secuTrial® - User Manual

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DZHK- Data Handling
University Medical Centre Goettingen
Department of Medical Informatics
Robert-Koch-Straße 40
D-37075 Goettingen
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1. Introduction

This user manual is supposed to facilitate your use of the secuTrial® system’s data entry tool (DataCapture). You can use DataCapture to capture, view and/or change medical data.

1.1. System Requirements

You may access secuTrial® DataCapture using various operating systems (such as Windows, MacOS, or Linux). You do not have to install any special software on your computer to be able to work with secuTrial® DataCapture. The software the tool required is installed on a central server. You can easily access it via any common browser (Microsoft Internet Explorer, Google Chrome, Mozilla Firefox, Safari etc.). We recommend the use of Mozilla Firefox or Microsoft Internet Explorer version 6.0 or later.

In your browser, you will need to enable JavaScript and SSL encryption as well as MetaRefresh (automatic redirecting). Java and ActiveX can be disabled. For security and data protection reasons, the cache should be cleared. If the browser provides any pop-up blocking, this must be disabled. If you need any support regarding browser settings, please contact your local system administrator.

1.2. General User Information

DataCapture is accessed via internet. A slow, unsecure, or unstable internet connection will inevitably lead to decreased system performance. The URL to be used (= internet address) for logging into DataCapture as well as your user identification (user name and password) have been sent to you via e-mail by the Data Handling task force of the University Medical Centre Goettingen. If not, please contact your study’s chief investigator.

Depending on which browser you are using, window view, menu layout, or print layout might differ slightly. All DataCapture features have been tested under common browsers. Please remember to never use the browser features “Reload”, “Back”, “Forward” or the browser context menu, but only the seCUtrial® navigation buttons (Figure 1).

![Figure 1: Navigation buttons on the upper right]
By clicking the CANCEL button (Figure 2), you will exit the current form without saving and will be redirected to the previous page.

![Cancel button](image)

*Figure 2: Cancel button*

By clicking the LOGOUT button, you will exit the application. If you want to log in again, you will need to re-enter your user identification and password.

If there is no connection to the server for more than 60 minutes, you will be logged out automatically (“connection to the server” means: saving by clicking the SAVE button or changing form pages, but not the mere entering of data into a form). This will ensure that no unauthorised individuals might gain database access or change your data records.

The time remaining until logout will be displayed in the browser window’s title bar. If you are logged out automatically, data you have not saved before will be lost. If you pause working, you should save the form you are working on (using the SAVE button) (Figure 2).

Most pages in DataCapture have a help function which you can open by clicking on the HELP button in the main menu at the top right of the screen. For orientation, the header of all secuTrial® pages will constantly display the current user data.
2. Login

![Login Mask](image)

**Figure 3: Login mask**

For your first DataCapture login, please access the URL send to you by the Data Handling (from now on: DH) task force. In order to login, you will need user identification, consisting of user name (user ID) and password, which were provided by the DH as well. Under “User-ID”, please enter your user identification exactly as it has been assigned to you (Figure 3).

At first login, you will be required to change the password sent to you. Please enter a password of your own choosing and do not share it with anyone else. For security reasons, your password must comply with specific criteria:

- use at least 8 characters
- use lower and upper case letters as well as numbers
- use at least one special character (e.g.: ? ! % + $ ! #).
- the new password must not be identical to the one sent to you.

You will be asked regularly to change your password (project setting). The new password must not be identical to the previous password.

**Important:** Please note that even though you already received a User ID and a password for the test system, you can’t use these to add patients into the productive system. DH will provide you with an additional identification.

2.1. Logout

Whenever you used your workstation and whenever you leave it, you must log out manually (LOGOUT in the upper menu bar) in order to prevent unauthorised individuals from using your account. After logout, you will see an information page. It will provide a link that will redirect you to the LOGIN page.
2.2. Changing Password

You can change your password at any time by clicking the MY ACCOUNT button on the LOGIN page. Just enter your previous password and provide a valid new password twice.

2.3. Forgotten Password

If you have forgotten your password, please contact the DH in Goettingen. They will send you a new password via e-mail afterwards. As your request will be processed manually, this might take up to one working day.
3. Welcome Page

The WELCOME page is the central access point for the individual secuTrial® features (Figure 4). Depending on the role assigned to you and the configuration, you can:

- Access and change your preferred language (MY ACCOUNT)
- Create a new patient (NEW PATIENT)
- Access patient information/Entering and Editing Data (SELECT)
- Access reports and statistics (REPORTS)
- View and write messages (MESSAGES)
- Import form data or discrepancies (IMPORT)
- Download documents (under DOWNLOAD AREA)

The WELCOME page contains general information regarding the use of the application. By using the HELP button, you can open more detailed descriptions for each individual feature. You can return to this starting point via the WELCOME button available on each DataCapture page.

3.1. My account

By using the MY ACCOUNT button, you can set up a preferred language for DataCapture (Figure 5). Currently, German and English are available. If you do not make a choice, the default setting of the project or of the current client will be used.