Getting to SDTM through CDASH and DFexport

Sandi Tennyson  Data Manager, DF/Net Research
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FDA requires SDTM formatted study data
SDTM regulation impacts DA

Using CDASH:
facilitates creation of SDTM-formatted datasets

CDASH standard impacts DM
CDASH aids formatting study data to SDTM
CDASH via Modules and Dfexport gets us closer to SDTM

#DFUG2018

Use of CDASH and Modules in DFsetup

Data Management CDASH

Data Analytics Domain Data to SDTM and ADaM

Data Tables in Domains

SDTM and ADaM

FDA – STANDARDS INTRODUCED
Modules lend themselves to Domains
Export by Module combines data within and across plates.

- **Modules** (instances)
- **DFexport**
- **Domains** (rows)
Modules to Domains

In practice:

Modules can be applied to rows of repeating domain data. (for example, the LB domain)
Safety Lab Data to LB Data Domain

Hematology
Plate 132

Serum Chemistry
Plate 133
### Safety Laboratory Results, page 1 of 3

#### 1. HEMOGRAM

<table>
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<tr>
<th>Item</th>
<th>Not reported</th>
<th>Normal</th>
<th>Abnormal</th>
<th>Clinically Significant?</th>
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<td>1c. MCV</td>
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<td>28</td>
<td>29</td>
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Using DFexport

| DFPLATE | DPSID | DPAMM | CHROM | CHROMB | DISTRC | LISTAT | LIGSEQ | LIGLEN | LIGMETH | LIGSCQS | LIGSEQC | ULRSCQS | ULRSTAT | LIGOVAL | LIGPROF | LIGRAGX | LIGSTAT | LIBRARY |
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| 1 0000 | 0000 | 0000  | 0000  | 0000   | 0000   | 0000   | 0000   | 0000   | 0000    | 0000   | 0000 | 0000   | 0000    | 0000    | 0000   | 0000   | 0000   | 0000   | 0000   |
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| 103   | 0000 | 0000  | 0000  | 0000   | 0000   | 0000   | 0000   | 0000   | 0000    | 0000   | 0000 | 0000   | 0000    | 0000    | 0000   | 0000   | 0000   | 0000   | 0000   |
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| 105   | 0000 | 0000  | 0000  | 0000   | 0000   | 0000   | 0000   | 0000   | 0000    | 0000   | 0000 | 0000   | 0000    | 0000    | 0000   | 0000   | 0000   | 0000   | 0000   |
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| 109   | 0000 | 0000  | 0000  | 0000   | 0000   | 0000   | 0000   | 0000   | 0000    | 0000   | 0000 | 0000   | 0000    | 0000    | 0000   | 0000   | 0000   | 0000   | 0000   |

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In practice:

*Applying modules correctly requires training*
Subject Encounter

1. Not applicable for this assessment time point.

2. Since the last visit, did the subject change any concomitant medications or treatments? (Include diary review)
   If yes, record/update the Concomitant Medications CRF appropriately.

3. Since the last visit, did the subject experience any adverse events? (Include diary review)
   If yes, record/update the Adverse Events CRF appropriately.

4. Did the subject meet the contraception requirements of the study?

For item 5, if subject was born male, or if subject was born female but is not of reproductive potential, mark “N/A”.

5. Urine pregnancy test result:

6. Did subject interim history indicate performance of vital signs, physical exam and/or procedures?
Using DFexport

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<th>DFNAME</th>
<th>DFMD</th>
<th>DFREF</th>
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</tbody>
</table>

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Challenges

Study Termination

1. Termination date: Date subject was last seen or evaluated in the study. 

2. Reason for termination. Mark all that apply:
   - 2a. Study complete
   - 2b. Subject chose to terminate
   - 2c. Lost to follow-up
   - 2d. Subject could not adhere to study visit schedule
   - 2e. Protocol deviation, specify:

2f. Adverse event/intercurrent illness
   - AE Page Number(s): 

3. Additional specifics:

Investigator's Printed Name/Signature:

Printed Name: Signature: 

Date/Name/YYYY: 

Complete or update AE Log.

OR date unknown

OR cause unknown
Challenges

Study Termination

Easier DFsetup for Data Managers
Use Only One Domain (Module)
Multiple Domains in One Module

Subject Encounter—Unscheduled Visit

1. Not applicable for this assessment time point.
2. Since the last visit, did the subject change any concomitant medications or treatments? (Include diary review)
   If yes, record/update the Concomitant Medications CRF appropriately.
   CRF Number 13
   CRF Number 14
   CRF Number 15
3. Since the last visit, did the subject experience any adverse events? (Include diary review)
   If yes, record/update the Adverse Events CRF appropriately.
   AE Number 20
   AE Number 21
   AE Number 22
4. Did the subject meet the contraception requirements of the study?
   CRF Number N/A
   For item 5, if subject was born male, or if subject was born female but is not of reproductive potential, mark "N/A".
5. Urine pregnancy test result:
   CRF Number N/A
6. Did subject interim history indicate review of vital signs, physical exam and/or procedures?
   CRF Number N/A
   If yes, complete the Vital Signs, Physical Exam and Procedures CRF.
7. Not applicable for this assessment time point.
8. CRFs completed at this visit. Mark all that apply.
   Protocol Deviation
   CRF Number
   Vital Signs, Physical Exam and Procedures
   Safety Laboratory Results
   Static Physician's Global Assessment
   Other, specify:
   Study Drug Accounting
   Study Termination
Questions?

Sandi Tennyson – sandi@dfnetresearch.com