



When you need
to be sure

SGS Pharma - Clinical Research

AS14 - Consistency, Speed, and Satisfaction: The Impact of TLF Mock Shell Centralisation

Jie Yang, Biostatistician
PHUSE US CONNECT 2026 | Austin, Texas | 22-26 March 2026

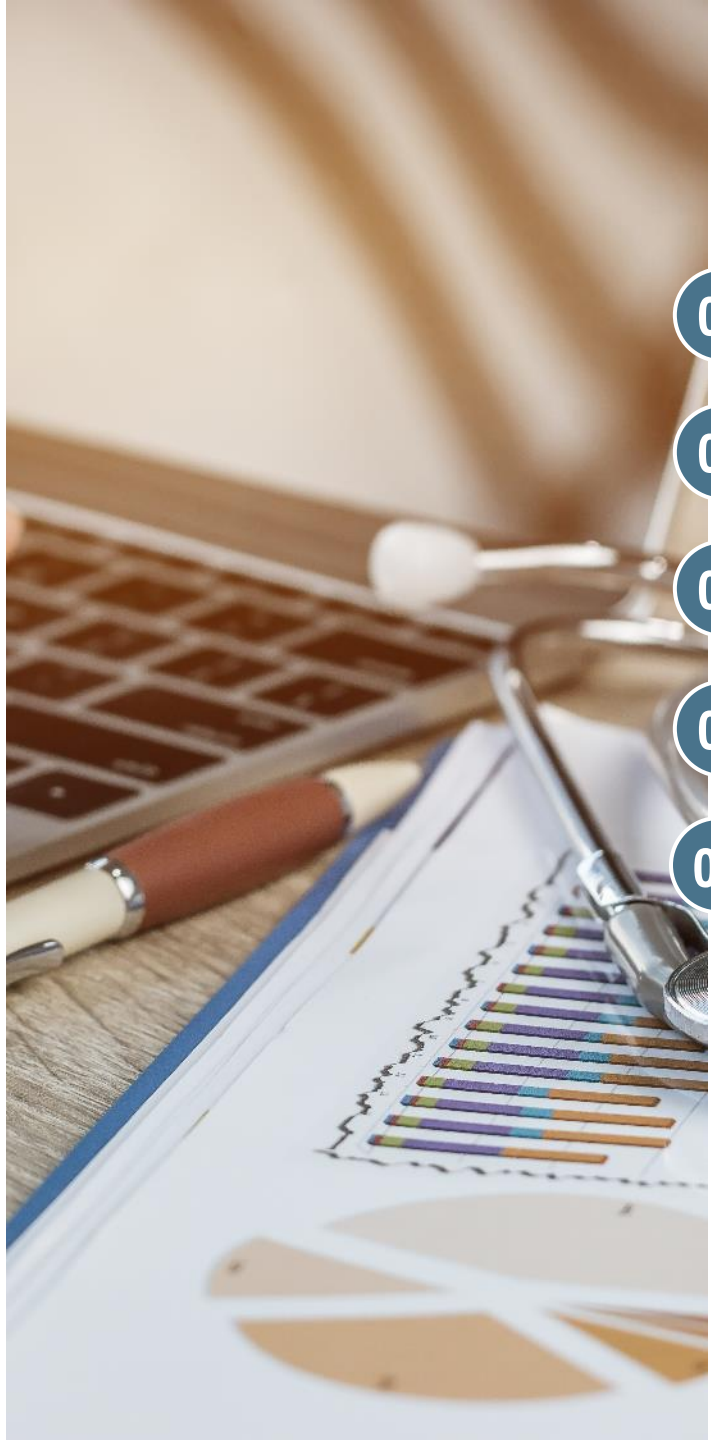




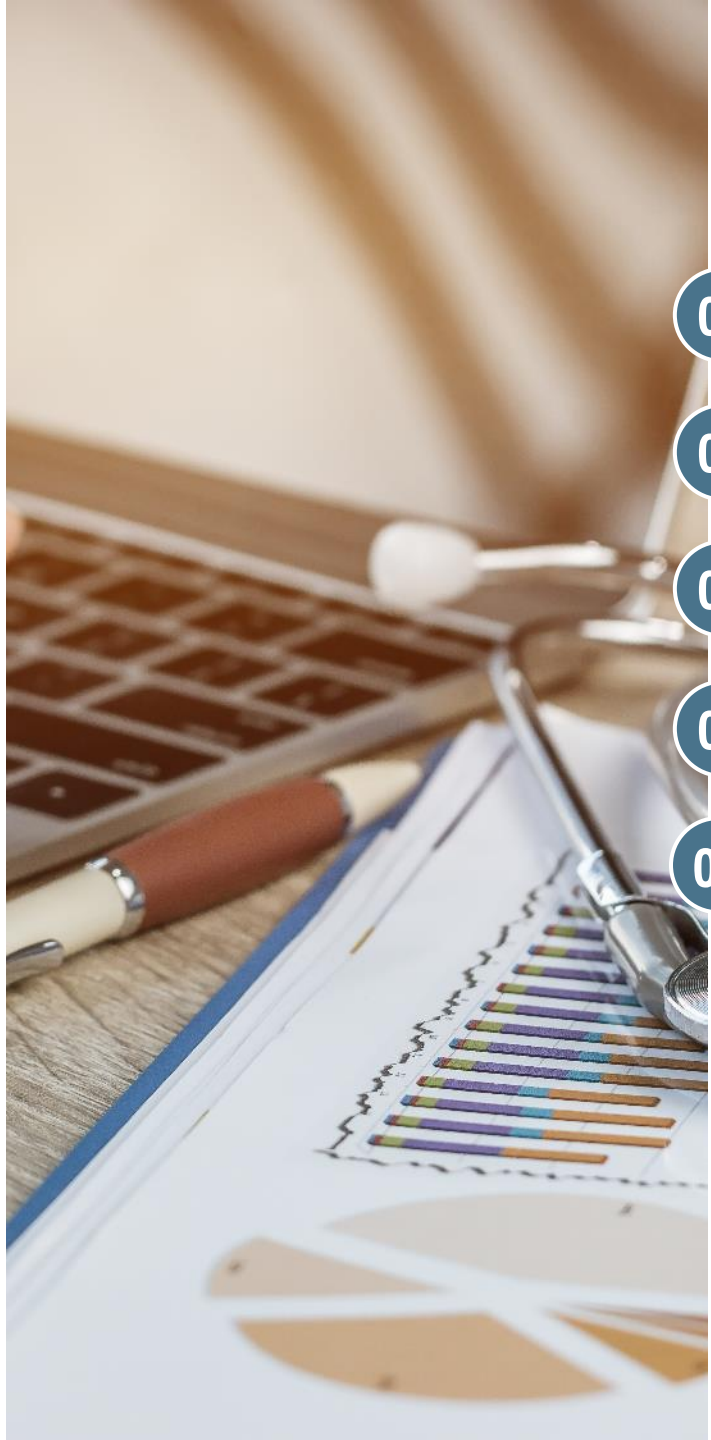
Disclaimer and disclosures

The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the opinions of PHUSE members, respective companies or organizations.

Agenda

- 
- 01 Introduction
 - 02 Study-specific TLF Mock Shell
 - 03 TLF Mock Shell Centralisation
 - 04 Benefits of the Transition
 - 05 Conclusion

Agenda

- 
- 01 **Introduction**
 - 02 Study-specific TLF Mock Shell
 - 03 TLF Mock Shell Centralisation
 - 04 Benefits of the Transition
 - 05 Conclusion

Introduction

Mock shell serves as visual guide, which defines the layout, structure and style of the table, listing and figure outputs.

STUDY IDENTIFIER - ANALYSIS VERSION

TABLE 14.3.X.X: ADVERSE EVENTS OVERVIEW

ANALYSIS SET: SAFETY

ANALYSIS PERIOD = XXX

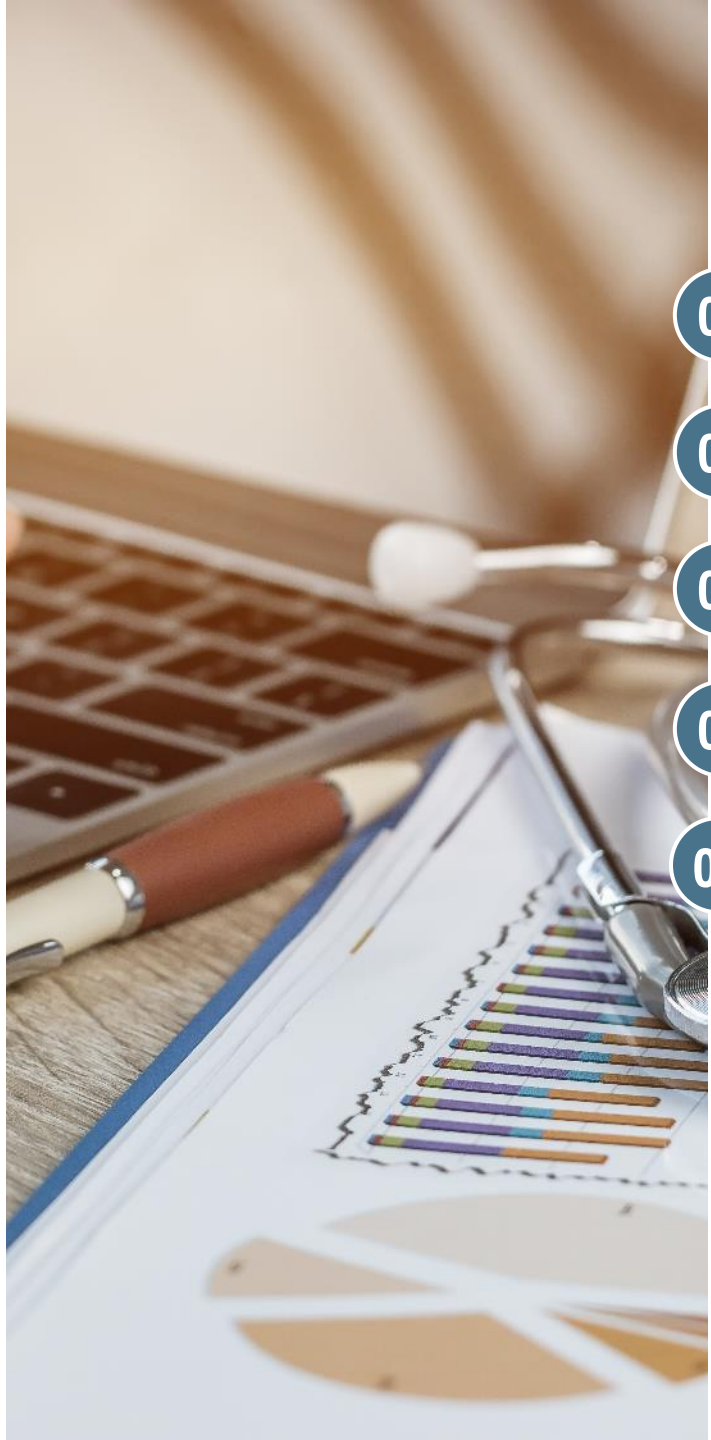
Page X of Y

	TREATMENT A (N=XX)			TREATMENT B (N=XX)			OVERALL (N=XX)		
TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE:	n	%	m	n	%	m	n	%	m
TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
SERIOUS TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
GRADE ≥3 TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
FATAL TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
TREATMENT-RELATED TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
SERIOUS TREATMENT-RELATED TEAE	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX
TEAE LEADING TO STUDY DISCONTINUATION	XX	XX.X	XX	XX	XX.X	XX	XX	XX.X	XX

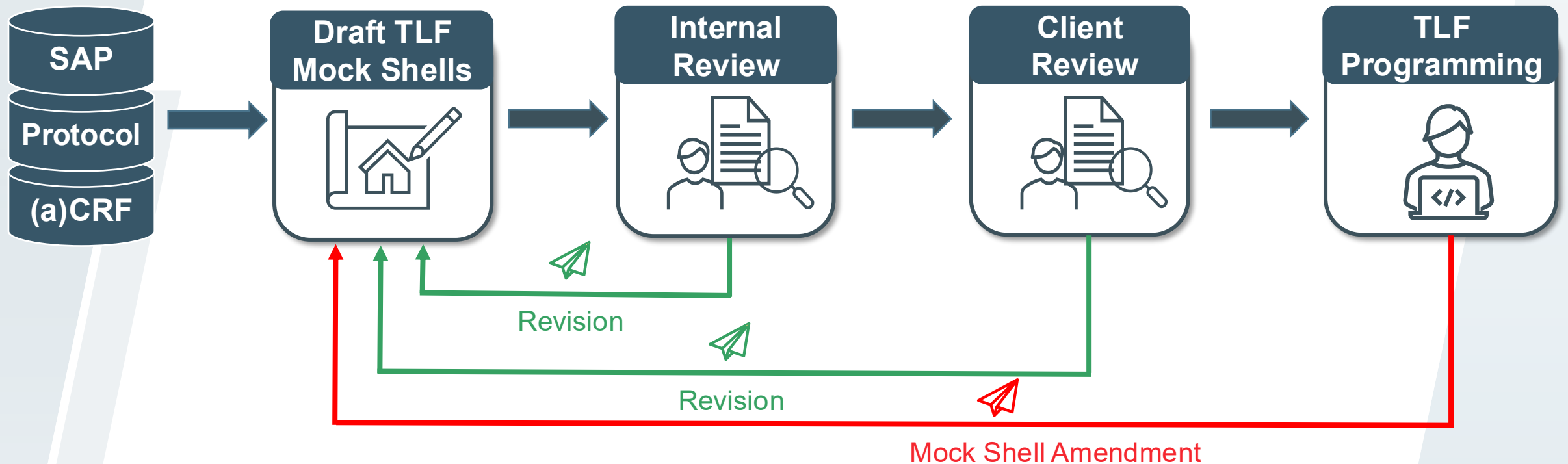
m: NUMBER OF EVENTS; n: NUMBER OF SUBJECTS WITH EVENT; TEAE: TREATMENT-EMERGENT ADVERSE EVENT.
THE DENOMINATOR FOR THE PERCENTAGE CALCULATIONS IS N, THE TOTAL NUMBER OF SUBJECTS IN THE SAFETY
ANALYSIS SET PER TREATMENT AND PER ANALYSIS PERIOD.
TREATMENT-RELATED IS DEFINED AS AT LEAST POSSIBLY RELATED TO THE INVESTIGATIONAL PRODUCT ACCORDING TO
THE INVESTIGATOR, OR A MISSING RELATIONSHIP.

[program name.sas] ddMMMyyyy hh:mm

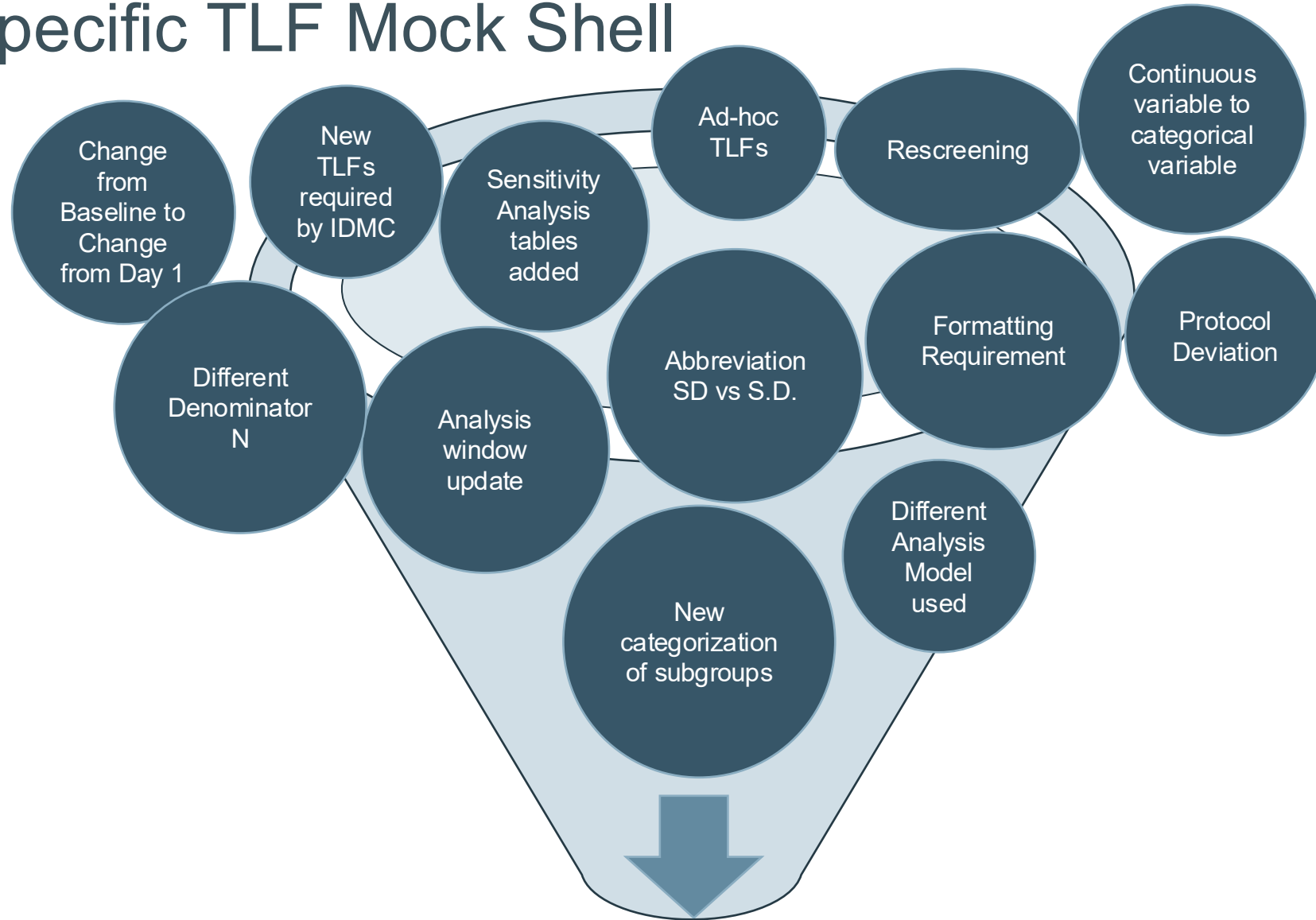
Agenda

- 
- 01 Introduction
 - 02 **Study-specific TLF Mock Shell**
 - 03 TLF Mock Shell Centralisation
 - 04 Benefits of the Transition
 - 05 Conclusion

Study-specific TLF Mock Shell: Process



Study-specific TLF Mock Shell



TLF Mock Shell Update

Study-specific TLF Mock Shell

Study-Specific TLF Mock Shell Challenges



Time Consuming & Costly

- ✗ Late programming onset



High Maintenance

- ✗ Iterative 'Review-Revision-Validation' cycles



Risks

- ✗ Programming errors, quality issues & delays



Redundancy

- ✗ Common TLF Mock Shells created repeatedly



Limited reusability

- ✗ Inconsistency & Over-customisation

Study-specific TLF Mock Shell: Challenges

STUDY IDENTIFIER - ANALYSIS VERSION

TABLE 1: DESCRIPTIVE STATISTICS OF LABORATORY TEST ACTUAL VALUES

ANALYSIS SET: SAFETY

LABORATORY CATEGORY: LABORATORY PARAMETER 1 (unit)

ANALYSIS VISIT	TREATMENT A (N=XX)	TREATMENT B (N=XX)

BASELINE		
n	XX	XX
Mean (SD)	XX.X (X.XX)	XX.X (X.XX)
SE	X.XX	X.XX
95% CI	XX.X; XX.X	XX.X; XX.X
Median	XX.X	XX.X
Q1; Q3	XX.X; XX.X	X.X; X.X
Min; Max	XX; XX	XX; XX

STUDY IDENTIFIER - ANALYSIS VERSION

TABLE 1: DESCRIPTIVE STATISTICS OF LABORATORY TEST ACTUAL VALUES

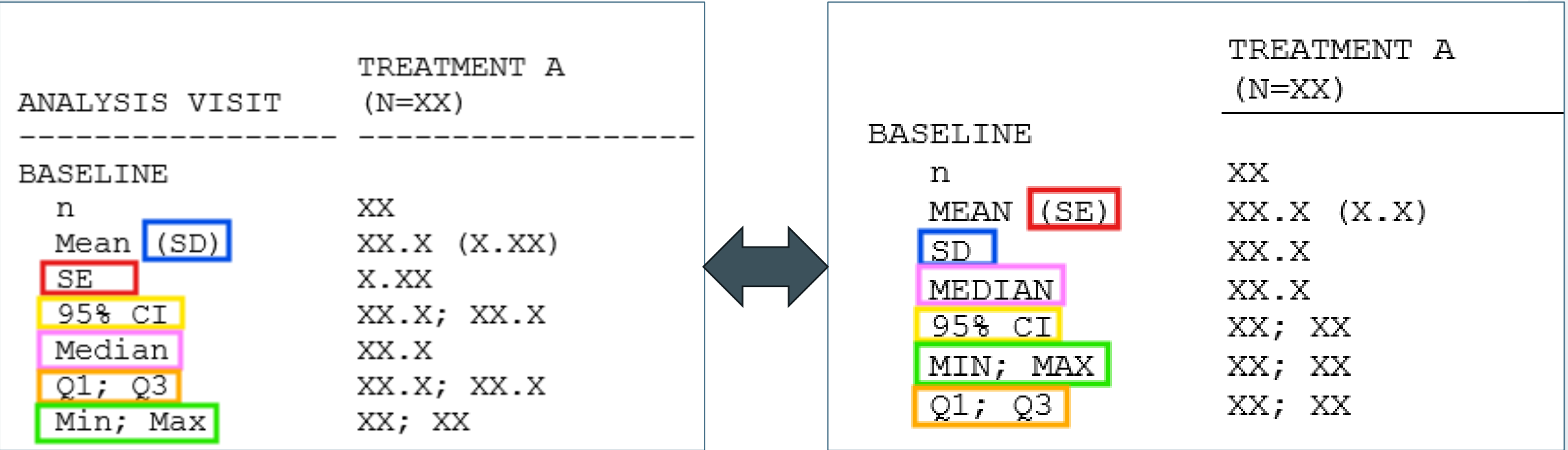
SAFETY ANALYSIS SET

LABORATORY CATEGORY: LABORATORY PARAMETER 1 (unit)

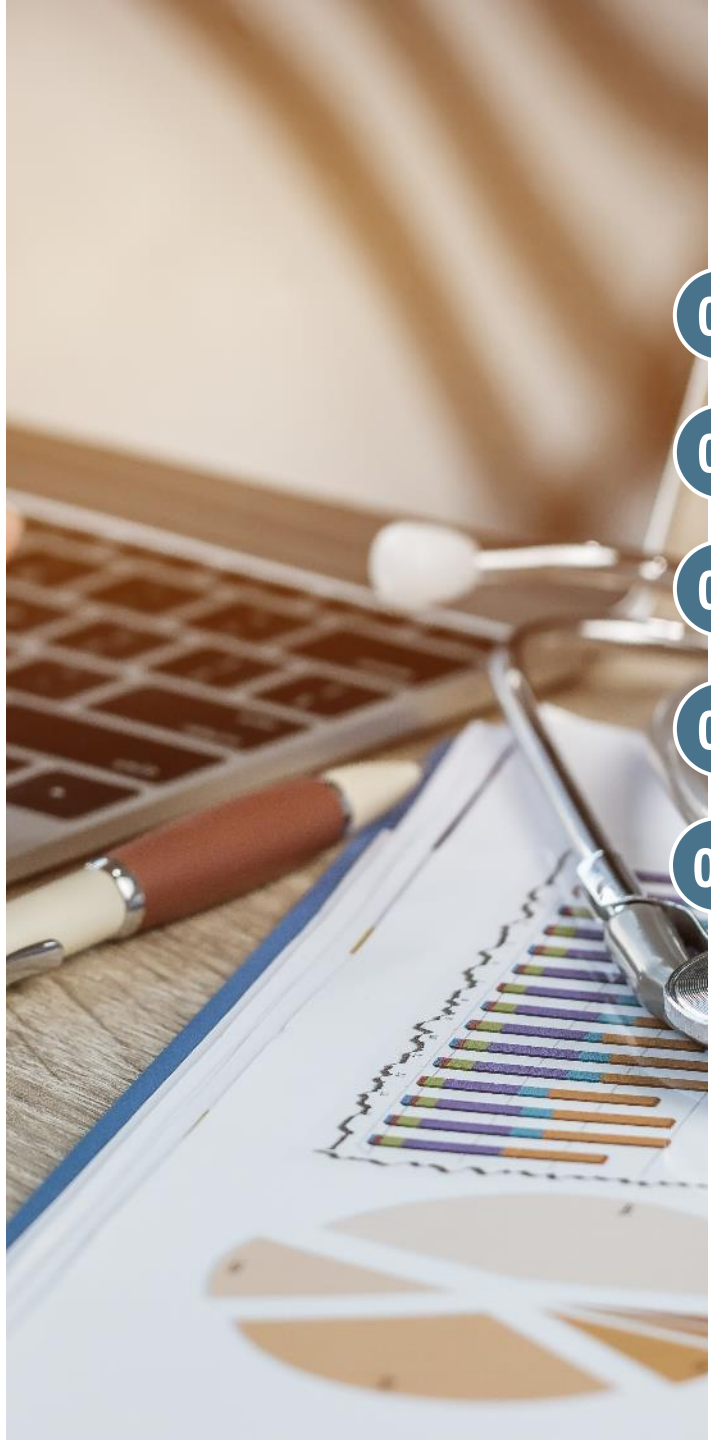
	TREATMENT A (N=XX)	TREATMENT B (N=XX)

BASELINE		
n	XX	XX
MEAN (SE)	XX.X (X.X)	XX.X (X.X)
SD	XX.X	XX.X
MEDIAN	XX.X	XX.X
95% CI	XX; XX	XX; XX
MIN; MAX	XX; XX	XX; XX
Q1; Q3	XX; XX	XX; XX

Study-specific TLF Mock Shell: Challenges



Agenda

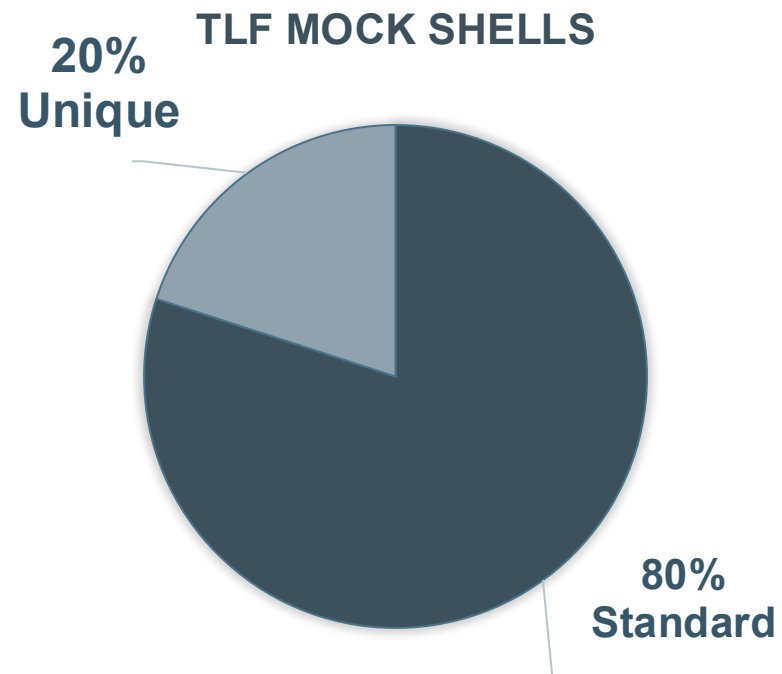
- 
- 01 Introduction
 - 02 Study-specific TLF Mock Shell
 - 03 **TLF Mock Shell Centralisation**
 - 04 Benefits of the Transition
 - 05 Conclusion

TLF Mock Shell Centralisation

An Alternative Approach

Improve efficiency without sacrificing quality

Rationale:



Central TLF Mock Shell Library

Version-controlled collection of standardised mock shells



User instructions



Standard layout and formatting specifications



Parameterised elements for study-specific inputs

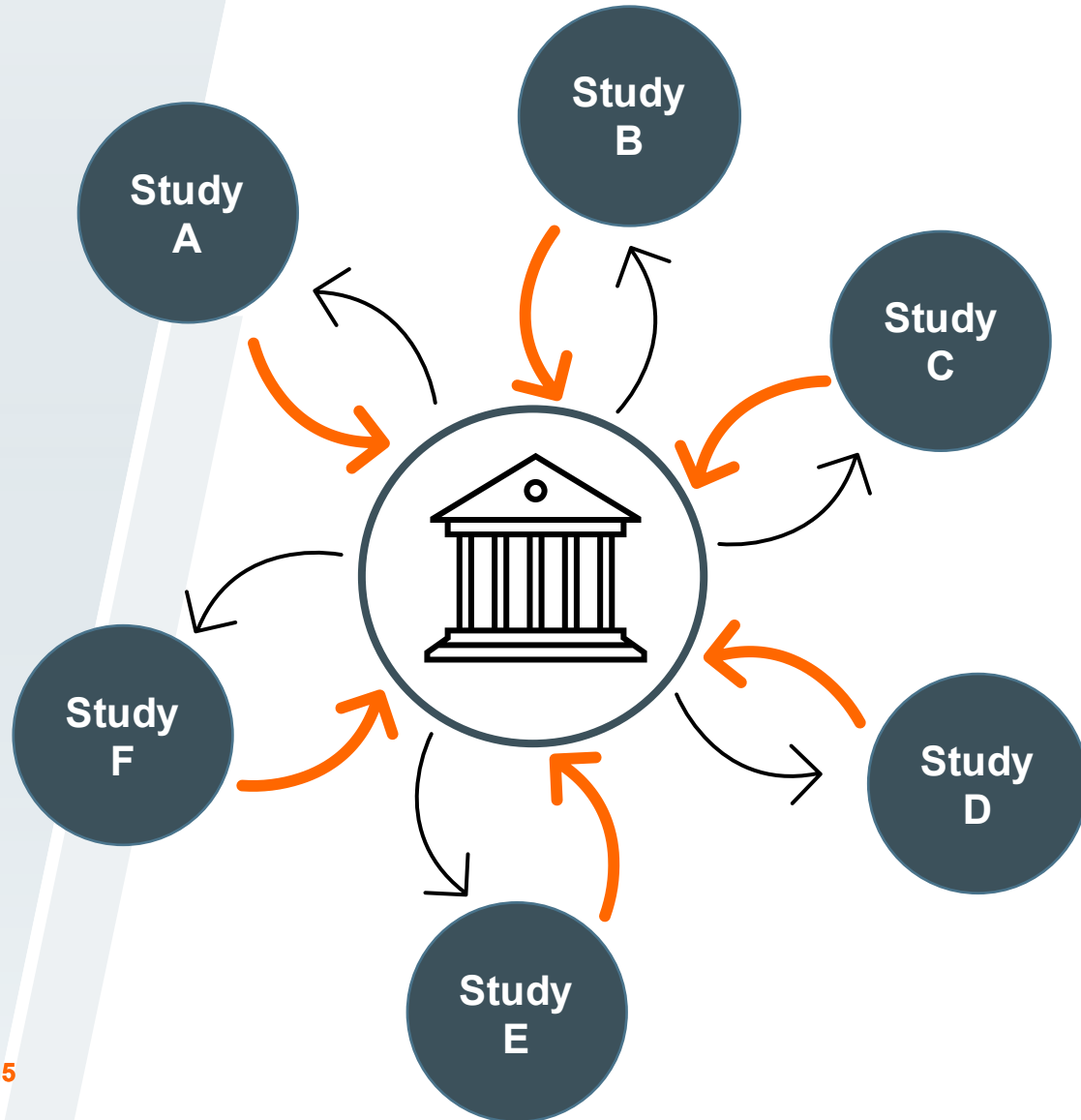


Therapeutic area and clinical phase agnostic



Coverage: disposition, demographics, AE, safety, PK, etc

Maintenance of the Central TLF Mock Shell Library



Version Control and Traceability

- Library admin
- Formal submission, review and version control for adding/retiring mock shell
- Collect user feedback continuously

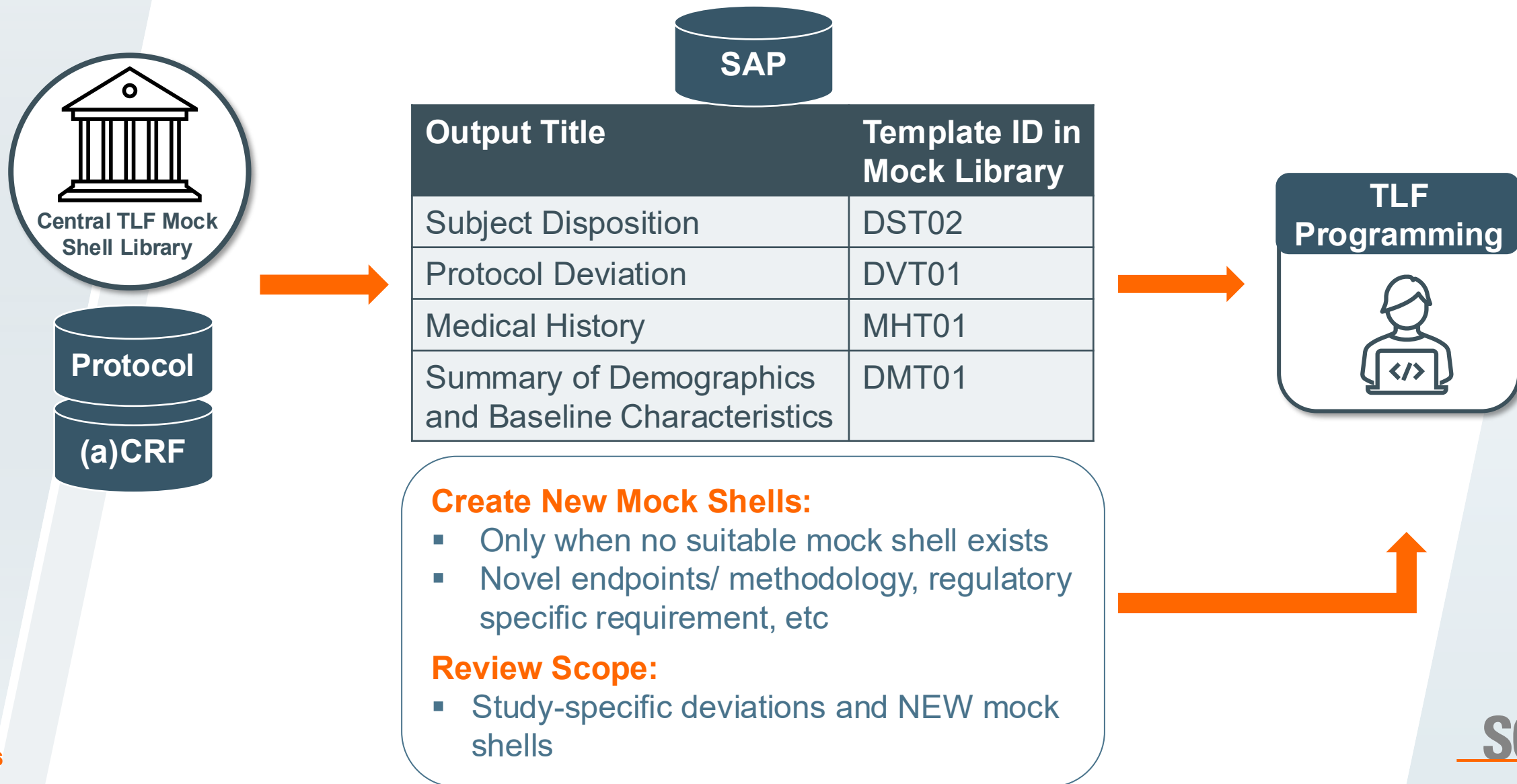


What deviates from the library?

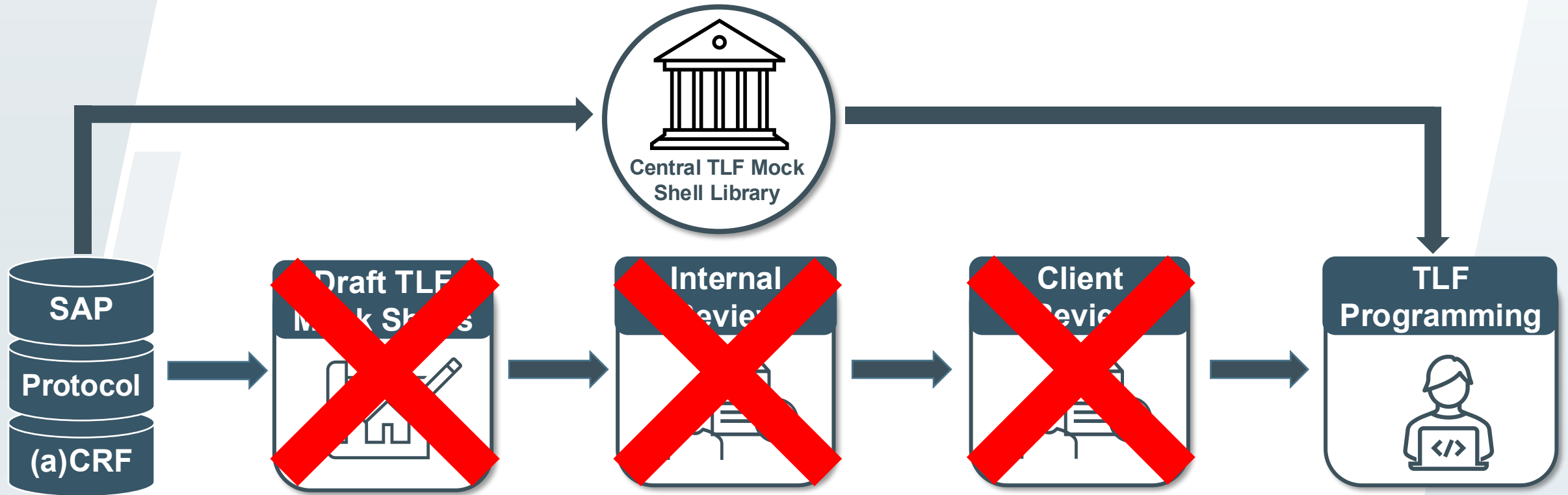


What can we add to the library?

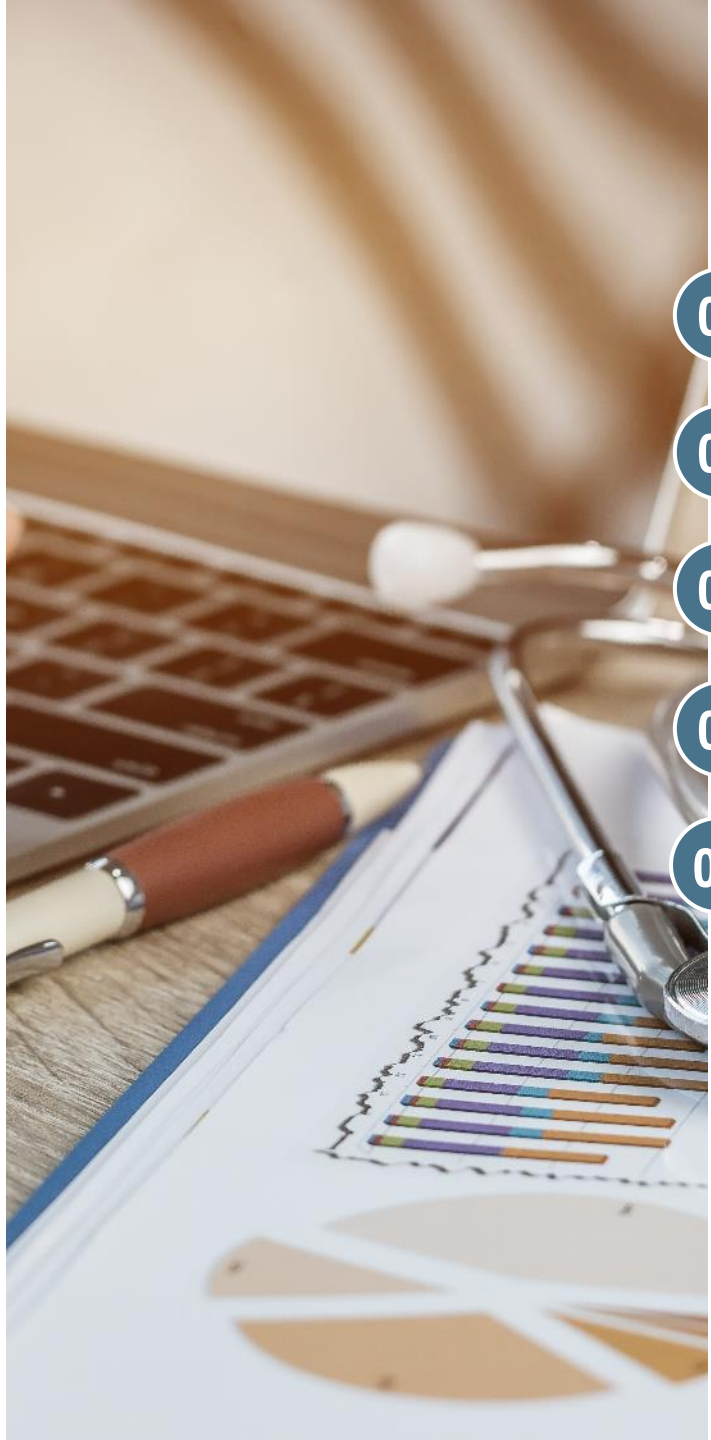
Using the Central TLF Mock Shell Library



Centralized TLF Mock Shell Library: Process



Agenda

- 
- 01 Introduction
 - 02 Study-specific TLF Mock Shell
 - 03 TLF Mock Shell Centralisation
 - 04 **Benefits of the Transition**
 - 05 Conclusion

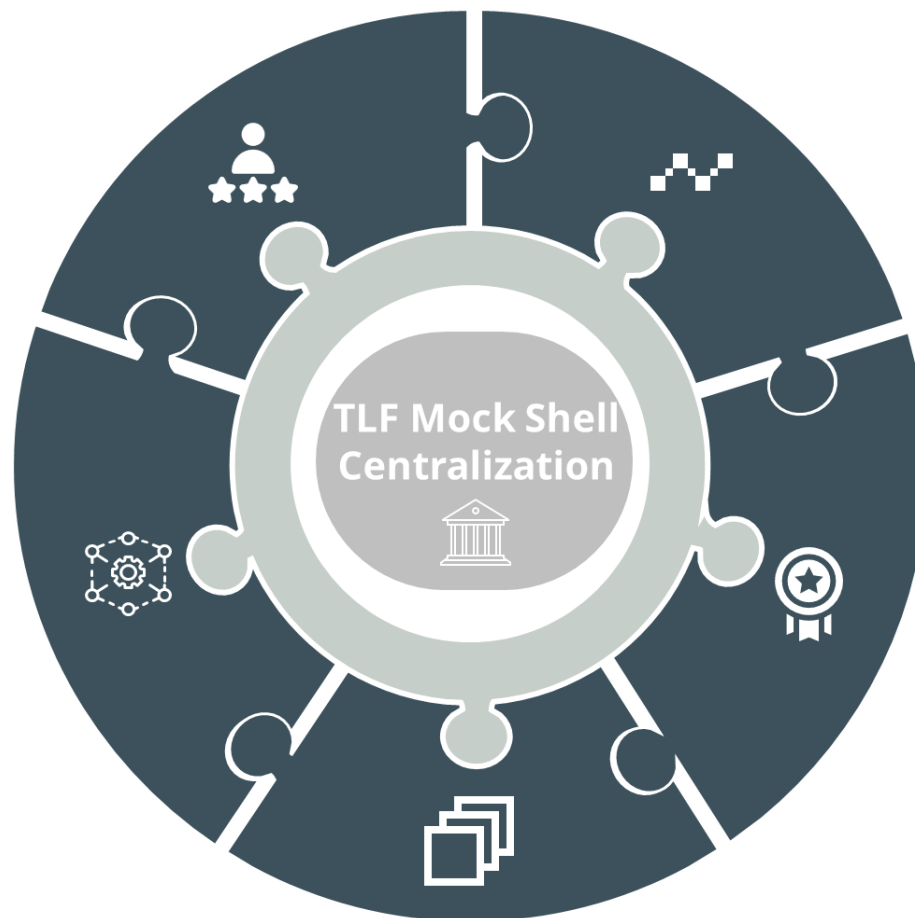
Benefits of TLF Mock Shell Centralisation

Satisfaction

- ✓ Clients: reduced review& consistent high quality
- ✓ Internal: less tedious work

Scalability

- ✓ Manage multiple studies with fewer resource
- ✓ Maintenance & version control of Central TLF Mock Library



Consistency Across Studies

Streamlined Process & Accelerated Timelines

- ✓ 90% time saved in mock shell creation
- ✓ Earlier programming onset

Ensured good quality

- ✓ Reflects best practices
- ✓ More time for analytical quality and study-specific nuances

Key to Success



Cross-client insight and extensive expertise



Standardisation with flexibility

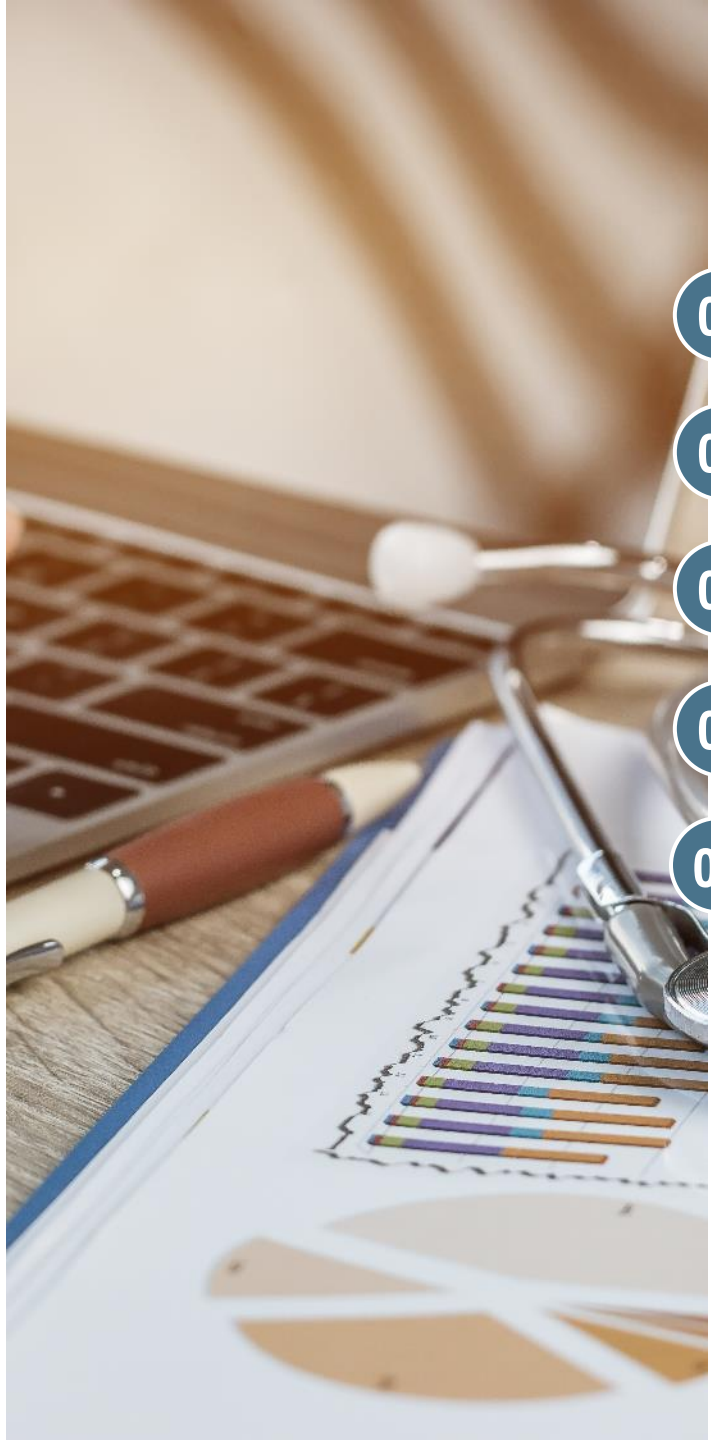


Recurrent internal trainings & feedback collection

- Template selection and parameterisation
- Correct translation and implementation from specs



Agenda

- 
- 01 Introduction
 - 02 Study-specific TLF Mock Shell
 - 03 TLF Mock Shell Centralisation
 - 04 Benefits of the Transition
 - 05 **Conclusion**

Conclusion

Conceptual shift with long-term gains:



➤ **Reduced budget**



➤ **Streamlined workflow**



➤ **High quality deliverables**



➤ **Increased user satisfaction**



Questions?

Contact us

Jie Yang
Biostatistician

✉ clinicalresearch@sgs.com

🌐 www.sgs.com/pharma

in sgs.com/linkedinpharma

👥 **Visit us at the SGS Booth**

