

Case Report Forms (CRF)

Protocol: PROTO-2661 - A Phase IV Study of Psoriasis Treatment

Version 1.5 - Generated 2025-04-19

STUDY OVERVIEW

Protocol Number:	PROTO-2661	Therapeutic Area:	Dermatology
Study Title:	A Phase IV Study of Psoriasis Treatment	Indication:	Psoriasis
Study Design:	Non-randomized, Open-label, Dose-escalation	Number of Subjects:	732
Study Duration:	6 weeks	Number of Sites:	40

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.

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- 16. Hospitalization
- 17. Disease-Specific Assessments

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-2661	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...	<input type="checkbox"/>	<input type="checkbox"/>
2.	Inclusion criterion #2 text...	<input type="checkbox"/>	<input type="checkbox"/>
3.	Inclusion criterion #3 text...	<input type="checkbox"/>	<input type="checkbox"/>
4.	Inclusion criterion #4 text...	<input type="checkbox"/>	<input type="checkbox"/>
5.	Inclusion criterion #5 text...	<input type="checkbox"/>	<input type="checkbox"/>

EXCLUSION CRITERIA

No.	Exclusion Criterion	Yes	No
1.	Exclusion criterion #1 text...	<input type="checkbox"/>	<input type="checkbox"/>
2.	Exclusion criterion #2 text...	<input type="checkbox"/>	<input type="checkbox"/>
3.	Exclusion criterion #3 text...	<input type="checkbox"/>	<input type="checkbox"/>
4.	Exclusion criterion #4 text...	<input type="checkbox"/>	<input type="checkbox"/>
5.	Exclusion criterion #5 text...	<input type="checkbox"/>	<input type="checkbox"/>

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-2661	Site ID:	_____
Subject ID:	_____	Visit:	_____

DEMOGRAPHICS FORM

Complete at screening visit

Date of Birth:	___ / ___ / _____ (DD/MMM/YYYY)
Sex:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Race:	<input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Other
Ethnicity:	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino
Height:	_____ cm
Weight:	_____ kg
Body Mass Index (BMI):	_____ kg/m ²

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

Protocol ID:	PROTO-2661	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.):

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

Protocol ID:	PROTO-2661	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:

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

Protocol ID:	PROTO-2661	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	<input type="checkbox"/> Yes <input type="checkbox"/> No
Systolic Blood Pressure	_____	mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Diastolic Blood Pressure	_____	mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Heart Rate	_____	bpm	<input type="checkbox"/> Yes <input type="checkbox"/> No
Respiratory Rate	_____	breaths/min	<input type="checkbox"/> Yes <input type="checkbox"/> No
Weight	_____	kg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Height	_____	cm	<input type="checkbox"/> Yes <input type="checkbox"/> No

If any clinically significant findings, please specify:

--

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

Protocol ID:	PROTO-2661	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	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
PR Interval	_____	msec	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
QRS Duration	_____	msec	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
QT Interval	_____	msec	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
QTc Interval	_____	msec	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

Overall Interpretation:

☐ Normal ☐ Abnormal, not clinically significant ☐ Abnormal, clinically significant

If abnormal, describe abnormalities:

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

Protocol ID:	PROTO-2661	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	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Hematocrit	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Red Blood Cells (RBC)	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
White Blood Cells (WBC)	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Neutrophils	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Lymphocytes	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Monocytes	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Eosinophils	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Basophils	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Platelets	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
CHEMISTRY				
Glucose	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
BUN	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Creatinine	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Total Bilirubin	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
AST	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
ALT	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Alkaline Phosphatase	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Total Protein	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Albumin	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Sodium	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Potassium	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Chloride	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal
Calcium	_____	_____	_____	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Normal

Comments on clinically significant findings:

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

Protocol ID:	PROTO-2661	Site ID:	_____
Subject ID:	_____	Visit:	_____

CONCOMITANT MEDICATIONS FORM

Medication Name: _____

Start Date (DD/MMM/YYYY):	___ / ___ / _____	End Date (DD/MMM/YYYY):	___ / ___ / _____ <input type="checkbox"/> Ongoing
Dose:	_____	Units:	_____
Frequency:	<input type="checkbox"/> Once <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN <input type="checkbox"/> Other (specify): _____	Route:	<input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> Topical <input type="checkbox"/> Other (specify): _____

Indication: _____

Taken for Adverse Event?

☐ Yes (specify AE): _____ ☐ No

Comments:

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

Protocol ID:	PROTO-2661	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:	<input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> Other: _____	Batch/Lot Number:	_____
Dose administered completely?	<input type="checkbox"/> Yes <input type="checkbox"/> 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:

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

Protocol ID:	PROTO-2661	Site ID:	_____
Subject ID:	_____	Visit:	_____

ADVERSE EVENTS FORM

Adverse Event Term: _____

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

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

Protocol ID:	PROTO-2661	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-2661	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
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
_____	_____	_____ _____ —	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Comments on assessments:

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

Protocol ID:	PROTO-2661	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-2661	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-2661	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-2661	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-2661	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):	_____