

Making Gross-to-Net a Reality for Expanding Oncology Therapy Manufacturer





PATH TO NET-PRICE PREDICTABILITY

For many emerging pharmaceutical companies, designing a gross-to-net (GTN) organization, process, methodology, and supporting technology to enable executing

against their commercial and financial strategy is a tremendous challenge. Such was the case for a pharmaceutical manufacturer that was looking to apply its antibody and protein technologies to the US oncology market. Approximately six month prior to submitting a BLA application for approval, the leadership team began working with IntegriChain around preparation for launch. The initial area of focus was GTN and there were numerous concerns including:

"This is about as seamless a process as it can be up to this point. I can't thank the IntegriChain team enough."

VP, Finance

- **Compliance**. How could they have a robust, audit-ready GTN process in time to close their first month of operations?
- **Timeliness**. Their parent company in Europe demanded very tight adherence to their on-time close processes and timelines.
- Resources. Identifying, hiring, and training a finance department to design and implement a GTN process in 12 months was a daunting task.

The first engagement between the two companies began more than 12 months before their ultimate launch. IntegriChain was asked to help the leadership team identify an appropriate GTN framework and develop a GTN model using advanced spreadsheet models. IntegriChain's Advisory Services covers a broad range of market access challenges including launch readiness, process and compliance, channel data management, patient access, revenue leakage, and more. Additionally, the Advisory team has deep expertise in government programs, CMS regulations and rulings, state pricing transparency, 340B, and Federal Supply Schedule (FSS) programs.



Advisory Services



Gross-to-Net Advisory

Leverage IntegriChain's GTN expertise, best practices and industry benchmarks to ensure an accurate, efficient and audit-ready GTN process

Through its GTN Advisory Services, IntegriChain was able to design and document a GTN Roadmap to Launch, which served as the blueprint for Day 1 readiness. With this framework in-hand, the manufacturers' leadership was confident they would be able to execute this roadmap on their own.

The Clock is Ticking

Not long after submitting their BLA application, the manufacturer received FDA approval and a mid-2020 PDUFA date. All of this accelerated the need for Day 1 readiness. However, the manufacturer was still struggling to operationalize their GTN plan. With launch a mere six months away, the leadership team contemplated shifting to a managed service for GTN but had serious reservations about accrual and forecast accuracy, transparency, and audit-readiness of all calculations in addition to being able to close the books on the first month of operations.



Based on the ongoing dialogue and initial work done around GTN, the manufacturers' leadership team invited IntegriChain back to demonstrate how the GTN managed service works as well as how they might be able to benefit from other outsourced



managed services. Both the manufacturer and IntegriChain realized that the leadership team had a clear vision of how their operations should work but lacked the time, resources, and best-practices to rapidly implement and make succeed. With its combination of managed services, advisory services, and complete market access platform, IntegriChain was clearly the ideal partner.

The Solution

In February 2020, the manufacturer selected IntegriChain's GTN solutions:

GROSS-TO-NET SOLUTIONS



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.



GTN Accruals. Increase speed and accuracy of GTN close and improve product-related decisioning with trusted, aligned and consistent data.

The manufacturer's leadership team was heavily involved early-on in all aspects of the GTN application configuration, report definition, and process design. This was critical to both ensuring efficient implementation of the managed service as well as to identifying additional ways in which IntegriChain could be of value.

For example, IntegriChain was engaged in March 2020 to assist with advisory services around contracting and pricing, including 340B, P-number, and Coverage Gap best practices. Additionally, IntegriChain was asked to assess the manufacturer's readiness in terms of the roadmap to achieve world-class data aggregation, 360-view of product performance, and deep insight into channel partner performance.

Advisory Services



Channel Advisory

Develop world-class channel data aggregation, refinement, data management and channel analytics strategies leveraging industry best practices and benchmarks.



Contracts & Pricing Advisory

Provide insight, benchmarks, and best practices to develop and implement higher-impact commercial and government contracting and pricing strategies.



With some of their basic GTN forecasting needs resolved, the leadership team and IntegriChain engaged in discussions around how to improve the data which was fueling the GTN calculations. Numerous discussions and workshops were conducted to

discuss how to ensure SOC compliance of incoming channel data, steps for achieving seamless integration of channel data with GTN processes, and best practices for transforming the data into high-impact analytics and insights. These discussions highlighted IntegriChain's expertise in understanding the end-to-end GTN process and, together with



IntegriChain's experience helping similar customers, the leadership team decided to increase their investment in the IntegriChain platform with the following solutions:

CHANNEL SOLUTIONS



Channel Data Aggregation

Aggregate all channel data sets, including distributor sales, distributor inventory, specialty pharmacy inventory, and product returns.

CONTRACT & PRICING SOLUTIONS



Rebate Managed Service. Timely, reliable and secure validation and processing of a wide range of fees and rebates including GPO membership, purchase-based admin fees, and coverage gap to meet regulatory and contractual commitments.



The Results

IntegriChain turned out to be the perfect fit for a number of reasons:

- Complete Vision. IntegriChain offered a complete market access platform, which supplemented their commercial operations and analytics landscape, delivered innovative technologies and approaches, and enabled the manufacturer to execute against their commercial and financial strategies.
- Tailored Implementation. The manufacturer was able to evaluate and choose
 the pieces of the platform they needed, at the pace they were able to move. This
 created a very trusted, low-pressure relationship and enabled a tailored solution
 to be implemented.
- Rapid Time-to-Value. Early and consistent commitment and engagement of the leadership combined with a phased implementation of the modules chosen by the manufacturer contributed to a highly efficient and rapid implementation.
- Extra TLC. IntegriChain implemented all required solutions in time for launch. However, IntegriChain wanted to be sure to alleviate the manufacturer's concern about being able to close the first month of operations. To address this issue, IntegriChain's implementation team performed a technical go-live of the GTN application several days ahead of schedule and executed a pre-close calculation ahead of the normal service cadence. All of this allowed the monthend Close Accrual process to begin 30 days ahead of schedule. The customer was thrilled with our efforts and ability to implement creative solutions to ensure a seamless and efficient process this first month of service.

Looking ahead, the manufacturer is likely to leverage additional IntegriChain solutions around analytics, data visualization, and potentially having IntegriChain become their primary government pricing service provider.

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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