



Oxford University Hospitals
NHS Foundation Trust

Data collection User Guide for the UK-wide myeloma outcome study of belantamab mafodotin

(Dr Faouzi Djebbari and Dr Grant Vallance)

**Oxford University Hospitals NHS Foundation Trust
December 2021**

Data collection from each of the different participating centres requires registering each patient on the portal, then collecting data electronically:

Step 1: patient registration followed by baseline patient and disease characteristics data, and baseline ocular assessment

Step 2: data entry for the following sections:

- Belantamab treatment
- Belantamab toxicity
- Ophthalmology follow ups
- Subsequent treatment
- Survival data and follow up

This guide will show you step-by-step how to enter data

Logging into the data collection portal



OpenClinica recommends using the latest version of Chrome, Firefox or Internet Explorer. While OpenClinica is designed to work on all standards-compliant browsers, we have not verified that the application functions correctly on other browsers or browser versions. If you do not have one of the above browsers installed you may need to contact your IT support group for assistance.

Login

User Name

Password

[Forgot Password?](#)

News

► Could not retrieve news.

In order to log in enter your given username and password, issued to you by Oxford Team managing this platform



Subject Matrix List to register patient and enter data

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/MainMenu

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | **Subject Matrix** | Notes & Discrepancies | Study Audit Log | Tasks

Support: Study Subject ID Go

Welcome to Belantamab Real-world

Notes & Discrepancies Assigned to Me: 0

Subject Enrollment By Site

Site	Enrolled	Expected Enrollment	Percentage
Oxford	0	20	0%

Subject Enrollment For Study

Study	Enrolled	Expected Enrollment	Percentage
Belantamab 1 Real-world	1	100	1%

Study Progress

Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	0	0%
completed	0	0%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Subject Status Count

Study Subject Status	# of Study Subjects	Percentage
available	1	100%
signed	0	0%
removed	0	0%

Alerts & Messages

Welcome to OpenClinica, Faouzi Djebbari. You last logged in on 11-Nov-2021.

Instructions

If needed you may change the study/site or request access to a new study with a different role.

Other Info

Study: Belantamab Real-world

Start Date: 29-Sep-2021

End Date: N/A

PI: Faouzi Djebbari

Protocol Verification/IRB Approval Date:

Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

Actions

- View
- Edit
- Remove
- Refresh

**On the front home page
Select Subject Matrix**

Registering a New Subject to start registration

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/ListStudySubjects

OpenClinica

Belantamab Real-world (proj_nmmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support Study Subject ID Go

Alerts & Messages

Instructions

Info

Icon Key

Statutes

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

signed

Locked

Invalid

Actions

View

Edit

Remove

Restore

Reassign

Sign

View All Icons

Subject Matrix for Belantamab Real-world

15 Show More Select An Event Add New Subject

Study Subject ID	Registration	Data Entry	Actions
OX-1			Apply Filter Clear Filter

Results 1 - 1 of 1.

Select add new subject to start data entry

Registering a New Subject to start registration and data entry

The screenshot shows the 'Add New Subject' form in the OpenClinica web application. The form includes the following fields and options:

- Study Subject ID:** A text input field.
- Person ID:** A text input field.
- Enrollment Date:** A date picker set to '11-Nov-2021'.
- Sex:** A dropdown menu with '-Select-' selected.
- Date of Birth:** A date picker.
- Study Event:** A dropdown menu with 'Registration' selected.
- Start Date:** A date picker set to '11-Nov-2021'.
- Buttons:** 'Add' and 'Cancel' buttons at the bottom of the form.

Four red arrows point from the explanatory text on the right to the following elements:

- Arrow 1 points to the **Study Subject ID** and **Person ID** fields.
- Arrow 2 points to the **Study Event** dropdown menu.
- Arrow 3 points to the **Add** button.
- Arrow 4 points to the **Enrollment Date** field.

Enter allocated subject ID. The subject ID must be anonymous with no patient identifiable information. It is usually a 3 letter word for your hospital (e.g. Oxford is OXF), followed by a number for each patient, e.g. OXF-1, OXF-2, etc.

Your 3 letter centre name is provided to you with your username and password for this database

Select "Registration" option

Enrolment date is the date of registration onto the database (i.e. today's date) . Select "registration" for study event. Start date is also the date of registration onto the database (i.e. today's date). Click add

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Entering Subject Baseline Patient Characteristics

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/AddNewSubject

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site fdjebbbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks Support Study Subject ID Go

Alerts & Messages

The Subject with unique identifier 'Test001' was created successfully.

Instructions

Other Info

Study: Belantamab Real-world

Study Subject ID: Test001

Start Date: 29-Sep-2021

End Date: N/A

PI: Faouzi Djebbbari

Protocol Verification/IRB Approval Date:

Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

Actions









































- View
- Edit
- Remove
- Restore
- Reassign
- Sign

View Subject: Test001

Study Subject Record

Events

Page 1 of 1 Find Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)									
Registration	11-Nov-2021		scheduled	   	<table><tbody><tr><td>1-Proj-MMY-98-Baseline-Patient-Characteristics</td><td>0.1</td><td></td></tr><tr><td>2-Proj-MMY-98-Baseline-Occular-Assessments</td><td>0.1</td><td></td></tr><tr><td>3-Proj-MMY-98-Baseline-Disease-Characteristics</td><td>0.2</td><td></td></tr></tbody></table>	1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	   	2-Proj-MMY-98-Baseline-Occular-Assessments	0.1	   	3-Proj-MMY-98-Baseline-Disease-Characteristics	0.2	   
1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	   												
2-Proj-MMY-98-Baseline-Occular-Assessments	0.1	   												
3-Proj-MMY-98-Baseline-Disease-Characteristics	0.2	   												

Go Back to Subject List

Once you have registered a subject as per previous slide, it will take you directly onto this baseline patient characteristics page. Click on the “enter data” tab

Entering Subject Baseline Patient Characteristics (diagnosis date and PS)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry?eventDefinitionCRFid=1& OpenClinica Initial Data Entry

1-Proj-MMY-98-Baseline-Patient-Characteristics 0.1 Test001

CRF Header Info

Disease (0/3) Comorbi... (0/19) Lab (0/9) -- Select to Jump --

Title: Disease

Page: Save Exit

Myeloma Diagnosis Date: 03-Nov-2014

Performance Status

Date:

ECOG Please enter

Return to top Save Exit

Date of initial myeloma diagnosis

Date of PS assessment closest to the time of starting belantamab

Once the form has been completed, click “save” to save data you entered

You will then be moved to the co-morbidities section of Baseline Patient characteristics

Entering Subject Baseline Patient Characteristics (co-morbidities)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Disease (3/3) Comorbi... (0/19) Lab (0/9) -- Select to Jump --

Title: Comorbidities

Page: Save Exit

Comorbidities

Age: Select No

Myocardial Infarction: Select No History of definite or probable MI (EKG changes and/or enzyme changes)

Congestive Heart Failure: Select No Exertional or paroxysmal nocturnal dyspnea and has responded to digitalis, diuretics, or afterload reducing agents

Peripheral Vascular Disease: Select No Intermittent claudication or past bypass for chronic arterial insufficiency, history of gangrene or acute arterial insufficiency, or untreated thoracic or abdominal aneurysm (≥6 cm)

Cerebrovascular Accident / Transient Ischaemic Attack: Select No

Dementia: Select No Chronic cognitive deficit

Chronic Obstructive Pulmonary Disease: Select No

Connective Tissue Disease: Select No

Peptic Ulcer Disease: Select No Any history of treatment for ulcer disease or history of ulcer bleeding

Liver Disease: Select No Severe = cirrhosis and portal hypertension with variceal bleeding history, moderate = cirrhosis and portal hypertension but no variceal bleeding history, mild = chronic hepatitis (or cirrhosis without portal hypertension)

Diabetes Mellitus: Select No

Hemiplegia: Select No

Moderate to Severe Chronic Kidney Disease: Select No Severe = on dialysis, status post kidney transplant, uremia, moderate = creatinine >3 mg/dL (0.27 mmol/L)

Solid Tumour: Select No

Leukaemia: Select No

Lymphoma: Select No

AIDS: Select No

Calculate the score via: <https://www.mdcalc.com/charlson-comorbidity-index-cci>

Charlson Score: No

Charlson Category: Select No

Return to top Save Exit

Co-morbidities, closest to the time of starting belantamab

Using the link, calculate CCI score based on data provided

Once the form has been completed, click “save” to save data you entered. You will then be moved to the lab data section of Baseline Patient characteristics

Entering Subject Baseline Patient Characteristics (lab data)



1-Proj-MMY-98-Baseline-Patient-Characteristics 0.1

Test001

▼ CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Navigation: Disease (3/3) | Comorbi...(19/19) | Lab (0/9) | -- Select to Jump --

Title: Lab

Page: Save Exit

Bloods Date: 01-Nov-2021

Creatinine: 123 (micromol/L)

e-GFR: 51

e-GFR Category: 30-59

Anaemia: Yes

Lymphopenia: No

Hypercalcaemia: Yes

Neutropenia: No

Thrombocytopenia: No

Return to top Save Exit

Lab data right prior to starting belantamab (or most recent available data)

Once the form has been completed, click save to be moved to eye history tab

Entering Subject Baseline Patient Characteristics (eye history)



1-Proj-MMY-98-Baseline-Patient-Characteristics 0.1

Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Comorbi...(19/19) Lab (9/9) Eye His...(0/4) -- Select to Jump --

Title: Eye History

Page: ☒ Mark CRF Complete

Glaucoma: No

Cataracts: Yes

Blepharitis: No

Dry Eyes: Yes

Return to top ☒ Mark CRF Complete

Eye history at baseline, prior to starting belantamab

Once the form has been completed, tick the box "mark CRF as complete" then click save to be move on to next section (ocular assessments)

Both steps are very important especially marking CRF as complete.

Entering Subject Baseline Ocular assessments

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/ViewStudySubject?id=2

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support Study Subject ID Go

Alerts & Messages

Instructions

Other Info

Study: Belantamab Real-world

Start Date: 29-Sep-2021

End Date: N/A

PI: Fauzi Djebbari

Protocol Verification/IRB Approval Date:

Icon Key

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

signed

Locked

Invalid

Actions

View

Edit

Remove

Restore

Reassign

Sign

View All Icons

View Subject: Test001









Study Subject Record

Events

Page 1 of 1

Find

Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Registration	11-Nov-2021		data entry started	  	<div>2-Proj-MMY-98-Baseline-Ocular-Assessments 0.1  3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2  1-Proj-MMY-98-Baseline-Patient-Characteristics 0.1 <input checked="" type="checkbox"/> 11-Nov-2021 (fdjebbari)   </div>

Group

Global Subject Record

Subject Casebook

Go Back to Subject List

Click here to start entering baseline ocular assessments

Because we ticked the box “mark CRF as complete” in the previous page, you can see that baseline patient characteristics section is ticked in green, meaning data entry is complete

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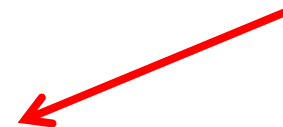
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Entering Subject Ocular Assessments data

The screenshot shows the 'OpenClinica Initial Data Entry' web application in Internet Explorer. The browser address bar displays the URL: <https://belantamab.myloma-research.org.uk/test/InitialDataEntry?eventDefinitionCRFId=28>. The form is titled 'Chemosis (left eye):' and contains two main sections: 'Right Eye' and 'Left Eye'. Each section includes dropdown menus for 'Conjunctival Injection (right eye):', 'Chemosis (right eye):', 'Corneal Epithelium (left eye):', 'Punctate Keratopathy (left eye):', 'Epithelial Oedema (left eye):', 'Stroma (left eye):', 'Stroma Active Opacity (left eye):', 'Stroma Active Oedema (left eye):', and 'Endothelium (left eye):'. There are also text areas for 'Endothelium (left eye) Comments:'. At the bottom of the form, there is a checkbox labeled 'Mark CRF Complete', a 'Save' button, and an 'Exit' button. A 'Return to top' link is also present.

All this data is usually provided by ophthalmology team from their review, and from ocular assessment worksheet



Once the form has been completed, tick the box “mark CRF as complete” then click save to be moved to baseline disease characteristics

Both steps are very important especially marking CRF as complete.

Entering Subject Baseline Disease characteristics

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site

fdjebbbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support | Study Subject ID | Go

Alerts & Messages

Your data has been saved and the CRF was marked complete.

Instructions

Study Events

Study Events: (1)

Registration

Status: data entry started

1-Proj-MMY-98 -Baseline-Patient-Characteristics 0.1

2-Proj-MMY-98 -Baseline-Occular-Assessments 0.1

3-Proj-MMY-98-Baseline-Disease-Characteristics

Enter or Validate Data for CRFs in Registration

Edit Study Event

Study Subject ID	Test001
Study Event	Registration
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	11-Nov-2021
Subject Event Status	data entry started
Last Updated by	fdjebbbari (11-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
3-Proj-MMY-98-Baseline-Disease-Characteristics	0.2				
1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	✓	fdjebbbari	n/a	
2-Proj-MMY-98-Baseline-Occular-Assessments	0.1	✓	fdjebbbari	n/a	

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Because we ticked the box "mark CRF as complete" in the previous page, you can see that baseline ocular assessments section is ticked in green, meaning data entry is complete

Click here to start entering baseline disease characteristics

Entering Subject Baseline Disease Characteristics (**Disease**)



3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2

Test001

▼ CRF Header Info

Navigation: Disease (0/4) | Lab (0/7) | Cytogen... (0/5) | -- Select to Jump --

Title: Disease

Page:

Disease

MM Subtype:

Amyloidosis?:

Plasma cell leukaemia?:

Extramedullary disease present?:

Return to top

Baseline disease data just prior to starting belantamab

Once the form has been completed, click “save” to save data you entered

You will then be moved to the lab data section of Baseline Disease characteristics

Entering Subject Baseline Disease Characteristics (lab data)



3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2

Test001

▼ CRF Header Info

« Disease (4/4) Lab (0/7) Cytogen... (0/5) » -- Select to Jump --

Title: Lab

Page:

Lab

Bloods Date: 01-Nov-2021

Albumin: 43 g/L

Albumin Category: ≥35g/l

B2M: 3.8 mg/L

B2M Category: 3.5-5.4

LDH: 290 u/L

LDH Elevated: Yes

Return to top

Baseline data just prior to
starting belantamab (or
most recent available data)

Once the form has been completed, click “save” to save data you entered

You will then be moved to the cytogenetics section of Baseline Disease characteristics

Entering Subject Baseline Disease Characteristics (Cytogenetics)



3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2

Test001

▼ CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Navigation: Disease (4/4) | Lab (7/7) | Cytogen... (0/5) | -- Select to Jump --

Title: Cytogenetics

Page:

NB. All known cytogenetic abnormalities

Bone Marrow Date: 01-Nov-2021

Percentage Plasma Cells: 45 (%)

Cytogenetics
Cytogenetic Risk: 1 - High Risk

Cytogenetics Abnormalities:

- ☐ t(4;14)
- ☐ t(14;16)
- ☐ t(14;20)
- ☒ del(17p)
- ☐ 1p loss
- ☐ 1qgain/amp
- ☐ del 13q
- ☐ Hypodiploidy
- ☐ Other (specify)
- ☐ Unknown

Cytogenetics Other Abnormalities: also

Return to top

Date and result of last bone marrow

All known cytogenetic data since diagnosis

Once the form has been completed, click “save” to save data you entered

You will then be moved to ISS and R-ISS section of Baseline Disease characteristics

Entering Subject Baseline Disease Characteristics (Staging)

3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2

Test001

▼ CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

◀ Cytogen...(5/5) Staging (0/2) Symptoms (0/2) ▶ -- Select to Jump -- ▼

Title: Staging

Page: Save Exit

Staging

You can calculate R-ISS staging via: <https://www.mdcalc.com/revised-multiple-myeloma-international-staging-system-r-iss>

ISS Staging Stage II

R-ISS Staging Stage II

Return to top Save Exit

Staging based on data collected, use link provided to stage ISS and R-ISS

Once the form has been completed, click “save” to save data you entered

You will then be moved to symptoms section of Baseline Disease characteristics

Entering Subject Baseline Disease Characteristics (Symptoms)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry

3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2 Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Cytogen... (5/5) Staging (2/2) Symptoms (0/2) -- Select to Jump --

Title: Symptoms

Page: ☒ Mark CRF Complete Save Exit

Symptoms at time of starting belantamab

Fatigue? Yes

Pain? Yes

Return to top ☒ Mark CRF Complete Save Exit

Symptoms just prior to starting belantamab

Once the form has been completed, tick “mark CRF as complete” then click save data you entered. This complete baseline disease data entry

You will then be moved to symptoms section of Baseline Disease characteristics

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/EnterDataForStudyEvent?eventId=1

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | **Subject Matrix** | Notes & Discrepancies | Study Audit Log | Tasks

Support: Study Subject ID Go

Alerts & Messages

Instructions

Info

Study Events

Study Events: (1)

Registration

Status: completed













- 1-Proj-MMY-98-Baseline-Patient-Characteristics 0.1
- 2-Proj-MMY-98-Baseline-Occular-Assessments 0.1
- 3-Proj-MMY-98-Baseline-Disease-Characteristics 0.2

Enter or Validate Data for CRFs in Registration

Edit Study Event

Study Subject ID	Test001
Study Event	Registration
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	11-Nov-2021
Subject Event Status	completed
Last Updated by	fdjebbari (11-Nov-2021)

CRFs in this study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	   
2-Proj-MMY-98-Baseline-Occular-Assessment	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	   
3-Proj-MMY-98-Baseline-Disease-Characteristics	0.2	<input checked="" type="checkbox"/>	fdjebbari	n/a	   

View this Subject's Record Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

If boxes are ticked in green, this means data is complete. If box is in orange, it means you saved some data but you have not completed all entries or you have not ticked the box "Mark CRF as complete"

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Click on subject matrix to start accessing treatment data platform

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/LetStudySubjects

OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site | fdjebbani (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support | Study Subject ID | Go

Subject Matrix for Belantamab Real-world

15 | Show More | Select An Event | Add New Subject

Study Subject ID	Registration	Data Entry	Actions
OX-1			Apply Filter Clear Filter
Test001			

Results 1 - 2 of 2.

Click this data entry folder, then click "schedule option" to prepare starting data entry

OpenClinica - Internet Explorer

https://belantamab.myloma-research.org.uk/test/CreateNewStudyEvent?studySubject

OpenClinica

Belantamab Real-world (proj_rmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support Study Subject ID Go

OpenClinica Community Edition

Alerts & Messages

Instructions

Other Info

Study: Belantamab Real-world

Start Date: 29-Sep-2021

End Date: N/A

PI: Faouzi Djebbari

Protocol Verification/IRB Approval Date:

Schedule Study Event for Test001

* indicates required field.

Study Subject ID: **Test001**

Study Event Definition: Data Entry (Non-repeating)

Start Date/Time: 11-Nov-2021 : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM) *

Leave this field blank if the end date/time is not applicable.

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

Proceed **Enter Data** **Cancel**

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de733e3ae6ca 2020-07-08 18:28 +0000

Leave end date blank, and click "Proceed to Enter Data" to start entering treatment data

- Alerts & Messages
- Instructions
- Info
- Study Events
 - Study Events: (2)
 - Registration
 - Data Entry
 - Status: data entry started
 - 5-Proj-MMY-98-Treatments-Toxicity
 - 6-Proj-MMY-98-Ophthalmology-Follow-ups
 - 7-Proj-MMY-98-Subsequent-Treatments
 - 8-Proj-MMY-98-Survival-Data
 - 4-Proj-MMY-98-Belantamab-Treatment

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test002
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST002
Start Date	16-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (16-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
5-Proj-MMY-98-Treatments-Toxicity	0.1				
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1				
7-Proj-MMY-98-Subsequent-Treatments	0.1				
8-Proj-MMY-98-Survival-Data	0.2				
4-Proj-MMY-98-Belantamab-Treatment	0.1		fdjebbari		

View this Subject's Record Exit

Workflow



Click on this folder to start entering belantamab treatment data

Belantamab Treatment data (dosing and response)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry?action=ide_s8eventDefini

OpenClinica Initial Data Entry

4-Proj-MMY-98-Belantamab-Treatment 0.1

Test002

CRF Header Info

Belanta...(0/20) Prior T...(0/8) Prior T...(0/1) -- Select to Jump --

Title: Belantanab

Page: Save Exit

Belantanab

Belantanab Start Date: 09-Nov-2020

Belantanab End Date: 07-Nov-2021 If treatment is ongoing, leave blank

Belantanab Number of Cycles Received: 14

Belantanab Dosing

Preservative-free Eyedrops: Yes

Cooling Eye Mask: Yes

Bandage Contact Lens: Yes

Starting Dose: 2.5mg/kg

Dose Reduction: Yes

New (reduced) Dose: 1.9mg/kg

New (reduced) Dose Comment: reduced due to G3 keratopathy

Reduction in Frequency? Other

Reduction Reason: 8-weekly

Prophylaxis

PCP Prophylaxis?: Yes

Antiviral Prophylaxis?: Yes

Fungal Prophylaxis?: Yes

Best response achieved to date

Enter all data where applicable and provide additional info where permitted on the form

Once complete, click save

This will take you to "prior treatments" section

Prior Treatments data

4-Proj-MMY-98-Belantamab-Treatment 0.1

Test002

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Belanta... (20/20) Prior T... (0/8) Prior T... (0/1) -- Select to Jump --

Title: Prior Treatment

Page: Save Exit

Prior Treatment

Prior Treatment	Treatment Line Number:	Treatment Line Description:	Treatment Date Start:	Treatment Date End:	Number of Cycles:	Best Response:	Relapse Date:
VCD	1	VCD x6 to VGPR	02-Nov-2015	02-Feb-2016	6	VGPR	29-Nov-2017
CTDa	2	CTDa x5 to PR	30-Nov-2017	07-May-2018	6	PR	11-Nov-2018

Add

Return to top

Save Exit

Enter prior lines of therapy by name and details, starting from 1st line therapy, to 2nd to 3rd etc, in chronological order, click add to add more lines

Once complete, click save

This will take you to “prior transplant” section

Prior Transplant data

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry

4-Proj-MMY-98-Belantamab-Treatment 0.1

Test002

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Belanta... (20/20) Prior T... (16/16) Prior T... (0/1) -- Select to Jump --

Title: Prior Treatment

Page: ☒ Mark CRF Complete Save Exit

Prior Transplant? Yes

Return to top ☒ Mark CRF Complete Save Exit

There is only 1 data item in this section

Once the form has been completed, tick “mark CRF as complete” then click save data you entered. This complete treatment data entry

You will then be moved to choose treatment toxicity folder

Alerts & Messages

Your data has been saved
and the CRF was marked
complete.

Instructions

Info

Study Events

Study Events: (2)

Registration

Data Entry

Status: data entry
started

4-Proj-MMY-98
-IsaPomDex-
Treatment 0.1

5-Proj-MMY-
98-Treatments-
Toxicity

6-Proj-MMY-
98-Ophthalmology
-Follow-ups

7-Proj-MMY-
98-Subsequent-
Treatments

8-Proj-MMY-
98-Survival-Data

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test001
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (12-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
5-Proj-MMY-98-Treatments-Toxicity	0.1				
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1				
7-Proj-MMY-98-Subsequent-Treatments	0.1				
8-Proj-MMY-98-Survival-Data	0.2				
4-Proj-MMY-98-IsaPomDex-Treatment	0.1		fdjebbari	n/a	

View this Subject's Record

Exit

Workflow

Study Event
Overview

Data Entry

Mark Event CRF Complete

Click on this folder to start entering
belantamab toxicity data

Belantamab toxicity data (All AEs)



5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

▼ CRF Header Info

AEs (0/5) Infecti...(0/5) Infusio...(0/4) -- Select to Jump --

Title: AEs

Page: Save Exit

AEs

AE Date:	AE Name:	AE Grade	Inpatient Stay Days:	Dose Reduction?	Treatment Discontinued?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Add

Return to top

Save Exit

Enter Yes, if this AE led to permanent treatment discontinuation

Enter each AE (adverse event) separately, click “add” to add more AEs

Once all AEs are entered, click save

This will take you to “infections” section

Belantamab toxicity data (infections)



5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

AEs (3/5) Infecti...(0/5) Infusio...(0/4) -- Select to Jump --

Title: Infections

Page: Save Exit

Infection Name:	Infection Grade:	Inpatient Stay Days:	Dose Reduction?	Treatment Discontinued?
pseudomonas pneumonia	4	5	No	No

Add

Return to top

Save Exit

Enter Yes, if this AE led to permanent treatment discontinuation

Enter each AE (adverse event) separately, click "add" to add more AEs

Once all infection are entered, click save

This will take you to "infusion reactions" section

Belantamab toxicity data (infections)



5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

AEs (3/5) Infecti...(0/5) Infusio...(0/4) -- Select to Jump --

Title: Infections

Page: Save Exit

Infection Name:	Infection Grade:	Inpatient Stay Days:	Dose Reduction?	Treatment Discontinued?
pseudomonas pneumonia	4	5	No	No

Add

Return to top

Save Exit

Enter Yes, if this AE led to permanent treatment discontinuation

Enter each AE (adverse event) separately, click "add" to add more AEs

Once all infection are entered, click save

This will take you to "infusion reactions" section

Belantamab toxicity data (infusion reactions)



5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

▼ CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

AEs (3/6) Infecti...(5/5) Infusio...(0/4) -- Select to Jump --

Title: Infusion Reactions

Page: Save Exit

Infusion Reactions

Infusion Reaction Date:	Infusion Cycle Number Reaction:	Infusion Grade:	Infusion Discontinued Treatment?
01-Nov-2021	1	2	No

Add

to top

Save Exit

Enter Yes, if this AE led to permanent treatment discontinuation

If more than one infusion reaction at different dates, enter each separately

Once all infusion reactions are entered, click save

This will take you to "support interventions" section

Belantamab toxicity data (supportive interventions)



5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Infusio...(4/4) Support...(0/2) Ocular...(0/8) -- Select to Jump --

Title: Supportive Treatment

Page: Save Exit

Supportive Treatment

Supportive Treatment Date	Supportive Treatment:	
04-Oct-2021	RBC transfusino during treatment	X
01-Nov-2021	Filgrastim during treatment	X
05-Sep-2021	Platelet transfusion during treatment	X

Add

Return to top Save Exit



This include the following supports:
RBC, platelets and filgrastim



Once all supports are entered, click save

This will take you to “ocular toxicities” section

Belantamab toxicity data (ocular toxicities)

5-Proj-MMY-98-Treatments-Toxicity 0.1

Test001

Once ocular AEs are entered, tick “Mark CRF as complete” then click save
This complete toxicity data entry

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Infusio...(4/4) Support...(6/6) Ocular...(0/8) -- Select to Jump --

Title: Ocular Toxicities

Page: ☐ Mark CRF Complete

Ocular Toxicities

Ocular AE Date:	Ocular AE Name:	Ocular AE Grade:	Ocular AE Admission:	Ocular AE Admission Days:	Ocular AE Reduced Dose:	Ocular AE Delay:	Ocular AE Discontinued:	
01-Nov-2021	Keratopathy	2	No	0	No	No	No	X

Return to top ☐ Mark CRF Complete

Yes means AE led to admission

Yes means AE led to dose reduction

Yes means AE led to permanent discontinuation

This will move data collection to this page

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OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site

fdjebbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support Study Subject ID Go

Alerts & Messages

Your data has been saved and the CRF was marked complete.

Instructions

Info

Study Events

Study Events: (2)

Registration

Data Entry

Status: data entry started

4-Proj-MMY-98-IsaPomDex-Treatment 0.1

5-Proj-MMY-98-Treatments-Toxicity 0.1

6-Proj-MMY-98-Opthalmology-Follow-ups

7-Proj-MMY-98-Subsequent-Treatments




















8-Proj-MMY-98-Survival-Data

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test001
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (12-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
6-Proj-MMY-98-Opthalmology-Follow-ups	0.1				  
7-Proj-MMY-98-Subsequent-Treatments	0.1				  
8-Proj-MMY-98-Survival-Data	0.2				  
4-Proj-MMY-98-IsaPomDex-Treatment	0.1		fdjebbari	n/a	   
5-Proj-MMY-98-Treatments-Toxicity	0.1		fdjebbari	n/a	   

View this Subject's Record Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

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Version: 3.15.7 - Changeset:
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Click ophthalmology follow up folder to start entering data

Ophthalmology follow up data

You have already entered baseline data (prior to cycle 1) so that's follow number 1. Patients normally see ophthalmologist pre-C2 (FU number 2), pre-C3 (FU number 3), and as required thereafter.

What needs to be entered here are the new findings since the baseline assessment (see examples below)

6-Proj-MMY-98-Ophthalmology-Follow-ups 0.1

Test001

CRF Header Info

Opthalm... (0/6)

Title: Ophthalmology Follow-up

Page: ☐ Mark CRF Complete

Save

Exit

Ophthalmology Follow-up

Ophthalmology Follow-up Number:	Ophthalmology Follow-up Date:	Ophthalmology Follow-up Findings:	Ophthalmology Follow-up Belantanab Cycle:	Ophthalmology Follow-up Belantanab Delay:	Ophthalmology Follow-up Belantanab Discontinue:
2	06-Sep-2021	Pre-cycle 2 Compared to baseline review, new G2 kratopathy is diagnosed	2	No	No
3	11-Oct-2021	Pre-cycle 3 No changes except for <u>keratopathy</u> escalating	3	Yes	No

Add

Return to top

☐ Mark CRF Complete

Save

Exit

Document key findings/changes/new AEs, since last follow up

Yes means FU findings led to dose delay

Yes means FU findings led to permanent D/C

Once all are entered, tick "Mark CRF as complete" then click save
This complete ophthalmology FU data entry

Subsequent treatment data

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Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Support: Study Subject ID | Go

Alerts & Messages

Your data has been saved and the CRF was marked complete.

Instructions

Info

Study Events

Study Events: (2)

Registration

Data Entry

Status: data entry started

4-Proj-MMY-98-IsaPomDex-Treatment 0.1

5-Proj-MMY-98-Treatments-Toxicity 0.1

6-Proj-MMY-98-Optthalmology-Follow-ups 0.1

7-Proj-MMY-98-Subsequent-Treatments

8-Proj-MMY-98-Survival-Data

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test001
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (12-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
7-Proj-MMY-98-Subsequent-Treatments	0.1				
8-Proj-MMY-98-Survival-Data	0.2				
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	✓	fdjebbari	n/a	
5-Proj-MMY-98-Treatments-Toxicity	0.1	✓	fdjebbari	n/a	
6-Proj-MMY-98-Optthalmology-Follow-ups	0.1	✓	fdjebbari	n/a	

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Click on this folder to enter subsequent treatment data

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Subsequent treatment data

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Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Support: Study Subject ID | Go

Alerts & Messages

Your data has been saved and the CRF was marked complete.

Instructions

Info

Study Events

Study Events: (2)

Registration

Data Entry

Status: data entry started

4-Proj-MMY-98-IsaPomDex-Treatment 0.1

5-Proj-MMY-98-Treatments-Toxicity 0.1

6-Proj-MMY-98-Optthalmology-Follow-ups 0.1

7-Proj-MMY-98-Subsequent-Treatments

8-Proj-MMY-98-Survival-Data

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test001
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (12-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
7-Proj-MMY-98-Subsequent-Treatments	0.1				
8-Proj-MMY-98-Survival-Data	0.2				
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	✓	fdjebbari	n/a	
5-Proj-MMY-98-Treatments-Toxicity	0.1	✓	fdjebbari	n/a	
6-Proj-MMY-98-Optthalmology-Follow-ups	0.1	✓	fdjebbari	n/a	

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Click on this folder to enter subsequent treatment data

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Subsequent treatment data

OpenClinica Initial Data Entry - Internet Explorer

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OpenClinica Initial Data Entry

7-Proj-MMY-98-Subsequent-Treatments 0.1

Test001

CRF Header Info

Subsequ...(0/8)

Title: Subsequent Treatment

Page: ☐ Mark CRF Complete [Save](#) [Exit](#)

Subsequent Treatment

Treatment Start Date:	Age at Treatment Start Date:	Treatment End Date:	Treatment Name:	Number of Cycles Received:	Response	MM Response Date:	Relapse
07-Nov-2021	69	21-Nov-2021	PanBorDex	1	PD	14-Nov-2021	

[return to top](#)

☐ Mark CRF Complete [Save](#) [Exit](#)

Enter data if patient moved to a subsequent therapy post-belantamab

Once this is complete, tick "Mark CRF as complete and click save

This will complete subsequent treatment data

Survival data

OpenClinica - Internet Explorer

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Belantamab Real-world (proj_mmy_98) | Change Study/Site | fdjebbari (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Support: Study Subject ID | Go

Alerts & Messages

Your data has been saved and the CRF was marked complete.

Instructions

Info

Study Events

Study Events: (2)

Registration

Data Entry

Status: data entry started

4-Proj-MMY-98-IsaPomDex-Treatment 0.1

5-Proj-MMY-98-Treatments-Toxicity 0.1

6-Proj-MMY-98-Optthalmology-Follow-ups 0.1

7-Proj-MMY-98-Subsequent-Treatments

8-Proj-MMY-98-Survival-Data

Enter or Validate Data for CRFs in Data Entry

Edit Study Event

Study Subject ID	Test001
Study Event	Data Entry
Location	N/A
Study Subject OID	SS_TEST001
Start Date	11-Nov-2021
End Date/Time	
Subject Event Status	data entry started
Last Updated by	fdjebbari (12-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
7-Proj-MMY-98-Subsequent-Treatments	0.1				
8-Proj-MMY-98-Survival-Data	0.2				
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	✓	fdjebbari	n/a	
5-Proj-MMY-98-Treatments-Toxicity	0.1	✓	fdjebbari	n/a	
6-Proj-MMY-98-Optthalmology-Follow-ups	0.1	✓	fdjebbari	n/a	

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Click on this folder to survival data

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Survival data (demographics)

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OpenClinica Initial Data Entry

8-Proj-MMY-98-Survival-Data 0.2

Test001

CRF Header Info

Demogra... (0/2) Vital S... (0/6) Symptoms (0/3) -- Select to Jump --

Title: Demographics

Page: Save Exit

Gender: Male

Age at start of Belantamab: 68 x years

Return to top Save Exit

Enter this data and click save to move to vital status

Survival data (vital status)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myloma-research.org.uk/test/InitialDataEntry

OpenClinica Initial Data Entry

8-Proj-MMY-98-Survival-Data 0.2

Test001

CRF Header Info

Your data has been saved. You can continue entering/editing data now or return at a later time.

Demogra... (2/2) Vital S... (0/6) Symptoms (0/3) -- Select to Jump --

Title: Vital Status

Page: Save Exit

Last Follow Up: 08-Nov-2021

Last Follow Up Vital Status: Dead

Date of Death: 07-Nov-2021

Reason for Death (if applicable): Progressive Disease

Reason for Death Description (if applicable): example: G5 pseudomonas pneumonia and progressive disease

Death within 30 days of Treatment: Yes

Return to top Save Exit

Enter this data and click save to move to symptom improvement/deterioration

Survival data (symptoms overall assessment)



8-Proj-MMY-98-Survival-Data 0.2


Test001

CRF Header Info




Your data has been saved. You can continue entering/editing data now or return at a later time.


Demogra... (2/2) Vital S... (6/6) Symptoms (0/3) -- Select to Jump --

Title: Symptoms

Page: ☒ Mark CRF Complete 

Symptoms and Wellbeing at Last Follow-up

Fatigue compared to baseline	<input type="text" value="Deterioration"/>	
Pain compared to baseline	<input type="text" value="Improvement"/>	
Performance Status Review:	<input type="text" value="Same Baseline"/>	

[Return to top](#) ☒ Mark CRF Complete 

COVID-19 vaccine data



8-Proj-MMY-98-Survival-Data 0.4

Test001

▼ CRF Header Info

Demogra...(2/2) Vital S...(6/6) Symptoms (3/3) -- Select to Jump --

Title: COVID-19

Page:

Vaccinated against COVID-19?

Number of COVID-19 vaccine doses received?

Date of last COVID-19 vaccine:

Anti-body Test Performed?

Anti-body Test Date:

Anti-bodies Detected?

Return to top



Enter this data and tick “Mark CRF as complete”

This will complete ALL data collection for the patient

Follow the same process to enter data for the next patient