

Evolution and Advancement of Data Management in Drug Development

- Recommendations for Organization and Talent Development as of 2025 -

(Executive Summary)

The drug development landscape is undergoing an unprecedented transformation, driven by patient-centric decentralized clinical trials (DCTs), the growing use of real-world data (RWD), rapid advances in AI and digital technologies, and the ongoing GCP Renovation. In this era of change, data managers should evolve beyond simply collecting and managing data. They are expected to become strategic contributors, engaging from the trial design stage and driving clinical trial success through data strategy planning and quality management. The key to optimizing the quality of clinical trial and enhancing efficiency lies in the strategic utilization of data managers. This document outlines the evolving role of data managers in response to increasingly diverse and complex clinical trials, and discusses the importance of optimizing organizational structures and developing talent to achieve such transformation, with a focus on the Japanese industry.

1. Transformation of Clinical Trials and Revolution of Data Management

Clinical trial environment, including those in Japan, is undergoing a period of transformation.^{[1] [2]} Trial designs that transcend traditional frameworks, such as Decentralized Clinical Trials (DCTs) and adaptive designs, are expected to become standard practice. Data sources are also becoming more diverse, including electronic health records, wearable devices, and electronic Patient Reported Outcomes (ePROs), requiring organizations to address the challenges of managing large volumes of data and accelerated data acquisition.

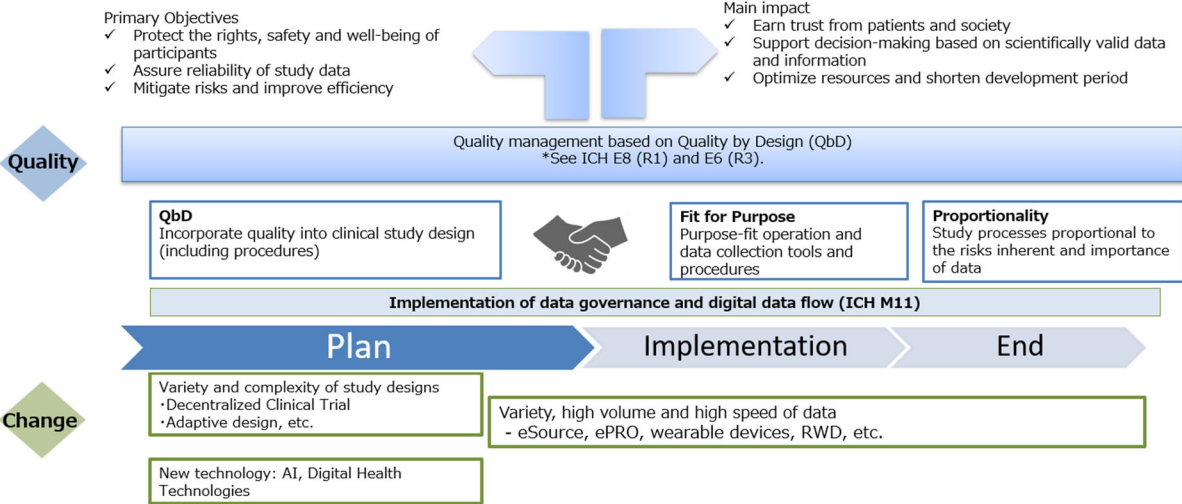
The adoption of these new trial methodologies and digital technologies is expected to accelerate further, potentially leading to a reorganization of leadership in multi-regional clinical trials (MRCTs) and global drug development. By proactively aligning with global trends in MRCTs and driving initiatives that contribute to worldwide clinical development, Japan can continue to secure strong participation opportunities and maintain its competitiveness in drug development.

Under these circumstances, data managers require a new approach to data management that goes beyond the traditional model focused primarily on "data collection and management." A Quality by Design (QbD) approach, which proactively builds quality into study design, is essential; ICH E8(R1) defines quality as "fitness for purpose." Accordingly, data managers should engage in upstream activities, including the development of data collection strategies and quality management plans aligned with study objectives. By doing so, they can also contribute to strengthening and sustaining Japan's competitiveness in drug development.

Furthermore, the importance of data governance incorporated in ICH E6(R3) continues to increase. Data managers should ensure data quality, integrity, and traceability, managing the entire end-to-end data lifecycle from study planning through post-trial data storage and disposal. When utilizing medical information collected during routine clinical practice in clinical trials, it is essential to evaluate their characteristics and risks and implement appropriate measures based on understanding relevant regulatory requirements. Additionally, technical proficiency, including system reliability assurance and audit trail management for each computerized system is crucial.

In view of these trends, the role of data managers should evolve from the traditional style, focused on "data collection and management", to becoming "strategic business partners" who optimize clinical trial quality and efficiency while effectively leveraging new technologies. The next chapter is highlighting the evolution of the technology and the process as key factors accelerating this transformation.

Figure 1. Changes in Clinical Studies and Quality Management



2. Evolution of Technology and Process

This section highlights representative technological advances related to data management and examines their impact on processes.

- Artificial Intelligence (AI): Technological innovations including AI are fundamentally transforming clinical trial workflows. For example, automation of data processing and abnormality detection is streamlining tasks that previously relied on manual effort which is expected to significantly shorten development timelines and improve quality consistency.
- Digital Data Flow (DDF): ICH M11, an international guideline for the electronic standardization and structuring of clinical study protocols, will be implemented soon. This guideline specified the standardization and structuring of protocol information, making DDF implementation possible. Multiple systems for data collection, trial management, and record retention can be integrated, leading to workflow automation and enhanced reusability. DDF is gaining attention as a foundational platform for streamlining the entire clinical trial lifecycle and enabling reliable data operations.
- Real-World Data (RWD): The use of RWD is increasing. Specific applications include using registry data as external control arms in rare disease and pediatric populations where randomized controlled studies are challenging, conducting feasibility assessments for clinical trials, optimizing study designs, and selecting investigational sites. In the future, label expansions based solely on RWD are anticipated. Such applications will require compliance with personal data protection regulations and establishment of quality assurance processes.

- Digital Health Technologies (DHT): Use of DHT, such as wearable devices and smartphone applications, is expected to increase. These technologies enable real-time monitoring of patients' daily activity levels and symptom changes without imposing significant burden, allowing for outcome assessments that more closely reflect real-world clinical practice. The introduction of DHT is a critical element in realizing truly patient-centric clinical trials.

3. Strategic recommendations for Organizations and Talent

To respond effectively to the significant environmental changes in the clinical trial, data managers should not only evolve and grow themselves, but organizations should also be optimized by the new scope of work of data management functions and new role and responsibility according to each company's specific circumstances.

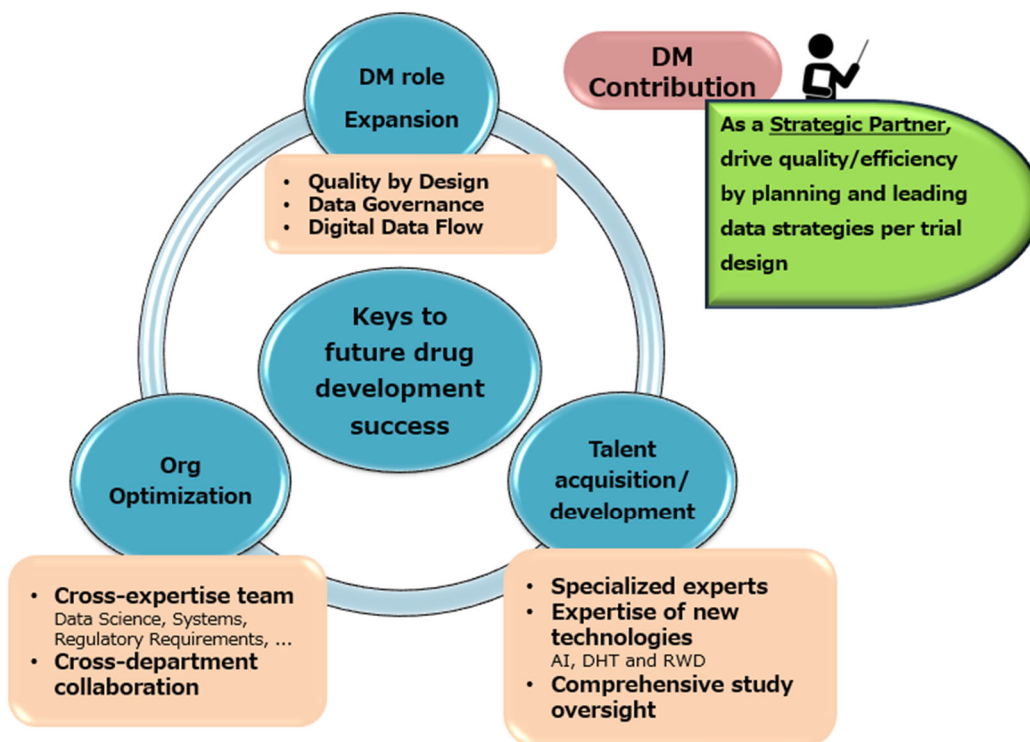
Simultaneously, securing and developing talent capable of fulfilling new roles is a critical priority.

Among the traditional management resources—people, assets, budget, and information—human capabilities, including creativity and collaborative capacity, have become the primary source of competitive advantage. At the same time, the value of information resources has dramatically grown. With advances in data utilization and AI, the quality and speed of corporate decision-making are now significantly influenced by how information is managed.

These changes in the business environment are also impacting data management operations in drug development, requiring faster and more flexible decision-making through information obtained via DDF and diverse data sources.

These facts suggest that there is a pressing need to establish educational programs and career pathways to develop next-generation data managers who are proficient in emerging technologies such as AI and DDF and capable of handling diverse data sources.

Figure 2. Strategic use of data managers: Roles, Organizations, and Talent Development



We hope this document will inspire upper management to consider organizational reforms and implement concrete actions tailored to their specific circumstances. Through these efforts, we anticipate that new roles for data managers will be identified, contributing to the further advancement of clinical development.

The content presented in this document is based on the report " Evolution and Advancement of Data Management in Drug Development - Recommendations for Organization and Talent Development 2025 -" published by Task Force 1-1 of the Data Science Expert Committee, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association. The full report includes detailed background on the discussions and specific recommendations, as well as one-pager appendix summarizing key concepts that symbolize the transformation of data management. We encourage you to read through the full report and utilize it for discussions and implementation at each company.

Full report*:

Evolution and Advancement of Data Management in Drug Development - Recommendations for Organization and Talent Development 2025 –

https://www.jpma.or.jp/information/evaluation/results/allotment/DS_202511_newdm.html

*Please note that the full report is prepared in Japanese, so we kindly ask that you translate it as needed.

References:

[1] Society of Clinical Data Management

The Evolution of Clinical Data Management to Clinical Data Science (Part 3) Society for Clinical Data Management Reflection Paper

<https://www.scdm.org/wp-content/uploads/2024/07/SCDM-Reflection-Paper-CDM-Role-Evolution-Part-3-Link-6.pdf>

[2] Society of Clinical Data Management

The evolution of Clinical Data Review Version 1 (April 2022)

<https://scdm.org/wp-content/uploads/2024/03/SCDM-The-evolution-of-Clinical-Data-Review-FINAL.pdf>

Please refer to the full report for other reference materials.

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