**INSTITUTION Name/Logo**

**IND XX,XXX**

**ANNUAL REPORT**

**DRUG TRADE NAME (GENERIC NAME, NAME OF ANTIBODY)**

**Reporting Period Covered in this Report: MM DD, YY to MM DD, YY**

Date of Report: MM DD, YY

Sponsor Name

Institution Name

Mailing Address

Mailing Address

Telephone

**CONFIDENTIAL**

**TABLE OF CONTENTS**

1. Study INFORMATION 1

1.1. Study Summary 3

1.2. Enrollment Update 3

1.3. Brief Description of Study Results 3

2. summary INFORMATION 4

2.1. Adverse Events: Frequent and Serious 4

2.2. Summary of IND Safety Reports 4

2.3. Study Subject Deaths 4

2.4. Study Subject Dropouts Due to an Adverse Drug Experience 5

2.5. Understanding of the Drug’s Action 5

2.6. List of Preclinical Studies 5

2.7. Summary of Manufacturing or Microbiological Changes 6

3. general investigational plan 6

4. investigator brochure 6

5. PHASE 1 Protocol Modifications 6

6. foreign marketing developments 6

7. OUTSTANDING BUSINESS WITH RESPECT TO the IND 6

8. Appendices 7

Appendix A. Adverse Events Listings for the (Study name) study 8

# **Study INFORMATION**

The original IND XX,XXX was submitted to the FDA on Date. This annual report summarizes data for all studies conducted under the IND from Date to Date. Table 1 presents an overview of all studies, completed and ongoing.

DRUG generic name (Trade Name®) is being evaluated under this IND for efficacy, safety, and tolerability in the treatment of disease or condition.

*Note-use table below for multiple studies under one IND. If only one study under IND, then list that and no table is needed.*

|  |  |  |  |
| --- | --- | --- | --- |
| Table 1: Clinical Studies Conducted with DRUG |  |  |  |
| **Protocol Number** | **Objective** | **Study Status** | **Final Report Location** |
| AB0001 | To test the safety and efficacy of oral DRUG in children and adults with disease who have condition | Complete | Serial No. 009 |
| AB0002 | To characterize the long-term use, safety, and efficacy of DRUG in children and adults with disease or condition in an observational study of AB0001 participants | Complete | Serial No. 0018 |
| AB0003 | To investigate the safety and efficacy of oral DRUG in children and adolescents with disease or condition X-Y years of age | In progress | N/A |

##

## **Study Summary**

**Title of Study:** AB0003: Multi-center, Multi-national, Randomized, Placebo-Controlled Trial of DRUG in Subjects with Disease or Condition X-Y Years Old

**Study Design:** Multicenter double-blind randomized clinical trial

**Purpose:** To investigate the safety and efficacy of oral DRUG in children and adolescents with disease who have condition

**Patient Population:** Male and female subjects X years and ≤ Y years of age with a diagnosis of disease

**Treatment Regimen:** Trade Name® (generic name) 250 mg of DRUG taken orally three times a day

**Study Duration:** Total duration of the treatment period for each subject is XX weeks

**Study Status:** Active, not recruiting

## **Enrollment Update**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Table 2: AB0003 Enrollment Update as of Date** |  |  |  |  |  |  |
| No. Planned/ Enrolled | No. Completed Dosing | No. Completed Study | No. Dropouts | Gender | Race/Ethnicity |
| 80/70 | XX | XX | 6 | M XX | Caucasian XX |
|  |  |  |  | F XX | Black X |
|  |  |  |  |  | Hispanic X |
|  |  |  |  |  | Other X |

## **Brief Description of Study Results**

No study results are available as yet.

# **summary INFORMATION**

## **Adverse Events: Frequent and Serious**

Appendix A contains the following tables of coded adverse event data for the AB0003 study, available as of Date:

* Most Frequently Occurring Treatment Emergent Adverse Events
* Incidence of Treatment Emergent Adverse Events
* Treatment Emergent Adverse Event Intensity
* Incidence of Treatment Emergent Serious Adverse Experiences - OR - Serious Adverse Experience (SAE) Narrative Summaries

The medical monitor sees no concerning trends in the AEs by severity or incidence. The AEs are similar to other disease or condition studies of similar duration.

Number SAE Reports were received during this reporting cycle. All were classified as unrelated to study drug by both the medical monitor and the site investigator.

**OR (if the listing is short and can fit onto one page):**

Adverse events (AE) reported during this reporting period for the AB0003 study are presented in Table X below.

## **Summary of IND Safety Reports**

During this reporting period, no serious adverse experiences resulted in the submission of an IND Safety Report in the AB0003 study.

**OR:**

During this reporting period, a total of # SAEs resulted in the submission of an IND Safety Report. # follow-up Safety Reports (Serial No. ###;mm/dd/yyyy) was/were also submitted.

## **Study Subject Deaths**

No patient deaths were reported for the AB0003 study during this reporting period.

**OR:**

A summary of patient deaths for the AB0003 study during this reporting period is presented in Table X.

## **Study Subject Dropouts Due to an Adverse Drug Experience**

No subjects were discontinued prematurely from the AB0003 study due to an adverse event during this reporting period.

**OR:**

A summary of subjects who were discontinued prematurely from the AB0003 study due to an adverse event is presented in Table X.

**Table X. Summary of Drop-Outs**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient ID** | **Dose Level/Regimen** | **Date of Randomization** | **Date of First Dose** | **Date of Discontinuation** | **Cause of Discontinuation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## **Understanding of the Drug’s Action**

No new information regarding the action of DRUG name has been obtained during this reporting period.

**OR (if applicable):**

Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the mechanism of action of the drug products referred to in IND XX,XXX:

NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets

IND ZZ,ZZZ – Antibiotic Oral

## **List of Preclinical Studies**

No preclinical studies were completed or in progress with DRUG name under the IND during this reporting period.

**OR (if applicable):**

"Enter number" preclinical studies were completed/are ongoing with DRUG name during this reporting period. They are summarized in Table X.

## **Summary of Manufacturing or Microbiological Changes**

Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the manufacturing of the drug products referred to in IND XX,XXX:

NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets

IND ZZ,ZZZ – Antibiotic Oral

# **general investigational plan**

**AB0003 –** Enrollment was closed at all X active study sites as of Date. We anticipate all study visits will be completed by Date. We plan to lock the database by Date.

During this reporting period the Data Monitoring Committee (DMC) conducted a planned comprehensive interim analysis involving data from all sites. Following the review the DMC Chair reported that the DMC sees no concerns regarding participant safety to date and approves the study to go forward without modification at this time.

The DMC will continue to review SAEs as they occur throughout the trial and may add additional analyses at any time.

# **investigator brochure**

The prescribing information for DRUG name is serving the function of an Investigator Brochure for the AB0003 study. The prescribing information was most recently revised in Month 201X.

# **PHASE 1 Protocol Modifications**

No Phase 1 studies have been conducted under the IND during this reporting period.

# **foreign marketing developments**

Not applicable.

# **OUTSTANDING BUSINESS WITH RESPECT TO the IND**

There is no outstanding business for which the FDA expects a reply, comment, or meeting.

# **Appendices**

**Appendix A. Adverse Events Listings for the (Study name) study**