*(NOTE: Blue Italicized Text is for instructional or informational purposes only and should be deleted prior to this report being finalized)*

**IND Annual Report**

**IND xxxxxx**

**Serial Number xxxx**

**Title of IND *(If a title is being used)***

**Reporting Period: xx/xx/xxxx to xx/xx/xxxx**

***(For an initial(#1) annual report, start with effective date and end with date of data analyzed to be included with this report. For subsequent reports, (#2-n) start with the previous report end date and end with date of data analyzed to be included with this report.)***

**Sponsor Investigator: xxNAMExx, MD**

**Children’s Hospital of Philadelphia**

**3401 Civic Center Boulevard**

**Philadelphia, Pennsylvania 19104**

**Annual Report Date: xx/xx/xxxx**

**Confidential**

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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).*

***General Note: Maintain all headings throughout this document. If a particular section doesn’t apply to your IND – state so!***

*The summary is required to include the following information for each study:*

## Title of Study

*The title of the study (with appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient populations, and a statement as to whether the study is completed. It may look something like the list below. Also, you can add a table here to list other study sites.*

**Title of Study:** Title

**IRB Number:** IRB xx-xxxxxx

**Study Design:** Open label, closed label, randomized etc.

**Purpose:** This study will…. .

**Patient Population:** Disease state, healthy, age, etc.

**Study Status:** Open, closed, enrolling, completed etc.

**Reporting Period:** This Report covers the period from xx/xx/xxxx to xx/xx/xxxx. Interval data for this reporting period is provided unless otherwise stated as study cumulative data.

## Enrollment Update

*The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason. Examples of tables that might be appropriate for your study are below. Use if appropriate or change to suit your needs. There should also be some verbiage summarizing progress.*

**Table 2-1 Subject Enrollment by Site**

*Note: For a single site study, this table is not needed and may be deleted.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Total Enrolled** | **First Enrollment Date** | **Last Enrollment Date** |
| Site 1 xxNAMExx  |  |  |  |
| Site 2 xxNAMExx  |  |  |  |
| Site 3 xxNAMExx  |  |  |  |
| Site 4 xxNAMExx  |  |  |  |
| **Total US sites** |  |  |  |
| Other country: site  |  |  |  |
| Other country: site |  |  |  |
| **Total non-US sites** |  |  |  |
| **All Sites** |  |  |  |

**Table 2-2 Subject Demographics**

*Adjust age ranges to more appropriately bracket the study specific subject population.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Female** | **Male** | **Both Genders** |
| **Ethnic Category**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| Hispanic or Latino  |  |  |  |  |  |  |
| Not Hispanic or Latino  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |
| **Racial Category (single category per participant)**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| White  |  |  |  |  |  |  |
| Black or African American  |  |  |  |  |  |  |
| Multiracial |  |  |  |  |  |  |
| Other  |  |  |  |  |  |  |
| **Total**  |  |  |  |  |  |  |
| **Age at Enrollment Category**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| 18 − 21 years  |  |  |  |  |  |  |
| 22 − 29 years  |  |  |  |  |  |  |
| 30 − 39 years  |  |  |  |  |  |  |
| 40 − 49 years  |  |  |  |  |  |  |
| 50 − 59 years  |  |  |  |  |  |  |
| **Total**  |  |  |  |  |  |  |

**Table 2-3 Status of Enrolled Participants**

*Note: Total enrollment numbers should logically be able to be balanced between consented, screen failures, treatment, follow-up and completed when factoring in early terminations/withdrawals.*

|  |  |  |
| --- | --- | --- |
| **Enrollment Status – Total Planned Enrollment = xx** | Current Reporting Period | Overall |
| 1. Total Number of Consented Subjects
 |  |  |
| 1. Number of Screen Failures After Consent
 |  |  |
| 1. Number of Subjects Starting Study Procedures/Treatment
 |  |  |
| 1. Number of Subjects Withdrawn or Discontinued from Study
 |  |  |
| 4.1 Withdrawal or Discontinued Due to Adverse Event  |  |  |
| 4.2 Withdrawal or Discontinued Due to Subject Request |  |  |
| 4.3 Withdrawal or Discontinued Due to Subject Death |  |  |
| 1. Number of Subjects who have completed all planned study visits
 |  |  |

## Brief Description of Study Results

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

# Summary Information

*Information obtained during the previous year’s clinical and nonclinical investigations.*

***Maintain all headings and if not applicable or none – so state.***

## Adverse Events: Frequent and Serious

*A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system. An example of a reporting table is below; add or remove items as indicated and update the values. If there are only a very few categories a narrative summary of those few items might provide more clarity.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Body System** | **Number this Reporting Period** | **Cumulative Number During Study** | **Cumulative Percentage of Overall Frequent and Serious Events** |
| Infections and infestations  |  |  |  |
| Injury, poisoning and procedural complications  |  |  |  |
| Infestations |  |  |  |
| Nervous system disorders  |  |  |  |
| Respiratory, thoracic and mediastinal disorders  |  |  |  |
| Blood and lymphatic system disorders  |  |  |  |
| Musculoskeletal and connective tissue disorders  |  |  |  |
| Gastrointestinal disorders  |  |  |  |
| General disorders and administration site conditions  |  |  |  |
| Hepatobiliary disorders  |  |  |  |
| Skin and subcutaneous tissue disorders  |  |  |  |
| Eye disorders  |  |  |  |
| Ear and labyrinth disorders  |  |  |  |
| Psychiatric disorders  |  |  |  |
| Vascular disorders  |  |  |  |
| Immune system disorders  |  |  |  |
| Metabolism and nutrition disorders  |  |  |  |
| Renal and urinary disorders  |  |  |  |
| Reproductive system and breast disorders  |  |  |  |
| Surgical and medical procedures  |  |  |  |
| Total |  |  |  |

## Summary of IND Safety Reports

*A summary of all IND safety reports submitted (****by you to this IND****) during the past year*.

***Maintain all headings and if not applicable or none – so state.***

## Study Subject Deaths

*A cumulative tabular list of subjects who died during participation in the investigation, with the cause of death for each subject.* ***Maintain all headings and if not applicable or none – so state.***

## Study Subject Dropouts Resulting from Adverse Drug Experiences

*A list of subjects who dropped out during the course of the investigation in association with any adverse experience, and narrative analysis of whether or not thought to be drug related. In other words, subjects who withdrew from the study because of intolerable side-effects. See enrollment status table above. The numbers from that table should be reflected in the details here.*

## 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.*

## 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.*

## Summary of Manufacturing or Microbiological Changes

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

# General investigational plan

*A description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The general investigation plan shall contain the information required under Sec. 312.23(a) (3)(iv).*

## Brief Description of the Overall Investigational Plan

*A brief description of the overall plan for investigating the drug product for the following year. The plan should include the following:*

### Rationale

*The rationale for the drug or the research study.*

### Indication(s) to be Studied

*The intended specific indication or condition to be treated for the drug or the research study.*

### 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).*

### Estimated Number of Subjects

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

### 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*

# Investigator Brochure

*If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.* ***Maintain all headings and if not applicable or none – so state.***

# Protocol Modifications

*A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.*

# 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 – just state:*

Not Applicable

# (Optional) Outstanding business with respect to IND

*(Optional – Delete this Section if not needed) If desired by the sponsor, a listing, log, or of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.*