## 7.13. Tables to Present

**Table 1.1: Subject Disposition** 

|                       | Site A | Site B | ••• | Total |
|-----------------------|--------|--------|-----|-------|
| Screened              |        |        |     |       |
| Randomised            |        |        |     |       |
| Arm A                 |        |        |     |       |
| Arm B                 |        |        |     |       |
| Withdrawn             |        |        |     |       |
| Reason for Withdrawal |        |        |     |       |
| Completed             |        |        |     |       |

Table 2.1: Number of protocol deviations by centre and category

| Type of Deviation  | Site A | Site B | ••• | Total |
|--|--------|--------|-----|-------|
| Patient was incorrectly included in the trial (did not meet all the inclusion and exclusion criteria |        |        |     |       |
| Patient pregnancy  |        |        |     |       |
| Other  |        |        |     |       |
| Total  | 1,     |        |     |       |

**Table 3.1: Summary of Baseline Demographics** 

| Variable      | Statistics   | Arm A<br>[N=XX] | Arm B<br>[N=XX] | All Subjects<br>[N=XX] |
|---------------|--------------|-----------------|-----------------|------------------------|
| Age (y)       | n            |                 |                 |                        |
|               | Mean (SD)    |                 |                 |                        |
|               | Median (IQR) |                 |                 |                        |
|               | Min, Max     |                 |                 |                        |
| Ethnicity (%) | Asian        |                 |                 |                        |
|               | Black        |                 |                 |                        |
|               | Mixed        |                 |                 |                        |
|               | White        |                 |                 |                        |
| Gender (%)    | Female       |                 |                 |                        |
|               | Male         |                 |                 |                        |
| Height (cm)   | n            |                 |                 |                        |
|               |              |                 |                 |                        |
| Weight (kg)   | n            |                 |                 |                        |
|               |              |                 |                 |                        |
| ВМІ           | n            |                 |                 |                        |
|               |              |                 |                 |                        |
| Pulse         | n            |                 |                 |                        |
|               |              |                 |                 |                        |
| Systolic BP   | n            | _               |                 |                        |
|               |              |                 |                 |                        |
| Diastolic BP  | n            |                 |                 |                        |
|               |              |                 |                 |                        |

Table 4.1: Summary of MVO2 values by treatment and visit

| Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----|-------|-----------|---|------|----|--------|-----|------|------|
| Α   | BL    | -         |   |      |    |        |     |      |      |
|     | M6    | No-Pacing |   |      |    |        |     |      |      |
|     | M12   | Pacing    |   |      |    |        |     |      |      |
| В   | BL    | -         |   |      |    |        |     |      |      |
|     | M6    | Pacing    |   |      |    |        |     |      |      |
|     | M12   | No-Pacing |   |      |    |        |     |      |      |

Table 4.2: Output of mixed-model test results for MVO2 by arm, treatment and timepoint

Type 3 Tests of Fixed Effects

Effect Num DF Den DF F Value Pr > F

Treatment

Period

Arm

xxxx

(Interaction Terms)

|                |           |        | Soluti | on for Fixed E | Effects  |    |    |         |         |
|----------------|-----------|--------|--------|----------------|----------|----|----|---------|---------|
| Effect         | Treatment | Period | Arm    | xxxx           | Estimate | SE | DF | t Value | Pr >  t |
| Intercept      |           |        | _      |                |          |    |    |         |         |
| Treatment      | •••       |        | _      |                |          |    |    |         |         |
|                |           |        | -      |                |          |    |    |         |         |
| Period         |           | •••    | -      |                |          |    |    |         |         |
|                |           | •••    |        |                |          |    |    |         |         |
| ARM            | -         | -      |        | -              |          |    |    |         |         |
|                | -         | -      |        | -              |          |    |    |         |         |
| xxxx           |           |        |        |                |          |    |    |         |         |
| (Interactions) |           | •••    |        |                |          |    |    |         |         |

### **Least Squares Means**

Effect Estimate Standard DF t Value Pr > |t| Adjustment Adj P

**Table 5.1.1: Summary of Echocardiographic Variables** 

| Variable* | Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----------|-----|-------|-----------|---|------|----|--------|-----|------|------|
|           | Α   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | No-Pacing |   |      |    |        |     |      |      |
|           |     | M12   | Pacing    |   |      |    |        |     |      |      |
|           | В   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | Pacing    |   |      |    |        |     |      |      |
|           |     | M12   | No-Pacing |   |      |    |        |     |      |      |

<sup>\*</sup>Variables to assess: LV end-diastolic diameter & volume, LV end-systolic diameter, LVEF and LVOT diameter.

Table 5.1.2: Output of mixed-model for Echocardiographic Variables by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Tests to be carried out on the following variables: LV end-diastolic diameter & volume, LV end-systolic diameter, LVEF and LVOT diameter.

**Table 5.2.1: Summary of BNP Values** 

| Arm | Visit | Treatment | Samples<br>Taken | Mean | SD | Median | IQR | Min. | Max. |
|-----|-------|-----------|------------------|------|----|--------|-----|------|------|
| Α   | BL    | -         |                  |      |    |        |     |      |      |
|     | M6    | No-Pacing |                  |      |    |        |     |      |      |
|     | M12   | Pacing    |                  |      |    |        |     |      |      |
| В   | BL    | -         |                  |      |    |        |     |      |      |
|     | M6    | Pacing    |                  |      |    |        |     |      |      |
|     | M12   | No-Pacing |                  |      |    |        |     |      |      |

Table 5.2.2: Output of mixed-model for BNP by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

**Table 5.3.1: Summary of Quality of Life Scores** 

| Variable* | Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----------|-----|-------|-----------|---|------|----|--------|-----|------|------|
|           | Α   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | No-Pacing |   |      |    |        |     |      |      |
|           |     | M12   | Pacing    |   |      |    |        |     |      |      |
|           | В   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | Pacing    |   |      |    |        |     |      |      |
|           |     | M12   | No-Pacing |   |      |    |        |     |      |      |

<sup>\*</sup>Variables to assess: ED5Q5L and Minnesota Scores

Table 5.3.2: Output of mixed-model for Quality of Life Scores by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Variables to assess: ED5Q5L and Minnesota Scores

**Table 5.4.1: Summary of Device Check Variables** 

| Variable* | Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----------|-----|-------|-----------|---|------|----|--------|-----|------|------|
|           | Α   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | No-Pacing |   |      |    |        |     |      |      |
|           |     | M12   | Pacing    |   |      |    |        |     |      |      |
|           | В   | BL    | =         |   |      |    |        |     |      |      |
|           |     | M6    | Pacing    |   |      |    |        |     |      |      |
|           |     | M12   | No-Pacing |   |      |    |        |     |      |      |

<sup>\*</sup>Variables to assess: %age HIS Paced, AF/SVT Burden, Impedance of RA, His & LV/ICD Leads, Pacing Thresholds of RA, His & LV/ICD Leads, P-Wave Amplitude, Total Fluoroscopy Time

Table 5.4.2: Output of mixed-model for Device Check Variables by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Variables to assess: %age HIS Paced, AF/SVT Burden.
Remaining variables are to be summarised only.

Table 5.5.1: Summary of Exercise Time values

| Variable* | Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----------|-----|-------|-----------|---|------|----|--------|-----|------|------|
|           | Α   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | No-Pacing |   |      |    |        |     |      |      |
|           |     | M12   | Pacing    |   |      |    |        |     |      |      |
|           | В   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | Pacing    |   |      |    |        |     |      |      |
|           |     | M12   | No-Pacing |   |      |    |        |     |      |      |

Table 5.5.2: Output of mixed-model for Exercise Time values by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

Table 5.6.1: Summary of Haemodynamic Response values

| Variable* | Arm | Visit | Treatment | n | Mean | SD | Median | IQR | Min. | Max. |
|-----------|-----|-------|-----------|---|------|----|--------|-----|------|------|
|           | Α   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | No-Pacing |   |      |    |        |     |      |      |
|           |     | M12   | Pacing    |   |      |    |        |     |      |      |
|           | В   | BL    | -         |   |      |    |        |     |      |      |
|           |     | M6    | Pacing    |   |      |    |        |     |      |      |
|           |     | M12   | No-Pacing |   |      |    |        |     |      |      |

Table 5.6.2: Output of mixed-model for Haemodynamic Response values by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

**Sub-Group Analysis Output** 

Table 6.1.1 -6.1.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for QRS Category

Please refer to output within Table 4.2

Table 6.1.4 -6.1.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for QRS Category dichotomised as Narrow QRS vs Non-Narrow QRS

Please refer to output within Table 4.2

Table 6.2.1 -6.2.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for PR Interval at Implantation (as continuous variable)

Please refer to output within Table 4.2

Table 6.2.4 -6.2.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for PR Interval at Implantation (as tertile groups)

Please refer to output within Table 4.2

Table 6.3.1- 6.3.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients grouped by E-A fusion

Please refer to output within Table 4.2

Table 6.4.1 -6.4.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for selective vs non-selective His capture

Please refer to output within Table 4.2

Table 6.5.1 -6.5.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients based on lead implantation (LV Lead vs His Lead)

Please refer to output within Table 4.2

Table 6.6.1 -6.6.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients dichotomised by Ejection Fraction

Please refer to output within Table 4.2

Table 6.7.1 -6.7.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients dichotomised by Device Type

Please refer to output within Table 4.2

Table 6.8.1 -6.8.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients BMI (as continuous variable)

Please refer to output within Table 4.2

Table 6.8.4 -6.8.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients BMI (as tertile groups)

Please refer to output within Table 4.2

Table 6.9.1 -6.9.3 - Output of mixed-model for MVO2 by arm, treatment and timepoint including sub-group variable for patients Max RER Value (as continuous variable)

Please refer to output within Table 4.2

Table 6.9.4 -6.9.6 - Output of mixed-model for MVO2 by arm, treatment and timepoint including sub-group variable for patients dichotomised

Please refer to output within Table 4.2

Table 6.10.1 -6.10.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients height (as continuous variable)

Please refer to output within Table 4.2

Table 6.10.4 -6.10.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients height (as tertile groups)

Please refer to output within Table 4.2

Table 6.11.1 -6.11.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for percentage-His pacing (as continuous variable)

Please refer to output within Table 4.2

b y

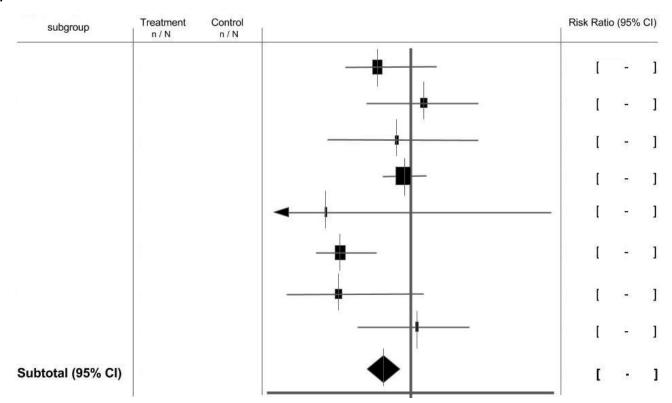
Table 6.11.4 -6.11.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for percentage-His pacing (d i c h o t o m i s e d )a s  $\leq$  9 5 % v s > 9 5 %

Please refer to output within Table 4.2

Table 6.12.1 -6.12.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for His-Pacing adherence (as binomial variable)

Please refer to output within Table 4.2

Table 6.11.1 -6.11.3: Forest Plot of Sub-Group Analysis for MVO2/Daily Activity/Haemodynamic Response \*



### \*To include:

- QRS Morphology (Dichotomised as Narrow QRS Duration/Non-Narrow QRS)
- PR Interval (Tertiles -Low vs Medium and Low vs High)
- Baseline Echocardiography (E/A Fusion)
- Selective vs Non-Selective His Bundle Pacing
- LV Lead vs His Lead
- Ejection Fraction Group (nDseirtionhotomised as ≤35
- Device Type (Dichotomised as ICD vs non-ICD)
- BMI (Tertiles -Low vs Medium and Low vs High)
- Max RER Score (Tertiles <0.95 vs 0.95-1.05, <0.95 vs >1.05)
- Height (Tertiles –Low vs Medium and Low vs High)
- Percentage His-pacing (dichotomi s e d a s ≤ 9 5 % v s > 9 5 %)
- Adherence to optimal pacing based on metrics obtained at V4/V5 and AE data (binary)

Table 7.1.1: Summary of Adverse Events by Treatment, Arm and Severity

|           |             | ίtγ  | ever     | S      |       |
|-----------|-------------|------|----------|--------|-------|
|           |             | Mild | Moderate | Severe | Total |
|           | Arm 1       |      |          |        |       |
| Pacing    | Arm 2 Total |      |          |        |       |
|           | Total       |      |          |        |       |
|           | Arm 1       |      |          |        |       |
| No-Pacing | Arm 2       |      |          |        |       |
|           | Total       |      |          |        |       |

Table 7.1.2: Summary of Adverse Events by Treatment, Arm and Relationship to Study

|              |      |  |          | Su       | Subjects with AEs* | \Es <sup>*</sup> |                    |       |
|--------------|------|--|----------|----------|--------------------|------------------|--------------------|-------|
| Treatment    | Arm  | No Relationship Unlikely Possible Probable | Unlikely | Possible | Probable           | Definitely       | Not Yet<br>Defined | Total |
| Pacing       | 1    |  |          |          |                    |                  |                    |       |
|              | 7    |  |          |          |                    |                  |                    |       |
|              | Both |  |          |          |                    |                  |                    |       |
| No-pacing    | _    |  |          |          |                    |                  |                    |       |
|              | 2    |  |          |          |                    |                  |                    |       |
|              | Both |  |          |          |                    |                  |                    |       |
| All subjects |      |  |          |          |                    |                  |                    |       |

|              |      |                                      |          |          | All AEs             |            |                    |       |
|--------------|------|--------------------------------------|----------|----------|---------------------|------------|--------------------|-------|
| Treatment    | Arm  | No<br>Relationship Unlikely Possible | Unlikely | Possible | Probable Definitely | Definitely | Not Yet<br>Defined | Total |
| Pacing       | _    |                                      |          |          |                     |            |                    |       |
|              | 2    |                                      |          |          |                     |            |                    |       |
|              | Both |                                      |          |          |                     |            |                    |       |
| No-pacing    | _    |                                      |          |          |                     |            |                    |       |
|              | 2    |                                      |          |          |                     |            |                    |       |
|              | Both |                                      |          |          |                     |            |                    |       |
| All subjects |      |                                      |          |          |                     |            |                    |       |

highest t h e w ith-randkinglAE willpbelused.AE′s subjects \* F 0 r

Table 7.2.1: Summary of Adverse Device Effects by Treatment, Arm and Severity

|           |             |      | ever     |        |       |
|-----------|-------------|------|----------|--------|-------|
|           |             | Mild | Moderate | Severe | Total |
|           | Arm 1       |      |          |        |       |
| Pacing    | Arm 2 Total |      |          |        |       |
|           | Total       |      |          |        |       |
|           | Arm 1       |      |          |        |       |
| No-Pacing | Arm 2       |      |          |        |       |
|           | Total       |      |          |        |       |

Table 7.2.2: Summary of Adverse Device Effects by Treatment, Arm and Relationship to Study

|              |      |                                      |          | 591      | Subjects with AEs* | h AEs*     |                    |       |
|--------------|------|--------------------------------------|----------|----------|--------------------|------------|--------------------|-------|
| Treatment    | Arm  | No<br>Relationship Unlikely Possible | Unlikely | Possible | Probable           | Definitely | Not Yet<br>Defined | Total |
| Pacing       | 1    |                                      |          |          |                    |            |                    |       |
|              | 2    |                                      |          |          |                    |            |                    |       |
|              | Both |                                      |          |          |                    |            |                    |       |
| No-pacing    | 1    |                                      |          |          |                    |            |                    |       |
|              | 2    |                                      |          |          |                    |            |                    |       |
|              | Both |                                      |          |          |                    |            |                    |       |
| All subjects |      |                                      |          |          |                    |            |                    |       |
|              |      |                                      |          |          | All AEs            | SI         |                    |       |
| Treatment    | Arm  | No<br>Relationship                   | Unlikely | Possible | Probable           | Definitely | Not Yet<br>Defined | Total |
| Pacing       | 1    |                                      |          |          |                    |            |                    |       |
|              | 2    |                                      |          |          |                    |            |                    |       |
|              | Both |                                      |          |          |                    |            |                    |       |
| No-pacing    | ~    |                                      |          |          |                    |            |                    |       |
|              | 2    |                                      |          |          |                    |            |                    |       |
|              | Both |                                      |          |          |                    |            |                    |       |
| All subjects |      |                                      |          |          |                    |            |                    |       |

highest t h e w ith-rammkinglAE willphe used.AE′s subjects \* For

Table 7.3.1: Summary of Serious Adverse Events by Treatment, Arm and Severity

| No-Pacing | Arm 1 Arm 2 |      |          |        |       |
|-----------|-------------|------|----------|--------|-------|
|           | Arm 2 Total |      |          |        |       |
| Pacing    | Arm 2       |      |          |        |       |
|           | Arm 1       |      |          |        |       |
|           |             | Mild | Moderate | Severe | Total |
|           |             | ity  | everi    | S      |       |

Table 7.3.2: Summary of Serious Adverse Events by Treatment, Arm and Relationship to Study

|              |      |  |          | SI       | Subjects with SAEs* | SAEs*      |                    |       |
|--------------|------|--|----------|----------|---------------------|------------|--------------------|-------|
| Treatment    | Arm  | No<br>Relationship Unlikely Possible Probable Definitely | Unlikely | Possible | Probable            | Definitely | Not Yet<br>Defined | Total |
| Pacing       | _    |  |          |          |                     |            |                    |       |
|              | 2    |  |          |          |                     |            |                    |       |
|              | Both |  |          |          |                     |            |                    |       |
| No-pacing    | _    |  |          |          |                     |            |                    |       |
|              | 2    |  |          |          |                     |            |                    |       |
|              | Both |  |          |          |                     |            |                    |       |
| All subjects |      |  |          |          |                     |            |                    |       |

| Treatment         Arm         No         Mot Yet         Not Yet         Total           Pacing         1         All subjects         1         All subjects         All subjects         Moleshing         Unlikely         Possible         Probable         Definitely         Defined         Total           Pacing         2         All subjects         1         All subjects         All subje |              |      |                    |          |          | All SAEs | <u>S:</u>  |       |
|---|--------------|------|--------------------|----------|----------|----------|------------|-------|
| 1 2 Both 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2  | Treatment    | Arm  | No<br>Relationship | Unlikely | Possible | Probable | Definitely | Total |
|   | Pacing       | 1    |                    |          |          |          |            |       |
|   |              | 2    |                    |          |          |          |            |       |
|   |              | Both |                    |          |          |          |            |       |
|   | No-pacing    | _    |                    |          |          |          |            |       |
|   |              | 2    |                    |          |          |          |            |       |
| All subjects  |              | Both |                    |          |          |          |            |       |
|   | All subjects |      |                    |          |          |          |            |       |

highest t h e subjects with-rammkinglAE wilphe used.AE′s \* For

Table 7.4.1: Summary of Serious Adverse Device Effects by Treatment, Arm and Severity

| ing       | Total       |      |          |        |       |
|-----------|-------------|------|----------|--------|-------|
| No-Pacing | Arm 2       |      |          |        |       |
|           | Arm 1       |      |          |        |       |
|           | Arm 2 Total |      |          |        |       |
| Pacing    |             |      |          |        |       |
|           | Arm 1       |      |          |        |       |
|           |             | Mild | Moderate | Severe | Total |
|           |             | ity  | ever     | S      |       |

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Table 7.4.3: Summary of Serious Adverse Device Effects by Treatment, Arm and Relationship to Study

|              |      |                    |          | <b>ω</b> I | Subjects with SAEs* | ı SAEs <sup>∗</sup> |                    |       |
|--------------|------|--------------------|----------|------------|---------------------|---------------------|--------------------|-------|
| Treatment    | Arm  | No<br>Relationship | Unlikely | Possible   | Probable            | Definitely          | Not Yet<br>Defined | Total |
| Pacing       | _    |                    |          |            |                     |                     |                    |       |
|              | 2    |                    |          |            |                     |                     |                    |       |
|              | Both |                    |          |            |                     |                     |                    |       |
| No-pacing    | 1    |                    |          |            |                     |                     |                    |       |
|              | 2    |                    |          |            |                     |                     |                    |       |
|              | Both |                    |          |            |                     |                     |                    |       |
| All subjects |      |                    |          |            |                     |                     |                    |       |
|              |      |                    |          |            | All SAEs            | <u>S</u> :          |                    |       |
| Treatment    | Arm  | No<br>Relationship | Unlikely | Possible   | Probable            | Definitely          | Not Yet<br>Defined | Total |
| Pacing       | ~    |                    |          |            |                     |                     |                    |       |
|              | 2    |                    |          |            |                     |                     |                    |       |
|              | Both |                    |          |            |                     |                     |                    |       |
| No-pacing    | _    |                    |          |            |                     |                     |                    |       |
|              | 2    |                    |          |            |                     |                     |                    |       |
|              | Both |                    |          |            |                     |                     |                    |       |
| All subjects |      |                    |          |            |                     |                     |                    |       |
|              |      |                    |          |            |                     |                     |                    |       |

highest t h e w ith-rammkinglAE willphe used.AE′s subjects \* F o r

Table 7.5.1 -7.5.4: Mixed Effect Logistic Regression output to investigate proportional rate occurrence for Rates of Death/Hospitalisation/Revision of Device/Extraction or Removal of Device by treatment, period and sequence

Please refer to series of output in Table 4.2.

**Table 7.6.1: Summary of Vital Signs Values** 

| Variable* | Arm | Visit | Variable* Arm Visit Treatment | Samples<br>Taken | _ | Mean | SD | n Mean SD Median Min. Max. | Min. | Мах |
|-----------|-----|-------|-------------------------------|------------------|---|------|----|----------------------------|------|-----|
|           | ⋖   | BL    |                               |                  |   |      |    |                            |      |     |
|           |     | M6    | Control                       |                  |   |      |    |                            |      |     |
|           |     | M12   | Treatment                     |                  |   |      |    |                            |      |     |
|           | В   | BL    | ı                             |                  |   |      |    |                            |      |     |
|           |     | M6    | Treatment                     |                  |   |      |    |                            |      |     |
|           |     | M12   | Control                       |                  |   |      |    |                            |      |     |

\*Variables to assess: Height, weight, pulse, BMI, Dia/Sys Blood Pressure Average

# Appendix A - Listings

**Listing A: Listing of MVO2 values** 

| End Date   |  |
|------------|--|
| Start Date |  |
|            |  |
|            |  |
| Type       |  |
| Site       |  |
| Subject    |  |
| Treatment  |  |

Listing B: Listing of protocol deviations

| End Date   |  |
|------------|--|
| Start Date |  |
|            |  |
|            |  |
| Туре       |  |
| Site       |  |
| Subject    |  |
| eatment    |  |

Listing C: Listing of protocol violations

| End Date   |  |
|------------|--|
| Start Date |  |
|            |  |
|            |  |
| Туре       |  |
| Site       |  |
| Subject    |  |
| Treatment  |  |

**Treatment: Pacing** 

|                        | Details                  |  |
|------------------------|--------------------------|--|
|                        | Rel. to<br>Study         |  |
|                        | Expected-<br>ness        |  |
|                        | SAE<br>Category          |  |
|                        | Days frm SAE E           |  |
|                        | nd Days frm D. Implant   |  |
|                        | SAE Er<br>Date           |  |
|                        | AE Start<br>Date Ongoing |  |
|                        | SAE Start<br>Date        |  |
| 9,,,,                  | AE Term                  |  |
| וני ו מכ               | Subj                     |  |
| ווכמנוווכווני ו מכוווק | Timepoint                |  |
| =                      | F                        |  |

**Treatment: No-Pacing** 

|   | Details                       |  |
|---|-------------------------------|--|
|   | Rel. to<br>Study              |  |
|   | Expected-<br>ry ness          |  |
|   | SAE<br>Catego                 |  |
|   | Days frm<br>Rand.             |  |
|   | SAE End Days frm Date Implant |  |
|   | SAE End<br>Date               |  |
|   | Ongoing                       |  |
|   | SAE Start<br>Date             |  |
| 0 | AE Term                       |  |
|   | Subj                          |  |
| 0 | Timepoint Subj                |  |

Listing E: Listing of Serious Adverse Device Effects

**Treatment: Pacing** 

|                        | iils  |  |
|------------------------|---|--|
|                        | Details   |  |
|                        | Rel. to<br>Device   |  |
|                        | Days frm SAE Expected- Rel. to Rand. Category ness Device |  |
|                        | SAE<br>Category   |  |
|                        | Days frm<br>Rand.   |  |
|                        | Days frm<br>Implant                                       |  |
|                        | SAE End Days frm<br>Date Implant                          |  |
|                        | AE Start Date Ongoing                                     |  |
|                        | SAE Start<br>Date   |  |
| 9,,,,                  | AE Term   |  |
|                        | Subj  |  |
| ווכמנוווכווני ו מכוווק | Timepoint   |  |

**Treatment: No-Pacing** 

| Timepoint Subj AE Term Date Ongoing Date Implant Rand. Category ness Device Details                                 |    |                     |  |
|---|----|---------------------|--|
| SAE Start Start Days frm Days frm SAE Expected-Rel. to  E Term Date Ongoing Date Implant Rand. Category ness Device |    |                     |  |
| SAE Start SAE End Days frm Days frm SAE Expected- E Term Date Ongoing Date Implant Rand. Category ness              |    | Details             |  |
| SAE Start SAE End Days frm Days frm SAE Expected- E Term Date Ongoing Date Implant Rand. Category ness              |    |                     |  |
| SAE Start SAE End Days frm Days frm Days frm Date Ongoing Date Implant Rand.  |    | Rel. to<br>Device   |  |
| SAE Start SAE End Days frm Days frm Days frm Date Ongoing Date Implant Rand.  |    | Expected-<br>ness   |  |
| SAE Start SAE End Days frm Days frm Days frm Date Ongoing Date Implant Rand.  |    | SAE<br>Category     |  |
| SAE Start  E Term Date Ongoing  |    | Days frm<br>Rand.   |  |
| SAE Start  E Term Date Ongoing  |    | Days frm<br>Implant |  |
| SAE Start Date Ongoing  |    | SAE End<br>Date     |  |
| E Term  |    | Ongoing             |  |
| point Subj AE Term  |    | SAE Start<br>Date   |  |
| spoint Subj   | 99 | AE Term             |  |
| point   |    |                     |  |
| i ii  |    | Timepoint           |  |

## REFERENCES

HOPE-HF Study Protocol v6.0 25Jan2018