

STATISTICAL ANALYSIS PLAN

TRIAL NAME

Principal Investigator(s):

Lead Statistician:

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Summary of Changes from Previous Version

Date	Description of Change (Include specific sections affected)	Rationale for Change

TABLE OF CONTENTS

1. Protocol summary.....	4
1.1 Specific Aims.....	4
1.2 Study Population	4
1.3 Description of Intervention	4
2. Study Outcomes.....	4
2.1 Primary Outcome	4
2.2 Secondary Outcomes.....	4
2.3 Exploratory (Tertiary) Outcomes.....	4
2.4 Any Other Outcomes (Optional example Cost Outcomes)	5
3. Additional Variables for Effectiveness Analyses (Covariates and Moderators)	5
4. Definition of Study Samples.....	5
4.1 Inclusion and Exclusion Criteria.....	5
4.2 Intent-to-Treat (ITT) Sample.....	5
4.3 Safety Analysis Sample	5
4.4 Other Samples (Optional).....	5
5. Definition of Treatment Adherence	5
6. Randomization and Blinding	5
7. Sample Size/Power	6
8. Statistical Analysis.....	6
8.1 Primary Outcome Analyses	6
8.1.1 Missing Data.....	6
8.1.2 Multiple Comparisons.....	6
8.2 Additional Effectiveness Analyses for Primary Outcome.....	6
8.2.1 Moderators (Example)	6
8.2.2 Dosing and Adherence (Example).....	6
8.3 Secondary Outcome Analyses	6
8.4 Exploratory Analyses on Tertiary Outcomes	6
9. Economics Analyses (Optional).....	6
10. Safety Monitoring Analyses	6
10.1 Adverse Event.....	6
10.2 Serious Adverse Event	6
10.3 AE/SAE Reporting Procedure.....	6
10.4 Safety Outcomes	6

10.5 Descriptive Safety Analysis	7
11. Interim Analyses	7
12. References	7

1. PROTOCOL SUMMARY

1.1 Specific Aims

Aim 1:

Aim 2:

Aim 3:

1.2 Study Population

1.3 Description of Intervention

2. STUDY OUTCOMES

2.1 Primary Outcome

Primary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

2.2 Secondary Outcomes

Secondary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

2.3 Exploratory (Tertiary) Outcomes

Tertiary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

2.4 Any Other Outcomes (Optional example Cost Outcomes)

Cost Outcomes	Brief Description of Measures	Measured By	Time Frame

3. ADDITIONAL VARIABLES FOR EFFECTIVENESS ANALYSES (COVARIATES AND MODERATORS)

Covariates and Moderators	Definition	Role	Data Source

4. DEFINITION OF STUDY SAMPLES

4.1 Inclusion and Exclusion Criteria

We will require all participants to meet all the following inclusion criteria to participate in the trial.

Inclusion Criteria	Rationale and Source

Participants who meet any of the exclusion criteria at baseline will be excluded from study participation.

Exclusion Criteria	Rationale

4.2 Intent-to-Treat (ITT) Sample

4.3 Safety Analysis Sample

4.4 Other Samples (Optional)

5. DEFINITION OF TREATMENT ADHERENCE

6. RANDOMIZATION AND BLINDING

7. SAMPLE SIZE/POWER

8. STATISTICAL ANALYSIS

8.1 Primary Outcome Analyses

8.1.1 Missing Data

8.1.2 Multiple Comparisons

8.2 Additional Effectiveness Analyses for Primary Outcome

8.2.1 Moderators (Example)

8.2.2 Dosing and Adherence (Example)

8.3 Secondary Outcome Analyses

8.4 Exploratory Analyses on Tertiary Outcomes

9. ECONOMICS ANALYSES (OPTIONAL)

10. SAFETY MONITORING ANALYSES

10.1 Adverse Event

10.2 Serious Adverse Event

10.3 AE/SAE Reporting Procedure

10.4 Safety Outcomes

10.5 Descriptive Safety Analysis

11. INTERIM ANALYSES

12. REFERENCES