# DZHK-SOP-P-02
# DICOM-Data export at the study center

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This SOP is a translation from the original German SOP and valid without signatures.

| | Author | Review | Approval by head of division | Release by DZHK |
|---|---|---|---|---|
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| Date | 17.09.2020 | 17.09.2020 | 17.09.2020 | 17.09.2020 |
| Signature | | | | |

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# 2 INTRODUCTION

## 2.1 LIST OF ABBREVIATIONS

| | |
|---|---|
| BDMS | Bilddatenmanagementsystem (image data management system) |
| DH | Datenhaltung (data handling) |
| DICOM | Digital Imaging and Communications in Medicine |
| eCRF | electronic Case Report Form |
| GDPR | General Data Protection Regulation |
| SOP | Standard Operating Procedure |
| THS | Treuhandstelle (trusted third party) |

## 2.2 OBJECTIVE

This SOP describes the transfer process of DICOM data from the study center to the DZHK infrastructure.

## 2.3 PURPOSE

This SOP is intended for study personnel involved in the documentation of clinical data in clinical systems.

## 2.4 APPLICATION AND TASKS

This SOP has to be used when documenting data in the clinical systems of the DZHK infrastructure.

## 2.5 TERMS AND DEFINITIONS

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

**Ethics Project** coordinates the drafts of the informed consent forms in line with the study objective and DZHK data use and supports the submission of the ethics applications to the individual institutions.

**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.

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

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

**Laboratory Information Management System** (LIMS) manages the available biomaterial samples.

**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.

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

### 2.6 Relations to other SOPs

| | |
|---|---|
| Data Generating Clinical SOPs | • DZHK-SOP-C-03 12- electrocardiogram<br>• DZHK-SOP-C-08 transthoracic echocardiography<br>• DZHK-SOP-C-06 MRT |
| Review of Clinical Data | DZHK-SOP-P-01 Review of clinical data |

### 2.7 Data Quality

**The data quality depends on whether the data is artifact-free, standardized and evaluable.**

The data quality can be increased by de-identifying the data before uploading them in such a way that the evaluators cannot draw conclusions about the patient's previous data records (e.g. patient pseudonym) or a study center (as a clear name or clinic ID) from the content. This FDA recommendation for clinical trials [1] goes beyond the GDPR [2].

## 3 Requirements

### 3.1 Technical/Organizational Requirements

- PC with one of the following browsers
  - Browser Google Chrome (75.0.3770 or newer)
  - Microsoft Edge
  - Firefox (68.0 or newer)
- Internet access
  - Port: 80
- For the integrated THS function "ID query based on identifying data":
  - installed certificate of the TTP

- **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

## 3.2 REQUIRED DATA

Exported Data in DICOM file format

## 3.3 INFORMATION NEEDED

Subject ID (case number or BDMS pseudonym)

## 3.4 STAFF

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

# 4 PROCEDURE OF IMPLEMENTATION/WORK PROCESS/WORK STEPS

## 4.1 PROCESS-FLOW-CHART

**Figure 1** shows the sequence of the individual work steps from data export to checking the data transfer. The individual steps are described in the following sections.

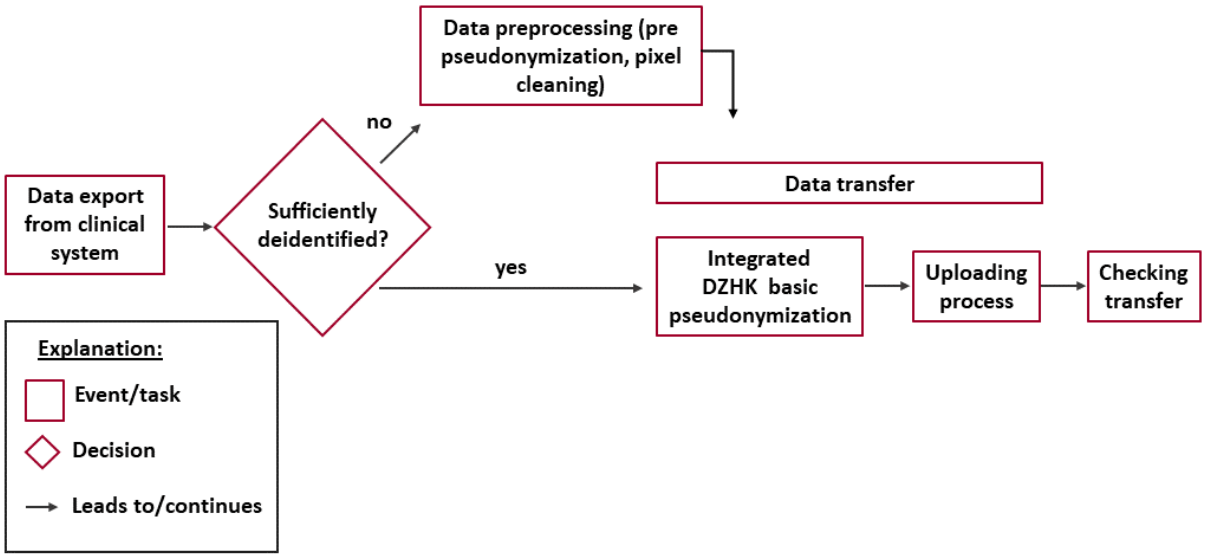



***Figure 1**: Process for data export*

## 4.2 DATA EXPORT FROM CLINICAL SYSTEMS

For the export from the clinical systems, only recommendations for the local implementation can be given here:

- If possible, record the data without burned-in image data and use the anonymization functions of the recording device if possible. Both will may save you the step of data pre-processing.
- **Export the data as soon as possible.** At some centers, some PACS systems are set up in such a way that data is compressed after a certain period of time. Some software solutions can only deal with this to a limited extent.
- If possible, avoid the step of burning the image data to DVD. Alternatives are the export to USB media, network directories and retrieval from the PACS using specific tools (e.g. DICOM-Cleaner [3]).
- **Also use the contacts of the BDMS-project team for specific advices (bdms@dzhk.de).**

## 4.3 DATA PRE-PROCESSING

**Pre-processing is necessary to remove information from the data that is not automatically removed in the following process step (see section 4.4 „Data Transfer“)**. This includes **information** burned in to the pixel data of the image or data in the DICOM header (additional image information in the file) that is not automatically changed in the upload process (see section 6.3 „DICOM-Pseudonymization Profile of the DZHK (Updated: 14.11.2017)“ ).

**This data pre-processing must be tested in advance with the study corelab/quality assurance (if available)**, to check the readability of the data processed in this data transfer.

**Removing burned-in data**

Image data may contain "burned-in" data of the study participant (name, date of birth) or data about the study site (study site, department, treating physician). **These must be electronically redacted ("blackout") manually using certain tools (e.g. DICOM Cleaner).** Table 1 lists typical places where such data can be found.

*Table 1 Possible places for burned-in image data*

| Modality | Typical locations for burned-in data |
|---|---|
| Computed Tomography | • radiation dose report (usually the last image of a series) |
| Echocardiography | • Status bar (at the top of the screen) |
| Cardiac catheterization | • radiation dose report (usually the last image of a series) |

**Removing identifying data from the DICOM header**

The device-specific anonymization tools should primarily be used if possible. A pseudonymization process applied in the DZHK basic profile during the upload containing the basic profile of DICOM Supplement 142:2017 is automatically.

**Any further removing that goes beyond this must be carried out using additional tools.**

Many centers offer de-identification functions for export. There, in particular, the data should be checked for burned-in data. A license-free option is the DicomCleaner tool, which removes data per DICOM header group. Technically experienced users can also use their own scripts - e.g. MatLab or Python - to remove/replace values of individual DICOM tags.
**The team of the BDMS (bdms@dzhk.de) can give you also advises here.**

## 4.4 DATA TRANSFER

Pre-processed data will be uploaded to the BDMS. During the upload process, certain DICOM fields of the header information are deleted/replaced from the data (see section 6.3 „DICOM-Pseudonymization Profile of the DZHK (Updated: 14.11.2017)“).

**In the study center, no values need to be entered in the eCRF in the BDMS,** since the eCRFs are filled out by central analysis units (CoreLabs).

The upload contains the following steps:

1) Open a suitable browser (see section 3.1 *Technical/Organizational )*
2) Log in with your username on http://bdms.dzhk.de
3) Check whether maintenance or other faults are pending in the welcome screen (Figure 4)*
4) Select „Data Entry & Processing“ (in the left sidebar)
5) Select the study (in the upper header element)
6) Open the visit plan (with button „Select Subject“ Figure 6)
7) Select the study participant via variant A „Select by name“ (Figure 7) or variant B „Search by ID“*
8) Open the visit (Figure 9)
9) Select the "Web Upload" button (bottom bar) (Figure 9)
10) Select DICOM files via „Drag-and-drop“, „Select Folder“ or „Select Files“* (Figure 10)
11) Wait for the upload process or start further parallel uploads*
12) Confirm the upload by pressing the button „Confirm“ (Figure 10) or wait for the 1 minute countdown
13) Check reports, if applicable

(See appendix for a leaflet: 6.4 DZHK – BDMS – DICOM Upload - User Guide)

Notes on the steps marked with the * symbol:

*Step 3.)* „Maintenance window“

The “Welcome Screen” announces maintenance windows for the BDMS. During the maintenance windows, uploads are usually canceled and uploads should be avoided here. Times are given in Coordinated Universal Time (UTC). To convert, add 1 hour to get Central European Winter Time or +2 hours to get Central European Summer Time.

*Step 7.)* „Selection of the study participants“

- Variant A „Select by name“:
  For this method, the certificate of the trusted third party must be installed on the computer.
  1.) Enter last or first name
  2.) Check that the correct patient is displayed

→ Forwarding to the visit plan

If there are any error messages, please also contact the trusted third party (**ths-dzhk@uni-greifswald.de**)

*Step 10.)* „Selection of DICOM files”

Here are two examples where browsers might encounter problems:

- For Windows: Here you should select files from paths that start with drives (“S:\directory”). UNC paths - like \\{server}\{directory} - can cause problems.
- The unsupported browser - Internet Explorer - is incompatible with the "Select Folder" function.

*Step 11.)* „Start of several upload processes“: It is possible to start further uploads to an ongoing upload process in order to enable a higher data throughput.

## 4.5 CHECKING THE TRANSFER

After the upload has been confirmed („confirmed“), users will receive an upload confirmation via email (Figure 2), an automated quality check (Figure 3) and a message in the inbox (Figure 5).

### 4.5.1 Checking the upload confirmation

The upload confirmation should be checked,

- whether the number of generated DICOM documents is correct:
  a. For ultrasound images, the number of DICOM files uploaded should match the number of DICOM documents created
  b. MRI and CT consist of series of images, so that several images can be combined into one DICOM document
- whether incorrect files occur

| Notification | Reason, Solution |
|---|---|
| Invalid DICOM file | It is not critical for the DICOMDIR file and other non-DICOM files. If it is DICOM data that should be uploaded, please contact bdms@dzhk.de. |
| Failed to upload DICOM file with modality „XX“ due to server error. | The flow of data was interrupted here and the file was not uploaded. Repeat the upload here at a later date or contact support bdms@dzhk.de. |

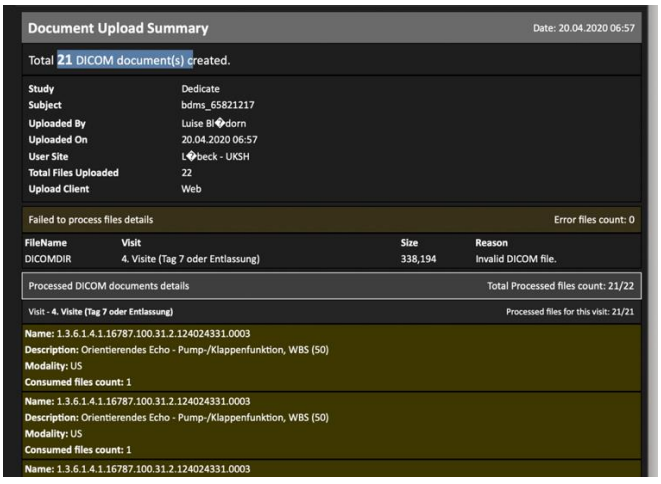



*Figure 2 Confirmation email "New Document(s) uploaded for subject XXXXX"*

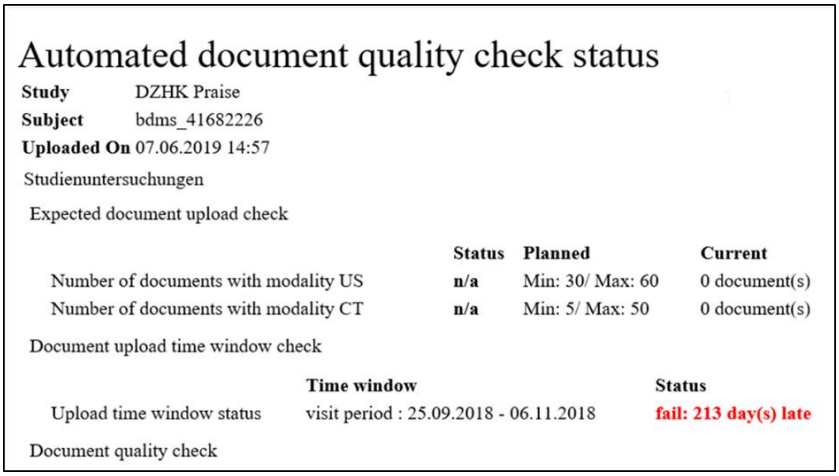
### 4.5.2 Checking the automatic quality check

In addition to the upload confirmation, another e-mail with the results of an automated quality check by "Trial Complete" is sent and filed as a notification. This "Automated document quality check status" contains the following information (Figure 3):

- Name of the study
- BDMS ID of the patient
- Name of the visit
- Upload time compared to the planned upload time window
- Successful image data pseudonymization
- Correct modality of image data
- Number of total image data uploaded per modality compared to planned documents

**The basic quality criteria (required image modalities per visit, minimum and maximum number of image documents to be uploaded per visit, upload time window after examination visit)** are defined individually for each study in the study design of the BDMS. The basis for this is the study protocol and the specifications by the study coordination. Timely recording has proven to be a quality criterion for clinical studies. **For the upload times, the time windows ("Upload time window check") of two months after the patient visit apply (according to the regulations from the DZHK-SOP-P-01).**

Properties that meet the quality criteria are highlighted in green in the e-mail (notification) - Properties that do not meet the quality criteria are highlighted in red (Figure 3). This gives the user and the QA manager a quick overview when reviewing the automatic e-mails (notifications) as to whether the image data upload was within the quality criteria or not. **If the quality criteria are not met, the user can react accordingly (user: optimization for the next image data upload, QA officer: Notification to user).**



Automated document quality check status

**Study** DZHK Praise
**Subject** bdms_41682226
**Uploaded On** 07.06.2019 14:57

Studienuntersuchungen

Expected document upload check

| | Status | Planned | Current |
|---|---|---|---|
| Number of documents with modality US | n/a | Min: 30/ Max: 60 | 0 document(s) |
| Number of documents with modality CT | n/a | Min: 5/ Max: 50 | 0 document(s) |

Document upload time window check

| | Time window | Status |
|---|---|---|
| Upload time window status | visit period : 25.09.2018 - 06.11.2018 | fail: 213 day(s) late |

Document quality check

*Figure 3 E-mail for automatic quality control after image data upload in BDMS (example).*

# 5 PERSONS INVOLVED

| Name | Function | Participation |
|---|---|---|
| Dipl.-Ing. Jens Schaller | Author | Drafting and Review of SOP |
| Dr. Roberto Lorbeer | Author | Drafting and Review of SOP |

# 6 APPENDIX

## 6.1 REFERENCES


1. „Clinical Trial Imaging Endpoint Process Standards Guidance for Industry“ U.S. Department of Health and Human Services Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), 04. 2018 https://www.fda.gov/media/81172/download
2. EU-Datenschutzgrundverordnung DS-GVO (EU) 2016/679 https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&qid=1669369218429&from=EN (last visited on 25.11.2022)
3. DicomCleaner™ http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html (last visited on 25.11.2022 14.04.2020)
4. Digital Imaging and Communications in Medicine (DICOM) Supplement 142: „Clinical Trial De-identification Profiles“, DICOM Standards Committee, Working Group 18 Clinical Trials, 300 N. 17th Street, Suite 1752 Rosslyn, Virginia 22209 USA, 25.01.2011

## 6.2 BDMS- USER INTERFACE

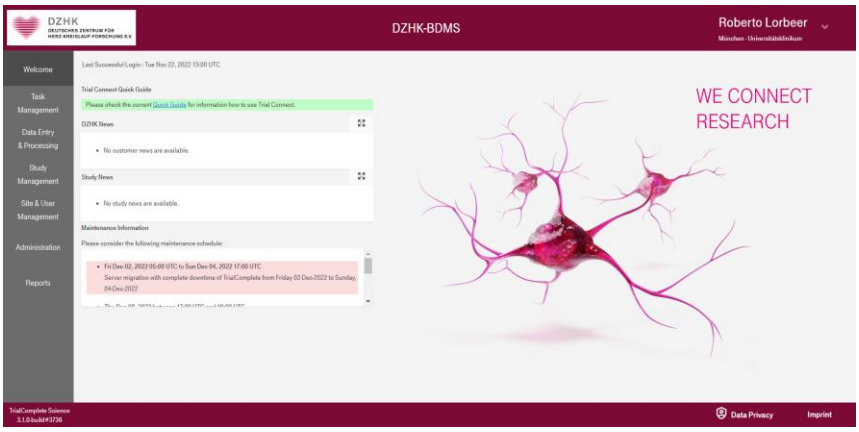



*Figure 4 The BDMS-Welcome-Screen shows the menu bar on the left and in the middle lists for messages of the BDMS infrastructure (DZHK News), the study (Study News) and the operator to maintenance windows.*

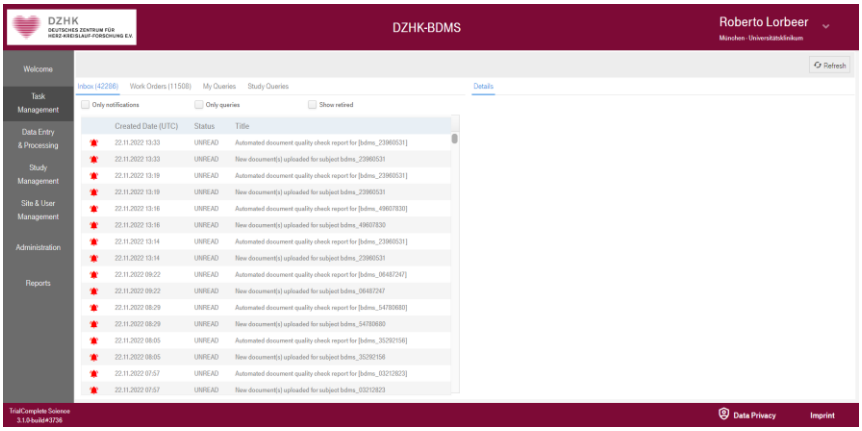



*Figure 5 View of the Task Management Menu with the tabs Inbox, Work Orders, My Queries and Study Queries.*

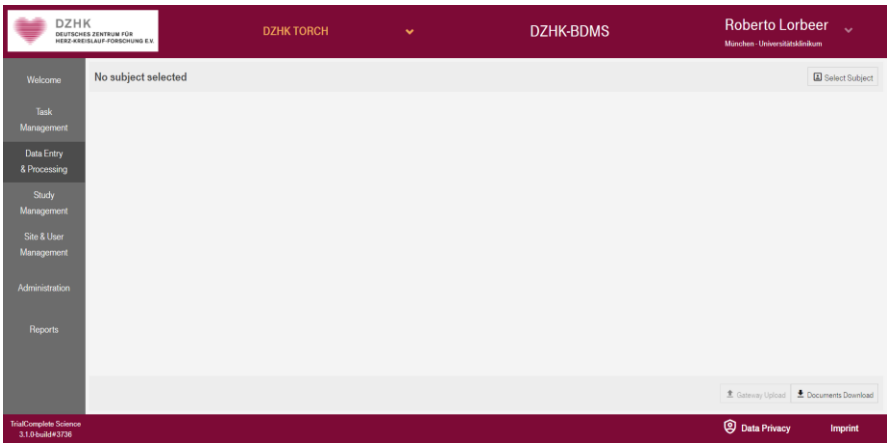



*Figure 6 Display of the "Data Entry & Processing" menu, if no subject has been selected in advance. Above in the banner the study can be changed (in this example "DZHK TORCH").*

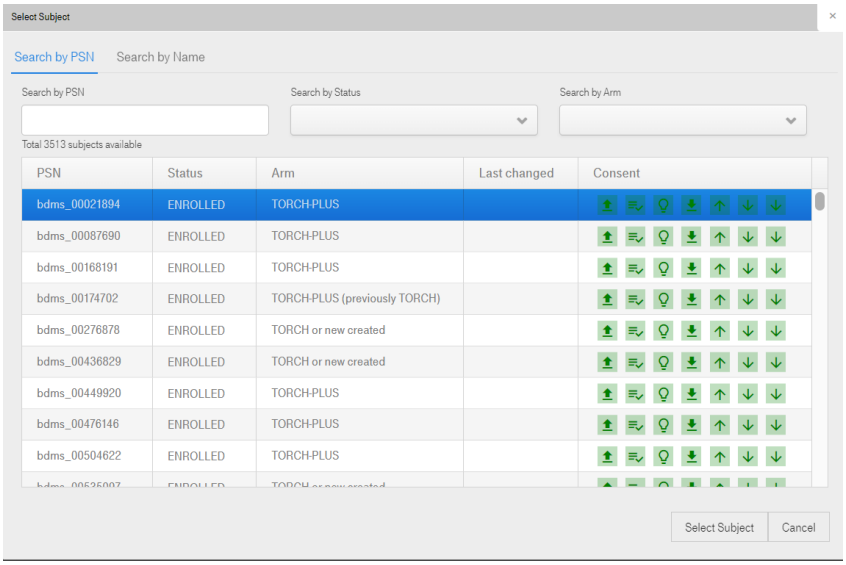



*Figure 7 "Select Subject Screen" in Search by PSN mode. Here with search options (PSN, status and arm) and display of the present consent status for BDMS functions (Consent).*

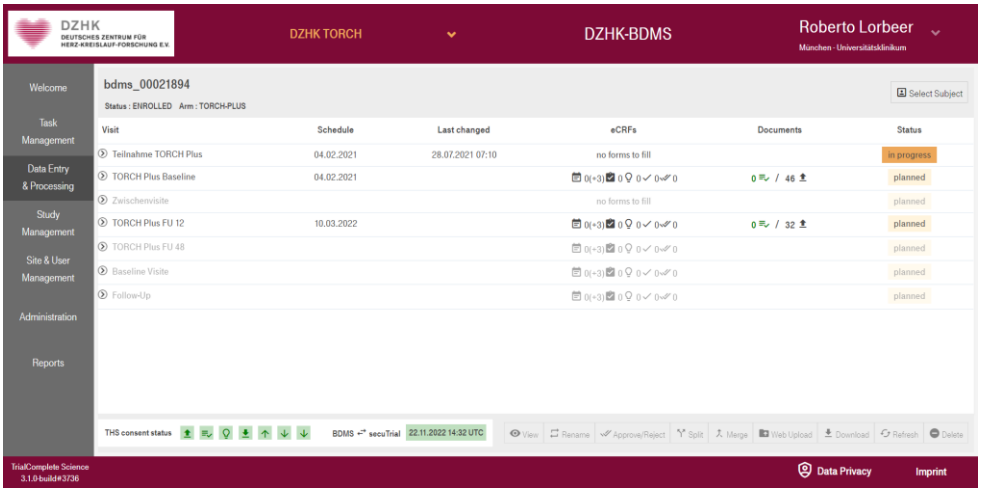



*Figure 8 Display of the visit plan with the individual visits (black font started in secuTrial). Below the visit plan, on the left, the consent status is shown and whether the data synchronization with secuTrial has taken place; on the right - editing options (active or deactivated (gray) depending on user rights).*

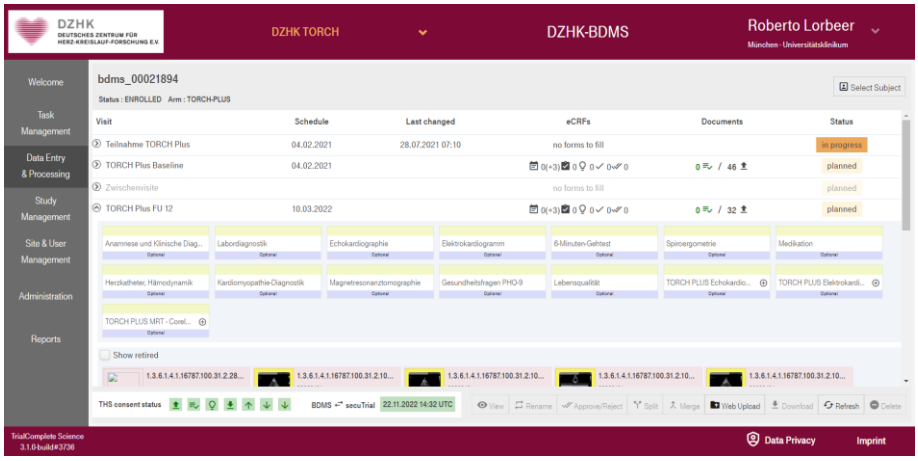



*Figure 9 Visit plan with selected visit so that individual functions can be selected for upload (black buttons on the lower bar).*

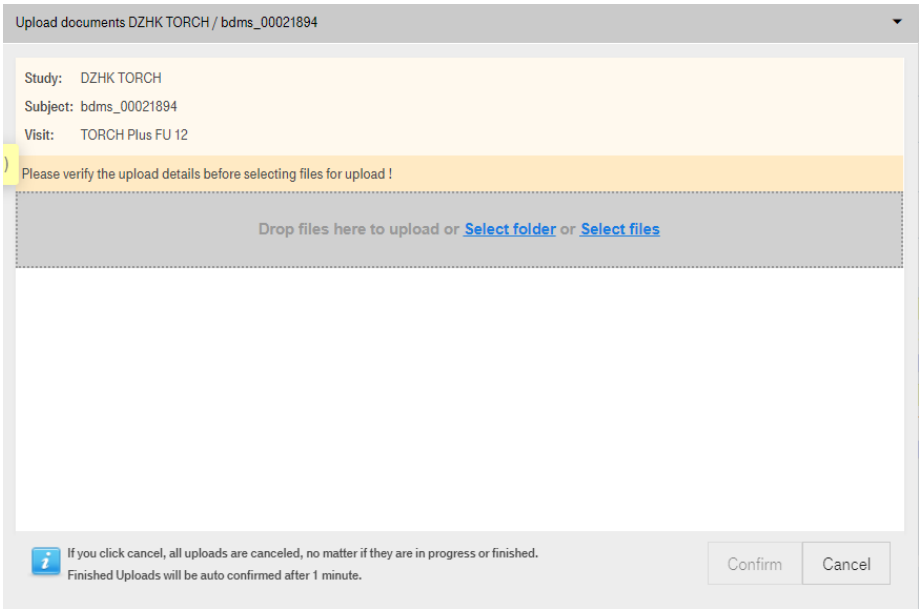



*Figure 10 Upload window for the "Web Upload" with information about the study participant and visit and the options for data selection (Select Folder or Select Files), as well as the confirmation button "Confirm".*

## 6.3 DICOM-Pseudonymization Profile of the DZHK (Updated: 14.11.2017)

This appendix stores the DICOM pseudonymization profile that is applied to each upload in BDMS.

The profile is based on the recommendations of the National Electrical Manufacturers Association (NEMA) and follows the abbreviations listed there.

The following action codes are used in the table:

D – replace with a non-zero length value that may be a dummy value and consistent with the VR
Z – replace with a zero length value, or a non-zero length value that may be a dummy value and con- sistent with the VR
X – remove
K – keep (unchanged for non-sequence attributes, cleaned for sequences)
C – clean, that is replace with values of similar meaning known not to contain identifying information and consistent with the VR
U – replace with a non-zero length UID that is internally consistent within a set of Instances
K/U – keep, if not possible, changed to internally consistent within a set of Instances

| Data Element Name | Data Element | BDMS-DZHK |
|---|---|---|
| Affected SOP Instance UID | (0000,1000) | K |
| Requested SOP Instance UID | (0000,1001) | K |
| Media Storage SOP Instance UID | (0002,0003) | K |
| Referenced SOP Instance UID in File | (0004,1511) | K |
| Instance Creator UID | (0008,0014) | K |
| SOP Instance UID | (0008,0018) | K |
| Study Date | (0008,0020) | K |
| Series Date | (0008,0021) | K |
| Acquisition Date | (0008,0022) | K |
| Content Date | (0008,0023) | K |
| Overlay Date | (0008,0024) | K |
| Curve Date | (0008,0025) | K |
| Acquisition DateTime | (0008,002A) | K |
| Study Time | (0008,0030) | K |
| Series Time | (0008,0031) | K |
| Acquisition Time | (0008,0032) | K |
| Content Time | (0008,0033) | K |
| Overlay Time | (0008,0034) | K |
| Curve Time | (0008,0035) | K |
| Accession Number | (0008,0050) | K |
| Failed SOP Instance UID List | (0008,0058) | K/U |

| | | |
|---|---|---|
| Institution Name | (0008,0080) | X |
| Institution Address | (0008,0081) | X |
| Institution Code Sequence | (0008,0082) | D |
| Referring Physician's Name | (0008,0090) | X |
| Referring Physician's Address | (0008,0092) | X |
| Referring Physician's Telephone Numbers | (0008,0094) | X |
| Referring Physician's Identification Sequence | (0008,0096) | X |
| Context Group Extension Creator UID | (0008,010D) | K |
| Timezone Offset From UTC | (0008,0201) | K |
| Station Name | (0008,1010) | X |
| Study Description | (0008,1030) | K |
| Series Description | (0008,103E) | K |
| Institutional Department Name | (0008,1040) | X |
| Physician(s) of Record | (0008,1048) | X |
| Physician(s) of Record Identification Sequence | (0008,1049) | X |
| Performing Physicians' Name | (0008,1050) | X |
| Performing Physicians' Identification Sequence | (0008,1052) | X |
| Name of Physician(s) Reading Study | (0008,1060) | X |
| Physician Reading Study Identification Sequence | (0008,1062) | X |
| Operators' Name | (0008,1070) | X |
| Operators' Identification Sequence | (0008,1072) | X |
| AdmittingDiagnoses Description | (0008,1080) | C |
| Admitting Diagnoses Code Sequence | (0008,1084) | C |
| Referenced Study Sequence | (0008,1110) | K |
| Referenced Performed Procedure Step Sequence | (0008,1111) | K |
| Referenced Patient Sequence | (0008,1120) | K |
| Referenced Image Sequence | (0008,1140) | K/U |
| Referenced SOP Instance UID | (0008,1155) | K/U |
| Transaction UID | (0008,1195) | K/U |
| Derivation Description | (0008,2111) | K |
| Source Image Sequence | (0008,2112) | K/U |
| Irradiation Event UID | (0008,3010) | K/U |
| Identifying Comments | (0008,4000) | C |
| Creator Version UID | (0008,9123) | K/U |
| Patient's Name | (0010,0010) | X |
| Patient ID | (0010,0020) | X |
| Issuer of Patient ID | (0010,0021) | X |
| TypeOfPatientID | (0010,0022) | X |
| Issuer of Patient ID Qualifiers Sequence | (0010,0024) | K |
| Patient's Birth Date | (0010,0030) | X |

| | | |
|---|---|---|
| Patient’s Birth Time | (0010,0032) | X |
| Patient’s Sex | (0010,0040) | K |
| Patient’s Insurance Plan Code Sequence | (0010,0050) | X |
| Patient’s Primary Language Code Sequence | (0010,0101) | X |
| Patient’s Primary Language Modifier Code Sequence | (0010,0102) | X |
| Other Patient IDs | (0010,1000) | X |
| Other Patient Names | (0010,1001) | X |
| Other Patient IDs Sequence | (0010,1002) | X |
| Patient’s Birth Name | (0010,1005) | X |
| Patient’s Age | (0010,1010) | K |
| Patient’s Size | (0010,1020) | K |
| Patient’s Weight | (0010,1030) | K |
| Patient Address | (0010,1040) | X |
| Insurance Plan Identification | (0010,1050) | X |
| Patient’s Mother’s Birth Name | (0010,1060) | X |
| Military Rank | (0010,1080) | X |
| Branch of Service | (0010,1081) | X |
| Medical Record Locator | (0010,1090) | X |
| Medical Alerts | (0010,2000) | X |
| Allergies | (0010,2110) | C |
| Country of Residence | (0010,2150) | X |
| Region of Residence | (0010,2152) | X |
| Patient’s Telephone Number | (0010,2154) | X |
| Ethnic Group | (0010,2160) | X |
| Occupation | (0010,2180) | X |
| Smoking Status | (0010,21A0) | K |
| Additional Patient’s History | (0010,21B0) | X |
| Pregnancy Status | (0010,21C0) | X |
| Last Menstrual Date | (0010,21D0) | X |
| Patient’s Religious Preference | (0010,21F0) | X |
| Patient Sex Neutered | (0010,2203) | X |
| Responsible Person | (0010,2297) | X |
| Responsible Person Role | (0010,2298) | X |
| Responsible Organization | (0010,2299) | X |
| Patient Comments | (0010,4000) | X |
| Contrast Bolus Agent | (0018,0010) | K |
| Device Serial Number | (0018,1000) | K |
| Device UID | (0018,1002) | K |
| Plate ID | (0018,1004) | K |
| Generator ID | (0018,1005) | K |

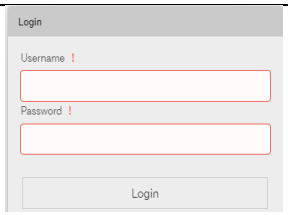
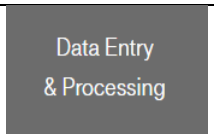
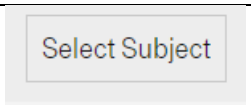
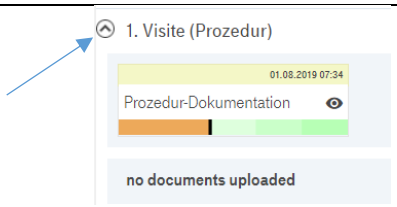
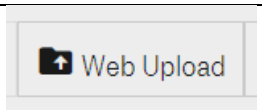
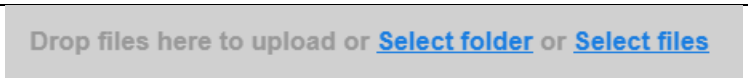
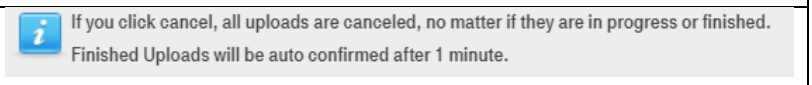
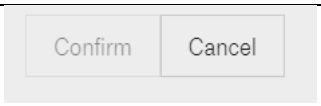
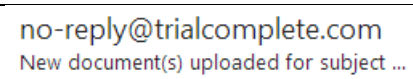
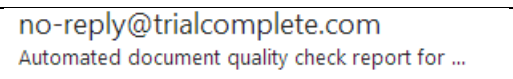
| | | |
|---|---|---|
| Cassette ID | (0018,1007) | K |
| Gantry ID | (0018,1008) | K |
| Protocol Name | (0018,1030) | K |
| Acquisition Device Processing Description | (0018,1400) | K |
| Acquisition Comments | (0018,4000) | K |
| Detector ID | (0018,700A) | K |
| Acquisition Protocol Description | (0018,9424) | K |
| Contribution Description | (0018,A003) | K |
| Study Instance UID | (0020,000D) | K/U |
| Series Instance UID | (0020,000E) | K/U |
| Study ID | (0020,0010) | Z |
| Frame of Reference UID | (0020,0052) | K/U |
| Synchronization Frame of Reference UID | (0020,0200) | K/U |
| Modifying Device ID | (0020,3401) | K/U |
| Modifying Device Manufacturer | (0020,3404) | K/U |
| Modified Image Description | (0020,3406) | K/U |
| Image Comments | (0020,4000) | K |
| Frame Comments | (0020,9158) | K |
| Concatenation UID | (0020,9161) | K/U |
| Dimension Organization UID | (0020,9164) | K/U |
| Palette Color Lookup Table UID | (0028,1199) | K/U |
| Large Palette Color Lookup Table UID | (0028,1214) | K/U |
| Image Presentation Comments | (0028,4000) | K |
| Study ID Issuer | (0032,0012) | X |
| Scheduled Study Location | (0032,1020) | K |
| Scheduled Study Location AE Title | (0032,1021) | K |
| Reason for Study | (0032,1030) | C |
| Requesting Physician | (0032,1032) | X |
| Requesting Service | (0032,1033) | X |
| Requested Procedure Description | (0032,1060) | X |
| Requested Contrast Agent | (0032,1070) | X |
| Study Comments | (0032,4000) | C |
| Admission ID | (0038,0010) | X |
| Issuer of Admission ID | (0038,0011) | X |
| Scheduled Patient Institution Residence | (0038,001E) | X |
| Admitting Date | (0038,0020) | K |
| Admitting Time | (0038,0021) | K |
| Discharge Diagnosis Description | (0038,0040) | C |
| Special Needs | (0038,0050) | C |
| Service Episode ID | (0038,0060) | X |

| | | |
|---|---|---|
| Issuer of Service Episode ID | (0038,0061) | X |
| Service Episode Description | (0038,0062) | X |
| Current Patient Location | (0038,0300) | X |
| Patient's Institution Residence | (0038,0400) | X |
| Patient State | (0038,0500) | X |
| Referenced Patient Alias Sequence | (0038,1234) | X |
| Visit Comments | (0038,4000) | K |
| Scheduled Station AE Title | (0040,0001) | K |
| Scheduled Procedure Step Start Date | (0040,0002) | K |
| Scheduled Procedure Step Start Time | (0040,0003) | K |
| Scheduled Procedure Step End Date | (0040,0004) | K |
| Scheduled Procedure Step End Time | (0040,0005) | K |
| Scheduled Performing Physician Name | (0040,0006) | X |
| Scheduled Procedure Step Description | (0040,0007) | X |
| Scheduled Performing Physician Identification Sequence | (0040,000B) | X |
| Scheduled Station Name | (0040,0010) | K |
| Scheduled Procedure Step Location | (0040,0011) | K |
| Pre-Medication | (0040,0012) | C |
| Performed Station AE Title | (0040,0241) | K |
| Performed Station Name | (0040,0242) | K |
| Performed Location | (0040,0243) | K |
| Performed Procedure Step Start Date | (0040,0244) | K |
| Performed Procedure Step Start Time | (0040,0245) | K |
| Performed Station Name Code Sequence | (0040,0248) | K |
| Performed Procedure Step ID | (0040,0253) | K |
| Performed Procedure Step Description | (0040,0254) | K |
| Request Attributes Sequence | (0040,0275) | K |
| Comments on Performed Procedure Step | (0040,0280) | K |
| Acquisition Context Sequence | (0040,0555) | K |
| Requested Procedure ID | (0040,1001) | X |
| Patient Transport Arrangements | (0040,1004) | X |
| Requested Procedure Location | (0040,1005) | X |
| Names of Intended Recipient of Results | (0040,1010) | X |
| Intended Recipients of Results Identification Sequence | (0040,1011) | X |
| Person Identification Code Sequence | (0040,1101) | X |
| Person Address | (0040,1102) | X |
| Person Telephone Numbers | (0040,1103) | X |
| Requested Procedure Comments | (0040,1400) | C |
| Reason for Imaging Service Request | (0040,2001) | C |
| Order Entered By | (0040,2008) | X |

| | | |
|---|---|---|
| Order Enterer Location | (0040,2009) | X |
| Order Callback Phone Number | (0040,2010) | X |
| Placer Order Number of Imaging Service Request | (0040,2016) | X |
| Filler Order Number of Imaging Service Request | (0040,2017) | X |
| Imaging Service Request Comments | (0040,2400) | C |
| Confidentiality Constraint on Patient Data Description | (0040,3001) | X |
| Referenced General Purpose Scheduled Procedure Step Transaction UID | (0040,4023) | K |
| Scheduled Station Name Code Sequence | (0040,4025) | K |
| Scheduled Station Geographic Location Code Sequence | (0040,4027) | K |
| Performed Station Geographic Location Code Sequence | (0040,4030) | K |
| Scheduled Human Performers Sequence | (0040,4034) | X |
| Actual Human Performers Sequence | (0040,4035) | X |
| Human Performers Organization | (0040,4036) | X |
| Human Performers Name | (0040,4037) | X |
| Verifying Organization | (0040,A027) | X |
| Verifying Observer Sequence | (0040,A073) | D |
| Verifying Observer Name | (0040,A075) | D |
| Author Observer Sequence | (0040,A078) | X |
| Participant Sequence | (0040,A07A) | X |
| Custodial Organization Sequence | (0040,A07C) | X |
| Verifying Observer Identification Code Sequence | (0040,A088) | K |
| Person Name | (0040,A123) | D |
| UID | (0040,A124) | U |
| Content Sequence | (0040,A730) | C |
| Template Extension Organization UID | (0040,DB0C) | K/U |
| Template Extension Creator UID | (0040,DB0D) | K/U |
| Graphic Annotation Sequence | (0070,0001) | K |
| Content Creator’s Name | (0070,0084) | Z |
| Content Creator’s Identification Code Sequence | (0070,0086) | X |
| Fiducial UID | (0070,031A) | K/U |
| Storage Media File- set UID | (0088,0140) | K/U |
| Icon Image Sequence (see Note 12) | (0088,0200) | X |
| Topic Title | (0088,0904) | X |
| Topic Subject | (0088,0906) | X |
| Topic Author | (0088,0910) | X |
| Topic Key Words | (0088,0912) | X |
| Digital Signature UID | (0400,0100) | X |
| Referenced Digital Signature Sequence | (0400,0402) | K |
| Referenced SOP Instance MAC Sequence | (0400,0403) | K |

| | | |
|---|---|---|
| MAC | (0400,0404) | K |
| Modified Attributes Sequence | (0400,0550) | K |
| Original Attributes Sequence | (0400,0561) | K |
| Text String | (2030,0020) | K |
| Referenced Frame of Reference UID | (3006,0024) | K/U |
| Related Frame of Reference UID | (3006,00C2) | K/U |
| Dose Reference UID | (300A,0013) | K/U |
| Reviewer Name | (300E,0008) | X |
| Arbitrary | (4000,0010) | X |
| Text Comments | (4000,4000) | X |
| Results ID Issuer | (4008,0042) | X |
| Interpretation Recorder | (4008,0102) | X |
| Interpretation Transcriber | (4008,010A) | X |
| Interpretation Text | (4008,010B) | C |
| Interpretation Author | (4008,010C) | X |
| Interpretation Approver Sequence | (4008,0111) | X |
| Physician Approving Interpretation | (4008,0114) | X |
| Interpretation Diagnosis Description | (4008,0115) | C |
| Results Distribution List Sequence | (4008,0118) | X |
| Distribution Name | (4008,0119) | X |
| Distribution Address | (4008,011A) | X |
| Interpretation ID Issuer | (4008,0202) | X |
| Impressions | (4008,0300) | C |
| Results Comments | (4008,4000) | C |
| Curve Data | (50xx,xxxx) | K |
| Overlay Data | (60xx,3000) | K |
| Overlay Comments | (60xx,4000) | K |
| Digital Signatures Sequence | (FFFA,FFFA) | X |
| Data Set Trailing Padding | (FFFC,FFFC) | K |

## 6.4 DZHK – BDMS – DICOM UPLOAD - USER GUIDE

| | |
|---|---|
| 1) Open the BDMS with a suitable browser | http://bdms.dzhk.de |
| 2) Log in with username and password |  |
| 3) Select "Data Entry & Processing" in the left sidebar |  |
| 4) Select a study |  |
| 5) Open the patient selection via "Select Subject" in the upper right corner |  |
| 6) Select a patient using "Search by PSN" or "Search by Name" |  |
| 7) Open a visit (with imaging) in the visit plan |  |
| 8) Press the button "Web Upload" (no software required) |  |
| 9) Select the DICOM files via "Drag-and-Drop", "Select Folder" or "Select Files" |  |
| 10) Wait for the upload process or start another parallel upload |  |
| 11) Confirm the upload by pressing the "Confirm" button |  |
| 12) Check the upload notification in your e-mail inbox |  |
| 13) Check the automatic quality check of the image data in your E-Mail mailbox |  |
| 14) In case of problems please contact | bdms@dzhk.de |