



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

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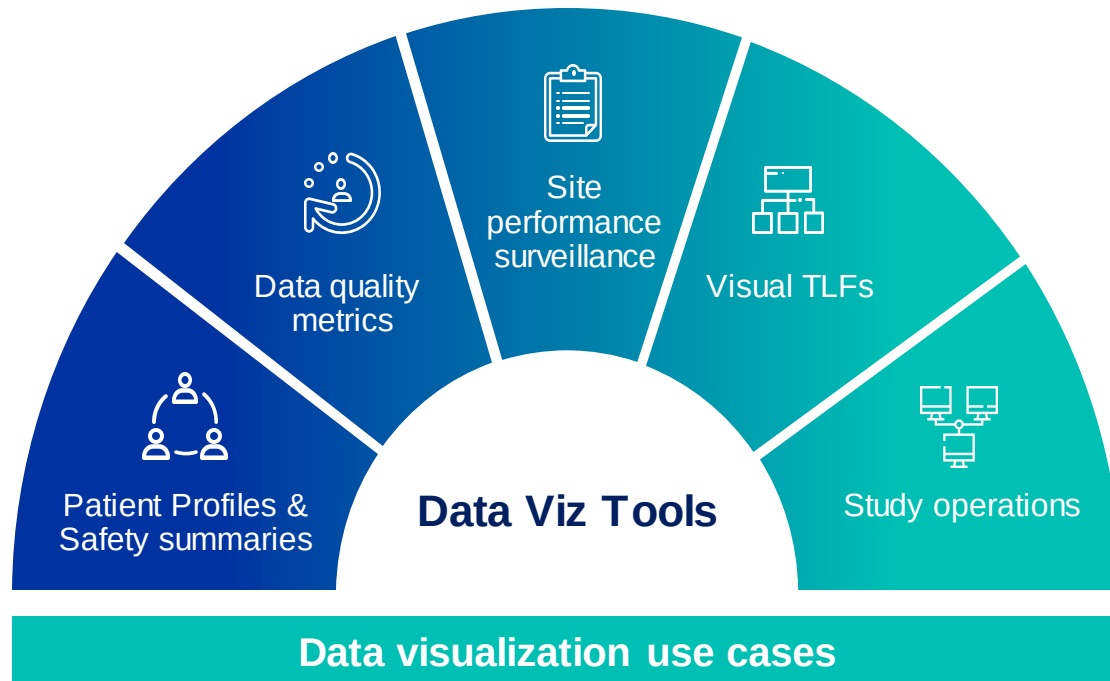
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1. Data Visualization in Clinical Trials
2. Tumor evaluation using RECIST Criteria- Importance
3. Data Visualization for Tumor Evaluation
4. Visual Tumor Journey- Approach, Strategy, Use Case Demonstration
5. Automation Approach
6. Key Takeaways

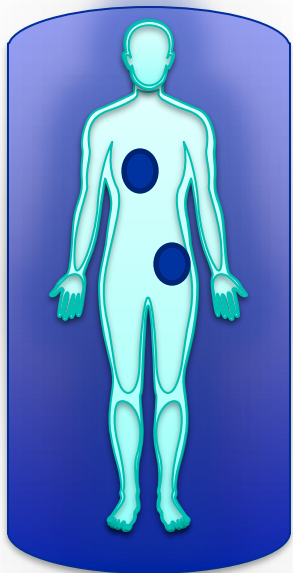
Data visualization in clinical trials

Why Data Visualization?

- Visible information spread is at **90%** of the instruction in the brain
- Helps understand complex data in a simple way
- Visuals are better than other mode of review
- Easier and Time Saving
- Support in Analytics with large quantum of data



Tumor evaluation using RECIST Criteria- Importance

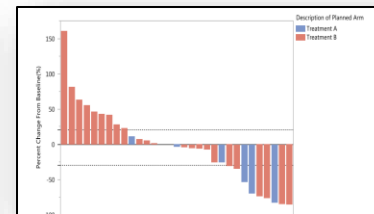
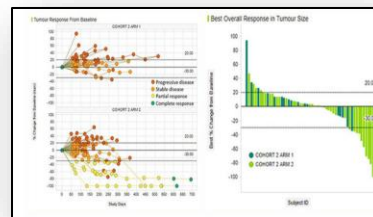
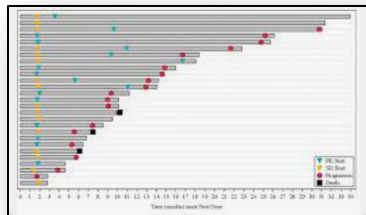


- Considered as Gold Standard for Solid Tumor assessment
- Standardized repeatable method for measuring response to therapy for solid tumors
- Objective Response Rate (ORR) & Best Overall Response (BOR) are the key endpoints in solid tumors
 - Additionally, RECIST helps to determine disease-free survival, progression-free survival
- RECIST evaluation/compliance is critical to early efficacy endpoint detection
- RECIST evaluation could be streamlined through visual & unified reports

Data Visualization in Tumor Evaluation

Enhanced data visualization need for RECIST checks

Current examples of tumor assessment visualization for RECIST checks*



RECIST criteria
to be checked**

RECIST 1.1	
Baseline Study	Follow Up
Target lesions - length diameter tumor >10mm - max 5, max 2 per organ - short axis lymph node >15mm - Determine SLD sum of length diameters	Determine SLD
Non-target lesions - lesions <10mm - non-measurable like pleural fluid, ascites, lymphangitis	Disappearance ? Stable? Progression?

RECIST 1.1	
	Response
CR	Disappearance of all lesions and pathologic lymph nodes
PR	≥ 30% decrease SLD no new lesions no progression of non-target lesions
SD	no PR - no PD
PD	≥ 20% increase SLD* compared to smallest SLD in study or progression of non-target lesions or new lesions

Currently available visualizations predominantly cover “Change from baseline only Target Lesion” which in our opinion may not be insufficient for RECIST 1.1 Checks. Thus, there is a need for enhanced data visualization.

What could help here?
A unified Visual-Tumor journey!

*Based on web search, for illustration purpose only (product/source info is not shown anywhere in the presentation)

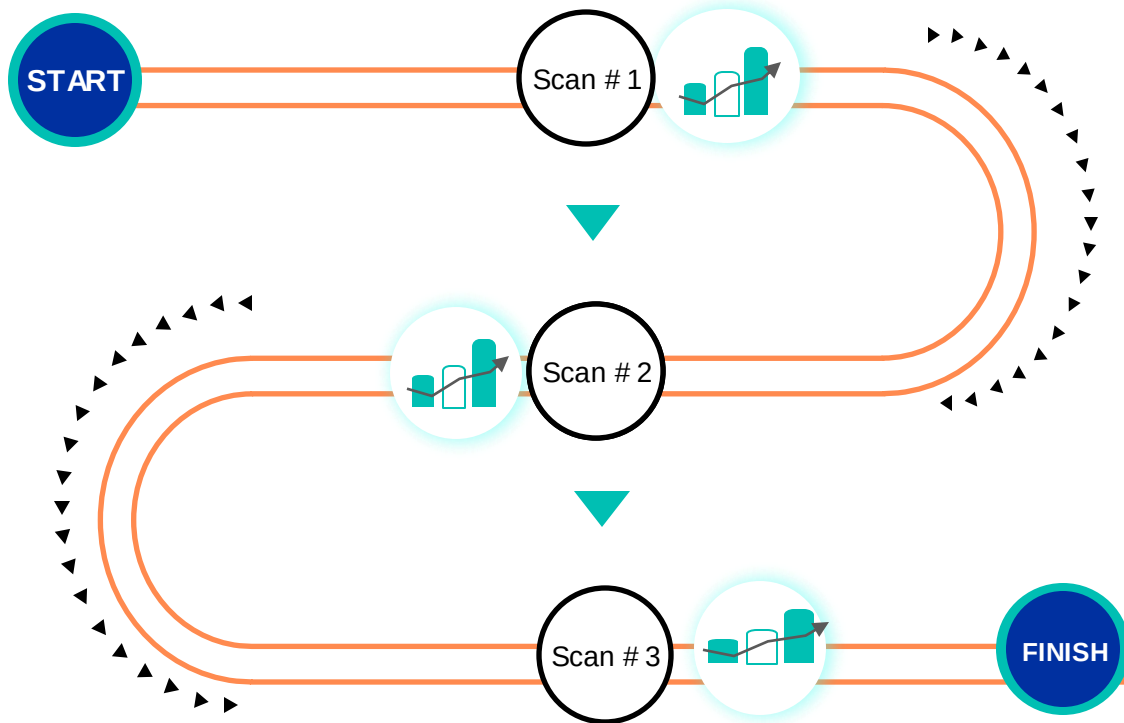
** <https://radiologyassistant.nl/more/recist-1-1/recist-1-1-1>

Visual Tumor Journey- Approach

Data Acquisition (14 to 15 CRFs)

- Screening target lesion
- Post-baseline target lesion
- Screening non-target lesions
- Post- baseline target lesion
- New lesion
- Overall Time point response
- Best overall response

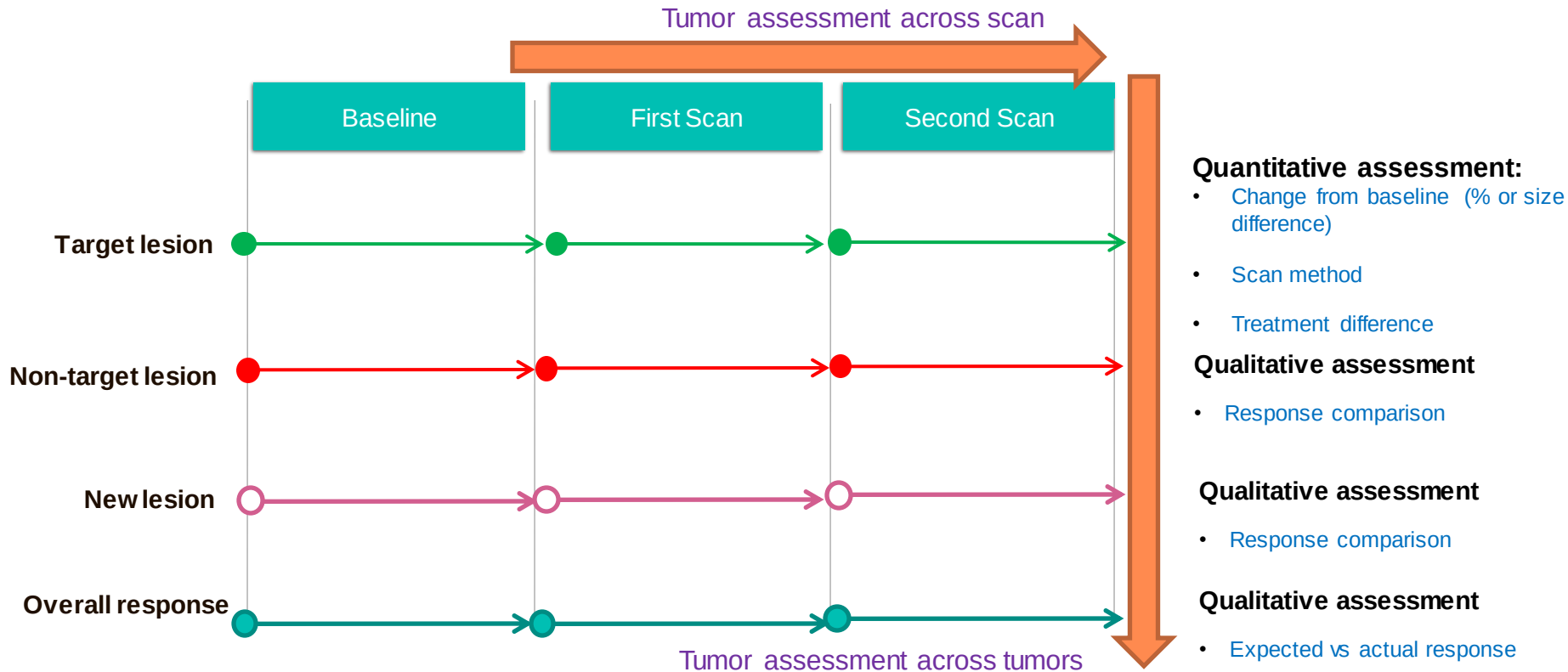
- Manual review & page by page review
- Time taking & tedious



Easy, visual & one-shelf review

Visual Tumor Journey- Data Angulation Strategy

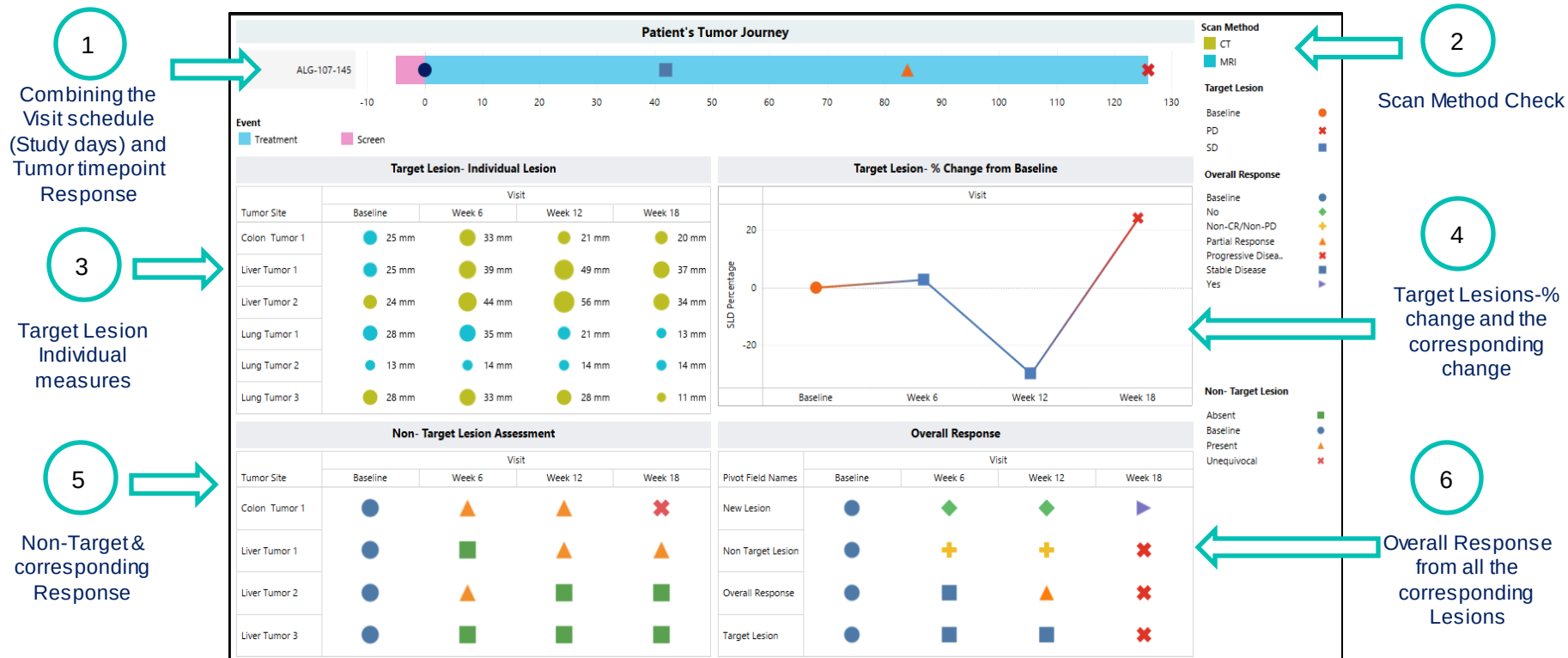
Data Angulation: Data Transformation & Data Dimension for intended viz!





Visual Tumor Journey- Demo Visualizations

Visual Tumor journey 360 Patient review

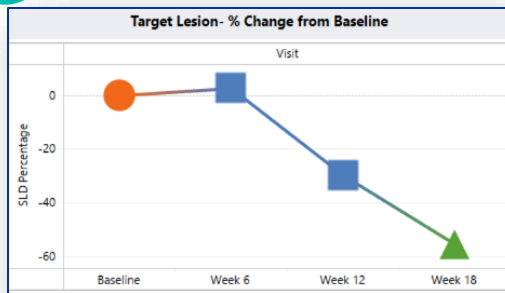


Ongoing Tumor response review workflow

1 Target lesion- individual lesion

Target Lesion- Individual Lesion				
Tumor Site	Visit			
	Baseline	Week 6	Week 12	Week 18
Colon Tumor 1	25 mm	33 mm	21 mm	20 mm
Liver Tumor 1	25 mm	39 mm	49 mm	37 mm
Liver Tumor 2	24 mm	44 mm	56 mm	34 mm
Lung Tumor 1	28 mm	35 mm	21 mm	13 mm
Lung Tumor 2	13 mm	14 mm	14 mm	14 mm
Lung Tumor 3	28 mm	33 mm	28 mm	11 mm

2 Target lesion- % change From baseline



3 Non- target lesion assessment

Non- Target Lesion Assessment				
Tumor Site	Visit			
	Baseline	Week 6	Week 12	Week 18
Colon Tumor 1	MRI	CT	CT	CT
Liver Tumor 1	MRI	MRI	MRI	CT
Liver Tumor 2	MRI	MRI	MRI	MRI
Liver Tumor 3	CT	CT	CT	CT
Lymph Node 1	MRI	CT	CT	CT
Lymph Node 2	CT	CT	CT	CT

4 Overall response

Overall Response				
Pivot Field Names	Visit			
	Baseline	Week 6	Week 12	Week 18
New Lesion	Green Diamond	Green Diamond	Green Diamond	Purple Circle
Non Target Lesion	Orange Triangle	Red X	Yellow Square	Red X
Overall Response	Orange Triangle	Red X	Orange Triangle	Red X
Target Lesion	Orange Triangle	Red X	Orange Triangle	Red X

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 response recorded for each of the scans
4. Review the overall response along with TL, NTL, and new lesion response to determine the patient's tumor status at the time point.

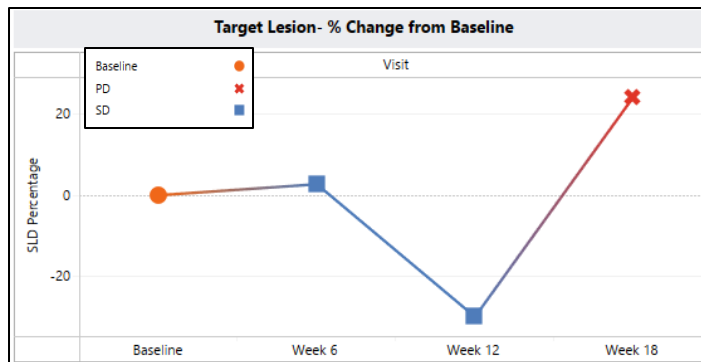
Target lesion visualization vs RECIST 1.1 compliance check

Viz 1: Target lesion- individual lesion

Tumor Site	Visit			
	Baseline	Week 6	Week 12	Week 18
Colon Tumor 1	25 mm	33 mm	21 mm	20 mm
Liver Tumor 1	25 mm	39 mm	49 mm	37 mm
Liver Tumor 2	24 mm	44 mm	56 mm	34 mm
Lung Tumor 1	28 mm	35 mm	21 mm	13 mm
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Scan Method	
■	CT
■	MRI

Viz 2: Target lesion- % change from baseline



1 At baseline, measurable if longest diameter ≥ 10 mm

2 At baseline, max of 5 tumor sites and max 2 per organ must be selected

3 At baseline, the Lymph node should be ≥ 15 mm, in this example, there is no Lymph node used as a TL.

7 Target response can be checked visually

CR	All TLS have disappeared or are ≤ 10 mm if lymph node.
PR	30% reduction in SOD compared to baseline.
PD	20% increase in SOD compared to nadir (smallest sum recorded) + 5mm Increase in SOD in absolute value.
SD	no PR, no PD.

Change from baseline also can be cross-verified with each of tumor assessment on the above graph

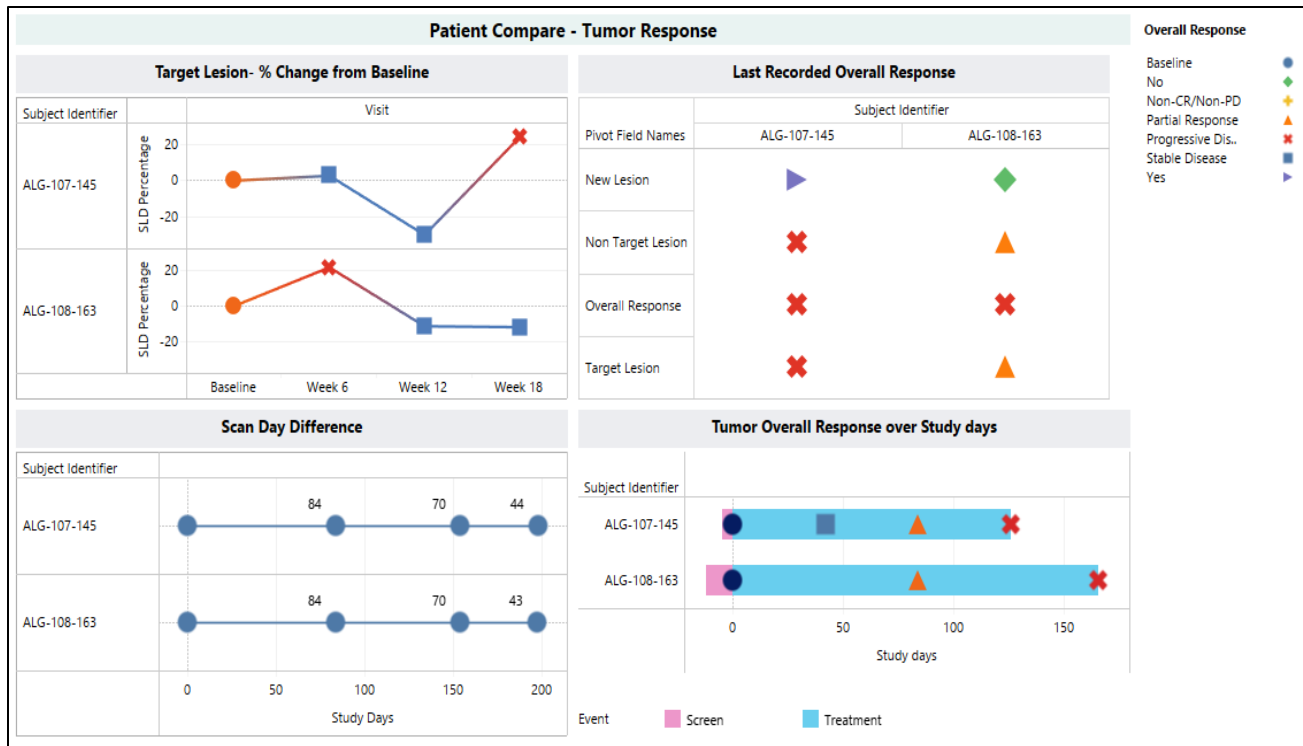
4 Across, the measurements- same scan method to be used which can be reviewed

5 If a TL is selected at the baseline, the same TLs should be followed-up for the rest of the visits)

6 Each tumor size is quite evident from the graph, easier to find any missing/inappropriate values

8 Change from baseline (%) can be plotted and reviewed for the corresponding responses. Flags include expected response based on derivation vs actual response

Review checks as per RECIST 1.1 guidelines

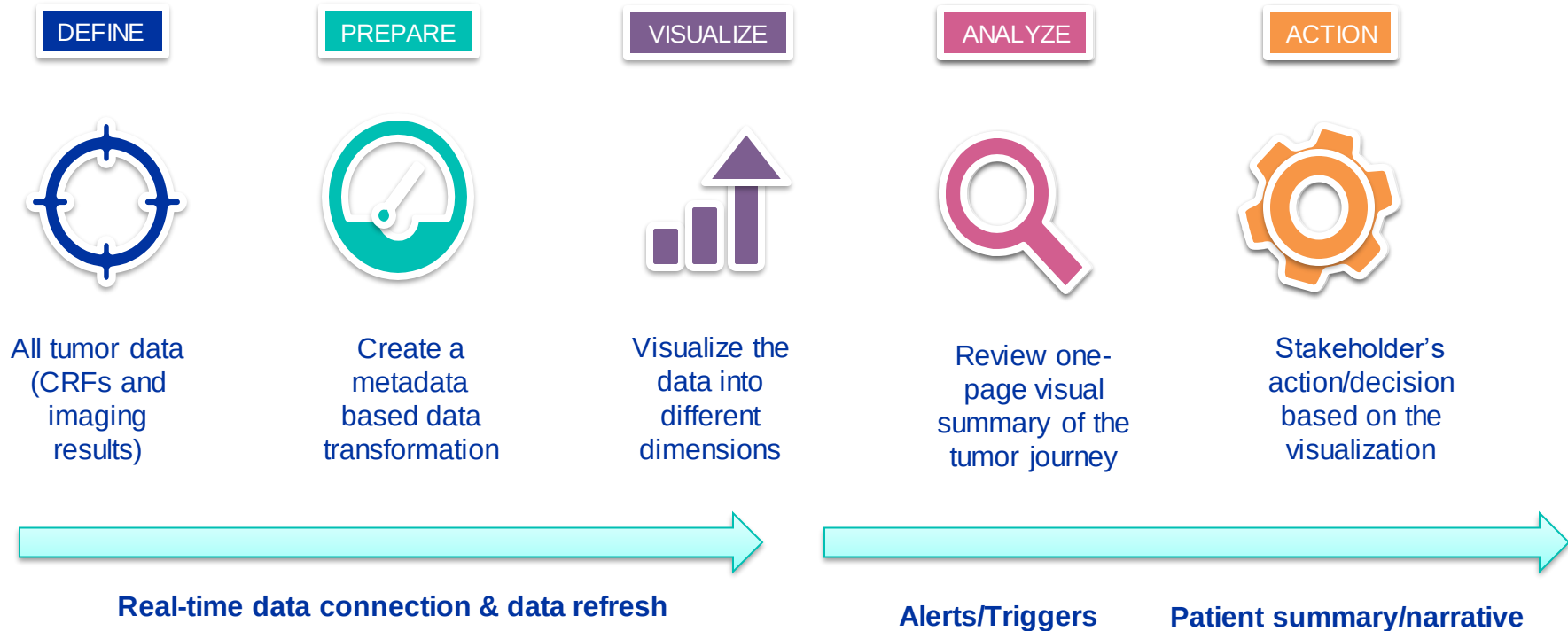


Selecting 2 or more patients allows the reviewer to compare tumor responses between patients

Common Comparison Parameters:

- Target Lesion % change
- Treatment Arms differences (can be included as Legend)
- Overall Response (Latest Time Point Response)
- Difference in Scan Intervals
- Time and event correlation

Automate the visual tumor evaluation journey



1. Visual Unified tumor Journey for faster decision making
2. Use the KISS (keep it simple and straight) dashboarding approach!
3. Data angulation/Data Transformations are needed for diverse review prospective
4. Tumor Journey could easily be combined with Patient Profiles
5. Ease of monitoring - saves, time & efforts
6. Near-Real time supports in - set-up of alert for early signals

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