

# **ALEA Randomisation User Manual**

ALEA Version: 18 upwards











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ALEA Randomisation User Manual NERO v1.0 27-JUN-2022

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### 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 <a href="https://prod.tenalea.net/ciru/DM/">https://prod.tenalea.net/ciru/DM/</a>

#### 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.

Login to Alea Dat	a Management					
Username	example@clinquest.com	Login				
Password		Login				
I forgot my password / I never logged in before						
Terms, conditions a	nd privacy	About				

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'.

Request change password for tenalea.net						
Email address	example@clinquest.com	Send Request				

Email address	example@clinquest.com	
		Send Request

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 <u>tenalea.net</u> 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 <u>click this link</u> 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 <u>clicking here</u>				
For any further instructions please contact support at notificationservice@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	example@clinquest.com	
New password		0
Confirm new password		
	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.

Change password for AL	ΞΛ
Change password for AL	
Your password has been changed	
Close window	
Rules, Regulations and Disclaimers	©tenalea.net
Kules, Regulations and Disclaimers	<u>©tenalea.net</u>

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

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').

🚺 Study 😢 Patients 🐶 Queries 🧀 SDV 🌐 Reports 💿 Options 🔒 User <
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-

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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.

Study	Δ 👻	Status	-	Last used 🛛 🗸	Last activity	4	Open		NERO
	Ŷ		\$	~ 7	~ 8				Niraparib Efficacy in Patients with Unresectable Mesothelioma: A
NERO		Open		27-Jun-2022 15:42:00	15-Jun-2022 11:15:39	<	enter	^ (	randomised phase II trial of Niraparib versus active symptom control in patients with previously treated mesothelioma
CONFIRMSTUD	Y	Pending				☆	enter		Mesothelioma patients with any histological subtype (epithelioid or non-epithelioid)
PROMDEP		Pending				☆	enter		and any site (pleural or peritoneal) who have previously received an approved systemic therapy containing platinum. NERO is not restricted by line of therapy.
RANDOMARGO		Pending				☆	enter		Type eCRF + Randomisation
RANDOMRIVA		Pending				☆	enter		Role NERO Administrator
REDUCE		Pending				\$2	enter		Study Scope Regional Study phase Pilot

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).

NERC	Privacy Gateway		Logged in as: I.hogan@soto	Logged in as: I.hogan@soton.ac.uk Logged in since: 27-Jun-2022 15:42:14 On: ACCEPTANCE logout					
	i) Study 🔮 Patients 🔀 Queries	🧼 SDV	III Reports 💿 Options 🕒 User	Alea <i>Diagnostics</i>					
🗄 Layout					Recent Patier	nts   臱 Add new Patie	ent [		
Drag a colum	nn header here to group by that column								
Status	😑 Patient key	△ Dossier	😻 Institute	🖃 📙 Clinician	Δ	🌛 Registration date	$\nabla$		
		7		♥	\$		V 9		
EXPERIM	🔒 NE2-1001024	open	Southampton General Hospital (1001)	Soton PI		15-Jun-2022			
	🔒 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			
	NE2-1234578	open	Southampton General Hospital (1001)	Soton PI		15-Jun-2022			
	🔒 NE2-1234556	open	Southampton General Hospital (1001)	Soton PI		15-Jun-2022			
	🔒 NE2-1234555	open	Southampton General Hospital (1001)	Soton PI		15-Jun-2022			
	🔒 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			
	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			
	🔒 NE2-1001777	open	Southampton General Hospital (1001)	Soton PI		14-Jun-2022			
	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.

	Recent patients   🦂 Add new patient				
臱 Registration date	臱 Last update	i I	Dossier	_	
	✓ ♥				
07/08/2013	07/08/2013 12:29	Û	open	-	

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).

#### NEW Patient

	Randomisation	
	NERO - Randomisation	
	Patient Details	
	Subject ID (assigned by Rave)	NE2-
	Patient Initials	
Þ	What is the patient's month and year of birth? (date should be in the format mm/yyyy)	
	Stratification factors	
	Patients histological subtype	Select ~
	Patients' response to prior platinum based chemotherapy	Select 🗸

2. If a user has permissions to enter patient data on behalf of more than one investigator, a popup 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).

elect clinician			~						
Drag a column header here to group by that column									
Clinician	Institute Name		-						
🚊 Good Hope PI, Good Hope PI (1000)	Good Hope (1000)		<b>^</b>						
📙 PI Royal Mars, PI Royal Mars (1002)	Royal Marsden (1002)								
📙 Soton PI, Soton PI (1001)	Southampton General H	Hospital (1001)							
			-						
	× (	Cancel 🧹	Ok						

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

NERO	÷	Privacy Gatew	/ay			Log	ged in as: I.ho	gan@soton.a	ac.uk Logge	d in since: 27-J	lun-2022 15:42:	14 On: ACCEPTANCI	E logout 📐
UNERO		i) Study	📔 Patients	🖓 Querie	s SDV	Reports	Options	🔒 User	< Alea	J Diagnostics			
NEW Patient												Close registra	tionform 🔀 🔋
Registration					Randor	nisation						Form status : New Lock status :	patient 💡 <table-cell></table-cell>
Patient id	: NEW				NERO -	Randomis	ation						<b>^</b>
Investigator	: Soton PI,	Soton PI (1001	)										
					Patient Deta	ails							
					Subject ID (a	issigned by Rav	e)		NE2-				- 1
				4	Patient Initia	ils							- 1
				•		patient's mont I be in the form		irth?		/			•
					Stratification	n factors							
					Patients hist	ological subtyp	e		Select		~		- 1
					Patients' res	ponse to prior	platinum base	d chemother	rapy Select		~		
					Randomisat	ion (derived af	ter submit, ple	ase close an	d reopen to	view; result to	copy to EPR)		*

- 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 : <b>New patient</b> Lock status :
Patient Details		
Subject ID (assigned by Rave)	NE2-9988776	
Patient Initials	QWE	
What is the patient's month and year of birth? (date should be in the format mm/yyyy)	1 / 2001	
Stratification factors		
Patients histological subtype	Epithelioid 🗸	
Patients' response to prior platinum based chemotherapy	=< 6 months V	
Randomisation (derived after submit, please close and rec	open to view; result to copy to EPR)	
Date of randomisation 27/06/202	2	
Any missing or erroneous items will be flagged	by a red boy a g. The 'Submit' by	itton will remain

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 : <b>New patient</b> Lock status :
Patient Details		
Subject ID (assigned by Rave)	NE2-9988776	
Patient Initials	Q	
What is the patient's month and year of birth? (date should be in the format mm/yyyy)	1 / 2001	
Stratification factors		
Patients histological subtype	Epithelioid ~	
Patients' response to prior platinum based chemotherapy	=< 6 months ~	
Randomisation (derived after submit, please close and red	open to view; result to copy to EPR)	
Date of randomisation 27/06/202	2	

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

The form will update to include the randomisation allocation:

	Epithelioid 🗸	
I	Form submitted	×
nı	The patient has been registered with a unique subject key of NE2-9988776 and has been randomised to treatment group Arm 2: Active Symptom Control.	
uk	Ok	
I.		.::

### 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.

NERC	)	÷	Privacy Gatew	vay			L	ogged in as: I.he	gan@soton	.ac.ı	uk Logge	l in since: 27-	Jun-2022	L5:42:14 On	ACCEPTANCE	logout
	-		i Study	을 Patients	🗘 Queries	🧼 S	DV Reports	Options	📙 User	•	Alea	🥜 Diagnostic	s			
🗄 Layout	10	IBIE	Œ											Recent Patier	nts 📋 🌭 Add new P	Patient 🛛 💽
Drag a colum	nn hea	ader here to group	p by that column													
Status		Patient key					ssier 🗑 Institute			-	Clinicia	n		۵		. ⊳
	7					♥				7				\$		~ 7
ARM2		NE2-9988776	;		(	0	pen outhampto	on General Hospit	al (1001)		Soton	PI			27-Jun-2022	
EXPERIM		NE2-1001024	ł			0	pen Southampto	on General Hospit	al (1001)		Soton	PI			15-Jun-2022	
EXPERIM		NE2-1001234	ł			0	pen Southampte	on General Hospit	al (1001)		Soton	PI			15-Jun-2022	
ARM2		NE2-1234566	5			0	pen Southampte	on General Hospit	al (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 Gatev	way			Log	ged in as: I.ho	gan@soton.	ac.uk Logg	ed in since: 27-Ju	un-2022 15:42:14 On: ACCE	PTANCE logout
• HERO		i Study	atients	🖓 Querie	s 😡 SDV	Reports	Options	📙 User	< Alea	Je Diagnostics		
Patient: NE2-9988776	Regist	tration date: 27	7-Jun-2022 Inv	estigator: Sot	ton PI						[	Close Patientdossier 🔀
Forms Patient N	E <b>2-9</b>	988776		Ŧ ?	Randon	nisation					Form status : Submitted 💡 Lock status : -	Close Form 🔀
Randomisation			0 0	en 🌷	NERO -	Randomis	ation					l
					The patient	has been succe	ssfully random	ised into ar	m: Arm 2 -	Active Symptom	Control	
					Patient Deta	ils						
					Subject ID (a	ssigned by Rav	ve)		NE2-9	988776		]
				4	Patient Initia	ls			QWE			

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

	NERO	Southampton Clinical Trials Unit Faculty of Medicine, University of Southampton Southampton General Hospital – MP 131 Southampton SO16 6YD
	Jack	Email: nero@soton.ac.uk
NE	RO Study	
	Soton PI Soton PI hampton General Hospital	
Sout	hampton,	
Pat Uni	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT).	y Lucy Hogan from Southampton Clinical Trials ment: Arm 2: Active Symptom Control
Pati Uni Pat	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT).	ment: Arm 2: Active Symptom Control
Pati Uni Pat	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT). tient has been randomised to treat Subject ID Patient initials	ment: Arm 2: Active Symptom Control NE2-9988774 QW
Pat Uni Pat	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT). tient has been randomised to treat Subject ID Patient initials Birth month	ment: Arm 2: Active Symptom Control NE2-998877 QWI
Pati Uni Pat	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT). tient has been randomised to treat Subject ID Patient initials Birth month Birth year	ment: Arm 2: Active Symptom Control NE2-998877 QWI 200
Pati Uni Pat	ient NE2-9988776 has been registered by t on 27 Jun 2022 at 14:54:00 (GMT). tient has been randomised to treat Subject ID Patient initials Birth month	ment: Arm 2: Active Symptom Control NE2-998877 QWI

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:

Study information	?	Ful	I notification log								Open views in	new window	
→ Galactic Access management	show	W E Layout C E E Recipient litter											
— 🦪 Setup Alerts	show		a column header here to group by th		umn ification △	Subject		Form	Shipmen	ıt	Recipients	Options	
─ i≡ Full alert overview	show		<u>ि</u>		8		7		2	4	,		
E Personal alert overview Notifications	show	•	Mon, 27 Jun 2022 13:55:42 GMT	NEF Ran	tO domisation	NE2-998877	6	Randomisatio	n	0	Recipients		
E Full notification overview	show	۲	Wed, 15 Jun 2022 09:17:18 GMT	NEF Ran	tO domisation	NE2-1001024	4	Randomisatio	'n	0	Recipients		
Personal notification overview	show	•	Mod. 15 Jun 2022 00:16:17 CMT	NEP	RO	NE2-100122	4	Dandomicati		0	Decinionte	100	

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.

