**USONA INSTITUTE**

**END OF STUDY REQUIREMENTS FOR IITs**

**Publications**

Please provide a copy of any publication that results from use of the Investigational Drug at least fifteen (15) days prior to submission and, if accepted by a peer-reviewed publication, within thirty (30) days following release. Institution also agrees to acknowledge Usona in any proposed manuscript (including but not limited to abstracts, posters, publications and/or presentations) as the provider of the Investigational Drug.

**Study Closeout**

Upon completion of the study, provide Usona with a copy of the final report/notice provided to the IRB or ethics committee.

**Safety Data Reporting**

A safety data summary report should be provided at the conclusion of the study.If possible, data should be transferred in one of the following formats: CDISC ODM-XML file (preferred) or Comma Separated Value (CSV) file. If the study’s data collection procedures do not enable export in one of these two formats, please compile a summary of study results using the template described below.

Please note that the safety data reporting requirements set forth below and in the supply agreement apply to all participants enrolled in studies conducted with psilocybin or placebo provided by Usona, regardless of treatment assignment.

The safety data summary report should contain the following information:

**Extent of Exposure**

Tables summarizing exposure to include demographic information (population, age, sex, and race). Example tables are provided below. Please provide a table for each treatment administered (psilocybin and placebo).

* Include duration and the number of participants exposed for specific time periods.
* Information on dose levels and the number of participants exposed.
* If available, include relevant drug concentration data (e.g., concentration at the time of an event, maximum plasma concentration, area under curve) for correlation with adverse events or laboratory changes in individual participants.

Table 1: Total participant exposure to [psilocybin and/or placebo] in [study title/protocol number].

|  |  |  |
| --- | --- | --- |
| Treatment | [Study Population] | Number of PARTICIPANTS Exposed\* |
| Psilocybin (including dose, route of administration, and periodicity) |  | XX |
| Placebo (including dose, route of administration, and periodicity) |  | XX |
| Total |  | XX |

\*Based on actual exposure data from completed studies.

Table 2: Cumulative participant exposure to [for psilocybin and/or placebo] in [study title/protocol number] by Age and Sex.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Number of PARTICIPANTS | | |
| **Age Range (years)** | **Male** | **Female** | **Total\*** |
| <18 |  |  |  |
| 18-65 |  |  |  |
| 66-75 |  |  |  |
| >75 |  |  |  |

\*Based on actual exposure data from completed studies.

Table 3: Cumulative participant exposure to [psilocybin and/or placebo] in [study title/protocol number] by Race.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Number of PARTICPANTS | | |
| **Racial Group** | **Male** | **Female** | **Total\*** |
| American Indian or Alaska Native |  |  |  |
| Asian |  |  |  |
| Black |  |  |  |
| Caucasian |  |  |  |
| Multi-racial |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |
| Not Reported |  |  |  |
| Unknown |  |  |  |

\*Based on actual exposure data from completed studies.

**Treatment Emergent Adverse Events (TEAEs)**

A table listing each TEAE, the number of participants in each treatment group in whom the event occurred, and the rate of occurrence. An example table is provided below. Please provide a table for each treatment administered (psilocybin and placebo).

* Adverse events should be grouped by System Organ Class (SOC) and assigned a MedDRA Preferred Term (PT).
* Each event may then be divided into [Common Terminology Criteria for Adverse Events](https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf) (CTCAE) 1-5 graded severity categories and assigned causality (e.g., unrelated or possibly, probably, or definitely related).

Table 4: Listings of TEAEs related to [psilocybin and/or placebo] in [study title/protocol number].

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Treatment Group X  Number of Participants in Treatment Group = X | | | | | | |
| **System Organ Class (SOC)** | **Preferred Term (PT)** | **TEAE Incidence**  **(# and % of participants)** | **Start Date** | **Stop Date** | **CTCAE Severity Grade** | **Causality Assessment** |
|  |  |  |  |  |  |  |

**Deaths and Serious Adverse Events (SAEs)**

Complete tables listing each occurrence of the following events. An example table is provided below. Please provide a table for each treatment administered (psilocybin and placebo).

* Deaths: all deaths during the study, including the post treatment follow-up period, should be listed by participant.
* SAEs: All serious adverse events should be listed and include the CIOMS or MedWatch identifier, if applicable.

Table 6: Listings of Deaths and Serious Adverse Events related to [psilocybin and/or placebo] in [study title/protocol number].

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Treatment Group X  Number of Participants in Treatment Group = X | | | | | | | |
| **System Organ Class (SOC)** | **Preferred Term (PT)** | **MedWatch / CIOMS Identifier (MCN)** | **Start Date** | **Stop Date** | **CTCAE Severity Grade** | **Causality Assessment** | **Serious Criteria\*** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\*An adverse event or suspected adverse reaction is considered serious if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

1. Death

2. Life-threatening

3. Hospitalization (initial or prolonged)

4. Disability

5. Congenital anomaly

6. Requires intervention to prevent permanent impairment or damage

Please provide the following documentation as attachments to the safety data summary report:

* Death Case Report Forms (CRFs) for each death that occurred during the study.
* MedWatch 3500A or CIOMS I Forms for every Suspected Unexpected Serious Adverse Reaction (SUSAR) submitted to regulatory authorities.
* Institutional SAE report forms for all SAEs.

Please ensure any forms used to record or report SAEs (e.g., institutional SAE report forms, MedWatch 3500A or CIOMS I form) contain the following information in the description of the event:

* The nature and intensity of the event.
* The clinical course leading up to event, with an indication of timing relevant to test drug/investigational product administration.
* Relevant laboratory measurement.
* Whether the drug was stopped, and when.
* Countermeasures.
* Post-mortem findings.
* Investigator's opinion on causality.