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Medtronic **Statistical Analysis Plan**	
Field Evaluation Plan	BlueSync™ Field Evaluation
Field Evaluation Plan Version	3.0
Sponsor/Local Sponsor	Medtronic, PLC. 8200 Coral Sea Street NE Mounds View, MN U.S.A. 55112 1-800-328-2518 Europe, Middle East, Africa Medtronic, Bakken Research Center B.V. Endepolsdomein 5 6229 GW Maastricht The Netherlands +31-43-35-66-566
Document Version	3.0

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1. Version History

Version	Summary of Changes	Author(s)/Title
1.0	• Not Applicable, New Document	Baerbel Maus, Senior Statistician
2.0	• Specification of follow-up start in Section 7.9.1.2 and 7.9.2.2 • Changes to analysis methods in section 7.9.1.3. and 7.9.1.4	Baerbel Maus, Senior Statistician
3.0	• Removed references to interim report since no interim report was created • In Section 4 added notes about transmission scheduling • Removed 'Figure 2: Patient enrollment over time' • [redacted] • Removed reference to analysis per region or country (Section 7.3) • Added note in Section 7.6 • Removed references to Android since MyCareLink Heart App for Android was not available at start of evaluation • Updated Section 7.8 • Updates to Section 7.9.1 and Section 7.9.2 with regard to data collection and selection of scheduled transmission used for analysis • Changed timeframe for patients' first activation to allow for more recent data in control cohort (Section 7.9.1.3) • Changes to analysis methods in Section 7.9.3 • [redacted]	Baerbel Maus, Senior Statistician

2. List of Abbreviations and Definitions of Terms

Abbreviation	Definition
CRT-P	Cardiac resynchronization therapy - Pacemaker
CIEDs	Cardiac implantable electronic devices
DWAS	Data Warehousing & Analytics Services
GEE	Generalized Estimating Equation
MCL	MyCareLink
MDT	Medtronic
PASS software	Power Analysis and Sample Size software
PHI	Protected Health Information
SAP	Statistical Analysis Plan
US	United States

3. Introduction

The BlueSync™ field evaluation is a multi-center, prospective, single-arm, post market non-interventional field evaluation. Patients included in the evaluation are patients indicated for pacemaker or CRT-P therapy and implanted with the commercial released Medtronic Azure™ Pacemaker or CRT-P Percepta™, Serena™, Solara™ CRT-P device within approved indications for use. Patients will be provided standard care after implant and are anticipated to be in the evaluation for approximately 12 months. BlueSync™ offers app-based remote monitoring via the patient's own smart device. The Azure™ Smart Pacemaker and Percepta™, Serena™, Solara™ CRT-P devices include a Bluetooth Low Energy chip that allows wireless communication between the pacemaker and the patient's smart device. The patient's smart device with BlueSync™ acts as a hub and transmits the data to the remote monitoring network.

The purpose of this field evaluation is to collect and evaluate information related to CareLink transmission compliance as well as patient perceived benefit of BlueSync™ and the health care provider perception of the value of BlueSync™ and satisfaction with BlueSync™. The primary goal is to learn how many CareLink quarterly scheduled transmissions are completed within a prescribed time period to assess CareLink scheduled transmission compliance. The evaluation will also assess adoption to remote monitoring, patient perceived benefit of BlueSync™ (how patients interact with the smart device application) and clinic perception of the value of BlueSync™ and satisfaction with BlueSync™ (benefits experienced by clinicians that use BlueSync™).

Remote monitoring of cardiac implantable electronic devices (CIEDs) has been shown to be cost effective, convenient and associated with reduced mortality. Patient compliance with monitoring is another important criterion which is important to clinicians. By demonstrating improved compliance with monitoring over time, the evaluation will support the primary benefits of BlueSync™ which are:

- Seamless remote monitoring via a patient's smart device, even outside the home, leads to increased adherence/compliance with monitoring
- Patient access to select information and automatic transmissions reduce workload and calls to the clinic

The following documents were used to create this Statistical Analysis Plan (SAP):

- BlueSync Field Evaluation Plan, Version 3.0, dated 19-JUL-2017

The SAP will need an update or amendment if a change in the field evaluation plan has major impact on the analysis described in the SAP. This SAP will be used to support the interim and final analysis of the BlueSync field evaluation. The Statistical Analysis Plan has been designed to document, before data is analyzed, the planned analyses that will be included in study reports. This SAP does not limit the analysis in reports, and additional analyses of the study data beyond this plan are expected. However, this document provides the basis for the statistical sections of reports. Analyses not planned in the SAP and incorporated into the final report will be referred to as "Additional Analysis".

4. Study Objectives

4.1 Primary Objective

To assess chronic CareLink transmission compliance (adherence to scheduled transmission), the primary objective is to compare the proportions of the CareLink quarterly scheduled transmissions that are completed within the prescribed window during the 12-month follow-up after the baseline visit in the CareLink Database between the evaluation patients who use the MyCareLink Heart™ (MCL) app and patients with low power devices and CareLink monitors 2490 (excluding wireless model 2490C).

- Four scheduled transmissions must occur quarterly, starting at month 3 of follow up (one scheduled at month 3, another scheduled at month 6, the next scheduled at month 9 and the last one scheduled at month 12). (Note: During study execution, sites were recommended to schedule transmissions quarterly but sites were also allowed to follow their standard of care.)

4.2 Secondary Objective

To assess acute CareLink transmission compliance (adherence to scheduled transmission), the secondary objective is to characterize the proportion of the CareLink bi-weekly scheduled transmissions that are completed within the prescribed window during the 1-month follow-up after the baseline visit in the CareLink Database via the MCL Heart™ app.

- Two scheduled transmissions must occur in the first month of follow up (one scheduled transmission at 2 weeks after device pairing and the second transmission 4 weeks after device pairing). (Note: During study execution, sites were recommended to schedule transmissions biweekly but sites were also allowed to follow their standard of care.)

The purpose of this objective is an early performance evaluation.

[redacted]

5. Field Evaluation Plan

5.1 Evaluation Design

The BlueSync™ Field Evaluation will be a multi-center, prospective, single-arm, post-market field evaluation. No randomization and/or blinding is performed in the evaluation.

One limitation of the evaluation design is that transmission compliance of the BlueSync patient group will be compared to a historical control group. Comparison will be done on data available from the CareLink Data Warehousing & Analytics Services (DWAS), but this comparison might be confounded by factors which cannot be controlled and are not available in the DWAS database.

5.2 Inclusion and Exclusion Criteria

Patients indicated for a pacemaker with or without Cardiac Resynchronization Therapy (CRT), or patients already implanted with a BlueSync™ compatible device, will participate in the specified screening process to determine eligibility for participation.
In order for patients to be considered for enrollment in the evaluation, they must meet all of the inclusion criteria and none of the exclusion criteria, and have completed device pairing.

Inclusion criteria:

- Patient will be/has been implanted with an Azure™ or Percepta™, Serena™, Solara™ CRT-P device compatible with BlueSync™ (both new and replacement devices are allowed)
- Patient must own a smart device (Smartphone or tablet) that meets system requirements and be willing to use during evaluation period.
- Patient must be able to complete the required 12-month follow-up after enrollment
- Patient must be legal age according to local law.

Exclusion criteria:

- Patient is unwilling to complete required surveys during 12-month evaluation period.

6. Determination of Sample Size

PASS (Power Analysis and Sample Size) software was used for sample size calculation. The sample size calculation is based on the primary objective.

Approximately 700 patients will be screened. 60% (420) of the targeted patient population are estimated to use smart technology, of which 60% (252) are estimated to meet the inclusion/exclusion criteria to be enrolled in the evaluation.
Assuming that attrition from enrollment through 12-month follow-up is 7%, a total of 252 enrolled patients would result in approximately 234 patients available to evaluate the primary goal of the evaluation.

7. Statistical Methods

Medtronic employees or designees will perform all statistical analyses. This Statistical Analysis Plan (SAP) has been developed to describe statistical methods, pre-specified data handling rules, and pre-specified analyses that will be included in the final evaluation report. Any change to the data analysis methods described in the SAP, and the justification for making the change, will be described in the final evaluation report. Additional exploratory analyses of the data may be conducted as deemed

appropriate. Missing data will not contribute to the objectives unless specified otherwise within the analysis methods.

7.1 Study Subjects

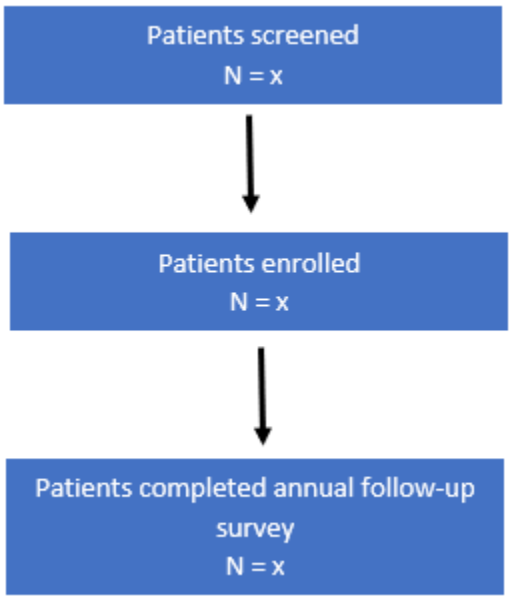
7.1.1 Disposition of Subjects

The evaluation will enroll patients who have been implanted with an Azure pacemaker or Percepta, Serena or Solara CRT-P device, meet all the inclusion criteria, and none of the exclusion criteria for the BlueSync™ field evaluation, and completed device pairing. A subject is considered enrolled when the device pairing of the BlueSync™ compatible device with the CareLink network via the My CareLink Heart App is completed.

The following table and figure will be considered to summarize patient disposition:

1. Table: Number of patients per center

Subject disposition will be summarized in a flowchart similar to the chart below.



7.1.2 Field Evaluation Plan (FEP) Deviations

This field evaluation will not collect deviations. Therefore, no summary of deviations from the field evaluation plan is planned.

If a patient has been enrolled but later it is determined that the patient did not fulfill inclusion/exclusion criteria at enrollment, e.g., regarding age, the patient will be excluded from any analysis.

7.1.3 Analysis Sets

Study manager and statistician(s) will determine the visit cut-off date and received data cut-off date for the final report as suitable.

Patients who rejected to consent will be excluded from the analysis cohorts given below. Patients who are enrolled in the evaluation but withdraw their consent during the evaluation, will be excluded with all their data from analysis cohorts given below.

For ancillary objective #1, only US patients will be included since patients in Europe were not screened. In Europe, patients' eligibility for the evaluation was already assessed before the screening survey was completed. Furthermore, the question "Was the patient screened before the MyCareLink Heart app was available for device pairing" will not be taken into account for analysis since sites did not interpret this question correctly. As a result, this question cannot be used to identify patients who were sequentially screened as was the initial intent for this question.

Table 1: Analysis cohorts

Cohort/Analysis set	Definition
Screened	All patients for who screening questionnaire has been completed excluding patients without consent
Enrolled	All patients who have completed device pairing and passed inclusion and exclusion criteria excluding patients without consent
Clinic	All clinics who have enrolled patients

Table 2: Analysis item and applicable cohort

Analysis Item	Analysis cohort
Screening summary	Screened
Primary objective	Enrolled
Secondary objective	Enrolled

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

7.2 General Methodology

Data summaries for categorical data will be summarized as count, e.g., number of patients, and/or number of events, and a percentage relative to the total number of patients/events. The denominator will be explicitly identified when not clear from the context. Continuous variables will be summarized by mean, standard deviation, median, quartiles, minimum, and maximum as applicable. Comments in open text fields will be reported in listings.
P-values for hypothesis testing will be evaluated based on one-sided testing using significance level of 0.025. Confidence intervals will be reported as two-sided 95% confidence intervals.

7.3 Center Pooling

The evaluation is expected to be conducted at approximately 30 hospital/clinics, 15 in Europe and 15 in the United States. Hospital/clinics will not exceed approximately 35 (15%) enrollments to ensure a diverse patient population experience across multiple geographies and types of hospitals. There is no minimum limit that each hospital/clinic must enroll. The data from all centers will be pooled.

7.4 Handling of Missing, Unused, and Spurious Data and Dropouts

All available data will be included in the data listings and tabulations. Missing data will not contribute to the objectives unless specified otherwise within the analysis methods. As applicable, the number of subjects/clinics/transmissions included in each analysis will be reported so that the reader can assess the impact of missing data.

Patients who are enrolled in the evaluation, but dropout during the evaluation due to other reasons than withdrawing consent, will be included in the analysis with the data collected until their dropout.

7.5 Adjustments for Multiple Comparisons

No adjustments for multiple comparison are planned.

7.6 Demographic and Other Baseline Characteristics

Demographics and other baseline characteristics are collected at screening.

Screening will occur prior to enrollment. All patients indicated for a pacemaker or CRT-P device that are identified sequentially by the clinics will be invited to participate in the screening process (Note: this was original intent but not done in the final execution of the study for all regions). It also includes patients with previous devices or already implanted BlueSync™ compatible devices.
The clinician will meet with the patient to conduct patient screening and complete a screening questionnaire to determine:

- Whether the patient is willing to do remote monitoring
- Whether the patient owns or has access to a smart device
- Whether the operating system on the patient's smart device is compatible with MCL Heart app
- Whether the patient is willing to participate in the evaluation
- Demographic information about the patient which will include:
  - Gender
  - Age (years)
  - Education
- Smart device experience
- Duration of smart device experience
- Type of smart device (Phone vs tablet, only one vs. multiple)
- Compatibility
- Comfort level with technology
- Smart device usage
- Type of smart device usage
  - Phone calls
  - Text messages
  - Email
  - Internet use

The information from the screening log will be summarized in descriptive tables.

7.7 Treatment Characteristics

The study product is the BlueSync™ Smart Monitoring System (BlueSync™). System components are as follows:

- System component #1
  - BlueSync™ Smart Monitoring System
  - MCL Heart app
    - MSW004 (IOS)
- System component #2
  - Azure™ Dual and Single Chambered Smart Pacemaker and Percepta™, Serena™, Solara™ CRT-P devices with Bluetooth enabled functionality
- Additional system components
- Patient's own smart device.

Exposure to the study product will be summarized using patient and clinic surveys collected at enrollment and during the annual follow-up visit or after all follow-up visits at a given site. Survey data will be summarized by descriptive statistics.

Device implant information is not being collected in this evaluation. No data collection of any surgical procedure characteristics is planned. Patients will receive standard of care after device implant. No medication information or information about concomitant therapies will be collected.

7.8 Interim Analyses

The primary objective will be analyzed after all patients have been enrolled and completed their 12-month follow-up/annual follow up. Interim analysis of the secondary as well as ancillary objectives will take place after 252 patients have been enrolled and at the time their 1 month follow up is reached. Enrollment and/or follow-up will not be stopped due to the interim analysis.

Table 3: Interim and final analysis specifications

	Interim analysis	Final analysis/final report
Data requirement	**All enrolled patients, at least 1 month**	**All enrolled patients, 12 months**
Primary objective		**x**
Secondary objective	**x**	**x**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

7.9 Evaluation of Objectives

7.9.1 Primary Objective

To assess chronic CareLink transmission compliance (adherence to scheduled transmission), the primary objective is to compare the proportion of the CareLink quarterly scheduled transmissions that are completed within the prescribed window during the 12-month follow-up after the baseline visit in the CareLink Database between the evaluation group and the control group of low power devices with 2490 CareLink monitors (excluding wireless model 2490C).

7.9.1.1 Hypothesis

Superiority

H_0: $p_E - p_C \leq 0$

H_1: $p_E - p_C > 0$,

where p_E is the proportion of compliance to scheduled transmissions in the evaluation group,
p_C is the proportion of compliance to scheduled transmissions in pacemakers or CRT-P devices with 2490 monitors.

7.9.1.2 Endpoint definition

For the evaluation patients, the primary endpoint will be the proportion of CareLink quarterly scheduled transmissions that are completed within prescribed window during the 12-month follow-up after the baseline visit in the CareLink Database.

For the evaluation patients, four quarterly transmissions should be scheduled by the clinic. Four scheduled transmissions should occur quarterly starting at month 3 of follow up (one scheduled at month 3, another scheduled at month 6, the next scheduled at month 9 and the last one scheduled at month 12). The starting point for follow-up time will be the device pairing date. The device pairing date is the date of first transmission in CareLink since a first transmission is to be sent during device pairing.

Scheduled transmissions are transmissions scheduled by a physician and documented in the CareLink Database.

The rationale for this endpoint is to assess compliance with scheduled transmissions.

For the control group, the primary endpoint will be the proportion of CareLink scheduled transmissions that are completed within the prescribed window during the 12-month follow-up after activation (first transmission) in the CareLink Database.

7.9.1.3 Analysis Methods

The data for this analysis will be extracted from two PHI (protected health information) data marts for the evaluation patients, one for European and one for US patients, and from the CareLink Warehousing & Analytics Services (DWAS) for the control group. Within these PHI marts and DWAS, the received CareLink transmissions are contained in dataset transmission while the scheduled transmissions are contained in dataset ClinicDeviceSchedule.

For the control group of patients enrolled in CareLink with low power devices and monitors 2490 (excluding wireless model 2490C), patients with the following inclusion criteria will be selected.

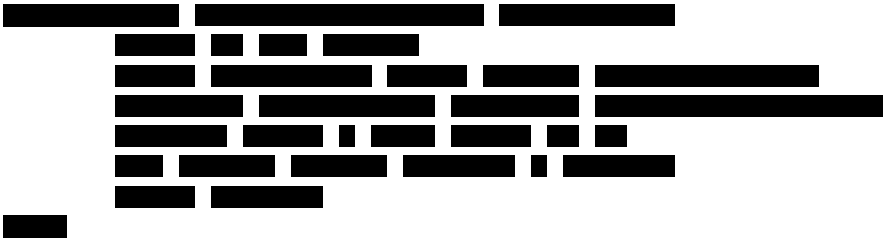
- Patients followed for at least a year after activation. Patients were activated (first transmission took place) in CareLink from 1st January 2016 to 1st December 2018.
    - All scheduled transmissions of this patient group 1 month after activation will be selected.
- Minimum sample allocation ratio (control/evaluation) of 4.
- Patients have a minimum age of 18 years.

For field evaluation patients and the control group, a proportion will be calculated where the numerator is the number of completed scheduled transmissions during follow-up and the denominator is the total number of expected scheduled transmissions during follow-up.

A scheduled transmission will be considered completed if a transmission is received by the CareLink system 1 day before the scheduled date and 5 days, incl. the 5th day, after the scheduled date. For example, if the scheduled date is 5 July, the transmission will be considered completed if the transmission is performed between 4 July (including) and 10 July (including). The information on whether a transmission has been received within this window can be seen in the CareLink database.

A scheduled transmission will be considered expected if it is received before patient exits the evaluation or if the patient has not exited (e.g., due to death, patient withdrawal, device explant, etc.) the evaluation before or at 5 days after the scheduled date of the transmission.

A correlated data method is required for the analysis since there are several transmissions per subject. A two-sided 95% confidence interval based on generalized estimating equations (GEE) for binomial distribution will be calculated for the proportion of completed scheduled transmissions in each group. An unmatched analysis will be performed to compare the proportion between BlueSync field evaluation patients and the control group. Estimates will be based on an empirical (or “sandwich”) estimator that is robust to the misspecification of the covariance structure. Analysis will be performed using SAS code similar to the code below.



[redacted]

In the code above group indicates the different groups and seq indicates the sequence of scheduled transmissions per subject. The dataset lsmeans contains the estimated proportions of completed scheduled transmissions per group with confidence intervals. Example output is given below:

[redacted]

To determine the difference in transmission success between the two groups the %***NLMeans*** macro will be applied. Example output from the %***NLMeans*** macro is shown below:

[redacted]

The dataset est created by the %***NLMeans*** macro contains the estimated difference

As alternative method if there are error messages with the code above, e.g., the %***NLMeans*** macro, the identity link will be used instead of the logit link. This applies a linear model to model the transmission success. If the transmission success rate is close to 0 or 1 for any of the groups, this could however lead to a confidence interval for the transmission success with borders below 0 or above 1 in which case the identity link should not be applied. SAS code similar to the code below will be used:

[redacted]

[redacted]

In the code above group indicates the different groups and seq indicates the sequence of scheduled transmissions per subject. The ODS dataset Diffs contains the difference in proportion between the two groups on percentage scale. The code above also gives a confidence interval on percentage scale for the proportions in the individual groups.

The point estimate for proportion of successful transmissions will be reported on percentage scale with the 95% confidence interval (CI) in a table similar to the one below.

Table 4: Transmission compliance for BlueSync field evaluation patient and DWAS control group

	Percentage	95% CI interval	P-value
Completed transmissions Blue Sync	72.2%	64.4% - 78.7%	
Completed transmissions DWAS control group	65.5%	60.0% - 71.0%	
Difference	6.7%	1.0% - 12.4%	0.03

An additional analysis might be considered where BlueSync field evaluation patients and control group patients will be matched on a couple of characteristics, e.g., gender, age group, number of device chambers, indicator of replacement/new implanted device status. Region (Europe vs US) will not be considered as a matching-criteria because only US data is available for the control group.

The following subgroup analysis might be performed, e.g., dependent on a sufficient sample size of the subgroups:

- iPad vs iPhone users to assess differential transmission compliance in these groups

7.9.1.4 Determination of Patients/Data for Analysis

All patients who are enrolled in the field evaluation will be used in the analysis of this objective (enrolled cohort). For the field evaluation patients, all scheduled transmissions after the first month will be used for analysis. Transmissions in the first month of follow-up will be excluded since they are considered in

another analysis and since the objective is to study longer term compliance. Transmissions which were scheduled or completed on or after the patient exit from BlueSync field evaluation will not be included in the analysis. If a site schedules more or less than the four quarterly transmissions expected by the BlueSync field evaluation or if transmissions are not scheduled quarterly, these transmissions will also be included in the analysis.

The control group of patients enrolled in CareLink with low power devices and monitors 2490 will be selected following criteria described in section 7.9.1.3.

7.9.2 Secondary Objective

To assess acute CareLink transmission compliance (adherence to scheduled transmission), the secondary objective is to characterize the proportion of the CareLink bi-weekly scheduled transmissions that are completed within the prescribed window during the 1-month follow-up after the baseline visit in the CareLink Database via the MCL Heart™ app.

7.9.2.1 Hypothesis

There are no prespecified hypotheses for this objective.

7.9.2.2 Endpoint definition

The proportion of the CareLink scheduled transmissions that are completed within prescribed window during the 1-month follow-up in the CareLink Database via BlueSync™ is the endpoint of interest. Scheduled transmissions are transmissions scheduled by a physician and documented in the CareLink Database. Two scheduled transmissions should occur in the first month of follow up (one scheduled transmission at 2 weeks and the second transmission at 4 weeks). The starting point for follow-up time will be the device pairing date. The device pairing data is the date of first transmission in CareLink since a first transmission is to be sent during device pairing.

7.9.2.3 Analysis Methods

The data for this analysis will be extracted from two PHI data marts for the evaluation patients, one for Europe and one for US. Within these PHI marts, the received CareLink transmissions are contained in dataset transmission while the scheduled transmissions are contained in dataset ClinicDeviceSchedule.

A proportion will be calculated where the numerator is the number of completed scheduled transmission in the first month of follow-up and the denominator is the total number of expected scheduled transmissions in the first month.

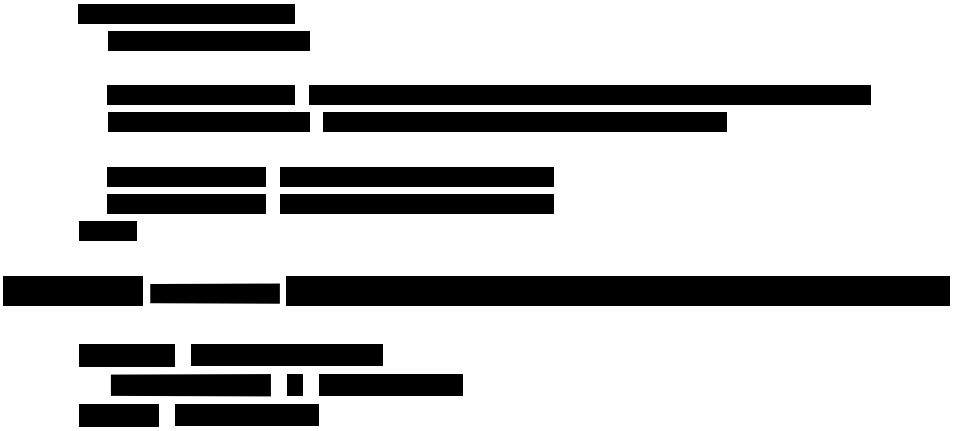
A scheduled transmission will be considered completed if a transmission is received by the CareLink system 1 day before the scheduled date and 5 days, incl. the 5th day, after the scheduled date. For example, if the scheduled date is 5 July, the transmission will be considered completed if the transmission is performed between 4 July (including) and 10 July (including). The information on whether a transmission has been received within this window can be seen in the CareLink database.

A scheduled transmission will be considered expected if it is received before patient exits the evaluation or if the patient has not exited (e.g., due to death, patient withdrawal, device explant, etc.) the evaluation before or at 5 days after the scheduled date of the transmission.

A correlated data method is required for the analysis since there are several transmissions per subject. A two-sided 95% confidence interval based on generalized estimating equations (GEE) for binomial distribution will be calculated for the proportion of completed scheduled transmissions. Analysis will be performed using SAS code similar to the code below.

In output table *Empirical Standard Error Estimates* as specified by requesting ODS table GEEEmpPEst, the standard error is reported on logit scale based on an empirical (or “sandwich”) estimator that is robust to the misspecification of the covariance structure. The standard error is highlighted in the sample output below.

The `ods output` statement exports this output table for further processing. Output dataset ESTIMATES will include variables ESTIMATE and STDERR for the point estimate and standard error on logit scale (numbers 0.9521 and 0.1745 in the example output above) as well as a lower and upper border of a 95% confidence interval on logit scale. The confidence interval is calculated using the 97.5% quantile of a normal distribution. The confidence interval is transferred back to percentage scale by applying the inverse logit transformation and multiplying by 100. This will be implemented using SAS code similar to the code below.



The point estimate for proportion of successful transmissions will be reported on percentage scale with the 95% confidence interval (CI) in a table similar to the one below.

Table 5: Transmission compliance, GEE model

	GEE estimate	95% CI interval
Completed transmissions	72.2%	64.4% - 78.7%

The following subgroup analysis might be performed, e.g., dependent on sufficient sample size in the subgroups:

- iPad vs iPhone users to assess differential transmission compliance in these groups

7.9.2.4 Determination of Patients/Data for Analysis

All patients who are enrolled in the field evaluation will be used in the analysis of this objective (enrolled cohort).
Transmissions which were scheduled or completed on or after the patient exit from BlueSync field evaluation will not be included in the analysis. If a site schedules more or less than the two biweekly

transmissions expected by the BlueSync field evaluation or if transmissions are not scheduled biweekly, these transmissions will also be included in the analysis as long as they are scheduled in the first month.

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[redacted]			
[redacted]	[redacted]	[redacted]	[redacted] (Y%)

The usability and health security patient questionnaire (Section B: How do you feel about using the MyCareLink Heart App) will be completed by patients after device pairing (only questions about device pairing) and at annual follow-up. The responses will be summarized in tables similar to the tables below.

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7.10 Safety Evaluation

The products used in the evaluation are market approved and used within the current indications for use as indicated in the product labeling. The collection of adverse event and patient death data is not required to meet the objective(s) of this evaluation. Thus, no assessment of safety data will be performed during this field evaluation.

7.11 Changes to Planned Analysis

Major changes to the statistical analysis plan will be summarized in a new version of the SAP. Minor deviations from the statistical analysis plan will be summarized in the final evaluation report.

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