WIFI
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Digital Data Flow (DDF) Workshop: Mastering USDM

Rob DiCicco (TransCelerate)
Dave Iberson-Hurst (CDISC)
Berber Snoeijer (CDISC)
William Illis (Novartis)
Belinda Griffin (DDF Program Manager)

PHUSE US Connect,
25 February 2024

Today's Speakers

Rob DiCicco

TransCelerate Portfolio VP-Process Harmonization

Dave Iberson-Hurst

CDISC DDF Product Owner

Berber Snoeijer

CDISC DDF Technical Lead

William Illis

Global Head, Collaboration & Technology Strategy, Novartis

Belinda Griffin

Digital Data Flow Program Manager

TransCelerate's Digital Data Flow Initiative aims to break the document paradigm

Re-Cap from Webinar

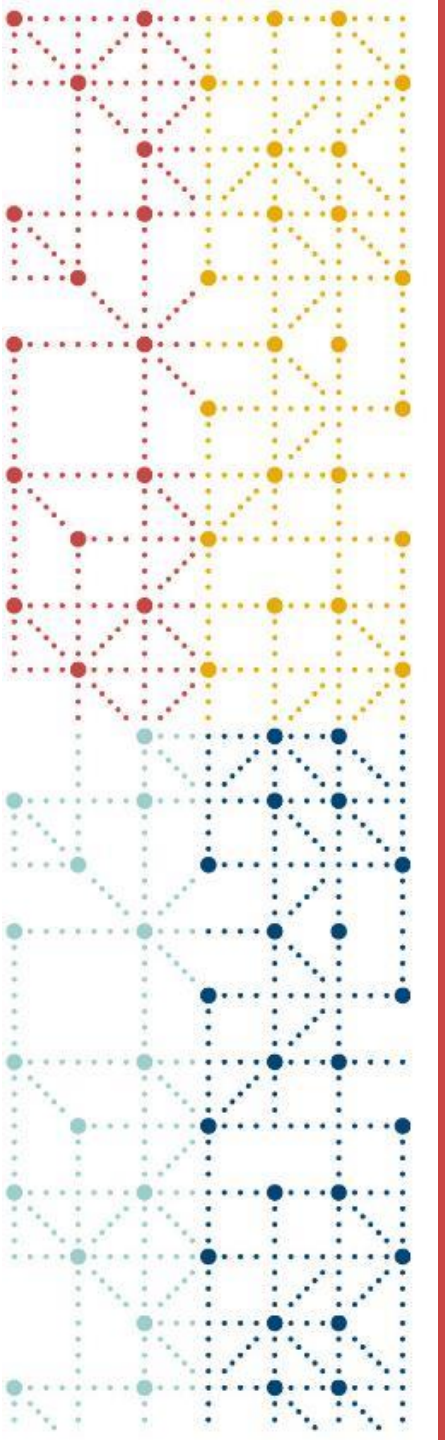
The DDF technical solution consists of two key components
USDM represents the standards aspect

Unified Study Definitions Model (USDM) – **developed with CDISC**; this is a published industry standard for specifying and structuring study definitions (design & protocol information) in a digital, machine-readable format promulgated and maintained by CDISC.

Study Definitions Repository (SDR) – Type of repository that is conformant with USDM and acts as a functioning, example approach to store protocol information and connect other producing and consuming systems to achieve interoperability. **Source code is available under an open-source license on the DDF Github** (see QR code at right).

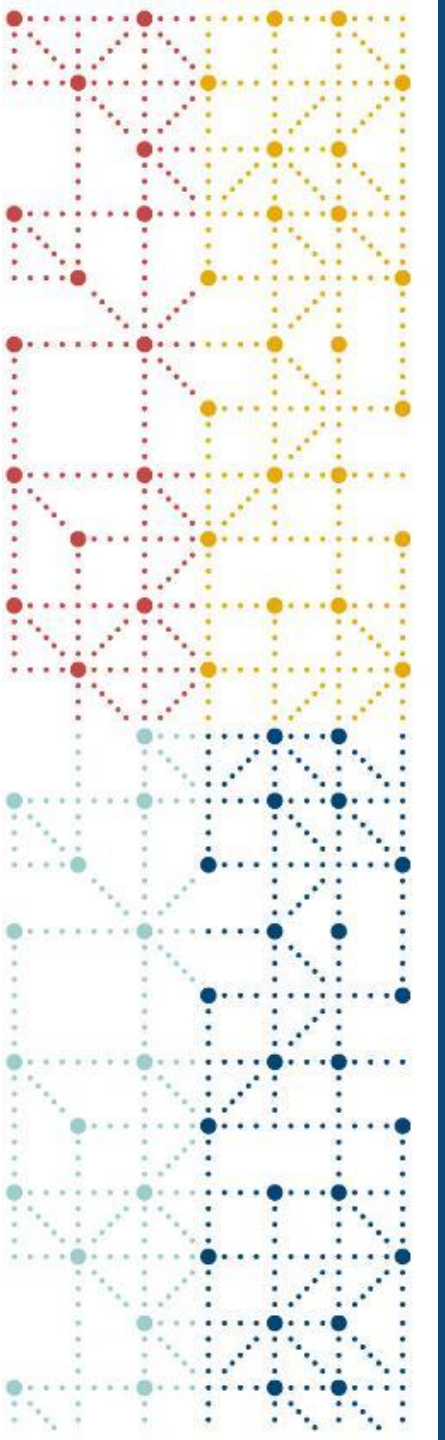
https://transcelerate.github.io/ddf-home/

TransCelerate BIOPHARMA INC.



Agenda

1. Introduction (Berber)
2. Overview of model (Dave)
3. Inclusion / Exclusion Criteria (Berber)
4. SoA & Timelines (Dave)
5. Biomedical Concepts (Dave)
6. Footnotes (Berber)
7. USDM and the ICH M11 document template (Dave)
8. Wrap Up

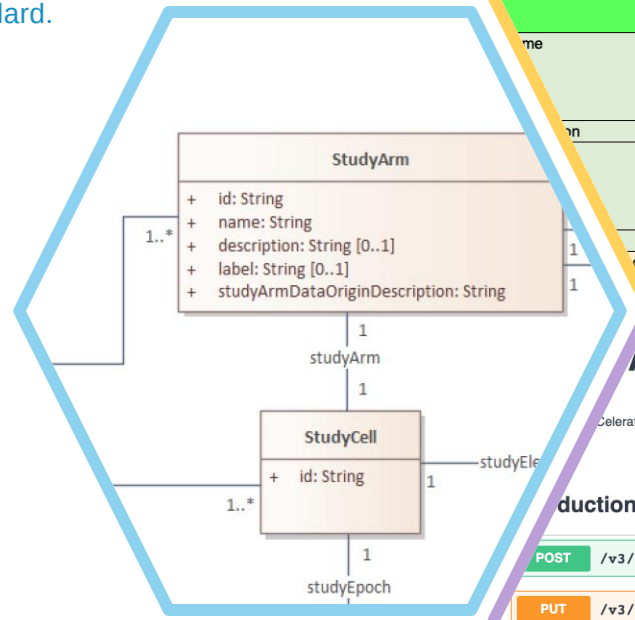


Introduction

The USDM Standard

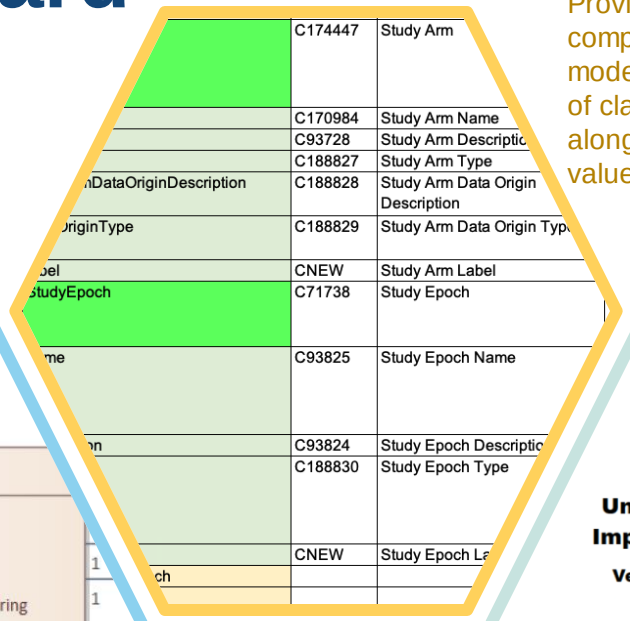
Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



CDISC Controlled Terminology

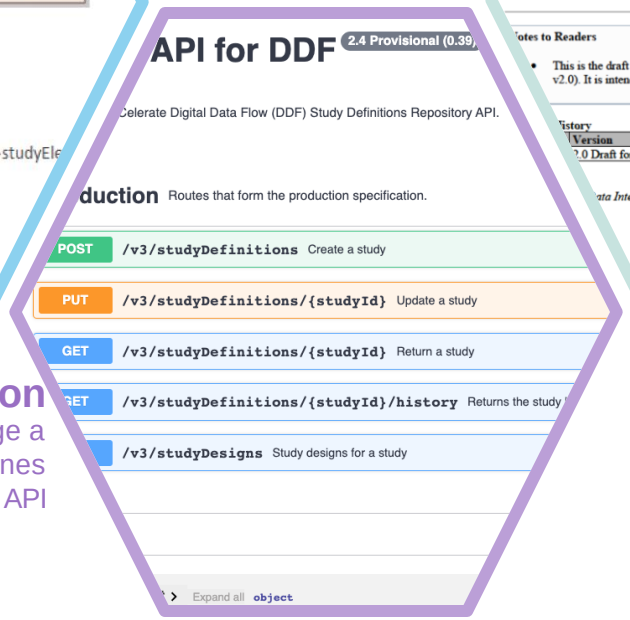
Provides further semantics, complementing the UML model. Includes the definition of classes and attributes along with the definition of value sets



	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Descriptio
	C188827	Study Arm Type
nDataOriginDescription	C188828	Study Arm Data Origin Description
riginType	C188829	Study Arm Data Origin Typ
el	CNEW	Study Arm Label
tudyEpoch	C71738	Study Epoch
me	C93825	Study Epoch Name
n	C93824	Study Epoch Descriptio
	C188830	Study Epoch Type
	CNEW	Study Epoch La
ch		

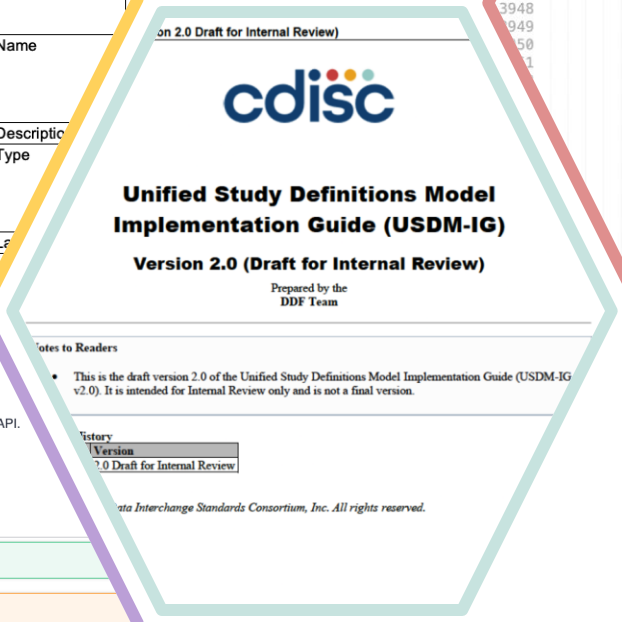
API Specification

Provides the means to exchange a single study between machines using a JSON API



Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard



Examples

Example protocols implemented in the USDM with associated JSON files and visualisations

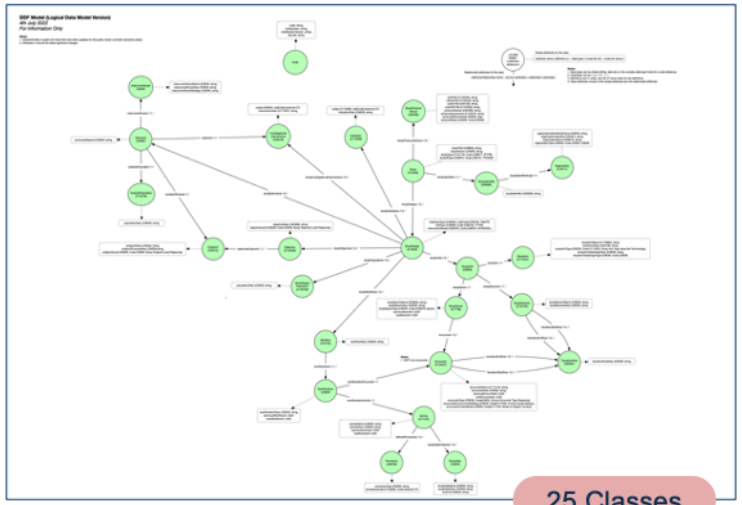
PUBLIC REVIEW

USDM Status

	PHASE ONE *July 2021 – July 2022*	PHASE TWO *Oct 2022 – June 2023*	PHASE THREE *July 2023 – Apr 2024*
Unified Study Definitions Model (USDM)	☑	☑	☑
Application Programming Interface (API) Specification	☑	☑	☑
CDISC Controlled Terminology	☑	☑	☑
Reference Architecture Conformance Tests	☑		*Being replaced by CDISC CORE rules*
Essential Users Stories	☑		
Architecture Principles	☑	*Still applicable*	*Still applicable*
Test Files		☑	☑
Implementation Guide		☑	☑

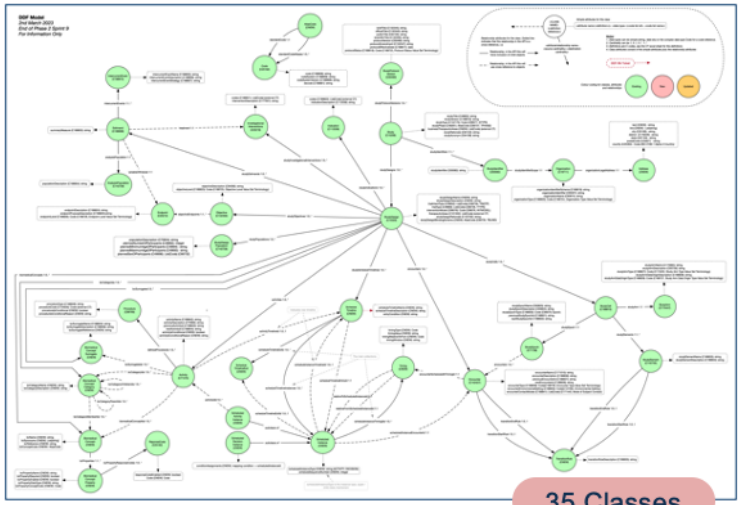
CDISC DDF / USDM: Phases One, Two and Three

Phase One



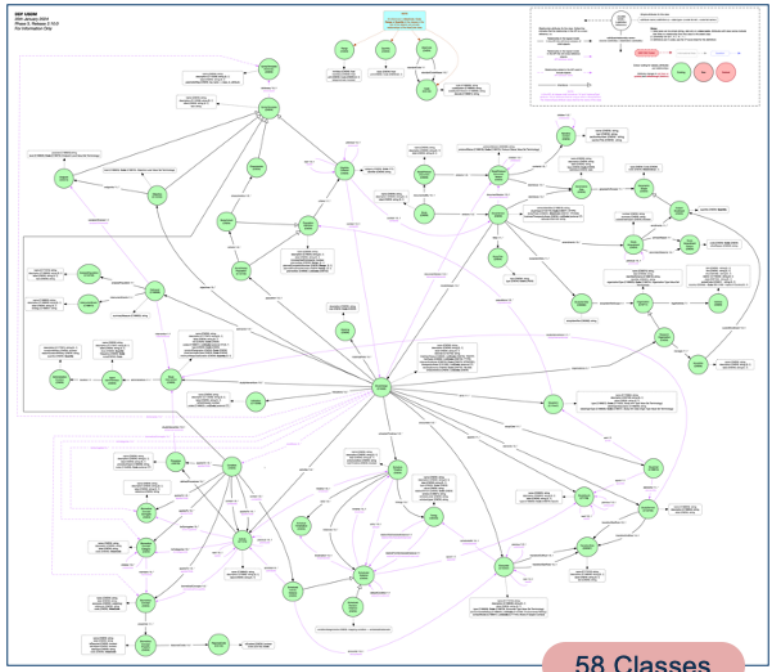
- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

Phase Two



- Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA) & Biomedical Concepts (BCs)
- The protocol document still an external entity

Phase Three



- Now contains structured and unstructured elements
- The entire protocol document can be held within the USDM
- Allows for the protocol document to be generated from the model

DDF Phase 3 USDM Scope

- Represent ICH M11 in USDM
- SDTM Trial Design Population
- Clinical Trial Registry Population
- Complex Studies/Cohorts
- Model Enhancements

CDISC Study Definition Repository RA Deliverables

- Unified Study Definitions Model (USDM) Class Diagram
- Application Programming Interface (API) Specification
- CDISC Controlled Terminology
- USDM Implementation Guide

Development and Review

2023

Date	Week #		Stage	Sprint #
05-Jul-23	1	Scoping	Development Sprints	1
12-Jul-23	2	Scoping	Development Sprints	1
19-Jul-23	3	Scoping	Development Sprints	2
26-Jul-23	4	Scoping	Development Sprints	2
02-Aug-23	5	Scoping	Development Sprints	3
09-Aug-23	6	Scoping	Development Sprints	3
16-Aug-23	7	Scoping	Development Sprints	4
23-Aug-23	8	Scoping	Development Sprints	4
30-Aug-23	9	Scoping	Development Sprints	5
06-Sep-23	10	Scoping	Development Sprints	5
13-Sep-23	11	Scoping	Development Sprints	6
20-Sep-23	12	Scoping	Development Sprints	6
27-Sep-23	13	Scoping	Development Sprints	7
04-Oct-23	14		Development Sprints	7
11-Oct-23	15		Development Sprints	8
18-Oct-23	16		Development Sprints	8
25-Oct-23	17		Development Sprints	9
01-Nov-23	18		Development Sprints	9
08-Nov-23	19		Development Sprints	10
15-Nov-23	20		Development Sprints	10
22-Nov-23	21		Development Sprints	11
29-Nov-23	22		Development Sprints	11
06-Dec-23	23		Development Sprints	12
13-Dec-23	24		Development Sprints	12
20-Dec-23	25		Development Sprints	13
27-Dec-23	26		Development Sprints	13

Development

Continuous Internal Review

2024

03-Jan-24	27		Development Sprints	13
10-Jan-24	28		Development Sprints	13
17-Jan-24	29		GGG Approval	14
24-Jan-24	30		GGG Approval	14
31-Jan-24	31		Public Review	15
07-Feb-24	32		Public Review	15
14-Feb-24	33		Public Review	16
21-Feb-24	34		Public Review	16
28-Feb-24	35		Resolve Comments	17
06-Mar-24	36		Resolve Comments	17
13-Mar-24	37		Resolve Comments	18
20-Mar-24	38		Resolve Comments	18
27-Mar-24	39		GGG Approval	19
03-Apr-24	40		GGG Approval	19
10-Apr-24	40		Publication	20
17-Apr-24	40		Publication	20

Public Review

USDM v3.0

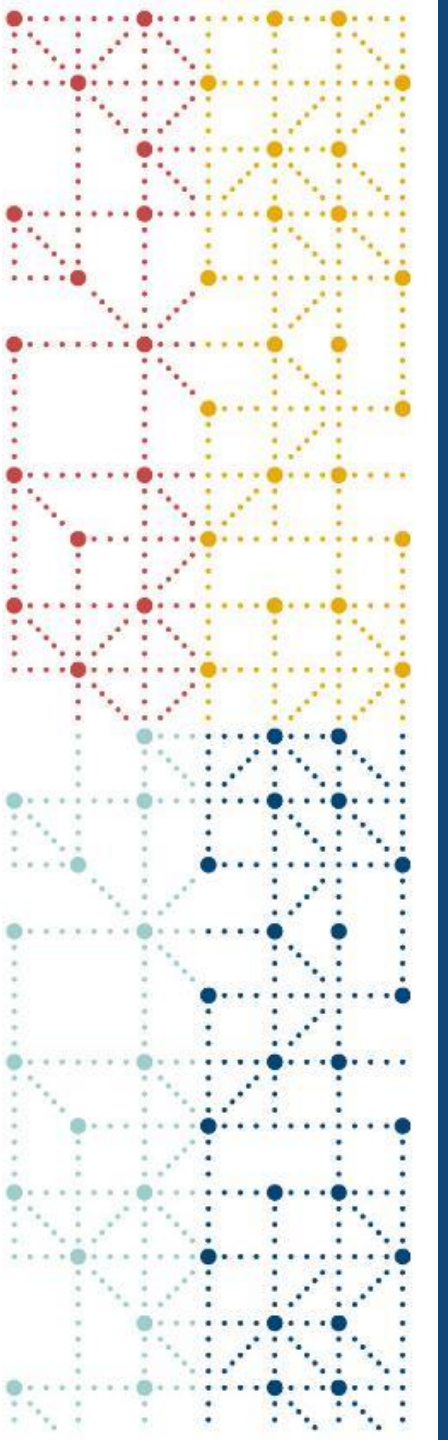
Phase 3 Information Webinar

Public Review Webinar

Presentations During US Connect

Monday February 26

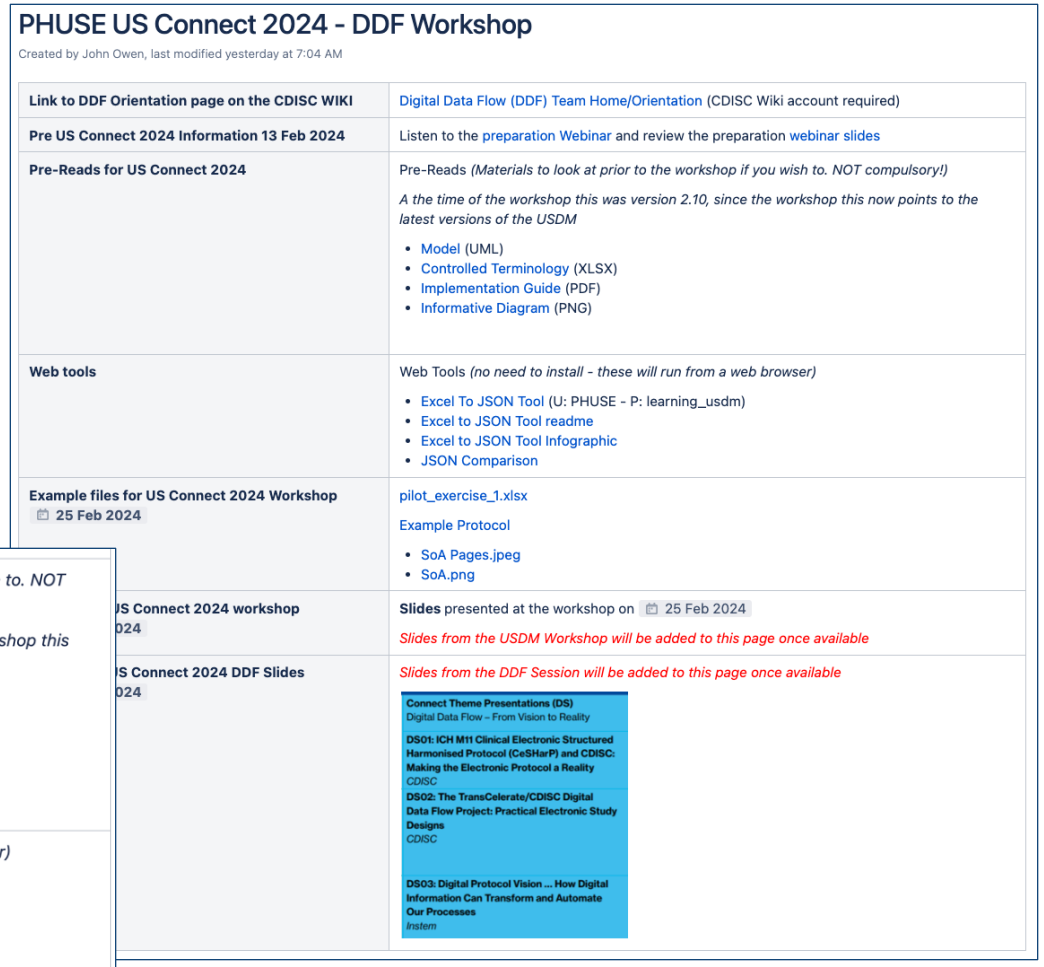
Time (EST)	Salon A	Salon B
9:00am–10:30am	**Keynote Speaker** – Peter Ronco, *Emmes* 'The Clinical Trial Process is Still Fundamentally Broken' | S	
10:30am–11:00am	**Morning Break** – Sponsored by Pinnacle 21 by Certara	
11:00am–11:30am	**DH01: How to Monitor SDTM Data Health** *Bioforum The Data Masters*	**Connect Theme Presentations (DS)** Digital Data Flow – From Vision to Reality **DS01: ICH M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality** *CDISC*
11:30am–12:00pm	**DH02: Eliminating SDTM Double Programming by Using a Validation Tool and Dummy Data** *SGS Health Science*	**DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs** *CDISC*
12:00pm–12:30pm	**DH03: Addressing Challenges in Structuring CDISC SDTM and ADaM Datasets to Report Adverse Events Spanning Two Treatment Periods** *MSD*	**DS03: Digital Protocol Vision ... How Digital Information Can Transform and Automate Our Processes** *Instem*



Model Overview

Wiki Page

- Make sure you have access!
- Base file for the exercises
- We will provide answers to the exercises after the workshop



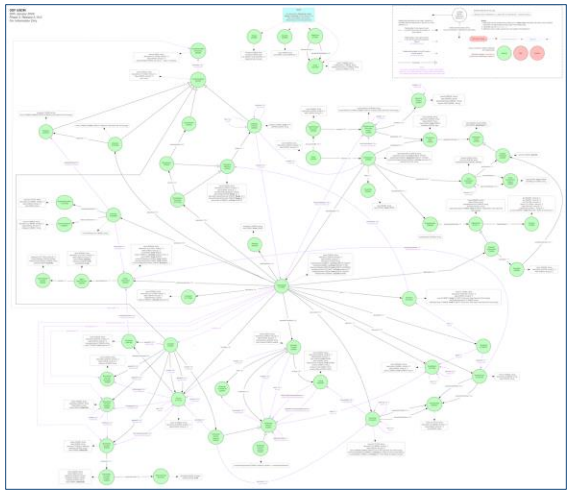
PHUSE US Connect 2024 - DDF Workshop

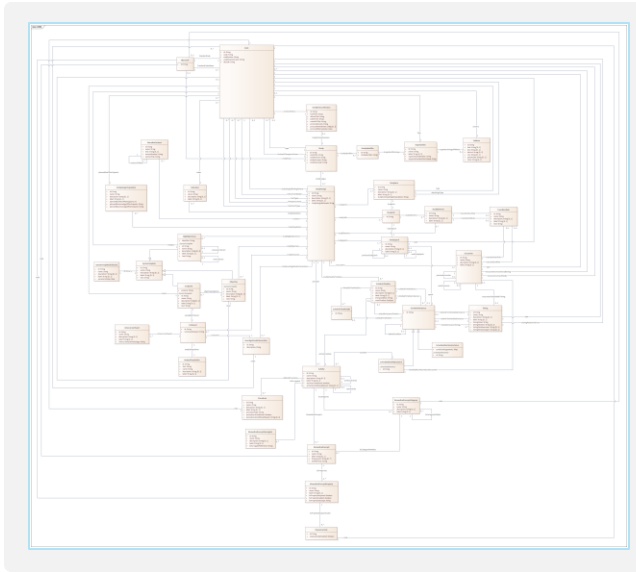
Created by John Owen, last modified yesterday at 7:04 AM

Link to DDF Orientation page on the CDISC WIKI	Digital Data Flow (DDF) Team Home/Orientation (CDISC Wiki account required)
Pre US Connect 2024 Information 13 Feb 2024	Listen to the preparation Webinar and review the preparation webinar slides
Pre-Reads for US Connect 2024	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 2.10, since the workshop this now points to the latest versions of the USDM* • Model (UML) • Controlled Terminology (XLSX) • Implementation Guide (PDF) • Informative Diagram (PNG)
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 US Connect 2024 Workshop 25 Feb 2024	pilot_exercise_1.xlsx Example Protocol • SoA Pages.jpeg • SoA.png
S Connect 2024 workshop 024	**Slides** presented at the workshop on 25 Feb 2024 *Slides from the USDM Workshop will be added to this page once available*
S Connect 2024 DDF Slides 024	*Slides from the DDF Session will be added to this page once available* Connect Theme Presentations (DS) Digital Data Flow – From Vision to Reality DS01: ICH M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality CDISC DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs CDISC DS03: Digital Protocol Vision ... How Digital Information Can Transform and Automate Our Processes Instem

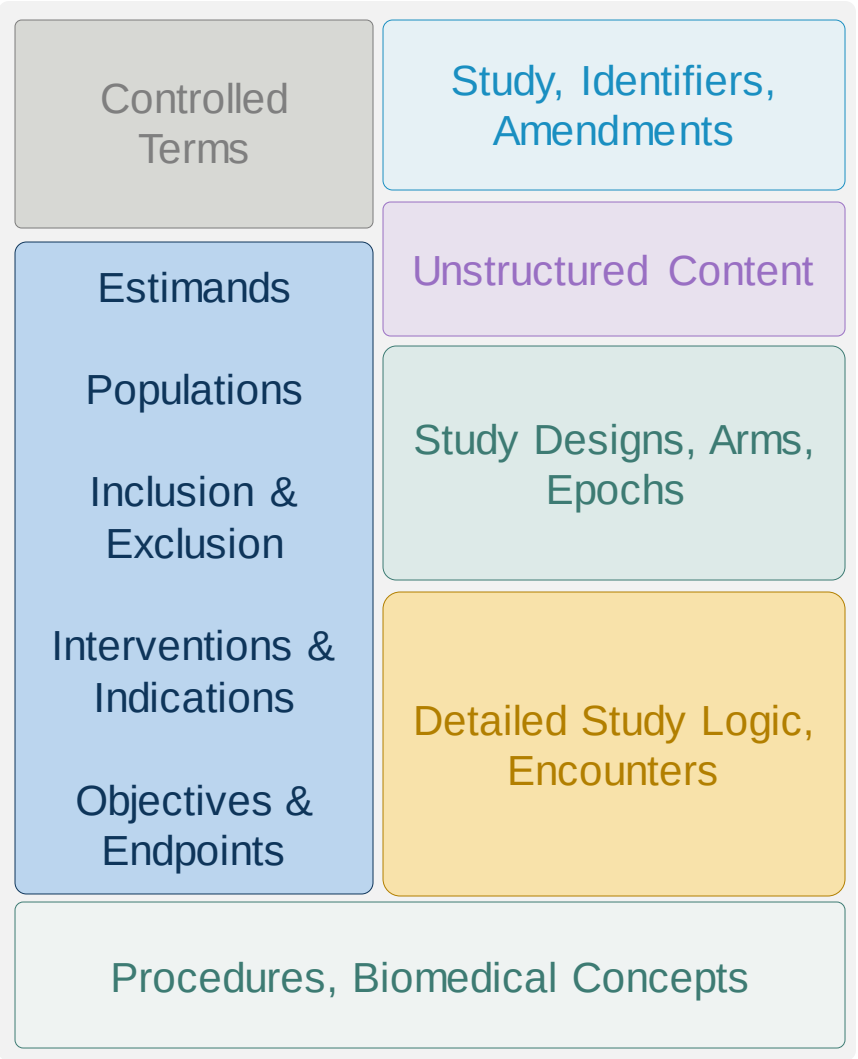
Pre-Reads for US Connect 2024	Pre-Reads *(Materials to look at prior to the workshop if you wish to. NOT compulsory!)* *A the time of the workshop this was version 2.10, since the workshop this now points to the latest versions of the USDM* • Model (UML) • Controlled Terminology (XLSX) • Implementation Guide (PDF) • Informative Diagram (PNG)
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 • M11 to USDM Mapping Tool
Example files for US Connect 2024 Workshop 25 Feb 2024	The baseline file for the workshop exercises pilot_exercise_1.xlsx The USDM Protocol infographic protocol.png The Example Protocol including: • SoA Pages.jpeg • SoA.png

USDM Content



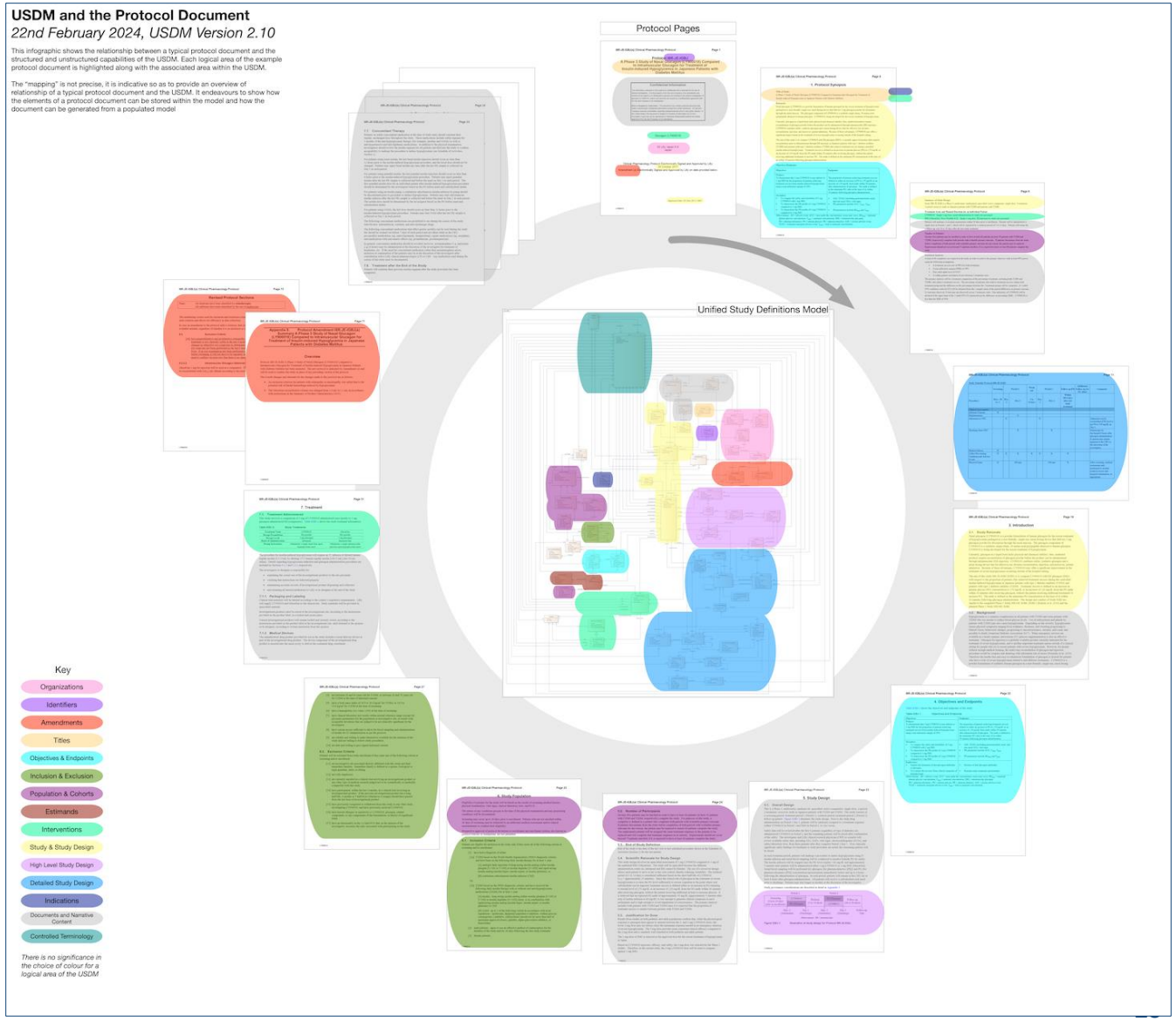


- Wiki page has
  - The UML diagram (normative)
  - An informative diagram
  - The Controlled Terminology



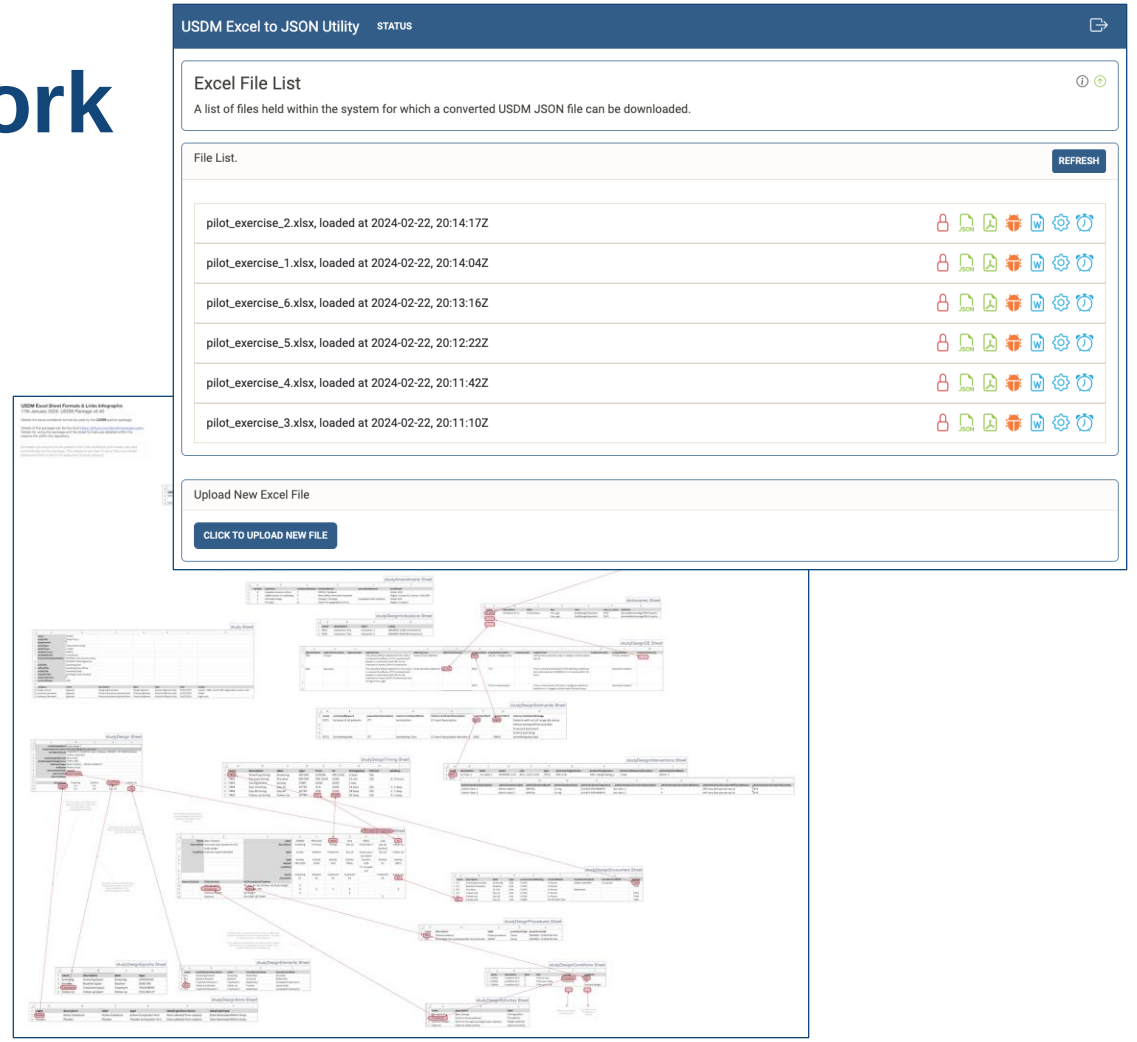
USDM and the Protocol

- Download the infographic from the wiki
- You can zoom in to see the detail
- Gives an overview of how a protocol is structured within the USDM
- How the USDM can support generation of a complete protocol



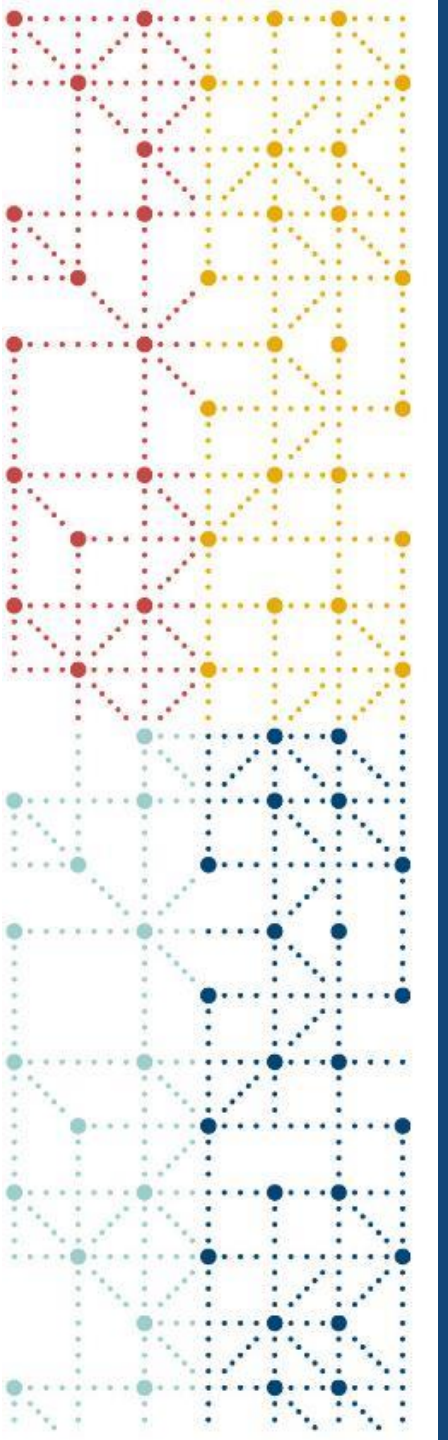
Exercise 1: Check We Can Work

- Simple exercise to check everybody can do the remaining exercises
- Steps
  - Take base example and rename the file to something unique to you
  - Upload your renamed file to the online tool
  - Examine the outputs
  - Have a look at the Excel sheet
  - Have a look at the Excel infographic

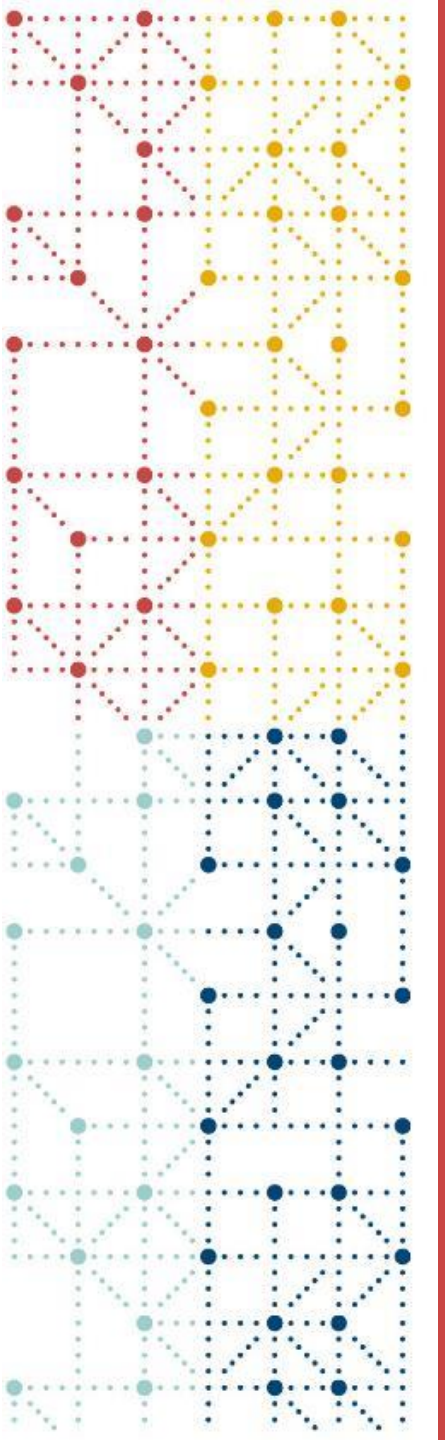


The Excel tool is a TEST TOOL.

We would NEVER use it for production work or protocol writing!



Focus Areas



Inclusion / Exclusion

Inclusion / Exclusion

- Model Class EligibilityCriterion
- Formatted text
- Inherits SyntaxTemplates class
  - References to structured elements stored elsewhere in the data model like:
    - Population characteristics
    - Activities
    - …

3.4.2.1. Inclusion Criteria

Patients may be included in the study only if they meet **all** the following criteria:

[1] Males and postmenopausal females at least 50 years of age.

[2] Diagnosis of probable AD as defined by National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's Disease and Related Disorders Association (ADRDA) guidelines (Attachment LZZT.7).

[3] MMSE score of 10 to 23.

[4] Hachinski Ischemic Scale score of ≤4 (Attachment LZZT.8).

[5] CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.

Eligibility Criteria

	A	B	C	D	E	F	G
1	**category**	**identifier**	**name**	**description**	**label**	**text**	**dictionary**
2	Inclusion	01	Age Criteria	The study age criterion		Subjects shall be between <usdm:tag name=\"min_age\"/> and <usdm:tag name=\"max_age\"/>	IE_Dict
3	Inclusion	02	Pop Criteria	The study population criterion		<usdm:tag name="\population\"/> as defined by the NINCDS and the ADRDA guidelines (Attachment LZZT.7)	IE_Dict
4	Inclusion	03	Diag Criteria	The study diagnosis criterion		<usdm:tag name=\"Activity1\"/> score of 10 to 23	AS_Dict
5	Exclusion	09	Previous Criteria	The previous xanomeline TTS criterion		Persons who have previously completed or withdrawn from this study or any other study investigating xanomeline TTS or the oral formulation of xanomeline.	
6							

Inclusion / Exclusion

Dictionary

	A	B	C	D	E	F	G
1	**name**	**description**	**label**	**key**	**class**	**xref**	**attribute**
2	IE_Dict	Dictionary for IE	IE Dictionary	min_age	StudyDesignPopulation	POP1	@plannedAge/Range/@maxValue
3				max_age	StudyDesignPopulation	POP1	@plannedAge/Range/@minValue
4				Population	StudyDesignPopulation	POP1	description
5	AS_Dict	Dictionary for Study Assessments	Assessment Dictionary	Activity1	Activity	MMSE	label

Eligibility Criteria

	A	B	C	D	E	F	G
1	**category**	**identifier**	**name**	**description**	**label**	**text**	**dictionary**
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6							

Inclusion / Exclusion

json


```
"criteria": [
  {
    "id": "EligibilityCriteria_1",
    "name": "Age Criteria",
    "label": "",
    "description": "The study age criterion",
    "text": "Subjects shall be between <usdm:tag name=\"min_age\"/> and <usdm:tag name=\"max_age\"/>",
    "dictionaryId": "SyntaxTemplateDictionary_1",
    "instanceType": "EligibilityCriteria",
    "category": {
      "id": "Code_346",
      "code": "C25532",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "Inclusion Criteria",
      "instanceType": "Code"
    },
    "identifier": "1",
    "nextId": EligibilityCriteria_2,
    "previousId": null,
    "contextId": StudyDesign_1
  },
```



```
"dictionaries": [
  {
    "id": "SyntaxTemplateDictionary_1",
    "name": "IE_Dict",
    "label": "IE Dictionary",
    "description": "Dictionary for IE",
    "parameterMap": {
      "min_age": "<usdm:ref klass=\"Range\" id=\"Range_3\" attribute=\"minValue\"></usdm:ref>,
      "max_age": "<usdm:ref klass=\"Range\" id=\"Range_3\" attribute=\"maxValue\"></usdm:ref>,
      "population":"<usdm:ref klass=\"StudyDesignPopulation\" id=\"StudyDesignPopulation_1\" attribute=\"description\"></usdm:ref>
      }
    },
    "instanceType": "SyntaxTemplateDictionary"
  },
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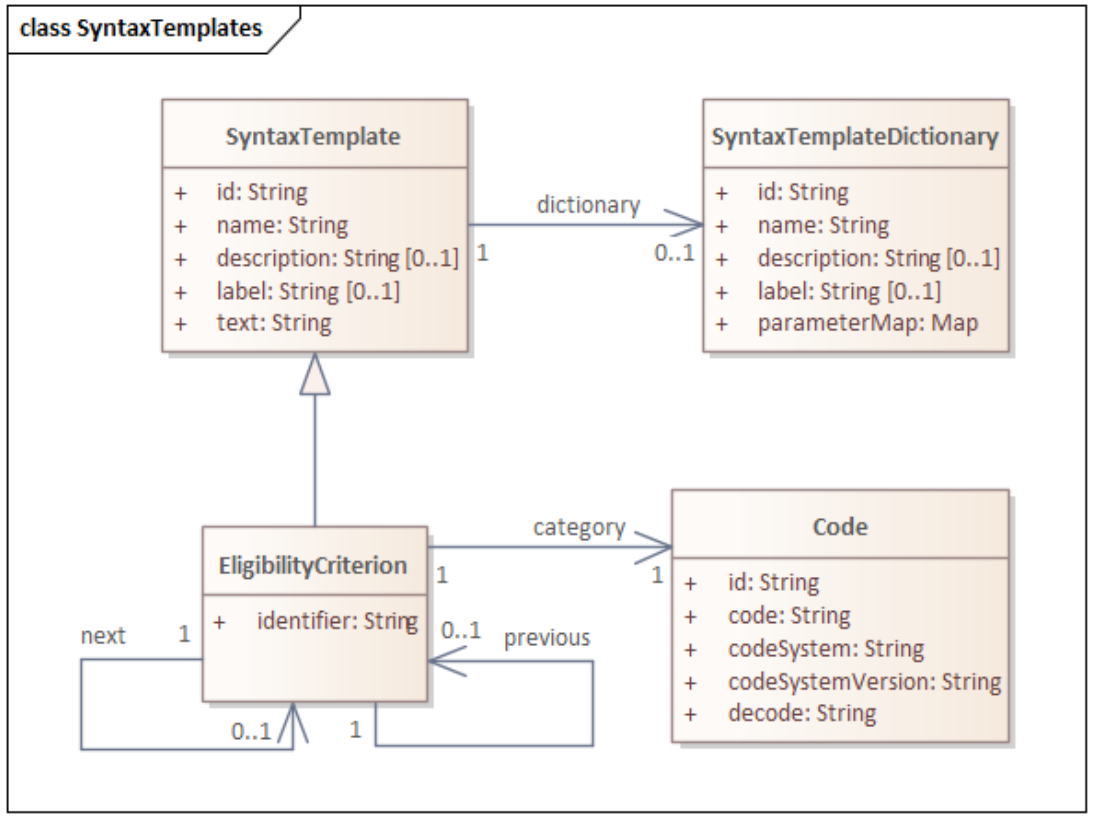
uml



Exercise 2: Inclusion / Exclusion

- Inclusion Criteria 4, add parameter to refer to activity in a similar way as Inclusion Criteria 3
- Sheets
  - studyDesignEligibilityCritieria
  - dictionaries

3.4.2.1. Inclusion Criteria

Patients may be included in the study only if they meet **all** the following criteria:

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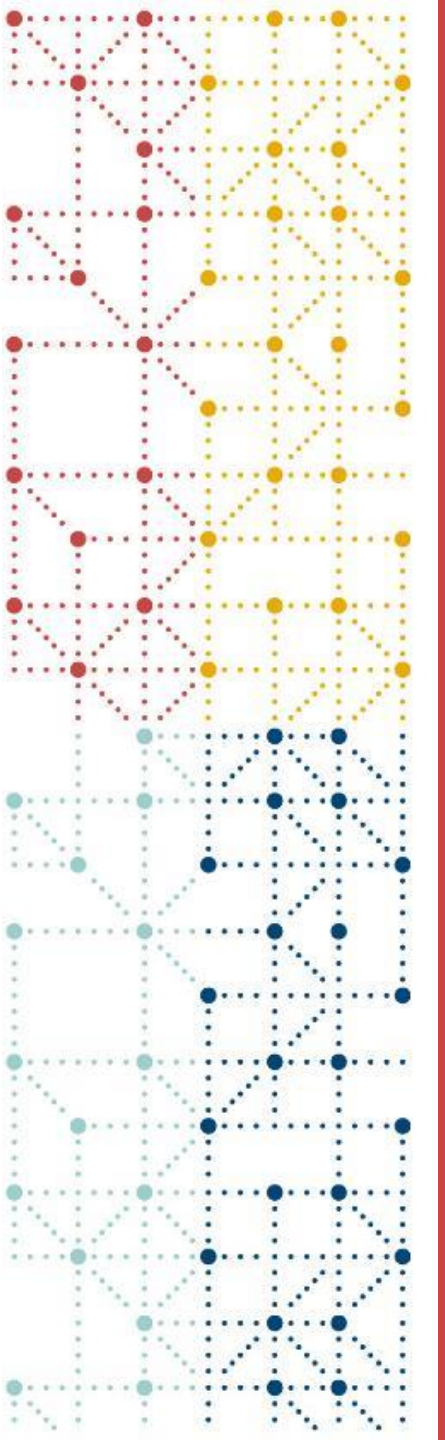
[5] CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.



Timelines

LZZT - Schedule of Activities

Protocol Attachment LZZT.1
Schedule of Events for Protocol H2Q-MC-LZZT(c)

	VISIT	1	2	3	4	5		7	8
ACTIVITY	WEEK	-2	-3	0	2	4		6	8
Informed consent		X							
Patient number assigned		X							
Hachinski ≤4		X							
MMSE 10-23		X							
Physical examination		X							
Medical History		X							
Habits		X							
Chest x-ray		X							
Apo E genotyping					X				
Patient randomized				X					
Vital signs/Temperature		X	X	X	X	X		X	X
Ambulatory ECG placed			X						
Ambulatory ECG removed				X					
ECG		X			X	X		X	X
Placebo TTS test		X							
CT Scan (if not within last year and patient passes all other screens)		X							
Concomitant Medications		X		X	X	X		X	X
Laboratory (Chem/Hemat):		X			X	X		X	X
Laboratory (Urinalysis)		X			X				
Plasma Specimen (Xanomeline)				X	X	X		X	
Hemoglobin A_{1C}		X[a]							
Study drug record Medications dispensed Medications returned				X	X	X		X	X
TTS Acceptability Survey									
ADAS-Cog		P		X					X
CIBIC+		P		X					X
DAD		P		X					X
NPI-X		P		X	X	X		X	X[b]
Adverse events		X	X	X	X	X		X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram
X = Performed at this visit.
X[a] = Performed at this visit if patient is an insulin-dependent diabetic.
X[b] = Performed at this visit and via telephone interview 2 weeks following this visit.
P = Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.

Schedule of Events for Protocol H2Q-MC-LZZT(c) (concluded)

	VISIT	9	10	11	12	13	ET	RT
ACTIVITY	WEEK	12	16	20	24	26		
Informed consent								
Patient number assigned								
Hachinski ≤4								
MMSE 10-23								
Physical examination						X	X	
Medical History								
Habits								
Chest x-ray								
Apo E genotyping								
Patient randomized								
Vital signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed								
Ambulatory ECG removed								
ECG		X	X	X	X	X	X	
Placebo TTS test								
CT Scan (if not within last year and patient passes all other screens)								
Concomitant Medications		X	X	X	X	X	X	X
Laboratory (Chem/Hemat):		X	X	X	X	X	X	
Laboratory (Urinalysis)		X			X		X	
Plasma Specimen (Xanomeline)		X		X			X	
Hemoglobin A_{1c}								
Study drug record Medications dispensed Medications returned		X	X	X	X	X	X	
TTS Acceptability Survey						X	X	
ADAS-Cog			X		X		X	X
CIBIC+			X		X		X	X
DAD			X		X		X	X
NPI-X		X[b]	X[b]	X[b]	X	X	X	X
Adverse events		X	X	X	X	X	X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram; ET = Early Termination; RT = Retrieval
X = Performed at this visit.
X[b] = Performed at this visit and via telephone interview 2 weeks following this visit.

Timeline

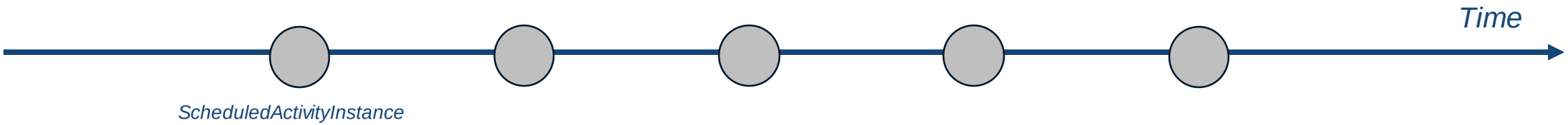
Timeline - SoA

Time

Small excerpt from LZZT, for purposes of explanation

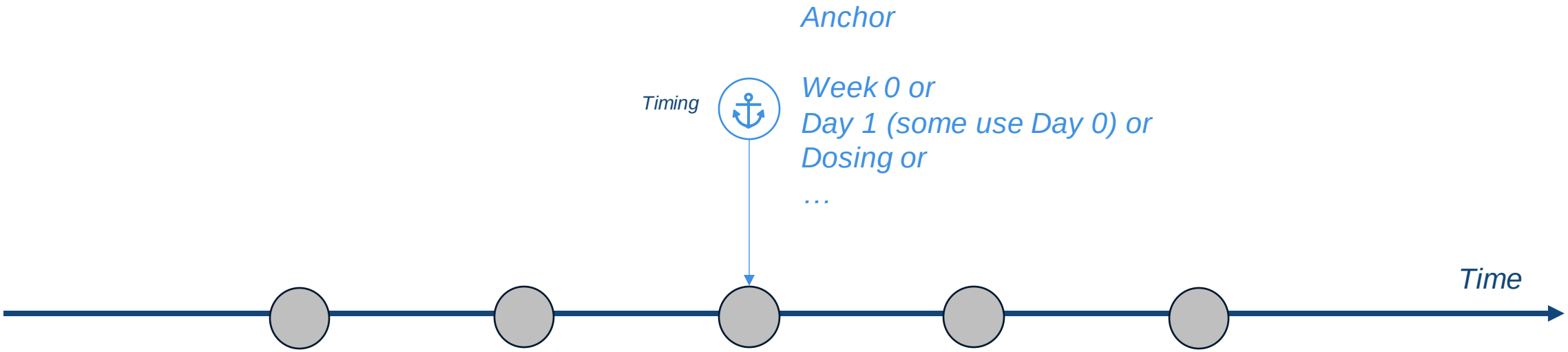
	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				

Timeline - Timepoints



	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				

Timeline – Timing I



Anchor

	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				

Timeline – Timing 2

The {from node} is before the [to node]

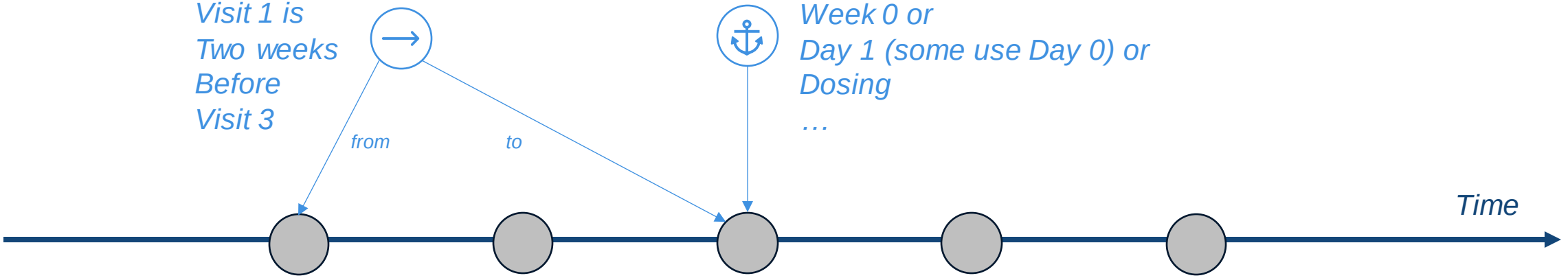
The {from node} is after the [to node]

Relative

Visit 1 is Two weeks Before Visit 3

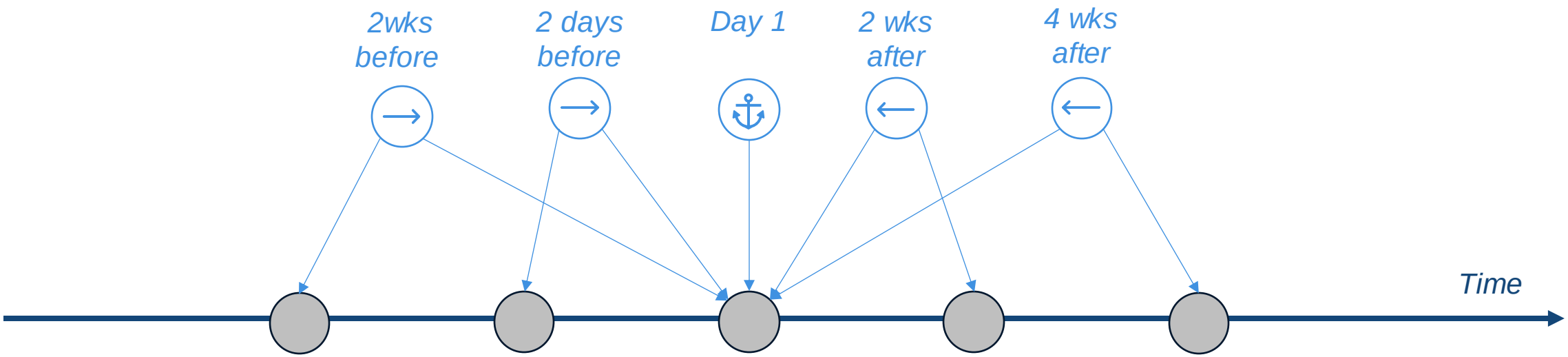
Anchor

Week 0 or Day 1 (some use Day 0) or Dosing …



		Relative		*Anchor*		
	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				

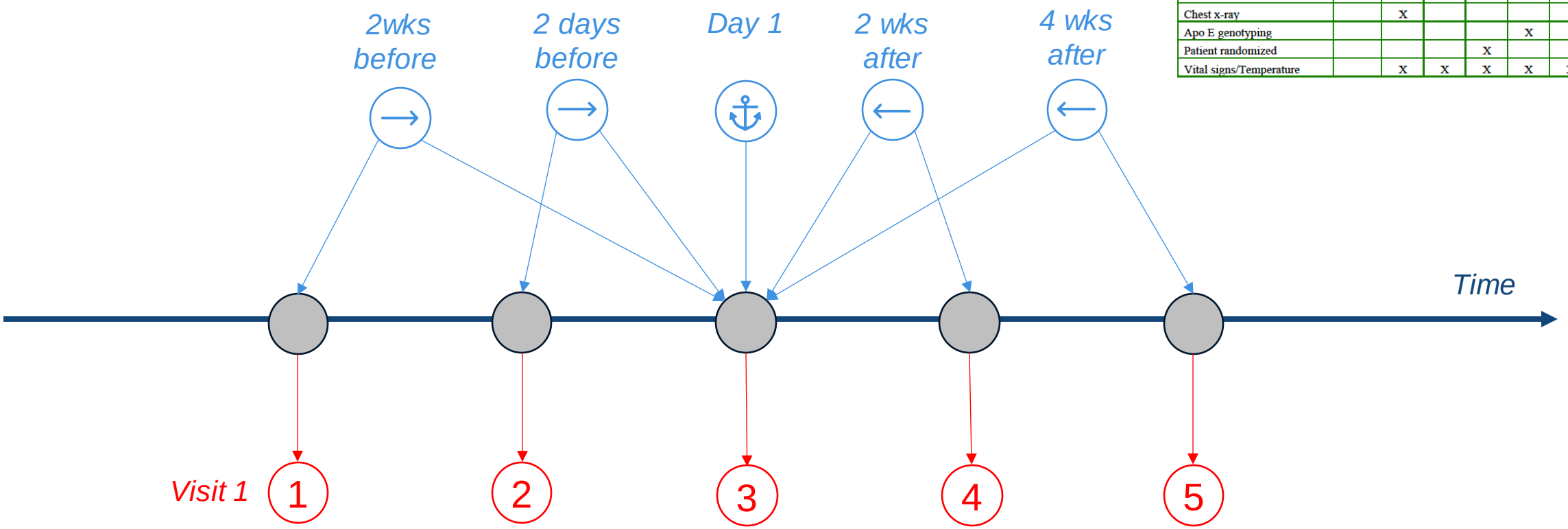
Timeline – Timing 3



	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				

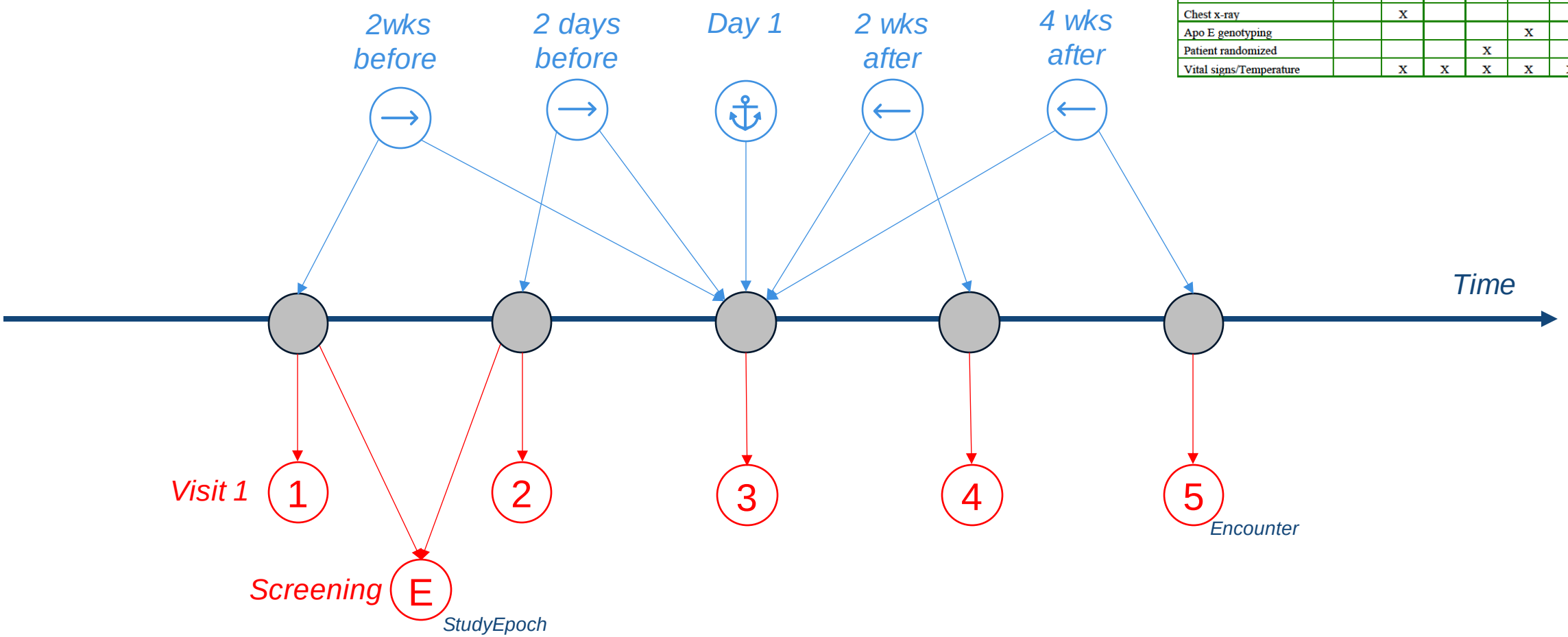
Timeline – Encounters (Visits)

	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				
Hachinski ≤4		X				
MMSE 10-23		X				
Physical examination		X				
Medical History		X				
Habits		X				
Chest x-ray		X				
Apo E genotyping					X	
Patient randomized				X		
Vital signs/Temperature		X	X	X	X	X



Timeline – Epochs

	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-3	0	2	4
Informed consent		X				
Patient number assigned		X				
Hachinski ≤4		X				
MMSE 10-23		X				
Physical examination		X				
Medical History		X				
Habits		X				
Chest x-ray		X				
Apo E genotyping					X	
Patient randomized				X		
Vital signs/Temperature		X	X	X	X	X

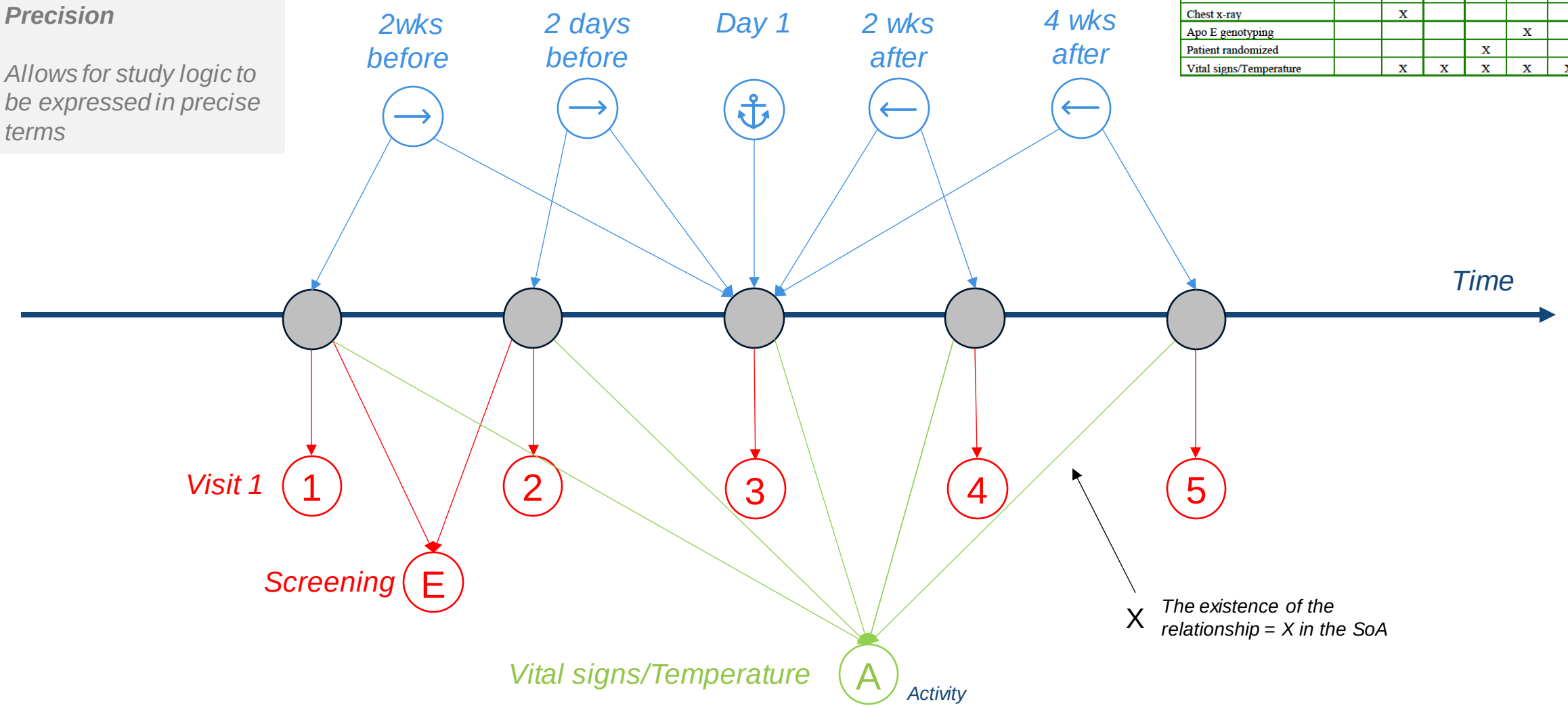


Timeline – Activities

Precision

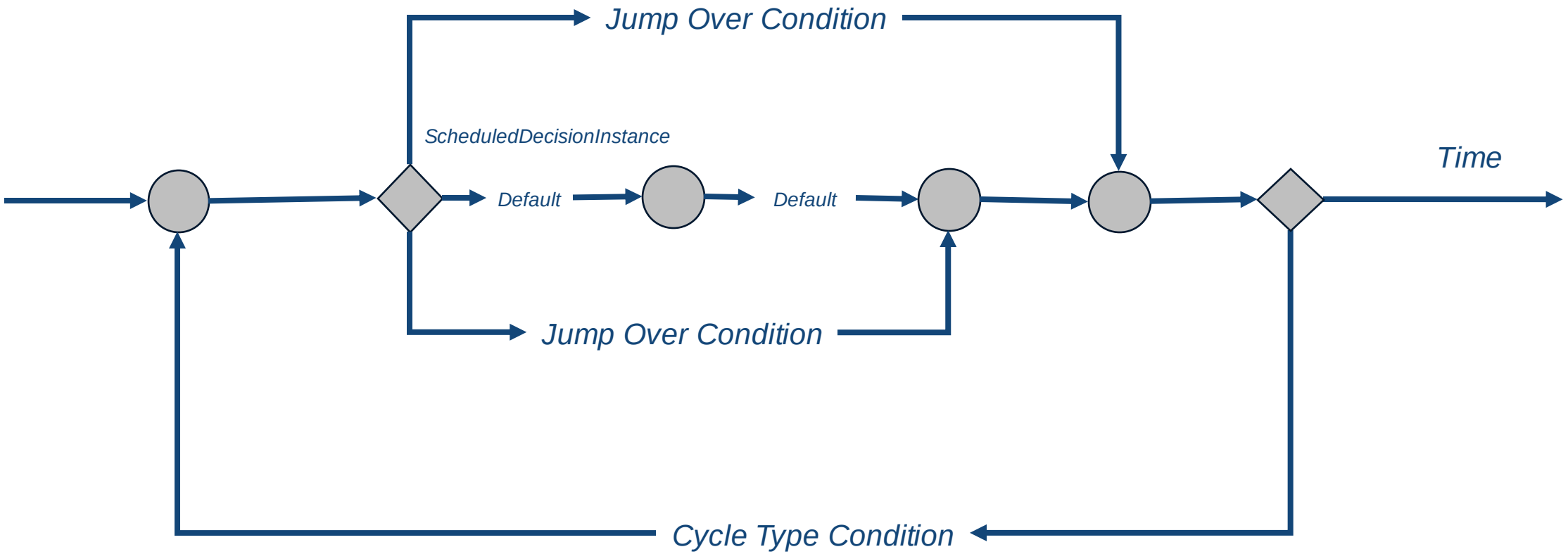
Allows for study logic to be expressed in precise terms

	VISIT	1	2	3	4	5
ACTIVITY	WEEK	-2	-.3	0	2	4
Informed consent		X				
Patient number assigned		X				
Hachinski ≤4		X				
MMSE 10-23		X				
Physical examination		X				
Medical History		X				
Habits		X				
Chest x-ray		X				
Apo E genotyping					X	
Patient randomized				X		
Vital signs/Temperature		X	X	X	X	X

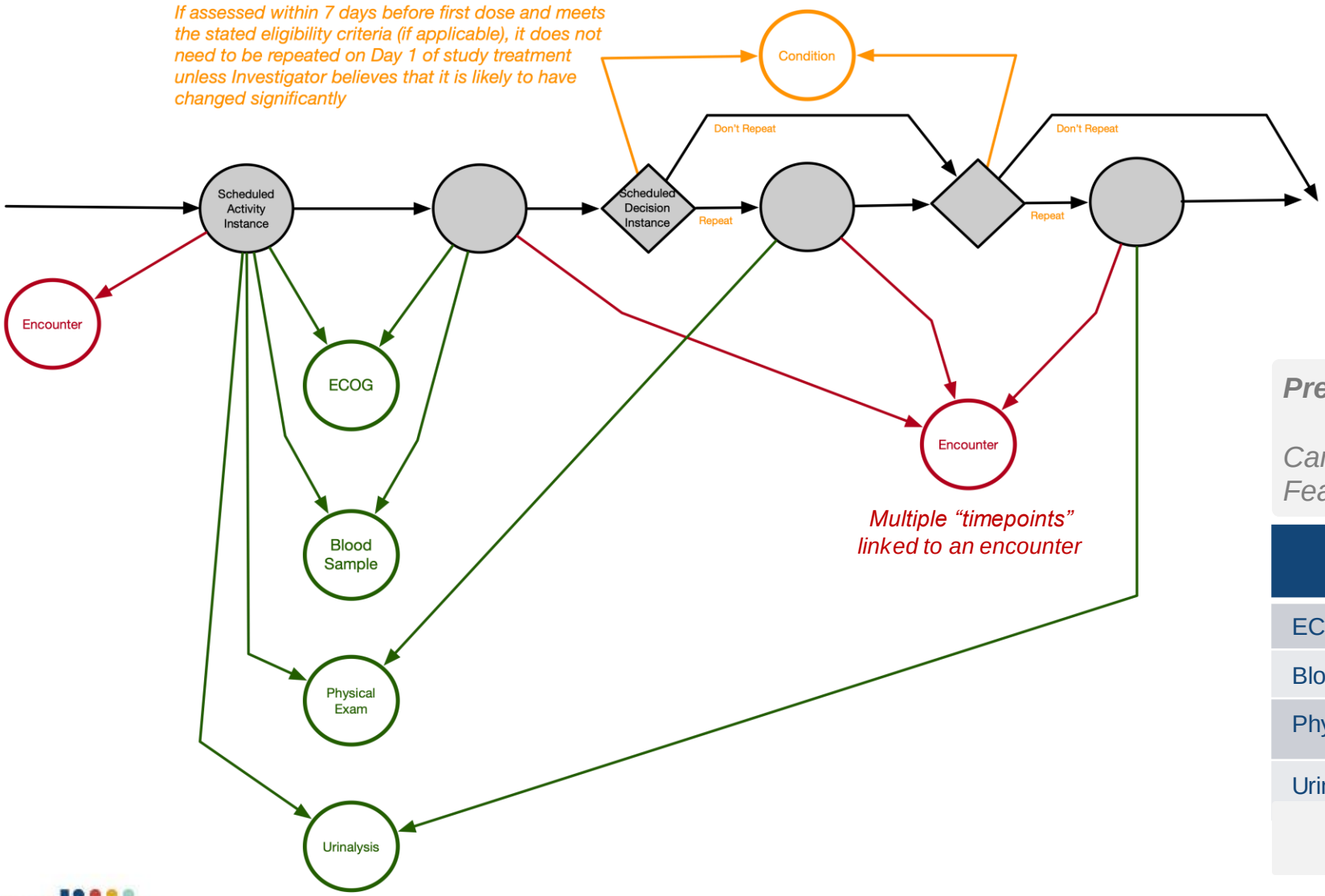


Vital signs/Temperature		X	X	X	X	X	

Timeline – Decision



Timelines - Conditions



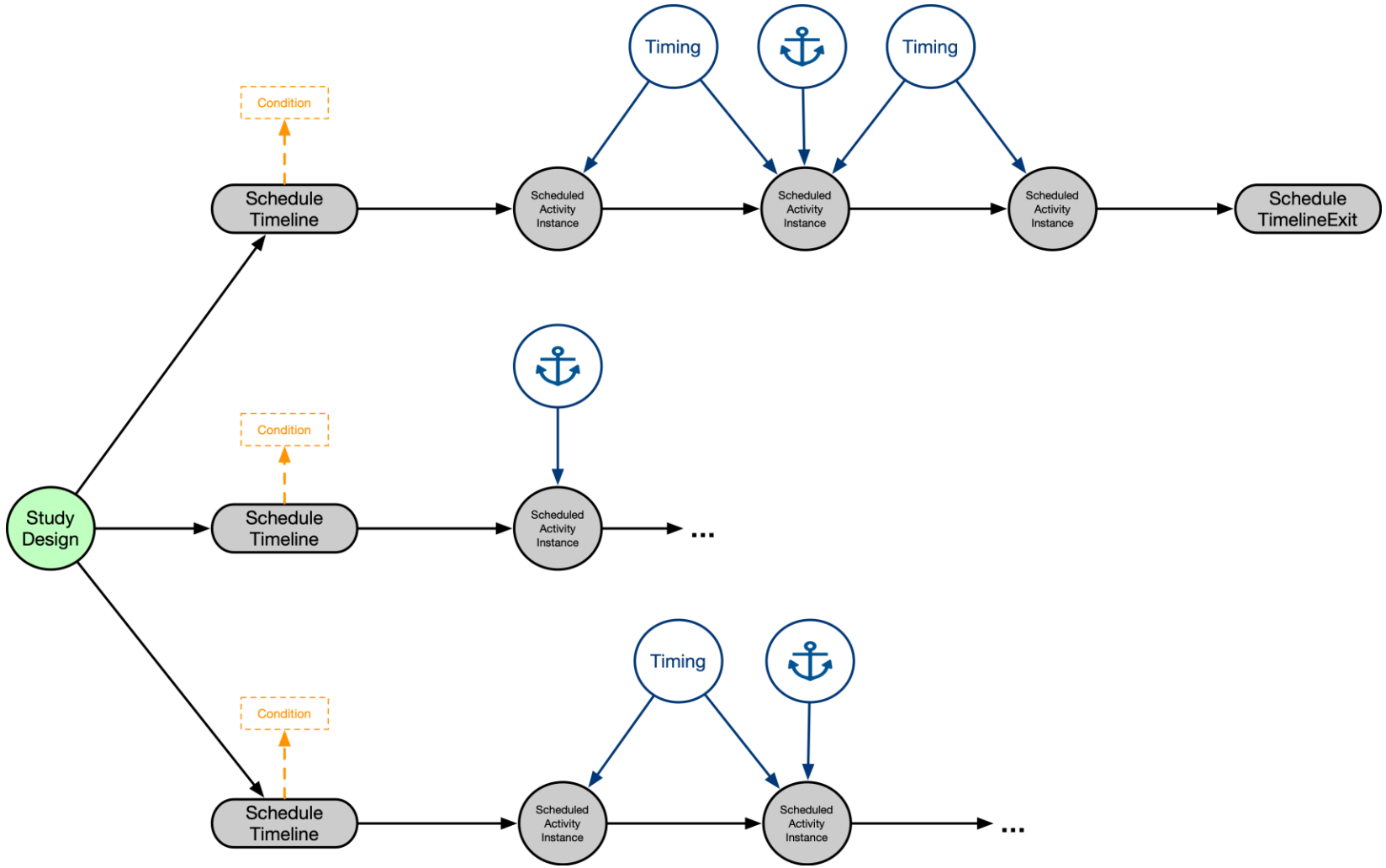
Presentation

Can derive an SoA from the USDM logic. Feature will be added to the Excel utility

	Encounter 1	Encounter 2
ECOG	X	X
Blood Sample	X	X
Physical Exam	X	Xa
Urinalysis	X	Xb

Marked as footnotes we would typically see in a protocol, we can do better

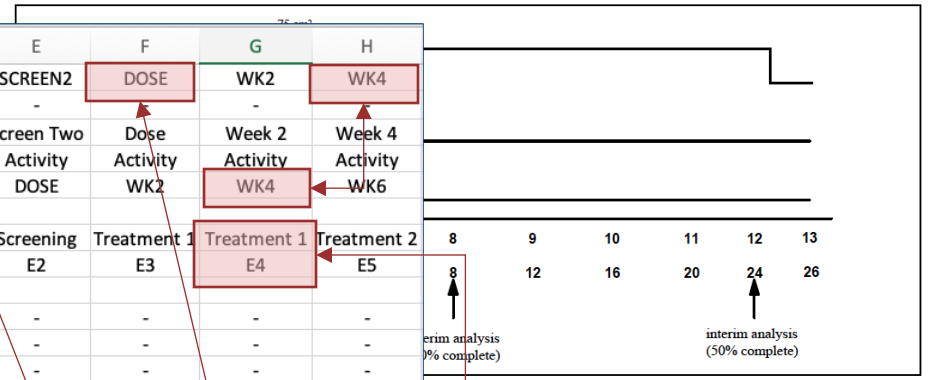
Timeline – Sub timelines



Timeline – LZZT Excel

	A	B	C	D	E	F	G	H
1	**Name**	Main Timeline	**name**	SCREEN1	SCREEN2	DOSE	WK2	WK4
2	**Description**	This is the main timeline for the study design.	**description**		-		-	
3	**Condition**	Potential subject identified	**label**	Screen One	Screen Two	Dose	Week 2	Week 4
4			**type**	Activity	Activity	Activity	Activity	Activity
5			**default**	SCREEN2	DOSE	WK2	WK4	WK6
6			**condition**					
7			**epoch**	Screening	Screening	Treatment 1	Treatment 1	Treatment 2
8			**encounter**	E1	E2	E3	E4	E5
9	**Parent Activity**	**Child Activity**	**BC/Procedure/Timeline**					
10		Informed consent		X	-	-	-	-
11		Inclusion/exclusion criteria		X	-	-	-	-
12		Patient number assigned		X	-	-	-	-
13		Demographics	BC:Date of Birth, BC:Sex, BC:Race	X	-	-	-	-
14		Hachinski <= 4		X	-	-	-	-
15		MMSE 10-23		X	-	-	-	-
16		Physical examination		X	-	-	-	-
17		Medical history		X	-	-	-	-
18		Habits		X	-	-	-	-
19		Chest X-ray		X	-	-	-	-
20		Apo E genotyping		-	-	-	X	-
21		Patient randomised		-	-	X	-	-
22		Vital signs / Temperature	BC:Systolic blood pressure, BC:Diastolic blood	X	X	X	X	X

Visits 1 through 13 should be scheduled relative to Visit 3 (Week 0 - randomization). Visits 4, 5, 7, 8, and 13 should occur within 3 days of their scheduled date. Visits 9, 10, 11, and 12 should occur within 4 days of their scheduled date. At Visit 13 patients will be given the option to enter the open-label extension phase (see Section 3.10.3. Study Extensions).

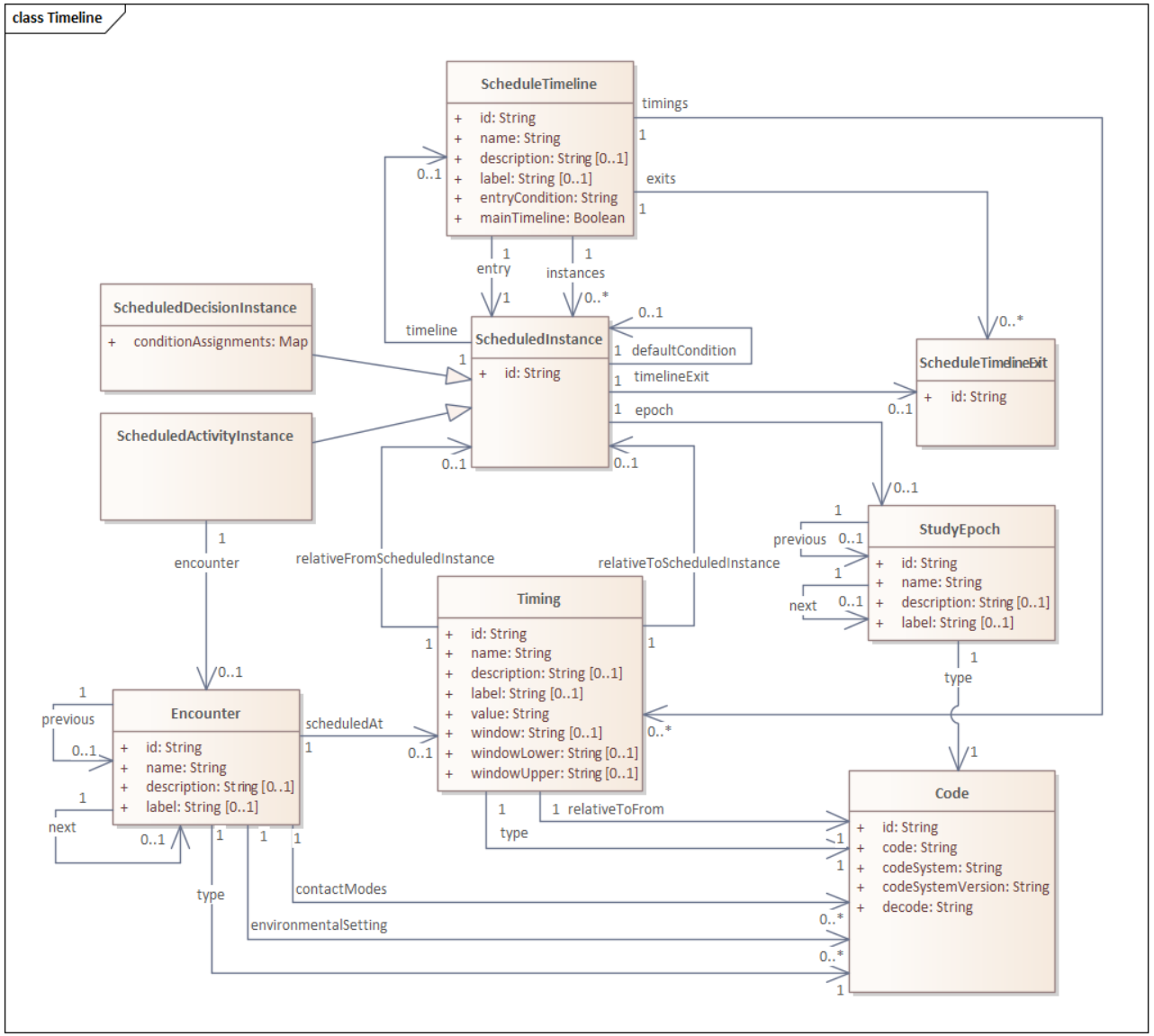


y design for Protocol H2Q-MC-LZZT(c).

Epochs & Encounters

	A	B	C	D	E	F	G	H	I
1	**name**	**description**	**label**	**type**	**from**	**to**	**timingValue**	**toFrom**	**window**
2	TIM1	Screening timing	Screening	BEFORE	SCREEN1	DOSE	2 weeks	S2S	
3	TIM2	Pre dose timing	Pre dose	BEFORE	SCREEN2	DOSE	2 days	S2S	-4..0 hours
4	TIM3	Dosing anchor	Dosing	FIXED	DOSE	DOSE	1 Day		
5	TIM4	Week 2 timing	Week 2	AFTER	WK2	DOSE	2 Weeks	S2S	-3..3 days
6	TIM5	Week 4 timing	Week 4	AFTER	WK4	DOSE	4 Weeks	S2S	-3..3 days
7	TIM6	Week 6 timing	Week 6	AFTER	WK6	DOSE	6 Weeks	S2S	-3..3 days
8	TIM7	Week 8 timing	Week 8	AFTER	WK8	DOSE	8 Weeks	S2S	-3..3 days
9	TIM8	Week 8 at home timing	Week 8 Home	AFTER	WK8N	WK8	2 Weeks	S2S	
10	TIM9	Week 12 timing	Week 12	AFTER	WK12	DOSE	12 Weeks	S2S	-4..4 days
11	TIM10	Week 12 at home timing	Week 12 Home	AFTER	WK12N	WK12	2 Weeks	S2S	
12	TIM11	Week 16 timing	Week 16	AFTER	WK16	DOSE	16 Weeks	S2S	-4..4 days
13	TIM12	Week 16 at home timing	Week 16 Home	AFTER	WK16N	WK16	2 Weeks	S2S	
14	TIM13	Week 20 timing	Week 20	AFTER	WK20	DOSE	20 Weeks	S2S	-4..4 days
15	TIM14	Week 20 at home timing	Week 20 Home	AFTER	WK20N	WK20	2 Weeks	S2S	
16	TIM15	Week 24 timing	Week 24	AFTER	WK24	DOSE	24 Weeks	S2S	-4..4 days
17	TIM16	Week 26 timing	Week 26	AFTER	WK26	DOSE	26 Weeks	S2S	-3..3 days
18	TIM17	Adverse Event	Adverse Event	FIXED	AE	AE	1 Day		
19	TIM18	Early Termination	Early Termination	FIXED	ET	ET	1 Day		

Timing – UML


class Timeline
ScheduleTimeline
+ id: String
+ name: String
+ description: String [0..1]
+ label: String [0..1]
+ entryCondition: String
+ mainTimeline: Boolean
timings
exits
entry
instances
ScheduledDecisionInstance
+ conditionAssignments: Map
ScheduledActivityInstance
timeline
ScheduledInstance
+ id: String
defaultCondition
timelineExit
epoch
ScheduleTimelineExit
+ id: String
encounter
relativeFromScheduledInstance
relativeToScheduledInstance
StudyEpoch
+ id: String
+ name: String
+ description: String [0..1]
+ label: String [0..1]
previous
next
type
Timing
+ id: String
+ name: String
+ description: String [0..1]
+ label: String [0..1]
+ value: String
+ window: String [0..1]
+ windowLower: String [0..1]
+ windowUpper: String [0..1]
Encounter
+ id: String
+ name: String
+ description: String [0..1]
+ label: String [0..1]
scheduledAt
relativeToFrom
Code
+ id: String
+ code: String
+ codeSystem: String
+ codeSystemVersion: String
+ decode: String
contactModes
environmentalSetting

Exercise 3: Timeline

- Start building a subject discontinuation timeline
- Sheets
  - studyDesign
  - studyDesignTiming
  - earlyTerminationTimeline (New Sheet)

3.10.1. Discontinuations

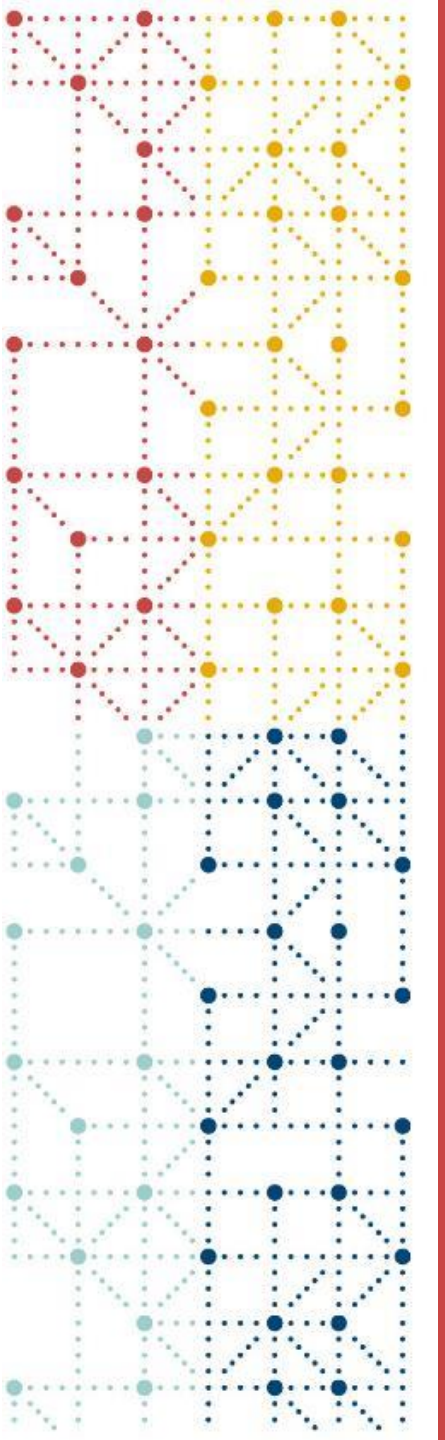
Participation in the study shall be terminated for any patient who is unable or unwilling to comply with the study protocol or who develops a serious adverse event.

In addition, patients may be discontinued for any of the following reasons:

- In the opinion of the investigator, a significant adverse event occurs or the safety of the patient is otherwise compromised.
- The patient requests to be withdrawn from the study.
- The physician in charge of the study or Lilly, for any reason stops the patient's participation in the study.

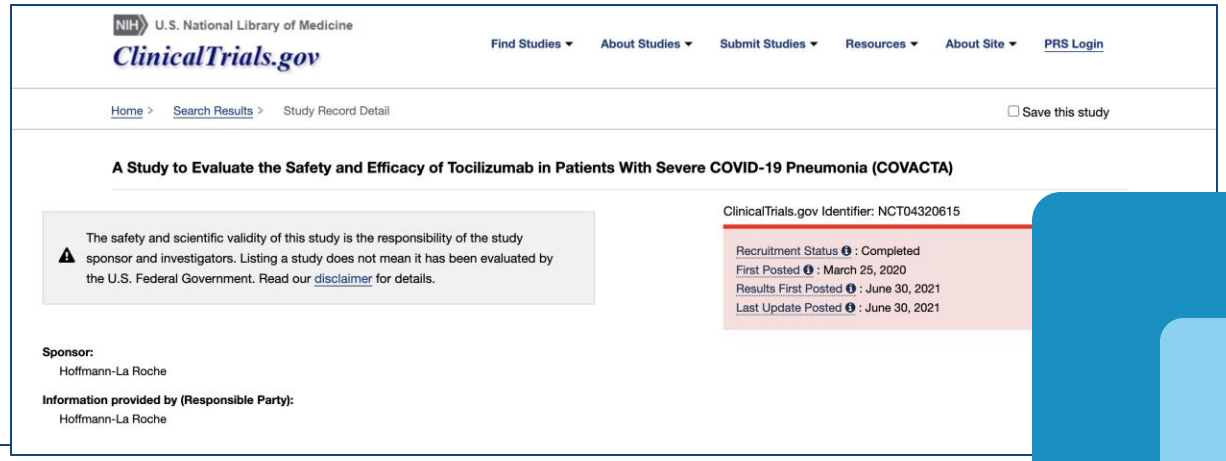
If a patient's participation terminates early, an early termination visit should be scheduled. Upon decision to discontinue a patient from the study, the patient's dose should be titrated down by instructing the patient to immediately remove the 25-cm^2 patch. Patients should be instructed to continue to apply a 50-cm^2 patch daily until the early termination visit, at which time the drug will be discontinued. Physical exam, vital signs, temperature, use of concomitant medications, chemistry/hematology/urinalysis labs, xanomeline plasma sample, TTS acceptability survey, efficacy measures, adverse events, and an ECG will be collected at the early termination visit.

In the event that a patient's participation or the study itself is terminated, the patient shall return all study drug(s) to the investigator.



Biomedical Concepts

Detailed Design and the SoA


NIH U.S. National Library of Medicine
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Home > Search Results > Study Record Detail

Save this study

A Study to Evaluate the Safety and Efficacy of Tocilizumab in Patients With Severe COVID-19 Pneumonia (COVACTA)

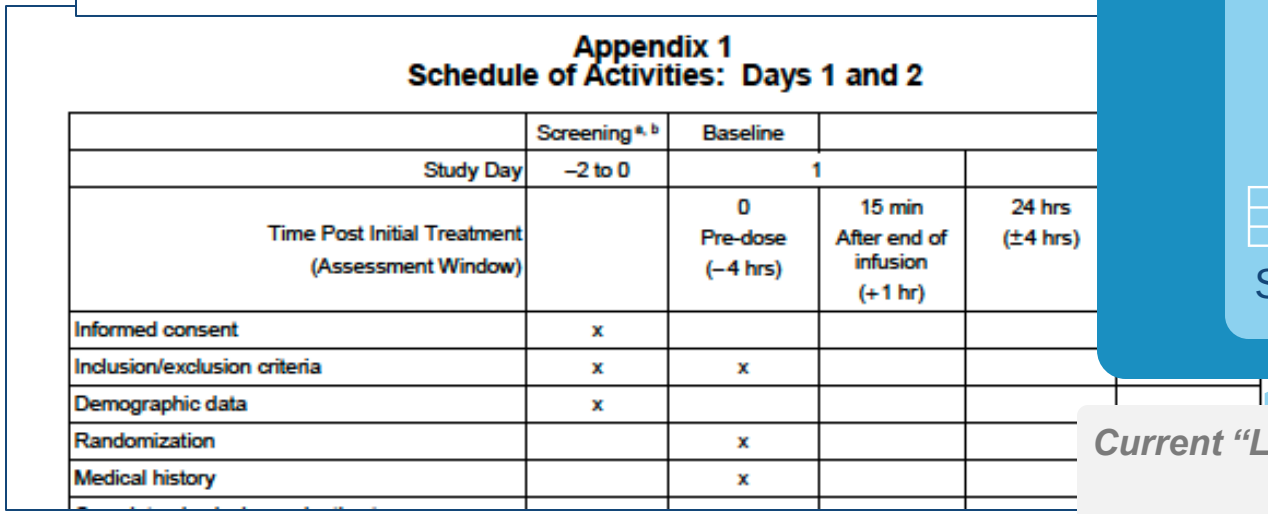
The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04320615

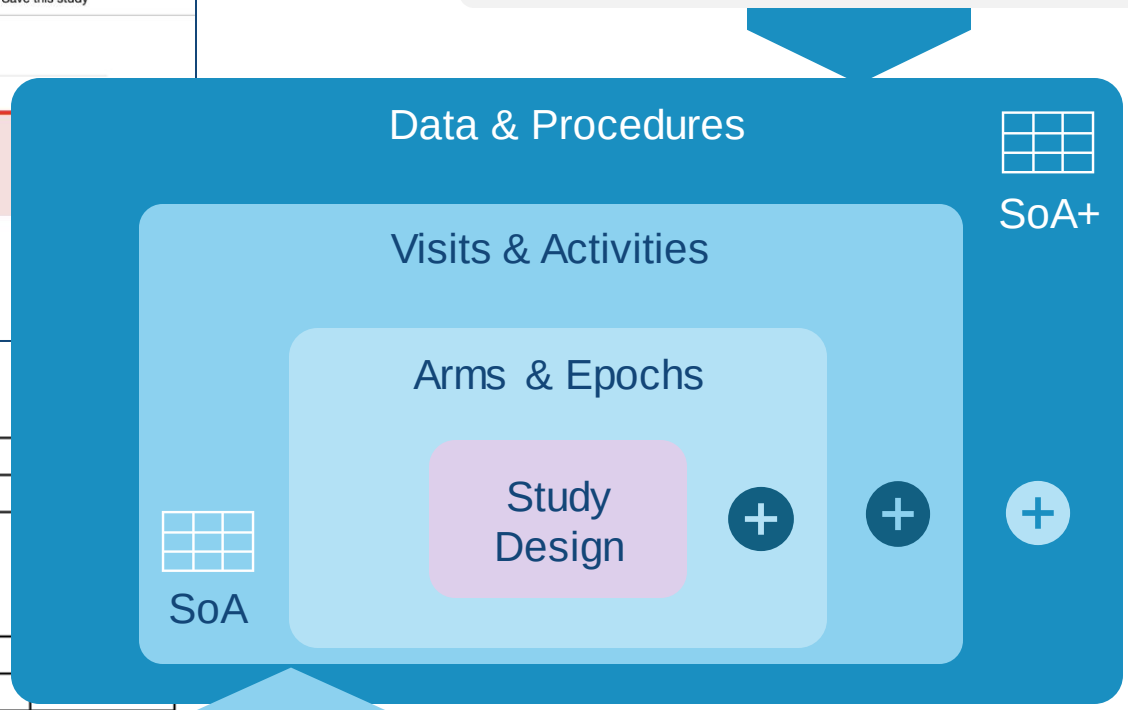
Recruitment Status : Completed
First Posted : March 25, 2020
Results First Posted : June 30, 2021
Last Update Posted : June 30, 2021

Sponsor:
Hoffmann-La Roche

Information provided by (Responsible Party):
Hoffmann-La Roche


Appendix 1
Schedule of Activities: Days 1 and 2

	Screening [a, b]	Baseline		
Study Day	–2 to 0	1		
Time Post Initial Treatment (Assessment Window)		0 Pre-dose (–4 hrs)	15 min After end of infusion (+1 hr)	24 hrs (±4 hrs)
Informed consent	x			
Inclusion/exclusion criteria	x	x		
Demographic data	x			
Randomization		x		
Medical history		x		



Increasing Detail

Provide precision on the data to be captured to the capture systems in a generic manner to facilitate automation. The data precision has not, typically, been in the "paper" protocol. It is SoA "plus", SoA+

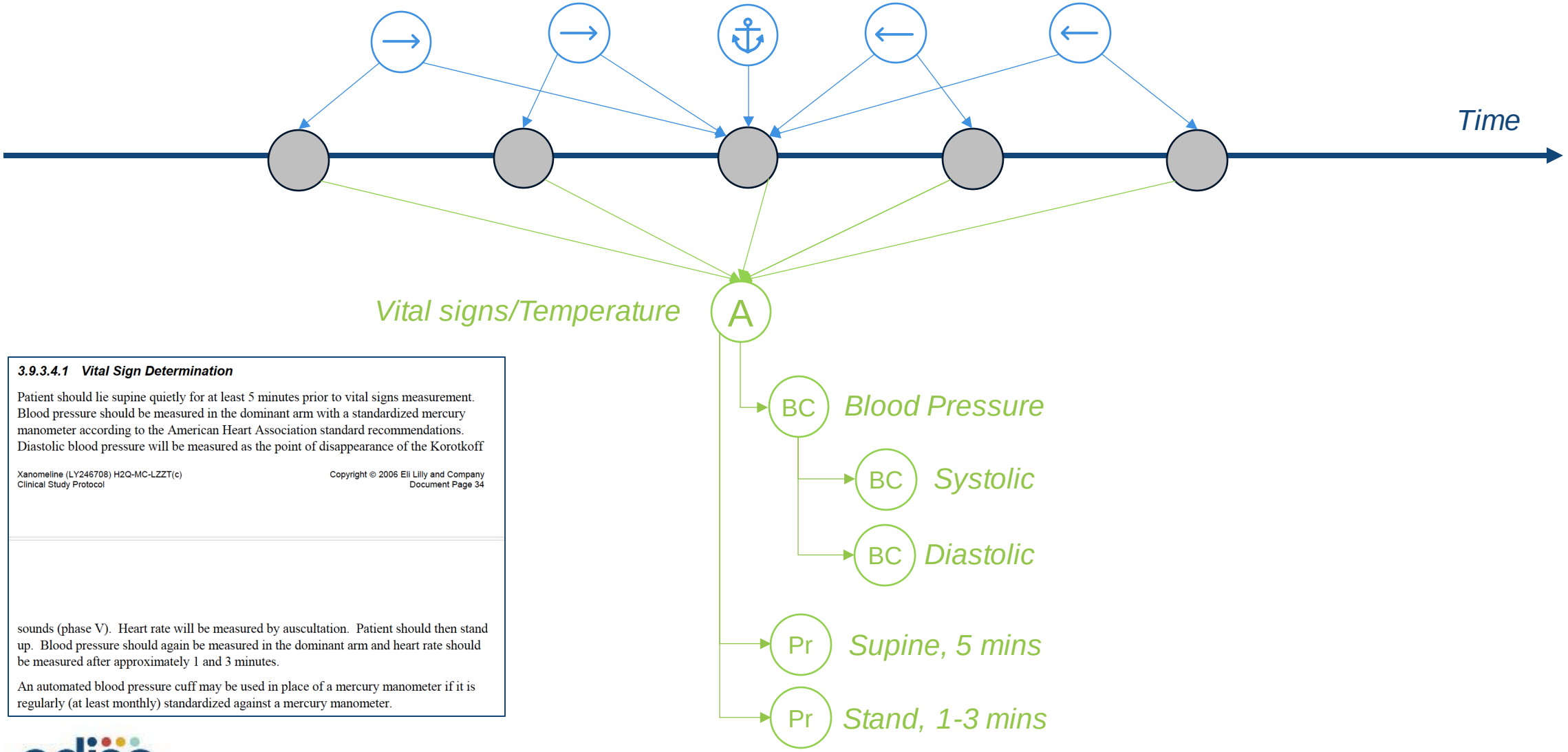
Current "Limit"

SoA is where we are today with associated footnotes and free text. Activities sit at a CRF form "level"

Technology Independent

Definition should be independent of any capture technology

Biomedical Concepts – Timeline



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

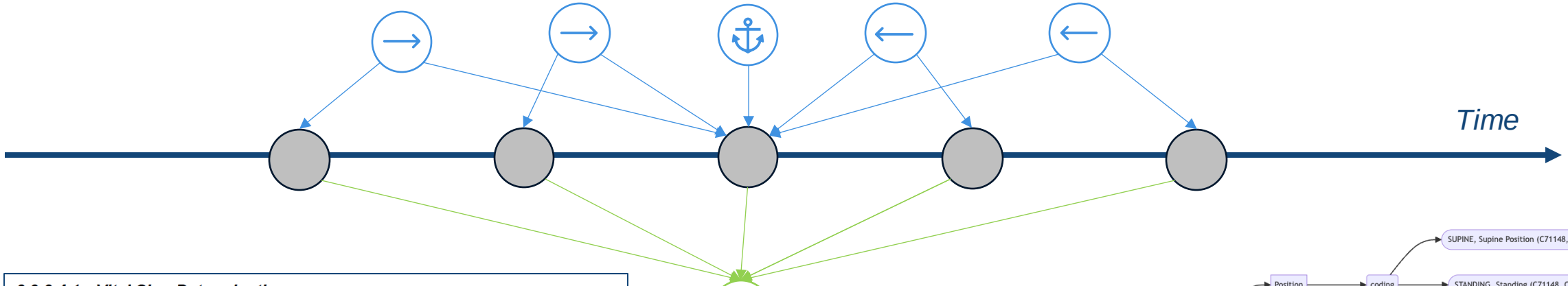
sounds (phase V). Heart rate will be measured by auscultation. Patient should then stand up. Blood pressure should again be measured in the dominant arm and heart rate should be measured after approximately 1 and 3 minutes.

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.

Biomedical Concepts – Precision

Precision

Allows for study logic to be expressed in precise terms



3.9.3.4.1 Vital Sign Determination

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Xanomeline (LY246708) H2Q-MC-LZZT(c)
Clinical Study Protocol

Document Page 34

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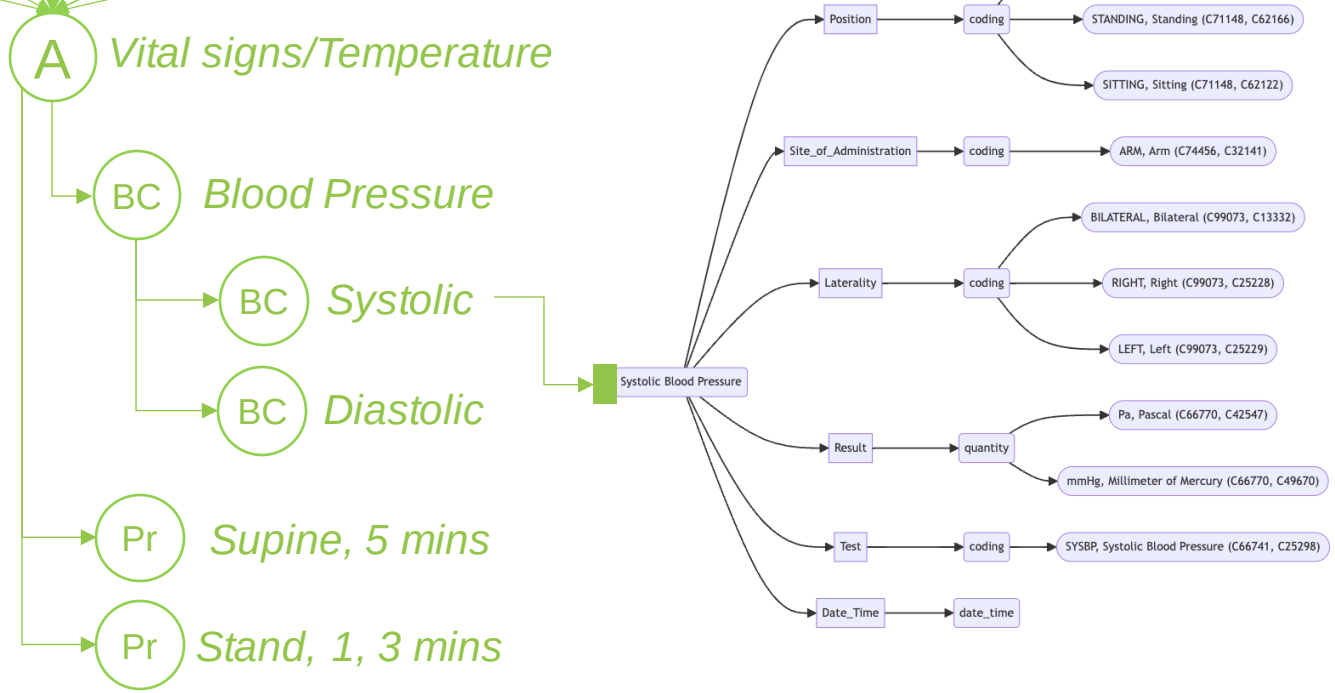
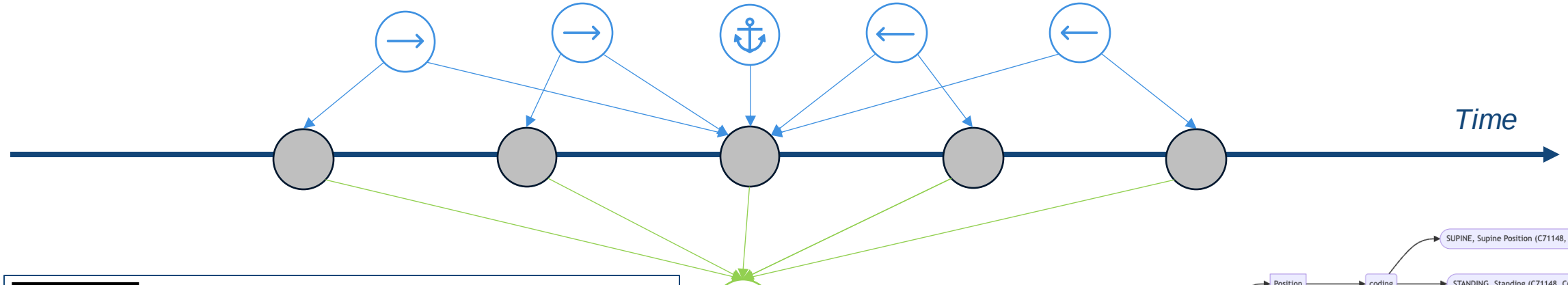
An automated blood pressure cuff may be used in place of a mercury manometer if it is regularly (at least monthly) standardized against a mercury manometer.



Biomedical Concepts – CRF



VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

INFORMATION NOT OBTAINED ☐ Not Entered In Database

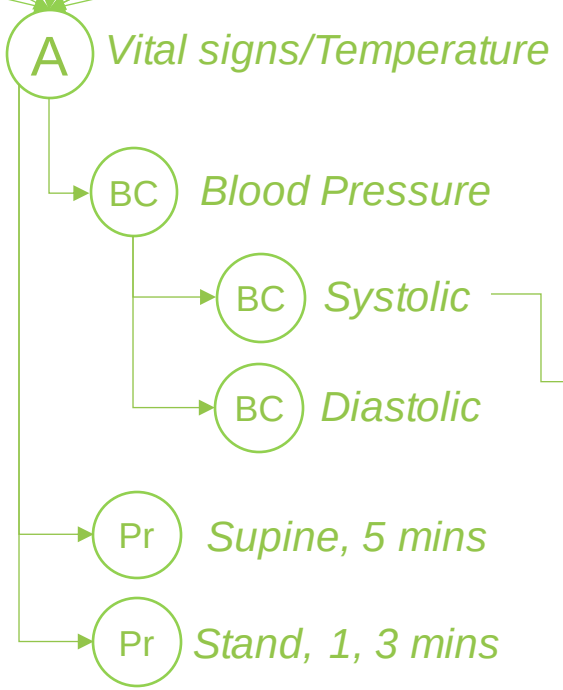
NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.

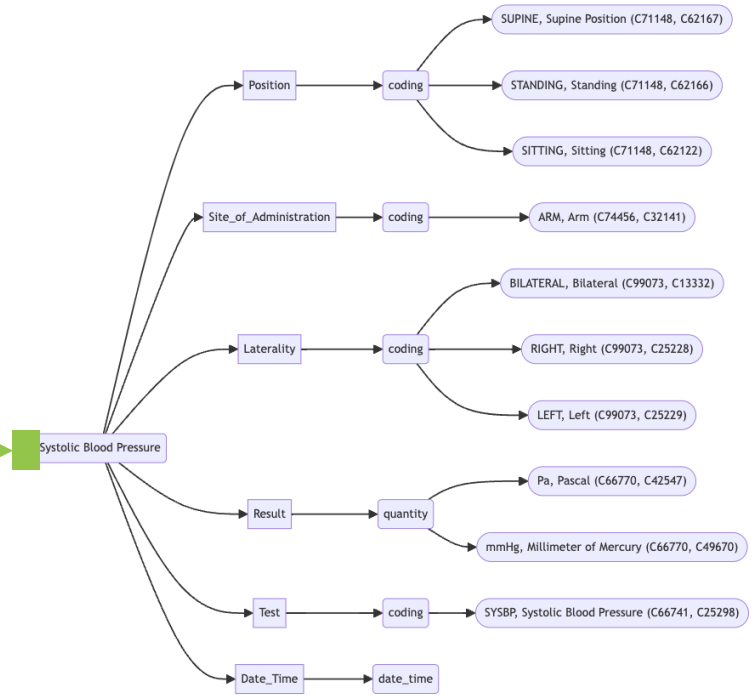
	(DNDE) Reference Time	Timing Code	Position (SU = Supine, ST = Standing)	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		

VSTPTNUM VSTPT VSPOS VSTESTCD VSORRESU VSORRES VSTESTCD VSORRESU VSORRES VSTESTCD VSORRESU

Automation

Getting close to building this from the eProtocol



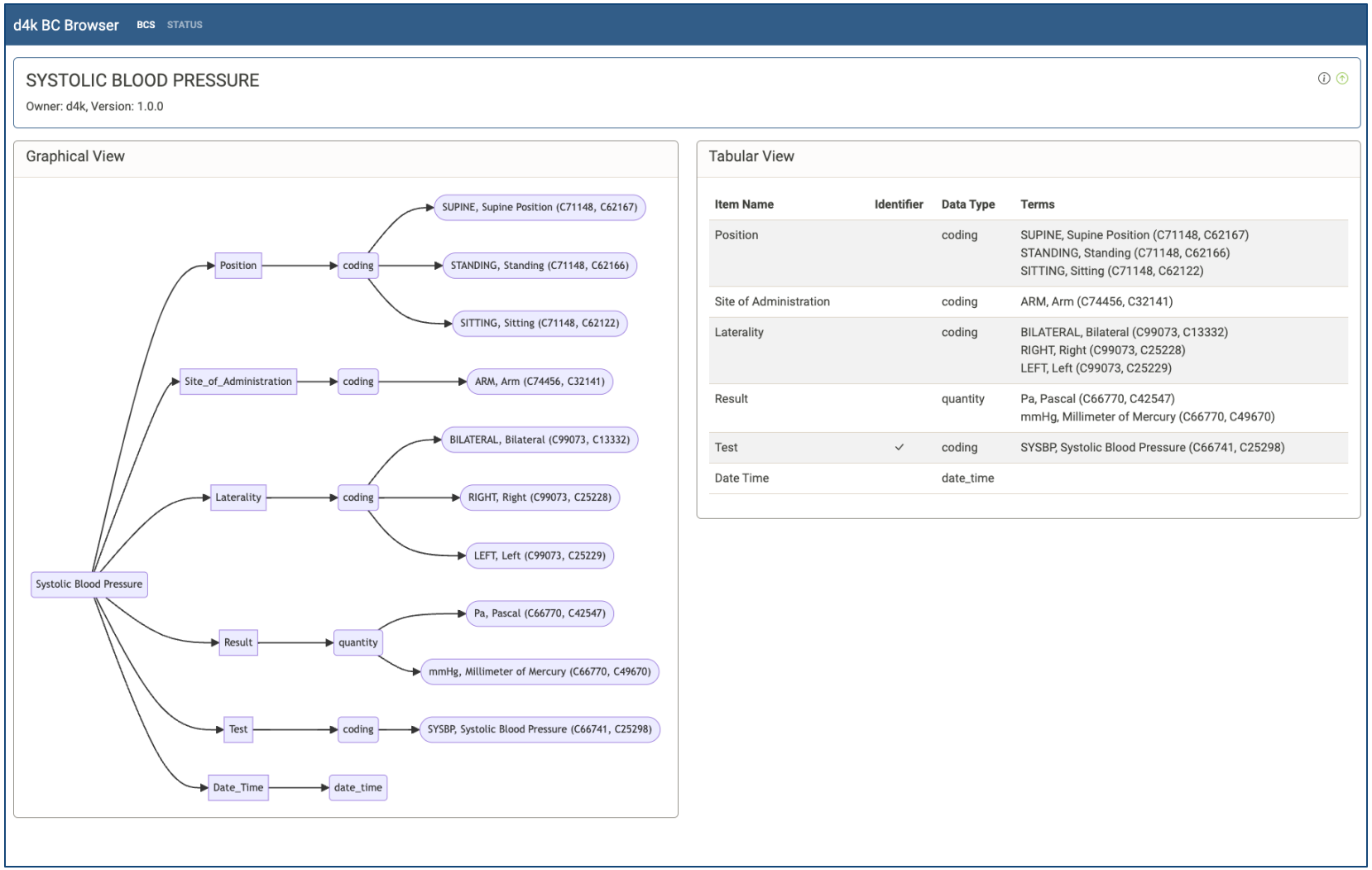


Biomedical Concepts – LZZT Spreadsheet

	A	B	C	D	E	F	G	H	I
1	**Name**	Main Timeline	**name**	SCREEN1	SCREEN2	DOSE	WK2	WK4	WK6
2	**Description**	This is the main timeline for the study design.	**description**	-	-	-	-	-	-
3	**Condition**	Potential subject identified	**label**	Screen One	Screen Two	Dose	Week 2	Week 4	Week 6
4			**type**	Activity	Activity	Activity	Activity	Activity	Activity
5			**default**	SCREEN2	DOSE	WK2	WK4	WK6	WK8
6			**condition**						
7			**epoch**	Screening	Screening	Treatment 1	Treatment 1	Treatment 2	Treatment 2
8			**encounter**	E1	E2	E3	E4	E5	E7
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 <= 4		X	-	-	-	-	-
15		MMSE 10-23		X	-	-	-	-	-
16		Physical examination		X	-	-	-	-	-
17		Medical history		X	-	-	-	-	-
18		Habits		X	-	-	-	-	-
19		Chest X-ray		X	-	-	-	-	-
20		Apo E genotyping		-	-	-	X	-	-
21		Patient randomised		-	-	X	-	-	-
22		Vital signs / Temperature	BC:Systolic blood pressure, BC:Diastolic blood pressure, BC:Body temperature, BC:Body Weight, BC:Body Height	X	X	X	X	X	X

BC *Systolic*

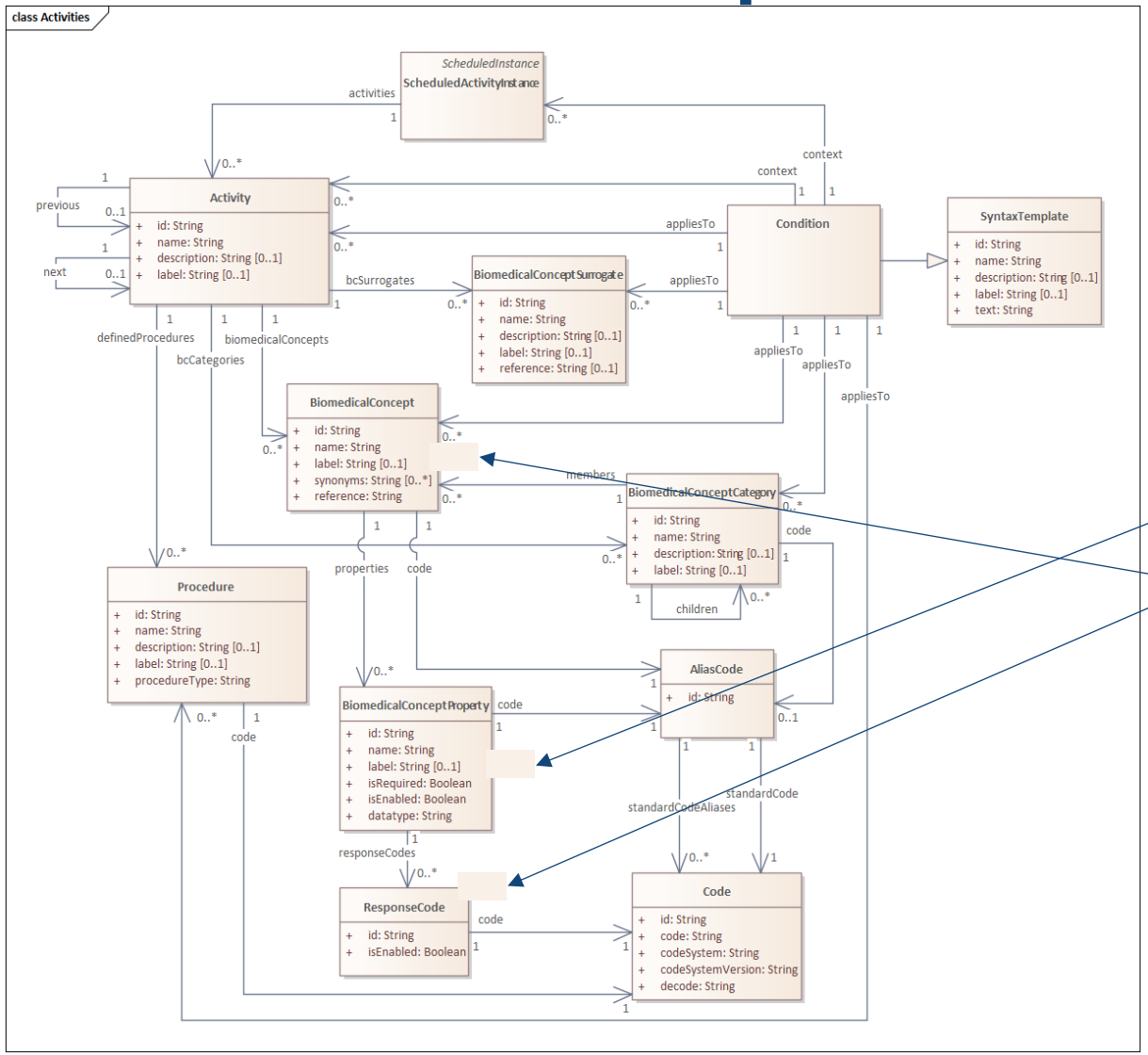
CDISC Library & Biomedical Concepts

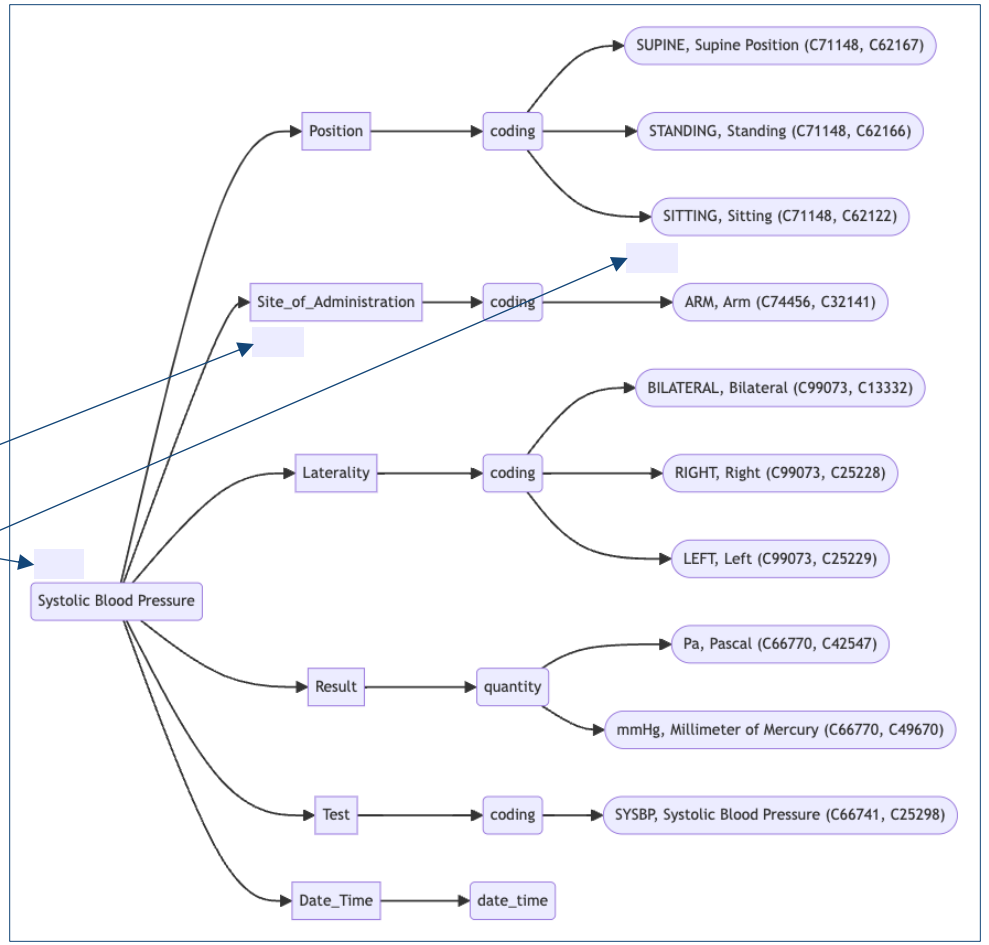


Excel - Some Restrictions

1. *Update to allow for full definition from CDISC Library to be deployed*
2. *Not handling BC categories yet. Only recently exposed by the CDISC Library API, need to catch up*

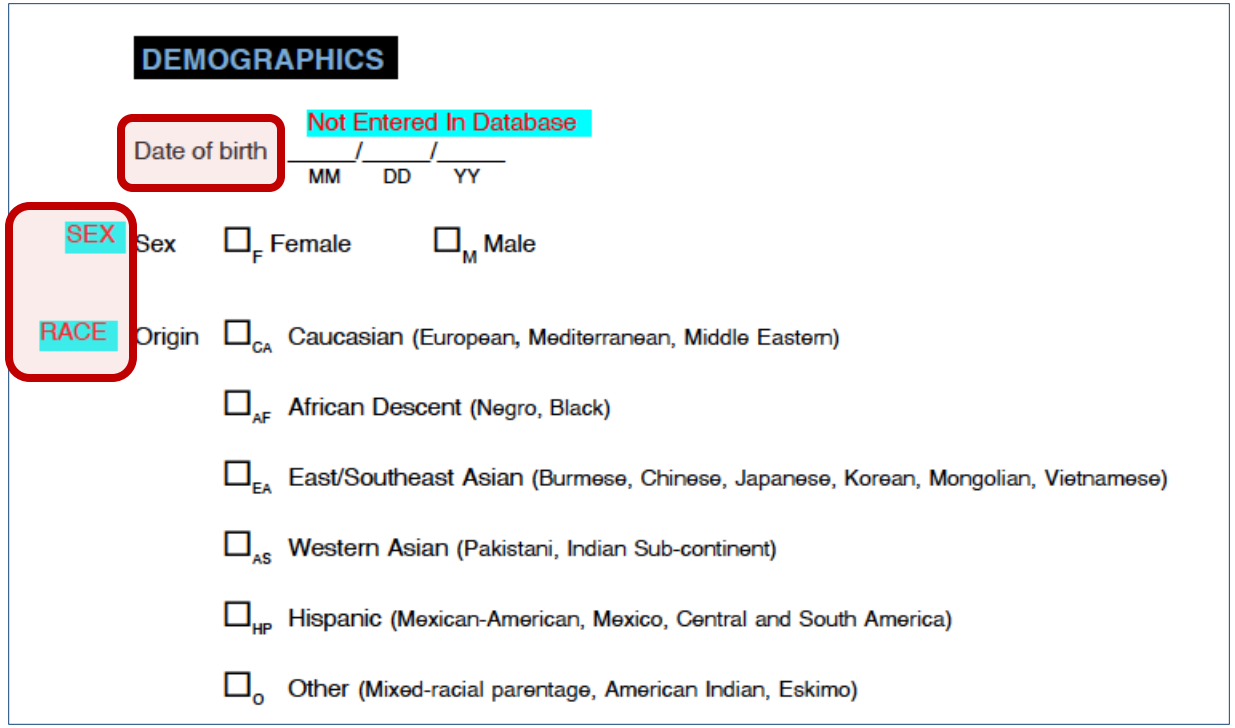
Biomedical Concept – UML

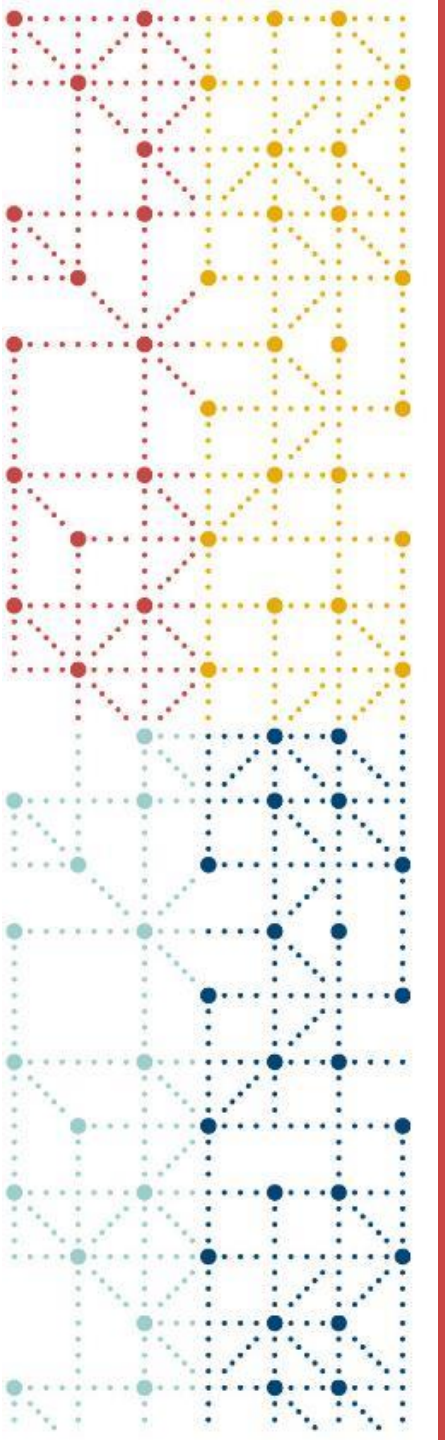




Exercise 4: BCs

- Add BCs to the demography activity
  - Date of Birth
  - Sex
  - Race
- Sheet
  - mainTimeline





Footnotes

Footnotes

1. Footnotes representing sub-timelines
2. Footnotes representing timing and/or order of activities
3. Footnotes representing alternative visit schedules
4. Repeated activities not presented in the SoA
5. Footnotes representing conditional activities and procedures
6. Footnotes representing optional/alternative encounter methods
7. Footnotes representing optional alternative measurement methods
8. Additional instructions for procedures and assessments
9. Specification of actual measurements for an activity
10. Visit windowing information
11. Eligibility requirements
12. Complex combinations of the above

=> timepoints: predose, 30 minutes, 1h, 2h, …

=> before all other, on day of admission, during admission, until end of …

=> visits in case of withdrawal, adverse events, optional visits …

=> online questionnaire, every 3 cycles, during wash-out...

=> only women with childbearing potential, discretion of investigator, when criteria are met, for cohort B, …

=> or perfomed by telephone, visits may take at home, …

=> urine or plasma pregnancy test, either Chest X-reay or CT scan

=> Assessed by a blinded asessor, samples will be send to, instructions for inhaler use, …

=> heamatology must include WBC differential count

=> plus or minus 3 days

=> assessment must demonstrate a value of …

=> the initial measurement should be … then repeated … within a timewindow of ...

Footnotes

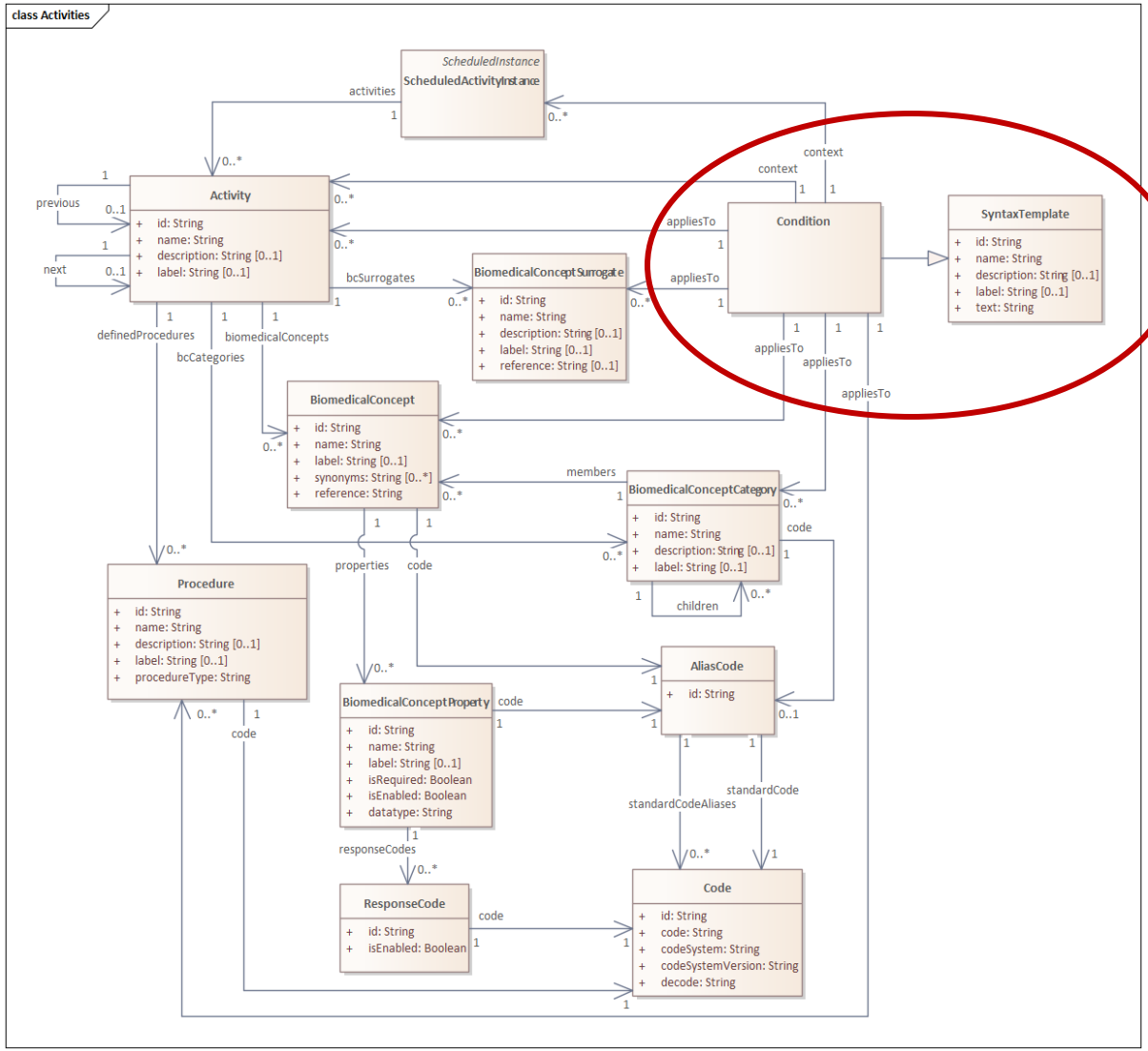
	VISIT	1	2	3	4	5		7	8
ACTIVITY	WEEK	-2	-.3	0	2	4		6	8
Hemoglobin A_{1C}		X^a							
Study drug record Medications dispensed Medications returned				X	X	X		X	X
TTS Acceptability Survey									
ADAS-Cog		P		X					X
CIBIC+		P		X					X
DAD		P		X					X
NPI-X		P		X	X	X		X	X^b
Adverse events		X	X	X	X	X		X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram
X = Performed at this visit.
X^a = Performed at this visit if patient is an insulin-dependent diabetic.
X^b = Performed at this visit and via telephone interview 2 weeks following this visit.
P = Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.

- X_a: if patient is an insulin-dependent diabetic
  => conditional
- X_b: and via telephone interview 2 weeks following this visit
  => repeated but not presented in SoA
- P: Practice only
  => additional instructions

Conditional footnotes

1. Define on what level they are conditional/optional? appliesTo
   - Activity
   - Procedure
   - BiomedicalConcept
   - BiomedicalConceptSurrogate
   - BiomedicalConceptCategory
2. Define the context, for example:
   - BCs within a specific Activity
   - BCs within a specific at a specific timing: ScheduledActivityInstance
3. Condition text can be presented as footnote by implementation



Conditional footnotes

Excel tool (limited functionality):

- Add to studyDesignConditions
- Option to add context
- Define appliesTo


```
"conditions": [
  {
    "id": "Condition_1",
    "name": "COND1",
    "label": "X",
    "description": "Condition for X",
    "text": "If this is true",
    "dictionaryId": null,
    "contextIds": [],
    "appliesToIds": [
      "Procedure_1"
    ],
    "instanceType": "Condition"
  }
],
```


	A	B	C	D	E	F
1	**name**	**description**	**label**	**text**	**context**	**appliesTo**
2	COND1	Condition for X	X	If this is true	Demographics	PR1
3						
4						
5						

studyDesignConditions | studyDesignActivities | studyDesignInterventions | studyD

Footnotes: Repeated activities not presented in the SoA

1. Identify the extra timepoints mentioned in the footnote
2. Add as instances to the timeline
3. Optionally link to encounter
   - By defining new encounter
   - By linking to existing encounter

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**Name**	Main Timeline	**name**	SCREEN1	SCREEN2	DOSE	WK2	WK4	WK6	WK8	WK8N	WK12	WK12N	WK16	WK16N
2	**Description**	This is the main timeline for	**description**	-	-	-	-	-	-	-	-	-	-	-	-
3	**Condition**	Potential subject identified	**label**	Screen One	Screen Two	Dose	Week 2	Week 4	Week 6	Week 8	Week NPI	Week 12	Week 12 NPI	Week 16	Week 16 N
4			**type**	Activity	Activity	Activity	Activity	Activity	Activity	Activity	Activity	Activity	Activity	Activity	Activity
5			**default**	SCREEN2	DOSE	WK2	WK4	WK6	WK8	WK8N	WK12	WK12N	WK16	WK16N	WK20
6			**condition**												
7			**epoch**	Screening	Screening	Treatment 1	Treatment 1	Treatment 2	Treatment 2	Treatment 2	Treatment 2	Treatment 2	Treatment 2	Treatment 2	Treatment
8			**encounter**	E1	E2	E3	E4	E5	E7	E8	E8	E9	E9	E10	E10
9	**Parent Activity**	**Child Activity**	**BC/Procedure/Timeline**												
33		Hemoglobin A1C	BC:HbA1c	X	-	-	-	-	-	-	-	-	-	-	-
34		Study drug		-	-	X	X	X	X	X	-	X	-	X	-
35		TTS Acceptability Survey		-	-	-	-	-	-	-	-	-	-	-	-
36	-	ADAS-Cog		X	-	X	-	-	-	X	-	-	-	X	-
37		CIBIC+		X	-	X	-	-	-	X	-	-	-	X	-
38		DAD		X	-	X	-	-	-	X	-	-	-	X	-
39		NPI-X		X	-	X	X	X	X	X	X	X	X	X	X
40															
41															

studyDesignArms | studyDesignEpochs | mainTimeline | adverseEventTimeline | ea

Exercise 5: Footnote

- Add in a condition that reflects the Practice Footnote
  - Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.
- Sheet
  - studyDesignConditions

	VISIT	1	2	3	4	5		7	8
ACTIVITY	WEEK	-2	-3	0	2	4		6	8
Informed consent		X							
Patient number assigned		X							
Hachinski ≤4		X							
MMSE 10-23		X							
Physical examination		X							
Medical History		X							
Habits		X							
Chest x-ray		X							
Apo E genotyping					X				
Patient randomized				X					
Vital signs/Temperature		X	X	X	X	X		X	X
Ambulatory ECG placed			X						
Ambulatory ECG removed				X					
ECG		X			X	X		X	X
Placebo TTS test		X							
CT Scan (if not within last year and patient passes all other screens)		X							
Concomitant Medications		X		X	X	X		X	X
Laboratory (Chem/Hemat):		X			X	X		X	X
Laboratory (Urinalysis)		X			X				
Plasma Specimen (Xanomeline)				X	X	X		X	
Hemoglobin A_{1C}		X[a]							
Study drug record Medications dispensed Medications returned				X	X	X		X	X
TTS Acceptability Survey									
ADAS-Cog		P		X					X
CIBIC+		P		X					X
DAD		P		X					X
NPI-X		P		X	X	X		X	X[b]
Adverse events		X	X	X	X	X		X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram

X = Performed at this visit.

X[a] = Performed at this visit if patient is an insulin-dependent diabetic.

X[b] = Performed at this visit and via telephone interview 2 weeks following this visit.

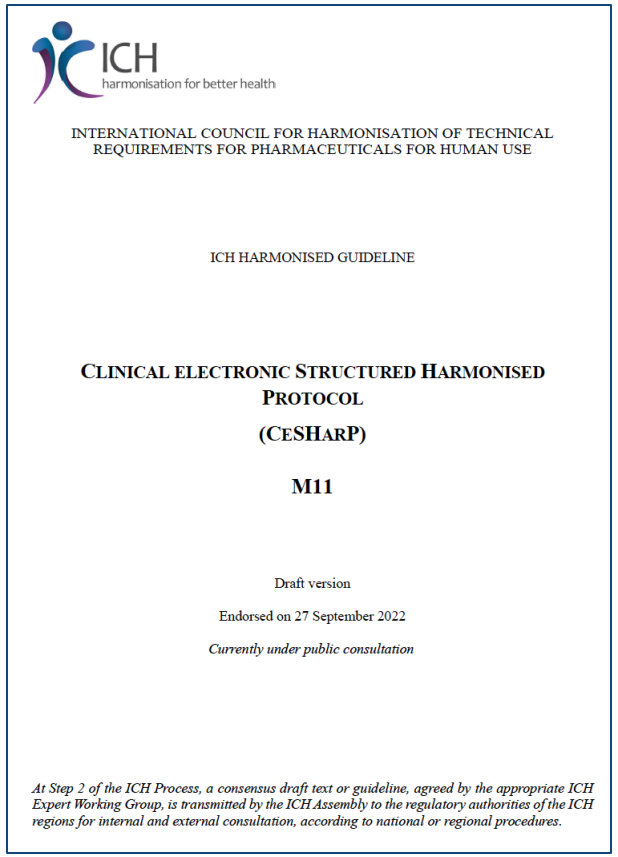
P = Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.

USDM and the ICH M11 Document

M11 Is …

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

https://www.ich.org/page/multidisciplinary-guidelines



ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

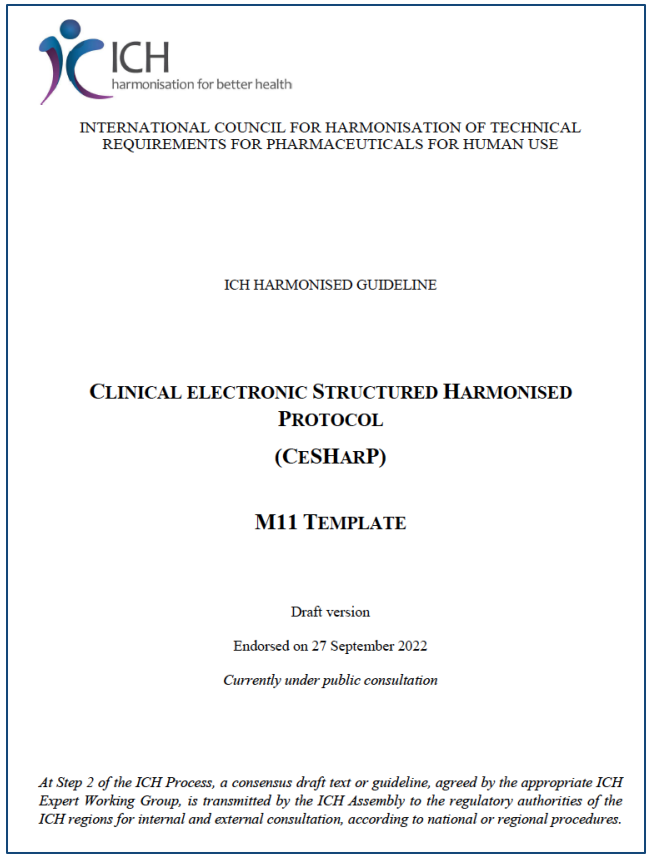
Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides background, purpose, and scope as a guideline



ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

Draft version

Endorsed on 27 September 2022

Currently under public consultation

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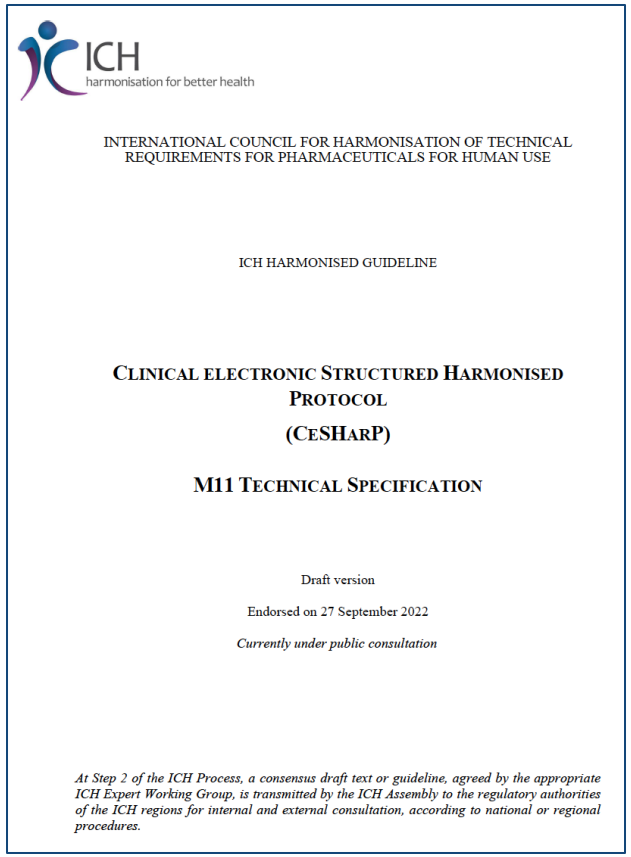
Provides the written format for the 'Interventional Clinical Trial Protocol Template'



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INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides the technical representation aligned with the guideline and protocol template

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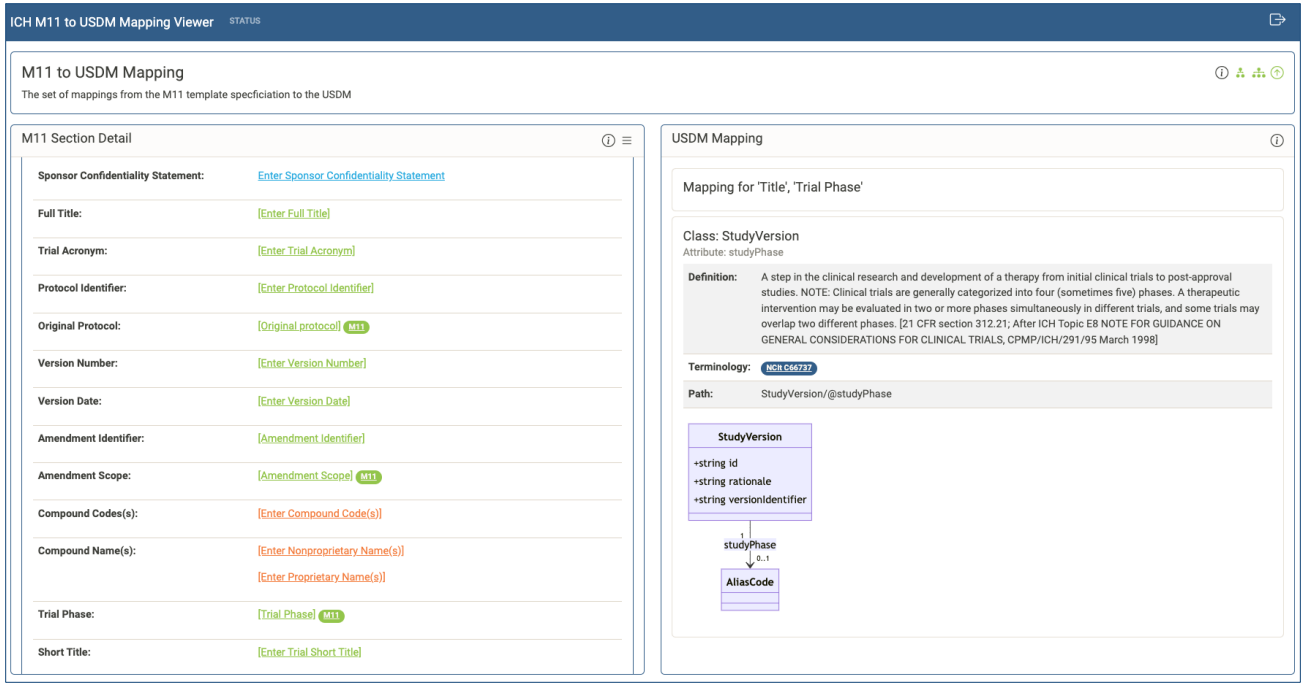
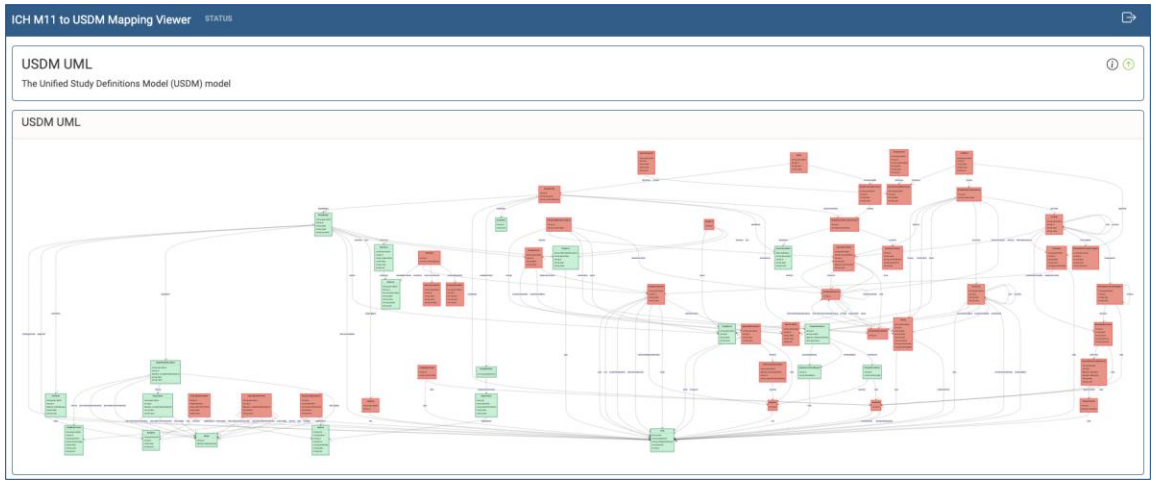
Idea for slide layout from Rebecca Baker

M11 Implementation

- USDM can support multiple protocol template formats
- Can support the M11 template
- Mapping Tool
  - Where the various data elements within M11 live in USDM
  - Link on the wiki page

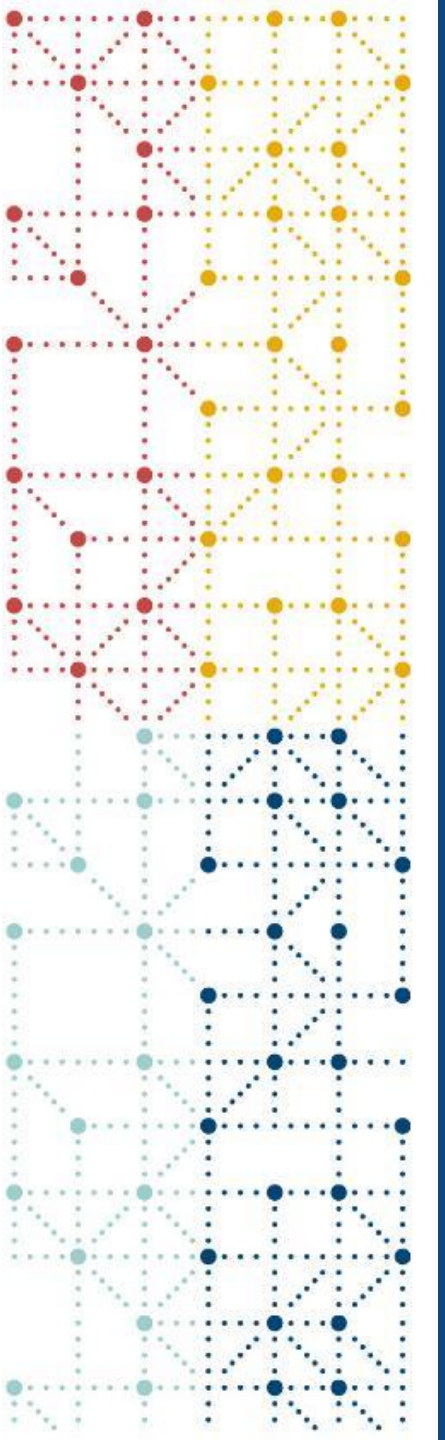




Exercise 6: ICH M11

- Replace the contents in row 2, the “text” column of the studyDesignContent sheet with the following
- `<usdm:macro id="section" name="title_page" template="m11"/>`
- Look at the PDF and the front page

Protocol Full Title:	[Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	[Sponsor Confidentiality Statement] Insert the Sponsor’s confidentiality statement, if applicable, otherwise delete.
Protocol Number:	[Protocol Number] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Version:	[Version] An optional field for use by the Sponsor at their discretion.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of the protocol, indicate Not Applicable.
Amendment Scope:	[Amendment Scope] [Country/Region Identifier] Acceptable entries for amendment scope are: “global” or “Country-specific/Regional” Use the ISO-3166 region or country identifier (for example, DE or EU). For global trials delete the Country/Region Identifier field.
Compound Number(s):	[Compound Number] Enter the Sponsor’s unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name]. [Proprietary Name]. [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
Trial Phase:	[Trial Phase] [Description of Trial Phase Other] Acceptable entries are: “Early Phase 1”, “Phase 1”, “Phase 1/Phase 2”, “Phase 2”, “Phase 2/Phase 3”, “Phase 3”, “Phase 4”,



Wrap Up

CDISC EU Interchange 2024

Tuesday 23rd April

CDISC Workshops

Digital Data Flow Workshop

9:00 AM-3:00 PM CET

- Deep dive into all aspects of the model and how study protocols and designs can be represented using the USDM
- Focused sessions covering the theory on an individual aspect of the model combined with hands-on exercises and discussion
- Timing, biomedical concepts, interventions, versioning, links with other standards such as SDTM, ICH M11, Trial Registries

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Day 2
25 April 2024

11:00 - 12:30
Session 6A: Digital Data Flow

Stijn Rogers, argenx
Europa 5

11:00 - 11:30
ICH M11 Presentation
Peter Van Reusel, CDISC

11:30 - 12:00
DDF Presentation
Dave Iberson-Hurst, CDISC

12:00 - 12:30
DDF: The Art of the Possible Becomes a Reality
Bron Kisler, Nurocor

13:30 - 15:30
Session 7A: Digital Data Flow

Sujit Khune, Novo Nordisk A/S
Europa 5

13:30 - 13:50
Development of Unified Studies Definition Model (USDM) Through Translation of the Human-Readable Protocols
Jasmine Kestemont, Innovion

13:50 - 14:10
Ripping up the Protocol: Pairing up USDM and ICH M11 to Inform Real-Time Study Builds
Zaid Al-Jubouri, Lindus Health

14:10 - 14:40
Demonstrating e2e Study Data Automation Using Extended USDM Model
Kirsten Walther Langendorf, data4knowledge ApS

14:40 - 15:00
From OpenStudyBuilder to the Digital Data Flow- USDM Format
Maurizio Mazzei, Neo4J

15:00 - 15:30
Panel Discussion

https://www.cdisc.org/events/interchange/2024-cdisc-tmf-europe-interchange

TransCelerate BIOPHARMA INC.

Additional Opportunities to Stay Involved with DDF?

Scan QR Code to explore DDF GitHub

- Download the SDR source code available on the Github
- Review the videos, newsletters and other archived materials posted on the GitHub
- Contribute and interact on the open discussion forums
- If you work for a TransCelerate member company, volunteer to join our core team
- Volunteer to join the CDISC USDM team (via CDISC website)

https://transcelerate.github.io/ddf-home/

Before we conclude….

Please respond to the following question via the Zoom chat:

What 1 word best describes today's workshop

TransCelerate – A Catalyst for Collaboration

We are a not-for-profit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community on solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

Since inception, TransCelerate has prioritized robust collaboration with key stakeholders across the R&D ecosystem to deliver hundreds of free and publicly available solutions.

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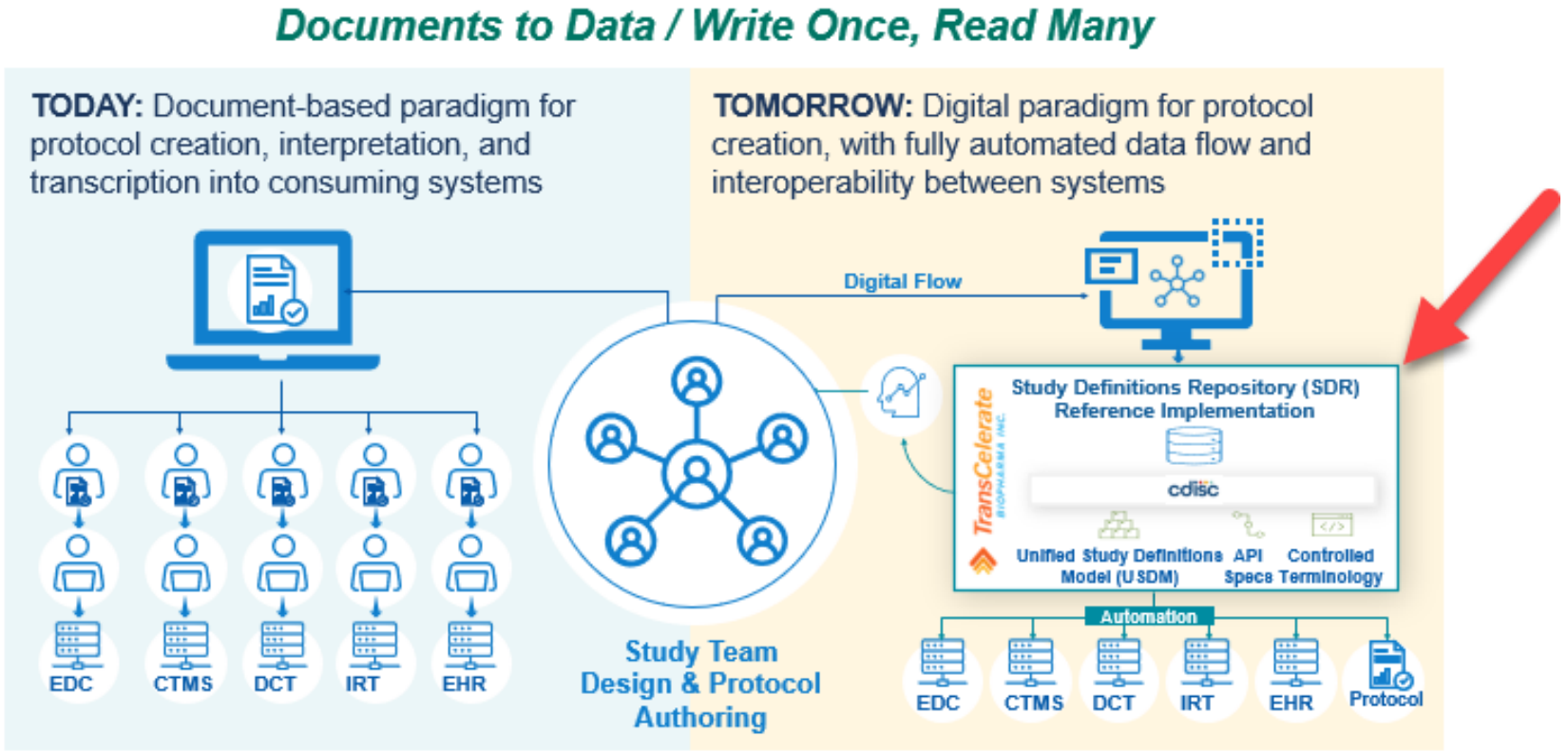
Digital Data Flow Ambition

Digital - standard representation of study protocol
- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability
- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort



Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights

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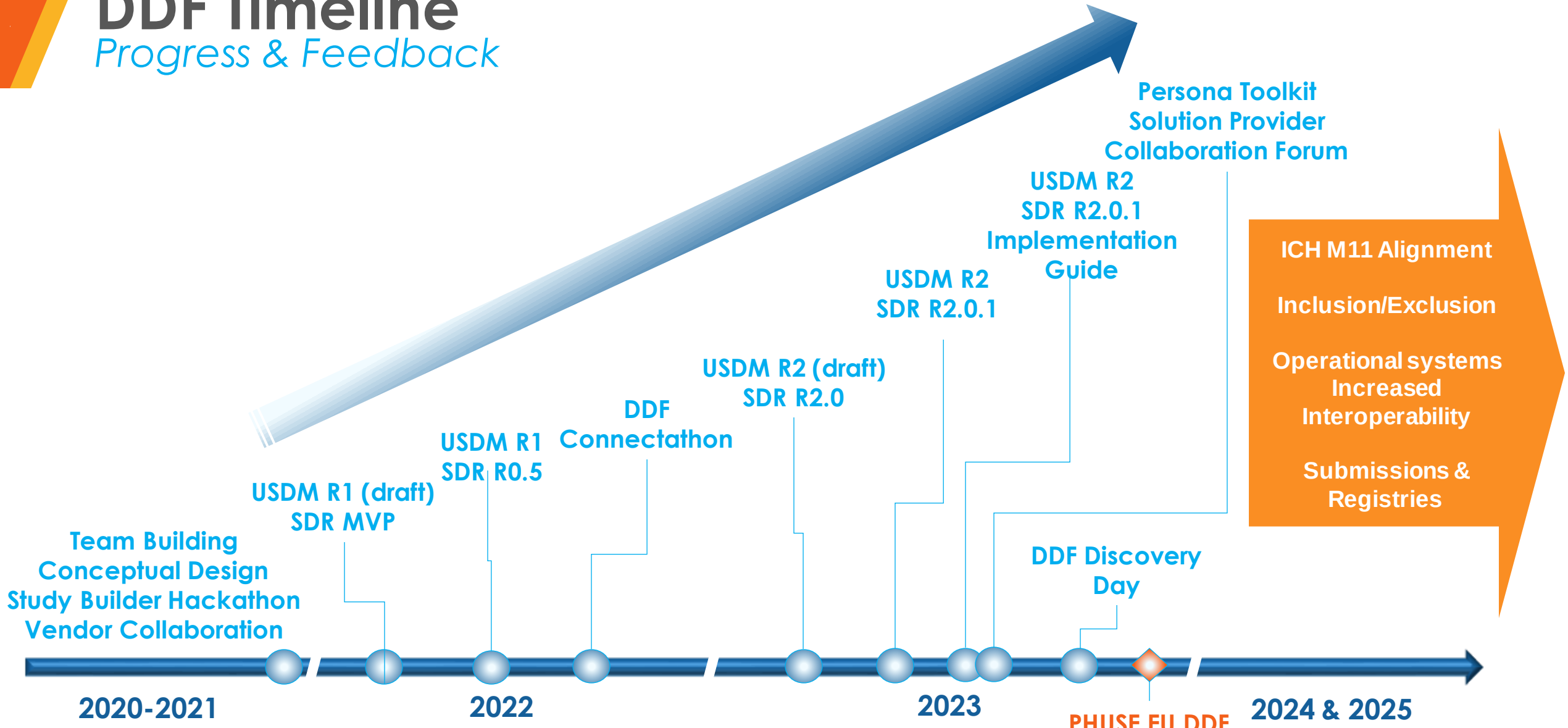
DDF Timeline

Progress & Feedback



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DDF Upcoming Events

Major/ Interactive Event | General Awareness | Virtual option available

Upcoming Events of 2023	Date
eClinical Forum Americas Janssen in Spring House, PA USA North America Meetings - eClinical Forum	24-26 October 2023
PHUSE EU Connect (TCB sponsored DDF hands-on workshop in collaboration with CDISC) Birmingham, UK PHUSE EU Connect 2023 | CDISC	5-8 November 2023 *(workshop on Nov 5th)*
DIA Japan Annual Meeting 2023 Ariake Central Tower Hall DIA Japan 2023 - About DIA Japan 2023 (diaglobal.org)	5-7 November 2023
TransCelerate DDF Webinar Modernizing Clinical Trials Using Digitized Protocol Information: An Exploration of New Tools for Digital Transformation Register Here	13 December 2023 10-11 AM EST
Anticipated Events for 2024	**Date**
SCOPE 2024	11-14 February 2024
PHUSE US Connect 2024	25-28 February 2024

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