Study Definitions Workbench User Guide

Dave Iberson-Hurst, 17th December 2024, Version 0.30.0
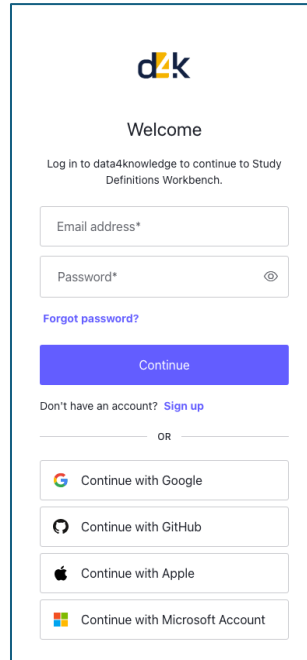
Access

Go to https://d4k-sdw.fly.dev/
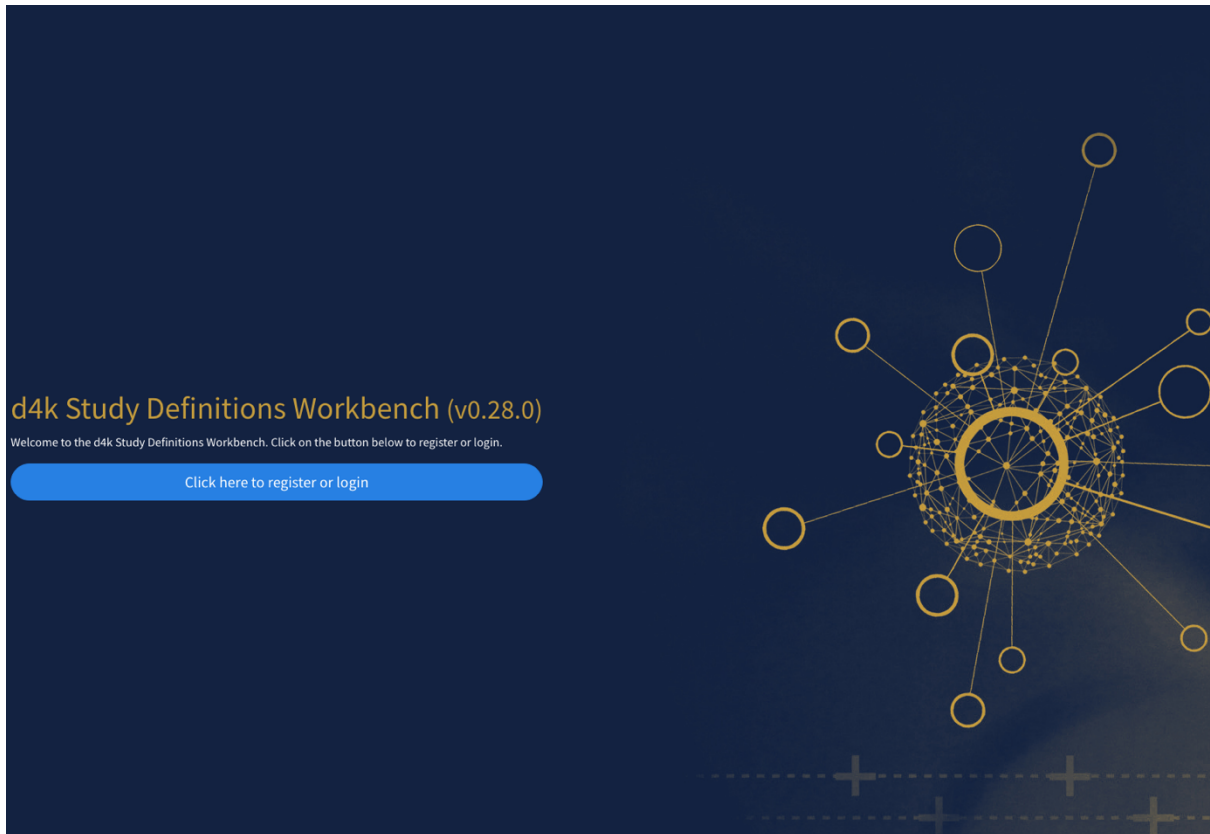
Click on the large button.

Note:

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

Sign Up & Login
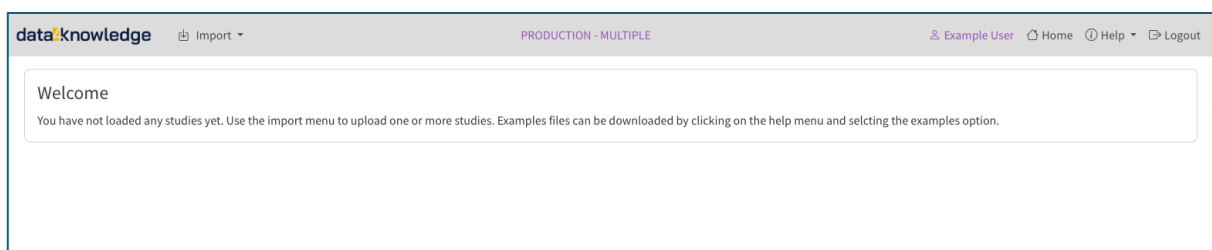
You should see a login / sign up screen.

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).

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.
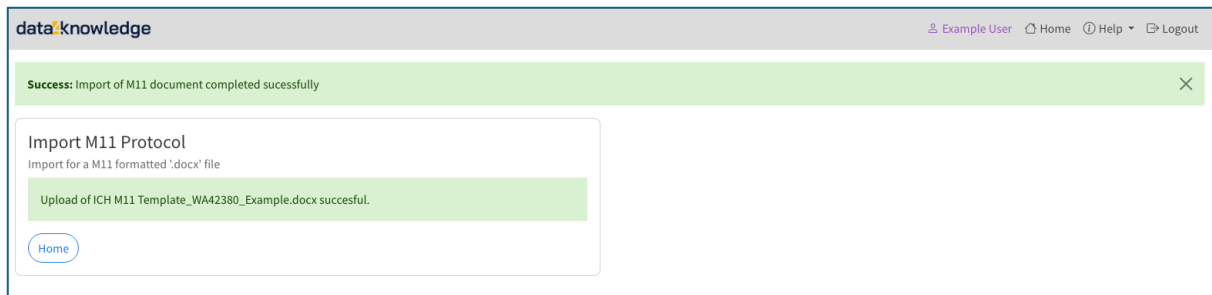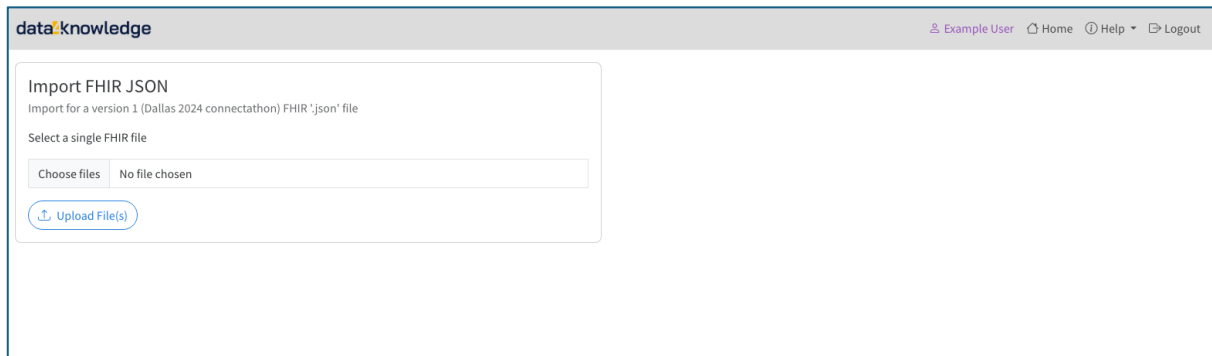
Return to the home page. An entry for the file loaded should be present containing high level information about the protocol. Note the blue "M11 Document" load type indicator.
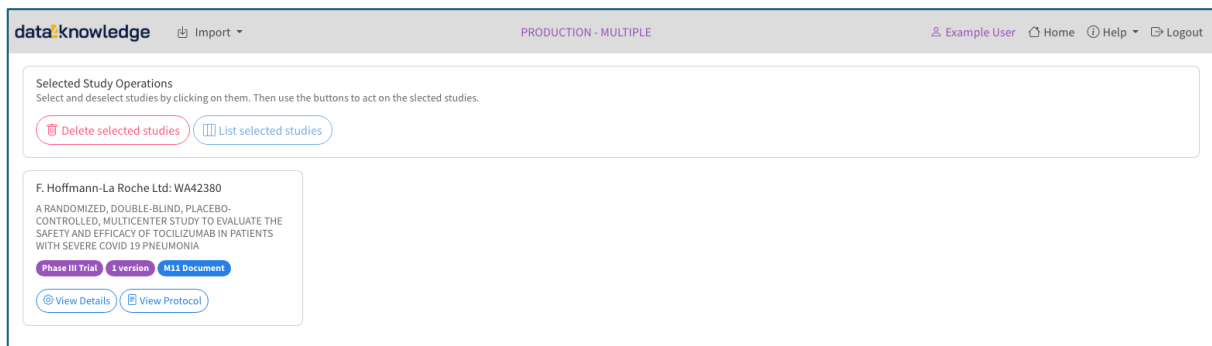
M11 Protocol in FHIR V1 Message (.json) Import
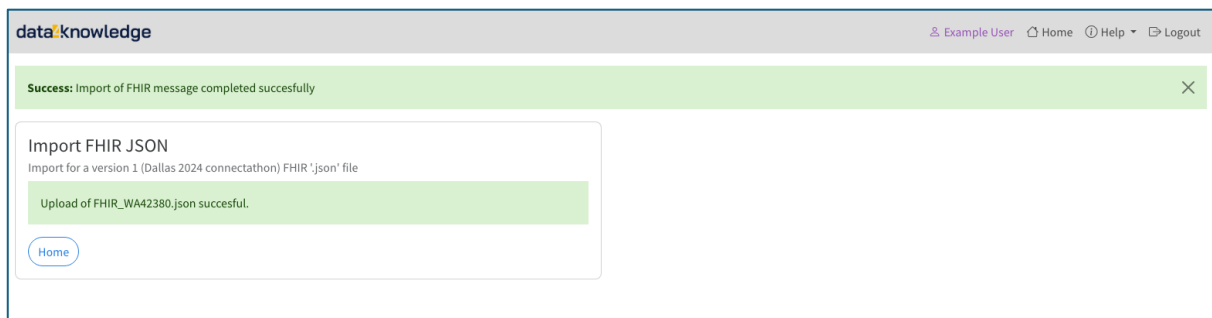
Click on the import menu and select the M11 FHIR v1 option. The import page will be displayed.

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.

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

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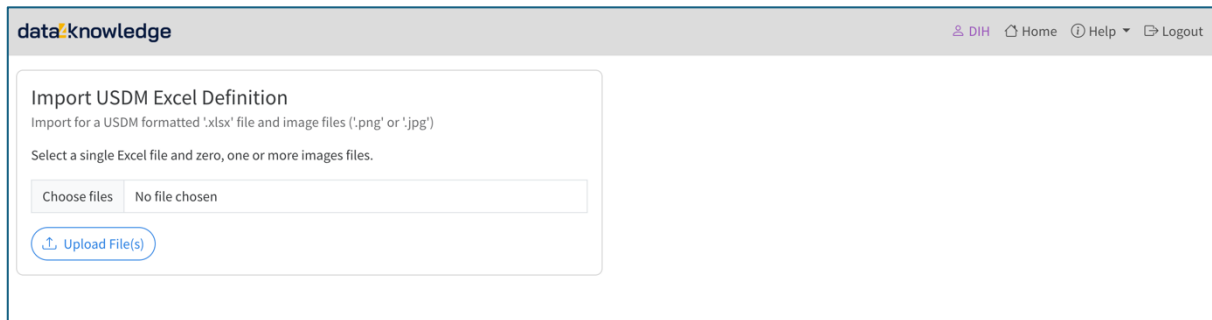
Phase III Trial   **1 version**   **FHIR**

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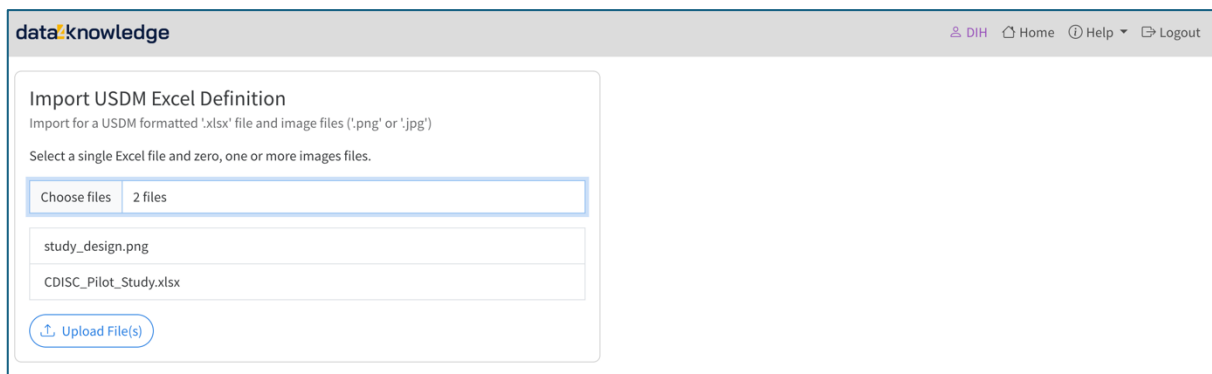
Click "Choose Files" and use the normal file selection mechanism to select a single USDM Excel file and any associated image files required to render the protocol document.

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.

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.
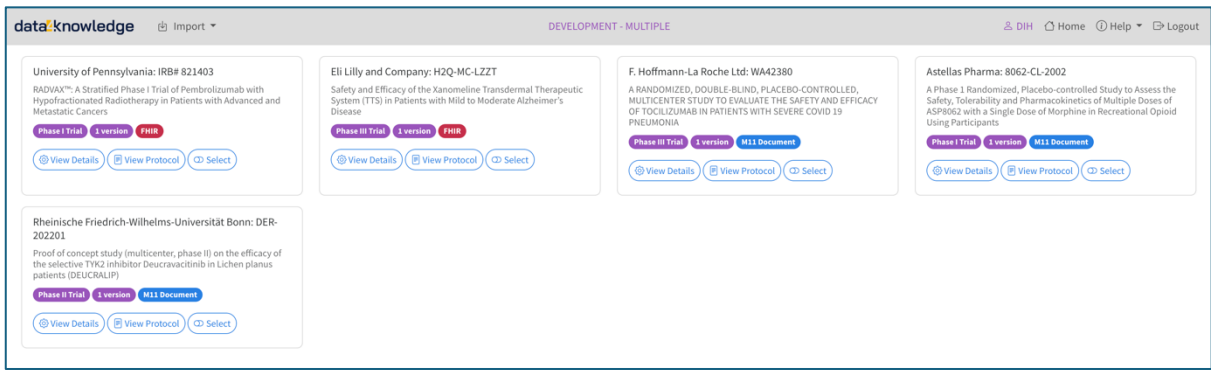
When one or more items are selected a new menu item, "Selection", will appear in the menu bar. Click the button again to de-select, it is just a toggle.
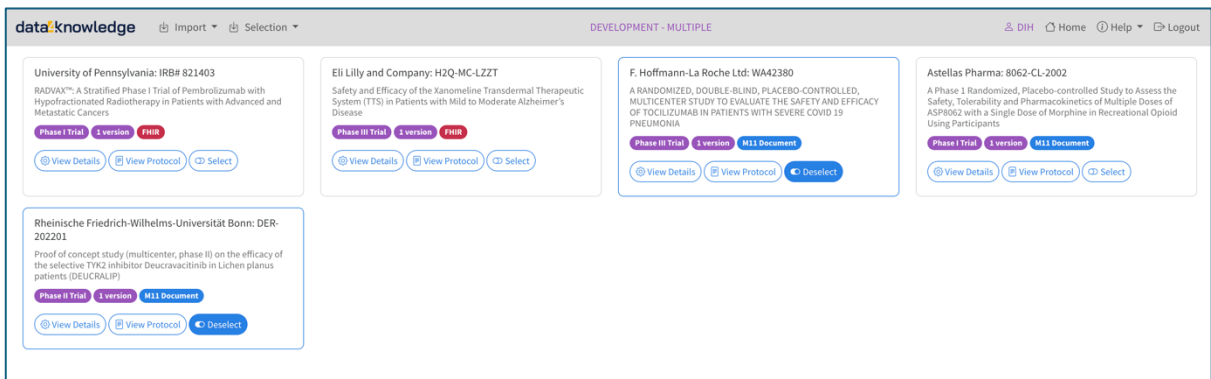
Click on the "Selection" menu item and then the "List Selected Studies" option. You should see something like the following.

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	Proof of concept study (multicenter, phase II) on the efficacy of the selective TYK2 inhibitor Deucravacitinib in Lichen planus patients (DEUCRALIP)
Trial Acronym:		DEUCRALIP
Sponsor Protocol Identifier:	WA42380	DER-202201
Original Protocol:	No	No
Version Number:	3	3
Version Date:		2023-11-07
Amendment Identifier:	3	3
Amendment Scope:	Global	Global
Compound Code(s):	Tocilizumab (RO4877533)	L04AA56
Compound Name(s):		Deucravacitinib SOTYKTU
Trial Phase:	Phase III Trial	Phase II Trial
Short Title:		DEUCRALIP
Sponsor Name and Address:	F. Hoffmann-La Roche Ltd	Rheinische Friedrich-Wilhelms-Universität Bonn Bonn, D-53127
Manufacturer Name and Address:		
Regulatory Agency Identifier Number(s):	EU CT Number: 2020-001154-22 IND Number: 148225 NCT Number: NCT04320615	EU CT 2022-502991-21-00
Sponsor Approval:		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.

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.

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:

...	@@ -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",