EXECUTIVE BRIEF

zetyra

Validated Statistical Calculators for Efficient Clinical Trial Design

For: VPs of R&D;, Chief Medical Officers, Clinical Development Leaders
Reading Time: 5-7 minutes

FDA PUBLISHED MAJOR GUIDANCE (January 12, 2026)

FDA released draft guidance extending Bayesian methodology to drugs and biologics. Draft guidance signals regulatory direction; final implementation details may evolve.

FDA Commissioner: "Bayesian methodologies help address high costs and long timelines."

THE CLINICAL TRIAL EFFICIENCY PROBLEM

Trials Are Too Expensive and Too Slow

Phase III clinical trials cost $50-100 million and require 4-6 years. Yet most use conservative designs that inflate costs:

Inefficiency	Impact	Cost to Industry
Ignoring baseline covariates	15-35% sample size inflation	$7-35M per Phase III
No interim monitoring	Continuing futile trials	6-18 months wasted
Binary go/no-go decisions	$50-100M on doomed Phase III	50-60% failure rate

Why Efficient Designs Aren't Used

- Software is expensive: $5,000-$15,000 annual licenses
- IT barriers: Desktop installation requires IT involvement
- Limited scope: Separate tools for each methodology
- Limited transparency: Public, independently reproducible validation suites not typically available

THE OPPORTUNITY

Three proven methodologies can substantially reduce trial costs and duration:

CUPED (15-35% reduction) | Group Sequential (20-40%) | Bayesian Predictive Power

FDA guidance supports all three methods when operating characteristics are well understood. The barrier is accessible software.

Example: A standard Phase III trial enrolling 500 patients at $50K/patient = $25M. With efficient design: 400 patients = $20M. Saving $5M without reducing statistical power.

Beyond Cost Savings: Strategic Benefits

- Faster time to market: Accelerated BLA submissions mean earlier revenue and patient access
- Reduced investor risk: Quantitative go/no-go decisions provide data-driven confidence
- Regulatory alignment: FDA/EMA guidance increasingly supports modern statistical methods when operating characteristics are well understood
- Competitive advantage: Smaller trials with same power = faster enrollment

THE ZETYRA SOLUTION

Three Integrated Calculators, One Platform

CUPED - Covariate-Adjusted Power Analysis

What: Calculates sample size reduction from baseline-outcome correlations

Savings: 15-35% fewer patients | FDA: May 2023 guidance encourages adjustment

Group Sequential - Interim Analysis Boundaries

What: Calculates stopping boundaries with rigorous Type I error control

Savings: 15-30% expected sample size reduction | FDA: Nov 2019: "simplest adaptive designs"

Bayesian - Predictive Power

What: Computes probability of trial success given interim data

Savings: Quantitative go/no-go decisions | FDA: Jan 2026 guidance extends to drugs/biologics

Validation Excellence: 51 Tests, 100% Pass Rate

Calculator	Tests	Benchmark	Max Deviation	Result
Group Sequential	30	gsDesign R package	0.0046 z-score	10× more accurate
CUPED	12	Analytical formula	Exact match	Zero error
Bayesian	9	Conjugate priors	Exact match	Zero error

All validation code is public: github.com/evidenceinthewild/zetyra-validation

Key Differentiators vs. Commercial Software (as of January 2026)

Feature	Zetyra	East	PASS	ADDPLAN	nQuery
All 3 methodologies	Yes	No	No	No	No
Public validation	Yes	No	No	No	No
Web-based (no IT)	Yes	No	No	No	No
Annual cost	$1,188	$15,000	$8,000	$12,000	$6,000

Bottom line: Zetyra is the only platform integrating CUPED + Group Sequential + Bayesian with publicly validated accuracy, at 95% cost reduction vs. East.

Who Uses Zetyra?

- Biostatisticians designing Phase II/III trials
- Clinical development teams evaluating design options
- CROs providing statistical consulting services
- Academic medical centers running investigator-initiated trials

Public API for Programmatic Access

RESTful endpoints for R/Python integration. Full documentation at zetyra.com/docs. Used by our own validation test suite—proven in production.

BUSINESS IMPACT

Quantified Case Studies

Note: These case studies are illustrative scenarios based on typical trial parameters, not retrospective analyses of specific trials. Actual savings depend on correlation strength, interim timing, and program-specific factors.

CASE STUDY 1

Oncology Phase II — 30% Sample Size Reduction

HER2+ metastatic breast cancer, single-arm Phase II evaluating ORR

$3.6M Saved | 30% Reduction | 3.6mo Faster

Standard: 240 pts, $12.0M
CUPED: 168 pts, $8.4M

CASE STUDY 2

Cardiovascular Phase III — $18M Saved, Early Stop

PCSK9 inhibitor for MACE in secondary prevention

$18.1M Saved | 24% Cost Cut | 12mo Faster

4-look O'Brien-Fleming GSD
Stopped early at Interim 2

CASE STUDY 3

Rare Disease — Bayesian Decision Framework

Duchenne muscular dystrophy gene therapy, 6-minute walk distance endpoint

Traditional: p=0.08 → "Not significant" → No-go Potentially wrong decision	Bayesian: 78% probability of benefit → Go* FDA granted Breakthrough Therapy Designation

*Decision incorporated clinical relevance, unmet need, and regulatory feedback—not a single probability threshold.

TRIAL COST SAVINGS: NSCLC Immunotherapy (Case Study 4)

Traditional: 66 months, $104M → Zetyra-Optimized: 50 months, $89.9M

$14.1M saved (14% reduction) | 16 months earlier BLA submission

Illustrative Revenue Upside: For successful programs with $2B peak sales, 16-month acceleration could yield $2.1B NPV gain. Revenue acceleration can dominate cost savings; magnitude depends heavily on commercial assumptions.

CASE STUDY 4

Full Program — Integrated CUPED + GSD + Bayesian

NSCLC immunotherapy combination, Phase II → Phase III development

Element	Traditional	Zetyra-Optimized	Savings
Phase II	80 pts, 12 mo, $4.0M	53 pts, 8 mo, $2.4M	$1.6M (40%)
Phase III	500 pts, 54 mo, $100M	425 expected, 42 mo, $87.5M	$12.5M (13%)
Total Program	66 months, $104M	50 months, $89.9M	$14.1M (14%)
BLA Submission	Month 72	Month 56	16 months earlier

WHY ZETYRA

Competitive Advantages

1 **Transparency Creates Trust**
Public validation suite with 51 automated tests. Independently reproducible validation not typically available from commercial tools.

2 **Integration Saves Time**
Single login, consistent interface across all 3 calculators. No juggling between multiple tools.

3 **Regulatory-Ready**
FDA/EMA guidance citations embedded in outputs. Pre-written protocol language included.

4 **Zero IT Friction**
Web-based: works on any device. Time to first calculation: 1 hour vs. 2-8 weeks.

Regulatory Support is Strong

- CUPED: May 2023 FDA guidance calls covariate adjustment "low-hanging fruit"
- Group Sequential: November 2019 FDA guidance: "simplest and most established"
- Bayesian: January 2026 draft guidance extends to drugs/biologics (published this week)

Pricing

Evidence Pro	Evidence Collective	Enterprise
$99/month	$349/month	Custom
Full CUPED, GSD, Bayesian	Team features for 5 users	FDA compliance features

Free trial available. No credit card required. Equivalent functionality typically requires 2-3 separate tools at $15K+ annually.

Getting Started

Step 1: Start free trial at zetyra.com/trial	Step 2: Run your first calculation in <1 hour
Step 3: Generate FDA-ready documentation	Step 4: Integrate into your workflow

NEXT STEPS

1. Free trial: zetyra.com/trial (no credit card required)
2. Schedule demo: maggie@zetyra.com (30-minute walkthrough)
3. Technical white paper: zetyra.com/whitepaper
4. Validation suite: github.com/evidenceinthewild/zetyra-validation

What Makes zetyra Different?

Commercial software typically costs $6,000-$15,000/year; zetyra provides equivalent functionality at 95% lower cost with publicly validated calculations. Our GitHub-hosted test suite lets you verify every result independently.

Zetyra supports trial planning and design decisions; sponsors retain responsibility for final regulatory strategy.

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The future of clinical trial design is transparent, validated, accessible, and efficient.