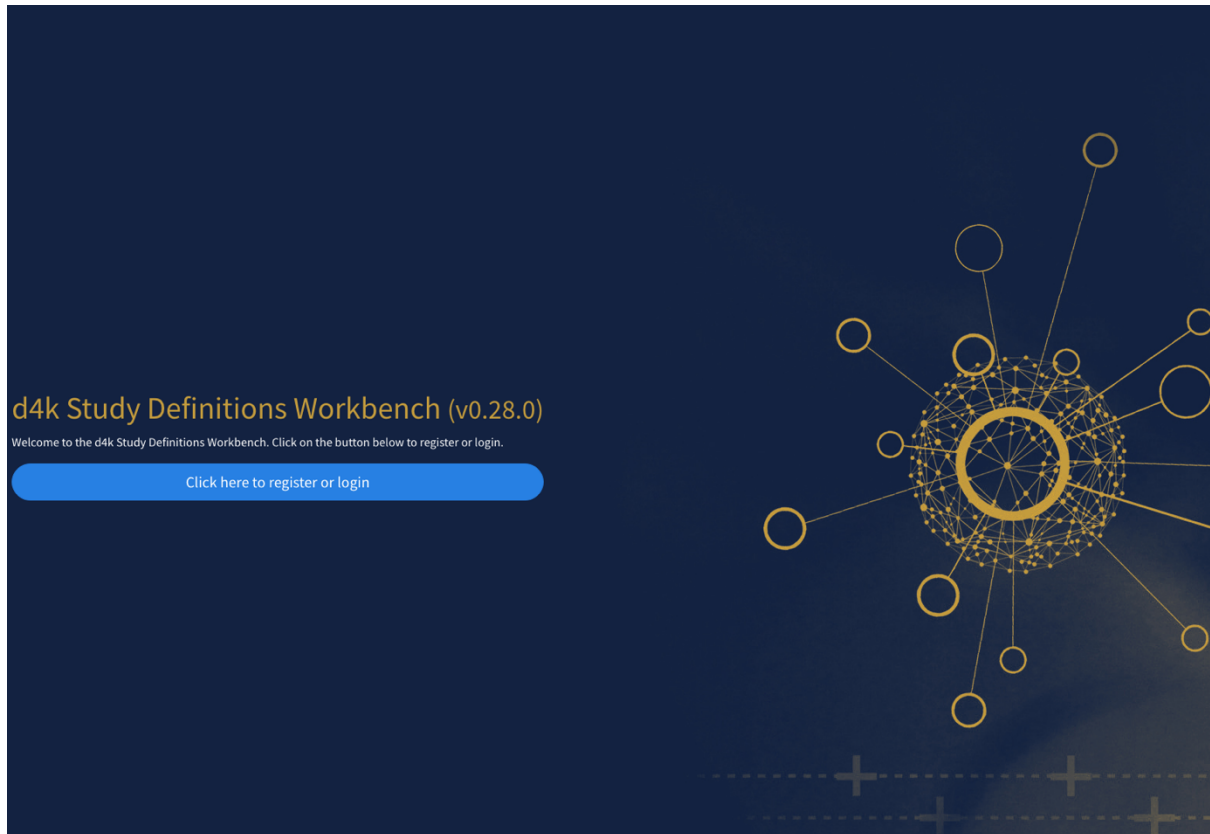


# Study Definitions Workbench User Guide

Dave Iberson-Hurst, 22<sup>nd</sup> December 2024, Version 0.30.0

## Access

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



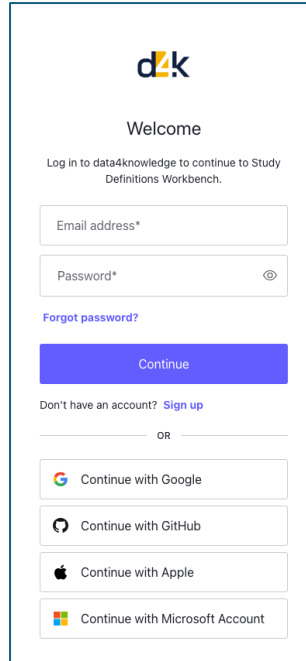
Click on the large button.

*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.

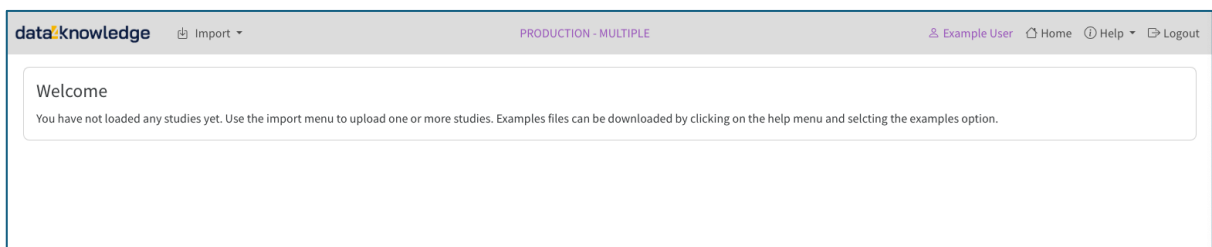


The image shows a login and sign-up interface for 'data4knowledge'. At the top is the 'd4k' logo. Below it is a 'Welcome' heading, followed by the text 'Log in to data4knowledge to continue to Study Definitions Workbench.' There are two input fields: 'Email address\*' and 'Password\*', with a toggle icon for password visibility. A link for 'Forgot password?' is below the password field. A blue 'Continue' button is next. Below the button, it says 'Don't have an account? [Sign up](#)'. A horizontal separator with 'OR' in the middle follows. Below this are four social login buttons: 'Continue with Google', 'Continue with GitHub', 'Continue with Apple', and 'Continue with Microsoft Account'.

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.

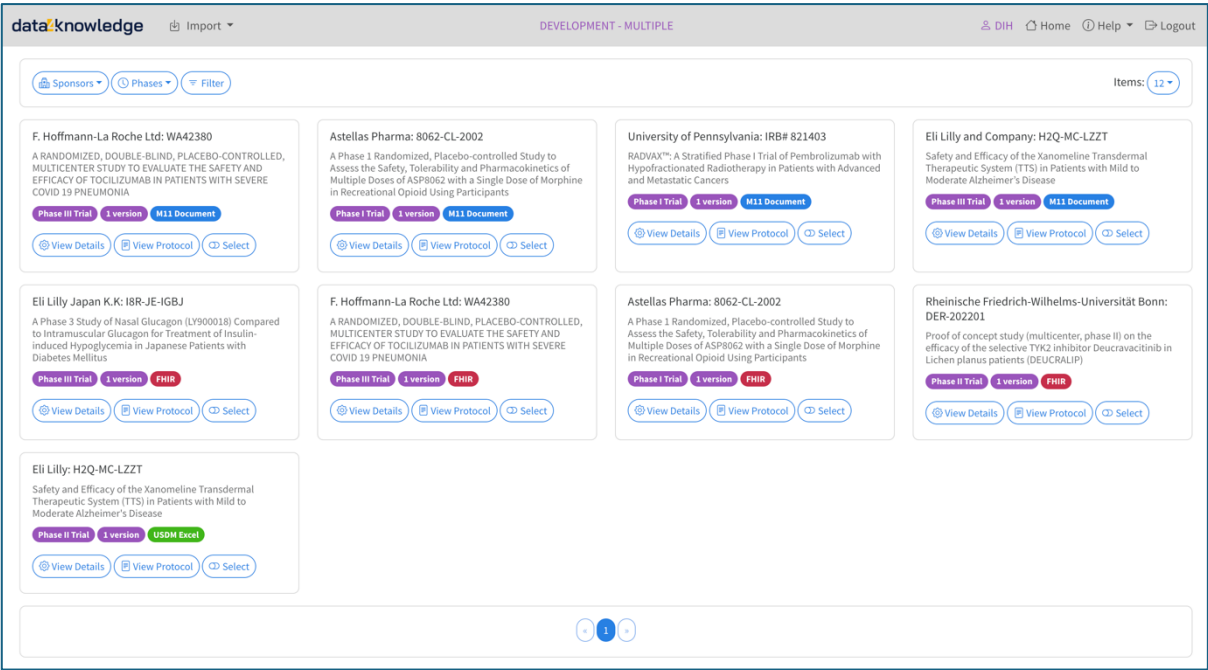
## Home Page

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).



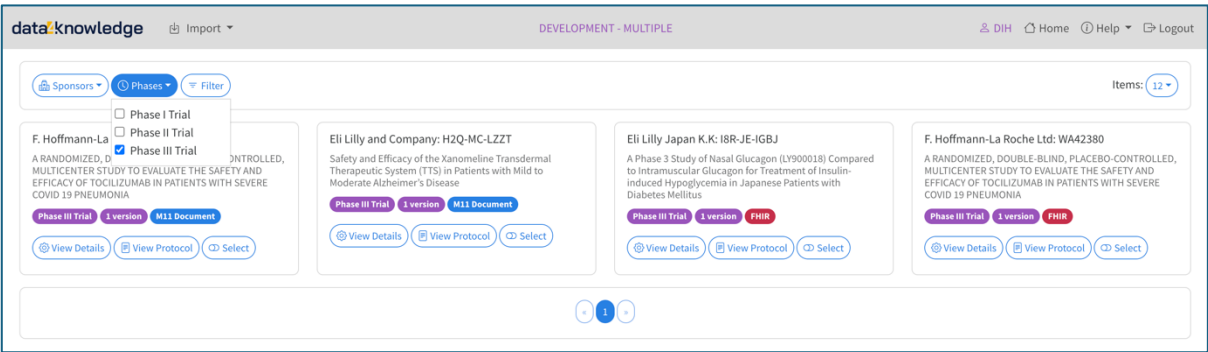
The image shows the home page of the 'data4knowledge' application. The top header bar contains the 'data4knowledge' logo on the left, an 'Import' button in the center, and user information on the right: 'PRODUCTION - MULTIPLE', 'Example User', 'Home', 'Help', and 'Logout'. Below the header is a 'Welcome' section with a message: 'You have not loaded any studies yet. Use the import menu to upload one or more studies. Examples files can be downloaded by clicking on the help menu and selecting the examples option.'

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:

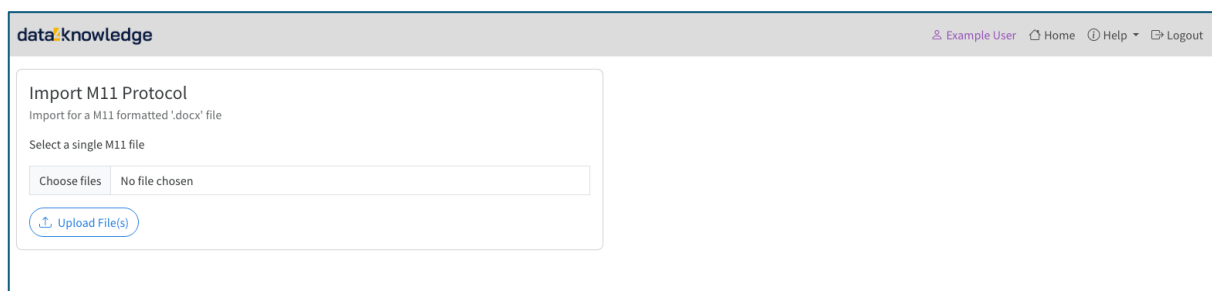
1. M11 Word Document (.docx)
2. M11 FHIR Message (.json)
3. USDM Excel (.xlsx)

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).

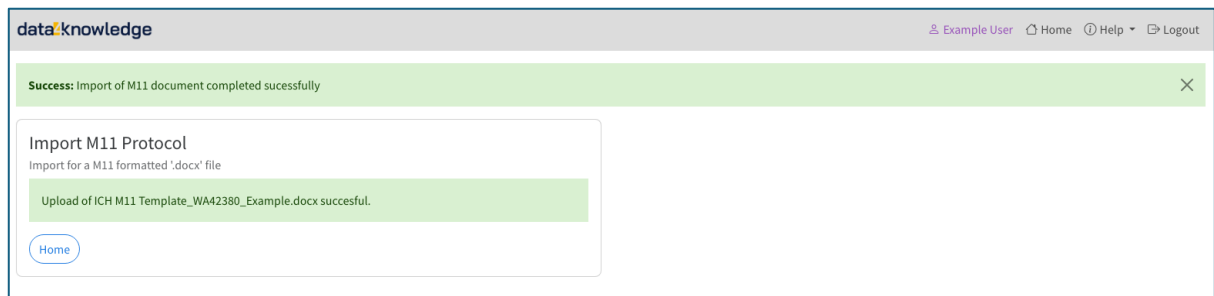
## M11 Protocol in MS Word (.docx) Import

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

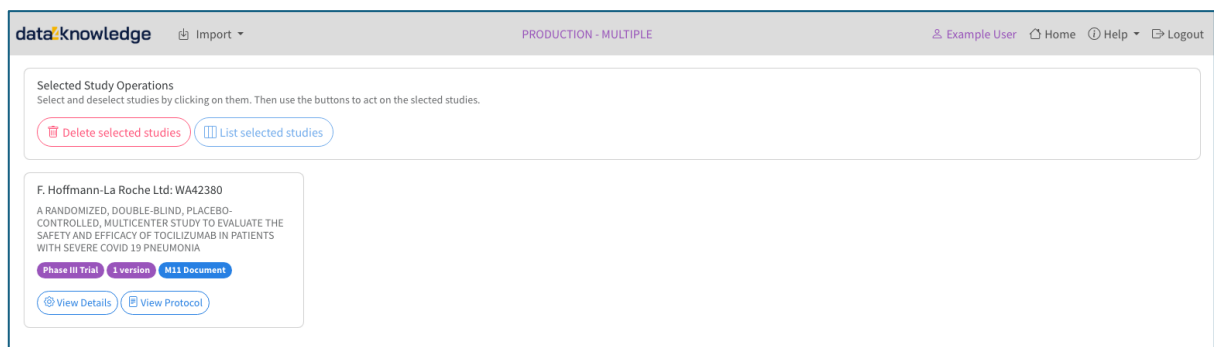
The screenshot shows a web application interface for 'dataknowledge'. The header includes a logo and navigation links: 'Example User', 'Home', 'Help', and 'Logout'. The main content area is titled 'Import M11 Protocol' and contains the instruction 'Import for a M11 formatted '.docx' file'. Below this, it says 'Select a single M11 file'. There is a file selection area with a 'Choose files' button and a 'No file chosen' status. At the bottom of this section is a blue 'Upload File(s)' button with an upward arrow icon.

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.

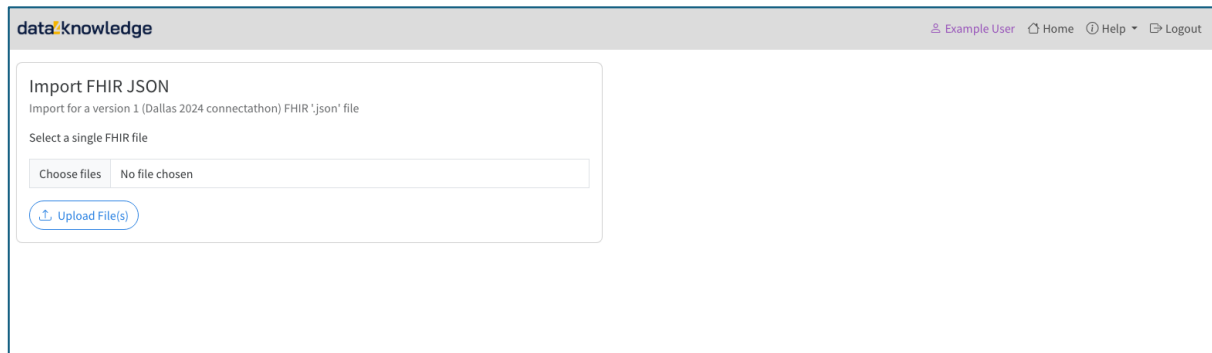


Return to the home page. An entry for the file loaded should be present containing high level information about the protocol. Note the blue “M11 Document” load type indicator.



# M11 Protocol in FHIR V1 Message (.json) Import

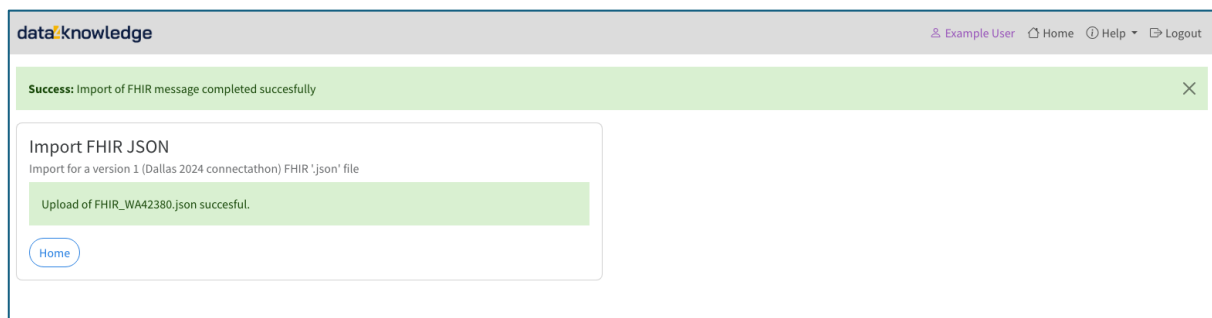
Click on the import menu and select the M11 FHIR v1 option. The import page will be displayed.



The screenshot shows the 'Import FHIR JSON' page in the 'dataknowledge' application. The page has a header with the 'dataknowledge' logo and user navigation links: 'Example User', 'Home', 'Help', and 'Logout'. The main content area is titled 'Import FHIR JSON' and includes the instruction 'Import for a version 1 (Dallas 2024 connectathon) FHIR '.json' file'. Below this, it says 'Select a single FHIR file'. There is a file selection interface with a 'Choose files' button and a text box showing 'No file chosen'. At the bottom of this section is an 'Upload File(s)' button with an upward arrow icon.

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.



The screenshot shows the 'Import FHIR JSON' page after a successful upload. A green success banner at the top reads 'Success: Import of FHIR message completed successfully'. Below this, the main content area shows the 'Import FHIR JSON' title and instruction. A green box displays the message 'Upload of FHIR\_WA42380.json succesful.'. At the bottom of the main content area is a 'Home' button.

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

Selected Study Operations

Select and deselect studies by clicking on them. Then use the buttons to act on the selected 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

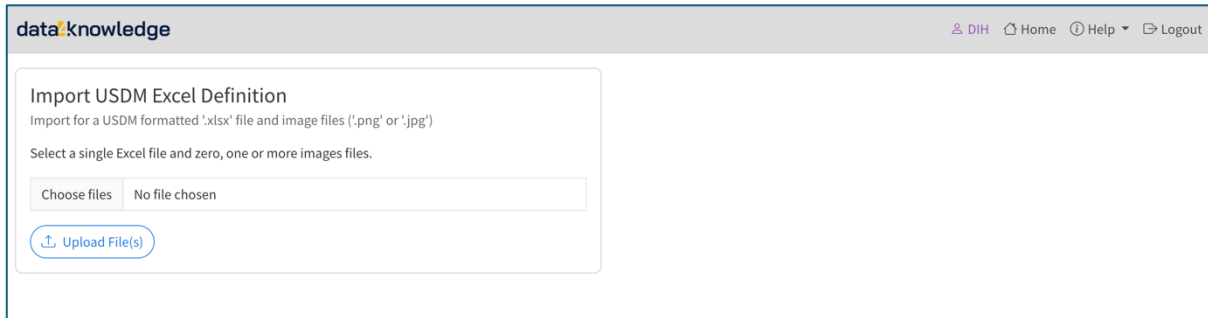
FHIR

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.



dataknowledge

DIH Home Help Logout

### Import USDM Excel Definition

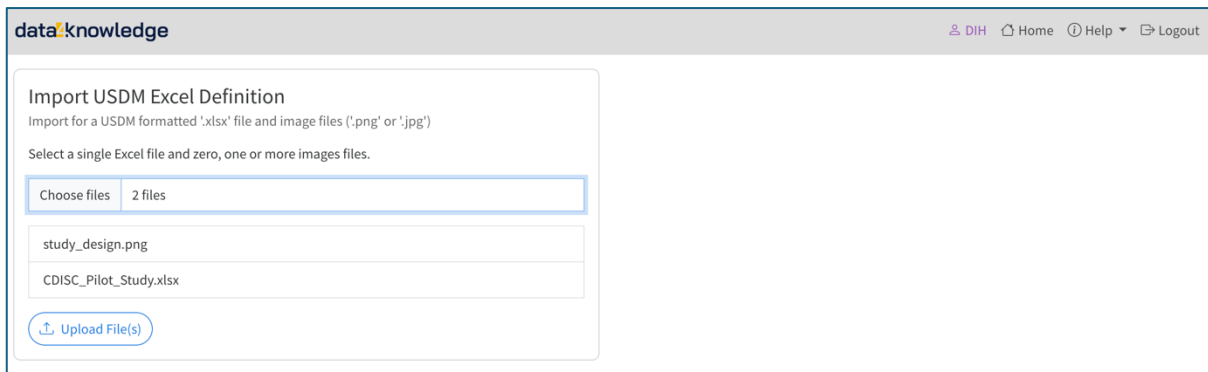
Import for a USDM formatted '.xlsx' file and image files ('.png' or '.jpg')

Select a single Excel file and zero, one or more images files.

Choose files No file chosen

[Upload File\(s\)](#)

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.



dataknowledge

DIH Home Help Logout

### Import USDM Excel Definition

Import for a USDM formatted '.xlsx' file and image files ('.png' or '.jpg')

Select a single Excel file and zero, one or more images files.

Choose files 2 files

study\_design.png

CDISC\_Pilot\_Study.xlsx

[Upload File\(s\)](#)

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.



**Selected Study Operations**  
Select and deselect studies by clicking on them. Then use the buttons to act on the selected studies.

Delete selected studies List selected studies

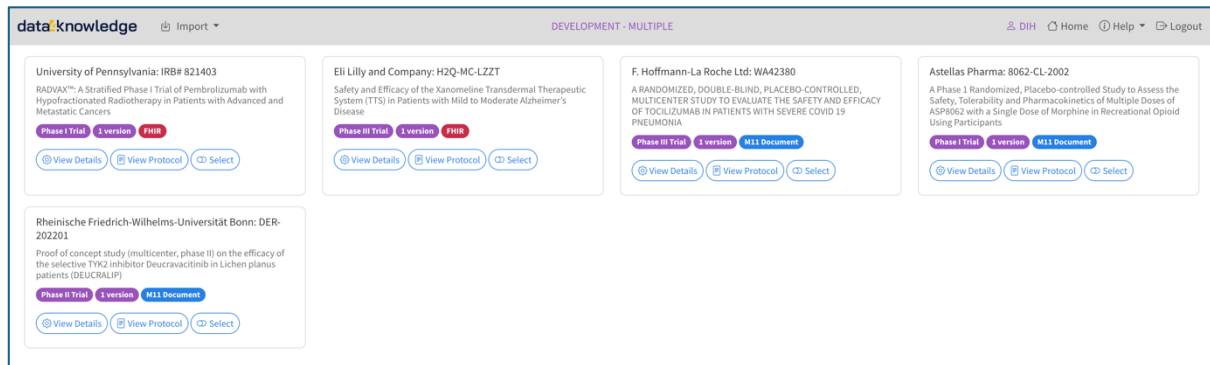
**Eli Lilly: H2Q-MC-LZZT**  
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease

Phase II Trial 4 versions USDM Excel

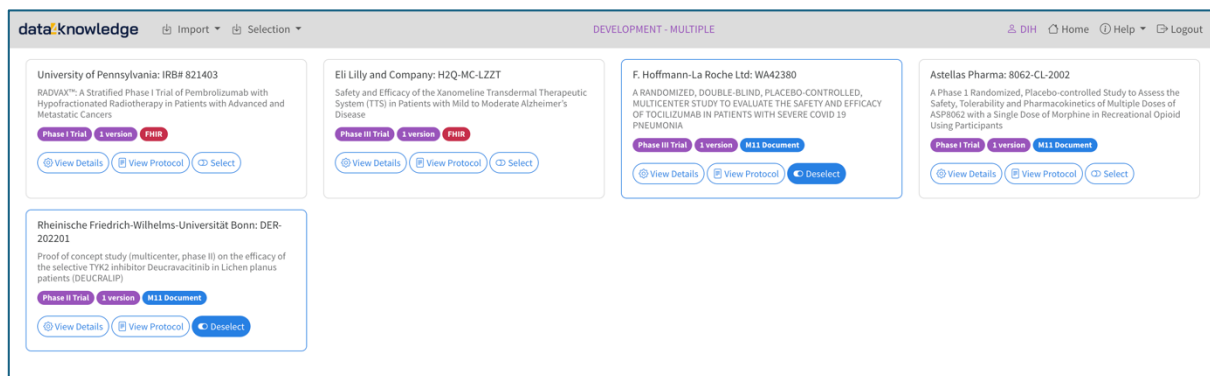
View Details View Protocol

# 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.

data:knowledge
Import
DEVELOPMENT - MULTIPLE
DIH
Home
Help
Logout

Title Page
Amendments

Sponsor Confidentiality Statement

This clinical study is being sponsored globally by F. Hoffmann-La Roche Ltd of Basel, Switzerland. However, it may be implemented in individual countries by Roche's local affiliates, including Genentech, Inc. in the United States. The information contained in this document, especially any unpublished data, is the property of F. Hoffmann-La Roche Ltd (or under its control) and therefore is provided to you in confidence as an investigator, potential investigator, or consultant, for review by you, your staff, and an applicable Ethics Committee or Institutional Review Board. It is understood that this information will not be disclosed to others without written authorization from Roche except to the extent necessary to obtain informed consent from persons to whom the drug may be administered.

Full Title:

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH SEVERE COVID 19 PNEUMONIA

Trial Acronym:

DEUCRALIP

Sponsor Protocol Identifier:

WA42380

Original Protocol:

No

Version Number:

3

Version Date:

2023-11-07

Amendment Identifier:

3

Amendment Scope:

Global

Compound Code(s):

Tocilizumab (RO4877533)

Compound Name(s):

Deucravacitinib SOTYKTU

Trial Phase:

Phase III Trial

Short Title:

DEUCRALIP

Sponsor Name and Address:

F. Hoffmann-La Roche Ltd

Manufacturer Name and Address:

Rheinische Friedrich-Wilhelms-Universität Bonn  
Bonn, D-53127

Regulatory Agency Identifier Number(s):

EU CT Number: 2020-001154-22 IND Number: 148225 NCT Number: NCT04320615

Sponsor Approval:

2023-11-07

Proof of concept study (multicenter, phase II) on the efficacy of the selective TYK2 inhibitor Deucravacitinib in Lichen planus patients (DEUCRALIP)

DER-202201

No

3

2023-11-07

3

Global

L04AA56

Deucravacitinib SOTYKTU

Phase II Trial

DEUCRALIP

Rheinische Friedrich-Wilhelms-Universität Bonn  
Bonn, D-53127

EU CT 2022-502991-21-00

2023-11-07

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.

dataknowledge

ViewsExportTransmit

STAGING - MULTIPLE

Guest DemoHomeHelpLogout

RADVAX™: A Stratified Phase I Trial of Pembrolizumab with Hypofractionated Radiotherapy in Patients with Advanced and Metastatic Cancers

Sponsor: University of Pennsylvania | Phase: Phase I Trial | Identifier: IRB# 821403 | Version:

Summary: Study Design

Overall Design

Key aspects of the design

Key aspects of the trial design are summarised below.

Intervention Model:	Open Label	Population Type:	With disease
Control Type:	N/A	Population Diagnosis or Condition:	Metast: Cancer
Control Description:	N/A	Population Age:	Minimum 18 year of age

Trial Schema

Overall trial schema

```
graph TD
    A[Screening  
Eligibility criteria  
and randomisation] --> B[Randomised  
to one of two arms]
    B --> C[Stratum 1: Metastatic & NSCLC - relapsed on PD-1 therapy  
Stratum 2: Pancreas, breast & other]
    C --> D[Add PD-1 therapy]
    D --> E[Interim analyses and monitoring]
    E --> F[Follow up (monitoring)]
    F --> G[Biomarkers and analysis]
```

Objectives, Endpoints, Estimands

Estimands, objectives and associated endpoints

Objective: To determine the safety of combining Pembrolizumab with hypofractionated radiotherapy in patients with advanced and metastatic cancers.

Hypothesis: Pembrolizumab will be safe and well tolerated in patients with advanced and metastatic cancers when combined with hypofractionated radiotherapy.

Interventions

Overview of Trial Interventions

## 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.

dataknowledge

DIH Home Help Logout

Version History

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:

Rows: 10

Begin typing to search ...

Version	Filename	Import Type	When	USDM JSON	USDM JSON Difference
1	CDISC_Pilot_Study_Baseline.xlsx	XLSX	2024-12-05 14:41:42	USDM JSON	No difference possible
2	CDISC_Pilot_Study.xlsx	XLSX	2024-12-05 14:42:14	USDM JSON	USDM JSON Diff

« 1 »

dataknowledge

DIH Home Help 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:

```
{
  "study": {
    "id": null,
    "name": "Study_CDISC PILOT - LZTZ",
    "description": null,
    "label": null,
    "versions": [
      {
        "id": "StudyVersion_1",
        "versionIdentifier": "2",
        "rationale": "The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strateg",
        "studyType": {
          "id": "Code_1",
          "code": "C98388",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2023-12-15",
          "decode": "Interventional Study",
          "instanceType": "Code"
        },
        "studyPhase": {

```

USDm JSON View

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:

[Back](#)

```
... @@ -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",
```