Paper DS07

Enhancing the standard utilization by creating a new pivotal role: The Standard Implementation Lead

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ABSTRACT

At Johnson & Johnson Innovative Medicine, we are in a continuous process of improving our R&D strategies. This vision is also reflected in our Clinical Data Standard (CDS) organization. Based on a gap analysis, we have identified areas of improvement of standard adoption and consumption.
With this presentation, I would share a new initiative where we are focusing on changing the culture towards the use of data standards by introducing a new pivotal role who acts as liaison between study team and CDS organization. The newly created Standard Implementation Lead (SIL) role is integrated in study team to promote the Enhancing Standard Utilization initiative's following 3 pillars. First advising and promoting the adoption of the new simplified connected standards. Then playing a central role in a new governance strategy. And finally, being a central actor to evaluate and increase standards compliance.

INTRODUCTION

In 2023, Johnson & Johnson (J&J) undertook an internal survey within the Integrated Data Analytics & Reporting department to assess the usage and identify gaps in the standard components utilized throughout the clinical trial lifecycle, from setup to submission. This initiative revealed several critical areas where standard component adoption was lacking, and compliance metrics fell short of optimal performance. However, the survey's purpose extended beyond merely evaluating adoption and consumption; it aimed to bring together standards users across various departments to share their insights, highlighting successful practices and areas needing improvement.

Key challenges identified included inconsistencies in data collection, excessive study-specific variations, and difficulties in aligning SDTM metadata with the SDTM library. Additionally, issues such as the inability to leverage standard programs for automating SDTM visualizations and TFLs due to duplication were noted. Addressing these concerns requires a cultural shift towards the proactive usage of standards, transitioning from passive compliance to active support that facilitates informed decision-making and promotes the integrity of data across the portfolio.

Considering these findings, the decision was made to launch a translational project designed to bridge the gaps among departments impacted by the development and application of standard components. This project was named the Enhanced Standards Utilization (ESU) project. To facilitate a more cohesive approach, the ESU project has identified three primary objectives:

1. Establishing a Strong Standards Mandate: The project underscores the necessity for all teams to adhere to prescribed standards throughout every phase of trial execution—from the design of electronic case report forms (eCRFs) to the preparation of tables, listings, and graphs. This mandate encourages uniformity and deters deviations that can complicate the data landscape.

2. Simplification of Standards Usage and Management: Through the implementation of Johnson & Johnson Connected Standards (JJCS), the aim is to create a more accessible framework for standards application across all therapeutic areas (TAs) and trials. Notably, the JJCS design is synchronized with the recently released FDA Analysis Standards, reinforcing the importance of compliance and easing the transition toward standardized practices.

3. Supporting Implementation at the Trial Level: A crucial aspect of the ESU project involves the establishment of the Standards Implementation Lead (SIL) role. This position is designed to facilitate seamless integration of standards throughout the trial lifecycle, acting as a bridge between trial teams, standards teams, and domain experts. The SIL will foster connectivity from protocol development through to data analysis, ensuring a comprehensive understanding and adherence to standards.

To underpin these objectives, the ESU project focuses on five key pillars: the standards themselves, the governance model, the tools employed, the processes followed, and the people involved. By fostering a supportive environment that encourages adherence to standards, the project aims to enhance overall quality and cost-efficiency while mitigating the risks associated with regulatory rejections of submission packages.

Ultimately, the ESU project serves not only as a framework for operational improvement but also as an opportunity to cultivate a mindset shift towards a more consistent and standardized approach within the organization. Through this collective effort, Johnson & Johnson is poised to enhance its capabilities, transform its processes, and position itself as a leader in clinical trial execution and submission data standards compliance.

DISCUSSION

The introduction of the Standards Implementation Lead (SIL) role is a significant step forward in enhancing operational efficiencies and ensuring adherence to standards across the clinical trial landscape at Johnson & Johnson (J&J). Positioned as a linchpin between study teams and the Standards team, the SIL is tasked with supporting study teams in maintaining adherence to established standards from the initial stages of trial design to the final submission. This comprehensive support encompasses various components including the protocol, electronic case report forms (eCRFs), external data transfers, analysis datasets (ADaM), and tables, figures, and listings (TFLs).

1. Support and Expertise

The establishment of the Standards Implementation Lead (SIL) role at Johnson & Johnson marks a deliberate strategy to enhance support for clinical trial teams by assigning SILs based on therapeutic areas (TAs) or discipline areas (DAs). This targeted assignment ensures that SILs not only develop deep expertise within their designated areas but also promote consistency across diverse trials. By serving as a critical conduit for knowledge and understanding, SILs empower teams to navigate the complexities of standards adherence more effectively.

The SIL's role extends beyond mere compliance; it emphasizes the downstream impacts associated with deviating from Johnson & Johnson Connected Standards (JJCS). This awareness is pivotal as it anchors the teams' efforts in the larger context of trial success, highlighting how stringent adherence to these standards can mitigate risks, enhance data quality, and streamline processes. By minimizing deviations from established practices, SILs contribute to a more harmonized operational framework, which is crucial for the efficient and effective implementation of clinical trials.

2. Collaborative Engagement

Collaboration stands at the heart of the SIL role, particularly in facilitating discussions with Cross Functional Study Teams (CFSTs). These interactions are critical for developing and refining standards strategies tailored to the unique requirements of each trial within J&J's expansive development framework. SILs provide essential guidance at the component build level, ensuring that all standards are complied with and that governance processes are adhered to systematically.

This close integration fosters a dynamic feedback loop between the SILs and the Clinical Data Standards (CDS) team, which is invaluable for evolving standards to meet the practical needs of trial teams. Such exchanges equip the CDS team with insights drawn directly from the field, enabling continuous improvement and refinement of the standards to ensure they remain relevant and user-friendly. Consequently, this collaborative engagement serves as a catalyst for driving innovation while maintaining compliance.

3. Early Success and Future Potential

Though still in its nascent stages, the SIL initiative has been met with an encouraging reception. CFST have welcomed the presence of SILs, appreciating their contributions to fostering dialogue and collaboration. High levels of engagement signal that teams recognize the added value the SIL role brings to their efforts, and this budding partnership is expected to produce downstream benefits that extend well beyond current trials.

The empowerment of teams through the SIL role addresses a significant gap that previously existed, where many teams struggled to navigate the complexities of standards compliance independently or with limited guidance. The Enhanced Standards Utilization (ESU) initiative, particularly through the introduction of the SIL role, promises a sustainable shift that enhances both team performance and trial outcomes.

4. Synergy with Organizational Initiatives

As teams adapt to new processes and handle personnel changes, the SIL role serves as a stabilizing force, providing much-needed expertise and support in these transitional phases. By embedding standards knowledge directly within trial teams, SILs effectively mitigate risks associated with compliance and project continuity.

This synergy reinforces J&J's commitment to delivering high-quality and consistent trial outcomes, essential for both internal stakeholders and regulatory authorities.

In summary, the SIL role significantly enhances standards adherence and fosters collaborative engagement within Johnson & Johnson's clinical trial ecosystem. With its focus on expertise, integration, and proactive support, the SIL position signals a pivotal shift toward greater standardization and efficiency in trial execution, laying the groundwork for future successes and innovations in clinical research.

CONCLUSION

In conclusion, the SIL role stands at the forefront of a proactive movement towards standardization and compliance at J&J. Its focus on collaboration, expertise, and awareness has the potential to drive considerable advancements in the fidelity and efficiency of clinical trials, setting the stage for lasting changes that will benefit the organization. As we continue this journey, the SIL will play an integral role in ensuring that J&J not only meets but exceeds industry standards in clinical trial execution.

CONTACT INFORMATION

Your comments and questions are valued and encouraged.
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