthma, chronic bronchitis), or has been or is currently being treated with pharmocologic therapy.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Diabetes **Seq No:** 3330

Definition: Indicate if the patient has a history of diabetes, regardless of duration of disease or need for antidiabetic agents. It does not include gestational diabetes.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Hypertension **Seq No:** 3340

Definition: Indicate if the patient has a history of hypertension defined as any one of the following:
1. History of hypertension diagnosed and treated with medication, diet and/or exercise.
2. Blood pressure greater than 140 systolic or 90 diastolic on at least 2 occasions.
3. Currently on antihypertensive pharmacologic therapy.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Renal Failure-Dialysis **Seq No:** 3350

Definition: Indicate if the patient received or is receiving dialysis as a result of renal failure.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

E. Diagnostic Studies

Field Name: Ejection Fraction Assessed **Seq No:** 3360

Definition: Indicate if the patient's ejection fraction was assessed before or during the EP lab visit via invasive (i.e. LV gram) or non-invasive testing (i.e. Echo).

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: EF % **Seq No:** 3370

Definition: Indicate the lowest Ejection Fraction percent that led to the decision to implant the ICD. The Ejection Fraction percent is the percentage of blood that has emptied from the ventricle at the end of the contraction.

Selections:

Field Name: EF Timeframe **Seq No:** 3380

Definition: Indicate the timeframe of the Ejection Fraction percent that led to the decision to implant the ICD.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	0 to 1 month	0 to 1 month (up to 30 days)
2	1 to 2 months	1 to 2 months (31-60 days)
3	2 to 3 months	2 to 3 months (61-90 days)
4	3 to 6 months	3 to 6 months (91-180 days)
5	6 to 12 months	6 to 12 months (181-365 days)
6	Greater than 12 months	Greater than 12 months (366 days and greater)

Field Name: Electrophysiology Study Done **Seq No:** 3390

Definition: Indicate if the patient had an EP Study prior to the ICD implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: EPS Timeframe **Seq No:** 3400

Definition: Indicate the timeframe of the most recent Electrophysiology study.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	0 to 1 month	0 to 1 month (up to 30 days)
2	1 to 2 months	1 to 2 months (31-60 days)
3	2 to 3 months	2 to 3 months (61-90 days)
4	3 to 6 months	3 to 6 months (91-180 days)
5	6 to 12 months	6 to 12 months (181-365 days)
6	Greater than 12 months	Greater than 12 months (366 days and greater)

Field Name: EPS Findings **Seq No:** 3410

Definition: Indicate the findings associated with the most recent Electrophysiology Study. If "No Arrythmias Induced" is selected, no other selections may be chosen.

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
0	No Arrythmias Induced	
1	VT Induced	
2	Non-sustained VT	
3	Sustained Monomorphic	
4	Sustained Polymorphic	
5	Ventricular Flutter Induced	
6	Ventricular Fibrillation Induced	
7	Results Unattainable	The results of the EP Study could not be obtained or located.

Field Name: QRS Duration **Seq No:** 3420

Definition: Indicate the patient's QRS duration in milliseconds from simultaneous (preferably 3 or more) ECG leads, including I, II, and VI, from the onset to the termination of the QRS.

Note: Indicate the most recent EKG findings prior to the ICD implant.

Selections:

Field Name: PR Interval Attainable **Seq No:** 3429

Definition: Indicate if the patient's PR Interval was attainable. No should be answered when a patient has Afib, a greater than 1st Degree Heart block or has a Ventricular Paced rhythm.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: PR Interval **Seq No:** 3430

Definition: Indicate the patient's longest measured time in milliseconds from onset of P wave to onset of QRS complex in any given ECG lead.

Note: Indicate the most recent EKG findings prior to the ICD implant.

Selections:

Field Name: AV Conduction **Seq No:** 3440

Definition: Indicate the patient's Atrioventricular Conduction rhythm.

Note: Indicate the EKG findings leading to the decision to implant the ICD.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Normal	
2	Abnormal-1st Degree Heart Block Only	
3	Abnormal-Heart Block 2nd or 3rd Degree (not paced)	
4	Paced(any)	

Field Name: Intraventricular Conduction **Seq No:** 3450

Definition: Indicate the patient's Intraventricular Conduction.

Note: Indicate the EKG findings leading to the decision to implant the ICD.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Normal	
2	Abnormal-Left Anterior Fascicular Block	
3	Abnormal-Left Posterior Fascicular Block	
4	Abnormal-LBBB	
5	Abnormal-RBBB	
6	Abnormal-Intraventricular Conduction Delay, Nonspecific	
7	Paced	
8	Abnormal-Bifascicular Block (RBBB Plus LAF)	
9	Abnormal-Bifascicular Block (RBBB Plus LPF)	

Field Name: Creatinine Level **Seq No:** 3460

Definition: Indicate the patient's most recent preoperative Creatinine level prior to the ICD implant. The creatinine level is measured in mg/dL.

Selections:

Field Name: BUN Level **Seq No:** 3470

Definition: Indicate the patient's most recent preoperative BUN (Blood Urea Nitrogen) level prior to the ICD implant. The BUN level is measured in mg/dL.

Selections:

Field Name: Sodium Level **Seq No:** 3480

Definition: Indicate the patient's most recent preoperative Sodium level prior to the ICD implant. The Sodium level is measured in mEq/L.

Selections:

Field Name: BNP Drawn **Seq No:** 3485

Definition: Indicate if the patient had a preoperative BNP (B-type Natriuretic Peptide) drawn prior to the ICD implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: BNP Level **Seq No:** 3490

Definition: Indicate the patient's most recent preoperative BNP (B-type Natriuretic Peptide) prior to the ICD implant. The BNP is measured in pg/mL.

Selections:

Field Name: Systolic BP **Seq No:** 3500

Definition: Indicate the patient's systolic blood pressure on day of implant prior to sedation. Measured in mm-Hg.

Selections:

F. ICD Procedure(s)

Field Name: ICD Indication **Seq No:** 3505

Definition: Indicate the reason for the first ICD implantation in this patient's lifetime.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Primary Prevention	Primary prevention is an indication for patients who are at risk for sudden death but have not yet suffered from a spontaneous life-threatening ventricular arrhythmia, syncope, or sudden cardiac death. (This includes patients who have never experienced syncope or cardiac arrest but have inducible ventricular tachycardia during electrophysiologic testing for risk stratification.)
2	Secondary Prevention	Secondary prevention is an indication for patients who have already experienced a spontaneous life-threatening ventricular arrhythmia, a cardiac arrest, or unexplained syncope with workup suggesting a high probability that a ventricular tachyarrythmia was the cause of the syncope.

Field Name: Reason(s) for Re-implantation **Seq No:** 3506

Definition: Indicate the reason(s) why device was re-implanted.

Note: Applicable only if Sequence Number 3250: Previous ICD, is "Yes".

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	End of Battery Life	The manufacturer's designation that the pulse generator battery has reached the end of its service life.
2	Device Upgrage	Replacement of a pulse generator with a model with additional pacing capabilities such as an upgrade from a single to a dual chamber device, or the replacement of a non-CRT device with a CRT device.
3	Device Infection	Replacement of a device because of an infection involving a previously implanted device
4	Device Malfunction	Device performance outside manufacturer's designated specification that cannot be resolved with reprogramming, necessitating in the replacement of the device, in the physician’s opinion.
5	Device Under Manufacturer Advisory/Recalled	A device model recognized by the manufacturer as demonstrating a recurring performance failure resulting in an advisory letter to physicians. This may or may not reach the level of an FDA designated recall.

Field Name: Mult ICDs implanted during admit **Seq No:** 3507

Definition: Indicate if multiple ICD devices were implanted during the current admission.

Note: This field is meant to capture whether an ICD was implanted AND explanted during the current admission. Code "No" if the patient had only one implant during the current admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Reason for Device Repl during admit **Seq No:** 3508

Definition: Indicate the reason(s) for multiple implants during the current admission.

Note: Applicable only if Sequence Number 3507: Multiple ICDs implated during this admission, is "Yes".

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Device Upgrade	Replacement of a pulse generator with a model with additional pacing capabilities such as an upgrade from a single to a dual chamber device, or the replacement of a non-CRT device with a CRT device.
2	Device Infection	Replacement of a device because of an infection involving a previously implanted device
3	Device Malfunction	Device performance outside manufacturer's designated specification that cannot be resolved with reprogramming, necessitating in the replacement of the device, in the physician's opinion.
4	Device Under Manufacturer Advisory/Recalled	A device model recognized by the manufacturer as demonstrating a recurring performance failure resulting in an advisory letter to physicians. This may or may not reach the level of an FDA designated recall.

Field Name: Implant Operator UPIN **Seq No:** 3510

Definition: Indicate the implanting physician's (U)nique (P)hysician (I)dentification (N)umber. UPINs, assigned by CMS, are used to uniquely identify physicians for Medicare billing purposes and may contain any letter or number character combination. The UPIN should be specified for the physician implanting the device, not the physician placing the leads. Implanting physician is determined by the individual institution.

Selections:

Field Name: Implant Operator NPI **Seq No:** 3515

Definition: Indicate the physician's (N)ational (P)rovider (I)dentifier. NPIs, assigned by CMS, are used to uniquely identify physicians for Medicare billing purposes. The NPI should be specified for the physician implanting the device, not the physician placing the leads.

Selections:

Field Name: Implant Operator First Name **Seq No:** 3520

Definition: Indicate the implant operator's first name.

Selections:

Field Name: Implant Operator Middle Name **Seq No:** 3525

Definition: Indicate the implant operator's middle name or middle initial.

Selections:

Field Name: Implant Operator Last Name **Seq No:** 3530

Definition: Indicate the implant operator's last name.

Selections:

Field Name: ICD Type **Seq No:** 3540

Definition: Indicate the type of ICD implanted.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Single Chamber	
2	Dual Chamber	
3	Biventricular	

Field Name: LV Lead Implantation Method **Seq No:** 3550

Definition: Indicate the method for implanting the LV lead.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Coronary Sinus	
2	Epicardial Lead	
3	Other	

Field Name: ICD Manufacturer **Seq No:** 3560

Definition: Indicate the manufacturer of the implanted or explanted ICD.

Selections:

Field Name: ICD Model Name **Seq No:** 3561

Definition: Indicate the model name of the implanted or explanted ICD.

Selections:

Field Name: ICD Model Number **Seq No:** 3562

Definition: Indicate the model number of the implanted or explanted ICD.

Selections:

Field Name: ICD Implant Device ID **Seq No:** 3565

Definition: Indicate the unique ACC assigned identification number associated with the implanted device. The ACC will assign a unique identification number for each unique ICD device manufacturer, model and model number. The list of ICDs will be maintained by the ACC and added to the data entry tool as each new device receives FDA approval. Third party software vendors certified by the ACC will be required to download and import the ICD master list so that newly approved devices can be specified and submitted to the ACC. Only one ICD Implant Device can be specified.Note: In the event of multiple implantations, code the final/last device implanted during the current admission.

Selections:

Field Name: ICD Implant Serial Number **Seq No:** 3566

Definition: Indicate the ICD Device Serial Number associated with the implanted device.

Selections:

Field Name: ICD Explant Device ID **Seq No:** 3570

Definition: Indicate the unique ACC assigned identification number associated with the explanted device. The ACC will assign a unique identification number for each unique ICD device manufacturer, model and model number. The list of ICDs will be maintained by the ACC and added to the data entry tool as each new device receives FDA approval. Third party software vendors certified by the ACC will be required to download and import the ICD master list so that newly approved devices can be specified and submitted to the ACC. Only one ICD Explant Device can be specified.

Note(1): Applicable only if Sequence Number 3250: Previous ICD, is "Yes". The intent of this field is to record the device in the patient at the time of admission for the current hospital stay.
Note(2): This field is NOT to be used in the event of multiple implantations (Sequence Number 3507:Multiple ICDs implanted during this admission, is "Yes").

Selections:

Field Name: ICD Explant Serial Number **Seq No:** 3571

Definition: Indicate the ICD Device Serial Number associated with the explanted device.

Selections:

G. Adverse Events

Field Name: Available Adverse Events **Seq No:** 3575

Definition: Indicate the Adverse Events that were downloaded from the ACC website and imported into the ICD data collection tool. This element will be used to determine if the participant has the right adverse events in the ICD data collection tool for every admission.

Selections:

Field Name: Adverse Events Exist **Seq No:** 3580

Definition: Indicate if the patient had any adverse events during or after the EP lab visit up until discharge. If "Yes" then complete the Adverse Events section.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Adverse Event **Seq No:** 3581

Definition: Indicate the Adverse Event that occurred during or after the EP lab visit up until discharge. The same adverse event can be repeated with a different adverse event date.

Note: The initial set of Adverse Events that should be collected are documented in Appendix A of the data dictionary. These Adverse Events may be updated periodically by the ACC. When the Adverse Events have been updated, participants utilizing non-ACC software will be instructed to download and import the latest version of Adverse Event file into their data collection tool.

Selections:

Field Name: Adverse Event Date **Seq No:** 3583

Definition: Indicate the date that the Adverse Event occurred.

Selections:

H. Discharge

Field Name: CABG During This Admission **Seq No:** 3590

Definition: Indicate if the patient had a CABG (Coronary Artery Bypass Graft Surgery) during the current admission.

Note: If multple CABGs are performed during this admission, code the date of the CABG performed closest to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: CABG Date **Seq No:** 3600

Definition: Indicate the date Coronary Artery Bypass Graft (CABG) Surgery was performed during the current admission.

Selections:

Field Name: PCI During This Admission **Seq No:** 3610

Definition: Indicate if the patient had a PCI during this admission.

Note: If multiple PCIs are performed during this admission, code the date of the PCI performed closest to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: PCI Date **Seq No:** 3620

Definition: Indicate the date PCI was performed during the current admission.

Selections:

Field Name: Vital Status **Seq No:** 3630

Definition: Indicate if the patient expired during the hospital stay. If "Yes," indicate the cause of death.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Alive	
2	Deceased-Cardiac Death	
3	Deceased-Non-Cardiac Death	

Field Name: Date of Death This Admit **Seq No:** 3640

Definition: Indicate the date the patient expired during this hospitalization.

Selections:

Field Name: Death in Lab **Seq No:** 3645

Definition: Indicate if the patient's death occurred in the lab where the device was implanted

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Date of Discharge **Seq No:** 3650

Definition: Indicate the patient's date of discharge.

Selections:

I. Discharge Medications

Field Name: Discharge Medication **Seq No:** 3660

Definition: Indicates the discharge medication.

Note: The initial set of discharge medications that should be collected are documented in Appendix B of the data dictionary. These medications may be updated periodically by the ACC. When the discharge medications have been updated, participants utilizing non-ACC software will be instructed to download and import the latest version of medication file into their data collection tool.

Selections:

Field Name: Discharge Medication Prescribed **Seq No:** 3665

Definition: Indicate if discharge medication was prescribed, not prescribed, contraindicated or blinded.

Note: "Blinded" should be specified if the patient was in a research study and the prescribing of this specific medication is unknown.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	
2	Contraindicated	
3	Blinded	

Appendix A - Adverse Events

ICD Registry™

Implantable Cardioverter Defibrillators Registry v1.08

Adverse Events

Field Name: Cardiac Arrest **Adverse Event Seq No:** ae001

Adverse Event ID: 1

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a cardiac arrest as documented by sudden cessation of cardiac activity so that the patient became unresponsive, with no normal breathing and no signs of circulation.

Field Name: Drug Reaction **Adverse Event Seq No:** ae002

Adverse Event ID: 2

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a drug reaction as documented by anaphylaxis, rash, etc.

Field Name: Cardiac Perforation **Adverse Event Seq No:** ae003

Adverse Event ID: 3

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a cardiac perforation as documented by migration of pacing or defibrillator lead to epicardial surface, resulting in pain, pericardial effusion, failure to capture, capture of diaphragm, phrenic nerve, or intercostals muscle of sufficient magnitude to require repositioning.

Field Name: Cardiac Valve Injury **Adverse Event Seq No:** ae004

Adverse Event ID: 4

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a cardiac valve injury as documented by manipulation of pacing or defibrillating leads that may tear a valve leaflet or chordae rendinae (usually manifests as a new regurgitant mumur appearing after the procedure).

Field Name: Conduction Block **Adverse Event Seq No:** ae005

Adverse Event ID: 5

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a conduction block as documented by manipulation of pacing or defibrillating leads that may injure parts of the specialized cardiac conducting system. (Usually manifest as a new RBBB or new noset of complete heart block in a person with preexisting LBBB).

Field Name: Coronary Venous Dissection **Adverse Event Seq No:** ae006

Adverse Event ID: 6

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a coronary venous dissection as documented by manipulation of pacing or defibrillating leads in the coronary sinus (CS) may result in a tear of the CS endothelium, with dissection into the CS wall. This may occasionally result in perforation of the CS.

Field Name: Hematoma **Adverse Event Seq No:** ae007

Adverse Event ID: 7

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced hematoma resulting in reoperation or transfusion.

Field Name: Lead Dislodgement **Adverse Event Seq No:** ae008

Adverse Event ID: 8

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a lead dislodgement as documented by movement of lead sufficient to require repositioning.

Field Name: Hemothorax **Adverse Event Seq No:** ae009

Adverse Event ID: 9

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a hemothorax as documented by accumulation of blood in thorax.

Field Name: Pneumothorax **Adverse Event Seq No:** ae010

Adverse Event ID: 10

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a pneumothorax as documented by air in thorax sufficient to require chest tube.

Field Name: Peripheral Nerve Injury **Adverse Event Seq No:** ae011

Adverse Event ID: 11

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced peripheral nerve injury as documented by sensory or motor loss of peripheral nerve function. This may result from external nerve compression as a result of positioning during an implantationprocedure, internal compression (e.g. secondary to hematoma formation) or direct nerve.

Field Name: Peripheral Embolus **Adverse Event Seq No:** ae012

Adverse Event ID: 12

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a peripheral embolus as documented by acute occlusion of an artery resulting from embolization of a cardiac or proximal arterial thrombus.

Field Name: Phlebitis - Superficial **Adverse Event Seq No:** ae013

Adverse Event ID: 13

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced superficial phlebitis as documented by signs of superficial venous inflammatio, such as local erythema, tenderness or swelling.

Field Name: Phlebitis - Deep **Adverse Event Seq No:** ae014

Adverse Event ID: 14

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced deep phlebitis as documented by occlusion of deep vein resulting in extremity swelling, plus or minus signs of inflammation.

Field Name: TIA **Adverse Event Seq No:** ae015

Adverse Event ID: 15

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a TIA as documented by loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.

Field Name: CVA/Stroke **Adverse Event Seq No:** ae016

Adverse Event ID: 16

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced a cerebrovascular accident (CVA) as documented by a central neurological deficit persisting for > 72 hours.

Field Name: MI **Adverse Event Seq No:** ae017

Adverse Event ID: 17

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced an MI during the EP lab visit or after lab visit until discharge (or before any subsequent lab visits) as documented by:
Definitions: NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)
The patient was hospitalized for a myocardial infarction documented in the medical record.
AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):
1) Troponin T or I:
a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.
2) CK-MB:
a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event. OR
b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.
3) Total CK:
a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING:
1) Either ST segment depression or T wave abnormalities; or
2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include:
a) unexplained nausea and vomiting; or
b) persistent shortness of breath secondary to left ventricular failure; or
c) unexplained weakness, dizziness, lightheadedness, or syncope.

ST ELEVATION MYOCARDIAL INFARCTION (STEMI)
Indicate whether the patient was hospitalized for an ST Elevation Myocardial Infarction (STEMI) documented in the medical record.
AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):
1) Troponin T or I:
a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.
2) CK-MB:
a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event; OR
b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.
3) Total CK
a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING ECG CHANGES:
1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two or more continguous leads with the cut-off points >=0.2 mV in leads V1, V2, or V3, or >=0.1 mV in other leads; OR
2) Development of any Q wave in leads V1 through V3, or the development of a Q-wave > or = to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6. (Q wave changes must be present in any two continguous leads, and be > or = to 1mm in depth.)

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Definition: Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as < or = to 10%. Each individual laboratory should confirm the range of reference values in their specific setting.

Field Name: Pericardial Tamponade **Adverse Event Seq No:** ae018

Adverse Event ID: 18

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced fluid in the pericardial space compromising cardiac filling, and requiring intervention as documented by either: 1) Echo showing pericardial fluid and signs of tamponade such as right heart compromise, or 2) Systemic hypotension due to pericardial fluid compromising cardiac function.

Field Name: AV Fistula **Adverse Event Seq No:** ae019

Adverse Event ID: 19

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced an AV fistula as documented by a connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Field Name: Infection Related to Device **Adverse Event Seq No:** ae020

Adverse Event ID: 20

Effective Date: 01/01/2004 **Expiration Date:**

Definition: Indicate if the patient experienced an infection related to the device.

Appendix B - Medications

ICD Registry™

Implantable Cardioverter Defibrillators Registry v1.08

Medications

Field Name: ACE-Inhibitor (any) **Medication Seq No:** m001
Category: Ace Inhibitor **Medication ID:** 1
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Amiodarone **Medication Seq No:** m002
Category: Antiarrhythmic Agent **Medication ID:** 2
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Disopyramide **Medication Seq No:** m003
Category: Antiarrhythmic Agent **Medication ID:** 3
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Dofetilide **Medication Seq No:** m004
Category: Antiarrhythmic Agent **Medication ID:** 4
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Flecainide **Medication Seq No:** m005
Category: Antiarrhythmic Agent **Medication ID:** 5
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Mexiletine **Medication Seq No:** m006
Category: Antiarrhythmic Agent **Medication ID:** 6
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Procainamide **Medication Seq No:** m007
Category: Antiarrhythmic Agent **Medication ID:** 7
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Propafenone **Medication Seq No:** m008
Category: Antiarrhythmic Agent **Medication ID:** 8
Effective Date: 01/01/2004 **Expiration Date:**

Field Name: Quinidine **Medication Seq No:** m009
Category: Antiarrhythmic Agent **Medication ID:** 9
Effective Date: 01/01/2004 **Expiration Date:**

Field Name:	Sotalol	**Medication Seq No:**	m010
Category:	Antiarrhythmic Agent	**Medication ID:**	10
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Other Anti. Arrhy.	**Medication Seq No:**	m011
Category:	Antiarrhythmic Agent	**Medication ID:**	11
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Hydralazine	**Medication Seq No:**	m012
Category:	Antihypertensive	**Medication ID:**	12
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	ARB (any)	**Medication Seq No:**	m013
Category:	ARB	**Medication ID:**	13
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	ASA	**Medication Seq No:**	m014
Category:	ASA	**Medication ID:**	14
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Beta-Blocker (any)	**Medication Seq No:**	m015
Category:	Beta Blocker	**Medication ID:**	15
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Diltiazem	**Medication Seq No:**	m016
Category:	Calcium Channel Blocker	**Medication ID:**	16
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Verapamil	**Medication Seq No:**	m017
Category:	Calcium Channel Blocker	**Medication ID:**	17
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Other CCB	**Medication Seq No:**	m018
Category:	Calcium Channel Blocker	**Medication ID:**	18
Effective Date:	01/01/2004	**Expiration Date:**	

Field Name:	Coumadin	**Medication Seq No:**	m019
Category:	Coumadin	**Medication ID:**	19

Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Digoxin	**Medication Seq No:**	m020
Category:	Digoxin	**Medication ID:**	20
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Diuretic (any)	**Medication Seq No:**	m021
Category:	Diuretic	**Medication ID:**	21
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Nitroglycerin SL, PRN	**Medication Seq No:**	m022
Category:	Nitrate	**Medication ID:**	22
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Nitroglycerin Long Acting	**Medication Seq No:**	m023
Category:	Nitrate	**Medication ID:**	23
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Clopidogrel	**Medication Seq No:**	m024
Category:	Platelet Aggregation Inhibitor	**Medication ID:**	24
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Ticlopidine	**Medication Seq No:**	m025
Category:	Platelet Aggregation Inhibitor	**Medication ID:**	25
Effective Date:	01/01/2004	**Expiration Date:**	
Field Name:	Statin (any)	**Medication Seq No:**	m026
Category:	Statin	**Medication ID:**	26
Effective Date:	01/01/2004	**Expiration Date:**	

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Appendix C: Data Dictionary for HMORN VDW

HMORN VDW Data Elements

Demographics

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
Gender		Char 1	'M' = Male 'F' = Female 'O' = Other 'T' = Transsexual 'U' = Unknown
Race1 Race2 Race3	Up to 3 different races can be reported for an individual	Char 2	'01' = "White" '02' = "Black" '03' = "American Indian, Aleutian, or Eskimo" '04' = "Chinese" '05' = "Japanese" '06' = "Filipino" '07' = "Hawaiian" '08' = "Korean" '09' = "Asian Indian, Pakistani" '10' = "Vietnamese" '11' = "Laotian" '12' = " Hmong " '13' = "Kampuchean" '14' = "Thai" '20' = "Micronesian, NOS" '21' = " Chamorran " '22' = " Guamanian , NOS" '25' = "Polynesian, NOS" '26' = "Tahitian" '27' = "Samoan" '28' = "Tongan" '30' = "Melanesian, NOS" '31' = "Fiji Islander" '32' = "New Guinean" '88' = "No others known" (valid in Race2 – Race5 only) '96' = "Other Asian, incl. Asian, NOS and Oriental, NOS" '97' = "Pacific Islander, NOS" '98' = "Other" '99' = "Unknown"

Variable	Description	Type	Coding
Hispanic		Char 1	'Y' = Yes 'N' = No ' ' = Unknown

Diagnoses

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
Enctype	Indicates the type of health care visit which occurred	Char 2	IP = Acute inpatient hospital stay ED = Emergency department visit AV = Ambulatory visit (outpatient clinics, same day surgery) TE = Telephone visit. IS = Non-acute institutional stay OE = Other visit (not overnight) LO = Lab only visit RO = Radiology only visit.
Provider	Identifier unique to the provider most responsible for the visit	Char 12	Local Code
DiagProvider	Provider associated with the actual diagnosis	Char 12	Local Code
Adate	Visit or admission date from source system	Num 4	
Dx	ICD-9 diagnosis code. Contains decimal point and alpha prefix as appropriate.	Char 6	###.## V##.## E###.#
Origdx	Original diagnosis from source system	Char 10	
Pdx	Flag. Indicating the category of this diagnosis	Char 1	P = Principal S = Secondary X = Not available

Encounters

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
Adate	Visit or admission date from source system	Num 4	
Ddate	Discharge date for inpatient admission (blank for most outpatient visits)	Num 4	
Provider	Identifier unique to the provider indentifying provider most responsible for the visit.	Char 12	Local Code
Enc_count	Count of visits if multiple visits on date to same provider	Num 4	Integer value
Enctype	Indicates the type of visit	Char 2	IP = Acute inpatient hospital stay ED = Emergency department visit AV = Ambulatory visit (outpatient clinics, same day surgery) TE = Telephone visit. IS = Non-acute institutional stay OE = Other visit (not overnight) LO = Lab only visit RO = Radiology only visit.
Encounter_subtype	Subcategories within an ENCTYPE to indicate more detail for type of visit	Char 2	AI = Acute inpatient stay (EncType = IP). OB = Observation bed. (EncType = IP) OC = Outpatient clinic visit. (EncType = AV) SD = Same day surgery. (EncType = AV) UC = Urgent care. (EncType = AV) HA = Hospital ambulatory. (EncType = AV, ED).

Variable	Description	Type	Coding
			HS = Hospice. (EncType = IS, OE) HH = Home health. (EncType = OE, TE) SN = SNF. (EncType = IS, OE) NH = Nursing home, including ICF). (EncType = IS.) RH = Rehab. (EncType = IS, AV) DI = Dialysis. (EncType = IS, AV) OT = Other non-hospital. (EncType = IS, OE, TE, EM, AV, LO, RO)
Facility_code	Local code that identifies hospital or clinic. .	Char 12	Local code
Discharge_disposition	Only applies to Facility claim based data.	Char 1	A = Discharged alive E = Expired U = Unknown
Discharge_status	Identifies the location to which the patient is discharged from an inpatient visit	Char 2	AF = Adult foster home AL = Assisted living facility AM = Against medical advice AW = Absent without leave EX = Expired HH = Home health HS = Hospice HO = Home/self care IP = Other acute inpatient hospital NH = Nursing home, including ICF OT = Other RS = residential facility RH = Rehab facility SH = Still in hospital SN = SNF
Drg	(Optional.) Diagnostic Related Group. Use for hospital and overnight visits. (only populated when enctype='IP' and encounter_subtype='AI')	Char 3	
Admitting_source	Only populated when enctype='IP'	Char 2	AV = Ambulatory visit ED = Emergency department

Variable	Description	Type	Coding
			AF = Adult foster home AL = Assisted living facility HH = Home health HS = Hospice HO = Home/self care IP = Other acute inpatient hospital NH = Nursing home, including ICF OT = Other RS = Residential facility RH = Rehab facility SN = SNF UN = Unknown
Department	Department where visit occurred	Char 4	ACUP=Acupuncture ALGY=Allergy AMBU=Ambulance Services ANES=Anesthesiology AUD=Audiology CARD=Cardiology CASR=Cast Room CHEM=Chemical and Alcohol Dependency CHIR=Chiropractic CMHL=Community Health CRIT=Critical Care Medicine CRMG=Care Management DENT=Dental DERM=Dermatology DIAL=Dialysis DME=Durable Medical Equipment EDUC=Education ENDO=Endocrinology ENT=Otolaryngology ER=Emergency Room FP=Family Practice GEN=Genetics GER=Gerontology/Geriatrics GI=Gastro-Intestinal Medicine HAP=Health Appraisals HEP=Hepatology HH=Home Health HOSP=Hospital Care HSPC=Hospice

Variable	Description	Type	Coding
			ICF=Intermediate Care Facility IM=Internal Medicine IMUN=Immunology IND=Industrial Medicine INF=Infectious Disease INFU=Infusion Center IR=Injection Room LAB=Laboratory MH=Mental Health NATU=Naturopathy NEUR=Neurology NEWB=Newborn NRSG=Neurosurgery NUCL=Nuclear Medicine NUT=Nutrition OBGN=Obstetrics/Gynecology OCTH=Occupational Therapy ONC=Oncology OPTH=Opthalmology OPTO=Optometry ORTH=Orthopedics OST=Osteopathy PAL=Palliative Care PATH=Pathology PC=Primary Care PEDS=Pediatrics PERI=Perinatology PHYS=Physiatry POD=Podiatry PSRG=Plastic Surgery PT=Physical Therapy PULM=Pulmonary Medicine RAD=Radiology RADT=Radiation Therapy RECT=Recreational Therapy REHB=Rehabilitation RESP=Respiratory Therapy RHEU=Rheumatology RN=Registered Nurse SNF=Skilled Nursing Facility SPOR=Sports Medicine SPTH=Speech Therapy SURG=General Surgery TRAN=Transplant URG=Urgent Care

Variable	Description	Type	Coding
			URO=Urology OTH=Other UNK=Unknown IND=Industrial Medicine INF=Infectious Disease

Enrollment

Variable Name	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
enr_start	Beginning date of enrollment period	Num 4	
enr_end	End of enrollment period	Num 4	
Ins_Medicaid	Flag for Medicaid coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Commercial	Flag for Commercial coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_PrivatePay	Flag for Private Pay coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_StateSubsidized	Flag for state subsidized coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_SelfFunded	Flag for coverage through an Employer group that insures itself.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_HighDeductible	Flag for coverage in a high-deductible plan.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Medicare	Flag for Medicare coverage, including Medicare Working Aged	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Medicare_A	Flag for Medicare Part A coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Medicare_B	Flag for Medicare Part B coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Medicare_C	Flag indicating the person	Char 1	"Y"=Yes

	had Medicare Part C coverage during the period.		"N" = No "U" or missing = Unknown
Ins_Medicare_D	Flag for Medicare Part D coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Ins_Other	Flag for Other type of coverage during the period.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
plan_hmo	Flag for some coverage under an HMO plan	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
plan_pos	Flag for some coverage under a point-of-service plan	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
plan_ppo	Flag for some coverage under a preferred provider organization plan	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
plan_indemnity	Flag for some coverage under a traditional indemnity plan.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
Drugcov	Flag for at least some payment/coverage for prescription drugs.	Char 1	"Y"=Yes "N" = No "U" or missing = Unknown
outside_utilization	Is this person/period likely to have substantial health care utilization outside the HMO system, under circumstances that would not result in a claim to the health plan	Char 1	Y = Yes, we expect the utilization capture for this person/period is incomplete. N = No, there is no reason to suspect we have incomplete capture of utilization. U = completeness of capture is unknown.
Enrollment_basis	The basis for capture of the medical record in the VDW.	Char 1	G = Geographic Basis I = Insurance Basis B = Both bases
Pcc	The clinic to which the patient is paneled in administrative record. Uses same code list as Facility_Code in Encounter table.	Char 12	Local Code
Pcp	The clinician to which the patient is paneled in administrative data. Uses same code list as Provider in Encounter table	Char 12	Local Code

Procedures

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
Adate	Visit or admission date from source system	Num 4	
Provider	Identifier unique to the provider indentifying provider most responsible for the visit.	Char 12	Local Code
Enctype	Indicates the type of visit.	Char 2	IP = Acute inpatient hospital stay ED = Emergency department visit AV = Ambulatory visit (outpatient clinics, same day surgery) TE = Telephone visit. IS = Non-acute institutional stay OE = Other visit (not overnight) LO = Lab only visit RO = Radiology only visit.
Performing Provider	Provider associated with the actual procedure.	Char 12	
pxdate	Date the procedure was performed, or ADATE (admission date) for the visit in which the procedure occurred	Num 4	
Px	Specific code which details the procedure performed	Char 6	
Origpx	Actual value from source data.	Char 10	
Codetype	Flag to indicate type of procedure code.	Char 1	I = ICD-9 C = CPT-4 H = HCPCS R = Revenue code L = Local homegrown O = Other
Pxcnt	Number of times the procedure was performed during the visit.	Num 4	

Labs

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	Studyid
Test_Type	Name of the test	Char 10	SODIUM = Sodium K = Potassium Serum BUN = CREATININE = Creatinine Blood/Serum/Plasma HGB = Hemoglobin in Blood HCT = Hematocrit in Blood INR = prothrombin International Normalized Ratio GLU_RAN = Blood Sugar Random GLU_F = Blood Sugar Fasting
Loinc	Logical Observation Identifiers Names and Codes	Char 10	Codes in the form of nnnnn-n
Local_cd	Non LOINC code related to lab test result	Char 25	Unique to each health plan
Battery_cd	Battery code	Char 50	Unique to each health plan
px	Related procedure code (most likely CPT)	Char 6	
Codetype	Specifies what type of code PX used	Char 1	C=CPT, I=ICD9, H=HCPCS, L=local home-grown, O=other
Order_dt	Date test was ordered	Num 4	
Lab_dt	Date specimen was collected	Num 4	
Lab_tm	Time specimen was collected	Num 4	
Result_dt	Date of test result	Num 4	
Result_tm	Time of test result	Num 4	
Result_C	Test result as short character	Char 8	
Modifier	Optional qualifier for RESULT_C value	Char 2	‘TX’=text ‘EQ’=equal ‘LT’=less than ‘LE’=less than or equal to ‘GT’=greater than ‘GE’=greater than or equal to
Result_unit	Units in which result is reported. Future recoding will probably be necessary to standardize among sites.	Char 11	possible values include %, IU/L, MEQ/L, MG/DL, THERAPEUTIC as well as others

Variable	Description	Type	Coding
Normal_low_C	Lowest value of normal range for this test/instrumentation/etc as short character.	Char 8	
Modifier_low	Optional qualifier for NORMAL_LOW_C value	Char 2	‘TX’=text ‘EQ’=equal ‘LT’=less than ‘LE’=less than or equal to ‘GT’=greater than ‘GE’=greater than or equal to
Normal_high_C	Highest value of normal range for this test/instrumentation/etc as short character.	Char 8	
Modifier_high	Optional qualifier for NORMAL_HIGH_C value	Char 2	‘TX’=text ‘EQ’=equal ‘LT’=less than ‘LE’=less than or equal to ‘GT’=greater than ‘GE’=greater than or equal to
Abn_ind	Abnormal result indicator	Char 1	‘AB’=abnormal 'C' =critical ‘AH’=abnormal high ‘CH’=critical high ‘AL’=abnormal low ‘CL’=critical low ‘IN’=Inconclusive ‘UK’=unknown ‘NL’=normal
Order_prov	Ordering provider	Char 6	Same coding scheme as rxmd in PHARMACY table or provider in ENCOUNTERS table.
Order_dept	Department of ordering provider	Char 4	Same coding scheme as department in ENCOUNTERS table.
Facility_code	Code indicating location, such as specific hospital or clinic, where order originated	Char 12	Same coding scheme as facility_code in ENCOUNTERS table.

Pharmacy

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
rxdate	sold date.	Num 4	

Variable	Description	Type	Coding
Ndc	National Drug Code	Char 11	
Rxsup	Number of days supply	Num 4	
Rxamt	Number of units (pills, tablets) dispensed. Net amount per day per NDC.	Num 4	
Rxmd	Prescribing MD Uses same coding scheme as PROVIDER in Utilization table	Char 9	

Vitals

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
Enctype	Visit Type	Char 2	IP = Acute inpatient hospital stay ED = Emergency department visit AV = Ambulatory visit (outpatient clinics, same day surgery) TE = Telephone visit. IS = Non-acute institutional stay OE = Other visit (not overnight) LO = Lab only visit RO = Radiology only visit.
Measure_Date	Date the vital signs were measured.	Num 4	
Tobacco	Tobacco Status	Num 3	1 = current user 2 = never 3 = quit/former user 4 = passive 5 = environmental exposure 6 = not asked 7 = conflicting
Tobacco_Type	Tobacco other than cigarettes used	Num 3	1 = Cigarettes only 2 = Other tobacco only 3 = Cigarettes and other tobacco 4 = None
HT	Height (inches)	Num 8	####.## = If can be represented in inches Null = HT is missing
WT	Weight (lbs)	Num 8	####.## = If can be represented in pounds Null = WT is missing
Diastolic	Diastolic blood pressure	Num 4	### = If can be represented in MmHg Null = Diastolic is missing

Variable	Description	Type	Coding
Systolic	Systolic blood pressure	Num 4	### = If can be represented in MmHg Null = Systolic is missing
BP_Type	Optional. Type of blood pressure taken	Char 1	R=Rooming O=Orthostatic M=Multiple E=Extended
Position	Optional. Position for Orthostatic Blood Pressures	Char 1	Blank/Null = unknown 1 = sitting 2 = standing 3 = supine

Death

Variable	Description	Type	Coding
Studyid	Person-level identifier created at each study site for the purpose of this study.	Num 4	
DeathDt	Date of death	Num 4	
DtImpute	Identify part of DeathDt imputed	Char 1	M = Month of date imputed D = Day of date imputed B = Both month and day imputed N = Not imputed
UnderCOD	Underlying cause of death is defined by the World Health Organization as the disease or injury that initiated the train of events leading directly to death, or the circumstances of the accident or violence, which produced the fatal injury.	Char 6	(ICD code)
Codetype	Describes the coding type for UnderCOD	Char 1	A = ICD-10 B = ICD-9 Missing when cause of death is unknown
Source	Means by which death data obtained	Char 1	S = State Death files N = National Death Index T = Tumor data M= Common Membership C=Clarity/HC (Others are locally defined)

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Appendix D: Data Dictionary for ICD Therapy Data Repository

Ascertainment

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
AbstractorID	Identity of individual doing the chart abstraction	Char 5	
A3_Abstraction_date	Date of abstraction	Date	
Batch_num	Number of Batch record was selected	Num 1	
A4a_FirstImplant_YN	Identifier for whether listed implant is subject's first implant	Num 1	1=Yes 2=No
A4b_Prev_Implant_Dt	Date of previous implant	Date	
A4b_does_Q5_exist	Does question #5 exist on form (used to identify form version)	Num 1	1=Yes 2=No
A5_deathdt_yr	Year of subject death	Num 2	
A5_deathdt_mo	Month of subject death	Num 2	
A5_deathdt_day	Day of subject death	Num 2	
C1_Followed_thru_end_YN	Was patient followed through end of study period	Num 1	1=Yes 2=No
C1A_Reason_ifN	If Patient was not followed through end date, why not?	Num 1	1=Death before end 2=Device turned off 3=Transferred Care 4=Other 5=10 Episodes
C1A_DOD	Date of death (if C1A_Reason_ifN = 1)	Date	
C1A_Turnoff	Date device was turned off (if C1A_Reason_ifN = 2)	Date	
C1A_Transfer	Date care was transferred (if C1A_Reason_ifN = 3)	Date	
C1A_Other	What occurred to end participant followup (if C1A_Reason_ifN = 4)	Char 255	
C1_Other_Date	Date "other" occurred (if C1A_Reason_ifN = 4)	Date	
C1A_10episodes	Date of last qualifying episode (if C1A_Reason_ifN = 5)	Date	
C2_Attached_surg_note_YN	Is surgical note attached?	Num 1	1=Yes 2=No
C2b_attached_reason_ifN	If no surgical note, why not?	Char 255	
C2_Attached_docA	Is interrogation report attached?	Num 1	1=Yes 2=No
C2_Int_rpt_dt	If interrogation report is present, what date?	Date	
C2_Int_rsn_ifN	If no interrogation report, why not?	Char 255	
C2_Attached_docB	Is clinical note attached?	Num 1	1=Yes 2=No
C2_Clin_note_dt	If clinical note is present, what date?	Date	
C2_reason_ifN	If no clinical note, why not?	Char 255	
Received	Timestamp set by row creation	DateTime	
Modified	Timestamp set by row update	DateTime	
Ascertainment_Comment	Comments left on ascertainment form	Char 255	

Main Table Interrogation

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
ImplantDt	Date of first implant	Date	
B3_EndDt	End date (based on abstracted end point)	Date	
B11_gappresent_YN	Was gap present in followup of > 6 months?	Num 1	1=Yes 2=No
B11_Gap_Comment	Comment regarding gap presence	Char 255	
B11_Main_Comments	Comments regarding interrogation followup in general	Char 255	
B11_diverted_episodes	How many diverted episodes are present in the interrogation data?	Num 2	
Total_TE	Total Treated Episodes	Num 2	

***Sub Table**

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
B4_Interrogation_Date	Date of interrogation	Date	
B5_Check_Type	Type of interrogation/check	Char 1	C=Clinic R=Remote H=Hospital O=Other
B6_Therapy_YN	Are therapies present during this interrogation?	Num 1	1=Yes 2=No
B8_Rpt_Available_YN	Is device Interrogation report available?	Num 1	1=Yes 2=No
B9_Device_Totals_YN	Are cumulative device totals available in report?	Num 1	1=Yes 2=No
B9b_Remote_dataYN	Is remote data available?	Num 1	1=Yes 2=No
B10_Clin_Notes_Avail_YN	Are clinical notes available?	Num 1	1=Yes 2=No
B11_Sub_Comments	Comments regarding this interrogation	Char 255	

**Sub table exists in a one-to-many relationship to the main table*

Episodes Requiring Therapy

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
B4_Interrogation_Date	Date of interrogation	Date	
B7_Dates_of_Episodes	Date of episode	Date	

Event Cover

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
Treated_Episode_Num	Which treated episode does this form refer to	Num 2	1-10
AbstractorID	Identity of individual doing the chart abstraction	Char 5	
2_three_or_more_episodes	Did 3 or more episodes occur in 24h?	Num 1	1=Yes 2=No
3_Interrogation_Date	Date of interrogation	Date	
4_Therapy_Date	Date of therapy	Date	
5_Therapy_time_H	Hour at which therapy occurred	Char 2	
5_Therapy_time_M	Minute at which therapy occurred	Char 2	
5_Therapy_time_S	Second at which therapy occurred	Char 2	
5_Time_type	Detail on how to interpret time (if available - AM/PM/Military)	Char 8	AM PM Military
6a_Rpt_attached	Device interrogation report attached?	Num 1	1=Yes 2=No
6a_Comment	Comment regarding interrogation report	Char 255	
6b_ECG_attached	Electrocardiogram attached?	Num 1	1=Yes 2=No
6b_Comment	Comment regarding electrocardiogram	Char 255	
6c_Clin_Note_attached	Clinical note attached?	Num 1	1=Yes 2=No
6c_Comment	Comment regarding clinical note	Char 255	
7_Episode_Comment	Overall episode comment	Char 255	

Main Table Central Review

Field Name	Description	Type	Coding
SID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
Reviewer_ID	Identity of central reviewer	Char 4	
Treated_Episodes	Are treated episodes present during the followup period?	Num 1	1=Yes 2=No

***Sub Table**

Field Name	Description	Type	Coding
Interrogation_Date	Interrogation Date	Date	
Treated_Episode	Treated episode number	Num 2	1-10
Episode_Date	Treated episode date	Date	
Unknown_Date	Is treated episode date unknown?	Num 1	1=Yes 2=No
Episode_Time_H	Hour at which treated episode occurred	Num 2	
Episode_Time_M	Minute at which treated episode occurred	Num 2	
Episode_Time_S	Second at which treated episode occurred	Num 2	
Unknown_time	Is time of treated episode uncertain?	Num 1	1=Yes 2=No
Time_type	Detail on how to interpret time (if available - AM/PM/Military)	Char 8	AM PM Military
Therapy_Type	Type of treatment applied	Num 1	1=ATP 2=Shock 3=Not an Episode 4=Unknown
Shock_count	Did episode include shocks?	Num 1	1=Yes, one shock 2=No 3=Yes, Multiple 4=Yes, Unsure of Count
Additional_shocks	If initial therapy was shock, did episode include additional shocks?	Num 1	1=Yes 2=No
Local_prov	Local provider's impression of treatment appropriateness	Char 1	A=Appropriate I=Inappropriate
Appropriate	Reviewers impression of approariteness of treatment	Num 1	1=Definitely Appropriate 2=Probably Appropriate 3=Uncertain 4=Probably Inappropriate 5=Definitely Inappropriate
Successful	If appropriate, was treatment successful?	Num 1	1=Yes 2=No
Cause	If inappropriate, what was cause?	Num 1	1=SVT/AF 2=Sensing 3=Other
Untoward_Rhythm	If inappropriate, did therapy cause untoward rhythm?	Num 1	1=Yes 2=No
Sufficient_Doc	Was documentation sufficient to make a determination of appropriateness?	Num 1	1=Yes by E-gram 2=No 3=Yes, by other clin. features 4=Yes, by local interp.
Notes	Comments on this treated episode	Char 255	

**Sub table exists in a one-to-many relationship to the main table*

Central Review Resolution

Field Name	Description	Type	Coding
SID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
Reviewer_ID	Identity of central reviewer	Char 4	
Interrogation_Date	Interrogation Date	Date	
Treated_Episode	Treated episode number	Num 2	1-10
Episode_time	Time of the episode	Time	
Time_type	Detail on how to interpret time (if available - AM/PM/Military)	Char 8	AM PM Military
Therapy_type	Type of treatment applied	Num 1	1=ATP 2=Shock 3=Not an Episode 4=Uncertain 5=Unresolved
Shock_count	Did episode include shocks?	Num 1	1=Yes, one shock 2=No 3=Yes, Multiple 4=Yes, Unsure of Count
Additional_shocks	If initial therapy was shock, did episode include additional shocks?	Num 1	1=Yes 2=No 3=Unresolved
Local_prov	Local provider's impression of treatment appropriateness	Num 1	1=Appropriate 2=Uncertain 3=Inappropriate 4=Unresolved
Appropriate	Reviewers impression of approariteness of treatment	Num 1	1=Definitely Appropriate 2=Probably Appropriate 3=Uncertain 4=Probably Inappropriate 5=Definitely Inappropriate 6=Unresolved
Successful	If appropriate, was treatment successful?	Num 1	1=Yes 2=No 3=Missing 4=Unresolved
Cause	If inappropriate, what was cause?	Num 1	1=SVT/AF 2=Sensing 3=Other 4=Unresolved
Untoward_Rhythm	If inappropriate, did therapy cause untoward rhythm?	Num 1	1=Yes 2=No 3=Unresolved
Sufficient_Doc	Was documentation sufficient to make a determination of appropriateness?	Num 1	1=Yes by E-gram 2=No 3=Yes, by other clin. features 4=Yes, by local interp. 5=Unresolved
Ext_rev	This therapy raised enough questions that the reviewers choose it for automatic external review	Num 1	1=Yes 2=No
Notes	Comments on this treated episode	Char 255	

Main Table External Review

Field Name	Description	Type	Coding
SID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
Reviewer_ID	Identity of central reviewer	Char 4	
Treated_Episode	Treated episode number	Num 2	1-10

*Sub Table

Field Name	Description	Type	Coding
Episode_Time_H	Hour at which treated episode occurred	Num 2	
Episode_Time_M	Minute at which treated episode occurred	Num 2	
Time	Time of treated episode (if known)	Time	
Initial_Therapy_type	Type of treatment applied initially	Num 1	1=ATP 2=Shock 3=Uncertain 4=Not an Episode
Shock_count	Did episode include shocks?	Num 1	1=Yes, one shock 2=No 3=Yes, Multiple 4=Yes, Unsure of Count
Additional_shocks	If initial therapy was shock, did episode include additional shocks?	Num 1	1=Yes 2=No
Local_prov	Local provider's impression of treatment appropriateness	Char 1	A=Appropriate I=Inappropriate
Appropriate	Reviewers impression of approariteness of treatment	Num 1	1=Definitely Appropriate 2=Probably Appropriate 3=Uncertain 4=Probably Inappropriate 5=Definitely Inappropriate
Successful	If appropriate, was treatment successful?	Num 1	1=Yes 2=No
Cause	If inappropriate, what was cause?	Num 1	1=SVT/AF 2=Sensing 3=Other
Untoward_Rhythm	If inappropriate, did therapy cause untoward rhythm?	Num 1	1=Yes 2=No
Sufficient_Doc	Was documentation sufficient to make a determination of appropriateness?	Num 1	1=Yes by E-gram 2=No 3=Yes, by other clin. features 4=Yes, by local interp.
Comments	General notes regarding this therapy	Char 255	

**Sub table exists in a one-to-many relationship to the main table*

External Review Resolution

Field Name	Description	Type	Coding
SID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
Reviewer_ID	Identity of central reviewer	Char 4	
Treated_Episode	Treated episode number	Num 2	1-10
Episode_time	Treated episode time	time	
Episode_time	Time of the episode	Time	
Time_type	Detail on how to interpret time (if available - AM/PM/Military)	Char 8	AM PM Military
Therapy_type	Type of treatment applied	Num 1	1=ATP 2=Shock 3=Not an Episode 4=Uncertain 5=Unresolved
Shock_count	Did episode include shocks?	Num 1	1=Yes, one shock 2=No 3=Yes, Multiple 4=Yes, Unsure of Count 5=Unresolved
Additional_shocks	If initial therapy was shock, did episode include additional shocks?	Num 1	1=Yes 2=No 3=Unresolved
Local_prov	Local provider's impression of treatment appropriateness	Num 1	1=Appropriate 2=Uncertain 3=Inappropriate 4=Unresolved
Appropriate	Reviewers impression of approariteness of treatment	Num 1	1=Definitely Appropriate 2=Probably Appropriate 3=Uncertain 4=Probably Inappropriate 5=Definitely Inappropriate 6=Unresolved
Successful	If appropriate, was treatment successful?	Num 1	1=Yes 2=No 3=Missing 4=Unresolved
Cause	If inappropriate, what was cause?	Num 1	1=SVT/AF 2=Sensing 3=Other 4=Unresolved
Untoward_Rhythm	If inappropriate, did therapy cause untoward rhythm?	Num 1	1=Yes 2=No 3=Unresolved
Sufficient_Doc	Was documentation sufficient to make a determination of appropriateness?	Num 1	1=Yes by E-gram 2=No 3=Yes, by other clin. features 4=Yes, by local interp. 5=Unresolved
Notes	Comments on this treated episode	Char 255	

Additional Implants

Field Name	Description	Type	Coding
StudyID	Subject-level Identifier, created at each site for the purpose of this study only	Num 8	
implantdate	Implant date for new implant or updated previous implant	Date	
enddate	New or updated end date	Date	
implantnum	Implant number (may either be new/additional or overwrite a previous implant)	1-X	
manuf	ICD device manufactururer	Char 50	
model	ICD device model	Char 50	
modnum	ICD device model number	Char 50	
icdtype	ICD device type	Num 1	1=Single Chamber 2=Dual Chamber 3=Biventricular

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Appendix E: Therapy Abstraction Documents

-Guidelines

-Forms and Instructions

-Shipping transmittal log

-Intake quality checklist

-Request for additional data form

ICD Longitudinal Study - Therapy Collection

Guidelines for Therapy Collection

GUIDELINES

The goals of the therapy collection process at the study sites, and the role of the site abstractors, are:

1. Account for ICD interrogations covering the participant's follow-up period (from Date of Implant to End Date).
2. Identify the presence of any treated arrhythmic episodes during the participant's follow-up period.
3. Collect pertinent documentation to assist central reviewers and external adjudicators in determining the type, appropriateness, and outcome of the identified therapies.

Ascertaining Device Interrogations

To ascertain a participant's complete set of device interrogations during their follow-up period, review of a wide range of data sources may be necessary. While there will be site-to-site variation, scheduled interrogations typically occur with some regularity, with a first interrogation shortly after implant and then follow-up visits perhaps every 3 months. Additional, unscheduled interrogations may occur following arrhythmic episodes resulting in ICD therapies.

Data archival may differ for each location conducting follow-up interrogations in your health system. Sources to consider for documenting all interrogations include:

- ICD clinic appointment schedules
- ICD clinic patient flow sheets
- ICD clinic interrogation files
    - archived paper reports
    - copies of electronic reports
    - device programmer interrogations archived on disks or flash drives
- ICD device manufacturer proprietary websites (for remote checks)
- Paceart reports or reports from comparable arrhythmia clinical management systems
- Operative reports
- History & physical reports
- Emergency room notes
- Hospital progress notes
- Cardiology consult notes
- Discharge/Expiration summaries
- Electronic Medical Record/Clinical notes, including encounter summaries, particularly for clinic visits following ER, inpatient, or out-of-system visits, or following unexpected gaps in interrogations

In addition, CPT procedure records with codes for ICD interrogation make a good starting point and likely identify a large proportion of a participant's known interrogations. Site data managers will be providing abstractors with a prefilled Participant Data Form containing, among other things, a list of dates corresponding to CPT codes associated with ICD checks (interrogations) occurring within or shortly after a participant's follow-up period. These dates provide clues to

the abstractor for when interrogation data is likely to be found. However CPT codes may miss some interrogations and therapies and so cannot be relied upon to exhaustively represent a complete list of interrogations.

CPT codes may do a particularly poor job of capturing interrogations occurring in inpatient settings, because of differences in billing. The Participant Data Form supplied by Site Data Managers will also include dates of inpatient hospitalization stays and emergency department visits occurring within or shortly after a participant's follow-up period. An approach to take following ER visit/hospitalizations is to pay particular attention to the next clinic visit to the participant's regular device follow-up provider, and examine whether any information was recorded that suggests the participant was interrogated or experienced a treated arrhythmic episode since that previous visit. Direct review of hospital/ER reports and notes may be necessary to determine if interrogations occurred and if any device therapies were present. For hospitalizations occurring after the last known interrogation, hospital records may be the only source of information about the potential occurrence of additional interrogations and presence of any ICD therapies.

Similarly, some patients may have a device interrogation, and may have experienced a treated arrhythmic episode, while away from the local area and/or through a provider outside of your health system. If there are clues to suggest that this has occurred, follow the approach described above for hospitalizations (although direct access to out of system records may not be possible).

In some instances, patients will receive follow-up testing done post-operatively that induces an arrhythmia for the purpose of testing ICD function. This type of testing will advance the counters and should be noted as such.

Another challenging situation you may come across is when a device is temporarily turned off during a surgery or another procedure and then turned on again after. Such an occurrence may cause the next interrogation report to only cover the period since the device was turned back on. Additional searching would be necessary to identify whether an interrogation report was obtained and archived for the period leading up to the surgery/procedure, and whether any treated episodes during that time had been noted.

When reviewing interrogation reports, it is important to be aware of **date ranges** provided on reports to ensure that the entire period of collection is accounted for. This will be helpful to suggest an interrogation may be missing if there is a gap in the coverage periods. You will be asked to identify any gaps in coverage, and to explain any periods of six months or greater between interrogations, such as if the participant was out of the service area and relevant documentation or comments from clinical notes are available. This may also help when considering the potential relevance of hospital/ER visits that may have occurred since the previous known interrogation. The date ranges will also be especially important when comparing clinic checks to remote (telephonic) checks as there may be duplication of information between the remote and clinic check device programmer reports. There may also be some historical data available on a remote check.

ICD Longitudinal Study - Therapy Collection

Guidelines for Therapy Collection

Identifying the Presence of ICD Treated Arrhythmic Episodes

The device interrogation reports, especially when they include the electrograms and treated episode descriptions, are the definitive source for central reviewers. These reports provide very thorough detail of episodes that will assist the Central Review and Adjudication Panel in identifying appropriateness of therapy. The electronic medical record and arrhythmia clinical management systems, such as Medtronic's Paceart, may be additional sources to assist in identifying the presence of ICD treated episodes. Pacemaker/ICD clinics may also have their own flow sheets which could be an excellent resource when looking for therapy data.

A treated episode is when ATP (antitachycardia pacing) and/or shock are delivered in response to what the device senses to be an arrhythmia. A single treated episode may contain multiple ATPs and/or shocks. The presence of a treated episode can be found in several places on an interrogation report. Treated episodes are listed in a device "log" with dates and times. This log is an excellent source for determining the presence of treated episodes when available. Device specific report examples are provided in this document. (See Below).

For each subject, we will be collecting a maximum of 10 treated arrhythmic episodes. Also, if more than three treated episodes occurred within a 24 hour time period, we will not collect or count any episodes which occurred after the third episode within that 24 hour period. In such a situation, we will continue collection again (and counting toward the maximum of 10) with the next treated episode that occurs after that 24 hour period.

Collecting Documentation

Requested documentation for **every participant** to support the central review of therapy collection will include the *implant surgery note* and the *last archived interrogation report and clinical note covering the follow-up period through the study end date or through the 10th treated episode.* These documents will also be valuable tools for the abstractor when completing the ICD Therapy Ascertainment Form and Interrogation Table. A key element within the surgery note is the presence and number of any test therapies, although the entire surgery note is requested. A key element within the last archived interrogation report is the cumulative device totals or device summary table, although the entire archived report is requested. Device totals, when available, support verification of therapy ascertainment. Device totals within interrogation reports can also help guide you when looking for therapies, but keep in mind, they may not be 100% complete or accurate. For example, therapy counters can be totally cleared due to power resets and follow-up testing shortly after implant will advance counters. Investigation through all interrogation dates needs to be performed.

For any **treated arrhythmic episodes**, requested documentation to support central review and adjudication includes:

- The *full interrogation report as archived or alternatively select and send the report components listed under Device Specific Report Examples below. Include the electrograms of the episode.*
- The *archived clinical note or other medical record source* containing the episode interpretation by the physician and/or nurse or other clinician.

Guidelines for Therapy Collection

EXAMPLES - Appendix A

Surgical Implant Note and Clinical Notes Examples
Included in Appendix A are examples of a surgical implant note and clinical notes (one with therapies and one without therapies) from archived data.

Paceart (Arrhythmia & Device Clinical Management System)
The Medtronic Paceart system, if used in your clinics, can provide several different relevant reports. Licensing agreements may be needed for individuals to access this software, but reports from this system may also be available in the medical record. The **Patient (Comprehensive) Event Summary** provides a list of ICD clinic appointments with dates and comments and may be a resource for identifying therapies. The **Generic ICD Report (episodes)** provides details of a specific check with settings and a listing of episodes with dates, type of episode, treatment and success of treatment. Examples of these two reports are included in Appendix A for your information. Interrogation reports of these episodes can then be investigated further to verify therapies and obtain requested documentation.

Potential limitations of Paceart include: 1) the system may not be used comprehensively for all patients and all interrogations at your center; 2) not all devices are transferable into the Paceart system as soon as they are released for use - there may be a delay before your Paceart system is updated to accept data transfer for a new device; 3) Different devices transfer data with varying degrees of completeness; 4) Episode (therapy data) transfer wasn't always available in Paceart so this may not give a complete picture of all past therapies. You should work with your center's pacemaker/ICD clinic to see if/how Paceart can be of benefit.

Device Specific Report Examples
The following description of device-specific reports is intended to serve as a reference to support identification of therapies. Each of the companies may have different names and presentations for reports and therapies. Some reports may even have different names depending on if the check was done as a clinic check vs. a remote check. Reports may be available as combined or separate data even within the same manufacturer. This list is provided as a guide and not all reports will be available for each participant. See corresponding examples of these reports for each manufacturer in Appendix A.

Boston Scientific *- Look for VF, VT or VT1 episodes*
(Remote checks are done through the Latitude system - only the last check is stored for most devices during the study period. Changes have been made to the system to enhance storage of interrogations for newer devices - must have access to retrieve.)

- **Quick Notes** – This report gives a brief overview of the device and will tell if there are any new therapies.
- **Conversion Summary Report** – Will give device totals since last reset, as well as device totals for the life of the device.
- **Arrhythmia Log Report** – Can list as many as the last 250 episodes. (In Latitude, for some devices this may only go back 18 months. In clinic programmer checks this may go back further.)

ICD Longitudinal Study - Therapy Collection

Guidelines for Therapy Collection

- **Ventricular Tachy Counters** - Will give a brief summary of episodes since last reset and device totals, as well as attempted therapies. Episodes will be broken down into the number of zones programmed which could include one, two or three zones; VF, VT or VT1.
- **Episode Detail and Electrograms** – This report describes the detail of the episode for which either ATP and/or shocks were delivered and also includes the electrograms for each therapy. This report is the best source for episode identification and is what reviewers will use to determine appropriateness and effectiveness of therapy.
- **Device Follow-up Report or Combined Follow-up Report** – This is a combined report of the complete check but will include a listing of device totals. The Ventricular Tachy Counters are listed as "Since Last Reset" and "Device Totals." The initial page of this report also lists "Events since last reset" (with the date of reset).
- **Parameters or Settings Report** – This report provides parameter and settings at the time of the interrogation.

Medtronic *- Look for VF, FVT and VT episodes*
(Remote checks are done through the Carelink system – checks are stored indefinitely – must have access to retrieve.)

- **Quick Look Report or Initial Report** – This report gives a brief overview of the device and will tell if there are any new therapies since last interrogation. Older episodes are also available by doing a "complete" interrogation.
- **Full Summary Report** – This is a combined report of the complete check and includes the **episode counters** report and **episode lists** report. Counters Report-includes episodes since last session or last interrogation, since last cleared and device lifetime totals.
- **VT/VF Counters** – This report lists data from the prior session, last session and device lifetime totals. Episodes will be broken down into the number of zones programmed which could include one, two or three zones; VF, VFT and VT.
- **Arrhythmia Episode List** - This report includes a list of episodes since the last interrogation.
- **Episode Detail and Electrograms** – This report describes the detail of the episode for which either ATP and/or shocks were delivered and also includes the electrograms for each therapy. The report may include a plot of the heart rate, actual electrograms of the episode and a detailed description of the episode and is the best source for episode identification. Reviewers will use this report to determine appropriateness and effectiveness of therapy.
- **Parameters** – This report provides parameters and settings at the time of the interrogation.

St. Jude Medical *- Look for VF, VT1, or VT2 episodes*
(Remote checks are done through the Merlin system - checks are stored indefinitely - must have access to retrieve.)
Note: St. Jude device lifetime totals cannot be relied upon to give the total number of therapies. Device total may not include therapies treated with ATP and do include extra data used in device maintenance. Data elements in St. Jude devices may also be retained in the programmer as archived data.

ICD Longitudinal Study - Therapy Collection

Guidelines for Therapy Collection

- **Fast Path Summary** – This is a combined report that includes the **Tachy Episode Summary** and **Tachy Episode Directory** which identifies episodes since last cleared. This report may also include parameters or settings.
- **Arrhythmia Episode List** - May also be called **VT/VF Episode Directory** and printed out as part of the FastPath Summary report. Episodes will be broken down into the number of zones programmed which could include one, two or three zones; VT1, VT2 or VF.
- **Tachy and Lifetime Diagnostic Report** – This report provides a Diagnostic Summary since last cleared, as well as Tachy & Lifetime Diagnostics.
- **Episode Detail and Electrograms** – This report describes the detail of the episode for which either ATP and/or shocks were delivered and also includes the electrograms for each therapy. This report is the best source for episode identification and is what reviewers will use to determine appropriateness and effectiveness of therapy.
- **Wrap-up Overview** – This is a combined report which may also include multiple other reports.
- **Parameters** – This report provides parameters and settings at the time of the interrogation.

Manufacturer Resources:
Your local manufacturer representatives may be able to help assist you with report selection within the websites and programmers. In addition, the manufacturers' main company contact information is provided below.

BOSTON SCIENTIFIC/GUIDANT	MEDTRONIC TECH SERVICES	ST. JUDE TECH SERVICES
TECH SERVICES and Latitude Tech Services 1-800-CAR-DIAC 1-800-227-3422 Latitude 1-800-CAR-DIAC and ask for Latitude support	1-800-505-4636 brady 1-800-723-4636 tachy Carelink 1-800-929-4043 PACEART--------1-800-PACEART Option 1	1-800-PAC-EICD 1-800-722-3774 Merlin 1-877-696-3754

Personal Direct and Indirect Identifiers
To assist abstractors in removing personal identifying information from reports being sent to Marshfield, a list of specific HIPAA Direct Identifiers is included below. Marshfield Clinic Research Foundation has Data Use Agreements (DUAs) with each of the sites participating in data collection. The DUAs permit sharing of a limited data set for the purposes of this study, and this includes sharing of dates on the reports or the forms you complete. Redacting names of facilities and physicians/providers is at the discretion of the submitting site. Please take extra care to review documents prior to sending to Marshfield to ensure all Direct Identifiers of participants have been removed.

Also, please note that the example reports attached to this Guidelines document have been taken a step further and completely deidentified, including removal of all participant-relevant dates. This was necessary because Marshfield Clinic Research Foundation does not have DUAs in place **as the data contributor** to each study site.

ICD Longitudinal Study - Therapy Collection

Guidelines for Therapy Collection

Direct Identifiers (Not Allowed)	
• Name • Postal address • Phone number • Fax number • Email • Social security number • Health plan numbers • Account numbers • Certificate/license number/vehicle identifiers & serial numbers, including license plate numbers • Device identifiers and serial number	• A unique identifying number, characteristic or code (**Note**: a code is not considered an identifier if it is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual) • URL • IP address numbers • Biometric identifiers, including finger and voice points • Full face photographic images and any comparable images

Shipping Completed Forms and Documentation to the Coordinating Center (Marshfield)

- Completed Therapy Collection Forms and documentation should be shipped to the Coordinating Center on your identified ship date (see Therapy Collection Shipping Schedule) with a Documentation Transmittal Log. On the transmittal log, list the Study ID number for each chart that is being shipped.
- Transmittal logs should be reviewed against the actual hard copy forms. The original transmittal logs should accompany the shipment. A copy of each transmittal log should be kept on file at the site.
- All documentation should be photocopied prior to shipment. The site will keep the copies on file and ship the originals. Forms should be organized for shipment in the same order in which they appear on the transmittal.
- Collection forms and documentation should be shipped to the Coordinating Center (Deb Multerer, 1000 N. Oak Avenue – ML-3, Marshfield, WI 54449) via Federal Express or similar secure and traceable shipment. A copy of the transmittal should also be faxed to Deb Multerer at 715-389-3535 on the day of the shipment.

ICD LONGITUDINAL STUDY - THERAPY COLLECTION
PARTICIPANT IDENTIFICATION COVER PAGE - Version 01/28/2011

Site Data Manager to supply prefilled form for each subject to assist abstractor in identification.
Do not include with shipment to Coordinating Center.

STUDY ID No._____ **Date of Implant** _____ (from NCDR Registry)

Local Identifying Information – Do Not Send This Page to Coordinating Center at Marshfield

Medical Record No. _____

Date of Birth _____

Gender _____

The site data manager can chose to add other identifying variables needed to support abstraction on this form or else supply them to the abstractor through other means (e.g., local ID numbers, name, etc.).

ICD LONGITUDINAL STUDY - THERAPY COLLECTION

PARTICIPANT DATA FORM - Version 01/28/2011

Site Data Manager to supply prefilled form for each subject before abstraction
Include with Shipment to Coordinating Center.

- **STUDY ID No. _____**

- 1st Implant Date _____
- 1st Device Manufacturer/Model Name/Model Number _____
- 1st ICD Device Type (from NCDR Registry): _____

- 2nd Implant Date _____
- 2nd Device Mfr/Model Name/Number _____
- 2nd ICD Device Type _____

- 3rd Implant Date _____
- 3rd Device Mfr/Model Name/Number _____
- 3rd ICD Device Type _____

- End Date:_____ (calculated from NCDR registry implant date—defined as 3 years post implant [2 years for 2009 implants])

- List of dates of ICD Interrogation CPT codes for the period from Date of Implant to the first occurrence of an ICD Interrogation CPT code after End Date (from VDW)

  _____
  _____
  _____

- List of dates of inpatient hospital stays for the period from Date of Implant to the first occurrence of hospitalization after End Date (from VDW)

  _____

- List of dates of Emergency Department visits for the period from Date of Implant to the first occurrence of an ER visit after End Date (from VDW)

  _____

ICD LONGITUDINAL STUDY – THERAPY COLLECTION

ICD THERAPY ASCERTAINMENT FORM with INTERROGATION TABLE

Site Abstractor to complete one form for each participant, after receiving Participant Data Form from site data manager.

PART A. Site Abstractor to Complete.

1. **STUDY ID No.**_____ 2. **Abstractor ID No.** _____ 3. **Date of Abstraction:** ____/____/_____ Mo/Day/Year

4. **Is there evidence in the medical record that ICD on Date of Implant was not the participant's first ICD?**

   _____ **Yes** ➔ **Enter date of prior ICD implant** _____/_____/_____ (*Stop abstraction if prior to 2006*)
   Mo/Day/Year
   _____ **No** (*Continue to Part B.*)

5. **Enter date of death, if any, found in the medical record** ➔ _____/_____/_____ (*Continue to Part B.*)
   Mo/Day/Year

PART B. Interrogation Table (separate page) - Site Abstractor to complete.

Complete the Interrogation Table by documenting device interrogations covering the period from the Date of Implant through the End Date provided on the Participant Data Form. Complete each row in its entirety for each interrogation noted.

PART C. Site Abstractor to Complete, after Part B (Interrogation Table).

1. **Was participant followed through End Date supplied on Participant Data Form?**

   _____ **Yes**

   _____ **No** (*Indicate reason, based on abstraction findings*)

   ____ Death before End Date ➔ Death Date (from record abstraction) _____/_____/_____ Mo/Day/Year

   ____ Device turned off permanently or explanted before End Date ➔ Date _____/_____/_____ Mo/Day/Year

   ____ Participant transferred care before End Date ➔ Date transferred _____/_____/_____ Mo/Day/Year

   ____ 10 treated episodes before End Date ➔ Date of 10th episode _____/_____/_____ Mo/Day/Year

   ____ Other ➔ Specify _____ ➔ Date last followed _____/_____/_____ Mo/Day/Year

2. **Copy source documents, remove direct participant identifiers, and include with this form:**

   a. Implant surgery note (from the Date of Implant.) - Attached?

      _____ **Yes**
      _____ **No** ➔ Reason _____

   b. Device Interrogation Report and Clinical Note(s) from last interrogation* – Attached?

      _____ **Yes** ➔ Date of Interrogation Report_____/_____/_____ Mo/Day/Year
      _____ **No** ➔ Reason _____

      _____ **Yes** ➔ Date of Clinical Note_____/_____/_____ Mo/Day/Year
      _____ **No** ➔ Reason _____

Send the entire interrogation report as archived or alternatively select and send just the following report components. Also, if you need to generate a new report printout from the web or electronic programmer archive, these are the reports of interest that may be available by manufacturer and should be included.
Boston Scientific: Quick Notes, Conversion Summary Report, Arrhythmia Log, Ventricular Tachy Counters, Episode Detail, Device Follow-up Report or Combined Follow-up Report, Parameters or Settings Report
Medtronic: Quick Look Report or Initial Report, Full Summary, VT/VF Counters, Arrhythmia Episode List, Episode Detail and Electrograms, Parameters
St. Jude: Fast Path Summary, Tachy Episode Summary, Tachy Episode Directory, Arrhythmia Episode List, VT/VF Episode Directory, Tachy and Lifetime Diagnostic Report, Episode Detail and Electrograms, Wrap-up Overview, Parameters

**If the last interrogation has no device report or clinical note archived, work backward until the last available device report or clinical note is found, ensuring entire study period is covered.*

**If follow-up was stopped with the 10th treated episode, the device report and clinical note from that corresponding interrogation should be sent rather than seeking out the last interrogation in the original follow-up period.*

3. **If the participant received any ICD therapies from the Date of Implant through the End Date, complete an ICD Treated Episode Cover Page for each treated arrhythmic episode.**

4. **Assemble the following forms and documents for submission – Participant Data Form, Ascertainment Form with Interrogation Table, Implant Surgery Note, Interrogation Report and Clinical Interpretation Note(s) from last interrogation (OR 10th treated episode) and an ICD Treated Episode Cover Page with corresponding source documents (device interrogation report, electrocardiograms, clinical note(s) with interpretation of episode) for each treated arrhythmic episode.**

ICD THERAPY ASCERTAINMENT INTERROGATION TABLE

Site abstractor to complete for device interrogations occurring during the participants follow-up period

PART B. Interrogation Table: *Complete each row in its entirety. Begin with the first device interrogation on or after the Date of Implant. Complete a row for each interrogation occurring through the End Date or to the 10th treated episode. It may be necessary to go to the next interrogation after the End Date to cover entire follow-up period. Note the presence and dates of any arrhythmic episodes requiring device therapies. Add comments as needed.*

1. Study ID No. _____ **2. Date of Implant** ____/____/____ (Mo/Day/Year) **3. End Date** ____/____/____ (Mo/Day/Year)

Interrogation Date *mm/dd/yyyy*	**Type of Check** *C-Clinic R-Remote H-Hospital O-Other (Specify)*	**Device Interrogation Report Available?** *Y/N*	**Cumulative Device Totals Available in Report?** *Y/N*	**Clinical Note Available?** *Y/N*	**Remote Data Available?** *Y/N/NA*	**Any Treated Episodes?** *Y/N/Unkn*	**Date(s) of Episode(s) Requiring Therapy** *mm/dd/yyyy; mm/dd/yyyy; mm/dd/yyyy; etc.*	**Comments**

☐ Gaps in follow-up were identified between interrogations. Explain: _____

_____

Additional Comments: _____

Page _____ of _____ (use additional sheets as needed) When complete, go to Part C on Ascertainment Form. 11/01/10

ICD THERAPY ASCERTAINMENT INTERROGATION TABLE

Site abstractor to complete for device interrogations occurring during the participants follow-up period

Additional Sheet

1. Study ID No. _____ **2. Date of Implant** ____/____/____ (Mo/Day/Year) **3. End Date** ____/____/____ (Mo/Day/Year)

Interrogation Date *mm/dd/yyyy*	**Type of Check** *C-Clinic R-Remote H-Hospital O-Other (Specify)*	**Device Interrogation Report Available?** *Y/N*	**Cumulative Device Totals Available in Report?** *Y/N*	**Clinical Note Available?** *Y/N*	**Remote Data Available?** *Y/N/NA*	**Any Treated Episodes?** *Y/N/Unkn*	**Date(s) of Episode(s) Requiring Therapy** *mm/dd/yyyy; mm/dd/yyyy; mm/dd/yyyy; etc.*	**Comments**

☐ Gaps in follow-up were identified between interrogations. Explain: _____

_____

Additional Comments: _____

Page _____ of _____ (use additional sheets as needed) When complete, go to Part C on Ascertainment Form. 11/01/10

ICD TREATED EPISODE COVER PAGE

Site Abstractor to complete a cover page for each treated arrhythmic episode. For each subject, collect a maximum of 10 treated arrhythmic episodes. Also, if more than three treated episodes occurred within a 24 hour time period, do not collect or count any episodes which occurred after the third episode within that 24 hour period. In such a situation, continue collection again (and counting toward 10) with the next treated episode that occurs after that 24 hour period.

1. **STUDY ID No.** _____ 2. **Abstractor ID No.** _____

3. **Interrogation Date:** _____/_____/_____ 4. **Treated Episode #** _____
Mo/Day/Year **(To be completed by Marshfield)**

5. **Date of treated arrhythmic episode:** _____/_____/_____
Mo/Day/Year

6. **Time of treated arrhythmic episode:** _ _ : _ _ : _ _ AM/PM/Military
Hour:min:sec

7. **Is this the third treated episode within a 24 hour time period?** ____ **Yes** ____ **No**

8. ***For this arrhythmic episode, obtain and attach copies of the device interrogation report, electrocardiograms, and the clinical note(s) containing the interpretations of the episode and the resulting therapy. Be sure to remove any direct identifiers.***

   Indicate below whether requested documents are attached and any explanation for missing documents.

   a. **Device Interrogation Report** - Attached? *Send the entire interrogation report as archived or alternatively select and send just the following report components. If you need to generate a new report printout from the web or electronic programmer archive, these are the reports of interest that may be available by manufacturer and should be included. See Guidelines document for specific examples of these reports:*
   Boston Scientific: Quick Notes, Conversion Summary Report, Arrhythmia Log, Ventricular Tachy Counters, Episode Detail, Device Follow-up Report or Combined Follow-up Report, Parameters or Settings Report
   Medtronic: Quick Look Report or Initial Report, Full Summary, VT/VF Counters, Arrhythmia Episode List, Episode Detail and Electrograms, Parameters
   St. Jude: Fast Path Summary, Tachy Episode Summary, Tachy Episode Directory, Arrhythmia Episode List, VT/VF Episode Directory, Tachy and Lifetime Diagnostic Report, Episode Detail and Electrograms, Wrap-up Overview, Parameters

   _____ Yes

   _____ No ➔ Explanation _____

   b. **Electrocardiograms** - Attached? *(From device interrogation report)*

   _____ Yes

   _____ No ➔ Explanation _____

   c. **Clinical Note(s) with Interpretation of Arrhythmic Episode/Therapy** - Attached?
   (EMR notes, Paceart report, device clinic flow sheet)

   _____Yes

   _____No ➔ Explanation_____

9. **Episode Comments** _____

_____

_____

Instructions for Completing ICD Therapy Ascertainment Form, ICD Therapy Ascertainment Interrogation Table and the ICD Treated Episode Cover Page

ICD PARTICIPANT IDENTIFICATION COVER PAGE

Identifiers from the VDW needed locally to facilitate abstraction (e.g. MRN, date of birth, gender) will be prefilled on a separate tear-off sheet, known as the Participant Identification Cover Page. This page will be prefilled by the site data manager and supplied to the site abstractor. This page and any other direct identifiers supplied locally by the site data manager to support abstraction (e.g. name, etc.) should not be included in the materials sent to the Coordinating Center in Marshfield.

ICD PARTICIPANT DATA FORM

For each patient selected for the ICD Longitudinal Study Therapy Collection, the site data manager will provide an ICD Participant Data Form prefilled with the following information. This form should be included in the submission to Marshfield.

- Unique Study ID Number
- Date of Implant (from NCDR registry)
- Device Manufacturer/Model Name/Model Number (from NCDR registry)
- ICD Type (from NCDR registry)
- Dates of any subsequent ICD Implant Records after Date of Implant (from NCDR registry)
- End Date (calculated from NCDR registry implant date); defined as: 3 years post implant [2 years for 2009 implants]
- List of dates of possible interrogations from Date of Implant through End Date as determined by CPT codes (from VDW).
- List of dates of inpatient hospital stays from Date of Implant through End Date (from VDW).
- List of dates of Emergency Department visits from Date of Implant through End Date (from VDW).

ICD THERAPY ASCERTAINMENT FORM WITH INTERROGATION TABLE

Part A. Site Abstractor to Complete.

1. **Study ID No.** Enter the Unique Study ID No. from the Participant Data Form. Include the site ID number as part of the number, i.e. 113-00025.

2. **Abstractor ID No.** Enter your abstractor ID number.

3. **Date of Abstraction.** Enter date of abstraction.

4. **Is there evidence in the medical record that ICD on Date of Implant was not the participant's first ICD?** While the study is taking steps to assure that the ICD identified by the NCDR registry is the participant's first ICD, it is possible that some members of the eligible cohort will have evidence of a prior ICD implant in the medical record. In such a situation, if the date of the earlier ICD implant is prior to

01/01/2006 or if the implant was performed outside of your health system, indicate this, enter date of prior ICD implant and **STOP** the abstraction at this point. Provide a copy of the implant note if available with the Ascertainment Form in your next shipment. If the prior implant date is within the study period (01/01/2006-12/31/2009), and the implant was performed within your health system, please enter the date of the prior implant, and continue abstraction with Part B. Include all implant notes in documentation. If No, continue to Part B.

5. **Enter date of death, if any, found in the medical record.** If the participant is deceased according to the medical record, enter the date of death and continue abstraction through the entire study period or up to the date of death, which ever comes first. This date may be after the study period in which case you would abstract through the end date provided on the Participant Data Form. If the participant is not deceased, leave blank and continue to Part B.

Part B. Interrogation Table.

1. **Study ID No.** Enter the Unique Study ID No. from the participant Data Form. Include the site ID number as part of the number, i.e. 113-00025.

2. **Date of Implant.** Enter the Date of Implant from the Participant Data Form.

3. **End Date.** Enter the End Date from the Participant Data Form. Do not change the End Date. You will have the opportunity in Part C to indicate whether and why a subject could not be followed to their predetermined End Date.

4. **Complete the Interrogation Table**. This will assist in the site's systematic ascertainment and will provide central reviewers with an understanding of what documentation is available and how this interrogation relates to other occurrences. Using the supplied Guidelines for Therapy Collection document as a reference, ascertain ICD interrogations and identify any treated arrhythmic episodes by listing the interrogations and corresponding data in chronological order. The dates of possible interrogations determined by CPT codes, the dates of inpatient hospital stays and the dates of Emergency Department visits provided on the Participant Data Form will help guide you. Please start with the earliest interrogation on or after the Date of Implant, and end with the first interrogation occurring on or after the End Date. Record the presence of any treated episodes occurring on or before the End Date, but not after the End Date. If you find evidence of a treated episode without having the formal documentation that an interrogation occurred, indicate the presence of the treated episode and complete the row as best you can. Do not leave any data elements blank. Completing each requested data element identifies that the record was reviewed and what type of information you used to determine if treated episodes occurred. Use the comment section to provide the Coordinating Center with information you feel will assist reviewers in understanding the data collection. Requested table elements include:

Instructions for Completing ICD Therapy Ascertainment Form, ICD Therapy Ascertainment Interrogation Table and the ICD Treated Episode Cover Page

- **Interrogation Date** – enter date of device interrogation (one date per row). Note that a device check performed for testing that may have been done following implant should be considered an interrogation and entered on the form. Even though the test was not a spontaneously occurring arrhythmic episode, it will advance counters, and so noting this information will be important to the reviewers for assessing completeness of data capture.

- **Type of Interrogation** (C-Clinic, R-Remote, H-Hospital, O-Other-Specify) – determine what type of interrogation took place and enter corresponding letter.

- **Device Interrogation Report Available?** - If entire or partial Device Interrogation Report is available to assist you in determining whether or not there was a treated arrhythmic episode enter Y. If there is no Device Report available enter N. (Device specific report examples by manufacturer are available in the Guidelines for Therapy Collection document.)

- **Cumulative Device Totals Available in Report?** – If Cumulative Device Totals are included in the Device Interrogation Report, enter Y. If not, enter N. (Abstractor may also note the actual device totals number in this column if it assists them in determining if additional therapies occurred.)

- **Clinical Note Available?** – Indicate the availability of a clinical note with interpretation or other medical record sources that assisted you in determining whether or not there was a treated arrhythmic episode. Clinical notes may include Paceart reports or other local documents (see Guidelines for Therapy Collection document for additional information).

- **Remote Data Available?** – If Type of Check was R-Remote, check the manufacturer's website for additional interrogation data. Enter Y/N/NA (not applicable for non-remote checks) accordingly. Specific websites per manufacturer are listed in the Guidelines for Therapy Collection document. If you entered N (No), explain reason for not checking the website in the comment field.

- **Any Treated Episodes?** – Indicate whether a treated episode occurred during this interrogation period. If treated episode is present, enter Y and continue row. If there were no treated episodes, enter N or Unkn, complete comments field if necessary and continue to next interrogation date. Please recall that both shocks and anti-tachycardia pacing (ATP) qualify as ICD treatment for arrhythmic episodes. Please refer to Guidelines for Therapy Collection document and device-specific report examples to help identify presence and number of treated arrhythmic episodes. An aborted therapy should also be considered a treated episode for purposes of this study and documentation should be collected.

Instructions for Completing ICD Therapy Ascertainment Form, ICD Therapy Ascertainment Interrogation Table and the ICD Treated Episode Cover Page

- **Date(s) of Episode(s) Requiring Therapy** – If treated episode(s) occurred, enter the date of each treated arrhythmic episode captured by this interrogation. Do not collect more than three treated episodes within a 24 hour period. Continue abstraction of additional treated episodes within that interrogation. In addition, please note in the comments field if abstraction was stopped after three treated episodes. Providing comments for this will help the Coordinating Center understand the progression of events and why counters may vary.

- **Comments** – Enter any comments for the interrogation you feel will assist the Coordinating Center.

Note: Abstractors should collect up to the first 10 treated episodes per subject. However, collect (and count towards those 10) no more than three treated episodes within any 24 hour period. In such a situation, continue collection (and counting again toward the 10) with the next treated episode that occurs after that 24 hour period. If you reach 10 total treated episodes using this approach, you should STOP data collection. The documentation for the 10th episode becomes the final interrogation. Otherwise, continue abstraction until you review the last interrogation covering any of the period between the implant and End Date.

Gaps in follow-up were identified between interrogations: If there are identified lapses in coverage during the follow-up period or if there are gaps between interrogations of six months or greater, check the box at bottom of the page and provide an explanation. See Guidelines for Therapy Collection document for additional information.

Additional Comments. Enter any additional comments that will assist Coordinating Center.

Page Number. Additional pages may be necessary to record all interrogations. Additional Interrogation Table sheets can be added as necessary. Enter the page number for each additional page.

When the interrogation table is complete, go to Part C. on Ascertainment Form.

Part C. Site Abstractor to Complete, after Part B (Interrogation Table).

1. **Was participant followed through End Date supplied on Participant Data Form?** If during your abstraction, you determine that the subject's clinical follow-up for device interrogations and treated episodes did not last up to their anticipated End Date, indicate this, the explanation, and the relevant date, including: death before End Date, device permanently turned off or explanted before End Date, care transferred outside the health system before the End Date, 10 treated episodes before End Date, or Other and specify reason.

2. **Copy source documents, remove direct participant identifiers and include with this form.** In this section, for all subjects, you are asked to provide a copy of the implant surgery note and the last device interrogation report and clinical notes. If you are unable to provide the information, check the appropriate box and provide an explanation. More information regarding documentation is provided in the Guidelines for Therapy Collection document.

3. **If the participant received any ICD therapies from the Date of Implant through the End Date, complete an ICD Treated Episode Cover Page for each treated arrhythmic episode**. Follow instructions provided below (and on the Cover Page itself).

4. **Assemble the forms and documents for submission as listed.**

ICD TREATED EPISODE COVER PAGE

Complete an ICD Treated Episode Cover Page for each treated episode (arrhythmic event leading to therapy). Please note there may be multiple treated episodes captured per interrogation. Also, each treated episode may have resulted in more than one therapy, including one or more ATP and/or one or more shocks, but the unit of observation in this study is the treated arrhythmic episode. **Note: If more than three treated episodes occurred within a 24 hour time period, do not count or complete an ICD Treated Episode Cover Page for any episodes which occurred after the third episode within that 24 hour period. In such a situation, continue collection again (and counting toward the 10 maximum treated episodes) with the next treated episode that occurs after that 24 hour period.**

1. **STUDY ID No.** Enter the Study ID No. supplied on Participant Data Form.

2. **Abstractor ID No.** Enter your ID number.

3. **Interrogation Date**: Enter the date of the Interrogation from the Interrogation Table.

4. **Treated Episode #: Please leave blank. This will be completed by Marshfield.**

5. **Date of treated arrhythmic episode:** Enter the date of the treated arrhythmic episode.

6. **Time of treated arrhythmic episode**: Enter time of arrhythmic episode. Circle AM/PM/Military if known.

7. **Is this the third treated episode within a 24 hour time period?** Answer Yes or No.

8. **Source documentation:** Attach source documentation of the treated episode. Indicate which reports are available by checking Yes or No. If reports are not available provide an explanation. Include the following:
   a. Device Interrogation Reports
   b. Electrocardiograms
   c. Clinical Notes with Interpretation of Arrhythmic Episode/Therapy. The local provider's interpretation and other archived clinical information about the episode are critical elements to support an accurate central review and adjudication process, especially for situations where the formal device report and electrograms are missing.

   Note reasons for missing or partially missing source documentation. See Guidelines for Therapy Collection for additional information.

9. **Episode Comments**. Enter any comments you feel will be of assistance to the Coordinating Center.

ICD Longitudinal Study – Therapy Collection

DOCUMENTATION TRANSMITTAL LOG

Please complete this transmittal log for ICD Participant Forms and Documentation that are currently being shipped to Marshfield. Keep a copy of this log at your site for your records and fax a copy to Deb Multerer at 715-389-3535.

Please ship charts with a copy of this transmittal log to:

Deb Multerer
ICD Study Manager
Marshfield Clinic Research Foundation
1000 North Oak Avenue – ML3
Marshfield, WI 54449
Ph: 715-389-3108

Site ID: _____

Date sent to Marshfield: _____

Study ID Number

Study ID Number

ICD Longitudinal Study

Date of Review: _____
Reviewer Initials: _____

Quality Assurance Chart Review Checklist

Study ID No. _____ Abstractor ID No. _____

ICD Therapy Ascertainment Form with Interrogation Table (page 1)

_____ Part A. items 1-5 complete.

_____ Part B. Interrogation Table is included.

_____ Part C. item 1. is complete.

_____ Part C. item 2. is complete.

_____ a. Implant note included or explanation provided if not.

_____ b. Last device interrogation/clinic note reports included or explanation provided.

Interrogation Table

_____ Part B. Interrogation Table items 1-3 completed. End date matches.

_____ Interrogation dates match dates provided on ICD Participant Data Form.

_____ Rows are complete for each interrogation date.

_____ Gaps of 6 months or greater are explained.

_____ If Type of Check is Remote – Remote Data Available box is completed.

_____ If Treated Episodes reported on table – A Treated Episode Cover Page with documentation is included. [ENTER # OF TREATED EPISODESAT BOTTOM OF TABLE]

_____ Date of Last interrogation report or 10th Treated Episode matches information provided on page 1, part 2.b.

Treated Episode Cover Page(s)

_____ Treated episode cover page(s) and documentation provided for each treated arrhythmic episode.

_____ Form is complete; all items completed

_____ Device interrogation reports are attached or explanation is provided.

_____ Electrocardiograms are attached or explanation is provided.

_____ Clinical notes with interpretation of episode are attached or explanation provided.

All

_____ All forms assembled as instructed.

_____ Reports are deidentified; PHI redacted.

_____ Comments are legible

ICD Longitudinal Study

Request for Additional Documentation

Study ID No: _____ Abstractor ID No: _____

Date of Request: _____

Documentation Requested	Included? Y/N/NA	Site Comments

Date of Response: _____

Fax or mail response with additional documentation if available to:

Deb Multerer
ICD Study Manager
Marshfield Clinic Research Foundation
1000 North Oak Avenue – ML3
Marshfield, WI 54449
Ph: 715-389-3108
Fax: 715-389-3535

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Appendix F: Therapy Adjudication Documents

-Glossary

-Central Review Form and Instructions

-Central Resolution Form and Instructions

-External Adjudication Form and Instructions

-Adjudication Resolution Form

Longitudinal ICD Study
Glossary for Central Review and External Adjudication Panels
(Information in Gray relevant to Central Review Only)

Table 1. General Definitions

Date of Interrogation	The date recorded as the day the ICD interrogation was performed either by date stamp from the programmer or documentation from other reported sources (e.g., CPT code, dictation note). The date is already documented on the Treated Episode Cover Page.
What is a treated episode?	An episode is an arrhythmic event, as defined by the device, which required treatment by the ICD including either antitachycardia pacing (ATP) or ICD shock. (An inappropriate therapy is considered an episode as long as therapy was delivered by the ICD). Counters advanced due to DFT testing will not be considered an episode but the interrogation report will be reviewed to identify that the therapy was not a spontaneously occurring treated episode.
Episode termination	*"An episode's termination was defined by the ICD re-detecting sinus rhythm and thus could include more than 1 shock (and/or ATP bursts)."* In addition to sinus rhythm, termination could be a paced rhythm or any heart rate that falls below the VT/VF detection rate cut off and consequently the device does not treat. * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51;1357-1365
Treated episode number	A subject's treated episodes will be numbered chronologically during the initial review process at Marshfield. When the review packets reach the panel, the Treated Episode Cover Page and the corresponding source documentation will already be separated into these consecutively numbered sections. Do not refer to the episode numbers listed on programmer print out. If an additional treated episode is identified during the central review process, please add that episode and its review results to the available row on the Central Review Form following the prenumbered episodes. Following the review process, the treated episodes will be renumbered chronologically before final data entry. For treated episodes sent for external adjudication review, additional identification will be added to the source documents to help identify and link episodes, clinical notes and interrogation data together.

Date of treated episode	Interrogation reports document the dates and times of recorded episodes. When supporting information is available to the site abstractor and the central coordinator, the Treated Episode Cover Page will already contain the abstracted date and time for each episode.
Time of treated episode	This time maybe expressed as AM, PM or Military Time and this expression can vary in the same patient between episodes, and sometimes may not be known. If there are inconsistencies in dates and/or times across source documents, decisions will be determined by preponderance of data.
ICD Therapy	*"The ICD therapy was defined as either antitachycardia pacing (ATP) or ICD shock."* * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51:1357-1365
What is ATP?	Any use of pacing stimulation technique including ramp, burst, burst +, etc. delivered as programmed for an episode of ventricular tachyarrhythmia or delivered as ATP before or during charge. In presence of a device interrogation report that could be expected to show this, or in presence of a local provider interpretation, assume no ATP during charge for a shock unless the ATP was specified.
What is shock therapy?	Any therapy recorded by the ICD as a shock delivered will qualify as a shock regardless of energy delivered. Aborted shocks are not considered a therapy.
Was ATP and/or shock appropriate?	*ATP and/or shock were considered to be appropriate if therapy was delivered for "device-detected VT/VF episodes that were confirmed to be ventricular in origin."* * Appropriate and Inappropriate Ventricular Therapies, Quality of Life, and Mortality Among Primary and Secondary Prevention Implantable Cardioverter Defibrillator Patients Results From the Pacing Fast VT REduces Shock Therapies (PainFREE Rx II) Trial. Sweeney MO, Wathen MS, Volosin K, Abdalla I, DeGroot PJ, Otterness MF, Stark AJ. *Circulation* 2005; 111:2898-2905.
Was ATP and/or shock inappropriate?	*"Any ICD therapy not delivered for VT or VF was deemed inappropriate..."* * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51;1357-1365 There will also be episodes for which it may be impossible to determine appropriateness of therapy due to incomplete or missing data, unclassified rhythms, or unresolved reviewer disagreement. These will be classified as "Uncertain".

Local provider's impression of appropriateness of the treated episode	This is the interpretation from the provider(s) involved in patient's care included in the clinical source documentation provided for review. The local provider impression (i.e., the 'call on the field') will be recorded as 'Appropriate' or 'Inappropriate'. A classification of 'Uncertain' for this field will be used if the local provider's impression is itself documented to be 'Uncertain', or if the local impression is missing from the source documentation or otherwise not informative.
Was ATP and or shock therapy Successful?	*"Successful ATP, applied during or before charging, was defined as termination of the fast rhythm and shock prevention."* For our study, successful ATP is being interpreted to accommodate any number of ATP sequences, provided ATP terminates the fast rhythm and no shock was employed. * Optimizing implantable Cardioverter-defibrillator treatment of rapid ventricular tachycardia: Antitachycardia pacing therapy during charging. Schoels W, Steinhaus D, Johnson WB, O'Hara G, Schwab JO, Jenniskens I, DeGroot PJ, Tang F, Helmling E, on behalf of the EnTrust Clinical Study Investigators). *Heart Rhythm*, Vol 4, Issue 7, pages 863 to 990 (July 2007) *Shock was successful if the arrhythmia terminated after a shock with the 'ICD re-detecting sinus rhythm and thus could include more than 1 shock (and/or ATP)."* * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51;1357-1365 In our study, return to baseline rhythm or a paced rhythm (not just sinus rhythm) would also be considered successful. In the presence of a local provider interpretation, assume an appropriate therapy was successful unless otherwise indicated, provided there is evidence that indicates the subject was no longer in ventricular arrhythmia at some later point in time.
Was ATP Unsuccessful?	An ATP attempt was classified as unsuccessful if the arrhythmia did not terminate or *' if the arrhythmia terminated, but immediate reinitiation of premature ventricular contractions (PVC's) resulted in shock delivery.'* * Optimizing implantable Cardioverter-defibrillator treatment of rapid ventricular tachycardia: Antitachycardia pacing therapy during charging. Schoels W, Stenihaus D, Johnson WB, O'Hara G, Schwab JO, Jenniskens I, DeGroot PJ, Tang F, Helmling E, on behalf of the EnTrust Clinical Study Investigators). *Heart Rhythm*, Vol 4, Issue 7, pages 863 to 990 (July 2007)
Was shock Unsuccessful?	When shock is delivered and the arrhythmia does not terminate with that *or subsequent shocks or ATP therapy*, the shock will be deemed unsuccessful.

VT Termination with ATP (Type I)	*"In type-1 termination, the VT ceases immediately after the last ATP pulse so the first post-ATP beat is a sinus or paced beat."* * Incidence and Characteristics of Type-2 Breaks in Response to Antitachycardia Pacing Therapy in Implantable Cardioverter Defibrillator Patients. Sharma V, DeGroot PJ, Wathen MS. *Journal of Cardiovascular Electrophysiology* 2003;14:1156-1162.
VT Termination with ATP (Type II)	*"...the same or different VT can persist for one or more beats after the final ATP pulse, and restoration of sinus or regular paced rhythm is delayed."* * Incidence and Characteristics of Type-2 Breaks in Response to Antitachycardia Pacing Therapy in Implantable Cardioverter Defibrillator Patients. Sharma V, DeGroot PJ, Wathen MS. *Journal of Cardiovascular Electrophysiology* 2003;14:1156-1162.
VF Termination	Apply the same definition for VF type I and II termination as used for VT
Arrhythmia discrimination between VT vs. VF	*"Arrhythmia diagnosis was not based on rigid arrhythmia definitions. Reviewers will base diagnosis on characteristics such as abruptness of onset of the arrhythmia, the morphology of the electrogram of the arrhythmia compared to the morphology of the electrogram in normal rhythm, the rate, the regularity of the arrhythmia, and the mode of termination."* The arrhythmia was not exclusively defined by detection zones. Clinical information such as symptoms during the event, could also be considered by the reviewers in making a diagnosis. * Analysis of Implantable Cardioverter Defibrillator Therapy in the Antiarrhythmics Versus implantable Defibrillators (AVID) Trial. Klein RC, Raitt MH, Wilkoff BL, Beckman KJ, Coromilas J, Wyse DG, Friedman PL, Martins JB, Epstein AE, Hallstrom AP, Ledingham RB, Belco KM, Greenle HL, and the AVID Investigators. *Journal of Cardiovascular Electrophysiology* 2003; 14: 940-948.
Inappropriate ATP or shock due to SVT and/or AF	*"Any ICD therapy not delivered for VT or VF was deemed inappropriate, and the rhythm triggering therapy categorized as: atrial fibrillation or atrial flutter (AF), supraventricular including sinus tachycardia (SVT), or inappropriate sensing using published criteria."* * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51;1357-1365 If rhythm triggering inappropriate ICD therapy (ATP or shock) was SVT and/or AF (A Fib/Flutter), it should be so indicated.

Inappropriate ATP or shock due to Sensing Problems	*"Inappropriate therapy occurs in the absence of tachycardia because nonphysiological or nonarrhythmic, physiological signals are oversensed and detected as arrhythmias. Nonphysiological signals usually are extracardiac. Physiological signals may be Intracardiac (P, R, or T waves) or extracardiac (myopotentials)."* * Advanced ICD Troubleshooting: Part I Charles D. Swerdlow; Paul A. Friedman *PACE* 2005;28:1322–1346.
Inappropriate ATP or shock due to Other	Therapy delivered for device malfunctions not classifiable as 'inappropriate sensing' will also be considered inappropriate and can be categorized under Other.
Appropriateness of therapy in presence of Unclassified Rhythm.	Rhythms triggering ICD therapy are considered to be unclassified if data or documentation with which to make the classification are missing, incomplete, or otherwise uninformative. For this study, unclassified rhythms will result in a designation of Uncertain appropriateness (see table 2.) * Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ; MADIT II Investigators. *J. Am. Coll. Cardiol.* 2008;51;1357-1365
Did inappropriate ATP cause untoward rhythm requiring therapy?	If ATP or shock was delivered for a NON ventricular rhythm (inappropriate therapy) and the ATP or shock caused VT or VF requiring further therapy it will be considered to have caused an untoward rhythm. If there is a local provider interpretation present, assume no untoward rhythm following an inappropriate therapy unless one is specified. If no local provider interpretation is present, then choose unknown.
Sufficient documentation to classify appropriateness of ICD therapy for any given episode.	Source documentation will be reviewed initially upon receipt by the therapy data collection center for determination of completeness by the study coordinator. If data are felt to be missing or incomplete, additional information will be requested from the investigation site. Before the records are passed on to the central review panel, the data will be considered to be as "complete" as can be, meaning no additional information is available. For each treated episode, the reviewer is asked to 'Indicate the highest level for which sufficient documentation was available to evaluate appropriateness'. The responses will include 3 levels of sufficiency, with assignment in hierarchical fashion, indicated here from highest to lowest: *electrogram*, which represents the presence of the relevant intracardiac electrogram(s) in the abstracted source documentation; *other clinical features in description or report*, which, in the absence of electrograms, would be selected to represent availability in the source documentation of specific descriptions of the standard features of ventricular tachyarrhythmias (or specific descriptions of their absence); *local interpretation*, which in absence of either of the higher levels of sufficiency, would be selected to reflect availability of the local provider's interpretation

	of the episode. A response of *No* would be selected if none of the 3 types of evidence were available. It is possible for there to be relevant information in the source documentation that could support a determination that a therapy was 'probably appropriate' or 'probably inappropriate', but that does not meet the definitions of any of the 3 specified levels of sufficiency, resulting in the selection of *No*. Likewise, it is also possible that the source documentation can be found to be sufficient, and yet the central/external review can record the therapy appropriateness as 'Uncertain', e.g., when intracardiac electrograms, key clinical features, or local clinical interpretation is fully captured, but for some reason, that evidence is not conclusive as to the exact nature of the arrhythmia.

Table 2. Levels of Appropriateness of Therapy

Categories	5 levels of appropriateness will be used to classify treated episodes for the purpose of initial central review and external adjudication. These can be compressed as needed into 3 categories during analysis and study reporting. As a general rule, the clinical interpretation regarding the appropriateness of ICD therapy will be that determined by the clinicians involved in the patient's care except in circumstances in which there is dependable evidence that the original clinical determination was incorrect. When it is clear that the local provider did not have access to the primary data source (i.e., the interrogation was performed elsewhere), 'Uncertain' should be the response for the review question about the local provider interpretation. In this case, 'Uncertain' should also be the response for the review question about appropriateness of therapy unless the reviewer has other relevant source material to support their decision. The occurrence of an episode can be identified from the programmer printouts alone but the appropriateness of therapy can not be assumed in this case.
Definitely Appropriate ICD therapy	The Central Review and External Adjudication Panels will consider ICD therapy to be **Definitely Appropriate** if intracardiac electrogram criteria are available and confirm ventricular arrhythmias. This requires direct review and confirmation of the rhythm either by the healthcare providers involved in the case or by members of the study's Central Review or External Adjudication Panels. A case in which ICD therapy is present and the Intracardiac electrograms are no longer available for review will be considered to be definitely appropriate only if there is written documentation in the clinical notes by the healthcare provider involved in the case of having personally reviewed the electrograms and specific description of the standard criteria for defining ventricular tachyarrhythmias, such as sudden onset, morphology change, presence of AV dissociation, etc., are present.

Probably Appropriate ICD therapy	The Central Review and External Adjudication Panels will consider ICD therapy to be **Probably Appropriate** if: 1) in the clinical judgment of the healthcare provider/s caring for the patient, the episode was documented to be VT or VF (i.e., 'Appropriate'), but some of the diagnostic elements (i.e. intracardiac electrograms or detailed description of the standard criteria for defining VT or VF), are missing from the source documentation, preventing full confirmation by the review panel; AND, 2) in the judgment of the reviewers it is felt that the evidence available in the source documentation does not contradict the local interpretation. ICD therapy may also be classified as **Probably Appropriate** when: 1) the local clinical interpretation was classified as 'Uncertain' ([see definition of Local provider's impression…' in Table 1, above] i.e., documented as uncertain, missing, or otherwise uninformative); AND, 2) in the judgment of the reviewers, the source documentation is suggestive of clinical criteria for VT/VF, but does not meet the strict threshold for 'definitely appropriate', as described above.
Uncertain regarding appropriateness of ICD therapy	As is the case in clinical practice, the designation of **Uncertain** regarding the appropriateness of ICD therapy is to be **avoided** when classification is otherwise possible. Consistent with the criteria used to assign appropriateness of ICD therapy, the Central Review and External Adjudication Panels will consider appropriateness of ICD therapy to be **Uncertain** in cases in which the local clinical interpretation was classified as 'Uncertain' ([see definition of 'Local provider's impression…' in Table 1 above] i.e., documented as uncertain, missing, or otherwise uninformative) and there is not evidence to the contrary in the source documentation to make a determination in either direction. Appropriateness of therapy for an episode will also be recorded as **Uncertain** by reviewers when adequate source documentation is present to confirm that the rhythm should be considered Unclassified. Appropriateness of therapy for an episode will also be considered **Uncertain** by reviewers if the panel members can not reconcile differences in their classification assignment. Records where appropriateness is classified as Uncertain by one or both reviewers, or classified with differing levels of appropriateness will undergo a resolution review conference, with consultation between reviewers to pursue consensus where possible. If consensus can not be reached on a specific level of appropriateness, the episode will then retain an uncertain classification.

Probably Inappropriate ICD therapy	Reviewers will consider the ICD therapy to be **Probably Inappropriate** if: 1) in the clinical judgment of the healthcare providers involved in the case, the episode was documented to be due to a rhythm/reason other than VT or VF (i.e., 'Inappropriate'), but necessary diagnostic elements (e.g., review of the Intracardiac electrograms; or detailed description in the clinical note describing the absent elements of VT and/or VF; or an adequate description of device malfunction) are not available from the source documentation, preventing full confirmation by the review panel. [Standard elements of VT/VF that would be absent include sudden onset, morphology change, presence of AV dissociation, etc.]; AND, 2) in the judgment of the reviewers it is felt that the evidence available in the source documentation does not contradict the local interpretation. ICD therapy may also be classified as **Probably Inappropriate** when: 1) the local clinical interpretation was classified as 'Uncertain' ([see definition of 'Local provider's impression…' in Table 1, above] i.e., documented as uncertain, missing, or otherwise uninformative); AND, 2) in the judgment of the reviewers, the source documentation is sufficient to satisfy clinical criteria for rhythms/reasons other than VT/VF, but does not meet the strict threshold for 'definitely inappropriate', as described below.
Definitely Inappropriate ICD therapy	Reviewers will consider ICD therapy to be **Definitely Inappropriate** if intracardiac electrogram criteria are available and consistent with therapy for something other than ventricular arrhythmias. This requires direct review and confirmation of Intracardiac electrograms either by the healthcare providers involved in the case, or members of either the Central Review Panel or External Adjudication Committee. A case in which ICD therapy is present and the Intracardiac electrograms are no longer available for review will be considered to be definitely inappropriate only if there is written documentation in the clinical notes by the healthcare provider involved in the case of having personally reviewed the electrogram; and including either a specific description of the absent criteria which rule out ventricular tachyarrhythmia or adequate description of device malfunction as a cause of the inappropriate therapy.

Table 3. Episode Collection Criteria:

Number of collected episodes	A total of 10 treated episodes will be collected. Abstractors have been asked to include what are reported as aborted therapies, so that it may be determined by central review whether therapy was delivered or not. No more than three treated episodes will be collected from any given 24 hour period. This limits the collection of multiple episodes during a VT storm utilizing an accepted definition of "storm" (greater than 3 episodes of VT/VF detected in a 24 hour period). * Electrical storm in patients with transvenous implantable cardioverter-defibrillators: Incidence, management and prognostic implications. Credner SC, Klingenheben T, Mauss O, Sticherling C, Hohnloser SH. *J Am Coll Cardiol.* 1998;32(7):1909-15. Data collection will end at the identification of 10 treated episodes. However if all true treated episodes are determined to be appropriate or if all true treated episodes are determined to be inappropriate, additional episode retrieval may be requested from the site to support the planned 'time to first event' analyses for primary (appropriate therapy) and secondary (inappropriate therapy) end points.
Grouping Episodes	In circumstances where multiple episodes are present and the dictation note groups them together (i.e., they are not broken down into single isolated episodes) with no clear description of specific therapy or results of therapy, the correct choice will be 'Uncertain' for questions about Initial Type of Therapy, whether the episode included any shocks, the local provider interpretation, and the appropriateness of therapy. For the purpose of data collection and abstraction, if there are potentially multiple episodes on the same day or interrogation, but no specific times for each episode is listed, or if it is not clear that at least 3 of the episodes were treated in a 24 hour period (maximum number per 24 hours to be collected by study) then only one episode will be recorded for any given day.

ICD LONGITUDINAL STUDY – THERAPY COLLECTION
ICD THERAPY CENTRAL REVIEW FORM – Version 04/11/11
Central Review Panel to complete one form for each participant; attach additional pages as necessary

GREEN FOLDERS ONLY: Based on the information provided, did participant experience any treated episodes during the follow-up period? _____Yes _____No (Return folder w/form to Deb – ML3)

STUDY ID No. ________________
REVIEWER ID No. ______________

ALL OTHER FOLDERS COMPLETE ONE ROW FOR EACH *TREATED EPISODE COVER PAGE* INCLUDED

Box 1. Date of Interrogation	Box 2. Treated Episode #	Box 3. Date of Treated Episode	Box 4. Time of Treated Episode	Box 5. What was initial type of therapy for this episode?	Box 6. If initial type was **ATP or Uncertain**, did the episode include any Shocks?	Box 7. If initial type was **Shock**, did the episode include any additional Shocks?	Box 8. Local provider indicated therapy for this episode was:	Box 9. Was initial therapy for this episode appropriate?	Box 10. If **appr.**, was therapy for this episode successful ?	Box 11. If **inappr.**, initial therapy for this episode was due to:	Box 12. If **inappr.**, did initial therapy for this episode cause trauma and/or [illegible] requiring further therapy?	Box 13. Indicate the highest level for which sufficient documentation was available to evaluate appropriateness	Box 14. Notes:
___/___/___ mm/dd/yy Uncertain	_______ #	___/___/___ mm/dd/yy Uncertain	__ : ___ AM PM MT Uncertain	ATP Shock Uncertain Not a Treated Episode **Stop Row**	Yes, one Yes, multiple Yes, unsure if one or multiple No Uncertain	Yes No Uncertain	Appropriate Uncertain Inappropriate	Definitely Appropriate Probably Appropriate Uncertain Probably Inappropriate Definitely Inappropriate	Yes No Uncertain	SVT/AF Sensing Problem Other: Specify in notes Uncertain	Yes No Uncertain	Yes, by E-gram Yes, by other clinical features in description or report Yes, by local interpretation only No	________ ________ ________ ________ ________ ________ ________
___/___/___ mm/dd/yy Uncertain	_______ #	___/___/___ mm/dd/yy Uncertain	__ : ___ AM PM MT Uncertain	ATP Shock Uncertain Not a Treated Episode **Stop Row**	Yes, one Yes, multiple Yes, unsure if one or multiple No Uncertain	Yes No Uncertain	Appropriate Uncertain Inappropriate	Definitely Appropriate Probably Appropriate Uncertain Probably Inappropriate Definitely Inappropriate	Yes No Uncertain	SVT/AF Sensing Problem Other: Specify in notes Uncertain	Yes No Uncertain	Yes, by E-gram Yes, by other clinical features in description or report Yes, by local interpretation only No	________ ________ ________ ________ ________ ________ ________

Instructions for Completing ICD Therapy Central Review Form

The data you receive for review will have been reviewed for completeness using the quality assurance checklist process. If data are determined to be missing, additional information or clarification will be requested from the site prior to submission for central review. Once data and forms are submitted to reviewers, all available data and all resources will have been exhausted.

The form has been color-coded to assist you in completing required boxes determined by a specific answer. Please complete each box accordingly. Please write legibly. Forms will be returned to reviewer if not complete.

Fill in the Study ID No. This number has been prefilled. Compare this number to the number located on the chart tab and on the forms included in the chart to ensure correct form is being completed.

Fill in Reviewer ID No. Your reviewer ID number has been prefilled.
Dr. Romel Garcia-Montilla 113-A
Dr. John Hayes 113-B
Dr. Param Sharma 113-C
Mary Suits-113-D
Dr. Humberto Vidaillet 113-E
Dr. Paul Varosy 113-F (Marshfield cases only)

GREEN FOLDERS ONLY: Based on the information provided, did participant experience any treated episodes during the follow-up period? A portion of the subjects you will review are a sampling of those with no treated episodes. If you determine there were treated episodes, check *Yes* and complete remainder of the form. If you determine there were no treated episodes, check *No* and stop review.

Box 1-Date of Interrogation: Date of interrogation been prefilled.

Box 2-Treated episode number: Treated episode number has been prefilled.

Box 3-Date of treated episode: Date of treated episode has been prefilled.

Box 4-Time of treated episode: Time of treated episode has been prefilled.

Box 5-What was initial type of therapy for this episode?: Determine the initial type of therapy for this episode and circle the appropriate answer. If you determine that this is not a treated episode circle "Not a treated episode" and stop row. Remember to consider that some devices have ATP during or before charge and this should be considered when evaluating initial therapy.

Box 6-If initial type of therapy was ATP or Uncertain did the episode include any shocks?:
If you determined in Box 5 that initial type of therapy for this treated episode was ATP or Uncertain, complete this box. Circle "Yes-one" if only one shock was delivered. Circle "Yes-multiple" if there was more than one shock delivered. Circle "Yes-unsure if one or multiple" if you know shock was delivered but cannot determine how many were

delivered. Circle "No" if no shocks were delivered. Circle "Uncertain" if you cannot determine if there were any shocks delivered. Skip Box 7 and proceed to Box 8.

Box 7-If Initial type of therapy was Shock did the episode include any additional Shocks?: If you determined in Box 5 that initial type of therapy for this treated episode was "Shock", complete this box. Circle "Yes" if it is known that one or more additional shocks were given. Circle "No" if you determine that no additional shocks were delivered. Circle "Uncertain" if you cannot determine if additional shocks were delivered. Proceed to Box 8.

Box 8-Local provider indicated therapy for this episode was: Review the clinical notes and documentation provided to determine the local provider's interpretation of appropriateness of therapy for this episode and circle answer. Proceed to Box 9.

Box 9-Was initial therapy for this episode appropriate?: Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining appropriateness of therapy and circle answer. Proceed to Box 10 if "Definitely Appropriate" or "Probably Appropriate". Skip Box 10 and proceed to Box 11 if "Probably Inappropriate" or "Definitely Inappropriate". If you cannot make a determination of appropriateness, circle "Uncertain", skip Boxes 10, 11, and 12, and proceed to Box 13.

Box 10-If appropriate, was therapy for this episode successful?: If you determined in Box 9 that initial therapy was "Definitely Appropriate" or "Probably Appropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining if therapy was successful and circle appropriate answer. If you cannot make a determination of success, circle "Uncertain". Skip Boxes 11 and 12, and proceed to Box 13.

Box 11-If inappropriate, initial therapy for this episode was due to: If you determined in Box 9 that initial therapy for this episode was "Probably Inappropriate" or "Definitely Inappropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining the reason for the inappropriate therapy and circle "SVT/AF" or "Sensing Problem." If neither of these describes the cause, circle "Other" and also specify in the Notes the reason for the inappropriate therapy. If you are unable to determine the cause, circle "Uncertain." Proceed to Box 12.

Box 12-If inappropriate, did initial therapy for this episode cause an untoward rhythm requiring further therapy?: Circle answer using guidance from the *Glossary for Central Review and External Adjudication Panel* document. Proceed to Box 13.

Box 13- Indicate the highest level for which sufficient documentation was available to evaluate appropriateness: Answer this question based on the extent of documentation you had available to complete Box 9 (Was initial therapy for this episode appropriate?). Circle the appropriate answer, using a hierarchichal assignment. If the electrogram was available, please indicate this. If not, but there was specific description of the standard features of ventricular tachyarrhythmias, then please choose this level. If neither of the above were provided, but there was a local provider interpretation available, please indicate this. Chose 'No' if none of the above were available. Please note, under the existing definitions, it is possible for there to be some relevant source

information provided that could support a determination of 'probably appropriate' or 'probably inappropriate' in Box 9, but that does not meet the specific definitions of any of the 3 levels of this sufficiency variable resulting in a 'No'.

Box 14-Notes: Use this area to explain any qualifying information needed, as well as to specify the description of "Other" if used in Box 11 to define reason for inappropriate therapy.

Complete one form for each participant, starting a new row for each Treated Episode Cover Page included in chart. Use additional forms if necessary.

Return chart and form to Deb Multerer-ML3

ICD Longitudinal Study – Central Review Resolution Form

Directions: For each item below, examine the responses from both reviewers and note any discrepant responses. For each discrepant response, discuss it with the co-reviewer and determine a mutually agreeable response. Then in the last column, Combined Reviewer Response, select the resolved (final) response that best answers each item. Mark any unresolved items as "Not resolved" and enter further comments at the end of the form if necessary. Also, be sure to follow the appropriate skip patterns based on your resolved answer. Some cases will be automatically chosen for external review. If, however, you and the co-reviewer believe this case should be nominated for guaranteed external review, please indicate so in the space designated on page 2. Return this completed form to Deb Multerer, ML3.

STUDY ID #			
Date of Interrogation: Treated episode number: Date of treated episode: Time of treated episode:	REVIEWER #1 RESPONSES ID: NAME:	REVIEWER #2 RESPONSES ID: NAME:	COMBINED REVIEWER RESPONSE:
Box # **5.** What was the initial type of therapy for this episode?			❍ ATP *(go to box 6)* ❍ Shock *(→ skip to box 7)* ❍ Uncertain *(go to box 6)* ❍ Not treated *(Stop)* ❍ Not resolved Box 8
6. If initial type was **ATP or Uncertain,** did this episode include any shocks?			❍ Yes, one ❍ Yes, multiple ❍ Yes, but number unclear ❍ No ❍ Uncertain ❍ Not resolved *Go to box 8*
7. If initial type was **Shock,** did this episode include any additional shocks?			❍ Yes ❍ No ❍ Uncertain ❍ Not resolved *Go to box 8*
8. Local provider indicated therapy for this episode was:			❍ Appropriate ❍ Uncertain ❍ Inappropriate ❍ Not resolved *Go to Box 9*
9. Was initial therapy for this episode appropriate?			❍ Definitely appropriate *(go to box 10)* ❍ Probably appropriate *(go to box 10)* ❍ Uncertain *(→ skip to box 13)* ❍ Probably inappropriate *(→ skip to box 11)* ❍ Definitely inappropriate *(→ skip to box 11)* ❍ Not resolved

10.	If Appropriate, was the therapy for this episode successful?			❍ Yes ❍ No ❍ Uncertain ❍ Not resolved *Go to box 13*
11.	If Inappropriate, initial therapy for this episode was due to:			❍ SVT / AF ❍ Sensing problem ❍ Other: _____ _____ ❍ Uncertain ❍ Not resolved *Go to box 12*
12.	If Inappropriate, did initial therapy for this episode cause untoward rhythm requiring further therapy?			❍ Yes ❍ No ❍ Uncertain ❍ Not resolved *Go to box 13*
13.	Indicate the highest level for which sufficient documentation available to evaluate the appropriateness of this episode?			❍ Yes, by E-gram ❍ Yes, by other clinical report features ❍ Yes, by local interpretation only ❍ No sufficient documentation ❍ Not resolved
Should this case be "manually" nominated for external review? ❍ Yes ❍ No *Some cases will automatically be chosen for external review based on responses. Indicating "Yes" guarantees this record will go for external review.*				
	Other comments or concerns related to this episode?	_____ _____		

Instructions for Completing ICD Therapy Central Review Resolution Form

The Corresponding Reviewer is to discuss discrepancy(s) for each treated episode with the second assigned reviewer and provide resolution for each discrepancy listed. Responses from both reviewers have been provided. Complete each box with final answer in the Combined Reviewer response column. If unable to resolve discrepancy, mark Not resolved and enter comments below if necessary. Forms will be returned to reviewer #1 if not complete.

Study ID No., Date of Interrogation, Treated episode number, Date of treated episode and Time of treated episode information has been prefilled.

Box 5-What was initial type of therapy for this episode?: Determine the initial type of therapy for this episode and mark the appropriate answer. If you determine that this is not a treated episode mark "Not treated" and stop. Remember to consider that some devices have ATP during or before charge and this should be considered when evaluating initial therapy. If you are unable to resolve, mark "Not resolved" and proceed to Box 8.

Box 6-If initial type of therapy was ATP or Uncertain did the episode include any shocks?: If you determined in Box 5 that initial type of therapy for this treated episode was ATP or Uncertain, complete this box. Mark "Yes-one" if only one shock was delivered. Mark "Yes-multiple" if there was more than one shock delivered. Mark "Yes-unsure if one or multiple" if you know shock was delivered but cannot determine how many were delivered. Mark "No" if no shocks were delivered. Mark "Uncertain" if you cannot determine if there were any shocks delivered. If you are unable to resolve, mark "Not resolved." Skip Box 7 and proceed to Box 8.

Box 7-If Initial type of therapy was Shock did the episode include any additional Shocks?: If you determined in Box 5 that initial type of therapy for this treated episode was "Shock", complete this box. Mark "Yes" if it is known that one or more additional shocks were given. Mark "No" if you determine that no additional shocks were delivered. Mark "Uncertain" if you cannot determine if additional shocks were delivered. If you are unable to resolve, mark "Not resolved." Proceed to Box 8.

Box 8-Local provider indicated therapy for this episode was: Review the clinical notes and documentation provided to determine the local provider's interpretation of appropriateness of therapy for this episode and mark answer. If you are unable to resolve, mark "Not resolved." Proceed to Box 9.

Box 9-Was initial therapy for this episode appropriate?: Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining appropriateness of therapy and mark answer. Proceed to Box 10 if "Definitely Appropriate" or "Probably Appropriate". Skip Box 10 and proceed to Box 11 if "Probably Inappropriate" or "Definitely Inappropriate". If you cannot make a determination of appropriateness, mark "Uncertain." If you are unable to resolve, mark "Not resolved." Skip Boxes 10, 11, and 12, and proceed to Box 13.

Box 10-If appropriate, was therapy for this episode successful?: If you determined in Box 9 that initial therapy was "Definitely Appropriate" or "Probably Appropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in

determining if therapy was successful and mark appropriate answer. If you cannot make a determination of success, mark "Uncertain". If you are unable to resolve, mark "Not resolved." Skip Boxes 11 and 12, and proceed to Box 13.

Box 11-If inappropriate, initial therapy for this episode was due to: If you determined in Box 9 that initial therapy for this episode was "Probably Inappropriate" or "Definitely Inappropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining the reason for the inappropriate therapy and mark "SVT/AF" or "Sensing Problem." If neither of these describes the cause, mark "Other" and specify the reason for the inappropriate therapy. If you are unable to determine the cause, mark "Uncertain." If you are unable to resolve, mark "Not resolved." Proceed to Box 12.

Box 12-If inappropriate, did initial therapy for this episode cause an untoward rhythm requiring further therapy?: Mark answer using guidance from the *Glossary for Central Review and External Adjudication Panel* document. If you are unable to resolve, select "Not resolved." Proceed to Box 13

Box 13- Indicate the highest level for which sufficient documentation was available to evaluate appropriateness: Answer this question based on the extent of documentation you had available to complete Box 9 (Was initial therapy for this episode appropriate?). Mark the appropriate answer, using a hierarchical assignment. If the electrogram was available, please indicate this. If not, but there was specific description of the standard features of ventricular tachyarrhythmias, then please choose this level. If neither of the above was provided, but there was a local provider interpretation available, please indicate this. Chose 'No' if none of the above were available. Please note, under the existing definitions, it is possible for there to be some relevant source information provided that could support a determination of 'probably appropriate' or 'probably inappropriate' in Box 9, but that does not meet the specific definitions of any of the 3 levels of this sufficiency variable resulting in a 'No'. If you are unable to resolve, mark"Not resolved."

Should this case be "manually" nominated for external review?: Based on your resolution responses and the selection criteria for external adjudication this case may be selected for external review. However, if one or both reviewers feel it warrants special attention for some reason you can nominate this case to be automatically selected for external adjudication regardless of the selection criteria. Select Yes or No accordingly.

Form Resolution Comments: Enter any comments you feel are pertinent to the resolution of the chart.

Return chart and form to Deb Multerer-ML3

Instructions for Completing ICD Therapy Central Review Resolution Form

The Corresponding Reviewer is to discuss discrepancy(s) for each treated episode with the second assigned reviewer and provide resolution for each discrepancy listed. Responses from both reviewers have been provided. Complete each box with final answer in the Combined Reviewer response column. If unable to resolve discrepancy, mark Not resolved and enter comments below if necessary. Forms will be returned to reviewer #1 if not complete.

Study ID No., Date of Interrogation, Treated episode number, Date of treated episode and Time of treated episode information has been prefilled.

Box 5-What was initial type of therapy for this episode?: Determine the initial type of therapy for this episode and mark the appropriate answer. If you determine that this is not a treated episode mark "Not treated" and stop. Remember to consider that some devices have ATP during or before charge and this should be considered when evaluating initial therapy. If you are unable to resolve, mark "Not resolved" and proceed to Box 8.

Box 6-If initial type of therapy was ATP or Uncertain did the episode include any shocks?: If you determined in Box 5 that initial type of therapy for this treated episode was ATP or Uncertain, complete this box. Mark "Yes-one" if only one shock was delivered. Mark "Yes-multiple" if there was more than one shock delivered. Mark "Yes-unsure if one or multiple" if you know shock was delivered but cannot determine how many were delivered. Mark "No" if no shocks were delivered. Mark "Uncertain" if you cannot determine if there were any shocks delivered. If you are unable to resolve, mark "Not resolved." Skip Box 7 and proceed to Box 8.

Box 7-If Initial type of therapy was Shock did the episode include any additional Shocks?: If you determined in Box 5 that initial type of therapy for this treated episode was "Shock", complete this box. Mark "Yes" if it is known that one or more additional shocks were given. Mark "No" if you determine that no additional shocks were delivered. Mark "Uncertain" if you cannot determine if additional shocks were delivered. If you are unable to resolve, mark "Not resolved." Proceed to Box 8.

Box 8-Local provider indicated therapy for this episode was: Review the clinical notes and documentation provided to determine the local provider's interpretation of appropriateness of therapy for this episode and mark answer. If you are unable to resolve, mark "Not resolved." Proceed to Box 9.

Box 9-Was initial therapy for this episode appropriate?: Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining appropriateness of therapy and mark answer. Proceed to Box 10 if "Definitely Appropriate" or "Probably Appropriate". Skip Box 10 and proceed to Box 11 if "Probably Inappropriate" or "Definitely Inappropriate". If you cannot make a determination of appropriateness, mark "Uncertain." If you are unable to resolve, mark "Not resolved." Skip Boxes 10, 11, and 12, and proceed to Box 13.

Box 10-If appropriate, was therapy for this episode successful?: If you determined in Box 9 that initial therapy was "Definitely Appropriate" or "Probably Appropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in

determining if therapy was successful and mark appropriate answer. If you cannot make a determination of success, mark "Uncertain". If you are unable to resolve, mark "Not resolved." Skip Boxes 11 and 12, and proceed to Box 13.

Box 11-If inappropriate, initial therapy for this episode was due to: If you determined in Box 9 that initial therapy for this episode was "Probably Inappropriate" or "Definitely Inappropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining the reason for the inappropriate therapy and mark "SVT/AF" or "Sensing Problem." If neither of these describes the cause, mark "Other" and specify the reason for the inappropriate therapy. If you are unable to determine the cause, mark "Uncertain." If you are unable to resolve, mark "Not resolved." Proceed to Box 12.

Box 12-If inappropriate, did initial therapy for this episode cause an untoward rhythm requiring further therapy?: Mark answer using guidance from the *Glossary for Central Review and External Adjudication Panel* document. If you are unable to resolve, select "Not resolved." Proceed to Box 13

Box 13- Indicate the highest level for which sufficient documentation was available to evaluate appropriateness: Answer this question based on the extent of documentation you had available to complete Box 9 (Was initial therapy for this episode appropriate?). Mark the appropriate answer, using a hierarchical assignment. If the electrogram was available, please indicate this. If not, but there was specific description of the standard features of ventricular tachyarrhythmias, then please choose this level. If neither of the above was provided, but there was a local provider interpretation available, please indicate this. Chose 'No' if none of the above were available. Please note, under the existing definitions, it is possible for there to be some relevant source information provided that could support a determination of 'probably appropriate' or 'probably inappropriate' in Box 9, but that does not meet the specific definitions of any of the 3 levels of this sufficiency variable resulting in a 'No'. If you are unable to resolve, mark "Not resolved."

Should this case be "manually" nominated for external review?: Based on your resolution responses and the selection criteria for external adjudication this case may be selected for external review. However, if one or both reviewers feel it warrants special attention for some reason you can nominate this case to be automatically selected for external adjudication regardless of the selection criteria. Select Yes or No accordingly.

Form Resolution Comments: Enter any comments you feel are pertinent to the resolution of the chart.

Return chart and form to Deb Multerer-ML3

ICD LONGITUDINAL STUDY – THERAPY COLLECTION PILOT
ICD THERAPY EXTERNAL ADJUDICATION FORM – Version 04/11/2011

External Adjudication Panel Member to complete one form for each treated arrhythmic episode selected for adjudication. All dates have been redacted and episodes are identified only by treated episode number. When completing each form, verify the Study ID No. and Treated Episode No. match the information on the ICD Treated Episode Cover Page and its corresponding documentation. Some documentation may be shared between treated episodes if occurring within the same interrogation. A separate form should be completed for each treated episode. Please see Instructions for Completing ICD Therapy External Adjudication Form document to assist you in completing this form. Please see Glossary for Central Review and External Adjudication Panel document for definitions of terms.

STUDY ID No. _____ REVIEWER ID No. _____

TREATED EPISODE No. _____

Box 1. Time of Treated Episode	**Box 2.** What was initial type of therapy for this episode?	**Box 3.** If initial type was ATP or Uncertain, did the episode include any Shocks?	**Box 4.** If initial type was Shock, did the episode include any additional Shocks?	**Box 5.** Local provider indicated therapy for this episode was:	**Box 6.** Was initial therapy for this episode appropriate?	**Box 7.** If appropriate, was therapy for this episode successful?	**Box 8.** If inappropriate, initial therapy for this episode was due to:	**Box 9.** If inappropriate, did initial therapy for this episode cause underlying rhythm requiring further therapy?	**Box 10.** Indicate the highest level for which sufficient documentation was available to evaluate appropriateness	**Box 11.** Notes:
__ : __	ATP	Yes, one	Yes	Appropriate	Definitely Appropriate	Yes	SVT/AF	Yes	Yes, by E-gram	_____
AM										_____
PM	Shock	Yes, multiple	No	Uncertain		No	Sensing Problem	No	Yes, by other clinical features in description or report	_____
MT					Probably Appropriate					_____
Uncertain	Uncertain	Yes, unsure if one or multiple	Uncertain	Inappropriate		Uncertain	Other: (Specify in Notes)	Uncertain		_____
					Uncertain					_____
	Not a treated episode **(Stop Row)**	No					Uncertain		Yes, by local interpretation only	_____
					Probably Inappropriate					_____
		Uncertain							No	_____
					Definitely Inappropriate					_____
										_____

Return completed form to:
Deb Multerer
ICD Study Manager
Marshfield Clinic Research Foundation
1000 North Oak Avenue – ML3
Marshfield, WI 54449

Instructions for Completing ICD Therapy External Adjudication Form

The data you receive for review will have been reviewed for completeness using the quality assurance checklist process. If data are determined to be missing, additional information or clarification will be requested from the site prior to submission for central/external review. Once data and forms are submitted to reviewers, all available data and resources will have been exhausted.

The form has been color-coded to assist you in completing required boxes determined by a specific answer. Complete each box accordingly. Please write legibly. Forms will be returned to reviewer if not complete or legible.

Study ID No., **Treated Episode No.** and your **Reviewer ID No.** will be prefilled. Please verify this information matches the documentation you are reviewing. All dates have been redacted and episodes are identified only by treated episode number.

Box 1-Time of treated episode: Enter time of treated episode from line item 6 on Treated Episode Cover Page. Circle "AM", "PM" or "MT" if available. If time is not able to be determined at all, circle "Uncertain".

Box 2-What was initial type of therapy for this episode?: Determine the initial type of therapy for this episode and circle the appropriate answer. If you determine that this is not a treated episode circle "Not a treated episode" and stop row. Remember to consider that some devices incorporate ATP during or before charge and this should be considered when evaluating initial therapy.

Box 3-If initial type of therapy was ATP or Uncertain did the episode include any shocks?: If you determined in Box 2 that initial type of therapy for this treated episode was "ATP" or "Uncertain", complete this box. Circle "Yes-one" if only one shock was delivered. Circle "Yes-multiple" if there was more than one shock delivered. Circle "Yes-unsure if one or multiple" if you know shock was delivered but cannot determine how many were delivered. Circle "No" if no shocks were delivered. Circle "Uncertain" if you cannot determine if there were any shocks delivered. Skip Box 4 and proceed to Box 5.

Box 4-If Initial type was Shock did the episode include any additional Shocks?: If you determined in Box 2 that initial type of therapy for this treated episode was "Shock", complete this box. Circle "Yes" if it is known that one or more additional shocks were given. Circle "No" if you determine that no additional shocks were delivered. Circle "Uncertain" if you cannot determine if additional shocks were delivered. Proceed to Box 5.

Box 5-Local provider indicated therapy for this episode was: Review the clinical notes and documentation provided to determine the local provider's interpretation of appropriateness of therapy for this episode and circle answer. Circle 'Uncertain' if the local provider's impression is itself recorded as 'Uncertain', or if the local impression is missing from the source documentation or otherwise not informative. Proceed to Box 6.

Box 6-Was initial therapy for this episode appropriate?: Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining appropriateness of therapy and circle answer. Then proceed to Box 7 if "Definitely Appropriate" or "Probably Appropriate". Or, skip Box 7 and proceed to Box 8 if "Probably Inappropriate" or "Definitely

Inappropriate". If you can not make a determination of appropriateness, circle "Uncertain", skip Boxes 7, 8, and 9, and proceed to Box 10.

Box 7-If appropriate, was therapy for this episode successful?: If you determined in Box 6 that initial therapy was "Definitely Appropriate" or "Probably Appropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining if therapy was successful and circle appropriate answer. If you can not make a determination of success, circle "Uncertain". Skip Boxes 8 and 9, and proceed to Box 10.

Box 8-If inappropriate, initial therapy for this episode was due to: If you determined in Box 6 that initial therapy for this episode was "Probably Inappropriate" or "Definitely Inappropriate", complete this box. Use the *Glossary for Central Review and External Adjudication Panel* to assist you in determining the reason for the inappropriate therapy and circle "SVT/AF" or "Sensing Problem." If neither of these describes the cause, circle "Other" and specify in the Notes the reason for the inappropriate therapy. If you are unable to determine the cause, circle "Uncertain." Proceed to Box 9.

Box 9-If inappropriate, did initial therapy for this episode cause an untoward rhythm requiring further therapy?: Circle answer using guidance from the *Glossary for Central Review and External Adjudication Panel* document. Proceed to Box 10.

Box 10- Indicate the highest level for which sufficient documentation was available to evaluate appropriateness: Answer this question based on the extent of documentation you had available to complete Box 6 (Was initial therapy for this episode appropriate?). Circle the appropriate answer, using a hierarchichal assignment. If the electrogram was available, please indicate this. If not, but there was specific description of the standard features of ventricular tachyarrhythmias, then please choose this level. If neither of the above were provided, but there was a local provider interpretation available, please indicate this. Choose 'No' if none of the above were available. Please note, under the existing definitions, it is possible for there to be some relevant source information provided that could support a determination of 'probably appropriate' or 'probably inappropriate' in Box 6, but that does not meet the specific definitions of any of the 3 levels of this sufficiency variable resulting in a 'No'.

Box 11-Notes: Use this area to explain any qualifying information needed, as well as to specify the description of "Other" if used in Box 8 to define reason for inappropriate therapy.

Return form to:
Deb Multerer
ICD Study Manager
Marshfield Clinic Research Foundation
1000 N Oak Ave – ML3
Marshfield, WI 54449

ICD Longitudinal Study – External Review Resolution Form

Directions: For each item below, examine the responses from both reviewers and note any discrepant responses. For any discrepant items, discuss it with the co-reviewer and determine a mutually agreeable response. The third reviewer has the source documentation to provide additional input should it be needed. Marshfield staff will record the combined reviewer response at the time of the resolution conference call.

STUDY ID # : 10200007			
Treated episode number: Time of treated episode:	REVIEWER #1 RESPONSES ID: NAME:	REVIEWER #2 RESPONSES ID: NAME:	COMBINED REVIEWER RESPONSE:
Box # **2.** What was the initial type of therapy for this episode?			❍ ATP *(go to box 3)* ❍ Shock *(→ skip to box 4)* ❍ Uncertain *(go to box 3)* ❍ Not treated *(Stop)*
3. If initial type was **ATP or Uncertain,** did this episode include any shocks?			❍ Yes, one ❍ Yes, multiple ❍ Yes, but number unclear ❍ No ❍ Uncertain *Go to box 5*
4. If initial type was **Shock,** did this episode include any additional shocks?			❍ Yes ❍ No ❍ Uncertain *Go to box 5*
5. Local provider indicated therapy for this episode was:			❍ Appropriate ❍ Uncertain ❍ Inappropriate *Go to box 6*
6. Was initial therapy for this episode appropriate?			❍ Definitely appropriate *(Go to box 7)* ❍ Probably appropriate *(Go to box 7)* ❍ Uncertain *(→ skip to box 10)* ❍ Probably inappropriate *(→ skip to box 8)* ❍ Definitely inappropriate *(→ skip to box 8)*
7. If Appropriate, was the therapy for this episode successful?			❍ Yes ❍ No ❍ Uncertain *Go to box 10*
8. If Inappropriate, initial therapy for this episode was due to:			❍ SVT / AF ❍ Sensing problem ❍ Other: _____ _____ ❍ Uncertain *Go to box 9*

9.	If Inappropriate, did initial therapy for this episode cause untoward rhythm requiring further therapy?			❍ Yes ❍ No ❍ Uncertain *Go to box 10*
10.	Indicate the highest level for which sufficient documentation available to evaluate the appropriateness of this episode?			❍ Yes, by E-gram ❍ Yes, by other clinical report features ❍ Yes, by local interpretation only ❍ No sufficient documentation
11.	Notes:	_____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____

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Appendix G: Abstraction/Adjudication Processes

- Description

- Data Flow Diagram

Appendix: LCISD Abstraction/Adjudication Processes

Abstraction Procedures

Medical records abstractors from each site receive training in study data collection procedures from the central coordination team, including the therapy collection coordinator, the study's ICD nurse, and electrophysiologists from the review and adjudication panels. General support and guidance from local site electrophysiology and ICD clinic staff is fostered to assure abstractor understanding of local clinical processes and access to local clinical data archives. The stated goal of therapy abstraction is to account for and record any ICD interrogations during the participants' follow-up periods, identify the presence of any treated arrhythmic episodes, and collect copies of pertinent source documentation, including interrogation reports with intracardiac electrograms and clinical notes with local provider interpretation.

Medical records for each study subject are targeted for abstraction after they accrue 3 years of follow-up, or sooner if their follow-up was truncated by a known death. Before abstraction, a distributed data management program prefills portions of the abstraction forms for each subject with selected data elements from the NCDR and VDW data files, including date of implant, device type, and dates of CPT 4 procedure codes for device interrogations, hospitalizations, and emergency room visits. Record review, however, is not limited to searching on those pre-printed dates. Aspects of medical records targeted to comprehensively capture interrogations and therapies include: ICD clinic appointment schedules, flow sheets, and arrhythmia clinical management systems; paper, electronic, and remotely archived ICD interrogation records; electronic medical records, including operative reports, history and physical reports, emergency room notes, hospital progress

notes, relevant cardiology consult notes, and discharge/expiration summaries. Following ER visits or hospitalizations, abstractors are instructed to evaluate the next clinic visit to the participant's regular device follow-up provider, and examine whether any information was recorded that suggests the device had been interrogated or that they had a treated arrhythmic episode since the previous device check. Direct review of hospital/ER records may also be needed to complete this evaluation. Abstractors are asked to provide a censoring date if they discover through medical record review that the subject could not be followed for the full 3 year period due to death, transfer of ICD care outside the health system, or if the device was explanted or permanently turned off.

Copies of relevant source documentation requested for all study subjects include the surgical implant note plus the device report and clinical note from the interrogation which covers the end of the subject's follow-up period. In addition, a copy of the device report with intracardiac electrograms, and any relevant clinical notes are requested for each treated arrhythmic episode. No more than three treated episodes are to be collected from any given 24 hour period, which will limit the influence of episodes that may represent a VT 'storm'. Because the marginal utility for the primary aims of the study diminishes with larger numbers of treated arrhythmic episodes per subject, the abstractors were also instructed to truncate collection after the 10^{th} treated arrhythmic episode for each subject. Records indicating the presence of diverted shocks are also to be collected if there is any suggestion that the episode may have included delivery of an anti-tachycardia pacing therapy during charge.

Upon receipt of submitted forms and source documentation at the therapy data coordinating center, the record for each subject undergoes a quality edit review. Missing

or unclear information in the abstraction results in a Request for Additional Documentation, which is then investigated at the site and returned. Abstractors are expected to explain any gaps between interrogations of greater than 6 months, as well as to identify any identified gaps in follow-up coverage based on observed dates of interrogation periods.

Review/Adjudication Procedures

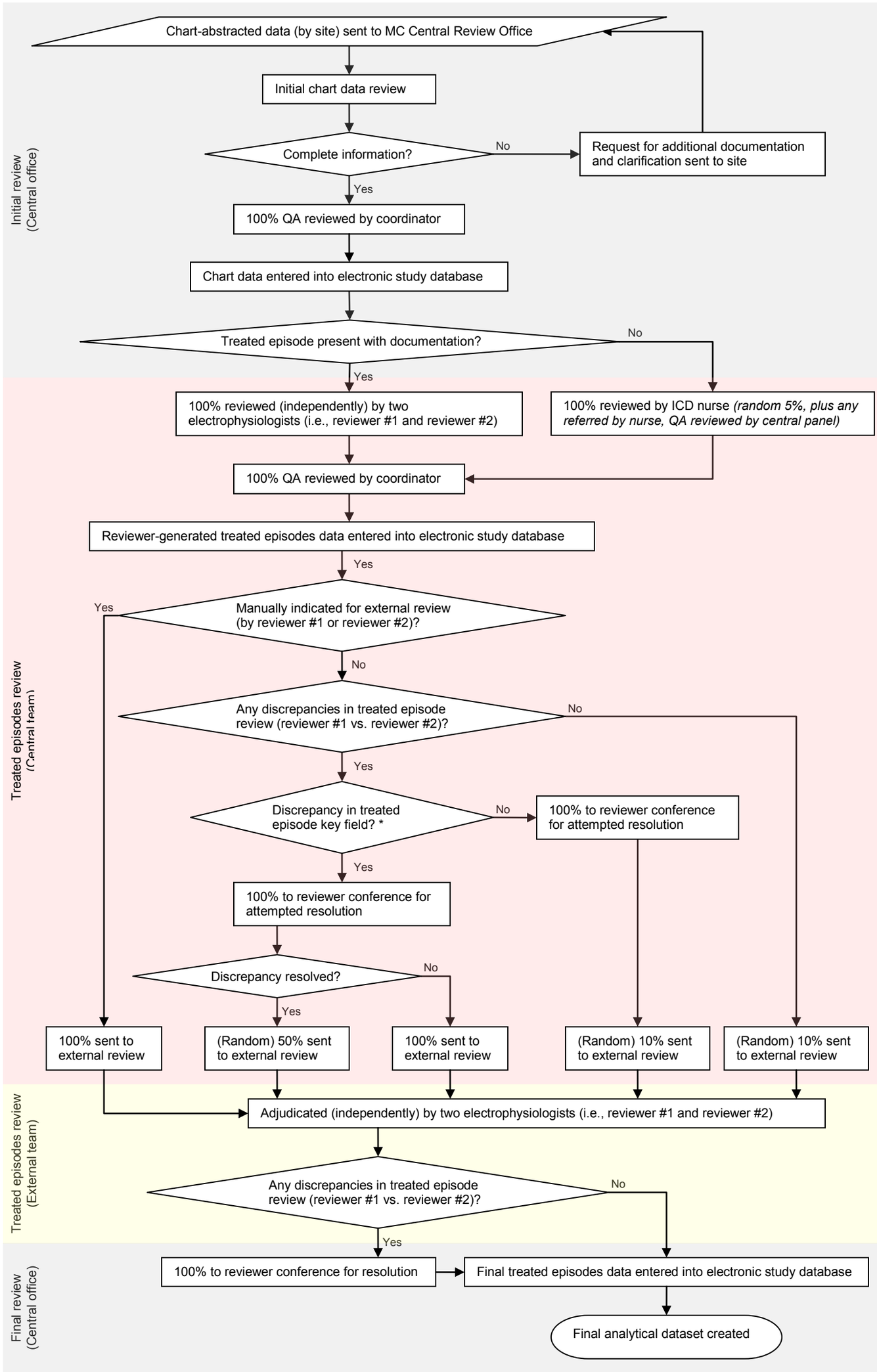
Every subject will undergo central clinical review. Records for subjects with any suspected treated episodes that have available clinical documentation will be reviewed independently by two randomly selected members of the Central Clinical Review panel. The panel consists of 4 Marshfield Clinic physicians (3 board-certified electrophysiologists and 1 hospitalist) with expertise in interpreting ICD device reports and clinical records. Records for subjects with suspected treated episodes that have only the local provider interpretation and no clinical documentation will be reviewed by the ICD Study nurse, with 5% randomly selected and any questionable records directly referred for blinded review by the Central Review Panel. Records for subjects with no suspected treated episodes following abstraction and intake quality check will be reviewed by the study manager and the study ICD Nurse, with 5% randomly selected for blinded Quality Review by the Central Review Panel. While the central review records will contain no direct identifiers, a sample of records for subjects cared for at Marshfield Clinic will undergo additional external review for quality assurance.

The purpose of the Central review is to generate key study variables for each treated arrhythmic episode from the clinical perspective. The review follows a Glossary and Review Procedures document based on literature sources and finalized through extensive

discussion of the expert panel members. Reviewers will confirm or refute the occurrence of a treated episode, verify the episode's date and time, determine the initial type of therapy, determine whether there were multiple therapies present, document the local provider interpretation of the episode, record the appropriateness of therapy, and evaluate the success of appropriate therapy or the presence of untoward arrhythmic effects of inappropriate therapies. Reviewers will also record the extent of source documentation available for each episode. An attempt to resolve discrepancies between independent reviews will occur via dialog or arbitration within the central panel membership.

A separate panel of 3 expert electrophysiologists will provide external adjudication of treated arrhythmic episodes. Selection of treated episodes for external review will include treated episodes with discrepancies that could not be resolved by the Central panelists, a large sample of treated episodes with resolved discrepancies, and a small sample of episodes without discrepancies for quality assurance. Central review members also can nominate any treated episode for external review. The external process will include independent reviews of 2 randomly selected panelists, with the third reviewer held in reserve for 3-way conference or final arbitration as needed on any disagreements. For treated episode records selected for external adjudication, the external panel's submitted findings will be final. Following completion of the review process, subjects whose abstraction was truncated after 10 treated episodes before the end of their 3-year follow-up period, and who did not have at least one appropriate and one inappropriate therapy recorded, will be cycled back to the site abstractors to complete the full 3 years of collection.

Appendix: General processes of data abstraction, review, and quality assurance in the LSICD.



ICD = Implantable Cardiac Defibrillator; MC = Marshfield Clinic; QA = quality assurance

* Key fields include (local) indication for, appropriateness of, outcome of, and/or sufficiency of treated episode. In addition, a discrepancy was also considered if the local provider indicated therapy for the treated episode was appropriate or inappropriate, while the central reviewer indicated therapy for the treated episode was uncertain.

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APPENDIX H: LSICD Therapy Collection Pilot, Selected Results

Selected Results among subjects, N=43

Prior Implant	Number	Percent
Yes	1	2.3
No	42	97.7
Follow up censored before anticipated end date*		
Yes	6	14.0
No	37	86.0
Surgical note documentation available		
Yes	40	93.0
No	3	7.0
Last interrogation documentation available		
Yes	35	81.4
No	8	18.6

* the earlier of 3 years post-implant or electronically documented date of death

Selected Results among treated episodes, N=162

	Number	Percent
Range per subject with treated episodes	1 to 36	
Date and time reported	162	100.0
Reported as missing electrograms	52	32.0
Reported as missing interrogation report	40	25.0
Reported as missing clinical interpretation	18	11.0
Reported as missing all source documentation	1	0.6

Numbers of interrogations

Total	**493**
Per Subject	
Mean	**11.5**
Median	**12**
Interquartile range	**8-13**
Range	**0-52**

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APPENDIX J
CVRN LONGITUDINAL STUDY OF ICDs
INVESTIGATIVE TEAM

KPCO: Frederick Masoudi MD (co-PI), David Magid MD, Karen Glenn BS, Nathaniel Jackson MS, Laura Muhs, Heather Nuanes, Pamela Peterson MD, Liza Reifler MPH, Paul Varosy MD

KPNC: Alan Go MD, Jason J. Dea, Dongjie Fan, MSPH, Michael Lauer, MD PhD, Liliana V. Metzger, Nina Sasso, Kiranjit Sidhu, Sue Hee Sung, MPH

KPNW: David Smith RPh, PhD, Jill Mesa, Amanda Petrik, Carmel Wax

KPSC: Kristi Reynolds PhD MPH, Britta Amundsen, MA, Jonathan Doris MD, Nigel Gupta, MD, Teresa Harrison SM, Jacqueline Porcel, MPH, Tony Yiu, MS

Marshfield Clinic Research Foundation/ Marshfield Clinic: Robert Greenlee PhD, MPH (co-PI), Marilyn Bruger, Jay Fuehrer, Romel Garcia-Montilla MD, John Hayes, MD, Aaron Miller PhD, Deborah Multerer, Param Sharma MD, Mary Suits RN, Jeff Van Wormer PhD, Humberto Vidaillet MD

Meyers Fallon: Jerry Gurwitz, MD, Robert J. Goldberg, PhD, Jane S. Saczynski, PhD, Jackie Fuller, Mark Mooradian

Henry Ford Health System: Andrea Cassidy-Bushrow PhD, Claudio Schuger MD, Dayna Johnson, MPH, Richard Krajenta, BS, Michelle Brown, RN, Debra Veryser, BA, RHIT, Judith Lehman RN, Claire Hooker, Heather Dakki MPH

Mayo Clinic: Stephen Hammill, MD

Touro College: Alan Kadish, MD