

Unifying RECIST (Tumour evaluation) data review using the data visual angulation technique

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Abstract

Data visualization in clinical trial data analytics is becoming instrumental in helping scientists understand vast amounts of data, identifying patterns and trends to make timely decisions and improve research outcomes. Tumor data evaluation using RECIST is considered the gold standard in solid tumor assessment. Although efficient reviewing of multiple tumor evaluation data is still a challenge in oncology trials, there may be better options than assorted visualizations, which are currently used. Therefore, an advanced visualization approach aimed at providing a 360-degree view of the patient's journey of tumor scans is the way forward. In this presentation, we will discuss data visual angulation approach (leveraging different dimensional views) for creating a 360-degree visual patient journey or storyboard of tumor data that enables a "one-stop" review of all tumor data points for easier, faster, and better interpretation.

Introduction

Increased complexity in protocol designs and disparate data sources are key challenges in the current clinical trial landscape and are likely to compound in the post-pandemic world. As a result, biopharma companies need innovative technology solutions to manage these challenges. A fully technology-enabled platform with seamless data inflow could be instrumental in ensuring successful trial outcomes. An impactful technology-enablement technique is data visualization, providing a holistic view of data for clinical researchers to access, review, and report clinical trial data effectively. Furthermore, data visualization can help identify anomalies, clinical logic, checks, trends, and patterns to ensure data quality throughout the clinical trial. Fig 1 shows the most common use cases where data visualization is critical and a few examples of tools in use.

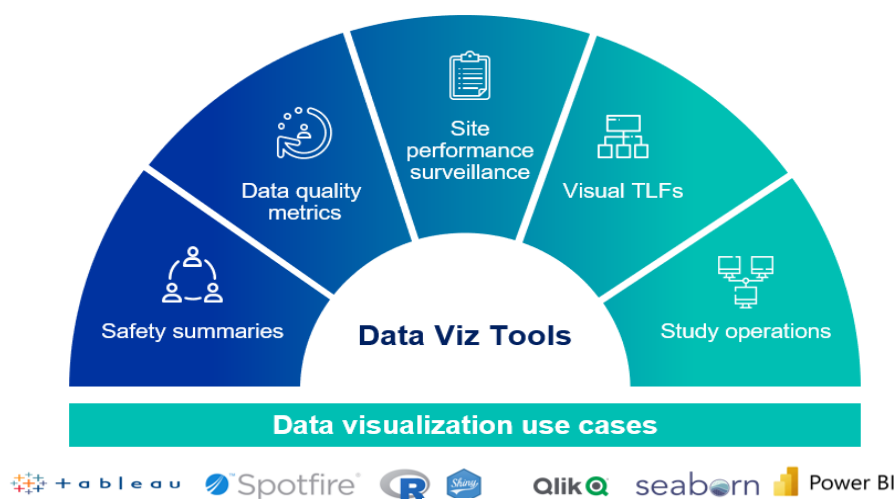


Fig: 1

Assessing tumor data using RECIST to understand the patient's tumor response which defines when patients improve (respond), stay the same (stable), or worsen (disease progression) due to treatments. Further, RECIST evaluation and compliance are crucial for assessing primary and secondary endpoints in solid tumors. Hence, streamlining the RECIST criteria review is always in need. The currently available visualization for the tumor data review used by Medical Monitors and data managers is majorly intended to review target lesions and their change based on treatment. However, for a complete tumor evaluation per RECIST criteria, all other tumor elements (such as a target lesion, non-target lesion, new lesion presence, timepoint response, and overall response) must also be considered.

Data Visual Angulation Technique

Manually performing data review and page-by-page basis of all these tumor assessments is tedious and time-consuming. Alternatively, a visual tumor journey could be generated through Data Angulation (i.e., creating different dimensional data transformations) that intuitively indicates start-to-end tumor assessments, allowing an effective and easy review. Fig 2 illustrates the data angulation technique, which looked at the data across scans and tumor assessments for a particular scan. It also helps to determine the quantitative assessment (e.g., Target Lesion) and qualitative assessment (e.g., Non-Target lesion and New lesion)

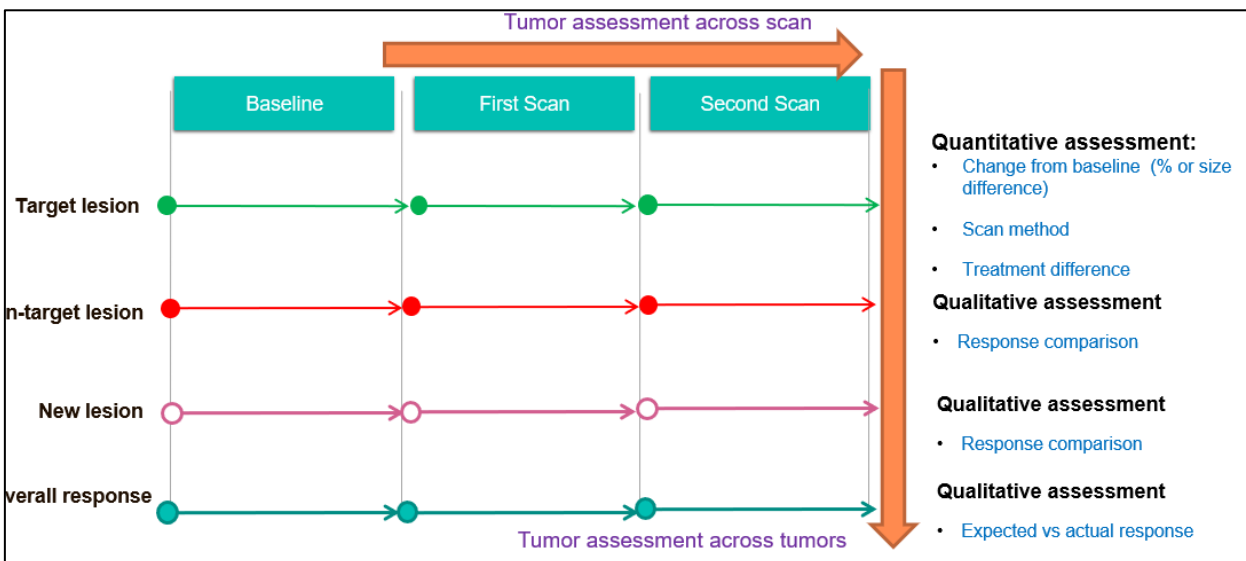


Fig: 2

Visual Tumor journey 360 Patient review

Using the data visual angulation technique, a 360-degree patient visual journey of tumor data showing the different dimensional views (Fig: 3) of all the critical RECIST criteria checks which data reviewers can easily review for compliance with RECIST 1.1.



Fig: 3

- Integrating tumor responses within patient visit schedules allows reviewers to determine tumor response changes over time.
- Consistency of the scan method (e.g., CT, MRI) can be checked to ensure the same lesion method is used across all scans.
- Each target lesion measurement, from baseline to subsequent scans, is useful for quantitatively assessing Target lesions.
- Percentage change from baseline helps to interpret the response of the target lesion based on the tumor size.
- Non-Target lesions (a qualitative assessment) responses were shown from baseline and across scans.
- Overall response and timepoint response for Target, Non-Target, and New Lesions provide the reviewers with a holistic review of all tumor assessments.

Ongoing Tumor response review workflow

For data reviewers, Fig: 4 shows a defined workflow which is helpful in identifying the issues/data anomalies effectively.



Fig: 4

1. Review the individual target lesion measurement with scan method & size across visits.
2. Review % change from baseline & response recorded for each of the scans.
3. Review the individual NTL (non-target lesion) with the response recorded for each scan.
4. Review the overall response along with TL, NTL, and new lesion response to determining the patient's tumor status at the time point.

Target lesion visualization vs RECIST 1.1 compliance check

With the defined Tumor response Assessment workflow, Fig: 5 shows all possible RECIST 1.1 criteria checks using Target lesion visualization.

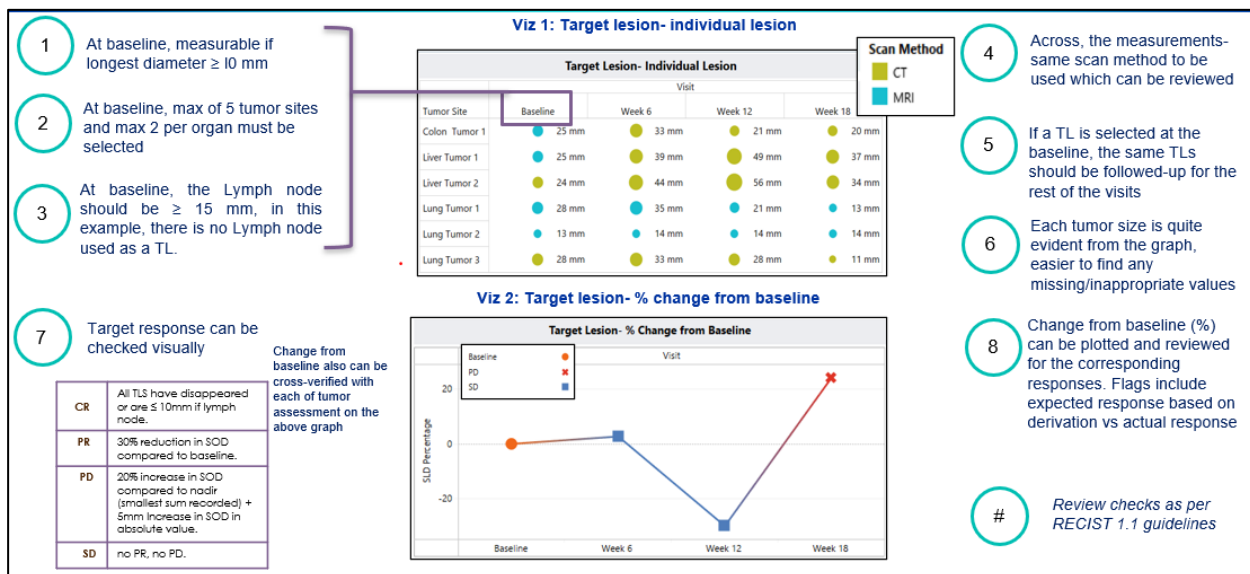


Fig: 5

Patient Compare

Patient comparison (Fig: 6) could also be useful for the reviewers to compare two or more patients. The same comparator features include percentage change from Target lesion, Non-target lesion, and new lesion between pairs of patients with varied treatments (or cohorts).



Fig: 6

1. Target lesion % change from baseline and corresponding responses
2. Non-Target lesion response comparison
3. The difference in the scan intervals between patients
4. Time and event correlation.

Automation

Efficiency could further be refined using an automation approach (Fig. 7) which starts by defining the requirements, creating the metadata needed for visualization, developing visualizations as per requirements, and data refresh in real-time. Additionally, various alerts could also be set up for reviewers automatically.

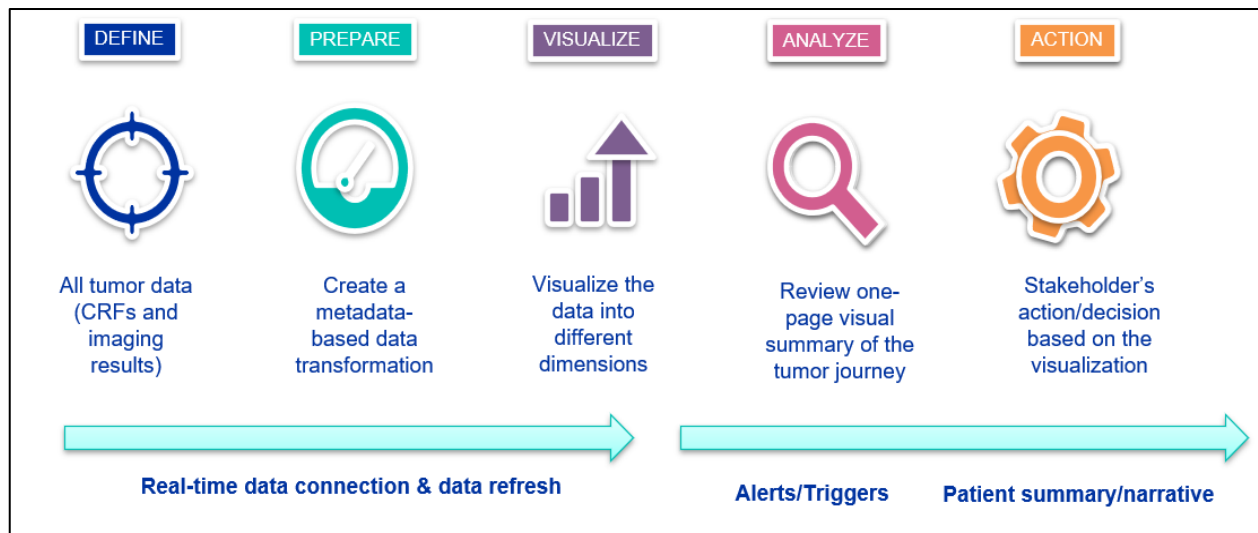


Fig: 7

Conclusion

The paper showed an effective approach to a 360-degree visual tumor journey based on RECIST 1.1 coupled with data angulation. This approach has benefits over other data visualizations and can further be studied for different dimensional views intended by the reviews (e.g., iRECIST or mRECIST). Automation of tumor data reviews and setting up signals/alerts based on various RECIST criteria checks could improve efficiency and faster decision-making.

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