



# Product Description I Terms

**secuTrial<sup>®</sup>**

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## 1. Introduction

- This manual explains the terms and definitions that are used within all secuTrial® tools and in the individual manuals.

**Since 5.0** In the current version the following new term has been introduced:

- Metadaten

### Purpose of secuTrial®

- secuTrial® is used for conducting clinical and observational studies in multiple centres. secuTrial® enables the direct, decentralised and electronic entering of study data (remote data entry) into a central database.

### Software structure

- secuTrial® is an application server software suite that consists of 5 individual tools. Data is entered and edited over the internet with a standard browser. It is not necessary for users to install a separate application on client computers.
- Access to all of the tools is controlled via a secure login page by entering a user name and password. There are three different user groups that have access to the tools. Access to these tools is governed by an internal rights system.

### Function area Tools

- There are 5 different tools, each with a separate URL and login check
  - **CustomerAdminTool** (*only setup*)  
Function: management of customers and administrators, creating project schemes (database (DB) areas), generating statistics, bundled message dispatch, file system checks (orphaned images, temporary files), archiving and deleting, DB documentation  
Login check: user in password file
  - **FormBuilder** (*only setup*)  
Function: creating and configuring projects, creating forms, project version control, internal DB adjustments  
Login check: participant in the AdminTool with management of participants and patients
  - **AdminTool** (*setup and productive*)  
Function: participant and patient management, roles and rights management, design customization. Customer-specific user interface  
Login check: administrator in the CustomerAdminTool
  - **DataCapture** (*setup and productive*)  
Function: entering patients, data capture, data overview (reports and statistics), query management, importing data  
Login check: participant or patient (only if patient self-documentation is used) in the AdminTool
  - **ExportSearchTool** (*setup and productive*)  
Function: searching for patients, exporting data  
Login check: participant in the AdminTool

### Installation and URLs

- Two separate areas fundamentally exist: "*setup*" and "*productive*". Each has its own tool sets and URLs. This enables data entry to be kept separate from the management of the test area and productive area. In the standard design the test area ("*setup*") can be identified by a green secuTrial® logo.

- To enable each customer (see: *Customer*) to have their own login page (which can be adjusted in design), the customer identifier must be included in the URL. The following example is for "K1". The part "(HOST)" is to be replaced by the URL of the application server. The identifier "ST21" can be replaced by a unique installation identifier. The tools for managing customers and projects are only installed once; those for participant management, data capture and data export are installed in both areas.
  
- "setup":
  - (HOST)/cgi-bin/WebObjects/ST21-setup-CustomerAdminTool.woa
  - (HOST)/cgi-bin/WebObjects/ST21-setup-FormBuilder.woa/wa/choose?customer=K1
  - (HOST)/cgi-bin/WebObjects/ST21-setup-AdminTool.woa/wa/choose?customer=K1
  - *Login participants:*  
(HOST)/cgi-bin/WebObjects/ST21-setup-DataCapture.woa/wa/choose?customer=K1
  - *Login patients (PSD):*  
(HOST)/cgi-bin/WebObjects/ST21-setup-DataCapture.woa/wa/pat?customer=K1
  - (HOST)/cgi-bin/WebObjects/ST21-setup-ExportSearchTool.woa/wa/choose?customer=K1
  
- "productive":
  - (HOST)/cgi-bin/WebObjects/ST21-productive-AdminTool.woa/wa/choose?customer=K1
  - *Login participants:*  
(HOST)/cgi-bin/WebObjects/ST21-productive-DataCapture.woa/wa/choose?customer=K1
  - *Login Patients (PSD):*  
(HOST)/cgi-bin/WebObjects/ST21-productive-DataCapture.woa/wa/pat?customer=K1
  - (HOST)/cgi-bin/WebObjects/ST21-productive-ExportSearchTool.woa/wa/choose?customer=K1

## 2. Specification of terms in secuTrial®

### Customer

- In the secuTrial® installation, separate areas can be set up for customers to enable separate logins, layouts, languages, participant management and editing of projects. secuTrial® can therefore be used as a real ASP solution.
- Customers are identified by a unique customer identifier and the customer management is conducted in a separate tool (see Function area Tools ).

### Customer / schema status

- The status of schemata and customers is displayed in the CustomerAdminTool using small icons. For schema-based projects the inactivation will only be displayed in the AdminTool and FormBuilder.
  - ❓ The customer / schema has been created. The schema is not being used for a project yet.
  - ⏸ The customer / schema has just been activated, the activation will become valid after the next restart / login. Or: the schema is active but the corresponding customer is inactive.
  - ✅ The customer / schema is active.
  - ❌ The customer / schema is inactive.
  - 🔒 The (setup and productive) project for a schema is locked. This status is only displayed in the project listings in the background area.

### Archiving history

- The inactivation, archiving and deletion of customers and (project-) schemes will be logged in the CustomerAdminTool in a separate history. The status of every action is displayed with an icon.
  - 🔄 The action (archiving / deletion) is just running in the background.
  - ✅ The archiving has finished successfully, after the next restart the archive will become valid.
  - ✅ The action (inactivation / activation / archiving / deletion) is valid.
  - ❌ The archive has become invalid due to reactivation.
  - ❌ The archiving / deletion has finished with errors.

### User

- An operator of the CustomerAdminTool is called a "user". The login check is conducted by means of a password file which is managed on the server by the secuTrial® system administrators.
- The CustomerAdminTool user manages the administrators (see: Administrator). The user can create new customers (and can also create the management scheme in the database) or centrally deactivate customers. In preparation for creating a new project, the user can create a new DB scheme.
- A user can also initialize, archive or delete project or customer archives, download the general database documentation or request a complete restart of the secuTrial® tool suite.

### Administrator

- An administrator is the person responsible for operating the AdminTool and therefore for the participants and the management of rights. The administrators are managed in the CustomerAdminTool.

- The administrators can have different rights to manage either the normal participant and role administration or the handle the randomization related informations.
- Administrators can be responsible for one database area or for both database areas (setup/productive).

## Participant

- Participants are people who participate actively or passively in gathering medical data. Their personal data and passwords are saved in the database. Participants have access to DataCapture and, depending on their role, also to the ExportSearchTool and the FormBuilder. The precise rights are defined their via roles and through their assignment to centres and projects.
- Each participant can be assigned to multiple centres (also from various projects) or to a single project. For this assignment, the participant is given a role which will define the participant's rights. If a person is to be assigned to multiple projects, a participant must be created for this person for each project. Participants can otherwise also be assigned to the different centres of the various projects.
- In the FormBuilder, projects are only displayed for participants who have the right to edit the project setup. This also applies to the copying of forms across projects. Only participants with the participant right *"May create and edit projects"* can create new projects. Irrespective of their role rights, these participants are also permitted to edit all of the projects for a given customer.

## Participant role

- A specific role is defined for every participant in DataCapture, the FormBuilder and the ExportSearchTool. These roles can vary for each centre. The rights for entering and exporting data as well as functions such as reviews and queries are controlled by assigning roles. The assignment of roles and rights is defined and assigned by the administrator in the AdminTool.
- When a patient (and thus the centre) is selected in DataCapture, this determines the role and the rights of the participant. If a participant is assigned to a project, that participant will always have this assigned role. The same role can be assigned in a centre or a project. The assigned role will be displayed to the participant as soon as a centre or a project has been defined. This defines the participant's access to data and the available functions. The role name should represent a summary of the rights. It has no significance with regard to content.
- Roles in the FormBuilder and ExportSearchTool are only differentiated by *"authorised to login"* or *"is not authorised to login"*. A more detailed division of functions exists only in the ExportSearchTool in the areas "Search" and "Export".

## Rights

- Rights define which (permanently implemented) functions can be conducted in DataCapture. Almost any combination of rights for a role is possible and results from the project workflow requirements. Role rights are divided into two groups: general rights and form rights.
- The monitoring rights Review A, Review B, Freeze and SDV can either be assigned as general rights as well as a form related right for a single form. If one of these rights has been assigned as a general right, it applies for all forms the role has access to, even if the respective form right hasn't been assigned.

### General rights

- Create new patients and enter patients into a (part) project
- Send messages
- Read messages

- Freeze visits and forms
- Set forms or all forms of a visit as “reviewed” (Review A) and revoke a Review A
- Set forms or all of the forms in a casenode as “reviewed” (Review B)
- Conduct a Source Data Verification (SDV)
- Use the Discrepancies Transfer Module (DTM)
- Editing visits
- View pseudonyms
- Edit project setups
- Release projects
- Perform searches
- Conduct exports
- Unblind randomization during export
- Delete exports

#### Form rights

- Display forms in the form overview
  - Show and read forms
  - Enter form data (with workflow DEC)
  - Edit form data (with workflow DEC)
  - Close data entry (with workflow DEC)
  - Revalidation
  - DDE 1 (with workflow DDE)
  - DDE 2 (with workflow DDE)
  - Ask a query
  - Answer a query
  - Close a query
  - Write a comment
  - Set Review A
  - Revoke Review A
  - Set Review B
  - Freeze
  - Enter Source Data Verification (SDV)
- In addition to the form rights which must be explicitly assigned for a project setup, the access rights must be assigned for all other resources defined in a project setup. These include automatic form-based messages, reports and statistics.

#### Participant rights

- In special cases just one participant per customer can be assigned the bundled participant right “*May create and edit projects*”. Even without a role, this participant has the facility to create a new project. All currently existing projects can also be edited by this participant without any further role checking. This participant is highlighted in the participant overview (**Last name, First name \*** ).

**Explanation:** The right to edit or create a new project cannot be directly (or indirectly through a centre) assigned via a role assignment if the project does not yet exist!

### Patient role

- If Patient Reported Outcome has been activated for a project, patient roles can be configured in the AdminTool. Due to the fact that a patient only has access to DataCapture, only the rights for entering data can be defined.

### General rights

- Create visits
- Pseudonym display

### Form rights

- Display the form in the form overview
- Open and read form
- Enter form data (with workflow DEC)
- Edit form data (with workflow DEC)
- Close data entry (with workflow DEC)

### Project

- A project represents a content-based study, i.e. the collection of patient data on a particular topic. Multiple centres can take part in a project. For this reason, a project is the highest administrative unit for centres and the highest hierarchy level for form descriptions (see: Form). The medical data of a project is saved in a separate DB scheme.
- There are two subgroups for projects: **"registry"** and **"part projects"**. The difference relates to the way in which patients are added to the project:
  - In a **registry**, patients are newly created and the new patient form (paper or PID Dispatcher) is filled out. A new pseudonym will be generated and assigned.
  - In a **part project**, only previously created patients are adopted from a registry. This is done by entering the previously assigned pseudonym. A new casenode will then be created for these patients in the part project only (see: "Casenode" = patient in a project).
- In the customer area, multiple registries and multiple part projects can exist and each pseudonym only occurs once. Each patient can only exist in one registry, but can participate in as many part projects as required. In each project the patient has their own casenode. Patients in a part project can originate from different registries.
- There are four different project versions:
 

1. Development version (currently being developed)	("Development")
2. Released development version before the productive mode	("Released")
3. Productive version	("Productive")
4. Archive version	("Archive")
- The different versions of a project can be viewed in the FormBuilder. In the test area ("*setup*"), the development version and the released development version can be worked on. In the productive area ("*productive*"), the productive version can be worked on. The FormBuilder only lists projects to which the current participant has editing rights.
- This procedure guarantees that the productive data entry takes place with a precisely defined and documented version. When releasing a development version in the FormBuilder to be transferred to

the productive version, the reason for release and the participant performing this procedure are recorded.

- When entering data in DataCapture, the version label that applies at the time of saving is also saved. This makes it possible to tell whether the value for an item was knowingly released by the participant or whether the item did not actually exist at the time. An example of such a situation is when a form item is subsequently extended.

### Schema

- A schema is a database area in Oracle, which belongs to a database user. Once created schemas can not be renamed.
- In secuTrial® a database schema is used for each project (actually two schemas, because a separate schema is created for the test area). The schema is created in the CustomerAdminTool.
- The schema is referred to with a name tag of at maximum 5 letters or digits. This name tag is then a name part in all tables of the project.
- Also for the participant management of the customers respective one schema is created for the setup area and one for the productive area. The entered name tag is then a name part of the schema for the participant management.

### Centre

- Participants who are working together on a study are summarized in a centre. Every centre is assigned to just one project. Once created, this assignment can no longer be changed.
- All patients are assigned to centres, which form the administrative units for patients. Each participant has just one role in a centre and therefore has the same set of rights for all of the patients in this centre. All participants (of the same role) of a centre have the same access rights to all of the patients in that centre. In order to add patients to a project, at least one centre must be created within this project.
- There are study centres and administrative centres. Patients who are assigned to administrative centres will not be taken into account in reports or statistics. This setting can be subsequently modified.

### Location

- Locations are actual places, in other words the addresses of hospitals, universities or medical practices together with additional information. Both centres and participants can be assigned to locations. Multiple participants and centres can be assigned to the same location.
- In secuTrial® locations do not have any structural importance beyond this.

### Country

- Countries can be included as additional information for centres and participants. A number of European countries are created by default for every customer. These can be edited or deleted at any time. As an alternative, countries can also be used for managing areas of responsibility.
- If a project has been configured as "*international*", the country will be displayed in the status information in DataCapture.
- Statistics can be created according to country. Only the patient data of the centres which have configured the same countries will then be taken into account. In this case a country should be entered for every centre.

## Patient

- A patient is a natural person in secuTrial® who has been entered into one or more projects. Every patient is initially entered into an administrative scheme with a pseudonym and an assignment to a centre. A patient is always created with a casenode simultaneously (see: "Casenode" = patient in a project).
- Only the medical data of a patient is saved in secuTrial®. The personal information and identifying data which is entered upon registration (e.g. name, date of birth, address) is not passed on to the secuTrial® server.
- A patient can be assigned up to three pseudonyms:
  - Pat-ID: this pseudonym is automatically generated when a new patient is created. It consists of a combination of three letters followed by three numbers. In the FormBuilder you can set whether the Pat-ID should be generally displayed in DataCapture. In the AdminTool a role-specific display can be optionally selected.
  - Add-ID: an Add-ID is generated only if this has been configured in the FormBuilder. You can freely choose any Add-ID and then enter it yourself into the new patient form. The possible format can be specified for the project, e.g. *"2 capital letters followed by 2-3 numbers"* or *the Add-ID can be generated automatically*. You have the option to only display the Add-ID in the patient overview of the AdminTool or to additionally display it in DataCapture. The Add-ID also can be switched on or off for all roles.
  - The Add-ID is the only ID to be changed subsequently. This option can be enabled in the customer area of the CustomerAdminTool. The actual editing is performed in the AdminTool.
  - Lab-ID: the Lab-ID is configured in the CustomerAdminTool. The Lab-ID is automatically generated in the same way as the Pat-ID and is displayed/not displayed in the AdminTool according to the role configuration.

## "Casenode" = patient in a project

- Patients are always added within the framework of a project. Every patient therefore receives a casenode which identifies them within the project. If a patient participates in multiple projects, the patient can have different casenodes but only exists once as a patient. Within a project there is only one casenode for each patient.
- If all of a patient's casenodes are individually deleted from the projects, in exceptional cases it is possible for a patient to exist without a casenode.

## Report

- In secuTrial® a report refers to lists of individual patients which either display a status, a form value or other property per patient. Reports do not contain summaries of patients. However, depending on the type of report it is possible to make status summaries per patient or per visit. According to the report type, all viewable patients are listed individually or as multiple entries, usually in text form. For a more detailed description of the different report types, please refer to Part II of the product description.
- From most reports, patients can be accessed via their pseudonyms and then displayed in the patient overview. From some reports it is possible to directly access a patient's form.

## Statistic

- Statistics are always patient summaries graphically presented as totals per time period or per property. It is possible to export statistics in the form of simple Excel files. For a more detailed description of the different types of statistics, please refer to Part II of the product description.

## Catalogue

- Catalogues are unique hierarchically structured reference works which can be incorporated into catalogue form questions. They are displayed in a separate pop-up window and can be searched for the required values.
- In addition to the preset (EPCC) catalogs in earlier secuTrial® versions, generic catalogs can also be imported for each customer in the FormBuilder. The required CSV import format can be found in the FormBuilder manual.
- Catalogs are only loosely linked to forms. The selected catalogue contents are saved as a text copy and not as a reference in the form. When performing an update (see section: Audit Trail), the already saved form data will therefore not be automatically updated! The used catalog version for selecting and validating the form entry will be additionally saved in the form.

## Form

- In clinical studies a patient's medical data is collected and bundled in case report forms (CRF). In the case of electronic data collection it is collected in electronic case report forms (eCRF).
- In secuTrial® these are simply referred to as “forms”. Forms are composed of two parts:
  1. Form description: defined in FormBuilder
  2. Medical dataset: entered in DataCapture
- Forms are symbolized in the form overview of DataCapture by a page icon (see: Icon key). The form overview displays the most important information about the status in a condensed format.

### Form description

- The form description gives instructions to the FormEngine (see: FormEngine and project setup) about the composition of the form from the defined components and rules. This description is saved in the database together with all other project setups. The description includes information about in which tables and columns the medical data should be saved.

### Medical dataset

- The medical data entered by a participant in DataCapture is saved in the tables as an individual dataset which is defined in the form description. These tables are located in the project-specific area (schema) for medical data in the database.
- Each saved dataset is given a unique document ID for this project which is also displayed in DataCapture.

## FormEngine and project setup

- The term *FormEngine* describes the generic form creation implemented in secu Trial®. A large number of preset form components have already been implemented and the selection, order, labelling and portrayal in database columns are specified in the FormBuilder.
- Many different functions can be configured for a project in the FormBuilder, such as the creation of reports, the AE workflow and the use of electronic signatures. All of the settings for the project setup are saved in the secuTrial® database in a DB scheme for all customers collectively, together with the FormEngine form descriptions for all of the project versions.

## Visit plan

- The visit plan contains the chronology of examinations when patient data has been captured in forms. There are two different types of visit plans in secuTrial®:
- **Project visit plan:** this visit plan is created in the FormBuilder. It serves as a template for the visit plans of patients. It defines the sequence of visits in connection with the entry date of the patient. This visit plan is saved in the project description and placed under its version control.
- **Patient visit plan:** this visit plan contains the individual visit plan for each patient and is created according to the project template. Every visit has a real, planned visit date. The patient visit plans are saved with the medical project data.

## Visit types

- In the project visit plan, various types of visits can be entered which differ in their chronological order and options.
- With **fixed visits** the visit date is calculated from the prescribed details. The participant cannot enter a date. The calculation is based on the date that was entered in the reference visit. All of the initial visits in the visit plan must be fixed visits.
- With **flexible visits** a permitted deviation (earlier or later) from the calculated date must be entered in addition to the prescribed interval.
- With **free visits** there is no prescribed interval between other visits or previous visits. However, the date of the visit can be restricted by entering a time frame. This is then compared with the current date and not the calculated date. This conforms with the previous method of proceeding in a flexible visit plan in secuTrial® version 2.2 and earlier versions.
- **Unscheduled visits** can be entered outside of the scheduled visit plan. They will be ignored when calculating the next scheduled visit. In order to enable this visit type to be used for alternative treatment plans, it is also possible to enter the interval to the last visit plus an optional time window. If no entries have been made, these visits can be freely set.

## Form overview

- In secuTrial® DataCapture the patient is the fundamental unit for collecting and editing medical data. To depict the course of a study, when selecting a patient an overview is displayed consisting of the visits of the study (horizontal time axis) and the forms it contains (vertical data axis). The forms are symbolized with small icons (see: Icon key) which at a glance display all basic information about the completion status, queries and monitoring status.
- The form overview is the central navigation view for a patient's data.

## Adverse Event /Serious Adverse Event

- There are two types of events: an Adverse Event (AE) and a Serious Adverse Event (SAE). An adverse event is to be classified as any untoward medical occurrence during the course of a study that must be recorded separately and usually also has to be reported. For a precise definition, please refer to the GCP and FDA guidelines.
- In secuTrial® a separate workflow is implemented for recording AEs and SAEs which can be used by creating Adverse Event forms including special rules.

## Audit Trail

- Clinical studies require data entries and changes to be traceable. For precise regulations, please refer to the GCP and FDA guidelines.
- In secuTrial® every entry and change in the medical dataset is recorded detailing who saved what and when. Editing a query, comment or performing a review is also treated as a change in the dataset because this at very least changes the form status (see 4: Form status). A copy of the previous dataset is entered into the Audit Trail each time something is saved.
- The Audit Trail for every form can be viewed in DataCapture. In the FormBuilder, for every project you can define whether the entire Audit Trail or only the data changes (“history”) should be displayed. This is only a filtered display. A complete Audit Trail will always be archived.
- Changes in the project setup are documented when a project is released by archiving the previous productive project setup. All project versions can be viewed in the FormBuilder.
- When updating catalogs, the previous catalog is kept as the archive version and can likewise continue to be viewed in the FormBuilder. In the case of catalog questions in the form or Audit Trail, the catalog version which is used is also specified in DataCapture.
- Changes to the administrative data of secuTrial® are logged in the ArchivLog in an incremental AuditTrail. This can be displayed in the log history or downloaded as an Excel file.
- Changes to the configuration of a customer in the CustomerAdminTool will be logged as changes in an audit trail. Actions conducted when completing the project workflow (archiving) will be tracked in the history of the CustomerAdminTool.

## Query

- A “query” workflow is implemented in secuTrial® for the purposes of monitoring and quality assurance. User-defined free text questions can be asked regarding every form item. These questions must be closed after being answered and after any further queries and new answers. Once a query has been asked, it cannot be deleted.
- The query workflow is linked with the Review B. It is not possible to create a review until all queries in that form have been closed. Asking a query cancels the Review B status.
- If the DEC workflow has been configured, asking a query (and also performing a review) is only possible after the DEC status has been set. The form can then only be edited again for the question which the query was asked about. When using the DDE workflow, monitoring (Queries, Reviews) is likewise only possible once the comparison has finished. If DDE is used together with the DEC workflow, the DEC status must also be set.
- By combining queries and reviews with the assignment of corresponding rights, the project workflow can be varied according to the requirements of the individual study.
- When using the DTM (see Discrepancies Transfer Module (DTM)) each query is displayed with either “M” (manual) or “A” (automatic) depending on whether it was created by a manual check (creation in the form) or an automatic check (creation during discrepancy processing).
- Answering an open query can also be triggered by changing the associated item value. This automated workflow is configured on a project by project basis in the FormBuilder.

### Comment

- In DataCapture participants can enter free text comments regarding form items as a personal information note or a note for others. This option is not linked to any other type of form status. Once created, comments cannot be changed or deleted.

### Data Entry Complete (DEC)

- This workflow can be configured for a project and enables data entry to be technically separated from quality assurance by monitoring in clinical studies.
- In DataCapture the data entry is then declared as complete for every form durch den Dateineingabe. The entered form data is saved and an additional form status is set (displayed with a green form symbol). An intermediate status can be saved as often as required without setting the status to complete.
- After setting the status to complete, the entry fields are locked against further editing. Only after a query has been asked can participants with the right to “modify data” edit the corresponding item question. When changing the data, a reason for making the change must be given in the form. This will then be displayed in the Audit Trail document history.
- Performing reviews, queries and source data verification (SDV) is only possible after data entry has been set to complete. However, comments can also be entered during data entry.
- The status *Data Entry Complete* can be revoked on the respective corresponding form (Reopen data entry). Data entry can only be reopened if no form query or review has been set.

### Source Data Verification (SDV)

- SDV is a workflow for checking the entered data. When performing SDV, the entered data is compared with the original document. If there are any deviations or matches, the status will be indicated accordingly.
- In secuTrial® an SDV status can be set for every item. If it is not necessary to check every single item, the status for all items per form, form family, visit or casenode can be globally set once data entry has been completed for one or more forms.
- When using the DEC workflow, SDV can only be performed after setting the DEC status. An open query will also prevent it from being performed. If a form value is changed after setting the SDV status to OK, the SDV status will be reset automatically. For this process an automatic message can be configured.

### Discrepancies Transfer Module (DTM)

- If external checking tools have been used for data quality assurance (e.g. SAS scripts), the results lists of these checks (=discrepancies) can be integrated in a defined format within secuTrial®. The imported results lists are then checked manually by monitors and when necessary transformed into queries.
- The data to be imported can be in XML or CSV format. A more detailed specification of data formats can be found in the appendix of the DataCapture manual.

### Double Data Entry (DDE)

- With Double Data Entry, two independent persons who each have a DDE right are able to enter data. The data will be recorded as two separate data sets. A third person can then compare the data, correct it as necessary and then finish the comparison if the data matches.

- Only once the comparison has finished can all other participants view the data and then edit and/or monitor it. The data set DDE 1 is continued as the original and the second data set DDE 2 is listed as an undisplayed duplicate only in the Audit Trail. DDE therefore takes precedent over all other secuTrial® form workflows (Review, Queries, SDV). When generating patient files you can select whether the duplicate is to be displayed in the Audit Trail.

### Centre Specific Project Versioning (CPV)

- To prevent the release of a new project version from automatically taking effect for all centres simultaneously, an option has been created to release the use of a new project version separately for each centre. Releasing a new project version does not change the used project version which is being used for existing centres. They will continue to use their assigned project version.
- Only when the new version is assigned to a centre in the AdminTool is this centre permitted to work with the new version.
- The CPV function determines the use of released and archived projects and only has an effect in the productive data area.

### Configuration patient deletion

- secuTrial® can be used both for registry purposes and studies. In registries the deletion of patients is required, in studies not.
- To enable the deletion of studies to be better controlled, it is possible to configure the deletion function per customer in the CustomerAdminTool, which allows the performance of the deletion to be limited in the productive AdminTool.
- The deletion can be configured furthermore per project in the FormBuilder, if the deletion is already allowed per customer. This configuration too, is only affecting the productive AdminTool.
- If the function has been activated all of that patient's data will be completely deleted from the database, the deletion process is logged in the audit trail of the AdminTool.
- If the delete function has been deactivated in the customer or the project, it is no longer possible to completely delete the patient in the productive AdminTool. Only the patient status can be set to „to be deleted“. Patients with that status are no longer editable in the DataCapture and can not be searched for or exported in the ExportSearchTool.
- In the setup AdminTool both the deletion of a single patient as well as the patients cleanup is always possible, unless the installation parameter "deletecasenode" in the configuration file was set to false.

### Missing Values (MV)

- When monitoring studies it is important to know if values haven't been entered by mistake or on purpose e.g. because the value hasn't been taken.
- To handle this question the function „Missing Values“ is available in secuTrial®, which can be configured for the whole project or separate items. Exceptions are items without an user entry (score field, score datefield (all intervals), layout dummy and randomfield).
- The function can also be configured that way, that all items with the MV status set to "Value not collected" will be considered as complete for the purposes of determining the completion status. The MV function can therefore be used instead of a "Ignore for completion status if..." rule. No separate form status will be saved for the MV function.
- The following options are available (maximum):

Icon	Label	MV-Status
☑	Value exists	--
⊗	Value not collected	2
⊗	Value not collected due to rule (only set automatically)	3
⊗	Other reason for missing value (optional, with free text entry)	4

## Randomization

- A randomization is often the basis to classify patients in different treatment groups as part of a clinical trial. To ensure an objective and even allocation of the patients an adequate randomization algorithm should be used.
- Randomizations are mostly used in connection with double-blind trials. Due to the separated management of randomization lists and an appropriate allocation of rights both double-blind trials and triple-blind trials (analysis without the knowledge of the allocated treatment) are practicable with secuTrial®.

**Randomization group** = Randomization arm, e.g. therapy form: placebo or verum

**Randomization number** = Blinding number, medication number, does not give any indication of the randomization group

**Randomization list** = Blinding list, assignment of randomization number to randomization group, depending on the configuration can also be used as a block list for implementing randomization

## Revalidation

- 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 also has the option to edit the data, either wholly or in part (during modification after DEC). In this case the validation will be carried out when saving data.

## Home centre

- With the corresponding project configuration a patient can be assigned to multiple centres. All these centres have access to the patient and can edit the patient's data corresponding to their role rights. The modification of the entries can be restricted by assigning visits to certain centres (see user manual FormBuilder: visits).
- The centre in which the patient was first created in the project will be referenced in the casenode table for this patient. This centre is the home centre. When changing centres only the home centre can be changed. The reference in the casenode will then be changed accordingly.

## Metadaten

- Metadata refers to information that describes the general environment of the currently open form. This includes:
  - Current centre (text), Current country (text)
  - Current visit (template), current visit date (date), current visit number (numbers), current visit number according to type (numbers), current total number of visits (numbers)

- Current adverse event number (numbers), current examination number (numbers), current adverse event date (date), current examination date (date)
- Entry date of the patient (date)
- Pat-ID of the patient (text), Add-ID of the patient (text), Lab-ID of the patient (text)
- Current role (text)
- Metadata can be used as a parameter value for a rule condition or can be used for assigning values by means of rules in a form item.

### 3. Patient status

#### Definition

- **Patient status:** for every patient only one defined status is possible.
- **Casenode status:** every patient has a casenode for each project in which the patient is participating; a patient can therefore have more than one status. A status entry in a casenode only relates to the specific project in which the casenode exists. Changes and values of the entries (see below) therefore only have an effect on the respective project.
- Both types of status are displayed and edited separately in the AdminTool. However, in DataCapture checking and representation is conducted together for both types (as a textual value in brackets after the patient).

#### Status overview

- The various status types that can be set have different effects within the various tools and functions. Normally the status is set according to rules, but they can also be directly edited in the AdminTool. The trigger for a status can therefore be a rule, directly setting the status in the AdminTool or the performance of another action (deleting) within the AdminTool.

#### Patient to be anonymized

Rule:	<i>"Delete pseudonym, if ..."</i> (DataCapture)
DataCapture:	not shown
Reports:	not listed
Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	cannot be searched
Export:	can be exported (only for <i>"all patients"</i> )
Export search:	can be exported (only via old search)
Bitmask:	1 + 2

#### Deleted pseudonym

Action:	Delete pseudonym (AdminTool)
DataCapture:	not shown
Reports:	not listed
Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	cannot be searched
Export:	can be exported (only for <i>"all patients"</i> )
Export search:	can be exported
Bitmask:	1 + 2

#### Patient frozen

Rule:	<i>"Freeze patient, if ..."</i> (DataCapture)
DataCapture:	Patient is displayed, forms can no longer be edited, no longer possible to create AEs, follow ups or new visits. Queries and comments are no longer possible.
Display:	<i>"(frozen)"</i> , red cross over form icons
Reports:	listed

Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	can be searched
Export:	can be exported (only for "all patients")
Export search:	can be exported
Bitmask:	8

#### Patient deceased

Rule:	<i>"Patient deceased, if..."</i> (DataCapture)
DataCapture:	Patient is displayed, normal form cannot be edited, AE forms can be edited, new AEs can be created. Queries and comments are only on AE forms. No new visits can be created.
Display:	<i>"(deceased)"</i> , black cross over the form icon
Reports:	listed
Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	can be searched
Export:	can be exported (only for "all patients")
Export search:	can be exported
Bitmask:	16

#### Patient to be deleted

Rule:	<i>"Delete patient, if ..."</i> (DataCapture)
DataCapture:	not shown
Reports:	not listed
Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	cannot be searched
Export:	cannot be exported
Export searches:	cannot be exported
Bitmask:	1 + 32

#### Patient deleted

Action:	Patient deleted (AdminTool)
Log archive	Action is logged

#### Casenode frozen

Rule:	<i>"Freeze casenode, if ..."</i>
DataCapture:	displayed, cannot be edited, no new visits, AEs
Display:	<i>"(frozen)"</i> , red cross over the form icons
Reports:	listed
Statistics:	evaluated
AdminTool:	displayed, editable
Old search:	displayed
New search:	can be searched
Export:	can be exported (all patients)

Export searches: can be exported  
 Bitmask: 8

#### Casenode to be deleted

Rule: *"Delete casenode, if ..."*  
 DataCapture: not shown  
 Reports: not listed  
 Statistics: can be evaluated  
 AdminTool: displayed, editable (but no function for deleting casenodes has been implemented yet!)  
 Old search: displayed  
 New search: cannot be searched  
 Export: cannot be exported  
 Export searches: cannot be exported  
 Bitmask: 1 + 32

#### Casenode deleted

Action: Casenode deleted from the project (AdminTool)  
 Log archive: Action is logged  
 DataCapture: not shown (in this project)  
 Reports: not listed (in this project)  
 Statistics: cannot be evaluated ((in this project)  
 AdminTool: Patient is displayed, if all casenodes for a patient are deleted, only the basic patient entry together with the pseudonym will be retained.  
 Old search: displayed  
 New search: cannot be searched (in this project)  
 Export: cannot be exported (in this project)  
 Export searches: cannot be exported (in this project)  
 Bitmask: not available

#### Casenode visit plan closed

Rule: *"Freeze following forms, if ..."*, the only status that can be revoked by the rule "Free following forms, if..."  
 DataCapture: displayed, editable (providing no form status has been set), no new visits, AE can be created  
 Reports: listed  
 Statistics: can be evaluated  
 AdminTool: displayed, editable  
 Old search: displayed  
 New search: can be searched  
 Export: can be exported  
 Export searches: can be exported  
 Bitmask: 128

## 4. Form status

### Status types

- The medical dataset of each form has a:
  - **Completion status:** empty / partially filled / completely filled / DEC set with errors: yes / no; with warnings: yes/no;
  - **Review status:** Review A: yes / no; Review B: yes / no; Freeze: yes / no; Sysfreeze: yes / no;
  - **Query status:** Open query / query answered / query resolved;
  - **DDE-Status:** Data entry / data entry complete / comparison finished / undisplayed
  - **Comment status:** comment posted / no comment posted.
  - **SDV status:** not done, in progress, deferred, not possible, verified with errors, not necessary, verified

### Completion status

- To calculate the completion status, it is normally checked whether a value has been entered or selected for all items created within the form. Via the rules system, this check can be ignored for some or all of the items. The completion status is displayed as a coloured form icon.
- If saving a form is prevented by triggering a breach of the rules and the form can only be saved by de-selecting "Check data", the form will be given the additional status "with errors". This status is displayed with a red exclamation mark next to the the form page.
- If a confirmation rule is triggered when saving a form, the form will be saved with the additional status "with warnings". This status is displayed with a grey exclamation mark next to the form page.
- If DEC has been configured, upon completing data entry the status "DEC" will be set. The icon will then be displayed as a green form symbol without taking into account any other completion status.

### Review status

- All entries in the review status have the effect that the form data can no longer be edited. Editing queries and comments is still possible. You can usually tell from the form icon which status has been set (see: Form status). The corresponding rights are necessary for setting a Review A, Review B and freezing. The status "sysfreeze" requires the editing rights to forms with the triggering rule.
- The Review A can only be reversed with special revoking rights.
- The Review B can be revoked by asking a query and can only be set again once the query has been resolved. This workflow is intended for the purposes of monitoring and data quality assurance.
- The freeze status is set by manually freezing a form or a visit. In order to freeze a form, either a review A, B or A+B must have already been set in the form. Unfreezing a form is only possible in exceptional cases from the AdminTool with the function "Unfreeze form". In this case only the freeze status will be removed, the review status will remain unchanged. When setting this status, the editing and monitoring of this data should be definitively completed.
- The sysfreeze status is set with the form rule *"Freeze following forms"*. It can be revoked with the rule *"Unfreeze following forms"*. *(The form with the release rule must then of course be edited again.)*

### Query status

- If at least one query in a form has not been answered (newly asked or reopened), the entire form will have the status *"Open query"*. If all queries have at least been answered, the entire form will have the status *"Query answered"*. The entire form is only given the status *"Query resolved"* when all of the queries have been resolved. The total number of queries in a form is irrelevant.
- In a form, the presence of a query regarding a question is indicated by a small "?" (open query), "!" (answered query) or "✓" (resolved query).

### Comment status

- If at least one comment has been made in a form, the comment status will be set to *"comment posted"*. This status is hidden in the form symbol by every query status.
- A comment in a form is displayed by a small "c" before a question.

### SDV status

- If Source Data Verification has been configured, every item and form is given a saved SDV status. These are logged in the AuditTrail tables and can be exported together with the other form data.
- When calculating a patient's SDV status, all visits are checked and summarized. These are calculated from the SDV status of the form families within the visit. The form family status in turn results from the SDV status of the forms it contains, which are ultimately generated from the SDV status of the contained items. Apart from the form status, this status is only calculated for display purposes and cannot be exported.

### DDE status

- The DDE status is used for double data entry. Once the comparison is finished, the original document will be given the status *"Comparison finished"* and the duplicate will be given the status *"Undisplayed"*.
- The DDE status is not displayed in the form icon. Until the comparison has finished, the two different datasets will be labelled with numbers preceding the form names. The status *"Data entry completed"* will then be displayed as "✓" before the respective number.

### Icon key

- In the form overview the form status is displayed by an icon per form family and form. The status is summarized with the completion status, indicated by different colours, and the other status types, represented by various additional symbols.
- Here the status is weighted by importance: for example an open query will hide a comment. The following overview shows the various possible colours and symbols.

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

Fig. 1: Various form and form family icons representing the different status

Color	Status	Description
	standard form	Used for the capture of normal data.
	Adverse Event form	For capturing data during the workflow of Adverse Events.
	Serious Adverse Event form	For capturing data during the handling of Serious Adverse Events.

Fig. 2: Form and form family icons for the various types of forms.

Symbol	Status	Description
	validation	The rule validation of this forms finished with problems (warning, error).
	comment	At least one comment has been posted.
	open query	At least one query is open.
	answered query	All queries in this form are answered.
	resolved query	All queries have been resolved.
	reviewed data	The form has been reviewed, all queries are answered (review A, review B, both).
	partly review	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).
	manually frozen	All editing and examination has been finished. No further processing allowed.
	frozen	The form is not longer editable (frozen by system).
	patient uneditable	The patient is not longer editable (frozen, deceased). In deceased patients new adverse events can still be created and edited.
	opened formfamily	If the formfamily has been opened the included forms are shown at the bottom of the page.

Fig. 3: Form and form family icons for representing the various status conditions.

SDV	Status	Description
	not done	No verification has been made on this item or form. (single or resulting status)
	in progress	Some items has yet not been verified or are deferred. So the verification is still in progress. (resulting status)
	deferred	A final verification is not possible at the moment. Perhaps a difference has been noticed which must be cleared. (single status)
	not possible	The original data has gone lost or a difference could not be cleared. So a verification could not be done. (single status)
	verified with errors	SDV has been made but for at least one item it was impossible. (resulting status)
	not necessary	A verification of this item or form is not necessary, e.g. when the SDV is only tested at random. (single or resulting status)
	verified	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)

Fig. 4: Icons for displaying the various status types of Source Data Verification (SDV). The icon is displayed for each item, form, family, visit and patient.

#### Indication of DDE status

Role right	Form status			
	unsaved	DDE entered	DDE entry complete	DDE comparison finished
without DDE		(1/2)	(1/2)	
DDE 1	(1)	(1)	(√1)	(--)
DDE 2	(2)	(2)	(√2)	(--)
DDE 1 and 2	(1&2)	(1&2)	(√1&√2)	