**Annual Report**

**IND XXXXX**

**[IND Title]**

Serial # [####]

Reporting Period: mm/dd/yyyy to mm/dd/yyyy

Name of Sponsor Investigator

Title, Department

Institution Name

Mailing Address

Telephone

Name of IND Contact [if applicable]

Title, Department

Institution Name

Mailing Address

Telephone

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# Study Information

A brief summary of the status of each study in progress and each study completed during the previous year (duplicate sections below for multiple studies). Specify which 12 months are covered by your report such as “the reporting period for this submission is from January 1, 2017 to December 31, 2017”.

IND XXXXX was submitted to the FDA on [dd/mm/yyyy]. This annual report summarizes data conducted under the IND from [dd/mm/yyyy] to [dd/mm/yyyy].

## Title of Study

**Title of Study:** [title]

**Study Design:** [open label, closed label, randomized etc.]

**Purpose:** The purpose of the study is to investigate…

**Patient Population:** [gender,disease state, healthy, age, etc.]

**Study Status:** [Active, enrolling, not recruiting, etc.]

## Enrollment Update

The total number of subjects initially planned for the study; the number of enrolled subjects to date, tabulated by age group, gender and race; the number of subjects who completed the participation; and the number of subjects who terminated the participation for any reason. The enrollment update can be described in text format or either one of the example tables included below may be used. The first example is the format that is generated by OnCore.

A total of [#] have been enrolled as of [dd/mm/yyyy]. Tabular summaries of enrollment and demographics (Table1.2-1) and the status of enrolled subjects (Table 1.2-2) are listed below

**Table 1.2-1 Subject Enrollment and Demographics**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category** |  |  |  |  |
| ***Ethnicity*** | **Females** | **Males** | **Unknown or Not Reported** | **Total** |
| Hispanic or Latino |  |  |  |  |
| Not Hispanic or Latino |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |
| **Total** |  |  |  |  |
|  |  |  |  |  |
| ***Race*** |  |  |  |  |
| American Indian or Alaska Native |  |  |  |  |
| Asian |  |  |  |  |
| Black or African American |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |
| White |  |  |  |  |
| More Than One Race |  |  |  |  |
| **Total** |  |  |  |  |

|  |  |
| --- | --- |
| Number of Subjects Planned |  |
| Number of Subjects Enrolled |  |
| Age on Enrollment |  |
| 18−21  |  |
| 22−29  |  |
| 30−39  |  |
| 40−49  |  |
| 50−59  |  |
| 60–69 |  |
| 70–79 |  |
| Gender |  |
| Male |  |
| Female |  |
| Race |  |
| American Indian or Alaska Native |  |
| Asian |  |
| Black or African American |  |
| Native Hawaiian or Other Pacific Islander |  |
| White or Caucasian |  |
| Unknown or Not Reported |  |

**Table 1.2-2 Status of Enrolled Participants**

|  |  |
| --- | --- |
| Total Enrolled |  |
| Total Completed Treatment |  |
| Total Completed Study |  |
| On Study |  |
|  On Treatment |  |
|  Completed Treatment |  |
|  Early Withdrawal |  |
| Early Withdrawal |  |
|  Subject withdrawn – by Subject PRIOR to enrollment |  |
|  Subject withdrawn – by Subject AFTER enrollment |  |
|  Subject withdrawn – by PI PRIOR to enrollment |  |
|  Subject withdrawn – by PI AFTER enrollment |  |
|  Death |  |
|  Subject lost to follow-up |  |
|  Subject refused follow-up |  |
|  Due to adverse events or complications |  |

## Brief Description of Study Results

If the study has been completed or if interim results are known, provide a brief description of any available study results.

There are no study results to report.

The results from the interim analysis are as follows:

The study results were reported … A copy of the report is attached (Attachment #).

# Summary Information

## Adverse Events

A narrative or tabular summary showing the most frequent and most serious adverse events by body system. An example of a reporting table is below. Adverse event totals may also be broken down into grades, as applicable.

A total of [#] SAEs during this reporting period, available as of [dd/mm/yyyy]. A [summary/tabular summary] is listed [below/in the table below/in Attachment #]:

The most frequent and serious adverse events observed tabulated by body system:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Adverse Event** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
|  | **N (%)** | **N (%)** | **N (%)** | **N (%)** | **N (%)** |
| **Body System** |  |  |  |  |  |
|  Type |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Summary of IND Safety Reports

A narrative or tabular summary of all IND safety reports submitted (by you to this IND) during the past year. An example of a reporting table is below.

During this reporting period, there have/has been [#] IND Safety Reports submitted. A total of [#] follow-up Safety Report(s) (Serial No. ###;mm/dd/yyyy) was/were also submitted.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Subject ID** | **Event Date** | **Submitted Date** | **Serial Number** | **Description** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## Study Subject Deaths

A narrative or tabular summary of all subjects who died during participation in the investigation, with the cause of death for each subject. An example of a reporting table is below.

A summary of patient deaths for the study during this reporting period is presented in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Subject ID** | **Date of Death** | **Date of Last Treatment**  | **Cause of Death** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Study Subject Dropouts Due to an Adverse Drug Experience

A narrative or tabular summary of all of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related, during the past year. An example of a reporting table is below.

There have been no subjects who have discontinued the treatment/study due intolerable adverse events.

A summary of subjects who were discontinued prematurely from the study due to an adverse event is presented in the table below.

| **Subject ID** | **Date of Discontinuation** | **Reason for Discontinuation** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

## Understanding of the Drug’s Action

A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, information from controlled trials, and information about bioavailability.

As of this report date, [there is no new information/no articles have been published] in relation to this study.

The following new information was obtained during the reporting period in relation to this study:

## List of Preclinical Studies

A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.

As of this report date, there have not been any [additional/new] preclinical studies [started/completed].

As of this report date, the following preclinical studies were [initiated/completed]:

## Summary of Manufacturing or Microbiological Changes

A summary of any significant manufacturing or microbiological changes made during the past year.

There were no manufacturing or microbiological changes during the reporting period.

A summary of the significant manufacturing/microbiological changes includes:

# General Investigational Plan

A brief description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The plan should include the following:

*(a) The rationale for the drug or the research study;*

*(b) The indication(s) to be studied;*

*(c) The general approach to be followed in evaluating the drug;*

*(d) The kinds of clinical trials to be conducted in the first year following the submission (if plans are not developed for the entire year, the sponsor should so indicate);*

*(e) The estimated number of patients to be given the drug in those studies; and*

*(f) Any risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug or related drugs.*

Include a summary of the items listed above or describe individually/copy from IND initial submission as listed below.

The general investigational plan for the coming year is as follows:

[See Investigational Plan section in the IND, include a summary description or itemize into headings listed below]

## Rationale

The rationale for the drug or the research study.

[See *Rationale* section in the IND application]

## Indication(s) to be Studied

[See *Indications to be Studied* section in the IND application]

## General Approach for Evaluation of Treatment

[See *General Approach for Evaluation of Treatment* section in the IND application]

## Planned Clinical Trials

The kinds of clinical trials to be conducted in the year following the submission (if plans are not developed for the entire year, the sponsor should indicate so).

[See *Planned Clinical Trials* section in the IND application]

## Estimated Number of Subjects

The estimated number of patients to be given the drug in planned studies.

[See *Estimated Number of Subjects* section in the IND application]

## Anticipated Risks

Any risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug or related drugs

[See *Anticipated Risks* section in the IND application]

# Investigator Brochure

If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.

The Investigator Brochure has not been modified during the reporting period.

The Investigator Brochure was revised/updated to include: A copy of the updated Investigator Brochure is attached (Attachment #).

# Phase 1 Protocol Modifications

A description of any significant Phase 1 protocol modifications, as well as any other changes not previously provided to the FDA, made during the previous year and not previously reported to the IND in a protocol amendment.

There have been no significant Phase 1 protocol modifications during this reporting period.

During the reporting period, the following protocol modifications were made: A copy of the current protocol is attached (Attachment #).

# Foreign Marketing Developments

A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country. This section applies to commercial sponsors – include “Not applicable” if the study does not have a commercial sponsor

Not applicable.

There have been no foreign marketing developments with the drug during the past year.

# Outstanding Business with Respect to the IND

If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

There is no outstanding business with respect to the IND for this study.

The following is a list of outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment or meeting:

# Attachments

Attachment 1 –

Attachment 2 –

**Attachment 1 -**