ClinicalTrials.gov PRS
Protocol Registration & Results System

June 2024

Pennington Biomedical
Research Center
Louisiana State University

Table of Contents

PBRC Login Information

Organization	PenningtonBRC
Login ID & Password	Request account from PRS Administrator: **Angela Ardoin**
ClinicalTrials.gov Identifier (NCT Number)	Assigned by system

Protocol Section

Study Identification

Organization's Unique Protocol ID	Use format: **PBRC and IRB Number** (ex. PBRC 2022-000)

Organization's Unique Protocol ID *

PBRC 2024-000

17 characters left

Brief Title	300 Characters or less
Acronym	Cannot include spaces
Study Type	Interventional, Observational, or Expanded Access

Brief Title *

Write a short, easy-to-understand version of the official study title using title case.

300 characters allowed , at least 18 characters required

Acronym [*]

Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Study Type *

- ○ Interventional
  Participants are assigned to one or more interventions, based on a protocol.
- ○ Observational
  Participants are **not** assigned to interventions based on a protocol.
- ○ Expanded Access
  Participants receive an experimental drug or device outside of a clinical trial protocol.

Official Title	Provide the title used in the study protocol. Use title case.

Official Title * 

Provide the title used in the study protocol. Use title case.

600 characters allowed

Secondary IDs	These should be provided if they exist. If the study is funded by a U.S. Federal Government agency, the grant or contract number must be included as a Secondary ID.

Secondary IDs [*] 

These should be provided if they exist. If the study is funded by a U.S. Federal Government agency, the grant or contract number must be included as a Secondary ID.

Secondary ID Type

- [x] US NIH Grant/Contract Award Number
- [ ] Other Grant/Funding Number
- [ ] Registry Identifier
- [ ] EU Trial (CTIS) Number
- [ ] EudraCT Number
- [ ] Other Identifier

US NIH Grant/Contract Award Number

R01DA013131, U01HL066582, 5R01HL123451-01A2

Tip: Look up the grant/contract award number using the NIH RePORTER.

30 characters allowed

Study Status	
Record Verification Date	Date the record is created or updated
Overall Recruitment	The recruitment status for the clinical study, based upon the status of the individual sites. If at least one facility in a multi-site clinical study has an Individual Site Status of "Recruiting," then the Overall Recruitment Status for the study must be "Recruiting." Select one.
Why Study Stopped * A brief explanation of the reason(s) why such clinical study was stopped (for a clinical study that is "Suspended," "Terminated," or "Withdrawn" prior to its planned completion as anticipated by the protocol).	• **Not yet recruiting:** Participants are not yet being recruited • **Recruiting:** Participants are currently being recruited, whether any participants have yet been enrolled • **Enrolling by invitation:** Participants are being (or will be) selected from a predetermined population • **Active, not recruiting:** Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled • **Completed:** The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred) • **Suspended *:** Study halted prematurely but potentially will resume • **Terminated *:** Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention • **Withdrawn *:** Study halted prematurely, prior to enrollment of first participant
Status Study Start Date	The estimated date on which the clinical study will be **open for recruitment of participants**, or **the actual date on which the first participant was enrolled.** **Note**: "Enrolled" means a participant's, (or their legally authorized representative's), agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.
Primary Completion Date Once the clinical study has reached the primary completion date, the responsible party must update the Primary Completion Date to reflect the actual primary completion date.	The date that the **final participant was examined** or received an intervention for the purposes of **final collection of data for the primary outcome**, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all primary outcomes.
Study Completion Date Once the clinical study has reached the study completion date, the responsible party must update the Study Completion Date to reflect the actual study completion date.	The date the **final participant was examined** or received an intervention for purposes of **final collection of data for the primary and secondary outcome measures** and adverse events (**for example, last participant's last visit**), whether the clinical study concluded according to the pre-specified protocol or was terminated.

Record Verification Date *

Month * Apr

Year * 2024

Overall Recruitment Status *

If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.

Recruiting

Study Start Date * §

Date of enrollment of the first participant.
The Day field is optional for anticipated dates.

Month	Day	Year
May	16	2024

Type

- (●) Anticipated
- ( ) Actual

Primary Completion Date *

Final data collection date for the primary outcome measures.
The Day field is optional for anticipated dates.

Month	Day	Year
Jul	16	2024

Type

- (●) Anticipated
- ( ) Actual

Study Completion Date * §

Final data collection date for the primary outcome measures, secondary outcome measures, and adverse event information.
The Day field is optional for anticipated dates.

Month	Day	Year
Dec	16	2024

Type

- (●) Anticipated
- ( ) Actual

Sponsor/Collaborators	
Responsible Party	Select Sponsor unless the **Principal Investigator** has been designated as Responsible Party or the Principal Investigator is the Sponsor. ELABORATION OF DEFINITIONS OF RESPONSIBLE PARTY
Sponsor	Primary organization conducting study and associated data analysis (not necessarily a funding source).
Collaborators	Organization(s) providing support: funding, design, implementation, data analysis or reporting. **Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)** **Enter only the organization name.**

Responsible Party, by Official Title *

Select the type of responsible party - usually the sponsor.

- ○ Sponsor
- ◉ Principal Investigator
- ○ Sponsor-Investigator

Investigator Information [*]

Investigator Name [Username]

Select a name from the list. It must be a person's full name.

- Select -

Investigator Official Title

254 characters allowed

Investigator Affiliation

This is typically the sponsor organization.

160 characters allowed

Oversight	
U.S. FDA-regulated Drug	Studying one or more U.S. FDA-regulated drug or biologic products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist. Indication that a clinical study is studying a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act. **Select Yes/No**.
U.S. FDA-regulated Device	Studying one or more U.S. FDA-regulated device products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist. Indication that a clinical study is studying a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act. **Select Yes/No**.

U.S. FDA-regulated Drug * §

Is the study investigating one or more U.S. FDA-regulated drug or biologic products?

- Yes
- No

U.S. FDA-regulated Device * §

Is the study investigating one or more U.S. FDA-regulated device products?

- Yes
- No

U.S. FDA IND/IDE (Not public)	Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)? If yes, list FDA Center and IND/IDE Number

U.S. FDA IND/IDE *

Is this study being done under a U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

- Yes
- No

Study Description	
Availability of Expanded Access	Will any non-protocol access to the investigational drug, biologic or device be provided? **If yes, list Expanded Access Record: ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record**

Availability of Expanded Access [*]

Will expanded access to the investigational drug, biologic, or device be provided?

- ◯ Yes
- ◯ No
- ◯ Unknown

Human Subjects Protection Review	Select IRB Status

Board Status *

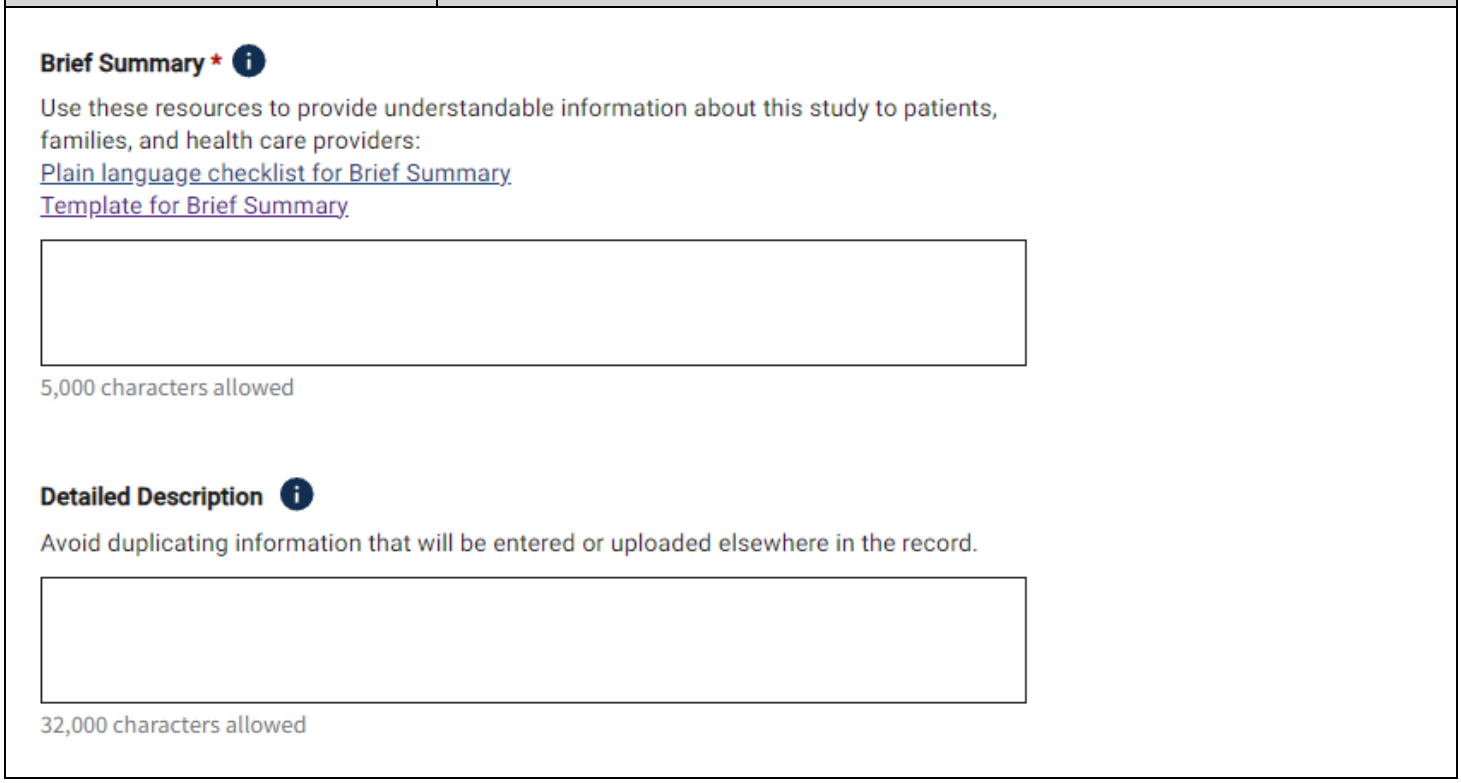
- Select -
- Request not yet submitted
- Submitted, pending
- Submitted, approved
- Exempt
- Submitted, denied
- Submission not required

Approval Number	Use IRB Study Number
Board Name	Institutional Review Board
Board Affiliation	Pennington Biomedical Research Center
Board Contact	225-763-2544 irb@pbrc.edu 6400 Perkins Road Baton Rouge, LA 70808
Data Monitoring Committee	Indicate whether a data monitoring committee has been appointed for this study.
FDA Regulated Intervention	If yes, it will ask again if **Section 801 Clinical Trial (ACT).**

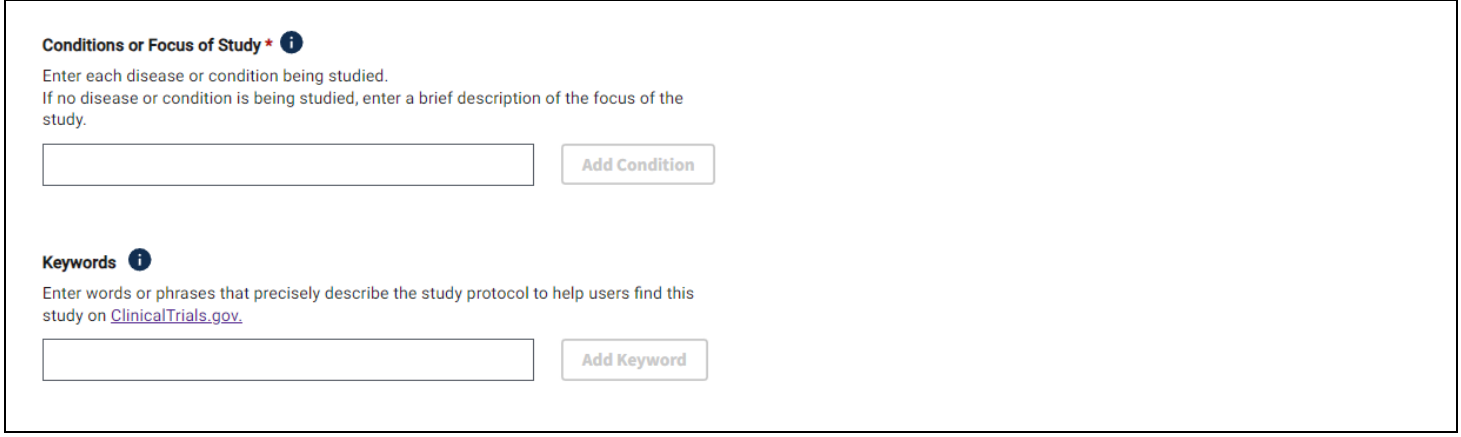
Data Monitoring Committee

- ◯ Yes
- ◯ No

Brief Summary	A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public. Plain Language Checklist for Brief Summary Template to write a brief study description in plain language
Detailed Description	Extended description of the protocol, including more technical information (as compared to the Brief Summary), if desired. Do not include the entire protocol; do not duplicate information recorded in other data elements, such as Eligibility Criteria or outcome measures.



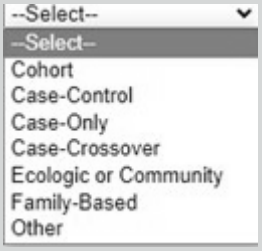
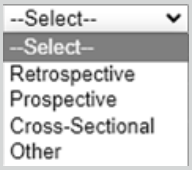
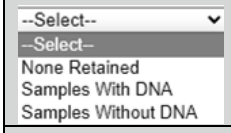
Conditions (or Focus of Study)	
Primary Disease (or Condition, or the Focus of the Study)	The name(s) of the disease(s) or condition(s) studied in the clinical study, or the focus of the clinical study.
Keywords	Words or phrases that best describe the protocol. Keywords help users find studies in the database.



Study Design	
Study Type (Same in Study Identification Section on page 2)	• **Interventional** (clinical trial): Participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes. • **Observational**: Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the study participants. This includes when participants receive interventions as part of routine medical care, and a researcher studies the effect of the intervention. ○ **Patient Registry**: An observational study that is also considered to be a Patient Registry. This type of study should only be registered once in the Protocol Registration and Results System (PRS), by the sponsor responsible for the primary data collection and analysis. ○ **Note:** The Agency for Healthcare Research and Quality (AHRQ) defines a Patient Registry as including an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, healthcare services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions. About Patient Registry • **Expanded Access**: An investigational drug product (including biological product) available through expanded access for patients who do not qualify for enrollment in a clinical trial. Expanded Access includes all expanded access types under section 561 of the Federal Food, Drug, and Cosmetic Act: (1) for individual patients, including emergency use; (2) for intermediate-size patient populations; and (3) under a treatment IND or treatment protocol. (For more information on data requirements for this Study Type, see Expanded Access Data Element Definitions).

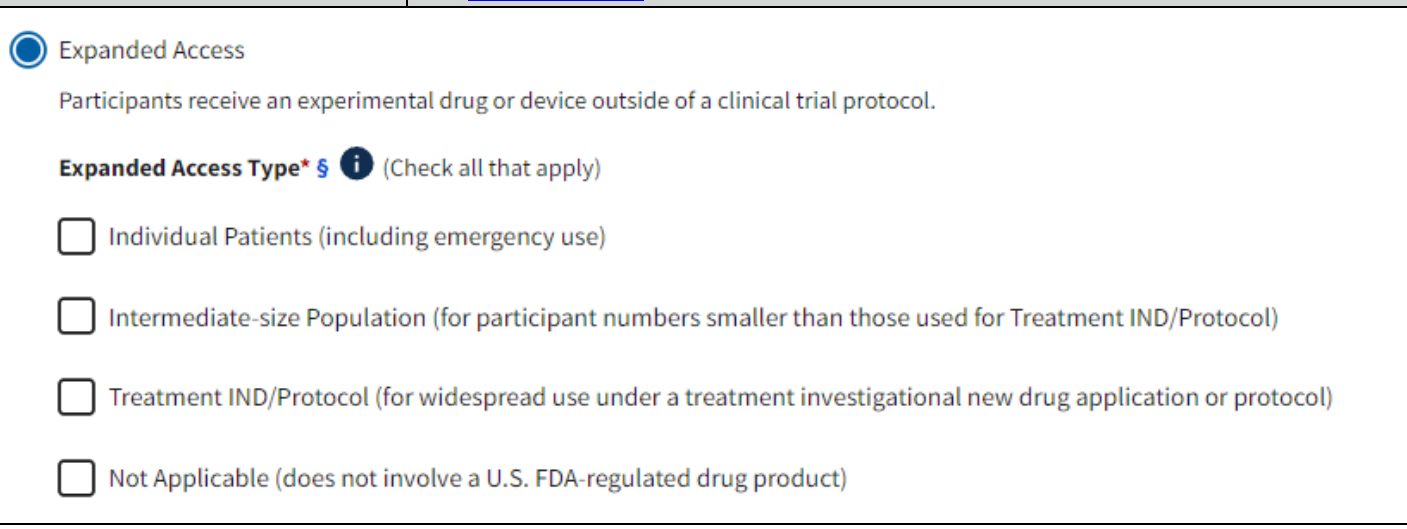
Study Design Interventional	
Primary Purpose (For interventional studies only) --Select-- --Select-- Treatment Prevention Diagnostic Supportive Care Screening Health Services Research Basic Science Device Feasibility Other	The main objective of the intervention(s) being evaluated by the clinical trial. • **Treatment:** One or more interventions are being evaluated for treating a disease, syndrome, or condition. • **Prevention:** One or more interventions are being assessed for preventing the development of a specific disease or health condition. • **Diagnostic:** One or more interventions are being evaluated for identifying a disease or health condition. • **Supportive Care:** One or more interventions are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function. • **Screening:** One or more interventions are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor. • **Health Services Research:** One or more interventions for evaluating the delivery, processes, management, organization, or financing of healthcare. • **Basic Science:** One or more interventions for examining the basic mechanism of action (for example, physiology or biomechanics of an intervention). • **Device Feasibility:** An intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. • **Other:** None of the other options applies.
Study Phase (For interventional studies only) N/A --Select-- N/A Early Phase 1 (or Phase 0) Phase 1 Phase 1/Phase 2 Phase 2 Phase 2/Phase 3 Phase 3 Phase 4	For a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21 and in 21 CFR 312.85 for phase 4 studies. Select only one. • **N/A:** Trials without phases (for example, studies of devices or behavioral interventions). • **Early Phase 1** (Formerly listed as "Phase 0"): Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information. • **Phase 1:** Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients. • **Phase 1/Phase 2:** Trials that are a combination of phases 1 and 2. • **Phase 2:** Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks. • **Phase 2/Phase 3:** Trials that are a combination of phases 2 and 3. • **Phase 3:** Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug. • **Phase 4:** Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.

Interventional Study Model --Select-- Single Group Parallel Crossover Factorial Sequential	The strategy for assigning interventions to participants. • **Single Group:** Clinical trials with a single arm • **Parallel:** Participants are assigned to one of two or more groups in parallel for the duration of the study • **Crossover:** Participants receive one of two (or more) alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study • **Factorial:** Two or more interventions, each alone and in combination, are evaluated in parallel against a control group • **Sequential:** Groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies
Model Description (For interventional studies only)	Provide details about the Interventional Study Model.
Number of Arms (For interventional studies only)	The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during all periods or phases. **Note:** "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.
Masking (For interventional studies only)	The party or parties involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual participants. Select all that apply. Roles, if Masking: • Participant • Care Provider • Investigator • Outcomes Assessor: The individual who evaluates the outcome(s) of interest • No Masking
Masking Description	Provide information about other parties who may be masked in the clinical trial, if any.
Allocation (For interventional studies only)	The method by which participants are assigned to arms in a clinical trial. • N/A (not applicable): **Select N/A for single-arm studies.** • Randomized: Participants are assigned to intervention groups by chance • Nonrandomized: Participants are expressly assigned to intervention groups through a non-random method, such as physician choice
Enrollment (Select Anticipated or Actual)	The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. **Note**: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

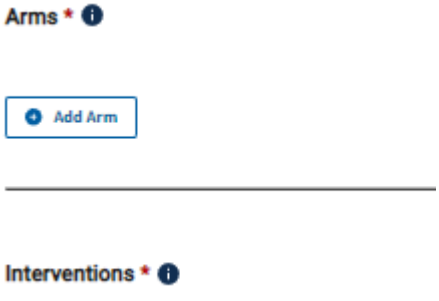
Study Design Observational (Patient Registry)	
Observational Study Model (Patient Registry) 	Primary strategy for participant identification and follow-up. Select one. • **Cohort:** Group of individuals, initially defined and composed, with common characteristics (for example, condition, birth year), who are examined or traced over a given time period. • **Case-Control:** Group of individuals with specific characteristics (for example, conditions or exposures) compared to group(s) with different characteristics, but otherwise similar. • **Case-Only:** Single group of individuals with specific characteristics. • **Case-Crossover:** Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (that is, control period). • **Ecologic or Community:** Geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (for example, air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (for example, healthcare system, laws or policies, median income, average fat intake, disease rate). • **Family-Based:** Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment. • **Other:** Explain in Detailed Description.
Time Perspective (For observational studies only) 	Temporal relationship of observation period to time of participant enrollment. Select one. • **Retrospective:** Look back using observations collected predominantly prior to subject selection and enrollment • **Prospective:** Look forward using periodic observations collected predominantly following subject enrollment • **Cross-sectional:** Observations or measurements made at a single point in time, usually at subject enrollment • **Other:** Explain in Detailed Description
Biospecimen Retention (For observational studies only) 	Indicate whether samples of material from research participants are retained in a biorepository. Select one. • **None Retained:** No samples retained • **Samples With DNA:** Samples retained, with potential for extraction of DNA from at least one of the types of samples retained (e.g., frozen tissue, whole blood) • **Samples Without DNA:** Samples retained, with no potential for DNA extraction from any retained samples (e.g., fixed tissue, plasma)
Biospecimen Description	Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).
Enrollment (Select Anticipated or Actual)	The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. **Note**: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.
Target Follow-Up Duration	For Patient Registries, the anticipated time period over which each participant is to be followed. Provide a number and select a Unit of Time (years, months, weeks, days).
Number of Groups/Cohorts	Number of study groups/cohorts. Enter "1" for a single-group study. Many observational studies have one group/cohort; case control studies typically have two. About Patient Registry

Study Design Observational (Not Patient Registry)	
Observational Study Model (Not Patient Registry) --Select-- --Select-- Cohort Case-Control Case-Only Case-Crossover Ecologic or Community Family-Based Other	Primary strategy for participant identification and follow-up. Select one. • **Cohort:** Group of individuals, initially defined and composed, with common characteristics (for example, condition, birth year), who are examined or traced over a given time period. • **Case-Control:** Group of individuals with specific characteristics (for example, conditions or exposures) compared to group(s) with different characteristics, but otherwise similar. • **Case-Only:** Single group of individuals with specific characteristics. • **Case-Crossover:** Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (that is, control period). • **Ecologic or Community:** Geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (for example, air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (for example, healthcare system, laws or policies, median income, average fat intake, disease rate). • **Family-Based:** Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment. **Other:** Explain in Detailed Description.
Time Perspective (For observational studies only) --Select-- --Select-- Retrospective Prospective Cross-Sectional Other	Temporal relationship of observation period to time of participant enrollment. Select one. • **Retrospective:** Look back using observations collected predominantly prior to subject selection and enrollment • **Prospective:** Look forward using periodic observations collected predominantly following subject enrollment • **Cross-sectional:** Observations or measurements made at a single point in time, usually at subject enrollment **Other:** Explain in Detailed Description
Biospecimen Retention (For observational studies only) --Select-- --Select-- None Retained Samples With DNA Samples Without DNA	Indicate whether samples of material from research participants are retained in a biorepository. Select one. • **None Retained:** No samples retained • **Samples With DNA:** Samples retained, with potential for extraction of DNA from at least one of the types of samples retained (e.g., frozen tissue, whole blood) • **Samples Without DNA:** Samples retained, with no potential for DNA extraction from any retained samples (e.g., fixed tissue, plasma)
Biospecimen Description	Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).
Enrollment (Select Anticipated or Actual)	The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. **Note**: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.
Number of Groups/Cohorts	Number of study groups/cohorts. Enter "1" for a single-group study. Many observational studies have one group/cohort; case control studies typically have two.

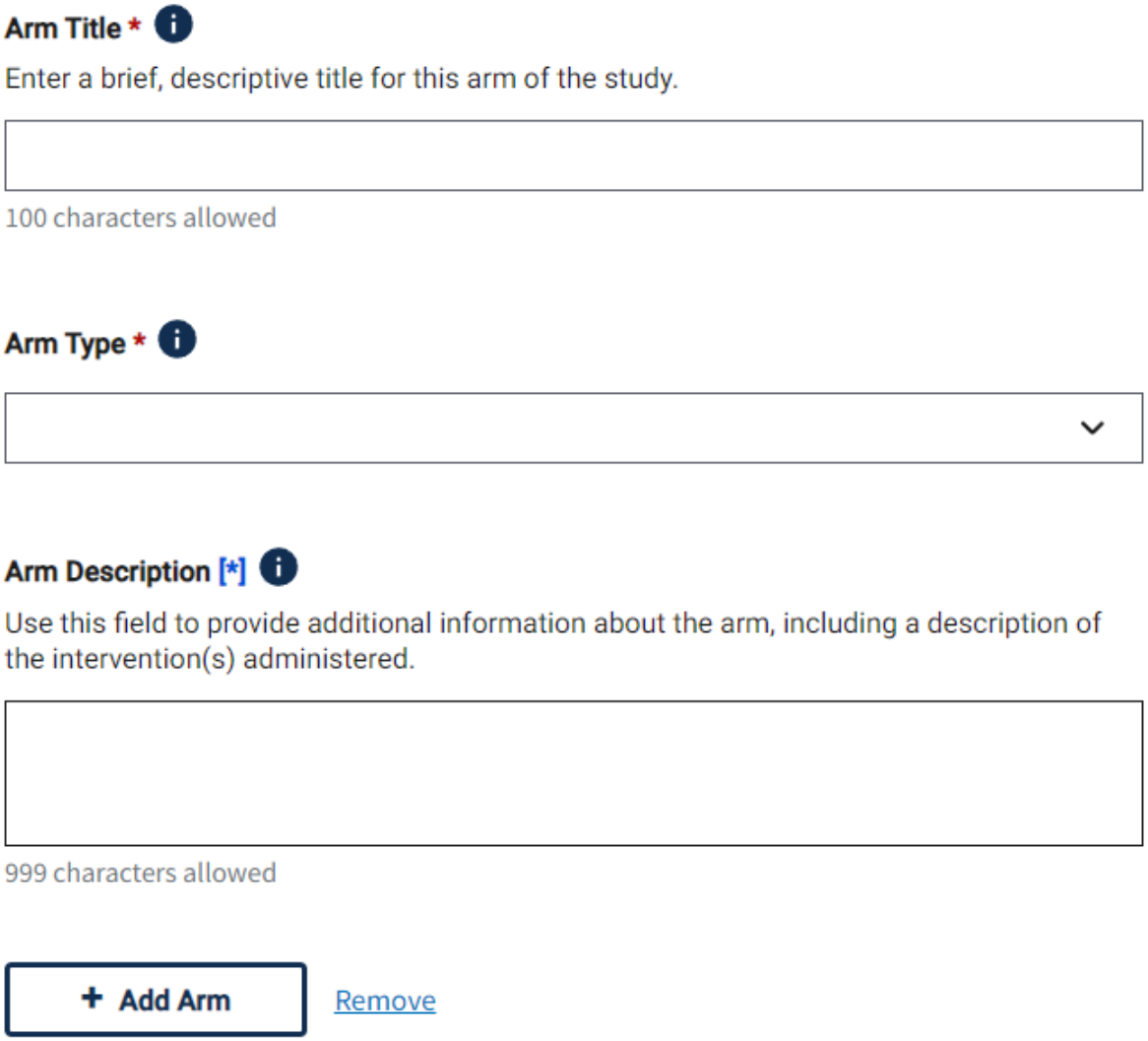
Study Design Expanded Access	
Expanded Access	Availability of an experimental drug or device outside of a clinical trial protocol
Expanded Access Type Expanded Access Definitions	The type(s) of expanded access for which the investigational drug product (including a biological product) is available, as specified in U.S. Food and Drug Administration (FDA) regulations. Select all that apply. • **Not Applicable:** Expanded access is for a product other than an investigational drug product (for example, device product) covered by FDA expanded access regulations (21 CFR 312) • **Individual Patients:** For individual participants, including for emergency use, as specified in 21 CFR 312.310 • **Intermediate-size Population:** For intermediate-size participant populations, as specified in 21 CFR 312.315 • **Treatment IND/Protocol:** Under a treatment IND or treatment protocol, as specified in 21 CFR 312.320



Arms and Interventions (Interventional Studies)	
Arm Information (For interventional studies only)	A description of each arm of the clinical trial that indicates its role in the clinical trial; provides an informative title; and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial. For drugs, use generic name and include dosage form, dosage, frequency, and duration. **Note**: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.



Arm Title	The short name used to identify the arm. If needed, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.
Arm Type	The role of each arm in the clinical trial. • Experimental • Active Comparator • Placebo Comparator • Sham Comparator • No Intervention • Other



Intervention Type 	For each intervention in the clinical study, the general type of intervention. Select one. • Drug: Including placebo • Device: Including sham • Biological/Vaccine • Procedure/Surgery • Radiation • Behavioral: For example, psychotherapy, lifestyle counseling • Genetic: Including gene transfer, stem cell and recombinant DNA • Dietary Supplement: For example, vitamins, minerals • Combination Product: Combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device • Diagnostic Test: For example, imaging, in-vitro • Other
Intervention Name	A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used. **For a drug, use generic name if established.** **Use the same name as in the associated Arm/Group Description(s).** **Other Intervention Name(s)** Other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers. Include brand names, serial numbers, and code names to improve search results on the ClinicalTrials.gov website.
Intervention Description	Details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical study. For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.
Arm or Group/Interventional Cross-Reference	If multiple Arms or Groups have been specified, indicate which Interventions (or exposures) are in each Arm or Group of the study, using the Cross-Reference check boxes.

Intervention Type * 

Select the type of intervention.

- Select -

Intervention Name * 

Enter a brief, descriptive name for the intervention. Use a non-proprietary (generic) name, if available.

200 characters allowed

Other Intervention Names (if any) [*] 

Enter one name at a time. Include any alternative names or numbers used to identify the intervention.

Add Other Name

200 characters allowed

Intervention Description * § 

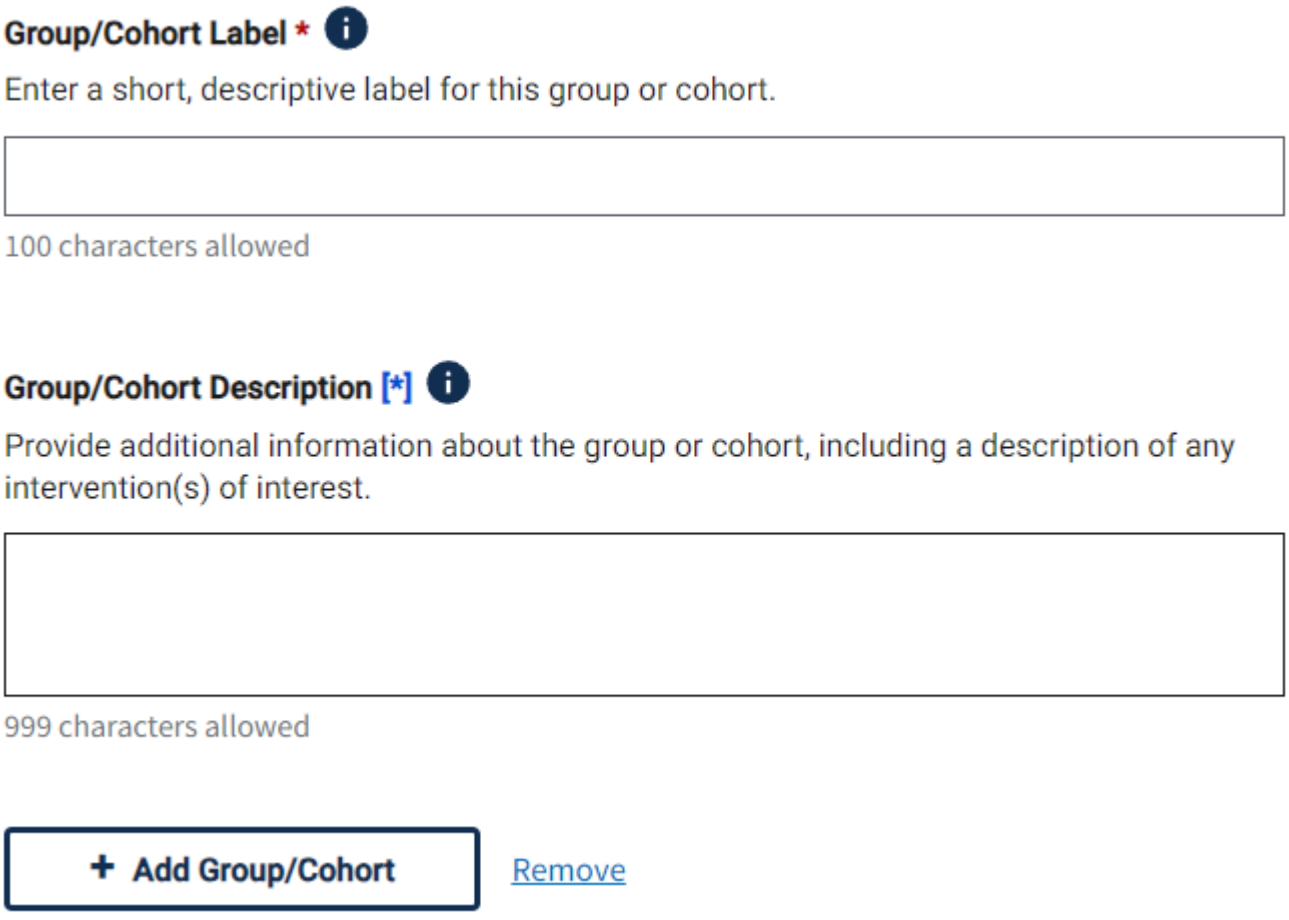
Add details that will distinguish this intervention from other interventions in this or another clinical study.

1,000 characters allowed

+ Add Intervention

Remove

Groups (Observational Studies)	
Group/Cohort Information (For observational studies only)	Specify the predefined participant groups (cohorts) to be studied, corresponding to Number of Groups specified under Study Design (for single-group studies, the following data elements are optional). Do not use this section to specify strata (Detailed Description can be used for that purpose, if desired).
Group/Cohort Label	The short name used to identify the group.
Group/Cohort Description	Explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure). **Note:** The overall study population should be described under Eligibility.



Outcome Measures	
Primary Outcome Measure Information	A description of each primary outcome measure (or for observational studies, specific key measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment). **Note**: "Primary outcome measure" means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical studies have one primary outcome measure, but a clinical study may have more than one. For each primary outcome measure, include the following information: • **Title**: Name of the specific primary outcome measure. • **Description**: Description of the metric used to characterize the specific primary outcome measure, if not included in the primary outcome measure title. • **Time Frame**: Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is the specific duration of time over which each participant is assessed (not the overall duration of the study).
Secondary Outcome Measure Information	A description of each secondary outcome measure (or for observational studies, specific secondary measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment). **Note**: "Secondary outcome measure" means an outcome measure that is of lesser importance than a primary outcome measure but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical study and is not specified as an exploratory or other measure. A clinical study may have more than one secondary outcome measure. For each secondary outcome measure, include the following information: • **Title**: Name of the specific secondary outcome measure • **Description**: Description of the metric used to characterize the specific secondary outcome measure, if not included in the secondary outcome measure title. • **Time Frame**: Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is the specific duration of time over which each participant is assessed (not the overall duration of the study).
Other Pre-specified Outcome Measures	Any other measurements, excluding post-hoc measures, that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. • **Title**: Name of the specific other pre-specified outcome measure • **Description**: Description of the metric used to characterize the specific other pre-specified outcome measure, if not included in the other pre-specified outcome measure title. • **Time Frame**: Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is the specific duration of time over which each participant is assessed (not the overall duration of the study).

Primary Outcome Measure *

Title *

254 characters allowed

Description [*]

999 characters allowed

Time Frame *

254 characters allowed

Edit Outcome Measures

Help Definitions

* Primary Outcome Measure:

Outcome 1

Title: Change from Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24

Description: The SPS-11 is a validated, self-reported instrument assessing average pain intensify over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score - Baseline Score).

Time Frame: Baseline and Week 24

+ Copy Outcome | Change Type | × Delete Outcome

+ Add Primary Outcome

[*] Secondary Outcome Measures: (if any)

+ Add Secondary Outcome

Other Pre-specified Outcomes:

+ Add Other Outcome

Continue Back Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

<table>
<tr><th colspan="3">Eligibility</th></tr>
<tr><td>Accepts Healthy Volunteers
(Optional for Observational Studies)</td><td colspan="2">Indication that participants who do not have a disease or condition, or related conditions or symptoms, under study in the clinical study are permitted to participate in the clinical study. Select Yes/No.</td></tr>
<tr><td colspan="3">The sex and, if applicable, gender of the participants eligible to participate in the clinical study.</td></tr>
<tr><td>Sex</td><td colspan="2">The sex of the participants eligible to participate in the clinical study. Select one.
Note: "Sex" means a person's classification as male or female based on biological distinctions.

• All: Indicates no limit on eligibility based on the sex of participants
• Female: Indicates that only female participants are being studied
• Male: Indicates that only male participants are being studied</td></tr>
<tr><td>Gender Based</td><td colspan="2">If applicable, indicate whether participant eligibility is based on gender. Select one.
Note: "Gender" means a person's self-representation of gender identity.

Yes: Eligibility is based on gender
No: Eligibility is not based on gender

Gender Eligibility Description: If eligibility is based on gender, provide descriptive information about Gender criteria.</td></tr>
<tr><td rowspan="2">Age Limits</td><td colspan="2">The minimum and maximum age of potential participants eligible for the clinical study, provided in relevant units of time.</td></tr>
<tr><td>Maximum Age
The numerical value, if any, for the maximum age a potential participant can be to be eligible for the clinical study.

Unit of Time
Select one.
• Years
• Months
• Weeks
• Days
• Hours
• Minutes
• N/A (No limit)</td><td>Minimum Age
The numerical value, if any, for the minimum age a potential participant must meet to be eligible for the clinical study.

Unit of Time
Select one.
• Years
• Months
• Weeks
• Days
• Hours
• Minutes
• N/A (No limit)</td></tr>
<tr><td>Eligibility Criteria</td><td colspan="2">A limited list of criteria for selection of participants in the clinical study, provided in terms of inclusion and exclusion criteria and suitable for assisting potential participants in identifying clinical studies of interest. Use a bulleted list for each criterion below the headers "Inclusion Criteria" and "Exclusion Criteria."</td></tr>
</table>

Study Population Description (For observational studies only)	A description of the population from which the groups or cohorts will be selected (for example, primary care clinic, community sample, residents of a certain town).
Sampling Method (For observational studies only)	Indicate the method used for the sampling approach and explain in the Detailed Description. Select one. • **Probability Sample**: Exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive participant sampling • **Non-Probability Sample**: Any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer

Contacts/Locations	
Central Contact Person (or Facility Contact required)	The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed.
Central Contact Backup	Person to contact if Central Contact is not available.
Overall Study Officials	Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator.
Official's Role	Position or function of the official. Select one • Study Chair • Study Director • Study Principal Investigator
Location/Facility	Pennington Biomedical Research Center Baton Rouge, Louisiana 70808
Site Recruitment Status	The recruitment status of each participating facility in a clinical study. • **Not yet recruiting**: Participants are not yet being recruited • **Recruiting**: Participants are currently being recruited, whether any participants have yet been enrolled • **Enrolling by invitation**: Participants are being (or will be) selected from a predetermined population • **Active, not recruiting**: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled • **Completed**: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, the last participant's last visit has occurred) • **Suspended**: Study halted prematurely but potentially will resume • **Terminated**: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention • **Withdrawn**: Study halted prematurely, prior to enrollment of first participant

Facility Contact	For each facility participating in a clinical study, provide the name or title, telephone number, and email address of a person to whom questions concerning the study and enrollment at that site can be addressed
Facility Contact Backup	Person to contact if Facility Contact is not available (that is, a second contact person).
Investigators	Investigators at the facility location. Role: • Site Principal Investigator • Site Sub-Investigator

IPD Sharing Statement	
Plan to Share IPD	Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one. • **Yes**: There is a plan to make IPD and related data dictionaries available. • **No**: There is not a plan to make IPD available. • **Undecided**: It is not yet known if there will be a plan to make IPD available.
IPD Sharing Supporting Information Type	The type(s) of supporting information that will be shared, in addition to the individual participant data set and data dictionaries for the IPD itself. Select all that apply. • Study Protocol • Statistical Analysis Plan (SAP) • Informed Consent Form (ICF) • Clinical Study Report (CSR) • Analytic Code
IPD Sharing Time Frame	A description of when the IPD and any additional supporting information will become available and for how long, including the start and end dates or period of availability. This may be provided as an absolute date (for example, starting in January 2025) or as a date relative to the time when summary data are published or otherwise made available (for example, starting 6 months after publication).
IPD Sharing Access Criteria	Describe by what access criteria IPD and any additional supporting information will be shared, including with whom, for what types of analyses, and by what mechanism. Information about who will review requests and criteria for reviewing requests may also be provided.
IPD Sharing URL	The web address, if any, used to find additional information about the plan to share IPD.

References	
Citations	Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation. **PubMed Identifier** Definition: PMID for the citation in MEDLINE **Citation** A bibliographic reference in NLM's MEDLINE format **Results Reference** Indicate if the reference provided reports on results from this clinical study. **Select Yes/No.**
Links	A website directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov. **URL** Complete URL, including http:// or https:// **Description** Title or brief description of the linked page.
Available IPD/Information	The individual participant data (IPD) sets and supporting information that are being shared for the study. Provide the following information for each: Available IPD/Information Type The type of data set or supporting information being shared. • Individual Participant Data Set • Study Protocol • Statistical Analysis Plan • Informed Consent Form • Clinical Study Report • Analytic Code • Other (specify) **Available IPD/Information URL** The web address used to request or access the data set or supporting information. **Available IPD/Information Identifier** The unique identifier used by a data repository for the data set or supporting information. **Available IPD/Information Comments** Additional information including the name of the data repository or other location where the data set or supporting information is available. Provide any additional explanations about the data set or supporting information and instructions for obtaining access, particularly if a URL is not provided.

Document Section

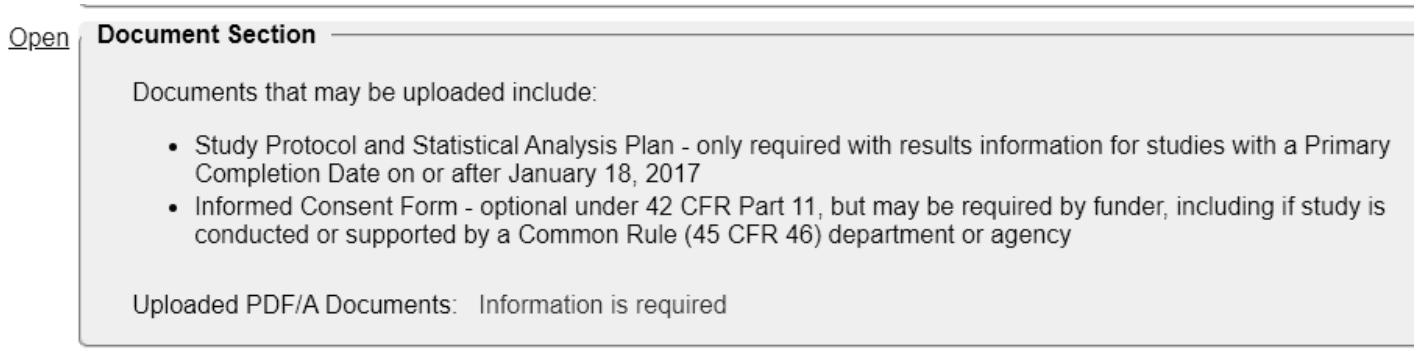
The full study protocol and statistical analysis plan must be uploaded as part of results information submission for studies with a **Primary Completion Date on or after January 18, 2017**. The protocol and statistical analysis plan may be optionally uploaded before results information submission and updated with new versions, as needed. Informed consent forms may optionally be uploaded at any time.

Each document must include a cover page with the Official Title of the study, NCT number (if available), and date of the document.

Uploaded study documents should be the most recent version reviewed by a human subjects protection review board (if applicable).

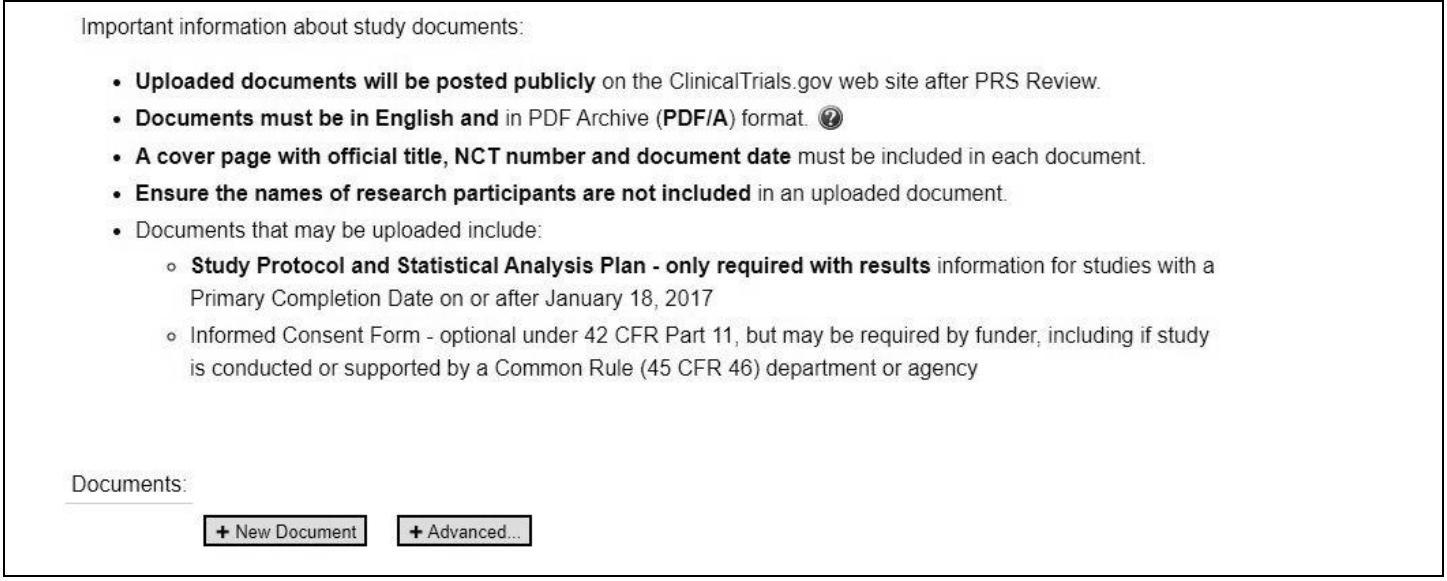
Documents must be uploaded in Portable Document Format Archival (PDF/A) format. It is strongly encouraged that the PDF/A file also be consistent with the PDF Universal Accessibility (PDF/UA) format, to optimize accessibility. For each uploaded document, provide the following information.

Document	The study protocol, statistical analysis plan, and/or informed consent form document(s) uploaded in Portable Document Format Archival (PDF/A) format. It is strongly encouraged that the PDF/A file also be consistent with the PDF Universal Accessibility (PDF/UA) format, to optimize accessibility. Each document must include a cover page with the Official Title of the study, NCT number (if available), and date of the document. **Note:** The study document may include redaction of names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan. Information that is otherwise required to be submitted as part of clinical trial registration or results information may not be redacted.



Document Type	Type of uploaded study document. Select one.
	• **Study Protocol**: The written description of the clinical study, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations (if the protocol document includes the statistical analysis plan, use "Study Protocol with SAP and/or ICF" option). **Note:** All amendments approved by a human subjects protection review board (if applicable), before the time of submission and that apply to all clinical trial Facility Locations must be included.
	• **Statistical Analysis Plan (SAP)**: The written description of the statistical considerations for analyzing the data collected in the study. Includes how data are analyzed, what specific statistical methods are used for each analysis, and how adjustments are made for testing multiple variables. If some analysis methods require critical assumptions, the written description should allow data users to understand how those assumptions were verified.
	• **Informed Consent Form (ICF)**: The final version of the legal document approved by a human subjects protection review board. It is written in lay language and describes, among other things, the study's purpose, procedures, risks and potential benefits.
	• **Study Protocol with SAP and/or ICF**: The study protocol that also includes a statistical analysis plan (SAP) and/or an informed consent form (ICF). Select one or both.
	  ○ Statistical Analysis Plan (SAP)
	  ○ Informed Consent Form (ICF)

Document Date	The date on which the uploaded document was most recently updated and, if needed, approved by a human subjects protection review board.
Subtitle	If there is more than one document for a study of the same Document Type, provide additional descriptive information to differentiate between documents. For example, there may be more than one document of the same Document Types if there are two populations studied in the same study (such as, infants and mothers). Do NOT use Subtitles for uploading a new version of the same document.



Results Section

Participant Flow

Results Templates and Examples: Information to document the progress of research participants through each stage of a study in a tabular format, including the number of participants who started and completed the clinical study.
(Identical in purpose to a CONSORT flow diagram but represented as tables).
The tabular presentation may be separated into "periods," each of which comprises an interval of study activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period. Participant Flow Template

Recruitment Details	Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (for example, medical clinic), to provide context.
Pre-assignment Details	Description of significant events in the study (for example, wash out, run-in) that occur after participant enrollment, but prior to assignment of participants to an arm or group, if any. For example, an explanation of why enrolled participants was excluded from the study before assignment to arms or groups.
Arm/Group Information	Arms or groups for describing the flow of participants through the clinical study. In general, it must include each arm to which participants were assigned. • **Arm/Group Title**: Descriptive label used to identify each arm or group. • **Arm/Group Description:** Brief description of each arm or group. In general, it must include sufficient details to understand each arm to which participants were assigned and the intervention strategy used in each arm.
Type of Units Assigned	If assignment is based on a unit other than participants, a description of the unit of assignment (for example, eyes, lesions, implants).

Period(s)	Discrete stages of a clinical study during which numbers of participants at specific significant events or points of time are reported. There is no limit to the number of periods that may be used to describe a single study. Each subsequent period represents a study stage following the previous period. That is, participants "flow" from earlier to later periods.
Period Title	Title describing a stage of the study. If only one period is defined, the default title is Overall Study. **When a study has more than one period, none of the Period Titles should be Overall Study.**
Started	Number of participants initiating the period. In the first period, it is the number of participants assigned to each arm or group. If assignment is based on a unit other than participants, also include the number of units at the beginning of the period. • **Comments:** Additional information about the Started milestone or Milestone Data.
Completed	Number of participants at the end of the period. If assignment is based on a unit other than participants, also include the number of units at the end of the period. • **Comments:** Additional information about the Completed milestone or Milestone Data.
Not Completed	Number of participants (and units, if applicable) that did not complete the study or period. This is calculated automatically by subtracting Completed from Started.
Additional Milestone(s)	Any specific events or time points in the study when the numbers of participants (and units, if applicable) are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, Started and Completed, within each period. • **Milestone Title:** Label describing the milestone • **Milestone Data:** Number of participants to reach the milestone, in each arm/group. If assignment is based on a unit other than participants, also include the number of units to reach the milestone. ○ Comments: Additional information about the milestone or data.

Reason Not Completed	Additional information about participants who did not complete the study or period. If reasons are provided, the total number of participants listed as Not Completed must be accounted for by all reasons for non-completion.
	• **Reason Not Completed Type:** Reason why participants did not complete the study or period. Select one.
	  ○ Adverse Event
	  ○ Death
	  ○ Lack of Efficacy
	  ○ Lost to Follow-Up
	  ○ Physician Decision
	  ○ Pregnancy
	  ○ Protocol Violation
	  ○ Withdrawal by Subject
	  ○ Other
	• **Other Reason:** A brief description of the reason for non-completion, if "Other" Reason Not Completed Type is selected.
	• **Reason Not Completed Data**: Number of participants in each arm or group that did not complete the study or period, for each Reason Not Completed.

Protocol Enrollment: 205
Total Started in Participant Flow: 200

Edit

Recruitment Details	Participants were recruited based on physician referral at 3 academic medical centers between February 2017 and January 2018. The first participant was enrolled on March 1, 2017 and the last participant was enrolled in December 2017.
Pre-assignment Details	Of 205 enrolled participants, 200 met inclusion criteria and were randomized to treatment.

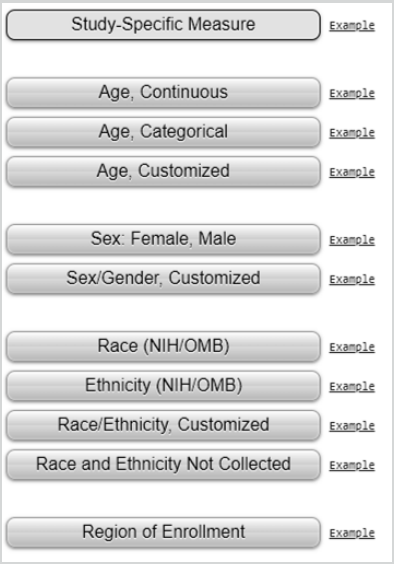
Arm/Group Title	Remuverol	Placebo	Total (Not public)
▼ Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet	
Period Title: **Overall Study**			
Started	101	99	200
Completed	80	81	161
Not Completed	21	18	39
Reason Not Completed			
Adverse Event	10	8	18
Withdrawal by Subject	5	4	9
Protocol Violation	2	2	4
Lack of Efficacy	1	1	2
Physician Decision	1	1	2
Lost to Follow-up	1	2	3
Pregnancy	1	0	1
(Not Public)	Not Completed =21 Total from all reasons =21	Not Completed =18 Total from all reasons =18	

Baseline Characteristics

A table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of participants in the clinical study. Baseline Characteristics Template

Arm/Group Information	Arms or comparison groups in the study, including all participants assessed at baseline as specified in the pre-specified protocol and/or statistical analysis plan. • **Arm/Group Title**: Descriptive label used to identify each arm or comparison group. • **Arm/Group Description**: Brief description of each arm or comparison group. In general, it must include sufficient detail to understand how the arm(s) or comparison groups were derived from the arm(s) to which participants were assigned in Participant Flow (if different) and the intervention strategy in each arm/group.
Baseline Analysis Population Information/Description	If the Overall Number of Baseline Participants (or units) differs from the number of participants (or units) assigned to the arm or comparison group and in the entire study population (total), a brief description of the reason(s) for the difference, such as how the analysis population was determined.
Overall Number of Baseline Participants	Number of all participants for whom baseline characteristics were measured, in each arm/group and in the entire study population (total).
Overall Number of Units Analyzed	If the analysis is based on a unit other than participants, the number of all units for which baseline measures were measured and analyzed, in each arm/group and in the entire study population (total).
Type of Units Analyzed	If the analysis is based on a unit other than participants, a description of the unit of analysis (for example, eyes, lesions, implants).

Baseline Measure Information	A description of each baseline or demographic characteristic measured in the clinical study. Required baseline measures include Age, Sex/Gender, Race, Ethnicity (if collected under the protocol), and any other measure(s) that were assessed at baseline and used in the analysis of the primary outcome measure(s).

Baseline Measure Title
 
	The name of the baseline or demographic characteristic measured in the clinical study. Select as many as needed.
	Note: Examples are provided when adding Baseline Measure (see screenshot left).
	• **Study-Specific Measure** (Template) Select as many as needed.
	• **Age** (Template) Select at least one of the following):
	  ○ Age, Continuous: For example - mean or median age
	  ○ Age, Categorical:
	  • <=18 years
	  • >18 and <65 years
	  • >=65 years
	  ○ Age, Customized: Customizable age categories
	• **Sex/Gender** (Template) Select at least one of the following:
	  ○ Sex: Female, Male
	  ○ Sex/Gender, Customized
	• **Race and Ethnicity** (Template)
	  ○ Race (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories
	  ○ Ethnicity (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories
	  ○ Race/Ethnicity, Customized
	  ○ Race and Ethnicity Not Collected
	• **Region of Enrollment**

Study-Specific Baseline Measure Title(s)	Additional descriptive information about the baseline measure, such as a description of the metric used to characterize the specific baseline measure.
Measure Type	The type of data for the baseline measure. Select one. • Count of Participants • Mean • Median • Least Squares Mean • Geometric Mean • Geometric Least Squares Mean • Number • Count of Units
Measure of Dispersion	Select one. • Not Applicable (only if Measure Type is "Number," "Count of Participants," or "Count of Units") • Standard Deviation • Inter-Quartile Range • Full Range
Number of Baseline Participants	The number of participants analyzed for the baseline measure, if different from the Overall Number of Baseline Participants, in each arm/group and the entire study population (total).

Number of Units Analyzed	The number of units analyzed for the baseline measure, if different from the Overall Number of Units Analyzed, in each arm/group and the entire study population (total).
Analysis Population Type	Indicate whether the baseline measure analysis is based on participants or units other than participants. Only applies if Type of Units Analyzed is specified. Select Participants/Other Units.
Measure Analysis Population Description	Explanation of how the number of participants (or units) for analysis was determined, if different from the Overall Number of Participants [or Units] Analyzed.
Category or Row Title	Name of distinct category or row for a baseline measure, if any. Category Titles are only for mutually exclusive and exhaustive categories summarizing data using the Measure Type of a "Count of Participants" or "Count of Units." Row Titles are for any type of data.
Baseline Measure Data	The value(s) for each baseline measure, for each arm/group and the entire study population (total). • **NA (Not Available) Explanation:** Explain why baseline measure data are not available, if "NA" is reported for Baseline Measure Data.
Unit of Measure	An explanation of what is quantified by the data (for example, participants, mm Hg), for each baseline measure.

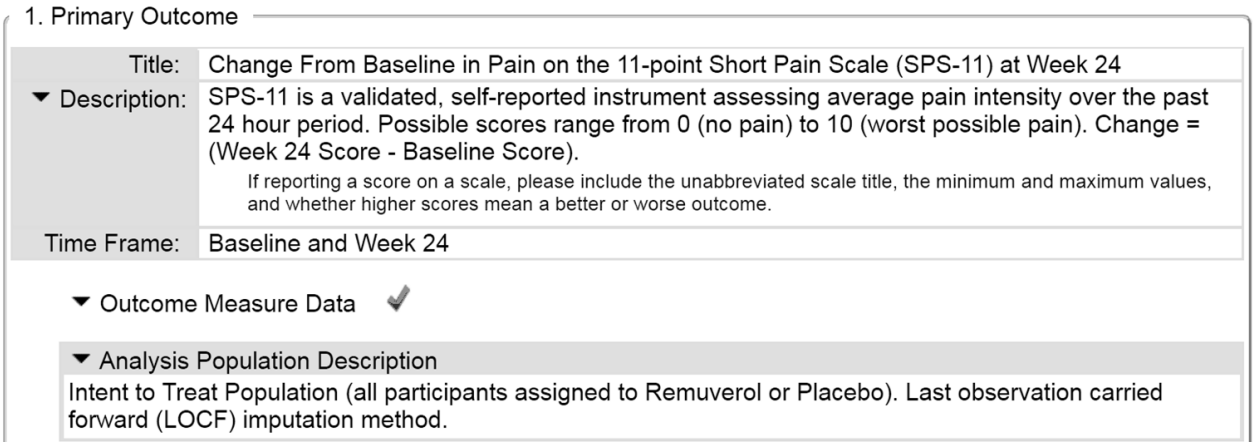
Baseline Measures Overview

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

Edit	Arm/Group Title / Arm/Group Description		Remuverol Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet		Placebo Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet		Total	
Edit	**Overall Number of Baseline Participants** Baseline Analysis Population Description		101		99		200	
Edit Delete	Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	101 participants		99 participants		200 participants	
			34.78 (9.72)		35.34 (10.71)		35.06 (10.23)	
Edit Delete	Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	101 participants		99 participants		200 participants	
		Female	60	59.41%	63	63.64%	123	61.5%
		Male	41	40.59%	36	36.36%	77	38.5%
Edit Delete	Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	101 participants		99 participants		200 participants	
		Hispanic or Latino	5	4.95%	4	4.04%	9	4.5%
		Not Hispanic or Latino	96	95.05%	95	95.96%	191	95.5%
		Unknown or Not Reported	0	0%	0	0%	0	0%
Edit Delete	Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	101 participants		99 participants		200 participants	
		American Indian or Alaska Native	1	0.99%	1	1.01%	2	1%
		Asian	0	0%	0	0%	0	0%
		Native Hawaiian or Other Pacific Islander	0	0%	0	0%	0	0%
		Black or African American	5	4.95%	4	4.04%	9	4.5%
		White	95	94.06%	94	94.95%	189	94.5%
		More than one race	0	0%	0	0%	0	0%
		Unknown or Not Reported	0	0%	0	0%	0	0%
Edit Delete	Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	101 participants		99 participants		200 participants	
	Canada		35	34.65%	35	35.35%	70	35%
	United States		44	43.56%	47	47.47%	91	45.5%
	Mexico		22	21.78%	17	17.17%	39	19.5%
Edit Delete	Quebec Task Force Classification of Spinal Disorders [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	101 participants		99 participants		200 participants	
		Class 0 (no pain)	16	15.84%	14	14.14%	30	15%
		Class 1 (pain without radiation)	73	72.28%	68	68.69%	141	70.5%
		Class 2 (pain with proximal extremity radiation)	12	11.88%	17	17.17%	29	14.5%
	[1] Measure Description: Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).							
Edit Delete	Body Mass Index Mean (Standard Deviation) Unit of measure: kg/m^2	Number Analyzed	101 participants		99 participants		200 participants	
			26.65 (4.50)		27.41 (4.72)		26.91 (4.55)	
Edit Delete	Short Pain Scale (SPS-11) Score Mean (Standard Deviation) Unit of measure: units on a scale	Number Analyzed	101 participants		99 participants		200 participants	
			6.48 (1.34)		6.57 (1.73)		6.52 (1.61)	
Edit Delete	Duration of Disc Herniation Mean (Standard Deviation) Unit of measure: years	Number Analyzed	101 participants		99 participants		200 participants	
			3.82 (3.18)		3.47 (2.95)		3.75 (3.06)	
Edit Delete	Height Mean (Standard Deviation) Unit of measure: cm	Number Analyzed	101 participants		99 participants		200 participants	
			186.42 (9.46)		176.91 (8.28)		181.33 (8.95)	
Edit Delete	Weight Mean (Standard Deviation) Unit of measure: kg	Number Analyzed	101 participants		99 participants		200 participants	
			77.03 (14.38)		78.53 (13.56)		77.98 (13.79)	

Outcome Measures	
A table of data for each primary and secondary outcome measure by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any. **Note:** Outcome measure information from the Protocol Section of the record will be copied into the Results Section the first-time results are created.	
Outcome Measure Information	A description of each outcome measure. Outcome Measure Template Outcome Measure Template Examples Statistical Analysis Template **Note:** "Outcome measure" means a pre-specified measurement that is used to determine the effect of an experimental variable on participants in the study. Post-hoc (that is, not pre-specified) outcome measures may also be reported.
Outcome Measure Type	The type of outcome measure. Select one. • Primary • Secondary • Other Pre-specified • Post-Hoc
Outcome Measure Title	Name of the specific outcome measure.
Outcome Measure Description	Additional information about the outcome measure, including a description of the metric used to characterize the specific outcome measure, if not included in the Outcome Measure Title.
Outcome Measure Time Frame	Time point(s) at which the measurement was assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is the specific duration of time over which each participant is assessed (not the overall duration of the study).
Anticipated Reporting Date	If Outcome Measure Data are not included for an outcome measure, provide the expected month and year they will be submitted.
Arm/Group Information	Arms or comparison groups in the study, including all arms or comparison groups based on the pre-specified protocol and/or statistical analysis plan. • **Arm/Group Title**: Descriptive label used to identify each arm or comparison group. • **Arm/Group Description:** Brief description of each arm or comparison group. In general, it must include sufficient detail to understand how the arm(s) or comparison groups were derived from the arm(s) to which participants were assigned in Participant Flow (if different) and the intervention strategy in each arm/group.

Analysis Population Information	• **Overall Number of Participants Analyzed**: Number of participants for whom an outcome measure was measured and analyzed, for each outcome measure and each arm/group. • **Type of Units Analyzed**: If the analysis is based on a unit other than participants, a description of the unit of analysis (for example, eyes, lesions, implants). • **Overall Number of Units Analyzed**: If the analysis is based on a unit other than participants, the number of units for which an outcome was measured and analyzed, for each outcome measure and each arm/group. • **Analysis Population Description**: If the Number of Participants Analyzed or Number of Units Analyzed differs from the number of participants or units assigned to the arm or comparison group, a brief description of the reason for the difference (such as how the analysis population was determined).



Outcome Measure Data Table	• **Measure Type**: The type of data for the outcome measure. Select one.
	  ○ Count of Participants
	  ○ Mean
	  ○ Median
	  ○ Least Squares Mean
	  ○ Geometric Mean
	  ○ Geometric Least Squares Mean
	  ○ Number
	  ○ Count of Units
	• **Measure of Dispersion/Precision:** Select one.
	  ○ Not Applicable (only if Measure Type is "Number," "Count of Participants," or "Count of Units")
	  ○ Standard Deviation
	  ○ Standard Error
	  ○ Inter-Quartile Range
	  ○ Full Range
	  ○ 80% Confidence Interval
	  ○ 90% Confidence Interval
	  ○ 95% Confidence Interval
	  ○ 97.5% Confidence Interval
	  ○ 99% Confidence Interval
	  ○ Other Confidence Interval Level
	  ○ Geometric Coefficient of Variation (only when Measure Type is "Geometric Mean")
	• **Other Confidence Interval Level**: The numerical value for the confidence interval level, if "Other Confidence Interval Level" is selected. Provide a rationale for choosing this level in the Outcome Measure Description.

Category or Row Title	Name of distinct category or row for an outcome measure, if any. Category Titles are only for mutually exclusive and exhaustive categories summarizing data using the Measure Type of a "Count of Participants" or "Count of Units." Row Titles are for any type of data. • **Number of Participants Analyzed**: The number of participants analyzed for the outcome measure in the row and for each arm/group, if different from the overall Number of Participants Analyzed. • **Number of Units Analyzed**: The number of units analyzed for the outcome measure in the row and for each arm/group, if different from the overall Number of Units Analyzed.
Outcome Measure Data	The measurement value(s) for each outcome measure, including each category/row and each arm/group. • **NA (Not Available) Explanation**: Explain why outcome measure data are not available, if "NA" is reported for Outcome Measure Data.
Unit of Measure	An explanation of what is quantified by the data (for example, participants, mm Hg), for each outcome measure.

Arm/Group Title	Remuverol	Placebo
▼ Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	101	99
Mean (Standard Deviation) Unit of Measure: units on a scale	-3.84 (0.61)	-2.08 (0.51)

Statistical Analyses	Result(s) of scientifically appropriate tests of statistical significance of the primary and secondary outcome measures, if any. Such analyses include: pre-specified in the protocol and/or statistical analysis plan; made public by the sponsor or responsible party; conducted on a primary outcome measure in response to a request made by FDA. If a statistical analysis is reported, "Comparison Group Selection" and "Type of Statistical Test" are required. In addition, one of the following data elements are required with the associated information: "P-Value," "Estimation Parameter," or "Other Statistical Analysis."
Statistical Analysis Overview	Summary description of the analysis performed.
Comparison Group Selection	The arms or comparison groups involved in the statistical analysis (check all to indicate an "omnibus" analysis). • **Comments**: Additional details about the statistical analysis, such as null hypothesis and description of power calculation.
Type of Statistical Test	Identifies the type of analysis. Select one. ○ Superiority ○ Non-inferiority ○ Equivalence ○ Other (for example, single group or other descriptive analysis) ○ Non-Inferiority or Equivalence (legacy selection) ○ Superiority or Other (legacy selection) • **Comments**: If "Non-inferiority" or "Equivalence," provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority or equivalence margin, and other key parameters.
Statistical Test of Hypothesis	Procedure used for statistical analysis of outcome measure data and the calculated p-value.

P-Value	Calculated p-value given the null hypothesis • **Comments**: Additional information, such as whether the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance
Method	The statistical test used to calculate the P-Value, if a P-Value is reported. Select one. ○ ANCOVA ○ ANOVA ○ Chi-Squared ○ Chi-Squared, Corrected ○ Cochran-Mantel-Haenszel ○ Fisher Exact ○ Kruskal-Wallis ○ Log Rank ○ Mantel Haenszel ○ McNemar ○ Mixed Models Analysis ○ Regression, Cox ○ Regression, Linear ○ Regression, Logistic ○ Sign Test ○ t-Test, 1-Sided ○ t-Test, 2-Sided ○ Wilcoxon (Mann-Whitney) ○ Other • **Other Method Name**: If "Other" is selected, provide name of statistical test. • **Comments**: Any other relevant information about the statistical test, such as adjustments or degrees of freedom.
Method of Estimation	Procedure used to estimate effect of intervention.
Estimation Parameter	Select one. • Cox Proportional Hazard • Hazard Ratio (HR) • Hazard Ratio, Log • Mean Difference (Final Values) • Mean Difference (Net) • Median Difference (Final Values) • Median Difference (Net) • Odds Ratio (OR) • Odds Ratio, Log • Risk Difference (RD) • Risk Ratio (RR) • Risk Ratio, Log • Slope • Other **Other Parameter Name**: The name of the estimation parameter, if "Other" Estimation Parameter is selected.
Estimated Value	The calculated value for the estimation parameter.

Confidence Interval **(If applicable)**	Expressed as a percentage. • **Level**: Expressed as a percentage • **Number of Sides**: Select 1-sided or 2-sided. • **Lower Limit**: Required if confidence interval is "2-sided" or if confidence interval is "1-sided" and no Upper Limit is entered. • **Upper Limit**: Required if confidence interval is "2-sided" or if confidence interval is "1-sided" and no Lower Limit is entered. • **NA (Not Available) Explanation**: Explain why the upper limit data are not available, if "NA" is reported as upper-limit of "2-sided" confidence interval.
Parameter Dispersion Type	Select one. • Standard Deviation • Standard Error of the Mean
Dispersion Value	The calculated value for the dispersion of the estimated parameter.
Estimation Comments	Any other relevant estimation information, including the direction of the comparison (for example, describe which arm or comparison group represents the numerator and denominator for relative risk).
Other Statistical Analysis	If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of any other scientifically appropriate tests of statistical significance.

1. Primary Outcome

Title:	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24
▼ Description:	SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score - Baseline Score). If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline and Week 24

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Intent to Treat Population (all participants assigned to Remuverol or Placebo). Last observation carried forward (LOCF) imputation method.

Arm/Group Title	Remuverol	Placebo
▼ Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	101	99
Mean (Standard Deviation) Unit of Measure: units on a scale	-3.84 (0.61)	-2.08 (0.51)

Edit ▼ Statistical Analysis 1 ✓

Delete

Statistical Analysis Overview	Comparison Group Selection	Remuverol, Placebo
	Comments	It was calculated that 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α= 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.002
	Comments	The threshold for statistical significance was p = 0.05.
	Method	Mixed Models Analysis
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-1.76
	Parameter Dispersion	Type: Standard Deviation Value: 0.80
	Estimation Comments	Treatment Difference = Remuverol - Placebo

Adverse Events	
Adverse Events	Any untoward or unfavorable medical occurrence in a participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether considered related to the participant's participation in the research. Three types of adverse event data are to be reported: "All-Cause Mortality," "Serious," and "Other (Not Including Serious)" Adverse Events. • **All-Cause Mortality**: The occurrence of death due to any cause. • **Serious Adverse Events**: Include adverse events that result in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization, or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. • **Other (Not Including Serious) Adverse Events**: Adverse events that are not Serious Adverse Events.
Total Number Affected by All-Cause Mortality	Overall number of participants, in each arm/group, who died due to any cause.
Total Number at Risk for All-Cause Mortality	Overall number of participants, in each arm/group, included in the assessment of deaths due to any cause (that is, the denominator for calculating frequency of all-cause mortality).
Total Number Affected by Any Serious Adverse Event	Overall number of participants affected by one or more Serious Adverse Events, for each arm/group.
Total Number at Risk for Serious Adverse Events **(or Number at Risk for each Serious Adverse Event Term required)**	Overall number of participants included in the assessment of serious adverse events (that is, the denominator for calculating frequency of serious adverse events), for each arm/group.
Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events	Specify the frequency of occurrence that an Other (Not Including Serious) Adverse Event must exceed, within any arm or comparison group, to be reported in the Other (Not Including Serious) Adverse Event table. The number for the frequency threshold must be less than or equal to the allowed maximum (5%). Do not include symbols (for example, > or %) in the data field; it will be expressed as a percentage. For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.

Total Number Affected by Any Other (Not Including Serious) Adverse Event Above the Frequency Threshold	Overall number of participants affected, for each arm/group, by at least one Other (Not Including Serious) Adverse Event(s) reported in the table. Adverse events reported in the table are those that occurred at a frequency exceeding the specified Frequency Threshold (for example, 5%) within at least one arm or comparison group.
Total Number at Risk for Other (Not Including Serious) Adverse Events **(or Number at Risk for each Other [Not Including Serious] Adverse Event Term required)**	Overall number of participants, for each arm/group, included in the assessment of Other (Not Including Serious) Adverse Events during the study (that is, the denominator for calculating frequency of Other (Not Including Serious) Adverse Events).
Adverse Event Term	Descriptive word or phrase for the adverse event.
Organ System	High-level categories are used to group adverse event terms by body or organ system. Select one. (Adverse events that affect multiple systems should be classified as "General disorders.") • Blood and Lymphatic System Disorders • Cardiac Disorders • Congenital, Familial and Genetic Disorders • Ear and Labyrinth Disorders • Endocrine Disorders • Eye Disorders • Gastrointestinal Disorders • General Disorders • Hepatobiliary Disorders • Immune System Disorders • Infections and Infestations • Injury, Poisoning and Procedural Complications • Investigations • Metabolism and Nutrition Disorders • Musculoskeletal and Connective Tissue Disorders • Neoplasms Benign, Malignant and Unspecified (Including Cysts and Polyps) • Nervous System Disorders • Pregnancy, Puerperium and Perinatal Conditions • Product Issues • Psychiatric Disorders • Renal and Urinary Disorders • Reproductive System and Breast Disorders • Respiratory, Thoracic and Mediastinal Disorders • Skin and Subcutaneous Tissue Disorders • Social Circumstances • Surgical and Medical Procedures • Vascular Disorders
Adverse Event Term Additional Description	Additional relevant information about the adverse event.
Source Vocabulary Name	Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (for example, SNOMED CT, MedDRA 10.0). Leave blank to indicate that the value specified as the Source Vocabulary for Table Default should be used.

Collection Approach	The type of approach taken to collect adverse event information. Select one or leave blank to indicate that the value specified as the Collection Approach for Table Default should be used. • **Systematic Assessment**: Any method of routinely determining whether certain adverse events have occurred. For example, through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method • **Non-Systematic Assessment**: Any non-systematic method for determining whether adverse events have occurred, such as self-reporting by participants or occasional assessment/testing
Adverse Event Data	• **Number of Participants Affected:** Number of participants, in each arm/group, experiencing at least one event being reported. • **Number of Participants at Risk:** Number of participants assessed, in each arm/group, for adverse events (that is, the denominator for calculating frequency of adverse events). Leave blank to indicate that the value specified as the total at risk in the arm/group for the table should be used. • **Number of Events:** Number of occurrences, in each arm/group, of the adverse event being reported.

Adverse Events Overview

Results Section | Download/Upload | Sort... | Help | Definitions | Show All

Edit	Time Frame	32 Weeks	
	Adverse Event Reporting Description		
	Source Vocabulary Name for Table Default	MedDRA (12.0)	
	Collection Approach for Table Default	Systematic Assessment	
Edit	Arm/Group Title	Remuverol	Placebo
	▸ Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...

All-Cause Mortality

		Remuverol Affected / at Risk (%)	Placebo Affected / at Risk (%)
Edit	Total	0/101 (0%)	0/99 (0%)

▾ Serious Adverse Events

			Remuverol Affected / at Risk (%)	Placebo Affected / at Risk (%)
Edit		Total	4/101 (3.96%)	0/99 (0%)
Edit	Blood and l...	Anemia iron deficiency †A	1/101 (0.99%)	0/99 (0%)
	Blood and l...	Idiopathic thrombocytopenic purpura †A	1/101 (0.99%)	0/99 (0%)
	Immune syst...	Viral meningitis †A	1/101 (0.99%)	0/99 (0%)
	Skin and su...	Psoriasis †A	1/101 (0.99%)	0/99 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Add Serious Adverse Event

▾ Other (Not Including Serious) Adverse Events

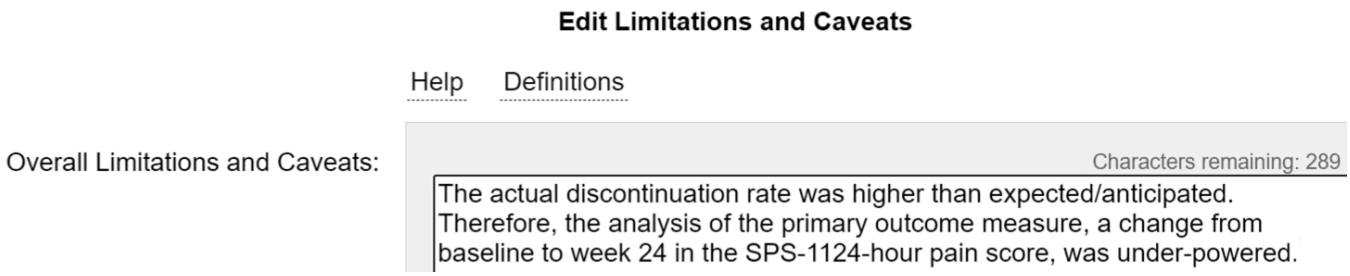
Edit	Frequency Threshold for Reporting Other Adverse Events	1%	

			Remuverol Affected / at Risk (%)	Placebo Affected / at Risk (%)
Edit		Total	98/101 (97.03%)	46/99 (46.46%)
Edit	Ear and lab...	Earache †A	35/101 (34.65%)	7/99 (7.07%)
	Endocrine d...	Hypothyroidism †A	27/101 (26.73%)	25/99 (25.25%)
	Eye disorde...	Conjunctivitis †A	13/101 (12.87%)	4/99 (4.04%)
	Gastrointes...	Nausea †A	12/101 (11.88%)	7/99 (7.07%)
	Gastrointes...	Stomachache †A	10/101 (9.9%)	2/99 (2.02%)
	Gastrointes...	Vomiting †A	10/101 (9.9%)	3/99 (3.03%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Add Other (Not Including Serious) Adverse Event

Limitations and Caveats	
Overall Limitations and Caveats	Describe significant limitations of the study. Such limitations may include not reaching the target number of participants needed to achieve target power and statistically reliable results or technical problems with measurements leading to unreliable or uninterpretable data. If appropriate, please describe limitations of the trial. **Examples:** Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.



More Information	
Certain Agreements	Information indicating whether an agreement exists between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the study, to discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.
Are all PIs Employees of Sponsor?	Indicate whether the principal investigator is an employee of the sponsor. Select one. • **Yes: The principal investigator is an employee of the sponsor** • **No: The principal investigator is not an employee of the sponsor**
Results Disclosure Restriction on PI(s)?	**If "No" to the previous question, the following information is required:** Indicate whether any agreement exists (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants participating in the clinical study) between the sponsor or its agent and the principal investigator (PI) that restricts in any manner the ability of the PI to discuss the results of the clinical study at a scientific meeting or any other public or private forum or to publish in a scientific or academic journal the results of the clinical study, after the Primary Completion Date. **Select Yes/No**. If there are agreements with multiple PIs who are not employees of the sponsor and there is a disclosure restriction on at least one PI, select "Yes."

PI Disclosure Restriction Type	Additional information about the results disclosure restriction. If there are varying agreements, choose the type below that represents the most restrictive of the agreements (for example, the agreement with the greatest embargo time period). Select one. • The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding study results for a period that is less than or equal to 60 days from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo. • The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding study results for a period that is more than 60 days but less than or equal to 180 days from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo. • Other disclosure agreement that restricts the right of the PI to disclose, discuss, or publish study results after the study is completed **Other Disclosure Restriction Description**: If "Other disclosure agreement..." is selected, describe the type of agreement including any provisions allowing the sponsor to require changes, ban the communication, or extend an embargo.
Results Point of Contact	Point of contact for scientific information about the clinical study results information.
Name or Official Title	The person who is designated the point of contact. This may be a specific person's name (for example, Dr. Jane Smith) or a position title (for example, Director of Clinical Trials).
Organization Name	Full name of the designated individual's organizational affiliation. • **Phone:** Office phone number of the designated individual. Use the format 123-456-7890 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code. • **Extension:** Phone extension, if needed • **Email:** Electronic mail address of the designated individual.
Delayed Results	A responsible party may delay the deadline for submitting results information if one of the two certification conditions below applies to the clinical study and the certification is submitted prior to the date of (i.e., the day before) the standard submission deadline for results information. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date. Alternatively, the responsible party may request an extension of the results submission deadline for good cause. **The NIH Director must grant the extension.**

Delay Results Type	• **Certify Initial Approval**: Trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed or cleared by FDA for any use before the Primary Completion Date of the trial, and the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study. • **Certify New Use**: Trial studies an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug, product (including a biologic product) or device product) has been filed or will be filed within one year with FDA. • **Extension**: Request, for good cause, an extension of the deadline for submitting results information **Note**: If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification under "Certify New Use," that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria: (1) the applicable clinical trial is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; (2) the applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted. [42 U.S.C. 282 (j)(3)(E)(v)(II) and 42 CFR 11.44(b)(3)]
Intervention Name(s)	Provide the name of one or more drugs, biological products, or devices to which the certification applies. For drugs, use generic name; for other types of interventions, provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol section.
FDA Application Number(s)	Provide at least one FDA application number (for example, NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."
Requested Submission Date (Required when Delay Results Type is "Extension.")	Estimate of the date on which the clinical study results information will be submitted, if the Delay Results Type is "Extension."
Explanation (Required when Delay Results Type is "Extension.")	Description of the reason(s) why clinical study results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request. Note that "pending publication" and delays in data analysis for unspecified causes are not considered good cause for an extension.