**20XX Annual Report**

**IND**

**[PROTOCOL TITLE]**

**Serial [000X]**

**[DATE]**

**Confidential**

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# Study information

**Title of Study:**

**Study Design:**

**Purpose:**

**Patient Population:**

**Study Status:**

## Enrollment Update

Total enrollment goal:

Total currently enrolled:

[Are there external sites? What are those enrollment numbers?]

**Table 1.2-1 Subject Enrollment by Site**

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Total Enrolled** | **First Enrollment Date** | **Last Enrollment Date** |
| Mt. Sinai |  |  |  |
| **Total US sites** |  |  |  |
| **Total non-US sites** |  |  |  |
| **Total subjects** |  |  |  |

**Table 1.2-2 Subject Demographics**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Female** | | **Male** | | **Both Genders** | |
| **Ethnic Category** | **N** | **%** | **N** | **%** | **Total** | **%** |
| Hispanic or Latino |  |  |  |  |  |  |
| Not Hispanic or Latino |  |  |  |  |  |  |
| **Total** |  |  |  |  |  | 100% |
| **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 |  |  |  |  |  |  |
| 60 years and older |  |  |  |  |  |  |
| **Total** |  |  |  |  |  | 100% |

**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 |  |

## Brief Description of Study Results

# Summary Information

## Adverse Events: Frequent and Serious

**N=**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Event** | **Grade (n)** | | | | **Total** |
| **1-2** | **3** | **4** | **5** |
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## Summary of IND Safety Reports

A summary list of all IND safety reports submitted during the past year is as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Protocol:  PI: | | | | |
| **Report#** | **Report (initial, f/u)** | **Event** | **ReportDate** | **Relationship to study drug** |
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## Study Subject Deaths

## Study Subject Dropouts Resulting from Adverse Drug Experiences

## Understanding of the Drug’s Action

## List of Preclinical Studies

## Summary of Manufacturing or Microbiological Changes

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# General investigational plan

## Brief Description of the Overall Investigational Plan

### Rationale

### Indication(s) to be Studied

## Primary Study Endpoints

## Secondary Study Endpoints

### Planned Clinical Trials

### Estimated Number of Subjects

### Anticipated Risks

# Protocol Modifications

Changes that were made to the protocol during past year that were reported to FDA and approved by IRB, and changes not yet reported.

# Foreign Marketing Developments

# Outstanding business with respect to IND