White paper

QuintilesIMS™

A Commercialization Accelerator *for Emerging Companies*

Building commercial operations capabilities in the ramp up to launch

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For any life sciences company bringing its first product to market, the "commercialization to-do list" is long and punctuated by one critical strategic decision after another. What market data will we need? What technology components will be required? What applications must we have in place? What should we build vs. buy vs. rent?

Often in as little as 18 months, they must pull together—or access—an entire commercial organization and infrastructure. Fortunately, companies anticipating their first marketing approval need not do it alone. There are lessons to be learned from those who've gone before and new options available given the latest technology advances and service delivery models.

The following pages are a guide through that maze of decisions, drawing upon our experience in working with industry leaders who've faced the same challenges. We offer our thoughts on what emerging companies need to consider as they stand up the platform and applications that will support a commercial enterprise – while avoiding the pitfalls that hold many larger commercial companies back from peak operating efficiency.

Defining the goal

The most advanced life sciences companies today accept that commercial operations capabilities are a strategic differentiator. The Operations function can serve as an engine for managing commercial models, increasing consistency, decreasing costs, and in the end, supporting the critical decisions that will determine market success. The function must be designed to:

- Address a multi-stakeholder environment & enable cross-functional alignment
- Capture best insights from multiple, diverse data sources
- Provide business critical information when and where it is needed
- Provide early warnings to enable proactive, rapid interventions
- Scale across countries, franchises, and business units
- Support the go-to-market strategy across multiple channels
- Engage with service providers who can work with covering the entire depth and breadth of information across various data and technology assets

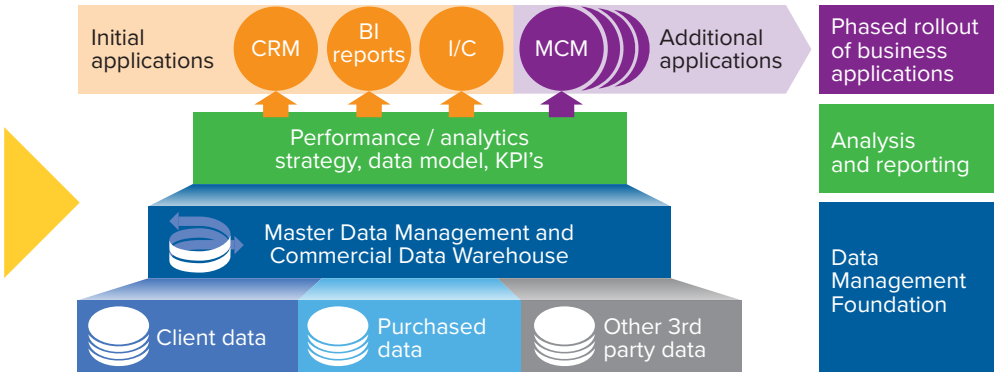
The infrastructure that supports these efforts must accommodate big data analytics (not just simple queries) and make best use of cloud computing and software as a service (SaaS) solutions designed specifically for the life sciences industry. When building the infrastructure, companies should consider the entire spectrum of information

and technology needs rather than address individual applications or work streams in isolation. Interoperability of all the different components is key to optimizing the commercial organization. When all of the necessary tools and resources are designed to work together, workflows are streamlined, data handoffs are minimized, and all internal stakeholders access “one version of the truth” from a central data repository.

The building blocks of the commercial infrastructure

All life sciences companies must deliver the right information to the right internal decision makers at the right time so that they can develop and implement effective sales and marketing strategies. Speed to insight has, in fact, become a significant factor in achieving competitive advantage, which has led to a race for data and the insight locked within it. The basic technology structure that supports nimble, real-time analysis of the necessary information consists of three layers, as depicted in Figure 1.

Figure 1: Key components of initial commercial infrastructure



The data management layer

The necessary data ecosystem is quite extensive and constantly expanding as information is available from more real-world sources. At a minimum, commercial organizations must acquire, integrate, and manage the following types of information:

- Customer reference data on healthcare professionals and organizations
- Internal data on customer segments and targets, territory alignments and personal interactions with customers (everything from service calls, samples to remote speaker programs)

Critical success factors

Achieving excellence in Commercial Operations entails:

- Centralizing governance, standards, and platforms that can be executed locally
- Relying on centralized, global platforms for data collection, leverage, and insights
- Delivering key stakeholder insights and commercial innovation via a centralized analytical engine
- Working with strategic global partners on next-generation capabilities

- Records on non-personal interactions with customers (ranging from digital marketing response to medical apps, event registrations and portal visits)
- Information on the environment, including advocacy groups, public policies, and regulations
- Performance data from secondary sources to include counts of total and new prescriptions as well as sales volumes
- Copay & voucher utilization
- Anonymized, longitudinal patient-level data
- Payer data on formulary designs and co-pay structures
- Tallies of expenditures by customer for aggregate spend reporting
- Details for expense management
- Individual performance data for incentive compensation, encompassing goals, call plans, and sales results
- Insights gleaned from listening to social media (which can be leveraged to better understand the market during strategy development and then to monitor opinions during campaign execution)

The warehouse layer

All of the above data sources—internal and external and structured and unstructured—will need to be stored in a way that will make it easy to extract meaning from them. A secure, cloud-based data warehouse would be accessed via the Web, with the architecture maintained either in a "public cloud" (such as those offered by Amazon AWS, Microsoft and Google), or a "private cloud" created exclusively for the use of a single company. Or the platform can be hosted within a service provider's on-premise data center. Regardless of where it resides, the platform should be built with open application program interfaces (APIs) to accept data from multiple sources and accommodate real-time access from various applications. The data then should be available to different types of users, on demand, and in rolebased views.

The entire commercial organization must have a consistent, 360-degree view of the customer through all consuming applications—a "single view of the truth" to avoid duplications and discrepancies. Plus, different data sources should not generate different reports with competing levels of relevancy and accuracy. Thus, the use and maintenance of the data will need to be carefully guarded. Indeed, a strong master-data management program is the key to realizing success with downstream applications. Master data management involves setting standards on data definitions, taxonomy, metrics and measures as well as developing policies and procedures for monitoring quality, handling discrepancies, and accessing the data. Master data management is now a must-have process to ensure a single version of truth.

The best architecture centralizes customer data in a customer hub that feeds into back-office systems (such as sales reporting, compliance reporting, compensation and contracting) as well as integrates with customer-based applications including sales force automation, call center support, order management systems, expense and finance systems, campaign management, speaker programs, websites and physician portals.

The analytics layer

An intelligent analytics platform must "sit on top of" the data warehouse in the technology stack to allow information to be distilled and insights extracted from it. The power of this platform is critical to good commercial practices, given the sheer volume, velocity, and variety of healthcare data that companies must cope with. Predictive ability, accuracy, and speed are key attributes of the effective analytics platform.

Commercial functions must have robust tools that allow them to access information, consume it easily, and make informed decisions rapidly. Increasingly, this takes the form of KPI-driven dashboards that deliver timely and relevant information in unique and appealing formats. Telling the "business story" is the cornerstone of success in providing valuable Business Intelligence (BI).

The platform should accommodate real-time analysis for nimble decision making and rapid intervention. The most sophisticated companies are moving away from retrospective analytics (which provide a picture of what happened in the recent past) to projecting future scenarios. A simple example of this is modeling to be able to guide reps in setting their call priorities based on predicted call efficiency.

When done well, this technology can help level the playing field so that small companies can compete effectively against established industry giants. Companies can make the most efficient use of their limited sales resources by spotting developing trends and directing their sales force accordingly. They might, for example, concentrate their sales force on those physicians who are likely to become high writers—either for the company's product or the competition's.

The applications layer

The operations function for the customer-facing arm of the company will need applications to support the following core business activities:

- Customer relationship management and closed loop marketing
- Business intelligence and performance management
- Incentive compensation management
- Territory alignment management
- Aggregate spend compliance

The golden record

The accuracy of a company's customer master file is not merely a matter of efficiency and effectiveness. It has strong legal and compliance implications. How can a company both gather field-reported data on customers and ensure that it is properly vetted before becoming the basis for targeting, sampling, call planning, messaging and compliance reporting?

What should happen, for example, when a doctor proves to a rep that she is a high-prescribing internist, but the home office classifies the doctor as a pediatrician and will no longer allow her to be detailed? Or, what should reps do when the address changes they submit don't stick?

The answer lies in having a well-conceived Master Data Management (MDM) strategy and in applying best practices in data governance and stewardship. These specialized responsibilities can now be outsourced—a solution that it is becoming an industry best practice in and of itself.

- Multichannel marketing
- Sample accountability and inventory management
- Revenue management

Best-in-class applications in these areas are interoperable, pre-integrated with industry data, globally relevant, and flexible. It may be tempting for start-up companies to rely on simple, point-solutions (such as spreadsheets and manual processes) to accomplish some of these tasks, particularly in the very early days of commercialization. However, within the first year post launch, the business processes typically grow exponentially more complex, and most companies will quickly find point solutions to be woefully inadequate. They won't scale, will be labor-intensive to operate and maintain, will fragment insights, and will inhibit cohesion across processes. It is both practical and economical to plan ahead and have scaleable applications ready at the time of launch.

It is worth noting that for smaller companies, the ability to conduct multichannel marketing is especially critical, as it allows them to operate with a smaller sales force. To be successful, multichannel marketing strategies must be built on the right customer understanding and segmentation, which involves having not just prescription data but an understanding of channel preferences and the ability to automate cross-channel campaigns.

A strong master-data management program is key to realizing success with downstream applications.

Pre-approval technology work streams

Once the dossier has been submitted to regulators for marketing authorization, pre-commercial companies must carefully balance the need to be prepared and ready to launch the product with the opposing need to manage costs and avoid investing in infrastructure prematurely. Some of the technological solutions that will be essential on Day 1 of launch need to be under consideration—if not already under development—a full year in advance of launch. For systems that must be in place upon launch, it is advisable to have them up and running with all users trained on them one month prior to the launch date.

The timeline below describes the various types of tools that are needed to operate commercially, along with the typical lead time required to develop them. Depending on your specific business plans, some of these may need to be ready at launch, while others may be needed well in advance of launch or in the not until the early post-launch period. Implementation time may vary from those below depending on your specific requirements.

System/tool	Purpose	Illustrative lead time
Data management		
Master Data Management (MDM) solution	Maintain a single version of the truth for a customer record and other domain records	4-12 months prior to launch (in sync with the data warehouse development)
Cloud-based data warehouse	Store and integrate data from multiple sources	4-12 months prior to launch, depending upon complexity of the market, data sources, and go-to-market strategy
Analytics		
Performance Management system	Monitor all of the factors that drive performance of the brand and market via dashboards and ad hoc reports	2-4 months, depending on complexity of the market
Business Intel/ Analytics platform	Provide insight into Rx and sales trends, market size, and competitive market share	2-4 months, depending on system. A pre-packaged web-based tool can be turned on more quickly.
Business applications		
Customer Relationship Management system	Automate and optimize field force activities, including call planning tools, call and sample capture, closed loop marketing, etc.	3-6 months prior to need, depending on complexity of configuration
Sample Inventory Management system (integrated with CRM)	Track all product samples throughout the chain of custody to ensure compliance	3-6 months, in conjunction with CRM
Territory Alignment software (or vendor)	Align providers, reps, and territories for optimal coverage, workload balance, and efficiency	2-4 months, depending on complexity of configurations
Incentive Compensation (IC) management system	Calculate and manage IC payout based on sales person's performance	2-4 months, based on complexity of incentive plans
Multichannel Marketing platform	Extend customer relationship through additional channels and execute personalized campaign journeys	2-6 months prior to need, based on complexity of MCM campaigns
Promotional Material Review system	Centralize materials and automate/track the review process through med/reg/legal	3-5 months prior to start of promo material development
Aggregate Spend reporting tool	Capture all spending on each physician for compliance reporting	3-5 months for an automated tool (another option is to outsource the function)
Speaker Bureau management system	Manage contracts, travel arrangements, track spending for speakers	2-4 months prior to start of speaker activities
Social Media data mining	Monitor and collect social media content to inform compliance and marketing decisions	2-4 months prior to need; can be used either pre- or post-launch depending on insights needed

Outsourcing partner selection

The right partner to support a new commercial organization has several core attributes:

A LIFE SCIENCES FOCUS

This extends from having an understanding of the overall market to intimate knowledge of the workings and requirements of commercial functions within the industry.

HEALTHCARE DATA EXPERTISE

This includes access to, and the ability to understand, interpret, and integrate different types of information available. A lack of such knowledge creates a long learning curve that newly commercialized companies can ill-afford to weather.

LEADING TECHNOLOGY CAPABILITIES

Partners should understand how novel, cloud-based applications can be used to scale solutions across and organization and should have predictive applications to enable proactive intervention.

A GLOBAL PRESENCE

Partners should have the ability to ramp up teams around the world, as required, that have deep knowledge of informatics, different therapeutic areas, and healthcare markets.

SCALABILITY

The best solutions are scalable and can easily accommodate volume impacts as a company's circumstances or market conditions change. With the right foundational elements in place, such transitions can be smooth.

A WIDE BREADTH OF SERVICES

Creating an integrated infrastructure in which every element works with every other element is far easier when a single provider can span several services, as opposed to having multiple vendors in the mix. A lack of connectivity devalues even the greatest components in the commercial solution.

A FOCUS ON INNOVATION AND CONTINUOUS IMPROVEMENT

The pace of new information and technology is such that commercial functions must be able to adapt quickly. To maintain competitive advantage and ensure ongoing efficiency, innovation processes and policies must be a vendor hallmark.

INTEROPERABILITY AMONG COMMERCIAL APPLICATIONS

Applications should be integrated so that changes in one—such as new information or transactions and modified rule sets—move seamlessly across other applications. In this way, everyone stays in sync with insights flowing effortlessly through the organization.

For a full checklist of recommended vendor qualifications, see Appendix A.

Information disconnected across the enterprise

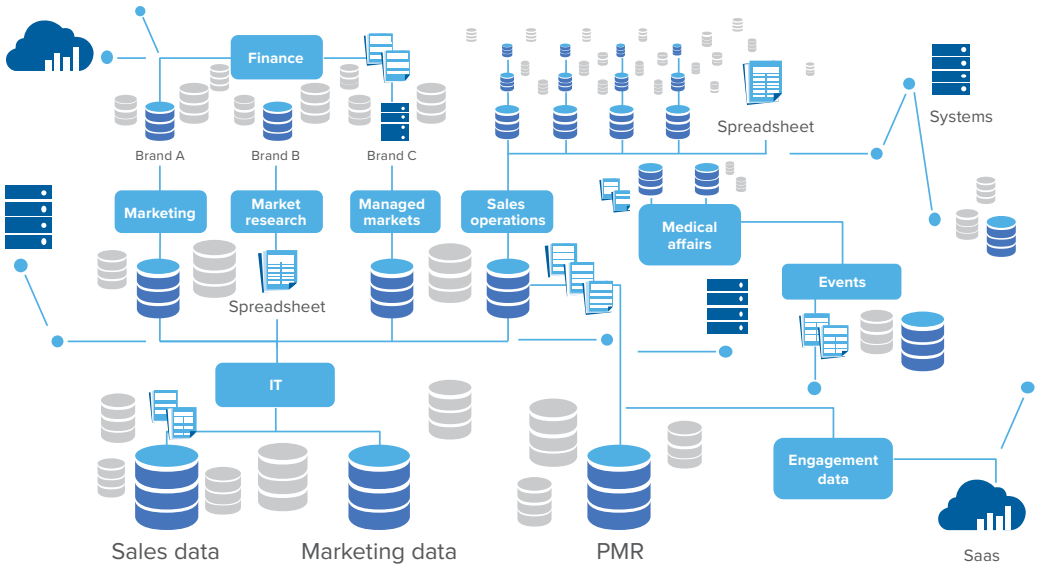
Data silos and gaps slow decision-making and speed of action

Recognizing that such fragmentation and complexity has re-introduced costs and led to information gaps that can hinder—and even misdirect—decision making, the most advanced companies are consolidating their external commercial partners. They're searching for partners with enough breadth to handle many aspects of the commercial ecosystem, altogether in one integrated system. By working with a few key external partners they can create a seamless workflow and adopt best-in-class approaches in an information-driven age.

They're drawing upon integrated solutions that are modular, flexible, global, and interoperable—while minimizing their own internal infrastructure. In this next generation approach, cost efficiencies are a consequence, rather than an overwhelming driver, of the arrangement.

Pre-commercial companies are in the enviable position of being able to bypass this early model and the fragmentation that comes from relying on too many external partners; they can adopt an efficient model from the outset.

Figure 2: What to avoid – the fragmented data and systems common in big pharma



The lessons from big pharma

Over the past 10 years, the leading players within the biopharmaceutical industry have been changing their commercial models to better address new stakeholders and competitive realities.

In the process, they've shifted various commercial responsibilities to outsourcing partners—unfortunately often in a piecemeal fashion. While this has achieved initial cost-cutting goals, it has also led to fragmented capabilities and information silos across multiple platforms, providers, and partners. (See Figure 2.) There's little visibility into what information the company has, where it sits, and how it could be useful. Information remains disconnected and doesn't flow easily to the people who need it.

CASE STUDY

Pulling it all together

When one biotech firm's oncology product received Fast Track designation by the U.S. Food & Drug Administration (FDA), the early-stage company suddenly needed to accelerate its launch plans. Just nine months prior to launch, it lacked the infrastructure, capabilities, and knowledge of specialized oncologists that it would need for successful commercialization. How could it deploy its commercial operations rapidly and in a way that was scalable?

The company turned to IMS Health for information assets, software solutions, managed services, and consulting. The company obtained physician and pharmacy data from IMS and relied on IMS to create a cloud-based data warehouse and provide a comprehensive platform and process for managing master data records. All key data assets were connected to support sales force automation and marketing applications, expense management, aggregate spend reporting, and speaker bureau management. The Customer Relationship Management (CRM) system needed to support 100 account executives engaging 1,000 specialized oncology practices. As a final step, the company, with IMS Health's help, rolled out flexible insight tools to produce executive dashboards and ad-hoc reports as well as track launch KPIs for Finance, Operations, Marketing, and Sales.

As a result, the commercial operation was in place for the company's first chemotherapy launch and is scalable to accommodate the company's next three launches.

Conclusion

While pre-commercial companies have their work cut out for them in pulling together a commercial operations function—with all of the data, infrastructure, and talent that entails—in a relatively short time frame, they stand to distinguish themselves in the way they go about it. They have the opportunity to avoid the inefficiencies from legacy systems and outmoded technologies that have been hindering the industry's larger players. They can go to market with the most advanced best-of-breed technologies available today—systems that are modular, flexible, global, and interoperable.

Today's cloud computing, analytics platforms, and full-featured applications can give emerging companies the speed to insight that they need to succeed in the market. In this way, technology is a great leveler; with robust data and powerful analytical tools, emerging companies can compete effectively against companies with far more extensive marketing and sales resources.

TAKE ACTION

Learn more about how IMS Health can help you build leading edge, integrated commercial capabilities as you prepare to bring your product to market. Contact us at: ***Nexxus@imshealth.com*** *or visit us on the web at* ***www.imshealth.com/nexxus***

Appendix A: Vendor/solution selection criteria

Partner attributes

Does the vendor understand the life sciences industry and the workings and requirements of all the functions within it? Will the systems be designed and supported by experts in the market itself?	☐
Is the vendor familiar with healthcare data enough to interpret and integrate the various types available?	☐
Does the vendor have the capacity to scale its solutions with you as you grow?	☐
Does the vendor have a global footprint to be able to support you around the world in different languages and time zones?	☐
Is the vendor's breadth of services sufficient to provide for connectivity between all of the components in the commercial solution?	☐
Does the vendor have extensive experience in "standing up" cloud-based applications and dealing with "big data?"	☐
Is the vendor ISO 9001 compliant? Many of the data and systems you'll need are critical assets with strong legal and compliance implications.	☐
Does the vendor have sufficient project management resources and success in program implementation as required for large-scale technology builds?	☐
Does the company have a history of innovation and continuous improvement?	☐
Is the technology provider an objective source of sales force reporting—e.g., separate from the contract sales organization?	☐

Infrastructure

Can the hosting environment accommodate high volumes of transactional data as well as unstructured data?	☐
Will the analytics platform be built with application program interfaces capable of accepting data from multiple sources and of accommodating rapid access from various applications?	☐
Does the platform have predictive capabilities in order to project future scenarios?	☐
Can components be deployed modularly?	☐
Will each tool integrate effectively with others?	☐

Applications

Will the master data management solution provide a consistent, 360-degree view of the customer through all consuming applications—a "single view of the truth?"	☐
Are the solutions pre-populated with industry data?	☐
Are the applications structured so as to capture all the data elements/activities needed and conform to common industry practices?	☐
Can the solutions address the specific requirements of diverse users?	☐
Will information be delivered in KPI-driven dashboards in unique and appealing formats?	☐

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