



# Product Description II FormEngine

secuTrial®

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## 1. Introduction

**Since 4.8** In the current version the following new function has been introduced:

- New rule „Input required or ignore completion status if ...“
- New rule „Display form, if ...“
- Multiple query messages

### 1.1 The FormEngine - translator between database and HTML form

- secuTrial® only generates forms (=eCRF) dynamically from the database contents on request. This means that two central functions are therefore required for the presentation of forms:
  1. A module which generates an HTML page containing the form (see below) in the centre part from the database contents. In secuTrial®, this module is called the FormEngine, and is integrated into the DataCapture (not visible to the user).
  2. A module with which the database fields which define the appearance of the forms can be filled and changed. This module is the FormBuilder, which enables the eCRF design within secuTrial®.

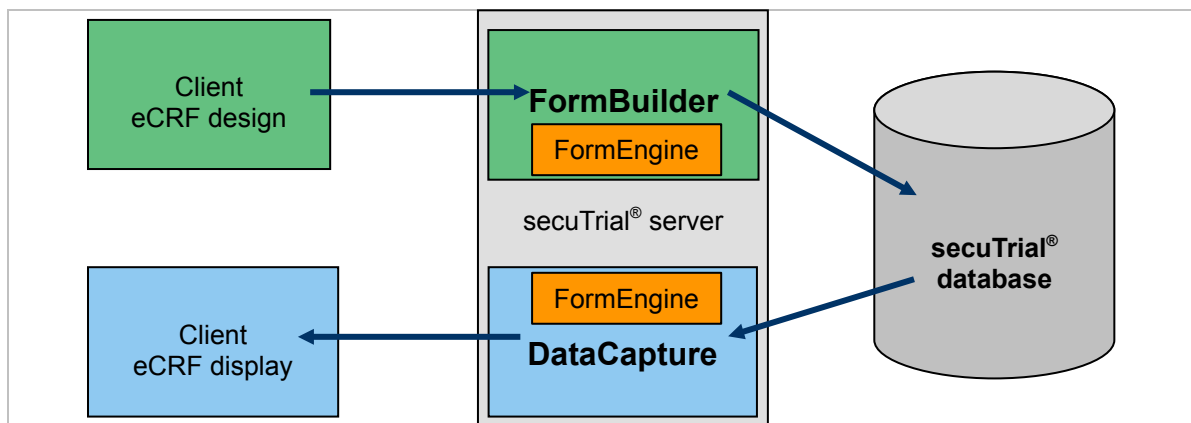


Fig. 1: Schematic depiction of eCRF generation. In the FormBuilder, the FormEngine is also used to preview the eCRF.

## 1.2 Page structure of an eCRF in the DataCapture

The screenshot displays the secuTrial eCRF DataCapture interface. It is structured into three main parts, indicated by orange brackets on the right:

- Part 1 (Header):** Contains patient and project information.
 

Date	24.08.2010 - 17:58 (CEST)	Patient	Pat-ID: pxe146
Clinical Investigator	Dipl.biol Susanne Schneider	1. visit	02.01.2000 (CET)
Project	Study 1 (24.08.2010 - 17:57:29 (CEST))	Form family	Base Examination
Centre	Centre B, Germany	Form	Personal Data

 Navigation links: Back | Help | Logout
- Part 2 (Main part):** Contains form fields for data entry.
  - Personal Data:** Birth (dd.mm.yyyy), Birth place, Allergies (dog, cat, house dust, not applicable), Sex (female, male), Weight, Height.
  - Pregnancy:** < Please choose > (dropdown), Week, < Please choose > (dropdown).
  - BMI:** IIF-Identification, Blood sample taken, Weight, Height, BMI (Score button), Comment.
- Part 3 (Footer):** Contains navigation buttons and a summary of the header data.
 

Buttons: Cancel, Calculate scores, Save, Save + close entry, Check data (checked).

Summary: Date: 24.08.2010 (CEST) Clinical Investigator: Dipl.biol Susanne Schneider Project: Study 1 (24.08.2010 - 17:57:29 (CEST)) Centre: Centre B Country: Germany Pat-ID: pxe146 1. visit: 02.01.2000 (CET) Form family: Base Examination Form: Personal Data

Fig. 2: Page structure of an eCRF in DataCapture.

- The secuTrial® eCRF pages always have the same structure, consisting of the header (1), main part (2) and footer (3). Formal data on the participant, patient and project plus menu buttons for general navigation are displayed in the header. The footer contains the buttons for saving or cancelling the form plus a summary of the header data underneath.
- The main part encompasses the form fields, in which the data are recorded. The FormEngine defines the structure of the centre part with its fields, whilst it has no influence on the window structure with the header and footer. The centre part is therefore the form in the stricter sense, which again has a typical structure.

## 1.3 Form structure

- A secuTrial® form has typical elements, some of which are present in each form or which can be used optionally. The way in which these elements appear in the DataCapture and how they are designated in the FormBuilder nomenclature is described here. A good knowledge of these standard elements and their positioning plus the related field in the FormBuilder is important, in order to
  - Compile the data records sensibly and
  - Fill in the correct fields on creation in the FormBuilder.
- The elements can be reflected in the following content breakdown:
  - Form number, form name, plus form description
  - Intermediate number, intermediate header
  - Question number, question, plus description and help text
  - Item number, item
  - Possible answers (e.g. labels for radiobutton)

Fig. 3 Nomenclature and localisation of the various form elements on an eCRF.

- This clearly shows that a content breakdown with a maximum of three layers can be portrayed within secuTrial® forms. The location of the specified elements in the HTML form is shown in the above figure.

## 1.4 Reports and statistics

- To obtain an overview of the medical data which have already been captured (entries in a form), generic reports and statistics which depict individual statuses or values from several patients together can be created in secuTrial®.
- Like the form description, the reports and statistics are also defined for each project in the Form-Builder, whilst the data are displayed in the DataCapture. As the forms are compiled generically via variable definitions, it is also necessary to create the evaluating reports and statistics generically.
- Reports and statistics differ in four ways as regards the evaluation and portrayal of the data:
  1. Summarisation of patients
  3. Patient sums are always displayed in the case of statistics. Reports list each patient individually.
  2. Filtering patients
 

Statistics always evaluate all patients from all centres; reports usually filter the centres (limitation possible with SQL reports) according to the current participant's access rights. The patient status is disregarded in statistics, i.e. patients which have been marked as "To be deleted" or have already been anonymised are also evaluated. These patients are not displayed in reports.

Exception: Patients entered in an administrative centre (AdminTool) are disregarded in the reports and statistics.
  3. Display
 

Statistics are displayed as graphics. Reports usually consist of text-based lists of data (exception: Icon report, image form report).
  4. Up-to-dateness



Statistics are generated once per night (configuration of the generation time per installation). Reports are created in the case of the current display and therefore show the respective data status at the point in time of the view.

## 1.5 Form family types

- Forms are organised in form families. In this case, the form family type defines the display and function of the forms which are contained.
- Each family may contain any number of forms. Only precisely one copy of certain family types can be created.

### Visit

- This is the standard type for normal study eCRFs. Any number of families can be created for this type.
- Visit families are displayed in the patient form overview on the first tab; in this case, the families are depicted beneath each other to form the vertical axis. The family names are displayed on the outer left.
- The display of forms which are contained is determined (apart from the assignment of rights) by the forms' inclusion in the visit plan.

### AdverseEvent

- This family contains the forms for the AE/SAE work flow. It can be created exactly once; the AE/SAE work flow for this project is only configurable if an AdverseEvent family exists.
- The AdverseEvent family is displayed on the patient form overview on the second tab. The family name is used as the tab label in this case. In the case of created AEs, the tab is emphasised in colour; in the case of a created SAE, the coloured marking is more intensive, and the patient form overview is always opened in this tab when calling the patient up.
- The AdverseEvent family forms are displayed according to the assignment of rights and the configured work flow. The AE/SAE work flow is explained in greater detail in the FormBuilder user manual.
- For the labelling of adverse event forms, all contained form items which do not originate from a repetition group can be selected. The corresponding item value of the saved form will then be displayed in the overview instead of the form name. If no value has been entered for an item, the form name will continue to be displayed.

### Casenode

- The casenode family contains all forms which have to be completed once for each patient irrespective of date, e.g. final reports. It can be created exactly once.
- The family is displayed on the patient form overview behind the AdverseEvent tab (if available); the family name serves as the tab label in this case.
- The family forms are displayed according to the assignment of rights and are all listed below one another.

### Image

- The image family contains forms which can be optionally created. As it has been created to display images, larger icons with a form thumbnail are displayed instead of the normal form icons. This family can be created exactly once.

- The family is displayed as the last tab in the patient form overview; the family name is also used as the tab label in this case.
- Like AEs/SAEs, image forms are created via a "New image form" link, and can then be assigned to either a patient, a visit or an AE/SAE examination. The forms are then listed in three rows (patient, visits, AE/SAE) in the sequence of their creation.
- The image family forms are not displayed automatically, but only if they are created explicitly (see above). However, selection of the possible forms is determined by the assignment of rights.

#### Subform

- The subforms which can be used in IASRepetitionGroups are created in this help family. An optional qualification test can also be created in this family. Any number of subform families with any number of forms can be created.
- Subform forms are not displayed directly; the assignment of rights also always occurs via the external main forms.

## 2. Form components

- An entire range of diverse form components is available in secuTrial® for both the question layer and the item layer. The questions are mainly responsible for the layout of the form, whilst the item types determine the type of data which are captured. However, there is also a range of types which allows only specific item types or makes special functions available.

### 2.1 Value check in the DataCapture

- A set of rules (also called plausibility check, edit check, FormLogic) is the sum of all checks to which the DataCapture subjects the incoming data. It can be subdivided into
  - Format check
  - Limit values
  - Plausibility in the stricter sense
  - Actions

#### Format check

- Format checks are carried out prior to saving when values are input in the DataCapture. These checks are firmly implemented for each item and cannot be configured.
- Incorrect inputs lead to error messages including the incorrect input. The input field is reset to the previous value. Format checks are only implemented for item types with free input; of course, such a check is not necessary in the case of types with specified answer options (e.g. radiobuttons).
- It is impossible to save an incorrectly formatted input. The catalog items are an exception to this: In this case, it is possible to ignore a datum's deviation from the current catalog by means of the "Check data" check box and to still save the values which are not present. The deviation is then evaluated as an error.

#### Rules

- The limit value and plausibility checks and the execution of actions are defined via the item rules defined in the FormBuilder.
- The calculation algorithm for score items is also created as a rule. This then defines the sequence and origin of the form values to be calculated with each other. The item value therefore only results from the evaluation of the rules.

### 2.2 Consistency check in the FormBuilder

- Consistency checks are carried out in the FormBuilder when creating and editing form descriptions. They determine which types are offered on the question, item and rule layers. Which conversions to other types are possible when and which other elements can be created are listed beneath the description for each component type in this section. The consistency check serves two objectives:
  - Prevention of data loss
  - Avoidance of type inconsistencies and rule errors.
- In this case, a distinction is made between whether the question or the item is still available as a pure development version or whether it has already been set to productive status (released). The distinction is actually made at the layer of the question or item, as these elements can also be subsequently added to a project which has already been set to productive status, and can then be changed relatively freely until setting to productive status is next carried out. The focus in this case is then on the avoidance of type inconsistencies.

- If the question or the item has already been set to productive status, data loss must be prevented under all circumstances. Adaptation of the layout, e.g. the switch from a layout beneath one another to a layout next to one another, remains possible.

## 2.3 Types

- The types are listed here in the sequence of the presumably most frequent use. This is also the sequence in which they are offered in the FormBuilder.

### IASStandardGroup

- As the name says, this involves the standard type with which 50 to 90% of questions can be covered in the majority of projects. To maintain the uniformity of the forms' layout, it is usually sensible to create all questions which do not expressly demand another type as an IASStandardGroup, even if they only have one item.

1. iASStandardGroup

First description with already fixed format.

Second description with possibility to enter html, e.g. **bold**

a) Horizontal-Radiobutton with reset option ☒ not applicable ☐ yes ☐ no

b) Textfield

Comment

Query

Fig. 4: Example of an IASStandardGroup with two items.

### Consistency check

- Non-productive:
  - Can be changed to IASUnitGroup or IASHorizontalUnitGroup as long as there are no items; on saving, the two mandatory fields (number field and unit list) are then created automatically.
  - IASStandardGroup with only one radiobutton (or check box) can be changed to a RB matrix (or check box matrix).
  - IASStandardGroup with lookup fields only (not with extendable lookup fields) can be changed to an IASMultipleSelection, IASCombinedSelection or IASHorizontalCombined-Selection.
- Productive: Can be changed to IASHorizontalGroup, IASAlternateStandardGroup.
- Except catalog fields, all item types can be created.

### IASAlternateStandardGroup

- The IASAlternateStandardGroup offers a slightly different design than the IASStandardGroup. The portrayal of the items which are contained begins directly behind the question's number label; the item text is displayed above the item input fields. All of the question's items are portrayed beneath one another on the whole.
- This component can be used e.g. if a very large image (see below) or items with very wide input fields are to be displayed in the form. This component extends the option of structuring the layout of forms.

Fig. 5: Example of an *IASAlternateStandardGroup* with an image item.

### Consistency check

#### – Non-productive:

- Can be changed to *IASUnitGroup* or *IASHorizontalUnitGroup* as long as there are no items; on saving, the two mandatory fields (number field and unit list) are then created automatically.
- Can be changed to *IASHorizontalGroup* or *IASStandardGroup* as long as it only contains number field, text field, text area, check box, radiobutton, pop-up or score field type items.
- *IASAlternateStandardGroup* with only one radiobutton (or check box) can be changed to a RB matrix (or check box matrix).
- *IASAlternateStandardGroup* with lookup fields only (not with extendable lookup fields) can be changed to an *IASMultipleSelection*, *IASCombinedSelection* or *IASHorizontalCombinedSelection*.

#### – Productive: Can be changed to *IASHorizontalGroup*, *IASStandardGroup*.

#### – Except catalog fields, all item types can be created.

### IASHeadline

- Serves to portray an intermediate header. This can be used to subdivide forms into clearly arranged sections or simulate a further hierarchical layer. As mentioned above, it is important to give early consideration to the implementation of a form layout with the options offered by secuTrial®. The breakdown with *IASHeadlines* may prove helpful in this case.
- The *IASHeadline* does not contain any items or description texts. The next layer is not therefore displayed if *IASHeadline* has been selected as the type. It is also not possible that the **HELP**, **COMMENT** and **QUERY** buttons do not appear next to an *IASHeadline*.

The screenshot shows a form with two main sections separated by a blue horizontal bar labeled 'Headline'. The top section, titled 'Checkbox Matrix', contains a label 'column 1' and two rows, 'Row 1' and 'Row 2', each with a radio button and a checkbox. The bottom section, titled 'Horizontal Group', contains three sub-groups: 'Radiobutton' with three radio buttons labeled 'red', 'green', and 'black'; 'Reset Radiobutton' with a radio button labeled 'not applicable' and three radio buttons labeled 'red', 'green', and 'black'; and 'Popup Group' with a dropdown menu showing '< Please choose >'. On the right side of each section, there are 'Comment' and 'Query' buttons.

Fig. 6: Example of the view of an IASHeadline between two other types.

**Attention:** If another type is converted into an IASHeadline, all items contained therein are deleted without warning!

### Consistency check

- Non-productive, productive: Can be changed to all other types, can always be deleted.
- No items can be created.

### IASHorizontalGroup

- This type is a standard type comparable with the IASStandardGroup, but arranges the items horizontally next to each other and not beneath each other. It is recommended when the texts and fields are very short (e.g. small radiobutton item and a date item) and you wish to save space (less scrolling). A HorizontalGroup can be used good subforms, when many repetitions are expected.

The screenshot shows a form titled '2. IASHorizontalGroup'. It contains two lines of text: 'This is the first description text. The formatting is predefined here.' and 'This is the second description text. The text here can be formatted with HTML tags, e.g. the text can be set **bold** or *italic*.' Below the text, there are two items: 'a) Horizontal Radiobutton (with reset option)' with three radio buttons labeled 'not applicable', 'yes', and 'no'; and 'b) Textfield' with a text input field followed by the label 'unit'. On the right side, there are 'Comment' and 'Query' buttons.

Fig. 7: Example of the view of an IASHorizontalGroup with two items.

- It is not sensible to integrate many more than approx. two to three items per group, as a full view is not otherwise guaranteed with all window widths. The IASHorizontalGroup should therefore be tested individually and with various browsers. In the case of excessively wide IASHorizontalGroups, a horizontal scroll bar appears, as table structures are not made up.
- Normally, the items are distributed evenly according to their number over the width of the page; with 3 items, each item therefore takes up 1/3 of the width of the page. The "Flexible column width" can be configured instead; the items are then arranged directly behind each other and are not distributed over the width of the page.

### Consistency check

- Non-productive: Can be changed to IASHeadline (items are deleted!), IASStandardGroup, IASAlternateStandardGroup.
- Productive: Can be changed to IASStandardGroup, IASAlternateStandardGroup.
- Except catalog fields, all item types can be created.

### IASRepetitionGroup

- The IASRepetitionGroup offers the option of creating questions or an entire form in such a way that, if necessary, it can be repeated any number of times without reserving a high number of empty database fields for this from the beginning. The standard application area is drugs: Per default, e.g. a

single question for a concomitant drug can be displayed here. If more than one concomitant drug is available, a MORE button can be used to load one or more further, empty fields with the same layout.

- With an IASRepetitionGroup, an empty shell for the fields to be repeated is simply created in the main form. The contents themselves (all questions and items in the repetition area) must be created in a separate form of the *Subform* type. This subform is then selected in the surrounding repetition question.

Fig. 8: Example of the view of an IASRepetitionGroup with an initial display of a subform repetition; a further question group (=subform) can be displayed via MORE.

- The number of initial and maximum repetitions can be defined. The MORE button can be replaced by another one; it must then already be present on the web server. If nothing is specified, the standard icon is used.
- Whether a DELETE button is to be displayed is defined for each IASRepetitionGroup. A button other than the standard button can also be defined here (attention: This button must be present on the web server too).

Fig. 9: View after the user has clicked onto MORE twice.

- For every IAS RepetitionGroup you can also define whether further repetitions are possible after DEC. If this option is selected and on condition that
  - the DEC status has been set in the form
  - the DEC status cannot be revoked
  - the form and the patient have not been frozen
  - the participant has the editing rights to make changes

the MORE button will be displayed again in DataCapture and the participant can create more repetitions for the repetition group.

- Consistency check

- **Non-productive:** Can be changed to all types.
- **Productive:** Can no longer be changed.
- No items can be created.

### IASHorizRBMatrix

- The radiobutton matrices offer a practical method for accommodating several questions with the same answer options in a tight space. The prerequisite for use is therefore
  - That this involves option questions (see Horizontal radiobutton )
  - That at least two questions with the same answer options are available,
  - That the layout in a single question (i.e. with a common help) is legitimate.
- In an IASHorizRBMatrix, the questions are arranged horizontally (in lines) and the answers vertically (in columns). They are suitable for question groups with short answer options and longer question texts. The standard example is the many items with *yes/no* or *yes/no/not applicable* as the answer.

Please read each item and circle the number that best describes how satisfied you are at this time.								Comment
Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.								Query
		Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1.	Material comforts home, food, conveniences, financial security	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.	Health - being physically fit and vigorous	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3.	Relationships with parents, siblings & other relatives-communicating, visiting, helping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4.	Having and rearing children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5.	Close relationships with spouse or significant other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Fig. 10: Example of the view of an IASHorizRBMatrix consisting of five items.

- On creating and editing the group of labels of a radiobutton in a RB matrix, the changes are always transferred to all groups of labels of all radiobuttons for the question.
- For the IASHorizRBMatrix it is also possible to display a reset option. This option can be added as the first or last option to the other answer options. The button text can also be edited. When saved, changes made to one radio button in a matrix will be transferred to all other radio buttons within the matrix.

### Layout-settings IASHorizRBMatrix

- To influence the table design for a radio button matrix, CSS classes have been introduced for the table elements. To edit the CSS, a layout assistant can be opened in a separate window.
- The width of the columns can be set in the upper area of the assistant. In addition, the table can be aligned either by manually dragging the table lines of the layout-preview or by directly setting the pixel value or percentage in the upper entry field in the CSS.
- Independent of the width division of the table, as many additional user entries as necessary can be made in a separate CSS area. This would for instance enable an alternating colour scheme for the table cells. For information on the necessary entries, please consult the relevant literature on CSS.



**Layout Horizontal radio button matrix**

Benutzen Sie die Querbalken zur Größenveränderung:

	1. Column	2. Column
Layout ?	yes	no
First question	<input type="radio"/>	<input type="radio"/>
Second question	<input type="radio"/>	<input type="radio"/>

Width 100% ? ☒

Layout (CSS) ?

```
table.fg_type_iashorizrbmatrix.fg_id_vxfmqsrld td.col0,
th.nc-th.thf0 {
    width: 50%;
}
table.fg_type_iashorizrbmatrix.fg_id_vxfmqsrld td.col1,
th.nc-th.thf1 {
    width: 25%;
}
table.fg_type_iashorizrbmatrix.fg_id_vxfmqsrld td.col2,
th.nc-th.thf2 {
    width: 25%;
}
```

User defined layout (CSS) ?

```
table.fg_type_iashorizrbmatrix.fg_id_vxfmqsrld { background-
color:#9999FF;
}
```

Fig. 11: Layout assistant for the CSS of a radio button matrix in FormBuilder.

**Note:** The layout assistant can be affected by your chosen browser. If you are experiencing problems, please try another browser.

### Consistency check

- **Non-productive:** Can be changed to IASHeadline (items are deleted!), IASHorizontalGroup, IASStandardGroup, IASAlternateStandardGroup, IASVertRBMMatrix.
- **Productive:** Can be changed to IASVertRBMMatrix, IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup.
- Only horizontal radiobuttons can be created.

### IASVertRBMMatrix

- In an IASVertRBMMatrix, the questions are arranged vertically (in columns) and the answers horizontally (in lines). They are suitable for the rarer case of question groups with short questions and longer answer texts, as these would not otherwise fit well into the narrow column designations. One example is the UPDRS score, in which the same questions are asked for various extremities (head, LU, RU, LL, RL, etc.), whilst the answer options are half sentences.
- The "Horizontal radiobutton" is also used as an internal item type in this vertical radio matrix, as this component's layout is determined by the question type only, and not by the item type.
- For the IASVertRBMMatrix it is also possible to display a reset option.(see IASHorizontalGroup).

- It is also possible for the IASVertRBMMatrix to influence the table design via the CSS layout-settings.

RIGIDITY						Comment
						Query
<u>Instructions to examiner:</u> Rigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity.						
Neck	RUE	LUE	RLE	LLE		
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Normal: No rigidity.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Slight: Rigidity only detected with activation maneuver.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.	

Fig. 12: Example of an IASVertRBMMatrix consisting of five items.

### Consistency check

- Non-productive:** Can be changed to IASHeadline (items are deleted!), IASHorizRBMMatrix, IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup.
- Productive:** Can be changed to IASHorizRBMMatrix, IASStandardGroup, IASHorizontalGroup.
- Only horizontal radiobuttons can be created.

### IASCheckboxMatrix

- In principle, the IASCheckboxMatrix functions like a horizontal radiobutton matrix: Several questions with the same answer options, which are to be portrayed as check boxes (i.e. multiple selection possible), can therefore be presented in compact form. The answer texts should be short in order to fit into the columns.

IASCheckboxMatrix				
<b>Drug usage:</b>				
Please check all that applies.				
	daily	sometimes	rarely	never
Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Illegal drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Fig. 13: Example of the view of an IASCheckboxMatrix.

- Despite the same appearance, there is a significant difference in logic versus the radiobutton matrices: As not only one answer is possible, each check box (i.e. each answer options) is regarded as **one** question with two answer options (NULL and one, i.e. "Not checked" or "Checked"). This makes creation very laborious and a high number of database fields are required. Rules additionally have to be individually defined for each check box.

Included Items (12)									
Displayed order	shown no.	+ / -	Item	Displayed order	Answer	Type	Database column	Delete from database	
▶ 10		+	Alcohol	1	daily	CheckBox	r1s1	Delete	
▶ 20		+	Alcohol	2	sometimes	CheckBox	r1s2	Delete	
▶ 30		+	Alcohol	3	rarely	CheckBox	r1s3	Delete	
▶ 40		+	Alcohol	4	never	CheckBox	r1s4	Delete	
▶ 50		+	Cigarettes	1	daily	CheckBox	r2s1	Delete	
▶ 60		+	Cigarettes	2	sometimes	CheckBox	r2s2	Delete	
▶ 70		+	Cigarettes	3	rarely	CheckBox	r2s3	Delete	
▶ 80		+	Cigarettes	4	never	CheckBox	r2s4	Delete	
▶ 90		+	Illegal drugs	1	daily	CheckBox	r3s1	Delete	
▶ 100		+	Illegal drugs	2	sometimes	CheckBox	r3s2	Delete	
▶ 110		+	Illegal drugs	3	rarely	CheckBox	r3s3	Delete	
▶ 120		+	Illegal drugs	4	never	CheckBox	r3s4	Delete	
New item									

Fig. 14: Overview of the items of the IASCheckboxMatrix in the FormBuilder from Fig. 13.

- On creation of the IASCheckboxMatrix, each check box must be created as an individual item (including rules). The same question text must be specified as the question text for all check boxes within a row. In the second step, each check box is then assigned with the corresponding label text as the column heading. All check boxes standing in the same column in a matrix must have the same (=same ID) label text.
- The sequence of the rows arises from the sequence created for the items, whereby the item in a row which is used to determine the sequence of the questions is taken by random. The sequence of the columns arises from the sequence which is specified in the labels. The evaluated column for the answer sequence is also rather random in this case. The data should therefore be set identically in the rows and columns, and the portrayal should be checked in the preview.

### Consistency check

- Non-productive: Can be changed to IASHeadline (items are deleted!)
- Productive: Can no longer be changed.
- Only check boxes can be created.

### IASMultipleSelection

- Special case of several hierarchically linked lookup tables (not extendable) which mutually influence each other: On selection of an entry in one of the lists, the form is reloaded, and the upper and lower lists are displayed filtered with adequate contents.

Fig. 15: Example of the view of an IASMultipleSelection consisting of three lookup tables: Without selection in the upper (left) lookup table, all elements are pre-loaded in the lower lookup table (see Fig. 18).

Fig. 16: Following selection in the middle lookup table, the corresponding entry is selected in the upper table (left). The possible lower values are filtered in the lower table (right).

- The different lookup tables must first have been created in the project and must accordingly be hierarchically linked. On compilation of the IASMultipleSelection, only the lookup tables possible from the hierarchy are also offered for the further items following the selection of the first lookup table.
- Normally, the items are distributed evenly according to their number over the width of the page; with 3 items, each item therefore takes up 1/3 of the width of the page. A "Flexible column width" can be configured instead; the items are then arranged directly behind each other and are not distributed over the width of the page.

### Consistency check

- Non-productive: Can be changed to IASHeadline (items are deleted!), IASCombinedSelection, IASHorizCombinedSelection, IASStandardGroup, IASAlternateStandardGroup or IASHorizontalGroup.
- Productive: Can be changed to IASCombinedSelection, IASHorizCombinedSelection, IASStandardGroup, IASAlternateStandardGroup or IASHorizontalGroup.
- Only lookup tables (not extendable) can be included. After creating the first lookup table, only the lookup tables hierarchically positioned below the first can be selected.

### IASCombinedSelection

- In content terms, virtually the same function as IASMultipleSelection, with the sole difference that only the first pull-down list is pre-loaded when loading the page. The layout is vertically beneath each other. Highly suitable for the portrayal of large, hierarchically structured lookup lists.

Fig. 17: Example of the view of an IASCombinedSelection: Without selecting the upper lookup table, no entries are yet displayed in the lower lookup tables.

### Consistency check

- Non-productive: Can be changed to IASHeadline (items are deleted!), IASHorizCombinedSelection, IASMultipleSelection, IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup.
- Productive: Can be changed to IASHorizCombinedSelection, IASMultipleSelection, IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup.
- Only lookup tables (not extendable) can be created.

## IASHorizCombinedSelection

- In content terms, the same function as IASCombinedSelection, but the layout is horizontally next to each other. In the case of a high number of items or lookup tables with very long contents, this layout may become unclear.

The screenshot shows a form titled 'IASHorizCombinedSelection'. It contains three horizontal lookup tables: 'Pet', 'Breed', and 'Colour'. The 'Pet' table has 'Cat' selected. The 'Breed' table has a dropdown menu open showing 'Siamese' and 'Persian'. The 'Colour' table is empty. To the right of the tables are 'Comment' and 'Query' buttons.

Fig. 18: Example of the view of an IASHorizontalCombinedSelection with selection of the upper lookup table (left). The middle table then contains only the possible entries for selection. The right lookup table does not yet contain any entries. These are only offered following selection of the middle lookup table.

- Normally, the items are distributed evenly according to their number over the width of the page; with 3 items, each item therefore takes up 1/3 of the width of the page. A "Flexible column width" can be configured instead; the items are then arranged directly behind each other and are not distributed over the width of the page.

### Consistency check

- Non-productive: Can be changed to IASHeadline (items are deleted!), IASCombinedSelection, IASMultipleSelection, IASStandardGroup, IASAlternateStandardGroup or IASHorizontalGroup.
- Productive: Can be changed to IASCombinedSelection, IASMultipleSelection, IASStandardGroup, IASAlternateStandardGroup or IASHorizontalGroup.
- Only lookup tables (not extendable) can be created. After creating the first lookup table, only the lookup tables hierarchically positioned below this can be selected.

## IASUnitGroup

- The IASUnitGroup consists of at least two items, whose types are firmly specified. It is intended to be able to specify data on measured values in various, previously defined units which are converted into a reference unit for saving in the database. The first question is a number field for inputting the measured value; the second consists of a pop-up, which contains the units.

**Welcome > Project > form family > Form > Question > Item**

**Project:** Study 1 (25.08.2010 - 11:52:52 (CEST)) { PROB - Registry / No. 2 - Development }

**Form family:** Laboratory forms { Visit }

**Form:** Laboratory measurements <mnpproblab>

**Question:** IASUnitGroup { IASUnitGroup }

---

**Type: \***  [Edit group of labels](#)

Displayed order	Label	DB value	Conversion factor	ID
1	mg	2	1000.0	5157
2	g	1	1.0	5156
3	kg	3	0.0010	5158

**Database column: \***  ?

▶ CDISC ODM export annotations ...

Containing rules (2)				
Displayed order	Name	+ / -	Type	Following action
▶ 10	Please select a unit.	+	Input required, if...	<a href="#">Delete</a>
▶ 11		+	Input not required, if...	<a href="#">Delete</a>

[New rule](#)

[Cancel](#) [Save and back](#) [Save](#) [top](#)

Fig. 19: Editing page for the unit pop-up of an IASUnitGroup in the FormBuilder.

- Conversion is carried out via the conversion factor of the pop-up's group of labels: Prior to saving in the database, each number field is calculated using the conversion factor. In this case, the reference unit must be given the conversion factor 1, and is taken over unchanged into the database. Otherwise, the input measured value is divided by the conversion factor and the result is saved in the database. For portrayal purposes, the database value is then multiplied by the conversion factor again and displayed in the input field.

**IASUnitGroup** [Comment](#) [Query](#)

**Measured value**   (= 5,000.000000 g)

**Measure done** ☐ yes ☐ no

**Time of measure**  -  hh:mm

Fig. 20: Example of an IASUnitGroup with the three units mg, g (reference unit) and kg and two additional items.

- So that the user knows what he is actually saving, the database value is also additionally displayed in the reference unit if he has not selected the reference unit. Due to this type of handling, the database values are all directly comparable without further conversion.
- On creation of an IASUnitGroup the two necessary items and a supplementary set of rules are already created during the first save.. The database columns are designated with a standard value and a standard reference unit is created. The units then have to be correspondingly exchanged and supplemented according to the relevant requirements. The columns can be renamed following creation. These items are created even if another (empty) question is converted into an IASUnitGroup.
- Due to possible rounding errors, the IASUnitGroup should only be used with reservation - an E-sig-nature should generally be used here with care.
- Additional items can also be defined in any sequence in an IASUnitGroup; in turn, their types can be freely selected from text fields, date fields, check boxes or radiobuttons. Further options include

lookup tables and score fields. However, deleting the individual pop-up or number items is not possible even after creating new items in an IASUnitGroup and the question is not productive.

### Consistency check

- Non-productive, Productive: Can only be changed to IASHorizontalUnitGroup.
- All items except number, popup, randomization buttons and catalog fields can be created as additional items. The two unit items cannot be deleted even when they are non-productive.
- In the sequence, the unit pop-up is always positioned directly behind the unit number field.

#### IASHorizontalUnitGroup

- Operates precisely like the IASUnitGroup, with the difference that several elements are arranged next to each other and not beneath each other. Additional items are portrayed in the specified sequence in front of or behind the two unit fields.

Fig. 21: Example of the view of an IASHorizontalUnitGroup with two additional items.

- Normally, the items are distributed evenly according to their number over the width of the page; with 3 items, each item therefore takes up 1/3 of the width of the page. A "flexible column width" can be configured instead; the items are then arranged directly behind each other and are not distributed over the width of the page.

### Consistency check

- Non-productive, Productive: Can only be changed to IASUnitGroup.
- All items except numbers, popup, randomization buttons and catalog fields can be created as additional items. The two unit items cannot be deleted even when they are non-productive.
- In the sequence, the unit pop-up is always positioned directly behind the unit number field.

#### IASCatalogGroup

- An IASCatalogGroup enables the usage of large, hierarchical structured catalogs to be used as reference books. The catalog must first be created within the customer (see the FormBuilder manual). On creation of an IASCatalogGroup, the catalog from which the values are to be subsequently read-out must be specified in addition to the standard data such as question text and sequence.
- If an IASCatalogGroup with items has been created, the user is able to open a window in which he can search for and select the desired value in the DataCapture by clicking onto the CATALOG button (field marked in colour on the outer left). Following selection, the available values are transferred from the catalog to the form and the catalog window is closed. The values are copied from the catalog as independent text and not only referenced from the catalog.

**Attention:** If the assigned catalog is changed and catalog items have already been created, these are deleted following one warning notice!

### Possible fixed catalogs

- At present (automatically created in secuTrial® versions prior to 3.3 only), 9 catalogs are firmly implemented in secuTrial®; these each form an excerpt of the cardiovascular diseases from the overall EPCC catalog in german:
  - Main and secondary diagnosis (congenital) ["Haupt- und Nebendiagnose (angeboren)"]
  - Secondary diagnosis (acquired) ["Nebendiagnose (erworben)"]

- Extra diagnosis [“Extra-Diagnose”]
- Operation/Intervention [“Operation/Intervention”]
- Intervention [“Intervention”]
- Symptom or risk factor [“Symptom oder Risikofaktor”]
- Complication [“Komplikation”]
- Measure [“Maßnahme”]
- HFN diagnosis [“HFN-Diagnose”]

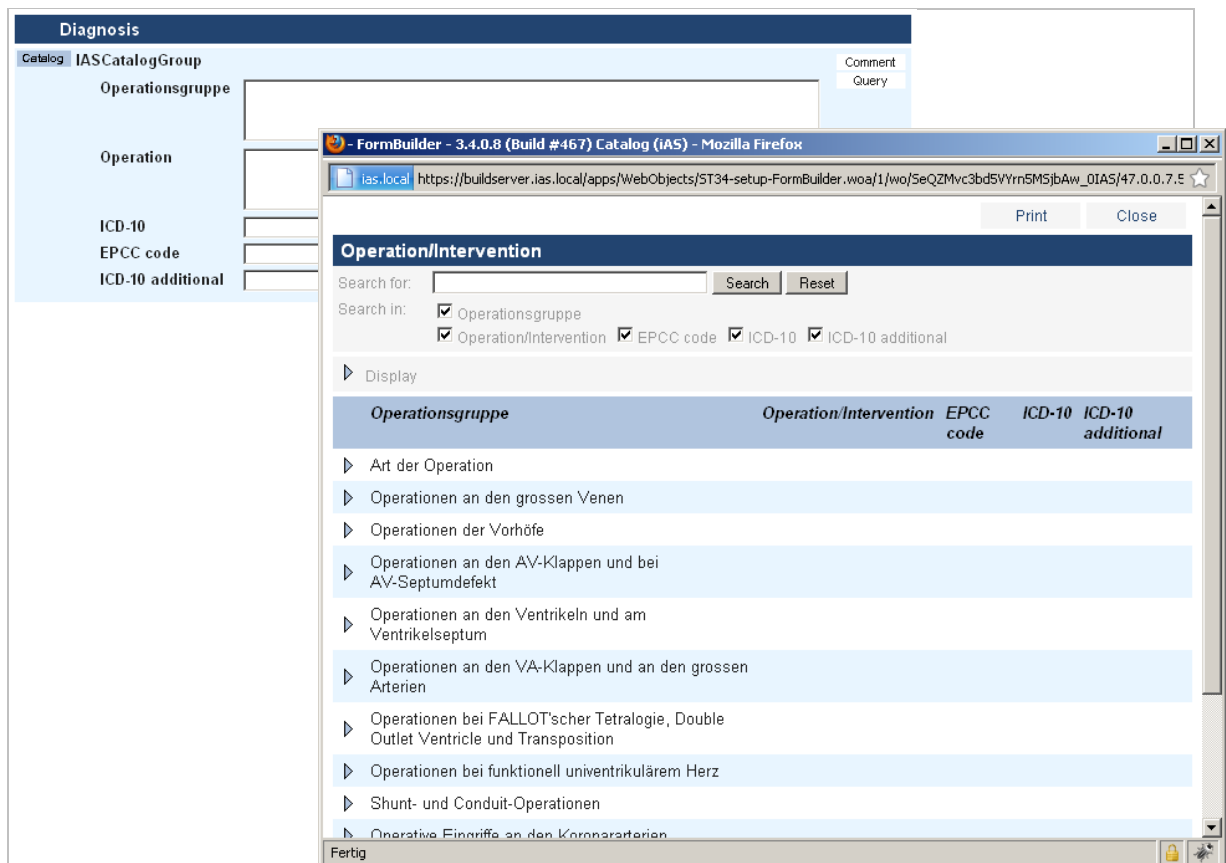


Fig. 22: Example of the view of an IASCatalogGroup with catalog pop-up (excerpt).

### Generic catalogs

- Further catalogs in a predefined CSV format (see FormBuilder user manual - Annex) can additionally be imported in the FormBuilder. The description of the layers and columns can be edited on import. Catalog contents can no longer be edited; however, catalogs can be reloaded (see below).
- Generic catalogs can be used exactly like firmly implemented catalogs, but remain restricted to the current customer.

### Reloading catalogs

- Generic catalogs can be reloaded in the FormBuilder by uploading a new CSV file. The previous version is then archived; it can continue to be viewed and also initially continues to be used in the productive area (see below).
- The relevant, current version is always used in the setup area; so that this is also used in the productive area, the relevant project must be set to productive status again. The relevant catalog version which is used is displayed at the bottom right edge in the catalog question; the relevant catalog version is also listed in the AuditTrail.



- Catalogs are only loosely linked to the form; the selected catalog contents are saved in the form as a text copy and not as a reference. On reloading, form data which have already been saved are not therefore automatically reloaded!

### Consistency check

- Non-productive: Can no longer be changed to other types as soon as a catalog field is created; the catalog can still be changed. On changing the selected catalog, all previously created catalog fields are deleted.
- Productive: Can no longer be changed.
- Only catalog fields can be created.

#### IASItemMatrix

- The IASItemMatrix provides a greater freedom in designing the eCRF layouts. It allows you to organize different item types in one table layout. Individual items can also be displayed across several columns or rows. A common heading can be displayed before each row and above each column.

Table component (new)	Headline of column 1	Headline of column 2	Comment Query
Headline of row 1	Radio button <input type="radio"/> yes <input type="radio"/> no		
Headline of row 2		Check box This is a <b>simple</b> selection option. <input type="checkbox"/>	

Fig. 23: Example of a table question component

- The items can be arranged in FormBuilder using the table layout assistant which features intuitive drag and drop functions. The initially separately created items of the question are dragged into the corresponding positions in the table. It is possible to extend the table or to merge columns and rows by selecting the table elements and moving the lines of the table. The online help instructions explain how to use the assistant.

Overview layout:

Edit ?

	Headline of column 1	line of c...
Headline of r...	Radio button (without HTML) <rb1>	
Headline of r...		Check box <cb>

+

Unused items:

Number field(without HTML) <z>		
-----------------------------------	--	--

Cancel Adopt

► CDISC ODM export annotations ...

Fig. 24: Layout assistant in FormBuilder.

- **Invisible items**: By explicitly positioning the items in the table structure, with these components it is possible to create invisible items by not assigning a position within the table for these items. These items are not displayed in the eCRF. However, these items will be treated as normal items both in

the rule evaluation and when creating queries and comments. In the implementation view, the invisible items will be listed below the displayed table in a separate section.

- **Layout-Dummy:** The label of an Layout-Dummy type item is now displayed in the complete column width of an ItemMatrix question component. For all other item types with input elements the label is only displayed in 30% of the column width.
- With an appropriate format of the dummy item HTML label, e.g. "<div style='width:100%; background-color:blue;'>my headline</div>", and a display over the complete table width (span over all included columns) the item can be used as a replacement for a subheading in an ItemMatrix question.

### Consistency check

- Non-productive: IASHorizontalGroup, IASStandardGroup, IASAlternateStandardGroup
- Productive: IASHorizontalGroup, IASStandardGroup, IASAlternateStandardGroup
- A small number of item types which are specifically linked to a question component type cannot be created in an IASItemMatrix. These include the catalogue field from the catalogue component and the conversion numeric field from the UnitGroup components.

## 2.4 Item types

- The item types are described in the sequence in which they are offered in the FormBuilder.
- Non-productive items can normally be changed to any item, unless
  - The external type prescribes a specific item type
  - The item is referenced by a rule
 Other restrictions are described under the corresponding types.
- On conversion of items, all captured test data are usually lost, as the corresponding column is deleted and recreated on changing the data type.

### Horizontal radiobutton

- The so-called radiobuttons can be used very well to operate questions which are answered according to the scheme "Yes" / "No" or "Little – medium – a lot". Only one option can ever be selected with these types. In this case, the number of selectable options (with yes/no e.g. two) and the text of the individual answer options (e.g. "Yes; no; not applicable") must be specified. This type is easy to implement and operate, resulting in a low error possibility (→ good data quality!). Many questions can be implemented in such an option form.
- In the medical data record, the selected option is saved as an integer, which is specified as "DB value" on creation of the radiobutton label. This principle also applies to pop-up items, which is why switching between these types can usually be carried out. (Whilst lookup tables, in contrast, are also stored as a number in the database, they are genuine references and are also portrayed differently in the internal secuTrial® data model.)
- This item type is portrayed horizontally.

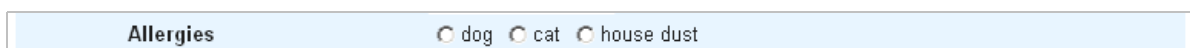


Fig. 25: Example of the view of a horizontal radiobutton.

- There are two ways to reset a radiobutton:
  - A radiobutton component without a reset option can be completely reset to NULL by double clicking on a selected answer option. This will then deselect all options in the radiobutton.

- A radiobutton component with a reset option can also be reset by selecting the radiobutton reset option. Double clicking on a selected answer option will automatically select the reset option. The position of the reset option can be placed at the beginning or the end of the defined options.

A horizontal radiobutton component for the question 'Sex'. It features three options: 'not applicable' (selected with a radio button), 'female', and 'male'.

Fig. 26: Example of the view of a reset radiobutton with the answer options female / male and the reset option at the beginning.

- The position of the reset option can also be set for the horizontal radio buttons as the first or last option.
- In the case of the radiobutton, a group of labels must be compiled in the FormBuilder. The item type and the relevant database column must be specified first, plus a relevant question text if desired. This must be saved, and the group of labels can then be edited.

The FormBuilder editing interface for a 'Horizontal-Radiobutton' item. It includes a table for defining answer options, a 'Displayed order' field, an 'Item' text field, and a 'Database column' field.

Displayed order	Label	DB value	Value for score calculation	ID
0	not applicable (Default) ?	NULL		
1	female	1		598
2	male	2		602

Additional fields: Type: Horizontal-Radiobutton, with reset option (checked), Edit group of labels (link), Displayed order: 50, shown no.: [ ], Item: Sex, Database column: gender ?

Fig. 27: Excerpt from the editing page of a horizontal radiobutton item with reset option in the FormBuilder.

- The answer option labels can be created and/or edited via "Edit group of labels". An alternative text other than "Not applicable" can be entered directly for the item in the corresponding field; this NULL option is always displayed first in the option list.
- If another text has been entered, the default text can be restored using the 'Default' button. In contrast to the default labelling, an entered text will only ever be displayed in the entered language, regardless of the currently selected user interface language.

**Welcome > Project > form family > Form > Question > Item**

**Project:** Study 1 (25.08.2010 - 15:19:59 (CEST)) { PROB - Registry / No. 2 - Development }

**Form family:** Base Examination { Visit }

**Form:** Personal Data <mnpprobersdata>

**Question:** Patient description 1 { IASStandardGroup }

**Item:** Sex { Horizontal-Radiobutton } <gender>

**Edit group of labels: "Patient description 1 - Sex <gender>"**

Inscriptions already used should not be changed contentwise.

No.	text	DB value	Conversion factor	ID	Delete from Compilation
1	female	1		598	<a href="#">Remove</a>
2	male	2		602	<a href="#">Remove</a>

[New label](#)

---

**Existing Labels: (Multiple choice with CTRL)**

cat (2 - 599)  
daily (2 - 5136)  
Delighted (1 - 5123)  
dog (1 - 603)  
g (1 - 1.0 - 5156)  
house dust (3 - 601)  
kg (3 - 0.0010 - 5158)  
mg (2 - 1000.0 - 5157)  
Mild: Rigidity detected without the activation maneuver, but full range of motion is easily... (2 - 5132)  
Mixed (4 - 5126)  
Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with... (3 - 5133)  
Mostly Dissatisfied (5 - 5127)  
Mostly Satisfied (3 - 5125)  
never (1 - 5135)  
no (2 - 600)

[Add](#)

**Unused labels in this project**

standard (1 - 1.0 - 5155)

[Delete](#)

[Cancel](#) [Save and back](#) [Save](#) [top](#)

**Fig. 28:** View of the editing page for the group of labels for the answer options of the corresponding item.

- The sequence of the answer options, plus the label text and the DB value saved in the data record can be defined. With the aid of **NEW LABEL**, it is possible to add a new label and specify a relevant DB value and conversion factor (for unit groups and score calculation). Alternatively, one or more already existing individual labels can be selected and added via **ADD**.
- The structure of the editing page is the same for both radiobutton types. The DB values which are used must be unique within a group of labels. A factor may also be additionally specified in the case of normal groups of labels for use in scores. When set, this is used to calculate the score instead of the database value. This is particularly helpful when creating (qualification) tests.

**Important:** Individual labels which are reused should only be subsequently changed with particular care, as the changes are carried out in all usages. Unclear compilations may particularly arise with subsequently changing the DB value! In the case of lists, the ID is always specified as the last numerical value to identify the various individual labels.

### Format check

- Not necessary.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup, HorizontalUnitGroup, IASVertRBMMatrix and IASHorizRBMMatrix.
- The group of labels is checked as regards the clarity of the assigned sequence, DB values and texts (distinction between capital and lower case letters). The check for unambiguousness of the text are only made as a warning,

- **Non-productive:** Cannot be changed in IASHorizRMatrix or IASVertRMatrix.
- **Productive:** Can be changed to vertical radiobutton and pop-up.

### Vertical-Radiobutton

Fig. 29: Example of a vertical radiobutton with reset option.

- The conditions which apply to the vertical radiobutton are the same as those for the horizontal radiobutton. However the layout is vertical.

### Pop-up

- Certain questions in an eCRF may have a limited and previously defined selection of possible answers. In this case, space may be saved by arranging them in a pop-up field, so that the user merely has to select the correct answer from the list during data input. In basic status, only one answer can ever be selected (otherwise, an IASRepetitionGroup must be created for repeated selection).

Fig. 30: Example of the view of a pop-up item. The question "Diagnosis" is answered by selecting an option in the selection list. The DataCapture view shows the selection list "folded down".

- Creation and editing are carried out as for the radiobutton. The text for not-selected options (data bank value NULL), Default "< Please choose >" can be configured per item as well.

### Format check

- Not necessary.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup (automatic) and IASHorizontalUnitGroup (automatic).
- **Non-productive:** Cannot be changed or deleted in IASUnitGroup and IASHorizontalUnitGroup.
- **Productive:** Can be changed to horizontal or vertical radiobutton except in IASUnitGroup and IASHorizontalUnitGroup, where it cannot be changed. Conversions between horizontal and vertical radiobuttons and pop-up items are possible as long as the external question component does not prescribe any restriction for the item types contained (e.g. only horizontal radiobuttons are allowed in radiobutton matrix components).
- The group of labels is checked as regards the clarity of the assigned sequence, DB values and texts (distinction between capital and lower case letters). The check for unambiguousness of the text are only made as a warning,

### CheckBox

- As a "non-answer" (the check box is not clicked) is also a valid statement in the case of check boxes, the rule "Input not required" is also created as specified so that the completion status takes this into consideration. If desired, of course, this rule can be removed again or edited.

**Welcome > Project > form family > Form > Question > Item**

Project: Study 1 (25.08.2010 - 18:30:32 (CEST)) { PROB - Registry / No. 2 - Development }

Form family: Base Examination { Visit }

Form: Diagnosis <mnpprobcatolo>

Question: sample { IASStandardGroup }

---

Type: \*

Displayed order:  shown no.:

Item:

Unit/format (HTML):

Database column: \*  ?

▶ CDISC ODM export annotations ...

Containing rules (1)				
Displayed order	Name	Type	Following action	Delete from database
<input type="text" value="10"/>		Input not required		<input type="button" value="Delete"/>

Fig. 31: Editing page for a check box in the FormBuilder.

Blood sample taken? ☐ yes

Fig. 32: Example of the view of a check box; the text behind the check box originates from the field "Unit/format".

- Special feature of an IASCheckboxMatrix: The same question text must be specified as the question text for all check boxes within a row in this case. In the second step, each box is then assigned with the corresponding label text. All boxes in a matrix, which are contained in the same column, must have the identical (same ID) label text. The value of the sequence, which is specified with the label, corresponds to the column number into which the check box is assigned.

### Format check

- Not necessary.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASCheckboxMatrix, IASUnitGroup and IASHorizontalUnitGroup.
- Non-productive: Cannot be changed in a IASCheckboxMatrix.
- Productive: Can no longer be changed.

## Time

- The time field is used to enable time data to be input. There are three different variants which differ depending on which time units are to be specified. In these variants, H stands for hours, M for minutes and S for seconds. In the database, time is saved in the same format as date.

Time of sampling:  -  hh:mm

Date of sampling:  -  dd.mm.yyyy

Fig. 33: Example of the view of a time and a (checked) date item.

- After selecting the item type you can define whether the formatting display should be shown next to the entry fields. The following options can be selected:
  - display
  - hide
  - display with optional fields
- With the last option, all not mandatory fields in the format will be placed in brackets. This option is not available for checked-time components.

Dates		
Only last option is mandatory:		
Hour, Minute, Second	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="button" value="Comment"/> <input type="button" value="Query"/>
Day, Month, Year	<input type="text"/> - <input type="text"/> - <input type="text"/> (tt).(mm).jjjj	
Day, Month, Year, Hour, Minute	<input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> tt.mm.jjjj hh:mm	
All options mandatory		
Hour, Minute, Second	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="button" value="Comment"/> <input type="button" value="Query"/>
Day, Month, Year	<input type="text"/> - <input type="text"/> - <input type="text"/> tt.mm.jjjj	
Day, Month, Year, Hour, Minute	<input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> tt.mm.jjjj hh:mm	

Fig. 34: Different format displays for the date components (top to bottom): hide, display with optional fields, displayed, hide, displayed, displayed.

### Item+time span / date+time span compare with value

Welcome > Project > form family > Form > Question > Item > Rule > Condition		
Project:	Study 1 (03.09.2010 - 12:12:08 (CEST))	{ PROB - Registry / No. 2 - Development }
Form family:	Base Examination	{ Visit }
Form:	Diagnosis	<mnpprobcatolo>
Question:	sample	{ IASStandardGroup }
Item:	Time of sampling:	{ Time HH:MM } <sample2>
Rule:		{ Input impossible, if... }
<hr/>		
Sequence position:	<input type="text" value="10"/>	
Error message: *	<input type="text"/>	
Parameter is read from: *	<input checked="" type="radio"/> own item <input type="radio"/> this item...	
<hr/>		
Compare or Assign Operator: *	equal value ▼	
<hr/>		
Compare Value: *	current date + timespan ▼	
Added timespan *	<input type="text" value="20"/> minutes	
<hr/>		
<input type="button" value="Cancel"/>	<input type="button" value="Save and back"/>	<input type="button" value="Save"/>
		<input type="button" value="top"/>

Fig. 35: Creation of a condition for a time item.

- In the FormBuilder, the condition "Item + time span" can be selected to create conditions for time or date items. In this case, the time span is always specified in the smallest unit of the item format. If

the compare with item e.g. has the format "DD-MM-YYYY", the time span is specified in days or, if the format is "HH-MM" in minutes.

- The same principle also applies to the *"Current date + time span"* type.
- The specified time span can be positive or negative, and is added to the item value (or current date) before evaluating the condition.

### Format check

- The format check is implemented in precisely the same way as for the date type (see below).

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.
- Non-productive: as long as an item has not been set to productive, it is possible to change the component type between "Time" and "checked Time" even if the item has been assigned rules.
- **Productive:** Can be changed to time or checked time, in which the information content is at least as large as in the productive version. I.e. *"Time HH:MM"* can be changed to *"Checked time HH:MM:SS"* but no longer to *"Checked time MM:SS"*.

### Date

- The date field is required e.g. in the question regarding the date of birth. Which scope and which format the date is to have are specified in the type selection with the letters Y, M and D for year, month and day.
- As with time fields you can define with this item type whether the formatting display should be shown next to the entry fields. The following options can also be selected here:
  - display
  - hide
  - display with optional fields
- In the database, date formats are handled as texts with a length of 14 characters with the format YYYYMMDDHHMMSS (year-month-day-hour-minute-second). There are therefore no text fields with a length of 14. Non-input fields are filled with blanks. On export, the output is usually shortened to the input format.

The screenshot shows a form titled "Personal Data" with a dark blue header. Below the header, there are two input fields. The first field is labeled "Date of birth" and contains three small input boxes followed by the text "dd.mm.yyyy". The second field is labeled "Birth place" and is a single text input box. To the right of these fields, there are two buttons: "Comment" and "Query".

Fig. 36: Example of a date field "Date DD-MM-YYYY".

### Format check

- Only numbers from permissible calendar ranges may be input, whereby the smaller fields can be left empty. In the case of a day-month-year field, only specifying the year and the month and omitting the day is permissible. Specifying the day and year and omitting the month is not permitted.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.



- Non-productive: as long as an item has not been set to productive mode, it is possible to change the component type between "Date" and "checked Date" even if the item has been assigned rules.
- Productive: Can be changed to date or checked date, in which the information content is at least as large as in the productive version. I.e. "*Date MM-YYYY*" can still be changed to "*Checked date DD-MM-YYYY*" but no longer to "*Checked date YYYY*".

#### Checked Time

- Identical to the normal time field; the difference involves the check of completion. Operates in-line with the "checked date".

#### Format check

- See checked date.

#### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.
- Non-productive: as long as an item has not been set to productive, it is possible to change the component type between "Time" and "checked Time" components even if the item has been assigned rules.
- Productive: Can be changed to time or checked time, in which the information content is at least as large as in the productive version. I.e. "*Time HH:MM*" can be changed to "*Checked time HH:MM:SS*" but no longer to "*Checked time MM:SS*".

#### Checked Date

- Identical to the normal date field; the difference involves the check of completion.

**Note:** The user cannot instantly distinguish between the simple date fields and the "*checked*" date/time fields!

#### Format check

- The difference involves the check of completion: In the case of a "checked date", all displayed fields must also be completed. In contrast, the relevant, smaller fields (e.g. omit month but specify year) can be omitted in the case of a "normal" date field. "Checked date" and normal date fields can only be compared via the set of rules if the date and/or time format matches.

#### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.
- Non-productive: as long as an item has not been set to productive, it is possible to change the component type between "Date" and "checked Date" even if the item has been assigned rules.
- Productive: Can be changed to date or checked date, in which the information content is at least as large as in the productive version. I.e. "*Date MM-YYYY*" can still be changed to "*Checked date DD-MM-YYYY*" but no longer to "*Checked date YYYY*".

#### Number

- The number item can be used to query numerical values of any size. Both the number of places in front of the point and those after the point must be defined in advance. In this case, "*Number x.y*" means: Number field with x places before and y places after the point.

<b>Measure of blood pressure</b>		<a href="#">Comment</a>
systole	<input type="text"/> mm Hg	<a href="#">Query</a>
diastole	<input type="text"/> mm Hg	

Fig. 37: Number fields with the format "Number 3.0".

Year of first diagnosis	<input type="text"/> yyyy
Dose	<input type="text"/> . <input type="text"/> number of pills per day

Fig. 38: Number field with the format "Number 2.1".

- The unit in which the input is to be interpreted can be portrayed behind the number field.
- For all number items it can be configured whether thousands should be displayed in text format with or without a thousands separator. This applies to the print view for forms, numbers displayed in the audit trail and in reports. During exports, all numbers will be exported without a thousands separator, as was the case in the past.

### Format check

- Only the input of numbers is permissible. The number's pre- and any post-decimal places are input in separate fields, with the result that the format of the decimal point is irrelevant. The only "Non-numerical" character which is permitted is a single minus symbol in the pre-decimal field.
- If the input of negative numbers is to be anticipated, it must be noted that the minus symbol is also counted as a number digit. If necessary, the pre-decimal field must then be selected one digit larger.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup (automatic creation without past-point digits) and IASHorizontalUnitGroup (automatic creation without past-point digits).
- Non-productive: Cannot be changed in IASUnitGroup or IASHorizontalUnitGroup.
- Productive: Can only be changed to a number which has at least as many or more pre- and post-decimal places as in the productive version.

### Textfield

- The text field type is used for free text data (designations, etc.). The size of the field and the maximum number of characters are coded via text field "x" with x = number of characters.
- In contrast to the TextArea, the text field is always one-line. At present, x= 1-10, 15, 20, 22, 25, 30, 35, 40, 50, 60, 70, 80 or 100 are possible.

Birth place	<input type="text"/>	<a href="#">Query</a>
Other comments:	<input type="text"/>	

Fig. 39: View of a TextField20 (above) and TextField 60 (below).

### Format check

- The input is restricted to the maximum number of defined characters. No other check regarding the type of input is carried out.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.

- **Productive:** Can be changed to TextArea or text field, in which the total text length is greater than or equal to the text length of the productive version.

### TextArea

- This field is used for free text data (comment, explanations, etc.). The size of the field and the maximum number of characters are coded via "TextArea x,y" with x = number of lines and y = number of characters.
- The following options are currently available:
 

x= 2	y= 25
x= 3, 6, 9	y= 20, 40, 60, 80
x= 4	y= 20

The screenshot shows a form titled "General examination". On the left, there is a text label "Please describe your impression of the patient's condition". To the right of this label is a large rectangular text area. In the top right corner of the form, there are two buttons: "Comment" and "Query".

Fig. 40: Example of the view of a TextArea3,40.

- As the evaluation capability of free text inputs is very limited, their use should be well considered. In addition to the option of saving in the form, the general comment function for each item exists in secuTrial® for inputting additional comments.
- When using the DDE function you can configure how a text item comparison should be carried out:
  - (compare
  - ignore case and whitespace
  - ignore completely

### Format check

- The input is restricted to the maximum number of defined characters. No other check regarding the type of input is carried out.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and HorizontalUnitGroup.
- **Productive:** Can be changed to TextArea or text field, in which the total text length is greater than or equal to the text length of the productive version.

### Lookup Table

- In the case of a lookup field, values from a database lookup table are offered to the user in a selection list. In the FormBuilder, this list is created in advance for a project as a "Imnp" table. Similar to the pop-up items, the contents are saved as references. In the case of extendable lookup tables, the user (in the DataCapture) can subsequently add values.
- Unlike pop-up items, the values in the lookup table itself are also saved in the project's medical database scheme and not in the multi-project scheme of all project setups.

The screenshot shows a form titled "Please describe a normal day of life:". It contains two main sections. The first section is labeled "Favorite activity" and has a dropdown menu with "Reading" selected and an "Others" button below it. The second section is labeled "Usual activity" and has a dropdown menu with "watching TV" selected, a "Selection" button below it, and a button with a right-pointing triangle. To the right of the form, there are two buttons: "Comment" and "Query".

**Fig. 41:** Example of the view of an extendable lookup table with the list of specified entries (top) and the view with the option of creating new entries (bottom). The drop-down lists show the correspondingly filtered selections.

- In the DataCapture, the specified entries and the values input by the participants are offered in two different lists. Switching is carried out via the SELECTION / OTHER button. In the FormBuilder, the entries are marked on the editing page of the lookup table with "FormBuilder" or "Participant".

Project: Study 1 (30.08.2010 - 17:30:46 (CEST)) (PROB - Registry / No. 2 - Development )							
Lookup tables "Study 1" (7)							
Description	Database table	Extendable	Parent table	Created	Date	Entries	Usage
Breed	Imnpbprobbreed	<input type="checkbox"/>	Pet <Imnpbprobpet>	<input checked="" type="checkbox"/>	25.08.2010 - 11:07 (CEST)	6	3
Colour	Imnpbprobcolour	<input type="checkbox"/>	Breed <Imnpbprobbreed>	<input checked="" type="checkbox"/>	25.08.2010 - 11:12 (CEST)	14	3
Favorite activities	Imnpbprobactivity	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	30.08.2010 - 17:21 (CEST)	6	2
Medicine	Imnpbprobmedics	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	02.06.2009 - 13:06 (CEST)	3	2 P
Pet	Imnpbprobpet	<input type="checkbox"/>		<input checked="" type="checkbox"/>	25.08.2010 - 11:07 (CEST)	3	3
Pregnancy	Imnpbprobpregnant	<input type="checkbox"/>		<input checked="" type="checkbox"/>	02.06.2009 - 12:40 (CEST)	2	3 P
Weeks	Imnpbprobweek	<input type="checkbox"/>	Pregnancy <Imnpbprobpregnant>	<input checked="" type="checkbox"/>	02.06.2009 - 12:40 (CEST)	5	3 P

**Description:** \* Favorite activities

**Database table:** \* Imnpbprobactivity

**Lookup type:** ☒ Extendable ☐ Simple (hierarchical)

**Created:** 30.08.2010 - 17:21 (CEST)

Entries (Setup-DB: 6)			
Displayed order *	Value *	Source	
0	Watching TV	Participant	
0	Working in the garden	Participant	
1	Reading	FormBuilder	Delete
2	Dancing	FormBuilder	Delete
3	Singing	FormBuilder	Delete
4	Knitting	FormBuilder	Delete
New value			

Cancel Save and back Save top

**Fig. 42:** Only the entries input in the FormBuilder can be edited on the editing page for all project lookup tables. The values additionally created by participants in the DataCapture can only be viewed.

- When setting projects with lookup tables to productive status, only the values entered in the FormBuilder are taken over into the productive version of the project from extendable lookup tables. Data input by participants in the test environment are ignored.

**Note** Extendibility involves the risk that the participants always simply re-enter their value instead of searching for existing entries. In the event of even slightly deviating notations (e.g. spelling errors), this then quickly leads to multiple entries of what is actually the same value. This may make evaluation unnecessarily difficult.

### Format check

- The input permits a maximum of 150 characters, whose format is not checked. Before a new entry is created, a check is carried out to determine whether the input value already exists, and this is then selected.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.
- Productive: Cannot be changed.

### Lookup Table (not extendable)

- In the case of a lookup field, values from a database lookup table are offered to the user in a drop-down list. This list is edited in the FormBuilder. It is created as a "lmp" table. As in the case of pop-up items, the contents are saved as references. The advantage of lookup tables in comparison with pop-up items is that they can be interlinked.

The image shows a form field with a light blue background. On the left, the text 'Pet' is displayed. To its right is a dropdown menu with the text '< Please choose >' and a small downward arrow. Further to the right, the text 'Family pet' is displayed, indicating the selected value from the dropdown.

Fig. 43: Example of the view of a lookup table (not extendable). The datum "Family pet" is read-out from the "Unit/format" field.

#### Format check

- Not necessary.

#### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup, IASHorizontalUnitGroup, IASCombinedSelection, IASHorizCombinedSelection and IASMultipleSelection.
- Non-productive: Cannot be changed to IASCombinedSelection, IASHorizCombinedSelection or IASMultipleSelection.
- Productive: Cannot be changed.

### Score (only calculated)

- For a more detailed description, see "Scores" at the end of the document. Scores are saved as number fields in the database. The accuracy or pre- and post-decimal places arises from the fields and formulae used for the calculation.
- If a value is read-out from a radiobutton or pop-up item to calculate a score, the entered conversion factor is used, if one has been defined, instead of the DB value of a label (label=answer option). In the case of e.g. evaluations, this can be used to evaluate just one of several possible answers as "correct" (=1) and all others as "incorrect" (=0) in order to then count all correct answers.

#### Configuration of the post-decimal places

- The number of post-decimal places can be configured in the FormBuilder. If no configuration is carried out in the FormBuilder, the number is determined as follows:
  - If a division operator is used, at least two post-decimal places are calculated.
  - At least the number of post-decimal places in the used number input fields are used.
  - In the case of a simple score, at least 0 post-decimal places are used; in the case of the normed score or the score function, at least two post-decimal places.
- The highest number from the upper three specifications is taken.
- If 0 has been determined as the number of post-decimal places, all calculated post-decimal places are displayed precisely as they are calculated (necessary on use of a point conversion factor with a score via radiobuttons).

#### Format check

- During calculation, division by 0 is checked and an error message is displayed instead.

#### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup and IASHorizontalUnitGroup.

- Non-productive: Cannot be changed as long as score rules are created for this item.
- Productive: Cannot be changed.

#### Time-Interval / Date-Interval

- The time/date interval field can be used to calculate time intervals. On creation of such an item, the calculation rule "Calculate date/time interval from..." is also automatically created. Precisely two time fields, between which the interval is to be calculated, must then be created as a condition for this rule.

The following interval formats are available for selection:

- Time interval H-M (calculated only)
  - Time interval H-M-S (calculated only)
  - Time interval M-S (calculated only)
  - Date interval Y (calculated only)
  - Date interval Y-M (calculated only)
  - Date interval Y-M-D (calculated only)
  - Date/time interval Y-M-D-H-M (calculated only)
- Calculation of the interval is carried out in the form via a score button as in the case of the numerical scores. The calculated value is portrayed in text form. The search for interval fields is carried out by inputting individual values per interval field.

#### Format check

- Not necessary.

#### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup, IASHorizontalUnitGroup
- Non-productive: Cannot be changed as long as score rules are created for this item.
- Productive: Cannot be changed.

#### Date score fields for calculation in numbers

- With date score fields, time interval calculations are carried out between two dates. The determined intervals are expressed as numbers for the purposes of further calculation. The unit of measurement is the smallest time unit entered. If the date value is entered as "dd, mm, yyyy", the result is calculated in days. When this item is created, the calculation rule "Date and time interval is calculated from ..." is automatically created at the same time. For this rule there are then two time fields which must be set up as a condition for making the calculations.
- Seconds M-S (calculated only)
  - Seconds H-M-S (calculated only)
  - Minutes H-M (calculated only)
  - Minutes Y-M-D-H-M (calculated only)
  - Days Y-M-D (calculated only)
  - Months Y-M (calculated only)
  - Years Y (calculated only)

- The interval calculation is carried out in the form via the score button, just as with the numerical scores. The calculated value is displayed as text. A search for the interval field is performed by entering numerical values or value ranges, just as with numerical fields.

### Format check

- Not necessary.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IASUnitGroup, IASHorizontalUnitGroup
- Non-productive: Cannot be changed as long as score rules are created for this item.
- Productive: Cannot be changed.

### Configurable Randomization-Button

- This button makes it possible to randomly distribute patients in one of two or more groups. In order to use the configurable randomization button, configurable randomization must be set up in the project. This option enables multiple randomizations. To do this, multiple randomization buttons can be created which can then be individually configured with regard to randomization algorithm, randomization groups and randomization stratification.
- This item component can be used in two different ways:
  - **Randomization per button:** When used in forms without "*Randomization*" processing, the randomization is performed in DataCapture by clicking on the button. It is saved immediately, independent of the form data.
  - **Randomization by saving:** In forms with "*Randomization*" processing, the button will not be displayed on the component. Instead, the randomization will be performed when the form is saved.

**Note:** Even if the randomization button is displayed in multiple visits via one and the same visit form, the randomization process can only be performed once for the individual component.

- After the project has been set to productive mode, it is no longer possible to change the basic configuration of the randomization button (algorithm, groups and stratification)

**Exception:** The stratification factors for *Range minimization* and *Variance minimization* can now be edited even if the randomization button has already been set to productive mode. The existing stratification factors can be edited or deleted and new stratification factors can be created. Please consider the consequences of any configuration change carefully!

- For every randomization button, a message can now be defined that can be triggered directly with the randomization of a patient and independently from or depending on the number of possible randomization options remaining.

### Different randomization algorithms

- The available configuration options for the randomization button depend on which algorithm has been selected.
- For implementing the configurable randomization, the following algorithms are available: The mathematical implementations of algorithms 2 to 7 were carried out by the Swiss Group for Clinical Cancer Research (SAKK).
  1. Extended stratified block without list (secuTrial®)
  2. Range minimization
  3. Variance minimization

4. Static unstratified single block randomization
  5. Static unstratified multi block randomization
  6. Static stratified block randomization
  7. Simple randomization
  8. External randomization (using list imports)
- In the following, the basic statistical principles and the configuration options of the various algorithms are explained.
  - Minimization (2, 3) is only used in stratified situations. This procedure uses different stratification factor levels and the stratification data of the patients instead of lists. The intention behind this is to achieve balanced ratios in every stratification factor level, which also leads to a balanced relationship within the entire patient set. A disadvantage of this procedure is that there is a possibility that the relationships cannot be achieved if there is only a small number of patients in a stratification factor level. An additional disadvantage is that strictly speaking it is deterministic and you could calculate the assignment of the next patient if you had knowledge of the patient data. You can get round this predictability issue by additionally configuring the random element.
  - The difference between range minimization and variance minimization is the distance deviation. It can be calculated how far away you are from a balanced situation if you put the patient in a certain arm. The issue of “how far away” is a question of metrics. Essentially, the range method corresponds with the 1-Norm, the variance method with the 2-Norm. The variance method is easier to calculate (in principle you do not need to look at the  $n+1$ . patients). The differences should be very small. The variance method tends to be slightly better.
  - Block randomization (4, 5, 6) requires lists to be defined beforehand (with one or more blocks) and can be used in stratified and unstratified situations. The purpose of this procedure is to achieve a certain distribution within a block and within the entire patient set. The advantage is that randomization lists can be created in advance.
  - Procedures 4 and 5 differ in the number of blocks to be specified within a list and are used in unstratified situations. If a new patient is being randomized, that patient will be assigned to the next available list element (treatment arm) of the current block. To avoid predictability it is therefore advisable to select different block sizes (procedure 5 also permits random generation of block sizes).
  - Procedure 6 is a stratified situation. A randomization list is created for each combination of the stratification factor levels of the patients. When a new patient is randomized, the list which corresponds to the patient's stratification factors will be selected first. Next, the patient is assigned to the next available list element (treatment arm), as in method 4 and 5. If there is a large number of stratification factor level combinations, the risk arises that only a few patients from certain lists will be processed, which can lead to an increased risk of incomplete lists and unbalanced relationships within the treatment arm.
  - Simple Randomization (7) is simplest mode of randomization. Patients are randomly assigned to a treatment arm.
  - By selecting external randomization (8) it is possible to also use any additional algorithms of your choice by importing lists accordingly.

### **1. Extended stratified block without list (secuTrial)**

- This is a block algorithm without a predefined list which guarantees an even distribution of the randomization groups. All previously randomized patients are taken into account, if applicable only patients from the same stratum. These patients are evaluated in the order of their randomization to determine the sequence of the previous random groups.



- The number of possible randomizations is only restricted if the randomization is carried out in blinded form or with the help of a centre assignment.

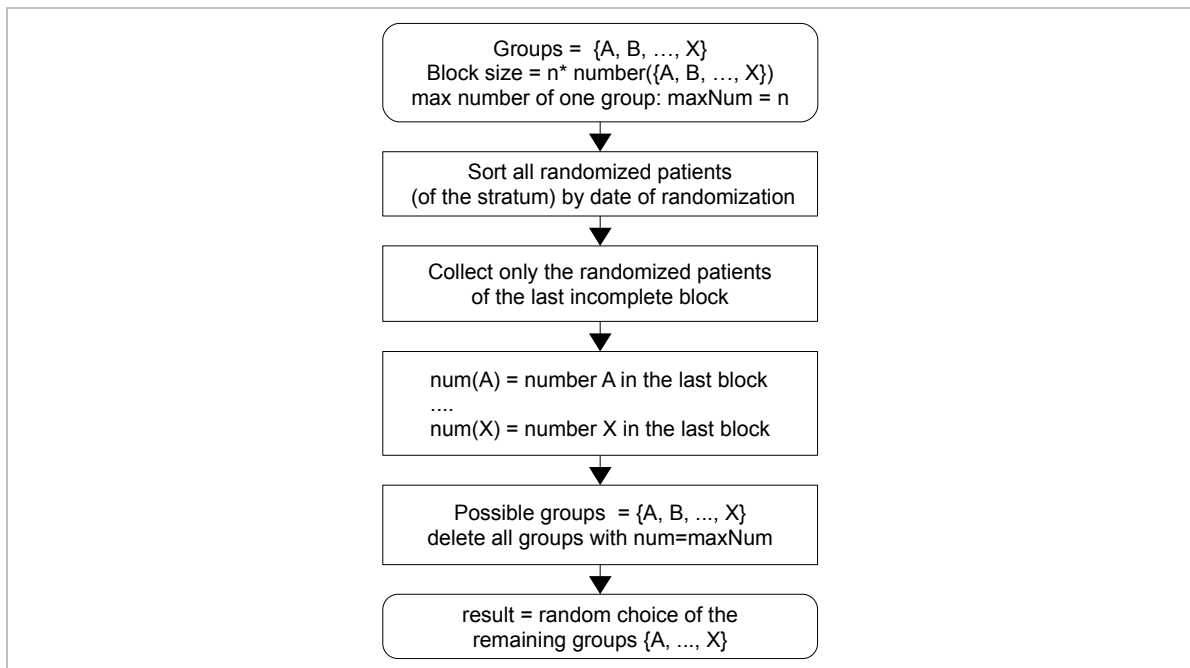


Fig.44: Determination of randomization with “Extended Stratified Block without list (secuTrial)” algorithm.

Block size:	Only multiple totals of the number of randomization groups can be defined.
Randomization groups:	At least two.
Weighting of the groups:	All groups equally frequently (1:1).
Stratification:	Possible: only the patients from the same stratum are used for determining the randomized patients of the last incomplete block.
Randomization list:	Only for blinding or with centre assignment.

## 2. Range minimization

- This algorithm evaluates all of the previously randomized patients from the same stratum for the randomization of the current patient. The distribution of the groups can be configured. Optionally the maximum number of patients to be randomized in the selection can be limited. The ratio of the various randomization groups to each other must remain within this number.

Probability:	Probability of 0-1 with which the randomization group determined by the algorithm will not be selected. With this random element the predictability is minimized.
Randomization groups:	At least 2.
Weighting of the groups:	Entry possible as ratio
Stratification:	Necessary. All randomized patients from all strata are required to determine the randomization.
Randomization list:	Only for blinding or with centre assignment.

## 3. Variance minimization

- This algorithm evaluates all of the previously randomized patients from the same stratum for the randomization of the current patient. The distribution of the groups can be configured. The maximum number of patients to be randomized can be optionally limited in the selection. The ratio of the various randomization groups to each other must remain within this number.

Probability:	Probability of 0-1 with which the randomization group determined by the algorithm will not be selected. With this random element the predictability is minimized.
Randomization groups:	At least 2.
Weighting of the groups:	Entry possible as ratio.
Stratification:	Necessary. All randomized patients from all strata are required to determine the randomization.
Randomization list:	Only for blinding or with centre assignment.

#### **4. Static unstratified single block randomization**

- This algorithm is based on a two-step procedure: first a randomization list is generated, which is then simply processed in sequence during the actual randomization. For the distribution of the groups in the list, various entries must be made. The distribution is only guaranteed within the list.

Restriction:	"restricted" or "unrestricted". With a restricted list the entered ratio correlates exactly. With unrestricted lists small deviations are possible.
Group allocation by:	"Accrual" or "Ratio" (see below).
Randomization groups:	At least 2.
Weighting of the groups:	"Accrual": specification of the number of patients per group, "Ratio": specification of the ratio of the groups to each other (specification of the number of patients when generating the list in the AdminTool).
Stratification:	Not possible.
Randomization list:	Required, created in the AdminTool.

#### **5. Static unstratified multi block randomization**

- This algorithm is based on a two-step procedure: first a randomization list is generated, which is then simply processed in sequence during the actual randomization. For the distribution of the groups in the list, various entries must be made. Depending on the configuration, the distribution is only guaranteed within a block.

Block size determination:	"fixed" or "variable".
Block size:	Entry required for "fixed" determination.
Multiplier:	Entry required for a "variable" determination. Here the block sizes are selected randomly with the size between block size and (multiplier * block size).
Restriction:	"restricted" or "unrestricted". With a restricted list the entered ratio correlates exactly. With unrestricted lists small deviations are possible.
Group allocation by:	"Accrual" or "Ratio" (see below).
Randomization groups:	At least 2.
Weighting of the groups:	"Accrual" specification of the number of patients per group, "Ratio": specification of the ratio of the groups to each other (specification of the number of patients when generating the list in the AdminTool).
Stratification:	not possible.
Randomization list:	required, created in the AdminTool.

#### **6. Static stratified block randomization**

- This algorithm is based on a two-step procedure: first a randomization list is generated, which is then simply processed in sequence during the actual randomization. For the distribution of the groups in the list, various entries must be made. The distribution is only guaranteed within the list. The lists for the different strata are saved one after the other in a list. For the stratification, via the data of the current patient only the respectively applicable section of the complete list is determined and then assigned

Restriction:	"restricted" or "unrestricted". With a restricted list the entered ratio correlates exactly. With unrestricted lists small deviations are possible.
Group allocation by:	"Accrual" or "Ratio" (see below).
Randomization groups:	At least 2.

Weighting of the groups:	"Accrual": specification of the number of patients per group, "Ratio": specification of the ratio of the groups to each other (specification of the number of patients when generating the list in the AdminTool).
Stratification:	Required.
Randomization list:	Required, created in the AdminTool.

## 7. Simple randomization

- This very basic algorithm simply involves the random selection of one of the defined randomization groups. It does not take into account any other ancillary conditions, ratios or previously conducted randomizations. The number of randomizations is only limited if the randomization is blinded.

Randomization groups:	At least 2.
Randomization lists:	Only for blinding.

## 8. External randomization (using list import) #5481

- The randomization algorithm is pre-defined by the order of the groups in the imported list. The randomization itself then follows the second step of the block list randomization: for the stratification, via the data of the current patient only the respectively applicable section of the complete list is determined and then assigned.

Randomization groups:	At least 2.
Stratification:	Possible. If stratification factors are entered, only the corresponding section of the imported randomization list will be used for the randomization.
Randomization lists:	Required, imported in the AdminTool.

### Stratification factors

- The use of stratification factors differs according to the algorithm. Stratifications factors can only be defined from visit forms or casenode forms.

### Evaluation of the current patient only

- With *external randomization* and the *static stratified block randomization* the stratification is only evaluated for the current patient. With these algorithms, for randomization buttons in a simple form, a relative visit must be entered as the source for the stratification factors, just like with rule conditions. This is only necessary if the stratification factor is determined from a visit form.
- With a randomization button in a randomization form, the stratification factors are always evaluated from the current form, regardless whether the form is contained within a visit and which visit.

### Evaluation of all randomized patients

- For the algorithms *extended stratified block without lists (secuTrial)*, *range minimization* and *variance minimization*, the stratification factors for all other patients are required in addition to the stratification factors for the current patient.
- It is not possible to enter a relative visit because no currently edited visit exists for the other patients. With these algorithms, for the stratification factors an absolute visit must be selected from the project visit templates. If the visits can be created multiple times, the first chronological visit of the selected type will always be evaluated for the stratification.
- If the stratification factor for a randomization button is determined in a randomization form, it will not be possible to enter the visit. For the current patient the factors will then always be determined by the current entry in the current form. For all other patients the value will be evaluated from the first chronological visit of the current visit type.

## Factor level definition

- For item stratification factors, at least one factor level must be defined. The levels are formed from logical expressions and each current value of the patient is represented in the expression by the term "value". Capitalizations of "value" and empty spaces before or after the operator are ignored.
- The database equivalents of each item are to be entered as comparative values. Radiobuttons and pop-up items, for example, are to be entered with the DB values. Fixed comparative texts are to be enclosed in single apostrophes or double quotation marks. With numbers, decimal points are to be entered with a period. secuTrial® date items are saved as text in the format: 'YYYYMMDDHHMMSS'. Empty spaces must be entered for fields without entries.
- The following types of comparison values are possible:
  - **Boolean literal (TRUE, FALSE)** The two Boolean Literals correspond with the "true" or "false" condition.
  - **Integer Literal (1, -5, 12340)** Whole numbers without further entries are calculated as integer literals.
  - **Double Literal (1.0, 3.1415, 1e-35, 2.3e6)** Numbers with a decimal point or exponential representation in scientific notation are calculated as double literals.
  - **String Literal ("some text", 'a label')** Text in double (") or single (') quotation marks is calculated as a string literal.
- As comparative operators the following entries are possible:
  - **x = y, x == y (equality)** Tests the equality of x and y
  - **x != y, x <> y (inequality)** Tests the inequality of x and y
  - **x > y (greater than)** Tests if x is greater than y
  - **x >= y (greater than or equal to)** Tests if x is greater than or equal to y
  - **x < y (less than)** Tests if x is less than y
  - **x <= y (less than or equal to)** Tests if x is less than or equal to y
  - **x AND y, x && y (and)** Tests x and y (equally true)
  - **x OR y, x || y (or)** Tests for x or y (equally true) or both
  - **NOT x, !x (not)** Tests for the negation of x (not equal to true)
  - **x XOR y (exclusive or)** Test for x or y (equal to true), not both
  - **IF test THEN x ELSE y (if-then-else)** Evaluates the expression "test"; if this is true, then the expression x is evaluated, otherwise the expression y
  - **() (parentheses)** Groups together expressions to force a sequence of evaluation. For example, the expression 1+2\*3 yields the result 7, whereas the expression (1+2)\*3 yields the result 9.
- Additional arithmetic operators are:
  - **x + y (addition)** Add x and y
  - **x - y (subtraction)** Subtract y from x

- $x * y$  (multiplication) Multiply x and y
- $x / y$  (division) Divide x by y
- $x ^ y$  (exponential, pow) Raise x to the exponent y
- $x \% y$  (modulo) Produces the remainder of the division of x by y

### Examples:

- Level for the item "Gender" which is coded with "male" (0) and "female" (1):
  - value = 0
  - value = 1
- Level for a measurement value item which is entered as a number with 3 decimal places:
  - value = 2
  - value >= 3.14
- Level for the item 'year of birth' which is entered as a year:
  - value < '1950 '
  - value >= '1950 ' AND value < '1960 '
  - value >= '1960 '

### Information on the randomization basis

- For randomizations using a *minimization* algorithm or the *extended stratified block without lists* (*secuTrial*) algorithm, the randomization information used as the basis for the randomization is now additionally saved as an entry in the database (*Tpxrandomize.randominfo*).
- Displaying this information has not yet been implemented.

### Example minimization (with omission of the tuple list):

```
Parameter: stratification factors
Age
    ([Age] >= 27 AND [Age] <= 32)
    ([Age] >= 33 AND [Age] <= 38)
    ([Age] >= 39 AND [Age] <= 44)
    ([Age] >= 45 AND [Age] <= 50)
Hospital
    [Hospital] = 'CN'
    [Hospital] = 'RU'
Language Score
    [Language Score] = 'L'
    [Language Score] = 'M'
    [Language Score] = 'H'
Sex
    [Sex] = 'M'
    [Sex] = 'F'

Parameter: treatmentArmsName
[A, B, C]

Parameter: allocatedPatients
Table[Age(int), Sex(class java.lang.String), Language Score(class java.lang.String), Hospital(class java.lang.String), UPN(int), Treatment Arm(class java.lang.String)]
Tuple[47,M,L,CN,1,B]
Tuple[47,F,H,CN,2,A]
Tuple[41,M,L,CN,3,C]
Tuple[38,F,H,RU,4,B]
Tuple[45,M,M,CN,5,C]
Tuple[27,M,L,RU,6,A]
Tuple[46,M,M,CN,7,B]
Tuple[49,F,M,CN,8,C]
Tuple[45,F,L,CN,9,C]
...
Tuple[47,M,M,RU,544,B]
Tuple[31,F,H,CN,545,C]
```

```

Tuple[38,M,L,RU,546,C]
Tuple[47,F,L,CN,547,C]

Parameter: newPatient
Patient: 548
Table[Age(int), Sex(class java.lang.String), Language Score(class java.lang.String), Hospital(class java.lang.String)]
Tuple[29,M,M,CN]

Parameter: treatmentArmWeighting
[1.0, 4.0, 5.0]

Imbalance Scores:

5.350000000000001 4.149999999999999 4.75

Considered TreatmentArms:

A    B    C

Stratum Matrix:

15   59   75
28   108  135
21   86   107
27   106  133

Chosen Treatment Arm: B

```

### Example "Extended stratified block without list (secuTrial)":

```

(centre-) casenodes:
1 cnid: 606      centre: Test      randomgroup: A test      assigndate: 2012-04-04 12:14:57
Etc/GMT
2 cnid: 607      centre: Test      randomgroup: B test      assigndate: 2012-04-04 12:19:03
Etc/GMT
3 cnid: 608      centre: Test      randomgroup: B test      assigndate: 2012-04-04 12:30:53
Etc/GMT
4 cnid: 609      centre: Test      randomgroup: A test      assigndate: 2012-04-04 12:43:00
Etc/GMT
5 cnid: 610      centre: Test      randomgroup: A test      assigndate: 2012-04-04 12:52:08
Etc/GMT

predicates (item strata):
[mnpias0demographie_sex] = 2
[mnpias0demography_year of birth] >= '1960      '

randomgroup-list of strata:
1:      A test

randomgroup-count:
A test  -> 1
B test  -> 0

```

### Format check

- Not necessary because no user entries or selections are made.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup and IASHorizontalGroup.
- Productive: With the exception of the randomization messages, the names of the randomization groups and the import identifier for stratification factors are all important configuration settings for randomization and cannot be changed after the item has been set to productive.
- In addition, there are also a number of tests beforehand to ensure that the overall configuration remains consistent.
- When copying or importing forms with randomization buttons between projects where different randomization configurations have been selected or in form families where randomization is not permitted, the randomization buttons may not be copied or imported as well.

- **Project:**  
the project settings for simple and configurable randomization (with optional blinding) cannot be changed if a corresponding randomization button still exists in the project.
- **Form:**  
it is not possible to simultaneously configure a form as a DDE form and a randomization form.
- In a randomization form, stratification factors can only be specified if no relative or absolute visit has been entered. The factors for the current patient are always taken from the current entry in the randomization form.
- **Button:**  
The stratification factors for a randomization button in a form which has not been additionally defined as a randomization form can only be taken from other forms. This guarantees that the randomization is implemented on the basis of saved stratification factors.
- **Randomization lists:**  
If a randomization button is deleted, any randomization lists which have already been uploaded will also be deleted. Randomizations which have already been executed for test patients will also be deleted. This is only possible in the setup area.
- If only individual stratification factors or levels are deleted from a randomization definition, the corresponding references to these stratification factors in the randomization list will also be deleted. In this case, previously executed randomizations in test patients will not be deleted.

#### Simple Randomization Button

- If you only require a simple randomization without the additional options of the configurable randomization button, this button enables you to distribute patients randomly into one of two groups. To use the simple randomization button, simple randomization must first be configured in the project and the names of the two randomization groups must be specified.
- The equal distribution basis for randomisation can be configured in the FormBuilder. You may select whether the patients are to be randomized per centre or project.
- After pressing the randomisation button, this disappears and the randomly generated subdivision into a group appears. This assignment is immediately saved as a patient property by clicking the button!



**Fig. 45:** Various views of the randomisation button: The button prior to randomisation is shown on the left; after randomisation and saving the form, the randomisation group is portrayed as a text instead of the button (right).

- The algorithm for determining a patient's membership of one of the randomisation groups is based on the basis of 4 and can be summarised as follows:
  - If an equal number of patients are contained in the randomisation groups, the probability of assignment to one of the two groups is 50:50.
  - If group A has more patients than group B, the probability of the next patient's again being assigned to group A is only 10:90.
- In the event of an imbalanced distribution, which is irrespective of the number of patients already contained in the groups, a very low number of participating patients may lead to very imbalanced distribution into the individual groups. However, the above described procedure almost always guarantees equal distribution even in the case of a low basic population of test persons.
- Each patient can only be assigned to a group once, as the result of random subdivision is saved immediately. As long as the relevant form has not yet been saved, the note "Not saved" is output be-

hind the portrayal of the randomisation group. The name of the randomisation group is additionally stored in the form in a text field with a length of 5.

- The allocated group is displayed in brackets in the DataCapture behind the patient's pseudonym.

#### **Format check**

- Not necessary, as no user inputs or selection take place.

#### **Consistency check**

- Can be created in IASStandardGroup, IASAlternateStandardGroup and IASHorizontalGroup.
- Productive: Cannot be changed.

#### **DB-Dummy**

- This component can only be created in an UnitGroup question component and will be created automatically as a third item during creation of a new UnitGroup. This component contains no input field or user interface at all, only a database column. In this column the user entry of the number input field of the UnitGroup is stored.
- If a UnitGroup contains a DB-Dummy component with a stored user input value, this value is directly displayed in the number input field without any recalculation. The calculation into the reference value of the UnitGroup is only done for the storage of the reference value (in the database column of the number field), not for the redisplay of the user input value (in the number field).
- No rules can be created on a DB-Dummy component. Rules for checking the reference values can be created on the number field of the UnitGroup.

**Note:** It is recommended to use a DB-Dummy component in all UnitGroups to store the user entered input directly!

#### **Format check**

- Not necessary, as no user inputs or selection take place.

#### **Consistency check**

- Can be created in IASUnitGroup and IASHorizontalUnitGroup.
- Productive: Cannot be changed.

#### **Layout-Dummy**

- This component contains no data input and is used to structure the layout in the form as a place holder. If you always have three items, and two items in only one question, e.g. in several IASHorizontalGroups lying beneath each other, this component can be created there as an additional 3rd item. The alignments are therefore maintained in the form layout.
- This component can be labelled and a desired width in pixels can be specified. On use as a pure place holder, however, this is not necessary.



Fig. 46: View of two IASHorizontalGroups, the lower one with integrated layout dummy. Labelled here for purposes of clarity.

### Format check

- Not necessary, as no user inputs or selection take place.

### Consistency check

- Can be created in IASStandardGroup, IASAlternateStandardGroup, IASHorizontalGroup, IAS-UnitGroup, IASHorizUnitGroup.
- Non-productive: Can be changed to all item types which are permitted in the question.
- Productive: Cannot be changed, but deleted.

### Image

- This component consists of a display area for the image / file symbol, whose size can be defined from 48x48 to 2000x2000 pixels. A link / button for uploading files is available. The file last saved is portrayed beneath the display area with original file names and information of file and image size.

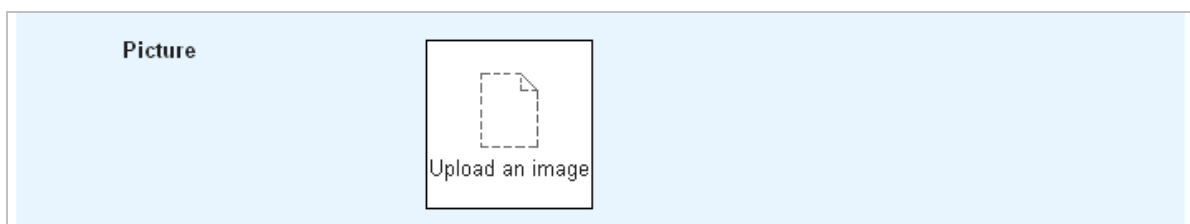


Fig. 47: View of an image component in the DataCapture before an image was uploaded.

- Arbitrary files can be uploaded in the image component. If this involves standard image formats (e.g. jpg, png, gif), these are stored in triplicate on the server:
  - Original file, can be downloaded again in this form
  - Web view for displaying in the form, scaled to the size defined for the item
  - Thumbnail for displaying in the AuditTrail and as a form icon, size 48x48 pixels.
- All other formats are stored only as original files on the server and are symbolised by an icon in the other locations.
- An applet is available for both uploading and displaying when processing DICOM images. On uploading, the personal data in the DICOM header and DICOMDIR are pseudonymised. Individual DICOM images or entire series can be uploaded; these are then stored in a zip file on the server together with a newly generated DICOMDIR file.

**Note:** The applet viewer is unsuitable for diagnosis!

- When using the DDE function you can configure how an image item comparison should be implemented:

- compare (text only)
  - compare including hash values or
  - ignore completely.
- The comparison with the hash value takes into account the checksum of the image binary data which is saved when uploading. This can be used as a type of image-content comparison. In a normal comparison, only a text representation of the image is compared with the image name, image size and file size.

### Format check

- In principle, any files can be uploaded, although this component has primarily been developed for the portrayal of images. Other file types are then symbolised via icons. The uploaded images are scaled and converted for displaying. Editing is carried out either via the integrated Java functions or the external programme ImageMagick.

### Consistency check

- Use only in saved forms and not in subforms.
- The *Image* component can also be used outside of *Image* families, but this component can only be configured in these to portray a form thumbnail.
- On use of rules, the image item can only be compared with the value "NULL". Testing can therefore only be carried out to determine whether an image is present.
- The displayed size in the form can be changed but the changes only apply for new uploaded forms. Existing forms are displayed in the form they have been created during upload.
- Non-productive: Can be changed to all item types which are permitted in the question.
- Productive: Cannot be changed.

### Catalogfield

- The catalog field can only be created in an IASCatalogGroup. The catalog elements which can be selected here are dependent on the question's catalog. The catalog layer and precisely which information is to be read-out from this layer must be determined in the item. The options for this vary depending on the catalog.
- The type and size of the input field portrayed in the form vary depending on the catalog definition and the selected catalog column. On use in the DataCapture, both direct input and selection via the catalog pop-up are possible.

Fig. 48: Example of the creation of a catalog field in the Operation/Intervention catalog in the FormBuilder.

- In the example in Fig. 43, the value is read-out from the Operation/Intervention layer; in this case, the information from this layer is the IPC-10 code.
- In contrast to lookup tables or pop-up items, the selected catalog values are saved verbatim in the form data record. This leads to the fact that the form inputs are independent of catalog changes. The catalog entries can be changed in the FormBuilder with the aid of catalog reloading.

### Format check

- On saving, a check is carried out to determine whether all inputs are also present in the specified location in the catalog. A check is also carried out to determine whether the combination is present in precisely this manner. Non-specified, upper layers are additionally added. Non-specified, lower layers can be left free.

### Consistency check

- Can be created in IASCatalogGroup only.
- Non-productive, productive: Cannot be changed.

## 2.5 Layout note

- Questions can be created with several items. In this case, almost any combination of individual types is possible. To obtain the most uniform eCRF layout possible, it is advisable to formulate the questions and answers on the same layer wherever possible:
- In the example below, the formulations "Sex", "Date of the examination" and "Allergies" have been specified on the "Question" layer. The fourth IASStandardGroup contains no displayed question text. Only a text, which is displayed in the ExportSearchTool to enable the selection of questions, has been input in the FormBuilder in this case. The questions "Dog", "Cat" have been input on the layer of the relevant items. All answer options have been specified on the items layer.

<b>Demographic Data</b>	IASHeadline
<b>Sex</b> <i>Horizontal-Radiobutton</i> <input type="radio"/> female <input type="radio"/> male	IASStandardGroup
<b>Date of examination</b> <i>Date DD-MM-YYYY</i> <input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	IASStandardGroup
<b>Allergies</b> If YES please specify below. <i>Horizontal-Radiobutton with Reset</i> <input checked="" type="radio"/> not applicable <input type="radio"/> yes <input type="radio"/> no	IASStandardGroup
<b>Dog</b> <input checked="" type="radio"/> not applicable <input type="radio"/> yes <input type="radio"/> no <b>Cat</b> <input checked="" type="radio"/> not applicable <input type="radio"/> yes <input type="radio"/> no <b>Others:</b> <i>Textfield 40</i> <input type="text"/>	IASStandardGroup

Fig. 49: Structure of a form with the aid of a combination of various item types.

### HTML formatting

- Only pure text can be input in normal input fields in the FormBuilder. In this case, and source material formats cannot be taken over. In contrast, German umlauts are automatically accepted.
- In certain fields which require frequent formatting (above all help texts), text can be formatted with HTML tags. The fields are marked with *(HTML)* behind the field designation. However, knowledge of these tags is required for this. The most important of these will be presented in the following.

#### Special characters:

Ä &Auml;  
 ä &auml;  
 Ö &Ouml;  
 ö &ouml;  
 Ü &Uuml;  
 ü &uuml;  
 ß &szlig;  
 < &lt;  
 > &gt;  
 & &amp;  
 " &quot;

#### Font markups:

- In the case of the following tags, it must be noted that they must usually have one code at the beginning (<x>) and one at the end (</x>) of the marked section, hence the notation.

<b>Bold</b>  
 <i>Italics</i>

#### Paragraphs

- Break: A return is activated with <br/> at the end of the line. Attention: Contrary to the rule, a break must never be closed (</br>)!
- Paragraph: Alternatively, enclosed paragraphs can be identified with a <p> before and a </p> after the paragraph.

<p>It is best to compare the result in the preview at an early stage.</p>

#### References

- References to static sites outside of secuTrial® can be inserted using the following specification:  
 <a href="http://www.example.com" class="underline">Reference text</a>

- Specifying "class" is optional. References are never portrayed underscored by the secuTrial® standard design; if you would like to insert the classic underscore here, this can be achieved using the above specification.

### 3. Rule types

- The FormBuilder is used to create the form description for the DataCapture. This not only enables the creation of the design and the assignment to the database fields; data input can be checked using an extensive and complex set of rules. This leads to a significant improvement in data quality.
- However, the diverse options for determining rules can also lead to undesired effects if these are not configured correctly. The intention of this document is therefore to attempt to describe the effects of the individual rules in greater detail.
- Rules can be subdivided according to various aspects, both according to the necessity of conditions and also according to their effects. The rules are described here in alphabetical sequence.

**Important:** To prevent application errors in the productive area, the rules and their effects should be extensively tested in the secuTrial® test area!

#### Consistency check

- In contrast to the upper layers of the form descriptions, rules can also always be deleted after setting to productive status, as this does not result in any data loss. As the conversion of rules leads to numerous complications, this is generally prohibited by the consistency check. In this case, the rule must simply be deleted and recreated in the desired form.
- Otherwise, rules also affect the deletion capability of form elements, which may lie in completely different project setup locations, particularly when form items are referenced within them.

**Example:** If, e.g. the "Entry" form contains the question "Did XY participate in the examination?" and a later "Laboratory" form contains the question "XY examination results", it should only be possible to complete this if the first question was answered "Yes". This condition can be simply created using the set of rules: The rule *"Input only possible if ..."* is created with the condition item "Entry-participation-xy"="Yes" for the corresponding items in the "Laboratory" form. In turn, this reference then means that both the item containing "Did XY participate in the examination?" and the entire form can no longer be deleted. In the FormBuilder, this restriction is displayed with the note *"(Not deletable because of references)"*. The references can be viewed in detail by opening the references popup linked to the undeletable note.

#### 3.1 Rule types and conditions

- One or more rules can be created for each database field, i.e. for each item. The rules which can be used are often restricted by the type of item or the database field.
- The „Hide when“-rule can be created also for all question types, including headlines (IASHeadline).
- A rule usually describes the effect which is to occur on fulfilment of the rule. Further conditions which describe the prerequisites under which the rule is fulfilled are usually required to fulfil the rule. These rules are marked in the text with *"If ..."*.
- The following generally applies: Rules are linked by AND, conditions by AND and OR. Rule conditions are evaluated in the order they were created and logically linked. When setting 'or' conditions, only one condition must be met to fulfil the rule. In contrast, in order for a question check to be successful (and enable saving), all 'and' conditions and rules must be fulfilled. Rules and conditions are checked independently of each other.
- For value adoptions and scores preconditions and execution conditions can be defined. Preconditions describe the situation in which the rule is applied only (definition similar to the rule "Input required, if ..."). Execution conditions describe the value to be adopted or the value calculation.

#### Rules without condition

- Input not required.

- Input required.

#### Rules with condition

- Hide when ...
- Show treatment arm if ...
- Freeze casenode if ...
- Delete casenode if ...
- Display form, if ...
- Confirm input if ...
- Input impossible if ...
- Input not required if ...
- Input required if ...
- Input required or ignore completion status if ...
- Input only possible if ...
- Hide when ...
- Free following forms if ...
- Freeze following forms if ...
- Free single form if ...
- Freeze single form if ...
- Form input not possible if ...
- Form input only possible if ...
- Limit reached if ...
- Generate message if ...
- Delete patient pseudonyms if ...
- Patient deceased if ...
- Freeze patient if ...
- Delete patient if ...
- Close adverse event if ...
- Limit value range if ...

#### Rules with preconditions and execution conditions

- Take date from ...
- Calculate normed score from ...
- Calculate score from ...
- Calculate score function from ...
- Take value from ...
- Take value if same visit day from ...

### 3.2 Rule types and effects

- Rules may have completely different effects. Certain of them only influence the completion status, others limit the value range and others in turn trigger actions. There are often two rules which describe the same result from different points of view, e.g. "Input impossible, if..." and "Input only possible if...". A check must then be carried out in the individual case to determine which of the two is more sensible.

**Example:** The rule that an input in the "Pregnant" field in form A is only possible if "Female" has previously been selected as the sex in form B is to be created. This could be defined in two ways, which differ above all as regards the handling of an unsaved form (here: B):

1. Input only possible if sex=female in form B.

An input is therefore only possible if the item in form B has exactly this value. If form B is not saved, there is no value for sex, and the condition is not met.

2. Input impossible, if sex <> female in form B.

An input is not therefore possible if the sex in form B has a value other than female. If form B is not saved, there is no value for sex, and the condition is met (NULL <> female).

- If rules of an item X refer to the completion status of another item Y, it is no longer possible to delete item Y or the form which contains Y. The DELETE button will be replaced by the message "Not deletable because of references". Via this message you can access a pop-up window to view the origin of the references.
- Rules can be ordered according to the following effects; certain rules fall into several categories in this case.

### Generic Assembling of Input Interface

- The rule "hide if ..." results in a dynamic adaptation of the current form according to already stored or currently entered form values. The evaluation of the rule conditions is immediately done during data entry if the conditions have been defined over the current form items. No server contact is necessary for this as the evaluation is implemented in Javascript and done directly in the Browser.

**Note:** For this rule evaluation extensible Javascript functions have been implemented. If you want to use own Javascript function you have to ensure that this functionality is not impaired. This particularly regards to the overwriting of any Javascript event handler!

### Calculation of the form completion status

- Hide when ...
- Ignore for completion status.
- Ignore for completion status, if ...
- Input impossible if ...
- Input only possible if ...
- Input required or ignore completion status if ...
- If these rules are fulfilled or an entry is prevented by these rules, the respective items won't be considered for the calculation of the completion status.

### Value range check

- Input impossible if ...
- Input required.
- Input required if ...
- Input only possible if ...
- Limit reached if ...
- Limit value range if ...
- As long as these rules are not fulfilled, the form cannot be saved. This check can only be bypassed using the "Check data" check box, which can be configured for each project. The form is then saved with the additional completion status "With errors".
- The "Confirm input" rule is a special case here: If this rule is fulfilled, the form can still be saved after displaying the error message by saving again. In this case, the completion status is always additionally marked "With warnings". This "rule relaxation" can additionally be activated for the following rules by means of the ONLY AS CONFIRMATION check box.



### Defined actions

- Hide when ...
  - Show treatment arm if ...
  - Freeze casenode if ...
  - Delete casenode if ...
  - Display form, if ...
  - Take date from ...
  - Confirm input if ...
  - Free following forms if ...
  - Freeze following forms if ...
  - Free single form if ...
  - Freeze single form if ...
  - Generate message if ...
  - Calculate normed score from ...
  - Delete patient pseudonyms if ...
  - Patient deceased if ...
  - Deactivate patient if ...
  - Freeze patient if ...
  - Delete patient if ...
  - Open serious adverse event if ...
  - Calculate score function from ...
  - Close adverse event if ...
  - Open adverse event if ...
  - Take value if same visit day from ...
  - Take value from ...
- If these rules are fulfilled a defined action is triggered.

### Form initialisation

- Take date from ...
  - Take value from ...
  - Take value if same visit day from ...
- These rules are only evaluated during form initialisation, and only when the form is opened for the first time and has not yet been saved.
  - These rules are used to enhance comfort: The participant no longer has to input certain data manually. On the other hand, however, these rules are also problematic: Under certain circumstances, it may be impossible for the participant to see that these data have not yet been saved although they are displayed.
  - If the value in the template is changed after the value has been adopted and saved, the subsequent data will not be changed automatically!

### Form prerequisites

- Form input not possible if ...
  - Form input only possible if ...
- These rules have no effects in the form in which they are created. They are not checked during either initialisation or saving.

- However, these rules can be selected as a prerequisite in another form. On initialisation of this other form, the rules in the preceding form data are then checked and, if necessary, the form to be opened is not released for editing. The rule error message is then displayed as a prerequisite message above the form.
- If such a rule is to be created as the prerequisite for a form in another visit, it must be noted when creating the condition that the compare with value cannot be selected most of the times from the "Current visit", as the rule is evaluated from another visit when checking the prerequisite.

#### Visit condition

- Show treatment arm if ...
- This rule has no effect in the form in which it was created. It is not checked upon initialisation or when saving. However, this rule can be selected as a condition for a treatment arm of the visit plan. Each rule can be selected as a condition for only one treatment arm.
- If a patient has been newly created, only visits without treatment arms will be initially created. When adding further visits, the rules for the treatment arm visits will be evaluated and the first visit with a fulfilled treatment arm rule will be created. Further visits in this treatment arm will then be created without new rule checks.

#### Item types

- Date / time                      Take date from ...
- Date / time interval            Calculate date / time interval from ...
- Date-Scorefield                Calculate date / time interval from ...
- Score (calculated only)        Calculate score function from ...  
    Calculate normed score from ...  
    Calculate score from ...
- Certain rules are firmly linked to the type and can only be used there. In turn, it is not usually possible to set other rules to these items.

### 3.3 Individual description

#### Hide when ...

Can be applied to:	All item components except DB-Dummy All question components
Condition:	Conditions from other forms or other visits. The own item cannot be used as a rule condition. The included items of a questions cannot be used as conditions for their enclosing question.
Type:	Action, Completion status
Check:	Initialisation, Saving, (revalidation)
Form status:	Hidden items will be treated as non-existent and will be ignored for the calculation of the form status.
Casenode status:	No effect
Error message:	No
Effect:	Items and question will be hidden. To specify the display of questions or items instead of hiding, the conditions for the 'Hide' rule has to be specified in inverse logic. Values in hidden items will be deleted (set to NULL). Rules on hidden items have no effect..

**Usage:** For visit forms, casenode forms, adverse event forms, image forms, sub-forms (within a sub-form only items of the own sub-form can be used as a rule condition.)

#### Show treatment arm if ...

**Can be applied to:** All item components except DB-Dummy and Layout-Dummy  
**Condition:** Depending on field type  
**Type:** Action  
**Check:** Create new visits  
**Form status:** No effect  
**Casenode status:** No effect  
**Error message:** No  
**Effect:** Creating visits for the assigned treatment arm is enabled.  
**Usage:** For visit forms

#### Freeze casenode if ...

**Can be applied to:** All item components except DB-Dummy and Layout-Dummy  
**Condition:** Depending on field type  
**Type:** Action  
**Check:** Saving, (revalidation)  
**Form status:** No effect  
**Casenode status:** Yes, mnpcs3 is set to 1  
**Error message:** No  
**Effect:** The status of the agpatient and casenode is set to "sysfreeze". Further editing in this project is no longer possible.  
**Usage:** For casenode forms in (genuine part) projects

#### Delete casenode if ...

**Can be applied to:** All item components except DB-Dummy and Layout-Dummy  
**Condition:** Depending on field type  
**Type:** Action  
**Check:** Saving, (revalidation)  
**Form status:** No effect  
**Casenode status:** Yes, mnpcs5 is set to 1  
**Error message:** No  
**Effect:** The status of the agpatient and casenode is set to "To be deleted". Further editing in this project is no longer possible. A further consequence must be that the agpatient and the medical data of the casenode are deleted.  
**Usage:** For casenode forms in (genuine part) projects

#### Display form, if ...

**Can be applied to:** All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)  
**Condition:** Depending on field type  
**Type:** Action

<u>Check:</u>	<u>Saving</u>
<u>Form status:</u>	<u>No effect</u>
<u>Casenode status:</u>	<u>No effect</u>
<u>Error message:</u>	<u>No</u>
<u>Effect:</u>	<u>Shows a form deviating from the normal form order in a project. In the FormBuilder a follow-up form can be defined, which is displayed directly afterwards if the rule condition is fulfilled in the DataCapture.</u>
<u>Usage:</u>	<u>Visit, casenode and image forms: When creating the rule in visit, casenode and image forms, other visit forms and casenode forms can be selected as follow-up forms.</u>
	<u>Adverse event forms: When creating the rule in adverse event forms, further adverse event forms can be specified as follow-up forms.</u>

#### Take date from ...

Can be applied to:	Time / checked Time Date / checked Date
Condition:	The source of the date must be specified as the source. The following are possible: Visits (visit plan date), AdverseEvent, examination or current date; specification of the item as a parameter is omitted.
Type:	Value take-over
Check:	Initialisation of unsaved forms or new repetition groups
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	The date is taken over from the corresponding meta information and the field is pre-assigned. With the assignment operator "take value + add value" a value is specified, which will then be added to the adopted value in the form.
Usage:	Date fields, convenience rule

#### Calculate date/time interval from ...

Can be applied to:	Date / Time-Interval (nur berechnet) Date / Time-section as a digit (nur berechnet)
Condition:	Fields from which the value is to be calculated
Type:	Action
Check:	Calculation of button click and during saving, (revalidation)
Form status:	Completion status on saving
Casenode status:	No effect
Error message:	No
Effect:	When calculating date score fields or intervals from date / time-interval fields defined date fields are needed to perform the calculation. For defining these date fields, the rule "calculate date/time interval from ..." has to be chosen and the two date fields have to be specified as the rule conditions.
Usage:	For calculating time intervals

**Confirm input if ...**

Can be applied to:	All item components except DB-Dummy and Layout-Dummy
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	No effect
Error message:	Yes, default: "Please confirm this entry."
Effect:	On meeting one of the defined conditions, the user is presented with an error message. After confirming again (=saving), the form is saved.
Usage:	For improbable but permissible inputs (e.g. age of the patient with Alzheimer's disease <40)

**Ignore for completion status.**

Can be applied to:	All item components except DB-Dummy and Layout-Dummy
Condition:	None
Type:	Form status
Check:	Saving, (revalidation)
Form status:	Completion status – complete
Casenode status:	No effect
Error message:	No
Effect:	A user input in this field is irrelevant to the completion status of the form.
Usage:	All forms. Additional information.

**Ignore for completion status, if ...**

Can be applied to:	All item components except DB-Dummy and Layout-Dummy
Condition:	Depending on field type
Type:	Form status
Check:	Saving, (revalidation)
Form status:	Completion status – when the condition is met, the field is regarded as complete, otherwise following input
Casenode status:	No effect
Error message:	No
Effect:	A user input in this field is irrelevant to the completion status of the form if one of the defined conditions is met.
Usage:	All forms. Additional information.

**Input impossible if ...**

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Value range
Check:	Saving, form prerequisite check, (revalidation)

Form status:	Completion status: If the rule is fulfilled and no input is made, the field is regarded as complete (although empty), otherwise following input
Casenode status:	No effect
Error message:	Yes; default: "No input allowed."
Effect:	If one of the defined conditions is met, the error message is displayed to the user and saving the form is impossible until he corrects his inputs or switches off the form check.
Usage:	All forms
Comment:	This rule functions like "Limit reached, if...", but has an effect on the completion status and leads to an own input check.

#### Input required

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	No
Type:	Form status
Check:	Saving, (revalidation)
Form status:	Completion status after input
Casenode status:	No effect
Error message:	Yes; default: "Input required!"
Effect:	A user input in this field is vitally necessary; the user is presented with the error message and cannot save the form until he has either entered (any) data or switches off the check.
Usage:	Mandatory fields, for important information

#### Input required if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Form status
Check:	Saving, (revalidation)
Form status:	Completion status after input
Casenode status:	No effect
Error message:	Yes; default: "Input required!"
Effect:	A user input in this field is vitally necessary if one of the defined conditions is met. The error message is displayed to the user, and the user cannot save the form until he has either entered (any) data or switches off the check.
Usage:	Conditional mandatory fields, for important information

#### Input required or ignore completion status, if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Yes Depending on field type
Type:	Form status, value range
Check:	Saving (revalidation)

<u>Form status:</u>	<u>After condition and input: if the condition is met after input, if the condition is not met the item is regarded as complete.</u>
<u>Casenode status:</u>	<u>No effect</u>
<u>Error message:</u>	<u>Yes (with fulfilled condition and missing value), default "Input required"</u>
<u>Effect:</u>	<u>Combines a mandatory entry field with an effect on the completion status. It can be defined in just the same way as an "Input only possible, if..." rule.</u>
<u>Usage:</u>	<u>Conditional mandatory fields, for important information</u>

#### Input only possible if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Value range
Check:	Saving, form prerequisite check , (revalidation)
Form status:	Completion status – when the rule is fulfilled, the field is regarded as complete, otherwise following input
Casenode status:	No effect
Error message:	Yes; default: "No input allowed."
Effect:	A user input in this field is only possible if one of the defined conditions is met. The error message is displayed to the user, and the user can only save the form if he undoes his input or switches off the check. (Withdrawing data is not possible in the case of radiobuttons; in this case, therefore, the reset radiobuttons should be used or you should attempt to work with other rules.)
Usage:	Conditional mandatory fields
Comment:	This rule functions like "Limit reached, if...", but has an effect on the completion status and leads to an own input check (and this similarly to "Input impossible, if ...").

#### Free following forms if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type, select date field as cut-off date (only the 1st condition is evaluated)
Type:	Action
Check:	Saving, (revalidation)
Form status:	Review status (SysFreeze withdrawn). No effect in the casenode form; in a visit form, this depends on whether a date is specified and the current form is included.
Casenode status:	Visit plan closed is cancelled again
Error message:	No
Effect:	In a casenode form, this rule has no effect; in a visit form, this depends on whether a date is specified and the current form is included. The intention of this is to cancel freezes which have been created due to the contrary rule (see rule: "Freeze following forms if ...") again. The form status in the tpxdocument is reset to "Editable". Manually frozen forms remain manually frozen.

**Usage:** Visit or casenode forms, withdraw the premature cancelling of data capture.

**Caution:** Caution with the combination with *Freeze following forms*: The rules do not cancel each other but are both executed!

#### Freeze following forms if ...

**Can be applied to:** All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)

**Condition:** Depending on field type, select date field as cut-off date (only the 1st condition is evaluated)

**Type:** Action

**Check:** Saving, (revalidation)

**Form status:** Review status – (SysFreeze) no effect in the casenode form; in a visit form, this depends on whether a date is specified and the current form is included.

**Casenode status:** Visit plan closed

**Error message:** No

**Effect:** In a casenode form, this rule has no effect on the form itself; in a visit form, this depends on whether a date is specified and the current form is included. All forms as of the selected date are frozen for input by setting the form status in the tpxdocument to "sysfreeze" (even if the form has already been manually frozen) when one of the defined conditions is met. As the patient status is not changed, the patient as such is classified as active. The rule "Free following forms, if ..." can be used to cancel the frozen status again (see rule: "Free following forms if ...").

**Usage:** Casenode forms, for the departure of patients or inclusion and exclusion criteria, premature cancelling of data capture.

**Caution:** Caution with the combination with *Free following forms*: The rules do not cancel each other but are both executed!

#### Free single form, if ...

**Can be applied to:** All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)

**Condition:** Depending on field type

**Type:** Action

**Check:** Saving, (revalidation)

**Form status:** No effect

**Casenode status:** No effect

**Error message:** No

**Effect:** Selective cancelling of freezes in a defined form. When the rule condition is fulfilled the form which has been specified in the rule will be opened everywhere that it has been frozen before. Is it a visit form, it will be opened in all created visits.

**Usage:** Selective withdraw the premature cancelling of data capture in a defined form.

**Caution:** Caution with the combination with *Freeze single form*: The rules do not cancel each other but are both executed!



**Freeze single form, if ...**

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	If a rule condition is fulfilled, the form which has been specified in the rule will be frozen everywhere that it is displayed. Is it a visit form, it will be frozen in all previously created visits. However, if the form is to be displayed in visits which have not yet been created, it can be filled in after these visits have been newly created.
Usage:	Selective premature cancelling of data capture in a defined form.

**Caution:** Caution with the combination with *Free single form*: The rules do not cancel each other but are both executed!

**Form input not possible if ...**

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type; specification of the item as a parameter is omitted.
Type:	Action
Check:	Form prerequisites check
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	This rule has no effect whatsoever in the form in which it is created. It is intended to be selected as a prerequisite in other forms. E.g.: Healthy control persons do not have to fill in any further forms.
Usage:	(Visit) forms to generate dependencies between forms.

**Form input only possible if ...**

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type; specification of the item as a parameter is omitted.
Type:	Action
Check:	Form prerequisites check
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	This rule has no effect whatsoever in the form in which it is created. It is intended to be selected as a prerequisite in other forms. E.g.: Healthy

control persons do not have to fill in any further forms. This rule is the pendant to "Form input not possible if ..."; which of the two is more sensible has to be checked in the individual case.

Usage: (Visit) forms to generate dependencies between forms.

#### Limit reached if ...

Can be applied to: All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)

Condition: Depending on field type

Type: Value range

Check: Saving, (revalidation)

Form status: Completion status – according input

Casenode status: No effect

Error message: Yes; default: "Limit reached!"

Effect: On meeting one of the defined conditions, the error message is displayed to the user, and the user cannot save the form until he has corrected the input or switches off the check.

Usage: Check of value range

Comment: This rule functions like *"Input impossible, if ..."*, but has no effect on the completion status and does not lead to an own input check.

#### Generate message if ...

Can be applied to: All item components except DB-Dummy and Layout-Dummy

Condition: Depending on field type, a message can be defined

Type: Action

Check: Saving, (revalidation)

Form status: No effect

Casenode status: No effect

Error message: No

Effect: On meeting the conditions defined via parameters, the previously defined message is sent (i.e. is saved in the database and displayed when next logging in).

Usage: Intended for adverse events and serious adverse events or for other important data (e.g. on reaching limits)

Comments: Depending on configuration, the pseudonyms used in the project can be selected for displaying in the message (Pat-ID and/or Add-ID and/or Lab-ID. The message can include questions of the form. The type of sending (via internal message or e-mail) is configured in the AdminTool.

For further informations on this type of message refer to see chapter 7.

#### Calculate normed score from ...

Can be applied to: Score

Condition: Values from other form fields are linked with the specified operators. Which field values are ignored on calculation and the number of "meaningless" values as of which calculation is to take place can be specified. The value for calculation is read-out from the conversion factor, if this is set, in the case of fields with groups of labels. Otherwise, the normal DB value is used.

Type:	Action
Check:	Saving, (revalidation), item or form button
Form status:	Completion status following calculation (Attention: further rules for completion checks should be placed after the calculation rule!)
Casenode status:	No effect
Error message:	No
Effect:	The field values are linked with the specified operators (normally addition). The total value is divided through the number of calculated values and multiplied with the given normalization factor (1 if not specified). If the field values do not specify any greater accuracy, the normed score is specified to two decimal places. The score is calculated on request (button click) or on saving the form. In the case of groups of labels, the conversion factors are used for calculation purposes if these are set. Otherwise, the DB value is used.
Usage:	Standard scores
Comments:	Scores are calculated on score fields with rules which usually consist of several conditions. When defining multiple score rules on an item they will be calculated in the defined sequence (and only with fulfilled preconditions). The value calculated last will then be saved.

#### Delete patient pseudonyms if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	Yes, mnpcs0 is set to 1.
Error message:	No
Effect:	Initially none in the own form. On meeting one of the defined conditions, the patient status is set to "Inactive". Alls forms are frozen for further editing. When logging in next, the patient can no longer be edited at all; he is no longer listed or found. As a consequence, the patient's pseudonym can be deleted in the AdminTool. Patients with the status "Inactive" are also no longer found by the ExportSearchTool.
Usage:	Casenode forms if the patient partially withdraws his consent: Anonymisation

#### Patient deceased if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	Yes, mnpcs4 is set to 1.
Error message:	No

Effect:	Usually none in the own form. On meeting one of the defined conditions, the patient status is set to "Deceased". The forms are frozen for editing.
Usage:	Casenode forms

#### Freeze patient if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	Yes, mnpcs2 is set to 1.
Error message:	No
Effect:	None in the own form. On meeting one of the defined conditions, the patient status is set to "Freeze". The forms can no longer be edited.
Usage:	Casenode forms

#### Delete patient if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Depending on field type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	Yes, mnpcs1 is set to 1.
Error message:	No
Effect:	Initially none in the own form. On meeting one of the defined conditions, the patient status is set to "To be deleted". The forms are frozen for further editing. When logging in next, the patient can no longer be edited at all; he is no longer listed or found. Further consequences should be: Deletion of the patient including all medical data. Patients with this status are also no longer found or exported by the ExportSearchTool.
Usage:	Casenode forms if the patient has completely withdrawn his consent.

#### Calculate score from ...

Can be applied to:	Score
Condition:	Fields from which the value is to be calculated
Type:	Action
Check:	Saving, (revalidation), button
Form status:	Completion status following calculation (Attention: further rules for completion checks should be placed after the calculation rule!)
Casenode status:	No effect
Error message:	No
Effect:	The score is calculated from the selected fields or/and a defined decimal number. This rule is exclusively intended for score fields. The score is calculated on request (button click) or on saving the form. In the case of

groups of labels, the multiplication factors are used for calculation purposes if these are set. Otherwise, the DB value is used. Please refer to the "Scores" section for the precise function.

Usage: For calculating sum values from other questions

Comments: Scores are calculated on score fields with rules which usually consist of several conditions. When defining multiple score rules on an item they will be calculated in the defined sequence (and only with fulfilled preconditions). The value calculated last will then be saved.

#### Calculate score function from ...

Can be applied to: Score

Condition: Fields from which the value is to be calculated

Type: Action

Check: Saving, (revalidation), button

Form status: Completion status – following calculation (Attention: further rules for completion checks should be placed after the calculation rule!)

Casenode status: No effect

Error message: No

Effect: The score is calculated via the specified parameters from the selected fields. This rule is exclusively intended for score fields. The score is calculated on request (button click) and on saving the form. In the case of groups of labels, the multiplication factors are used for calculation purposes if these are set. Otherwise, the DB value is used. See "Scores" section for the precise function.

Usage: For calculating sum values from other questions

Comment: Scores are calculated on score fields with rules which usually consist of several conditions. When defining multiple score rules on an item they will be calculated in the defined sequence (and only with fulfilled preconditions). The value calculated last will then be saved.

#### Open serious adverse event if ...

Can be applied to: All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section) in an adverse event form

Condition: Depending on field type

Type: Action

Check: Saving, (revalidation)

Form status: No effect

Casenode status: No effect

Error message: No

Effect: AdverseEvent status is set to "Is SAE". The first available SAE form is offered/opened as the subsequent form.

Usage: AE forms, for creating an SAE form for converting from AE to SAE via rules

#### Close adverse event if ...

Can be applied to: All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section) in a adverse event form

Condition:	Depending on type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	The status of the adverse event (AE/ SAE) to which the form belongs is set to "Closed". The further creation of examinations (follow-ups) in this AE is therefore no longer possible.
Usage:	Adverse event forms

#### Open adverse event if ...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section) in a adverse event form
Condition:	Depending on type
Type:	Action
Check:	Saving, (revalidation)
Form status:	No effect
Casenode status:	No effect
Error message:	No
Effect:	The status of the adverse event (AE/ SAE) to which the form belongs is set to "open". The further creation of examinations (follow-ups) in this AE is therefore again possible.
Usage:	Adverse event forms (reverse rule for "Close adverse event")

#### Take value from...

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Specification of the item as a parameter is omitted.
Type:	Action
Check:	Initialisation of unsaved forms or new repetition groups.
Form status:	No effect
Casenode status:	No effect
Error message:	Error message, if adopted value Wert + added value does not match the defined item format and can not be displayed (e.g. value „10“ in a „1,0“ number field).
Effect:	The value of the field defined in the condition is taken over into the current field. Sensible for taking over information with a high probability of remaining identical from previous visits (e.g. date of birth, sex). With the assignment operator "take value + add value" a value is specified, which will then be added to the adopted value in the form.
Usage:	All forms, as a convenience method

#### Note:

Value take-over only ever takes place once. When saving the initial form for a second time, the value in the take-over form is not overwritten. It is also additionally possible to manually change the taken-over value. This may lead to the fact that the values no longer correspond!

**Take value if same visit day from...**

Can be applied to:	All item components except DB-Dummy, Layout-Dummy and all calculable items without entry (Score, Date-Interval, Date-section)
Condition:	Specification of the item as a parameter is omitted.
Type:	Action
Check:	Initialisation of unsaved forms or new repetition groups.
Form status:	No effect
Casenode status:	No effect
Error message:	Error message, if adopted value Wert + added value does not match the defined item format and can not be displayed (e.g. value „10“ in a „1,0“ number field).
Effect:	The value of the field defined in the condition is taken over into the current field if the date of the form visit is the same as the date from the origin value. Sensible for taking over information with a high probability of re-maining identical from previous visits (e.g. date of birth, sex). With the assignment operator "take value + add value" a value is specified, which will then be added to the adopted value in the form.
Usage:	Visit forms, as a convenience method

**Limit value range if...**

Can be applied to:	Number Date /checked Date Time / checked Time Horizontal / vertical Radiobutton Popup
Condition:	Depending on field type, specification of a max. and min. value
Type:	Action
Check:	Saving, (revalidation)
Form status:	Completion status after input
Casenode status:	No effect
Error message:	Yes; default: "Limit reached!"
Effect:	On meeting one of the defined conditions and non-adherence to the specified value range, the error message is displayed to the user, and he is unable to save the form until he has adapted the value or switched off the check.
Usage:	Conditional check of value range.

**3.4 Scores**

- A score is a value which is calculated from various user data in other items. Simple scores can be used to simply count answers. If e.g. an entire question catalog always has the answer options "Yes"/"No", whereby yes is saved with 1 and no with 0 in the database, the number of questions answered "Yes" can be quickly determined by totalling all database values.
- Scores are defined via rules. The calculation of a score is specified by the execution conditions of the rule. The execution of a score rule can be restricted by the preconditions. However score rules will be evaluated in a preliminary step before evaluating the data check rules regardless their sequence and display in the form. This ensures that the rules for checking the calculated score values can always be correctly evaluated.

- When defining multiple score rules for an item all these rules will be executed, but only the value calculated last will be saved. If according to the preconditions no value can be calculated for score rules, the score value will be reset to NULL.
- Scores can be calculated via number items, fixed decimal places or also radiobuttons and pop-ups, as the DB values are then used as data. If the conversion factor is also set in the case of a label in addition to the DB value, this is used for calculation instead of the DB value.
- Scores are calculated with the accuracy which can also be input by the user in the evaluated items. If the user is able to specify three post-decimal places, the score is also calculated to three post-decimal places. A normed score and a function score, however, are always calculated to an accuracy of two decimal places (see Score (only calculated)). When defining the score rules, you can also specify the accuracy by entering the number of decimal places. The calculation will then be rounded to this number of decimal places.
- When defining multiple score rules with different accuracies on an item, the maximum size of the minimum and maximum precision of the calculation is calculated for the entire via all of the score rules for that item.
- The mathematical portrayal of the desired functions and processing in the programme deviate slightly. The score always operates according to the following pattern:

result = result op parameter

- whereby op refers to one of the following operators: "Add value", "Subtract value", "Multiply by value" and "Divide by value". This operation is carried out for each parameter. This results in a type of bracketing (start with result=0):

result = (((0 op parameter1) op parameter2 ) op parameter3)

- Parameter refers to the value which is read-out from the specified field. Assume that we have the following questions:

Is the sky blue?	yes=1	no=0
Is the sun shining?	yes=1	no=0
Are the flowers in bloom?	yes=1	no=0

- And the score is intended to provide a type of assessment of how good the weather is by calculating the sum of the questions from: Number of "Yes" in (sky, sun, flowers). A simple score with three parameters would then be created:

Parameter 1	"Add value" read-out value from question "Is the sky blue?"
Parameter 2	"Add value" read-out value from question "Is the sun shining?"
Parameter 3	"Add value" read-out value from question "Are the flowers in bloom?"

- For the calculation of scores, the AND conditions can be used as a bracketing level. When calculating scores, all of the AND conditions in a group will first be applied before the application of the OR groups. The arithmetic operator of the first AND condition is used as the arithmetic operator for the OR group.



**Example:**

**Type: \***

**Rule name:**

**Sequence position:**

**Parameters for the calculation:**

ignore this value during calculation

calculate only when maximum number of this uncounted values

post decimal positions  ?

Rule conditions (3)						
Position		Error message	Operator	Comparison value	Question	Delete from database
10	10	<input type="button" value="New and condition"/>	<u>add value</u>	Item	<za1>	<input type="button" value="Delete"/>
<b>or...</b>						
20	10	<input type="button" value="and..."/>	<u>subtract value</u>	Item	<za2>	<input type="button" value="Delete"/>
	20	<input type="button" value="New and condition"/>	<u>multiply value</u>	Item	<za3>	<input type="button" value="Delete"/>
<input type="button" value="New or condition"/>						

Fig. 50: Definition of a score calculation with bracketing via an AND group.

- The above definition produces the calculation:  $A - (B * C)$

#### Calculate score from ...

- This function only enables the execution of simple additions, subtractions, multiplications and divisions.
- Which number is not to be taken into consideration in the calculation (e.g. don't know = 9) can be defined in advance so that only sensible answers are used.
- So that a minimum number of input values can be demanded for the calculation, the number of uncounted values only for which the calculation is to be carried out can additionally be specified. This specification will be treated analogously to possible preconditions.

#### Calculate normed score from ...

- On calculation of the normed score, the result of all operations is automatically divided by the number of calculated values (calculated values are all values which does not match the to-be-ignored value). This calculation can be used e.g. to determine the mean value.
- Functions such as "Ignore following value on calculation" or "Only calculate with a maximum of so many uncounted values" (see "Calculate score from") can also be used in the case of this score.
- The calculated value (e.g. mean value) can also be multiplied by an arbitrary factor. This multiplication is used e.g. to portray estimated sums if not all values to be included for a sum can be specified and the sum of all required values is still to be calculated.

```

result = result/(number of sensible answers) * factor
Sum A = 1
Sum B = 2
Sum C = NULL
Result = 4.5
Result = sum of A and B /2 sensible answers * 3

```

#### Calculate score function from ...

- The function score, which offers even more options, is additionally available to achieve even greater flexibility when calculating scores. A multiplication factor (if none is specified, multiplication by 1 is carried out) and a function can additionally be selected for each parameter. The functions implemented are:

simple multiplication (without function selection):  $a \times \text{item value}$

natural logarithm	$a \times \ln(\text{item value})$
power function	$a \times \text{item value}^{\text{exponent}}$
exponential function:	$a \times \text{basis}^{\text{item value}}$
natural exponential funktion:	$a \times e^{\text{item value}}$

- If you then have e.g. the following function for calculating the body surface (in m<sup>2</sup>) from the height (in cm) and weight (in kg):

$$\text{surface} = \text{weight}^{0.425} \times \text{height}^{0.725} \times 0.7184$$

Subdivision into parameters should initially be considered. Indicated by brackets here:

$$\text{surface} = [\text{weight}^{0.425}] [x \text{height}^{0.725} \times 0.7184]$$

The formula can now be implemented with the following parameter (as the calculation always starts with the result "0", the first parameter should always be added):

Parameter 1: "Add value", read value out from question "Weight", multiplication factor 0.01, exponential function, exponent 0.425

Parameter 2: "Multiply by value", multiplication factor 0.7184, read value out from question "Height", exponential function, exponent 0.725

#### Calculate date/time lag from ...

- When calculating date score fields as numbers or calculating intervals from time/date interval fields, defined date fields are required in order to perform the calculation. To define these date fields, select the *Calculate date/time lag from...* rule. When creating one of the two item types, this rule will always be automatically created.
- The two date values used for the calculation will each be created as a new OR condition for the rule.
- Freely defined date/time entries, the current date, the current date plus time entries as well as values from items (plus time value) can be used for the calculation.
- When selecting items, only date or time fields are offered which have the same format as the current score date item.

#### Handling of "NULL"

- When creating rules, it must be noted that not inputting values leads to the database NULL value. This is not comparable with the explicit specification of "No" or "False". This leads to complications, particularly in the case of radiobuttons and check boxes, if the input is to be compelled or prevented.
- IASCheckBoxes are programmed in such a way that they convert an unclicked status into a NULL. A rule which is intended to state that a check box should be answered actively with "No" is not therefore possible.
- The reset option is available to enable resetting to NULL in the case of radiobuttons. The standard label of the "NULL" option is "not applicable" (specified via the LanguageBundle). However, a deviating label can also be specified for each item.

### 3.5 Compare value "text-format"

- The compare with value "Text format" can be selected in the FormBuilder to create conditions for text items. When completing the form, only the text which corresponds (or does not correspond, depending on the condition definition) to the defined format can be input.
- The TEST button is used to open a pop-up, in which you can test whether the text format which you have configured meets your requirements. The question mark opens an overview of the different configuration options.

Sequence position:	<input type="text" value="10"/>
Error message: *	<input type="text" value="Wrong format!"/>
Parameter is read from: *	<input checked="" type="radio"/> own item <input type="radio"/> this item...
Compare or Assign Operator: *	<input type="text" value="equal value"/>
Compare Value: *	<input type="text" value="text format"/>
Compare Value: * (format)	<input type="text" value="LLLLL"/> <input type="button" value="Test"/> <input type="button" value="?"/>

Fig. 51: Example of the condition for a specified text format of 5 lower case letters

- The format for permissible text inputs can be defined here. When completing the form, only the text which corresponds (or does not correspond, depending on the condition definition) to this format can be input. The needed format is added automatically to the specified error message.
- The format defines how long the text may be and how it is compiled from capital or small letters and numbers. The format is specified via individual characters. The characters stand for the following in this case:

#### Character

##### Letters and numbers:

- C** 1 arbitrary letter
- L** 1 small letter
- U** 1 capital letter
- N** 1 individual number
- A** 1 letter or a number

##### As before, but optional:

- c** 0-1 letters
- l** 0-1 small letters
- u** 0-1 capital letters
- n** 0-1 individual numbers
- a** 0-1 letters or numbers

##### Place holder:

- #** 1 or more arbitrary characters

##### Special characters:

- 1 hyphen
- .** 1 point
- \_** 1 underscore
- :** 1 colon
- (...)** (and other special characters...)

#### Format examples:

- CCCCC** 6 arbitrary letters
- LLLLL** 6 small letters
- LLNNN** 3 small letters followed by 3 numbers
- CAAAAA** 6 letters or numbers; no number is permitted at the beginning
- UNNnnn** 1 capital letter followed by 2-5 numbers
- UU-Nnn** 2 capital letters followed by 1 hyphen, followed by 1-3 numbers

**C#**      1 letter followed by arbitrary characters

## 4. Visit types

- A project's visit plan can be compiled from different visit types which differ as regards the calculation and flexibility of the visit date. The option of inserting unscheduled visits between the "normal", scheduled visits also exists .
- A patient's scheduled visits are numbered in the sequence of their creation. The unscheduled visits are numbered individually by type, also in the sequence of creation. If permitted, the chronological sequence may deviate from the numbering.
- All visits are always displayed in chronological sequence in the patient's form overview.

### 4.1 Fixed visit

- In the case of fixed visits, the point in time of the visit is calculated from the specified data. The participant cannot input a date. The calculation is based on the date which was input in the reference visit. All of a visit plan's initial visits must be fixed or flexible visits.

### 4.2 Flexible visit

- In the case of flexible visits, the possible deviation upwards and downwards from the calculated point in time must be specified in addition to the planned interval.

### 4.3 Free visit

- In the case of free visits, there is no planned interval from other visits and therefore also no preceding visit. However, the visit date can be restricted by specifying a time span; this is not then compared with the calculated date but with the current date.

### 4.4 Unscheduled visit

- Unscheduled visits can be created outside of the specified visit plan. They are skipped on calculation of the next scheduled visit, even if "*Preceding*" has been entered as the reference visit for the next scheduled visit. So that this visit type can also be used for alternative treatment plans, however, the interval from the preceding visit plus an optional time window can also be specified here. If no data are input, these visits can be set entirely as desired.

## 5. Report types

### 5.1 SQL

- Lists of various data types can be created in a report in this case. This type necessitates certain knowledge regarding the secuTrial® data model and SQL (see Annex). In contrast to the majority of others, the results of the reports can be easily sorted and filtered. On the other hand, this type only enables an automatic test of the current participant's access rights to a limited extent. It is therefore possible for a participant to view data in the DataCapture which he is not normally permitted to see due to his roles and rights.

secuTrial®				
Date	31.08.2010 - 19:24 (CEST)			Close
Participant	Dipl.biomed Susanne Schneider			Print
Project	Study 1 (31.08.2010 - 19:23:50 (CEST))			
SQL Report				
Pat-ID	Saved	Completed	Birthdate	Sex
< All >				
xel012	2010/08/31	No	01.05.1976	female
xel012	2010/08/31	No	01.05.1976	female
jqj789	2010/08/31	No	17.06.1964	male
jqj789	2010/08/31	No	17.06.1964	male
xyx219	2010/08/31	Yes	30.11.1957	male
zpu285	2009/11/11	No		
zpu285	2009/11/11	No		
xkx764	2009/11/11	No		
xkx764	2009/11/11	No		
ick371	2010/08/31	No	12.02.1982	female
ick371	2010/08/31	No	12.02.1982	female

**Fig. 52:** Example of the view of an SQL reports. Filtering by pseudonym (top drop-down list) and sorting according to the other data have been defined here. In the case of date specifications, it must be noted that sorting is carried out on a text basis. The value "Saved" is read-out from the saving time stamp here, whilst the value "Birthdate" represents a form item. If a form, as in this case, is available in several visits, a patient may also be listed several times in this report type.

- The parts of a SELECT statement are defined individually for an SQL report, whereby the basic framework is specified by secuTrial®. Nesting is therefore only possible to a limited extent. The following parts can be defined:
  - SELECT (columns)
  - WHERE (condition)
  - GROUP BY (grouping)
  - HAVING (group limitation)
- The statement is executed in the participant administration scheme of the relevant, current customer. Access is therefore only possible to the tables for which the corresponding DB user has read rights. In the secuTrial® database, this includes all tables for the project belonging to this customer from the corresponding DB area, the project setup tables (SRTSetup/setadm) and the general look-up tables (SRTLlibrary/libadm). This means that only the test project tables can be accessed in the setup DataCapture and only the productive project tables in the productive DataCapture. The test area is always used in the FormBuilder; the statement and execution in the DataCapture are then adapted to the current area. To do this, the corresponding user is automatically added in front of the referenced tables, providing the table owner has not already been entered.
- All tables which are used should be specified without scheme names. On execution of the report, these are added by the system depending on area, and therefore enable the transfer of an SQL re-

port from the setup area to the productive area. This also functions for tables in nested conditions and for tables from other projects in the same customer area.

**Note:** Please do not specify any database users in front of the tables, as this prevents the automatic transfer of the reports from the setup to the productive area!

- If the tables which are used contain a project's casenode table, a restriction to those centres in which the current participant is a member is automatically added to the defined statement.
- Linking a report entry to the call-up of a patient only functions if the report contains a pseudonym (pseudonym=Pat-ID, aid=Add-ID or labid=Lab-ID) for the patient as a column specification.
- The SELECT statement generated from the data is portrayed beneath the definition of the fields under the point "SQL". To increase the clarity the statement will be wrapped after each element (e.g. „FROM“). Lines longer than 100 characters (print preview: 80), will be wrapped automatically at the last blank included.
- The "Test status" link is available to test the validity of the generated SQL statement. A small wait window then opens, and the SQL is executed in the background. If the status is "OK", the SELECT statement has been correctly edited by the database. If an error occurred, the error message generated by the database is displayed beneath the listed report, and the data can be corrected accordingly. As additional information, the contained number of lines is specified in the wait window on completion of the SQL query. The test result will be saved until the next time the report is edited. If you change the report or simply save it again, then you must repeat the status test.

**Important:** When designing an SQL report, make sure that valid table links are created. An unintentional cross product may block the whole database! The validity check for SQL report is therefore only carried out on request, and not automatically as in the case of the other types.

- In addition to the selected column, a "*DISTINCT*" may also be specified in the definition of the first output columns.
- Knowledge of the database structure is necessary to formulate a correct SQL statement. This does not correspond to the exported data structure! For a description of the individual database tables, please refer either to the database descriptions which can be downloaded in the CustomerAdminTool. The relationships between the most important project tables are described in the graphics in the Annex.
- There is also a clickable "i" icon next to all text fields which enable such elements. By clicking the icon a pop-up help window will open, which describes the database structure for the project, administration and project set-up tables. The description corresponds with the documentation contained in the project dossier and the DB documentation that can be downloaded in the CustomerAdminTool.

By clicking on a table or column name you can append the name to the end of the statement.		
▶ devn5	Form and meta tables of patient data	
▼ b4975devadm	Participant administration and general patient information	
▶ ADMINLOG	Log table for the AdminTool. An unitary incremental audit trail for all objects is written.	
▶ ADMINLOGOBJECT	Each single database object changed from within the AdminTool is logged here with it's changes. Some values (Passwords, medical data) are masked thereby.	
▶ ATCENTRE	Information about a centre. A centre could represent a clinic, a topically work group or a practice. The main information is the name. A centre is the basic access unit to the patient pool. All members of a centres have the same (according role) rights to all patients in the centre. Prior to each save, a copy of the original data is stored in this table.	
▼ CENTRE	Information about a centre. A centre could represent a clinic, a topically work group or a practice. The main information is the name. A centre is the basic access unit to the patient pool. All members of a centres have the same (according role) rights to all patients in the centre.	
ADMINISTRATIVE	NUMBER	Flag: if set the centre will be ignored in the generation of reports and statistics [0=normal centre, 1=administrative centre].
AGNAME	VARCHAR2(100)	Unique name in whole setup of customer and area (setup/productive).
AIDPREFIX	VARCHAR2(15)	Project unique centre prefix for the additional patient ID (AID) if configured in project.
CID	NUMBER	Foreign key to B4975devadm.COUNTRY (CID).
CTRID	NUMBER	Primary key.
EMAIL	VARCHAR2(100)	Email address of person in charge.
LOCID	NUMBER	Foreign key to setadm.LOCATION (LOCID).
MAXPATIENTS	NUMBER	If set the value limits the maximal possible number of patients in the centre.
PROJECTID	NUMBER	Foreign key to setadm.PROJECT (PROJECTID). During creation the centre is assigned to a project. This assignment can not be changed

**Fig. 53:** Excerpt from the database description of the project ('devioas0') and administration tables ('iasdevadm') The database description is opened via the 'i' icon.

- Click on the table or column name in the pop-up window to insert the table or column name from which the pop-up was opened into the text field. If the pop-up for one of the elements was opened, the pop-up will close after the selection is made (this is necessary because the corresponding text field is determined by opening the pop-up).
- As an additional report property you can set the number of simultaneously displayed rows in DataCapture. If you make an entry here, the result of the SELECT will be displayed page by page with the configured number of rows per page in DataCapture. This setting should be used if a large number of results is expected.
- It is possible to download SQL reports as MS Excel files. In the file all of the displayed datasets will be listed, taking into account any previously set dataset filters. The number of datasets will be listed in the information at the beginning. All of the datasets in the file will be listed below each other, even if they are displayed page by page in the report. Any highlighting of datasets will not be displayed in the Excel file.



<b>No.</b>	7	
<b>Name *</b>	SQL Report	
<b>Type *</b>	<input checked="" type="radio"/> SQL <input type="radio"/> Single field <input type="radio"/> Single field per visit <input type="radio"/> Status <input type="radio"/> Queries details <input type="radio"/> Icon display <input type="radio"/> Image forms	
<b>Style definition of the rows</b>	odd rows < Please choose > Preview even rows < Please choose > Preview	

<b>Columns (select) *</b>	(Please supply either a table+column or a db-function, not both.)	
1	Display <input type="radio"/> hidden <input checked="" type="radio"/> shown <input type="checkbox"/> sortable <input checked="" type="checkbox"/> selectable ? Table * patient ? Table alias p Column (*) pseudonym ? Title (*) Pa-ID ? DB-function Variable name * V1 Ordered by < Please choose > Remove	
2	Display <input type="radio"/> hidden <input checked="" type="radio"/> shown <input checked="" type="checkbox"/> sortable <input type="checkbox"/> selectable ? Table * probdocument ? Table alias d Column (*) Title (*) Saved ? DB-function to_char(mnpdate, 'yyyy/mm/dd') ? Variable name * V2 Ordered by < Please choose > Remove	
3	Display <input type="radio"/> hidden <input checked="" type="radio"/> shown <input checked="" type="checkbox"/> sortable <input type="checkbox"/> selectable ? Table * Table alias Column (*) Title (*) Completed ? DB-function (case when (isformcomplete(d.completionstatus)=1) then 'Yes' else 'No' end) ? Variable name * V3 Ordered by < Please choose > Remove	
4	Display <input type="radio"/> hidden <input checked="" type="radio"/> shown <input type="checkbox"/> sortable <input type="checkbox"/> selectable ? Table * mnpprobersdata ? Table alias m Column (*) Title (*) Birthdate ? DB-function value_to_date(m.birthdate, 'DD.MM.YYYY') ? Variable name * V4 Ordered by < Please choose > Remove	
5	Display <input type="radio"/> hidden <input checked="" type="radio"/> shown <input type="checkbox"/> sortable <input type="checkbox"/> selectable ? Table * Table alias Column (*) Title (*) DB-function value_to_label('mnpprobersdata', 'gender', m.gender) ? Variable name * V5 Ordered by < Please choose > Remove	

<b>Conditions (where)</b>		New column
1	Left table *	p ?

Fig. 54: Upper part of the editing page of the SQL report from Fig. 52 with specification of the portrayed values. The validity of an SQL report can be checked from the report overview using the "Test status" link.

Conditions (where)		New column
1	Left table * Left column * Predicate * Right table Right column (*) Right constant compare value (*) <input type="button" value="Remove"/>	<input type="text" value="p"/> <input type="text" value="pid"/> <input type="text" value="="/> <input type="text" value="probcasenode"/> <input type="text" value="pid"/> <input type="text"/> <input type="text"/>
2	Left table * Left column * Predicate * Right table Right column (*) Right constant compare value (*) <input type="button" value="Remove"/>	<input type="text" value="probcasenode"/> <input type="text" value="cnid"/> <input type="text" value="="/> <input type="text" value="probcaservisitplan"/> <input type="text" value="cnid"/> <input type="text"/> <input type="text"/>
3	Left table * Left column * Predicate * Right table Right column (*) Right constant compare value (*) <input type="button" value="Remove"/>	<input type="text" value="probcaservisitplan"/> <input type="text" value="cvpid"/> <input type="text" value="="/> <input type="text" value="d"/> <input type="text" value="cvpid"/> <input type="text"/> <input type="text"/>
4	Left table * Left column * Predicate * Right table Right column (*) Right constant compare value (*) <input type="button" value="Remove"/>	<input type="text" value="d"/> <input type="text" value="mnpdid"/> <input type="text" value="="/> <input type="text" value="m"/> <input type="text" value="mnpdid"/> <input type="text"/> <input type="text"/>

Highlighted rows	
SQL	<input type="button" value="New condition"/> <input type="button" value="New highlighting"/> <pre> SELECT p.pseudonym V1, to_char(mnpdate, 'yyyy/mm/dd') V2, (case when (isformcomplete(d.completionstatus)=1) then 'Yes' else 'No' end) V3, value_to_date(m.birthdate, 'DD.MM.YYYY') V4, value_to_label(null, 'mnppropersdata', 'gender', m.gender) V5 FROM iasdevadm.patient p, devprob.probdocument d, devprob.mnppropersdata m, devprob.probcasenode, devprob.probcaservisitplan WHERE (p.pid = DEVPROB.probcasenode.pid) AND (DEVPROB.probcasenode.cnid = DEVPROB.probcaservisitplan.cnid) AND (DEVPROB.probcaservisitplan.cvpid = d.cvpid) AND (d.mnpdid = m.mnpdid) </pre>

Fig. 55: Lower part of the editing page of the SQL report from Fig. 52 with specification of the table joins and the emerging SELECT statement.

## DB functions

- DB functions which encapsulate a higher SELECT statement complexity or convert values into a legible form are often required here. The usual Oracle or the following secuTrial® functions can be used as functions:
  - **BOOLEAN\_TO\_LABEL**(value, yes, no)  
For check box items: If the check box is clicked (value=1) the text specified in "Yes" is fed back, otherwise "No".
  - **VALUE\_TO\_DATE**(value,format)  
For date or time items: The value is fed back in the specified format. The item value will only be reformatted and not be converted into a real date (sorting alphanumeric). The following formats are possible:
    - 'YYYY'
    - 'YYYY'
    - 'MM.YYYY'
    - 'MM.YYYY HH:MI'
    - 'DD.MM.YYYY-HH:MI'
    - 'DD.MM.YYYY HH:MI:SS'
    - 'DD.MM.YYYY-HH:MI:SS'
    - 'HH:MM'

'HH:MM:SS'  
 'HH:MM-DD.MM.YYYY'  
 'HH:MM DD.MM.YYYY'  
 'YYYY/MM/DD'  
 'YY/MM/DD'  
 'YYYY/MM/DD HH:MI'

— **STANDARD\_DATE**(value, format, language)

For complete date only form items, the language has to be supplied as third parameter for month names, possible values: 'DE', 'EN', 'FR'. The following date formats are possible:

'DDMMYYYY'  
 'DDMONYYYY'  
 'YYYYMMDD'  
 'YYYYMONDD'

— **VALUE\_TO\_LABEL**('table', 'column', value)

For radiobutton and pop-up items: After specifying the form table and the field column, the specified numerical value is converted into the corresponding label. (Table and column name has to be given in lower case and enclosed by single quotation marks. The parameter list of this function is increased by the system.) With little response options the use of the SQL standard function "CASE" is recommended due to the faster execution.

— **IS\_OVERDUE**(date)

For marking exceeded (visit) date values: If the transferred, real date is NULL or already exceeded, an exclamation mark with HTML marking (red, bold) is fed back, otherwise a (forced) blank.

— **ISFORMCOMPLETE**(completionstatus)

For checking the form's completion status. If the "complete" flag is set, the function feeds back "1".

- For the following functions the 'tpxdocument' has to be replaced with the name of the corresponding project table. The other labels in single quotes are examples and can be replaced.

— **VISIT\_COMPLETION**('tpxdocument', cvpid, visitid, 'empty', 'partial', 'complete')

Summarizes the completion status of the visit defined by cvpid and visitid. As a result one of the given labels is returned.

— **VISIT\_DEC\_COMPLETION**('tpxdocument', cvpid, visitid, 'empty', 'partial', 'complete', 'finished')

Summarizes the completion status of the visit defined by cvpid and visitid. As a result one of the given labels is returned. If the status DEC is set in all forms the 'finished' label will be returned, regardless of the stored completion status of the forms.

— **VISIT\_FAMILY\_COMPLETION**('tpxdocument', cvpid, visitid, 'form family', 'empty', 'partial', 'complete')

Summarizes the completion status of the visit formfamily defined by cvpid, visitid and family name. As a result one of the given labels is returned.

— **VISIT\_FAMILY\_DEC\_COMPLETION**('tpxdocument', cvpid, visitid, 'form family', 'empty', 'partial', 'complete', 'finished')

Summarizes the completion status of the visit formfamily defined by cvpid, visitid and family name. As a result one of the given labels is returned. If the status DEC is set in all forms the 'finished' label will be returned, regardless of the stored completion status of the forms.

— **FAMILY\_COMPLETION**('tpxdocument', 'form family', projectid, 'empty', 'partial', 'complete')

Summarizes the completion status of the formfamily defined by name and projectid. As a result one of the given labels is returned. Usable for casenode families or visit families displayed in only one visit.

— **FAMILY\_DEC\_COMPLETION**('tpxdocument', 'form family', projectid, 'empty', 'partial', 'complete', 'finished')

Summarizes the completion status of the formfamily defined by name and projectid. As a result one of the given labels is returned. If the status DEC is set in all forms the 'finished' label will be returned, regardless of the stored completion status of the forms. Usable for casenode families or visit families displayed in only one visit.

- For the following review-check functions these labels are possible for 'review type' to check for a single or combined type of review:
  - 'A' (Review A)
  - 'B' (Review B)
  - 'A-B'
  - 'FREEZE' (frozen by rule)
  - 'A-FREEZE'
  - 'B-FREEZE'
  - 'A-B-FREEZE'
  - 'LOCK' (manually frozen)
  - 'A-LOCK'
  - 'B-LOCK'
  - 'A-B-LOCK'
  - 'FREEZE-LOCK'
  - 'A-FREEZE-LOCK'
  - 'B-FREEZE-LOCK'
  - 'A-B-FREEZE-LOCK'
- **VISIT\_REVIEW**('tpxdocument', cvpid, visitid, 'review type', 'none', 'partial', 'all')  
Determines if the review status of all savable forms of the visit matches the given review type and returns the appropriate, given label.
- **VISIT\_FAMILY\_REVIEW**('tpxdocument', cvpid, visitid, 'family name', 'review type', 'none', 'partial', 'all')  
Determines if the review status of all savable forms of the visit and formfamily matches the given review type and returns the appropriate, given label.
- **FAMILY\_REVIEW**('tpxdocument', 'family name', projectid, 'review type', 'none', 'partial', 'all')  
Determines if the review status of all savable forms of the formfamily matches the given review type and returns the appropriate, given label.
- Instead of a DB function, sub-queries or "CASE WHEN" constructions can also be inserted.

## 5.2 Free SQL

- In addition to the SQL report there is an additional report type "Free SQL". With this report type, the Select statement can be freely formulated in a large text field. The statement must begin with a "SELECT" and must not end with a semi-colon. Outer brackets will be ignored when checking. When displaying this report manual entered linewraps will remain. Lines longer than 100 characters (print preview: 80), will be wrapped automatically at the last blank included.
- Furthermore, the text must not include a number of fixed terms as commands (text in single quotation marks will be ignored). The forbidden commands are listed in the help text.
- For the statement to also be displayed in DataCapture, a description must additionally be entered for every column (this is optional for columns which are not to be displayed). In the description, the column name or alias (if set) from the statement must be used as the variable name. Apart from this, the description is to be defined according to the attributes of the previous SQL report. A new attribute that can be entered in the description is whether a patient can be accessed via the column (=column includes one of the pseudonyms) or a form (=column includes the document ID).
- This report will also be automatically extended with the corresponding DB users in the table. To limit the report to the centres of the current participant, the place-holder <CENTRES> can be used to reference all centre IDs of the current participant. These will then be bundled as a set (IDs listed in brackets, e.g. "(125, 5, 7,13)"). In FormBuilder, all centres in the project are used instead of the centres of the current participant.

- In the free text statement, the parameter list of the function VALUE\_TO\_LABEL is also extended by the current project version.
- To enable the statement to be checked for forbidden commands, the window for checking the SQL status is only active once the report has been saved. For this reason, when saving an SQL report, a message will be displayed (only once) that saving will reset the SQL status.

The screenshot shows the 'SELECT statement' editor with the following SQL code:

```
SELECT
  patient.pseudonym P1,
  centre.agname ZENTRUM
FROM centre, patient, n5casenode
WHERE (patient.pid = n5casenode.pid) AND (centre.ctrid = n5casenode.ctrid) AND
centre.ctrid IN <CENTRES>
GROUP BY pseudonym, agname
```

Below the statement editor, the 'Columns' section allows defining the display of the first 10 columns. The first column is defined as follows:

- Display:** 10
- Column is:** ☒ hidden ☒ shown ☐ sortable ☐ selectable
- Title:** Patient
- Variable name:** P1
- Ordered by:** ASC
- Buttons:** Remove, New column description

At the bottom, there are buttons for 'Highlighted rows' and 'New highlighting'.

Fig. 56: Free text field for entering the SQL statement and separate definition of the displayed columns.

- For this SQL report type it is likewise possible to define row highlighting based on the variable name of the column description.

### 5.3 Single field

- A single form value for all visits is portrayed in this report. If the selected form is not displayed in all visits, this visit is skipped or omitted in the portrayal.

The screenshot shows the 'Weight' report view. At the top, there is a header with the secuTrial logo and metadata:

- Date:** 31.08.2010 - 19:34 (CEST)
- Participant:** Dipl.biol Susanne Schneider
- Project:** Study 1 (31.08.2010 - 19:34:11 (CEST))

On the right, there are buttons for 'Close', 'Print', and 'Excel'.

The main content area is titled 'Weight' and shows a summary for 'Centre A' (No patients included) and 'Centre B' (table below).

Pat-ID	1. visit	2. visit
ick371 (A)		
jqj789	123.2 kg	
pxe146		
xel012	75.4 kg	
xkx764	76.0 kg	
xyx219 (B)	63.8 kg	70.0 kg
zpu285		

Fig. 57: Example of the view of a single field report in the DataCapture; in this case, the portrayal of the patients weight.

- Numerical fields offer the additional option of particularly emphasising values above or below a specified limit value. In the case of fields with a defined unit, a check box can be used to select whether these are to be displayed in the report.

Fig. 58: Configuration of the single field report from Fig. 57 in the FormBuilder: To do this, the form field and the limit value are additionally selected after specifying the "Single field" report type. For this report, the limit value has been specified as 100. All values above this are emphasised in red. The defined unit is displayed in this report.

## 5.4 Single field per visit

- As a refinement of the Single field report, a different field for portrayal can also be selected for each visit. In this case, the same data can be input as in a single field report. A heading can additionally be defined for each field.

Multiple values					
Centre A					
No patients included.					
Centre B					
Pat-ID	1. visit			2. visit	3. visit
	Birthdate	Sex	Weight	Weight	Weight
ick371 (A)	12.02.1982	female			
jqj789	17.06.1964	male	123.2 kg		
pxe146					
xel012	01.05.1976	female	75.4 kg		
xkx764			76.0 kg		
xyx219 (B)			63.8 kg	70.0 kg	71.0 kg
zpu285					

Fig. 59: Example of the view of a report on single fields per visit: Three different fields have been selected for the first visit, a single field for the other visits.

- Visits or casenode forms can be selected. Several fields can be defined for each visit. Exceeded limit values can also be emphasised for numerical values in this report type (see: "Single field" section).
- The sequence of the items can be explicitly specified. Use the SORT VIEW button to carry out changes to the sorting. Your sorting changes can be accepted in this way.

## 5.5 Status

- The status information for all visit forms can be displayed via the visits. There are different types of status: Review, completion status, query and comments. In the case of status reports, the data are listed in separate tables sorted by centre. To shorten the loading times, the user can specify that the different centres are only to be displayed individually. Only the list of patients in the first centre is then initially displayed, the other centre can then be displayed via the. (If the participant is only in one centre, the data from this centre are displayed immediately.)
- For status reports you can select whether the report is sorted by visit type or chronologically. For example, it may be that the used patient visits differ from each other in different treatment arms and displaying a combined overview would be difficult in the report.
  - When sorting by visit type, the treatment arms are listed separately.
  - When sorting reports chronologically, the patient visits are listed in the order of the current patient.
- For projects using CPV, reports can be sorted chronologically or by visit type.

Pat-ID	1. visit	2. visit	3. visit	Patient status	Adverse Event	Images
ick371 (A)						
jqj789						
pxe146						
xel012						
xkx764						
xyx219 (B)						
zpu285						

Fig. 60: Example of the view of a status report on the completion status; this is made clear here using coloured style sheets (light blue=empty, medium blue=partly filled, midnight blue=complete).

- On creation of a new status report (completion status, query, comments and review), all status checks possible for the selected status field are already created in the correct sequence.

### Review

- Here, all forms which can be saved must be reviewed again so that the entire visit has the status "Review". An individual review is not displayed here.
- The various statuses can be marked via text specifications and the selection of a style sheet. A preview clarifies the effect of the style sheet in this case.

**secuTrial®** Date: 31.08.2010 - 19:56 (CEST) Participant: Dipl.biol Susanne Schneider | Print | Logout

**Welcome > Project**

Project: Study 1 (31.08.2010 - 19:56:00 (CEST)) { PROB - Registry / No. 2 - Development }

**Edit reports: "Study 1" (9)**

Copy	No.	Report	Status	Type	Print	Delete from database
<input type="radio"/>	1	Completion status	Ok	Status	Print	Delete
<input type="radio"/>	2	Image overview	Ok	Image forms	Print	Delete
<input type="radio"/>	3	Queries	Ok	Queries details	Print	Delete
<input type="radio"/>	4	IIF	Incorret definition	Single field	Print	Delete
<input type="radio"/>	5	Height	Ok	Single field	Print	Delete
<input type="radio"/>	6	Icon overview	Ok	Icon display	Print	Delete
<input type="radio"/>	7	SQL Report	Check status	SQL	Print	Delete
<input type="radio"/>	8	Weight	Ok	Single field	Print	Delete
<input type="radio"/>	9	Multiple values	Ok	Single field per visit	Print	Delete

[Copy report](#) [New report](#)

---

**No.**

**Name \***

**Type \*** ☐ SQL ☐ Single field ☐ Single field per visit ☒ Status ☐ Queries details ☐ Icon display ☐ Image forms

☐ Show reports of all Centre immediately ☐ Display count ☐ display all pseudonyms

**Style definition of the rows**

odd rows Preview

even rows Preview

---

**Statusfield \***  [?](#)

**Display \*** [?](#)

1	Text	<input type="text"/>	if	data entry complete	is set	style	greenbg	<a href="#">Preview</a>	<a href="#">Delete</a>
2	Text	<input type="text"/>	if	completely filled	is set	style	blue6bg	<a href="#">Preview</a>	<a href="#">Delete</a>
3	Text	<input type="text"/>	if	partly filled	is set	style	blue4bg	<a href="#">Preview</a>	<a href="#">Delete</a>
4	Text	<input type="text"/>	if	empty	is set	style	blue2bg	<a href="#">Preview</a>	<a href="#">Delete</a>

**Empty column**

[Cancel](#) [Save and back](#) [Save](#) [top](#)

Fig. 61: Editing a status reports, in this case the completion status (see Fig. 60). The upper part of the page lists all reports created for this project. Clicking onto a name loads the report into the lower part of the page for editing. The middle part offers the option of inputting general data. The lower part shows the status selected for display and, on the outer right, the pre-view of the style sheets.

### Completion status

- The completion statuses of all forms which can be saved are added here. A visit is only completely filled when all forms which can be saved are completely filled (see Fig. 60).

### Query

- If at least one single, open query is created on all of a visit's forms, this results in the status "Open query" for the entire visit. If all queries in all forms have been answered, the entire visit has the status "Answered query". Accordingly, all queries in all forms must be closed to obtain the overall status "Closed query".



## Comments

- One single comment on any form sets the visit status to "Comment" in this case.

## Source Data Verification (SDV)

- The SDV states of all forms which can be saved are added here. It can be checked for the following summary SDV status values:
  - not done (all status are "not done")
  - in process (at min. one status is "not done")
  - not necessary (all status are "not necessary")
  - verified (at min. one status is "verified", no status is "not done" or "verified with problems")
  - verified with problems (at min. one status is "verified with problems", no status is "not done")

## 5.6 Query details

- Query details shows an individual list of all queries which have been created. A filter option enables only queries with certain properties to be called up.

secuTrial®

Date31.08.2010 - 20:13 (CEST)

ParticipantDipl.biol Susanne Schneider

ProjectStudy 1 (31.08.2010 - 19:56:00 (CEST))

Close

Print

Queries

Status	Patient	Centre	Author	Released	resolved	Form	Item
< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >
▶ !	M#1213	xyx219	Centre B	Dr Jonas	31.08.10	Personal Data - Date of birth	
▼ !	M#1214	xyx219	Centre B	Dr Jonas	31.08.10	Personal Data - Picture	
	? Dr Ulrike Jonas		31.08.2010 - 20:07 (CEST)	The picture is still missing!			
	! Dipl.biol Susanne Schneider		31.08.2010 - 20:12 (CEST)	Sorry, answer to wrong query. Picture has been added lately.			
▼ !	M#1215	xyx219	Centre B	Dr Jonas	31.08.10	Diagnosis - How often does the symptoms occur?	
	? Dr Ulrike Jonas		31.08.2010 - 20:08 (CEST)	This value is unlikely with the diagnosis above!			
	! Dipl.biol Susanne Schneider		31.08.2010 - 20:12 (CEST)	No, this was exactly measured.			
▶ ?	M#1216	jqj789	Centre B	Dr Jonas	31.08.10	Personal Data - Weight	

Fig. 62: Example of the view of a query report. The portrayal is roughly comparable with that of an SQL report. The queries can be sorted using the grey title bars and filtered via the drop-down lists.

- Clicking onto the triangles at the start of the line enables the questions and answers to be shown and hidden. The patient can be called up via the pseudonym; clicking onto the form and question text immediately calls up the corresponding form. This enables a rapid overview of and access to all queries which have not yet been edited, including across all patients.

### Print page for paper-based query answers

- To support paper-based query handling in hybrid studies a new print page has been added to the query report where an answer form could be printed for each open query.
- The form automatically includes the position of the query (e.g. visit, form, question and item) and the current query status (question, possible answers and re-queries). Below is an empty field for writing down the answer and signature.

**Print**

☒ Paper based answers

Query-DCF Title \*

<p>  
Please check the data for this query and put your answer into the section "your answer" below.  
</p>  
<p>Send the dated and signed form back to your study office.  
</p>

Info text on print page (HTML)

Context information: ☒ all, including visit or adverse event and document-ID ☐ reduced, only form family ?

Signature ?


Fig. 63: section for the configuration of the print page for paper-based query answers.

- This additional print function can be activated in the FormBuilder under "Print" - "paper based answers" per query report (see fig. 63). The following parameters can be changed:
  - **Title:** Here you can enter the name of the answer form which will also be the name of the button in the query report by which the print page can be reached.
  - **Info text on print page (HTML):** Here you can configure the first text paragraph for additional informations.
  - **Context informationen:** Here the amount of displayed item information on the print page can be configured. When selecting the option "reduced" only information regarding form family, form, question and item is displayed. The information regarding visit, respective adverse event and the document-ID is then omitted.
  - **"Signature":** Replace here the label "Signature" with your own text.

A short online help explains the respective configuration options.

## 5.7 Icon display

- This display reveals a summary of all status reports. In the header, individual status displays can be selected or deselected by clicking on the status type.
- For icon reports you can select whether the report is sorted either by visit type or chronologically. For example, it may be that the used patient visits differ from each other in different treatment arms and displaying a combined overview would be difficult in the report.
  - When sorting by visit type, the treatment arms are listed separately.
  - When sorting reports chronologically, the patient visits are listed in the order of the current patient.
- For projects using CPV, reports can be sorted chronologically or by visit type.



Date 31.08.2010 - 20:13 (CEST)  
Participant Dipl.biol Susanne Schneider  
Project Study 1 (31.08.2010 - 19:56:00 (CEST))

Close  
Print

**Icon overview**

Display the following states:
☒ Completion status
☒ Review / Frozen
☒ Queries
☒ Comments
☒ Patient status

**Centre A (0)**  
No patients included.

**Centre B (7)**

Pat-ID	1. visit	2. visit	3. visit	Patient status	Adverse Event	Images
ick371 (A)						
jqj789						
pxe146						
xel012						
xkx764						
xyx219 (B)						
zpu285						

Fig. 64: Example of the view of an icon report. Here, the status information is summarised in the same icons as those displayed in the patient form overview. The display of the various status components can be selected and deselected via the title bar.

## 5.8 Image forms

- This report type lists all image forms created for each patient with a display of the thumbnail which has been configured. Information on the form name, assignment, created when and by whom, is displayed as a tool tip.

**secuTrial®** Date: 31.08.2010 - 20:19 (CEST) Close  
 Participant: Dipl.biolog Susanne Schneider  
 Project: Study 1 (31.08.2010 - 20:17:04 (CEST)) Print

**Image overview**

Participant: < All > Date: < All >

▼ Centre A (0)  
 No patients included.

▼ Centre B (7)

ick371 (A) (1)  
 Image form

jqj789 (0)

pxe146 (4)  
 Image form Image form Image form Image form

xel012 (0)

xkx764 (1)  
 Image form

xyx219 (B) (0)

zpu285 (0)

Fig. 65: Example of the view of an image form report. All forms are portrayed as thumbnails in a horizontal row via the image items defined in the form.

- The displayed name and the colours of the rows can be configured for this report.

## 5.9 Validation (Error report)

- The report type *Validation* or error report can be created as another report type.
- The report is displayed in a separate window. The validation report only lists entries for which the current participant has at least reading rights for the (main) form and if the form is also visible (not hidden) in DataCapture.
- The report is displayed page by page in the DataCapture (configuration in the FormBuilder, default 100 rows per 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 the majority of the displayed information. The selected method of sorting is indicated by a small arrow next to column name. The report can be downloaded as an Excel file. All of the filtered entries in the report are listed in a table (not divided into pages). If the reports consists of more than 10 000 lines the reports will be split up into multiple table sheets with 10 000 lines per sheet. The report can also be printed as displayed (page by page).

<div> <div>secuTrial®</div> <div> Date 29.01.2013 - 14:35 (CET)  Clinical Investigator Dipl. biol. Susanne Schneider  Project Example Study (29.01.2013 - 14:31:00 (CET)) </div> </div> <div>Close</div> <div>Print</div> <div>Excel</div>				
Validation report (63 lines)				
Show: <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Centre <input checked="" type="checkbox"/> Visit / AE <input checked="" type="checkbox"/> Form <input type="checkbox"/> Table <input type="checkbox"/> Completion status <input type="checkbox"/> Form status <input type="checkbox"/> Date <input type="checkbox"/> Version <input type="checkbox"/> Item <input type="checkbox"/> Column <input type="checkbox"/> Query status <input type="checkbox"/> Value <input checked="" type="checkbox"/> Message <input type="checkbox"/> Rule <input checked="" type="checkbox"/> Type				
NOTE: The listing may be out of date because of value changes (in referenced forms) or rule changes since data entry.				
Patient	Visit / AE	Form	Message	Type
< Please choose >	< Please choose >	< Please choose >	< Please choose >	< Please choose >
! dhz086	1. Adverse Event	Adverse Event	Eingabe erforderlich!	rule error
! dhz086	2. Adverse Event	Adverse Event	Eingabe erforderlich!	rule error
! dhz086	1. visit	DST-Test	Eingabe erforderlich!	rule error
! dsu0877	2. visit	DST-Test	Eingabe erforderlich!	rule error
! gnt320	1. visit	Components	Input required!	rule error
! gnt320	1. Adverse Event	Adverse Event	The description must be given if the event type is 'other'	rule error
! gnt320	1. Adverse Event	Adverse Event	Therapy must be specified if 'yes' is ticked.	rule error
! gnt320	1. Adverse Event	Adverse Event	Input required!	rule error
! ige813	1. visit	DST-Test	Eingabe erforderlich!	rule error
! ige813	2. visit	Komponenten	Eingabe erforderlich!	rule error
! ige813	2. visit	ITM Test Form	Bitte Angabe machen!	rule error

Fig. 66: Example of an 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.

**Note:** An validation report set up after the update on secuTrial® version 4.4 will not display any content because validation messages have not yet been saved. In existing studies, the revalidation function can be used to save the validation messages for the first time

## 6. Statistics types

- Two types of information can basically be evaluated: Information on the number of patients and information on the number of patients per answer value in a specific item.
- The type of portrayal depends on the number of portrayed parameters; there are graphics for two or three parameters which are dependent on each other, whereby the type of graphic may in turn be two- or three-dimensional.
- Non-saved forms or no answer in the evaluated field are handled identically. The data statistics are optionally created for all created patients, patients per centre or patients per country. This can be selected under "Generation" in the relevant statistics.
- If the statistics include the evaluation of form datasets, only compared datasets will be evaluated when using the DDE function. All other datasets, including previously entered datasets, are treated as "Not saved".

### 6.1 Chart type

- The type of portrayal can be selected via a drop-down list on configuration of the statistics. The graphics types each possible for the number of information dimensions are offered. The pie chart can only be used for two parameters, whilst the staggered bar charts are only used for three parameters.

#### Line chart

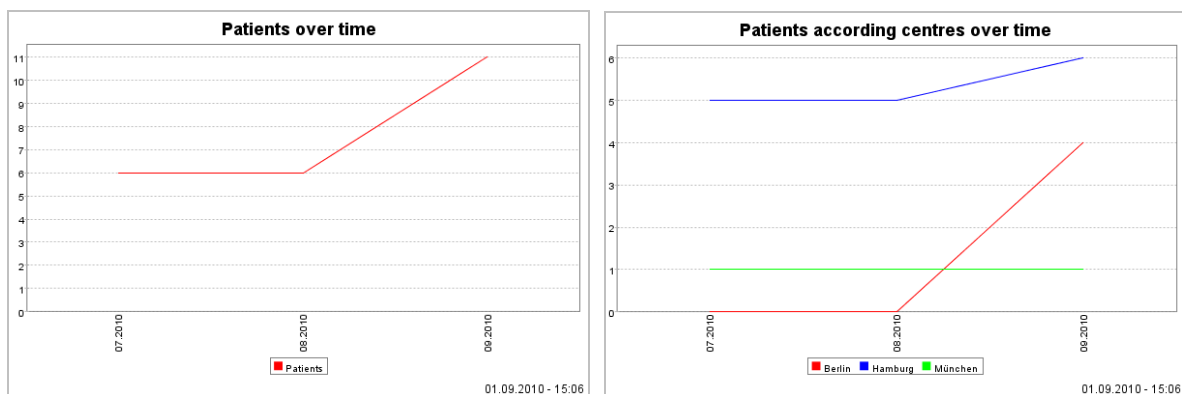


Fig. 67: Examples of the view of statistics as a line chart for two parameters (left) and three parameters (right).

#### Bar chart / 3D

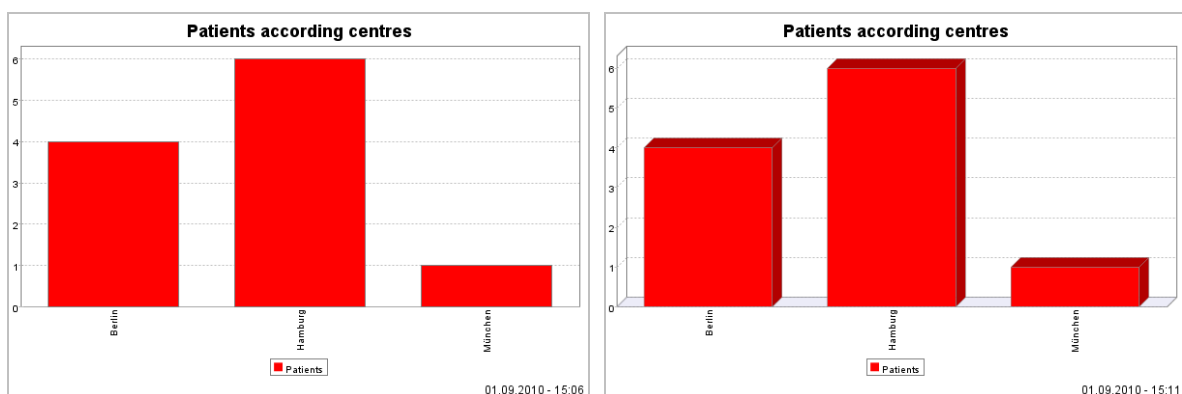


Fig. 68: Examples of the view of statistics as a simple bar chart and a 3D bar chart for two parameters.

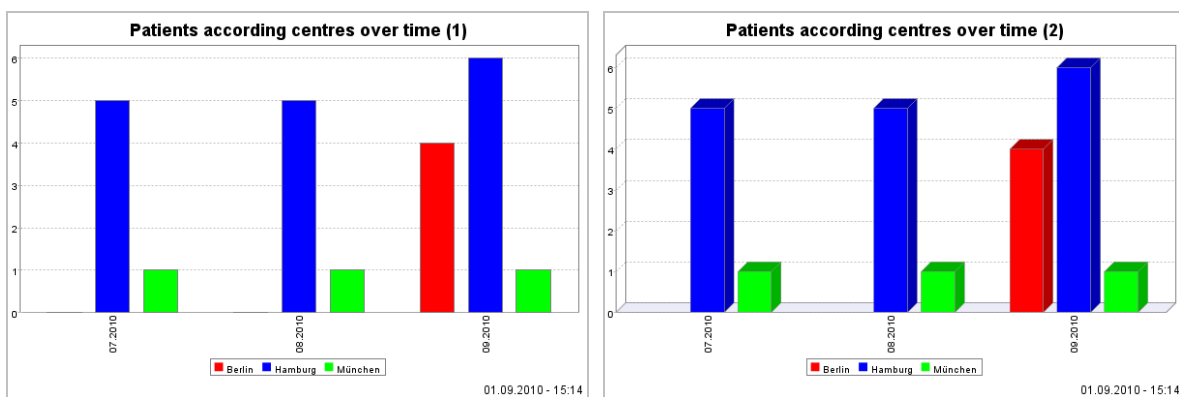


Fig. 69: Examples of the view of statistics as a normal bar chart and a 3D bar chart for three parameters.

### Staggered bar chart / 3D

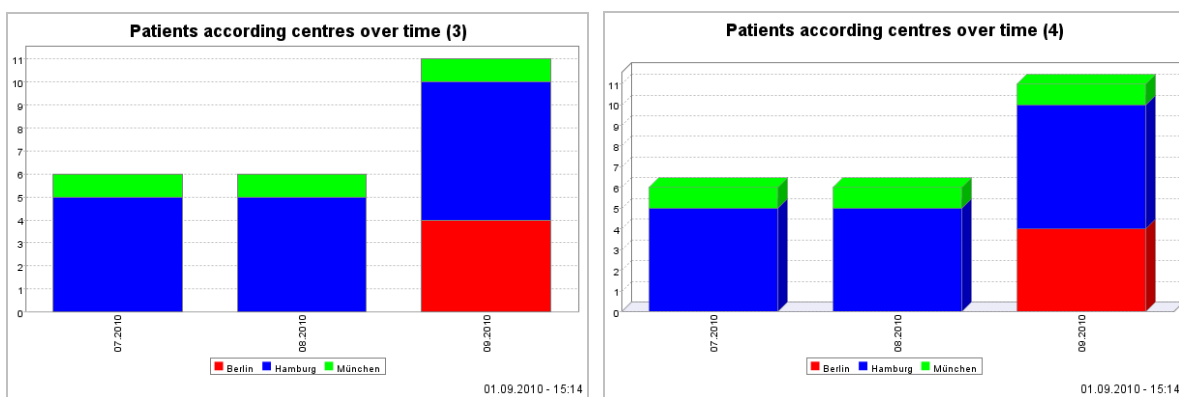


Fig. 70: Examples of the view of statistics as a staggered bar chart and a 3D bar chart for three parameters.

### Horizontally staggered bar chart / 3D

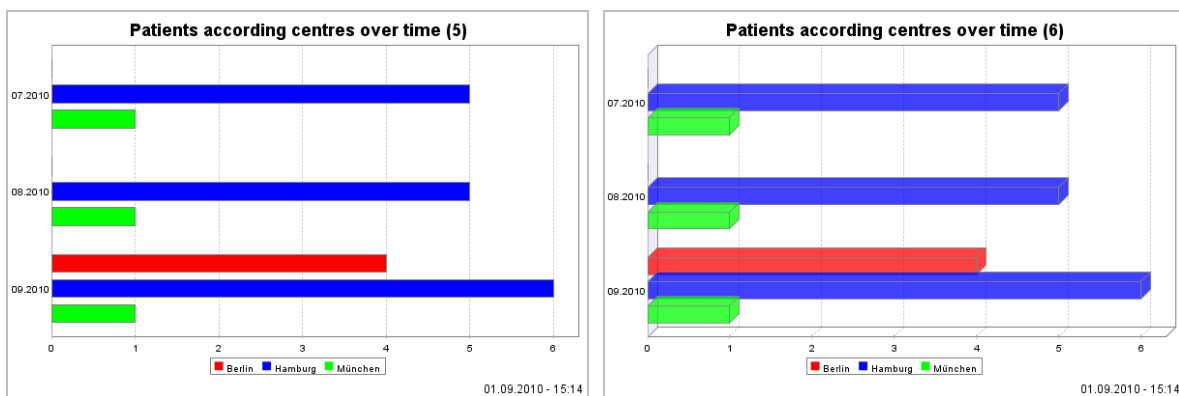


Fig. 71: Examples of the view of statistics as a normal, horizontally staggered bar chart and a 3D bar chart for three parameters.

## Pie chart / 3D

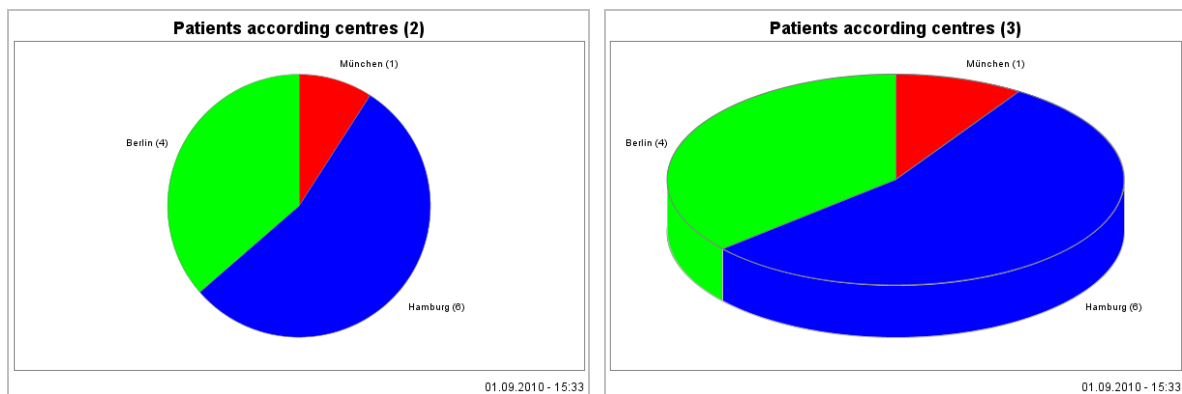


Fig. 72: Examples of the view of statistics as a normal pie chart and a 3D pie chart for two parameters.

## 6.2 Evaluated information

### Recruitment

- Four defined statistics, which are listed in the following, and for which additional parameters have to be selected are available for displaying information on the status of recruitment.
  - "Patients over time"
  - "Patients according to centres"
  - "Patients according to centres over time"
  - "Patients over visits"

### Data fields

- Six statistics, which are listed in the following, for which the item from normal visit or casenode forms has to be specified besides additional parameters, and from which the data are read-out, are available for displaying information from specific data fields.
  - "Discrete items (one visit)"
  - "Discrete items (all visits)"
  - "Discrete items (casenode)"
  - "Numeric items (one visit)"
  - "Numeric items (all visits)"
  - "Numeric items (casenode)"
- Discrete items refers to the group of items which are stored in the database with a firmly defined value (e.g. radiobuttons and pop-ups).
- Numeric items refers to number fields.
- "One visit" means the portrayal of the number of patients with a specific item content from a specific visit
- "All visits" means the portrayal of the number of patients with a specific item content over all of a visit plan's visits
- "Casenode" means the portrayal of the number of patients with a specific item content from a casenode form



- There are no statistics regarding adverse event forms.

## 6.3 Configuration options

### Category

- Categories summarise several statistics which are connected to each other. E.g. several charts referring to hepatic values may be assigned to the "Hepatic values" category. Depending on type, the category's default setting is "Recruitment" or "Data".

### Time configuration

- You may choose between day, month and year for the time axis subdivision. This enables the statistics to be adapted to the run time of your project. You can choose between various options to portray the time configuration.
- In the case of data statistics on data in an individual visit, the visit to be evaluated additionally has to be specified. "*Earliest visit with stored form*" refers, as the data basis, to the earliest visit of the entire visit plan for each patient, in which the relevant form was actually saved (selection "<Visit plan>". If "*Latest visit with stored form*" has been selected, of course, the last visit is used for evaluation. To enable the selection to be limited, you may also select a concrete visit type for evaluation.

### Evaluation

- Evaluation can be carried out via the cumulative or absolute frequency. In the case of the cumulative frequency, all results are summarised.
- On cumulative portrayal in the case of the statistics "*Patients over time*", the number of new patients created in the 2nd month is added to the number of new patients created in the 1st month. On absolute portrayal, the number of new patients created is portrayed individually for each month
- In the case of the statistics "*Patients over visits*", three results are always portrayed.
  - The first result represents the number of all patients.
  - The second result represents the number of patients, which have stored forms in this visit.
  - The third result represents the number of patients with a specific visit status (see "Evaluated status").
- In the case of this statistics type, cumulative portrayal means that the first result also contains the patients from the two other results, and the second result those from the third.

Statistics "Study 1" (3)	
Recruitment statistics:	<div> <div>▶ 1 Patients over time</div> <div>[ Patients over time ] Remove</div> </div>
▼ 2 Title *	<div>Patients according centres over time</div> <div>[ Patients according centres over time ] Remove</div>
Category	Recruitment ?
Time configuration *	<div>Month time period</div> <div>MM.YYYY label (x-axis)</div> <div>Created evaluated date (patient in project)</div>
Evaluation	Cumulative frequency
Label x-axis	
Label y-axis	
Chart type *	line chart
Generation *	per project ?

Fig. 73: Example: Statistics with "completion status" selected as "Evaluated status" and "Cumulative frequency" as "Evaluation".

- In the same statistics type, absolute portrayal means that the first result contains only those patients which have been created but not yet saved forms. The second result represents all patients which

have been saved but are not yet complete. The third result represents only the completed visits (see Fig. 73).

- On portrayal of data statistics over all visits, absolute values in the relevant visit are always portrayed.

### **Evaluated status**

- The user can choose between the two different types *"completion status"* and *"Review"*.
- In the case of *"completion status"* you have the option of choosing between the values "Completely filled" and "data entry complete" in the drop-down list.
- In the case of *"Review"*, you may choose between the values *"medical review (A)"*, *"data review (B)"*, *"review (A+B)"* and *"manual freezing"* in the drop-down list.

### **Visit**

- As visit forms may be displayed multiple times in various visits and the medical data records are stored in the same table, the visit from which the data record for the statistics is to be taken additionally has to be specified in the case of certain statistics types, so that each patient is only counted once. The data record saved first or last can be selected to do this.
- On creation of the statistics for a specific visit, the visit type which this involves (visit 1, visit 2, etc.) must be specified in the drop-down field. This step is omitted in the case of statistics on *"all visits"* and *"casenode"*.

### **Item**

- On creation of statistics on discrete items (radiobuttons and popup items) or numerical items, the item from which the value is to be read-out must also be specified in addition to the above described data. To do this, select the form in which the item is found from the front drop-down list. The item can now also be selected in the rear drop-down list.

### **Value ranges**

- For numerical items, the value range into which the saved data are to be subdivided for evaluation has to be specified. For a sensible evaluation, at least two value ranges should be specified.
- A plausibility check, which warns you in the event of overlaps or gaps in the value range, is available. If desired, this warning can be ignored by saving again.

### **Generation**

- The data statistics can be optionally generated per project, centre or country.
- On generation per centre or country, several statistics files are generated for each statistics definition. In the AdminTool, rights are still assigned via the assignment of roles to the statistics definition.
- The display in the DataCapture is carried out depending on the current participant's role rights and assignment to the centres. In the case of centre statistics, only the statistics files for his centres are displayed to the participant. In the case of country statistics, assignment to a centre within the country is sufficient to be able to view the statistics file.

## 7. Messages

### 7.1 Types, general settings

- Messages can be generated in secuTrial® from four different levels.
  - Project messages (bundled, not bundled)
  - Form messages.
  - Randomization messages.
  - Rule messages.
- You can substitute the following placeholder in the subject:
  - <CENTRE> = Name of current centre of the patient
  - <PAT-ID> = Pat-ID of the patient
  - <ADD-ID> = Add-ID of the patient
  - <LAB-ID> = Lab-ID of the patient
  - <RANDOM> = Randomization(s) of the patient (in a blinded randomization the randomization number of the patient will be shown, in a unblinded randomization the randomization group of the patient).
- For all message types it is possible to select the included information individually.

The screenshot shows the 'Content' configuration window. It includes the following fields and options:

- Email format:** ☒ HTML ?
- Title:** Message from Visite 1 <RANDOM> ?
- Notes:** ☒ Text for automatic delivery
- Start of message:** Dear Mr.
- Contains:**
  - Patient: ☒ Pat-ID, ☒ Add-ID, ☒ Lab-ID, ☒ URL to patient, ☒ Form, ☒ Name, ☒ Email
  - Centre: ☒ Name, ☒ Email
  - Participant: ☒ Name, ☒ Role, ☒ Address, ☒ Email
- End of message:** Best regards.

*Fig. 74: Selecting the standard information for the content of a message. The available selection options differ according to the message type; this example shows the configuration of a follow-up form message.*

- The following options can be selected:
  - Note regarding automatically generated e-mail
 

To prevent users from trying to answer automatically generated e-mails, the note "This is an automatically generated e-mail. Please do not reply to this message." can be placed at the beginning of the e-mail.
  - Note regarding multiple messages

- (Only configurable for form messages) If a message is defined as a form follow-up action, this may be triggered and sent multiple times if a form is edited more than once. The defined notification text will be placed above the message if the message is triggered more than once. *(Note: because the sending action itself is not recorded, the currently defined trigger will be searched for in the Audit Trail. If this already exists, the message will be considered to have been sent out again.)*
- Patient
- The availability of pseudonyms depends on the project and customer configuration.
  - Pat-ID  
(Only configurable when using the Pat-ID in the project)
  - Add-ID  
(Only configurable when using the Add-ID in the project)
  - Lab-ID  
(Only configurable when using the pseudonym display in the customer)
  - URL for the patient  
If this option is selected, a URL for directly accessing the patient is included in the message.
- Form  
The form entries can only be selected if the message is triggered during form editing.
  - SDV items  
(Only configurable for SDV messages) By selecting this option, items which reset the SDV status when edited are also listed in the message.
  - Query item  
(Only configurable for query messages) This option includes the queried item in the message.
  - Query text  
(Only configurable for query messages) The current query entry is included in the message.
  - URL for the form  
(Cannot be configured when creating a patient or empty visit messages) By selecting this option, a URL for directly accessing the form is included in the message

**Note:** By clicking the URL in a message for directly accessing patients or forms the URL is called up in the browser (e-mail programme function, alternatively copy the URL in the browser's address line) and the usual login page for DataCapture will be initially displayed.

- The participant signs in with their usual user name and password. After successful authentication, the participant will be directly taken to the form overview of the patient (with patient URL) or form view (with form URL).
- If the participant does not have the rights to edit that patient or form, after successfully logging in an error page will be displayed and the participant will remain on the Welcome page.
- The URLs are also contained in internal messages, for example in sent messages. Clicking on the URL will likewise open the DataCapture login page, even though the participant has already logged in.
- Centre
  - Name

- E-mail
- Participant

If "Name" and "Role" are selected, they will be summarised in one row. If only one option is selected, then "Participant" (for "Name") or "Role" will be put first.

- Name
- Role
- Address
- E-mail

**Note:** When defining messages for bundled message dispatch, please bear in mind that the more specific the content, the more messages will be sent. This is because bundling is based on a comparison of the message content.

- For example, if only the centre and the patient are contained as general information in a query message, only one message will be sent for each of the patients within the dispatch interval. If the query text is also included, a separate message will be sent for each individual query.
- In addition you can assign HTML tags to the definition of beginning and end texts by selecting the configuration "HTML Format". This also means vice-versa that simple line breaks within the templates will be ignored. With HTML formatted messages, the automatically included information from form questions will also be formatted similar to the way in which messages copies are displayed in DataCapture. The preset question texts will be displayed in bold face and the data entered by the user will be displayed with normal formatting.

## 7.2 Project messages

### Bundled messages

- Bundled messages in secuTrial® are messages, which are generated when processing queries, on automatic reset of a SDV status or at empty visits. These are not dispatched directly, but are initially collected and dispatched at the defined point in time and interval.
- The point in time and interval are set in the AdminTool, whereas the message content is set in the FormBuilder. In this case, identical message types are summarised: If e.g. 10 queries are submitted when monitoring a single patient, these are summarised to form one message (see note for bundled message dispatch above).
- Multiple messages can be defined in a project for the different triggers in the query work flow. For example, this makes it possible to define a message for a new query in different languages. This can then be sent to different roles according to the language used.
- For empty visit messages, you can additionally configure the time period for the messages. To do this, enter the start and end time of the message and the interval in days with regard to the planned visit date.
- When configuring messages for the trigger "Empty visits" you can define multiple messages, e.g. for different message time periods. In this way different reminders can be sent before and after a planned visit date (see fig. 75).
- If a project uses the bundled message dispatch, is therefore determined by the defined project messages.

### Not bundled messages

- With the project messages, another message can be defined for the trigger "Patient created". This message is not sent as a bundled message dispatch but immediately when a patient is created.

Message dispatch:	Notification at ... (5)	internal title	New notification
	🕒 Empty visit (1 day after to 2 days after)	"Leere Visite 1 Tag nach"	Delete
	🕒 Empty visit (1 day before to 0 days after)	"Leere Visite 1 Tag vor"	Delete
	🕒 Empty visit (2 days before to 1 day before)	"Leere Visite 2 Tage vor"	Delete
	🕒 Query asked	"Query gestellt"	Delete
	🕒 SDV reset	"Nachricht bei SDV"	Delete

Fig. 75: Overview of all project messages on the project configuration page. Bundled message dispatches are indicated with a clock icon.

### 7.3 Form messages

- For all form (and rule messages), in addition to the general settings questions can be dispatched from the current form or questions from other forms and /or other visits can be added in the messages.
- Which forms and sources are available to choose from depends on the message form and the selected form for the question which is to be added. In the case of visit forms, both relative visits (similar to the definition of rule conditions) and defined visits from the project visit plan can be selected. If the visit defined here has been created multiple times in a patient, the first visit of this type will be used for the message.
- You can mark in addition the resending of messages through an additional template text which can be entered accordingly. This information will then be displayed before the message if the message was previously triggered with the current settings in the audit trail of the form. This indicates that the result has already been reported, e.g. in the case of an automatic Adverse Event message.

Content	
Email format:	<input checked="" type="checkbox"/> HTML ?
Title:	Adverse Event occurred ?
Note for multiple dispatch:	This event has already been reported. Please check for red marked changes. ?
Start of message:	Ladies and gentlemen  please inspect the included information.
End of message:	Best regards  Your Study-Team
Dispatched form questions	
Markup of changed form values:	<input checked="" type="checkbox"/> ?
20	Therapie Remove
Form questions:	< Please choose > Add

Fig. 76: Configuration of marked up changes in the message template.

- If the option "Markup of changed form values" has been configured from you for this message type this will always exclusively be used for questions from the current message form. Only with these questions it is possible to compare the current values with the last entries in the audit trail. For all other questions the time of the message dispatch does not correlate with the date of saving the data in the audit trail.

Displayed order	Form	Question	Source / Visit	Attach images	
10	< same form >	10 - Frage 1	current visit	<input checked="" type="checkbox"/>	<button>Remove</button>
20	< same form >	30 - Subform	current visit	<input checked="" type="checkbox"/>	<button>Remove</button>
30	Statistics <mnpr5form3>	20 - HRBM	current visit	<input type="checkbox"/>	<button>Remove</button>

Form questions add:

Form:  Question:

Source / Visit:  ☐ Add images as attachments

Fig. 77: Adding form questions, specifying the visit and selecting the attach image option on the message editing page.

- For questions that are included in the message and contain image items, you can also select whether saved image files are to be attached to the message
- If an image attachment has been selected for at least one question, the message will be automatically set to HTML and can no longer be changed. For messages that are only sent internally within secuTrial®, no images can be attached, even if this has been specified in the message definition.

**Note:** Only images smaller than 5 MB can be sent. When creating messages, please note that both the sending and receiving e-mail servers may have restrictions on the size of e-mails. This limit can soon be reached even when sending multiple small image files.

- You can define multiple messages as a follow-up action. This enables different messages to be configured for different form actions, e.g. when entering form data (select completion status as the trigger) or for monitoring (select form status as the trigger).

Conditions:

Messages:

- Message: "Nachricht aus Visite (Folgeaktion)" <completion status>
- Message: "Interner Titel" <completion status>

Fig. 78: List of all form messages on the form editing page.

## 7.4 Randomization messages

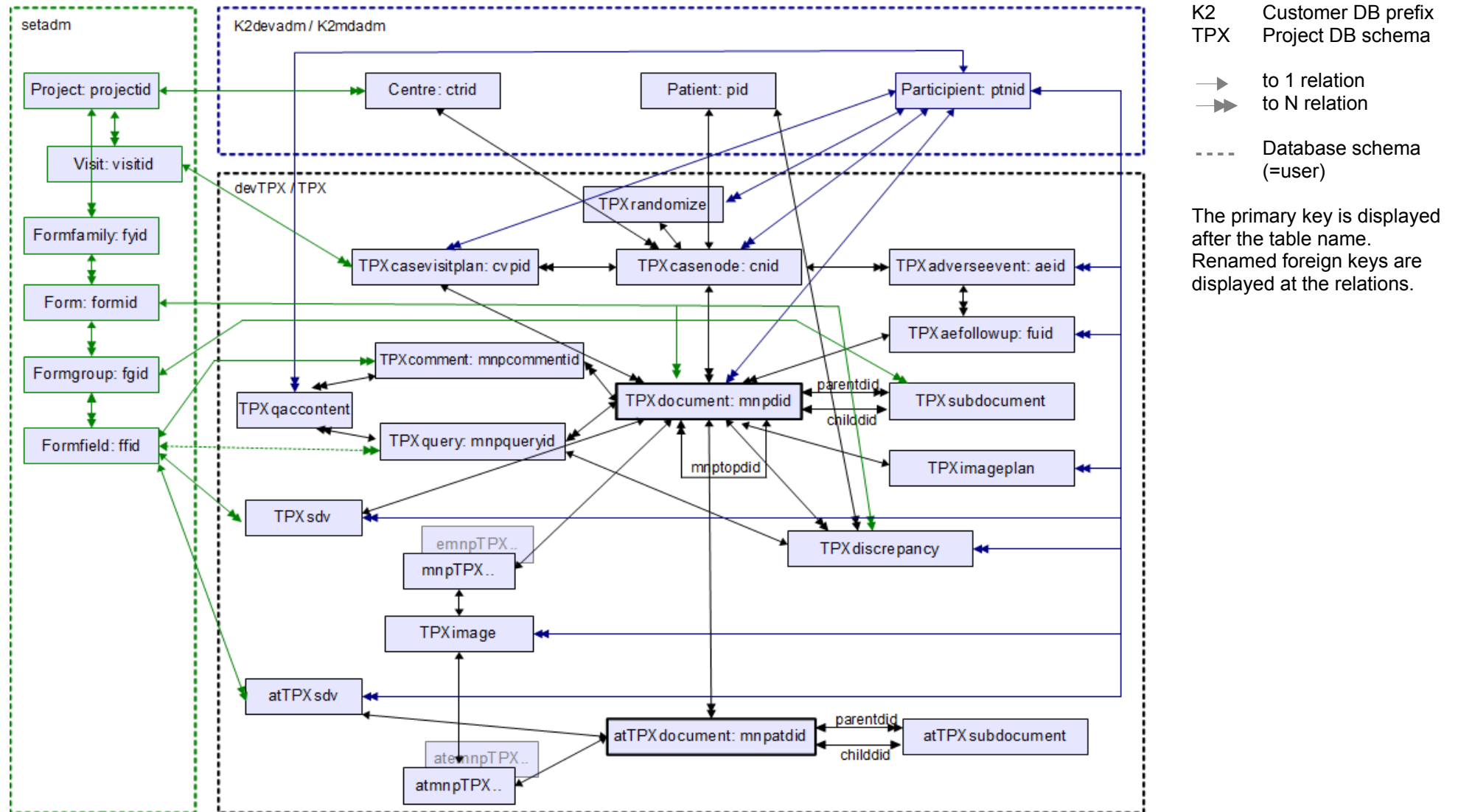
- In addition you can define a message inside the *Configurable Randomization Button* item as another message type.
- You can set the message to be triggered directly with the randomization of a patient or depending on the number of possible randomization options remaining. The message will then be sent, if the exact amount of entries is available for each randomization group (with necessary centre affiliation also per centre).

## 7.5 Rule messages

- As with form messages additional questions and pictures from the actual form or questions and pictures from other forms and / or visits can be included and sent in this message type (see Form messages).

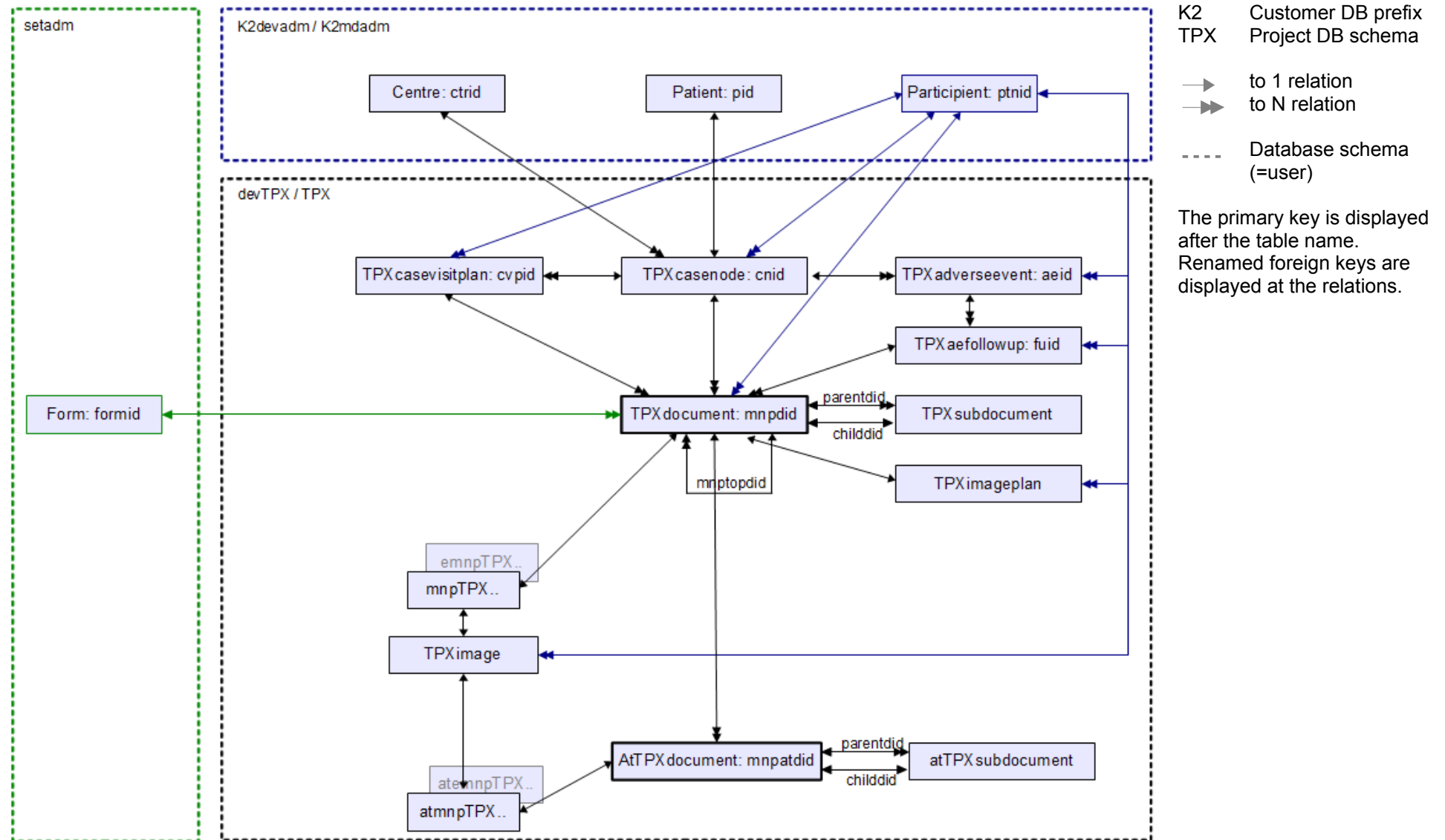
## 8. Annex

### 8.1 secuTrial® database structure: Essential project tables

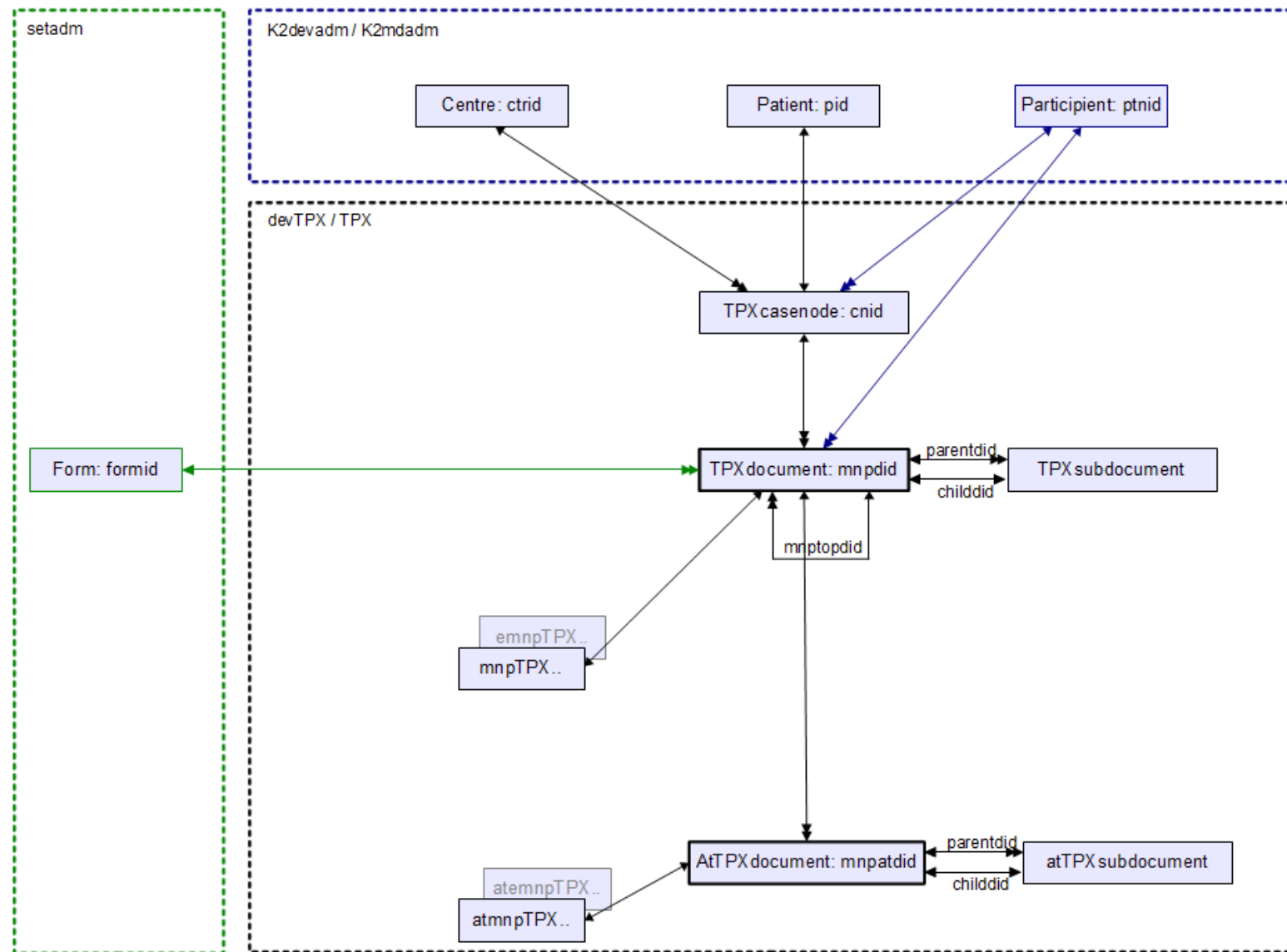




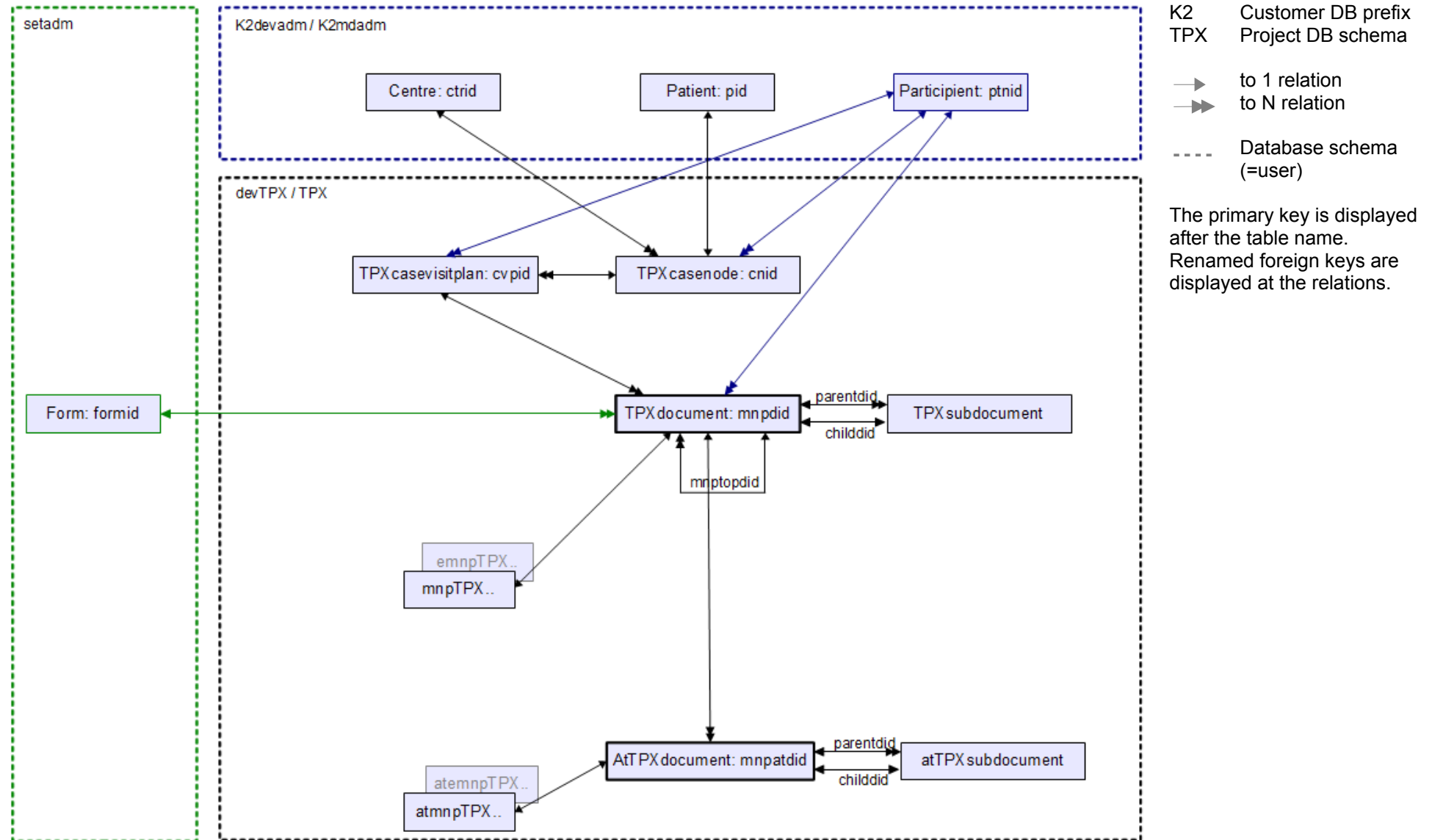
## Form data



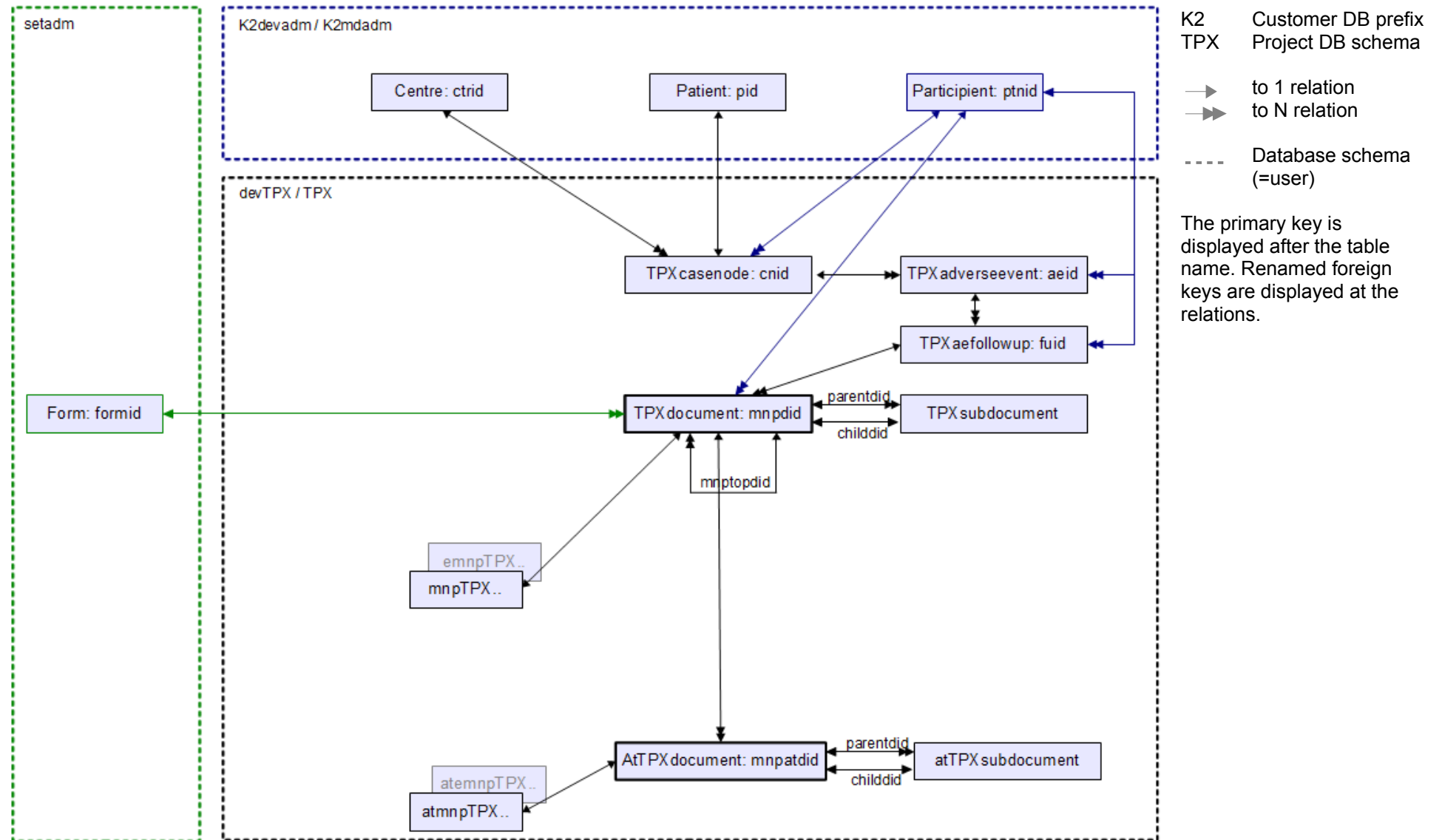
## Casenode forms



## Visit forms



## Adverse Event forms



- To enable simplified SQL statements for reports, the structure of the medical project database schemes has been extended. New columns have been introduced to allow the shortening of joins (light blue lines).
- The following tables have been extended (TPX is the placeholder for the project scheme name):

#### ***TPXdocument***

<i>pid</i>	NUMBER	NULL	Foreign key to <i>Patient</i> in the corresponding participant administration. Value corresponds to the value in the related <i>TPXcasenode</i> . Will only be set for main (outer) forms.
<i>ctrid</i>	NUMBER	NULL	Foreign key to <i>Centre</i> in the corresponding participant administration. Value corresponds to the value in the related <i>TPXcasenode</i> . Will only be set for main (outer) forms.

#### ***TPXquery, TPXcomment***

<i>mnptopdid</i>	NUMBER	NULL	Foreign key to the outer <i>TPXdocument</i> of the query or comment. If the query/comment has been set for a main form, this is the same value as in <i>mnpdid</i> .
------------------	--------	------	--

- Due to the double storage of the foreign keys to the patient and centre in the central *TPXdocument* table, it is now much easier to retrieve summarised form information for a specific patient or centre, for example the date of the last saved form. There is no need to distinguish between casenode, visit or adverse event forms in this case.
- Thanks to the additional storage of the main form in queries and comments, it is easier to list all queries or comments for each patient.

8.2 Available SDTM variables						
AE: Adverse Events						Events General Observation Class
Variable	Prefix	Variable label	Type	Core	Role	Description
AEDECOD	yes	Standardized Treatment Name	Char	req	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
AEENTPT	yes	End Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25" or "VISIT 2".
AESCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
AEPRESP	yes	Pre-specified	Char	perm	Record Qualifier	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
AEMODIFY	yes	Modified Name	Char	perm	Synonym Qualifier of --TRT, --TERM or --ORRES	If the value for --TRT, --TERM or --ORRES is modified for coding purposes, then the modified text is placed here.
AELOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: RIGHT ARM for an injection.
AETERM	yes	Reported Term	Char	req	Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.
AEBODSYS	yes	Body System or Organ Class	Char	exp	Record Qualifier	Body system or system organ class from a standard hierarchy (e.g. MedDRA) associated with an event. Example: GASTROINTESTINAL DISORDERS.
AESEV	yes	Severity/Intensity	Char	perm	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.
AESER	yes	Serious Event	Char	exp	Record Qualifier	Is this a serious event? Valid values are "Y" and "N".
AEACN	yes	Action Taken with Study Treatment	Char	exp	Record Qualifier	Describes changes made to the study treatment as a result of the event. Examples: DOSE INCREASED, DOSE NOT CHANGED.
AEACNOTH	yes	Other Action Taken	Char	perm	Record Qualifier	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment.
AEREL	yes	Causality	Char	exp	Record Qualifier	Records the investigator's opinion as to the causality of the event to the treatment. ICH E2A and E2B examples include NOT RELATED, UNLIKELY RELATED, POSSIBLY RELATED, RELATED.
AERELNST	yes	Relationship to Non-Study Treatment	Char	perm	Record Qualifier	An opinion as to whether the event may have been due to a treatment other than study drug. Example: "MORE LIKELY RELATED TO ASPIRIN USE."

Variable	Prefix	Variable label	Type	Core	Role	Description
AEPATT	yes	Pattern of Event	Char	perm	Record Qualifier	Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT.
AEOUT	yes	Outcome of Event	Char	perm	Record Qualifier	Description of the outcome of an event. Examples: RECOVERED/RESOLVED, FATAL.
AESCAN	yes	Involves Cancer	Char	perm	Record Qualifier	Was the event associated with the development of cancer? Valid values are "Y" and "N".
AESCONG	yes	Congenital Anomaly or Birth Defect	Char	perm	Record Qualifier	Was the event associated with congenital anomaly or birth defect? Valid values are "Y" and "N".
AESDISAB	yes	Persist or Signif Disability/Incapacity	Char	perm	Record Qualifier	Did the event result in persistent or significant disability/incapacity? Valid values are "Y" and "N".
AESDTH	yes	Results in Death	Char	perm	Record Qualifier	Did the event result in death? Valid values are "Y" and "N".
AESHOSP	yes	Requires or Prolongs Hospitalization	Char	perm	Record Qualifier	Did the event require or prolong hospitalization? Valid values are "Y" and "N".
AESOD	yes	Occurred with Overdose	Char	perm	Record Qualifier	Did the event occur with an overdose? Valid values are "Y" and "N".
AESMIE	yes	Other Medically Important Serious Event	Char	perm	Record Qualifier	Do additional categories for seriousness apply? Valid values are "Y" and "N".
AECONTRT	yes	Concomitant or Additional Trtmt Given	Char	perm	Record Qualifier	Was another treatment given because of the occurrence of the event? Valid values are "Y" and "N".
AETOXGR	yes	Toxicity Grade	Char	perm	Record Qualifier	Records toxicity grade using a standard toxicity scale (such as the NCI CTCAE). Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define.xml document.
AESTDTC	yes	Start Date/Time of Observation	Char	exp	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
AEENDTC	yes	End Date/Time of Observation	Char	exp	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
AEDUR	yes	Duration	Char	perm	Timing Variables	Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the C RF and not derived.
AEENRF	yes	End Relative to Reference Period	Char	perm	Timing Variables	Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFS TDTC and RFENDTC in Demographics.
AEENRTPT	yes	End Relative to Reference	Char	perm	Timing Variables	Identifies the end of the observation as being before or after the

Variable	Prefix	Variable label	Type	Core	Role	Description
		Time Point				sponsor-defined reference time point defined by variable --ENTP T.
AECAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.

CE: Clinical Events						Events General Observation Class
Variable	Prefix	Variable label	Type	Core	Role	Description
CEDECOD	yes	Standardized Treatment Name	Char	perm	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
CEENRTPT	yes	End Relative to Reference Time Point	Char	perm	Timing Variables	Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable --ENTP T.
CESTTPT	yes	Start Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --STRTPT. Examples: "2003-12-15" or "VISIT 1".
CESTRTPT	yes	Start Relative to Reference Time Point	Char	perm	Timing Variables	Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable --ST TPT.
CEENRF	yes	End Relative to Reference Period	Char	perm	Timing Variables	Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFS TDTC and RFENDTC in Demographics.
CESTRF	yes	Start Relative to Reference Period	Char	perm	Timing Variables	Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.
CEDY	yes	Study Day of Visit/Collection/Exam	Num	perm	Timing Variables	Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
CEENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
CESTDTC	yes	Start Date/Time of Observation	Char	perm	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
CEDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
CESEV	yes	Severity/Intensity	Char	perm	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODER-



Variable	Prefix	Variable label	Type	Core	Role	Description
						ATE, SEVERE.
CEBODSYS	yes	Body System or Organ Class	Char	perm	Record Qualifier	Body system or system organ class from a standard hierarchy (e.g. MedDRA) associated with an event. Example: GASTROINTESTINAL DISORDERS.
CETERM	yes	Reported Term	Char	req	Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.
CEREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
CESTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
CEOCCUR	yes	Occurrence	Char	perm	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
CEPRESP	yes	Pre-specified	Char	perm	Record Qualifier	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
CESCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
CECAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
CEENTPT	yes	End Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25" or "VISIT 2".

**CM: Concomitant Medications****Interventions General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
CMDOSFRM	yes	Dose Form	Char	perm	Variable Qualifier of --DOSE	Dose form for the treatment. Examples: TABLET, CAPSULE.
CMDECOD	yes	Standardized Treatment Name	Char	perm	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
CMDOSTXT	yes	Dose Description	Char	perm	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
CMMODIFY	yes	Modified Name	Char	perm	Synonym Qualifier of --TRT, --TERM or --ORRES	If the value for --TRT, --TERM or --ORRES is modified for coding purposes, then the modified text is placed here.
CMTRT	yes	Name of Treatment	Char	req	Topic	The topic for the intervention observation, usually the verbatim

Variable	Prefix	Variable label	Type	Core	Role	Description
						name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
CMDOSE	yes	Dose	Num	perm	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
CMCLASCD	yes	Class Code	Char	perm	Variable Qualifier of --TRT	Used to represent code for --CLAS.
CMCLAS	yes	Class	Char	perm	Variable Qualifier of --TRT	Class for a medication or treatment, often obtained from a coding dictionary.
CMINDC	yes	Indication	Char	perm	Record Qualifier	Denotes the indication for the intervention (e.g., why the therapy was taken or administered).
CMDOSU	yes	Dose Units	Char	perm	Variable Qualifier of --DOSE	Units for --DOSE, --DOSTOT, or --DOSTXT (Examples: ng, mg, mg/kg).
CMREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
CMDUR	yes	Duration	Char	perm	Timing Variables	Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the C RF and not derived.
CMSTDTC	yes	Start Date/Time of Observation	Char	perm	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
CMENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
CMDOSRGM	yes	Intended Dose Regimen	Char	perm	Variable Qualifier of --DOSE	Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.
CMSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
CMDOSTOT	yes	Total Daily Dose	Num	perm	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
CMDOSFRQ	yes	Dosing Frequency per Interval	Char	perm	Variable Qualifier of --DOSE	Usually expressed as the number of doses given per a specific interval. Examples: QD, BID, TID, QID.

**CO: Comments Domain**

Special Purpose

Variable	Prefix	Variable label	Type	Core	Role	Description
COVAL	yes	Comment	Char	req	Topic	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn.

DA: Drug Accountability						Findings General Observation Class
Variable	Pre fix	Variable label	Type	Core	Role	Description
DACAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
DASCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
DASTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
DAREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
DATESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRMIN, EYEEXAM.
DATEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
DAORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
DAORRESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
DASTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
DASTRESN	yes	Numeric Result/Finding in Standard Units	Num	perm	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
DASTRESU	yes	Standard Units	Char	perm	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
DADTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.

DM: Demographic						Special Purpose
Variable	Prefix	Variable label	Type	Core	Role	Description
DMDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
AGEU	no	Age Units	Char	exp	Qualifier Variables	Units associated with AGE.
AGE	no	Age	Num	exp	Qualifier Variables	Age expressed in AGEU. May be derived as (RFSTDTC-BRTHDTC), but BRTHDTC may not be available in all cases (due to subject privacy concerns).
BRTHDTC	no	Date/Time of Birth	Char	perm	Qualifier Variables	Date/time of birth of the subject in ISO 8601 character format.
RFENDTC	no	Subject Reference End Date/Time	Char	exp	Qualifier Variables	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.
RFSTDTC	no	Subject Reference Start Date/Time	Char	exp	Qualifier Variables	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.
SEX	no	Sex	Char	req	Qualifier Variables	Sex of the subject.
RACE	no	Race	Char	exp	Qualifier Variables	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race ( <a href="http://www.fda.gov/cder/guidance/5656fml.htm">http://www.fda.gov/cder/guidance/5656fml.htm</a> )
ETHNIC	no	Ethnicity	Char	perm	Qualifier Variables	The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity ( <a href="http://www.fda.gov/cder/guidance/5656fml.htm">http://www.fda.gov/cder/guidance/5656fml.htm</a> ).
ARMCD	no	Planned Arm Code	Char	req	Qualifier Variables	ARMCD is limited to 20 characters and does not have special character restrictions.
ARM	no	Description of Planned Arm	Char	req	Qualifier Variables	Name of the Arm to which the subject was assigned.
DS: Disposition						Events General Observation Class
Variable	Prefix	Variable label	Type	Core	Role	Description
DSDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.

DSSTDY	yes	Study Day of Start of Observation	Num	perm	Timing Variables	Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
DSSTDTC	yes	Start Date/Time of Observation	Char	exp	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
DSTERM	yes	Reported Term	Char	req	Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.
DSSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
DSCAT	yes	Category	Char	exp	Grouping Qualifier	Used to define a category of topic-variable values.
DSDECOD	yes	Standardized Treatment Name	Char	req	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.

**EG: ECG Test Results****Findings General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
EGCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
EGPOS	yes	Position of Subject During Observation	Char	perm	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
EGTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
EGELTM	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
EGTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
EGTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
EGDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
EGEVAL	yes	Evaluator	Char	perm	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, VENDOR.

Variable	Prefix	Variable label	Type	Core	Role	Description
EGDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
EGBLFL	yes	Baseline Flag	Char	exp	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
EGMETH-OD	yes	Method of Test or Examination	Char	perm	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
EGNAM	yes	Laboratory/Vendor Name	Char	perm	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.
EGXFN	yes	External Filename	Char	perm	Record Qualifier	Filename for an external file, such as one for an ECG waveform or a medical image.
EGSTRESU	yes	Standard Units	Char	perm	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
EGSTRESN	yes	Numeric Result/Finding in Standard Units	Num	perm	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
EGSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
EGOR-RESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
EGORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
EGRFTDTC	yes	Date/Time of Reference Time Point	Char	perm	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
EGTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
EGTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
EGLOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: RIGHT ARM for an injection.

Variable	Prefix	Variable label	Type	Core	Role	Description
EGREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
EGSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
EGSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.

**EX: Exposure**

## Interventions General Observation Class

Variable	Prefix	Variable label	Type	Core	Role	Description
EXENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
EXSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
EXTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
EXADJ	yes	Reason for Dose Adjustment	Char	perm	Record Qualifier	Describes reason or explanation of why a dose is adjusted. Examples ADVERSE EVENT, INSUFFICIENT RESPONSE, NON-MEDICAL REASON.
EXVAMTU	yes	Treatment Vehicle Amount Units	Char	perm	Variable Qualifier of --VAMT	Units for the treatment vehicle. Examples: mL, mg.
EXVAMT	yes	Treatment Vehicle Amount	Num	perm	Record Qualifier	Amount of the treatment vehicle administered or given.
EXTRTV	yes	Treatment Vehicle	Char	perm	Record Qualifier	Vehicle for administration of treatment, such as a liquid in which the treatment drug is dissolved. Example: SALINE.
EXTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
EXLOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: RIGHT ARM for an injection.
EXLOT	yes	Lot Number	Char	perm	Record Qualifier	Lot number for the intervention described in --TRT.
EXROUTE	yes	Route of Administration	Char	perm	Variable Qualifier of --TRT	Route of administration for the intervention. Examples: ORAL, INTRAVENOUS.
EXDOSRGM	yes	Intended Dose Regimen	Char	perm	Variable Qualifier of --DOSE	Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.
EXDOSTOT	yes	Total Daily Dose	Num	perm	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
EXDOSFRQ	yes	Dosing Frequency per Interval	Char	perm	Variable Qualifier of --DOSE	Usually expressed as the number of doses given per a specific interval. Examples: QD, BID, TID, QID.

Variable	Prefix	Variable label	Type	Core	Role	Description
EXDOSFRM	yes	Dose Form	Char	exp	Variable Qualifier of --DOSE	Dose form for the treatment. Examples: TABLET, CAPSULE.
EXDOSU	yes	Dose Units	Char	exp	Variable Qualifier of --DOSE	Units for --DOSE, --DOSTOT, or --DOSTXT (Examples: ng, mg, mg/kg).
EXDOSTXT	yes	Dose Description	Char	perm	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
EXTRT	yes	Name of Treatment	Char	req	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
EXDOSE	yes	Dose	Num	exp	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
EXELTM	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
EXTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
EXDUR	yes	Duration	Char	perm	Timing Variables	Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the C RF and not derived.
EXSTDTC	yes	Start Date/Time of Observation	Char	exp	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.

**IE: Inclusion/Exclusion Criteria Not Met****Findings General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
IECAT	yes	Category	Char	req	Grouping Qualifier	Used to define a category of topic-variable values.
IESCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
IETESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
IEDTC	yes	Date/Time of Collection	Char	req	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.



Variable	Prefix	Variable label	Type	Core	Role	Description
IEORRES	yes	Result or Finding in Original Units	Char	req	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
IESTRESC	yes	Result or Finding in Standard Format	Char	req	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
IETEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.

### LB: Laboratory Test Results Findings General Observation Class

Variable	Prefix	Variable label	Type	Core	Role	Description
LBCAT	yes	Category	Char	exp	Grouping Qualifier	Used to define a category of topic-variable values.
LBRFTDTC	yes	Date/Time of Reference Time Point	Char	perm	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
LBSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
LBREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
LBTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
LBTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
LBORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
LBORRESU	yes	Original Units	Char	exp	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
LBORNRLLO	yes	Normal Range Lower Limit-Original Units	Char	exp	Variable Qualifier of --ORRES	Lower end of normal range or reference range for results stored in --ORRES.
LBORNRLHI	yes	Normal Range Upper Limit-Original Units	Char	exp	Variable Qualifier of --ORRES	Upper end of normal range or reference range for results stored in --ORRES.

Variable	Prefix	Variable label	Type	Core	Role	Description
		ginal Units			--ORRES	--ORRES.
LBSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
LBSTRESN	yes	Numeric Result/Finding in Standard Units	Num	exp	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
LBSTRESU	yes	Standard Units	Char	exp	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
LBSTNRLO	yes	Normal Range Lower Limit-Standard Units	Num	exp	Variable Qualifier of --STRESC and --STRESN	Lower end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).
LBTOX	yes	Toxicity	Char	perm	Variable Qualifier of --TOXGR	Description of toxicity quantified by --TOXGR such as NCI CTCAE Short Name. Examples: HYPERCALCEMIA, HYPOCALCEMIA. Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define.xml document.
LBTOXGR	yes	Toxicity Grade	Char	perm	Record Qualifier	Records toxicity grade using a standard toxicity scale (such as the NCI CTCAE). Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define.xml document.
LBSTNRHI	yes	Normal Range Upper Limit-Standard Units	Num	exp	Variable Qualifier of --STRESC and --STRESN	Upper end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).
LBSTNRC	yes	Normal Range for Character Results	Char	perm	Variable Qualifier of --STRESC	Normal range or reference range for results stored in --STRESC that are character in ordinal or categorical scale. Example: Negative to Trace.
LBNRIND	yes	Normal/Reference Range Indicator	Char	exp	Variable Qualifier of --ORRES	Used to indicate the value is outside the normal range or reference range. May be defined by --ORNRLO and --ORNRHI or other objective criteria. Examples: Y, N; HIGH, LOW; NORMAL; ABNORMAL.
LBNAM	yes	Laboratory/Vendor Name	Char	perm	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.

Variable	Prefix	Variable label	Type	Core	Role	Description
LBLOINC	yes	LOINC Code	Char	perm	Synonym Qualifier of --TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.
LBSPEC	yes	Specimen Material Type	Char	perm	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
LBSPCCND	yes	Specimen Condition	Char	perm	Record Qualifier	Defines the condition of the specimen. Example: CLOUDY.
LBMETHOD	yes	Method of Test or Examination	Char	perm	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
LBBLFL	yes	Baseline Flag	Char	exp	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
LBFAST	yes	Fasting Status	Char	perm	Record Qualifier	Indicator used to identify fasting status. Valid values include Y, N, U or null if not relevant.
LBDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
LBDTCT	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
LBENDTCT	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
LBTPPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
LBTPPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
LBELTM	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
LBTPPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
LBSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.

**MB: Microbiology Specimen****Findings General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
MBNAM	yes	Laboratory/Vendor Name	Char	perm	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.

Variable	Prefix	Variable label	Type	Core	Role	Description
MBORRESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
MBRESCAT	yes	Result Category	Char	exp	Variable Qualifier of --ORRES	Used to categorize the result of a finding. Example: MALIGNANT or BENIGN for tumor findings.
MBSPEC	yes	Specimen Material Type	Char	perm	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
MBSTRESU	yes	Standard Units	Char	perm	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
MBSPCCND	yes	Specimen Condition	Char	perm	Record Qualifier	Defines the condition of the specimen. Example: CLOUDY.
MBSTRESN	yes	Numeric Result/Finding in Standard Units	Num	perm	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
MBMETHOD	yes	Method of Test or Examination	Char	exp	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
MBSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
MBBLFL	yes	Baseline Flag	Char	perm	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
MBSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
MBELTM	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
MBTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
MBREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
MBTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.

Variable	Prefix	Variable label	Type	Core	Role	Description
MBRFTDTC	yes	Date/Time of Reference Time Point	Char	perm	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
MBLOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: RIGHT ARM for an injection.
MBCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
MBSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
MBTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
MBTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
MBTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
MBDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
MBORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
MBDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
MBLOINC	yes	LOINC Code	Char	perm	Synonym Qualifier of --TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.

**MH: Medical History****Events General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
MHBODSYS	yes	Body System or Organ Class	Char	perm	Record Qualifier	Body system or system organ class from a standard hierarchy (e.g. MedDRA) associated with an event. Example: GASTROINTESTINAL DISORDERS.
MHTERM	yes	Reported Term	Char	req	Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.
MHMODIFY	yes	Modified Name	Char	perm	Synonym Qualifier of --TRT, --TERM or --ORRES	If the value for --TRT, --TERM or --ORRES is modified for coding purposes, then the modified text is placed here.

Variable	Prefix	Variable label	Type	Core	Role	Description
MHREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
MHSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
MHOCCUR	yes	Occurrence	Char	perm	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
MHPRESP	yes	Pre-specified	Char	perm	Record Qualifier	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
MHSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
MHENTPT	yes	End Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25" or "VISIT 2".
MHDECOD	yes	Standardized Treatment Name	Char	perm	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
MHCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
MHENRTPT	yes	End Relative to Reference Time Point	Char	perm	Timing Variables	Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable --ENTPT.
MHENRF	yes	End Relative to Reference Period	Char	perm	Timing Variables	Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFS TDTC and RFENDTC in Demographics.
MHENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
MHSTDTC	yes	Start Date/Time of Observation	Char	perm	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
MHDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.

MS: Microbiology Susceptibility						Findings General Observation Class
Variable	Prefix	Variable label	Type	Core	Role	Description
MSMETHOD	yes	Method of Test or Examination	Char	exp	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
MSNAM	yes	Laboratory/Vendor Name	Char	perm	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.
MSBLFL	yes	Baseline Flag	Char	perm	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
MSORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
MSDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
MSSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
MSTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
MSDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
MSTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
MSCAT	yes	Category	Char	req	Grouping Qualifier	Used to define a category of topic-variable values.
MSTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
MSTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
MSREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
MSTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
MSSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
MSELTM	yes	Planned Elapsed Time from	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a

		Time Point Ref				planned fixed reference (--TPTREF) such as "Previous Dose" or "Pre vious Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
MSSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
MSSTRESN	yes	Numeric Result/Finding in Standard Units	Num	exp	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
MSSTRESU	yes	Standard Units	Char	exp	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
MSLOINC	yes	LOINC Code	Char	perm	Synonym Qualifier of --TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.
MSRESCAT	yes	Result Category	Char	exp	Variable Qualifier of --ORRES	Used to categorize the result of a finding. Example: MALIGNANT or BENIGN for tumor findings.
MSORRESU	yes	Original Units	Char	exp	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.

**PC: Pharmacokinetic Concentrations****Findings General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
PCSPEC	yes	Specimen Material Type	Char	perm	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
PCORRESU	yes	Original Units	Char	exp	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
PCSPCCND	yes	Specimen Condition	Char	perm	Record Qualifier	Defines the condition of the specimen. Example: CLOUDY.
PCSTRESU	yes	Standard Units	Char	exp	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
PCMETHOD	yes	Method of Test or Examination	Char	perm	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
PCSTRESN	yes	Numeric Result/Finding in Standard Units	Num	exp	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN



Variable	Prefix	Variable label	Type	Core	Role	Description
						should store all numeric test results or findings.
PCFAST	yes	Fasting Status	Char	perm	Record Qualifier	Indicator used to identify fasting status. Valid values include Y, N, U or null if not relevant.
PCSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
PCEVLINT	yes	Evaluation Interval	Char	perm	Timing Variables	Evaluation interval associated with an observation such as a finding --TESTCD, represented in ISO 8601 character format. Example: -P2M to represent a period of the past 2 months as the evaluation interval for a question from a questionnaire such as SF-36.
PCDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
PCREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
PCTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
PCSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
PCELTM	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
PCTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
PCTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT,

Variable	Prefix	Variable label	Type	Core	Role	Description
						SYSBP, RRMIN, EYEEXAM.
PCENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
PCSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
PCTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
PCDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
PCTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
PCORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
PCLLOQ	yes	Lower Limit of Quantitation	Num	exp	Variable Qualifier of --STRESN	Indicates the lower limit of quantitation for an assay. Units will be those used for --STRESU.
PCCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
PCNAM	yes	Laboratory/Vendor Name	Char	exp	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.

### PE: Physical Examination

## Findings General Observation Class

Variable	Prefix	Variable label	Type	Core	Role	Description
PEORRESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
PEORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
PETEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
PETESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRRMIN, EYEEXAM.
PELOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site.

						Example: RIGHT ARM for an injection.
PEMODIFY	yes	Modified Name	Char	perm	Synonym Qualifier of --TRT, --TERM or --ORRES	If the value for --TRT, --TERM or --ORRES is modified for coding purposes, then the modified text is placed here.
PEREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
PESTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
PESCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
PECAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
PESTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
PEDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
PEEVAL	yes	Evaluator	Char	perm	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, VENDOR.
PEMETHOD	yes	Method of Test or Examination	Char	perm	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.

**PP: Pharmacokinetic Parameters****Findings General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
PPSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
PPORRESU	yes	Original Units	Char	exp	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.

Variable	Prefix	Variable label	Type	Core	Role	Description
PPCAT	yes	Category	Char	exp	Grouping Qualifier	Used to define a category of topic-variable values.
PPORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
PPRFTDTC	yes	Date/Time of Reference Time Point	Char	exp	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
PPTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
PPSPEC	yes	Specimen Material Type	Char	exp	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
PPTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRMIN, EYEEXAM.
PPREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
PPSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
PPSTRESN	yes	Numeric Result/Finding in Standard Units	Num	exp	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
PPSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
PPSTRESU	yes	Standard Units	Char	exp	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
PPDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.

QS Questionnaires					Findings General Observation Class	
Variable	Prefix	Variable label	Type	Core	Role	Description
QSCAT	yes	Category	Char	req	Grouping Qualifier	Used to define a category of topic-variable values.
QSEVLINT	yes	Evaluation Interval	Char	perm	Timing Variables	Evaluation interval associated with an observation such as a finding --TESTCD, represented in ISO 8601 character format. Example: -P2M to represent a period of the past 2 months as the evaluation interval for a question from a questionnaire such as SF-36.
QSSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-

Variable	Prefix	Variable label	Type	Core	Role	Description
						specified intervention was not answered. Should be null or have a value of NOT DONE.
QSREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
QSTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRMIN, EYEEXAM.
QSTEST	yes	Name of Measurement, Test or Examination	Char	REQ P	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
QSORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
QSORRESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
QSSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
QSSTRESN	yes	Numeric Result/Finding in Standard Units	Num	perm	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
QSSTRESU	yes	Standard Units	Char	perm	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
QSBFL	yes	Baseline Flag	Char	exp	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
QSDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
QSDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
QSTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPNUM and --TPREF.

Variable	Prefix	Variable label	Type	Core	Role	Description
QSTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
QSELT	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Pre vious Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
QSTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELT, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
QSRFTDTC	yes	Date/Time of Reference Time Point	Char	perm	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
QSSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.

### SC Subject Characteristics Findings General Observation Class

Variable	Prefix	Variable label	Type	Core	Role	Description
SCORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
SCTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
SCTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRMIN, EYEEXAM.
SCSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
SCSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
SCORRESU	yes	Original Units	Char	perm	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
SCREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
SCDTC	yes	Date/Time of Collection	Char	perm	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
SCSTRESU	yes	Standard Units	Char	perm	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.
SCSTRESN	yes	Numeric Result/Finding in	Num	perm	Result Qualifier	Used for continuous or numeric results or findings in standard

Variable	Prefix	Variable label	Type	Core	Role	Description
		Standard Units				format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
SCSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
SCCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.

**SU Substance Use Interventions****General Observation Class**

Variable	Prefix	Variable label	Type	Core	Role	Description
SUDOSFRQ	yes	Dosing Frequency per Interval	Char	perm	Variable Qualifier of --DOSE	Usually expressed as the number of doses given per a specific interval. Examples: QD, BID, TID, QID.
SUENTPT	yes	End Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25" or "VISIT 2".
SURROUTE	yes	Route of Administration	Char	perm	Variable Qualifier of --TRT	Route of administration for the intervention. Examples: ORAL, INTRAVENOUS.
SUSTDTC	yes	Start Date/Time of Observation	Char	perm	Timing Variables	Start date/time of an observation represented in ISO 8601 character format.
SUENDTC	yes	End Date/Time of Observation	Char	perm	Timing Variables	End date/time of the observation represented in ISO 8601 character format.
SUDUR	yes	Duration	Char	perm	Timing Variables	Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the CRF and not derived.
SUSTRF	yes	Start Relative to Reference Period	Char	perm	Timing Variables	Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.
SUENRF	yes	End Relative to Reference Period	Char	perm	Timing Variables	Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by

Variable	Prefix	Variable label	Type	Core	Role	Description
						RFS TDTC and RFENDTC in Demographics.
SUSTTPT	yes	Start Reference Time Point	Char	perm	Timing Variables	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --STRTPT. Examples: "2003-12-15" or "VISIT 1".
SUENRTPT	yes	End Relative to Reference Time Point	Char	perm	Timing Variables	Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable --ENTPT.
SUDOSFRM	yes	Dose Form	Char	perm	Variable Qualifier of --DOSE	Dose form for the treatment. Examples: TABLET, CAPSULE.
SUDOSU	yes	Dose Units	Char	perm	Variable Qualifier of --DOSE	Units for --DOSE, --DOSTOT, or --DOSTXT (Examples: ng, mg, mg/kg).
SUDOSTXT	yes	Dose Description	Char	perm	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
SUMODIFY	yes	Modified Name	Char	perm	Synonym Qualifier of --TRT, --TERM or --ORRES	If the value for --TRT, --TERM or --ORRES is modified for coding purposes, then the modified text is placed here.
SUTRT	yes	Name of Treatment	Char	req	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
SUDOSE	yes	Dose	Num	perm	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
SUCLASCD	yes	Class Code	Char	perm	Variable Qualifier of --TRT	Used to represent code for --CLAS.
SUCLAS	yes	Class	Char	perm	Variable Qualifier of --TRT	Class for a medication or treatment, often obtained from a coding dictionary.
SUREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
SUOCCUR	yes	Occurrence	Char	perm	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
SUSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.
SUDECOD	yes	Standardized Treatment Name	Char	perm	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
SUDOSTOT	yes	Total Daily Dose	Num	perm	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.



VS Vital Signs Findings						General Observation Class
Variable	Prefix	Variable label	Type	Core	Role	Description
VSCAT	yes	Category	Char	perm	Grouping Qualifier	Used to define a category of topic-variable values.
VSRTDTC	yes	Date/Time of Reference Time Point	Char	perm	Timing Variables	Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format.
VSSTAT	yes	Completion Status	Char	perm	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
VSREASND	yes	Reason Not Done	Char	perm	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.
VSLOC	yes	Location of Dose Administration	Char	perm	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: RIGHT ARM for an injection.
VSTESTCD	yes	Short Name of Measurement, Test or Examination	Char	req	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYS-BP, RRMIN, EYEEXAM.
VSTEST	yes	Name of Measurement, Test or Examination	Char	req	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
VSPOS	yes	Position of Subject During Observation	Char	perm	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
VSORRES	yes	Result or Finding in Original Units	Char	exp	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, POS.
VSORRESU	yes	Original Units	Char	exp	Variable Qualifier of --ORRES	Unit for --ORRES. Examples: IN, LB, kg/L.
VSSTRESC	yes	Result or Finding in Standard Format	Char	exp	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
VSSTRESN	yes	Numeric Result/Finding in Standard Units	Num	exp	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
VSSTRESU	yes	Standard Units	Char	req	Variable Qualifier of --STRESC and --STRESN	Standardized units used for --STRESC and --STRESN. Example: mol/L.

Variable	Prefix	Variable label	Type	Core	Role	Description
VSBLFL	yes	Baseline Flag	Char	exp	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.
VSDRVFL	yes	Derived Flag	Char	perm	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
VSDTC	yes	Date/Time of Collection	Char	exp	Timing Variables	Collection date and time of an observation represented in ISO 8601 character format.
VSTPT	yes	Planned Time Point Name	Char	perm	Timing Variables	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See --TPTNUM and --TPTREF.
VSTPTNUM	yes	Planned Time Point Number	Num	perm	Timing Variables	Numeric version of planned time point used in sorting.
VSELTm	yes	Planned Elapsed Time from Time Point Ref	Char	perm	Timing Variables	Planned Elapsed time in ISO 8601 character format relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.
VSTPTREF	yes	Time Point Reference	Char	perm	Timing Variables	Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.
VSSCAT	yes	Subcategory	Char	perm	Grouping Qualifier	Used to define a further categorization of --CAT values.