ALEA Instruction

ALEA is a web-based registration- and randomization tool for clinical trials. As a user you will have direct access to the production environment.

Log in and password

If you never used ALEA, start by entering the address:

https://prod.tenalea.net/karolinska/DM/

You will get the following screen:

Login to Alea Data Management					
Username Password		Login			
I forgot my password / I never logged in before					
Terms, conditions and privacy About					

Click on: I forgot my password / I never logged in before

You'll be taken to a screen that asks you to enter your email address. Click on Send Request-button. Close the screen. If you receive a reply with a red text that says that your email address is not in the system, make sure first that you have typed the correct e-mail address, secondly, contact the responsible study coordinator.

You will within a few minutes receive an email with the following content:

Password change request					
You have requested to receive your user account details by email to mail address [mats.hellstrom@karolinska.se].					
You are registered at tenalea.net as user [mats.hellstrom@karolinska.se].					
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/karolinska/dm/DEChangePW.aspx?PwdChangeRequestID=55ad19ab-ba43-44b3- bd0f-6f9111eaa3cc					
After setting your password you can login to ALEA data management by clicking here					
For any further instructions please contact support at karolinska@tenalea.net					

Click on **click this link** and enter the email address and password twice on the next screen:

Password expiration The password you set now will ex- prompted to renew your password forgotten password in the TENALI menu.	pire in 365 days. When you log in after your password has expir g after logging in. You can change your password at any time b A login screen, or by selecting <i>Change password</i> from the data	ed, you are y selecting management
Password length The password you set should have	a minimum length of 8 characters.	
Accountname	example@clinquest.com	
New password	0	
Confirm new password		
	Set password	

Confirm user terms. Then you go back to the above screen and log in to ALEA by clicking **clicking here** at the bottom

You are now an ALEA-user.

How to register/randomizing a patient in ALEA

Prior to randomization in the SENOMAC study – Please note the following excerpt from the protocol:

In the inclusion and exclusion criteria, "sentinel node" describes all those lymph nodes (≤ 4) harvested at sentinel lymph node biopsy, including those removed due to abnormal appearance or consistency in the absence of uptake of blue dye or radioactive isotope.

Log into ALEA via the following address:

https://prod.tenalea.net/karolinska/DM/

After successful login, you will come to ALEA's website. To the left you will see the / the studies you have access to:

Alea Data Manag Study Selection	jement -	version v4.0.5	457.17325				Logged	in as	main had	lahoon dhar alfaala se L	ogged in since: 16-12-2014 O	n: PRODUCTION logo
P Recent	1 🔿 M	arked	🗧 Ali	Pending	V Oper	n 🗹 Suspended	Close	d	3	Access managemen	t	Enter 🥪
Study DEMOBLOCK Predix Her2	△ ♥	Status Pending Pending	v V	Last used 02/04/2014 14:26 15/12/2014 15:49	⊽ ⊻ Ÿ	Last activity	× 9	 ▼ ★ ☆ 	Open enter enter	DEMOBLOCK Demo blocked rando	misation	Śź
										Type Role Study Scope Study phase Current patient accrual First entered patient Last entered patient Last activity	Randomisation System role: Study nurse International Pilot 2 15-12-2014 10:48 15-12-2014 11:18	

Enter 📀

Select a study and click on

up at the right side. You will then come to the study site:

DEMOBLOCK	AleaGateway:	TTP	Logged in as	matter hade	a.s	e Logged in since:	16.12.2014 08:41
	i) Study	Patients	📙 User	< Alea			
Study information				Study i	nfo DEMOBLO	СК	
General study info	show	1		Study short	DEMO	DBLOCK	
Study documents Study data	oper	1		Long study	title Demo	blocked random	isation
Study accrual	show	1		Description			
Study options		_		Study Scop	e Intern	ational	
Study logo	show	1		Study phase	e Pilot		
				Current pat	ient accrual 2	2014 10:49	
				Last entere	d patient 15-12	-2014 10:48	
			4	Last activity	/ 13-12	2014 11.10	
			}				

At the top there are four tabs:

- Study Information about the study and some info about eg enrollment.
- Patients Data about patients included on your site as well as the ability to register new patients
- User information about and for users. Here you can change your password.
- Alea Information about the system and the company behind.

Only the Patients-tab will be described here

Register/randomizing

After logging in, select a study and click on

Enter 🥝

Then click on the tab Patients. You'll be taken to a screen with a list of included patients. The screen can of course be completely empty if you have not yet registered/randomized any patient.

Then click on the button Add new patient to the far right.

You'll be taken to a registration form that looks different depending on the study. See example below:

DEMOBLOCK AleaGateway: TTP Logged in as Study AleaGateway: TTP Logged in as Study	karolinska.se Logged in sir	ince: 16.12.2014 08:41 On: PRODUCTION Language: en-GB logout
B NEW Patient		Close registrationform 🔀
Registration	Randomisation form	Form status New patient Close Form 🔀
Patient id : NEW	Study: DEMOBLOCK - Form: Randomisatio	on form
Registration date : 16/12/2014 Investigator : Vernersson, Johanna (101)	Study site	Karolinska University Hospital
	Initials of the patients Enter two digits	
	Gender of the patient	•
	Pregnant	\$
	Date of birth	
	Age of patient	
		SUBMIT FORM

Fill in the information in the form to the right. Date is written dd/mm/yyyy. When you are done and verified that everything seems correct, click the button **SUBMIT FORM**. Click the OK button and you will then receive a confirmation message with information that the patient is registered, study number, randomization-result and the information you filled in earlier. You will also receive an email with the same content.

	Close registrationform 🔀
Randomisation form	Form status New patient Close Form 🔀
The patient has been assigned stud treatment arm A.	dy number 101-001, and has been allocated to
Questions	Answers
Study site	Karolinska University Hospital
Initials of the patients Enter two digits	AB
Gender of the patient	FEMALE
Pregnant	no
Date of birth	01/01/1960
Age of patient	54
Randomisation: A vs B	۵

When you click on Close registration form, you are returned to the patient overview and the patient you recently registered should now be shown there.