

COSMOS Trial

OpenClinica Manual

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Acronyms

eCRF	Electronic case record form
EDC	Electronic data capture

Document History

Doc #	Title	Version	Date	Description	Author
ABA-22-1	COSMOS Trial OpenClinica Manual	0.1	2021-01-19	Initial Draft	Dr Grant D. Vallance
		1.0	2021-02-01	Initial Version	Dr Grant D. Vallance

Introduction

OpenClinica is an electronic data capture (EDC) system aimed at clinical trials. It has been extensively used in this context. For instance, the world-renown RECOVERY trial which determines the efficacy of COVID-19 treatments uses it. It is also fairly user-friendly and reasonably intuitive to use with a bit of guidance, which this document provides.

Technical Support

If you have any technical problems or difficulties then please email: openclinica@cosmos-myeloma.org.uk, saying who you are and what the issue is. It would be helpful to have a descriptive subject line, prefixed with **COSMOS Trial OpenClinica ...** with a summary description of the issue. E.g. **COSMOS Trial OpenClinica Cannot login** or **COSMOS Trial OpenClinica Site Down**.

OpenClinica Demonstration/Training

If desired a demonstration of OpenClinica and training on how to use it can be provided if desired. However, we have found that for most users, using OpenClinica is fairly intuitive.

To organise a demonstration please get in contact via openclinica@cosmos-myeloma.org.uk.

System Use

Getting a username and password

- To use the system a username and password will need to be created on your behalf.
- To obtain a username and password please email openclinica@cosmos-myeloma.org.uk, with the following subject-line: **COSMOS Trial OpenClinica Username Request**. In the body, please give your name and the site you are at. E.g. Dr Grant D. Vallance, Oxford. A username and password will be returned to you along with instructions on how to log-in.
- You may change the assigned password if you wish after logging in.

Logging in

- Either:
 - (1) Go to the project website at: <https://cosmos-myeloma.org.uk/> and choose the **COSMOS Myeloma Database** link OR/
 - (2) Use the direct link: <https://cosmos-myeloma.org.uk/prod/pages/login/login>
- Enter supplied username and password in the **User Name** and **Password** fields respectively.

Changing Password

- Click on the **Task** menu and choose **Update Profile**
- Enter the current password into **Old Password** field
- Enter your desired password into the **New Password** field
- Click on **Confirm Profile Change** button to save.
- **NB.** You may have to enter a phone number – a dummy phone number is fine.

Password Reset

- If you cannot login or have forgotten or lost either your username and/or password then please email openclinica@cosmos-myeloma.org.uk, with the following subject-line: **COSMOS Trial OpenClinica Reset**. In the body of your message please give your name and the site you are at. E.g. Dr Grant D. Vallance, Oxford. Your username and a password will be returned to you.
- Again, you may change the assigned password if you wish after logging in.

Adding a Subject

- To add a subject either:
 - (1) Click on the **Add Subject** menu OR/
 - (2) Click on the **Task** menu and choose **Add Subject**
- Fill in the **Study Subject ID** field
 - This will be a combination of letters designated site and a subject number. E.g. **OX-1**.
 - The identifiers go in sequence. E.g. **OX-1, OX-2, OX-3** ...
 - **NB.** Please ensure the subject log matching Study Subject IDs to patients is kept up to date. See site manual for details.

Study Subject ID	NHS Number	MRN	Surname	Firstname	Gender	DOB
OX-1	111-111-1111	123456	Nonymous	Andrew	Female	27/03/1950

- Fill in the **Date of Enrolment** ... using the date of consent.
- Fill in the **Sex**
- Fill in the **Year of Birth**. Only the four digits for the year will be permitted.
- Click on either **Save and Assign Study Event**, **Save and Add Next Subject**, or **Save and Finish** button as appropriate

Save and Assign Study Event

- This allows the user to add 1 or more study events immediate to the subject. The first study event is the **Study Start/End** event, followed by **Baseline, 3 Months**, ... etc.
- Assigning Study Events to subjects will be covered later in this manual. The best way

Save and Add Next Subject

- Allows the user to add another subject as per the above **Adding a Subject**.
- Repeat as often as needed to add subjects as per the above.

Save and Finish

- Saves the user and returns to the home screen.

Subject Matrix

- The **Subject Matrix** is the main way you will interact with study subjects once they have been added to the system. At a glance you can see the subjects in your site and their status—which study events have started, in process, and completed.
- You can also use the **Subject Matrix** to focus on particular events for your subjects and see which eCRF or eCRFs have yet to be started, are started, and are completed.
- The **Subject Matrix** is present on the home screen or can be accessed via the **Subject Matrix** menu or via the **Tasks** menu (choose **Subject Matrix**).

Schedule an Event

- To schedule an Event not already scheduled click on the button under the Event. E.g. **Baseline, 3 months, 6 months** etc. and choose **Schedule**.
- Notwithstanding the Event you clicked on above, you can choose a different event using the **Study Event Definition** dropdown, *otherwise just leave as-is*.
- You do not need to add anything else unless you want to change the default date and add a time. *This is not necessary*. You do not need to add an **End Date/Time**:
- If you wish you can schedule further events by clicking on **Schedule Another Event: (optional)**. You can do this another 4 times if desired.
- As a rule, only schedule events for which you wish to add data for.
- Click on the **Proceed to Enter Data** which will take you to the first eCRF for that event

View/Enter Data for a Scheduled Event

- To either view or enter data for an event that has already been scheduled then click on the event which has been started and then choose and click on **View/Enter Data**.
- This will take you to the page for this particular Event. It will comprise of one or more eCRFs that will need to be filled in. For instance, the **Baseline** event has 8 eCRFs whereas the **Study Start/End** event only has 1 eCRF.
- To *view* the data for an eCRF click on the **View** button under **Actions**
- To *enter data* for an eCRF click on the **Enter Data button** under **Actions** for that eCRF
- This will take you to the eCRF entry page.

eCRF Entry

- An eCRF has one or more 'tabs' which data items to be entered. For example, the **Medical and Examination** eCRF has 5 'tabs'. If you enter the data and press the **Save** button then it will take you the next tab in sequence if there are any.
- If an eCRF form has only 1 tab then there will be the option to 'Mark CRF complete'. *Do not do this unless data entry *really* is complete.* It will require administrative action to unlock. Otherwise, this option is on the last tab of the eCRF.
- To save the data in the tab then click on the **Save** button, otherwise click on the **Exit** button which will then take you back to the **Subject Matrix**.

Date Fields

- Date fields are designated with a Calendar button beside them. Clicking on the Calendar button gives you a widget to enter the date. *This is the recommended way to add dates to a date field.* Manual date entry requires the dd-Mmm-YYYY format. So for the 2nd of February 2021 you would enter 02-Feb-2021. The widget takes care of this for you.

eCRF Guidance

EVENT: Study Beginning and End – **eCRF:** Demographics

- The age is calculated by subtracting the censor date from the year of birth.
- **ONLY FINALISE THIS eCRF ONCE THE PATIENT COMES OFF-STUDY.**

Schedule Study Event

- You can directly **Schedule Event** via the **Task** menu selecting **Schedule Event**, *but this is NOT the recommended workflow because you have to remember the **Study Subject ID:** and the **Study Event Definition:** not already scheduled.* It is better to work through the **Subject Matrix** as described above OR/ if you are adding a new Subject by clicking on Save and Assign Event button.