SEND Readiness

Challenges and Opportunities for Sponsors

PhUSE Single-Day Event

Building High-quality
e-Data Submissions for
FDA Review

December 2, 2015

Sandor Schoichet
Director, Meridian Management Consultants

(415) 828-1302
sschoichet@meridianmc.com

SEND Compliance Objectives

SEND compliance should involve more than implementing a new data format

- Building sponsor-owned integrated study data repositories
- Improving end-to-end data quality and consistency across all study data sources, and between SEND datasets and traditional Study Reports
- Streamlining submission of validated data sets and documentation to FDA
- Providing new data analysis and review tools to keep up with FDA Reviewers … and improve internal cross-study data accessibility
- Implementing new business processes within both sponsors and CROs to cover all of the above

SEND implementation is a strategic opportunity, not just an FDA mandate

Vision

- Sponsors need a shared vision for how SEND implementation will improve their R&D operations

New Sponsor Requirements

CROs can't implement all SEND compliance requirements, even for sponsors outsourcing 100% of their non-clinical studies

- Design, documentation, and validation of the SEND data model must be integrated into study plans, budgets, and contracts
- Specifications for the integrated SEND data model must be coordinated across internal labs and external CROs
- Consistency between SEND datasets and traditional study reports must be actively managed
- Sponsors now responsible for managing a GLP / 21CFR Part 11 non-clinical data repository, even if it's virtual
- Study teams must learn new analytic tools to validate data submissions and interact effectively with FDA reviewers
- SEND data management and submission processes must track ongoing evolution of requirements and specifications

New elements of the sponsor's study workflow

- Mapping internal LIMS data extracts to SEND data model
- Integrating external CRO datasets
- Dataset versioning and error handling
- Validation and submission of integrated datasets to FDA
- Creating Define Files, Validation Reports, and Study Data Review Guides
- Coordinated response to FDA queries across Study Reports and SEND datasets

SEND Implementation Challenges

SEND implementation is more complex and time consuming than most sponsors expect!

- Need an empowered business process owner and supporting governance model
- Stakeholder education and engagement is required at the Study, Program, and business management levels
- Coordination and planning with CROs
- Adequate implementation, training, and testing resources in the face of competing priorities
- FDA submission process validation across the data custody chain requires ~3-6 test study submissions to exercise
- Concern over premature FDA Kick-Start test submissions … but FDA likely to become less responsive by late 2016
- Current annual budget planning cycle is in the middle of the SEND test submissions window … next year is too late!

Sponsors need an integrated vision for SEND compliance now, in order to budget critical resources for 2016

SEND stakeholders

- Senior management (project portfolio and budgeting)
- Study Directors and Program Managers.
- Non-clinical Tox and Safety
- Non-clinical Data Mgmt., Monitors, and Biostatistics (study design, data collection and analysis)
- Internal labs
- External CROs and CRO Outsourcing group
- Regulatory (compliance, operations, FDA liaison)
- IT (repository compliance, communications)
- QA/QC
- Operations Excellence

SEND Implementation Opportunities

New data standards and software allow major improvements in non-clinical study workflow

- Improved “R&D ROI” through better end-to-end data QA, management, and accessibility
- Match FDA analysis capabilities for smooth submission review communications
- Provide new analysis, visualization, and cross-study comparison capabilities for toxicology, safety, PKD, …
- Facilitate lab and CRO collaborations through up-front Study Data Specification
- Generate tables for the Study Team directly from the SEND repository, providing a ‘single source of truth’
- Potential to reduce overall study costs through more efficient and automated operations

Potential efficiencies

- Higher initial data quality
- Fewer protocol amendments
- Early access to interim datasets
- Automated dataset integration and versioning
- Automated study table generation
- Expedited FDA review
- Faster response to review questions

SEND Implementation Timeline

FDA mandated compliance deadlines are closer than they appear …

- *Now* is the time to create a positive vision for SEND implementation to drive 2016 objectives and budget
- Objectives for 2016 should include business process definition, systems implementation, and end-to-end data quality from CROs to FDA

You're not alone

- FDA concerned about Kick-Start resource availability as deadlines approach
- CROs and vendors must support multiple sponsors

Pro Forma Timeline