FTLA INSIGHTS

Firsttimelaunchalliance.com

Q3 2026 Summary Edition



TABLE OF CONTENTS

INTRODUCTION TO THE FTLA.....3

RECENT WEBINARS: 4

IN-PERSON EVENT.....10

INSIGHTS DOCUMENTS: 14

UPCOMING WEBINARS:.....16

UPCOMING IN-PERSON EVENTS 17

INNOVATION INCUBATOR.....18

THANK YOU TO OUR SPONSORS!.....19

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:

MAKING AI WORK FOR YOUR FIRST LAUNCH: WHERE IT DRIVES COMMERCIAL AND MEDICAL IMPACT, AND WHERE IT DOESN'T

Date: July 15, 2026
Time: 11–12PM EST
Speakers: FTLA, Beghou & SpringWorks Therapeutics

Summary:
As part of FTLA's "Launch Ready: The Critical Decisions" webinar series, this session examined where artificial intelligence can create meaningful commercial and medical impact for first-time launch organizations—and where investment may add cost, complexity, or risk without a proportional return. Rahul Chouhan and Nicole Ventrone of Beghou, joined by Troy Unfried of SpringWorks Therapeutics, grounded the discussion in the realities of emerging biopharma: lean teams, limited runway, evolving operating models, and little margin for error while core launch capabilities are still being built.

The panel emphasized that the central question is not whether to use AI, but where it can improve decisions, execution, and stakeholder engagement in ways that are practical, measurable, and appropriate for the organization's maturity. Participants were encouraged to prioritize focused use cases, establish strong data and governance foundations, preserve human accountability, and avoid overbuilding solutions that may need to be redesigned as commercial and medical operations evolve.

Key Insights:
A central theme of the webinar was that AI should begin with a defined business or medical need—not with the technology itself. First-time launch organizations should identify decisions, workflows, and stakeholder interactions where faster synthesis, better prioritization, or reduced administrative effort can materially improve launch execution.

Commercial applications can be valuable where AI helps teams organize market intelligence, identify patterns, prioritize accounts or activities, prepare field teams, and generate more timely insights from fragmented information. However, these applications require clear objectives, relevant data, and integration into the workflows where decisions are actually made.

Within medical affairs, AI can support activities such as literature synthesis, insight aggregation, scientific-content preparation, and identification of emerging themes across engagements. The panel reinforced that these tools should augment qualified medical judgment rather than replace it, particularly where scientific accuracy, context, and compliant communication are essential.

The discussion also highlighted the importance of organizational readiness. AI initiatives are more likely to deliver value when ownership, data access, review responsibilities, escalation paths, privacy expectations, and success measures are defined before deployment. For lean launch teams, a small number of well-governed use cases can create more value than a broad portfolio of disconnected pilots.

Finally, the panel cautioned against using AI where the underlying process is unstable, the data are incomplete, the risk of error is high, or human trust and interpretation are central to the outcome. In those situations, process design, data quality, and operating-model clarity should come first; automation can follow once the foundation is strong enough to support it.

Key Takeaways:
- Start with a specific commercial or medical decision, workflow, or stakeholder need rather than beginning with an AI platform.
- Prioritize a limited number of use cases with measurable value, manageable risk, and clear operational ownership.

- Use AI to augment commercial and medical teams through better synthesis, prioritization, preparation, and insight generation—not to replace accountable human judgment.
- Establish data quality, access, privacy, compliance, review, and escalation requirements before moving a use case into production.
- Avoid automating unstable processes or scaling pilots that are not connected to day-to-day commercial and medical workflows.
- Build solutions that can mature with the organization rather than overengineering an enterprise model before launch needs are clear.
- Define success measures early and continue only where AI improves speed, quality, consistency, or decision-making enough to justify the investment.

This session reinforced that effective AI adoption is a launch operating-model decision, not simply a technology purchase. First-time launch companies that focus on high-value use cases, build the right data and governance foundations, and keep accountable experts in the loop will be better positioned to capture practical benefits without creating unnecessary complexity or risk.

To access the full webinar recording and additional insights, please visit the FTLA website:
Making AI Work for Your First Launch Webinar Recording.

SUPPLY CHAIN COMPLIANCE FOR FIRST-TIME LAUNCHES: AVOIDING COSTLY MISSTEPS ACROSS DSCSA, DATA, AND DISTRIBUTION

Date: August 12, 2026
Time: 11–12PM EST
Speakers: FTLA, NNIT, MedPro Systems & McKesson Third Party Logistics
Summary:
This FTLA webinar brought together experts from NNIT, MedPro Systems, and McKesson Third Party Logistics to examine the compliance, data, and distribution decisions first-time launch organizations must address before their first commercial shipment. The session focused on the interconnected requirements of the Drug Supply Chain Security Act (DSCSA), serialization, authorized trading partner verification, state licensing, customer and location data, third-party logistics onboarding, channel design, packaging, and physical distribution readiness.

The panel emphasized that DSCSA compliance is not a stand-alone technology project or a responsibility that can be transferred entirely to vendors. The product-license holder remains accountable for ensuring that serialized physical product and its corresponding transaction data move together through the supply chain. Success requires a cohesive operating model that connects the manufacturer, contract manufacturing and packaging partners, serialization platform, 3PL, downstream trading partners, quality, regulatory, information technology, supply chain, and commercial teams.

Speakers also stressed that first-time launch organizations must prepare for both the expected process and the “unhappy path.” Serialization-data errors, invalid or expired licenses, unreadable labels, packaging constraints, incomplete customer records, and unresolved exceptions can place product on hold, block orders, delay distribution, or trigger suspect-product investigations. Early planning, integrated data, testing, clear ownership, and defined escalation pathways are therefore essential to protecting compliance, revenue, and patient access.

Key Insights:
DSCSA requires the physical product and its serialized data to remain aligned as the product moves from packaging through distribution. Manufacturers need a defined approach for generating, managing, retaining, and exchanging serial numbers and product-event data through an Electronic Product Code Information Services system. That environment must be configured with accurate product, site, partner, and location master data and integrated with contract manufacturers, contract packagers, 3PLs, and downstream trading partners.

A comprehensive serialization and DSCSA strategy should be established before implementation begins. The panel recommended documenting the business processes, systems, data exchanges, owners, partners, transactions, integration points, validation requirements, standard operating procedures, and support model across the end-to-end network. Without this cohesive roadmap, individual vendors and functions may move forward independently and create gaps between physical operations, digital records, and compliance responsibilities.

The manufacturer remains accountable even when activities are outsourced. Supply chain commonly serves as the overall business owner because it sits between manufacturing and downstream commercial distribution, but successful execution requires close partnership with information technology, quality, regulatory, manufacturing, commercial operations, and external providers. Each party's responsibilities, decision rights, escalation paths, and ongoing support obligations should be defined before launch.

Authorized trading partner verification depends on trusted and continuously monitored data. State Board of Pharmacy licenses, practitioner licenses where applicable, Drug Enforcement Administration registrations for controlled products, Global Location Numbers, Food and Drug Administration registration data, addresses, expiration dates, license status, class of trade, and other customer attributes may reside across multiple sources and change over time. Verification should occur as early as possible during customer or trading partner onboarding and should feed the customer master, enterprise resource planning, customer relationship management, order-management, and 3PL environments.
Trading partner status should not be treated as a one-time onboarding check. Licenses can be issued, renewed, suspended, allowed to lapse, reissued under new identifiers, or removed from state-board sources. Facilities can relocate or close, and even address or suite-number changes can disrupt matching. The panel recommended regular monitoring of the full customer universe, with at least monthly refreshes and more frequent checks surrounding renewal periods or identified changes.

Poor customer and location data can create both operational and compliance consequences. Orders may be held, canceled, or blocked; serialized transaction data may be sent against an unverifiable location; returns may not be processed correctly; and shipments may be prevented from leaving the 3PL. Shipping to an organization that is not an authorized trading partner—or being unable to demonstrate that verification occurred—can create a compliance violation regardless of intent. From the 3PL perspective, clean serialization data is a prerequisite for receiving product. If the serialized file does not match the physical shipment, the product may be placed on hold while the manufacturer, packaging partner, serialization provider, and 3PL investigate. Significant discrepancies may escalate into suspect-product scenarios. Testing the data flow and first-shipment process before commercial inventory arrives can prevent launch-critical stock from becoming stranded.
Distribution readiness also depends on early decisions about channel design, title model, licensing, product configuration, packaging, returns, invoicing, and the downstream customer experience. The organization must determine where it intends to ship, whether it or another party will take title, which state licenses are required, how customers will order and receive product, how returns will be managed, and how financial and operational data will be reconciled.

Packaging and temperature requirements can constrain distribution options if they are addressed too late. Storage conditions, cold-chain or controlled-room-temperature requirements, shipper dimensions, case quantities, aggregation levels, ancillary kits, combination-product components, label placement, barcode readability, and specialty-pharmacy or distributor receiving preferences should be reviewed with the 3PL before packaging and submission decisions become difficult to change.

Complex products and distribution models benefit from end-to-end dry runs. For temperature-sensitive, ultra-low-temperature, direct-to-site, or tightly controlled shipments, test shipments allow the manufacturer and its partners to evaluate packaging, handoffs, data exchange, delivery timing, receiving procedures, and escalation routes before live product moves. Dry runs can reveal operational issues that are not visible in system testing alone.

Exception management must be designed before launch. Serialization creates additional exception types and can make investigations more complex because the physical product, serialized identifiers, transaction history, and regulatory reporting requirements must remain aligned. Organizations should define intake, triage, investigation, correction, escalation, documentation, and reporting processes, including who must be contacted and what timelines apply when an issue cannot be resolved immediately.

The panel recommended beginning serious 3PL engagement approximately 12 months before the planned launch when possible, while recognizing that internal requirements definition and selection activities should begin earlier. Sufficient runway allows the organization and 3PL to complete contracting, quality agreements, channel and title-model decisions, licensing preparation, system configuration, serialization testing, label and packaging assessment, operational onboarding, and dry runs without compressing critical activities into the final prelaunch period.

Key Takeaways:

- Build an end-to-end DSCSA and serialization strategy that connects physical product, serialized data, systems, partners, processes, validation, governance, and ongoing support.
- Recognize that the product-license holder retains accountability for compliance even when manufacturing, packaging, serialization, distribution, or data services are outsourced.
- Assign clear business ownership, typically through supply chain, with strong participation from information technology, quality, regulatory, manufacturing, commercial operations, and external partners.
- Define requirements and begin 3PL planning early, with approximately 12 months for formal onboarding when possible and additional time for internal preparation and partner selection.
- Configure and validate the serialization environment, including product, site, partner, and location master data, before commercial product is packaged or distributed.
- Test the complete flow of physical product and serialized transaction data across the contract manufacturer or packager, serialization platform, 3PL, and downstream trading partners.
- Verify authorized trading partners and customers as early as possible during onboarding and integrate the results into master-data, customer, ordering, distribution, and enterprise systems.
- Monitor state licenses, Drug Enforcement Administration registrations, Global Location Numbers, addresses, and trading partner status continuously rather than relying on a one-time verification.
- Align channel strategy, title model, state licensing, customer onboarding, returns, invoicing, and distribution operations before launch.
- Review packaging dimensions, aggregation, label readability, storage conditions, temperature controls, ancillary components, and downstream customer receiving requirements early.
- Perform dry runs for complex, temperature-sensitive, direct-to-site, or tightly controlled distribution models.
- Establish exception-management procedures, owners, investigation timelines, escalation paths, and reporting requirements before the first commercial shipment.
- Prepare for the “unhappy path” by identifying who will respond when product, data, licensing, packaging, or distribution issues occur.
- Maintain direct working relationships between corresponding manufacturer and partner functions so information technology, quality, supply chain, regulatory, and operational issues can be resolved quickly.
- Treat compliance data as an operational launch asset because inaccurate or outdated information can block orders, hold inventory, delay revenue, and prevent product from reaching patients.

This session reinforced that supply chain compliance is an integrated launch capability, not a final precommercial checklist. First-time launch organizations must connect DSCSA strategy, serialization technology, customer and trading partner data, licensing, packaging, distribution operations, and exception management within a single coordinated operating model. Companies that define ownership early, engage their partners with sufficient runway, validate physical and digital workflows, and prepare for exceptions will be better positioned to launch compliantly, protect revenue, and maintain reliable patient access.

To access the full webinar recording and additional insights, please view:
Supply Chain Compliance for First-Time Launches: Avoiding Costly Missteps Across DSCSA, Data, and Distribution Webinar Recording

FROM DRIFT TO DIRECTION: STRENGTHENING DECISION-MAKING AND CROSS-FUNCTIONAL COLLABORATION FOR FIRST-TIME LAUNCHES

Date: September 2, 2026
Time: 11–12 PM EST
Speakers: FTLA, Sage Advisors, NNIT, and former CTI BioPharma leaders

Summary:
This FTLA webinar examined how emerging biopharma organizations can move from organizational drift to coordinated launch execution by strengthening decision-making, cross-functional collaboration, and organizational readiness. Andrew DeMarco of Sage Advisors, Caitrin O'Shea of NNIT, and former CTI BioPharma leaders Jim Fong and Joe Mansfield discussed the transformation required as a clinical-development company becomes a fully integrated biotechnology organization capable of launching its first product.

The panel emphasized that first-time launch readiness extends beyond plans, budgets, and hiring. Companies must establish a shared mission, provide functions with the information and context needed to make timely decisions, and develop operating rhythms that connect clinical, regulatory, medical, commercial, manufacturing, finance, legal, and external partners. Drawing on CTI BioPharma's experience, the speakers demonstrated how disciplined investment gates, transparent communication, early commercialization planning, collaborative hiring, and consistent execution can strengthen both launch readiness and enterprise value.

Key Insights:
A first product launch is also an organizational transformation. Emerging companies are not simply preparing a product for market; they are evolving from closely connected clinical-development teams into integrated organizations capable of commercial execution. This transition changes how the company allocates resources, evaluates opportunities, engages partners, makes decisions, and defines long-term value.

Decision discipline is a launch capability. First-time launch organizations face continual decisions related to staffing, vendors, budgets, operating models, timelines, and execution. Delaying decisions out of fear of making the wrong choice can create greater risk by compressing timelines and disrupting dependent activities. Leaders should ensure decisions are informed, coordinated, clearly understood, and allowed to stand unless new evidence warrants a change.

Misalignment often reflects unequal information rather than fundamental disagreement. The panel noted that differences in available information, terminology, and interpretation can create the appearance of cross-functional conflict. Leaders can reduce this friction by educating stakeholders before decisions are requested, sharing relevant context, clarifying definitions, and ensuring affected functions understand the rationale and organizational implications of a proposed direction.

Recurring communication creates shared accountability. At CTI BioPharma, weekly company-wide meetings reinforced milestones, priorities, and next steps, while weekly launch-team meetings connected manufacturing, clinical, commercial, and other functions around dependencies and execution. This cadence helped functions see themselves as contributors to a shared launch mission rather than as separate teams responding to commercial requests.

Culture is established through repeated leadership behaviors. Radical transparency, early stakeholder involvement, constructive disagreement, listening, and accountability must be modeled consistently. Leaders should assess organizational dynamics early, define the culture required for launch, and address barriers before siloed decisions, informal communication patterns, or unresolved conflict become embedded in the organization.

Hiring and partner selection should begin with the launch mission. The panel recommended evaluating employees, consultants, and vendors based on experience that matches the company's resources, timelines, operating model, and cultural expectations—not solely on prestigious company backgrounds, personal familiarity, or strong résumés. Lean launch

environments require leaders and partners who can collaborate across functions, work hands-on, manage ambiguity, and maintain execution discipline.

Launch capabilities should be built earlier than many organizations expect. Companies should begin shifting their organizational mindset by mid-Phase 2 or the beginning of Phase 3 and may need to start building launch capabilities two to three years before commercialization. External partners can provide structure, guardrails, coordination, and specialized expertise, but internal leaders remain responsible for the mission, decisions, culture, and cross-functional alignment.

CTI BioPharma's experience illustrated the relationship between launch readiness and company value. Despite limited cash and compressed timelines, the organization began preparing approximately 14 months before potential approval, used milestones and spending gates to manage investment, and continued operating as though it would launch independently. Sustained execution and commercial performance ultimately contributed to a substantially stronger strategic outcome.

Key Takeaways:

- Treat first-time launch preparation as an enterprise transformation, not solely a commercial workstream or product-launch plan.
- Define a clear mission, vision, values, and strategic direction before launch decisions and organizational complexity accelerate.
- Begin building organizational and launch capabilities by mid-Phase 2 or early Phase 3, with sufficient time to practice cross-functional collaboration before approval pressure peaks.
- Provide stakeholders with shared information, education, terminology, and context before requesting major decisions.
- Establish recurring company-wide and cross-functional launch forums to communicate priorities, monitor dependencies, resolve issues, and reinforce shared accountability.
- Make launch decisions in a timely and coordinated manner, document the rationale, and avoid repeatedly changing direction without material new evidence.
- Engage clinical, regulatory, medical, manufacturing, finance, legal, commercial, and other affected functions early enough to shape the strategy rather than react to completed plans.
- Create an environment where constructive disagreement is invited, examined, and resolved without isolating people who challenge the prevailing view.
- Assess organizational culture and collaboration barriers early, then reinforce transparency, inclusion, listening, and accountability through consistent leadership behavior.
- Hire employees and select partners against the launch mission, operating model, required behaviors, and comparable experience—not reputation or familiarity alone.
- Balance experienced launch leaders with high-potential contributors who are willing to learn quickly, work hands-on, and operate effectively in a lean environment.
- Use consistent interview criteria and cross-functional interview panels to evaluate execution ability, self-awareness, collaboration, cultural alignment, and comfort with ambiguity.
- Bring external launch-planning and specialist partners in early enough to provide structure, guardrails, coordination, and visibility across interdependent activities.
- Use milestones and investment gates to balance launch readiness with financial discipline, particularly when resources, cash, and approval timelines remain uncertain.
- Prepare the organization to launch independently even when partnership or acquisition is part of the long-term strategy, because organizational readiness can materially influence both launch success and enterprise value.

This session reinforced that effective first-time launch execution depends on how quickly and consistently an organization can align people, information, decisions, and actions. Companies that establish a shared mission, educate stakeholders, invite constructive disagreement, maintain disciplined communication, select the right employees and partners, and begin building collaborative capabilities early will be better positioned to navigate complexity, execute with confidence, and create sustainable value.

To access the full webinar recording and additional insights, please view:
From Drift to Direction: Strengthening Decision-Making and Cross-Functional Collaboration for First-Time Launches Webinar Recording

IN-PERSON EVENT

BUILDING BETTER PARTNERSHIPS: INSIDE MCKESSON THIRD PARTY LOGISTICS OPERATIONS

Date: September 16, 2026
Time: 8:30 AM–8:00 PM
Location: Shepherdsville and Clermont, Kentucky
Hosts and Contributors: FTLA, McKesson Third Party Logistics, NNIT, Beghou, Compass Pathways, and participating first-time launch leaders

Summary:
The FTLA Kentucky event brought first-time launch leaders inside McKesson Third Party Logistics operations for a full day dedicated to one connected launch journey: **learn, see, apply, and connect**. Unlike a traditional conference built around presentations alone, this immersive program paired expert-led discussions with a guided distribution-center tour, candid peer dialogue, practical launch-planning exercises, and an evening networking reception at Jim Beam Distillery.

The day began by mapping the complete product path to the patient and examining how decisions made across clinical development, manufacturing, packaging, supply chain, commercial operations, market access, quality, regulatory, finance, legal, information technology, and external partners ultimately converge at launch. Participants then stepped beyond the meeting room and into the operational environment, seeing firsthand the people, systems, controls, data exchanges, storage requirements, physical handoffs, and exception pathways that must work together before a product can reach a patient.

The afternoon moved from observation to application. First-time launch practitioners and industry experts explored the clinical-to-commercial transition, channel and distribution design, patient services, reimbursement, evidence and payer value, state licensing, serialization, systems integration, quality agreements, risk management, and Day 1 execution. The discussions were intentionally candid, giving attendees direct access to lessons that are often learned only after a launch encounters delays, product holds, access barriers, or avoidable operational complexity.

What made the Kentucky event distinctive was the opportunity to connect strategy with real operations. Attendees did not simply hear that launch decisions are interdependent—they saw where those decisions surface inside a 3PL, challenged assumptions with experts, compared approaches with peers, and left with practical questions and actions for their own organizations. The formal program concluded with an evening reception and dinner at Jim Beam, where conversations continued well beyond the final session.

The Experience:
The event was structured to follow the launch journey from early strategy through execution:

- **FTLA and McKesson 3PL Welcome:** Establishing the objectives for a day centered on practical, cross-functional learning.
- **Product Path to Patient:** Mapping how upstream development, manufacturing, packaging, supply chain, commercial, access, and quality decisions shape the downstream patient experience.
- **Guided Site Tour:** Examining 3PL operations in practice, including receipt, storage, inventory control, serialized data, order processing, distribution, and exception management.
- **Networking Lunch:** Creating space for attendees to compare one decision, dependency, or risk with a peer outside their immediate function.
- **Commercialization Front Lines:** Hearing directly from launch leaders operating under compressed timelines and managing real-world trade, distribution, patient support, and channel decisions.

- **Building the Complete Access Strategy:** Exploring how route of administration, site of care, payer evidence, pricing, reimbursement, patient services, and provider economics influence whether an approved product can actually reach patients.
- **Quality, Compliance, and Risk Management with a 3PL:** Clarifying what can be outsourced, what remains with the manufacturer, and where ambiguity can create launch-threatening risk.
- **Turning Learning into Action:** Connecting the day's lessons to milestone-based launch plans, cross-functional dependencies, decision rights, and next steps.
- **Jim Beam Reception and Dinner:** Extending the peer exchange and relationship-building that make in-person FTLA events uniquely valuable.

Key Insights:

Launch execution is an interconnected system—not a sequence of isolated workstreams. A first launch cannot be managed as separate clinical, manufacturing, supply chain, access, commercial, quality, and technology plans. Decisions in one area create requirements, constraints, and risks elsewhere. The organizations best positioned for launch are those that make these interdependencies visible early and manage them through a shared enterprise plan.

The product path to the patient should be designed backward from the patient and site of care. Route of administration, treatment setting, prescribing workflow, dispensing channel, reimbursement model, monitoring requirements, ancillary materials, packaging configuration, and patient-support needs all influence the operating model. Working backward helps organizations identify the right partners, data, licenses, systems, evidence, and capabilities before expensive decisions become difficult to reverse.

A facility tour reveals dependencies that slides cannot. Seeing McKesson 3PL operations firsthand made the consequences of upstream decisions tangible. Packaging dimensions, label placement, aggregation, barcode readability, temperature controls, serialized data, customer records, order quantities, shipping configurations, and escalation procedures all affect whether product can move efficiently through the distribution network. What may appear to be a minor design choice upstream can become a costly operational constraint downstream.

The clinical-to-commercial transition requires an enterprise mindset shift. Clinical success establishes the opportunity to launch, but commercialization requires the organization to understand how a product will be manufactured, packaged, licensed, distributed, prescribed, reimbursed, supported, and monitored in the real world. Retaining clinical knowledge while introducing experienced commercial, access, supply chain, quality, and operational leadership can accelerate this transition and reduce preventable gaps.

Starting early is more than a scheduling advantage—it is a risk-control strategy. Several discussions reinforced that launch-critical activities often require more runway than expected. State licensing, contracting, partner selection, evidence generation, packaging validation, serialization, system integration, channel design, data setup, and quality agreements can each become schedule drivers. Beginning early gives teams time to educate leadership, challenge assumptions, resolve dependencies, and adjust as clinical, regulatory, or funding conditions change.

Channel strategy must reflect how patients will actually access treatment. Companies must decide whether product will move through full-line wholesale, specialty distribution, specialty pharmacy, direct-to-site, buy-and-bill, or another model. Those choices affect licensing, title transfer, contracting, inventory, reimbursement, patient support, data visibility, and provider experience. A channel that looks efficient on paper can fail if it does not match the site-of-care workflow or the realities of prescribing and reimbursement.

Market access is the fourth launch hurdle. Regulatory approval confirms that a product is safe, effective, and can be manufactured to quality standards; it does not guarantee reimbursement. Payers evaluate value through clinical differentiation, standard of care, budget impact, cost offsets, evidence, covered population, and the broader economics of treatment. Access strategy and evidence planning therefore need to begin while clinical-development decisions can still be influenced—not after the label is finalized.

Patient access can break even when product is commercially available. A prescription sent to the wrong pharmacy, an incomplete benefits investigation, an unclear monitoring requirement, missing product information in an electronic health record, insufficient payer coverage, or an unprepared site of care can prevent treatment. Day 1 readiness must extend beyond having inventory in the channel to ensuring that providers, pharmacies, service partners, payers, and patients can navigate the complete access pathway.

The right partner is not simply the partner that says it can perform the work. Attendees stressed the importance of rigorous partner selection, relevant references, cross-functional evaluation, and direct engagement with the people who will support the account. Strong partners challenge assumptions, identify risks, respond thoughtfully, understand the operating model, and demonstrate that they will remain engaged when the launch moves beyond the proposal and into execution.

A 3PL should be involved while the operating model is still being shaped. Early engagement allows the 3PL to identify potential constraints involving channel design, packaging, storage, temperature control, ancillary kits, shipping configuration, downstream customer requirements, licensing, serialized data, and exception handling. Waiting until the model is effectively locked may leave the company with limited and expensive options.

Technical readiness is not the same as operational readiness. A system connection may test successfully while the first commercial shipment still fails because serialized data do not match the physical cases, a barcode cannot be scanned, an aggregation hierarchy is incorrect, a temperature logger is unexpected, customer information is missing, or the escalation contact is unclear. Dry runs and end-to-end simulations expose these issues before commercial inventory and patient access are at risk.

DSCSA links the physical product and its data throughout the supply chain. Serialized identifiers, physical cases, pallets, transaction data, and trading-partner records must remain aligned. A misplaced case, extra bottle, incorrect label, or data mismatch can trigger a suspect-product investigation and place inventory on hold for an extended period. First-time launch organizations need ownership, governance, technical capability, and clear exception processes—not merely a serialization vendor.

Exceptions should be designed into the operating model. Launch teams naturally focus on the expected pathway, but operational resilience depends on planning for the unhappy path. Temperature excursions, shipping disruptions, customs sampling, missing licenses, unreadable labels, incorrect aggregation, delayed data, product damage, recalls, and after-hours delivery can all occur. Teams should know in advance who decides, who investigates, who communicates, what data are required, and how product disposition will be determined.

Execution may be outsourced; accountability cannot. A manufacturer can rely on contract manufacturers, packagers, serialization providers, 3PLs, specialty distributors, pharmacies, consultants, and technology vendors, but it remains accountable for the product, quality decisions, compliance, partner oversight, and patient outcome. Contracts and quality agreements should define responsibilities precisely rather than relying on broad statements about compliance with applicable laws.

Quality must be represented across the launch journey. Quality is not a final release step. It affects supplier qualification, packaging, stability, serialization, distribution, deviations, product disposition, recalls, change control, documentation, and post-launch governance. Under-resourcing or involving quality too late can delay product release and create avoidable risk across multiple partners.

Governance must continue beyond implementation. Launch hypercare may require daily communication, but effective partnership also depends on a sustainable governance model. Manufacturers and partners should regularly review performance, exceptions, upcoming changes, forecasts, emerging risks, and improvement opportunities. The strongest relationships create transparency early enough to prevent surprises rather than merely report them after the fact.

Key Takeaways:

- Build one enterprise commercialization plan that connects clinical, regulatory, manufacturing, packaging, supply chain, commercial, market access, medical, quality, finance, legal, information technology, and external partners.

- Map both the **product path to the patient** and the **patient success journey**, then identify where they intersect at the point of care.
- Start with the intended patient, provider, treatment setting, and access experience before finalizing channel, packaging, partner, or system decisions.
- Begin commercialization planning well before approval and accelerate long-lead activities as clinical confidence, funding, and regulatory milestones develop.
- Engage the 3PL early enough to influence packaging, channel, licensing, serialized data, customer setup, logistics, quality, and exception-management decisions.
- Select partners through a disciplined process that evaluates relevant experience, execution teams, responsiveness, references, risk management, and cultural fit—not familiarity alone.
- Clarify whether the launch will use a title, non-title, or transitional distribution model, and understand that title transfer does not automatically eliminate state licensing obligations.
- Treat state licensing as a launch-critical workstream with dependencies on domicile, operating structure, manufacturing partners, 3PL selection, intended customers, and state-specific requirements.
- Own serialized product data and design the DSCSA model so physical product and digital transaction records remain aligned across every handoff.
- Bring the contract packager, serialization provider, 3PL, technology teams, quality, and downstream partners together to test actual cases, labels, files, and aggregation—not only interfaces.
- Conduct end-to-end dry runs for the first commercial shipment, temperature-sensitive products, specialized channels, direct-to-site models, and high-risk patient pathways.
- Define the Day 1 plan in hours and days, including label finalization, batch release, packaging, receipt, serialized data, customer readiness, order processing, and channel availability.
- Establish an exception playbook covering product holds, data discrepancies, temperature excursions, customs issues, damaged shipments, recalls, suspect product, and after-hours events.
- Specify decision rights, contacts, notification timelines, evidence requirements, and product-disposition authority in contracts, quality agreements, procedures, and launch playbooks.
- Align market access, trade and distribution, patient services, field reimbursement, sales, medical, data, and site-of-care support so providers receive one coherent access experience.
- Engage payers early enough to understand evidence expectations, budget impact, standard-of-care comparisons, patient population, and the value story.
- Test whether prescriptions can be written, routed, adjudicated, supported, dispensed, delivered, and administered—not simply whether product can leave the warehouse.
- Maintain daily visibility during launch hypercare and transition to ongoing governance that addresses performance, risk, upcoming changes, and continuous improvement.
- Use cross-functional timelines to make assumptions, dependencies, funding decisions, and milestone changes visible to leadership.
- Plan to launch independently even when partnership or acquisition remains possible; a credible, executable launch plan protects optionality and strengthens enterprise value.

Why Being in the Room Mattered:
The Kentucky event demonstrated the value of experiencing launch operations rather than discussing them only in theory. Attendees saw the distribution environment, questioned experts responsible for real launch execution, heard candid lessons from leaders working through compressed commercialization timelines, and compared decisions with peers facing similar challenges. The day created space for questions that rarely surface in large conferences or polished presentations: What happens when the first serialized file does not match the product? Who makes the disposition decision? Which licenses determine where product can ship? How does a provider find and prescribe the product on Day 1? What does a 3PL need from the manufacturer before inventory arrives? Where will the patient journey fail if access, distribution, and support are not designed together?

Those conversations—and the relationships built around them—are difficult to reproduce after the fact. FTLA's in-person events offer direct access to operating environments, experienced practitioners, emerging-company peers, and launch-enabling partners who are willing to share what worked, what failed, and what they would do differently. For organizations

preparing for a first launch, missing these discussions can mean learning the same lessons later, under greater pressure and at a much higher cost.

The Kentucky program made one message unmistakable: **the best time to discover a launch dependency is in a room full of experienced peers and partners—not during the first commercial shipment.**

FTLA will continue creating opportunities for members to see launch operations firsthand, pressure-test decisions, build trusted relationships, and convert insight into action. Future programs will build on the Kentucky experience with the same commitment to candid discussion, practical learning, and access that cannot be replicated through a webinar or slide deck alone.

If you missed Kentucky, the next FTLA in-person experience should already be on your calendar.

INSIGHTS DOCUMENTS:

FROM COMMERCIALIZATION DATA FOUNDATION TO LAUNCH ADVANTAGE

Source: Beghou
Insight Document: *What First-Time Launch Teams Need for AI, Analytics, and Scalable Operations*

Summary:
This Beghou insight document examines how first-time launch organizations can build a modern commercialization data foundation that supports immediate launch decisions while preparing the company for advanced analytics, automation, and AI-enabled operations. Unlike larger pharmaceutical organizations, emerging biopharma companies often begin without legacy systems, entrenched processes, or complex technology environments. Although this creates resource and readiness challenges, it also provides an opportunity to build a connected, scalable foundation from the start.

The central premise is that commercialization data foundations can no longer be designed solely to consolidate information and produce static reports. First-time launch teams increasingly need governed, interoperable, and usable data environments that connect behavioral, market, medical, and operational context. This allows teams to understand what is happening, why it is happening, and what actions should follow—without relying on lengthy manual analysis or fragmented functional interpretations.

The document provides a practical roadmap for sequencing data, technology, governance, workflows, and organizational capabilities across the launch journey. It emphasizes starting with the decisions the organization must support, prioritizing investments by business impact and implementation complexity, and determining which capabilities should be accessed flexibly through partners versus owned as durable internal assets.

Key Insights:
A modern commercialization data foundation should function as an operating layer that connects strategy, execution, analytics, and decision-making across the organization. Traditional reporting foundations remain important, but reporting alone is insufficient for launch teams that need reusable business logic, governed access, interoperable workflows, and faster movement from business question to decision and action.

The first step is to define the launch decisions the foundation must support. Questions such as which healthcare professionals or accounts to prioritize, where patients fall out of the treatment journey, which market signals indicate prescribing potential, and how commercial, medical, and market access teams align around shared priorities should guide data and technology investments. Starting with these decisions helps teams distinguish launch-critical capabilities from investments that can wait.

Connected foundations can improve patient identification, market understanding, targeting, forecasting, field planning, medical insight generation, access strategy, supply chain operations, and performance management. For rare and difficult-to-identify patient populations, combining claims, structured and unstructured electronic medical record data, clinical expertise, and external validation can reveal disease signals that traditional approaches may miss. Greater patient visibility can materially improve forecasting, referral analysis, engagement planning, and launch confidence.

AI creates value when it is applied to trusted data, defined workflows, and clearly governed business problems. Practical applications include automated data-quality checks, metadata creation, business-rule documentation, compliance pre-review, natural-language querying, medical and market insight synthesis, predictive targeting, patient journey analytics, and anomaly detection. AI can also strengthen the foundation itself by identifying inconsistencies, structuring information, and accelerating data preparation.

Not every AI-enabled use case should move forward at the same time. High-impact, lower-complexity opportunities—such as standardizing launch KPIs, automating vendor data-quality checks, structuring medical engagement data, or flagging common content-review issues—can provide early value. More advanced opportunities, including precision targeting, next-best-action workflows, integrated access alerts, conversational analytics, and patient-finding models, should be sequenced deliberately as organizational readiness matures.

Some opportunities should be used selectively or deferred. Narrow productivity tools may support learning but are unlikely to influence launch outcomes on their own. Complex integrations for noncritical workflows, fully autonomous field or medical assistants, personalized promotional content at scale, and enterprise-wide AI programs without defined use cases can consume resources without delivering sufficient near-term value.

The document also highlights the importance of deciding what to rent and what to own. Early in the launch journey, targeted datasets, partner-managed environments, vendor-hosted tools, specialized analytics support, and point-in-time analyses can provide speed and flexibility. As launch approaches, organizations may need greater ownership of recurring datasets, shared definitions, integrated infrastructure, governance, reporting logic, and internal accountability. Renting can be a strategic path to ownership rather than a temporary compromise.

Regardless of the sourcing model, first-time launch organizations should retain ownership of business definitions, governance expectations, validation requirements, review pathways, and feedback loops. Vendor decisions should also account for whether data and outputs can be accessed, combined, and applied within future analytics and AI-enabled workflows. Restrictions that limit interoperability or reuse may create the need for expensive rebuilding later.

Key Takeaways:

- Start with the launch decisions, workflows, and business questions the data foundation must support rather than beginning with a technology platform.
- Build a connected foundation that brings together market, behavioral, medical, patient, access, operational, and performance context.
- Establish shared definitions, reusable business logic, governance, data-quality expectations, and clear ownership early.
- Sequence foundational capabilities around launch milestones instead of attempting to build a fully mature enterprise environment from the start.
- Prioritize investments using both business impact and implementation complexity.
- Focus early efforts on capabilities that improve launch decision quality, reduce manual effort, strengthen data readiness, or create reusable assets.
- Apply AI pragmatically where it improves structure, quality, context, compliance, workflow readiness, or access to launch-critical insights.
- Preserve qualified human review and accountability for regulated, scientific, commercial, and medical decisions.
- Use flexible partner, managed-service, and vendor models when speed, specialized expertise, and learning are more important than permanent ownership.
- Own the data, definitions, governance, and capabilities that support recurring cross-functional decisions and day-to-day launch execution.

- Evaluate vendor contracts and platforms for interoperability, data rights, scalability, and support for future AI-enabled workflows.
- Treat the commercialization data foundation as part of the launch operating model—not simply as a reporting or technology workstream.

This insight document reinforces that first-time launch companies do not need to replicate the technology footprint of a large pharmaceutical organization. They need a right-sized, connected foundation that helps a lean team learn faster, identify patients more effectively, coordinate across functions, and make confident decisions as market conditions evolve. When investments are sequenced around launch priorities and supported by trusted data, clear governance, and intentional ownership choices, AI and advanced analytics can help emerging organizations compete with greater speed and agility.

To access the full insight document and additional guidance, please view:
From Commercialization Data Foundation to Launch Advantage: What First-Time Launch Teams Need for AI, Analytics, and Scalable Operations

UPCOMING WEBINARS:

WINNING THE LAUNCH:

Defining Success Beyond Approval for First-Time Launchers

Date: November 19, 2026
Time: 11AM–12PM ET

Hear from **NNIT**, **Beghou**, and **Sage Advisors** in this interactive panel discussion that will challenge traditional definitions of launch success and explore the diverse perspectives that shape organizational decision-making.

For many emerging biopharmaceutical companies, success is often measured by achieving key development milestones such as positive clinical data, a successful NDA/BLA submission, regulatory approval, or manufacturing readiness. Yet industry data consistently demonstrates that many organizations struggle to meet launch expectations even after achieving these milestones. Why?

The reality is that "winning" means different things to different stakeholders.

For Clinical Development teams, success may be advancing a program through key milestones. Regulatory leaders may define success as achieving approval without delays.
Manufacturing and Supply Chain organizations focus on reliable product availability and uninterrupted patient access.
Commercial teams evaluate success through market adoption, demand realization, and achieving business objectives.
Investors may view success through growth, valuation, or acquisition outcomes. Ultimately, each function participates in a relay race where success depends on effectively passing the baton to the next team.
In this thought-provoking panel discussion, participants will examine why strong science alone is not always enough, how organizational silos can undermine launch readiness, and why cross-functional alignment is often the deciding factor between commercial success and commercial disappointment.

What You'll Learn:

- How different functions define launch success and winning.
- Common barriers that prevent organizations from achieving launch objectives despite promising therapies.
- The critical capabilities and "engines" that must operate in concert to support successful commercialization.
- Why first-time launchers face unique challenges compared to experienced commercial organizations.
- The importance of aligning around patient success while balancing commercial realities.
- Lessons learned from organizations that have successfully navigated the journey from development-stage company to commercial enterprise

Attendees will be **encouraged to participate** through audience polling and discussion around their own definitions of winning, creating a collaborative exchange of ideas rather than a traditional presentation.

The ultimate question explored throughout the session will be simple but powerful: **When your product reaches the market, how will your organization define "winning" and what must be true to achieve it?**

Register Here

UPCOMING IN-PERSON EVENTS

First-Time Launch Alliance Summit

Boston, 2026

Date: November 5, 2026
Time: 12PM–5PM (lunch 12pm–1pm, networking reception 5pm–7pm)
Location: Omni Boston Hotel at Seaport (450 Summer St, Boston, MA 02210)

The First-Time Launch Alliance (FTLA) is meeting once again to bring together first-time launch teams and commercialization leaders for an immersive day focused on the real-world challenges of preparing for and executing a first launch.

If you're preparing for your company's first commercial launch, this is an opportunity to step away from the day-to-day, learn from peers, and work through the decisions that matter most.

With limited seats to keep the experience dynamic and interactive, this is where insight meets impact. Don't miss it!

What to Expect:

- **Open + Frame:** Complimentary lunch at 12:00pm as we set the stage and frame the critical challenges facing first-time launch teams
- **Industry Panels:** Hear directly from industry leaders through two 45-minute panels featuring perspectives, experiences, and lessons from the industry
- **Collaborate:** Roll up your sleeves for a 75-minute breakout exercise designed to work through launch challenges together
- **Synthesize:** Bring it all together through facilitated readouts, turning the day's conversations into practical takeaways you can take back to your team

Event Schedule:

- 12pm: Networking lunch
- 1:00pm: Conference start
- 5:00pm: Conference ends
- 5–7pm: Networking reception

Panel Session: The Next Chapter of Commercialization for Emerging Biopharma

This Beghou-led panel will explore how first-time launchers build enough commercial capability to compete without pretending the future is settled. Drawing on experience across emerging, mid-sized, and large pharma, the discussion will examine where a lean organization can punch above its weight, where human judgment matters most, how commercial functions align around shared assumptions, and which lessons travel across company sizes.

Panelists:

- Adrienne Lovink, CEO, Beghou
- Lisa Lejuwaan, SVP – Head of Sales, DBV Technologies
- Katie Jepsen, Commercial Biotech Industry Leader
- Christian Hansen, Lead – Global Integrated Analytics, Sanofi

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

Thank you to our sponsors!



INNOVATION INCUBATOR

Innovation Incubator – IT Foundations

Date: October through December 2026

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

THANK YOU TO OUR SPONSORS!

SPONSORS: LAUNCH ENABLERS

PLATINUM

nnit

SAGE ADVISORS
LIFE SCIENCE CONSULTING

McKESSON
Third Party Logistics®

MedPro Systems

cencora

beghou

GOLD

&people

SILVER

CareMetx

BRONZE

tracelink.
NETWORK FOR GREATER GOOD

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

---

James Zenevitch
Founder of FTLA
JZEN@nnit.com
+1 (978) 994-5119

Visit the FTLA website

FIRST-TIME LAUNCH ALLIANCE

Credible. Connected. Collaborative.