Study Definitions Workbench User Guide

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

# Access

Go to [https://d4k-sdw.fly.dev/](https://d4k-sdw-staging.fly.dev/)

A screenshot of a computer

Description automatically generated

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.

A screenshot of a login form

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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).

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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.

A screenshot of a computer

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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.

A screenshot of a chat

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# 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.

A white rectangular object with a black border

Description automatically generated with medium confidence

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.

A screenshot of a computer

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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.

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# 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.

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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.

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

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# USDM in MS Excel (.xlsx) Import

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

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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.

A screenshot of a login box

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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.

A screen shot of a movie

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# 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.

A screenshot of a chat

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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.

A screenshot of a computer

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

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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.

A screenshot of a medical information

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# 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.

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