ABSTRACT
Strategic management of oncology trials requires clinical study team to synthesize range of patient and disease information from multiple sources. Monitoring tumor progression is very important in oncology trials. Traditionally we used to generate several reports for scientist to monitor the data. Our team decided to leverage data analytics tools to create interactive dashboard that enables our researcher to get quick insight of patient tumor time course data.

The interactive dashboard available on intranet displays collected data about patient enrollment, PFS/OS events, non target and target lesion, swimmer plot with an aim to facilitate both data exploration and data quality check by summarizing tumor information for each patient or group of patients. It displays the Sum of Longest Diameters (SLD), the Target Lesions (TL) and RECIST criteria, such as Overall Response (OR), Best Overall Response (BOR) and the appearance of new lesions. Dashboard has several user-friendly features that help reviewer to compare old and new data, review individual or entire population and others. Depending on the project needs, the dashboard can be easily customized by adding new data or visualizations and those visualizations can be tailored with the graphical interface. The dashboard has resulted in faster insight and reduced time spent in consolidating the data thereby helping in overall understanding of the trials.

INTRODUCTION
In oncology drug development, early phase clinical trials evaluate safety and identify evidence of biological drug activity, such as tumor shrinkage. Endpoints for later phase efficacy studies commonly evaluate whether a drug provides a clinical benefit such as prolongation of survival or an improvement in symptom. Monitoring tumor progression is very important in the success of oncology trials. Traditionally statistical programmer generates several statistical reports for scientists to review and understand the data during trial.

Our team decided to leverage some of the newer BI technologies for data analysis and visualization. We evaluated different tools like R/Shiny, Spotfire, SAS dashboard, JReview and Tableau to develop tumor dashboard. We have built several insightful dashboards that has helped our researcher in understanding of key study data points and improved decision making. The dashboard is available on company intranet and in this paper, we focus on our Tumor Dashboard.

CURRENT LANDSCAPE
To review and understand the relationship between treatment and tumor progression, study team requests for several tables and listings during the trial. Programming team generates reports in SAS such as Listing of Response per RECIST, Listing of Best Overall Response, Tumor Burden Change Over Time, Overall Survival, swimmers plot and others. It takes time and resources to generate several of these reports. Since the report are static, the reviewer has to go back and forth between several tables and listing to understand the relationship between data, spot outliers and errors. The process is resource intensive from the programming and review perspective.

OTHER TECHNOLOGIES
We evaluated the BI/Visualization technologies to see if we can enhance the data reporting to allow the reviewer to understand the relationship between different data points, provide interactivity, and implement it at enterprise level. We evaluated SAS Analytics, Spot fire, JReview, R/Shiny and Tableau. Overall, all of them provide powerful tools to visualize the data and enhance the efficiency of the programming process.
We noticed that our customers gravitate towards the more visually appealing Tableau display, as well as its user-friendly GUI. Also in our setup Tableau was easy to configure, manage and scale up.

BUILDING OUR DASHBOARD

By developing a consolidated tumor dashboard, we strive to bring together a lot of scientific information in one place to make the study team able to review and fully understand the relationship between the data easily. We used the combination of SDTM and ADaM datasets to develop our dashboard. Our researchers appreciate the features in the dashboard that helped them to understand the data that we have collected and identify relationship between all the subjects-state, safety, efficacy, time dependent and covariate variables. The dashboard has interactive filters, tool tip that has detailed information about the data point, change analysis and allow for easy downloads. We developed complex queries from multiple domains like DM, EX, TR, TU and RS. Once the dashboard is developed, we validate the data points and publish it on the company intranet. The dashboard can be auto-refreshed or manually refreshed whenever the new data is extracted from the EDC allowing study team to review the data in real-time and able to make quick decision.

METRICS

We looked at the key tumor data points and information that are important to our study team. Tumor change evaluation is an important feature in oncology studies: tumor regression and disease progression are commonly used endpoints in clinical trials. In solid tumor studies, target lesions, non target lesions and new lesions are measured or otherwise recorded. A sum of the longest diameter (SLD) for all target lesions are calculated and reported as the baseline SLD, as a reference by which to characterize the objective tumor response. Subject responses, OR and BOR, are evaluated using RECIST 1.1 guidelines.

LANDING PAGE

The landing page of the dashboard provides a high-level summary of the subject status in the study as shown in Figure 1.

<table>
<thead>
<tr>
<th>Study Drug ABC (Data Extract: 01JAN2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
</tr>
<tr>
<td>Patients on Study</td>
</tr>
<tr>
<td>Cohort 1</td>
</tr>
<tr>
<td>Patients on Study Drug</td>
</tr>
<tr>
<td>Cohort 1</td>
</tr>
<tr>
<td>Patients on Companion Drug</td>
</tr>
<tr>
<td>Cohort 1</td>
</tr>
<tr>
<td>Dose Level 1</td>
</tr>
<tr>
<td>Cohort 1</td>
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<tr>
<td>Dose Level 2</td>
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<tr>
<td>Cohort 1</td>
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<td>PD</td>
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<tr>
<td>Cohort 1</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Cohort 1</td>
</tr>
</tbody>
</table>

Figure 1. Tumor Dashboard – Patient Summary

The reviewer is able to get count of subject in each cohorts and other information. The dashboard can be easily customized to add more information.
OVERVIEW GRAPHS

Investigators in oncology trials are interested to know whether or not a subject had a response to study and the timing of that response in relation to the administration of study drug. The next two panels in our dashboard provides information about the subject response to the treatment and sum of longest diameter of the tumor. Our Overall Response dashboard allows reviewer to know about each of the subject status in the study, about their response assessment at different visit, change in treatment plan and any adverse events. By hovering mouse at different assessments the reviewer is able to get more information about that assessment in the tool tip. The reviewer is also able to filter subject by dose level. The interactive graphical swimmer plot allows user to review the data and also identify any data entry errors like subject ABC-065 in figure 2.

![Overall Response Graph](image)

Figure 2. Overall Response

Sum of longest diameter of the tumor is important measurement and impacts the efficacy end points in oncology trials. We used study ADaM dataset to build this dashboard. Reviewing this dashboard allows the team to understand if tumor is shrinking or progressing for each subjects, understand trends of different cohort, spot data errors and make decision related to safety of the patients. Each of the SLD line in the dashboard corresponds to a subject. The subject selected from the top two panels is then further analyzed in the detail panels with subject target lesions, non target lesions and new lesions.
SUBJECT LEVEL GRAPHS

Our next two dashboards allow the study team to review lesion level information for the subjects in the study. Zooming in at subject level, Target Lesion graph as well as New Lesion and Non Target Lesion table display the tumor progression over time. Figure 5 shows that subject ABC-123 has one new lesion and one non target lesion. Additional information is included in the tooltip which pops up automatically when hovering over the graph, as shown in Figure 4 when we mouse over the line plot.
FEEDBACKS

Our study team found the dashboard easy to navigate, and our training was very short related to some system features. The team quickly started using the dashboard to review the data and provided us their
feedbacks. The team was amazed to find key complex data points in one dashboards that allowed them to get quick understanding of data and reduced their review time.

CONCLUSION

Static reporting will always have a place in scientific reporting. Interactive dashboard is useful in regular monitoring of data and allows to visualize and understand complex relationship between the data. Our dashboards are refreshed on weekly basis. Clinical scientist found the tumor dashboard useful in their weekly/monthly data review and easy to navigate instead of requesting programming team to generate multiple tables and listings. Reviewers could easily filter for each subject, site or cohort, navigate between different panels, track changes and query questionable data all in one place. Interactive tool tip allows to summarize relevant data at each assessment visit. Dashboards in addition to static report is a greatly useful in synthesizing patient information, helping with quicker insight about the treatment, speeding the decision making and empowering our clinical scientists.

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DISCLAIMERS

The data used to generate the figures are dummy data. The views expressed in this paper are those of the authors and are not intended to reflect the views of the author’s employer.

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