PharmaSUG 2026 - Paper DV-443

From Static Outputs to Living the Data

A Visualization framework transforming Clinical Data into a Continuous Asset

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ABSTRACT

Keeping unmet patient needs at the center of drug development, delays from the pace of the reporting processes directly translate into lost opportunities. Where power is often said to lie in the data, in the drive for speed, it's worth reflecting – are we truly learning from the data to its potential? The reliance on labor-intensive static TLFs- other than the cost associated, slows adaptation and constrains rapid insight generation and decision-making. This presentation introduces introduction to an R-shiny and Java based Data Visualization framework- a dynamic, interactive approach that re-imagines clinical data consumption. By shifting from static deliverables to curated, self-service dashboards, the approach enables teams to efficiently explore data – filtering, drilling-down, and participant-level interrogations. This provides Safety, Clinical Scientists, and Medical Writers immediate access to interactive safety/efficacy views, faster signal evaluation, enhanced collaboration, and earlier regulatory initiation. It reshapes the role of Biostats- from ad-hoc output generators to scalable, high-value data enablers. It is embedded across the study lifecycle reducing redundant outputs, minimizing rework, and prioritizing analyses that directly support reporting, including real-life examples of the impacts during high-pressure regulatory interactions. Audience will learn what it takes to develop a framework to dynamically study the data and how adopting a dynamic visualization mindset can materially shorten cycle times, improve cross-functional transparency, and move organizations toward upper-quartile performance. Ultimately, the presentation would demonstrate how clinical data can evolve from static documentation into a continuously accessible asset- accelerating insights, enhancing quality, and better serving patients awaiting new therapies.

INTRODUCTION

During clinical development, organizations collect and generate enormous volumes of data, yet much of that information is still consumed through static tables, listings, and figures (TLFs) produced at fixed milestones. While static outputs remain essential for traceable, archival reporting, they can be poorly suited to the day-to-day reality of modern study execution—where questions evolve quickly, decisions are time-sensitive, and multiple functions must align on a shared evidence base. In this setting, time lost waiting for new or revised outputs is more than just operational inefficiency; it can delay clinical interpretation, slow signal evaluation, and postpone downstream reporting activities.

A key limitation of a TLF-centric workflow is that it forces anticipation. Teams must decide in advance which displays they might need, often generating large packages "just in case." Yet in the drive to move as fast as possible, teams also necessarily do not generate every potentially informative TLF across all domains, endpoints, and alternative cuts of the data. This creates a practical risk: meaningful patterns may remain hidden simply because the relevant view was never specified, programmed, and quality controlled. In other words, a static-output model can inadvertently narrow what is learned—not due to lack of scientific intent, but because insight is constrained by what was pre-defined as a deliverable.

Static outputs can also constrain discovery because they assume the most important subgroup questions are known upfront. In reality, clinical interpretation is iterative: interest in a particular subgroup often emerges only after reviewing early outputs, when unexpected patterns prompt new questions (for example, a safety signal suggesting exploration by baseline risk factors, concomitant medications, or time-on-treatment; or an efficacy trend raising questions about prior therapy, disease characteristics, or

exposure). When these “newly discovered” subgroup hypotheses arise midstream, a static workflow typically requires additional programming and QC cycles, which slows learning and can discourage broader exploration.

Interactive visualization provides a complementary consumption model: curated dashboards that allow users to filter, stratify, and drill down in real time—moving from population-level summaries to participant-level context within a governed environment. Rather than replacing validated reporting, this approach shifts exploratory work and routine question-answering toward self-service interaction, while reserving formal static outputs for the subset of analyses required for decision packages, clinical study reports, and submissions. When implemented with appropriate governance, role-based access, and quality controls, an interactive framework can reduce redundant output production, accelerate cross-functional collaboration across Safety, Clinical Science, Biostatistics, and Medical Writing, and support earlier initiation of reporting activities.

This paper describes a practical clinical data visualization framework built on R-shiny and Java designed as a GxP compliant tool in a regulated environment. We focus on what it takes to move from “static deliverables” to “living the data”—where analysis results become a continuously accessible asset that supports faster insight generation, enables discovery of unanticipated subgroups, and improves the efficiency of escalating exploratory findings into formally reported analyses. We also discuss time-critical scenarios—such as responding to health authority questions—where interactive exploration can help teams converge quickly on definitions, cohorts, and hypotheses before finalizing traceable outputs through established reporting processes.

MINDSET SHIFT FROM STATIC DELIVERABLES TO “LIVING THE DATA”

Clinical teams do not struggle because they lack data; they struggle because learning from the data is often gated by deliverables. A static TLF package answers a predefined set of questions well, but it is inherently less suited to the iterative, exploratory nature of interpretation—where new questions emerge as soon as initial results are reviewed, and where understanding often depends on moving quickly between summaries and participant-level context.

1. Reframing the requirements: enable learning, not just reporting

A more effective model separates two distinct needs:

- **Exploratory learning (high frequency):** rapid interrogation, “what-if” slicing, and follow-up questions that evolve as patterns emerge.
- **Official reporting (high rigor):** traceable, validated outputs for decision packages, clinical study reports, and submissions.

The goal is not to eliminate static outputs, but to reduce how often teams must wait for them to learn. This is particularly important when timelines are tight and when it is unrealistic to pre-specify every potentially informative cut of the data.

2. What “living the data” means in practice

“Living the data” refers to making analysis results continuously accessible in a curated, governed environment so stakeholders can:

- Navigate from population-level summaries to participant-level detail without initiating a new programming cycle
- Test and refine new subgroup hypotheses that were not anticipated during specification
- Rapidly iterate on questions as clinical interpretation evolves (e.g., exploring potential drivers, time windows, baseline factors, concomitant therapy, exposure patterns)
- More instream insights to the data and not limited to the pre-defined milestones.

This shifts the workflow from "request → produce → QC → consume" to "explore → align → formalize," where only the subset of findings that matter for decision-making or disclosure are escalated into formally programmed, traceable outputs.

3. Curated self-service is the key (not unlimited exploration)

A successful interactive approach is not an open sandbox. It is a curated product:

- Dashboards are designed around common clinical questions (safety, efficacy, disposition, exposure, participant profile views).
- Interactions are standardized (filters, stratification, drill-down paths), which improves usability and reduces ambiguity.
- Saved-views as a mode of communication that allow teams to share a specific cut of the data during cross-functional discussions, improving transparency and alignment without generating a new static package.

Curation ensures the experience is scalable across studies and that the exploratory layer remains consistent and interpretable.

4. Benefits that matter before you talk about technology

This learning model changes the day-to-day experience for study teams in ways that are directly relevant to regulated development:

- Faster signal triage: quicker movement from "there is a trend" to "what is driving it?"
- Reduced late-cycle churn: fewer rounds of ad-hoc requests because many questions can be answered through governed drill-down first
- Better cross-functional alignment: clinical, safety, statistics, and writing teams can anchor discussions on the same interactive views rather than exchanging static files with different cuts and timestamps
- More complete learning under time pressure: when it's not feasible to generate "all possible TLFs," interactive interrogation helps reduce the risk of missing potentially informative patterns simply because they were not pre-programmed

INTRODUCING A DYNAMIC AND INTERACTIVE DATA VISUALIZATION TOOL

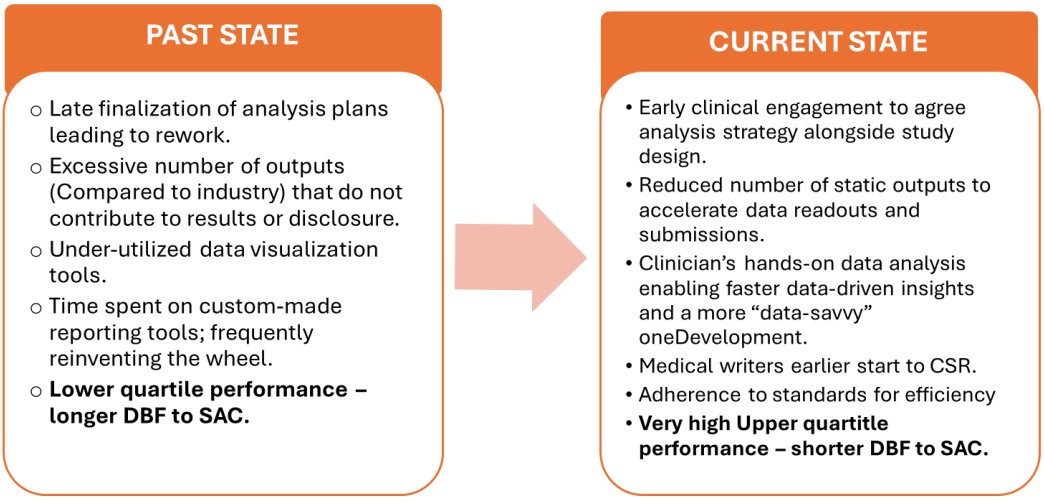
With an intention of converting the data into a continuous asset, RAPIDO DV (**R**eporting & **A**nalysis **P**lan **I**mproving **D**esign and Delivery of **O**utputs – **D**ata **V**iewer) is designed as an interactive, dynamic clinical data visualization capability that helps teams consume analysis results through curated dashboards rather than relying solely on static tables, listings, and figures (TLFs). It combines an explicit process shift—"explore first, formalize selectively"—with an enabling technology layer that makes governed dashboards available to authorized users instream.

WHAT RAPIDO IS INTENDED TO ACHIEVE

RAPIDO is intended to modernize and transform how clinical study results are consumed—shifting effort away from producing large volumes of "just-in-case" static outputs and toward faster, self-service exploration of key domains. In practice, this means enabling study teams to answer many routine follow-up questions immediately (e.g., "Does this pattern persist in a subgroup?", "Which participants are driving this trend?", "Is this effect concentrated at certain timepoints?") through interactive filtering and drill-down, rather than waiting for additional bespoke TLF programming cycles.

A second, equally important aim is collaboration: RAPIDO supports cross-functional teams in aligning on the view of the data during safety review, clinical interpretation, and reporting preparation—enhancing the overall understanding of the data, reducing the confusions from different static cuts or versions of outputs and introducing newer and efficient ways to collaborate over data and communicate.

Finally, RAPIDO is designed to preserve rigor where it matters most. This framework supports rapid exploration and shared understanding to maintain the aim of meeting organization's upper quartile goals of going as fast as we can to better serve the unmet need of the patients.



WHO USES RAPIDO (AND WHY A CROSS-FUNCTIONAL AUDIENCE MATTERS)

RAPIDO is intended for a broad, cross-functional study audience—not just statisticians and programmers, but also stakeholders who interpret and communicate results, such as clinical scientists/physicians, safety scientists, and medical writers. This multi-function design is deliberate: many time-critical study questions arise outside of programming teams, and RAPIDO aims to reduce dependency on iterative "back-and-forth" output requests by enabling safe, self-service exploration for appropriately trained and authorized users.

In practice, RAPIDO supports two categories of users:

- **Enablers:** This group primarily comprises of Biostatistics and Clinical Programmers who enable the study by loading the data and configuring dashboards so that the fit for purpose domains are available for the team members, variables and parameters have meaningful labels, and the tool behaves in a consistent manner matching the study setup.

- **Consumers:** This group can be referred to as real users for the framework as they use dashboards to explore results, test hypotheses, and make meaningful interpretations and decisions driven by data. The list of consumers is not limited to:
    - Clinical Scientists, Medical Monitors/ Physicians
    - Safety Scientists
    - Medical / Scientific Writers, Publishing Team
    - Biostatistics and Clinical Programming
    - Biomarkers and Value Evidence Outcome teams
    - Clinical Pharmacology, Modeling and Simulation team
    - Additional study and project team members who are authorized to explore study results.

HOW RAPIDO IS USED BY END USERS (WHAT THE EXPERIENCE LOOKS LIKE)

From an end-user perspective, RAPIDO is organized to support a natural review flow: start broad, focus quickly, and then drill into the details needed to interpret what is happening.

After selecting a study (or analysis area), the interface is typically structured around:

- A dashboard menu that organizes content into common review areas (e.g., population, safety, subject profile/listings, and generic views),
- Each dashboard comes with a filter panel that allows users to subset and stratify the data (supporting both planned and newly emerging subgroup questions),
- The main results area displays summaries and visualizations, often with drill-down to participant-level detail for clinical interpretation and case review.
- Various options available to save the filters either at the subject list level which enables jumping quickly from one dashboard to another studying the same subjects; or saving the entire analysis which are available to all users.

This layout directly supports the “living the data” workflow: users can iteratively refine the question they are asking—moving from an observed pattern to the subgroup where it is concentrated, and then to the participants contributing to it—without waiting for additional static deliverables to be produced.

“Saved views” to accelerate cross-functional alignment

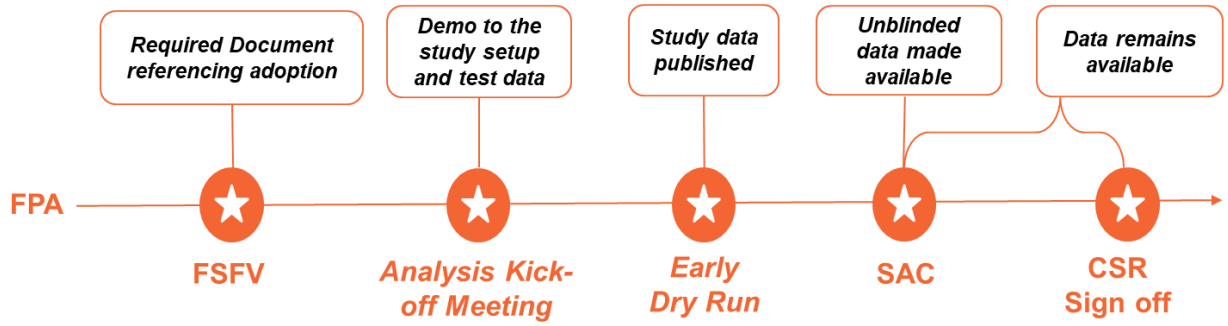
A key collaboration feature is bookmarking (saved views). Users can save a specific configured view—capturing the relevant filters and display selections—and share it with colleagues so that discussions are anchored to the same question and the same slice of the data (e.g., “these participants, this subgroup,

this time window"). This improves reproducibility of cross-functional review and reduces ambiguity that can arise when teams describe results verbally or via screenshots without context.

HOW STUDIES ARE ENABLED IN RAPIDO (SETUP AND CONFIGURATION)

RAPIDO's usefulness depends on consistent, high-quality study setup. Before consumers can use dashboards reliably, each study undergoes a setup step where datasets are loaded and a study configuration—often referred to as data mapping—is reviewed and adjusted so that dashboards behave as intended.

Following workflow explains the adoption of RAPIDO in the life cycle of the study:



The mapping process typically includes configuring multiple elements such as:

- which dashboards are enabled,
- how key variables are mapped,
- ordering and display conventions,
- how variables and parameters are defined for analysis and visualization, and
- which bookmarks (including any standard bookmarks) are enabled,

followed by a publishing step that makes the configured views available to end users.

USED CASES FOR DIFFERENT FUNCTIONS:

Clinical programmers:

- Reduces the number of static outputs you create for study teams, over time resulting in improved efficiency and a reduction in cycle times.
- Provides you with dynamic data outputs for your clinical data consumers, supporting cycle time efficiency.
- Ensures that the ad-hoc work that you do is absolutely needed for inclusion in the study report, disclosure or other publications externally (no more nice-to-have outputs).
- Allows comprehensive and integrated knowledge of the end-to-end results from trials.

Clinical Statisticians:

- Reduces the number of static outputs you create for study teams, over time resulting in improved efficiency and a reduction in cycle times.
- Enables you to configure, filter and analyse data and create dashboards for consumption by the clinical teams you support, allowing clinical study teams to self-serve data, supporting cycle time efficiency.
- Accelerates response time to study result queries (including regulatory questions) through rapid investigation and identification of results of scientific or regulatory interest.
- Ensures that the ad-hoc work that you do is absolutely needed for inclusion in the study report, disclosure or other publications externally (no more nice-to-have outputs).
- Frees up more time to spend on high-value activities (e.g., QDM, POS, etc.).

Safety Scientists & Physicians / Clinical Scientists and Medical Monitors and other study team members:

- Access to interactive safety outputs and other key summaries and figures.
- Access to primary, secondary and exploratory endpoint data and results.
- Easy filtering, sorting and searching of data and results.
- Independently produce dynamic exploratory analyses and results.
- Seamlessly drill down from summary level results to individual participant level details and dynamically create groups of participants of interest.
- Enhanced understanding of study data.

Medical Writers:

- Accelerated report writing and submissions. Interactive dashboards enable a reduction in static listings, summary tables and figures produced within Biostats, resulting in faster Statistical Analysis Complete (SAC) delivery and an earlier start to report writing.
- Enhanced understanding of study data as a result of dynamic exploration.
- Access to participant-level primary, secondary and exploratory endpoint data and results which can be used as a source in reports.
- Improved collaboration through workflows for sharing data insights.

CORE CAPABILITIES OF THE FRAMEWORK

Once a study is enabled and users have access, the practical question becomes: what does this tool let a team do that is difficult, slow, or fragmented in a static-output workflow? The capabilities below describe the audit controlled functional building blocks that make “explore → align → formalize” workable in real study execution. They are intentionally designed to support iterative review: starting with broad situational awareness, narrowing quickly to the relevant subgroup or time window, and then confirming interpretation through participant-level context, while keeping the experience consistent enough for cross-functional use.

1) CURATED DASHBOARDS ALIGNED TO HOW STUDY TEAMS REVIEW DATA

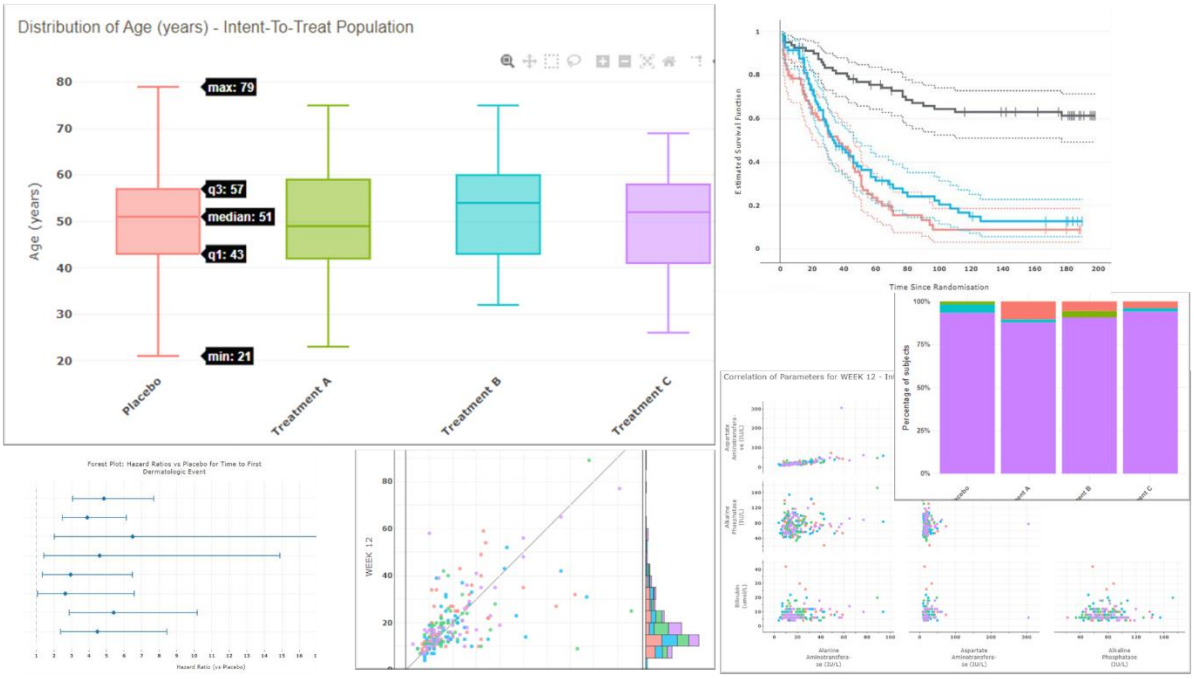
RAPIDO DV organizes content into dashboards that reflect common review needs (e.g., population, safety, subject profiles/listings, and flexible generic views). This structure matters

because it reduces the cognitive and operational load of “finding the right output” and instead gives teams a predictable navigation model for recurring questions—supporting faster orientation and more efficient review cycles.

There are various dashboards available to study the data in an organized way:

- Baseline Characteristics catering to any data point captured at baseline including stratification factors
- Concomitant Medications including anti-cancer therapies and surgeries
- Medical History along with other disease characteristics
- Adverse Events with the provision of studying by severity/outcome/action taken
- Laboratory with range of analysis from abnormal trends/shifts to correlations
- Other safety analysis including ECGs, Vital Signs etc
- Dosing and other drug exposure
- Efficacy wrt key endpoints
- PK concentration and parameters
- Generic Dashboard: All other domains can be studied on Generic dashboard
- Subject Listings based on SDTMs and ADaMs
- Patient Narratives for understanding the entire story of a subject

For each of these dashboards offers the ability to perform analysis based on any continuous/categorical datapoints in the form of summary statistics or frequencies and unlimited graphical representation of the data ranging from aggregated figures to individual subject data. There are various visualizations available: Correlation Plots, Box Plots, Dot Plots, Line Plots, Shift Plots, Bar Plots, Trend/outlier plots, Kaplan Meier, Hazards Ratios and many more.



Note: Synthetic/Test Data has been used to generate the visualizations

2) INTERACTIVE FILTERING AND STRATIFICATION (RAPID HYPOTHESIS TESTING)

The filtering experience is designed to help users iteratively refine the real question by studying all subgroups. Users can subset and stratify results to:

- Check whether a pattern holds across key groups or emerges in an unanticipated subgroup
- Focus on particular time windows/periods/visits (as configured for the study)
- Re-run the same logic across multiple views while maintaining consistent definitions

This is particularly valuable when questions evolve mid-review and the “right” cut of the data is not obvious until initial patterns are seen.

3) DRILL-DOWN FROM SUMMARY PATTERNS TO PARTICIPANT-LEVEL CONTEXT

The tool supports moving from aggregate summaries directly into participant-level detail. This helps teams close the gap between “a signal exists” and “we understand what is driving it,” enabling practical interpretation questions such as:

- Which participants contribute most to the observed pattern?
- Is the trend isolated to a subset or broadly distributed?
- What contextual details (timing, co-occurrence, baseline characteristics) help explain it?

4) PARTICIPANT-CENTRIC WORKFLOWS (CREATING/REUSING SUBJECT SETS)

A common real-world workflow is to identify a set of participants in one view and then carry that set across other dashboards to build an integrated interpretation. RAPIDO DV supports this by enabling users to dynamically create participant groups of interest and reuse them across views—helping teams connect evidence across domains without manually stitching together multiple static listings.

5) SAVED VIEWS / BOOKMARKS (REPRODUCIBILITY AND TEAM COLLABORATION)

To support collaboration without ambiguity, RAPIDO DV allows users to save their work in a reusable form:

- Saved analyses that preserve the full view state (filters + display selections) and can be revisited or shared with other authorized users
- Standard bookmarks based on standard analysis done across organization

This makes cross-functional discussions more precise: instead of describing a cut of the data verbally (or recreating it from scratch), teams can align on the exact same configured view.

IMPACT CASES (WHAT CHANGED AND WHY IT MATTERS)

The value of a dynamic, interactive visualization approach is not limited to better views; it changes how quickly teams can move from an emerging question to a shared understanding. Unlike traditional static-output workflow, with governed self-service dashboards, many questions can be answered (or more precisely scoped) through interactive exploration first, reserving formal programming effort for the subset of outputs that are decision- or disclosure-critical.

Some of the evident impacts after the adoption of this framework can be categorized as:

1) **Speed / cycle time:** With earlier access to interpretable results and faster triage of questions, there is a faster movement from "we see a pattern" to "we understand what is driving it."
2) **Reduced output volume and rework:** Fewer "just-in-case" static outputs created up front and reduced late-cycle churn because many exploratory questions do not require new bespoke deliverables.
3) **Higher quality interpretation:** Rapid drill-down to participant-level context improves confidence in interpretation and helps confirm whether an observed signal is real, localized to a subset, or driven by a few participants. Easier iteration on newly emerging subgroup hypotheses that were not anticipated at specification time.
4) **Cross-functional transparency and alignment:** Clinical, safety, statistics/programming, and medical writing teams can anchor discussions on a consistent, governed view of the data, rather than comparing different static cuts or versions. Saved-views enable teams to discuss the exact same slice of data, improving reproducibility of interpretation.
5) **Improved responsiveness in time-critical interactions:** Interactive exploration accelerates early understanding and scoping (definitions, cohorts, drivers), enabling formal outputs for official use to be produced more efficiently and with fewer iterations.

EXAMPLES FROM LIVE STUDIES:

Case 1: Rapid definition of a sensitivity-analysis population

Trigger: A health authority requests sensitivity analyses focused on a subset described by an operational concept (e.g., participants with early censoring).

Typical friction with static-only workflows: Multiple iterations may be required to define the subset precisely, request new listings, validate edge cases, and align on the final definition across functions.

How interactive dashboards helped: The team explored distributions of timing and reasons, tested alternative cut points, and drilled down to participant-level records to confirm inclusion/exclusion rules.

Outcome: The team converged on a reproducible definition faster, allowing formal analyses and traceable outputs to proceed with fewer rework cycles.

Case 2: Characterizing "unknown/other" categories within a regulator-defined subgroup

Trigger: A health authority requests additional characterization of event reasons (e.g., deaths or discontinuations) within a specific subgroup definition.

Typical friction with static-only workflows: Understanding drivers can require multiple new subgroup tables and listings, slowing clinical review and delaying the scope of required official outputs.

How interactive dashboards helped: The team filtered to the subgroup, compared patterns across event categories, and used participant-level drill-down to support rapid clinical review and targeted data clarification questions.

Outcome: The response was scoped more precisely, and formal output generation focused on the minimum necessary deliverables—improving turnaround time.

Case 3: Late-cycle exploratory checks to support external communication readiness

Trigger: After primary analyses, stakeholders request rapid exploratory checks (e.g., patterns in a specific treatment period, feasibility of biomarker-defined subgroup summaries, timing of subsequent therapies).

Typical friction with static-only workflows: These questions can generate large volumes of ad-hoc outputs with uncertain value.

How interactive dashboards helped: Stakeholders explored feasibility and signal strength interactively, then agreed which questions warranted escalation to formal programming.

Outcome: Fewer low-value outputs were produced, and effort was concentrated on analyses that materially supported decisions and external communication planning.

Across these scenarios, the consistent impact is that interactive, governed visualization reduces the time spent getting to the right question and accelerates alignment on what is needed. This is particularly valuable under compressed timelines, where it is not realistic to pre-program every informative cut of the data as a static deliverable. By enabling rapid exploration while preserving a clear boundary for official reporting, teams can learn earlier, collaborate more effectively, and formalize only what matters.

WHAT'S NEXT (FUTURE PLANS)

Future development focuses on extending interactive exploration into a more complete, end-to-end evidence workflow—while strengthening traceability, broadening accessibility, and supporting more instream decision-making.

1) **Strengthening traceability and reproducibility from exploration to formalization**

   A key next step is to make exploratory work more directly reusable by enabling users to download not only the resulting visualization/output, but also the underlying R code used to generate it—together with metadata (e.g., dataset/version identifiers, filter states, parameter selections, timestamps, and provenance). This would allow teams to move faster from exploration to formalization while improving reproducibility and audit readiness.

2) **Evolving reporting expectations: toward interactive submission packages**

As regulators and industry continue to modernize data review practices, a longer-term direction is to move from purely static submission packages toward interactive submission experiences (or interactive companion artifacts), where appropriate. This would require clear conventions for traceability, controlled versions, and unambiguous linkage between interactive views and official interpretations.

3) **Enabling deeper instream use through direct database connectivity**

To support more instream activities, another future direction is the ability to read data directly from source databases (with appropriate controls), reducing latency between data availability and review. This would enable near-real-time exploration during active study execution, while still enforcing governance around access, blinding, and appropriate use.

4) **Expanding analytics breadth: new and less common dashboard**

To reduce the "long tail" of one-off outputs, the framework is planned to be extended with additional dashboards that cover less common or more specialized analyses. The aim is to make it easier for teams to answer atypical questions through standardized interactive patterns rather than bespoke programming.

5) **Adding guided usability to accelerate adoption**

To increase intuitiveness for new or infrequent users, a guided tour feature (contextual walkthroughs, tooltips, and "how to interpret this view" prompts) can reduce training burden and improve consistent usage across functions.

6) **Scaling the data pipeline: crowd-sourced and standardized preprocessing**

Future capability can also include more structured ways to crowd-source data preprocessing and preparation steps—e.g., shared reusable transformations, standardized derivations, and quality checks—so study teams can contribute improvements while maintaining governance and consistency.

7) **Extending access beyond internal users (externalization)**

Finally, controlled externalization of access—such as enabling secure access for selected external collaborators—could broaden the value of interactive review while requiring strong controls for authorization, segregation, confidentiality, and data minimization.

CONCLUSION

Interactive clinical data visualization can operationalize a "living the data" mindset and "data as a continuous asset" by enabling governed, self-service exploration of analysis results through curated dashboards, rapid filtering/stratification, and drill-down to participant-level context. By shifting routine learning from static deliverables to dynamic interrogation—while still producing decision- and disclosure-critical tables and figures through established controlled reporting processes—teams can reduce late-cycle churn, improve cross-functional transparency, and respond more quickly to time-critical questions,

including those arising during regulatory interactions. Ultimately, this approach helps organizations move from episodic, milestone-based data consumption to continuous insight generation—accelerating interpretation, strengthening collaboration, and better serving patients awaiting new therapies.

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