200x Annual Report

IND xxxxxx

Title of IND Goes Here (If a title is being used)

Serial xxxx

xx Month 200x

Confidential

Table of Contents

(Table of contents: may be best to recreate when you have completed your document!)

1 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:

1.1 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

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.

1.2 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 things.

Table 1.2-1 Subject Enrollment by Site

Site	Total Enrolled	First Enrollment Date	Last Enrollment Date
University of Somewhere			
Somewhere else University			
State Hopsital			
County of Public Health			
Total US sites			
Other country: site			
Other country: site			
Total non-US sites			
All Sites			

Table 1.2-2 Subject Demographics

	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 1.2-3 Status of Enrolled Participants

Total Enrollment	
Total Completed Treatment	
On Study	
On treatment	
Completed treatment	
Off treatment early	
Terminated Study Early	
Completed treatment	
Off treatment early	
Completed Protocol Follow−up	
Completed treatment	
Off treatment early	
Termination associated with an adverse experience	

1.3 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

2 SUMMARY INFORMATION

Information obtained during the previous year's clinical and nonclinical investigations, including. ***Maintain all headings and if not applicable or none – so state.***

2.1 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.

Body System	N	Incidence
Infections and infestations	27	56.3%
Injury, poisoning and procedural complications	12	25.0%
Investigations	12	25.0%
Nervous system disorders	10	20.8%
Respiratory, thoracic and mediastinal disorders	10	20.8%
Blood and lymphatic system disorders	9	18.8%
Musculoskeletal and connective tissue disorders	9	18.8%
Gastrointestinal disorders	7	14.6%
General disorders and administration site conditions	6	12.5%
Hepatobiliary disorders	5	10.4%
Skin and subcutaneous tissue disorders	4	8.3%
Eye disorders	3	6.3%
Ear and labyrinth disorders	2	4.2%
Psychiatric disorders	2	4.2%
Vascular disorders	2	4.2%
Immune system disorders	1	2.1%
Metabolism and nutrition disorders	1	2.1%
Renal and urinary disorders	1	2.1%
Reproductive system and breast disorders	1	2.1%
Surgical and medical procedures	1	2.1%

2.2 Summary of IND Safety Reports

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

2.3 Study Subject Deaths

A list of subjects who died during participation in the investigation, with the cause of death for each subject.

2.4 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 whether or not thought to be drug related. In other words, subjects who withdrew from the study because of intolerable side-effects.

2.5 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 biovailability.

2.6 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.

2.7 Summary of Manufacturing or Microbiological Changes

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

3 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).

3.1 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:

3.1.1 Rationale

The rationale for the drug or the research study.

3.1.2 Indication(s) to be Studied

3.1.3 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).

3.1.4 Estimated Number of Subjects

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

3.1.5 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

4 INVESTIGATOR BROCHURE

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

5 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.

6 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

7 OUTSTANDING BUSINESS WITH RESPECT TO 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.