

MANUAL

ALEA Instructions for Cytogeneticists

ID: HDC-OP-CDM-342-2-MN- 4

KMS Version: 4

1. PURPOSE

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

2. SCOPE

The manual is applicable for Cytogeneticists.

This document is also available on the HOVON website.

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
06DEC2016		Data Management User Manual build 16.1
21DEC2017		ALEA 18.1 New Features

5. DOCUMENT HISTORY

Version	Date	Description of change
V-schijf	20NOV2015	ALEA instructions for Cytogeneticists (original version)
V-schijf	29NOV2016	Unknown (V-schijf version 2)
V-schijf	02FEB2018	Unknown (V-schijf version 3)
2	22JAN2019	Unknown (V-schijf version 4)
3	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
4	19NOV2021	ALEA version changed to 18.1 (in purpose of this document and required an related documents)
		Chapter 2: ALEA version changed to 18.1

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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 18.1.

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:

<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). 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.

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.

2.4 Login



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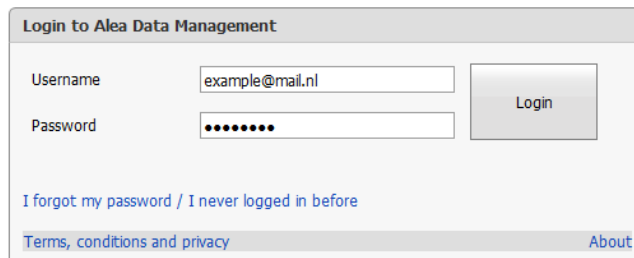
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The URL to the ALEA portal is: <https://aleaclinical.com/Hovon/DM/DELogin.aspx?>

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



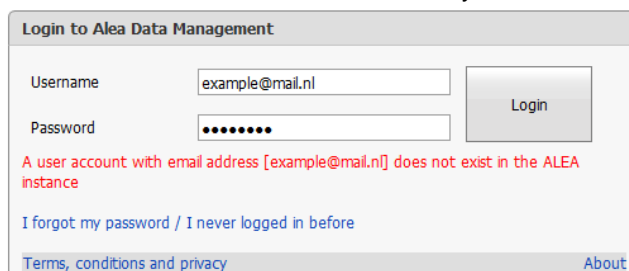
Logging in for the first time

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 *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

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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	Status	Last used	Last activity	Open
CARTHADEX	Pending	27/02/2014 10:16	27/02/2014 10:18	[star] [enter]
DEMOBLOCK	Pending			[star] [enter]
HO103	Pending	05/03/2014 07:32	05/03/2014 07:24	[star] [enter]

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.

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

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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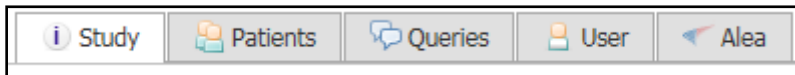
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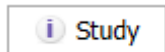
4. Study overview

A study homepage is organized according to the following tabs:

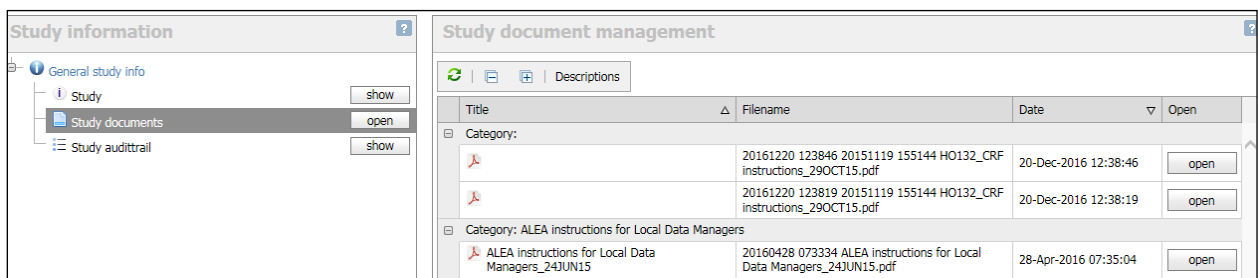


Please note that these tabs are only available if you are not working in a Patient Dossier (Chapter 5).

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, titled 'Study information', contains a tree view with 'General study info' (show), 'Study' (show), 'Study documents' (open), and 'Study audittrail' (show). The right panel, titled 'Study document management', contains a table of documents with columns for Title, Filename, Date, and Open.

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

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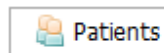
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5. Patients overview

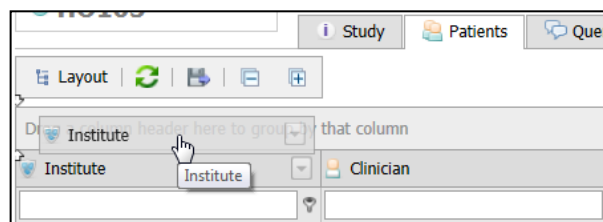
By selecting the Patients tab from the study homepage, the eCRF can be accessed.



The default study overview appears.

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 perform Cytogenetic Review 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.

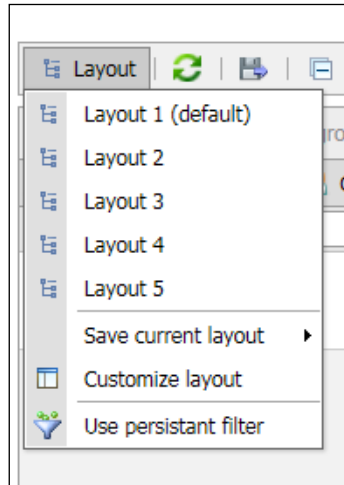
It is possible to add more columns to the Patient overview. To do so, select the option 'Layout' → 'Customize layout':

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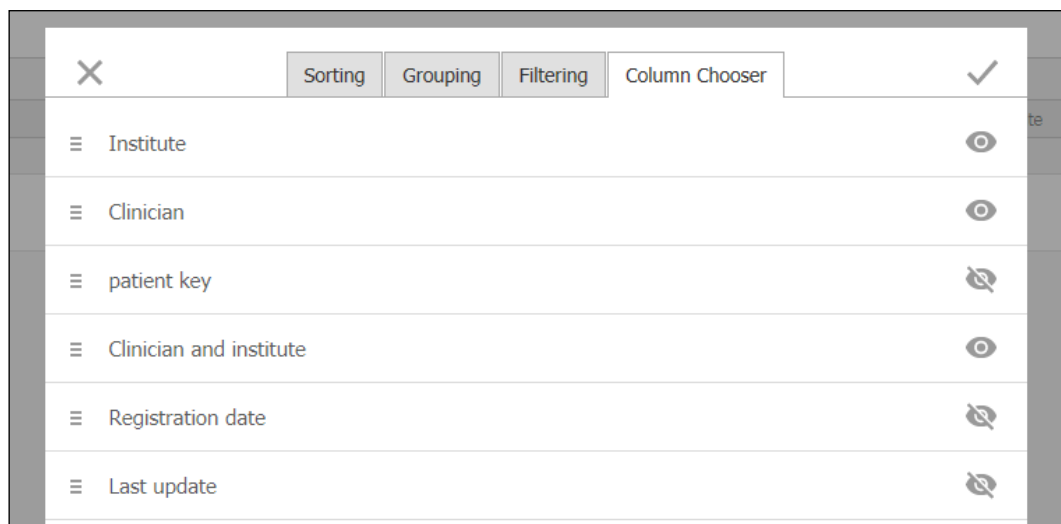
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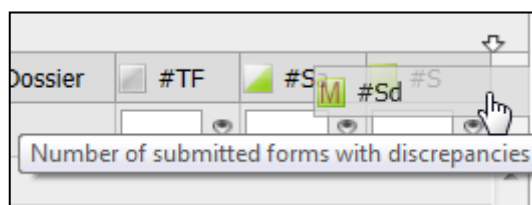
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A Field Chooser is displayed with the tabs 'Sorting', 'Grouping', 'Filtering' and 'Column Chooser'.



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:

#TF: Total number of forms

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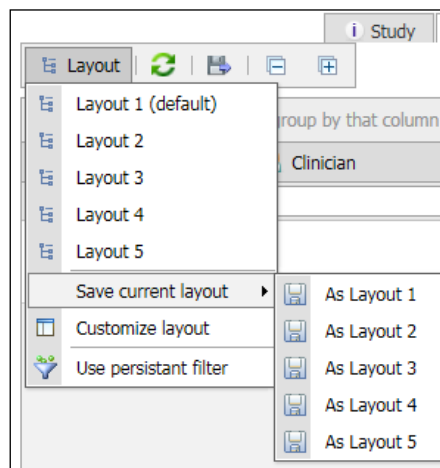
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#Sa:	Number of saved forms
#S:	Number of submitted forms (without discrepancies and without missing values)
#Sd:	Number of submitted forms with discrepancies
#Sm:	Number of submitted forms with missing values
#V:	Number of verified Forms
#L:	Total 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': If you choose for 'Layout1', the preferred layout will appear at the start of the next session



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 can be used by every role to provide comments or extra information.

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Patient summary			
Patient	004		
Reg.Date	08-Aug-2018 09:06:34		4
Clinician			
Institute	EMCCENTRUM - NL -Rotterdam-EMCcentrum -		
Total forms entered	3	Locked Forms	0
Saved Forms	0		
Submitted Forms	1		
- with discrepancies	0		
- with missing values	0		
Verified Forms	2		
Queries	On forms	On patient	Total
Open queries	0	0	0
Replied queries (not closed)	1	0	1
Closed queries	0	0	0
SDV	Marked for SDV	SDV -	SDV +
	0	0	0
Annotations	On forms	On patient	Total
	0	0	0
<i>Last summary update 09-Oct-2018 12:50:32</i>			

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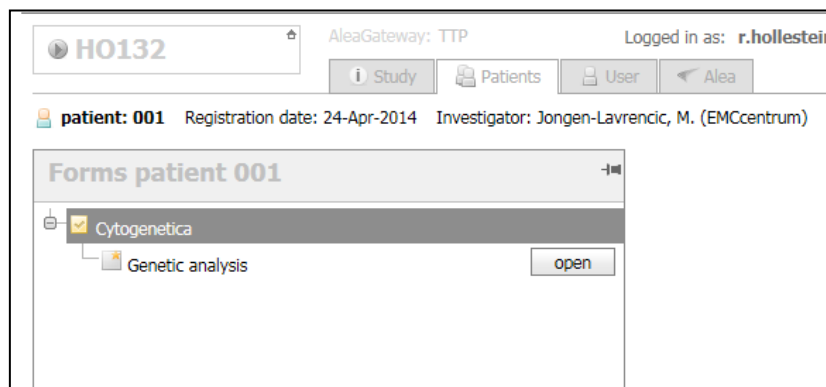
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6. Patient dossier

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 will only be able to open and enter data into the form you have been authorized to; i.e. the Genetic analysis form, in the event Cytogenetics.

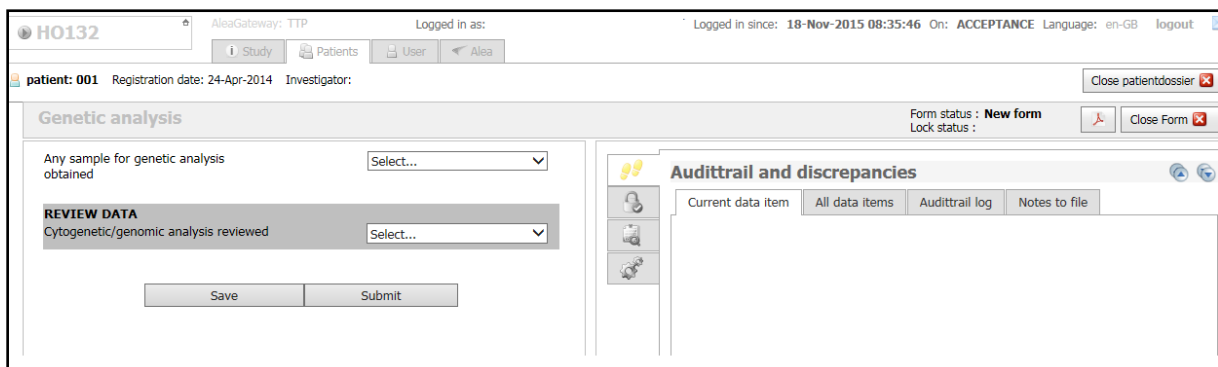


The screenshot shows the ALEA patient dossier interface. At the top, there is a search bar with 'HO132' and navigation buttons for 'Study', 'Patients', 'User', and 'Alea'. The user is logged in as 'r.hollestein'. Below this, patient information is displayed: 'patient: 001', 'Registration date: 24-Apr-2014', and 'Investigator: Jongen-Lavrencic, M. (EMCcentrum)'. The main area is titled 'Forms patient 001' and contains a tree panel with a plus sign on the left. The tree shows 'Cytogenetica' expanded, with 'Genetic analysis' listed below it. An 'open' button is visible next to 'Genetic analysis'.

NOTE: 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. You can change the width of each section by moving the slide-bar to the left / right, or expand / collapse screens by clicking on the little arrows.

7. Entering and editing data

To enter or edit data on a Form, click the Open button of the applicable form. Depending on the position of the pin in the Tree panel (see NOTE above), the screen will be divided in 2 or 3 sections. Start entering data by answering the first question in the right panel (Any sample for genetic analysis obtained). The items in the grey area will be completed by the reviewer later in the process.



The screenshot shows the 'Genetic analysis' form in the ALEA system. The form is titled 'Genetic analysis' and has a status of 'New form'. It contains two main sections: 'Any sample for genetic analysis obtained' and 'REVIEW DATA'. The first section has a 'Select...' dropdown menu. The second section has a 'Cytogenetic/genomic analysis reviewed' dropdown menu. Below these sections are 'Save' and 'Submit' buttons. To the right of the form is an 'Audit trail and discrepancies' panel with tabs for 'Current data item', 'All data items', 'Audit trail log', and 'Notes to file'. The 'Current data item' tab is selected, showing a list of items. The top of the form includes navigation buttons for 'Study', 'Patients', 'User', and 'Alea', and a 'Close patientdossier' button.

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7.1 Conditional items

Some items are conditionally hidden and will only appear depending on answers to previous questions.

HO132 AleaGateway: TTP Logged in as:

Study Patients User Alea

patient: 001 Registration date: 24-Apr-2014 Investigator:

Genetic analysis

Any sample for genetic analysis obtained
no
yes

REVIEW DATA
Cytogenetic/genomic analysis reviewed

Save Submit

By answering the first question selecting the option 'yes', the applicable items become visible:

Genetic analysis

Any sample for genetic analysis obtained

Date of sample for cytogenetic analysis

CYTOGENETIC ANALYSIS
Cytogenetic analysis

FISH ANALYSIS
FISH analysis done

ARRAY ANALYSIS
ARRAY analysis done

REVIEW DATA
Cytogenetic/genomic analysis reviewed

Save Submit

Please note that the red marked items are mandatory to answer.
By selecting the option 'done', the applicable items become visible:

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Any sample for genetic analysis obtained	<input type="text" value="yes"/>
Date of sample for cytogenetic analysis	<input type="text" value="17/11/2015"/>
CYTOGENETIC ANALYSIS	
Cytogenetic analysis	<input type="text" value="done"/>
Material	<input type="text" value="Select..."/>
Number of mitoses examined	<input type="text"/>
Number of banded cells fully analyzed	<input type="text"/>
General classification	<input type="text" value="Select..."/>
Number of cells with normal karyotype	<input type="text"/>
Number of cells with clonal abnormality	<input type="text"/>
Abnormalities present in	<input type="text" value="Select..."/>
Constitutional chromosome abnormality	<input type="text" value="Select..."/>
Karyotype (according to current ISCN nomenclature)	
<input type="text"/>	
Karyograms sent to HOVON Data Center	<input type="text" value="Select..."/>
PLEASE SEND IN REPRESENTATIVE KARYOGRAMS TO HDC	
FISH ANALYSIS	
FISH analysis done	<input type="text" value="Select..."/>
ARRAY ANALYSIS	
ARRAY analysis done	<input type="text" value="Select..."/>
REVIEW DATA	
Cytogenetic/genomic analysis reviewed	<input type="text" value="Select..."/>
<input type="button" value="Save"/> <input type="button" value="Submit"/>	

7.2 Repeated groups

Some (sections on) CRF's are arranged in so called repeating groups, meaning that multiple similar entries can be added according to need. For example, on the Genetic analysis form, multiple FISH and ARRAY probes can be entered, each probe with the applicable items arranged as a group.

By default, the first group is being displayed. To *add* a group, click 'Insert item':




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
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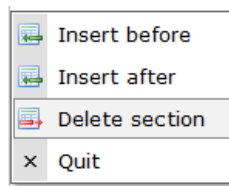
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 **Report percentage of cells only if above cut-off level**

Probe/Target	Select...
Probe name/manufacturer/specification	
Material	Select...
Specify other material	
Number analyzed	
Percentage Normal [%]	
Percentage Loss [%]	
Percentage Gain [%]	
Percentage Translocation [%]	

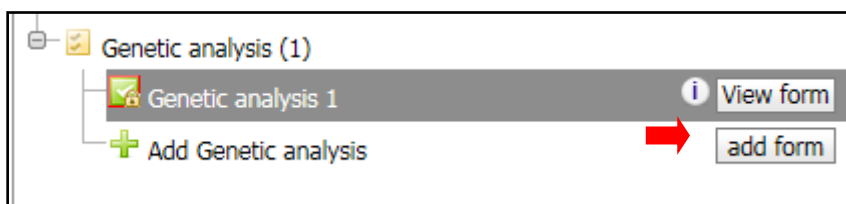
 Insert item

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



7.3 Repeated Forms

In some studies the form is a repeating form. 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.



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

7.4 Annotations

Annotations are like yellow post-it remarks / sticky notes on the CRF. Creating one works similar to creating queries. The user can create annotations, which should be checked by the CDM.

In the patient dossier in each form, you have the possibility to create an annotation on a data item level, form lever or patient level.

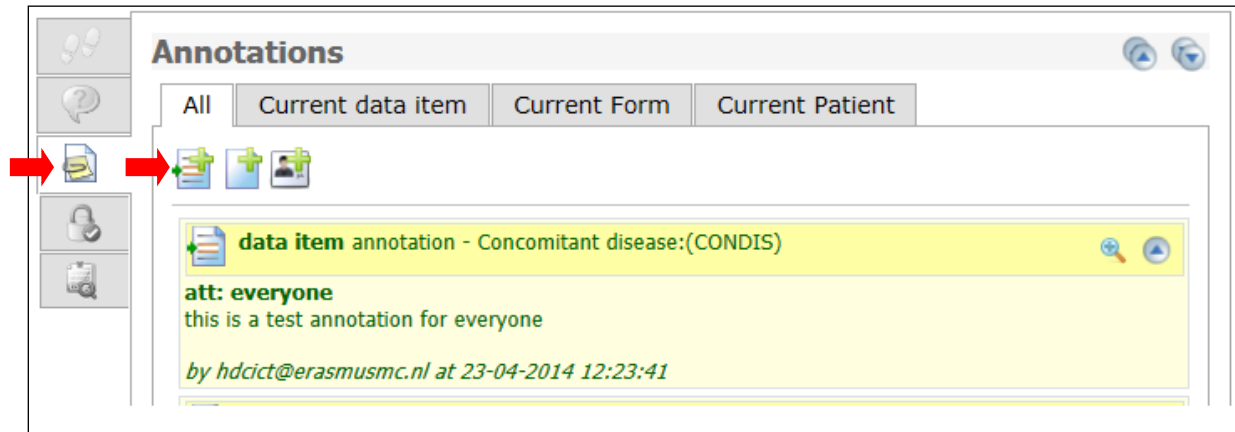
Annotations are not used in the analysis of the data and are not a part of the data export for statistical purposes.

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

7.5 Saving and submitting

After entering data, save the form by clicking the Save button at the bottom of the form. Next to the Save button there is a Submit button, which will only be enabled when all required items are entered and all discrepancies - if any - in the Audit trail and discrepancies menu have been addressed (see 7.5). Do not use the Submit button; only after the review proces, the reviewer should submit the form. The review proces is described in chapter 9.

7.6 Audit trail and discrepancies

Some items are marked with red dotted lines and have 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). This type of discrepancy can be resolved by entering a correct value at the item. If this is not possible, it must be resolved by providing a reason (see 7.7).

Please note that if the data is changed after the form has been submitted, a discrepancy will appear on the changed item (but will not be marked by a red line) and you have to provide a reason (see 7.7).

7.7 Resolving discrepancies

To view the discrepancies select the option "Audittrail and discrepancies" on the right window of the screen. In default this option and the tab "All data item" is shown.

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The screenshot shows the 'Genetic analysis' form. On the right side, the 'Audittrail and discrepancies' tab is highlighted with a red circle. The form includes fields for 'Any sample for genetic analysis obtained' (yes), 'Date of sample for cytogenetic analysis' (16/11/2015), 'CYTOGENETIC ANALYSIS' (done), 'Material' (BM), 'General classification' (NN), 'Abnormalities present in' (not present), and 'Constitutional chromosome abnormality' (no). The 'Karyotype' field is also present.

Usually it is more efficient to select the tab "All data items", to see all discrepancies:

This screenshot shows the 'Audittrail and discrepancies' section with the 'All data items' tab selected, circled in red. It displays a list of discrepancies for 'FISH analysis done (FISH3)', 'ARRAY analysis done (ARRAY3)', and 'Karyotype (KARYO)'. Each entry shows a 'value discrepancy' and a 'resolve' button.

If a discrepancy cannot be resolved by entering a (correct) value at the corresponding item, the discrepancy should be resolved by the following procedure:

This close-up shows a discrepancy entry for '(CLASS)'. The text indicates a 'value changed after previous submit of form' with a 'previous value: 2' and an 'entered value: 1'. The 'resolve' button is circled in red.



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Resolve audittrail issue

control message	CLASS value changed after previous submit of form
previous value	2
new value	1

reason

Cancel Ok

Resolve audittrail issue

control message	CLASS value changed after previous submit of form
previous value	2
new value	1

reason

- Corrected value
- Unknown at this moment
- Value is correctly entered
- As CRF
- Not done
- Not applicable
- Other

Resolve audittrail issue

control message	KARYOHDC value changed after previous submit of form
previous value	0
new value	1

reason

Corrected value

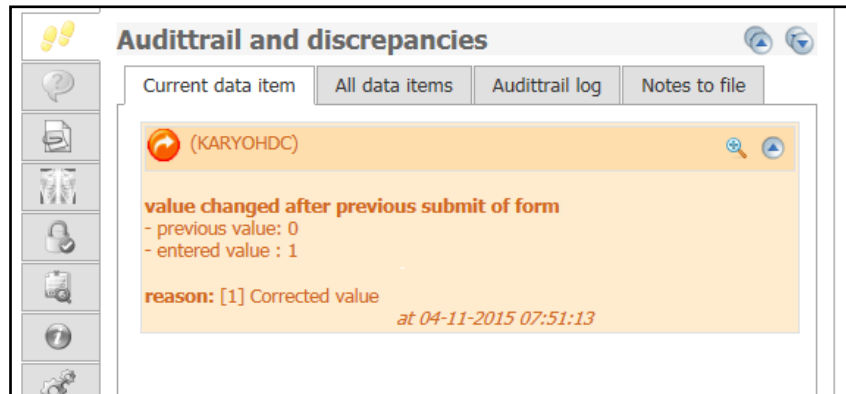
Cancel Ok

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7.7 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).
- A date can be entered using the date-picker  or by typing dd/mm/yyyy.

8. Providing karyograms

For the time being the applicable karyograms should be send as separate files (pdf or jpg) attached to an e-mail to hdc@erasmusmc.nl.

In the subject of the e-mail should be mentioned: Karyograms HOXXX

Please identify the file with HOVON study number, study subject (patient) number and sample date (e.g. HO132_324_12SEP2015).

Preferably this should be mentioned both in the file name and in the file itself.

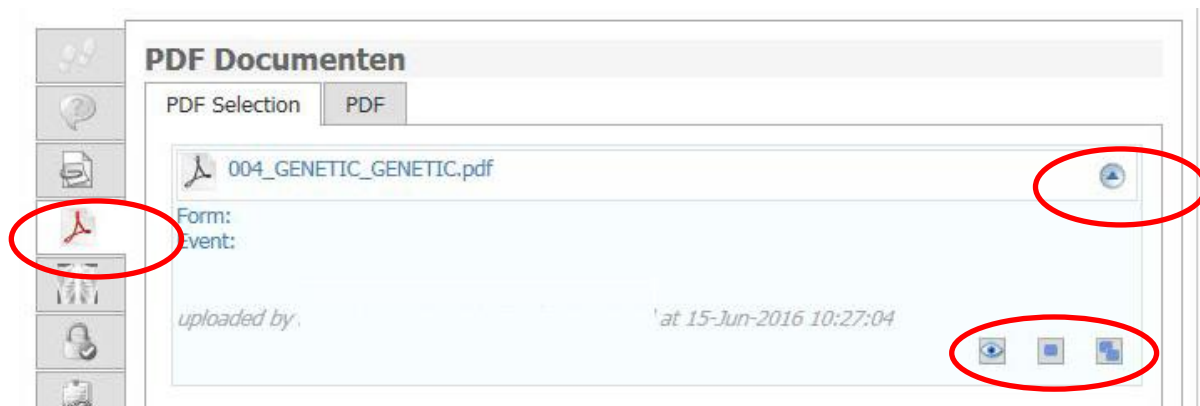
Please make sure to send in the karyograms simultaneously with submitting data in the e-CRF.

9. Review process

The central review of the genetic data will be performed by the cytogeneticists designated for the study.

They will receive an overview and karyograms from the HOVON Data Center (HDC) of patient data which can be reviewed.

The data can be reviewed in the database directly; using the corresponding karyogram if applicable.



After reviewing the data, the reviewer should complete the items on the e-CRF in the grey area:

REVIEW DATA	
Cytogenetic/genomic analysis reviewed	Select... ▼

First select an applicable option; only select the option 'no' if it was not possible to review the genetic data in the end. The option 'reviewed without karyograms' should only be selected if data of cytogenetic analysis have been reported but a karyogram was never provided.

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REVIEW DATA	
Cytogenetic/genomic analysis reviewed	yes
Reviewer	
Date review	03/11/2015
Questions	open question
Question and answer text (please include initials and date)	
Optional; enter your question here with initials and date (RH 03NOV2015)	
Changes made by reviewer	no
Comment of the reviewer	
Optional	

The items should be completed as shown above. If there are changes made by the reviewer in the genetic data items of the CRF (e.g. obvious errors or mistakes), please select 'yes' at 'Changes made by reviewer' and report the change in the text-field 'Comment of the reviewer'.

If there are remaining questions for the local cytogeneticist, the reviewer is able to type a question into the Questions-box. In response to the question, the cytogeneticist responsible for the applicable site can change data on the form if applicable and provide an answer in the Answers-box.

The reviewer reviews the answers and corrects the data if necessary.

If there are no (more) questions and the reviewed data is correct, the reviewer should submit and verify the form. Submitting is only possible if all discrepancies in the 'audit-trail' have been resolved, as described in 6.4-6.6.

After submitting the form should be verified by the following procedure:
Select the indicated tabs on the right window of the screen:

The screenshot displays the 'Genetic Analysis' form interface. On the left, the 'FISH ANALYSIS' section includes fields for 'FISH analysis done' (set to 'done'), 'Material' (set to 'BM'), 'Probe/Target' (set to '20q12'), 'Probe name/manufacturer/specification' (set to 'BBP'), 'Number analysed' (200), 'Percentage Normal' (77), 'Percentage Loss' (4), 'Percentage Gain' (6), and 'Percentage Translocation' (7). Below this is an 'Insert item' section with 'Metaphase FISH different from interphase FISH' set to 'no'. The 'ARRAY ANALYSIS' section includes 'Array analysis done' (set to 'done'), 'Array type' (set to 'eed'), and 'Material' (set to 'BM'). On the right, the 'Form locks and Sign Off' panel shows 'Lock status' and 'History' tabs, with buttons for 'Set verified' and 'Lock form'. The top right corner of the interface shows 'Form status: New form' and 'Lock status:'.

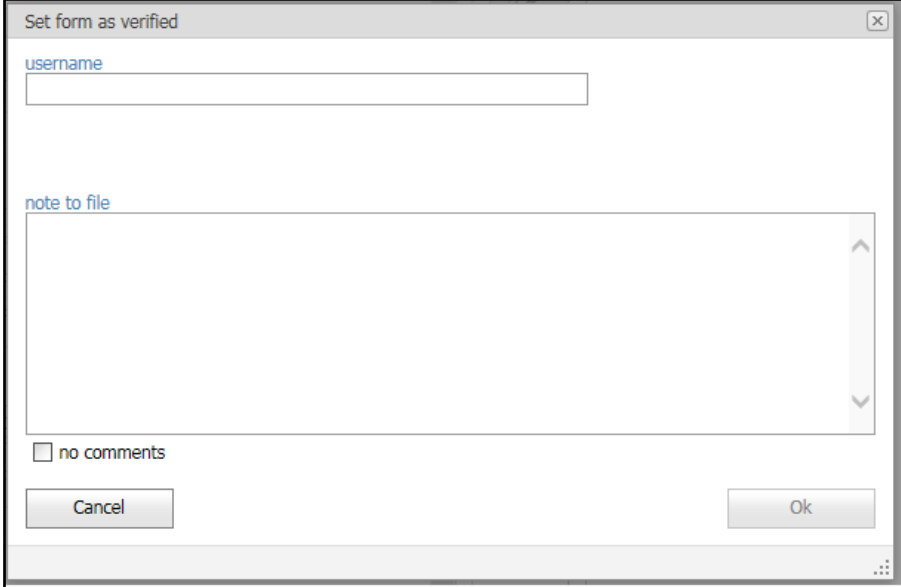
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Complete the pop-up window (enter comments or select no comments) and click Ok (twice):



The screenshot shows a dialog box titled "Set form as verified" with a close button (X) in the top right corner. Inside the dialog, there is a text input field labeled "username". Below it is a larger text area labeled "note to file" with a vertical scrollbar on the right side. At the bottom left, there is a checkbox labeled "no comments". At the bottom, there are two buttons: "Cancel" on the left and "Ok" on the right.

The status verified is a signal for the HDC that the review is completed. When the review is completed, the HDC closes the queries.

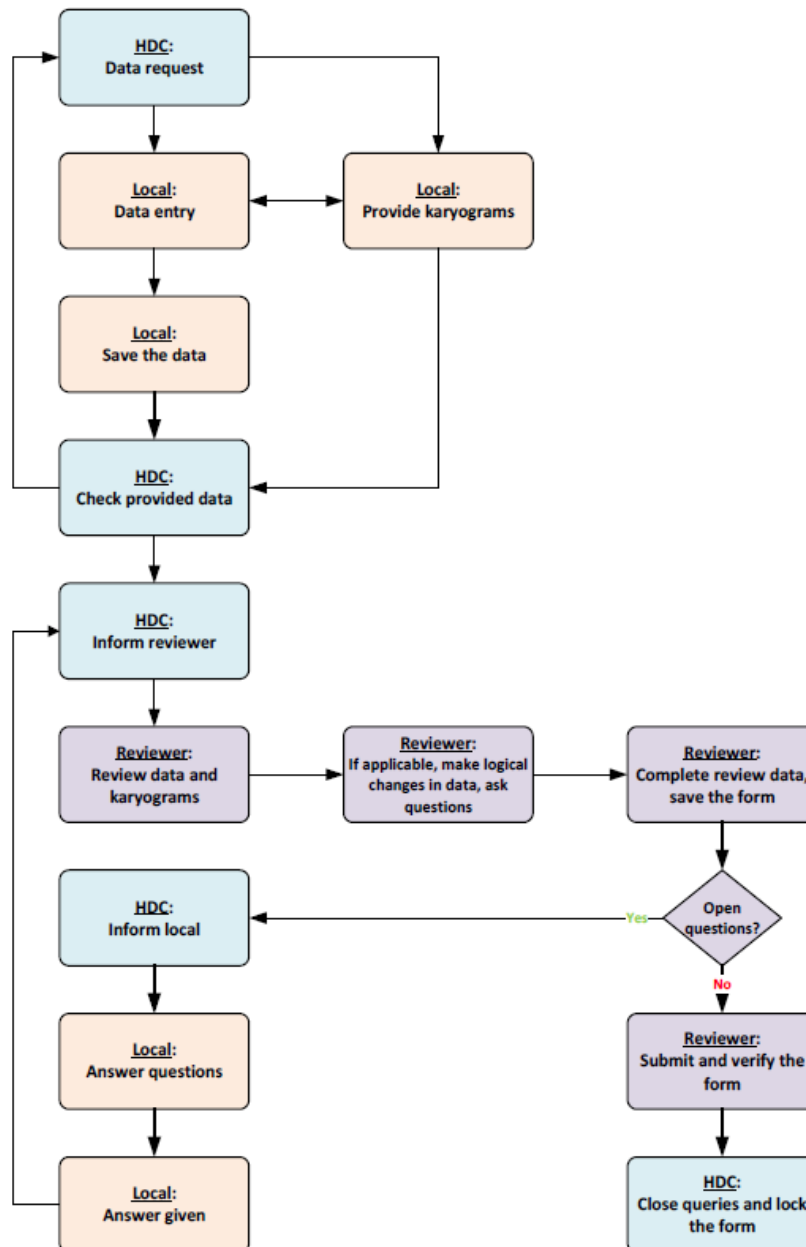
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HOVON workflow for cytogenetic data collection in ALEA



¹ Ask questions in the *Question and answers text box*; complete with name/initials and date

² The reviewer should only 'save' the form as long as there are questions, and submit the form if there are no more questions

³ Answer questions in the *Question and answers text box* (complete with name/initials and date)

⁴ Set item *Questions* to *Answer given* and save the form

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10. 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

11. Alea

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

12. 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

