FIRST-TIME LAUNCH ALLIANCE

FTLA INSIGHTS

Firsttimelaunchalliance.com

Q1 2026 Summary Edition

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INTRODUCTION TO THE FTLA

The FTLA exists to empower emerging pharma, biotech, and med device companies with the capabilities, connections, and confidence they need to navigate the complex launch landscape.

What is the First-Time Launch Alliance (FTLA)?
The First-Time Launch Alliance (FTLA) is a collaborative community launched May 2025 now boasting more than 600 leaders across 400 organizations, united by a shared mission: to accelerate launch readiness and reduce the complexity of commercialization for emerging biopharma.

Built by and for FTLs, FTLA offers:

- **FTLA Summits**: Live events with panels, roundtables, networking, and solution building.
- **Quarterly Webinar Series:** Virtual space for shared learning and deep dives on priority topics.
- **Innovation Incubators (FTLA I²):** Member driven workgroups tackling topics like Right-Sized AI for Launch, IT Strategy & Roadmap, and NDA/BLA Readiness.
- **Community Engagement**: A private LinkedIn group for member-driven engagement and content exchange.
- **Executive Committee**: Sponsor and member representation guiding strategic direction and shaping upcoming initiatives.

If you haven't yet joined, now's the time to be part of the movement shaping the future of first-time launch success.

FTLA Insights: Your Source for All-Things FTLA
FTLA Insights is designed to move beyond theory and into practice. Each edition shares quarterly summaries of our FTLA events, webinars, and real-world insights from emerging biopharma companies.

First-time launches remain defining moments for emerging biopharma companies. Success hinges not only on scientific and regulatory achievements but on cross-functional orchestration – strategy, operations, supply chain, market access, and enabling functions all working in lockstep.

We hope *FTLA Insights* sparks fresh thinking and provides practical guidance as you prepare for your own launch – whether in the USA, Europe, or beyond.

EARLY INSIGHTS SHAPING AI ADOPTION

Date: January 28, 2026
Time: 11–12PM EST
Speakers: FTLA, Sage Advisors, Beghou, MedPro Systems, TraceLink, and NNIT

Summary
In the past quarter, the First-Time Launch Alliance (FTLA) hosted its most highly attended webinar to date, bringing together industry sponsors and member participants to explore the evolving role of artificial intelligence (AI) in emerging biotech organizations. The session focused on early insights from FTLA's AI Innovation Incubator, combined with practical perspectives from leading sponsors on how AI is being applied today across supply chain, commercial operations, regulatory environments, and enterprise data strategy. The discussion reinforced a central theme: while AI adoption is accelerating rapidly, success for first-time launch companies hinges not just on technology, but on organizational readiness, data maturity, and disciplined execution.

Key Insights
Several consistent themes emerged across both the Innovation Incubator findings and sponsor presentations. First, there is strong alignment that AI can significantly improve patient outcomes, enhance clinical trial execution, and support more effective interaction with regulatory bodies such as the FDA.

At the same time, many organizations acknowledged that AI capabilities are advancing faster than internal operating models, creating gaps in governance, leadership alignment, and organizational readiness.

Data readiness was also identified as a critical enabler, AI's effectiveness is directly dependent on the quality, structure, and standardization of underlying data, requiring organizations to define clear data standards and remediate gaps before scaling solutions.

Finally, the discussion reinforced that AI will augment, not replace, human decision-making, enabling teams to shift from manual, repetitive tasks toward higher-value strategic activities.

Key Takeaways
- Start with focused, high-value use cases: Pilot AI in targeted areas that demonstrate quick impact before scaling.
- Prioritize data quality and governance: Establish clear standards, assess data quality, and remediate gaps early.
- Embed compliance and controls from the outset: Ensure AI initiatives align with regulatory, validation, and data privacy requirements.
- Drive adoption through change management: Organizational alignment and user trust are essential to realizing AI value.
- Leverage ecosystem partners: Sponsors demonstrated how external platforms and expertise can accelerate AI readiness and execution.

The FTLA has now completed it's AI Innovation Incubator and published the output on May 11th, 2026. Members can expect deeper insights, actionable use cases, and collaborative opportunities to support AI adoption across their organizations. To explore the full findings and recommendations, download the Innovation Incubator Insights report on the FTLA website:

FTLA AI Innovation Incubator (I^2) Insights

OPERATIONAL BLIND SPOTS: THE QUALITY RISKS THAT JEOPARDIZE COMMERCIAL LAUNCH

Date: February 2, 2026
Time: 11–12PM EST
Speakers: FTLA and NNIT

Summary
In this FTLA webinar, NNIT led an in-depth discussion on one of the most critical, and often underestimated, phases of the product lifecycle: the transition from clinical development to commercial launch. The session focused on identifying "operational blind spots" that emerge as organizations scale, highlighting how risks that remain invisible at clinical stage can rapidly surface under commercial, regulatory, and market pressures.

The webinar emphasized that successful commercialization is not solely dependent on product quality or scientific innovation, but on the strength and readiness of the surrounding operational ecosystem including quality systems, partner networks, and data integrity practices

Key Insights
Organizations often struggle not because risks are unknown, but because those risks remain unseen, as blind spots typically emerge from a lack of visibility rather than intentional oversight. Data integrity challenges are rarely isolated to a single process and instead reflect systemic issues, where subtle operational behaviors that seem acceptable at clinical scale can create significant regulatory exposure when volume and complexity increase.

Many organizations operate under a false sense of readiness, assuming that complete documentation and training records equate to inspection preparedness, when in reality true readiness is demonstrated through consistent operational performance under regulatory scrutiny.

Scaling from clinical to commercial operations introduces exponential complexity, as processes, equipment, and supply chains often behave differently under increased demand, exposing risks that were not apparent at smaller scale. Partner readiness represents one of the most critical and least visible risk areas, with organizations frequently underestimating the need to independently verify partner capabilities in areas such as documentation access, training competency, and performance under inspection conditions.

Key Takeaways
- Start commercial readiness earlier than expected
    - Readiness should begin in parallel with late-stage clinical development, not after Phase III, to allow sufficient time to build integrated systems, validated workflows, and partner alignment.
- Prioritize visibility, control, and assurance as core readiness pillars following a practical framework centered on:
    - Visibility: Early identification of risks across internal operations and partner networks
    - Control: Consistent, reliable execution of processes under commercial conditions
    - Assurance: Independent validation that systems and teams can perform under inspection pressure
- Test readiness through simulation, not assumption
    - Mock inspections, documentation retrieval drills, and cross-functional readiness exercises are critical to uncovering hidden gaps before regulatory inspections.
- Address operational behaviors—not just documented processes
    - Many compliance gaps stem from execution inconsistencies rather than missing procedures, reinforcing the need for competency-based training and real-time monitoring.
- Leverage advanced analytics and AI to enhance visibility
    - Emerging tools can help identify risks early by analyzing data patterns, detecting anomalies, and simulating regulatory scrutiny across systems.

This session reinforced a critical message for first-time launch organizations: the greatest risks to commercialization are rarely technical, they are operational. By proactively illuminating blind spots and strengthening cross-functional readiness, organizations can significantly improve launch success and avoid costly delays.

Watch the webinar recording here

FUTURE PROOF YOUR PATIENT SUPPORT PROGRAM LAUNCH

Date: March 4, 2026
Time: 11–12PM EST
Speakers: FTLA and CareMetx

Summary
As part of FTLA's "What It Takes to Launch" webinar series, this session focused on how emerging biopharma organizations can design and implement patient support programs (PSPs) that are not only effective at launch but scalable and adaptable over time. The discussion explored how manufacturers can better anticipate patient, provider, and payer complexities in today's evolving access landscape.

The session emphasized that patient support programs serve a critical role in bridging access gaps, reducing administrative burden, and supporting patient adherence. With increasing reimbursement complexity, prior authorization hurdles, and affordability challenges, PSPs must be intentionally designed to address both patient and provider friction points across the treatment journey.

Key Insights
Organizations that successfully launch patient support programs begin planning at least two years prior to commercialization, using early inputs such as distribution models, patient populations, and anticipated payer coverage to shape foundational program design.

Effective patient support programs must be designed around the real-world complexities faced by both patients and providers, including affordability challenges, access barriers, and administrative burdens such as prior authorizations and site-of-care restrictions.

There is a clear industry shift toward hybrid operating models, where companies combine internal capabilities with external partner expertise to achieve greater flexibility, scalability, and access to innovation.

Organizations are increasingly prioritizing outcome-based success metrics, such as time to therapy initiation, patient adherence, and persistence on treatment, rather than relying solely on traditional operational or call-center performance indicators.

Advancements in AI and automation are enabling manufacturers to streamline patient intake, digitize manual processes, and improve payer interactions, ultimately reducing delays and accelerating the patient journey to therapy.

Key Takeaways
- Start PSP strategy early in development to avoid reactive decision-making closer to launch
- Design programs around real-world patient and provider barriers, not assumptions
- Evaluate build vs. buy vs. hybrid models based on long-term scalability and internal capabilities
- Prioritize data strategy from day one to enable continuous optimization
- Leverage automation and AI selectively to enhance efficiency while preserving high-touch support where needed
- Avoid overengineering at launch—focus on prioritized capabilities and iterative improvement

Programs that succeed are those built with flexibility, data-driven insight, and patient-centricity at their core, and that evolve alongside the market rather than remaining static. As the access and reimbursement landscape continues to grow more complex, forward-looking planning and the right partner ecosystem will be critical to long-term success.

View the full webinar recording and additional resources here:

Future Proof Your Patient Support Program Launch

FTLA SUMMIT: SAN DIEGO

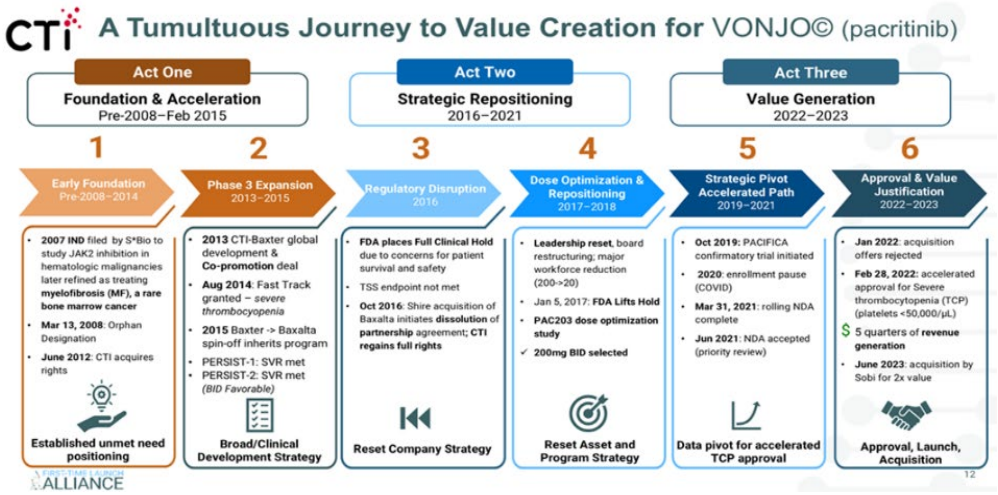
Date: March 25, 2026
Time: 1–5PM PT

FTLA Summit- San Diego was the opportunity to hear live from biotech company CIT BioPharma and gain firsthand perspectives on how they overcame obstacles over a 12-year journey to successfully launch their product and increase their overall value for a successful acquisition. CTI's former Chief Commercial Officer walked us through the 12-year journey of common milestones that all FTLs must take on their commercialization journey along with the unexpected and should-have-been expected events that needed to be handled along the way.

Following the panel discussion, the Summit was turned over to our FTLA participants for candid deep-dive functional breakouts sharing experiences and lessons among them along with an opportunity to dig deeper with CTI panelists - all for valuable learnings, lessons and take-aways for action in their companies moving forward.

Keynote Panel Highlights – CTI: An FTL Success Story
Panelists:

Keynote Panel Summary
Part 1 of the panel had CTI's former Chief Commercial Officer provide an overview with deep dive experiences over the 12-year commercialization journey following CTI's acquisition of Pacritinib rights in 2012. Later branded as VONJO, it was approved by the FDA in February 2022 for the treatment for underserved adults with a serious form of blood cancer called myelofibrosis, particularly for patients whose disease is considered more advanced and who also have very low platelet counts.



CTI's commercialization journey 2012-2023 after acquiring Pacritinib

Key insights

- **Early Development:** Identifying key target patients and how this asset would be differentiated in the market. CTI identified an unmet need in patients with low platelet counts and initiated clinical trials to address this niche.
- **Regulatory Setbacks and Organizational Restructuring**: CTI faced a clinical hold from the FDA in 2016 due to safety concerns, leading to the dissolution of a joint venture, major workforce reductions, divestment of non-core assets, and a change in leadership. The new CEO adopted a collaborative approach with the FDA, agreeing to additional studies to regain regulatory momentum.
- **Strategic Pivot:** During COVID-19: The COVID-19 pandemic disrupted clinical trial enrollment, but CTI successfully negotiated with the FDA to file for accelerated approval using available phase 2 and partial phase 3 data, contingent on completing a confirmatory study post-pandemic.
- **Market Shaping and Commercial Preparation**: The team invested in redefining the disease landscape, publishing new research, and educating key opinion leaders to create demand for pacritinib.
- **Company Culture and Talent**: Hiring was highly intentional, focusing on candidates with the right attitude and adaptability for a resource-constrained environment.
- **Launch Execution and Acquisition Outcome:** CTI launched pacritinib with a lean team and limited budget, exceeding sales expectations and attracting acquisition offers. After demonstrating sustained revenue growth, CTI was acquired at a significantly higher valuation, validating the team's strategic and operational decisions.

In Part 2 of the panel, NNIT facilitated a rich panel discussion across the unique participation of key CTI leaders that had joined over different time intervals of the CTI commercialization journey. Here are some key insights from the conversation:

- **Cross-Functional Collaboration and Culture Building**: All the panelists agreed that cross-functional collaboration, intentional culture building, and transparent communication all played a critical role in overcoming challenges and achieving CTI BioPharma's successful launch.
- **Breaking Down Silos**: The CTI team established regular cross-functional meetings involving technical operations, regulatory, quality, supply chain, and commercial teams to ensure alignment on priorities, risk management, and process simplification, which was essential for efficient operations with limited resources.
- **Intentional Hiring and Team Cohesion**: Hiring decisions prioritized attitude, adaptability, and culture fit over pedigree, with panel interviews and behavioral assessments ensuring new hires would thrive in a high-risk, high-reward environment. This approach fostered strong team cohesion and commitment.
- **Education and Transparency**: The executive team implemented company-wide calls to educate all employees about different functions, fostering understanding and buy-in across clinical and commercial teams. This transparency reduced friction and facilitated effective collaboration.

- **Leadership Engagement**: Leaders, including the CEO and COO, actively participated in interviews, field visits, and direct communication with staff, reinforcing a culture of shared responsibility and demonstrating commitment from the top down.

Roundtable Takeaways
Facilitators and participants engaged in breakout sessions focused on commercial leadership, strategy, market access, and technical operations, generating actionable insights, common mistakes to avoid, and early actions for first-time launch organizations. Breakouts were organized around four tracks: cross-functional commercial leadership, commercial strategy and market activation, market access, and technical operations. Each group was tasked with identifying three key decisions, two common mistakes, and one early action relevant to their domain.

Insights from Breakouts were shared across the plenary.
Readouts from the Technical Operations breakout included the importance of planning for global expansion from the outset, managing inventory carefully, leveraging external partners, and ensuring cross-functional communication. Mistakes to avoid included overbuying inventory and assuming organizational knowledge. Early actions emphasized building robust data systems and fostering a collaborative culture.

Watch the recording here

UPCOMING FTLA WEBINARS

4-Part Webinar Series

Launching your first product demands more than planning; it requires the right decisions, partners, and infrastructure at exactly the right time. The First-Time Launch Alliance Webinar Series brings together experienced launch leaders and industry experts to tackle the most critical operational, commercial, and organizational challenges biotech companies face on the road to launch.
Each session delivers practical insights, real-world lessons, and actionable strategies designed specifically for teams preparing for, or actively navigating a first commercial launch.

Register for the webinar series here

Session Two: How do you build supply chain resilience for your first launch?
Date: June 3, 2026
Time: 11AM ET
Session led by: McKesson Third Party Logistics

Learn how emerging biopharma companies can design flexible, risk-resistant supply chains that withstand uncertainty while ensuring product availability at launch and beyond.

Session Three: Hiring your first (or next) critical roles
Date: June 16, 2026
Time: 11AM ET
Session led by: AmpersandPeople

Learn how emerging biopharma companies can design flexible, risk-resistant supply chains that withstand uncertainty while ensuring product availability at launch and beyond.

Session Four: How do you build supply chain resilience for your first launch?
Date: June 3, 2026
Time: 11AM ET
Session led by: McKesson Third Party Logistics

Learn how emerging biopharma companies can design flexible, risk-resistant supply chains that withstand uncertainty while ensuring product availability at launch and beyond.

UPCOMING SPONSOR EVENTS

Building Better Partnerships Event: Inside McKesson Third Party Logistics Operations

Date: September 16, 2026
Time: 9AM–5PM ET (Breakfast starts at 8:30AM, Networking cocktail reception from 5–8PM)
Location: McKesson Distribution Center (170 Clermont Rd, Suite A, Shepherdsville, KY 40165)
Sponsored by : McKesson Third Party Logistics

Join us for a full-day program designed to strengthen alignment between first-time launch organizations and their 3PL partners. The day will feature educational sessions, collaborative working sessions, and a guided site tour of McKesson 3PL's distribution center, offering an inside look at day-to-day operations.
Lunch and networking reception are included!

Event Schedule:

- Understanding 3PL Operations: Capabilities, Scale & Service Models
- Guided Tour: McKesson 3PL Facility
- Key Operational Requirements for First-Time Launch Companies
- Strategies for Seamless 3PL Integration
- Case Study: Preparing for Day 1 Commercial Distribution
- Regulatory, Quality & Compliance Considerations When Working with a 3PL
- The Role of FTLA: Helping Emerging Biotechs Scale Successfully
- Interactive Discussion: Common PItfalls & Best Practices

Register for the event here

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About First-Time Launch Alliance (FTLA)

The FTLA brings together biopharma leaders and innovators who are dedicated to the successful first-time launch (or subsequent launches) of commercial biopharma products. Operated by FTL leadership with strategic direction provided by the executive committee, the FTLA creates a vibrant, expert-driven community that shares knowledge, drives innovation, and elevates execution—so that every launch is set up for success and every patient benefits from new therapies.

Visit the FTLA website

FIRST-TIME LAUNCH ALLIANCE

Credible. Connected. Collaborative.

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