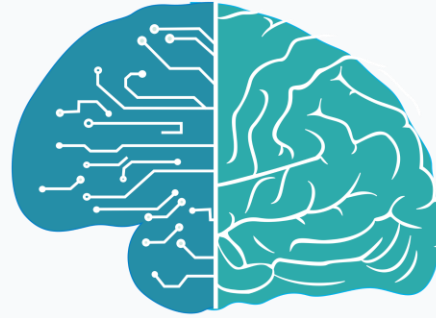




OncoTrialMind

Oncology Clinical Trial Intelligent Decision-Making Center

From Data to Insight at Speed: Optimizing Data-Driven Decision-Making

Zhiping Yan, Dizal Pharmaceutical Co., Ltd.

Disclaimer

The contents represent solely the personal views of the presenter and do not necessarily reflect the stance of the employer

Our Needs in Early Oncology Clinical Trials

01



Phase I Dose Escalation Designs

BOIN · 3+3 · mTPI

02



Dose Selection & Optimization

PK/PD · E-R · ANN

03



Go / No-Go Decision

Bayesian Posterior Prob.

04



Aggregate Safety Analysis

AE · Co-occurrence Network

05



Phase II Study Designs

Simon · Bayesian TTE

06



mPFS Prediction

ORR-informed · PFS Trajectory Projection



The Problem We Were Solving

Decision Analysis Are Fragmented
Across Dozens of Scripts

-
- Clinical data analysis is often scattered across multiple independent systems, and statistical programming and medical review tools lack interoperability, leading to discontinuous information transfer. Manual export/import collaboration is error-prone and time-consuming.
 - The traditional process takes several days or more from data release to report generation, making it difficult to respond quickly to safety signals or strategy changes. Such delays in dynamic decision-making can jeopardize patient safety and clinical development progress.
 - Statistics, medical, clinical pharmacology, and programming teams work on different platforms, resulting in high communication costs and frequent version inconsistency issues. The lack of a unified environment hinders real-time feedback and rapid iterative analysis.

“

Can one platform replace this patchwork and produce audit-ready evidence in real time?

”

▼ See the answer on the next slide

OncoTrialMind — One Platform, Complete Solution

OncoTrialMind™

Oncology Clinical Trial Intelligent Decision-Making Center

Integrated platform empowering medical, statistical, and clinical pharmacology teams — from data ingestion to Go/No-Go decisions. Seamless Bayesian inference, adaptive trial simulation, and real-time risk intelligence.



Phase I/II Intelligent Decision Platform

BAYESIAN · DOSE ESCALATION · GO/NO-GO



Dose escalation designs (3+3, BOIN, etc.)



Bayesian statistical inference



Safety monitoring & AE analytics



Efficacy assessment & early signals



Exposure-response analysis (E-R)



ML risk prediction (toxicity/response)



RP2D Planning-Multi-Discipline team (MDT) assessment



Go/No-Go decision framework



Competitive benchmark intelligence



Integrated for early-phase oncology trials



Launch Decision Platform



Oncology Study Simulator

ADAPTIVE DESIGNS · POWER · PPOS · SSR



Parametric survival simulation + empirical power



Sample size & event target optimisation



Group sequential boundaries (GSB)



Multiplicity control (PFS, OS, ORR)



Target event count prediction



Non-proportional hazards (delayed, crossing)



Bayesian predictive probability of success (PPoS)



Frequentist conditional power & OC curves



Adaptive SSR: Promising Zone / Unconditional Power



Integrated for late-phase oncology trials



Launch Study Simulator

Enterprise R Shiny Server · Role-based access enabled | Click to launch respective decision tool

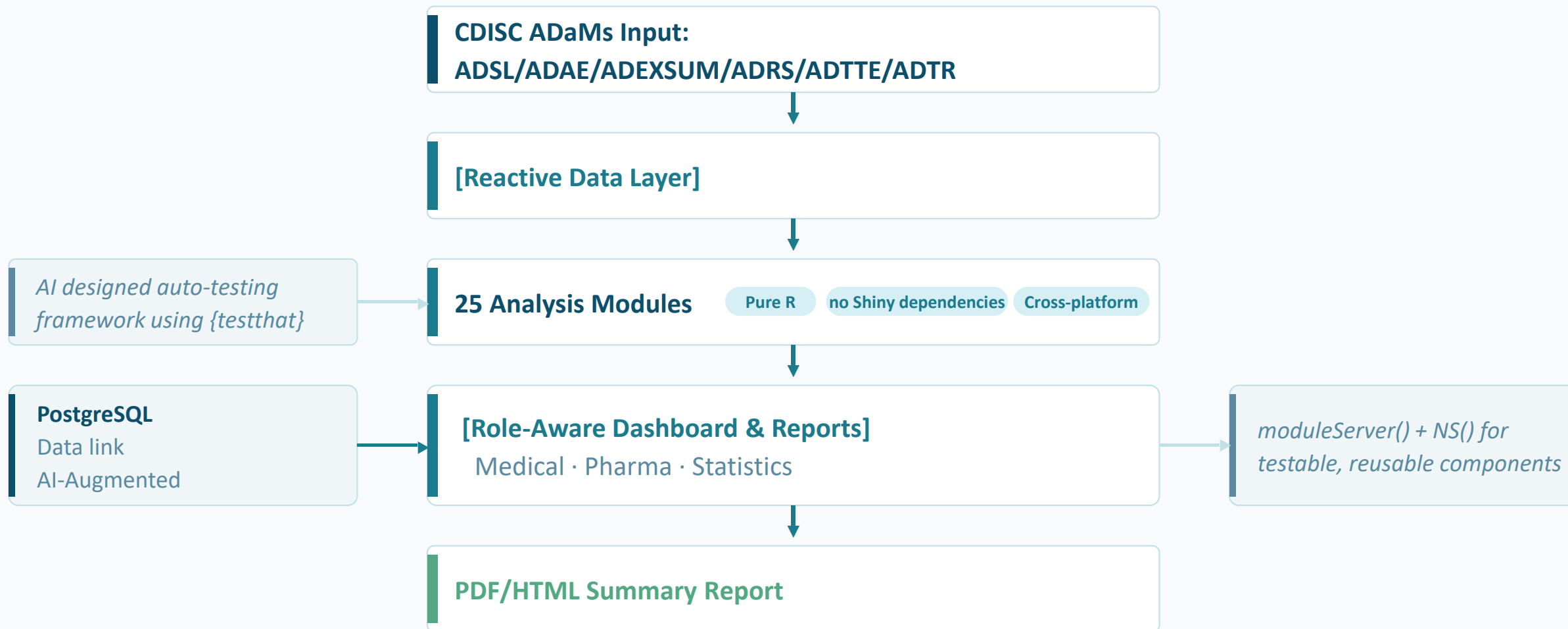
© OncoTrialMind — Advanced Clinical Intelligence Framework · For biostatistics & medical decision teams



New Features in OncoTrialMind

- AI-Augmented R Shiny Platform for Oncology Clinical Trial Decision Intelligence
- Role-Based Dashboard & Automated Regulatory-Ready Reporting
- Unified Evidence Synthesis Under One Reactive Data Layer
- Comprehensive Bayesian Decision Suite
- AI Signal Intelligence Engine
- Competitive Benchmark Intelligence + ClinicalTrials.gov Integration

OncoTrialMind-Architecture at a Glance



✓ Designed for a Regulated Environment

Technology Stack

Component	Technology	Rationale
Web framework	R Shiny + bslib	Reactive UI without JavaScript expertise
Data link	PostgreSQL	Open-source; Data connection and share
Interactive plots	plotly, ggplot2, visNetwork	Client-side interactivity
MCMC	Custom Metropolis-Hastings (base R)	No JAGS/Stan dependency
Bayesian computation	Base R (dbeta, pbeta, qbeta)	Conjugate closed-form posteriors
ML	stats::glm, stats::kmeans	Zero external ML dependencies
Parallelism	furrr	Parallel OC simulations
Report generation	rmarkdown / flextable	Automated Word/HTML output
Data wrangling	dplyr, tidyr, purrr	Tidyverse consistency

Data Infrastructure: CDISC-Native + PostgreSQL Persistence

Input Formats

- ▶ ADSL — Subject-level demographics
- ▶ ADAE — Adverse events
- ▶ ADEXSUM — Exposure summary
- ▶ ADRS — Response endpoints
- ▶ ADTTE — Time-to-event
- ▶ ADTR — Tumor response
- ▶ PK exposure data (CSV)

In-app upload with automatic CDISC column normalization

PostgreSQL Persistence

- ▶ All results serialised as JSONB
 - ↳ → analysis_results table
- ▶ Decision audit log:
 - ↳ timestamp · user role · parameters
- ▶ Evidence score history
 - ↳ trend tracking over interim analyses
- ▶ Multi-project support
 - ↳ per-project PostgreSQL connection pools

AI-Designed Validation Cases for Key Results

Test case	Expected	Platform output	Status
Simon Optimal ($p_0=0.2$, $p_1=0.4$, $\alpha=0.05$, power=80)	$N_1=13$, $r_1=3$, $N=43$, $EN(p_0)=20.6$	✓ Exact match	✓
BOIN boundaries ($\phi=0.25$)	$\lambda_1=0.197$, $\lambda_2=0.298$	✓ Exact match	✓
Jeffreys posterior $r=15$, $n=60$	$P(\pi > 0.20) \approx 82\%$	82.1%	✓
CRM MCMC R-hat	≤ 1.05 on all runs	Displayed live	✓
Bootstrap CI coverage (simulation)	Nominal 95%	94.2–95.8% across scenarios	✓

Does It Work?

Benchmark Against Published Results

- ✓ Statistical results verified by multiple AI coding agents
- ✓ AI-designed auto-testing framework using {testthat}

```
# tests/testthat/test-bayesian_stats.R
#
# Unit tests for R/bayesian_stats.R
# Covers: compute_posterior_go, compute_posterior_safety,
#         detect_prior_data_conflict, compute_conditional_power
#
# GxP Reference: OQ test cases BAS-TC-01 to BAS-TC-20
# Numerical expectations cross-checked against:
# - OQ TC-40 / TC-43 in validation/scripts/oq_test_suite.R
# - R analytic baseline: pbeta(0.2, 7.5, 13.5, lower.tail=FALSE) = 0.9993
#
# --- compute_posterior_go ---

test_that("BAS-TC-01: posterior Go with 7/20 responders yields analytically correct p_go", {
  # Jeffreys prior: Beta(0.5, 0.5); post = Beta(7.5, 13.5)
  # Analytic: pbeta(0.2, 7.5, 13.5, lower.tail=FALSE) = 0.9460 (rounded to 4 dp)
  expected <- round(pbeta(0.2, 7.5, 13.5, lower.tail = FALSE), 4)
  res <- compute_posterior_go(n_resp = 7L, n_total = 20L,
                             threshold = 0.2, decision_cutoff = 0.8)
  expect_equal(res$p_go, expected, tolerance = 1e-4)
  expect_equal(res$decision, "Go \u2713")
})

test_that("BAS-TC-02: posterior Go decision matches explicit decision_cutoff boundary", {
  # p_go returned should trigger Go when >= cutoff and No-Go when < cutoff
  go <- compute_posterior_go(7L, 20L, threshold = 0.2, decision_cutoff = 0.8)
  nogo <- compute_posterior_go(2L, 20L, threshold = 0.2, decision_cutoff = 0.8)

  expect_equal(go$decision, "Go \u2713")
  expect_match(nogo$decision, "No-Go|Wait")
})

test_that("BAS-TC-03: posterior mean ORR lies within 95% credible interval", {
  res <- compute_posterior_go(5L, 20L)
  expect_lt(res$ci_95_lower, res$post_mean_orr)
  expect_gt(res$ci_95_upper, res$post_mean_orr)
  expect_gte(res$ci_95_lower, 0)
  expect_lte(res$ci_95_upper, 1)
})
```

Regulatory & Validation Considerations

✓ Designed for Regulated Environment

- AI-assistant documentation delivered with the system:

Document	GxP standard
Validation Plan (VP)	GAMP 5
User Requirements Specification (URS)	21 CFR Part 11 / EU Annex 11
Installation Qualification (IQ)	GAMP 5
Operational Qualification (OQ)	GAMP 5
Performance Qualification (PQ)	GAMP 5
Validation Summary Report (VSR)	ICH Q10

 **Statistical methods:** Fully documented in STATISTICAL_METHODS.md (17 sections, 5 000+ words) — covers all formulas, prior choices, MCMC settings, convergence diagnostics, and references.

Role-Aware Dashboard: One App, Three Perspectives

*The Right Information to
the Right Person
at the Right Time*



Medical Monitor

► Patient-level Safety

KEY WIDGETS

AE Summary

AE Co-occurrence Network

Patient ML Risk Table

- Real-time AE surveillance
- Network graph: co-occurrence patterns
- ML individual patient risk scoring



Pharmacometrician

► PK / PD Analysis

KEY WIDGETS

E-R Scatter (Logistic/Emax/ANN)

Therapeutic Window

Quartile Analysis

- Logistic / Emax / ANN model fitting
- Therapeutic window visualisation
- Exposure quartile response breakdown



Statistician

► Decision Evidence

KEY WIDGETS

Bayesian Go/No-Go

Simon 2-Stage

BOIN Boundaries

Trajectory Projection

- Posterior probability Go/No-Go engine
- Simon 2-stage interim decision rules
- BOIN dose escalation boundaries
- Response trajectory projection

Role-Aware Dashboard

ONCOLOGY CLINICAL TRIAL — INTELLIGENT DECISION-MAKING CENTER

Trial Status Overview

Go/No-Go
NO-GO

Posterior P(Go)
0.0%

P(Excess Toxicity)
0.0%

Last updated
2026-04-17 09:23

Live

Quick Navigation

Decision Center

AI Support

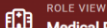
Safety

Efficacy

Stat Design

Dose Escal.

Role-specific view: Role selected above



ROLE VIEW

Medical Physician — Clinical Safety Dashboard



Safety Population
254



Any TEAE
218 (85.8%)



Grade ≥3 AE
29 (11.4%)



SAE
3 (1.2%)

Treatment Arm Safety Comparison

Arm	N	Any TEAE	Grade ≥3	SAE
Placebo	86	65 (75.6%)	5 (5.8%)	0 (0%)
Xanomeline Low Dose	84	77 (91.7%)	10 (11.9%)	1 (1.2%)
Xanomeline High Dose	84	76 (90.5%)	9 (10.8%)	2 (2.4%)

ML Safety Intelligence

High-Risk Patients
11 (4%)
of 254 scored patients

CUSUM Signal
✓ Normal
No DLT seq.

Top Recommended Action:

Maintain standard AE reporting schedule; continue routine DSMB oversight

Top 5 Adverse Events (by Patient Incidence)

Pruritus	55 (21.7%)
Application site pruritus	50 (19.7%)
Erythema	36 (14.2%)
Application site erythema	30 (11.8%)
Rash	27 (10.6%)

Trial Metrics

DEMOGRAPHICS

Enrolled
254 (Safety: 254)

Male
111 (43.7%)

Median Age
77 yrs

ECOG Grade
0 (135)

END OF TREATMENT

Completed Trt
110

Discontinued
144

Ongoing
0

END OF STUDY

Completed Study
110

Withdrawn
144

Ongoing
0

MORTALITY

Deaths
3 (1.2%)

→ Full details in the Safety Assessment and ML Safety Strategy tabs.

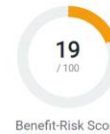
Decision Center

Integrated Decision Recommendation Details

REASSESS POPULATION

Based on synthesis of efficacy (Bayesian Go/No-Go), safety (posterior toxicity), PK/PD evidence, response data, and study design completeness.

Efficacy: No-Go Safety: Acceptable at RP2D **-0.0**



Evidence Maturity Dependencies

17%

1 / 6 analyses completed

- Clinical data (ADAE/ADSL)
- Response data (ADRS)
Requires: Clinical data
- PK exposure data
- ✓ Bayesian Go/No-Go
- Dose escalation design
Requires: Clinical data
- Simon's two-stage design
Requires: Response data

Critical
High
High
Critical
Medium
Medium

Benefit-Risk Radar



Integrated Findings

Evidence Matrix

Decision Audit Log

Pattern Mining

Score Trend

Auto-generated cross-domain signals updated in real time as data and analyses change.

Safety Population: Full (SAFL = Y) To analyze a sub-population, use the filter in Safety Assessment → Population Filter.

✗ Efficacy: Bayesian $P(\text{ORR} > 20\%) = 0.0\% < \text{Go cutoff (80\%)} \cdot \text{Observed ORR} = 8.1\% (15/185) < \text{min. threshold (20\%)}$

✓ Safety: $P(\text{DLT} > 33\%) = 64.7\%$ at evaluated doses — **Acceptable at RP2D** | EWOC constraint satisfied at RP2D (~200 mg) — safety confirmed at optimised dose | AE data: DLT Summary Ready

✓ MTD Estimate: ~200 mg (EWOC: satisfied)

⚠ SAE: 21.1% of participants experienced ≥ 1 serious adverse event | Drug-related SAE: 11.4% — safety score adjusted -7 pts

i PK/PD: No exposure data — upload CSV to enable ER analysis

i Response: No ADRS data — upload to compute ORR

🔍 **Cross-domain signal:** Acceptable safety at optimised dose but insufficient efficacy — consider dose escalation, population enrichment, or biomarker selection

Bayesian Engine

Audit Trail

Real-time Sync

Multi-role View

AI Signal Intelligence Engine

Signal Status

Efficacy 1	Critical
Safety 6	Critical
PK/PD 1	No Data
Cross-Domain 0	No data
Data Completeness 1	Info
ML Prediction 5	Critical

Active Alerts

ML Utility Score: 33.5% Utility score 0.335 [Efficacy $\times$ 0.20 = +0.000; Tox $\times$ 0.60 = -0.388; ML risk $\times$ 0.20 = -0.077]. 3 evidence stream(s) integrated. Caution: Consider dose de-escalation or cohort expansion
PK Exposure Data Absent No PK exposure CSV loaded — Exposure-Response analysis unavailable Upload individual PK exposure file (AUC/Cmax prefix columns) to enable ER analysis
PK Exposure Data Not Uploaded No PK exposure CSV loaded — Exposure-Response analysis unavailable Upload individual PK exposure file (AUC/Cmax prefix columns) to enable ER analysis
Sequential Safety Signal: Within Acceptable Range CUSUM statistic (0.00) is well below the decision boundary (3.0). No evidence of systematic DLT rate increase. Maintain standard AE reporting schedule; continue routine DSMB oversight

Bayesian posterior $P(\text{ORR} > 20\%) = 0.0\%$ — below the 80% decision cutoff. Safety assessment: $P(\text{DLT} > 33\%) = 64.7\%$ — in the caution zone. **5 critical signals require immediate attention: Drug-Related Grade ≥ 3 AE Rate (30.8%); Critical: $\geq 30\%$ Patients Classified as High-Risk; Bayesian & ML Safety Signals Converge — High Alert; High Grade ≥ 3 AE Rate (40.5%); Low Efficacy Posterior Probability.** Recommended next action: *Initiate DSMB emergency review; halt dose escalation pending safety assessment*

Recommendations Trial Trajectory RP2D Planning Decision Pathway ML Safety Strategy Executive Summary

AI Intelligence — Executive Summary

Generated: 2026-04-16 15:33

Action Required

5 critical signals in: Safety, ML Prediction, Efficacy



Critical Signals

5

Halt / DSMB review needed — Safety, ML Prediction, Efficacy



Warnings

6

Elevated risk — Safety, ML Prediction



Positive Signals

1

Favorable findings — ML Prediction

Bayesian Posterior State

Efficacy: $P(\text{ORR} > 20\%) = 0.0\%$ (cutoff 80%)

Safety: $P(\text{DLT} > 33\%) = 64.7\%$

Domain Signal Status

Domain	Top Status	Crit Warn Pos i Info	Top Signal
Efficacy	Critical	1	Low Efficacy Posterior Probability
Safety	Critical	2 4	Drug-Related Grade ≥ 3 AE Rate (30.8%)
PK/PD	No Data	1	PK Exposure Data Not Uploaded
Cross-Domain	No data	—	—
Data Completeness	Info	1	PK Exposure Data Absent
ML Prediction	Critical	2 2 1	Critical: $\geq 30\%$ Patients Classified as High-Risk

AI Executive Brief (DMC Synthesis)

Click 'Generate Brief' to synthesize clinical findings dynamically using the generative AI model.

Generate Brief



NLP Signal Parsing



Auto Signal Detection



Evidence Score

Phase I Dose Escalation Designs

Design Parameters

Dose Levels (comma-separated)

100,200,400,600,800

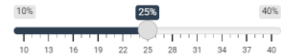
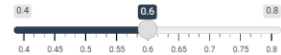
True DLT Rates per Dose (for OC evaluation, comma-separated)

0.05,0.10,0.25,0.40,0.60

True DLT rates are for OC evaluation only; not clinically observable.

Design Type

- ☐ 3+3 Classic Design
☒ BOIN Design
☐ mTPI Design
☐ Compare Designs (3+3 vs BOIN)

Target DLT Rate (φ) $\varphi_1 = \varphi \times$  $\varphi_2 = \varphi \times$ 

Max Participants per Dose Level



Max Total Enrollment



True MTD
400mg



Correct MTD Selection
45.9%



Mean Enrollment
 24.8 ± 10.2



λ_e / λ_d Boundaries
0.197 / 0.298

Decision Rules / Boundary Table

Operating Characteristics (MTD Selection Frequency)

Enrollment Distribution

BOIN Optimal Boundaries

Target DLT rate φ 25%

φ_1 (low-toxicity equivalence bound) 0.150

Decision Rules

Observed DLT rate at current dose ($\hat{p}$):

- $\hat{p} \leq 0.1968 \rightarrow$ Escalate
- $0.1968 < \hat{p} < 0.2984 \rightarrow$ Stay at current dose

BOIN Decision Table (by sample size)

Participants at Dose (n)	Elimination threshold (DLTs)	Escalate if DLTs $\leq$	Stay if DLTs in	De-escalate if DLTs $\geq$
1		0	1-0	1
2	2	0	1-0	1
3	3	0	1-0	1
4	4	0	1-1	2

1-10 of 12 rows

Previous 1 2 Next

Single-trial simulation path

Step	Dose	Cohort	n	DLTs	Obs. DLT Rate	True DLT Rate	Decision
1	100mg	3	3	0	0.0%	5.0%	↑ Escalate
2	200mg	3	3	0	0.0%	10.0%	↑ Escalate
3	400mg	3	3	1	33.3%	25.0%	↓ De-escalate
4	200mg	3	6	0	0.0%	10.0%	↑ Escalate

1-10 of 11 rows

Previous 1 2 Next

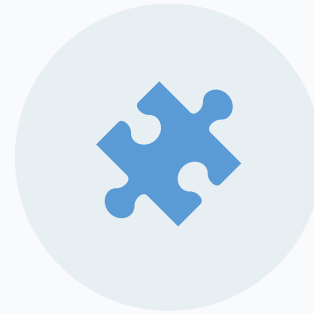
Comprehensive Bayesian Decision Suite



GO/NO-GO EFFICACY
DECISION: BETA-
BINOMIAL CONJUGATE
MODEL



BAYESIAN PREDICTIVE
PROBABILITY OF
SUCCESS



JOINT EFFICACY–
TOXICITY BAYESIAN
PHASE II DESIGN



BAYESIAN TTE PHASE II
DESIGN



Posterior Probability



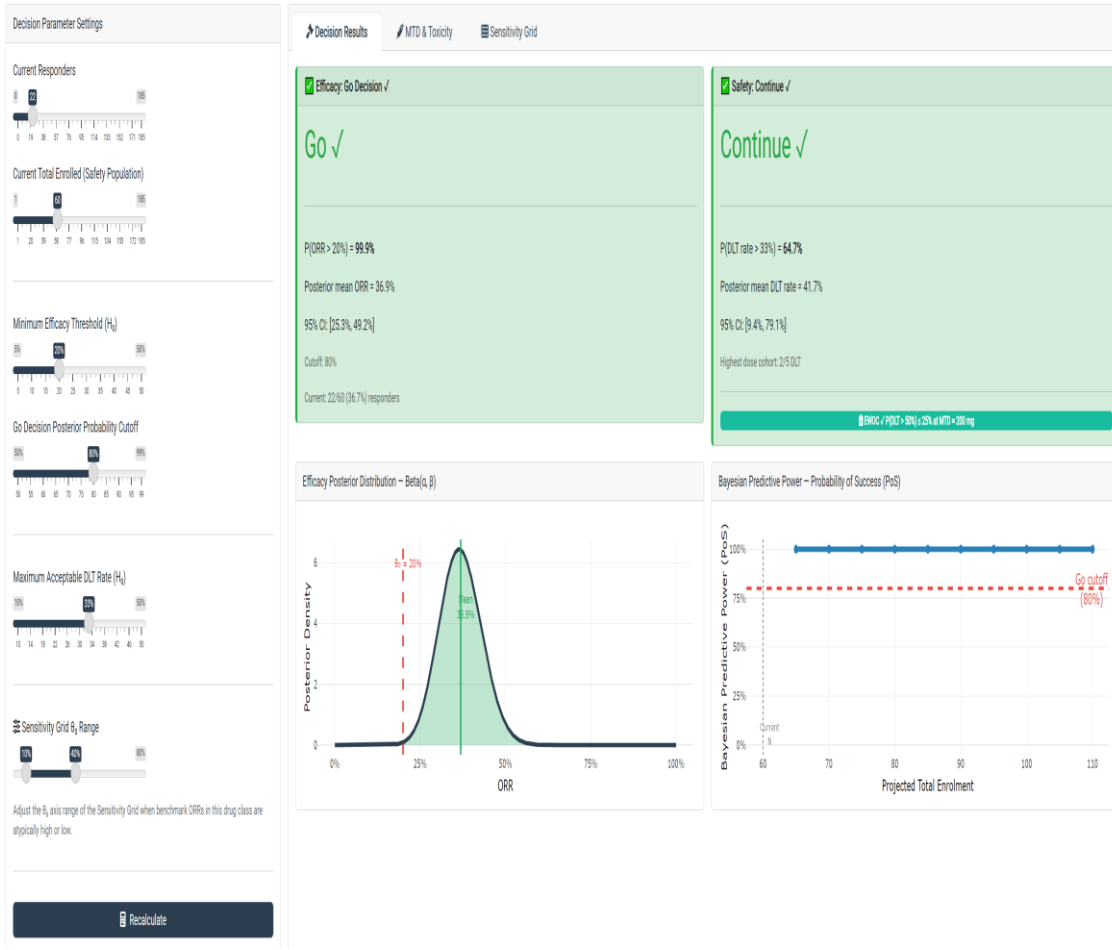
Go/No-Go Framework



Interim Decision Rules

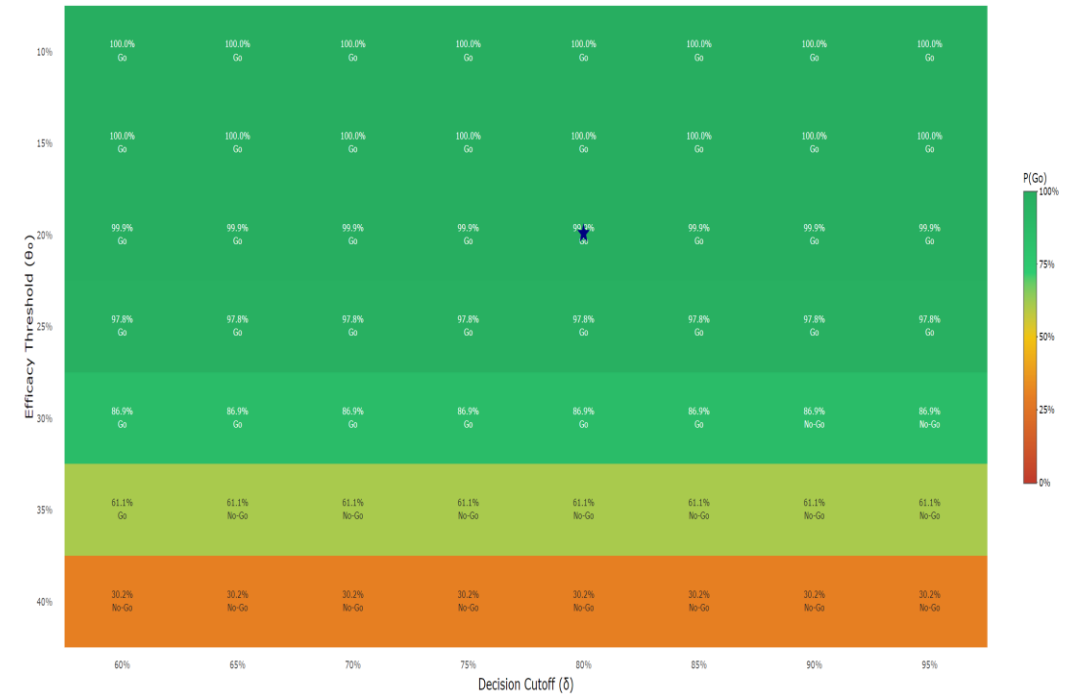
Bayesian Go/No-Go with Real-Time Sensitivity Grid

Go/No-Go Decision Panel



Real-Time Sensitivity Grid

$P(\text{ORR} > \theta_0 | \text{data})$ across every combination of efficacy threshold (θ_0 , y-axis) and decision cutoff (δ , x-axis). Green = Go; Red = No-Go. Updates automatically when responder sliders change. ★ = current setting.



Go Scenarios
39 / 56



% Scenarios: Go
70%



Min θ_0 for Go ($\delta = 80\%$)
10%



Posterior Probability



Sensitivity Grid



Decision Audit Trail

Joint Efficacy–Toxicity Bayesian Phase II Design

Design Parameters

Efficacy Threshold (λ_E)

Minimum acceptable response rate (H_0 boundary).

0.05 0.2 0.5

Toxicity Threshold (λ_T)

Maximum acceptable DLT rate.

0.1 0.3 0.6

Posterior Decision Cutoffs

η_E – Go: $P(\pi_E > \lambda_E | \text{data}) \geq \eta_E$

0.5 0.8 0.99

η_F – Futility: $P(\pi_E \leq \lambda_E | \text{data}) \geq \eta_F$

0.5 0.8 0.99

η_T – Toxicity: $P(\pi_T \geq \lambda_T | \text{data}) \geq \eta_T$

0.5 0.8 0.99

Tox Go Cutoff – $\min P(\pi_T < \lambda_T | \text{data})$ for GO

FDA §V.D.1: must be pre-specified. Default 0.50 (majority probability of acceptable toxicity).

0.1 0.5 0.9

Interim Schedule

Comma-separated N values (last = final).

20,35,50

Beta Priors

Interim Decision

Decision Boundaries

Operating Characteristics

Design & References

Enter current enrollment data to compute posterior probabilities and the adaptive trial decision at any interim look.

Patients enrolled (N)

20

Efficacy events (responses)

5

Toxicity events (DLTs)

3

Efficacy Posterior (π_E)

Posterior mean 26.2%
95% Credible Interval [10.2%, 46.4%]
 $P(\pi_E > 20\%)$ 0.725
 $P(\pi_E \leq 20\%)$ 0.275

Toxicity Posterior (π_T)

Posterior mean 16.7%
95% Credible Interval [4.4%, 34.9%]
 $P(\pi_T < 30\%)$ 0.936 (need ≥ 0.50)
 $P(\pi_T \geq 30\%)$ 0.064

Trial Decision

Continue Enrollment

Enrolled: 20 | Responses: 5 | DLTs: 3
Efficacy rate: 25% | DLT rate: 15%

Posterior Probability vs. Decision Thresholds



Joint Efficacy–Toxicity

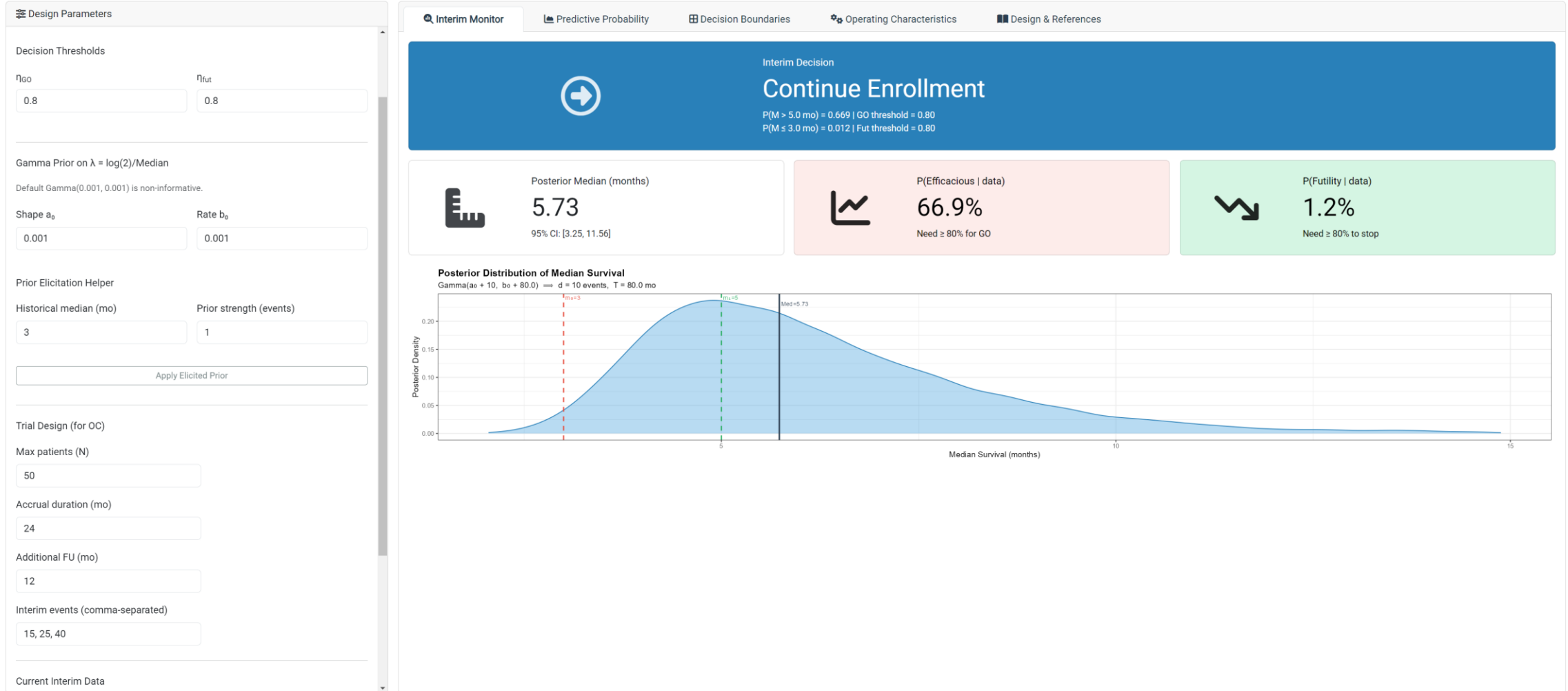


Toxicity Boundary

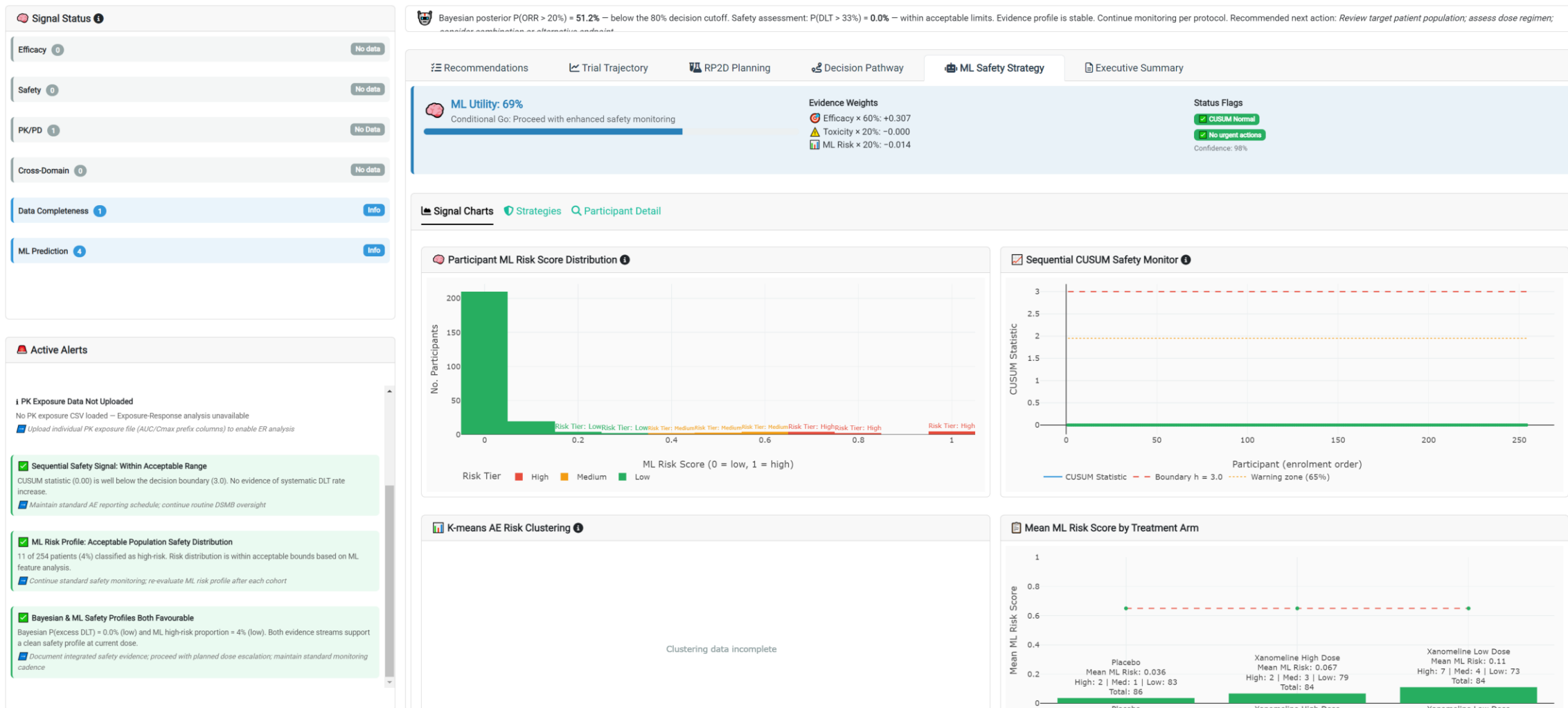


Efficacy Gate

Bayesian optimal phase II design with TTE endpoint



ML Safety Monitoring



Competitive Benchmark Intelligence + ClinicalTrials.gov Integration

Database
Efficacy
Safety
Positioning
MAP Prior
NMA
Intelligence
ClinicalTrials.gov

Filters

Line of Therapy

☒ 1L
☒ 2L
☒ 2L+
☒ 3L+

Drug Class

All classes

Indication

All indications

Publication Year

2016 2019 2024

Upload Custom Benchmark CSV

Browse No file selected

Download Template Reset

Missing Value Imputation

Variables to impute

ORR (%) × Grade≥3 AE (%) ×
N Patients ×

Impute Missing Values

16 missing cell(s) across 7 variable(s) in current DB.

Competitor Benchmark Registry 21 studies

CSV Excel

Show 25 entries

Search:

ID	Drug	Class	Indication	Line	Phase	Year	N	ORR%	ORR CI lo	ORR CI hi	CRR%	CRR CI lo	CRR CI hi	mPFS(mo)	mOS(mo)	Grz3%	SAE%	Disc%	Key Toxicities	
BM-001	Docetaxel	Chemotherapy	Advanced Solid Tumor	2L+	Phase III	2019	314	13.2	9.8	17.3	2.1	1.1	4.5	3.0	10.8	54.8	22.3	11.2	Neutropenia, Fatigue, Nausea	Smit
BM-002	Pemlirab	Checkpoint Inhibitor	Advanced Solid Tumor	2L+	Phase II	2021	105	23.8	15.9	33.5	5.7	2.6	11.9	4.2	14.2	16.2	12.1	5.7	Fatigue, Immune colitis, Rash	Chen
BM-003	Pemlirab	Checkpoint Inhibitor	Advanced Solid Tumor	2L+	Phase II	2021	48	37.5	23.9	52.7	10.4	4.5	22.2	6.8	19.3	18.8	14.6	6.3	Fatigue, Immune colitis, Rash	Chen
BM-004	Cevostinib	TKI	Advanced Solid Tumor - EGFR mt	1L	Phase III	2022	279	54.8	48.9	60.7	22.6	18.1	27.8	11.2	26.7	30.1	18.4	7.8	Rash, Diarrhea, Paronychia	Wai
BM-005	Loralectib	TKI	Advanced Solid Tumor - ALK+	1L	Phase III	2023	149	59.4	51.1	67.3	26.2	19.8	33.8	14.1		25.5	15.2	5.4	Edema, Hyperlipidemia, Weight gain	Ki
BM-006	Furatinib	TKI	Advanced Solid Tumor - HER2+	2L+	Phase II	2022	180	42.1	34.8	49.7	8.9	5.5	14.0	7.8	16.5	34.7	19.8	9.1	Diarrhea, Nausea, Fatigue	Park e
BM-	Sacrelumab-DXd	ADC	Advanced	2L+	Phase III	2023	261	43.1	37.1	49.2	11.9	8.5	16.4	9.2	18.9	40.2	24.3	10.8	Nausea,	Lit



ClinicalTrials.gov



Competitor Benchmark



Gap Analysis

AI-Augmented Summary Report

Report Settings

TRIAL INFORMATION

Compound / Trial Name

DRUG X

Data Cut-off Date

16 Apr 2026

Prepared By

Name / Team

MEETING TYPE

Internal Go/No-Go

SECTIONS TO INCLUDE

☒ Go/No-Go Decision

☒ Safety Summary

☒ Efficacy Summary

☒ Dose Escalation

☒ RP2D MDT Assessment

☒ ML Safety Insights

☒ Trial Design Status

ANALYSIS SETTINGS

Efficacy Population Flag

No population flags found – import data first.

Generate Report

Decision Meeting Summary Report

2026-04-16 18:45

ONCOLOGY CLINICAL TRIAL INTELLIGENT DECISION-MAKING HUB

Decision Meeting Summary Report

Developed by Dizal Pharma Solutions - For Internal Decision Support Use Only

Compound / Trial: --

Data Cut-off: 16 Apr 2026

Meeting Type: Internal Go/No-Go Review

Prepared By: --

Generated: 2026-04-16 18:45

1. Go/No-Go Decision — Bayesian Beta-Binomial Analysis

Overall Decision

Go

P(ORR > θ_0 | data)

83.4%

Posterior Mean ORR

25.4%

95% Credible Interval

[15.4%, 37%]

Observed Responders

15 / 60

Parameter	Setting	Posterior Result	Decision
Efficacy Threshold (θ_0)	20%	P(ORR > 20%) = 83.4%	83.4% $\geq$ 5 $\rightarrow$ Go ✓
Decision Cutoff (δ)	80%	Go if P(Go) $\geq$ 80%	Go
Max Toxicity Threshold (θ_{tox})	33%	P(DLT rate > 33%) = 31.1%	✓ Safety acceptable

Statistical Method:

Bayesian Beta-Binomial model with Jeffreys prior Beta(0.5, 0.5). Go if $P(\pi > \theta_0 | \text{data}) \geq \delta$. Safety: Stop if $P(\text{DLT} > \theta_{tox} | \text{data}) \geq 80\%$.

References:

Berry et al. (2010) Bayesian Adaptive Methods for Clinical Trials; FDA Bayesian Statistics Guidance (2019); ICH E9(R1) Addendum (2019).

2. Safety Summary

ADAE/ADSL not loaded. Import data via 'Import Data' to populate this section.

3. Efficacy Summary

ADRS not loaded. Import ADRS data to populate this section.

4. Dose Escalation Status

DLT summary data not available. Ensure ADAE/ADSL are loaded.



Auto Narrative



Evidence Package



Audit-ready

How Does OncoTrialMind Differ from What's Already Out There?



CDISC Data Ingestion

Auto column normalisation



Real-time Bayesian Go/No-Go

Posterior probability engine



Role-aware Dashboards

Monitor · PK · Statistician



ML Safety Monitoring

Patient risk scoring · AE alert



NMA + Competitor Benchmarking

ClinicalTrials.gov · Gap analysis



PostgreSQL Audit Persistence

JSONB · Audit trail · Multi-project



AI-Augmented Summary Report

Auto-narrative · Evidence pack



Open Source R-native

Shiny · Reproducible · Auditable



Transformation from Passive Response to Proactive Insight



Built-in statistical models

Integrate Bayesian methods, multiple hypothesis tests with safety signal analysis, support one-click execution, and enhance the efficiency and consistency of the analysis



Rapid iterative analysis

It empowers statisticians to expeditiously experiment with diverse analysis strategies, thereby substantially reducing the validation and optimization cycle



Visual drag-and-drop operation

Through an intuitive interface, hierarchical analysis and subgroup exploration can be accomplished, which reduces the technical threshold and improves usability



Real-time sharing of results

Support the prompt sharing of statistical results with the medical team to facilitate cross-functional collaboration



Accelerate the feedback loop

Compress the medical verification feedback cycle from a weekly basis to a daily basis to expedite the decision-making process.



Efficient collaborative works

Achieve a close interaction between data analysis and medical judgment to improve the overall research efficiency.

Conclusions



Integration wins over specialization — a unified platform reduces decision latency from days to minutes



Bayesian methods + real-time UI = better risk communication — sensitivity grids and trajectory projections let teams explore “what if” interactively, not post-hoc



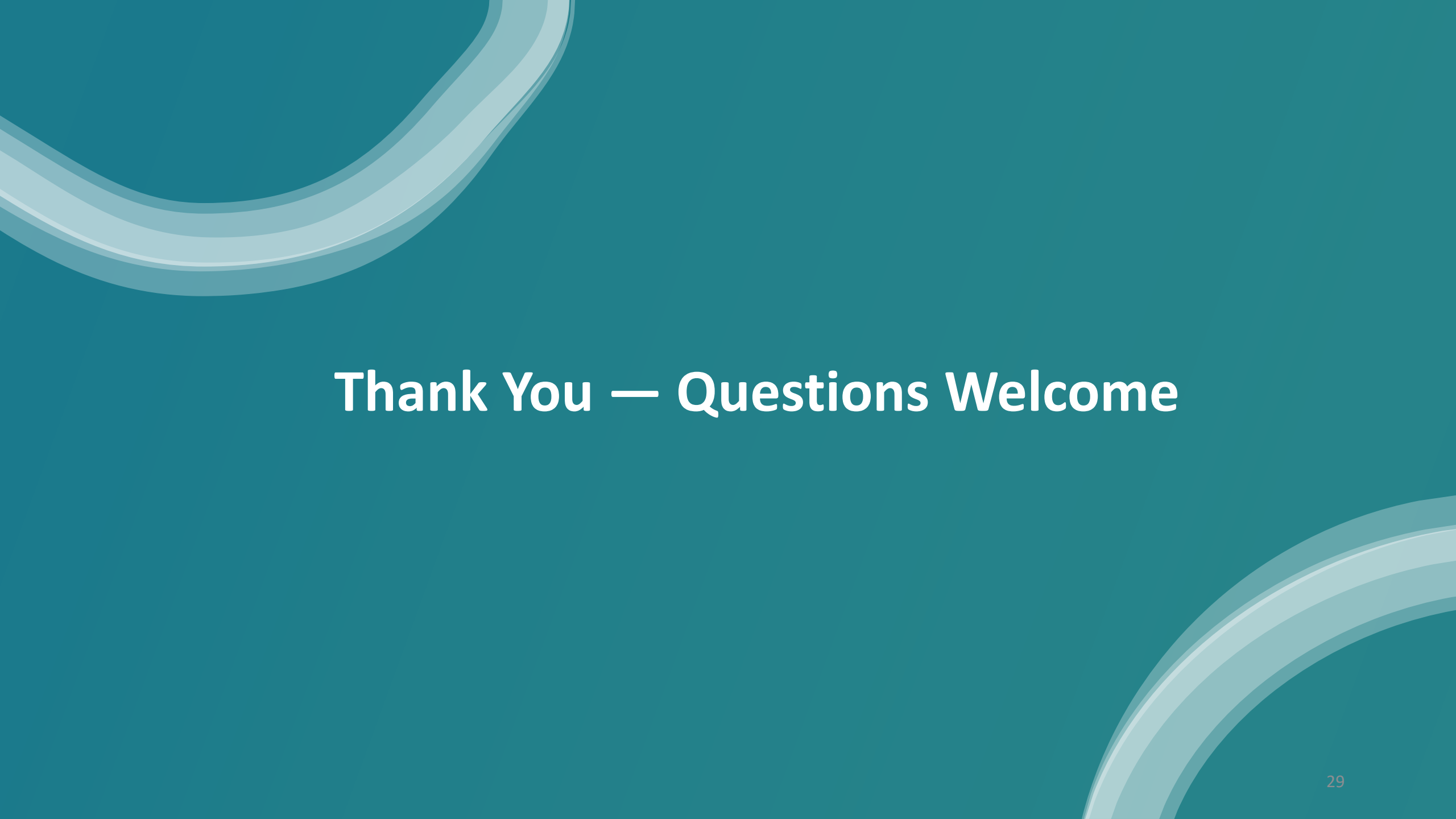
Regulatory readiness is a design choice, not an afterthought — validation documentation, audit logging, and explicit limitation statements were built in from day one



Future Directions: LLM-assisted natural language query: “Show me all patients with Grade 3 rash on Arm B” → reactive filter via LLM API (prototype in R/nlq_engine.R)

References

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Thank You — Questions Welcome