

From Specification to CSR – Toward a Unified Analysis and Review Platform

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March 18, 2025



QUESTION:

What makes generating TLFs in
clinical research so time consuming
and expensive?

Agenda

1. TLF Development Process Pain Points

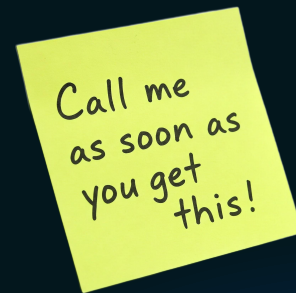
- a. Communication
- b. Collaboration
- c. Iteration
- d. PROC EYEBALL

2. Solutions From Specification to CSR

- a. Unified Communication and Collaboration
- b. Less iteration, less PROC EYEBALL
- c. More automation

De-Centralization in Communication

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



In-person meetings



Voice calls



Email



DM (Teams, Slack, et al.)



Multiple QC Trackers



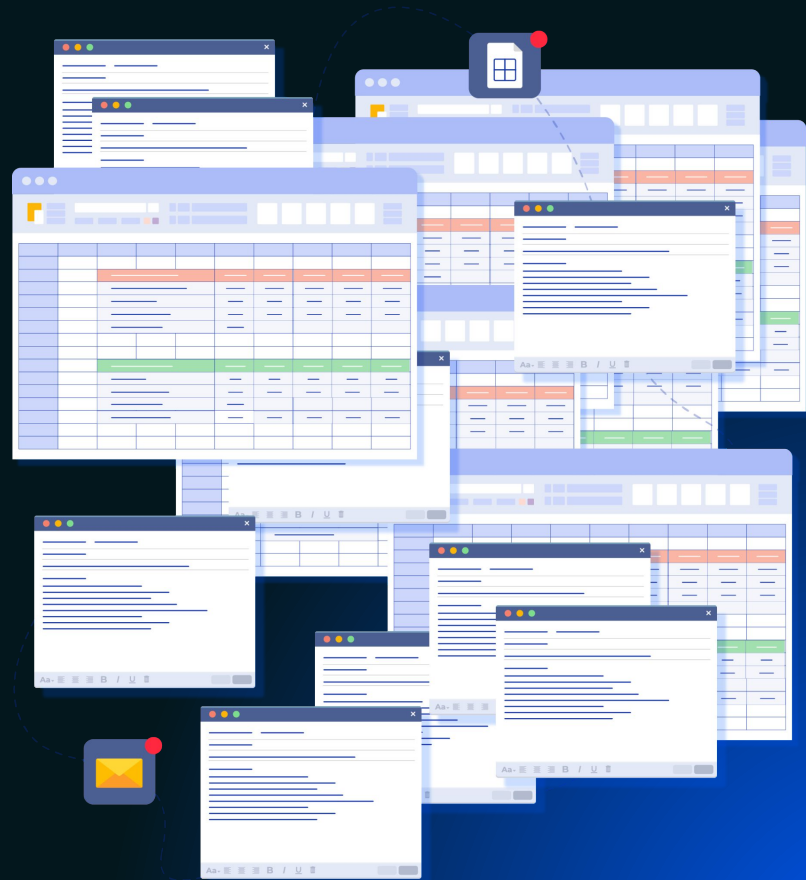
Marked-up PDFs

Communication Breakdown

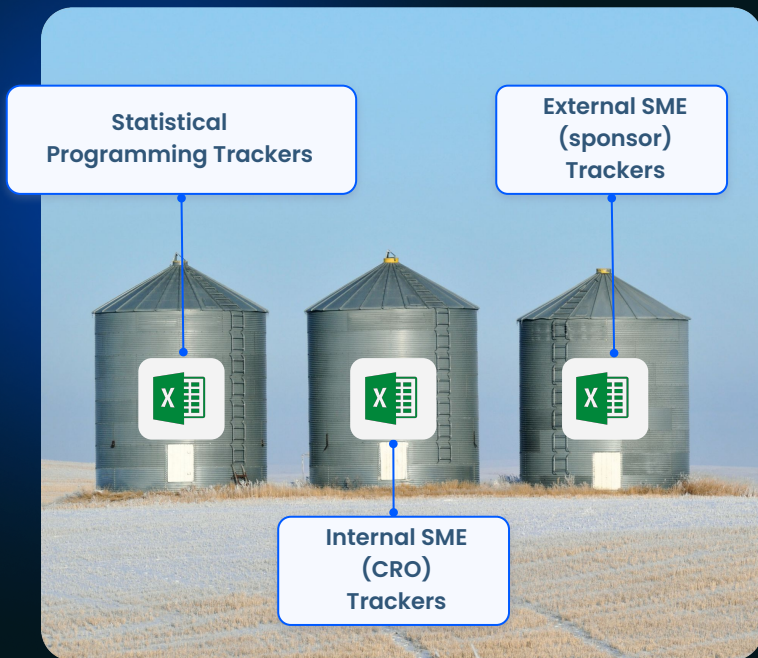
(with apologies to Led Zeppelin)

- Subject 20023 was randomized but never took drug
- Subject 10009 was screened and failed for study Study XYZ302, but later rescreened and given a new SubjectID.
- Six patients did not have visit data for the primary endpoint due to clinic being closed for COVID. This impacts the conclusions drawn from the tables.
- **Who needs to know and how do you ensure that the right people are aware of these important data points?**

Email, Phone calls, DM, QC Tracker?

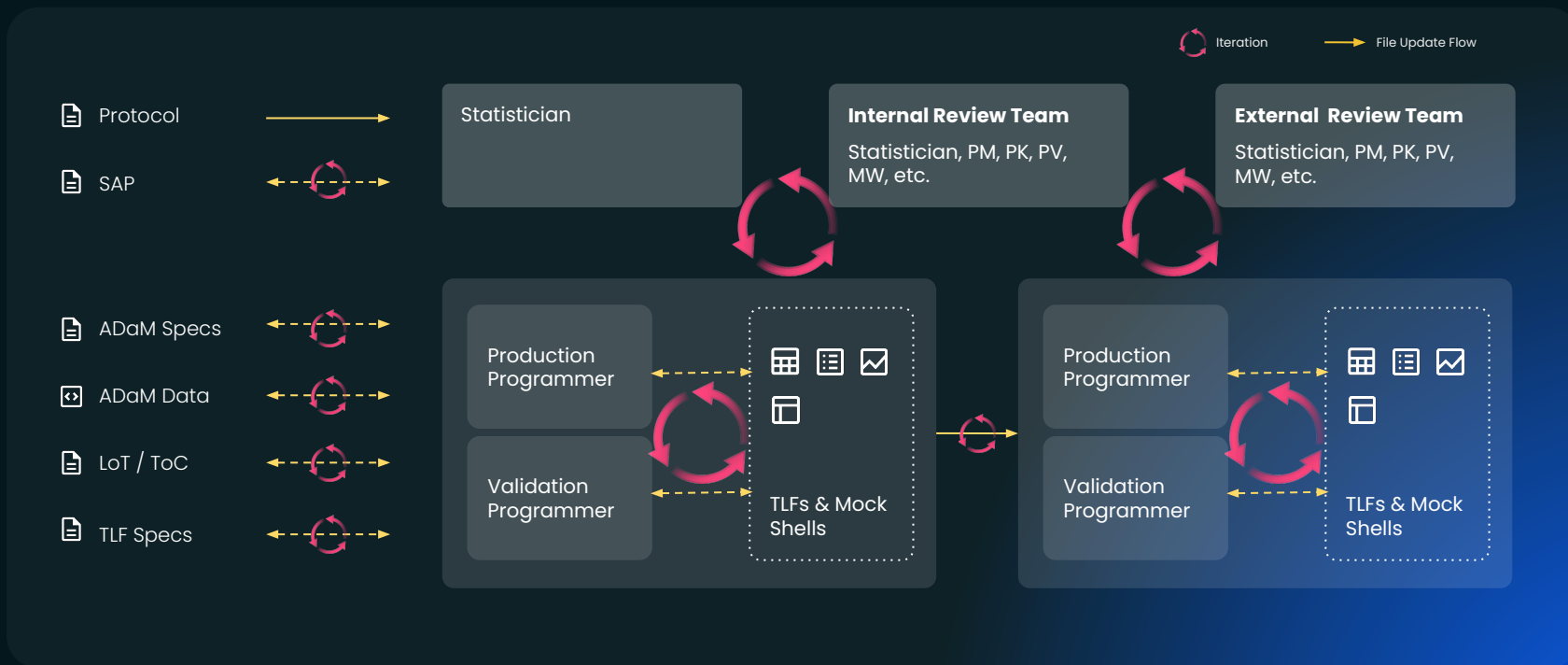


Collaboration Silos (by design!)



- Sequential, duplicative, iterative reviews of study documents and TLFs
- Fragmented communication streams
- Information loss leading to repeated questions, redundant conversations, and decision-making based on incomplete information

Endless Iteration



Proc Eyeball



Resultant Pain Points

Maintenance of multiple communication pathways

Disjointed conversations

Lost institutional knowledge leads to poor decision-making



Manual review is expensive and time-consuming

High volume, high pressure environment leads to mistakes, oversights

QUALITY SUFFERS!



Guiding Principles –

Communication, Collaboration, Automate



Single point of communication

allow users to comment, discuss, verify, cross-check, directly on outputs, down to the cell level, on every table



Bring together outputs and core documents

to the same unified workspace. Reduce delays associated with multiple communication streams



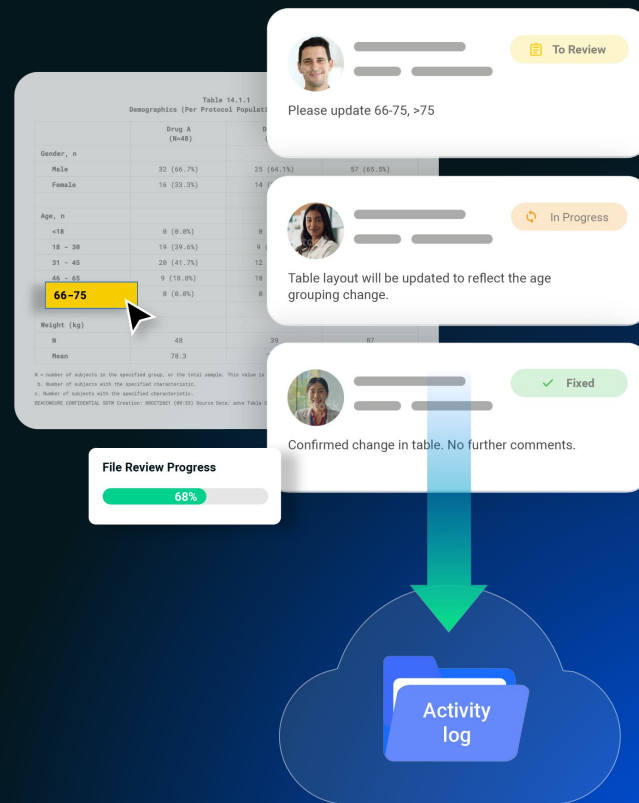
Automate!
Automate!
Automate!



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

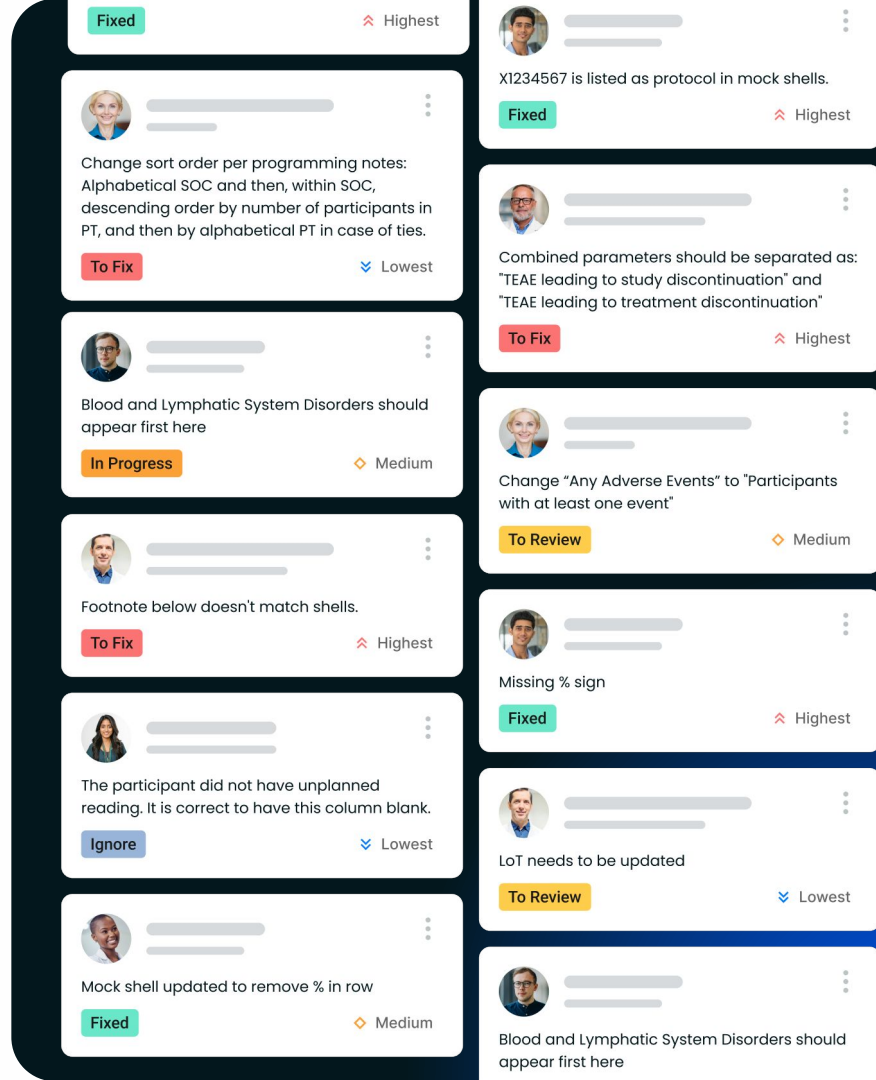
Solution

A Better Approach: A Unified TLF Development Space



Consolidate Review Into a Single Secure Platform

- Programmer QC spreadsheet
- Internal reviewer spreadsheet
- External reviewer spreadsheet
- Multiple emails with varied distribution lists
- Direct messaging (Teams, Slack, What'sApp)
- Reviewer comments in marked-up PDF



The collage displays 12 individual review cards, each with a reviewer's profile picture, name, and status. The cards are arranged in two columns. The left column contains 6 cards, and the right column contains 6 cards. Each card has a status label (Fixed, To Fix, In Progress, To Review, Ignore) and a priority indicator (Highest, Medium, Lowest). The review text varies, including comments on programming notes, blood and lymphatic system disorders, footnotes, participant reading, mock shells, and adverse events.

Reviewer	Status	Priority	Review Text
[Profile]	Fixed	Highest	X1234567 is listed as protocol in mock shells.
[Profile]	To Fix	Lowest	Change sort order per programming notes: Alphabetical SOC and then, within SOC, descending order by number of participants in PT, and then by alphabetical PT in case of ties.
[Profile]	In Progress	Medium	Blood and Lymphatic System Disorders should appear first here
[Profile]	To Fix	Highest	Footnote below doesn't match shells.
[Profile]	Ignore	Lowest	The participant did not have unplanned reading. It is correct to have this column blank.
[Profile]	Fixed	Medium	Mock shell updated to remove % in row
[Profile]	To Fix	Highest	Combined parameters should be separated as: "TEAE leading to study discontinuation" and "TEAE leading to treatment discontinuation"
[Profile]	To Review	Medium	Change "Any Adverse Events" to "Participants with at least one event"
[Profile]	Fixed	Highest	Missing % sign
[Profile]	To Review	Lowest	LoT needs to be updated
[Profile]	To Review	Lowest	LoT needs to be updated
[Profile]	Fixed	Medium	Blood and Lymphatic System Disorders should appear first here

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

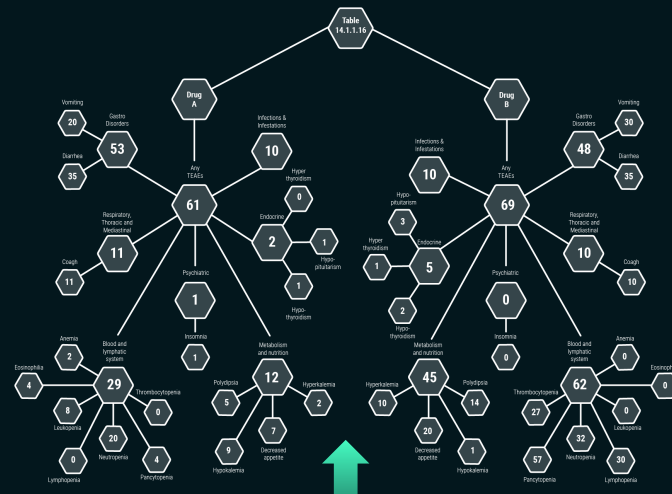


Table 14.1.1.16
TEAE Occurring in >5% of Subjects in at least One Treatment Group in Study by System Organ Class and Preferred Term (Safety Population)

	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	28 (16.4%)	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%)
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%)
Thrombocytopenia	0	27 (23.1%)
Endocrine disorders	2 (1.7%)	5 (4.3%)
Hypert thyroidism	0	1 (0.8%)
Hypoparathyroidism	1 (0.8%)	3 (2.6%)
Hypothyroidism	1 (0.8%)	2 (1.7%)
Metabolism and nutrition disorders	12 (10.1%)	45 (38.5%)
Hyperkalemia	2 (1.7%)	10 (8.5%)
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
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 14.1.1.20
Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

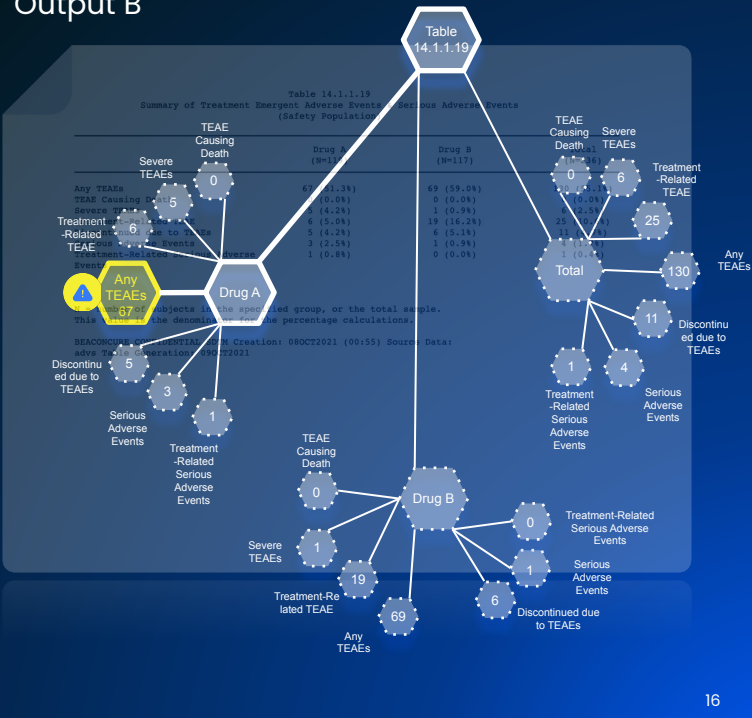
	Drug A (N=119)	Drug B (N=117)
Any Treatment-Emergent Adverse Events	61 (51.3%)	69 (59.0%)
Gastrointestinal Disorders	53 (32.8%)	48 (41.0%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	20 (16.8%)	30 (25.6%)
Infections & Infestations	10 (8.4%)	10 (8.5%)
Influenza	10 (8.4%)	10 (8.5%)
Respiratory, Thoracic and 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
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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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Cross-Table Validation of AE Sequence

Output B



Automate, Automate, Automate

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

Automated Validation Balances Human-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

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



Q & A

Thanks for participating!

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