ALEA Instruction

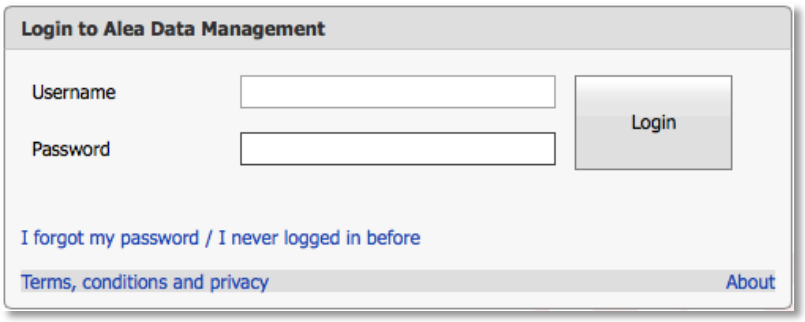
ALEA is a web-based registration- and randomization tool for clinical trials. As a user you will have direct access to the production environment.

Log in and password

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

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

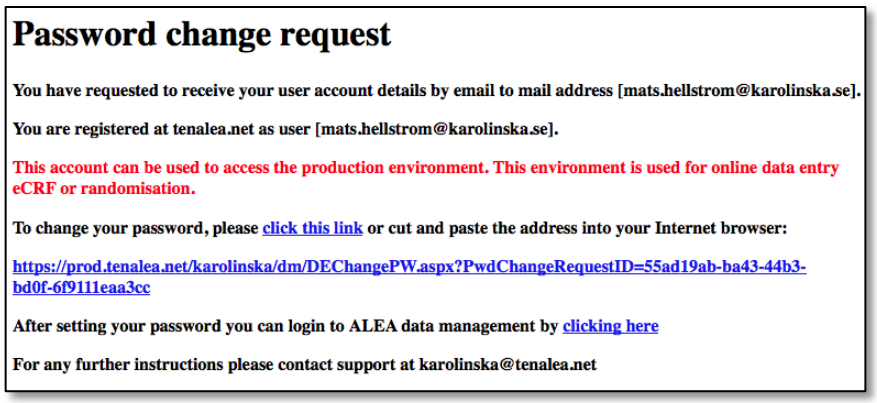
You will get the following screen:



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:

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

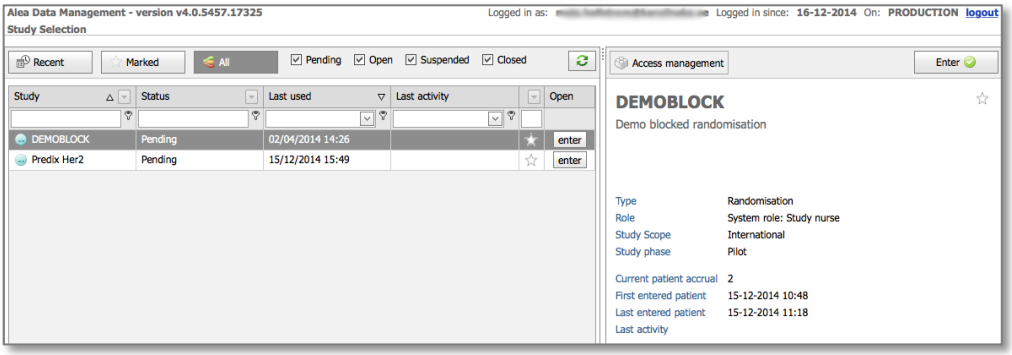
Prior to randomization in the SENOMAC study – Please note the following excerpt from the protocol:

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.

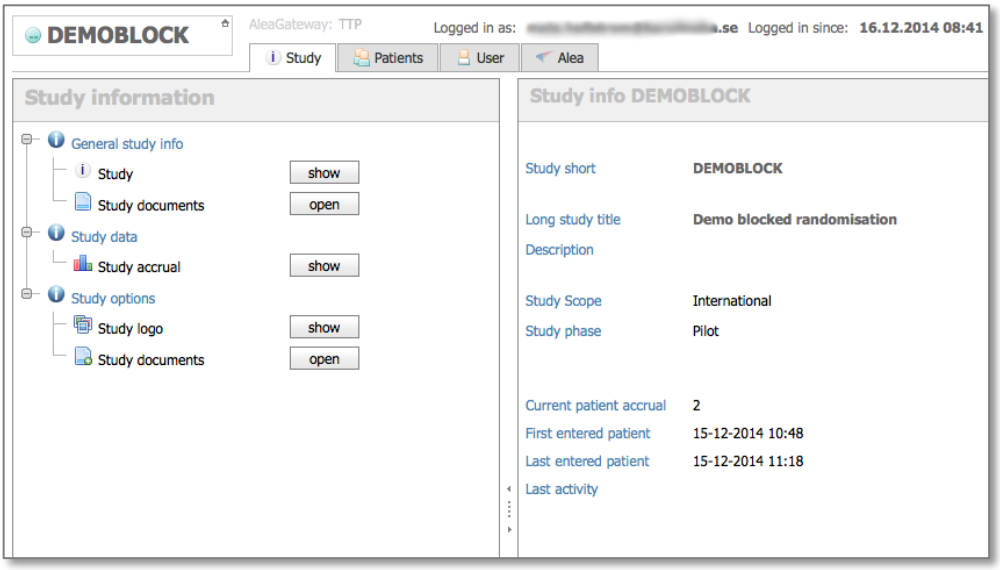
Log into ALEA via the following address:

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

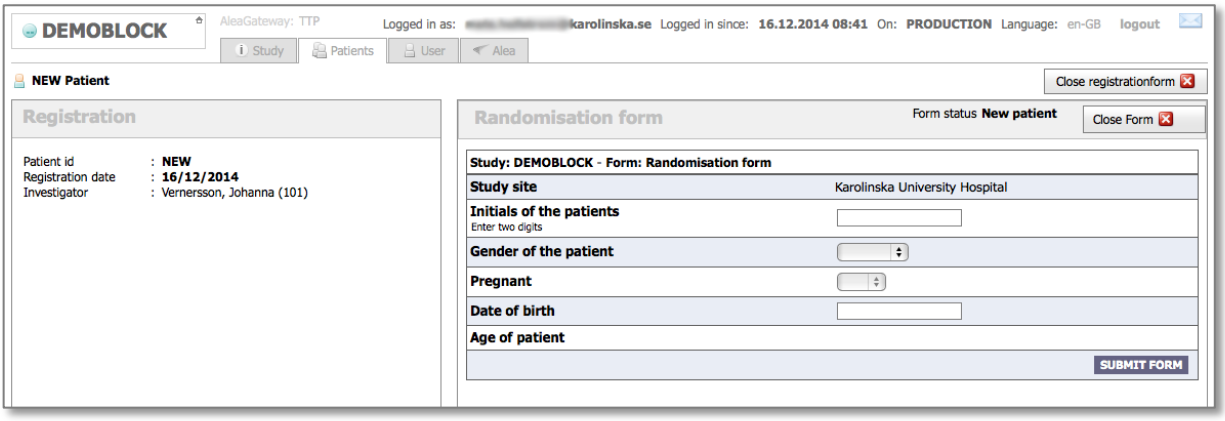
After logging in, select a study and click on

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.

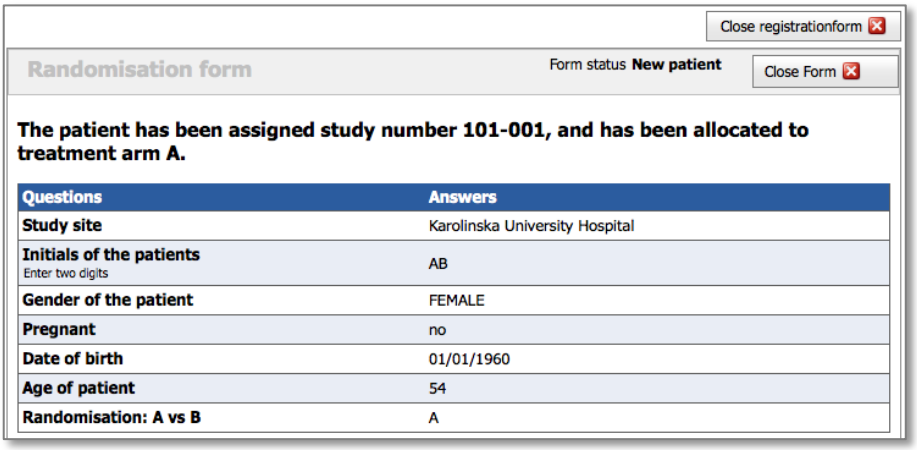
Then click on the button

to the far right.

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



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.



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.