



PATTERNS EMERGING FROM CHAOS

6th June 2018, PhUSE US Connect, Raleigh
Alan Cantrell

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AGENDA

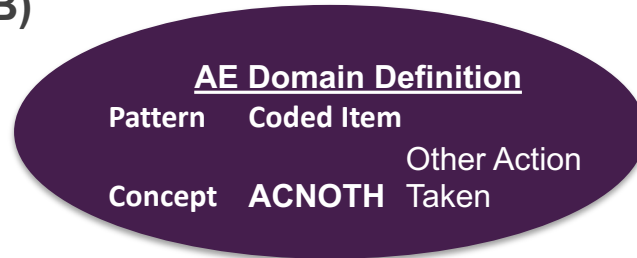


- Introduction
- Historical changes to structure
- Metadata Linkage
- Metadata changes and impact
- Governance and patterns
- Conclusion

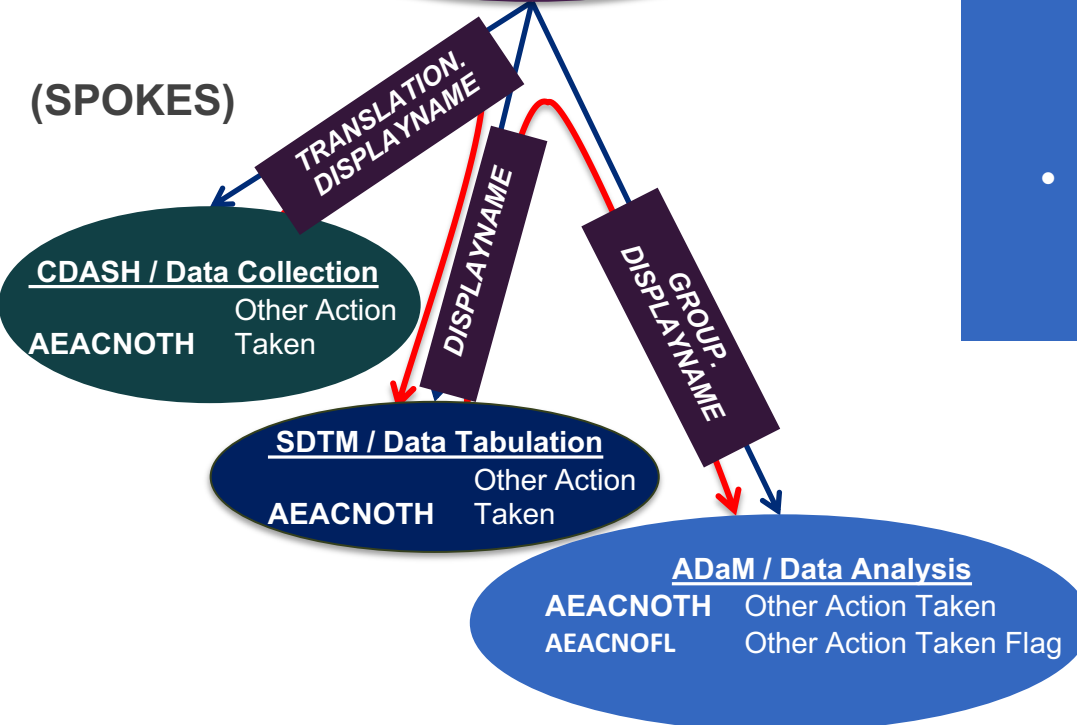
INTRODUCTION

- *ISO 21090 BASED
CLINICAL RECOGNIZABLE
CONCEPTS*
- *DATA IS MAPPED TO AND
FROM A HUB*
- *USABLE FOR CDISC AND
OTHER DATA MODELS*

(HUB)



(SPOKES)



- Mapping by declaration to concepts
- Allows End to End (E2E) data flow dry-run without data
- Study teams worry about the what not the how

HISTORICAL CHANGES TO STRUCTURE - I



A specification documents the requirements and rules for mapping from source to a target

The specification is dependent on the source and target metadata. If either changes the specification needs to be adapted – it acts as a bridge

Source metadata could be updated by a protocol amendment or change in expectations by sponsor

HISTORICAL CHANGES TO STRUCTURE - II



Example

Protocol Version 1

**Adverse Event Start Date collected in format ddmmyyyy, e.g.
06JUN2018**

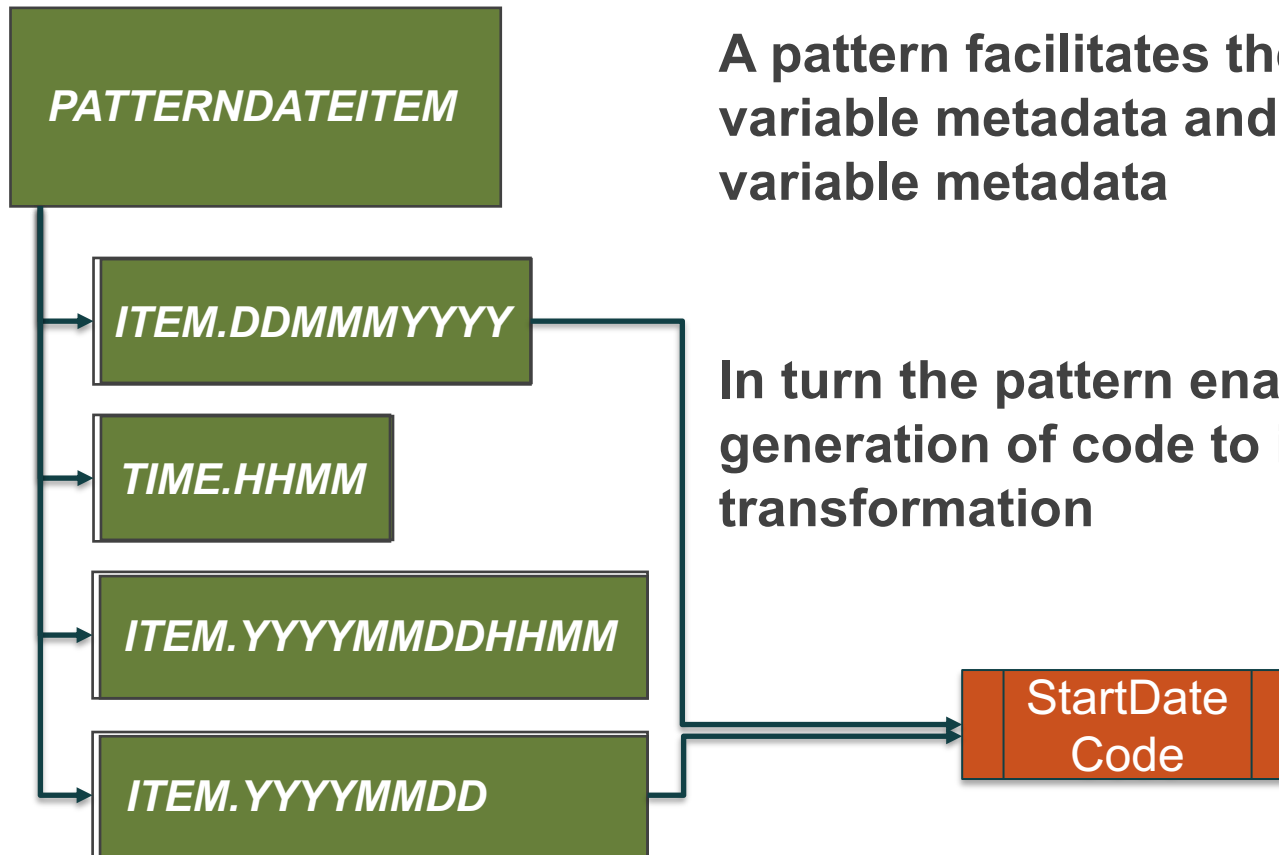
Protocol Amendment 1

Adverse Event Start Time is added to the data collection instrument, e.g. 14:00 and Adverse Event Start Date collection format is changed to yyymmdd, e.g. 20180606

METADATA LINKAGE

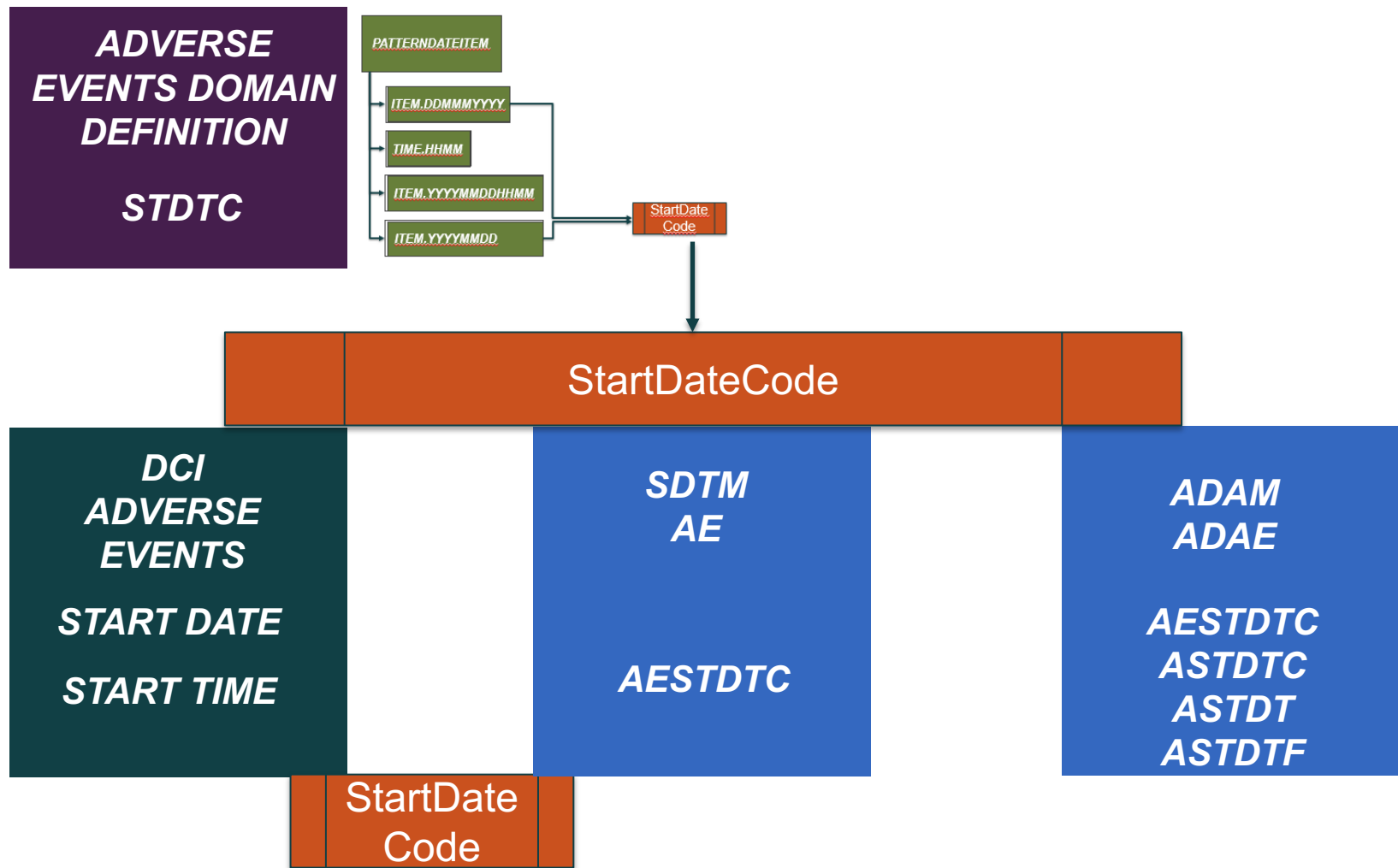
A pattern facilitates the reading in of variable metadata and outputting of variable metadata

In turn the pattern enables the generation of code to implement this transformation

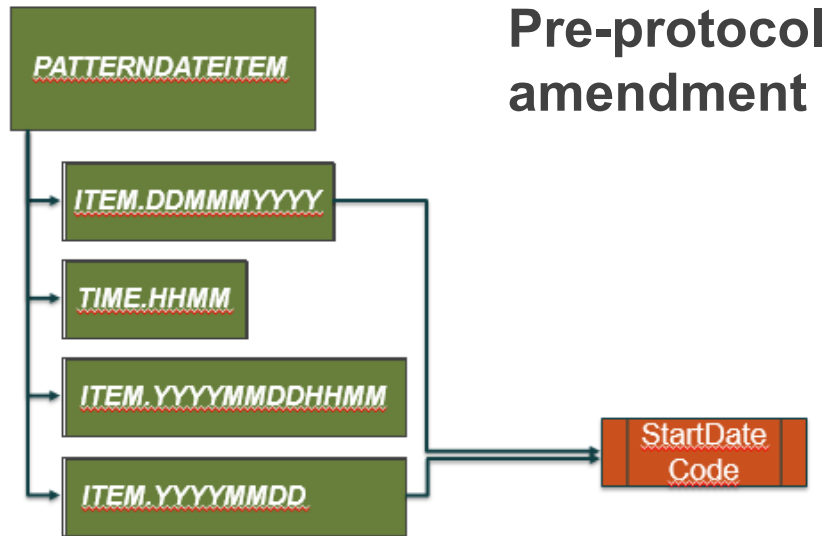


```
* Date variables;  
** Start Date;  
%gmPatternDateItem(  varsIn  =  aeStDat_raw = item.ddmmyyyy  
                      , varsOut =  aeStDtC   = item.yyyymmdd  
                      , codeOut = startDateCode  
                      );
```

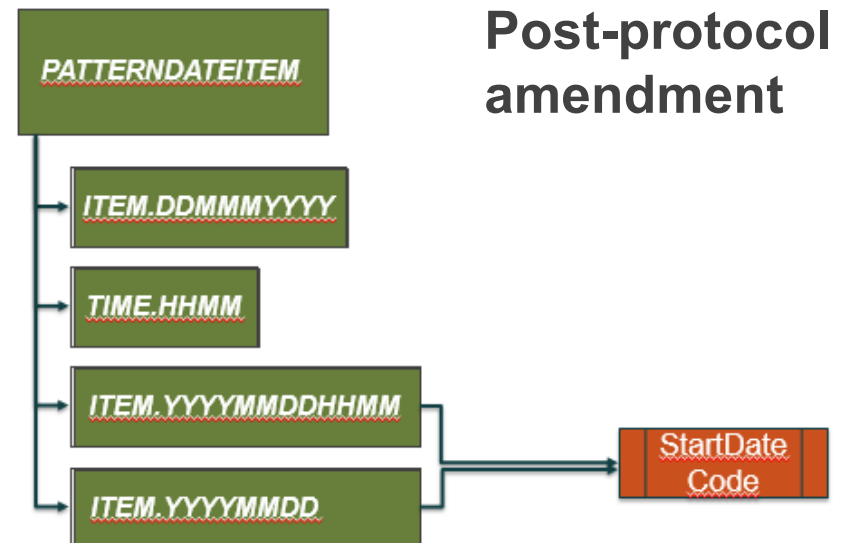
METADATA CHANGES AND IMPACT - I



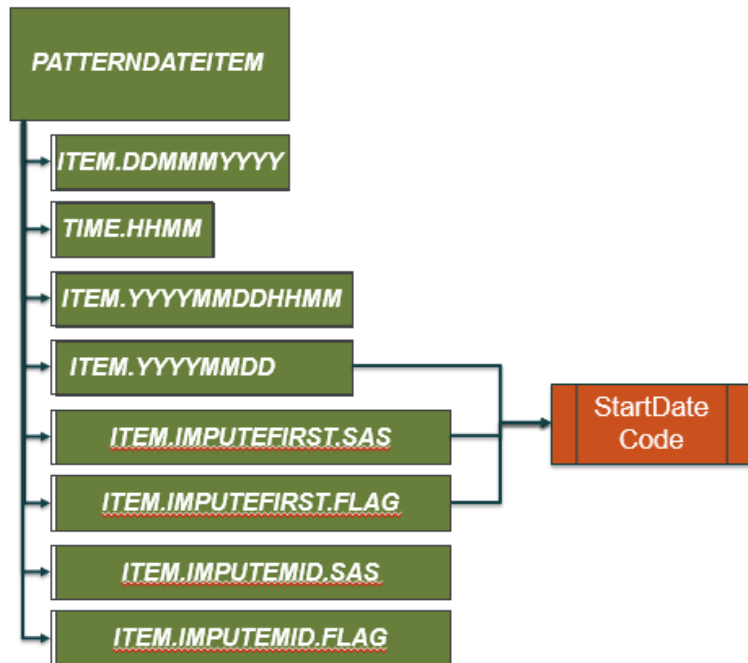
METADATA CHANGES AND IMPACT - II



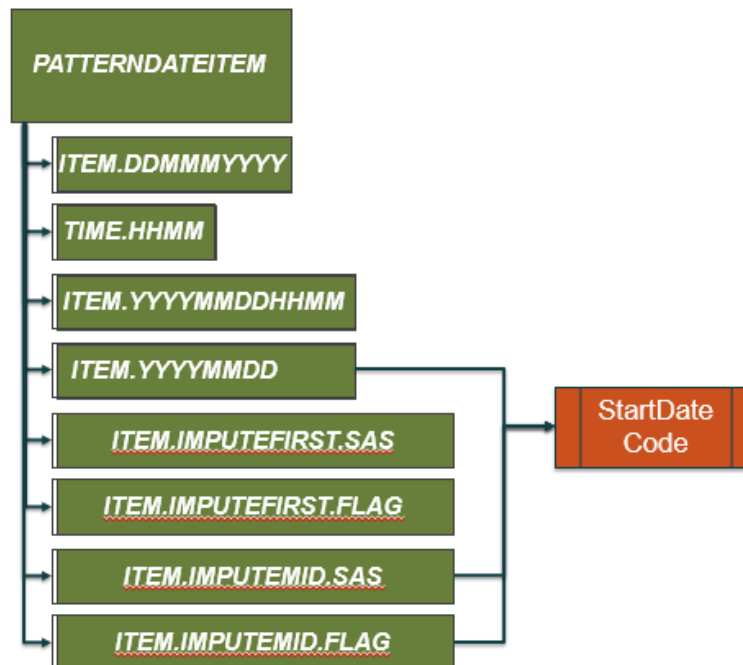
Changing the format of the source metadata retains the connectivity between the data collection instrument and SDTM but updates the related source code



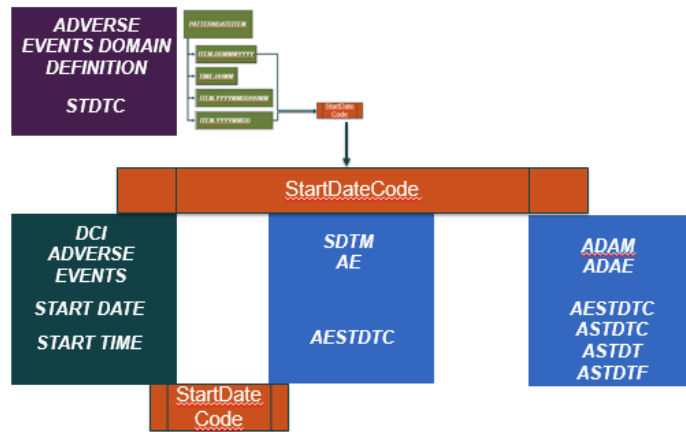
METADATA CHANGES AND IMPACT - III



In addition, a change to the Statistical Analysis Plan could impact the method for imputing the analysis date and flags such as ASTDT / ASTDTF



GOVERNANCE AND PATTERNS



Metadata is stored within the MDR and is version controlled

Updated metadata is used to generate updated mapping code



Code related to metadata is retained using subversion

CONCLUSION

Using patterns to connect form items, SDTM and ADaM variables to a central hub ensures changes to metadata allow connectivity to remain in place.

Patterns emerging from chaos



QUALITY



CONSISTENCY



EFFICIENCY

QUESTIONS



For more information:

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Come and see us at PAREXEL's booth!

Visit our MDR resource portal at:
<https://www.parexel.com/solutions/clinical-research/global-data-operations/clinical-metadata-repository-mdr>

THANK YOU