

NEST: Now & Future

How Could We Generate & Deliver Clinical Insights Even Faster?

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China Open Source Clinical Reporting summeR Event

Agenda

1. An Overview of NEST
2. NEST's Current Capabilities
3. Our Vision on Insights Generation
4. Call for Collaboration

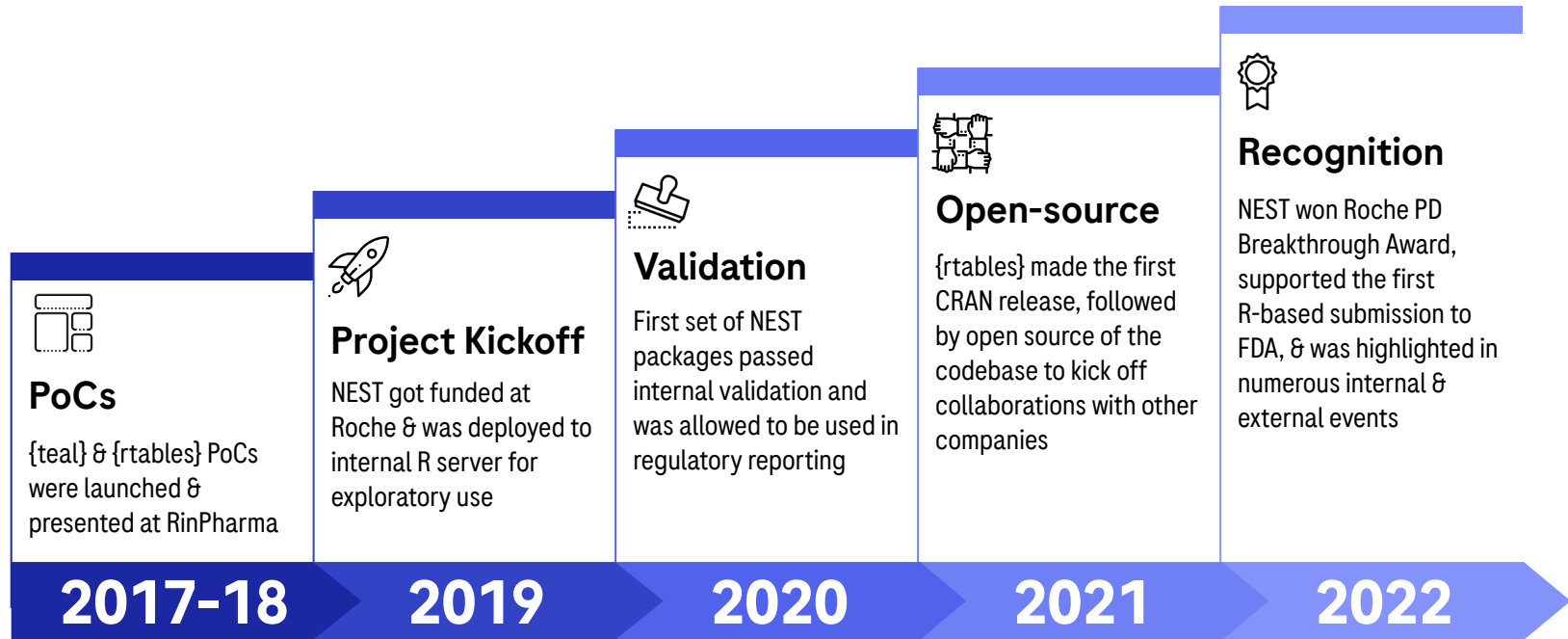
An Overview of NEST



A collection of open-sourced R packages, which enables fast and efficient insights generation under clinical research settings, for both exploratory and regulatory purposes.

Our Journey Through Time

How NEST has evolved in the past 6 years?



NEST in Numbers

What NEST has accomplished so far?

User

1000+

Over 1000 users have tried NEST internally & externally, covering pharma, CRO, & academia

TLG Template

200+

We open-sourced a catalog of 200+ TLGs for clinical reporting

Contributor

200+

Over 200 people across the world have contributed to NEST codebase

R Package

45

So far, we have built 45 packages under NEST, with 36 of them already open-sourced

Shiny Module

70+

{teal} framework offers over 70 built-in shiny modules

Partner

5

We have partnered with 5 pharma companies to co-develop NEST

NEST's Current Capabilities

Regulatory Reporting

A complete solution for R-based submission

Streamlined Workflow



Catalog for Common TLGs

TLG Catalog



Biomarker Catalog




Foundational R Packages



A Short Demo of TLG Catalog

Fully reproducible R code for common analyses in clinical reporting

TLG Catalog



Introduction

- Tables >
- Listings >
- Graphs >
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TLG Catalog

Tables, Listings, and Graphs Catalog


Introduction

A catalog of Tables, Listings, and Graphs output produced by NEST tools.

See the full index of available TLG templates on the [Index page](#).

License

This catalog as well as code examples are licensed under the Apache License, Version 2.0.



<https://insightengineering.github.io/tlg-catalog/>

From TLG Catalog to Streamlined Workflow

Building a framework towards automated insights generation



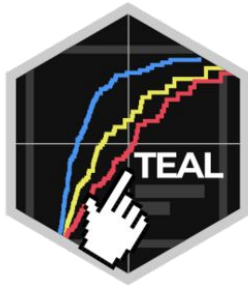
Instead of manually copying over from previous studies, individual TLG scripts are **automatically generated** based on metadata

Seamless integration of metadata with execution tool enables standard outputs to be created **easily** from auto-generated scripts

This workflow is now in production use on the new AWS-based computing environment (OCEAN), which will be gradually adopted by all clinical studies at Roche

For Exploratory Analyses

A scalable, modularized Shiny framework



- A **shiny framework** centered around **reusable modules** that abstracts UI/server logic from the app developer
- Streamlines creation of web-apps that offers: **dynamic filtering** facility, code **reproducibility**, **reporting engine**, many **data summarization and visualizations**

A gallery of {teal} apps:

<https://insightengineering.github.io/teal.gallery/demo.html>

Our Vision on Insights Generation

It Was Never About SAS vs. R

Then, why we made the change?



Talent out of university more likely to know open-source programming languages



Open source offers unprecedented **opportunities:**

01

Get latest developments more rapidly

02

Be able to switch between languages and contexts more easily

03

Collaboration with external partners

Prototypes with Great Potential

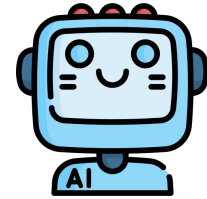
With what we have today, how to further improve efficiency on insights generation?



An industry collaborative effort on building and open-sourcing a catalog of harmonized TLGs in clinical study reporting



A companion app that connects output creation with delivery, review, and well-controlled data exploration



An LLM-based chatbot that enhances user experience on all NEST products

{falcon}

What if all companies adopt the same standard in clinical reporting?



<https://pharmaverse.github.io/falcon/>

Company

5

5 pharma companies join efforts to co-develop {falcon}

Developer

12

12 developers collaborate following agile framework

Template

11

11 templates were released according to FDA's proposed safety guidance

Layout

1

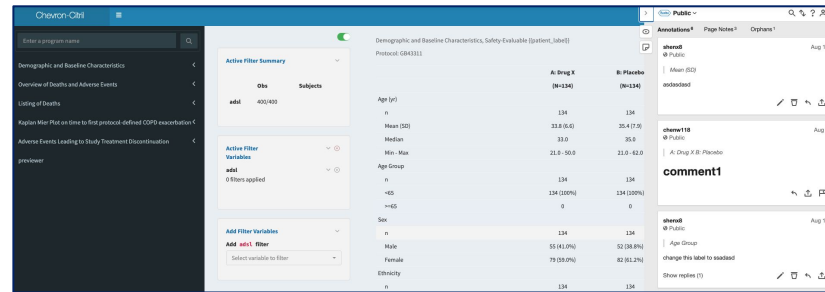
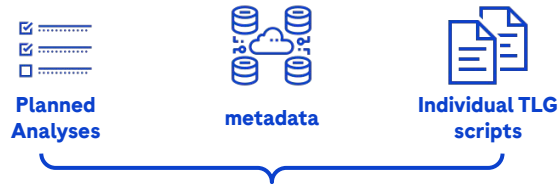
Envisioning to harmonize TLG layouts for clinical reporting

Regulatory Report Dashboard

What if insights delivery, review, & exploration all happen at the same place?



On top of a set of automatically generated scripts for individual TLGs, this app is also automatically created, with NO coding required



List of all planned analyses for regulatory reporting, with search functionality

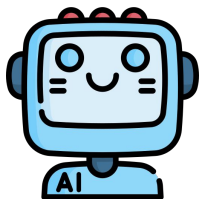
Controlled filter panel with only predefined subgroup analyses

Review panel displaying same layout with static output

Comment panel to save & trace feedback from all stakeholders

LLM-based NESTbot

What if every user has his own assistant when learning, using, & exploring NEST packages?



Trained with curated data & internally hosted

Integrated with cutting-edge LLM

Able to create TLGs with NL prompts

Able to expand to other products

NESTbot 🤖 the NEST specialist at your disposal

This prototype bot has knowledge of the TLG manuals and is flexible to learn more.

what is NEST

NEST in this context refers to a set of packages in R programming language used for data analysis and visualization. The 'nestcolor' package is part of this set and it contains functions for managing visual conventions of NEST graphs. It is used to apply a standardized color palette to NEST ggplot2 plots and graphical teal modules for greater continuity and cohesiveness among NEST package visualizations.

tell me more about tern

The "tern" package is an R package designed for creating tables and graphs used for clinical trial reporting. It offers a wide range of functionality, and some of its outputs can be incorporated into teal applications for interactive data exploration. Related to "tern", there's the "teal.modules.clinical" package, which provides teal modules for interactive data analysis.

You can install the latest version of "tern" from CRAN using the command `install.packages("tern")` in your R environment. If you wish to install the latest development version directly from GitHub, you can use the `remotes::install_github("leightsteengineering/tern")` command.

Keep in mind that if you're installing from GitHub, it's recommended to create and use a GITHUB_PAT.

To learn more about how to use this package, you can refer to the package vignettes using the `browseVignettes(package = "tern")` command.

The "tern" package uses "rtables" as the table engine, and the TLG Catalog, a website showcasing many examples of clinical trial tables, listings, and graphs, is associated with it.

Disclaimer: This prototype is at very early stage & there is currently no intention to share further information about it

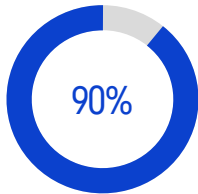
Our Vision

Switching from SAS to R is just the beginning, much more excitement awaits ahead

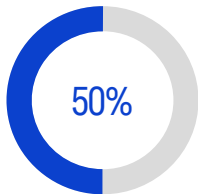
NEST, together with a modern computing platform, is set to deliver significant efficiency gains in clinical reporting

With more adoption, process improvements, continuous innovation, collaboration, as well as new technologies –

Estimated time savings in creating standard TLGs



Estimated time savings in creating customized TLGs



Automated pipeline for multi-purpose insights delivery



Redefine how pharma industry creates & delivers clinical insights

Call for Collaboration

Benefits of Open Source

Why NEST packages are free for all?

Imagine a world where ...



*every company (large & small), charity, academic group, etc., all have access to **free** solutions to support creating a clinical submission*



*regulators receive more **consistent** packages delivered using **trusted code**, thus speeding up approval times and patient access*



less resource intensive** clinical reporting leads to individual data science talents being freed to help generate **new scientific insights



*our regulatory pathways are **revolutionized**, opening the doors for less paper-based submissions via **interactive tools***

Call for Collaboration

The best time to join the journey was 2 years ago. The second best time is now.



<https://pharmaverse.org/>



<https://pharmaverse.slack.com/>



<https://github.com/insightsengineering>

Q & A

Doing now what patients need next