ClinicalTrials.gov

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Expanded Access 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 (*Optional if Expanded Access Type is "Individual Patients"*):

[*]Acronym (if any):

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

If Expanded Access does not involve a U.S. FDA-regulated drug product, select "Not Applicable".

*§Expanded Access Type (select all that apply): ☐ Not Applicable ☐ Individual Patients ☐ Intermediate-size Population ☐ Treatment IND/Protocol

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) (*Optional if Expanded Access Type is "Individual Patients"*):

[*]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) (*Optional if Expanded Access Type is "Individual Patients"*):

[*]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:

*Expanded Access Status (select one): ◯ Available ◯ No longer available ◯ Temporarily not available ◯ Approved for marketing

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:

3. SPONSORS/COLLABORATORS (CONTINUED)

*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

*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:

5. STUDY DESCRIPTION

*Brief Summary (using lay language):

Detailed Description:

6. CONDITIONS AND KEYWORDS

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

[*]Conditions or Focus of Study (*Optional if Expanded Access Type is "Individual Patients"*):

1.

2.

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

Keywords:

1.

2.

7. INTERVENTIONS

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

Intervention 1: *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) (*Optional if Expanded Access Type is "Individual Patients"*):	[*]Other Intervention Name 2 (if any) (*Optional if Expanded Access Type is "Individual Patients"*):

[*]Intervention Description (*Optional if Expanded Access Type is "Individual Patients"*):

Intervention 2: *Intervention Type (select one): ◯ Drug ◯ Device ◯ Biological/Vaccine ◯ Procedure/Surgery ◯ Radiation ◯ Behavioral ◯ Genetic ◯ Dietary Supplement ◯ Combination Product ◯ Diagnostic Test ◯ Other

7. INTERVENTIONS (CONTINUED)

*Intervention Name:

[*]Other Intervention Name 1 (if any) (*Optional if Expanded Access Type is "Individual Patients"*):

[*]Other Intervention Name 2 (if any) (*Optional if Expanded Access Type is "Individual Patients"*):

[*]Intervention Description (*Optional if Expanded Access Type is "Individual Patients"*):

8. ELIGIBILITY

[*]Sex/Gender (*Optional if Expanded Access Type is "Individual Patients"*):

[*]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: (*Optional if Expanded Access Type is "Individual Patients"*):	[*]Minimum Age:	[*]Unit of Time:	[*]Maximum Age:	[*]Unit of Time:

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

[*]Eligibility Criteria (*Optional if Expanded Access Type is "Individual Patients"*):

9. 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

9. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION (CONTINUED)

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:

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

10. REFERENCES

Enter as many Citations and Links items as needed. Additional fields are available in the PRS.

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

Links:	URL:

Description: