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A 'Shiny' New Perspective: Unveiling Next-Generation Patient Profiles for Medical and Safety Monitoring

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ABSTRACT

In clinical trials, patient profile listings are vital for medical and safety monitoring, offering a dynamic visual representation of individual patient information. Reliance on manual methods to coalesce and analyze patient data for these listings has posed challenges in data integration, speed, interactivity, and flexibility. Addressing these issues, our Clinical Data Science team has developed an innovative Patient Profiles R Shiny app, revolutionizing patient data visualization and reporting in clinical trials.

The Patient Profiles R Shiny app outperforms the manual workflow through seamless integration of data from various clinical trial sources, enhancing coherence and utility for medical and safety monitoring. It effectively displays longitudinal data, enabling the tracking of temporal changes and the identification of correlations between medical history, demographics, adverse events, lab results, and other patient information. Highly customizable, the app's interface can be tailored to the Medical and Safety Monitoring team's needs, providing unmatched flexibility in data visualization. Additionally, its interactive graphs and tables allow for a thorough exploration of complex data relationships, aiding monitors in understanding information more holistically, quickly, and accurately.

This advancement represents a significant shift in how medical professionals and stakeholders interact with patient-level data. The app's ability to integrate and display data from various sources facilitates a seamless review and interaction, enabling sound, evidence-based decision making. In essence, the Patient Profile R Shiny app leverages advanced technology to make large, dynamic data sets comprehensible and actionable, setting a new standard of data visualization in the pharmaceutical and biotechnology industry.

INTRODUCTION

During clinical trials, efficiency and precision in monitoring participant data play critical roles in safeguarding patient safety and ensuring the integrity of trial outcomes. A cornerstone of effective clinical monitoring lies in the comprehensive understanding of patient profiles, which integrate a wide array of individual participant data ranging from medical history and demographics to adverse events and lab results. Medical and safety monitors meticulously review this participant data to ensure that data quality and clinical standards are consistently upheld, patient safety is prioritized, and swift actions are taken to mitigate any potential risks to safety or the success of the clinical trial. Traditionally, the creation and analysis of patient profile listings are manual and time-intensive tasks, fraught with challenges including data fragmentation, latency in updates, and limited analytical flexibility.

To address these challenges, our Clinical Data Science team developed the Patient Profiles R Shiny application. This app collates data from different clinical trial sources, providing dynamic, interactive visualizations. Furthermore, it allows for the real-time analysis of participant data, which aids in the proactive identification of potential issues and the efficient discovery of clinical insights. This tool empowers our Medical and Safety Monitoring team to directly focus on analyzing clinical trial data, bypassing the need for manual data wrangling to uncover insights and make clinical decisions.

CHALLENGES WITH TRADITIONAL METHODS

Traditional clinical data monitoring has largely depended on static patient profile listings, which introduce three distinct challenges in the process: the limited availability of real-time source data, the complexity in integrating data from multiple sources, and the rigidity in customizing data visualization. These constraints often result in a fragmented and retrospective understanding of a patient's clinical journey as data is not automatically updated and temporal changes cannot be analyzed efficiently. Additionally, these listings must be repeatedly generated — a process that is both time consuming and prone to error.

STATIC DATA

A lack of real-time data in traditional patient profile listings presents several drawbacks. Each new piece of information necessitates the generation of an updated listing, a process that fails to be self-updating and demands considerable effort to maintain. This raises questions about the timeliness and reliability of the data, as it does not reflect the ongoing, fluid nature of clinical trials. For example, missing data, resolved queries, and repeated test results are not immediately presented to monitors, which can influence the interpretation of the data in the short-term. Static listings are not only cumbersome to produce, but also fall short in efficiently revealing trends and insights, leading to a less proactive and potentially outdated understanding of patient data.

LACK OF DATA INTEGRATION

The absence of seamless data integration in clinical data capture methods requires monitors and/or programmers to manually download and collate information from disparate sources to form a complete picture. This labor-intensive process is not only time consuming, but also prone to human error, which can compromise the integrity of the data analysis. Given the dynamic nature of clinical trial data, viewing data in these disconnected, static snapshots significantly delays the journey from potential discovery to actionable conclusion as new, relevant results keep emerging.

INFLEXIBLE VISUALIZATION

It's crucial for medical and safety monitors to be able to interact with clinical data in a manner that aligns with their unique analytical approach, facilitating insights and enabling the uncovering of key patterns, drivers, or root causes. The predefined nature of graphs and tables in traditional data visualization tools offers an inflexible experience and a one-dimensional perspective on patient data trends. Such rigidity forces monitors to revert to source data for comprehensive context, requiring additional data manipulation in tools like Excel to filter, analyze, and graph data. This limitation significantly slows the discovery process and fails to support the nuanced analysis necessary for critical decision making in clinical monitoring.

APP FEATURES

The creation of the Patient Profiles R Shiny app was initiated by partnering with the Medical and Safety Monitoring team to capture the requirements and inefficiencies they encounter when reviewing participant data during a clinical trial. Fundamental to the app's design is the integration of core functionalities to facilitate immediate adoption, such as the display of comprehensive patient data encompassing demographics, vital signs, participant status, electronic patient reported outcomes (ePRO), concomitant medications, medical and surgical histories, adverse events, laboratory results, and electrocardiogram (ECG) data. All this data is presented in an intuitive mix of interactive tables and graphical representations to enable clinical review workflows.

ENHANCED DATA INTEGRATION

The Patient Profiles app stands out from more traditional methods by efficiently consolidating distinct data streams from electronic data capture (EDC) systems, electronic patient reported outcomes (ePRO), laboratory results, and ECG systems into a single, cohesive narrative. This harmonization is conducted behind the scenes, where the app's algorithms automatically import, clean, and transform the raw data into a unified format. The transformed data is then woven into a detailed 'data story' that is presented to medical and safety monitors. By organizing and contextualizing each participant's journey on the clinical trial, the app removes the onus of manual correlation, enabling monitors to discern medical patterns and connections with ease. Figure 1 shows how our team was able to integrate all these data sources.

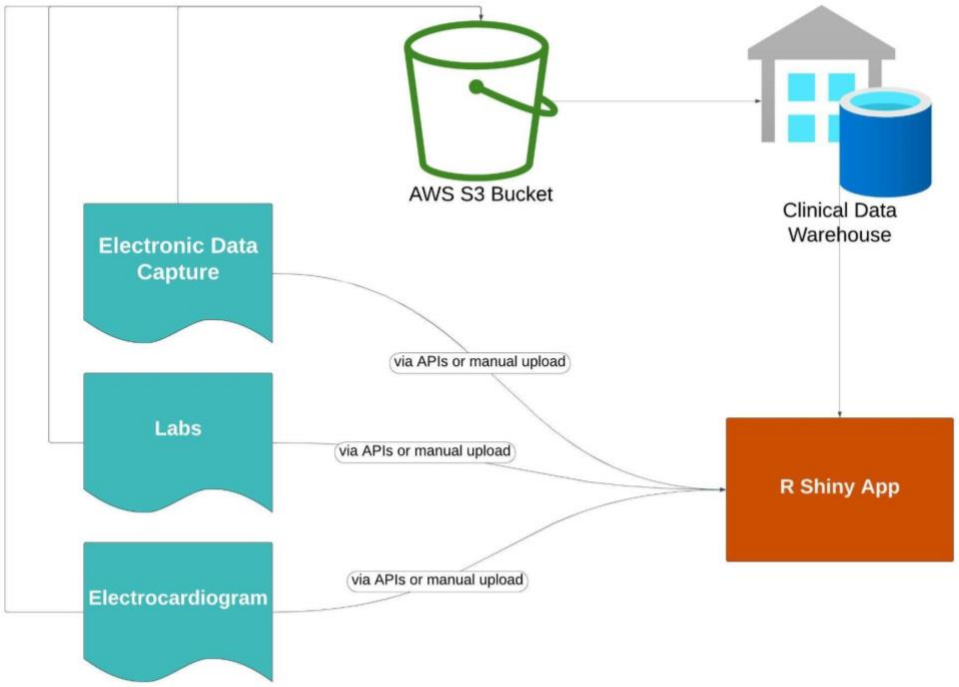


Figure 1. Diagram of the source data flow to the app via automatic data pipelines to an AWS S3 bucket and then a clinical data warehouse. The app also allows data to flow via Application Programming Interfaces (APIs) or manual data uploads.

With the app, data is automatically migrated to a central repository and queried server-side via a clinical data warehouse. However, programmers also still have the option to manually upload and integrate data straight from the source. This seamless fusion not only saves time, but also enhances the accuracy and efficiency of medical decision-making, offering a robust platform for professionals to draw conclusions with confidence and precision.

INTERACTIVITY AND FLEXIBILITY IN DATA VISUALIZATION

The app's architecture was conceived with the traditional format of patient profile listings at its core, allowing for a consolidated view of each participant's information on a single page akin to a digital version of a patient's chart. Through the integration of a ‘selectInput’ feature, medical and safety monitors can effortlessly navigate and select individual trial participants from a dropdown menu. Once a participant’s SubjectId is selected, reactive functions that compile and display the pertinent participant details are triggered. Figure 2 is an example of how this works under the hood to showcase the vitals table for a monitor’s selected SubjectId:

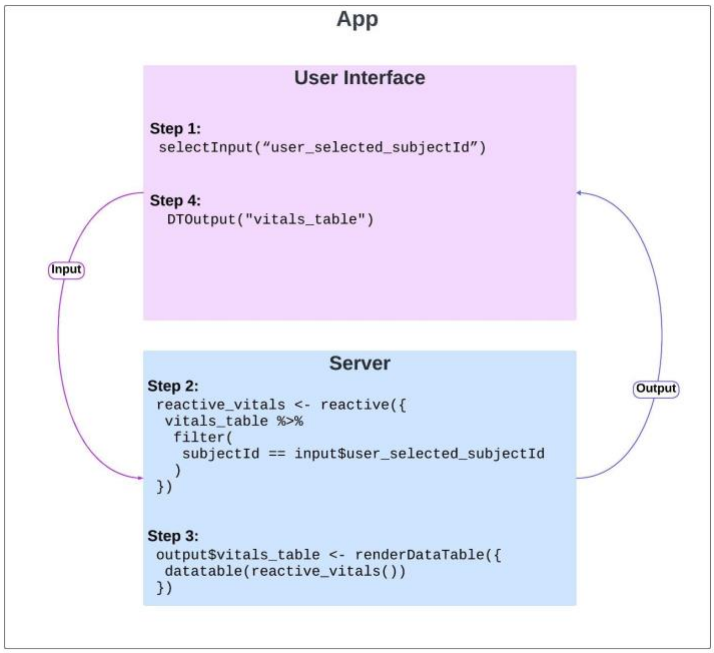
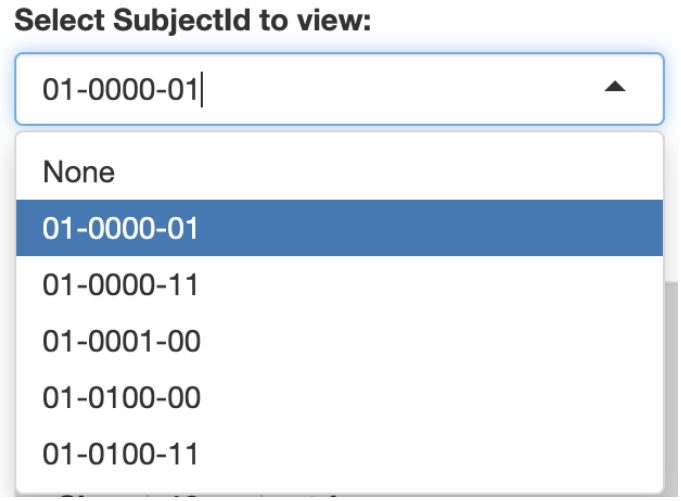
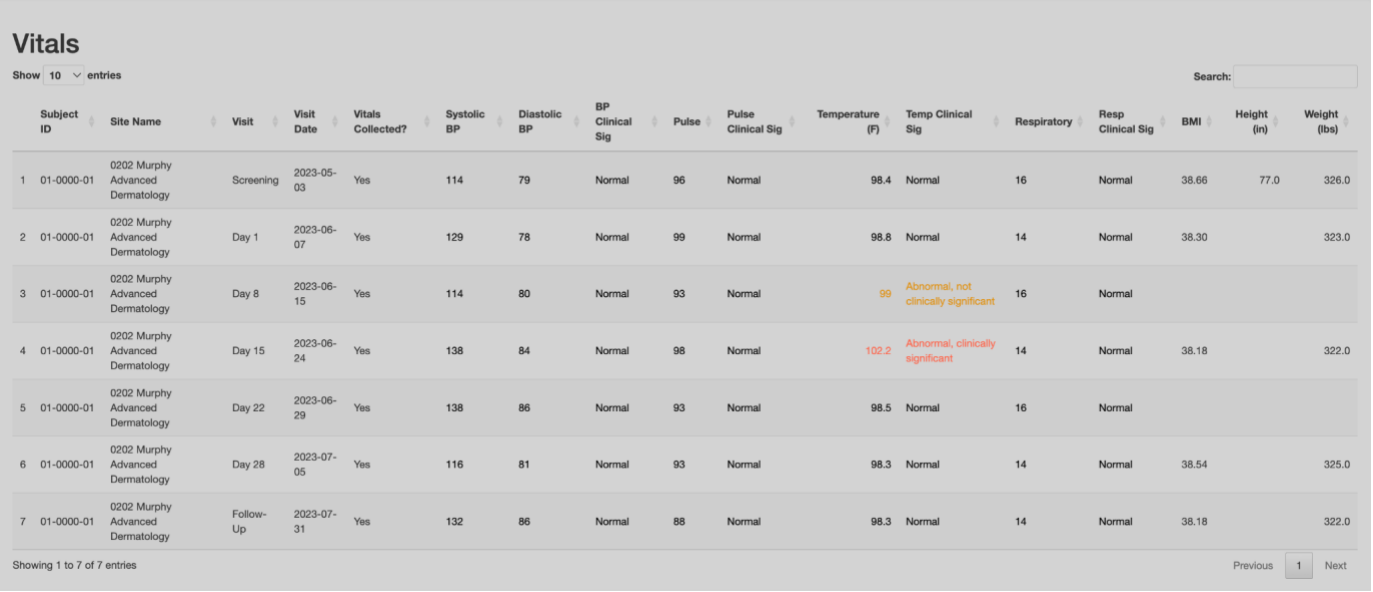


Figure 2. Diagram showing the selectInput functionality in the app's user interface and how it interacts with the reactive functions on the server-side to render the corresponding participant's vitals table.

Below, Output 1 shows the resulting dropdown menu in the app's user interface and Output 2 shows the resulting vitals table for the selected participant:



Output 1. Dropdown menu to select a specific participant's profile in the app.



Vitals

Show 10 entries Search:

	Subject ID	Site Name	Visit	Visit Date	Vitals Collected?	Systolic BP	Diastolic BP	BP Clinical Sig	Pulse	Pulse Clinical Sig	Temperature (F)	Temp Clinical Sig	Respiratory	Resp Clinical Sig	BMI	Height (in)	Weight (lbs)
1	01-0000-01	0202 Murphy Advanced Dermatology	Screening	2023-05-03	Yes	114	79	Normal	96	Normal	98.4	Normal	16	Normal	38.66	77.0	326.0
2	01-0000-01	0202 Murphy Advanced Dermatology	Day 1	2023-06-07	Yes	129	78	Normal	99	Normal	98.8	Normal	14	Normal	38.30		323.0
3	01-0000-01	0202 Murphy Advanced Dermatology	Day 8	2023-06-15	Yes	114	80	Normal	93	Normal	99	Abnormal, not clinically significant	16	Normal			
4	01-0000-01	0202 Murphy Advanced Dermatology	Day 15	2023-06-24	Yes	138	84	Normal	98	Normal	102.2	Abnormal, clinically significant	14	Normal	38.18		322.0
5	01-0000-01	0202 Murphy Advanced Dermatology	Day 22	2023-06-29	Yes	138	86	Normal	93	Normal	98.5	Normal	16	Normal			
6	01-0000-01	0202 Murphy Advanced Dermatology	Day 28	2023-07-05	Yes	116	81	Normal	93	Normal	98.3	Normal	14	Normal	38.54		325.0
7	01-0000-01	0202 Murphy Advanced Dermatology	Follow-Up	2023-07-31	Yes	132	86	Normal	88	Normal	98.3	Normal	14	Normal	38.18		322.0

Showing 1 to 7 of 7 entries Previous 1 Next

Output 2. Vitals table for the selected participant's SubjectId.

The integration of the 'selectInput' feature provides a straightforward and flexible approach to data navigation, mimicking the familiarity of flipping through a patient's chart, but with the added advantage of instant digital retrieval. This system allows for a more dynamic interaction with participant data, allowing monitors to transition from traditional methods to a more advanced, yet user-friendly, digital platform.

Color-Coded Alerts

In addition to making the data more accessible, the app also elevates the presentation of the data, offering a clinically intuitive and well-organized display. A color-coding system within the data tables and graphs was implemented to enhance the utility of the app as well as user engagement. Text indicators are programmed to change color based on factors, such as the participant's status—red for 'Screen Fail' and green for 'Completed Treatment'—while graphs adopt similar visual cues, with abnormal vital and lab results that are clinically significant flagged in red, and those of other possible significance in yellow. This not only heightens visual awareness, but also facilitates a rapid assessment of data significance over time. Figure 3 shows how color-coded alerts draw immediate attention to critical issues and emerging patterns:

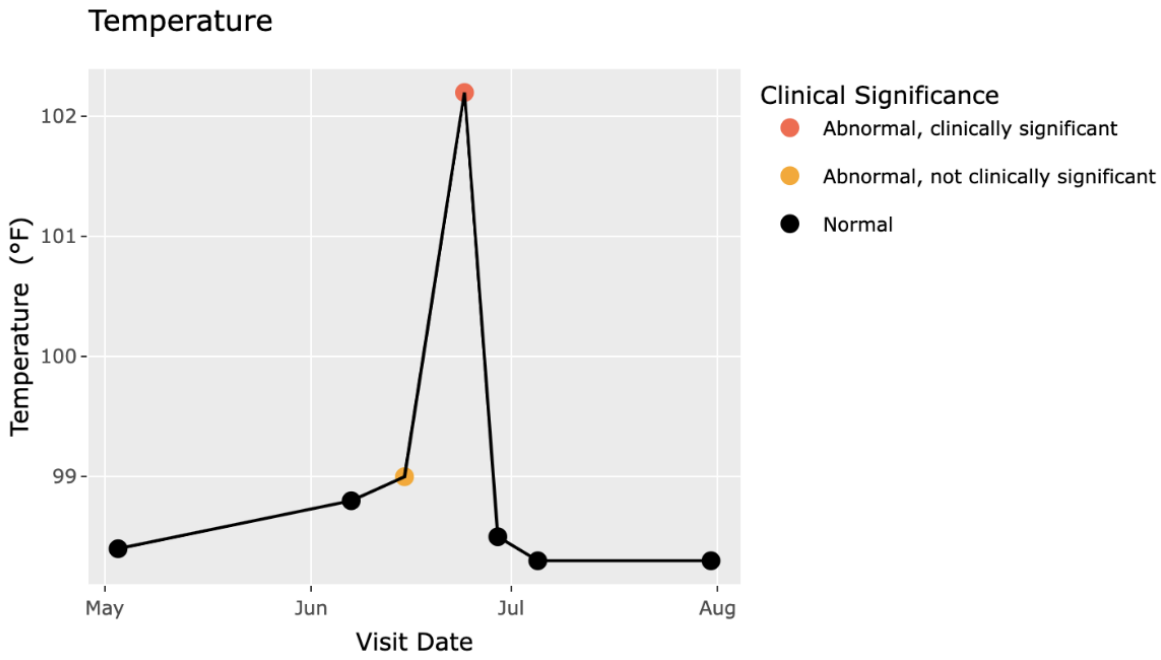


Figure 3. Graph showing a participant's temperature overtime with clinical significance color-coded.

This visual strategy marks a significant advancement over traditional data review methods, facilitating quicker, more intuitive analysis and reducing the time to intervention. The medical monitor can immediately identify that this patient has a fever and look for other vital signs and medications logged at the same time. The safety monitor can check if there were adverse events associated with this event, view other lab results, and make decisions to mitigate risk.

Hovering text

Alongside colorful alerts, the app is enriched with hover text features on graphical elements. Figure 4 shows the concomitant medications graph, which allows for an unobstructed view of underlying data on demand. This addition is aimed at promoting a more fluid and adaptable interaction with the data, streamlining the monitor's experience, and enabling a deeper, more accessible understanding of the information presented.

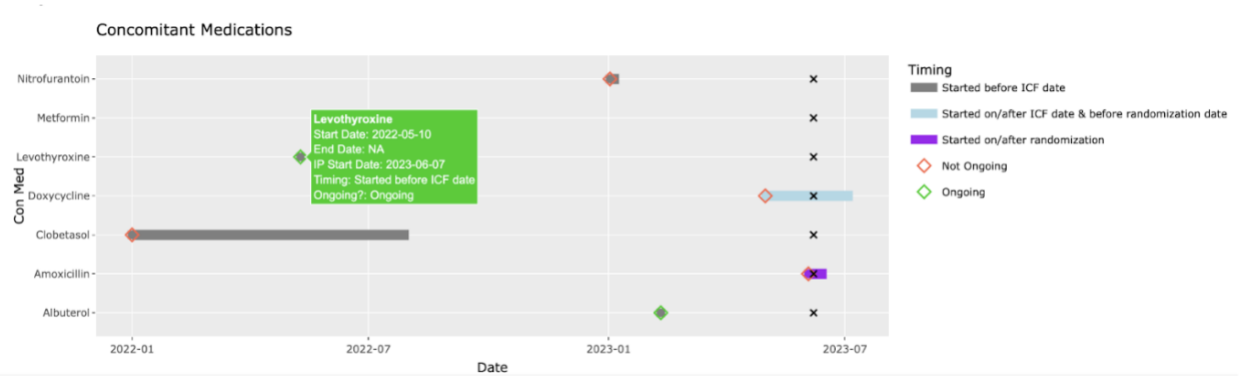


Figure 4. Graph showing a participant's concomitant medications, the timelines for when they were taken, and whether the participant is currently taking the medications.

The data points in the graph denoted by 'x' mark the Investigational Product (IP) start date for the participant. The horizontal bars showcase medication start and end dates and the green and red diamond points show whether the participant is currently taking the medication. Hovering over a datapoint on the graph shows all this contextual information together.

By hovering over the Levothyroxine data point, the monitor can see the exact medication start date, the IP start date, the timing of the medication start date (i.e., before the participant gave informed consent, between informed consent and participant randomization, or on/after participant randomization), and that the participant is currently taking the medication. Rather than flip through multiple tables to determine this information, the monitor can see it altogether and gain additional context that might be needed to make a medical or safety decision.

Temporal Changes

Viewing temporal changes in laboratory data allows monitors to track participant responses and identify trends or potential adverse effects over time. The app takes advantage of real-time data integration by enabling monitors to visualize these temporal changes dynamically and interactively. Figure 5 shows how lab results are reported in both tabular and graphical formats:

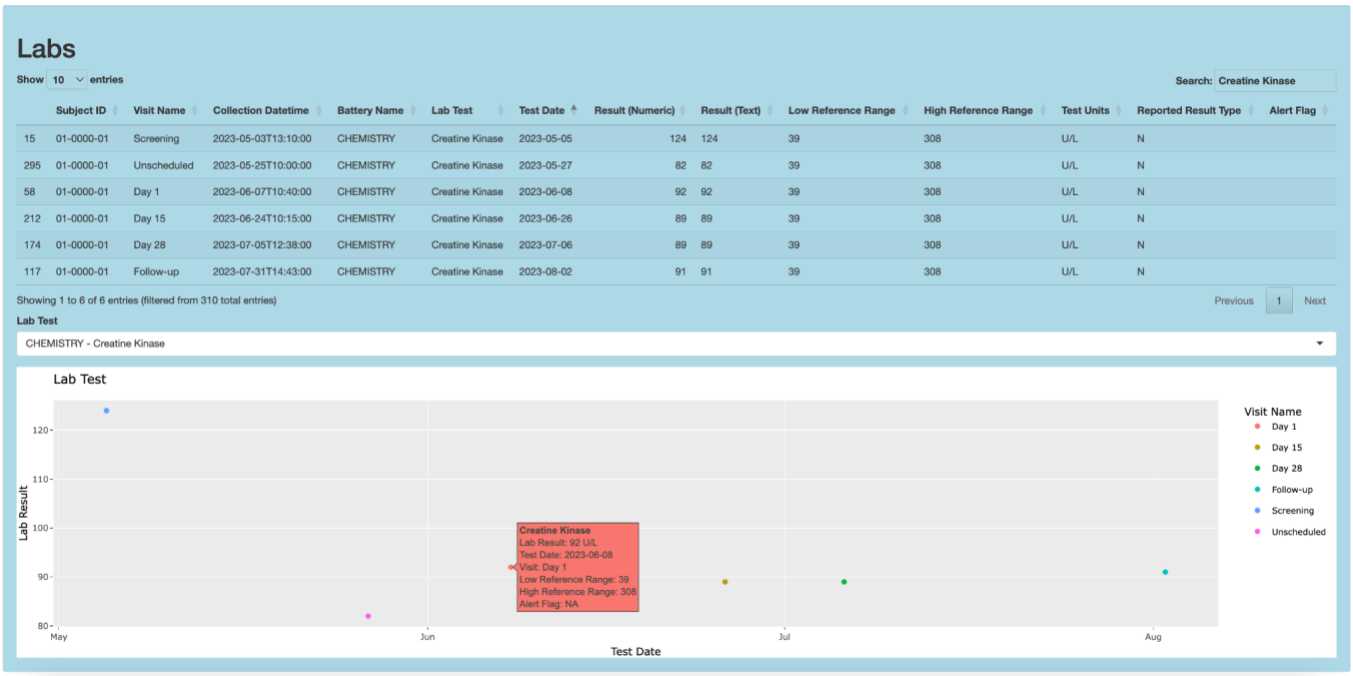


Figure 5: Laboratory data for a specific participant showcased in both an interactive tabular and graphical format.

The Labs table allows the monitor to filter for specific lab tests in the upper right corner and sort by columns, such as 'Test Date'. In addition, the monitor can also visualize the same lab results over time in an interactive graphical format. This flexibility in viewing temporal changes empowers monitors to navigate and analyze complex datasets in ways that resonate with their expertise and process, thereby optimizing the clinical review workflow and potentially improving patient safety.

CONCLUSION

By addressing the inherent limitations and inefficiencies of manual data analysis methods, our Clinical Data Science team was able to build a flexible and interactive tool for patient data visualization. The Patient Profiles R Shiny Application's ability to integrate disparate data sources and display longitudinal changes empowers medical and safety monitors to discern critical data points and trends. The customizable interface and interactive features of the app cater to the specific needs of the monitoring

teams, thereby enhancing their ability to make informed, evidence-based decisions. Overall, this work demonstrates the utility of advanced programming and data visualization methods to automate critical workflows, such as medical and safety monitoring on clinical trials. We are now exploring additional functionality, such as custom alerts, anomaly detection, and data aggregation features, which will further improve efficiency in this space.

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