

CHANGE-MRI

CTEPH DIAGNOSIS EUROPE



User Manual

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1 Log in to OpenClinica

Access to OpenClinica is provided via a web browser (Mozilla Firefox or Microsoft Internet Explorer)

via the webpage: www.change-mri.de

(then click on "zur Datenbank"/"database an then „login“)

Or using directly the following link:

<https://simpc2.mh-hannover.de:8443/OpenClinica/MainMenu>

Browser configuration:

- JavaScript must be enabled
- Pop-up blockers must be disabled

Provide user name and password you received via e-mail and click Login.



Reset password

For security purposes you have to reset your password at first log in. Your new password must be at least eight characters long.

Reset password

Welcome to OpenClinica, Chris Cole. Your current password has been set by the system or has expired. In order to continue, you MUST change your password below.

* Indicates required field.

Old Password: *

New Password: *

Confirm New Password: *

Password Challenge Question: *

Password Challenge Answer: *

2 OpenClinica homepage

The OpenClinica homepage is the main page for the current study or site. It is displayed when you log in or when you click “Home” in the navigation bar. The navigation bar provides access to the main features in OpenClinica. The page contains your user name, the study name, name of the study site and a summary of subjects entered by your site. To manage subjects click “Subject Matrix”.

Name of Study and Site **Subject Matrix** **Navigation Bar** **User name**

OpenClinica Community Edition

CHANGE-MRI MRI: CTB Biometrie-MHH (CTB_Biometrie_MHH) Change Study/Site

fischer (Data Manager) en | Log Out

Home | **subject Matrix** | Notes & Discrepancies | Study Audit Log | Tasks

Report Issue | Support | Study Subject ID | Go

Alerts & Messages

Instructions

Info

Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

Actions

- View
- Edit
- Remove
- Restore
- Reassign
- Sign

Welcome to CHANGE-MRI MRI

Notes & Discrepancies Assigned to Me: 0

Subject Enrollment By Site

Site	Enrolled	Expected Enrollment	Percentage
CTB-Biometrie-MHH	7	10	70%

Study Progress

Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	4	57%
completed	3	43%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Subject Status Count

Study Subject Status	# of Study Subjects	Percentage
available	7	100%
signed	0	0%
removed	0	0%

3 Subject Matrix

The “Subject Matrix” is a table with event information for all subjects. You can view, enter, and change information.

OpenClinica Community Edition

CHANGE-MRI MRI : CTB-Biometrie-MHH (CTB_Biometrie_MHH) | Change Study/Site

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks ▾

Alerts & Messages ▾

Instructions ▾

Info ▾

Icon Key -

Subject Matrix for CTB-Biometrie-MHH ⓘ

◀ ▶ 15 Show More Select An Event **Add New Subject**

Study Subject ID	V_MRI	Actions
		Apply Filter Clear Filter
CM-TB-0001	✓	🔍 ✕ ↻
CM-TB-0002	📄	🔍 ✕ ↻
CM-TB-0003	✓	🔍 ✕ ↻
CM-TB-0004	📄	🔍 ✕ ↻
CM-TB-0005	📄	🔍 ✕ ↻
CM-TB-0006	📄	🔍 ✕ ↻
CM-TB-0007	✓	🔍 ✕ ↻

Ergebnisse 1 - 7 von 7.

Statures

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

Actions

- View
- Edit
- Remove
- Restore
- Reassign
- Sign

3.1 Add a new subject from Subject Matrix

To add a new subject and schedule the first event follow steps below:

1. Click “Add New Subject” link in the “Subject Matrix”.
The “Add New Subject” page opens. Complete the information on the page as described in the following steps. Some of the information might be optional, an asterisk (*) indicates a mandatory field.
2. Enter the “Study Subject ID”.
3. Enter “Enrollment Date” in the specified format, or click the calendar icon to select it. (Date of enrollment = Date of signed informed consent).

4. Select „**Sex**“.
5. Enter “**Year of Birth**”.
6. Select first “**Study Event**” from the drop-down list.
7. Enter “**Start Date**” for the event, or click the calendar icon to select it.
(Start Date = e.g. date of MRI, SPECT...)
8. Click “**Add**” to create the new subject or click “**Cancel**” to discard entered information.

Add New Subject

Study Subject ID: *

Enrollment Date:  *

Sex:  *

Year of Birth: (YYYY) *

Study Event:  *

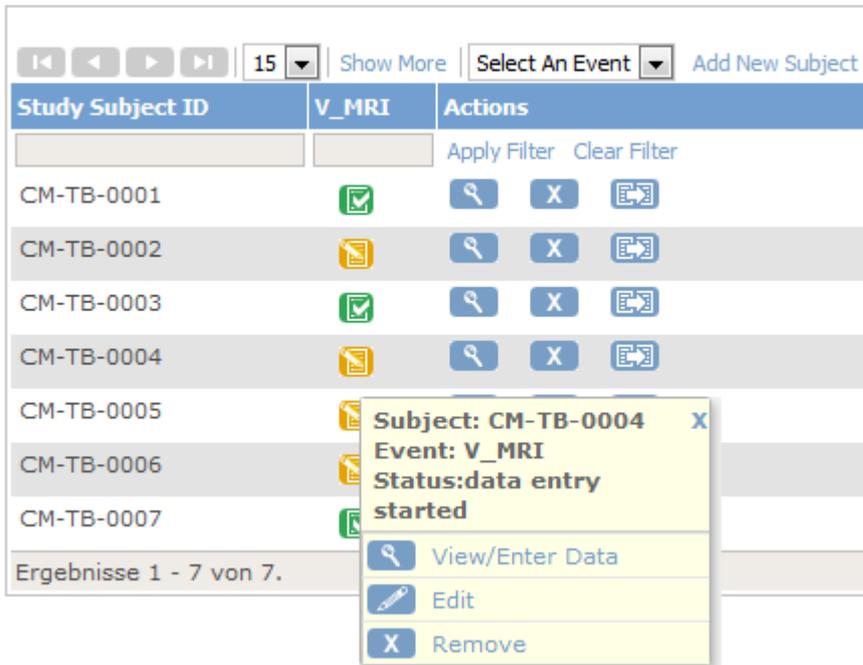
Start Date:  *

3.2 View and enter event data in Subject Matrix

Each cell in the “**Subject Matrix**” contains a status icon of the event: green – data entry complete; yellow - data entry incomplete; blue – event not scheduled. In the “**Subject Matrix**” you are able to perform following actions depending on your role and access rights for the study: “**Schedule**”, “**View**”, “**Enter Data**”, “**Edit**”, “**Remove**”, or “**Add Another Occurrence**”. Click on the status icon to choose the action.

Subject Matrix after Clicking the Icon in the V_MRI-Column for Subject ID CM-TB-0004:

Subject Matrix for CTB-Biometrie-MHH



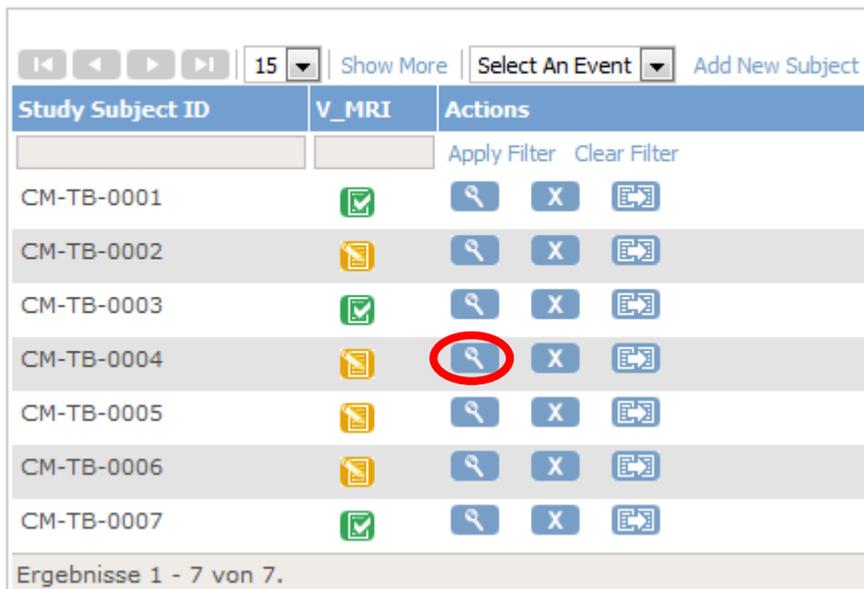
The screenshot shows a table with columns 'Study Subject ID', 'V_MRI', and 'Actions'. The 'V_MRI' column contains icons representing different events. A context menu is open over the 'V_MRI' icon for subject CM-TB-0004. The menu items are: 'Subject: CM-TB-0004', 'Event: V_MRI', 'Status: data entry started', 'View/Enter Data', 'Edit', and 'Remove'.

Study Subject ID	V_MRI	Actions
CM-TB-0001		  
CM-TB-0002		  
CM-TB-0003		  
CM-TB-0004		  
CM-TB-0005		  
CM-TB-0006		  
CM-TB-0007		  

3.3 View and edit details for a subject in subject casebook

To view detailed information for a subject, click the view icon  in the “Actions” column.

Subject Matrix for CTB-Biometrie-MHH



The screenshot shows the same table as above. The magnifying glass icon in the 'Actions' column for subject CM-TB-0004 is circled in red.

Study Subject ID	V_MRI	Actions
CM-TB-0001		  
CM-TB-0002		  
CM-TB-0003		  
CM-TB-0004		  
CM-TB-0005		  
CM-TB-0006		  
CM-TB-0007		  

The subject casebook opens with the sections “**Study Subject Record**” and “**Events**”. To show or hide a section, click plus or minus. The event section is shown by default.

View Subject: CM-TB-0004 ⓘ

Study Subject Record ← Study Subject Record (click plus sign to expand)
 Events

Page 1 of 1 [Find](#) [Schedule New Event](#)

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
V_MRI	04-Jul-2016		data entry started	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	MRI_DCE V1.2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Group
 Global Subject Record
 Subject Casebook
[Go Back to Subject List](#)

Study subject record section

The “**Study Subject Record**” section provides overall information about the subject. To make changes for the study subject, click “**Edit Record**”, which opens the “**Update Study Subject Details**” page.

View Subject: CM-TB-0005 ⓘ

Study Subject Record [Audit Logs](#) | [Edit Record](#)

Study Subject ID	CM-TB-0005	Person ID ⓘ	
Secondary ID		Year of Birth ⓘ	1977
OID	SS_CMTB0005	Sex ⓘ	Female
Status	available	Enrollment Date ⓘ	05-Jul-2016
Study Name	CHANGE-MRI MRI	Site Name	CTB-Biometrie-MHH

4 Study events

In OpenClinica study events are associated with type, date(s), status, and a package of case report forms (CRFs).

4.1 Schedule a study event

1. To create a new event click “**Schedule New Event**” in the event section.

2. Enter information in the “**Schedule Study Event**” page. Time boxes can be left blank. As each event in the Change MRI study is performed only in one day and no events are planned to be split please leave the “**End Date**” boxes empty.

Schedule Study Event for CM-TB-0008 ?

* indicates required field.

Study Subject ID: **CM-TB-0008**

Study Event Definition: *

Start Date/Time: : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM)

Leave this field blank if the end date/time is not applicable.

- Schedule Another Event: (optional)

Proceed to Enter Data

Cancel

3. After completion of scheduling information you can schedule another event or select the option to enter data.

4.2 Update study events

You can update information for an event, such as the date or status:

1. In the “**Subject Matrix**”, click the respective **event-item** and the “**Edit**” icon.

View Subject: CM-TB-0004 ?

Study Subject Record

Events

Page 1 of 1 **Find** [Schedule New Event](#)

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
V_MRI	04-Jul-2016		data entry started	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	MRI_DCE V1.2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Group

Global Subject Record

Subject Casebook

[Go Back to Subject List](#)

Subject Matrix for CTB-Biometrie-MHH

Navigation:     | 15 | Show More | Select An Event | Add New Subject

Study Subject ID	V_MRI	Actions
		Apply Filter Clear Filter
CM-TB-0001		  
CM-TB-0002		  
CM-TB-0003		  
CM-TB-0004		  
CM-TB-0005		
CM-TB-0006		
CM-TB-0007		
Ergebnisse 1 - 7 von 7.		

Subject: CM-TB-0004 X

Event: V_MRI

Status: data entry started

 View/Enter Data

 Edit

 Remove

2. The “**Update Study Event**” page opens. Change the date or other information.
3. Click “**Submit Changes**”. The “**View Subject**” page opens, showing the updated information for the event.

5 Enter data into a CRF

To view and enter data of a study event, click “**View/Enter Data**” in the “**Subject Matrix**” (remember that events have to be scheduled first).

In the following “**Enter or Validate Data for CRFs**” page event information is provided in a table of all CRFs in that study event.

Enter or Validate Data for CRFs in V_MRI ?

Edit Study Event	
Study Subject ID	CM-TB-0008
Study Event	V_MRI
Location	N/A
Study Subject OID	SS_CMTB0008
Start Date	21-Jul-2016
End Date/Time	
Subject Event Status	scheduled
Last Updated by	0

Enter data into CRF

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
MRI_DCE	V1.2				

[View this Subject's Record](#)

[Exit](#)

There are 3 different eCRF subtypes for the chage MRI study:

1. MRI
2. SPECT
3. Gold standard

5.1 MRI eCRF – Step-by-step instructions

1. After clicking the “Enter Data” icon in the actions column for that CRF, the MRI CRF opens.

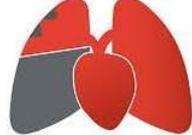
MRI_DCE V1.2  test

▼ CRF Header Info

MRI-DCE...(0/42)

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.


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Page: Mark CRF Complete **Save** **Exit** 

Begin MRI Scan

Date * Time (-Select-)*

Reading

Date * Time (-Select-)*

Reader (-Select-)*

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event Yes No*

Examination completed (according to the STP) Yes No*

Quality of the MRI scan for diagnosis of pulmonary embolism Diagnostic Not diagnostic*

Lung parenchyma or thorax changes

Lung parenchyma or thorax changes Yes No*

Actionable incidental findings

Actionable incidental findings present Yes No*

Prior examinations used in hospital database for interpretation of DCE MRI
(Only fill in data, if prior examinations have been used !)

Enter prior examinations within a dropdown list

List of prior examinations	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/> 	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Enter other prior examinations within a free text field

Other prior examination	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/> 	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Return to top Mark CRF Complete **Save** **Exit** 

2. Select study date and time of imaging from the drop-down menu.

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin MRI Scan

Date: 13-Jun-2016  * Time: 15:00  *

3. Select date of reading and time of reading from the drop-down menu.

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin MRI Scan

Date: 13-Jun-2016  * Time: 15:00  *

Reading

Date: 13-Jun-2016  * Time: 17:00  *

4. Select the name of reader, or enter your name, if necessary.

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin MRI Scan

Date: 13-Jun-2016  * Time: 15:00  *

Reading

Date: 13-Jun-2016  * Time: 17:00  *

Reader: C01_Reader#1  *

5. Answer all items concerning adverse events, completeness and quality of examinations.

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.

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Page: Mark CRF Complete

Begin MRI Scan

Date: 13-Jun-2016 Time: 15:00

Reading

Date: 13-Jun-2016 Time: 17:00

Reader: C01_Reader#1

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No

Please specify allergic contrast reaction or adverse events:

Examination completed (according to the STP): Yes No Please comment:

List of completed sequences (according to the STP): T1 GRE triplane, True FISP axial, True FISP coronal, T2 HASTE axial (-multi-select-)

Quality of the MRI scan for diagnosis of pulmonary embolism: Diagnostic Not diagnostic

- Allergic contrast reaction or adverse events related to administration of contrast material?
- Examination complete? (According to the study protocol)
- Quality of Images (Diagnostic vs. non.diagnostic)

6. Pulmonary embolism present? (Do not select "yes" if perfusion defects seen on the scan are not caused by emboli)

Pulmonary embolism

Pulmonary embolism present: Yes No (segmental/subsegmental hypoperfusion not explained by changes in lung parenchyma)

If you select "yes", an illustration of the segmental anatomy of the lungs will appear, and you will have to decide for each segment if pulmonary embolism is

- Absent ("no")
- Segmental pulmonary embolism

- Subsegmental pulmonary embolism
- Or if the segment has been resected previously.
- Or if the study is non diagnostic (segment cannot be scored, e.g. because of artifacts)

Pulmonary embolism

Pulmonary embolism present Yes No

Segment Anatomie der Lunge

Rechte Lunge		Linke Lunge	
0	1 apikal	0	1 apikal
1	2 post.	1	2 post.
2	3 ant.	2	3 ant.
3	4 lat.	3	4 sup.
4	5 med.	4	5 inf.
5	6 sup.	5	6 sup.
6	7 med. bas.	6	7 ant.-med. bas.
7	8 ant. bas.	7	8 lat. bas.
8	9 lat. bas.	8	9 post. bas.
9	10 post. bas.	9	10 post. bas.

Right lung pulmonary embolism (PE)

Right lung segment 1 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 2 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 3 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 4 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 5 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 6 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 8 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 9 No PE Segmental Subsegmental Resected Not Diagnostic

Right lung segment 10 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung pulmonary embolism (PE)

Left lung segment 1/2 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung segment 3 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung segment 4 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung segment 5 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung segment 6 No PE Segmental Subsegmental Resected Not Diagnostic

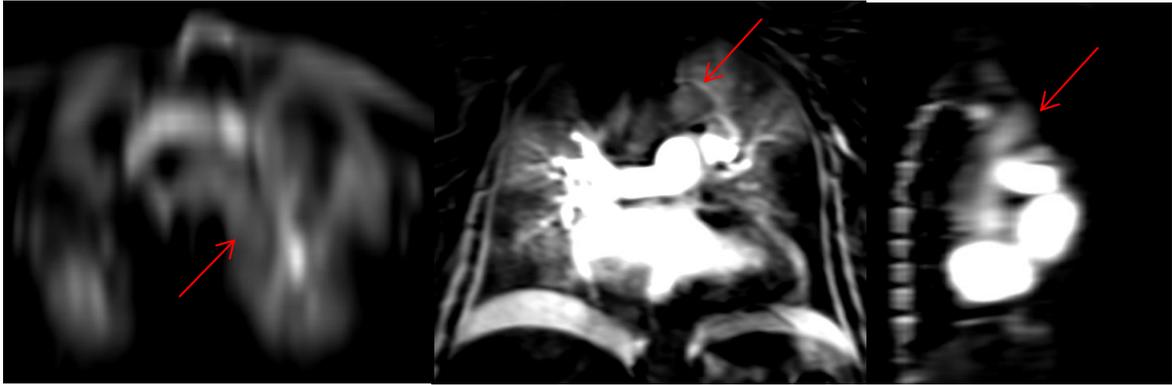
Left lung segment 8 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung segment 9 No PE Segmental Subsegmental Resected Not Diagnostic

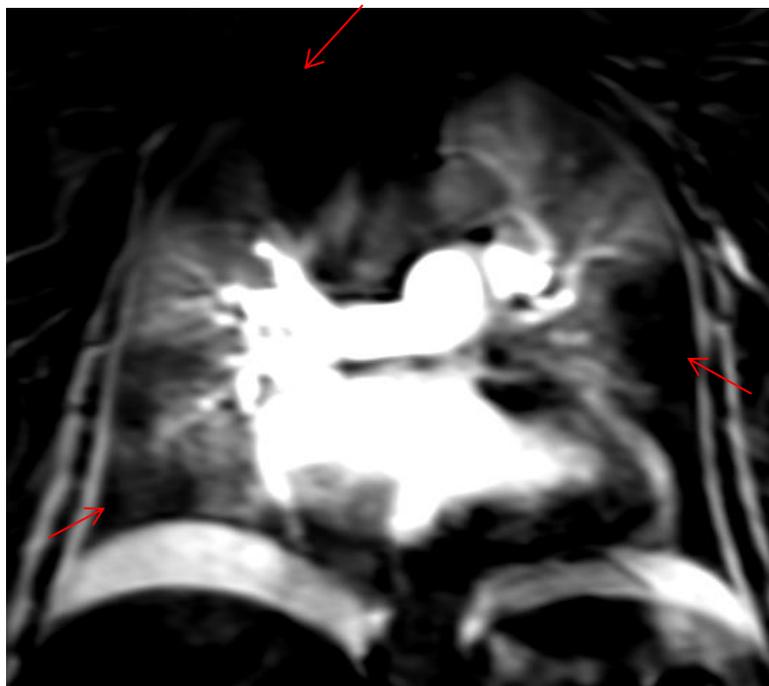
Left lung segment 10 No PE Segmental Subsegmental Resected Not Diagnostic

Suggestions how to read dynamic contrast enhanced MRI

- Read in 3D at maximum intensity projection (**15mm slices MIP**).
- Use **subtracted** images
- Choose the best frame/parenchymal phase with **early contrast in aorta**



- If hypoperfusion in a segment is uncertain utilize the other dynamic enhancement frames over time to determine if hypoperfusion is present
- Use anatomic lung map in eCRF as reminder for segment anatomy

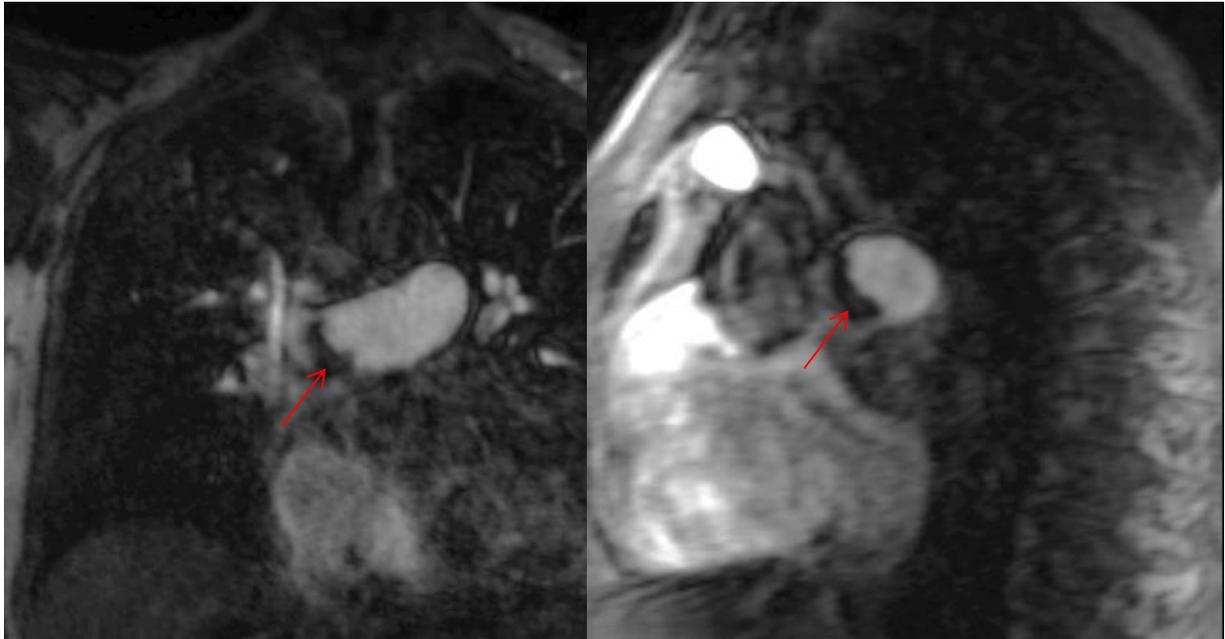


Example of CTEPH with hypoperfused segments

7. Mark if you observe presence of **central thrombus, webs or central to segmental vessel occlusion.**

Central thrombus

Central thrombus webs or central to segmental vessel occlusion present Yes No *



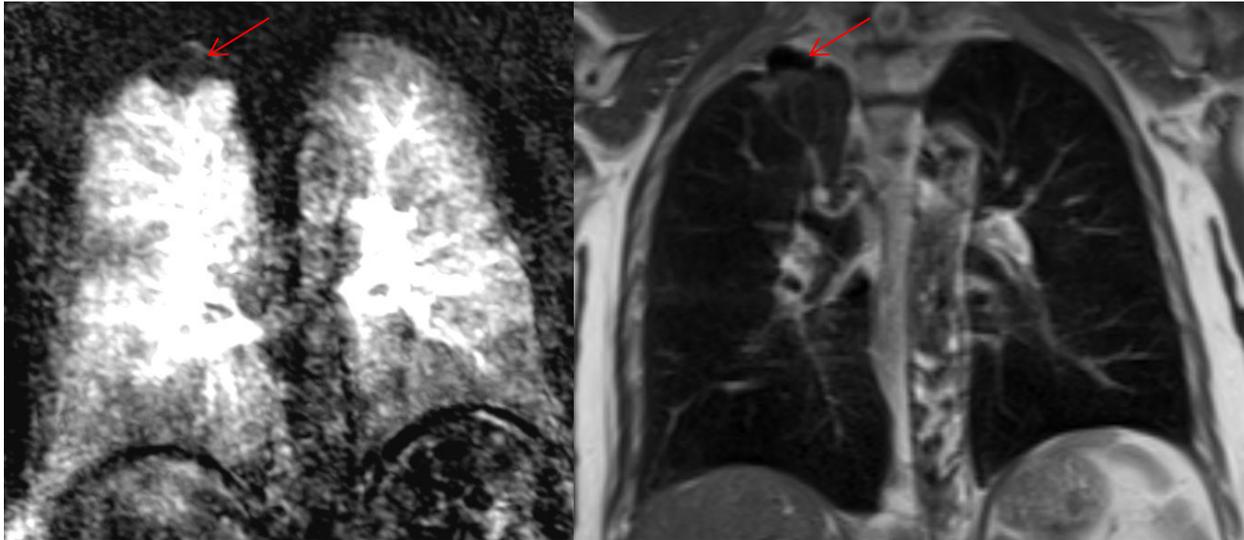
8. Select lung and thorax changes that may be the cause for hypoperfusion. If **lung parenchymal changes** are more likely to be the reason for hypoperfusion, go back to the rating of Dynamic Contrast MRI and correct.

Lung parenchyma or thorax changes

Lung parenchyma or thorax changes Yes No *

List of lung parenchyma or thorax changes

- emphysema * (-multi-select-)
- fibrosis
- scars
- atelectasis
- pleural effusion
- lung tumor
- infiltrate/pneumonia
- other



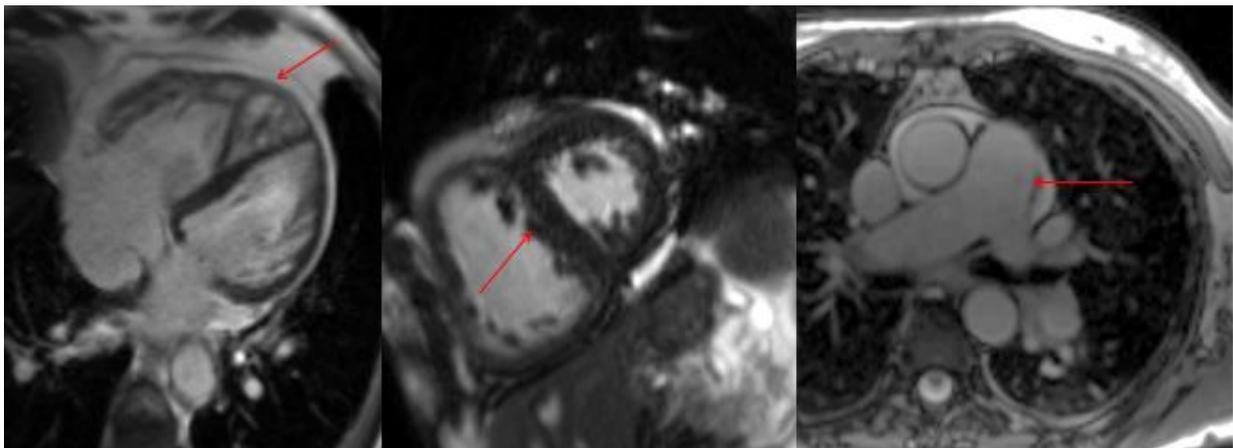
Example of subsegmental hypoperfusion due to bullae

9. Mark if **right heart strain** or pulmonary hypertension is present

- Flattened septum
- Paradox septal bouncing
- RV – hypertrophy
- RV – dilatation
- Main pulmonary artery > 30mm diameter or diameter main pulmonary artery > diameter ascending aorta

Right heart strain or CTEPH

Right heart strain present Yes No *



10. Diagnose CTEPH if hypoperfusion and signs of right heart strain or pulmonary hypertension are present.

CTEPH diagnosis Yes No *

11. Enter actionable incidental findings, e.g. tumors, aneurysm...

Actionable incidental findings

Actionable incidental findings present Yes No *

Actionable incidental findings

12. Enter prior examinations (at an earlier hospital visit) that were used for the interpretation of MRI. DO NOT USE exams other than chest X ray from the current hospital visit! You may also use the free-text field below.

Enter prior examinations within a dropdown list

List of prior examinations	Date of prior examination	
CT pulmonary angiography	07-Jun-2016	X
<input type="button" value="Add"/>		

Enter other prior examinations within a free text field

Other prior examination	Date of prior examination	
(-None-)		X
<input type="button" value="Add"/>		

[Return to top](#) Mark CRF Complete 

13. If you have completed the CRF, select “Mark CRF complete”.

Prior examinations used in hospital database for interpretation
(Only fill in data, if prior examinations have been used !)

Enter prior examinations using a dropdown list

List of prior examinations	Date of prior examination	
(-None-)		X
Add		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
(-None-)		X
Add		

Return to top

Mark CRF Complete **Save** **Exit**

14. Press “Save” to finish and save.

5.2 SPECT eCRF – Step-by-step instructions

1. After clicking the “Enter Data” icon in the actions column for that CRF, the SPECT CRF opens.

VQ-SPECT V1.2 

cm-01-0014

▼ CRF Header Info

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'o Mark CRF Complete' before clicking the SAVE-Button.



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Page: Mark CRF Complete **Save** **Exit** 

Begin Imaging

Date * Time (-Select-)*

Reading

Date * Time (-Select-)*

Name of VQ-SPECT Reader (-Select-)*

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event Yes No*

Examination complete Yes No* (according to the STP)

Quality of the VQ-SPECT Image Diagnostic Not diagnostic*

Perfusion SPECT Yes No*

Ventilation SPECT Yes No*

SPECT/CT examination Yes No*

Lung parenchyma or thorax changes

Lung parenchyma or thorax changes Yes No*

Prior examinations used in hospital database for interpretation
(Only fill in data, if prior examinations have been used !)

Enter prior examinations using a dropdown list

List of prior examinations	Date of prior examination	
<input type="text"/> (-None-)	<input type="text"/> 	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
<input type="text"/> (-None-)	<input type="text"/> 	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Return to top Mark CRF Complete **Save** **Exit** 

2. Select study date and time of imaging from the drop-down menu.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin Imaging

Date: Time: *

Reading

Date: * Time: *

Name of VQ-SPECT Reader: *

3. Select date of reading and time of reading from the drop-down menu.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin Imaging

Date: * Time: *

Reading

Date: * Time: *

4. Select the name of reader, or enter your name, if necessary.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin Imaging

Date: 05-Oct-2016 * Time: 9:30 *

Reading

Date: 05-Oct-2016 * Time: 14:30 *

Name of VQ-SPECT Reader: Derlin, Thorsten *

5. Answer all items concerning adverse events, completeness and quality of examinations.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete **Save** **Exit**

Begin Imaging

Date: 05-Oct-2016 * Time: 9:30 *

Reading

Date: 05-Oct-2016 * Time: 14:30 *

Name of VQ-SPECT Reader: Derlin, Thorsten *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No *

Examination complete: Yes No * (according to the STP)

Quality of the VQ-SPECT Image: Diagnostic Not diagnostic *

Perfusion SPECT: Yes No *

Perfusion SPECT Radiotracer: 99mTc-MAA 99mTc-HSA * ↺

Ventilation SPECT: Yes No *

Ventilation SPECT Radiotracer: 99mTc-DTPA 99mTc-Technegas * ↺

SPECT/CT examination: Yes No *

- Allergic contrast reaction or adverse events related to administration of contrast material?
- Examination complete? (According to the study protocol)
- Quality of Images (Diagnostic vs. non.diagnostic)
- Perfusion SPECT performed?
 - o Select the radiotracer used in your institution
- Ventilation SPECT performed?
 - o Select the radiotracer used in your institution
- SPECT/CT performed? (as part of either ventilation or perfusion scanning or both)?

6. Pulmonary embolism present? (Do not select “yes” if perfusion defects seen on the scan are not caused by emboli)

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete **Save** **Exit**

Begin Imaging

Date: 05-Oct-2016 * Time: 9:30 *

Reading

Date: 05-Oct-2016 * Time: 14:30 *

Name of VQ-SPECT Reader: Derlin, Thorsten *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No *

Examination complete: Yes No * (according to the STP)

Quality of the VQ-SPECT Image: Diagnostic Not diagnostic *

Perfusion SPECT: Yes No *

Perfusion SPECT Radiotracer: 99mTc-MAA 99mTc-HSA * ↻

Ventilation SPECT: Yes No *

Ventilation SPECT Radiotracer: 99mTc-DTPA 99mTc-Technegas * ↻

SPECT/CT examination: Yes No *

Pulmonary embolism

Pulmonary embolism present: Yes No * ↻

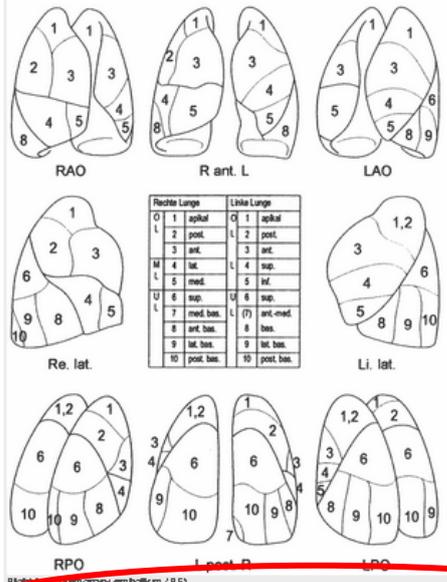
If you select “yes”, an illustration of the segmental anatomy of the lungs will appear, and you will have to decide for each segment if pulmonary embolism is

- Absent (“no”)
- Segmental pulmonary embolism
- Subsegmental pulmonary embolism
- Or if the segment has been resected previously.
- Or if the study is non diagnostic (segment can not be scored, e.g. because of artifacts)

Pulmonary embolism

Pulmonary embolism present Yes No

Segmentanatomie der Lunge



Right lung pulmonary embolism (PE)

- Right lung segment 1 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 2 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 3 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 4 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 5 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 6 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 8 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 9 No PE Segmental Subsegmental Resected Not Diagnostic
- Right lung segment 10 No PE Segmental Subsegmental Resected Not Diagnostic

Left lung pulmonary embolism (PE)

- Left lung segment 1/2 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 3 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 4 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 5 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 6 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 8 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 9 No PE Segmental Subsegmental Resected Not Diagnostic
- Left lung segment 10 No PE Segmental Subsegmental Resected Not Diagnostic

- Enter values for the relative distribution of perfusion and ventilation, derived from planar imaging.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
 To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete **Save** **Exit** 

Begin Imaging

Date: 05-Oct-2016 * Time: 9:30 *

Reading

Date: 05-Oct-2016 * Time: 14:30 *

Name of VQ-SPECT Reader: Derlin, Thorsten *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No *

Examination complete: Yes No * (according to the STP)

Quality of the VQ-SPECT Image: Diagnostic Not diagnostic *

Perfusion SPECT: Yes No *

Perfusion SPECT Radiotracer: 99m-Tc-MAA 99mTc-HSA * 

Ventilation SPECT: Yes No *

Ventilation SPECT Radiotracer: 99mTc-DTPA 99mTc-Technegas * 

SPECT/CT examination: Yes No *

Pulmonary embolism

Pulmonary embolism present: Yes No * 

Relative distribution of perfusion (Planar examination)

Left lung: 43 * (%)=>Format: nnn Right lung: 57 * (%)=>Format: nnn

Relative distribution of ventilation (Planar examination)

Left lung: 47 * (%)=>Format: nnn Right lung: 53 * (%)=>Format: nnn

8. Select if lung parenchyma or thorax pathology is seen (only in case of SPECT/CT). If SPECT/CT has not been performed, select “no”.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete **Save** **Exit**

Begin Imaging

Date: 05-Oct-2016 * Time: 9:30 *

Reading

Date: 05-Oct-2016 * Time: 14:30 *

Name of VQ-SPECT Reader: Derlin, Thorsten *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No *

Examination complete: Yes No * (according to the STP)

Quality of the VQ-SPECT Image: Diagnostic Not diagnostic *

Perfusion SPECT: Yes No *

Perfusion SPECT Radiotracer: 99m-Tc-MAA 99mTc-HSA * ↻

Ventilation SPECT: Yes No *

Ventilation SPECT Radiotracer: 99mTc-DTPA 99mTc-Technegas * ↻

SPECT/CT examination: Yes No *

Pulmonary embolism

Pulmonary embolism present: Yes No * ↻

Relative distribution of perfusion (Planar examination)

Left lung: 43 * (%)=>Format: nnn Right lung: 57 * (%)=>Format: nnn

Relative distribution of ventilation (Planar examination)

Left lung: 47 * (%)=>Format: nnn Right lung: 53 * (%)=>Format: nnn

Lung parenchyma or thorax changes

Lung parenchyma or thorax changes: Yes No *

If you select “yes”, a multi-select menu will appear. Select all items you identified on the CT images.

VQ-SPECT (0/45)

Title: VQ-SPECT

Instructions: Separate decimals with a point, not a comma.
 To finalize the CRF select 'a Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete **Save** **Exit** 

Begin Imaging

Date: 05-Oct-2016  * Time: 9:30  *

Reading

Date: 05-Oct-2016  * Time: 14:30  *

Name of VQ-SPECT Reader: Derlin, Thorsten  *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: Yes No *

Examination complete: Yes No * (according to the STP)

Quality of the VQ-SPECT Image: Diagnostic Not diagnostic *

Perfusion SPECT: Yes No *

Perfusion SPECT Radiotracer: 99m-Tc-MAA 99mTc-HSA * 

Ventilation SPECT: Yes No *

Ventilation SPECT Radiotracer: 99mTc-DTPA 99mTc-Technegas * 

SPECT/CT examination: Yes No *

Pulmonary embolism

Pulmonary embolism present: Yes No * 

Relative distribution of perfusion (Planar examination)

Left lung: 43 * (%) =>Format: nnn Right lung: 57 * (%) =>Format: nnn

Relative distribution of ventilation (Planar examination)

Left lung: 47 * (%) =>Format: nnn Right lung: 53 * (%) =>Format: nnn

Lung parenchyma or thorax changes

Lung parenchyma or thorax changes: Yes No *

List of lung parenchyma or thorax changes (-multi-select-):

- emphysema
- fibrosis
- scars
- atelectasis
- pleural effusion
- lung tumor
- infiltrate/pneumonia

Other lung parenchyma or thorax changes:

9. Select prior examinations (only if you used any)
 - select type and date of prior examination used. You may also use the free-text field below.

Prior examinations used in hospital database for interpretation
(Only fill in data, if prior examinations have been used !)

Enter prior examinations using a dropdown list

List of prior examinations	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/>	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/>	<input type="button" value="X"/>
<input type="button" value="Add"/>		

[Return to top](#) Mark CRF Complete

10. If you have completed the CRF, select “Mark CRF complete”.

Prior examinations used in hospital database for interpretation
(Only fill in data, if prior examinations have been used !)

Enter prior examinations using a dropdown list

List of prior examinations	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/>	<input type="button" value="X"/>
<input type="button" value="Add"/>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
<input type="text" value="(-None-)"/>	<input type="text"/>	<input type="button" value="X"/>
<input type="button" value="Add"/>		

[Return to top](#) Mark CRF Complete

1. Press “Save” to finish and save.

5.3 Goldstandard eCRF and image data storage

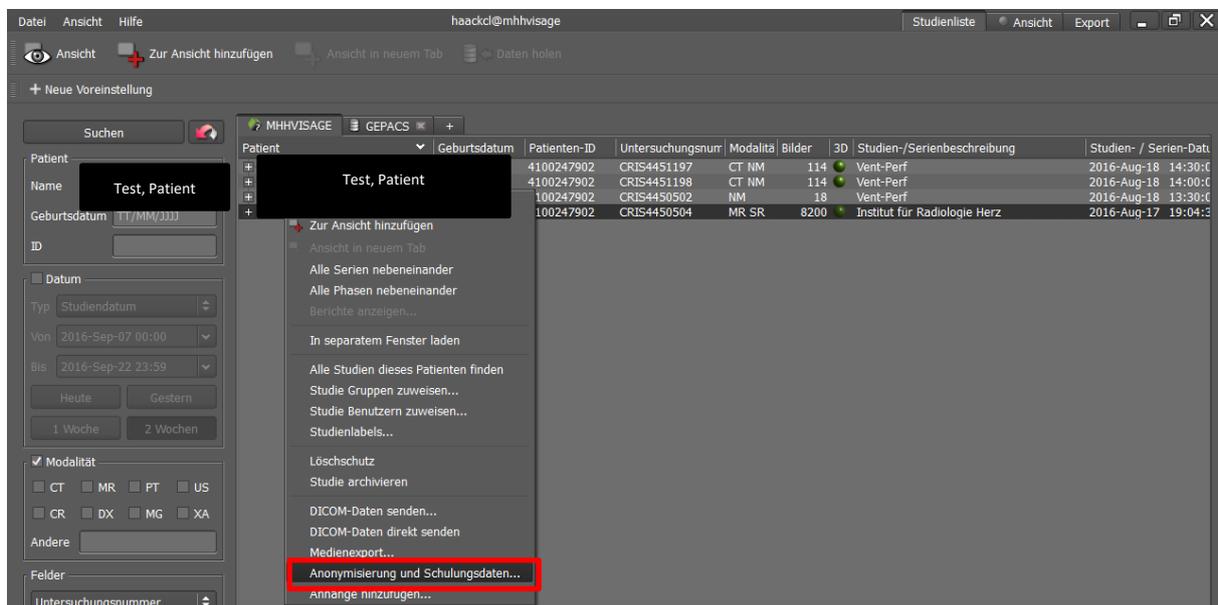
The eCRF Goldstandard has to be filled in 30 – 37 days after the MRI-scan and consists of three tasks:

- pseudonymization
- image data storage
- data entry eCRF

1. Pseudonymization

In the following example we use the program “Visage” for the pseudonymization:

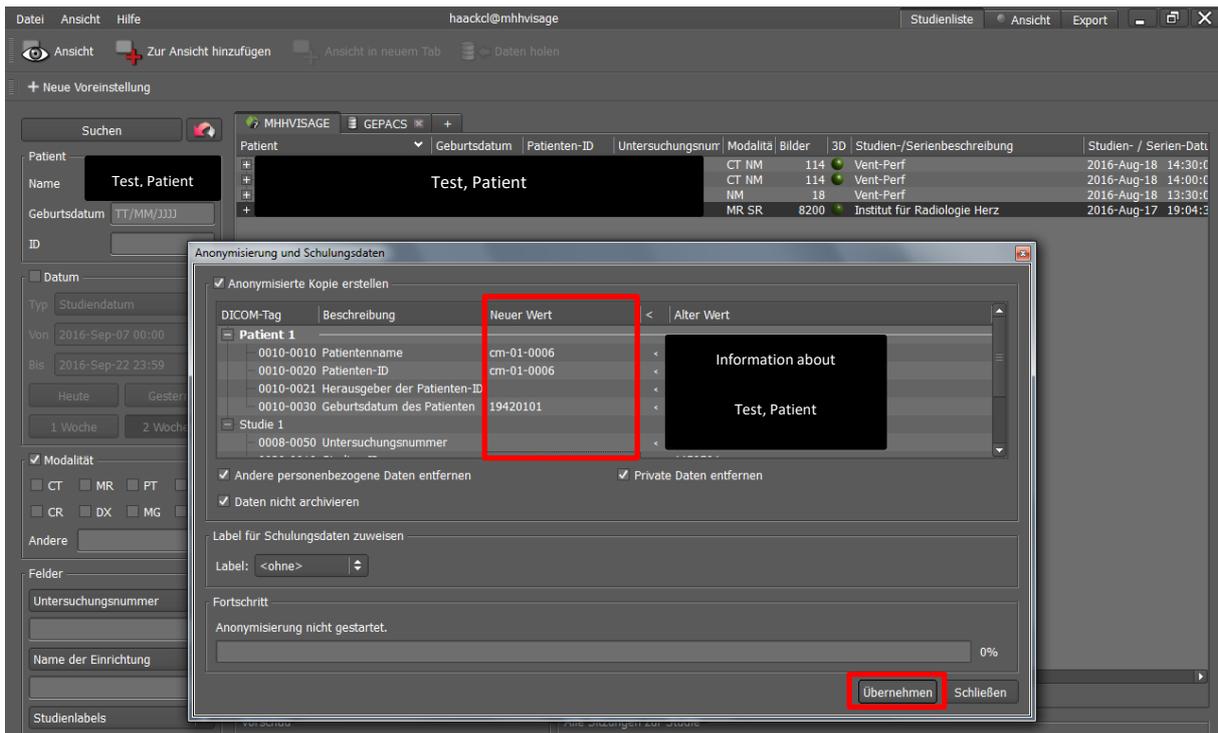
- Search the system for the patient (clear name)
- Choose the MRI scan and check the correct enrollment date (refer to pseudonym-list)
- Select “Anonymisierung und Schulungsdaten” by right mouse key



- Replace cleared patient data by following pseudonymization data in a newly opened function and confirm (refer to pseudonym-list)

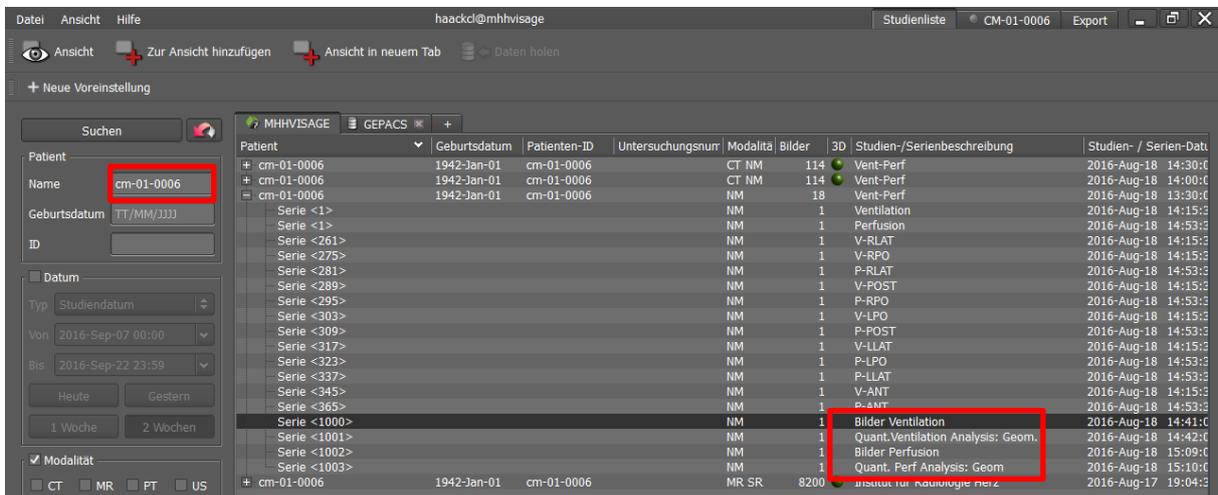
Pseudonymization data:

Patient name	subject ID of patient
Patienten-ID	subject ID of patient
Patient birth	set to 01.01. "real year of birth".
Exam number	leave field blank, or delete entries
Study- ID	Change-MRI
Study description	make no changes
Study comments	make no changes
Name of institute	make no changes

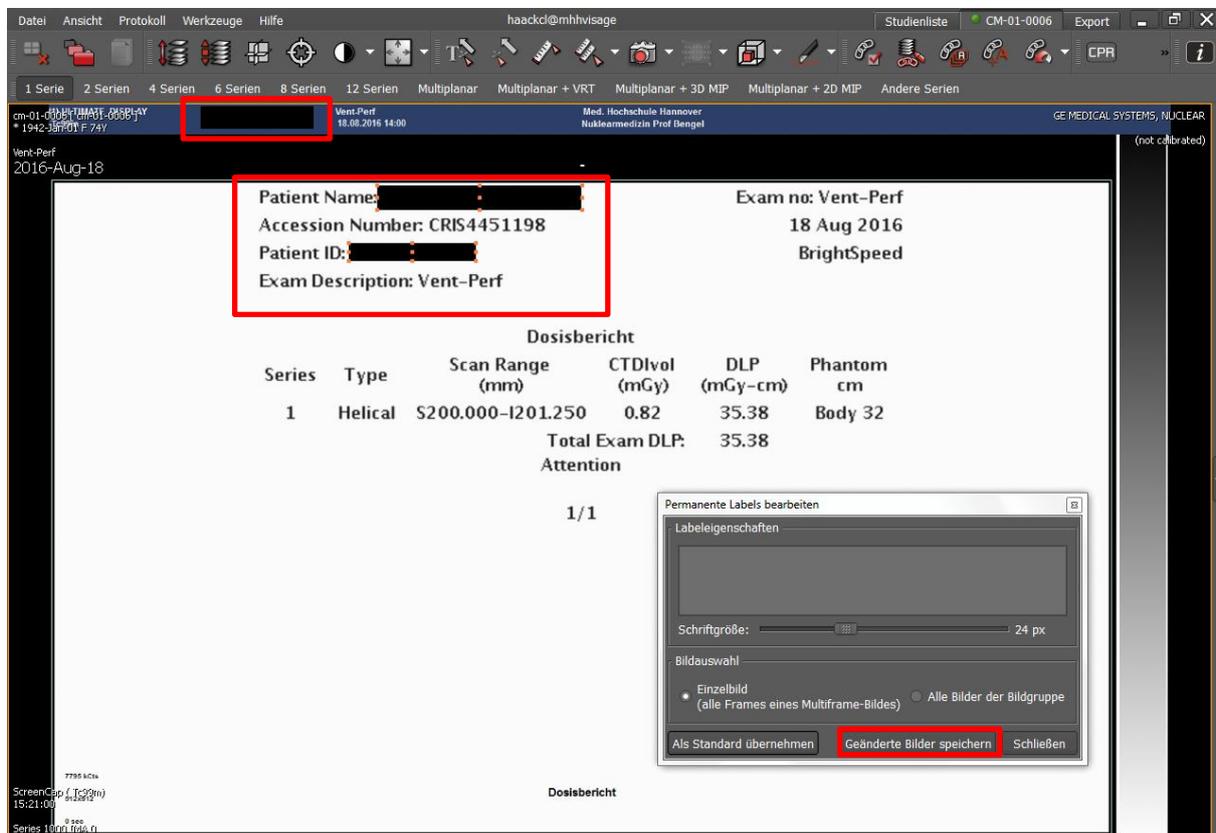
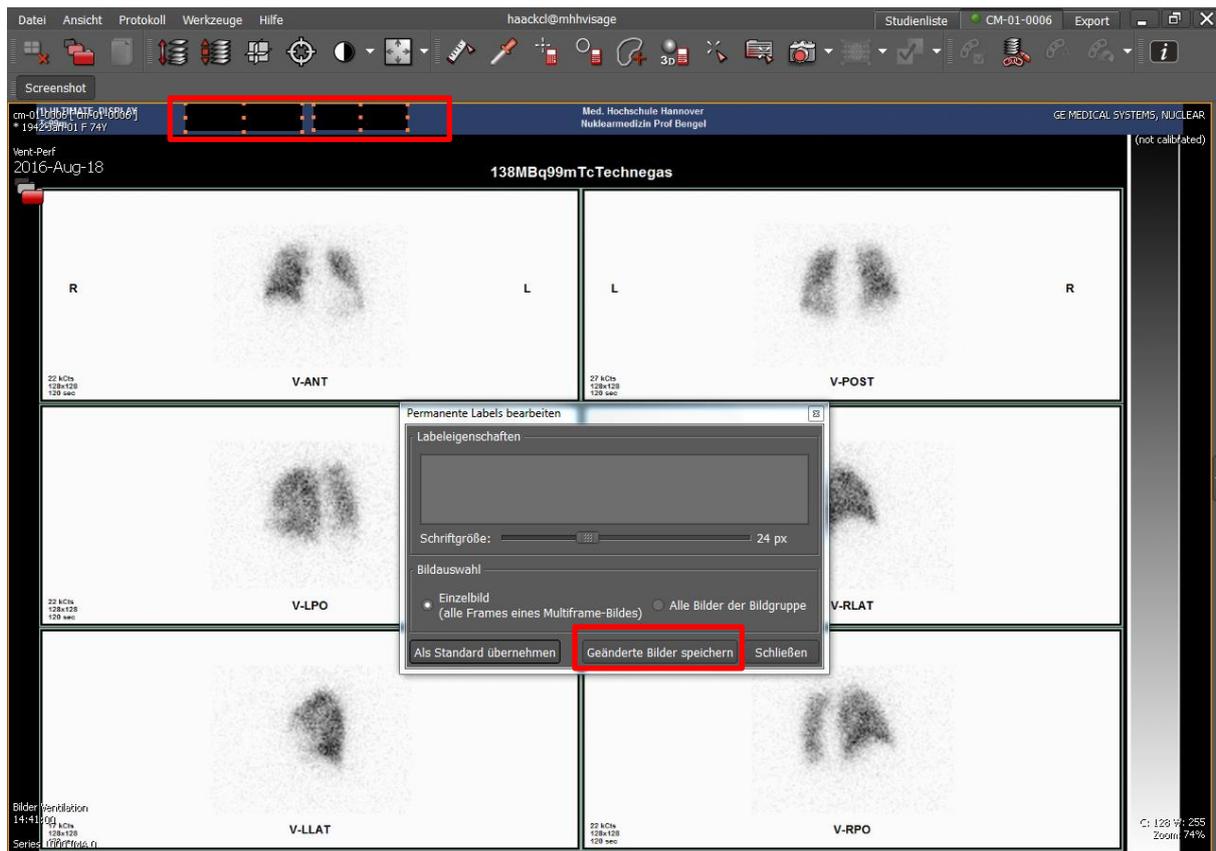


It is important to check, that all identifying patient data are completely pseudonymised or deleted. (Check data that might be stored within an image, e.g. in the dose- report.)

Search the system for patient subject ID and check all images, especially the SPECT-data, for identifying patient data.



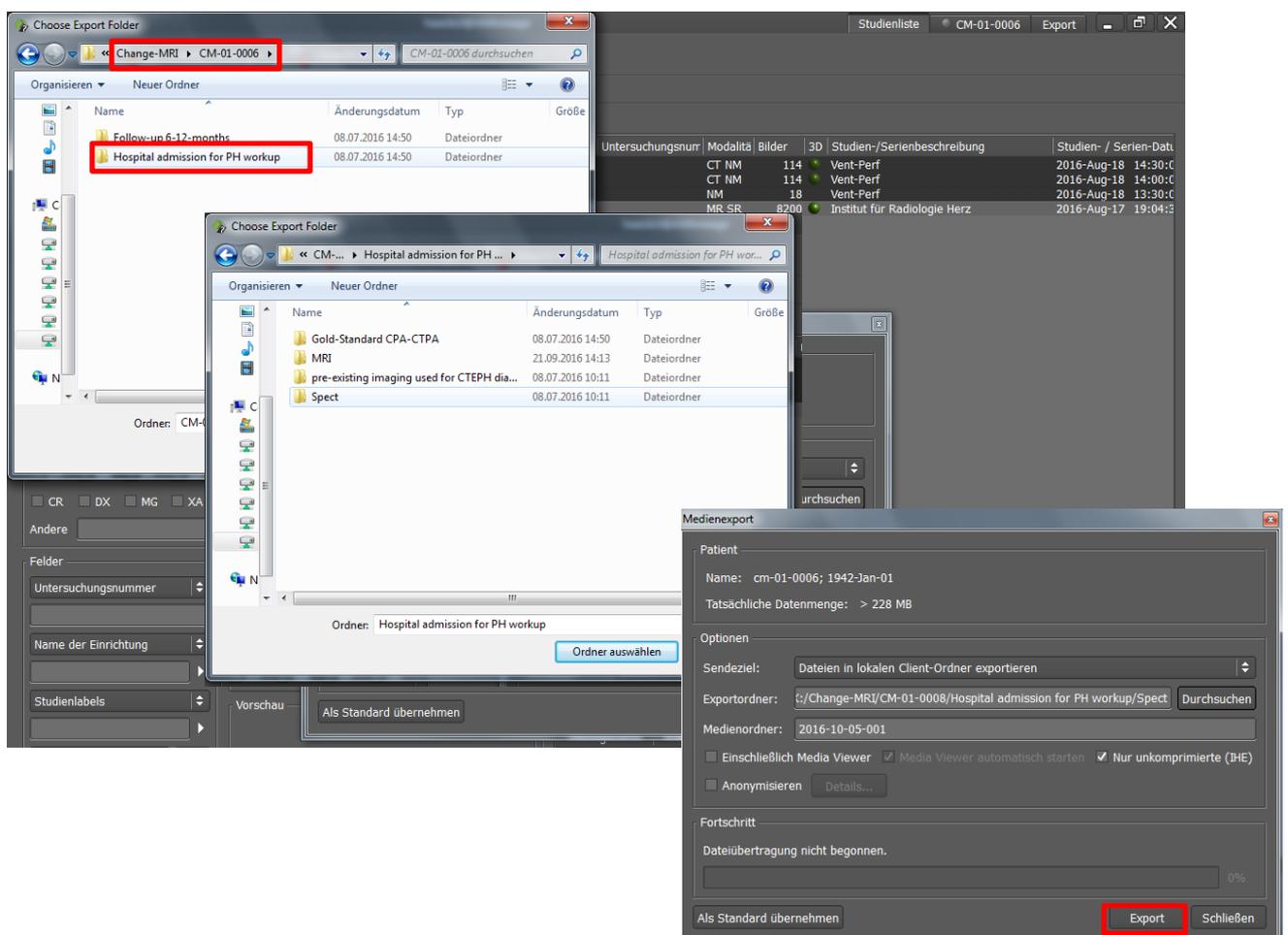
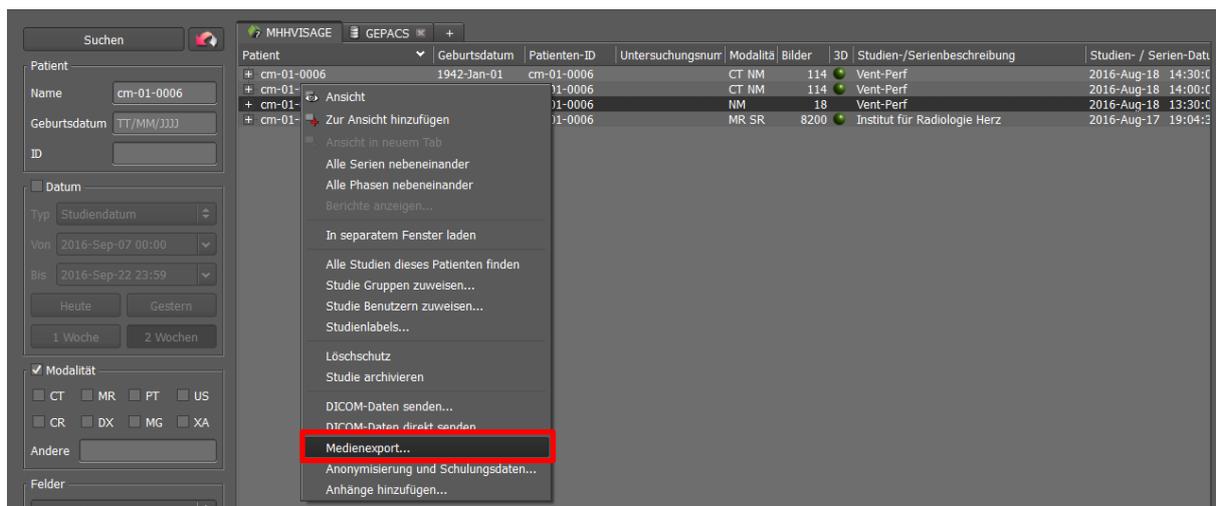
Visage is able to black identifying patient data in the images:



2. Image data storage

If all identifying patient data are completely pseudonymised, deleted or blacked, the image data storage can be started using Visage:

- Select MRI data by right mouse key
- Choose "Medienexport"
- Choose the folder CHANGE MRI with the correct subject ID
- Choose MRI or SPECT data storage in the hospital admission for PH workup
- select the correct folder for the image export and press "exportieren", the data storage starts



Fill in the correct clinical data from the hospital information system:

Pay attention to the different nomenclature between english (eCRF) and german (hospital information system):

Lung function:

eCRF:	hospital information system
TLC pred.	TLC-B
FVC pred.	VCmax
FEV1 pred.	FEV1
FEV1/FVC	FEV1/VCmax
DLCO pred.	TLCO

Right heart catheter:

eCRF:	hospital information system
mPAP	PAPm
PVR *(dyn)	PVR "Wert" dyn

Finish the data entry with "Save" button, don't use the „Mark CRF Complete" checkbox.

This function is used later, after the values have been checked by our biometrics.

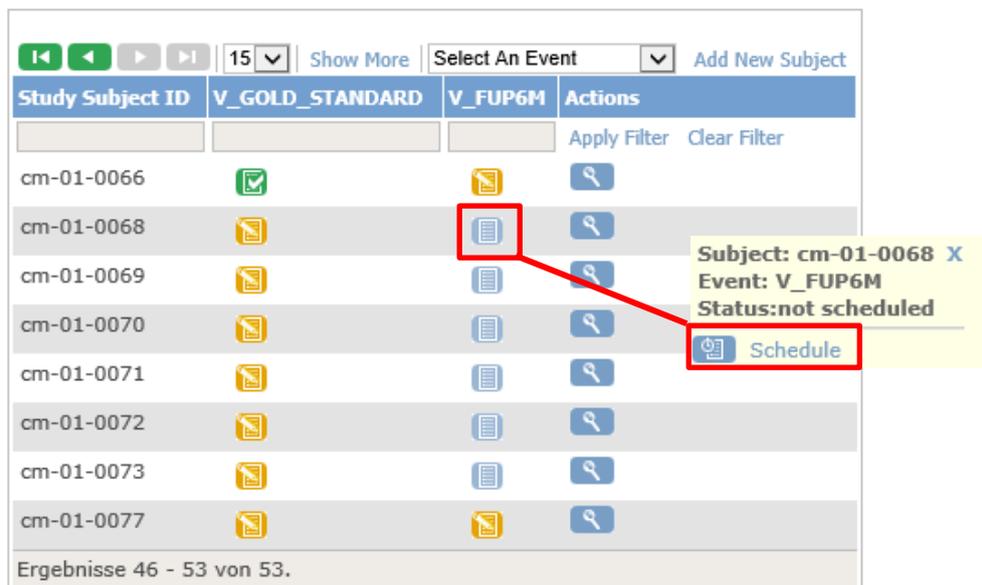
5.4 Follow_Up6Months eCRF

The FUP6M eCRF (6 months Follow up) has to be filled in at the period of 6 to 12 months after the MRI Scan. The earliest begin of data entry, should be started 6 months after the MRI Scan. If no data is entered after 7 months, a query will be sent as reminder.

As soon as all necessary data are available, the entry into the eCRF should be made once.

For the eCRF data entry, select the "V_FUP6M" Event at the added patients. Use the right patient ID and choose "schedule" to get to the FUP eCRF:

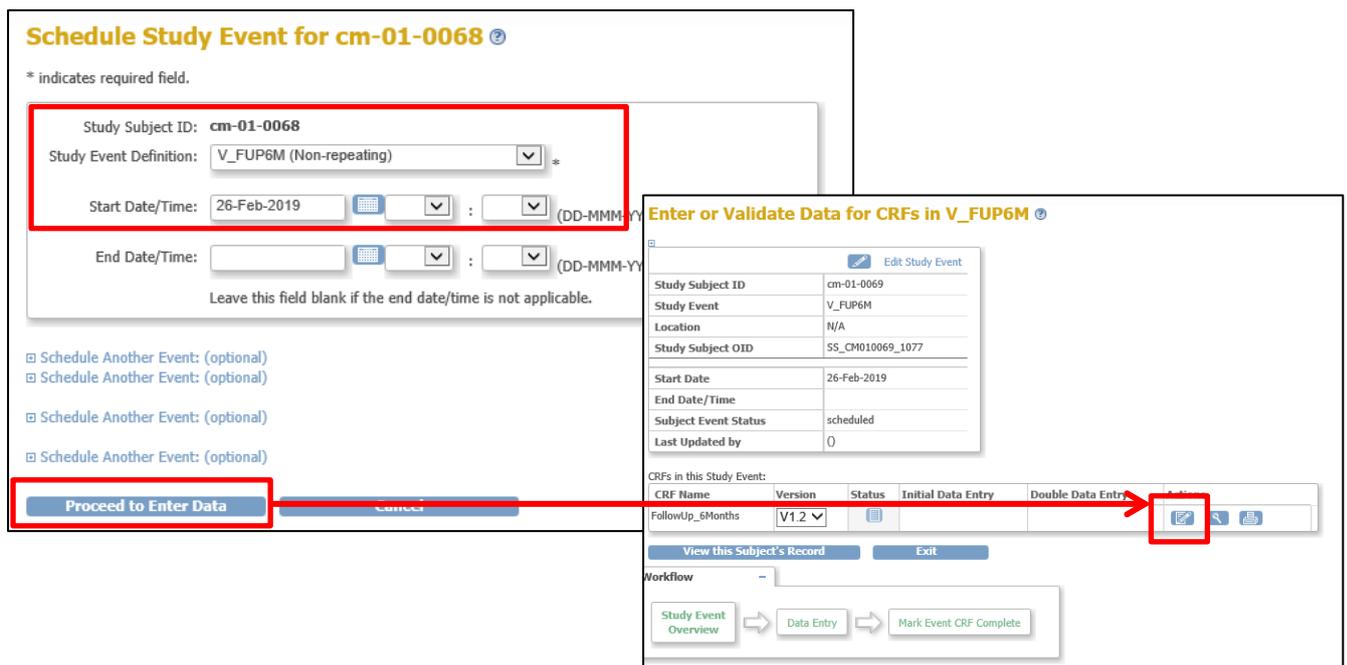
Subject Matrix for C01-BREATH-Hannover



Study Subject ID	V_GOLD_STANDARD	V_FUP6M	Actions
cm-01-0066	<input checked="" type="checkbox"/>		
cm-01-0068			
cm-01-0069			
cm-01-0070			
cm-01-0071			
cm-01-0072			
cm-01-0073			
cm-01-0077			

Ergebnisse 46 - 53 von 53.

Check the right event and the date of the data entry (actual date is automatically deposited), continue with "proceed to enter data" and enter the valid data:



Schedule Study Event for cm-01-0068

* indicates required field.

Study Subject ID: **cm-01-0068**

Study Event Definition: V_FUP6M (Non-repeating) *

Start Date/Time: 26-Feb-2019 : (DD-MMM-YY)

End Date/Time: : (DD-MMM-YY)

Leave this field blank if the end date/time is not applicable.

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Proceed to Enter Data

Enter or Validate Data for CRFs in V_FUP6M

Study Subject ID	Study Event	Location	Study Subject OID	Start Date	End Date/Time	Subject Event Status	Last Updated by
cm-01-0069	V_FUP6M	N/A	SS_CM010069_1077	26-Feb-2019		scheduled	0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry
FollowUp_6Months	V1.2			

Initial Data Entry

View this Subject's Record Exit

Workflow: Study Event Overview → Data Entry → Mark Event CRF Complete

The eCRF consists of six items to be entered:

- **CTPA (= CT pulmonary angiography) examination must** be entered only, if a **CTPA** examination has been performed **within 1 to 12 months** after MRI scan and **no CTPA** is entered within the **Gold-standard eCRF**.
- **CPA (= Catheter pulmonary angiography) examination must** be entered only, if a **CPA** examination has been performed **within 1 to 12 months** after MRI scan and **no CPA** is entered within the **Gold-standard eCRF**.
- **Right Heart Catheter (=RHC) results** should be entered, if the examination has been performed **within 1 to 12 months** after MRI scan.
- **Final Clinical Diagnosis** this item contains the latest available clinical diagnosis, which may be **CTEPH, Pulmonary Hypertension** (incl. classification) or **other diagnosis**.

FOLLOW_... (15/33)

Title: Within 6 to 12 months post MRI

Subtitle: If there are several exams always enter the exam closest to the MRI date

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

CTPA (= CT pulmonary angiography) examination

CTPA up to 30 days post MRI entered in CRF ? Yes No *

CTPA 1 to 12 months post MRI present ? Yes No * 

Date  *

Pulmonary embolism (=PE) detected ? PE No PE Not Diagnostic * 

CPA (= Catheter pulmonary angiography) examination

CPA up to 30 days post MRI entered in CRF ? Yes No *

Right Heart Catheter (=RHC) results

Right heart catheter within 1 to 12 months post MRI present ? Yes No *

Final Clinical Diagnosis

CTEPH diagnosis ? Yes No *

➔ For the final clinical diagnosis, use the most recent medical report, if available.

- **CTEPH Treatment** this item must be entered, if the final diagnosis is CTEPH. It may contain **Drug treatment**, **treatment endarterectomy** or **treatment ballon angioplasty**
- **Did the patient die within 12 months post MRI?** If possible enter **date** and **cause** of death.

The screenshot shows two sections of a CRF form, both highlighted with red rounded rectangles. The top section is titled "CTEPH Treatment" and contains three sub-sections:

- Drug treatment ?**: Radio buttons for Yes (selected), No, and Unknown. Below is a text area for "Name of the Drug(s)" containing a question mark, with a note: "* (if more than one, please separate names by ',' or enter '?' if unknown)".
- Treatment endarterectomy ?**: Radio buttons for Yes (selected), No, and Unknown. Below is a date field for "Date of endarterectomy" containing "04-Feb-2019".
- Treatment ballon angioplasty ?**: Radio buttons for Yes, No (selected), and Unknown.

 The bottom section is titled "Did the patient die ?" and contains:

- Did the patient die within 12 months post MRI ?**: Radio buttons for Yes (selected), No, and Unknown.
- Date of death**: A date field containing "27-Feb-2019".
- Cause of death**: A text field containing a question mark, with a note: "* (enter '?' if unknown)".

 At the bottom of the form, there are buttons for "Return to top", "Mark CRF Complete" (checkbox), "Save", and "Exit".

If **pseudonymised** (see 5.3 part 1: Pseudonymization) image data are entered and present, they should be stored within the sites SFTP area in folder ...**Follow-up 6-12-months\Gold-Standard CPA-CTPA\CTPA (Computed Tomography Pulmonalis Angiography)** or in ...**Follow-up 6-12-months\Gold-Standard CPA-CTPA\CPA (catheter pulmonary angiography)**).

Finish the data entry with "Save" button, don't use the „Mark CRF Complete" checkbox. This function is used later, after the values have been checked by our biometrics.

6 OpenClinica error messages

After clicking the **"SAVE"** button OpenClinica performs validation/plausibility/format checks to ensure data integrity. For each failed check OpenClinica displays an error message which may be used as a link to the respective item of the CRF (marked by one or two bold red exclamation marks). These issues have to be solved before the CRF data can be saved to the database. In the following chapters error messages are listed and solutions are provided.

6.1 Error: Missing data in a required field

This error message occurs, if a required (see asterix * right beside the item) data field is empty. The problem may be solved by entering data for the item.

MRI_DCE V1.2  **CM-TB-0008**

▼ CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

[Missing data in a required field.]

MRI-DCE...(0/42)

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
To finalize the CRF select 'Mark CRF Complete' before clicking the SAVE-Button.



Page: Mark CRF Complete 

Begin MRI Scan

Date: * Time: *

Reading

Date: * Time: *

Reader: *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event: **!** Yes **!** No *

Location of the Problem

6.2 Error: Only provide if

This error message occurs, if the previous saved version of the CRF contains data for an additional inserted item, but the cause for the insertion of the additional item in the current version of the CRF has been dropped out.

E.g. in the previous saved CRF version an allergic contrast reaction “**skin eruption**” has been entered and in the current CRF version only the radio button for “**Allergic contrast reaction**” has been switched from “**Yes**” to “**No**” but the text field still contains “**skin erythema**”. To solve this class of problems, the odd item must be cleared. The method of how to clear an item depends on the type of the item:

- Text fields: Delete the entered text
- Checkboxes: Deselect all checkboxes
- Single- or multiselect dropfields: Deselect all items by <CTRL>+<SPACE>

- Radio buttons: Using the blue “UNDO” button  right beside the item

MRI_DCE V1.2 

CM-TB-0008

▼ CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

- **[Only provide if allergic reaction or AE]**

MRI-DCE...(12/42)

Title: MRI-DCE-T

Instructions: Separate decimals with a point, not a comma.
 To finalize the CRF select '☐ Mark CRF Complete' before clicking the SAVE-Button.

Page: Mark CRF Complete **Save** **Exit** 

Begin MRI Scan

Date  * Time *

Reading

Date  * Time *

Reader *

Adverse events, completeness and quality of examination

Allergic contrast reaction or adverse event Yes No *

Please specify allergic contrast reaction or adverse events ! *

6.3 Message: MRI/SPECT PE=... has been entered! Please click “SAVE” again...

This kind of messages may occur only in MRI or SPECT CRFs. The cause for the message is a technical hint of OpenClinica to allow sending an Email to the Change-MRI Email daemon to allow in-place diagnostic. To solve the problem just click “SAVE” again.

6.4 Error: Input exceeds required width=...

This error message is caused by the OpenClinica format check for numerical input data, if e.g. a numerical input field is limited to 2 digits (format: nn), but the entered data format was 4 digits (=1000). To solve the problem, the entered data must be adjusted to fit the specified format definitions.

The screenshot shows a form titled "Right Heart Catheter (=RHC) results". It includes a question "Right heart catheter within 1 to 6 months post MRI present?" with radio buttons for "Yes" (selected) and "No". Below this are two input fields: "RA" with a value of "1000" and "mPAP" with a value of "678". The "RA" field has a red exclamation mark icon and a tooltip that reads "* (mmHg) =>Format: nn (-1 if not measured)". The "mPAP" field has a tooltip that reads "* (mmHg) =>Format: nnn (-1 if not measured)".

6.5 Error: The input you provided is not an integer., Input exceeds required width=...

This error message is caused by the OpenClinica format check for numerical input data, if e.g. text is entered instead of a numerical value. To solve the problem, the entered data must be adjusted to a numerical value (e.g. -1, if not present).

The screenshot shows the same form as above, but the "RA" input field now contains the text "---". It has a red exclamation mark icon and a tooltip that reads "* (mmHg) =>Format: nn (-1 if not measured)". The "mPAP" field remains "678" with its tooltip "* (mmHg) =>Format: nnn (-1 if not measured)".

6.6 Error: CRF Unavailable

OpenClinica prevents that more than one user enter data at the same time in one CRF. If you try to enter data during another user is already entering data OpenClinica will not show you the CRF but instead display a message that the CRF is unavailable. The message will also indicate the user currently editing the CRF. When the other user exits the CRF, you will be able to edit it.

7. Uploading of files to the SFTP area (Central pooling)

7.1 Introduction

Before a procedure is initiated please read carefully the instructions for every step of the procedure.

This SOP is intended for the data entry user of the CHANGE-MRI study. It describes the procedure for uploading of DICOM data files for central reviewing (e.g. MRI or SPECT). Additional modalities can be included if necessary. **IMPORTANT: All the files must be pseudonymised and identified with the correct patient identification number before the files can be uploaded.** See the respective SOPs for Pseudonymisation provided by the Study Centre in Hannover.

7.2 What is needed for secure FTP-Uploading of files?

The suggestion is to use the “FileZilla” client that is a free SFTP tool. Of course you can use any other efficient secure file transfer (sFTP) tool. In the following description you find information for downloading, installing, configuring and using the “FileZilla” tool.

Procedure

1.1. Download of FileZilla

Go to the following internet site and download the client setup file for the tool (note that an internet site might be available in your language of origin for your country):

<https://filezilla-project.org/>

Load down a current version. (We did it with FileZilla_3.9.0.3_win32-setup.exe)

1.2. Installation

Administrative privileges are required. Double click the setup file and follow the install instructions.

1.3. Application for a user account at the FTP-Server for CHANGE-MRI

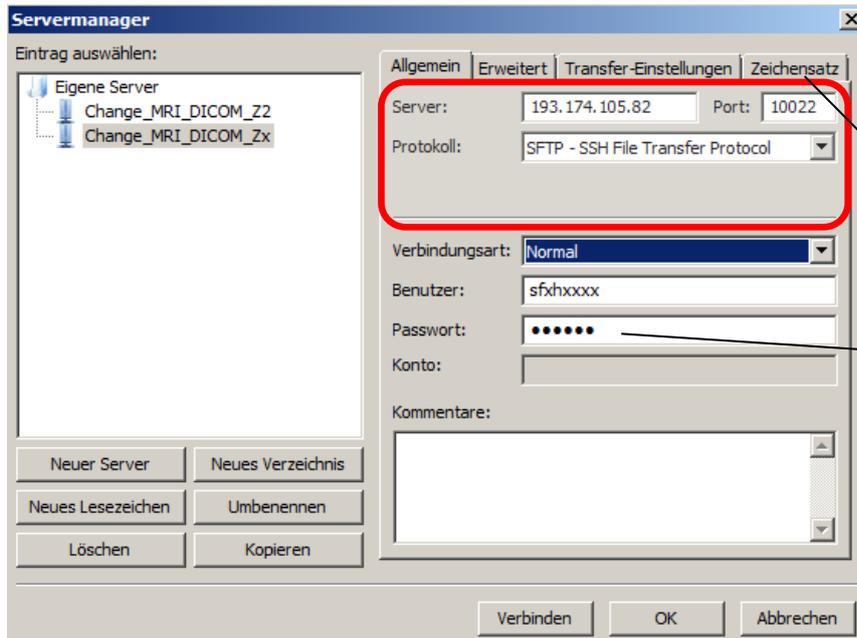
An application form is provided. After you received your account data you are able to configure the FileZilla tool

1.4. Configuration

After start of FileZilla got to File → Site Manager.

You will get the needed information by application data:

Customize according for New Site → , Host → , Port →, and User →



Customize the server connect with

Will be provided with your user application

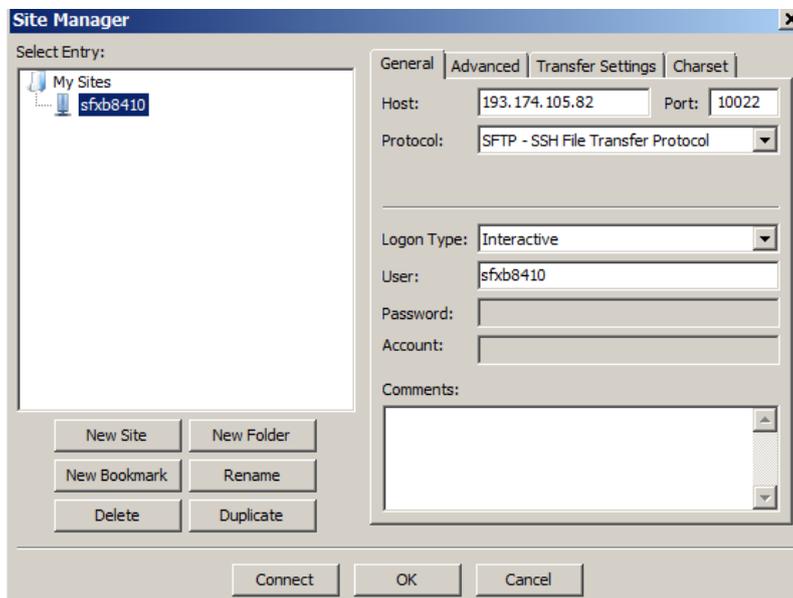
Save the customization with OK.

1.5. Use of FileZilla for file uploading

After successful customising start the session

File → Site Manger → select **your** site.

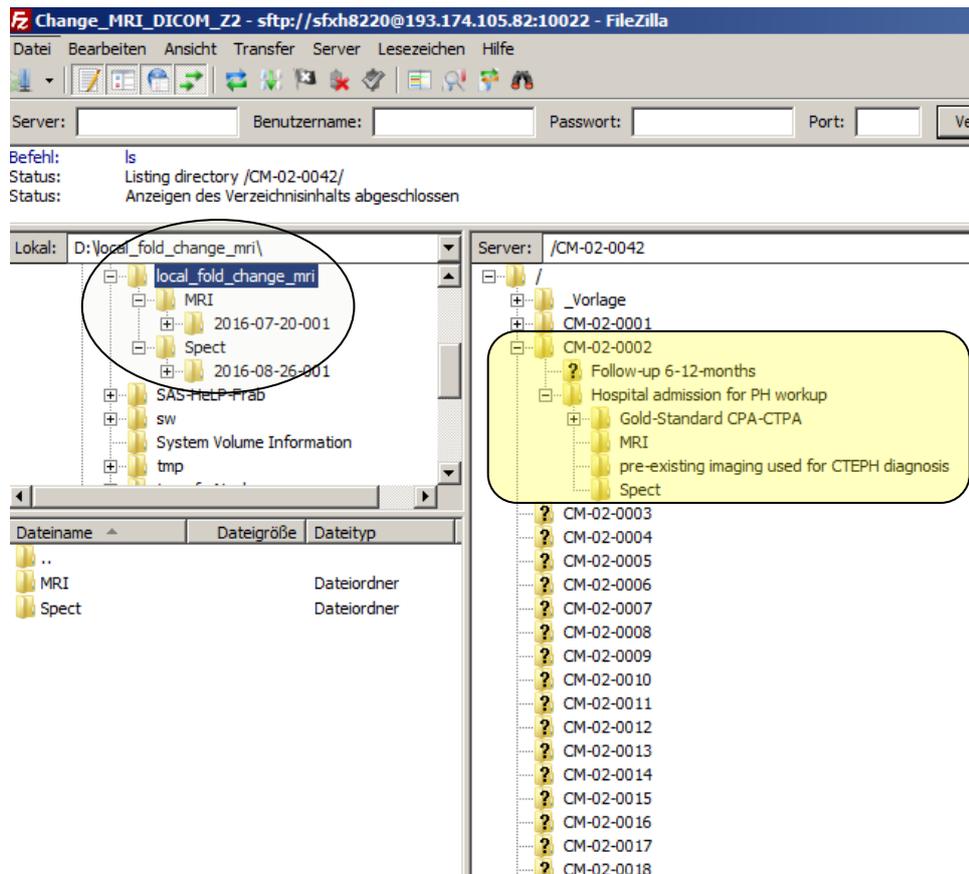
Here an example server connect is used



Connect and enter your password



Then you will find a similar situation (e.g. centre 2 here) as shown in the next picture.



On the left-hand side you can find your local site with local and network drives.

Please create here a similar local directory structure as on the remote site already is prepared. See the arrow above

On the right-hand side you can see the Remote file system on the SFTP-Server in Hannover.

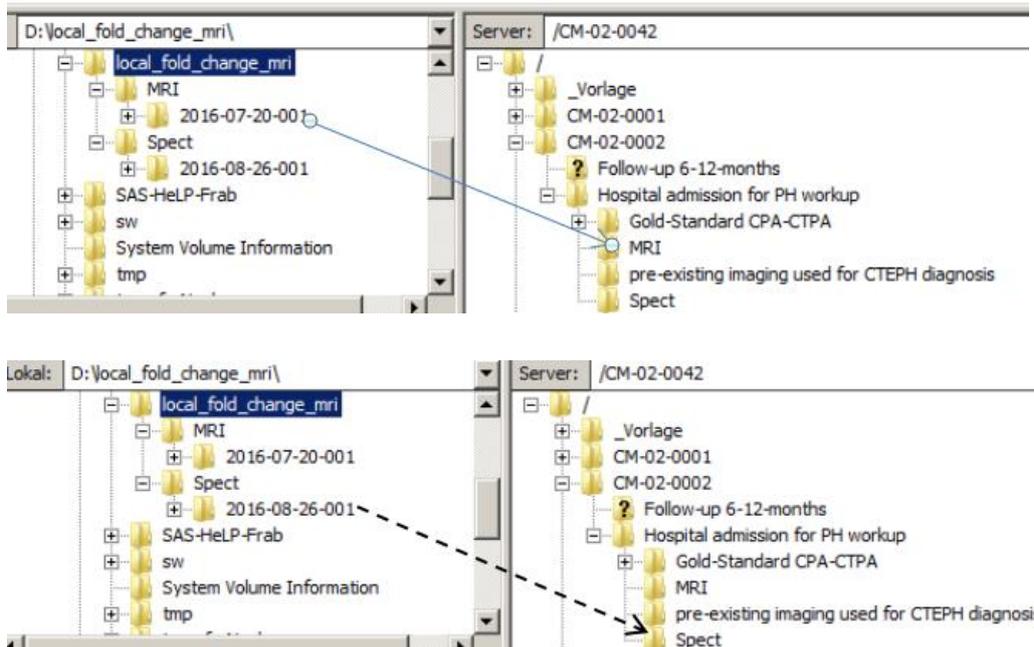
Each study site has on the SFTP-Server a directory tree similar to what is shown in the picture above on the right side. If you are a member of site 2 you only can access the site specific sFTP area for centre 2. If you want to upload files for patient CM-02-002 go to the respective directory. There you will find a prepared directory structure with sub folders 'Follow-up 6-12-months', 'Hospital admission for PH workup' on the right side.

It is recommend creating a similar directory tree on your local computer where you can collect the files up to the next upload. You can copy the e.g. MRI scanning '2016-07-20-001' from MRI per drag and drop from your local MRI directory to the remote sftp area .

Please assure yourself, that **ALL FILES ARE ANONYMISED AND PROVIDED WITH THE CHANGE-MRI PATIENT-ID** (CM-Site-No-Patient-No: e. g. CM-02-045).

Just so the files are able to be linked to the associated patient!

Copy from local to Remote:



Mark the files in the left side of the browser, press the left mouse button and drag the files to the destination folder on the remote site.

In Append you can find the 'Application for a secure FTP-Account', at most two accounts in different sftp areas are available for one site. Only one account (one user & password combination) is available for one sftp area.

Version	Author(s)	Date	Changes	Approved by
1.0				
1.1				

Application for a secure FTP-Account

Hereby, the Change-MRI clinical centre (short name of clinical centre) applies for a site-specific account to access the area of the file pooling secure FTP server to which image files (and ISFs,TIFs) within the Change-MRI project should be uploaded. Single FTP-Account per modality (MRI/VQSpect) per site.

The following person¹ will be responsible for this account and ensure clinical and account data security and confidentiality.

Data must be pseudonymised before uploading.

Modality	First name	Last name	Profession	Email address	Signature
1 MRI					
2 VQSpect					

.....
Date, place and signature of applicant 1

.....
Date, place and signature of applicant 1

Please email the signed and scanned form to Change-MRI-DM@mh-hannover.de. You and the individuals will then be provided with login details and the required information.

¹This must be a known person to the Change-MRI management