

STANDARD OPERATING PROCEDURE ALEA

Login, Randomization, Kit Dispensation, and Study Supply Management

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1. ALEA Log in

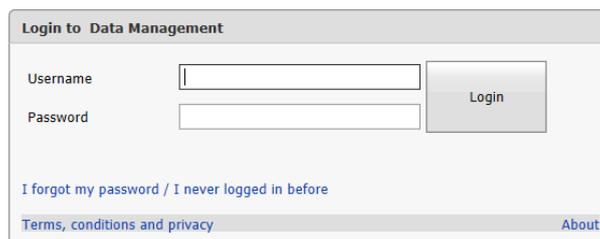
Step 1. Open ALEA

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 request¹).



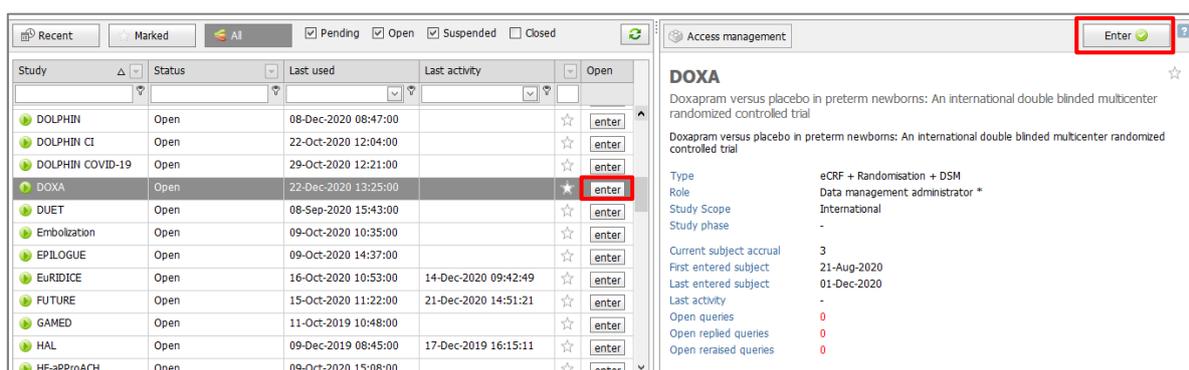
When you want to log in for the first time or you have forgotten your password, click on 'I forgot my password / I never logged in before' and follow the steps*.

* **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 every quartile!

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.



Study	Status	Last used	Last activity	Open
DOLPHIN	Open	08-Dec-2020 08:47:00		enter
DOLPHIN CI	Open	22-Oct-2020 12:04:00		enter
DOLPHIN COVID-19	Open	29-Oct-2020 12:21:00		enter
DOXA	Open	22-Dec-2020 13:25:00		enter
DUET	Open	08-Sep-2020 15:43:00		enter
Embolization	Open	09-Oct-2020 10:35:00		enter
EPILOGUE	Open	09-Oct-2020 14:37:00		enter
EuRIDICE	Open	16-Oct-2020 10:53:00	14-Dec-2020 09:42:49	enter
FUTURE	Open	15-Oct-2020 11:22:00	21-Dec-2020 14:51:21	enter
GAMED	Open	11-Oct-2019 10:48:00		enter
HAL	Open	09-Dec-2019 08:45:00	17-Dec-2019 16:15:11	enter
HF-aProACH	Open	09-Oct-2020 15:08:00		enter

DOXA

Doxapram versus placebo in preterm newborns: An international double blinded multicenter randomized controlled trial

Doxapram versus placebo in preterm newborns: An international double blinded multicenter randomized controlled trial

Type: eCRF + Randomisation + DSM
 Role: Data management administrator *
 Study Scope: International
 Study phase: -
 Current subject accrual: 3
 First entered subject: 21-Aug-2020
 Last entered subject: 01-Dec-2020
 Last activity: -
 Open queries: 0
 Open replied queries: 0
 Open reaised queries: 0

You can mark your favorite studies by clicking the star in the upper right corner of the summary section.

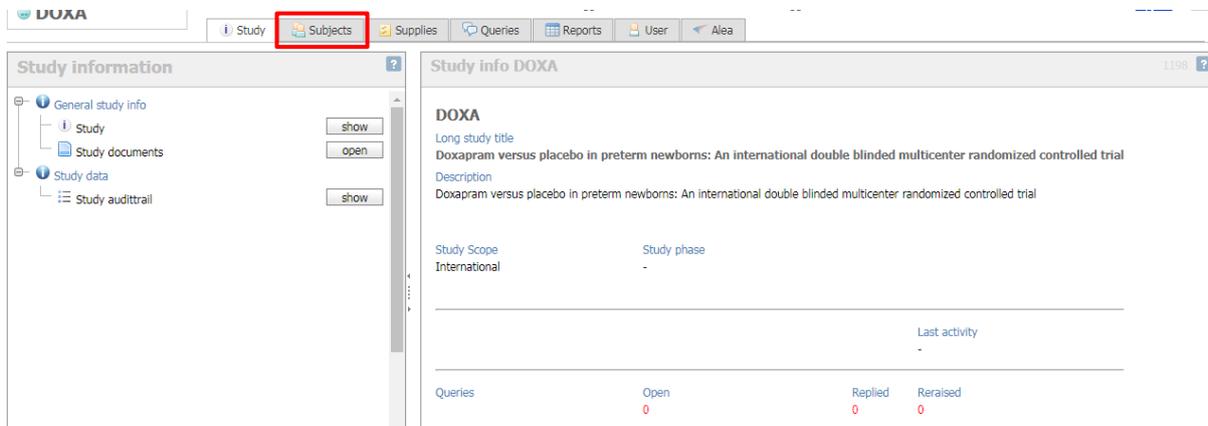
¹ At the start of the clinical trial you were asked to fill in an account request form. When this is not yet done, you can request a form by sending an e-mail to invent.ctc@erasmusmc.nl.

2. Randomization

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

Step 2. Open list of study subjects.

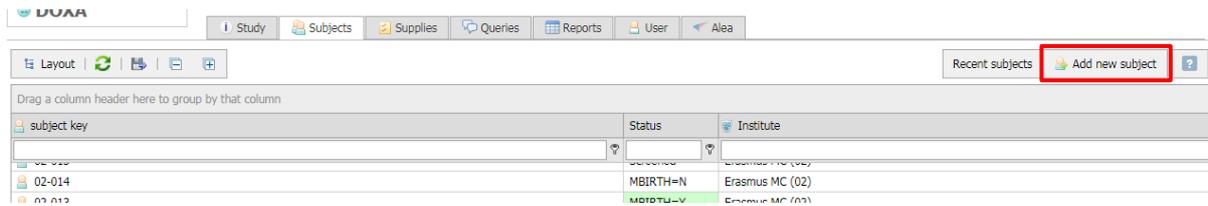
The front page of the DOXA-Trial appears. Select 'Subjects' in the top bar.



The screenshot shows the DOXA-Trial interface. The top navigation bar includes 'Study', 'Subjects' (highlighted with a red box), 'Supplies', 'Queries', 'Reports', 'User', and 'Alea'. The main content area is titled 'Study information' and 'Study info DOXA'. The 'Study info DOXA' section displays the study title 'DOXA', description 'Doxapram versus placebo in preterm newborns: An international double blinded multicenter randomized controlled trial', and study scope 'International'. The 'Subjects' menu is highlighted with a red box.

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.

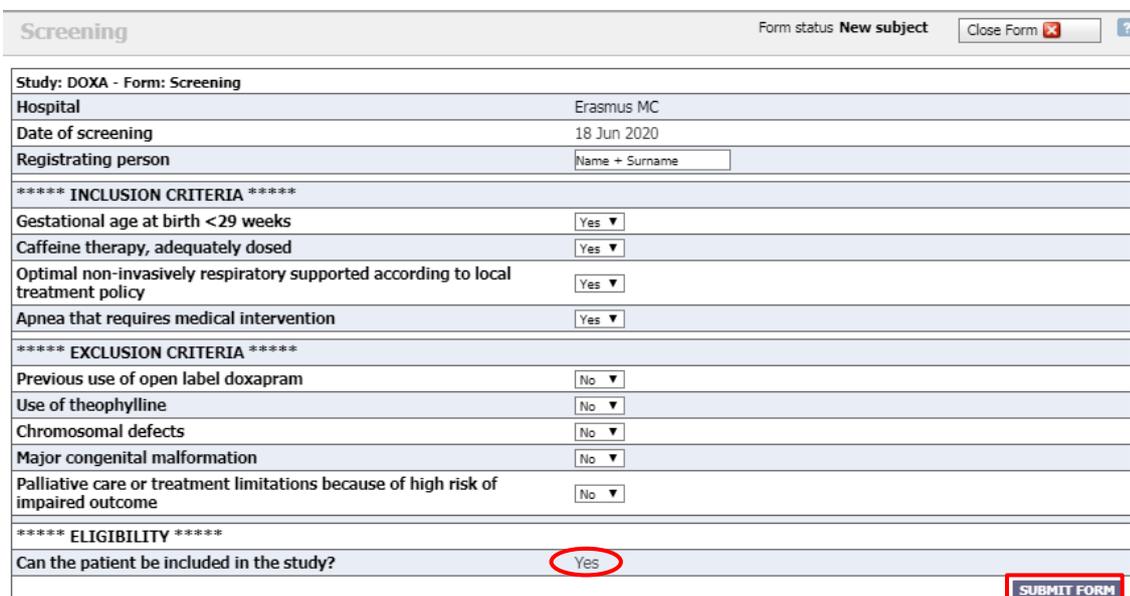


The screenshot shows the DOXA-Trial interface with a table of subjects. The 'Add new subject' button is highlighted with a red box. The table has columns for 'subject key', 'Status', and 'Institute'. The table contains the following data:

subject key	Status	Institute
02-014	MBIRTH=N	Erasmus MC (02)
02-014	MBIRTH=N	Erasmus MC (02)

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 screenshot shows the 'Screening' form. The form status is 'New subject'. The form contains the following fields:

- Study: DOXA - Form: Screening
- Hospital: Erasmus MC
- Date of screening: 18 Jun 2020
- Registrating person: Name + Surname

**** INCLUSION CRITERIA ****

- Gestational age at birth <29 weeks: Yes
- Caffeine therapy, adequately dosed: Yes
- Optimal non-invasively respiratory supported according to local treatment policy: Yes
- Apnea that requires medical intervention: Yes

**** EXCLUSION CRITERIA ****

- Previous use of open label doxapram: No
- Use of theophylline: No
- Chromosomal defects: No
- Major congenital malformation: No
- Palliative care or treatment limitations because of high risk of impaired outcome: No

**** ELIGIBILITY ****

Can the patient be included in the study? Yes

SUBMIT FORM

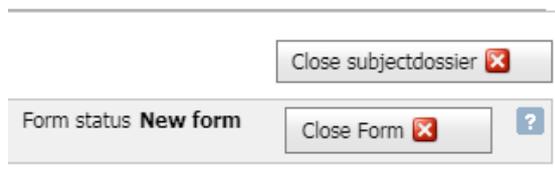
The subjectnumber of the patient appears at the top of the submitted form.



Questions	Answers
Hospital	Erasmus MC

Step 5. Close the subjectdossier

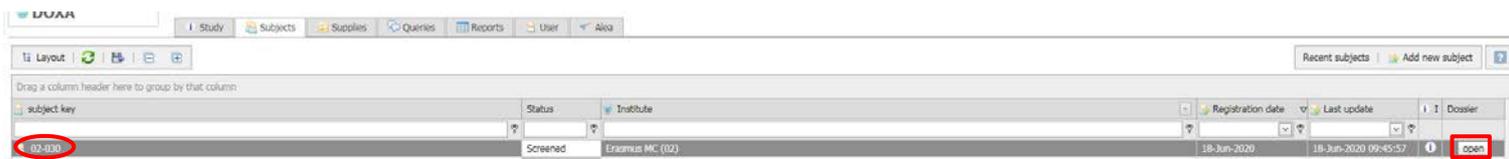
Select 'Close subjectdossier' in the top right corner of the page.



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!**



***** MULTIPLE BIRTH *****	
Multiple birth?	Yes
Should newborn be randomized to same arm as sibling (in case of multiple birth)	Yes, sibling has already been randomized
Subjectnumber of randomized sibling	
SUBMIT FORM	

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'.

subject: 02-030 Registration date: 18-Jun-2020 Investigator: Simons, S.H.P. Close subjectdossier

Forms subject 02-030

- Screening open
- Randomization open
- Kit Dispensation open

Kit Dispensation Form status: New form Close Form

Study: DOXA - Form: KIT Dispensation

Date of dispensation: 18 Jun 2020

Registering person:

***** KIT DISPENSATION *****

Sufficient Inventory: Yes **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'.

subject: 02-030 Registration date: 18-Jun-2020 Investigator: Simons, S.H.P. Close subjectdossier

Forms subject 02-030

- Screening open
- Randomization open
- Kit Dispensation open
- Extra Kit Dispensation (0)
- Unscheduled

Kit Dispensation Form status: Submitted Close Form

***** Subject 02-030 has been dispensed kit **10071** *****

Questions	Answers
Date of dispensation	18 Jun 2020
Registering person	Jarinda
***** KIT DISPENSATION *****	
Sufficient Inventory	Yes

3. Extra Kit Dispensation

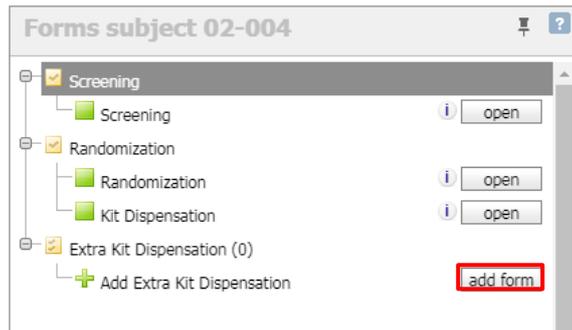
Step 1. Log in to ALEA according to the instructions at page 2.

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

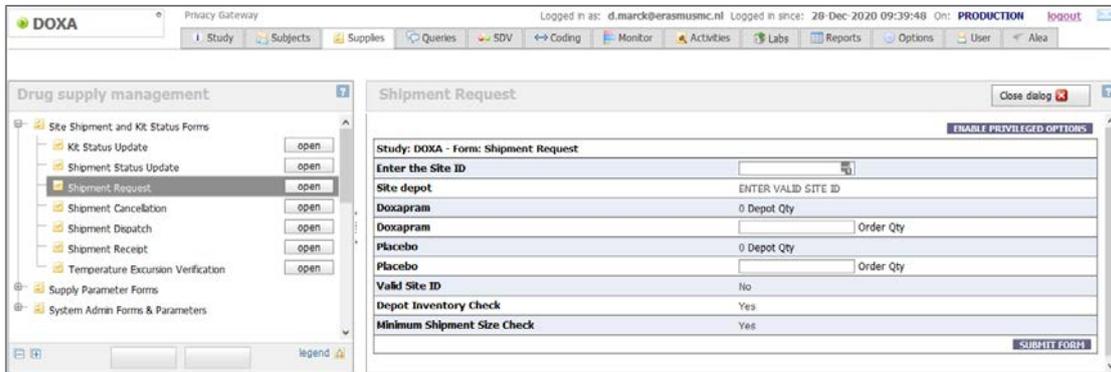
4.1. Order new study medication for local Hospital Pharmacy or for NICU/Ward-pharmacy

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:
 - Local Hospital Pharmacy is <center code+A> e.g. for Leiden '04A'
 - 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.

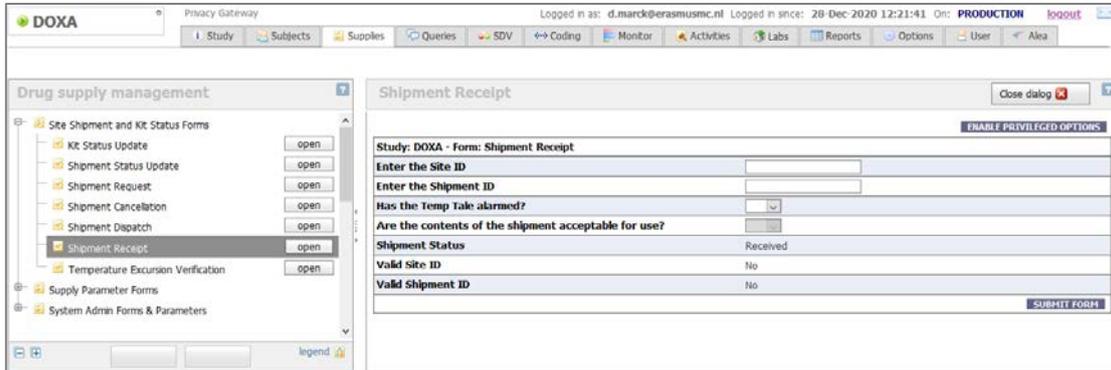
4.2. Receive study medication

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



The screenshot shows the DOXA web application interface. The top navigation bar includes 'Study', 'Subjects', 'Supplies', 'Queries', 'SDV', 'Coding', 'Monitor', 'Activities', 'Labs', 'Reports', 'Options', 'User', and 'Alka'. The main content area is titled 'Drug supply management' and 'Shipment Receipt'. The 'Shipment Receipt' form contains the following fields:

Study: DOXA - Form: Shipment Receipt	
Enter the Site ID	<input type="text"/>
Enter the Shipment ID	<input type="text"/>
Has the Temp Take alarmed?	<input type="checkbox"/>
Are the contents of the shipment acceptable for use?	<input type="checkbox"/>
Shipment Status	Received
Valid Site ID	No
Valid Shipment ID	No

Buttons for 'ENABLE PRIVILEGED OPTIONS' and 'SUBMIT FORM' are visible at the bottom right of the 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:
 - 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'
- **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.