



***From Study Set-up to Data Cleaning: A
swift Study Build with CDISC Standards.***

Benjamin Devriendt – 23-MAR-2017



Concepts



A Standardized Database



Standardization vs User Friendliness / EDC Limitations



Benefits in the Data Management process



Conclusion

Concepts

■ **Standardization**

- *The process of implementing and developing technical standards based on the consensus of different parties that include firms, users, interest groups, standards organizations and governments. Standardization can help to maximize compatibility, interoperability, safety, repeatability, or quality. It can also facilitate commoditization of formerly custom processes*

(Source: Wikipedia)

■ **Library**

■ **Data Collection Modules (DCM)**

■ **Tabulation (SDTM)**

Concepts

■ *Standardization*

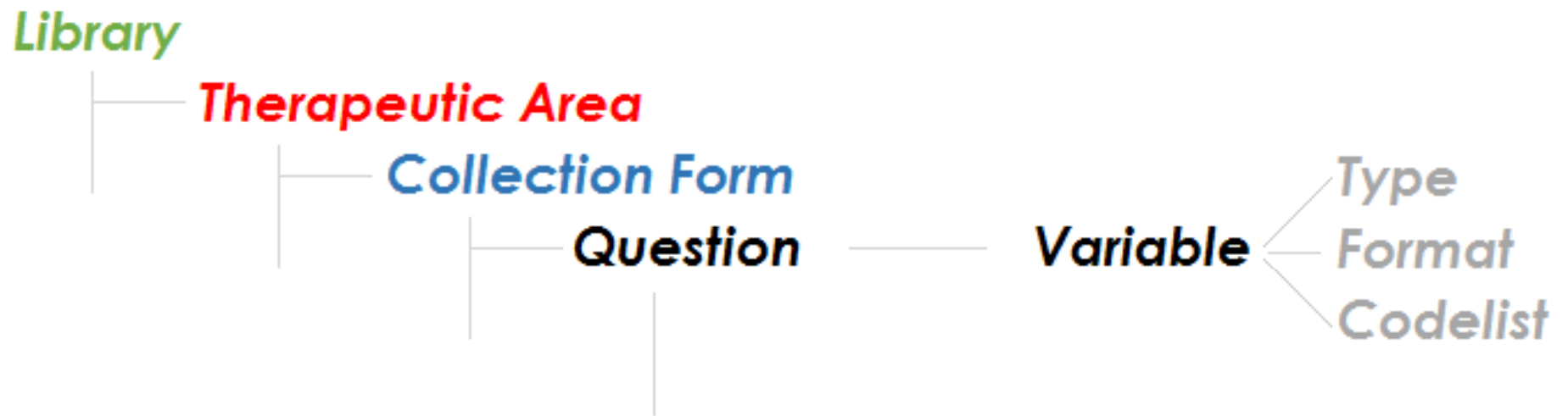
■ ***Library***

- ***Computer*** - *Collection of software or data usually reflecting a specific theme or application. (Source: Dictionary.com)*

■ *Data Collection Modules (DCM)*

■ *Tabulation (SDTM)*

Concepts



Concepts

Therapeutic Area	Module	Questions	Variables	Type	Codelist/Format	Standard Version
General	Laboratory Test Results - Biochemistry & Hematology	Sponsor	SPONSOR	[free text]	prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Protocol	STUDYID	[free text]	prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Country	COUNTRY	[free text]	collected/prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Site	SITEID	[site id text box]	collected/prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Screening Number	SCREENID	[free text]	collected	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Subject	SUBJID	[free text]	collected/prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Investigator	INVID	[investigator id text box]	collected/prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Investigator Name	INVNAM	[free text]	collected/prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Visit	VISIT	[free text]	prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Visit Number	VISITNUM	[visit number text box]	prefilled	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Planned Time Point	LBTP	[option buttons]	TPT#X	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Was the sample collected?	LBPERF	[option buttons]	NY#X	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Laboratory Name	LBNAM	[free text]		CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	[X Hours] Fasting?	LBCOND	[option buttons]	NY#Y	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Collection Date	LBDAT	[date box {DD-MON-YYYY}]		CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Collection Time	LBTIM	[24-hr clock]		CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Test	LBTEST			CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Result	LBORRES			CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Units	LBORRESU		UNIT#X	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Not Done	LBSTAT	[checkbox {Not Done}]	ND#X	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Clinically Significant?	LBCLSIG	[option buttons]	NY#Y	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Comments	COVAL	[free text]		CDASH 1.1

Modules

Value Level Metadata

Codelist

Concepts

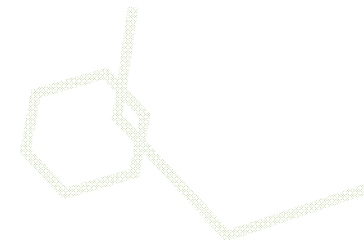
Variable	Test code	Test	Category	Result Format	Units	Standard version
LBTEST	HGB	Hemoglobin	Hematology	[numeric field]	[prefilled {g/dL}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	HCT	Hematocrit	Hematology	[numeric field]	[prefilled {fraction (L/L)}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	RBC	Erythrocyte Count	Hematology	[numeric field]	[prefilled {10 ¹² /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	PLAT	Platelet Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	WBC	Leukocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	NEUT	Absolute Neutrophil Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	LYM	Lymphocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	MONO	Monocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	EOS	Eosinophil Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	BASO	Total Basophil Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	CREAT	Creatinine	Biochemistry	[numeric field]	[prefilled {μmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	BUN	Blood Urea Nitrogen	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	URATE	Urate	Biochemistry	[numeric field]	[prefilled {μmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	SODIUM	Sodium	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	K	Potassium	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	CL	Chloride	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	BICARB	Bicarbonate	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	MG	Magnesium	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	CA	Calcium	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	PHOS	Phosphate	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	GLUC	Glucose	Biochemistry	[numeric field]	[prefilled {mmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	ALB	Albumin	Biochemistry	[numeric field]	[prefilled {g/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	PROT	Protein	Biochemistry	[numeric field]	[prefilled {g/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	AST	Aspartate Aminotransferase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	ALT	Alanine Aminotransferase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	BILI	Total Bilirubin	Biochemistry	[numeric field]	[prefilled {μmol/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	ALP	Alkaline Phosphatase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	LIPASET	Lipase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	LDH	Lactate Dehydrogenase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1
LBTEST	CK	Creatine Kinase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1

Modules

Value Level Metadata

Codelist

Concepts



Codelist	Sub-codelist	Submission Value	Display text
NY	NY#X; NY#Y; NY#Z	Y	Yes
NY	NY#X; NY#Y; NY#Z	N	No
NY	NY#X; NY#Z	NA	Not Applicable
NY	NY#Z	U	Unknown
ND	ND#X	NOT DONE	Not Done
UNIT	UNIT#X	g/dL	Gram per Deciliter
UNIT	UNIT#X	fraction (L/L)	fraction (L/L)
UNIT	UNIT#X	10 ¹² /L	10 ¹² /L
UNIT	UNIT#X	10 ⁹ /L	10 ⁹ /L
UNIT	UNIT#X	umol/L	μmol/L
UNIT	UNIT#X	mmol/L	mmol/L
UNIT	UNIT#X	g/L	g/L
UNIT	UNIT#X	U/L	U/L

Modules

Value Level Metadata

Codelist

Concepts

- *Standardization*

- *Library*

- ***Data Collection Module (DCM)***

- *Collection of questions revolving around the same sub-part of a domain, a module.*

- *Tabulation (SDTM)*

Concepts

ADVERSE EVENTS		SCREEN ID: AE_001	
SPONSOR	Sponsor	[free text]	prefilled
STUDYID	Protocol	[free text]	prefilled
COUNTRY	Country	[free text]	collected/prefilled
SITEID	Site	[site id text box]	collected/prefilled
SCREENID	Screening Number	[free text]	collected
SUBJID	Subject	[free text]	collected/prefilled
INVID	Investigator	[investigator id text box]	collected/prefilled
INVNAM	Investigator Name	[free text]	collected/prefilled

Adverse Events			
AEYN	Were any adverse events experienced?	[option buttons {Yes; No}]	NY#X
AESPID	[Line Number]	[numeric field]	
AETERM	Adverse Event	[free text]	
AESER	Serious	[option buttons {Yes; No}]	NY#X
AESTDAT	Start Date	[date box {DD-MON-YYYY}]	
AESTTIM	Start Time	[24-hr clock]	
AEENDAT	End Date	[date box {DD-MON-YYYY}]	
AEENTIM	End Time	[24-hr clock]	
AEONGO	Ongoing?	[option buttons {Yes; No}]	NY#X
AESEV	Severity	[option buttons {Mild; Moderate; Severe}]	AESEV
AETOXGR	Toxicity Grade	[option buttons {Grade 1; Grade 2; Grade 3; Grade 4...}]	TOXGRV4
AEACN	Action Taken with Study Treatment	[option buttons {Dose Increased; Dose Not Changed; Dose Reduced; Drug Interrupted...}]	ACN

Concepts

- *Standardization*

- *Library*

- *Data Collection Modules (DCM)*

- ***Tabulation (SDTM)***

- *Display of a database in table structure and formatted for review.*

Concepts

AE =	ADVERSE EVENTS	SCREEN ID: AE_001	
	Sponsor	[free text]	prefilled
	Protocol	[free text]	prefilled
	Country	[free text]	collected/prefilled
	Site	[site id text box]	collected/prefilled
	Screening Number	[free text]	collected
	Subject	[free text]	collected/prefilled
	Investigator	[investigator id text box]	collected/prefilled
	Investigator Name	[free text]	collected/prefilled

Adverse Events			
[NOT SUBMITTED]	Were any adverse events experienced?	[option buttons {Yes; No}]	
AESPID	[Line Number]	[numeric field]	
AETERM	Adverse Event	[free text]	
AESER	Serious	[option buttons {Yes; No}]	NY#X
AESTDTC	Start Date	[date box {DD-MON-YYYY}]	
AESTDTC	Start Time	[24-hr clock]	
AEENDTC	End Date	[date box {DD-MON-YYYY}]	
AEENDTC	End Time	[24-hr clock]	
[NOT SUBMITTED]		[option button {Yes; No}]	
AEENTPT = [final study visit date]	Ongoing?	If Yes, AEENTPT = ONGOING If No, AEENTPT = BEFORE	
AESEV	Severity	[option buttons {Mild; Moderate; Severe}]	AESEV
AETOXGR	Toxicity Grade	[option buttons {Grade 1; Grade 2; Grade 3; Grade 4...}]	TOXGRV3
AEACN	Action Taken with Study Treatment	[option buttons {Dose Increased; Dose Not Changed; Dose Reduced; Drug Interrupted...}]	ACN

Agenda



Concepts



A Standardized Database



Standardization vs User Friendliness / EDC Limitations



Benefits in the Data Management process



Conclusion



A Standardized Database

 **Pick-up of questions from Library / Generating DCMs**

 **Setting-up the Database / Generating the Forms**

 **Generating CRF**

Therapeutic Area	Module	Questions	Variables	Type	Codelist/Format	Standard Version			
General	Laboratory Test Results - Biochemistry & Hematology	Sponsor	SPONSOR	[free text]	prefilled	CDASH 1.1			
General	Laboratory Test Results - Biochemistry & Hematology	Protocol	STUDYID	[free text]	prefilled	CDASH 1.1			
General	Laboratory Test Results - Biochemistry & Hematology	Country	Variable	Test code	Test	Category	Result Format	Units	Standard version
General	Laboratory Test Results - Biochemistry & Hematology	Site	LBTEST	HGB	Hemoglobin	Hematology	[numeric field]	[prefilled {g/dL}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Screening Number	LBTEST	HCT	Hematocrit	Hematology	[numeric field]	[prefilled {fraction (L/L)}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Subject	LBTEST	RBC	Erythrocyte Count	Hematology	[numeric field]	[prefilled {2012/L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Investigator	LBTEST	PLAT	Platelet Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Investigator Name	LBTEST	WBC	Leukocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Visit	LBTEST	NEUT	Absolute Neutrophil Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Visit Number	LBTEST	LYM	Lymphocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Test Results - Biochemistry & Hematology	Planned Time Point	LBTEST	MONO	Monocyte Count	Hematology	[numeric field]	[prefilled {10 ⁹ /L}]/[option buttons (acc to protocol)]	CDASH 1.1
General	Laboratory Te	Codelist	Sub-codelist	Submission Value	Display text				
General	Laboratory Te	NY	NY#X; NY#Y; NY#Z	Y	Yes				
General	Laboratory Te	NY	NY#X; NY#Y; NY#Z	N	No				
General	Laboratory Te	NY	NY#X; NY#Z	NA	Not Applicable				
General	Laboratory Te	NY	NY#Z	U	Unknown				
General	Laboratory Te	ND	ND#X	NOT DONE	Not Done				
General	Laboratory Te	UNIT	UNIT#X	g/dL	Gram per Deciliter				
General	Laboratory Te	UNIT	UNIT#X	fraction (L/L)	fraction (L/L)				
General	Laboratory Te	UNIT	UNIT#X	10 ¹² /L	10 ¹² /L				
General	Laboratory Te	UNIT	UNIT#X	10 ⁹ /L	10 ⁹ /L				
General	Laboratory Te	UNIT	UNIT#X	umol/L	umol/L				
General	Laboratory Te	UNIT	UNIT#X	mmol/L	mmol/L				
General	Laboratory Te	UNIT	UNIT#X	g/L	g/L				
General	Laboratory Te	UNIT	UNIT#X	U/L	U/L				
		LBTEST	PROT	Protein	Biochemistry	[numeric field]	[prefilled {g/L}]/[option buttons (acc to protocol)]	CDASH 1.1	
		LBTEST	AST	Aspartate Aminotransferase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1	
		LBTEST	ALT	Alanine Aminotransferase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1	
		LBTEST	BLI	Total Bilirubin	Biochemistry	[numeric field]	[prefilled {umol/L}]/[option buttons (acc to protocol)]	CDASH 1.1	
		LBTEST	ALP	Alkaline Phosphatase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1	
		LBTEST	LPASET	Lipase	Biochemistry	[numeric field]	[prefilled {U/L}]/[option buttons (acc to protocol)]	CDASH 1.1	



	Lab Test Results - Biochemistry & Hematology		
LBPERF	Was the sample collected?		[option buttons {Yes; No; Not Applicable}]
LBNAM	Laboratory Name		[free text]
LBDAT	Collection Date		[date box {DD-MON-YYYY}]
LBTIM	Collection Time		[24-hr clock]

	Test	Result	Units	Not Done	Clinically Significant?	Comments
HCT	Hematocrit	[numeric field]	[prefilled {fraction (L/L)}]/ [option buttons (acc to protocol)]	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
PLAT	Platelet Count	[numeric field]	[option buttons (acc to protocol)] [prefilled {10 ⁹ /L}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
NEUT	Absolute Neutrophil Count	[numeric field]	[option buttons (acc to protocol)] [prefilled {10 ⁹ /L}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
CREAT	Creatinine	[numeric field]	[option buttons (acc to protocol)] [prefilled {(mmol/L)}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
AST	Aspartate Aminotransferase	[numeric field]	[option buttons (acc to protocol)] [prefilled {U/L}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
ALT	Alanine Aminotransferase	[numeric field]	[option buttons (acc to protocol)] [prefilled {U/L}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
BILI	Total Bilirubin	[numeric field]	[option buttons (acc to protocol)] [prefilled {(mmol/L)}]/	[checkbox (Not Done)]	[option buttons {Yes; No}]	[free text]
	LBTEST	LBORRES	LBORRESU UNIT#X	LBSTAT ND#X	LBCLSIG NY#Y	COVAL

A Standardized Database

❏ Pick-up of questions from Library / Generating DCMs

❏ **Setting-up the Database / Generating the Forms**

❏ Generating CRF



Lab Test Results - Local

Visit: Screening : Day -1 to 1 ▾

Was the sample collected? Yes No

Laboratory Name

Collection Date

Collection Time

Row Tools	Test	Result	Units	Low Normal	High Normal	Not Done	Abnormal	Clinically Significant?	Comments
1 <input type="checkbox"/>	Hematocrit ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
2 <input type="checkbox"/>	Platelet Count ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
3 <input type="checkbox"/>	Absolute Neutrophil Count ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
4 <input type="checkbox"/>	Aspartate Aminotransferase ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
5 <input type="checkbox"/>	Alanine Aminotransferase ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
6 <input type="checkbox"/>	Total Bilirubin ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
7 <input type="checkbox"/>	Creatinine Clearance ▾	<input type="text"/>	<input type="text" value=""/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>

A Standardized Database

- ❏ Pick-up of questions from Library / Generating DCMs
- ❏ Setting-up the Database / Generating the Forms
- ❏ **Generating CRF**



Lab Test Results - Local

Was the sample collected? Yes
 No

Laboratory Name

Collection Date

Collection Time



Test	Result	Units	Low Normal	High Normal	Not Done	Abnormal	Clinically Significant?	Comments
1 Hematocrit ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
2 Platelet Count ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
3 Absolute Neutrophil Count ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
4 Aspartate Aminotransferase ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
5 Alanine Aminotransferase ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
6 Total Billirubin ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
7 Creatinine Clearance ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>

Agenda



Concepts



A Standardized Database



Standardization vs User Friendliness / EDC Limitations



Benefits in the Data Management process



Conclusion

Standardization vs User Friendliness / EDC Limitations

■ --DTC in Findings

- *On EDC, Investigators prefer to type once the data.*
- *In SDTM, each measurement should have a date/time.*
- *Need to map and convert date/time from CDASH to SDTM*

■ Variables

- *Screens belonging to one same domain*
- *Variables of the same name*
- *But Variables names are unique on some EDC*
- *Need to deviated from pure CDASH to remediate*
- *Increased time to map to SDTM*

Agenda



Concepts



A Standardized Database



Standardization vs User Friendliness / EDC Limitations



Benefits in the Data Management process



Conclusion



Benefits in the Data Management process

■ CRF Completion Guidelines (CCG)

- *Standardized CRF allows a transportable completion guidelines from one study to another*
- *Time efficient*

■ Patient Profile

■ Reconciliation Listings

■ Edit checks

■ Data Management Quality Plan (DMQP)

Benefits in the Data Management process

■ *CRF Completion Guidelines (CCG)*

■ ***Patient Profile***

- *Standardized CRF allows harmonization of patients profiles*
- *Time efficiency and Quality by ensuring Consistency*

■ *Reconciliation Listings*

■ *Edit checks*

■ *Data Management Quality Plan (DMQP)*

Benefits in the Data Management process

■ *CRF Completion Guidelines (CCG)*

■ *Patient Profile*

■ ***Reconciliation Listings***

- *External Vendors Data*

- *Medical Review (AE –CM)*

 - Standardized files facilitate reconciliation by making discrepancies easier to spot

 - Gain in Quality Control and Time Efficiency

■ *Edit checks*

■ *Data Management Quality Plan (DMQP)*

Benefits in the Data Management process

■ CRF Completion Guidelines (CCG)

■ Patient Profile

■ Reconciliation Listings

■ **Edit checks**

- **Standardized checks between variables of a same Domain**
 - E.g.: Fire a query if LBORRES is missing and LBORRESU has been completed.
- **Standardized cross checks**
 - Between 2 domains
 - E.g.: Fire a query if AEACN= 'DRUG WITHDRAWN' and there is no DSDECOD = 'ADVERSE EVENT' as 'DISPOSITION EVENT' (DSCAT).
- **UAT**
 - Standardized scripts can be transported from one study to the other
 - Transportability of checks ensures a consistency in the quality of the data

■ Data Management Quality Plan (DMQP)

Benefits in the Data Management process

- *CRF Completion Guidelines (CCG)*

- *Patient Profiles*

- *Reconciliation Listings*

- *Edit checks*

- ***Data Management Quality Plan (DMQP)***

- *Since Data Management Quality Plan (DMQP) can be standardized, its writing in the Data Validation Document (DVD) can be standardized as well.*

Agenda



Concepts



A Standardized Database



Standardization vs User Friendliness / EDC Limitations



Benefits in the Data Management process



Conclusion

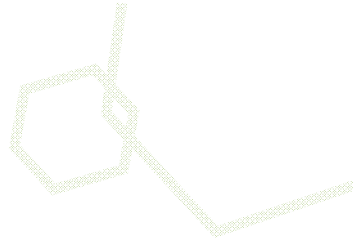
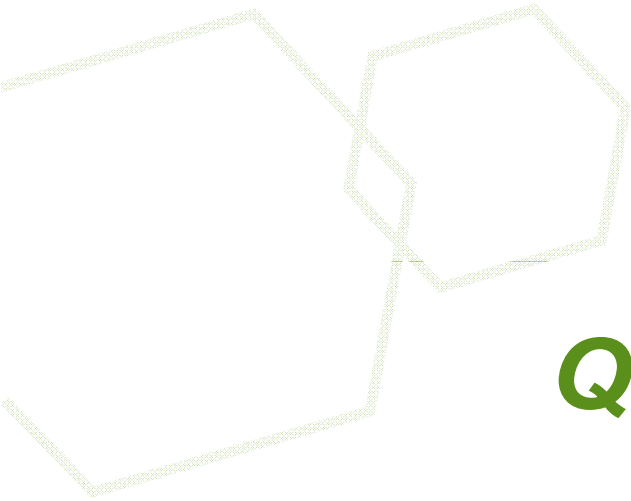
Conclusion

■ *Standardized study*

- *Overall Standardization of documentation*
- *Quality*
- *Repeatability /Transportability*
- *Overall Time Efficiency*



Questions...





ROI²
return on investment
through
return on information

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