

# ALEA instructions for Local Investigator

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This document provides instructions, guidelines and background information for Local Investigator regarding the Electronic Data Capture (EDC) system of ALEA, as implemented by the Erasmus MC – HOVON Data Center.

**Erasmus MC – HOVON Data Center**

**22JAN2019**

**Version: 03**

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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.

Instructions are applicable to ALEA Data management version 17.1.

Manuals for ALEA are available for:

- Central Data Management (CDM)
- Central Laboratory (CLAB)
- Cytogeneticist/ Cytogenetic Review
- Local Data Management (LDM)
- Local Investigator (LI)
- Pathology/ Pathology Review (PA)

This ALEA Manual is suitable for general HOVON studies. Specific directions for filling out the forms can be found in study specific instructions. Slight variations in the examples given in the manual might be due to the study-design and to the eCRFs used.

### 2.1 Data organization

The data are organized around Events and associated Forms (CRFs). Events can be considered as separate, consecutive phases during the conduct of the trial (e.g. Registration/ Randomisation, On Study, Treatment, Follow Up). Events include one or more different Forms (e.g. Lab Results, Treatment Details, Response Evaluation). An example of an Event and associated Forms:

<u>Event</u>	<u>Forms</u>
Treatment	Treatment Details Lab Results Response Evaluation

Some Forms are not linked to specific Events and defined as independent Events (e.g. Adverse Events, Concomitant Medication).

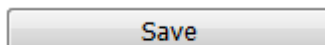
### 2.2 Workflow

Data follows a certain workflow before it is ready for statistical analysis. Specific user roles (the Local Data management (LDM), Central Data Management (CDM), the Local Investigator (LI)) are responsible for a certain stage of the workflow:



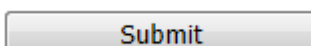
#### Saving

First the data are entered and saved by the LDM. Data can be saved at all times; it is not required to complete all fields in order to be able to save the Form. ALEA automatically saves every two minutes.



#### Submitting

The Submit button will be enabled when all data meet automated checks (e.g. boundary checks and inconsistency checks), all required fields are completed and all discrepancies are properly addressed (see chapter 6.3). If data are modified afterwards, the status Submit is revoked, and the Form has to be submitted again (with reasons provided why data were changed).



### Verifying

Once data are submitted the CDM reviews the provided information. Manual queries can be raised and the CDM can set the form to Verified. A Form can be verified, even if there are outstanding queries or discrepancies. This status indicates to the LDM that the CDM has reviewed the Form and that queries – if any - can be answered. Editing a verified Form will revoke the status Verified.

Set verified

### Signing and Locking

When there are no more open queries, the LI can sign off the Forms.

Sign Off

Signing off a Form will automatically lead to locking for further data entry. The CDM can also lock or unlock forms (if necessary), before forms are signed off by the LI. Unlocking after Forms were already signed off requires resigning by the LI.

Lock form(s)

Unlock form(s)

## 2.3 Request for account

Users who don't have access to ALEA studies initiated by the Erasmus MC – HOVON data center (HDC), can request form a *general* ALEA user account. ALEA accounts are created on the basis of personal e-mail accounts via a request form (Appendix A). A personal e-mail account can only be used for one role within ALEA, hence it requires several e-mail accounts for users with more than one role in ALEA.

Next, access to the *study specific* database will be granted to study personnel (i.e. the Local (sub)Investigator(s) and Local Data Manager(s)) by the Trial Manager of the study.

## 2.4 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.

Login to Alea Data Management

Username

Password

Login

[I forgot my password / I never logged in before](#)

[Terms, conditions and privacy](#) [About](#)

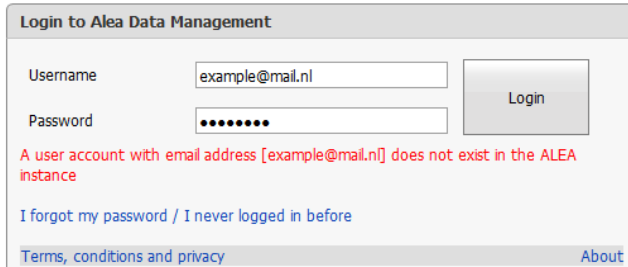
Logging in for the first time

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](mailto:info@formsvision.net)) with a one-time link.

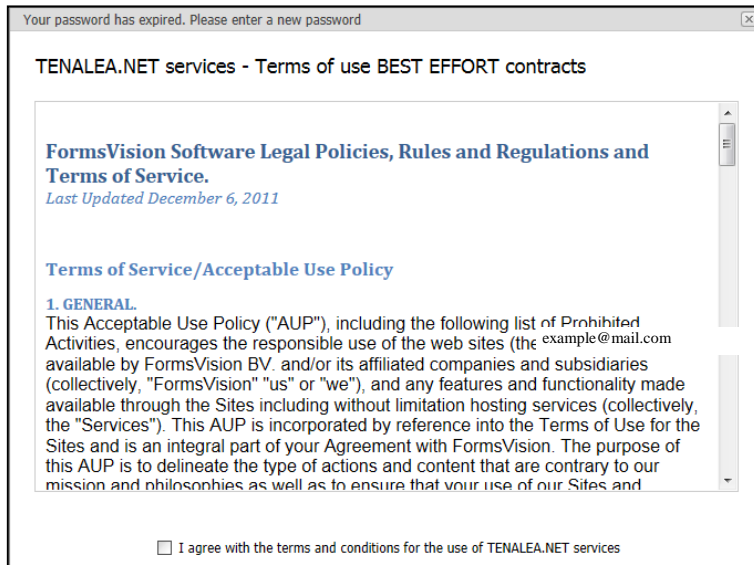
**!** **IMPORTANT:** For security reasons, this link expires within 30 minutes after receiving the email. Check your spam or junkmail folder if no email is received.

The following message may appear:

- No account has been provided yet, please contact the trial manager of the study
- 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.

Your password has expired. Please enter a new password ✕

**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.

Your password has expired. Please choose a new password, enter it in both fields and confirm by pressing set password.

Accountname

New password

Confirm new password

Your password has been changed

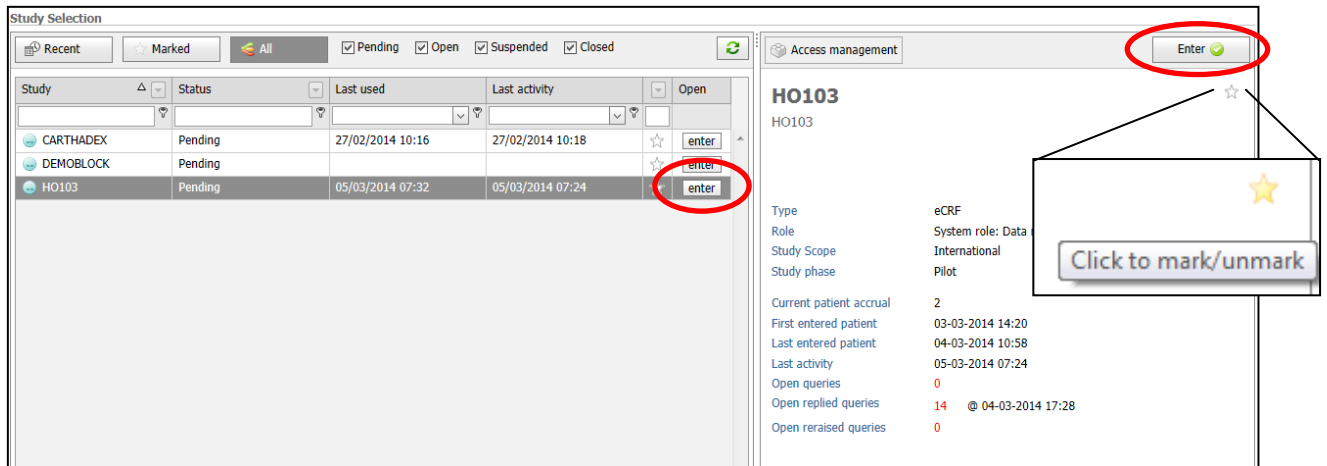
### 3. Study Selection and organization

#### Study Selection

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 you have access to and a brief summary of the highlighted study.

You can mark your favorite studies by clicking the star in the upper right corner of the summary section or by clicking the star in the column (on the left of the enter button).

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

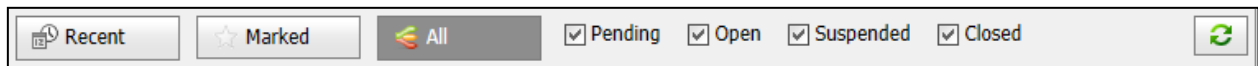


A study specific homepage appears, displaying the selected study on the study button in the upper left corner. To return to the Study Selection page, click this study button.



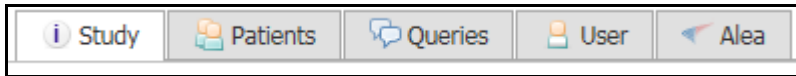
#### Organizing studies

Studies can be shown or hidden according to several criteria. Default all studies are displayed. By (un)selecting one or more criteria, ALEA shows the respective studies. For example, favorite studies can be displayed by clicking Marked.



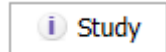
## 4. Study overview

A study homepage is organized according to the following tabs:

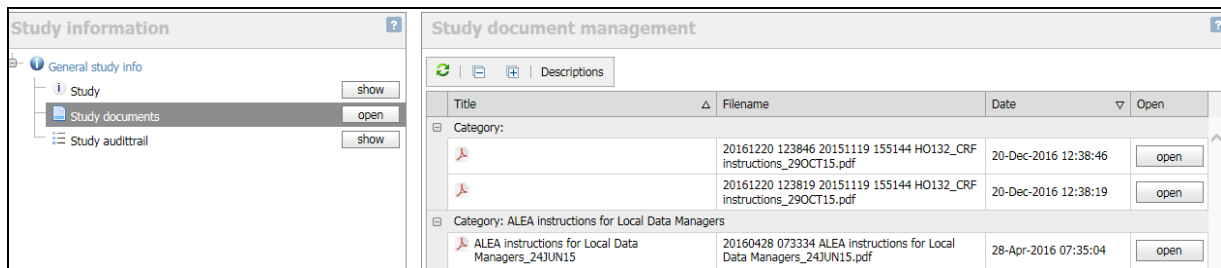


Please note that these tabs are only available if you are not working in a Patient Dossier (Chapter 5).

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).



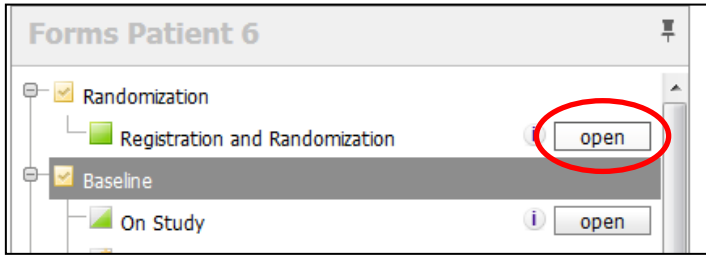
The screenshot shows two panels. The left panel, 'Study information', has a tree view with 'Study documents' selected and an 'open' button. The right panel, 'Study document management', shows a table of documents.

Title	Filename	Date	Open
Category:			
	20161220 123846 20151119 155144 HO132_CRF instructions_29OCT15.pdf	20-Dec-2016 12:38:46	open
	20161220 123819 20151119 155144 HO132_CRF instructions_29OCT15.pdf	20-Dec-2016 12:38:19	open
Category: ALEA Instructions for Local Data Managers			
ALEA instructions for Local Data Managers_24JUN15	20160428 073334 ALEA instructions for Local Data Managers_24JUN15.pdf	28-Apr-2016 07:35:04	open

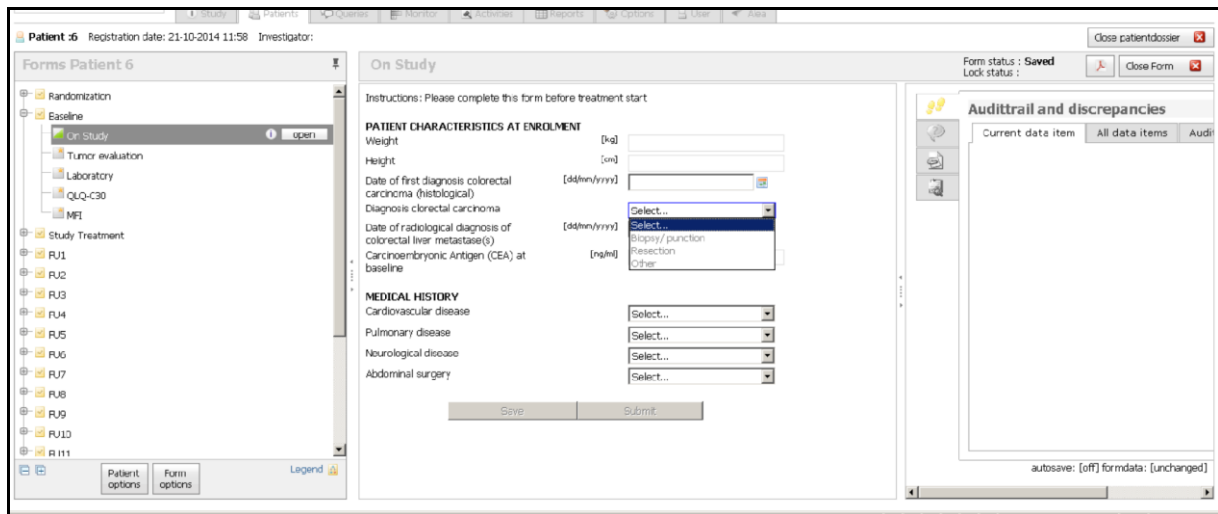


## 5. eCRF pages

To enter a Form, click the Open button:



An example of an eCRF page is given below:




Instructions on how to enter and edit data and how to manage queries are outlined in separate LDM Instructions, which are provided to the LDM.

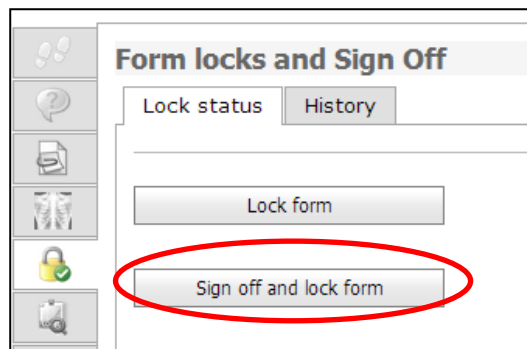
## 6. Signing off Forms

**!** **IMPORTANT:** Once Forms are signed, they are automatically locked for further data editing.

**!** **IMPORTANT:** Please do not 'submit' or 'save' the form again. The form will lose the verified status if it is 'resubmitted' and/or 'saved' again. Please sign directly.

### Signing and locking a single form.

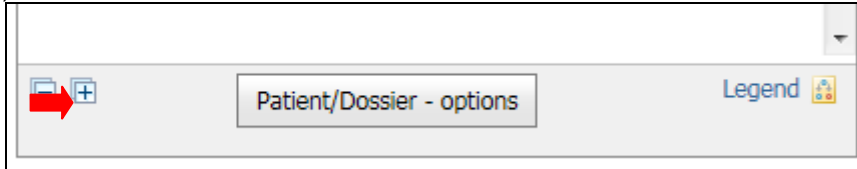
To Sign Off and Lock a single opened Form, click the  icon of the Form locks and Sign Off menu (in the right screen panel), followed by the 'Sign off and lock form' button:



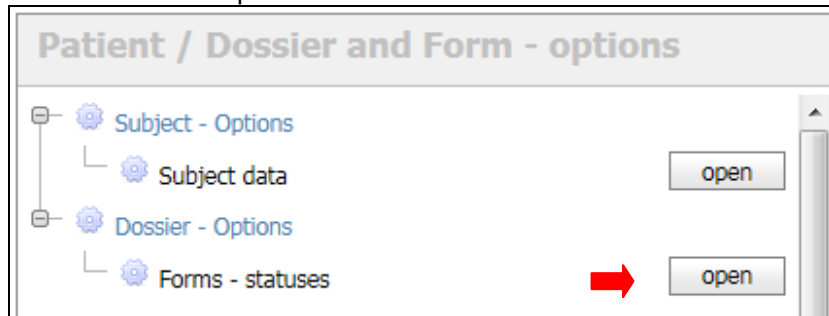
The History tab in the Form locks and Sign Off menu provides a trail of all Locking and Unlocking related activities that occurred, including dates, times and the user(s) who performed these activities.

Signing and locking multiple forms

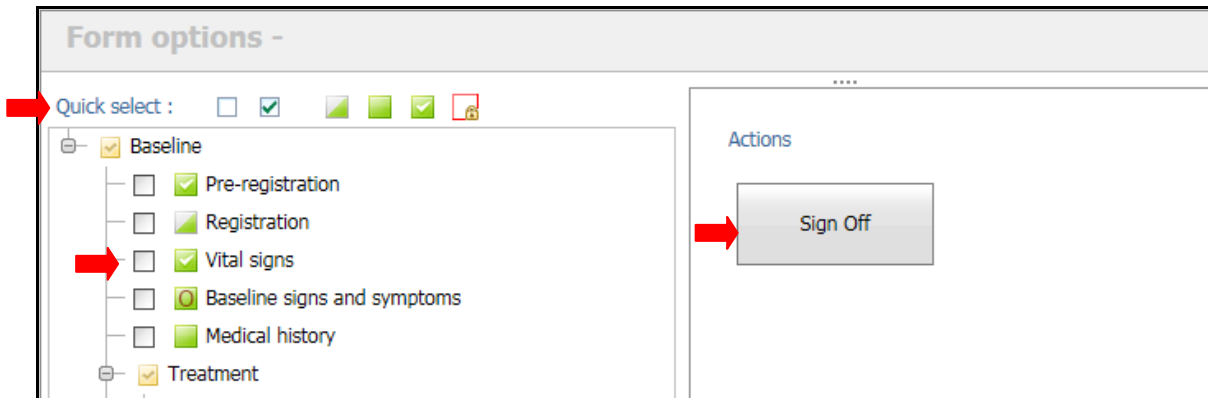
To sign off multiple Forms of a patient, click the 'Patient/Dossier - options' button at the bottom of the tree panel (left).



Click the 'open' button next to the option 'Forms – statuses'.



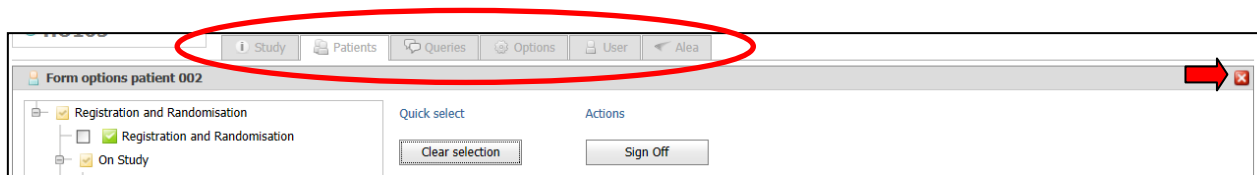
Select, one by one, the Forms you wish to Sign Off in the tree panel, or quick-select multiple forms by using the 'Quick select' buttons at the top of the tree panel (e.g. quick-select all Verified Forms by clicking the  button). Then click the 'Sign Off' button to sign off the selected Forms:



Only forms with status Verified (; see appendix B) can be signed off by the Local Investigator . These forms have been saved and submitted by the LDM and validated by the CDM and no further data editing is expected. In addition all queries on the form should be resolved by the LDM and closed by the CDM.

Once a Form status is changed into Signed Off, this is indicated by the  icon associated with the Form. To unlock Forms, contact the CDM. After unlocking, forms need to be Signed Off again.

**!** **IMPORTANT:** Always close the current Form Options screen in order to re-enable other functions.



## 7. Query management

If applicable, queries about data inconsistencies are being raised by the CDM and addressed by the LDM in ALEA. Instructions about query management are outlined in separate LDM instructions.

## 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) and the settings that are in place. Via Application user settings you can reset the layouts that were previously created to the default versions.

study	study status	role	account status
HO132	OPEN	Local data manager *	Activated

## 9. Alea

The last tab contains information about ALEA. This section is not applicable to you.

## 10. Summary









**Please adhere to the following flow for data management:**

- Fill out the Forms in chronological order at all times, to prevent unnecessary discrepancies.
- Resolve discrepancies preferably by providing the correct data in the Form. Only if the correct data has already been entered, answer the discrepancy by clicking on the Resolve button.
- Submit the Forms as soon as possible (which enables CDM to check the data), but not before the data is complete and no further data editing is expected.
- Reply to queries (either in the patient dossier (right panel) or via the query tab). All red queries need to be addressed. (Orange queries need to be handled by CDM). In the end, all queries should be green = closed.
- Once a Form is checked by CDM and no open queries remain, the LI can sign off the Form, which will automatically lock the Form for further data-entry/editing.
- Once all Forms are signed off data management for that patient is done.

## Appendix A: ALEA Account Request Form

For the latest version of the ALEA Account Request Form, please check the HOVON web site or contact the HOVON Data Center ([hdc@erasmusmc.nl](mailto:hdc@erasmusmc.nl))

## Appendix B: Field Chooser box options

Field	Description <sup>1</sup>
#A	Total number of data item annotations
#A-F	Total number of form level annotations
#A-P	Total number of patient level annotations
#FQ-C	Number of closed queries on Forms
#FQ-O	Number of open queries on Forms; Open initial, form level, queries
#FQ-R	Number of non-closed queries on Forms: Open form level queries with replies
 #L	Total number of locked forms
#PQ-C	Number of closed queries on Patient
#PQ-O	Number of open queries on Patient
#PQ-R	Number of non-closed queries on Patient
 #S	Number of submitted forms (without discrepancies and without missing values)
 #Sa	Number of saved forms
 #Sd	Number of submitted forms with discrepancies
 #Sm	Number of submitted forms with missing values
#TF	Total number of forms
#TQ-C	Combination of all closed patient- and form level queries
#TQ-O	Number of open queries on Patients and Forms; Combination of all open patient- and form level queries
#TQ-R	Number of non-closed queries on Patients and Forms; Combination of all non-closed patient- and form level queries
	Number of verified Forms
	Clinician and Institute code; Combination of institutes and all investigators per institute
	Study name: Could be useful when making an export of the patient overview.

<sup>1</sup> All numbers are displayed *per patient*

## Appendix C: Statuses of Forms

