ClinicalTrials.gov

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Observational Study Protocol Registration Template

For more information, see How to Register Your Study at https://clinicaltrials.gov/ct2/manage-recs/how-register.

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

1. STUDY IDENTIFICATION

*Unique Protocol Identification Number:

*Brief Title:

*§Official Title:

[*]Acronym (if any):

*Study Type (select one): ◯ Interventional ● Observational ☐ Observational—Patient Registry ◯ Expanded Access

More than one Secondary ID can be entered. If more than two are needed, more space is available in the PRS.

[*]Secondary ID 1 (if any):

[*]Secondary ID 1 Type (select one): ◯ U.S. National Institutes of Health (NIH) Grant/Contract Award Number ◯ Other Grant/Funding Number ◯ Registry Identifier ◯ EudraCT Number ◯ Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*]Description 1:

[*]Secondary ID 2 (if any):

[*]Secondary ID 2 Type (select one): ◯ U.S. National Institutes of Health (NIH) Grant/Contract Award Number ◯ Other Grant/Funding Number ◯ Registry Identifier ◯ EudraCT Number ◯ Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*]Description 2:

2. STUDY STATUS

*Record Verification Date: Month: Year:

*Overall Recruitment Status (select one): ◯ Not yet recruiting ◯ Recruiting ◯ Enrolling by invitation ◯ Active, not recruiting ◯ Completed ◯ Suspended (halted prematurely but may resume) ◯ Terminated (halted prematurely) ◯ Withdrawn (no participants enrolled)

If the Overall Recruitment Status is "Suspended," "Terminated," or "Withdrawn," provide the reason why the study was stopped.

*§Why Study Stopped:

Day is not required for Anticipated dates.

*§Study Start Date:	*Type (select one):	◯ Anticipated	◯ Actual	[*]Day:		*Month:		*Year:
*Primary Completion Date:	*Type (select one):	◯ Anticipated	◯ Actual	[*]Day:		*Month:		*Year:
*§Study Completion Date:	*Type (select one):	◯ Anticipated	◯ Actual	[*]Day:		*Month:		*Year:

3. SPONSORS/COLLABORATORS

*Responsible Party, by Official Title (select one): ◯ Sponsor ◯ Principal Investigator ◯ Sponsor-Investigator

Investigator Information is required only for "Principal Investigator" or "Sponsor-Investigator."

[*]Investigator Information:

Investigator Name:

Investigator Official Title:	Investigator Affiliation:

*Name of the Sponsor

Enter as many Collaborators as needed. Additional fields are available in the PRS.

Collaborators (if any):

Name of Collaborator 1:	Name of Collaborator 2:

4. OVERSIGHT

Studies a U.S. FDA-regulated Drug Product (select one): ◯ Yes ◯ No

Studies a U.S. FDA-regulated Device Product (select one): ◯ Yes ◯ No

[*]Pediatric Postmarket Surveillance of a Device Product (select one): ◯ Yes ◯ No

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

U.S. Food and Drug Administration IND or IDE (select one): ◯ Yes ◯ No

If Yes, provide information below:

[*]FDA Center (select one): ◯ CDER ◯ CBER ◯ CDRH	[*]IND/IDE Number:	[*]IND Serial Number:

[*]Availability of Expanded Access (select one): ◯ Yes ◯ No ◯ Unknown [*]Expanded Access Record NCT Number:

[*]Product Manufactured in and Exported from the U.S. (select one): ◯ Yes ◯ No

*Human Subjects Review:

*Human Subjects Protection Review Board Status (select one): ◯ Request not yet submitted ◯ Submitted, pending ◯ Submitted, approved ◯ Exempt ◯ Submitted, denied ◯ Submission not required

If the study is not required to be registered under 42 CFR Part 11, is not funded in whole or in part by the U.S. Government, and is not conducted under an IND or IDE, the following information is required.

[*]Board Approval Number:	[*]Board Name:

[*]Board Affiliation:

[*]Board Contact:	Phone:	Ext.:	Email:
	Address:		

Data Monitoring Committee (select one): ◯ Yes ◯ No

FDA Regulated Intervention (select one): ◯ Yes ◯ No

If Yes, indicate whether this is an applicable clinical trial as defined in U.S. Public Law 110-85, Title VIII, Section 801.

Section 801 Clinical Trial (select one): ◯ Yes ◯ No

5. STUDY DESCRIPTION

*Brief Summary (using lay language):

5. STUDY DESCRIPTION (CONTINUED)

Detailed Description:

6. CONDITIONS AND KEYWORDS

Enter as many Conditions as needed. Additional fields are available in the PRS.

*Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study:

1.

2.

Enter as many Keywords as needed. Additional fields are available in the PRS.

Keywords:

1.

2.

7. STUDY DESIGN (OBSERVATIONAL)

*Observational Study Model (select one): ◯ Cohort ◯ Case-Control ◯ Case-Only ◯ Case-Crossover ◯ Ecologic or Community Studies ◯ Family-based ◯ Other

*Time Perspective (select one): ◯ Retrospective ◯ Prospective ◯ Cross-sectional ◯ Other

Biospecimen Retention (select one): ◯ None Retained ◯ Samples With DNA ◯ Samples Without DNA

Biospecimen Description:

*Enrollment Type (select one): ◯ Anticipated ◯ Actual | Number of Subjects:

*Number of Groups/Cohorts:

*Patient Registry Information:

*Target Follow-Up Duration: | Unit of Time (select one): ◯ Years ◯ Months ◯ Weeks ◯ Days

8. GROUPS AND INTERVENTIONS/EXPOSURES

Enter as many Groups as needed. Additional fields are available in the PRS.

Group 1:

*Group/Cohort Label: | [*]Group/Cohort Description:

Group 2:

*Group/Cohort Label: | [*]Group/Cohort Description:

Enter as many Interventions as needed. Additional fields are available in the PRS.

Intervention/ Exposures 1:

*Intervention Type (select one): ◯ Drug ◯ Device ◯ Biological/Vaccine ◯ Procedure/Surgery ◯ Radiation ◯ Behavioral ◯ Genetic ◯ Dietary Supplement ◯ Combination Product ◯ Diagnostic Test ◯ Other

*Intervention Name:

8. GROUPS AND INTERVENTIONS/EXPOSURES (CONTINUED)

[*]Other Intervention Name 1 (if any):

[*]Other Intervention Name 2 (if any):

*§Intervention Description:

Intervention/ Exposures 2:

*Intervention Type (select one): ◯ Drug ◯ Device ◯ Biological/Vaccine ◯ Procedure/Surgery ◯ Radiation ◯ Behavioral ◯ Genetic ◯ Dietary Supplement ◯ Combination Product ◯ Diagnostic Test ◯ Other

*Intervention Name:

[*]Other Intervention Name 1 (if any):

[*]Other Intervention Name 2 (if any):

*§Intervention Description:

*Group/Interventional Cross-Reference:

	Intervention 1	Intervention 2
Group 1	☐	☐
Group 2	☐	☐

9. OUTCOME MEASURES

Enter as many Outcome Measures as needed. Additional fields are available in the PRS.

Outcome 1: *Primary Outcome Measure:

*Title:

*Time Frame:

[*]Description:

Outcome 2: *Primary Outcome Measure:

*Title:

*Time Frame:

[*]Description:

Outcome 3: [*]Secondary Outcome Measure:

*Title:

*Time Frame:

9. OUTCOME MEASURES (CONTINUED)

[*]Description:

Outcome 4: [*]Secondary Outcome Measure:

*Title:

*Time Frame:

[*]Description:

Outcome 5: Other Pre-specified Outcome Measure:

*Title:

*Time Frame:

[*]Description:

Outcome 6: Other Pre-specified Outcome Measure:

*Title:

*Time Frame:

[*]Description:

10. ELIGIBILITY

*Sex/Gender:

*Sex (select one): ◯ All ◯ Female ◯ Male

[*]Gender-Based (if any): ◯ Yes ◯ No

If Yes, provide descriptive information about the Gender Based criteria.

Gender Eligibility Description:

*Age Limits:	*Minimum Age:	*Unit of Time:	*Maximum Age:	*Unit of Time:

Accepts Healthy Volunteers (select one): ◯ Yes ◯ No

Provide bulleted lists (one criterion per bullet) below the headers "Inclusion Criteria" and "Exclusion Criteria."

*Eligibility Criteria:

10. ELIGIBILITY (CONTINUED)

*Study Population Description:

*Sampling Method (select one): ◯ Probability Sample ◯ Non-Probability Sample

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

*Central Contact Person:	First Name:	Middle Initial:	*Last Name or Official Title:
Degree:			
*Phone:	Ext.:	*Email:	
Central Contact Backup:	First Name:	Middle Initial:	Last Name or Official Title:
Degree:			
Phone:	Ext.:	Email:	

Enter as many Overall Study Officials as needed. Additional fields are available in the PRS.

Overall Study Official 1:	First Name:	Middle Initial:	Last Name:
Degree:		Organizational Affiliation:	

Official's Role (select one): ◯ Study Chair ◯ Study Director ◯ Study Principal Investigator

Overall Study Official 2:	First Name:	Middle Initial:	Last Name:
Degree:		Organizational Affiliation:	

Official's Role (select one): ◯ Study Chair ◯ Study Director ◯ Study Principal Investigator

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

*Individual Site Status (select one): ◯ Not yet recruiting ◯ Recruiting ◯ Enrolling by invitation ◯ Active, not recruiting ◯ Completed ◯ Suspended (halted prematurely but may resume) ◯ Terminated (halted prematurely) ◯ Withdrawn (no participants enrolled)

*Facility Contact:	First Name:	Middle Initial:	*Last Name or Official Title:
Degree:			
*Phone:	Ext.:	*Email:	
Facility Contact Backup:	First Name:	Middle Initial:	Last Name:
Degree:			
Phone:	Ext.:	Email:	

Enter as many Investigators as needed. Additional fields are available in the PRS.

Investigators:	First Name:	Middle Initial:	Last Name:
Degree:			

Role (select one): ◯ Site Principal Investigator ◯ Site Sub-Investigator

12. IPD SHARING STATEMENT

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

Plan to Share IPD (select one): ◯ Yes ◯ No ◯ Undecided

Describe the IPD sharing plan, including which IPD will be shared with other researchers.

IPD Sharing Plan Description:

IPD Sharing Supporting Information Type (select all that apply):

☐ Study Protocol ☐ Statistical Analysis Plan ☐ Informed Consent Form ☐ Clinical Study Report ☐ Analytic Code

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

IPD Sharing Time Frame:

IPD Sharing Access Criteria:

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

IPD Sharing URL:

13. REFERENCES

Enter as many Citations, Links, and Available IPD and Supporting Information items as needed. Additional fields are available in the PRS.

Citations:	PubMed Identifier:	Citation:
	Results Reference (select one): ◯ Yes ◯ No	
Links:	URL:	

Description:

Available IPD and Supporting Information:

Available IPD/Information Type (select one): ◯ Individual Participant Data Set ◯ Study Protocol ◯ Statistical Analysis Plan ◯ Informed Consent Form ◯ Clinical Study Report ◯ Analytic Code ◯ Other (specify)

Available IPD/Information URL:

Available IPD/Information Identifier:

Available IPD/Information Comments: