

Findings about “Findings about”

Madhura Khare, Cytel

Session CD02 - PHUSE 2014

Disclaimer

Any comments or statements made herein are solely those of the author and do not necessarily reflect the views of company.

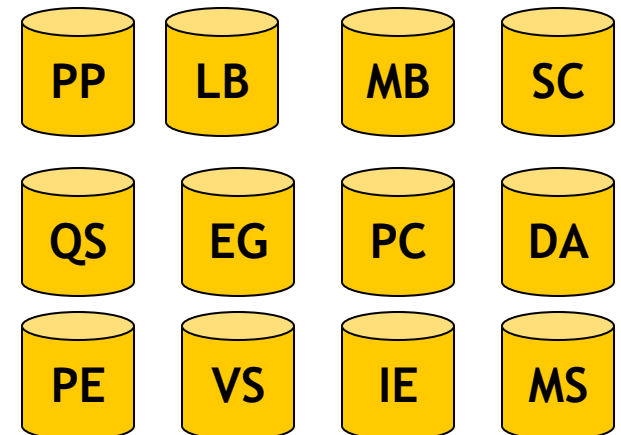
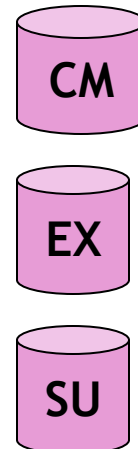
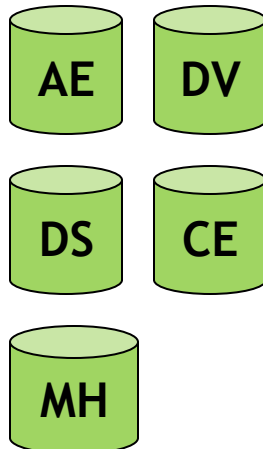
Agenda

- ❑ Introduction
- ❑ Findings About
 - ✓ Intervention
 - ✓ Events
- ❑ Examples
- ❑ Summary
- ❑ Discussion/ Questions

Introduction

Most of the observations collected will be represented in one of the *General Observation Class*.

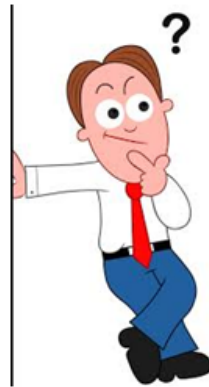
General Observation Class



Introduction

What happens if information does not fit into Events or Interventions -

e.g. - Reasons for not taking concomitant medications



Introduction

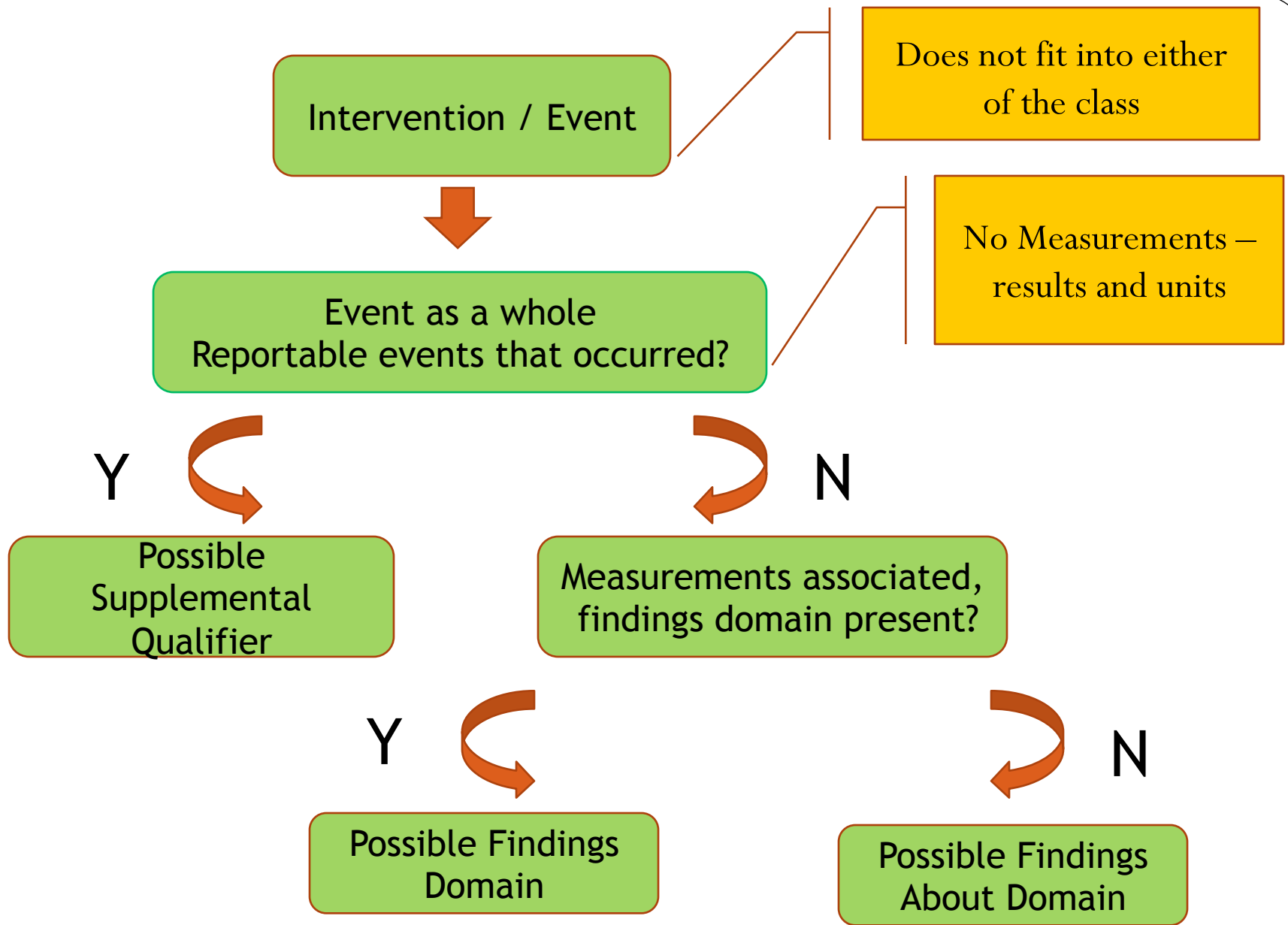
- ❑ Gives additional information
- ❑ Is not as suitable to be supplemental qualifier



Use of Findings About Domain

Findings About (FA)

- ❑ Specialization of Findings general observation class
- ❑ Event or Intervention
- ❑ Vertical Structure
- ❑ Important Variables -
 - ✓ --OBJ
 - ✓ --TESTCD



Steps to go through



Findings about Intervention - CASE1 Vitamin D Usage

Study Brief

- ❑ PHASE III, Multicenter Study to Compare the Therapeutic Efficacy and Safety in Subjects with kidney disease
- ❑ Vitamin D supplements - one of co-mediations along with standard of care

FORM: Reason for no baseline Vitamin D Usage

- | | | |
|------------------------|--------------------------------|--------------------------|
| If not vitamin D, Why? | Elevated Serum Calcium | <input type="checkbox"/> |
| | Elevated Serum Phosphorus | <input type="checkbox"/> |
| | Elevated Calcium X Phosphorous | <input type="checkbox"/> |
| | Not Prescribed | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |

Usage of Findings About

- ❑ Do not include information about dose and frequency etc.
- ❑ Different reasons can go in Suppqual variables
- ❑ To utilize information further in Tables/Listings easily

aCRF

FORM: Reason for no baseline Vitamin D Usage

SDTM Data Set Name = FA

FA.DOMAIN = 'FA'

If not vitamin D, Why?

FA.FATESTCD = 'REASNTKN'

FA.FAOBJ = 'VITAMIN D'

- Elevated Serum Calcium
- Elevated Serum Phosphorus
- Elevated Calcium X Phosphorous
- Not Prescribed
- Other

FA.FAORRES



Findings about Intervention -
CASE2
Prior Radiotherapy for Current
Malignancy

Study Brief

- ❑ Phase I/II, Open - label, Oncology study.
- ❑ Tolerability, safety, pharmacokinetics, and efficacy of study treatment.
- ❑ Prior radio therapy

Form: Prior Radiotherapy for Current Malignancy

TYPE

External beam
Brach therapy
Total body
Single Beam

Start Date

Stop Date

FORM: Prior Radiotherapy for Current Malignancy

Best Response	Complete Response	<input type="checkbox"/>
	Partial Response	<input type="checkbox"/>
	Stable Response	<input type="checkbox"/>
	Progressive Disease	<input type="checkbox"/>
	Unable to evaluate	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Was chemotherapy part of a concurrent therapy?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

Did progression occur?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

Date of Progression

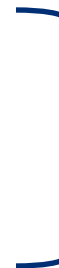
Usage of Findings About

- Type and start and end date of radiotherapy



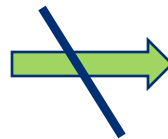
PR domain

- Best response chemotherapy ,
progression



Supplemental Qualifier

Significant data



Dump

aCRF

SDTM Data Set Name = FA

FA.DOMAIN = 'FA'

FA.FACAT = 'HISTORICAL RADIOTHERAPY'

FA.FAOBJ = 'RADIOTHERAPY'

FA.FAPRESP = 'Y'

There are multiple pages being mapped to FA domain in this study which is why FACAT is used to categorize those observations

FORM: Prior Radiotherapy for Current Malignancy

Best Response

FA.FATESTCD = 'BESTRSP'

Complete Response

Partial Response

Stable Response

Progressive Disease

Unable to evaluate

Not Done

FA.FAORRES

Was chemotherapy part of a concurrent therapy?

FA.FATESTCD = 'CHEMO'

Yes

No

FA.FAORRES

Did progression occur?

FA.FATESTCD = 'PRG'

Yes

No

FA.FAORRES

Date of Progression

PHUSE 20

FA.FADTC

Data Snapshot

DOMAIN	USUBJID	PRSPID	PTRTR	VISIT	PRDOSFRM	PRPRES
PR	ABC1230101	DAY2-000-018	RADIOTHERAPY	DAY2	EXTERNAL BEAM	Y

DOMAIN	USUBJID	FASPID	FATESTCD	VISIT	FASTRESC	FAOBJ	FAPRESP
FA	ABC1230101	DAY2-000-018	PRG	DAY2	Y	RADIOTHERAPY	Y
FA	ABC1230101	DAY5-000-010	BESTRSP	DAY5	STABLE DISEASE	RADIOTHERAPY	Y

Row	STUDYID	RDOMAIN	IDVAR	RELTYPE	RELID	Row
1	ABC	PR	PRSPID	ONE	1	1
2	ABC	FA	FASPID	MANY	1	2

**Findings about Intervention -
CASE3
Standard of Care Administration Time on
PK Collection Days**

Study Brief

- ❑ Phase II, randomized, Oncology study.
- ❑ IP or placebo with standard of care (SOC) in Postmenopausal Women with Metastatic Breast Cancer.
- ❑ Standard of Care (SOC) administration time on PK collection

FORM : SOC ADMINISTRATION TIME ON PK COLLECTION DAYS

Date and time of SOC administration

Did subject eat a meal within 2 hours prior to SOC dose?

Did subject vomit within 1 hour after SOC administration?

Usage of Findings About

- ❑ Do not describe an Intervention as a whole
- ❑ Intervention on PK collection days has different timing from the rest of the study days

aCRF

FORM:SOC ADMINISTRATION TIME ON PK COLLECTION DAYS

SDTM Data Set Name = FA

FA.DOMAIN = 'FA'

FA.FACAT = 'PK'

Date and time of SOC administration

FA.FATESTCD = 'OCCUR'

FA.FAORRES = 'Y'

FA.FAOBJ = 'SOC'

FA.FADTC

Did subject eat a meal within 2 hours prior to SOC dose?

FA.FATESTCD = 'OCCUR'

FA.FAORRES

FA.FAOBJ = 'MEAL'

FA.FAEVLINT = '-P2H'

FA.FATPTREF = 'PK SOC'

Did subject vomit within 1 hour after SOC administration?

FA.FATESTCD = 'OCCUR'

FA.FAORRES

FA.FAOBJ = 'VOMIT'

FA.FAEVLINT = 'P1H'

FA.FATPTREF = 'PK SOC'

Findings about Event- CASE4 Clinical Features of Seizure

Study Brief

- ❑ Phase III, randomized, efficacy and safety study with Chronic Kidney Disease.
- ❑ To compare efficacy of study treatment with placebo for reducing ionized parathyroid (iPTH) levels.
- ❑ Adverse event of interest is **SEIZURE**

FORM: CLINICAL FEATURES OF SEIZURE

Clinical Features
Associated with
Seizure

Impairment of Consciousness

Abnormal Motor Activity

Incontinence

Accidental Injury

Post-Event Weakness

Usage of Findings About

Clinical features of seizure

Only creating 1 Record with --TERM as
SEIZURE

FORM: CLINICAL FEATURES OF SEIZURE

SDMT Data Set Name = FA

FA.DOMAIN = 'FA'

FA.FACAT = 'SEIZURE CLINICAL FEATURES'

FA.FAPRESP = 'Y'

Clinical Features Associated with Seizure -

FA.FATESTCD = 'OCCUR'

Impairment of Consciousness

FA.FAORRES = 'Y'

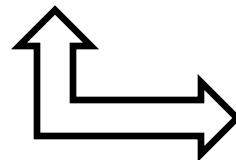
FA.FAOBJ

Abnormal Motor Activity

Incontinence

Accidental Injury

Post-Event Weakness



Special Case
CASE5
Cosmetic Product Trial

REVLON

NEW
**COLORSTAY WHIPPED™
 CREME MAKEUP**
 WITH 24-HOUR WEAR

Finally, truly radiant makeup-effects ultimate performance. The moisture-like texture helps lift up your skin, and the time-release formula balances skin for a flawless look. All day. Flexible wear without flaking, caking or fading. *Revlon®*

brandchannel.com
 http://www.brandchannel.com

L'ORÉAL

Dove
 ULTIMATE CLEAR

Get Softer, Smoother
 Underarms in Just Five Days

Try Dove Ultimate Clear

[Free Sample](#)

Dove
 ULTIMATE CLEAR
 smooth
 cashmere

OLAY
 REGENERIST

Smother, firmer-looking skin and
A SURPRISINGLY SPA-LIKE FEEL.

GARNIER MEN
 PowerLight

Study Brief

- ❑ Cosmetic trial - can stimulate the skin to result in clinically visible differences, as far as whiteness is concerned
- ❑ Spots on face or chin were exposed
- ❑ Objective : Increased whiteness
- ❑ Fairness is measured using Chroma - meter
- ❑ L*Intensity

Data Snapshot

DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ	SRORRES	SRLOC	VISITNUM
SR	33444-101010	1	LINTN	LSTAR INTENSITY	CP1	56.71	FORE HEAD	1

- ❑ Skin Response data
- ❑ Study - Cosmetic - many cosmetic product
- ❑ SROBJ - cosmetic product name
- ❑ Recently added to SDTMIG version 3.2

Summary

- ❑ Observations about events or interventions that cannot fit into standard domain
- ❑ It's a solution to map data that cannot be handled by supplemental qualifiers

Summary

- ❑ Use is rare but its importance is prodigious.

References

- ❑ CDISC SDTM Implementation Guide
Version 3.1.3 and 3.2
- ❑ <http://www.cdisc.org/>



Thank You