Medtronic **Clinical Investigation Plan**	
Clinical Investigation Plan (CIP)	**Surgical** PRODUCT SURVEILLANCE REGISTRY (PSR) PLATFORM BASE
Sponsor/Local Sponsor	Medtronic, Inc. Operational Headquarters 710 Medtronic Parkway Fridley, MN 55432 Note: Other geographies and/or locations are included under a separate cover.
Document Version	Version 3, 25 Feb 2025 Comprised of: PSR Core Version 9, 19 May 2020 Surgical Appendix Version 3, 25 Feb 2025 Note: A record of CIP approvers is maintained under a separate cover and can be requested if required per local regulations.

Confidentiality Statement

1. Investigator Statement

Clinical Investigation Plan (CIP)	**Surgical** PRODUCT SURVEILLANCE REGISTRY (PSR) PLATFORM BASE
Document Version	Version 3, 25 Feb 2025
I have read the protocol, including all appendices, and I agree that it contains all necessary details for me and my staff to conduct this registry as described. I will conduct this registry as outlined herein. I agree to comply with Federal Regulations (21 CFR Part 11, 50 and 56), the International Standard (ISO) 14155, and applicable regional/local regulations. I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation and conduct of the registry without the prior written consent of Medtronic. I will provide all registry personnel under my supervision copies of the protocol and access to all information provided by Medtronic. I will discuss this material with them to ensure that they are fully informed about the registry.	
Investigator's Signature:	
Investigator's Name:	
Institution:	
Date:	

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2. Glossary

Acronym	Term
AD	Addendum
ADE	Adverse Device Effect
AE	Adverse Event
AP	Analysis Plan
CEC	Clinical Event Committee
CFR	Code of Federal Regulations
CIP	Clinical Investigation Plan
CRF	Case Report Form
CTA	Clinical Trial Agreement
DD	Device Deficiency
DRF	Data Release Form
EC	Ethics Committee
eCRF	Electronic Case Report Form
FD	Financial Disclosure
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
IC	Informed Consent
ICF	Informed Consent Form
IFU	Instructions for Use
IRB	Institutional Review Board
ISO	International Organization for Standardization

Acronym	Term
LAR	Legally Authorized Representative
MEC	Medical Ethics Committee
PI	Principal Investigator
PSR	Product Surveillance Registry
RA	Regulatory Authority
SADE	Serious Adverse Device Effect
REB	Research Ethics Board
SAE	Serious Adverse Event
US	United States of America
USADE	Unanticipated Serious Adverse Device Effect

3. Synopsis

Clinical Study Type	Post-Market Registry
Product Status	Medtronic market released products Instructions for Use (IFU) and/or product labelling provided in their respective manuals
Sponsor	Medtronic, Inc. Operational Headquarters 710 Medtronic Parkway Fridley, MN U.S.A. 55432 1-800-633-8766 Note: Medtronic, Inc. is the funding source for the Product Surveillance Registry
Local Sponsor	All Medtronic geographies and/or locations are listed under a separate cover
External Organizations	External organizations involved in the clinical investigation, if applicable, will be listed under a separate cover
Purpose/Overview	• Provide continuing evaluation and periodic reporting of safety and effectiveness of Medtronic market-released products for their intended use • Obtain real-world performance and safety information from a global network of hospitals, clinics, and clinicians intended to represent the range of clinical environments in which Medtronic products are used • Support post-market surveillance activities and post-approval studies that are initiated by Medtronic, regulated by local governments, or are conducted to fulfill government and/or regulatory authority requests • Obtain clinical evidence to guide the development and improvement of medical devices, therapies, device guidelines, and patient services/solutions • Provide clinical data to support health economics and clinical outcomes research
Objectives	Serve as an ongoing source of product performance, patient safety and clinical outcomes information associated with the use of market-released products. Objectives include: • To identify device failures, adverse events or adverse event trends • To characterize patient outcomes

	• To characterize patterns of product use • To characterize predictors of performance and effectiveness • To identify potential signals for emerging performance issues
Study Design	Patient-centric, active post-market registry with an extensible design allowing products to be added following market release. Patients are enrolled and followed in accordance with the routine care practices of their care provider.
Eligibility Criteria	Inclusion Criteria: • Patient or legally authorized representative (LAR) provides authorization and/or consent per institution and geographical requirements • Patient has or is intended to receive or be treated with an eligible Medtronic product • Patient is consented within the enrollment window of the therapy received, as applicable Exclusion Criteria: • Patient who is, or is expected to be, inaccessible for follow-up • Participation is excluded by local law • Patient is currently enrolled or plans to enroll in concurrent drug/device study that may confound the PSR results Note: Additional criteria may be required, refer to Condition/Therapy Appendix for further guidance.
Study Procedures and Assessments	Medtronic products are used to monitor, diagnose and/or treat many medical conditions. The PSR is an observational registry intended to collect data consistent with routine clinical care practices. In general, data collection includes: • Demographics • Medical History • Procedure Information • Patient Status • Adverse Events • Outcome Measures • Device Deficiencies In-person follow-up frequency is intended to align with routine clinical care practices consistent with real-world data collection.

	However, in real-world clinical settings, routine care practices may vary for several reasons including but not limited to: physician preference, a patient's condition and/or personal circumstances; therefore, to mitigate potential bias and ensure a robust data set, sites are required to report patient status at regular intervals regardless of whether the patients are seen in-person. Events are reported upon a site's first awareness throughout a patient's participation. Reportable events include: • Device-Related Events • Procedure-Related Events • Therapy-Relevant Events[1]

Note[1]: Additional therapy-specific details may be provided in the Condition/Therapy Appendix.

4. Introduction

4.1. Background

Medtronic's commitment to quality is exemplified in our mission, "To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service." Consistent with this commitment, Medtronic has continually worked to develop systems and processes to more effectively monitor product performance following market release. Medtronic launched the global Product Surveillance Registry (PSR) in 2011, which was built on more than 25 years of post-market clinical surveillance experience to create a comprehensive product registry.

The PSR is sponsored by Medtronic and is comprised of a global network of hospitals, clinics and clinicians from which reliable real-world product safety and patient clinical outcome information is generated. It leverages a common infrastructure designed for the collection, analysis and dissemination of surveillance information for multiple Medtronic device technologies.

4.2. Purpose

The purpose of the PSR is to provide continuing evaluation and periodic reporting of safety and effectiveness of market-released products for their intended use. PSR data will support post-market surveillance activities and post-approval studies that are initiated by Medtronic, regulated by local governments, or are conducted to fulfill government and/or regulatory authority requests. The PSR will also obtain clinical evidence to guide the development and improvement of medical devices, therapies, device guidelines, patient services/solutions and provide clinical data to support health economics and

clinical outcomes research. Conducting product surveillance in populations over time provides an effective means of assessing product performance, patient safety and clinical outcomes. Product surveillance is the systematic collection, analysis, and interpretation of performance data, as well as its dissemination and application.

The PSR is designed to provide a repository of data for conducting signal detection activities for identification of emerging patient safety or performance issues. It is designed to obtain real-world performance and safety information from a global network of hospitals, clinics, and clinicians intended to represent the range of clinical environments in which Medtronic products are used. It provides a mechanism for gaining an increased understanding of the relationship between a product's performance and clinical outcomes, as well as improving patient safety by identifying potential performance trends.

The PSR data are intended to benefit and support interests of patients, hospitals, clinicians, regulatory bodies, payers, and industry by streamlining the clinical surveillance process and facilitating leading edge performance assessment via the least burdensome approach.

4.3. Eligible Products

Eligible products include market-released products. Approved indications of use for each market-released product are defined in the Instructions for Use (IFU) and/or product labelling. Not all Medtronic market-released products are eligible for enrollment. Product eligibility is based on the determination that there is an interest or requirement for obtaining additional information to further characterize product performance following market release. Medtronic may limit enrollment using an Enrollment Guide typically when the number enrolled is adequate to effectively assess product performance or product availability is restricted.

5. Objectives

5.1. Objectives

Conducting active post-market surveillance is dynamic. Therefore, the PSR is designed to adapt as technology, information, and/or requirements change with the capability of aggregating multiple surveillance data sources, providing increased value and utility in terms of product performance assessment. The objective of the PSR is to serve as an ongoing source of product performance, patient safety and clinical outcomes information associated with the use of market-released products.

Objectives include:

- To identify device failures, adverse events or adverse event trends

- To characterize patient outcomes
- To characterize patterns of product use
- To characterize predictors of performance and effectiveness
- To identify potential signals for emerging performance issues

6. Design

6.1. General

The PSR is designed to conduct active post-market surveillance. The PSR has an extensible design allowing products to be easily added following market release. Only patients treated with an eligible product can be enrolled, refer to Section 4.3. Data collection is intended to align with routine clinical care practice.

The PSR is patient-centric, following patients receiving one or more therpaies over their continuum of clinical care. Sites may participate and contribute to the surveillance of multiple therapies. Sites are not required to participate in all PSR-supported conditions and/or therapies.

The PSR Platform Base CIP format has a modular design which provides a framework for the collection of surveillance data to support Medtronic's product portfolio. The PSR Platform Base CIP for a given Condition/Therapy is comprised of the following:

- PSR Core: defines elements applicable to all PSR patients, products, conditions, or therapies
- PSR Condition/Therapy Appendix: expands on the content of the PSR Core to further define specific procedure and data collection requirements for a given Condition/Therapy and is intended to align with routine care practices

The PSR Platform Base CIP is referred to as "CIP" throughout this document. The CIP for a given Condition/Therapy defines all minimum patient and site participation requirements (Refer to Figure 1).

Figure 1: PSR Platform Base CIP Modular Design

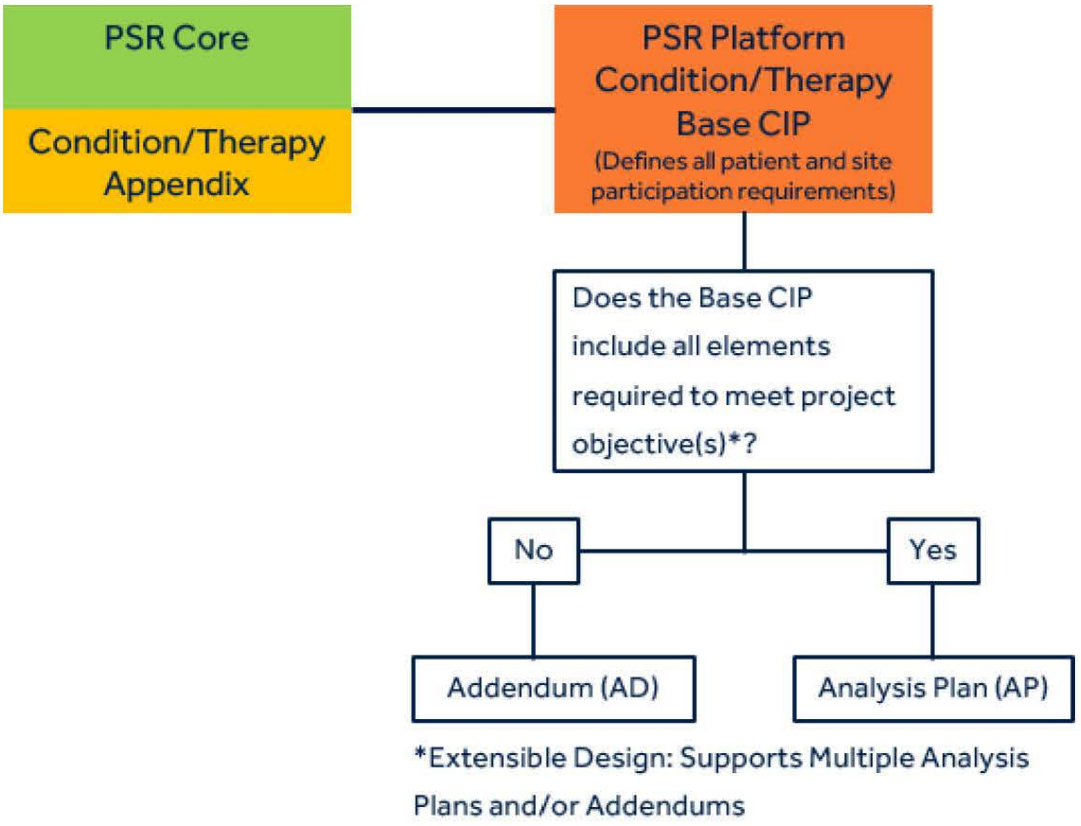
6.2. Analysis Requirements

Specific analysis requirements are documented, as applicable, and are integrated with the CIP in one of two ways, either via an associated Analysis Plan (AP) or Addendum (AD). Refer to the decision process provided in (Figure 2).

An AP, at a minimum, specifies the intended sample size estimates, analysis time points, reporting, etc. for a sub-population (and their data) from the overall PSR cohort of a given Condition/Therapy. The AP document can be specific to a patient population, therapy, product or product group and defines how the data will be analyzed. It does not contain any procedures or data collection requirements that differ from the CIP; therefore, an AP has no impact on the patient or how the site conducts PSR activities.

An AD can be specific to a patient population, therapy, product or product group, but unlike the AP, it does contain procedure and/or data collection elements that differ from the CIP. The AD describes the specific procedures that differ from the CIP (e.g., regulatory directed requirement), therefore an AD may impact the patient and/or how the site conducts PSR activities. An AD may have IRB/ Ethics Board, consent and potentially regulatory implications; therefore, additional site readiness activities may be needed, refer to Section 9.2. An AD includes, but is not limited to, unique procedure requirements, objectives/endpoints, statistical methodology, analysis cohort, and reporting timelines.

Figure 2: Decision tree for use of AP or AD



6.3. Steps Taken to Minimize Bias

Sites must meet pre-defined criteria to be selected to participate in the registry. The following methods may be incorporated to further minimize potential bias:

- Sites will consider enrollment of all eligible patients
- Enrollment may be limited at a site level by product and/or by therapy
- Events may be adjudicated by an independent review committee, as determined by therapy or regulatory requirements
- Diverse geographical site representation
- Sites represent various types of practice settings including university, community, public and private
- Data may be assessed by an independent reviewer (e.g., Core lab) as determined by therapy
- Procedures and data collection requirements are standardized

In addition, confounding variables and factors will be taken into consideration during data analysis, as applicable. Confounding variables and factors may include, but are not limited to:

- Medical history (e.g., comorbidities, surgical history)
- Patient-related factors (e.g., age, sex)
- Concomitant therapies

6.4. Duration

The duration of the registry may vary per Condition/Therapy and has no anticipated overall end date.

6.5. Rationale

The PSR is designed to conduct active post-market surveillance in populations over time providing an effective means of assessing product performance, patient safety and clinical outcomes. The PSR has an extensible design allowing products to be added on an on-going basis.

7. Product Description

7.1. General

Eligible products include Medtronic market-released products. Not all Medtronic market-released products are enrolled into the PSR. Product eligibility is based on the determination that there is an interest or requirement for obtaining additional information to further characterize product performance following market release.

8. Selection of Subjects

8.1. Registry Population

Patients are treated with an eligible Medtronic market-released product. The PSR supports active post market surveillance of multiple products used in the clinical care of numerous patient conditions for which Medtronic offers treatment.

8.2. Subject Enrollment

Enrollment of a patient is complete once the Informed Consent Form (ICF) or the Data Release Form (DRF) and an Authorization, if applicable, have been obtained. The following data will be collected at Enrollment:

- Consent (DRF or ICF) signature and date

If consent is waived, or is not required by local regulations, refer to the Condition/Therapy Appendix for patient enrollment information.

Patients are to be enrolled within an enrollment window defined by the therapy received. Refer to the Condition/Therapy Appendix for specific enrollment criteria. It is the site's responsibility to maintain a log of all patients enrolled in the registry. A consent/enrollment tracking tool may be provided to sites to assist in tracking the attempts to enroll eligible patients.

Retrospective patient enrollment may be allowed in certain instances. Refer to the Condition/Therapy Appendix for more enrollment details, if applicable.

8.3. Inclusion Criteria

- Patient or legally authorized representative (LAR) provides authorization and/or consent per institution and geographical requirements
- Patient has, or is intended to receive or be treated with, an eligible Medtronic product (Section 4.3)
- Patient is consented within the enrollment window of the therapy received, as applicable

Additional criteria may be required, refer to Condition/Therapy Appendix for furtherguidance.

8.4. Exclusion Criteria

- Patient who is, or is expected to be, inaccessible for follow-up
- Patient is excluded by local law
- Patient is currently enrolled in, or plans to enroll in, any concurrent drug/device study that may confound the PSR results (i.e. no required intervention that could affect interpretation of all-around product safety and/or effectiveness)

Additional criteria may be required, refer to Condition/Therapy Appendix for further guidance.

9. Site Selection and Readiness

9.1. Site Selection

Sites participating in the PSR are located globally. At a minimum, the following criteria will be met before sites are selected for participation:

- Site clinicians are or will be users of Medtronic products
- Site has strong interest in active post-market surveillance

- Site has adequate resources, facilities, equipment and support staff
- Site can comply with registry requirements, local laws or regulations, and Medtronic requirements
- Sites are responsible for ensuring practicing clinicians are appropriately licensed/qualified
- Sites are responsible to ensure practicing clinicians are not debarred, disqualified, or working under sanctions in applicable regions
- PI qualifications confirmed

The role of the principal investigator (PI) is to implement and manage the day-to-day conduct of the registry as well as ensure data integrity and the rights, safety and well-being of the patients involved in the registry. The PI shall be qualified by education, training and experience to assume responsibility for the proper conduct of the clinical registry in accordance with the CIP and applicable local regulations.

9.2. Site Readiness

Prior to enrolling any patients into the PSR, sites must fulfill all local law, regulatory and sponsor requirements. The term Ethics Board will be used to define Institutional Review Board (IRB), Medical Ethics Committee (MEC), Research Ethics Board (REB), or Human Research Ethics committee (HREC). Participation readiness includes but is not limited to:

- Ethics Board approval or a written statement by the Ethics Board Chairperson or PI stating that approval is not required or documentation that approval is not required per local law
- Documented Ethics Board and sponsor approval of the ICF or DRF (if required), CIP and associated Addendums (as applicable)
- A legally executed Clinical Trial Agreement (CTA)
- Insurance certificates (as required per geography)
- Regulatory authority notification/approval, if required
- Documented training

Sites are authorized to enroll patients in accordance with the CIP. A list of sites, including PI and institutions, participating in the registry is available under a separate cover.

Medtronic will provide PSR participating sites with applicable registry materials (e.g., site binder). Note: If an AD (Refer to Section 6.2) is required, additional site readiness activities specific to the AD may be required.

9.3. Training

Training includes an overview of, but not limited to, registry objectives, purpose, consent process, design, data collection, reporting and applicable regulations.

Any registry personnel assisting with execution of PSR-related tasks will require CIP training on the activities pertinent to their involvement. Training will be documented. Additional meetings or conference calls may be scheduled to address ongoing site training. Following appropriate training, delegation of tasks will be documented.

10. Registry Procedures

10.1 Clinical Data Collection and Procedure Descriptions

Medtronic products may be used to monitor, diagnose and/or treat many medical conditions, therefore the following sections provide a general summary of the type of information gathered and procedures applicable for all PSR enrolled patients regardless of their condition, procedure, and therapy received (Refer to Table 1 for an example).

The PSR is an observational registry intended to collect data consistent with routine clinical care practices. Real-world clinical practice routines are not consistent across sites (i.e., physician preference, patient's condition and/or personal circumstances); therefore, to mitigate potential bias and ensure a robust data set, patient status is required to be reported at regular intervals regardless of whether the patients are seen in-person. Refer to the Condition/Therapy Appendix for more detailed data collection and procedure requirements for a particular patient condition and therapy.

Data collection is intended to reflect routine clinical care procedures and may include prospective and retrospective data. Data collection details and CRFs (where required) are provided under separate cover.

10.2 Schedule of Events

Table 1: Example of Data Collection Requirements

	Enrollment	Baseline	Procedure (*)	Follow-up	Exit
ICF or DRF Signed and Dated	X				
Demographics		X			
Outcome measures (if applicable)		X		X	X

	Enrollment	Baseline	Procedure (*)	Follow-up	Exit
Medical History		X			
Device/System Information (if applicable)			X	X	
Procedure Details (*)			X		
Patient Status/Treatments		X	X	X	X
System Modification/ Retreatment			Upon Site's First Awareness		
Adverse Events	Upon Site's First Awareness				
Device Deficiencies	Upon Site's First Awareness				
Deaths	Upon Site's First Awareness				
CIP Deviations	Upon Site's First Awareness				

(*): Treatment initiation for those products which do not have a procedure

10.3 Informed Consent

Informed consent is defined as legally effective, documented confirmation of a patient's (or their LAR, legal representative, or guardian) voluntary agreement to participate in the PSR. Data Release Forms may also be utilized for the PSR since the PSR is focused on collecting real-world data available through medical records.

Patient consent will be obtained in accordance with local law and regulations. The ICF or DRF is signed only after all relevant information regarding participation has been provided to the patient. Consent must be obtained by PI or authorized designee. The ICF or DRF is applicable to all PSR patients as required. The ICF or DRF must include all information relevant to the patient's decision to participate. The ICF or DRF, and any applicable authorizations, must be approved by the sponsor and the site's Ethics Board unless an Ethics Board waiver for consent is obtained. The ICF or DRF documents must be maintained in such a way as to assure control of the document (i.e. version and/or date) such that the version(s) approved by the Ethics Board are clear with a documented change history for all revisions.

The process for obtaining informed consent shall:

- Avoid any coercion of, or undue/improper influence of patients to participate

- Not waive or appear to waive patient's legal rights
- Provide documents to the patient in a language she/he can read and understand
- Use language that is non-technical and understandable to the patient or legal representative
- Provide ample time for the patient to read and understand the ICF/DRF in order to consider participation
- Include a dated signature by the patient or legal representative acknowledging that their participation in the PSR is voluntary
- Include a dated signature by the responsible PI or authorized designee (if required by local law).

If the patient can't read or write, or is not able to fully understand all aspects of the registry, a witnessed and supervised (impartial third party) oral patient information consent is allowed as long as detailed documentation of the process is recorded in the patient's case history and the witness signs and dates the patient ICF or DRF on behalf of the patient. The ICF/DRF and any other information should be read aloud and explained within his/her ability to understand. Whenever possible, the patient/LAR shall sign ("make his mark", sign or otherwise physically mark the document to indicated consent) on the ICF/DRF. The impartial witness shall sign and personally date the ICF/DRF and Authorization (as determined by local law) to attest that the information was accurately explained, and consent was freely given.

Vulnerable patients are individuals who are unable to fully understand all aspects of the registry that are relevant to the decision to participate, or who could be manipulated or unduly influenced as a result of a compromised position, expectation of benefits or fear of retaliatory response. Examples of vulnerable patients may include a(n) infant, child and juvenile, seriously ill or unconscious patients, or patients with a mental or intellectual disability. Special consideration is required for vulnerable patients when considered for PSR participation. Patients who are considered "vulnerable" are to be consented according to the relevant local laws and regulations of the country in which they are located, as well as any other institutional requirements that apply, including those specified by the Ethics Board.

Unless waived by the Ethics Board, the signed ICF or DRF and the authorization (as determined by local law) must be filed at the site. A signed and dated copy of the ICF or DRF and any other authorizations, must be provided to the patient. The original signed ICF or DRF and the authorization (if required) or other privacy language where required by law, must be retained and made available for review by sponsor site monitors, auditors, or regulatory inspectors.

The consent process should be documented at each site, at minimum, with a progress note in the patient's case history. The consent process should ensure important new information is provided to patients throughout the registry, which may relate to the patient's willingness to continue participation in the registry. The consent process should follow local laws and regulations as applicable.

The ICF and DRF templates are not updated with each CIP revision unless the revision impacts the elements of the ICF or DRF template. The ICF and DRF can be revised independently of the CIP. Medtronic must approve any adaptation of the templates. For all sites requiring an ICF or DRF, the Ethics Board, Medtronic and regulatory authorities, if applicable, must approve the final ICF or DRF.

10.4 Baseline

The enrollment and baseline visit can occur at the same time. A general summary of the type of patient information collected at baseline includes but is not limited to:

- Confirmation of eligibility
- Demographics
- Medical history
- Baseline outcome measures for specific therapies and/or patients

10.5 Procedures

A general summary of the type of information collected at procedure or start of treatment includes but is not limited to:

- Device information (e.g., model, serial number)
- General relevant procedure information (e.g., placement methods & location, technique, and device measurements, as applicable by therapy)

10.6 Follow-up

Patient follow-up collection requirements are intended to generally align with the routine clinical care practices of the patient care providers consistent with real-world data collection. Refer to the applicable Condition/Therapy Appendix for follow-up frequency and data submission requirements specific to a given patient condition, procedure and/or therapy.

10.6.1 Frequency of Follow-up

At least one status update is to be reported annually for all PSR enrolled patients or until follow-up is complete, patient exit or death, or surveillance of the product is no longer active.

Refer to the applicable Condition/Therapy Appendix for the follow-up/data submission requirements for a given patient condition, procedure and/or therapy, which may be more frequent than annually.

The minimum follow up/data submission frequency is intended to facilitate regular updates regarding patient/device status and assess site reporting compliance.

10.6.2 Modes of Data Collection

The PSR may employ multiple modes of data collection as applicable to a given patient population and/or condition to ensure the most robust and reliable surveillance dataset is available for the wide

range of therapies and products supported within the PSR. Modes of collection may include such methods as:

- In-office patient clinic visit
- Remote technology device transmissions/uploads
- Direct to patient telephone, telehealth, email, or mail contact
- Web or application-based patient completed surveys

If, in the cases of direct to patient data collection, there is any indication that the patient has experienced or is possibly experiencing a reportable adverse event, the PSR participating site and Medtronic will be notified for appropriate follow-up.

Refer to the applicable Condition/Therapy Appendix for modes of data collection employed for a given patient condition, procedure and/or therapy.

10.6.3 Follow-up Duration

Duration of follow-up is determined by the condition, procedure, and therapy received (Refer to the Condition/Therapy Appendix).

10.6.4 Lost to Follow-up

A patient may be considered lost to follow-up when a patient's status is unknown. Confirmation that a patient is lost to follow-up will be obtained and documented prior to patient exit. When patients are lost to follow-up, registry personnel will make efforts to confirm the vital status of the patient.

Specific processes for determining Lost to Follow up status will be outlined in the Condition/Therapy Appendix.

10.7 System Modification/Retreatment

A system modification is any occurrence that changes either the status or the functionality (e.g., active to inactive) of a product. A system modification will be reported if the system or product is modified (e.g., electrically abandoned, explant, repositions, replacements, revisions) and can occur at any time. In the event of a system modification that results in the patient no longer being treated with a PSR eligible product (e.g., all eligible products are explanted), the patient must be exited.

A retreatment is a treatment performed a second or subsequent time.

Note: System Modification/Retreatment is not applicable to all Condition/Therapies; refer to the Condition/Therapy Appendix.

10.8 Patient Death

All deaths must be reported to Medtronic as soon as possible after the clinician/registry personnel first learns of the death. The PI will be required to review and acknowledge patient deaths.

Death Classification

Cause of death will be reported along with the clinician's assessment of product relatedness.

Death Data Collection

For adjudicated deaths, sufficient supporting documentation may be requested to properly adjudicate and classify a patient's death, if required. Provide as much of the following information as possible:

- Death certificate (if allowed by state/local law)
- Death summary/hospital records (if allowed by state/local law)
- Autopsy report (if allowed by state/local law)
- Device or image data, if applicable and available

Further supporting evidence that is not originally provided by the site may be requested by Medtronic to aid in the adjudication of the death.

10.9 Assessment of Safety

Event trends will be analyzed by Medtronic at regular intervals. In the event of an unanticipated occurrence rate or trend, Medtronic will review the specific details behind those observations and determine what, if any, action is appropriate. Examples of the review could include determining the root cause of the trend, review design, manufacturing data and other collected clinical data for correlation.

10.10 Recording Data

Data collection will be completed using printed or electronic case report forms (CRFs or eCRFs) designed to collect PSR reportable information. Registry personnel reporting the data are responsible for ensuring the accuracy and completeness of the recorded data. Visual and/or automated data checks will be performed by Medtronic. Procedures used for data review and issuing/resolving data discrepancies will be documented in a Data Management Plan. Registry personnel will be responsible for resolving all identified data discrepancies.

10.11 Deviation Handling

A deviation is defined as an event that did not occur according to requirements specific to regulations, CIP and/or associated AD. Examples include but are not limited to improper or incomplete ICF or DRF, patient did not meet eligibility criteria, etc.

Deviations will be reported and submitted to Medtronic each time a deviation occurs. The description of the deviation and justification must be documented and submitted to Medtronic.

Once a deviation has been identified it should be reported to Medtronic via CRF as soon as possible. Deviations may be identified through numerous sources, including but not limited to telephone conversations, site monitoring, patient record, or data review.

It is the site's responsibility to report deviations in compliance with their Ethics Board policies and/or local laws. For reporting requirements, refer to Table 3.

Medtronic is responsible for reviewing deviations and identifying any necessary corrective and/or preventive actions. Medtronic will determine whether any subsequent action is needed (e.g., amending the CIP or training). Repetitive or serious compliance issues may represent a need to initiate a corrective action plan and, in some cases, may necessitate suspending a site's ability to enroll until the problem is resolved.

Every attempt must be made to avoid registry deviations. If the PI and/or registry personnel anticipates, contemplates, or makes a conscious decision to deviate from PSR requirements, agreements or regulations, prior approval by Medtronic's registry team is required. In addition, prior approval is not necessary in situations where unforeseen circumstances are beyond the clinician's control.

10.12 Subject Exit, Withdrawal or Discontinuation

The rationale for patient exit should be documented in the patient's case history. Patients may be exited from the PSR under the following circumstances:

- Patient chooses to withdraw (e.g., consent withdrawal)
- PI deems withdrawal necessary (e.g., medically justified, failure of patient to maintain adequate registry compliance)
- Patient enrolled (signed ICF or DRF) prior to procedure or anticipated product use but procedure and/or product used not eligible for PSR enrollment
- All enrolled eligible products are inactive (e.g., electrical abandonment, product explant)
- Patient death
- Patient is no longer available for follow-up (i.e., lost to follow-up, refer to 10.6.4)

  NOTE: If the patient is determined to be lost to follow up, documentation will be obtained, and the patient may be exited from the PSR. In addition, requirements set-forth by the Ethics Board must be followed by sites.
- Site closure
- Patient has completed PSR follow-up requirements

11. Risks and Benefits

There are no expected additional benefits or risks relative to participation in the PSR as data is being collected on routine medical care and all products are market-released. Products eligible for enrollment are market-released and should be used in accordance with approved labeling.

12. Adverse Events and Device Deficiencies

12.1. Definitions/Classifications

All products enrolled in the PSR are approved with demonstrated evidence of safety and effectiveness for their intended use. Event definitions align with the International Organization for Standardization standard 14155 (ISO 14155); however, products followed in the PSR are approved, not investigational, and the purpose of the PSR is not to demonstrate product safety and effectiveness for the purpose of obtaining product approval, new material or design change for medical device already on the market.

Table 2: Adverse Event and Device Deficiency Definitions

Adverse Event (AE) (ISO 14155):	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other person, whether or not related to the investigational medical device and whether anticipated or unanticipated. Note 1: This definition includes events related to the investigational medical device or the comparator. Note 2: This definition includes events related to the procedure involved. Note 3: For users or other persons, this definition is restricted to the investigational medical device.
Adverse Device Effect (ADE) (ISO 14155):	Adverse event related to the use of an investigational medical device. Note 1: This definition includes any adverse event resulting from insufficient or inadequate instructions for use or the deployment, implantation, installation, or operation, or any malfunction of the medical device.

	Note 2: This definition includes any event resulting from user error or from intentional misuse of the medical device.
Serious Adverse Event (SAE) (ISO 14155):	Adverse event that: a) led to a death b) serious deterioration in the health of the subject, users or other persons as defined by one or more of the following: • a life-threatening illness or injury • a permanent impairment of a body structure or a body function including chronic disease • in-patient or prolonged hospitalization • medical or surgical intervention to prevent permanent impairment to body structure or a body function c) led to foetal distress, foetal death or a congenital abnormality or birth defect including physical or mental impairment. Note: Planned hospitalization for a pre-existing condition or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.
Serious Adverse Device Effect (SADE) (ISO 14155):	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Serious Health Threat (ISO 14155):	Signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects' users or other persons, and that requires prompt remedial action for other subjects, users or other persons. Note: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.
Procedure-Related Adverse Event:	Adverse event that is related to the procedure of a device/system of interest.

Unanticipated Serious Adverse Device Effect (USADE) (ISO 14155):	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment.
Device Deficiency (DD) (ISO 14155):	Inadequacy of a medical device with respect to its identity, durability, reliability, usability, safety or performance. Note: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling. This definition includes device deficiencies related to the investigational medical device of the comparator.

12.2. Reporting of Adverse Events & Device Deficiencies

Timely, accurate, and complete reporting and analysis of safety information for surveillance is crucial for the protection of patients, clinicians, and the sponsor. Reporting and analysis of safety data are mandated by regulatory authorities worldwide. Medtronic has established Standard Operating Procedures (SOPs) to ensure compliance with global regulatory safety reporting requirements. PSR activities are conducted in accordance with these SOPs. Since the safety reporting requirements and classification systems vary for each regulatory agency, requirements from the geographies are taken into account.

Only a subset of AEs will be reported. Events reportable to Medtronic as applicable for a given patient population include:

- Device-Related
- Procedure-Related
- Therapy-Relevant

Adverse events associated with users, or other persons than the patient, will not be captured in the registry, but should be reported through standard global complaint handling processes.

Only reportable events as defined in the Condition/Therapy Appendix are required to be submitted to Medtronic and all must be reported upon the site's first awareness of the occurrence. Refer to the Therapy/Condition Appendix for additional details, anticipated events, and a list of non-reportable events, if applicable.

The site will report any updates to an event for any changes in status of a previously reported event (i.e., change in action, change in outcome, and change in relatedness).

Any supporting evidence that could assist in the assessment and classification of the event may be requested (e.g., device data). Further supporting evidence that is not originally provided by the site may be requested by Medtronic to aid in the adjudication of an event.

All events will be followed until the event has resolved, is ongoing with no further actions to be taken, patient exit or registry closure, whichever occurs first.

The reporting PI and/or registry personnel is required to follow any reporting requirements of their Ethics Board and local or national law.

The site will report the clinician's assessment of the event relative to relatedness (e.g., device or procedure) and seriousness. Upon receipt of the events at Medtronic, a Medtronic representative will review for completeness and when necessary will request clarification and/or additional information from the site.

Regulatory reporting of Adverse Events will be completed according to local and national law and regulatory requirements. Refer to Table 3 and Table 4 for a list of required site and Medtronic reporting requirements. It is the responsibility of the site to comply with the Adverse Event reporting requirements of their Ethics Board.

All sites are required to follow their local regulatory reporting requirements for market-released products.

Device deficiencies information will be collected throughout the registry and be reported to Medtronic upon site's first awareness. Specific event reporting requirements may be outlined for a given condition, procedure and/or therapy in the Condition/Therapy Appendix.

13. Data Review Committees

A Clinical Event Committee (CEC) may conduct a review of reported events and deaths at regular time intervals, if applicable. The need for CEC review will be determined by Condition/Therapy and the end use of the data (e.g., regulatory reporting, publications, etc.). Use of a CEC will be documented in the associated AP or AD. The CEC is a committee comprised of independent experts with applicable technical and clinical backgrounds.

The committee will be provided with the reporting clinician's assessment of the event and actions taken. The committee is responsible for reviewing the clinician's assessment and adjudicating the event as applicable. If the CEC disagrees with the clinician's assessment, the rationale will be provided to the clinician. Both determinations are retained. The CEC determination will be used for analysis purposes.

14. Statistical Design and Methods

The purpose of the PSR is to better characterize the safety and/or performance of market-released products, therefore sample size calculations serve to ensure sufficient precision for characterization of performance. The exact definition of sufficient precision will vary based on the intended end use of the data and product type. The general concept is that sample sizes should be large enough to generate meaningfully narrow confidence intervals for population parameters of interest. Specific analysis requirements, statistical methods including required effective sample size determinations are defined in the PSR associated AP or AD; refer to Section 6.2.

Medtronic reserves the right to limit or close enrollment to minimize potential bias. Fifteen percent (15%) of an estimated total projected enrollment may be used as a guideline for determining if a product should be closed to enrollment at a particular site. Site specific enrollment closure for a product will be communicated in writing to the individual impacted site.

15. Ethics

15.1.Statement(s) of Compliance

All products will be followed per the CIP, associated addendums (if applicable), ethical principles that have their origin in the Declaration of Helsinki and in accordance with Good Clinical Practices (GCP), which includes, but not limited to, Federal Regulations (21 CFR Part 11, 50 and 56), ISO 14155 and applicable regional/local regulations.

The Declaration of Helsinki principles have been implemented in the PSR, by means of the patient data release or informed consent process, Ethics Board approval or a written statement by the Ethics Board Chairperson or PI stating that approval is not required or documentation that approval is not required per local law, training, public clinical trial registration (e.g., clinicaltrials.gov, etc.), risk benefit assessment, publication policy, etc.

PSR activities shall not begin until all required approvals and documents from the Ethics Board and regulatory authorities, if needed, have been received. Any additional requirements imposed by the Ethics Board or regulatory authority shall be followed, as appropriate.

Medtronic contracts with participating institutions/investigators through a CTA that defines the scope and responsibilities and associated compensation related to carrying out the obligations under a clinical registry sponsored by Medtronic.

The registry has been intentionally designed to collect data on routine clinical care practice with market released products for the purpose of product surveillance. Due to the registry design, there are some

exceptions that apply to the above regulations. A list of exceptions is maintained under a separate cover.

16. Study Administration

16.1. Monitoring

Medtronic uses a risk-based approach to monitor the regulatory and reporting compliance of the PSR to ensure the overall integrity and quality of the data through the following combination of the actions:

- Automated data logic checks
- Statistical analysis to identify data trends or anomalies
- Statistical analysis to identify sites that are outliers relative to other participants
- Source verification using available in-house data (e.g., data transmission)
- Regulatory and reporting compliance trends
- Interim clinical monitoring visits
- Site Audits

The aggregate of activities will provide a measurable level of confidence in the dataset. The respective PSR Monitoring Plan will define, in greater detail, the risk-based approach for PSR monitoring.

Trained sponsor representatives or delegates appointed by Medtronic may perform registry monitoring in order to ensure that the registry is conducted in accordance with the CIP, the CTA, and applicable regulatory and local requirements. Medtronic, or delegates, must therefore be allowed access to the patient's case histories (clinic and hospital records, and other source data/ documentation) upon request as per the CTA and Informed Consent (ICF) or Data Release Form (DRF), as applicable.

During monitoring visits, the monitor will perform monitoring activities by review of original patient documents. The monitor must have direct access to original source documentation, certified copies of the original source, or supervised access in situations where direct access is not possible.

16.2. Data Management

Data will be collected using an electronic data management system or data transmissions, and manually via paper CRF if required. Data reporting by the site will be completed and submitted by persons with applicable documented training (i.e. authorized persons). All data will be stored in a secure, password-protected database. Access to all reported data will be controlled by Medtronic.

The accuracy and completeness of site reported data will be confirmed with an approval by the PI or authorized designee.

Medtronic will review site reported data to monitor data quality, data discrepancies will be created as required and forwarded to the site for resolution. Registry personnel are responsible for the timely submission of data and the resolution of discrepancies.

The PI should create and maintain documentation of the type and location of source documents. All reported data elements should be supported in the patient's case history (i.e., source documentation). Any time the database reported data are the only record, it should be appropriately documented with rationale. In these cases, an alternate method of source documentation is highly recommended.

For products capable of transmitting data, device data uploads/transmissions will be collected for Medtronic products only. These data will be obtained directly from the submitted device file (e.g., transmission, etc.) therefore, additional source verification will not be required. Upon receipt, device data will be maintained and retrieved for analysis and reporting.

16.3. Direct Access to Source Data/Documents

The site shall provide direct access to source data for monitoring, audits, EC review, adjudication of events and regulatory authority inspections, per local regulatory requirements. As required, permission for direct access to source documents from the patient, hospital administration and national regulatory authorities shall be obtained.

16.4. Confidentiality

Confidentiality of data shall be observed by all parties (e.g., Medtronic, regulatory bodies, etc.) and all data shall be secured against unauthorized access. The privacy of each patient and confidentiality of his/her information shall be preserved in reports and when publishing any data, in accordance with local laws and regulations.

16.5. Liability

Warranty information is provided in the product packaging for the market released products. Package requirements may vary by geography.

Medtronic maintains appropriate clinical liability insurance coverage as required under applicable laws and regulations and will comply with applicable local law and custom concerning specific insurance coverage. If required, a clinical insurance statement/certificate will be provided to the Ethics Board.

16.6. CIP Amendments

A CIP Amendment will be prepared when there are significant changes, corrections, or modifications that impact patient safety, ethical conduct, data integrity, or design. All revisions will be documented in the version history and require Ethics Board and Medtronic approval, and Regulatory Authority approval, if applicable.

16.7. Record Retention

16.7.1 Site Records

The site is responsible for the preparation and maintenance of records cited below. Records are subject to inspection by Medtronic for compliance and should be retained for 2-years from the last patient follow-up or longer, if required by local law or site policy.

- All essential correspondence and approvals that pertains to the PSR, including that with the Ethics Board, Medtronic or regulatory body
- Fully executed original CTA between site and Medtronic
- CIP, ICF or DRF form (all approved versions)
- PSR Associated Addendums, if applicable
- Registry personnel training documentation
- Any other records required by a regulatory authority or applicable standard (e.g., delegation log, financial disclosure (FD)/conflict of interest statement)
- Patient's case history records, per applicable standards, including:
    - All patient completed DRF or ICF forms
    - All patient authorizations, (applicable geographies)
- Reportable Events and Deaths
- Device Deficiencies

The PI is responsible for ensuring practicing clinicians are appropriately licensed/qualified. Medtronic will not inspect these records to assess compliance to institutional policy, regulations, or local law. Medtronic representatives or regulatory authorities may perform auditing activities if deemed necessary to evaluate the conduct of PSR activities.

16.7.2 Medtronic Records

Medtronic will maintain the following records for each site:

- All related essential correspondence that pertains to the site
- Fully executed CTA

- All Ethics Board approval or determination (Ethics Board waiver) documentation
- All approved CIP versions
- All approved DRF, ICF and Authorization forms (authorization forms in applicable geographies)
- All reported data including CRFs, images, device data obtained via remote transmission or device uploads for applicable products, medical information received to support adjudication of adverse events and deaths.
- Training, compensation, monitoring records

Other records required per local regulations will be maintained.

16.8. Reporting Requirements

16.8.1. Site Reports

The site is responsible for the preparation and submission of the reports to Medtronic and/or the Ethics Board cited in Table 3. In addition, if an Ethics Board takes any action with respect to PSR pertinent documentation it must be forwarded to Medtronic. Sites are responsible to submit reports per applicable regulations to all required parties.

Table 3: Site Reports

Report	Submit To	Description
Withdrawal of Ethics Board approval	Medtronic	Notification within five working days
Other actions by Ethics Board	Medtronic	Any actions taken by the Ethics Board that affects any aspect of the PSR conduct must be submitted to Medtronic as soon as possible.
Deaths	Medtronic Ethics Board (as required)	The site must submit notification of all deaths to Medtronic and licensing authority, if applicable per local law, upon site's first awareness. The site must also report to their Ethics Board per their requirements/local law.
Adverse Events	Medtronic Ethics Board (as required)	The site must submit all Adverse Events (device, procedure-related and therapy-relevant) to Medtronic and licensing authority, if applicable per local law, upon site's first awareness. The site must also report to their Ethics Board per their requirements/local law.

Report	Submit To	Description
Deviation	Medtronic Ethics Board (as required)	Deviations should be reported to Medtronic and to Ethics Boards, competent authorities or other regulatory bodies per their requirements and/or local law.

16.8.2. Medtronic Reports

Medtronic will complete reports per product-specific requirements, as shown in Table 4. Medtronic will comply to any local reporting requirements, if applicable. Medtronic may also provide participating sites with periodic reports that will present both site PSR status and aggregate information. In addition, participating sites will have access to their own registry data for ad hoc reporting.

Table 4: Medtronic Reports

Report	Submit to	Description
Progress Report	Regulatory Authority	Progress reports will be submitted to regulatory authority as required, and to PI & Ethics Boards as requested.
Adverse Events	Regulatory Authority Ethics Board	Summary of reportable Events will be provided to Regulatory Authorities per their requirements, (any negative trends will be reported to participating clinicians as appropriate). Summary of reportable Events may be provided to other applicable parties as required per local regulations.
Withdrawal of Ethics Board approval	Participating Sites Regulatory Authority	Notification within five working days after the sponsor first learns of the withdrawal of approval. To be reported to Regulatory Authorities as required.
Withdrawal of regulatory approval, if applicable	Participating Sites Ethics Board	Notification within five working days after sponsor first learns of the withdrawal of approval. To be reported to Regulatory Authorities as required.

16.9. Publication and Use of Information

Sites may publish the results of and information from their PSR collected data provided the publication is made in accordance with the terms and conditions of the agreement between the site and Medtronic. Publications utilizing PSR data will be processed in accordance with Medtronic Standard Operating Procedures and Policies. A publication strategy designed to provide direction and support in the development of clinical publications may be utilized. The strategy will outline the number of committees, membership criteria, authorship criteria, criteria for developing manuscripts, abstracts and public presentations, publication approval and publication timelines.

16.9.1. Publication Committees

The PSR may have multiple Publication Committees to align with numerous therapies or products supported by the PSR. Medtronic will assess recommendations put forth by the committees and will review and comment on publications. Committees may be at a therapy or product level as warranted by the intended use of the data. Members may include, but are not limited to, participating clinicians, team members, and Medtronic representatives including research scientists, statisticians, and others as applicable.

The Publication Committees are responsible for the following:

- Overseeing the development of manuscripts and abstracts
- Reviewing, approving and prioritizing publications
- Providing input on the scientific merit and clinical relevance of publications
- Applying and enforcing the authorship guidelines set forth in the publication strategy

Publication Committee membership does not automatically qualify a member for authorship.

16.9.2. Criteria for Determining Authorship

Authorship for manuscripts will follow the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, ICMJE guidelines (www.icmje.org) and be based on the following criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition, the following should be implemented:

- First author and all subsequent authorship will be determined by contribution to each of the above criteria. All authors must sign the manuscript that will be submitted.
- A minimum of verbal approval prior to submission is the minimum required for an abstract.
- All clinicians not listed as co-authors will be acknowledged and will be individually listed in an appendix as permitted by the scientific journal.
- Medical writer support must be disclosed either by inclusion of the medical writer as an author or in the Acknowledgements, depending on the contribution.

16.9.3. Publication Requests

Publication requests will be evaluated for scientific validity and the ability of Medtronic to provide resources. They will be approved by the responsible Publication Committee which will need to ensure that requests do not present conflicts with other geographical regions. If multiple geographies contribute data, co-authorship will be determined using the guidelines for authorship selection described above.

16.9.4. Publication of Results

A description of the clinical registry shall be registered in a publicly accessible database. Results will be made publicly available.

16.10. Suspension or Early Termination

Suspension is a temporary postponement of PSR activities relating to enrollment at a site or at a registry level. Termination is the termination of site PSR activities at a site or at a registry level.

16.10.1. Criteria for Suspension or Early Termination

Reasons for suspension or termination of a site may include but is not limited to:

- Ethics Board approval expiration
- Consistent non-compliance to the CIP (e.g., failure to follow patients, etc.)
- Lack of enrollment
- Non-compliance to regulations and the terms of the CTA with Medtronic
- Ethics Board suspension of the site

Considerations related to PSR suspension and termination include but is not limited to:

- If Medtronic suspends or terminates the PSR, Medtronic will promptly inform the site of the suspension/termination along with the reason and inform regulatory authorities, where required.
- If Medtronic suspends or terminates the PSR, the site must inform the patients, where required.
- In the case of PSR suspension or termination, for reasons other than a temporary Ethics Board approval lapse, the site will promptly inform the Ethics Board, if applicable

If the site suspends or terminates participation without prior agreement of Medtronic:

- The site must promptly inform Medtronic and provide a detailed written explanation of the termination or suspension
- The site must promptly inform the institution (where required per regulatory requirements)
- The site must promptly inform the Ethics Board, if applicable
- The site must inform the patients, where required.

If the Ethics Board suspends or terminates its approval:

- The site must promptly inform Medtronic and provide a detailed written explanation of the termination or suspension within five business days
- Patient enrollment must stop until the Ethics Board suspension is lifted
- Patients already enrolled should continue to be followed in accordance with the Ethics Board policy or its determination that an overriding safety concern or ethical issue is involved
- The site must inform his/her institution (where required per local requirements)
- The site must promptly inform the patients, where required.

17. References

Brown, L., Bright, R., Tavros, D., Medical Device Epidemiology and Surveillance, Wiley Publishing 2007

Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Heart Rhythm, Volume 3, No. 10, October 2006

Gliklich RE, Dreyer NA: Registries for Evaluating Patient Outcomes: A User's Guide. 2nd Edition. AHRQ publication No. 13-EHC111. April 2014

18. Appendices

Surgical Condition/Therapy Appendix

19. Version History

Version history is maintained within a separate document.

Condition/Therapy Appendix: Surgical

A. Surgical and Medical Procedure Background

The Product Surveillance Registry (PSR) supports a wide range of surgical and medical procedures completed using one or more Medtronic products in open, minimally invasive, robotic, endoscopic, and percutaneous procedures.

Often classified as the 'traditional type' of surgery, open surgery occurs when incisions are made in a patient through which surgeons insert various instruments to conduct the surgery.

Minimally invasive surgery (MIS) is a technique where operations are performed through small incisions in the body whereby surgical instrumentation are inserted allowing the procedure to be performed with minimal tissue interruption (e.g. laparoscopic surgery).

Robot-assisted laparoscopic surgery utilizes a Robotic Assisted Surgical Device (RASD) to provide three-dimensional visualization and articulation of the robotic instrument wrists.

Additionally, endoscopic and percutaneous surgical procedures offer additional options to perform MIS. Endoscopic surgeries involve the insertion of a long, thin tube, typically with the use of a camera and light, directly into the body to perform a surgical procedure.

Percutaneous surgery is characterized by being done through one or more small puncture sites or minor incisions through the skin, often without direct visualization of the underlying anatomy.

Details on each of the market approved study devices (including e.g. device description, contra-indications and potential complications) are included in the current applicable version of the Instructions for Use document.

B. Data Collection

Steps to minimize bias in the PSR Surgical patient population align with Section 6.3 (Steps Taken to Minimize Bias). These steps are followed to ensure enrollments are an appropriate representation of the patient population. Product specific known or foreseeable factors available in product labeling/IFU may be taken into consideration. Medtronic may limit enrollment using an Enrollment Guide to account for specific cohorts of product use and ensure adequate enrollments to effectively assess study objectives.

B.1 Enrollment

Patients may be enrolled prior to or after the surgical or medical procedure. Whether a particular cohort under this CIP enrolls patients before or after surgery or both, is defined in the applicable analysis plan or addendum. The site will make every attempt to approach all eligible patients for enrollment and

perform a thorough review of the patient's medical record to ensure requested baseline and medical history information is complete. When enrolling a patient before surgery, procedures are recommended to occur within 30 days of consent. When enrolling a patient after surgery, it is recommended to do so within 30 days following the procedure. If deemed necessary, the study team is allowed to deviate from those 30 days before or following surgery, provided justification in the applicable analysis plan or addendum.

If the patient is enrolled into the registry prior to the surgical or medical procedure but the procedure is not completed with an eligible product, the patient will be exited from the registry. The data that is to be collected on patients exited early will include the Enrollment CRF and the Exit CRF at minimum. Other CRFs, if collected, will be defined in the applicable analysis plan or addendum. No data will be collected after the patient is exited. Vulnerable patient populations such as pediatric patients may be enrolled when the use of the device is approved in the population and region per the applicable instructions for use (IFU). Regional requirements will be followed and described in the applicable analysis plan or addendum.

Sites may submit to their Ethics Board for a full waiver of consent if applicable. Patients at sites where the Ethics Board *has not* granted a full waiver of consent are considered enrolled once informed consent has been obtained. Patients at sites where the Ethics Board *has* granted a full waiver of consent are considered enrolled once the patient's eligibility is assessed and verified and the Enrollment CRF is complete. Relevant enrollment data collected for eligible patients include but are not limited to:

- Eligibility verification (i.e. Section 8.3 Inclusion Criteria and Section 8.4 Exclusion Criteria).

Study activities (e.g., data collection and entry) can only start after the patient is enrolled in the study.

B.2 Baseline

The following types of data may be collected at baseline for enrolled patients regardless of procedure performed:

- Demographics
- Medical History
- Surgical History
- Vital signs
- Quality of Life or satisfaction measurements, if applicable

B.3 Procedure

The following types of data may be collected for enrolled patients as applicable for the procedure performed:

- Perioperative details
- Device details
- Adverse Events, Device Deficiencies, Deaths, and deviations are to be reported to Medtronic upon awareness
- Imaging, if applicable
- Procedure recordings, if applicable
- Quality of Life or satisfaction measurements, if applicable

B.4 Follow-up Reporting Frequency & Data Collection

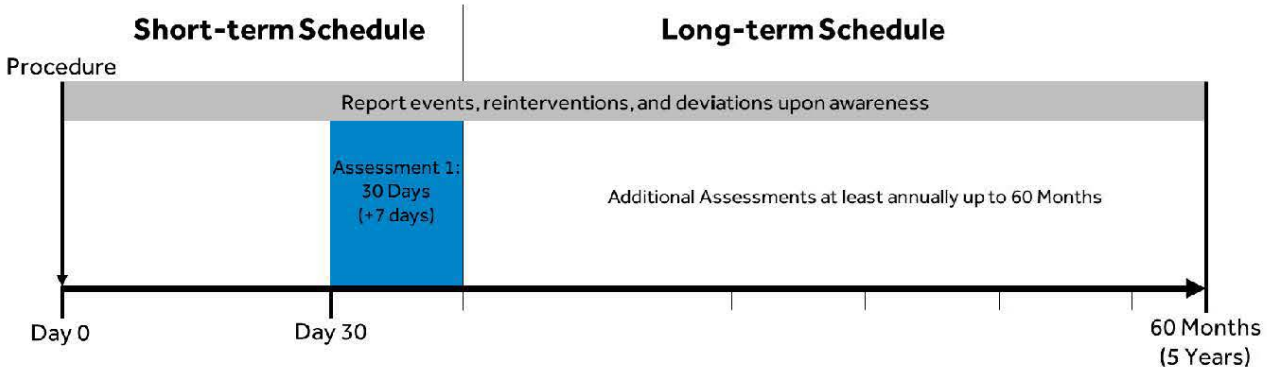
Patients will be treated in accordance with the routine clinical practices of their respective care provider. However, in 'real world' clinical practice, the frequency of in-person follow-up visits may vary for many reasons (e.g., patient's personal circumstances, condition, physician preference, etc.) resulting in more or fewer in-person visits.

As a result, the PSR is based on an active surveillance model which requires sites to complete a patient status assessment post-procedure, regardless of whether the patient is seen in-person per the physician's routine follow-up care practices. This approach ensures a robust dataset while increasing the continual awareness of patient status throughout their registry participation.

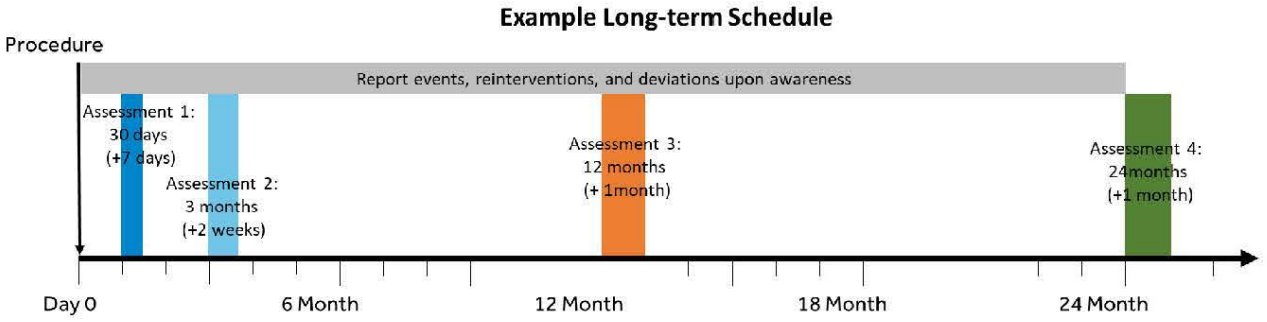
Data will be captured through 30 days post-procedure (to be reported between day 30 and 37) at a minimum and may be captured up to 60 months (or 5 years) post-procedure (Figure 1).

For procedures requiring long-term follow-up data, assessments will be collected at least annually with a maximum follow-up duration of 60 months at which time the patient will be exited (Figure 1). The total duration of follow-up for products requiring long-term follow-up data collection will be determined by various factors including but not limited to product lifecycle, recurrence rate, or regulatory requirements. The timing of the patient assessments and exit will be outlined in the corresponding Analysis Plan or Addendum. Refer to Figure 2 for an example of a long-term follow-up data collection schedule.

Surgical Appendix - Figure 1: Follow-up Schedules



Surgical Appendix - Figure 2: Example of a Long-term Schedule



Follow-up data will be collected for enrolled patients and may include, but are not limited to:

- Patient status
- Readmissions
- Imaging information, if applicable
- Procedure recordings, if applicable
- Quality of Life or satisfaction measurements, if applicable
- Adverse Events, Device Deficiencies, Deaths, reinterventions, and deviations are to be reported to Medtronic upon awareness

B.5 Events

All procedure or device related events are to be reported upon site awareness. Submit any additional supporting evidence which could assist in the assessment and review. Further supporting evidence not originally provided by the site may be requested by Medtronic to aid in the adjudication of the event.

Refer to Table 1 below for Unavoidable Adverse Events, which if resolved within the timeframe specified, are **not** required to be reported.

Surgical Appendix - Table 1: Unavoidable Adverse Events

Event Description	Time Frame (hours) from end of Procedure
Anesthesia related nausea / vomiting/ headache	24 hours
Low-grade fever (<100°F or < 37.8°C)	48 hours
Pain at Access Site	72 hours
Mild to moderate bruising / ecchymosis at access site	168 hours (7 days)
Back pain related to lying on the table	72 hours
Constipation	72 hours
Postoperative pain and/or complications that the Investigator considers common and within normal limits for the procedure and its related medication.	

Refer to Table 2 below, for a listing of potential **reportable** Adverse Events. The listing is provided to facilitate more complete and consistent reporting and is not intended to be a comprehensive listing of all reportable events.

Patients with adverse events that have not resolved at the time of the final registry timepoint will be followed until resolution, for up to 30 days after the final registry timepoint, or other applicable period as defined in the analysis plan or addendum.

Surgical Appendix - Table 2: Potential Reportable Adverse Events

Allergic reactions	Inflammatory reaction	Seroma
Bleeding/hematoma	Inadvertent injuries to other tissues or organs	Thromboembolic complications
Blood transfusion	Nerve damage	Vascular injury
Cardiopulmonary complications	Nerve entrapment	Visceral adhesions
Chronic pain	Hernia Recurrence	Visceral injuries
Damage to pericardium	Renal failure	Wound dehiscence
Infection	Respiratory complications	

The site will report the clinician's assessment of an adverse event relative to relatedness (e.g., device or procedure), seriousness and severity. The definitions for seriousness and relatedness can be found in section 12.1, Table 2: Adverse Event and Device Deficiency Definitions. The definitions for severity are in Table 3 below.

Surgical Appendix - Table 3: Definitions for Event Severity

Event type	Severity Definition
Mild event	Signs, or symptoms that are easily tolerated by the subject, or are clinical or diagnostic observations of the investigator.
Moderate event	Signs, or symptoms that cause discomfort and interfere with normal functioning. Local or non-invasive intervention may be indicated.
Severe event	Signs, or symptoms that disable the subject, are medically significant, lead to hospitalization or prolongation of hospitalization.

B.6 Lost to Follow-up

Follow-up data may be collected via medical record review within the expected reporting period. In cases where a subject interaction is required for a study endpoint, subjects may be considered lost to follow-up if at least two attempts to contact the subject are unsuccessful. The method of attempt (e.g., one letter and one phone record, or two letters) must be documented in the subject's source documentation. In addition, regulation set forth by the governing EC/IRB must be followed.

B.7 Exit

Enrolled patients will be exited from the registry once the applicable duration of follow-up has been completed unless exited early for unavoidable reasons. Patients with an ongoing reportable Adverse Event or Device Deficiency at the time of final registry timepoint will be followed until resolution for up to 30 days after the final registry timepoint, or other applicable period as defined in the analysis plan or addendum.

B.8 Schedule of Data Collection

Surgical Appendix - Table 4: Data Collection Schedule

	Enrollment and Baseline	Procedure	Follow-up Assessment
Informed Consent, if applicable	X		
Patient status		X	X
Demographics and Medical and Surgical History	X		
Vital signs	X	X	X
Procedure information		X	
Imaging, if applicable	X	X	X
Product and/or therapy information, if applicable	X	X	X
Quality of Life or satisfaction measurements, if applicable	X	X	X
Readmission			X
Reintervention		Reported upon site awareness	
Procedure/Device Related Adverse Events		Reported upon site awareness	
Device Deficiencies		Reported upon site awareness	
Deaths		Reported upon site awareness	
Deviations	Reported upon site awareness		

C. Data Collection Details

Data collection details and CRFs (where required) are provided under separate cover.