

DZHK-SOP-P-02 DICOM-Data upload to the DZHK infrastructure

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Notice of change:

- JAVA-based upload option has been removed
- Renamed TrialConnect to TrialComplete
- Online user application form has been supplemented
- Added correction options for incorrect data upload
- Responsibilities added

Note: Printouts are not subject to the update process!

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Signature	This SOP is a translat signatures.	tion from the original G	erman SOP and valid	without

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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Fill form
DG	Data handling
DICOM	Digital imaging and communications in medicine
eCRF	Electronic case report form
GDPR	General data protection regulation
IDMS	Image data management system (German BDMS)
LIMS	Laboratory information management system
SOP	Standard operating procedure
THS	Trusted third party

1.2 OBJECTIVE

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

1.3 SCOPE

This SOP shall be followed when transferring data into the DZHK infrastructure. This SOP is intended for study personnel tasked with uploading image data and their documentation into IDMS.

1.4 RESPONSIBILITIES

Study-unspecific system training is provided by DZHK employees. Additionally, study-specific training is provided by representatives of the sponsor.

1.5 APPLICATION AND TASKS

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

1.6 TERMS 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.

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

Ethics coordination 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 individual institutions.

Image data management system (IDMS) 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.

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.

1.7 RELATIONS TO OTHER SOPS

Data Generating Clinical SOPs	DZHK-SOP-C-03 12-electrocardiogram
	DZHK-SOP-C-08 transthoracic echocardiography
	DZHK-SOP-C-06 MRT
	DZHK -SOP-P-09-DICOM-Download
	• DZHK-SOP-P-10-eCRFs
Review of Clinical Data	DZHK-SOP-P-01 Review of clinical data

1.8 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 centre (as a clear name or clinic ID) from the content. This FDA recommendation for clinical trials [1] goes beyond the GDPR [2].

2 **R**EQUIREMENTS

2.1 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: 443 (HTTPS)

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- Optional: For the integrated THS function "ID query based on identifying data":
 - o installed certificate of the TTP

• Access to the IDMS system

- Application for registration, change or deregistration of a user access for the DZHK IT infrastructure <u>https://service4studies.dzhk.de/en/studienzentren/it-nutzerzugang/</u>
 → Role of the user in IDMS
- Access data and further information will be sent by the IDMS-project (contact <u>bdms@dzhk.de</u>), a password link will be sent automatically by TrialComplete system

2.2 REQUIRED DATA

• Exported Data in DICOM file format

2.3 INFORMATION NEEDED

• Subject ID (case number or IDMS pseudonym)

2.4 STAFF

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

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3 PROCEDURE OF IMPLEMENTATION/WORK PROCESS/WORK STEPS

3.1 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

3.2 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 centres, 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 (for example DICOM-Cleaner [3]).
- Also use the contacts of the IDMS-project team for specific advices (<u>bdms@dzhk.de</u>).

3.2.1 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 3.3 "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

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is not automatically changed in the upload process (see section 5.2 "DICOM-Pseudonymization Profile of the DZHK (Updated: 14.11.2017)").

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

3.2.2 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 shall 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) 	

3.2.3 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 shall be carried out using additional tools

Many centres 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 IDMS (<u>bdms@dzhk.de</u>) can give you also advice here.

3.3 DATA TRANSFER

Pre-processed data will be uploaded to the IDMS. During the upload process, certain DICOM fields of the header information are deleted/replaced from the data (see section 5.2 "DICOM-Pseudonymization Profile of the DZHK (Updated: 14.11.2017)").

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

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The upload contains the following steps:

- 1) Open a suitable browser (see section 2.1 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 5)*
- 4) Select "Data Entry & Processing" (in the left sidebar)
- 5) Select the study (in the upper header element) (see Figure 7)
- 6) Click on the "Select Subject" button (see Figure 7, top right). Subsequently, a window will appear showing you all the participants.
- 7) To efficiently locate a patient, please use the "Search by PSN" tab (see Figure 8). Here, you have the option to identify the desired subject using three search options ("Search by PSN", "Search by Status", "Search by Arm"). For instance, if you input a query in the "Search by PSN" section, only the matching study participants will be instantly and dynamically displayed to you in real-time.**
- 8) Click on the subject to select it. Then, click on "Select Subject" to open the visit schedule (see Figure 8Figure 8)
- 9) Open the visit (Figure 9 and Figure 10)
- 10) Select the "Web Upload" button (bottom bar) (Figure 10). Check the visit in the dialogue window (see Figure 11)
- 11) Select DICOM files via "Drag-and-drop", "Select Folder" or "Select Files" (Figure 11)***
- 12) Wait for the upload process or start further parallel uploads****
- 13) Confirm the upload by pressing the button "Confirm" (Figure 11) or wait for the 1 minute countdown
- 14) Check reports, if applicable

(See appendix for a leaflet: 5.3 DZHK – IDMS – DICOM Upload - User Guide)

Notes on the steps marked with the * symbol:

*The "Welcome Screen" announces maintenance windows for the IDMS. During the maintenance windows, uploads are usually cancelled 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.

** The selection of the subjects can also be made through the "Select by Name" tab. Here, the search can be conducted by last and first name. For this method, the trust centre certificate must be installed on the computer. If there are any error messages regarding this, please also contact the trust centre at ths-dzhk@uni-greifswald.de.

*** 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.
- **** It is possible to start further uploads to an ongoing upload process in order to enable a higher data throughput.

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3.3.1 Checking the upload confirmation

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 6).

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	The flow of data was interrupted here and the file was not		
with modality "XX" due to	uploaded. Repeat the upload here at a later date or contact		
server error.	support <u>bdms@dzhk.de</u> .		

Document	Upload S	Summary		Date: 20.04.2020 06:57
Total 21 DICC	OM docum	ient(s) c <mark>reated.</mark>		
Study		Dedicate		
Subject		bdms_65821217		
Uploaded By		Luise Bl�dorn		
Uploaded On		20.04.2020 06:57		
User Site		L�beck - UKSH		
Total Files Uplo	aded	22		
Upload Client		Web		
Failed to proces	s files details			Error files count: (
FileName	Visit		Size	Reason
DICOMDIR	4. Visit	e (Tag 7 oder Entlassung)	338,194	Invalid DICOM file.
Processed DICO	M document	ts details		Total Processed files count: 21/2
Visit - 4. Visite (Tag	7 oder Entlas	sung)		Processed files for this visit: 21/2
Name: 1.3.6.1.4.	1.16787.100	.31.2.124024331.0003		
Description: Orie	ntierendes E	Echo - Pump-/Klappenfunktion, WBS (50)		
Modality: US				
Consumed files o	ount: 1			
Name: 1.3.6.1.4.	1.16787.100	.31.2.124024331.0003		
Description: Orie	ntierendes E	Echo - Pump-/Klappenfunktion, WBS (50)		
Modality: US				
Consumed files	ount: 1			

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

3.3.2 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):

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- Name of the study
- IDMS 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 IDMS. 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).

Autom	ated docum	nent qualit	y ch	eck statu	s	
Study	DZHK Praise					
Subject	bdms_41682226					
Uploaded O	n 07.06.2019 14:57					
Studienunter	rsuchungen					
Expected de	ocument upload check					
			Status	Planned		Current
Number	of documents with mo	dality US	n/a	Min: 30/ Max: 6	50	0 document(s)
Number	of documents with mo	dality CT	n/a	Min: 5/ Max: 50)	0 document(s)
Document u	pload time window ch	neck				
		Time window			Statu	15
Upload t	ime window status	visit period : 25.0	9.2018 - 0	06.11.2018	fail:	213 day(s) late
Document of	quality check					

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

3.4 CORRECTION OPTIONS FOR INCORRECT DATA UPLOAD

To remove incorrectly uploaded data or correct data in incorrect visits, please follow the steps below:

Open the visit with incorrect image data by following steps 1 to 8 in the section 3.3.

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Checking the image data:

- 1. After **successful upload**, the image data appears in the visit window (press the "Refresh" button if necessary). For very large data sets, the visibility of the image data may take a little longer.
- 2. The **small preview boxes** of the image data (see Figure 4) show the modality of the image data (e.g. DICOM MR in purple, DICOM CT in green), the series description and the CoreLab test status (NEW, ACCEPTED, REJECTED) using appropriate information and coloring).



Figure 4: Image data preview box

By a "Mouse-over" on a small preview box, a larger box opens with further information to be checked (e.g. BodyPart, Seriesdate [recording date], uploader and upload date).
 Clicking on "View large thumbnail" opens a large preview image of the image series. Here the image can be checked for content and the presence of burned-in patient data.

Deleting of image data:

1. **Select image data:** Click on the image data to be deleted. Selection of multiple image data possible by holding CTRL [Hold CTRL key and click on images]

- 2. Delete: Use the "Delete" button in the bottom bar (Figure 9)
- 3. Confirmation: Click "OK" to confirm the deletion process
- 4. **Verify deletion:** deleted image data will still be displayed. Go to the next study participant and select the previous one again. The deleted images should no longer be visible.

Moving image data into correct visits:

- 1. **Select image data:** Click image data to move. Selection of multiple image data possible by holding CTRL [Hold CTRL key and click on images]
- 2. **Move:** Select the gear icon of a highlighted image. Only the visits in which data can be saved are displayed. Click on the correct visit.
- 3. Check the move: Check in the visits whether the data was moved successfully.

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4 **R**EFERENCES

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

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5 APPENDIX

5.1 IDMS- USER INTERFACE



Figure 5 The IDMS-Welcome-Screen shows the menu bar on the left and in the middle lists for messages of the IDMS infrastructure (DZHK News), the study (Study News) and the operator to maintenance windows.

	(5.2ENTRUM FÜR SLAUF-FORSCHUNG E.V.		DZHK-B	DMS	Roberto Lorbeer Minchen-Universitätskfinikum	
Welcome						O Refresh
Task Management	Work Orders (1150 Only notifications	us) My Queries Study Q	uenes	Details		
Data Entry & Processing	Created Date (UTC) 22.11.2022 13:33	Status Title UNREAD Automated do	roument quality sheek report for [bdms_23000531]			
Study Management	22.11.2022 13.13 22.11.2022 13.13	UNREAD New docume. UNREAD Automated do	nt(s) uploaded for subject bdms_23980531 soument quality obsek report for [bdms_23980531]			
Site & User Management	22.11.2022 13:19 22.11.2022 13:16	UNREAD New docume UNREAD Automated do	et(a) uploaded for subject bdms_22960531 tournest quality sheck report for [bdms_49607830]			
Administration	22.11.2022 13:16 22.11.2022 13:14 22.11.2022 13:14	UNREAD New docume UNREAD Automated do	nt(s) upmasted for subject bdms_49607830 Tournent quality obeck report for [bdms_23980531] If(s) uninsided for subject bdms_23980571			
Reports	22.11.2022 09.22 22.11.2022 09.22	UNREAD Automated do UNREAD New docume	tournent quality check report for [bdms_06487247]			
	22.11.2022 08.29 22.11.2022 08.29	UNREAD Automated de UNREAD New docume	cournent quality shock report for [bdms_54780680] tt(s) uploaded for subject bdms_54780680			
	22.11.2022 08:05 22.11.2022 08:05	UNREAD Automated de UNREAD New docume	cournest quality sheck report for [bdms_35282156] tt(s) uploaded for subject bdms_35282158			
	22.11.2022 07.57 22.11.2022 07.57	UNREAD Automated do UNREAD New docume	soument quality obeck report for [bdms_03212823] vt(s) uploaded for subject bdms_03212823			
TrialComplete Solonce 3.1.0-build#3736					Data Privacy	Imprint

Figure 6 View of the Task Management Menu with the tabs Inbox, Work Orders, My Queries and Study Queries.

DZH	SZENTRUM FÜR SLAUF-FORSCHUNG E.V.	DZHK TORCH	DZHK-BDMS	Roberto Lorbeer 👡 Munchen - Universitätsklinikum
Welcome	No subject selected			Select Subject
Task Management				
Data Entry & Processing				
Study Management				
Site & User Management				
Administration				
Reports				
				Gateway Upload Documents Download
TrialComplete Science 3.1.0-build#3736				Data Privacy Imprint

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Figure 7 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").

arch by PSN Sear	ch by Name							
earch by PSN		Search by Status	Sea	arch by Arm				
			*					~
tal 3513 subjects available								
PSN	Status	Arm	Last changed	Consent				
bdms_00021894				± =, Q	<u>+</u>			
bdms_00087690	ENROLLED	TORCH-PLUS		± =, Q	<u>+</u>	\uparrow	\mathbf{V}	$\mathbf{\Psi}$
bdms_00168191	ENROLLED	TORCH-PLUS		± =, Q	<u>+</u>	$\mathbf{\uparrow}$	$\mathbf{\Psi}$	$\mathbf{\Psi}$
bdms_00174702	ENROLLED	TORCH-PLUS (previously TORCH)		± =, Q	<u>.</u>	\uparrow	$\mathbf{\Psi}$	$\mathbf{\Psi}$
bdms_00276878	ENROLLED	TORCH or new created		± =, Q	<u>+</u>	\uparrow	$\mathbf{\Psi}$	$\mathbf{\Psi}$
bdms_00436829	ENROLLED	TORCH or new created		± =, Q	<u>+</u>	\uparrow	$\mathbf{\Psi}$	\mathbf{V}
bdms_00449920	ENROLLED	TORCH-PLUS		± =, Q	<u>+</u>	\uparrow	$\mathbf{\Psi}$	$\mathbf{\Psi}$
bdms_00476146	ENROLLED	TORCH-PLUS		± =, Q	<u>+</u>	\uparrow	$\mathbf{\Psi}$	$\mathbf{\Psi}$
bdms_00504622	ENROLLED	TORCH-PLUS		± =, Q	<u>.</u>	\uparrow	\mathbf{v}	$\mathbf{\Psi}$
hdma_00525007	ENDOLLED	TODOH as now arouted		A - 0			1	11

Figure 8 "Select Subject Screen" in Search by PSN mode. Here with search options (PSN, status and arm) and display of the present consent status for IDMS functions (Consent).

DZHI DEUTSCHE HERZ-KRE	K Is zentrum für Islauf-forschung ex.	DZHK TORCH	~	DZHK-BDMS	Roberto Lo München - Universitä	orbeer 👡
	bdms_00021894 Status : ENROLLED Arm : TORCH-PLUS					Select Subject
Task Management	Visit	Schedule	Last changed	eCRFs	Documents	Status
0.5	③ Teilnahme TORCH Plus	04.02.2021	28.07.2021 07:10	no forms to fill		in progress
Vata Entry & Processing	③ TORCH Plus Baseline	04.02.2021		□ 0(+3) □ 0 ♀ 0 ✓ 0 ✓ 0	0 ≂√ / 46 ±	planned
~	② Zwischenvisite			no forms to fill		planned
Management	③ TORCH Plus FU 12	10.03.2022		E 0(+3) ■ 0 ♀ 0 ✓ 0 ✓ 0	0 ≕ / 32 ±	planned
	TORCH Plus FU 48			₿ 0(+3) 🖾 0 🖓 0 🗸 0 🖋 0		planned
Management	Saseline Visite			₿ 0(+3) 0 0 0 0 0 0 0 0 0		planned
	● Follow-Up			₿ 0(+3) 0 0 0 0 0 0 0 0 0		planned
	THS consent status 🟦 💷 👰 🛓 🛧	↓ ↓ BDMS + [*] secuTrial	22.11.2022 14:32 UTC	View 🛱 Rename 🗸 Approve/Reject Y Split I M	erge 🖿 Web Upload 🛓 Download	🕫 Refresh 🖨 Delete
TrialComplete Science 3.1.0-build#3736					Data Privacy	/ Imprint

Figure 9 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).

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DZH DEUTSCH HERZ-KR	K RS ZENTRUM FÜR EISLAUF-FORSCHUNG E.V.	DZHK TOR	сн 🗸		DZHK-BDMS	Rol	berto Lorbeer	~
	bdms_00021894 Status : ENROLLED Arm : TORCH	4PLUS					L Sele	ect Subject
Task Management	Visit	Schedule	Last chi	anged	eCRFs	Documents	Status	
	③ Teilnahme TORCH Plus	04.02.202	28.07.202	1 07:10	no forms to fill		in progress	
Data Entry & Processing	③ TORCH Plus Baseline	04.02.202	1	Ē	0(+3) 🖾 0 🖓 0 🗸 0 🖋 0	0 ≕ / 46 ±	planned	
urroceany	② Zwischenvisite				no forms to fill		planned	
Study Management	TORCH Plus FU 12	10.03.202	12	1	0(+3) 🖆 0 ♀ 0 ✓ 0 ≪ 0	0 ≕ / 32 ±	planned	
Site & User Management	Anamnese und Klinische Diag Optensi	Labordiagnostik Optime	Echokardiographie Optional	Elektrokardiogramm Optewi	6-Minuten-Gehtest Geteral	Spiroergometrie Optional	Medikation Optimal	
	Herzkatheter, Härnodynamik Optieval	Kardiomyopathie-Diagnostik Optimal	Magnetresonanztomographie Opticeal	Gesundheitsfragen PHO-9 Optenel	Lebensqualität Cysowii	TORCH PLUS Echokardio	TORCH PLUS Elektrokardi	•
	TORCH PLUS MRT - Corel () Optimal							
	Show retired	0.31.2.28 1.3.6.1.4.	1.16787.100.31.2.10	1.3.6.1.4.1.16787.100.31.2.10.	1.3.6.1.4.1.16787.1	1.3.6.1	1.4.1.16787.100.31.2.10	
	THS consent status 🟦 🖶 🕴	Q ≛ ↑ ↓ ↓ BDM	IS +* secuTrial 22.11.2022 14:3	2 UTC O View II Renz	ime 🖉 Approve/Reject 🦞 Spl	it 🏌 Merge 🖿 Web Upload	Download O Refresh	• Delete
TrialComplete Science 3.1.0-build#3736						() ()	Data Privacy In	nprint

Figure 10 Visit plan with selected visit so that individual functions can be selected for upload (black buttons on the lower bar).

Upload documents DZHK TORCH / bdms_00021894		-
Study: DZHK TORCH Subject: bdms_00021894 Visit: TORCH Plus FU 12 Please verify the upload details before selecting files for upload !		
Drop files here to upload or <u>Select folder</u> or <u>Select files</u>		
If you click cancel, all uploads are canceled, no matter if they are in progress or finished. Finished Uploads will be auto confirmed after 1 minute.	Confirm	Cancel

Figure 11 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".

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5.2 DICOM-PSEUDONYMIZATION PROFILE OF THE DZHK (UPDATED: 14.11.2017)

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

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

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

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

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Cassette ID	(0018,1007)	К
Gantry ID	(0018,1008)	К
Protocol Name	(0018,1030)	К
Acquisition Device Processing Description	(0018,1400)	К
Acquisition Comments	(0018,4000)	К
Detector ID	(0018,700A)	К
Acquisition Protocol Description	(0018,9424)	К
Contribution Description	(0018,A003)	К
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)	К
Frame Comments	(0020,9158)	К
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)	К
Study ID Issuer	(0032,0012)	Х
Scheduled Study Location	(0032,1020)	К
Scheduled Study Location AE Title	(0032,1021)	К
Reason for Study	(0032,1030)	С
Requesting Physician	(0032,1032)	Х
Requesting Service	(0032,1033)	Х
Requested Procedure Description	(0032,1060)	Х
Requested Contrast Agent	(0032,1070)	Х
Study Comments	(0032,4000)	С
Admission ID	(0038,0010)	Х
Issuer of Admission ID	(0038,0011)	Х
Scheduled Patient Institution Residence	(0038,001E)	Х
Admitting Date	(0038,0020)	К
Admitting Time	(0038,0021)	К
Discharge Diagnosis Description	(0038,0040)	С
Special Needs	(0038,0050)	С
Service Episode ID	(0038,0060)	Х

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

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

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MAC	(0400,0404)	К
Modified Attributes Sequence	(0400,0550)	К
Original Attributes Sequence	(0400,0561)	К
Text String	(2030,0020)	К
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)	Х
Arbitrary	(4000,0010)	Х
Text Comments	(4000,4000)	Х
Results ID Issuer	(4008,0042)	Х
Interpretation Recorder	(4008,0102)	Х
Interpretation Transcriber	(4008,010A)	Х
Interpretation Text	(4008,010B)	С
Interpretation Author	(4008,010C)	Х
Interpretation Approver Sequence	(4008,0111)	Х
Physician Approving Interpretation	(4008,0114)	Х
Interpretation Diagnosis Description	(4008,0115)	С
Results Distribution List Sequence	(4008,0118)	Х
Distribution Name	(4008,0119)	Х
Distribution Address	(4008,011A)	Х
Interpretation ID Issuer	(4008,0202)	Х
Impressions	(4008,0300)	С
Results Comments	(4008,4000)	С
Curve Data	(50xx,xxxx)	К
Overlay Data	(60xx,3000)	К
Overlay Comments	(60xx,4000)	К
Digital Signatures Sequence	(FFFA,FFFA)	Х
Data Set Trailing Padding	(FFFC,FFFC)	К

5.3 DZHK – IDMS – DICOM UPLOAD - USER GUIDE

1) Open the IDMS with a suitable browser	http://bdms.dzhk.de	
2) Log in with username and password	Login	
	Username ! Password ! Login	

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3) Select "Data Entry & Processing" in the left sidebar	Data Entry & Processing	
4) Select a study	Dedicate 🗸	
5) Open the patient selection via "Select	Salaat Subject	
Subject" in the upper right corner		
6) Select a patient using "Search by PSN" or "Search by Name"	Search by PSN Search by Name	
7) Open a visit (with imaging) in the visit		
plan	01.08.2019 07:34 Prozedur-Dokumentation no documents uploaded	
8) Press the button "Web Upload" (no software required)	Web Upload	
9) Select the DICOM files via "Drag-and- Drop", "Select Folder" or "Select Files"	Drop files here to upload or <u>Select folder</u> or <u>Select files</u>	
10) Wait for the upload process or start another parallel upload	<i>i</i> If you click cancel, all uploads are canceled, no matter if they are in progress or finished. Finished Uploads will be auto confirmed after 1 minute.	
11) Confirm the upload by pressing the "Confirm" button	Confirm Cancel	
12) Check the upload notification in your e-mail inbox	no-reply@trialcomplete.com New document(s) uploaded for subject	
13) Check the automatic quality check of	no-reply@trialcomplete.com	
the image data in your E-Mail mailbox	Automated document quality check report for	
14) In case of problems please contact	bdms@dzhk.de	

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