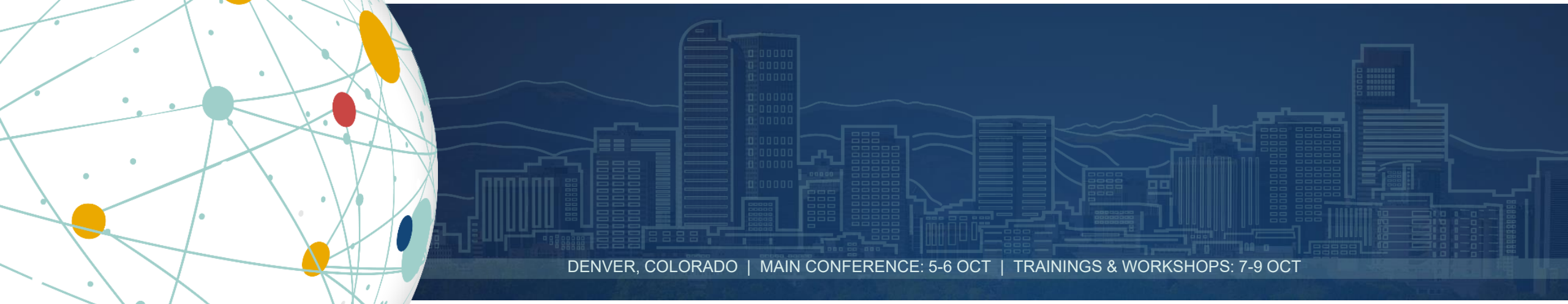


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Leveraging Enterprise AI in TMF Management

How Governance Enables Confidence and Compliance

Brittany Walker, Principal Consultant, USDM Life Sciences

Speaker

Brittany Walker
Principal Consultant
USDM Life Sciences

- Brittany works with sponsors and CROs on TMF operations, eTMF implementation, and the validation and governance of GxP computerized systems.
- Her focus is how compliance obligations are met in practice: what evidence is required, who owns each decision, and whether the record holds up under inspection.
- She works within an organization that supports more than 900 life sciences organizations and brings twenty-five years validating GxP systems.

Agenda

1. What's changing in TMF management
2. What an enterprise AI platform is and how it's validated
3. A framework for risk and control
4. Four TMF use cases
5. Rolling it out

THE QUESTION

Could your study answer this today?

“Show me the evidence that Amendment 2 was fully implemented at Site 104—every record it should have generated, where each one lives, and who confirmed it.”

Minutes
baseline

Systems
baseline

People
baseline

Citations
baseline

Four shifts have changed the TMF control problem

1

Essential records widened

Communications and decision rationale are now explicitly in scope.

2

Evidence remains distributed

Authoritative evidence stays in the systems that created it.

3

Response windows are short

A defensible answer may be requested in days, not months.

4

AI capabilities arrive continuously

Features and models change on vendor release cycles.

The gap is between where evidence lives and where the answer must be produced.

Sources: ICH E6(R3); EMA TMF Guideline §3.4; FDA remote-assessment guidance. Regulatory status and applicability vary by source.

Existing obligations, new method

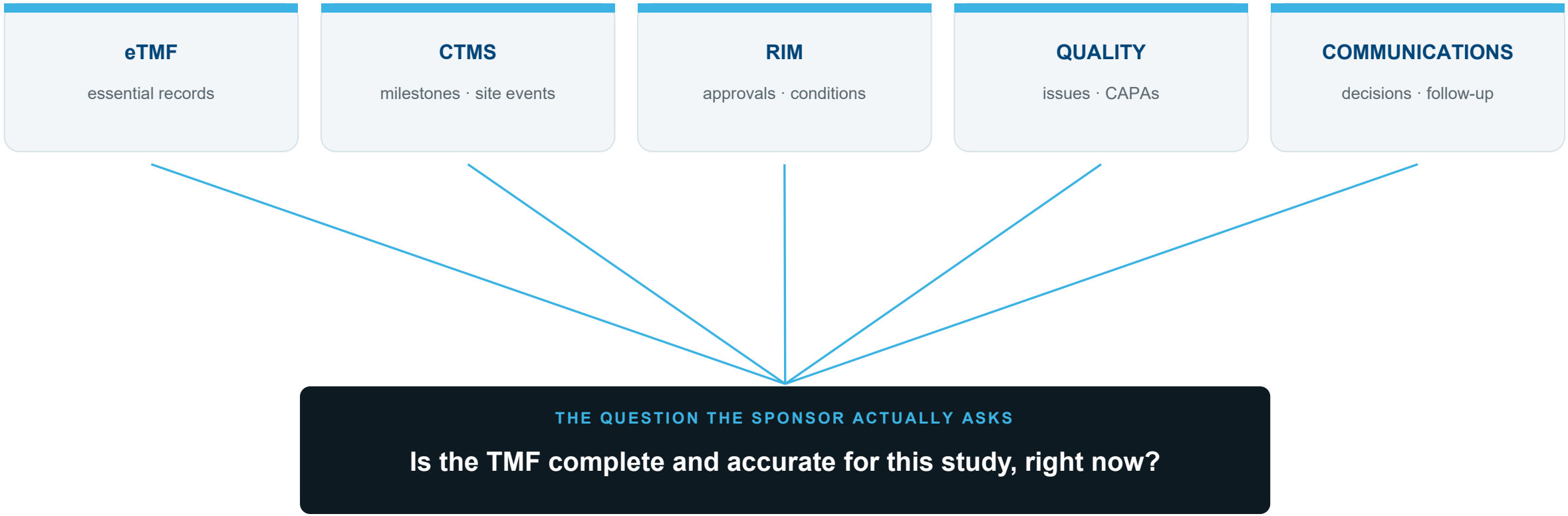
Color indicates authority status—not agency.

BINDING CLINICAL REQUIREMENTS	ICH E6(R3) · EMA computerized-systems guidance
JOINT NON-BINDING PRINCIPLES	FDA and EMA good AI practice principles
INTERPRETIVE / WARNING SIGNALS	MHRA Inspectorate blog
CONTEXT-DEPENDENT OR ADJACENT	EU AI Act · draft Annex 22 (GMP)

Validate the configured use without making the eTMF dependent on it.

The TMF answer is assembled across systems

Authoritative repositories remain the sources of truth.



Each repository holds authorized evidence. None of them holds the answer.

Connect evidence; do not replace authority

AUTHORITATIVE SOURCE SYSTEMS

RIM · CTMS · Quality · Communications · eTMF

↓

PERMISSION-AWARE SYNTHESIS

Retrieve · compare · reconcile · cite

Runs under the requesting user's permissions. Every claim carries its source.

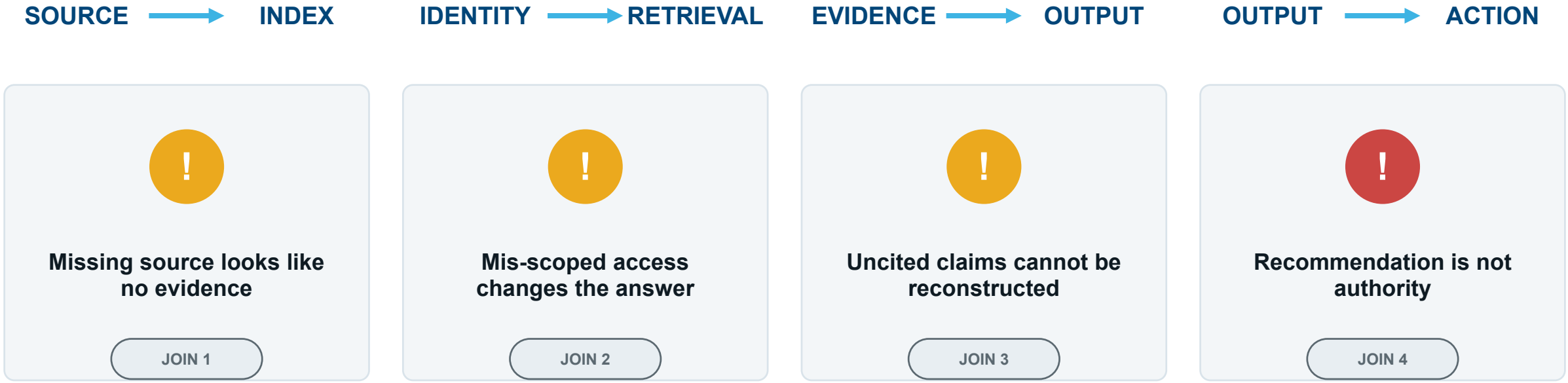
↓

CITED, REVIEWABLE ANSWER

Claims resolve to evidence; the reviewer owns the conclusion.

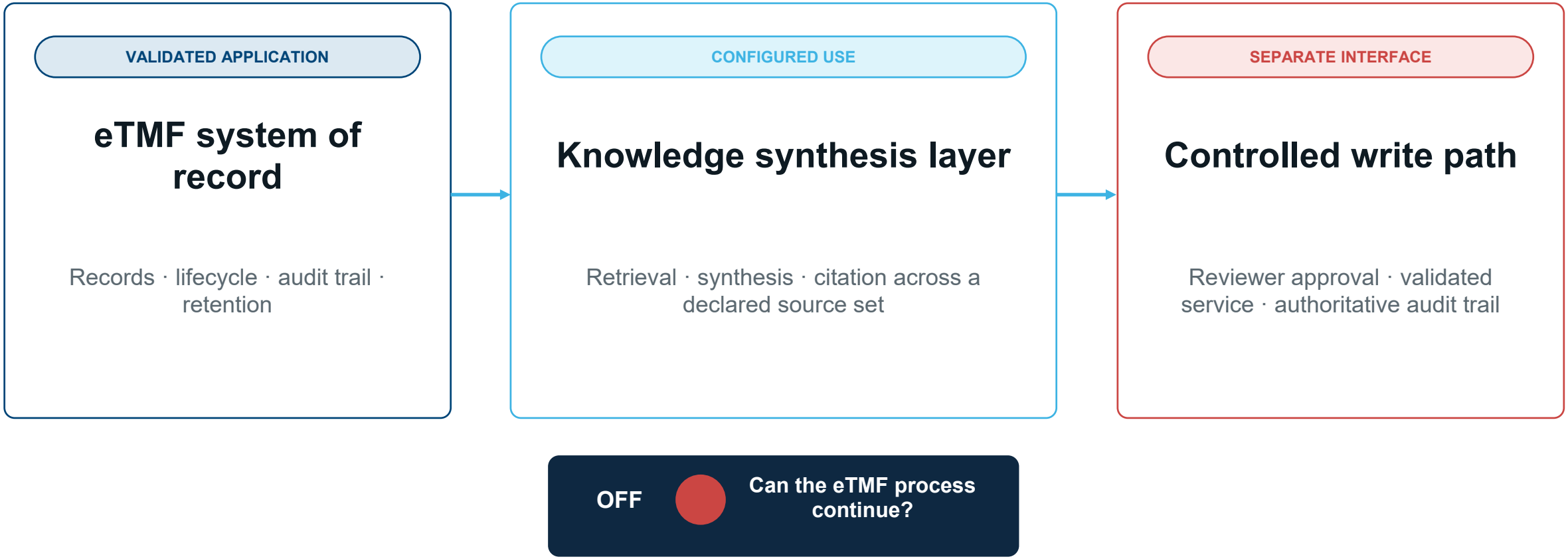
NO AUTONOMOUS REGULATED ACTION

Control the joins, not only the model



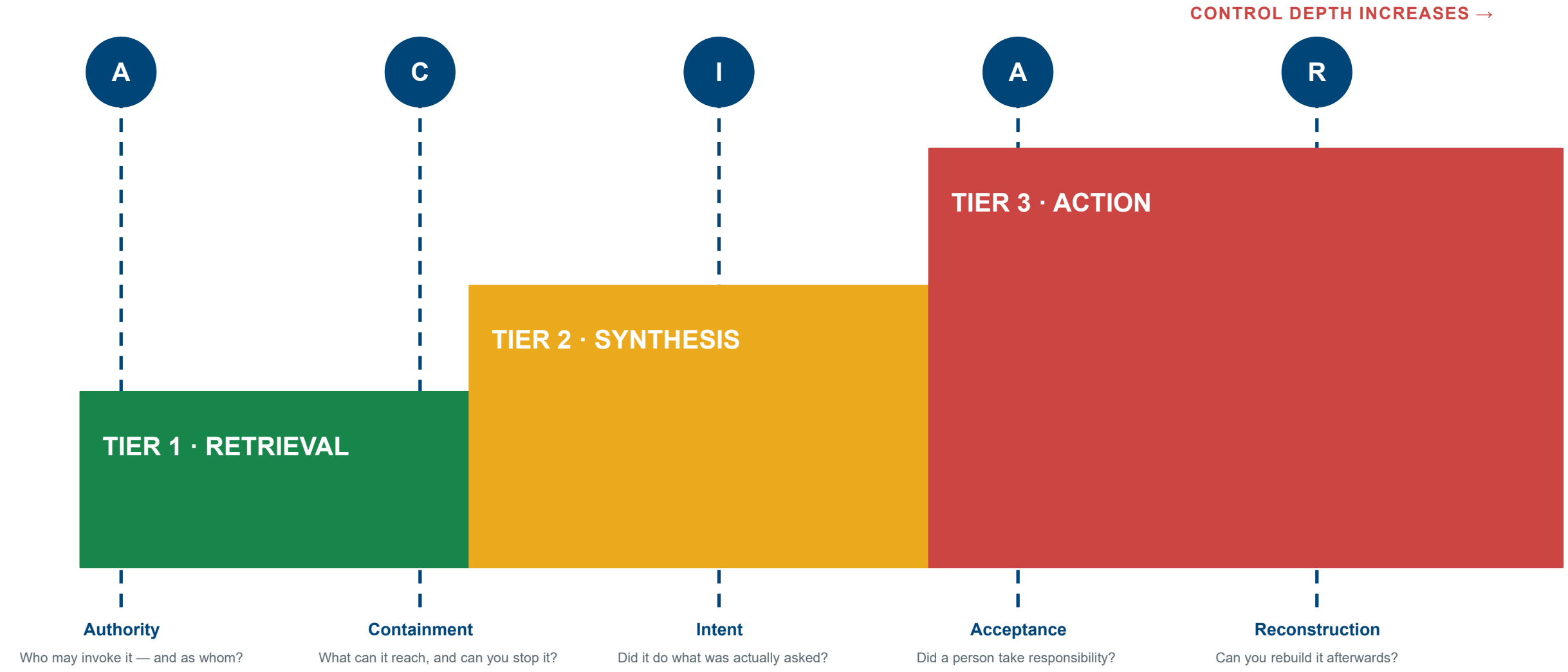
The control surface is the connection between systems, evidence, people, and action.

Validated separately. Governed together.

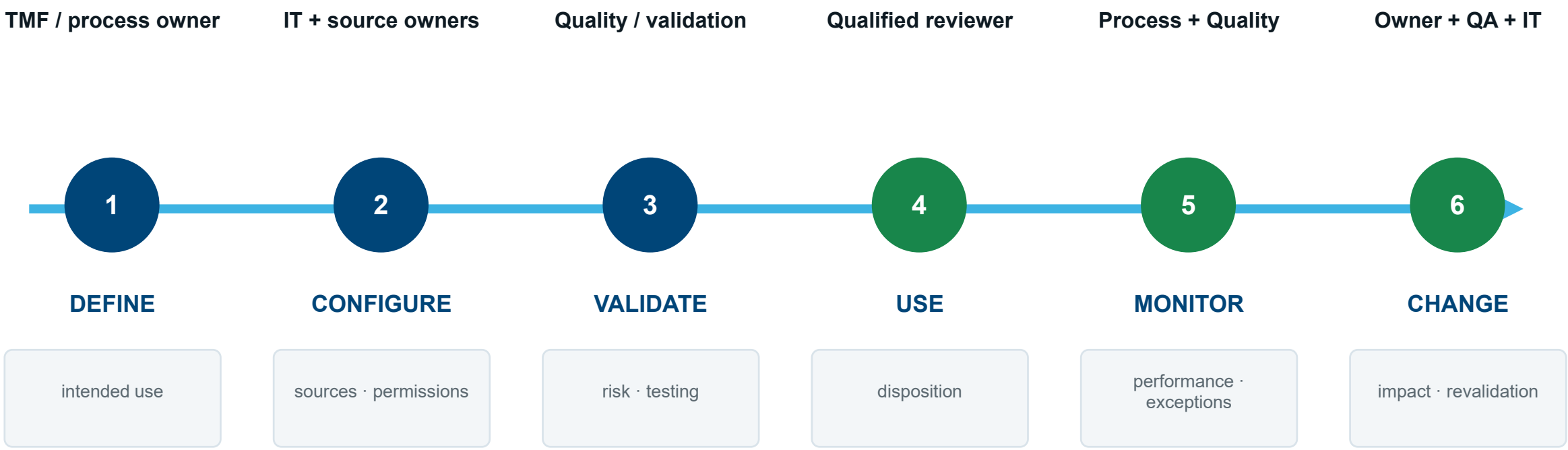


Customer-deployed layer: deliberate configuration. Vendor-activated feature: change to a validated system.

The tier sets depth; the controls set coverage



Ownership moves with the configured use



Accountability changes at each handoff; the evidence must travel with it.

Four TMF questions, the same five controls

The tier moves with what the question requires. The controls do not.

TIER 2

1 · TMF completeness

QUESTION

Was the amendment implemented at each active site?

OUTPUT

Expected-record matrix + exceptions

HUMAN DECISION

Reviewer dispositions each gap.

TIER 1

2 · Sponsor oversight retrieval

QUESTION

Where is the evidence of recurring issues?

OUTPUT

Cited summary + review queue

HUMAN DECISION

Reviewer confirms relevance.

TIER 2

3 · Correspondence reconciliation

QUESTION

Which copy is the essential record?

OUTPUT

Candidates + operative version

HUMAN DECISION

Reviewer confirms record and class.

TIER 2 → 3

4 · Shared-folder intake

QUESTION

What belongs in the TMF—and what is missing?

OUTPUT

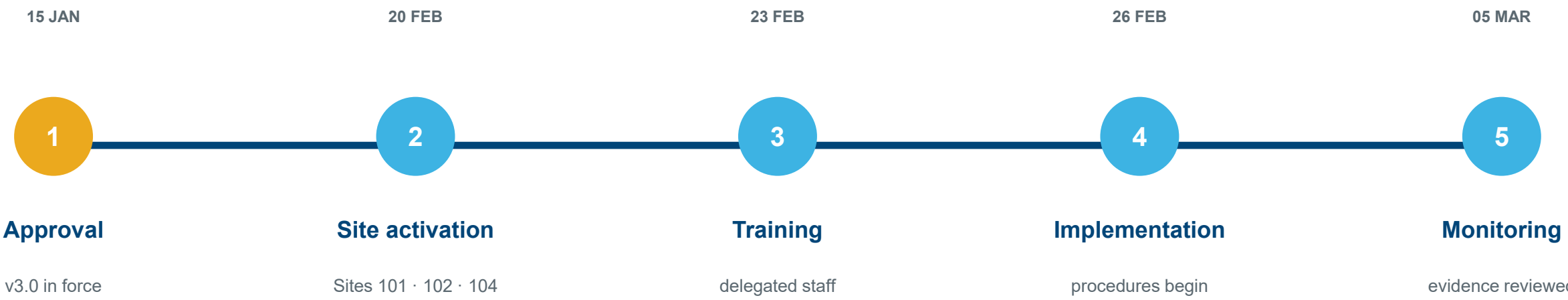
Classification + metadata proposal

HUMAN DECISION

Reviewer approves each write.

Use case one runs end to end. The other three show the same controls at different depths.

Amendment 2 is approved—but is it implemented?



What evidence should this event have generated at each active site?

No single system holds the answer

REGULATORY

Amendment 2 · v3.0

conditions · training required

CLINICAL

v2.1 on file

IRB approvals · revised ICF

SITE RECORDS

training by site

completion and amendment version

CORRESPONDENCE

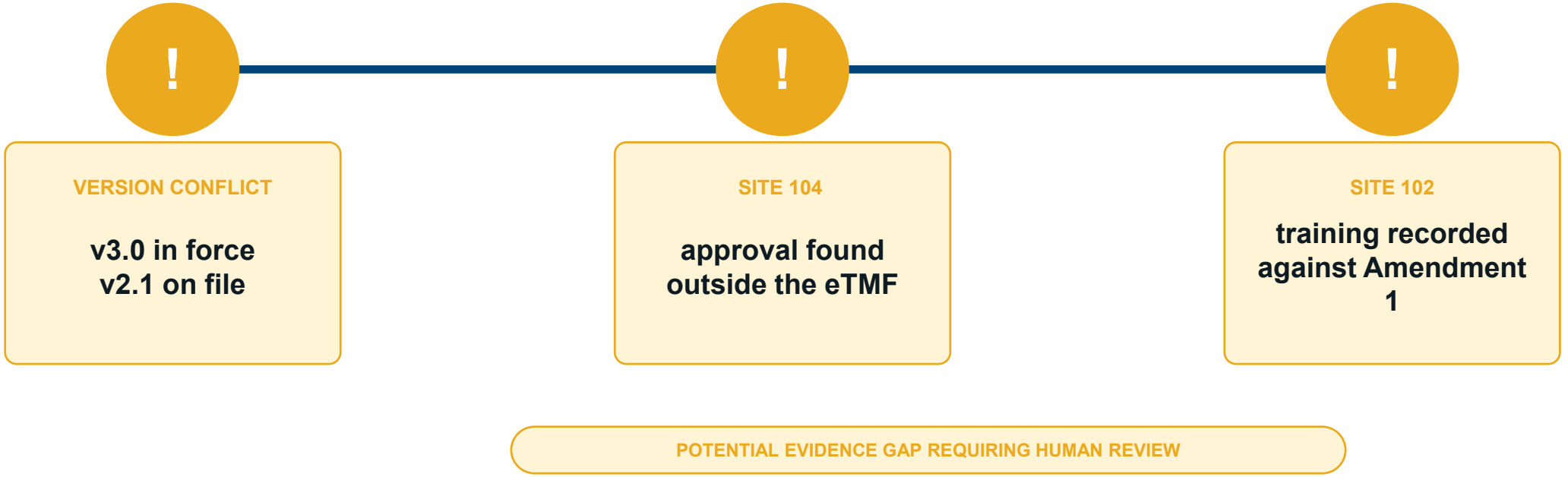
implementation discussion

email · delivery folders



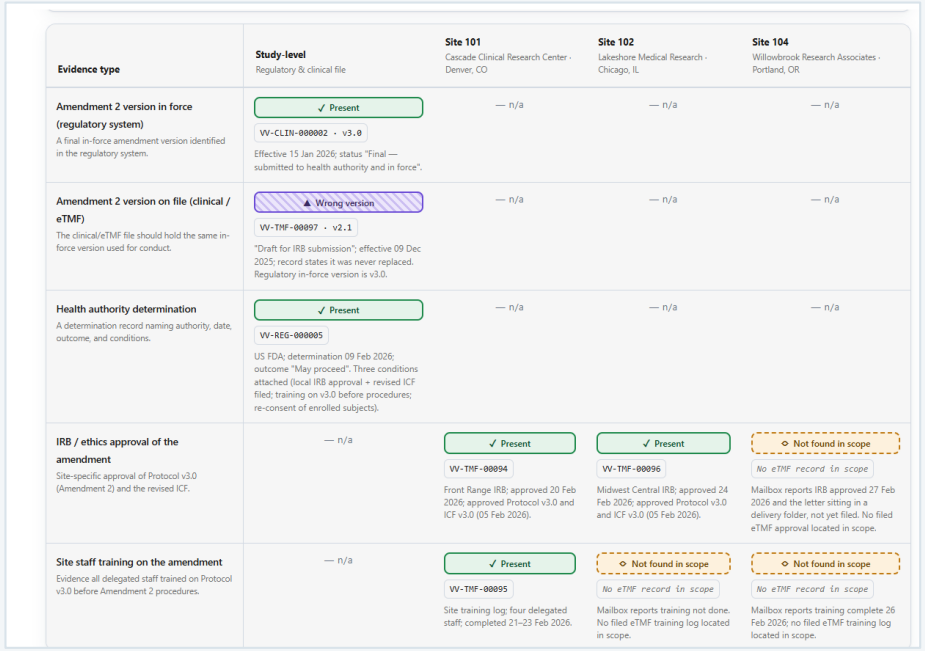
The layer retrieves and aligns evidence. It does not resolve discrepancies.

Three potential evidence gaps require review



A reviewer confirms the evidence and the disposition

Evidence presented to the reviewer — expected records by site



Evidence type	Study-level Regulatory & clinical file	Site 101 Cascade Clinical Research Center · Denver, CO	Site 102 Lakeshore Medical Research · Chicago, IL	Site 104 Willowbrook Research Associates · Portland, OR
Amendment 2 version in force (regulatory system) A final in-force amendment version identified in the regulatory system.	✓ Present VV-CLIN-000002 · v3.0 Effective 15 Jan 2026; status "Final — submitted to health authority and in force".	— n/a	— n/a	— n/a
Amendment 2 version on file (clinical / eTMF) The clinical/eTMF file should hold the same in-force version used for conduct.	▲ Wrong version VV-TMF-00097 · v2.1 "Draft for IRB submission"; effective 09 Dec 2025; record states it was never replaced. Regulatory in-force version is v3.0.	— n/a	— n/a	— n/a
Health authority determination A determination record naming authority, date, outcome, and conditions.	✓ Present VV-REG-000005 US FDA; determination 09 Feb 2026; outcome "May proceed". Three conditions attached (local IRB approval + revised ICF filed; training on v3.0 before procedures; re-consent of enrolled subjects).	— n/a	— n/a	— n/a
IRB / ethics approval of the amendment Site-specific approval of Protocol v3.0 (Amendment 2) and the revised ICF.	— n/a	✓ Present VV-TMF-00094 Front Range IRB; approved 20 Feb 2026; approved Protocol v3.0 and ICF v3.0 (05 Feb 2026).	✓ Present VV-TMF-00096 Midwest Central IRB; approved 24 Feb 2026; approved Protocol v3.0 and ICF v3.0 (05 Feb 2026).	⋄ Not found in scope *No eTMF record in scope* Mailbox reports IRB approved 27 Feb 2026 and the letter sitting in a delivery folder, not yet filed. No filed eTMF approval located in scope.
Site staff training on the amendment Evidence all delegated staff trained on Protocol v3.0 before Amendment 2 procedures.	— n/a	✓ Present VV-TMF-00095 Site training log: four delegated staff; completed 21–23 Feb 2026.	⋄ Not found in scope *No eTMF record in scope* Mailbox reports training not done. No filed eTMF training log located in scope.	⋄ Not found in scope *No eTMF record in scope* Mailbox reports training complete 26 Feb 2026; no filed eTMF training log located in scope.

Synthetic study data · recommendation only

REVIEWER DISPOSITION

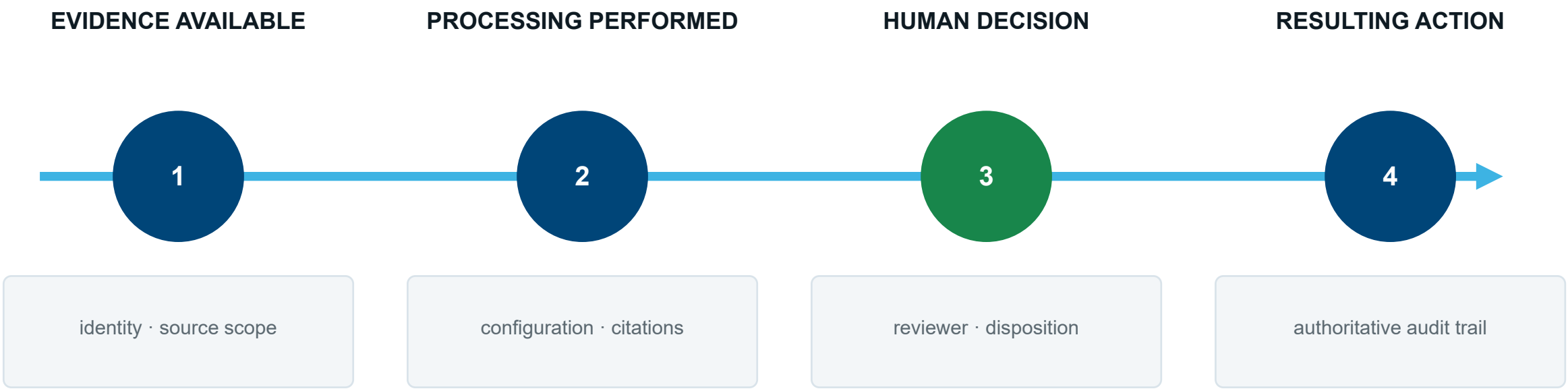
ACCEPT | REJECT | MODIFY | ESCALATE

Reviewer J. Chen · TMF Lead

Rationale Evidence confirmed; filing location corrected; follow-up assigned.

HUMAN DECISION RECORDED

Traceability connects the complete event



Auditability exists within each layer. Traceability correlates the layers.

Where is the evidence of a recurring issue?

Synthetic study data. Retrieval only — the layer proposes nothing and files nothing.

Record	Search outcome
Implementation evidence	Integrity / retention
Training, logger, and IMV-05/06 evidence not found in the declared source scope.	PI countersignature and the retention rule not found in the declared source scope; documents state synthetic data.
Locate before closure.	Escalate for reviewer confirmation.

Classification and recommendations are proposals, not decisions.

Retrieved across the declared source set; every line resolves to a record.

THE QUESTION

Show the evidence of repeated monitoring findings at Site 102, and whether they were resolved.

WHAT THE LAYER RETURNED

A cited summary and a review queue — including what it could not find in scope.

THE HUMAN DECISION

A reviewer confirms relevance, and owns the escalation.

CONTROLS EXERCISED

A C I A R depth set by Tier 1

A null result is a finding. “Nothing returned” is only assurance if the scope was declared.

Which copy is the essential record?

Synthetic study data. The layer proposes an operative version; it does not declare one.

Record	Search outcome	Recommendation
MVR-102-2026-02	Mailbox thread	CAA-102-2026-03
The eTMF; Site 102 content, Site 101 metadata.	Discussion and acceptance history; outside eTMF.	Collaboration site; sponsor acceptance and rationale; outside eTMF.
Retain; resolve metadata.	Supporting record only.	**Proposed essential record.** Confirm eTMF filing.

Candidates and the proposed essential record, each resolving to its source.

THE QUESTION

Sponsor acceptance was discussed in a mailbox thread and on a collaboration site. Which one is the record?

WHAT THE LAYER RETURNED

Every candidate, the interpretation applied, and one proposed essential record — never a declared one.

THE HUMAN DECISION

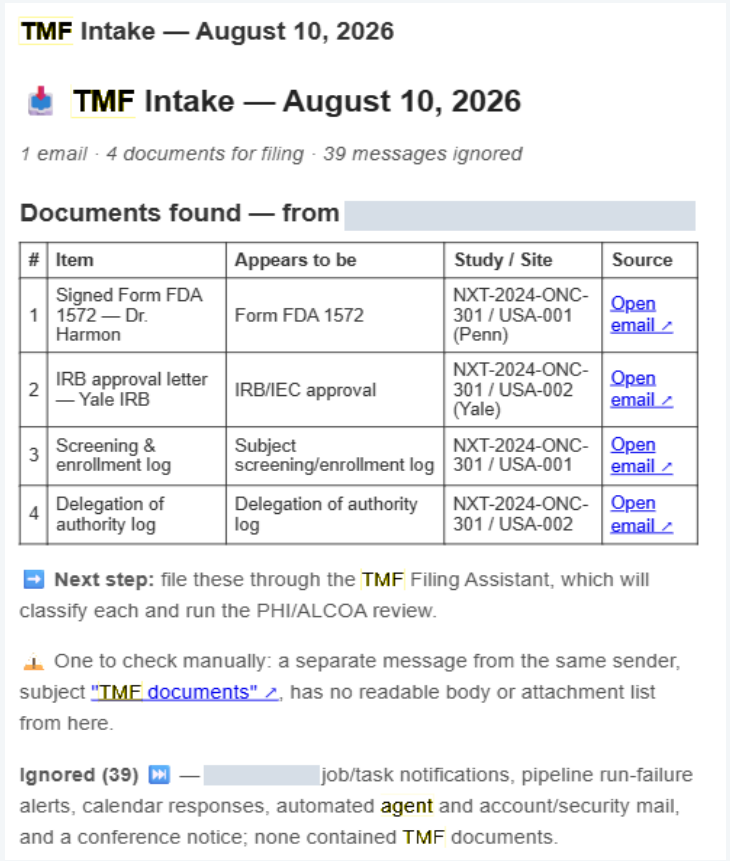
A reviewer confirms the record and its classification before anything is filed.

CONTROLS EXERCISED A C I A R depth set by Tier 2

Interpretation is shown on screen, so the reviewer can disagree with it.

Intake evidence: what was considered and set aside

Synthetic study data; a disconnected channel is stated, not assumed.



TMF Intake — August 10, 2026

TMF Intake — August 10, 2026

1 email · 4 documents for filing · 39 messages ignored

Documents found — from

#	Item	Appears to be	Study / Site	Source
1	Signed Form FDA 1572 — Dr. Harmon	Form FDA 1572	NXT-2024-ONC-301 / USA-001 (Penn)	Open email ↗
2	IRB approval letter — Yale IRB	IRB/IEC approval	NXT-2024-ONC-301 / USA-002 (Yale)	Open email ↗
3	Screening & enrollment log	Subject screening/enrollment log	NXT-2024-ONC-301 / USA-001	Open email ↗
4	Delegation of authority log	Delegation of authority log	NXT-2024-ONC-301 / USA-002	Open email ↗

Next step: file these through the TMF Filing Assistant, which will classify each and run the PHI/ALCOA review.

One to check manually: a separate message from the same sender, subject "TMF documents" ↗, has no readable body or attachment list from here.

Ignored (39) — job/task notifications, pipeline run-failure alerts, calendar responses, automated agent and account/security mail, and a conference notice; none contained TMF documents.

1 **43 messages considered** Declared source set

2 **4 candidates retained** Classification proposed

3 **39 set aside** Reason recorded

4 **Chat not connected** Scope limitation disclosed

Inspector question: What did it look at, what did it ignore, and can you show the ignored set?

Filed, or returned — with the reason recorded

Synthetic study data. A filing path is proposed for each document; anything that cannot be filed goes back to a named owner.

Classification & disposition

Document	Proposed filing path
Form-FDA-1572_Harmon_signed.pdf	Site Management → Site Set-up → **Form FDA 1572**
Screening-Enrollment-Log.pdf	Site Management → Site Management → **Subject Log**
Delegation-of-Authority-Log_DRAFT.pdf	Site Management → Site Set-up → **Site Signature Sheet**
IRB-Approval-Letter_Yale.pdf	IRB or IEC and other Approvals → IRB or IEC Trial Approval → **IRB or IEC Approval**

Not filed — return to owner

Screening & Enrollment Log (USA-001) → return to **L. Ramirez, CRC** at Penn Oncology Clinical Trials Unit, copying PI Jonathan Harmon, MD. The log must be re-issued with all subject identifiers removed so that subjects are identified by subject ID (1001–1005) only: strike the patient name, DOB, MRN, and contact phone columns entirely, and delete the sponsor note, which discloses subject #1003's home address and subject #1002's daughter's name, phone, and power-of-attorney status. While they are at it, ask them to correct the DOB for subject 1003, entered as `27/06/1950` where every other row uses MM/DD/YYYY. Once redacted, resubmit for filing as Subject Log.

Delegation of Authority & Signature Log (USA-002) → return to **Cameron Regan, MD**, PI at Yale Cancer Center. This needs to be completed and executed as a final record, not a DRAFT, before it can be filed as a Site Signature Sheet. Specifically: the PI must sign and date the log; row 1's altered start date must be redone with a single line-through, initials, and date rather than the current obscured value; row 3 needs the sub-investigator's name and signature; row 4 needs M.

Left: proposed classification and filing path. Right: what was not filed, and exactly what must be corrected first.

THE PROPOSAL

Document type, metadata, and filing path — put to a person for approval.

THE EXCEPTION

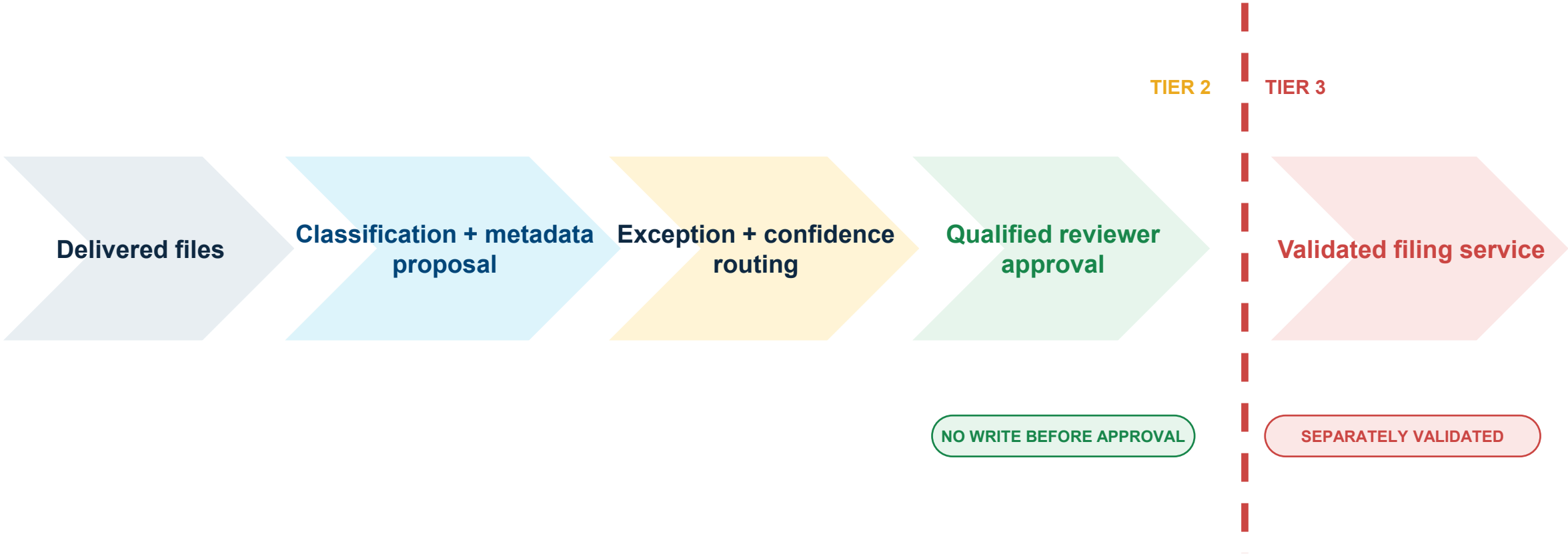
Returned to a named owner, with the specific correction required.

THE BOUNDARY

No write, no closure, and no compliance statement by the layer.

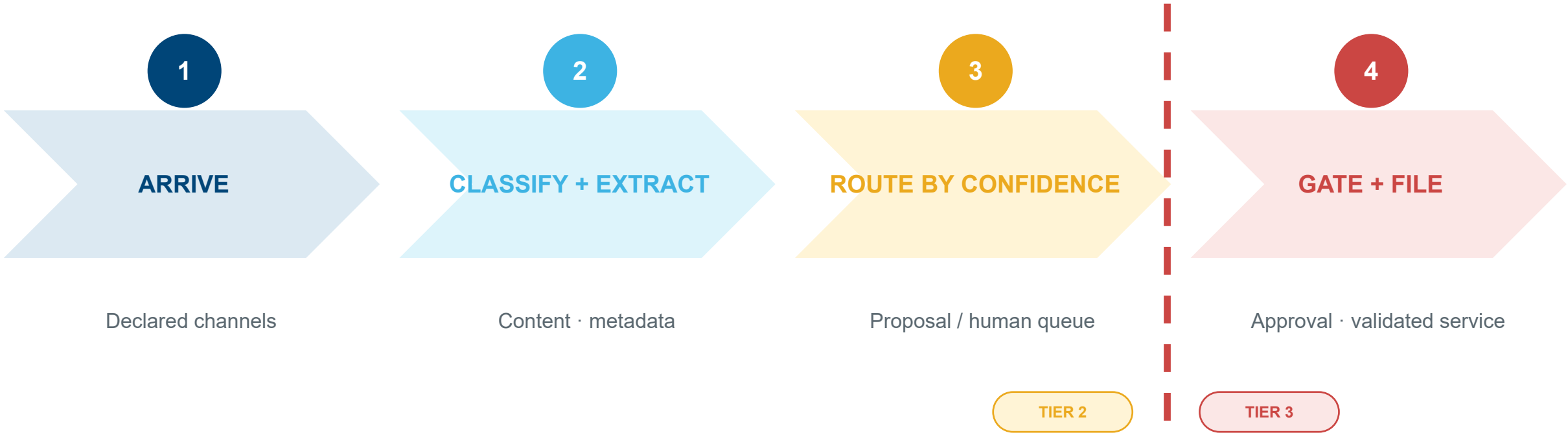
Every proposal can be refused, and the refusal carries its reason.

Recommendation first; controlled action second



Initial scope: recommendation only—no eTMF write-back.

Intake runs continuously; the control boundary must not drift



Changing the confidence threshold changes the validated control.

Four failures a demonstration will not reveal

Review without examination

400 proposals cleared in 11 minutes

CONTROL → Sample reviews · monitor decision time

Null result read as assurance

Nothing returned from an incomplete scope

CONTROL → Declare connected and excluded sources

Scope change without reassessment

Retrieval used to decide whether a record is missing

CONTROL → Re-score when the question changes

Omission in the summary

Conflict retrieved but not shown to the reviewer

CONTROL → Test recall · retain retrieved set

From finding evidence to defining what counts

Every control in this framework creates work that only a TMF professional can do.

A · C — Declare what is in scope

The answer is bounded by what was connected. Someone has to own the declared source set and re-score it when the question changes.

NEW WORK → Source scope as a controlled document

I — Define what should exist

The expected-record set comes from TMF expertise. Only a TMF professional can say what an amendment should have generated at an active site.

NEW WORK → Owns the reference set and its seeded exceptions

A — Disposition, with a rationale

The work shifts from locating records to deciding what each finding means, recorded against a named person who is qualified to decide it.

NEW WORK → Reviewer qualification defined; dispositions retained

R — Be able to rebuild it

Whoever answers must be able to reconstruct that answer months later, for someone who was not in the room when it was produced.

NEW WORK → Decides what is retained, and for how long

None of this is new judgment. It is the same judgment, made earlier and written down — and it is the part the layer cannot do.

Measure the current path to a defensible answer

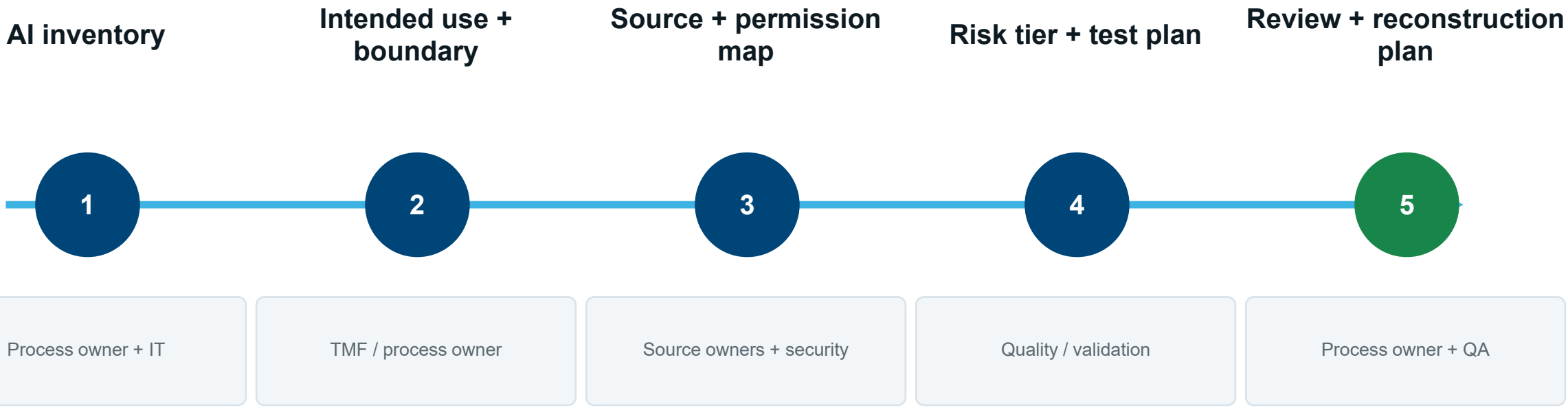
Amendment 2 · Site 104

Ask the same question. Record what the process actually requires.

00 Minutes	00 Systems	00 People	00 Citations
to a reviewable answer	actually opened	consulted	produced

Record the baseline before evaluating improvement.

Start with five artifacts—before tool selection



Tool selection comes after the control model.

Confidence in the system; confidence in the record

Two different claims, and the first is what makes the second defensible.

CONFIDENCE

The system is governed and validated

- Intended use and boundary written before anything is configured
- Risk tier assigned, and the five controls tested at that depth
- Reviewer defined, qualified, and named on every disposition
- Change control and drift monitoring, with retesting decisions recorded

EVIDENCE → Validation package, test results, release decision

Answers: can you defend the tool?

COMPLIANCE

The TMF is complete and accurate

- Expected records derived from what actually happened, per site
- Gaps surfaced for human disposition — never auto-closed
- Versions and duplicates reconciled to one operative record
- Every statement resolves to a retrievable record the reviewer can open

EVIDENCE → Cited answer, retained retrieval set, disposition record

Answers: can you defend the file?

Governing the tool is what makes the statement about the file defensible. One is confidence. The other is compliance.

Governance turns a capable tool into a defensible one

1

TIER

sets validation depth

2

CONTROLS

define what must be demonstrated

3

EVIDENCE

proves the system operated as intended

A defensible answer connects authority, evidence, review, and action.



Thank you!