# **ALEA Instruction**

ALEA is a web-based registration- and randomisation tool for clinical trials. As a user you will have direct access to the production environment, i.e. the "real-patient" database.

### Login and password

If you never used ALEA, follow the link:

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

The following screen will appear:

Login to Alea Data Mar	nagement		
Username Password		Login	
I forgot my password / I	never logged in before		
Terms, conditions and priv	vacy		About

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

You'll be transferred to a screen that asks you to enter your email address. Click on Send Requestbutton. Close the screen. If you receive a reply with a warning (red text) that states that your email address is not in the system, make sure that you have typed the correct e-mail address. If the email address is correct but the warning appears, contact the responsible study manager.

You will 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 click this link 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 es prompted to renew your passwor forgotten password in the TENAL menu.	pire in 365 days. When you log in after your password has expired, you ard after logging in. You can change your password at any time by selecting A login screen, or by selecting <i>Change password</i> from the data managem
Password length The password you set should hav	a minimum length of 8 characters.
Accountname	example@clinquest.com
New password	
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/randomise a patient in ALEA

Log into ALEA via the following link:

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

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

Recent	Ma	arked	🧯 All	Pending 🗹	Open	Suspended V Clos	ed	3	Access managemen	t	Enter 🥥
Study DEMOBLOCK Predix Her2	△ - ♥	Status Pending Pending	* •	Last used 02/04/2014 14:26 15/12/2014 15:49	⊽ ⊽	Last activity	<ul> <li>▼</li> <li>☆</li> </ul>	Open enter enter	DEMOBLOCK Demo blocked rando	misation	ž
									Type Role Study Scope Study phase Current patient accrual First entered patient Last entered patient	Randomisation System role: Study nurse International Pilot 2 15-12-2014 10:48 15-12-2014 11:18	

Select a study and click on

Enter 🥥

at the right side. You will then enter the study site:

DEMOBLOCK     AleaGateway: TTP     Logged in	as: .se Logged in since: 16.12.2014 08:41
(i) Study 🔚 Patients 💾 Use	r < Alea
Study information	Study info DEMOBLOCK
General study info     General study info     Study show     Study documents     open     Study data     General study acrual     Study data     Study	Study short     DEMOBLOCK       Long study title     Demo blocked randomisation       Description     International       Study Scope     International       Study phase     Pilot
	Current patient accrual 2 First entered patient 15-12-2014 10:48 Last entered patient 15-12-2014 11:18 Last activity

At the top of the screen there are four tabs:

- Study Information about the study and some info about enrollment etc.
- Patients Data about patients included at 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.

In this manual, only the Patients-tab will be described.

## **Register/randomise**

After logging in, select a study and click on



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/randomised any patient.

A registration form will appear. Note, this form can look different depending on the study. See example below:

DEMOBLOCK     AleaGateway: TTP     Logged     Study     Patients     Logged	in as: karolinska.se Logged in since	: 16.12.2014 08:41 On: PRODUCTION Language: en-GB logou	rt 🖻	
NEW Patient		Close registration	form 🕻	
Registration	Randomisation form	Form status New patient Close Form	1 🛛	
Patient id : NEW	Study: DEMOBLOCK - Form: Randomisation	form		
Registration date : 16/12/2014 Investigator : Vernersson, Johanna (101)	Study site	Karolinska University Hospital		
aun 2004 €uith stantas stant va stantas	Initials of the patients Enter two digits			
	Gender of the patient	•		
	Pregnant	÷		
	Date of birth			
	Age of patient			
		SUBMIT	FORM	

Complete 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, randomisation-result and the information you entered. You will also receive an email with the same content.

	Clos	se registrationform
Randomisation form	Form status New patient	Close Form 🔀
The patient has been assigned reatment arm A. Questions Study site	study number 101-001, and has been alloc: Answers Karolinska University Hospital	ated to
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	

After clicking the Close registration form, you are redirected to the patient overview. The patient you recently registered should now appear there.