Evaluation Plan

Title	BlueSync™ Field Evaluation
Product Name	BlueSync™ Smart Monitoring System
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
Manufacturer	Medtronic, Inc. Operational Headquarters 710 Medtronic Parkway Minneapolis MN 55432 (+1) 763-514-4000
Document Version	Version 2.0

Confidentiality Statement

Sponsor Contact

Medtronic, Inc. is sponsoring the BlueSync™ Field Evaluation. Regional contact information is provided below. This information may be subject to change during the course of the field evaluation. Periodic updates to the evaluation contact information will be sent to hospital/clinics as needed.

Table 1: Evaluation Sponsor Contact Information

Evaluation Contacts	
Worldwide Program Leader Name, Title: Keith Holloman, Sr. Clinical Research Specialist Direct Phone: 1-763-525-1645 Direct Fax: 1-763.526.5897 keith.holloman@medtronic.com	*Europe Program Leader* Name, Title: Bart Wessels, PhD, Clinical Research Specialist Direct Phone: +31-611-347-595 Direct Fax: +31 (0)43 356 6514 bart.wessels@medtronic.com

1. Version History

Version	Summary of Changes	Author(s)/Title
1.0	Not Applicable, New Document	Keith Holloman, Sr. Clinical Research Specialist
2.0	Changes to transmission intervals Statistical analysis of the evaluation objectives will be included in a separate document. Therefore, all statistical analysis methods have been removed from the evaluation plan.	Keith Holloman, Sr. Clinical Research Specialist

2. Investigator Statement

Investigators will be provided with a separate investigator agreement to document their obligation and commitment with respect to field evaluation conduct.

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3. Glossary

Term	Definition
AF	Atrial fibrillation
app	Application
Azure™	Azure™ Smart Pacemaker
BlueSync™	BlueSync™ Smart Monitoring System
CRT-P	Cardiac Resynchronization Therapy Pacemaker
MCL Heart app	MyCareLink Heart App
Percepta™, Serena™, Solara™	BlueSync compatible CRT-P devices
Smart device	Smartphone or Tablet

4. Synopsis

Title	BlueSync™ Field Evaluation
Type	Post Market Non-Interventional Field Evaluation
Product Name	BlueSync™ Smart Monitoring System (BlueSync™)
Sponsor	Medtronic, Inc. Cardiac Rhythm and Heart Failure Clinical Research 8200 Coral Sea Street NE Mounds View, MN U.S.A. 55112 1-800-328-2518
Regional Sponsor	Medtronic, Bakken Research Center B.V. Endepolsdomein 5 6229 GW Maastricht The Netherlands +31-43-35-66-566
Patient included in evaluation	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.
Purpose	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 health care provider perception of the value of BlueSync™ and satisfaction with BlueSync™ (benefits experienced by clinicians that use BlueSync™).
Product Status	The evaluation will be conducted using the components described in Table 2 Only market released components will be used. Instructions for use of the devices used in this evaluation are provided in their respective manuals.

Table 2: System component information for the BlueSync™ Smart Monitoring System in Europe

Model Name	Model Number	Serial Number Prefix
Azure™ XT DR MRI SureScan™	W2DR01	RNF
Azure™ S DR MRI SureScan™	W3DR01	RNJ
Azure™ XT SR MRI SureScan™	W2SR01	RNE
Azure™ S SR MRI SureScan™	W3SR01	RNI
Percepta™ CRT-P Quad MRI SureScan™	W4TR04	RNV
Percepta™ CRT-P MRI SureScan™	W1TR04	RNU
Serena™ CRT-P Quad MRI SureScan™	W4TR05	RNX
Serena™ CRT-P MRI SureScan™	W1TR05	RNW
Solara™ CRT-P Quad MRI SureScan™	W4TR06	RNZ
Solara™ CRT-P MRI SureScan™	W1TR06	RNY

System component #1

- BlueSync™ Smart Monitoring System
- MCL Heart app
    - MSW002 (Android), MSW004 (IOS)

System component #2

- Azure™ Dual and Single Chambered Smart Pacemaker and Percepta™, Serena™, Solara™ CRT-P devices with Bluetooth enabled functionality, as indicated in Table 2

Additional system components

- Patient's own smart device.

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.
Sample Size	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. The evaluation is expected to be conducted at approximately 30 centers, 15 in Europe and 15 in the United States. Up to approximately 35 patients will participate per hospital/clinic participating in the evaluation. Clinicians will sequentially screen patients who are indicated for implant with a pacemaker or CRT-P device. Patients who will be/have been implanted with an Azure™ Pacemaker or Percepta™, Serena™, Solara™ CRT-P device will be invited to participate in the evaluation if the specified selection criteria are met. Patients will complete a visit during enrollment which is standard of care. Additionally, patients will complete a survey during the enrollment visit and once during the 12-month follow-up after enrollment to measure patient engagement.
Duration	The expected evaluation duration is approximately 16 months: Four months for enrollment of all patients and 12 months to complete follow-up. The duration of individual patient participation will be 12 months of follow-up from enrollment.
Screening Criteria	Patient indicated for a pacemaker with or without Cardiac Resynchronization Therapy (CRT)
Inclusion/Exclusion Criteria	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 • Patients must be of legal age according to local law Exclusion criteria: • Patient unwilling to complete required surveys during 12-month evaluation period. •

Evaluation Procedures and Assessments	**Screening**: 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 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: • Age • Education • Smart device experience • Smart device usage • Smart device type (Apple vs Android, phone vs tablet, only one vs. multiple) If the patient declines participation in the evaluation, the reasons will be documented on the screening log. **Enrollment**: 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 procedures will be completed after implant and within two week of discharge from the hospital or clinic. For patients who had a BlueSync™ compatible device implanted previously this can be longer than two weeks from discharge. • The process to pair the MCL Heart app and the patient's smart device to the patient's implanted device will be completed. Specific instruction will be provided to the clinic and patient under separate cover. • After the patient's implanted device is paired with the MCL Heart app, a transmission will be sent to confirm that the MCL Heart app in the patient's smart device is paired with the patient's implanted device. • The patient will complete their first survey to assess patient perceived benefit of BlueSync™. • A clinician survey corresponding to each patient will be completed to assess clinic perception of value of BlueSync™. **Twelve Month Follow-up Period After Enrollment:** • A total of six scheduled transmissions with the MCL Heart app will be completed during the 12-month follow-up period. • Two transmissions will be scheduled to occur in the first month of follow up (one scheduled transmission 2 weeks after enrollment and

	another four weeks after enrollment).
	• Four quarterly scheduled transmissions must occur starting at month 3 of follow up after enrollment (one scheduled at month 3, another scheduled at month 6, the next scheduled at month 9 and the last one scheduled at month 12).
	• During the 12-month follow-up period after enrollment patients will complete a survey during a scheduled annual device follow-up visit to assess patient perceived benefit of BlueSync™
	• In situations where a routine device follow-up visit is not scheduled the survey can be completed using remote options.
	• Clinician surveys corresponding to each patient will be completed to assess health care provider perception of value of BlueSync™ and satisfaction with BlueSync™ at 12 months
	• At each clinic, a workflow questionnaire will be completed by clinic personnel after all enrolled patients have completed the device pairing.
	• Clinic personnel will complete and maintain a technical/transmission issues log which will include but not be limited to:
	  • Inefficiencies associated with transmission workflow and/or MCL Heart application use.
	  • Unscheduled transmissions and action taken
	  • The transmission/issues log will be maintained by the clinic until all enrolled patients have completed the 12 months Field Evaluation duration.
	
	Evaluation completion:
	• The patient's participation in the evaluation will end after 12 months of follow-up.

Safety Assessments	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.

5. Introduction

5.1. Background

Modern cardiac disease management seeks to integrate multiple device technologies and capabilities to optimize disease management and health outcomes. The BlueSync™ Smart Monitoring System utilizes a Bluetooth enabled smart device application to interface with the Azure™ Smart pacemaker to provide wireless remote monitoring for patients.

The use of smart device technology allows for the integrated monitoring by a smart device and eliminates the "bedside monitor". The informative and reassuring app allows the patient to view the status of CareLink

transmission, physical activity and provides access to educational information which creates a completely new experience for the patient.

Since Medtronic has never launched a product that relies on patients utilizing their own smart device instead of a home monitor, BlueSync™ will be evaluated for compliance, patient perceived benefit, and value to the clinic using the technology as well as for identifying workflow issues in this new paradigm.

Value of Remote Monitoring for pacemaker patients

The 2015 HRS Expert Consensus Statement on Remote Interrogation states that remote monitoring represents the new standard of care with alert-driven in-person evaluation replacing most routine office interrogations.

Early detection of arrhythmias, lead issues and battery Recommended Replacement Time may lead to important clinical actions for pacemaker patients. Pacemaker patients have a high risk of atrial fibrillation (AF). AF is a known risk factor for stroke. For example, there is an opportunity (outside the scope of this evaluation) to better manage AF leveraging the pacemaker capabilities[1].

In large studies, remote monitoring of pacemaker patients is associated with:

- Increased survival: Patients with high remote monitoring adherence had 53% greater survival than low remote monitoring and 140% greater survival than no remote monitoring[2]
- 26% faster diagnosis of clinical actionable events (PREFER)[3]
- 66% fewer hospitalizations from atrial arrhythmias (COMPAS)[4]
- 56% fewer ambulatory visits (COMPAS)[4]
- Lower health care expenditures in office visits among patients with permanent pacemakers[5]

5.2. Purpose

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 value of BlueSync™ and satisfaction with BlueSync™. Collection of this data will support development of clinical evidence that can be used to aid in market adoption. 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 field evaluation will also assess adoption to remote monitoring, patient perceived benefit of BlueSync™ (how patients interact with the MCL Heart application) and clinic perception of value of BlueSync™ and satisfaction with BlueSync™ (benefits experienced by clinicians that use BlueSync™. A description of the statistical analysis of the evaluation will be included in the BlueSync Statistical Analysis Plan.

The expected evaluation duration is 16 months; four months for enrollment and twelve months to complete follow-up. The duration of individual patient participation will be 12 months from enrollment date.

6. Evaluation Design

The BlueSync™ Field Evaluation will be a multi-center, prospective, single-arm, post-market field evaluation. BlueSync™ compatible devices that will be part of this field evaluation are listed in

Table 2

The purpose of this field evaluation is to collect and evaluate information related to CareLink transmission compliance as well as adoption of remote monitoring, patient perceived benefit of BlueSync™ and the health care provider perception of value of BlueSync™ and satisfaction with BlueSync™.

Approximately 700 patients will be screened. It is estimated that 60% (420) of the screened patients will use smart technology and 60% (252) of these patients will meet the inclusion/exclusion criteria to be enrolled in the evaluation.

Assuming attrition from enrollment through 12 month of follow-up is 7%, a total of 252 patients will be enrolled in this evaluation to allow approximately 234 patients to have Azure™, or Percepta™, Serena™, Solara™ CRT-P device implanted and compatible with BlueSync™ and MCL Heart app downloaded onto the patient's smart device and patients been followed for 12-month with a total of six scheduled transmissions to occur remotely.

The evaluation will be conducted at approximately 30 hospital/clinics, 15 in Europe and 15 in the United States. Up to approximately 35 patients will participate from each hospital/clinic participating in the evaluation.

6.1. Duration

The expected total evaluation duration is approximately 16 months: 4 months for patient enrollment and at least twelve months for the patient follow-up. Patients are anticipated to be in the evaluation for approximately 12 months. Patients will complete an enrollment visit and then complete participation in the evaluation after the 12 months follow-up period. Patients will not be replaced with newly enrolled patients upon completion of participation in the evaluation. As described above, the sample size accounts for attrition.

6.2. Rationale

Medtronic has developed the BlueSync™ feature which is a cardiac monitoring system that is secure, reliable, provides select information to patients about their pacemaker or CRT-P device and only needs the patient's smart device to monitor the patient remotely. BlueSync™ connects the pacemaker or CRT-P device via low energy to the patient's smart device and the CareLink network. BlueSync™ allows for automatic transmission of device data through the use of Bluetooth technology as long as the smart device is kept within one meter of the implanted device.

This evaluation provides an opportunity to confirm that BlueSync™ will improve patient compliance to scheduled transmission as recorded in the CareLink Network. See Section 5.2 for further background information and evaluation of collected data. See Section 11 for further background on the evaluation design.

7. Product Description

7.1. Evaluation Components

The BlueSync™ compatible devices used in the evaluation have FDA and CE mark approval and are market released. See Table 3 for model names and numbers.

Table 3: System component information for the Azure™ Smart Pacemaker

Model Name	Model Number	Serial Number Prefix
Azure™ XT DR MRI SureScan™	W2DR01	RNF
Azure™ S DR MRI SureScan™	W3DR01	RNJ
Azure™ XT SR MRI SureScan™	W2SR01	RNE
Azure™ S SR MRI SureScan™	W3SR01	RNI
Percepta™ CRT-P Quad MRI SureScan™	W4TR04	RNV
Percepta™ CRT-P MRI SureScan™	W1TR04	RNU
Serena™ CRT-P Quad MRI SureScan™	W4TR05	RNX
Serena™ CRT-P MRI SureScan™	W1TR05	RNW
Solara™ CRT-P Quad MRI SureScan™	W4TR06	RNZ
Solara™ CRT-P MRI SureScan™	W1TR06	RNY

7.2. Product Use

BlueSync™ offers app-based remote monitoring via the patient's own smart device: The Azure™ pacemaker and Percepta™, Serena™, Solara™ CRT-P devices. Azure™ pacemakers include a Bluetooth Low Energy chip that allows wireless communication between the pacemaker and the patient smart device. The patient's smart device acts as a hub and transmits the data through the MCL Heart app to the remote monitoring network (see Figure 1). In addition, the MCL Heart app provides additional information to the patient such as his/her physical activity, transmission status and background information (see Figure 2).

Figure 1 Explanation of BlueSync™

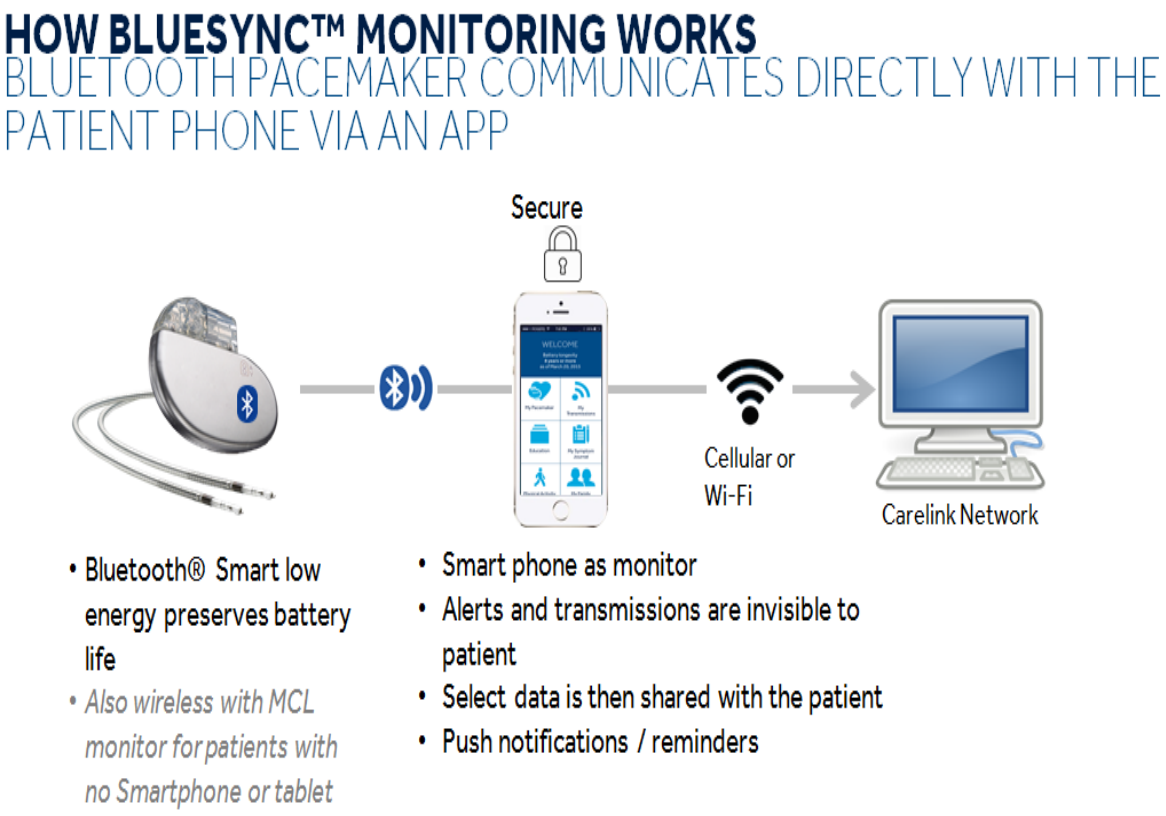
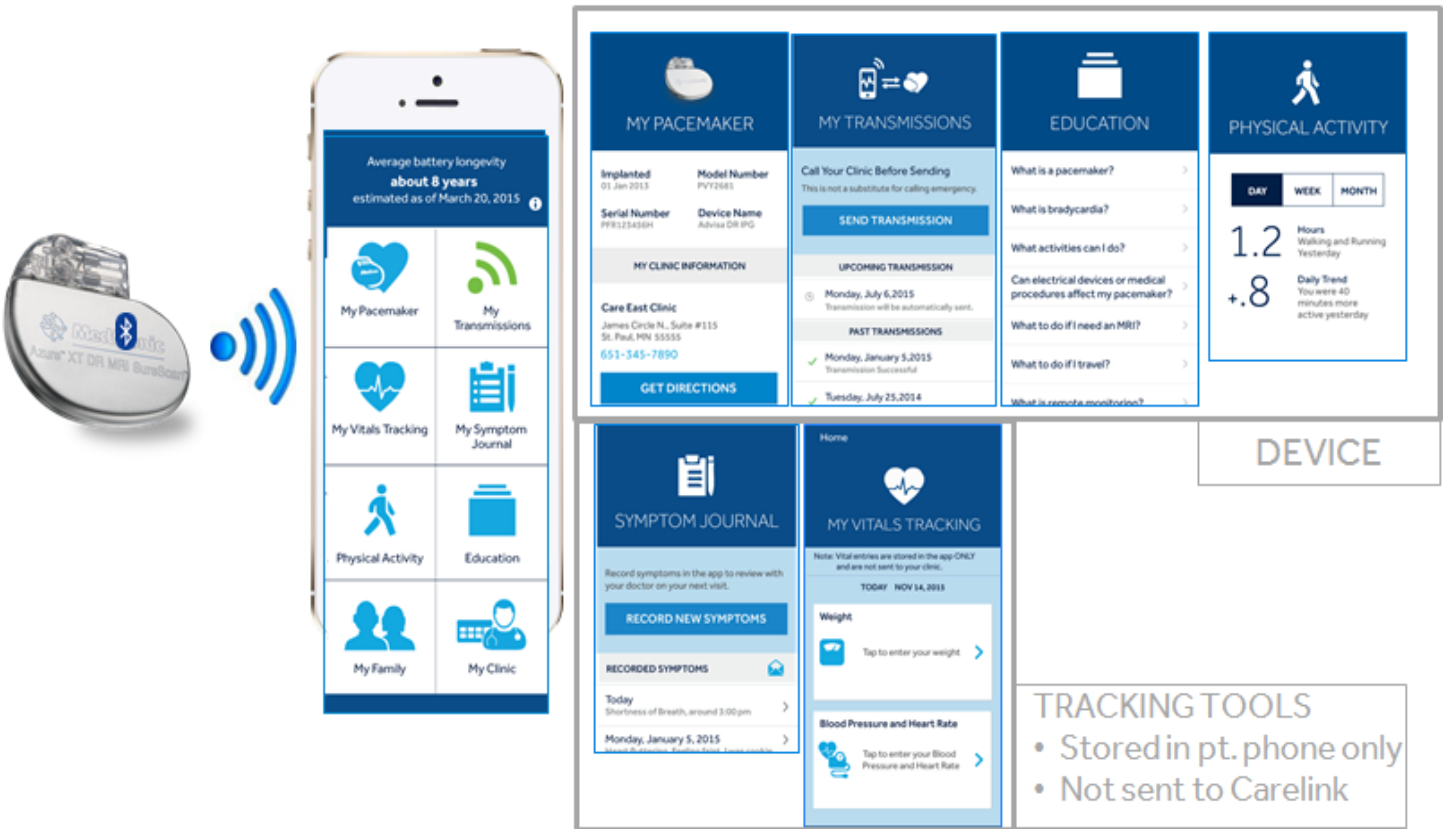


Figure 2 MyCareLink Heart App Operation



8. Selection of Patients

8.1. Evaluation Population

The evaluation will enroll patients who have been implanted with an Azure pacemaker or Percepta, Serena or Solara CRT-P devices, meet all of the inclusion criteria, and none of the exclusion criteria for the BlueSync™ field evaluation, and completed device pairing.

8.2. 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. See section 9.4.

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.

8.3. Minimization of Bias

In summary, potential sources of bias that may be encountered in this evaluation have been considered and minimized by careful evaluation design.

Selection of patients, treatment of patients, and evaluation of evaluation data are potential sources of bias. Methods incorporated in the evaluation design to minimize potential bias include (but are not limited to):

- Hospital/clinics will not exceed approximately 35 (15%) enrollments to ensure a diverse patient population experience across multiple geographies and types of hospitals.
- All center personnel will be trained in evaluation transmissions workflow and other procedures to ensure consistency across all geographies and evaluation centers.
- All patients indicated for a pacemaker or CRT-P device will be screened sequentially to determine their ability to participate in the evaluation.
- Data collection requirements and evaluation procedures will be standardized across all hospital/clinics

9. Evaluation Procedures

Prior to performing evaluation related procedures, all hospital/clinics must have documentation from Medtronic of hospital/clinic readiness.

Sponsor representatives may provide support as required for the evaluation under supervision of the Primary Investigator, including:

- Provide evaluation training relevant and pertinent to the involvement of personnel conducting evaluation activities and investigator responsibilities
- Technical support under the supervision of an evaluation investigator, but no data entry, shall be performed by Medtronic personnel or their representatives at all hospital/clinics

9.1. Hospital/Clinic Personnel Requirements

All hospital/clinic personnel involved in the evaluation must be experienced in remote monitoring.

The role of the Primary Investigator is to implement and manage the day-to-day conduct of the field evaluation as well as ensure data integrity and the rights, safety and well-being of the patients involved in the field evaluation.

The Primary Investigator shall:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the field evaluation

The Primary Investigator shall be able to demonstrate that the proposed evaluation hospital/clinic:

- Has the required number of eligible patients needed within the recruitment period
- Has a qualified staff and adequate facilities for the foreseen duration of the field evaluation
- Has adequate time and resources to conduct the evaluation throughout the duration of the evaluation

Hospital Clinic personnel training will be completed prior to participation in this evaluation. lists the requirements to be completed for evaluation personnel prior to conducting any evaluation procedure.

9.2. Hospital/Clinic Approval to Participate in Field Evaluation

During the process to prepare sites for participation in the evaluation (prior to patient enrollment), Medtronic will train hospital/clinic personnel on the Field Evaluation Plan data collection and reporting tools. If new members join the evaluation center team, they will receive training on the applicable field evaluation requirements relevant to their role before contributing to the field evaluation.

A Field Evaluation Agreement shall be entered into effect by Medtronic, the participating hospital/clinic and/or the Primary Investigator at each evaluation hospital/clinic as per local legal requirements, and returned, fully executed, to Medtronic prior to the commencement of any evaluation activities. Financial aspects of conducting and reporting on the evaluation will be specified in the agreement. By signing and dating the agreement the investigator indicates approval of the field evaluation.

Prior to performing evaluation related activities, the following requirements shall be fulfilled:

- Fully executed Field Evaluation Agreement
- Documentation of contact list of hospital/clinic personnel

- Documentation of evaluation hospital/clinic personnel training

Medtronic will provide each evaluation center with field evaluation materials (i.e. patient binders, workflow instructions) and documentation of evaluation center/investigator readiness; this letter must be received prior to patient enrollment.

9.3. Schedule of Events

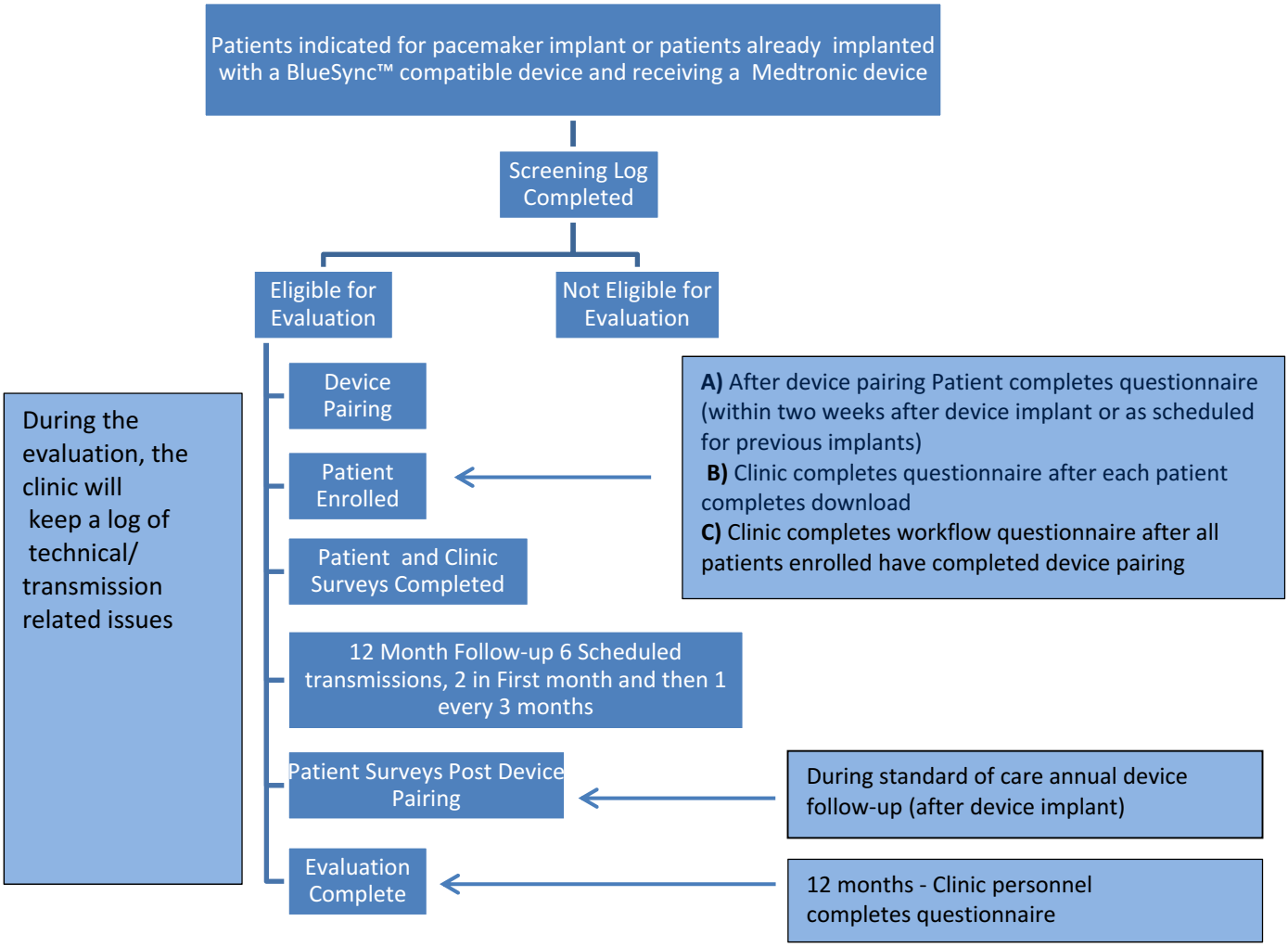
Field evaluation data is collected at designated time points throughout the evaluation as indicated in Table 4. At the end of the evaluation, the data will be frozen and retained by Medtronic.

Table 4: Data collection and evaluation procedure requirements

Field Evaluation Data Collection Requirements	Screening	Device Pairing	2 weeks	4 weeks	3 months	6 months	9 months	12 months	Annual Device Follow-up	Evaluation Completion (12 months)
Evaluation eligibility confirmed	X									
Patient Screening	X									
Enrollment		X								
Patient Demographics	X									
Patient Education and smart device usage	X									
[redacted]										
Scheduled Transmissions Post Device Pairing			X	x	x	x	x	x		x

* A total of six scheduled transmissions with the MCL Heart app will be completed during the 12-month follow-up period. The first two scheduled transmissions must occur at 2 and 4 weeks after enrollment. Four scheduled transmissions must occur quarterly 1 each 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).

Figure 3 Evaluation Screening, Enrollment and Follow-up



9.4. Patient 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. 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 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
- Education
- Smart device experience
- Duration of smart device experience
- Type of smart device
- Compatibility
- Comfort level with technology
- Smart device usage
- Type of smart device usage:
  - Phone calls
  - Text messages
  - Email
- Internet Use

If the patient declines participation in the field evaluation, the reasons will be documented on the screening log.

Patient screening must be completed prior to discharge from the hospital or clinic and before enrollment.

9.5. Enrollment

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 of the BlueSync™ compatible device with the CareLink network via the My CareLink Heart App.

The following procedures will be completed after implant and within two weeks of discharge from the hospital or clinic. For patients who had a BlueSync™ compatible device implanted previously this can be longer than two weeks from discharge:

- The MCL Heart app will be downloaded on the patient's smart device after implant and the process for pairing the MCL Heart app to the Azure device will be initiated. Specific instructions will be provided to the clinic and patient under separate cover.
- After the patient's implanted device is paired with the MCL Heart app, a transmission will be used to confirm that the MCL Heart app in the patient's smart device is paired with the patient's implanted device. The patient will complete their first survey to assess patient perceived benefit of BlueSync™.
- A clinician survey corresponding to each patient will be completed to assess clinic perception of value of BlueSync™ and satisfaction with BlueSync™.

9.6. Twelve Month Follow-up Period

Twelve Month Follow-up Period after enrollment:

- A total of six scheduled transmissions with the MCL Heart app will be completed during the 12-month follow-up period.
- Two scheduled transmissions must occur in the first month of follow up (one scheduled transmission at two weeks and the second transmission at four weeks after enrollment).
- Four quarterly scheduled transmissions must occur, 1 each 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).
- During the 12-month follow-up period after enrollment patients will complete a survey during a scheduled annual device follow-up visit to assess patient perceived benefit of BlueSync™. In those situations where a routine device follow-up visit is not scheduled the survey will be completed using remote options.

- Clinician surveys corresponding to each patient survey will be completed to assess clinic perception of value of BlueSync™ and satisfaction with BlueSync™ at baseline and 12 months.
- A workflow questionnaire will be completed by clinic personnel after all enrolled patients have completed the device pairing.
- Clinic personnel will complete and maintain a technical/transmission issues log which will include but not be limited to:
    - Inefficiencies associated with transmission workflow and/or MCL Heart application use.
    - Unscheduled transmissions and action taken
    - The transmission/issues log will be maintained by the clinic until all enrolled patients have completed the 12 months Field Evaluation duration.

9.7. Evaluation Completion

The participants' involvement in the evaluation will end after 12 months from enrollment or after one of the following occur:

- Patient refuses to complete the second survey
- Patient decides to withdraw from the evaluation
- Investigator withdraws patient

Following completion of the evaluation, patients will continue to receive standard medical care. There will be no further evaluation-related activities after evaluation is complete.

9.8. Recording Data

Patient questionnaires will be entered directly into an online electronic data management system or collected via paper and entered into the electronic data management system. The option used by the patient to complete the questionnaire will be based upon what is most appropriate.

10. Risks and Benefits

10.1. Potential Risks

There are no incremental risks introduced to the patient as a result of participation in this evaluation.

The safety and clinical performance of the market released systems in this evaluation have been demonstrated through previous pre-clinical testing and clinical studies in similar populations, but not necessarily the same population as this evaluation. Continuous monitoring, assessment and documentation of risk will be performed by the investigator.

10.2. Potential Benefits

BlueSync™ may offer no benefit. The information gained from this evaluation could result in the improved management of other patients with bradycardia and heart failure conditions. Additionally, information collected from this evaluation may assist in the design of new product(s)/therapy (ies) and/or instructions for use.

10.3. Risk-Benefit Rationale

The risk-benefit analysis has shown that there are no major or minor additional risks associated with the BlueSync™ feature.

11. Statistical Analysis

Medtronic employees or designees will perform all statistical analyses. A separate Statistical Analysis Plan (SAP) will be developed to describe statistical methods, pre-specified data handling rules, and pre-specified analyses that will be included in the evaluation report.

12. Evaluation Administration

12.1. Data Management

Data will be collected using an electronic online based platform. Data will be stored in a secure, password-protected database. All records and other information about patients participating in this evaluation will be treated as confidential.

12.2. Investigator Records

The investigator is responsible for the preparation and retention of the records cited below. All of the below records should be kept in the Investigator Hospital/clinic File (i.e., the evaluation binder provided to the investigator) or Patient Evaluation Binder. The following records must be maintained as required by local law or hospital administration after the date on which the field evaluation is terminated

- All correspondence between sponsor and the investigator that pertains to the investigation, including required reports
- Signed and dated Field Evaluation Agreement
- Evaluation training records for hospital/clinic staff

12.3. Sponsor Records

Medtronic shall maintain the following accurate, complete, and current records:

- All correspondence which pertains to the evaluation
- Signed Field Evaluation Agreements,
- Names of the institutions in which the evaluation will be conducted
- Statistical analyses and underlying supporting data
- The Evaluation Plan and evaluation related reports, and revisions
- Evaluation training records for hospital/clinic personnel and Medtronic personnel involved in the evaluation

13. References

Refer to Appendix A

14. Appendices

APPENDIX A: BIBLIOGRAPHY

1 Chen KP et al. Reduction of atrial fibrillation in remotely monitored pacemaker patients: results from a Chinese multicenter registry. Chin Med J (Engl). 2013 Nov;126(22):4216-21

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5. Ladapo J, et al. Remote Monitoring of Implantable Cardiovascular Devices is Associated with Reductions in Healthcare Utilization. Presented at HRS 2014.