


AI Strea

AI-Driven Metadata Integration

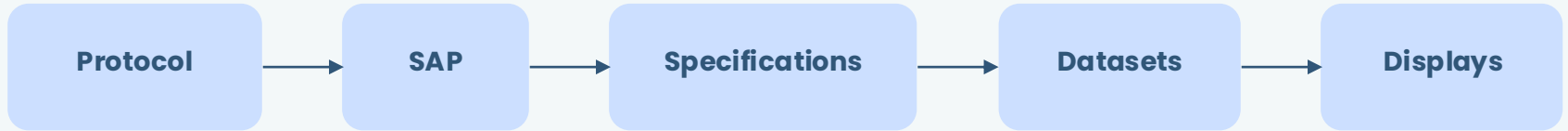
Transforming TLF Development Through
Unified Metadata Management

A vertical line with a teal dot at the top and bottom, positioned to the left of the speaker names.

Ilan Carmeli, Beaconcure COO and Co-Founder
Achinoam Ravet Perel, Head of customer success

The Challenge: Traditional Approach

Fragmented process:



- Each artifact **built manually** or semi-manually in isolation
- **Constant revisions** lead to inconsistencies and discontinuities
- Information **siloed** across documents—difficult to trace connections
- **Inefficient reuse** and validation of study artifacts

The Business Impact of Fragmentation



Inefficiency

Sequential, manual processes waste time and resources



Inconsistency

Data conflicts arise from isolated artifact development



Discontinuity

Revisions break traceability between artifacts



Scalability

Growing study complexity strains existing workflows



Regulatory Risk

Audit trails fragmented across multiple systems

Why Now?

Why This Approach?

- 1. GenAI Maturity:** enable reliable metadata extraction (not available 1-2 years ago)
- 2. Regulatory Acceptance**
- 3. Study Complexity Explosion:** Protocols are getting larger; manual workflows breaking
- 4. Industry Timing:** Major pharma piloting AI solutions internally (competitors moving now)



The Paradigm Shift

Today

Document-Centric Model

- × Separate artifacts
- × Manual linkage
- × Limited traceability
- × Revision bottlenecks
- × Data silos
- × Auditor friction



AI-Enabled

Metadata-Driven Model

- ✓ Unified repository
- ✓ Automated integration
- ✓ Full traceability
- ✓ Real-time updates
- ✓ Seamless reuse
- ✓ Audit-ready



How AI Transforms the Workflow



Extract

GenAI processes
Protocol, SAP, Specs,
Datasets, Displays



Integrate

Link metadata facets
into unified
repository



Validate

Ensure consistency
automatically



Trace

Maintain
bidirectional links
to original artifacts



Enable

Support agile updates
with instant
propagation

Demo Video

Behind the scene

```
SELECT  
CASE  
WHEN GROUP1  
THEN 'With  
WHEN GROUP1  
THEN AESOC  
ELSE '  
*/  
END AS "Number  
Number (%) of S  
Preferred Term"  
COUNT(DISTING  
END) AS  
(DISTING  
END) AS  
COUNT(DISTING  
USUBJID END) AS  
FROM ADAE  
WHERE  
TRTEMFL = 'Y' AND AESER = 'N'  
GROUP BY  
ROLLUP (  
AESOC,  
AEDECOD  
)  
ORDER BY  
AESOC ASC NULLS FIRST,  
AEDECOD ASC NULLS FIRST;
```

Verify Assistant

What could cause the miscount of abdominal pain AE in Placebo for safety population? SP

10/24/2025 10:02

Verify Assistant ▶ Share

According to the metadata of the base table, the SAE flag (AESER) was not used. Therefore, the base table value includes all TEAE (2), not only Non-Serious TEAE (1).

Type your message here ↑



Generative Metadata Review in Verify

verify Projects Help and Support

File name.rtf 100%

Comparison Base Table GenAI Table

Table 14.1.1.6
Basic Results Disclosure for Treatment-Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set

Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
Number (%) of Subjects: by SYSTEM ORGAN CLASS and Preferred Term			
With Any Adverse Event	42 (43.8)	48 (42.1) 41 (43.1)	39 (37.2) 51 (54.2)
Blood And Lymphatic System Disorders	2 (2.1)	0	0
Eosinophilia	2 (2.1)	0	0
Gastrointestinal Disorders	4 (4.2)	12 (12.4)	22 (23.4)
Abdominal pain	1 (1.0)	1 (1.1)	3 (3.2)
Abdominal pain upper	0	0	4 (4.3)
Diarrhoea	0	2 (2.1)	1 (1.1)
Lip swelling	2 (2.1)	0 1 (1.1)	0 1 (1.1)
Nausea	1 (1.0)	7 (7.4)	17 (18.1)

Ask to edit the table or inquire about its metadata

Metadata Report

Source Data

Variables

Assumptions

- Population Definition:** Full Analysis Set defined as FASFL="Y" (all randomized subjects who received at least one dose of study medication). Table title and footnote explicitly state FAS definition.
- NRI Implementation:** ANLD1FL="Y" flag implements Non-Responder Imputation logic, identifying subjects with baseline assessment available for Week 12 analysis. Subjects without baseline are excluded from the denominator. Footnote states subjects who withdrew are counted as non-responders.
- Response Criterion:** CRIT1FL="Y" indicates subjects achieving IGA response (Clear or Almost Clear with ≥ 2 points improvement from baseline). Missing or "N" values treated as non-responders per NRI principle.
- Treatment Variable:** TRT01A (Actual Treatment) used for treatment grouping according to SAP definitions.

Statistics Specification

Reject Accept

Validation & Regulatory Compliance

AI Extraction Layer

- **Automated Validation Engine**
(99%+ accuracy gates)
- **Manual Review Gates**
(Critical metadata only)
- **Audit Trail Generation**
(FDA-compliant logging)



Compliance Assurance

- ✓ 21 CFR Part 11 Ready
- ✓ Traceability to Source
- ✓ AI Validation Records
- ✓ Change Management
- ✓ Regulatory Submission Ready

Fast-Track Implementation: From Days to Value



Week 1

Setup & Pilot

Days 1-3: Environment setup

Day 4-5: First study loaded

Day 6-7: Live testing



Week 2-3

Feedback Loop

Day 8-10: User feedback

Day 11-14: Refinements

Execution: iterate continuously



Week 4+

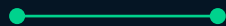
Scale & Optimize

Day 15+: Production rollout
Continuous improvement

New studies: 30-40% faster

Q&A

Thank You



Contact:

Ilan Carmeli
COO and Co-Founder

ilan@beaconcure.com