

DS09

Metadata to support ADaM generation

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LLOQ/ULOQ

2 Flowchart

	Screening	Run-in										Rando- misation	
Visit(V), Phone (P)	V1	V2	P3	V4	P5	V6	P7	V8	P9	V10	P11	V12	V1
Timing of Visit (Weeks)	-1	0	2	4	6	8	10	12	14	16	18	20	24
Visit Window (Days)	-7 to 0	0	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
SUBJECT RELATED INFORMATION AND ASSESSMENTS													
Informed consent and Demography ^a (Appendix 3)	X												
Childbearing potential ^b (Appendix 5)	X												
Inclusion criteria (6.1)	X	X											
Exclusion criteria (6.2)	X	X											
Run-in criteria (6.3.1)		X											

SDTM

ADaM program templates

ADaM

Normal Ranges



⚠ TOPICCD	⚠ PARAM	⚠ PARAMCD	⊕ PARAMN	⚠ AVALLB
BP_DIASTOLIC	Diastolic Blood Pressure (mmHg)	C25299X	3050	Diastolic blood pressure (mmHg)
BP_SYSTOLIC	Systolic Blood Pressure (mmHg)	C25298X	3030	Systolic blood pressure (mmHg)

2 Flowchart

PHUSE EU Connect 2020

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MDMQ

MedDRA

LLOQ/ULOQ

MDVISIT

	Screening	Run-in										Rando- misation	
	V1	V2	P3	V4	P5	V6	P7	V8	P9	V10	P11	V12	V1
	-1	0	2	4	6	8	10	12	14	16	18	20	24
	-7 to 0	0	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
SUBJECT RELATED INFORMATION AND ASSESSMENTS													
Informed consent and Demography ^a (Appendix 3)	X												
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Run-in criteria (6.3.1)		X											

MDFLOW

SDTM

ADaM program templates

ADaM

MDNR

Normal Ranges

MDATC



MDPARAM

⚠	TOPICCD	⚠	PARAM	⚠	PARAMCD	⊕	PARAMN	
	BP_DIASTOLIC		Diastolic Blood Pressure (mmHg)		C25299X		3050	Diastolic blood pressure (mmHg)
	BP_SYSTOLIC		Systolic Blood Pressure (mmHg)		C25298X		3030	Systolic blood pressure (mmHg)

Metadata dataset advantages

- *One point of definition*
- Alignment across trials
- Standardized metadata structure facilitates ADaM program alignment
 - Less overhead when moving programmers between trials
- Complete container for submission
 - Executable programs
 - No external data references

MDPARAM - Parameter Specific Metadata

- ***One record per topic parameter code***
- For each assessment in a trial MDPARAM contains a record with all associated attributes.
- Key in alignment across trials
- Link to SDTM through TOPICCD

Column	Label
STUDYID	Study Identifier
TOPICCD	Topic Code
PARAM	Parameter
PARAMCD	Parameter Code
PARAMN	Parameter (N)
PARCATy	Parameter Category y
AVALU	Analysis Value Units
AVALLB	Parameter Axis Label
RFASTFL	Fasting Required Flag
LOGYN	Log Transform
CONVFAC	Conversion Factor to Alternative Unit
DECIMALS	Decimal Precision of Analysis Value
CHGLB	Change from Baseline Label
PCHGLB	Percent Change from Baseline Label
R2BASELB	Ratio to Baseline Label

- Use flow
 - MDFLOW
 - MDNR
 - ADEG
 - ADLB
 - ADPE
 - ADQSxx
 - ADVS
 - ...

MDVISIT - Visit Labels Metadata

- ***One record per analysis visit***
- Key in assigning analysis visit names across datasets
- AVISITN links to SDTM variable VISITNUM

Column	Label
STUDYID	Study Identifier
AVISITN	Analysis Visit (N)
AVISIT	Analysis Visit
VISLABEL	Visit Label
VISTPCD	Visit Type Code
AVISITw	Analysis Visit w <descriptive text>
AVISITwN	Analysis Visit w <descriptive text> (N)
PVISFL	Planned Visit Flag
EDPVISFL	Endpoint Visit Flag

- Use flow
 - MDFLOW
 - ADCM
 - ADEG
 - ADLB
 - ADPE
 - ADQSxx
 - ADVS
 - ...

MDFLOW - Flowchart Metadata

- ***One record per parameter per analysis visit***
- Contains the entire flow chart information from the protocol
- Key in assigning eligibility flag
- Link to SDTM through TOPICCD, Analysis visit and timepoint

Column	Label
STUDYID	Study Identifier
PARAMCD	Parameter Code
PARAM	Parameter
PARAMN	Parameter (N)
ATPTN	Analysis Timepoint (N)
TPTLB	Time Point Label
TOPICCD	Topic Code
AVISITN	Analysis Visit (N)
BASETYPE	Baseline Type
ABLFL	Baseline Record Flag
ASSMTYPE	Assessment type

- Use flow
 - ADEG
 - ADLB
 - ADPE
 - ADQSxx
 - ADVS
 - ...

Using MDFLOW for addressing analysis eligibility

```
data adlb_anel;  
  merge adlb_01(in=a)  
    mdflow (in=b);  
by topiccd avisitn;  
if a;  
  * Unscheduled assessments;  
  if not b then do;  
    anelfl = "Unscheduled assessments";  
    anelrea = 'Unscheduled assessment.';  
  end;  
run;
```

- MDFLOW only include planned visits and the planned assessment at the visit
- Analysis eligibility is addressed by a match in MDFLOW

MDMQ - MedDRA Query Analysis Dataset

- ***One record per Customized Query Name per preferred term***
- Facilitates updates to AEs of special interest within a category or modifying the query name across trials

Column	Label
STUDYID	Study Identifier
SMQNAM	SMQ Query Name
SMQNAMN	SMQ Query Name (N)
SMQSC	SMQ Query Scope
CQNAM	Customized Query Name
CQNAMN	Customized Query Name (N)
CQSC	Customized Query Scope
MQPTCD	MQ Preferred Term Code
MQPT	MQ Preferred Term
MQHLTCD	MQ High Level Term Code
MQHLT	MQ High Level Term
MQHLGTCD	MQ High Level Group Term Code
MQHLGT	MQ High Level Group Term
MQSOCCD	MQ System Organ Class Code
MQSOC	MQ System Organ Class
DICTVER	Dictionary Version

- Use flow
- ADAE

MDNR - Normal Range Metadata

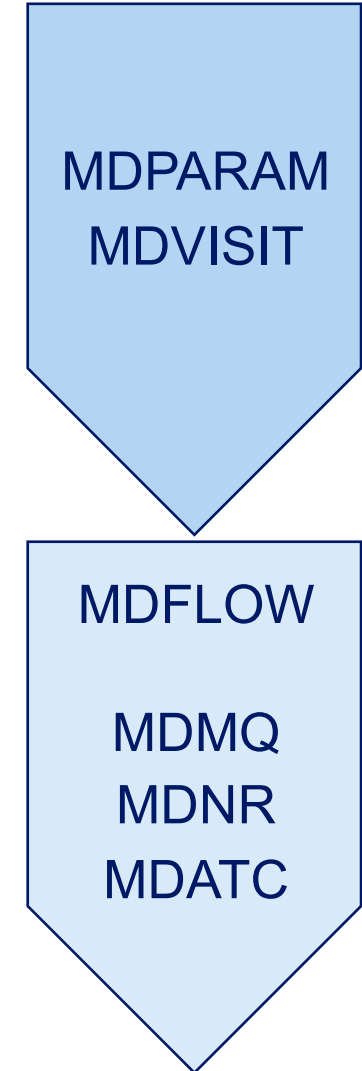
MDATC - ATC Codelist Metadata

- MDNR
 - *One record per parameter per lab per sex per age group per starting point*
 - Use flow: ADLB
- MDATC
 - *One record per level 4 ATC term*
 - Use flow: ADCM

Metadata template programs

- The metadata templates provide programmers with a set of almost ready-to-use metadata programs
 - Requires standardized input from stakeholders
- Consistent way of maintaining and using metadata
 - Govern the metadata flow and the one point of definition
- Less overhead when programmers move across projects

Metadata Flow



Metadata dataset advantages – Key take-away

- *One point of definition*
- *Alignment across trials*
- Standardized metadata structure facilitate ADaM program alignment
 - Less overhead when moving programmers between trials
- Complete container for submission
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MDCODE	Code List Metadata	One record per codelist per order
MDCOL	Metadata Columns	One record per dataset per named column
MDFLOW	Flowchart Metadata	One record per parameter per analysis visit
MDMQ	MedDRA Query Analysis Dataset	One record per Customized Query Name per preferred term
MDNR	Normal Range Metadata	One record per parameter per lab per sex per age group per starting point
MDOUTPUT	Output Specific Metadata	One record per output in the clinical trial report
MDPARAM	Parameter Specific Metadata	One record per topic parameter code
MDVISIT	Visit Labels Metadata	One record per analysis visit
MDATC	ATC Codelist Metadata	One record per level 4 ATC term

Thank you

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