

Delivering the Commercialization Platform for Success in Women's Health



BRINGING INNOVATION TO MARKET

Women's healthcare is a large and growing market, fueled by the growing awareness of early diagnoses and advanced therapies as well as innovative drugs. In 2013, an emerging pharmaceutical manufacturer was seeking to introduce a new drug to improve women's health. Unfortunately, the road to launch hit a roadblock when they received a complete response letter (CRL) from the FDA.

After four years of additional research and testing, the manufacturer re-submitted their application for approval only to receive a second CRL verdict. Finally, the manufacturer addressed outstanding product issues and submitted their approval application in mid-2019. It was around this time that IntegriChain, based on a prior relationship with the head of market access, began working with this manufacturer. The leadership team was finally confident in a smooth road to launch and defined two critical elements of their commercialization strategy including:

- **Contracting Strategy.** Since women's health is a particular concern in underserved segments of the population, the team felt they needed to contract with both commercial payers as well as participate in government programs such as Medicaid and Medicare.
- **Channel Design.** Based on the large audience and low level of complexity in terms of route of administration, a retail/mail-order channel of distribution was selected.



However, the team has a number of concerns about their launch readiness (below). Based on these issues, the executives began looking for potential go-to-market partners who would be able to gradually address these concerns.

01. Payer Approval

Their therapy was more expensive than other oral-based drugs and there was a concern over coverage from Medicaid/Medicare.



02. Inventory Visibility

Lack of visibility into distribution and downstream inventory could result in stock-outs and patient frustration.



03. Net Price Predictability

The highly competitive market meant tight margins and therefore, tight control over accruals and forecasting was critical.



04. Immediate Compliance

Being in compliance with channel agreements as well as Commercial and Government payer contracts on Day 1 was essential.



05. Vendor Management

Team has little bandwidth to manage separate vendors for contracting, channel data, gross-to-net, government pricing and rebate management.



Insights Gained

While the manufacturer was waiting for FDA approval, IntegriChain continued to work with the manufacturer to better understand their launch-related needs and shared with them experiences with similar pre-commercial IntegriChain customers. Several key issues surfaced during these numerous discussions, all of which contributed to developing a strong, growing, and trusted relationship:

- **Value of a Platform.** The manufacturer shared a common vision of being able to manage multiple facets of market access using a common analytics and data platform.
- **Importance of Data Quality.** Significant concerns were raised regarding how to get high-quality product and inventory data to simplify and accelerate decision-making.
- **Complexity of GTN.** The leadership team developed a deep understanding of the challenges around GTN accrual, forecasting, and scenario modeling processes.







The Solution

With the approval by the FDA in early 2020, the team began to accelerate its commercial activities with a targeted initial shipment in the fourth quarter of 2020. Based on the prior dialogue and established relationship, IntegriChain was invited to present its blueprint for launch success. The manufacturer was particularly impressed with several aspects of IntegriChain's offering:

- **Managed Service.** This was particularly attractive given the limited resources to effectively operationalize government pricing contracts and process Medicaid rebates.
- **Data Management.** IntegriChain's ability to aggregate data from a wide array of wholesalers, pharmacies, and other retailers and leverage that data to provide near real-time insight into downstream inventory was appealing.
- **Gross-to-Net.** The leadership team was so focused on engaging with the FDA and getting the necessary contracts and pricing methodologies in place that

they fell behind on putting a gross-to-net process in place. IntegriChain was able to design and implement a rapid GTN roadmap to launch and was also the only potential partner that could flow all of the contract- and channel-related discounts, fees, and rebates into a consistent, audit-ready accrual and forecasting model.

Based on the established relationship, IntegriChain's capabilities and experience enabling more than 100 product introductions in the past three years, the manufacturer decided in June 2020 to move forward with the following IntegriChain solutions:

CHANNEL DATA SOLUTIONS	 <p>Channel Data Aggregation Aggregate all channel data sets, including distributor sales, distributor inventory, specialty pharmacy inventory, and product returns.</p>  <p>Inventory Analytics 100% visibility to downstream inventory, from the retail pharmacy shelf to specialty, mail and institutional channels. Reduce risk of channel stock-outs, accrual risks while improving forecast accuracy with total pipeline inventory reporting.</p>
CONTRACT & PRICING SOLUTIONS	 <p>Government Pricing (GP) Managed Service. Expert management of complexities and compliance requirements of GP, including comprehensive and auditable control reports covering all price calculation details to ensure contractual commitments around regulated pricing submissions are met.</p>  <p>Rebate Managed Service. Timely, reliable and secure contract management, formulary validation and processing of the full range of claims including Medicaid, Managed Care, Tricare, and Coverage Gap to meet contractual commitments around rebate claims processing.</p>
GROSS-TO-NET SOLUTIONS	 <p>GTN Forecasts. Achieve consistent, audit-ready GTN forecasts leveraging IntegriChain's industry-proven GTN methodology library, improve forecast accuracy and create "what-if" scenario models.</p>  <p>GTN Accruals. Increase speed and accuracy of GTN close and improve product-related decisioning with trusted, aligned and consistent data.</p>

The Outcome

With all of the contracting, pricing, channel data and gross-to-net operations all working on a common data and analytics platform, the manufacturer is confident in the ability of their commercialization platform to handle their current and anticipated growth. As the business matures, the manufacturer envisions additional investment, primarily in the area of data visualization and analytics. The leadership team believes this is the key to more effective contracting and pricing, driving stronger channel relationships, as well as improving patient initiation and adherence to their innovative therapy.

“To meet our Q4 launch target, we had to address several critical market access needs. IntegriChain was the only partner that not only had the breadth and depth of expertise, but had played a key part in drug launches many times before”

Sr VP, Market Access

About IntegriChain

IntegriChain delivers Life Sciences' only comprehensive data and business process platform for market access. More than 220 life science manufacturers of all size and complexity rely on IntegriChain's analytics, applications, managed services and expert advisors to power their operations and harness the value of their channel, patient and payer data. IntegriChain has played a vital role in more than 70% of product launches over the past two years including 35 first launches. For more information, please visit www.integrichain.com or ic@integrichain.com



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