# Outcome Monitoring

Outcome assessments are outlined in Table [X]. Outcome monitoring will also be supported by the collection of data via the Australian Interventional Pharmacotherapy and Psychedelic-Assisted Psychotherapy Research Registry (AIPPAP-RR) developed by the Australian National University (ANU). The benefit of using the Registry is that the prescriber (or delegate) will contribute to the National data around the outcomes associated with psychedelic-assisted psychotherapy (PAP).

## Registry Registration Process

Registering a participant for the Registry can be done following the process below.

1. The prescriber (or delegate) approaches the Registry to notify of their plan to treat someone with PAP. This will be done via email to [papregistry@anu.edu.au](mailto:papregistry@anu.edu.au) or via the website link [here](https://medicalschool.anu.edu.au/research/projects/australian-interventional-pharmacotherapy-psychedelic-assisted-psychotherapy/register-your-patient). Consent must be obtained from the participant prior to referring them to the Registry. The referral will include the following:
   1. Patient’s full name and email address;
   2. Prescriber’s full name and email address;
   3. Patient’s age;
   4. Treatment (psilocybin or MDMA) and indication;
   5. Patient’s confirmation of consent to participate in the Registry.
2. The referral information of the person undergoing treatment is entered into the Registry by ANU staff, triggering an automated email with a link to the Participant Information and Consent Form (PICF).
   1. Individuals undergoing psychedelic therapy will only be providing consent to participate in the Registry; consent in regard to the delivery of PAP will be the responsibility of the prescriber. **Engagement in PAP will not be dependent on consenting to participate in the Registry.**
3. If the participant consents, the prescriber (or delegate) is emailed a link to commence the collection of the participant’s medical history, planned date/s for chosen therapy, and the short clinical global impression questionnaire (the participant will also receive a link to commence the collection of Registry data).
4. Both the prescriber (or delegate) and the participant will be sent a series of questionnaires before, during, and after their proposed treatment, with follow-up periods of 12 months for PAP. The questionnaires used in the Registry are listed in Table [X].

**Note**: The Registry collects data at numerous timepoints; however, the RANZCP Clinical Memorandum recommends data be collected before, end of treatment, and at the 3-month follow up for patient’s receiving PAP. In addition to these timepoints, selected clinical outcomes will be communicated to the prescriber (or delegate) via the Registry in between dosing sessions as well as at 6, 9, and 12 months post the final integration session. This allows for enhanced monitoring of patient outcomes and a long-term follow-up period.

The prescriber or their delegate has access to the patient’s clinical outcome results via a link provided by the Registry. Most of the outcome monitoring will be via the ANU Registry as indicated in shaded boxes below.

*Table [X]. Assessments and outcome monitoring schedule for MDMA- and psilocybin-assisted psychotherapy*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Questionnaire/**  **Assessment** | **MDMA**  **PTSD** | **Psilocybin**  **Depression** | **Results sent from AIPPAP-RR** | **Baseline, end treatment, and follow up assessments (shading = via ANU Registry)** |
| **[insert any additional outcome monitoring here e.g., psychiatric assessment, medical assessment etc.]** |  |  |  |  |
| Impact of Event Scale Revised (IES-R) | X |  | X | X |
| Patient Health Questionnaire 9 (PHQ-9) | X | X | X | X |
| Depression, Anxiety, and Stress Scale 21 (DASS-21) | X | X | X | X |
| Generalized Anxiety Disorder Assessment 7  (GAD-7) | X | X | X | X |
| Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) | X | X | N/A | X |
| Stanford Expectations of  Treatment Scale (SETS) | X | X | N/A | X |
| Psychological insight Questionnaire (PIQ) | X | X | N/A | X |
| Multidimensional Health Locus of Control (Form C) (MHLC) | X | X | N/A | X |
| 10-Item Personality Inventory (TIPI) | X | X | N/A | X |
| Mystical Experiences Questionnaire (MEQ30) | X | X | N/A | X |
| Assessment of Quality Of Life-AoQoL8D | X | X | X | X |
| Self-efficacy for Managing Chronic Disease 6-item Scale Scored (SEMCD) | X | X | N/A | X |
| CGI (Clinical Global Impression) – Severity |  |  | N/A | X |
| CGI – Improvement |  |  | N/A | X (end of treatment and follow ups) |
| CGI – Side Effects | X | X | N/A | X |

These assessments have been selected based on the recommendation by the [International Consortium for Health Outcomes](https://www.ichom.org/patient-centered-outcome-measure/depression-anxiety/) in depression and anxiety. Other assessment tools will be added to monitor the patient’s progress if clinically useful by the therapist team.

## Primary Outcome Assessment

[Select relevant primary outcome assessment one below]

Treatment-resistant depression (psilocybin): continuous scores on the PHQ-9 (baseline – follow up post final PAP cycle).

Post-traumatic stress disorder (MDMA): continuous scores on the IES-R (baseline – follow up post final PAP cycle).

## Secondary Outcome Assessments

According to Table [X], all patients will be invited to enrol into the AIPPAP-RR for monitoring of psychedelic treatment outcomes.  Other assessment tools may be added to monitor the patient’s progress if clinically useful by the therapist team.