Roche Generic Example

1 PROTOCOL SUMMARY

AP1234

1.1 Protocol Synopsis

1.2 Trial Schema

1.3 Schedule of Activities

2 INTRODUCTION

2.1 Purpose of Trial

2.2 Summary of Benefits and Risks

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3 TRIAL OBJECTIVES, ENDPOINTS AND ESTIMANDS

3.1 Primary Objectives

Primary Objective	Primary Endpoint
The primary efficacy objective for this study is to evaluate the efficacy of TCZ compared with placebo in combination with SOC for the treatment of severe COVID-19 pneumonia	Clinical status assessed using a 7-category ordinal scale at Day 28

4 TRIAL DESIGN

4.1 Description of Trial Design

4.1.1 Participant Input into Design

4.2 Rationale for Trial Design

4.2.1 Rationale for Comparator

4.2.2 Rationale for Adaptive or Novel Trial Design

4.2.3 Other Trial Design Considerations

4.3 Access to Trial Intervention After End of Trial

4.4 Start of Trial and End of Trial

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5 TRIAL POPULATION

5.1 Selection of Trial Population

5.2 Rationale for Trial Population

5.3 Inclusion Criteria

Inclusion criteria are:

- 1. Something
- 2. Something else

5.4 Exclusion Criteria

Exclusion criteria are:

- 1. Dont do this
- 2. And don't do that

5.5 Lifestyle Considerations

5.5.1 Meals and Dietary Restrictions

5.5.2 Caffeine, Alcohol, Tobacco, and Other Habits

5.5.3 Physical Activity

5.5.4 Other Activity

5.6 Screen Failures

6 TRIAL INTERVENTION AND CONCOMITANT THERAPY

6.1 Description of Trial Intervention

6.2 Rationale for Trial Intervention

6.3 Dosing and Administration

6.3.1 Trial Intervention Dose Modification

6.4 Treatment of Overdose

6.5 Preparation, Handling, Storage and Accountability

6.5.1 Preparation of Trial Intervention

6.5.2 Handling and Storage of Trial Intervention

6.5.3 Accountability of Trial Intervention

6.6 Participant Assignment, Randomisation and Blinding

6.6.1 Participant Assignment

6.6.2 Randomisation

6.6.3 Blinding and Unblinding

Blinding and unblinding text here please

6.7 Trial Intervention Compliance

6.8 Concomitant Therapy

6.8.1 Prohibited Concomitant Therapy

6.8.2 Permitted Concomitant Therapy

6.8.3 Rescue Therapy

6.8.4 Other Therapy

7 DISCONTINUATION OF TRIAL INTERVENTION AND PARTICIPANT WITHDRAWAL FROM TRIAL

7.1 Discontinuation of Trial Intervention

7.1.1 Criteria for Permanent Discontinuation of Trial Intervention

7.1.2 Temporary Discontinuation or Interruption of Trial Intervention

7.1.3 Rechallenge

7.2 Participant Withdrawal from the Trial

7.3 Lost to Follow-Up

7.4 Trial Stopping Rules

8 TRIAL ASSESSMENTS AND PROCEDURES

8.1 Screening/Baseline Assessments and Procedures

8.2 Efficacy Assessments and Procedures

8.3 Safety Assessments and Procedures

8.3.1 Physical Examination

8.3.2 Vital Signs

8.3.3 Electrocardiograms

8.3.4 Clinical Laboratory Assessments

8.3.5 Suicidal Ideation and Behaviour Risk Monitoring

8.4 Adverse Events and Serious Adverse Events

8.4.1 Definitions of AE and SAE

8.4.2 Time Period and Frequency for Collecting AE and SAE Information

8.4.3 Identifying AEs and SAEs

8.4.4 Recording of AEs and SAEs

8.4.5 Follow-up of AEs and SAEs

8.4.6 Reporting of SAEs

8.4.7 Regulatory Reporting Requirements for SAEs

8.4.8 Serious and Unexpected Adverse Reaction Reporting

8.4.9 Adverse Events of Special Interest

8.4.10 Disease-related Events or Outcomes Not Qualifying as AEs or SAEs

8.5 Pregnancy and Postpartum Information

8.5.1 Participants Who Become Pregnant During the Trial

8.5.2 Participants Whose Partners Become Pregnant

8.6 Medical Device Product Complaints for Drug/Device Combination Products

8.6.1 Definition of Medical Device Product Complaints

8.6.2 Recording of Medical Device Product Complaints

8.6.3 Time Period and Frequency for Collecting Medical Device Product Complaints

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8.6.4 Follow-Up of Medical Device Product Complaints

8.6.5 Regulatory Reporting Requirements for Medical Device Product Complaints

8.7 Pharmacokinetics

8.8 Genetics

8.9 Biomarkers

8.1 Immunogenicity Assessments

8.1.1 Medical Resource Utilisation and Health Economics

9 STATISTICAL CONSIDERATIONS

9.1 Analysis Sets

9.2 Analyses Supporting Primary Objective(s)

9.2.1 Statistical Model, Hypothesis, and Method of Analysis

9.2.2 Handling of Intercurrent Events of Primary Estimand(s)

9.2.3 Handling of Missing Data

9.2.4 Sensitivity Analysis

9.2.5 Supplementary Analysis

9.3 Analysis Supporting Secondary Objective(s)

9.4 Analysis of Exploratory Objective(s)

9.5 Safety Analyses

9.6 Other Analyses

9.7 Interim Analyses

9.8 Sample Size Determination

9.9 Protocol Deviations

10 GENERAL CONSIDERATIONS: REGULATORY, ETHICAL, AND TRIAL OVERSIGHT

10.1 Regulatory and Ethical Considerations

10.2 Committees

10.3 Informed Consent Process

10.4 Data Protection

10.5 Early Site Closure or Trial Termination

11 GENERAL CONSIDERATIONS: RISK MANAGEMENT AND QUALITY ASSURANCE

11.1 Quality Tolerance Limits

11.2 Data Quality Assurance

11.3 Source Data

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12 APPENDIX: ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS - DEFINITIONS, SEVERITY, AND CAUSALITY

12.1 Further Details and Clarifications on the AE Definition

12.2 Further Details and Clarifications on the SAE Definition

12.3 Severity

12.4 Causality

13 APPENDIX: DEFINITIONS AND SUPPORTING OPERATIONAL DETAILS

13.1 Contraception and Pregnancy Testing

13.1.1 Definitions Related to Childbearing Potential

13.1.2 Contraception

13.1.3 Pregnancy Testing

13.2 Clinical Laboratory Tests

13.3 Country/Region-Specific Differences

13.4 Prior Protocol Amendments

14 APPENDIX: GLOSSARY OF TERMS

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15 APPENDIX: REFERENCES

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