Accenture Accelerated R&D Services
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CDISC Standards:
A Catalyst for Industry Transformation

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Introduction

Pharmaceutical companies are focused on implementing CDISC data standards\(^1\), primarily to ensure compliance with Food and Drug Administration (FDA) mandates that go into effect December 2016. The new mandates require that clinical trial data be compiled and submitted in forms that are accurate, reliable and reproducible. In addition to compliance, most companies agree that data standards will also deliver potential commercial and operational benefits, allowing more efficient sharing of clinical information among pharmaceutical, bioscience and medical device companies; clinical services organizations; and technology developers—all of which will speed time to market of new products. In fact, CDISC research found that standardizing data and use of eSubmissions would, on average, save a company $180M per submission (18 percent of the total cost), and two years in the typical clinical development program lifecycle\(^2\).

Despite these potential benefits, standards adoption has been slow and fraught with barriers. For example, while nearly a quarter (23 percent) of companies surveyed has used standards in the last six to 10 years (preliminary FDA guidance on data standards was released in 1999), a larger percentage (36 percent) moved toward adopting standards only in the last three to five years. Beyond agreeing on the data attributes (e.g., format, nomenclature, content and structure), data standards pose a challenge for companies given the:

- Diversity of functions and data repositories involved in effective data management, and;
- Need to transition from proprietary data systems and constructs.

Nonetheless, the FDA deadline looms large, as do similar requirements under consideration by the European Medicines Agency (EMA) and Japan’s Pharmaceuticals and Medical Device Agency (PMDA). Companies no longer have the luxury of time; they must find ways of overcoming barriers and expediting adoption of data standardization. For these reasons, Accenture conducted a survey of executives at life sciences organizations to explore various dimensions of clinical data standards implementation (see sidebar, About the Survey). Important areas explored in the survey consist of:

- Industry impact of CDISC (Clinical Data Standards Interchange Consortium) standards, including potential benefits and barriers.
- The challenges of metadata management generally, consisting of governance and infrastructure.
- The utility of a data standards maturity model, and how it could spur faster, higher rates of adoption of data standards.

The overall picture that emerged is an industry embracing data standardization more quickly than in the past, yet still wrestling with many implementation challenges that will require organizational changes to reap the potential benefits of standardization efforts.

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1. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and free.
Important Survey Findings on Data Standardization

Beyond the challenge of migrating or mapping proprietary data to CDISC standards, top challenges identified by respondents included the need to train people to implement standards, put in place management processes to ensure compliance with the new standards, and develop governance structures to ensure value capture impose significant demands on already stretched resources.

Nonetheless, given the regulatory mandate to adopt data standards, the issues are how best to implement standards and capture the potential benefits of facilitating data exchange with regulatory and business partners and reducing development cycles. Important findings consist of:

- **Agreement on business importance and drivers of standards.** The vast majority of respondents (94 percent) cited regulatory compliance as the most important current reason for adopting data standards, while a slightly smaller percentage (88 percent) believe CDISC standards will be important to maintain compliance over the long run. Of the respondents 94 percent currently submit to the FDA, 76 percent to the EMA, and 54 percent to the PDMA. While regulatory compliance is far and away the primary driver of data standardization, nearly 80 percent of respondents also see the need for consistent data across the clinical data life cycle, and 66 percent believe standards will enhance operational efficiency.

- **Different data standards are used.** SDTM (Study Data Tabulation Model) was by far the most frequently chosen CDISC standard for regulatory submissions (74 percent use it now for regulatory submissions vs. 92 percent in the future), followed by ADaM (Analysis Data Model (56 percent use now vs. 82 percent in the future) and Define-xml (57 percent use now, 74 percent in the future). About half of the respondents (49 percent) said they integrated SDTM, ADaM and CDASH standards cross-functionally, while 36 percent have integrated standards separately in functional areas or were unsure of functional consistency (15 percent).

74%
Now use SDTM was the most frequently chosen CDISC standard for regulatory submissions.

92%
Will use SDTM as the chosen CDISC standard for regulatory submissions in the future.
Organizational barriers to implementing standards are significant. Companies are clearly at different starting points and maturity levels in their journey toward data standardization. Consequently, different implementation issues take precedence depending on where companies are on the adoption curve. Over half (52 percent) of the respondents viewed the difficulty in building governance processes as the primary organizational challenge. Yet other challenges abound as well:

- 53 percent cited both insufficient internal knowledge of, or experience with CDISC standards and lack of support of new standards, processes and infrastructure as important challenges.
- 47 percent of respondent’s organizations are contending with multiple versions of CDISC standards.
- About 30 percent cited both difficulty in hiring new professionals with CDISC knowledge and resistance from study teams in moving away from the legacy approach as barriers.

Governance and integration pose current and future challenges. Approximately half (49 percent) of the respondents noted that implementation of their selected data standard was cross functional, yet a sizable portion (36 percent) revealed that standards were implemented separately within functional areas. As indicated above, nearly half of the respondents have governance challenges, with specific challenges ranging from limited resources within functions (30 percent) to a dearth of cross-functional resources (23 percent). Indeed, 53 percent stated that only part-time resources were deployed to their standards organization and 56 percent revealed that only modest technology support was provided to enable governance workflows. Nonetheless, there is wide recognition that more structured governance will yield potential benefits mostly to improve standards awareness (58 percent), ensure standards compliance (52 percent), and centralize accountability and authority (48 percent).
• **Metadata management is valuable capability, but gaps persist.**
  A clear majority (55 percent) stated that metadata management would both improve efficiency and allow faster maintenance of standards. Yet, organization of metadata was fragmented, with 43 percent using spreadsheet-based standards metadata, and only 30 percent using metadata repositories (MDRs). A significant percentage—18 percent—of respondents indicated that they were not using standards metadata. Of those using MDRs, two-thirds (63 percent) use them for basic data definition as well as data mapping and transformation. Despite the challenge of metadata management, 68 percent see the value in evolving to consistency of data across studies.

• **Use of outsourcing varied.**
  Nearly 63 percent of respondents were using STDM outsourced data creation and exchange while only a third of companies chose that route for ADaM (34 percent) and Define-xml (37 percent).

### How to Evolve: Standards Maturity Models Can Help

As with any new undertaking, getting started and maintaining momentum are difficult, particularly when legacy processes and capabilities are not easily evolved. The questions for many organizations are: how to keep making progress toward data standardization given the scarcity of resources and experience, and—once data standardization efforts are in flight—how to ensure that the potential benefits are captured?

The responses to the survey as well as Accenture’s work with companies to implement data standards reveal five different levels of maturity in three dimensions: data standardization capability, metadata management and data governance. Accenture synthesized these levels and dimensions in a Clinical Data Standards Capability Maturity Model (see levels below). Understanding and taking a methodical approach to moving through the phases of maturity in each category brings both new challenges and insights. Ultimately, companies that reach level 4 or 5 will reap the most benefits from data standardization. Yet, many companies are currently focusing on moving from levels 1 or 2 to level 3, underscoring both the peril and the promise of achieving data standardization in time to comply with regulatory mandates.

#### Level 1: Limited Use of CDISC Standards

- **Maturity of Data Standardization:** Rudimentary use of standards that are not ready for submission
- **Metadata Management:** No standards metadata management
- **Standards Governance:** No standards governance

#### Level 2: CDISC Standards for Regulatory Submission

- **Maturity of Data Standardization:** Use of standards for compliance in regulatory submissions
- **Metadata Management:** Siloed manual management of spreadsheet-based metadata; limited metadata-driven processing
- **Standards Governance:** Siloed standards governance with limited dedicated staff
Level 3: Operational Efficiency Enhanced by Centralized MDR

Maturity of Data Standardization: Use of CDISC standards for operational efficiency improvement beyond regulatory submissions
Metadata Management: Introduction of centralized MDR and development of standard metadata using MDR; limited metadata-driven processing
Standards Governance: Dedicated resources as part of a standards governance team across functional areas, supported by an MDR solution

Level 4: Standards-based Metadata-driven End-to-End Automated Clinical Data Lifecycle

Maturity of Data Standardization: Full data integration of CDISC standards from trial design to submission
Metadata Management: Study definitions manually pulled down from trial-level standards metadata within the MDR for automating metadata-driven processing
Standards Governance: Dedicated standards governance framework across the clinical organization, with governance process workflows enabled within the MDR

Level 5: Data-driven Business Process enabled by Semantic Technology

Maturity of Data Standardization: CDISC data integration and interaction with other standards (e.g., EHR) enabled by semantic technology
Metadata Management: Protocol-driven study definitions automatically generated from trial-level standards metadata enabled by semantic metadata
Standards Governance: Enterprise-wide use of standards governance

Making Data Standardization a Reality: A Hypothetical Case Study

The challenges and approaches to implementing CDISC standards across the data lifecycle are illustrated in the following hypothetical case study for a mid-tier pharmaceutical firm seeking to move from Level 1 to Level 2 on the Clinical Data Standards Capability Maturity Model. The organization requested assistance in assessing its progress on implementing data standards and developing a plan to complete standardization.

Situation Analysis

Prior to partnering with an outside data strategy firm, the organization was stuck in the very early stages of exploring CDISC standards. An analysis of the current state revealed that:

- Knowledge of CDISC Standards within the organization was minimal.
- There were very few corporate resources that could help enable standardization beyond data collection tools.
- There was no centralized, structured, data storage existed for clinical trials data.
Recommendations

To help this company move to the next level in the Clinical Data Standards and meet compliance mandates, recommendations included:

- Conducting a phased implementation of CDASH and SDTM in an integrated manner, capitalizing on the initial work already performed with CRF standards.
- Implementing NCI/CDISC Controlled Terminology.
- Deploying spreadsheet-based Metadata Management within Functional Areas.
- Evaluating possible Metadata Driven processes.
- Adopting a cross-functional standards governance process, including the necessary support resources.
- Clarifying a process for submitting, logging, and tracking standards requests.

To help the client organization reach these goals, a team knowledgeable about clinical trial data and management would focus on the following, delivering a range of services and developing important end-products. These services and products consist of:

- Developing a CDISC Assessment and Implementation Plan that ensures compliance by the December 2016 deadline.
- Conducting CDISC Training
- CDISC use in CRF Design and core standard CRFs.
- Performing SDTM data specifications and mapping.
- Developing and executing a CDISC awareness campaign.
- Developing, testing, and refining a CDISC Metadata management spreadsheet.

Implementation

With the insights from the assessment and a solid implementation plan, the organization is well-positioned to take the next steps in implementing CDISC standards. These include:

- Refinement of important messages to and from upper management re importance of data standards
- Identification of target audiences

- Implementation of an education plan
- Provide overview training on CDISC standards
- Provide targeted training on CDISC
- Provide data collection tool training with respect to CDISC

- Oversight of the standards
- Escalation point for unresolved issues
- Defined standard domains
- Initial mapping of specifications

Until recently, companies have had the luxury of time in advancing clinical data standards in their organizations. While some pharmaceutical firms have invested significantly in standardization and are reaping the potential benefits of their efforts, all organizations must now focus on implementing standards to meet the FDA December 2016 mandate. Accenture and CDISC research reveal that there are both compelling business reasons to achieve standardization sooner rather than later, as well as proven methods to move toward a mature level of clinical data capability.
About Accenture

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