

Considerations in ADaM Occurrence Data: Handling Crossover Records for Non-Typical Analysis

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Introduction



Introduction

- ▶ Typical Analysis
- ▶ Non-Typical Analysis
- ▶ Data Structure of Typical and Non-Typical Analyses



Typical Analysis



Typical Analysis

– Overview

- ▶ Focused typically around Subject count analysis
- ▶ Emergence of Recorded Events on study

Typical Analysis

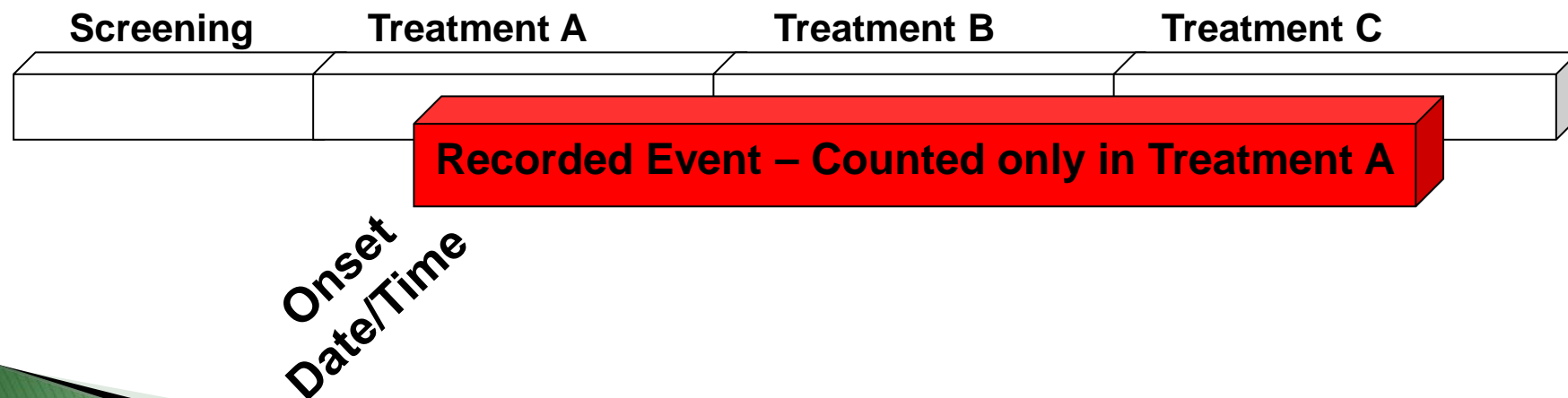
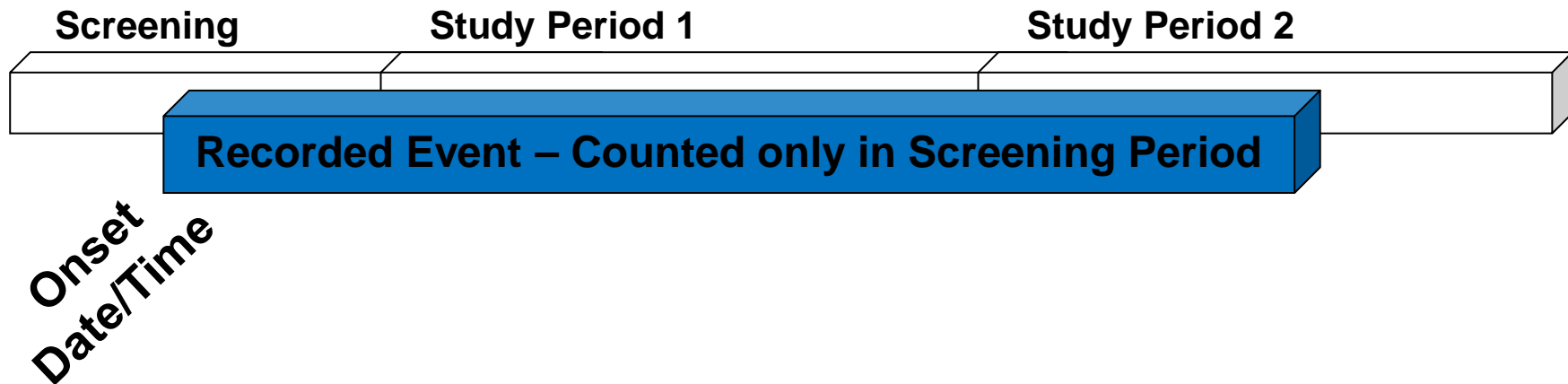
- Output Shell

| Recorded Event | <Treatment/Period X> n (%) | <Treatment/Period X> n (%) |
|----------------------|-------------------------------|-------------------------------|
| < Recorded Event 1 > | xx (xx.x%) | xx (xx.x%) |
| < Recorded Event 2 > | xx (xx.x%) | xx (xx.x%) |
| < Recorded Event 3 > | xx (xx.x%) | xx (xx.x%) |
| < etc. > | | |

Treatment/Period is assigned to the treatment/period in which the onset/start date/time of the recorded event occurred.

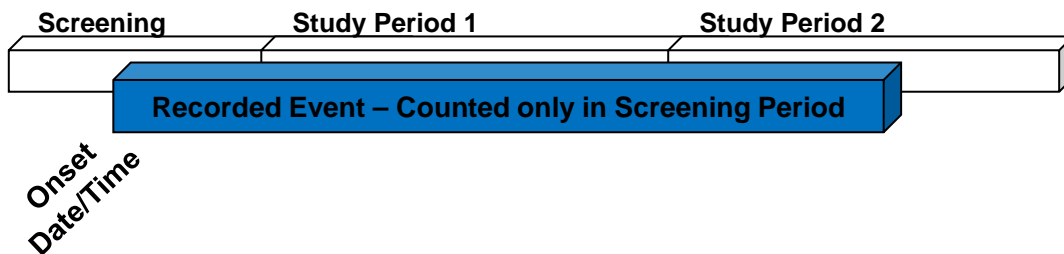


Typical Analysis – Study Timeline



Typical Analysis

- Data Mapping (Conmed)



SDTM Data

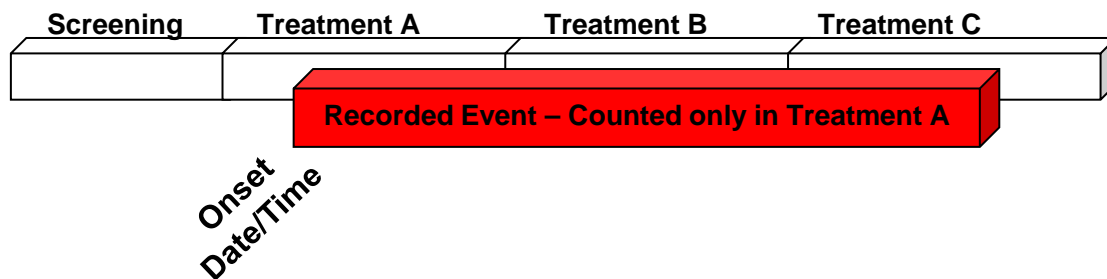
| CMSEQ | CMDECOD | CMSTDTC | CMENDTC | (cont.) |
|-------|-----------|------------|------------|---------|
| 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | ... |

ADaM Data

| CMSEQ | CMDECOD | CMSTDTC | CMENDTC | APERIOD | (cont.) |
|-------|-----------|------------|------------|-----------|---------|
| 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | Screening | ... |

Typical Analysis

- Data Mapping (AE)



SDTM Data

| USUBJID | AESEQ | AEDECOD | AESTDTC | AEENDTC | (cont.) |
|---------|-------|----------|------------|------------|---------|
| 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | ... |

ADaM Data

| USUBJID | AESEQ | AEDECOD | AESTDTC | AEENDTC | TRTA | TRTEMFL | APERIOD | (cont.) |
|---------|-------|----------|------------|------------|------|---------|---------|---------|
| 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | A | Y | 1 | ... |



Non-Typical Analysis

Non-Typical Analysis

– Overview

- ▶ Focused around Recorded Event count analysis
- ▶ Incidence of Recorded Events on study



Non-Typical Analysis

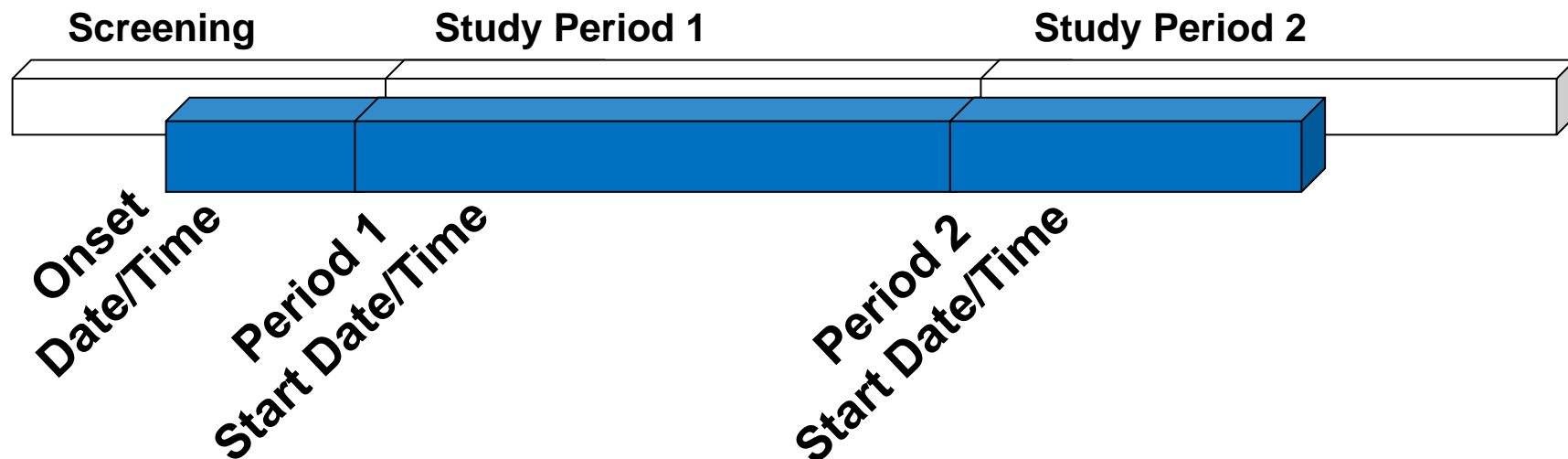
- Output Shell

| Recorded Event | Screening n (%) | Period 1 n (%) | Period 2 n (%) |
|----------------------|--------------------|-------------------|-------------------|
| < Recorded Event 1 > | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Recorded Event 2 > | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Recorded Event 3 > | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < etc. > | | | |

Period is assigned to the study period in which the recorded event occurred or continued to occur in until resolved or the end of study.



Non-Typical Analysis - Study Timeline



Non-Typical Analysis – Data Mapping (Conmed)

SDTM Data

| USUBJID | CMSEQ | CMDECOD | CMSTDTC | CMENDTC | (cont.) |
|---------|-------|-----------|------------|------------|---------|
| 001 | 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | ... |

ADSL

| USUBJID | AGE | ARM | ACTARM | AP01SDT | AP02SDT | (cont.) |
|---------|-----|-----|--------|------------|------------|---------|
| 001 | 35 | A | A | 2015-06-01 | 2015-08-01 | ... |

ADaM Data

| USUBJID | CMSEQ | CMDECOD | CMSTDTC | CMENDTC | APERIOD | (cont.) |
|---------|-------|-----------|------------|------------|----------------|---------|
| 001 | 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | Screening | ... |
| 001 | 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | Study Period 1 | ... |
| 001 | 12 | IBUPROFEN | 2015-05-14 | 2015-09-30 | Study Period 2 | ... |



Data Structure of Typical and Non-Typical Analyses



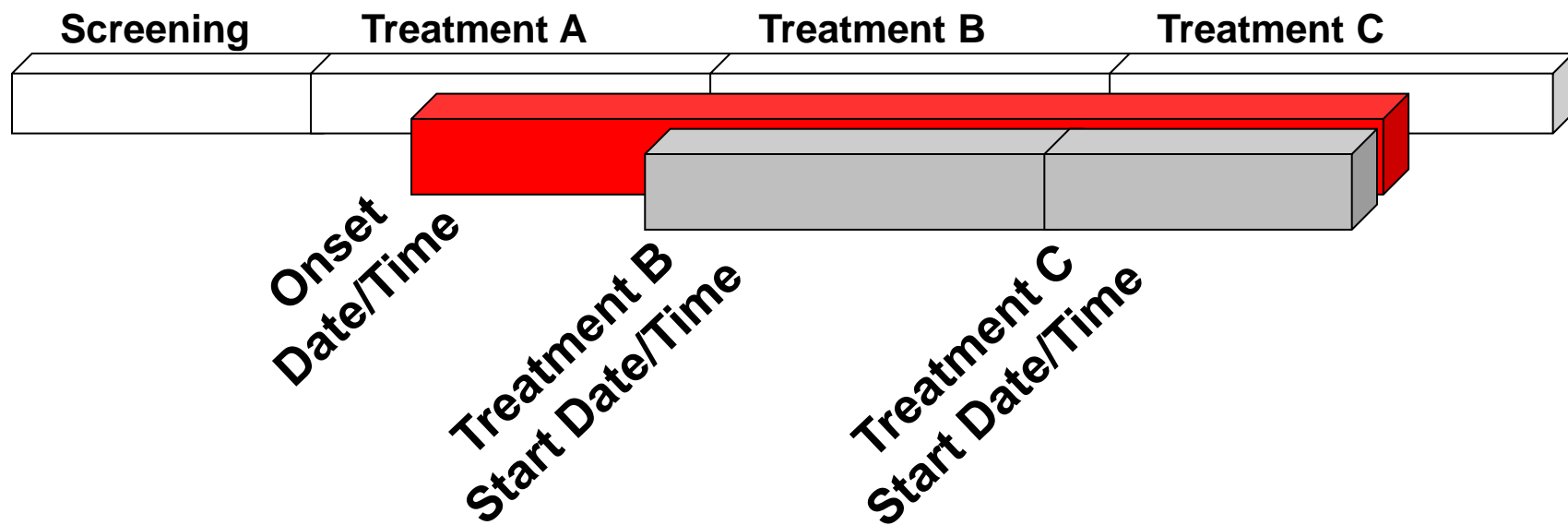
Occurrence ADaM Data Structure

- ▶ Working towards the end goal using ADaM data sets maintains efficiencies through:
 - Reducing the number of created, unnecessary variables in the data set
 - Reducing the number of retained variables from the input SDTM data set(s)
 - Focusing solely on the specific analyses and the required study information or data



Both Types of Analyses

- Study Timeline



Both Types of Analyses –Data Mapping (AE)

SDTM Data

| USUBJID | AESEQ | AEDECOD | AESTDTC | AEENDTC | (cont.) |
|---------|-------|----------|------------|------------|---------|
| 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | ... |

ADSL

| USUBJID | AGE | ARM | ACTARM | TR01SDT | TR02SDT | TR03SDT | (cont.) |
|---------|-----|-----|--------|------------|------------|------------|---------|
| 002 | 32 | ABC | ABC | 2015-10-10 | 2015-11-11 | 2015-12-12 | ... |

ADaM Data

| | USUBJID | AESEQ | AEDECOD | AESTDTC | AEENDTC | ASTDT | AENDT | ADURN | (cont.) | |
|---|---------|-------|----------|------------|------------|-----------|-----------|---------|---------|---------|
| 1 | 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | 31OCT2015 | 03JAN2016 | 63 | ... | |
| 2 | 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | | | | ... | |
| 3 | 002 | 7 | HEADACHE | 2015-10-31 | 2016-01-03 | | | | ... | |
| | | | | | | TRTA | TRTEMFL | APERIOD | ANL01FL | (cont.) |
| 1 | | | | | | A | Y | 1 | Y | ... |
| 2 | | | | | | B | | 2 | | ... |
| 3 | | | | | | C | | 3 | | ... |

Conclusion

Conclusion

- ▶ Start with the end in mind
- ▶ Keep things as simple as possible
- ▶ Add records to the data, if needed, for an increase in programming efficiency
- ▶ Maximizes the analysis-ready capabilities while maintaining the appropriate traceability

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