



Maturing Standardisation

The Switch from Spreadsheet-Based Standards to a Metadata Repository (MDR)



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PHUSE EU Connect Belfast 2022

Agenda

1. MDR set-up process
2. MDR development process
3. Where are we now?



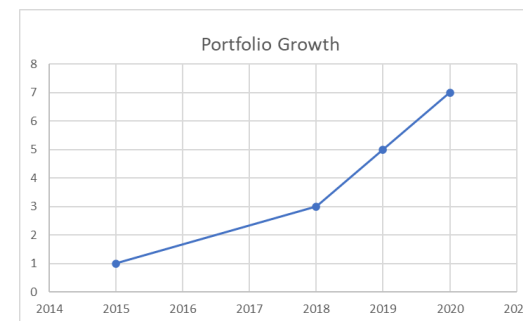
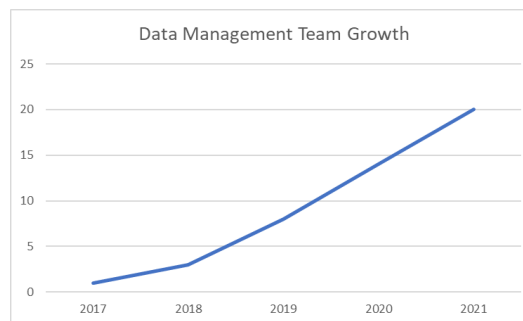


1. MDR set-up process

Rationale



- Expanding team
- Rapidly growing portfolio
- Manual updates to library



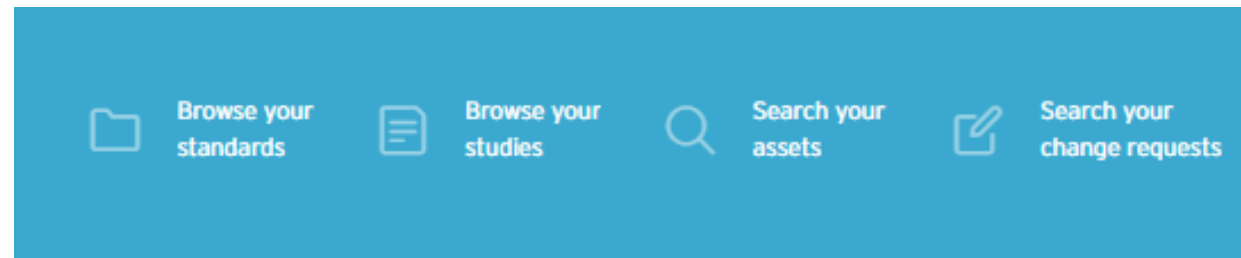
AutoSave Off Tracker - update to Library.xlsx Search

	A	B	C	D	E
1	Date	Version	Changes	Details	Reason
2	20210202	Draft Version			
3	20200217	Draft Version	Datasets	Correction of various Typos	
4			Variables	Correction of various Typos	
5				Removal of Length Values	Trial Specific Post Processing Activity
6				Removal of Significant Digit Values	Trial Specific Post Processing Activity
7				added details in columns J and K	Column J: VISITNUM (reminder to add codelist, not trial specific)
8				Added column Q: Core	On request for internal use
9			Value Level	detail added	
10			where clauses	detail added	
11			codelists	Correction of various Typos	
12				addition of new codelists	
13				removal of synonyms	Per Pinnacle 21 webinar, FDA expects update of synonyms to existing data in datasets, synonym mappings from source data to be described in csdrg for traceability
14				completion of decoded values for NCI CT	
15			Datasets	Correction of various Typos	
16				addition of SUPPSV	on request of 1904/1905 trials
17			Variables	Correction of various Typos	
18				addition of SUPPSV vars	
19			Value Level		
20			where clauses		
21			codelists	Correction of various Typos	
22				removal of duplicates	
23				addition of new codes	

Minimal requirements



- Off-the-shelf
- Intuitive
- Easy re-use
- Front-end and back-end visualisations
- Versioning





End-user objectives for MDR implementation

- Data standards governance
- CRF design in parallel with protocol development
- Early definition of trial-level expectations
- Standardised communication with external parties
- Simplified EDC UAT

Selection criteria



- CRF and data collection metadata specifications
- SDTM metadata
- Customisation
- Governance
- Cost
- Short time to implementation

Supplier Excellence Scorecard

Supplier	Proton Silica Supply
Scorecard Date	Friday, November 18, 2016
Reviewed By	Billy Buyer
Supplier Contact	Sammy Salesman

TOTAL POINTS EARNED	OVERALL SCORE
92%	A

Category 1: Price Performance											
Item	Description	Weight %	A	B	C	D	F	Your Score			
Pricing	Supplier's price relative to competitors	15%	10%+ Below Average		Average		10%+ Above Average	A			
Discounts	Does supplier offer discounts for early payment?	10%	0%+ Discount	5% Discount	2% Discount	2% Discount	No Discount	A			
RFQ Turnaround	How quickly does supplier return RFQs?	5%	Within Hours	Same AM or PM	Same Day	Two Days	How to be Cheated	C			
Clarity of Quotes	Are quotes clear and easy to understand?	5%	Yes		Clarifications Required		Hard to Understand	A			
Quote Validity Time	How long are quotations valid?	5%	60+ Days	30-59 Days	30 Days	14-30 Days	Less Than Two Weeks	A			
Total % Available in This Category:			40%		Total % Supplier Earned in This Category:						
					38%						

Category 2: Quality											
Item	Description	Weight %	A	B	C	D	F	Your Score			
DPPM	Supplier's DPPM percentage	10%	0% / Flawless	1-2%	3-5%	5-10%	11+%	A			
Documentation	Documentation is clean, legible	5%	Flawless		Requires Buyer Assistance		Excessive Errors	B			
Packaging	Packaging integrity prevents damage on receipt	5%	No Damages on Receipt		Occasional Damage		Frequent Damage	C			
Expiration	Compliance with quality codes, subjective score	7%						B			
QMS Registrations	ISO 9001, AS9120, NADCAP, QSL - 2pts each	8%	All 4 QMS Registrations	3 Registrations	2 Registrations	1 Registration	No Registrations	A			
Total % Available in This Category:			35%		Total % Supplier Earned in This Category:						
					30%						

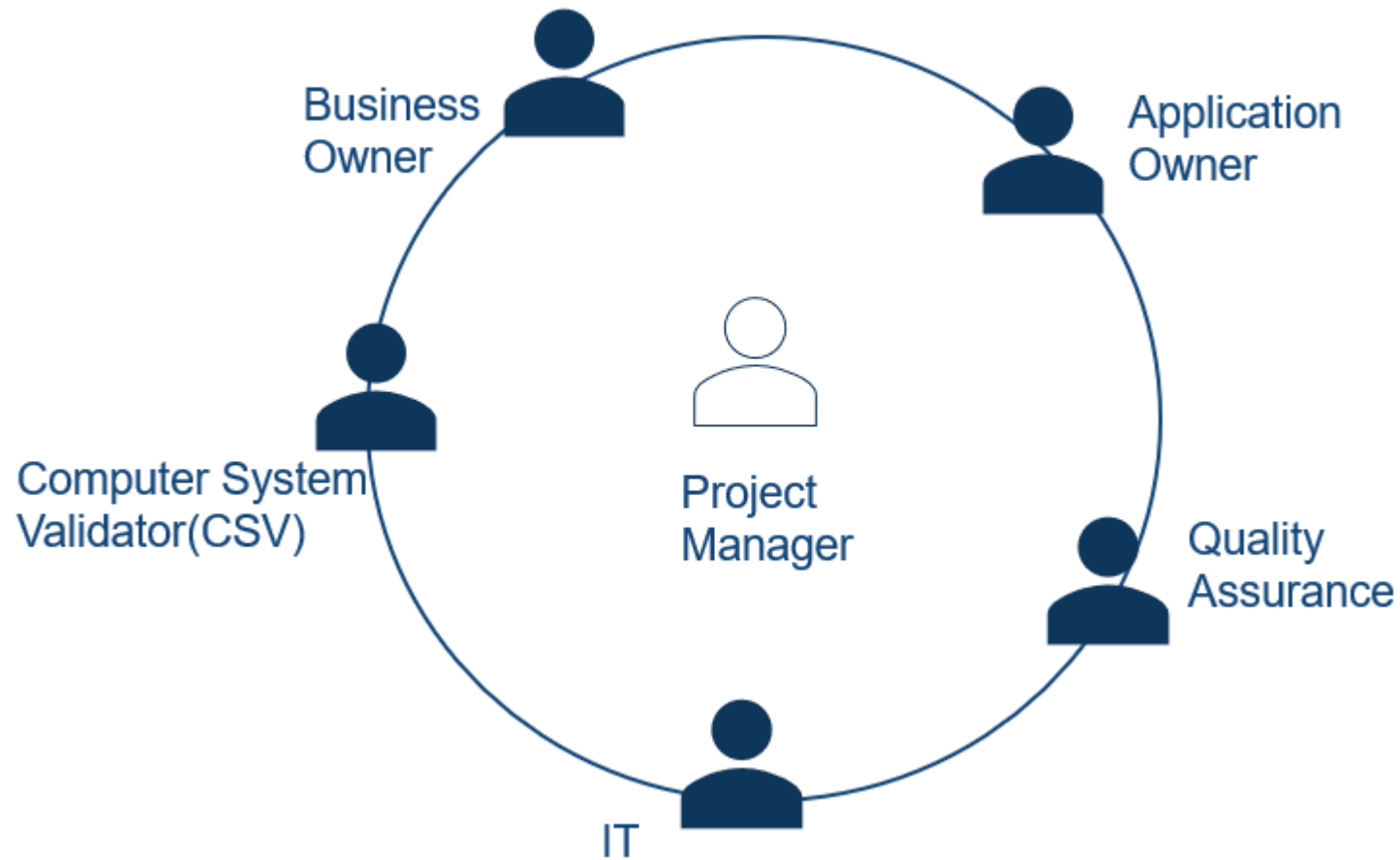
Category 3: Inventory & Stockholding Support											
Item	Description	Weight %	A	B	C	D	F	Your Score			
LTA	Supplier has a signed LTA in place	10%	0% / Flawless	1-2%	3-5%	5-10%	11+%	A			
OTD	Supplier's OTD percentage, last 6 months	5%	100%	95-99%	90-95%	85-90%	0-84%	B			
% In Stock Orders	Percentage of orders that ship immediately from stock and do not roll to a backorder	8%	100%		90%		<90%	A			
Packaging	Packaging integrity prevents damage on receipt	2%	No Damages on Receipt		Occasional Damage		Frequent Damage	A			
Total % Available in This Category:			25%		Total % Supplier Earned in This Category:						
					24%						

Score Weighting	
A	100%
B	80%
C	50%
D	30%
F	0%

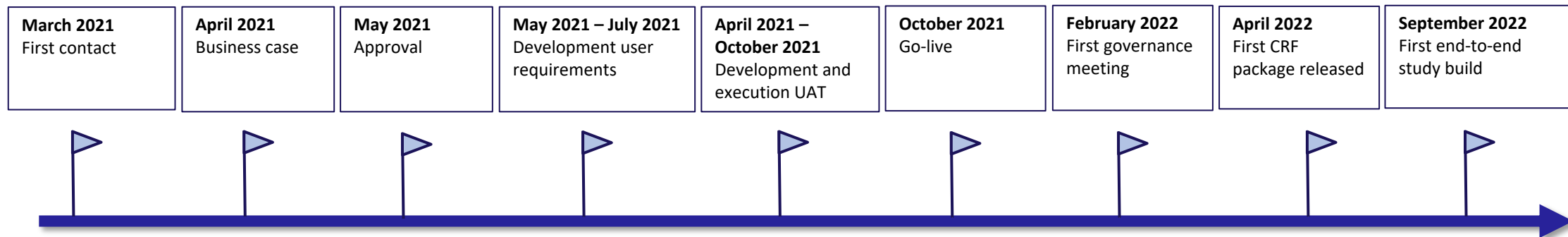
Overall Grade Weighting	
59%	F
60%	D
70%	C
80%	B
90%	A

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Implementation team



Timelines to implementation



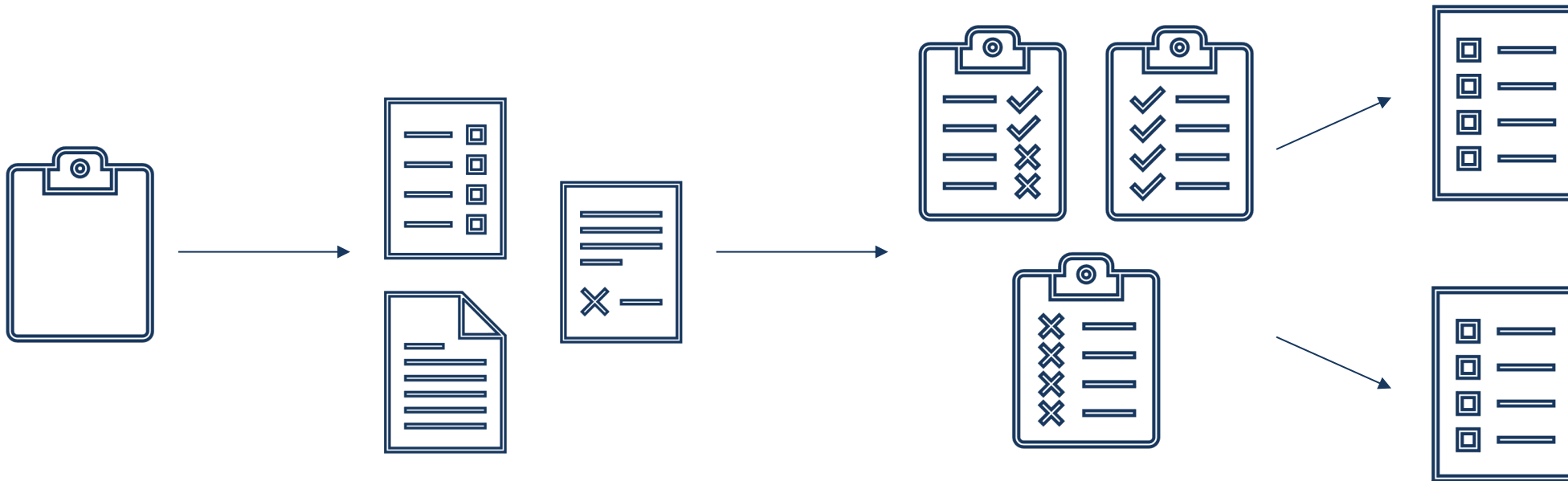


2. MDR development process

Standards development



- Rare disease area → different indications with different endpoints





Development challenges

- System abilities vs. user requirements
- Learning process
- 80/20 rule
- Use of terminologies

Eligibility		
1.1	Eligibility review can be performed	☐ Yes ☐ No

Adverse Events		
1.15	Was the adverse event serious?	☐ Yes <i>AESER</i> ☐ No

Vital Signs												
1.1	Vital signs performed	☐ Yes <i>Y = [Not submitted]</i> Vital signs date (DD-MMM-YYYY) <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> ☐ No <i>N = VSSTAT = NOT DONE when VSTESTCD = VSALL</i> Reason vital signs not performed										



Data standards governance process

Input

Prior and Concomitant Therapy		
1.1	Medication/therapy	
1.2	Indication	☐ Adverse Event If Adverse Event, choose the corresponding AE log line ☐ Medical History If Medical History, choose the corresponding MH log line ☐ Prophylaxis ☐ Other If Prophylaxis or Other, please specify

Review Comments DMLs

Comment	Response
Do we need 'study disease' as indication? Or do you expect the site to select 'MH' (while usually this is collected on a separate form and cannot be selected as corresponding MH	Add disease under study Discuss within governance: - Other option needed? - If prophylaxis, specification needed?

Discuss with Governance Team

Form Review and Questions Prior and Concomitant Therapy

- Indication for CM, should we add to form
 - Other
 - Specification of prophylaxis

Prior and Concomitant Therapy		
1.1	Medication/therapy	
1.2	Indication	☐ Adverse Event If Adverse Event, choose the corresponding AE log line ☐ Medical History If Medical History, choose the corresponding MH log line ☐ <Indication under study> ☐ Prophylaxis ☐ Other If Prophylaxis or Other, please specify

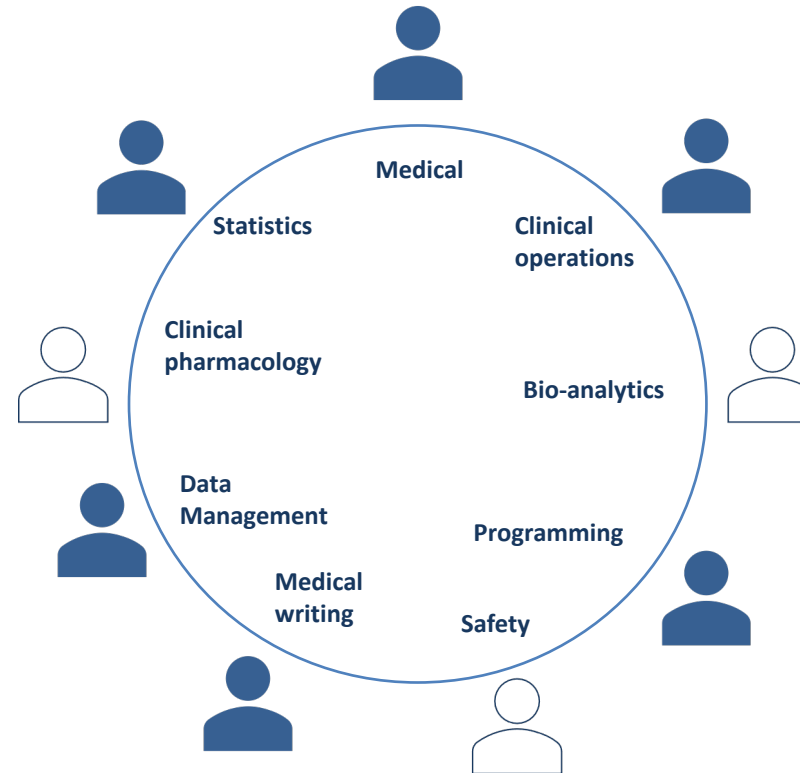
Output

Prior and Concomitant Therapy		
1.1	Medication/therapy	
1.2	Indication	☐ Adverse Event If Adverse Event, choose the corresponding AE log line ☐ Medical History If Medical History, choose the corresponding MH log line ☐ <Indication under study> ☐ Prophylaxis

Data Standards Governance Team



- Governance team
 -  Core team members
 -  Ad hoc team members
- Tracking of conclusions and rationale





3. Where are we now?

Significant simplification



Before

Physical Examination

Assessment done? Yes 

Verify 

Date performed (dd MMM yyyy) 22 Aug 2019 

Verify 

Time of assessment (HH:nn) 10 : 30 

Verify 

Please examine all indicated body systems and select the appropriate response:

- If an abnormality is present at Roll-Over visit, please cross-check with Medical History form

- If a new, clinically significant finding is found after signing informed consent, please also cross-check with Adverse Events form

- Myasthenia Gravis related abnormalities should not be reported on this page

Physical Examination, Log Lines

All  Search field value: '0' or '1' for check

<	Body system	If other, please specify	Result	If abnormal, please specify	If abnormal, clinically significant?
1	General appearance		Normal 		
2	Skin		Normal 		
3	Lymph nodes		Normal 		
4	Musculoskeletal/extremities		Abnormal 	sequelae right hip avascular necrosis, stable 	No 
5	Abdomen		Normal 		
6	Cardiovascular		Normal 		
7	Respiratory		Normal 		
8	Neurological		Normal 		
9	Other		Not done 		

After

Subject Number  Folder Name 

Physical Examination

Physical exam performed

... 

Reason physical exam not performed

Physical exam date

dd

... 

 yyyy

Weight

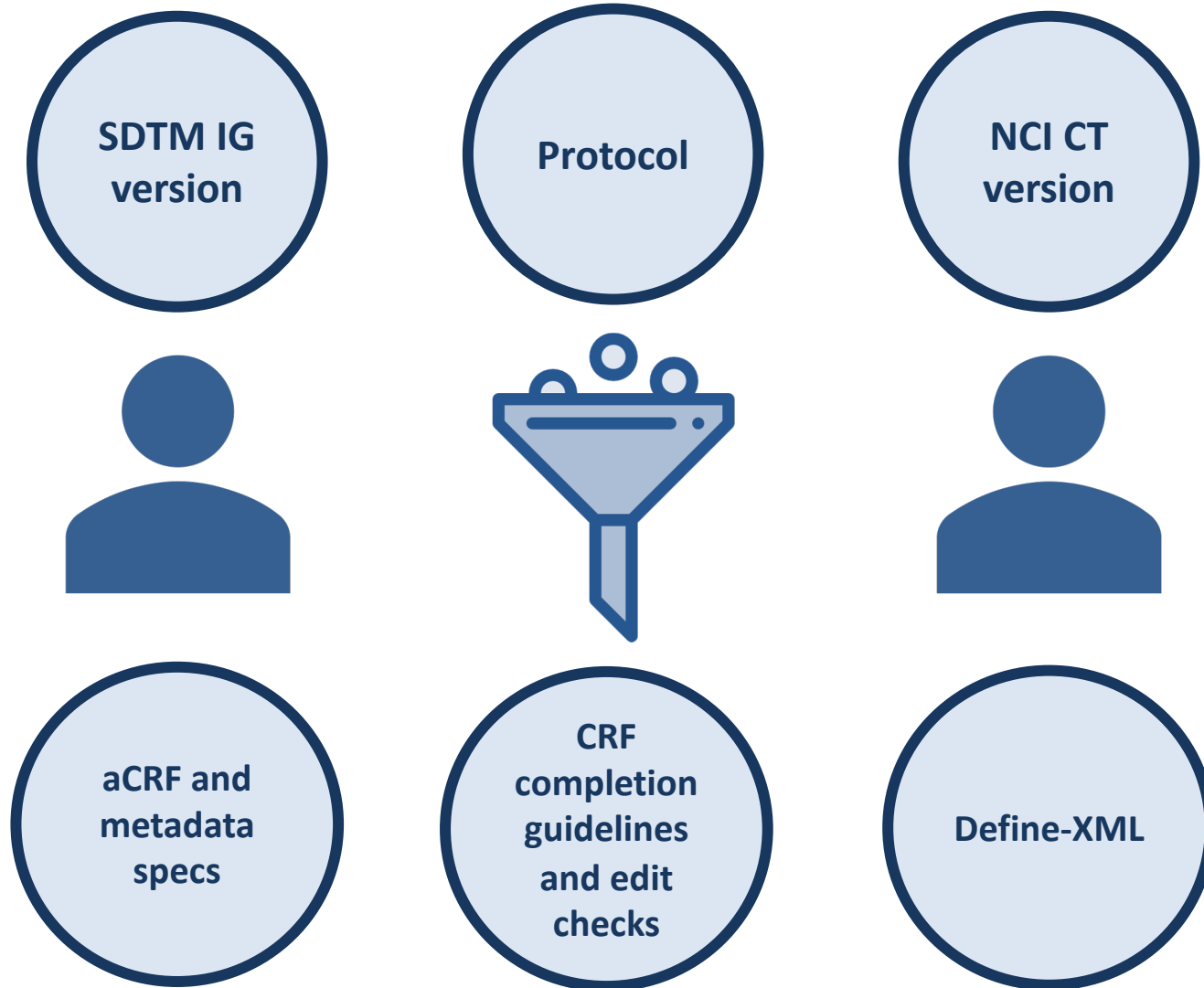
... 

Height

... 

BMI kg/m2

Study build



Deliverables study build



aCRF

Completion
guidelines
and edit
checks

Define-
XML

Demographic Data and Informed Cons

- Datasets
- Controlled Terminology

Standard
Study Name Demographic Data and Informed Consent Record
Study Description Demographic Data and Informed Consent Record
Protocol Name Demographic Data and Informed Consent Record
Metadata Name Define-XML
Metadata Description Define-XML

Dataset	Description	Class
DM	Demographics	SPECIAL PURPOSE

Go to the [top](#) of the Define-XML document

DM (Demographics) - SPECIAL PURPOSE

Variable	Label / Description	Type	Role	Length & Display Format
STUDYID	Study Identifier	text	Identifier	
DOMAIN	Domain Abbreviation	text	Identifier	
USUBJID	Unique Subject Identifier	text	Identifier	
SUBJID	Subject Identifier for the Study	text	Topic	
RFSTDTC	Subject Reference Start Date/Time	datetime	Record Qualifier	
RFENDTC	Subject Reference End Date/Time	datetime	Record Qualifier	
RFXSTDTC	Date/Time of First Study Treatment	datetime	Record Qualifier	
RFXENDTC	Date/Time of Last Study Treatment	datetime	Record Qualifier	
RFICDTC	Date/Time of Informed Consent	datetime	Record Qualifier	
RFPENDTC	Date/Time of End of Participation	datetime	Record Qualifier	

Date/Time of Define-XML document generation: 2022-10-20T09:36:18

Form Identifier	Question Identifier	Question text	Condition identifier	Condition
--DAT				Check for future dates
X_DM	DM_AGE	Age at informed consent	DM_AGE_C1	Sites <> JPN: Age at informed consent should be equal to or greater than 18 years.
X_DM	DM_AGE	Age at informed consent	DM_AGE_C2	JPN sites: Age at informed consent should be equal to or greater than 20 years.
X_DM	DM_BIRTHYY	Birth year	DM_BIRTHYY_C1	Check that birth year is before the date ICF obtained.
X_DM	DM_BIRTHYY	Birth year	DM_BIRTHYY_C2	Check that the calculated age (derived from the year of birth at time of ICF signature) corresponds to the reported age.
X_DM	DM_RACE	Race (tick all that apply)	DM_RACE_C1	At least one of the following race categories should be checked: - American Indian or Alaska Native - Asian - Black or African American - Native Hawaiian or other Pacific Islander - White - Other OR Not Reported should be checked. OR Unknown should be checked. Note: If Not Reported or Unknown is checked, the other items should remain blank.
	DM_RACE	Race (tick all that apply)	DM_RACE_C2	Check if 'other' is ticked that the specify field does not contain a pre-defined
X_DM	DS_IC_DSSTDAT	Date informed consent obtained	DS_IC_DSSTDAT_C1	Date ICF obtained should be equal to or after ICF version date.
X_DM	DS_IC_DSSTDAT	Date informed consent obtained	DS_IC_DSSTDAT_C2	Date ICF obtained should be equal to or after protocol version date.
X_DM	DS_IC_DSSTDAT	Date informed consent obtained	DS_IC_DSSTDAT_C3	Check that the date ICF obtained <= screening visit date
X_DM	XD_INITSCRN	Previous participant ID	XD_INITSCRN_C1	Check that if a previous participant ID is reported: - that this is an existing participant. - that it is reported for only one participant. - that the previous participant ID is registered as screen failure.

Learnings



- Test end-to-end study build
 - Smooth process
 - Versioning and identifiers
- Overall MDR implementation
 - Clear overview of data collected so far
 - Simplified data collection
 - Better control of study set-up

Thank you!



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Or visit booth 14 after this session!