Paper SD01

Standards Implementation with Knowledge Driven, AI Powered Platform

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ABSTRACT

In today's rapidly evolving clinical research landscape, the implementation of data standards has become mandatory, driven by regulatory bodies such as the FDA. However, organizations face significant challenges, including fragmented metadata, prolonged release cycles, and insufficient validation against regulatory guidelines.

This white paper explores how ClinCafe's iCLIMB revolutionizes standards implementation through the integration of Artificial Intelligence (AI), enabling automation of complex tasks like SDTM annotations and streamline standards governance via build-in workflows. The built-in governance workflows accelerate metadata review, enhance compliance with FDA and CDISC guidelines, and reduce metadata release cycle times. Additionally, iCLIMB's seamless integration with upstream Electronic Data Capture (EDC) and downstream validation systems ensures comprehensive metadata data management and reporting capabilities.

INTRODUCTION

As the landscape of clinical research continues to advance, the complexity of implementing these standards increases. Standardization helps ensure data consistency, accuracy, and interoperability across studies and regulatory submissions. However, organizations face several challenges when navigating this dynamic environment.

To address these challenges, ClinCafe introduced iCLIMB (Integrated Clinical MetaBase), a cutting-edge technology platform specifically designed to streamline and optimize the management of clinical data standards. iCLIMB overcomes significant barriers in clinical standards implementation by integrating Artificial Intelligence (AI), built-in standards governance workflows, and seamless integration with key data systems like Electronic Data Capture (EDC) and data reporting systems.

This white paper outlines the revolutionary capabilities of iCLIMB and explores how it addresses the following critical challenges:

- Fragmented metadata across disparate platforms.
- Lack of intelligent systems to support standards implementation.
- Insufficient validation against CDISC and FDA guidelines.
- Limited innovation in AI for standards development.
- Prolonged standard library release cycles.
- Inefficient integration with upstream and downstream systems.

AI INTEGRATION: DRIVING INNOVATION IN STANDARDS IMPLEMENTATION

In today's rapidly evolving technological landscape, Artificial Intelligence (AI) is no longer a topic of future but a necessity. iCLIMB incorporates AI to revolutionize how clinical data standards are implemented, maintained, and governed.

AI-POWERED SDTM ANNOTATION

SDTM annotations are essential for capturing metadata for new or existing study forms. iCLIMB's AI-driven Predict annotation feature within the aCRF module streamlines the process of populating annotations for new fields or forms at both study and library levels. The self-learning algorithm, which improves with user feedback, enhances efficiency and accuracy. As a result, study teams can reduce manual efforts and ensure faster, more precise SDTM annotation.

AI ASSISTANCE IN CONCEPT IDENTIFICATION

Maintaining alignment with the ever-changing Controlled Terminology (CT) updates from CDISC can be challenging. iCLIMB's AI facilitates this by comparing sponsor-defined CT with CDISC's latest updates, identifying similar concepts using natural language processing (NLP). This dramatically reduces manual efforts, minimizes errors, and speeds up the review process, ensuring continuous compliance.

Through AI integration, iCLIMB transforms how clinical research organizations (CROs) and sponsors manage complex standards, offering a streamlined approach that ensures data governance at every level.

STANDARDS GOVERNANCE: BUILT-IN WORKFLOW FOR EFFICIENCY

Effective standards governance is vital for ensuring that conceptual metadata remains reusable, interoperable, and compliant with regulations. Traditional governance models, often bogged down by extensive manual review and approvals, can delay the implementation of new standards.

iCLIMB'S STANDARDS GOVERNANCE WORKFLOW

iCLIMB introduces a built-in workflow for standards metadata governance, enabling continuous standards maintenance and faster delivery. The workflow supports the review and approval of change requests, significantly reducing the cycle time for metadata updates and promoting real-time collaboration between stakeholders.

By reducing delays and fostering collaboration, iCLIMB allows organizations to manage their data standards more efficiently and align their processes with regulatory guidelines.

INTEGRATION WITH FDA AND CDISC GUIDELINES

The iCLIMB platform is designed to streamline regulatory compliance by seamlessly integrating FDA and CDISC guidelines. In today's dynamic regulatory landscape, staying updated with evolving standards can be challenging for CROs and sponsors.

iCLIMB addresses this by incorporating CDISC SDTM annotation rules in both MSG v1 and v2. The platform also includes comprehensive FDA and CDISC metadata and define.xml validation checks. Furthermore, all PDF exports are fully compliant with FDA requirements for document formatting. By embedding these guidelines into its workflow, iCLIMB ensures that organizations maintain compliance throughout the entire process of metadata creation and submission.

SYSTEM INTEGRATIONS: EDC AND VALIDATION SYSTEMS

iCLIMB has been designed with robust integration capabilities that span both upstream and downstream systems. At present it supports seamless integration with Medidata Rave and will shortly have the capabilities to integrate ODM EDC extracts as well.

The platform's Architect Loader Spreadsheet (ALS) ingestion framework allows for efficient data exchange and synchronization between Rave and iCLIMB. In addition, iCLIMB offers custom export options for integrating metadata with downstream validation and reporting systems.

Looking ahead, iCLIMB will leverage the CDISC Library through CDISC REST APIs, ODM Ingestion and DATASET JSON capabilities and offer capabilities to publish metadata through iCLIMB REST APIs, expanding its integration potential and enhancing interoperability.

STANDARD TOOLKIT: ENHANCING EFFICIENCY WITH SMART TOOLS

In iCLIMB, standards development is made more efficient through its Smart Compare and Smart Search tools, which help organizations compare sponsor-defined concepts with CDISC standards, reducing duplication and redundancy.

SMART SEARCH AND COMPARE

iCLIMB's Smart Search and Compare feature scans the entire database for metadata similarity, providing users with direct links to the relevant entries. The platform uses both word/character similarity and meaning-based algorithms to ensure highly accurate results. This feature allows teams to avoid creating redundant metadata, saving time and resources.

DEFINE.XML

Define.xml is a critical part of regulatory submissions, outlining the SDTM or ADaM metadata package for a study. iCLIMB's Define.xml module automates the creation of the Define package, which includes Define.xml, Define.pdf, aCRF.pdf, and other necessary files. By generating these documents early and consistently throughout a study's lifecycle, iCLIMB mitigates downstream programming delays and enhances data harmonization, ensuring traceability from data collection to submission.

CONCLUSION

As the clinical research industry continues to evolve, the need for robust, intelligent platforms for managing clinical data standards becomes paramount. iCLIMB stands out as a pioneering solution that integrates AI-driven processes, built-in governance workflows, and seamless system integration to meet the growing demands of standards implementation.
By embracing FAIR principles (Findable, Accessible, Interoperable, and Reusable) and incorporating the latest FDA and CDISC guidelines, iCLIMB enables organizations to manage their data with unprecedented efficiency and compliance. Its ability to guide users in creating standards that align with evolving regulations, while blending perfectly the human intelligence with the power of AI, positions iCLIMB as a critical tool in the future of clinical data standards governance.

RECOMMENDED READING

1. ClinCafe Website – https://clincafe.com
2. LinkedIn Blog - https://www.linkedin.com/pulse/how-iclimb-revolutionizes-standards-implementation-7mnce/?trackingId=r6IFMMx0Si2phsDNSXKz%2BQ%3D%3D
3. FDA Validation Rules - https://www.fda.gov/media/103587/download
4. CDISC SDTM Conformance Rule - https://www.cdisc.org/standards/foundational/sdtmig/sdtm-and-sdtmig-conformance-rules-v2-0
5. CDISC Metadata Submission Guidance - https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

CONTACT INFORMATION

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