Case Report Forms (CRF)

Protocol: PROTO-1072 - A Phase I Study of COVID-19 Treatment

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STUDY OVERVIEW

Protocol Number:	PROTO-1072	Therapeutic Area:	Infectious Disease
Study Title:	A Phase I Study of COVID-19 Treatment	Indication:	COVID-19
Study Design:	Non-randomized, Open-label, Dose-escalation	Number of Subjects:	755
Study Duration:	74 weeks	Number of Sites:	26

This document contains blank Case Report Forms (CRFs) for clinical trial data collection. These forms are provided for educational purposes to practice SDTM annotation. Each form represents a different aspect of clinical data collection that would be mapped to SDTM domains.

TABLE OF CONTENTS

GENERAL INSTRUCTIONS

• Complete all required fields in each form
• Use black or blue ink
• Write legibly in BLOCK CAPITALS
• For dates, use DD/MMM/YYYY format (e.g., 01/JAN/2025)
• Cross out errors with a single line, initial and date the correction
• Do not use correction fluid or tape
• The investigator or authorized delegate must sign and date all completed forms

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

SCREENING/ELIGIBILITY FORM

Complete the following Screening/Eligibility information

Eligibility Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

INCLUSION CRITERIA

No.	Inclusion Criterion	Yes	No
1.	Inclusion criterion #1 text...	■	■
2.	Inclusion criterion #2 text...	■	■
3.	Inclusion criterion #3 text...	■	■
4.	Inclusion criterion #4 text...	■	■
5.	Inclusion criterion #5 text...	■	■

EXCLUSION CRITERIA

No.	Exclusion Criterion	Yes	No
1.	Exclusion criterion #1 text...	■	■
2.	Exclusion criterion #2 text...	■	■
3.	Exclusion criterion #3 text...	■	■
4.	Exclusion criterion #4 text...	■	■
5.	Exclusion criterion #5 text...	■	■

ELIGIBILITY DETERMINATION

Does the subject meet all inclusion criteria and none of the exclusion criteria?
■ Yes, subject is eligible ■ No, subject is not eligible

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

DEMOGRAPHICS FORM

Complete at screening visit

Date of Birth:	___ / ___ / _____ (DD/MMM/YYYY)
Sex:	■ Male ■ Female
Race:	■ White ■ Black or African American ■ Asian ■ American Indian or Alaska Native ■ Other
Ethnicity:	■ Hispanic or Latino ■ Not Hispanic or Latino
Height:	_____ cm
Weight:	_____ kg
Body Mass Index (BMI):	_____ kg/m²

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

MEDICAL HISTORY FORM

Record all relevant medical history. Include significant past and ongoing conditions.

Medical Condition/Disease: _____

Start Date (DD/MMM/YYYY):	___ / ___ / _____ ■ Unknown	End Date (DD/MMM/YYYY):	___ / ___ / _____ ■ Ongoing
Is condition currently active?	■ Yes ■ No	Severity:	■ Mild ■ Moderate ■ Severe
Treatment for condition:	■ Yes ■ No	If Yes, specify:	_____ _____

Additional Details (diagnosis, symptoms, relevant tests, procedures, etc.):

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

PHYSICAL EXAMINATION FORM

Examination Date: ___ / ___ / _____ (DD/MMM/YYYY)

Body System	Normal	Abnormal	Not Examined	If Abnormal, provide details
General Appearance	■	■	■	
Skin	■	■	■	
HEENT	■	■	■	
Lymph Nodes	■	■	■	
Cardiovascular	■	■	■	
Respiratory	■	■	■	
Abdomen	■	■	■	
Musculoskeletal	■	■	■	
Neurological	■	■	■	
Other (specify):	■	■	■	

Are any abnormal findings clinically significant? ■ Yes ■ No

Additional Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

VITAL SIGNS FORM

Measurement Date and Time: ___ / ___ / _____ ___:___ (DD/MMM/YYYY HH:MM 24-hour format)

Position: ■ Sitting ■ Supine ■ Standing

Parameter	Result	Units	Clinically Significant
Temperature	_____	°C	■ Yes ■ No
Systolic Blood Pressure	_____	mmHg	■ Yes ■ No
Diastolic Blood Pressure	_____	mmHg	■ Yes ■ No
Heart Rate	_____	bpm	■ Yes ■ No
Respiratory Rate	_____	breaths/min	■ Yes ■ No
Weight	_____	kg	■ Yes ■ No
Height	_____	cm	■ Yes ■ No

If any clinically significant findings, please specify:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

ECG ASSESSMENT FORM

ECG Date and Time: ___ / ___ / _____ ___:___ (DD/MMM/YYYY HH:MM 24-hour format)

Position: ■ Supine ■ Semi-recumbent ■ Other (specify): _____

Parameter	Result	Units	Reference Range	Abnormal
Heart Rate	_____	bpm	_____	■ Yes ■ No
PR Interval	_____	msec	_____	■ Yes ■ No
QRS Duration	_____	msec	_____	■ Yes ■ No
QT Interval	_____	msec	_____	■ Yes ■ No
QTc Interval	_____	msec	_____	■ Yes ■ No

Overall Interpretation:

■ Normal ■ Abnormal, not clinically significant ■ Abnormal, clinically significant

If abnormal, describe abnormalities:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

LABORATORY TESTS FORM

Sample Collection Date and Time: ___ / ___ / _____ ___:___ (DD/MMM/YYYY HH:MM 24-hour format)

Sample Type: ■ Blood ■ Urine ■ Other (specify): _____

Fasting Status: ■ Fasting (≥8 hours) ■ Non-fasting

Test	Result	Units	Reference Range	Abnormal
HEMATOLOGY				
Hemoglobin	_____	_____	_____	■ High ■ Low ■ Normal
Hematocrit	_____	_____	_____	■ High ■ Low ■ Normal
Red Blood Cells (RBC)	_____	_____	_____	■ High ■ Low ■ Normal
White Blood Cells (WBC)	_____	_____	_____	■ High ■ Low ■ Normal
Neutrophils	_____	_____	_____	■ High ■ Low ■ Normal
Lymphocytes	_____	_____	_____	■ High ■ Low ■ Normal
Monocytes	_____	_____	_____	■ High ■ Low ■ Normal
Eosinophils	_____	_____	_____	■ High ■ Low ■ Normal
Basophils	_____	_____	_____	■ High ■ Low ■ Normal
Platelets	_____	_____	_____	■ High ■ Low ■ Normal
CHEMISTRY				
Glucose	_____	_____	_____	■ High ■ Low ■ Normal
BUN	_____	_____	_____	■ High ■ Low ■ Normal
Creatinine	_____	_____	_____	■ High ■ Low ■ Normal
Total Bilirubin	_____	_____	_____	■ High ■ Low ■ Normal
AST	_____	_____	_____	■ High ■ Low ■ Normal
ALT	_____	_____	_____	■ High ■ Low ■ Normal
Alkaline Phosphatase	_____	_____	_____	■ High ■ Low ■ Normal
Total Protein	_____	_____	_____	■ High ■ Low ■ Normal
Albumin	_____	_____	_____	■ High ■ Low ■ Normal
Sodium	_____	_____	_____	■ High ■ Low ■ Normal
Potassium	_____	_____	_____	■ High ■ Low ■ Normal
Chloride	_____	_____	_____	■ High ■ Low ■ Normal
Calcium	_____	_____	_____	■ High ■ Low ■ Normal

Comments on clinically significant findings:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

CONCOMITANT MEDICATIONS FORM

Medication Name: _____

Start Date (DD/MMM/YYYY):	___ / ___ / _____	End Date (DD/MMM/YYYY):	___ / ___ / _____ ■ Ongoing
Dose:	_____	Units:	_____
Frequency:	■ Once ■ BID ■ TID ■ QID ■ PRN ■ Other (specify): _____	Route:	■ Oral ■ IV ■ IM ■ SC ■ Topical ■ Other (specify): _____

Indication: _____

Taken for Adverse Event?

■ Yes (specify AE): _____ ■ No

Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

STUDY TREATMENT ADMINISTRATION FORM

Study Treatment Name: _____

Administration Date (DD/MMM/YYYY):	___ / ___ / _____	Administration Time:	___:___ (24-hour format)
Dose Level:	_____	Units:	_____
Route:	■ Oral ■ IV ■ IM ■ SC ■ Other: _____	Batch/Lot Number:	_____
Dose administered completely?	■ Yes ■ No	If No, actual dose administered:	_____

Was there a compliance issue? ■ Yes ■ No

If Yes, specify reason:

■ Adverse Event ■ Protocol Deviation ■ Lost Medication ■ Forgot to Take
■ Other (specify): _____

Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

ADVERSE EVENTS FORM

Adverse Event Term: _____

Start Date (DD/MMM/YYYY):	___ / ___ / _____	End Date (DD/MMM/YYYY):	___ / ___ / _____ ■ Ongoing
Severity/Intensity:	■ Mild ■ Moderate ■ Severe	Action Taken with Study Treatment:	■ None ■ Interrupted ■ Discontinued
Serious:	■ Yes ■ No	If Yes, SAE Report Completed:	■ Yes ■ No ■ N/A
Relationship to Study Treatment:	■ Not Related ■ Unlikely ■ Possible ■ Probable ■ Definite	Outcome:	■ Recovered/Resolved ■ Recovering/Resolving ■ Not Recovered/Not Resolved ■ Recovered with Sequelae ■ Fatal ■ Unknown

If Serious, indicate reason(s):

■ Death ■ Life-threatening ■ Hospitalization (initial or prolonged)
■ Disability/Incapacity ■ Congenital Anomaly/Birth Defect
■ Important Medical Event ■ Other (specify): _____

Description of Adverse Event (including relevant history, diagnostic tests/procedures):

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

SERIOUS ADVERSE EVENTS FORM

Complete the following Serious Adverse Events information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Serious Adverse Events Details:

Parameter	Value/Finding	Units	Comments
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Additional Notes/Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

EFFICACY ASSESSMENTS FORM

Complete the following Efficacy Assessments information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Assessment	Result/Score	Units	Clinically Significant Change
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A
_____	_____	_____	■ Yes ■ No ■ N/A

Comments on assessments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

QUALITY OF LIFE QUESTIONNAIRE FORM

Complete the following Quality of Life Questionnaire information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Questionnaire Type: ■ SF-36 ■ EQ-5D ■ FACT ■ Other: _____

Domain	Score	Range	Comments
Physical Functioning	_____	_____	
Role-Physical	_____	_____	
Bodily Pain	_____	_____	
General Health	_____	_____	
Vitality	_____	_____	
Social Functioning	_____	_____	
Role-Emotional	_____	_____	
Mental Health	_____	_____	
Overall Score	_____	_____	

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

STUDY COMPLETION/EARLY TERMINATION FORM

Date of Assessment: ___ / ___ / _____ (DD/MMM/YYYY)

Study Status:

■ Completed ■ Early Termination

If Early Termination, primary reason:

■ Adverse Event ■ Death ■ Protocol Violation ■ Lost to Follow-up
■ Withdrawal of Consent ■ Study Terminated by Sponsor ■ Physician Decision
■ Other (specify): _____

If Adverse Event, specify:

Were all End of Study procedures completed? ■ Yes ■ No

If No, specify procedures not completed and reason:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

PROTOCOL DEVIATION FORM

Complete the following Protocol Deviation information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Protocol Deviation Details:

Parameter	Value/Finding	Units	Comments
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Additional Notes/Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

HOSPITALIZATION FORM

Complete the following Hospitalization information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Hospitalization Details:

Parameter	Value/Finding	Units	Comments
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Additional Notes/Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____

Protocol ID:	PROTO-1072	Site ID:	_____
Subject ID:	_____	Visit:	_____

DISEASE-SPECIFIC ASSESSMENTS FORM

Complete the following Disease-Specific Assessments information

Assessment Date: ___ / ___ / _____ (DD/MMM/YYYY)

Disease-Specific Assessments Details:

Parameter	Value/Finding	Units	Comments
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Additional Notes/Comments:

Name of Person Completing Form:	_____
Signature:	_____
Date (DD/MMM/YYYY):	_____