



DH10

Metadata On The Go: Achieving Metadata Accuracy And Consistency Continually

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SGS - Agriculture, Food and Life, Life Sciences - Clinical Research

WHEN YOU NEED TO BE SURE

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Metadata: Data About Data

- Is it just data about data?
 - No, there is much more...
- Metadata in clinical world
 - Exchange
 - Review
 - Analysis
 - Reporting
- What makes it usable?
 - Standardization
- Is that all we need?

The Concept And The Context

- Concept: standardization - compliance to CDISC SDTM
- Context: processes, entities, requirements and expectations
- Programmer: use concepts and act in context
 - What you know and what you do
 - Apply concepts and leverage flexibility in every context
 - **Be efficient**
- Context is dynamic!

Quality Metadata: The Ride Is Bumpy

- Switch of environments
 - Test / Production
 - Consistent and compliant with data both the environments
 - How do we make sure every snapshot is qualitative?

- Standards that change
 - Upgrades to new version releases
 - If ongoing trial, how do we retain all the applicable contextual metadata?
 - How do we do it efficiently?

Quality Metadata: The Ride Is Bumpy

- Conflict of standards
 - Sponsor, SDTM and 'within'
 - Ex: Variable length too long for actual data
 - VISIT variable

Issue Summary				
Source	Pinnacle 21 II	Publisher ID	Message	Severity
Found	Feedback			
CM				
SD1082	FDAC036	Variable length is too long for actual data	Error	2
VISIT: please include an explanation in the SDRG (false positives) that the length of the variable is adapted to the maximum length of data captured <u>across</u> all datasets.				

- Non-DM datasets
 - PC, PD, PP....
 - Blinded trials: datasets received on the day of lock
- On The Go!

Quality Metadata = Quality Databases

- What is quality metadata?
 - Consistent
 - Accurate
 - Sharable
- Is it achievable?
 - Using MDRs, in-house developed applications and open source tools
- How do we do it continually?
 - The SGS workflow: Quality metadata at any point of time

The SGS Workflow – Tools

Hierarchical Metadata Repository

- Historical, current and generic
- Standardization and reuse

CDISC SDTM

SPONSOR / SGS
STANDARD

THERAPEUTIC
AREA

TRIAL
METADATA

The SGS Workflow – Tools

The Annotation Tool

- Physical attributes
- Codelist values linked to MDRs, Alerts

SGS Annot tool

HOME
CRF
REPORTS
LIBRARIES (1357)

002. ----- 12-lead ECG.....|.....36|.....17|.....

Physical Attribute	Code	Value
Heart rate (bpm)	EGORRES	when EGTESTCD = EGHRMN (format 999)
RR interval (ms)	EGORRES	when EGTESTCD = RRAG (format 999)
PR interval (ms)	EGORRES	when EGTESTCD = PRAG (format 999)
QRS duration (ms)	EGORRES	when EGTESTCD = QRSAG (format 999)
QT interval (uncorrected) (ms)	EGORRES	when EGTESTCD = QTAG (format 999)
Rhythm analysis/morphology (add all that apply)	EGORRES	when EGTESTCD = OTHFIND (format 999)

ADDANNOT - Mozilla Firefox
bews101:9080/ordsprod1/f?p=10650:4:1696305450712:::P4_TRIGGER,P4_ANNOTREFID:EDIT,165781
AVCOND.....Atrioventricular Conduction
AXISVOLT.....Axis and Voltage
CHYPENL.....Chamber Hypertrophy or Enlargement
EGALL.....All Tests
EGCOMP.....Comparison to a Prior ECG
EGHRMED.....ECG Median Heart Rate
EGHRMN.....ECG Mean Heart Rate
EGHRMN.....ECG Mean Heart Rate
HR.....HR Interval
HRMAX.....Summary (Max) Heart Rate
HRMEAN.....Summary (Mean) Heart Rate
HRMED.....Summary (Median) Heart Rate
HRMIN.....Summary (Min) Heart Rate
INTP.....Interpretation

The Metadata Centre – Metadata Checks

- Integrated into conversion
- Ad hoc – On click of a button

	Chk	Check Id	Name	Description	Tot Cnt	Ok Cnt	Nok Cnt	Nap Cnt	Lines Of Output	Status	Comments
	☐	1.01	MC_Prc_Chk_Unique_Keys	Keys are not uniquely defined for following domains in DATADEF	5	1	1	1	-	-	-
	☐	1.02	MC_Prc_Chk_CD_VS_DATA	Check if a codelist is attached to a variable in VARDEF, that the variable does not contain any other values except for those listed in CD for that codelist.	5	0	0	0	-	-	-



The SGS Workflow – Tools

The Metadata Centre – Metadata Checks

- Synchronizes with new releases
- Flexibility at various levels

METADATA CENTER

swapna_pothula [Feedback](#) [Switch app](#) [P](#)

HOME TABLES **DICTIONARY SYNC** AUDIT AUDIT COLUMNS SPONSOR REPORT CHECKS

Table

VALDEF

VALUEOID

Sync

row(s) 1 - 73 of 73

Sync	Rwid	Valueoid	Valval	Vallabel	Datatype	Lngh	Decdig	Numfmt	Origin	Varorder	Codelst	Valuelst	Std
☐		FA.FATESTCD	FEV1_PCT	FEV1 as % of Predicted	text	-	-	-	-	021	-	-	-
☐		FA.FATESTCD	FEV1_PRD	FEV1 Predicted	text	-	-	-	-	022	-	-	-
☐		FA.FATESTCD	FVC_PCT	FVC as % of Predicted	text	-	-	-	-	024	-	-	-
☐		FA.FATESTCD	VOLPERF	Volume of Perfusion	text	-	-	-	-	057	-	-	-
☐		IS.ISTESTCD	HAI	Hemagglutination Assay	text	-	-	-	-	001	-	-	-
☐		IS.ISTESTCD	HEMAGG	Hemagglutination Inhibition	text	-	-	-	-	002	-	-	-



The SGS Workflow – Tools

The Metadata Centre – Metadata Checks

- Generates interactive reports for sponsor review
- Filters to streamline reports

METADATA CENTER

swapna_pothula Feedback Switch app

HOME TABLES DICTIONARY SYNC AUDIT AUDIT COLUMNS **SPONSOR REPORT** CHECKS

Show All Datedef Vardef Valdef CD

Changed since 01-Jan-2015

Print Report Download

VARDEF

DATASETS ADDED/REMOVED

Tble	Dataset	Varname	Action	Audit Date
AD_VARDEF	CE	CETERM	VARIABLE REMOVED	13-JAN-2015
AD_VARDEF	DA	DAELTM	VARIABLE REMOVED	13-JAN-2015
AD_VARDEF	DA	DAGRPID	VARIABLE REMOVED	13-JAN-2015
AD_VARDEF	DA	DAORRESU	VARIABLE REMOVED	13-JAN-2015
AD_VARDEF	DA	DAREASND	VARIABLE REMOVED	13-JAN-2015

SDTM Checks and Pinnacle21

- Compliance with CDISC SDTM
- SDTM checks runs on every extract from eSource
- Pinnacle21 is run before major milestones

SDTM discrepancies - PROD						
Drag a column header here to group by that column						
Output	SDTM Rule Id	SDTM Rule Label	Domain	Count	Description	Message
output	SDTM_003	REQ_VAR_COMPLETED	AE_SAS	2	Check per domain that variables listed in the implementation guide as Required are completed on each record in the dataset.	REQUIRED VARIABLE CONTAINS NO VALUE
output	SDTM_027	USUBJID_VISITNUM_VISIT_PRES_SV	PC_SAS	3	Check if [VISITNUM] is completed that [USUBJID] - [VISITNUM] - [VISIT] combination exists in [SV].	[USUBJID] - [VISITNUM] - [VISIT] EXPECTED IN S
output	SDTM_044	ORRESU_STRESU_COMPLETED	LB_SAS	2	Check if [--ORRESU] is completed that [--STRESU] is completed.	[--STRESU] VALUE MISSING
output	SDTM_052	ORRES_STAT_NOT_BOTH_EMPTY	IS_SAS	192	Check that [--ORRES] and [--STAT] are not both empty.	[--ORRES] and [--STAT] VARIABLES BOTH EMPTY
output	SDTM_052	ORRES_STAT_NOT_BOTH_EMPTY	PC_SAS	928	Check that [--ORRES] and [--STAT] are not both empty.	[--ORRES] and [--STAT] VARIABLES BOTH EMPTY
output	SDTM_071	ARMCD_ARM_AVAILABLE_IN_DM	TA_SAS	24	Check that each [ARMCD] - [ARM] combination from [TA] is available in [DM].	[ARMCD] - [ARM] IN [TA] NOT FOUND IN [DM]
output	SDTM_074	ETCD_SCR_PRESENT_TA	TA_SAS	24	Check that at least one record per [ARMCD] with [ETCD] = 'SCR' is present in [TA].	SCR ELEMENT MISSING FOR [ARMCD] IN [TA]
output	SDTM_076	TABRANCH_NOT_COMPLETED	TA_SAS	8	Check if [ETCD] <> 'SCR' that [TABRANCH] is not completed.	[TABRANCH] NOT EXPECTED
output	SDTM_086	ORRES_ISO8601_FORMAT	IE_SAS	2	Check if [--TEST]* contains 'DATE' or 'TIME', or [--TESTCD] ends with 'DTC' or '_D' that the [--ORRES] and [--STRESC] are in ISO8601 --DTC format.	DTC FORMAT IN [--ORRES]/[--STRESC] NOT COM
output	SDTM_087	QVAL_ISO8601_FORMAT	SUPPEC_SAS	26	Check if [QLABEL]* contains 'DATE' or 'TIME', or [QNAM] ends with 'DTC' or '_D' that the [QVAL] is in ISO8601 --DTC format.	DTC FORMAT IN [QVAL] NOT COMPLIANT WITH 1
output	SDTM_087	QVAL_ISO8601_FORMAT	SUPPEX_SAS	26	Check if [QLABEL]* contains 'DATE' or 'TIME', or [QNAM] ends with 'DTC' or '_D' that the [QVAL] is in ISO8601 --DTC format.	DTC FORMAT IN [QVAL] NOT COMPLIANT WITH 1
output	SDTM_089	VAL_UPPER_CASE	SUPPEC_SAS	71	Check if no code list is attached to a character variable, that the values of that variable are in upper case.	VALUE NOT IN UPPERCASE
output	SDTM_089	VAL_UPPER_CASE	SUPPEX_SAS	71	Check if no code list is attached to a character variable, that the values of that variable are in upper case.	VALUE NOT IN UPPERCASE

The SGS Workflow – Driven By Deliverables

■ Where do I start, where do I begin?

- (e)CRF review
- (e)CRF annotation

Action Taken **AEACN**
DRUG WITHDRAWN
☐ Permanently discontinued
☐ No action taken
DOSE NOT CHANGED
☐ Not applicable

■ All set to go...

- Database set up
- When to create metadata?
- What to include / exclude?

Metadata Centre – The IN / EX States

- Created during database set up
- Trial specific metadata with IN/EX states
- Metadata views generated based on states


METADATA CENTER
swapna_pothula
Feedback
Switch app
(DMDEV)
Logout (TEST)

HOME
TABLES
DICTIONARY SYNC
AUDIT
AUDIT COLUMNS
SPONSOR REPORT
CHECKS

Table CD SGSSTATE CODELST SGSSTATE

☐		ACN	C	DOSE REDUCED	-	DOSE REDUCED	-	-	-	IN	DMPROC	-
☐		ACN	C	DRUG INTERRUPTED	-	DRUG INTERRUPTED	-	-	-	IN	DMPROC	-
☐		ACN	C	DRUG WITHDRAWN	-	DRUG WITHDRAWN	-	-	-	IN	DMPROC	-
☐		ACN	C	NOT APPLICABLE	-	NOT APPLICABLE	-	-	-	IN	DMPROC	-
☐		ACN	C	UNKNOWN	-	UNKNOWN	-	-	-	EX	DMPROC	-
☐		AECAT	C	ADVERSE EVENT	-	ADVERSE EVENT	-	-	-	EX	DMPROC	-
☐		AEREL	C	CERTAIN	-	CERTAIN	-	-	-	EX	DMPROC	-

SGSSTATE
ADD
update


Metadata Center – Metadata Checks

- Checks are run on views
- OK, NOTOK, NAP statuses – flexibility to programmer
- Interactive reports: Ease the sponsor review process

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METADATA CENTER

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Feedback

Switch app

HOME

TABLES

DICTIONARY SYNC

AUDIT

AUDIT COLUMNS

SPONSOR REPORT

CHECKS

Show All

Checks

History

Check Detail

Checkid

1.01

Batch action

STATUS

Status

NAP

row(s) 1 - 5 of 5

Chk	Stat	Domain	Status	Hash	Creation Date	Entry Id	Comments
☐	☐	MH	NAP	D99DA0F7F12C2D9BC427A8ED48D417693384EA49	25-AUG-2016	METADATA	-
☐	☐	LB	NOK	2D19585E07C54A3E38D858EAE003904FDB3ADA0	25-AUG-2016	METADATA	-
☐	☒	PC	OK	36F780FDBDA5B2B2CE85C9EBB57086D1880AE757	25-AUG-2016	METADATA	-
☐		VS	-	B8A1E1DC56DFB4912A6DD518664883F8000965AE	25-AUG-2016	METADATA	-
☐		CM	-	1060274BC90076809718CFF9566DB8EAA1ABFB5	25-AUG-2016	METADATA	-

Download

row(s) 1 - 5 of 5

- Is a result of concepts and tools implemented at both conceptual and contextual level
- Equips and enables programmers
 - **Create quality metadata**
 - **On the go**
 - **Continually!**
- Well, most of the times...

- Empty datasets
 - Database Lock
 - Submission

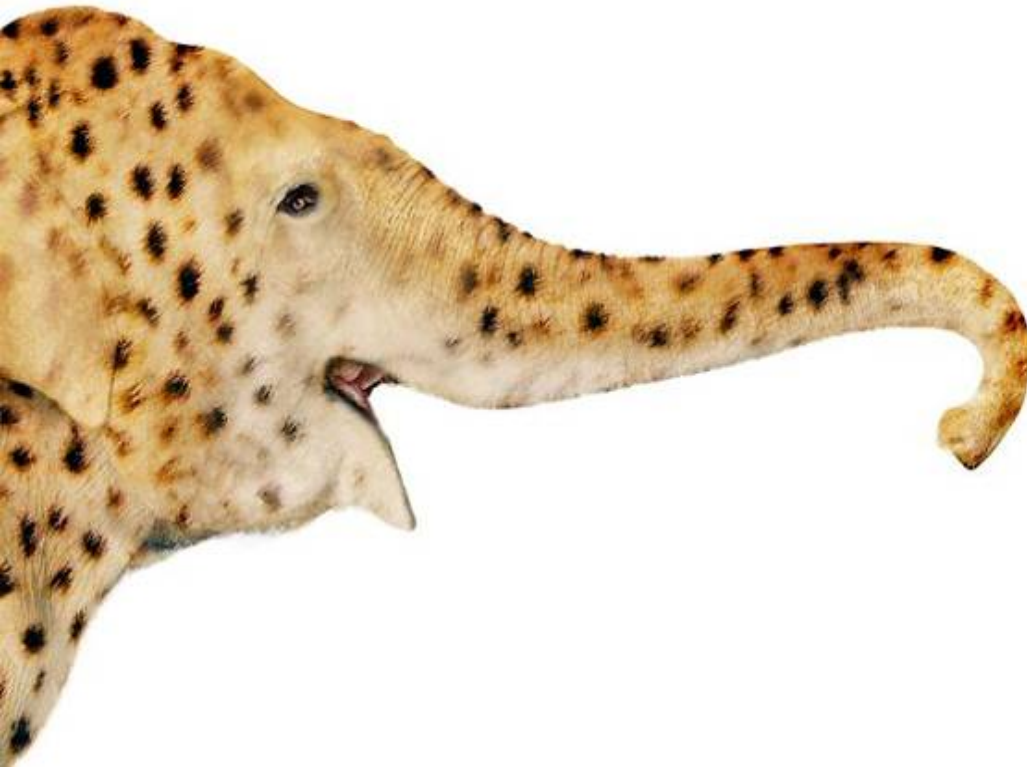
We Need More...

- Proactive, metadata driven approach
- Integration of people and processes
- SMEs
- Experience & Expertise
- Acknowledge the need for flexibility
 - **Standardization and Flexibility – Each Is Equally Important!**



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Thank You!



WHERE EXPERIENCE MEETS SPEED

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