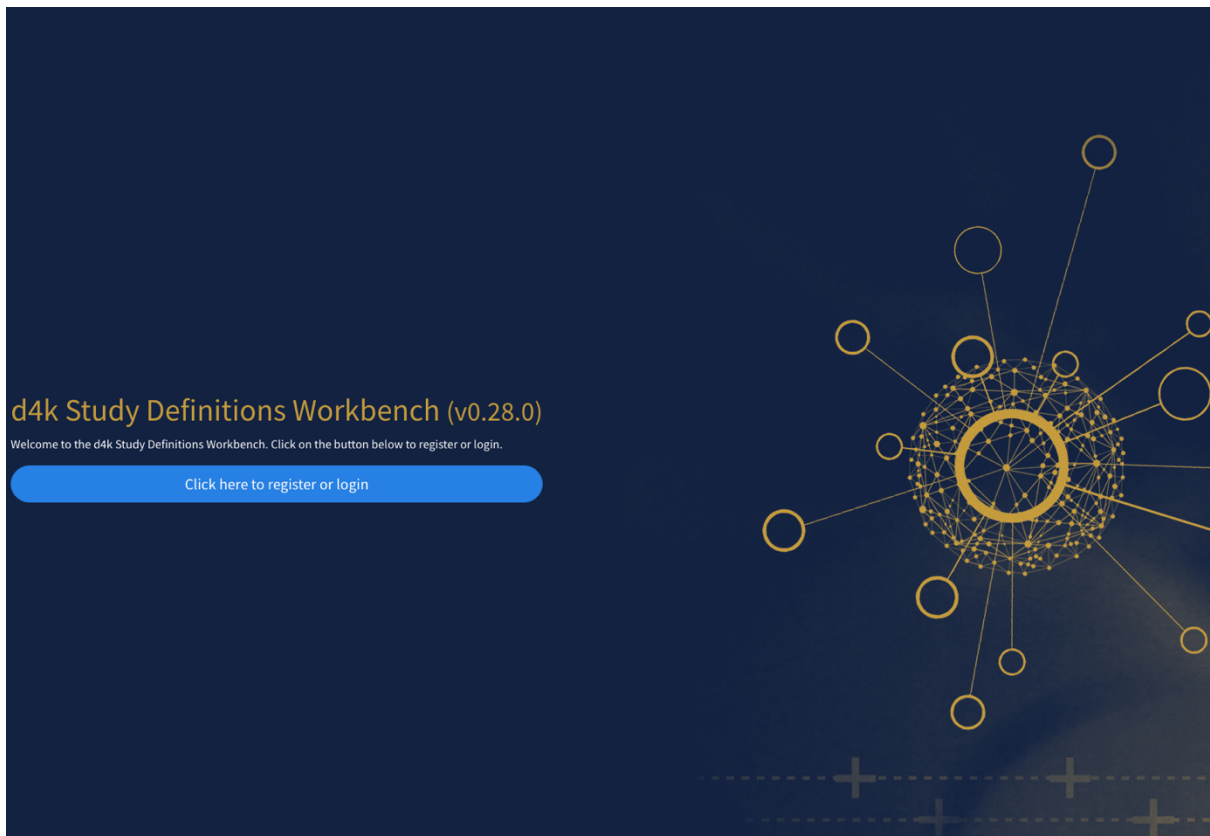


# Study Definitions Workbench User Guide

Dave Iberson-Hurst, 5<sup>th</sup> December 2024

## Access

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



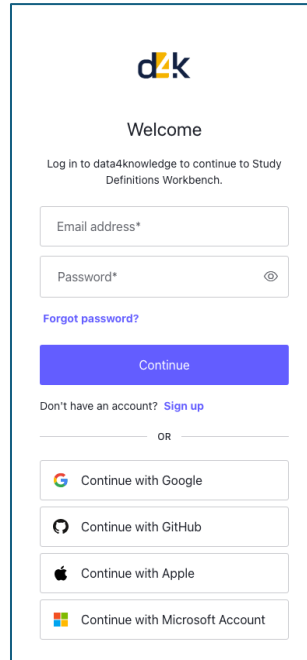
Click on the large button.

*Note:*

1. *The version will change as time passes*
2. *The tooling is a beta, expect one or two issues.*

# Sign Up & Login

You should see a login / sign up screen.

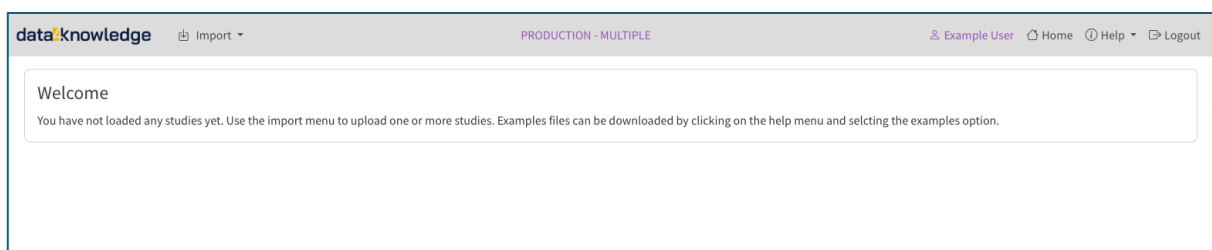


The image shows a login and sign up screen for 'data4knowledge'. At the top is the 'dk' logo. Below it is the heading 'Welcome'. A sub-heading says 'Log in to data4knowledge to continue to Study Definitions Workbench.' There are two input fields: 'Email address\*' and 'Password\*'. Below the password field is a link 'Forgot password?'. A blue 'Continue' button is below that. Underneath is a link 'Don't have an account? Sign up'. A horizontal line with 'OR' in the center separates the login section from the sign up section. Below the line are four buttons for social login: '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 'data4knowledge'. The top navigation bar includes the 'data4knowledge' logo, an 'Import' dropdown menu, the text 'PRODUCTION - MULTIPLE', a user profile 'Example User', and links for 'Home', 'Help', and 'Logout'. Below the navigation bar is a 'Welcome' message in a box. The message says: '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.'

# 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

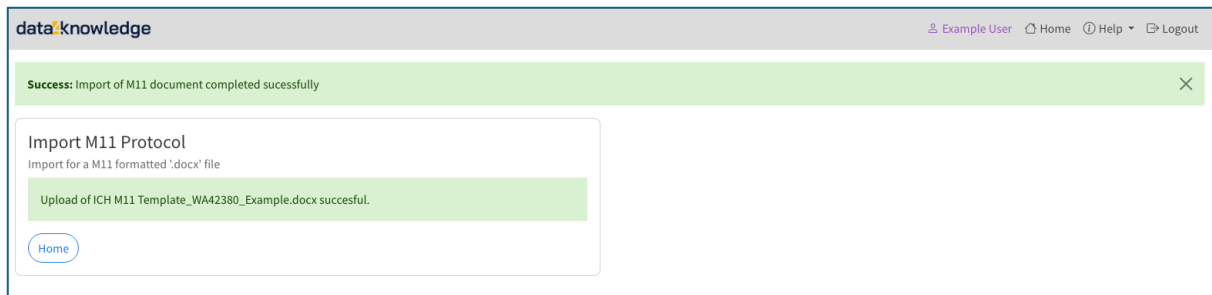
Click on the import menu and select the M11 Document option. The import page will be displayed.



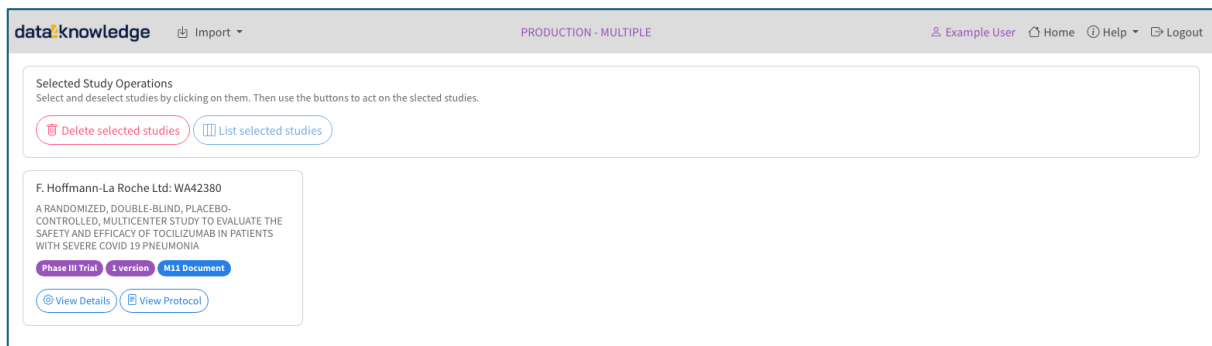
The screenshot shows the 'dataknowledge' application interface. At the top, there is a header bar with the logo on the left and navigation links 'Example User', 'Home', 'Help', and 'Logout' on the right. The main content area is titled 'Import M11 Protocol' and includes the instruction 'Import for a M11 formatted '.docx' file'. Below this, it says 'Select a single M11 file'. There is a file selection box with a 'Choose files' button and the text 'No file chosen'. At the bottom of the selection area is a blue button with a cloud icon and the text 'Upload File(s)'.

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.

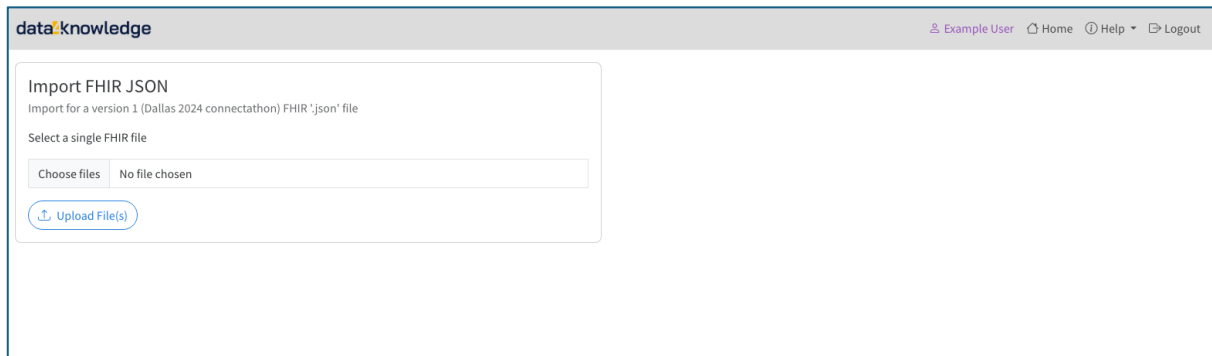


Return to the home page. An entry for the file loaded should be present containing high level information about the protocol. Note the blue “M11 Document” load type indicator.



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

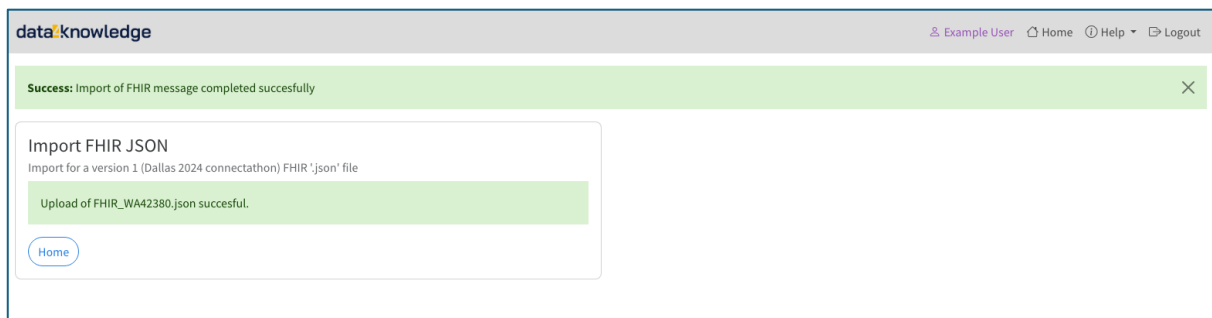
Click on the import menu and select the M11 FHIR v1 option. The import page will be displayed.



The screenshot shows the 'Import FHIR JSON' page in the 'dataknowledge' application. The page has a header with the application name and user information. The main content area contains a form with the title 'Import FHIR JSON' and a subtitle 'Import for a version 1 (Dallas 2024 connectathon) FHIR '.json' file'. Below this, there is a section 'Select a single FHIR file' with a file selection interface. The interface includes a button labeled 'Choose files' and a text area showing 'No file chosen'. At the bottom of the form, there is a blue button labeled 'Upload File(s)'.

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 message banner at the top reads 'Success: Import of FHIR message completed successfully'. Below the banner, the form title 'Import FHIR JSON' and subtitle 'Import for a version 1 (Dallas 2024 connectathon) FHIR '.json' file' are still present. A green message box within the form area states 'Upload of FHIR\_WA42380.json succesful.'. At the bottom of the form, there is a blue button labeled 'Home'.

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

dataknowledge

Import

PRODUCTION - MULTIPLE

Example UserHomeHelpLogout

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

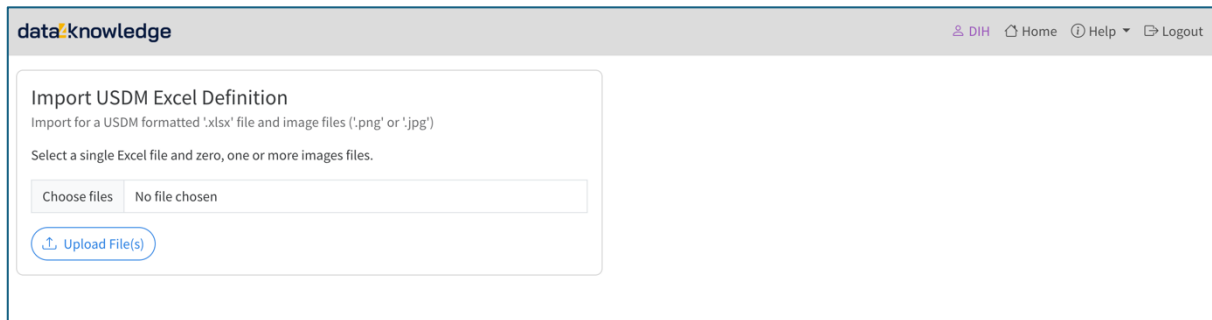
FHIR

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

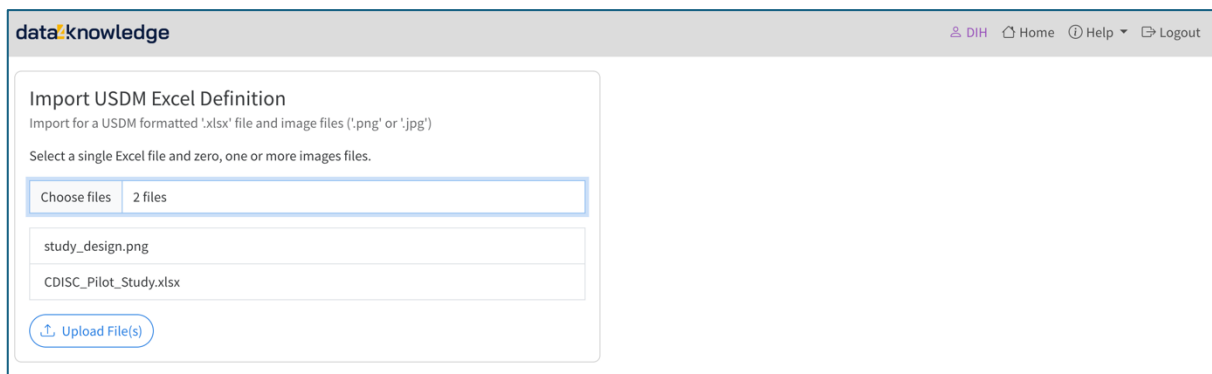
Import for a USDM formatted '.xlsx' file and image files ('.png' or '.jpg')

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.

dataknowledge

Import

PRODUCTION - MULTIPLE

DIH

Home

Help

Logout

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

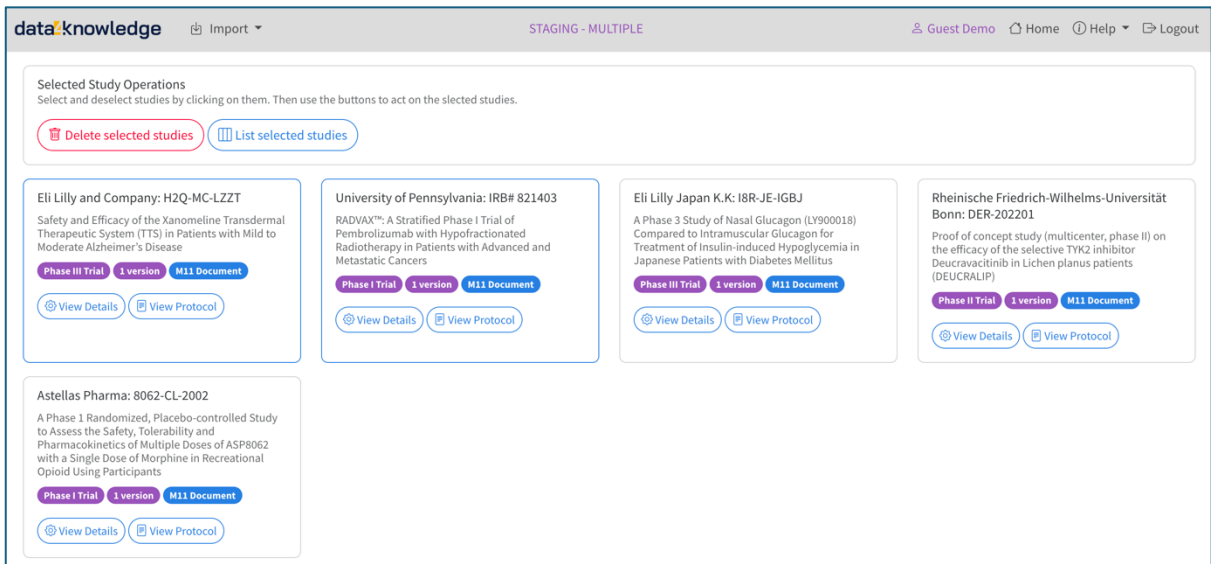
View Details

View Protocol

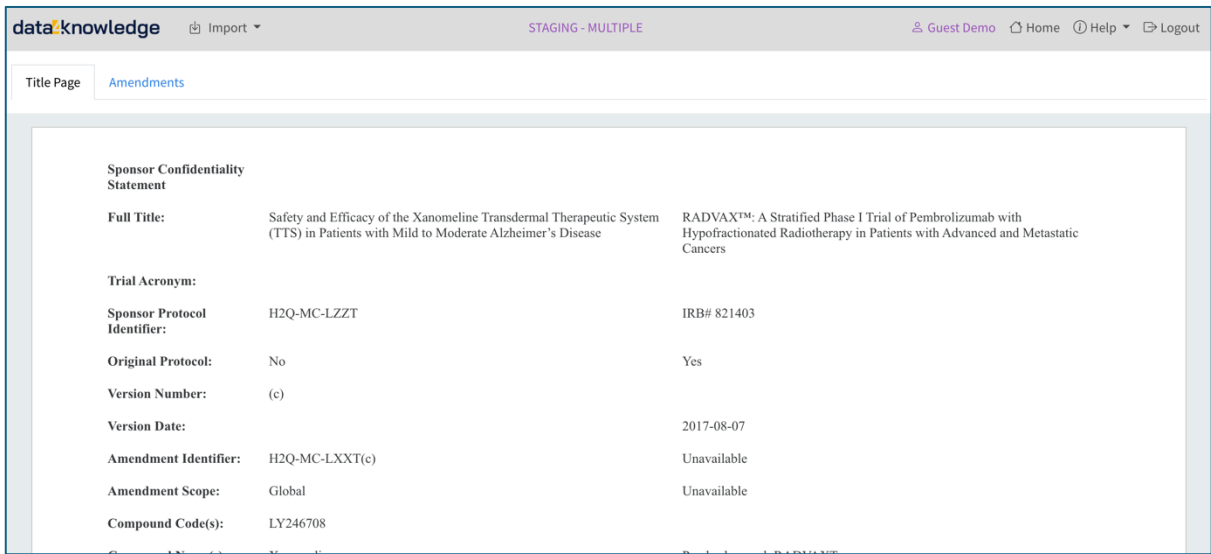


# Side By Side Page

Select two or more protocols by clicking on the relevant items (anywhere in the boxes), you should see a blue border around the selected items. Click again to de-select, it is just a toggle.



Click the “List Selected Studies” button. 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.

dataknowledge

Views

Export

Transmit

STAGING - MULTIPLE

Guest Demo

Home

Help

Logout

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:	Metastatic Cancer
Control Description:	N/A	Population Age:	Minimum 18 year of age

Trial Schema

Overall trial schema

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.

## 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

DIHHomeHelpLogout

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

DIHHomeHelpLogout

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_PIL0T - 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: {
```

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:

... @@ -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",