

Interactive Exploration of Top Line Results: Integrating DaVinci with Teal

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Agenda

- ➔ Interactive Exploration of Top Line Results
- ➔ Modular App Creation
- ➔ Integrating Teal within DaVinci
- ➔ Inside the Top Line Results App
- ➔ Bringing Apps to the Trial Teams
- ➔ Our Experiences so far

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Interactive Exploration of Top Line Results

Exploring top line results (TLR) post-database lock enables quick assessment of efficacy, safety, statistical significance, next steps,...

Static PDF outputs

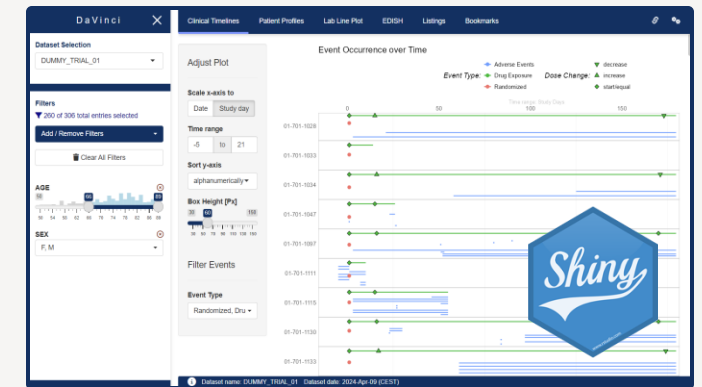
Table 15.2.1.1: 1 Multiple contrast test results of non-flat dose response shape for time to first pulmonary exacerbation up to week 48 - Treated set

	Cox model§	Average effect	Exponential*#	Linear*	Bmax 1*	Bmax 2*
Contrast:						
BI 1mg		-0.0543	-0.1460	-0.8292	-0.9000	
BI 2.5mg		-0.6326	-0.6881	-0.5080	-0.4033	
BI 5mg		-0.7725	-0.7108	-0.2329	-0.1656	
Multiple Contrast Test:-						
t statistic		5.6336	5.4411	2.6221	1.9931	
adj. p-value		<0.0001	<0.0001	0.0077	0.0495	
Akaike Information Criterion (AIC):		8.4660	11.6746			
Model Weight:		0.8293	0.1667			
Hazard Ratio (95% CI):						
BI 1mg vs Placebo	1.25 (0.86, 1.98)	0.79	0.83 (0.65, 1.06)	0.65 (0.55, 0.76)	0.55 (0.44, 0.64)	
BI 2.5mg vs Placebo	0.42 (0.22, 0.78)	0.47	0.51 (0.28, 0.92)	0.34 (0.23, 0.50)	0.33 (0.20, 0.54)	
BI 5mg vs Placebo	0.08 (0.03, 0.20)	0.07	0.07 (0.03, 0.17)	0.11 (0.05, 0.25)	0.17 (0.07, 0.40)	

PDF

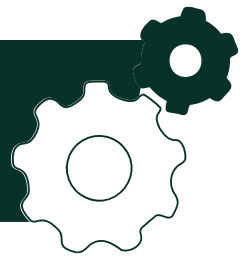
- ✗ Scroll through tons of data
- ✗ Many rows, columns, pages make the eye “slip”
- ✗ Slow and error-prone
- ✗ Frontloading

Interactive R/Shiny apps



- ✓ Dynamic filters and drill-down for tailored insights
- ✓ Quick and comprehensive visualization of TLRs
- ✓ Facilitate storytelling and decision-making
- ✓ Reduce additional analysis requests

Modular App Creation

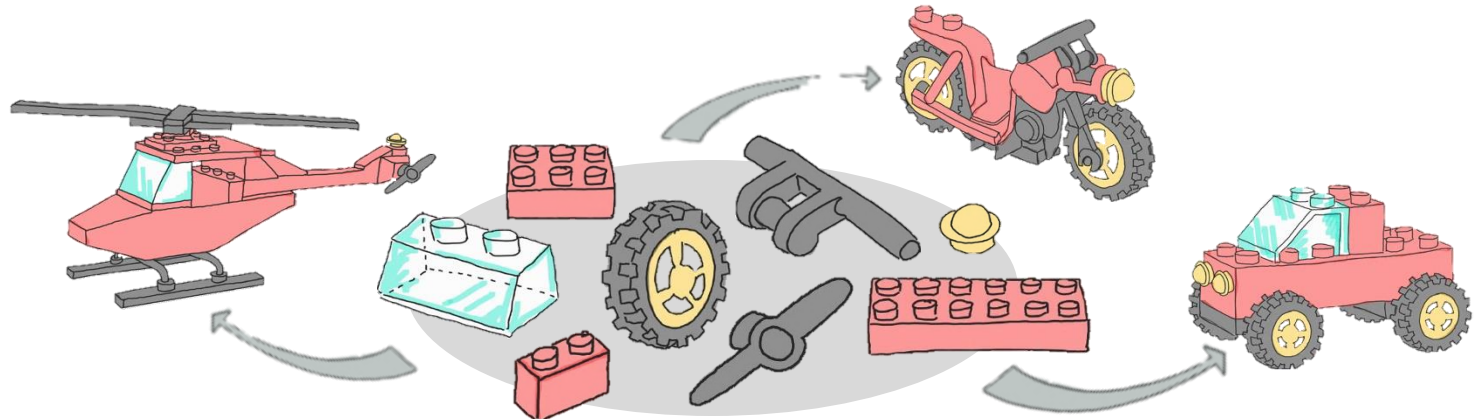


- One comprehensive stand-alone app that satisfies the needs of as many studies as possible quickly becomes unwieldy with trial-specific adjustments being impossible
- Therefore: R/Shiny modules serve as functional building blocks that can be composed into **customized, trial-specific apps**
- Modular open-source frameworks to support interactive TLR exploration:

DaVinci



Teal



Integrating Teal within DaVinci



- {dv.teal} enables the usage of DaVinci and Teal modules within a single app
- Provides a **generic wrapper function** that facilitates the integration of Teal modules within the DaVinci framework
- Limitations:
 - Reporter functionality not supported
 - Bookmarking only partially supported for teal modules

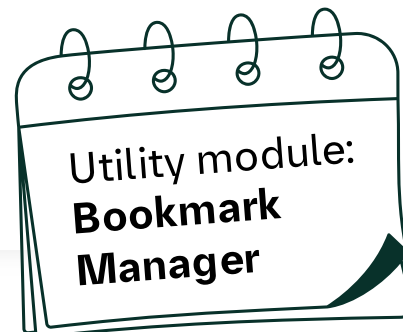
```
01 data_list <- list("ADSL" = pharmaverseadam::adsl)
02 var_browser <- dv.teal::mod_teal(
03   module_id = "mod01",
04   teal_module = teal.modules.general::tm_variable_browser(),
05   j_keys = teal.data::default_cdisc_join_keys
06 )
07 dv.manager::run_app(
08   data = list("demo" = data_list),
09   module_list = list("Variable Browser" = var_browser),
10   filter_data = "ADSL"
11 )
```

Inside the Top Line Results App

Patient-Level Exploration and Safety Review

Patient Profiles, Hierarchy Table for AEs
→ DaVinci

Demographic Explorer, Variable Browser
→ Teal



Visualization of Lab Values

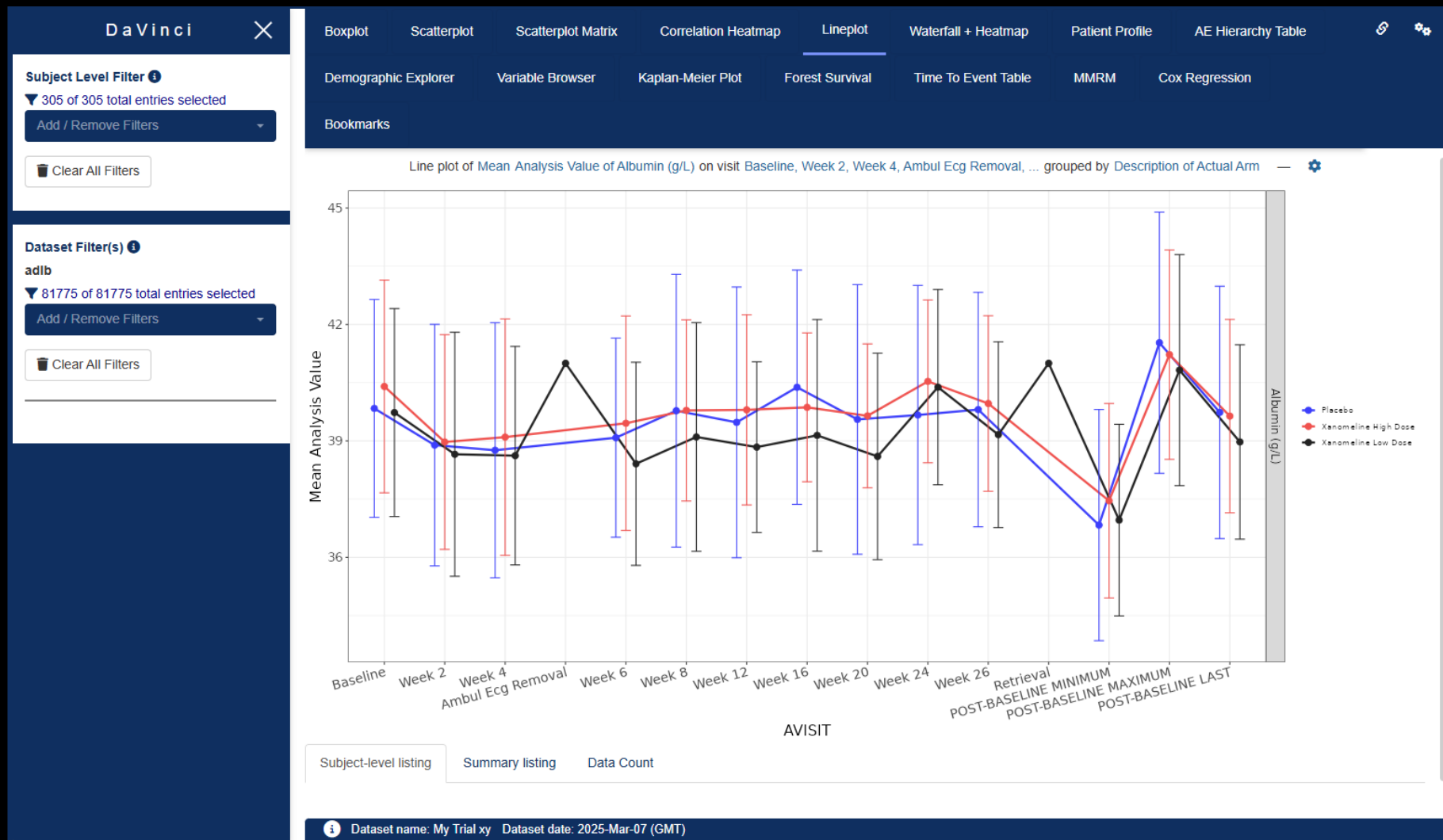
Boxplot, Scatterplot, Scatterplot Matrix, Correlation Heatmap, Lineplot, Waterfall + Heatmap

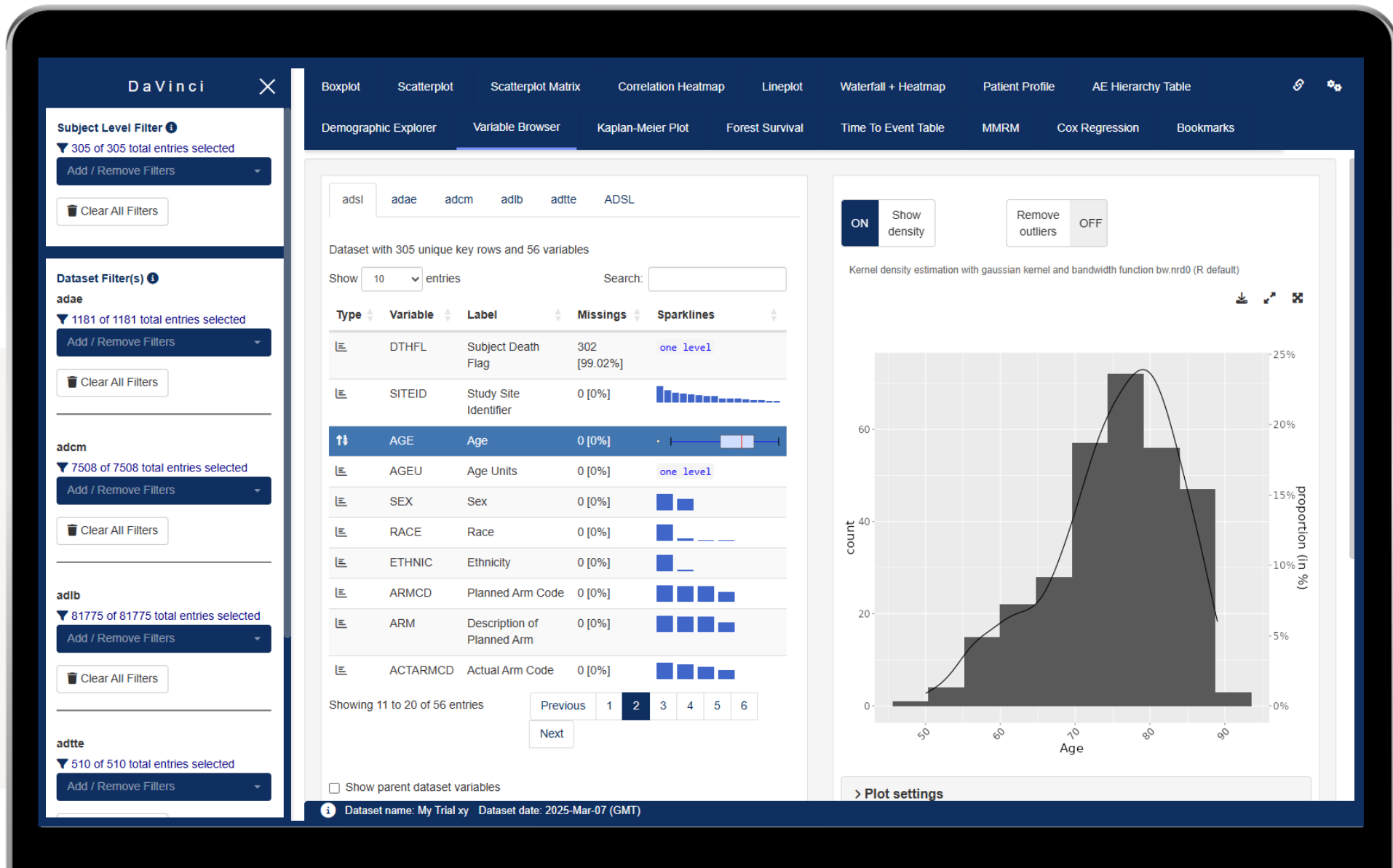
→ DaVinci modules with drill-down functionality

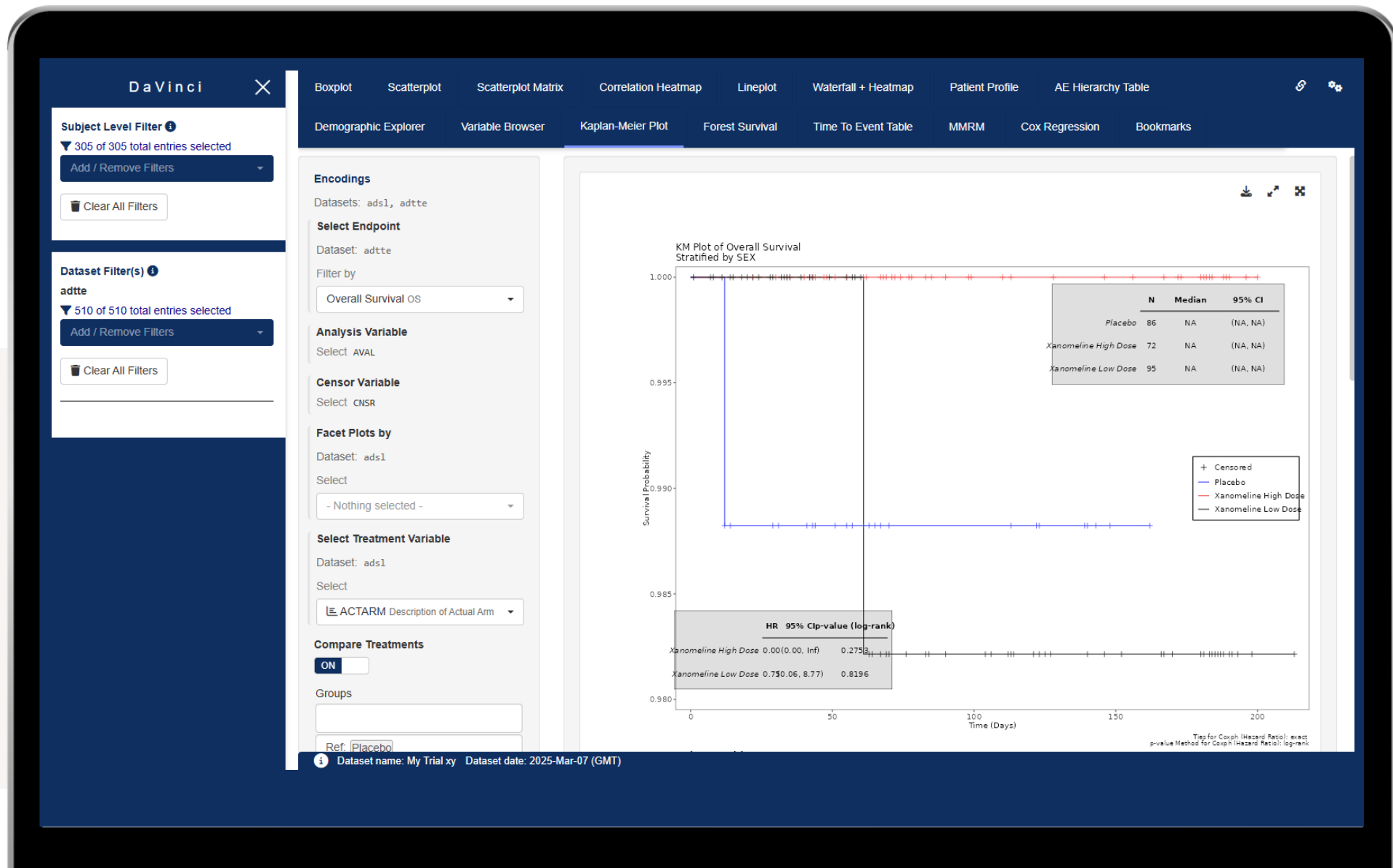
Time-to-Event and Survival Analysis

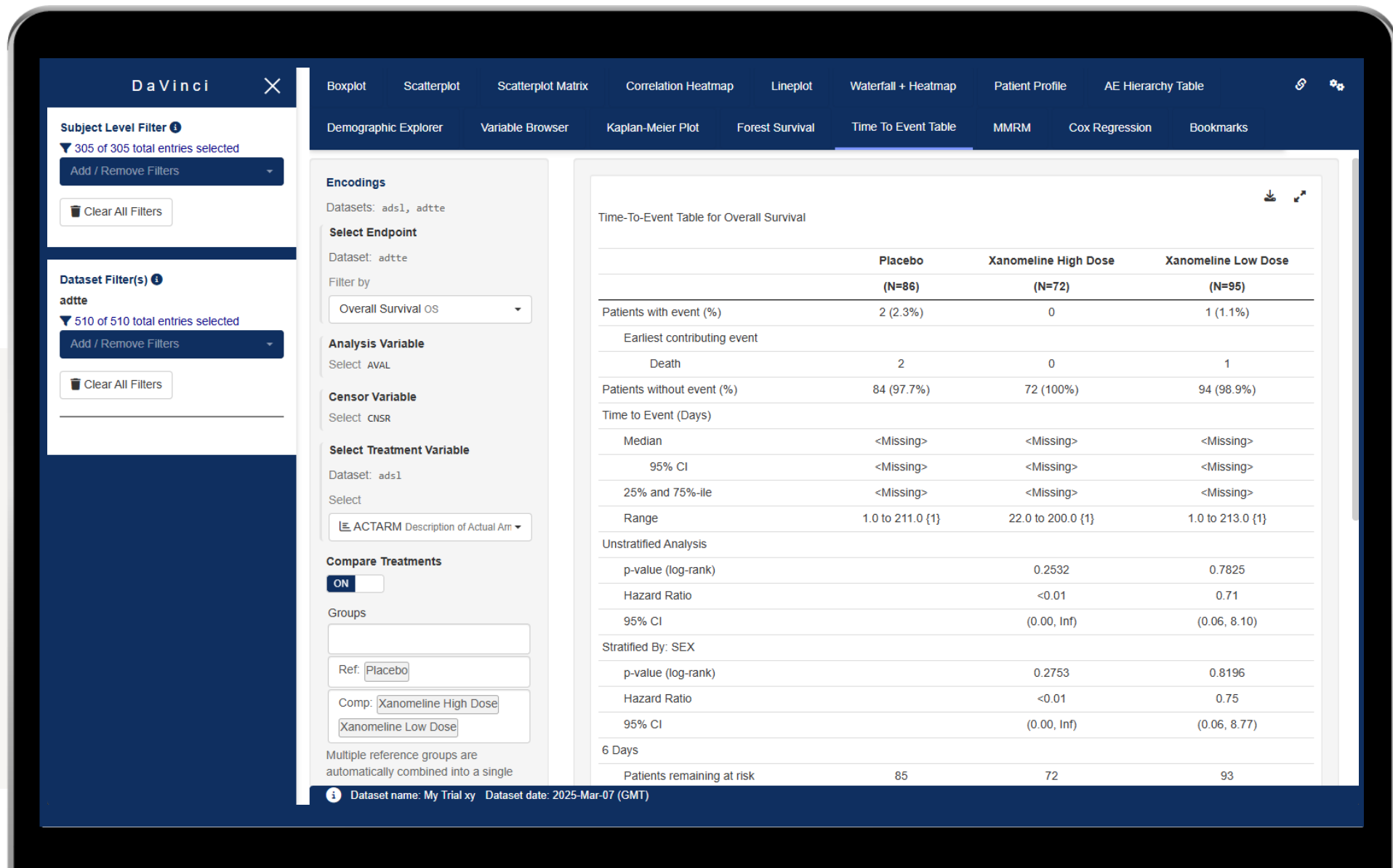
Kaplan-Meier plot, Forest Survival plot, Time-to-Event table, MMRM, Cox Regression

→ Teal modules



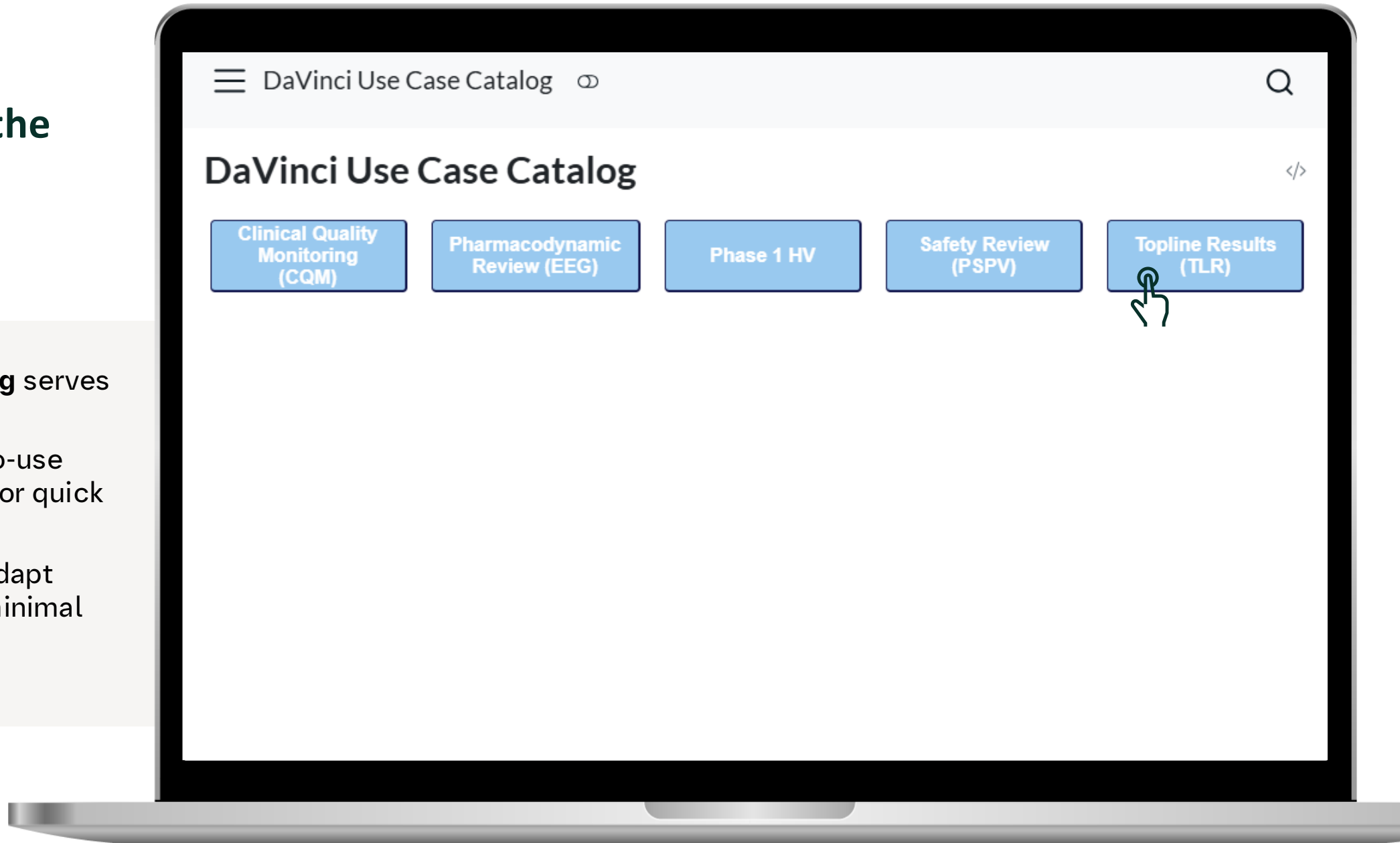






Bringing TLR Apps to the Trial Teams

- **Use Case Catalog** serves as starting point
- Provides ready-to-use code templates for quick setup
- Trial teams can adapt templates with minimal effort



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DaVinci Use Case Catalog About/Help Use Cases ▾

Topline Results (TLR)
General Outputs ▾
Boxplot
Scatterplot
Scatterplot Matrix
Correlation Heatmap
Lineplot
Patient Profile
AE Hierarchy Table
Demographic Explorer
Variable Browser
Kaplan-Meier Plot
Forest Survival Plot
Time to Event Table
MMRM Analysis
Cox Regression Model
Bookmark Manager
Onco Outputs ▾
Best Overall Response
Objective Response
Downloads

```
46 strata_var = choices_selected(  
47   choices = variable_choices(data_list$adsl, c("SEX", "RACE")),  
48   selected = "SEX"  
49 ),  
50 time_points = choices_selected(  
51   choices = c(6, 8),  
52   selected = 6  
53 ),  
54 event_desc_var = choices_selected(  
55   choices = variable_choices(data_list$adtte, "EVNTDESC"),  
56   selected = "EVNTDESC",  
57   fixed = TRUE  
58 )  
59 )  
60  
61 tte_tab <- dv.teal::mod_teal(  
62   module_id = "tte_tab",  
63   teal_module = tm_t_tte_mod,  
64   j_keys = j_keys  
65 )  
66  
67 # Step 5 - Run app  
68 dv.manager::run_app(  
69   data = list("My Trial xy" = data_list), # TODO: adapt name of data  
70   module_list = list("Time To Event Table" = tte_tab),  
71   filter_data = "adsl" # takes all variables of ADSL for global filtering
```

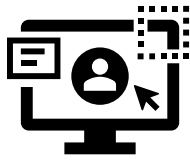
Our Experiences and Outlook

**Technical
set-up
works**



**Interactive apps
help to reduce
workload**

(e.g. by minimizing
the set of additional
post-hoc
evaluations)



**Effective
visualizations are
very helpful for
clear
communication**



**Dedicated
people
required for
interactive
tools**



Training Roll Outs

**Validation of Interactive
Applications**

**AI/LLM inclusion in
our R Posit Solution**

Positive feedback from various people across different departments

What is currently hot



Thank you!
Any questions?

In case of questions please contact:

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