[Logo]

Title

Annual Report

Reporting Period:

Date of Submission:

[IND Holder Address]

**CONFIDENTIAL**

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# Individual Expanded Access Information

**Title of Expanded Access:**

**Expanded Access Design:**

**Purpose:**

**Patient Population:**

**Study Status:**

## Enrollment Update

**Table 1.1 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 Expanded Access to date

## Summary Information

### Adverse Events: Frequent and Serious

*A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.*

*A reference to the letter of authorization to cross reference an Ind from the drug manufacturer can also be included here.*

### Summary of IND Safety Reports

*A summary of all IND safety reports submitted during the past year.*

*A reference to the letter of authorization to cross reference an Ind from the drug manufacturer can also be included here.*

### Expanded Access Subject Deaths

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

*A reference to the letter of authorization to cross reference an Ind from the drug manufacturer can also be included here.*

### Expanded Access 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, whether or not thought to be drug related.*

*A reference to the letter of authorization to cross reference an Ind from the drug manufacturer can also be included 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.*

Or

*[Insert reference to IND in LOA] e.g. Please see IND XXXXX*

### 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.*

Or

*[Insert reference to IND in LOA] e.g. Please see IND XXXXX*

### Summary of Manufacturing or Microbiological Changes

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

*[Insert reference to IND in LOA] e.g. Please see IND XXXXX*

# General Expanded Access plan

## Brief Description of the Overall Investigational Plan

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

## Protocol and/or Treatment Plan Modifications

*Summary of IND submissions to date:*

*Serial numbers 0000: Initial IND request*

*0001:*

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# Outstanding business with respect to IND

*No outstanding business with respect to IND.*