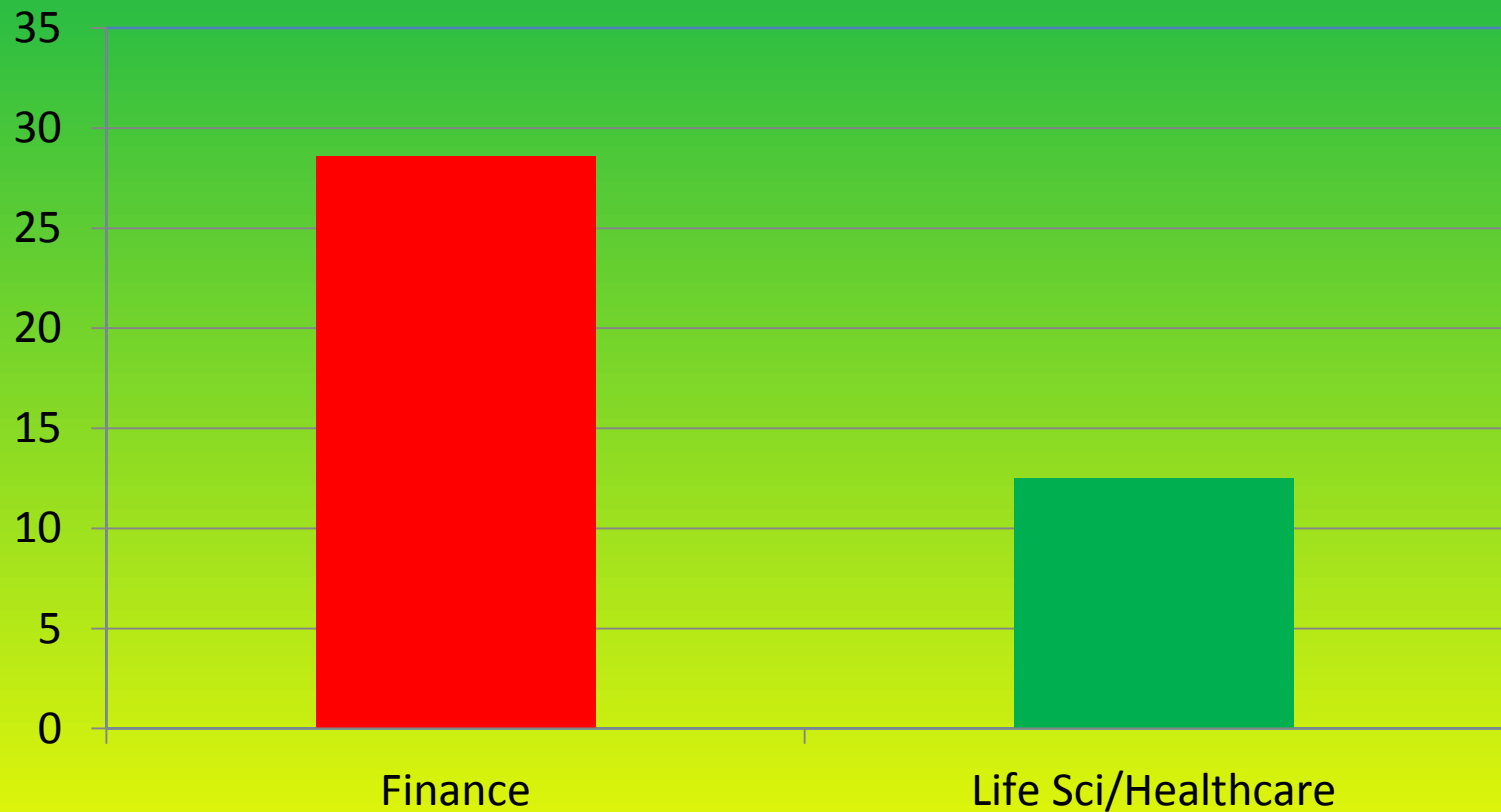


EX+EC+DA = ADDA
A CDISC Approach to Calculating
Drug Accountability

Haibin Shu
Founder and Principal Consultant

March 12, 2015

SAS Users Distribution



Based on SAS 2013 revenue

Disclaimer

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- Any views or opinions in this presentation are solely those of the author.

Introduction

- What is drug accountability?
 - ✓ Information related to the accountability of study drug such as receipt, dispensing, return, and packaging (SDTMIG3.1.2)

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 - ✓ Information related to the accountability of study drug such as receipt, dispensing, return, and packaging (SDTMIG3.1.2)
 - ✓ Calculated as percentage:
$$\text{Study Drug Taken/Dispensed} \times 100\%$$

Introduction

- What is drug accountability?
 - ✓ Generally require 80 – 120%
 - < 80%
 - > 120%
 - ✓ Poor compliance is problematic
 - < 80%
 - > 120%

Introduction

- Examples
 - ✓ Forgot to take my pills

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- Examples
 - ✓ Forgot to take my pills
 - ✓ Forgot having taken my pills

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 - ✓ Forgot to take my pills
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 - ✓ Stolen

Introduction

- Examples
 - ✓ Forgot to take my pills
 - ✓ Forgot having taken my pills
 - ✓ Stolen
 - ✓ Couldn't open it
 - ✓ Too big to swallow
 - ✓ Somebody borrowed mine!

Agenda

- CRF collection
- CDISC domains
- Compliance Calculation
- Challenges
- Easy case
- Difficult case
- Final thoughts

CRF Collections – Root of Issues

- Log-page style
- Visit-by-Visit page style
- Diary style

Illustration 1

- Log-page style

| Start Date and Time (DD/MMM/YYYY) (00:00 ~ 23:59) | Stop Date and Time (DD/MMM/YYYY) (00:00 ~ 23:59) | Total Volume Dispensed (ml) | Total Volume After Infusion (ml) | Infusion Status |
|---|--|---------------------------------------|--|------------------------|
| _ _ / _ _ _ /20 _1 _ _ _ : _ _ | _ _ / _ _ _ /20 _1 _ _ _ : _ _ | | | |

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|---|--|---|--|------------------------|
| EXSTDTC | EXENDTC | DAORRES | DAORRES | EXADJ |
| _ _ / _ _ /20 _ _ _ _ : _ _ | _ _ / _ _ /20 _ _ _ _ : _ _ | DATESTCD = DISPAMT | DATESTCD = RETAMT | |

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$$\% \text{ CMP} = (\text{DISPAMT} - \text{RETAMT}) / \text{PROJAMT} \times 100\%$$

Illustration 2

- Visit-by-Visit page style

| | | | | |
|---|--|--------------|--|--|
| Pills Dispensed (DD/MMM/YYYY) (00:00 ~ 23:59) | Pills Returned (DD/MMM/YYYY) (00:00 ~ 23:59) | VISITNUM = a | | |
| DAORRES DATESTCD = DISPAMT | DAORRES DATESTCD = RETAMT | | | |

| | | | | |
|---|--|--------------|--|--|
| Pills Dispensed (DD/MMM/YYYY) (00:00 ~ 23:59) | Pills Returned (DD/MMM/YYYY) (00:00 ~ 23:59) | VISITNUM = b | | |
| | | | | |

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|---|--|--------------|--|--|
| | | | | |

$$\%CMP = (DISPAMT_a - RETAMT_b) / PROJAMT_{EX} \times 100\%$$

- Visit-by-Visit page style
 - ✓ DISPAMT_a
 - ✓ RETAMT_b
 - ✓ PROJAMT_{EX}

Illustration 3

- (e)Diary style

EC

| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | ... |
|-------|-------|-------|-------|-------|-----|
| √ | √ | | √ | | |

ECSTDTC

ECOCCUR

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- (e)Diary style

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ECSTDTC

ECOCCUR



EX

Derive EXSTDTC, EXENDTC, EXDUR,
etc.

Illustration 3

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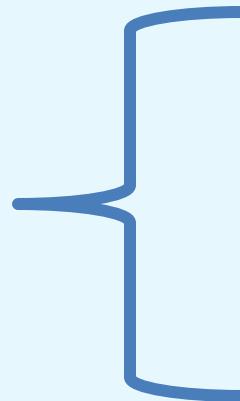
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Cross reference DISPAMT, RETAMT etc.

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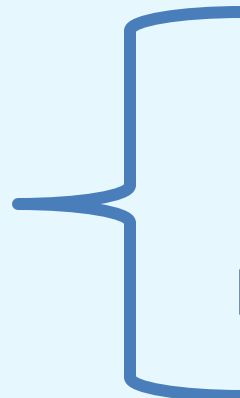
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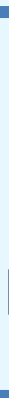
ECSTDTC

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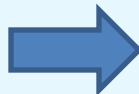
EX

Derive EXSTDTC, EXENDTC, EXDUR, etc.



DA

Cross reference DISPAMT, RETAMT etc.



DA

Derive actual usage etc.

ADDA

CMP % etc.

Comparisons – Challenges of Diversity

| | Log | Visit-by-Visit | Diary/eDiary |
|------------------------|------------|-----------------------|---------------------|
| Quality Control | + | +++ | ++/+++ |
| Programming | +++ | + | ++ |
| Cost Estimate | +++ | ++ | + |

+++ : Most favored in the corresponding categories

+ : Least favored in the corresponding categories

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- EX: EXSTDTC, EXENDTTC etc. => PROJAMT
- EC: ECSTDTC, ECENDTTC etc. => EX, DA
- DA: DISPAMT, RETAMT, DAORRES => %CMP

Challenges

- For Visit-by-Visit pages, it's not always easy to connect $DISPAMT_a$ with $RETAMT_b$

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 - ✓ Practically not all packs/kits were returned at the following Visit – it is difficult to construct CMP % at a Visit level

Overall CMP % was used: $\Sigma DISPAMT_a - \Sigma RETAMT_b$

Challenges

- Supporting listing, like

| USUBJID | VISITNUM | Dispensed Bottles | Dispensed Amount | Returned Bottles | Returned Amount | Other Information such as pills lost |
|---------|----------|---------------------------|------------------|---------------------------|-----------------|--------------------------------------|
| | a | A, B, C, etc. (DASCAT) | (DISPAMT) | A, C, etc. (DASCAT) | (RETAMT) | |
| | b | D, E, etc. (DASCAT) | | B, D, E, etc. (DASCAT) | | |

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| | b | D, E, etc. (DASCAT) | | B, D, E, etc. (DASCAT) | | |

Every dispensed bottle should be accounted for!

Pseudo Code Samples

1. Assign dispense sequence based on Dispense/Visit Date

```
if prev_DISPDT < cur_DISPDT | 0 < prev_Visit < cur_Visit  
then seq_disp + 1;
```

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```
if prev_DISPDT < cur_DISPDT | 0 < prev_Visit < cur_Visit  
then seq_disp + 1;
```

2. Derive return sequence to intertwine with dispense sequence

```
if seq_disp = 1 then seq_ret = 2;  
if seq_disp = 2 then seq_ret = 3;
```

...

Final Thoughts

- CRF design – *having the end in mind*

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- CRF design – *having the end in mind*
- Equipping with relevant CDISC domains knowledge – will help in preparations and making thoughtful decisions
- Benefit of standards – quality, efficiency, and cost-effectiveness

Appreciation

Thanks CDISC
organization and all
who volunteered
their valuable time
and efforts on the
ongoing standards
p r o j e c t s !



Q & A

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Further discussions:

haibin@accuclinglobal.com

610.457.8118