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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Proving Your TMF Has Not Changed: A Post-Export, Zero-Custody Verification Model Validated in Blinded Multi-Operator Conditions

Fernando Telles, MD | Methodology Lead for AuditLog.AI Research Initiative

Session 6E: TMF Validation and Governance | 6 Oct 2026, 12:00–12:30

Agenda

1. The Custody-Boundary data integrity problem
2. Why this matters
3. Proposed solution
4. Empirical validation
5. International multi-site extension

Speaker, Funding & Declaration of interests



Dr. Telles is a clinician-scientist and inventor of the audit systems evaluated in this study.

The software engineers (JY, BH) involved in system development and Stage IV blinded verification were salaried employees. To mitigate inventor bias, Dr Telles was excluded from blinded verification, human verification time assessment, and primary outcome classification. Deterministic verification outcomes were derived from cryptographic invariants, and correctness was independently verified by blinded operators. Independent investigators (Operators 2 and 5), who had no financial interest in the technology, performed blinded verification tasks. The study design, pre-specification, and time-anchoring of all execution states prior to analysis further constrained investigator influence.

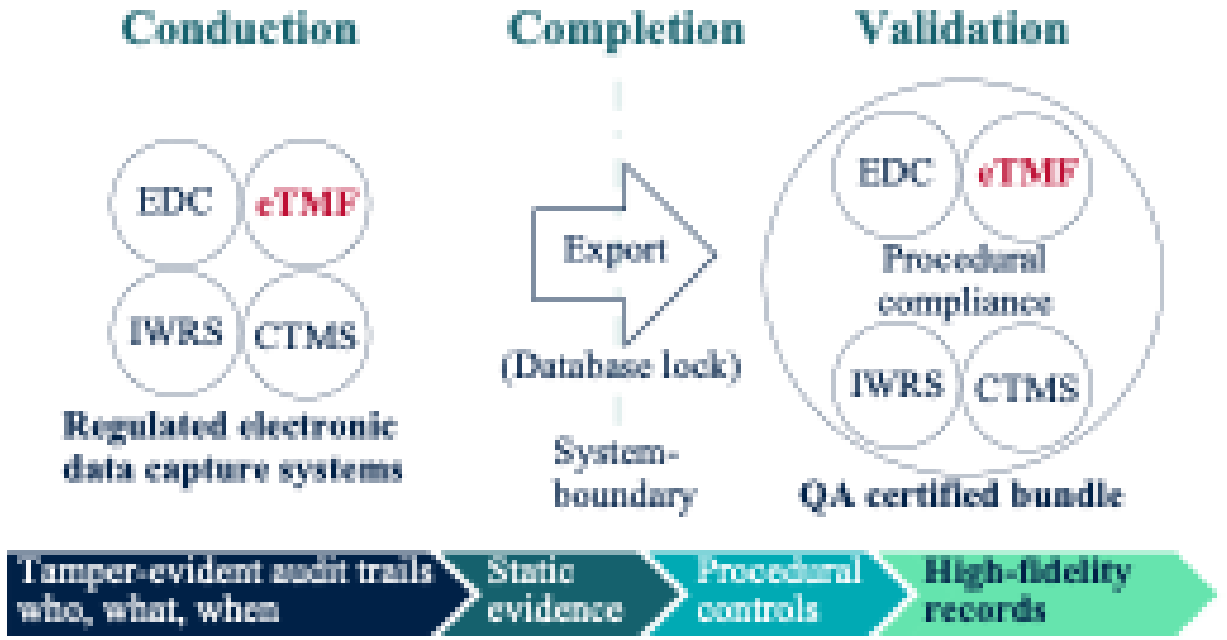
Fernando Telles, BMedSc(Adv) MD(Dist)
Methodology Lead for **AuditLog.AI Research Initiative**
Director, Cardiovascular Diagnostic Audit AI Pty Ltd (CDA-AI), Melbourne, Australia
Co-Director, Telles Investments Pty Ltd (intellectual property holder of related patent PCT/AU2026/050652)

Funding statement
CDA-AI, supported by the Australian Government R&D Tax Incentive Program (R&DTI; Project: AuditLog.AI; PQXC8SXVS), funded the audit systems infrastructure development and maintenance evaluated in this study. The funder had no role in data collection, data analysis, data interpretation, or writing of the report.

Clinical Trials

Foundational to evidence-based medicine

- **Evidence is exported**
  from originating systems
- **QA validates**
  the package's integrity, completeness, and procedural compliance



Certification is **appropriate** and **required**

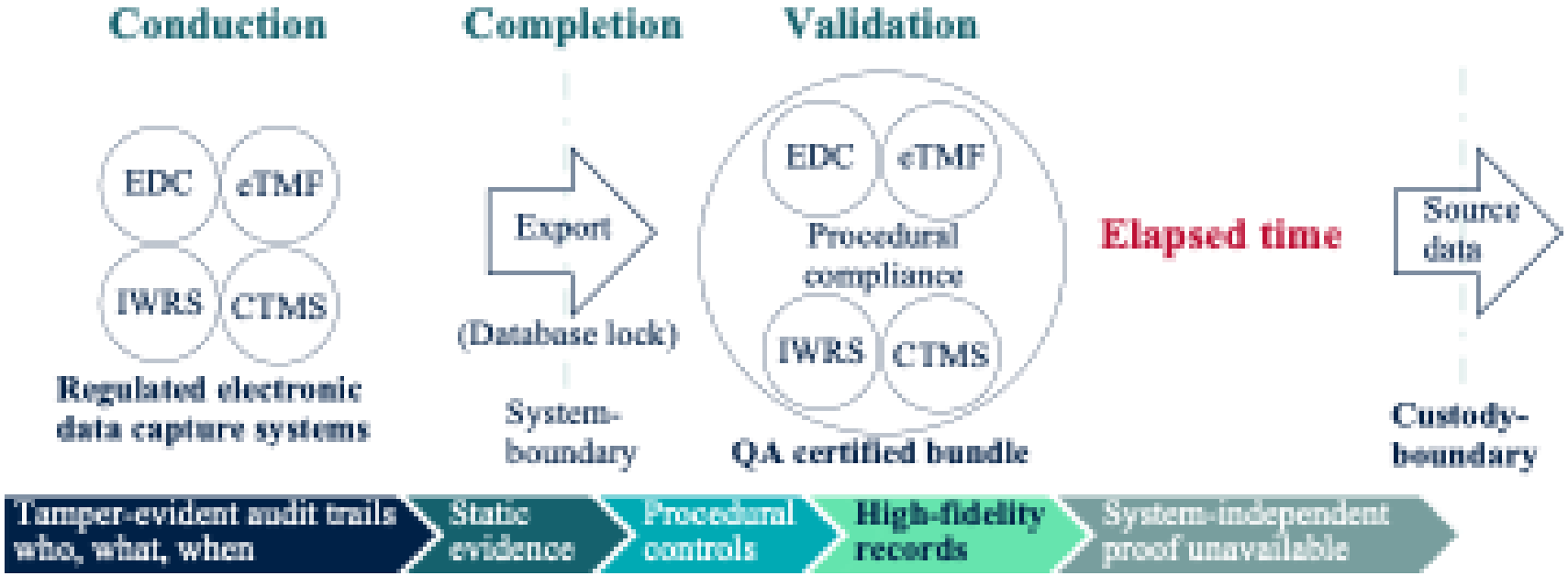
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Clinical Trials

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[at a single timepoint]

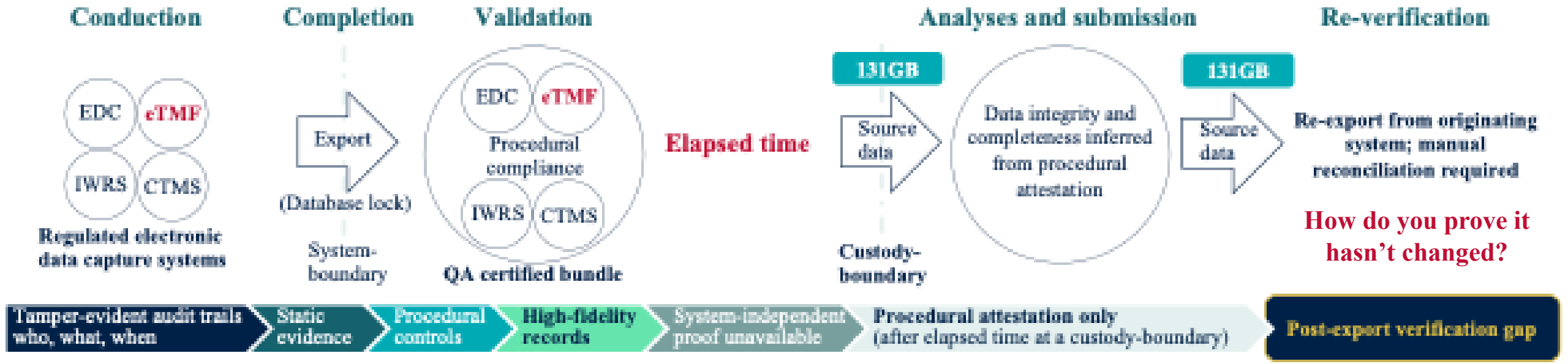


Certification is **appropriate** and **required**

However, it is a **snapshot** and **cannot be carried forward**

The Custody-Boundary Problem

Once evidence **leaves** a validated **eTMF**, no mechanism proves it is **unchanged**



At every subsequent timepoints

- **Regulatory submission**
- **Scientific analysis**
- **Data custody handoff**

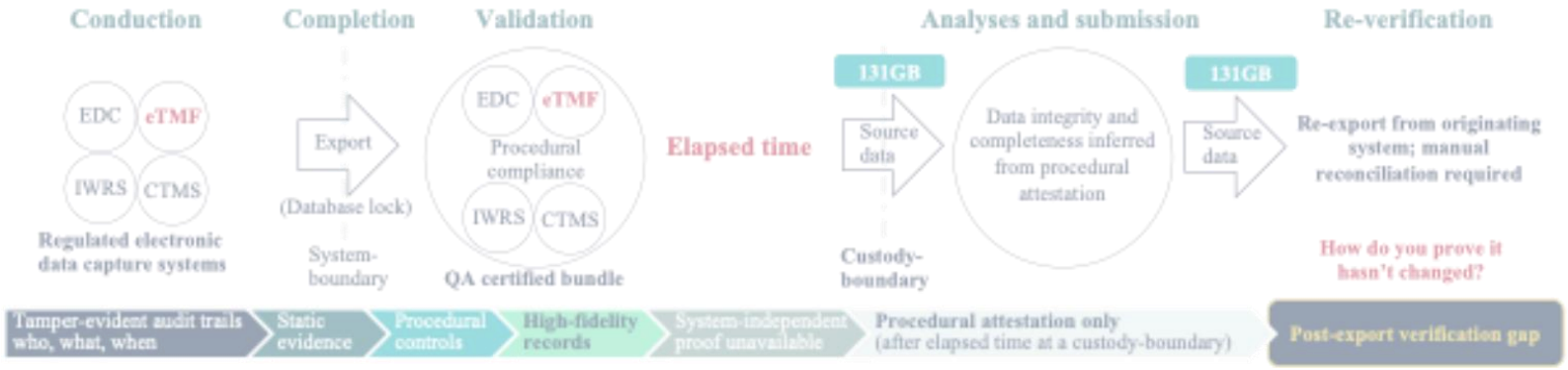
Re-verification requires:

- **Access** to the originating system
- Vendor log extraction
- **Manual reconciliation**
- or re-export

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The Custody-Boundary Problem

- None of these provide **mathematical proof** at **scale** that can be applied to **routine testing**
- None operate without continued participation of the system that generated the data.



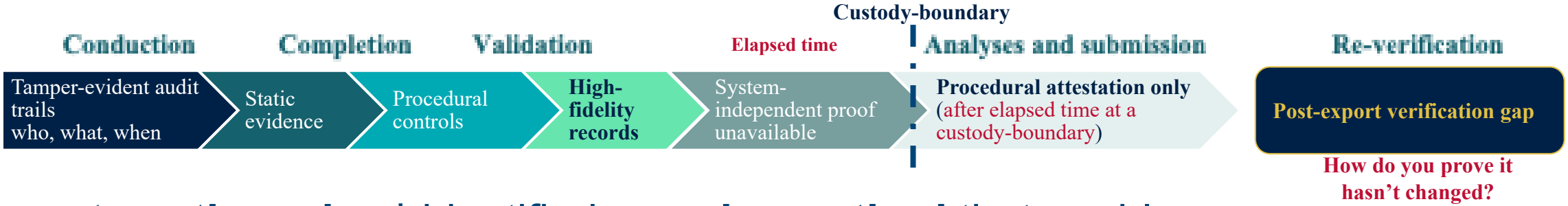
Re-verification requires:

- **Access** to the originating system
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- **Manual reconciliation**
- or re-export

If that system has since been retired, the vendor relationship terminated, or the trial staff dispersed …even this **retrospective pathway closes**.

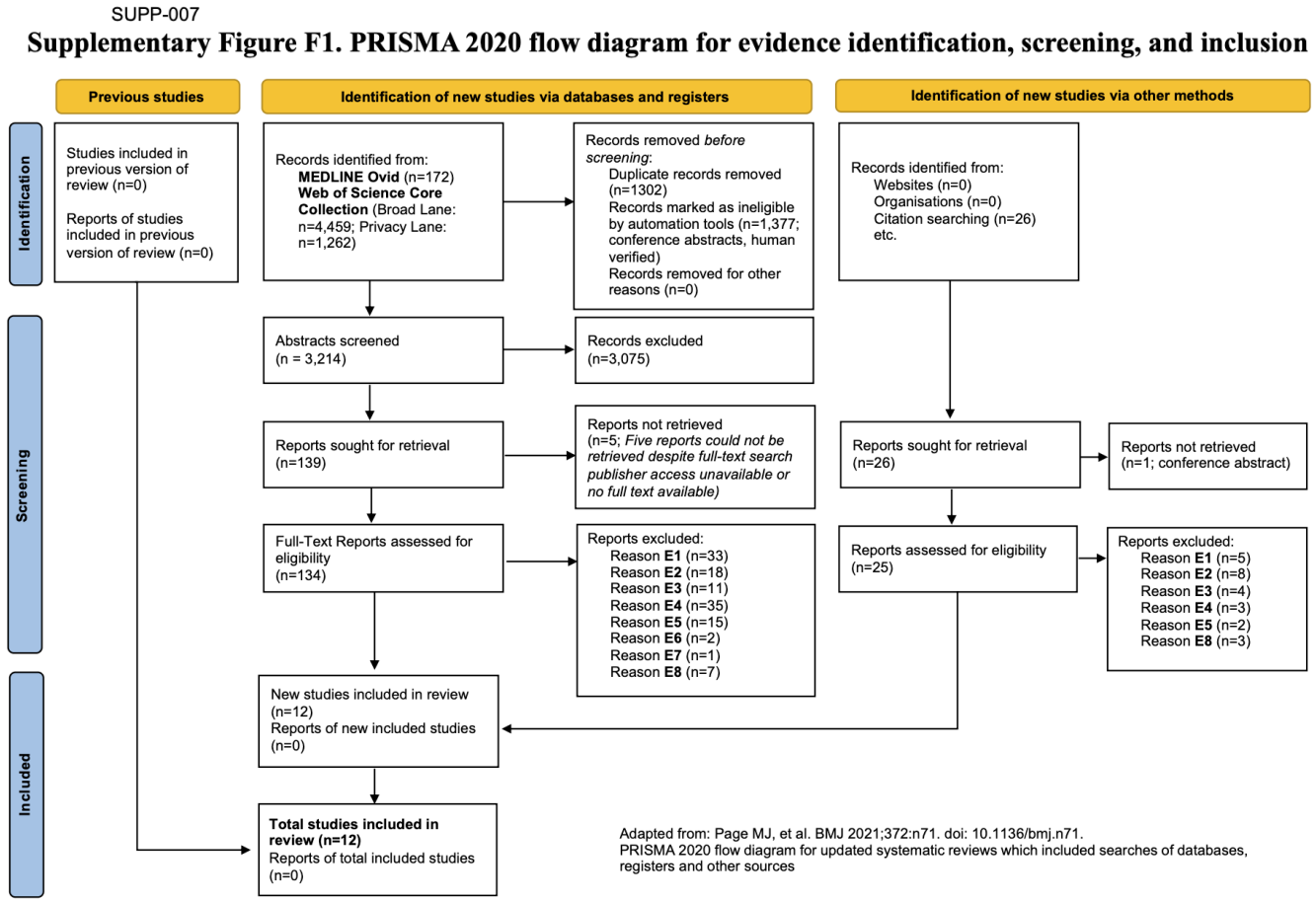
What remains is procedural attestation, not objective proof.

The Custody-Boundary Problem



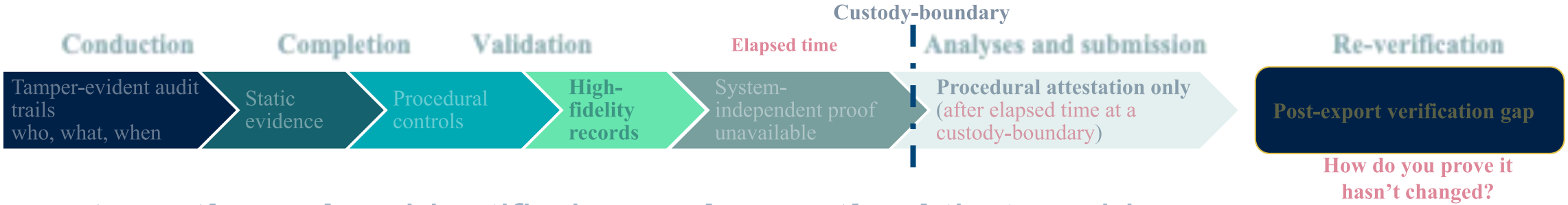
Our **systematic review*** identified **no prior method** that enables:

1. **Deterministic** verification of **post-export** clinical evidence **integrity** and **completeness**
2. **Without transfer** of the source data
3. **Without continued participation** of the originating system



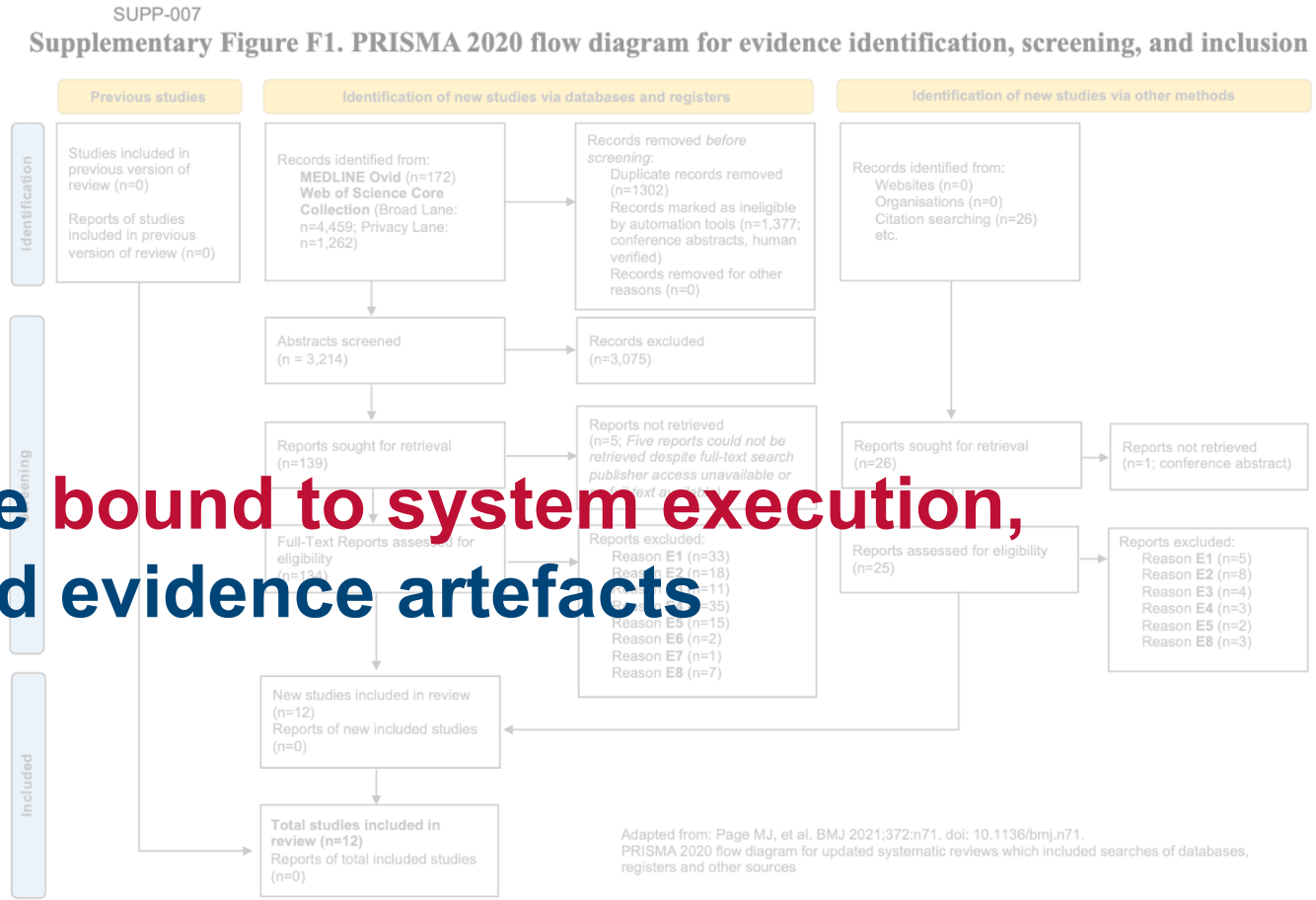
* Telles F. **Supplementary Materials for Stage IV Cryptographic Audit Validation: Methods, Protocols, and Reproducibility Outputs.** *Zenodo 2026.* https://doi.org/10.5281/zenodo.18501508

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Integrity assurances are bound to system execution, not to exported evidence artefacts

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Telles F. **Supplementary Materials for Stage IV Cryptographic Audit Validation: Methods, Protocols, and Reproducibility Outputs.**
Zenodo 2026. https://doi.org/10.5281/zenodo.18501508

Why This Matters

Undetected integrity **failures** can **propagate**

- Biased analyses
- Incorrect regulatory decisions
- **Unsafe patient care**

46.4% of recent published claims are **not** precisely **reproducible***

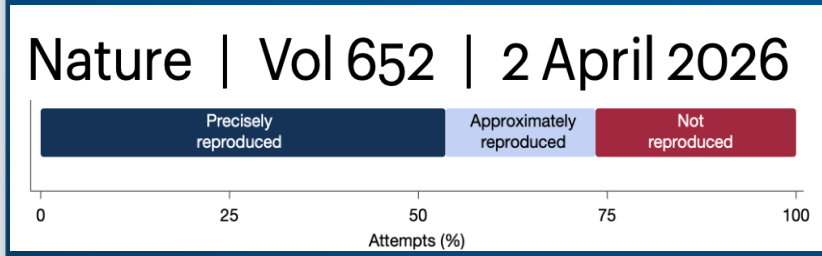
Existing controls focus on:

- Electronic data capture
- In-system audit trails during trial conduct
- Procedural controls

Existing interventions focus on:

- Data sharing (open access, preregistration, ICMJE)
- Reporting standards (CONSORT, PRISMA)





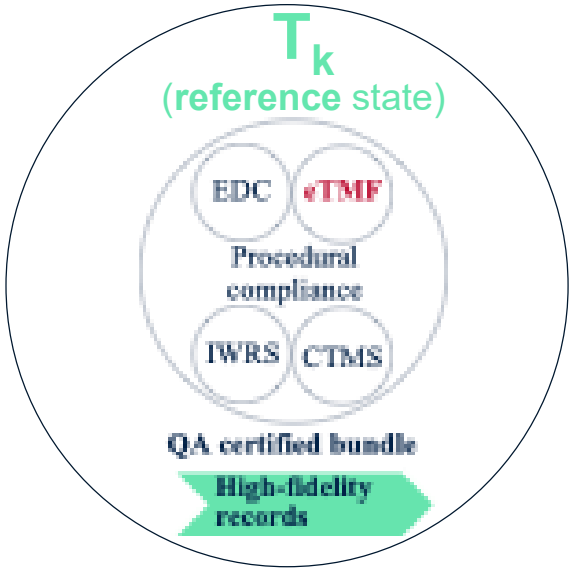
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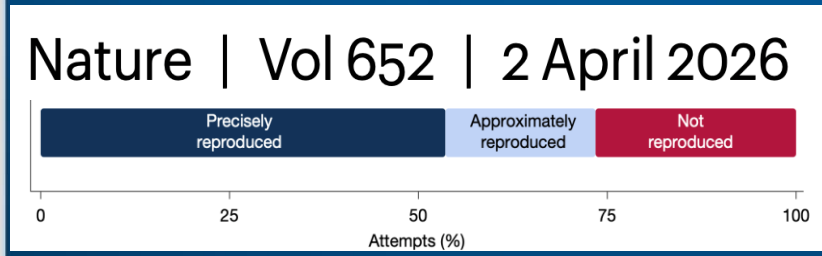
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None verify the evidence-state itself once data leaves a validated operational system

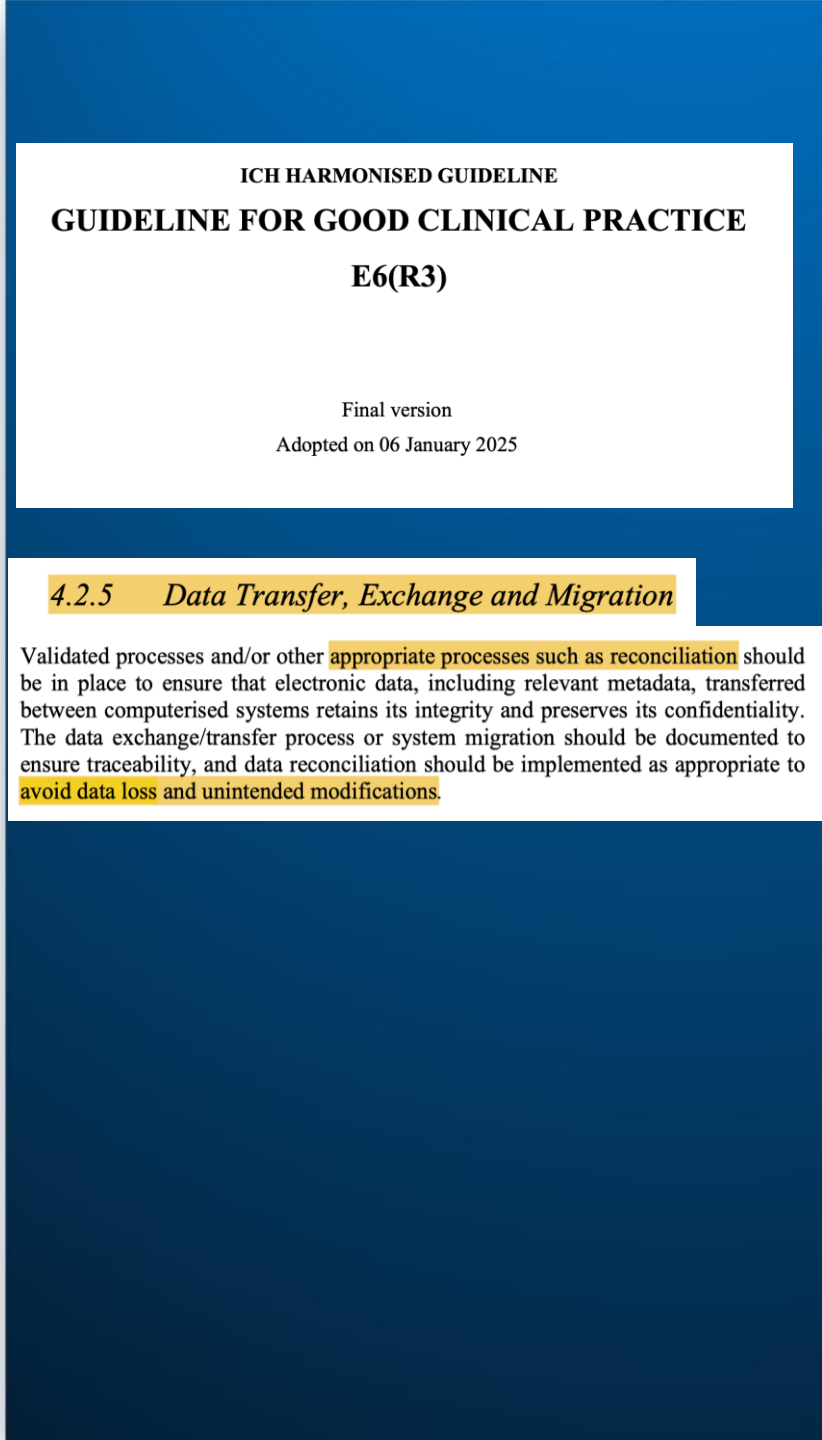


[1]*Miske O, Abatayo AL, Daley M, et al. Investigating the reproducibility of the social and behavioural sciences. Nature 2026; 652(8108): 126–34.*

Why This Matters

ICH E6(R3) §4.2.5 acknowledges the risk

- "*avoid data loss* [including relevant metadata] *and unintended modifications*" during data transfer, exchange and migration
- Naming reconciliation as an appropriate process for detection



ICH HARMONISED GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R3)

Final version

Adopted on 06 January 2025

4.2.5 Data Transfer, Exchange and Migration

Validated processes and/or other appropriate processes such as reconciliation should be in place to ensure that electronic data, including relevant metadata, transferred between computerised systems retains its integrity and preserves its confidentiality. The data exchange/transfer process or system migration should be documented to ensure traceability, and data reconciliation should be implemented as appropriate to avoid data loss and unintended modifications.

Why This Matters

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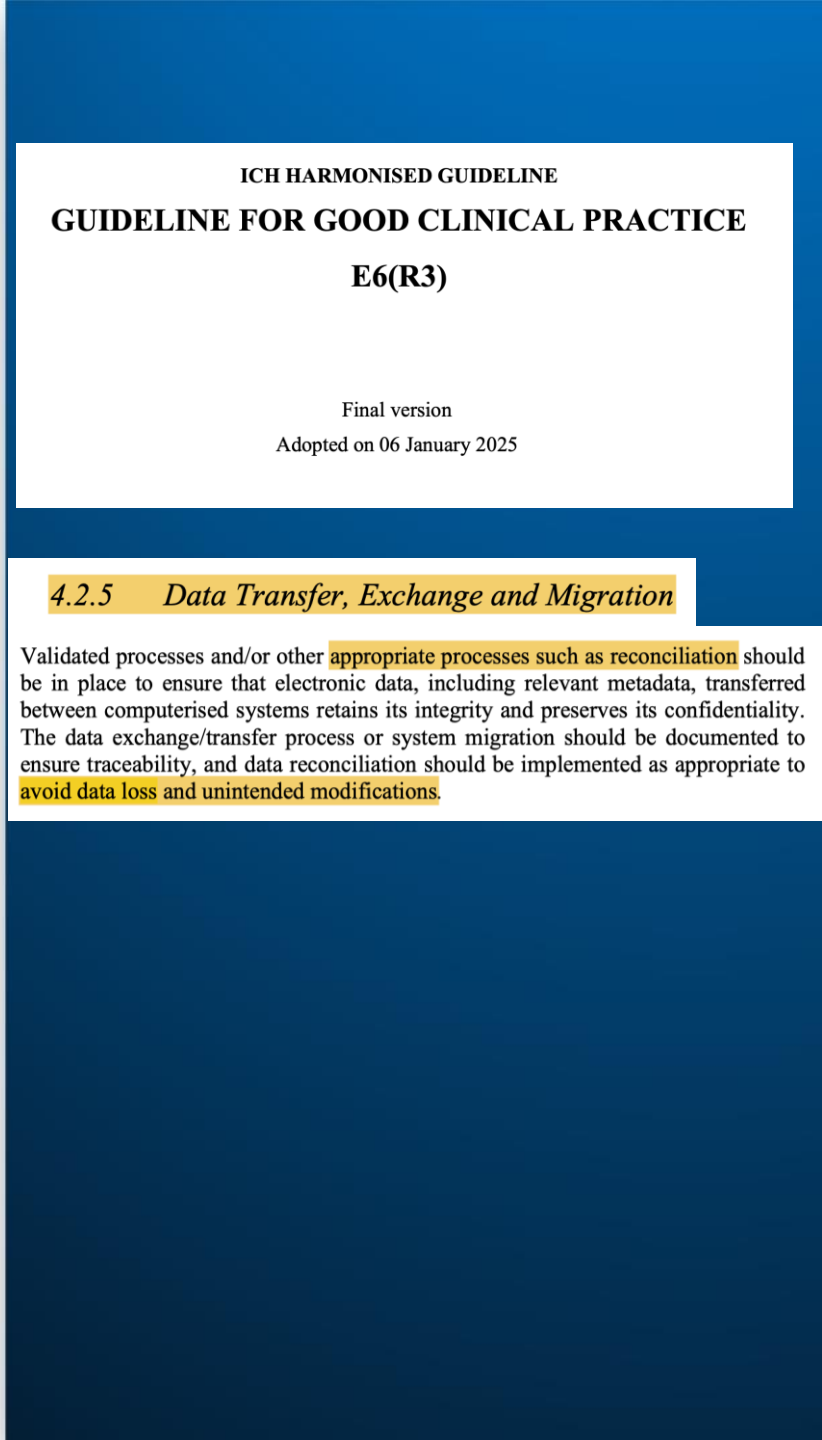
- "*avoid data loss* [including relevant metadata] *and unintended modifications*" during data transfer, exchange and migration
- Naming reconciliation as an appropriate process for detection

A large trial dataset:

- Thousands of discrete files
- Gigabytes of images, datasets, procedures and audit trails

Manual reconciliation is not feasible at scale

Verification remains targeted, it is **not routinely tested**



ICH HARMONISED GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R3)

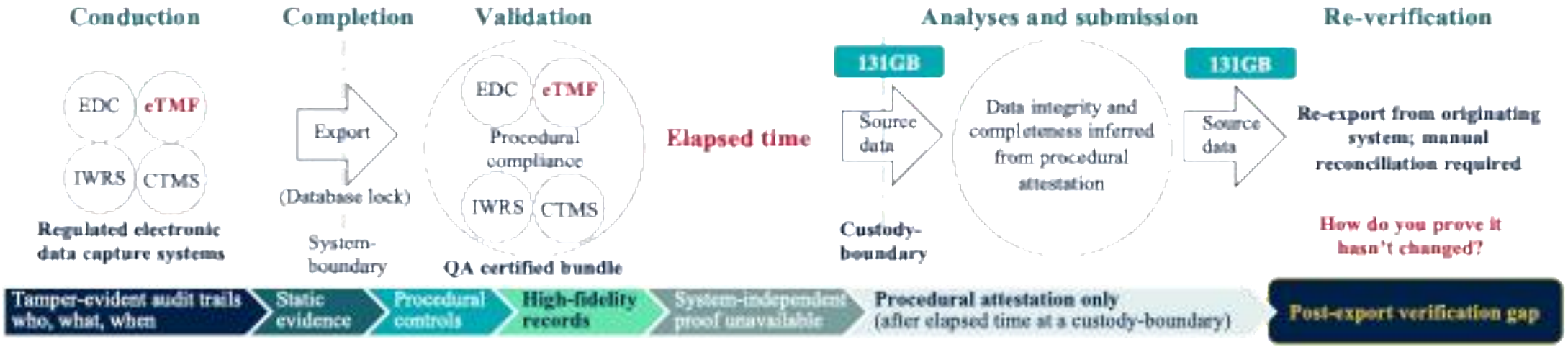
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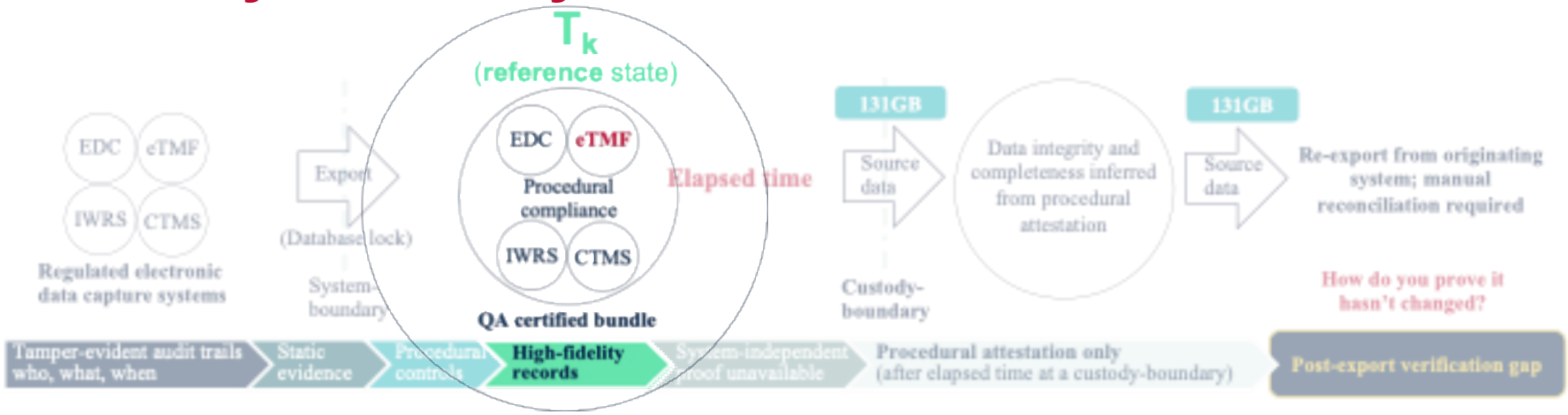
The Custody-Boundary Problem



To address this, we engineered a dual-software architecture

- Operating at the custody boundary
- Without originating system integration
- Without source data transmission

The Custody-Boundary Problem



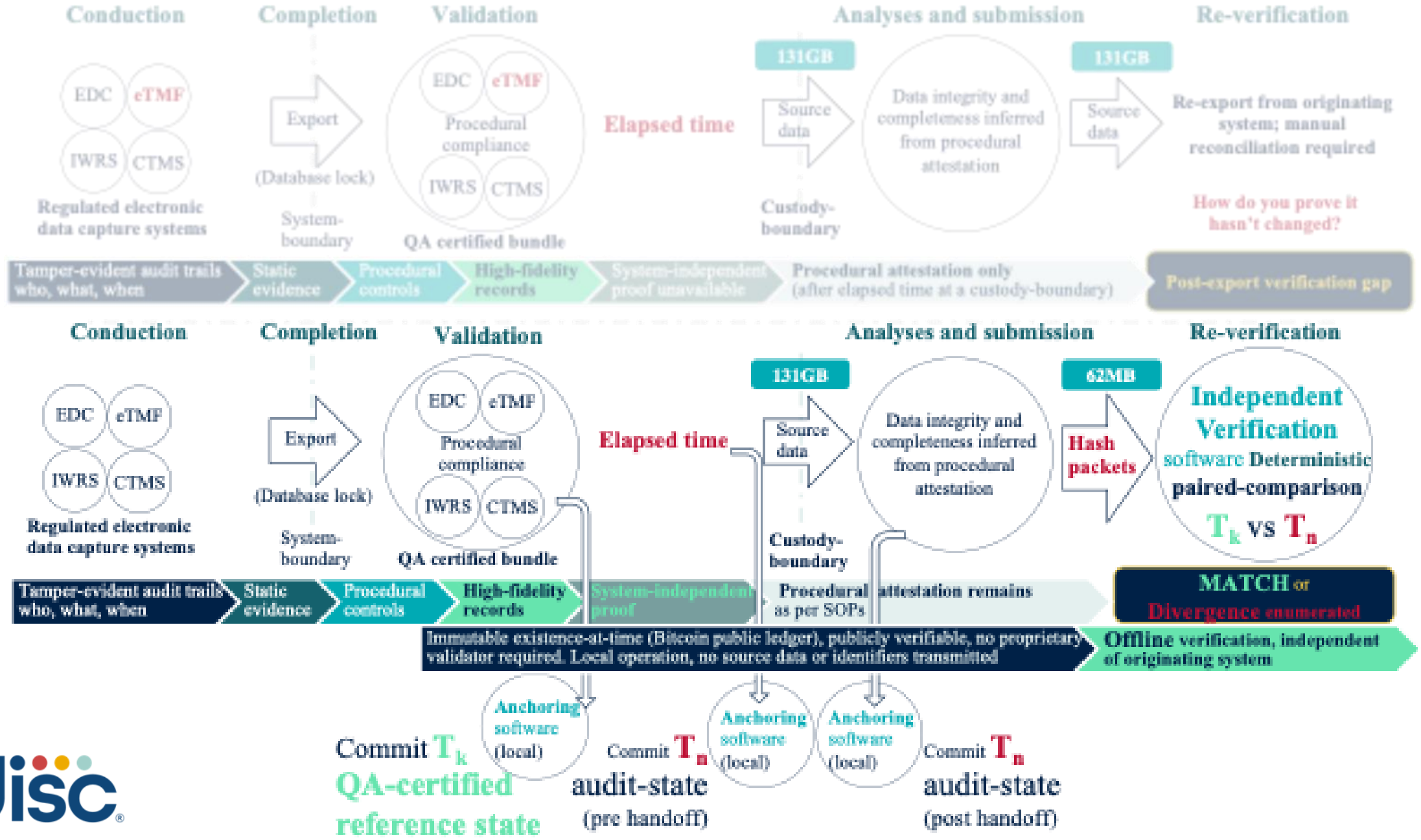
To address this gap, we engineered a dual-software architecture

- Operating at the custody boundary
- Without originating system integration
- Without source data transmission

To enable independent **verification against a reference state**

[QA Validation] … is a **snapshot** and can ~~cannot~~ **be carried forward**

The Custody-Boundary ~~Problem~~ Solution



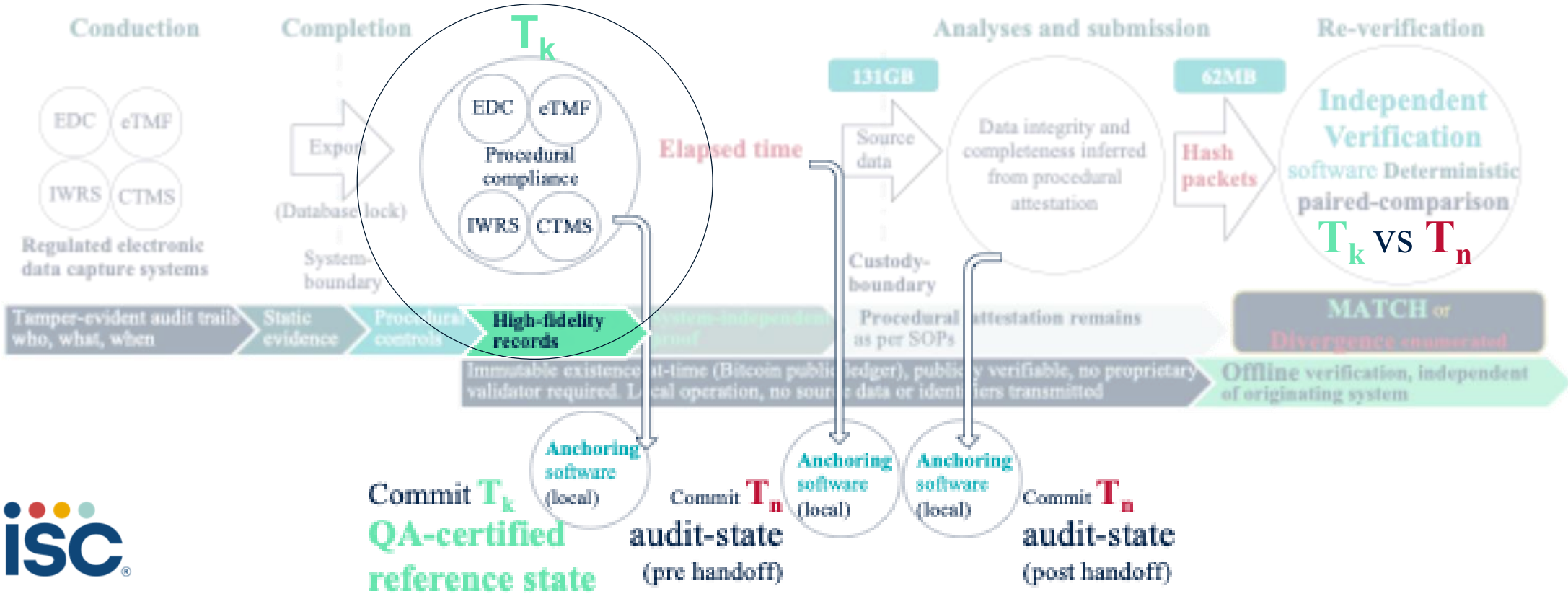
The Custody-Boundary ~~Problem~~ Solution

To enable:

- **verification against a reference** state
- Independent of the system that generated the data
- Independent of elapsed time
- Without access to raw data or identifiers

[QA]Certification is **appropriate** and **required**

…a **snapshot** and **can** ~~**cannot**~~ **be carried forward**
[through paired-comparison]



How It Works:

Zero-Custody, Hash-Only Verification

- **Two independent software**

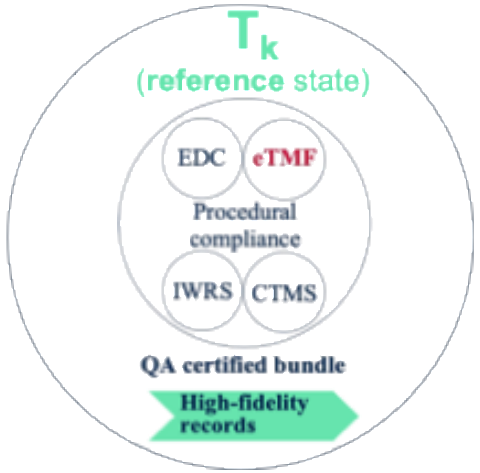
  Anchoring – Custodian Environment (**local**)
  Verification – system-independent · **offline** · any authorised party

- **Dual-Layer Verification Architecture**

  Evidence Integrity (per-file) – Dual-hash* signature
  Evidence-Set Membership (per-bundle) – Evidence Set Fingerprint (**ESF**)[+]

- **Paired-Comparison Design T_k vs T_n**

  T_k: Validated reference state
  T_n: Any later comparison state



Verification using **hash-only** packets
(no raw data or identifiers)

1. Freeze & Hash

- Read-only protections
- Computes fingerprints*

(no raw evidence or identifiers exit)

2. Time-Anchor

- Evidence-state committed
- Hash-only
- Public blockchain[+]

(verifiable existence-at-time)

3. Re-Verify (T_K vs T_n)

- **MATCH**

OR

- **Divergence**

(altered items and/or membership differences explicitly enumerated)

[+] Bitcoin mainnet via OP_RETURN
* Dual-hash: SHA-256, then RIPEMD-160 on the SHA-256 output
[+] ESF: Order-independent SHA-256, any addition, removal, alteration, or reassignment produces a mismatch

Empirical Validation
Study design overview (Stage IV)

- **Prospective**, single-site*, blinded, multi-operator
(pre-specification and time-anchoring of all execution states prior to analysis)
- Reference corpora **exported** and time-**anchored**
(cross-platform MacOS → Windows)
- Each corpus cloned
  one copy **unchanged**
  one copy deliberately **modified**
- **12** paired audit **arms**
  Labelled references (T_k) compared against one unchanged and one altered corpus (T_n) in **randomized** order
- Three **Blinded** auditors (inventor was excluded)
- Two **independent workstations**
- **Correctness** of software output **verified** against keys **post-reveal**

*Cardiovascular Diagnostic Audit & AI Pty Ltd, Melbourne, Australia



Telles F, Francis S, Yang J, Hookey B, Woo A, Levy P, Leeson P
Deterministic custody-boundary verification of digital clinical trial audit trails across blinded multi-operator cross-platform environments without source data transfer: a validation study
[UNDER PEER REVIEW PROCESS]

Tamper Category Taxonomy

Human-generated adversarial tamper challenge

IIIA-challenge

- multiple violation classes (content edits, deletions, insertions, swaps, and metadata-only modifications)
- rename-only negative controls (*which do not alter artefact bytes)

Machine-generated (HMAC) adversarial tamper challenge

IIIB-challenge

- deletion-only regimen generated
- HMAC-randomized file selection.

	Tamper Source	Content Modification	Deletion	Insertion	Swap	Metadata Tamper	Rename Only Control
IIIA-challenge	Human-designed adversarial	Yes	Yes	Yes	Yes	Yes	Yes*
IIIB-challenge	HMAC-randomized deletion	No	Yes	No	No	No	No
IIIB-challenge (Multi)	HMAC-randomized deletion	No	Yes	No	No	No	No

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[UNDER PEER REVIEW PROCESS]

Under adversarial conditions
The method achieved:

230,253	100% / 0	κ = 1.0
evidence files verified	sensitivity / false positives	inter-operator agreement

	Verification Layer	Total Items Verified	True Positives (TP)	True Negatives (TN)	False Positives (FP)	False Negatives (FN)	Sensitivity	Specificity	False Positive Rate	False Negative Rate
IIIA-challenge	Evidence	13,194	324	12,870	0	0	1	1	0	0
	Membership	1,536	156	1,380	0	0	1	1	0	0
IIIB-challenge	Evidence	217,059	555	216,504	0	0	1	1	0	0
	Membership	20,430	450	19,980	0	0	1	1	0	0
Stage IV (Pooled)	Evidence	230,253	879	229,374	0	0	1	1	0	0
	Membership	21,966	606	21,360	0	0	1	1	0	0

All results shown derive from blinded executions by 3 independent operators; analyses performed by the study lead were excluded.

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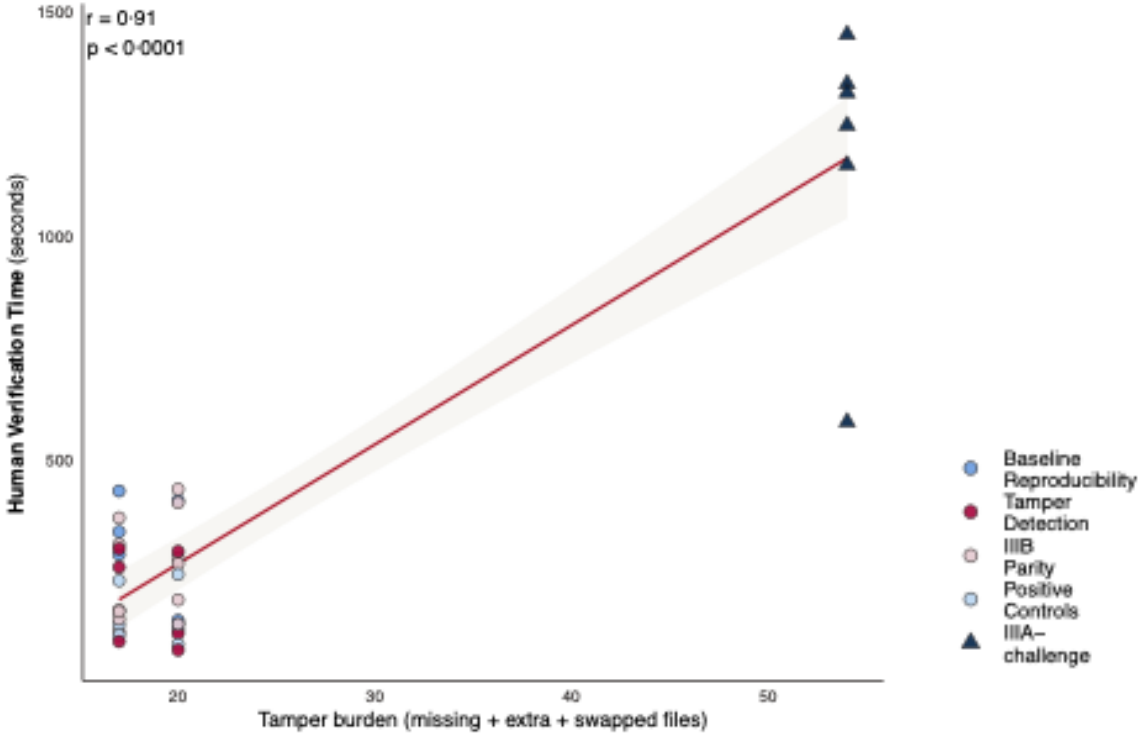
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[UNDER PEER REVIEW PROCESS]

We quantified the human effort
required to verify software correctness

Mean	Pass-like	Fail-like
0.076 s/file	0.031 s/file	0.12 s/file
for all audits combined	for Proof-of-Unchanged	when divergences detected

- Verification **effort scaled with tamper burden**

Human Verification Time versus Tamper Burden (Fail-like arms)



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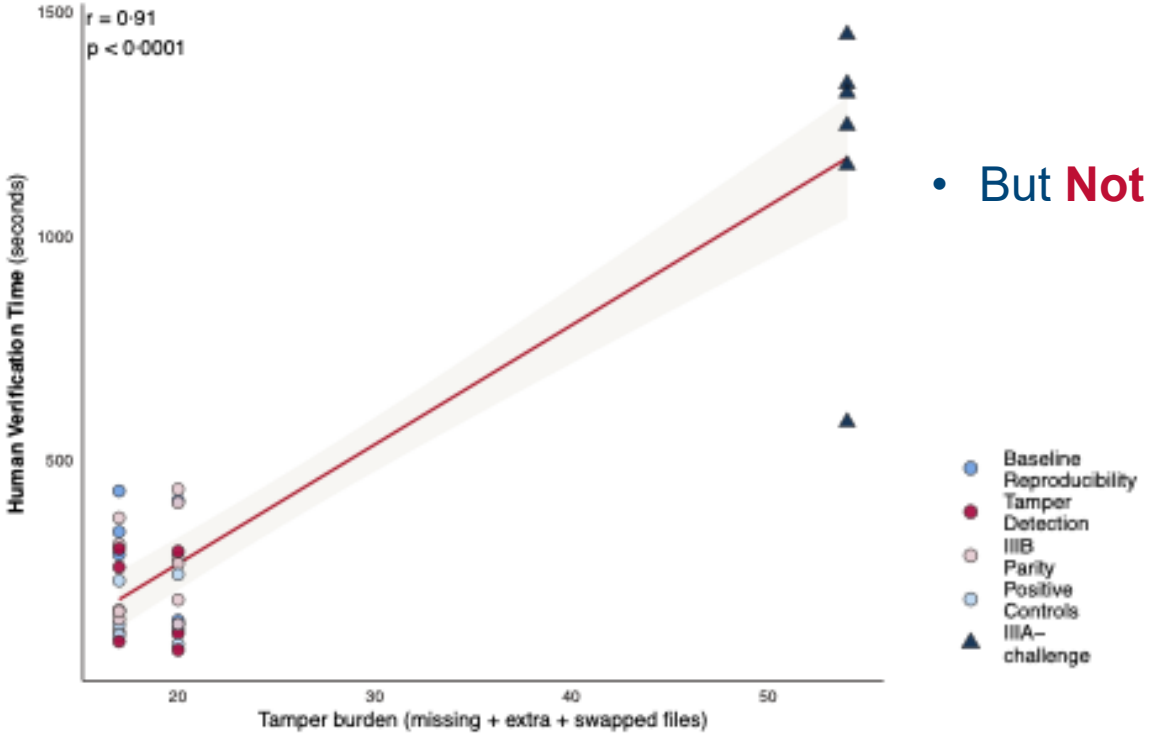
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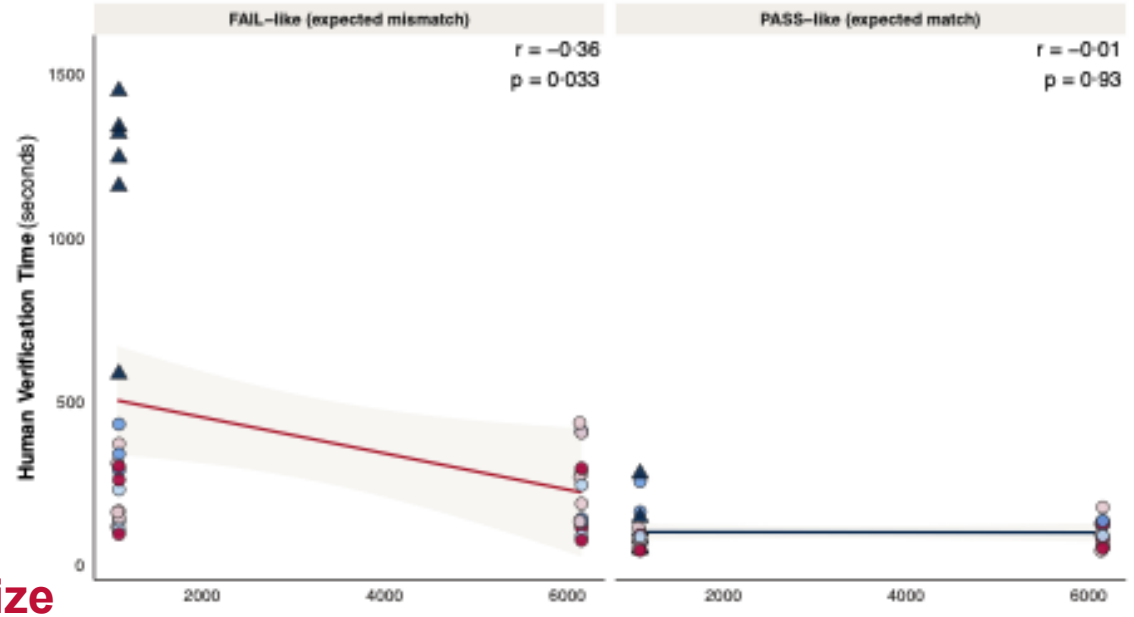
Human Verification Time versus Tamper Burden (Fail-like arms)



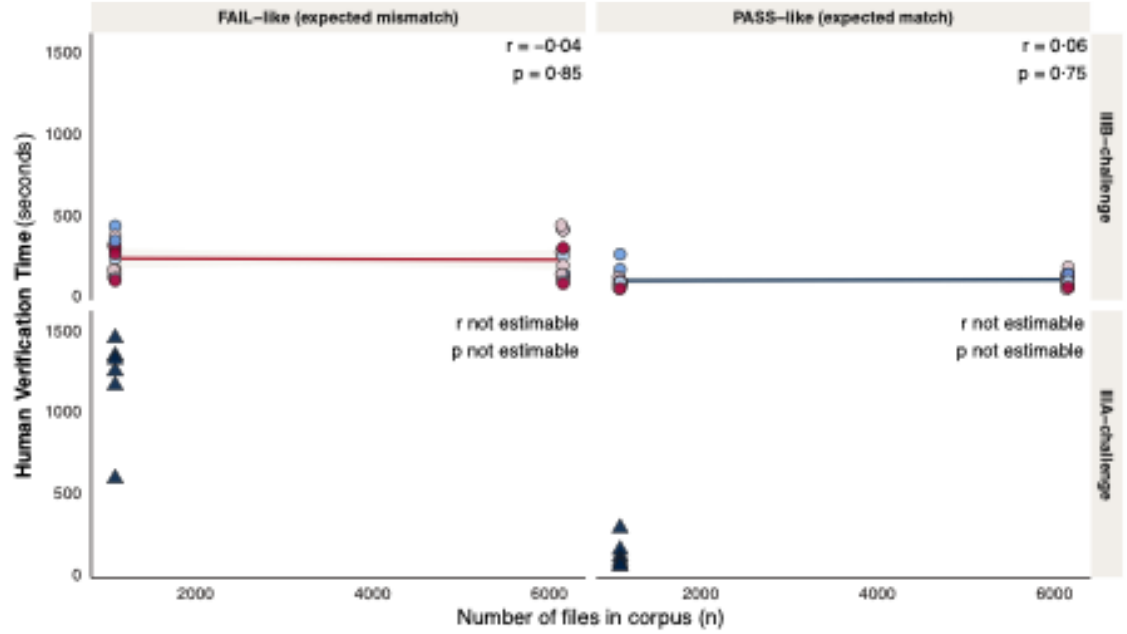
- But **Not corpus size**

Human Verification Time versus Corpus Size

A – Pooled across stages



B – Stratified by challenge source



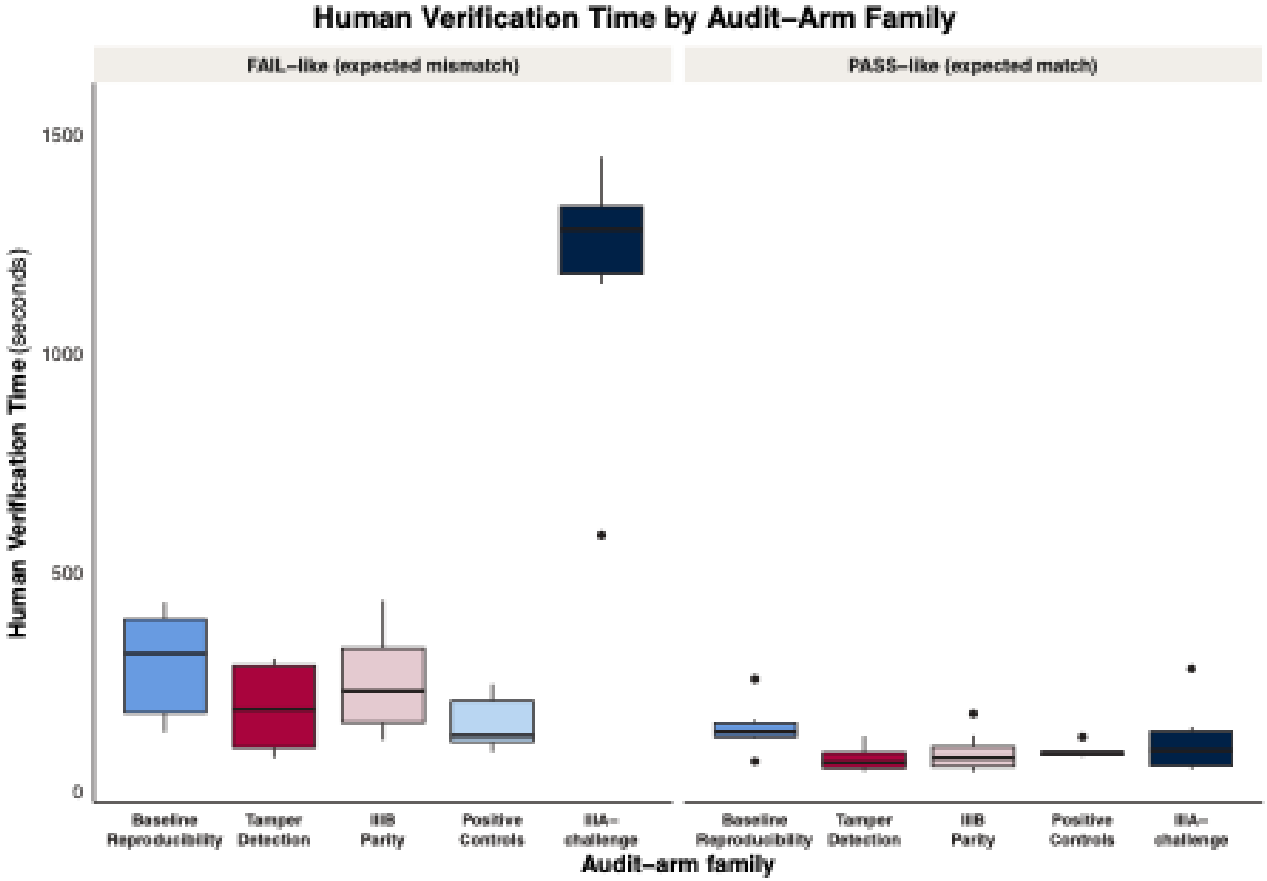
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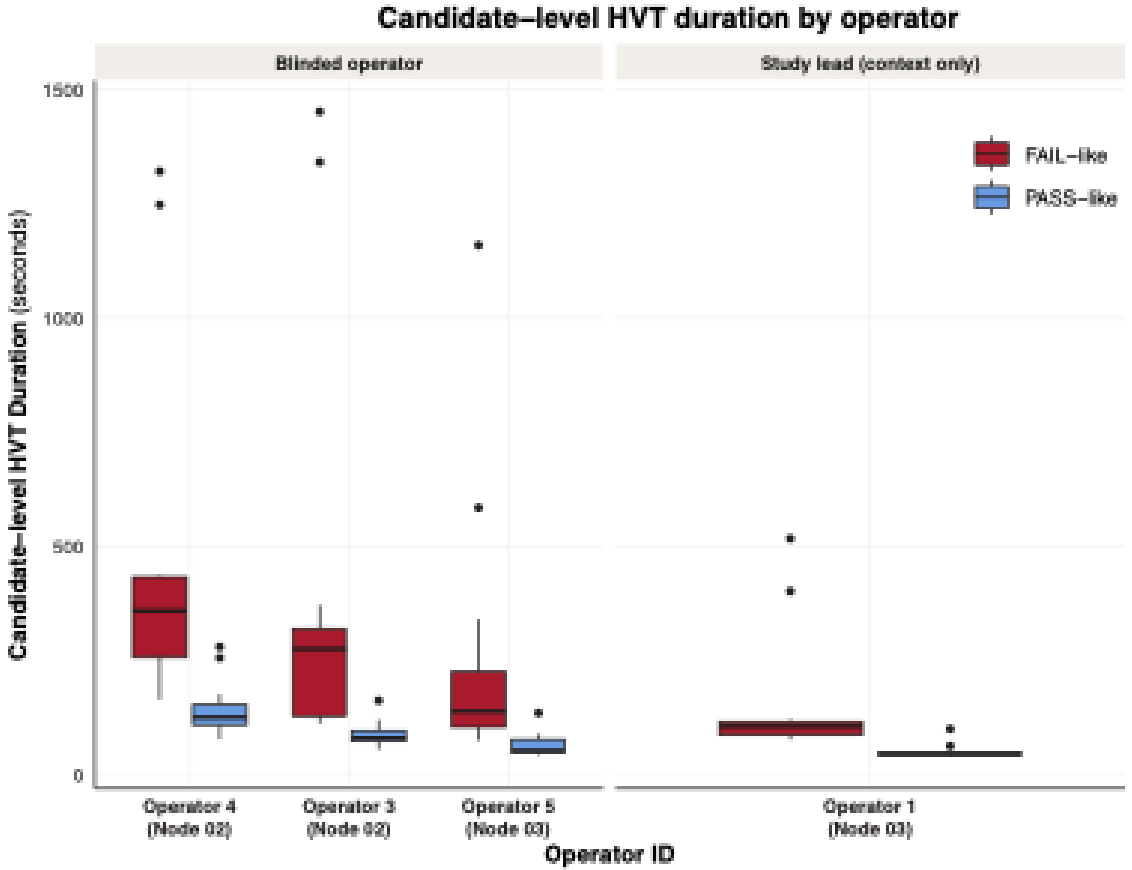
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[UNDER CONSIDERATION] Ther Innov Regul Sci

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- Verification **effort** scaled with tamper burden
- But **Not** corpus size

Human verification cost is proportional to divergences rather than to the volume of data being verified





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[UNDER PEER REVIEW PROCESS]

Verification using hash-only packets

- **compact** for cross jurisdiction analyses
- enable verification of file-level integrity and corpus-level completeness
- **without raw data** transfer
- or reliance on originating systems

	Node	Node	Original Evidence (n)	Original Evidence Size (Mb)	Anchored Evidence (n) †	Anchored Evidence Size (Mb)	Identifiers Present	Hash-Only Verification Packet (n) *	Packet Size (Mb)	Identifiers Present	Post-QMS Analysis Output (n)	Analysis Output Size (Mb)	Identifiers Present
Stage I	Node 01	Positive Controls	12,954	59,184.80	64,904	59,276.64	Yes	38,836	59.01	No	..	..	
Stage II	Node 01	Baseline	1,090	10,395.49	5,691	10,414.64	Yes	3,262	6.32	No	..	..	
Stage IIIA	Node 01	Baseline	1,093	10,395.51	5,567	10,414.54	..	3,262	5.44	..	..	..	
		Tamper	1,087	10,394.50	5,720	10,414.85	..	3,262	5.68	..	..	..	
		Positive Controls	1,087	10,395.47	5,682	10,415.00	..	3,262	5.44	..	..	..	
		IIIA Pooled	3,267	31,185.48	16,969	31,244.39	Yes	9,786	16.56	No	..	..	
Stage IIIB	Node 01	Multi Baseline	6,152	5,993.13	31,327	6,047.08	..	18,457	30.31	..	..	..	
		Baseline	1,087	10,395.47	5,683	10,415.49	..	3,262	5.89	..	..	..	
		Multi Tamper	6,135	5,984.30	31,228	6,041.25	..	18,397	32.81	..	..	..	
		Tamper	1,070	10,355.15	5,591	10,374.65	..	3,211	5.36	..	..	..	
		Multi Positive Controls	6,152	5,993.13	31,327	6,047.34	..	18,457	29.98	..	..	..	
		Positive Controls	1,087	10,395.47	5,682	10,414.73	..	3,262	5.34	..	..	..	
		IIIB Pooled	21,683	49,116.65	110,838	49,340.55	Yes	65,046	109.68	No	..	..	
Stage IV	Node 02	Multi Baseline A	6,152	5,993.13	27,206	6,013.91	..	18,457	6.54	..	..	..	
		Baseline A	1,087	10,395.47	4,740	10,402.41	..	3,262	1.26	..	..	..	
		Multi Baseline B	6,152	5,993.13	27,206	6,014.19	..	18,457	6.70	..	..	..	
		Baseline B	1,087	10,395.47	4,740	10,402.43	..	3,262	1.27	..	..	..	
		Multi Tamper	6,132	5,984.28	27,118	6,005.40	..	18,397	6.75	..	..	..	
		Tamper	1,070	10,355.15	4,662	10,361.74	..	3,211	1.26	..	..	..	
		Multi Positive Controls	6,152	5,993.13	33,358	12,006.70	..	18,457	6.43	..	..	..	
		Positive Controls	1,087	10,395.47	5,827	20,797.49	..	3,262	1.25	..	..	..	
		Node 02 Pooled	28,919	65,505.23	134,857	82,004.28	Yes	86,765	31.45	No	696	17.09	No
	Node 03	Multi Baseline A	6,152	5,993.13	27,206	6,013.93	..	18,457	6.28	..	..	..	
		Baseline A	1,087	10,395.47	4,740	10,402.64	..	3,262	1.19	..	..	..	
		Multi Baseline B	6,152	5,993.13	27,206	6,014.22	..	18,457	6.59	..	..	..	
		Baseline B	1,087	10,395.47	4,740	10,402.13	..	3,262	1.23	..	..	..	
		Multi Tamper	6,132	5,984.28	27,118	6,004.60	..	18,397	6.45	..	..	..	
		Tamper	1,070	10,355.15	4,662	10,361.68	..	3,211	1.21	..	..	..	
		Multi Positive Controls	6,152	5,993.13	33,358	12,006.82	..	18,457	6.38	..	..	..	
		Positive Controls	1,087	10,395.47	5,827	20,797.68	..	3,262	1.19	..	..	..	
		Node 03 Pooled	28,919	65,505.23	134,857	82,003.70	Yes	86,765	30.52	No	632	16.74	No
		Stage IV Pooled	57,838	131,010.47	269,714	164,007.97	Yes	173,530	61.98	No	1,328	33.83	No

	Original Evidence (n)	Original Evidence Size (Mb)	Hash-Only Verification Packet (n) *	Packet Size (Mb)
Stage IV Pooled	57,838	131,010.47	173,530	61.98

~131GB → 62 MB

Telles F, Francis S, Yang J, Hookey B, Woo A, Levy P, Leeson P
Deterministic custody-boundary verification of digital clinical trial audit trails across blinded multi-operator cross-platform environments without source data transfer: a validation study
[UNDER PEER REVIEW PROCESS]

Methodology Scope Boundaries

Limitations

The model establishes **integrity** facts **against** **a** **reference-state** (T_k) only:

The paired-comparison design **detects change**:

- Evidence **integrity** (byte-identity) and ESF **membership** equivalence (Evidence Set Fingerprint)

The **Zero-custody** design means it cannot verify the contents of a reference validated state used for comparison; it **detects divergences relative to the reference state**, **not whether the validation was correct**

It **does not** evaluate:

- clinical meaning, scientific validity, regulatory compliance, intent, or root cause.

Divergence is informational and non-accusatory

- Enumeration bounds **proportional review** to the minimum delta set (files and ESF membership mismatches, if any)
- **Interpretation, materiality, and response remain under human and institutional governance.**

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International multi-site extension (in progress)

Software hash-only mathematical audit without access to source data or identifiers

Dataset 1, FICTI-PDA

- **Synthetic-simulated** Phase II RCT export bundle (no real patients)
- 3 graded tamper tiers

Dataset 2, Stage IV multi-site replication

(sub-study)

- Original 12 audit-arms
- Re-blinded

SYNTHETIC DATA. NO CLINICAL, REGULATORY, OR EFFICACY CLAIM

Corpus	Integrity condition	What an auditor would conclude
Tk	Validated reference state anchored on export	No significant benefit / increased harm signal
NC01	Independent negative control 01	unchanged
NC02	Independent negative control 02	unchanged
T1	Unintentional human error	Null effect maintained / data-quality issues only
T2	Mild dishonesty + selective omission	Borderline-significant benefit
T3	Overt fraud (multi-file; audit trail tampered)	Apparent mortality reduction / "wonder drug"

n=70 [simulated] extremely-preterm infants (23–32 wks GA) w/ haemodynamically significant PDA, primary endpoint composite death or rescue intervention by day 30

FICTIROVAN is not a real or proposed compound; it is a fictional name used for this synthetic simulation.
It does not refer to, or resemble in mechanism, any real or investigational agent

Telles, F. (2026). OSF Pre-Registration Amendment – WP73B Challenge Extension. Zenodo. https://doi.org/10.5281/zenodo.20976077

Integrity failure	Tamper-Tier Instantiation under evaluation in PhD program (FICTI-PDA Stage V)	Regulatory grounding
1 – Unintentional human error	Errors in data handling, transcription, or documentation at or after the post-export custody boundary	"Failure to adequately maintain case histories… Failure to report adverse events accurately and correctly to the IRB; Revisions on source worksheets were unclear; Failure to document dates related to serious adverse events" – IMARC BIMO Warning Letter Findings [1]
2 – Selective omission and secondary parameter manipulation	Changing or omitting data such that the research is not accurately represented; includes selective outcome-reporting or outcome-switching post-unblinding	"Falsification is… changing or omitting data or results such that the research is not accurately represented in the research record" – George & Buyse, 2015 [2]; "Assessment of efficacy" is a named Protocol Compliance deficiency sub-area in both FDA and EMA GCP inspection frameworks [3]
3 – Adverse effects suppression	Deleting records from safety datasets; reducing apparent drug-related harm burden	"Failure to report serious adverse events SAEs according to the protocol" – IMARC BIMO Warning Letter Findings [1]; "failure to manage safety events… will constitute a serious breach which needs to be reported" – EMA Guideline for the notification of serious breaches [4]; "Safety reporting" is a named Protocol Compliance deficiency sub-area in both FDA and EMA GCP inspection frameworks [3]
4 – Consent backdating	Modifying ICF timestamps to make post-hoc consent appear pre-randomisation	"Failure to obtain informed consent in accordance with 21 CFR Part 50" – IMARC BIMO Warning Letter Findings [1]; "19 of the 26 sites had findings [in Human Subject Protection], with both agencies identifying findings at 11 of the 19 sites" – Sellers et al., 2022 [3]
5 – Primary outcome manipulation	Tampering with primary outcome data after unblinding	Serious harmful effects of data fraud in clinical trials include potential harm to patients [2]
6 – Allocation flipping	Changing treatment allocation in the randomisation log for selected subjects from PLACEBO to FICTIROVAN in order to attain desired statistical outcome	"Charges against Snyder and Peugot of falsification of data, including the randomization assignments… Felony convictions followed… permanent debarment by the FDA" – George & Buyse, 2015 [2]; "Randomization, blinding and codes of study drug" is a named Documentation deficiency sub-area in both FDA and EMA GCP inspection frameworks [3]

StageV | FICTI-PDA | Integrity Failure Taxonomy

[1] IMARC. Analysis of FDA BIMO Warning Letter Findings. 2019. (IMARC_FDA_warning_letters_2019_REV.pdf)
[2] George SL, Buyse M. Data fraud in clinical trials. Clin Investig (Lond). 2015;5(2):161–173. doi: 10.4155/cli.14.116
[3] Sellers S, et al. Descriptive Analysis of Good Clinical Practice Inspection Findings from FDA and EMA. Ther Innov Regul Sci. (2022)56:753–764.
[4] European Medicines Agency. Guideline on notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol. EMA/698382/2021. 2023

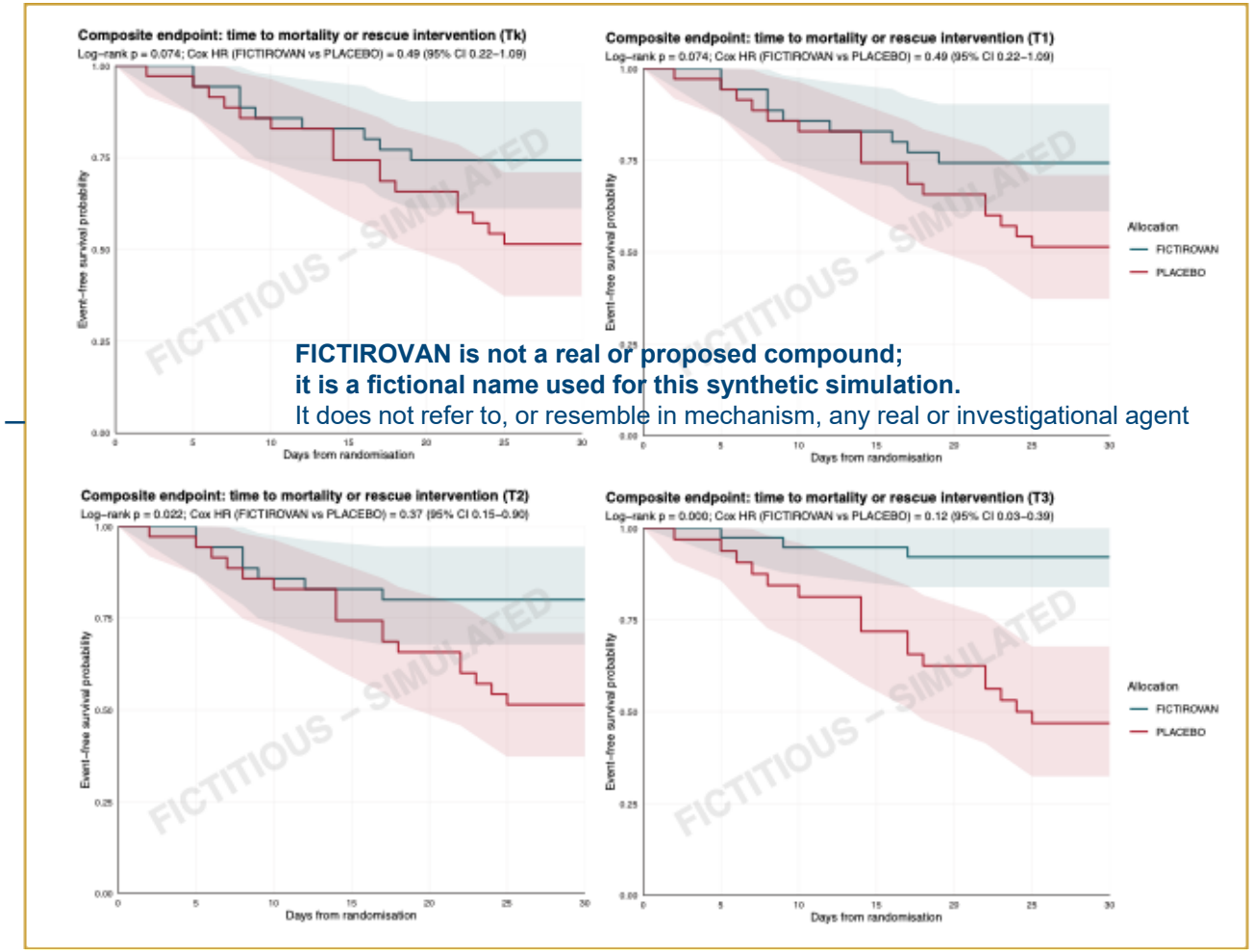
Pre-scripted statistical arc – what the corpus tests (selective disclosure only)

Each tamper tier is calibrated to produce a clinically distinct and interpretable statistical outcome.

Research Question 3 – Regulatory-grounded, mechanism-agnostic detection:

Does cryptographic custody-boundary verification correctly detect the integrity failure classes documented in regulatory inspection findings and research misconduct literature – including unintentional human error, selective omission, adverse-effects suppression, consent backdating, primary outcome manipulation, and allocation falsification – as instantiated across graded tamper severity tiers in the FICTI-PDA corpus; and is detection mechanism-agnostic, operating correctly whether modifications are introduced manually or via AI-assisted execution under human directives, without requiring knowledge of the tamper mechanism, tools used, or identity of modified files?

SYNTHETIC DATA. NO CLINICAL, REGULATORY, OR EFFICACY CLAIM



⚠ SIMULATION ONLY – Patient data derived from published reference ranges. All patients, outcomes and the drug FICTIROVAN are entirely fictitious.

Telles, F. (2026). OSF Pre-Registration Amendment – WP73B Challenge Extension. Zenodo. https://doi.org/10.5281/zenodo.20976077

Software Hash-only Mathematical Audit (without access to raw data or identifiers)

STEP 1: Download public hash-packets

Stage V Pre-Registration and Stage IV Multi-Site Replication Hash-Only Verification Packets for International Blinded Challenge Trial of Post-Export Clinical Trial Evidence Verification (WP73B Amendment)

Hash Packet

≈3.3 MB (source: ~33 MB)

Mendeley Data

Published: 25 June 2026 | Version 1 | DOI: 10.17632/f52gxw8k.1

Contributor: Fernando Telles

STEP 2: Perform paired-comparisons independently



Machine-deterministic output MATCH or **Divergence enumerated**
Constant human verification time for MATCH (**Proof-of-Unchanged**) **independent of corpus size**

Offline verification, independent of originating system

DATASET 1 – Labelled reference T_k vs **QMS 01 to 05**

Reference T_k vs audit candidate QMS01
Reference T_k vs audit candidate QMS02
Reference T_k vs audit candidate QMS03
Reference T_k vs audit candidate QMS04
Reference T_k vs audit candidate QMS05
Two MATCH (negative control 01 and 02)
Three MISMATCH (tampered tiers T1, T2, T3)

Paired-comparisons
T_k vs T_a
Correctly classify as
MATCH or MISMATCH

DATASET 2 – Labelled reference A labelled vs **QMS 01/02**

12 audit arms:
Reference corpus (A) **vs** audit candidate **QMS 01**
Reference corpus (A) **vs** audit candidate **QMS 02**
One MATCH and **one MISMATCH** per arm
IV Baseline Reproducibility; IV Tamper Detection; IIIB Parity; IIIB Positive Controls; IIIA Baseline Reproducibility; IIIA Tamper Detection

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Sites Confirmed & Recruiting

Independent Site 1, Confirmed

- Boston Children's Hospital & Harvard Medical School
- Principal Investigator: Philip Levy, MD

Scientific Collaboration

- University of Oxford
- Prof. Paul Leeson

Coordinating site:

AuditLog.AI Research Initiative, CDA-AI Pty Ltd, Melbourne, Australia

Eligibility:

Sponsor | CRO | Regulator | Academic Institution

(enrolment is open on a rolling basis)

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Three Takeaways

1. Deterministic at the byte level

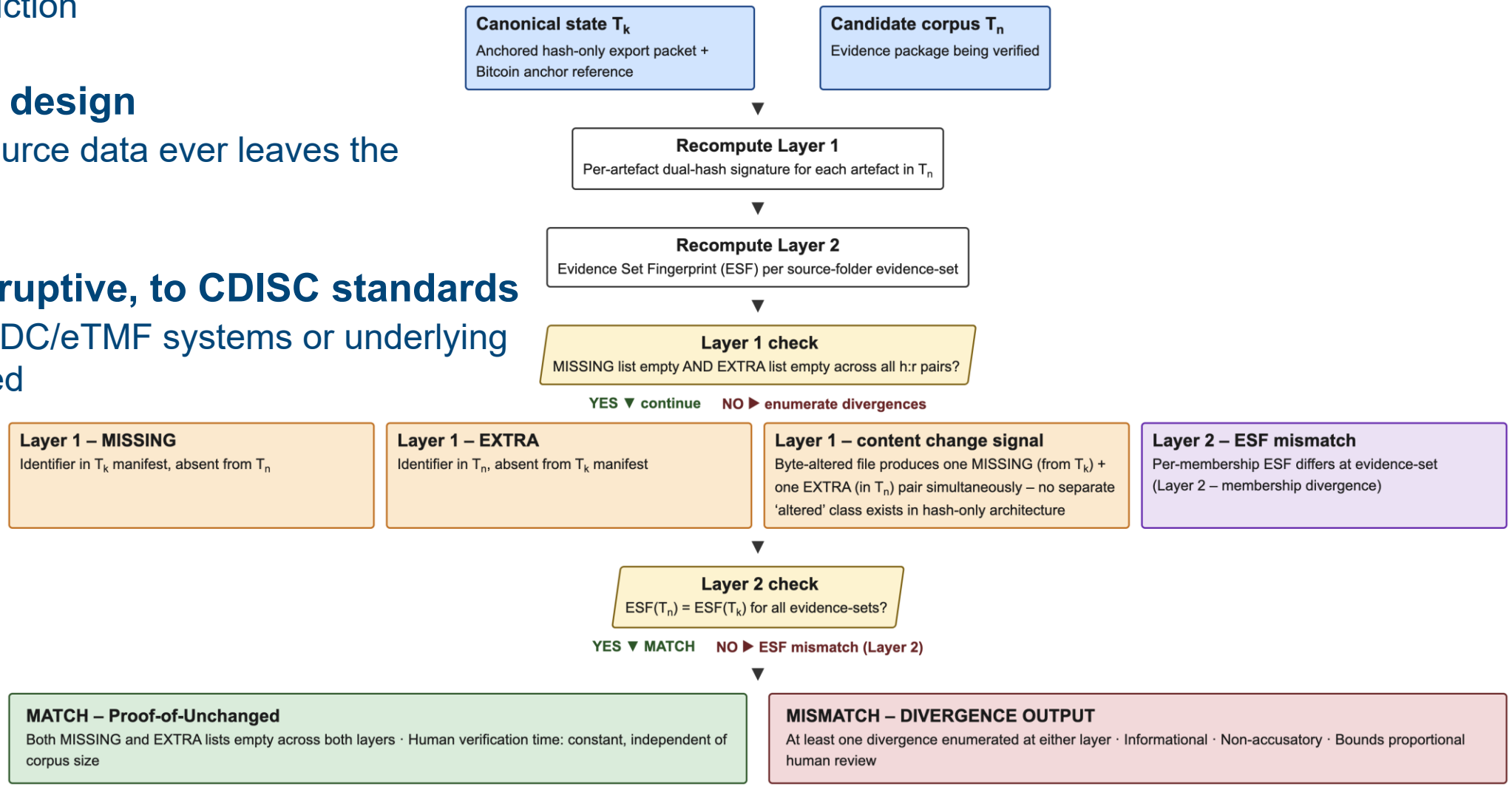
Verification is a mathematical operation on file bytes, not a procedural reconstruction

2. Zero-custody by design

No raw evidence or source data ever leaves the originating site

3. Additive, not disruptive, to CDISC standards

No change to in-trial EDC/eTMF systems or underlying GCP principles required



Three Takeaways

1. Deterministic at the byte level

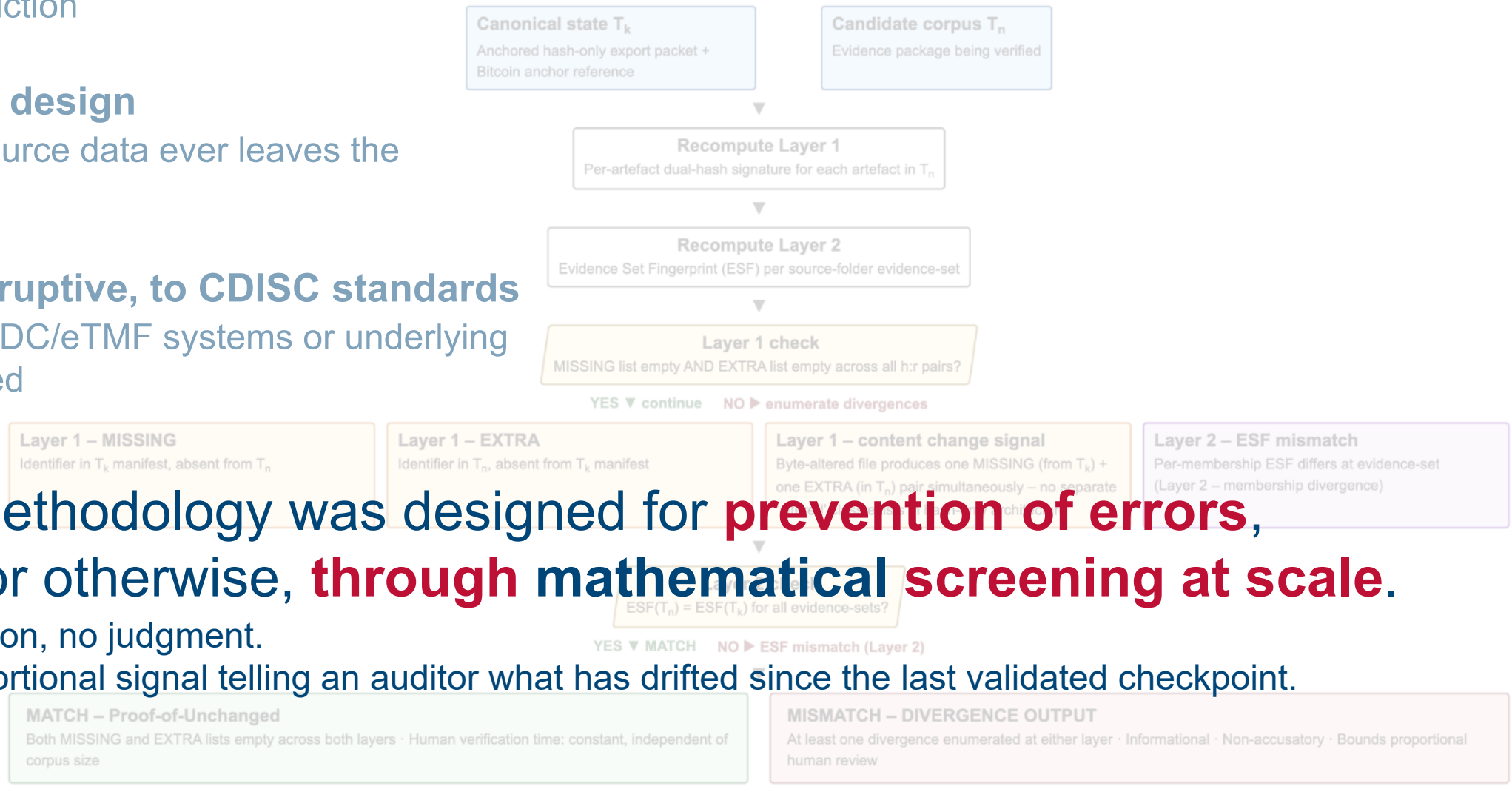
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The methodology was designed for **prevention of errors**, intentional or otherwise, **through mathematical screening at scale**.

No accusation, no judgment.
Just a proportional signal telling an auditor what has drifted since the last validated checkpoint.

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Resources & Collaboration

An invitation to scientific collaboration and participation in the Stage V International Blinded Challenge Trial

WP73B Challenge Extension protocol[1] available at:
https://doi.org/10.5281/zenodo.20976077

WP73B Public Dataset[2] available at:
https://dx.doi.org/10.17632/f52jgxvw8k.1

Dataset 1 verification can be completed independently without any contact.

Contact: fernando.telles@auditlog.ai



[1]Telles, F. (2026). OSF Pre-Registration Amendment – WP73B Challenge Extension. Zenodo. https://doi.org/10.5281/zenodo.20976077

[2]Telles, Fernando (2026), “Stage V Pre-Registration and Stage IV Multi-Site Replication: Hash-Only Verification Packets for International Blinded Challenge Trial of Post-Export Clinical Trial Evidence Verification (WP73B Amendment)”, Mendeley Data, V1, doi: 10.17632/f52jgxvw8k.1