Paper DV04

Safety at a Glance: Enhancing Participant Monitoring in Oncology Trials with Data Visualisation

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ABSTRACT

Oncology is among the most complex therapeutic areas in clinical trials. Participants often have compromised health, making them susceptible to adverse events, sensitive to interactions with concomitant medications, and prone to having abnormal assessment results. To ensure patient safety, it is essential to have a system in place that provides comprehensive overview of their data. This enables early detection and accurate evaluation of critical findings, allowing for timely intervention.

This presentation will demonstrate how data visualisation dashboards using Tableau can be used to facilitate data and safety review in oncology trials, while also discussing limitations that must be considered. Our approach combines the use of reusable standardised dashboards, including domain-specific views and patient profiles, together with customized dashboards, tailored to trial specific requirements (e.g., different disease evaluation criteria). This setup ensures that reviewers have real-time overview of clear, interactive visuals, enabling rapid identification of safety concerns and prompt appropriate action.

INTRODUCTION

Oncology is the biggest therapeutic area amongst clinical trials, making up ~25% of all studies[1]. These trials often have complex design, that involves frequent visits, assessments, and procedures. They also impose strict eligibility criteria. Participants enrolled in the study often have compromised health, making them more susceptible to adverse events and sensitive to interactions with concomitant medications. In addition to this, they are also prone to abnormal assessment results. All those factors result in high data volume and complexity. It is important for patient safety that medical reviewers keep a close eye on the data, such as disease history, (Serious) Adverse Events, Dose-Limiting Toxicities, assessment results (laboratory values, vital signs, ECG readings, performance status …), procedures, study drug administration information, concomitant medications and supportive care and disease response and progression throughout the trial. To ensure that, an efficient review strategy is needed, that provides a comprehensive overview and allows for quick review of most important parameters, using the most recent data available.

The data review can be performed through different platforms, the most common review methods being direct review in the EDC system as well as via programmed reports and tables. Both review methods have their strong and weak points:

Review method	Advantages	Disadvantages
Review directly in EDC	• Immediate access to new or updated data and queries • Quick cleaning – medical reviewer and site/CRA work in the same system • Broad overview of data per patient – all forms	• Limited cross-patient overview • Limited cross-domain overview • Not all data available (external vendor data) • Time-consuming review
Review of programmed reports/tables	• Display multiple subjects/visits/domains together • Some flexibility in display options – sorting, filtering, … • Possibility to combine data sources (e.g. EDC and external vendor data)	• Depending on the source – data not always up-to-date • Not always easy to spot patterns/outliers • Time-consuming review, if multiple large listings

As an alternative solution, at SGS we have developed data visualisation dashboards using Tableau, to support the data and safety review both by our internal teams, as well as external end users.

SGS SOLUTION – TABLEAU DATA VISUALISATION DASHBOARDS

Nowadays, a wide range of data visualisation tools are available on the market, and several programming languages offer powerful data visualisation capabilities. Each tool/language comes with its own strengths, limitations and implementation considerations.

At SGS, we selected Tableau as the data visualisation platform for presenting clinical data to clients and medical professionals for several reasons:

- User-friendly interface – the dashboards are intuitive and straightforward for end users to navigate.
- Interactive and dynamic dashboards – the output of the dashboards can be tailored with the use of filters, to display the data subsets that are most relevant at the moment (e.g., specific subject groups or data meeting particular parameter(s) criteria). Other functionalities, such as tooltips and drill-down features, enhance and facilitate the data exploration and analysis.
- Drag and drop interface – it makes Tableau accessible to a wide range of users, including those without extensive programming background, and easier to learn. Additionally, it allows for quick creation and modification of the dashboards, which is useful when e.g. we want to share some mock dashboards with an end user, to make sure we are on the same page about the visualisations to be provided.
- Flexible and customisable dashboards – depending on the situation, already existing dashboards can be modified to suit the needs of the end user, or new dashboards can be created.
- Various data sources possible – the dashboards can be based on diverse data sources (or a combination of different sources), including e.g., SDTM, raw EDC data, third party transfers in different formats, …
- Data protection/security – Tableau guarantees strict separation of client environments through the use of, so called, sites. A site represents a collection of users, groups, and content (such as workbooks and data sources) that is fully isolated from any other sites on the server.

DASHBOARDS STRATEGY

To meet the aforementioned review needs of oncology trials, SGS has developed different types of dashboards, described in detail below.

- **Standard dashboards**

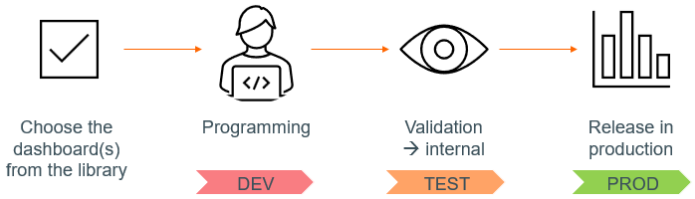
  The concept behind standard dashboards was to build a library of reusable visualisations covering domains and scenarios commonly encountered across different trials and therapeutic areas. These dashboards were designed to support diverse user needs, such as data cleaning, medical safety review and safety meetings, medical monitoring, and patient narratives.

  Our preferred and most efficient approach to develop standard dashboards is to base them on SDTM data. Due to the standardised nature of SDTM, these dashboards can be reused across multiple studies and accommodate a wide range of end users. An additional benefit is that once such dashboard has been validated, it requires minimal validation when deploying it in a new study (taking into account trial specifics, that might cause some differences compared to the dummy data used in the library dashboard). As a result, dashboards can be released to production shortly after the SDTM production datasets become available (validation of the source SDTM data itself is performed through a separate Quality Control (QC) process).

  The process for setting up the standard dashboards in the study consists of following steps:

  - The end user chooses the dashboards from the library, to be used in the study.
  - SGS Data Visualisation Creator programs the dashboards, using the validated trial SDTM test data – in the development environment.
  - SGS Data Visualisation Coordinator validates the dashboards, based on the pre-specified test plan – in the test environment.
  - SGS Data Visualisation Creator releases the dashboards in production environment.

Figure 1. Process flow of standard dashboards in a trial.



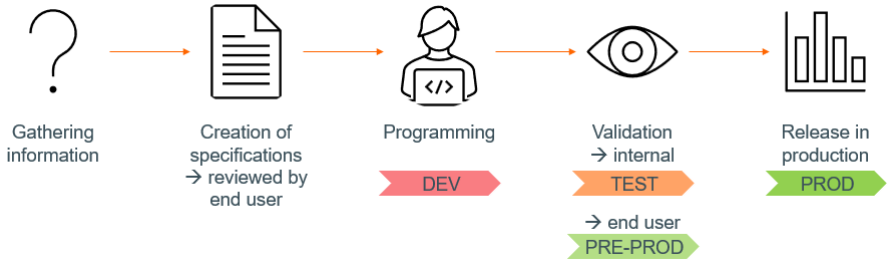
- **Custom dashboards**

  There are situations, in which an end user might need other visualisations than what is already covered in the standard dashboards library. Custom dashboards can take many different forms and address various needs, depending on the trial characteristics and the purpose of the dashboard. They can be based on an

existing standard dashboard that gets modified or new dashboards can be programmed from scratch. Custom dashboards can be based on various data sources i.e. not only SDTM, but also raw EDC data, data transfer from a third party in different formats or on a combination of different data sources.
The process for setting up the custom dashboards in the study is more complex than in case of the standard dashboards and includes the steps described below.

- SGS Data Visualisation team gathers information on end-user needs, such as what data should be included in the dashboard, how it should be displayed (e.g., type of graph, filters, …), data source, any study timeline constraints, and the specific tasks or purposes for which the dashboard will be used within the study.
  After receiving the information, the Data Visualisation team discusses the approach and assesses potential challenges and issues. If deeper insight into trial details is required, Data Visualisation Coordinator reaches out to other teams involved in the project (Data Management, Medical Safety, Electronic Data Collection, etc.) to gather their expertise. If necessary, additional discussions with the end user can be scheduled.
- SGS Data Visualisation Coordinator creates specifications, describing the content, design and working principle of the custom dashboard. Often, especially for more complex dashboards, mock visualisations are included in the specifications, to provide better insight to the end user on how the final dashboard will look like.
  The specifications are sent to end user for review, and once they are approved, the SGS Data Visualisation team continues to the next step.
- SGS Data Visualisation Creator programs the dashboards, using the validated test data from the target source – in the development environment.
- SGS Data Visualisation Coordinator validates the dashboards, based on the pre-specified test plan in the test environment. The dashboard is verified against the specifications to ensure that all agreed-upon visualizations and functionalities have been implemented. The content is validated using test data to confirm that all data is loaded into the correct locations, no information is missing, and any data manipulations performed during preprocessing (e.g., calculating average values for repeated measurements) are correctly applied. In addition, the practical usability of the dashboard is checked, including verification that filters function correctly, visualizations are readable, and legends are clear.
  After internal validation, dashboards are shared with end user for validation in a special pre-production environment. During the validation, team members can verify if the dashboard fulfils all their needs, get acquainted with it and get a real-life feeling of working with it. In case of any comments, the process restarts from the dashboard programming, until the dashboard is approved.
- SGS Data Visualisation Creator releases the dashboards in production environment.

Figure 2. Process flow of custom dashboards in a trial.



Both standard and custom dashboards can be divided into three groups, based on their content:

- **Domain-specific dashboards:** Provide an overview of data from a specific domain (e.g., adverse events, concomitant medications, lab results, vital signs, …) for all subjects in the study. With the use of filters, end user can choose only a specific subset of subject population to be displayed, for example only dosed subjects, or subjects belonging to a specific cohort.
- **Cross-domain dashboards:** Display information from different domains and potential relationships between them. Depending on the dashboard and domains involved, they can provide an overview of all subjects (with filters to choose specific subject subsets), or information for one chosen subject at the time. Example dashboards: adverse events/concomitant medications/medical history, adverse events with lab results, tumour results with disease response, …
- **Patient profiles:** Provide comprehensive overview of data from multiple domains (adverse events, medical history, concomitant medications, study drug exposure, ECG results, vital signs, lab results) on a timeline, per subject. Additionally, some help tables are included for the ease of review.

DATA VISUALISATION DASHBOARDS IN AN ONCOLOGY TRIAL

In order to achieve a comprehensive overview of study data and provide the end user the possibility to perform an in-depth review, multiple dashboards need to be used. Various reviewers have their own specific working methodology and might prefer slightly different combination of dashboards, but generally from our experience, their choice consists of several standard dashboard (of all content types, as described above) and often a couple of custom dashboards, tailored to the trial specifics, such as different disease evaluation criteria. An example set of dashboards used for an oncology study looks as following:

Standard dashboards	**Custom dashboards**
Domain-specific dashboards: • Adverse events • Medical history • Concomitant medications • Procedures • Physical examination • Lab results • ECG • Vital signs • Study drug exposure	Domain-specific dashboards: • Cardiovascular system results • Performance status
Cross-domain dashboards: • Adverse events/concomitant medications/medical history	Cross-domain dashboards: • Initial diagnosis and cancer history • Waterfall plot (tumour results/disease response) • Spider plot (tumour results/disease response) • Swimmer plot (timeline of disease response/disposition events)
Patient Profile • Timeline: adverse events, medical history, concomitant medications, study drug exposure, ECG results, vital signs, lab results	

Below several examples of the dashboards are shown, with some of their functionalities depicted.

Figure 3. Domain-specific dashboard – Adverse Events Overview. The output of the dashboard can be adapted, using filters relating to the subset of subjects (orange box) or to the parameters of the AE-s (purple box).

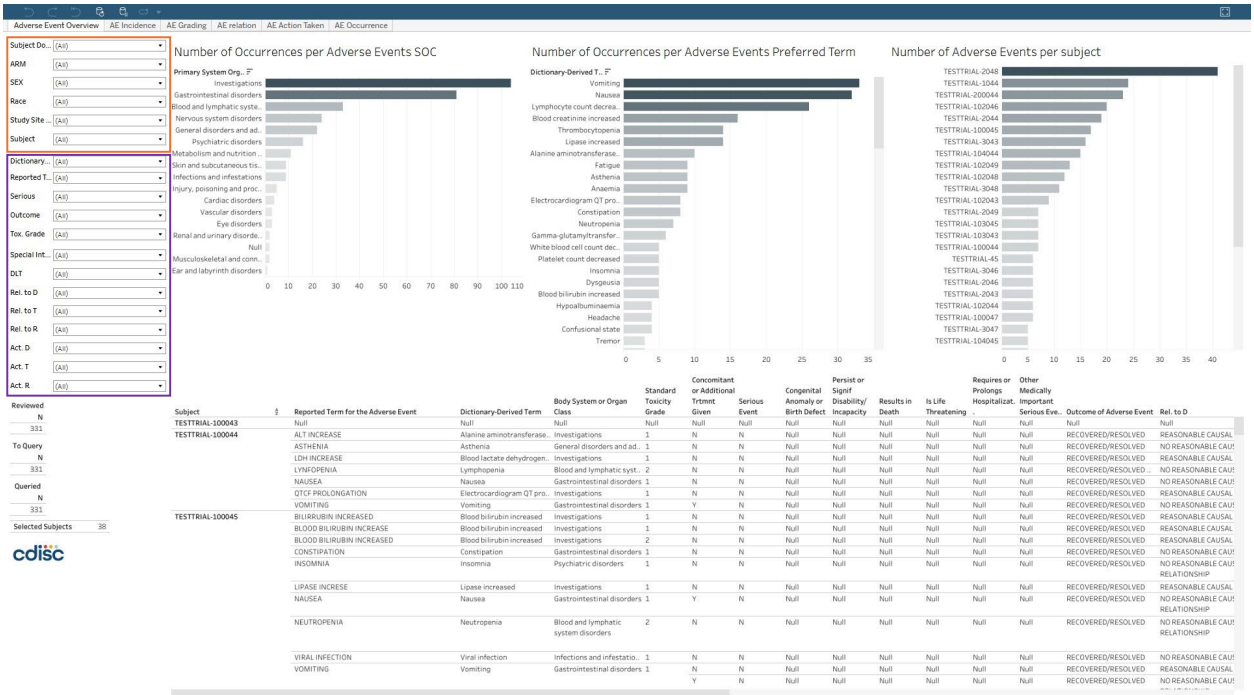


Figure 4. Domain-specific dashboard – Adverse Events Overview, after applying filters to display only SAE-s (purple box) from a specific cohort (orange box).

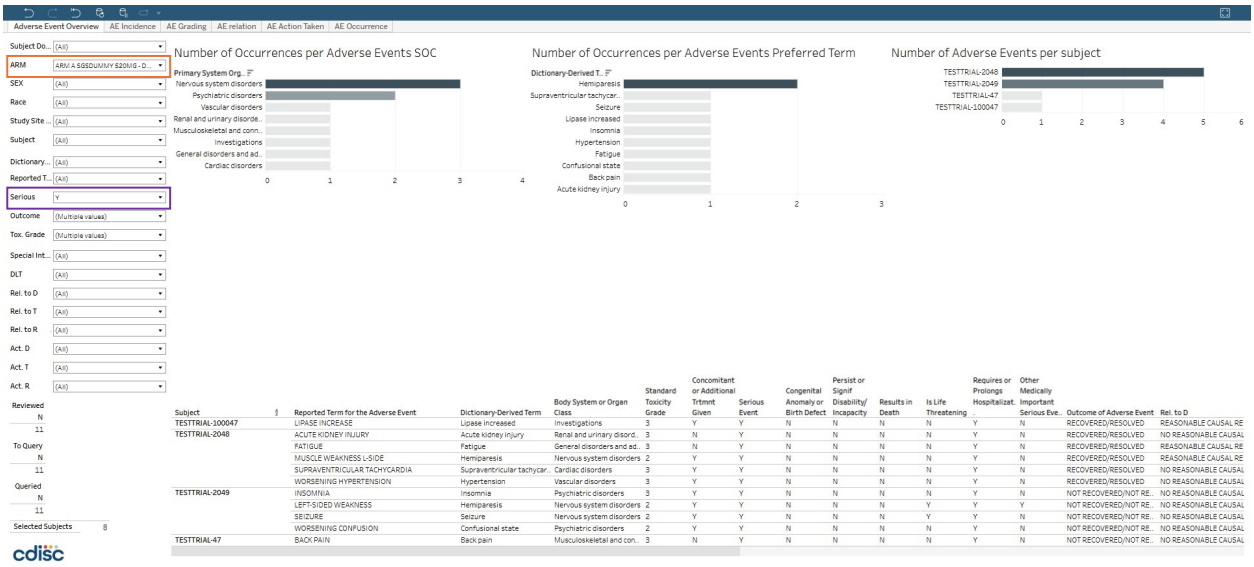


Figure 5. Domain-specific dashboard – Lab Overview, with colour code indicating high/normal/low results, the normal ranges and the average line of displayed results.

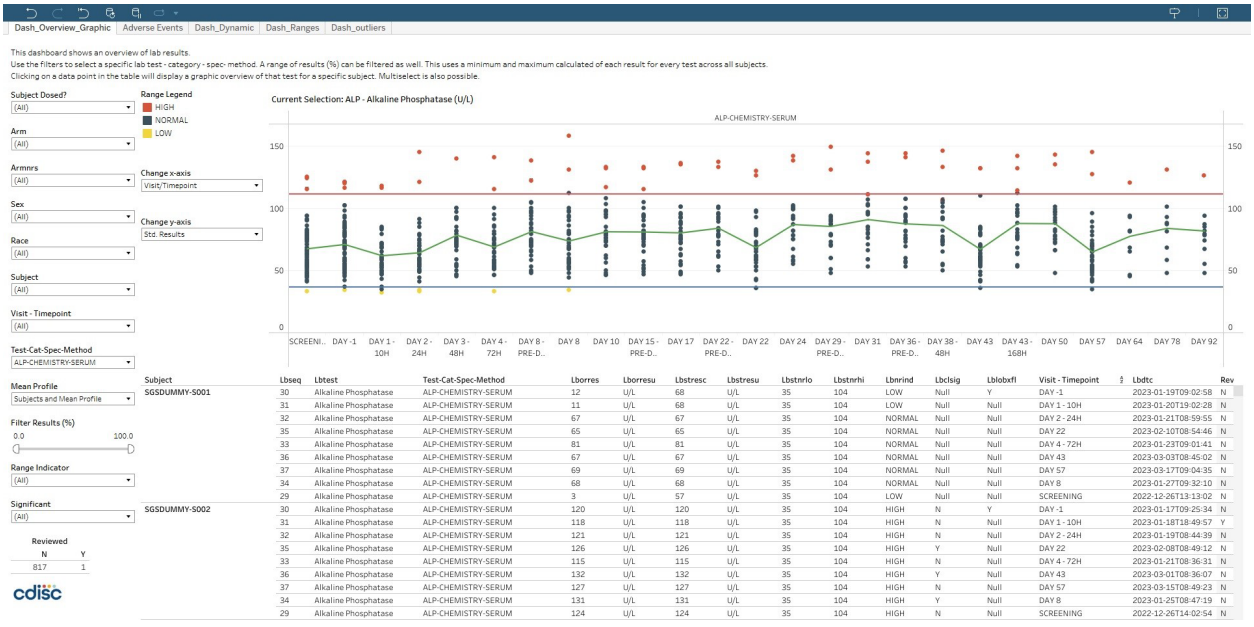


Figure 6. Domain-specific dashboard – Lab Overview. By hovering over a data point, a tooltip with additional information appears.

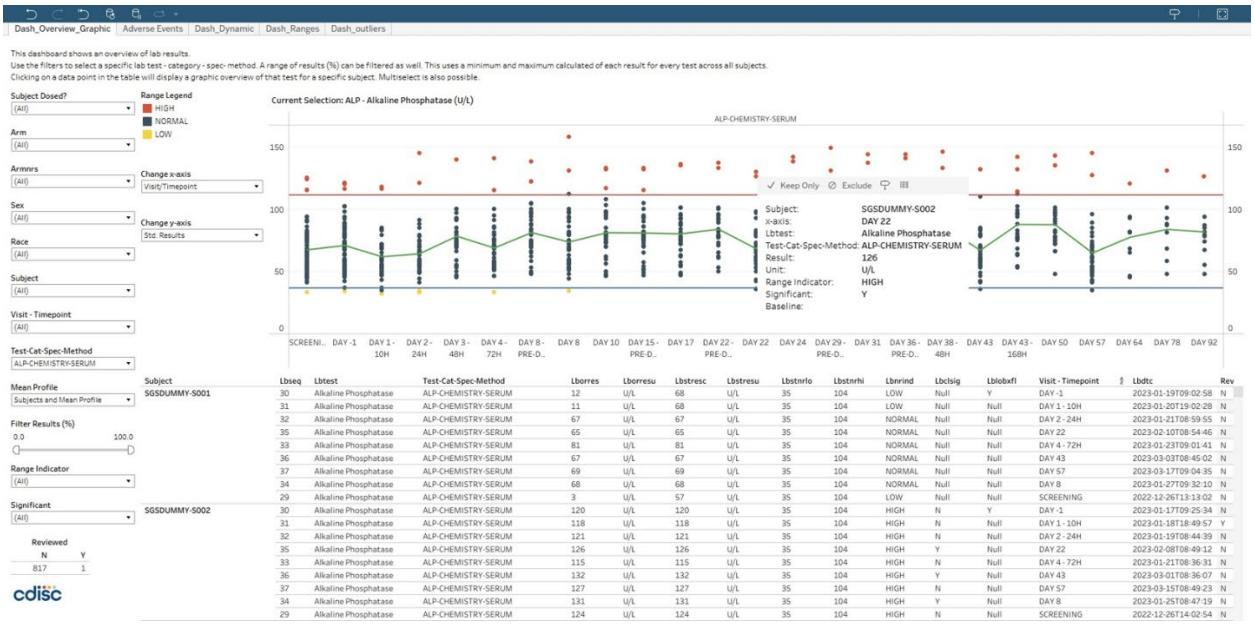


Figure 7. Cross-domain dashboard – AE/CM/MH. The dashboard includes RELREC connections, by clicking e.g. on an AE, the dashboard is filtered to only show CMs linked to this AE (and the other way around, same principle applies to MH-CM relationships) – see Figure 8.

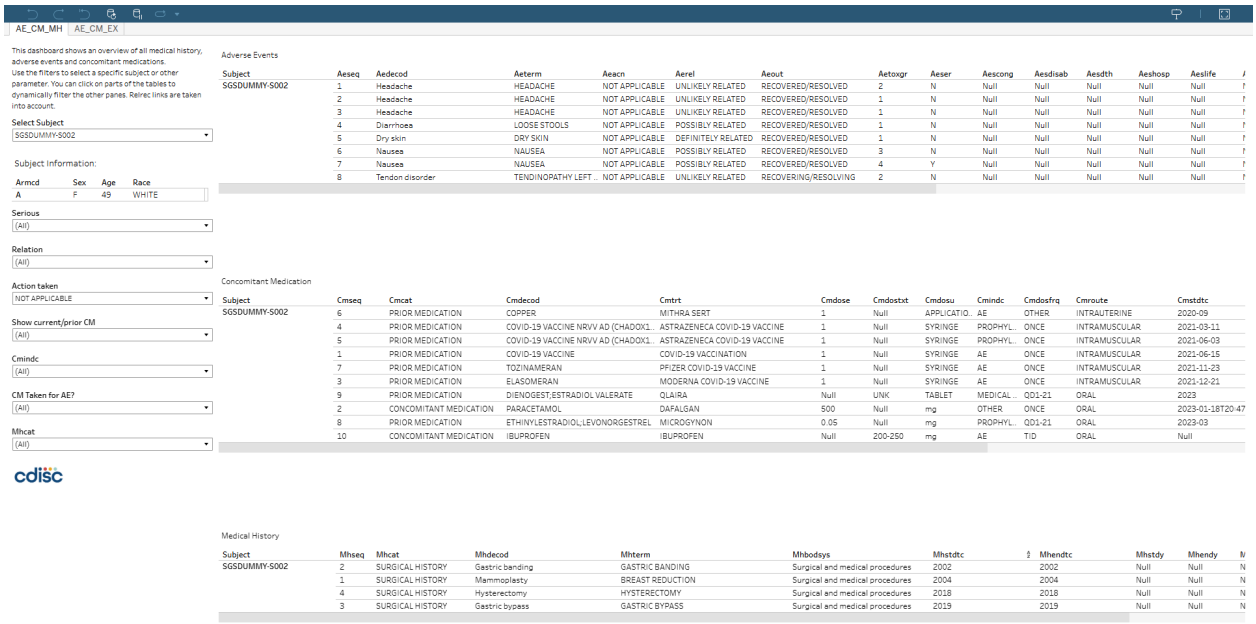


Figure 8. Cross-domain dashboard – AE/CM/MH, filtered to show the CM linked to the chosen AE.

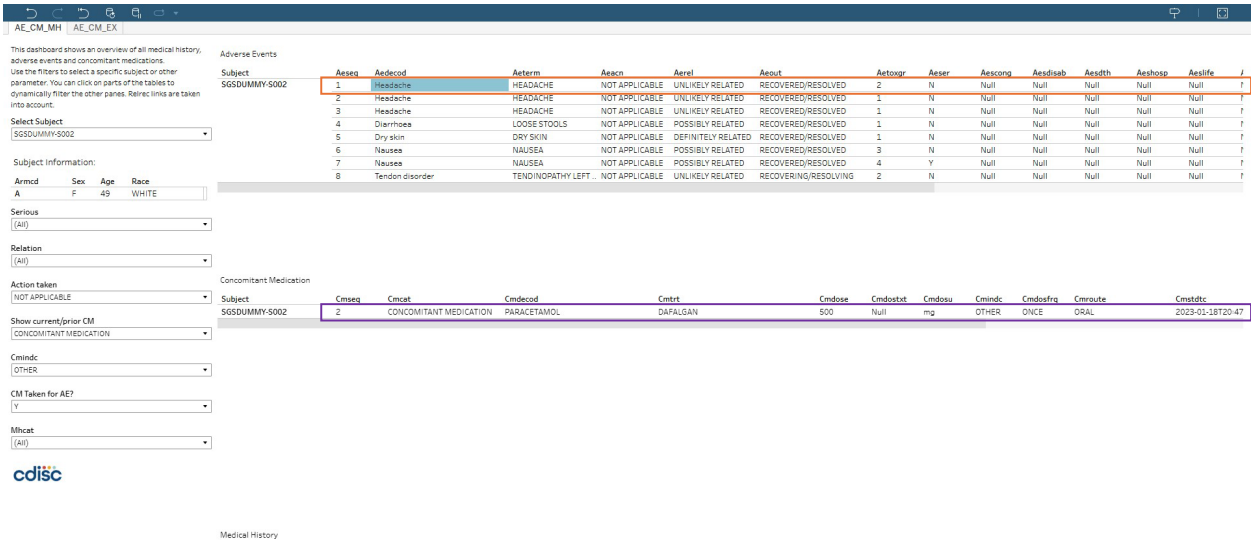


Figure 9. Patient Profile.

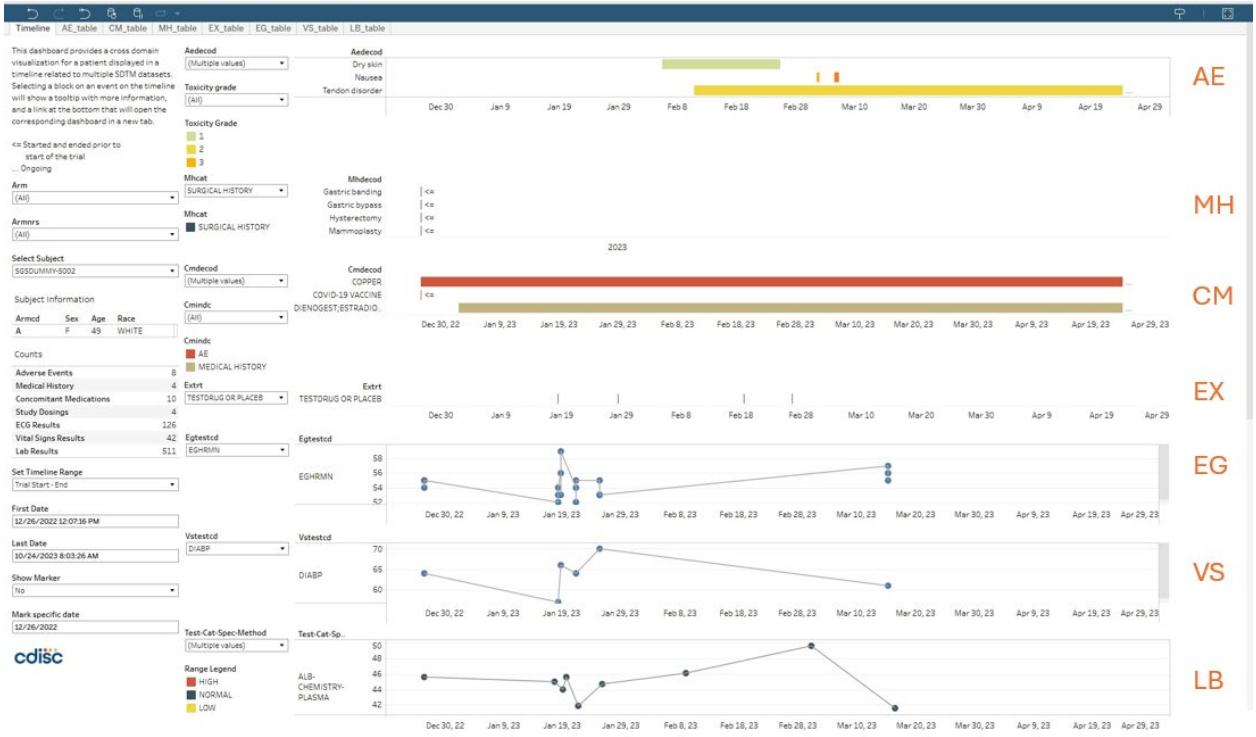


Figure 10. Cross-domain dashboard – Waterfall plot.

Figure 11. Cross-domain dashboard – Spider plot.

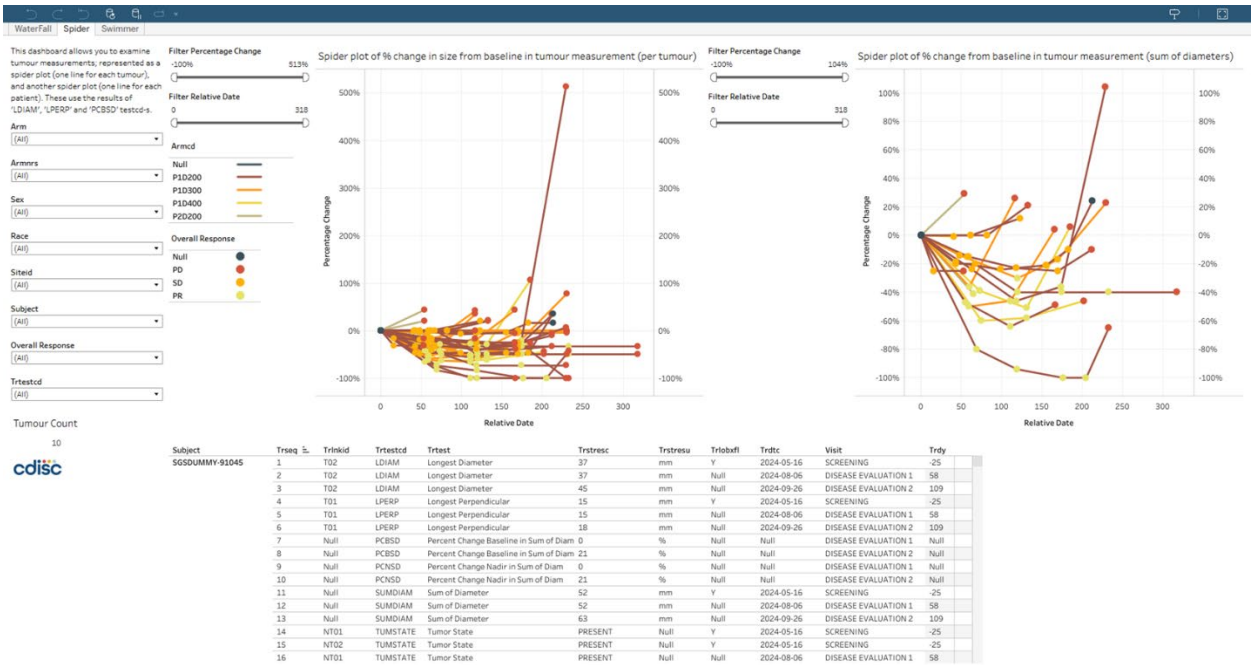
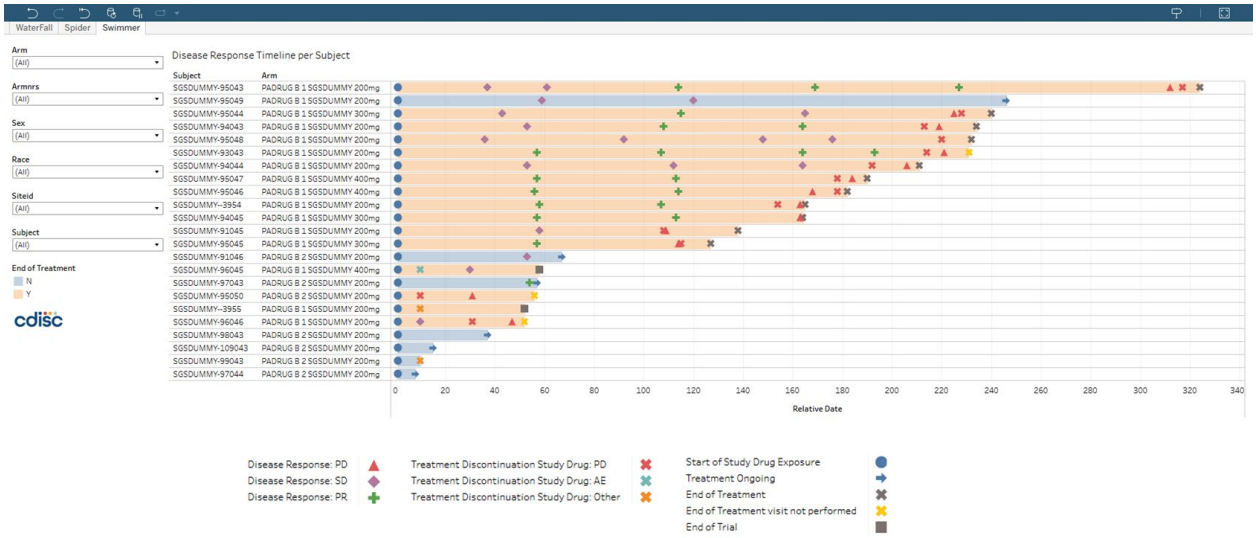


Figure 12. Cross-domain dashboard – Swimmer plot.



ADVANTAGES AND LIMITATIONS

Using data visualisation dashboards in Tableau comes with a great range of advantages, however it also has some limitations, both aspects discussed in more detail below.

ADVANTAGES

- **Improved and simplified data presentation:**
  Tableau dashboards enable transforming complex trial data into clear, interactive visualisations, making interpretation and analysis easier. They provide a comprehensive overview of all subjects, while also allowing detailed views for specific subsets or individual subjects. Users can filter data to focus on relevant information, ensuring flexibility in review. They can also save their filters for the future use, and quickly apply them when needed, which results in time efficiency.
- **Data and safety review optimisation.**
  The use of combination of various dashboards enables early detection of safety trends, allowing potential issues to be identified before they escalate. The outliers can be spotted at a glance, and users can drill down into data details, getting immediate insight into critical data points. Several dashboards offer cross-domain views for analysis of potential relationships between different domains. This streamlined approach supports quicker and more informed decision-making throughout trial conduct.
- **Follow-up on trial progression:**
  In addition to numerous visualisations suited to safety review, our library also contains standard dashboards that allow for following up on trial progression, such as enrollment and disposition dashboards.
- **Streamlining collaboration between team members and meetings:**
  Tableau offers several export options for data and visualisations, that can afterwards be integrated, for example, into reports. Those can be used to support safety meetings, such as SRC (Safety Review Committee) or DSMB (Data and Safety Monitoring Board). Users can share their comments directly in the system, which facilitates efficient communication and feedback. Additionally, while normally the trial dashboards are refreshed regularly with the most recent data, there is a possibility to create separate study environments or snapshots with fixed underlying data. Those can also come in handy for e.g., safety meetings or interim lock.
- **Quick implementation in the trial:**
  As mentioned before, the standard dashboards present in the library can be set up and ready to use shortly after SDTM data is available.
- **Customisable solutions:**
  The dashboards are fully customisable and adaptable to the unique requirements and specifics of each trial, both with regards to the technical aspects (e.g., different data sources) as well as the dashboards content (e.g., different disease evaluation criteria).

LIMITATIONS

- The amount of data that can be displayed on a single dashboard is limited due to size and clarity constraints. As a result, multiple dashboards are often required to provide a complete overview. However, the reviewers must also carefully choose the visualisations, since using excessive number of dashboards can reduce efficiency.
- Tabular data can provide more detailed overview of results.
- When the data is refreshed, it is not always easy to see what has changed or is new compared to the previous refresh.
- There are some limitations in dashboard programming capabilities. Advanced calculations are not always possible directly in Tableau, which poses a need for additional data pre-processing.
- In case of the custom dashboards, depending on factors such as data source, amount of data to be included, type of visualisations etc., the setup and validation of the dashboard might be complex.

As a result, achieving optimal results may require combining multiple review systems to ensure a complete and effective analysis.

CONCLUSION

Oncology, as a major and complex therapeutic area, requires a comprehensive data review system that supports early detection and accurate evaluation of critical findings. Using combination of standard and custom data visualisation dashboards developed in Tableau, tailored to oncology trials, is an efficient solution for supporting data and safety review. They provide clear and straightforward presentation of complex data, supporting early identification of safety signals and emerging trends. This results in a more time-efficient approach than other review methods. Furthermore, they facilitate improved collaboration among stakeholders.

SOURCES

1) https://clinicaltrials.gov

CONTACT INFORMATION

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