

MANUAL

ALEA Instructions for Registration

ID:	HDC-OP-CDM-342-2-MN- 7	KMS Version:	2
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1. PURPOSE

This document provides instructions, guidelines and background information using the Electronic Data Capture (EDC) system of ALEA (version 17.1) , as implemented by the Erasmus MC – HOVON Data Center.

2. SCOPE

The manual is applicable for the registration of patients.

3. TERMS & ABBREVIATIONS

Term (Abbreviation <i>if applicable</i>)	Definition
CDM	Central Data Manager/ Central Data Management
CRF	Case Report Form
EDC	Electronic Data Capture
HCD	HOVON Data Center
LDM	Local Data Manager/ Local Data Management
LI	Local Investigator (new: Site PI (Site Principal Investigator))
SDV	Source Data Verification
Site PI	Site Principal Investigator

4. REQUIRED & RELATED DOCUMENTS

#	Type	Document title
N.A.		

5. DOCUMENT HISTORY

Version	Date	Description of change
1	02AUG2019	ALEA instructions for registration of patients (original version)
2	13MRT2020	Chapter 2: Change text to Local Data Management (LDM)/ Site Principal Investigator (Site PI) and added 'Screening database'.
		Document: Change term Local Investigator (LI) to Site Principal Investigator (Site PI) in document
		Chapter 2: Sentence changed to 'The examples given in this manual may slightly differ in studies, due to study-design and eCRFs used'
		Chapter 2.2: Change Picture Workflow and deleted information considering signing off.
		Summary: Sentences changed in relation to signing off

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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)/ Site PI (Site Principal Investigator)
- Pathology/ Pathology Review (PA)
- Patient registration on the site.
- Screening database.

This ALEA Manual is suitable for general HOVON studies. The examples given in this manual may slightly differ in studies, due to study-design and eCRFs used.

Specific directions for filling out the forms can be found in study specific instructions

2.1 Data organization

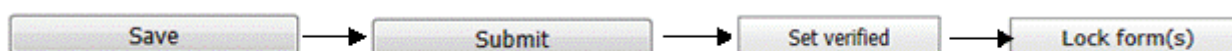
The data are organized around Events and associated Forms (CRFs). Events can be considered as separate, consecutive phases during the conduct of the trial (e.g. Registration/ Randomisation, On Study, Treatment, Follow Up). Events include one or more different Forms (e.g. Lab Results, Treatment Details,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

Event	Forms
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). Also, some forms that are filled out by for example central lab are in separate events.

2.2 Workflow

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



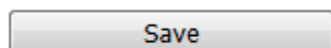
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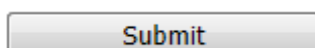
Saving

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.



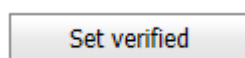
Submitting

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. 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).



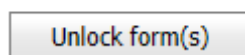
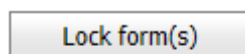
Verifying

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.



Locking

When there are no more open queries, the CDM can lock the Forms.
In addition CRF can be locked at the request of the site by means of an e-mail to the HOVON Data Center.



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 for 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.

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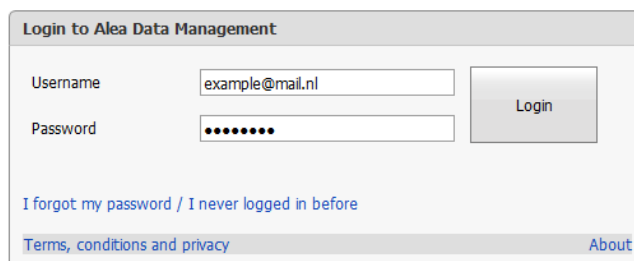
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2.4 Login

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.



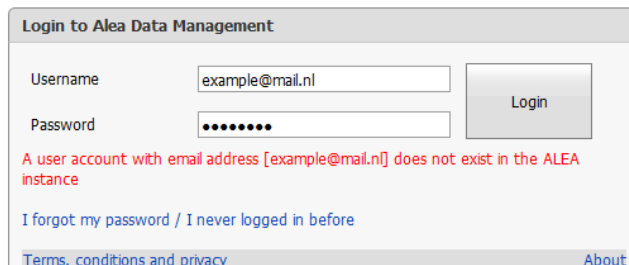
Logging in for the first time

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 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:

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Your password has expired. Please enter a new password

TENALEA.NET services - Terms of use BEST EFFORT contracts

FormsVision Software Legal Policies, Rules and Regulations and Terms of Service.
Last Updated December 6, 2011

Terms of Service/Acceptable Use Policy

1. GENERAL.
This Acceptable Use Policy ("AUP"), including the following list of Prohibited Activities, encourages the responsible use of the web sites (the example@mail.com available by FormsVision BV. and/or its affiliated companies and subsidiaries (collectively, "FormsVision" "us" or "we"), and any features and functionality made available through the Sites including without limitation hosting services (collectively, the "Services"). This AUP is incorporated by reference into the Terms of Use for the Sites and is an integral part of your Agreement with FormsVision. The purpose of this AUP is to delineate the type of actions and content that are contrary to our mission and philosophies as well as to ensure that your use of our Sites and

☐ I agree with the terms and conditions for the use of TENALEA.NET services

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).

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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 *forgot* *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

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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.

Study Selection

Recent Marked All Pending Open Suspended Closed

Study	Status	Last used	Last activity	Open
CARHADEX	Pending	27/02/2014 10:16	27/02/2014 10:18	enter
DEMOBLOCK	Pending			enter
HO103	Pending	05/03/2014 07:32	05/03/2014 07:24	enter

HO103

HO103

Type
Role
Study Scope
Study phase

Current patient accrual
First entered patient
Last entered patient
Last activity
Open queries
Open replied queries
Open reraised queries

eCRF
System role: Data
International
Pilot

2
03-03-2014 14:20
04-03-2014 10:58
05-03-2014 07:24
0
14 @ 04-03-2014 17:28
0

Click to mark/unmark

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.

HO103

Logged in as: p.cornelisse@erasmusmc.nl Logged in since: 30.04.2014 15:26 On: DEVELOPMENT Language: en-GB logout

Study Patients Queries Reports User Alea

Study information

- General study info
 - Study show
 - Study documents open
- Study data
 - Study accrual show
 - Study audittrail show

Study info HO103

HOVON

Organizing studies

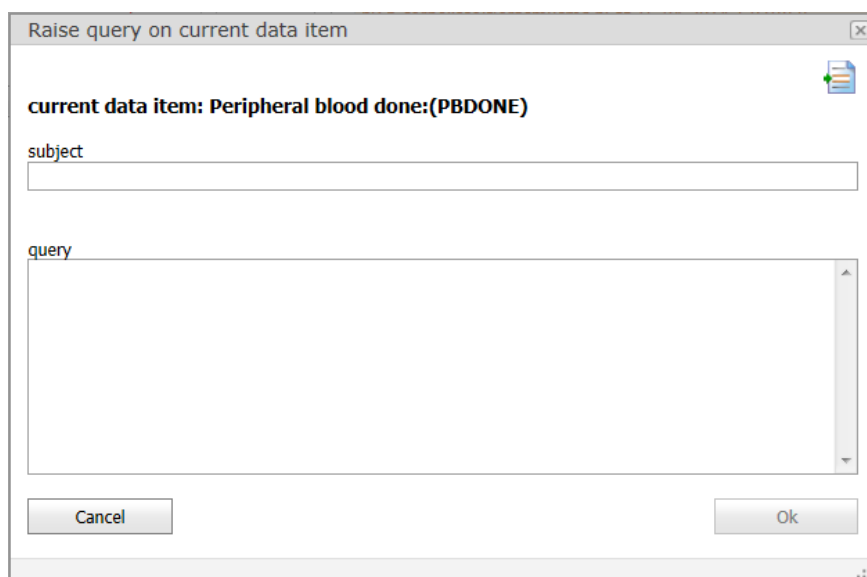
Studies can be shown or hidden according to several criteria. Default all studies are displayed. By (un)selecting one or more criteria, ALEA shows the respective studies. For example, favorite studies can be displayed by clicking Marked.

Recent Marked All Pending Open Suspended Closed



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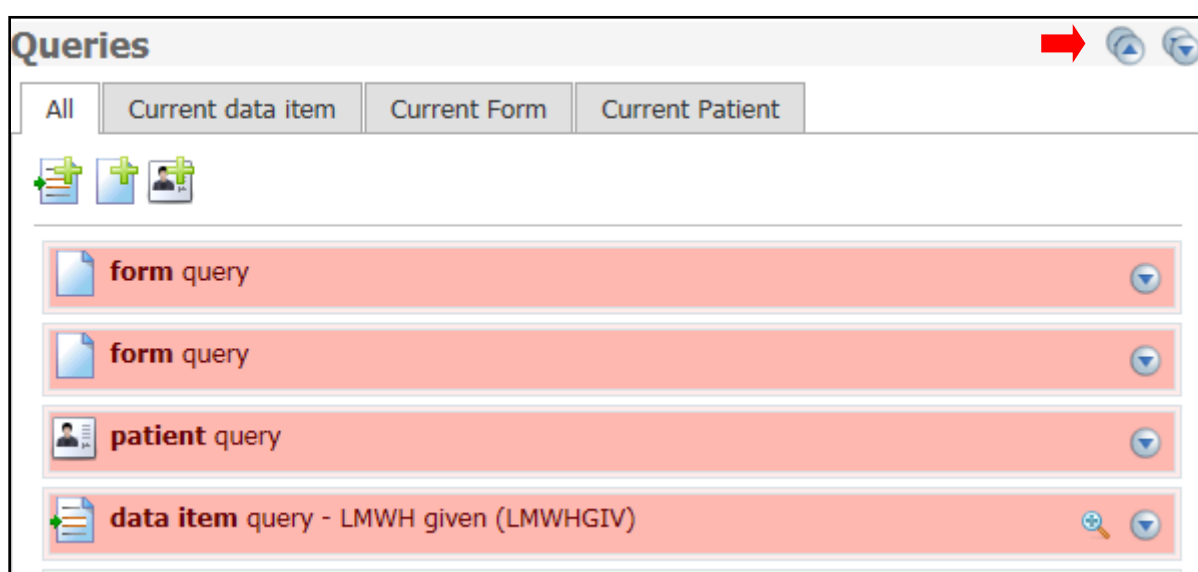
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In all query three levels, the queries can be edited before sending or deleted. You can choose in the horizontal tab pane, to show all 3 levels of patient queries at once, or only the current data item querie(s) (where your cursor is currently at), or only form level queries or only patient level queries.

Next to that you can collapse all queries using the collapsing button at the top right corner  or the expanding icon  to show less or more details on the queries.



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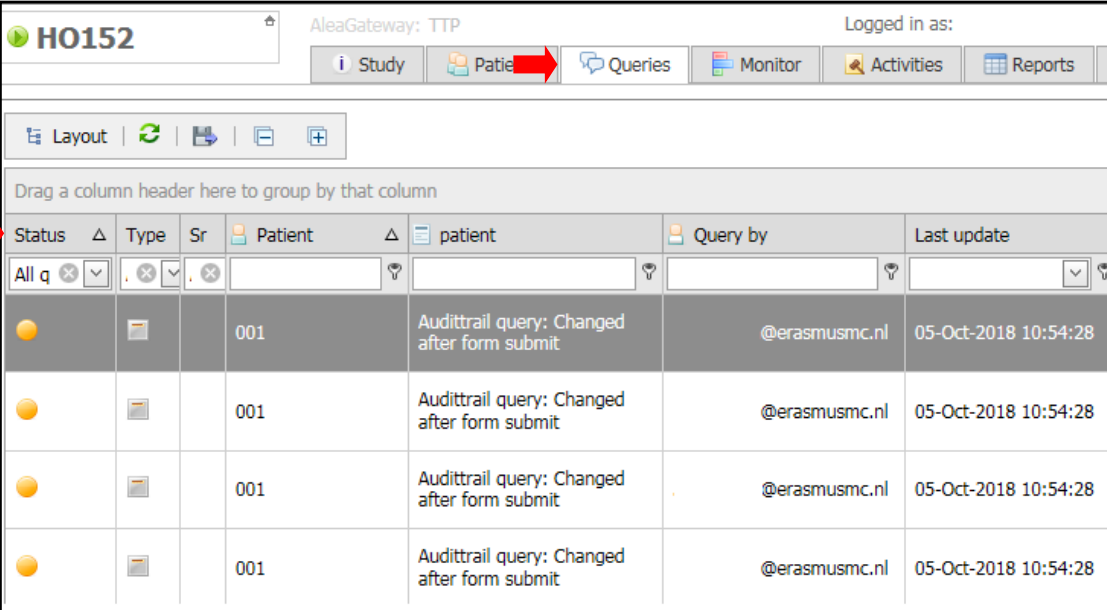
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Queries can also be shown for all patients together, using the main queries tab you can see all queries for one study.



Status	Type	Sr	Patient	patient	Query by	Last update
All q						
		001		Audittrail query: Changed after form submit	@erasmusmc.nl	05-Oct-2018 10:54:28
		001		Audittrail query: Changed after form submit	@erasmusmc.nl	05-Oct-2018 10:54:28
		001		Audittrail query: Changed after form submit	@erasmusmc.nl	05-Oct-2018 10:54:28
		001		Audittrail query: Changed after form submit	@erasmusmc.nl	05-Oct-2018 10:54:28

You can sort by:

- status (all queries, open queries , replied queries , re-raised queries , closed queries ,
- type (all type queries, data item query, form query, patient query),
- Sr (= sources) (all sources, manual queries, SDV (Source Data Verification) queries, form discrepancies, form missing data).
- Patient key (=patient id)
- Query by
- Last update
- Clinician

In this main queries tab you are able to add patient a query or Reply, Reraise or Close a query. So please note, in this section you are not able to create a manual query to an item or a form. You can however navigate swiftly to a Dossier or a Form by using the applicable buttons.

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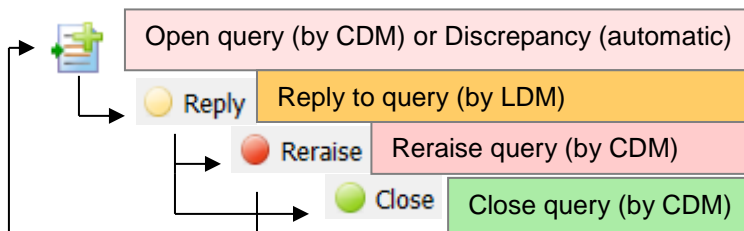
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The screenshot shows the ALEA interface. On the left, there is a table with columns 'by' and 'Last update'. It lists three queries from 'erasmusmc.nl' with dates: 13/03/2014 13:26, 17/03/2014 15:02, and 14/03/2014 12:05. On the right, a detailed view of a query is shown. At the top, there are buttons: 'Reply', 'Reraise', 'Close', 'Dossier', and 'Form'. The query text is: 'Query on data item WHO: Audittrail query: override validation override validation: - Please answer this question'. Below this, there are three response boxes: 'Unknown at this moment', 'WHO is unknown', and 'unacceptable', each with a timestamp from erasmusmc.nl. Red arrows point from the 'Add patient query' button and the query list to the detailed view.

Actions that can be taken:

- For open queries → you can close them (for instance if the LDM provided a sufficient answer, in form of a reply to a discrepancy (query subject is override validation).
- For replied queries → you can re-raise them (if the answer is still insufficient) or close them (if the answer is sufficient).
- For re-raised queries → if answered by LDM the query is replied, you can close them or re-raise them again.

The following query flow is followed through:



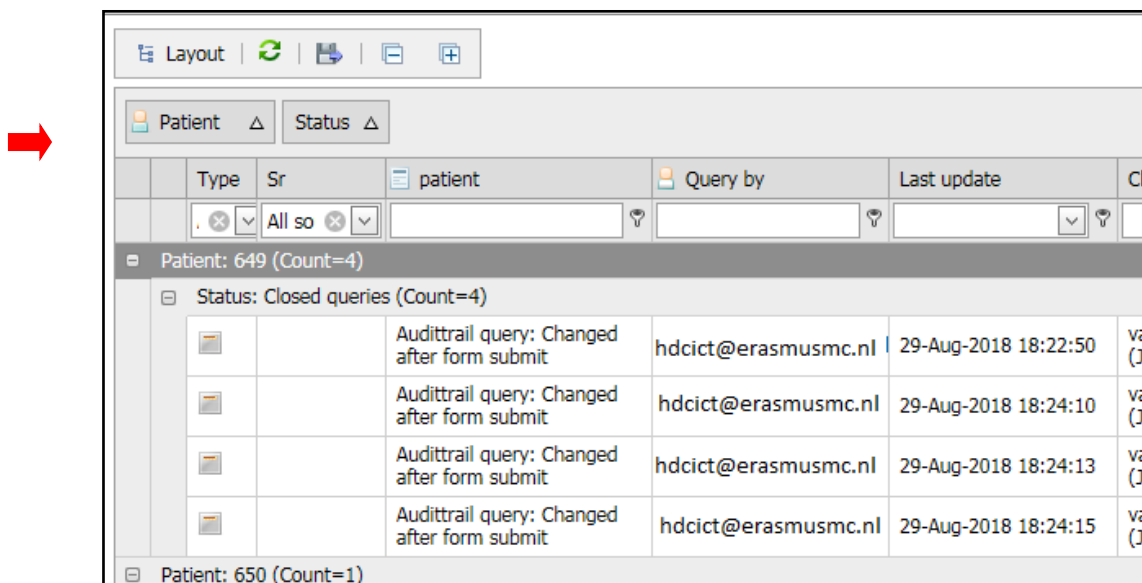
The screenshot shows the ALEA interface with a query on data item NEW. The query text is: 'Query on data item NEW: Audittrail query: override validation override validation: - This field cannot be blank'. Below this, there are three response boxes: 'Corrected value', 'unacceptable', and 'unacceptable', each with a timestamp from erasmusmc.nl. A red arrow points to the 'Corrected value' box.

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The queries Layout is a grid layout, so that you can sort the columns at your own leisure. For instance you can drag patient and status to the header to sort by patient and then by status, so that only replied queries are shown.



Please remember to save the Layout to have it ready next time (Layout1 is the default layout that will open each time you navigate to the Patients tab).

7.3.2. Edit or Delete queries

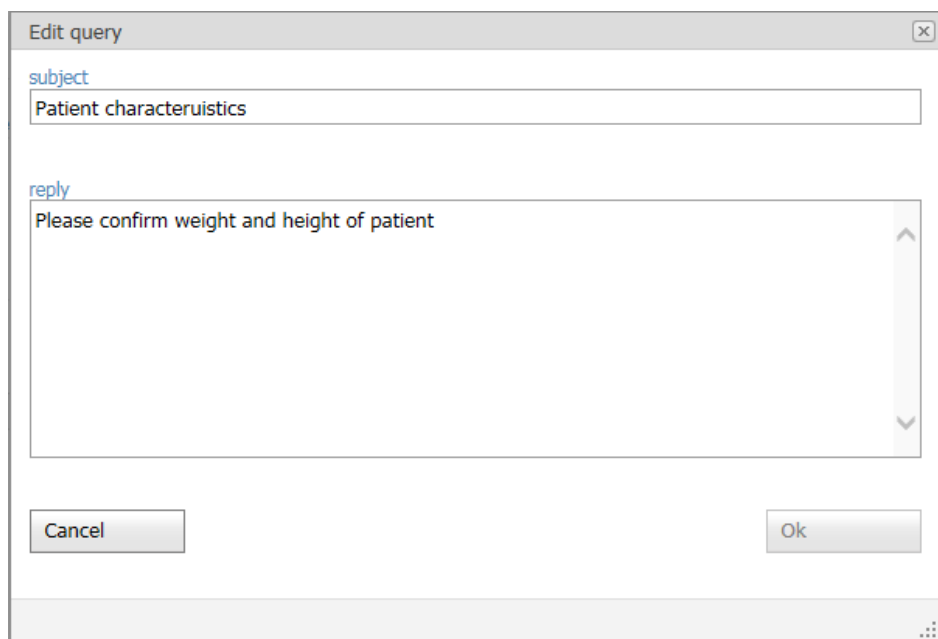
In addition the CDM can decide to edit the query or to delete the query.

To edit a query the box 'edit' in the query box is chosen and query text can be changed. Choose 'OK' or 'Cancel' as applicable.

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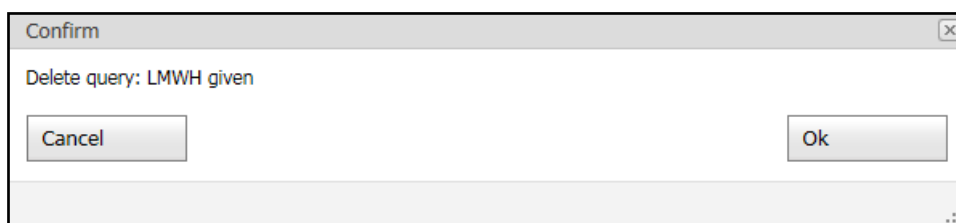
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The screenshot shows a dialog box titled "Edit query". It has two main text areas. The first, labeled "subject", contains the text "Patient characteruistics". The second, labeled "reply", contains the text "Please confirm weight and height of patient". At the bottom of the dialog, there are two buttons: "Cancel" on the left and "Ok" on the right. The dialog box has a standard Windows-style title bar with a close button (X) in the top right corner.

To delete a query the box 'delete' in the query box is chosen. Clicking 'OK' will remove the query from the query list



The screenshot shows a dialog box titled "Confirm". It contains the text "Delete query: LMWH given". At the bottom of the dialog, there are two buttons: "Cancel" on the left and "Ok" on the right. The dialog box has a standard Windows-style title bar with a close button (X) in the top right corner.

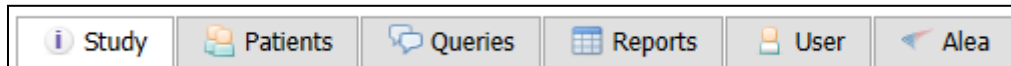
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4 Patient registration

A study homepage is organized according to the following tabs:

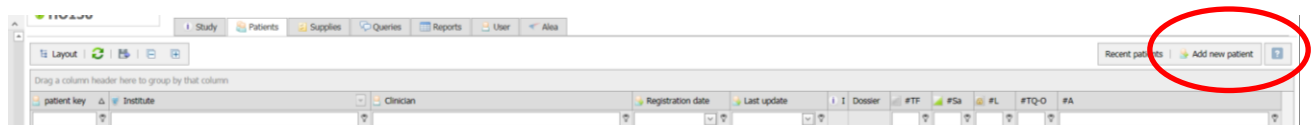


Please note that these tabs are only available if you are not working in a Patient Dossier.

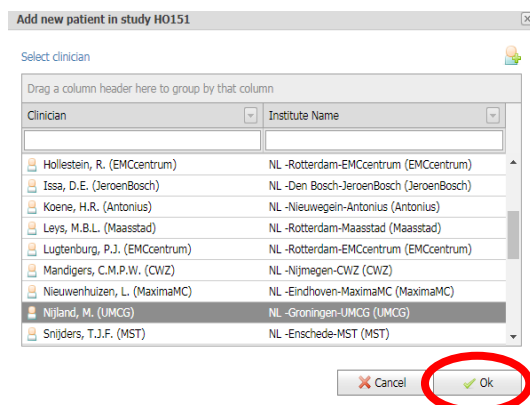
By selecting the Patients tab from the study homepage, the overview of patients in your hospital is opened.

patient key	Institute	Clinician	Registration date	Last update	Dossier	#TF	#Sa	#L	#TQ-O
001	NL-Amsterdam-VUMC (VUMC)		02-Aug-2018 11:14:58	05-Oct-2018 10:54:35	open	10	8	0	0
002	NL-Amsterdam-VUMC (VUMC)		04-Oct-2018 13:51:59	05-Oct-2018 10:54:54	open	1	0	0	0

If you are authorized to register or randomize a new patient, click the Add new patient button in the upper right corner:



If you have access to patient data in several hospitals you may have to select the clinician: select the applicable clinician and click the Ok button:



If you are working in one hospital only, you may not see this question.

A registration form will open:

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Form status : New patient
Lock status :

GENERAL PATIENT DATA
Registering person or caller
Registration hospital
Responsible physician
Year of birth
Sex
Date of registration

PATIENT DATA
If this patient was referred from another hospital, please indicate hospital name
Age at registration
Date of diagnosis
Date of written informed consent
Pathology number
Original Pathology laboratory

NL-Groningen-UMCG

Select...

13/06/2019

[dd/mm/yyyy]

[dd/mm/yyyy]

Submit

Complete all items (all red-dotted boxes are mandatory). If all items have been completed and all answers are eligible for registration, the Submit button becomes available (items with answers that are not eligible remain red).

Treatment with systemic immunosuppressive medications, including but not limited to prednisone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor (anti-TNF) agents within 2 weeks prior to date of registration; inhaled corticosteroids and mineralocorticoids are allowed

no

Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule

no

Submit

Click the Submit button to register the patient. After submitting the Submit button will be disabled. Click on the Close registration form button to close the registration form and return to the patient overview. The new patient will have been added.

After the patient has been registered/randomized, a notification will be sent by e-mail to all relevant persons at the site.

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5. 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.

User profile @erasmusmc.nl

Version **17.1**
Environment **hovona**
Environment **ACCEPTANCE**
Last login **04/10/2018 13:38:01**
Password expires **01 February 2019**

You have been granted access to the following studies

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

6. Alea

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

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7. 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 CDM can lock the Form, which will automatically prevent the Form for further data-entry/editing.
- Once all Forms are locked, the data management for that patient is done.

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Appendix A: ALEA Account Request Form









For the latest version of the ALEA Account Request Form, please check the HOVON web site (tab 'ALEA' under 'Studies' and 'Algemene studie-informatie') or contact the HOVON Data Center (hdc@erasmusmc.nl).

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Appendix B: Field Chooser box options

Field	Description ¹
#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.

¹ All numbers are displayed *per patient*

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Appendix C: Statuses of Forms

