
Implementing the CDISC Standards in DataFax

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The CDISC Standard

- **Clinical Data Interchange Standards Consortium**
- **Operational Data Model (ODM)**
Electronic acquisition and exchange of clinical trials information
- **Study Data Tabulation Model (SDTM)**
CRF data models
- **Case Report Tabulations Data Definition Specification (CRT-DDS)**
CRF data definitions



Objectives

- Gauge difficulty with implementing standard
- Explore possibilities for standardization
- Streamline transfer data set process
 - Use in absence of sponsor specification
 - Realize efficiencies with regard to timelines/cost
- Develop standard CDISC tools



Scope

- Cross-sectional, multi-center, observational trial
 - 19 CRFs
 - Short duration (~ 6 months)
 - Medium size: 2400 subjects
- SDTM
 - Special purpose/general class domain models
 - AE, DM, CO, LB, etc.
 - Supplemental Qualifiers
 - No Trial Design
 - No Related Records



Approach

- **CRF Annotation**
 “Implied” mapping specification
- **Database Design**
 Determination of included fields
 - Required, Expected, Permissible
 Determination of defaulted/derived fields
 - Default: STUDYID, DOMAIN
 - Derived: --BLFL, --DY
- **Database Build**
- **Transfer Data Set Programming**
 Assignments/Derivations, etc. in SAS



Results

CRF Page	Fields		Variables			Model			Domains	
	Unique Fields on CRF	OF	OF/SAS	SAS	Model Variables	Variables Used	Variables on SUPQUAL	Standard Domain	Non-Standard Domain	
01: Screening Log	19	5	33%	10	57%	5	-	-	-	SL
02: Inclusion/Exclusion Criteria and Baseline Medical History	7	3	43%	4	57%	12	24	19	0	IE, MH
03: Reproductive History	17	9	53%	8	47%	5	-	-	-	RH
04/05: Concomitant Medications Log	16	9	56%	7	44%	16	32	32	8	CM
06/07: Interim Medical History	11	5	45%	8	55%	5	-	-	-	IH
08: Full Physical Examination	12	4	40%	8	80%	7	22	17	2	PE, VS
09: Symptom-Directed Physical Examination	10	4	40%	8	80%	7	22	17	2	PE, VS
10/11/12: Demographics	49	18	37%	31	63%	5	20	19	30	DM
13: Laboratory Testing	25	5	20%	20	80%	15	43	40	8	LB
14: Chemistry	9	4	44%	5	56%	31	43	40	2	LB
15: Hematology and Immunology	10	4	40%	6	60%	30	43	40	2	LB
16: Urine Analysis	19	7	37%	12	63%	21	43	40	7	LB
17/18: Stool Analysis	23	3	13%	20	87%	5	-	-	-	SB
19: Volunteer Status Change Form	18	6	33%	12	67%	5	18	11	12	DS
Total	239	102	43%	137	57%	213	332	347	73	



Results Summary

- **Application of Standards**
 - 8 of 15 special class/general purpose domains
 - 4 non-standard domains
 - 89% of model variables
 - 73 SUPPQUAL variables
- **Application to Database**
 - 38% of fields on CRF defined/populated in DataFax
 - 21% of all variables defined/populated in DataFax
 - 62% of fields on CRF defined/populated in DF/SAS
 - 35% of all variables defined/populated in DF/SAS
 - 44% of all variables defined/populated in SAS



Lessons Learned

- CRF annotation/"mapping" difficult
- Interpretation of standard requires many assumptions/input from sponsor
 - Requires workable knowledge of standard
- Doubled database development/transfer data set programming time
- Trial selected not optimal
- Much use of SAS
 - Constrained by CRF



Findings Relative to Initial Objectives

- Gauge difficulty with implementing standard
Difficult
- Explore possibilities for standardization
Possibilities exist, but constrained as each trial is different
- Streamline transfer data set process
Use in absence of sponsor specification
Realize efficiencies with regard to timelines/cost
At this point, more resource intensive
- Develop standard CDISC tools
Many Possibilities



Questions

- Who interprets/maps standards?
DBA, DM Lead, Biostatistician
- Where to apply standards?
Database, Hybrid, Transfer Data Sets
- Who codes to the standard?
DBA, SAS Programmer



Objectives (Modified)

- **Assign Responsibility for Implementation**
SDTM: DM, ADaM: Biostats
Guidance from contract
- **Determine Proper Application of Standards**
SDTM: Database or Transfer Data Set Programming
ADaM: Analysis Programming
- **Develop CDISC Compliant Structures**
CRFs, Database Structures, Edit Checks, Analysis Files, TFLs



Objectives (Modified)

- **Changes to SOPs/WPs**
- **Training Program**
Multi-tiered: intensive for “mappers” and programmers, less so for CRAs, DM staff
- **Long Term Implementation**
Transition from SAS to XML



Plan

- **Cross functional team**
CRF design, DBA, DM, Biostats, Programming
Involvement in all phases provides training
efficiencies
- **Dual track solutions**
CDISC compliant solution
Standard solution



Q & A

- **Questions**

