

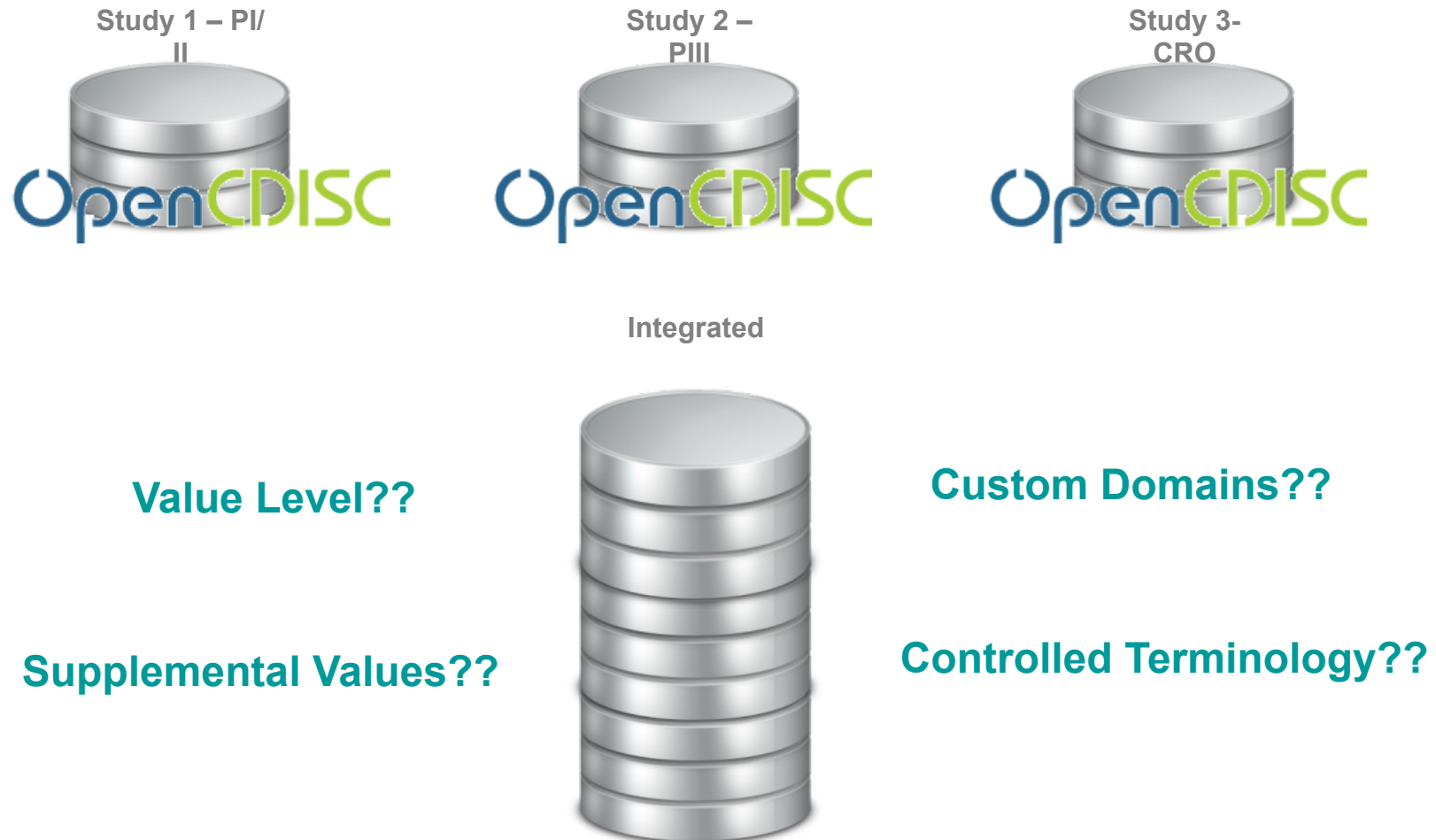


ICON

CD04 - Ensuring Compliant and Consistent Data Mappings for SDTM-based Studies – an ICON Approach

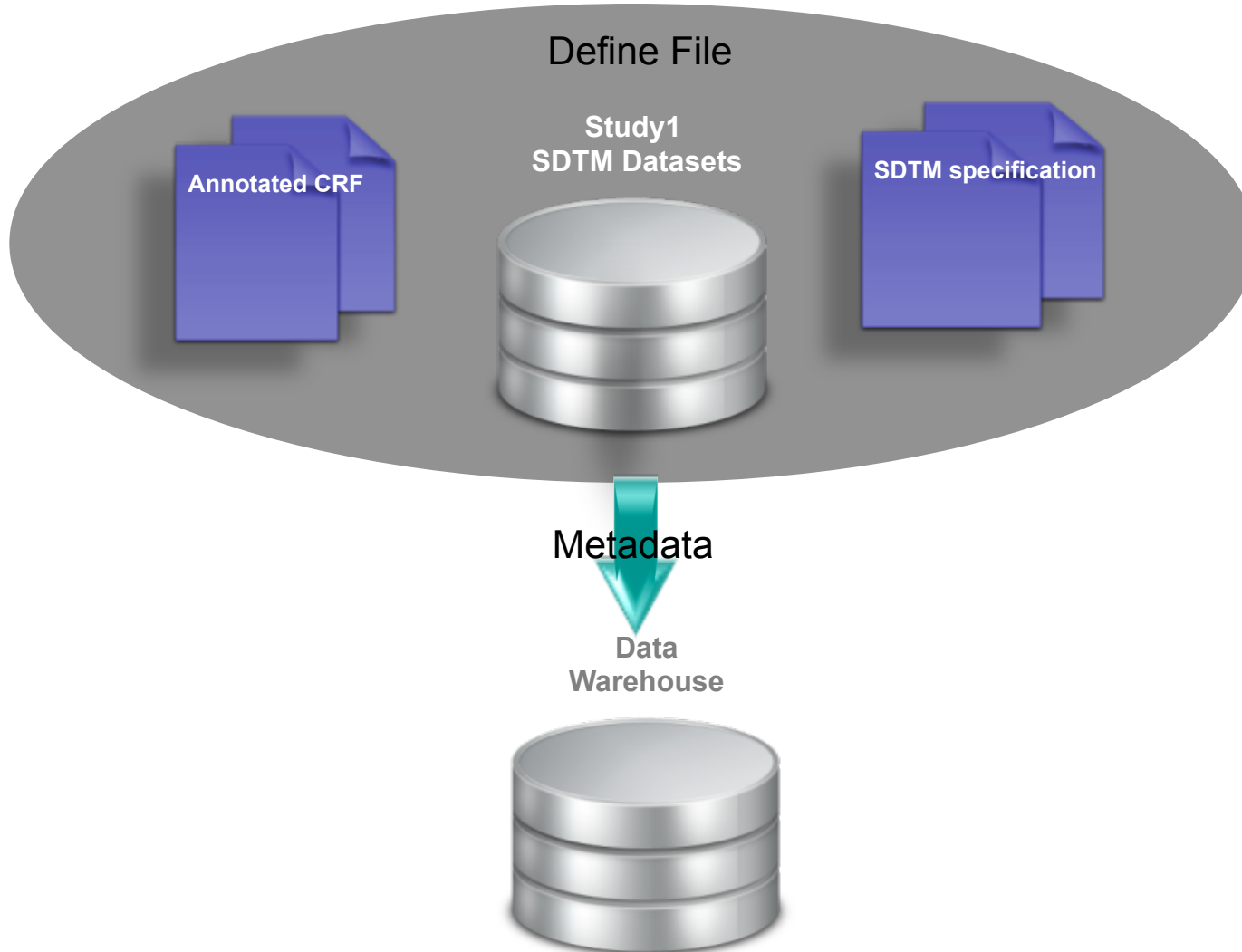
Jennie Mc Guirk
11th October 2011

Setting the Scene

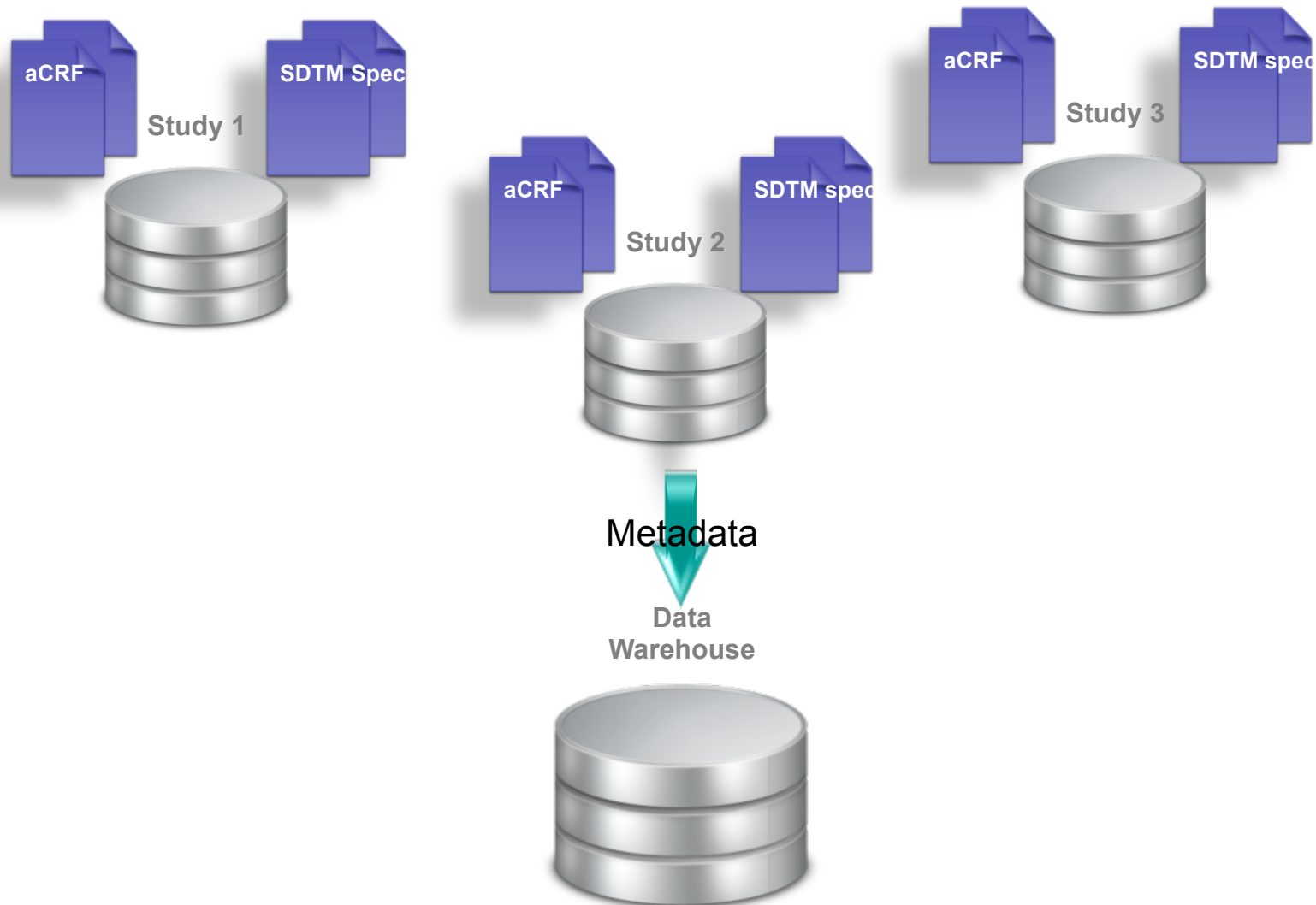


- **Compliance – single study**
 - Independent Review / Interpretation of IG
 - Validation methodologies (e.g. Double programming)
 - Integrity Checks
 - WebSDM
 - OpenCDISC
 - Define Checker
- **Consistency – multiple studies**
 - Data Warehouse Tool

Data Warehouse Build – single study



Data Warehouse Build – multiple studies



- 7 Reports

- Report 1: Summary of Domain Distribution by Study.
- Report 2: Summary of Variable Distribution by Study.
- Report 3: Summary of Variable Values by Study.
- Report 4: SDTM Pairing of Test Code and Test Name.
- Report 5: SDTM Extended Paired Variables.
- Report 6: SDTM Nested Variable Values.
- Report 7: CRF Page Number Comparisons.

Summary of Domain Distribution by Study

SDTM Domains in aCRF and Specs
Studies : Study 1, Study 2, Study 3

SDTM_Domain	SDTM_SUP Pxx	aCRF_Page_Header	aCRF_Pag	Study Number	Protocol_Nu mber	acrf_link	spec_link
AE	SUPPAE	Adverse Events	89	Study 1	Study 1	aCRF	Specs
AE	SUPPAE	Adverse Events	55	Study 2	Study 2	aCRF	Specs
AE	SUPPAE	Adverse Events	49	Study 3	Study 3	aCRF	Specs
ZO	SUPPZO	An Efficacy Assessment	18	Study 1	Study 1	aCRF	Specs
ZO	SUPPZO	An Efficacy Assessment	33	Study 2	Study 2	aCRF	Specs
ZO	SUPPZO	A Safety Assessment	25	Study 3	Study 3	aCRF	Specs



Consistency of Custom Domain Names

Summary of Variable Distribution by Study

Variables and variable values in aCRF cross-checking Specs and CRT
Studies : Study 1, Study 2, Study 3

			Study 1			Study 2			Study 3		
Domain	Variable	Label	aCRF	Spec	CRT	aCRF	Spec	CRT	aCRF	Spec	CRT
SUPPAE	AEHLGT	High Level Group Term	Y	Y	Y	Y	Y	Y	Y	Y	Y
SUPPAE	AEHLGTCD	High Level Group Term Code	Y	Y	Y	Y	Y	Y	Y	Y	Y
SUPPAE	AEHLT	High Level Term	Y	Y	Y	Y	Y	Y	Y	Y	Y
SUPPAE	AEHLTERM	High Level Term	Y	Y	Y	Y	Y	Y	Y	Y	Y
SUPPAE	AEHLTCD	High Level Term Code	Y	Y	Y	Y	Y	Y	Y	Y	Y



Consistency of Supplemental Variable Values

Summary of Variable Values by Study

Variables and variable values in aCRF cross-checking Specs and CRT

Studies : Study 1, Study 2, Study 3

			Study 1		Study 2		Study 3	
Domain	Variable	Value	CRT	spec	CRT	spec	CRT	spec
→ EG	EGORRES	NEGATIVE	Y	Y	Y	Y		
→ EG	EGORRES	NEG					Y	Y
→ EG	EGSTRESC	NEGATIVE	Y	Y	Y	Y		
→ EG	EGSTRESC	NEG					Y	Y



Consistency of Value Level

SDTM Pairing of Test Code and Test Name

Paired variable values in CRT, cross-checking Specs
Studies : Study 1, Study 2, Study 3

Domain	Variable	--TESTCD	--TEST	Study 1		Study 2		Study 3	
		Value	Label	CRT	Spec-	CRT	Spec-	CRT	Spec-
LB	LBTESTCD	ALB	Albumin	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALP	Alkaline Phosphatase	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALT	Alanine Aminotransferase	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	BILI	Bilirubin	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	LBALL	Laboratory Test Results					Y	Y
→ LB	LBTESTCD	LBALL	Labs Data	Y	Y	Y	Y		
LB	LBTESTCD	CREAT	Creatinine	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	BASO	Basophils	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	PTT	Partial Thromboplastin Time			Y	Y	Y	Y
→ LB	LBTESTCD	PTT	Activated Partial Thromboplastin Time	Y	Y				
LB	LBTESTCD	RBC	Erythrocytes	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	WBC	Leukocytes	Y	Y	Y	Y	Y	Y



Consistency of Extensible Controlled Terminology

SDTM Extended Paired Variables

Extension 1 paired variable values in CRT, cross-checking Specs
Studies : Study 1, Study 2, Study 3

						Study 1		Study 2		Study 3	
Domain	Variable	Value	Label	STRESU/Q EVAL	CAT/QORIG	CRT	Spec-	CRT	Spec-	CRT	Spec-
LB	LBTESTCD	ALB	Albumin	g/L	CHEMISTRY	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALP	Alkaline Phosphatase	IU/L	CHEMISTRY	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALT	Alanine Aminotransferase	IU/L	CHEMISTRY	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	BILI	Bilirubin	mg/dL	URINALYSIS	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	BILI	Bilirubin	umol/L	CHEMISTRY	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	CREAT	Creatinine	umol/L	CHEMISTRY	Y	Y	Y	Y		
→ LB	LBTESTCD	CREAT	Creatinine	mg/dL	CHEMISTRY					Y	Y
→ LB	LBTESTCD	WBC	Leukocytes	/HPF	URINALYSIS	Y	Y	Y	Y	Y	Y
→ LB	LBTESTCD	WBC	Leukocytes	x10 ³ /uL	HEMATOLOGY	Y	Y	Y	Y	Y	Y



Consistency of Paired Variables

SDTM Nested Variables

Nested paired variable values in CRT, cross-checking Specs
Studies : Study 1, Study 2, Study 3

						Study 1		Study 2		Study 3	
Domain	Variable	Value	Label	NestVar1	NestVar2	CRT	Spec-	CRT	Spec-	CRT	Spec-
LB	LBTESTCD	ALB	Albumin	CHEMISTRY	BLOOD	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALP	Alkaline Phosphatase	CHEMISTRY	BLOOD	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	ALT	Alanine Aminotransferase	CHEMISTRY	BLOOD	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	BILI	Bilirubin	CHEMISTRY	BLOOD	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	BILI	Bilirubin	URINALYSIS	URINE	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	WBC	Leukocytes	HEMATOLOGY	BLOOD	Y	Y	Y	Y	Y	Y
LB	LBTESTCD	WBC	Leukocytes	URINALYSIS						Y	Y
LB	LBTESTCD	WBC	Leukocytes	URINALYSIS	URINE	Y	Y	Y	Y		



Consistency of Nested Variables

CRF Page Number Comparisons

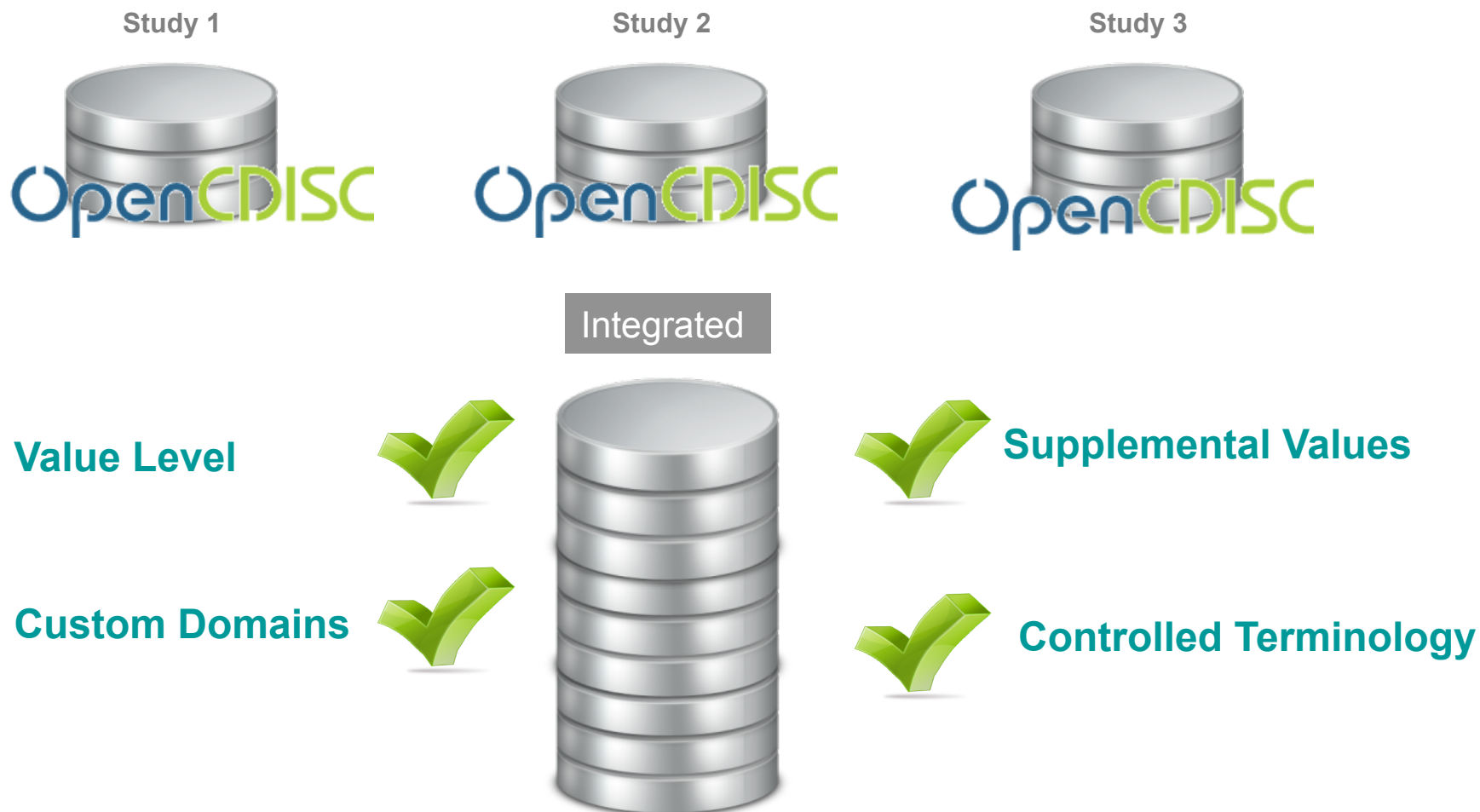
Comparison of Variable Origin
Study : Study 1

Domain	Variable	aCRF Origin	Spec Origin	Message	Different Origin
AE	AEACNOTH	CRF Pages 123, 127	CRF Pages 123, 125, 127	Item AE.AEACNOTH is referenced on [CRF Pages 123, 127], however the define.xml references [CRF Pages 123, 125, 127]	Y
AE	AECAT	CRF Pages 122, 123, 126, 127	CRF Pages 122, 123, 126, 127		
AE	AEENDTC	CRF Pages 123, 127	CRF Pages 123, 127		
AE	AEENRPT	CRF Pages 123, 127	CRF Pages 123, 127		
AE	AEOOUT		CRF Pages 123, 127	Item AE.AEOOUT is referenced on [], however the define.xml references [CRF Pages 123, 127]	Y
AE	AEREL	CRF Pages 123, 127	CRF Pages 123, 127		
AE	AESER	CRF Pages 123, 125, 127	CRF Pages 123, 127	Item AE.AESER is referenced on [CRF Pages 123, 125, 127], however the define.xml references [CRF Pages 123, 127]	Y
AE	AESV	CRF Page 127	CRF Page 127		
AE	AESTDTC	CRF Pages 123, 127	CRF Pages 123, 127		
AE	AETERM	CRF Pages 123, 127	CRF Pages 123, 127		



Consistency of aCRF and Define File

Conclusion



- Effective Tool for individual / large scale projects
- Benefits
 - Efficient Data Integration
 - Report runs on individual study data -> no need for integration
 - ICON developed SAS tool -> Low cost to create & maintain
 - Harmonisation as new studies introduced to drug program
 - Harmonisation as company standards or IG evolves
 - Code reuse - SDTM, ADaM and TLGs
 - Aid Health Authority Review
- Current Enhancement
 - Adding filtering to just highlight inconsistencies
- Future Enhancement
 - Add further reports / checks as required

Co-author: Steven Thacker

Tool Developer: Annie Gou

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