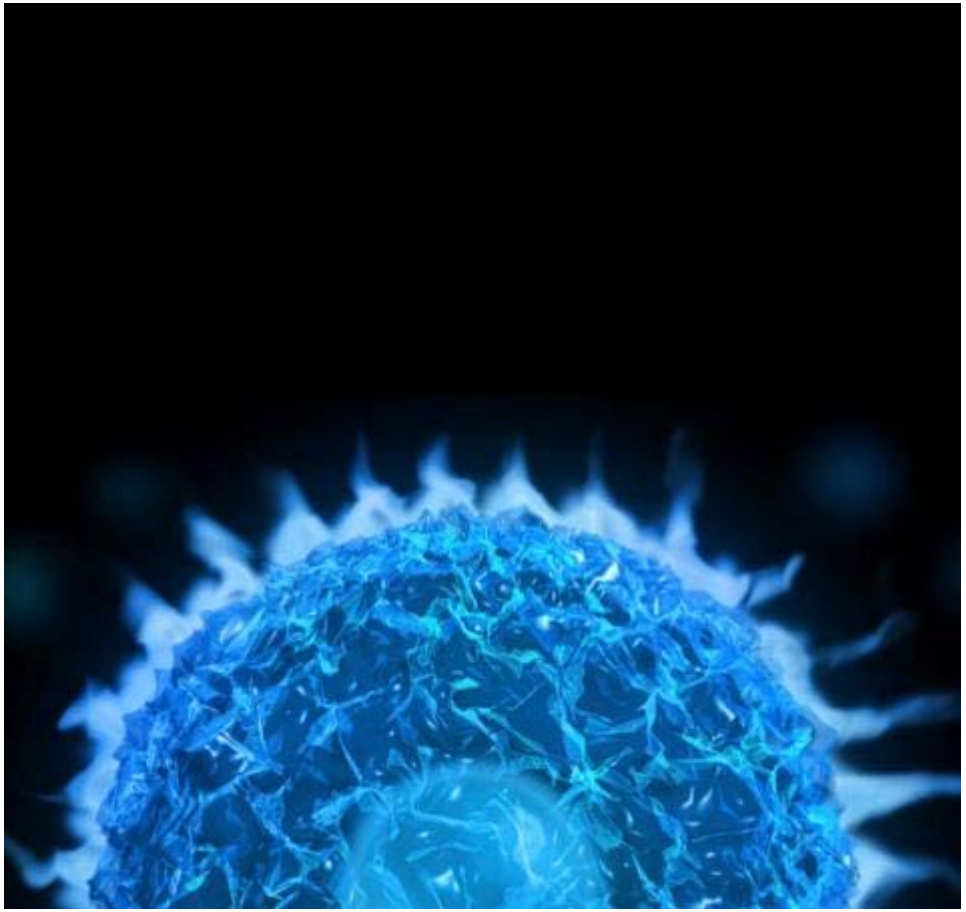

DS- Disposition

THE ROLE OF ONE DOMAIN

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CDISC

. . . not just the latest

code schema

CDISC

a philosophy

of uniformity,

of integration,

and of completeness

UNIFORMITY

- of the format for variables
  - Dates, Parameter codes, --SEQ, --SPID, etc
- of the design of domains
  - findings, events, interventions each with a style
  - Required, Expected, Permissible

INTEGRATION

- of planned and actual,
  - TE and TV
  - DS and SV
- reported and standardized
  - --ORRES and --STRESN

COMPLETENESS

- Central hub dataset (DM, ADSL)
- All data reported
- Audit trail is clear
- Numeric and character
  - xxDTC, xxDT, xxDY
  - STRESC/N

CDISC-ADAM

- Uniformity
- Integration
- Completeness

  ongoing issues for today's ADaM committee

FUNCTION OF DS

- TE and TV report the planned elements and visits
- SV reports the actual subject visits
- DS reports the actual subject epochs

FUNCTION OF DS (2)

- Just as TV and SV are unblinded info shared with both the subject and the clinical investigator
- TE and DS should be blinded to preserve the double blind (how long is the run-in period, dose escalation or cross-over)
- Double blind means investigator doesn't know if the subject is on drug A or B

DS IN ***SDTM IG V3.2***

"... include protocol milestones, such as randomization, as well as subject's completion status or reason for discontinuation for the entire study or each phase or segment of the study, including screening and post-treatment follow-up..."

DS REQUIRED VARIABLES

- STUDYID
- DOMAIN
- USUBJID
- DSSEQ
- DSTERM
- DSDECOD
- DSCAT
- DSSTDTC

DS REQUIRED VARIABLES (2)

- STUDYID – study identifier
- DOMAIN = “DS”
- USUBJID – subject identifier
- DSSEQ – a sequence number

DS REQUIRED VARIABLES (3)

- DSTERM – verbatim name of event or protocol milestone
- DSDECOD – controlled term for event or protocol milestone
- DSCAT – DISPOSITION EVENT, PROTOCOL MILESTONE, or OTHER EVENT
- DSSTDTC – Start date/time of event

BUILDING DS-CHOOSING THE RECORDS

- **Start with a schedule of events**
- **Mark each milestone**
  - screening
  - randomization
  - each treatment change
  - end of dosing
  - any follow-up events
  - disposition (EOS)

- **Building DS-choosing the records**
- Start with a schedule of events

FOR EXAMPLE, A STUDY SCHEDULE

Screening	**Visit 1**
Randomization visit	**Visit 2**
Run-in dosing one	**Visit 3**
Run-in dosing two	**Visit 4**
Experimental dose 1A	**Visit 5**
Experimental dose 1B	**Visit 6**
Experimental dose 1C	**Visit 7**
Wash-out Period	**Visit 8**
Experimental dose 2A	**Visit 9**
Experimental dose 2B	**Visit 10**
Experimental dose 2C	**Visit11**
Follow-Up Visit	**Visit 12**

MARKING THE STUDY SCHEDULE

Screening	Visit 1
Randomization visit	Visit 2
Run-in dosing one	Visit 3
Run-in dosing two	Visit 4
Experimental dose 1A	Visit 5
Experimental dose 1B	Visit 6
Experimental dose 1C	Visit 7
Wash-out Period	Visit 8
Experimental dose 2A	Visit 9
Experimental dose 2B	Visit 10
Experimental dose 2C	Visit11
Follow-Up Visit	Visit 12

Chose each milestone

- screening visit 1
- randomization visit 2
- each treatment change visits 3, 5, 8, & 9
- disposition (EOS) visit 12 or e.term

SO 7 RECORDS PER SUBJECT?

- Completing subjects *in this study* will have seven (7) unique records in the DS dataset.
- One record per protocol milestone per subject
- Fewer for Screen Failures, Refused Consent or Early Terminators

EXAMPLE

STUDYID	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSSTDTC
BOB-101	B101-001	1	Screening	SCREEN	Protocol Milestone	10-22-15
BOB-101	B101-001	2	Randomization	RANDOM	Protocol Milestone	10-29-15
BOB-101	B101-001	3	Run In Dose1	DOSING	Protocol Milestone	11-05-15
BOB-101	B101-001	4	Run In Dose2	DOSING	Protocol Milestone	11-12-15
BOB-101	B101-002	1	Screening	SCREEN	Protocol Milestone	10-22-15
BOB-101	B101-002	2	Early Termin	ERLYTRM	Disposition Event	10-31-15
BOB-101	B101-003	1	Screening	SCREEN	Protocol Milestone	10-23-15
BOB-101	B101-003	2	Randomization	RANDOM	Protocol Milestone	10-30-15
BOB-101	B101-003	3	Run In Dose1	DOSING	Protocol Milestone	11-06-15
BOB-101	B101-004	1	Screening	SCREEN	Protocol Milestone	10-24-15
BOB-101	B101-005	1	Screening	SCREEN	Protocol Milestone	10-25-15
BOB-101	B101-005	2	Randomization	RANDOM	Protocol Milestone	11-01-15
BOB-101	B101-005	3	Run In Dose1	DOSING	Protocol Milestone	11-08-15
BOB-101	B101-006	1	Screening	SCREEN	Protocol Milestone	10-31-15

GREAT!!

How to use it ??

Dear Clinical Operations,

If I could provide you with a list of the status of all of the subjects in each of your clinical trials, broken out by updated (changed) status and totals for each milestone attained in the clinical trial, each time when I receive a refreshed source dataset, would you like that?

Your Statistical Programmer,

WHAT DOES THAT MEAN?

- **A simple report (a chippie** – *simple for you but adds great value to your company***)**
- **Run once each time you receive data**
- **For each study**
- **Stats about Each Milestone**
- **Contrast Total and New**

Protocol Milestone	Visit	Day	Completed	(%)	Newly Completed	(%)
Screening	1	-14	26	100%	0	0
Randomization visit	2	-7	25	96%	0	0
Run-in dosing one	3	1	22	85%	0	0
Experimental dose 1A	5	15	21	81%	0	0
Wash-out Period	8	36	21	81%	3	14%
Experimental dose 2A	9	43	20	77%	5	25%
Follow-Up Visit	12	64	20	77%	7	35%
Early Terminated	99	Any	6	23%	1	17%

PROGRAMMING NEEDS

- **Macro variables - dates of the two data loads**
- **Sort the new dataset**
- **Keep the previous version's dataset**
- **Compare to new dataset**
- **Create Flag variable for new milestone**
- **Tabulate results (proc freq or proc tabulate)**
- **Save most recent as old**

DON'T FORGET

- **Display the Date PROMINENTLY**
- **Identify the Study (Studies)**
  - »Think: ISS/ ISE
- **Identify CURRENT or COMPLETE**
- **Identify Yourself**