



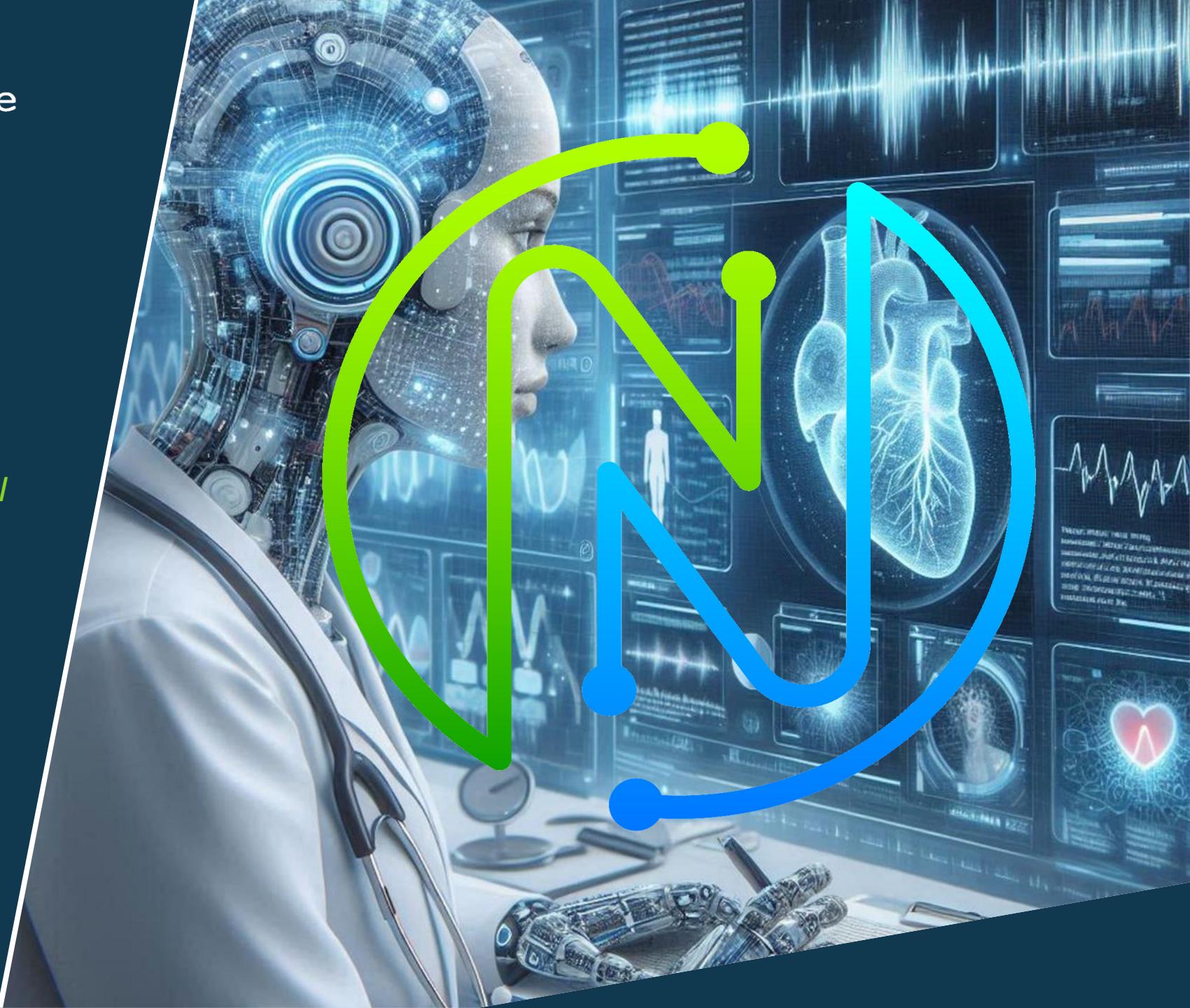
# NarromaticAI

*Supporting the Medical Writing Process with R, Shiny, and GenAI*



**Matthew Kumar (author)**  
Robert Adams (presenter)

2024-09-17





# About the author

Blog: [Matthew Kumar \(matt-kumar.netlify.app\)](https://matt-kumar.netlify.app)



LinkedIn: <https://www.linkedin.com/in/matthew-kumar-24910629/>

**Matthew Kumar**   [About](#)   [Projects](#)   [Blog](#)   [Talks](#)   [Publications](#)



## Biography

I'm currently a Associate Director, Lead Computational Scientist with over 10 years experience in statistical methods, programming and data visualization across multiple industries. My main weapons of choice are R, Shiny, git, and python for descriptive and inferential analyses, creating custom reports or dashboard solutions and building interactive web applications.

My formal education includes an MSc.in Biostatistics from the University of Toronto and a Honor's B.A. in Psychology from York University. I have taken a number of courses and workshops related to advanced analytics, software development and computing. I am a strong proponent of continuing education, self-learning and early adoption & experimentation. My current pursuits are learning cloud technologies such as Azure, and building robust applications around large language models (LLMs).

I currently live in Toronto, Ontario with my loving wife and mini labradoodle.

### Interests

- R, Shiny Development
- Statistical Methods
- Data Visualization
- UI and UX

### Education

- MSc in Biostatistics, 2012  
University of Toronto
- Specialized Honor's BA in Psychology, 2009  
York University

[✉](mailto:matthew.kumar@bayer.com) [Twitter](#) [GitHub](#) [LinkedIn](#)

## Portfolio

ideas, prototypes, full-blown projects



**story creator**  
A simple react app that creates a story using ChatGPT from user topics



**shinyMeta**  
An example of using shinyMeta to recreate a plot designed in a shiny app



**GHA and Shiny**  
Github Actions for auto-deployment of shiny apps on shinyapps.io

## Recent Posts

musings, snippets, throwaways

**custom langchain agents**  
AI, LLMs and ChatGPT have been all the 🚀 the last 12 months and I haven't written about it here... until now. Today I want to write about an interesting problem that the langchain can potentially solve.  
Last updated on Mar 29, 2024 · 4 min read

**saving sessions (+ shinylive)**  
It pains me 😞 that whenever I contemplate using shiny for a work-related project, the question of allowing users to save and restore their progress 💬💡 inevitably arises. While there are a variety of ways to do so in shiny (e.g., sessionState, shinyProxy, etc.), one common approach is to use the shinySession package to save the session state to disk and then load it back in later. This is a good solution for most cases, but it has its limitations, particularly when it comes to saving progress in a live environment like shinylive. In this post, I'll explore some alternatives and discuss how they might be used in combination with shinySession to create a more robust saving mechanism.  
Last updated on Nov 25, 2023 · 4 min read

**DevOps Bootcamp**  
Preface I'll preface with this post is related to a project I lead at work. I can't share too many details about it here unfortunately (including code), but what I can safely share is my experience and process 🎉.  
Last updated on Jul 4, 2023 · 5 min read

**reading files with purrr**  
I feel like there are countless examples on how to read a directory of .csv files into R using purrr 📊. However, in those examples the setup is potentially many CSV files being read in and stacked into a single data frame.  
Last updated on Jul 4, 2023 · 2 min read



## **Disclaimer:**

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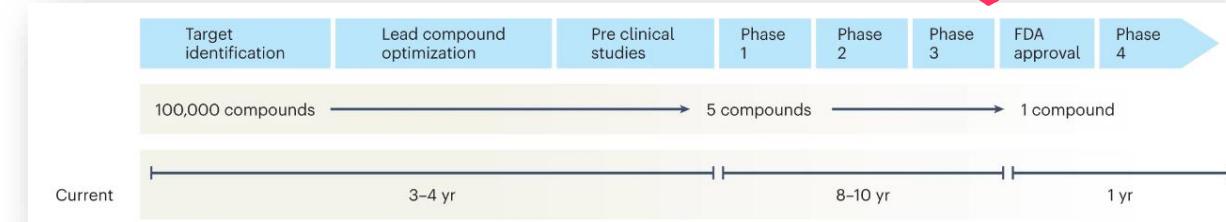
# The Medical Writing Process



Wrapping it up...

## // Assume a **blinded pivotal Phase III oncology trial**

- // Study conducted over several years
- // Consumed \$\$\$ (millions)
- // Crucial milestone for any Pharma company
- // **Results** of studies are primarily **TLFs (tables, listings, figures - the actual data)** and a **CSR (clinical study report)** which are shipped to authorities in order to request market authorization of a drug for a specific indication
- // Data unblinding → Results exists in thousands (literally!!!) of tables → Narratives need to be written that describe study outcomes (efficacy), adverse events (safety), demographics, ... and many more summary tables
- // Challenges: tedious, manual, time consuming, lot of responsibilities, lot of details, document styling, subtle scientific language, time lines...



Monthly Report			
Category	Quantity	Quantity	Total
Category 1	100	100	200
Category 2	200	200	400
Category 3	300	300	600
Category 4	400	400	800
Category 5	500	500	1000
Category 6	600	600	1200
Category 7	700	700	1400
Category 8	800	800	1600
Category 9	900	900	1800
Category 10	1000	1000	2000
Category 11	1100	1100	2200
Category 12	1200	1200	2400
Category 13	1300	1300	2600
Category 14	1400	1400	2800
Category 15	1500	1500	3000
Category 16	1600	1600	3200
Category 17	1700	1700	3400
Category 18	1800	1800	3600
Category 19	1900	1900	3800
Category 20	2000	2000	4000
Category 21	2100	2100	4200
Category 22	2200	2200	4400
Category 23	2300	2300	4600
Category 24	2400	2400	4800
Category 25	2500	2500	5000
Category 26	2600	2600	5200
Category 27	2700	2700	5400
Category 28	2800	2800	5600
Category 29	2900	2900	5800
Category 30	3000	3000	6000
Category 31	3100	3100	6200
Category 32	3200	3200	6400
Category 33	3300	3300	6600
Category 34	3400	3400	6800
Category 35	3500	3500	7000
Category 36	3600	3600	7200
Category 37	3700	3700	7400
Category 38	3800	3800	7600
Category 39	3900	3900	7800
Category 40	4000	4000	8000
Category 41	4100	4100	8200
Category 42	4200	4200	8400
Category 43	4300	4300	8600
Category 44	4400	4400	8800
Category 45	4500	4500	9000
Category 46	4600	4600	9200
Category 47	4700	4700	9400
Category 48	4800	4800	9600
Category 49	4900	4900	9800
Category 50	5000	5000	10000
Category 51	5100	5100	10200
Category 52	5200	5200	10400
Category 53	5300	5300	10600
Category 54	5400	5400	10800
Category 55	5500	5500	11000
Category 56	5600	5600	11200
Category 57	5700	5700	11400
Category 58	5800	5800	11600
Category 59	5900	5900	11800
Category 60	6000	6000	12000
Category 61	6100	6100	12200
Category 62	6200	6200	12400
Category 63	6300	6300	12600
Category 64	6400	6400	12800
Category 65	6500	6500	13000
Category 66	6600	6600	13200
Category 67	6700	6700	13400
Category 68	6800	6800	13600
Category 69	6900	6900	13800
Category 70	7000	7000	14000
Category 71	7100	7100	14200
Category 72	7200	7200	14400
Category 73	7300	7300	14600
Category 74	7400	7400	14800
Category 75	7500	7500	15000
Category 76	7600	7600	15200
Category 77	7700	7700	15400
Category 78	7800	7800	15600
Category 79	7900	7900	15800
Category 80	8000	8000	16000
Category 81	8100	8100	16200
Category 82	8200	8200	16400
Category 83	8300	8300	16600
Category 84	8400	8400	16800
Category 85	8500	8500	17000
Category 86	8600	8600	17200
Category 87	8700	8700	17400
Category 88	8800	8800	17600
Category 89	8900	8900	17800
Category 90	9000	9000	18000
Category 91	9100	9100	18200
Category 92	9200	9200	18400
Category 93	9300	9300	18600
Category 94	9400	9400	18800
Category 95	9500	9500	19000
Category 96	9600	9600	19200
Category 97	9700	9700	19400
Category 98	9800	9800	19600
Category 99	9900	9900	19800
Category 100	10000	10000	20000

# Medical Writing – The past



- // Stats Programmer
- // creates TLFs
- // creates RTF document with all tables
- // Ships RTF to MW
- // MW takes template, copies over 10s to 100s of tables
- // Writes narratives describing table content

text	Placebo N=86 (100%)	Xanomeline High Dose N=84 (100%)	Xanomeline Low Dose N=84 (100%)	Total N=254 (100%)
Age				
n	86	84	84	254
Mean (SD)	75.2 (8.6)	74.4 (7.9)	75.7 (8.3)	75.1 (8.2)
Median	76.0	76.0	77.5	77.0
Min, Max	52, 89	56, 88	51, 88	51, 89
Age Category 1				
65-80	42 ( 48.8%)	55 ( 65.5%)	47 ( 56.0%)	144 ( 56.7%)
<65	14 ( 16.3%)	11 ( 13.1%)	8 ( 9.5%)	33 ( 13.0%)
>80	30 ( 34.9%)	18 ( 21.4%)	29 ( 34.5%)	77 ( 30.3%)
Race				
AMERICAN INDIAN OR ALASKA NATIVE	0	1 ( 1.2%)	0	1 ( 0.4%)
BLACK OR AFRICAN AMERICAN	8 ( 9.3%)	9 ( 10.7%)	6 ( 7.1%)	23 ( 9.1%)
WHITE	78 ( 90.7%)	74 ( 88.1%)	78 ( 92.9%)	230 ( 90.6%)
Sex				
F	53 ( 61.6%)	40 ( 47.6%)	50 ( 59.5%)	143 ( 56.3%)
M	33 ( 38.4%)	44 ( 52.4%)	34 ( 40.5%)	111 ( 43.7%)
Ethnicity				
HISPANIC OR LATINO	3 ( 3.5%)	3 ( 3.6%)	6 ( 7.1%)	12 ( 4.7%)
NOT HISPANIC OR LATINO	83 ( 96.5%)	81 ( 96.4%)	78 ( 92.9%)	242 ( 95.3%)
Baseline BMI (kg/m^2)				
n	86	84	83	253
Mean (SD)	23.64 (3.67)	25.35 (4.16)	25.06 (4.27)	24.67 (4.09)
Median	23.40	24.80	24.30	24.20
Min, Max	15.1, 33.3	13.7, 34.5	17.7, 40.1	13.7, 40.1
Baseline Height (cm)				
n	86	84	84	254
Mean (SD)	162.57 (11.52)	165.82 (10.13)	163.43 (10.42)	163.93 (10.76)
Median	162.60	165.10	162.60	162.85
Min, Max	137.2, 185.4	146.1, 190.5	135.9, 195.6	135.9, 195.6
Baseline Weight (kg)				
n	86	84	83	254
Mean (SD)	62.76 (12.77)	70.00 (14.65)	67.28 (14.12)	66.65 (13.73)
Median	60.55	69.20	64.90	66.00
Min, Max	34.0, 86.2	41.7, 108.0	45.4, 106.1	34.0, 108.0
Safety Population Flag				
Y	86 (100.0%)	84 (100.0%)	84 (100.0%)	254 (100.0%)

The age demographic characteristic of the clinical trial population shows a mean age of 75.1 years, with a median age of 77.0 years. The age range spans from 51 to 89 years. Notably, the majority of participants (56.7%) fall within the 65-80 age category, while 30.3% are above 80 years old, and 13.0% are below 65 years old.

In terms of sex, the population is predominantly female, with 56.3% of participants identifying as female and 43.7% as male. A comparison between the treatment groups reveals that the Xanomeline High Dose group has a slightly higher proportion of males (52.4%) compared to the Placebo group (38.4%).

The ethnicity demographic characteristic shows that the majority of participants (90.6%) identify as White, followed by 9.1% identifying as Black or African American, and 0.4% identifying as American Indian or Alaska Native. The proportion of Hispanic or Latino participants is 4.7%. Overall, the population is predominantly non-Hispanic or non-Latino (95.3%).



# The Medical Writing Process

Day-to-day challenges MWs face while writing reports / summary documents



- // **Loads of data**, but our templates specify what needs to be included; **only a subset is used**
- // Find and **copy-paste tables / figures** from large Word files over to Word report / summary document template, reformat to fit requirements
- // Not possible to filter or sort or do anything with **static data tables**
- // Spend a lot of time writing **basic descriptions of contents** of a table / figure – **quite predictable text**
  - // Due to short timelines, **less time to interpret** the data
  - // Some tables (e.g., lab values or patient-reported outcomes with baseline and changes from baseline by cycle or visit) are long and complex, making it **difficult to distinguish the relevant messages**, also it is easy to miss something of relevance

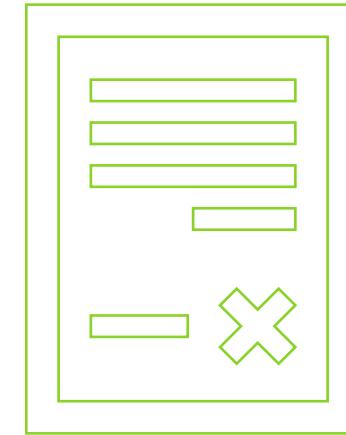
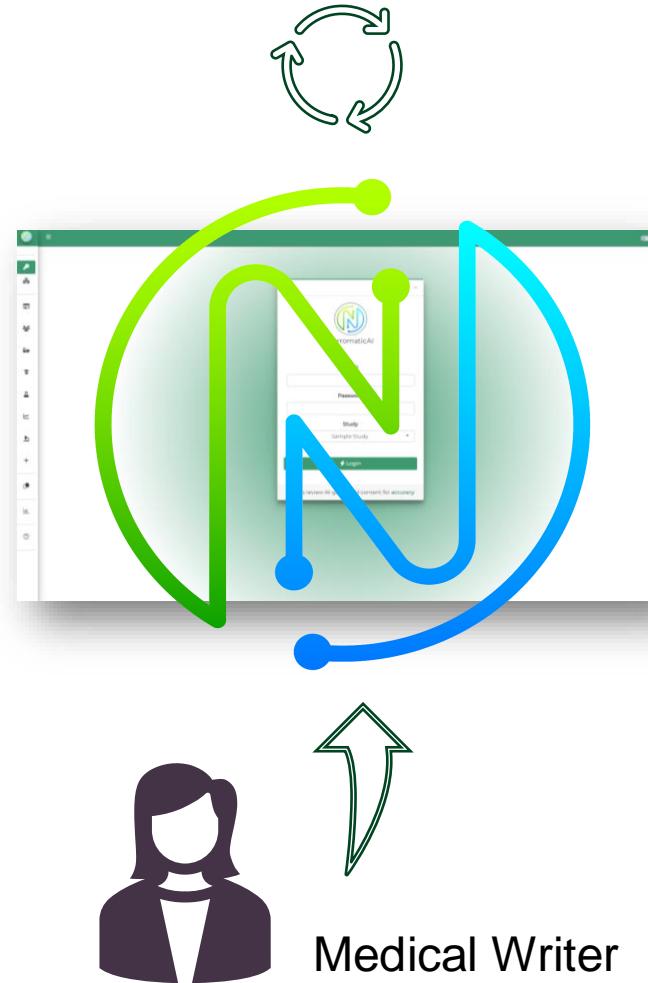
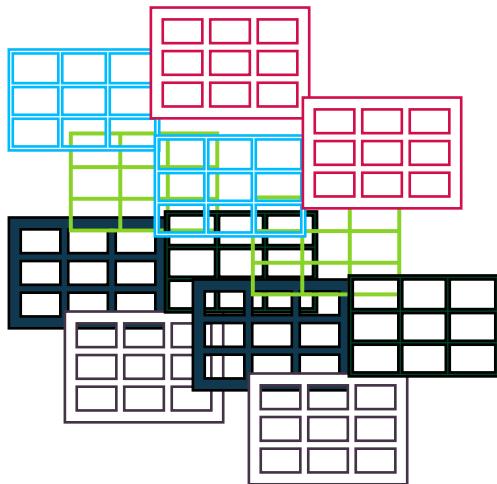
# The idea

## Large Language Models

Llama-3 70B  
Llama-3 8B  
GPT-3.5  
GPT-4o  
GPT-4 Turbo  
...



Tabular study data  
&  
meta data



High-quality, data-driven  
first draft of selected  
CSR sections



# The tech

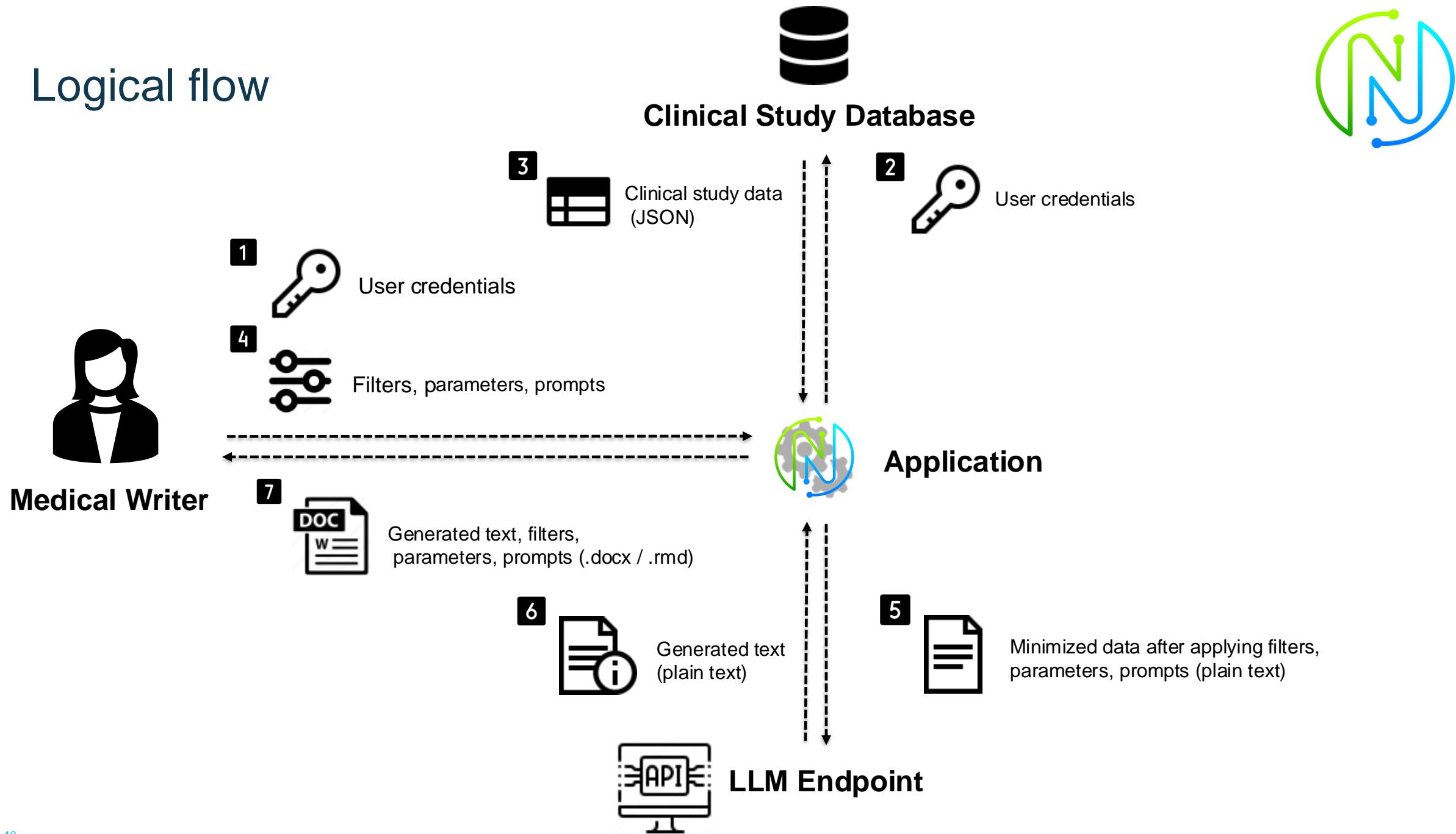
Non-exhaustive



- // R-Shiny application
- // shiny + bs4dash + shinyjs + shinyWidgets + shinybusy + shinytoastr
- // A little custom JS magic 
- // Tables: **flextable**
- // API & Data connectivity: **ssh** & **httr2**
- // Data handling: tidyverse (**tidyr**, **dplyr**, **stringr**, **purrr**, et al.)
- // Output document handling: **officer**, **rmarkdown**
- // ...
- // Hosted on  **posit**™ Connect



# Logical flow





# LLM API code wrapped in a dedicated R-package

Internally released



## mygenassistR



Access myGenAssist API from R

### Welcome

Hi 🦆! This package is designed to ease in the access of [myGenAssist](#) services from R. It's developed to work in both local and cloud (i.e. Science-at-Scale) instances of R.

Please familiarize yourself with the terms of use and official myGenAssist documentation [here](#).

### Installation

You can clone this repository locally or install directly from your console:

```
remotes::install_github('bayer-int/mygenassistR')
```

### Getting Started

Please take a look at the articles to get started. These articles include strategies, concepts and code for working with the package. Happy coding!



# NarromaticAI – Mission

Accelerating Regulatory Writing with AI



The screenshot shows the NarromaticAI web application. At the top, there's a navigation bar with tabs for "Disclaimer" and "About". On the right side of the header, there's a "DRAFT" badge and an "Information" button. The main content area features the title "Narromatic - Accelerating Regulatory Writing with AI" and a subtitle explaining the "Intent": "Provide a high-quality, data-driven first draft of select CSR sections using generative AI." Below this, it shows the "App Version: 1.0.9000". A large, stylized "N" logo is centered in the middle of the page. The bottom section contains two contact cards. The left card is for Matthew Kumar, Lead Computational Scientist, with a photo, contact information, and an "Information" button. The right card is for Kathy Gelato, Submission Medical Writer, with a photo, contact information, and an "Information" button.

Narromatic - Accelerating Regulatory Writing with AI

"Intent:" Provide a high-quality, data-driven first draft of select CSR sections using generative AI.

App Version: 1.0.9000

Information DRAFT

Matthew Kumar  
Lead Computational Scientist

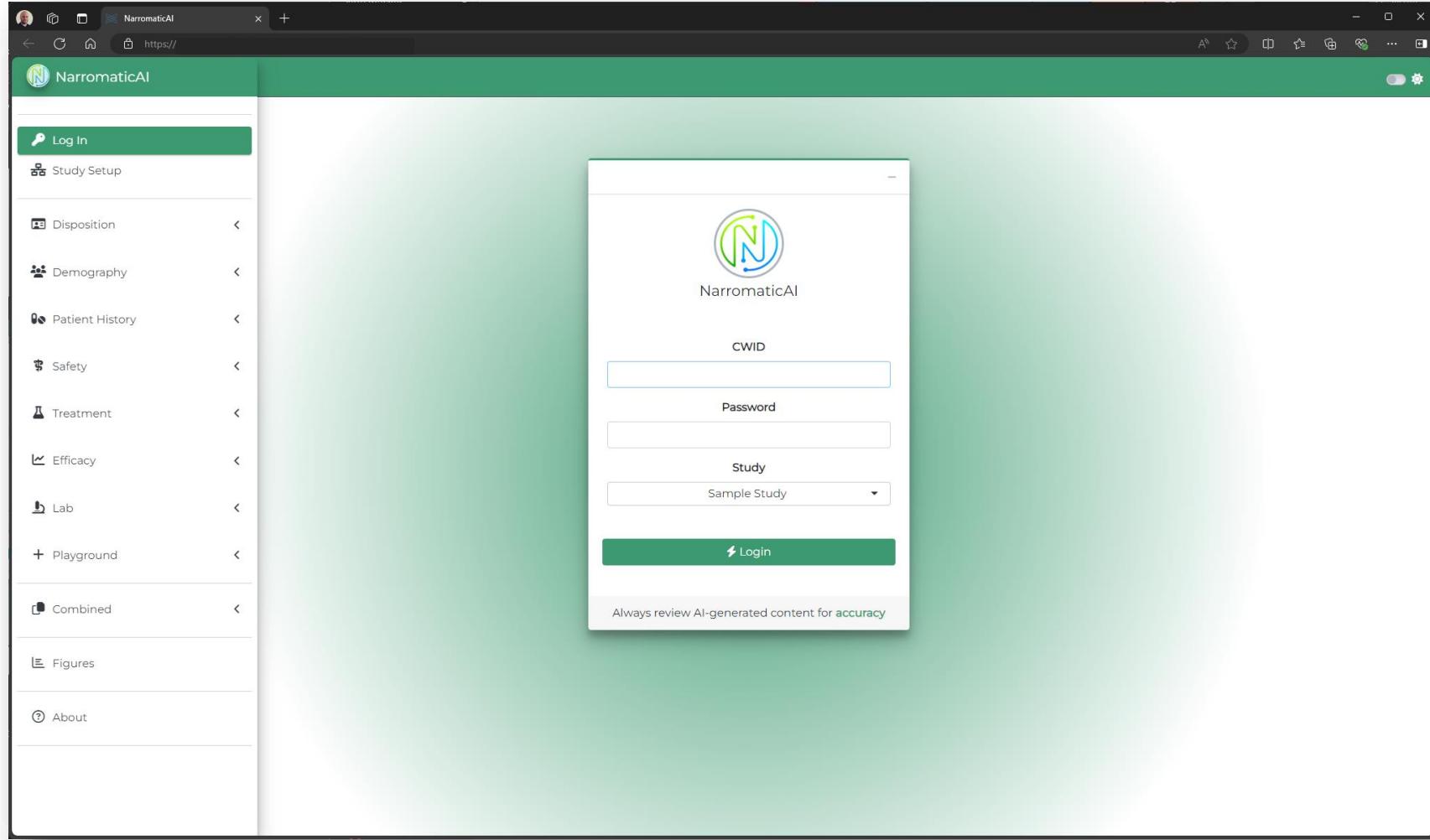
Contact: matthew.kumar@bayer.com

Kathy Gelato  
Submission Medical Writer

Contact: kathyann.gelato@bayer.com

# NarromaticAI – workflow

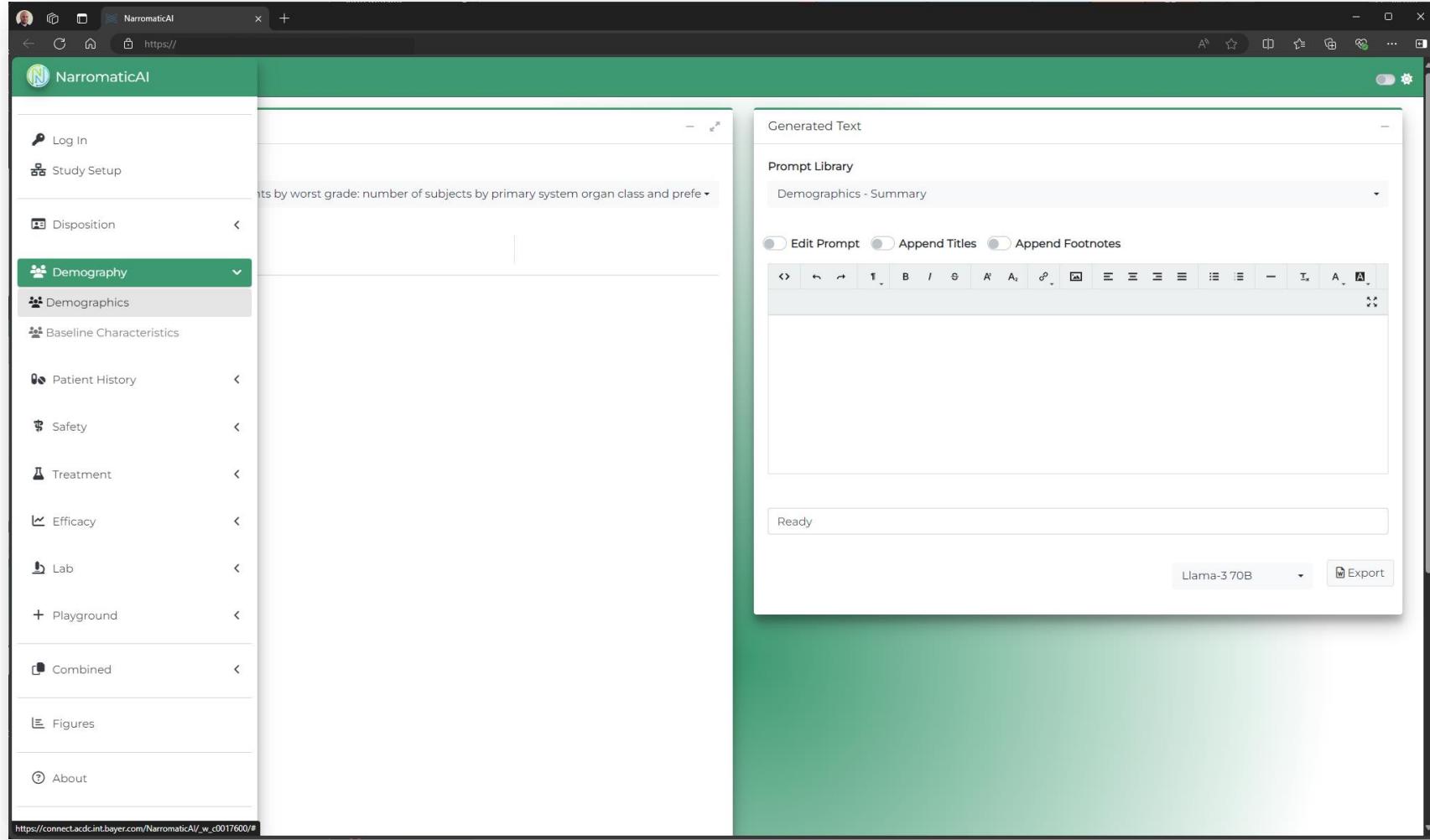
## Login & choosing study



The screenshot shows a web browser window for the NarromaticAI application. On the left, a sidebar menu lists various study components: Log In, Study Setup, Disposition, Demography, Patient History, Safety, Treatment, Efficacy, Lab, Playground, Combined, Figures, and About. The main area displays the NarromaticAI login screen, which includes fields for CWID, Password, and Study (set to Sample Study), and a 'Login' button. A note at the bottom of the login form reads: "Always review AI-generated content for accuracy".

# NarromaticAI – workflow

## Choosing domains of interest

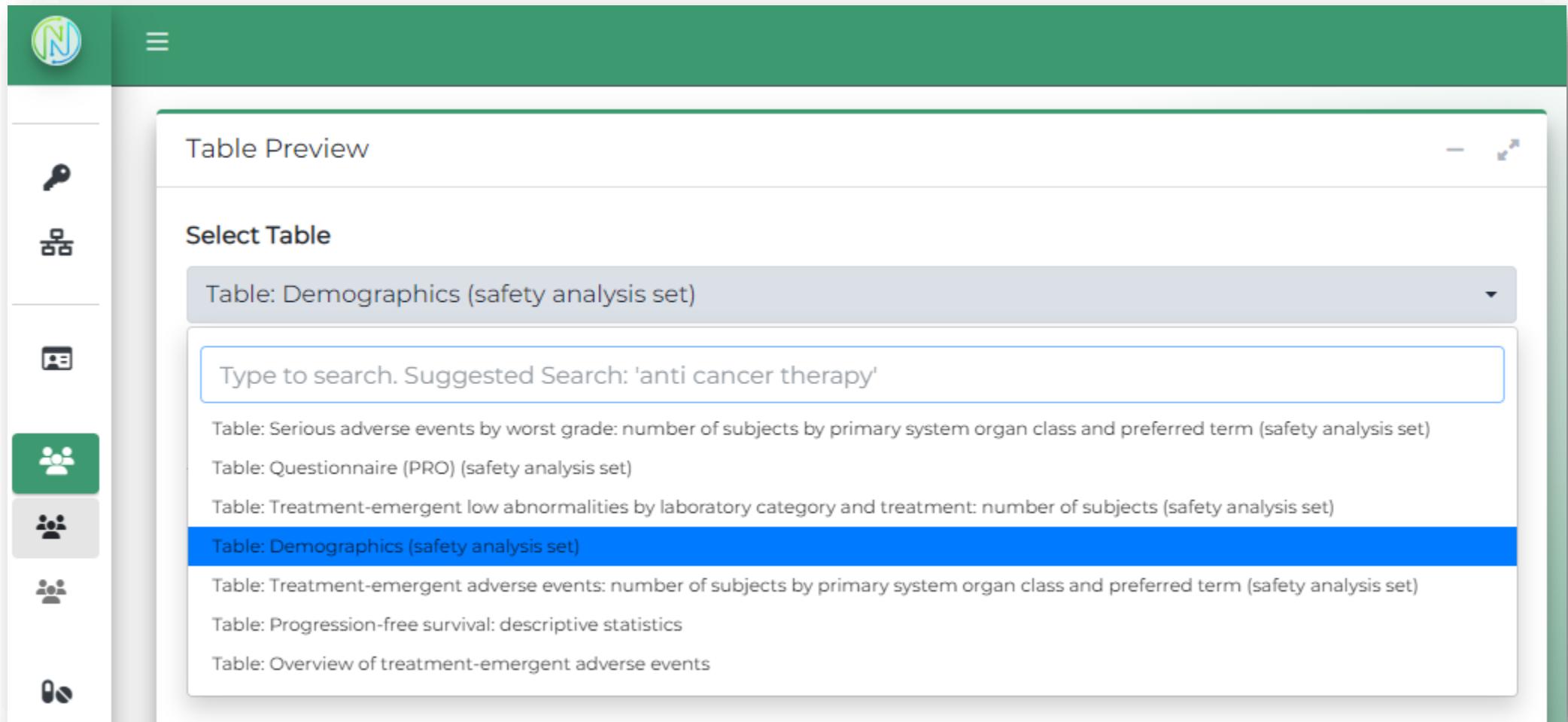


The screenshot shows the NarromaticAI web application interface. On the left, a sidebar lists various study domains: Demography, Demographics, Baseline Characteristics, Patient History, Safety, Treatment, Efficacy, Lab, Playground, Combined, Figures, and About. The 'Demography' item is currently selected, indicated by a green background and a dropdown arrow icon. The main content area is titled 'Generated Text' and contains a rich text editor with a toolbar for bold, italic, underline, etc. A 'Prompt Library' dropdown is set to 'Demographics - Summary'. At the bottom right of the editor are buttons for 'Edit Prompt', 'Append Titles', 'Append Footnotes', and an 'Export' button. The status bar at the bottom shows the URL [https://connect.acdc.int.bayer.com/NarromaticAI/\\_w\\_c0017600/#](https://connect.acdc.int.bayer.com/NarromaticAI/_w_c0017600/#).

# NarromaticAI – workflow



Table select (titles are populated from meta data)

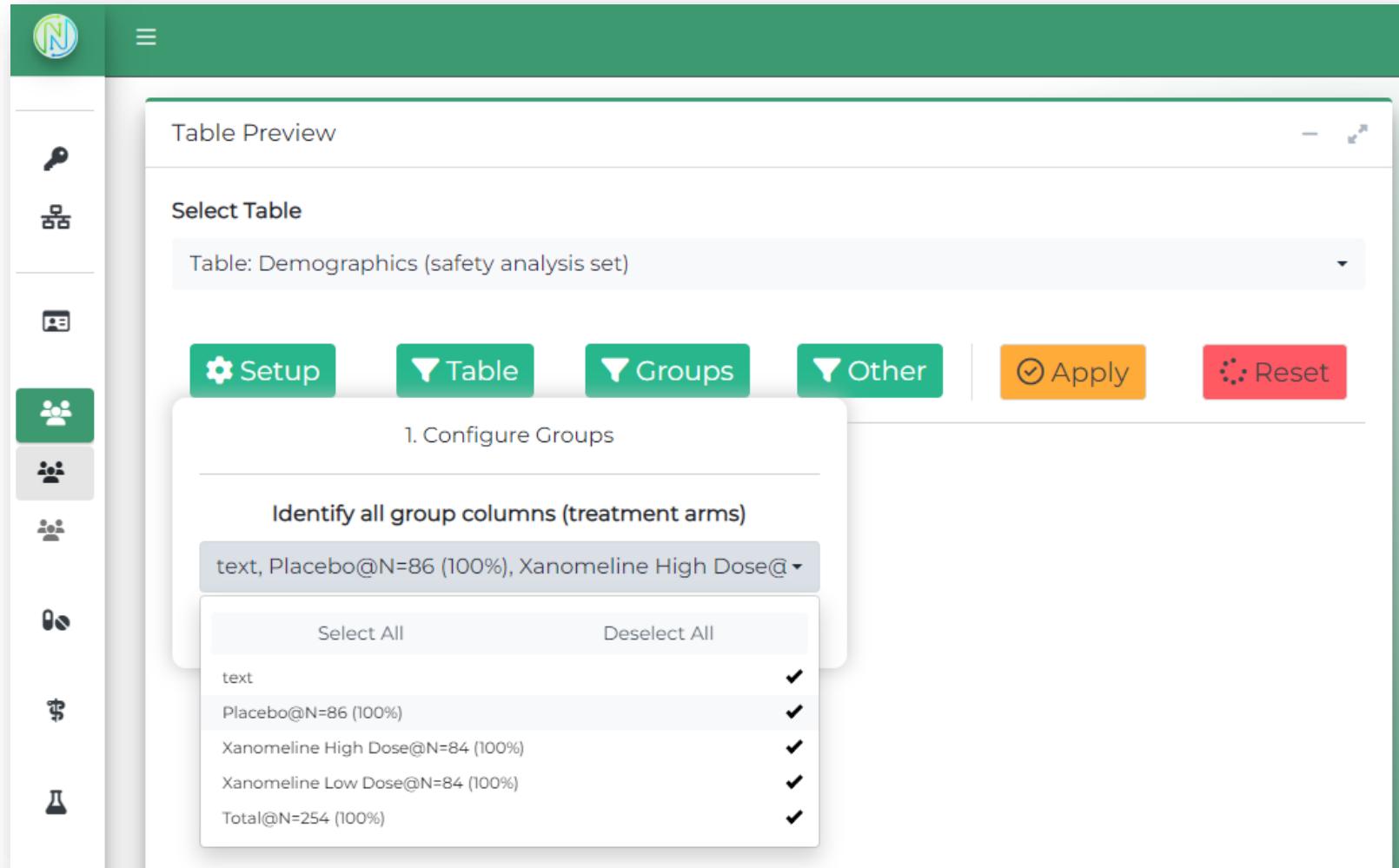


The screenshot shows the NarromaticAI user interface. On the left is a vertical sidebar with icons: a key (top), a document (second), a person (third), two people (fourth), three people (fifth), and a gear (bottom). The main area has a green header with the NarromaticAI logo and a menu icon. Below the header is a 'Table Preview' section with a search bar containing the placeholder 'Type to search. Suggested Search: 'anti cancer therapy''. A dropdown menu lists several table titles:

- Table: Demographics (safety analysis set) (highlighted in blue)
- Table: Serious adverse events by worst grade: number of subjects by primary system organ class and preferred term (safety analysis set)
- Table: Questionnaire (PRO) (safety analysis set)
- Table: Treatment-emergent low abnormalities by laboratory category and treatment: number of subjects (safety analysis set)
- Table: Demographics (safety analysis set) (highlighted in blue)
- Table: Treatment-emergent adverse events: number of subjects by primary system organ class and preferred term (safety analysis set)
- Table: Progression-free survival: descriptive statistics
- Table: Overview of treatment-emergent adverse events

# NarromaticAI – workflow

## Configure table display



The screenshot shows the NarromaticAI interface for configuring table display. On the left is a vertical toolbar with icons for key, table, groups, users, filters, and costs. The main area has a green header bar with a menu icon. Below it is a 'Table Preview' section with a dropdown menu set to 'Table: Demographics (safety analysis set)'. A central configuration panel is open, showing a 'Setup' tab and a 'Groups' tab. The 'Groups' tab is active, displaying a sub-panel titled '1. Configure Groups' with the sub-instruction 'Identify all group columns (treatment arms)'. A dropdown menu lists items: 'text, Placebo@N=86 (100%), Xanomeline High Dose@...'. A modal dialog box is overlaid on this, containing 'Select All' and 'Deselect All' buttons, and a list of items with checkboxes: 'text' (checked), 'Placebo@N=86 (100%)' (checked), 'Xanomeline High Dose@N=84 (100%)' (checked), 'Xanomeline Low Dose@N=84 (100%)' (checked), and 'Total@N=254 (100%)' (checked).

# NarromaticAI – workflow

## Filtering / sorting / thresholding tables



The screenshot shows the NarromaticAI application interface. On the left, there is a vertical navigation sidebar with the following items:

- Log In
- Study Setup
- Disposition
- Demography
- Patient History
- Safety** (selected)
- AE Overview
- AEs by SOC and PT
- AEs by Grade / Intensity
- Intervention-related AEs 1
- Intervention-related AEs 2
- Serious AEs
- Discontinuation
- Deaths
- Treatment
- Efficacy
- Lab
- Playground

This screenshot shows the 'Table Preview' feature. At the top, there are several buttons: 'Setup' (green), 'Table' (green), 'Groups' (green), 'Other' (green), 'Apply' (orange), and 'Reset' (red). Below these are two dropdown menus: 'Threshold (%)' set to 0, and 'Select Arms to apply threshold' set to 'Primary System Organ'. A modal window is open, titled '2. Filter entire table', containing the following fields:

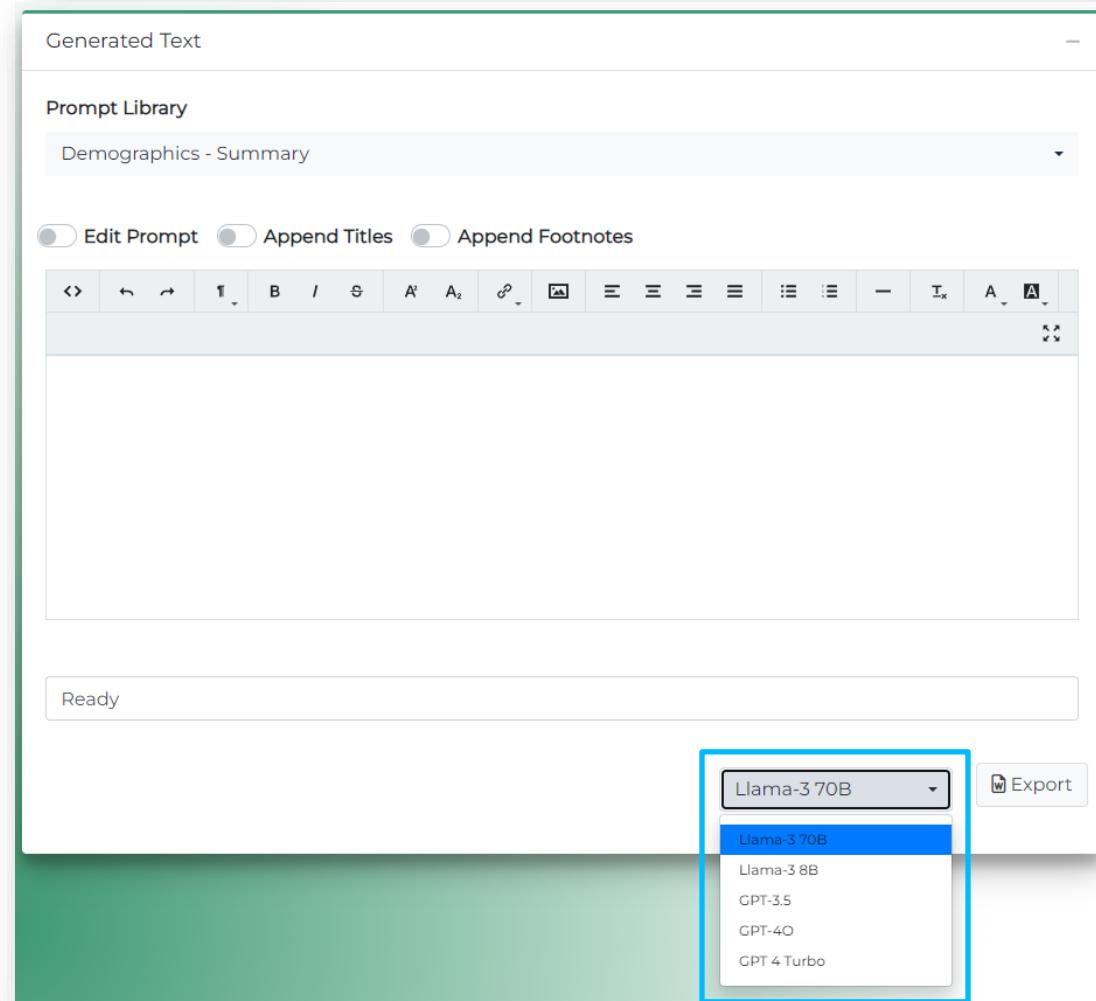
- Threshold (%): 0
- Select Arms to apply threshold: Primary System Organ
- Display levels:
  - Highest (e.g. SOC, Drug Class)
  - Lowest (e.g. PT or Drug Subclass)
- Select Sort Arm: Primary System Organ
- Sort Direction: Ascending

The main table displays data for 'Treatment-emergent adverse events: number of subjects by primary system organ class and preferred term'. It includes columns for 'Primary System Organ', 'Xanomeline Low Dose N=84 (100%)', and 'Total N=254 (100%)'. The data is sorted by primary system organ.

This screenshot shows the final output of the 'Table Preview' feature. At the top, there are buttons: 'Setup' (green), 'Table' (green), 'Groups' (green), 'Other' (green), 'Apply' (orange), and 'Reset' (red). The table below is titled 'Table: Treatment-emergent adverse events: number of subjects by primary system organ class and preferred term (safety analysis set)'. It compares Placebo N=86 (100%) with Xanomeline High Dose N=84 (100%), Xanomeline Low Dose N=84 (100%), and Total N=254 (100%). The table includes a header for 'Primary System Organ Class', 'Preferred Term', 'MedDRA Version 23.1', and columns for 'Placebo N=86 (100%)', 'Xanomeline High Dose N=84 (100%)', 'Xanomeline Low Dose N=84 (100%)', and 'Total N=254 (100%)'. The data is presented in a grid format with various categories and their corresponding subject counts and percentages.

# NarromaticAI – workflow

## Text generation – Choosing a LLM



The screenshot shows the NarromaticAI interface for text generation. At the top, there's a header "Generated Text". Below it is a "Prompt Library" section with a dropdown menu set to "Demographics - Summary". There are three toggle buttons: "Edit Prompt" (selected), "Append Titles", and "Append Footnotes". A toolbar with various text editing icons follows. In the main area, there's a large text input field and a "Ready" button below it. At the bottom right, there's a dropdown menu for selecting an LLM, currently showing "Llama-3 70B" which is highlighted with a blue box. Other options in the dropdown include "Llama-3 8B", "GPT-3.5", "GPT-4O", and "GPT 4 Turbo". An "Export" button is also visible.

# NarromaticAI – workflow

Text generation – Choosing a prompt from the library



The screenshot shows the NarromaticAI interface. On the left, the 'Table Preview' section displays a table titled 'Demographics (safety analysis set)' comparing Placebo (N=86) and Xanomelte High Dose (N=84). The table includes columns for Age, Race, Sex, Ethnicity, Baseline BMI, Baseline Height, and Baseline Weight. On the right, the 'Generated Text' section shows a 'Prompt Library' dropdown menu with options like 'Demographics - Summary', 'Demographics - Lean', 'Medical History - Summary', etc. A modal window titled 'Generated Text' is open, showing the selected 'Demographics - Summary' prompt.

Table Preview

Select Table

Table: Demographics (safety analysis set)

Setup Table Groups Other Apply Result

Table Demographics (safety analysis set)

	Placebo N=86 (100%)	Xanomelte High Dose N=84 (100%)	Xanomelte Low Dose N=84 (100%)	Total N=254 (100%)
Age				
n	86	84	84	254
Mean (SD)	75.2 (10.6)	74.4 (10.8)	75.7 (10.3)	75.1 (10.2)
Median	76.0	76.0	77.3	77.0
Min, Max	52, 89	56, 88	53, 88	51, 89
Age Category				
<60	42 (48.8%)	55 (65.5%)	47 (56.0%)	144 (56.7%)
=60	34 (39.5%)	31 (37.5%)	31 (38.5%)	93 (35.0%)
>60	30 (34.8%)	18 (21.4%)	29 (36.3%)	77 (30.2%)
Race				
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (12%)	0	1 (0.4%)
BLACK OR AFRICAN AMERICAN	8 (9.2%)	9 (10.7%)	6 (7.2%)	23 (8.7%)
WHITE	78 (89.7%)	74 (88.9%)	78 (92.8%)	230 (90.6%)
Sex				
F	53 (61.5%)	40 (47.6%)	50 (59.3%)	143 (56.3%)
M	33 (38.5%)	44 (52.4%)	34 (40.7%)	101 (43.7%)
Ethnicity				
HISPANIC OR LATINO	3 (3.5%)	3 (3.6%)	6 (7.2%)	12 (4.7%)
NOT HISPANIC OR LATINO	83 (96.5%)	89 (96.4%)	78 (92.8%)	242 (95.3%)
Baseline BMI (kg/m <sup>2</sup> )				
n	86	84	84	253
Mean (SD)	25.64 (3.87)	25.35 (4.36)	25.06 (4.27)	24.87 (4.09)
Median	23.40	24.80	24.30	24.20
Min, Max	19.3, 33.3	13.2, 34.5	12.2, 40.3	12.1, 40.3
Baseline Height (cm)				
n	86	84	84	254
Mean (SD)	162.57 (11.32)	160.82 (10.12)	163.43 (10.42)	163.92 (10.76)
Median	162.60	165.10	162.60	162.88
Min, Max	137.2, 185.4	146.3, 190.5	155.9, 191.4	135.9, 195.6
Baseline Weight (kg)				
n	86	84	85	253
Mean (SD)	62.79 (12.77)	70.00 (14.68)	67.28 (14.12)	66.88 (14.12)
Median	60.35	69.20	64.90	66.70
Min, Max	34.0, 106.2	41.7, 108.0	45.4, 106.1	34.0, 108.0
Safety Population Flag				
Y	86 (100.0%)	86 (100.0%)	86 (100.0%)	254 (100.0%)

Generated Text

Prompt Library

Demographics - Summary

Demographics - Lean

Medical History - Summary

Medical History - Lean

Safety Overview - Summary

# NarromaticAI – workflow

## Text generation – Editing the prompt



Generated Text

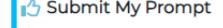
Prompt Library

Demographics - Summary

Edit Prompt  Append Titles  Append Footnotes

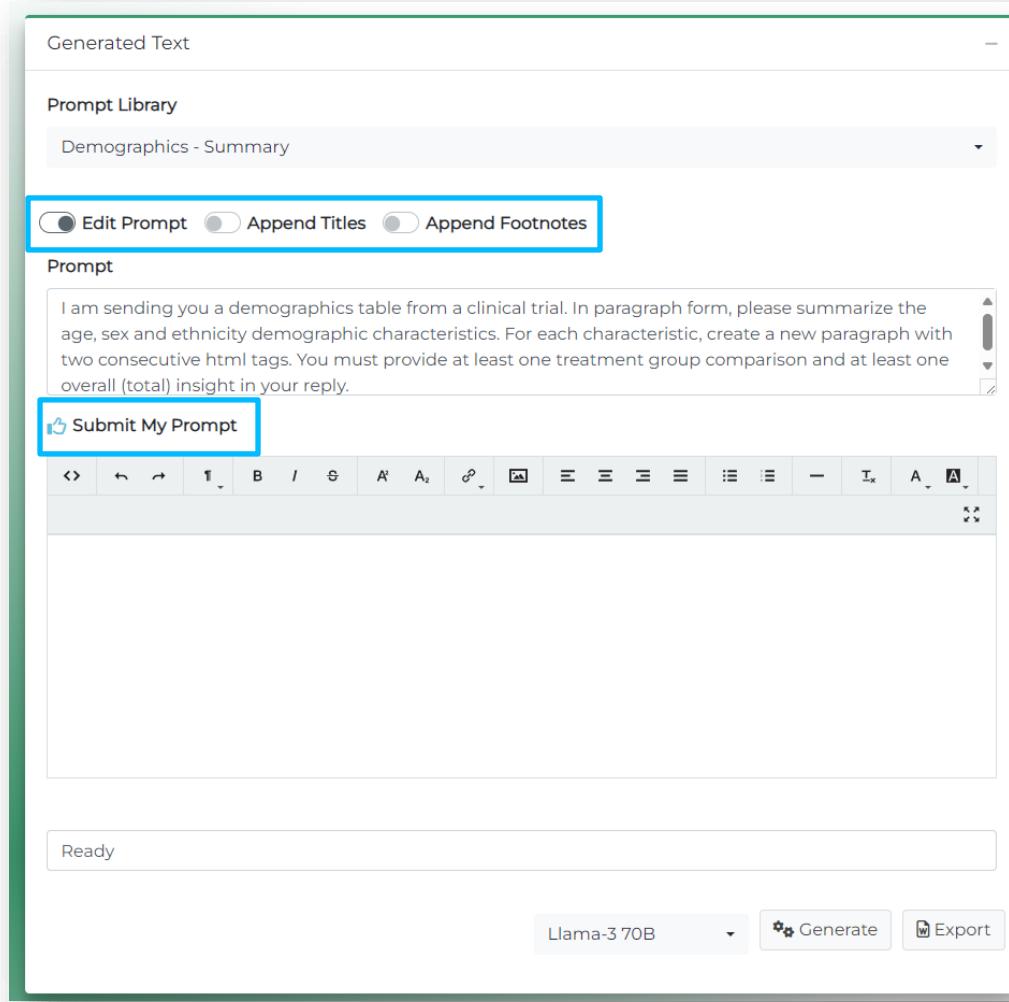
Prompt

I am sending you a demographics table from a clinical trial. In paragraph form, please summarize the age, sex and ethnicity demographic characteristics. For each characteristic, create a new paragraph with two consecutive html tags. You must provide at least one treatment group comparison and at least one overall (total) insight in your reply.

 Submit My Prompt

Ready

Llama-3 70B



# NarromaticAI – workflow

## Generated text streams



**Generated Text**

**Prompt Library**  
Demographics - Summary

Edit Prompt  Append Titles  Append Footnotes

**Prompt**

I am sending you a demographics table from a clinical trial. Please summarize the age, sex and ethnicity demographic characteristics. For each characteristic, create a new paragraph with two consecutive html tags. You must provide at least one treatment group comparison and at least one overall (total) insight in your reply.

**Submit My Prompt**

The age demographic characteristic of the clinical trial population shows a mean age of 75.1 years, with a median age of 77.0 years. The age range spans from 51 to 89 years. Notably, the majority of participants (56.7%) fall within the 65-80 age category, while 30.3% are above 80 years old, and 13.0% are below 65 years old.

In terms of sex, the population is predominantly female, with 56.3% of participants identifying as female and 43.7% as male. A comparison between the treatment groups reveals that the Xanomeline High Dose group has a slightly higher proportion of males (52.4%) compared to the Placebo group (38.4%).

The ethnicity demographic characteristic shows that the majority of participants (90.6%) identify as White, followed by 9.1% identifying as Black or African American, and 0.4% identifying as American Indian or Alaska Native. The proportion of Hispanic or Latino participants is 4.7%. Overall, the population is predominantly non-Hispanic or non-Latino (95.3%).

**Stream Complete**

Llama-3 70B

# Enhancing Shiny's Capabilities

JS text editor + streaming for a better user experience – bridges waiting time while the AI “thinks”



The screenshot shows the Trumbowyg WYSIWYG editor. At the top, there's a large orange header with the title "Trumbowyg" in white, accompanied by a yellow megaphone icon and some small icons. Below the title, it says "A lightweight WYSIWYG editor". Underneath that, it describes the plugin as "Light, translatable and customisable jQuery plugin" and "Beautiful design, generates semantic code, comes with a powerful API". There are two buttons: "Get started" and "See Demos". The main area is a text editor with a toolbar at the top containing icons for bold, italic, underline, etc. Below the toolbar, there's a text area with placeholder text in Latin: "Lorem ipsum dolor sit amet, consectetur adipiscing elit, **some text bold** sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat." and "Duis aute **some link** irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.". At the bottom, there are two buttons: "Default" and "With plugins".

## // Challenge

- // Only the full response can be processed, i.e. waiting until API request is finished → full answer block placed in editor
- // LLMs response takes a while (e.g. caused by heavy API load)
- // Unsatisfactory user experience

## // Solution

- // External custom JS that is communicated by Shiny's session features
  - // E.g. setInputValue & sendCustomMessage
- // Allows streaming of LLM results into Trumbowyg editor
- // User “sees“ text being generated

# NarromaticAI – workflow

## Text Formatting



The screenshot shows the NarromaticAI interface for generating text. The main window is titled "Generated Text" and displays a "Prompt Library" section with "Demographics - Summary" selected. Below the library are three toggle buttons: "Edit Prompt" (selected), "Append Titles", and "Append Footnotes". A toolbar with various text editing icons follows. The generated text content discusses age demographics, sex distribution, and ethnicity. At the bottom, a "Stream Complete" message is shown above a control bar with "GPT-4O", "Generate", and "Export" buttons.



# NarromaticAI – workflow

## Markdown Export



### About

Textual summaries were created using generative AI. Be sure to review all content for correctness. This content was generated as of 2024-09-01 by

### Table

Table: Demographics (safety analysis set)

text	Placebo N=86 (100%)	Xanomeline High Dose N=84 (100%)	Xanomeline Low Dose N=84 (100%)	Total N=254 (100%)
Age				
n	86	84	84	254
Mean (SD)	75.2 (8.6)	74.4 (7.9)	75.7 (8.3)	75.1 (8.2)
Median	76.0	76.0	77.5	77.0
Min, Max	52, 89	56, 88	51, 88	51, 89
Age Category 1				
65-80	42 (48.8%)	55 (65.5%)	47 (56.0%)	144 (56.7%)
<65	14 (16.3%)	11 (13.1%)	8 (9.5%)	33 (13.0%)
>80	30 (34.9%)	18 (21.4%)	29 (34.5%)	77 (30.3%)
Race				
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (1.2%)	0	1 (0.4%)
BLACK OR AFRICAN AMERICAN	8 (9.3%)	9 (10.7%)	6 (7.1%)	23 (9.1%)
WHITE	78 (90.7%)	74 (88.1%)	78 (92.9%)	230 (90.6%)
Sex				
F	53 (61.6%)	40 (47.6%)	50 (59.5%)	143 (56.3%)
M	33 (38.4%)	44 (52.4%)	34 (40.5%)	111 (43.7%)
Ethnicity				
HISPANIC OR LATINO	3 (3.5%)	3 (3.6%)	6 (7.1%)	12 (4.7%)
NOT HISPANIC OR LATINO	83 (96.5%)	81 (96.4%)	78 (92.9%)	242 (95.3%)
Baseline BMI (kg/m <sup>2</sup> )				
n	86	84	83	253
Mean (SD)	23.64 (3.67)	25.35 (4.16)	25.06 (4.27)	24.67 (4.09)
Median	23.40	24.80	24.30	24.20
Min, Max	15.1, 33.3	13.7, 34.5	17.7, 40.1	13.7, 40.1
Baseline Height (cm)				
n	86	84	84	254
Mean (SD)	162.57 (11.52)	165.82 (10.13)	163.43 (10.42)	163.93 (10.7)
Median	162.60	165.10	162.60	162.85
Min, Max	137.2, 185.4	146.1, 190.5	135.9, 195.6	135.9, 195.6
Baseline Weight (kg)				
n	86	84	83	253
Mean (SD)	62.76 (12.77)	70.00 (14.65)	67.28 (14.12)	66.65 (14.1)
Median	60.55	69.20	64.90	66.70
Min, Max	34.0, 86.2	41.7, 108.0	45.4, 106.1	34.0, 108.0
Safety Population Flag				
Y	86 (100.0%)	84 (100.0%)	84 (100.0%)	254 (100.0%)

### Generated Text

The age demographic characteristic of the clinical trial population shows a mean age of 75.1 years, with a median age of 77.0 years. The age range spans from 51 to 89 years. Notably, the majority of participants (56.7%) fall within the 65-80 age category, while 30.3% are above 80 years old, and 13.0% are below 65 years old.

In terms of sex, the population is predominantly female, with 56.3% of participants identifying as female and 43.7% as male. A comparison between the treatment groups reveals that the Xanomeline High Dose group has a slightly higher proportion of males (52.4%) compared to the Placebo group (38.4%).

The ethnicity demographic characteristic shows that the majority of participants (90.6%) identify as White, followed by 9.1% identifying as Black or African American, and 0.4% identifying as American Indian or Alaska Native. The proportion of Hispanic or Latino participants is 4.7%. Overall, the population is predominantly non-Hispanic or non-Latino (95.3%).

### User Options

Below is a summary of recorded user options and filters applied to the table.

#### ▼ Table Settings

Setting	Value
File Name	/opt/rstudio-connect/mnt/tmp/Rtmp0idEvwt_gcat_4_1.addm_1.json
Selected as Arms	text && Placebo@N=86 (100%) && Xanomeline High Dose@N=84 (100%) && Xanomeline Low Dose@N=84 (100%) && Total@N=254 (100%) && FALSE
Table Threshold	0
Threshold applied on Arms	text && Placebo@N=86 (100%) && Xanomeline High Dose@N=84 (100%) && Xanomeline Low Dose@N=84 (100%) && Total@N=254 (100%)
Display Levels	1 && 2
Sorting Arm	text
Sorting Direction	Default
Arm 1 - Incidence	text
Arm 2 - Incidence	Placebo@N=86 (100%)
Higher or Lower	Higher
Incidence Threshold high	0
Incidence Threshold low	0
Gen AI Model	GPT-4O

#### ▼ User Prompt

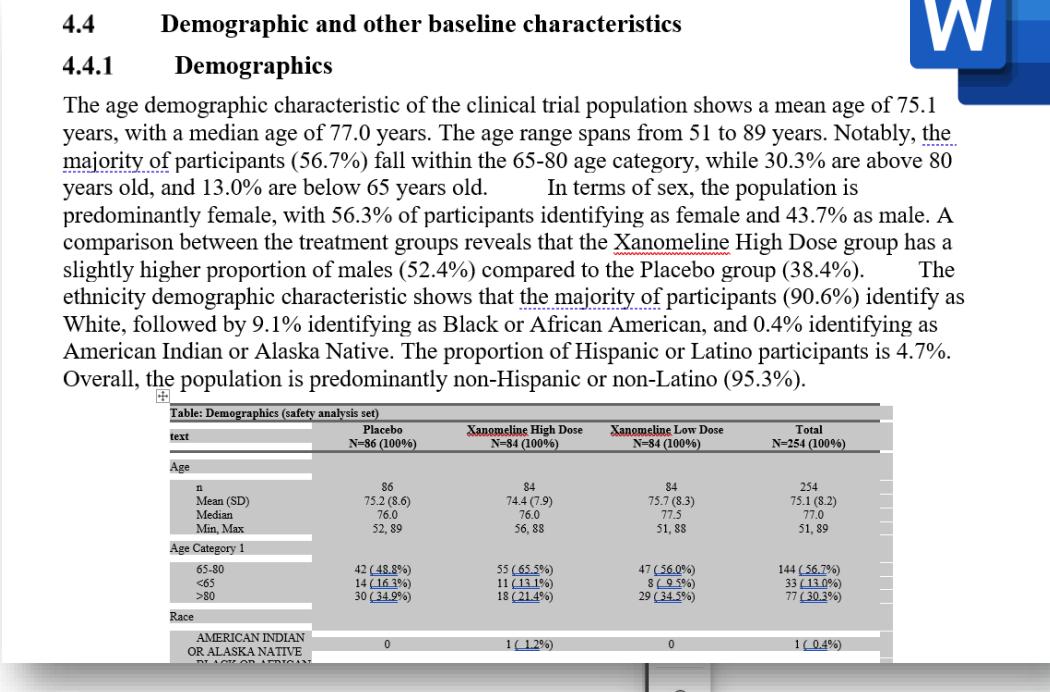
I am sending you a demographics table from a clinical trial. In paragraph form, please summarize the age, sex and ethnicity demographic characteristics. For each characteristic, create a new paragraph with two consecutive html tags. You must provide at least one treatment group comparison and at least one overall (total) insight in your reply.

Here is the table represented as a comma separated string:  
(a copy of the table inserted)

# NarromaticAI – workflow

Saving session (can be shared) or output into TransCelerate CSR Word Template



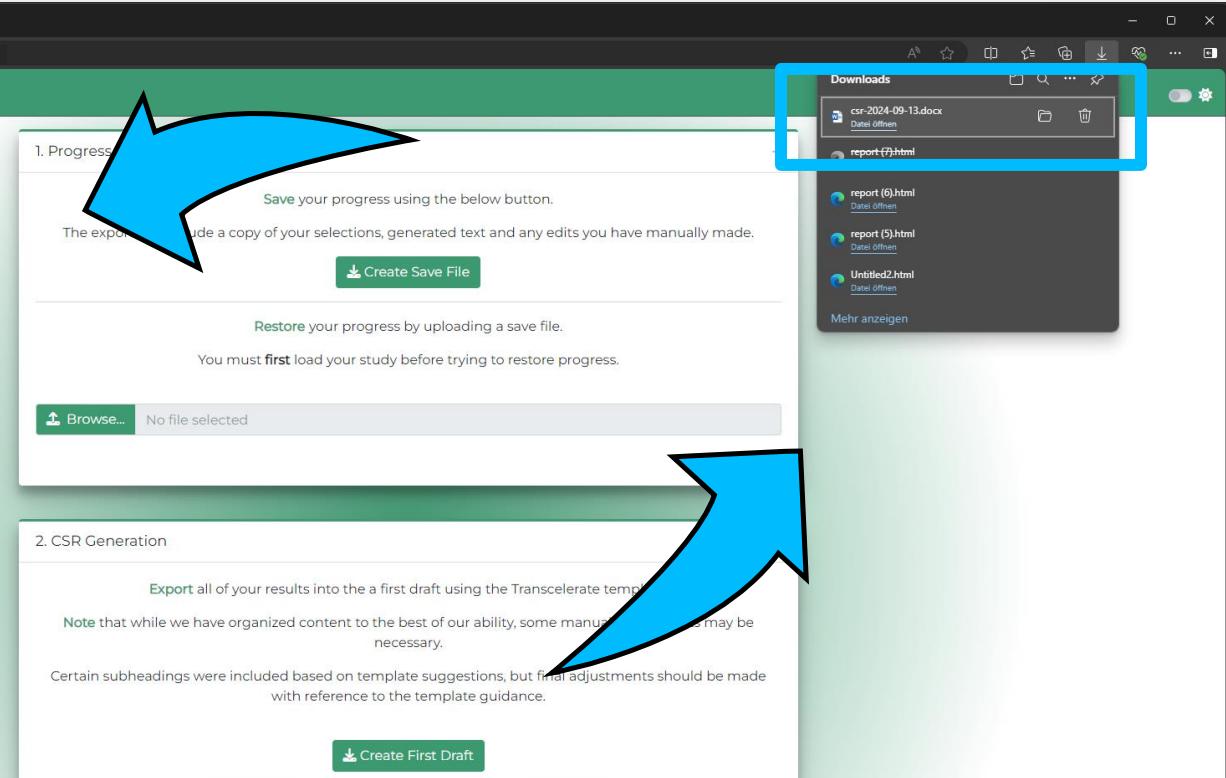


**4.4 Demographic and other baseline characteristics**

**4.4.1 Demographics**

The age demographic characteristic of the clinical trial population shows a mean age of 75.1 years, with a median age of 77.0 years. The age range spans from 51 to 89 years. Notably, the majority of participants (56.7%) fall within the 65-80 age category, while 30.3% are above 80 years old, and 13.0% are below 65 years old. In terms of sex, the population is predominantly female, with 56.3% of participants identifying as female and 43.7% as male. A comparison between the treatment groups reveals that the Xanomeline High Dose group has a slightly higher proportion of males (52.4%) compared to the Placebo group (38.4%). The ethnicity demographic characteristic shows that the majority of participants (90.6%) identify as White, followed by 9.1% identifying as Black or African American, and 0.4% identifying as American Indian or Alaska Native. The proportion of Hispanic or Latino participants is 4.7%. Overall, the population is predominantly non-Hispanic or non-Latino (95.3%).

	Placebo N=86 (100%)	Xanomeline High Dose N=84 (100%)	Xanomeline Low Dose N=84 (100%)	Total N=254 (100%)
<b>Age</b>				
n	86	84	84	254
Mean (SD)	75.2 (8.6)	74.4 (7.9)	75.8 (8.3)	75.2 (8.2)
Median	76.0	76.0	77.5	77.0
Min, Max	52, 89	56, 88	51, 88	51, 89
<b>Age Category 1</b>				
65-80	42 (48.8%)	55 (65.5%)	47 (56.0%)	144 (56.7%)
<65	14 (16.3%)	11 (13.1%)	8 (9.5%)	33 (13.0%)
>80	30 (34.9%)	18 (21.4%)	29 (34.5%)	77 (30.3%)
<b>Race</b>				
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (1.2%)	0	1 (0.4%)



1. Progress

Save your progress using the below button.

The export will include a copy of your selections, generated text and any edits you have manually made.

**Create Save File**

Restore your progress by uploading a save file.

You must first load your study before trying to restore progress.

**Browse...** No file selected

2. CSR Generation

Export all of your results into a first draft using the Transcelerate template.

Note that while we have organized content to the best of our ability, some manual adjustments may be necessary.

Certain subheadings were included based on template suggestions, but final adjustments should be made with reference to the template guidance.

**Create First Draft**

# NarromaticAI – Next Level: Figure Description



Screenshot of the NarromaticAI web interface showing a Forest Plot and generated text.

**Figure Preview**

Select Figure: Figure: Forest Plot

Type to search. Suggested Search: 'swimmer plot'

Figure: Forest Plot

Figure: Kaplan Meier (Intersecting Curves)

Figure: Kaplan Meier (Non-Intersecting Curves)

Figure: Spider Plot (Best Overall Response)

Figure: Waterfall Plot

No prior local therapy      456 (76)      454 (165)      0.40 (0.30–0.52)      82.7/61.2%  
Prior docetaxel      103 (21)      102 (35)      0.52 (0.30–0.89)      78.5/62.5%  
No prior docetaxel      471 (70)      474 (166)      0.37 (0.28–0.49)      85.5/63.3%  
Low-volume disease      220 (14)      203 (47)      0.25 (0.14–0.46)      93.3/79.4%  
High-volume disease      354 (77)      373 (154)      0.43 (0.33–0.57)      78.2/53.6%  
Low risk      275 (35)      281 (76)      0.42 (0.28–0.62)      88.0/71.9%  
High risk      261 (55)      250 (122)      0.34 (0.25–0.47)      78.9/48.5%

0.0      0.5      1.0      1.5      2.0  
Favors ENZA + ADT      Favors PBO + ADT

**Generated Text**

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

You can only make a request to this model once per minute.

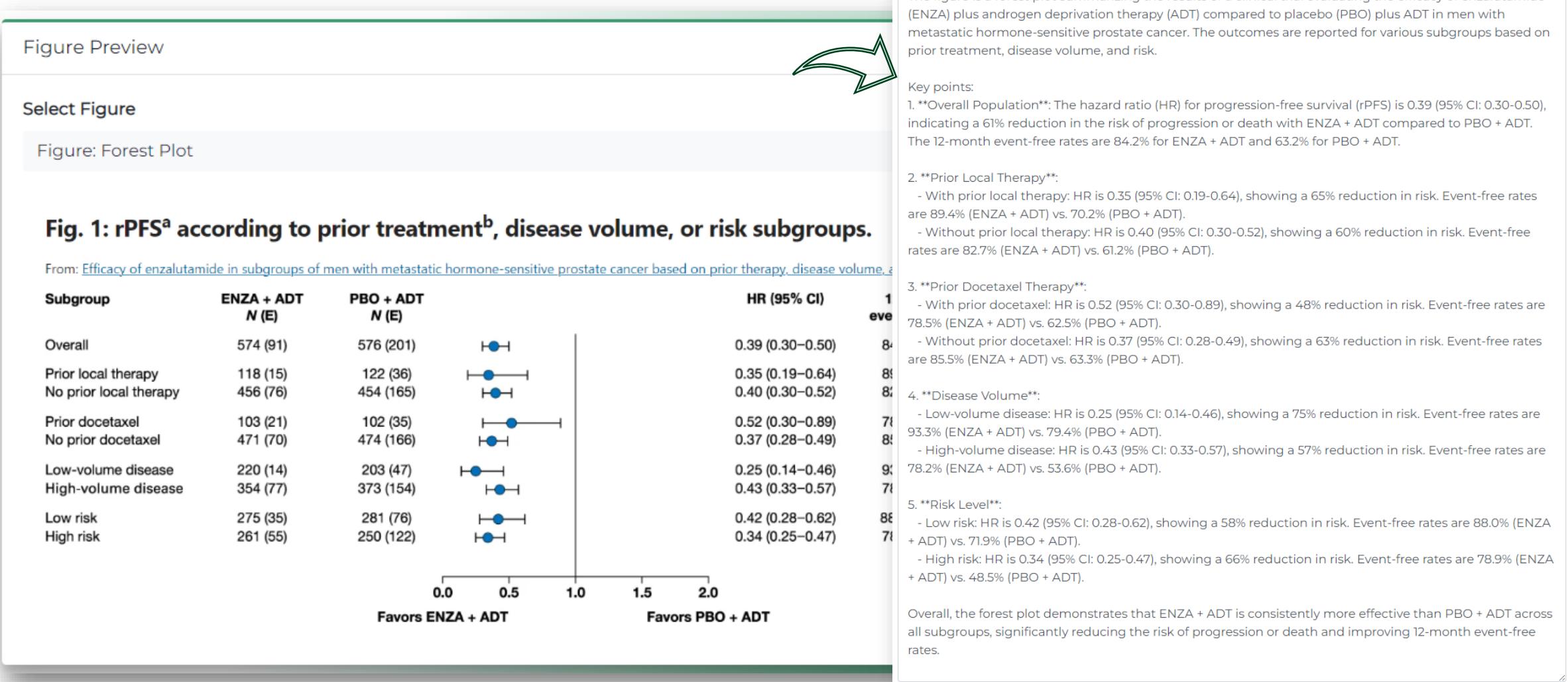
Generate Export

LLMs with visual capabilities, e.g., gpt4-vision-preview (legacy) or GPT-4 Turbo with Vision

# NarromaticAI – Next Level: Figure Description using LLMs



Forest Plot – taken from published (non-Bayer) data: DOI: [10.1038/s41391-021-00436-y](https://doi.org/10.1038/s41391-021-00436-y)



# NarromaticAI – Next Level: Figure Description using LLMs

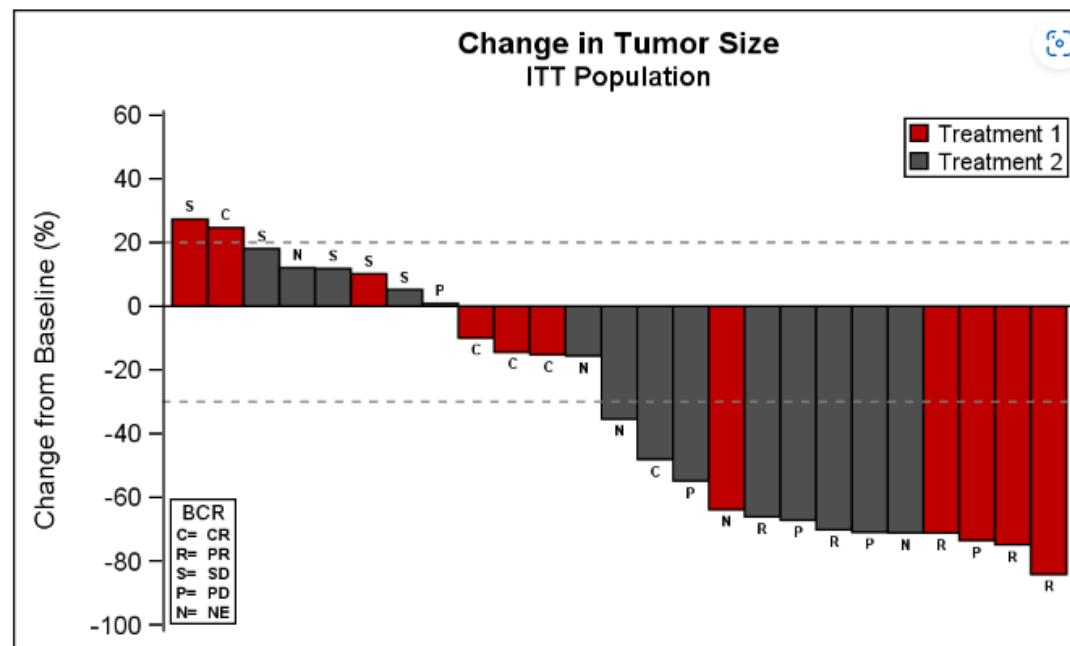


## Waterfall Plot

### Figure Preview

#### Select Figure

Figure: Waterfall Plot



The waterfall plot depicts the change in tumor size from baseline for individual patients in the ITT (Intention-To-Treat) population, comparing two treatments: Treatment 1 (red bars) and Treatment 2 (gray bars). Each bar represents a single patient, with bars extending above the zero line indicating tumor growth and bars extending below the zero line indicating tumor shrinkage.

#### Key insights:

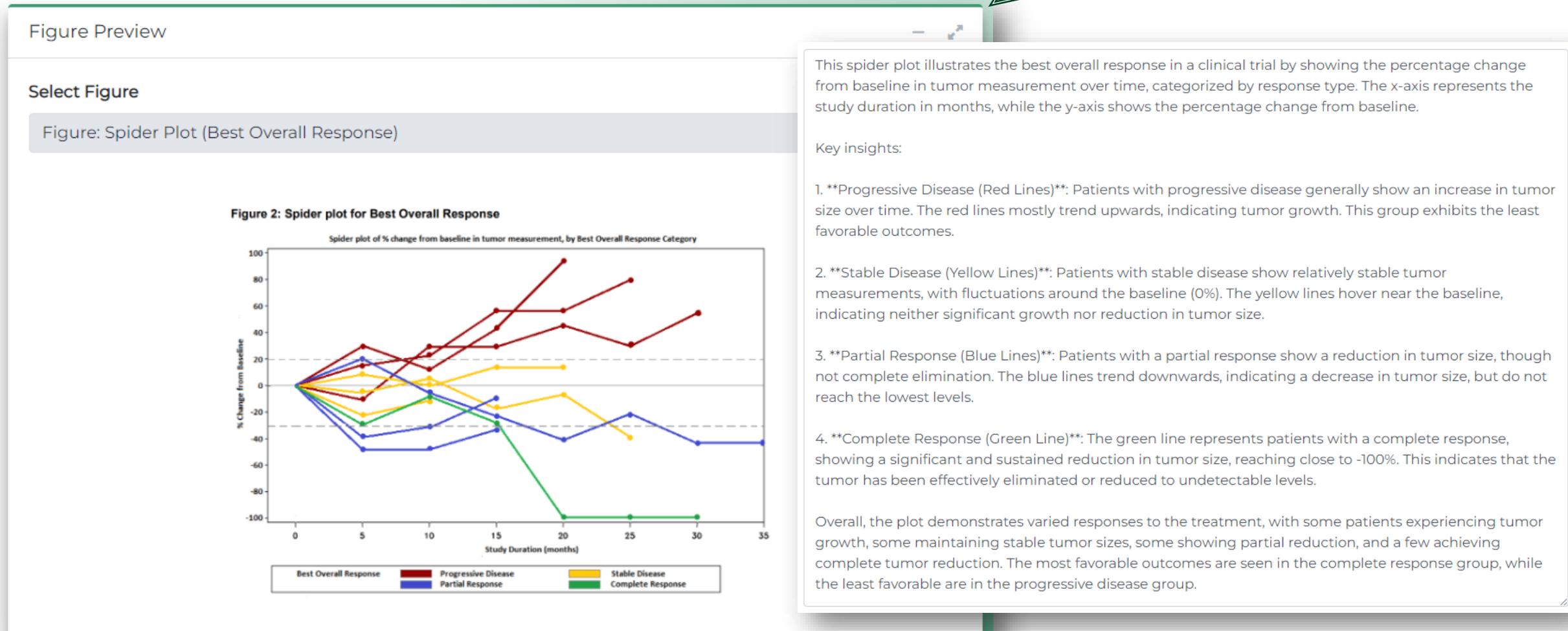
- \*\*Treatment Efficacy\*\*: A larger number of patients in the Treatment 1 group (red bars) experienced substantial tumor shrinkage compared to those in the Treatment 2 group (gray bars).
- \*\*Response Categories\*\*: The plot includes various response categories:
  - CR (Complete Response)
  - PR (Partial Response)
  - SD (Stable Disease)
  - PD (Progressive Disease)
  - NE (Not Evaluable)These are indicated by the letters C, R, S, P, and N respectively, on the bars.
- \*\*Tumor Growth\*\*: A few patients in both treatment groups experienced tumor growth, but there are more patients with tumor shrinkage in the Treatment 1 group.
- \*\*Clinical Benefit\*\*: The data suggest that Treatment 1 might be more effective in reducing tumor size compared to Treatment 2, as indicated by the preponderance of negative changes (tumor shrinkage) in the red bars.

Overall, this figure suggests that Treatment 1 has a more favorable impact on reducing tumor size in the ITT population compared to Treatment 2.

# NarromaticAI – Next Level: Figure Description using LLMs



## Spider Plot





# Potential of LLMs for Medical Writing process

...and beyond



...as new trial designs (e.g., adaptive), content (e.g., TLF displays/catalogs) and concepts (e.g., estimands) evolve rapidly, a rule set approach will have diminishing utility, effectively shortening automations benefit and scope...

...the use of AI, particularly LLMs, have the potential to match this pace and shift the focus from

***rigid automation → dynamic generation***

...advances and the greater availability of these technologies have empowered us to do more, and think how to leverage this technology with the aim of **reducing the time and effort** spent on shared deliverables



R + Shiny + GenAI =



- // R stack (R, tidyverse, flextable, shiny, rmarkdown) plays well along with GenAI / LLMs
- // Implementation of many convenience functions wrt filtering, displaying, prompt handling etc. increase user experience
- // GenAI is a game changer when it comes to supporting Medical Writers getting a first draft **F A S T L Y**
- // Learnings are universally applicable
- // Plug and play of models easy: prepared for future evolution of LLMs



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# NarromaticAI

*Supporting the Medical Writing Process with R, Shiny, and GenAI*



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