Adopting ICH M11 CeSHarP Guidelines for Oncology Protocol Digitalization: Findings and Action Recommendations

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Shaurya Deep Bajwa*, Vatsal Chhaya, Foram Shethia, Kapil Khambholja
Catalyst Clinical Research, Wilmington, NC, USA

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INTRODUCTION

Developing and reviewing oncology protocols is a complex process for the protocol development team and medical writers. This often results in delays in regulatory approval and difficulties in running and reporting on complex trials.

The Tufts Center for the Study of Drug Development found that oncology protocols often have similar or fewer endpoints, eligibility criteria, and procedures compared to other drugs, adding to the complexity.

- **Endpoints:** Phase II oncology protocols averaged 18.5 endpoints, and Phase III averaged 14.6, compared to 21.6 and 21.0 in non-oncology, respectively.
- **Eligibility Criteria:** Oncology trials averaged 29.3 (Phase II) and 30.2 (Phase III) versus 32.3 and 30.1 for non-oncology.
- **Distinct Procedures:** Oncology protocols had 34.4 and 34.1 distinct procedures (Phase II and III), compared to 31.8 and 35.1 for non-oncology.
- **Review Frequency:** From 2014–2019, Phase II oncology protocols underwent 4.8 internal reviews (vs. 3.9 for others), while Phase III oncology protocols had 9.7 (vs. 5.9).[1]

Given the urgency to expedite cancer treatments, there is a pressing need for advanced methodologies to streamline oncology protocol development and review processes. Protocol digitalization, guided by the ICH M11 Clinical Electronic Structured Harmonised Protocol **(ICH M11 CeSHarP) M11** guidelines, represents a key solution to overcoming these challenges by standardizing and digitizing clinical study protocols.[2]

This poster investigates the application of the ICH M11 CeSHarP guidelines in the oncology space, addressing how they can mitigate challenges such as complex methodologies, unstructured content, and diverse patient populations.

METHODS

Introduction of CeSHarP

- Draft guideline introduced by the **International Council for Harmonisation** (ICH) in 2018.
- Updated in September 2022.

Objective of Guidelines

- Standardize and streamline the creation and review of interventional clinical trial protocols.
- Enable digitalization of protocol creation and review processes.

Features

- Provides a comprehensive protocol template.
- Includes technical specifications for digitalizing various protocol sections.

Implementation Process:

To explore the practical application of the ICH M11 CeSHarP guidelines in oncology, we utilized publicly available digital templates aligned with the guidelines. Our approach involved several key steps:

1. Digital Template Identification

- Reviewed ICH M11 guidelines and public templates to identify oncology protocol sections for digitalization.

- Focused on sections like study design and endpoints that meet regulatory needs for accelerated approvals.

2. In-house Practice

- Tested identified templates within oncology protocols to assess usability.

- Refined the process to ensure templates captured essential details and complied with regulatory standards.

3. Review and Roadmap Development

- Evaluated digitalized sections for ICH M11 CeSHarP compliance and oncology requirements.

- Developed a roadmap for full protocol digitalization, ensuring alignment with regulatory evidentiary needs for accelerated approvals.

FINDINGS OF PROTOCOL DIGITALIZATION PILOT

Key Complexities:
The adoption of the ICH M11 CeSHarP guidelines in oncology has proven effective in addressing several key complexities:

1. **Intricate Methodologies**: The guidelines provide a structured framework that simplifies the incorporation of complex methodologies.
2. **Unstructured Content**: The standardized template helps to transform unstructured content into a more organized, easily reviewable, and uniform format.
3. **Varied Patient Characteristics**: The flexible nature of the ICH M11 CeSHarP template allows researchers to tailor the protocol to the specific characteristics of the patient population.

Collaborative Review and Associated Benefits:
The ICH M11 CeSHarP template enhances content reuse and seamless electronic exchange of protocol data, promoting interoperability between systems and facilitating collaborative review. This reduces redundant efforts, simplifies complex reviews, lowers administrative burden, and improves protocol quality, ultimately accelerating the development timeline for new cancer drugs and treatments.

SWOT ANALYSIS FOR PROTOCOL DIGITALIZATION PROCESS

STRENGTHS	WEAKNESSES
• Standardized structure ensures consistency across trials. • Enhances interoperability and collaboration across systems. • Facilitates faster reviews and regulatory submissions by reusing content. • Reduces administrative burden, improving efficiency and protocol quality. • Aligns with global regulatory standards, supporting international trials.	• Initial setup requires significant time and resources. • Resistance to change, especially in complex trials. • User interface issues in digital solutions, lacking user-friendly design. • Template drawbacks: redundancy and unclear information in some sections. • Requires IT expertise, regulatory compliant secured framework, and technical support. • Technical glitches and regular updates may cause system incompatibility.
OPPORTUNITIES	**THREATS**
• Scalable across multiple therapeutic areas beyond oncology. • Supports faster approvals, particularly in accelerated oncology drug development. • Integration with AI tools for protocol optimization and data analysis. • Enhances collaboration with external partners like CROs and regulators. • Opportunity to improve template clarity and reduce redundancy.	• Regulatory updates could affect compliance with new requirements. • Cybersecurity risks related to digital data exchange and storage. • Inconsistent global adoption may create challenges for multinational trials. • Delays in implementation could reduce competitive advantage in drug development. • Risk of technical glitches or system failures due to software updates.

CONCLUSION AND RECOMMENDATIONS

To overcome these challenges and maximize the benefits of adopting ICH M11 CeSHarP guidelines, we recommend:

- **Cross-functional Training**: Conduct training sessions for medical writing and digital technology professionals.
- **Digital Oncology Writing Hackathons and Pilot Programs**: Organize hackathons and pilot programs tailored for oncology to encourage innovative problem-solving.
- **Strategic Partnerships**: Foster partnerships between regulatory bodies, industry, and academia to share best practices and promote ICH M11 CeSHarP adoption.

Let's collaborate and inspire people to design and deliver better clinical trials by leveraging digital capabilities and effective adoption of guidelines such as ICH M11 CeSHarP.

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CONTACT INFORMATION

Shaurya Deep Bajwa
Sr. Medical Writer - RWE Analyst II
Catalyst Clinical Research
Email: shaurya.bajwa@catalystcr.com
www.CatalystCR.com

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