



PHIL

*The Pharmacometrics
Integrated Landscape*



Training for Externals





What is PHIL?

The “Pharmacometrics Integrated Landscape” (PHIL) is the new validated cloud based IT landscape for our Pharmacometrics department.

It provides:

- The central file repository for data, models, code, documentation
- Traceability of data flows
- Project specific integrated communication
- Validated data import from multiple sources
- Support for quality control
- Interactive development environments

It will be continuously extended to provide

- Execution environments for R, SAS, NONMEM, OSP
- Support for output generation and publishing



What does PHIL mean for collaboration

Our partners get read and write access to files in PHIL.

This allows:

- Download of source data
- Upload of new files
- Upload of external actions with their results
- Traceability and QC support
- Integrated communication

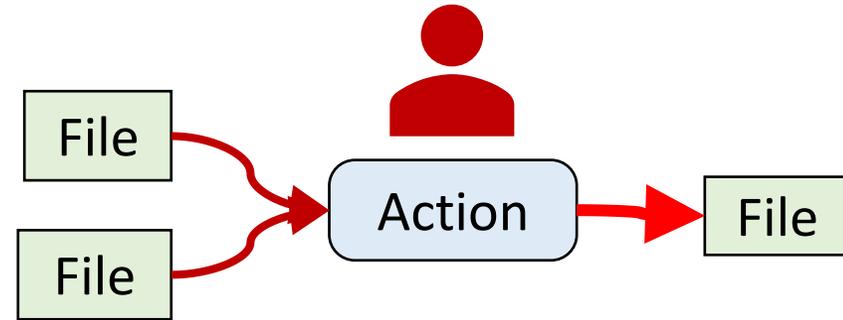


Files and Actions

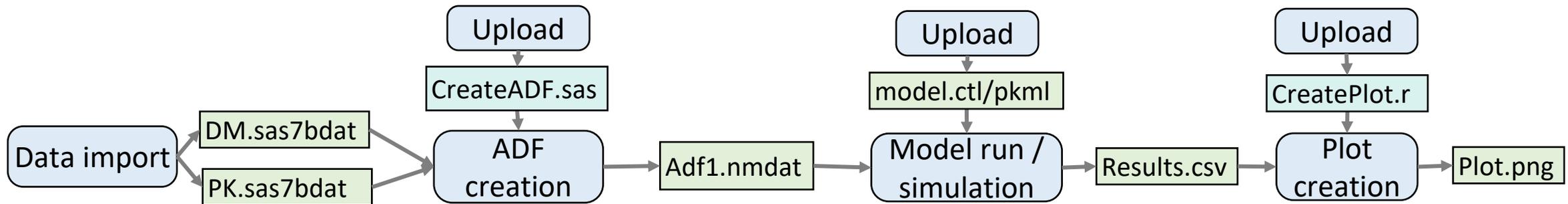
PHIL is more than a file repository, it

- handles versioning of files
- keeps track of the actions on files and
- provides communication features.

Actions consume input files and produce output files:



Example:



The stored action-file relationships provide traceability of the data flow.

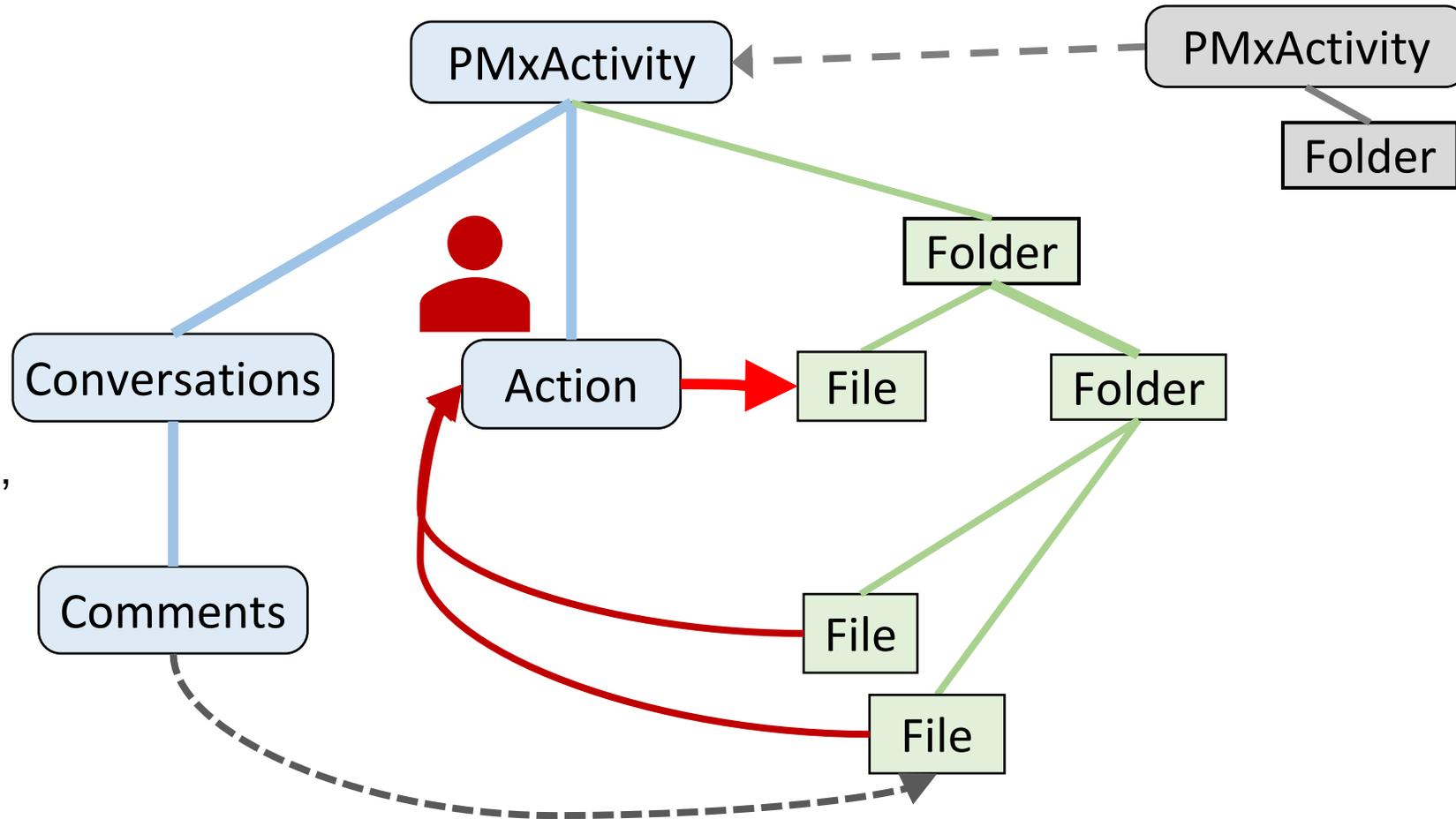


Important entities in PHIL

Files, Actions, and communication are organized in Activities

A PMxActivity can reference multiple other public PMxActivities as “read only”!

Conversations consist of Comments, which can reference files.





Support of quality management

The stored action-file relationships provide besides traceability also effective support of quality management: This consists of **quality control of actions** (single work steps) documented as QC status by the user and computation of **validity of files** (under GxP) based on the QC status of all actions involved in its production by PHIL.

The meaning of the QC status is slightly different for

- actions for import/upload of files into PHIL completely created in other systems
- actions which produce output files based on input files from PHIL

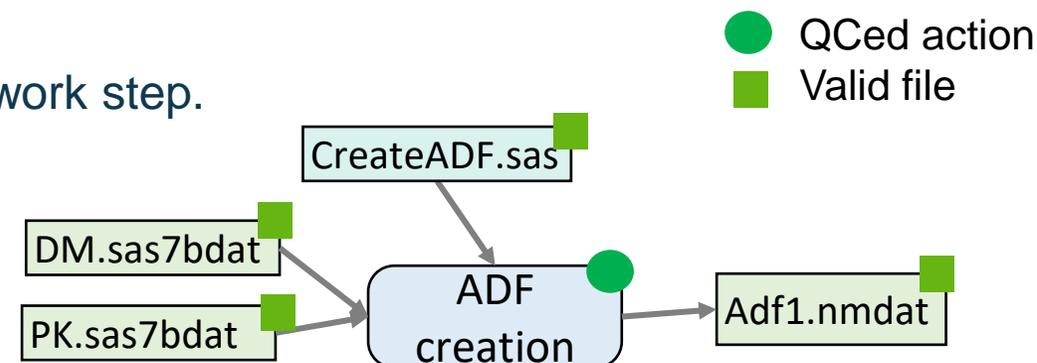
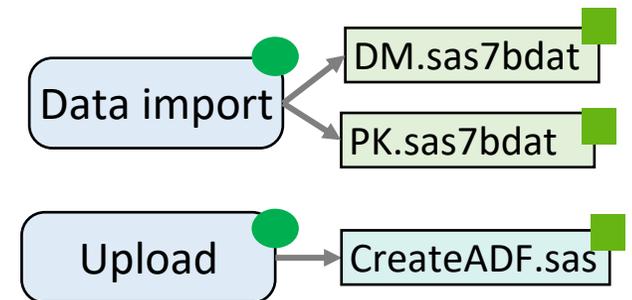
a) The QC status of an Import/"Upload file" Action relates to the whole workflow producing the uploaded/imported file.

The output file uploaded/imported by a "QCed" Action is considered as valid.

b) The QC status of an action (e.g. "Uploaded external action") producing output files from input files in PHIL relates just to that work step.

The output files of an Action are computed to valid, if and only if

- the Action (executed in a GxP validated environment) is "QCed" (quality controlled)
- AND all input files are valid.





PHIL live demo

<https://pmx.int.bayer.com>



Register at PHIL

Steps:

1. Get E-mail
2. Change password
3. Attend training

1

Welcome to Bayer PHIL

Von:

Hi,

You have been invited to Bayer PHIL.
 Your username is **Sample**, your temporary password is **I&Jeo20Y**
 You can go to <https://dev.pmx.int.bayer.com/> in order to login.

Kind Regards,
 Your Bayer Team

3

PHIL Activities Actions More

Welcome to the PHIL training page!

Please follow the instructions below to get access to PHIL

1. Read the training slides. Additionally, you are free to watch the training video for a better comprehension of PHIL.
2. Confirm that you have conducted and understood the training slides.
3. After pressing the confirmation button, you will be redirected to the PHIL login page. Re-login into PHIL in order to successfully complete the training confirmation.
4. Inform your Bayer partner that you have completed the training.

PHIL Training Video

The training video serves as a supplement to the training slides. It is recommended to watch it in addition to the slides.

PHIL Training Slides

The training slides contain the most important information about PHIL as well as short explanations of its functionalities.

[Read Training Slides](#)

2

Sign in with your corporate ID

[Bayer](#)

Sign in with your username and password

Username

Password

or

[Forgot your password?](#)

[Sign in](#)

Need an account? [Sign up](#)

Change Password

Please enter your new password below.

New Password

Enter New Password Again

- ✓ Password must contain a lower case letter
- ✓ Password must contain an upper case letter
- ✓ Password must contain a special character
- ✓ Password must contain a number
- ✓ Password must contain at least 8 characters

[Send](#)



Login at PHIL

Steps:

- Go to **<https://pmx.int.bayer.com>**
- Sign in with username and password
- You see now a list of all PMx Activities you have access to
- Select the Activity you want to work in

Sign in with your corporate ID

Sign in with your username and password

Username

Sample

Password

.....

[Forgot your password?](#)

Sign in

Need an account? [Sign up](#)

Activities:

- Name: PMx study number
- Each Activity stores its files in one repository
- To each Activity, repositories of other Activities can be attached to with read-only access
- Organize the work consisting of many actions and conversations

PHiL Activities Actions More ▾

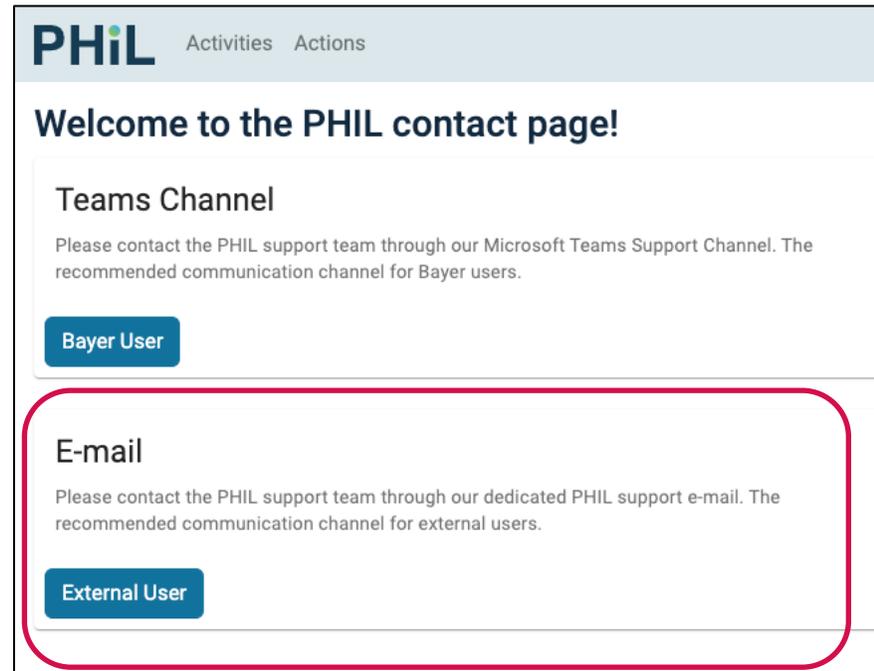
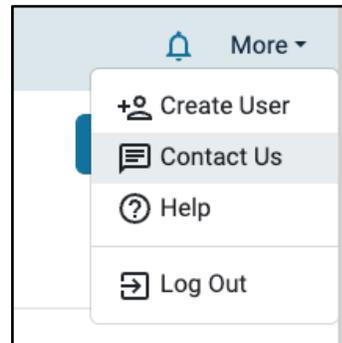
My Activities Create New

PMX Study No.	BayNumber	Project ID	Type
JPMX0001	BAY12345	P001	Standard
CPMX0816	BAY12345	P001	Standard



Contact us

- Contact information can be found under “More” → “Contact Us”
- As external user, please contact us via E-mail
- E-Mail address:
54888d1d.bayergroup.onmicrosoft.com@emea.teams.ms





File explorer

- The file explorer allows you to navigate through the available activities:
 - The main activity with read-write permission is always on the top (marked by black font)
 - Read-only activities are listed below (marked by gray font)
 - Inside read-only activity: files can be downloaded and copied into main activity
- Inside the main activity:
 - Files can be renamed, moved, copied, and hidden.
 - New folders can be created (Button on top of the file list)
- Note: Due to GxP-regulations, files cannot be deleted, but using hide makes them disappear for users in the file explorer view.

The screenshot displays the File Explorer interface for a project named 'Demo_Franziska_1'. The interface is divided into three main sections: a left sidebar, a middle tree view, and a right main view.

Left Sidebar: Shows a 'File Explorer' section with a 'Conversations' button. Below it, there are two tree views for 'Demo_Franziska_1' and 'Test_Thomas', listing various folders and files.

Middle Tree View: Shows the current directory structure, including folders like 'Input_data', 'Objectives', 'QC', 'Reporting', 'Scripts', 'TestFileTransfer1', and 'TestFileTransfer2', along with files like 'ae.sas7bdat', 'Doc2 copy 15.docx', etc.

Right Main View: Displays a table of files with columns for Name, Size, Last Updated Date, and Last Updated By. A context menu is open over the file 'Doc2 copy 5.docx', showing options such as Download, Compress & Download, Generate External Download Link, Hide, Rename, Move, Copy, Creating Action, and Properties.

Name	Size	Last Updated Date	Last Updated By
Input_data			
Objectives			
QC			
Reporting			
Scripts			
TestFileTransfer1			
TestFileTransfer2			
ae.sas7bdat	648 KB	2023-05-11 09:33:41	radu.nicoara@protonmail.com
Doc2 copy 15.docx	5:26		franziska.hellmundt@bayer.com
Doc2 copy 28.docx	5:27		franziska.hellmundt@bayer.com
Doc2 copy 32.docx	5:28		franziska.hellmundt@bayer.com
Doc2 copy 5.docx	5:25		franziska.hellmundt@bayer.com
Test_large_archive.zip	2:05		franziska.hellmundt@bayer.com
test_upload.txt	1:50		ruby.lim@bayer.com
test1705925.txt	1:50		ruby.lim@bayer.com



Conversations

To communicate about Activity related topics, use the Conversation tool (see sidebar)

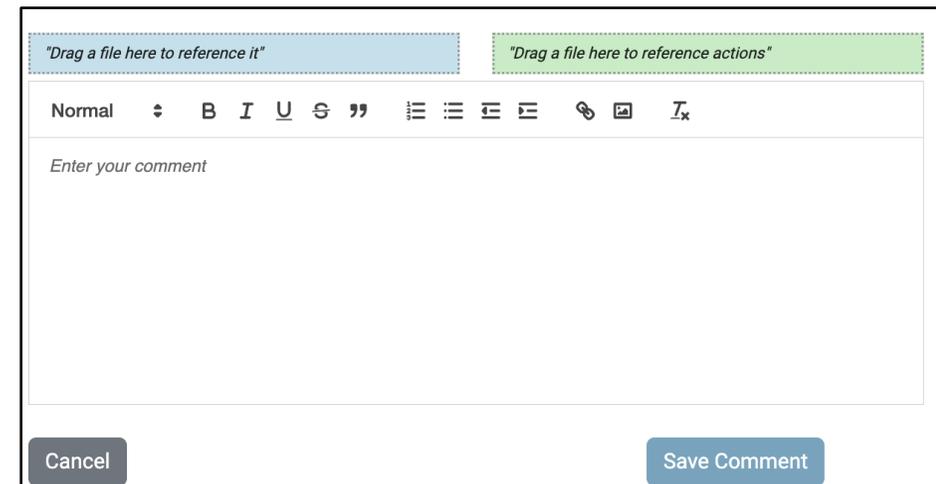
The screenshot displays the PHIL interface with the following components:

- Header:** PHIL logo, Activities, Actions, Token.
- Left Sidebar:** Test_Thomas profile, File Explorer, and Conversations (highlighted with a red box and a '2' notification badge).
- Main Content Area:** File Explorer view for Test_Thomas, showing a tree structure of folders (Input_data, Objectives, Objectives08, QC, Reporting, Scripts, Tools) and files (AE_metadata.csv, AE.csv, DM_metadata.csv, DM.csv, test.txt).
- Right Panel:** A conversation window titled "Datantalk" containing a list of messages:
 - Message 1: "do we still need this" (sent 05/01/2023 10:29).
 - Message 2: "please test" (sent 05/01/2023 13:55).
 - Message 3: "ACTION ID 39206" header, "can you review?" (sent 06/02/2023 09:02).
 - Message 4: "ACTION ID 39206" header, "Yes" (sent 06/02/2023 09:05).
 - Message 5: "Thomas Gaub" (sent 06/02/2023 09:06).
 - Message 6: "ACTION ID 39206" header, "Replied to: 'Yes'" (sent 06/02/2023 09:06).



Read and write comments

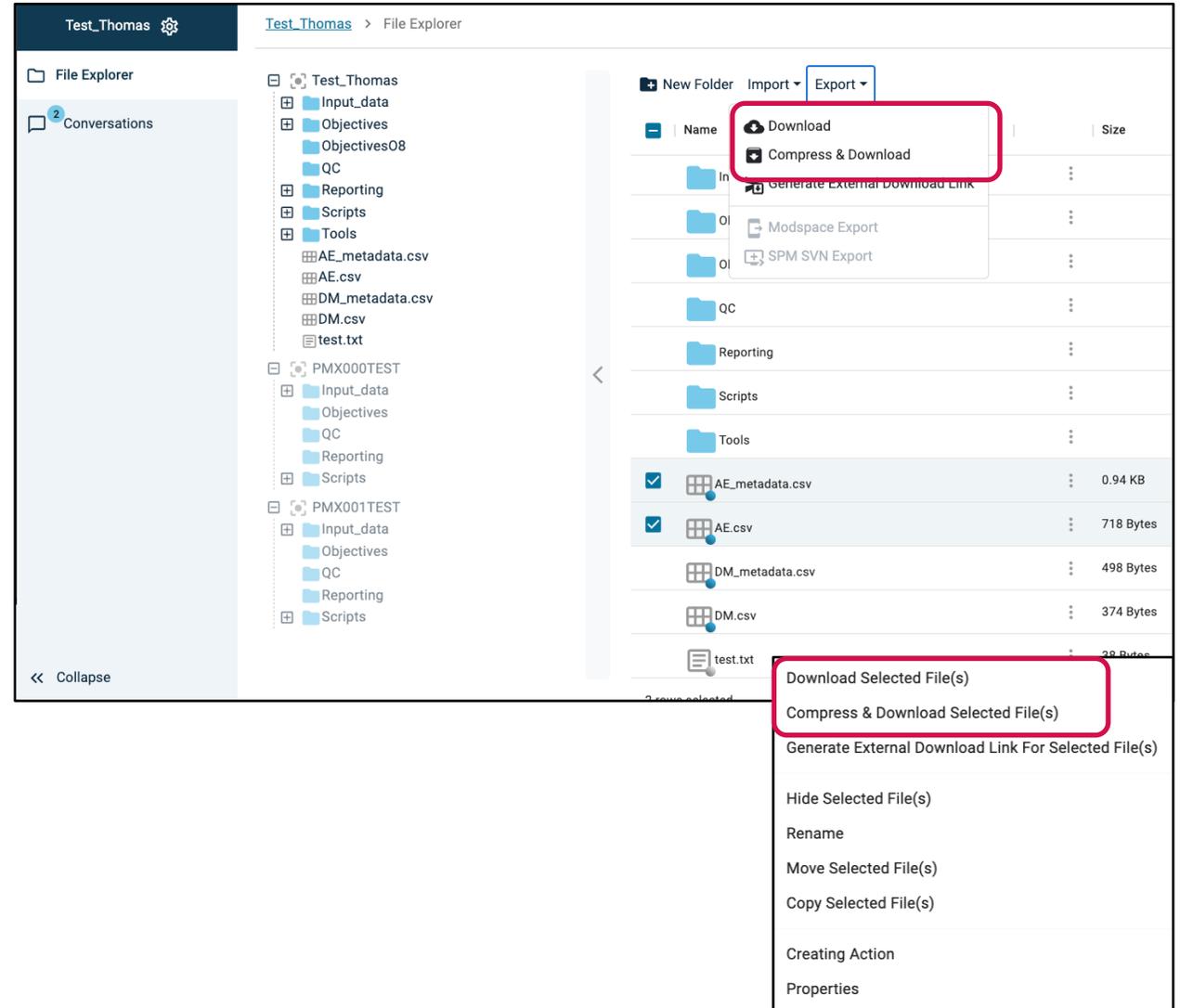
- You can select a previously created conversation (Drop down) or create a new one (Plus button)
- Under each conversation, multiple comments can be created
- In one conversation, you can:
 - Create a new comment (scroll to the bottom)
 - Reply to an existing comment (arrow on the bottom of a comment; the little pen allows you to edit the comment, if you created it)
 - Reference people by using @USERNAME. The corresponding user will be notified via mail
 - Link to files, via dragging & dropping the corresponding files into the comment
 - As reference to the file (Drag & drop file into the blue box)
 - As reference to the creating action of one file (Drag & drop file into the green box)





Download

- Navigate to the relevant folder
- Select one or multiple files by clicking on the checkboxes next to them (appear by hovering over them)
- Select the menu item “Download” under “Export” or in the context menu next to the files (Tree dots)
- To compress files in a zip folder, select “Download & compress”. This download option can also be used for folders.

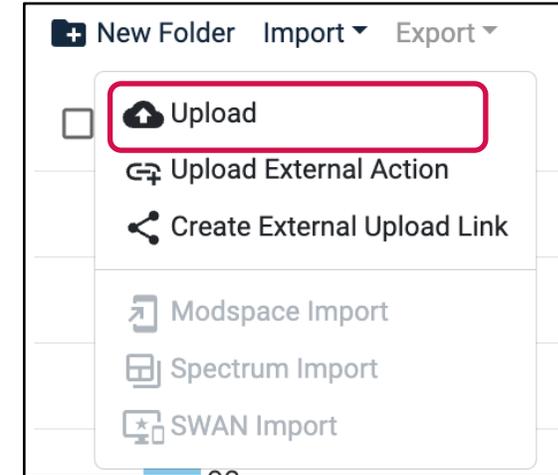




Upload files

- Navigate to the folder in which the files should be uploaded
- Select the menu item “Upload” under “Import”
- Add files via
 - Clicking on “Choose files” → Navigate through the open files dialogue
 - Drag & drop files from local file explorer
- Add a description
- Specify the quality control status (For options see slide 11)

Note: Large files might need a bit longer to upload

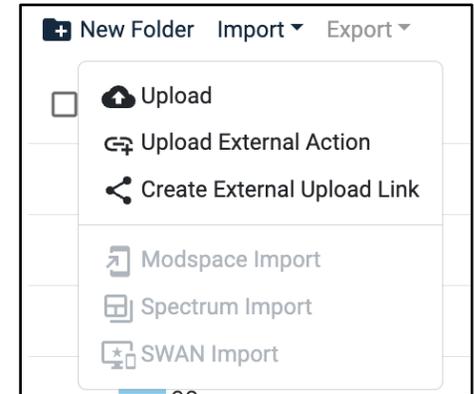
A screenshot of a dialog box titled 'Upload File to /'. It contains a 'File *' section with a 'Choose files' button and a 'No file chosen' label. Below this, a file named 'PopulationData.xlsx' is listed with a close button 'x'. The 'Upload Description' section has a text input field containing 'New data set'. The 'Quality Controlled Status' section has a dropdown menu set to 'QCed'. At the bottom right, there are 'Cancel' and 'Upload' buttons.



Upload external actions

Next to the simple “Upload”, PHIL offers the option to specify the upload with additional information on how uploaded files were created, i.e., what action was used and which files from PHIL had been used as input. Thereby, traceability information is created.

- Navigate to the folder in which the files should be uploaded
- Select the menu item “Upload External Action” under “Import”
- Specify the action type and assign the files:
 - New Result Files – new files which have been created through the action
 - Input Files from PHIL – files which have been previously downloaded from PHIL and used as input to create the new result files
 - Describing Files – additional files which are related to an Action, e.g., log file, additional documentation, DISL file. Describing files are not included in the validity computation.
- Set the Quality Controlled Status of the Action you performed
- Optionally, a description can be added

A screenshot of a dialog box titled "Upload External Action into '/'". It contains several sections: "New Result Files" and "Input Files from PHIL", each with a "Choose files" button and "No file chosen" text; "Describing Files" with a "Choose files" button and "No file chosen" text; "Upload Description*" with a text input field containing "Enter description"; "Quality Controlled Status" with a dropdown menu set to "None"; and "Action Type" with a dropdown menu set to "ADF Creation". A "Cancel" button is at the bottom left, and an "Upload" button is at the bottom right. A separate inset shows the "Action Type" dropdown menu expanded, listing: "ADF Creation" (checked), "Plot Creation", "Report Creation", "Model Execution", and "Other Action".

Note: To ensure traceability, you can only use files as Input Files, which are already present in PHIL. These files will be identified by PHIL, but they will not be uploaded again. If you select a file that is not present in PHIL, you receive an error message and you cannot continue. Of course, you can upload such files before uploading the external action!



File properties – navigation along the data flow

View components:

- File versions (see next slide)
- Creating Actions: every file can only have one creating action
- Consuming Actions

All files listed under Creating/Consuming Actions are links to the properties of the respective file.

Using these links, the user can navigate through the data workflow back and forth!

The screenshot displays the 'Properties of "AE_metadata.csv"' window, which is divided into three main sections: File Versions, Creating Actions, and Consuming Actions. A red rounded rectangle highlights the 'Files' column in the Creating Actions table, which contains links to other file properties.

Revision	Path	Created At ↓	User	Size	Validity	MD5	
1	AE_metadata.csv	2022-11-10 16:28:58	radu.nicoara@bayer.co...	0.94 KB	false	3b5e092c0a52c6533c...	

Total Rows: 1

Id	Revision	Type	Files	QC Status	Executed ... ↓	User	Description
31874	1	SpectrumIm...	Test_Thomas/AE.csv - (1) - Output Test_Thomas/AE_metadata.csv - (1) - Output Test_Thomas/DM.csv - (1) - Output Test_Thomas/DM_metadata.csv - (1) - Output	QC Ready	2022-11-10 16:25:28	radu.nicoara...	

Total Rows: 1

Id	Revision	Type	Files	QC Status	Executed ... ↓	User	Description
47449	1	ModSpaceE...	Test_Thomas/AE_metadata.csv - (1) - Input	None	2023-03-21 08:35:20	thomas.gau...	Tesz

Total Rows: 1



File version

- To inspect the Creating and Consuming Actions for a specific file version, a filter can be set by selecting a version on the top. This allows to follow the usage of one file version.
- The revision number is related to the “path version “ → path + revision number is the unique identifier for an object
 - Renaming or moving a file does not break the file versioning, but changes the file path
 - For a new file path, the revision number starts again with 1

Properties of "UAT_FILETransfer/Data2/newName.txt"

File Versions:

Revision	Path	Created At	User	Size	Validity	MD5	
<input type="checkbox"/>	UAT_FILETransfer/Data2/newName.txt	2023-05-17 09:43:13	franziska.hellmundt@bayer...	35 Bytes	false	4e1522248cc9b1dde0b9719...	
<input type="checkbox"/>	UAT_FILETransfer/Data1/newName.txt	2023-05-17 09:41:10	franziska.hellmundt@bayer...	35 Bytes	false	4e1522248cc9b1dde0b9719...	
<input type="checkbox"/>	UAT_FILETransfer/Data1/test.txt	2023-05-16 13:02:13	franziska.hellmundt@bayer...	35 Bytes	false	4e1522248cc9b1dde0b9719...	
<input checked="" type="checkbox"/>	UAT_FILETransfer/Data1/test.txt	2023-05-16 12:06:11	franziska.hellmundt@bayer...	20 Bytes	false	5dd39cab1c53c2c77cd3529...	

Total Rows: 4

Creating Actions:

Id	Revision	Type	Files	QC Status	Executed At	User	Description
52608	1	Upload	Test_FileTransfer_Franziska/UAT_FILETransfer/Data1/test.txt - (1) - Output	None	2023-05-16 12:06:09	franziska.hellmu...	Test Upload

Total Rows: 1

Consuming Actions:

Id	Revision	Type	Files	QC Status	Executed At	User	Description
52611	1	Download	Test_FileTransfer_Franziska/UAT_FILETransfer/Data1/test.txt - (1) - Input	None	2023-05-16 13:01:39	franziska.hellmu...	



Creating action

To inspect details about the creating action of a file, click on “Creating Action” in the context menu of a file:

- Details include:
 - Type – type of Action
 - User – who conducted the Action
 - Files – list of all the files which were part of the action, labeled as Input, Output, or Describing
 - Write Comment – directly add a comment to an existing conversation, incl. direct referencing of the Action in the comment
- Editable Properties:
 - Possibility to change the Quality Controlled Status
 - Add a Description with details about the Status change
 - Changes can be tracked via the History at the bottom

Edit Action Number 31874

Details

Type	SpectrumImport
Executed At	2022-11-10 16:25:28
User	radu.nicoara@bayer.com
Source Folder	
Environment	PHIL Base System
Status	Success
Status Description	
Additional Details	
Files	<ul style="list-style-type: none">Test_Thomas/AE.csv - (1) - OutputTest_Thomas/AE_metadata.csv - (1) - OutputTest_Thomas/DM.csv - (1) - OutputTest_Thomas/DM_metadata.csv - (1) - Output
Referenced Comment #12184 Conversation: Datantalk	Please Review <small>thomas.gaub@bayer.com - 09/02/2023 09:27</small>
Write Comment	<input type="text"/> Write Comment in Conversation

Editable Properties

Description:

Quality Controlled Status:

History

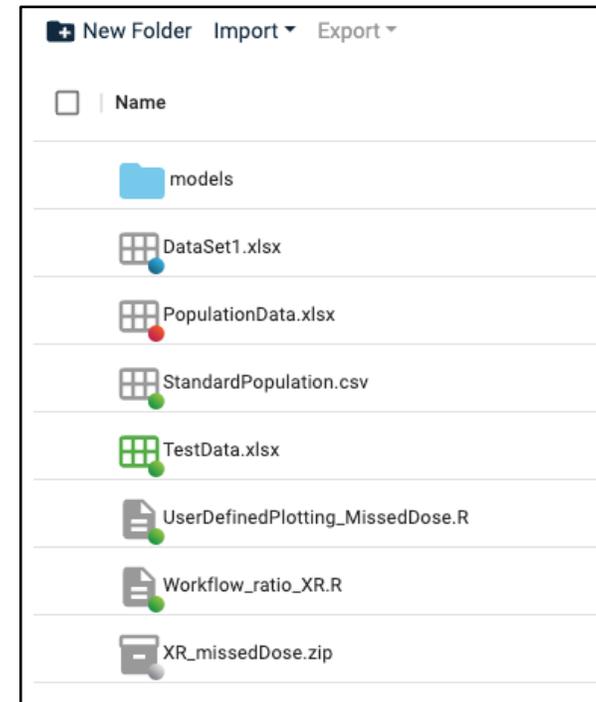
Date	User	Old Data	New Data
2023-02-21 07:37:18	thomas.gaub@bayer.com	{\"description\": \"\", \"qualityCheckStatus\": \"QCed\"}	{\"description\": \"]]]]\", \"qualityCheckStatus\": \"QC Ready\"}
2023-01-27 08:46:40	thomas.gaub@bayer.com	{\"description\": \"\", \"qualityCheckStatus\": None}	{\"description\": \"\", \"qualityCheckStatus\": \"QCed\"}
2022-11-10 16:25:28	radu.nicoara@bayer.com		{\"description\": \"\", \"qualityCheckStatus\": None}

Cancel



File explorer – Quality management

- Icons of single files indicate information about the quality control status of actions and the validity of files
- Hovering over the icons explicitly mentions the status
 - Color of the icon:
 - Gray: File is not valid
 - Green: File is valid
 - Color of the little dot:
 - Gray: Creating Action's QC status is undefined
 - Blue: Creating Action is ready for QC
 - Green: Creating Action is QCed
 - Red: Creating Action's QC failed

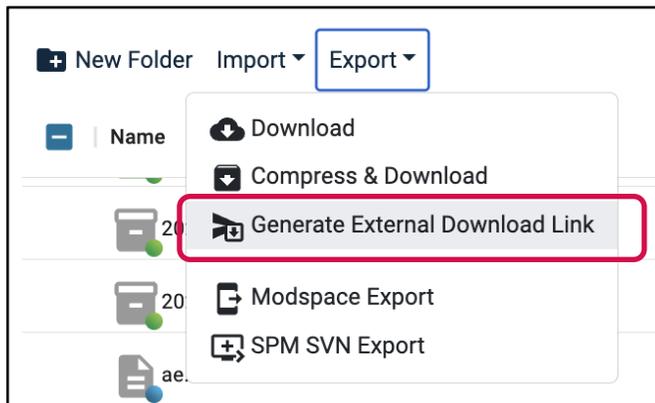




Download files via an external download link

- People who have no access to PHIL can download files via links
- These links need to be provided from someone with PHIL access:
 - Select files, which should be downloaded
 - Select the menu item “Create External Download Link” under “Export”
 - Specify the recipient and add a message if required and send the link
 - A link will be sent via E-Mail to download the files

Note: The external download link has an expiration date of 10 days



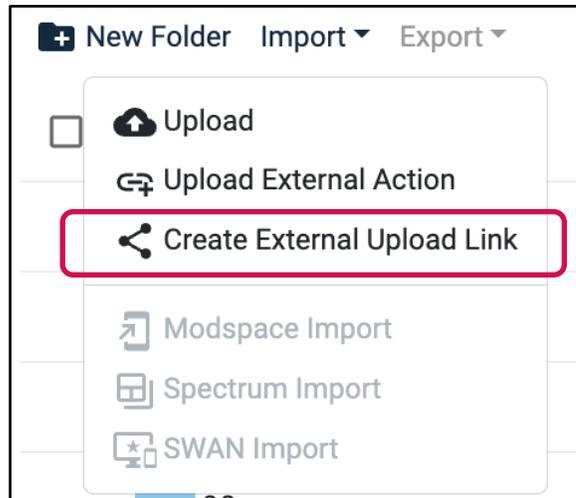
A screenshot of the 'Create External Link for Downloading' dialog box. The dialog has a title bar with a close button (X). The main content area is divided into sections: 'Generating Link for downloading files:' with a list of files (AE_metadata.csv, AE.csv); 'Recipient Email Address' with a text input field containing 'Enter an Email Address'; and 'Additional Message' with a text area containing 'Enter additional message'. A 'Send Link' button is located at the bottom right of the dialog.



Upload files via an external upload link

- People who have no access to PHIL can upload files via links
- These links need to be provided from someone with PHIL access:
 - Browse to the folder in which the files should be uploaded
 - Select the menu item “Create External Upload Link” under “Import”
 - Specify the recipient and add a message if required and send the link

Note: The external upload link has an expiration date of 10 days



A screenshot of the 'Create External Link for upload into "/" form. The form has a title bar with a close button (X). It contains two input fields: 'Recipient Email Address' with a placeholder 'Enter an Email Address' and 'Additional Message' with a placeholder 'Enter additional message'. A 'Send Link' button is located at the bottom right of the form.



Trainings video

Should we link to the trainings video?