STANDARD OPERATING PROCEDURE ALEA

Login, Randomization, Kit Dispensation, and Study Supply Management

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1. ALEA Log in

Step 1. Open ALEA
There are two different ways to open de module:
- Open URL: http://ctc-erasmusmc.nl/alea
- Open URL: https://neonatology.eu/ → Select the blue section '*ik ben arts, verpleegkundige, onderzoeksmedewerker*' → Log in with Gebruikersnaam (*<Gebruikersnaam per ziekenhuis>*) and Wachtwoord (*<Wachtwoord per ziekenhuis>*) → Select 'N3 Research' in the top bar → Select 'Doxa Trial' → 'Randomization' → 'RANDOMIZE NEW PATIENT'

Step 2. Log in with your account
You can log in with the e-mail address and the password you have set before (same as your account request[1]).
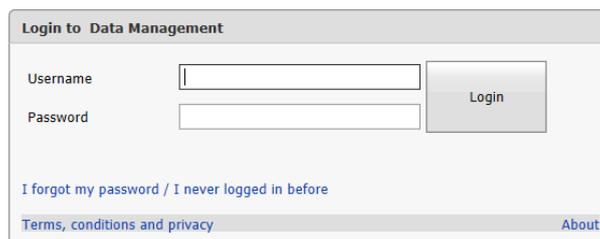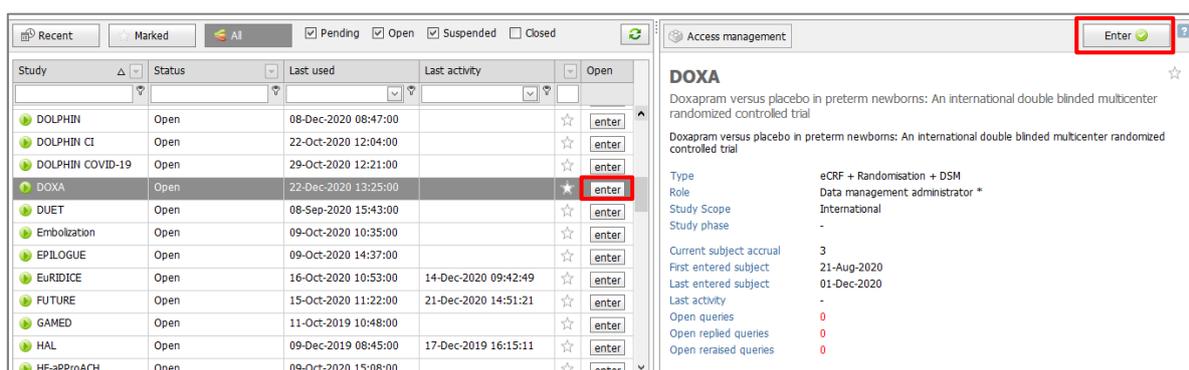

When you want to log in for the first time or you have forgotten your password, click on **'I forgot my password / I never logged in before'** and follow the steps*.

_ IMPORTANT._ For security reasons:_
- *The link expires within an hour after receiving the e-mail. Please check your spam or junkmail folder when no e-mail is received.*
- *A password is only valid for three months in ALEA. The password needs to be adjusted <u>every quartile</u>!*

Step 3. Select 'DOXA' as study *(if applicable)*
When you have access to multiple studies in ALEA, you will enter a selection page after login. Click the '**Enter**' button of the highlighted study or the '**Enter**' button in the header of the summary section to open the DOXA-Trial.

You can mark your favorite studies by clicking the star in the upper right corner of the summary section.
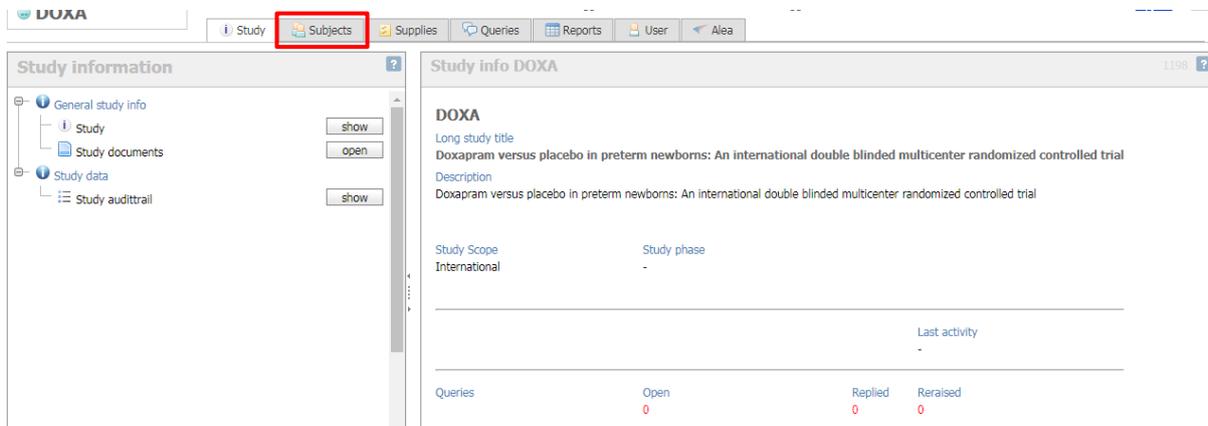
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[1] At the start of the clinical trial you were asked to fill in an account request form. When this is not yet done, you can request a form by sending an e-mail to invent.ctc@erasmusmc.nl.

2. Randomization

Step 1. Log in to ALEA according to the instructions at page 2.
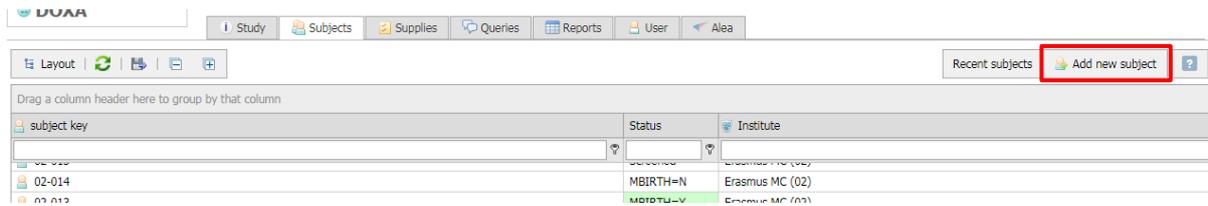
Step 2. Open list of study subjects.
The front page of the DOXA-Trial appears. Select '**Subjects**' in the top bar.

Step 3. Add a new subject to the study.
Select '**Add new subject**' in the top right of the page to add a new subject to the database.
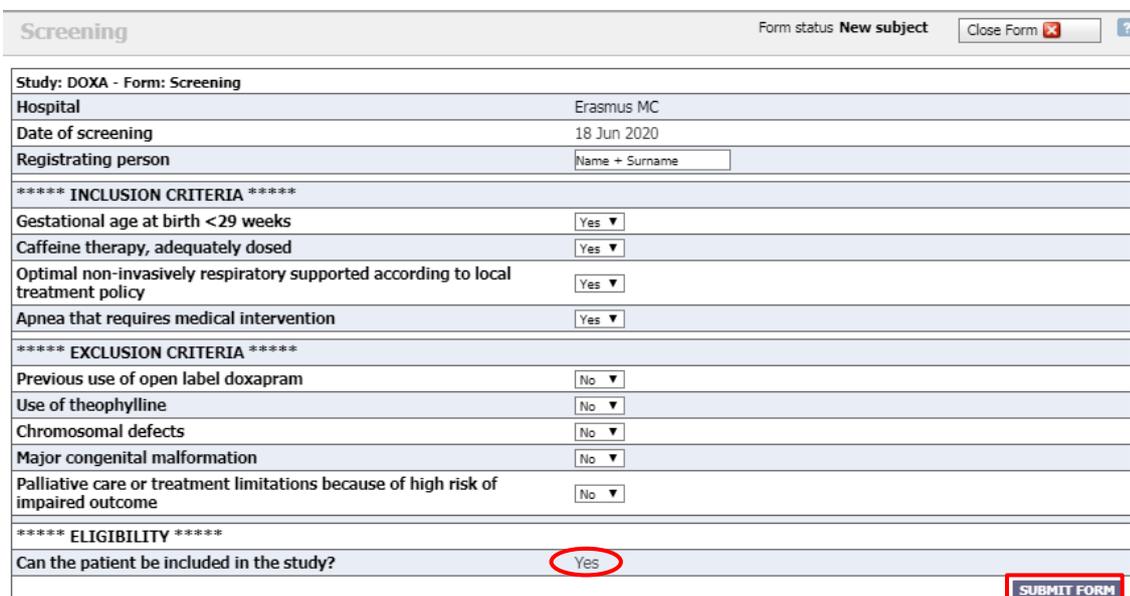

Step 4. Submit the screenings form
Please fill in the form. Under '**ELIGIBILITY**' is shown if the patients can be included in the study. Submit the form via '**SUBMIT FORM**' at the bottom right of the page.

The subjectnumber of the patient appears at the top of the submitted form.

Step 5. Close the subjectdossier
Select '**Close subjectdossier**' in the top right corner of the page.
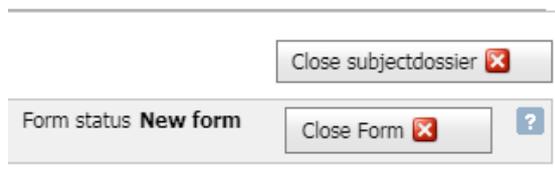
*If a patient is **ELIGIBLE** for inclusion, continue to step 6. If a patient is **NOT ELIGIBLE** for inclusion there is no further action required.*

Step 6. Continue to randomization.
'**Open**' the dossier of the patient again. Check for the right subjectnumber!
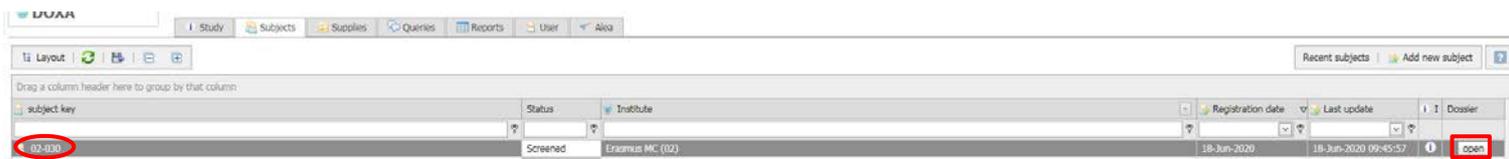
When 'Screening' is completed a green square is shown. Select '**Open**' by **Randomization** to open the randomization form. Fill in the form and '**SUBMIT FORM**'.

*In case of twins where parents choose to randomize the patients to the same treatment arm, this should be selected under **MULTIPLE BIRTH**. The subjectnumber (xx-xxx) of the sibling should be noted if he/she is already randomized. **Check for the correct subjectnumber!***

Continue to step 7 on the next page..

Step 7. Dispense a medication kit.
When '**Randomization**' is completed a green square is shown. '**Open**' Kit Dispensation to link a Kit to a subjectnumber. Fill in name + surname and '**SUBMIT FORM**'.

The dispensed kit is shown at the top of the submitted form. If required, the form can be printed by printing the page in the web browser. Close the form by selecting '**Close subjectdossier**'.

3. Extra Kit Dispensation

Step 1. Log in to ALEA according to the instructions at page 2.

Step 2. Open the dossier of the subject.
Go to '**Subjects**' and '**open**' the dossier of the subject. Check for the correct subject number!

Step 3. Add Extra Kit Dispensation form.
Select '**add form**' to dispense an extra kit to a participant. Complete and submit the form according to the instructions mentioned in step 8.
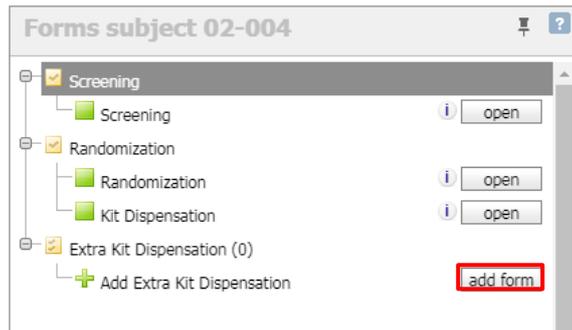
Step 4. Complete the form according to the instructions at page 5.
Fill in name + surname and '**SUBMIT FORM**'. The dispensed kit is shown at the top of the submitted form. If required, the form can be printed by printing the page in the web browser. Close the form by selecting '**Close subjectdossier**'.

4. Drug Supply Management

For clinical trials where the Drug Supply Management (DSM) module is enabled and configured, the Hospital Pharmacy Erasmus MC, Local Hospital Pharmacy and NICU/Ward-pharmacy have the option to send and receive study medication.

Flow of the steps in ALEA to enable allocation of study medication to subjects:

1. Local Hospital Pharmacy orders study medication via **STEP 4.1** using Site ID **<center code+A>**
2. Central Hospital Pharmacy Erasmus MC sends ordered study medication to Local Hospital Pharmacy
3. Local Hospital Pharmacy receives study medication in ALEA via **STEP 4.2**
4. Local Hospital Pharmacy creates order to NICU/Ward Pharmacy via **STEP 4.1**
5. Local Hospital Pharmacy sends allocated kits for shipment to NICU/Ward Pharmacy using Site ID **<center code>**
6. NICU/Ward Pharmacy confirms to have received the kits via **STEP 4.2**
7. Study medication is available in ALEA to be allocated to a subject

4.1. Order new study medication for local Hospital Pharmacy or for NICU/Ward-pharmacy

How can I order new study medication? In this section we will discuss the relevant procedure for this.

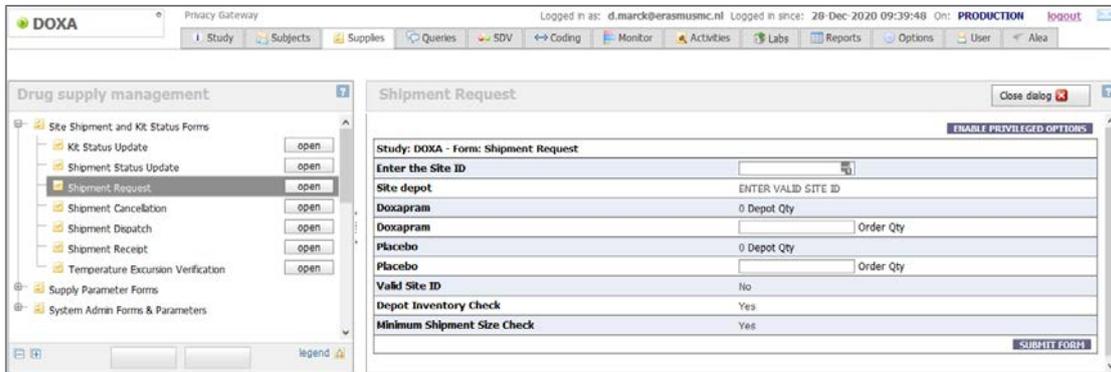**Step 1. Log in to ALEA according to the instructions at page 2.**

Step 2. Open the 'Shipment Request' form
On the 'Supplies' tab, click on the 'open' button behind the 'Shipment Request' form

Step 3. Fill in the 'Shipment Request' form
When the 'Shipment Request' form has been opened, the order details can be entered. When entering the quantities to be delivered the system will check immediately whether there is sufficient stock available for delivery.

> Notes:
> - **Site ID: The unique code of the site / pharmacy to which the delivery must be made. This means:**
>   o **Local Hospital Pharmacy is**   **<center code+A>**   **e.g. for Leiden '04A'**
>   o **NICU/Ward-pharmacy is**   **<center code>**   **e.g. for Leiden '04'**
>
> - **Site depot:** The unique code of the site / pharmacy who will make the delivery. This is automatically determined based on the above item, i.e. an order for the NICU in Leiden with Site ID '04A'will use the local Hospital Pharmacy as a stock, so the Site Depot in this case is '04';
> - **Study medication:** The quantity to be ordered can be specified here. The maximum quantity to be ordered from the depot is also visible here;

Step 4: Submit in the 'Shipment Request' form to place your order by clicking on 'SUBMIT FORM'.

After completing the 'Shipment Request' form, it can be submitted by clicking the submit button. When there are no issues found, the order will be created and the shipment ID is displayed. A confirmation email has also been sent to the email used as a login, as well as an email to the Local Hospital Pharmacy with the numbers of all kits that need to be dispatched.
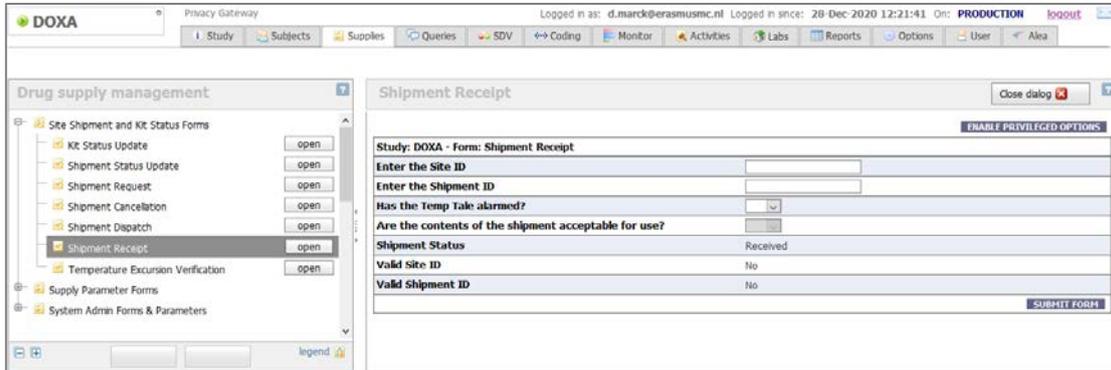
4.2. Receive study medication
In this section we will discuss how to receive a shipment.

Step 1. Log in to ALEA according to the instructions at page 2.

Step 2. Open the 'Shipment Receipt' form.
On the 'Supplies' tab, click on the open button behind the 'Shipment Receipt' form

Step 3. Fill in the 'Shipment Receipt' form.
When the 'Shipment Receipt' form has been opened, the details can be entered.

> Notes:
> - **Site ID: The unique code of the site / pharmacy to which the delivery must be made. This means:**
>   - **Local Hospital Pharmacy is**   **<center code+A>**   **e.g. for Leiden '04A'**
>   - **NICU/Ward-pharmacy is**   **<center code>**   **e.g. for Leiden '04'**
> - **Shipment ID:** The unique shipment ID which is generated by requesting a new shipment;

Step 4. Submit in the 'Shipment Receipt' form.
After completing the 'Shipment Receipt' form, it can be submitted by clicking the submit button. When there are no issues found, the order will be available for dispensing.