

ALEA Instruction

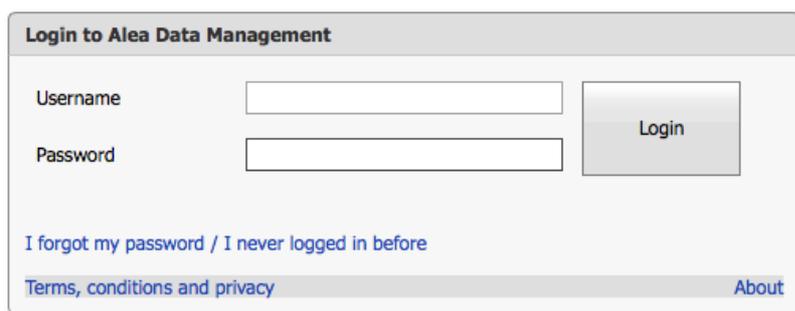
ALEA is a web-based registration- and randomization tool for clinical trials. As a user you will have direct access to the production environment.

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

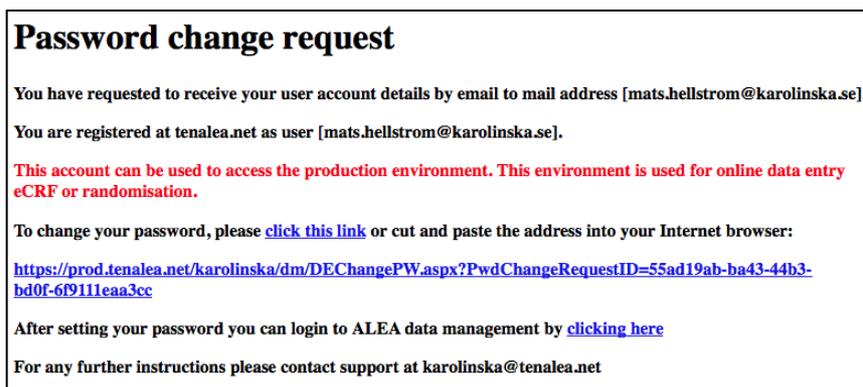
[I forgot my password / I never logged in before](#)

[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 [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 expire in 365 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 *forgot 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.

Accountname

New password 

Confirm new 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

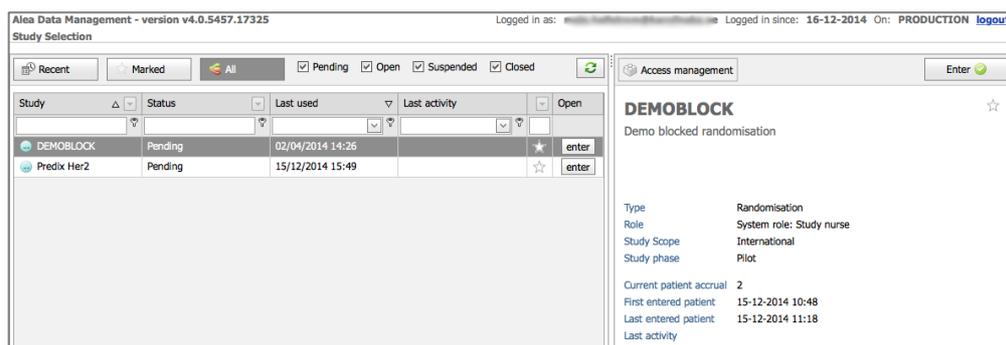
Prior to randomization in the SENOMAC study – Please note the following excerpt from the protocol:

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.

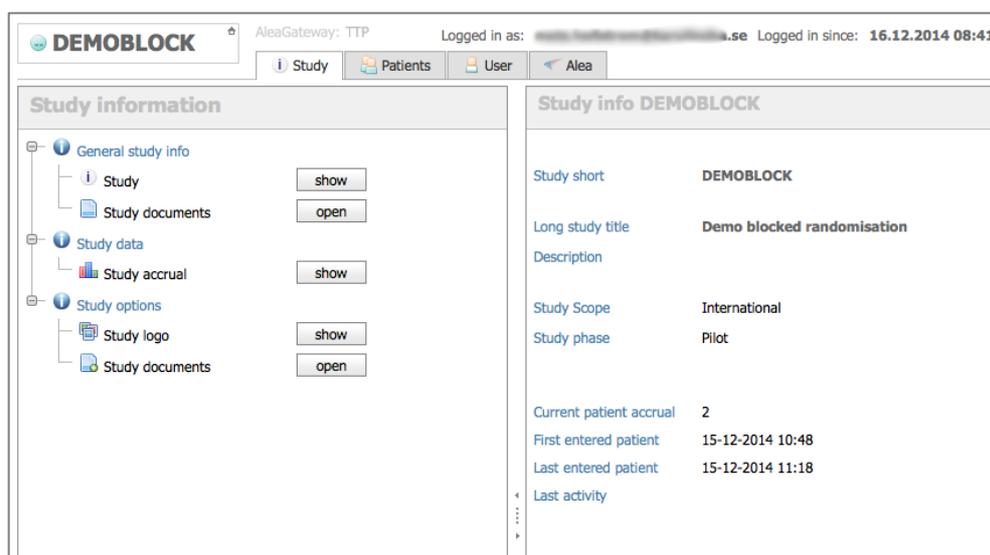
Log into ALEA via the following address:

<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:



Select a study and click on  up at the right side. You will then come to the study site:



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



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



to the far right.

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

NEW Patient

Registration

Patient id : NEW
Registration date : 16/12/2014
Investigator : Vernersson, Johanna (101)

Randomisation form

Form status New patient

Study: DEMOBLOCK - Form: Randomisation form

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.

Randomisation form

Form status New patient

The patient has been assigned study number 101-001, and has been allocated to treatment arm A.

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	A

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.