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Boston Breakthroughs: A Dashboard-Driven Approach to Metadata and Audit Trails with SAS Clinical Acceleration

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ABSTRACT

Clinical trial organizations face increasing demands for transparency, traceability, and regulatory compliance. This presentation introduces the concept of growing regulatory expectations in clinical trials, followed by an overview of the importance of metadata and audit trails in ensuring data integrity and submission readiness. An interactive dashboard built using SAS Visual Analytics on SAS Viya will be demonstrated, leveraging metadata and audit trail data from a clinical trial stored in SAS Clinical Acceleration Repository on SAS Viya. The dashboard visualizes metadata changes and audit trail logs, illustrating why understanding and interpreting these elements is critical for compliance and efficient workflows. The work highlights how dashboard driven insights enable clinical programmers, data managers, and regulatory professionals to conduct faster data reviews, improve traceability, and support regulatory submissions through enhanced transparency.

INTRODUCTION

Clinical trial organizations are operating in an environment of increasing regulatory scrutiny, tighter timelines, and heightened expectations for transparency and traceability. Regulatory authorities such as the U.S. Food and Drug Administration (FDA) require organizations to demonstrate how clinical data is created, modified, reviewed, and approved throughout the lifecycle of a study. As a result, organizations must move beyond reactive audit trail reviews and adopt more proactive and transparent approaches to oversight.

Good Clinical Practice (GCP) standards, which are internationally recognized, require the establishment and maintenance of secure audit trails and full data traceability. As clinical trials become more complex and distributed across teams and systems, the ability to monitor and interpret audit trail activity has become increasingly critical.

Audit trails form the foundation for data integrity in clinical trials. In this context, an audit trail is a secure, system-generated, time-stamped record that tracks all changes made to the data throughout its lifecycle. These records are unalterable chronological logs that capture events such as dataset creation, modification, timestamps, and user identification. Each audit record is accompanied by metadata, descriptive information that provides context about the data interaction, allowing every data point to maintain a traceable lineage.

Audit trails are essential to ensuring data integrity and demonstrating regulatory compliance. Traceability enables clinical trial processes and results to be reviewed, verified, and validated by stakeholders from initial data creation through final submission outputs. Additionally, audit trail data supports identification of unauthorized activity, verification that data has not been altered improperly, and timely detection and correction of errors.

Despite their significance, audit trail records can be difficult to analyze. They are typically embedded within statistical computing environments (SCEs), which are designed to generate audit trails but do not always support exploratory analysis or easy review across studies, users, or time periods. As a result, audit trail data can remain underutilized.

By transforming audit trail data into an interactive dashboard, organizations can gain faster and more meaningful insights, enable cross-functional review, and improve transparency – without requiring stakeholders to access the SCE directly. This paper presents a dashboard-driven approach to visualizing audit trail data and metadata to support proactive oversight and regulatory readiness.

SIGNIFICANCE

Audit trail data generated by an SCE can be leveraged outside of the SCE to provide more accessible and actionable insights. Rather than replacing the SCE, this approach complements it by enabling visualization and analysis tailored to regulatory oversight.

In this demonstration, SAS Clinical Acceleration is used as the statistical computing environment, and SAS Visual Analytics on SAS Viya is used to build the dashboard. Audit trail data was extracted from the SAS Clinical Acceleration Repository using the repository's REST APIs. A REST API lets one program ask another program for data or tells it to perform an action, using standard web requests. The extracted data was then imported into SAS Visual Analytics for report development. While this example uses SAS technologies, the concepts and best practices presented are applicable to other SCEs and visualization tools.

Visualizing audit trail data through an interactive dashboard transforms a complex data set into an accessible decision-support tool. Patterns and anomalies become easier to identify, review across studies and users become more efficient, trend analysis over time is enabled, and communication between programmers, data managers, and regulatory teams is improved.

When building an audit trail dashboard, incorporating both project level and person-level views is a best practice. This dual-level approach allows stakeholders to answer high-level oversight questions as well as detailed questions without navigating raw audit trail tables.

BEST PRACTICES FOR BUILDING AN AUDIT TRAIL DASHBOARD

An effective audit trail dashboard should be designed to meet the needs of multiple stakeholders, ranging from high-level oversight to detailed record-level review. Best practices include building distinct yet connected pages that allow stakeholders to explore audit trail data without being overwhelmed. In this demonstration, the dashboard is organized into four sections: an overview page, a project activity page, a user activity page, and a raw audit records page.

OVERVIEW PAGE: HIGH-LEVEL AUDIT TRAIL SUMMARY

The Overview Page serves as the entry point to the dashboard and provides stakeholders with a comprehensive overview of the audit data. This view enables stakeholders to understand the audit activity patterns without diving into individual studies or users.

Best practices for the overview page include presenting summary metrics such as KPIs, key variables featured, offering interactive filtering capabilities, and maintaining a consistent color and design scheme. Summary metrics include high-level key performance indicators (KPIs), such as total audit events, number of unique users, number of projects, and number of file types. These provide a snapshot of audit activity (Figure 1). Other visuals should prominently display key variables such as project names, names of users, and the date range. This helps stakeholders understand the scope and relevance of the data, as demonstrated in Figure 1. Figure 1 also incorporates interactive filtering capabilities for project, users, and time periods, which allow stakeholders to refine the analysis and focus on areas of interest. Finally, there should be a consistent color and design scheme throughout dashboard pages to facilitate readability. All figures support a consistent design scheme.

An overview page provides establishes context and guides stakeholders toward areas that may warrant deeper investigation (Figure 1).

Figure 1. Overview Page of Dashboard

PROJECT ACTIVITY PAGE: STUDY-LEVEL AUDIT ANALYSIS

The Project Activity Page is designed to provide study-level insight into audit activity across one or more studies. This view enables stakeholders to understand where changes are occurring, who is making those changes, and when key modifications take place over the course of a study.

Figures 2-4 showcase best practices for a project activity page, including project-specific summary metrics, project activity details, temporal analysis, and interactive filtering and drill-down capabilities. Project-specific summary metrics comprise KPIs such as number of users, files, and items modified, which provide a snapshot of activity for selected projects (Figure 2). Visualizations help elucidate project activity details, showing which users modified which projects, along with the types of files involved, which helps stakeholders understand the nature of study activity (Figure 3). Temporal analysis conveys creation and modification timelines that allow stakeholders to identify periods of heightened activity or unexpected modifications within a study (Figure 4). Interactive filtering and drill-down capabilities for the Project Activity Page include filtering by project and time, which enables focused analysis while preserving the ability to review activity across all projects, as demonstrated by Figures 2-4.

This page helps stakeholders understand which studies are experiencing high levels of change, detect unusual activity, and prioritize further review when necessary.

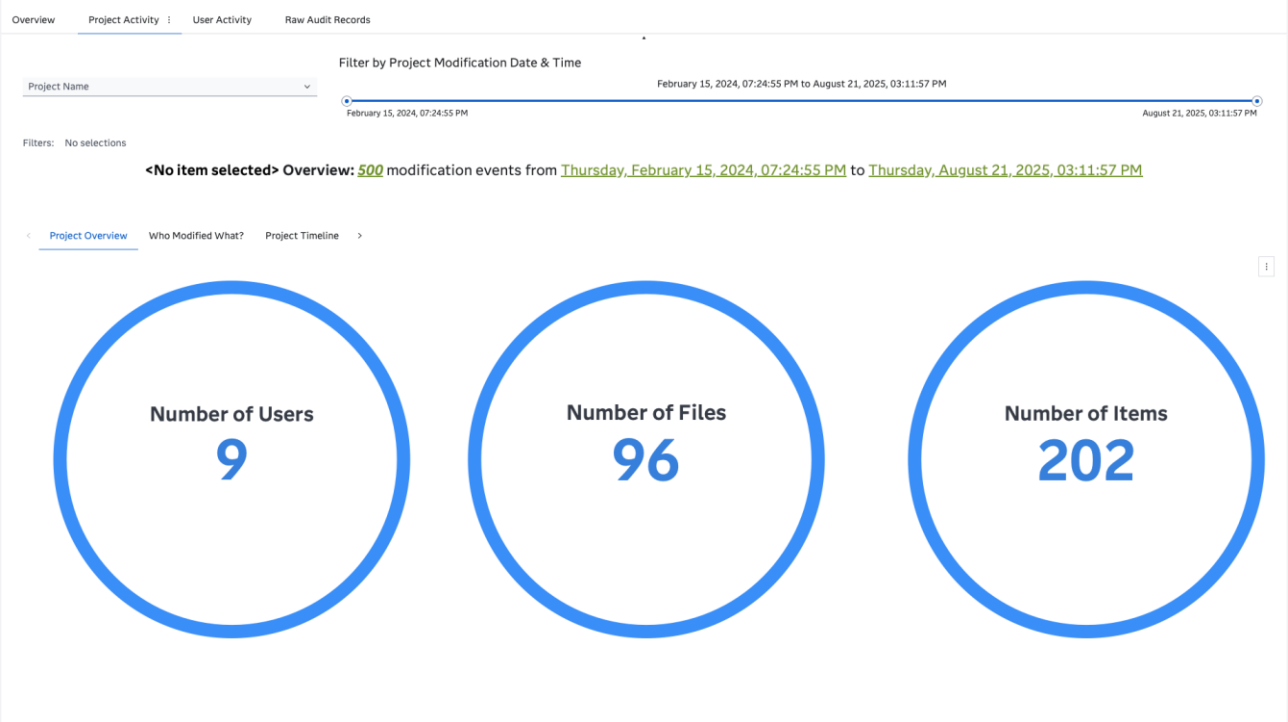

Figure 2. KPIs for Project Activity

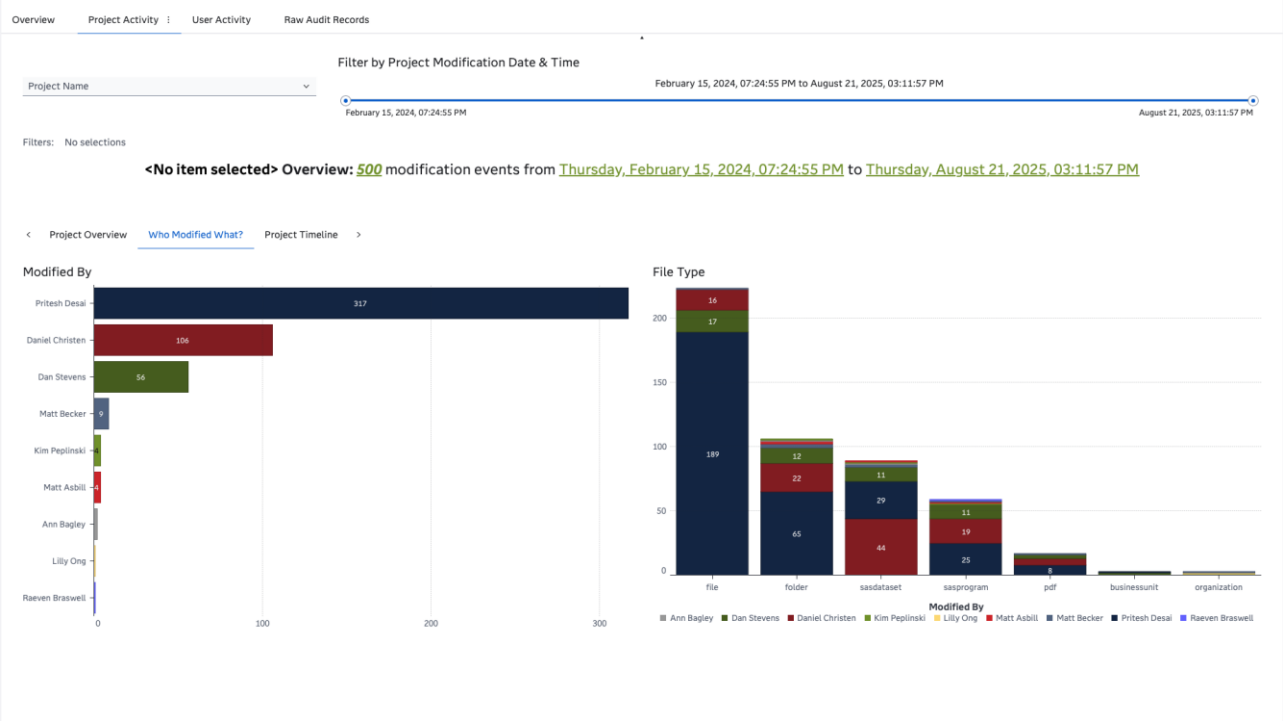

Figure 3. Who Modified What for Projects

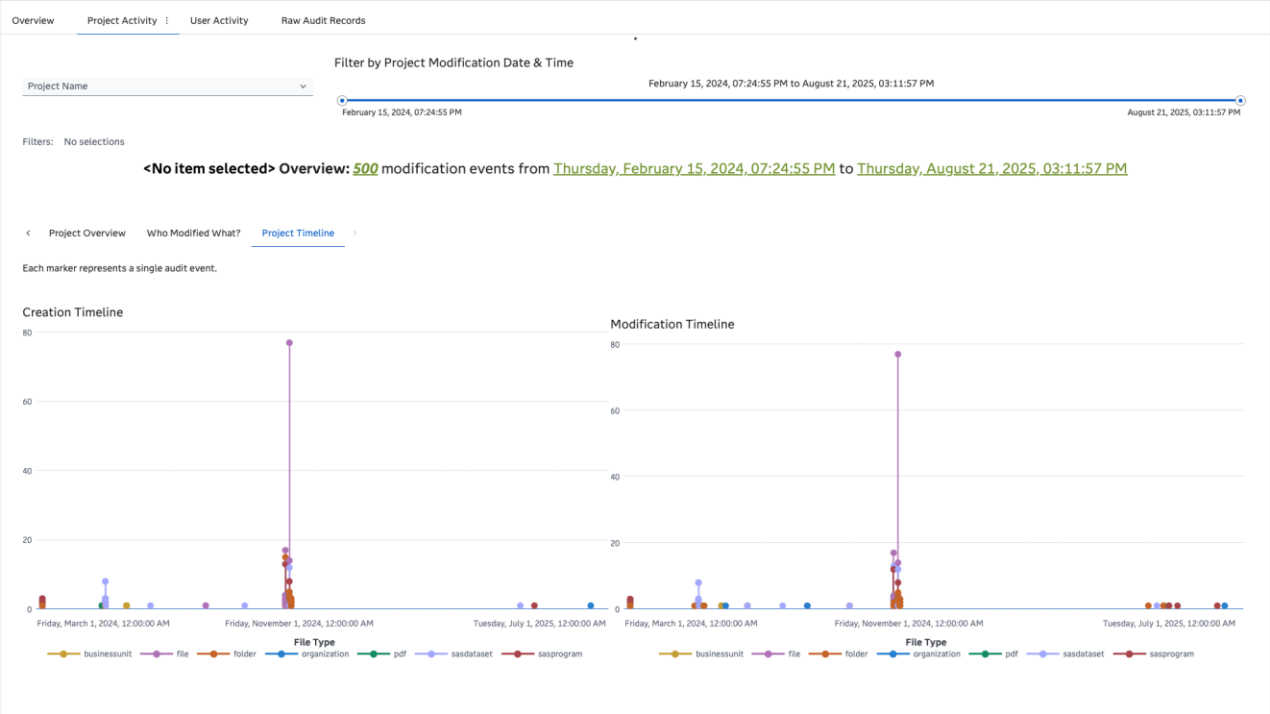

Figure 4. Project Timeline

USER ACTIVITY PAGE: PERSON-LEVEL AUDIT ANALYSIS

While the project-level section of the dashboard shows where changes are occurring, the User Activity Page focuses on who is making them. This page is valuable for reinforcing accountability and supporting role-based oversight.

Figures 5-7 demonstrate best practices for the User Activity Page, including user-level summary metrics, visualizations showing cross-project visibility, user-specific timelines, and interactive filtering and drill-down capabilities. User-level summary metrics include KPIs that indicate total modifications, number of items modified, number of projects modified, number of projects created, and number of items created (Figure 5). These KPIs provide a clear overview of individual user activity. Figure 6 contains visualizations showing cross-projects, revealing which projects a user has modified. This clarifies the scope of user involvement across studies. User-specific timelines such as creation and modification timelines help place user activity in a temporal context, as demonstrated in Figure 7. Lastly, interactive filtering and drill-down capabilities such as filtering by user and time period support a focused review and user-driven comparative analysis (Figures 5-7).

Overall, the User Activity Page reinforces accountability while avoiding the need to manually review audit logs for individual users.

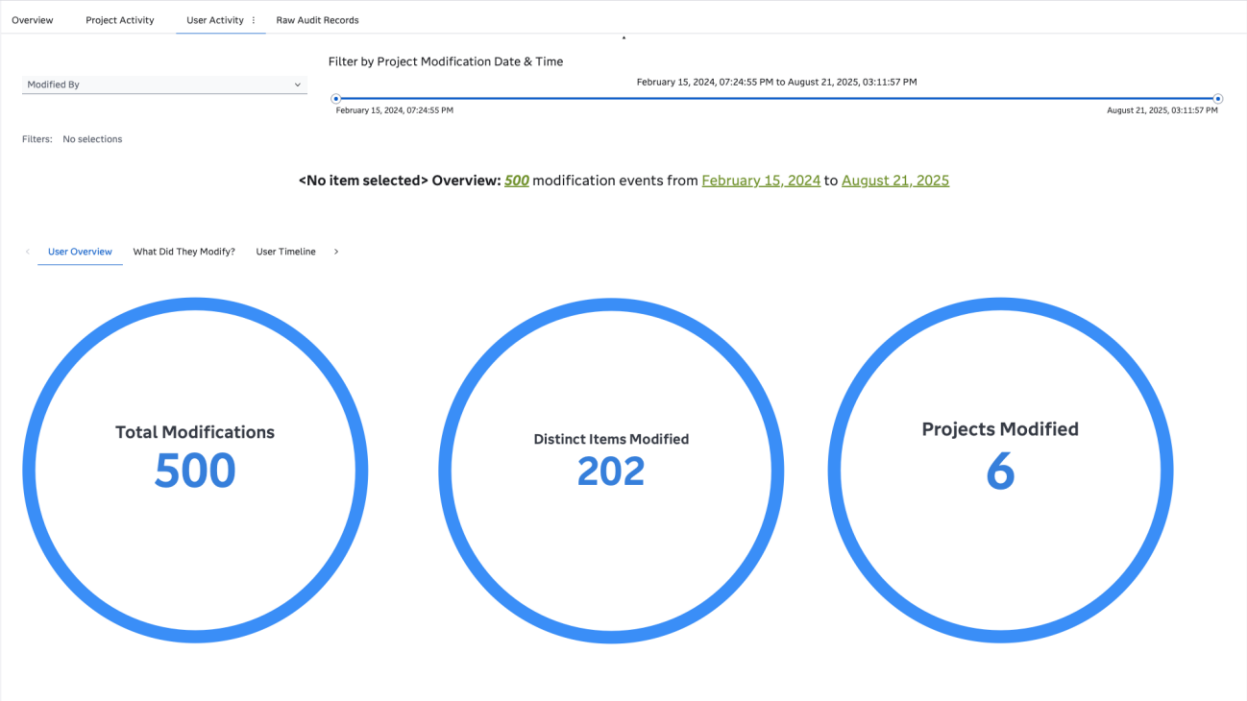

Figure 5. KPIs for User Activity

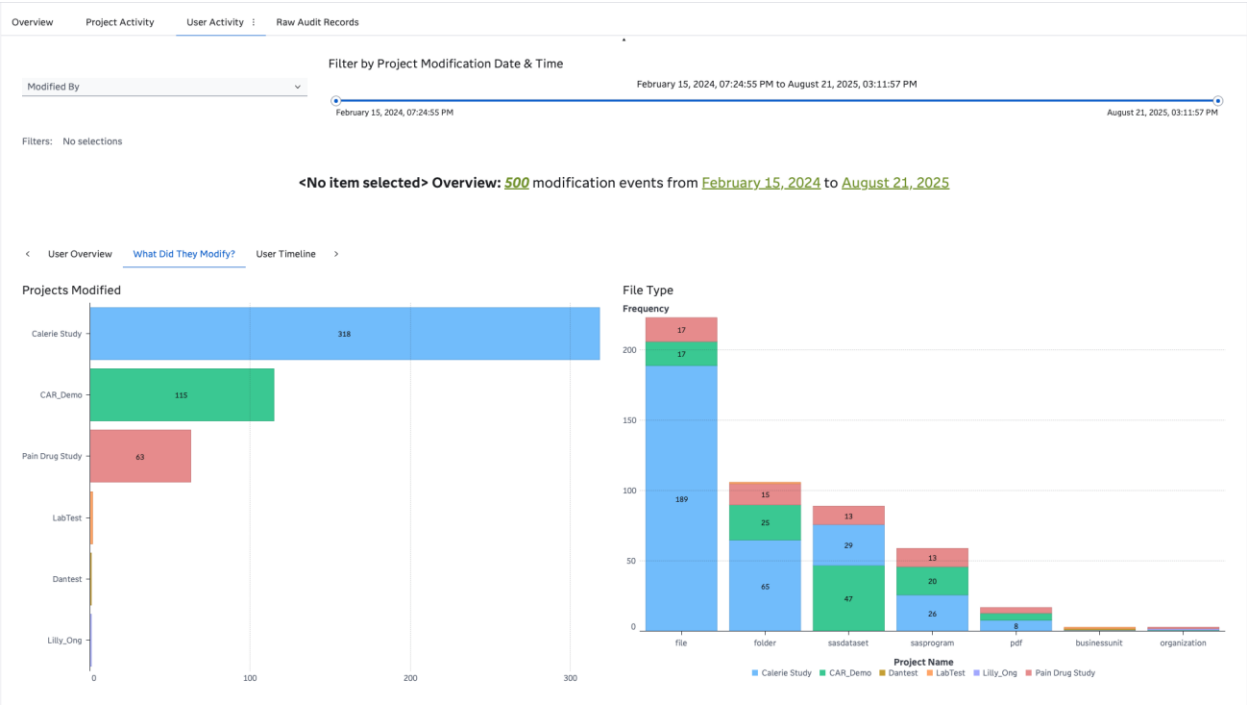

Figure 6. What Users Modified

Figure 7. User Timeline

RAW AUDIT RECORDS PAGE: DETAILED TRACEABILITY

The Raw Audit Records Page of the dashboard provides access to the underlying audit trail data and serves as the foundation for traceability. This page enables stakeholders to validate specific events and review detailed audit trail data.

Figures 8 and 9 illustrate best practices for the raw audit records page, including tabular presentation, filtering capabilities, and alignment with the other pages. Tabular presentation of comprehensive metadata comprises audit records in a list table format (Figure 8). This enables stakeholders to review detailed event-level data if necessary. Filtering capabilities include filters for user, project and timeframe, supporting efficient identification of specific audit events (Figure 9). This tabular representation of the data should align with the other pages to complement and provide supporting detail for the visual summaries presented on those previous pages.

Importantly, the Raw Audit Records Page ensures that high-level insights remain traceable to individual audit events.

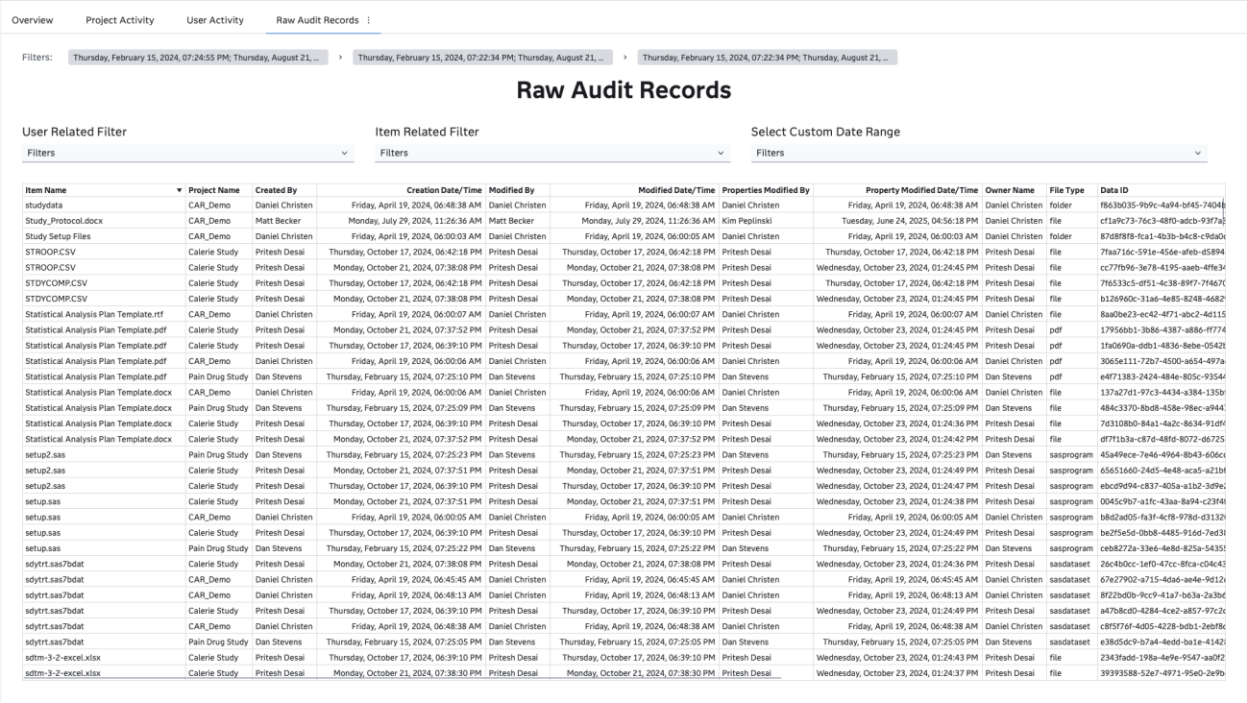

Figure 8. Raw Audit Records List Table

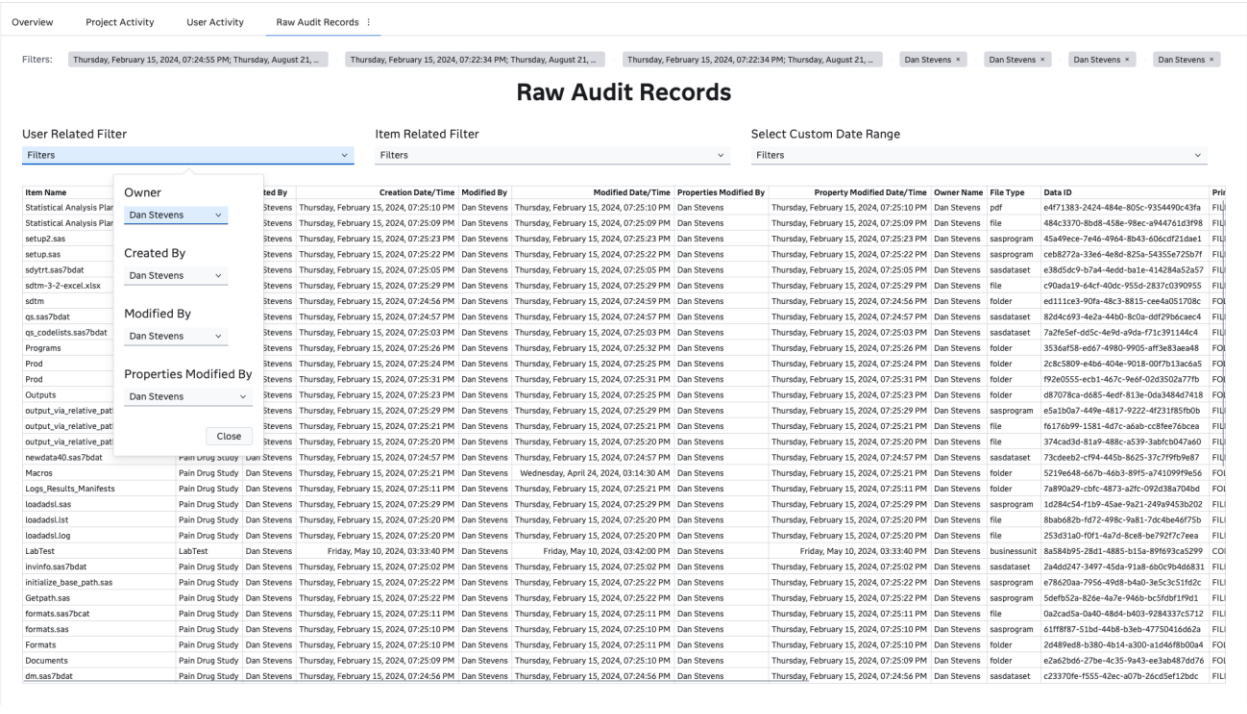

Figure 9. Audit Records Table Filtered

CONCLUSION

Audit trails are essential components of regulatory compliance in clinical trials, supporting transparency, traceability, and accountability throughout the data lifecycle. However, their value is only fully realized when audit trail data can be easily accessed, understood, and analyzed.

By leveraging audit trail data generated by an SCE and visualizing it through an interactive dashboard, organizations can transform compliance data into actionable insights, without requiring stakeholders to access the SCE directly. Dashboard-driven audit trail review enables faster data assessment, clearer traceability, and improved regulatory readiness.

Applying best practices in audit trail visualization, including both project-level and person-level perspectives, allows organizations to gain meaningful oversight while maintaining compliance. While demonstrated using SAS tools, the principles and best practices described in this paper are applicable across platforms and environments. By adopting a dashboard-driven approach, organizations can move from reactive compliance toward proactive, transparent data governance.

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