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Bridging Patient and Trial Level Insights

Catharina Dahlbo, Capish, Malmö, Sweden
Eva Kelty, Capish, Malmö, Sweden

ABSTRACT

Behind every clinical data point is a patient, a person whose safety, comfort, and trust depends on how clearly we can see the full picture of their journey. Protecting patients requires moving beyond aggregated charts and static summaries to visualizations that bring together every relevant detail in context. In today's decentralized, data-rich trials, this means connecting clinical measures, operational activities, and patient-reported experiences into a coherent, patient level view.

This poster will show how integrated, interactive visualizations can reveal the complete patient story, linking symptoms, lab trends, adverse events, and protocol deviations alongside lived experiences. Such a holistic perspective enables teams to recognize patterns early, act on subtle signals, and address risks before they escalate. The result is a shift from isolated data review to continuous, patient-focused oversight, ensuring each decision supports the individual's well-being as well as the trial's progress.

INTRODUCTION

Clinical trial data review has traditionally been organized around domains and deliverables rather than around patients. Laboratory data, adverse events, protocol deviations, dosing, and patient-reported outcomes are reviewed in separate outputs, often at an aggregated level. While this approach supports formal analysis and reporting, it is not well suited for continuous oversight or early signal detection at the individual patient level.

At the same time, the nature of clinical trials has changed. Decentralized designs, remote assessments, wearables, and ePRO have increased both the volume and frequency of collected data. Operational complexity has grown alongside clinical complexity, introducing new challenges related to adherence, visit timing, device reliability, and data completeness. Under these conditions, it becomes increasingly difficult to maintain a clear understanding of what is happening to individual patients using static, disconnected outputs.

The core challenge is not a lack of data, but a lack of integrated context. Protecting patients requires tools that allow reviewers to see how clinical changes, operational events, and patient-reported experiences interact over time. We want to describe how integrated interactive visualizations can bridge patient level understanding with trial-level insight. The paper discusses how an integrated visualization tool addresses this challenge by improving efficiency, clarity, and timeliness in patient-focused trial oversight.

LIMITATIONS OF TRADITIONAL TRIAL REVIEW APPROACHES

Aggregated summaries are essential for understanding overall trial behavior, but they are inherently limited when the objective is to identify emerging risks at the patient level. Averages and frequencies can obscure gradual but clinically meaningful changes in individual participants. Static listings require time-consuming manual review and do not easily reveal temporal relationships across domains.

In practice, clinical reviewers often compensate by asking medical monitors, statisticians, and programmers to reconstruct patient histories across multiple outputs. This process is inefficient and difficult to scale, particularly when data is updated frequently. More importantly, it tends to be reactive rather than proactive. By the time a concerning pattern is identified, opportunities for early intervention may already have passed.

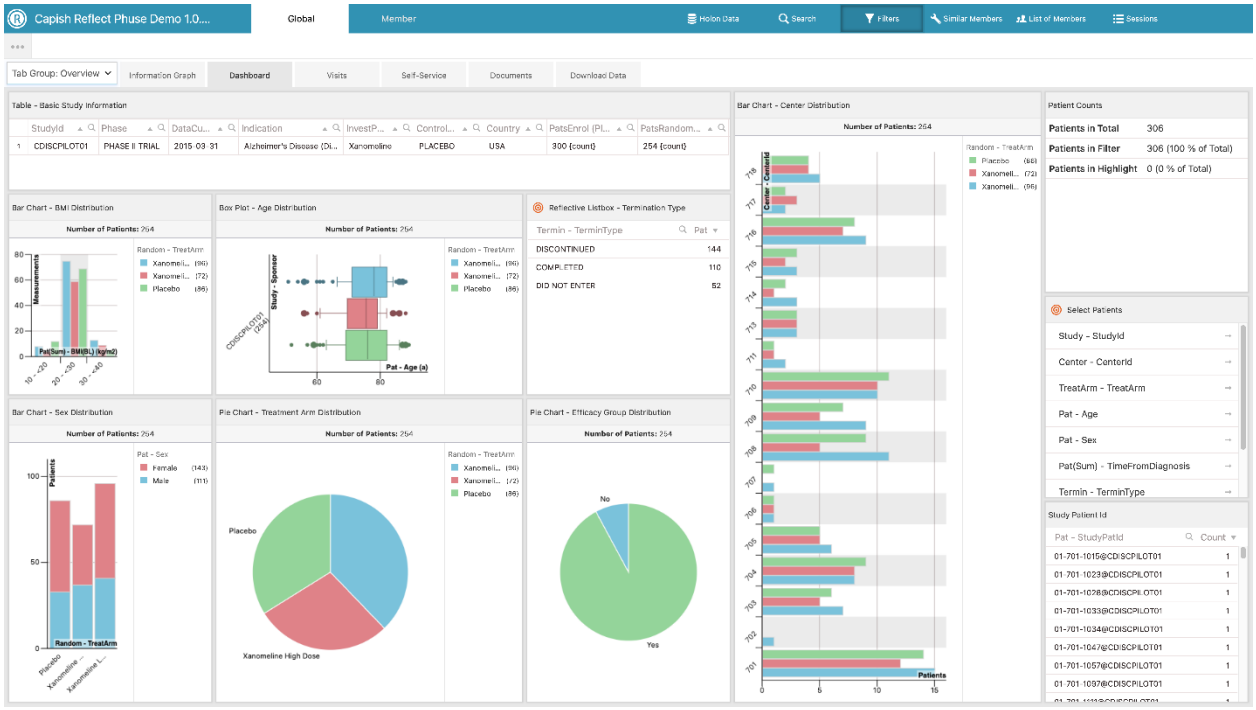
As trials become more data-rich and operationally complex, the cost of delayed insight increases. Teams need to identify patients who are struggling, sites where processes are failing, or patterns that may indicate emerging safety concerns. Doing so effectively requires tools that make these patterns visible without extensive manual effort.

INTEGRATED PATIENT LEVEL VISUALIZATION AS A SOLUTION

Integrated interactive visualization shifts the focus of data review from isolated domains to the patient journey. Instead of asking reviewers to connect information after the fact, the visualization brings relevant data together in a common temporal context. Clinical measures, safety events, operational activities, and patient-reported outcomes are aligned on a common timeline, allowing relationships to be observed directly.

Having a tool designed around this principle enables users to view the trial as a whole while also supporting rapid navigation to individual patients, sites, or subsets of interest. A reviewer can start with a trial-level overview, identify an area of potential concern, and then immediately explore the underlying patient level details without switching tools or outputs.

The objective is not to show everything at once, but to show what matters first. Default views should prioritize readability and highlight clinically meaningful exceptions. Users should be able to add layers, zoom in, or switch parameters when needed, but the initial state must remain interpretable within seconds.



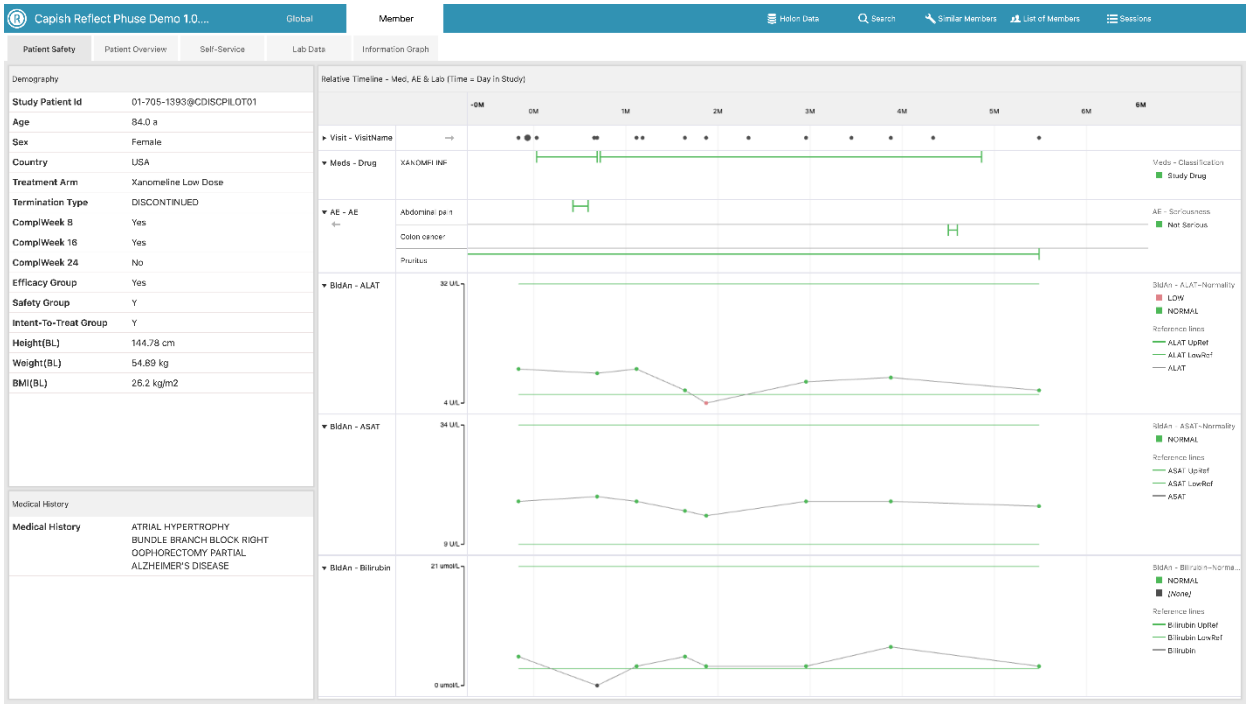
The figure above illustrates the PHUSE dataset after curation and standardization to achieve consistency across domains. This preparation reduces the need for manual data handling and allows users to focus on analysis and insight generation rather than data cleaning. The dashboard shown is one of several interactive views, enabling data to be quickly filtered, highlighted, and grouped to support further exploration.

This dual perspective is central to efficiency. Trial-level views help teams understand whether issues are isolated or systematic, while patient level views provide the depth needed to assess risk, understand causality, and determine appropriate action. The ability to move seamlessly between these perspectives reduces review time and cognitive load while improving confidence in the conclusions drawn.

REVEALING THE COMPLETE PATIENT STORY

Laboratory trends can be viewed alongside adverse events, dosing history, visit timing, and protocol deviations. Patient-reported outcomes add an additional layer by capturing how the patient experiences symptoms and treatment burden over time.

When these elements are viewed together, subtle but important patterns become easier to detect. A gradual laboratory change may gain significance when it coincides with worsening patient-reported symptoms. An adverse event may be better understood in the context of a missed dose or delayed visit. A cluster of protocol deviations may explain unexpected variability in clinical outcomes.

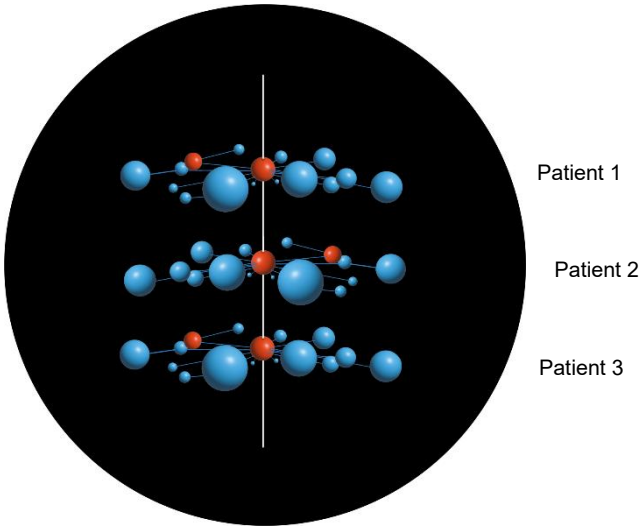


This figure illustrates how patient level review can be performed efficiently when multiple clinical and operational domains are aligned in a single timeline. Laboratory trends (ALT/AST/bilirubin) can be interpreted in the context of exposure periods, visit timing, and adverse event occurrences, making temporal relationships and emerging deviations easier to detect. Such integrated views support faster follow-up and more informed safety decision-making.

With a tool that supports this type of exploration by enabling interactive filtering, zooming, and drill-down, reviewers can focus on specific time windows, endpoints, or event types and immediately see how different data sources relate to one another. This interactive approach reduces reliance on intuition or memory and replaces it with transparent, reproducible insight.

A GRAPH DATABASE ENABLES DUAL PERSPECTIVES

A graph database can be interpreted as a multi-layer graph database, where each horizontal plane represents a separate patient level layer. Within each layer, nodes represent patient-specific entities such as visits, lab results, adverse events, treatments, and operational events, while edges represent the relationships between them. Stacking the layers illustrates how the same underlying graph structure can be repeated across many patients, enabling both individual patient exploration within a layer and cross-patient comparison across layers.



This layered graph database concept helps explain why switching between trial-level and patient level views can be done so efficiently. Each layer represents one patient with the same underlying data structure, meaning the same types of nodes (e.g., labs, visits, AEs, dosing) and relationships exist for every participant. Because all patient layers follow a consistent model, the system can aggregate patterns across layers to provide a trial-level overview, and then instantly drill down into a specific patient layer to review the detailed journey behind a signal.

EFFICIENCY GAINS IN DAY-TO-DAY TRIAL OVERSIGHT

One of the primary benefits of an integrated visualization tool is efficiency. Reviewers no longer need to search across multiple reports to understand a single patient's situation. Instead, relevant information is accessible in one place, updated as new data arrives.

This efficiency has practical implications for several key activities. Safety review meetings can focus on interpretation and decision-making rather than data reconstruction. Ongoing medical monitoring becomes more proactive, as reviewers can quickly identify patients who deviate from expected patterns. Operational issues, such as missed visits or protocol deviations, are easier to spot and address before they impact patient safety or data integrity.

For statistical programmers and data scientists, these tools also reduce duplication of effort. Standard analysis datasets can be reused to power both traditional outputs and interactive review, ensuring consistency while extending the value of existing data preparation work. The result is a more streamlined workflow that supports both regulatory rigor and real-time insight.

SUPPORTING EARLY DETECTION AND MITAGATION

Early detection of emerging issues is critical for protecting patients. Integrated patient level visualization makes it easier to recognize weak signals that might otherwise be overlooked. These signals may include gradual changes, combinations of events across domains, or patterns that only become apparent when viewed over time.

By identifying such patterns earlier, teams can intervene sooner. This may involve closer follow-up of individual patients, targeted site communication, or adjustments to monitoring focus. In each case, the goal is to prevent escalation rather than respond after harm has occurred.

Importantly, this approach does not replace formal analysis or reporting. Instead, it complements them by providing continuous, contextual insight that informs decision-making between scheduled analyses. This type of tool acts as a decision-support tool that enhances situational awareness while maintaining traceability to underlying data.

CONCLUSION

Behind every data point there is a patient, and effective trial oversight depends on seeing the full context of that patient's journey. In decentralized, data-rich clinical trials, traditional static and aggregated outputs are no longer sufficient on their own. Integrated, interactive visualization tools enable a more efficient and patient-focused approach by connecting clinical measures, operational activities, and patient-reported experiences in a coherent view.

By supporting seamless navigation between trial-level overviews and individual patient narratives, such tools improve efficiency, facilitate early signal detection, and strengthen patient safety oversight. The result is a shift from isolated data review to continuous, patient-centered decision-making, ensuring that both individual well-being and trial progress are supported throughout the study lifecycle.

REFERENCES

1. PHUSE test data, CDISCPILOT https://github.com/phuse-org/TestDataFactory/tree/main/Updated
2. The Table Has Turned, C. Dahlbo, A. Berg, PP18 PHUSE EU Connect 2022
3. Graph vs Table – A Complex Question, C. Dahlbo, E. Kelty, PP05 PHUSE EU Connect 2023
4. Harness the Data's Potential in a Clinical Trial, C. Dahlbo, E. Kelty, PP13 PHUSE US Connect 2024
5. The Utilization of an Interface Based on a Graph Database, C. Dahlbo, E. Kelty, PP09 PHUSE EU Connect 2025

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Catharina Dahlbo
Email: catharina.dahlbo@capish.com

Author Name: Eva Kelty

Email: eva.kelty@capish.com

Company: Capish
Address: Lokgatan 8
Work Phone: +46 40 108880

Website: Capish.com