

KEY VOCABULARY

Term	中文	Meaning / use
clinical data transformation	临床数据转换	The controlled process of turning collected trial data into standardized analysis-ready or submission-ready structures.
SDTM mapping	SDTM 映射	Linking source variables and values to SDTM domains, variables, terminology, and rules.
human-in-the-loop	人在回路	A workflow in which AI proposes or assists, while a qualified person reviews important outputs.
mapping suggestion	映射建议	A proposed source-to-target relationship that still requires verification.
controlled terminology	受控术语	Standardized allowed values governed by a terminology authority such as CDISC/NCI.
transformation rule	转换规则	Explicit logic describing how source data become standardized target data.
traceability	可追溯性	The ability to reconstruct where a standardized value came from and how it was derived.
conformance check	符合性检查	A deterministic check that tests whether data follow a standard or formal rule.
exception handling	异常处理	The process for routing ambiguous or nonstandard cases for special review.
confidence threshold	置信阈值	A rule for deciding when an AI suggestion can proceed automatically or needs review.
audit trail	审计追踪	A record of changes, approvals, versions, and user actions.
versioned metadata	版本化元数据	Metadata whose changes are tracked so past mappings can be reproduced.
submission readiness	申报就绪状态	The state in which data and metadata are sufficiently complete, standardized, and validated for regulatory submission.
deterministic validation	确定性验证	Repeatable programmed checks that return the same result for the same input.
operational bottleneck	运营瓶颈	A process step that limits throughput because it is slow, manual, or error-prone.

USEFUL PHRASES

1. **automate repetitive mapping work** - *AI can automate repetitive mapping work while preserving expert oversight.*
2. **preserve transparency and control** - *The workflow should preserve transparency and control.*
3. **route ambiguous cases to human review** - *Low-confidence mappings should be routed to human review.*
4. **validate generated code before execution** - *Generated transformation code must be validated before production use.*
5. **reconcile source and target metadata** - *Programmers should reconcile source and target metadata.*
6. **keep mapping logic version controlled** - *The team should keep mapping logic version controlled.*
7. **separate suggestion from approval** - *A regulated workflow should separate suggestion from approval.*
8. **measure both efficiency and error rates** - *Teams should measure both efficiency and error rates.*
9. **maintain an auditable decision trail** - *Each accepted mapping should maintain an auditable decision trail.*
10. **treat automation as a controlled pipeline** - *The organization should treat automation as a controlled pipeline rather than a chatbot feature.*

COMPREHENSION QUESTIONS

1. Which clinical-programming activities does SAS identify as manual bottlenecks?
2. Why is human review important for AI-assisted SDTM mapping?
3. Which platform controls support a regulated AI workflow?
4. What does the CDISC China program suggest about the direction of SDTM automation?
5. Which mapping decisions could be automated, and which should be escalated?

RETELLING PROMPTS

30 sec: Bottleneck -> AI assistance -> human approval.

45 sec: Source -> mapping -> checks -> code -> validation -> approval -> SDTM.

60 sec: Explain how AI changes CRO SP work without removing accountability.

5-MINUTE SPEAKING / OUTPUT TASK

Minute 1: Choose one mapping such as AESEV, CMSTDTC, VSPOS, LBTESTCD, or VISIT/VISITNUM.

Minutes 2-3: Check semantic fit, terminology, derivation, reuse, and stored evidence.

Minute 4: Add confidence thresholds, deterministic checks, exception routing, and versioned approval.

Minute 5: Give an accept/reject recommendation.

ONE SENTENCE TO KEEP

AI can accelerate SDTM mapping when it reduces repetitive interpretation, but the regulated value comes from controlled metadata, deterministic validation, and an auditable human approval path.