

DZHK-SOP-P-09

Download DICOM-Data from DZHK infrastructure

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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!

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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
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BDMS	Biosignal and imaging 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 data export of DICOM data from the DZHK-BDMS to a central analysis unit (Corelab) for image data evaluation.

1.3 SCOPE

This SOP is intended for study staff responsible for the evaluation of image data from the DZHK-BDMS and the documentation of image-related clinical data.

1.4 RESPONSIBILITIES

General system training is conducted by DZHK staff. Additional, 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.

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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	<ul style="list-style-type: none"> • 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-10-eCRFs
Review of Clinical Data	<ul style="list-style-type: none"> • 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

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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 DOWNLOAD DICOM- IMAGE DATA

There are two download options:

- **Participant-based download:** Image data for each study participant can be selected for download in the visit schedule (see 3.1).
- Typically, the **study-based download** is recommended. In this case, the appropriate image data from multiple study participants are downloaded in one operation based on reports and selection criteria (see 3.2).

3.1 PARTICIPANT-BASED DOWNLOAD

The download process follows these steps:

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)*.
4. Select "*Data Entry & Processing*" (in the left sidebar) (Figure 3).
5. Choose the study (Figure 3).
6. Click on the "*Select Subject*" button. Subsequently, a window with all study participants will be displayed.
7. To efficiently locate a study participant, please use the "*Search by PSN*" tab (Figure 4). Here, you have the option to identify the desired study 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*" input field, only the matching study participants will be displayed in real-time.
8. Click on the study participant to mark it. Then click on the "Select Subject" button to open the visit schedule (Figure 4).
9. Open the visit (Figure 5).
10. Select images to download by clicking on them. You can select multiple images by holding down the CTRL key while clicking the first and then the last image.
11. Click the "Download" button (bottom bar).** The number of image data will be displayed in the download button.
12. Wait for the download process to complete.

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Instructions regarding steps marked with the * symbol:

**In the "Welcome Screen," maintenance windows for the BDMS are announced, during which functions may be interrupted without prior notice. 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.*

***In Firefox, you may receive a message stating that the browser has blocked the opening of a pop-up window on this website. Alongside, a "Settings" button appears. Please allow pop-ups in the settings to continue the download.*

Click on "Download," then TrialComplete prepares the download package, and the browser-specific download dialog allows you to save it. The download location depends on the features of the browser you are currently using. Once you click the "Download" button, a zip file is generated, named after the study name and the current timestamp in UTC. The internal data structure is as follows: Zip Archive\Study\Patient\Visit\Series{Images}

3.2 STUDY-BASED DOWNLOAD

The study-based download consists of two steps. In the first step, data is selected based on a report (3.2.1), and in the subsequent step, the download package is created from this selection (3.2.2).

3.2.1 Data Selection

First, you need to download a report with your own custom search criteria listing the image data of patients that match your search criteria:

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)
4. Select "*Reports*" (in the left sidebar)
5. Choose the report "*T204-DICOM_Webdownload_Template_light*". For more DICOM tags and finer selection, choose "*T203-DICOM_Webdownload_Template*".
6. Refine your search by setting the search criteria (e.g., modality, study center, upload date). If you leave the search fields empty, all criteria in that search field will be selected.
7. Optional: Click on "*Preview*" to see a preview of the bulk report.
8. Click on "Excel" to download the report and note the location where it is saved.**

Instructions for steps marked with * can be found under section 3.1 in the notes.

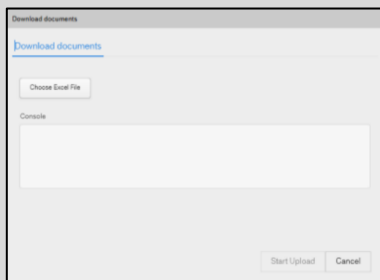
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3.2.2 Creating the download package

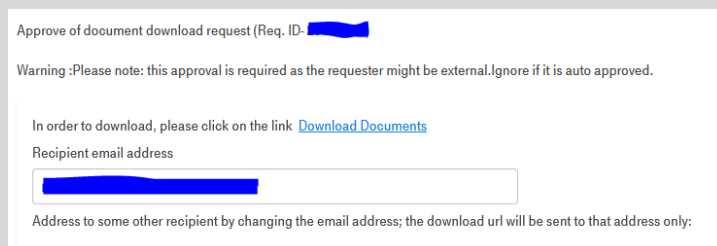
1. Go back to "[Data Entry & Processing](#)" (in the left sidebar)
2. Select the study.
3. After selecting a study, the TrialComplete workspace will display the heading "*No subject selected*". At the same time, you will find the "[Documents Downloads](#)" button below:



4. Select "[Download Documents](#)".
5. In the following dialog, click on "[Choose Excel File](#)" and select the report you saved in the previous step (3.2.1) by clicking "[Open](#)."



6. Click "[Start Upload](#)" to upload the Excel table. Once the process is complete (document IDs listed in the "[Console](#)" section), click "[OK](#)." A confirmation email ("Document download request received") has been sent with the note "*Kindly check your work order*".
7. Go to "[Task Management](#)" (in the left sidebar).
8. Click on "[Work Orders](#)". Here, you will find a new entry titled "[Document Download \(Req. ID-\[Numbers\]\)](#)," which was generated by your upload start. Click on this entry. Your email address should be listed under "[Recipient email address](#)".
9. Click the "[Generate Package](#)" button below. TrialComplete will now generate the download package and the corresponding link. This may take some time. While waiting, the following message will appear: "[Generate Package request is submitted already. The Link will be available soon](#)".
10. After generation, the following text will appear. Click on "[Download Documents](#)" and the browser-specific download dialog will allow you to save the download as a zip file.



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The download location depends on the features of the browser you are currently using. Once you click the "Download" button, a zip file is generated, named after the study name and the current timestamp in UTC. The internal data structure is as follows: Zip Archive\Study\Patient\Visit\Series{Images}.

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

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6 APPENDIX

6.1 BDMS-USER INTERFACE

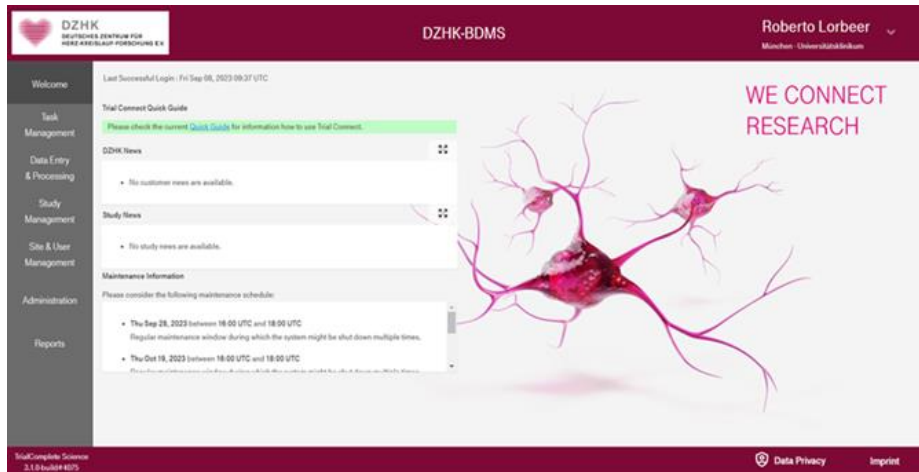


Figure 1: The BDMS-Welcome-Screen shows the menu bar on the left and in the middle lists for messages of the BDMS infrastructure (DZHK News), the study (Study News) and the operator to maintenance windows.

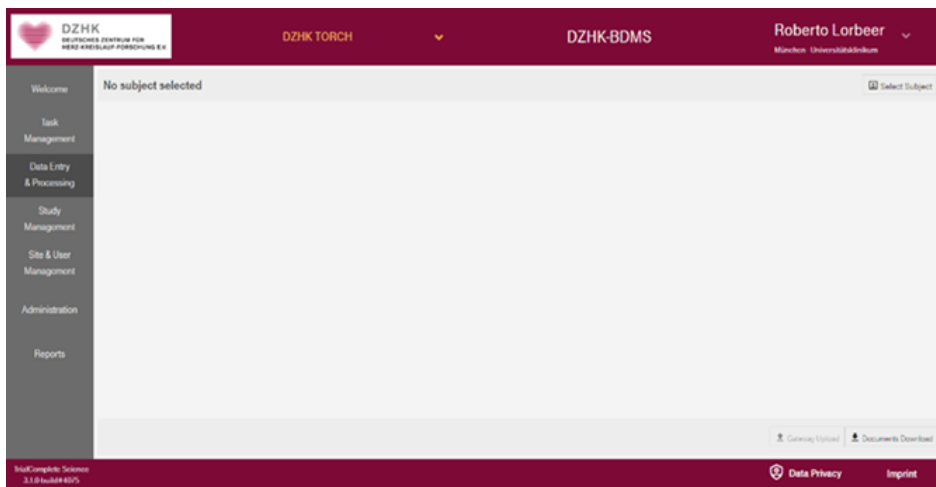


Figure 2: View of the Task Management Menu with the tabs Inbox, Work Orders, My Queries and Study Queries.

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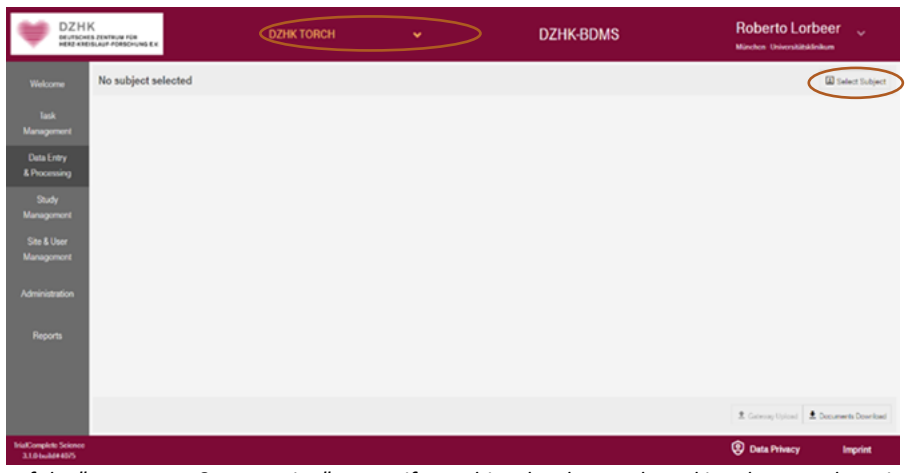


Figure 3: Display of the "Data Entry & Processing" menu, if no subject has been selected in advance. Above in the banner the study can be changed (in this example "DZHK TORCH").

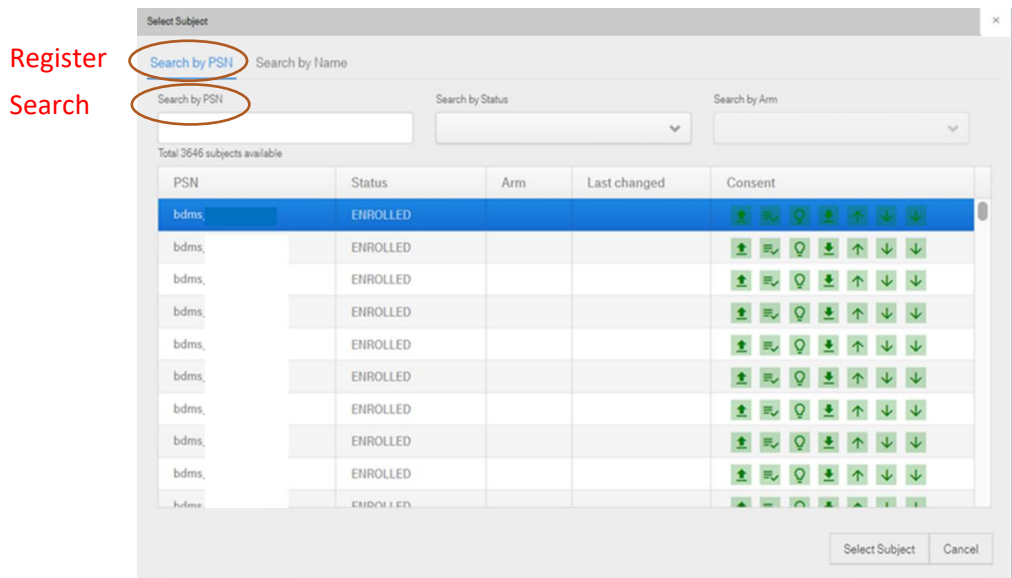


Figure 4: Select Subject Screen in Search by PSN mode. Here with search options (PSN, status and arm) and display of the present consent status for BDMS functions (Consent).

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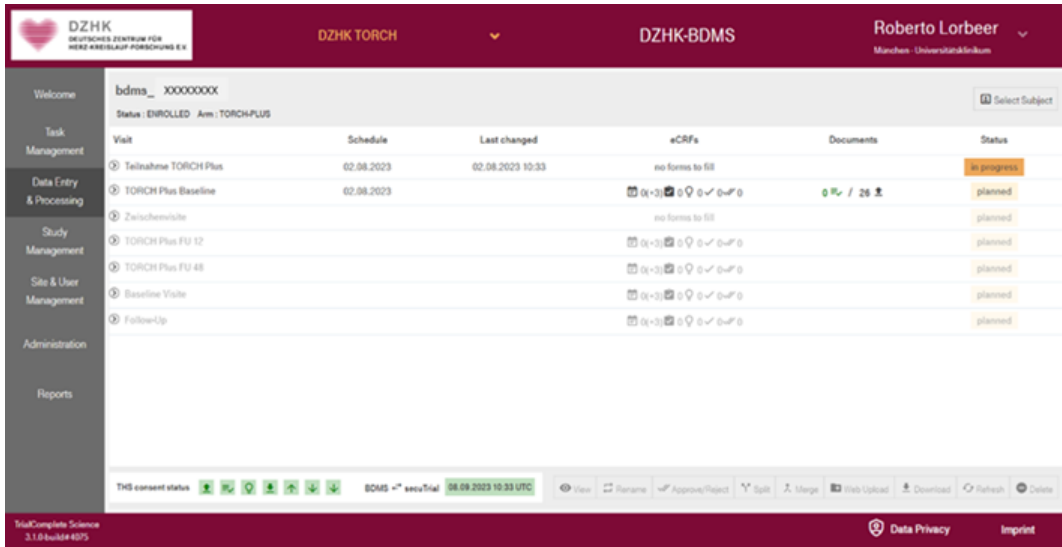


Figure 5: Display of the visit plan with the individual visits (black font started in secuTrial). Below the visit plan, on the left, the consent status is shown and whether the data synchronization with secuTrial has taken place; on the right - editing options (active or deactivated (gray) depending on user rights).



Figure 6: Visit plan with selected visit so that individual functions can be selected for upload (black buttons on the lower bar)

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