Clinical Trials and SDTM standards

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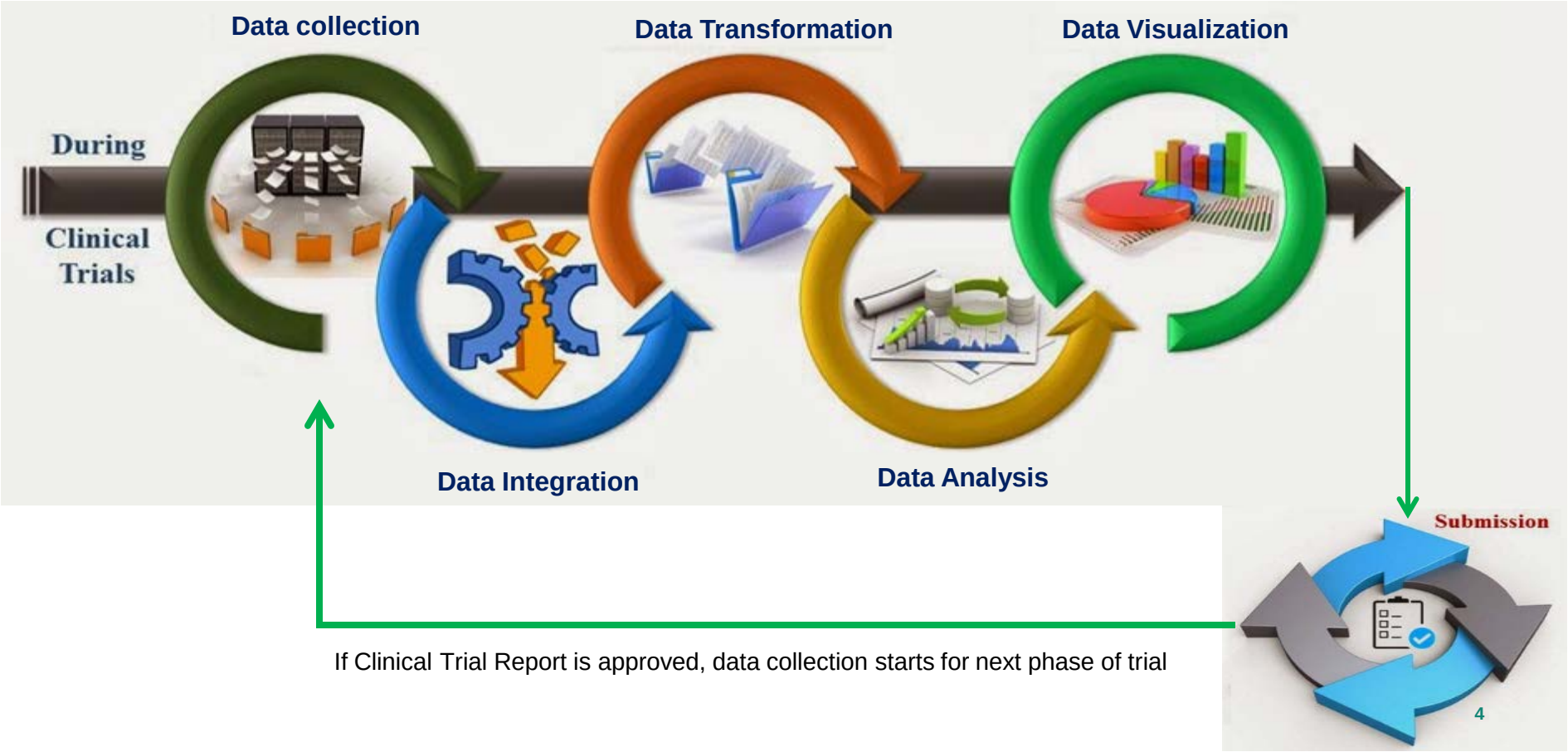
Agenda

- Clinical Trials Overview
- CDISC : A Global Approach
- Industrial Standardization Techniques
- Programming Techniques to Optimize Data Standards
- Conclusion

Clinical Trials Overview

CDISC : A Global Approach



If Clinical Trial Report is approved, data collection starts for next phase of trial

CDISC Roadmap by 2020

CFAST

To develop Therapeutic Area (TA) Standards

PMDA Input & FDA TA Specifications (Prostate Cancer)

TA Standards (Ebola) and Others in Pipeline

SHARE

Metadata repository for CDISC standards,

Application Program Interface (API),

End to End standards for Mapping

Foundational Standards

Focus on SDTM, ADaM, Controlled Terminology, Version Control and Validation Rules

Adoption and Healthcare Link

Education (online, webinars, Classroom), TA standard workshop, launch **eSource HCL** projects

(eDiary, ePRO)

Compatible data standards to enable automation and streamlining of the entire research process to dramatically reduce costs and speed the development of therapies for patients

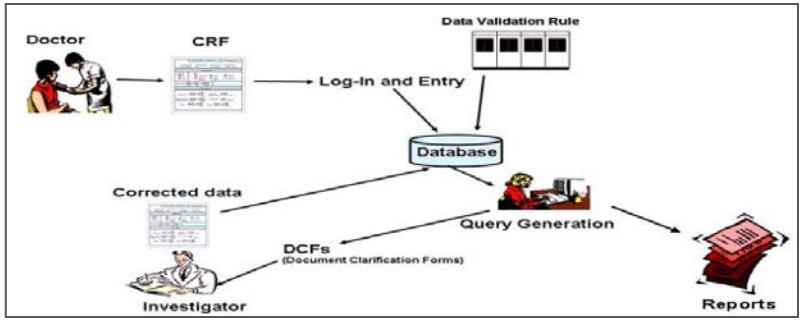
How Industrial Standardization Techniques can be achieved ?

ICON
A Symbol of Excellence

Common Protocol Template

Site Qualification and Training (SQT)

Quality Management System (QMS)



Shared Investigator Platform (SIP)

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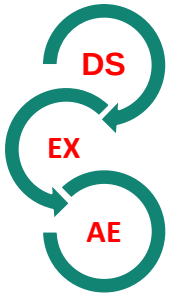
Optimization using Programming Techniques

Real time scenarios

Check #1

It provides a count for Number of subjects randomized, treated, completed, number of subjects with SAE and Number of Deaths.

CHECK	COUNT
Number of Subjects Randomized	50
Number of Subjects Treated	46
Number of Subjects Completed	4
Number of Subjects with SAE	13
Number of Deaths	7



Real time scenarios

Check #2

It provides a high level summary of source data like domain name, label, number of observation, number of subjects

DOMAIN	LABEL	NUMBER_OF_OBSERVATION	NUMBER_OF_SUBJECTS
AE	Adverse Events	390	219
CM	Concomitant Medications	1942	606
CO	Comments	17732	771
DM	Demographics	787	787
DS	Disposition	12932	787
EG	ECG Test Results	18876	776
EX	Exposure	8290	704
IE	Inclusion/Exclusion Criteria Not Met	64	46
LB	Laboratory Test Results	87888	780
MH	Medical History	2317	608
PE	Physical Examination	4413	711
QS	Questionnaires	100494	780
SE	Subject Elements	2154	787
SUPPAE	Supplemental Qualifiers - AE	388	218
SUPPCM	Supplemental Qualifiers - CM	1816	590

DOMAIN	LABEL	NUMBER_OF_OBSERVATION	NUMBER_OF_SUBJECTS
SUPPDM	Supplemental Qualifiers - DM	794	787
SUPPDS	Supplemental Qualifiers - DS	2937	786
SUPPEG	Supplemental Qualifiers - EG	76083	771
SUPPEX	Supplemental Qualifiers - EX	33155	704
SUPPLB	Supplemental Qualifiers - LB	512119	768
SUPPMH	Supplemental Qualifiers - MH	3227	593
SUPPPE	Supplemental Qualifiers - PE	4392	711
SUPPQS	Supplemental Qualifiers - QS	9355	696
SUPPSV	Supplemental Qualifiers - SV	2	2
SV	Subject Visits	10812	787
TA	Trial Arms	6	
TE	Trial Elements	3	
TI	Trial Inclusion/Exclusion Criteria	32	
TS	Trial Summary	57	
TV	Trial Visits	39	
VS	Vital Signs	16072	776

Real time scenarios

Check #3

Frequency of missing values. It provides a domain wise frequency of missing Values

DOMAIN	VARIABLE	RECORDS_MISS	SUBJ_MISS
DM	DMDY	83	83
DM	DTHDTC	787	787
DM	DTHFL	787	787
DM	ETHNIC	477	477
DM	RACE	2	2
DM	RFENDTC	83	83
DM	RFICDTC	1	1
DM	RFPENDTC	785	785
DM	RFSTDTC	83	83
DM	RFXENDTC	83	83
DM	RFXSTDTC	83	83

DOMAIN	VARIABLE	RECORDS_MISS	SUBJ_MISS
SUPPAE	QEVAL	388	218
SUPPCM	QEVAL	1816	590
SUPPDM	IDVAR	794	787
SUPPDM	IDVARVAL	794	787
SUPPDM	QEVAL	794	787
SUPPDS	QEVAL	2937	786
SUPPEG	QEVAL	76083	771
SUPPEX	QEVAL	33155	704
SUPPLB	QEVAL	512119	768
SUPPMH	QEVAL	3227	593
SUPPPE	QEVAL	4392	711
SUPPQS	QEVAL	9355	696
SUPPSV	QEVAL	2	2

Real time scenarios

Check #4

List of subjects with Randomization date is after RFSTDTC

USUBJID	firstdose	randdate
CPH-301-201030-110-032	2016-07-19T17:29:00	2016-07-20
CPH-301-201030-110-052	2016-10-17T23:57:00	2016-10-18
CPH-301-201030-111-002	2016-05-12T19:26:00	2016-05-13
CPH-301-201030-111-003	2016-05-17T18:55:00	2016-05-18
CPH-301-201030-111-004	2016-05-17T18:11:00	2016-05-18
CPH-301-201030-111-006	2016-05-17T18:48:00	2016-05-18
CPH-301-201030-111-007	2016-05-16T20:08:00	2016-05-17

Real time scenarios

Check #5
List of subjects with date of last exposure after date of completion/discontinuation.

Unique Subject Identifier	Last Study Drug Date	Date of Completion/Discontinuation Date
201212-0003	2016-07-22	2016-07-21
201212-0004	2016-08-02	2016-08-01

Real time scenarios

Check #6

Discrepancy between actual assessment day (XXDY) and planned visit day (VISITDY)

DOMAIN	USUBJID	XXSEQ	VISIT	VISITDY	XXDY	DIFFERENCE
LB	201212-0003	5	WEEK 3	22	36	14
LB	201212-0003	6	WEEK 4	29	44	15
LB	201212-0003	7	WEEK 5	36	50	14

Real time scenarios

Check #7

List of subjects with DTHDTC before BRTHDTC.

USUBJID	Birth Date	Death Date
201212-0003	1973-05-21	1970-03-01

Real time scenarios

Check #8

List of subjects with non-missing Randomization date and missing ARM and vice versa.

USUBJID	ARM	RandDate
201212-0001	P	
201212-0002		2016-12-24
201212-0003	TRT	
201212-0004	P	
201212-0005	TRT	

Real time scenarios

Check #9

List of subjects with non-missing XXTRT but missing XXDECOD

DOMAIN	USUBJID	XXTRT	XXDECOD
CM	201212-0005	(DEXERYL) DEXATOPIA, GLYCEROL, VASELINE, LIQUID PARAFFINE	
CM	201212-0004	BECLOMETASON/FORMOTEROL INHPR	
CM	201212-0001	CARBOPLATIN AND PEMETREXED	
CM	201212-0001	CARBOPLATIN PLUS PACLITAXEL	
CM	201212-0005	CARBOZANTINIB	

Real time scenarios

Check #10

List of subjects with duplicates rows (This applies to all SDTM datasets)

DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT
LB	201212-0004	314	K	Potassium	CHEMISTRY
LB	201212-0004	315	K	Potassium	CHEMISTRY
LB	201212-0005	169	GLUC	Glucose	CHEMISTRY
LB	201212-0005	170	GLUC	Glucose	CHEMISTRY
LB	201212-0005	170	GLUC	Glucose	CHEMISTRY
LB	201212-0005	171	GLUC	Glucose	CHEMISTRY

Real time scenarios

Check #11

Missing Lab units when Lab results are captured

DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	VISIT	LBDTC
LB	201212-004	29	CREAT	Creatinine	CHEMISTRY	0.80		WEEK 3	2015-10-13T15:00
LB	201212-004	30	BASO	Basophils	HEMATOLOGY	0.05		WEEK 3	2015-10-13T19:45
LB	201212-004	41	MONO	Monocytes	HEMATOLOGY	1.2		WEEK 3	2015-10-13T15:00
LB	201212-004	42	MONO	Monocytes	HEMATOLOGY	1.1		WEEK 3	2015-10-13T19:45

Real time scenarios

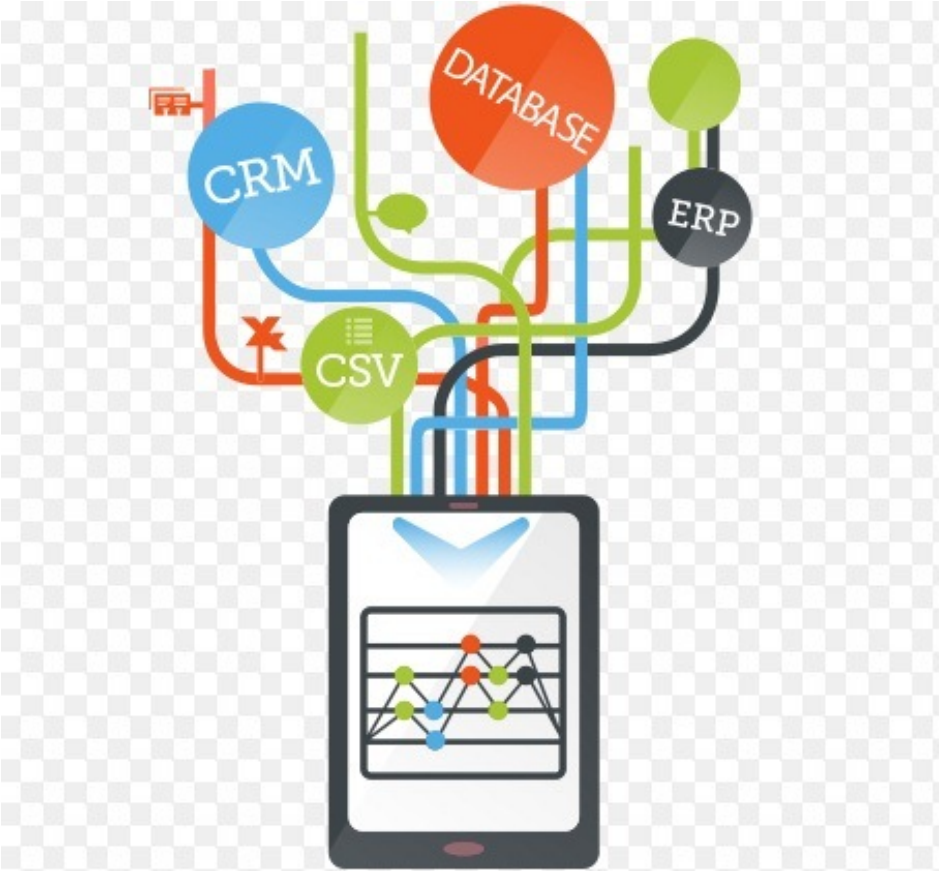
Check #12

Frequency of LAB units and identifying Rare Units.

LBTESTCD	LBORRESU	COUNT	RARE_FLAG
ALB	g/L	26	.
K	%	2	1
EOS	10^9/L	47	.
EOSLE	%	33	.
T3FR	pg/dL	1	1

Summary of Business Case Findings

Is Programming the only way to get Standard Data?



References

- https://www.cdisc.org/
- http://www.fda.gov/forpatients/approvals/drugs/

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Any move towards
STANDARDIZATION is
a move in the
RIGHT DIRECTION

Thank you

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