

Single Day Event

Enhancing DMC Decisions:
Data Visualization for Stronger Safety
Reporting and Futility Assessment

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Challenges in DMC Decision-Making

Volume & Complexity of Data:

- **Overload:** Too much data can make it hard to identify what's relevant.
- **Scarcity:** Lack of reliable or up-to-date information can lead to poor decisions.

Delayed Safety Signal Detection and Futility Outcomes

- Urgent decisions may need to be made without full analysis, increasing the risk of errors.

Static Reports vs. Dynamic Insights

- Traditional Statistical Monitoring Methods while rigorous often obscure towards emerging trends in complex datasets.

Communication Gaps Between Stakeholders

- Miscommunication or lack of transparency can lead to misunderstandings and misalignment.



Advanced Data Visualization Technique

Data visualization enhances:



Safety signal
detection



Futility
assessment



Communication
and transparency



Demonstrate
real-world
examples and
best practices



Data Visualizing in Volume & Complexity Data



Transforms raw data into actionable insights



Improves pattern recognition



Facilitates real-time monitoring



Supports evidence-based decisions

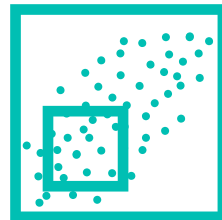


Visualizing Safety Data



Key Metrics:

- Adverse Events (AEs)
- Serious Adverse Events (SAEs)
- Lab abnormalities



Effective Visuals:

- Heatmaps for AE frequency
- Kaplan-Meier curves for time-to-event
- Forest plots for subgroup analysis



Heatmap of Adverse Event (AE) Frequency

Purpose:

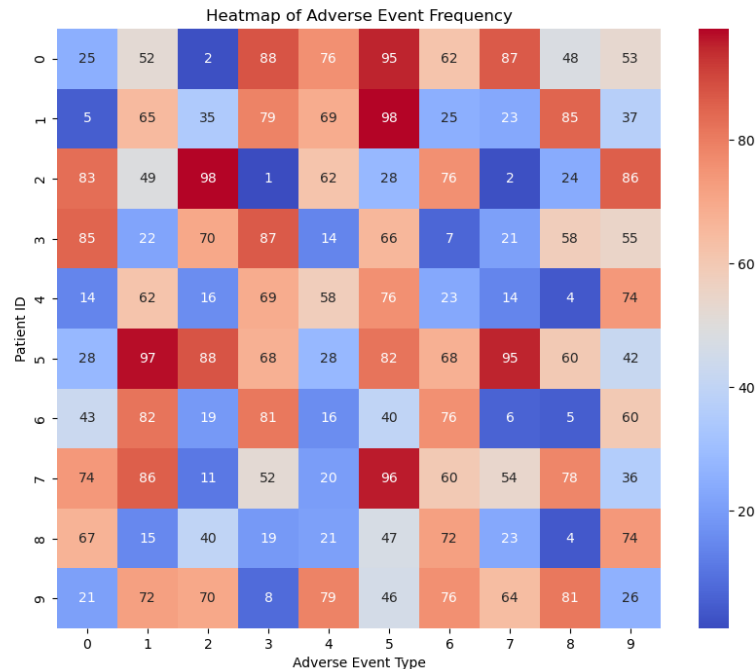
To quickly identify patterns or clusters of adverse events across patients or treatment arms.

How to interpret:

- Rows represent individual patients.
- Columns represent different types of adverse events.
- Color intensity indicates frequency or severity.

Use case:

Spotting a concentration of high-frequency AEs in a specific group can trigger safety reviews or protocol amendments.





Kaplan-Meier-like Survival Curve

Purpose:

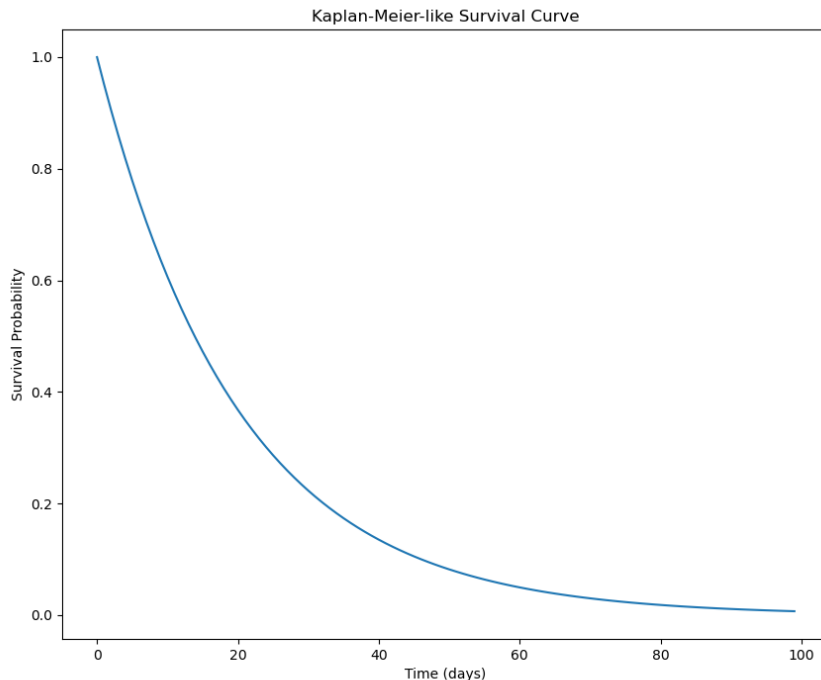
To visualize the probability of survival over time.

How to interpret:

- X-axis: Time (e.g., days since treatment start).
- Y-axis: Probability of survival.
- The curve shows how quickly patients are experiencing events (e.g., death, disease progression).

Use case:

Helps DMCs assess treatment efficacy and compare survival between arms.





Forest Plot for Subgroup Analysis

Purpose:

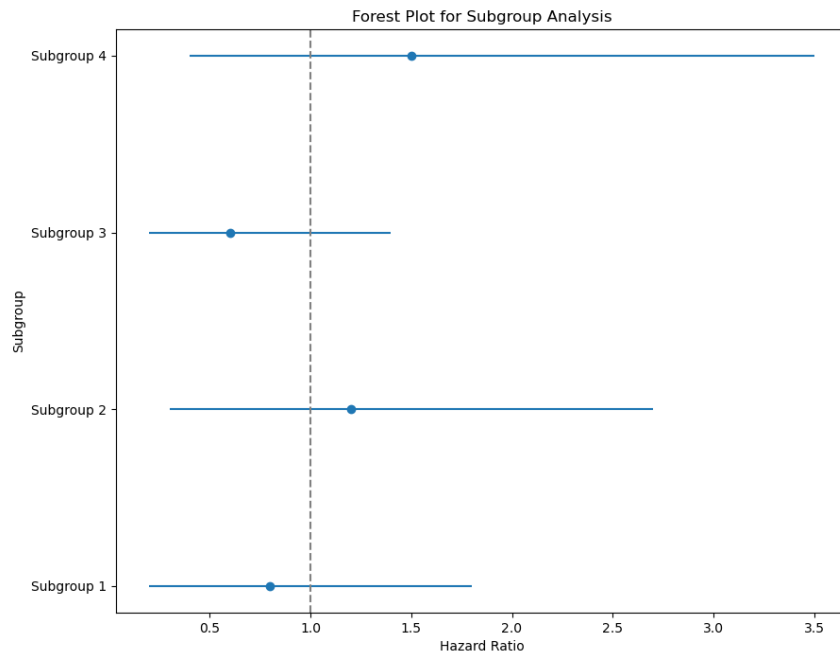
To evaluate treatment effects across different patient subgroups.

How to interpret:

- Each line represents a subgroup (e.g., age, gender, comorbidity).
- The dot is the hazard ratio (HR); the horizontal line is the confidence interval (CI).
- A vertical line at $HR = 1$ indicates no effect.

Use case:

Identifies whether certain subgroups benefit more or less from treatment, guiding personalized medicine decisions.





Visualizing Futility Assessment

What is Futility?

- Low probability of demonstrating treatment benefit



Key Tools:

- Conditional power plots
- Predictive probability charts
- Bayesian posterior distributions



Conditional Power Plot

Purpose:

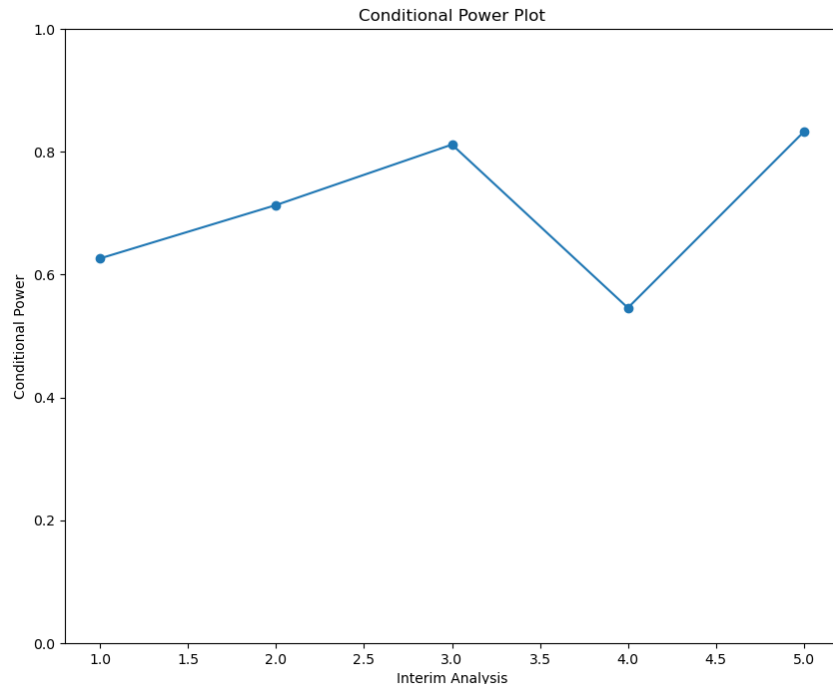
To estimate the probability of achieving statistical significance at the end of the trial, based on interim data.

How to interpret:

- X-axis: Interim analysis points.
- Y-axis: Conditional power (0 to 1).
- A rising curve suggests increasing confidence in treatment efficacy.

Use case:

Helps DMCs decide whether to continue, modify, or stop a trial early for futility.





Predictive Probability Chart

Purpose:

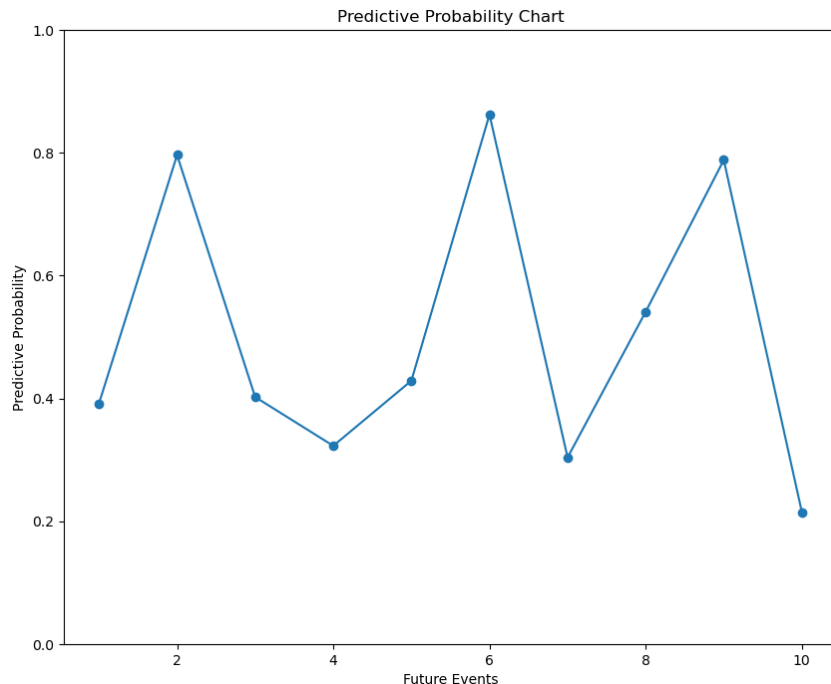
To forecast the likelihood of trial success based on current trends and future event assumptions.

How to interpret:

- X-axis: Number of future events.
- Y-axis: Probability of success.
- Helps visualize how accumulating more data might affect trial outcomes.

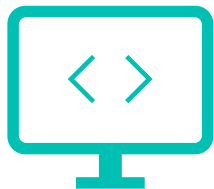
Use case:

Supports adaptive trial designs and early stopping decisions.



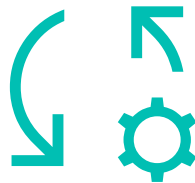


Tools & Technologies



Software:

- R (ggplot2, Shiny), Python (Plotly, Dash), Spotfire, Tableau



Automation:

- Real-time dashboards, API integrations with EDC systems



Compliance:

- 21 CFR Part 11, audit trails, reproducibility



Real Time Dash Boards

Real time dashboards, API integrations with EDC systems are shared below frequently helping Biostatisticians and DMC team.

- Safety Dashboard
- Efficacy Dashboard



Safety Dashboards

- Demographics
- AE Distribution
- AE Incidence Rate
- CM Reporting Rate
- VS, EG and Laboratory Baseline Change
- Hy's Law



Demographics

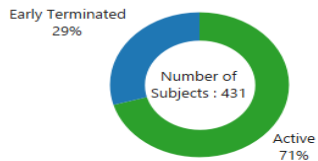
[Back to Index](#)**Country**

(All)

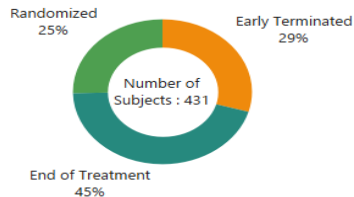
Site Identifier

(All)

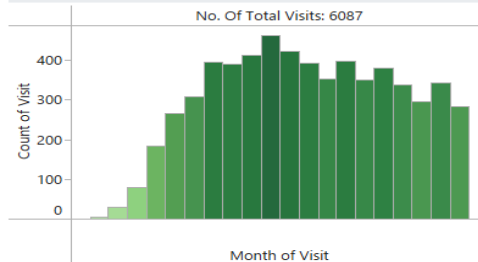
1.1.1 Overall Subject Status



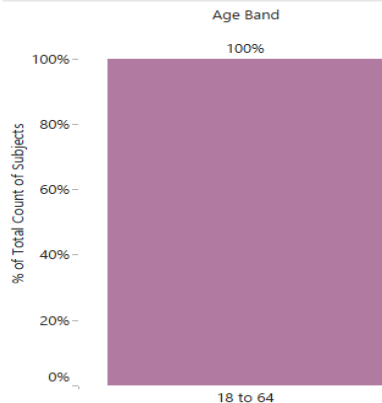
1.1.2 Enrolled Status Distribution



1.1.3 Visit Accruals by Time



1.1.4 Enrolled Subjects by Age

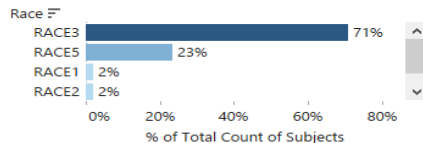


Count of Male : 316

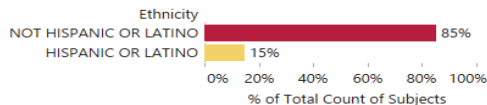


Count of Female : 115

1.1.5 Enrolled Subjects by Race



1.1.6 Enrolled Subjects by Ethnicity



1.1.7 Enrolled Subjects by Geography





AE Distribution

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Country

(All)

Site Identifier

(All)

Subject Identifier

(All)

Adverse Event Distribution By

System Organ Class

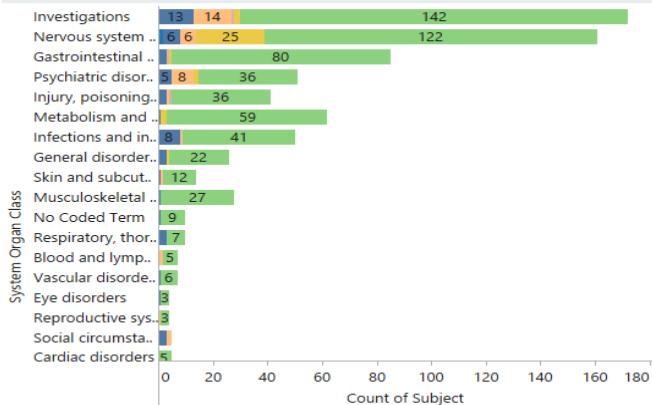
Group By

Action taken

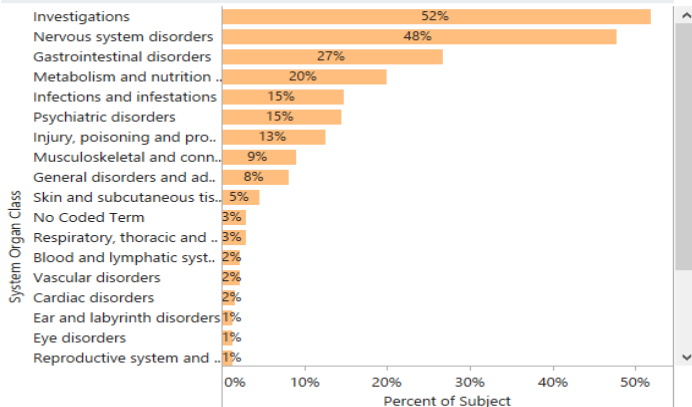
Group Details

- DOSE NOT CHANGED
- DOSE REDUCED
- DRUG INTERRUPTED
- DRUG WITHDRAWN
- NOT APPLICABLE
- Unspecified/Not Provided

3.2.1 Adverse Event Distribution by System Organ Class



3.2.2 Adverse Event % Distribution by Subject



3.2.3 Adverse Event - Details on Demand

Subject Identi..	System Organ Class	Adverse Event	Severity	Serious Event	Causality	Outcome	Start
1001-002	Investigations	Weight Gain	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	08/0
1001-002	Investigations	Increased Waist Circumference	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	08/1
1001-003	Investigations	Weight Gain	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	09/1
1001-003	Investigations	Waist Increased	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	09/1
1001-004	Nervous system disorders	Excessive Sedation	MILD	N	DEFINITELY NOT RELATED	RECOVERED/RESOLVED	07/2
1001-004	Investigations	Elevated White Blood Cells in Urine	MODERATE	N	DEFINITELY NOT RELATED	NOT RECOVERED/NOT RESOLV..	07/2
1001-006	Investigations	Weight Gain	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	11/0
1001-006	Investigations	Increased Waist Circumference	MILD	N	PROBABLY RELATED	NOT RECOVERED/NOT RESOLV..	11/0



AE Incidence Rate





CM Reporting Rate

[Back to Index](#)

Country

(All)

Site Identifier

(All)

Subject Identifier

(All)

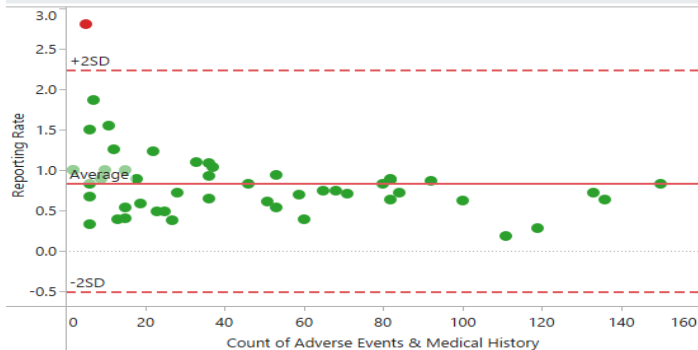
Concomitant Medication Distri..

Product

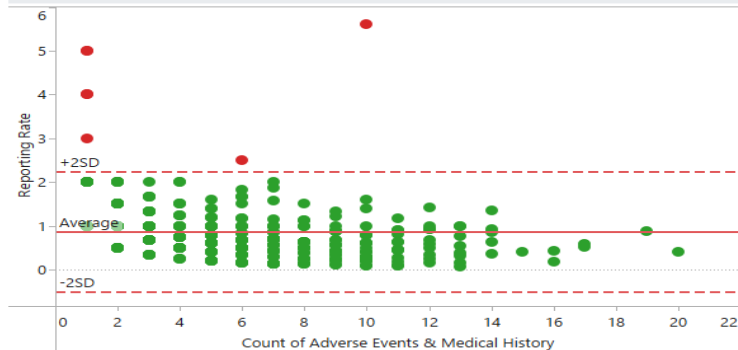
Indication

- ☒ (All)
- ☒ ADVERSE EVENT
- ☒ DIETARY SUPPLEMENT
- ☒ OTHER
- ☒ PRE-EXISTING
- ☒ PROPHYLAXIS
- ☒ Unspecified\Not Provided

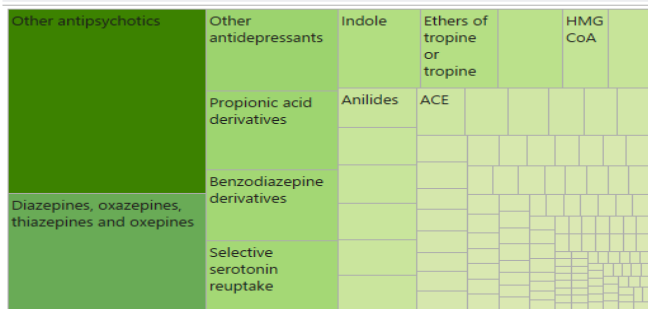
4.1.1 Concomitant Medication Reporting Rate by Site



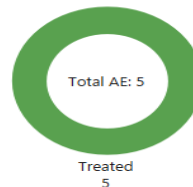
4.1.2 Concomitant Medication Reporting Rate by Subject



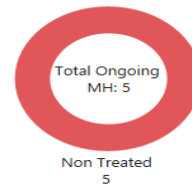
4.1.3 Concomitant Medication Frequency - Product



4.1.4 Concomitant Medications vs Adverse Events



4.1.5 Concomitant Medications vs Ongoing Medical History



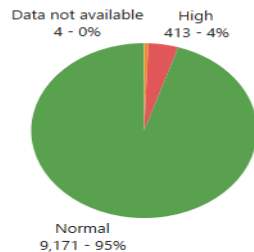


ECG Results Distribution

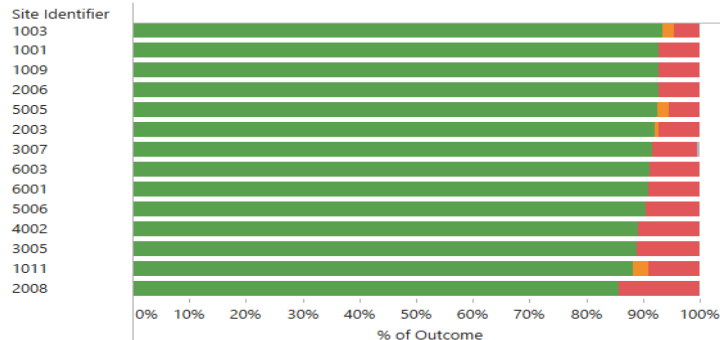
[Back to Index](#)**Country****Site Identifier****Subject Identifier****Test Name****Outcome**

- ☐ Low
- ☐ High
- ☒ Normal
- ☐ Data not available

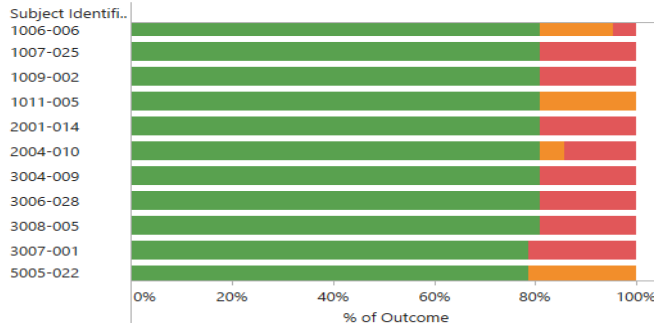
7.3.1 ECG - Result Distribution by Study



7.3.2 ECG - Result Distribution by Site



7.3.3 ECG - Result Distribution by Subject



7.3.4 ECG - Result Details on Demand

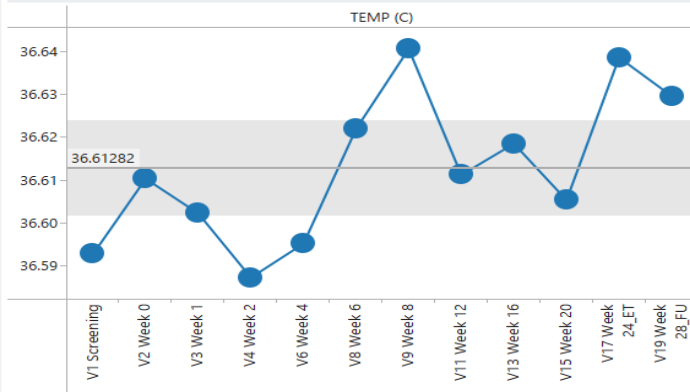
Subject Identifier	Site Identifier	Country	Domain	Test Name	Result
1001-002	1001	NaN	ECG	ECG Mean Heart Rate	59
1001-002	1001	NaN	ECG	ECG Mean Heart Rate	70
1001-002	1001	NaN	ECG	ECG Mean Heart Rate	68
1001-002	1001	NaN	ECG	ECG Mean Heart Rate	58
1001-003	1001	NaN	ECG	ECG Mean Heart Rate	51
1001-003	1001	NaN	ECG	ECG Mean Heart Rate	59
1001-003	1001	NaN	ECG	ECG Mean Heart Rate	55
1001-003	1001	NaN	ECG	ECG Mean Heart Rate	57
1001-004	1001	NaN	ECG	ECG Mean Heart Rate	58



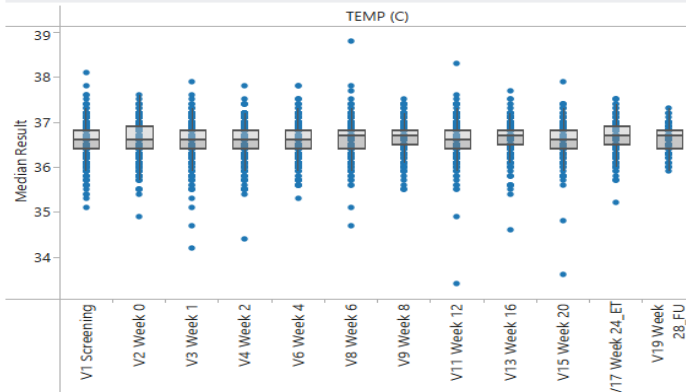
VS Baseline Changes

[Back to Index](#)**Country****Site Identifier****Subject Identifier****Visit Name****Test Name****Visit Category**

6.1.1 Vital Signs - Mean Value Trend by Visit



6.1.2 Vital Signs - Median IQR Distribution by Visit



6.1.3 Vital Signs - Details on Demand

Site Identifier	Subject Identifier	Visit Name	Test Name	Collection Date	Result	Result Units	Outcome
4005	4005-010	V4 Week 2	TEMP	3/17/2017 12:00:00 AM	36.5	C	Normal
4005	4005-010	V6 Week 4	TEMP	3/30/2017 12:00:00 AM	36.4	C	Normal
4005	4005-010	V8 Week 6	TEMP	4/13/2017 12:00:00 AM	36.7	C	Normal
4005	4005-010	V9 Week 8	TEMP	4/27/2017 12:00:00 AM	36.3	C	Normal
4005	4005-010	V11 Week 12	TEMP	5/25/2017 12:00:00 AM	36.8	C	Normal
4005	4005-010	V13 Week 16	TEMP	6/22/2017 12:00:00 AM	36.7	C	Normal
4005	4005-010	V15 Week 20	TEMP	7/20/2017 12:00:00 AM	36.5	C	Normal



Laboratory Baseline Change

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Country

(All)

Site Identifier

(All)

Subject Identifier

(All)

Visit Name

(All)

Test Name

Potassium

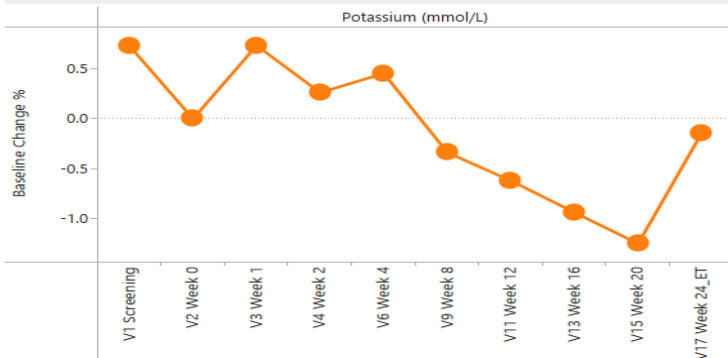
Baseline View

Baseline Change %

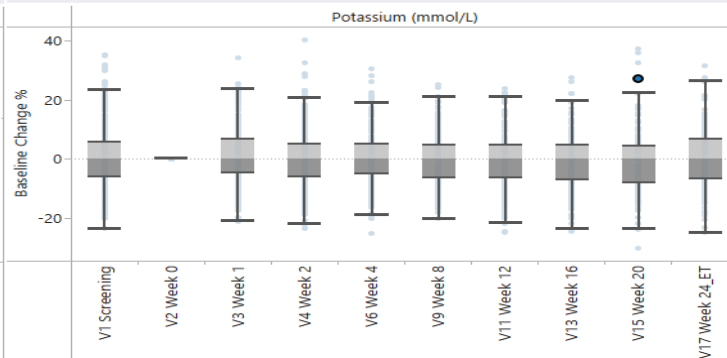
Visit Category

scheduled

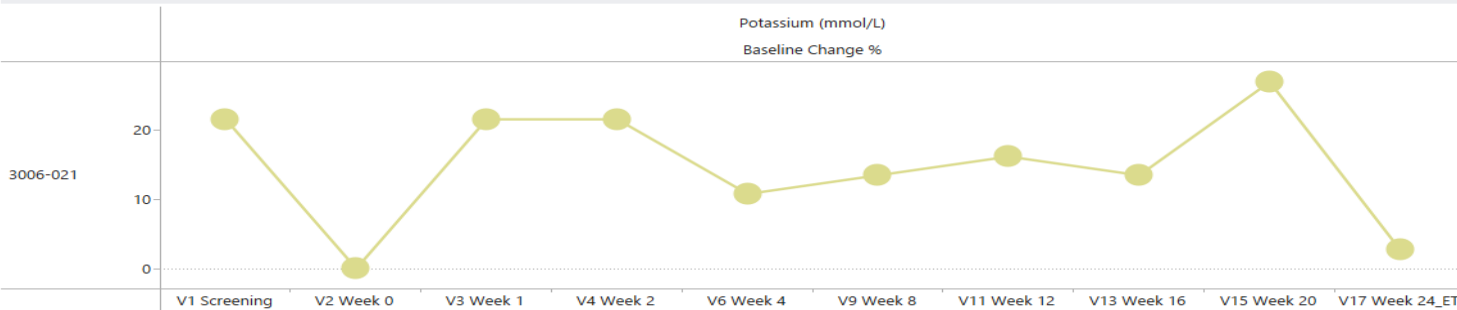
5.2.1 Laboratory - Baseline Change % Trend



5.2.2 Laboratory - Baseline Change % Distribution

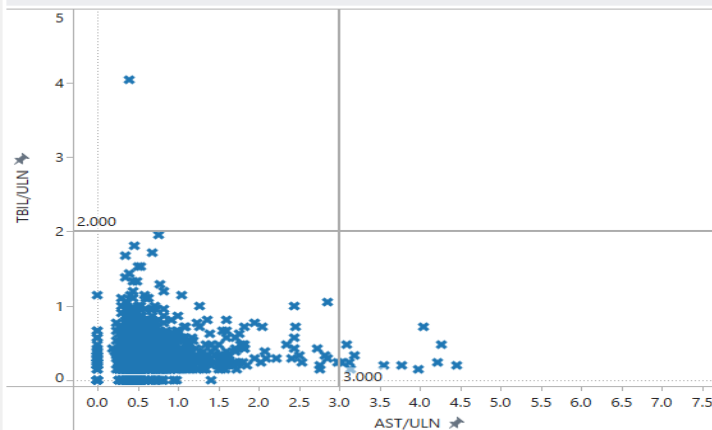
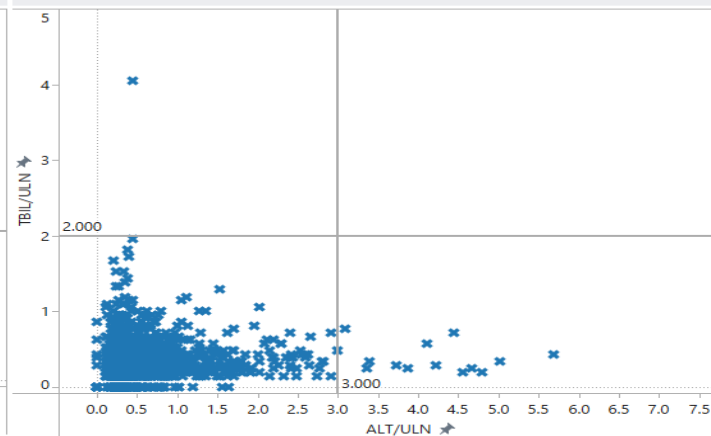


5.2.3 Laboratory - Baseline Change % by Subject





Hy's Law

[Back to Index](#)**Country****Site Identifier****Subject Identifier****Visit Name****Gender**☒ (All)☒ F☒ M**5.4.1 AST vs Total Bilirubin****5.4.2 ALT vs Total Bilirubin****5.4.3 Laboratory - Details on Demand**

Subject Identifier	Site Identifier	Visit Name	Date of Specimen Collecti..	Test Name	Result	Result Units	Upper Limit	Proportion
2003-001	2003	V9 Week 8	Null	Chloride	97	mmol/L	110	0.88
2003-001	2003	V9 Week 8	Null	Lactate Dehydrogenase	143	U/L	242	0.59
2003-001	2003	V9 Week 8	Null	Creatine Kinase	311	U/L	200	1.55
2003-001	2003	V9 Week 8	Null	Alkaline Phosphatase	114	U/L	129	0.88
2003-001	2003	V9 Week 8	Null	HDL Cholesterol	1.93	mmol/L	99999	0.00
2003-001	2003	V9 Week 8	Null	Urate	0.49	mmol/L	0.51	0.96
2003-001	2003	V9 Week 8	Null	Hemoglobin A1C	5.7	%	6	0.95

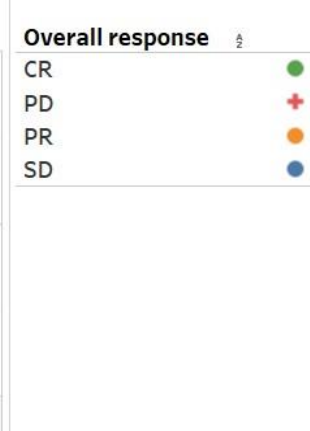
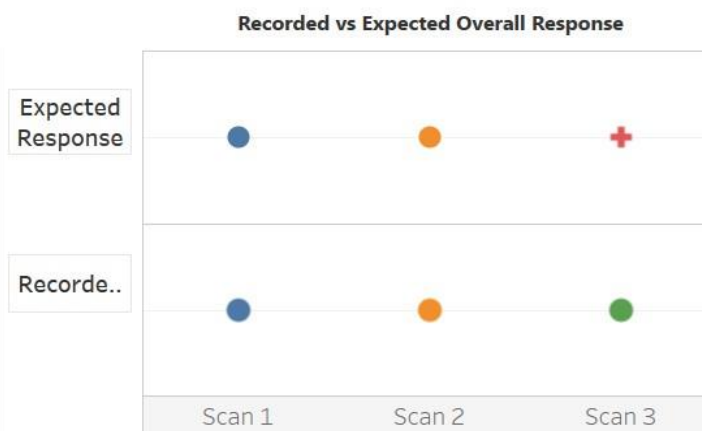
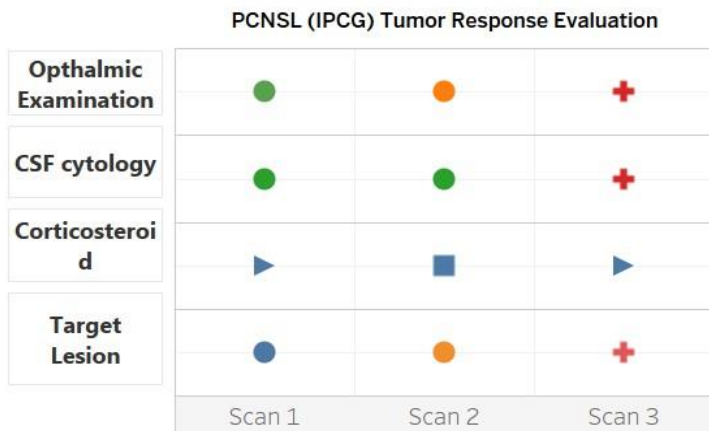
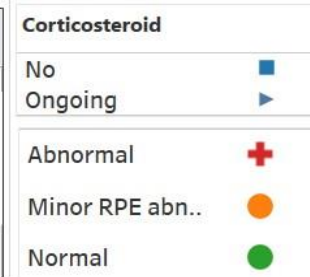
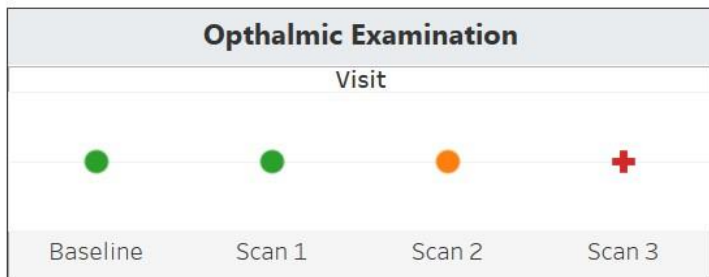


Efficacy Dashboard

- Standard Oncology Dashboards
- RECIST
- Karnofsky
- Tumor Progression
- Response Over Time



Standard Oncology Dashboards





Standard Oncology Dashboards

Target Lesion Individual				
Location	Visit			
Frontal lobe, Left	● 11mm	● 15mm	● 21mm	● 37mm
Frontal lobe, Right	● 15mm	● 17mm	● 25mm	● 30mm
Meninges	● 11mm	● 13mm	● 19mm	● 24mm
Temporal Lobe, Right	● 11mm	● 15mm	● 25mm	● 40mm
	Baseline	Scan 1	Scan 2	Scan 3



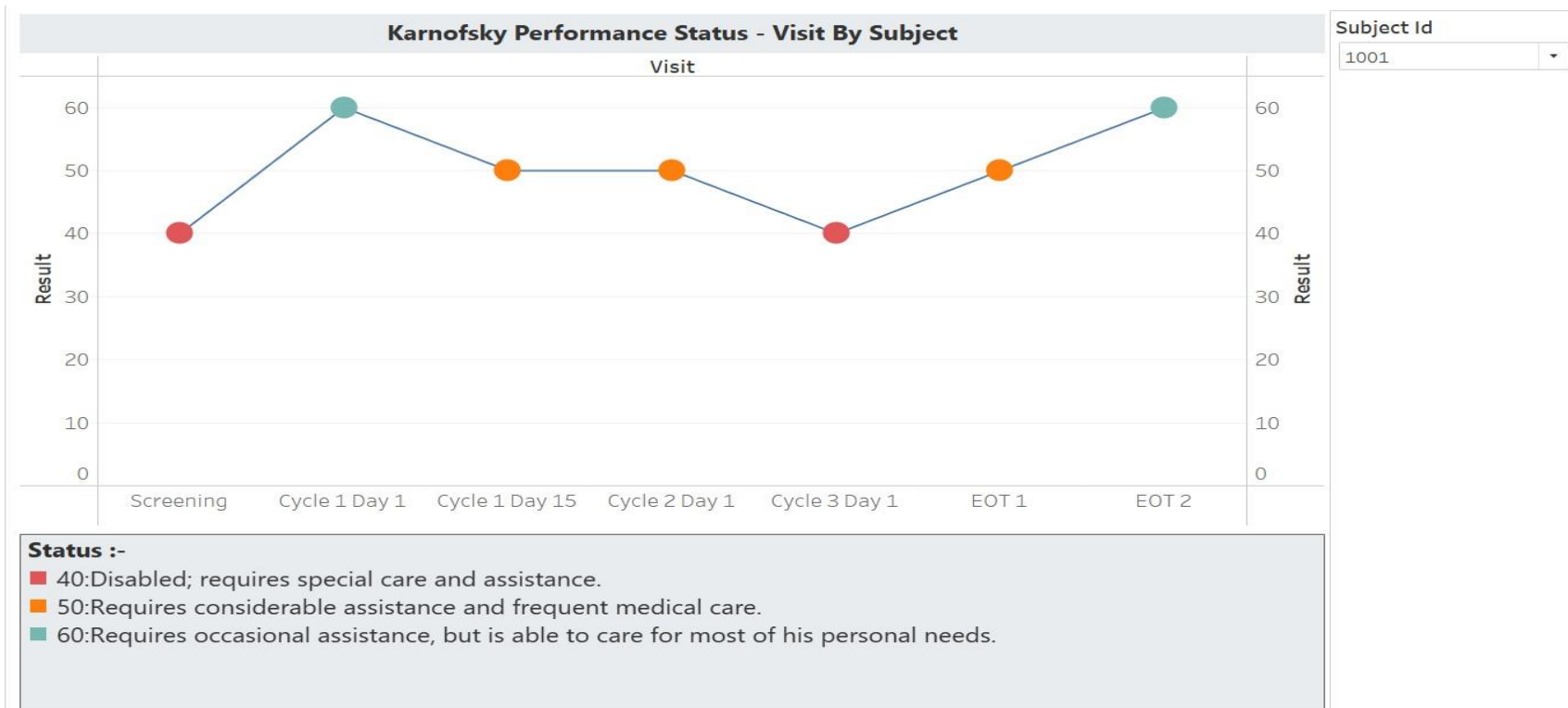


Standard Oncology Dashboards - RECIST





Standard Oncology Dashboards - Karnofsky





Oncology Dashboards – Tumor Progression

Patient ID: ALG-107-145

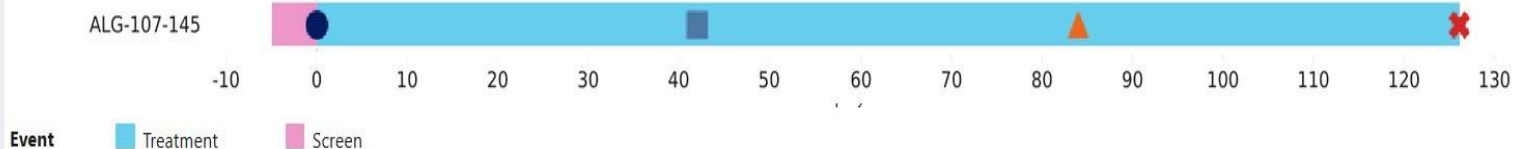
Scan Method

- CT
- MRI

Target Lesion

- Baseline
- PD
- SD

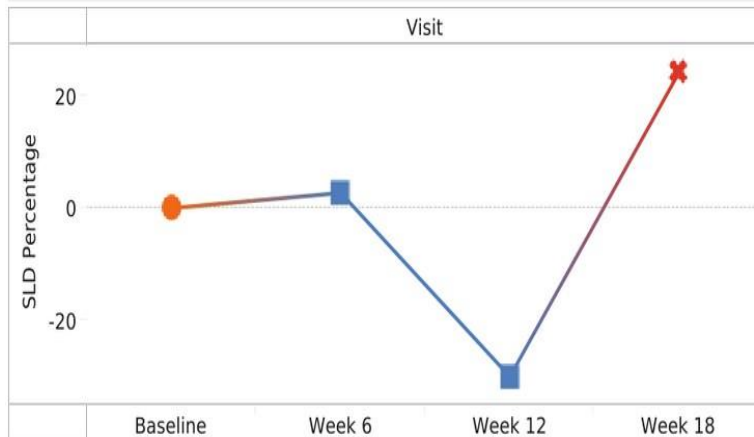
4.1 Patient's Tumor Journey



4.2 Target Lesion- Individual Lesion

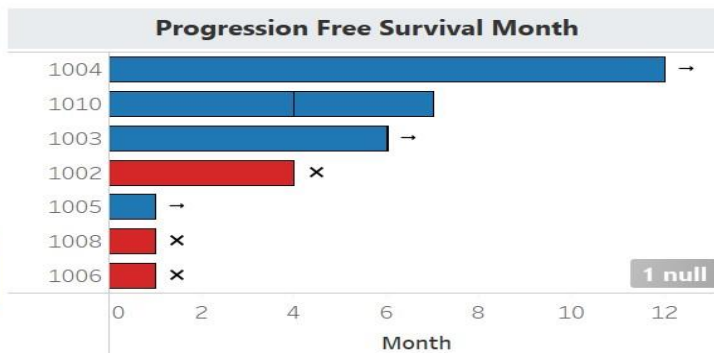
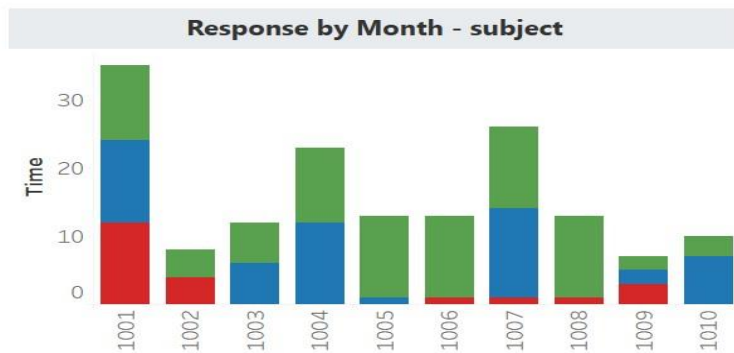
Tumor Site	Visit			
	Baseline	Week 6	Week 12	Week 18
Colon Tumor 1	25 mm	33 mm	21 mm	20 mm
Liver Tumor 1	25 mm	39 mm	49 mm	37 mm
Liver Tumor 2	24 mm	44 mm	56 mm	34 mm
Lung Tumor 1	28 mm	35 mm	21 mm	13 mm
Lung Tumor 2	13 mm	14 mm	14 mm	14 mm
Lung Tumor 3	28 mm	33 mm	28 mm	11 mm

4.3 Target Lesion- % Change from Baseline





Oncology Dashboards – Response Over Time



Best Response

CR

PR

PD

Response

x PD

→ PR



Interactive Dashboards for DMCs

Benefits:

- ✓ Drill-down capabilities
- ✓ Real-time updates
- ✓ Custom views for different stakeholders
- ✓ Demo Screenshots (optional)



Communicating Insights Effectively

Use

Use color coding, annotations, and storytelling

Tailor

Tailor visuals to audience expertise

Highlight

Highlight risk-benefit trade-offs



Future Directions



**AI-driven Signal
Detection**



**Natural Language
Summaries Of
Visual Data**



**Integration With
Wearable And
Real-world Data**



Key Takeaways



Data visualization is not just aesthetic—it's strategic.



Enhances clarity, speed, and confidence in DMC decisions.



Empowers proactive safety management and efficient trial conduct.



Key Engagements

ASK

— Biostatisticians

- What's one visualization you'd like to see in your next DMC meeting?

— Statistical Programmers

- What's one visualization you'd like to program and generate to support our Biostatisticians?





Q&A

Questions and Discussion

Reference:

- Safety and Efficacy Dashboards are referred from the tool deployed by PFM
- [Use of Data Monitoring Committees in Clinical Trials | FDA](#)
- [4.4 Advanced Visualization Techniques | Data Science for Health Informatists](#)
- [Guideline on Data Monitoring Committee](#)



The Global Healthcare Data Science Community

Contact Channels

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✉ office@phuse.global
🌐 phuse.global

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▶ [/phusetube](https://youtube.com/phusetube)
🌐 [/company/phuse](https://linkedin.com/company/phuse)