DIA 2024
GLOBAL ANNUAL MEETING
SAN DIEGO, CA | JUNE 16-20
60TH ANNIVERSARY
CHARTING NEW HORIZONS

Data Insight Generation: Leveraging Data Visualization in Study Planning, Monitoring, Exploration, Reporting and Submission

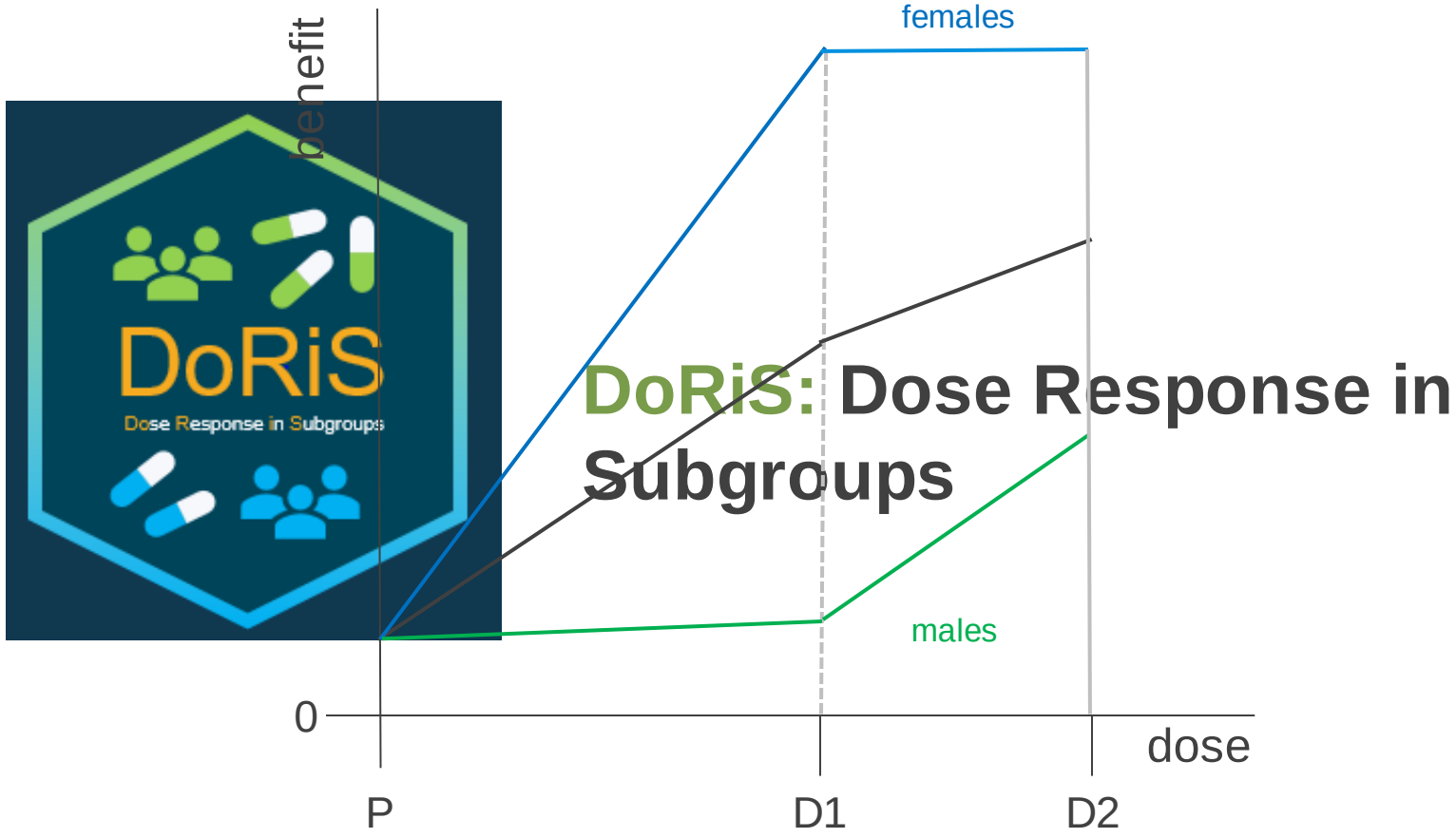
Study Planning, Reporting

Matthew Kumar
Lead Computational Scientist
Bayer

Disclaimer – Content Slide

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Communities or affiliates, or any organization with which the presenter is employed or affiliated.
-

Apps to Support **Dose Finding: DoRiS**



- Identification of patients for personalized dosing

Identification of patients for personalized dosing with DoRiS

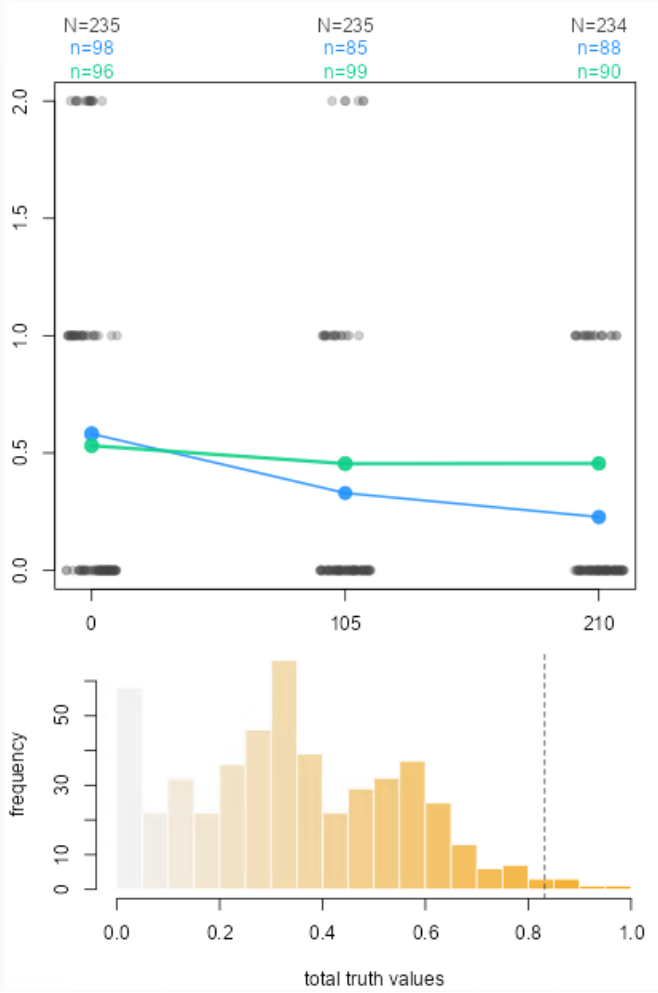
DoRiS - Dose Response in Subgroups

Scatter Plots | About

Description | Evaluation

Show 10 entries Search:

	subgroups:levels	p-value	total truth values	dose : 0	dose : 105	dose : 210
	All	All	A	A	A	A
27	FAC_MCHC: > median	0.012	0.832	0.496	1	1
35	FAC_CK: > median	0.024	0.773	0.319	1	1
7	RACEN: ASIAN	0.07	0.667	0	1	1
12	CNTYGR1N: Asia Pacific	0.072	0.667	0	1	1
13	CNTYGR1N: Eastern Europe	0.082	0.642	0	0.927	1
29	FAC_SGPT: > median	0.102	0.611	0	0.834	1
3	AGEGR01N: >75	0.154	0.566	0.699	0	1
4	SEX: F	0.152	0.545	0.872	0.512	0.251
	BMIGRPN:					



Subgroup factor

FAC_MCHC

subgroup level

> median

Upper limit y:

2

Lower limit y:

0

- [ ] Add overall mean
- [x] Add subgroup complement line
- [ ] Add for all other subgroup level(s)
- [ ] Add background(s) for the truth values
- [x] Add points to graph
- [x] Jitter points

One easy access to all our apps

www.biostatisticsinnovationcenter.org

B.I.C BIOSTATISTICS INNOVATION CENTER

How to get the apps

AdEPro
R-package on CRAN | source code on GitHub | article | video

BReasy
source code on GitHub

DetectoR
source code on GitHub

DoRiS
appearing soon

dosedesignR
R-package on CRAN

elaborator
source code on GitHub | article

interim
R-package on CRAN

interimApp
R-package on CRAN

Megaplots
appearing soon

safetygraphicsif
source code on GitHub

Subgroup Explorer (subscreen)
R-package on CRAN | source code on GitHub | article

About ...

The Biostatistics Innovation Center at Bayer

Reporting: Clinical Study Report (CSR) Automation

Idea:

- Automate the creation of a high quality, first draft CSR for standard sections (text and table)
- Current process, pain points and efficiencies
- Embracing new ways of working
- Co-development *with* Medical Writing (MW)

Clinical Study Report (CSR) Automation

Narromatic / Narromatic AI:

- Automation based on ARD-*like* format from standard TLF catalogs

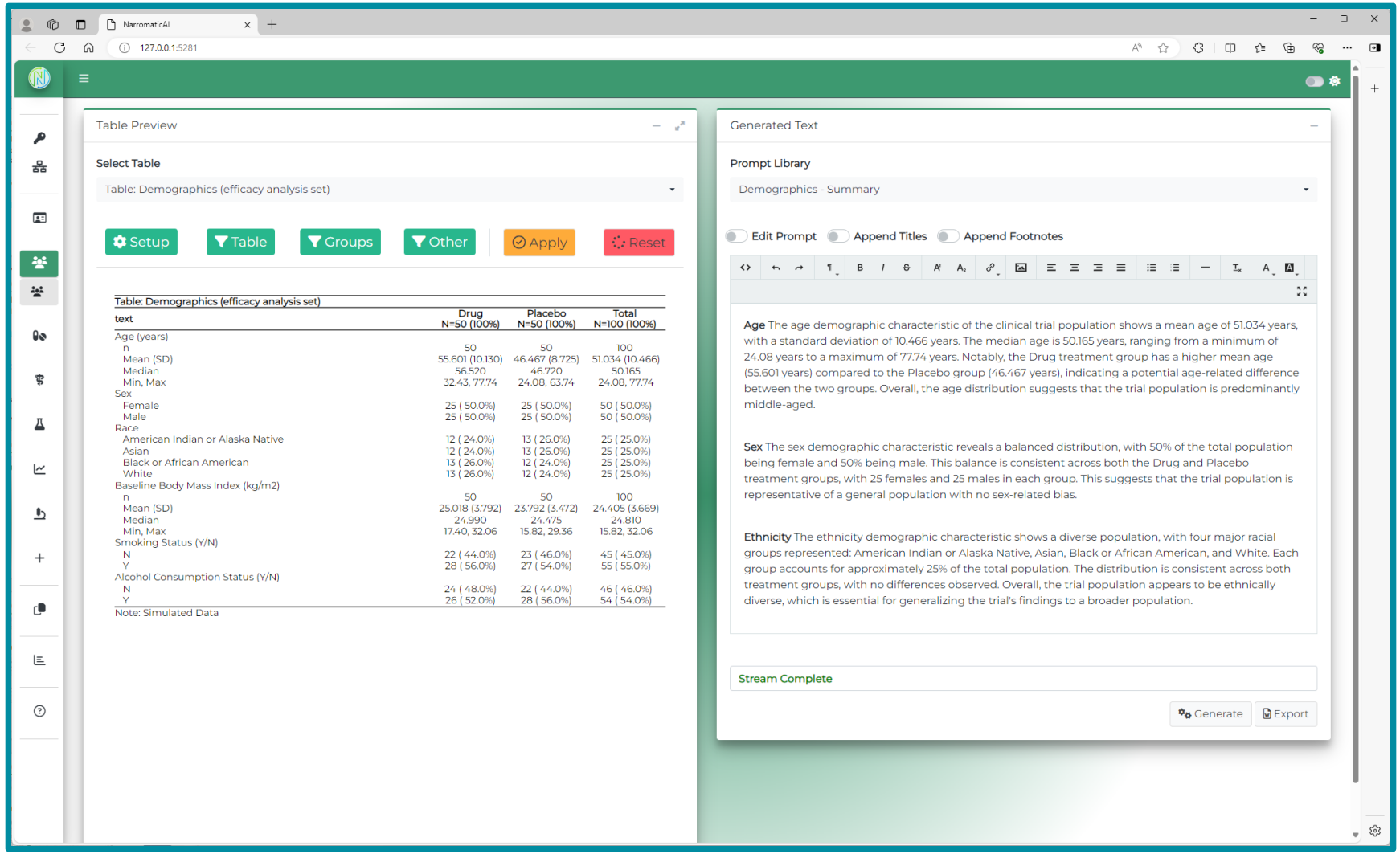
- Current: Text is generated according to “rule sets” crafted by MW (rigid) against standard TLFs

- Emerging: Text generation using AI with prompts crafted by MW (dynamic)

- All results inserted into a CSR template (docx) / Quarto html

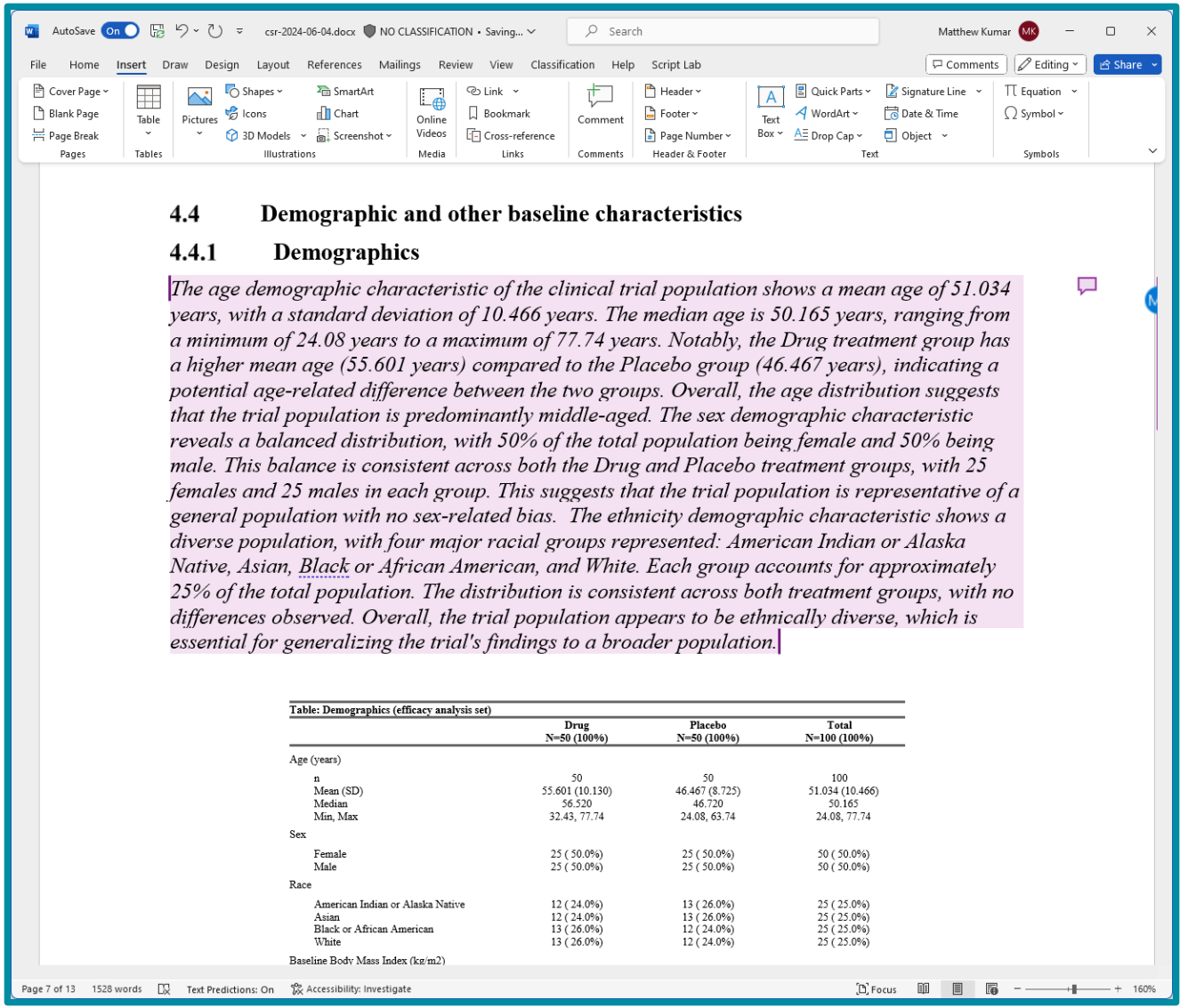
Clinical Study Report (CSR) Automation

Common Interface



Clinical Study Report (CSR) Automation

Export



4.4 Demographic and other baseline characteristics

4.4.1 Demographics

The age demographic characteristic of the clinical trial population shows a mean age of 51.034 years, with a standard deviation of 10.466 years. The median age is 50.165 years, ranging from a minimum of 24.08 years to a maximum of 77.74 years. Notably, the Drug treatment group has a higher mean age (55.601 years) compared to the Placebo group (46.467 years), indicating a potential age-related difference between the two groups. Overall, the age distribution suggests that the trial population is predominantly middle-aged. The sex demographic characteristic reveals a balanced distribution, with 50% of the total population being female and 50% being male. This balance is consistent across both the Drug and Placebo treatment groups, with 25 females and 25 males in each group. This suggests that the trial population is representative of a general population with no sex-related bias. The ethnicity demographic characteristic shows a diverse population, with four major racial groups represented: American Indian or Alaska Native, Asian, Black or African American, and White. Each group accounts for approximately 25% of the total population. The distribution is consistent across both treatment groups, with no differences observed. Overall, the trial population appears to be ethnically diverse, which is essential for generalizing the trial's findings to a broader population.

Table: Demographics (efficacy analysis set)

	Drug N=50 (100%)	Placebo N=50 (100%)	Total N=100 (100%)
Age (years)			
n	50	50	100
Mean (SD)	55.601 (10.130)	46.467 (8.725)	51.034 (10.466)
Median	56.520	46.720	50.165
Min, Max	32.43, 77.74	24.08, 63.74	24.08, 77.74
Sex			
Female	25 (50.0%)	25 (50.0%)	50 (50.0%)
Male	25 (50.0%)	25 (50.0%)	50 (50.0%)
Race			
American Indian or Alaska Native	12 (24.0%)	13 (26.0%)	25 (25.0%)
Asian	12 (24.0%)	13 (26.0%)	25 (25.0%)
Black or African American	13 (26.0%)	12 (24.0%)	25 (25.0%)
White	13 (26.0%)	12 (24.0%)	25 (25.0%)
Baseline Body Mass Index (kg/m2)			

Clinical Study Report (CSR) Automation

Flexibility

Prompt

I am sending you a demographics table from a clinical trial. In point form, please summarize the age, sex and ethnicity demographic characteristics. You must provide at least one treatment group comparison and at least one overall (total) insight as separate bullet points in your reply. Highlight notable differences in red font. Additionally, comment on alcohol and smoking status.

Demographic Characteristics:

- The mean age of the total population is 51.034 years, with a standard deviation of 10.466 years.
- The median age is 50.165 years, ranging from 24.08 to 77.74 years.
- The population is evenly divided between males and females, with 50% in each group.
- The racial distribution is diverse, with no single group making up more than 26% of the population. The distribution is as follows: American Indian or Alaska Native (25%), Asian (25%), Black or African American (25%), and White (25%).

Treatment Group Comparison:

- The mean age of the drug group is 55.601 years, which is 9.134 years older than the placebo group, with a mean age of 46.467 years.

Overall Insight:

- The population has a relatively low mean body mass index (BMI) of 24.405 kg/m2, indicating that the majority of participants are of normal weight or slightly overweight.

Alcohol and Smoking Status:

- About 55% of the population are smokers, with a similar proportion in both the drug and placebo groups.
- About 54% of the population consume alcohol, with a slightly higher proportion in the placebo group (56%) compared to the drug group (52%).

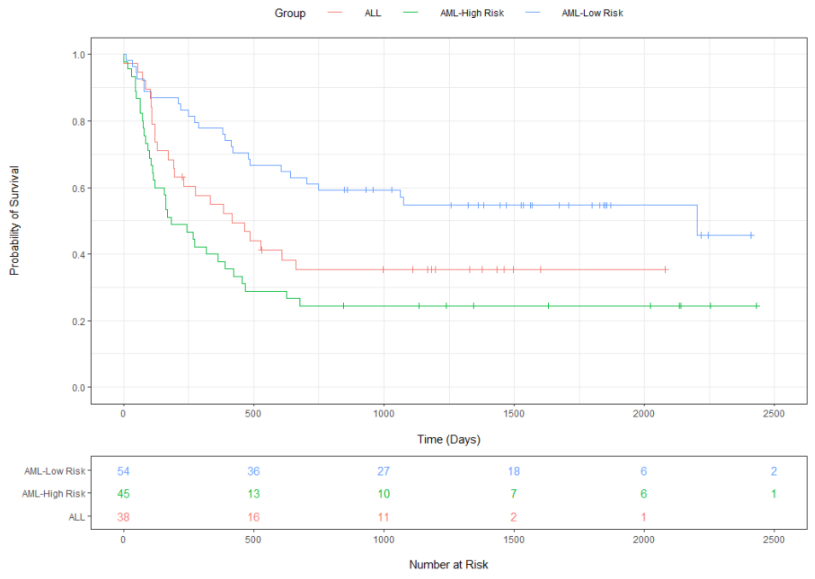
Clinical Study Report (CSR) Automation

Interpreting Figures

Figure Preview

Select Figure

Fig_3.2_Overall_Survival.png



Generated Text

Prompt

Here is a result from a clinical trial. Please interpret this figure and provide a high level summary and insights.

This figure presents a Kaplan-Meier survival analysis of three groups of patients: ALL (Acute Lymphoblastic Leukemia), AML-High Risk (Acute Myeloid Leukemia - High Risk), and AML-Low Risk (Acute Myeloid Leukemia - Low Risk).

The x-axis represents the time in days, while the y-axis represents the probability of survival. The survival curves for each group are color-coded: red for ALL, green for AML-High Risk, and blue for AML-Low Risk. The number of patients at risk at different time points is also provided below the graph.

Key insights:
1. The AML-Low Risk group (blue line) has the highest probability of survival over time. The survival probability remains relatively high even after 2000 days.

2. The ALL group (red line) shows a moderate probability of survival, lower than the AML-Low Risk group but higher than the AML-High Risk group.

3. The AML-High Risk group (green line) has the lowest probability of survival, with a steep decline in survival probability within the first 500 days.

4. The number of patients at risk decreases over time for all groups, with the AML-High Risk group having the steepest decline in patient numbers.

Overall, the figure indicates that patients with AML-Low Risk have the best prognosis, while those with AML-High Risk have the poorest prognosis. The ALL group falls in between these two in terms of survival probability.

Generate Export

Future Directions

- Saving progress, collaborate with colleagues, restore settings, multiple (re)-exports
- Investigate the technical application to patient narratives, content re-use with protocol and/or SAP, QC activities
- Integration into other internal document repositories for efficiency
- Towards open-source

Acknowledgement

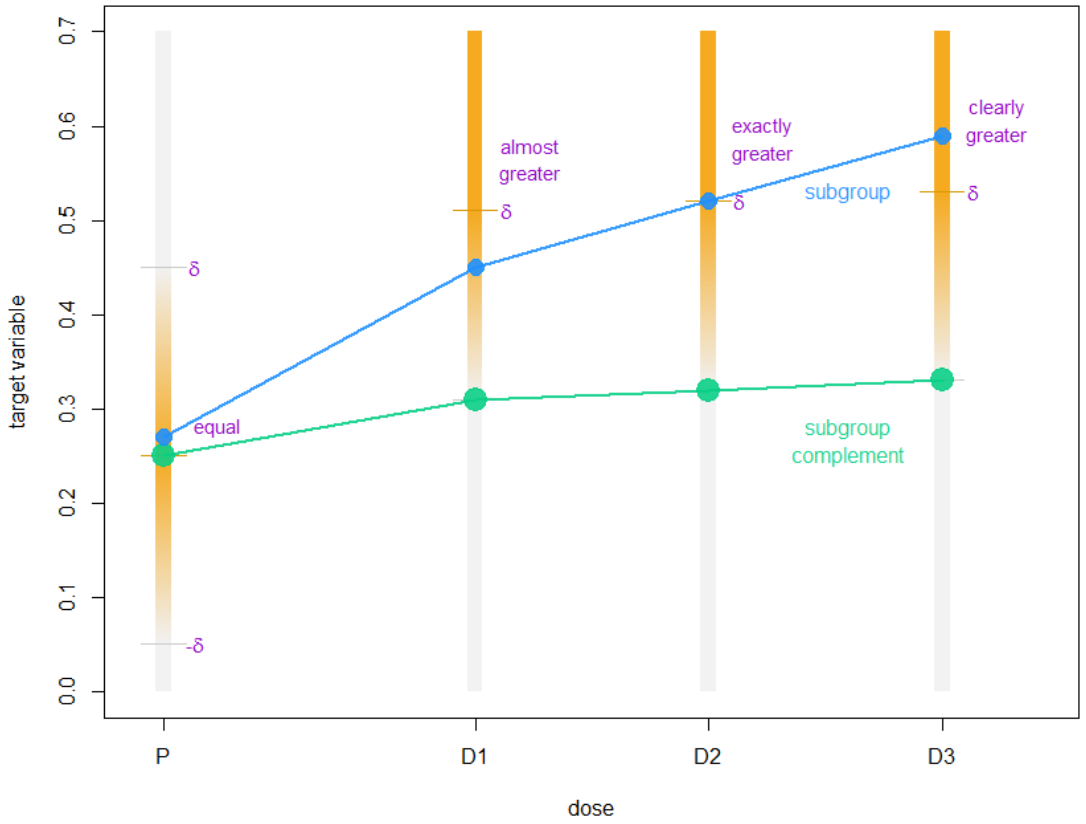
Matthew Kumar

Lead Computational Scientist

Bayer

Back Up

Identification of patients for personalized dosing with DoRiS



Say in which pattern of deviation you are interested, e.g.
equal – greater – greater – greater

Specify δ, a clinically meaningful difference in which you are interested.

A truth value for the difference in each dose to match the pattern is assigned, based on δ (using fuzzy logic).

The total truth value is determined.

A permutation test is performed with the total truth value.

Clinical Study Report (CSR) Automation

Rule Based Text

Data Source: https://github.com/phuse-org/PODR