

Cross functional standards governance for pharma

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ABSTRACT

The regulatory and standards environment for clinical research continue to expand and evolve, putting increasing pressure on sponsor companies and vendors to navigate and manage internal and global standards content for consumption within their business process.

Over the past few years, GSK has adapted its standards governance process to reflect the need for increased flexibility and responsiveness in the management and governance of clinical data standards.

We will discuss the structures GSK has put in place to provide the connectivity between day-to-day curation of the standards content, intelligence and development of adoption strategies, and governance, decision making and resource management. We will discuss how proposals and information are captured, triaged and escalated from individual standards teams, and how this is tracked and shared with the business.

INTRODUCTION

Until recently, 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, intelligence and development of adoption strategies, and governance, decision making and resource management within individual companies. This paper discusses this need and investigates potential governance mechanisms to support it.

THE PROBLEM - EVOLVING DATA STANDARDS GOVERNANCE NEEDS

The benefits of global adoption of industry standards are well understood and have been the topic of many previous publications. Whereas in the past, global standards have been leveraged by companies to help achieve interoperability and common interpretation, and drive efficiency, the emergence of regulatory expectations around the use of industry standards has driven a need for a far fuller and complete adoption of these standards, and with it a far deeper understanding of these standards is required across the business.

Even as global industry standards become more complete and stable, the rate of change is still rapid and continuous, including e.g. the introduction of new domains or classes, and the ever-growing terminology set. Despite the intentions of standards development organisations (SDOs) to develop commonly understood standards, considerable implementation decisions are still required within adopting companies, and these decisions often require an intimate knowledge of both the data and the standards themselves.

It is widely recognized that different companies are travelling significantly different trajectories in terms of standards adoption. In the case of CDISC standards, some companies have set out to implement beginning-to-end (B2E) standards from the outset, whereas others have limited the set to SDTM and ADaM (i.e. not including CDASH). Furthermore, the rate of adoption of new standards (e.g. versions of SDTM) varies substantially between companies, with the result that companies are working with different versions across the industry. Even if companies were able to

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better align, there remains the challenge created by the existence of older studies which may continue to use older versions or even legacy sponsor standards.

These variations are compounded by similar variations and further divergence within regulatory agencies. The main impact is that companies must cover a superset of requirements in a way which (ideally) allows them to support multiple regulatory pathways with the same data.

HISTORICAL APPROACH TO STANDARDS GOVERNANCE

Prior to the regulatory adoption of global clinical data standards such as CDISC, sponsor companies and CROs were able to maintain a relatively simple model for the governance and curation of standards within their companies. While

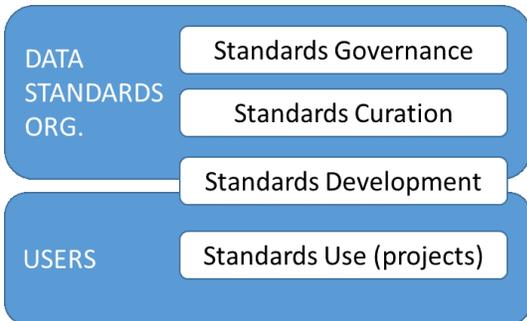


Figure 1: (Simplified) standards adoption for company internal standards

global standards could be referenced or included in the standards set, there was no formal requirement for compliance which allowed a more flexible approach to standards development and implementation.

In the case of core standards, this was largely handled within companies by a central Data Standards organization, responsible for the production and maintenance of the standards, with input from the business community as required. The result is essentially a “top-down” approach to standards implementation, with the users primarily acting in a role 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 which are mandated on the regulatory pathway requires a more diversified approach to standards development, and governance for adopters. A fundamental difference in the application of global standards within a company is the need for complete adherence at the point of delivery (i.e. use on a study), whereas in-house standards could accommodate more flex at the point of use. While global industry standards such as CDISC continue to grow and evolve, a significant amount of sponsor-specific decisions are required in order to define complete standards. An impact of these factors is a need for end-users to be much more directly involved with the design and implementation of the standards, in order to ensure standards are adopted in a way which ensures practicality of use.

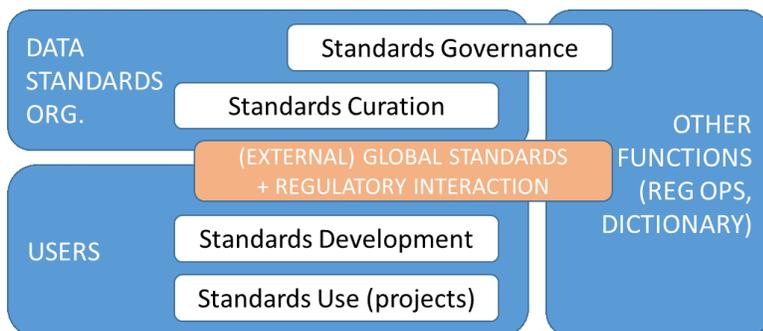


Figure 2: Standards governance and development needs may be different for global industry standards

The absorption of new content, guidance, and other information coming from global standards teams demands a high level of external engagement. Practically, it is beneficial for implementers to ensure representation from their business users on external standards teams, as this ensures optimised knowledge transfer in both directions.

Furthermore, there is a need for more connected intelligence between the standards and regulatory-facing personnel in order to attribute priority and criticality of updates and generate appropriate change efforts.

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CHALLENGES

A difficulty created by a more matrix-based approach to the standards intelligence and governance is the need within a company 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. There is a risk of localised solutions, leading to disconnects between systems and processes, and further slowing the rate of change.

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.

A MODERNISED APPROACH TO STANDARDS GOVERNANCE

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. In meeting these needs, it is important to recognise that the individuals who ultimately enable resource and approve significant change efforts (i.e. senior stakeholders) are not the same individuals who are immersed in the day-to-day use and implementation of the standards. Whereas internal standards could to some degree flex to accommodate the process and technology needs around them, the requirement for compliance with external standards leads to the need for systems and processes to adapt around them. Given the rate and depth of change within the standards and regulatory space, external and internal information must be filtered and triaged in such a way that allows intelligence and business proposals to be appropriately prioritised.

EXTERNAL STANDARDS IMPLEMENTATION REQUIRES ONGOING RESOURCE AND DECISION-MAKING

As discussed above, the regulatory requirements around industry standards have enforced the need for adopting organisations to have more proactive implementation strategies, in some cases facilitating process or systems change. The result is that project-facing business functions (in particular Data Management, Stats & Programming and Regulatory Operations functions) may be much more directly and heavily impacted by content changes, even those that on the surface may seem fairly innocuous.

A solution is to ensure that Standards Governance decisions are made within a governance body with appropriate functional representation (a Governance Board). Such a board should minimally include representation from Data Standards, Data Management, Stats & Programming, Regulatory Operations and Dictionary/Coding functions. At GSK, the remit of the “Clinical Data Standards Board” is to;

- Drive momentum for change across business functions
- Ratify proposals, and appropriately enable resources
- Define operating principles
- Drive and monitor compliance
- Manage risk

Not all topics fit neatly – some require regional input, or escalation to higher business approval processes. Other topics may be better discussed within a smaller subset of the board. Care must be taken in selecting which topics are passed through the board, in order to achieve a balance between broad awareness and input, and efficiency. To meet this goal, a smaller group of core members meet to review topics and assess fitness for review by the board, and in some cases alternative mechanisms are identified to progress a topic.

CROSS-FUNCTIONAL INTELLIGENCE SHARING AND EXTERNAL INFLUENCE IS NEEDED

While the presence of a Governance Board ensures that the wider business can be appropriately leveraged, a mechanism is required to ensure that the expanse of new external information and internal developments can be appropriately filtered and condensed for consumption, both by the Board and the wider business. This demands input from contributors from across the business who are appropriately externally and internally engaged to be aware of upcoming change. These individuals need to be able to meet, share and triage information and develop proposals and recommendations for consumption by the Governance Board.

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Within GSK, we have set up a “Clinical Data Standards Advisory Committee”, whose remit, on behalf of the Clinical Data Standards Board, is to;

- Triage and track emergent changes in standards and regulatory environment
- Facilitate cross-functional awareness and input
- Assess impact of changes on business systems and processes
- Develop proposals and recommendations for implementation of change initiatives
- Facilitate feedback to external teams

The Advisory Committee collates, assesses and prioritises new information as it emerges, resulting in action in one of three categories;

- Watch (i.e. set a schedule for review)
- Communicate (either upwards or downwards as needed),
- Develop (either Proposal or Recommendation as appropriate to the topic)

Proposals and recommendations are then passed up to the Board (where there is a significant cross-functional impact) or taken up within individual functions as appropriate.

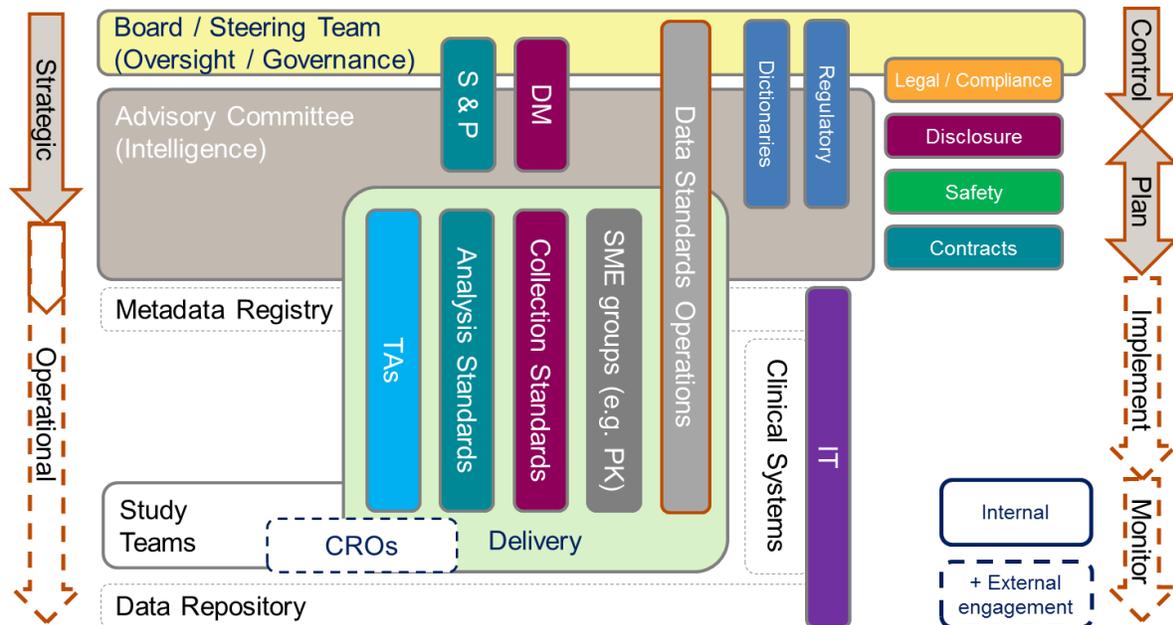


Figure 3: A modernised standards governance structure

EVERY COMPANY SHOULD HAVE A DATA STANDARDS CATALOGUE

An unfortunate reality of global industry standards is that adoption of new content is typically not instantaneous nor synchronous across the industry. Once content, versions or complete new standards are released, regulators and the wider industry must assess the impact of adoption and plan as necessary. The result is that regulators and sponsor companies are operating on different adoption schedules.

This situation can create a significant challenge in terms of ensuring clear transparency and line-of-sight for end-users of key information relating to the status and ownership of primary standards within the company. In order to address this, it is beneficial to be able to track this information centrally, to allow users to easily see the status of these standards internally and externally.

A simple way of achieving this is to centrally maintain a Clinical Data Standards Catalogue. A catalogue of this nature allows a company to track the following information;

- Internal status of standards (and specific versions of those standards)
- External and internal owner(s)

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- Release dates (planned/actual) (global/internal) (draft/final)
- Requirement dates for specific regulatory regions
- Impacted systems/processes
- Stakeholder mapping

The Catalogue might be managed by appropriate Data Standards Leads or directly by the Clinical Data Standards Advisory Committee, and thus updated with new information from external sources as it becomes available. In order to ensure effectiveness of this approach, those responsible for the catalogue must be closely connected with external industry activities and/or be adequately connected with other staff who

END USERS AS CONTENT DEVELOPERS FACILITATES COMMUNICATION INTERNALLY AND EXTERNALLY

One reaction to the emergence of widely-adopted industry standards is that the industry at large is beginning to look to technologies (i.e. metadata registries) as a means to centrally manage beginning-to-end standards content within their individual organisations and even to share content beyond their walls. An implication of this is that it may seem intuitive that beginning-to-end content development should also become more central.

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.

A model which has proved to be effective is to have a team of users representing the different business units (e.g. therapeutic teams), led and overseen by one or more standards experts acting in the role as standards lead. In this model, user representatives can fulfil 3 key responsibilities;

- Content ownership for one or more topics (e.g. domains)
- Primary contact and representative on behalf of their business unit (e.g. TA)
- Contribution to general discussion and review

Standards leads (i.e. staff whose direct responsibility is for the curation and oversight of the standards) are responsible for planning and tracking required updates, leading meetings and the general curation of the standards within the metadata content store.

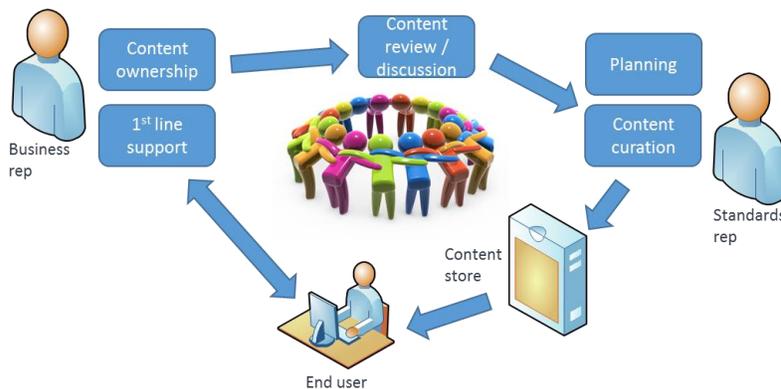


Figure 4: Business reps as content owners

This model is particularly effective as it provides a high level of integration with the business functions, and allows business users to act as external reps in a way which facilitates the flow of information between external and internal standards teams and project-facing business groups. The individual contributors in this model serve as excellent content developers, as they are able to use their past and current experience to develop designs which both meet the requirements of the standards as well as optimally addressing the functional needs for their business unit.

CONCLUSION

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. In particular, the likelihood of impacts on process and technology, and wider cross-functional organization is increased.

To address these challenges, a more evolved structure for standards curation and governance is recommended, to ensure proactive and efficient handling of emergent standards and regulatory requirements. Central to this approach

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

To facilitate this, the engagement of end users from the business to drive standards content development and the assimilation of information from external teams is suggested as a means of ensuring compliant and functionally optimized solutions.

Keeping track of the many standards and associated versions which are active within a company is not straightforward, and it is difficult for end users to keep on top of this changing information. 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, and 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.

CONTACT INFORMATION

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