secuTrial®

DATA ENTRY, SEARCH AND VALIDATION

INSTRUCTION MANUAL

VERSION 1.5 – JANUARY 2024

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*Note: For illustration purpose, whilst this manual remains generic, it may sometimes resort to form examples taken from a generic study other than the study you’re working on. In such cases, please consider the aim of the illustration rather than the exact example it displays.*
Introduction

secuTrial® is a Web-based clinical data management system fully compliant with ICH-GCP and FDA recommendations. The tool has been adopted by the majority of Swiss CTUs, including CRC/HUG (CTU of the Geneva University Hospitals) to manage clinical trials data.

The system is composed of several modules (FormBuilder, DataCapture, AdminTool, CustomerAdminTool, and the ExportSearchTool). The FormBuilder module allows the eCRF development. The DataCapture module is meant for electronic data capture and data validation, while the ExportSearchTool module is used to search and to export data. The administration modules allow the management of projects, patients, centers, study participants and the roles and permissions that are assigned to them.

To enter and validate data within the eCRF you are going to make use of the Data Capture module.

You may possibly be also involved in testing and validating the eCRF during its development phase.

Throughout the production phase, as an investigator (or a reviewer), you will access the data capture module to enter (or validate) data from the study into the electronic system.

! This document summarizes the different steps that investigators, monitors and any validator need to know in order to enter and validate data during the production phase and before the final data export and the database closure.

secuTrial® Platform at HUG -- https://secutrial.hcuge.ch/...
Web addresses (URL) to use during the trial

The links to our general secuTrial platform are the following

[Set-Up / Test Mode]

- Data Capture: Set-Up Mode (development and test mode)
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-setup-DataCapture.woa/

- Search and Export Data: Set-Up Mode (development and test mode)
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-setup-ExportSearchTool.woa/

[Production Mode]

- Data Capture: Production Mode
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-productive-DataCapture.woa/

- Search and Export Data: Production Mode
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-productive-ExportSearchTool.woa/

From any of these links, you will be invited to select the customer you are registered for.

Note: In some cases your browser may warn you - for security reasons - not to continue connecting to the secuTrial server. Since secuTrial is a highly secure system, please trust the certification and pursue your connection.
User-ID and password

The access to the data entry module is created by the Data Manager upon request by the Sponsor and/or the Principal Investigator. Accesses are strictly personal. To ensure security access is denied after four wrong attempts. In case of problem you should contact the CRC Data Manager at:

datamanager.crc@hcuge.ch

!!

Please, keep in mind that your secuTrial® account is strictly personnel and your access parameters must remain confidential.

In the production mode, you are responsible and accountable for any active or passive action performed in secuTrial® with your login parameters, as it is made under your name.

!!

At your first access, the system will ask you to change the password received from Data Manager with a new personal password.

1. 

2. 

3. 

4. 

You should choose a password with at least 7 characters plus at least 1 number, excluding passwords easily identifiable (such as your user ID or the study name). The system will require a new password change every 3 months.

If you happen to forget your password, you may simply click on the 'Forget password' button and you will receive an email to set up a new password. Failing to provide the right password several times will deactivate your account. In such case you will need to contact the data managers.

The system requires a 2-factors authentication mechanism. You will receive a code sent to your e-mail address that you will need to provide to secuTrial.
DataCapture Welcome page

The Welcome page (1)

You should NOT use your browser tool bar to navigate, to disconnect or for screen refreshing. Please use ONLY secuTrial options to navigate in the interface (Logout, Back, Cancel, etc…)

New Patient: create a new patient entry

Select: Direct access to a specific patient’s eCRF. Thanks to his add-ID.

This Welcome area contains important and most up-to-date information and documents, as well as many references to related resources.

You should make sure to read this section carefully.

Study specific documents for the user (in the Download area)

You should make sure to read these documents.
The Welcome page (2)

**Time left** before you are disconnected. After 20 minutes of inactivity the system will require you to login again. Be aware that if you are disconnected all non saved data are lost ➔ **save your data regularly!**

- **My account:** configure your account data (your e-mail, phone, address, preferred reports, language, etc.)
- **Reports:** enrolled patients list, progress of the forms and other data reports
- **Messages:** get to this area to access your messages. Message usually signal some specific events (e.g. patient inclusion, withdrawal, etc.) and serve as information exchange between participants.

Depending on the rights you are granted, and the project configuration, you may have access to other options on the upper-right menu, such as:

- **Mass action:** perform batch operations - such as reviewing and validating - per center, all visits, per visit, all forms, rather than form by form.
- **Import:** import data from external files rather than capturing it manually (the project must be properly configured to be able to deal with this option)
Creation of a new patient: New patient

Click on *New Patient* from the main screen (welcome page)

Select your project. Enter patient Add-ID.

![Screenshot of the user interface](image)

**Notice**

Add-ID: ET-GE-01

Patient and Visit plan have been added to the database successfully.

Click on *Continue*, the new patient’s Visit Plan with all the forms to be filled will appear.

Always use the Back option to go back to a previous page. Do not use your browser tool bar!
Changing the visits plan

*Please note:* Entry dates within the Visit Plan matrix are only indicative. The eCRF should usually contain appropriate fields within the forms to manually capture the date of visit.

The visits plan includes the forms for each of the study visits. The visit dates are calculated based on the study flow chart. The protocol allows some flexibility on visit dates, which can be modified in the following way:

**Information** regarding the project, the current patient, and your own role.

Click on *Edit Visit plan*.

The Visit Plan matrix
The new visits plan with the modified date will appear opposite to the old one. All the following visits will also be shifted to comply with the study visits interval described in the protocol. Depending on the situation it may be necessary to modify the following visits manually one by one.

Entry date can be altered, but it should comply to the pre-defined entry windows set up by the data managers (contact Data Manager). Empty visits can be deleted, as long as they never contained any data or a form that has been saved.
Data Entry

For every patient three tabs (or more) are available: the Visit Plan containing the majority of the forms, the Adverse Events containing the Adverse Event and Serious Adverse Events forms, and a tab or more for the patient file (e.g. patient inclusion, history, demography, withdrawal, etc.). Some studies may include an extra tab for images (e.g. radiography).

To start data entry, you generally will have to fill out some patient file forms (‘casenodes’: typically inclusion, randomization, demography, etc.). You may also start with the first form of the first visit, depending on how your project is configured. In our example, we start from a Visit form.
Help may be available for some items. Click on Help on the right, next to the question. You may also add any type of comments (free text) related to the question by clicking on Comment.

Enter data and click on Save when you are finished.

The Save + close entry button should be used only when the data have been checked and are considered complete (see below DEC status). This action is reversible as long as the form has not been reviewed by a monitor or a validator.

Continue data entry with the following forms.

Some coherence rules allow verification of data entry during the filling of the forms. The following examples show some of the rules used in this eCRF.
This field is mandatory. If the information is not available, it is possible anyway to save the form by un-checking the Check data box and clicking twice on the save button. The form will be marked as violating rules.

Other example of rule violation (conditional mandatory fields)

Rules have been forced three times as neither the birthdate, nor the questions on menopause and pregnancy have been filled. A red exclamation point shows that the form has been saved with forcing of the rules.

The form has been saved despite missing birth date: the icon is only partially colored.
**Missing values (MV)**

Optional (if configured for the project)

For all items configured with the function "Missing Values", a new icon is displayed next to the entry field (see below). Clicking on this icon opens the popup window for setting the "Missing Value" status.

When opening a form for the first time, all MV status are set by default to "Value exists". When editing the form, you can indicate that a field has been intentionally left empty by setting the MV status to "Value not collected". The following options are available:

When the form is saved, all items for which a value exists will automatically be set to "Value exists". For items without a value and the entry "Value exists" an error message will be displayed, stating that either a value must be entered or MV must be set to "Value not collected". This error message will be treated as a "hard" error message. Saving the form is then only possible by unchecking the "Check data" checkbox.

All items with the MV status set to "Value not collected" will be considered as complete for the purposes of determining the completion status.
Data Entry Complete (DEC) status

When all the questions in a form have been completed and data are considered complete and correct, the form can be saved and closed (signed) with the Save + close entry button (DEC status).

Once closed, the form will be read-only and can be queried and reviewed.

A green form denotes a Data Entry Complete (DEC) status. Data are not editable anymore.

This number does not exist for this patient but the form can be validated.

As long as data validation (reviewing) is not yet done, you can open again this form and modify it using the Reopen data entry button.

However as soon as a query has been made, or a validation status has been applied (source data verification, Review A, Review B), modifications will only be possible by answering reviewer queries, and on a question by question basis.
Creating additional visits

Si...

Create a new visit by clicking on Next visit.

Choose among the proposed visits the one to create.

Enter the date of the new visit and save.

The new visit will be fitted in the visits plan depending on its date and the date of the other planned visits.
Patient inclusion: freezing and freeing following forms

In general, if a patient is not included, his following forms will not be accessible for data entry.

In many studies, a detailed inclusion form must be initially filled out. Depending on how inclusion/exclusion criteria are defined, following forms may be frozen or freed. Freezing forms is in general reversible. Once all inclusion/exclusion conditions are met, following forms are free again for editing.

Example of an inclusion form:

Patient is pregnant or lactating. This is an exclusion criterion in this example.

Click on Save button, sign the form and go back to Visit Plan.
Withdrawal

If the patient withdraws from the study, you should be able to report the reason in an appropriate form that is specific to your study. In general, such action should prevent from adding any new visit to the visit plan.

No patient deletion is allowed. Only in some very specific cases (patient duplication, patient with no consent, patient wishing his data to be completely erased...) that a deletion may be considered. Deletion is decided between Sponsor, PI and Data Manager and is fully documented. Appropriate actions for deletion can then be taken by the data manager.
The Audit Trail (and SDV History)

The Audit Trail provides an overview of all changes that have been made and saved in the current form. It can be accessed after the form has been saved for the first time. To view the Audit Trail, click on the Audit Trail button from the main menu at the top right of the form.

SDV History provides a complete chronological report on how SDV validation has been performed on the form. To view the SDV History – if it is available - click on the SDV History button.

An Audit Trail report

Audit Trail & SDV History
Access to patient list and other reports

From the welcome page…

On the welcome page of secuTrial, click on the **Reports** tab

The different reports are listed and are accessible by clicking on their links. A list of patient is almost always present: **Overview patients and forms**. This list displays all visits for all patients.

You can access to a patient eCRF by clicking on his/her **Add-ID**
Search patients by criteria

The Search (Export & Search) module is accessible from the following address:

- Search and Export Data: **Set-Up Mode** (development and test mode)
  
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-setup-ExportSearchTool.woa/

- Search and Export Data: **Production Mode**
  
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-productive-ExportSearchTool.woa/

In order to be familiar with the search interface, please, make sure read the search section of the following document:

https://secutrial.hcuge.ch/crc/docs/sT-Manuel-ExportSearchTool-EN.pdf

Two steps are involved when searching for patients:

1) **Create a search form / specify the search criteria:**

   The forms displayed in DataCapture form the basis for the search. The questions that are relevant for the search are determined from the forms. The search forms are always automatically saved and then further parameters can be added.

2) **Specify search parameters:**

   In the prepared search forms parameters can be entered and a concrete search request can then be sent to the database. After the secuTrial® database has been searched, a list of all patients corresponding to the specified criteria will be provided.

   The results of a search in secuTrial® database is always a list with patients. It is possible to export all the data for patients or only the list itself.

   All search functions can only be conducted within a project. You need to select a project in order to access the search area of the ExportSearchTool.

   In the search area of ExportSearchTool you can:
   - create new search forms
   - use previously created search forms for new searches
   - copy previously created search forms
   - delete search forms you have created
   - initiate and use all of the functions in the header menu (e.g. also a direct export without filtering)

   The Search functionalities can also be accessed from the DataCapture interface (see ‘Advanced Search’ on the hope page right menu). Construction of queries is similar to the Search module.
The Deviation module

Within the DataCapture module, and if the project is configured to report and manage deviations, a deviation module lets you declare, assess, and confirm any type of deviations. Special permissions are needed to use this module.

If you are interested in activating the deviation module, please contact our data management team.
Reviewing Data

secuTrial offers various ways to support the data management workflow which is typical in medical studies. This includes locking patient data after data entry has been completed (DEC) and enabling various reviews to check the data before releasing it for further processing.

Pre-reviews include SDV (source data verification status).

The first review can be performed with the REVIEW A for each individual form or for an entire visit. The review can be revoked with the REVOKE REVIEW A. Typically, monitoring actions are performed using Review A.

A second review can be performed with the REVIEW B for each individual form or for all forms belonging to the patient. A review B can be revoked only by generating a query. Typically, final review actions are performed using Review B by the sponsor or his delegate. Depending on your validation requirements, you may opt to perform or not Review B actions.

The final locking of a form is performed using a FREEZE for each individual form or for each visit on the Visit Plan. Afterwards it is no longer possible to perform reviews and/or create queries.

As a rule, the prerequisite for manual locking is that the form (or forms of a visit) has already undergone a Review A and/or a Review B.

If only a Review A is the prerequisite: manually locking the patient’s file also locks all forms with open queries.

Under certain conditions forms can also be locked automatically, for example if it has been declared in a withdrawal form that the patient no longer wishes to participate in the study.

In all cases, mass actions can be associated with all of these processes, as long as the project is configured to carry on mass actions (cf. below).
Reviewing: data source verification (SDV)

Green forms are those signed by the investigator as complete and correct (DEC status). To apply the DEC status, the investigator must sign the form using the ‘close entry’ button. The monitor or the validator can therefore start to verify the most important information and the source documents related to this form. secuTrial allows pointing out in the eCRF if source data have been monitored (as long as the project is configured to allow for data source verification).
Reviewing: monitor/validator’s Query to investigators?

When the monitor or any validator checks source data or any another information on the eCRF, he/she can generate queries (questions) for the investigator regarding any item on any form.

By clicking on the **Query** button, the monitor can generate a query (question) for the investigator. He/she can sign and save the query by clicking the **Sign + save** button.

A question mark appears on the form icon, as well as on data for which the query has been generated.
Issuing a global query over the entire form

It is also possible, and sometime necessary, to extend a query to the whole form. To perform this global query operation, click on ‘Queries’ within the closed form (top bar menu at the right side) and choose ‘New form query’.

Reviewing: investigator responding to the monitor/validator query!

At next connection, the investigator will see in the patient list (Overview patients) that some queries are posted (the question mark). He/she has access to the patient eCRF by clicking on the Add-ID.

In the Visit Plan the investigator can access to the form of interest.

He/she can then modify the entry, pointing out the reason for changing and save this change by clicking on Sign + save modification. In this case, answers to the monitor are automatic (Query automatically answered because of value change with reason: "Le dosage était incorrect") and the question mark is replaced with an exclamation mark.

Version 1.5 – 19.01.2024

Last update: K Mostaguir
Even if a change of entry is not necessary the investigator should still answer to the query (i.e. explaining why no change is made).

The investigator answers to the query, signs and saves by clicking on the **Sign + save**

Weather the investigator changed the entry or only answered without data change, the icon in the form and next to the item changes from a question mark to an exclamation mark !
**Statine interruption**

**Confirmation of Virological status / HIV RNA < 50 copies/ml**

<table>
<thead>
<tr>
<th>Statine</th>
<th>Name</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>amlostatine</td>
<td>30 mg</td>
</tr>
</tbody>
</table>

If HIV RNA < 50 copies/ml since > 3 months, and all screening inclusion criteria were answered - YES -

**PROCEED TO STATINE INTERRUPTION TODAY**
**Reviewing: the monitor/validator closes the Query**

The monitor can either close the query (**resolve query**), or re-open it (**reopen query**) while notifying the reason in the text area. In both cases he/she should sign and save (**Sign + save**).

If the monitor has closed the query, the query icon presented with an exclamation mark (!) is replaced by the icon OK. If he/she has re-opened the query the icon will switch back to a question mark.
Reviewing: the monitor/validator applies the Reviewed status

Review A or B:

<Reminder>
The first review can be performed with the REVIEW A for each individual form or for an entire visit. The review can be revoked with the REVOKE REVIEW A. Typically, monitoring actions are performed using Review A.

A second review can be performed with the REVIEW B for each individual form or for all forms belonging to the patient. A review B can be revoked by generating a query. Typically, final review actions are performed using Review B (sponsor or sponsor delegate).

When the monitor or a validator has finished the validation of a form (verification of all source data and closure of any pending query) he/she can apply the review A or B status.
Reviewing: practical notes on closing and reopening forms

When a form has been closed (DEC: ‘close entry’) no data can be directly modified, unless the form is reopened (‘reopen data entry’), or by answering queries. Validation on a closed form include source data verification (SDV), issuing queries and applying review status (Review A/B).

Closed forms (DEC) without Review A/B and no SDV applied

- Data cannot be modified and no repetition block may be added (unless explicitly configured to accept additional repetition blocks).
- The form can be re-opened for modifications, unless it contains a query, a reported SDV, or if it has been Reviewed A/B.
- If a query is issued, an investigator is able to only modify the queried question.
- Issuing a form query (a query over the entire form) gives the possibility to modify any value in the form.
- If the form contains a repetition group, and that this group has been configured by the data managers to allow the addition of more groups, then the investigator is able to add additional repetition groups to the closed form.

Closed forms without Review A/B

- An investigator (without revoking right for Review A) cannot reopen the form.
- A revoke Review A switches the form back to the closed form status (DEC), see above.
- Investigators are able to answer any open query and modify their content (answer query). With form level queries, the entire form can be modified.
- Answering queries and modifying data cancel any Review A/B status.
• If a query has been issued (even if resolved), it is **no longer possible to reopen the form.** Any modificatoin will require to issue new queries.

**Closed forms with SDV**

• As long as there is an item with a reported **SDV** status the form cannot be reopened anymore.
• It is possible to **reinitialise** all SDV status (setting all SDV status to ‘not done’) and therefore allow the reopening of the form (as long as it doesn’t contain any query, and doesn’t hold a Reviewd status).
• If the form contains a **repetition group**, and that this group has been configured by the data managers to allow the addition of more groups, then the investigator is able to add additional reptition groups to the closed form. This doesn’t affect the already reported SDV.
• Investigators are able to answer any open query and **modify** their content (answer query).
• Any modified item loses his SDV status. Inchanged items keeps their SDV status.
• If a query has been issued (even if resolved), it is no longer possible to reopen the form. Any modificatoin will require to issue new queries.

**Mass action**

To carry out simplified monitoring/validation actions, **Mass Action** role right may be granted. This right is assigned to some specific participants. The actions which can be performed are determined by additional role rights for **Review A**, **Revoke Review A**, **Review B**, **Freeze forms** and **Revalidation**.

If the participant has the right to perform mass actions, the link for carrying out these mass actions is displayed on the **Welcome page**.

**Revalidation**

A revalidation can be carried out for an individual form or as a mass action.

A revalidation conducts the same data validation evaluation which is carried out with a normal data entry by checking the existing rules and form actions. The purpose of the revalidation is to provide a facility for checking the data, even if there is no data editing option.

In an individual form, the revalidation cannot be conducted if the participant has also the right to edit data. In such case the validation will be carried out regardlessly when the form is saved.

The following conditions to perform a revalidation are required:

• Form revalidation right
Individual form: no possibility to edit the data
No form freeze
The patient is not frozen for editing or is not in a ‘deceased’ status

During a revalidation, the results of the rule evaluation are checked as follows:

- Changes in score items
- Changes in form completion status and error/warning status
- Changes in the validation report

The possible effects of a revalidation are as follows:

- Saving the form with (score) value changes and/or changed completion status
- Resetting review A and B
- Resetting the SDV status (only if necessary)
- Updating the validation report
- Sending form and rule messages
- Freezing or unfreezing follow-up forms
- Setting the patient status
- Setting the AE status (opening or closing AE)
- Answering queries

Withdrawing reviews:

If a revalidation has been carried out, any reviews that have been performed will be reset. As a revalidation changes the form value, the form status or the error messages, a new form validation is recommended.

SDV:

If in a score item the item value has been changed by the revalidation, and if SDV had already been conducted, the SDV status will be reset (if applicable).

Query answering:

If there was an open query, and if automatic query answering has been configured, the revalidation will also trigger a query automatic answer (providing the participant has answering rights for the form).

Simplified monitoring Review A actions / sponsor validation Review B actions (optional)

If particular role rights are granted, the participant may be given a Mass Action menu option on the Welcome page. This action can be launched to start simplified monitoring actions.
Here, participants can make a selection from all projects, centers, forms and actions for which they have the corresponding action rights as well as the right to perform mass actions. The following actions can be carried out as a mass action:

- **Review A**
- **Revoke review A**
- **Review B**
- **Freeze forms**
- **Form revalidation**

For all actions, except for revoking review A, it is possible to select whether unsaved forms should also be edited.

After selecting the action, click on the **Analyse** button to launch the action. During the analysis a progress bar will be displayed. After completion of the analysis, an overview page will be displayed listing all editable and non-editable patients and forms. The details of the list can be viewed down to the individual form level. This list can be downloaded as an Excel file. Only patients and forms which can be edited will be used when carrying out the selected action.
Example of the preliminary results of the analysis with a list of editable and non-editable forms.

By clicking on the **Save REVIEW A** button (labeled with the corresponding action) the action will be carried out and saved. In addition, the result list will be initially displayed listing all patients and forms that can be processed.
After the action has been completed, the progress bar will disappear and the buttons will be displayed. The result of the entire action displays the number of successfully processed forms (=OK) and the number of forms which could not be edited. No distinction is made between previously saved forms and unsaved forms. Details of individual form can be viewed by cascading the result list. The final result list can also be downloaded as an Excel file.

By conducting a revalidation, the results are even more precisely differentiated:

- **OK**
- **OK (with rule violations)**
- **No action**
- **Invalid preconditions**
- **Error**

**OK (with rule violations):** If error or warning messages occur during a revalidation, the form will still be saved and given the status 'with errors' or 'with warnings'. In this case, the mass action behaves as if the participant has deselected the 'Check data' checkbox in the individual form.

**No action:** If the revalidation did not result in any changes (see above section on revalidation), the revalidation will likewise not be saved in the mass action.

**Invalid preconditions:** As the revalidation of a form can have an effect on other forms via rules (e.g. changed form preconditions, frozen forms), before performing a revalidation the form preconditions for each individual form are checked again. If not fulfilled (or no longer fulfilled), the form will not be edited any further and will be marked as such.
Example of a revalidation results page

**The Validation Report**

The report is displayed page by page and each error message is listed in a separate row. The following information can be displayed. The display can be selected via the options at the top of the page:

- **Patient** *(pseudonym by project configuration and role rights)*
- **Centre**
- **Visit / AE** *(visit or adverse event label)*
- **Form**
- **Table**
- **Completion status**
- **Form status** *(review, freeze)*
- **Date** *(of the error message)*
- **Version** *(of the project at the time of validation)*
- **Item**
- Column
- Query status (of the validation message item)
- Value (of the item)
- Message
- Rule (brief description at the time of validation)
- Type (type of error message, for example rule error, rule confirmation)

The report can be sorted and filtered by a large part of the displayed criteria. The selected method of sorting is indicated by a small arrow next to column name. The report can be downloaded as an Excel file.

Example of a validation report.

The form overview of the listed patients can be accessed via the patient details (pseudonym, centre). The corresponding form can be directly accessed via the details for each validation message (e.g. form, message).

Up-to-date status

The validation report lists the validation messages saved in the database which were valid when the form was saved. If the data validation has changed since then, either because of changes to the rule definition in a form or because a value has been changed in another form which was used as a value threshold in a rule check, the validation report may not display the current data validation status. If relevant changes are made to the rule definitions, it is advisable to update the validation report via a mass action revalidation of the project.
The Patient File

Investigators or Monitors can export patients’ entire eCRF as an HTML file. The Patient File is located on the upper right menu bar from the patient Visit Plan.

Patient files are an extended form of documentation in which all of the forms of one or more patients can be downloaded as an HTML file and then printed out. The difference compared to the normal printing function lies in the data configuration options. Whereas the print function always prints exactly one form, the patient file function can be used for example to download all forms of all of the patients in a centre for printing.

Data export

Data are exported using the ExportSearchTool. Data validation is usually required beforehand. Data validation in secuTrial follows the « Review A » (clinical data review) and/or the « Review B » (global data review) processes.

Exports, which are highly configurable, include all eCRF data, as well as all meta-data, project configuration, participants’ roles, centers, audit trails, comments, queries, etc. Responsibility for data export are shared between the Sponsor (or his delegates) and the Data Manager.

Interim data exports may be performed, as long as they are defined and scheduled in the protocol.

The Export (Export & Search) module is accessible from the following address (only if you have the permission for):

- Search and Export Data: Set-Up Mode (development and test mode)
  
  https://secutrial.hcuge.ch/apps/WebObjects/ST21-setup-ExportSearchTool.woa/
Search and Export Data: **Production Mode**


In order to be familiar with the export interface, please, make sure read the *export* section of the following document:


**Data Import**

Some projects may be configured for batch data import. Data can therefore be imported from external files directly into the system. The process of importing data is described in a separate document:

[https://secutrial.hcuge.ch/crc/docs/secuTrial-DataImport.pdf](https://secutrial.hcuge.ch/crc/docs/secuTrial-DataImport.pdf)

**Closing the project**

Please, refer to the following instructions (French, under the secuTrial sectoin):

[https://redcap-crc.hug.ch/public/docs/REDCap_InstructionsClotureArchivage.pdf](https://redcap-crc.hug.ch/public/docs/REDCap_InstructionsClotureArchivage.pdf)
Additional resources and contact

secuTrial resources and links at CRC: https://secutrial.hcuge.ch/

Centre de recherche clinique HUG / UniGE: https://www.hug.ch/crc

Data Management at CRC: https://www.hug.ch/centre-recherche-clinique/data-management

Contact: Datamanager.CRC@hcuge.ch
## Annex I: Form Overview

### Form Overview

<table>
<thead>
<tr>
<th>Icon</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Icon]</td>
<td>without d-table</td>
<td>These forms will not be stored in the database.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>not stored</td>
<td>No data has been entered yet.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>empty</td>
<td>The form has been saved empty. In the form family at least one form has been stored empty.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>partially filled</td>
<td>At least some data has been entered but not all mandatory fields have been filled.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>completely filled</td>
<td>All mandatory fields have been filled.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>data entry complete</td>
<td>The data entry is finished. This status does not display the underlying completion status.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Color</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Icon]</td>
<td>standard form</td>
<td>Used for the capture of normal data.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>Adverse Event form</td>
<td>For capturing data during the workflow of Adverse Events.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>Serious Adverse Event form</td>
<td>For capturing data during the handling of Serious Adverse Events.</td>
</tr>
</tbody>
</table>

### Symbol

<table>
<thead>
<tr>
<th>Icon</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Icon]</td>
<td>validation</td>
<td>The rule validation of this forms finished with problems (warning, error).</td>
</tr>
<tr>
<td>![Icon]</td>
<td>comment</td>
<td>At least one comment has been posted.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>open query</td>
<td>At least one query is open.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>answered query</td>
<td>All queries in this form are answered.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>resolved query</td>
<td>All queries have been resolved.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>reviewed data</td>
<td>The form has been reviewed, all queries are answered (review A, review B, both).</td>
</tr>
<tr>
<td>![Icon]</td>
<td>partly review</td>
<td>In a form family only a part of the forms has been given the status review A (upper flag) or B (lower flag). If all included forms had been reviewed, the flag becomes green (last example, upper flag)</td>
</tr>
<tr>
<td>![Icon]</td>
<td>manually frozen</td>
<td>All editing and examination has been finished. No further processing allowed.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>frozen</td>
<td>The form is not longer editable (freezed by system).</td>
</tr>
<tr>
<td>![Icon]</td>
<td>patient uneditable</td>
<td>The patient is not longer editable (frozen, deceased). In deceased patients new adverse events can still be created and edited.</td>
</tr>
</tbody>
</table>
| ![Icon] | opened formfamily | If the formfamily has been opened the included forms are
<table>
<thead>
<tr>
<th>SDV</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not done</td>
<td>No verification has been made on this item or form. (single or resulting status)</td>
</tr>
<tr>
<td></td>
<td>in progress</td>
<td>Some items have yet not been verified or are deferred. So the verification is still in progress. (resulting status)</td>
</tr>
<tr>
<td></td>
<td>deferred</td>
<td>A final verification is not possible at the moment. Perhaps a difference has been noticed which must be cleared. (single status)</td>
</tr>
<tr>
<td></td>
<td>not possible</td>
<td>The original data has gone lost or a difference could not be cleared. So a verification could not be done. (single status)</td>
</tr>
<tr>
<td></td>
<td>verified with error</td>
<td>SDV has been made but for at least one item it was impossible. (resulting status)</td>
</tr>
<tr>
<td></td>
<td>not necessary</td>
<td>A verification of this item or form is not necessary, e.g. when the SDV is only tested at random. (single or resulting status)</td>
</tr>
<tr>
<td></td>
<td>verified</td>
<td>The verification has been finalized and there were no differences. The resulting status could include some items where the verification was not necessary. (single or resulting status)</td>
</tr>
</tbody>
</table>