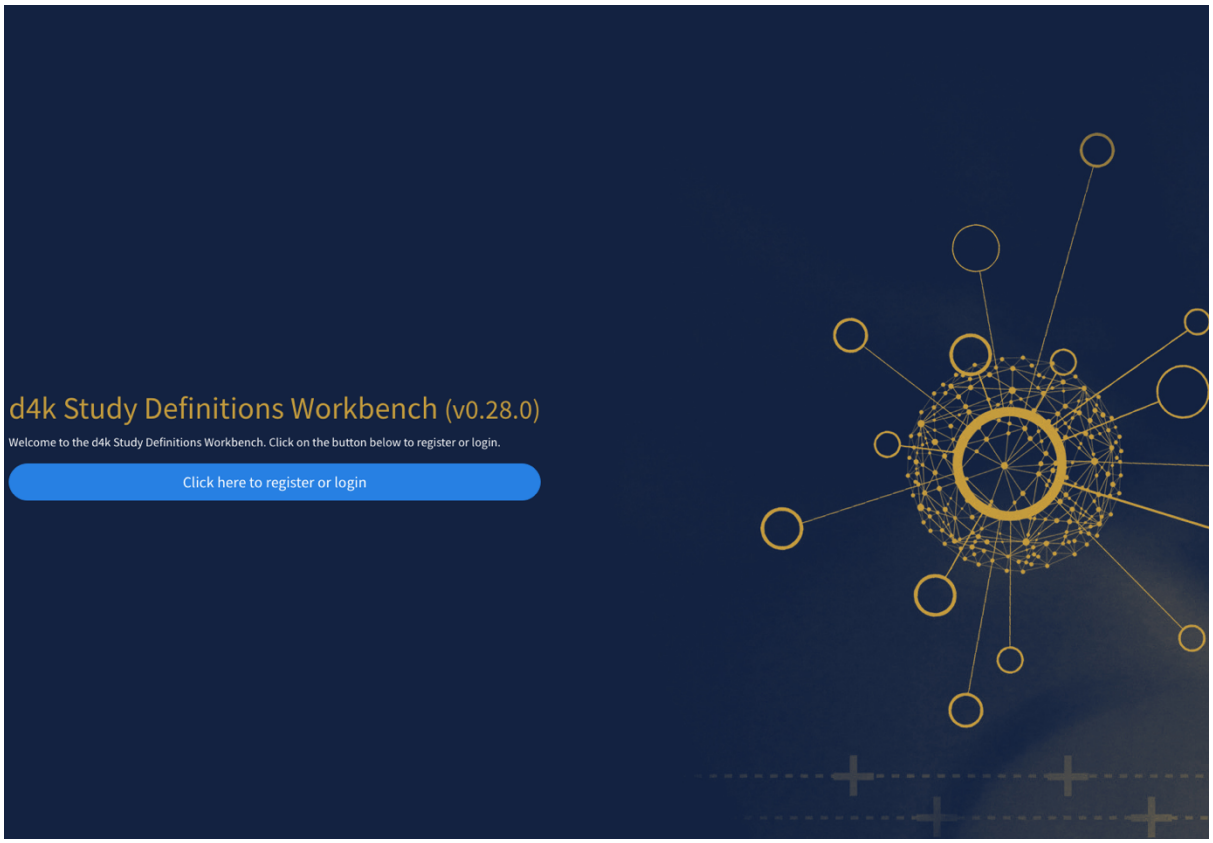
Study Definitions Workbench User Guide

Dave Iberson-Hurst, 22nd December 2024, Version 0.30.0

Access

Go to https://d4k-sdw.fly.dev/



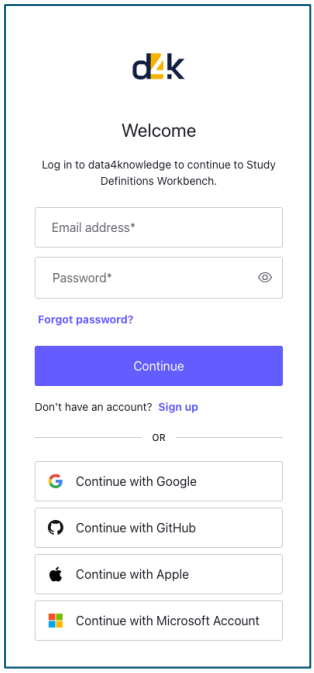
Click on the large button.

Note:

1. *The version will change on this splash screen.*
2. *The tooling is a beta, expect one or two issues.*

Sign Up & Login

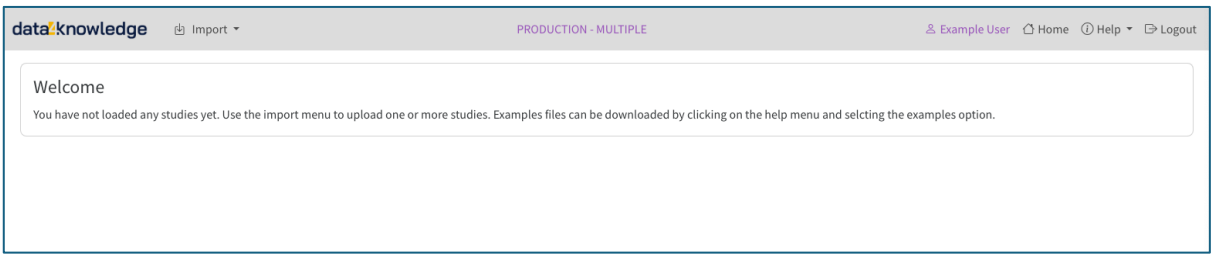
You should see a login / sign up screen.



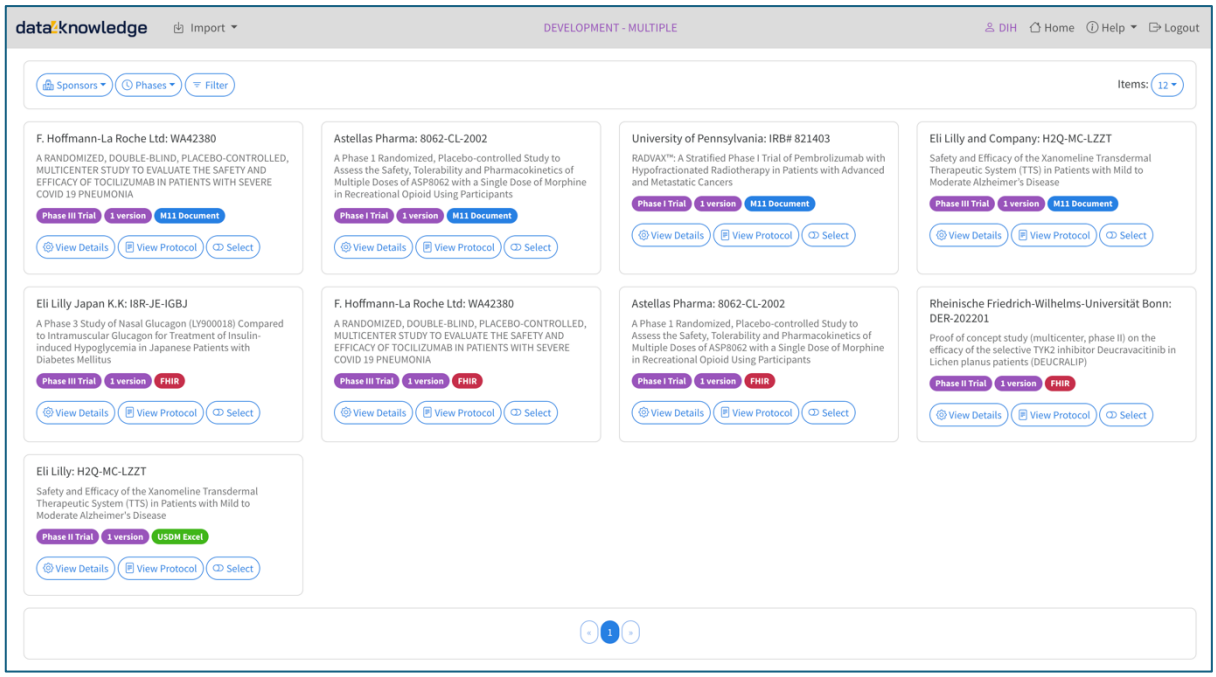
If you do not have an account, please sign up using the available options (email / password, Google, GitHub, Apple or Microsoft- not Office365). Otherwise, login as normal.

Home Page

You should see the home page. On first entering the system no data will be loaded. You can always return to the home page by clicking the “Home” menu option (top right) or clicking the logo image (top left).

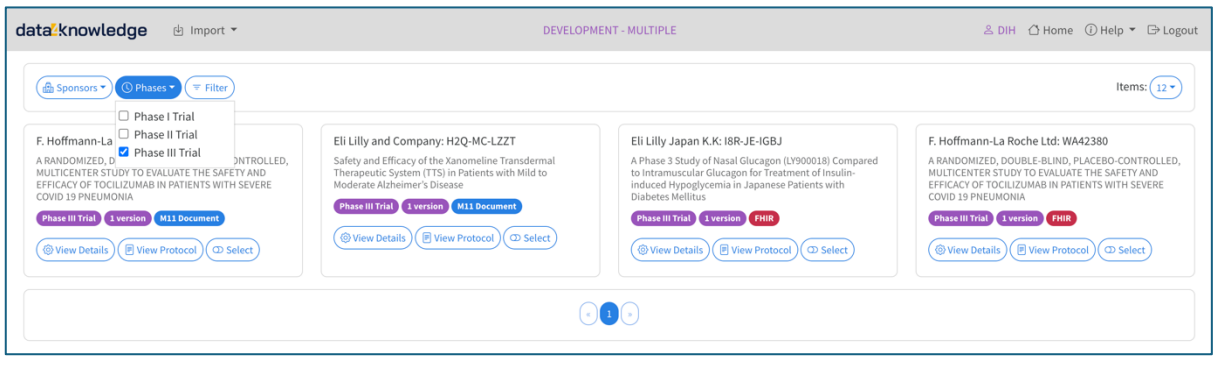


When the home page has items to display (see import below), it will display a default 12 items per page. with an ability to page through items and change the number of items per page.



The page navigation is at the bottom of the display while the page size can be selected at the top right.

There is also a filter mechanism at the top left. Select a combination of the sponsor and/pr phase and click the filter button. Note that the sponsor names and phases are built from the set of studies loaded not all possible values.



Import Data

Currently three types of import are supported:

1. M11 Word Document (.docx)
2. M11 FHIR Message (.json)
3. USDM Excel (.xlsx)

Example M11 Word or USDM Excel files are available via the Help-> Examples (top right) menu.

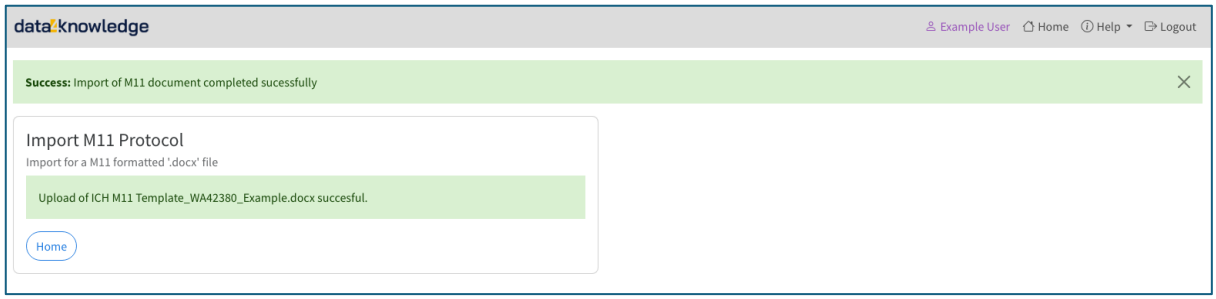
When data is imported the system maintains separate versions for each study and by type of import. For example, Protocol X loaded from a M11 '.docx' file is kept separate from Protocol X loaded from a FHIR JSON file. This allows them to be compared. The coloured pills indicate the type of load (see below).

M11 Protocol in MS Word (.docx) Import

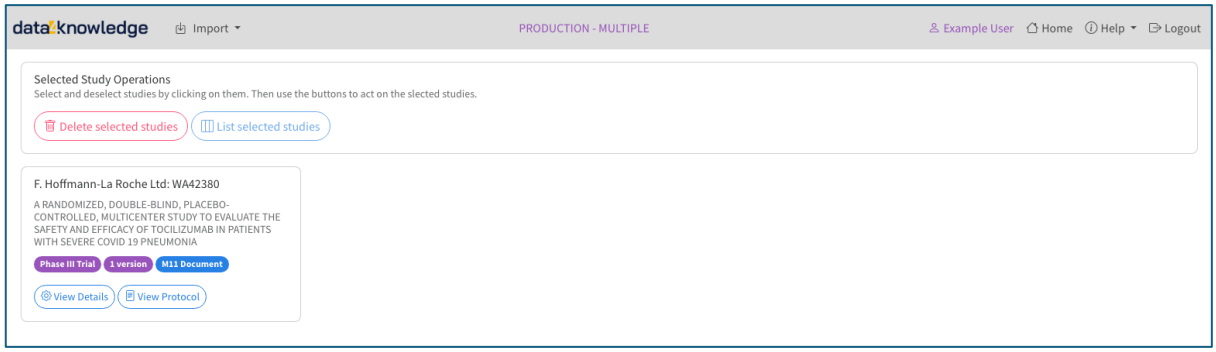
Click on the import menu and select the M11 Document option. The import page will be displayed.

Click "Choose Files" and use the normal file selection mechanism to select a single M11 Protocol Word document.

Click "Upload File(s). The system will respond saying the file is uploaded and then shortly after a "success" message should appear as follows.

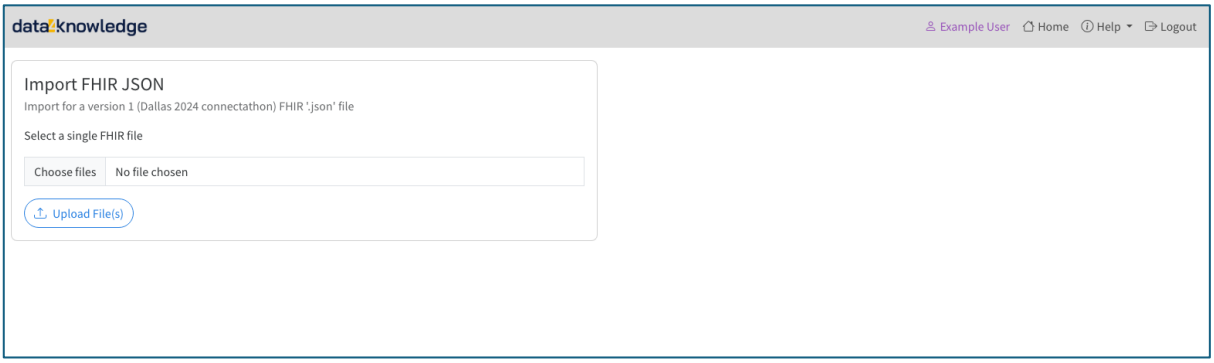


Return to the home page. An entry for the file loaded should be present containing high level information about the protocol. Note the blue “M11 Document” load type indicator.



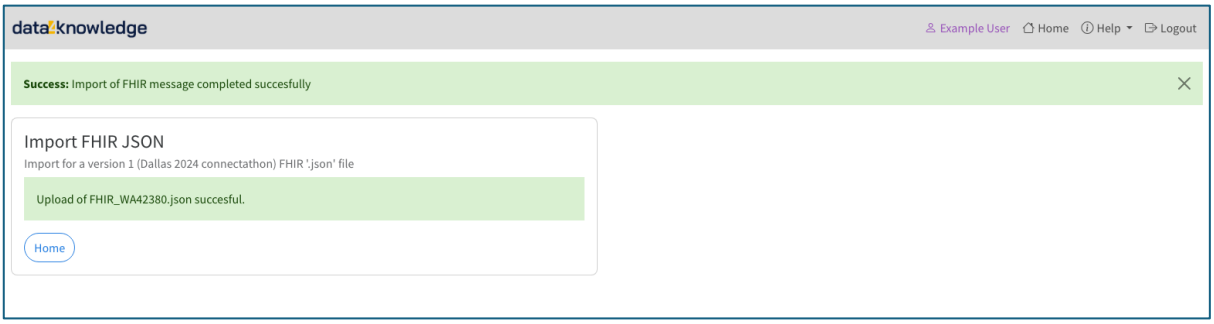
M11 Protocol in FHIR V1 Message (.json) Import

Click on the import menu and select the M11 FHIR v1 option. The import page will be displayed.

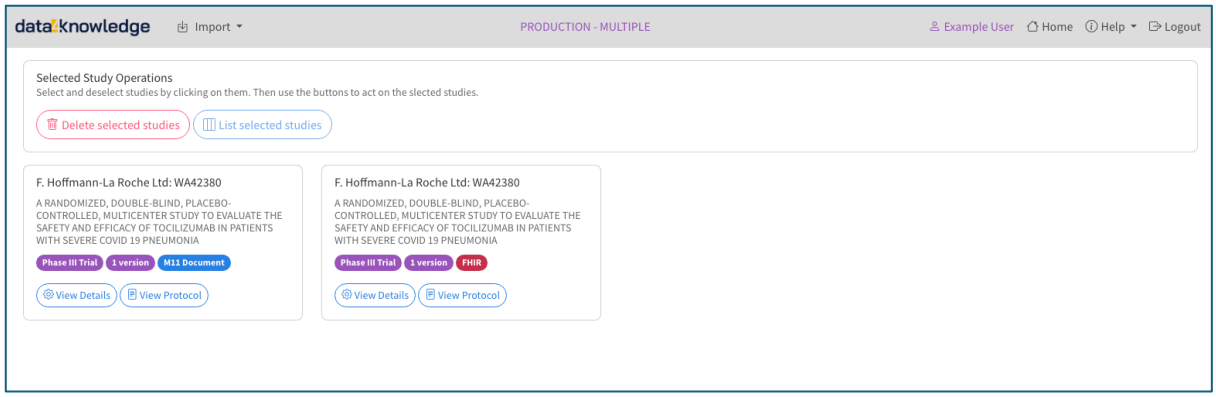


Click “Choose Files” and use the normal file selection mechanism to select a single M11 FHIR JSON file.

Click “Upload File(s). The system will respond saying the file is uploaded and then shortly after a “success” message should appear as follows.



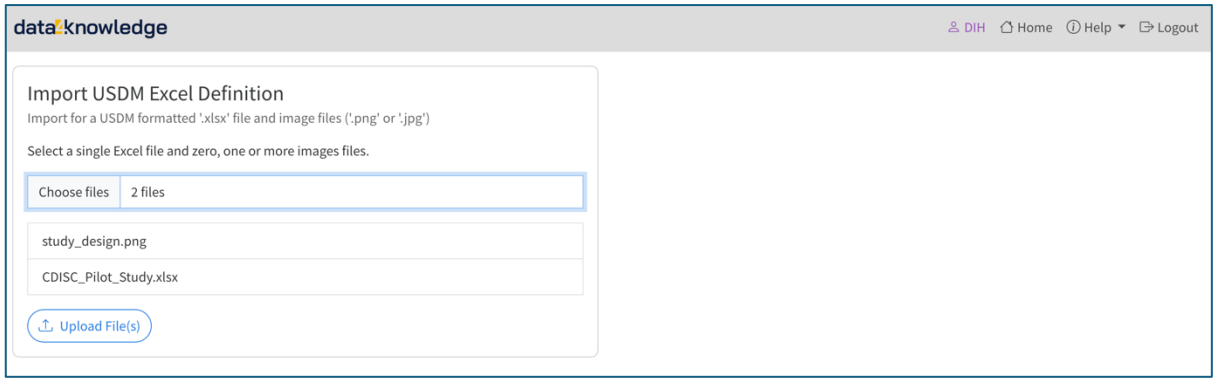
Return to the home page. An entry for the protocol loaded should be present. Note the red “FHIR” type indicator.


data4knowledge
Import
PRODUCTION - MULTIPLE
Example User
Home
Help
Logout
Selected Study Operations
Select and deselect studies by clicking on them. Then use the buttons to act on the slected studies.
Delete selected studies
List selected studies
F. Hoffmann-La Roche Ltd: WA42380
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH SEVERE COVID 19 PNEUMONIA
Phase III Trial
1 version
M11 Document
View Details
View Protocol
F. Hoffmann-La Roche Ltd: WA42380
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH SEVERE COVID 19 PNEUMONIA
Phase III Trial
1 version
FHIR
View Details
View Protocol

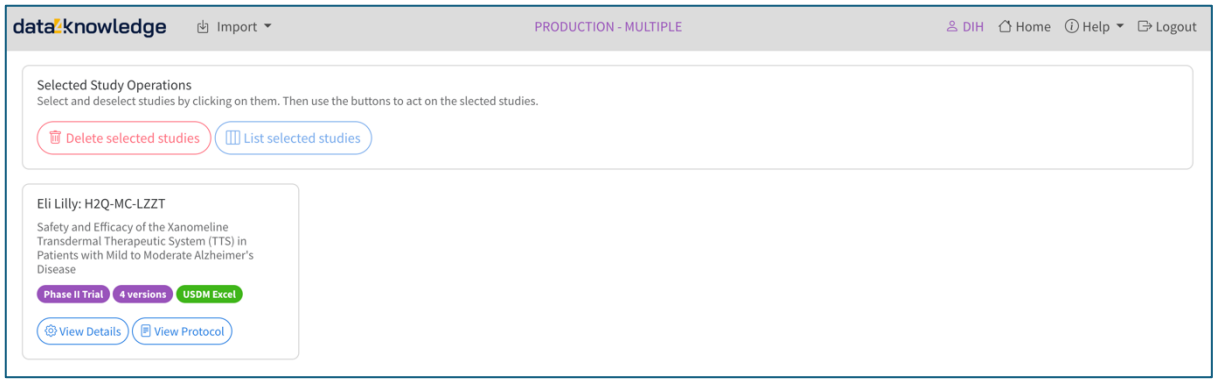
USDM in MS Excel (.xlsx) Import

Click on the import menu and select the USDm Excel option. The import page will be displayed.

Click “Choose Files” and use the normal file selection mechanism to select a single USDM Excel file and any associated image files required to render the protocol document.



Click “Upload File(s). The system will respond saying the file is uploaded and then shortly after a “success” message should appear. Return to the home page.


data4knowledge
Import
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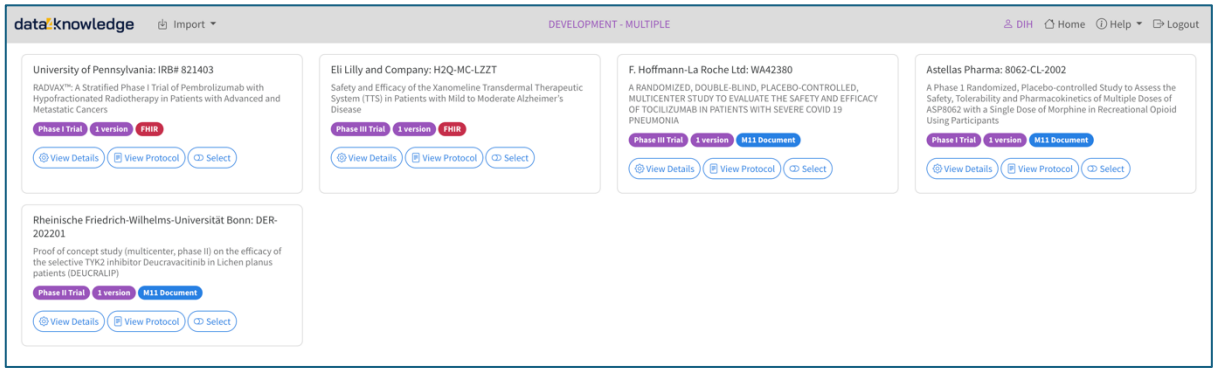
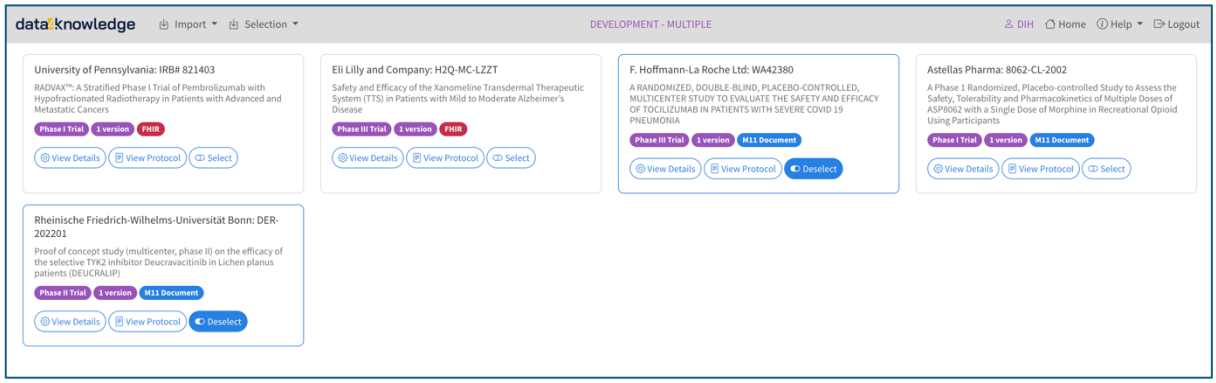
Selected Study Operations
Select and deselect studies by clicking on them. Then use the buttons to act on the slected studies.
Delete selected studies
List selected studies
Eli Lilly: H2Q-MC-LZZT
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease
Phase II Trial
4 versions
USDM Excel
View Details
View Protocol

Side By Side Page

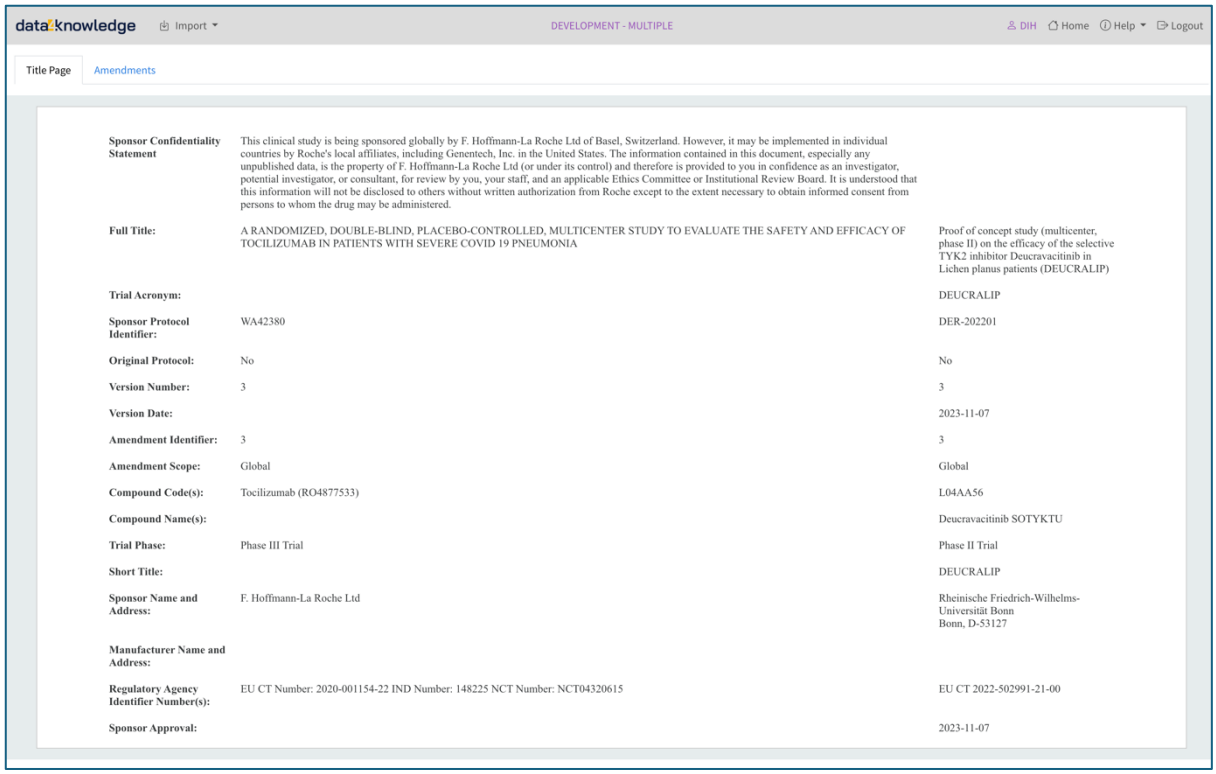
Select two or more protocols by clicking on the select button within the relevant items, you should see a blue border appear around the selected items.



When one or more items are selected a new menu item, “Selection”, will appear in the menu bar. Click the button again to de-select, it is just a toggle.



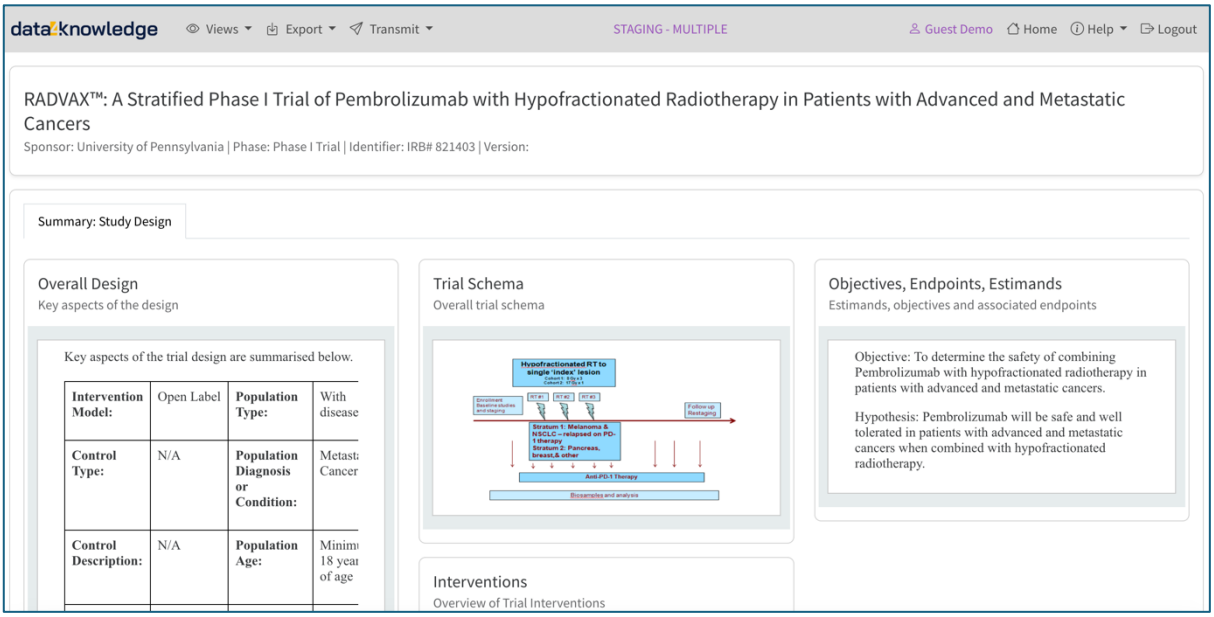
Click on the “Selection” menu item and then the “List Selected Studies” option. You should see something like the following.



Click on the Home button (top right) or the logo (top left) to get back to the home page.

Details Page

From the home page, clicking the “View Details” button for a study will get you to the details view. Use the view menu at the top to see the other views.



Export

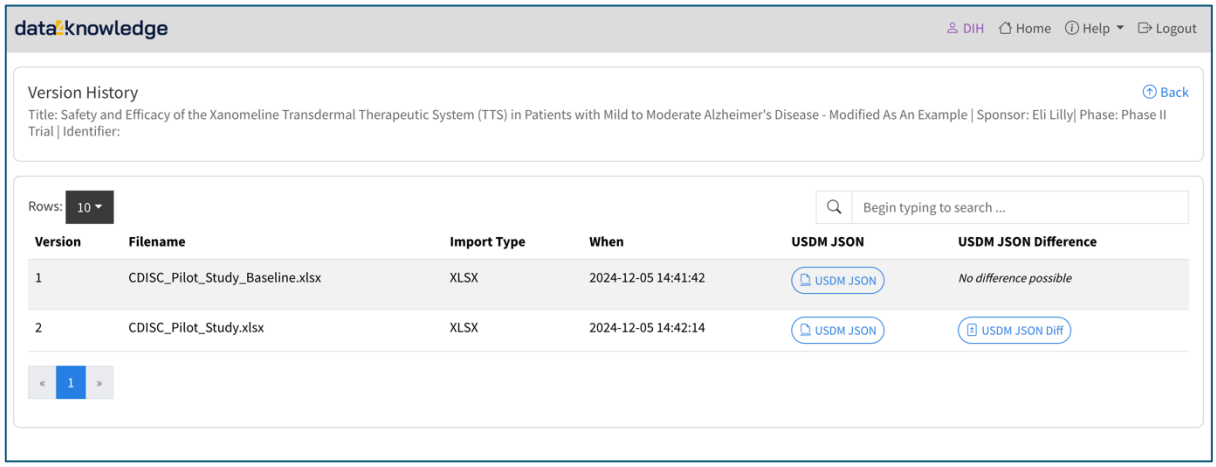
The Export menu on the details view page allows for a study to be exported as a

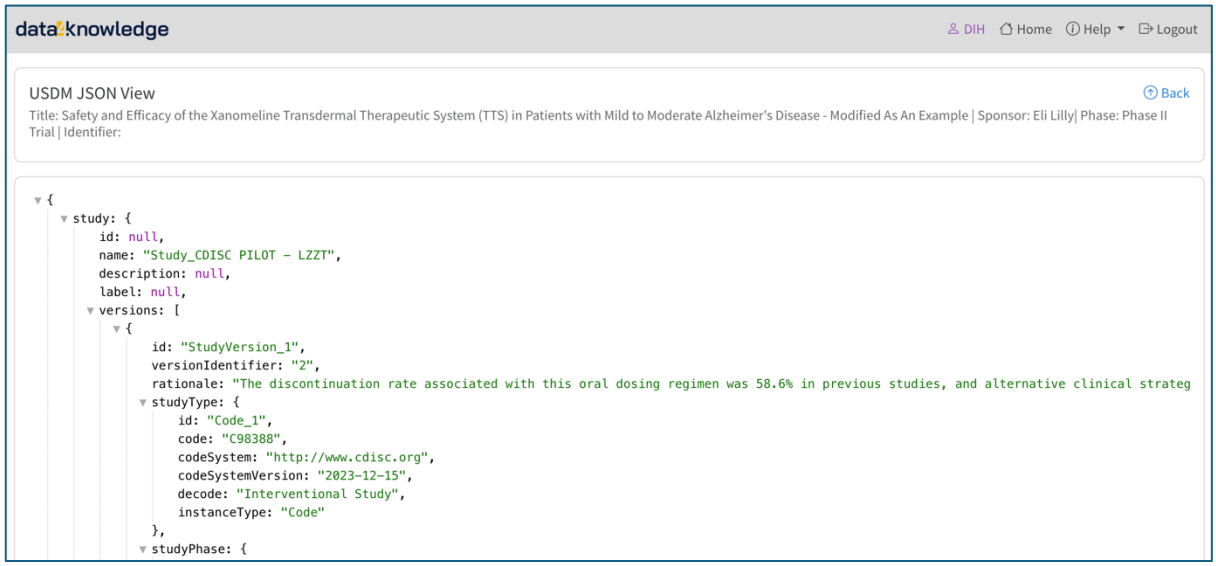
1. FHIR v1 message in JSON format
2. USDM model in JSON format
3. The protocol rendering as a PDF

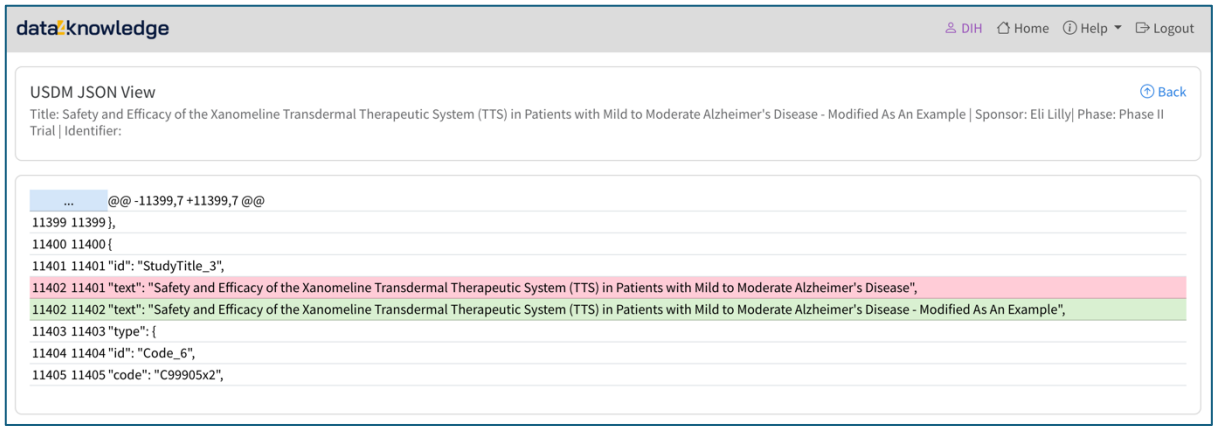
The downloads work in the standard way.

Version History and Differences

The version history for a given study / protocol and import type can be viewed via the details page. The USDM JSON can be viewed and, if multiple versions are stored, the differences can be inspected.






data knowledge
DIH
Home
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Logout
USDM JSON View
Back
Title: Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease - Modified As An Example | Sponsor: Eli Lilly| Phase: Phase II Trial | Identifier:
... @@ -11399,7 +11399,7 @@
11399 11399 },
11400 11400 {
11401 11401 "id": "StudyTitle_3",
11402 11401 "text": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
11402 11402 "text": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease - Modified As An Example",
11403 11403 "type": {
11404 11404 "id": "Code_6",
11405 11405 "code": "C99905x2",