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Essential Elements Of A Data Management Plan For Outsourced Drug Development

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Bringing innovative and life-sustaining drugs to the world is the mission of the pharmaceutical industry.

Historically, the time, cost, and effort to bring new drugs to market has been a challenge, with only 13% of all drugs in development taking up to 10 years to be launched commercially. However, the global need for a COVID-19 vaccine has rewritten the rules of drug development. The benefits of harnessing data efficiently and effectively have never been more apparent. To most pharma organizations, that means establishing a digital integration or transformation strategy and linking that to a comprehensive data management plan.

As drug sponsors extend the development and manufacturing enterprise to include CDMO partners, the ability to rapidly and accurately share access to relevant data can have a profound impact on both time to market and simplifying program decision-making. Understanding the key characteristics of an effective data management plan as they relate to contract service providers is important in developing an effective data management plan.

THE DATA MANAGEMENT PLAN

A clearly defined data management plan must link to each aspect of both the digital strategy and its digital road map. The digital strategy will capture the intended performance outcomes from embarking upon a digital transformation journey, while the road map will define the steps and milestones in that journey. Figure 1 (p. 14) captures the essential elements of a comprehensive data management plan, which are discussed below:

Data Management Strategy

The data management strategy should define the major elements in a data management plan required to achieve the objectives of the overall digital strategy. It should always begin with an assessment of the current state, identifying gaps and mitigations both within internal systems and with outside contract service providers. It should capture the requirements for all stakeholders impacted by the digital transformation, including platform and architectural considerations, resource assignments and capability gaps, technology adoption strategies (e.g., the adoption of industrial Internet of Things [IIoT]), and the process that will be used for program rollout.

Data Governance

Data governance addresses the data management functions associated with managing shared data responsibilities across an enterprise, the measurement criteria that will be used to monitor progress against the plan, as well as the plan's ability to support the defined business objectives of the digital strategy. Data governance structures must be scalable and include the management of processes that promote collaborative decision- making and the management of meta data associated with each data asset. They must also address roles and responsibilities and include issue and change management while incorporating the intended regulatory, compliance, cybersecurity, and overall data integrity considerations associated with GxP data used to support drug development.

Data Quality

Data quality refers to everything from data generation through analysis that can affect the integrity of the data, and is intended to establish systems and practices that will prevent the incursion of redundant, obsolete, and trivial data as part of data management. It provides context for an organization to understand the nature of the data being managed by the plan. Combined with a structured risk management framework, the organization can avoid decision-making errors from nonqualified data.

Data Operations

Data operations addresses the systems and processes used to ensure that data requirements are fully specified and traceable across all transactions, changes are managed and requirements are in place, and source data collected is verified as authoritative. It is a core component of ensuring data integrity. The operations step ensures that controls are in place throughout the data's life cycle, and that systems and controls are defined for source data both internal and external.

Architecture

This step is intended to establish an optimal data layer design to facilitate effective data sharing and analysis, focusing on:

- establishing architectural standards for data representation, access, and distribution
- defining the technology architecture
- ensuring that processes are in place to address data versioning, retention, archiving, and retrieval, along with ensuring compliance with all regulatory requirements based upon the intended use of the data
- ensuring that the data layer design addresses the data acquisition, generation, storage, and transport as defined by the digital strategy.

Infrastructure

The infrastructure requirements for executing the data management plan address the organizational roles, responsibilities, and governance systems related to administering each step within the plan. In addition, these processes must address the compliance requirements and systems essential to managing GxP data from both inside and outside the organization.

Support Systems

The support systems constitute the governance framework that can be used by the organization to measure performance against its processes defined within the data management plan. Of specific concern are the processes associated with data acquisition, storage, extraction, abstraction, transformation, aggregation, reporting, and analysis.

CONTRACT SERVICE PROVIDER CONSIDERATIONS

If the drug development program is being supported by an outside contract service provider (CSP) such as a CDMO or analytical testing or clinical testing contract service provider, the ability to rapidly gain access to development data can have a profound impact on shrinking time to market, but can significantly complicate the governance framework utilized for the data.

When engaging a CDMO for early-stage process development and clinical development support, there are several points within an engagement where data management processes can be introduced.

Development Agreement

The development agreement defines at a high level the services that will be supplied by the CDMO. Development is distinguished from clinical material manufacturing in that the drug sponsor leverages the CDMO's internal technical expertise and know-how to assist the characterization and scale-up of the process. The development agreement is one vehicle for discussing any innovation rights issues that may arise within the process development that could impact the drug sponsor's or CDMO's proprietary intellectual property or trade secrets. Implicit in this discussion is the generation and management of the data derived from these studies. Understanding the intended use of the source data is critical at this juncture if the drug sponsor wants to utilize a data strategy that is outside the CDMO's current QMS (quality management system). If the data is not acquired automatically and must be input by the CDMO, the drug sponsor should work with the CDMO to define the roles and responsibilities associated with data entry and verification activities.

It is important for the drug sponsor to remember that a CDMO's QMS is built to support its commercial customers and their products and, hence, a development drug sponsor's ability to materially stray from the current policies and procedures may be limited. For example, it may be impossible within some CDMOs' existing QMS frameworks for a drug sponsor to get access to development and characterization data prior to QA approval from the CDMO, which can take many weeks. There are several software solutions that can be used to rapidly gain access to data and organize data for analysis. Skyland PIMS, for example, is a process management software that provides a common conduit, analysis framework, and repository for data analysis during drug development. QbDVision is another process management solution that provides a structured framework for process development, data analysis, and data visualization. Solutions such as these do not require the CDMO to make a large infrastructure investment and can significantly streamline the process development exercise. Incorporating these solutions can be managed procedurally for CDMOs that operate a separate development QMS from their commercial programs. Typically, the key consideration associated with these systems is a clearly articulated liability component within the development and quality agreements that defines the expectations of the CDMO and drug sponsor in terms of managing the data in these solutions. For CDMOs that only operate under one QMS, it is still possible to incorporate specific nonstandard data acquisition and management practices via client-specific protocols.

Figure 1. Components of a comprehensive data management plan

Supply Agreement

For commercial programs that look to efficiently gather data related to products being manufactured at a CDMO, the same liability elements should be captured in the final supply agreement, with specific roles and responsibilities and processes linking to the drug sponsor's data management plan articulated in the final quality agreement.

THE DIGITAL TRANSFORMATION IS INEVITABLE

There is no turning back for the pharma industry's commitment to digital transformation. The establishment of a cogent digital transformation strategy and road map will capture the business performance attributes the organization is seeking to harness to drive business performance. The tactical component required to realize the digital strategy is the data management plan, which will define the processes, systems, and standards required to ensure the data being acquired meets the requirements for ensuring data integrity and complies with applicable regulatory compliance standards throughout the data's life cycle.

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