TWIST-EFS - TLFs for ROP

Invalid Date

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

| **Patient Status at Follow-Up** | **30 Days** | **6 Months** | **1 Year** | **2 Years** |
| --- | --- | --- | --- | --- |
| Eligible for Visit | 42/42 (100%) | 33/42 (78.6%) | 32/42 (76.2%) | 20/42 (47.6%) |
| Visit Completed Within Window | 32/42 (76.2%) | 27/42 (64.3%) | 21/42 (50%) | 11/42 (26.2%) |
| Visit Completed Outside Window | 9/42 (21.4%) | 3/42 (7.1%) | 3/42 (7.1%) | 0/42 (0%) |
| Visit Not Performed | 1/42 (2.4%) | 12/42 (28.6%) | 18/42 (42.9%) | 31/42 (73.8%) |
| [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: % | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 09JUL2025 Run Date (Time): 05Aug2025 (11:41) | | | | |

# Table 3 Demographics and Baseline Characteristics

| **Baseline Characteristic** | **Total** |
| --- | --- |
| Age (Years) | 73.2 ± 10.3 (42) 76 (44, 90) |
| BMI (kg/m²) | 27.5 ± 6 (42) 27.1 (18.6, 52.7) |
| Sex at Birth         Female         Male | 16 / 42 (38.1%) 26 / 42 (61.9%) |
| NYHA Class         Class II         Class III | 11 / 42 (26.2%) 31 / 42 (73.8%) |
| LVEF (TTE)         21 - 25         26 - 30         31 - 35         36 - 40         41 - 45         46 - 50         51 - 55         56 - 60         61 - 65 | 2 / 40 (5%) 4 / 40 (10%) 2 / 40 (5%) 5 / 40 (12.5%) 9 / 40 (22.5%) 2 / 40 (5%) 5 / 40 (12.5%) 5 / 40 (12.5%) 6 / 40 (15%) |
| Stroke | 6 / 42 (14.3%) |
| Atrial Fibrillation | 28 / 42 (66.7%) |
| PCI | 13 / 42 (31%) |
| CABG | 12 / 42 (28.6%) |
| Continuous variables: Mean ± SD (n); Median (min, max) | |
| Categorical measures: n/Total N (%) | |
| Source: t3\_baselinedem.R Extract Date: 28JUL2025 Run Date (Time): 05Aug2025 (11:41) | |

# Table 8: CEC Adjudicated Endpoints for Events up to 1 Year

|  | **Early Events   (≤ 30 Days)** | | **Late Events   (> 30 days to 1 Year)** | | **Total Events** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Event** | **No. Events** | **Patients** | **No. Events** | **Patients** | **No. Events** | **Patients** |
| Death | 1 | 1/42 (2.4%) | 6 | 6/41 (14.6%) | 7 | 7/42 (16.7%) |
| Stroke | 0 | 0/42 (0.0%) | 2 | 2/41 (4.9%) | 2 | 2/42 (4.8%) |
| Bleeding¹ | 4 | 4/42 (9.5%) | 7 | 7/41 (17.1%) | 11 | 10/42 (23.8%) |
| Major Vascular Complications Requiring Surgery to Repair | 1 | 1/42 (2.4%) | 0 | 0/41 (0.0%) | 1 | 1/42 (2.4%) |
| Major Cardiac Structural Complications Requiring Surgery to Repair | 1 | 1/42 (2.4%) | 0 | 0/41 (0.0%) | 1 | 1/42 (2.4%) |
| Stage 2 or 3 Acute Kidney Injury (Including New Dialysis) | 0 | 0/42 (0.0%) | 5 | 3/41 (7.3%) | 5 | 3/42 (7.1%) |
| Myocardial Infarction or Coronary Ischemia Requiring PCI or CABG | 0 | 0/42 (0.0%) | 0 | 0/41 (0.0%) | 0 | 0/41 (0.0%) |
| Unexpected Cardiogenic Shock | 0 | 0/42 (0.0%) | 3 | 3/41 (7.3%) | 3 | 3/42 (7.1%) |
| Any Valve-Related Dysfunction, Migration, Thrombosis, or Other Complications Requiring Surgery or Repeat Interventions | 2 | 2/42 (4.8%) | 3 | 3/41 (7.3%) | 5 | 5/42 (11.9%) |
| [1] Includes fatal, life-threatening, extensive or major bleeding as defined by MVARC  Categorical measures: n/N (%). Source: t8\_CEC\_MAEs.R Extract Date: 2025JUL28 Run Date (Time): 05Aug2025 (11:41) | | | | | | |

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

| **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 | 2 | 2/42 (4.8%) | 13 | 9/41 (22.0%) | 15 | 10/42 (23.8%) |
| Non-elective mitral valve re-intervention, percutaneous or surgical | 2 | 2/42 (4.8%) | 3 | 3/41 (7.3%) | 5 | 5/42 (11.9%) |
| Categorical measures (%) | | | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 2025JUL28 Run Date (Time): 05Aug2025 (11:41) | | | | | | |

# Table 13 NYHA Class: Unpaired Analysis

| **NYHA Class** | **Baseline   (N=41)** | **30 Days   (N=41)** | **6 Months   (N=30)** | **1 Year   (N=24)** |
| --- | --- | --- | --- | --- |
| Class I | - | 9/41 (22.0%) | 10/30 (33.3%) | 11/24 (45.8%) |
| Class II | 11/41 (26.8%) | 23/41 (56.1%) | 14/30 (46.7%) | 8/24 (33.3%) |
| Class III | 30/41 (73.2%) | 8/41 (19.5%) | 4/30 (13.3%) | 3/24 (12.5%) |
| Class IV | - | 1/41 ( 2.4%) | 2/30 ( 6.7%) | - |
| Categorical measures (%) | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 2025JUL28 Run Date (Time): 05Aug2025 (11:41) | | | | |