

NEST 2.0 and How AI helps our development

Joe Zhu

Principal data scientist / NEST business lead

27-3-206

Disclosures & Disclaimers 披露及免责声明

- The materials provided in this presentation or any comments or information provided by the presenter are for scientific knowledge exchange purpose ONLY.
- Nothing conveyed or provided in this presentation should be considered medical advice.
- It may contain information of approved or unapproved medical products. Information provided is NOT for promoting prescriptions.
- All rights reserved.

- 本演示文稿中提供的材料或演示者提供的任何评论或信息仅用于科学知识交流。
- 本演示文稿中传达或提供的任何内容均不应被视为医疗建议。
- 它可能包含已批准或未批准的医疗产品的信息。提供的信息不用于宣传处方。
- 版权所有

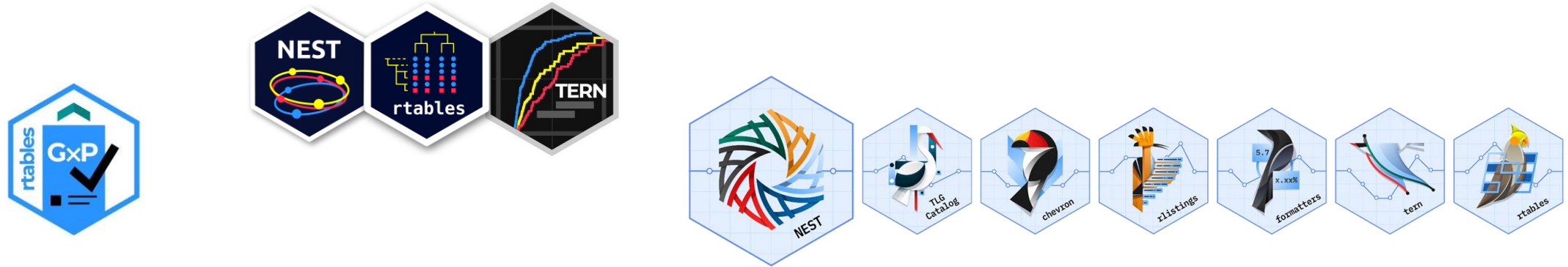
Overview

- NEST project history from 0.1 to 2.0
- Documents creation
 - Docx
 - Autoslider
- AI integration

The End-to-End clinical reporting open-source projects



NEST v0.1 to v1.0 workflow



	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age (yr)	-	-	-	-
n	xx.	xx.	xx.	xx.
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x
Continous Level Biomarker 1	-	-	-	-
n	xx.	xx.	xx.	xx.
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age (yr)				
n	134	134	132	400
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.7)	34.9 (7.4)
Median	33.0	35.0	35.0	34.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0	20.0 - 69.0
Continous Level Biomarker 1				
n	134	134	132	400
Mean (SD)	6.0 (3.6)	5.7 (3.3)	5.6 (3.5)	5.8 (3.4)
Median	5.4	4.8	4.6	4.8
Min - Max	0.4 - 17.7	0.6 - 14.2	0.2 - 21.4	0.2 - 21.4

Benchmark Comparison: gtsummary vs. tfrmt vs. rtables



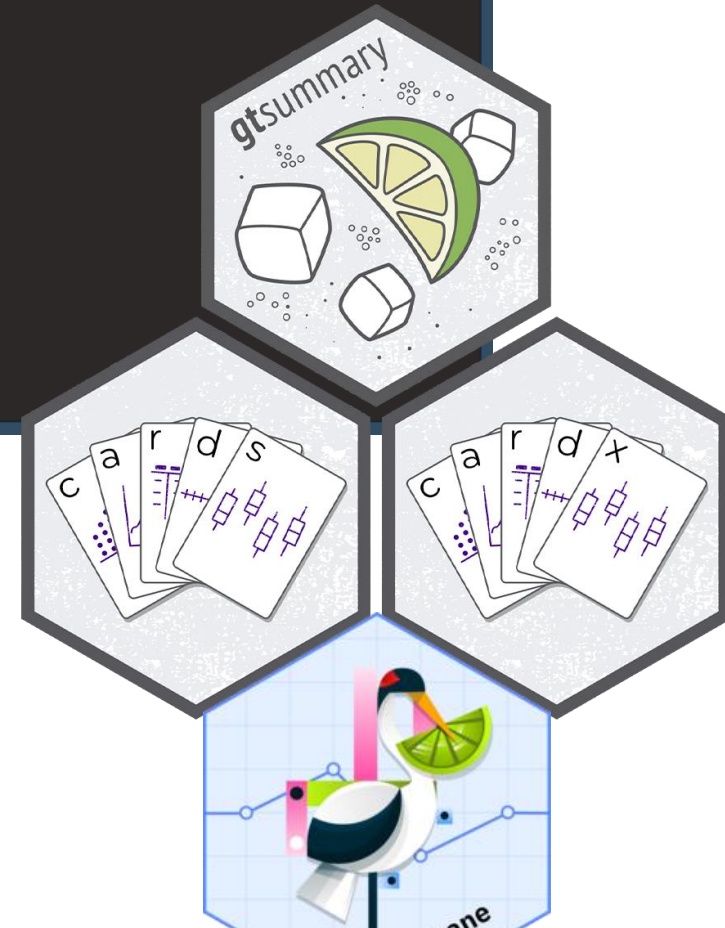
Feature	gtsummary	tfrmt	rtables
Primary Philosophy	Analysis + Formatting: Performs the math and styles the output simultaneously.	Metadata-Driven Formatting: Decouples the analysis from the display logic.	Layout-First Structure: Defines a rigid hierarchical "tree" before applying data.
Syntax Style	Tidyverse-friendly, pipe-based (<code>\$%>%\$</code>).	Declarative metadata objects.	Structural "Layout" functions (e.g., <code>split_rows_by</code>).
Learning Curve	Low: Very intuitive for standard summaries.	Medium: Requires understanding the ARD format.	High: Steep curve to master the layout/tree logic.

NEST 2.0



```
1 library(gtsummary)
2 library(tidyverse)
3
4 trial %>%
5   select(trt, age, grade, response) |
6
7
```

5:37 (Top Level) R Script



Pharmaverse examples

- <https://pharmaverse.github.io/examples/>

pharmaverse examples



Introduction

- SDTM >
- ADaM >
- TLG >
- Documents >
 - Slides
 - Documents
- Interactive >
- Logs >

pharmaverse examples

The true beauty of pharmaverse (and open source in general) is when efforts from various different developers are combined to create a whole greater than the sum of the individual parts. By design in R, no single package will ever completely cover a use case, but together we can make complex tasks increasingly simple.

This book contains end-to-end examples of using pharmaverse packages together to achieve common clinical data analysis tasks such as Tables/Listings/Graphs. The examples use consistent source test raw datasets from `{pharmaverseraw}`, `{SDTM}`, and `{pharmaverseadam}` respectively.

We'll endeavour to include a selection of examples here over time, e.g. to help users when trying out the packages (such as Oncology or Vaccines) analyses.

Note that this examples book should only be used to show how collections of packages can be used in conjunction. Specific package usages would always be covered in the package site vignettes and no need to repeat here.

Running the examples



Pharmaverse examples (中文)



- <https://pharmaverse.github.io/examples/>



介绍

SDTM >

亚当 >

TLG >

人口统计表

不良事件

药代动力学

文件 >

交互的 >

日志 >

电子提交 >

Chinese (Simplified) ▾

Powered by Google Translate

TLG

概述

本节演示如何使用 Pharmaverse 软件包创建用于临床研究报告的表格、列表和图表 (TLG)。TLG 是临床研究报告和监管申报文件的重要组成部分，能地呈现研究结果。

这些示例展示了两种不同的方法，利用 ADaM 数据集作为输入来生成出版质量的输出。

我应该采用哪种方法？

分析结果数据集 (ARD) NEW

最适合：

- 实施 CDISC 分析结果标准的组织



Rtables word document output



- export_as_docx

Parameter Code	Visit		
NCI CTCAE Grade at Visit	Baseline NCI CTCAE Grade		
	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
CRP			
WEEK 1 DAY 8			
Not Low (n)	116	110	101
Not Low	103 (88.8%)	91 (82.7%)	88 (87.1%)
1	3 (2.6%)	5 (4.5%)	6 (5.9%)
2	4 (3.4%)	9 (8.2%)	2 (2.0%)
3	3 (2.6%)	4 (3.6%)	4 (4.0%)
4	3 (2.6%)	1 (0.9%)	1 (1.0%)
1 (n)	4	7	5
Not Low	3 (75.0%)	7 (100%)	4 (80.0%)
3	1 (25.0%)	0	1 (20.0%)
2 (n)	5	6	11
Not Low	5 (100%)	5 (83.3%)	8 (72.7%)
1	0	0	1 (9.1%)
3	0	0	2 (18.2%)
4	0	1 (16.7%)	0
3 (n)	6	8	5
Not Low	6 (100%)	7 (87.5%)	5 (100%)
3	0	1 (12.5%)	0
4 (n)	3	3	10
Not Low	2 (66.7%)	3 (100%)	7 (70.0%)
1	0	0	2 (20.0%)
2	1 (33.3%)	0	0
4	0	0	1 (10.0%)
WEEK 2 DAY 15			
Not Low (n)	105	111	116
Not Low	93 (87.7%)	93 (83.8%)	100 (86.2%)
1	3 (2.8%)	4 (3.6%)	8 (6.9%)
2	5 (4.7%)	7 (6.3%)	2 (1.7%)
3	2 (1.9%)	5 (4.5%)	6 (5.2%)
4	3 (2.8%)	2 (1.8%)	0
1 (n)	15	9	2
Not Low	13 (86.7%)	8 (88.9%)	1 (50.0%)
2	0	1 (11.1%)	0
3	2 (13.3%)	0	0
4	0	0	1 (50.0%)
2 (n)	3	3	6
Not Low	3 (100%)	3 (100%)	4 (66.7%)
1	0	0	1 (16.7%)
3	0	0	1 (16.7%)
3 (n)	7	7	6
Not Low	7 (100%)	6 (85.7%)	5 (83.3%)
2	0	1 (14.3%)	0
4	0	0	1 (16.7%)
4 (n)	3	4	2
Not Low	3 (100%)	3 (75.0%)	2 (100%)
1	0	1 (25.0%)	0
WEEK 3 DAY 22			
Not Low (n)	119	110	114
Not Low	104 (87.4%)	92 (83.6%)	94 (82.5%)
1	3 (2.5%)	4 (3.6%)	9 (7.9%)
2	5 (4.2%)	7 (6.4%)	2 (1.8%)
3	4 (3.4%)	5 (4.5%)	7 (6.1%)
4	3 (2.5%)	2 (1.8%)	2 (1.8%)

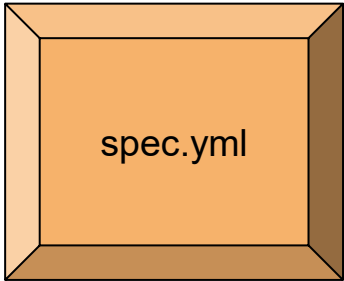
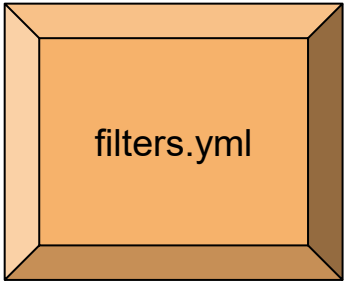
Parameter Code	Visit		
NCI CTCAE Grade at Visit	Baseline NCI CTCAE Grade		
	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
WEEK 4 DAY 29			
Not Low (n)	101	119	111
Not Low	88 (88.1%)	100 (84.0%)	96 (86.5%)
1	3 (3.0%)	4 (3.4%)	6 (5.4%)
2	4 (4.0%)	8 (6.7%)	1 (0.9%)
3	2 (2.0%)	5 (4.2%)	6 (5.4%)
4	3 (3.0%)	2 (1.7%)	2 (1.8%)
1 (n)	10	5	6
Not Low	9 (90.0%)	5 (100%)	5 (83.3%)
1	5 (100%)	0	1 (16.7%)
2	1 (10.0%)	0	0
2 (n)	13	4	6
Not Low	13 (100%)	3 (75.0%)	5 (83.3%)
1	0	0	1 (16.7%)
2	0	1 (25.0%)	0
3 (n)	8	2	6
Not Low	6 (75.0%)	1 (50.0%)	5 (83.3%)
1	0	1 (50.0%)	0
2	0	0	1 (16.7%)
3	2 (25.0%)	0	0
4 (n)	2	4	3
Not Low	2 (100%)	4 (100%)	1 (33.3%)
1	0	0	1 (33.3%)
3	0	0	1 (33.3%)
WEEK 5 DAY 38			
Not Low (n)	115	112	111
Not Low	102 (88.7%)	94 (83.9%)	96 (86.5%)
1	2 (1.7%)	4 (3.6%)	6 (5.4%)
2	5 (4.3%)	7 (6.2%)	2 (1.8%)
3	3 (2.6%)	5 (4.5%)	5 (4.5%)
4	3 (2.6%)	2 (1.8%)	2 (1.8%)
1 (n)	5	7	6
Not Low	5 (100%)	4 (57.1%)	5 (83.3%)
1	0	1 (14.3%)	1 (16.7%)
2	0	2 (28.6%)	0
2 (n)	5	11	6
Not Low	5 (100%)	11 (100%)	6 (100%)
3 (n)	8	2	7
Not Low	6 (75.0%)	2 (100%)	4 (57.1%)
1	1 (12.5%)	0	1 (14.3%)
3	1 (12.5%)	0	2 (28.6%)
4 (n)	1	2	2
Not Low	1 (100%)	2 (100%)	1 (50.0%)
1	0	0	1 (50.0%)

AutoslideR Workflow

```

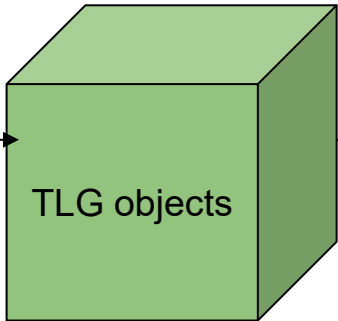
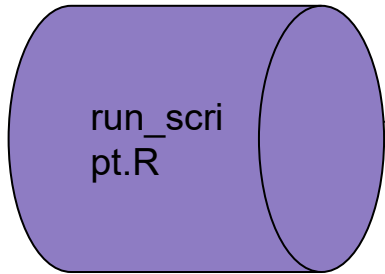
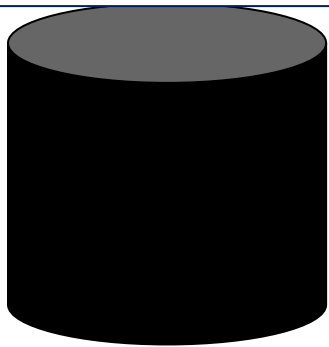
ITT:
  title: Intent to Treat Population
  condition: ITTFL == 'Y'
  target: adsl
  type: slref

SER:
  title: Serious Adverse Events
  condition: AESER == 'Y'
  target: adae
  type: anl
  
```



```

- program: t_dm_slide
  titles: Patient Demographics and Baseline Characteristics
  footnotes: 't_dm_slide footnote'
  paper: L6
  suffix: ITT
  args:
    arm: "TRT01A"
    vars: ["SEX", "AGE", "RACE", "ETHNIC", "COUNTRY"]
  
```



Optional comprehensive templates for users to start with

Patient Demographics and Baseline Characteristics, Full Analysis Set

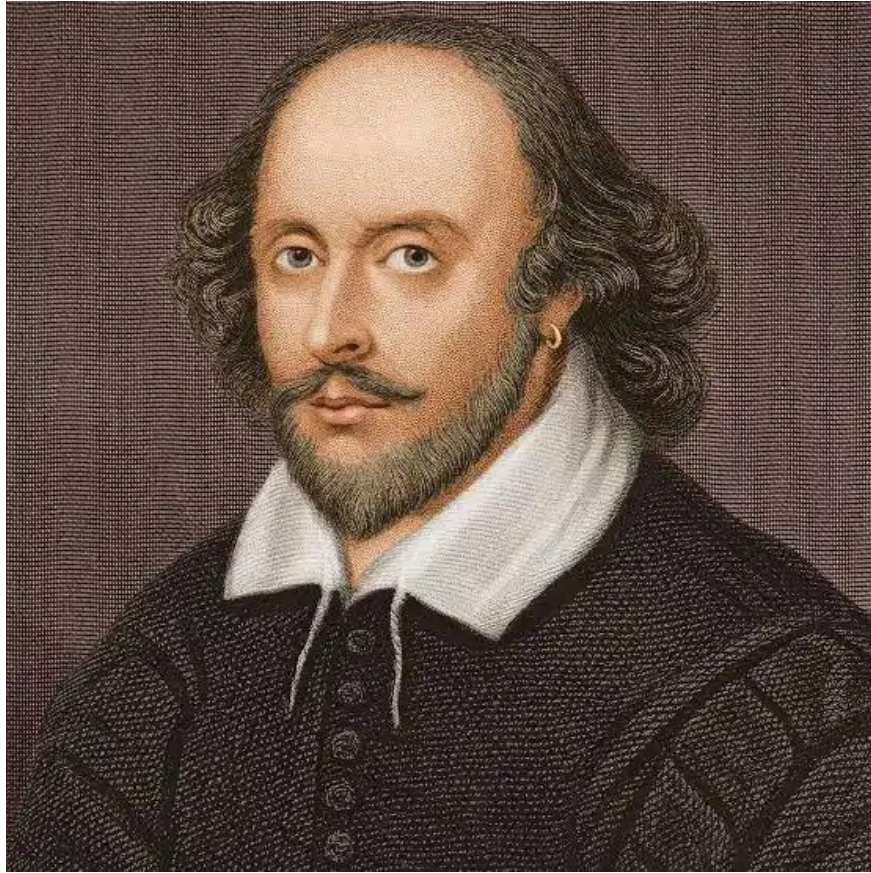
	A: Drug X	B: Placebo	C: Combination	All Patients
Sex				
F	79 (59%)	82 (61.2%)	70 (53%)	231 (57.8%)
M	55 (41%)	52 (38.8%)	62 (47%)	169 (42.2%)
Age				
Median	33.00	35.00	35.00	34.00
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0	20.0 - 69.0

t_dm_slide footnote
Confidential and for internal use only;

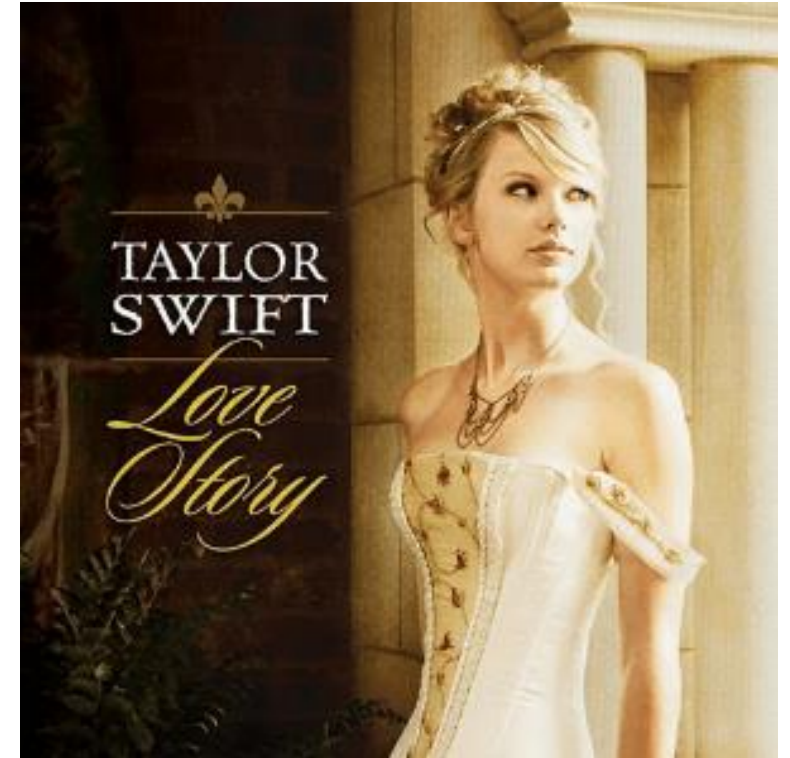
Why AI Excels at Understanding DOCX Tables

- **Explicit Hierarchy and Relationships**
- **Rich Metadata and Properties**
- **Standardization and Predictability**
- **Separation of Content and Presentation**

Focus on the use case, not AI



AI



use case

The Structural Skills Gap

The Statistical Programmer

- Extensive clinical domain expertise
 - e.g., deep understanding of study protocols, therapeutic areas, and patient data nuances
- Deep understanding of CDISC, SDTM, and ADaM standards
- Mastery of legacy workflows and end-to-end clinical reporting

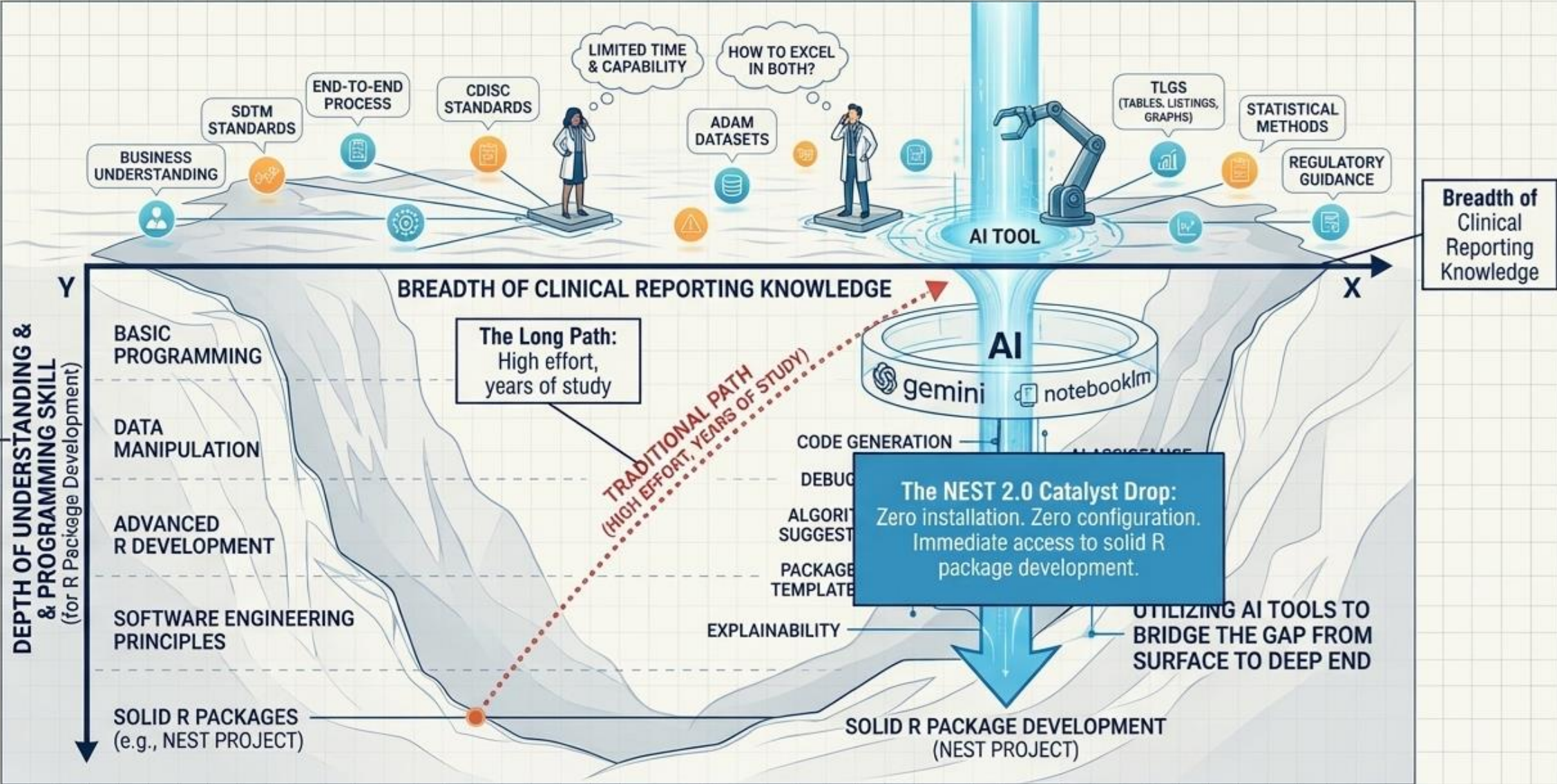
The R Package Developer





- Deep software engineering principles
- Advanced R development capabilities
- Creating robust, efficient, and solid R packages

The Aviary catalog requires both. Crossing this gap traditionally requires years of specialized study.

Bypassing the Learning Curve



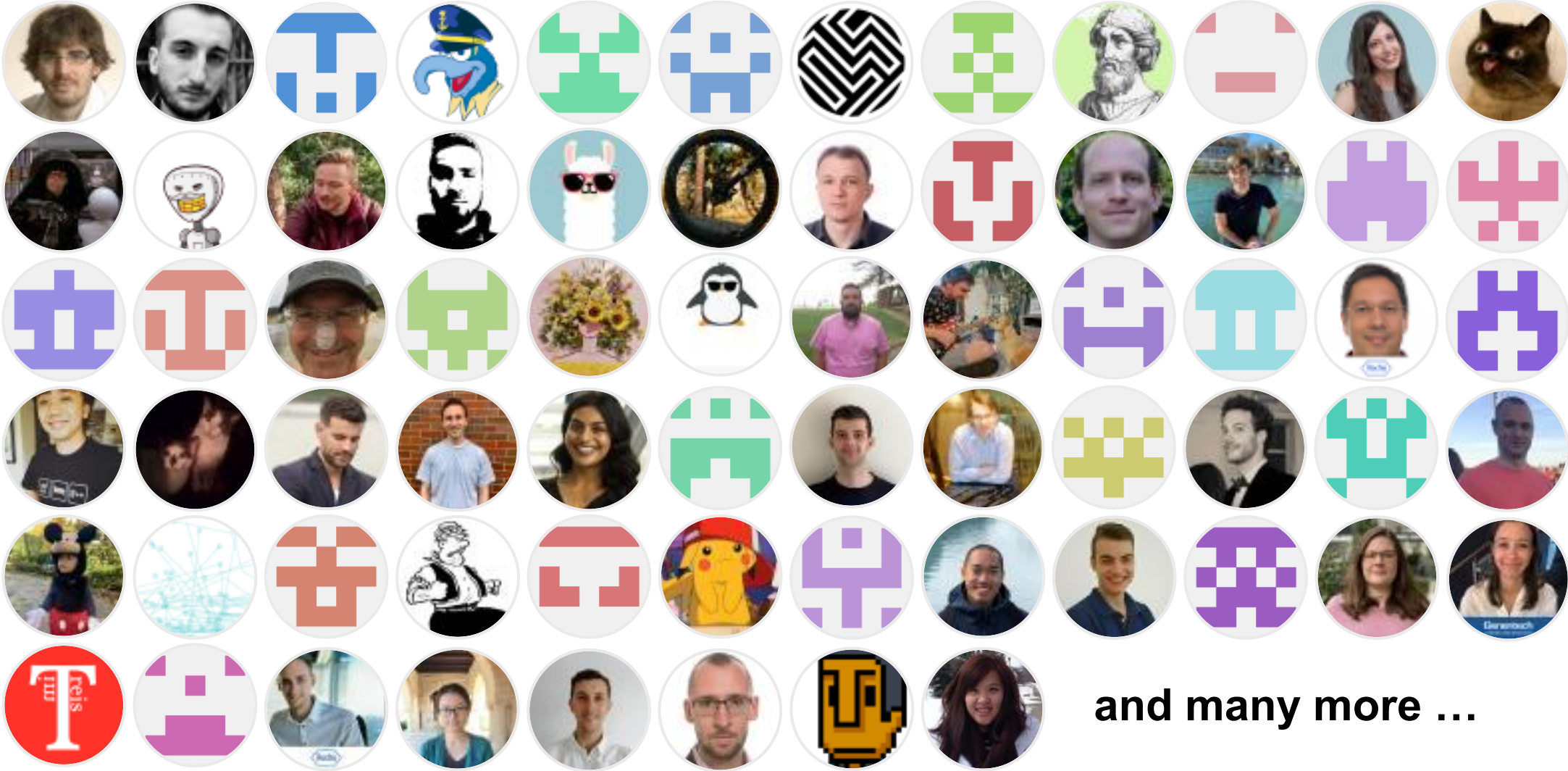
The AI Catalyst Toolkit

	 Template Creator (Gemini)	 Catalog Reviewer (NotebookLM)
Primary Function	Code Generation & Scaffolding	Automated Sanity Checks & QC
Required Input	TLG Catalog programming notes and prompts	Output documents (.docx) paired with source scripts (.R)
Expected Output	Core template files (R/, inst/, tests/)	Diagnostic validation notes and bug reports

Summary

- NEST team contributes 11 R packages towards pharmaverse initiative, and continuously working closely with other project teams shaping the future of clinical reporting using R
- NEST 2.0 workflow streamlines the work process without creating a table shells, and use analysis result data
- We extend the TLG creation process downstream to document generations in docx and pptx
- The documents can interact with AI for insights generation
- We use AI to accelerate our output creation and checks

Acknowledgement



and many more ...