Abbott	Clinical Investigation Plan Cover Page

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GEMINI
Study of Gemini Rechargeable Spinal Cord Stimulation (SCS) System
Study Document No: ABT-CIP-10485
Version A
Date: 11-FEB-2022

Sponsor

Abbott
6901 Preston Rd
Plano, TX 75024
United States

Clinical Investigation Plan

ABT-CIP-10407
CRD 1030

Study of Gemini Rechargeable Spinal Cord Stimulation (SCS) System

Version Number	B
Date	February 11, 2022
Planned Number of Sites and Region(s)	Up to 8 sites in Australia
Clinical Investigation Type	Pre-market, prospective, single-arm, non-randomized, open-label, multi-center clinical study.
Abbott Medical Expert	[redacted]
Sponsor	Abbott Neuromodulation 6901 Preston Rd Plano, TX 75024
Electronic Data Capture Software	Oracle Clinical

Clinical Investigation Plan

ABT-CIP-10407
CRD 1030

Study of Gemini Rechargeable Spinal Cord Stimulation (SCS) System

SITE PRINCIPAL INVESTIGATOR SIGNATURE PAGE

I have read and agree to adhere to the clinical investigation plan and all regulatory requirements applicable in conducting this clinical investigation.

Site Principal Investigator

Printed name:
Signature:
Date:

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COMPLIANCE STATEMENT:

This clinical investigation will be conducted in accordance with this Clinical Investigation Plan, the Declaration of Helsinki, ISO 14155:2020 standard and the appropriate local legislation(s). The most stringent requirements, guidelines or regulations must always be followed. The conduct of the clinical investigation will be approved by the appropriate Ethics Committee (EC) of the respective clinical site and as specified by local regulations.

Clinical Investigation Plan

1. INTRODUCTION

Spinal cord stimulation (SCS) is a well-established treatment for chronic intractable pain. The purpose of this study is to collect confirmatory data to show that the Gemini Spinal Cord Stimulation neuromodulation system functions as intended in a clinical setting.

The clinical investigation will be conducted in accordance with this CIP. All investigators involved in the conduct of the clinical investigation will be qualified by education, training, or experience to perform their tasks, and training will be documented appropriately.

1.1. Background and Rationale

1.1.1. Background

It is estimated that 20.4% (50 million) of US adults suffer from chronic pain and 8% of adults have high-impact chronic pain [1]. The economic burden of chronic pain is high worldwide, with annual costs estimated as high as $635 billion dollars in the US [2]. Chronic pain has been linked to loss of mobility, opioid dependence, anxiety, and depression, leading to an overall decrease in quality of life [1]. Additionally, up to 15% of all chronic pain patients are unresponsive to standard medical therapy, and therefore, seek alternative options [2]. Considering the long-term detrimental effects of opioid use and its societal impact [3] , it is imperative to explore alternative strategies for handling long-term pain management.

SCS is a commonly utilized form of neurostimulation developed by Abbott and other companies over the past four decades to address chronic pain. It is a minimally invasive and reversible procedure in which leads are placed into the epidural space. When an electrical current is applied to the leads, large myelinated fibers of the dorsal column are stimulated, mitigating pain. Abbott is an established manufacturer of neurostimulation systems, including spinal cord stimulators that can deliver tonic stimulation and the BurstDR™ waveform [4-6]. Tonic stimulation delivers impulses at a consistent amplitude, frequency, and pulse width, and typically produces paresthesia over the patient's area of pain. In contrast, BurstDR™ stimulation delivers impulses in rapid succession, known as a burst train, followed by a short silent phase. Programmable parameters include the amplitude of the burst train, the time from onset of one burst train to the onset of the next burst train (burst rate), and the rate of pulses within each train (intra-burst rate). Amplitudes programmed for burst are typically lower than those traditionally used for tonic stimulation, typically resulting in pain suppression without paresthesia.

Abbott has produced both rechargeable and non-rechargeable (primary cell) systems. Primary cell systems contain an implanted battery of sufficient size to power the implant for its expected lifetime and are surgically replaced upon battery depletion. Rechargeable systems utilize a wireless power transfer system to allow patients to recharge the batteries of the implanted system. Rechargeable systems allow for longer useful life of implanted systems, especially in cases where higher power stimulation settings are desired. Rechargeable systems also allow for smaller implanted devices, as the battery does not need to be large enough to support the entire implant lifetime.

The investigational device for this study is the new Gemini rechargeable SCS system, including IPG, charger, and supporting programmer and controller. The investigational system is compatible with Abbott's existing on-market SCS leads, extensions and adapters. [redacted] The investigational system also leverages Abbott's iPad clinician programmer app and iPhone patient controller app to provide clinician and patient control of the implanted device.

1.1.2. Rationale for Conducting this Clinical Investigation

The benefits of SCS and BurstDR therapy are well established. The Gemini SCS system introduces a novel IPG, charger, and supporting applications. Extensive testing has been performed to demonstrate safety, functionality, usability, and efficacy of these devices and this study is designed to further support those data with clinical experience. Many facets of the system leverage Abbott's existing on-market technologies such as approved leads, iOS patient controller and clinician programmer applications, patient contacting materials etc., which have been demonstrated as safe through previous testing and field experience. The study focuses on safety events that could be attributed to the new charging system and is designed to detect any serious effects caused by the new component of the system. The study further supports the Gemini SCS system under the European Medical Devices Regulation (EU MDR) which requires the manufacturer to generate sufficient clinical evidence on the device for CE-Mark. This standard is internationally recognized, [redacted].

2. CLINICAL INVESTIGATION OVERVIEW

2.1. Clinical Investigation Objective

2.1.1. Primary Objective

The objective of this study is to collect confirmatory data to show that the Gemini SCS neuromodulation system functions as intended in a clinical setting.

2.2. Devices Used in the Clinical Investigation

2.2.1. Name of the Devices Under Investigation

The following investigational components of the Gemini SCS neuromodulation system will be used in this clinical investigation:

Device name	Model	Manufacturer	Region	Investigational or Market Released
Gemini SCS IPG	32400	Abbott	Australia, Europe	Investigational
Gemini Wireless Charger	16000			
Gemini Clinician Programmer App	55600			
Gemini Patient Controller App	55500			
IPG Pocket Sizer	12720			
IPG Port Plug	12710			
Charger AC Adapter	16720			
Charging Apparel, SCS (reusable)	16750			
Gemini Charging Cable	16710			

These investigational components are used with on-market leads and accessories (CL1014851).

2.2.2. Indication for Use

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following:

failed back surgery syndrome, intractable low back and leg pain, angina pectoris and peripheral vascular disease.

2.2.3. Description of the Devices Under Investigation

The Gemini SCS IPG is a 16-channel, rechargeable electronic device designed to be connected to one or more leads with up to 16 total electrodes. The IPG is powered by a hermetically sealed rechargeable battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation to nerve structures. A wireless charger placed over the IPG recharges the battery of the implanted device. The IPG and wireless charger communicate via Bluetooth with an external programmer and a patient control device. The external programmer enables the clinicians to adjust and fine-tune the low intensity pulses of current that stimulate the nerve structures. Patients are provided with a controller to further control and assess the status of the system.

Additional information and details on the components of the Gemini rechargeable SCS system are available in the Investigator Brochure.

2.2.4. Summary of Preclinical Studies

The Gemini Investigator Brochure contains details of bench testing and preclinical studies conducted with the Gemini rechargeable SCS system.

3. CLINICAL INVESTIGATION DESIGN

This is a pre-market, prospective, single-arm, non-randomized, open-label multi-center clinical study designed to show that the Gemini SCS neurostimulation system functions as intended in a clinical setting.

The study is designed to report on 20 subjects who receive a Gemini SCS implant and complete follow-up. [redacted] The clinical investigation will be conducted at up to 8 centers in Australia.

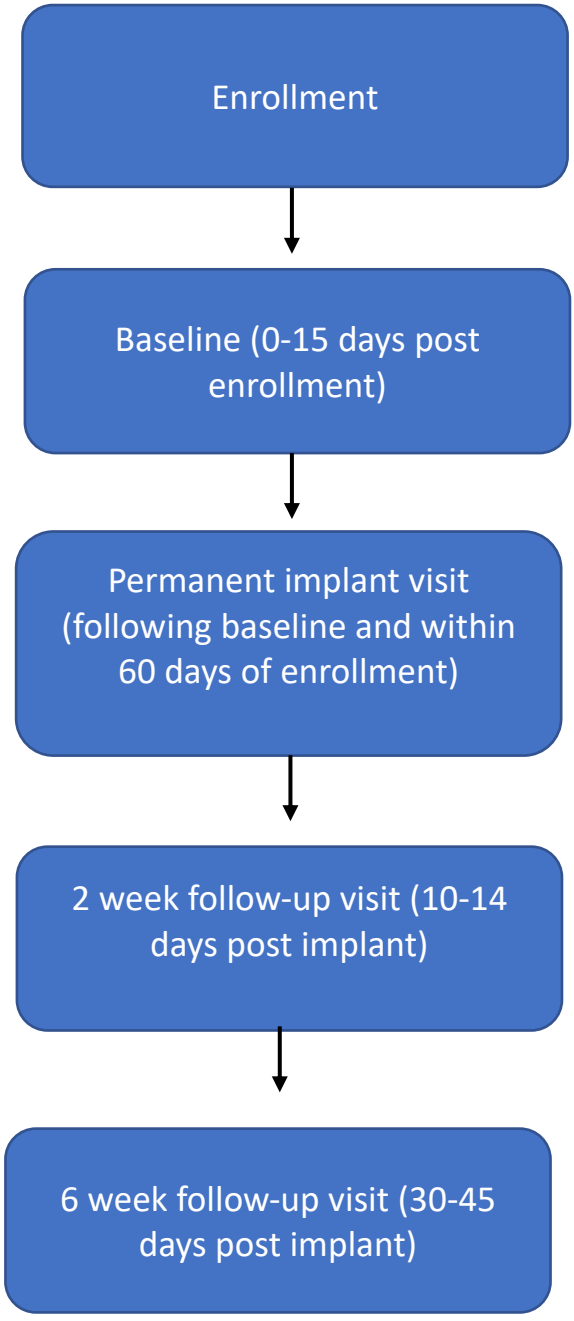
The Sponsor has designed this clinical investigation to involve as little pain, discomfort, fear, and any other foreseeable risk as possible for subjects. Refer to the Risks Analysis section of this clinical investigation plan for details.

3.1. Clinical Investigation Procedures and Follow-up Schedule

The flowchart and the follow-up requirements of this clinical investigation are described below. Enrollment, baseline and permanent implant can occur on the same day.

Clinical Investigation Plan

Figure 1: Clinical Investigation Flowchart



3.2. Measures Taken to Avoid and Minimize Bias

An independent Clinical Events Committee (CEC) will adjudicate all serious adverse events, including all deaths, and all non-serious device- and procedure-related adverse events.

3.3. Suspension or Early Termination of the Clinical Investigation

While no formal statistical rule for early termination of the clinical investigation for insufficient effectiveness of the device under investigation is defined, the Sponsor reserves the right to discontinue the clinical investigation at any stage or reduce the follow-up period with suitable written notice to the investigator. Possible reason(s) may include, but are not limited to:

- Unanticipated adverse device effect (e.g., UADE) occurs and it presents an unreasonable risk to the participating subjects
- Further product development is cancelled

If the Sponsor discontinues the clinical investigation, sites will follow subjects per routine hospital practice with device-related AEs reported to the Sponsor as per vigilance/commercial reporting requirements. The investigator shall return all clinical investigation materials (including devices that are not currently implanted) to the Sponsor and provide a written statement to the EC (if applicable). All applicable clinical investigation documents shall be subject to the same retention policy as detailed in Section 11.5 of the CIP.

If the Sponsor suspends or prematurely terminates the clinical investigation at an individual site in the interest of safety, the Sponsor will inform all other Principal Investigators.

If suspension or premature termination occurs, the Sponsor will remain responsible for providing resources to fulfill the obligations from the CIP and existing agreements for following the subjects enrolled in the clinical investigation, and the Principal Investigator or authorized designee will promptly inform the enrolled subjects at his/her site, if appropriate.

A Principal Investigator, EC, or regulatory authority may also suspend or prematurely terminate participation in the clinical investigation at the investigational site for which they are responsible. The investigators will follow the requirements specified in the Clinical Trial Agreement.

If a suspended investigation is to be resumed, a prior approval should be obtained from the EC and a notification should be sent to the regulatory bodies.

4. ENDPOINTS

4.1. Confirmatory Safety Endpoint

The confirmatory safety endpoint is the rate of serious adverse events adjudicated as related to the investigational IPG and/or charging system. No formal hypothesis test will be evaluated, but data for the endpoint will be used to confirm whether Gemini SCS system functions as intended.

4.2. Additional Endpoints

Additional endpoints are reported using descriptive statistics, without hypothesis testing:

- All serious adverse events
- Non-serious adverse events related to device, procedure, stimulation, charging, or MRI (investigational device and on-market devices)

Additional data collected:

- Patient satisfaction
- Patient experience with charging
- NRS score change
- PROMIS-29 change
- Charging history
- Stimulation programs used
- Stimulation programs available

5. SUBJECT SELECTION AND WITHDRAWAL

5.1. Subject Population

This clinical investigation will enroll subjects scheduled to receive a Gemini SCS implant for an approved chronic pain indication. Patients must meet all general eligibility criteria and provide written informed consent prior to sites conducting any investigation-specific procedures not considered standard of care.

5.2. Subject Recruitment/Screening and Informed Consent

5.2.1. Subject Recruitment and Screening

A member of the site's clinical investigation team previously trained to the CIP must evaluate patients for the general clinical investigation eligibility criteria, and if applicable, will enter the patients into a site-specific screening log. A patient who does not satisfy all general eligibility criteria prior to informed consent is considered a screen failure and should not be enrolled in the clinical investigation.

Sites will ask patients meeting all inclusion criteria and no exclusion criteria to sign an Informed Consent form following the established Informed Consent process (described in Section 5.2.2) to participate in the clinical investigation. Sites will enter these patients into the screening log. Once a duly dated and signed Informed Consent form is obtained, the clinical investigation-specific procedures may begin.

5.2.2. Informed Consent

The Investigator or an authorized designee (if applicable) will conduct the Informed Consent process, as required by applicable regulations and the center's EC. This process will include a verbal discussion with the patient on all aspects of the clinical investigation that are relevant to the patient's decision to participate, such as details of clinical investigation procedures,

anticipated benefits, and potential risks of clinical investigation participation. Sites must inform patients about the right to withdraw from the clinical investigation at any time and for any reason without sanction, penalty, or loss of benefits to which the patient is otherwise entitled. Withdrawal from the clinical investigation will not jeopardize future medical care or relationship with the investigator.

During the discussion, the Principal Investigator or an authorized designee will avoid any improper influence on the patient and will respect patient's legal rights. Financial incentives will not be given to patients. Patients may be compensated for time and travel directly related to the participation in the clinical investigation. The site shall provide the patient with the Informed Consent form written in a language that is understandable to the patient and that has been approved by the center's EC. The patient shall have adequate time to review, ask questions, and consider participation. The Principal Investigator or an authorized designee will make efforts to ensure that the patient understands the information provided. If the patient agrees to participate, the patient must sign and date the Informed Consent form, along with the person obtaining the consent prior to any clinical investigation-specific procedures. The site will file the signed original in the patient's hospital or research charts and provide a copy to the patient. All serious adverse events and any device-related adverse events as defined in Section 7.1 are reportable once a subject has signed and dated the ICF.

Sites will report any failure to obtain informed consent from a patient to the Sponsor within 5 working days and to the reviewing center's EC according to the EC's reporting requirements.

If, during the clinical investigation, new information becomes available that can significantly affect a subject's future health and medical care, the Principal Investigator or authorized designee (if applicable) will provide this information to the subject. If relevant, sites will ask the subject to confirm their continuing informed consent in writing.

5.2.2.1. Special Circumstances for Informed Consent

This clinical investigation excludes individuals unable to make the decision to participate in a clinical investigation on their own or who are unable to fully understand all aspects of the investigation 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. This clinical investigation excludes individuals under the age of 18 or age of legal consent from the clinical investigation population. The clinical investigation excludes Individuals unable to read or write. The clinical investigation excludes pregnant or breastfeeding women.

5.3. Eligibility Criteria

5.3.1. General Eligibility Criteria

Assessment for general eligibility criteria is based on medical records of the site and interview with a candidate patient. Patients must meet all inclusion criteria to participate in the clinical investigation. If any exclusion criteria are met, the patient is excluded from the clinical investigation and cannot be enrolled (screen failure).

If any clinical and/or laboratory tests are required for patient screening and are not included in a site's standard tests, they must be completed after written informed consent is obtained.

5.3.2. Inclusion Criteria

1. Subject is indicated for an SCS system, or has an implanted SCS system and is scheduled to receive an IPG replacement.
2. Subject is scheduled to receive a new IPG permanent implant and has completed a successful SCS trial in the last 6-months, OR subject is scheduled to undergo an all-in-one procedure OR has an implanted SCS system for an approved chronic pain indication.
3. Subject has a documented NRS pain score of ≥ 6 after at least 5 days without stimulation OR has an implanted functioning SCS system with NRS pain score of ≤ 4.
4. Subject must provide written informed consent prior to any clinical investigation-related procedure.
5. Subject is at least 18 years at the time of enrollment.
6. Subject is capable and willing to recharge an implanted IPG.

5.3.3. Exclusion Criteria

1. Subject's SCS trial was unsuccessful.
2. Subject is currently participating, or intends to participate, in another clinical investigation that may confound the results of this study, as determined by Abbott.
3. Subject has or will receive more than one IPG.
4. Subject is pregnant or breastfeeding or plans to become pregnant during the clinical investigation follow-up period.
5. Subject has other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's assessment, could limit the subject's ability to participate in the clinical investigation.
6. Subject has or is scheduled to receive an intrathecal pump.
7. Subject is part of a vulnerable population (section 5.2.2 of the clinical investigational plan).

5.4. Subject Enrollment

A subject is considered enrolled in the study when the following conditions are met:

1. Subject has provided written informed consent, and
2. Subject has been determined to meet all inclusion/exclusion criteria.

5.5. Subject Withdrawal and Discontinuation

Each subject meeting all eligibility criteria shall remain in the clinical investigation until completion of the required follow-up period; however, a subject's participation in any clinical investigation is voluntary. The subject has the right to withdraw at any time without penalty or loss of benefit. Conceivable reasons for discontinuation may include the following:

- Subject does not have the Gemini neurostimulation system implanted within 60 days of enrollment
- Subject death
- Subject voluntary withdrawal
- Subject is lost to follow-up as described below
- Subject's follow-up is terminated according to Section 3.3
- Subject's Gemini rechargeable SCS system has been explanted
- Subject's trial was unsuccessful (for 'all-in-one' procedures)

Sites must notify the Sponsor of the reason for subject discontinuation. Investigators must also report this to their respective EC as defined by their institution's procedures.

No additional follow-up is required or data recorded from subjects once withdrawn from the clinical investigation.

However, if a subject withdraws from the investigation due to problems related to the safety or performance of the device under investigation, the investigator shall ask for the subject's permission to follow the subject's condition outside of the clinical investigation.

Lost to Follow-up

If the subject misses the scheduled 6-week follow-up visit and the attempts at contacting the subject detailed below are unsuccessful, then the subject is considered lost to follow-up. Site personnel shall make all reasonable efforts to locate and communicate with the subject (and document these efforts in the source documents), including the following:

- A minimum of two telephone calls or electronic communications on different days over the specified follow-up window to contact the subject should be recorded in the source documentation, including date, time and initials of site personnel trying to make contact.
- If these attempts are unsuccessful, the site should send a letter (certified if applicable) to the subject.

Note: Telephone contact with a General Practitioner, another physician or a relative without the presence of the subject, as well as indirect documentation obtained via discharge letters, will not be considered as subject contact.

5.6. Number of Subjects

The study is designed to report on 20 subjects who receive a Gemini SCS implant and complete follow-up. [redacted]

5.7. Total Expected Duration of the Clinical Investigation

Subjects participating in this clinical investigation will be followed for approximately 6 weeks after the permanent implant procedure. [redacted]

6. TREATMENT AND EVALUATION OF ENDPOINTS

6.1. Baseline/Pre-procedure

6.1.1. Baseline Assessments

Baseline visit should occur no more than 15 days after enrollment. If an SCS trial was performed, baseline pain and functional assessments should be made after at least 5 days without stimulation. If it is not possible to have stimulation off for at least 5 days, baseline data may be obtained from medical records from the last 6 months. The baseline pain score reported should be the score used to evaluate the inclusion and exclusion criteria (no stimulation NRS ≥ 6, stimulation NRS ≤ 4). The following baseline data will be collected:

- Patient demographics
- Pain diagnosis (specifically the subject's primary indication for neuromodulation) and pain location
- Pain history (time with chronic pain, previous treatment)
- Prior interventions (e.g. physical therapy, injections, surgeries) to treat the presenting condition
- Numeric Rating Scale (NRS) for pain intensity
- PROMIS-29
- Adverse events (if applicable)

6.2. Permanent System Implant

Implantation of the neurostimulation system will be performed according to the sites standard operating procedures and should be consistent with instructions in the IFU. It should be performed after the baseline assessments and no later than 60 days from the enrollment visit. If it has not occurred within 60 days after Enrollment, the subject will be withdrawn (Section 5.5). Following system implantation, the stimulator will be activated and programmed by trained personnel either during post-operative recovery or at an office visit in accordance with the physician's and hospital's standard operating procedures. The subject's spinal cord stimulator will be programmed according to the most recent Abbott programming guidance. After programming, the subject will receive a patient programmer and will be instructed on how to use the system to relieve their pain.

The investigator or delegate will instruct the subject on use of the charger, including weekly charging after the initial wound healing period.

A charging plan for the patient should satisfy the following criteria:
- First battery charge prior to attending the 2-week follow up visit
- Weekly battery charge after 2 weeks

The following information will be collected at the permanent system implant:

- Neurostimulation system device information
- Lead type(s) and location
- Programming parameters subject is using at the end of device activation
- All serious adverse events including deaths (if applicable)
- Non-serious adverse events related to device, procedure, stimulation, charging, or MRI (if applicable)
- Withdrawal (if applicable)
- Device deficiency (if applicable)
- Additional Surgery (if applicable)

6.3. Follow-up Assessments

6.3.1. 2-Week Follow-up (In-Person, Phone Call or Telehealth Visit)

A 2-week follow-up visit, which may occur in person, by telephone or as a telehealth visit, will occur 10-14 days after permanent implant. The 2-week follow-up visit provides an opportunity for the site to confirm that the patient understands the charging plan and has the opportunity to report any adverse events. If the clinician programmer is connected to the subject's IPG all reports will be downloaded. The following data will be collected:

- All serious adverse events including deaths (if applicable)
- Non-serious adverse events related to device/procedure/stimulation/charging/MRI (if applicable)
- Charging history (if applicable)
- Stimulation programs used since permanent implant (if applicable)
- Stimulation programs available at the end of the visit (if applicable)
- Withdrawal (if applicable)
- Device Deficiency (if applicable)
- Additional Surgery (if applicable)

6.3.2. 6-Week Follow-up (In-Person Visit)

Subjects will be followed at a 6-week follow-up visit that will occur 30-45 days after permanent implant. The following data will be collected:

- All serious adverse events including deaths (if applicable)
- Non-serious adverse events related to device, procedure, stimulation, charging, or MRI (if applicable)

- NRS
- PROMIS-29
- Patient satisfaction
- Patient charging experience
- Charging history
- Stimulation programs used since permanent implant
- Stimulation programs available at the end of the visit
- Withdrawal (if applicable)
- Device Deficiency (if applicable)
- Additional Surgery (if applicable)

During the 6-week follow-up visit, site personnel will connect to the subject's IPG using the CP. Site personnel will use the CP to collect the charging history, programming and program use details as PDF files.

6.3.3. Patient Reported Outcome (PRO) Measures

The Coordinator or designee will administer the patient-reported outcome questionnaires, via paper for later transcription to EDC. It is important the subject understands the meaning of all words and instructions in the questionnaires. The subject should be instructed to ask any questions about the questionnaires if further explanation is needed. Once the questionnaires are completed, the Coordinator or designee will review for completeness to verify that all questions have been answered according to the directions provided.

The following validated PRO measures will be collected:

- NRS for pain intensity
- PROMIS-29

6.3.3.1. Pain Numerical Rating Score (NRS)

The pain NRS consists of 1 question that will be asked by interviewing the subjects. Patients will be asked to rate, from 0 (no pain) to 10 (worst imaginable pain), their pain at the time of study visit specific to the area(s) of chronic pain being treated. A higher score indicates greater pain intensity.

6.3.3.2. Patient-Reported Outcome Measure Information System (PROMIS-29)

The PROMIS-29 is an adult scale developed in partnership with the National Institutes of Health (NIH) in the United States to estimate overall quality of life by assessing the following domains known to impact activities of daily living: physical function, sleep disturbance, depression, anxiety, fatigue, pain interference, pain intensity, and social role satisfaction. The scale requires subjects to rate the frequency and/or severity of symptoms and experiences related to each of these domains. A total score is calculated and transformed against normative data into a t score indicating global quality of life in relation to population norms. Subscales are defined by each domain described above and can be examined separately to parse separate symptoms or deficiencies in quality of life. The final item is an 11-point pain intensity numerical rating scale (NRS) by which the subject rates their average pain over the past 7 days. Subjects should read each item and check the one box that most closely represents their response.

6.3.4. Unscheduled Visits

An unscheduled visit is defined as a visit that occurs between the required follow-up visits for non-standard of care issues, such as a potential or actual adverse event. If the clinician programmer is connected to the subject's IPG all reports will be downloaded. Any data collected related to the clinical study endpoint should be documented by completing the appropriate CRF (see schedule of events table).

Following an unscheduled visit, the subject will be seen for the next scheduled study visit within window.

6.3.5. Schedule of Events

Clinical Investigation Plan

CIP Activity	Enrollment	Baseline	Permanent Implant Procedure	Follow-up visits 2-week (10-14 days post implant)	Follow-up visits 6-week (30-45 days post implant)	Unscheduled visit
Subject evaluated for eligibility	X					
Informed Consent Process	X					
Demographics		X				
Medical History		X				
Pain diagnosis and pain location		X				
NRS for pain intensity		X			X	
PROMIS-29		X			X	
Patient charging experience					X	
Patient Satisfaction					X	
Implant procedure and system data			X			
Device Programming			X	(X)	X	(X)
Charging History				(X)	X	(X)
Stimulation programs used				(X)	X	(X)
Stimulation programs available			X	(X)	X	(X)
Device deficiency			(X)	(X)	(X)	(X)
Additional surgery (System revision, Replacement/Explant)				(X)	(X)	(X)
Serious adverse events		(X)	(X)	(X)	(X)	(X)
Procedure- Device-charger- stimulation- MRI-related Adverse Events			(X)	(X)	(X)	(X)
Withdrawal		(X)	(X)	(X)	(X)	(X)

(X)-Indicates event may occur at visit

7. Adverse Events

To comply with worldwide standards and guidelines on clinical investigation adverse event reporting, the Sponsor has adopted uniform and worldwide applicable standard definitions and reporting timelines to be used and adhered to by the investigators.

7.1. Definition

7.1.1. Adverse Event

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device under investigation.

As part of ISO14155 Section 3.2, the Adverse Event definition has the following notes:

Note 1: This definition includes events related to the medical device under investigation or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to medical devices under investigation.

7.1.2. Serious Adverse Event

If the AE meets any of the criteria below, it is regarded as a serious adverse event (SAE).

a) Led to a death,
b) Led to a serious deterioration in health of the subject, that either resulted in
    1. a life-threatening illness or injury, or
    2. a permanent impairment of a body structure or a body function, or
    3. in-patient hospitalization or prolongation of existing hospitalization, or
    4. medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function.
    5. chronic disease
c) Led to fetal distress, fetal death or a congenital abnormality or birth defect.

Note: A planned hospitalization for a pre-existing condition, or a procedure required by the CIP without a serious deterioration in health, is not considered to be an SAE.

7.1.3. Device Deficiency/Device Malfunction (if applicable)

Device deficiency is defined as an inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling. This includes the failure of the device to meet its performance

specifications or otherwise perform as intended. Note: performance specifications include all claims made in the labeling of the device.

A device malfunction is the failure of a device to meet its performance specifications or otherwise perform as intended, when used in accordance with the instructions for use or CIP.

7.2. Device Relationship

Determination of whether there is a reasonable possibility that an investigational product or device under investigation caused or contributed to an AE is to be **determined by the Investigator** and recorded on the appropriate CRF form. Determination should be based on the assessment of temporal relationships, evidence of alternative etiology, medical/biologic plausibility and patient condition (pre-existing condition).

7.2.1. Unanticipated (Serious) Adverse Device Effect [U(S)ADE]

Unanticipated serious adverse device effect (USADE) refers to any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

7.3. Adverse Event and Device Deficiency/Device Malfunction Reporting

7.3.1. Adverse Event Reporting

Safety surveillance and reporting starts as soon as the patient completes the ICF. All serious adverse events and any device-related adverse events, including those observed during the implant procedures and all-in-one/ on-table trials, will be reported.

Safety surveillance and reporting will continue until the subject performs the last follow-up visit, the subject is deceased, the subject concludes participation in the clinical investigation, or the subject withdraws from the clinical investigation. All serious and non-serious procedure- and device-related adverse event data, including deaths and device deficiency data, will be collected throughout the life of the study and will be reported to the Sponsor on a CRF. Additional information with regards to a procedure- and device-related adverse event should be updated within the appropriate CRF.

Unchanged, chronic, non-worsening or pre-existing conditions are not AEs and should not be reported.

The Sponsor will provide an offline form to allow the investigator to report SAEs in the event the entry cannot be made in the EDC. This does not replace the EDC reporting system. Sites must still enter all information in the EDC system as soon as feasible.

<u>SAE Reporting</u>

The investigator must report all SAEs to the Sponsor as soon as possible but no later than outlined below.

Clinical Site	Reporting timelines
All Sites	Sites must report SAEs to the Sponsor no later than 3 calendar days from the day the site personnel became aware of the event or as per

	the investigative site's local requirements, if the requirement is more stringent than those outlined.

Sites must record the date the site staff became aware that the event met the criteria of an SAE in the source document. The Investigator will further report the SAE to the local EC according to the institution's EC reporting requirements.

The following adverse events will be collected in this study for investigational devices as well as the approved devices:

- All serious adverse events including deaths
- Non-serious adverse events related to device/procedure/stimulation/Charging/MRI
- USADE
- DD

7.3.2. Unanticipated Serious Adverse Device Effect Reporting to Sponsor and IRB (if applicable)

The Sponsor requires the Investigator to report any USADE to the Sponsor within 3 calendar days of the investigator's knowledge of the event, unless local requirements are more stringent, and to the EC per EC requirements.

7.3.3. Device Deficiency/Malfunction Reporting (if applicable)

Sites should report all device deficiencies/malfunctions on the appropriate CRF form.

The investigator must report all device deficiencies/malfunctions to the Sponsor as soon as possible but no later than outlined below.

Clinical Sites	Reporting timelines
All Sites	Sites must report device deficiencies/malfunctions to the Sponsor no later than 3 calendar days from the day the site personnel became aware of the event or as per the investigative site's local requirements, if the requirement is more stringent than those outlined.

Sites must report device deficiencies/malfunctions to the EC per the investigative site's local requirements.

In the event of a device deficiency/malfunction and the investigational device is not implanted, sites should return the device to the Sponsor.

If investigational devices are explanted for any reason, the investigator should arrange for the device to be returned to the Sponsor. See appendix VII for additional details.

All investigational device explant procedures shall be performed at the discretion of the study investigator, and should follow the specific processes of the participating site.

Sites will have access to an offline form to allow the investigator to report device deficiencies/malfunctions if sites cannot enter the information in the EDC system. This does not replace the EDC reporting system. Sites must still enter all information in the EDC system as soon as feasible.

Sites should report all device deficiencies/malfunctions to the Sponsor's Customer Service Department.

7.3.4. Adverse Event Reporting to Country Regulatory Authorities by the Sponsor

The Sponsor will report SAEs and reportable device deficiencies/malfunctions to the country regulatory authority, per local requirements.

Note: Reportable device deficiencies/malfunctions include device deficiencies/malfunctions that might have led to an SAE if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate. These are handled under the SAE reporting system.

8. STATISTICAL CONSIDERATIONS

The following section describes the statistical methods for the clinical investigation. A separate Statistical Analysis Plan (SAP) will provide additional details on statistical analyses.

8.1. Analysis Populations

1. The following populations will be used in the analyses for this study.
    1. [redacted]
    2. [redacted]

8.2. Statistical Analyses

This section describes the analysis for the confirmatory safety endpoint and additional endpoints. Further details are provided in the Statistical Analysis Plan.

8.2.1. Confirmatory Safety Endpoint

The confirmatory safety endpoint for this study is the rate of SAEs related to the IPG and/or charging system.

The confirmatory endpoint will be summarized as the number and percentage of subjects with IPG and/or charging system related SAEs, along with exact 95% Clopper-Pearson confidence intervals.

8.2.2. Additional Endpoints

Descriptive summary statistics will be presented for additional endpoints. Continuous variables will be summarized using mean and standard deviation. Categorical variables will be summarized using counts and percentages. The 95% confidence intervals for each type of data will be provided as appropriate.

8.3. Sample Size Calculation

[redacted]

8.4. Timing of Analysis

The analysis will be performed after all enrolled subjects have completed their 6-week visits or withdrawn from study.

8.5. Planned Interim Analysis

[redacted]

8.6. Withdrawal from the study

If a subject withdraws from the study prior to the permanent IPG implant procedure, that subject shall be reported, excluded from analysis of endpoints except for a serious adverse event. If a subject withdraws after permanent implant procedure has begun, that subject shall be reported and included in the analysis of endpoints for the available data.

8.7. Deviations from Statistical Plan

The Sponsor will document any major changes in an amendment to the protocol or statistical analysis plan (SAP), and any minor changes to the planned analysis in the final report.

9. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator/institution will permit direct access to source data/documents for performing clinical investigation-related monitoring, audits, EC review and regulatory inspections.

Subjects providing informed consent are agreeing to allow clinical investigation monitors or regulatory authorities, including foreign countries, to review in confidence any records identifying the subjects in this clinical investigation. This information may be shared with regulatory agencies; however, the Sponsor undertakes not to otherwise release the subject's personal and private information.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.1. Selection of Clinical Sites and Investigators

The Sponsor will select investigators qualified by training and experience to participate in the clinical investigation. Sites will be selected based upon review of a recent site assessment, if applicable, and the qualifications of the investigators who will participate in the clinical investigation.

10.2. Clinical Investigation Finances and Agreements

Abbott will finance the clinical investigation and will compensate investigational sites for participation in the clinical investigation per the conditions of agreement between Abbott and the investigational site.

10.3. CIP Amendments

The Sponsor will provide approved CIP amendments to the Investigators prior to implementing the amendment. The Principal Investigator is responsible for notifying the EC or equivalent committee of the CIP amendment (administrative changes) or obtaining EC's approval of the CIP amendment (changes in subject care or safety), according to the instructions provided by the Sponsor with the CIP amendment.

Sites must document in writing acknowledgement/approval of the CIP amendment by the EC prior to implementation of the CIP amendment. Sites must also provide copies of this documentation to the Sponsor.

10.4. Training

10.4.1. Site Training

All Investigators and clinical investigation personnel are required to attend Sponsor training sessions, which may be conducted at an Investigator's meeting, a site initiation visit, or other appropriate training sessions. Over-the-phone or self-training may take place as required. Training of Investigators and clinical investigation personnel will include, but is not limited to, the CIP requirements, investigational device usage, electronic case report form completion, and clinical investigation personnel responsibilities. All Investigators and clinical investigation personnel that are trained must sign a training log (or an equivalent) upon completion of the training. Prior to signing the training log, Investigators and clinical investigation personnel must not perform any CIP-related activities that are not considered standard of care at the site.

10.5. Monitoring

Sponsor and/or designee will monitor the clinical investigation over its duration according to the CIP-specific monitoring plan which will include the planned extent of source data verification.

Prior to initiating any procedure, the Sponsor monitor (or delegate) will ensure that the following criteria are met:

- The investigator understands and accepts the obligation to conduct the clinical investigation according to the CIP and applicable regulations and has signed the Clinical Trial Agreement.
- The Investigator and his/her staff should have sufficient time and facilities to conduct the clinical investigation and should have access to an adequate number of appropriate subjects to conduct the clinical investigation.
- Sites must have source documentation (including original medical records) to substantiate proper informed consent procedures, adherence to CIP procedures,

adequate reporting and follow-up of adverse events, accuracy of data collected on case report forms, and device information.

- The Investigator/site will permit access to such records and will maintain a monitoring visit sign-in log at the site. The Investigator will agree to dedicate an adequate amount of time to the monitoring process. The Investigator and/or research coordinator will be available for monitoring visits. It is expected that the Investigator will provide the monitor with a suitable working environment for review of clinical investigation-related documents.

10.6. Deviations from CIP

The Investigator should not deviate from the CIP for any reason except in cases of medical emergencies when the deviation is necessary to protect the rights, safety, and well-being of the subject, or to eliminate an apparent immediate hazard to the subject. In that event, the Investigator will notify Sponsor immediately by phone or in writing.

The Sponsor will not grant any waivers for CIP deviations. Sites must report all deviations to the Sponsor using the Deviation CRF. The Sponsor will monitor the occurrence of CIP for evaluation of investigator compliance to the CIP and regulatory requirements and handle according to written procedures. Investigators will inform their EC or equivalent committee of all CIP deviations in accordance with their specific EC or equivalent committee reporting policies and procedures.

In the event of repeated non-compliance, as determined by the Sponsor, a Sponsor's monitor or company representative will attempt to secure compliance by one or more of the following (and not limited to):

- Visiting the investigator and/or delegate
- Telephoning the investigator and/or delegate
- Corresponding with the investigator and/or delegate

Repeated non-compliance with the signed agreement, the CIP, or any other conditions of the clinical investigation may result in further escalation in accordance with the Sponsor's written procedures, including securing compliance or, at its sole discretion, the Sponsor may terminate the investigator's participation in the clinical investigation.

10.7. Quality Assurance Audit

A Sponsor representative or designee may request access to all clinical investigation records, including source documentation, for inspection during a Quality Assurance audit.

If an investigator is contacted by a Regulatory Agency in relation to this clinical investigation, the Investigator will notify Sponsor immediately. The Investigator and Research Coordinator must be available to respond to reasonable requests and audit queries made during the audit process. The Investigator must provide the Sponsor with copies of all correspondence that may affect the review of the current clinical investigation (e.g., Form FDA 483, Inspectional Observations, Warning Letters, Inspection Reports, etc.). The Sponsor may provide any needed assistance in responding to regulatory audits.

10.8. Sponsor Auditing

1. The Sponsor shall prepare an audit plan as well as the operating procedures for the related duties and conduct audits in accordance with the audit plan and the operating procedures.
2. Individuals engaged in auditing (hereinafter referred to as "auditor") shall be different than those in charge of medical device development or monitoring.
3. The auditor shall prepare an audit report documenting the matters confirmed in the audit to certify and verify that the audit has been conducted and submit them to the Sponsor.

10.9. Committees (add as applicable for clinical investigation)

10.9.1. Clinical Events Committee (CEC)

The CEC is an independent adjudication body comprised of qualified physicians who are not participants in the clinical investigation. The CEC will review and adjudicate pre-specified events reported by investigators or identified by Safety personnel for the clinical investigation as defined in the CEC charter and according to definitions provided in this CIP.

11. DATA HANDLING AND RECORD KEEPING

Sponsor and/or its affiliates will maintain documentation of the systems and procedures used in data collection for the duration of the clinical investigation.

CRF data collection will be performed through a secure web portal and only authorized personnel will access the EDC system using a unique username and password to enter, review or correct data. Passwords and electronic signatures will be strictly confidential.

The data will be subjected to consistency and validation checks within the EDC system and supplemental review by the Sponsor.

At the end of the clinical investigation, completed CRF images with the date-and-time stamped electronic audit trail indicating the user, the data entered, and any reason for change (if applicable) will be provided to the investigational sites, if requested.

For the duration of the clinical investigation, the Investigator will maintain complete and accurate documentation including, but not limited to, medical records, clinical investigation progress records, laboratory reports, CRFs, signed ICFs, device accountability records (if applicable), correspondence with the EC and clinical investigation monitor/Sponsor, adverse event reports, and information regarding subject discontinuation or completion of the clinical investigation.

11.1. Protection of Personally Identifiable Information

The Sponsor respects and protects personally identifiable information collected or maintained for this clinical investigation.

The Sponsor implements technical and physical access controls to ensure that Personal Information is accessible only to and processed only on a ‘need to know ’basis, including periodic review of access rights, and revocation of access when an individual’s employment is terminated or the individual transitions to a role that does not require access to Personal Information, and appropriate restrictions on physical access to premises, facilities, equipment, and records containing Personal Information.

The Sponsor requires the investigational sites to enter only pseudonymous Personal Information (key-coded) necessary to conduct the clinical investigation, such as the patient’s medical condition, treatment, dates of treatment, etc., into Sponsor’s data management systems. The Sponsor discloses as part of the clinical investigation informed consent process that some Sponsor representatives still may see Personal Information at the participating sites for technical support of the participating physicians on the device implant or procedures, monitoring and quality control purposes. All parties will observe confidentiality of Personal Information always throughout the clinical investigation. All reports and data publications will preserve the privacy of each subject and confidentiality of his/her information.

The Sponsor data management systems and processes were designed, developed, and tested according to industry standards to appropriately safeguard Confidential Information (including any Personal Information) against unauthorized access and/or interference by third parties, intrusion, theft, destruction, loss or alteration. Clinical Investigation data are encrypted in transit and at rest.

The Sponsor maintains a Privacy Incident procedure that complies in all respects with Applicable Law and industry best practices.

11.2. Data Management Plan

A Data Management Plan (DMP) will describe procedures used for data review, data cleaning, and issuing and resolving data discrepancies. If appropriate, the Sponsor may update the DMP throughout the duration of the clinical investigation. The Sponsor will track and document control all revisions.

11.3. Source Documentation

Regulations and GCP require the Investigator to maintain information in the subject's original medical records that corroborates data collected on the CRFs. To comply with these regulatory requirements/GCP, sites should include the following information in the subject record at a minimum and if applicable to the clinical investigation:

- Medical history/physical condition of the subject before involvement in the clinical investigation sufficient to verify CIP entry criteria
- Dated and signed notes on the day of entry into the clinical investigation referencing the Sponsor, CIP number, subject ID number, and a statement that informed consent was obtained
- Dated and signed notes from each subject visit (for specific results of procedures and exams)
- AEs reported and their resolution, including supporting documents, such as discharge summaries, operative notes, follow-up clinic notes, and lab results including documentation of site awareness of SAEs and of investigator assessment of device relationship for SAEs.
- Subject's condition upon completion of or withdrawal from the clinical investigation
- Any other data required to substantiate data entered into the CRF
- Patient reported outcome measures may be completed using CRF worksheets. This serves as source documentation.

11.4. Case Report Form Completion

Site research personnel trained on the CIP and CRF completion will perform the primary data collection clearly and accurately based on source-documented hospital and/or clinic chart reviews. The investigator will ensure accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor on the CRFs and in all required reports.

Sites will collect data on all subjects enrolled into the clinical investigation.

Only authorized site personnel will be permitted to enter the CRF data through the EDC system deployed by the Sponsor. The Sponsor will use an electronic audit trail to track any subsequent changes of the entered data.

11.5. Record Retention

The Sponsor and Investigator/Site will archive and retain all documents pertaining to the clinical investigation as per the applicable regulatory record retention requirements. The Investigator must obtain permission from Sponsor in writing before destroying or transferring control of any clinical investigation records.

11.6. Investigational Devices Accountability

The Sponsor ships investigational products only to the Principal Investigator (the responsible leader of the investigational site) or his/her legal designee of each site, after sites receive documentation of site activation and shipping authorization is complete.

The Investigator or an authorized designee must maintain adequate records of the receipt and disposition of each investigational device, including part number, batch/lot number, and serial number (if applicable), date used, subject identification, and treating physician.

Storage locations for the devices at investigational sites must be locked with access restricted only to investigators and authorized personnel.

Sites must return all investigational devices associated with a device failure or device deficiency, that are not implanted, to the Sponsor.

If investigational devices are explanted for any reason, the investigator should arrange for the device to be returned to the Sponsor. See Appendix VII for additional details.

All investigational device explant procedures shall be performed at the discretion of the study investigator, and should follow the specific processes of the participating site.

Sites must return unused investigational devices to the Sponsor.

The clinical investigation will use an Inventory Accountability Log supplied by the Sponsor for device accountability. The Inventory Accountability Log must document the disposition of all investigational devices including those that have been returned to Sponsor.

12. ETHICAL CONSIDERATION

12.1. Ethics Committee Review and Approval

The Principal Investigator at each investigational site will obtain EC approval for the CIP and ICF/other written information provided to the patient prior to consenting and enrolling patients in this clinical investigation. The site must receive the approval letter prior to the start of this clinical investigation and provide a copy to the Sponsor.

Sites will submit any amendments to the CIP as well as associated ICF changes to the EC and written approval obtained prior to implementation, according to each institution’s EC requirements.

No changes will be made to the CIP or ICF or other written information provided to the patient without appropriate approvals, including EC, the Sponsor, and the regulatory agencies (if applicable).

Until the clinical investigation is completed, the Investigator will advise his/her EC of the progress of this clinical investigation, per EC requirements. Written approval must be obtained from the EC yearly to continue the clinical investigation, or according to each institution's EC requirements.

Sites will not perform any investigative procedures, other than those defined in this CIP, on the enrolled subjects without the written agreement of the EC and the Sponsor.

13. CLINICAL INVESTIGATION CONCLUSION

The clinical investigation will be concluded when:

- All sites are closed AND
- The final report has been provided to investigators or the Sponsor has provided formal documentation of clinical investigation closure.

The Sponsor will submit the clinical investigation report within one year of the end of the investigation to the investigational sites, competent authorities and reviewing IRBs and ECs.

14. PUBLICATION POLICY

The data and results from the clinical investigation are the sole property of the Sponsor. The Sponsor shall have the right to access and use all data and results generated during the clinical investigation. The Investigators will not use this clinical investigation-related data without the written consent of the Sponsor for any purpose other than for clinical investigation completion or for generation of publication materials, as referenced in the Clinical Trial Agreement. Single-center results are not allowed to be published or presented before the multi-center results. The Sponsor must review and approve any proposals for publications or presentations by the investigators in a timely manner in compliance with the Sponsor's publication policy set forth in the Clinical Trial Agreement.

15. RISK ANALYSIS

15.1. Anticipated Clinical Benefits

While there are no guaranteed clinical benefits associated with participation in this clinical study, it is expected that patients implanted with a Gemini SCS system will experience similar improvements in symptoms relating to chronic pain as patients implanted with other commercially available SCS neurostimulation systems such as reduction in perceived pain.

[redacted]

15.2. Foreseeable Adverse Events and Anticipated Adverse Device Effects

Risks associated with the specified device and procedure, together with their likely incidence, are described in the IB/IFU. There may be risks related to the device under investigation that are unknown at present. Likewise, the exact frequency of the risk is unknown.

The use of a neurostimulation system involves risks. In addition to the risks commonly associated with surgery, below are listed the anticipated potential adverse effects with the use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (if either occurs, turn off your EPG/IPG immediately)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, or changes in electrode position relative to the spinal cord
- Changes in stimulation or reduced pain relief due to lose electrical connections
- Changes in stimulation or reduced pain relief due to lead failure.
- Stimulation in unwanted places such as the ribs or chest
- Changes in stimulation or reduced pain relief due to lead migration
- Epidural hemorrhage
- Hematoma
- Infection
- Spinal cord compression
- Paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis below the level of implant
- Weakness below the level of implant
- Clumsiness below the level of implant
- Numbness below the level of implant
- Pain below the level of implant
- Persistent pain at the lead site
- Persistent pain at the IPG site
- Seroma (mass or swelling) at the IPG site
- Seroma at the lead incision site
- Allergic or rejection response to device/implant materials
- Implant migration

- Skin erosion around the implant
- Loss of stimulation due to premature battery depletion or battery failure

The following potential adverse events may be associated with charging the system and are listed as warnings or precautions in the IFU:

- Heating or discomfort at surgical staples while recharging. Charging should not be carried out while staples are in place
- Heating or discomfort at the pocket while recharging
- Interference with another implanted medical device

The following potential adverse events may occur in the MRI environment:

- Lead electrode heating resulting in tissue damage or serious patient injury
- IPG heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in overstimulation or shocking sensations
- Damage to the IPG or leads causing the system to fail to deliver stimulation or causing the system to deliver overstimulation
- Damage to the functionality or mechanical integrity of the IPG resulting in the inability to communicate with the IPG
- Movement or vibration of the IPG or leads

15.3. Residual Risks Associated with the Device Under Investigation, as Identified in the Risk Management Report / Risk Analysis Report

All risks have identified risks have been mitigated as far as possible through application of appropriate controls and inspections and determined to be within acceptable levels.

Residual risks are disclosed in the IFU in the form of clear instructions of what actions to take or to avoid, to avoid a hazardous situation of harm from occurring (contra-indications, warnings, and precautions). The anticipated AEs disclosed in the IFU (and CIP Appendix V) provide further information to enable the user, and potentially the patient, to make an informed decision that weighs the residual risk against the benefit of using the device.

A detailed description of the risk analysis process, residual risks, and associated mitigations is presented in the Investigators Brochure (CL1014827).

15.4. Risks Associated with Participation in this Clinical Investigation

The risks involved with this study are comparable to those associated with the implant of any other commercially available neurostimulation system. Risks specific to Abbott neurostimulation systems are outlined in the associated IFU, and these disclosed risks are not modified by participation in this study.

15.5. Steps Taken to Control or Mitigate Risks

The Sponsor will employ measures throughout the course of this study to minimize these risks such as clearly defined inclusion and exclusion criteria, proper consenting process, selection of investigational sites that have a sufficient level of clinical expertise, investigator selection, and

appropriate training for all involved in the study activities. In-depth recommendations, special precautions and instructions regarding patient selection, device handling, device placement and system removal are included in IFU documents of all devices included in this study. All device-related adverse events and device deficiencies will be reported to the Sponsor and will be monitored internally for safety surveillance purposes.

15.6. Risk to Benefit Rationale

The risks associated with Abbott's neurostimulation systems are anticipated to be comparable to those associated with the use of other commercially available neurostimulation systems. The patients participating in this study are indicated for using a neurostimulation system as part of their standard medical management and are subject to the risks associated with these devices. Refer to the Investigational Brochure for details.

15.7. References

1. Dahlhamer, J., et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016.* MMWR Morb Mortal Wkly Rep, 2018. **67**(36): p. 1001-1006.
2. Gaskin, D.J. and P. Richard, *The economic costs of pain in the United States.* J Pain, 2012. **13**(8): p. 715-24.
3. Rudd, R.A., et al., *Increases in Drug and Opioid-Involved Overdose Deaths - United States, 2010-2015.* MMWR Morb Mortal Wkly Rep, 2016. **65**(50-51): p. 1445-1452.
4. Deer, T., et al., *Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform.* Neuromodulation, 2018. **21**(1): p. 56-66.
5. Falowski, S.M., et al., *Improved Psychosocial and Functional Outcomes and Reduced Opioid Usage Following Burst Spinal Cord Stimulation.* Neuromodulation, 2020.
6. Deer, T.R., et al., *Novel Intermittent Dosing Burst Paradigm in Spinal Cord Stimulation.* Neuromodulation, 2020.
7. [redacted]
8.
9.

Clinical Investigation Plan

APPENDIX I: ABBREVIATIONS AND ACRONYMS

AE	Adverse Event
CEC	Clinical Events Committee
CIP	Clinical Investigation Plan
CP	Clinician Programmer
CRF	Case Report Form
DD	Device Deficiency
DMP	Data Management Plan
EC	Ethics Committee
EDC	Electronic Data Capture
FAS	Full Analysis Set
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
IFU	Instructions for Use
IPG	Implantable Pulse Generator
MRI	Magnetic Resonance Imaging
NRS	Numerical Rating Scale
PRO	Patient Reported Outcome
PROMIS	Patient-Reported Outcomes Measurement Information System
SAE	Serious Adverse Event
SCS	Spinal Cord Stimulation
SD	Standard Deviation
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

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APPENDIX II: SITE CONTACT INFORMATION

Contact information for each participating clinical site is available under a separate cover by contacting the Sponsor at:

Abbott
6901 Preston Rd
Plano, TX 75024

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APPENDIX III: LABELS

IFU documents will be kept under a separate cover and are available upon request.

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APPENDIX IV: CASE REPORT FORMS

Case Report Forms will be kept under a separate cover and are available upon request.

Clinical Investigation Plan

APPENDIX V: INFORMED CONSENT FORM

The study specific sample Informed Consent Form will be kept under a separate cover and is available upon request.

Clinical Investigation Plan

APPENDIX VI: MONITORING PLAN

A copy of the Monitoring Plan can be obtained upon request from the Sponsor Clinical Project Manager for the clinical investigation.

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APPENDIX VII: EXPLANT, RETURN AND ANALYSIS OF THE IPG

The disposition of explanted Gemini SCS IPGs warrants special consideration, as their proper return will allow for analysis, providing valuable information on performance and possible failure modes.

Clinical study sites' responsibilities for explant and return of the device: Abbott requests that all Gemini SCS IPGs which are explanted by the investigators, or are explanted at other sites and recoverable by the investigators, be returned to Abbott as follows:

- Contact the Abbott clinical manager(s) for the study as soon as it is learned that the IPG will be (or has been) explanted. The clinical manager(s) will provide shipping instructions to ensure the IPG is delivered to Abbott Neuromodulation's Product Performance group for failure analysis. Note: Device(s) shall be shipped to the return address as soon as possible and no later than 15 calendar days.
- Used devices may present a health hazard. All possible safety measures shall be taken when handling used or explanted products to reduce the potential for staff to come into physical contact with potentially contaminated devices. Ensure that the device is free of gross contamination. If necessary, remove moisture by wiping with a dry cloth or towel. Note: Do not sterilize or sanitize the device.
- Place the device in a leakproof biohazard container or bag, and seal.
- Place the biohazard container or bag into a Device Return Kit. Include sufficient packing materials so that the biohazard container or bag is packed snugly. The outer packaging must be clearly labelled as "Biohazard".
- If the explant is associated with any alleged device deficiency, include a description of the deficiency. Clearly print the Return number and/or Product Event Record (PER) number on the outside of the sealed box.
- Follow all instructions of the Abbott clinical manager in shipping the explanted device to:

Attn: Abbott Returns Department
6901 Preston Road
Plano TX, 75024 USA

Abbott **responsibilities for the analysis of an explanted and returned device:** Gemini SCS IPGs that are explanted and returned will, upon receipt at Abbott, be evaluated according to Abbott's normal failure analysis practice for returned product.

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APPENDIX VIII: REVISION HISTORY

Amendment Number	Version	Date	Details	Rationale
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Clinical Investigation Plan

APPENDIX IX: CIP SUMMARY

Clinical Investigation Name and Number	CRD_1030 Gemini
Title	Study of Gemini Rechargeable Spinal Cord Stimulation (SCS) System
Objective(s)	The objective of this study is to collect confirmatory data to show that the Gemini Spinal Cord Stimulation neuromodulation system functions as intended in a clinical setting.
Device Under Investigation	Gemini rechargeable Spinal Cord Stimulation (SCS) System
Number of Subjects Required for Inclusion in Clinical Investigation	The study is designed to report on 20 subjects who receive a Gemini SCS implant and complete follow-up. [redacted]
Clinical Investigation Design	Prospective, pre-market, non-randomized, multi-center, single-arm study
Confirmatory Safety Endpoint	The rate of serious adverse events adjudicated as related to the IPG and/or charging system.
Subject Follow-up	• Enrollment/Baseline • Permanent Implant • 2-week (10-14 days) follow-up post implant (in office, phone call, telemedicine) • 6-week (30-45 days) follow-up post implant (in office)
Inclusion Criteria	1. Subject is indicated for an SCS system, or has an implanted SCS system and is scheduled to receive an IPG replacement. 2. Subject is scheduled to receive a new IPG permanent implant and has completed a successful SCS trial in the last 6-months, OR subject is scheduled to undergo an all-in-one procedure OR has an implanted SCS system for an approved chronic pain indication. 3. Subject has a documented NRS pain score of ≥ 6 after at least 5 days without stimulation OR has an implanted functioning SCS system with NRS pain score of ≤ 4. 4. Subject must provide written informed consent prior to any clinical investigation-related procedure. 5. Subject is at least 18 years at the time of enrollment. 6. Subject is capable and willing to recharge an implanted IPG.

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Exclusion Criteria	1. Subject's SCS trial was unsuccessful. 2. Subject is currently participating, or intends to participate, in another clinical investigation that may confound the results of this study, as determined by Abbott. 3. Subject has or will receive more than one IPG. 4. Subject is pregnant or breastfeeding or plans to become pregnant during the clinical investigation follow-up period. 5. Subject has other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's assessment, could limit the subject's ability to participate in the clinical investigation. 6. Subject has or is scheduled to receive an intrathecal pump. 7. Subject is part of a vulnerable population (section 5.2.2 of the clinical investigational plan).