

**TWIST-EFS (2024-13)**

**TABLE SHELLS FOR DSMB**

|  |  |
| --- | --- |
| Protocol Title: | Transcatheter Mitral Valve Replacement with the INNOVALVE System Trial – Early Feasibility Study |
| Protocol Number: | 2024-13, Revision B |
| Shell Version: | 1.0 |
| Date: | July XX, 2025 |
| Author: | Luke Hall, Isabelle Weir |

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# TABLES

## Table 1 Enrollment by Site

**Enrolled/Implanted Population (N=xx)**

| **Site Number** | **Site Name** | **Enrolled1**  **(N=xx)** | **Implanted2**  **(N=xx)** |
| --- | --- | --- | --- |
| xx | xxxxxxxx | x/xx (xx.x%) | x/xx (xx.x%) |
| xx | xxxxxxxx | x/xx (xx.x%) | x/xx (xx.x%) |
| xx | xxxxxxxx | x/xx (xx.x%) | x/xx (xx.x%) |
| [1] Enrolled: A patient is considered enrolled if they have signed informed consent and have the study procedure attempted (defined as introduction of the investigational delivery system into the patient).  [2] Implanted: A patient is considered implanted if they have undergone the study procedure and leave the operating room with the study valve in place.  Categorical measures: %  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | |

*Programming Note: Sort by highest enrolling site*

## Table 2 Patient Disposition & Follow-up Visit Compliance by Interval

**Enrolled Population (N=xx)**

| **Patient Status at Follow-Up** | **Patient Count** | | | |
| --- | --- | --- | --- | --- |
| **30 Days** | **6 Months** | **1 Year** | **2 Years** |
| Eligible for Visit¹ | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Visit Completed within Window2 | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Visit Completed Outside Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Reason Visit Not Performed (Reasons Below) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Pending Visit Within Visit Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Missed Visit (Past Window) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Died Within Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Withdrew within Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Lost to Follow-Up Within Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Ineligible for Visit | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Visit Not Due | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Died Before Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Withdrew before Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Lost to Follow-Up Before Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Exited for Other Reason Before Window | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| [1] Patients are eligible if they complete the visit or their visit window is open and prior to FU visit window , they (a) are alive , (b) are not explanted,  (c) did not withdraw from study,  (d) are not lost to FU  [2] Specify the visit window: 30 Days FU window (23-37 days), 6 FU window (166-194 days), 1 year FU window (335-390 days)  Categorical measures: % (n/Total N) Source: program name.sas  Extract Date: DDMMMYYYY  Run Date (Time): DDMMMYYYY (hh:mm) | | | | |

## Table 3 Demographics and Baseline Characteristics

**Enrolled Population (N=xx)**

| **Baseline Characteristic** | **Total** |
| --- | --- |
| Age (Years) | xx.x ± x.xx (n)  xx.x (xx, xx) |
| Sex at Birth  Female  Male | x/xx (xx.x%)  x/xx (xx.x%) |
| Body Mass Index (kg/m²) | xx.x ± x.xx (n)  xx.x (xx.x, xx.x) |
| NYHA Class  Class I  Class II  Class III  Class IV | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) |
| LVEF (TTE) (%) | xx.x ± x.xx (n)  xx.x (xx.x, xx.x) |
| STS Score for MR Replacement | xx.x ± x.xx (n)  xx.x (xx.x, xx.x) |
| EuroSCORE II | xx.x ± x.xx (n)  xx.x (xx.x, xx.x) |
| CAD | x/xx (xx.x%) |
| MI | x/xx (xx.x%) |
| Stroke | x/xx (xx.x%) |
| Atrial Fibrillation | x/xx (xx.x%) |
| PPM | x/xx (xx.x%) |
| PCI | x/xx (xx.x%) |
| CABG | x/xx (xx.x%) |
| Pulmonary hypertension | x/xx (xx.x%) |
| COPD | x/xx (xx.x%) |
| Chronic kidney disease | x/xx (xx.x%) |
| Cancer | x/xx (xx.x%) |
| Continuous variables: Mean ± SD (n); Median (min, max)  Categorical measures: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | |

## Table 4 Device Success at exit from OR/Cath Lab (per Device Analysis)

**Enrolled Population (N=xx)**

| **Variable** | **Summary Statistics** |
| --- | --- |
| Device Success1 | x/xx (xx.x%)  [xx%, xx%] |
| Device deployed as intended | x/xx (xx.x%)  [xx%, xx%] |
| Delivery System Successfully Retrieved as Intended | x/xx (xx.x%)  [xx%, xx%] |
| [1] Device Success: Device is deployed as intended and the delivery system is successfully retrieved as intended at the time of the patient’s exit from the cardiac catheterization laboratory.  Categorical variables: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | |

## Table 5 Procedural Success at Discharge (Per Patient Analysis)

**Implanted Population (N=xx)**

| **Variable** | **Summary Statistics** |
| --- | --- |
| Procedural Success1 | x/xx (xx.x%)  [xx%, xx%] |
| Device Success | x/xx (xx.x%)  [xx%, xx%] |
| No clinically significant paravalvular leak on TTE at time of Discharge | x/xx (xx.x%)  [xx%, xx%] |
| [1] Procedural Success: Device success without significant paravalvular leak (PVL) on a TTE [greater than mild (1+) paravalvular regurgitation as assessed by the echo core lab).  Categorical variables: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | |

## Table 6 Clinical Success at 30 days (Per Patient Analysis)

**Implanted Population (N=xx)**

| **Variable** | **Summary Statistics** |
| --- | --- |
| Clinical Success1 | x/xx (xx.x%)  [xx%, xx%] |
| Procedural Success | x/xx (xx.x%)  [xx%, xx%] |
| No MAEs at 30 Days2 | x/xx (xx.x%)  [xx%, xx%] |
| [1] Clinical Success: Procedural success without MAEs at 30 days  Categorical variables: % (n/Total N)  Source: program name.sas  Extract Date: DDMMMYYYY  Run Date (Time): DDMMMYYYY (hh:mm) | |

## Table 7 MR Grade Reduction at 30 days (Per Patient Analysis)

**Implanted Population (N=xx)**

| **Variable** | **Summary Statistics** |
| --- | --- |
| MR < 2+ as measured by TTE1 | x/xx (xx.x%)  [xx%, xx%] |
| [1] MR Grade Reduction: MR <2+ at 30 days as measured by TTE.  Categorical variables: % (n/Total N)  Source: program name.sas  Extract Date: DDMMMYYYY  Run Date (Time): DDMMMYYYY (hh:mm) | |

## Table 8 CEC Adjudicated Major Adverse Events (MAEs) at 30 days (Safety Endpoint)

**Enrolled Population (N=xx)**

| **Variable** | **30 Days** | |
| --- | --- | --- |
| **No. Events** | **Patients** |
| **Composite MAE** | x | x/xx (xx.x%) |
| All-cause death | x | x/xx (xx.x%) |
| Stroke | x | x/xx (xx.x%) |
| Myocardial infraction (MI) | x | x/xx (xx.x%) |
| All-cause Hospitalization | x | x/xx (xx.x%) |
| Durable LVAD implant | x | x/xx (xx.x%) |
| Heart transplant | x | x/xx (xx.x%) |
| Renal complications requiring unplanned dialysis or renal replacement therapy | x | x/xx (xx.x%) |
| Severe bleeding1 | x | x/xx (xx.x%) |
| Non-elective mitral valve re-intervention, percutaneous or surgical | x | x/xx (xx.x%) |
| Major access site and vascular complications | x | x/xx (xx.x%) |
| Major cardiac structural complications | x | x/xx (xx.x%) |
| Device embolization | x | x/xx (xx.x%) |
| [1] Includes fatal, life-threatening, extensive or major bleeding as defined by MVARC  Categorical variables: % (n/Total N)  Source: program name.sas  Extract Date: DDMMMYYYY  Run Date (Time): DDMMMYYYY (hh:mm) | | |

*Programming Notes: 30 days (0-30 days)*

## Table 9 CEC adjudicated Major Adverse Events

**Enrolled Population (N=xx)**

| **Variable** | **6 months** | | **1 year** | | **2 years** | |
| --- | --- | --- | --- | --- | --- | --- |
| **No. Events** | **Patients** | **No. Events** | **Patients** | **No. Events** | **Patients** |
| **Composite MAE** | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| All-cause death | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Disabling stroke | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Myocardial infraction (MI) | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| All-cause Hospitalization | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Durable LVAD implant | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Heart transplant | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Renal complications requiring unplanned dialysis or renal replacement therapy | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Severe bleeding1 | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Non-elective mitral valve re-intervention, percutaneous or surgical | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Major access site and vascular complications | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Major cardiac structural complications | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Device embolization | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| [1] Includes fatal, life-threatening, extensive or major bleeding as defined by MVARC  Categorical variables: % (n/Total N)  Source: program name.sas  Extract Date: DDMMMYYYY  Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

*Programming Notes: 6 months (0-180 days), and 1 year (0-365 days).*

## Table 10 CEC Adjudicated Deaths

**Enrolled Population (N=xx)**

| **Category** | **Early Events (≤ 30 Days)** | **Late Events (> 30 Days to 1 Year)** | **Total Events** |
| --- | --- | --- | --- |
| **All** | **All** | **All** |
| All-Cause | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Cardiovascular | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Non-cardiovascular | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Categorical measures: %  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | |

## Table 11 CEC Adjudicated Heart Failure Hospitalizations and Non-elective Mitral Valve Reinterventions

**Enrolled Population (N=xx)**

| **Category** | **Early Events (≤ 30 Days)** | | **Late Events (> 30 Days to 1 Year)** | | **Total Events** | |
| --- | --- | --- | --- | --- | --- | --- |
| **No. Events** | **Patients** | **No. Events** | **Patients** | **No. Events** | **Patients** |
| Heart Failure Hospitalization | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Non-elective mitral valve re-intervention, percutaneous or surgical | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Categorical measures: %  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

## Table 12 Site Reported SAEs

**Enrolled Population (N=xx)**

| **MedDRA HLGT/PT** | **Early Events (≤ 30 Days)** | | **Late Events (> 30 Days to 1 Year)** | | **Total Events** | |
| --- | --- | --- | --- | --- | --- | --- |
| **No. Events** | **Patients %(n/N)** | **No. Events** | **Patients %(n/N)** | **No. Events** | **Patients %(n/N)** |
| xxxx | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| xxxxx | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| xxxxx | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| xxxxxxxxx | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| xxxxxxx | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Total | x | x/xx (xx.x%) | x | x/xx (xx.x%) | x | x/xx (xx.x%) |
| Categorical measures: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

## Table 13 NYHA Class: Unpaired Analysis

Implanted Population (N=xx)

| **NYHA Class** | **Baseline** | **30 Days** | **6 Months** | **1 Year** |
| --- | --- | --- | --- | --- |
| Class I | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Class II | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Class III | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Class IV | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Categorical measures: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | |

## Table 14 MR Grade by Core Lab TTE: Unpaired Analysis

**Implanted Population (N=xx)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Mitral Regurgitation** | **Baseline** | **Discharge1** | **30 Days** | **6 Months** | **1 Year** | **……** |
| None / Trace | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| Mild | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| Mild-Moderate | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| Moderate-Severe | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| Severe | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| Non-evaluable | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |  |
| [1]Discharge or Day 7 whichever occurs first  Categorical measures: % (n/Total N)  Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

## Table 15 Transthoracic Echocardiogram (TTE) by Core Lab – Unpaired Analysis-Mitral

**Enrolled Population (N=xx)**

| **Echo TTE Variable** | **Baseline** | **Discharge1** | **30 Days** | **6 months** | **1 year** |
| --- | --- | --- | --- | --- | --- |
| Follow Up TTE Completed2 | NA | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| LA Volume | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| LVEDD (mm) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| LVESD (mm) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| LVEDV (ml) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| LVESV (ml) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Ejection Fraction (%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Transmitral Antegrade Peak Gradient (mmHg) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Transmitral Antegrade Mean gradient (mmHg) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Transvalvular MR  None/Trace  Mild  Mild-Moderate  Moderate-Severe  Severe |  | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) |
| Paravalvular MR  None/Trace  Mild  Mild-Moderate  Moderate-Severe  Severe |  | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) |
| Cumulative MR  None/Trace  Mild  Mild-Moderate  Moderate-Severe  Severe | x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%)  x/xx (xx.x%) |  |  |  |  |
| Clinically significant paravalvular leak | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Device Migration | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Device Embolization | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Device Thrombus3 | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Device Malposition | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| Significant LVOT Obstruction4 | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) | x/xx (xx.x%) |
| [1] Discharge or Day 7 whichever occurs first  [2] Denominator for TTE Completed should be the patients who have had the respective FU visit  [3] Device thrombosis: Any thrombus attached to or near an implanted valve AND increase in mean MV gradient ≥ 5 mmHg when compared to echocardiographic assessment performed at discharge as assessed by the echo core laboratory  [4] LVOT Obstruction (MVARC, ACC/AHA and Sponsor Definition) ≥10 mmHg increase in LVOT peak gradient attributable to TMVR\* as compared to baseline assessment, resulting in peak LVOT gradient ≥ 30 mmHg. \*Sub-aortic gradients may occur at various levels and may also be influenced by day-to-day activities, including diet and medications. It is important to consider all attributable factors associated with increased myocardial contractility, decreased ventricular volume, or decreased afterload.  Continuous variables: Mean ± SD (n); Median (min, max); [95% CI by normal approximation]  Categorical measures: % (n/Total N)  Source: program name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | |

# LISTINGS

**Listing 1 Site Reported SAE**

**Enrolled Population (N=xx)**

| **Patient ID** | **AE Number** | **Days Post Procedure** | **MedDRA HLGT** | **MedDRA PT** | **Relationship to the Study Device** | **Relationship to the to Study Procedure** |
| --- | --- | --- | --- | --- | --- | --- |
| xxxxxx | xxxx | xx | xxxxx | xxxx | Not related | Not related |
|  |  |  |  |  | Unlikely related | Unlikely related |
|  |  |  |  |  | Possibly related | Possibly related |
|  |  |  |  |  | Probably related | Probably related |
|  |  |  |  |  | Related (causal relationship) | Related (causal relationship) |
| Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

**Listing 2 CEC Adjudicated Deaths**

**Enrolled Population (N=xx)**

| **Patient ID** | **Days Post Procedure** | **Categorical Cause of Death** | **If cardiovascular, primary reason** | **Relationship to the Study Device** | **Relationship to the Study Procedure** |
| --- | --- | --- | --- | --- | --- |
| xxxxxxxxxx | xx | xx | Cardiovascular (CV) | xxx | Not related |
| xxxxxxxxxx | xx | xx | Non-cardiovascular (Non-CV) | xxx | Unlikely related |
|  |  |  |  |  | Possibly related |
|  |  |  |  |  | Probably related |
|  |  |  |  |  | Related (causal relationship) |
|  |  |  |  |  |  |
| ………….. |  |  |  |  |  |
| Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | |

**Listing 3 Site Reported Death**

**Enrolled Population (N=xx)**

| **Patient ID** | **AE #** | **Days Post Procedure** | **Categorical Cause of Death** | **Primary Reason of death** | **Relationship to Device** | **Relationship to Study Procedure** |
| --- | --- | --- | --- | --- | --- | --- |
| xxxxxxxxxx | xx | xx | Cardiovascular (CV) | xxx | Not related | Not related |
| xxxxxxxxxx | xx | xx | Non-cardiovascular (Non-CV) | xxx | Unlikely related | Unlikely related |
|  |  | xxx |  |  | Possibly related | Possibly related |
|  |  |  |  |  | Probably related | Probably related |
|  |  |  |  |  | Related (causal relationship) | Related (causal relationship) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| ………….. |  |  |  |  |  |  |
| Source: program name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | | | |

**Listing 4 CEC Adjudicated Heart Failure Hospitalizations and Non-elective Mitral Valve Reinterventions**

**Enrolled Population (N=xx)**

| **Patient ID** | **AE #** | **Days Post Procedure** | **Relationship to Study Device** | **Relationship to Study Procedure** |
| --- | --- | --- | --- | --- |
| xxxxxxxxxx | xx | xx | Not related | Not related |
|  |  |  | Unlikely related | Unlikely related |
|  |  |  | Possibly related | Possibly related |
|  |  |  | Probably related | Probably related |
|  |  |  | Related (causal relationship) | Related (causal relationship) |
| ………….. |  |  |  |  |
| Source: program\_name.sas Extract Date: DDMMMYYYY Run Date (Time): DDMMMYYYY (hh:mm) | | | | |

# FIGURES

## Figure 1 Linear Graph of Cumulative Enrollment by Month

Enrolled Population (N=xx)

*Programming Notes: (Place holder for now)*