cdisc

2026 Korea CDISC Day

29 October 2026 · Seoul, Korea

Implementation of ICH M11 in Korea and Expected Benefits

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Session 1 · 29 October 2026



Agenda

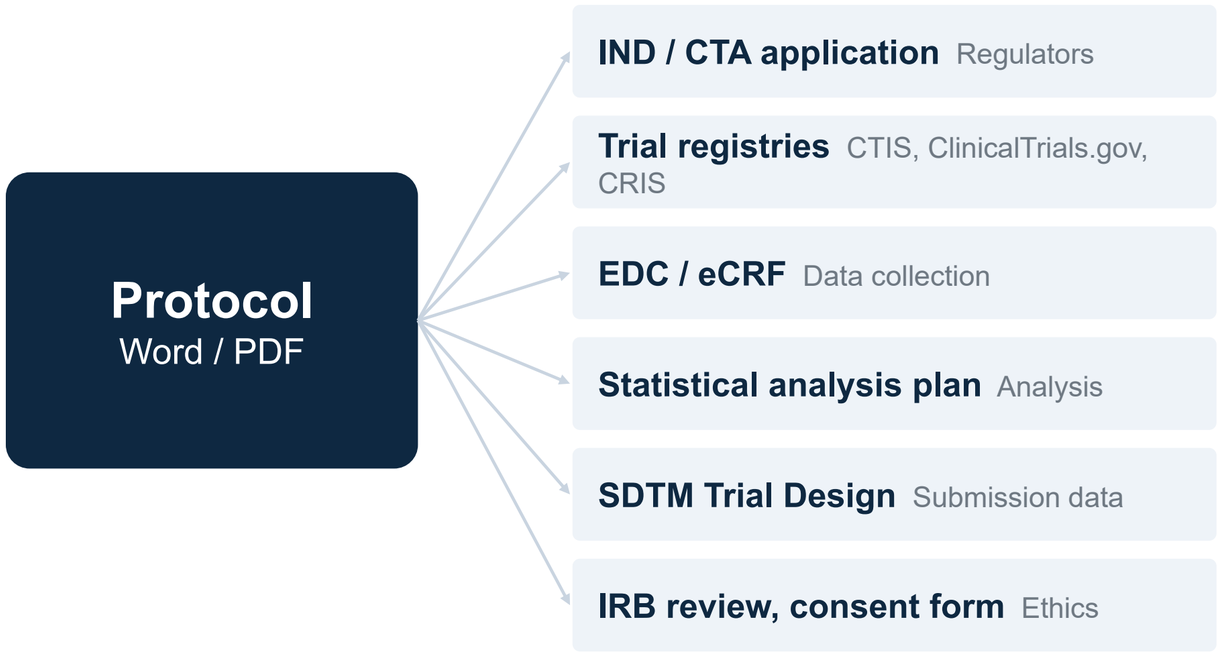
1. ICH M11 in brief
2. Implementation in Korea: the ARICTT council
3. Expected benefits for data flow
4. Summary

ICH M11 in Brief

Clinical electronic Structured Harmonised Protocol (CeSHarP)

Why a Harmonised, Structured Protocol

The same protocol content is re-entered by hand into each downstream system



76%

of protocols had ≥1 substantial amendment (57% in 2015)

3.3

amendments per amended protocol (mean), up 60% from 2.1

260 days

mean time to last oversight approval of an amendment (median 190)

$535K

median direct cost of one Phase III substantial amendment

ICH M11 Guideline §1.1: *"Variability in format and core content among sponsors contributes to inefficiencies."*

Getz KA, et al. Ther Innov Regul Sci 2016. doi:10.1177/2168479016632271 · Getz K, et al. Ther Innov Regul Sci 2024. doi:10.1007/s43441-024-00622-9

Toward a Common Protocol: From Templates to M11

2010	2013	2015	2017	2018	2025	2025
CDISC PRM v1.0 Protocol Representation Model	**SPIRIT 2013** Minimum protocol items	**TransCelerate CPT** Common Protocol Template	**NIH-FDA template** Phase 2 and 3 IND protocols	**ICH M11 concept paper** Endorsed November 2018	**SPIRIT 2025** 34 minimum items	**ICH M11 Step 4** Template and TS adopted

ICH M11 brings these templates and the idea of a protocol data model into one harmonised ICH standard.

Chan AW, et al. SPIRIT 2025 statement. BMJ 2025;389:e081477. doi:10.1136/bmj-2024-081477

ICH M11: Three Linked Documents


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

Final Version

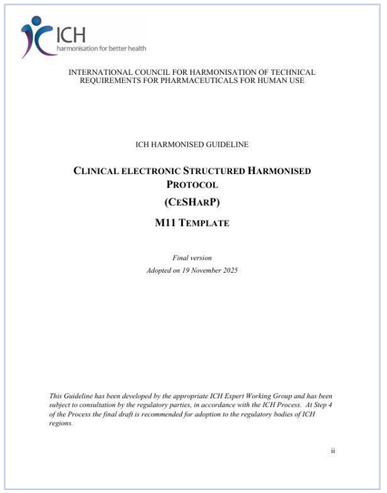
Adopted on 19 November 2025

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of ICH regions.

Guideline

6 pages

Scope and general design principles


ICH
harmonisation for better health

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M11 TEMPLATE

Final version

Adopted on 19 November 2025

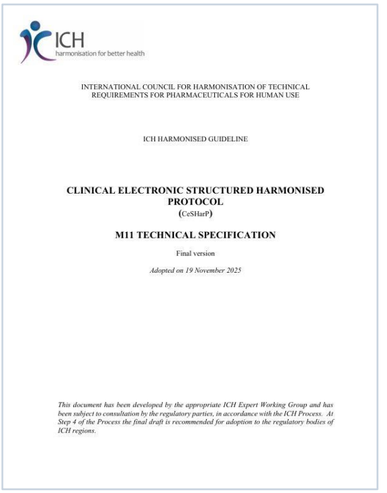
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ii

Template

67 pages

Table of contents, common headings, instructions


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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

M11 TECHNICAL SPECIFICATION

Final version

Adopted on 19 November 2025

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Technical Specification

245 pages

Data elements, conformance, code lists

Nov 2018 — Concept paper

Sep 2022 — Step 2, public consultation

Feb 2025 — Revised TS consultation

19 Nov 2025 — Step 4, all three documents

May 2026 — FDA final guidance

11 Jun 2026 — EU effective date

Template: 14 Sections, Execution-Critical Content First

1. **Protocol Summary**
2. Introduction
3. Objectives and Estimands
4. Trial Design
5. Trial Population
6. Trial Intervention
7. Discontinuation
8. Assessments and Procedures
9. AE, SAE, Pregnancy
10. Statistical Considerations
11. Oversight and General Considerations
12. Supporting Details
13. Glossary
14. References

§1 Protocol Summary = Synopsis, Trial Schema, Schedule of Activities (SoA)

Design principles (§2.1)

- Build common core content
- Serve the needs of stakeholders
- Define content for electronic exchange
- Design for content re-use
- Maintain flexibility

Needs of investigators and site staff were prioritised; higher-level headings are fixed, many lower-level sections can be adapted.

Technical Specification: Every Field Is a Defined Data Element

Term (Variable)	[Trial Phase]
Data Type	Valid Value
Data (D), Value (V) or Heading (H)	V
Definition	C48281
User Guidance	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Conformance	Required
Cardinality	One to one; Sponsor Protocol Identifier
Relationship content from ToC representing the protocol hierarchy	Title Page
Value	Code List C217045: ICH OID 2.16.840.1.113883.3.989.2.3.1.18 Early Phase 1 (C54721); Phase 1 (C15600); Phase 1/Phase 2 (C15693); Phase 1/Phase 2/Phase 3 (C198366); Phase 1/Phase 3 (C198367); Phase 2 (C15601); Phase 2/Phase 3 (C15694); Phase 2/Phase 3/Phase 4 (C217024); Phase 3 (C15602); Phase 3/Phase 4 (C217025); Phase 4 (C15603)
Business rules	**Value Allowed**: Yes **Relationship**: Heading; Sponsor Protocol Identifier **Concept:** C48281 ICH OID 2.16.840.1.113883.3.989.2.3.3.16
Repeating and/or Reuse Rules	No

Example: [Trial Phase] element in the M11 Technical Specification

≈575
data elements (author's count)

23
M11 code lists (author's count)

C217023
NCI subset for M11 terms

Each element specifies

Data type	Text, valid value, number, date
Definition	NCI Thesaurus C-code
Conformance	Required, optional, conditional
Cardinality	One to one, one to many
Value	ICH M11 controlled terminology
Business rules	Allowed values, relationships, OID

ICH and CDISC agreed that CDISC maintains M11 terminology and keeps it freely available to the public.

Estimands and Amendments Become Structured Content

Estimands (ICH E9(R1))

§1.1.1 objectives and estimands in the synopsis, “in natural, nontechnical (layperson) language”

§3 a table per objective to “precisely describe the associated estimand(s)”

- Treatment
- Population
- Variable (endpoint)
- Intercurrent events and strategies
- Population-level summary

Amendment Details (front matter)

- **Reason** Primary and secondary, from a pick list
- **Scope** Global or not global
- **Enrolment** Approximate % enrolled at sponsor approval
- **Safety or rights** Substantial impact: yes or no
- **Data reliability** Substantial impact: yes or no
- **History** §12.3 Prior protocol amendments

Implementation in Korea

The ARICTT public-private council, 2026

ARICTT: A Public-Private Council on Clinical Trial Regulation

Advanced Regulatory Innovation for Clinical Trials Transformation

- Experts from industry, academia, hospitals and government
- Open discussion of regulatory issues and preparation of recommendations
- 2026: MFDS-funded research project, Seoul National University (Mar to Nov)

ARICTT
Advanced Regulatory Innovation for Clinical Trials Transformation

2022

Decentralised clinical trials

2023

Digital technology, e-consent, recruitment

2024

EHR use, registry-based trials, AI

2025

Labelling of investigational products

2026

Quality by Design (QbD) and ICH M11

arictt.org

2026 Structure: Two Expert Bodies Under One Steering Committee

Steering Committee

9 institutions and associations: hospitals and academia 2, sponsor associations 4, government agencies 3

Modernization Working Group

Topic: Quality by Design

- 11 members, monthly
- Hospitals, MFDS, KIDS, global and domestic pharma, CROs
- Output: QbD recommendation

Regulatory Science Task Force

Topic: ICH M11

- 12 members, monthly
- Hospitals, MFDS, KIDS, pharma, CRO, eClinical and data companies
- Output: Korean M11 guideline (draft)

Supported by an advisory panel (participant view, legal) and a secretariat (SNU research operations team). KIDS: Korea Institute of Drug Safety and Risk Management

How ARICTT Chose and Prepared the 2026 Topics

1

Topic selection

Steering committee criterion: timeliness and field demand. The joint kickoff fixed two topics: QbD and ICH M11

2

Overseas resources

Recommendations and toolkits from CTTI, ICH, MHRA, TransCelerate and CDISC; side-by-side tables against the source text

3

Member cases

Case collection form; cases shared and discussed at task force meetings

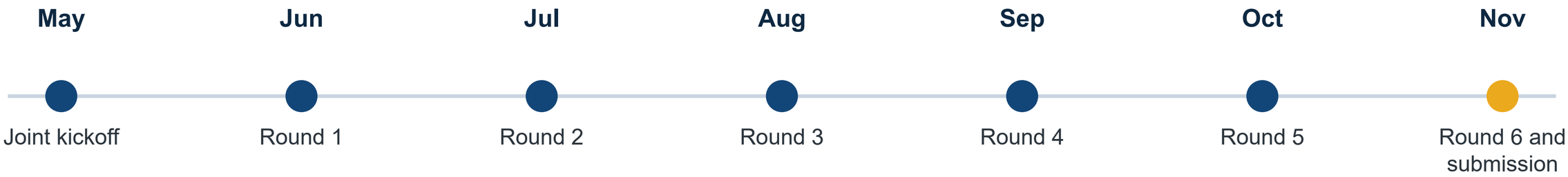
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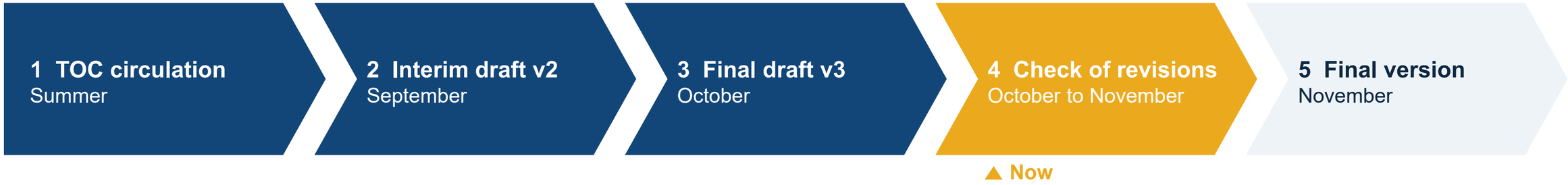
Open table of contents

Draft TOC circulated on the platform before the full text was drafted

Why M11 in Korea: protocol formats differ by sponsor, and global M11 adoption makes a Korean version timely for sponsors, CROs, sites and IRBs.

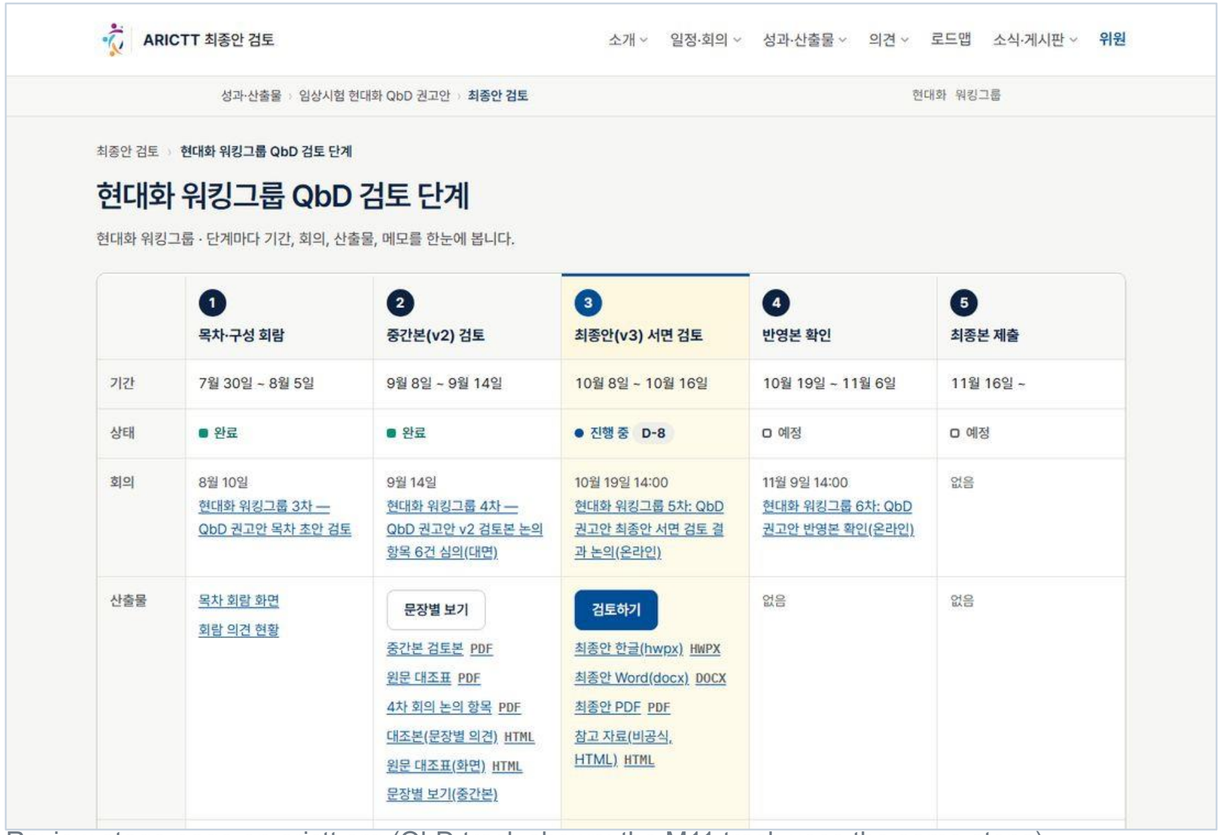
2026 Process: Monthly Meetings and a Five-Step Review





Key decision: prepare the guideline as a recommendation for stepwise adoption, not an immediate mandate.

A Web Platform for Open and Member Comments



Review stage page on arictt.org (QbD track shown; the M11 track uses the same steps)

1. **Two channels**
   Public comments from anyone; member comments after login

2. **Comment where it applies**
   On the table of contents, the glossary and single sentences of a draft

3. **Every comment answered**
   Secretariat records accepted, partly accepted, not accepted or for discussion

4. **Transparent loop**
   Disposition table shared; changes carried into the next version

Korean M11 Guideline: Translation Plus Local Annexes

Faithful translation of ICH M11

Ch. 1 to 3 Introduction, design principles, template conventions

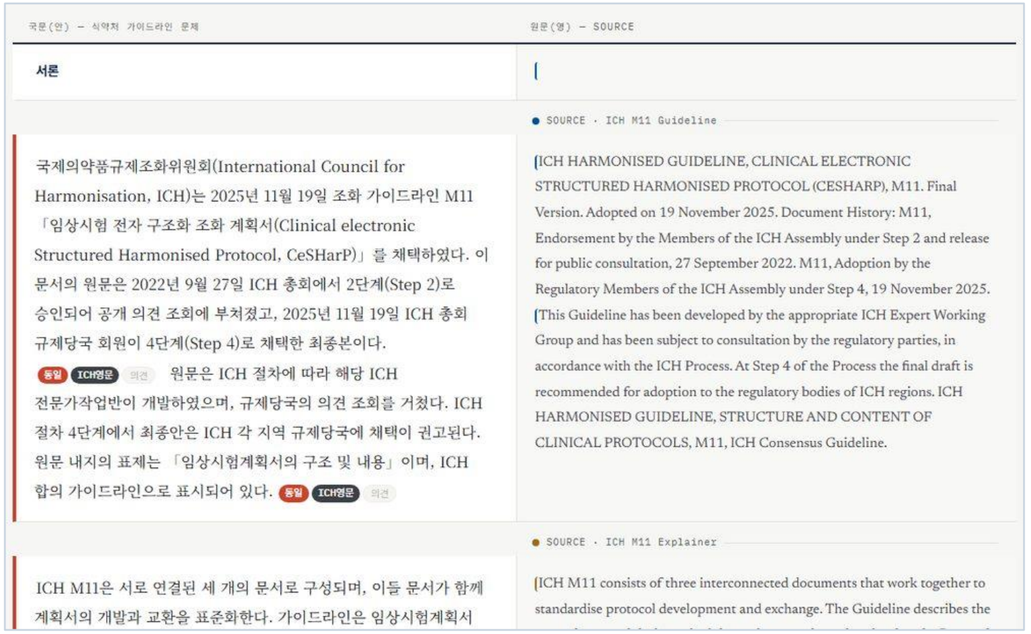
Appendix 1 Korean M11 Template, plus a Word form for sponsors

Added for use in Korea

Appendix 2 Glossary of 59 terms with English and source

Appendix 3 Map of Korean protocol requirements to M11 sections

Appendix 4 Notes for use in Korea, stepwise adoption



Review screen: Korean draft beside the ICH original

Status: draft v3 (October 2026), under committee review
A private-sector recommendation; no regulatory effect unless MFDS acts

Terminology: One Korean Term for Each M11 Concept

- Terms defined in Korean GCP come first, then MFDS guidance documents
- English original shown at first use
- Terms without precedent agreed by comment and recorded with their source
- Common alternative wordings listed for reference only

M11 term	Korean term	Source
trial participant	임상시험대상자	Korean GCP
protocol amendment	임상시험 변경계획서	Korean GCP
estimand	추정대상모수	MFDS estimand guideline (2023)
schedule of activities	임상시험 일정표	Set in this guideline
conformance	준수 요건	Set in this guideline
cardinality	발생 수	Set in this guideline
protocol deviation	임상시험계획서 이탈	Set in this guideline

Korean Protocol Requirements Fit the M11 Structure

16 required protocol items (Enforcement Rule on the Safety of Pharmaceuticals, Art. 24(2)) mapped to M11 sections

1 **Title, phase, ID, revisions** Title Page, Amendment Details	2 **Synopsis** §1.1	3 **Background, benefit-risk, dose rationale** §2.1, 2.2, 6.2	4 **Objectives** §3
5 **Population, withdrawal, sample size** §5, 7, 10.11	6 **Design, allocation, blinding** §4.1, 4.2, 6.7, 1.2	7 **End and early termination** §4.3, 4.4, 10.9	8 **Investigational product** §6.1, 6.3, 6.6
9 **Dosing, concomitant drugs, compliance** §6.3, 6.4, 6.8, 6.10	10 **Procedures, SoA, AE reporting** §1.3, 8, 9	11 **Statistics** §10	12 **Data management** §11.7 to 11.9
13 **Ethics and administration** §11.1, 11.3, 11.6, 11.8, 11.12	14 **Sponsor, principal investigator** Title Page, §11.2	15 **Comparative dissolution (BE only)** No M11 section: §12.2	16 **Other necessary items** §12.2, added appendix

Stepwise, Voluntary Adoption

Now	Voluntary use alongside existing templates; refer to the M11 table of contents and terms; share problems found
Preparation	Pilot selected sections in authoring and review; collect partial-use cases with their scope stated
Later	Wider scope and timing are not set by this guideline

Points for each stakeholder (Appendix 4)

Sponsors
Map current template items to M11 sections; update SOPs and review steps

CROs
Expect extra mapping work early; standard terms, examples and training help

Investigators, sites
Synopsis, schema and SoA up front; update SOP and source-form cross-references

IRBs
Align review checklists with M11 section numbers

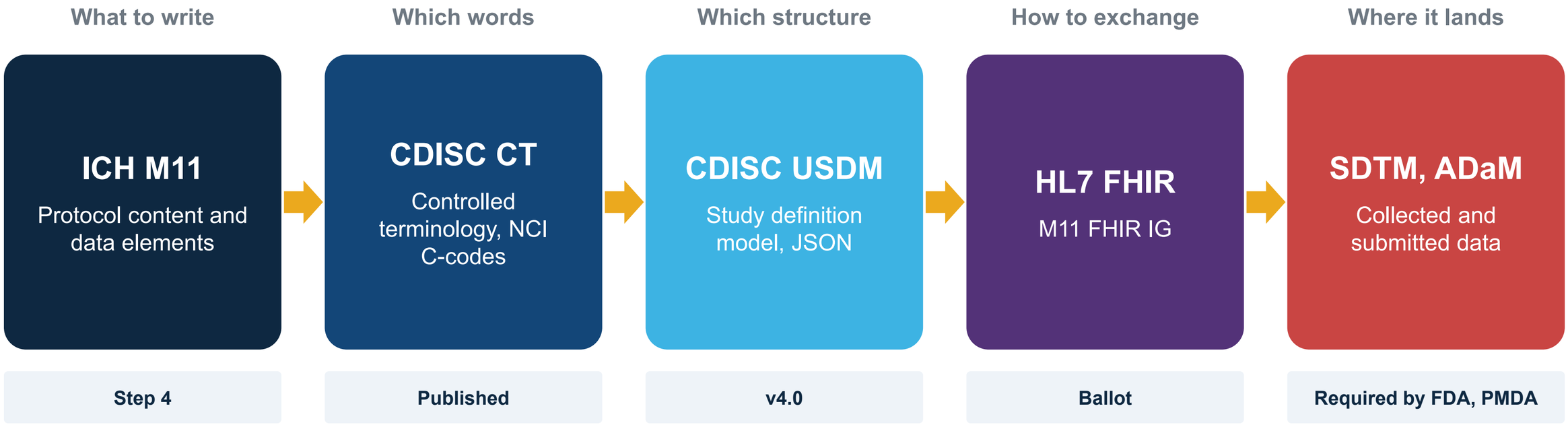
Expected Benefits

From a protocol document to reusable, structured data

Expected Benefits by Stakeholder

Sponsors and CROs	One structure across trials; content reused for registries, CRFs and the SAP instead of reformatting
Investigators and sites	Synopsis, schema and SoA in the same place in every protocol, from any sponsor
IRBs	Predictable location of items; faster completeness checks; amendments summarised in one table
Regulators	Consistent review across sponsors; a basis for future structured exchange
Participants and public	Registry entries and plain-language summaries from the same source content

Where M11 Sits Among Data Standards



Shared NCI C-codes link an M11 field, a USDM attribute and an SDTM value, so one definition can travel the whole chain.

Example: One Code From Protocol to SDTM

M11 Technical Specification

[Trial Phase]
Valid value, required
Phase 2 **C15601**

§1.2 Trial Schema
Arm: High Dose
Epoch: Treatment 2
Element: 54 mg + 27 mg TTS

USDM v4.0 JSON

```
"studyPhase": {
 "standardCode": {
  "code": "C15601"
  "decode": "Phase II Trial" }}
```

```
{ "id": "StudyCell_13",
  "armId": "StudyArm_3",
  "epochId": "StudyEpoch_3",
  "elementIds": ["StudyElement_5"] }
```

SDTM

TS domain
TSPARMCD = TPHASE
TSVAL = "PHASE II TRIAL"
TSVALCD = **C15601**

TA domain
ARM = "High Dose"
TAETORD = 3, ETCD = EL5
EPOCH = "Treatment 2"

Values from the CDISC Pilot Study (LZZT) USDM v4.0 example; SDTM TS per SDTMIG v3.3. TA mapping is conceptual.

Clinical Pharmacology in the M11 Template

Section	Template text
§1.3 SoA	“When applicable for studies with extensive sampling (e.g., serial PK sampling), a separate table may be added.”
§4.1 Design	“sentinel dosing (or lack thereof), dose escalation, and cohort expansion”
§4.3 Stopping rules	“when a cohort or dose escalation should be terminated”
§5.5.1 Meals	“timing of meals relative to dosing”
§6.2 Dose rationale	“differences in trial population characteristics (e.g., age, sex, race) that could lead to differences in pharmacokinetics and pharmacodynamics”
§8.5 PK	“Define the PK parameters to be calculated and the calculation methods.”
§10.4.1.1 Analysis	“describe the model (inputs and outputs), the underlying assumptions, and the method of model fitting”

Example: PK Sampling Times Planned Once, Reused Downstream

Food-effect crossover: fasted and fed, 2 periods, 20 participants, 7-day washout (our pilot template)

M11 §1.3 SoA

Main table: visits D-14, D1, D8, D17

Separate PK sampling table:
13 times per period
0, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 48 h

“When applicable for studies with extensive sampling (e.g., serial PK sampling), a separate table may be added.”

USDM Timing

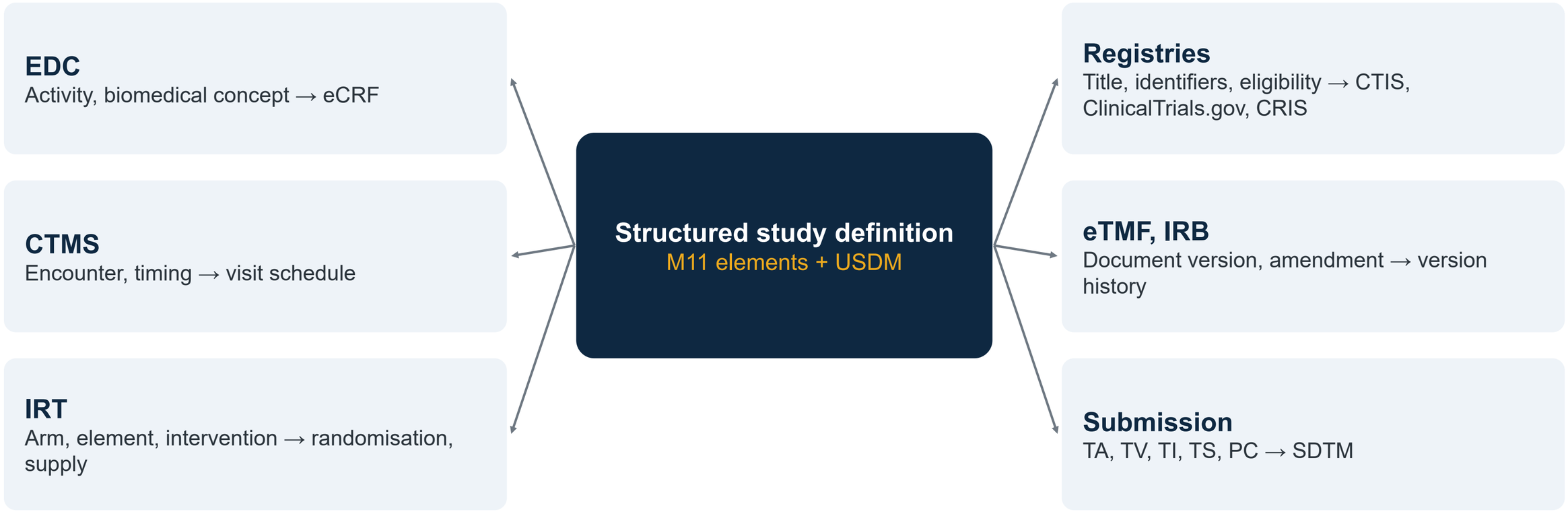
```
"instanceType": "Timing",
"label": "0.5 h post-dose",
"type": "After",
"value": "PT30M",
"relativeToFrom":
    "Start to Start",
"relativeTo..": "DOSE_P1"
```

SDTM PC planned times

NUM	PCTPT	PCELTM	REF
1	PRE-DOSE	PT0H	DOSE P1
2	0.5 H POST-DOSE	PT30M	DOSE P1
3	1 H POST-DOSE	PT1H	DOSE P1
…	…	…	…

Nominal times fixed as ISO 8601 values at the design stage, before any data are collected

Linking the Structured Protocol to Trial Systems



Now available: USDM-based commercial tools (TransCelerate DDF Solution Showcase 2026); OpenStudyBuilder exports USDM.

SNUH Pilot: A Standards-Based Data Flow Prototype

1
M11 protocol
TOC structure, M11 to USDM mapping spec

In design

2
Study definition
USDM v4-shaped JSON export (subset)

Built

3
Phase 1 designs
BE 2×2, 3-way, SAD, MAD, food effect, DDI

Built

4
eCRF, collection
CDASH fields, NCI CT, audit trail

Built

5
Standard outputs
SDTM, ADaM, Define-XML 2.1, Dataset-JSON

Built

6
Checks
CDISC CORE; Part 11 and E6(R3) self-check

Built

Aim
Test one standards chain from protocol design to submission files, focused on phase 1 and BE studies

Limits
Prototype, not system-validated; not used for real trial data; USDM subset with own extensions

Take-Home Messages

1. ICH M11 sets one international standard for protocol structure (Template) and for data elements with controlled terminology (Technical Specification).

2. In Korea, the ARICTT council has drafted a Korean M11 guideline with a glossary and a map to Korean requirements, recommending stepwise, voluntary adoption.

3. Combined with CDISC CT, USDM, FHIR and SDTM, protocol content can move to EDC, CTMS, registries and submission data without re-entry.

Thank You

Ki Young Huh · Seoul National University Hospital

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