

Attachment 2 - ClinicalTrials.gov Registration Data Entry Screenshots

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB No: 0925-0586
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

NOTICE

The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The Classic PRS remains available for users who need to access features that have not yet been migrated to the Modernized PRS.

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [How to Apply](#) on ClinicalTrials.gov for information on how to apply for a PRS account.

See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.

[Send email to ClinicalTrials.gov PRS Administration.](#)

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#) | [HHS Vulnerability Disclosure](#)

OMB No: 0925-0586
EXPIRATION DATE: 03/31/2026

Public reporting burden for this collection of information is estimated to average from 15 minutes to 45 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address.

Classic PRS

Create New Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Studies may only be registered by the Responsible Party.** The Responsible Party for a clinical study is the Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who meets specific requirements.
 - o When a study is subject to U.S. Food and Drug Administration regulations and conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE Holder is considered the Sponsor or Sponsor-Investigator.
 - o When a study is not conducted under an IND or IDE, the entity or single person who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the Sponsor or Sponsor-Investigator.
2. **Use the PRS account of the Sponsor or Sponsor-Investigator to register the study.** If the Sponsor has designated the Principal Investigator to be the Responsible Party for a study, that study must be registered using the PRS account of the Sponsor.
3. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the Responsible Party (IND/IDE holder or the person or organization who initiates the study and who has authority and control over the study) or its designated principal investigator (PI).
4. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization (or designated PI), as Responsible Party is registering the study.
5. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document** for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

* Brief Title:

[Special Characters](#)

[*] Acronym:
(if any)
If specified, will be included at end of Brief Title in parentheses.

* Study Type:

- Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational** participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

Continue

Cancel

* Required
 * § Required if Study Start Date is on or after January 18, 2017
 [*] Conditionally required (see Definitions)

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Arms and Interventions
- Outcome Measures
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK

Edit Study Identification

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym: (if any)
If specified, will be included at end of Brief Title in parentheses.

* § Official Title:

[*] Secondary IDs: (if any)

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required (see Definitions)

Edit Study Status

[Help](#) [Definitions](#)

* Record Verification Date: Month: Year:

* Overall Recruitment Status:
Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: Day: Year: Type:
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: Day: Year: Type:
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: Day: Year: Type:
Final data collection date for study.

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required (see Definitions)

Edit Sponsor/Collaborators

[Help](#) [Definitions](#)

* Responsible Party:
Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

Investigator Information

Investigator Name [Username]:
Select the investigator's PRS account.
The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.
[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

* 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**.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Edit Oversight

[Help](#) [Definitions](#)

* § 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 \(PDF\)](#).

* § 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 \(PDF\)](#).

Unapproved/Uncleared Device:
Studying at least one device product that is not yet approved or cleared by the U.S. FDA for any use? If "Yes" and this is a FDAAA 801 applicable clinical trial (ACT), the study record will not be posted on ClinicalTrials.gov unless posting is authorized.

Pediatric Postmarket Surveillance:
Required only if this study is a pediatric postmarket surveillance of a device product ordered by the U.S. FDA.

* 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)?

FDA Center:
Formerly IND/IDE Grantor

IND/IDE Number:

IND Serial Number:
4 digit number entered on the U.S. FDA IND application, Form 1571, if any.

[*] Availability of Expanded Access:
Will any non-protocol access to the investigational drug, biologic or device be provided? [\[About Expanded Access records\]](#)

Expanded Access Record:
ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record

* Human Subjects Protection Review: Board Status:

Data Monitoring Committee:

FDA Regulated Intervention:

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Study Description

[Help](#) [Definitions](#)

* Brief Summary:

[Special Characters](#)

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

Continue Back Quit

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required (see Definitions)

Edit Conditions

[Help](#) [Definitions](#)

* Conditions or Focus of Study:

x Delete

x Delete

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.

+ Add Condition

Keywords:

x Delete

+ Add Keyword

Continue Back Quit

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required (see Definitions)

Edit Interventional Study Design

[Help](#) [Definitions](#)

* Study Type: Interventional

* § Primary Purpose:

* Study Phase:
Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model:

Model Description:

* § Number of Arms:

* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor
- None (Open Label)
Check all roles that are masked or check None (Open Label).

Masking Description:

* § Allocation:
Select N/A for single-arm studies.

* § Enrollment: Number of Participants: Type:

Continue **Back** **Quit**

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Arms

[Help](#) [Definitions](#)

Arms:

* Arm Title:
Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

* Arm Type:

[*] Arm Description:
Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

Continue **Back** **Quit**

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Interventions

[Help](#) [Definitions](#)

Arms: [No Arms have been specified.]

Interventions:

* Intervention Type: --Select--

* Intervention Name:

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

[*] Other Intervention Names:

(if any)

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

* § Intervention Description:

Do not repeat information already included in arm/group descriptions.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Arm/Intervention Cross-Reference

[Help](#) [Definitions](#)

* Cross-Reference:

Arms	Interventions	
	Drug: Intervention 1	Drug: Intervention 2
Experimental: Arm 1	<input type="checkbox"/>	<input type="checkbox"/>
Active Comparator: Arm 2	<input type="checkbox"/>	<input type="checkbox"/>

Check boxes for Interventions associated with each Arm in the study.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Outcome Measures

[Help](#) [Definitions](#)

* Primary Outcome Measure:

Outcome 1

Title:

Description:

Time Frame:

[*] Secondary Outcome Measures:
(if any)

Outcome 2

Title:

Description:

Time Frame:

Other Pre-specified Outcomes:

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Eligibility

[Help](#) [Definitions](#)

* Sex:
Biological sex of eligible participants.

[*] Gender Based:
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

* Age Limits: Minimum: Years Maximum: Years

* § Accepts Healthy Volunteers:

* Eligibility Criteria:

Inclusion Criteria:
-

Exclusion Criteria:
-

[Special Characters](#)

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Overall Contacts

[Help](#) [Definitions](#)

* Central Contact Person: First Name: MI: Last Name: Degree:
 Phone: Ext: Email:
 Either Central Contact or Facility Contacts are required.
 The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Central Contact Backup: First Name: MI: Last Name: Degree:
 Phone: Ext: Email:

Overall Study Officials:

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Edit Location

[Help](#) [Definitions](#)

* Facility: Name:
 City:
 State/Province: ZIP/Postal Code:
 Country:

* Site Recruitment Status:
 Recruitment status for this individual location.

* Facility Contact: First Name: MI: Last Name: Degree:
 Phone: Ext: Email:

Facility Contact Backup: First Name: MI: Last Name: Degree:
 Phone: Ext: Email:

Either Central Contact or Facility Contacts are required.
 The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Investigators:

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit IPD Sharing Statement

[Help](#) [Definitions](#)

Plan to Share IPD:

Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Plan Description:

Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

IPD Sharing:

Supporting Information:

Check all types of supporting information that will be shared.

- Study Protocol
- Statistical Analysis Plan (SAP)
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Analytic Code

Time Frame:

Describe when the data will become available and for how long.

Access Criteria:

URL:

Web address (if any) with additional information about the plan to share IPD.

Continue

Back

Quit

* Required

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

[*] Conditionally required (see Definitions)

Edit References

[Help](#) [Definitions](#)

Citations: PubMed ID:

Use the [PubMed Citation Matcher](#) to search for citations based on journal name, date, author(s), title and other criteria.

Citation:

Results Reference:

Links: URL:

Description:

Available IPD/Information: References to deidentified individual participant data (IPD) sets and supporting information.

Data/Information Type:

URL:

Web site, if any, where IPD or information can be accessed, downloaded or requested.

Identifier:

Unique ID used by a data repository, if applicable.

Comments:

If no web site is provided, explain how the data or information can be accessed.

* Required

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

[*] Conditionally required (see Definitions)

You have finished data entry for the Protocol Section.

Review any Errors, Warnings or Notes and make changes as needed. Select Preview to see a rough approximation of how the record will appear on ClinicalTrials.gov.

Select the "Record Summary" link in the top left corner of the page to see next steps for finishing the record submission process.

Modernized PRS

Create New Record

Review these tips before creating a record. [Cancel record creation](#)

Definitions

1. Use the PRS account of the study sponsor.
 - a. Verify that the study sponsor (the initiator of the trial) has a PRS account and that you are using a login for that account.
 - b. For help, see:
[How to Apply for a PRS Account](#)
2. Only the [responsible party](#) can register the study.
 - a. You can create the record even if you are not the responsible party, but only the responsible party can approve and submit it. The responsible party will be notified when the necessary information has been entered.
 - b. For help, see:
[How do I determine who is the responsible party for a study?](#)
3. The study should be registered only once.
 - a. A study with multiple collaborators or sites should only be registered by the study's responsible party.
 - b. All study sites should be listed in a single study record.

- * Required
- * **S** Required if Study Start Date is on or after January 18, 2017
- [*]** Conditionally required


Organization's Unique Protocol ID * 

30 characters allowed

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.

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.

Create Record

[Cancel record creation](#)

Study Status Definitions

Use this module to enter the start and completion dates for the study, as well as the study's recruitment status.

*** Required**
*** § Required if Study Start Date is on or after January 18, 2017**
[†] Conditionally required

Record Verification Date * ⓘ

Month * **Year ***

Overall Recruitment Status * ⓘ

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

Study Start Date * § ⓘ

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

Month **Day** **Year**

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**

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
<input type="text" value="v"/>	<input type="text"/>	<input type="text"/>

Type

- Anticipated
- Actual

[Save Changes](#)

Sponsors and Collaborators

[Definitions](#)

Use this module to enter information about the organization and individuals responsible for starting, funding, designing, and conducting the expanded access.

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required

Responsible Party, by Official Title * ⓘ

Select the type of responsible party - usually the sponsor.

- Sponsor
- Principal Investigator
- Sponsor-Investigator

Name of the Sponsor * ⓘ

Collaborators ⓘ

Enter the **name of an organization** providing support for the expanded access.

 [Add Collaborator](#)

160 characters allowed

[Save Changes](#)

[Clear Unsaved Changes](#)

Oversight

[Definitions](#)

Use this module to describe oversight of the interventions involved in this study.

* Required

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

[*] Conditionally required

U.S. FDA-Regulated Product

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

Unapproved/Uncleared Device * § ⓘ

Is the study investigating a device product that is not approved or cleared by the U.S. FDA?

Yes

No

Pediatric Postmarket Surveillance [*] ⓘ

Is this study a pediatric postmarket surveillance of a device product that was required by the U.S. FDA?

Yes

No

Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information

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

Human Subjects Protection Review *

Board Status * 

- Select - 

Data Monitoring Committee

Data Monitoring Committee 

Yes

No

Save Changes

[Clear Unsaved Changes](#)

Study Description

Definitions

Use this module to describe the study protocol.

* Required

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

[*] Conditionally required

Brief Summary * ⓘ

Use these resources to provide understandable information about this study to patients, families, and health care providers:

[Plain language checklist for Brief Summary](#)

[Template for Brief Summary](#)

5,000 characters allowed

Detailed Description ⓘ

Avoid duplicating information that will be entered or uploaded elsewhere in the record.

32,000 characters allowed

Save Changes

Conditions

Definitions

* Required

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

[*] Conditionally required

Conditions or Focus of Study * ⓘ

Enter each disease or condition being studied.

If no disease or condition is being studied, enter a brief description of the focus of the study.

Add Condition

Keywords ⓘ

Enter words or phrases that precisely describe the study protocol to help users find this study on [ClinicalTrials.gov](#).

Add Keyword

Save Changes

Study Design

Definitions

Use this module to define the methods that will be used in this interventional study, including the strategy for assigning participants to intervention(s).

* Required

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

[*] Conditionally required

Primary Purpose * § ⓘ

Select the option that best describes the aim or goal of the study intervention(s).

Study Phase * ⓘ

Select one. Use "N/A" for trials that do **not** involve drug or biologic products.

Interventional Study Model * § ⓘ

Model Description

If needed, include additional details about the Interventional Study Model.

1,000 characters allowed

Number of Arms * § ⓘ

Enter the total number of arms participants might be assigned to over the course of the clinical study.

Masking * § ⓘ

Select all roles that are masked, or select "None (Open Label)."

- Participant
 - Care Provider
 - Investigator
 - Outcomes Assessor
 - None (Open Label)
-

Masking Description

If there are other parties who are masked in the clinical trial besides those listed above, use this space to describe those parties.

1,000 characters allowed

Allocation * § ⓘ

Select N/A for single-arm studies.

Enrollment * § ⓘ

Number of Participants

Type

- Anticipated
 - Actual
-

Save Changes

Arms

[← Back to Arms and Interventions](#)

* Required

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

[*] Conditionally required

Arm Title * i

Enter a brief, descriptive title for this arm of the study.

100 characters allowed

Arm Type * i

Arm Description [*] i

Use this field to provide additional information about the arm, including a description of the intervention(s) administered.

999 characters allowed

[Remove](#)

Interventions

[← Back to Arms and Interventions](#)

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required

Intervention Type *

Select the type of intervention.

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](#)

Save Changes

Outcome Measure Information

[← Back to Outcome Measures](#)

Use this module to describe the primary, secondary, and other pre-specified outcome measures that will be collected and analyzed.

- All primary and secondary outcome measures that are listed in the study's protocol must be reported.
- At least one primary outcome measure must be entered.

* Required

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

[*] Conditionally required

Outcome Measure Type

Primary Outcome Measure

Secondary Outcome Measure

Other Pre-Specified Outcome

Primary Outcome Measure * i

Title * i

254 characters allowed

Description [*] i

999 characters allowed

Time Frame * i

254 characters allowed

Save Changes

[Clear Unsaved Changes](#)

Outcome Measure Information

[← Back to Outcome Measures](#)

Use this module to describe the primary, secondary, and other pre-specified outcome measures that will be collected and analyzed.

- All primary and secondary outcome measures that are listed in the study's protocol must be reported.
- At least one primary outcome measure must be entered.

* Required

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

[*] Conditionally required

Outcome Measure Type

Primary Outcome Measure

Secondary Outcome Measure

Other Pre-Specified Outcome

Secondary Outcome Measure **[*]** **i**

Title * **i**

254 characters allowed

Description **[*]** **i**

999 characters allowed

Time Frame * **i**

254 characters allowed

Save Changes

[Clear Unsaved Changes](#)

Eligibility

Definitions

Use this module to describe the characteristics of people who can participate in the study.

* Required

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

[*] Conditionally required

Accepts Healthy Volunteers * §

Accepts Healthy Volunteers * § ⓘ

Does the study accept people who do not have the disease or condition being studied?

Yes

No

Sex/Gender *

Sex * ⓘ

Select the biological sex of people eligible to participate in the study.

- Select -




Gender Based [*] ⓘ

Is a person's eligibility to participate in the study according to their biological sex limited by their gender identity?.

Yes

No

Age Limits * 

Specify the age range of people who are eligible to participate in the study.

Minimum Age *

- No Limit (NA)
- Minimum Age Limit

Minimum Age *

Unit of Time *

- Select - 

Maximum Age *

- No Limit (NA)
- Maximum Age Limit

Maximum Age *

Unit of Time *

- Select - 

Eligibility Criteria * 

Inclusion Criteria:	
-	
Exclusion Criteria:	
-	

19,950 characters left

Save Changes

Contacts

[< Back to Contacts and Locations](#)

On this page, identify a central contact and study officials.

- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required

Central Contact Person *

Enter the main contact person for the study. If there isn't one, enter a contact for each individual facility in the Locations section.

First Name

Middle Initial

62 characters allowed

Last Name or Official Title *

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number *

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email *

254 characters allowed

Central Contact Backup 

Enter a person to contact if the central contact isn't available.

First Name

Middle Initial

62 characters allowed

Last Name or Official Title

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email

254 characters allowed

Overall Study Official 


Identify the people who provide scientific leadership for the study.


Location

[< Back to Contacts and Locations](#)

On this page, enter a location where the study is taking place.

* Required

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

 Conditionally required

Facility Information *

Enter the full name and location of the facility.

Country

Select the country for this study location.

City

State/Province

ZIP/Postal Code

Facility Name

254 characters allowed

Site Recruitment Status *

Select the recruitment status for this study location.

Facility Contact * 

Enter a facility contact for this location.

First Name

Middle Initial

62 characters allowed

Last Name or Official Title *

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number *

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email *

254 characters allowed

Facility Contact Backup

Enter a person to contact if the facility contact isnt available.

First Name

Middle Initial

62 characters allowed

Last Name or Official Title

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email

254 characters allowed

Investigators

Enter the full name of an investigator at this study location.

[Clear Unsaved Changes](#)


IPD Sharing Statement


Definitions

You are not required to provide information about plans to share individual participant data (IPD) in order to register your trial on [ClinicalTrials.gov](https://clinicaltrials.gov). However, the International Committee of Medical Journal Editors (ICMJE) requires that this information be included as part of trial registration in order for the results of studies to be published in ICMJE journals. This policy applies to trials that began enrolling participants on or after January 1, 2019.

You can learn more about the ICMJE policy [here](#).

* Required

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

 Conditionally required

Plan to Share IPD

Do you plan to share IPD with other researchers? If you select Yes, you will be asked to describe the plan.

Yes

No

Undecided

Plan Description

Describe which specific IPD will be shared.

1,000 characters allowed

IPD Sharing ⓘ

Please specify any supporting information that will be made available and when and how IPD will be shared.

Supporting Information

Select all that apply.

- Study Protocol
- Statistical Analysis Plan (SAP)
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Analytic Code

Time Frame ⓘ

Indicate when the IPD and supporting information will be available (start date) and for how long (end date).

1,000 characters allowed

Access Criteria ⓘ

Describe who will be able to access the IPD and supporting information, what they will be able to access, and how they will be able to access it.

1,000 characters allowed

URL ⓘ

Provide a web address for finding more information about the IPD sharing plan.

3,999 characters allowed

Save Changes

[Clear Unsaved Changes](#)

References

[Definitions](#)

You can use this module to:

- List citations for publications that provide background on this study's protocol or report results for this study
- Provide links to websites that give general information about the study
- Describe how to access individual participant data sets and any supporting information

* Required

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

[*] Conditionally required

Citations

Provide a citation by entering the PubMed ID (PMID) or PubMed Central ID (PMCID) or by typing the full citation in the space provided.

How Will You Enter Your Citation?

Enter the PubMed ID

Enter the ID to autofill the full PubMed citation. If you don't know the ID, you can search for it [here](#).

14 characters allowed

Type in the Citation

Enter a **single** citation, using as much of the following information as possible:
Authors, Article title, Journal name, Publication date, Volume number and pages.

Links ⓘ

Enter links to websites that provide information that is directly related to the study protocol.

URL ⓘ


3,999 characters allowed

Description ⓘ

254 characters allowed

[Remove](#)

Available IPD and Supporting Information 

Data/Information Type 


- Select - 

URL 

3,999 characters allowed

Identifier 

30 characters allowed

Comments 

1,000 characters allowed

+ Add Available IPD/Information

[Remove](#)

Save Changes

[Clear Unsaved Changes](#)