Whitepaper

IntegriChain®

Top 10 Gross-to-Net Accounting Practices for Successful Product Launches in the Life Sciences Industry

The Gross to Net Difference

In the life sciences industry, Gross-to-Net (GTN) accounting has emerged as a competitive differentiator. Firms seeking to maximize success for newly launched therapies understand that GTN – when done right – can improve patient access to therapies while driving revenues.

GTN, of course, involves the web of accounting activities associated with launching therapies: pricing and contracting, forecasting, chargebacks and rebates, accruals, compliance, and more. To manage it effectively, you need clear, flexible processes and smart data management. To use it as a differentiator that shareholders reward, you also need insight and help from a trusted partner with tools, know-how, and experience.

IntegriChain has helped dozens of life sciences firms stand up sophisticated GTN programs supported by technology and expertise. Based on working with these customers, we've developed a top 10 list of the most important practices to adopt when moving forward with GTN in the life sciences industry. Read on.

#10: Address the Talent Dilemma

You have two main options when it comes to GTN expertise: hire or outsource. Some organizations have the resources to hire experts and manage processes internally. Many organizations underestimate the difficulty in finding qualified candidates and the complexity of forecasting nuanced, lagged programs like coverage gap, commercial price protection, market and product lifecycle events. As a result, most organizations launching for the first time, however, seek out a partner.

Maybe you need a quarter of an analyst, half a data scientist, and some part-time management. This is difficult to hire. The right partner can help across a wide range of areas, including:

- Government price reporting
- Commercial contracting/analytics
- Rebate/chargeback processing
- GTN forecasting and management

Another factor is automation. Today's leading GTN partners offer managed services

that automate the way data is aggregated, reconciled, analyzed, and shared. From setting up data source documentation to closing the books, managed services are an important way that lean firms are maximizing their resources.

#9:   Form Cross-Functional Teams

 It is a common misunderstanding that Gross to Net processes are owned exclusively by Finance. The fact is that multiple stakeholders across Market Access, Sales Operations and Marketing are critical to tightly managed GTN line items. Therefore cross-functional teams must be considered a critical success factor.

Particularly with start-ups and first-launch firms, the GTN function acts as a hub of activity and insight that helps focus the organization as a whole. This function is often headed by a strong, consensus-builder in either the finance or the market access team who acts as a central point of contact and has a stake in ensuring that critical information on pricing and contracts flows throughout the organization.

Cross-functional, however, doesn't mean singular. Successful organizations establish multiple teams that work across silos. Examples include pricing committees, GTN working teams, or sales. When such teams

work from a single source of the truth based on a consolidated view of all relevant datasets, consensus for moving forward is the result. Now it's possible to establish processes for GTN forecasting and accrual management. Now you can move forward as a single organization with a common purpose and full transparency at the strategic and operational levels.

#8:   Evaluate Enrollment in Government Programs and Understand Launch Pricing and Contracting Strategies

Participation in major government programs such as the Medicaid Drug Rebate Program, Public Health Services, Medicare Part D Coverage Gap, and the Federal Supply Schedule (FSS) Service is not necessarily a requirement for every new product launch.

Enrollment in such programs should be evaluated on a case-by-case basis with the understanding that participation in certain programs may require participation in others. Ultimately, decisions need to be made based on visibility into all available options and an analysis that considers the impact on long-term commercial strategies.

Much is riding on the price you initially set for soon-to-be-launched drugs or therapies. Indeed, decisions made early on regarding launch price, commercial discounting, and government programs can have GTN implications for the life of the product. Many nuances of timing and structure must be carefully considered to ensure new products are set up for long-term GTN success. Getting started early on these issues can make a significant difference.

#7:   Establish your Approach to Accruals

Accrual strategies are typically based on assumptions or analogs – or a mixture of both. Analogs to other therapies in the market can help you set a solid accrual baseline with confidence. But in cases where a new therapy is highly innovative – or even revolutionary – what precedents can you look to?

In such cases, it is often possible to find analogs in the industry for discrete aspects of the drug your firm is producing. Perhaps your product shares a common delivery mechanism with other drugs that can provide a relevant returns analog. Or maybe your product targets people 65 and over – in which case other drugs focused on the same demographic may provide a relevant coverage gap analog.

Next, you need to set up an accrual method. Will you track accruals at the point of sale or when you close the books at the end of the month or quarter? In either case, you need to be compliant with ASC 606 regulations that require you to choose between "most likely" and "expected method" for revenue recognition. The most likely method is typically based

on solid analogs with predictable revenues. The expected method usually involves multiple analogs and assumptions, each of which is weighted to arrive at a revenue forecast. Either way, establishing these methods early in the GTN process can help your launch go smoothly.

#6:   Know your Patient and Follow the TRx

In the life sciences industry, knowing your patient means understanding patient data. This requires sophisticated analytics.

Proper understanding of metrics associated with patient demographics, patient comorbidities, the patient/payer mix – and much more – can provide valuable insight into GTN line items. Based on these metrics, you can more effectively make downstream predictions and improve planning.

A new launch, however, has little of this data on hand – for the simple reason that the history of the launch has yet to be written. Instead, firms move forward based on assumptions – much of these coming from smart people in the organization with deep experience and broad understanding of the patient. Another source for early metrics comes from the cross-fertilization associated with the establishment of cross-functional teams. In addition, the right kind of launch partner can help add to the knowledge base up front and make it easier for your organization to generate and share the needed insight moving forward.

When devising your GTN methodology, the fundamental consideration is the difference between being reactive and proactive. Reactive methodologies typically involve manual accounting processes, Excel spreadsheets, and a lot of work on the backend to generate a true picture of GTN reality. Proactive methodologies require a more systematic approach that automates accounting processes and enables more real-time views of GTN.

Any GTN methodology will involve the following three key areas of concern:

- **Demand and inventory tracking**: Here, demand is focused on how many scripts are being written and making their way into patients' hands. Inventory is simply the product count in warehouses, in transit, or already delivered to pharmacies and healthcare facilities. Relatively straightforward, demand and inventory tracking are often done with spreadsheets and manual processes.

- **Unit and rate accounting**: If your objective is to accurately report and predict demand and inventory, here is where things get more complicated. Think of "unit" as the volume of product being moved and "rate" as the price – where the ultimate price is determined in a complex fashion that involves government mandates and discounting that often act as a tax on the manufacturer. A proactive approach to GTN seeks to build a bottom-up understanding of unit and rate accounting that goes beyond the simple calculation of volume x price. Without such a bottom-up approach that gets into the weeds of volume and pricing from the get-go, GTN teams need to spend a lot of time on the back end to accurately generate reports and forecasts that reflect reality.

- **Financial vs business views**: Finally, effective GTN teams have the capability of pivoting between financial views of GTN and business views of the same. For operational teams, this is critical. Financial views, for example, are required to

reflect transactions as they stand at the time of reporting. But in an industry where lags from Medicaid rebates and elsewhere are par for the course, such a view can wreak havoc with forecast accuracy. Thus, it is necessary to maintain a parallel business view – one that reflects the relevant "true-ups" that account for actual GTN standing after all transactions are cleared. Ultimately, this level of accounting requires a proactive approach to GTN with automation and the support of sophisticated systems capable of managing the underlying accounting complexity.

#4: Build your Forecast and Accrual Models

No GTN process gets off the ground without models. The question is how many do you build? Do you need models both for forecasting and accruals? Or will one of these suffice? Who owns them? What do they look like? These are all critical considerations.

Whatever your choice, adopting a systemized approach supported by technology and tools is a proven best practice for successful GTN processes. With a such a system, data visibility and control over the models is transparent. Forecast and accrual models can talk to one another. SOC compliance can be automated as well – with a transparent audit trail, clear documentation, and the ability to generate compliance reports on demand.

Ultimately, your GTN system needs to go beyond the limitations of individual spreadsheets sitting on siloes servers. Look for a web-based system that consolidates your view of relevant data, supports dashboards and sophisticated analytics, and makes collaboration across teams part of your day-to-day workflow.

#3:   Develop Patient Funnel Models for Complex GTN Channels

A patient funnel model takes an operational and analytical view of GTN line items to provide insight into a wide range of metrics regarding patient population, comorbidity, therapy area, product, pricing, and more. Ultimately, this insight helps you understand who, from your total patient population, may be eligible for specific programs (coverage gap, copay, etc.). This can help you to more accurately estimate unit utilization.

One best practice is to determine, as early as possible, which team should maintain ownership over the patient funnel model. Possibilities include operations, market access, or contracts and pricing – because these teams already own the assumptions, know the patients, and understand the associated programs.

Another best practice is to clearly understand the different versions of data used by different teams to generate copay or coverage gap forecasts. While different versions of the data may be important to simulate aggressive vs conservative launch scenarios, you nevertheless need to clearly communicate which version of the data (sales, utilization, shipments, demand, etc.) underpins the analysis.

#2:   Get Audit Ready

Clear systematic documentation is at the heart of compliance. To get audit-ready, you need to have all your documentation up to date and in place. What are your assumptions? What analog data have you used to make these assumptions? What methodology are you using to close your books? What are your inventory levels? Data for all of these areas needs to be made visible to management and – particularly if you're publicly traded – to regulators as well.

An important best practice in this regard is to engage with a CPA or some other firm with auditing and accounting expertise. The goal is to take compliance and auditing to the next level of revenue whitepapers and automated SOC controls. Getting this all in place takes time and requires audit and management review. For new product launches, the right GTN business partner can help you develop and maintain the core documentation required – which, ultimately, will help you move toward a successful first quarter close.
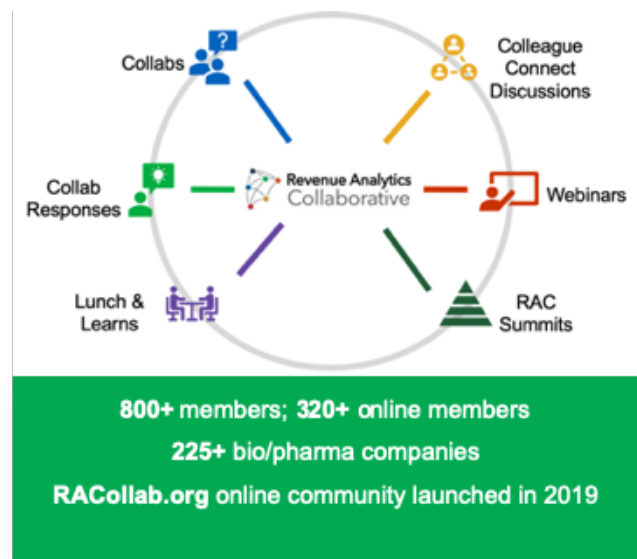
#1: Join and Participate in the Revenue Analytics Collaborative

By far, the most important single step you can take to ensure GTN success for new product launches is to join – and participate in – the Revenue Analytics Collaborative (RAC). Formed in 2014, the RAC now has more than 800 members from more than 230 different companies – with a vibrant online community of approximately 400 active participants as well.

The RAC is a collaborative, private, and anonymous network of business and financial professionals who own, support, and analyze commercial and governmental GTN data, processes, and systems in life sciences companies. Anonymizing all data and comments, the RAC maintains confidentiality and complies with regulations such as HIPPA. The RAC also produces informative benchmarks and hosts 'collabs' (industry shares) to share critical industry information and help companies meet their GTN challenges.

RAC members can join in discussion summits, learning sessions, networking opportunities, and more. IntegriChain, a longtime corporate member, regularly sponsors such events to help spread the GTN message and stay on top of evolving trends. The RAC is a great way to learn the fundamentals of GTN processes, access relevant data for making launch

800+ members; 320+ online members
225+ bio/pharma companies
RACollab.org online community launched in 2019

assumptions, and measure your own program against the experiences of peers in the field. This can help your organization avoid the pitfalls of setting up your GTN program and help your firm launch its product with greater likelihood of success. To join the RAC, simply visit RACollab.org.

Moving Forward with IntegriChain

There are a few themes that serve as a common thread throughout this paper. The first is to start early. GTN is not a process that can be "slapped together" quickly or as an afterthought. Early action helps ensure success for any new product launch. The second theme is understanding the "big picture". GTN depends on a multitude of inputs, many of which come from other teams such as market access, contracts and pricing and more. Bringing together stakeholders from across the organizations, aligning on key metrics and timeframes and defining a shared vision of success is essentials. The final theme is expertise. Whether it is designing your accrual strategy or your GTN methodology, having access to a community like the RAC and subject matter experts like IntegriChain can help ensure Day 1 readiness.

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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.