

# 4

## MyStudy: A StudyBuilder Tutorial

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In this chapter, you will get a quick introduction to using StudyBuilder Professional Edition (this tutorial is also applicable to StudyBuilder Enterprise Edition users). The aim is to introduce you to the study wizard and show you some of the settings associated with a typical project.

The tutorial will demonstrate designing a basic registry for newborns to keep track of their growth. It is assumed that data will be collected at multiple centres in several countries on paper, Microsoft Windows 95 and Microsoft Windows CE devices.

The tutorial is divided into sections that match the major topics in the study wizard along with a brief introduction to using the system produced.

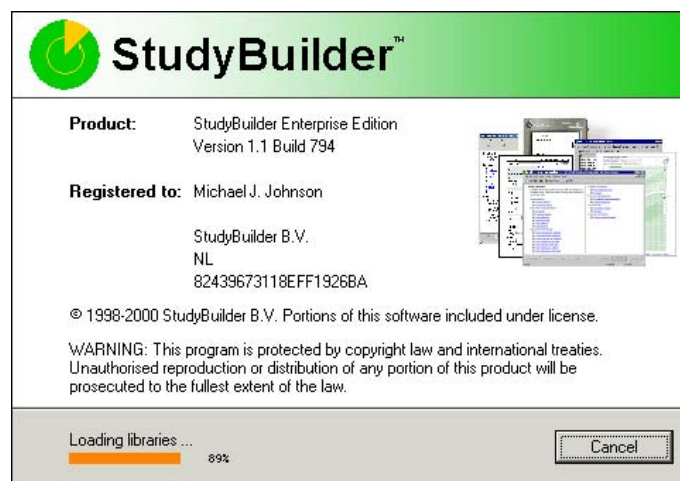
### Creating a new study

This first section of the tutorial provides step-by-step instructions for creating a new StudyBuilder study. The aim of the section is to familiarise you with common StudyBuilder commands, windows and settings that you will use when creating and working with a study.

### Start StudyBuilder Professional Edition

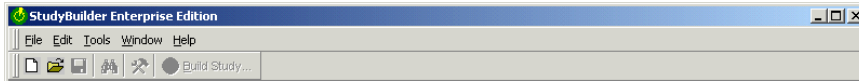
Find the icon for StudyBuilder Professional Edition on your system and start the program. This will typically be in your 'Start' menu, on your desktop or in the folder where you installed the software. While the program starts you will see a progress bar showing the study libraries loading. This can take a few minutes on slower systems.

**Figure 1** The startup screen



When the program has finished loading you will see a menu bar and toolbar appear as shown in Figure 2.

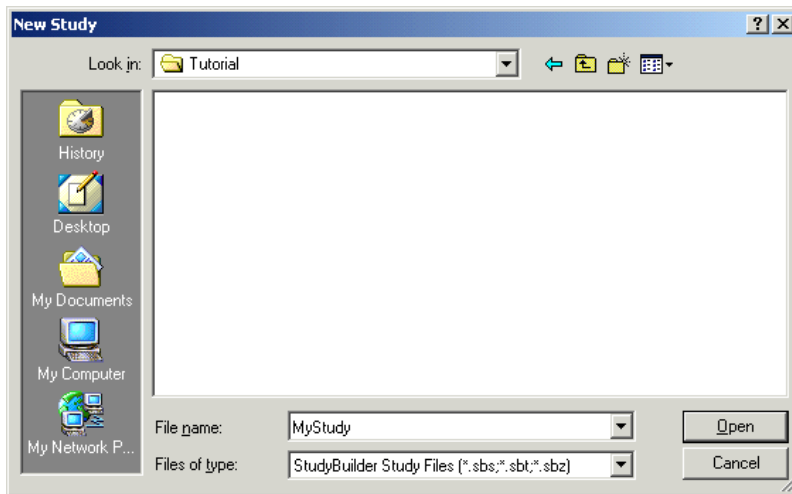
**Figure 2 The menu bar**



### Create a new study

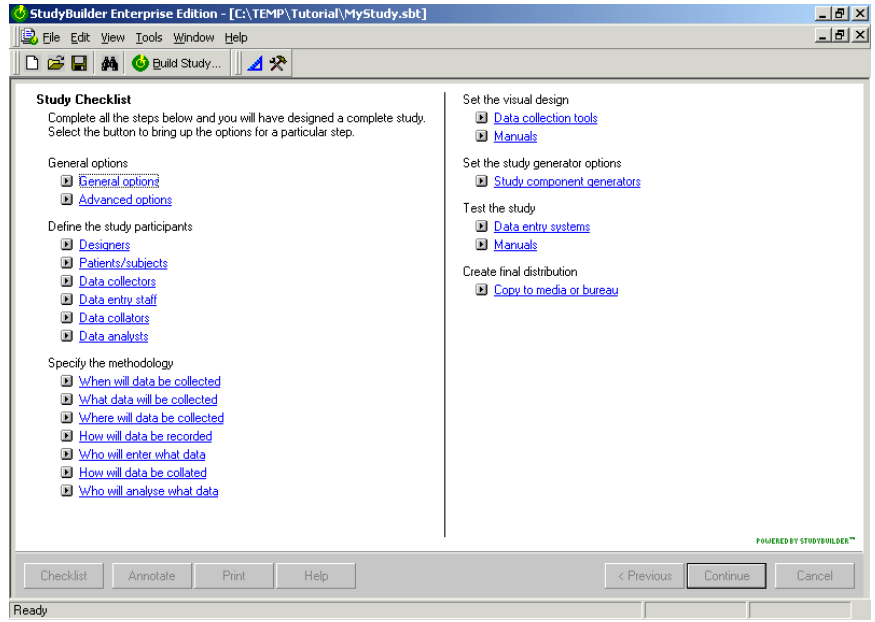
From the menu bar, select **File > New > Study...**. The program displays the **New Study** window (Figure 3). This window allows you to select a file name for your new study and a location on your hard drive or network to store it.

**Figure 3 The New Study window**



Make sure that you are in a directory where you wish to save the study. Enter a file name for the study, then click **Open**. The program will then create a study wizard window for your study.

Figure 4 The Study Wizard



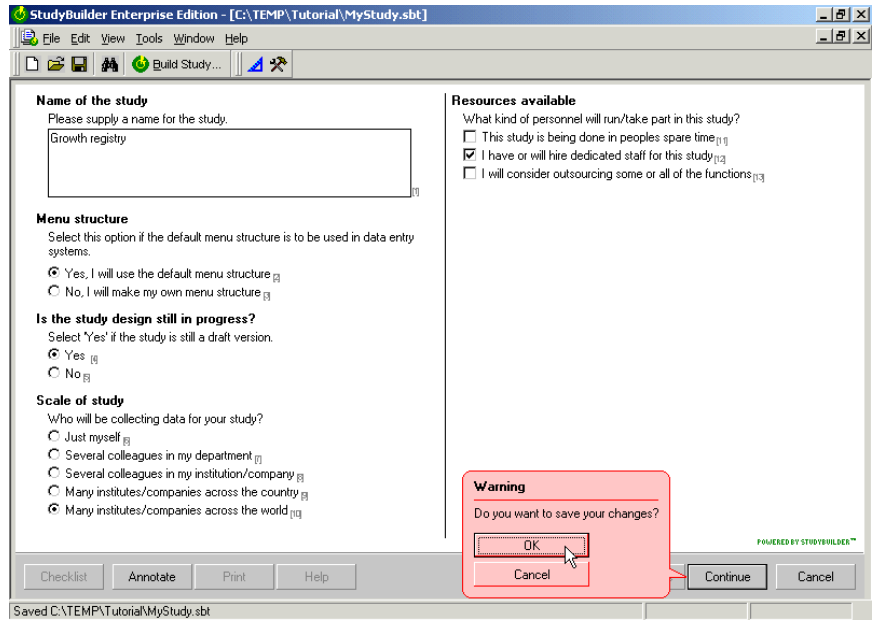
You are now ready to start designing your study.

## General options

### The General options section

With the study wizard open at the Study Checklist screen, click on the first button or hyperlink in the **General options** section of the checklist. You will see the **General options** page of the study wizard (Figure 5).

Figure 5 The General Options section



Type in a name for the study (for this example, use 'Growth registry') in the first question on the page. The program suggests that you use the default menu structure and you should not change this option. The study design is still in progress, so the 'Is the study design still in progress' section should be set to 'Yes'.

The scale of the study determines whether there are multiple centres in the study. In the case of this example there are multiple centres in multiple countries so the appropriate option should be selected. We will assume that dedicated staff are available for this study and select the appropriate option in the 'Resources available' section.

Once the appropriate selections have been made, click on the **Continue** button. A message asking you to confirm that you wish to save your changes will appear. You should click **OK** and you will be returned to the study checklist of the study wizard.

### **The Advanced options section**

Next click on the **Advanced options** section in the study checklist. You will then see a screen requesting what type of study you wish to design. Select the **Patient registry** option. Click on the **Continue** button and confirm that you wish to save the changes by clicking **OK**.

You have successfully configured the general options of the study.

## **Participants**

The next step of the design process is to specify the participants in the study, from designers through to subjects. With the study wizard open at the Study Checklist screen, click on the first button or hyperlink in the **Define the study participants** section of the checklist. You will see the **Designers** section of the study wizard

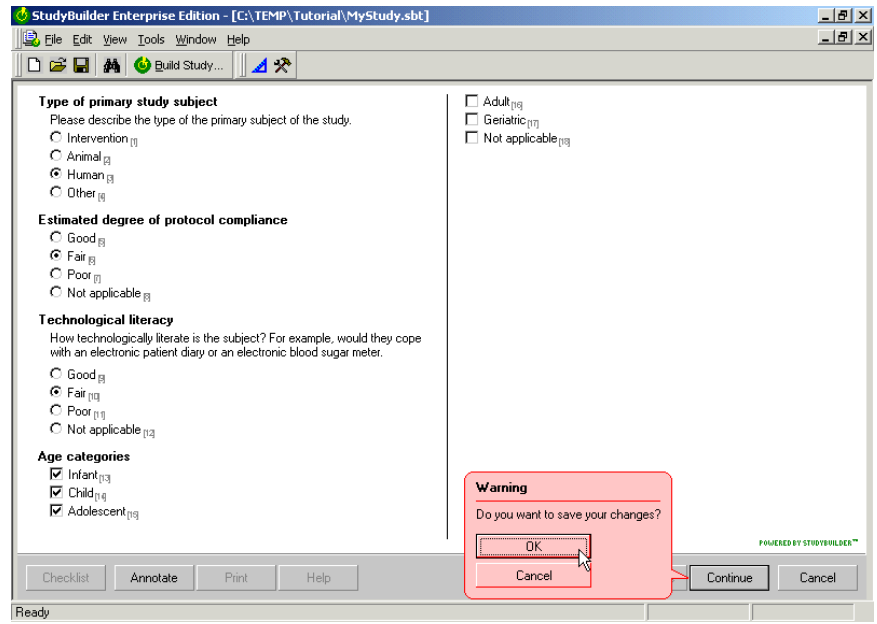
### **The Designers section**

If you are using StudyBuilder Professional Edition you are not able to register individual study designers as it is a single user product and your information is stored within your certificate of study authorship. If you are using StudyBuilder Enterprise Edition you will see a screen allowing you to register individual designs and password protect your study design. We will not use this feature for this tutorial so users of both products should select the **Cancel** button and return to the main study checklist.

### **The Patients/Subjects section**

Click on the **Patients/Subjects** button or hyperlink in the study checklist to go to the Patients/Subjects section.

**Figure 6 The Patients/Subjects section**



The **Type of primary subject** is **Human** so the appropriate option should be selected. This is a universal registry being performed by individuals who wish it to succeed so **Estimated degree of protocol compliance** should be **Fair**. We are proposing to use Microsoft Windows computers for data collection so we will estimate **Technological literacy** as **Fair**. The study is designed to track patients throughout the time that they are growing so the **Age categories** will include **Infant, Child** and **Adolescent**.

Once the appropriate settings have been selected, the **Continue** button should be clicked and the settings saved by choosing **OK**.

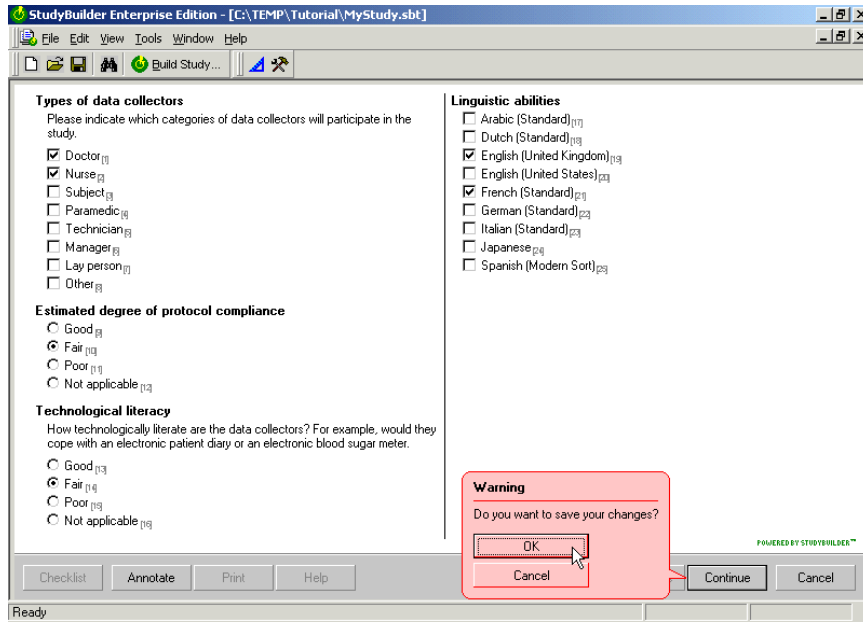
### **The Data Collectors section**

Click on the **Data collectors** button or hyperlink in the study checklist to go to the data collectors section.

Data collectors are the people who will actually ask the subjects or make measurements to be recorded into the system. In this particular study, the **Types of data collectors** will typically be **Doctors** and **Nurses**. They are likely to be well practiced in these techniques so one would expect the **Estimated degree of protocol compliance** to be **Fair** and their **Technological literacy** also to be **Fair**. For the purposes of this tutorial we will assume the **Linguistic abilities** to be primarily **English (United Kingdom)** and **French (Standard)**.

Once the appropriate settings have been selected, the **Continue** button should be clicked and the settings saved by choosing **OK**.

Figure 7 The Data Collectors



## The Data Entry Staff section

We now turn to the data entry staff. Click on the **Data Entry Staff** button or hyperlink in the study checklist to go to the data entry staff section.

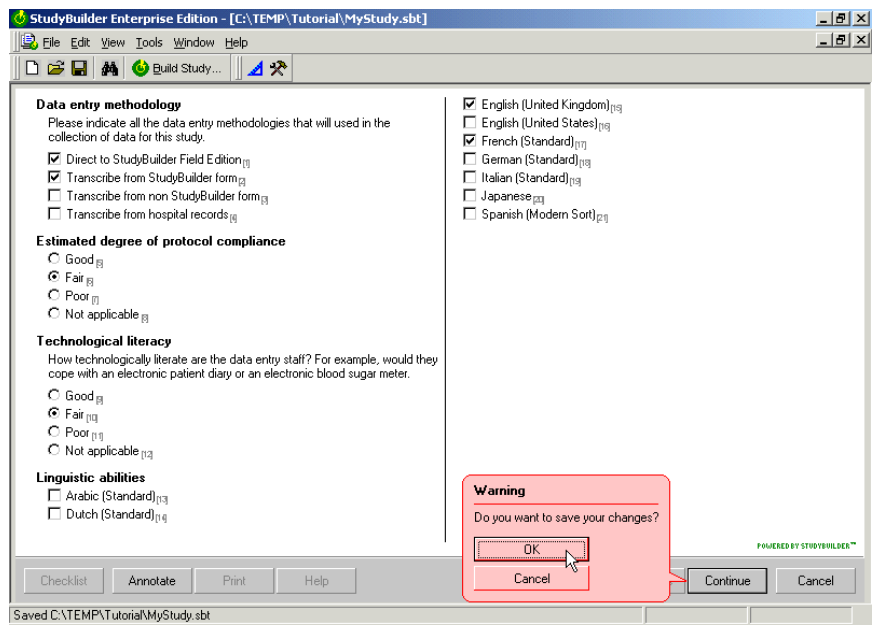
In the case of individuals measuring data and entering it directly into a computer, these individuals are considered both data collectors and data entry staff. In the case where information is being transcribed from paper forms into a computer, the data entry staff are the individuals performing the transcription.

In this particular example, the **Data Entry methodology** includes **Direct to StudyBuilder Field Edition** (the name of the product used to collect data in the field). This will probably be the case for people using Microsoft Windows CE palmtop computers in front of patients. The **Transcribe from StudyBuilder form** will also be applicable as the program will be producing paper forms for data collection and experience suggests that many individuals providing data for a registry prefer using paper.

We assume once again that the **Estimated degree of protocol compliance** is **Fair** and that the **Technological literacy** of the subjects is also **Fair**. We also assume that the **Linguistic abilities** of the data entry staff are the same as the data collection staff, that is **English (United Kingdom)** and **French (Standard)**.

Once the settings have been selected, click **Continue** and save the settings by choosing **OK**.

Figure 8 The Data Entry Staff section



### The Data Collators section

Click on the **Data Collators** button or hyperlink in the study checklist to go to the data collators section.

Data collators are the individuals who will manually check data entered into the system for errors that the automatic checks do not detect. For a registry, the **Collation methodology** might often not be applied until final analysis, however best practice suggests that a continuous **Review and query** process should be in place. We will use this methodology for this example and the appropriate options should be selected in this section.

The **Technological literacy** and **Linguistic abilities** should be set to the same values as in previous screens.

Once the appropriate settings have been selected, click **Continue** and save the settings by choosing **OK**.

### The Data Analysts section

Click on the **Data Analysts** button or hyperlink in the study checklist to go to the data analysts section.

For a standard easy to import and analyse, in the **Data repository** section, choose **International Data Standards Consortium CSV file**. Click **Continue** and save the settings by choosing **OK**.

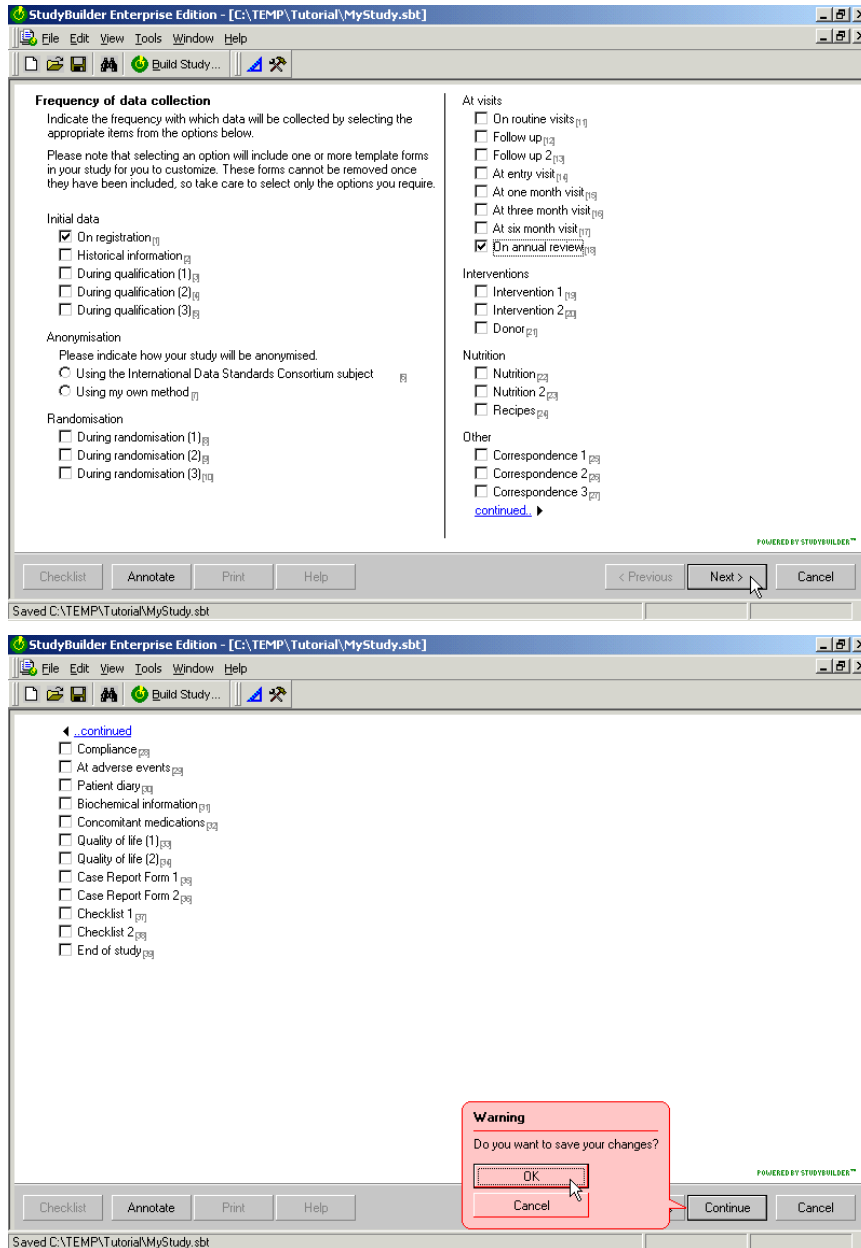
## Methodology

Having finished specifying who the various participants in the study are, we now turn to the methodology that will be used to actually implement the study. Once again, a series of sections should be worked through to define the study structure.

## When will data be collected

For this simple registry we will record subject information at a registration visit and once a year at an annual review. Figure 9 shows selecting these options.

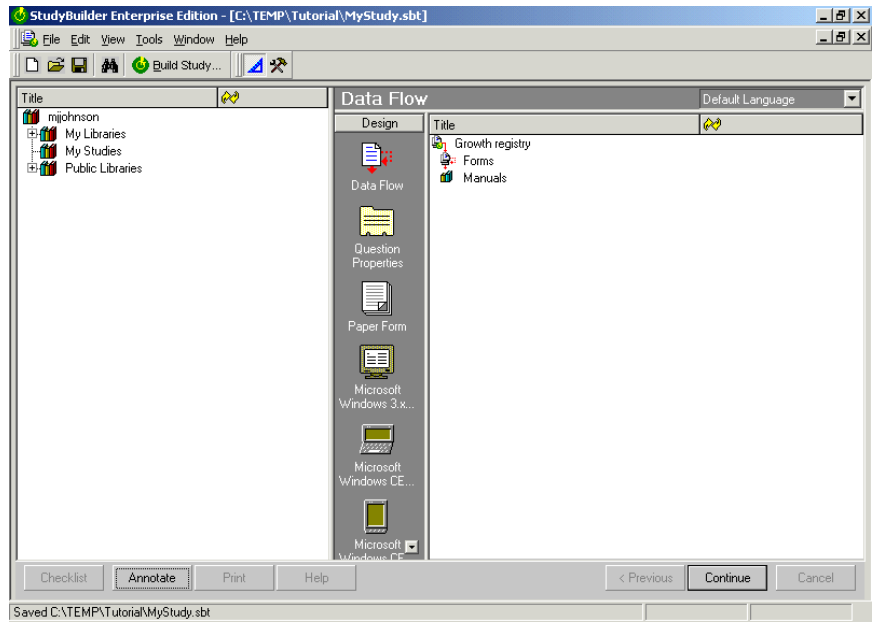
Figure 9 Specifying when data will be collected



## What data will be collected

Next we will actually select what data will be collected at each visit. In the main study checklist, click on the **What data will be collected** button or hyperlink. You will see a screen similar to that shown in Figure 10.

**Figure 10 What data will be collected section**



The left hand side of the screen is the question library from which we will drag questions to be asked onto the right hand side of the screen that is used to display the order in which questions will be asked and to preview the materials.

On our registration form we will assume that we want to ask the following questions:

- Subject number
- Given name
- Family name
- Sex
- Date of birth

and on the annual review form we will ask:

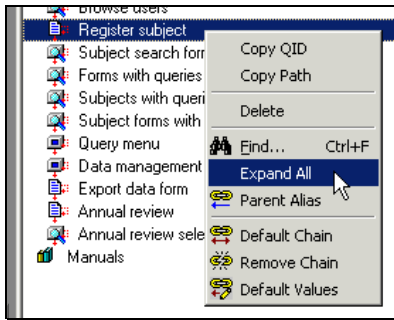
- Date of visit
- Height
- Weight

The next step is to select these questions from the StudyBuilder Standard Question Library and drag them on the form. First of all we need to identify the forms so that we know where to drag the questions.

Double click on the 'Forms' object in the data flow in the right hand window. You will see a list of forms displayed. Most of the forms are screens that will be displayed for administering the study and can be ignored for now. Find the form labeled **Register subject** and click the right hand button on your mouse. A menu will appear and with the left

hand button on your mouse you should select **Expand All** as shown in Figure 11.

**Figure 11 Expanding the data flow of a form**

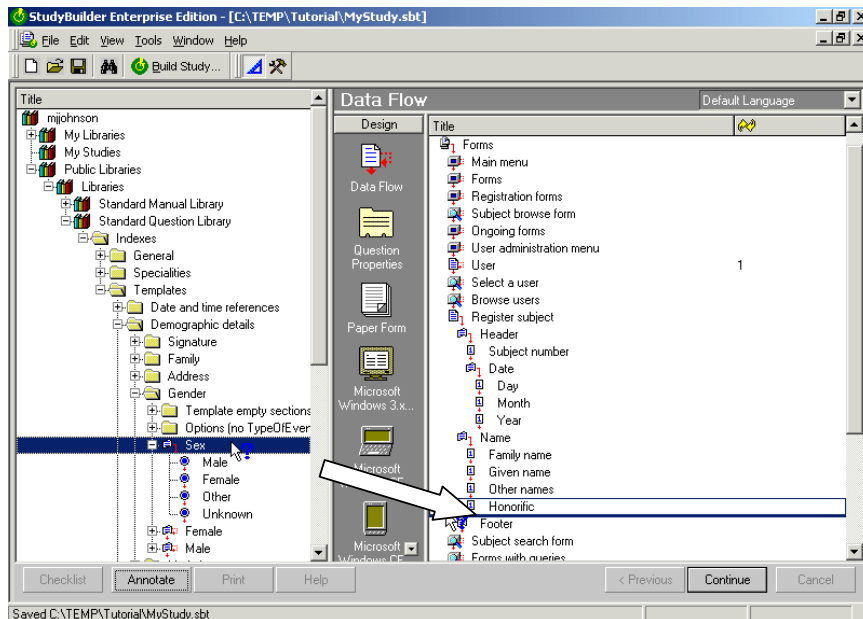


You will then see a list of the questions already asked on the form (Subject number, date of visit, name). We want to add Date of birth and Sex to the form so in the left hand window, double click on the following:

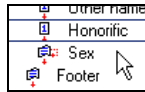
**Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Templates >> Demographic details >> Gender >> Sex**

Now click on the item **Sex** in the left hand window and drag the item over to just above the section **Footer** in the **Register subject** form on the right hand side as illustrated in Figure 12. Let go of the mouse button and you should see the results shown in Figure 13.

**Figure 12 Dragging a question from the library onto a form**

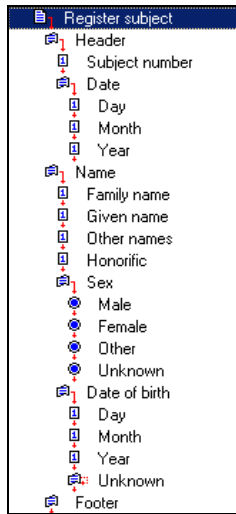


**Figure 13 A question dropped onto a form**



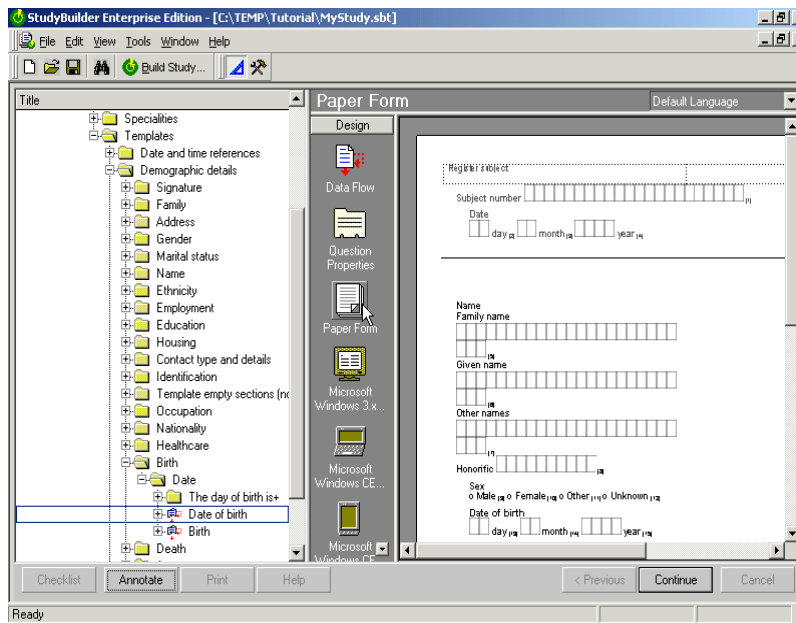
Now do the same for the **Date of birth** question stored in: **Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Templates >> Demographic details >> Birth >> Date >> Date of birth** and the final **Register subject** form data flow should be as in Figure 14.

**Figure 14 Complete data flow of the register subject form**



To preview the paper version of this form, click on **Register subject** in the data flow and click on **Paper Form** item in the **Design bar** as shown in Figure 15.

**Figure 15** Previewing the paper form



Click on **Data Flow** in the **Design** bar to return to the data flow and find the **Annual Review** form. Click on it and then right click and select **Expand All**.

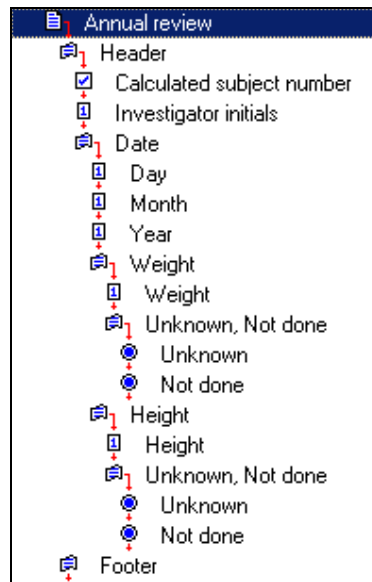
Now add the following questions from the standard question library into the annual review form as you did before:

**Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Specialties >> Growth >> Growth Registration >> Height**

**Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Specialties >> Growth >> Growth Registration >> Weight**

When complete you should have a data flow for the annual review form similar to that shown in Figure 16.

**Figure 16 The completed annual review form**



You have now finished selecting what questions will be asked in your (admittedly very simple) registry. Click **Continue** at the bottom of the screen and you will be returned to the study wizard study checklist.

### **Where will data be collected**

For this particular registry we will assume that the study will be taking place at two centres, The Hospital, London, United Kingdom (site 1) and at L'Hôpital, Paris, France (site 2).

In the study design wizard, click on the **Where will data be collected** option and you will be taken to a section with three options:

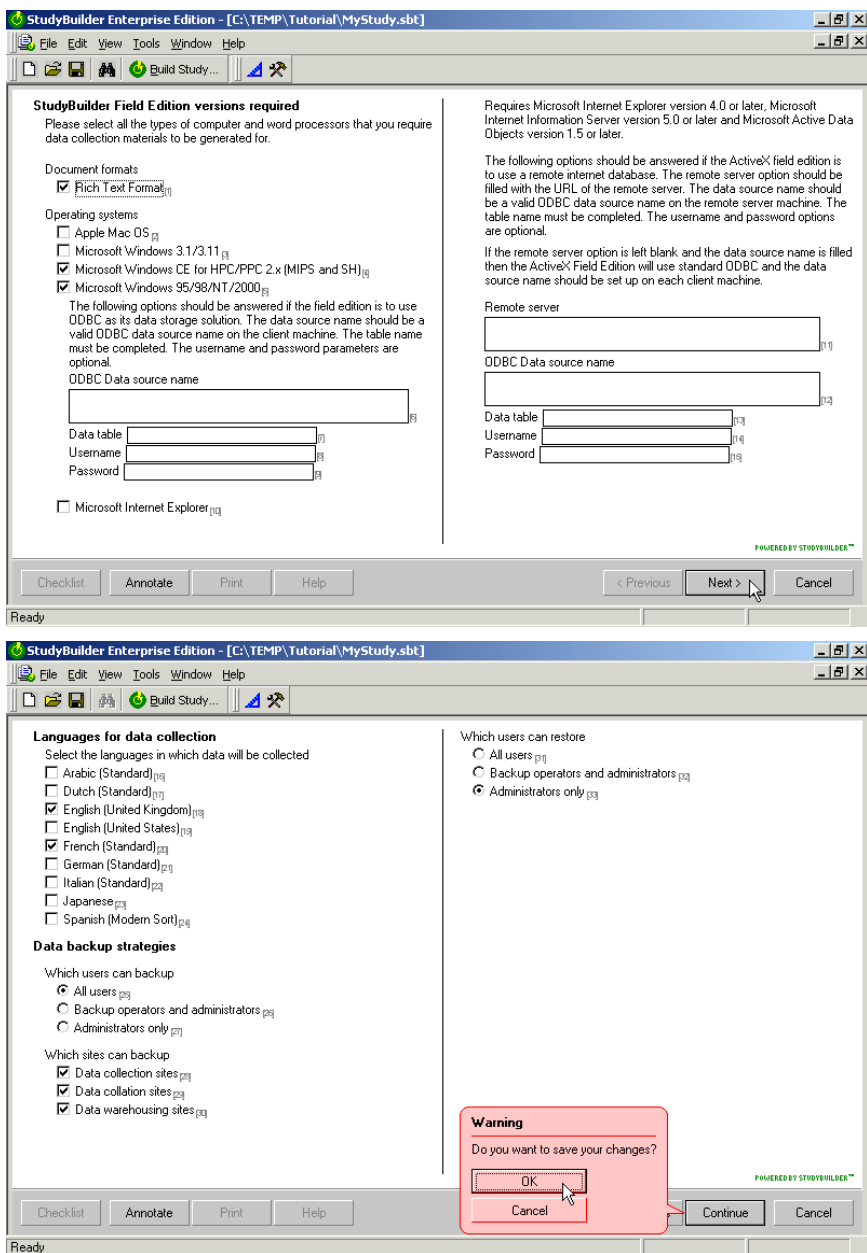
- Add a site
- Review a site
- Delete a site

Click on **Add a site** and you will be presented with a site registration form that you can fill in with the details for site 1. When complete, click **OK** and repeat the process for the second site. This acts as your site logbook.

### **How will data be recorded**

We now need to specify in what format data will be recorded. We want to collect data on paper, on Microsoft Windows 95 compatible computers and on Microsoft Windows CE compatible palmtops. The materials need to be in English and French. In addition we want all users and sites to be able to backup data. Figure 17 shows the appropriate settings for this project.

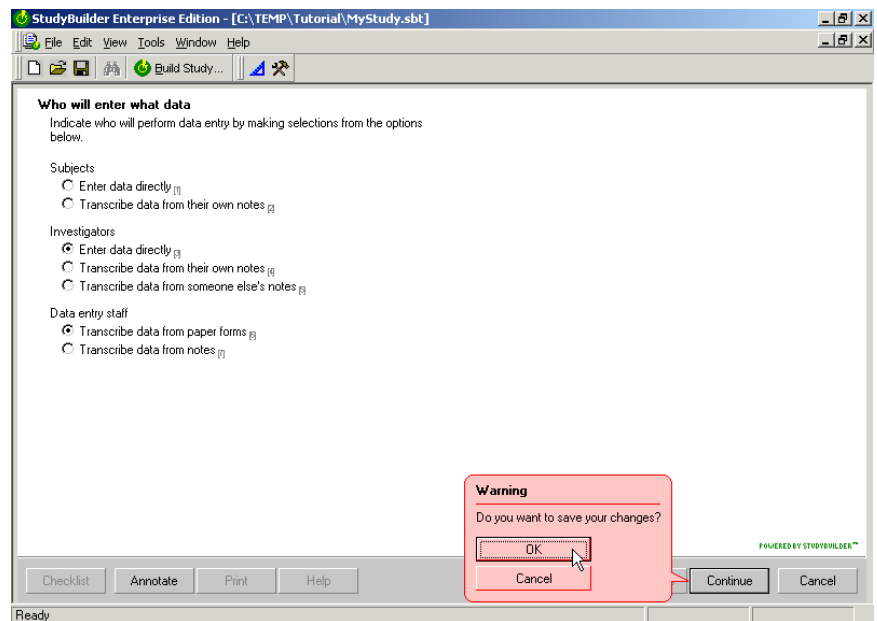
**Figure 17 How data will be recorded at the sites**



### Who will enter what data

Having specified how the data will be collected we now need to indicate whether the data is first or second hand. For this registry we assume that the investigators will be making measurements themselves. Therefore the **Subjects** section has no entry. In the **Investigators** section we record that they **Enter data directly**. **Data entry staff** will **Transcribe data from paper forms**.

**Figure 18 Who will enter what data**



### **How will data be collated**

We also need to specify how data will be collated. In our registry design we have assumed that all the centres will be feeding data to a single point. Within a centre, because we have palmtops and desktops we need to define an extra step where the palmtops synchronise data with desktops that then forward data to the national centre.

At the study wizard checklist, select the **How will data be collated** option and indicate that data will be collated **At a single centre**.

In the **Data collation strategies** section select **Site supply data centre** (assuming that the registry sites supply data to a data centre that then does all the reporting).

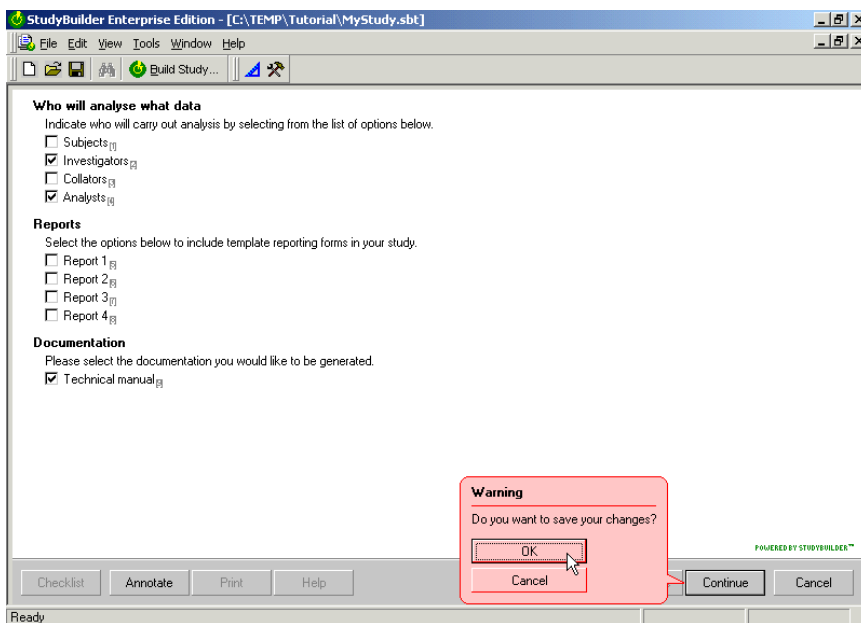
You should also select **Palmtops synchronise with desktops** to indicate that the palmtops should use desktops as a staging point for the data rather than sending their data directly to the data centre.

### **Who will analyse what data**

The final step in defining the methodology is to indicate how the data will be analysed. In the study wizard, choose the **Who will analyse what data** option and you will be presented with the options shown in Figure 19.

For this particular study, we will allow **Investigators** and **Analysts** to analyse data by giving them permission to export data. In addition, in the **Documentation** section we indicate that we would like to have a technical manual generated so that written definition of the questions in the study and the validation criteria that are applied to them.

**Figure 19 Who will analyse what data**



Having chosen these options, press **Continue** followed by **OK** and you have almost finished designing your study.

## Visual design

StudyBuilder Professional Edition and StudyBuilder Enterprise Edition come with a number of different templates to allow you to modify the presentation of the forms and manuals that the system generates. For the purposes of this tutorial we will use the default values and therefore do not need to change anything in the **Visual design** section of the study wizard.

## Study generators

StudyBuilder Professional Edition and StudyBuilder Enterprise Edition allow you to fine-tune the process that is used to generate studies. This is particularly useful when dealing with very complicated study designs. Because the study used for this tutorial is very simple, none of the options in the **Study generators** section of the study wizard are of any relevance to this example.

## Testing

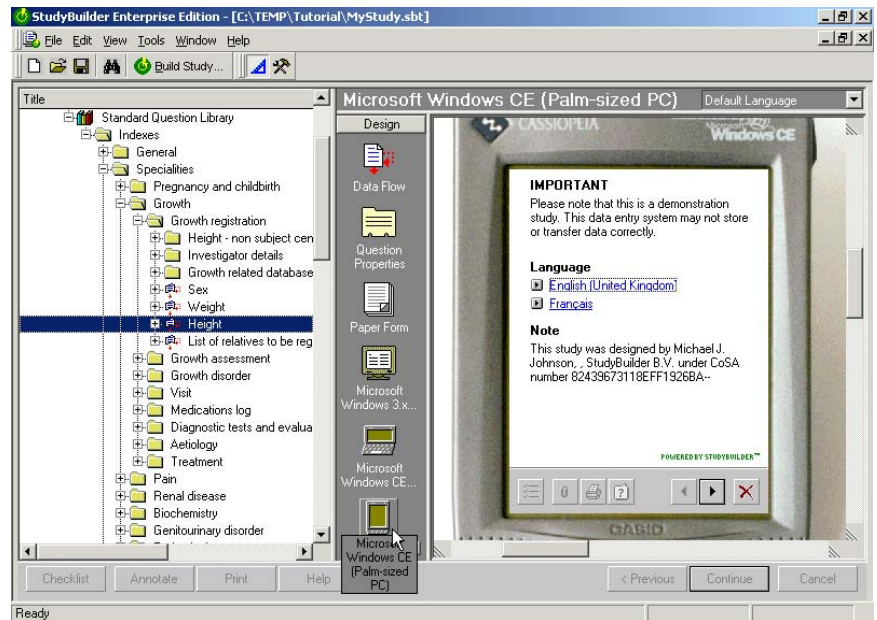
You have now completed your study design. To test that it works properly you should try entering some real data into one of the live previews that the software provides.

For example, we will check that we can register a patient on a Microsoft Windows CE device.

To switch to a live preview of the system you need to switch to the study studio. You can do this by returning to the **What data will be collected** section of the study wizard.

Once in the design studio you need to switch to a preview of StudyBuilder Field Edition for Microsoft Windows CE/PocketPC by selecting the appropriate icon in the design bar as shown in Figure 20.

**Figure 20 A live preview of the study on a palmtop**

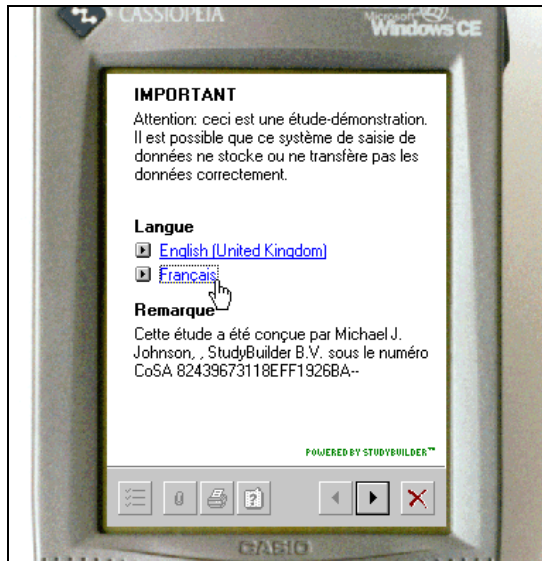


Note that if the preview does not fit exactly in the window you can use the scroll bars to centre the display in the preview window.

### Log into the system

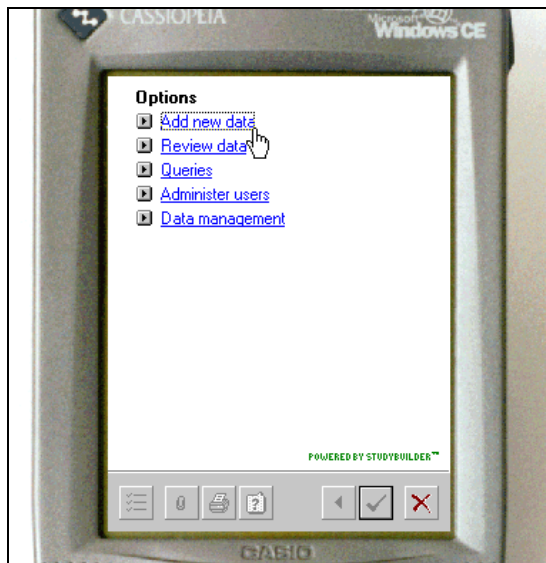
The preview behaves as the live data entry system will. For example, if you click on the button or hyperlink marked **Français** the preview will display the French version of the screen. Click on **English (United Kingdom)** to get back.

**Figure 21 The login screen in French**



Click on the arrow pointing right at the bottom right hand corner of the screen. This is the equivalent of the **Next** button on a desktop computer and will take you to the next screen. Click **Next** again and you will be asked to supply a username and password. Unless you configure users when you have logged in, it is not necessary to enter a username and password, so click on the green tick (the equivalent of the **Continue** button) and the system will display the main menu shown in Figure 22.

**Figure 22 The StudyBuilder Field Edition main menu**

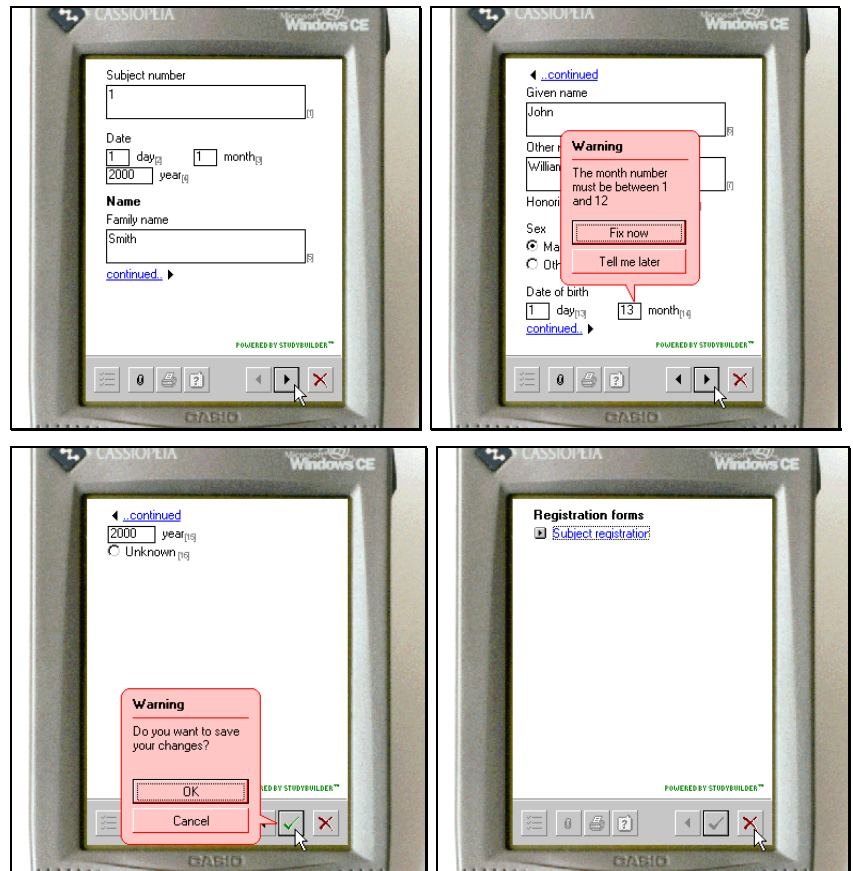


Note that not all studies will have all these options. Only the options appropriate to your study will be included.

## Add a subject

Now register a subject. Click on the **Add new data** button or hyperlink and you will be presented with a choice of **Registration forms** or **Ongoing forms**. Click on **Registration forms** and click on the **Subject registration** button or hyperlink. You can now enter data as shown in Figure 23. Notice how the 'deliberate mistake' causes a warning to be generated.

Figure 23 Entering data in a live preview



Once the form has been saved you are returned to the registration form menu. Press the red cross button (equivalent to the **Cancel** button) to return up a level in the menu structure until you back at the choice between **Registration forms** and **Ongoing forms**.

## Add an annual review

Click on **Ongoing forms** and then on **Annual review** and you will see a search form. Click on the **Show all** button and you will be shown a list of all (one) of the patients in the system. Click on the button next to the subject that you would like to enter a data entry form for and you will be taken to the data entry page. Note that the subject number is drawn with a yellow background. This means that you cannot change its value. You can then enter data for the annual review as before.