

DS07: Enhancing the standard utilization by creating a new pivotal role:

The Standards Implementation Lead

PHUSE EU Connect 2024

Marc-Antoine Prodhomme
David Parkinson
12 NOV 2024
Strasbourg

Johnson & Johnson
Innovative Medicine

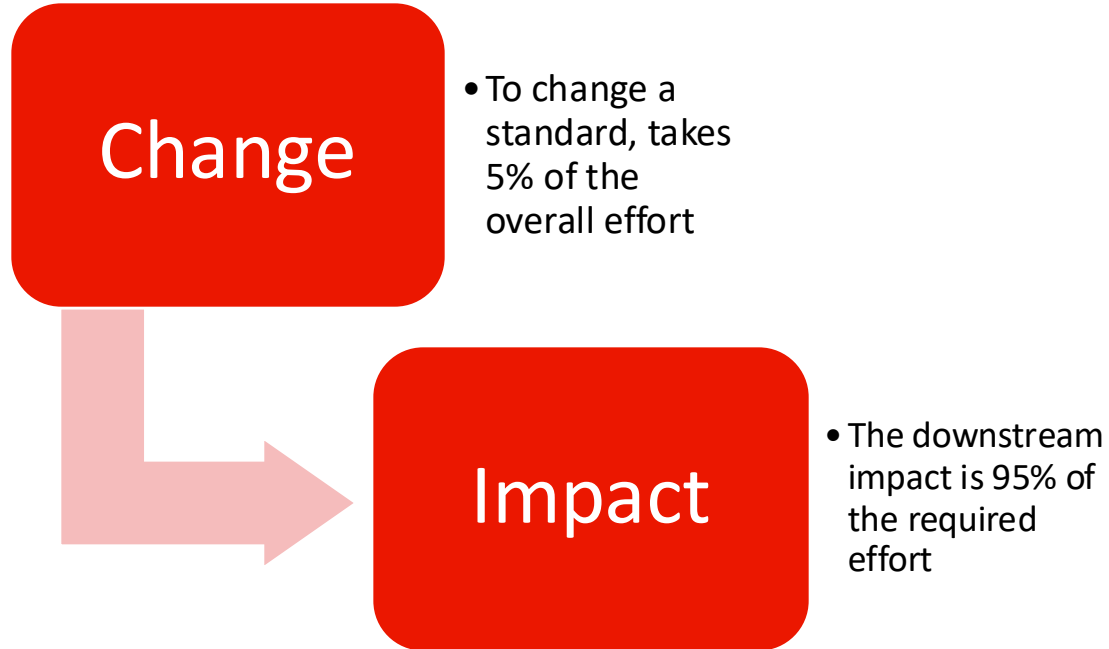


The opinions expressed are those of the authors and do not necessarily represent the opinions of PHUSE, members' respective companies or organizations, or the products' respective companies mentioned. It is the reader's responsibility to determine if and how change management would best suit their need. Additionally, the authors do not endorse any specific commercial products or services.

Introduction: Gap analysis and Enhancing Standards Utilization (ESU) project

Impact analysis

Deviation from the Standards has far-reaching knock-on effects for the lifetime of not only the study, but for any submission as well.



Changing the culture towards the use of standards

Changing from a passive to an active support model, will help ensure the right decisions are being made at the right time to drive more consistent & higher quality data throughout the portfolio.

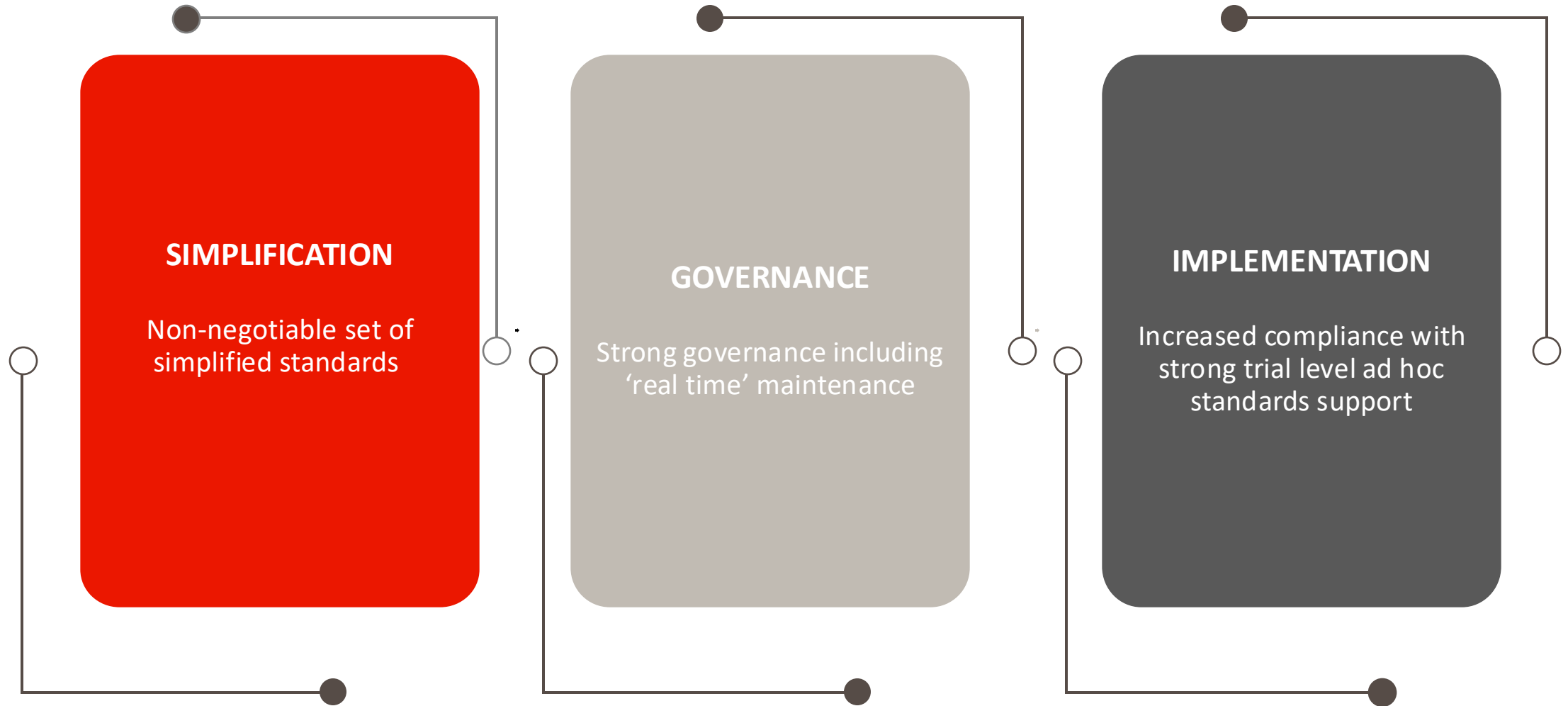


Why are we doing this now?

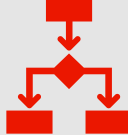


ESU Objectives

Increase return on investment of standards



ESU Project Recommendations

	 STANDARDS	 GOVERNANCE	 PEOPLE	 PROCESS	 TOOL
Past State	- High variability across TAs - Multiple legacy versions	- No mandate - Unclear governance - Inefficient change management process	Standards team disconnected from trial process	- Standards not embedded in trial set-up documentation - No strong compliance reporting	- No centralization - Weak version control - No metrics
ESU					
Current State	- Johnson & Johnson Connected Standards (JJCS) - Updated technical implementation	- Strong governance - New maintenance and change management process	New clinical data standards role embedded with trial team: Standards Implementation Lead (SIL)	- Inclusion of Standards Implementation Lead (SIL) - Compliance process for each component	- Controlled terminology tool - Baseline metrics and trial compliance dashboard

New supporting role:

The Standards Implementation Lead (SIL)



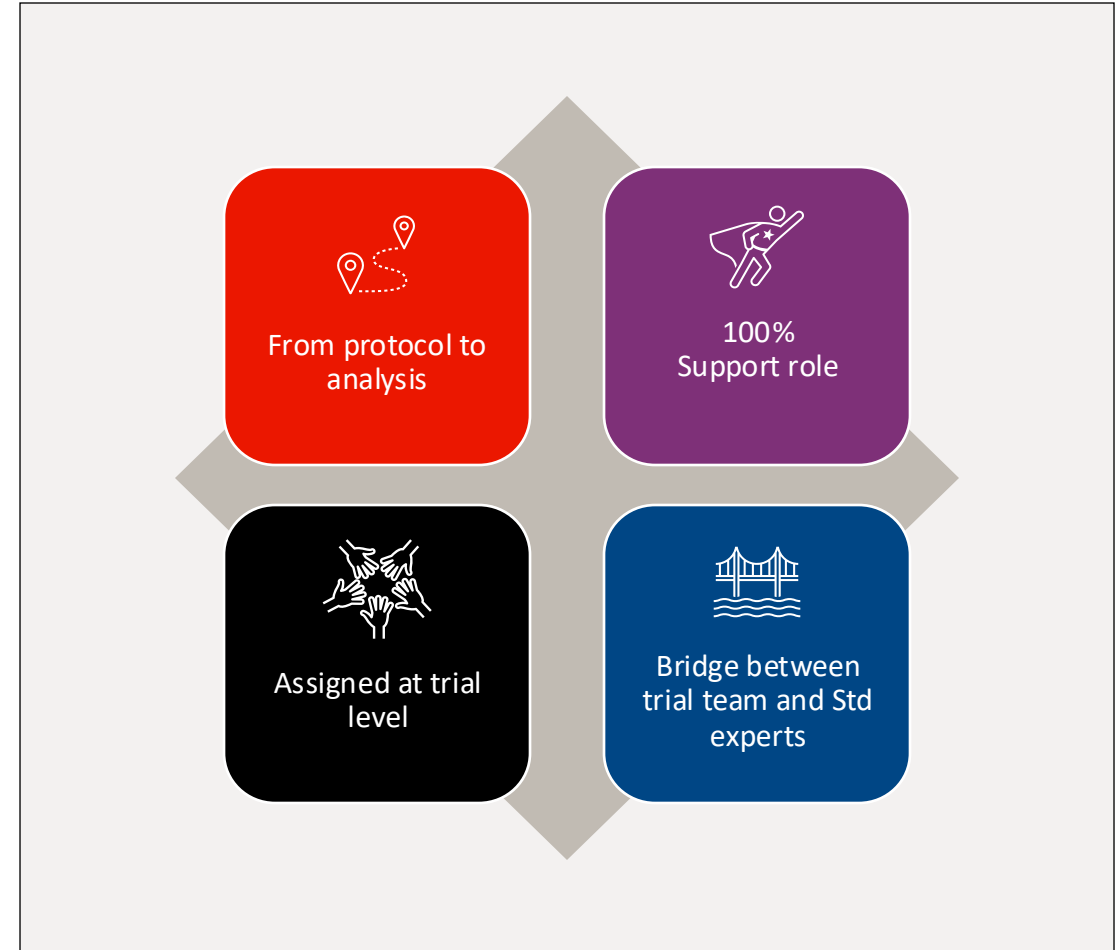
Connecting the study teams with standards

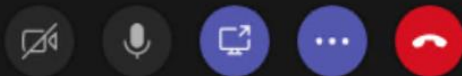
Ensuring correct use of J&J Connected Standards

- Evaluating adoption
- Increasing compliance
- Eliminating bad practices
- Reinforcing best practices

Promoting standards at study level

- Facilitating change request process
- Providing timely implementation guidance
- Connecting study team with the appropriate governance teams and standards experts
- Relieving other functions from the burden of standards expertise knowledge





Conclusion



Future



Monitor

Thank you

If you have more questions, please contact:

Marc-Antoine Prodhomme
mprodhom@its.jnj.com

David Parkinson
DParkin1@ITS.JNJ.com

Johnson & Johnson
Innovative Medicine