

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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1. PURPOSE

This document provides instructions, guidelines and background information for 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 Central Laboratory.


3. TERMS & ABBREVIATIONS

Term (Abbreviation <i>if applicable</i>)	Definition
CDM	Central Data Manager/ Central Data Management
CLAB	Central Laboratory
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
06DEC2016		Data Management User Manual build 16.1
21DEC2017		ALEA 17.1 New Features

5. DOCUMENT HISTORY

Version	Date	Description of change
1	22JAN2019	ALEA instructions for Central laboratory (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.
		Chapter 6: Delete sentence on Signing off by LI and delete sentence 'The icon  indicates..... (resolved) discrepancy'
		Chapter 7.4 Annotations added to Manual
		Summary: Summary: Sentences changed in relation to signing off.

6. MANUAL

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

1. Table of Contents

1. Table of Contents	2
2. ALEA	3
2.1 Data organization.....	3
2.2 Workflow.....	3
2.3 Request for account	4
2.4 Login.....	5
3. Study Selection and organization	8
4. Study overview.....	9
5. Patients overview	10
6. Patient dossier	14
7. Entering and editing data.....	16
7.1 Conditional items.....	16
7.2 Repeated groups	16
7.3 Discrepancies.....	17
7.4 Annotations.....	20
7.5 Verification	21
7.6 Saving and submitting	21
7.7 Repeated Forms	21
7.8 Tips and Tricks	21
8. Query management	23
9. User	25
10. Alea	25
11. Summary	26
Appendix A: ALEA Account Request Form	27
Appendix B: Field Chooser box options	28
Appendix C: Statuses of Forms.....	29

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

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

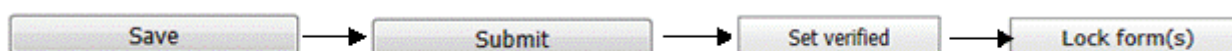
The data are organized around Events and associated Forms (CRFs). Events can be considered as separate, consecutive phases during the conduct of the trial (e.g. Registration/ Randomisation, On Study, Treatment, Follow Up). Events include one or more different Forms (e.g. Lab Results, Treatment Details,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



MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

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.

Save

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).

Submit

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

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.

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 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.

MANUAL

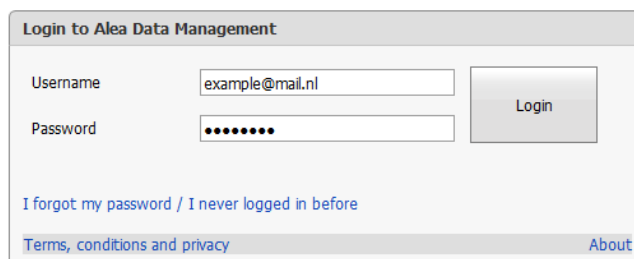
ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

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.



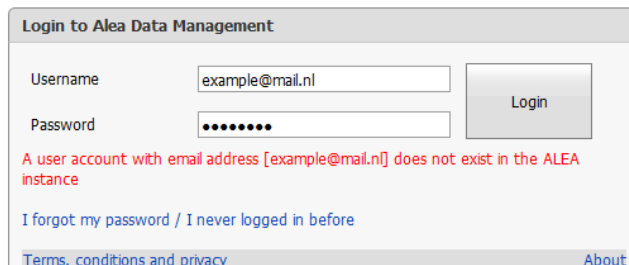
Logging in for the first time

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:

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

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).

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

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

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

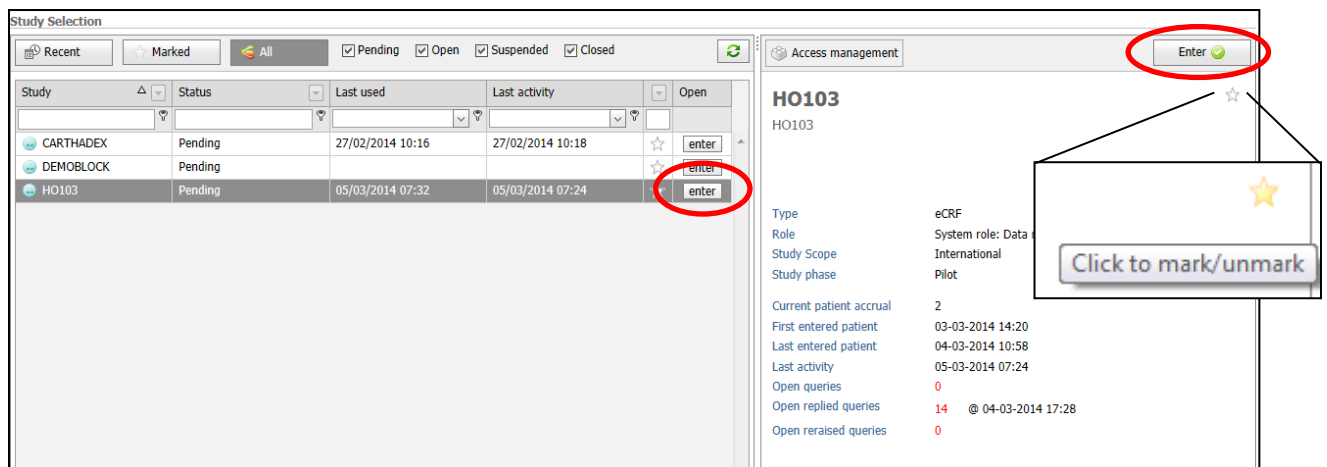
3. Study Selection and organization

Study Selection

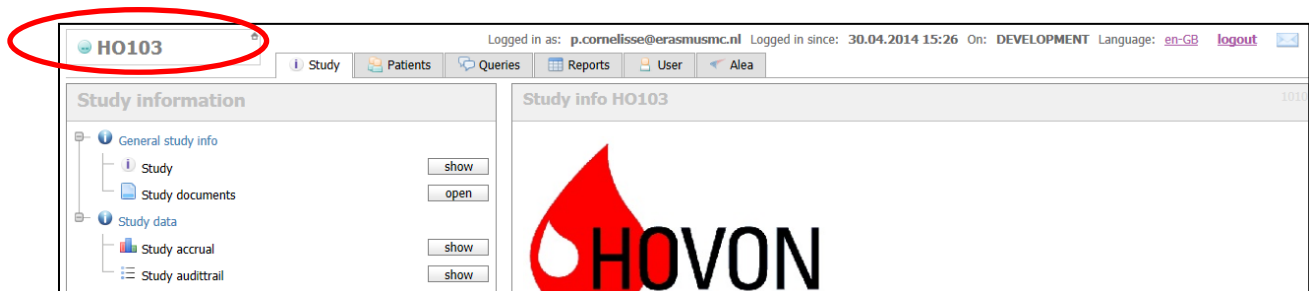
If you have access to multiple studies, you will enter a Study Selection page upon login. This split-screen shows an overview of all studies you have access to and a brief summary of the highlighted study.

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.

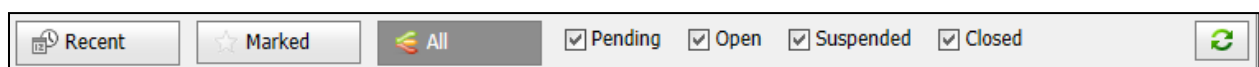


A study specific homepage appears, displaying the selected study on the study button in the upper left corner. To return to the Study Selection page, click this study button.



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.



MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

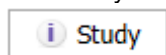
4. Study overview

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).

Study information

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

Study document management

Refresh Print Export | Descriptions

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

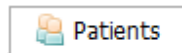
MANUAL

ALEA Instructions for Central Laboratory

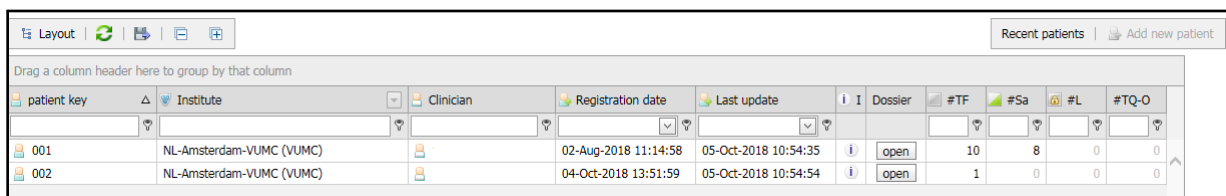
ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

5. Patients overview

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



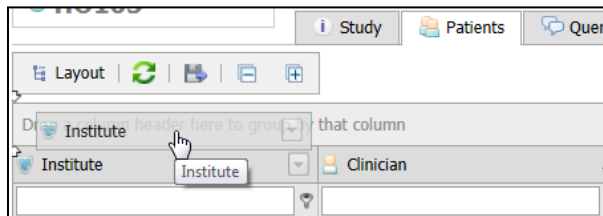
The default study overview appears.



The screenshot shows the 'Patients' tab in the study overview. At the top, there is a toolbar with 'Layout', a refresh icon, and a '+'. Below this is a header row for the grid with columns: patient key, Institute, Clinician, Registration date, Last update, Dossier, #TF, #Sa, #L, and #TQ-O. The first two rows of data are visible, both for 'NL-Amsterdam-VUMC (VUMC)'. The first row has a patient key of 001, registration date 02-Aug-2018 11:14:58, last update 05-Oct-2018 10:54:35, and 10 TFs. The second row has a patient key of 002, registration date 04-Oct-2018 13:51:59, last update 05-Oct-2018 10:54:54, and 1 TF. There are 'open' buttons next to the Dossier column for both patients.

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

In this Patient Grid you can easily sort by any given column by dragging the selected column header(s) to the upper bar (reading 'Drag a column header here to group by column'). For instance, it could be convenient to sort by 'Institute' if you provide data of the Central Laboratory for multiple sites. Alternatively the little arrows on the right side of the column could be useful for sorting on specific items.



If you drag columns back to the column header row of the grid, you undo the sorting.

It is possible to add more columns to the Patient overview. To do so, select the option 'Layout' → 'Customize layout':

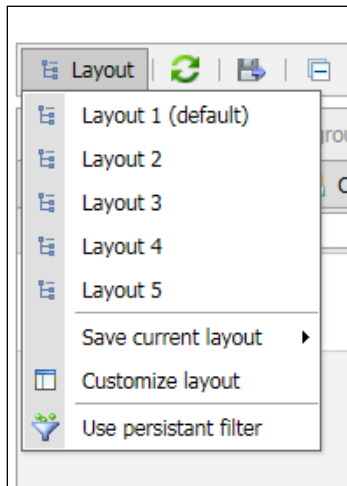
MANUAL

ALEA Instructions for Central Laboratory

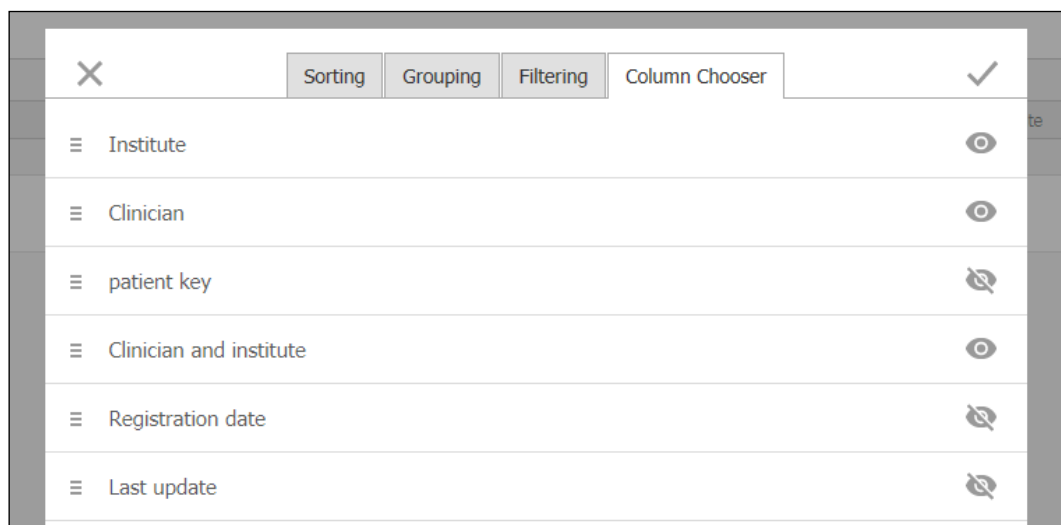
ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

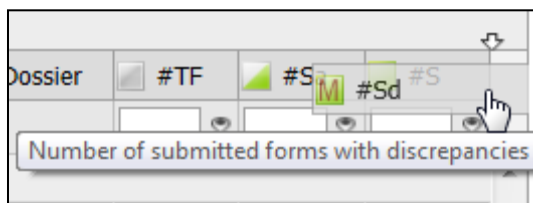
2



A Field Chooser is displayed:



By clicking/unclicking the preferred fields from the Column Chooser, followed by ✓ in the upper right corner the columns are added to your preferred settings.



For example, the following fields could be useful:

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

#TF:	Total number of forms
#Sa:	Number of saved forms
#S:	Number of submitted forms (without discrepancies and without missing values)
#L:	Total number of locked forms
#TQ-O:	Number of open queries on Patients and Forms
#TQ-R:	Number of non-closed queries on Patients and Forms

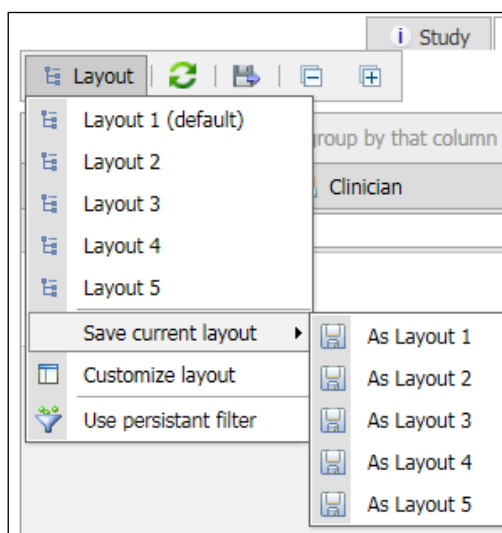
For a complete overview of all optional Fields, see appendix B

If you would like to save a certain layout (i.e. configuration of columns) in order to re-use it during subsequent sessions, click 'Layout' → 'Save current layout' → 'As layout X':


Layout 1 is the layout that will be used as the (personal) default for the study.:

If necessary, a separate patient overview must be set for each study.

Please do not use the option 'Set as study default'. The option 'Set as study default' is meant for setting a default patient overview for local data managers just before the start of a new study



Patient summary

Clicking the icon  in a patient row will show the Patient Summary with the most important details (e.g. number of forms entered, number of open, replied and closed queries, whether or not SDV (Source Data Verification) was executed and number of annotations). Annotations are used by the LDM or the CDM to provide comments or extra information.

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

Patient summary

Patient
Reg.Date
Clinician
Institute

004
08-Aug-2018 09:06:34
EMCCENTRUM - NL -Rotterdam-EMCCentrum -

4 ?

Total forms entered
Saved Forms
Submitted Forms
- with discrepancies
- with missing values
Verified Forms

3
0
1
0
0
2

Locked Forms

0

Queries
Open queries
Replied queries (not closed)
Closed queries

On forms
0
1
0

On patient
0
0
0

Total
0
1
0

SDV

Marked for SDV
0

SDV -
0

SDV +
0

Annotations

On forms
0

On patient
0

Total
0

Last summary update 09-Oct-2018 12:50:32

MANUAL

ALEA Instructions for Central Laboratory

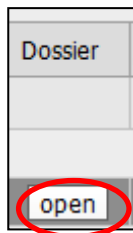
ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

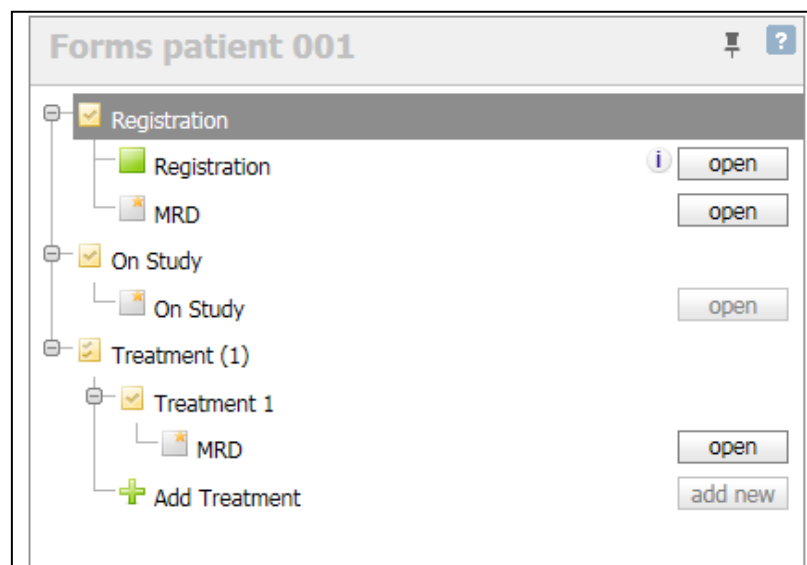
6. Patient dossier

To open a patient dossier, click the Open button in the row of the applicable patient.

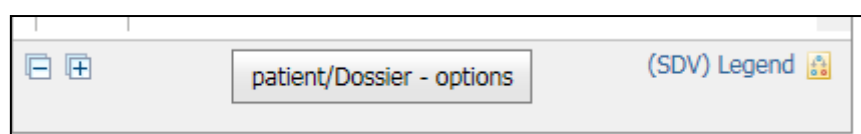


Once you have opened a patient dossier, a tree panel at the left side of the screen shows all the events that have been specified for the study (see example below). The data are organized around Events and associated Forms (CRFs). The events contain all the applicable forms. To expand an event, click on the plus before the event; to expand all events, click on the plus sign at the bottom left of the Forms section.

You only able to open and enter data into the form you have been authorized to; for instance the MRD form.



The (SDV= Source Data Verification) Legend link opens a pop-up screen that explains all statuses of completion (see Appendix C):



MANUAL

ALEA Instructions for Central Laboratory



ID: HDC-OP-CDM-342-2-MN- 6




KMS
Version:

2

NB: The Patient and Dossier options buttons are not applicable for Central laboratory.

Please note the difference between Saved  and Submitted  statuses.

If the pin at the top right corner of the Tree panel is pointed downwards , the Tree remains visible once opening a Form. Setting the pin in the horizontal position  by clicking on it, will hide the Tree panel once opening a Form. This allows for more space to display the middle and right panes.

Clicking on the icon  next to the Open button of a filled out Form opens a Form Summary. If the icon is red , there are open discrepancies / queries to be answered. If the icon is orange , this indicates that you have resolved discrepancies / queries that were not yet reviewed by the CDM.

MANUAL

ALEA Instructions for Central Laboratory

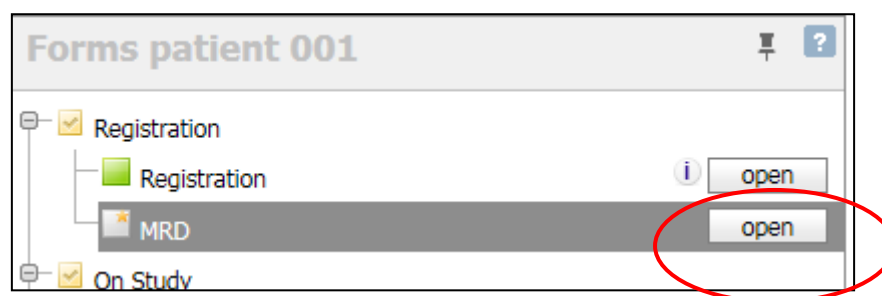
ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

7. Entering and editing data

To enter or edit data on a Form, click the Open button:



Depending on the position of the pin in the Tree panel (see chapter 5), the screen will be divided in 2 or 3 sections. You can change the width of each section by moving the slide-bar to the left or to the right, or expand / collapse screens by clicking on the little arrows.



7.1 Conditional items

Some items are conditionally hidden and will only appear depending on answers to previous questions (e.g. if 'other, specify' is selected, a specification box will appear).

7.2 Repeated groups

Some (sections on) CRF's are arranged in groups, meaning that multiple similar entries can be added according to need. For example on the MRD Events Form, information from several MRD Targets (PCR-Targets, including Target, Target information) can be entered, each PCR-Target arranged as a group.

By default, the first group is being displayed. To *add* a group (e.g. Information on Targets (PCR-Targets), click 'INSERT ITEM' (**NB**: this doesn't clearly stand out as a button):

MANUAL


ALEA Instructions for Central Laboratory

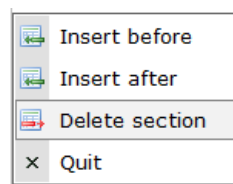
ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
-----	------------------------	-----------------	---

Information on Targets (PCR-Targets)


Target	Select...
Target Info	
Quantitative Range	Select...
Sensitivity	Select...
MRD Conclusion	Select...
MRD level	

Insert item

To *remove* a group, hover the mouse over the to-be-removed group until the  icon appears at the left margin. By clicking this icon and selecting 'Delete section' one can delete the respective group:



7.3 Discrepancies

Some items are marked with red dotted lines and an associated value discrepancy in the Audit trail and discrepancies menu  in the right panel. These include required items which cannot be left blank, and entered values that do not meet certain pre-set criteria or checks (e.g. a date in the future).

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6


KMS
Version:

2

The screenshot shows the 'MRD' form interface. On the left, the 'MRD ASSESSMENT BY CENTRAL LAB' section includes fields for 'PCR MRD test done' (dropdown with 'yes'), 'Material' (dropdown with 'Select...'), 'Date sample' (calendar icon), and 'Additional information of sample' (text area). Below this is the 'Information on Targets (PCR-Targets)' section with dropdowns for 'Target', 'Target Info', 'Quantitative Range', 'Sensitivity', 'MRD Conclusion', and 'MRD level'. On the right, the 'Audittrail and discrepancies' panel is active, showing a list of items with 'value discrepancy' messages. The 'Current data item' tab is selected, showing 'Flow cytometry done (FLOW)' and 'Flow sensitivity [%] (FSSENS)' with 'value discrepancy' messages. The 'WHO performance status: (WHO)' item is also visible.

This close-up screenshot focuses on the 'Audittrail and discrepancies' panel. The 'Current data item' tab is selected, and a 'value discrepancy' message is shown for the 'WHO performance status: (WHO)' item. The message states: 'value discrepancy - Please answer this question'. A 'resolve' button is visible next to the message.

At the top of the Audit trail and discrepancies menu in the right panel you can select the tab 'Current data item' to see the value discrepancy of the item that is currently selected in the Form, or the tab 'All data items' to see discrepancies for all items of the Form.

Clicking the  icon marks the item to which the discrepancy applies with a blue border.

Always try to address the discrepancy by entering / correcting the respective value in the Form. After providing an answer that does not lead to any other discrepancies, the red dotted line and the discrepancy will disappear.

However, if a value is truly missing or does not meet the pre-set criteria / check, a reason should be provided to override the discrepancy. Click the 'resolve' button and select a default reason from the dropdown list, or choose 'other' (which should be further specified). The options 'As CRF' is to be used when copying a value from a paper CRF. The option 'Value correctly entered' is to be used when the entered value is correct even though out of range.

NB: Addressing a discrepancy via the Resolve button will lead to a query that needs to be reviewed by CDM and should therefore be avoided as much as possible.

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

2

The screenshot displays the ALEA system interface. On the left, the 'PATIENT CHARACTERISTICS AT ENROLMENT' section includes fields for Weight [kg], Height [cm], Date of first diagnosis colorectal carcinoma (histological) [dd/mm/yyyy], Date of radiological diagnosis of colorectal liver metastase(s) [dd/mm/yyyy], and Carcinoembryonic Antigen (CEA) at baseline [ng/ml]. Below this is the 'MEDICAL HISTORY' section with checkboxes for Cardiovascular disease, Pulmonary disease, Neurological disease, and Abdominal surgery. A red arrow points from the 'Date of first diagnosis colorectal carcinoma (histological)' field to the 'Audittrail and discrepancies' panel. This panel shows a 'value discrepancy' for 'Date of first diagnosis colorectal carcinoma (histological) (DDIAGPCC)' with the message '- Value is missing. Please provide.' and a 'resolve' button. A dialog box titled 'Resolve audittrail issue' is open, showing the control message 'DDIAGPCC value discrepancy' and the error '- Value is missing. Please provide.' The 'reason' dropdown menu is open, showing options: 'Corrected value', 'Unknown at this moment', 'Value is correctly entered', 'As CRF', 'Not done', 'Not applicable', and 'Other'.

Once you answer a discrepancy the color changes to orange (i.e. reason is proposed). A discrepancy can either be closed by CDM when the reason is accepted, or be reraised when the proposed reason is declined. Reraised discrepancies (colored red) should be re-addressed, until accepted by CDM.

The screenshot displays two audit trail messages. The top message is orange and titled 'override validation'. It contains the text 'Audittrail query: override validation' and 'override validation: - Please answer this question'. It is signed 'by erasmusmc.nl at 30-04-2014 07:27:32' and has a 'reply' button. The bottom message is red and also titled 'override validation'. It contains the text 'Audittrail query: override validation' and 'override validation: - Please answer this question'. It is signed 'by erasmusmc.nl at 30-04-2014 07:27:35' and has a 'reply' button. Below the signature, it says 'Value is correctly entered'. At the bottom, it says 'Query reraised : this is incorrect -dmslkadfkjsfjlsjfkds' and 'by hdcict@erasmusmc.nl at 30-04-2014 14:20:23'. A red arrow points to the 'reply' button.

MANUAL

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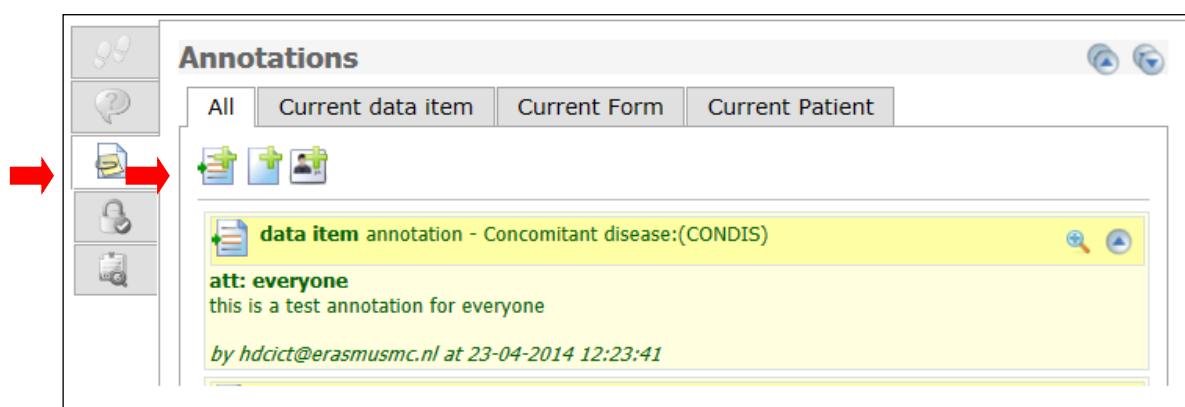
ID: HDC-OP-CDM-342-2-MN- 6

KMS
Version:

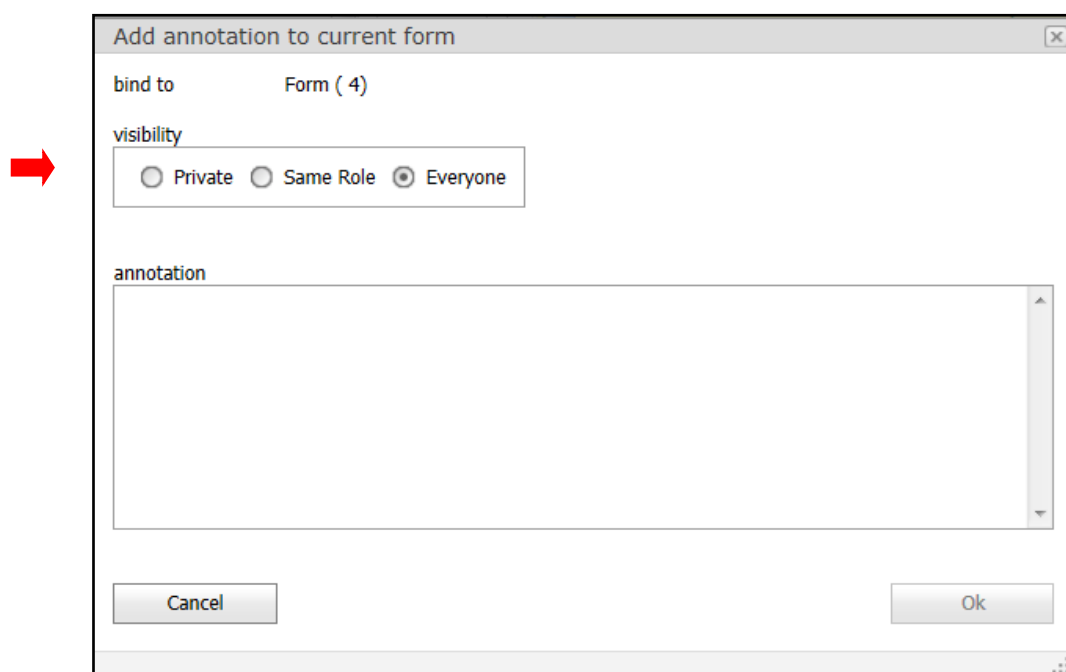
2

7.4 Annotations

Annotations are like yellow post-it remarks / sticky notes on the CRF. Creating one works similar to creating queries. Also the LDM can create annotations, so please be sure to check them. In the patient dossier in each form, you have the possibility to create an annotation on a data item level, form level or patient level.



When creating an annotation you can choose to either make one for yourself (private), for the same role (for instance so that other users in the same role can see them too – preferred option), or to everyone (now also the LDM and the SPI can see the annotation). Once an annotation has been created you cannot remove it anymore.



MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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7.5 Verification

After providing the MRD and flow cytometric data all discrepancies need to be resolved. The information need be verified before closing the form.

VERIFICATION

Verification by
J.G. de Vries

7.6 Saving and submitting

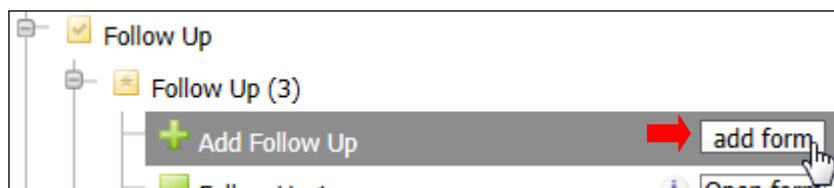
After entering all data, you can save the form by clicking the Save button.

The Submit button will be enabled when all required items are entered and all discrepancies – if any – have been addressed. Only submit a Form if you think all data are correct and complete and no further data editing is expected.

NB: Eventually all Forms need to be submitted before data review by the CDM is possible.


7.7 Repeated Forms

Some Forms are repeating forms (e.g. Follow Up). Add a new form by clicking the Add form button in the Tree panel, and click OK to confirm.



A new form is added to the tree and will open. Add Forms when needed and enter data in chronological order.


7.8 Tips and Tricks

- Using the tab key to move to the next item is faster and more efficient than using the mouse.
- With shift + tab you navigate to the previous item.
- The icon  indicates a dropdown list, from which you can select the desired option. You can also type the first letter of the applicable answer option (e.g. y for yes)

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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- Dates can be picked through the date picker  or entered manually. Be aware that when using the date picker and clicking the double arrows to the left or right (<< and >>) one jumps a year back and forth. When using the single arrow (< and >), one jumps a month back and forth respectively. When entered manually, it is not necessary to type separators (i.e. / or -). For example, if one enters 01012015 ALEA recognizes this as a date and transforms it into 01/01/2015. If the date is today, you can enter “t” and the date of today will be displayed.

NB: For instructions on how to fill out the eCRF, see the study specific CRF guidelines.

MANUAL

ALEA Instructions for Central Laboratory

ID: HDC-OP-CDM-342-2-MN- 6

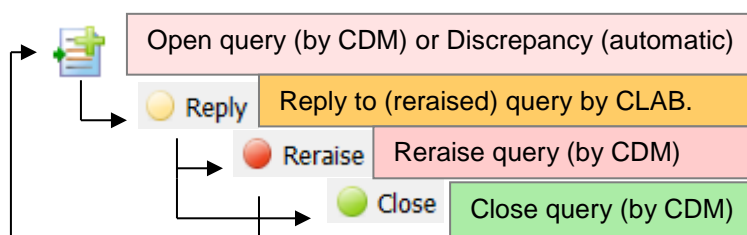
KMS
Version:

2


8. Query management

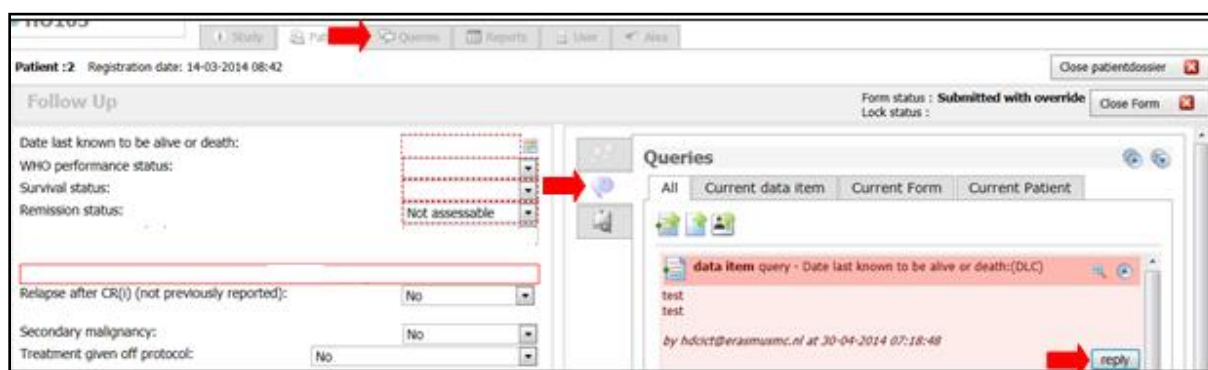
Most checks are raised automatically (discrepancies). In contrast, queries can be raised manually by the CDM. Queries can relate to a specific data item, to a specific form or to a patient. All discrepancies and queries should be addressed. Once you replied, the CDM can take action.

A typically query flow is depicted below:







Please note that even though the status remains “Replied”, the CDM can have re-raised the query, so always look at the color of the query: red means that there is still an answer required from the LDM.

You can reply to queries in the Queries menu  on the right panel in the patient dossier.



In the Query overview (after clicking the Query tab) you can sort by:

- status (all queries, open queries , replied queries , reraised 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 (= patient i.d.)
- Patient (subject of query)
- Query by
- Last update

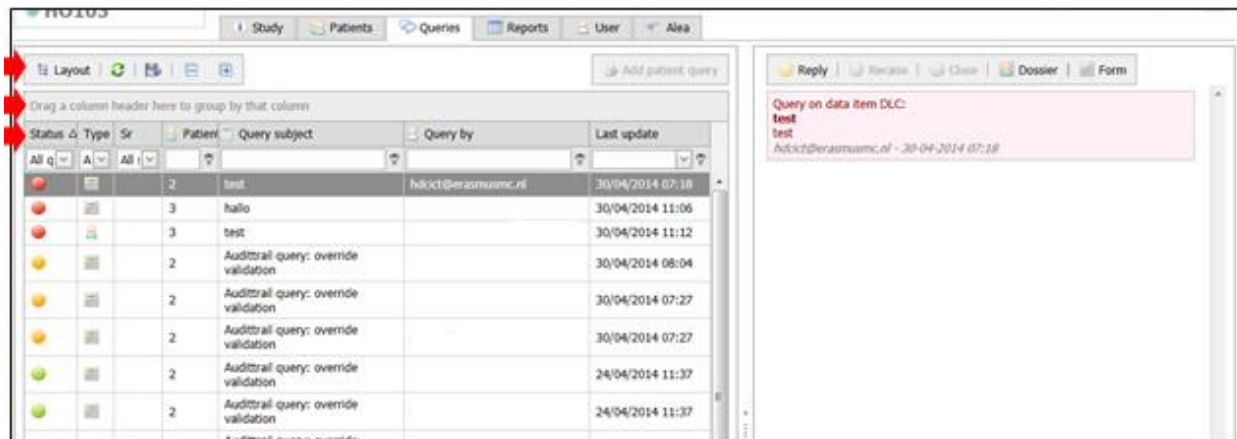
In the Query grid you can also easily customize your sorting by dragging the selected column header(s) to the upper bar (reading ‘Drag a column header here to group by column’), similar to what

MANUAL

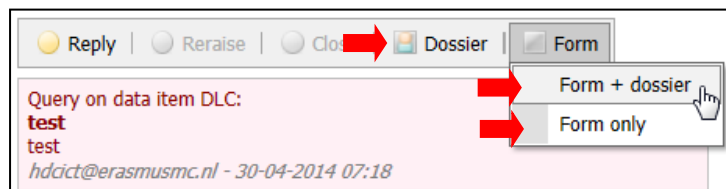
ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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was described in chapter 4 regarding the Patient Overview. Settings can be saved via the Layout button → save current layout.



To view the CRF-item to which the query applies you can navigate to Dossier (to go to the patient dossier), Form+Dossier (to go directly to the specific form in the patient dossier), or Form only.



MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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9. 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

10. Alea

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

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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11. 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.

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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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).

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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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*

MANUAL

ALEA Instructions for Central Laboratory

ID:	HDC-OP-CDM-342-2-MN- 6	KMS Version:	2
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Appendix C: Statuses of Forms

