

An RShiny App for Real-Time Continuous Safety Monitoring in Post-POC Trials: A Bayesian Approach to Decision-Making

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Agenda

- Background and Motivation
- RShiny App Overview
- Workflow
- Decision support
- Simulated Case Study
- Discussion: Strengths, Future Work
- Key Takeaways

Background and Motivation:

Why Continuous Safety Monitoring?

- Post-POC trials generate high-volume, complex safety data
- Periodic static reports delay detection of emerging safety signals and slow down action
- Regulators are increasingly emphasizing continuous, data-driven safety surveillance [1]
- Teams need usable tools—without heavy coding or custom analysis

RShiny App Overview

Key features:

- Intuitive user interface
- Configurable priors and robustification options
- Real-time safety insights
- End-to-end Bayesian workflow

App workflow

- Input Data
- Run analysis with progress feedback
- Visualize Results

Continuous Safety Monitoring Analysis

Placebo Prior Distribution Parameters

c(1, 2957 + 1, 84573 / 100)

Robustify (Y/N)

Y

Robust Weight

0.2

Completed Trials Data

Browse...

completed_trial

Upload complete

Blinded Trials Data

Browse...

blind_trials_pt.

Upload complete

Random Ratio Data

Browse...

rand_ratio.rds

Upload complete

SAE Name

Depression

Random Seed

12345

Number of Chains

4

Warmup Iterations per Chain

10000

Sampling Iterations per Chain

5000

Run Analysis

Text Results

Density Plot

Forest Plot

Running analysis... Step 4: Preparing Data for Sampling...

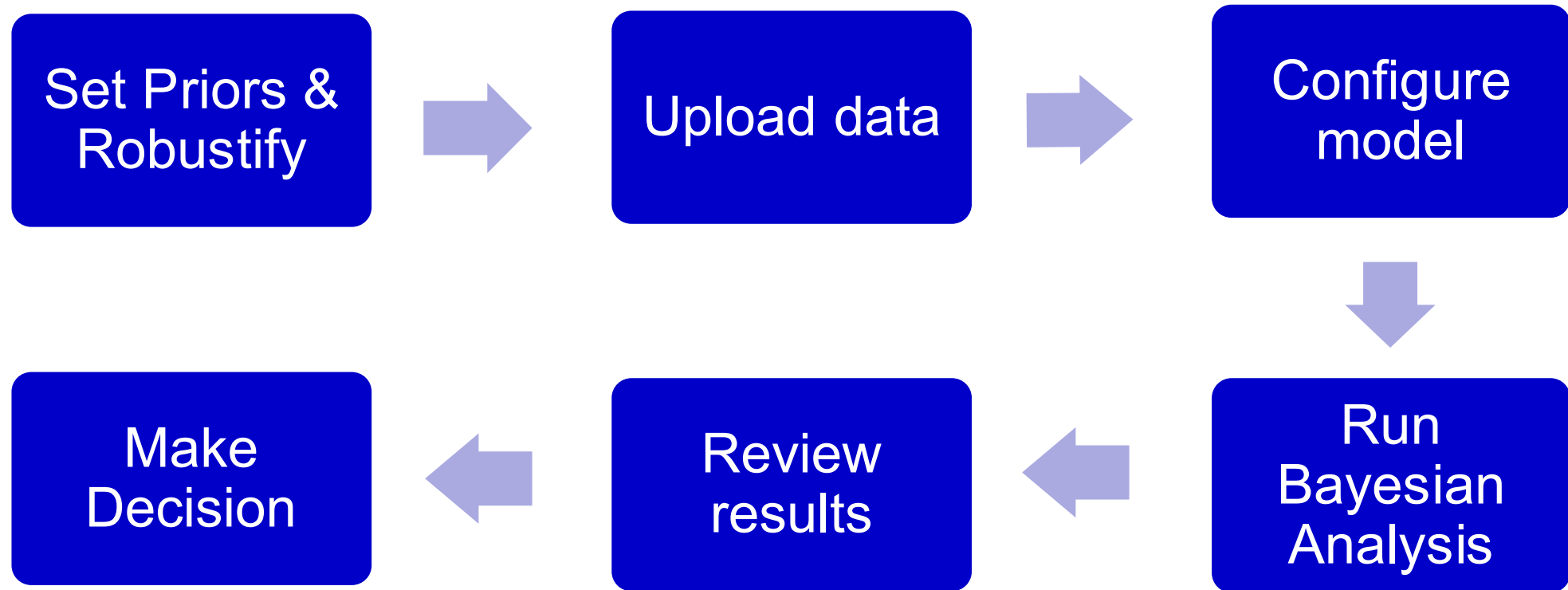
Decision support

- Posterior probability $P(\theta_e > \theta_c)$
- Predefined thresholds support safety governance decisions
- Continuous learning framework — Posterior probability **re-updates** with each data refresh, reflecting all available evidence (not fixed interim snapshot)

Case study: simulated trial

- 100-patient simulated dataset
- Depression-related safety outcome
- Illustrative example (not a real trial) —
Demonstrates the end-to-end workflow of
the app

Case study: Workflow



Case study: key results

Text Results

$P(\theta_e > \theta_c) = P(RR > 1) = P(IR_DIFF > 0)$: 0.951950

Summary Table for θ_e , θ_c , ir_diff and rr :

variable	mean	median	sd	q5	q95
thetae	5.55	5.46	1.72	3.06	8.58
thetac	2.51	3.34	1.13	0.65	3.56
relative.risk	3.28	2.08	3.77	1.01	8.96
ir_diff	3.04	2.94	2.04	0.03	6.65

θ_e : Incidence Rate for experimental arm

θ_c : Incidence Rate for control arm

relative.risk: θ_e/θ_c

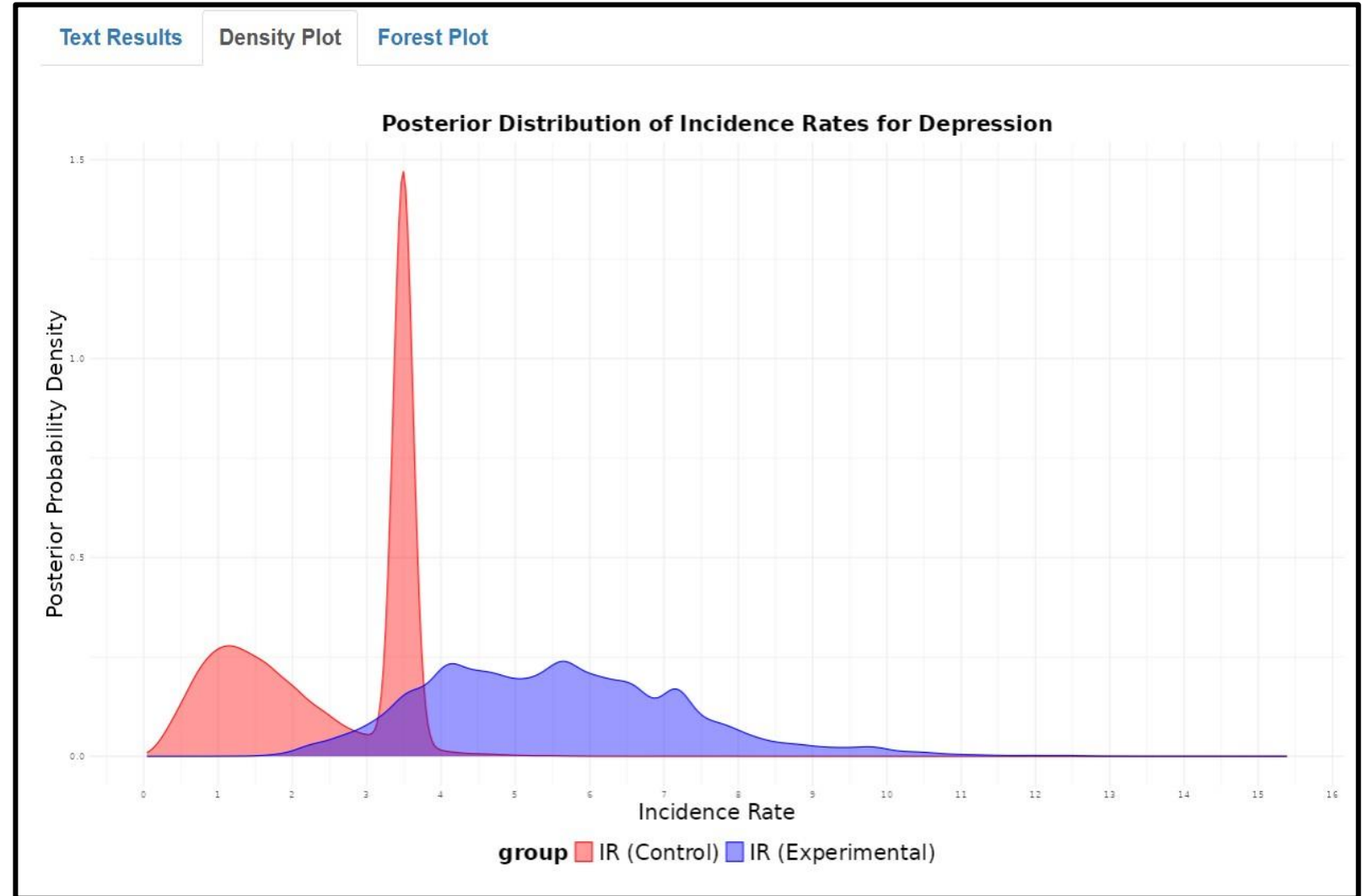
ir_diff: $ir(\text{experimental}) - ir(\text{control})$

q5: Lower 95% Credible Interval Bound

q95: Upper 95% Credible Interval Bound

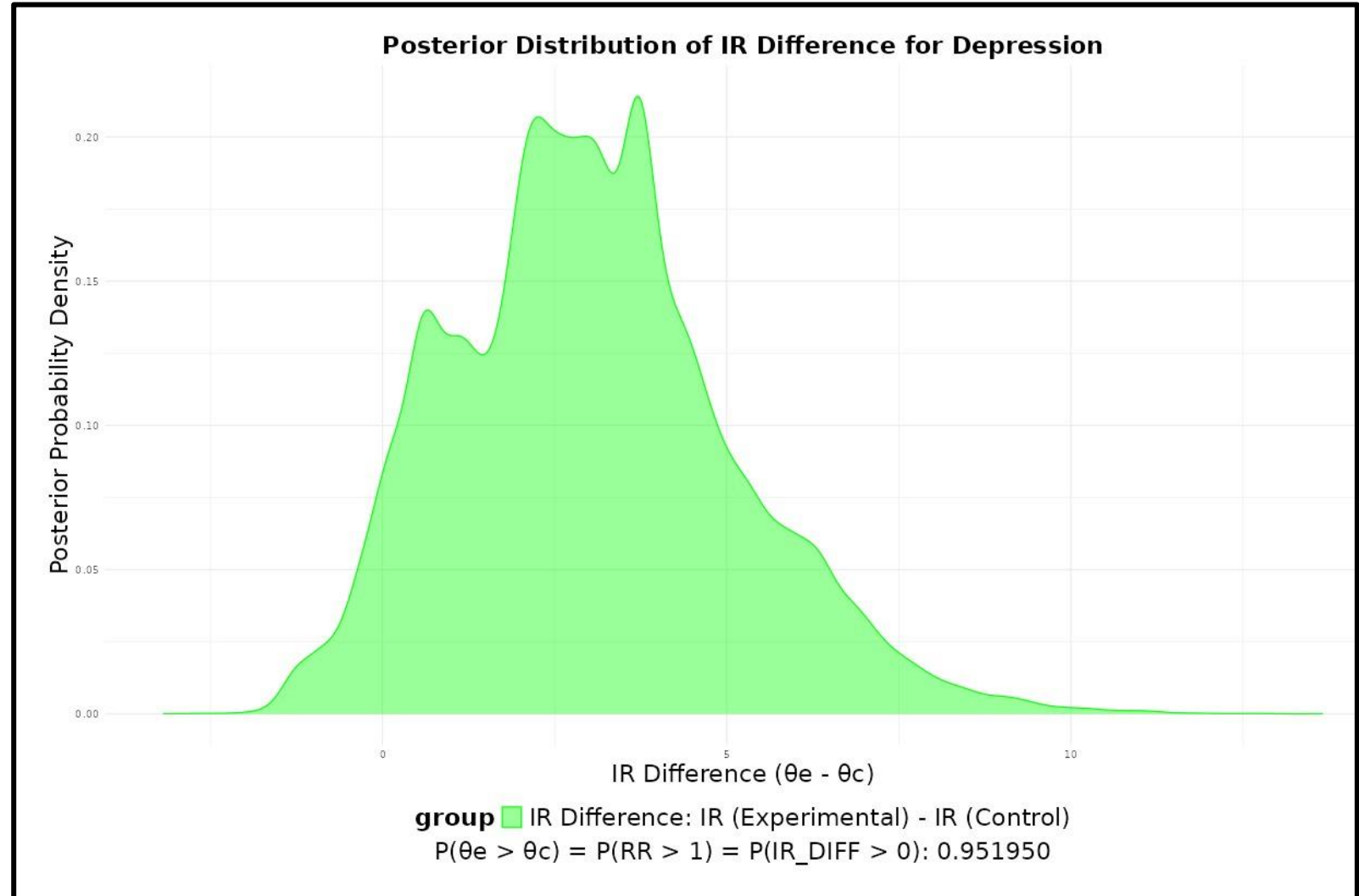
Case study: key results

Density Plot: Incidence Rate



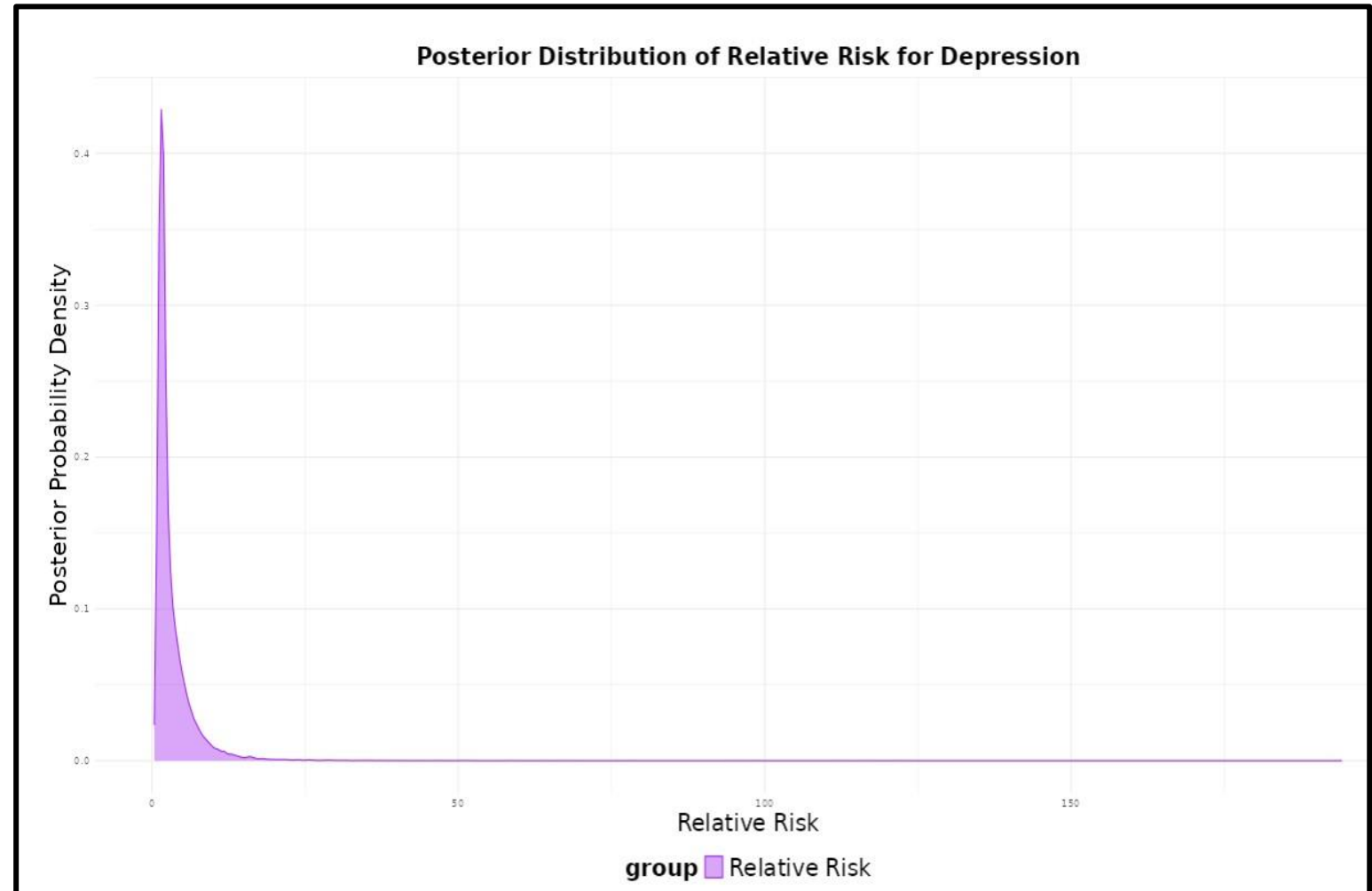
Case study: key results

Density Plot: IR Difference



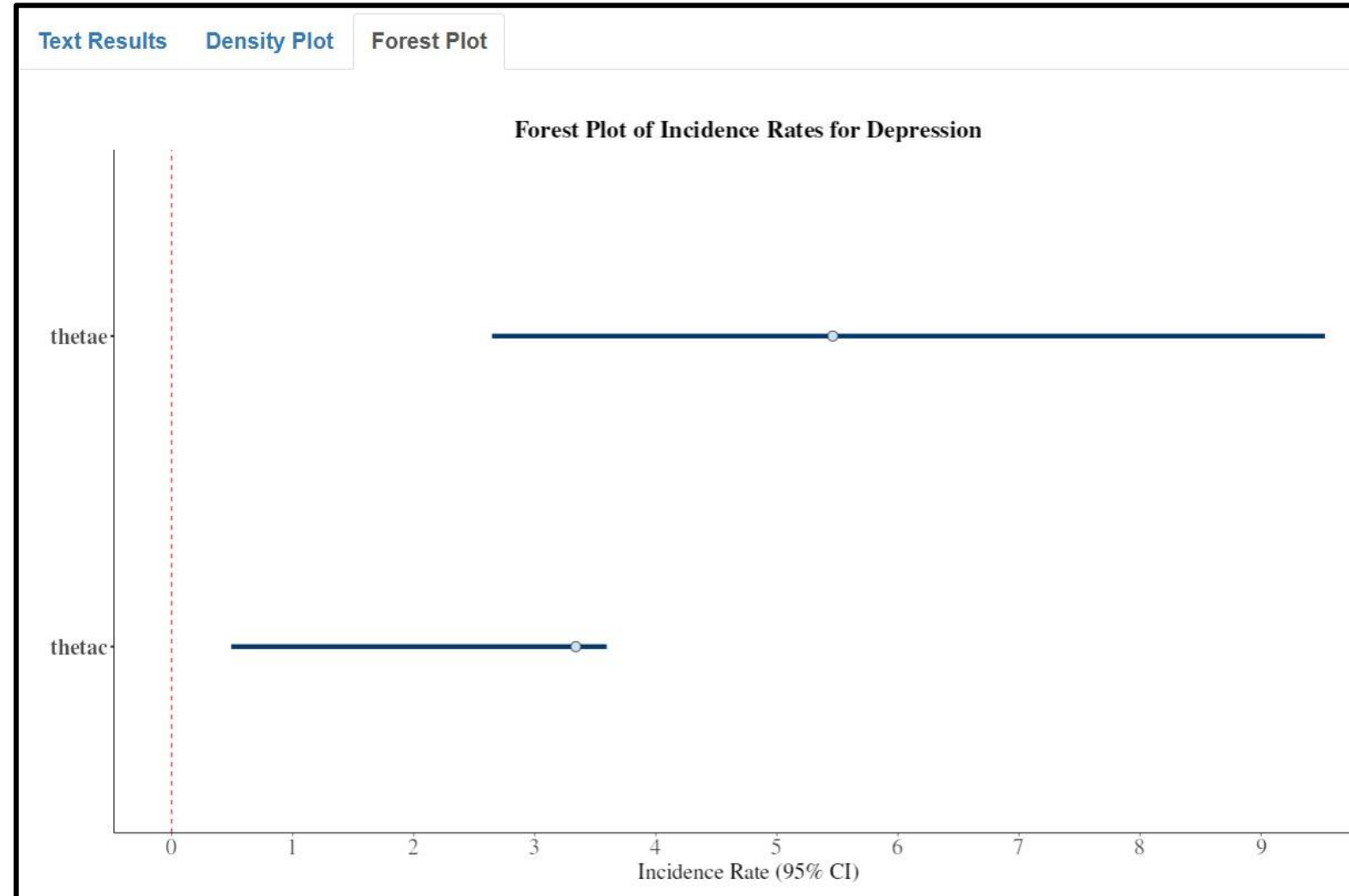
Case study: key results

Density Plot: Relative Risk



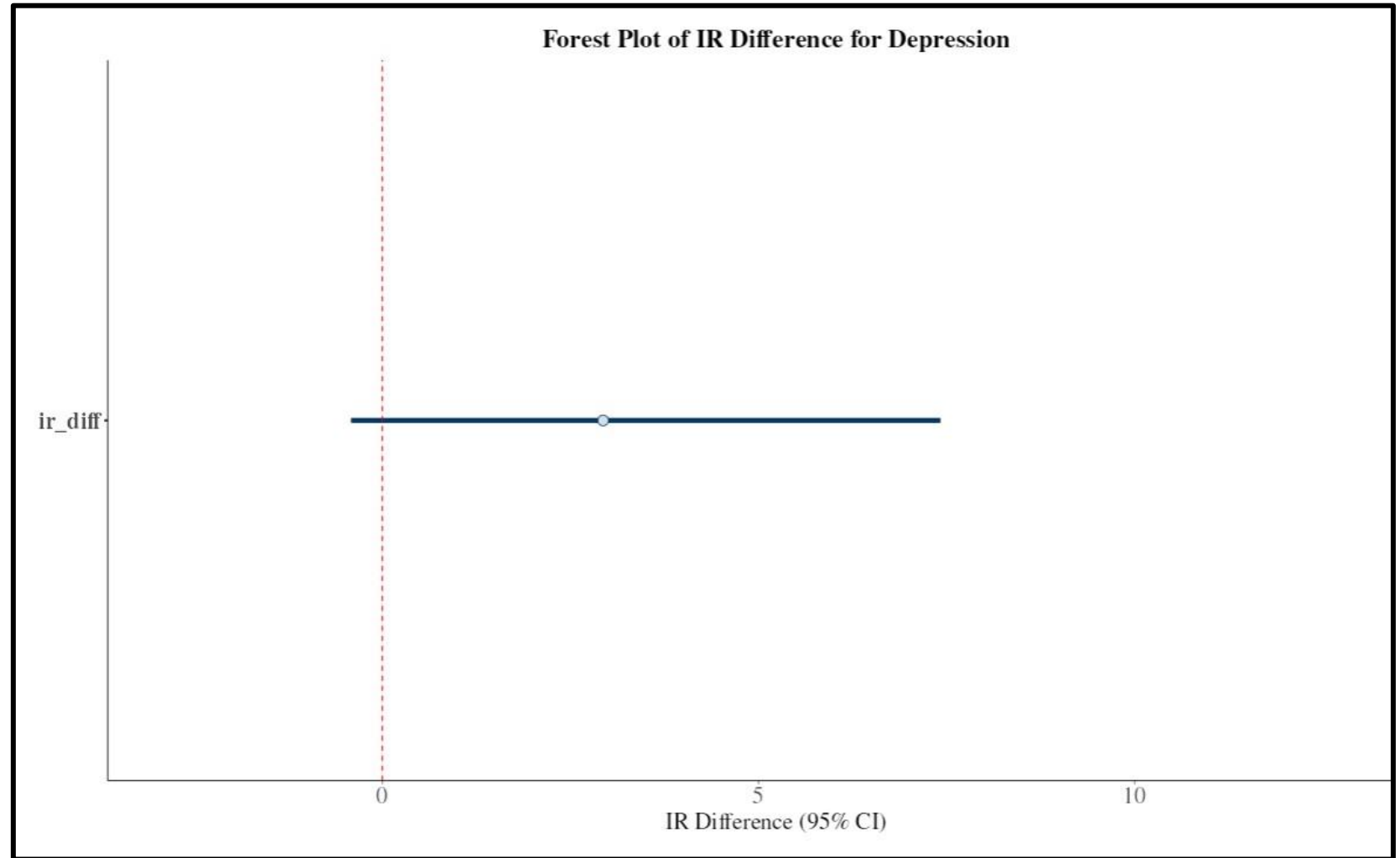
Case study: key results

Forest Plot: Incidence Rate



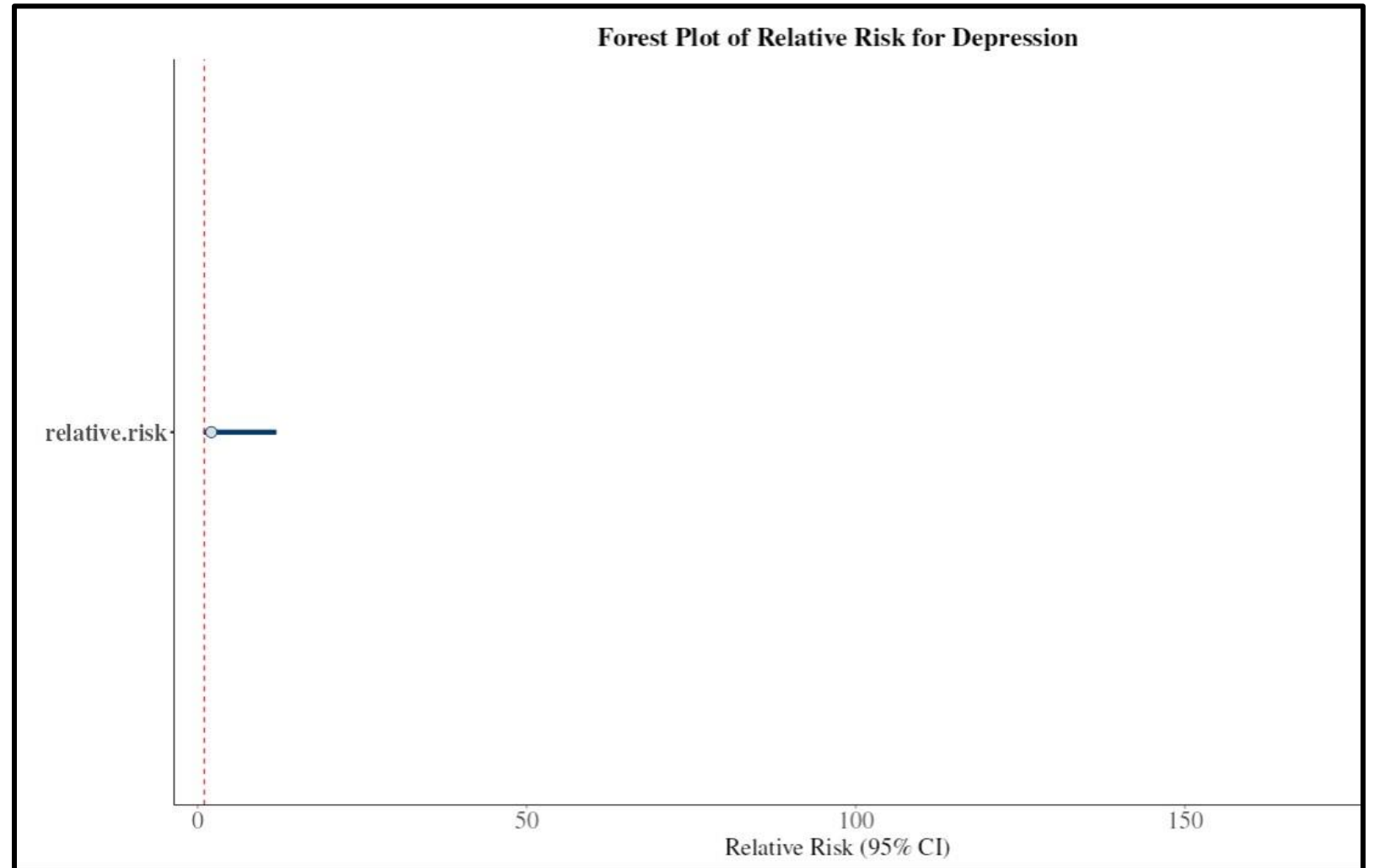
Case study: key results

Forest Plot: IR Difference



Case study: key results

Forest Plot: Relative Risk



Case study: Overall Findings

- Text results, density plots, and forest plots consistently show higher risk in the treatment group.
- This pattern indicates a potential safety signal that warrants closer monitoring and further evaluation.

Case Study: **Decision support**

- Key Result: $P(\theta_e > \theta_c) = 0.952$
- Threshold: 0.9355
- Interpretation: Strong evidence of a potential safety signal in the *treatment group*
- Decision: Consider unblinding for further safety evaluation, subject to clinical and governance review

Discussion & Future Work

Key Strengths of the App:

- Real-time insights accelerate safety review cadence
- Low barrier to use for clinicians and non-programmers
- Regulatory-aligned Bayesian monitoring
- Combines numerical summaries and intuitive visualizations for decision-making

Discussion & Future Work

Future Enhancements:

- Integrate enterprise systems to enable automation
- Extend validation across diverse study designs
- Expand safety endpoints and incorporate system severity grading
- Increase flexibility in model structures and methods

Key Takeaways

- Continuous safety monitoring after proof of concept
 - Data accrual → decisions, not fixed milestones
- RShiny app makes Bayesian analysis accessible
 - Complex methods → clear, interactive results
- Bayesian decision rules for uncertainty
 - Probability thresholds → faster, more consistent safety actions

References

1. U.S. Food and Drug Administration (FDA). (2025). Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies: Guidance for Industry. U.S. Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>
2. Stan Development Team. (2025). Stan Modeling Language: User's Guide and Reference Manual (Version 2.37). <https://mc-stan.org/docs/>
3. Gabry, J., Češnovar, R., Johnson, A., & Stan Development Team. (2025). cmdstanr: R Interface to CmdStan (Version 0.9.0). <https://mc-stan.org/users/interfaces/cmdstanr>
4. Chang, W., Cheng, J., Allaire, J. J., Xie, Y., Sievert, C., Schloerke, B., & Posit Software. (2025). shiny: Web Application Framework for R (Version 1.12.0). <https://cran.r-project.org/package=shiny>
5. Gelman, A., Carlin, J. B., Stern, H. S., Dunson, D. B., Vehtari, A., & Rubin, D. B. (2013). Bayesian Data Analysis (3rd ed.). CRC Press. ISBN: 9781439840955
6. Muehleemann, N., Zhou, T., Mukherjee, R., Hossain, M. I., Roychoudhury, S., & Russek-Cohen, E. (2023). A tutorial on modern Bayesian methods in clinical trials. Therapeutic Innovation & Regulatory Science, 57(3), 402–416. <https://doi.org/10.1007/s43441-023-00515-3>

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Questions?

Thank you!

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