



Detecting Trends Before They Appear: AI-Driven Visualizations in Clinical Trials

2.3.2026

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A BIOMETRICS FSP

CELEBRATING 30 YEARS

What the Current Challenge Is

81%

Sites Utilizing Digital Tools

80%

Trials Fail Initial Enrollment Goals

THE GAP

Dashboard Overinvestment
Bottleneck Underinvestment

ROI Impact: Key Takeaways

- Strategic ROI: reduce decision lag and accelerate trial timelines
- Financial ROI: ~4-6x ROI potential when properly implemented

Current Reality of Tech Stack

Tech Adoption Ceiling

- **Issue:** 1% adoption rate change between Feb 2021 to Feb 2022
- **Why:** Current tech investment lacks balance; bottleneck not addressed
- **Trend:** Projected 22.6% CAGR between 2025-2030

EDC / ePRO Adoption

- **Benefit:** reduce trial timeline by 20%; improve data quality by >50%
- **Status quo:** 80% EDC adoption; 45% ePRO adoption

AI Patient Finding

- **The REAL bottleneck:** ~50% of sites enrolled ≤ 1 patient
- **Status quo:** only 15% adoption rate

Key Insight: Technology adoption is not a linear path. Success requires addressing people, process, and data infrastructure challenges alongside tool selection.

AI Patient Finding: Amgen Case Study

ATOMIC AI

Machine learning (ML) model that quickly analyzes large amounts of diverse data and predicts the most optimal trial sites for patient enrollment

Faster Patient Enrollment

Amgen's internal analysis shows **3x** faster enrollment at ATOMIC-prioritized sites and **50%** enrollment time reduction in cut mid-stage trial

Optimistic Projection

Amgen predicts by 2030, AI will have “helped it shave two years off the decade or more it typically takes to develop a drug”

Tech Stack Selection Strategy

Small Pharma

- Pre-emptive cost mitigation
- Focus on immediate operational needs
- Smaller budgets require high-impact choices
- **Case study:** Recursion's AI-simulated trials to determine best patient stratification

Large Pharma

- Improve existing operational efficiency
- Focus on standardization efforts
- Larger budgets enable comprehensive solutions
- **Case study:** Pfizer's "agentic workflow" to streamline protocols/due diligence across global sites.

Evolution: Necessity-Driven → ROI-Driven Approach

- **Pandemic-era adoption:** Emergency response to logistical needs to ensure trial continuity
- **Post-pandemic adoption:** ROI-focused strategy to resolve critical bottlenecks & promote innovation

AI-technology Stack: Small vs. Big Pharma

Recursion Pharmaceuticals

Small/Mid Pharma Approach

STRATEGY

"ClinTech" AI Effort

Uses machine learning and AI-simulated trials using real-world data to identify optimal patient enrollment stratification and hotspots before trial begins

KEY LESSONS

- Target smart protocol & feasibility design
- Minimize amendments
- Cost-effective for smaller trials
- Focus on precision matching

Pfizer

Big Pharma Approach

STRATEGY

"Agentic Flow" AI System

Multi-agent AI orchestration that autonomously manages trial operations, from site selection to protocol optimization.

KEY LESSONS

- End-to-end trial workflow automation
- Global site network optimization
- Resource-intensive infrastructure
- Highly scalable across multiple trials

Portfolio Management: 40/40/20 Framework

40%

Core

40%

High-ROI Tech

20%

Experimentation

Framework Breakdown:

- **Core (40%):** Mandatory compliance tools & infrastructure (e.g. EDC licenses & CDISC compliance)
- **High-ROI Tech (40%):** Tech to overcome bottlenecks (e.g. eConsent platform & patient-finding AI)
- **Experimentation (20%):** Novel AI R&D (e.g. AI dashboard pilot program)

Hypothetical Case Study: A small biotech with tech budget of \$300,000 to \$400,000/year

- **Core (40%):** \$120,000 to \$160,000
- **High-ROI (40%):** \$80,000 on patient-finding AI; \$40,000 on eConsent; \$40,000 on site selection analytics
- **Experimentation (20%):** \$60,000 to \$80,000

Decision Lag: The Hidden Cost

Definition:

The time delay between when data becomes available and when actionable decisions are made based on that data. This lag compounds across trial phases, significantly impacting timelines and costs.

Last Patient Out (LPO) to Database Lock (DBL):

- (1) Data cleaning → (2) Final data review → (3) External data reconciliation → (4) Coding & locking
- **Average timeline:** ~4 weeks

Example of Financial Impact

- One-day delay → \$40,000 direct costs + \$500,000 lost revenue → **~\$540,000 waste**
- Ten-day delay → **~\$5.4 million USD waste**

Decision Lag (Continued)



Other examples:

- **Data reconciliation:** waiting for site coordinate to input finalized data into EDC
- **Medical monitor review:** waiting for physician to review & sign on safety profiles
- **Regulatory notification:** waiting for acknowledgement from an Institutional Review Board

How AI data visualizations improve decision lag:

- Accelerated pattern recognition
- Early warning through trend analysis
- Data standardization
- Real-time data input
- ...

Solution: Strategic Dashboard Deployment

Reducing Decision Lag

Real-time visibility into trial metrics enables faster identification of issues and accelerated decision-making.

Safety Signal Detection

Automated monitoring allows for early identification of “red light” signals, with a 90% detection sensitivity

Study Timeline Reduction: 11.5% Case Study

Novel real-time AI analytics model decreases 26-week trial timeline by 3 weeks (~11.5% reduction) in Sponsor X

Dashboard ROI

The Data Challenge

More real-world data is needed to establish definitive ROI metrics.

High ROI

Meta-analysis of 450,000 trials shows 4-6x ROI for AI dashboards in clinical trials. Per \$1 invested, you get a \$4-6 return

Selecting the Optimal Language

R

- Open-source
- Modern visualization
- Lower licensing costs but requires specialized developer skills.

Versus.

SAS

- Enterprise-grade,
- Extensive validation
- Higher licensing costs, but established compliance framework.

Hypothetical Case Study: 30-member biotech team

1. **R:** \$150,000 (compliance) + \$30-50,000 (IDE) + \$20-40,000 (package management) + \$360,000 (IT staffing) = ~\$515,000 to \$605,000/year
2. **SAS:** \$175,000 (license) + \$150,000 (compliance) + \$0 (IDE/package management) + \$270,000 (IT staffing) = ~\$550,000/year

Benefits Beyond ROI

Risk Mitigation

Early identification of deviations, enrollment issues, and safety signals reduces downstream risk and costly corrections

Regulatory Expectations

Ensuring data quality to fulfil core regulatory expectations from FDA & EMA

CRA Efficiency

Researchers spend less time on data gathering and more time on meaningful site interactions

Unquantifiable Value

Boost stakeholder confidence & identify optimal subpopulations for drug candidate

These qualitative benefits often exceed direct financial ROI and compound over time

CRA Efficiency: Bayer Case Study



Context

Adverse drug events (AE) refer to drug-related injuries that could cause harm to patients. In clinical trials, preventing AE with precision is critical for improving patient safety

Before

Bayer was processing hundreds of thousands of unstructured AE reports across different channels. One team, for example, reviewed 10,000 records daily

Solution

Bayer's AE-detection AI generates real-time inference streamlined across multiple systems, with ~170 ms average response time. This AI technology significantly reduces manual processing times, and allows CRA to focus on relevant information and decision making

Conclusion

Implement Strategic Portfolio Approach

There is no one-size-fits-all solution. Choosing the context-appropriate technology portfolio is what is important.

High ROI Incentives

Dashboard investments reduce decision lag, accelerating trial timeline and maximizing stakeholder value

Accept Uncertainty as Insurance

Treat technology investment as essential protection against catastrophic trial failures

Questions?

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