

Data Standards and Governance Workstream

PhUSE EU Connect 2018

DS01 - Legacy Data Conversion Project

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Content

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- Conversion Approach
- Challenges
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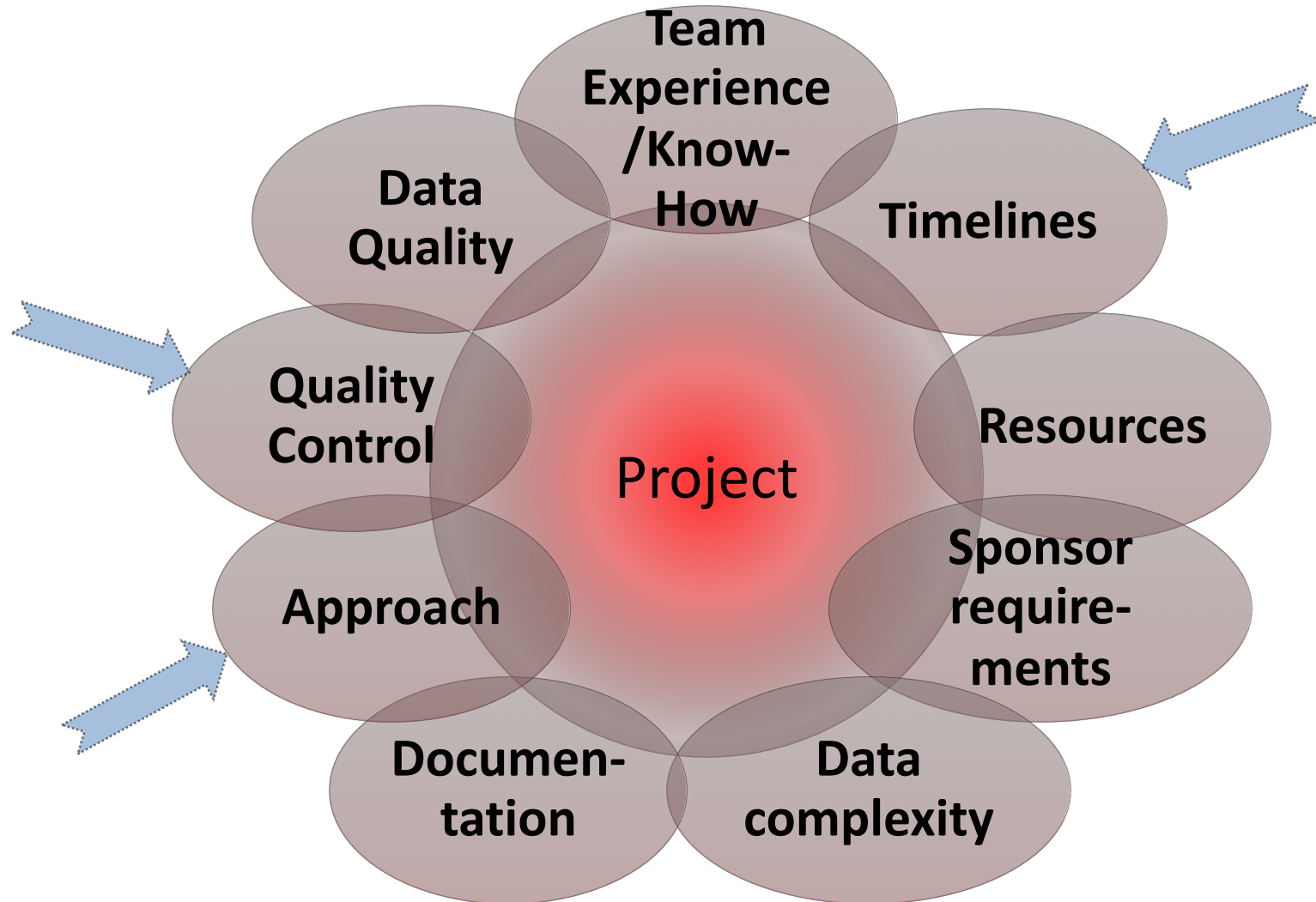
Introduction - Prerequisites

<u>SDTM</u>	<u>ADaM</u>
SDTM IG v3.1.3 + v1.3	ADaM IG v1.0 + v2.1
Sponsor Model Extensions	
Sponsor Guidelines	
aCRF Standard	TLFs
Sponsor CT	
Sponsor Checklist (blank)	

Introduction - Deliverables

<u>SDTM</u> 10 Studies	<u>ADaM</u> 5 Studies + ISS
XPTs, define (v1.0)	
Pi21	
Reviewers Guide	
SAS programs	
aCRF	TLFs
Legacy Specs	
Sponsor Checklist	

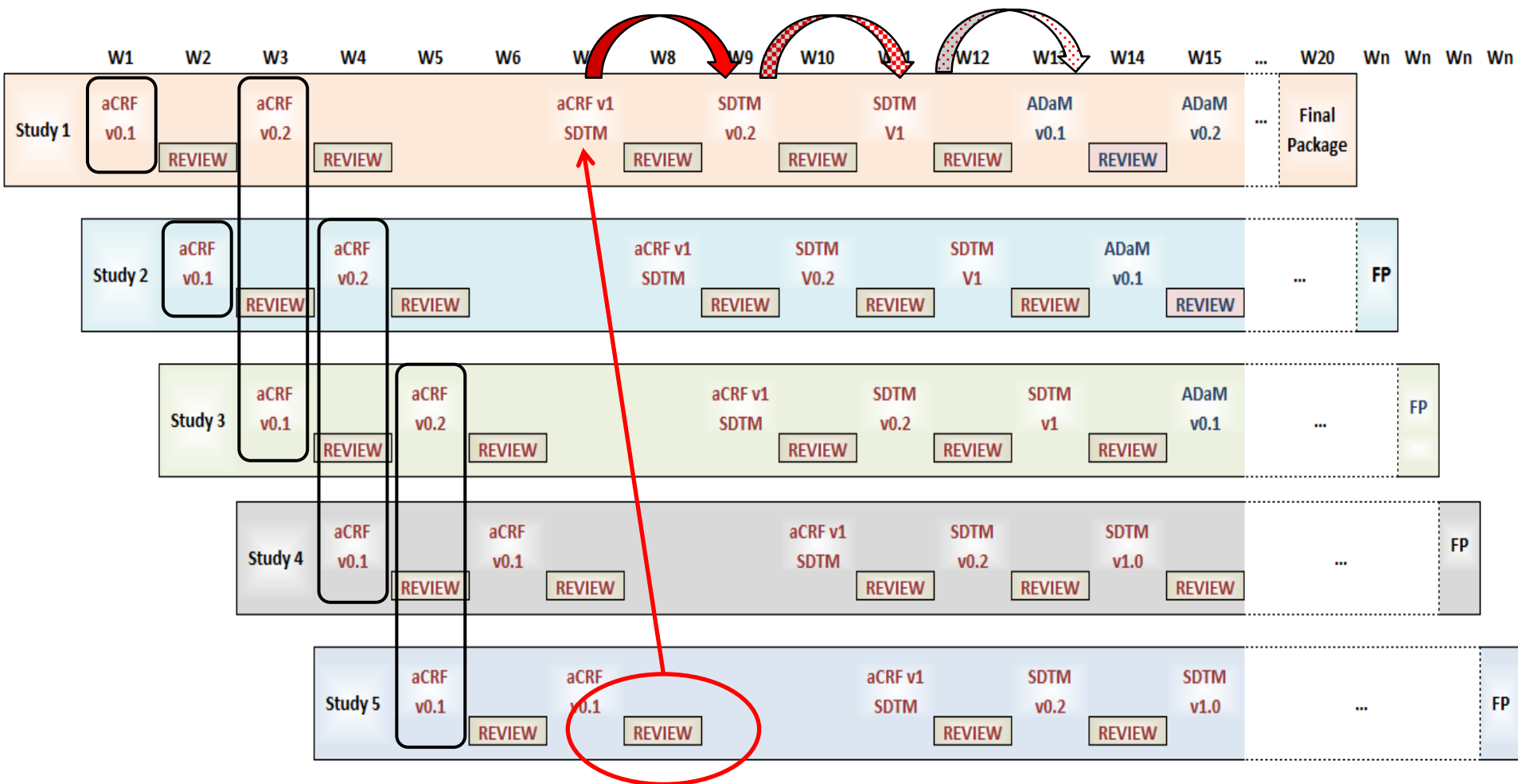
Introduction – our Focus



Conversion Approach - Validation and QC

Deliverable	Tool / QC Step
aCRF	-> Sponsor metadata checks (compliance) -> Manual review
SDTM/ ADaM	-> Double programming -> Pinnacle 21 (compliance) -> Sponsor metadata checks (compliance)
SDTM	-> Manual review legacy mapping + spot checks
ADaM	-> Sponsor checks (compliance) -> Traceability to legacy CSR TLFs
Define.xml	-> Sponsor metadata checks -> Pinnacle 21 (compliance)

Conversion Approach - Staggered



Later study aCRF finding → change in 1st (+ 2nd?) study SDTM !

Challenges

- Issue Log

Precise specifications and feedback comments leverage review activities and use of Issue Logs within team



Risk Register - Sample				Project	Project Manager	Author	Project Manager	Status	
This risk register is for the "Sample Project"									100%
Project Name		Project Manager		Risk / Impact					
Sample Project		John Doe		High / High					
Project Manager		John Doe		Medium / Low					
Project Manager		John Doe		Medium / Low					
Project Manager		John Doe		Medium / Low					
Risk ID		Risk Category		Risk Description		Probability		Severity	
Risk ID <td colspan="2">Risk Category</td> <td colspan="2">Risk Description</td> <td colspan="2">Probability</td> <td colspan="2">Severity</td>		Risk Category		Risk Description		Probability		Severity	
1		P Smith	6/1/2013	Ordering	A risk that users will be delayed 2-4 weeks later which will impact the time of the project	High	Medium	Active	P Smith / J Hall
2		S Kelly	7/1/13	Product	Users may not like the new system and therefore not use it which will result in less revenue	Medium	Medium	Active	S Kelly / B Clark
3		S Kelly	8/1/13	Product	Users may not like the new system and therefore not use it which will result in less revenue	Medium	Medium	Active	S Kelly / S Kelly

- Data Quality and use of Data Standards

- QC Expectations – what has been checked before delivery

Challenges

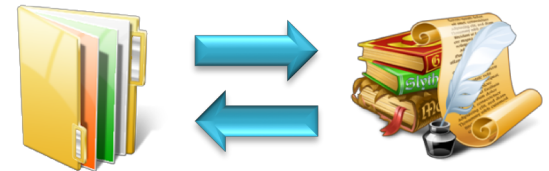
- Which study first?



- ADaM impacted by SDTM changes



- Discrepancies vs original CSRs

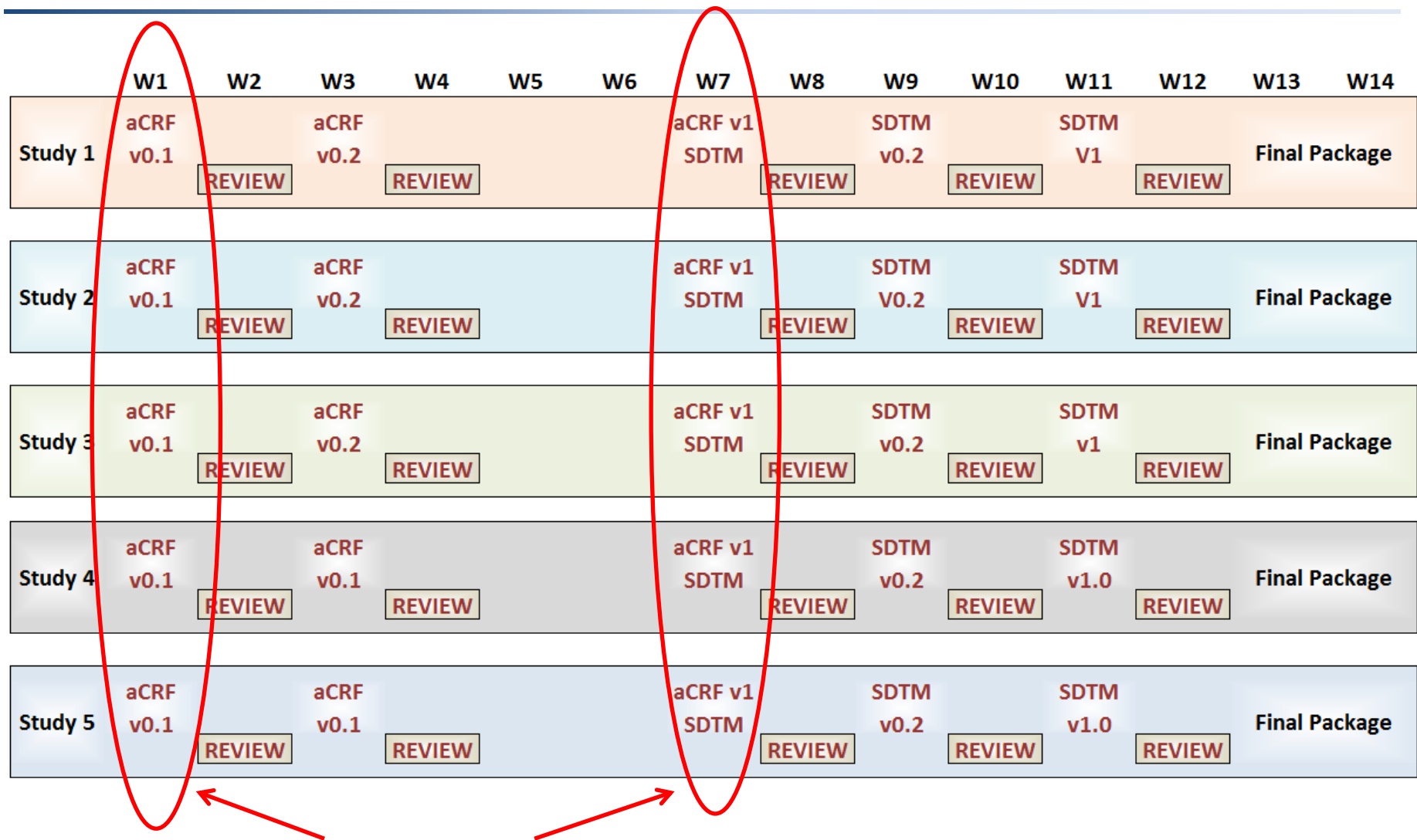


Challenges

- Conversion & Review Approach:
 - Review effort underestimated
 - Staggered Approach suboptimal



Conversion Approach – “by-type”



Focus on selected domain types

Recommendations, Conclusion

Flowchart Review Approach Bucket I vs II

Bucket I - SDTM Review Approach and Cycles



Bucket II – SDTM Review Approach and Cycles



Recommendations

- Start with one representative study, then switch to “by-type”
- Pool CT mapping across studies
- Annotate external DTS
- SDTM/ADaM team overlap

Recommendations

- Include Trial Design with aCRF
- Interact with FDA - as early as possible
 - (questions to eData Team at any time)
- Communication, Issue Handling



Conclusion

- *“If you fail to plan, you are planning to fail.”*
(Benjamin Franklin)

- Ensure all material is available



- Clarify expectations
 - DSP deliverables
 - Sponsor surveillance



"Miss Wilcox, send in someone to blame."

=== Good collaboration ===



Contact the Authors

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