

Best Practices in Data Standards Implementation Governance



Project Scope
Best Practices in Data Standards Implementation Governance will cover the following areas: • Building and maintaining the contents of data standards repositories. • Extending data standards for individuals projects/studies. • Maintaining Sponsor extensions to data standards. • Scope of data standards governance: ◦ What areas should be covered by governance? (e.g. CRF, external data, tabulation, analysis, RWE, etc...). ◦ What should be governed centrally vs permitted on studies? • Feedback/communication to/with SDOs.

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Objectives & Deliverables	Timelines
Publish White Paper	Q4 2023
Potentially make updates to White Paper following PHUSE Steering Committee and Public Review feedback	Q3 2023

CURRENT STATUS	Q1 2024
• Finishing draft white paper and sending for PHUSE/public reviews	