



FormsVision

ALEA Randomisation User Manual

ALEA Version: 18 upwards



Contents

1. Web address and login procedure	3
1.1 About ALEA	3
1.2 Setting your password and logging in	3
1.3 Changing your password.....	6
2. Navigating the ALEA system.....	7
2.1 The landing page.....	7
2.2 Study menu	7
2.3 Patient grid.....	7
3. Adding new subjects	8
3.1 Choosing an investigator.....	8
3.2 Completing the randomisation form	11
3.3 Closing the form and returning to the patient grid	12
4. Exiting the system	14
4.1 Logging out.....	14

1. Web address and login procedure

1.1 About ALEA

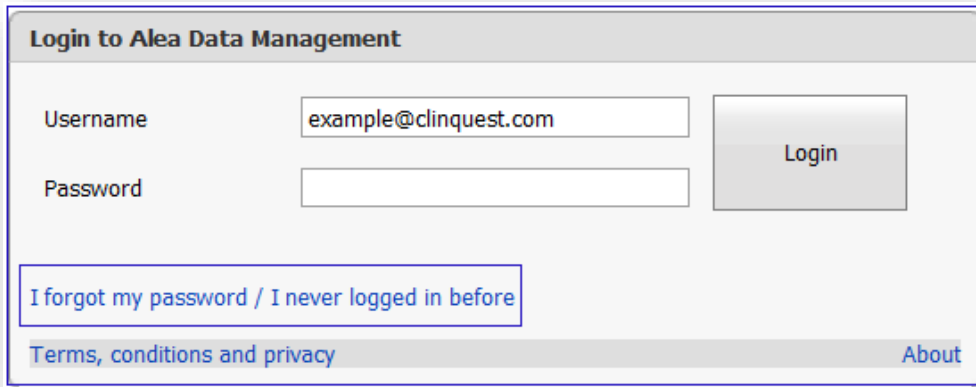
This section explains how a user can get access to the ALEA Data Management environment.

The ALEA 18 Data Management environment operates as a Software as Service (SaaS). As a result, users can access the Data Management environment using commonly available web browsers, i.e. Internet Explorer 7.0 and higher, Mozilla FireFox, Google Chrome, Safari (Apple), and Android 4.0 and higher.

Access to the ALEA randomization system is via <https://prod.tenalea.net/ciru/DM/>

1.2 Setting your password and logging in

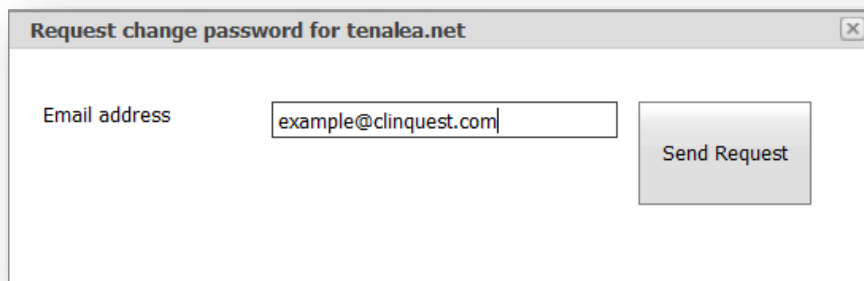
After selecting the URL/web address of the ALEA Data Management environment, a login screen is displayed.



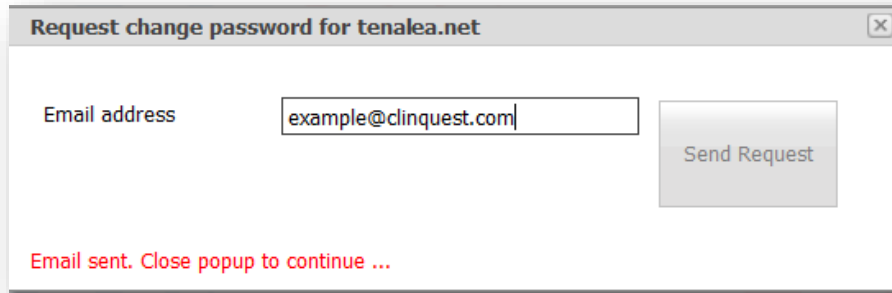
The screenshot shows a web form titled "Login to Alea Data Management". It contains two input fields: "Username" with the value "example@clinquest.com" and "Password" which is empty. To the right of these fields is a "Login" button. Below the input fields is a link that says "I forgot my password / I never logged in before". At the bottom of the form, there are two links: "Terms, conditions and privacy" on the left and "About" on the right.

If accessing the site for the first time, click the link 'I forgot my password/ I never logged in before'.

Enter the e-mail address which was used to create the ALEA account and press the button 'Send request'.



The screenshot shows a web form titled "Request change password for tenalea.net". It contains one input field labeled "Email address" with the value "example@clinquest.com". To the right of this field is a "Send Request" button.



An e-mail is sent to the submitted e-mail address. This email will contain similar text to that shown below.

Password change request

You have requested to receive your user account details by email to mail address [example@clinquest.com]

You are registered at [tenalea.net](#) as user [example@clinquest.com]

This account can be used to access the production environment. This environment is used for online data entry eCRF or randomisation.

To change your password, please [click this link](#) or cut and paste the address into your Internet browser:

<https://prod.tenalea.net/CQ/dm/DEChangePW.aspx?PwdChangeRequestID=b51863dd-1572-49d0-be0c-44ca36101993>

After setting your password you can login to ALEA data management by [clicking here](#)

For any further instructions please contact support at notificationsservice@tenalea.net

Click the link in the 'Password change request' email. This will redirect you to a page on which a password can be created.

Important: make sure you click the link **within 30 minutes** after receiving the Password change request email. For security reasons, a time frame of 30 minutes after submitting a password change request has been set for allowing users to change their password.

Password expiration

The password you set now will expire in 120 days. When you log in after your password has expired, you are prompted to renew your password after logging in. You can change your password at any time by selecting *forgotten password* in the TENALEA login screen, or by selecting *Change password* from the data management menu.

Password length

The password you set should have a minimum length of 8 characters.

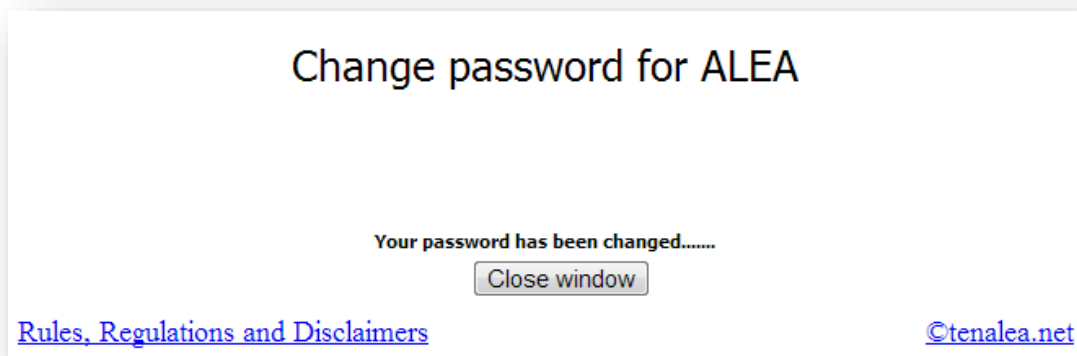
Password complexity rules

The password you set now must be in compliance with requirements from regulatory authorities. As a result, your password must contain:

- at least one lowercase character
- at least one uppercase character
- at least one special character (!@#\$%^&*()<>?)
- at least one numerical (0123456789).

Accountname	<input type="text" value="example@clinquest.com"/>
New password	<input type="password"/> !
Confirm new password	<input type="password"/>
<input type="button" value="Set password"/>	

Enter a password with a minimum length of 8 characters and which contains at least one digit and one special character. Enter the password again in the '**Confirm new password field**' and press the button '**Set password**'. A window will appear which signifies the password was changed successfully.

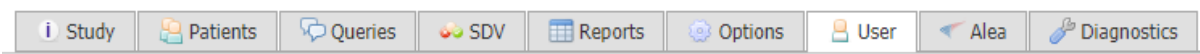


Close the window and go back to the web address (<https://prod.tenalea.net/ciru/DM/>).

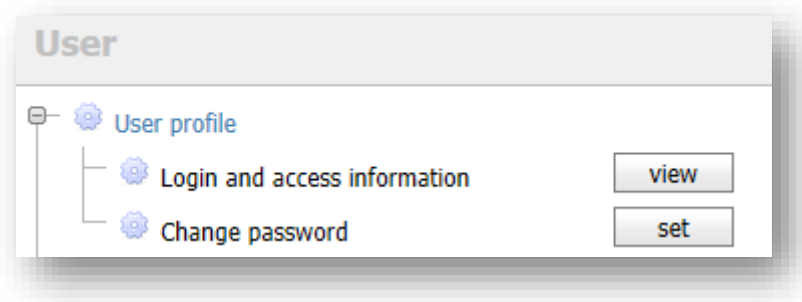
Under '**username**', use your e-mail address. Next, enter the previously established password and press the '**Login**' button.

1.3 Changing your password

Click on the **'User'** tab. (If you have access to more than one study, please 'enter' a study to access the tab view – see section 2.1 'Landing Page').



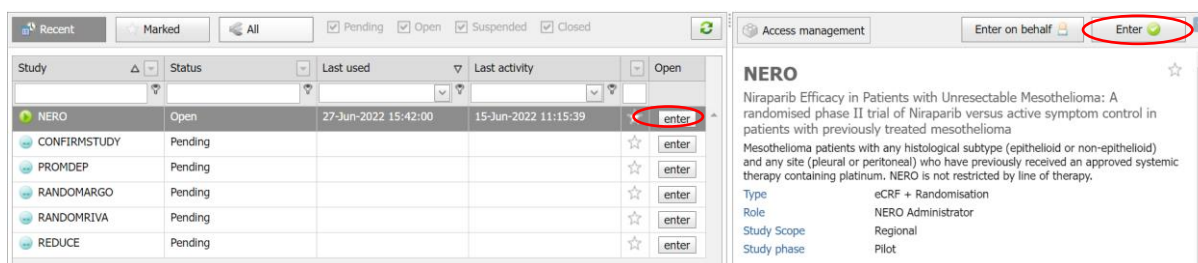
Via the **'Change Password'** option on the left hand pane click on the **'set'** button and follow the reset instructions.



2. Navigating the ALEA system

2.1 The landing page

Note that, when a user has access to more than one study, a 'landing page' is presented first.

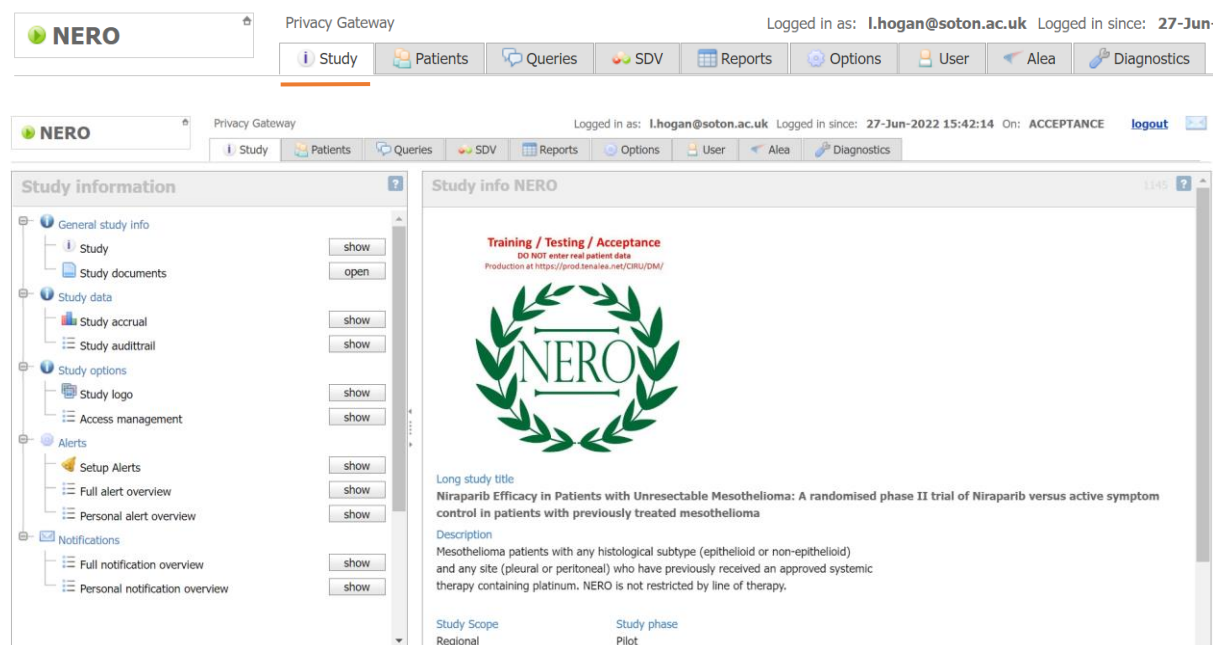


If the landing page is displayed, click the row of the study for which you like to perform randomisation. In the panel on the right hand side, some information regarding the selected study is displayed (e.g. your role in the study, number of patients included in the study, etc.).

To access the study, click the 'enter' button alongside the NERO study name, or in the top right hand corner.

2.2 Study menu

After accessing the study, the 'Study' tab is displayed by default. The tab displays general information about the study.



2.3 Patient grid

The second tab contains the 'Patient Grid'. This lists all patients included in the study. Depending on your permissions, you might see a subset of the patients (for example the patients at your site).

NERO Privacy Gateway Logged in as: l.hogan@soton.ac.uk Logged in since: 27-Jun-2022 15:42:14 On: ACCEPTANCE [logout](#)

Study Patients Queries SDV Reports Options User Alea Diagnostics

Layout Recent Patients Add new Patient

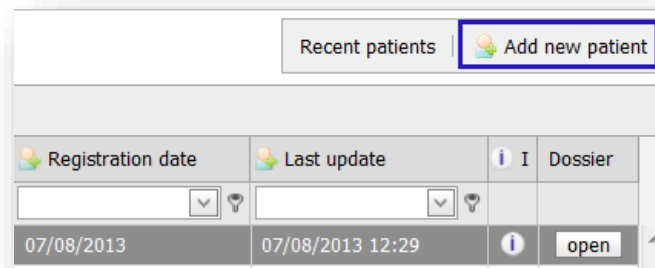
Drag a column header here to group by that column

Status	Patient key	Dossier	Institute	Clinician	Registration date
EXPERIM	NE2-1001024	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1001234	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
ARM2	NE2-1234566	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1234578	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1234556	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1234555	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1234569	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
ARM2	NE2-1234568	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1001726	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
ARM2	NE2-1001299	open	Southampton General Hospital (1001)	Soton PI	14-Jun-2022
EXPERIM	NE2-1001777	open	Southampton General Hospital (1001)	Soton PI	14-Jun-2022
EXPERIM	NE2-1002123	open	Royal Marsden (1002)	PI Royal Mars	06-Jun-2022

3. Adding new subjects

3.1 Choosing an investigator

To register a new patient, click **'Add new patient'** at the far right of the page.



Pressing *Add new patient* will result in one of two outcomes:

1. If a user has permissions to enter patient data on behalf of only one investigator/PI, the Randomisation Form is automatically displayed (see below).

Randomisation

NERO - Randomisation

Patient Details

Subject ID (assigned by Rave)

Patient Initials

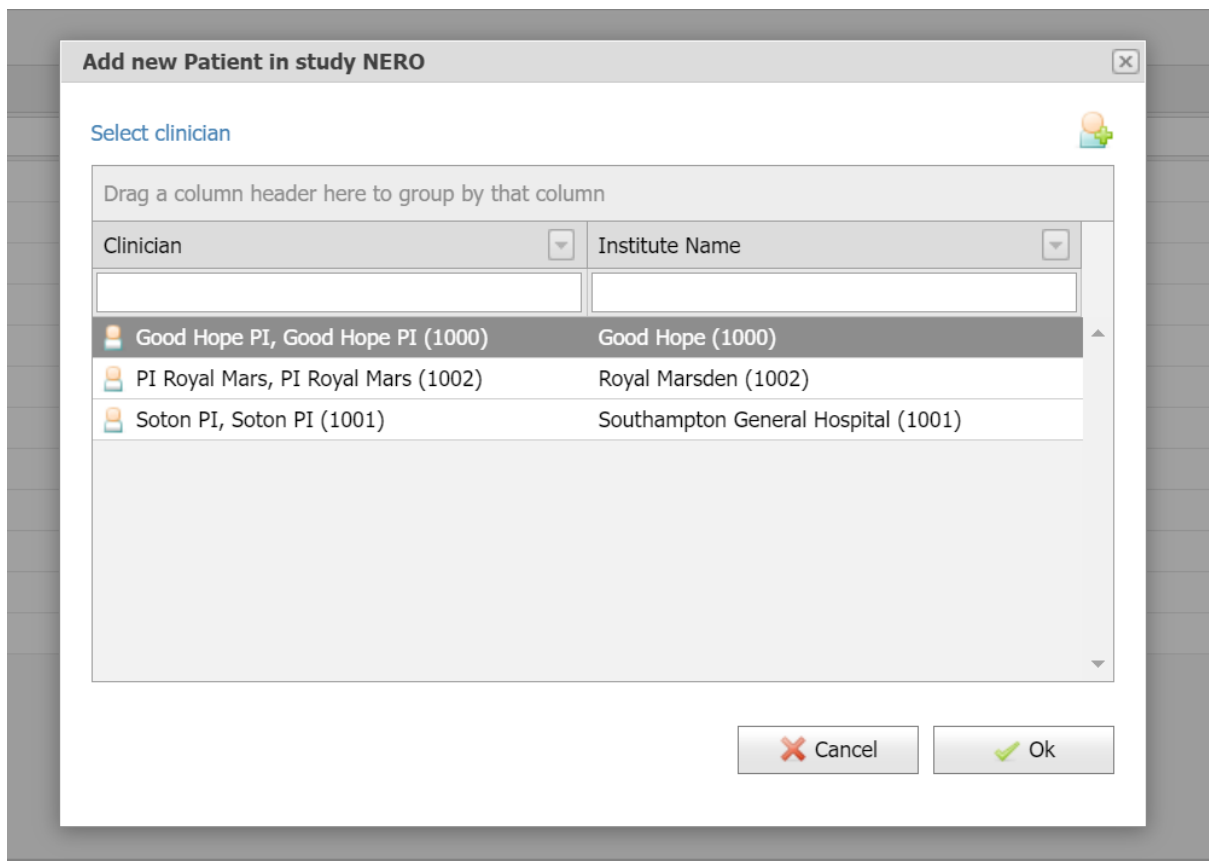
What is the patient's month and year of birth?
(date should be in the format mm/yyyy) /

Stratification factors

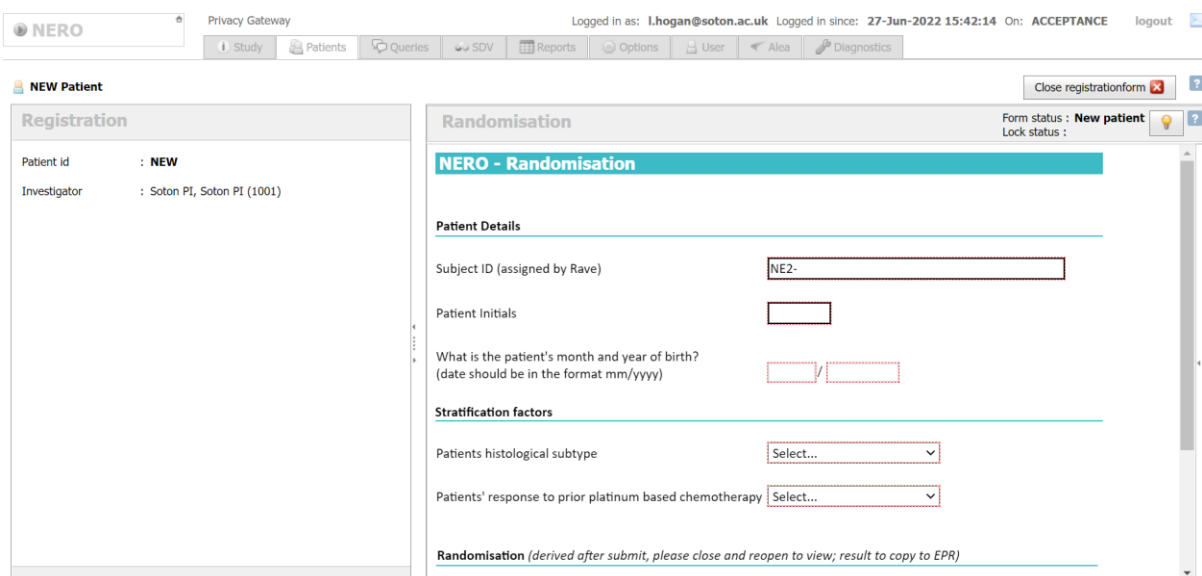
Patients histological subtype

Patients' response to prior platinum based chemotherapy

2. If a user has permissions to enter patient data on behalf of more than one investigator, a pop-up window is displayed first. The pop up window contains the list of clinicians from which the user can select the name on behalf of whom to register a new patient (see below).



After selecting the responsible Investigator/clinician, the Randomisation Form is displayed. The page is divided in two parts.



1. **Left side;** shows the name of the Investigator/clinician.
2. **Right side;** the Randomisation Form containing the data items to be completed is displayed in the centre of the screen.

3.2 Completing the randomisation form

Enter the required details on the Randomisation Form and click on 'Submit'.

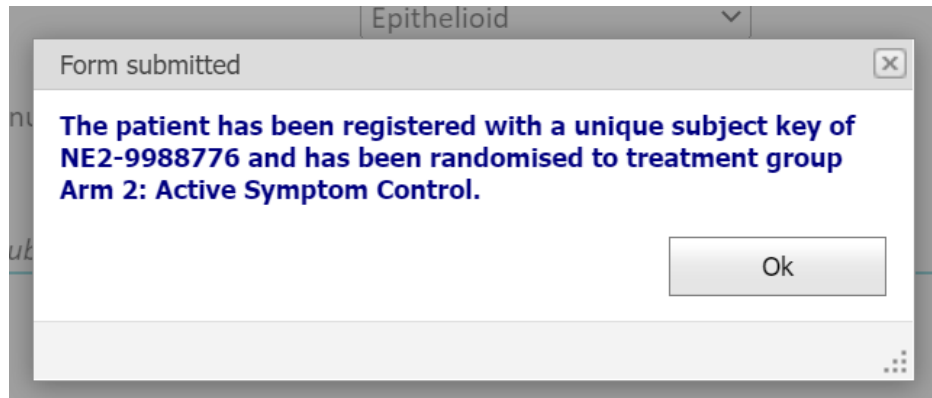
Randomisation		Form status : New patient Lock status :
Patient Details		
Subject ID (assigned by Rave)	<input type="text" value="NE2-9988776"/>	
Patient Initials	<input type="text" value="QWE"/>	
What is the patient's month and year of birth? (date should be in the format mm/yyyy)	<input type="text" value="1"/> / <input type="text" value="2001"/>	
Stratification factors		
Patients histological subtype	<input type="text" value="Epithelioid"/>	
Patients' response to prior platinum based chemotherapy	<input type="text" value="=< 6 months"/>	
Randomisation <i>(derived after submit, please close and reopen to view; result to copy to EPR)</i>		
Date of randomisation	<input type="text" value="27/06/2022"/>	

Any missing or erroneous items will be flagged by a red box, e.g. The 'Submit' button will remain greyed out until the errors are fixed.

Randomisation		Form status : New patient Lock status :
Patient Details		
Subject ID (assigned by Rave)	<input type="text" value="NE2-9988776"/>	
Patient Initials	<input type="text" value="Q"/>	
What is the patient's month and year of birth? (date should be in the format mm/yyyy)	<input type="text" value="1"/> / <input type="text" value="2001"/>	
Stratification factors		
Patients histological subtype	<input type="text" value="Epithelioid"/>	
Patients' response to prior platinum based chemotherapy	<input type="text" value="=< 6 months"/>	
Randomisation <i>(derived after submit, please close and reopen to view; result to copy to EPR)</i>		
Date of randomisation	<input type="text" value="27/06/2022"/>	

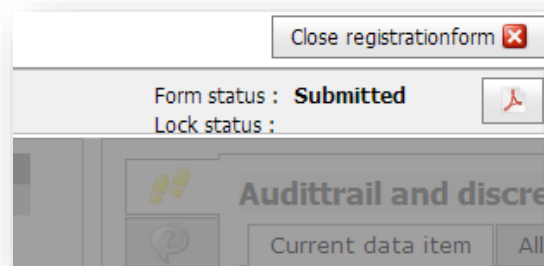
Correct any highlighted item(s) where appropriate. Click on 'Submit' to complete the randomisation.

The form will update to include the randomisation allocation:



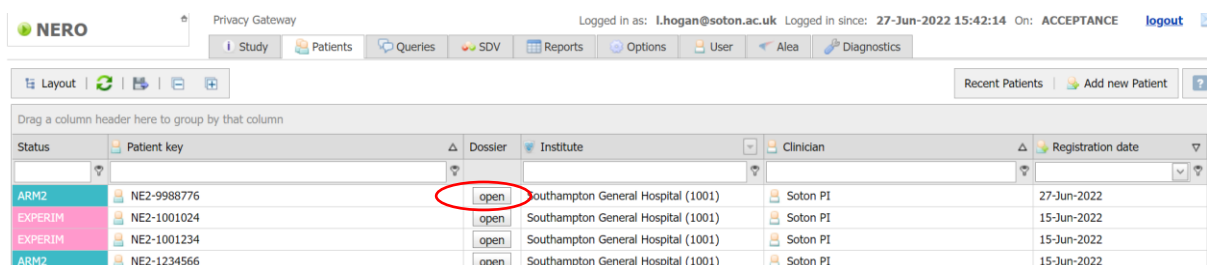
3.3 Closing the form and returning to the patient grid

Close the Randomisation screen by clicking the 'Close registrationform' button at the top right of the eCRF.



After closing the 'Patient registrationform', the Patient Grid is displayed again, showing the last registered patient at the top of the list. Please note that the update time is recorded in Central European Time due to the location of the ALEA servers.

With the 'open' button in the last column of the Patient Grid one can re-access the patient dossier.



Status	Patient key	Dossier	Institute	Clinician	Registration date
ARM2	NE2-9988776	open	Southampton General Hospital (1001)	Soton PI	27-Jun-2022
EXPERIM	NE2-1001024	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
EXPERIM	NE2-1001234	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022
ARM2	NE2-1234566	open	Southampton General Hospital (1001)	Soton PI	15-Jun-2022

From the left hand pane click on the 'open' button that appears next to the Randomisation form. This will redisplay the information submitted along with the randomisation result.

NERO Privacy Gateway Logged in as: I.hogan@soton.ac.uk Logged in since: 27-Jun-2022 15:42:14 On: ACCEPTANCE logout

Study Patients Queries SDV Reports Options User Alea Diagnostics

Patient: NE2-9988776 Registration date: 27-Jun-2022 Investigator: Soton PI Close Patientdossier

Forms Patient NE2-9988776 Randomisation Form status: Submitted Lock status: - Close Form

NERO - Randomisation

The patient has been successfully randomised into arm: Arm 2 - Active Symptom Control

Patient Details

Subject ID (assigned by Rave)

Patient Initials

A PDF notification will be issued via email confirming the randomisation result to NERO@soton.ac.uk



Southampton Clinical Trials Unit
 Faculty of Medicine, University of
 Southampton
 Southampton General Hospital – MP 131
 Southampton
 SO16 6YD

Email: nero@soton.ac.uk

NERO Study

Attn: Soton PI Soton PI
 Southampton General Hospital

Southampton,

Patient NE2-9988776 has been registered by Lucy Hogan from Southampton Clinical Trials Unit on 27 Jun 2022 at 14:54:00 (GMT).

Patient has been randomised to treatment: Arm 2: Active Symptom Control

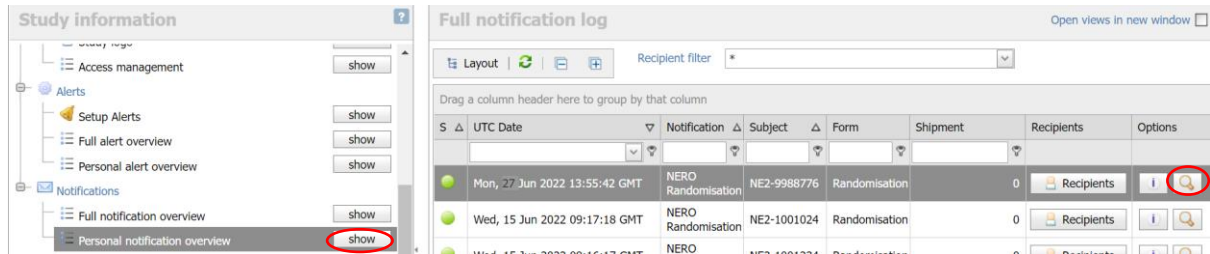
1 Subject ID	NE2-9988776
2 Patient initials	QWE
3 Birth month	1
4 Birth year	2001
5 Histology	Epithelioid
6 Response to platinum based chemotherapy	=< 6 months
7 Date of randomisation	27 Jun 2022

Note that the timestamp recorded on the notification will reflect Central European Time as the system servers are hosted in the Netherlands. As a result, the timestamp may be an hour ahead of local time.

To view the PDF via ALEA select the Study tab:



Click on Show Personal Notification Overview and select the corresponding magnifying glass icon:



This will allow you to view or download the document.

4. Exiting the system

4.1 Logging out

To exit the system click on the **'logout'** icon which can be found at the top right hand side of the screen.

A rectangular button with the text "logout" in a sans-serif font.