



## User Manual

### Content

1 Log in to OpenClinica .....	3
2 OpenClinica homepage .....	4
3 Subject Matrix .....	5
3.1 Add a new subject from Subject Matrix.....	5
3.2 View and enter event data in Subject Matrix .....	6
3.3 View and edit details for a subject in subject casebook .....	7
4 Study events.....	8
4.1 Schedule a study event .....	8
4.2 Update study events .....	9
5 Enter data into a CRF.....	11
5.1 MRI eCRF – Step-by-step instructions.....	12
5.2 SPECT eCRF – Step-by-step instructions .....	21
5.3 Goldstandard eCRF and image data storage.....	31
5.4 Follow_Up6Months eCRF.....	37
6 OpenClinica error messages.....	39

6.1 Error: Missing data in a required field .....	40
6.2 Error: Only provide if ....	40
6.3 Message: MRI/SPECT PE=... has been entered! Please click "SAVE" again.....	41
6.4 Error: Input exceeds required width=...	42
6.5 Error: The input you provided is not an integer., Input exceeds required width=....	42
6.6 Error: CRF Unavailable .....	42
7. Uploading of files to the SFTP area (Central pooling).....	42
7.1 Introduction .....	42
7.2 What is needed for secure FTP-Uploading of files? .....	43

# 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](http://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:  \*

[Change Password](#) [Exit](#)

## 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.

**Icon Key**

**Statuses**

- 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

    15         Show More         Select An Event         Add New Subject		
Study Subject ID	V_MRI	Actions
		Apply Filter Clear Filter
CM-TB-0001		 X 
CM-TB-0002		 X 
CM-TB-0003		 X 
CM-TB-0004		 X 
CM-TB-0005		<div>           Subject: CM-TB-0004 X            Event: V_MRI            Status: data entry started            View/Enter Data            Edit            Remove         </div>
CM-TB-0006		
CM-TB-0007		
Ergebnisse 1 - 7 von 7.		

### 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

    15         Show More         Select An Event         Add New Subject		
Study Subject ID	V_MRI	Actions
		Apply Filter Clear Filter
CM-TB-0001		 X 
CM-TB-0002		 X 
CM-TB-0003		 X 
CM-TB-0004		 X 
CM-TB-0005		 X 
CM-TB-0006		 X 
CM-TB-0007		 X 
Ergebnisse 1 - 7 von 7.		

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	<a href="#">View</a> <a href="#">Edit</a> <a href="#">X</a>	MRI_DCE   V1.2   <a href="#">View</a>   <a href="#">View</a>   <a href="#">View</a>   <a href="#">View</a>

[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](#)

<b>Study Subject ID</b>	CM-TB-0005	<b>Person ID</b> ?	
<b>Secondary ID</b>		<b>Year of Birth</b> ?	1977
<b>OID</b>	SS_CMTB0005	<b>Sex</b> ?	Female
<b>Status</b>	available	<b>Enrollment Date</b> ?	05-Jul-2016
<b>Study Name</b>	CHANGE-MRI MRI	<b>Site Name</b>	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)
- ☐ Schedule Another Event: (optional)
- ☐ Schedule Another Event: (optional)
- ☐ 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		<input type="text"/>		<b>Find</b>	<a href="#">Schedule New Event</a>
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


    15  <a href="#">Show More</a> Select An Event  <a href="#">Add New Subject</a>		
Study Subject ID	V_MRI	Actions
<input type="text"/> <input type="button" value="Apply Filter"/> <input type="button" value="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 

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

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


Enter data into CRF

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.




Page: ☐ Mark CRF Complete   

**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"/> (-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"/> (-None-)	<input type="text"/> 	<input type="button" value="X"/>
<input type="button" value="Add"/>		


Return to top ☐ Mark CRF Complete   

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 'o Mark CRF Complete' before clicking the SAVE-Button.

  
**CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE

Page: ☐ Mark CRF Complete   

Begin MRI Scan

Date   Time  

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 'o Mark CRF Complete' before clicking the SAVE-Button.


  
**CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE

Page: ☐ Mark CRF Complete   

Begin MRI Scan

Date   Time  


Reading


Date   Time  

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 'o Mark CRF Complete' before clicking the SAVE-Button.



  
**CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE


Page: ☐ Mark CRF Complete   

Begin MRI Scan

Date   Time  

Reading


Date   Time  

Reader  

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 'to Mark CRF Complete' before clicking the SAVE-Button.

 CHANGE-MRI  
CTEPH DIAGNOSIS EUROPE

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	
1	apikal	1	apikal
2	post.	2	post.
3	ant.	3	ant.
4	lat.	4	sup.
5	med.	5	inf.
6	sup.	6	sup.
7	med. bas.	7	ant. med. bas.
8	ant. bas.	8	bas.
9	lat. bas.	9	lat. bas.
10	post. bas.	10	post. bas.

**Rechte Lunge 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

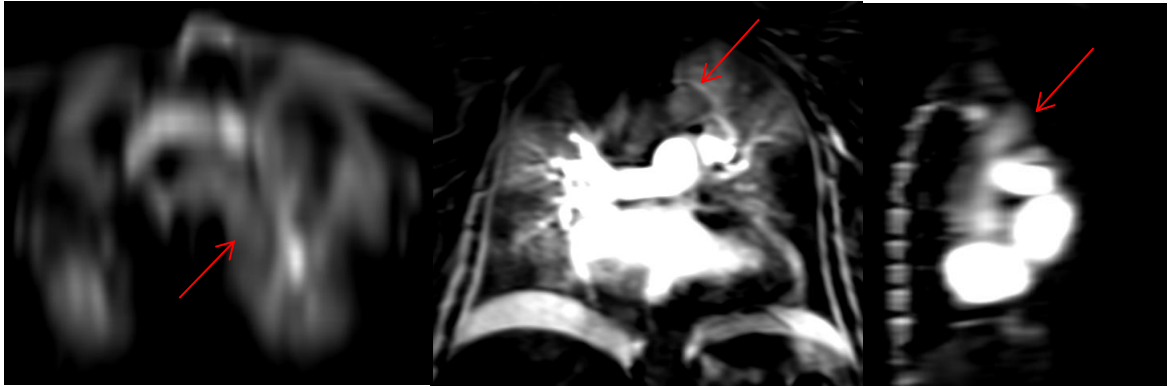
Left lung segment 8 ☐ No PE ☐ Segmental ☐ Subsegmental ☐ Resected ☐ Not Diagnostic

Left lung segment 9 ☐ No PE ☐ Segmental ☐ Subsegmental ☐ Resected ☐ Not Diagnostic

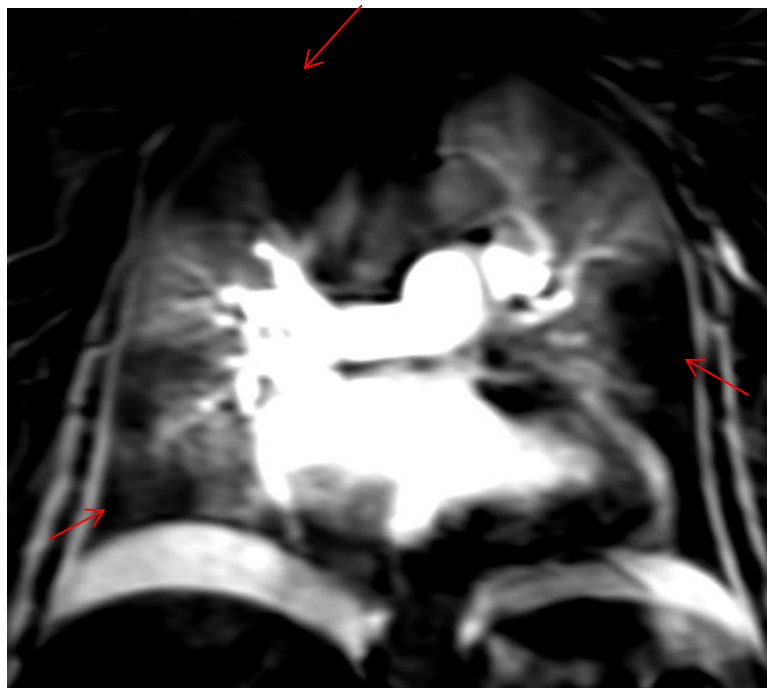
Left lung segment 10 ☐ No PE ☐ Segmental ☐ Subsegmental ☐ Resected ☐ Not Diagnostic

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**

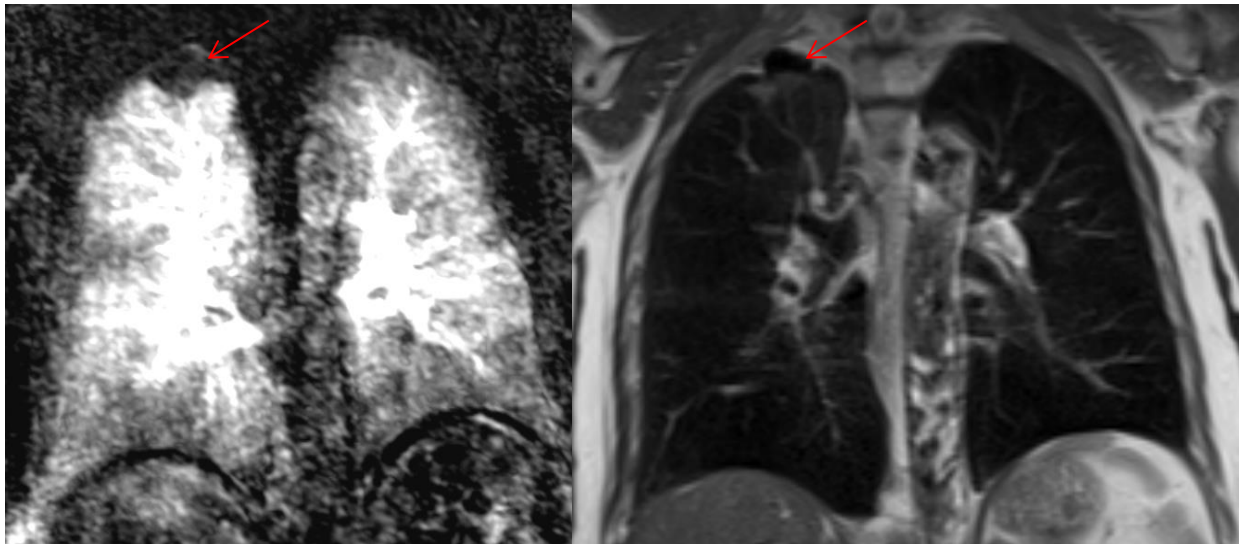
Lung parenchyma or thorax changes

☒ Yes ☐ No \*

List of lung parenchyma or thorax changes

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

\* (-multi-select-)



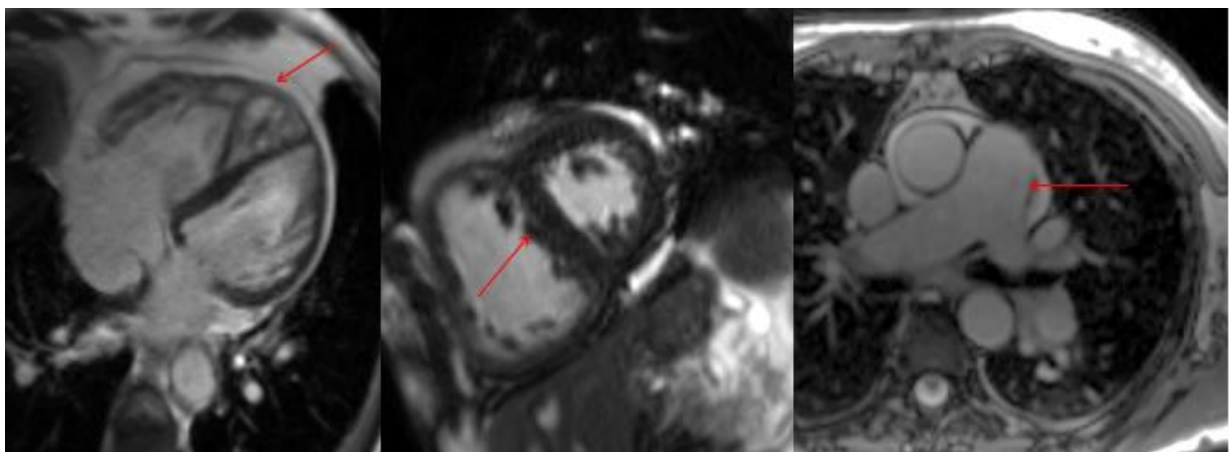
Example of subsegmental hypoperfusion due to bullae

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
<a href="#">Add</a>		

**Enter other prior examinations within a free text field**

Other prior examination	Date of prior examination	
(-None-)		X
<a href="#">Add</a>		

[Return to top](#) ☐ Mark CRF Complete [Save](#) [Exit](#)

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
<b>Add</b>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
(-None-)		X
<b>Add</b>		

[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 'a Mark CRF Complete' before clicking the SAVE-Button.


  
CHANGE-MRI  
CTEPH DIAGNOSIS EUROPE

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"/>
<b>Add</b>		

**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"/>
<b>Add</b>		


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 **Save** **Exit** 

**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 **Save** **Exit** 

**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.





**CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE


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

**Begin Imaging**

Date   \* Time   \*

**Reading**

Date   \* Time   \*


Name of VQ-SPECT Reader   \*


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 ☐ 99m-Tc-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 'a Mark CRF Complete' before clicking the SAVE-Button.




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

**Begin Imaging**

Date:   \* Time:  \*

**Reading**

Date:   \* Time:  \*

Name of VQ-SPECT Reader:  \*


**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 \* 

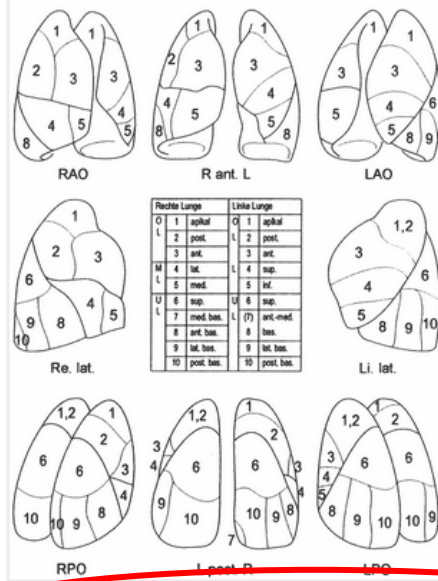
If you select “yes”, an illustration of the segmental anatomy of the lungs will appear, and you will have to decide for each segment if pulmonary embolism is

- 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

7. 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  \* Time  \*

**Reading**

Date  \* Time  \*

Name of VQ-SPECT Reader  \*

**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  \* (%) =>Format: nnn Right lung  \* (%) =>Format: nnn

**Relative distribution of ventilation (Planar examination)**


Left lung  \* (%) =>Format: nnn Right lung  \* (%) =>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  \* Time  \*

**Reading**

Date  \* Time  \*

Name of VQ-SPECT Reader  \*

**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  \* (%) =>Format: nnn Right lung  \* (%) =>Format: nnn

**Relative distribution of ventilation (Planar examination)**

Left lung  \* (%) =>Format: nnn Right lung  \* (%) =>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  \* Time  \*

**Reading**

Date  \* Time  \*

Name of VQ-SPECT Reader  \*

**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  \* (%) =>Format: nnn Right lung  \* (%) =>Format: nnn

**Relative distribution of ventilation (Planar examination)**

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

**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 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	
(-None-)		X
<a href="#">Add</a>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
(-None-)		X
<a href="#">Add</a>		

[Return to top](#) ☐ Mark CRF Complete [Save](#) [Exit](#)

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	
(-None-)		X
<a href="#">Add</a>		

Enter other prior examinations using a free text field

Other prior examination	Date of prior examination	
(-None-)		X
<a href="#">Add</a>		

[Return to top](#) ☒ Mark CRF Complete [Save](#) [Exit](#)

1. Press “Save” to finish and save.

### 5.3 Goldstandard eCRF and image data storage

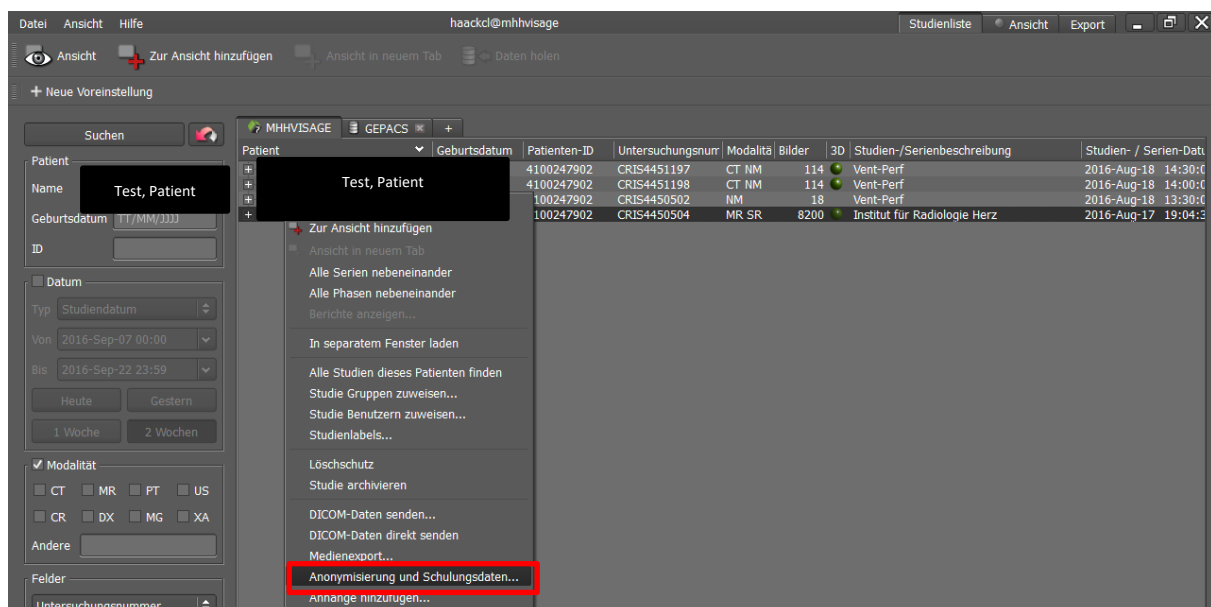
The eCRF Goldstandard has to be filled in 30 – 37 days after the MRI-scan and consists of three tasks:

- pseudonymization
- image data storage
- data entry eCRF

#### 1. Pseudonymization

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

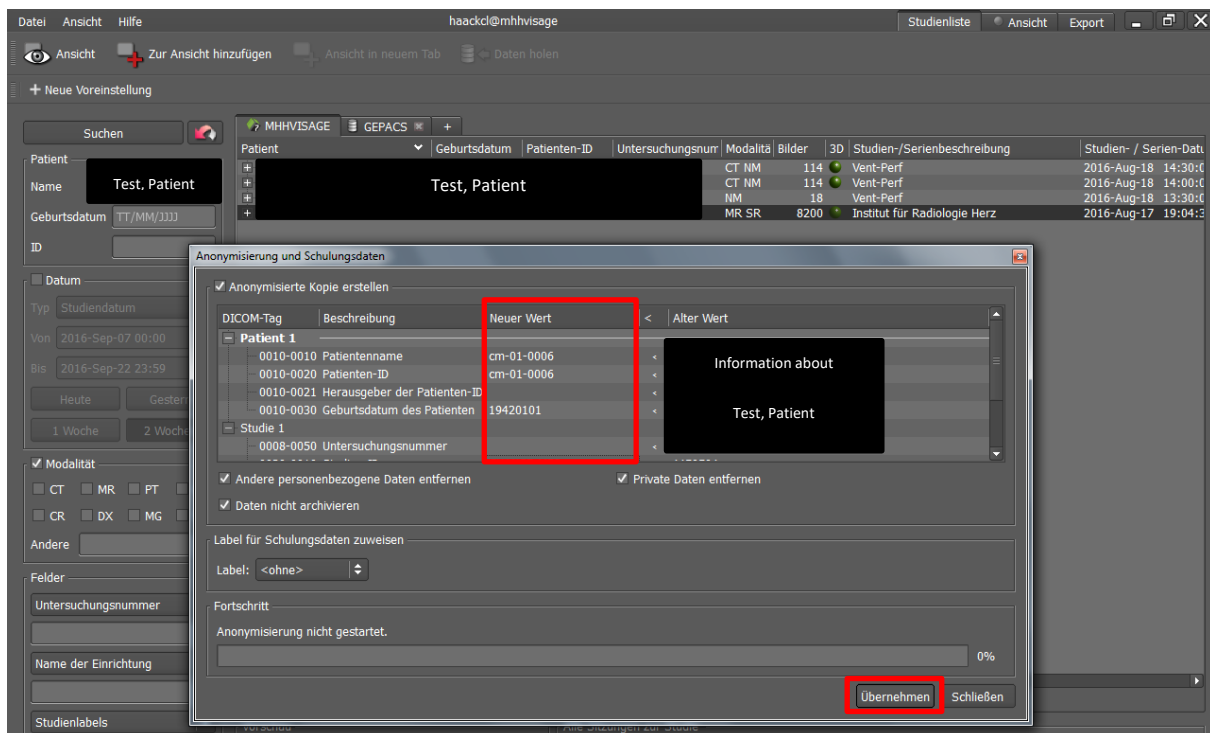
- Search the system for the patient (clear name)
- Choose the MRI scan and check the correct enrollment date (refer to pseudonym-list)
- Select “Anonymisierung und Schulungsdaten” by right mouse key



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

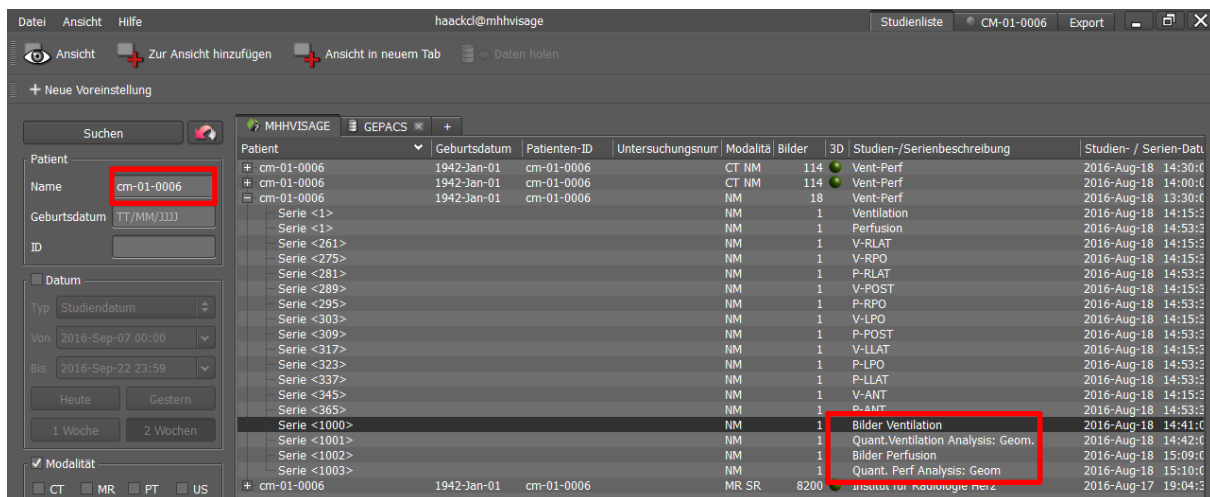
Pseudonymization data:

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



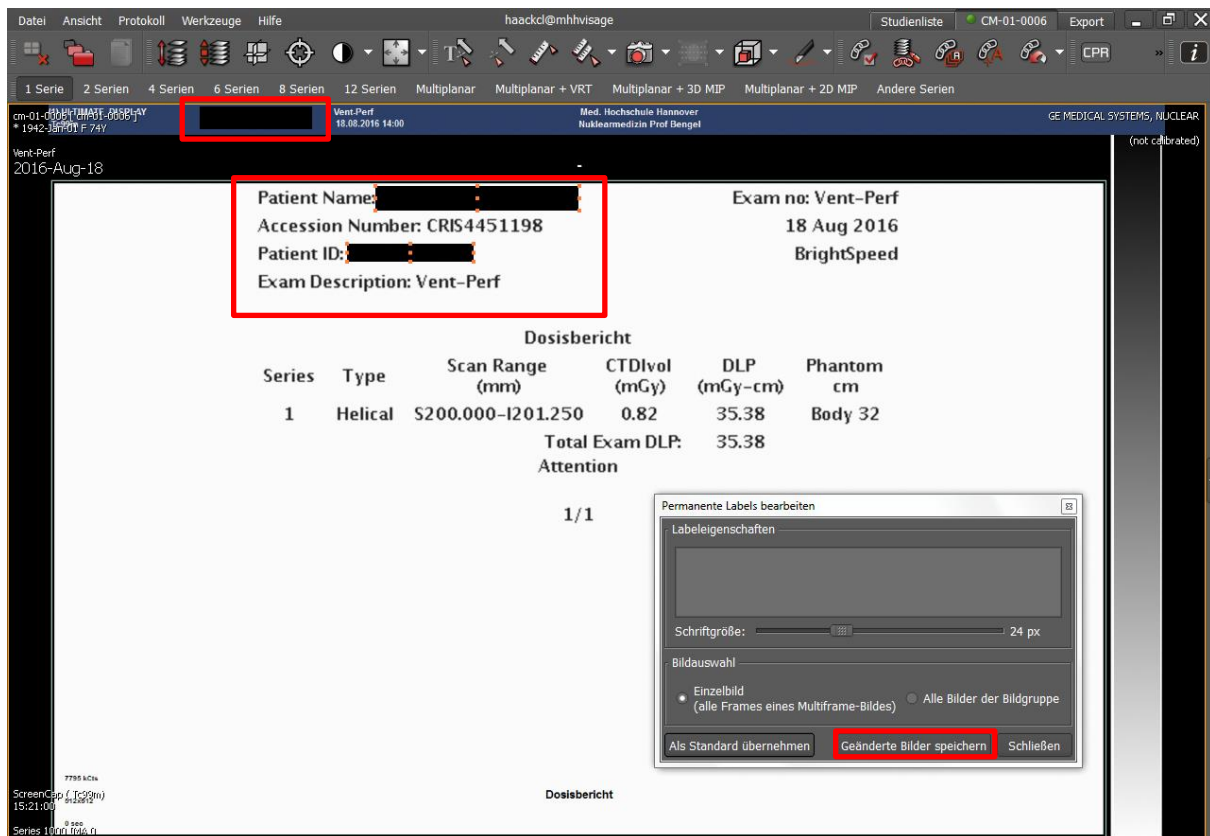
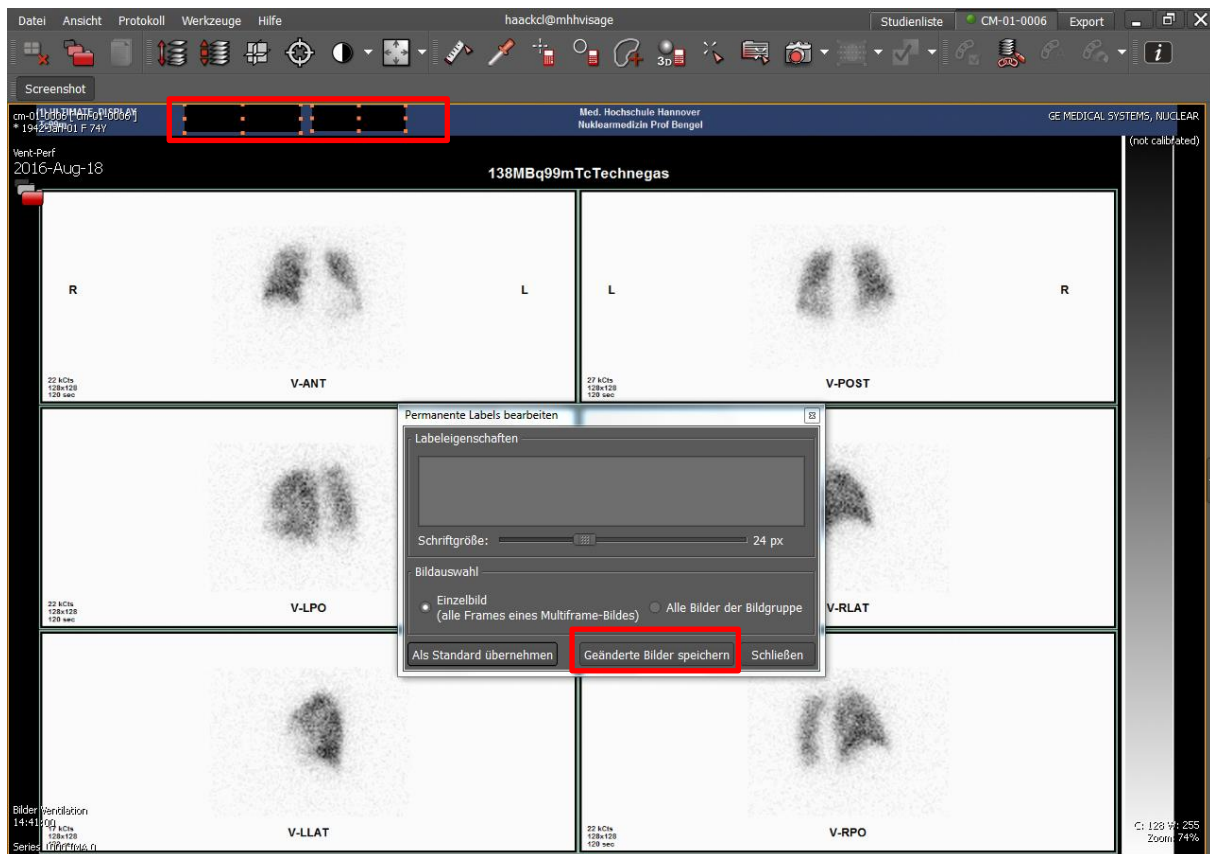
It is important to check, that all identifying patient data are completely pseudonymised or deleted.  
(Check data that might be stored within an image, e.g. in the dose- report.)

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





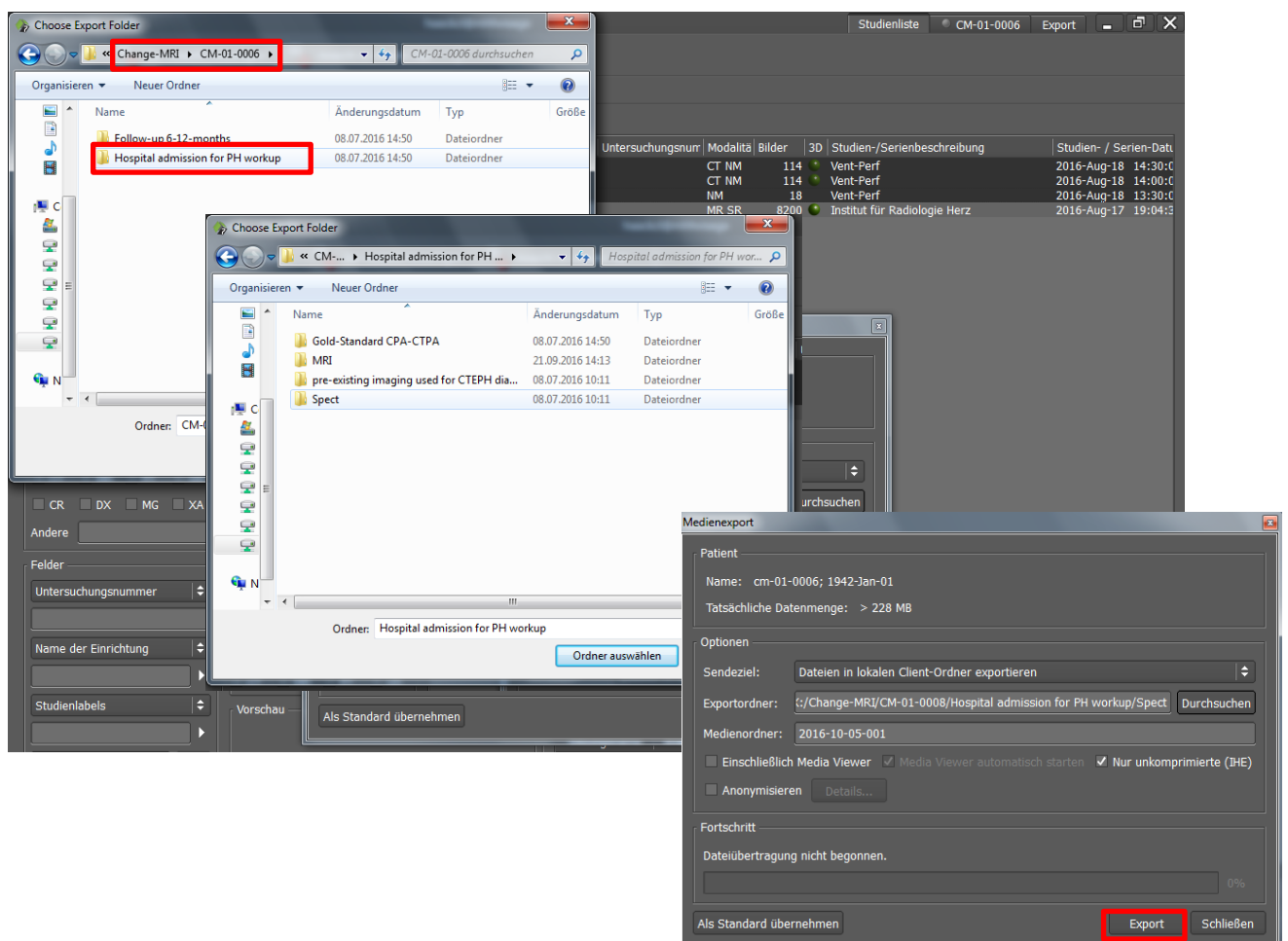
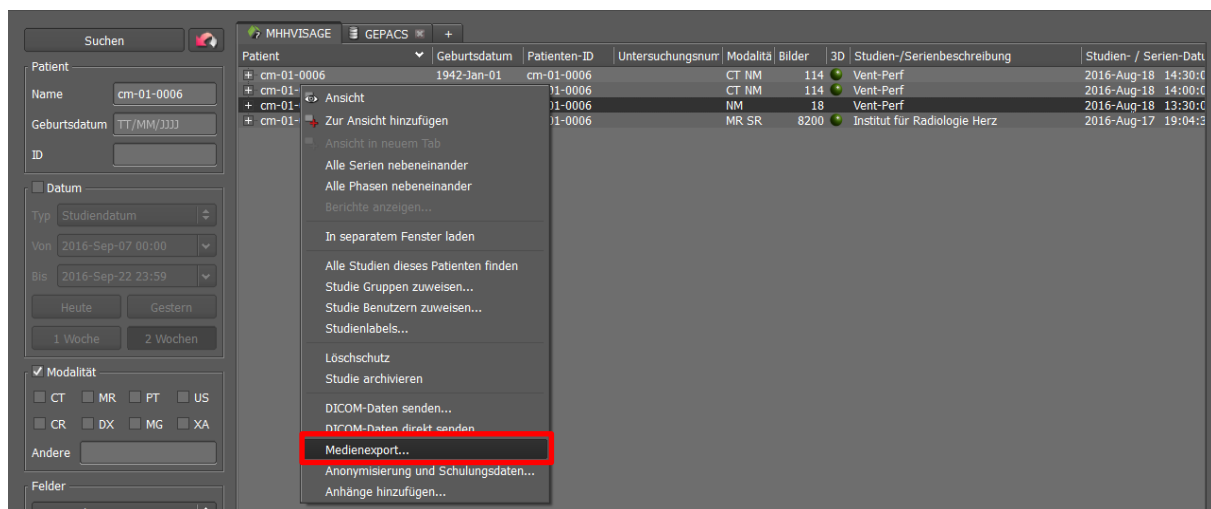
Visage is able to black identifying patient data in the images:



## 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



[illegible]

Add a new subject, equivalent to data entry for MRI or SPECT in the eCRF.

### Add New Subject

Study Subject ID:


Enrollment Date:

Sex:

Year of Birth:

Study Event:

Start Date:



**CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE

Page: ☐ Mark CRF Complete
Save
Exit

**CTPA (= CT pulmonary angiography) and/or CPA (= Catheter pulmonary angiography)**

CTPA examination

CTPA present ? ☐ Yes ☒ No \*

CPA examination

CPA present ? ☐ Yes ☒ No \*

**Right Heart Catheter (=RHC) results**

Right heart catheter present ? ☒ Yes ☐ No \*

RA	<input type="text"/>	* (mmHg) =>Format: nn (-1 if not measured)
mPAP	<input type="text"/>	* (mmHg) =>Format: nnn (-1 if not measured)
PAWP	<input type="text"/>	* (mmHg) =>Format: nn (-1 if not measured)
CO	<input type="text"/>	* (L/min) =>Format: nnn.n (-1 if not measured)
CI	<input type="text"/>	* (L/min/m2) =>Format: nnn.n (-1 if not measured)
PVR	<input type="text"/>	* (dyn) =>Format: nnnn (-1 if not measured)
SV02	<input type="text"/>	* (%) =>Format: nn (-1 if not measured)

**6 min walking distance test**

6 min walking distance test present ? ☐ Yes ☐ No \*

**Lung Function (=LUFU) Test**

Lung function test present ? ☐ Yes ☐ No \*

**Patient history and clinical indication**

Patient history and/or clinical indication present ? ☐ Yes ☐ No \*

Return to top ☐ Mark CRF Complete
Save
Exit

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

**CTPA (= CT pulmonary angiography) and/or CPA (= Catheter pulmonary angiography)**

CTPA examination  
CTPA present ? ☐ Yes ☒ No \*

CPA examination  
CPA present ? ☐ Yes ☒ No \*

**Right Heart Catheter (=RHC) results**

Right heart catheter present ? ☒ Yes ☐ No \*

RA	4	(mmHg) =>Format: nn (-1 if not measured)
mPAP	23	(mmHg) =>Format: nnn (-1 if not measured)
PAWP	11	(mmHg) =>Format: nn (-1 if not measured)
CO	4.3	(l/min) =>Format: nnn.n (-1 if not measured)
CI	2.2	(l/min/m2) =>Format: nn.n (-1 if not measured)
PVR	223	(dyn) =>Format: nnnn (-1 if not measured)
SvO2	70	(%) =>Format: nn (-1 if not measured)

6 min walking distance test  
6 min walking distance test present ? ☐ Yes ☐ No \*

**Lung Function (=LUFU) Test**

Lung function test present ? ☒ Yes ☐ No \*

TLC pred.	77	(%) (25-160%) =>Format: nnn (-1 if not measured)
FVC pred.	87	(%) =>Format: nnn (-1 if not measured)
FEV1 pred.	88	(%) (>70%) =>Format: nnn (-1 if not measured)
FEV1/FVC	81	(%) (30-100%) =>Format: nnn (-1 if not measured)
DLCO pred.	36	(%) (20-99%) =>Format: nnn (-1 if not measured)

Patient history and/or clinical indication  
Patient history and/or clinical indication present ? ☐ Yes ☐ No \*

**Rechtsherkatheteruntersuchung vom 19.08.2016 - 10:00 vom 19.08.2016**  
Hämodynamik  
Lokalanästhesie mit 5ml Procain 2%. Keine Sedierung.  
O2 0 l/min, RA 4 mm Hg, PAPm 23 mm Hg, PAPsyst 41 mm Hg, PAWP 11 mm Hg, TPG 12 mm Hg, DPG 2 mm Hg, CO 4.3 l/min, CI 2.2 l/min/m2, SV 84 ml, SVR 1524 dyn, SVR 19, 1 WU, PVR 223 dyn, PVR 2,8 WU, PaO2 72 Torr, SaO2 96 %, SvO2 70 %.

**Bemerkungen**  
Problem- und komplikationsloser Untersuchungsverlauf. Sonographisch gesteuerte Punktion des Gefäßes.

**Beurteilung**  
Keine signifikante pulmonale Hypertonie. Erniedrigtes Herzzeitvolumen.

**TTE vom 19.08.2016**  
Zusammenfassung:  
1: Gute systolische linksventrikuläre Funktion.  
2: Gute systolische rechtsventrikuläre Funktion TAPSE 21 mm.  
3: Hinweis auf diastolische Dysfunktion.  
4: Leichte Aortenklappenstenose.  
5: Leichte Mitralklappeninsuffizienz.  
6: Kein Perikarderguss.  
7: Echokardiographisch kein sicherer Hinweis auf pulmonale Hypertonie (PAP syst. ca. 33 mmHg + ZVD, fehlende Zeichen der Rechtsherzbelastung).

**Untersuchungsbefunde:**  
**PNE Lungenfunktion vom 18.08.2016**  
Bodyplethysmographie  
VCmax 2,54 l, 87% vom Soll  
FEV1 2,06 l, 88% vom Soll  
FEV1/VCmax 81 %  
MEF25-75 80% vom Soll  
sRAWtot 47% vom Soll  
TLC-B 4,26 l, 77% vom Soll  
RV-B 1,72 l, 76% vom Soll  
RV/TLC-B 40 %  
Diffusionskapazität  
TLC-He 3,64 l, 66% vom Soll  
TLCO 2,71 mmol/min/kPa, 36% vom Soll  
KCO 0,78 mmol/min/kPa/l, 55% vom Soll

**Nuklearmed. Bef vom 18.08.2016**  
Fragestellung:  
Ausschluss/Nachweis einer (chronisch-rezidivierenden) Lungenarterienembolie als Ursache für eine pulmonale Hypertonie (PAH).  
Befund:  
Keine Voruntersuchung vorliegend.  
Ventilationsszintigraphie:  
Die Seitenanteile am ventilierten Gasvolumen betragen im geometrischen Mittel links 42%, rechts 58%.  
Es zeigt sich eine weitgehend homogene Nuklidverteilung planar ohne Nachweis von segmentalen/

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

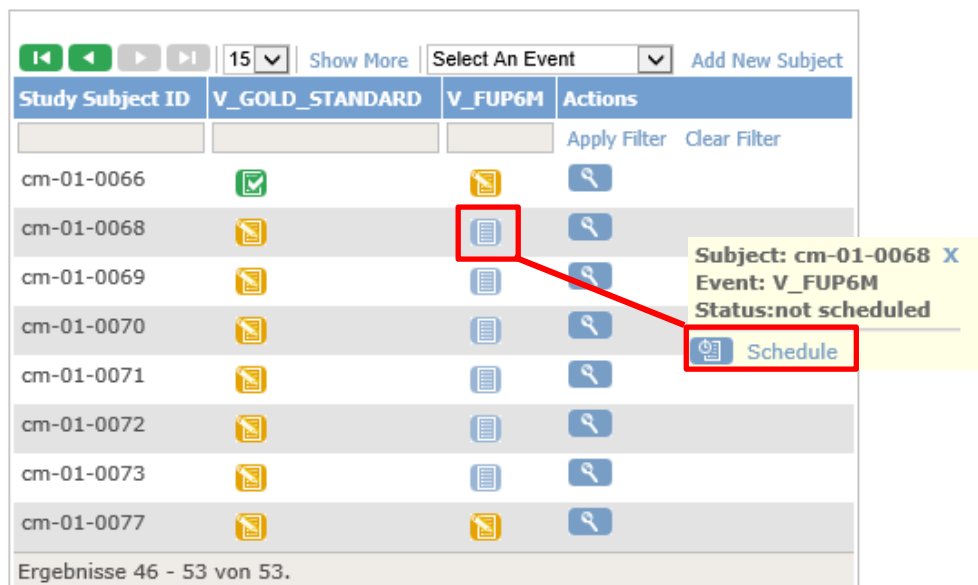
The FUP6M eCRF (6 months Follow up) has to be filled in at the period of 6 to 12 months after the MRI Scan. The earliest begin of data entry, should be started 6 months after the MRI Scan. If no data is entered after 7 months, a query will be sent as reminder.

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:

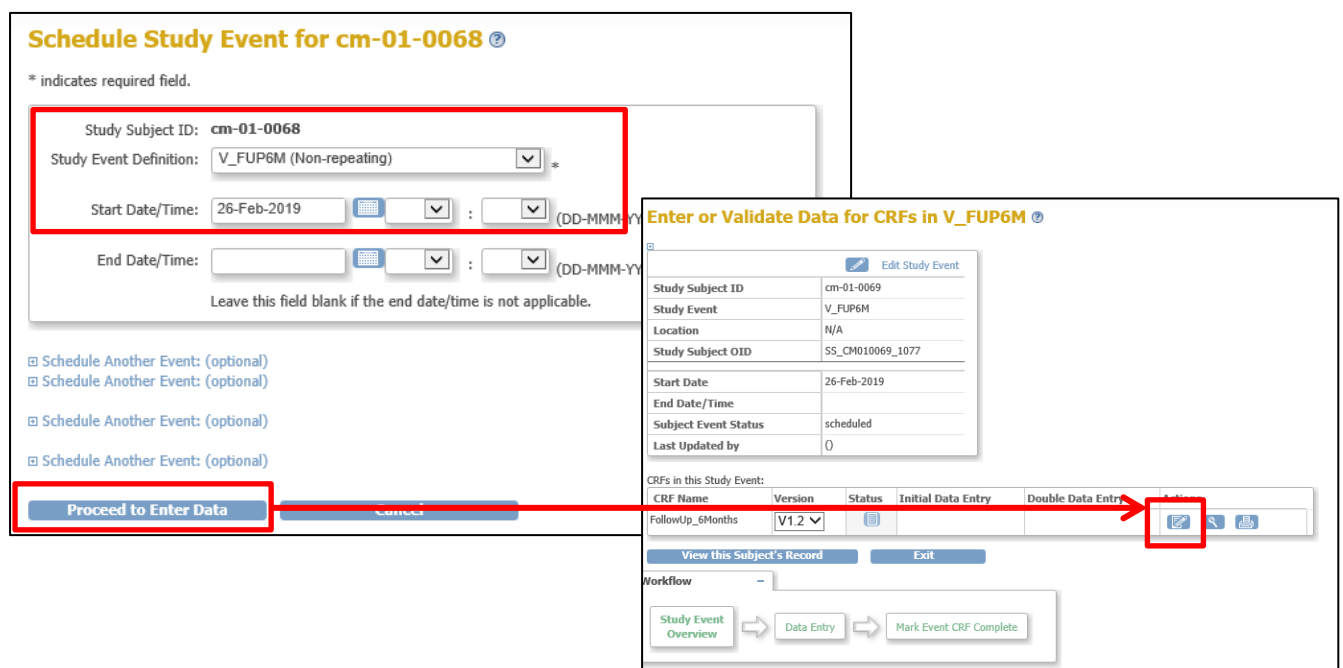
### Subject Matrix for C01-BREATH-Hannover



Study Subject ID	V_GOLD_STANDARD	V_FUP6M	Actions
cm-01-0066			
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 Event**

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			

**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.

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.


 **CHANGE-MRI**  
CTEPH DIAGNOSIS EUROPE

Page: ☐ Mark CRF Complete   

**Begin MRI Scan**

Date: 21-Jul-2016  \* Time: 5:00 \*

**Reading**

Date: 21-Jul-2016  \* Time: 7:30 \*

Reader: C02\_Reader#1 \*

**Adverse events, completeness and quality of examination**

Allergic contrast reaction or adverse event: ☒ Yes ☐ No \*

## 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 has a section for "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" and "mPAP". The "RA" field contains the value "1000" and has a red exclamation mark icon to its left, indicating an error. The "mPAP" field contains the value "678". Both fields have a tooltip that says "(mmHg) =>Format: nn (-1 if not measured)" for RA and "(mmHg) =>Format: nnn (-1 if not measured)" for mPAP.

## 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 in 6.4. The "RA" field now contains the value "---" and has a red exclamation mark icon to its left, indicating an error. The "mPAP" field still contains the value "678". Both fields have a tooltip that says "(mmHg) =>Format: nn (-1 if not measured)" for RA and "(mmHg) =>Format: nnn (-1 if not measured)" for mPAP.

## 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 b 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

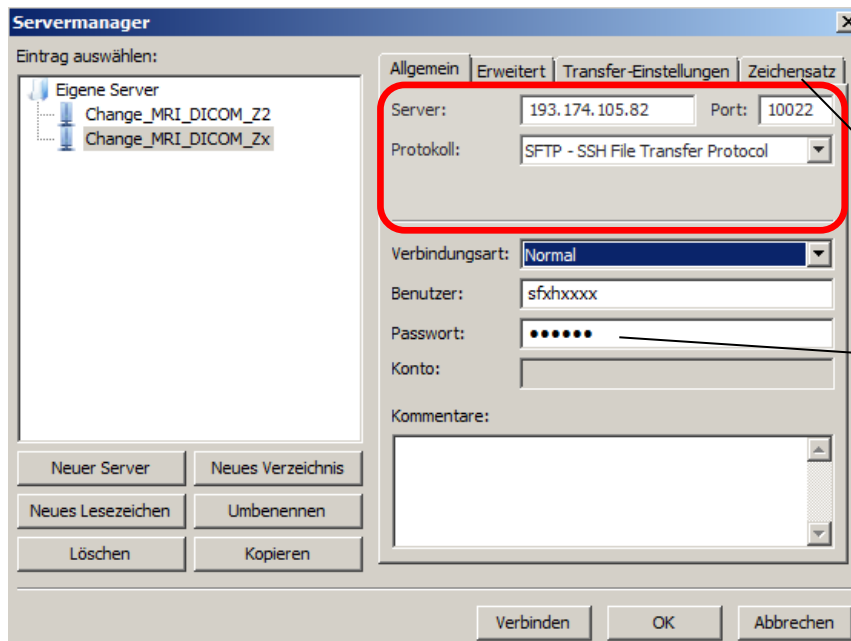
An application form is provided. After you received your account data you are able to configure the FileZilla tool

#### 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

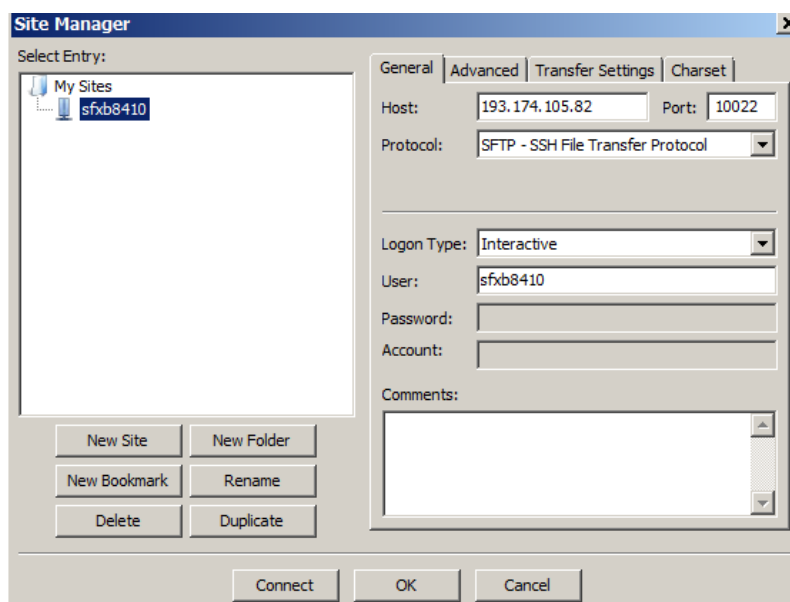
Save the customization with OK.

#### 1.5. Use of FileZilla for file uploading

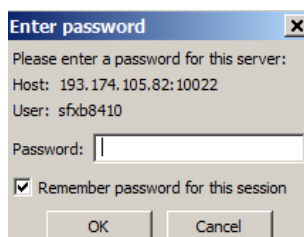
After successful customising start the session

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

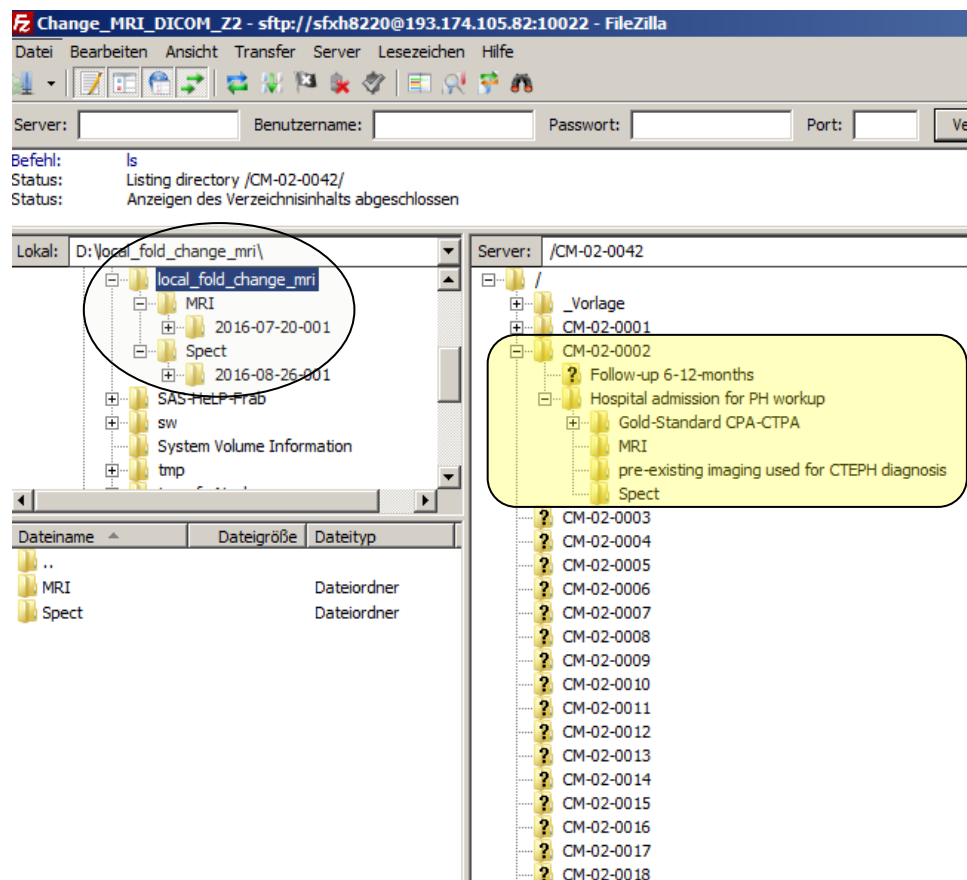
Here an example server connect is used



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.

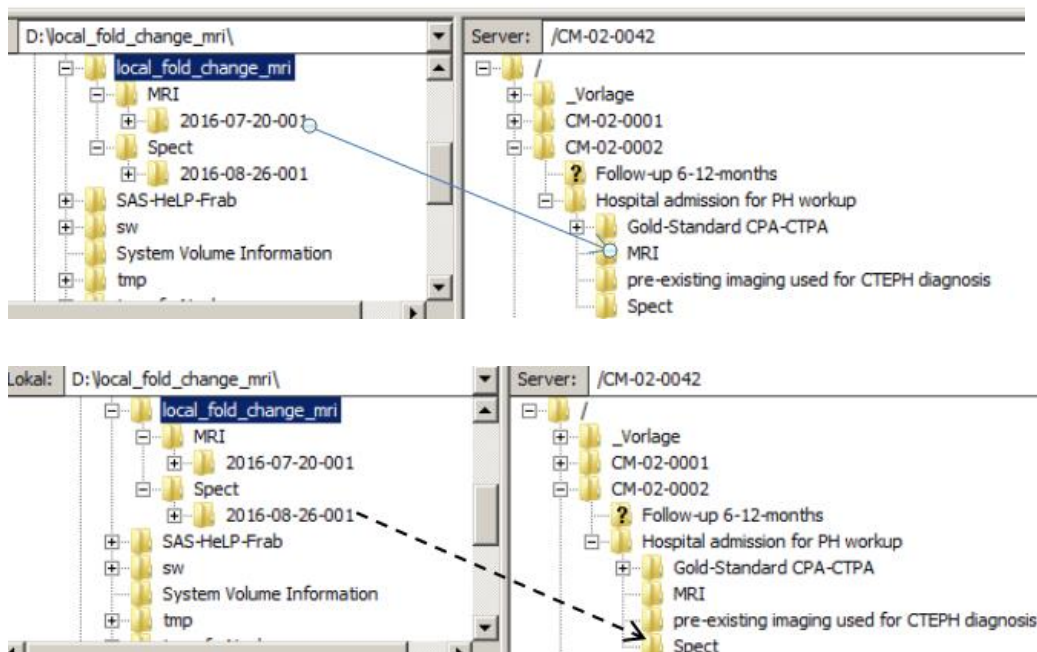
Each study site has on the SFTP-Server a directory tree similar to what is shown in the picture above on the right side. If you are a member of site 2 you only can access the site specific sFTP area for centre 2. If you want to upload files for patient CM-02-002 go the respective directory. There you 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 person<sup>1</sup> 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](mailto:Change-MRI-DM@mh-hannover.de). You and the individuals will then be provided with login details and the required information.

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<sup>1</sup>This must be a known person to the Change-MRI management