DZHK-SOP-P-10
eCRF-documentation in DZHK BDMS

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Notice of change: Correction of incorrectly linked reference sources due to formatting errors

Note: Printouts are not subject to the update process!

	Scientific author	Scientific review	Approval WGCR spokesperson	Approval DZHK
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Signature	**This SOP is a translation from the original German SOP and valid without signatures.**			

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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Full form
BDMS	Biosognal and image data management system
DH	Data handling
DICOM	Digital imaging and communications in medicine
eCRF	Electronic case report form
LIMS	Laboratory information and management system
SOP	Standard operating procedure
THS	Trusted third party

1.2 OBJECTIVE

This SOP describes the documentation of reading results of image-related clinical data from the DZHK-BDMS in the eCRFs of the DZHK-BDMS.

1.3 SCOPE

This SOP is aimed at the study staff who are entrusted with the reading of image data from the DZHK-BDMS and the documentation of image-related clinical data.

1.4 RESPONSIBILITIES

General system training is carried out by DZHK staff. Additionally, study-specific training is provided by representatives of the sponsor.

1.5 APPLICATIONS AND DEFINITIONS

Data handling (**DH**) operates the system for capturing clinical data in the form of electronic forms (eCRFs).

DICOM-Header is a data set that contains each DICOM file and includes information about patients, device and acquisition settings.

DICOM-Tags are individual pieces of information that together form the DICOM header.

DZHK infrastructure consists of the ethics coordination, the technical infrastructures and the transfer office.

Ethics coordination supports the development of drafts of the informed consent in line with the study objective and DZHK data reuse and supports the application process for ethics approval at the individual institutions.

Biosignal and image data management system (BDMS) is the system for acquiring data in DICOM format and the measured values determined from it.

Laboratory information and management system (LIMS) manages the available biomaterial samples.

Study-Corelab is a central lab of a study that evaluates the DICOM data.

Trusted third party (THS) manages patient consents and is the only entity in the DZHK infrastructure that has knowledge of the assignment of identifying data (study participant name) and pseudonyms.

1.6 RELATIONS TO OTHER SOPS

Data Generating Clinical SOPs	• DZHK-SOP-K-03 basic ECG • DZHK-SOP-K-08 echocardiography • DZHK-SOP-K-06 MRI • DZHK -SOP-P-02-DICOM-Upload • DZHK-SOP-P-09-DICOM-Download
Review of Clinical Data	• DZHK-SOP-P-01 Review of clinical data

2 REQUIREMENTS

2.1 TECHNICAL/ORGANIZATIONAL REQUIREMENTS

- PC with one of the following browsers
    - Browser Google Chrome (75.0.3770)
    - Microsoft Edge
    - Firefox (ab 68.0)
- Internet access
    - Port: 443 (HTTPS)
- Access to the BDMS system
    - Application for registration, change or deregistration of a user access for the DZHK IT infrastructure https://service4studies.dzhk.de/en/studienzentren/it-nutzerzugang/

    → Role of the user in BDMS
    - Access data and further information will be sent by the BDMS-project (contact bdms@dzhk.de), a password link will be sent automatically by TrialComplete system

2.2 INFORMATION NEEDED

- BDMS pseudonym or patient's clear name [only when using THS function], visit

2.3 STAFF

- Data transfer can be performed by clinical study assistants after they have been instructed in the SOP or have completed training.

3 PROCEDURE

3.1 OPENING ECRF FOR EDITING

Follow these steps to open the eCRFs:

1. Open a suitable browser (see Section 2.1).
2. Log in with your username at https://dzhk.trialcomplete.com
3. Check if there is any maintenance or other disruptions on the Welcome Screen

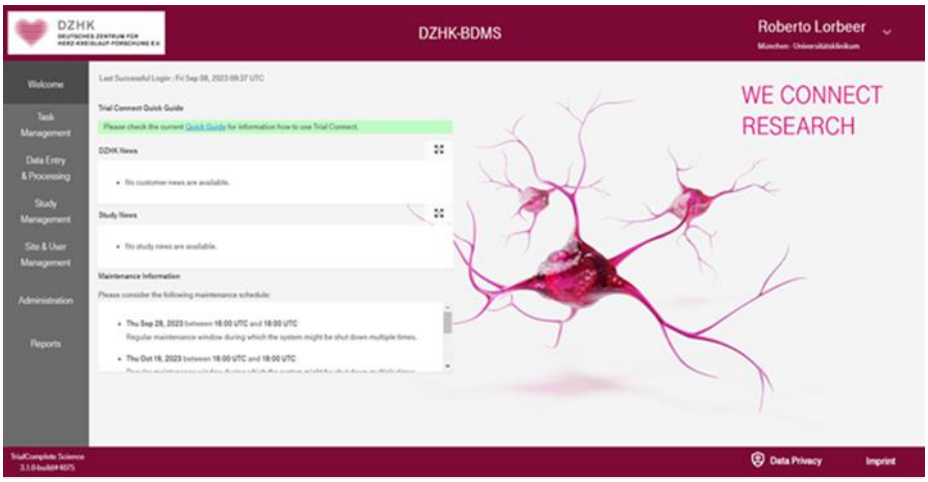

Figure 1: The BDMS Welcome Screen displays the menu bar on the left and in the center, lists for notifications from the BDMS infrastructure (DZHK News), the study (Study News), and the operator regarding maintenance windows.

Note: On the "*Welcome Screen*" maintenance windows for the BDMS are announced, during functions may be interrupted without prior notice. The times are provided in Coordinated Universal Time (UTC). To convert, add 1 hour for Central European Winter Time or +2 hours for Central European Summer Time.

4. Select "*Data Entry & Processing*" from the left sidebar.

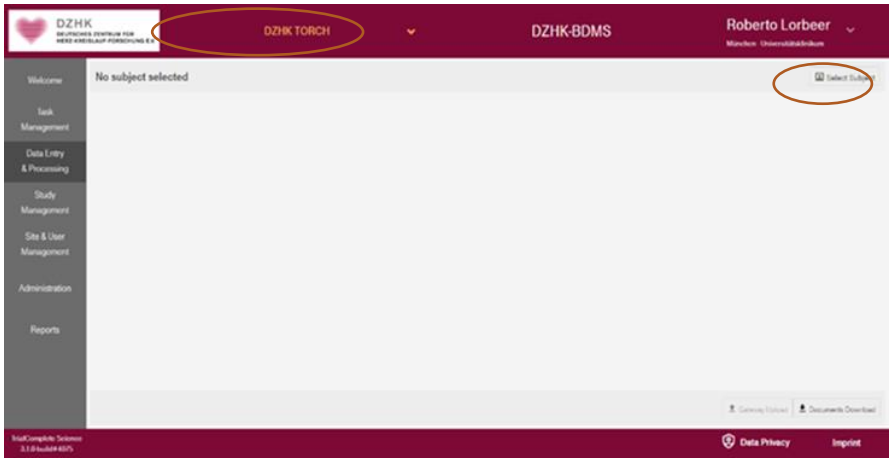

Figure 2: Representation of the "Data Entry & Processing" menu, if no subject has been selected beforehand. Above in the banner, the study can be changed (in this example, "DZHK-Torch").

5. Select the study (see Figure 2).
6. Click on the "*Select Subject*" button (see Figure 2). Subsequently, a window with all study participants will be displayed.
7. To efficiently locate a participant, please use the "*Search by PSN*" tab. Here, you have the option to identify the desired participant using three search options ("*Search by PSN*", "*Search by Status*", "*Search by Arm*"). For example, if you enter a value in the "*Search by PSN*" section, only the matching participants will be displayed instantly.

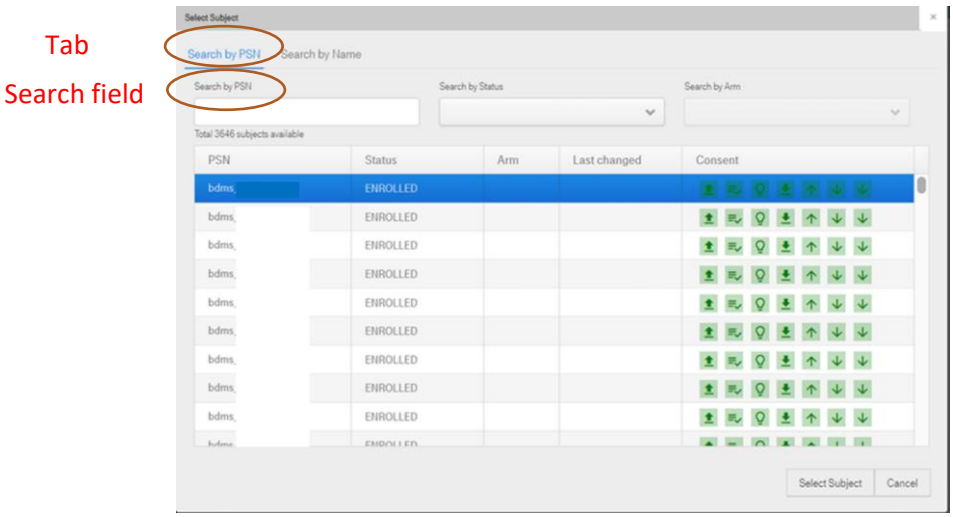

Figure 3: "Select Subject Screen" in "Search by PSN" mode displaying the current consent status for BDMS functions (Consent). Selection criteria via the fields "Search by PSN", "Search by Status", "Search by Arm".

8. Highlight the study participant by clicking with the mouse and then select "*Select Subject*" (Figure 3) to open the visit schedule (Figure 4)

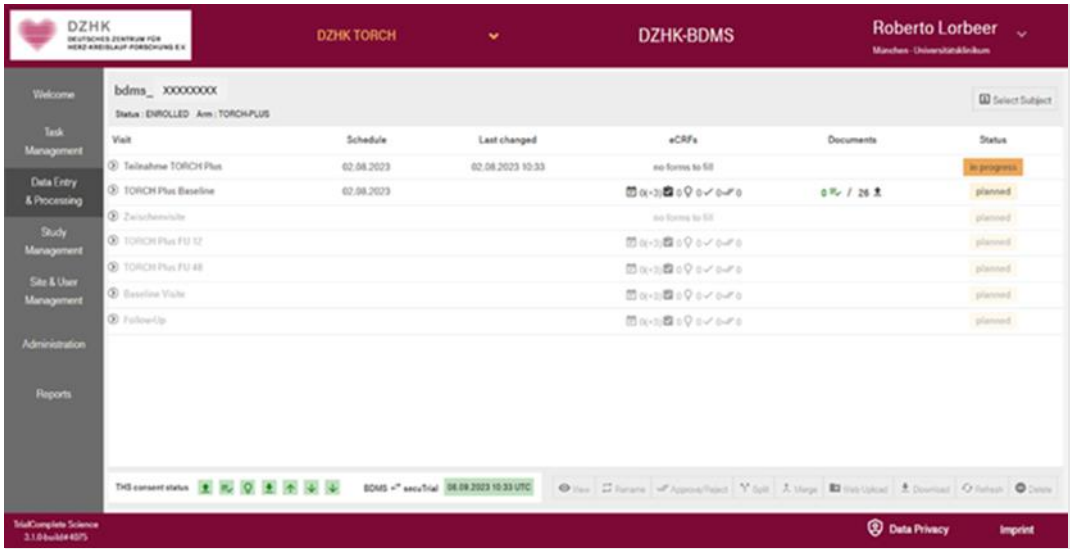

Figure 4: Representation of the visit schedule with the individual visits (in black text initiated in secuTrial). Active visits, whose eCRFs may be filled out, are written in black. Visits that have not been activated yet are written in gray. Below the visit schedule on the left side, the consent status is displayed, as well as whether the data synchronization to secuTrial has occurred; on the right side, editing options are shown (displayed in black (active) or gray (disabled) depending on user rights).

9. Open the relevant active visit by clicking on the arrow symbol to the left of the visit name. Here you will find the eCRFs along with a color bar representing their status. The individual statuses are described in section 3.2. Open the eCRF by clicking on one of the first three icons (✎, ⊕, ⊙) in the blue highlighted table below Figure 5.

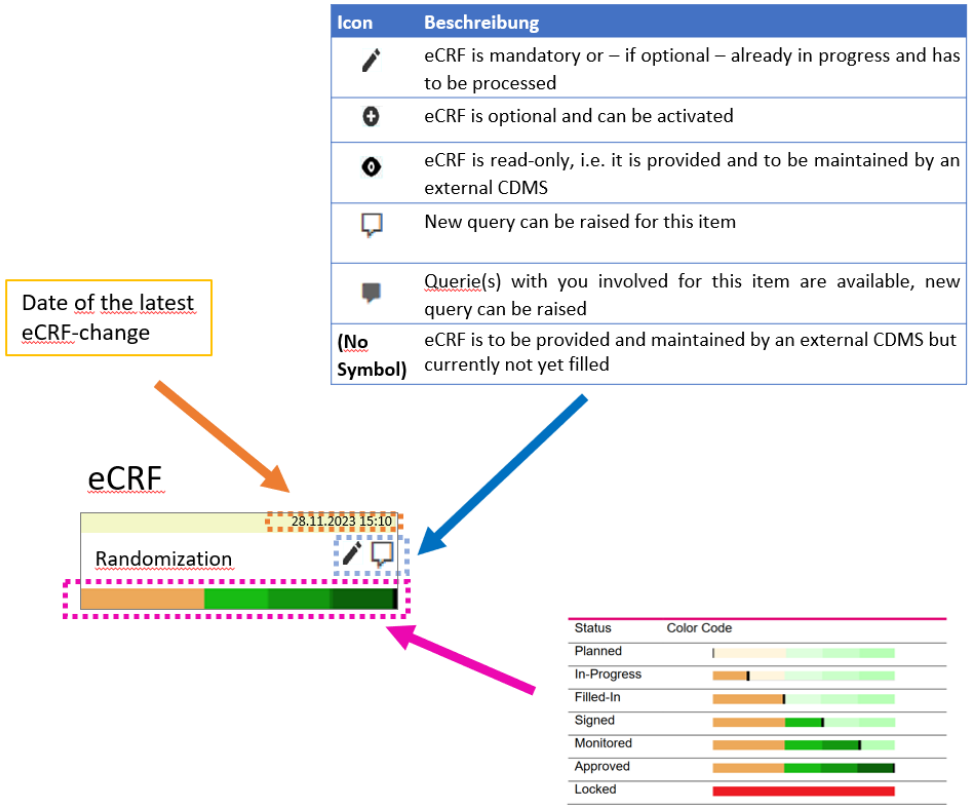

Figure 5: Representation of an eCRF named "Randomization"; Header (highlighted in orange): Date of the last eCRF modification; Icon bar (highlighted in blue): By clicking on one of the first 3 icons, the eCRF can be opened; for queries, the two speech bubble icons; Footer (highlighted in pink): Editing status of the eCRFs.

3.2 EDITING AND VALIDATING ECRFS

3.2.1 Status Change

The eCRFs are represented by a color bar indicating their status. Table 1 lists the various status possibilities.

Authorized users may enter data in eCRFs if the eCRFs are in the "Planned" and "In-Progress" status. You can change the eCRF status using the checkboxes and buttons at the bottom of the eCRF to move to a higher or previous status. The changes should be made in the sequence according to Table 1.

Table 1: Available eCRF Status and Description and Sequence

eCRF Status	Details	Status Change
Planned	The eCRF is new and no data has been entered	(Automatically set)
In Progress	The eCRF contains data but is not fully filled out for signing or has not been signed yet	Automatically set to "In Progress" once data is entered and saved.
Filled In	The eCRF has been completed and validated according to the study design's validation rules.* The form is ready for signing.	Set manually to "Filled In"
Signed	The eCRF has been completed and validated according to the study design's validation rules*. The signing user takes responsibility for the accuracy of the entered data (see TrialComplete Guideline, section 'eCRF signed'). The signature can only be revoked by users with appropriate roles using the "Modify" button.**	Set manually to "Signed"
Monitored	Data has been reviewed by a monitor.	Set manually to "Monitored"
Approved	Data has been released/approved	Set manually to "Approved"

Notes regarding the table:

*Validation can be performed at any time using the "*Validate*" button. If this validation fails, you will receive a notification that the status cannot be changed.

**If an eCRF is in the "*Monitored*" status or higher, it can be reset to "*In-Progress*" to modify the data. The eCRF signature will be removed in this case.

3.2.2 Value Range

In an electronic case report form (eCRF), there are fields for capturing various parameters, such as weight in grams. These fields are provided with a defined value range. If the entered value is outside of this value range - whether higher or lower - the value is considered invalid and not accepted.

The following validation checks can take place:

- Integer values or decimal places
- Number of decimal places
- Lower or upper value range limit
- English notation (dot as comma)
- Mandatory field

When you click the "Validate" button, the system highlights the eCRF items with invalid values in red (see Figure 6). You can retrieve the validation error message for each error using the "Mouse-Over" function.

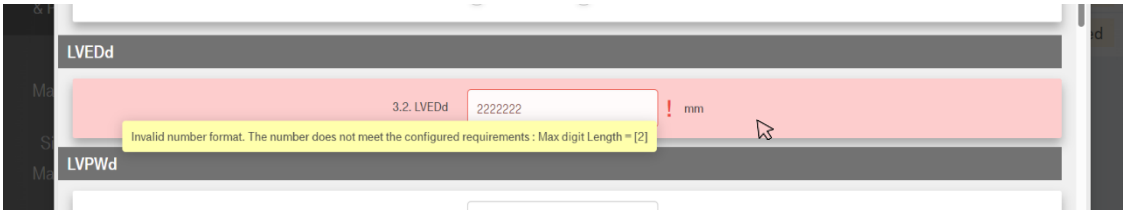

Figure 6: Validation error message on Mouse-Over. Further information about validation errors (red background of the item) can be displayed by hovering the mouse over the red exclamation mark icon. In this example, a maximum of 2 digits are accepted.

3.3 Filling out eCRFs using an XML file

If configured for the individual study, the currently opened eCRF can be filled out with an eCRF-specific XML file. This process will support manual entry of eCRF data by pre-filling. By clicking on "*Upload XML*", a dialog for selecting an XML file will open, and its elements will be imported into the opened eCRF. Afterward, it can be validated (see Table 1). This functionality is available for eCRFs in the "NEW" and "IN PROGRESS" statuses. Once the confirmation process has begun (statuses "*FILLED IN*", "*SIGNED*", "*MONITORED*", "*APPROVED*"), this functionality will be deactivated.

4 References

None

5 Participating Persons

Name	Role	Contribution
Dipl.-Ing. Jens Schaller	First author	Draft
Dr. Roberto Lorbeer	Reviewer	Scientific review
M. Sc. Tayfun Kilic	First author	Draft