Cross Functional Standards Governance for Pharma

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Introduction

Global industry standards adoption by sponsor companies and CROs has been driven by practical needs and operational benefit within those individual organisations. Companies have been able to pick and choose in terms of the standards which they utilize, and when and how to adopt new versions as they are released.

Key regulatory agencies (most notably the FDA and PMDA) are now requiring a wide range of clinical data standards within drug submissions, and along with other data sharing and reuse benefits these are driving the adoption of industry standards at a previously unprecedented scale.

These environmental changes have created a new and unmet need in curation of the standards content, development of adoption strategies, and governance, decision making and resource management within individual companies.

Managing the Change
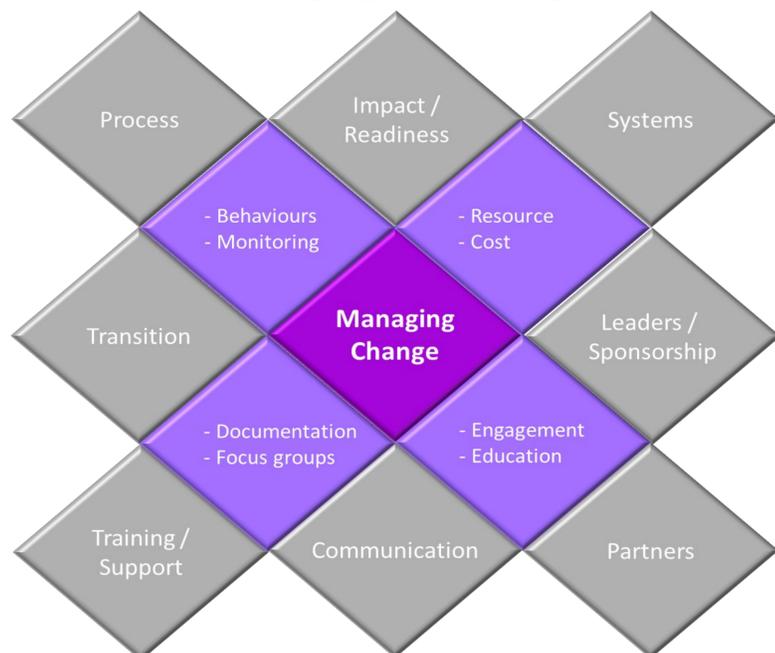
A difficulty created by a more matrix-based approach to the standards intelligence and governance is the need for cross-functional mechanisms to share and collate relevant information and drive change initiatives. It is not adequate to simply extend the approach to standards governance traditionally contained within a data standards organisation, as the impacts often reach beyond the data standards themselves (e.g. impacts on systems, processes, up and downstream impacts on other functions).

In addressing emergent standards or regulatory requirements, it can be challenging to get engagement from cross-functional partners early enough to enable change, particularly where the changes required impact systems and/or processes, and therefore often have a significant resource impact on the business.

A further challenge for sponsor companies and CROs is the difficulties involved in maintaining a common pace of adoption. It is complex for sponsor companies to get third party suppliers to transition at the same rate, and even more complex for CROs to navigate the differing rates of adoption of their clients.

Historical Approach

Prior to the regulatory adoption of global clinical data standards e.g. CDISC, sponsor companies and CROs were able to maintain a simple model for the governance and curation of standards.

- No formal requirement for compliance which allowed a more flexible approach to standards development and implementation.

- Core standards were largely handled within companies by a central Data Standards organization, responsible for the production and maintenance of the standards.
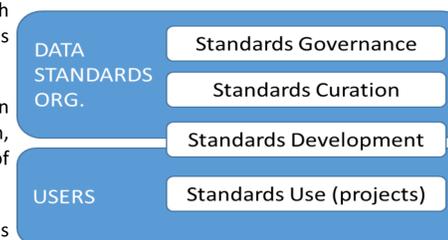

The result, a "top-down" approach to standards implementation, with the users acting as consumers of the standards, and the data standards organization having a reasonable amount of autonomy in terms of the implementation of the sponsor standards.

Differences

The use of global standards on the regulatory pathway requires a diversified approach to standards development, and governance for adopters.

- Adherence at the point of delivery whereas in-house standards could accommodate more flexibility at the point of use.

- Absorption of new content and guidance from global standards teams demands a high level of external engagement.

- Representation from their business on external standards teams, as this ensures optimised knowledge transfer in both directions.
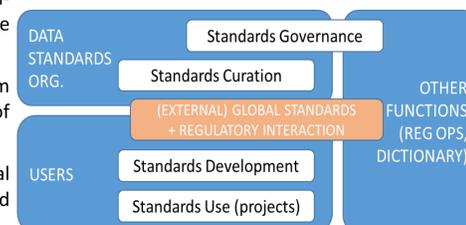
There is a need for more connected intelligence between the standards and regulatory teams in order to prioritise, manage criticality of updates and generate appropriate change efforts.

A Modernised Approach
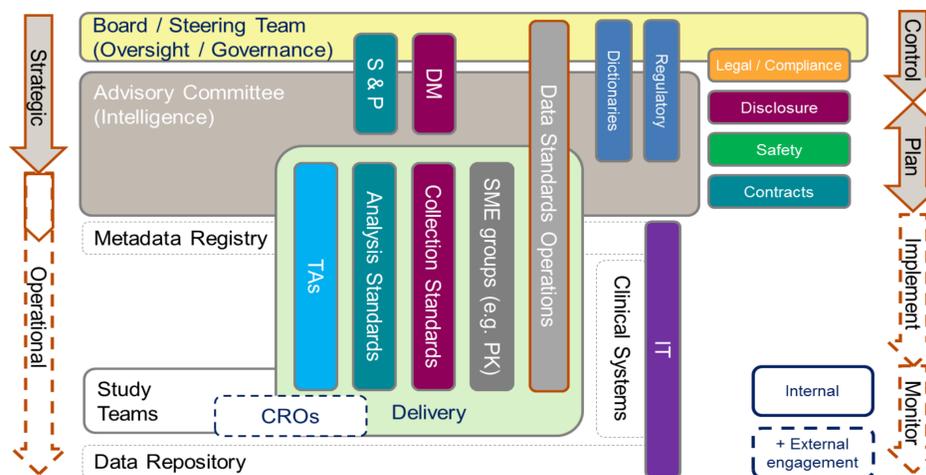
In order to facilitate the ongoing change within a large cross-functional organisation, a modernised approach to standards control is required, which addresses the many functional layers and management levels at which governance and oversight is required, from detailed content management through to senior stakeholder engagement. A possible solution is to:

- Ensure Standards Governance decisions are made within a governance body with appropriate functional representation

- An Advisory Committee to collate, assess and prioritise new information as it emerges

- Maintain a Clinical Data Standards Catalogue this allows a company to track internal status of standards, release dates, requirement dates for specific regulatory regions, impacted systems / processes & stakeholder mapping

However, as the need for adherence at the point of delivery increases, so the role of the end user in defining the useable implementation of standards becomes far more critical. Data designs must be fit for purpose and this is best facilitated by having end-users directly responsible for the development of content.
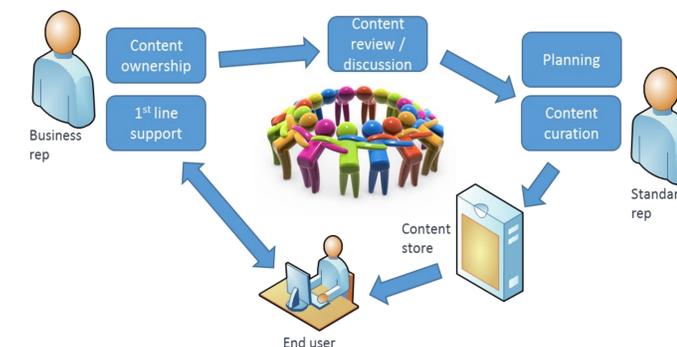
This model is particularly effective as it provides a high level of integration with business functions, allows business users to act as external reps to facilitate the flow of information between external and internal standards teams and project-facing business groups.

Recommendations

For sponsor companies and CROs, 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. To address these challenges, some recommendations are:

- A more evolved structure for standards curation and governance to ensure proactive and efficient handling of emergent standards and regulatory requirements.

- Increased engagement with cross-functional business users which enhances the flow of information between external sources, internal standards teams and end users.

- Engagement of end users from the business to drive standards content development.

- The use of a standards catalogue within a company

- Two levels of governance : a Board responsible for approval of general operating principles and new work efforts, and enabling of resource, and an Advisory Committee for tracking and managing the company standards, identifying the need for remediation, and defining and planning updates to the standards as appropriate.