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ICH M11 in Practice: From Computable Protocol Vision to Regulatory Reality

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Speaker



Ron Fitzmartin

Decision Analytics

- Regulatory science and drug development leader with 25+ years of experience across FDA and industry, spanning regulatory policy, clinical data standards, submissions, informatics, and global harmonization.
- Former Senior Informatics Advisor at FDA CDER and CBER on clinical data standards and IDMP standards. Former ICH M11 Regulatory Chair and Rapporteur, and ICH M8 eCTD Regulatory Chair.
- Industry experience: senior roles in biostatistics, clinical data management, and informatics supporting global drug development programs.
- Current work focuses on global data standards, regulatory workflow modernization, and evaluation of AI tools for regulatory use.

Agenda

1. Why Protocols Need to Become Computable
2. Two Use Cases Built on the M11 Framework
3. Use Case 1 — Prospective Structured Authoring
4. Use Case 2 — Protocol Intelligence
5. Where This Goes Next

Protocols Connect Every Trial Function—but Each Team Needs Different Information



Clinical operations

Execution plans, feasibility, and logistics



Data managers

CRFs, edit checks, and CDASH/SDTM structures



Statisticians

Endpoints, trial design, and analysis plans



Investigators & CRCs

Eligibility, conduct, recruitment, and safety



Ethics committees

Participant protection and risk–benefit review



Regulatory bodies

Study design adequacy and submission review

One protocol. Six critical perspectives.

Manual Protocol Work Carries Material Cost, Amendment, and Delay Burdens

~1/3
Trial costs tied to monitoring / Source Data Verification

76%
Protocols with ≥1 amendment (up from 57%)

260 days
Mean time from amendment need to approval

Cost / impact	Phase II	Phase III
Direct amendment cost	$141,000	$535,000
Manual data effort	33.3%	33.3%
Approval cycle	260 days	260 days

Protocols with ≥1 amendment:
57% → 76%

Mean amendments per protocol:
2.1 → 3.3

Amendment data: Tufts CSDD, 950 protocols / 2,188 amendments (2024); Tufts CSDD Phase II/III benchmark (2016).

Two Decades of Collaboration Built the Foundations for Computable Protocols

2002 · Early models
Computable trial-design relationships and simulation

2010 · CDISC Protocol Representation Model
Developed with NIH/NCI, FDA, and HL7 participation

2015 · TransCelerate Common Protocol Template
Reusable core content and structure for industry-wide protocol authoring

2018 · ICH M11 Concept Paper endorsed

2025 — ICH M11 reaches Step 4:
Guideline, Template, and Technical Specification

2026 — FDA issues final M11 guidance,
template, and technical specification

From Narrative to Computable: Four Real Steps

Each stage of the ladder is a real, named thing — not just a label.

01

NARRATIVE

READ

Prose-based PDF protocol

Study design buried in paragraphs; relationships interpreted by hand.

02

STANDARDIZED

ORGANIZE

TransCelerate CPT

Common structure, easier to read and navigate — still fundamentally a document.

03

STRUCTURED

REPRESENT

ICH M11

Required content and explicit section-level structure, internationally harmonized.

04

COMPUTABLE

USE

M11 Tech Spec (via USDM)

Compare design alternatives, validate relationships, run scenarios.

SEMANTIC METADATA — from Structured onward (not a rung of its own)

No controlled terminology exists yet at Narrative or Standardized — nothing structured to attach it to.

"The goal is not simply a better-formatted protocol.
The goal is a reusable study-design asset."

Two Use Cases Built on the M11 Framework

Two different starting points for making protocol information computable and reusable

Use Case 1 — USDM→SDE Pipeline (prospective)

A continuous flow from authoring through validation, governed review, tested exchange, to source data extraction — for protocols authored as M11-conformant from the start.



Use Case 2 — Protocol Intelligence (retrospective)

AI-assisted extraction of structured, M11-organized content from legacy, non-M11 protocols already in use.



Different starting points, same standard

Both anchor to M11's categories — prospectively, every required field; retrospectively, the salient fields the source protocol actually contains.

Use Case 1:
Prospective Structured Protocol Authoring

One Computable Protocol Can Serve Distinct Disciplinary Views



M11/USDM to Source Data Extraction

M11 Authoring and Source Data Extraction Workflow

M11 Authoring Cloud Platform

Structured M11/USDM Authoring
Protocol content is loaded or authored on the platform

Continuous services during authoring

M11 Validation
Structure, required content, terminology, and business rules.

SoA Mapping to USDM
Map protocol visits, activities, arms, endpoints, etc. to USDM trial structure

Rendered Outputs
- Discipline-specific protocol views
- PDF / DOCX rendered protocol

Protocol team review and approval before release

Cross-Functional Protocol Review & Approval

Private & Shared Group Spaces

- Medical Writing
- Clinical
- Data Management
- Clinical Trial Ops
- Biostatistics
- Safety
- Monitors
- Regulatory Affairs
- QA / GCP

Approved SOA JSON

SDE
Ingests approved SOA JSON & generates study / CDASH extraction screens

Clinical Site
EHR OCR/NLP & source document uploads

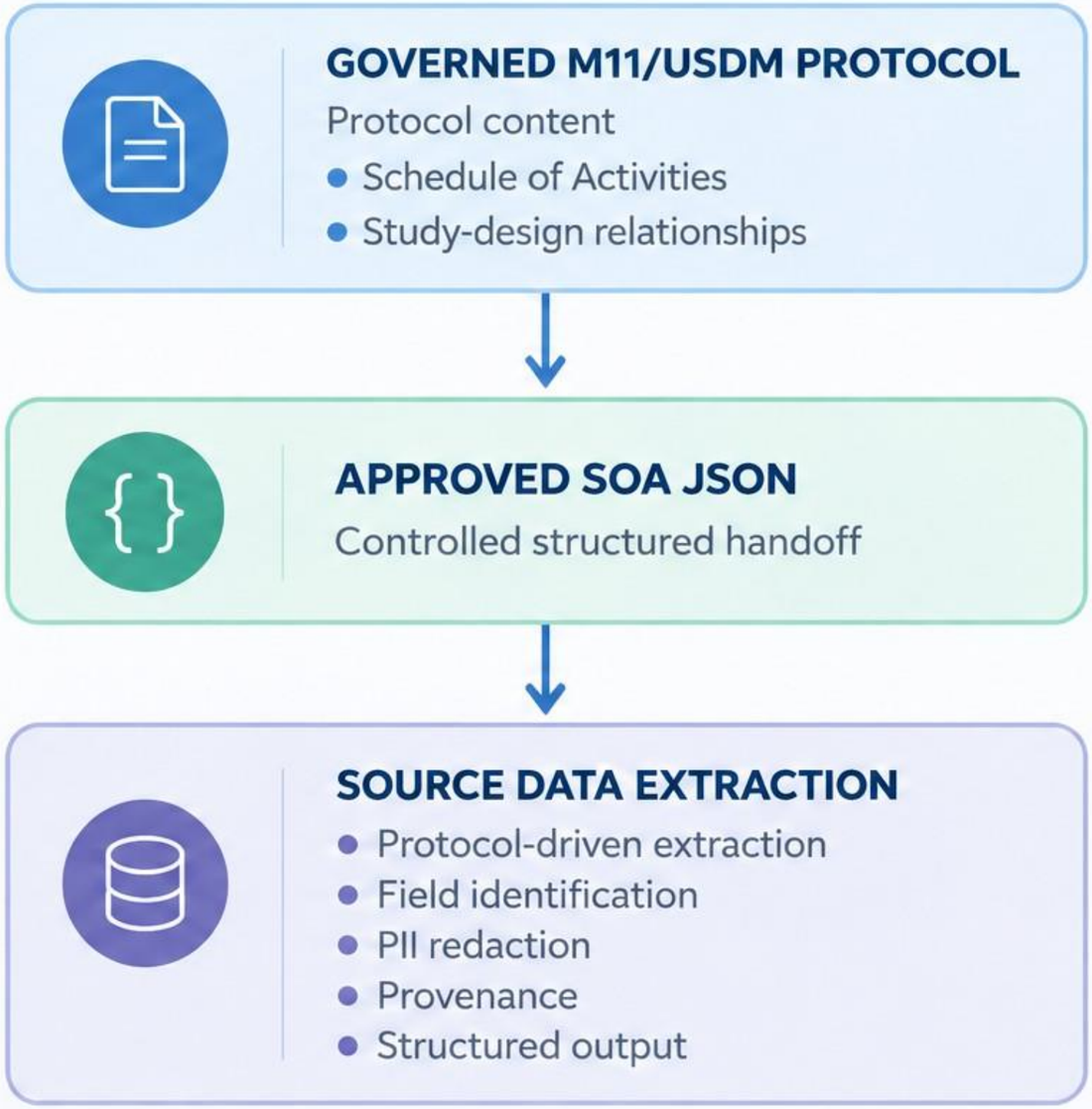
Extraction & Redaction
Source-linked extraction and PII redaction with audit trail.

Monitoring
Data Verification of linked redacted source

Dataset Readiness
SDTM datasets returned

From M11 Computable Protocol to: eCRF Generation | Trial Registries & EU CTIS | SAP | SDTM | CSR

The Approved Schedule of Activities Becomes the Downstream Handoff



The SOA JSON handoff is an implementation choice in this use case, not an M11 requirement.

Source Data Extraction (SDE) Use Case Results Suggest Efficiency Potential

Source-reported processing-time values (minutes per patient)



53%

reported workflow reduction

Source-estimated potential avoided effort: $9M–$16M on a $50M Phase III trial.

Fitzmartin, R. “From Protocol to SDTM: Implementing ICH M11 with the USDMI Structure,” CDISC Europe Interchange, May 2026.

Use Case 2:
Retrospective Protocol Intelligence

A Proof of Concept

Field Extraction Maps Historical PDF Protocols to M11 Fields

An AI model reads each protocol; the field list itself comes directly from the ICH M11 Technical Specification and Template

- **Protocol Summary**
- **Trial Objectives and Associated Estimands**
- **Trial Design**
- **Trial Schema**
- **Schedule of Activities**
- **Amendment Details**
- **Trial Population**
- **Statistical Considerations**

Source protocol stays unchanged; extract and map only what each M11 field asks.

Each dashboard field maps to a named M11 field with Required, Conditional, or Optional status—and stated conditions where applicable.

Multiple Runs, Reconciled;

Every Value Lifted from Its Source

01



Search the whole document by content

Do not rely on legacy section numbering or matching headings

02



Run the model multiple times

Same extracted text, each run a fresh request — reconciled afterward.

03



Locate exact passage and page

An AI model identifies the source location; code lifts the text verbatim.

04

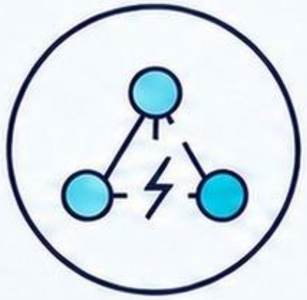


Verified before display

Each cited passage is checked a second time before it's allowed to display.

No model-composed, paraphrased, or summarized field values.

Four Safeguards Keep Extraction Traceable and Reviewable



Reconciliation, not majority vote

Where more than one run exists, disagreements are surfaced — never resolved by silent vote.



Fabrication guard

Require topical source evidence before accepting any AI-proposed value.



Compilation-wide regression testing

Check every fix against all 13 protocols across 3 therapeutic areas.



Visible failure

Flag unresolved fields explicitly, never a silent “blank”

Original source is truth • Values carry citations • Human review stays in the loop • Failure is visible.

Each M11 Field Gets an Explicit State

Found
The protocol's own words, with exact source page — never AI-composed or paraphrased.

Not available
Whole document searched; content judged absent. If an independent check finds related text elsewhere, disclose that and do not confirm absence.

Not applicable
Conditional M11 item; stated condition is not met

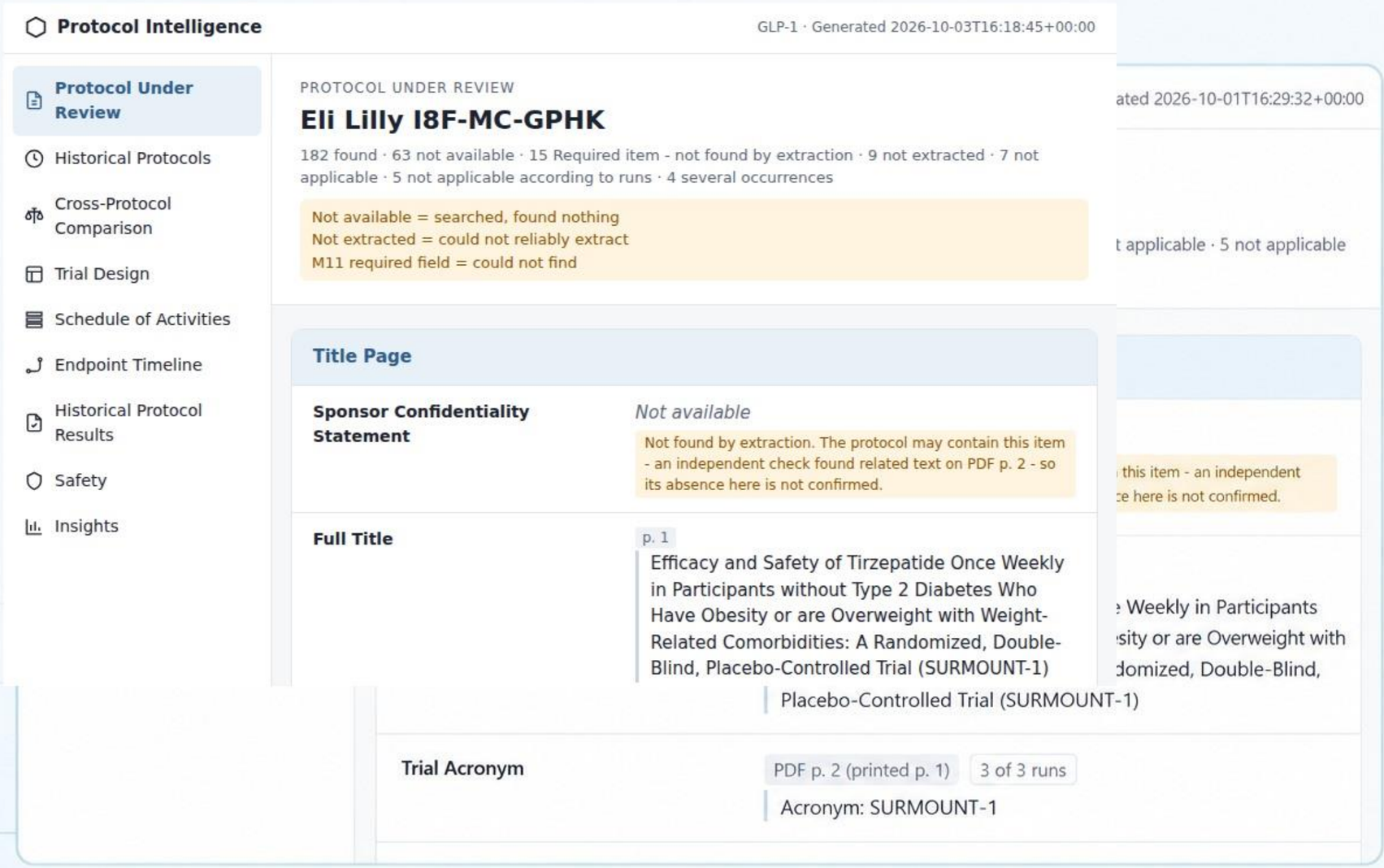
Not extracted
Content may be present but could not be reliably captured

Required item — not found by extraction
Shown as a gap to close, not confirmed absence

Not available ≠ Not extracted: an extraction miss is never proof of absence.

No vague blanks. No silent assumption that missing extraction means missing content.

Protocol Under Review: M11 Fields, Verbatim Text, and Source Traceability



M11 order

Named specification fields, not legacy section order

Source passage

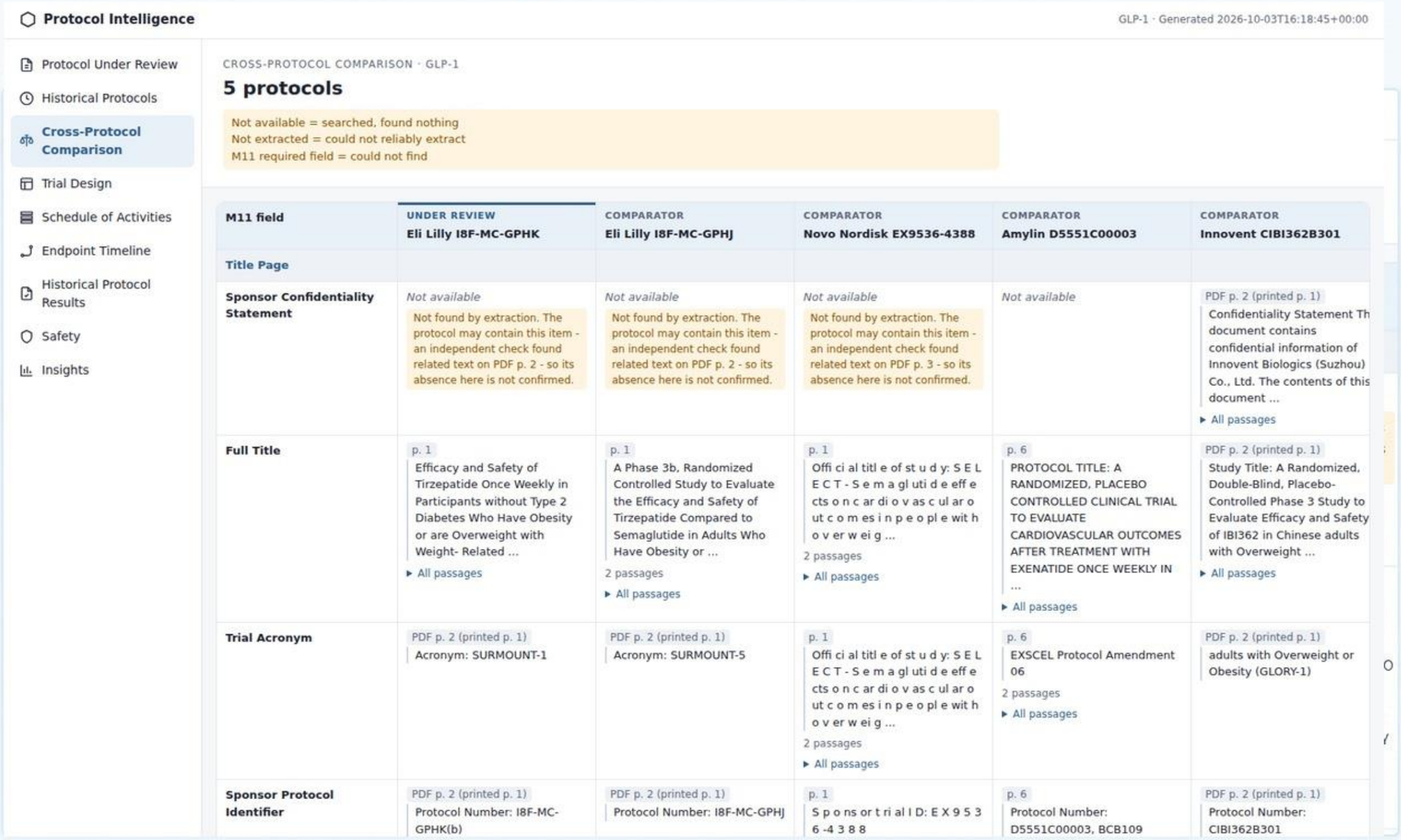
Verbatim text with exact PDF page

Run agreement

Independent reading status stays visible

GLP-1 example · protocol under review · a field not found by extraction is not automatically absent.

Cross-Protocol Comparison: M11 Fields as Rows, Protocols as Columns



Scope

GLP-1 therapeutic area · five protocols

Comparable view

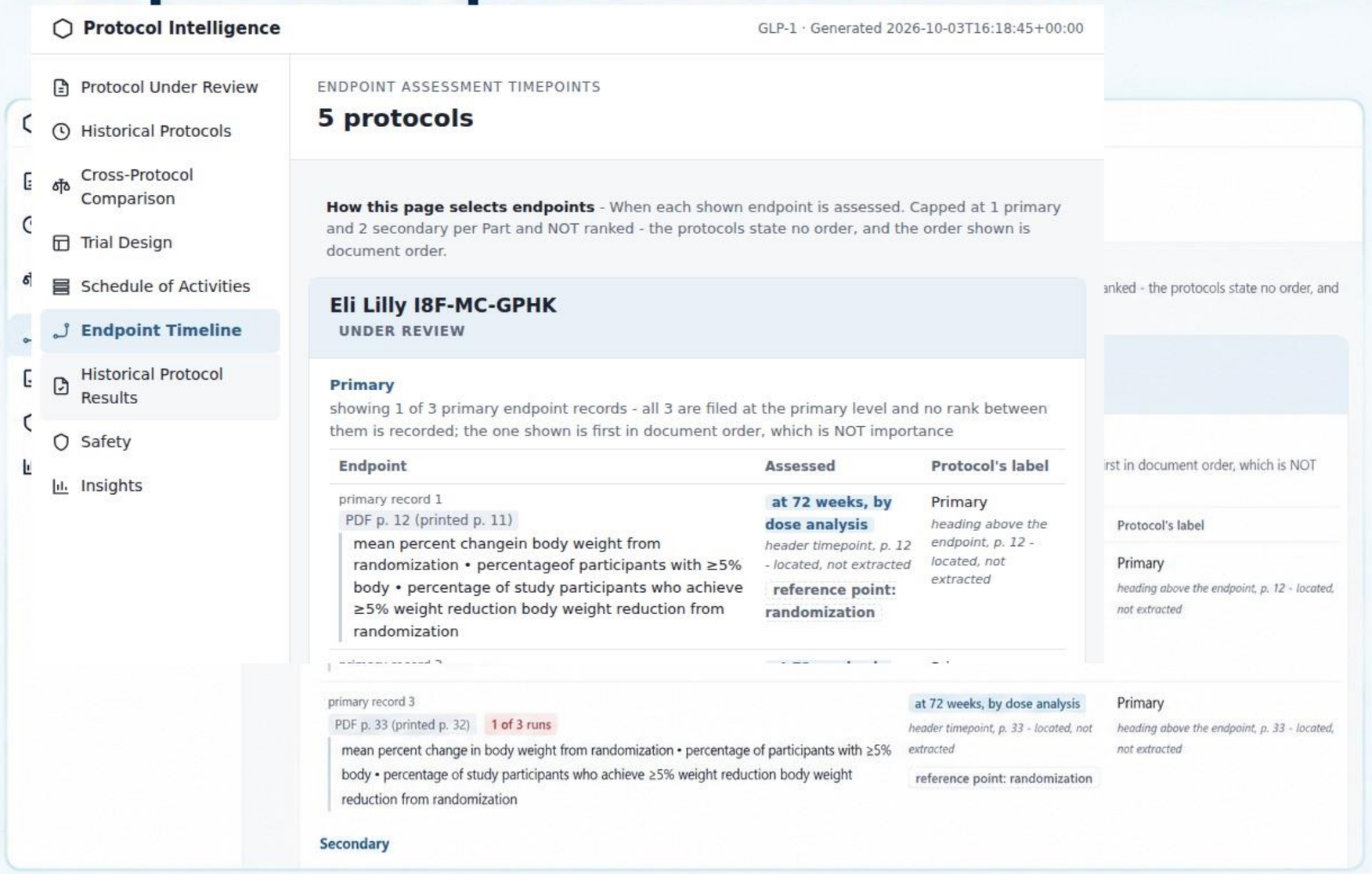
Protocol under review plus historical comparators

Interpret carefully

A warning such as 'not found by extraction' does not confirm the protocol lacks the item; run agreement and citations remain visible.

Side-by-side comparison is scoped to protocols within the same therapeutic area.

Endpoint Timepoints: Preserve Where the Evidence Appears



GLP-1 dashboard · endpoint assessment timepoints

Context matters

A timepoint found in a table header is marked ‘located, not extracted’

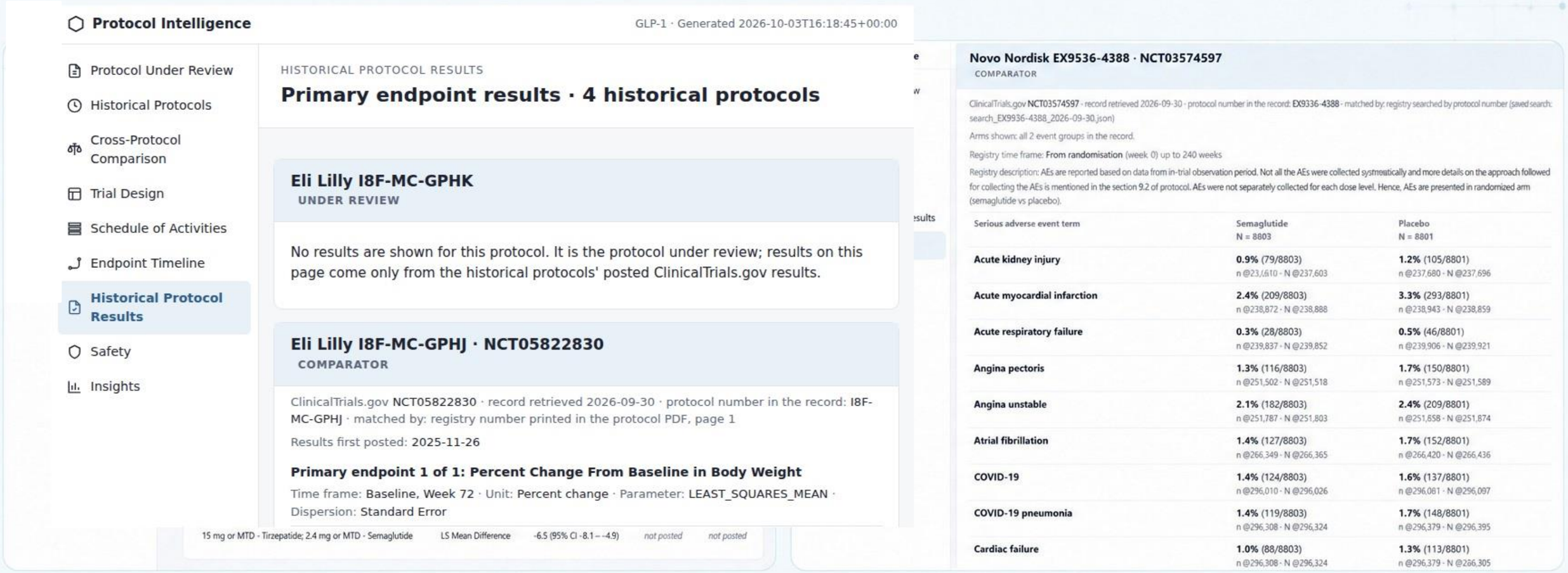
No false ranking

Endpoints stay in document order when the protocol states no rank.

Source precision

The displayed assessment timing and reference point retain their cited page context.

Historical Outcomes and Safety: Registry Data with Traceable Provenance



OUTCOMES

Posted ClinicalTrials.gov outcomes for historical comparators; the protocol under review intentionally has no results on this page.

SAFETY

Serious adverse events and adverse events at the protocol's reporting threshold; arm counts and citations remain visible.

Values are sourced to saved registry records and independently verified at the value level.

What Makes the Comparison Trustworthy



Anchor to M11

Use the Step 4 Technical Specification and Template



Extract, don’t transform

Map each field to exact protocol words and page



Verify before display

Independent source checks and page-level release gate



Compare responsibly

Side-by-side protocols within therapeutic area; AI observations clearly segregated

The source document remains unchanged. Every displayed value can be traced to its source.

Where This Goes Next



One protocol, reused everywhere.

Authoring, review, exchange, submission — read once.



No more starting over.

A shared library makes decades of protocols comparable.



Scaling this takes an institution.

The models can learn new therapeutic areas — that takes training resources beyond what one consultant has.



Get a real accuracy number.

Sampled across protocols and field types, checked by more than one expert — enough for a real confidence interval.

Not a better document. A protocol every system downstream can actually read.

Thank You!

