

ALEA Instruction

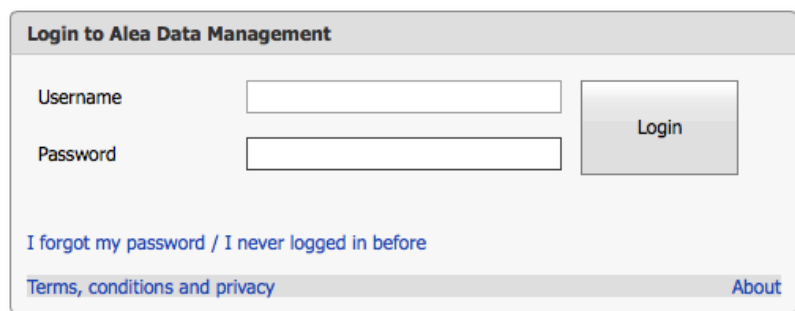
ALEA is a web-based registration- and randomisation tool for clinical trials. As a user you will have direct access to the production environment, i.e. the “real-patient” database.

Login and password

If you never used ALEA, follow the link:

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

The following screen will appear:

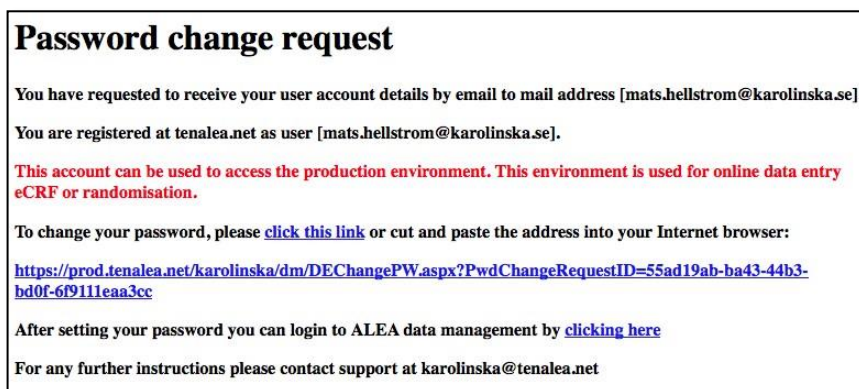


The screenshot shows a web form titled "Login to Alea Data Management". It contains two input fields: "Username" and "Password". To the right of these fields is a "Login" button. Below the input fields, there is a link that says "I forgot my password / I never logged in before". At the bottom of the form, there are two links: "Terms, conditions and privacy" and "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 Request-button. 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:



The screenshot shows an email titled "Password change request". The content of the email is as follows:

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 *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.

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

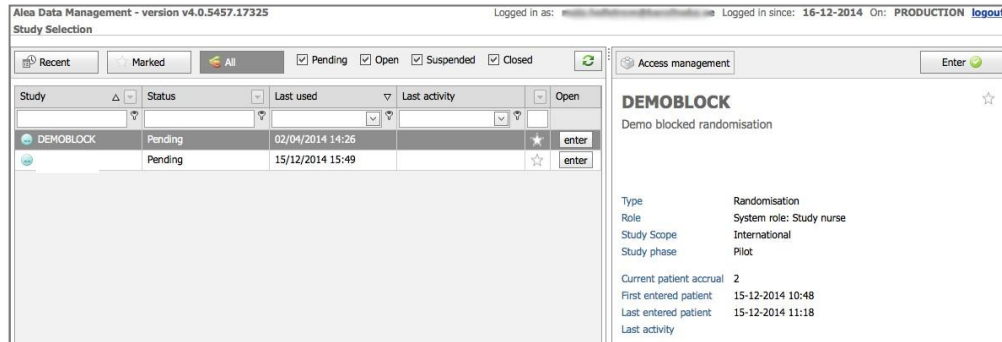
You are now an ALEA-user.


How to register/randomise a patient in ALEA

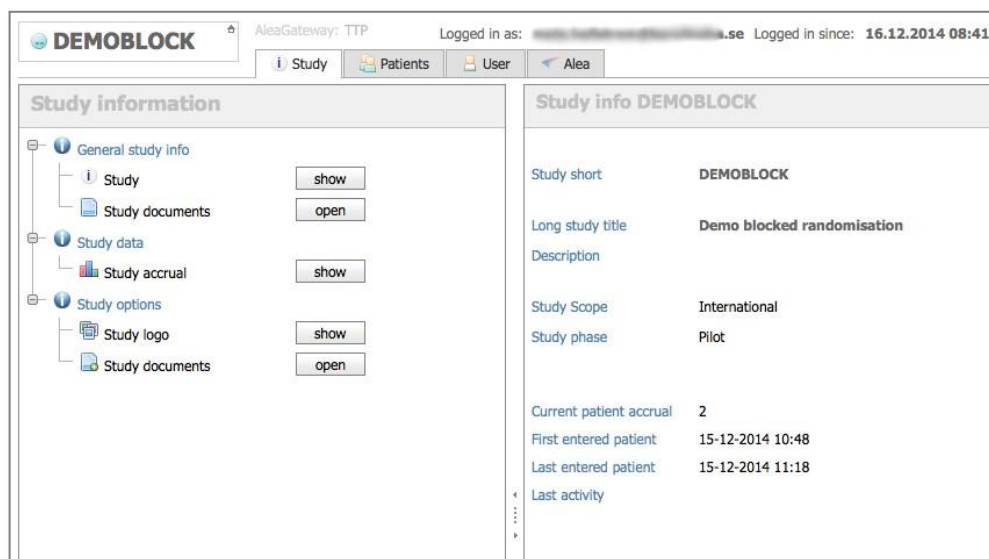
Log into ALEA via the following link:

<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:



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



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

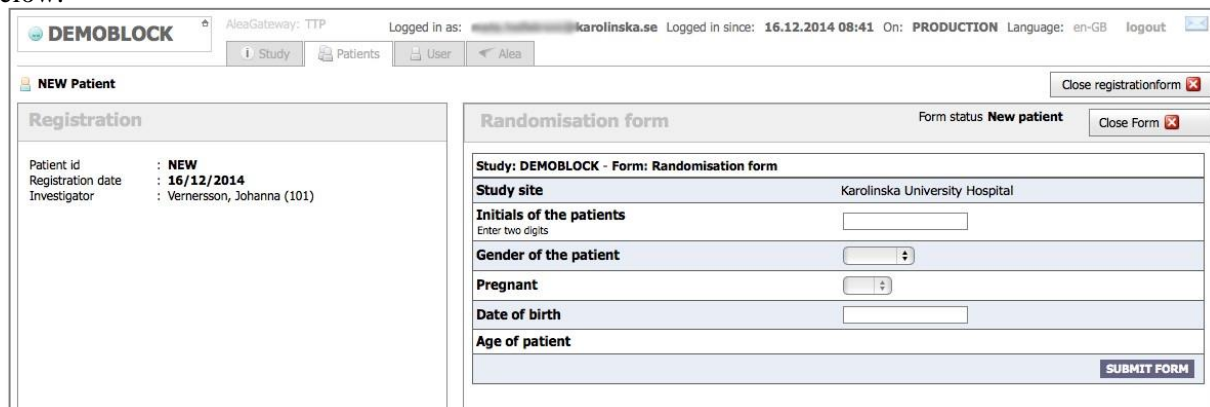
After logging in, select a study and click on



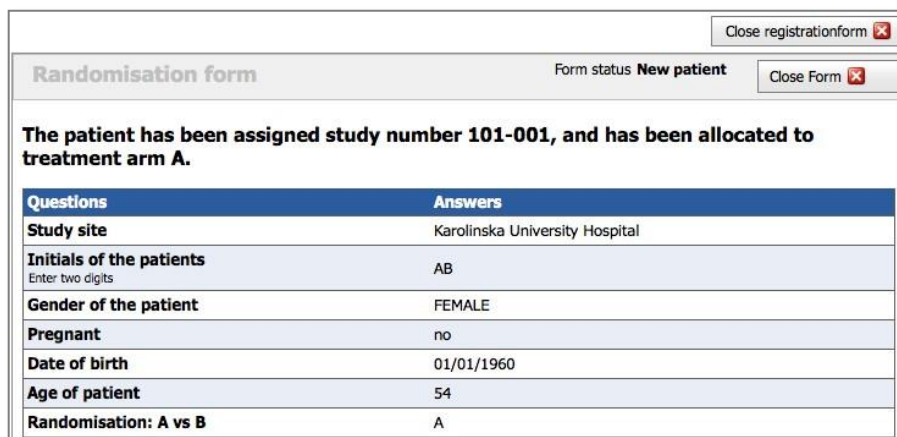
Then click on the tab Patients. You'll be taken to a screen with a list of included patients. The screen can of course be completely empty if you have not yet registered/randomised any patient.

Then click on the button  to the far right.

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



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.



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

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