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| **Usona Institute Investigational Drug Supply Program****Safety Update Form****For reporting period 22 January 2023 – 21 January 2024****Due to Usona Institute by: 15 February 2024** |
| **For each investigator-initiated study, please fill out the following information, indicating N/A where necessary. Do not include any personally identifiable information (PII).** |
| **PI / Sponsor** |  |
| **IND / CTA # / EudraCT #** |  |
| **Study title** |  |
| **Treatment indication** |  |
| **Psilocybin dose and dosage form administered**(Ex: 25 mg capsule, 5 mg capsule, custom) |  |
| **Treatment comparator dose and dosage form** | [ ]  100 mg Niacin capsule[ ]  25 mg MCC capsule[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Clinical trial status** | [ ]  Ongoing[ ]  Complete |
| **Clinical trial start date** (First subject enrolled) |  |
| **Anticipated study completion date**(Last patient last visit) |  |
| **Anticipated date Final Clinical Study Report (CSR) available** |  |
| **Planned total # subjects enrolled**  |  |
| **# Subjects enrolled** (Do not include screen fails) |  |
| **# Subjects dosed psilocybin**(Please report per dose/dosage form; N/A if treatment assignment is not unblinded) |  |
| **# Subjects dosed placebo or comparator** (Please report comparator name, route of administration, and dose, if applicable) |  |
| **# Serious Adverse Events (SAEs) in study regardless of causality/expectedness**(Please provide a copy of every initial and follow-up report) | *Institutional SAE forms may be submitted for initial and follow-up SAE reports. If any SAE was reported as a SUSAR to a regulatory authority, please provide the MedWatch 3500A or CIOMS I forms.*  |
| **# Safety Reports (e.g., Serious, Unexpected, Suspected Adverse Reactions [SUSARs]) submitted to Regulatory Authorities (FDA MedWatch 3500A / CIOMS I Forms)**(Please provide a copy of every submitted initial and follow-up report) |  |
| **List AEs that occurred in ≥ 5% of subjects within each treatment arm**(Classified by MedDRA System Organ Class and Preferred Term) |  |
| **Check how additional details of AEs will be provided** | [ ]  Annual Report / DSUR[ ]  Final Clinical Study Report |
| **# Subjects who discontinued in association an adverse event, whether or not thought to be drug related** |  |
| **# Subjects who died**  |  |