

Background

- In medical affairs and market access (MMA), programming activities mainly focus on exploratory analysis
- Large quantities of event-based requests (EBR) have become a big burden for MMA biostatistics and programming
- We built a comprehensive R Shiny app to help statisticians, programmers, and clinical teams explore/analyze data
- This app helps in deciding whether a formal EBR is required, reducing the number of EBRs needed

2. Table Builder

- Create tables based on common templates
- Available templates: Demographic, Safety (AE), and Efficacy (Summary by Visit, Survival, Response)
- Users have the option to upload data and select desired variables to use (e.g. the treatment variable)
- Additional options: apply filters, subgroup analysis, add titles and footnotes, select statistical methodology and analysis periods, etc.

File Upload

Choose an ADSL file?

Browse...

adsl.sas7bdat

Upload complete

Treatment

TRT01P

Treatment (N) (optional)

None

Subgroup (optional)

None

Show Total column

Filters

Variables

AGE, SAFFL

AGE

50

to

70

SAFFL

Y

Update Filters

- Examples:** Demographic, AE by SOC/PT, and Survival

Demographic Table			
Variable	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Age			
n	86	84	84
Mean (SD)	75.2 (8.59)	74.4 (7.89)	75.7 (8.29)
Median	76.0	76.0	77.5
Q1, Q3	69.0, 82.0	70.5, 80.0	71.0, 82.0
Min, Max	52, 89	56, 88	51, 88
Sex			
F	53 (61.6)	40 (47.6)	50 (59.5)
M	33 (38.4)	44 (52.4)	34 (40.5)

Adverse Events by System Organ Class/Preferred Term			
System Organ Class Preferred Term	Placebo (N=86)	Xanomeline High Dose (N=72)	Xanomeline Low Dose (N=96)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 (24.4)	36 (50.0)	51 (53.1)
Overall total number of GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	48	118	126
APPLICATION SITE PRURITUS	6 (7.0)	21 (29.2)	23 (24.0)
APPLICATION SITE ERYTHEMA	3 (3.5)	14 (19.4)	13 (13.5)
APPLICATION SITE DERMATITIS	5 (5.8)	7 (9.7)	9 (9.4)
APPLICATION SITE IRRITATION	3 (3.5)	9 (12.5)	9 (9.4)
APPLICATION SITE VESICLES	1 (1.2)	5 (6.9)	5 (5.2)
FATIGUE	1 (1.2)	5 (6.9)	5 (5.2)
APPLICATION SITE URTICARIA	NA	1 (1.4)	2 (2.1)

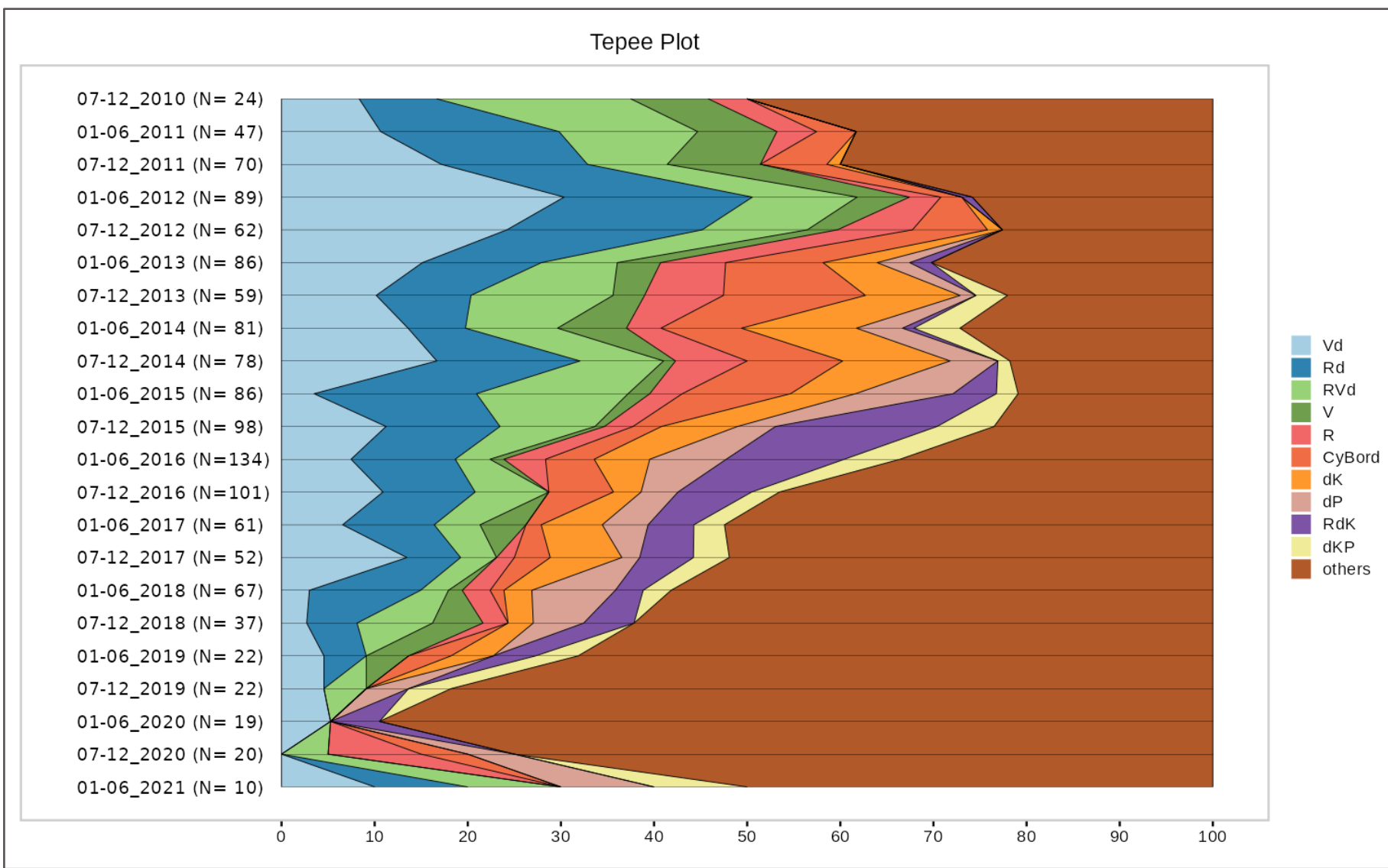
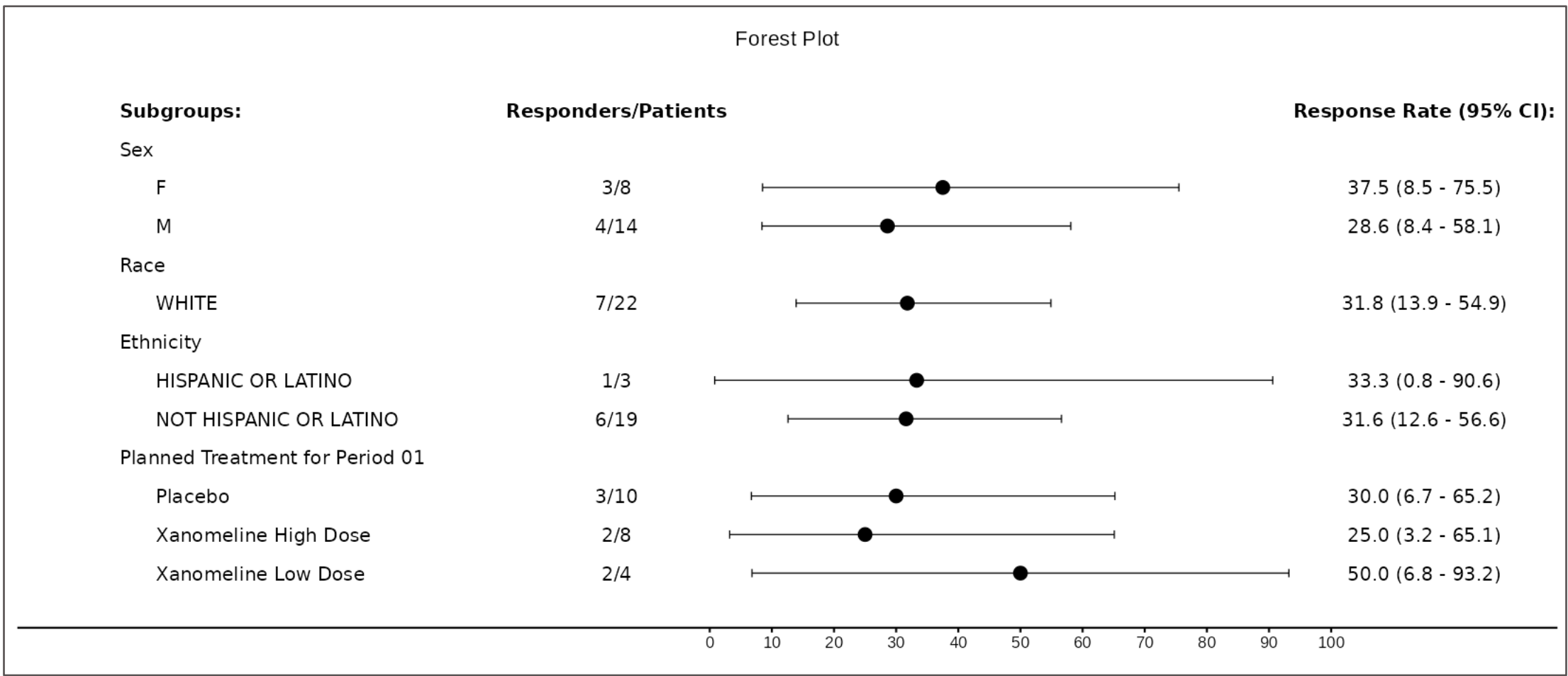
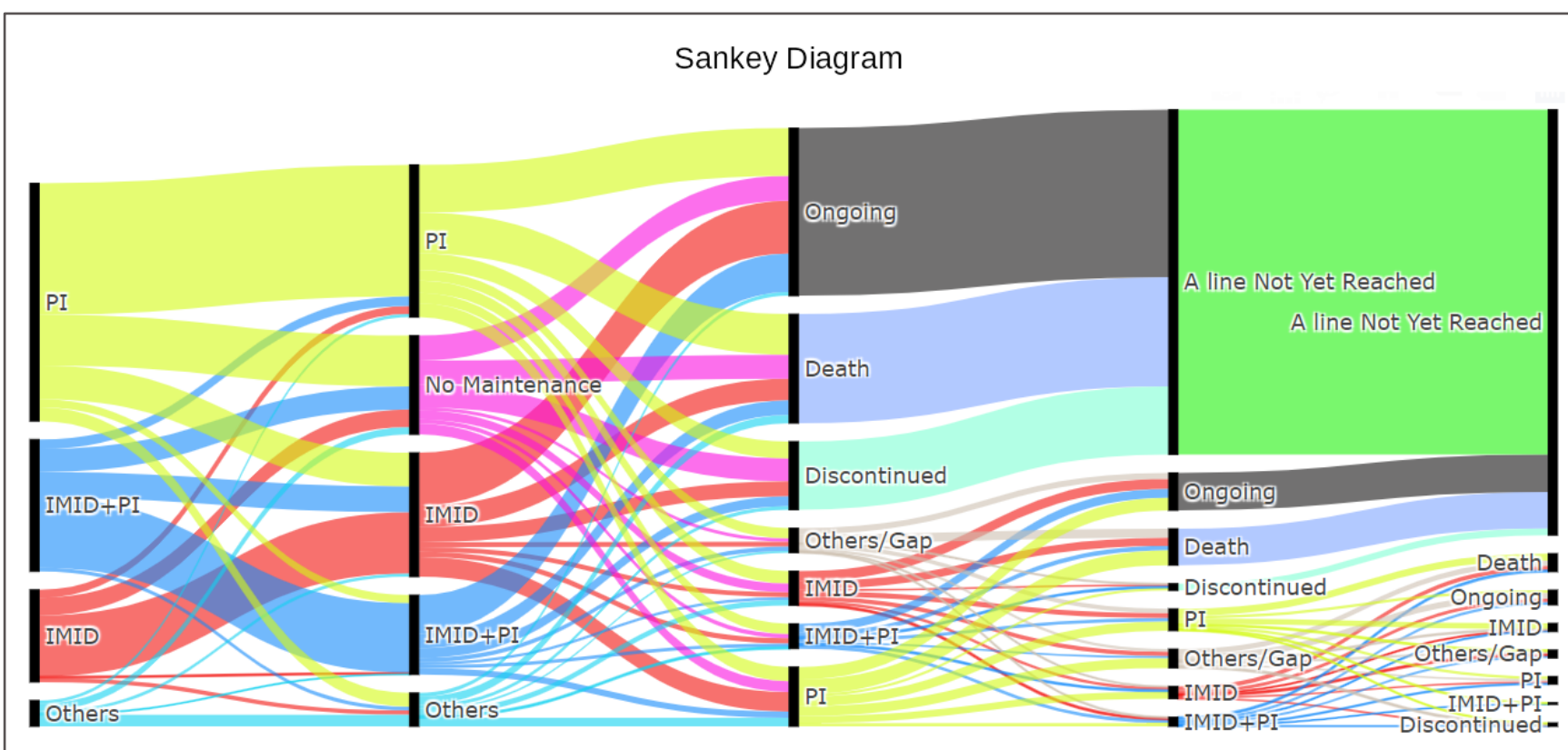
Survival Table		
Survival	Placebo (N=86)	Xanomeline High Dose (N=84)
Status		
Event (%)	3 (3.5)	2 (2.4)
Censored (%)	83 (96.5)	82 (97.6)
Time in Months		
25th Percentile (95% CI)	64.0 (12.0, NA)	43.0 (43.0, NA)
Median (95% CI)	175.0 (12.0, NA)	64.0 (43.0, NA)
75th Percentile (95% CI)	175.0 (12.0, NA)	64.0 (43.0, NA)
HR (95% CI)		2.79 (0.35, 22.09)
P-value		0.3299
Probability of PFS % (95% CI)		
At 18 Months	80.0 (20.4, 96.9)	
At 24 Months	80.0 (20.4, 96.9)	
Follow-Up (months)		
Median (95% CI)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
Min, Max	1.00, 175.00	1.00, 64.00

Overview

- A flexible, dynamic, and powerful review and analysis tool suitable for post-processed data/SDTM/ADaM/RWD
- Evaluate cohort/subgroup/population size
- High efficiency; one template generates numerous outputs
- Expands usage from programmers to other groups: statisticians, clinicians, clinical scientists, WWPS, & HEOR
- Three main sections:*
 - Data Exploration
 - Table Builder
 - Graph Builder

3. Graph Builder

- Create plots based on common templates
- Available templates: Survival, Bar, Correlation, Sankey, Tepee, Swimmer, and Forest
- Similar customization options as Table Builder
- Examples:** Sankey, Forest, and Tepee



Acknowledgments:
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1. Data Exploration

- There are many options available to explore both BDS and subject-level data
- Monitor data quality: missing values in data are shown, grouped by parameter

Data Source

Missing Percentage

Assessment Units

Statistical Summary

Missing Percentage

show

25

entries

Search:

	Parameter	# Missing	N	% Missing
1	Absolute Lymphocyte Count	388	1381	28.10%
2	Absolute Neutrophil count	327	1381	23.68%
3	Alanine Aminotransferase	368	1381	26.65%
4	Aspartate Aminotransferase	426	1381	30.85%
5	Beta-2 Microglobulin	687	1381	49.75%
6	Creatinine	717	1381	51.92%

- Evaluate outliers: view statistical summary (outliers emphasized with red text) and corresponding boxplot
- View at the subject, assessment, visit, or subset level

Data Source

Missing Percentage

Assessment Units

Statistical Summary

Statistical Summary

Select Variables

Absolute Lymphocyte Coun

Filter Range

0

to

13126

Auto (IQR)?

Reset

Show more options

show

25

entries

Search:

	Variable	n	Minimum	Maximum	Mean	Median	Std Dev
1	Absolute Lymphocyte Count (%)	43	0	50	22.233	21	14.721
2	Absolute Lymphocyte Count (10^9/L)	896	0	135.0624	2.271	0.894	9.289
3	Absolute Lymphocyte Count (NR)	10	1	15	7.6	5	5.739

Showing 1 to 3 of 3 entries

Previous

1

Next

Summary Graph

Display all points

Absolute Lymphocyte Count (%)

Absolute Lymphocyte Count (10^9/L)

Absolute Lymphocyte Count (NR)

Parameter (Unit)

Value

- Apply inclusion/exclusion criteria to create an attrition table, to view the size of different subgroups/populations

Data Source

Population Selection

Statistical Summary

Inclusion/Exclusion Criteria

Variables

AGE, SAFFL

AGE

50

to

70

SAFFL

Y

Update Filters

Attrition Table

Height (px)

200

Total cohort size
N = 306

↓

1. 50 ≤ AGE ≤ 70
N = 77

↓

2. SAFFL: Y
N = 65

Excluded N = 229

Excluded N = 12