

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

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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?](#)

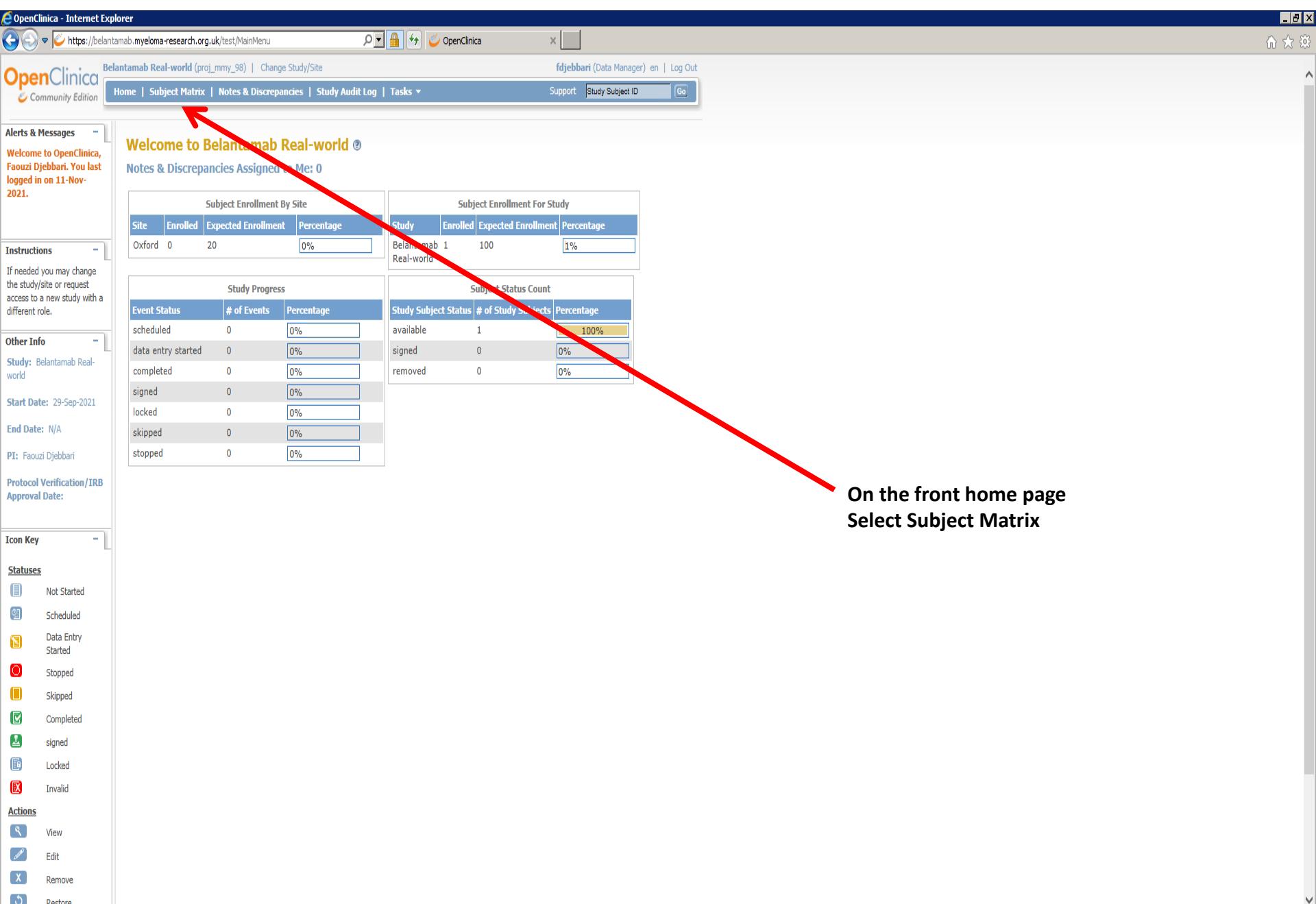
News

» 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.myeloma-research.org.uk/test/MainMenu

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

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
- Reopen

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 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%

On the front home page
Select Subject Matrix

Registering a New Subject to start registration

OpenClinica - Internet Explorer

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

fdjebbari (Data Manager) en | Log Out

OpenClinica Community Edition

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

Support | Study Subject ID | Go

Alerts & Messages

Instructions

Info

Icon Key

Statuses

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

Actions

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

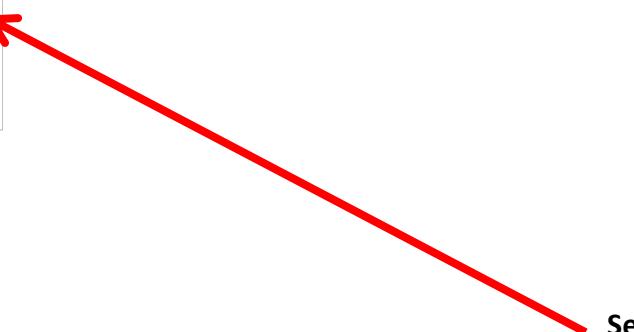
View All Icons

Subject Matrix for Belantamab Real-world

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

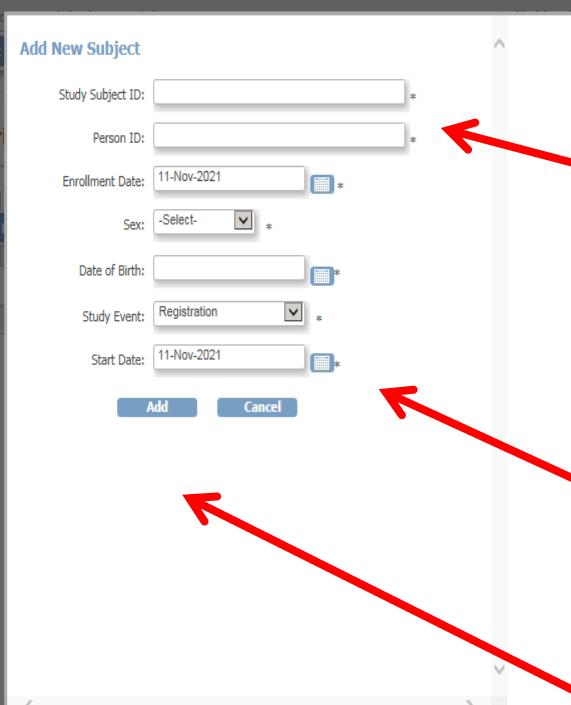
Study Subject ID	Registration	Data Entry	Actions
OX-1			

Results 1 - 1 of 1.



Select add new subject to start data entry

Registering a New Subject to start registration and data entry



OpenClinica - Internet Explorer
Belantamab Real-world (pre-approval) - Belantamab Myeloma Research
https://belantamab.myeloma-research.org.uk/test>ListStudySubjects

Add New Subject

Study Subject ID: *

Person ID: *

Enrollment Date: 11-Nov-2021

Sex: -Select- *

Date of Birth:

Study Event: Registration *

Start Date: 11-Nov-2021

Add Cancel

Subject ID Go

Subject Matrix

Study Subject ID

OX-1

Results 1 - 1 of 1.

Not Started
Scheduled
Data Entry Started
Stopped
Skipped
Completed
Signed
Locked
Invalid
Actions
View
Edit
Remove
Restore
Reassign
Sign
All Icons

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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OpenClinica Community
Version: 3.15.7 - Changeset: de733e3ae6ca 2020-07-08 18:28 +0000

Entering Subject Baseline Patient Characteristics

OpenClinica - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/AddNewSubject

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

OpenClinica

fdjebbari (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 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
- 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 border="1"><tr><td>1-Proj-MMY-98-Baseline-Patient-Characteristics</td><td>0.1</td><td>  </td></tr><tr><td>2-Proj-MMY-98-Baseline-Ocular-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></table>	1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	  	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	  												
2-Proj-MMY-98-Baseline-Ocular-Assessments	0.1	  												
3-Proj-MMY-98-Baseline-Disease-Characteristics	0.2	  												



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.myeloma-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: 03-Nov-2014 Date:

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://belantab.myeloma-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

Mycardial Infarction: Select History of definite or probable MI (EKG changes and/or enzyme changes)

Congestive Heart Failure: Select Exertional or paroxysmal nocturnal dyspnea and has responded to digitalis, diuretics, or afterload reducing agents

Peripheral Vascular Disease: Select 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

Dementia: Select Chronic cognitive deficit

Chronic Obstructive Pulmonary Disease: Select

Connective Tissue Disease: Select

Peptic Ulcer Disease: Select Any history of treatment for ulcer disease or history of ulcer bleeding

Liver Disease: Select 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

Hemiplegia: Select

Moderate to Severe Chronic Kidney Disease: Select Severe = on dialysis, status post kidney transplant, uremia, moderate = creatinine > 3 mg/dL (0.27 mmol/L)

Solid Tumour: Select

Leukaemia: Select

Lymphoma: Select

AIDS: Select

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

Charlson Score:

Charlson Category: Select

Save Exit

Return to top

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)

OpenClinica Initial Data Entry - Internet Explorer

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

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.

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-GRF: 51

e-GRF Category: 30-59

Anaemia: Yes

Lymphopenia: No

Hypercalcaemia: Yes

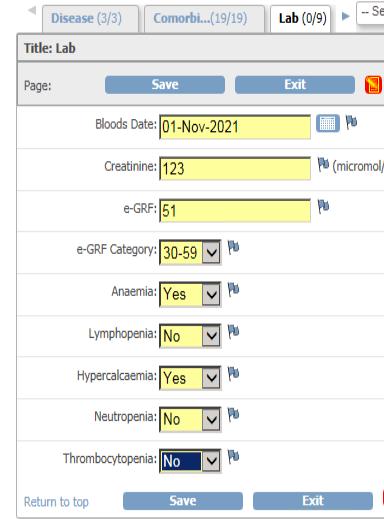
Neutropenia: No

Thrombocytopenia: No

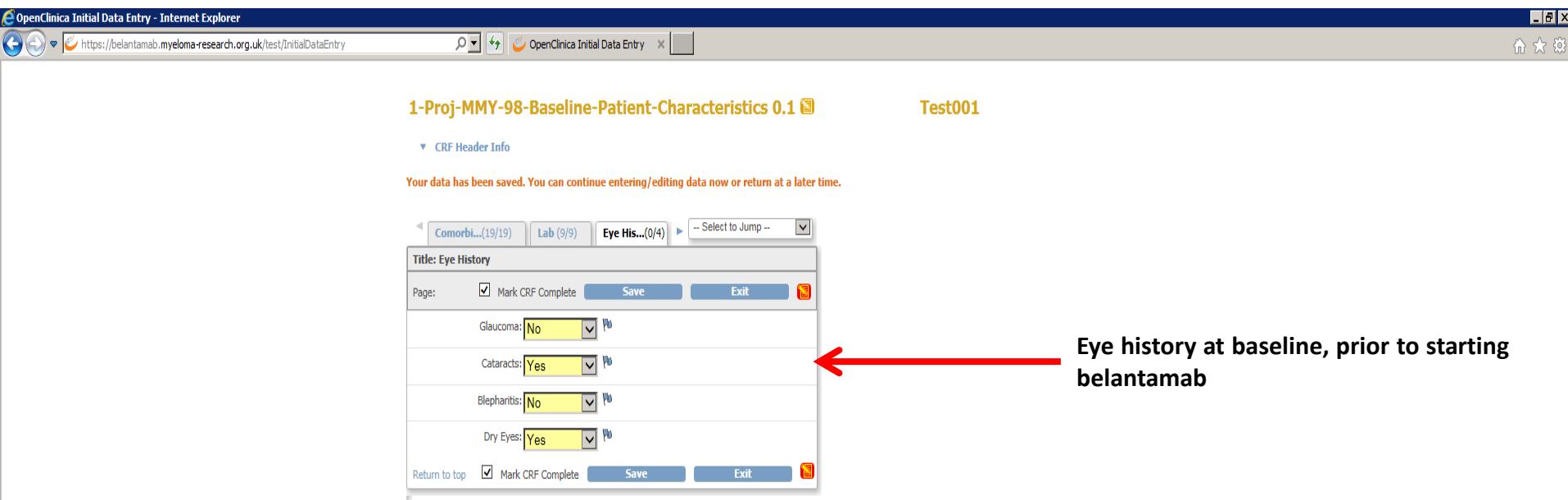
Return to top Save Exit

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)



OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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 Save Exit

Glaucoma: No
Cataracts: Yes
Blepharitis: No
Dry Eyes: Yes

Return to top Mark CRF Complete Save Exit

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.myeloma-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: Fouazi 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
- 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	   	<table border="1"><tr><td>2-Proj-MMY-98-Baseline-Ocular-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><tr><td>1-Proj-MMY-98-Baseline-Patient-Characteristics</td><td>0.1</td><td>    </td></tr></table>	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	    
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	    												

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

Entering Subject Ocular Assessments data

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?eventDefinitionCRFId=2&... OpenClinica Initial Data Entry

Chemosis (left eye): Select

Right Eye

Conjunctival Injection (right eye): Select

Chemosis (right eye): Select

Left Eye

Corneal Epithelium (left eye): Select

Punctate Keratopathy (left eye): Select

Epithelial Oedema (left eye): Select

Stroma (left eye): Select

Stroma Active Opacity (left eye): Select

Stroma Active Oedema (left eye): Select

Endothelium (left eye): Select

Comments:

Right Eye

Corneal Epithelium (right eye): Select

Punctate Keratopathy (right eye): Select

Epithelial Oedema (right eye): Select

Stroma (right eye): Select

Stroma Active Opacity (right eye): Select

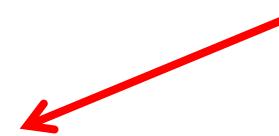
Stroma Active Oedema (right eye): Select

Endothelium (right eye): Select

Comments:

Return to top Mark CRF Complete Save Exit

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.myeloma-research.org.uk/test/InitialDataEntry
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: (1)
Registration
Status: data entry started
1-Proj-MMY-98
-Baseline-Patient-Characteristics 0.1
2-Proj-MMY-98
-Baseline-Ocular-Assessments 0.1
3-Proj-MMY-98-Baseline-Disease-Characteristics

Enter or Validate Data for CRFs in Registration ②

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: fdjebbari (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	<input checked="" type="checkbox"/>	<input type="button" value="Edit"/>		<input type="button" value="Print"/> <input type="button" value="View"/> <input type="button" value="Search"/> <input type="button" value="Print"/>
1-Proj-MMY-98-Baseline-Patient-Characteristics	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	<input type="button" value="Edit"/> <input type="button" value="Print"/> <input type="button" value="View"/> <input type="button" value="Search"/> <input type="button" value="Print"/>
2-Proj-MMY-98-Baseline-Ocular-Assessments	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	<input type="button" value="Edit"/> <input type="button" value="Print"/> <input type="button" value="View"/> <input type="button" value="Search"/> <input type="button" value="Print"/>

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

View this Subject's Record | Exit

Workflow: Study Event Overview → Data Entry → Mark Event CRF Complete

Entering Subject Baseline Disease Characteristics (Disease)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?action=id_e_s&eventDefini
OpenClinica Initial Data Entry

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

▼ CRF Header Info

Disease (0/4) Lab (0/7) Cyogen... (0/5) -- Select to Jump --

Title: Disease

Page: Save Exit

Disease

MM Subtype: IgA
Amyloidosis?: No
Plasma cell leukaemia?: No
Extramedullary disease present?: No

Return to top Save Exit

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)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?eventCRFId=3§ionId=3

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

▼ CRF Header Info

Disease (4/4) Lab (0/7) Cyogen... (0/5) -- Select to Jump --

Title: Lab

Page: Save Exit

Lab

Bloods Date: 01-Nov-2021

Albumin: 43

Albumin Category: ≥35g/l

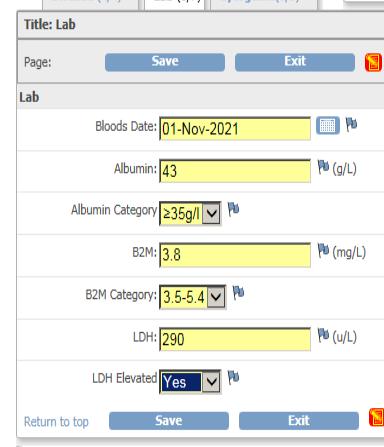
B2M: 3.8

B2M Category: 3.5-5.4

LDH: 290

LDH Elevated: Yes

Return to top Save Exit



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

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

Entering Subject Baseline Disease Characteristics (Cytogenetics)

OpenClinica Initial Data Entry - Internet Explorer

https://belantamab.myeloma-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.

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

Title: Cytogenetics

Page: Save Exit

NB. All known cytogenetic abnormalities

Bone Marrow Date: 01-Nov-2021

Percentage Plasma Cells: 45 (%)

Cytogenetics: 1 - High Risk

Cytogenetic Risk:

Cytogenetics Abnormalities: t(4;14) t(14;16) t(14;20) del(17p) 1p loss 1q gain/amp del 13q Hypodiploidy Other (specify) Unknown

Cytogenetics Other Abnormalities: also,

Return to top Save Exit

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.myeloma-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.

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

Title: Symptoms

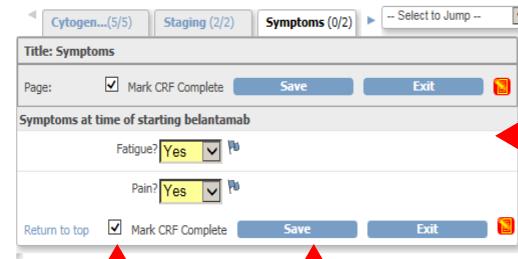
Page: Mark CRF Complete Save Exit

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.myeloma-research.org.uk/test/EnterDataForStudyEvent?eventId=1 OpenClinica fdjebbari (Data Manager) en | Log Out

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

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

Support Study Subject ID Go

Alerts & Messages

Instructions

Info

Study Events

Study Events: (1)

Registratio

n

Status: completed

1-Proj-MMY-98

-Baseline-Patient-Characteristics 0.1

2-Proj-MMY-98

-Baseline-Ocular-Assessments 0.1

3-Proj-MMY-98

-Baseline-Disease-Characteristics 0.2

Enter or Validate Data for CRFs in Registration

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-Ocular-Assessments	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

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Click on subject matrix to start accessing treatment data platform

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"

OpenClinica - Internet Explorer

https://belantamab.myeloma-research.org.uk/test>ListStudySubjects

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 ▾

Icon Key ▾

Statuses

- 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			  
Test001			  

Results 1 - 2 of 2.



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

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OpenClinica - Internet Explorer

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

OpenClinica

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

fdjebbari (Data Manager) en | Log Out

OpenClinica Community Edition

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: 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.

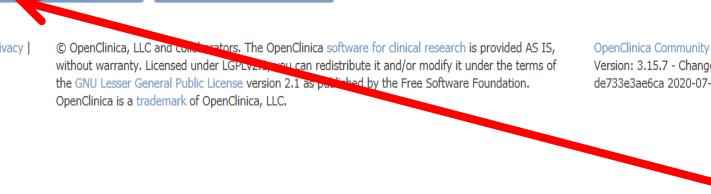
Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Proceed to Enter Data **Cancel**

 **Proceed to Enter Data**

Leave end date blank, and click “Proced to Enter Data” to start entering treatment data

OpenClinica - Internet Explorer

https://belantamab.myeloma-research.org.uk/test/EnterDataForStudyEvent?eventId=4

OpenClinica

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

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Support | Study Subject ID | Go

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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

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: Study Event Overview → Data Entry → Mark Event CRF Complete

Click on this folder to start entering belantamab treatment data

Belantamab Treatment data (dosing and response)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?action=id_s&eventDefini

4-Proj-MMY-98-Belantamab-Treatment 0.1 Test002

▼ CRF Header Info

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

Title: Belantamab

Page: Save Exit

Belantamab

Belantamab Start: 09-Nov-2020

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

Belantamab Number of Cycles Received: 14

Belantamab Dosing

Preservative-free: Yes
Eyedrops:

Cooling Eye Mask: Yes
Bandage Contact Lens:

Starting Dose: 2.5mg/kg
Dose Reduction: Yes

New (reduced) Dose: 1.9mg/kg
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

Once complete, click save

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

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

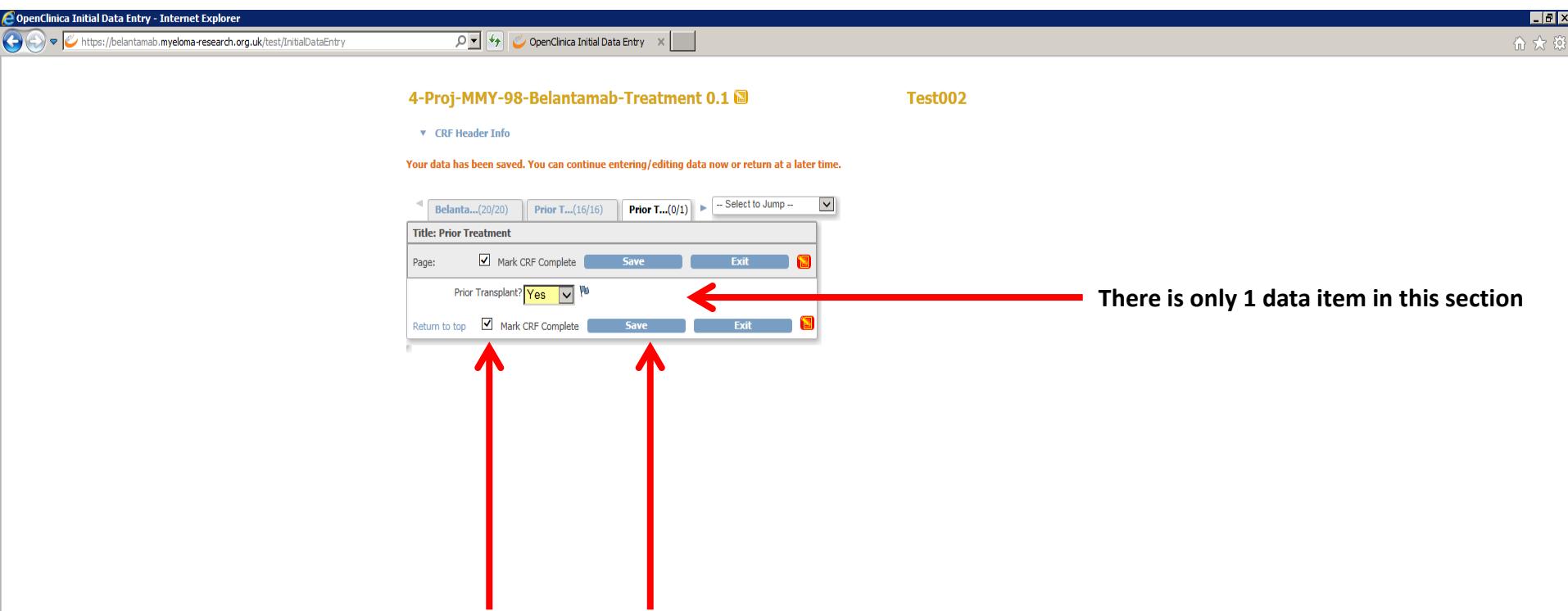
Save Exit

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.myeloma-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

OpenClinica - Internet Explorer

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

OpenClinica

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

fdjebbari (Data Manager) en | Log Out

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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)

Registratio

n

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

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	<input checked="" type="checkbox"/>	<input type="button"/>	<input type="button"/>	
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1	<input type="checkbox"/>	<input type="button"/>	<input type="button"/>	
7-Proj-MMY-98-Subsequent-Treatments	0.1	<input type="checkbox"/>	<input type="button"/>	<input type="button"/>	
8-Proj-MMY-98-Survival-Data	0.2	<input type="checkbox"/>	<input type="button"/>	<input type="button"/>	
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	<input checked="" type="checkbox"/>	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

Enter Yes, if this AE led to permanent treatment discontinuation

AEs (0/6) 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?

Add

Return to top

Save Exit

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)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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

Title: Infections

Page: Save Exit

Infections

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

Add

Return to top Save Exit

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

Enter Yes, if this AE led to permanent treatment discontinuation

Belantamab toxicity data (infections)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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

Title: Infections

Page: Save Exit

Infections

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

Add

Return to top Save Exit

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

Enter Yes, if this AE led to permanent treatment discontinuation

Belantamab toxicity data (infusion reactions)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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

↑ Go 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)

OpenClinica Initial Data Entry - Internet Explorer

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

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 transfusion during treatment
01-Nov-2021	Filgrastim during treatment
05-Sep-2021	Platelet transfusion during treatment

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)

OpenClinica Initial Data Entry - Internet Explorer
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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

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

Infusio...(4/4) Support...(5/6) Ocular...(0/8) - Select to Jump --

Title: Ocular Toxicities

Page: Mark CRF Complete Save Exit

Occular Toxicities

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

Add

Return to top

Mark CRF Complete Save Exit

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

OpenClinica - Internet Explorer <https://belantamab.myeloma-research.org.uk/test/InitialDataEntry>

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

fdjebbari (Data Manager) en | Log Out

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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)

Registratio

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-Ophthalmology-Follow-ups

7-Proj-MMY-98-Subsequent-Treatments

8-Proj-MMY-98-Survival-Data

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

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

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)

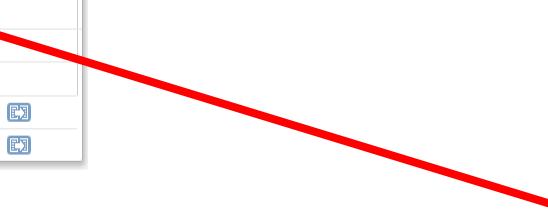
CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
6-Proj-MMY-98-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	<input checked="" type="checkbox"/>	fdjebbari	n/a	  
5-Proj-MMY-98-Treatments-Toxicity	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  

[View this Subject's Record](#) [Exit](#)

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete



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

Ophthalm... (0/6)

Title: Ophthalmology Follow-up

Page: Mark CRF Complete 

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 <u>keratopathy</u> is diagnosed	2 	No 	No 
3 	11-Oct-2021 	Pre-cycle 3 No changes except for <u>keratopathy</u> escalating	3 	Yes 	No 

Mark CRF Complete 

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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Support | Study Subject ID | Go

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

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Study Events: (2)
Registratio n
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
-Ophthalmology-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

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	   
8-Proj-MMY-98-Survival-Data	0.2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	   
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	n/a	   
5-Proj-MMY-98-Treatments-Toxicity	0.1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	n/a	   
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	n/a	   

Click on this folder to enter subsequent treatment data

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

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Subsequent treatment data

OpenClinica - Internet Explorer
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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
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Study Events: (2)
Registratio n
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
-Ophthalmology-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

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	  
8-Proj-MMY-98-Survival-Data	0.2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	  
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  
5-Proj-MMY-98-Treatments-Toxicity	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  

Click on this folder to enter subsequent treatment data

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

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Subsequent treatment data

OpenClinica Initial Data Entry - Internet Explorer https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?action=ide_s&eventDefin... 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
https://belantamab.myeloma-research.org.uk/test/InitialDataEntry
OpenClinica

Belantamab Real-world (proj_mmy_98) | Change Study/Site
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Support | Study Subject ID | Go

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

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Study Events: (2)
Registratio n
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-Ophthalmology-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

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	  
8-Proj-MMY-98-Survival-Data	0.2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	  
4-Proj-MMY-98-IsaPomDex-Treatment	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  
5-Proj-MMY-98-Treatments-Toxicity	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  
6-Proj-MMY-98-Ophthalmology-Follow-ups	0.1	<input checked="" type="checkbox"/>	fdjebbari	n/a	  

Click on this folder to survival data

View this Subject's Record | Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

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Survival data (demographics)

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https://belantamab.myeloma-research.org.uk/test/InitialDataEntry?action=id_e_s&eventDefini

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

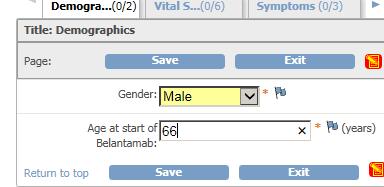
Page: Save Exit

Gender: Male

Age at start of: 66 Belantamab:

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.myeloma-research.org.uk/test/InitialDataEntry

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

Last Follow Up: 08-Nov-2021

Last Follow Up Vital Status: Dead

Date of Death: 07-Nov-2021

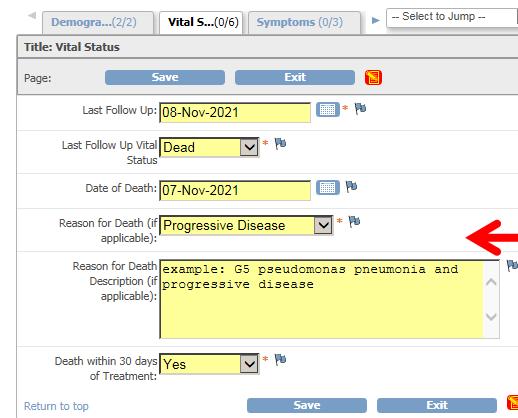
Reason for Death (if applicable): Progressive Disease

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

Death within 30 days of Treatment: Yes

Save Exit

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



Survival data (symptoms overall assessment)

OpenClinica Initial Data Entry - Internet Explorer https://belantamab.myeloma-research.org.uk/test/InitialDataEntry

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...(5/6) Symptoms (0/3) Select to Jump

Title: Symptoms

Page: Mark CRF Complete Save Exit

Symptoms and Wellbeing at Last Follow-up

Fatigue compared to baseline Pb

Pain compared to baseline Pb

Performance Status Pb
Review:

Return to top Mark CRF Complete Save Exit



COVID-19 vaccine data

OpenClinica Administrative Editing x + belantamab.myeloma-research.org.uk/test/AdministrativeEditing?eventCRFId=8§ionId=41&tab=4&exitTo=ViewStudySubject?id=2 Error

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

Test001

▼ CRF Header Info

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

Title: COVID-19

Page: Save Exit

Vaccinated against COVID-19? Yes

Number of COVID-19 vaccine doses received? 3

Date of last COVID-19 vaccine: 01-Nov-2021

Anti-body Test Performed? Yes

Anti-body Test Date: 14-Dec-2021

Anti-bodies Detected? Yes

Return to top Save Exit



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