DAILY ENGLISH READING

5 August 2026 · 30-minute active reading pack for Davin

TODAY'S QUESTION

Can a structured protocol become the source code of a clinical trial?

WHY SELECTED

ICH M11 turns protocol structure and selected content into standardized, electronically exchangeable fields. For SP teams, this creates an upstream metadata source for trial-design domains, specifications, analysis metadata and amendment impact checks.

Difficulty: C1 · ICH M11 + USDM + metadata-driven automation

READING ORDER · 30 MINUTES

Min	Task	Focus
0-3	Preview	Predict which protocol fields could drive SDTM or ADaM metadata.
3-15	M11	Read the overview and scan the guidance, template and technical specification.
15-20	CDISC DDF	Review the USDM model, terminology, API and conformance rules.
20-25	Implementation	Read the current Protocol-to-SDTM use case.
25-30	Output	Design one controlled automation chain.

SOURCES · OPEN ACCESS

MAIN · FDA · May 2026
M11 Clinical Electronic Structured Harmonised Protocol
Official guidance page

SUPPORT 1 · CDISC
Digital Data Flow / Unified Study Definition Model
Official project page

SUPPORT 2 · CDISC Europe 2026
From Protocol to SDTM
Programme description

BRIEF BACKGROUND

Traditional protocols are interpreted repeatedly to build EDC forms, monitoring plans, SDTM domains, analysis specifications, SAPs and reports.

The final M11 package contains guidance, a harmonized template and a technical specification with standardized fields and terminology.

CDISC USDM supplies a reusable study-definition model supported by terminology, APIs, an implementation guide and conformance rules.

Structured protocol data can drive automation, but sponsor standards, mapping decisions, collected-data checks and expert review remain necessary.

Amendment handling is the decisive control: affected artifacts must be identified, regenerated, regression-tested and approved.

KEY VOCABULARY

Term	中文	Meaning / use
structured protocol	结构化方案	A protocol represented with standardized fields, sections and terminology.
harmonised template	协调统一模板	A common protocol structure agreed across regions.
technical specification	技术规范	Rules defining fields, formats, terminology and exchange.
machine-readable	机器可读的	Structured so software can reliably parse and reuse it.
data element	数据要素	A defined unit of information such as an endpoint or visit.
controlled terminology	受控术语	Standardized permitted values and meanings.
electronic exchange	电子交换	Transfer of structured information between systems.
downstream process	下游流程	A later activity that consumes protocol information.
manual transcription	人工转录	Re-entering information from one document or system into another.
single source of truth	单一事实来源	An authoritative source used consistently across outputs.
study definition	研究定义	Structured representation of design, arms, epochs, objectives and endpoints.
provenance	来源与处理轨迹	Evidence showing origin and transformation history.
conformance rule	一致性规则	An executable rule checking whether content follows a standard.
version alignment	版本对齐	Keeping related artifacts synchronized with the same approved version.
metadata-driven automation	元数据驱动自动化	Automation controlled by structured definitions rather than hard-coded text.

USEFUL PHRASES

1. **represent protocol content as structured data**
M11 represents protocol content as structured data rather than narrative text alone.

2. **enable electronic exchange across systems**
Standardized fields enable electronic exchange across systems.

3. **reduce repeated manual transcription**
A digital protocol can reduce repeated manual transcription.

4. **serve as a single source of truth**
The approved study definition can serve as a single source of truth.

5. **drive downstream study-build activities**
Structured protocol elements can drive downstream study-build activities.

6. **maintain alignment across artifacts**
Teams must maintain alignment across the protocol, SAP and datasets.

7. **apply conformance rules automatically**
Software can apply conformance rules automatically.

8. **preserve end-to-end provenance**
The workflow should preserve end-to-end provenance.

9. **separate structured facts from generated narrative**
The system should separate structured facts from generated narrative.

10. **treat amendments as controlled changes**
Protocol amendments should be treated as controlled changes to shared metadata.

COMPREHENSION QUESTIONS

1. What are the three components of the M11 package?

2. Why does repeated protocol interpretation create risk?

3. Which USDM deliverables support reuse and validation?

4. Why are programmers still required?

5. How should amendments propagate downstream?

RETELLING PROMPTS

30 seconds: Narrative problem -> structured protocol -> benefit.

45 seconds: Protocol -> USDM -> eCRF/SDTM -> validation -> analysis.

60 seconds: Explain how M11 could change an SP team's work.

5-MINUTE SPEAKING / OUTPUT TASK

Your role: Propose one protocol-to-programming automation pilot.

Minute 1: Select TS/TA/TE, an SDTM spec, endpoint metadata, SAP comparison or amendment analysis.

Minutes 2-3: Define inputs, deterministic transformations, LLM scope, checks and approval.

Minute 4: Add versioning, change detection, regression testing and rollback.

Minute 5: State success criteria.

ONE SENTENCE TO KEEP

A structured protocol can become the controlled source code of a clinical trial only when downstream transformations are versioned, validated and traceable.