

The  
5-Step  
Process for  
Ensuring  
Launch  
Readiness

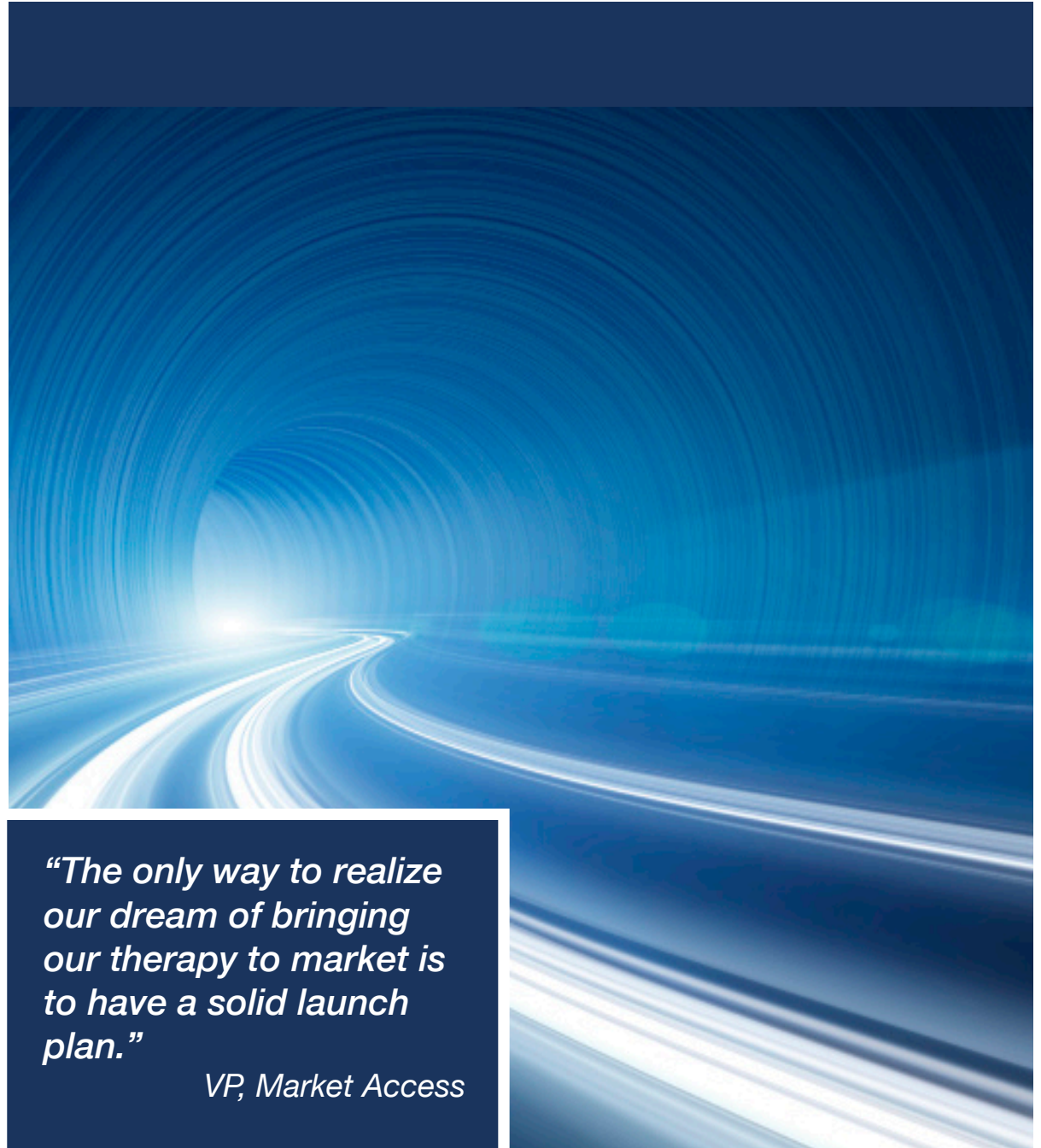


# The Path to a Successful Launch

Over the past 3 years, IntegriChain has helped life sciences companies launch more than 100 products. In addition, we've helped more than 35 companies launch their first drug in just the last 24 months. So we know a thing-or-two about Day 1 readiness.

While every company is different, we have seen a fairly common 5-step path than many pre-commercial companies follow:

1. Establish the right payer and distribution contracts and ensure critical pricing processes, such as government pricing and Medicaid rebates are in place
2. Build the foundation for forecasting and measuring profitability
3. Leverage data to begin building data-driven, long-lasting relationships with channel partners, payers and specialty pharmacies.
4. Apply automation to drive scale and efficiency
5. Utilize analytics to identify opportunities for improving performance as well as optimizing the patient journey



*“The only way to realize our dream of bringing our therapy to market is to have a solid launch plan.”*

*VP, Market Access*



## Find a Back Office “Partner”

The first step involves creating a solid back-office capability. In most cases, this starts with contracting, pricing, and rebate management. Depending on your contracting strategy, you might need a variety of commercial and government payer contracts. One area of particular concern involves data-related contractual commitments. It is essential that your contract details what channel and/or patient data is required from your distribution and pharmacy partners. In the case of specialty drugs, contracts also need to detail expectations around patient service programs, costs, reporting, metrics, and service levels.

If government contracts are involved, you will also require a clear definition and documentation of your government pricing methodology along with a bullet-proof process to ensure all relevant prices (AMP, BP, ASP, NFAMP, etc.) are filed accurately and on-time. In addition, you will need an equally robust rebate management capability to ensure rebates are processed in an accurate and timely manner, and supports collaboration with federal and state Medicaid agencies. Lastly, it is essential that reporting and auditability be top-of-mind in setting up the back-office data models, systems, and processes.

## Build Foundation for Profitability Analysis

With a strong contract, pricing, and rebate management foundation in place, most Life Sciences manufacturers quickly turn their attention to profitability and gross-to-net (GTN) analysis. The financials of pre-commercial companies are heavily scrutinized by investors, auditors, and regulators, and having a well-defined, transparent, and consistent approach to GTN is critical. While most people immediately think about forecasting accuracy when GTN is mentioned, accrual management might be even more important and vastly under-rated in terms of importance of forecasting timeliness and accuracy. With limited time and scarce GTN expertise, many manufacturers turn to a managed service model to provide basic GTN capabilities, often starting with a spreadsheet-driven approach and then evolving to a highly automated, turnkey model.



*“Ideally, we’d love to be able to determine net-price in a consistent and predictable manner on Day 1. Given our resource levels and limited GTN expertise, leveraging a managed service model makes total sense.”*

*Chief Commercial Officer*



## Proactively Engage Channel and Specialty Pharmacy Network

To ensure a successful launch, manufacturers need to have the right processes, systems, and data to determine whether their product is in the right place, getting to the right patients, and whether patients are actually initiating and staying on the medication. As noted above, this all begins with the data-related obligations defined in the contract. From an operational perspective, most manufacturers contract with a data aggregation service that can pull together all of the relevant channel and/or patient data.

In addition, manufacturers also look for data enrichment and governance solutions that can improve the quality of the data and turn mountains of inbound data files into insight that can drive and accelerate decision-making. The data can show critical access insights such as whether product availability is an issue or where patients are encountering obstacles in getting the therapy they need. Manufacturers need this data to ensure they are able to actively manage their distribution channel and enforce contractual commitments.

## Automate Workflows for Efficiency

As the manufacturer brings these capabilities online, there is often a shift from basic operations (i.e, making them work) to applying automation to reduce the workload on the constrained set of resources. GTN is one area where automation is first applied. Spreadsheet-driven models are replaced with a truly automated, turnkey service that provides “what-if” modeling capabilities that simply aren’t possible with manual approaches. Beyond GTN, data analytics is another area where automation is frequently applied.

*“Having an automated process for gross to net accruals and forecasting dramatically improves our accuracy and audit-readiness.”*

*Senior Director,  
Sales Accounting*



Manufacturers shift from relying on periodic reports delivered by email to more dashboards and other visualizations as well as automated email reports to leadership that provide near real-time data to accelerate and streamline decision-making.

# Analyze

In the past, many manufacturers tried to make critical market access decisions using siloed data from their corporate data warehouse or from a generic data lake. Unfortunately, these approaches delivered un-enriched, siloed data that simply does not support actionable insights.

Conversely, we've seen that customers who adopt a comprehensive platform, even in a phased model, for launch readiness have all of the data, whether it is channel, rebate, contract, accrual or patient data, enriched and in a single, purpose-built platform. This enables them to achieve benefits that other organizations only dream of, including:

- Shifting from being reactive to proactive
- Dramatically improving operational performance of specialty pharmacy partners
- Using benchmark data to compare performance across payer and distribution channels
- Clear line-of-sight into access-related obstacles impacting patient initiation
- Prevention of stock-outs and excessive returns
- Rapid identification and remediation of payer-related issues including prior authorizations, denials and other policy restrictions
- Confidence in meeting all contractual and pricing commitments and filings



# Summary

Preparing for a launch that has been years in the making is no easy feat. It is easy to lose track of time and all of the key access-related capabilities that need to be in place.

Emerging manufacturers consistently choose IntegriChain as their launch partner, enabling them to stay focused on their core development work while IntegriChain puts a market-proven launch platform in place.



## About IntegriChain

IntegriChain is Life Sciences' data and application backbone for patient access and therapy commercialization. More than 250 manufacturers rely on IntegriChain's ICyte Platform to orchestrate commercial and government payer contracting, patient services, and distribution channels. ICyte is the first and only platform that unites the financial, operational, and commercial data sets required to support therapy access in the era of specialty and precision medicine. With ICyte, Life Sciences innovators are digitalizing labor-intensive processes – freeing up their best talent to identify and resolve coverage and availability hurdles and to manage pricing and forecasting complexity. IntegriChain is backed by Accel-KKR, a leading Silicon Valley technology private equity firm.

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