MANUAL		
ALEA instructions for screening database		
ID: HDC-OP-CDM-342-2-MN-8	KMS Version:	3

1. PURPOSE
This document provides instructions, guidelines and background information for the screening database using the Electronic Data Capture (EDC) system of ALEA (version 18.1), as implemented by the Erasmus MC – HOVON Data Center.

2. SCOPE
This manual is applicable Local Data Managers with registration rights, Site Principal Investigators, Central Data Managers and users with only Patient registration rights.
This document is also available on the HOVON website.

3. TERMS & ABBREVIATIONS

Term (Abbreviation *if applicable*)	Definition
CRF	Case Report Form
EDC	Electronic Data Capture
HCD	HOVON Data Center
ICF	Informed Consent Form
LI	Local Investigator (new: Site PI (Site Principal Investigator))
Site PI	Site Principal Investigator

4. REQUIRED & RELATED DOCUMENTS

#	Type	Document title
N.A.		

5. DOCUMENT HISTORY

Version	Date	Description of change
1	01APR2019	ALEA instructions for screening Database (Original version)
2	13MAR2020	Changed picture in chapter 3 and chapter 5.
3	19NOV2021	ALEA version changed to 18.1 (in purpose of this document)

6. MANUAL

1. Table of Contents

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2. ALEA

ALEA is supported by most commonly available web browsers (i.e. Internet Explorer 7.0 and higher, Mozilla FireFox, Google Chrome, Safari (Apple), and Android 4.0 and higher).
Used documentation: Forms Vision ALEA data management User Manual v.5.4.

This ALEA Screenings database manual is suitable for HOVON studies for which patients need to be screened. Whether a screenings database is used is mentioned in the protocol of the trial or is specified by the trial manager.

2.1 Workflow

The following workflow is followed when a patient is registered in the screenings database (see also flow shown below).
If a patient is suitable to enter the screenings database, the patient first needs to sign a general screenings ICF (1). The patient is entered into the screenings database (2) and the site receives an email with further instructions and a screening number which is clearly different from a usual Patient ID (the mark up starts with SCR (from Screening) and the site name (for example AMC) and 999 before the 5 digits of the sequence number) (3). Also the central lab is notified that a patient is entered for screening, so that they know that samples are coming their way (4).
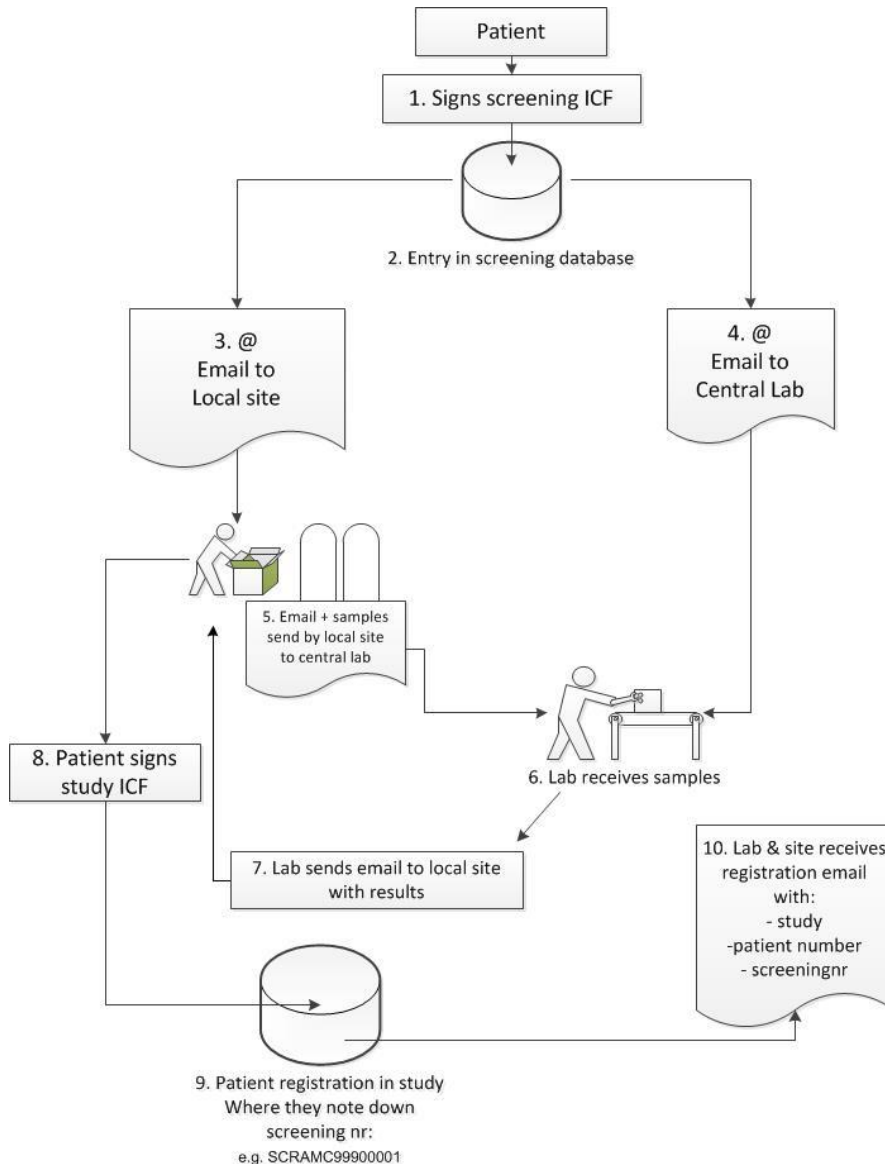
Following the instructions received in the email, the site sends samples (marked with the screening number) together with the print out email to the central lab (5) using the screening lab kit as is explained in the lab manual. The lab analyses the samples (6) and sends the results by email to the site (7) (using the email addresses previously filled out in step 2). If the patient is eligible for the study, the patient signs the study ICF (8). Then the patient can be registered within the study database (9), during that step also the screening number is requested to be able to connect the screening number with the Patient ID.
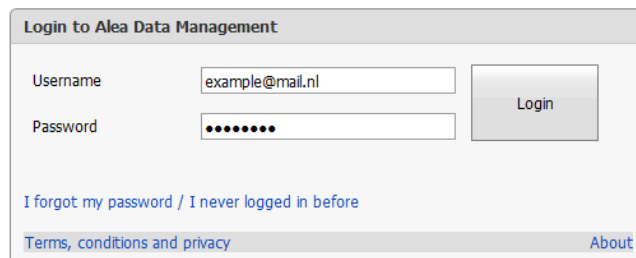
2.2 Request for account

For the screenings database a separate account access is necessary.
However, opposed to the study databases, the screenings database will also accept general email accounts (e.g. trialbureau@hospital.nl) to be used to register new patients.
If you wish to request an account to access the screenings database, please fill out a ALEA user account form, that can be found on the HOVON website.

2.3 Login

The URL to the ALEA portal is: https://aleaclinical.com/Hovon/DM/DELogin.aspx

It is recommended to bookmark this link in the Favorites section of your web browser.

Logging in for the first time
Through the option "I forgot my password / I never logged in before" you can send a request to receive an email (from EMC TENALEA Mail Service info@formsvision.net) with a one-time link.

! **IMPORTANT**: For security reasons, this link expires within 30 minutes after receiving the email. Check your spam or junk mail folder if no email is received.

The following message may appear:
No account has been provided yet → please contact the HOVON Data Center (hdc@erasmusmc.nl)
The email address is incorrectly entered → check the spelling

After logging in for the first time, using your email address as username, the following message appears:

By agreeing with the terms and conditions, the following screen will be displayed. Here you can enter a (new) password. Choose a password with a minimum length of 8 characters, containing at least one digit (e.g. 1,2,3).

Once your password has been successfully changed/accepted, the account has been activated and ALEA is accessible.

3. Open screenings database

If you have access to multiple studies, you will enter a Study Selection page upon login. This split-screen shows an overview of all studies (including the 'study' called screenings database).

Open the Screenings database 'study' either by clicking the Enter button of the highlighted study or the Enter button in the header of the summary section.

4. Study overview

A study homepage is organized according to the following tabs:
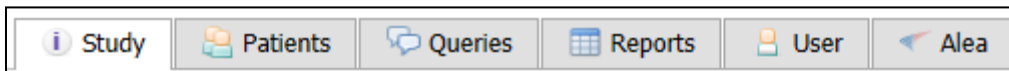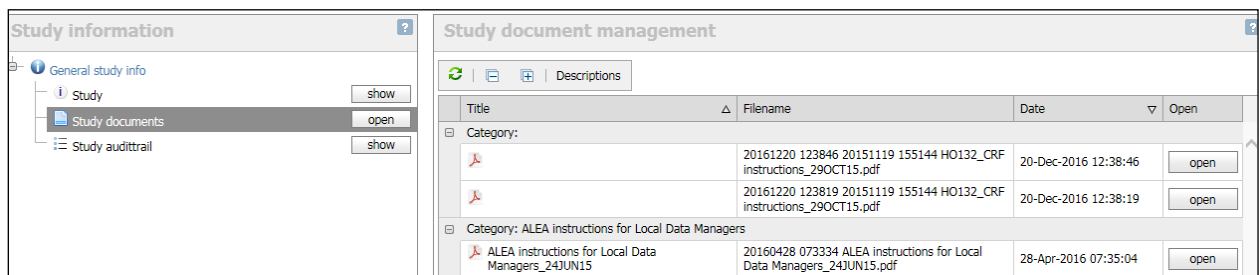
Please note that these tabs are only available if you are not working in a Patient Dossier (Chapter 5).

The Study tab shows the study details:
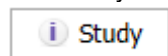
Here you can access study documents (if available, e.g. CRF instructions) or information on study accrual (with the option to adjust the chart settings).

5. Patients overview

By selecting the Patients tab from the study homepage, the eCRF can be accessed.

The default study overview appears.

You will see that the clinician is in this case a dummy name as the screenings database will be used for more than one trial with different Site Principal Investigators (previously called Local Investigators).
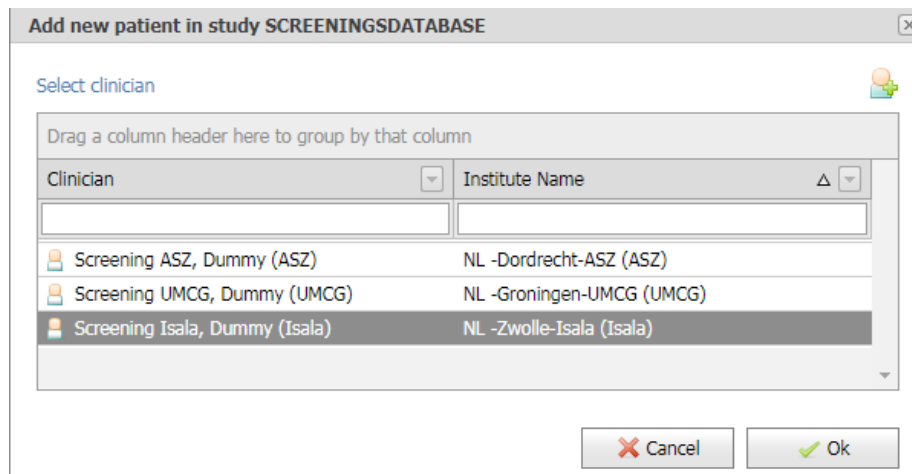
6. Add new patient

To add a new patient, click on the top right button:

If your account has access to multiple sites to register patients for, please select the applicable site (with the dummy Site PI). This step is not shown for accounts that have access to just one site.

Thereafter fill out the items as shown below. All red marked items are obligatory.

General site data

Registrating person	Name of the person who is filling out this form.
Local Investigator	Email address of the (potential) site PI (or otherwise known as Local Investigator).
Local Coordinator	Email address of the person who is locally coordinating the sample shipment.
Responsible physician	Email address of the physician. This can be the same as the Local Investigator, of course the email with the results will only be send out once.
General email address	Here you can fill out other email addresses that need to receive the central lab results. Please divide them by semicolon (;) if there are multiple addresses.

Please note, only the account registering the patient for screening, will receive a screening notification from ALEA with the screening number.

Patient data

Age at registration	Current age of the patient.
Sex	Sex of the patient.
Date informed consent	This is the screenings Informed Consent date.

Disease area

Disease area	Select the disease area which is concerned, for instance AML/MDS.

Diagnosis analysis request   Once the disease area is filled out a further specification is requested. This might be just one analysis request, but it can be more than one.

Sample date   Date on which the sample was taken. If there are multiple dates, take first date.

If there are mistakes made in the filled out data, the fields are marked with a red dotted line and at the right side of the screen in section 'Audittrail and discrepancies' is visible what is viewed as incorrect.

Once all obligatory fields are filled out and all discrepancies are solved, the submit button becomes active.

Once you submit the data the screening number is shown on the screen:

Also an email is sent out to the account email address that was logged in.

! **IMPORTANT:** He/she should forward it to other site personnel that might need this information (like the person who takes the sample and should write down the screening number on the sample)

Once the screening form was submitted, you can close the registration form at the top right corner.

! **IMPORTANT:** It is strongly recommended to check the filled out data once more to see if no spelling mistakes were made in the email addresses and the age and sample date is correctly provided. This will make sure that the central lab is able to correctly identify the samples and send the results to the correct people.

If there was a (spelling) mistake made, please inform the HOVON Data Center immediately (hdc@erasmusmc.nl) so that the screeningsdatabase can be updated and the central lab can be informed.

7. Query management, reports and ALEA

Although the query tab is visible for this screenings database, no queries will be raised on these forms.
Also no reports are available for this screenings database.
The last tab contains information about ALEA. This section is not applicable to you.
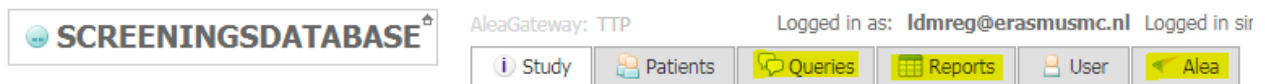
8. User

The tab User displays your User Profile, containing information about the role that has been assigned to you (e.g. Local Data Manager with registration rights) and the settings that are in place.
Via Change password, you can provide a new password if you wish to do so.