FTLA INSIGHTS

Firsttimelaunchalliance.com

Q2 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 400 leaders across 320 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:

- Innovation Incubator (FTLA I²): Workstreams tackling topics like "Right-Sized AI for Launch," NDA readiness, and alternative distribution models
- Launch Summits and Webinars: Live and virtual spaces for shared learning, networking, and solution building
- Community Engagement: A private LinkedIn group, roundtables, and member-driven 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 (FTLs) 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.

RECENT WEBINARS:

THE CRM DECISION: CHOOSING THE RIGHT COMMERCIAL FOUNDATION

Date: May 21, 2026
Time: 11–12PM EST
Speakers: FTLA & MedPro Systems

Summary:
As part of FTLA's "Launch Ready: The Critical Decisions" webinar series, this session focused on one of the foundational commercial infrastructure decisions facing first-time launch organizations: how to select and implement the right CRM platform. The discussion was led by Dan Leffler of MedPro Systems, who framed the CRM decision as more than a software selection exercise. Instead, he emphasized that CRM readiness depends on understanding the people who will use the system, the data they need at the point of interaction, and the workflows that will carry that data across the organization.

The session also addressed the current state of disruption in the CRM market, including the separation between Veeva and Salesforce, the increasing importance of AI-enabled functionality, and the expanding set of boutique CRM providers that may be better suited for smaller or first-time launch organizations. Rather than defaulting to a single market-leading option, participants were encouraged to evaluate multiple providers, consider implementation partner capacity, and make CRM decisions based on launch-specific needs, data strategy, compliance requirements, and long-term scalability.

Key Insights:
A central theme of the webinar was that CRM success begins with clarity around the users and personas that matter most to the launch model. First-Time Launch organizations must determine whether the CRM will primarily support field sales representatives, medical science liaisons, field reimbursement managers, key account managers, or other roles, because each persona creates different data, workflow, integration, and compliance requirements.

The discussion also reinforced that data quality must be designed into the process at the point of capture. If field teams are forced to manually enter incomplete or unverified healthcare provider information, downstream processes become slower, less reliable, and more difficult to govern. By enabling real-time access to trusted data sources at the point of interaction, organizations can reduce duplicate data requests, improve confidence in compliance reporting, and accelerate commercial execution.

The CRM market is undergoing significant change as Veeva and Salesforce evolve independently and as AI becomes a more central part of commercial technology strategy. While Veeva remains a familiar and historically dominant life sciences CRM option, Salesforce is increasingly associated with AI-enabled capabilities, and other boutique vendors may offer faster, more tailored implementations for emerging companies with narrow launch needs.

The session also highlighted that the implementation partner is as important as the CRM platform itself. Larger platforms often require external system integrators, while smaller vendors may provide a more hands-on model. For First-Time Launchers with lean internal teams, the ability to secure practical implementation support, responsive guidance, and fit-for-purpose configuration can materially affect launch readiness.

Finally, Dan emphasized that AI will only be as effective as the data and processes behind it. Even the most advanced AI-enabled CRM capabilities will produce poor recommendations if the underlying healthcare provider, customer, interaction, and workflow data are incomplete or inconsistent.

Key Takeaways:
- Define the CRM user personas first, because field roles, medical roles, reimbursement roles, and account roles each create different system requirements.

- Build trusted data access into the point of interaction to reduce manual entry, duplicate data requests, and downstream cleanup.
- Evaluate multiple CRM options, including dominant platforms, secondary providers, and boutique vendors, rather than assuming one default answer.
- Treat the system integrator or implementation partner as a critical part of the CRM decision.
- Assess CRM vendors based on how well they support near-term launch needs and long-term growth.
- Consider AI capabilities, but prioritize clean data, governance, and workflow design before relying on AI-enabled features.
- Start CRM planning early, particularly given potential implementation capacity constraints across the market.

This session reinforced that the CRM decision is a commercial foundation decision, not simply a technology purchase. First-time launch companies that define their personas, data needs, workflows, and partner model early will be better positioned to move quickly, remain compliant, and scale effectively after approval.

To access the full webinar recording and additional insights, please visit the FTLA website:
MedPro Systems Webinar Recording: CRM Decision.

BUILDING SUPPLY CHAIN RESILIENCE FOR YOUR FIRST LAUNCH

Date: June 3, 2026
Time: 11–12PM EST
Speakers: FTLA & McKesson Third Party Logistics

Summary:
This FTLA webinar, hosted with McKesson Third Party Logistics, focused on how first-time launch organizations can build supply chain resilience before approval and avoid the operational delays that can compromise launch execution. The session explored the product path to patient from a 3PL perspective, with particular emphasis on early partner engagement, channel strategy, cold chain and controlled substance requirements, inventory planning, temporary title models, state licensing, DSCSA readiness, serialization, packaging, data flow, and quality/regulatory coordination.

The panel emphasized that First-Time Launch companies often view risk primarily through clinical or regulatory milestones, while underestimating the commercial and operational risk embedded in supply chain design. Speakers reinforced that the 3PL should be treated as an extension of the manufacturer's business, not simply a vendor. A strong 3PL partner should support launch planning, identify bottlenecks early, provide operational and regulatory expertise, enable scalability, and help manufacturers prepare for real-world disruptions such as weather events, cold chain complexity, data exceptions, packaging issues, and licensing gaps.

Key Insights:
A recurring theme was that supply chain resilience must be built well before approval. The panel advised that First-Time Launch companies begin engaging 3PL partners as early as 24 months before launch, and sometimes up to three years in advance for complex therapies. Early engagement allows the manufacturer and 3PL to clarify requirements, evaluate channel design, support state licensing strategy, and prepare for changing regulatory timelines, including accelerated approval pathways and priority review scenarios.

The discussion also highlighted the importance of defining operational requirements early, including storage conditions, cold chain needs, controlled substance requirements, packaging constraints, forecast assumptions, customer experience expectations, and downstream distribution models. Our speakers emphasized that manufacturers should distinguish between non-negotiable requirements and nice-to-have preferences, because overly complex or narrowly defined requirements can reduce flexibility and create avoidable launch risk.

Data readiness, serialization, and DSCSA execution were presented as critical launch enablers. The panel described the need to align master data, GTINs, lots, serial numbers, product hierarchy, labeling, packaging, and data exchange pathways before launch. The physical product and its digital record must move together through the supply chain, and unresolved data mismatches can delay distribution, revenue recognition, and patient access.

The session also underscored the importance of exception handling. Even when planning is strong, serialization or packaging data issues can occur with early batches. A 3PL with experience working through downstream exceptions with distributors, specialty pharmacies, and other trading partners can prevent small data or packaging issues from escalating into launch disruptions.

Finally, the panel addressed temporary title models as a practical launch mechanism for first-time launch companies that may not yet have complete state licensing coverage. Temporary title can help manufacturers get product to market quickly after approval, though it may carry additional cost and should be managed as a short-term strategy that transitions as licensing readiness improves.

Key Takeaways:

- Engage a 3PL partner early, ideally 18 – 24 months before launch, and earlier for complex products or accelerated timelines.
- Treat the 3PL as an extension of the business, with shared accountability for launch execution, risk mitigation, and patient access.
- Define must-have operational requirements early, including cold chain, controlled substances, packaging, storage, transportation, and downstream customer experience.
- Build redundancy and contingency planning into the supply chain to address weather events, distribution disruptions, and operational failure modes.
- Align production planning, forecast assumptions, safety stock, and 3PL storage capacity before launch.
- Evaluate temporary title as a way to support timely launch while state licensing activities are completed.
- Validate data structure, labeling, packaging, serialization, DSCSA data flow, and repository handoffs together before launch.
- Pressure test exception handling processes before the first commercial lots move through the network.
- Avoid fragmented vendor ecosystems where possible, because misalignment across vendors can create unnecessary operational complexity.
- Preserve flexibility in packaging, channel strategy, and submission assumptions to avoid narrowing launch options too early.

This session reinforced that first-time launch supply chain readiness is not a downstream operational detail; it is a strategic launch dependency. Companies that engage partners early, design for resilience, validate data flow, and prepare for exceptions will be better positioned to protect revenue, maintain compliance, and ensure that product reaches patients without avoidable disruption.

To access the full webinar recording and additional insights, please visit the FTLA website:
FTLA / McKesson Webinar Teams Recording.

HIRING YOUR FIRST (OR NEXT) CRITICAL ROLES

Date: June 16, 2026
Time: 11–12PM EST
Speakers: FTLA & AmpersandPeople

Summary:
This FTLA webinar, hosted with AmpersandPeople, focused on how emerging biopharma organizations should plan, sequence, and execute the first or next wave of critical commercial and launch-enabling hires. The discussion positioned launch hiring as a strategic operating model decision rather than a simple org-chart exercise. Speakers emphasized that First-Time Launch organizations must account for the company's therapeutic focus, distribution model, geography, available

internal talent, budget, partner ecosystem, and launch complexity when determining which capabilities to hire, borrow, or outsource.

The session also reinforced that launches are difficult, high-change environments that require people who can operate with ambiguity, collaborate across functions, work hands-on, and remain effective when responsibilities shift quickly. AmpersandPeople highlighted common hiring traps, including over-relying on familiar veterans whose most recent launch experience may not match the current environment, importing legacy large-company thinking into lean launch settings, and waiting too long to bring in commercial leadership, data, market access, medical affairs, commercial operations, and marketing capabilities.

Key Insights:
No two first-time launches require the same commercial organization design. The right structure depends on factors such as therapeutic focus, distribution model, geography, internal talent, international ambitions, and decisions about which work should be built internally versus supported by external partners.

Change management is a launch-readiness requirement. The presenters emphasized the need to recognize the people who helped the organization get to its current stage, communicate repeatedly and clearly, and prepare legacy team members to welcome new roles rather than viewing them as a threat.

Budget and resourcing alignment with finance should happen early. Launch teams should distinguish between temporary problems that can be solved through outside support and enduring capabilities that need to become part of the organization, while also avoiding both under-resourcing and duplicated work.

Hiring timing requires deliberate planning. Commercial leaders often need at least 12 months of runway, and 18 months can be better for certain leadership roles, but the webinar did not provide a single universal answer for exactly when to make the first commercial hire because the decision depends on company context, approval risk, and readiness to act on commercial plans.
Commercial operations was presented as an example of an early, highly cross-functional role that has evolved materially as technology, automation, AI, governance, promotional review, data, and field-enablement needs have changed.

Candidate evaluation should test for launch mindset, recent relevant experience, comfort with ambiguity, cross-functional leadership, drive, hands-on execution, vendor management, and ability to balance “I” contributions with true team collaboration.

The presenters warned against two recurring hiring traps: the “old reliable” trap of defaulting to known colleagues without testing fit for the current launch, and legacy thinking that assumes past playbooks will automatically work in today’s compliance, digital, payer, and launch environment.

Key Takeaways:
- Tailor the launch organization to the product, market, channel strategy, geography, and operating model rather than copying a generic org chart.
- Align finance, leadership, and launch teams on which capabilities should be hired, borrowed, outsourced, or delayed before headcount decisions become urgent.
- Avoid hiring too late; build enough runway for critical commercial, market access, medical affairs, commercial operations, marketing, and data capabilities to shape launch readiness before approval pressure peaks.
- Use structured interview filters for ambiguity, cross-functional execution, launch mindset, vendor partnership, and hands-on builder behavior.
- Balance experienced launch veterans with high-potential, execution-oriented talent so the early organization has both pattern recognition and capacity to do the work.
- Over-communicate commercial launch plans, recognize legacy contributors, and make onboarding a deliberate change-management process.

To access the full webinar recording and additional insights, please visit the FTLA website:
Ampersand People FTLA Webinar Recording.

FROM FRAGMENTED LAUNCH DATA TO AGENTIC ORCHESTRATION

Date: June 30th, 2026
Time: 11–12PM EST
Speakers: FTLA & TraceLink

Summary:
This FTLA webinar, hosted with TraceLink as part of the Critical Decisions series, focused on how First-Time Launch organizations can move from fragmented launch data and partner-dependent execution to a more connected, orchestrated commercial operating model. The discussion framed launch as a network challenge, not a single-company problem, because emerging biopharma companies must coordinate across internal functions and external partners such as CDMOs, CMOs, contract packagers, 3PLs, wholesalers, pharmacies, healthcare systems, and regulators.

TraceLink emphasized that First-Time Launchers often operate with lean teams, compressed timelines, high scrutiny, and fragmented processes managed through email, PDFs, portals, and spreadsheets. While those methods may feel familiar, they can create operational debt, delayed visibility, manual reconciliation, and reactive issue management. The session introduced the idea of an agentic business network and an "integrate once, operate with everyone" model as a way to create trusted partner connectivity, digital product identity, standardized transaction exchange, digitally orchestrated processes, and governed AI agents that support launch execution while preserving human accountability.

The webinar also connected commercialization readiness to FTLA's broader AI readiness themes. AI was not positioned as a starting point or stand-alone tool; rather, presenters reinforced that reliable AI-enabled launch execution depends on organized data foundations, structured processes, defined governance, clear permissions, measurable use cases, and audit-ready human oversight.

Key Insights:
Launch execution is a network orchestration challenge. First-Time Launch companies must coordinate product, partner, transaction, quality, logistics, compliance, and customer data across organizations that each have their own systems, processes, timelines, and constraints. A custom point-to-point integration model can help solve short-term needs, but it is difficult to scale and may create downstream operational debt.

Digital product identity is more than a compliance requirement. Serialization, traceability, product master data, serialized product events, product status, and market-specific track-and-trace data create a trusted data layer for launch operations. In the U.S., this connects directly to DSCSA readiness, but the broader value extends to inventory visibility, saleability, exception management, returns, recalls, reimbursement, and future AI-enabled workflows.

Business transactions function as launch signals. Purchase orders, PO acknowledgements, ASNs, inventory updates, receiving advice, shipping notices, and invoices should be treated as operational signals that can power proactive orchestration. When those signals remain trapped in emails, PDFs, portals, or spreadsheets, teams have less ability to detect problems early, reconcile exceptions, or make timely decisions.

Not every launch process can be fully automated on day one, but critical processes should be visible, structured, trackable, and connected. Examples discussed included batch record review, CMO site readiness, tech-transfer coordination, SOP alignment, label and artwork coordination, DSCSA compliance exception management, and change requests. Structuring these processes creates a shared operating framework for both human teams and AI agents.

Governed agents can function as scalable teammates for lean launch teams. The session distinguished a generic chatbot from an agent that understands a specific process, transaction, product, partner rule, exception path, and escalation model. Agentic readiness requires defined roles, objectives, tasks, decisions, rules, permissions, human review points, audit trails, and KPIs so that automation enhances execution without creating uncontrolled risk.

Partner adoption depends on shared value. TraceLink emphasized that partner participation improves when manufacturers and external partners align around mutual KPIs such as on-time-in-full performance, cycle-time reduction, forecast visibility, resource planning, exception reduction, and operational efficiency. The stronger the visibility across the relationship, the more both sides can reduce risk and improve execution confidence.

Key Takeaways:

- Do not wait until approval to design the launch "nervous system." Start with the operating model, data model, partner model, compliance model, and orchestration model early enough to test them before launch pressure peaks.
- Treat serialization and traceability as commercial execution foundations, not only compliance workstreams.
- Move launch-critical data exchange away from fragmented email, PDF, portal, and spreadsheet workflows where possible, and toward standardized, machine-readable transaction and process signals.
- Use an integrate-once network architecture to reduce the burden of partner-by-partner connectivity and support scalability across launch one and future launches.
- Define agentic use cases with clear roles, permissions, escalation logic, human accountability, and auditability before relying on AI for launch-critical work.
- Align KPIs with external partners so that orchestration creates a win-win model for manufacturers, CMOs/CPOs, 3PLs, and downstream commercial partners.

To access the full webinar recording and additional insights, please visit the FTLA website: TraceLink FTLA Webinar Recording.

UPCOMING WEBINARS:

MAKING AI WORK FOR YOUR FIRST LAUNCH:

Where it Drives Commercial and Medical Impact, and Where It Doesn't

Date: July 15, 2026
Time: 11AM-12PM EST

Emerging biopharma companies aren't deciding whether to invest in AI. They're deciding **where it will strengthen** their commercial and medical organizations versus adding cost and complexity without proportional return. For first-time launchers, that **decision is high-stakes**: lean teams, limited runway, and no margin to course-correct while core product launch capabilities are still being built.

The real risk isn't just underinvesting. It's overbuilding too early or locking in approaches that require rebuilding as commercial and medical operations mature.

In this session grounded in the realities of first launches, **Beghou's** Rahul Chouhan and Nicole Ventrone and Troy Unfried of **SpringWorks Therapeutics,** will share how commercial and medical teams are applying AI in real launch scenarios and where it remains premature.

View the Recording

SUPPLY CHAIN COMPLIANCE FOR FIRST-TIME LAUNCHES:

Avoiding Costly Missteps Across DSCSA, Data and Distribution

Date: August 12, 2026
Time: 11AM-12PM

Explore the critical compliance, data governance, and distribution considerations that can make or break a first launch. Experts will share practical strategies for navigating DSCSA requirements, serialization, trading partner onboarding, license verification, and compliant distribution operations.
Hosted by: NNIT, McKesson 3PL, and MedPro Systems

Register Here

FROM DRIFT TO DIRECTION:
Strengthening Decision-Making and Cross-Functional Collaboration for First-Time Launches
Date: August 26, 2026
Time: 11AM-12PM

Discover how emerging biotech teams can improve alignment, clarify responsibilities, engage partners more effectively, and create the decision-making structure necessary to navigate increasing launch complexity.
Hosted By: Sage Advisors

Register Here

UPCOMING IN-PERSON EVENTS

Building Better Partnerships Event
Inside McKesson Third Party Logistics Operations
Date: September 16, 2026
Time: 9AM-5PM
Reception to Follow

Join us on Wednesday, September 16 in Shepherdsville/Clermont, KY, 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.
The program will conclude with an evening networking reception at Jim Beam Distillery

Register for our event below:
https://app.smartsheet.com/b/form/019d735df17976d2b95105a99de73933

First-Time Launch Alliance Summit
Boston, 2026
Date: November 5, 2026
Time: 12PM-5PM

Boston is Back!
By bringing together experienced industry leaders, functional experts, and peers facing similar challenges, First-Time Launch Alliance creates a collaborative environment where practical knowledge is shared, meaningful connections are built, and launch readiness becomes achievable.

Join us for the second annual FTLA Summit—an exclusive gathering designed for the executives and cross-functional teams responsible for turning launch strategy into commercial success. Through candid discussions, interactive workshops,

expert-led sessions, and real-world case studies, you'll gain actionable insights across commercialization, market access, medical affairs, supply chain, quality, regulatory, and AI-enabled launch execution.

As many of you know, this isn't a traditional conference. It's a highly collaborative experience where attendees engage directly with industry experts, exchange lessons learned with fellow launch leaders, and leave with practical strategies they can immediately apply to their organizations.

Attendance is intentionally limited to foster meaningful dialogue, peer networking, and hands-on collaboration. If you're preparing for your first launch—or helping others do the same—the FTLA Summit is where you'll find the knowledge, partnerships, and confidence to accelerate launch success. **Join us on November 5th!**

Register for our event below:
https://app.smartsheet.com/b/form/019e6fe1f49277c99b6be356933ae475

INNOVATION INCUBATOR

Innovation Incubator – IT Foundations

Date: August through Septe

For first-time launch companies, **early technology decisions** often become the long-term operating foundation of the business. The challenge is **knowing where to start**, what to prioritize, and how to build a digital landscape that can scale and sustain the company over time.

In our next I², we'll explore practical approaches for connecting:

- Supply Chain & Manufacturing
- Clinical & Regulatory
- Quality & Compliance
- Commercial & Patient Operations
- Financial Processes & Data
- Cross-Functional Visibility & Integrations

Because successful launches are not only powered by great science, but they are also enabled by connected operations, data, and technology built to grow with the business.

Fill out this form to get involved:
https://app.smartsheet.com/b/form/019eb238bb8078dc97e4c6b01d5bbc82

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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

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