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Silos Belong on Farms, Not Desktops

Smarter Collaboration for Better Workflows

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Counting Up Our Communication Strategies

How many ways do you communicate with your team about study-related issues?

In-person meetings

Voice calls

Email

DM (Teams, Slack, et al.)

QC Trackers

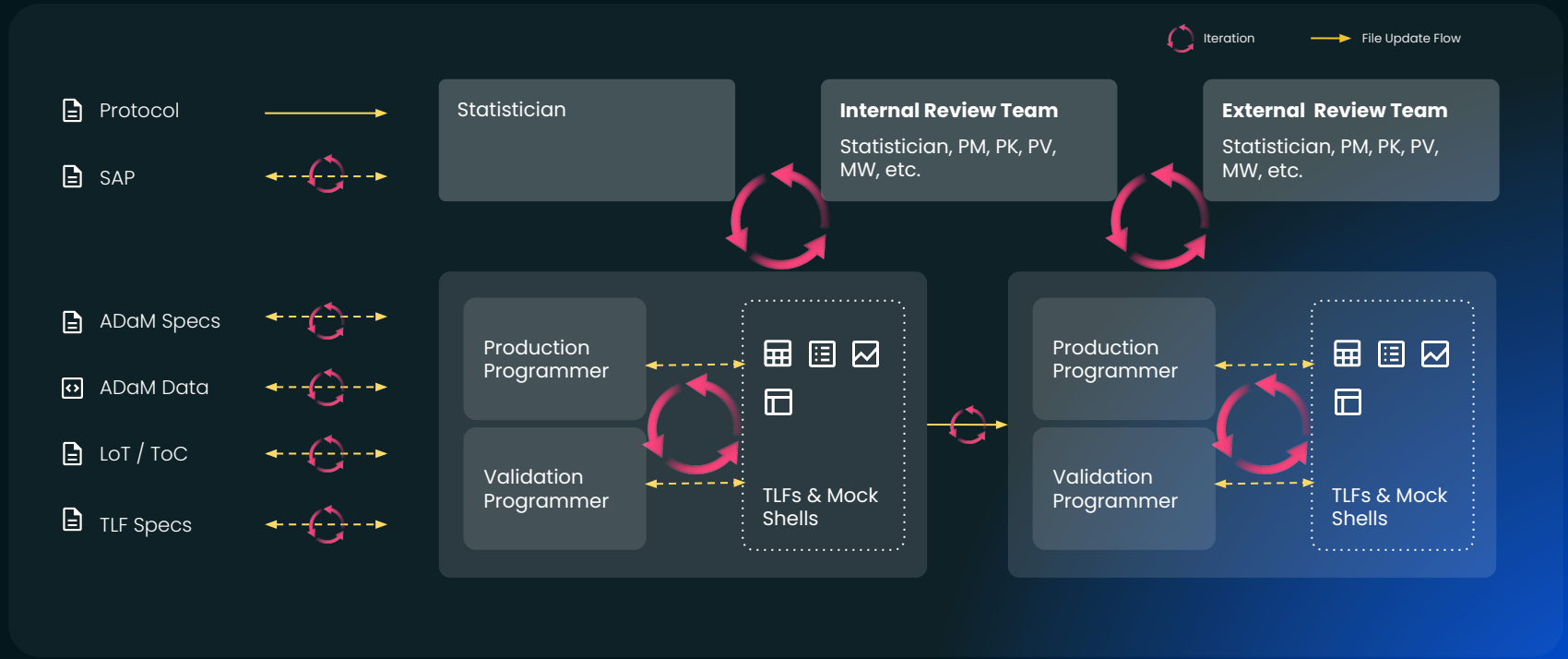
Marked-up PDFs

Evaluating Our Communication Strategies

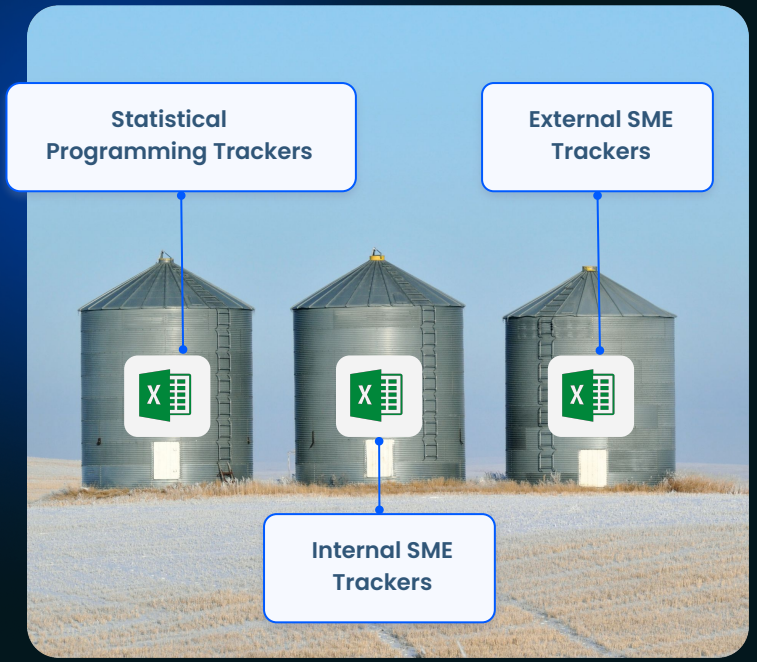
How many of us have…

- Had to dig through multiple communication platforms to reconstruct an algorithm discussion?
- Been left off of an important email discussion?
- Curated multiple sets of TLF ‘tracker’ comments on a table set?

Communication in TLF Development and Review



The Challenge of Clinical TLF Review



- Multiple stakeholders performing sequential, repetitive, iterative reviews of TLFs and study documents
- Fragmented communication channels
- Siloed (by design!) conversations
- Information loss leading to repeated questions, redundant conversations, inconsistent or incomplete decision-making

Resultant Pain Points

Broken/redundant communications

Extended review cycles

Delayed issue resolution

Lost institutional knowledge

Inconsistent implementations

QUALITY SUFFERS!

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Organizing Principle –
Unify Communication/Collaboration Stream

- **Bring together outputs and core documents** to the same unified workspace. Reduce delays associated with multiple communication streams.

- **Single point of communication** - allow users to comment, discuss, verify, cross-check, directly on outputs, down to the cell level, on every table

- Capture decision-making in **traceable and transparent audit trail** for documentation and institutional memory

A Better Approach: A Unified Collaboration Space

- **Centralized discussions**
  Discussions take place in one platform with shared visibility
- **Easy to use**
  Everything a reviewer needs in one place
- **Direct annotations**
  Comment directly on the displays, ToCs, and mock shells, not in QC trackers
- **Real-time updates**
  Instant confirmation that your comments are sent, addressed, resolved, and documented

Consolidate Review Into a Single Secure Platform

- Programmer QC spreadsheet
- Internal reviewer spreadsheet
- External reviewer spreadsheet
- Multiple emails with varied distribution lists
- Reviewer comments in marked-up PDF

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Benefits of Unified Collaboration

Streamlined Communication Channel

- Review comments appear directly on digitized TLFs
- Reduced time spent searching for information
- Compress issue adjudication timelines
- Trace CRO-Sponsor handoffs and requests in one place

Improved Efficiency, Higher Quality

- One communication method, not 6
- Automate task assignment
- Track status at individual and study level to react quickly and time-sensitively
- Address gaps and open issues

Real-Time Oversight of Deliverables

- Monitor deliverable status at both programmer and deliverable levels
- Preserve institutional memory
- Enable fast, informed decision-making
- Capture KPIs and performance metrics

Automated Activity Log generates immutable records of all actions and decisions

Automate More Manual Checks So You Can Focus on Analysis

Early-Stage High Quality Outputs

- Address errors upstream
- Cut rework and delays with early remediation
- Traceability throughout the drug development life cycle. Compare TLF iterations and track versions

Validation core builds trust and balances man-machine workload

- Formats, titles, & footnotes
- Consistency with reference mock shells & LoT
- Arithmetic & hierarchies
- Cross-table consistency
- Cross-deliverable comparisons

Clear Visibility Throughout Review

- Clear communications about your data journey from raw through CSR
- Capture metrics to analyze issue trends and root causes
- Optimize processes and allocate resources based on real-time analytics

Automated Activity Log generates immutable records of all actions and decisions

AI-enabled Conversion of Static Files into a Robust Structured Database

- → TLF metadata is extracted and clustered to facilitate standardized validation checks and automated analysis
- → Standardized, digitized table sets and data files allow users to search, compare, and extract data for additional processing, all from a secure, cloud based environment
- → AI model improves over time as more data are incorporated, and is easily adapted to new data, such as new formats and new logical groupings

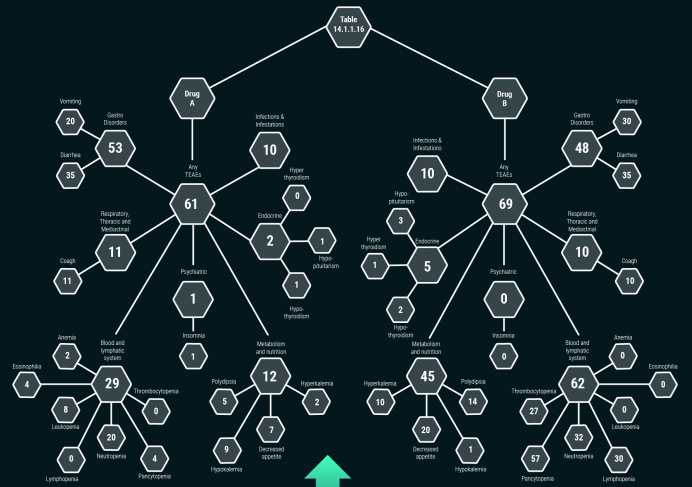

Table 14.1.1.16

TEAE Occurring in >5% of Subjects in at least One Treatment Group in Study by System Organ Class and Preferred Term (Safety Population)

	Drug A (N=119)	Drug B (N=117)
Any TEAEs	61 (51.3%)	69 (59.0%)
Gastro Disorders	53(32.8%)	48 (41.0%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	20 (16.8%)	30 (25.6%)
Infections & Infestations	10 (8.4%)	10 (8.5%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (8.5%)
Cough	11 (9.2%)	10 (8.5%)
Blood and lymphatic system disorders	29 (24.4%)	62 (53%)
Anaemia	2 (1.7%)	0
Eosinophilia	4 (3.4%)	0
Leukopenia	8 (6.8%)	0
Lymphopenia	0	30 (25.6%)
Neutropenia	20 (16.8%)	32 (27.4%)
Pancytopenia	4 (3.4%)	57 (48.7%)
Thrombocytopenia	0	27 (23.1%)
Endocrine disorders	2(1.7%)	5 (4.3%)
Hyperthyroidism	0	1 (0.8%)
Hypopituitarism	1 (0.8%)	3 (2.6%)
Hypothyroidism	1 (0.8%)	2 (1.7%)
Metabolism and nutrition disorders	12 (10.1%)	45 (38.5%)
Hyperkalaemia	2 (1.7%)	10 (8.5%)
Polydipsia	5 (4.2%)	14 (12.0%)
Decreased appetite	7 (5.9%)	20 (17.1%)
Hypokalaemia	9 (7.6%)	1 (0.8%)
Psychiatric disorders	1 (0.8%)	0
Insomnia	1 (0.8%)	0

Digitized files allow AI-enabled comparisons across every output

Summary Table

Table 14.1.1.19
Summary of Treatment Emergent Adverse Events & Serious Adverse Events
(Safety Population)

	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any TEAEs	67 (51.3%)	69 (59.0%)	130 (55.1%)
TEAE Causing Death	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe TEAEs	5 (4.2%)	1 (0.9%)	6 (2.5%)
Treatment-Related TEAE	6 (5.0%)	19 (16.2%)	25 (10.6%)
Discontinued due to TEAEs	5 (4.2%)	6 (5.1%)	11 (4.7%)
Serious Adverse Events	3 (2.5%)	1 (0.9%)	4 (1.7%)
Treatment-Related Serious Adverse Events	1 (0.8%)	0 (0.0%)	1 (0.4%)

N = number of subjects in the specified group, or the total sample.
This value is the denominator for the percentage calculations.

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advs Table Generation: 09OCT2021

Overall AE Table

Table 14.1.1.11
Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

	Drug A (N=119)	Drug B (N=117)
Any Treatment-Emergent Adverse Events	61 (51.3%)	69 (59.0%)
Gastro Disorders	53(32.8%)	48 (41.0%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	20 (16.8%)	30 (25.6%)
Infections & Infestations	10 (8.4%)	10 (8.5%)
Influenza	10 (8.4%)	10 (8.5%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (8.5%)
Cough	11 (9.2%)	10 (8.5%)
Blood and lymphatic system disorders	29 (24.4%)	62 (53%)
Anemia	2 (1.7%)	0
Eosinophilia	4 (3.4%)	0
Leukopenia	8 (6.8%)	0
Lymphopenia	0	30 (25.6%)
Neutropenia	20 (16.8%)	32 (27.4%)
Pancytopenia	4 (3.4%)	57 (48.7%)
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Metabolism and nutrition disorders	12 (10.1%)	45 (38.5%)
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Polydipsia	5 (4.2%)	14 (12.0%)
Decreased appetite	7 (5.9%)	20 (17.1%)
Hypokalemia	9 (7.6%)	1 (0.8%)
Psychiatric disorders	1 (0.8%)	0 (0.0%)
Insomnia	1 (0.8%)	0 (0.0%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
Subjects are only counted once per event in each row.
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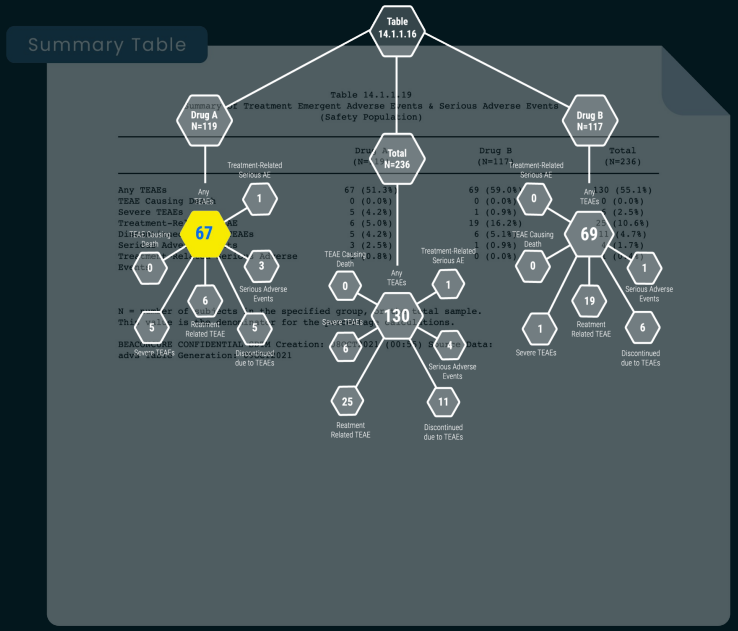
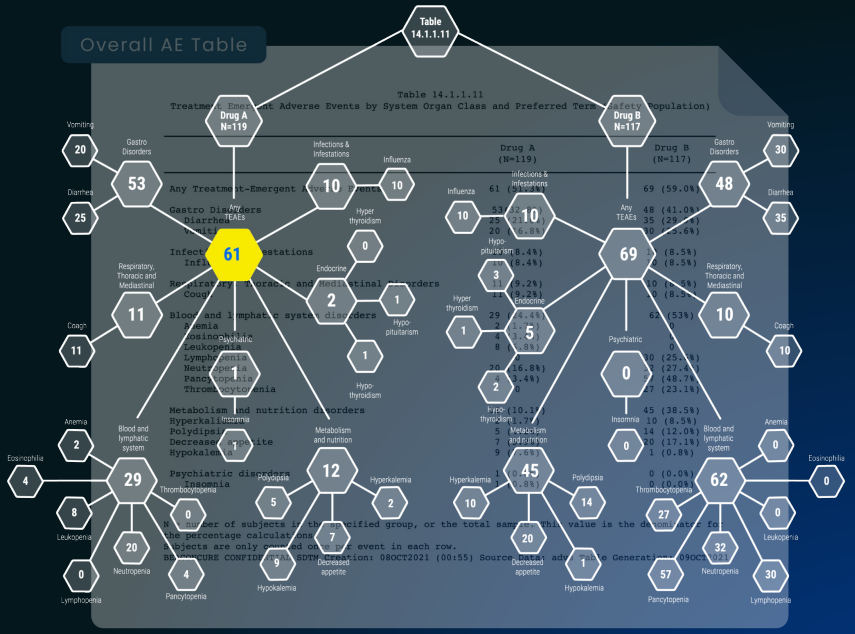
No customized code or study-specific configurations needed, saving time and improving process quality

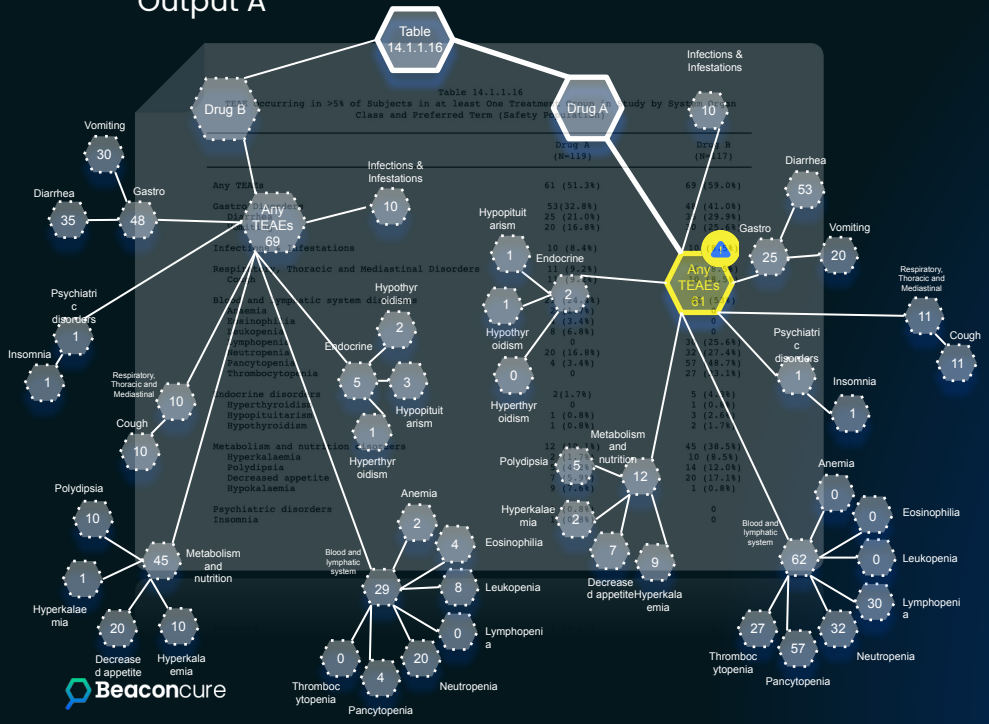




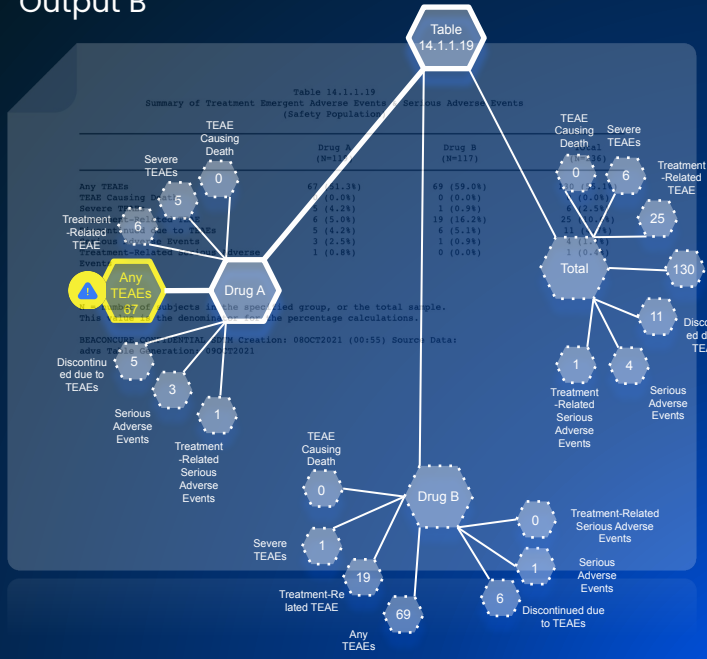
AI-Enabled TLF Validation

Cross-Table Validation of AE Sequence

Output A



Output B




AI


AI

Thank You

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