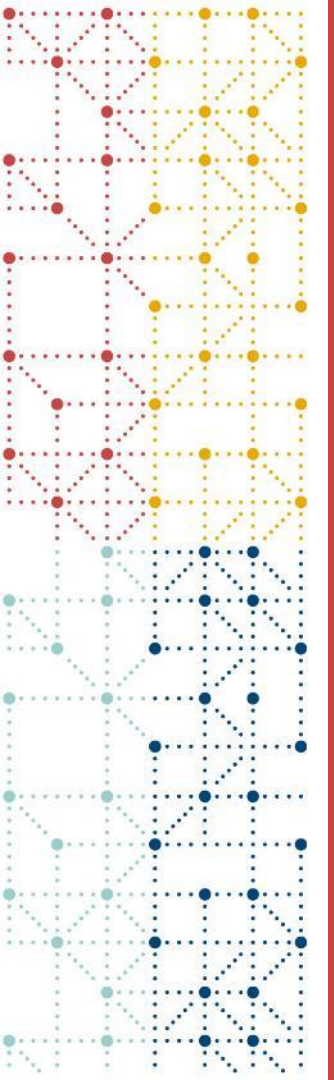
Digital Data Flow (DDF) Workshop: Mastering USDM

PHUSE EU Connect 2023 Workshop – Follow Up

28th November 2023



Welcome

USDM Excel to JSON Resources

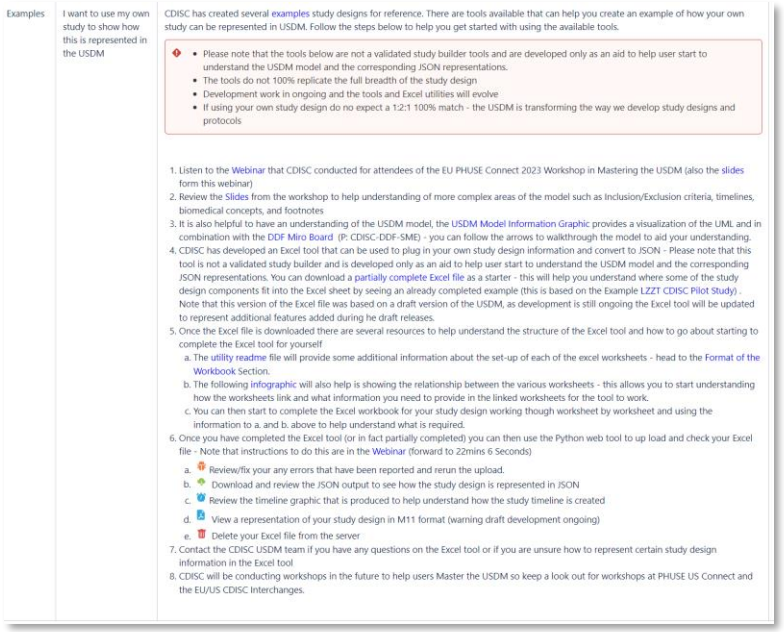
EU PHUSE WIKI Page

PHUSE EU Connect 2023 - DDF Workshop

Created by John.Owen, last modified just a moment ago

Pre EU Connect 2023 Information 27 Oct 2023	Listen to the preparation Webinar and review the preparation webinar slides
Pre-Reads for EU Connect 2023	Pre-Reads *(Materials to look at prior to the workshop if you wish to. NOT compulsory!)* *A the time of the workshop this was version 2.5, since the workshop this now points to the latest versions of the USDM* • Model (UML) • Controlled Terminology (XLSX) • Implementation Guide (PDF) • Informative Diagram (PNG) • Miro Board (Web) (P: CDISC-DDF-SME) (or if you prefer you can download a PDF of the Miroboard)
Web tools	Web Tools *(no need to install - these will run from a web browser)* • Excel To JSON Tool (U: PHUSE - P: learning_usdm) • Excel to JSON Tool readme • Excel to JSON Tool Infographic • JSON Comparison
Example files for EU Connect 2023 Workshop 05 Nov 2023	CDISC_Pilot_Study_Baseline.xlsx Example Protocol • SoA Pages.jpeg • SoA.png
Slides from EU Connect 2023 workshop 05 Nov 2023	**Slides** presented at the workshop on 05 Nov 2023
CDISC DDF EU Connect 2023 workshop 07 Nov 2023	2023 11 07 PHUSE Peter VR DS01 M11 - PHUSE EU Connect v0.5.pdf 2023 11 07 PHUSE DAVE IH DS02 V3.pdf
EU Connect 2023 Follow-up Webinar 28 Nov 2023	Listen to the preparation Webinar and review the preparation webinar slides

DDF WIKI Orientation Page



Examples	I want to use my own study to show how this is represented in the USDM	CDISC has created several examples study designs for reference. There are tools available that can help you create an example of how your own study can be represented in USDM. Follow the steps below to help you get started with using the available tools.

- Please note that the tools below are not a validated study builder tools and are developed only as an aid to help user start to understand the USDM model and the corresponding JSON representations.
- The tools do not 100% replicate the full breadth of the study design
- Development work in ongoing and the tools and Excel utilities will evolve
- If using your own study design do no expect a 1:2:1 100% match - the USDM is transforming the way we develop study designs and protocols

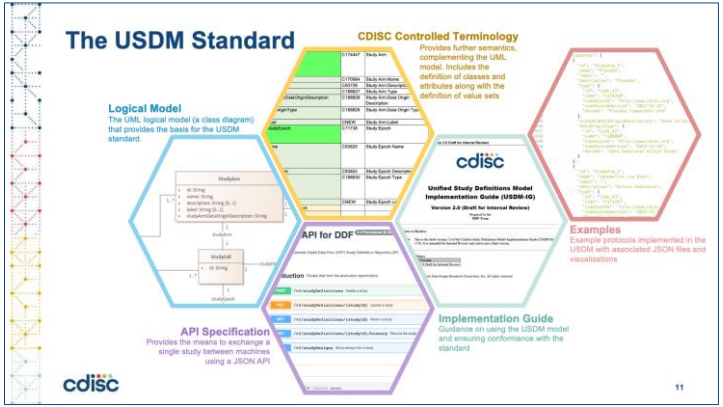
1. Listen to the Webinar that CDISC conducted for attendees of the EU PHUSE Connect 2023 Workshop in Mastering the USDM (also the slides form this webinar)
2. Review the Slides from the workshop to help understanding of more complex areas of the model such as Inclusion/Exclusion criteria, timelines, biomedical concepts, and footnotes
3. It is also helpful to have an understanding of the USDM model, the USDM Model Information Graphic provides a visualization of the UML and in combination with the DDF Miro Board (P: CDISC-DDF-SME) - you can follow the arrows to walkthrough the model to aid your understanding.
4. CDISC has developed an Excel tool that can be used to plug in your own study design information and convert to JSON - Please note that this tool is not a validated study builder and is developed only as an aid to help user start to understand the USDM model and the corresponding JSON representations. You can download a partially complete Excel file as a starter - this will help you understand where some of the study design components fit into the Excel sheet by seeing an already completed example (this is based on the Example LZZT CDISC Pilot Study) . Note that this version of the Excel file was based on a draft version of the USDM, as development is still ongoing the Excel tool will be updated to represent additional features added during he draft releases.
5. Once the Excel file is downloaded there are several resources to help understand the structure of the Excel tool and how to go about starting to complete the Excel tool for yourself
   a. The utility readme file will provide some additional information about the set-up of each of the excel worksheets - head to the Format of the Workbook Section.
   b. The following infographic will also help is showing the relationship between the various worksheets - this allows you to start understanding how the worksheets link and what information you need to provide in the linked worksheets for the tool to work.
   c. You can then start to complete the Excel workbook for your study design working though worksheet by worksheet and using the information to a. and b. above to help understand what is required.
6. Once you have completed the Excel tool (or in fact partially completed) you can then use the Python web tool to up load and check your Excel file - Note that instructions to do this are in the Webinar (forward to 22mins 6 Seconds)
   a. Review/fix your any errors that have been reported and rerun the upload.
   b. Download and review the JSON output to see how the study design is represented in JSON
   c. Review the timeline graphic that is produced to help understand how the study timeline is created
   d. View a representation of your study design in M11 format (warning draft development ongoing)
   e. Delete your Excel file from the server
7. Contact the CDISC USDM team if you have any questions on the Excel tool or if you are unsure how to represent certain study design information in the Excel tool
8. CDISC will be conducting workshops in the future to help users Master the USDM so keep a look out for workshops at PHUSE US Connect and the EU/US CDISC Interchanges.

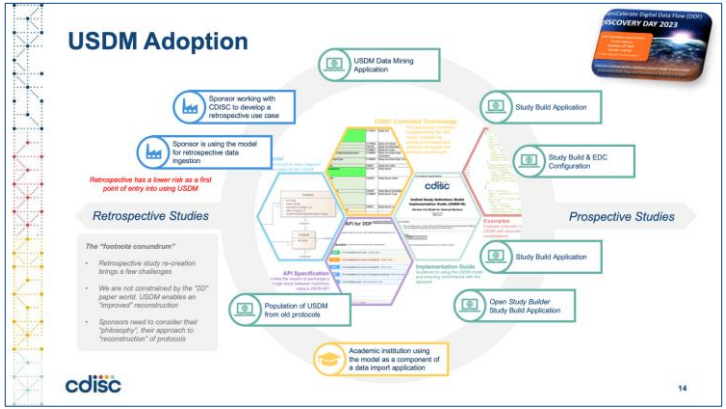
Agenda

1. Purpose
2. Online Tool
3. Further Example
4. Questions

Purpose – A Reminder

- Purpose was to “provide an introduction” to the Unified Study Definitions Model (USDM)
- We used the Excel spreadsheet to show the model “working”
- The Excel spreadsheet was designed to generate test data
- It should **NEVER** be used for production work! ☺

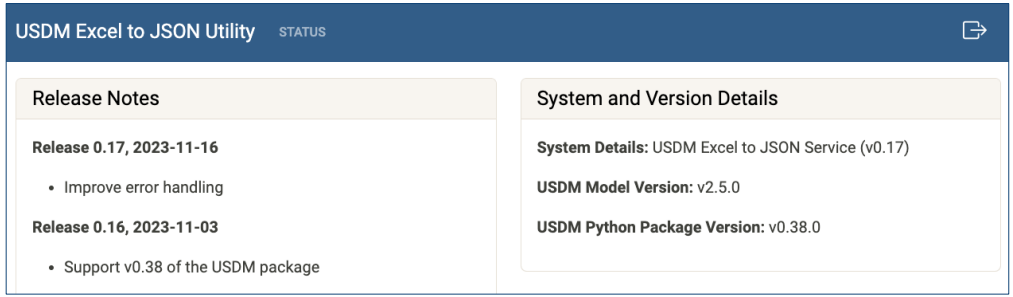




Two Presentations from the EU Connect. *These presentations provide more details about the M11, DDF and USDM work.*	**Connect Theme Presentations (DS)** Digital Data Flow – From Vision to Reality **DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality** *CDISC* **DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs** *data4knowledge & CDISC*

Online Tool

- Supports v2.5.0 of the USDM
- Three example files uploaded
  - Base CDISC Pilot
  - DM Biomedical Concepts added
  - Vital Signs timeline
- The tool will be upgraded
  - V2.7.1 support coming soon
  - Will involve changes to the spreadsheet format!
- If bugs encountered, please send the Excel file causing the error, we will see if we can fix the error handling, improve the tool



Vital Signs Timeline Example I

Protocol

3.9.3.4.1 Vital Sign Determination

Patient should lie supine quietly for at least 5 minutes prior to vital signs measurement. Blood pressure should be measured in the dominant arm with a standardized mercury manometer according to the American Heart Association standard recommendations. Diastolic blood pressure will be measured as the point of disappearance of the Korotkoff

sounds (phase V). Heart rate will be measured by auscultation. Patient should then stand up. Blood pressure should again be measured in the dominant arm and heart rate should be measured after approximately 1 and 3 minutes.

An automated blood pressure cuff may be used in place of a mercury manometer if it is regularly (at least monthly) standardized against a mercury manometer.

CRF

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

INFORMATION NOT OBTAINED ☐ Not Entered In Database

NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.

Position
SU = Supine
ST = Standing

VSTPTNUM
VSTPT
VSPOS
VSTESTCD

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU	VSORRESU VSORRES	/
1.	1 minute	816	ST		/ VSTESTCD VSORRESU VSORRES
2.	3 minutes	817	ST	VSTESTCD VSORRESU VSORRES	

Vital Signs Timeline Example II

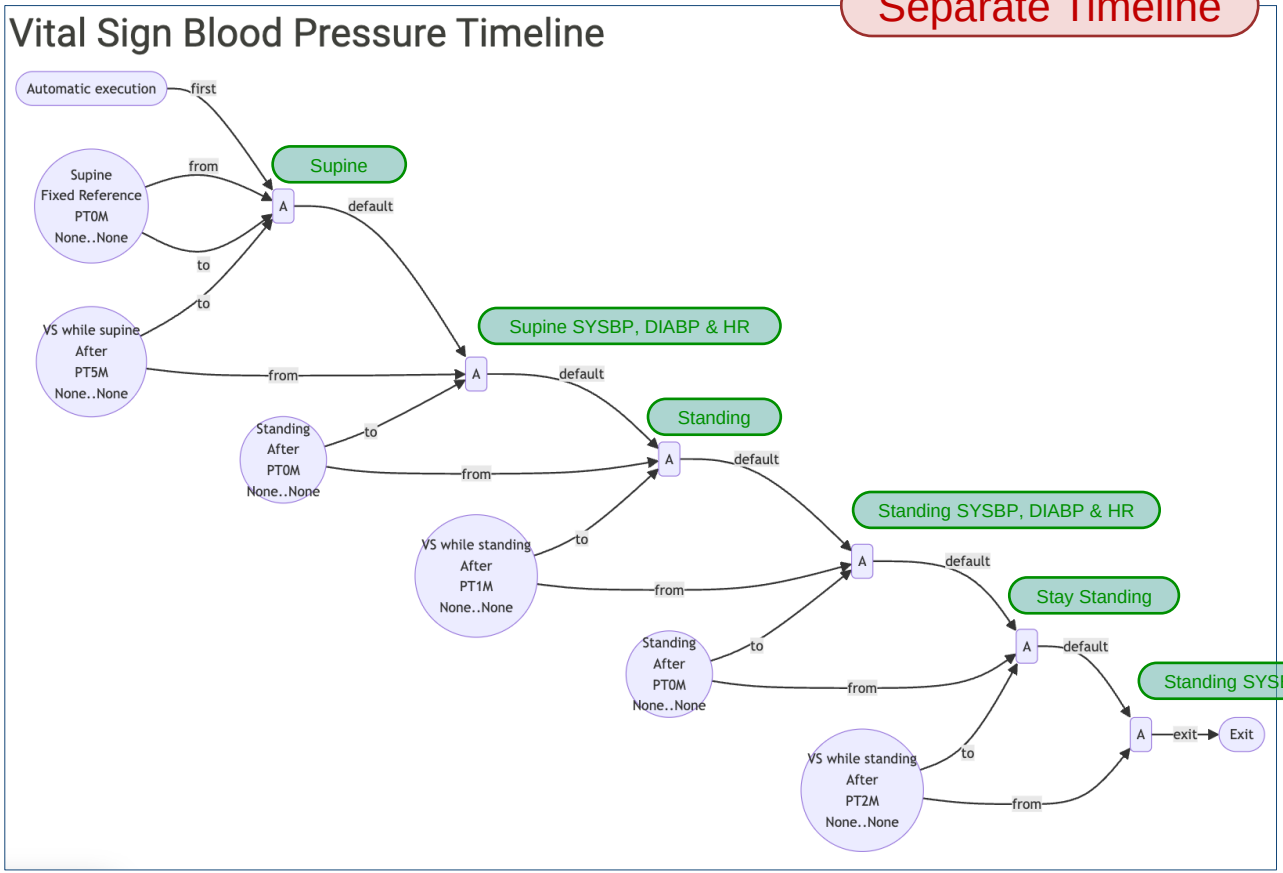
Separate Timeline

	A	B	C	D	E	F	G	H	I
1	**Name**	Vital Sign Blood Pressure Timeline	**name**	VS_5MIN	VS_SUPINE	VS_1MIN	VS_STAND1	VS_2MIN	VS_STAND3
2	**Description**	BP Profile	**description**						
3	**Condition**	Automatic execution	**label**	5 minute supine	Vital signs supine	1 minute standing	Vital signs after 1 min standing	2 minute standing	Vital signs after 3 min standing
4			**type**	Activity	Activity	Activity	Activity	Activity	Activity
5			**default**	VS_SUPINE	VS_1MIN	VS_STAND1	VS_2MIN	VS_STAND3	(Exit)
6			**condition**						
7			**epoch**						
8			**encounter**						
9	**Parent Activity**	**Child Activity**	**BC/Procedure/Timeline**						
10		Supine	PR: PR_SUPINE	X					
11		Vital Signs Supine	BC:Systolic blood pressure, BC:Diastolic blood pressure, BC: Heart Rate		X				
12		Stand	PR: PR_STAND			X		X	
13		Vital Signs Standing	BC:Systolic blood pressure, BC:Diastolic blood pressure, BC: Heart Rate				X		X

	A	B	C	D	E	F	G	H	I
1	**name**	**description**	**label**	**type**	**from**	**to**	**timingValue**	**toFrom**	**window**
20	TIM19	Supine	Supine	FIXED	VS_5MIN	VS_5MIN	0 mins		
21	TIM20	VS while supine	VS while supine	AFTER	VS_SUPINE	VS_5MIN	5 mins	S2S	
22	TIM21	Standing	Standing	AFTER	VS_1MIN	VS_SUPINE	0 min	E2S	
23	TIM22	VS while standing	VS while standing	AFTER	VS_STAND1	VS_1MIN	1 min	S2S	
24	TIM23	Standing	Standing	AFTER	VS_2MIN	VS_STAND1	0 min	E2S	
25	TIM24	VS while standing	VS while standing	AFTER	VS_STAND3	VS_2MIN	2 min	S2S	

Vital Signs Timeline Example III

Separate Timeline



Vital Signs Timeline Example IV

Initiated From The Main Timeline

	A	B				
1	**Name**	Main Timeline	**name**	SCREEN1	SCREEN2	DOSE
2	**Description**	This is the main timeline for the study design.	**description**	-	-	-
3	**Condition**	Potential subject identified	**label**	Screen One	Screen Two	Dose
4			**type**	Activity	Activity	Activity
5			**default**	SCREEN2	DOSE	WK2
6			**condition**			
7			**epoch**	Screening	Screening	Treatment 1
8			**encounter**	E1	E2	E3
9	**Parent Activity**	**Child Activity**	**BC/Procedure/Timeline**			
10		Informed consent		X	-	-
11		Inclusion/exclusion criteria		X	-	-
12		Patient number assigned		X	-	-
13		Demographics		X	-	-
14		Hachinski		X	-	-
15		MMSE		X	-	-
16		Physical examination		X	-	-
17		Medical history		X	-	-
18		Habits		X	-	-
19		Chest X-ray		X	-	-
20		Apo E genotyping		-	-	-
21		Patient randomised		-	-	X
22		Vital signs / Temperature	BC:Body temperature, BC:Body Weight, BC:Body Height, TL: vsBloodPressure	X	X	X