Paper DV06

Patient Profiles v2.0: Easy and Quick Clinical Trial Insights in Tableau

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ABSTRACT

The patient profile is an important tool during the conduct of clinical trials for many stakeholders. Monitoring adverse events, medications, study dosings, medical history, vital signs, electrocardiograms and laboratory results can lead to meaningful insights.
A picture is worth a thousand words, data visualisations are more powerful than reviewing data in tabular format. Using Tableau® software, we created a patient profile dashboard that combines this CDISC data on a single timeline. Possible relationships between adverse events and medication or other domains are made clearly visible. The dashboards are always up-to-date with the latest changes as monitored at the clinical sites because of our existing automated raw to CDISC SDTM conversion pipeline. Using filters, users can focus on a specific period of time, or quickly switch to a different subject, all dynamically on the same page. Through examples, we illustrate the potential of patient profile dashboards in clinical trial research by providing a holistic view of patient data, facilitating data-driven insights, and fostering collaboration among multidisciplinary teams.
In this paper we will focus on the improvements we have made on this dashboard.

INTRODUCTION

Clinical trials are fundamental to the advancement of medical science and the development of new medicines. Efficient management and analysis of patient data are essential to ensure trial success. Traditional data analysis methods sometimes lack the agility required to extract meaningful insights from complex and diverse clinical trial datasets. Data visibility plays a critical role in clinical trials. It enables pharmaceutical companies and clinical research organizations to effectively monitor trial progress, access up-to-date data, and stay informed about key clinical developments. Data visualization tools, such as Tableau, offer an innovative solution by enabling the creation of dynamic and interactive dashboards. These dashboards provide a comprehensive overview of patient data, enhancing decision-making, and improving patient care.

THE RIGHT TOOL FOR THE JOB

Today there are many data visualisation tools on the market. Tableau, Microsoft PowerBi, Tibco Spotfire or Qlik to name a few. Also more programming language are providing easy ways to visualize data like R Shiny or SAS for instance. These are all tools commonly used in the field of data analysis and visualization, each with its own strengths and considerations.

At SGS we chose for Tableau for a couple of reasons. Tableau is a widely used data visualization tool known for its user-friendly interface and powerful visualization capabilities. It allows for creating interactive and dynamic dashboards without requiring extensive programming knowledge. Some advantages of using off-the-shelf data visualization software like Tableau for dashboard creation in clinical trial research:

Ease of use and rapid prototyping: The drag-and-drop interface makes it accessible to a wide range of users, including non-programmers. With the quick prototyping and iteration of dashboards, we can rapidly create and modify visualisations. This is especially useful when we are working with the client to develop custom dashboards. We can quickly show some mock dashboards based on dummy data to get everyone on the same track as quickly as possible.

Interactivity: Tableau offers a variety of interactive features, such as filters, tooltips, and drill-down capabilities. These features enhance data exploration and facilitate on-the-fly data analysis.

Data Connection: the software supports the connection to various data sources including databases, spreadsheets cloud-based platforms and SAS datasets. This is essential for integrating diverse clinical trial data.

While you could argue that programming language like R can offer dashboards with more complexity because users can leverage the full capabilities of R programming to pre-process data, perform statistical analyses, many off-the-shelf data visualization tools also supports and easily integrates Python and R code nowadays. It generally requires a

stronger programming background compared to Tableau and therefore has a steeper learning curve. Your choice ultimately depends on the specific needs and skill sets of the clinical trial research team.

PATIENT PROFILE DASHBORD

A patient profile dashboard is a visual representation of comprehensive individual patient-related information, presented in an interactive and user-friendly format. In the context of clinical trial research, a patient profile dashboard serves as a centralized platform to aggregate, analyze, and monitor various aspects of patient data collected during the course of a clinical trial with the focus on core safety data to review the subject safety during study. It offers a holistic view of each patient's adverse events (AE), concomitant medications (CM), medical history (MH), treatment progression, procedures (vital signs, electrocardiography,…), study visits (SV), randomization (cohorts, groups,…), laboratory data (LB) and other relevant information. The primary goal of a patient profile dashboard is to provide researchers, clinicians, and other stakeholders with a clear and concise overview of individual patient journeys within the trial and can be used for data cleaning, medical safety review / safety meetings, medical monitoring or patient narratives and more.

DEVELOPMENT OF PATIENT PROFILE DASHBOARDS

2.1 Data Integration and Preparation:

The foundation of effective patient profile dashboards lies in the integration and preparation of diverse data sources, including patient demographics (DM), laboratory results (LB), and treatment information (EX/EC), concomitant medications (CM), ... Data preprocessing involves cleaning, transforming, and structuring the data to facilitate meaningful visualizations. For our standard patient profile dashboard, we have chosen to use the SDTM SAS datasets as source for our standard patient profile dashboard. This means we take the SDTM DM, AE, CM, EX/EC, MH, SV, LB, … and accompanying SUPP-- domains as source.

2.2 Dashboard quality, security and validation

Designing patient profile dashboards involves careful consideration of user requirements and visualization best practices. Interactive features such as filters, parameter controls, and drill-down capabilities empower users to explore data from various angles. To ensure the quality of our dashboards, driven by our data visualization SOP, we follow the Software Development Life Cycle (SDLC) process when developing dashboards. Meaning that for each set of dashboards we carefully analyse the request from the client, plan, design and develop the dashboards; test, validate and deploy them in production. The lifecycle of such dashboards is all documented in the SDLC system.

We have a **validation** process that starts at the eCRF up to the DV dashboard. This means that source data for the dashboard are already validated SDTM files, by a different Quality Control (QC) process. The dashboards themselves exist in three different environments for development, testing and production. The creation of the dashboards happens in the development stage, and validation is performed after moving to the testing stage. Both processes, creation and validation are defined by an SOP. Test data is entered in the eCRF, and this QC source data is then compared to the dashboard output for validation. The real benefit of our standard dashboards based on SDTM datasets is that validated dashboards can be re-used for other projects without the need for re-validation, as long as the same data structure is used, and no dashboard updates were necessary. Ultimately, this means that we can deploy the standard dashboards quickly after SDTM datasets are available which in our process is not long after first patient in see Figure 1. And as our raw data to SDTM conversion is an automated process, this leads to early & real-time availability of the dashboards which are up to date with the latest eCRF and other external data.

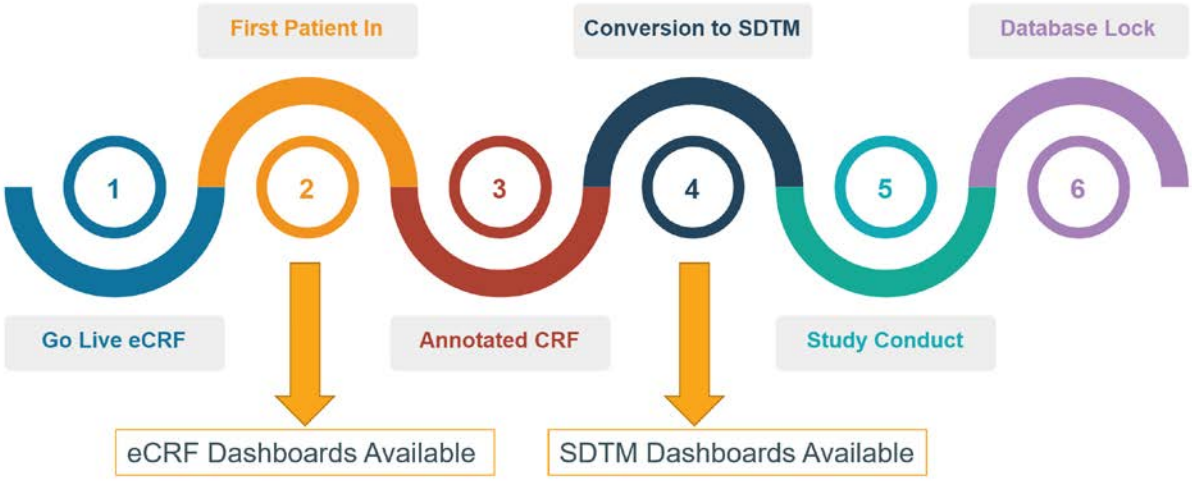

Figure 1: Availability of dashboards during setup of a trial

Security is another important topic. With Tableau we can guaranty strictly separated environments per client. In Tableau-speak, the term "site" is used as a collection of users, groups and content (workbooks, data, sources) that's walled off from any other groups and content. Another way to say this is that Tableau Server supports multi-tenancy by allowing administrators to create sites on the server for multiple sets of users and content.
All server content is published, accessed, and managed on a per-site basis. Each site has its own URL and its own set of users. Each site's content (projects, workbooks, and data sources) is completely segregated from content on other sites.

VERSION 2.0 OF PATIENT PROFILES

In its initial iteration, version 1.0 of our Patient Profile Data Visualization Dashboard served as a valuable tool for safety data review, but it had its limitations. Two primary challenges were identified:

Lack of Flexibility: Version 1 required substantial preparatory work to harmonize data sources from various domains into a unified structure for the dashboard. This rigidity made it challenging to integrate new domains seamlessly, hindering the adaptability and scalability of the system. Another disadvantage of the harmonized data source was that we could only provide a limited amount of additional information in the views and accompanying tooltips, missing e.g the toxicity grade in the adverse events view or the indication in the concomitant medication view.

Limited User Interactivity: User interaction within the first version was constrained. On domain level it was not possible for the end user to filter on specific events, findings or tests of interest (e.g. only show specific adverse events of concomitant medication) meaning you always end up with the complete overview of all tests and could potentially get lost in the details that aren't necessary applicable for your review.

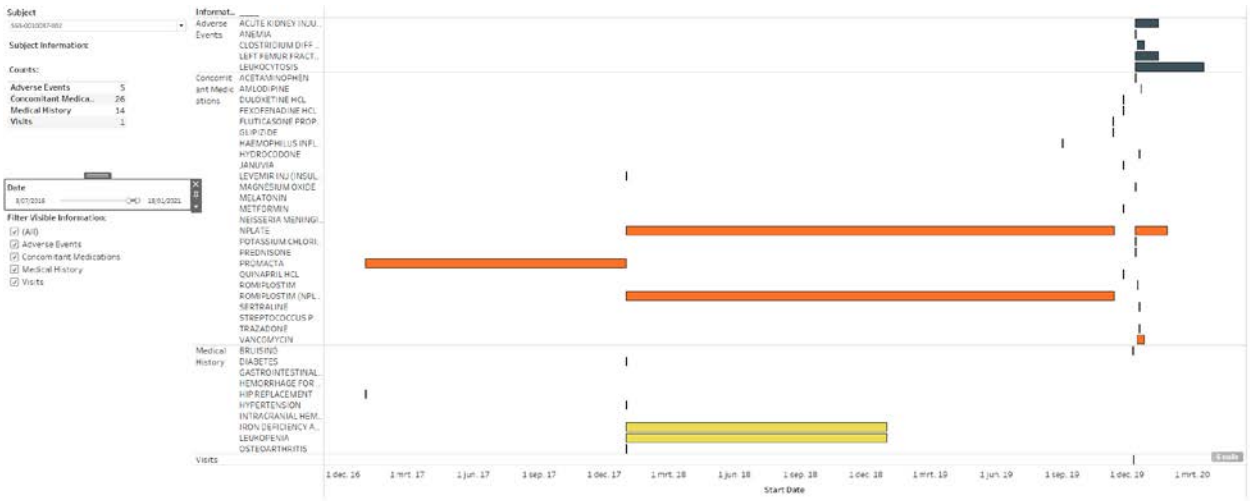

Figure 2:Patient Profile Dashboard v1.0

What's new in version 2.0

In response to the limitations in version 1.0, we have invested in the development of Patient Profile Data Visualization Dashboard Version 2.0 (Figure 3), addressing these key issues and introducing several notable improvements:

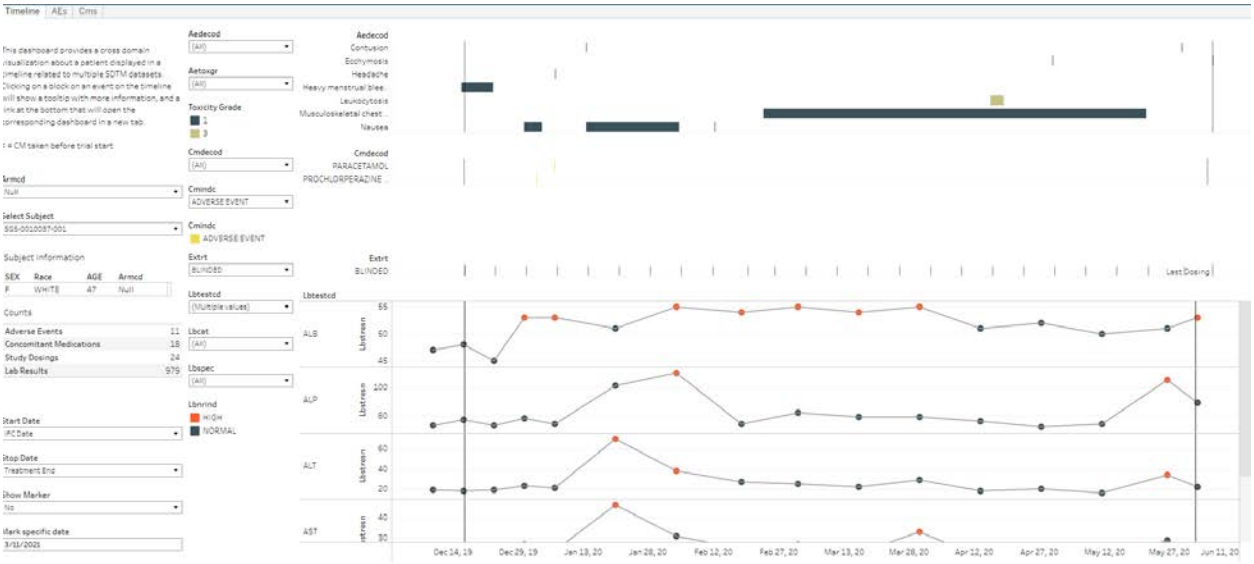

Figure 3: Patient Profile Dashboard v2.0

Enhanced Flexibility

Version 2.0 has been engineered with a modular architecture (Figure 4), allowing for the effortless integration of new domains and data sources. This means that we have created one dashboard that consists of several separate dashboards per domain. This flexibility streamlines the process of expanding the dataset, ensuring that user can readily access a broader spectrum of patient information. One of the big advantages of the first version was that all data was visible on one timeline due to the fact that all data from the different domains were integrated in one file. A big challenge of the second version was to make sure that the now separate dashboards would sync in time with all other dashboards.

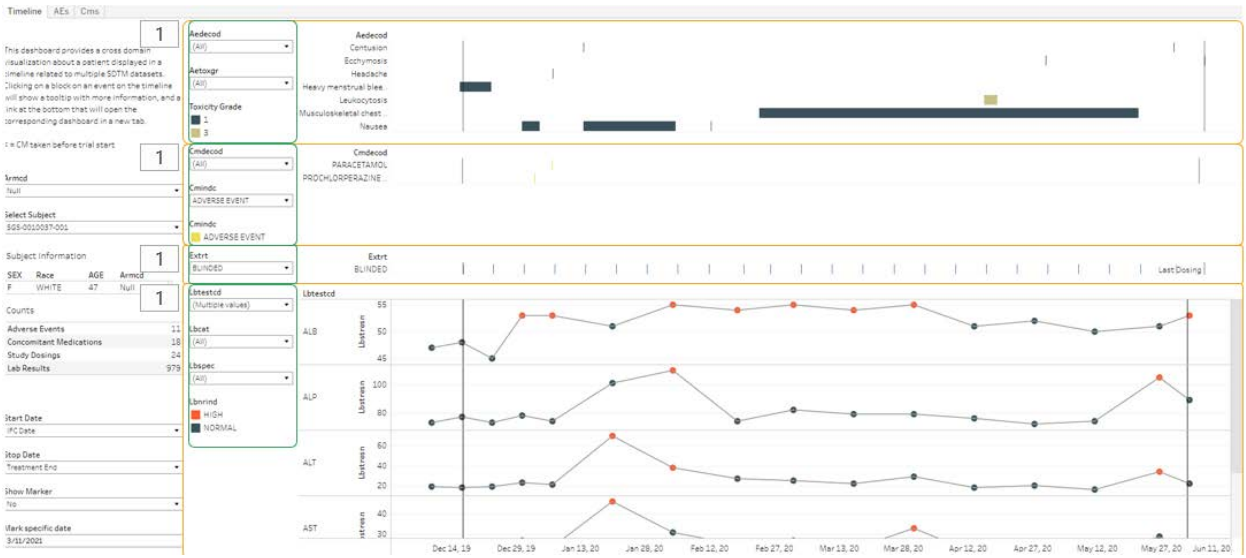

Figure 4: Modular architecture

Interactive User Experience

We have enriched the user experience by introducing advanced interactive features. Users can now engage more deeply with the data, enabling them to explore, analyse, and extract insights intuitively. The upgraded interface provides domain specific customizable views, dynamic filtering options (Figure 5), and real-time data interactions, empowering users to make informed decisions swiftly. As all domain dashboards are now actually separate dashboards, we were able to provide the user with domain specific views and filter options. Tackling the issue we had with v1.0, the user can now select the findings and test that are of interest, rather than having to deal with too much information. A great benefit in Tableau, is that the user can save all the selected filters, meaning that the next time the user returns to the patient profile dashboards, all filters will be saved but the data will be refreshed. Those saved settings can easily be shared with team members, so they can immediately benefit from a fully customised patient profile.

Improved Performance

Version 2.0 boasts enhanced performance and speed, ensuring that data retrieval and visualization occur with lightning-fast responsiveness. This improvement allows for smoother and more efficient data analysis, promoting productivity in clinical trial workflows.

Improved drill down capabilities

Another benefit of this modular architecture is that it allows the user to dive deeper into the raw SDTM data straight from specific datapoints from within the patient profile dashboard. E.g. by clicking on a vital signs result, Tableau will navigate to a vital signs (VS) specific table containing the VS SDTM data already filtered on your subject where the user can find all available information.

Figure 5:Improved user interaction per domain

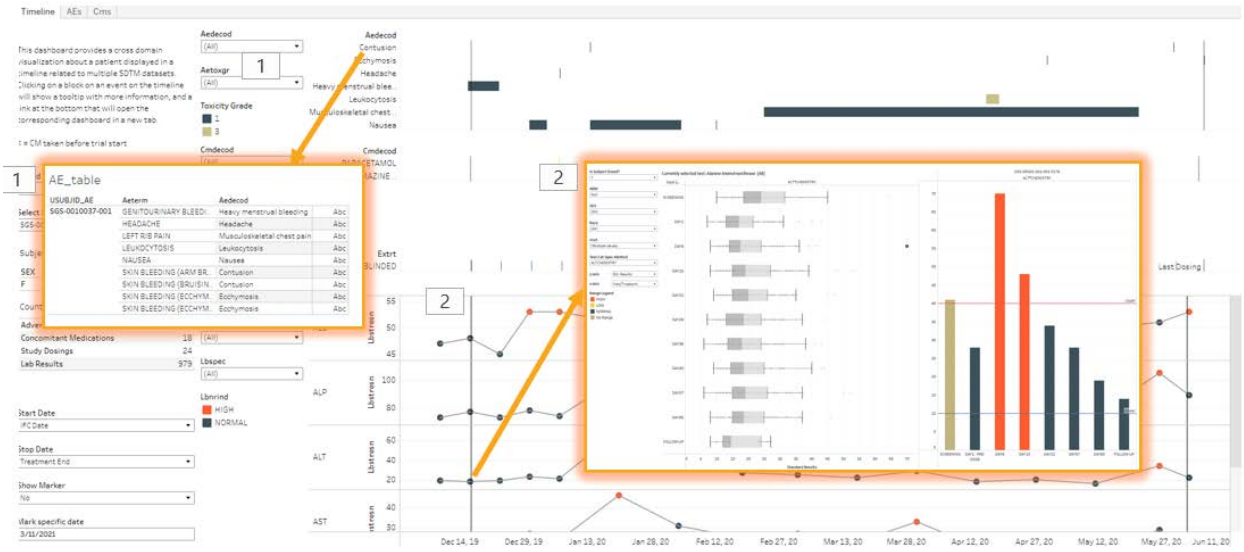

Figure 6: Enhanced drilldown

FUTURE DIRECTION

The evolution of patient profile dashboards holds promise for further enhancing clinical trial research. Future developments may involve integration with artificial intelligence and machine learning algorithms for predictive analytics. Also here Tableau could potentially play its part, powered by machine learning (ML), Einstein Discovery delivers predictions and recommendations within Tableau workflows. Einstein Discovery offers an intuitive, no-code environment that empowers anyone to quickly and confidently create powerful predictive models without needing to write algorithms.

CONCLUSION

The development and evolution of our patient profile dashboard has been a remarkable journey, marked by significant improvements from version 1.0 to version 2.0. Our commitment to enhancing flexibility, adaptability, scalability and interactivity has resulted in a tool that meets the demands of clinical research data analysis. Another standout feature is the use of SDTM as a data source in our dashboard. This means that it can be easily deployed across a wide range of clinical trials, streamlining the integration of data and increasing its utility in various research contexts. By allowing end users to customize the dashboard to their specific needs, this standard dashboard becomes a highly adaptable and indispensable asset. This adaptability is a significant advantage that sets our dashboard apart from others.

CONTACT INFORMATION

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

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