ICH
harmonisation for better health

ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)

FDA and Health Canada Regional ICH Consultation

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International Council for Harmonisation
of Technical Requirements
for Pharmaceuticals for Human Use

Legal Notice

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The Problem

- **No internationally harmonized standard template for the format and content to support consistency across sponsors and exchange of protocol information.**
- Lack of harmonization **contributes to inefficiencies and** difficulties in reviewing and assessing clinical protocols by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders.

Inefficiencies Stemming from Lack of Harmonization

<u>Lack of harmonization</u> leads to inconsistent quality of protocols, resulting in:

- Delayed timelines for product development, which may delay access to medicines for patients;
- Resource-intensive manual activities, which increase the cost and complexity of clinical research and drug development;
- Inefficient use of knowledge and duplication of effort;
- Inability to leverage tools that allow reuse, review, analysis, and reporting; and
- Limit the exchange/utilization of data collected in each protocol.

Value of M11

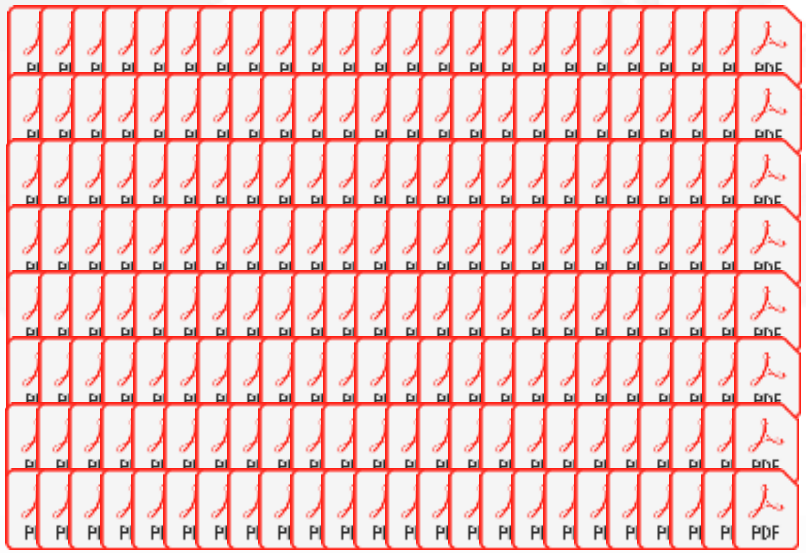
- **Establishes a common Table of Contents**
- **Highlights basic requirements for protocols**
- **Impact similar to CTD/eCTD**
- **Foundational step toward a “digitized protocol”**

Value of an ICH Protocol Template

- Predictable
  - Structure
  - Content
  - Level of detail
  - Presentation (of some content)
- Common instructions
- Flexibile where needed
- Consistent with other relevant ICH Guidelines
- Acceptable in all ICH countries

Why Clinical electronic Structured Harmonized Protocol (CeSHarP)?

It usually isn't like this anymore…



but this isn't much better!

Value of an Electronic, Structured Protocol Template

Foundational step toward a "digitized protocol"

- Granular content can be exchanged, extracted, translated, reassembled, or processed as individual pieces or as a whole set
- Additional standards can be developed in the future by ICH or other SDOs to govern contents within the protocol
- Creates foundational requirements to enable informatics and software development

Value of an Electronic, Structured Protocol Template

All of the benefits of a traditional template…

- Searchable content and metadata
- Tailored experience
- Collaboration and Continuity
- Downstream automation
- Future standardization and automation

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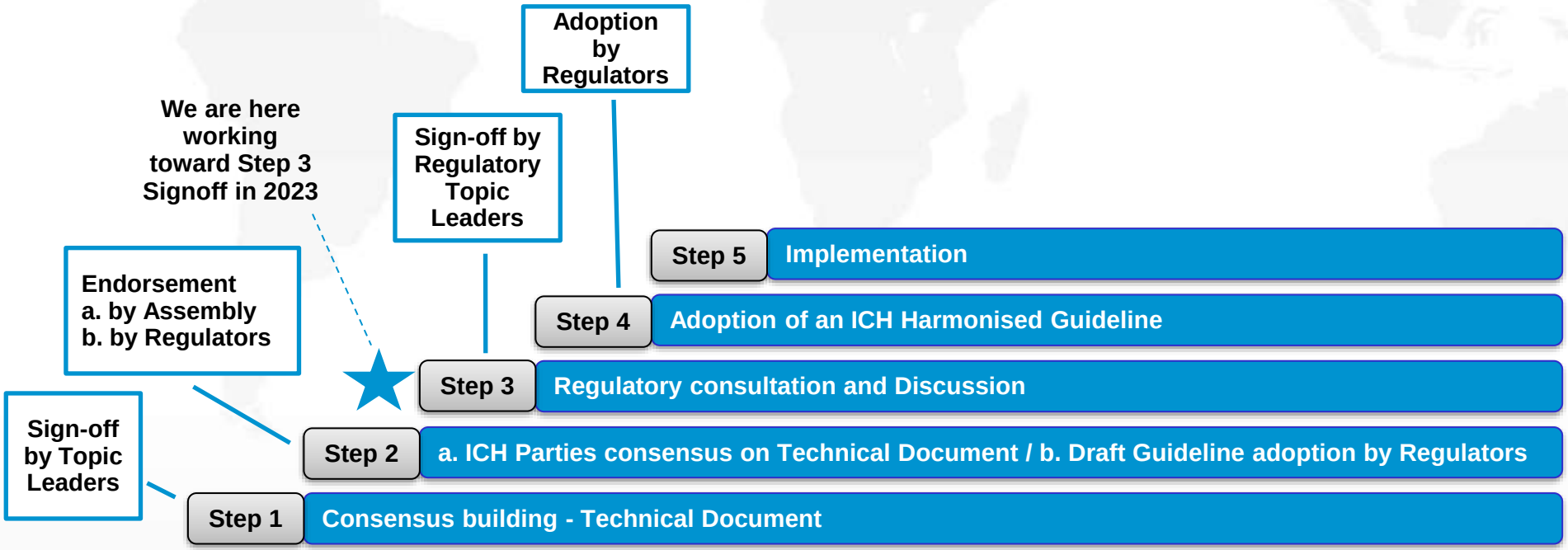
Steps in the ICH Process



Breadth of Coordination

- Structure & Content of Clinical Study Reports
- Ethnic Factors in Acceptability of Foreign Data
- Good Clinical Practice
- General Considerations in Clinical Trials
- Statistical Principles for Clinical Trials
- Clinical Trials in Pediatric Populations
- Multi-Regional Clinical Trials
- Adaptive Clinical Trials
- Electronic Standards

ICH M11 Deliverables

- **ICH M11 is a new harmonised guideline on the clinical protocol that specifies comprehensive organization with standardized content (including both required and optional components).**
- **Deliverables**
  - A Template to include identification of headers, common text and a set of data fields and terminologies which will be the basis for efficiencies in data exchange
  - A Technical Specification that uses an open, nonproprietary standard to enable electronic exchange of clinical protocol information

How to Think About the M11 Documents

- **Guideline is like the container**
  - Not expected to change over time
- **Template and Technical Specification are like ice and water**
  - Different forms of the same matter
  - Will change over time

ICH M11 Guideline - Objectives

The purpose of the Guideline is to describe the general protocol design principles and approach used to develop the separate associated documents, the ICH M11 Clinical electronic Structured Harmonised Protocol Template (Template) and the Technical Specification that are acceptable to all regulatory authorities of the ICH regions.

Scope

- **The** Template and Technical Specification are applicable to interventional clinical trials of medicinal products across all phases and therapeutic areas of clinical research.

- **Out of Scope**
  - Neither the Guideline nor the Template or Technical Specification are intended to specify processes related to development and maintenance of a protocol.
  - They do not supersede or negate other guidelines that establish requirements for protocol content.
  - They do not provide instruction on the development of a well-designed trial or characterize a well-crafted final protocol.

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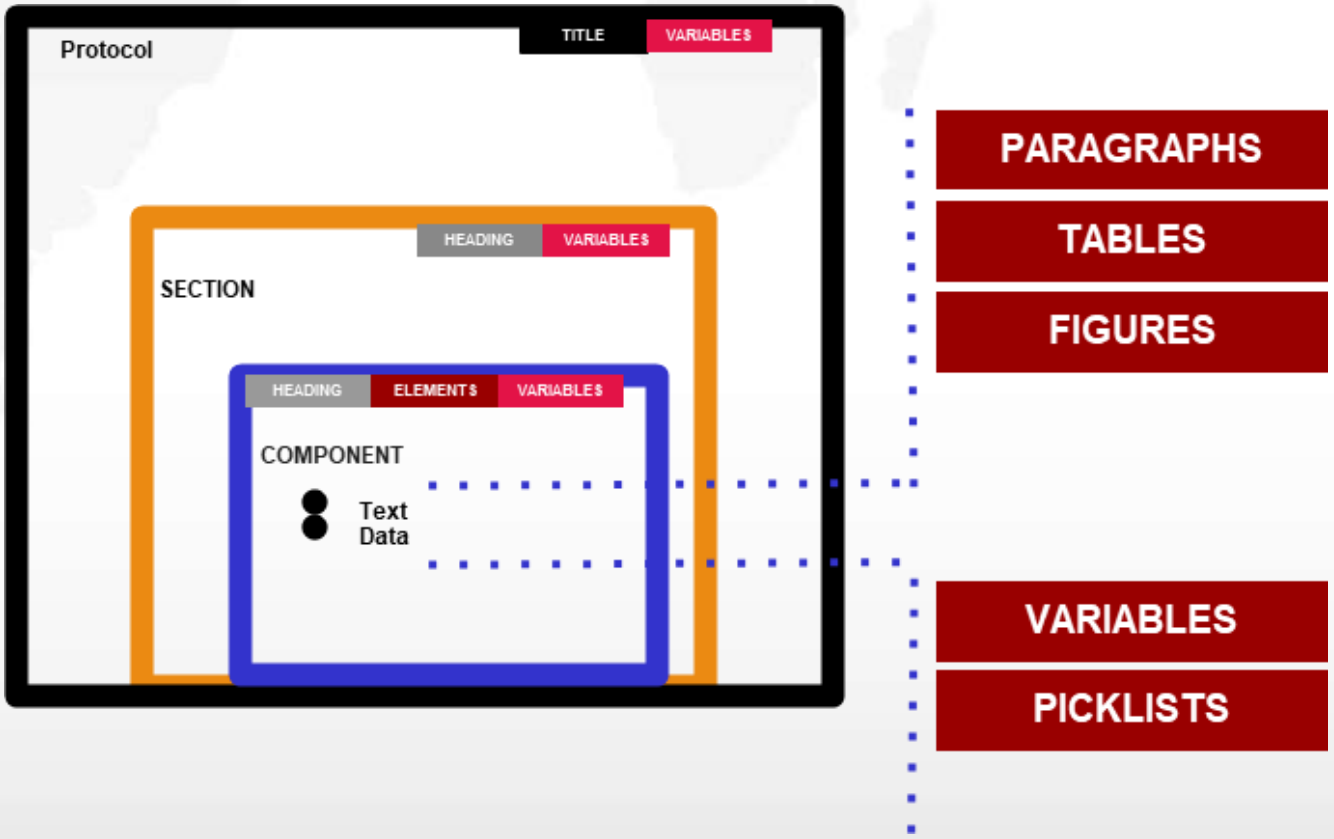
Objectives and Benefits – Technical Specification

The Technical Specification presents

- business requirements and common structured protocol content components
- conformance, cardinality, and other technical attributes that enable the electronic exchange of protocol content
- an open, non-proprietary standard for electronic exchange enables development of interoperable electronic tools to facilitate exchange, review, and execution of protocols.

Content Model Example - Protocol

The content model identifies each piece of content and defines relationships (hierarchy) to enable information exchange at different levels of granularity.



A Look at the Technical Specification

Includes…

…detailed descriptions of the structured content components

…specific data fields

…blocks of text-based content

…other defining attributes

…business rules as established in the Template

Overall Rules

Term (Variable)	Overall rules
Data Type	Text
Topic, Value or Header	H
Definition	
User Guidance	
Conformance	Rules
Cardinality	
Relationship content from ToC representing the protocol hierarchy	All document
Relationship (reference to high level conceptual model)	
Value	REQUIRED Level 1 and Level 2 headings
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Important Considerations

- The Technical Specification is at an early stage of maturity as certain terms (variables) in this version (e.g., Cardinality, Definition, Relationship to Conceptual Model) are to be addressed post-public consultation as ICH M11 progresses through the formal ICH procedure.
- The Template and Technical Specification are versioned documents. As clinical protocol requirements evolve and technology advances, they may be revised subject to a change control process.

More on the Technical Specification

- **Not (yet) a complete specification, but we need input now from:**
  - Software developers and the vendor community
  - IT professionals
  - Data standards experts
  - Data managers, statisticians
- **Current version is a restatement of the protocol template**
  - Does not reflect a complete data model
  - Does not specify a standard or all details necessary for message exchange
- **Additional refinement of the Tech Spec will proceed in partnership with one or more Standards Development Organizations (SDOs)**
  - Conceptual, logical, and physical models
  - Message exchange
  - Will include additional opportunities for engagement and review

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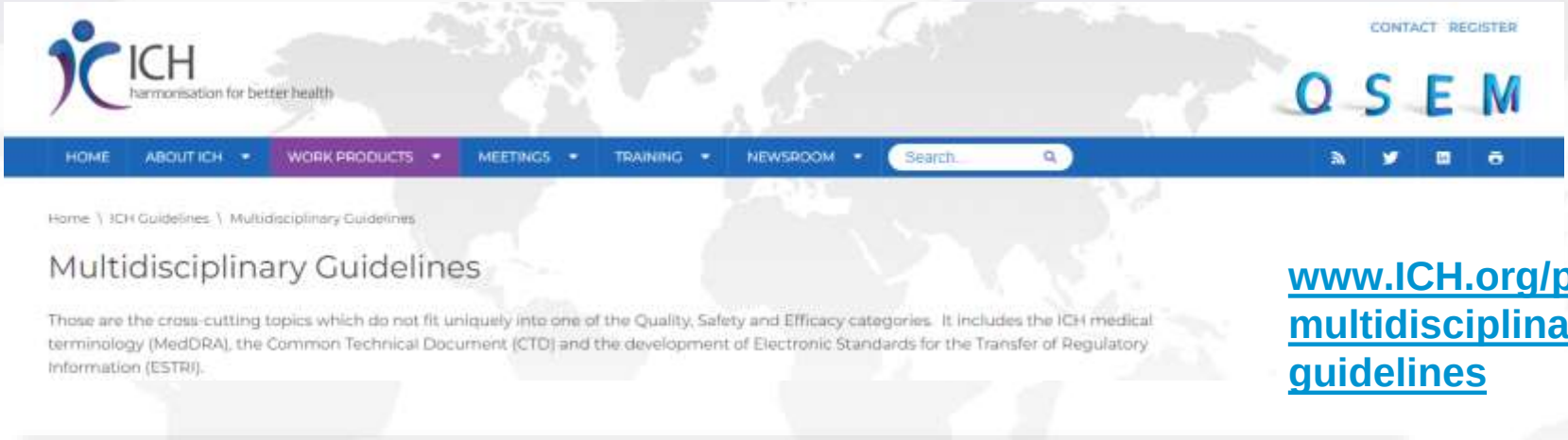
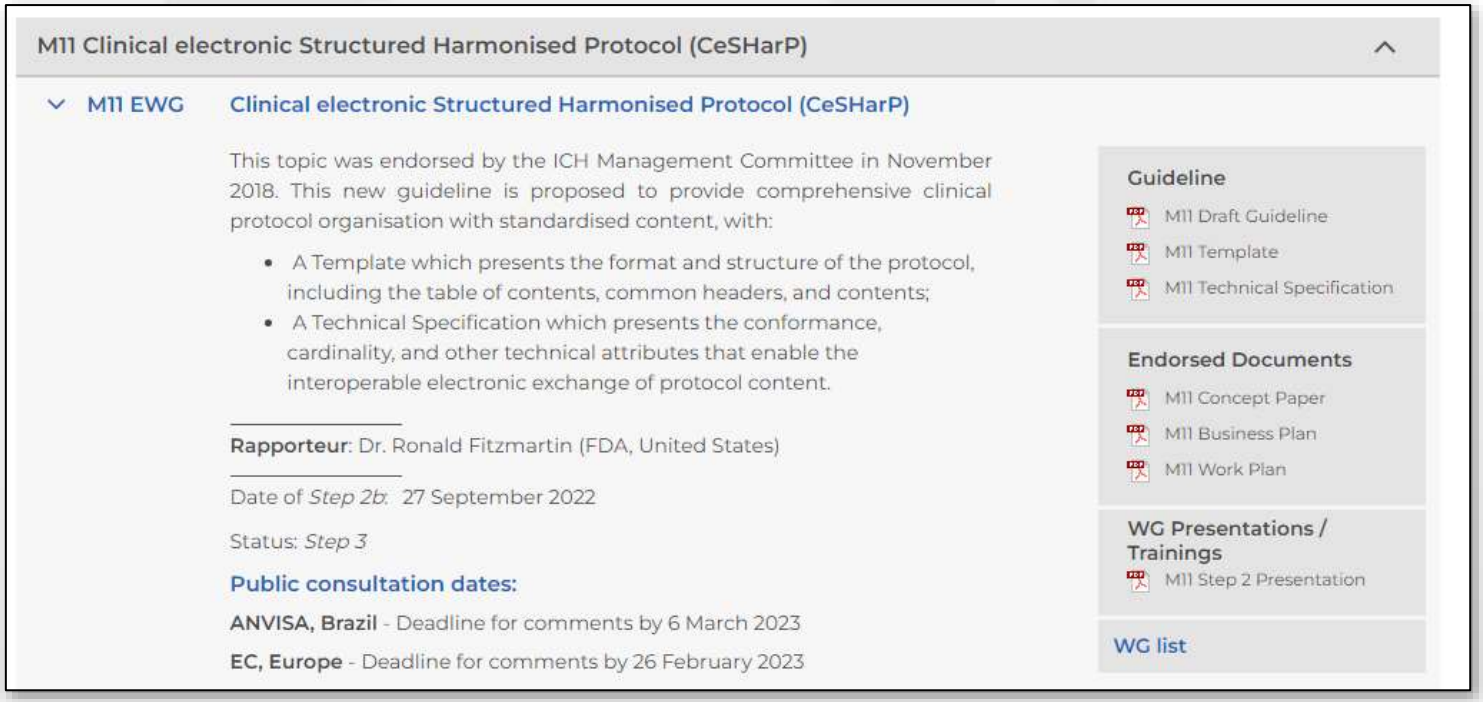
Conclusion

A harmonised clinical protocol Template and Technical Specification for electronic exchange of protocol information will enhance the ability of sponsors, regulators, investigators, and other stakeholders to initiate, review, and conduct clinical research, resulting in more efficient drug development and delivery of medicines to patients.

For More Information



www.ICH.org/page/multidisciplinary-guidelines



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Thank You

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