

Multi-Analyst Reanalysis of IPD on Esketamine and Suicidality (Team 1, 2, 3),

SAP Template (To be completed by each team)

1. Objectives

- **Primary objective:** State the main objective of the meta-analysis.
 - **Secondary objective(s):** State the secondary objective(s) of the meta-analysis.
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2. Study Methods

2.1. Design

- Specify the type of meta-analysis being conducted (e.g., IPD meta-analysis).
 - Introduce the PICOS framework, which will be detailed in the next section.
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2.2. Participants, Interventions, Comparators, Outcomes, and Study Design (PICOS)

2.2.1. Participants

- Define participant selection criteria **at the study level**.
- Define participant selection criteria **at the individual level** (if only specific subgroups are analyzed within a trial).

2.2.2. Interventions

- Describe the intervention in detail (e.g., *esketamine*), including dose, route of administration, and any relevant characteristics.

2.2.3. Comparators

- Describe the comparator(s) used in the IPD meta-analysis (e.g., placebo, or any other relevant comparator).

2.2.4. Study Outcomes

Detail the outcomes selected to address the research question. For each outcome, specify:

- **Outcome Measure Type:**
 - Primary
 - Secondary
 - Other pre-specified / post-hoc
- **Outcome Measure Title:** Name of the specific outcome measure.
- **Outcome Measure Description:** Additional information about the outcome measure, including a description of the metric used, if not already included in the title.
- **Outcome Measure Time Frame:** Time point(s) at which the measurement is assessed, specific to each outcome (e.g., “change from baseline to week 4”).
- **Outcome Type:** Type of data (e.g., continuous, binary, time-to-event, censored).

2.2.5. Study Design

- Define the design of the studies included in the IPD meta-analysis (e.g., randomized controlled trials, crossover studies, double-blind studies, etc.).

3. Statistical Analysis

3.1. General Context

- Describe the context of the meta-analysis project, including a reference to the master protocol submitted to YODA.

3.2. Software

- All analyses will be performed using **R**.

3.3. Meta-analysis (for each outcome)

For each outcome, specify:

1. Type of IPD meta-analysis (one-stage or two-stage).
2. Statistical method used.
3. Exploration and handling of statistical heterogeneity.
4. Plots to be produced (e.g., forest plot, funnel plot, other visualizations).
5. Association measures used and approach to assessing uncertainty (e.g., confidence intervals, prediction intervals).
6. Any other relevant analytical considerations not covered above (including exploration of moderators).