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### 1. Create a form family

- Log into the FormBuilder and click on the name of the project (=study), you want to edit. First you have to create a form family. Click on the button NEW FORM FAMILY. Enter a name for the form family and select a family type (visit, adverse event, casenode (=forms independent of a visit), sub form (form sections that can be repeated with special question types, eg, drugs). Click on the SAVE button.

**Note:**

All forms, questions and items can be deleted as long as the project was not migrated into productive or condition references refer to parts of the project setup (see chapter 5).

### 2. Create a form (=eCRF)

- You now have the option to copy a form from an existing project or create a new form. The form should be assigned a useful name. In order that your entries in the database can be saved, choose the checkbox SAVE in the section PROCESSING. Then a unique name for the database table has to be assigned.

The screenshot shows the 'secuTrial®' software interface for creating a new form. The top navigation bar includes 'Welcome > Project > form family > Form'. The main configuration area is as follows:

- Project:** DVMD (26.05.2010 - 13:37:20 (CEST))
- Form family:** Demographic
- Form name (overview):** Anamnese
- Processing:**
  - radio button selected: user input
  - radio button: display only
  - checkbox selected: save
  - checkbox: print
- Database table:** mnpproh\_anamnese
- Displayed order:** 21
- Displayed No.:** [empty field]
- Form name (title):** [empty field]
- Description (HTML):** [empty text area]
- Get values from visit before:**
  - radio button selected: only according to single rules only if the days are equal
  - radio button: everytime the whole Form
  - radio button: whole form but
- Validation and rules:**
  - checkbox: Markup (rule based) mandatory fields
  - checkbox: check of completion
  - checkbox: immediate validation (with a question mark icon)

Please correct the marked invalid data.

Please check marked entries before saving.
- Form error message (Default):** [empty text area]
- Form confirmation message (Default):** [empty text area]

At the bottom are three buttons: 'Cancel', 'Save and back', and 'Save'.

Figure 1: Example configuration of a form.

- If you made all the necessary settings (these are always marked with a red asterisk), click **SAVE**. Then a corresponding table in the database for the new form is created.

### 3. Create questions in a form

- After that you can define a new question (section of the form). Click on the button **NEW QUESTION**, select the type and enter the question text. The question type determines the possible item (=variable) types that can be included into the question and determines the layout of this part of the form. You could omit the question text for layout reasons, but you must enter a unique question label for search. If you supply a question text it will be copied into the unique label if you left that empty. With the option **QUERY AND COMMENT MENU** you can enable the user in the DataCapture to enter queries or comments for the items of this question according to the user's role and rights. After click on **SAVE** you can create new items.

### 4. Create items in a question

- To create a new item (=variable) click on the button **NEW ITEM**. The item type must be selected (eg radio button, numeric field, text field, date field ...) and the name of the database column must be specified. Furthermore, you can here enter an item label and/or an unit.

The screenshot shows the secuTrial software interface for creating a new item. The top header displays the secuTrial logo, the date (15.06.2010 - 13:51 (CEST)), and the participant (Pr.Dr. Jonas). The top right has links for 'Preview' and 'Logout'. The main content area shows the current project details: DVMD (15.06.2010 - 13:51:14 (CEST)), Form family: Demographic, Form: Demographics, and Question: demographics. Below this, the 'Item' configuration section is shown. It includes fields for Type (set to Date DD-MM-YYYY), Displayed order (60), Item (labeled 'Day of birth'), and Unit/format (HTML). The Database column is set to 'date'. There are also sections for CDISC ODM export annotations and a note about IAS standard group. At the bottom of the configuration panel are 'Cancel', 'Save and back', and 'Save' buttons, along with a 'top' link.

Figure 2: Example configuration of an item.

- During save a column for this item is created in the database table of the form.

### 5. Create plausibility checks.

- Once the item is saved, you can create plausibility checks for this item. Click the **NEW RULE** button and select from the pull-down menu a rule (for example, "Input impossible, if..."). Click **SAVE**. If the rule depends on conditions, indicated by "if ..", you have to define these now.
- Click **NEW CONDITION**. A rule condition consists of the comparison of two values. You can now determine which parameters shall be compared and from where the parameters shall be read from. If you choose **THIS ITEM**, you have to select the form, item and visit for the referenced parameter value. You have to select the compare operator and the compare value for the parameter. The compare value can be a fixed value depending on parameter type or another item (only items of the same type can be compared). Do not forget to supply an expressive error message and click on **SAVE**.

- You can view the resulting form at any edit level by clicking on PREVIEW in the upper right of each page.

## 6. Additional preconditions for data entry

- Your form is now complete. To see it in the DataCapture, it still needs the following conditions.

### Visit plan

- If you return to the project level, you can edit the visit plan by click on the corresponding link. Create and configure visits for your project. You must display the newly created form in the corresponding visit(s) by selecting the appropriate checkboxes in the lower matrix. Casenode forms will be displayed always independent of any visit, adverse event forms will be displayed only if an adverse event is created for an individual patient.

### AdminTool: Rights

- In the AdminTool you must assign the necessary rights for the newly created forms. This is done on the role edit page. Select your project from the lower drop down list, assign the appropriate form rights and click on SAVE.

## 7. The eCRF in the DataCapture

- To be able to enter medical information into the created eCRF (=form), you need to log in the DataCapture and create a new patient. Just click on the button NEW PATIENT in the menu bar. After entering the personal data of the patients (this data will not be stored on the server) and the entry date, a pseudonym is generated and you see the patient visit plan overview. To view and edit further visits, you can click on the button NEW VISIT and then enter the date of the next visit if requested.
- At the patient visit plan overview you can see the icons of the form families of the respective visits. If you click on a form family, you see the included forms below. By clicking on a form icon the eCRF will open and you can now enter and save data.

The screenshot shows the secuTrial DataCapture interface. At the top, there is a header with patient details: Date 15.06.2010 - 14:14 (CEST), Alleskönner Hobby Admin, Project Basisregister (15.06.2010 - 14:13:36 (CEST)), Centre Berlin, Patient Visite 1, Pat-ID cia493, Add-ID <not set>, Visit 01.01.2000 (CET) "ja", Form family Registrierung/Studienaufnahme, Form Anamnese. To the right are links for Back, Help, and Logout.

The main area shows a navigation breadcrumb: > Welcome > Patient cia493 > Anamnese. Below this is a section titled "Anamnese" with a sub-section "itemtext". There are input fields for Date of birth (dd.mm.yyyy unit) and two dropdown menus for First description and second description. On the right, there are buttons for Help, Comment, and Query, and a "Save" button. At the bottom, there is a footer with the same patient and project details as the header.

Figure 3: The resulting eCRF ready for data entry.

- From the menu option REPORTS on the WELCOME page you can access lists of included and accessible patients summarizing or listing different properties (the reports can be defined as project properties in the FormBuilder). A single report will open in a separate window. By clicking on a pseudonym in the list the visit plan of the selected patient will open in the main window.