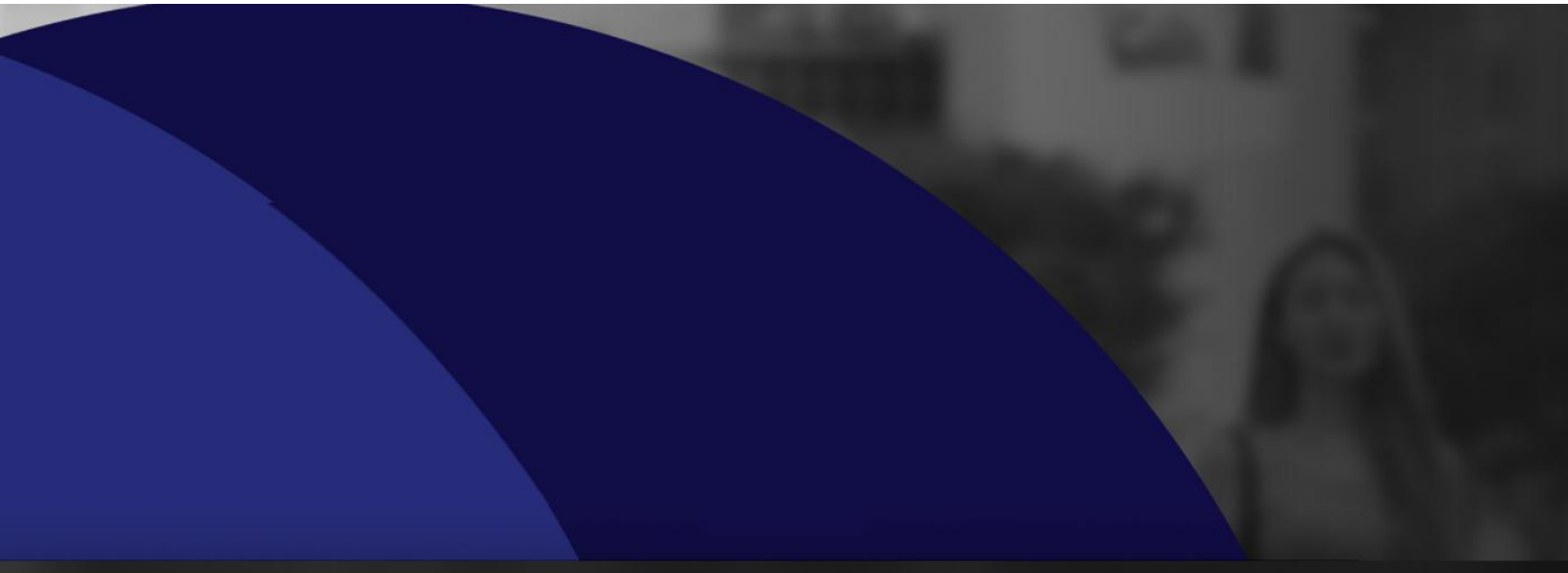
GRYT HEALTH

Patient-Centered AI in Drug Development

The PACE Framework

Keeping *humanity* at the forefront of AI in drug development to reduce risk and maximize outcomes.



Pipeline **A**cceleration **C**ouncil **E**levating the Patient Voice

Executive Summary

Artificial Intelligence (AI) in drug development is no longer theoretical. It is operational; yet, 95% of custom enterprise GenAI tools fail to deliver profit & loss impact. The difference between the 5% that succeed and the 95% that fail comes down to one factor: how effectively AI systems integrate human judgment at critical decision points.

One of the highest-stakes decision points in drug development is Informed Consent (IC), where patients choose whether to participate in a trial. This moment determines trial velocity, data quality, and ultimately, if promising therapies reach patients who need them.

The PACE Framework addresses this gap. It is being co-created by leaders spanning global pharmaceutical companies, CROs, patient advocacy organizations, and real-world evidence providers — many of whom are patients and caregivers. PACE is developing a structured methodology for building AI systems that enhance rather than undermine Informed Consent.

With how significant AI's promise is to getting new treatments safely to market faster, we have a vested interest in ensuring its success, as industry professionals and as patients.

This briefing outlines why patient-centered AI is becoming a competitive imperative, identifies the specific risks of poorly implemented AI in clinical trials, and presents an actionable framework. We invite pharmaceutical leaders to join a working group developing the first pillar: Inclusive Data Strategy, with measurable metrics for AI input quality and output validation.

A Generational Evolution is Underway

AI adoption in drug development is accelerating against a backdrop of structural and economic pressures. We organize the key drivers into three interrelated buckets: 1) Economic, 2) Regulatory, and 3) AI Outcomes. Together these forces shape both the urgency and the risk profile for AI interventions in drug development.

The pharma industry is undergoing a **generational evolution due to three interrelated drivers**.



1) Economic Drivers

The pharma industry is facing a sizable patent cliff, with hundreds of billions in sales at risk as more than 190 products lose exclusivity between 2022 and 2030. The industry has faced large-scale patent cliffs before, including 2016. However, while the 2016 patent cliff was projected to erode $100 billion in brand-name sales, the current expirations will put over $300 billion at risk. Source: BioSpace

Additionally, 100% tariffs on pharmaceuticals remain a possibility. Although tariffs will impact certain drug manufacturers more than others, pharma companies remain in a "holding pattern" as tariffs play out. Source: Fierce Pharma



2) Regulatory Drivers

The FDA has cited "a heavy workload and limited resources" as contributing factors to struggling to deliver timely decisions. In March, 2025, the FDA took a heavy blow, losing around 3,500 staff as HHS enacted department overhauls. Further consolidation is anticipated. Source: BioSpace



3) AI Outcomes: The 5% Success Factor

An MIT study, "State of AI in Business 2025", reveals only 5% of custom enterprise GenAI tools reach production and deliver measurable P&L impact. The 95% failure rate stems from predictable gaps:

- Problem misalignment: Building AI capabilities before defining the specific clinical or operational problem
- Data fragmentation: Inability to integrate structured trial data with unstructured patient insights
- Stakeholder disconnect: Technical teams building models without input from clinical operations or patient communities
- Measurement gaps: No clear metrics linking AI outputs to trial outcomes (enrollment rates, retention, representation, data quality)

The organizations achieving success share a common approach: they integrate domain expertise (clinical, regulatory, patient experience) into AI development from day one.

For pharmaceutical companies, this pattern has direct implications. The question is not whether to adopt AI in drug development, but how to structure AI initiatives to fall within the successful 5% rather than the failed 95%.

Informed Consent: Where AI Success is Won or Lost

IC represents the highest-leverage intervention point for AI in drug development for three reasons:

1. **Financial Impact**: Patient recruitment accounts for 40% of clinical trial budgets, and 80% of trials face delays due to enrollment challenges. AI that improves IC processes directly impacts the most expensive bottleneck in drug development.

2. **Data Quality Foundation**: Poor IC processes lead to patients who do not fully understand protocols, resulting in protocol deviations, missing data, and higher dropout rates. AI that enhances patient understanding at IC improves downstream data integrity.

3. **Equity and Trust**: IC is where patients from underrepresented demographics decide whether to participate. AI systems trained on narrow datasets will perpetuate enrollment disparities, limiting both trial diversity and market access for approved therapies.

Every AI application in drug development should be evaluated against this standard: "Does this enhance or hinder Informed Consent?"

This question should be asked at project inception, before model development begins, by teams that include patient voice representatives, clinical operations leaders, and AI engineers working collaboratively.

Speed alone is not success. Faster enrollment that compromises patient understanding creates downstream risks: regulatory delays from protocol deviations, compromised data quality, and erosion of patient trust that makes future recruitment harder.

Patient-Centered AI is not a values statement – It is a risk mitigation strategy with measurable ROI.

Patient-centered AI is not a values statement. It is a risk mitigation strategy with measurable ROI. If we do not get this right now, we risk entrenching ineffective, and/or unethical approaches that are challenging to unwind.

About the PACE Council

PACE was established in Q2 2025 as a strategic initiative of Gryt Health, Inc., convening 18 founding members who collectively represent:

- 300 years of combined experience in clinical operations, patient engagement, and drug development
- Leadership roles at Top 10 pharmaceutical companies, leading CRO's, and NIH-recognized patient advocacy organizations
- Direct lived experience as patients, survivors, and caregivers across therapeutic areas including oncology, cardiology, rare disease, and chronic conditions

PACE members have contributed to regulatory submissions for 40+ approved therapies and designed patient engagement strategies for trials enrolling 100,000+ patients globally.

The Council operates as a pre-competitive collaboration focused on establishing industry standards – not vendor solutions – for patient-centered AI implementation.

Our **mission** is to ensure all patient demographics are integrated in AI development and use to deliver equitable outcomes that provide competitive advantages.

Founding Members



The multi-disciplinary functions of PACE's founding members shaped our mission:



Strategic Pillars

PACE provides a structured approach for pharmaceutical companies to evaluate, design, and deploy AI in drug development. Each pillar includes assessment tools, decision frameworks, and success metrics.

Together, the pillars will establish as a **framework to optimize inputs that reduce risk and maximize outcomes** with AI in drug development:

Inclusive Data Strategy → Transparent Development → Patient-Centric Trial Delivery → Regulatory Alignment → Scalability & Global Reach

Invitation to Join: Data Strategy Working Group

PACE is launching a 90-day sprint to develop the Inclusive Data Strategy pillar, with release targeted for March 1, 2026.

We are seeking 12 pharmaceutical leaders to join the working group, specifically those with:

- Authority to influence AI strategy or clinical trial design at their organization
- Direct experience with patient recruitment challenges, health equity initiatives, and/or real-world evidence
- Ability to contribute 5 hours monthly for virtual working sessions and asynchronous collaboration

Working group members will:

- ✓ Co-create the data representativeness scoring rubric
- ✓ Pilot-test assessment tools on real AI use cases
- ✓ Receive early access to the framework ahead of public release
- ✓ Be recognized as contributing authors on the published framework

The deliverable will be immediately actionable. Pharmaceutical companies will be able to assess their AI initiatives against clear standards for data inclusivity before committing development resources.

This is a pre-competitive collaboration. The framework will be published as an open-access industry resource, not a proprietary product.

To express interest or learn how you can lead this evolutionary moment:

- Email: Uma@Grythealth.com
- Include: Your name, organization, role, and specific expertise you'd like to contribute

Applications will be reviewed on a rolling basis through December 19, 2026

PACE is a strategic initiative of Gryt Health, Inc. This briefing was developed with guidance from the founding council members and patient advocates committed to ensuring AI in drug development serves all patients equitably.

For all other questions, please contact:

Dave Craig
Co-Founder & CEO
Dave@grythealth.com

Uma Rana
Chief of Strategic Partnerships
Uma@grythealth.com