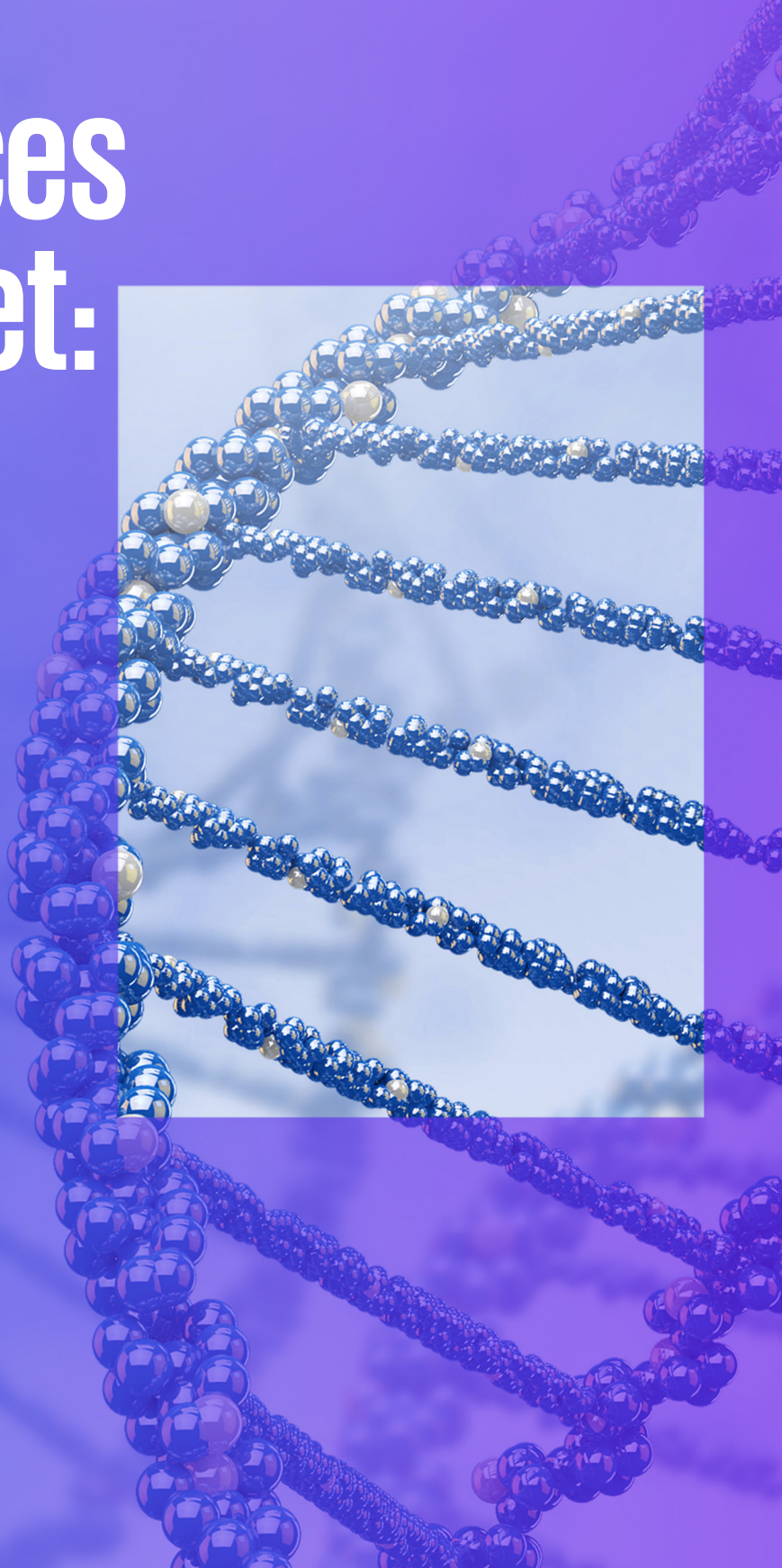# Life Sciences Gross to Net: Getting it Right

Introduction

Pharmaceutical manufacturers have long had complex go-to-market models: a dizzying array of payor and distribution channel contracts, patient support programs, government contracts, etc. These involve myriad direct and indirect discounts, rebates, patient programs, fees, and other factors driving difference between gross and net sales.

The situation has only become more complex in recent years due to regulatory changes and ever-evolving market strategies. This underscores the importance of gross-to-net (GTN) processes, which identify the true net-price, provide inputs to forecasts, and assist in the development of pricing strategies. Despite the importance of GTN calculations, many pharmaceutical companies have fallen behind in tracking this crucial metric, due to the unique nature of these calculations to each manufacturer, compounded by the multitude of variable factors and inputs that influence each calculation, which can vary over time. Failure to develop accurate GTN models and calculations can lead to misstatements of net revenues that directly affects manufacturers' bottom lines.

Further, it is important to keep in mind that GTN is highly individualized to each manufacturer. Therefore, any probable solution(s) to the GTN challenges will depend heavily on legacy systems, as well as current investments in technology, education, and training on current GTN calculation methodology.

This paper explores how manufacturers are able to improve and optimize their GTN processes in a fast-paced market. Refining operational processes, specifically in data analytic capabilities, will enhance the GTN model and equip manufacturers with what is needed to develop effective pricing strategies.

GTN Challenges

- Data silos prevent vendor and customer teams from consolidating information in a consistent efficient manner

- Analysis and supporting models, are manual processes (e.g. Excel spreadsheets)

- Access to channel data may be limited and significantly lagged (e.g. retail sales, Medicaid claims, etc.)

- Rebate/discount amounts are based on industry-wide data and factors (e.g. total government sales, etc.)

- Contractual terms and regulatory requirements are constantly evolving

What's changing and its impact

Innovation has continued to thrive across the worldwide pharmaceutical market, particularly in segments that have historically been less populated, including rare disease, cell, and gene therapy, etc. Due to the increased focus on innovation in these segments, as well as the growth of biosimilar competition, pharmacy benefit manager (PBM) formulary placement has become more competitive, requiring manufacturers to provide better rebates and incentives. The trickle-down effect of this shift in negotiation power has widened the gross-to-net gap.

Life sciences and pharmaceutical manufacturers face challenges in forecasting their net revenue because product pricing adjustments (discounts) to their gross revenue are overly complex, vary across market segments and customers, and contain high-data volumes to process. The challenge associated with forecasting net sales directly affects accrual management and product reserve accuracy. Moreover, due to the complexity and uniqueness of pricing adjustments, traditional spreadsheet-based approaches to forecasting lack scalability and are unable to incorporate interdependencies between market segments.

The complexity of GTN calculations is due to the complication associated with accurately forecasting future claims. These claims consist of payor coverage and the respective rebates and discounts, dispensing fees and commissions, payor, and distribution channel contracts, etc. Additionally, there are multiple workstreams across the manufacturing entity that participate in the various aspects of the GTN cycle, resulting in several internal dependencies in addition to the several external dependencies, some of which include the regulatory changes, lag time in obtaining claims from partners, etc.

Complexity of GTN

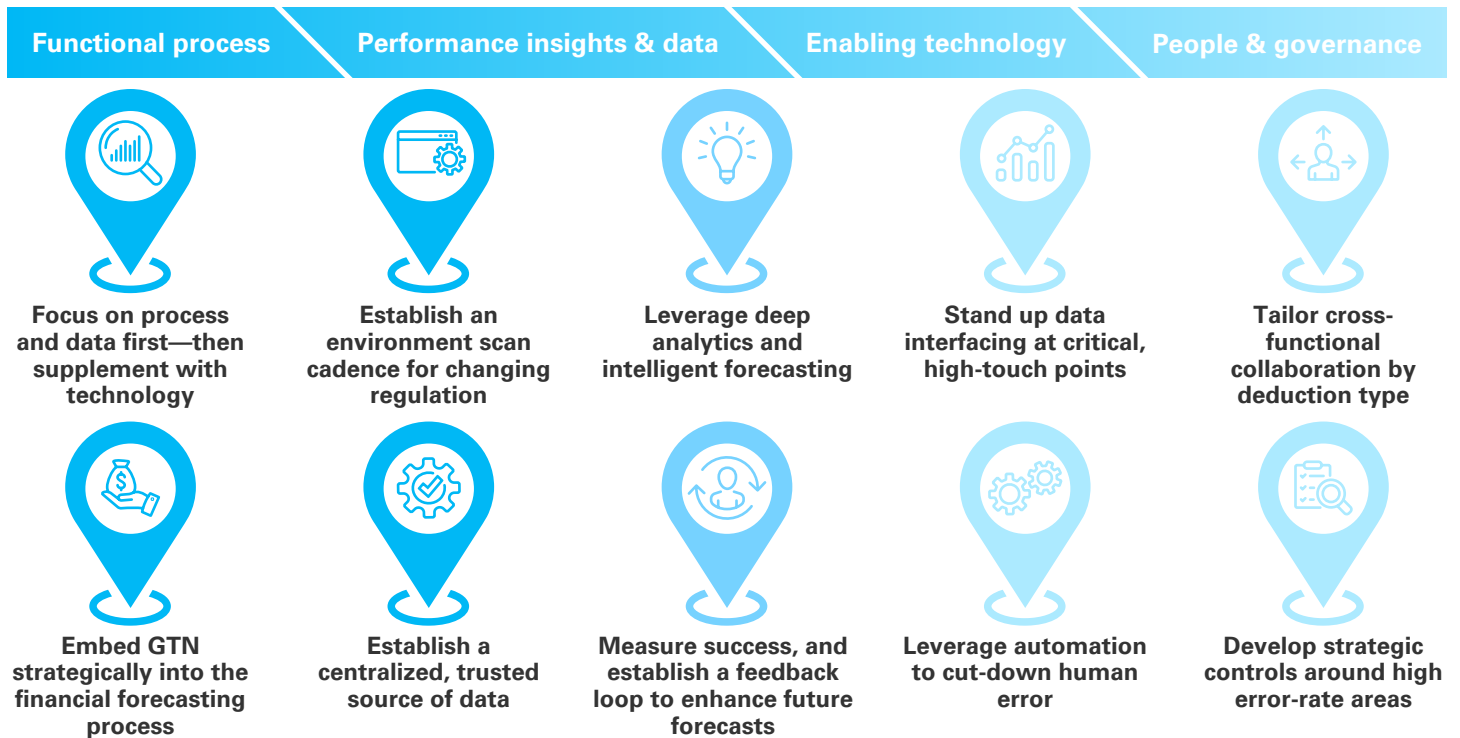| 01	02	03	04	05
Multiple systems involved that don't interface with each other	Manual process as a result of the lack of interfacing of systems that requires forecasters to make manual one off adjustments	Constantly evolving regulatory environment in both the US and other jurisdictions	Inherent long lag time in obtaining actual claims vs. the forecasted claims	Multiple teams involved in the GTN cycle that don't communicate well with each other—Contracts Pricing, Government Pricing, Revenue Accounting, FP&A, Legal, Accounts Payable

Achieving and maintaining GTN accuracy in a rapidly changing market requires a number of focus areas across the operating model

Functional process	Performance insights & data	Enabling technology	People & governance

Focus on process and data first—then supplement with technology

Establish an environment scan cadence for changing regulation

Leverage deep analytics and intelligent forecasting

Stand up data interfacing at critical, high-touch points

Tailor cross-functional collaboration by deduction type

Embed GTN strategically into the financial forecasting process

Establish a centralized, trusted source of data

Measure success, and establish a feedback loop to enhance future forecasts

Leverage automation to cut-down human error

Develop strategic controls around high error-rate areas

The healthcare landscape is constantly evolving, and, due to the intricacy of pharmaceutical GTN models, any number of market fluctuations can affect the myriad GTN inputs. For example, manufacturer rebates and discounts continue to expand as other players, such as distributors, become more concentrated, gain more negotiation power, etc. Therefore, as list prices continue to rise alongside the economic variability and high inflation, the GTN bubble expands, increased rebates are paid to distributors, and net prices fall.

A white paper by the USC Schaeffer School for Health Policy and Economics published findings showing that rising rebates demanded by PBMs is positively correlated with the rising list price in prescription drugs; on average, there is a $1 increase in rebates associated with a $1.17 increase in drug list price.[1] Pharmacy benefit managers regularly negotiate formulary placement of certain drugs depending on various metrics, including favorable rebate terms offered by the manufacturers. To maintain a favorable formulary position in increasingly crowded therapeutic areas, manufacturers facing patent expiration and biosimilar competition will require significant negotiation with the PBMs and require them to provide PBMs with more favorable terms.

In addition to the changing landscape between the various stakeholders themselves, there are also regulatory requirements and new legislation that will have downstream GTN implications. In April 2022, the Center for Medicare and Medicaid Services (CMS) issued a Final Rule that eliminates PBMs use of direct and indirect remuneration fees (DIR), which took effect in January 2024. As a result of the Final Rule, PBMs are no longer able to retroactively submit claims for these price concessions, which in turn will eliminate some variability in GTN forecasting with regards to these fees.

Also beginning January 2024, the Inflation Reduction Act (IRA) inflation penalty used to calculate rebates may now result in Unit Rebate Amounts (URA) that are higher than the Average Manufacturer Price (AMP), resulting in losses per unit sold. The 2024 rebate cap removal is expected to reduce margins on mature and established drugs, which are likely to be the most affected class of drugs. Additionally, manufacturers with portfolios that currently experience penny pricing are expected to face the most adverse impact to net price. Implementation of the IRA rebate cap removal will result in significant competitive landscape changes, specifically with manufacturers adapting new commercial strategies, including lower margins and less inflationary changes, with remaining and upcoming commercialized products. As we proceed through the next few years, we will see additional changes implemented by pharmaceutical manufacturers because of the provisions and requirements of the IRA.

[1] Source: U.S. Consumers Overpay for Generic Drugs, May 31, 2022.

The path forward

Pharmaceutical manufacturers need to constantly monitor their GTN processes, which includes maintenance and enhancement of accounting, reporting, and forecasting systems to maximize the use of data-driven insights.

These process enhancements can enable organizations to provide the best information to stakeholders for commercial and operational strategy and decisions, which includes determining viability by product, profitability by customer, and channel. Whether you've already pinpointed your goals and challenges for GTN processes or are looking to plan for the future, we can assist in mapping out your path forward.

To drive better results, the refined process should:

> Enhance data validity and consistency

> Enable predictive analytics

> Increase efficiencies and lower the risk of inaccurate reporting

> Reduce manual efforts

> Realize rapid speed to value through enhancements delivered

KPMG Deal Advisory & Strategy offers a complete range of integrated growth and performance enhancement services to support clients throughout the GTN cycle. We have extensive experience in assisting clients with establishing, evaluating, and enhancing their GTN function through a comprehensive, cross-functional approach that incorporates best practices in data and signals, informed drivers, and intelligent analytics. We come with deep GTN accounting and FP&A operating model design experience, including resources that have extensive work experience at pharmaceutical and drug wholesale-distributor organizations.

Examples of the engagements we support include:

> **Product Launch and Commercialization Analytics**
Assist in translating product and market research into financial forecasting models equipped with levers across distribution, provider, payor, and patient benefits channels

> **Cyclical Forecasting and Accrual Support**
Support and facilitate monthly and quarterly cyclical closes including accrual determination, re-baselining of assumptions, and forecast updates on a monthly, quarterly, or annual basis

> **Situational Modeling and Scenario Planning**
Enables cross-channel impact planning and modeling to quantitatively assess and measure the contracting, discounting, and pricing strategies on overall GTN liabilities and expenses

> **Revenue Leakage Framework**
Review documentation of baseline assumptions utilized to define the levers across distribution, provider, payor, and patient benefits channels

For more information, contact us:
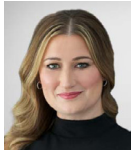
Kristin Pothier
U.S. Sector Leader, Life Sciences - Principal, G&S
617-549-2779
kpothier@kpmg.com

Alex Neil
U.S Deal Advisory & Strategy Sector Leader for Healthcare & Lifescience
949-885-5561
alexneil@kpmg.com

Chandan Dargan
Managing Director, Life Sciences – Deal Advisory & Strategy
609-664-6456
cdargan@kpmg.com

Steven Pham
Director, Life Sciences – Deal Advisory & Strategy
267-242-6756
stevenpham@kpmg.com

We would like to thank our contributors:

Sophie Kijel, Dawn Nagel, Jordan Seiferas

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