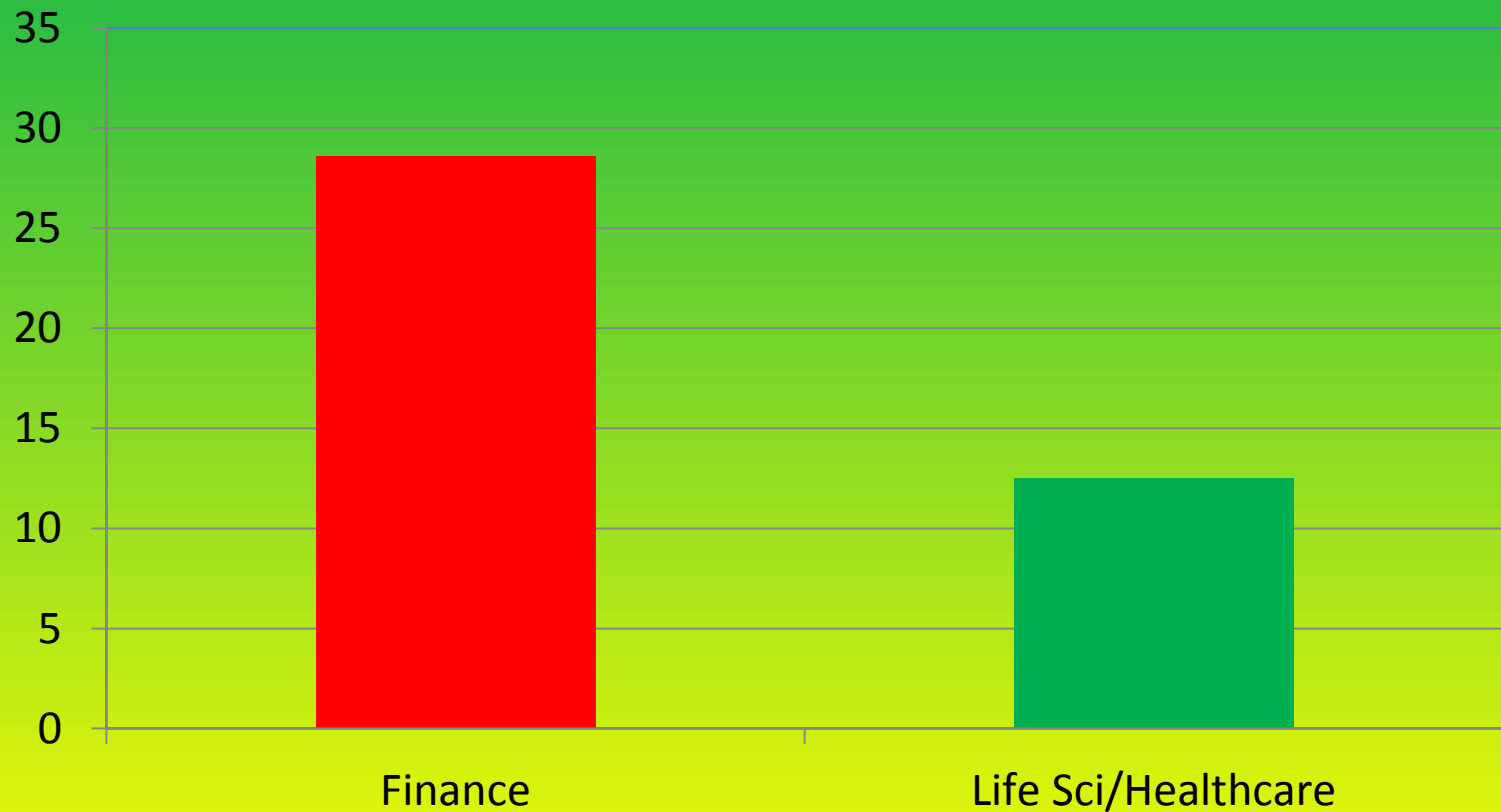


EX+EC+DA = ADDA
A CDISC Approach to Calculating
Drug Accountability

Haibin Shu
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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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- What is drug accountability?
 - ✓ 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 _ _ _ _ : _ _	_ _ / _ _ _ /20 _ _ _ _ : _ _			

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
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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- Visit-by-Visit page style

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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

Illustration 3

- (e)Diary style

EC

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

ECSTDTC

ECOCCUR



EX

Derive EXSTDTC, EXENDTC, EXDUR,
etc.

Illustration 3

- (e)Diary style

EC

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

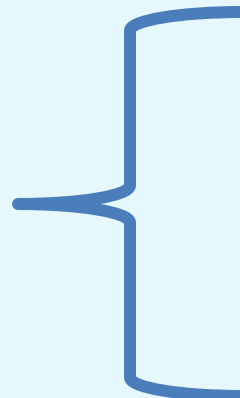
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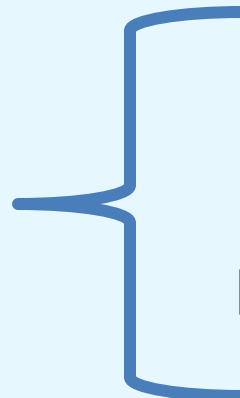
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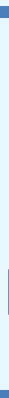
ECSTDTC

ECOCCUR



EX

Derive EXSTDTC, EXENDTC, EXDUR, etc.

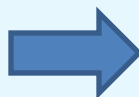


DA

Cross reference DISPAMT, RETAMT etc.

ADDA

CMP % etc.



DA

Derive actual usage 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

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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:

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