Cross-functional Standards Governance for Pharma

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PhUSE 2017
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Cross-functional Standards Governance for Pharma

Agenda

– The challenge
– Examples
– A modernised approach
Standards Governance for global industry standards

The challenge
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The challenge

- Behaviours
- Monitoring

- Resource
- Cost

- Documentation
- Focus groups

- Engagement
- Education

Managing Change

Process

Impact / Readiness

Systems

Transition

Leaders / Sponsorship

Training / Support

Communication

Partners
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The challenge
Cross-functional implementation challenges for global standards

Examples
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Examples

- Stats & Programming
- Data management
- Clinical Dictionaries
- Systems / IT
- Trial Summary for legacy studies
- Clinical Operations
- Pharmacokinetics
- Regulatory Operations
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Examples

Stats & Programming
Data management
Clinical Dictionaries
Systems / IT
Pharmacokinetics
PK Terminology
Clinical Operations
Regulatory Operations

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Examples

- Stats & Programming
- Data management
- Clinical Dictionaries
- Systems / IT
- WHO-DD adoption (PMDA and FDA)
- Pharmaco-kinetics
- Clinical Operations
- Regulatory Operations
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Examples

- Stats & Programming
- Data management
- Clinical Dictionaries
- Systems / IT
- Pharmaco-kinetics
- Clinical Operations
- Regulatory Operations
- RACE coding
An updated approach to cross-functional standards governance
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A modernised approach
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Clinical Data Standards – Board & Advisory Committee

Clinical Data Standards Board
- Define principles
- Drive and monitor compliance
- Communicate / Advocate / Engage
- Sponsor work streams

Corporate Governance

Standards lifecycle decisions

Proposals Issues Escalations

Implementation plans Communications Principles Decisions

Clinical Data Standards Advisory Committee

STANDARDS TEAMS

FUNCTIONS

Intelligence on industry standards and regulatory requirements Proposals
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Clinical Data Standards - Advisory Committee

- Clinical Data Standards Advisory Committee
  - Triage
  - Track
  - Assess

- Clinical Data Standards Board
- Stakeholders

- Functional reps / accountable persons
- Functional teams

- Industry standards & teams

- PROPOSALS
- UPDATES

- ISSUE TRACKING / SUPPORT

- INPUT / INFLUENCE
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Every company should have a standards catalogue

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*Business users as 1st line support and content developers*

![Diagram showing the process of cross-functional standards governance in the Pharma industry]

- **Business rep**
- **Content ownership**
- **1st line support**
- **Content review/discussion**
- **Planning**
- **Content curation**
- **End user**
- **Content store**

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In summary

– The adoption of global industry standards has increased the complexity and impact of change management related to the implementation of new standards, versions and content. In particular, the likelihood of impacts on process and technology, and wider cross-functional organization is increased.

– A more evolved structure for standards curation and governance is recommended, through significantly increased engagement with cross-functional business users which enhances the flow of information between external sources, internal standards teams and end users, and helps drive standards content development.

– The use of a standards catalogue within a company is highly recommended as a mechanism to ensure clear line of sight for all staff.

– Two levels of governance are recommended;
  – a Board which is responsible for approval of general operating principles and new work efforts, and enabling of resource, as well as advocacy and risk management.
  – an Advisory Committee which is responsible for tracking and managing the company standards, identifying the need for remediation, and defining and planning updates to the standards as appropriate.
Thank you. Questions?