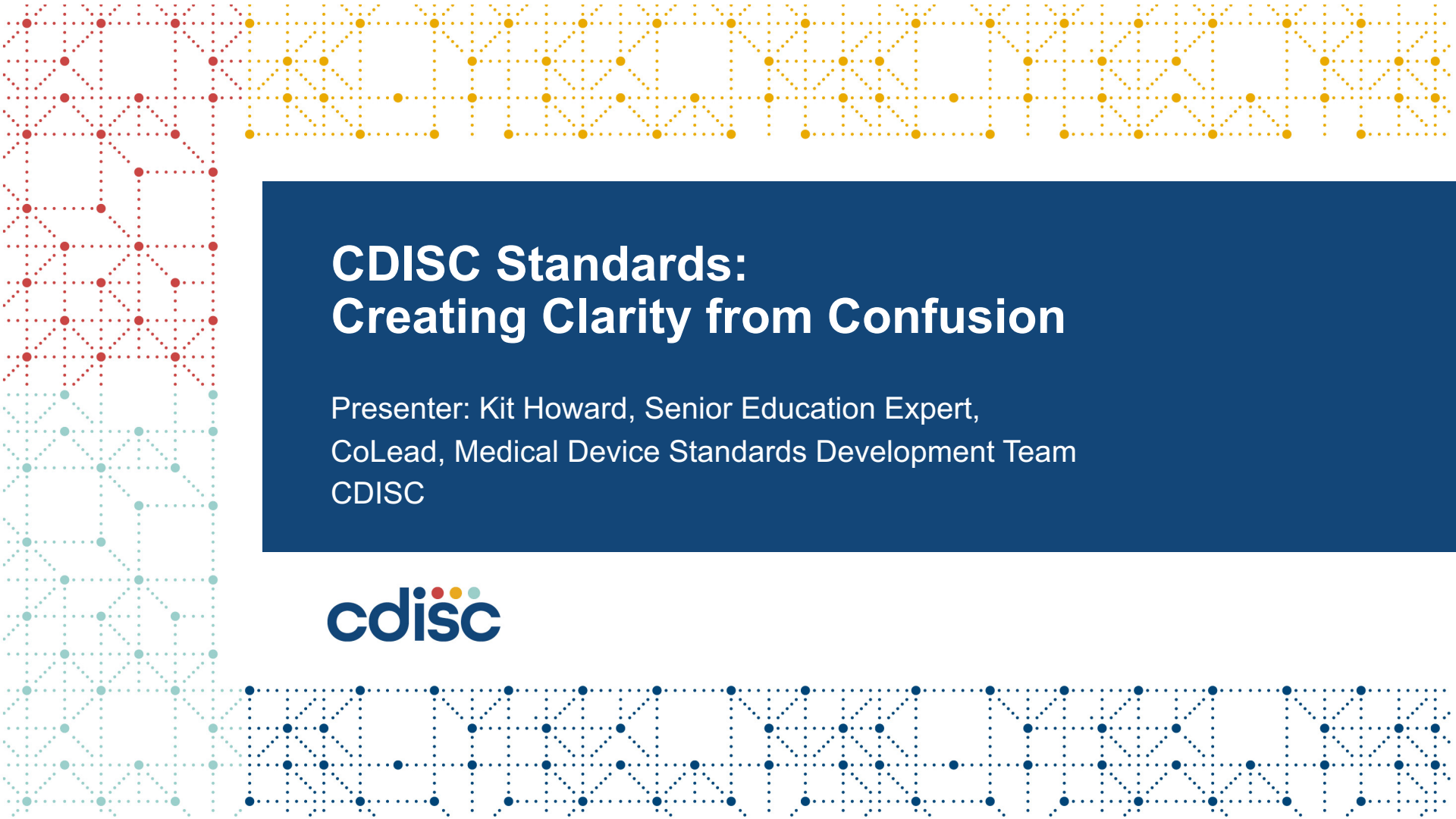




CDISC Standards: Creating Clarity from Confusion

Presenter: Kit Howard, Senior Education Expert,
CoLead, Medical Device Standards Development Team
CDISC



Learning Outcomes

- 
- Describe Exposure as Collected (EC), its uses and its relationship to Exposure (EX)?*
 - Differentiate relative timing variables and their Controlled Terminology*
 - Use the “generally not used” variables appropriately*
 - Identify the kinds of data can and should not go in Medical History (MH)*



Part 1: Exposure as Collected and as Reported

Definitions

EC (Exposure as Collected)



*Information known during
study conduct*

*May include things that were
planned and did not happen*

Contains collected data

EX (Actual Exposure)



Bottle A = Treatment



Bottle B = Control

*Information known
after the study is complete*

*Intended only for things that
happened*

Usually mostly derived

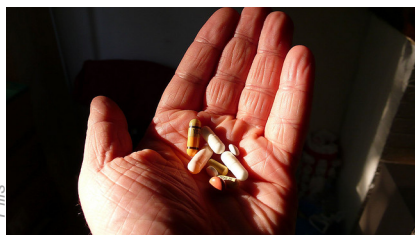
Examples of EC and EX

Description	EC	EX
Double blind study	Blinded data: 2 tablets	Unblinded data: 250 mg/day
Missed doses	Missed: 4 tablets	Taken: 750 mg
Calculated dosage	20 mg/kg (subject weighs 75 kg)	1,500 mg/day



Case 1: Dosing One Pill at a Time

EC



Exposure

Day 3

Was Study Treatment Administered?

☐ No

☒ Yes If "Yes", please provide the following.

Date Administered

03 May 2013

Day Month Year

<i>Assigned</i>	<i>Protocol</i>	<i>Derived from ECSTDTC</i>	<i>Derived</i>	<i>Derived</i>		
ECPRESPb	ECOCUR	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY
Y	Y	TREATMENT	2013-05-03	2013-05-03	3	3

Case 1: Dosing One Pill at a Time

EC

ECPRESP	ECOCUR	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY
Y	Y	TREATMENT	2013-05-03	2013-05-03	3	3



Randomization
Code



EX

EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EPOCH	EXSTDTC	EXENDTC
DRUG X	1000	mg	TABLET	QD	ORAL	TREATMENT	2013-05-03	2013-05-03

COISC



Part 2: Relative Timing Variables

Nice Timing Situation

Medical History

MH

Did the subject report any clinically significant medical history conditions within [protocol-specified time period] prior to the study?

☐ No

MHYN

☒ Yes - (please complete the form)

Line #	Condition	Start Date	End Date	Ongoing
	MHTERM	MHSTDAT	MHENDAT	MHONGO
1	Hypertension	May 2015	Dec 2017	☐
2				☐
				☐

Not So Nice Timing Situation

As of when???

Prior and Concomitant Medications

Were any medications taken? Include medications that were taken within [protocol-defined time period] before or during study treatment.

☐ No

☒ Yes

CMYN

CMTRT

CMSTDAT

CMENDAT

CMONGO

CMINDC

Medication

Start Date

End Date

Ongoing

Indication

Benedryl &
Sudafed

2 | 3 | M | A | Y | 2 | 0 | 1 | 3

Day

Month

Year

| | | | | | | |

Day

Month

Year

☐ No

☒ Yes

Seasonal
allergies

☐ No

☐ Yes

| | | | | | | |

Day

Month

Year

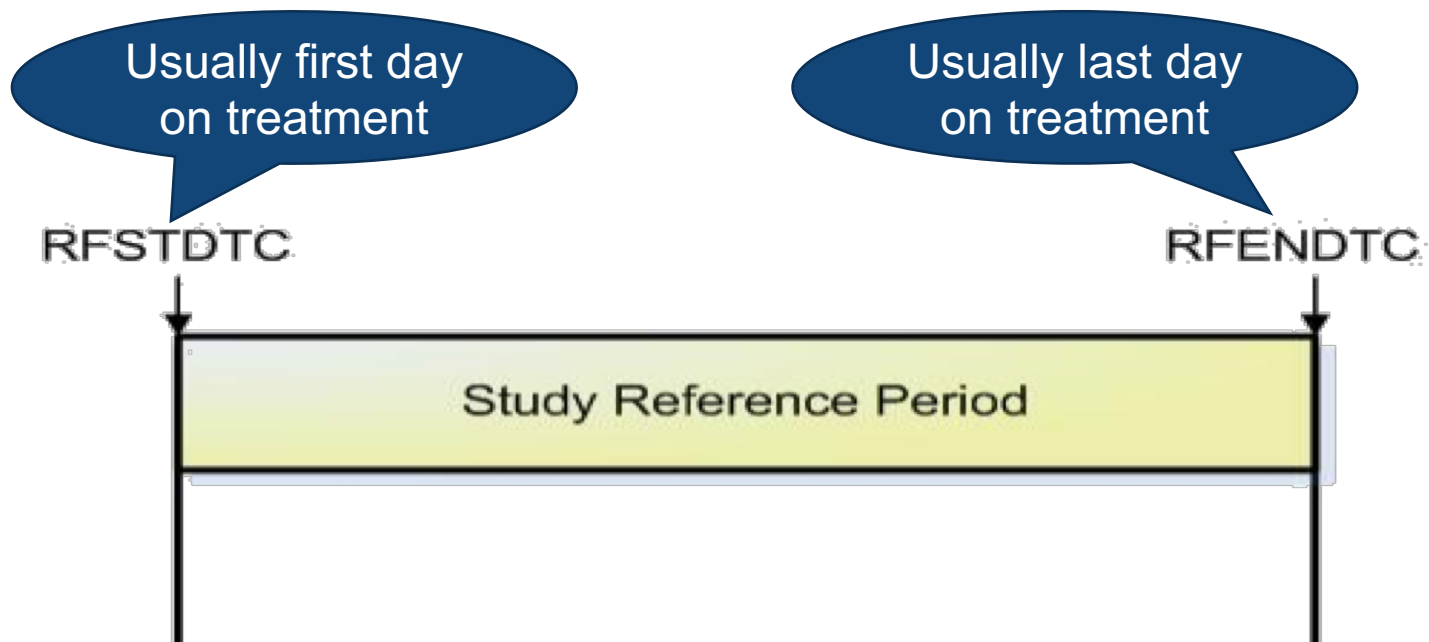
| | | | | | | |

Day

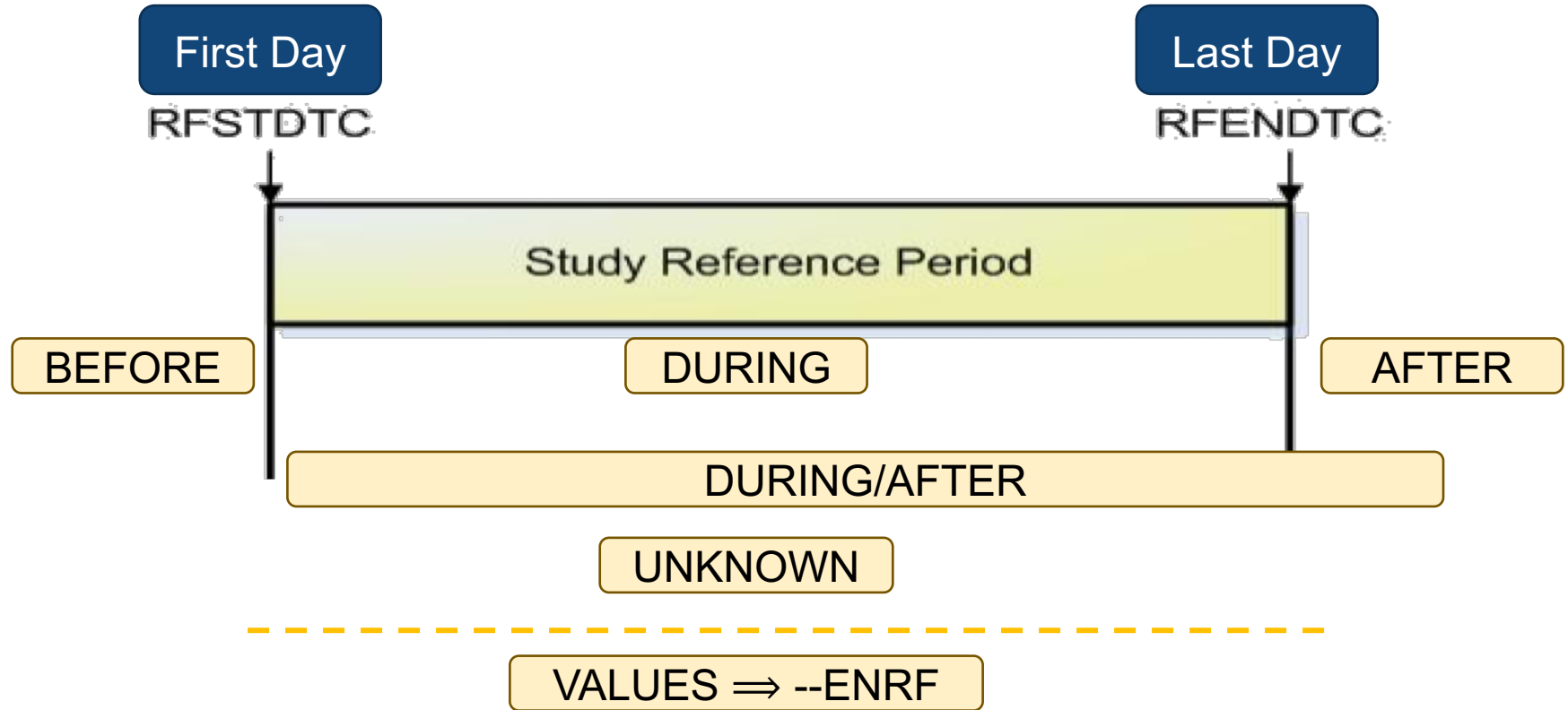
Month

Year

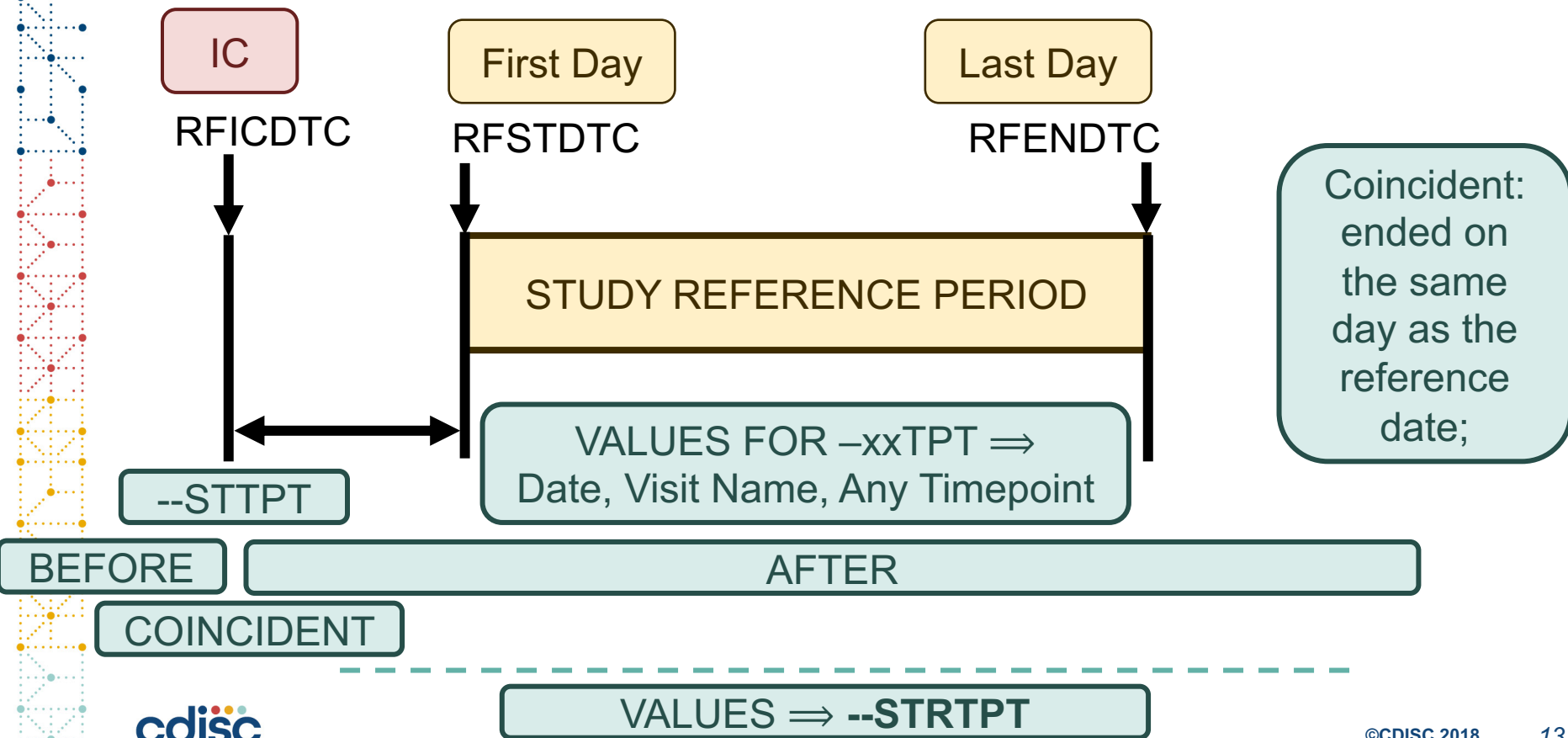
First Solution: Study Reference Period



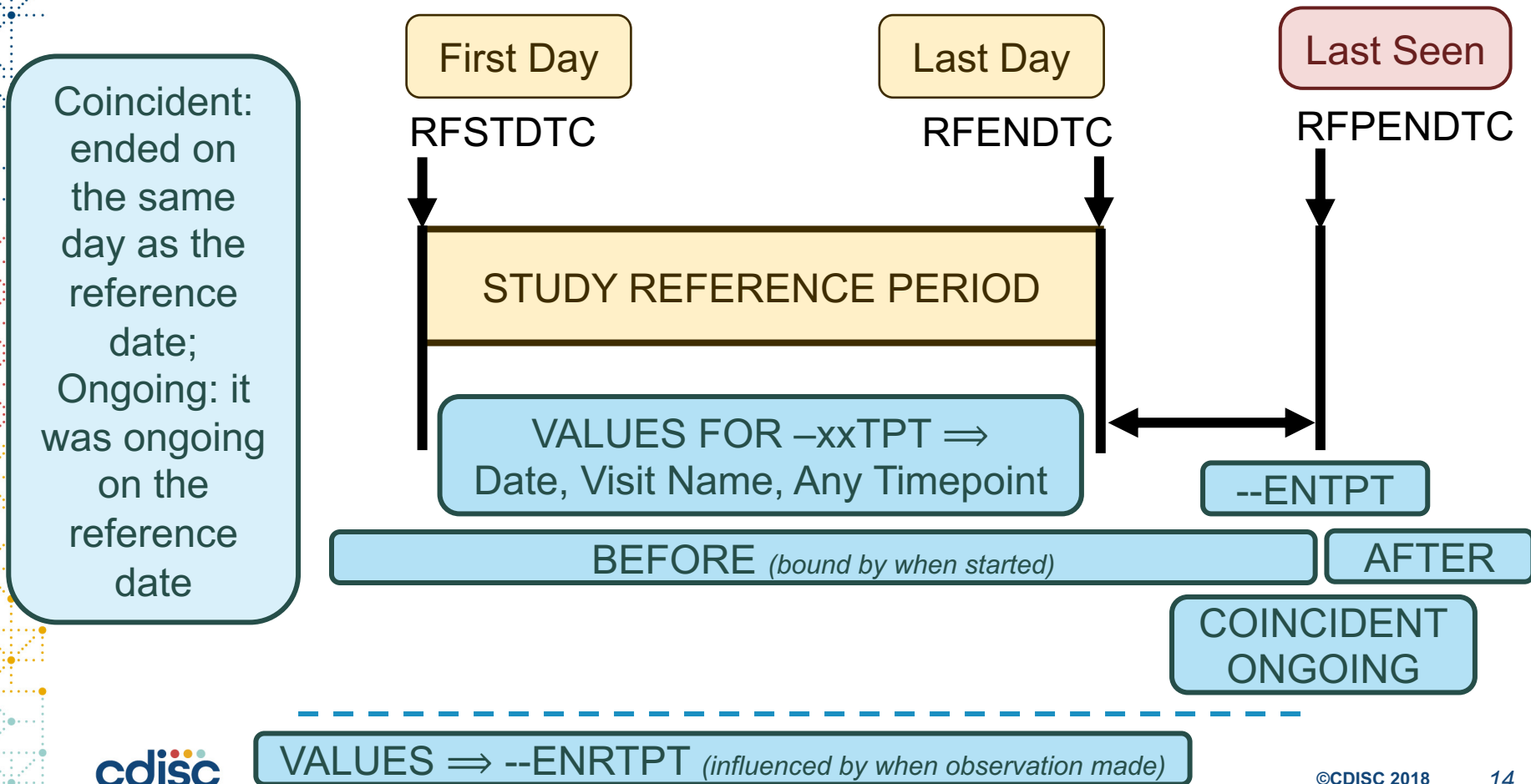
When Did the CM End Compared to This Period?



What is the Status of the Non-Study Med on This Date?



What is the Status of the Non-Study Med on This Date?





Part 3: Using “Generally Not Used” Variables

What is in the SDTM IG?

7. Any identifiers, timing variables, or events general observation class qualifiers may be added to the MH domain, but the following Qualifiers would generally not be used in MH: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

This was meant to be helpful!

It means we had no use case at that time

Use them if you have a use case



Part 4: What Data Can Go in Medical History?

Understanding the Medical History (MH) domain

Generally accepted definition of MH

- “A record of information about a person’s health. ...allergies, illnesses, surgeries, immunizations, and results of physical exams and tests.”* i.e., all relevant past personal experience

SDTMIG definition of MH

- “An events† domain that contains data that includes the subject's prior medical history at the start of the trial”**

SDTM definition of “Event”

- Something that happens; may or may not happen to everyone, may be planned or unplanned

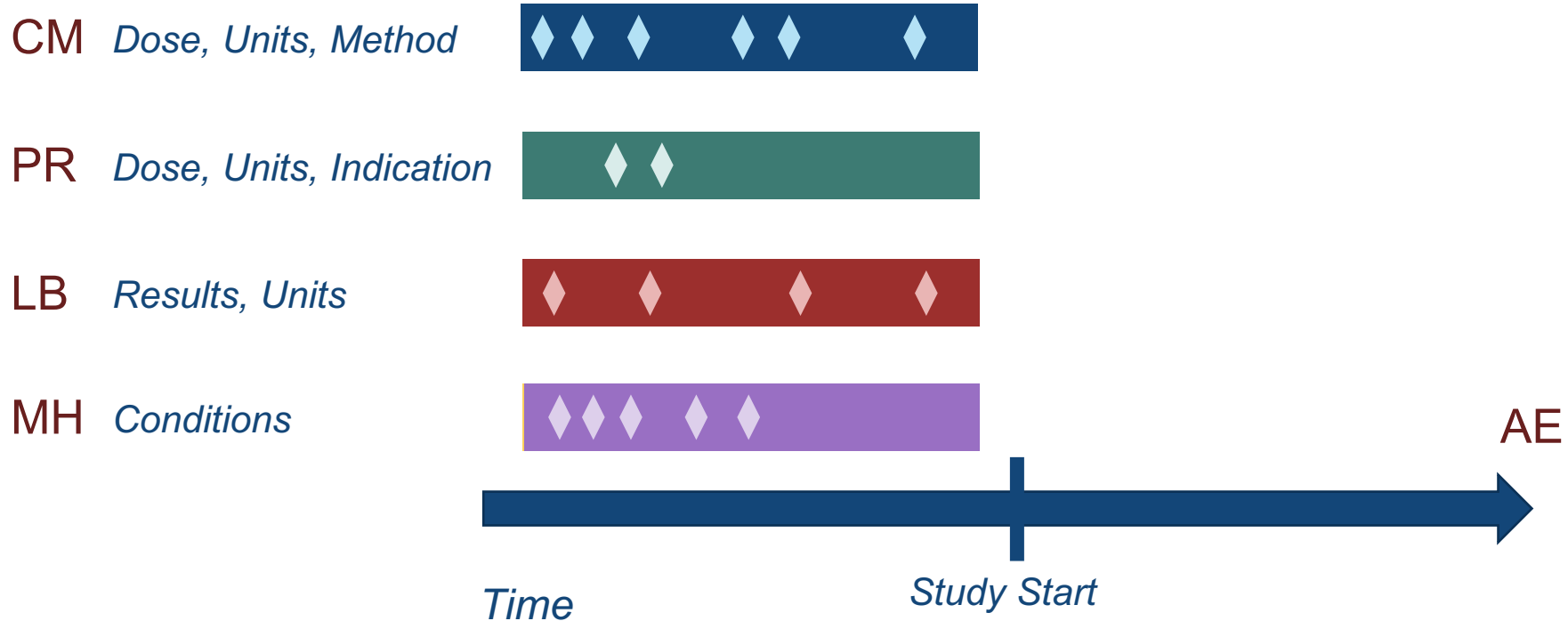
*Source: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/medical-history>

**NCI-EVS controlled terminology

†SDTM definition of “events”

What Domain to Use for Prior Information?

Two considerations: content and timing





Thank you for Attending!

cdisc.org

The logo for CDISC (Clinical Data Interchange Standards Consortium). It features the word "cdisc" in a dark blue, lowercase, sans-serif font. Above the "i" and "s" are four small, colored dots: red, yellow, green, and blue, arranged horizontally.