

## Driving Gross-to-Net Visibility and Control

*In this Perspectives interview, IMS Managed Markets Services' Mark Linver explains how companies can get a better handle on critical gross-to-net reporting and accrual processes by leveraging technology and best practices that help them more efficiently manage their accrual dollars and reduce revenue leakage.*

**Q: We are in a time of change unlike any other in this industry. Recent health care reform legislation will again alter the DNA of the industry in some critical areas relating to pricing, reimbursement, and value measurement. How do you see these changes unfolding?**

**A:** The first key area that I'm witnessing change or concern revolves around revenue leakage. Especially during a down economy, manufacturers are trying to ensure that all spend is accounted for and that they can accrue for discounts and returns properly, including chargebacks, rebates (Medicaid, Managed Care, Part D), returns and adjustments, admin fees, FFS, and cash discounts. Over the last year, accrual management has become a high visibility area for external auditors, who are focusing on whether manufacturers implemented a disciplined accrual management approach and if manufacturers have properly accrued. The second area is aggregate spend reporting. As more states begin to require spend reporting and with the Federal Sunshine Act now enacted as part of the recent health care reform legislation, manufacturers will work quickly to install or configure systems that will allow them to meet new compliance requirements.

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**Q: How can companies not only prepare for this change, but undertake the change proactively?**

**A:** Manufacturers I've spoken with are working to implement analysis systems that will give them a more accurate view of their accruals. To facilitate this, we recommend performing a current state assessment to diagnose people, processes, technology, location, and organization.

The assessment will identify gaps between existing operations and industry best practices, pinpoint potential areas to implement best practices, and identify risks and gaps within overall gross-to-net forecasting and accruals management processes to provide a roadmap for optimization and solutions implementation.

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**Mark Linver, Senior Principal, IMS Managed Markets Services**, has more than 20 years experience in successfully implementing appropriate solutions that solve real business needs. He has experience in managing complex projects that require process and requirements definition, technology development, and integration with business process. For the past six years, Mark has been involved in numerous audit and gross-to-net projects that have provided clients with quick returns on their investments in methodology, process, and systems. He has successfully managed large-scale contract management, clinical system implementation, fulfillment/help desk, IT strategy, and business intelligence projects for Fortune 50 pharmaceutical companies.

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**Q: How does this tie into Finance’s view of the gross-to-net picture? Why should people outside of Finance care?**

**A:** Gross-to-net is a collection of systems, data, processes, and people that work together to manage, monitor, and report on financial elements related to sales discounts. Finance teams need to work with business data owners to understand contracting changes, data trends, lag times, anomalies, and any process or systems breakdowns during a reporting period. Finance groups will always see the numbers but they need help in understanding them so that they can make sound decisions to make appropriate gross-to-net adjustments.

**Q: How does a company know that its gross-to net-processes are worst in class? What are the three to five practical questions a business executive should ask?**

**A:** Here are my top four:

- How much effort do you put into preparing for the gross-to-net portion of your yearly financial audit in time and resources?
- How do you verify your gross-to-net general ledger balances? Do you find your organization scrambling at the last minute to update the previous year’s manually intensive gross-to-net spreadsheet?
- Are you at odds with IT about how to generate sales and payment data files from different systems and locations?
- Do you accrue in real-time or at month end? What is your accrual calculation methodology? What forecasting model do you use? Are you leveraging third-party data?

**Q: Can you provide any examples of companies preparing for change?**

**A:** Like most complex business processes, you can’t simply install off-the-shelf systems for gross-to-net management. Manufacturers are all addressing the business issue in different ways with different technologies. Some use Excel spreadsheets, custom Access tools, and others customized routines in SAP or Oracle. The most successful I’ve seen are those

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*“Are you at odds with IT about how to generate sales and payment data files from different systems and locations?”*

manufacturers that implemented documented policies and procedures that support analysis methodologies as well as “drill down” tools. Drill down analysis tools allow business sponsors to closely monitor accruals throughout the year and make adjustments as necessary. The drill down capability is important in that it allows users to investigate anomalies in any of the discount areas and develop any reports required during an audit.

A specific example of a best practice audit by a manufacturer is one where we helped develop policies and procedures as well as drill down reports that the manufacturer uses to analyze accruals and adjust rates during the year. The full solution provided controls, discipline, and insight into operations that they previously didn't have. Towards the end of the implementation the manufacturer's gross-to-net accruals were audited by its external auditors. The manufacturer was able to produce detailed policies, procedures, and analysis reports for the auditors before the audit started. Having detailed information available to the external auditors before and during the audit helped the auditors proceed with minimal disruption to the manufacturer. The feedback we received from the auditor was that this was the smoothest gross-to-net accruals audit they ever experienced.

**Q: What are IMS's unique capabilities in this area? How are they different from conventional consultants?**

**A:** Our unique and comprehensive approach to tackling the challenges of gross-to-net has been developed by leveraging our industry leading experience and expertise in managed market services. We work closely with internal and external auditors, finance, IT, and commercial operations professionals extending our analysis of the impact of gross-to-net methodologies to government pricing as well as commercial operations effectiveness. We provide gross-to-net consulting services to life science companies in the following areas:

- Development of forecasting and accrual methodologies
- Development of automated tools for accrual rate monitoring and analysis
- Analysis, true-up, or reconciliation of gross-to-net reserve balances
- Development of gross-to-net management system that integrates all three areas
- Accrual rate analysis and maintenance
- Forecasting and accrual analysis and maintenance
- Reserve balance analysis and reconciliation

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## Percentages of Pharma Revenue Subject to Settlements and Discounts:

### Brand

- Rebates: 10% - 20%
- Chargebacks: 10% - 20%
- Admin fees: 3%
- Medicaid rebates: 15% - 25%
- Cash discounts: 2%
- Returns: 1% - 2%

### Generic

- Rebates: 5% - 25%
- Chargebacks: 30% - 90%
- Medicaid rebates: 15% - 50%
- Cash discounts: 2%
- Returns (including shelf stock adjustment reserve): 2% - 5%

The key is to take a deep dive into the transaction details of the numbers that make up gross-to-net balances across all sales discounts or deductions to produce a holistic financial view for our clients. The hundreds of thousands of transactions that need to be analyzed are difficult to manage for our clients and competitors. We have the skill set and toolset to decompose the data, analyze it, and produce meaningful results. We also leverage our in-house statistical services group and IMS data assets to integrate our client's data with our data to build sophisticated accruals forecasting models.

For example, one of our clients had significant challenges accruing for rebates due to fluctuations in formulary positioning. Not knowing which plans are not following the agreed upon formulary positioning of the product until the utilization was received and scrubbed left this client in a position of over-accruing. Our models took the client's data and merged it with IMS data to build a forecasted view of their accruals based on actual sales data cross referenced with formulary data.

### **Q: Do today's processes and technologies actually exacerbate gross-to-net issues?**

**A:** From our experience, we've seen that most companies have a methodology for calculating and managing gross-to-net accruals. However, methodologies vary from manufacturer to manufacturer: Do they employ statistical forecasts, regression analysis, spreadsheets, SAP/Oracle reports, drill down analysis, accrual rate adjustment, etc. Analysis and accrual management methodologies today are partially limited by a lack of off-the-shelf tools. Manufacturers are having to build custom systems or make do with complicated spreadsheet applications to manage accruals. Each presents issues and risks where errors can be introduced.

### **Q: What are practical options for companies to get started in understanding their gross-to-net picture? What is the time investment needed from them? Who should drive it?**

**A:** Before a manufacturer can implement a production gross-to-net system the current forecasting and accrual management methodology must be understood. Once accrual forecasting models have been developed, a system design can be created.

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Accordingly, before a system can be developed or application determined a manufacturer should evaluate and enhance its forecasting and accrual methodologies for its gross-to-net deduction items, including:

- Chargebacks
- Medicaid Rebates; SPAP, and supplemental programs
- Managed care rebates (PBM and Part D)
- Customer rebates (e.g., VIVA, PVIP, 321, etc.)
- Returns
- Cash discounts
- Discuss and review other business provisions that may be impacting industry
- Develop an accruals forecasting system prototype, using Excel, Oracle, and Access as appropriate; this will test forecasting approaches and methodologies

Next, they should develop formula specifications for forecasting and accrual models as well as functional specifications for the accruals management function and contain:

- Formula specifications for the forecasting and accrual models
- Mathematical formulae to calculate accrual percentages based on historical data
- Requirements for accruals forecasting operational and management reports

This effort takes approximately 12 weeks. The project sponsor is usually out of the Finance organization.

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