

# SoA and CRF Technical Note

Dave Ibersen-Hurst, 25th March 2022

## Changes

- 25<sup>th</sup> March 2022 – First draft

## Purpose

This note provides a quick overview of how a Schedule of Activities (SoA) and an electronic Case Report Form (eCRF) can be generated from data contained within an instance of the DDF Unified Study Definitions Model (USDM).

This note is based on some early prototyping work undertaken using a logical representation of the USDM placed into a property graph representation and populated with the data for a single study design. This work can be found in Github at <https://github.com/data4knowledge/ddf>

## Model Extract

The following figure extracts the main classes involved in the processing necessary to generate a SoA or a CRF. The figure is a logical representation and has been simplified so as to show the relevant classes and for the purposes of illustration with the section classes and the many-to-many tables removed. The USDM UML model should be referenced as the normative artefact.

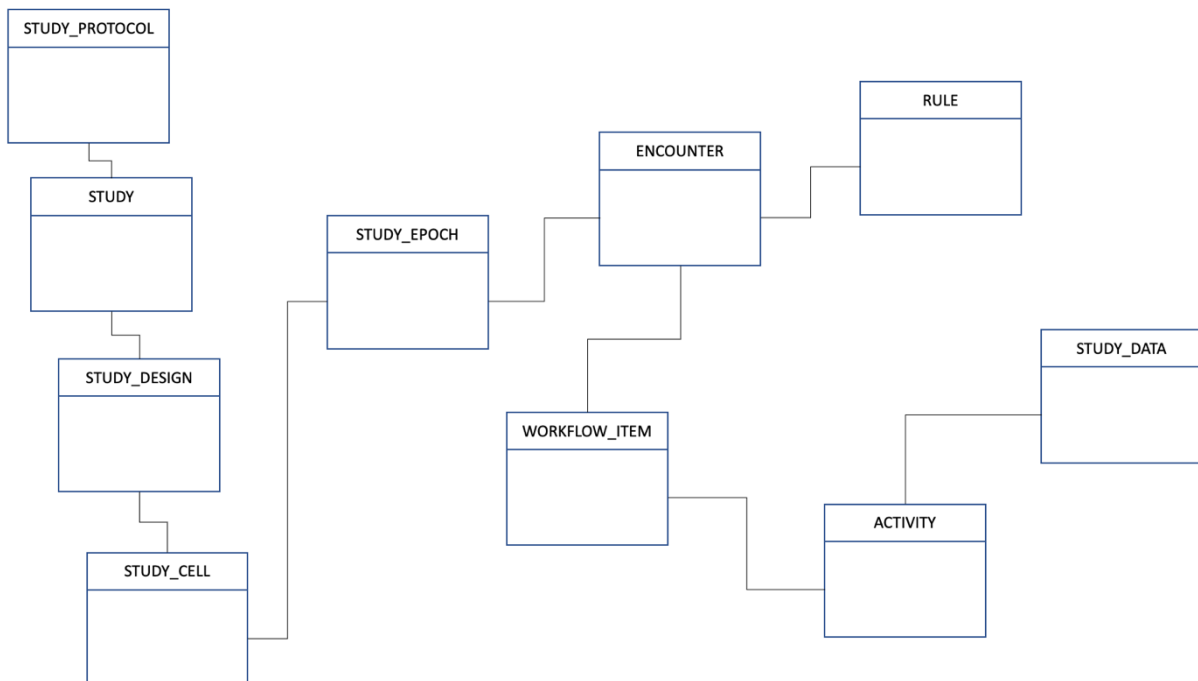


Figure 1 – Simplified USDM

## Schedule of Activities

For the schedule of activities, the need is to assemble the study epochs and associated visits (encounters) for the columns and the activities for the rows. This is achieved by navigating the model gathering the required data. The links between visits (encounters) and activities are then determined by the linking provided by the workflow items.

The output of the SoA from the prototyping work is shown below

Schedule of Assessments for DDR

	SCREEN	RUN-IN	RUN-IN	RUN-IN	TREATMENT	TREATMENT	TREATMENT	TREATMENT	TREATMENT	TREATMENT	TREATMENT	TREATMENT	FOLLOW-UP	FOLLOW-UP
	SCREENING VISIT	RUN-IN VISIT 1	RUN-IN VISIT 2	RUN-IN VISIT 3	CYCLE 1, TREATMENT DAY 1	CYCLE 1, TREATMENT DAY 3	CYCLE 1, TREATMENT DAY 5	CYCLE 2, TREATMENT DAY 1	CYCLE 2, TREATMENT DAY 3	CYCLE X, TREATMENT DAY 1	CYCLE X, TREATMENT DAY 4		FU 1	FU 2
		-D5	-D3	-D1	D1	D3	D5	D1	D3	D1	D4		W2	W4
Informed consent	X													
Eligibility criteria	X													
Demography	X													
Medical history	X													
Disease characteristics	X													
Physical exam	X		X										X	
Height	X													
12-lead ECG	X	X	X	X									X	
Hematology (predose)	X			X									X	
Chemistry (predose)	X			X									X	
Serology	X	X	X	X	X			X		X			X	
Urinalysis	X			X									X	
Pregnancy test	X			X										
Ensure availability of medication X					X			X		X				
Hospitalization		X			X			X		X				
Weight					X			X					X	
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Figure 2: Schedule of Activities

## ODM and eCRF

To generate an ODM and then visualize with a XSLT stylesheet follows the same process as followed as for the SOA. The processing goes one step further down the model to the study data items to get to the ecrf\_link attribute that may contain a link to a resource that can be used to access the resource that represents the activity.

For the prototype/demonstration code a simple approach was taken:

1. If the ecrf\_link was empty, a local library of ODM files (a directory of ODM files) was accessed and a simple name match search performed. If a form match (first match) was found, that form was extracted and used to build the study CRF
2. If the ecrf\_link was populated it was assumed to point to either an ODM form (XML) or a BC definition (YAML). The ODM form is used as is (first form) or the BC was translated into a simple ODM form using the CDISC Library to build the required terminology.
3. If no match or link was found a blank ODM form was added to the study CRF

The various ODM forms were then built into one single study ODM file and passed through the stylesheet to render into a human readable form.

The figure below shows the CDISC eCRF Portal Demographics form visualized within the CRF produced.

**Form DM - Demographics**  
*CRF instructions: DM - Demographics*

BIRTHDAT	1.1	What is the subject's date of birth?	dd/mm/yyyy <input type="text"/>	
			<small>The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</small>	
AGE	1.2	What is the subject's age?	<input type="text"/>	
AGEU	1.3	What is the age unit used?	<input type="text"/>	
SEX	1.4	What is the sex of the subject?	<input type="radio"/> Female (F) <input type="radio"/> Male (M) <input type="radio"/> Unknown (U) <input type="radio"/> Undifferentiated (UNDIFFERENTIATED) <input type="radio"/> Hispanic or Latino (HISPANIC OR LATINO) <input type="radio"/> Not Hispanic or Latino (NOT HISPANIC OR LATINO) <input type="radio"/> Not Reported (NOT REPORTED) <input type="radio"/> Unknown (UNKNOWN)	
ETHNIC	1.5	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	<input type="radio"/> American Indian or Alaska Native (AMERICAN INDIAN OR ALASKA NATIVE) <input type="radio"/> Asian (ASIAN) <input type="radio"/> Black or African American (BLACK OR AFRICAN AMERICAN) <input type="radio"/> Native Hawaiian or Other Pacific Islander (NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER) <input type="radio"/> White (WHITE) <input type="radio"/> Not Reported (NOT REPORTED) <input type="radio"/> Unknown (UNKNOWN)	
RACE	1.6	Which of the following five racial designations best describes you? (More than one choice is acceptable.)	<input type="radio"/> Other (OTHER)	DM.RACE
RACEOTH	1.7	What was the other race?	<input type="text"/>	

Figure 3: CRF Example