European Federation of Pharmaceutical Industries and Associations

ACT EU: Clinical Trial Data Analytics Workshop

ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)

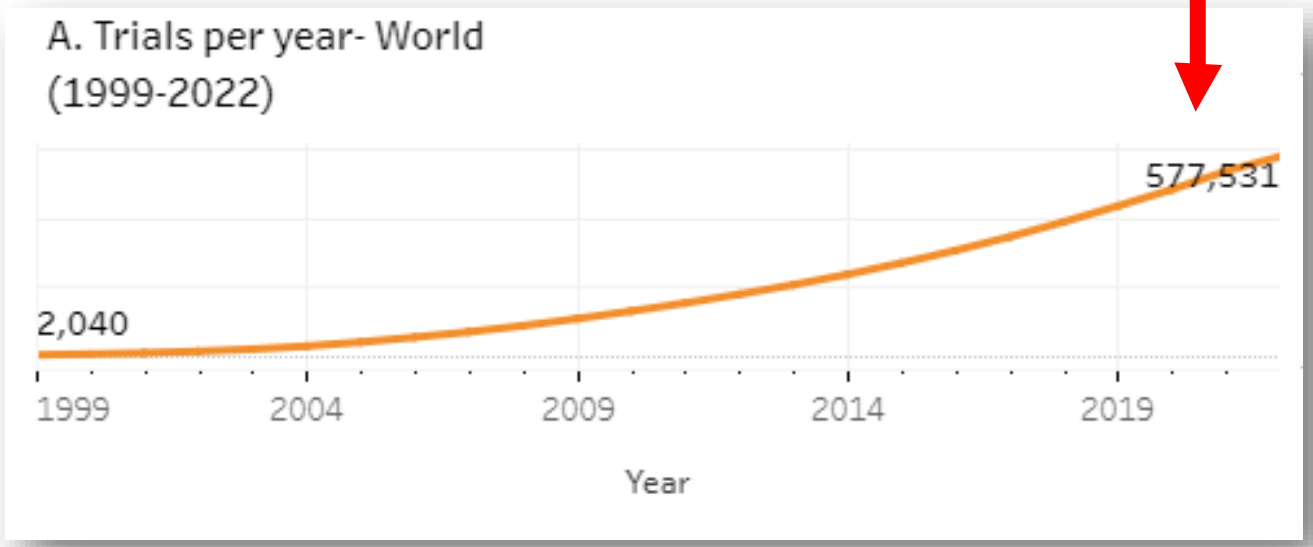


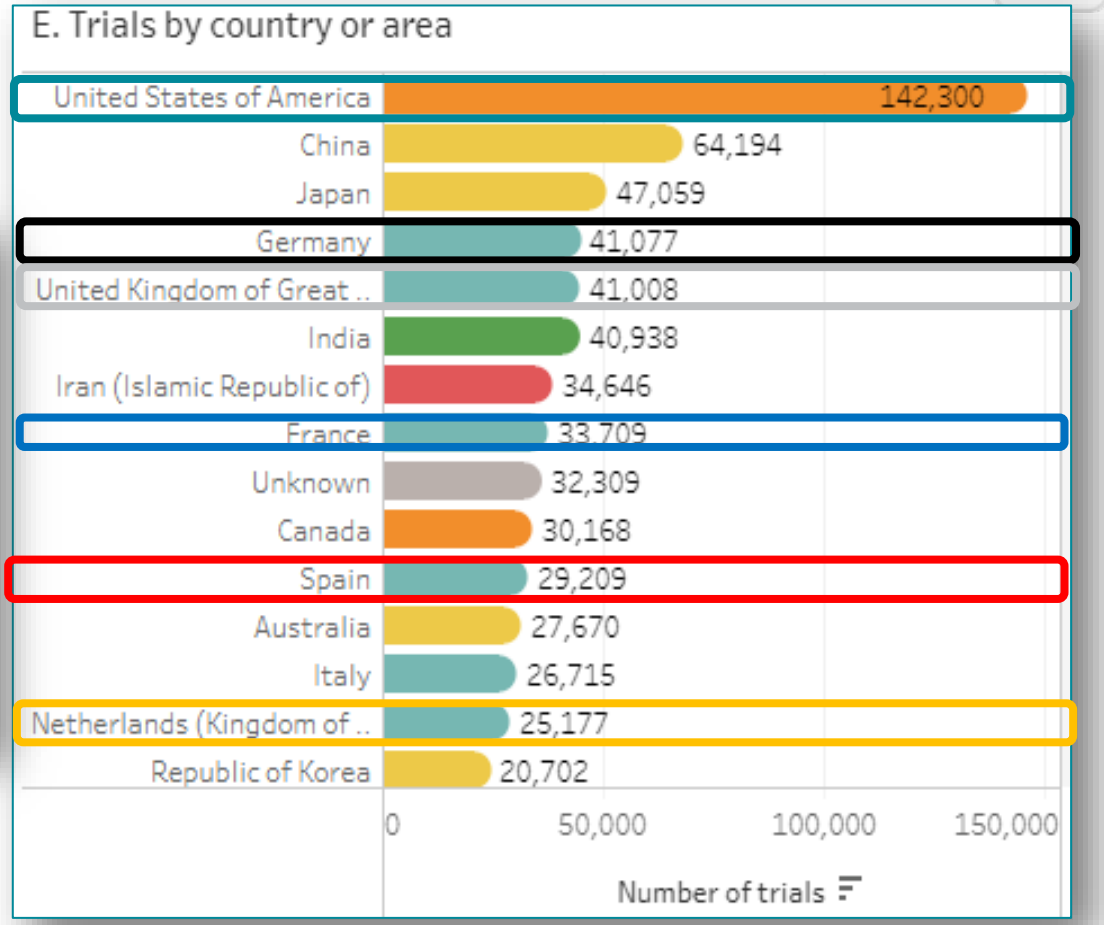



Vada A. Perkins
VP, Global Head of Regulatory Intelligence & Policy
ICH M2 EFPIA Topic Leader
Boehringer-Ingelheim
Jan 2024

Number of Interventional Clinical Trials in 2022

577,531



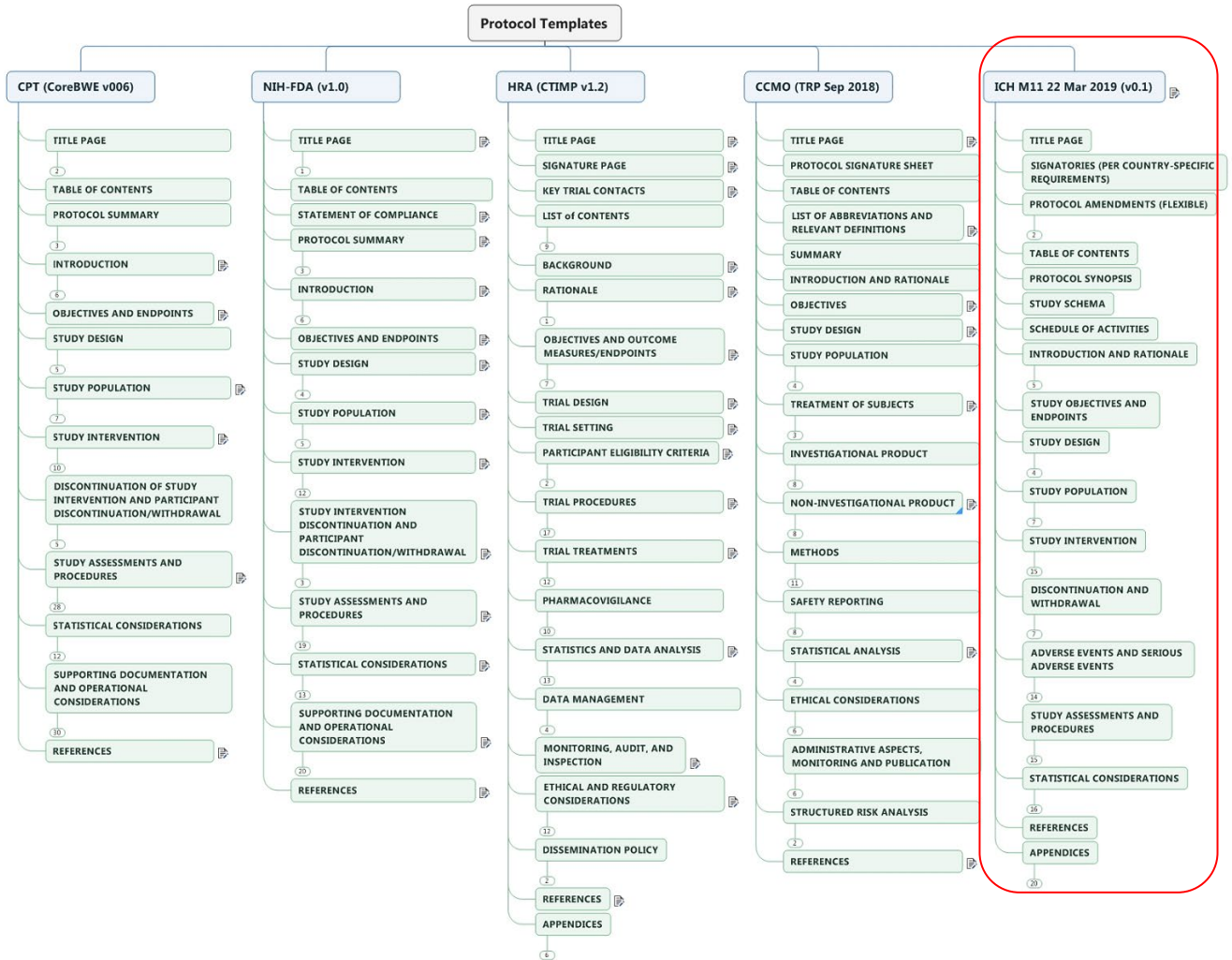


Number of trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2022) (who.int)

Impact without an Internationally Standardised Clinical Protocol

- Delayed timelines due to inconsistency and lack of clarity
- **Resource-intensive manual activities**
- Increased costs
- **Inefficient reuse of knowledge** and duplication of effort
- Inability to leverage tools for **review**, **analysis**, and **reporting**
- **Limited exchange/utilization** of data collected in each protocol

M11 Clinical Protocol Template Landscape



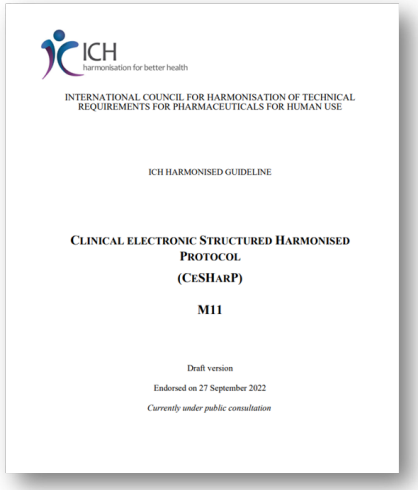
1. TCB, 2. NIH-FDA, 3. NHS Health Research Authority, UK, 4., Central Committee on Research, NL

M11 Collaborations w/other ICH EWGs

- 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 Template can be exchanged using many formats

Guideline & Template → Tech Spec → Technical Implementation Guide → FHIR Profiles


ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

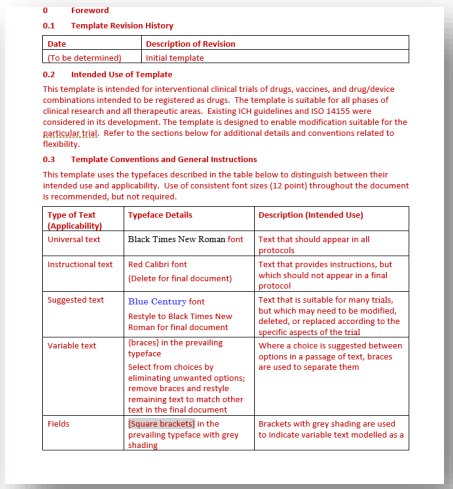
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
(CESHARP)

M11

Draft version

Endorsed on 27 September 2022

Currently under public consultation


0 Foreword

0.1 Template Revision History

Date	Description of Revision
(To be determined)	Initial template

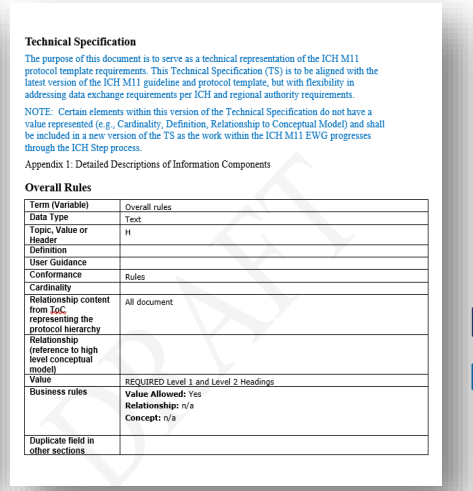
0.2 Intended Use of Template

This template is intended for interventional clinical trials of drugs, vaccines, and drug/device combinations intended to be registered as drugs. The template is suitable for all phases of clinical research and all therapeutic areas. Existing ICH guidelines and ISO 14155 were considered in its development. The template is designed to enable modification suitable for the particular trial. Refer to the sections below for additional details and conventions related to flexibility.

0.3 Template Conventions and General Instructions

This template uses the typefaces described in the table below to distinguish between their intended use and applicability. Use of consistent font sizes (12 point) throughout the document is recommended, but not required.

Type of Text (Applicability)	Typeface Details	Description (Intended Use)
Universal text	Black Times New Roman font	Text that should appear in all protocols
Instructional text	Red Calibri font (Delete for final document)	Text that provides instructions, but which should not appear in a final protocol
Suggested text	Blue Century font Restyle to Black Times New Roman for final document	Text that is suitable for many trials, but which may need to be modified, deleted, or replaced according to the specific aspects of the trial
Variable text	(braces) in the prevailing typeface Select from choices by eliminating unwanted options; remove braces and restyle remaining text to match other text in the final document	Where a choice is suggested between options in a passage of text, braces are used to separate them
Fields	[Square brackets] in the prevailing typeface with grey shading	Brackets with grey shading are used to indicate variable text modelled as a


Technical Specification

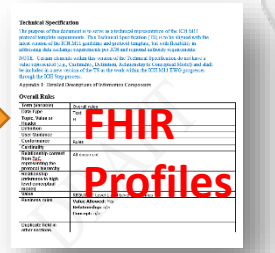
The purpose of this document is to serve as a technical representation of the ICH M11 protocol template requirements. This Technical Specification (TS) is to be aligned with the latest version of the ICH M11 guideline and protocol template, but with flexibility in addressing data exchange requirements per ICH and regional authority requirements.

NOTE: Certain elements within this version of the Technical Specification do not have a value represented (e.g., Cardinality, Definition, Relationship to Conceptual Model) and shall be included in a new version of the TS as the work within the ICH M11 EWG progresses through the ICH Step process.

Appendix 1: Detailed Descriptions of Information Components

Overall Rules

Term (Variable)	Overall rules
Data Type	Text
Topic, Value or Header	H
Definition	
User Guidance	
Conformance	Rules
Cardinality	
Relationship content from IoC 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	



Electronic Document
Human Readable Form

Standard Message Exchange Formats*

cdisc

Machine - Readable Form

Per ICH Regional Requirements