TRIANGLE INSIGHTS GROUP
INSIGHTS THAT INSTILL CONFIDENCE

Insights and Perspectives Series

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IDN Engagement Strategy:
Why All Therapeutics Need One

- Driven in part by hospital system consolidation and outcomes-based reimbursement, integrated delivery networks (IDNs) have increasing influence on therapeutic utilization in the United States.
- As these networks further integrate and exert control in the outpatient setting, they will be increasingly important for pharmaceutical products not traditionally administered in the hospital inpatient setting.
- Driving access and utilization in these settings poses a unique set of challenges, but should be integral to commercial strategy.
- Triangle Insights Group has developed a framework to guide pharmaceutical manufacturers in identifying key factors and stakeholders that are critical to crafting an integrated delivery network strategy that drives commercial success in this evolving landscape.

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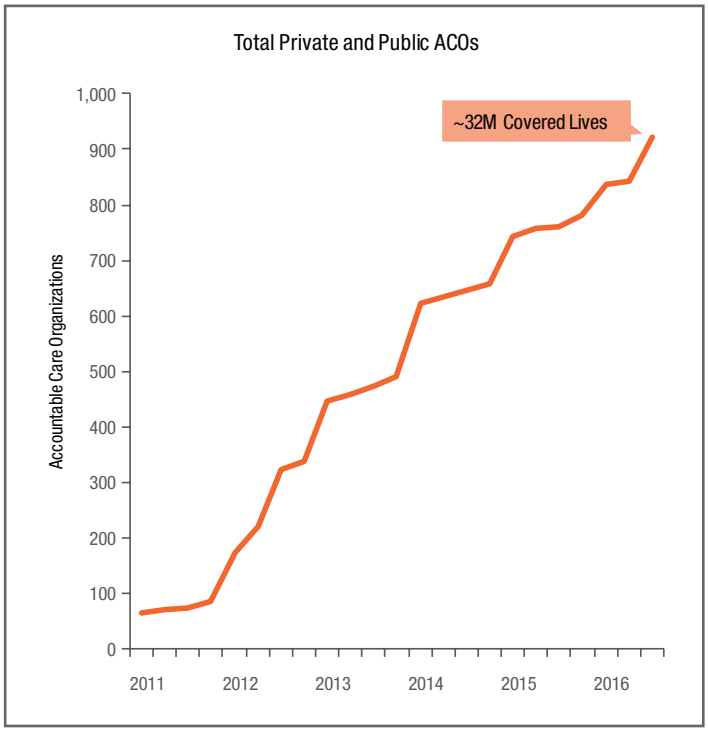
Introduction

Over the past ten years, the US has witnessed the continued evolution of health systems into highly consolidated integrated delivery networks (IDNs). The level of influence of the IDN has grown substantially as networks integrate not only acute hospitals and outpatient providers, but also payer groups (e.g., Baylor Health Care, Geisinger).[1,2,3] Healthcare system commercial strategy was previously only a priority for therapeutic products intended primarily for inpatient utilization. However, with the growing influence of IDNs, utilization of therapies typically administered outside of the inpatient setting is increasingly controlled by IDN stakeholders. With a clear understanding of IDN objectives and key stakeholders, pharmaceutical manufacturers can tailor their IDN strategy based on their product offerings to successfully navigate the evolution of the IDN landscape and drive commercial success.

While the integration of acute hospitals into small, non-integrated networks initially began in the late 1980's and continued through the 1990's, various external pressures over the past decade have accelerated integration and vastly influenced the structure of the resulting networks [see Figure 1: The Expansion of Accountable Care Organizations and Alternative Payment Models].[1]

Figure 1: The Expansion of Accountable Care Organizations and Alternative Payment Models[1]



Source: Centers for Medicare and Medicaid, Accountable Care Organizations; Leavitt Partners; Accountable Care Learning Collaborative; Growth of ACOs and Alternative Payment Models in 2017, Health Affairs.

System participation in accountable care organizations (ACO) has grown rapidly since 2011 and the Affordable Care Act. Within the IDN space, there is a continued trend of evolving reimbursement models that are likely to spur continued system integration to maximize reimbursement.

In addition to ACOs, other alternative payment models are beginning to develop within the public and private sector. The Health Care Payment Learning and Action Network proposes several potential models that may continue to evolve within the IDN space, including population or condition based payments and updated fee-for-service models with opportunities for shared savings.

More specifically, government-sponsored programs and legislation have been introduced in an effort to contain rising healthcare costs while upholding quality of care provided to patients. These programs have utilized both financial incentives and disincentives to meet their objectives (e.g., Health and Human Services "Quality Initiative" [2001], CMS Hospital Quality Alliance [2007], Affordable Care Act [2010]).[4,5] In order to maximize incentives and minimize associated penalties, systems have further integrated and become more consolidated in their decision-making across individual inpatient and outpatient institutions.[6] One key example of this was the initiation of the reimbursement framework for Accountable Care Organizations (ACO) in 2011 which incentivized providers and hospitals to meet quality of care metrics by sharing in Centers for Medicare and Medicaid (CMS) cost savings [see next page for Table 1: Highlighted Quality Improvement Programs].[7,8] The introduction of quality and performance metrics shifted hospital and system focus from solely achieving positive near-term outcomes, which are incentivized by the Diagnosis-Related Group (DRG) reimbursement system, to placing unprecedented importance on attaining long-term, sustainable patient outcomes.[9] Regardless of the approach (incentive or disincentive), the result is the same: reimbursement and profitability are inextricably bound to quality of care and overall hospital performance.

As networks continue to integrate across the spectrum of care settings, their influence over the utilization of traditionally non-inpatient pharmaceuticals is magnified. A clear understanding of key decision-makers and their incentives in the IDN will help frame the communication of value for products not historically impacted by the IDN realm of influence.

Table 1: Highlighted Quality Improvement Programs

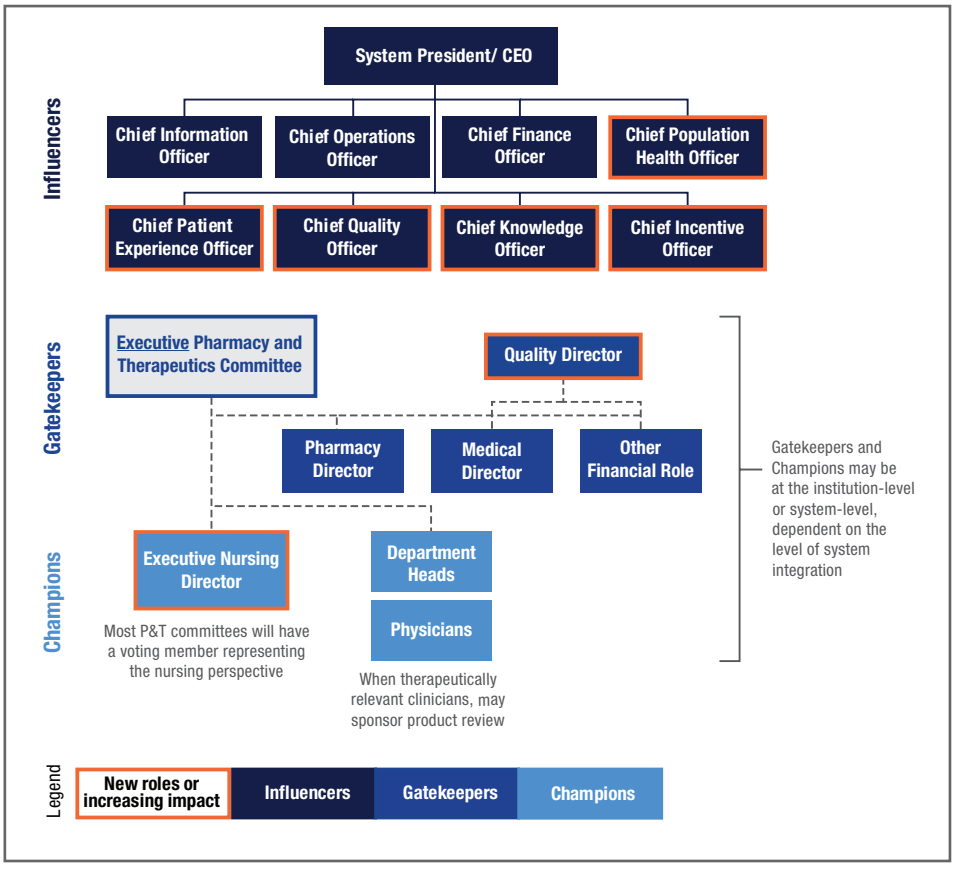
Program Title	Objective	Financial Impact to Hospital
Hospital Readmission Reduction Program	Improve all-cause hospital readmission rates	Reduction in DRG payments across all their admissions when exceeding national average
Hospital Acquired Condition Reduction Program	Improve quality of inpatient care and reduce frequency of preventable adverse events	Hospitals in the bottom most quartile for hospital-acquired conditions receive a reduction in payments
Hospital Inpatient Quality Reporting Program	Incentivize hospitals to report internal quality and outcomes data	Hospitals that report quality measures receive a higher annual market basket update (measure of inflation in goods/ services used to treat CMS patients)
Hospital Value-Based Purchasing Program	Performance-based payment strategies that link financial incentives to quality of care	Hospitals with high performance scores are eligible for net-positive incentive payments; those with low scores are at risk of losing up to 1.5% of base operating DRG payments

Sources: Centers for Medicare and Medicaid; CMS National Impact Assessment of the CMS Quality Measures Report; Centers for Medicare and Medicaid, Quality Measures

IMPACT OF INCREASING INTEGRATION: Evolving Roles of Key IDN Stakeholders

Key stakeholder roles have evolved within IDNs to accommodate organizational changes and navigate shifting reimbursement mechanisms that place more emphasis on patient outcomes and provider performance. Understanding how three key categories of stakeholders—"Influencers," "Gatekeepers," and "Champions"—are motivated and incentivized within the IDN can have meaningful consequences on the optimal commercialization strategy to target integrated systems [see Figure 2: Key IDN Stakeholders and their Evolving Roles].

Figure 2: Key IDN Stakeholders and their Evolving Roles



Source: Triangle Insights Group Analysis

Influencers: One notable shift in the landscape of IDN stakeholders has been the evolution of the C-suite to encompass roles focused on performance measures and reimbursement [see Figure 3: Evolving C-Suite Roles: A Snapshot of Population Health Officers]. Influencers such as Chief Population Health Officers, Chief Patient Experience Officers, and Chief Quality Officers are incentivized to meet performance- and quality-based metrics across inpatient and outpatient care settings. These individuals may even be tasked with developing a continuity of care strategy that encompasses the outpatient setting for patients with chronic conditions to avoid costly inpatient admissions. While not directly involved in formulary inclusion or prescribing decisions, they can be highly influential in product access and utilization decisions through the design of system-wide tools for behavior incentivization and restriction (e.g., order sets, performance metric tracking). Influencers are likely to be more receptive when a product or portfolio value proposition is aligned with system-wide priorities (e.g., budget and profitability, health economics and outcomes, performance metrics).

Figure 3: Evolving C-Suite Roles: A Snapshot of Population Health Officers

The genesis of the role Chief Population Health Officer has its roots in a forward-thinking response to address outcomes-based reimbursement and avoid overutilization of ambulatory and inpatient care. Primarily physicians by training, with experience in public health, these C-suite Influencers are charged with providing coordinated care across settings to increase the overall health of their community. To accomplish their broader population health objectives, these Influencers are increasingly tasked to lead the physician network within the system.

Source: Triangle Insights Group Analysis; Becker's Hospital Review- Leadership and Management, Chief Population Health Officers

Gatekeepers: In addition to the administrative-level influencers, garnering the support of system-wide Gatekeepers (typically clinical and pharmacy leadership), will be key for any therapeutic access in the IDN channel. These individuals determine inclusion or exclusion on the IDN formulary and additional use restrictions for therapeutic products. As individuals with both patient care and administrative responsibilities, they will be the most likely to evaluate products in terms of impact to clinical outcomes across settings of care (inpatient, outpatient, post-discharge, etc.). Communicating an attractive message for these stakeholders can be challenging, but necessary in gaining system access for some therapeutics. Given the focus on formulary spend, products demonstrating clear economic value and improved outcomes for the system are viewed more favorably by these stakeholders.

Champions: Traditionally, clinicians are most likely to serve as product Champions. IDN Champions are most closely associated with the day-to-day intricacies of patient care and will be aligned to value propositions that demonstrate direct clinical improvement over standard-of-care in both the inpatient and outpatient settings. In most systems, a product endorsement by a clinical champion is required for formulary inclusion and incorporation into system-wide protocols. Therefore, identifying and developing Champions is integral to gain system access and utilization.

As system integration continues and stakeholder roles are modified to encompass more than traditional hospital responsibilities, engagement with Influencers, Gatekeepers and Champions will become a critical aspect of IDN strategy. Furthermore, understanding the priorities that motivate each relevant stakeholder, and highlighting the product/portfolio benefits most aligned with those priorities will be crucial in garnering favorability and uptake.

ADAPTING TO INTEGRATION: Strategic Implications for the Pharmaceutical Industry

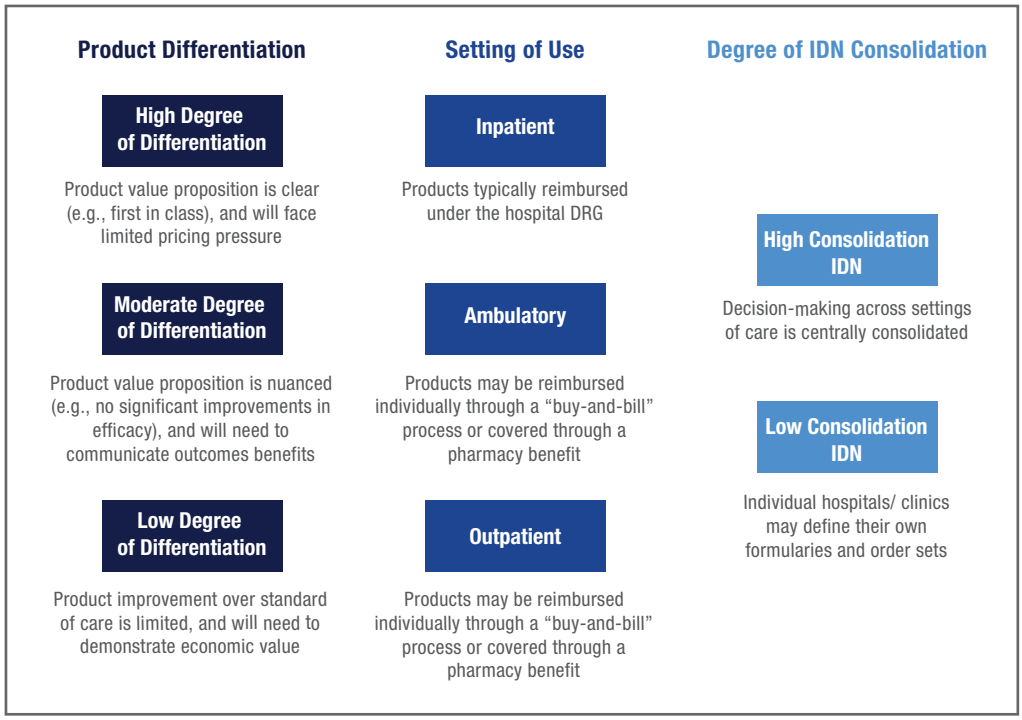
In this evolving IDN landscape, a clear strategy for engagement with Champions, Gatekeepers and Influencers in the IDN will be increasingly important for new products. The engagement strategy should account for three key dimensions in order to identify the stakeholders with the greatest influence and receptivity to the product value proposition: "Product/ Portfolio Differentiation," "Product Setting of Use," and "Degree of IDN Consolidation" [see next page for Figure 4: Triangle Insights Group IDN Commercial Considerations]. Using this framework to tailor engagement to the relevant stakeholders within the system can be the difference in attaining commercial success and failing to achieve revenue expectations.

To demonstrate the use of this framework, assume a hypothetical product (Product E) is used chronically in epilepsy patients for the prevention of seizures. Due to the nature of the condition, a large share of the target patient population would initiate the chronic therapy while in the emergency room or inpatient setting after a bout of seizures. The patient would then continue use post-discharge, filling the prescription through a retail or mail-order pharmacy. Product Setting of Use: Inpatient, Outpatient.

Although there are a number of generically available oral anti-epileptics, Product E provides some benefits due to an improved safety profile offering reduced somnolence and decreased sialorrhea (drooling) with similar efficacy to generic benzodiazepines. Product Differentiation: Moderate.

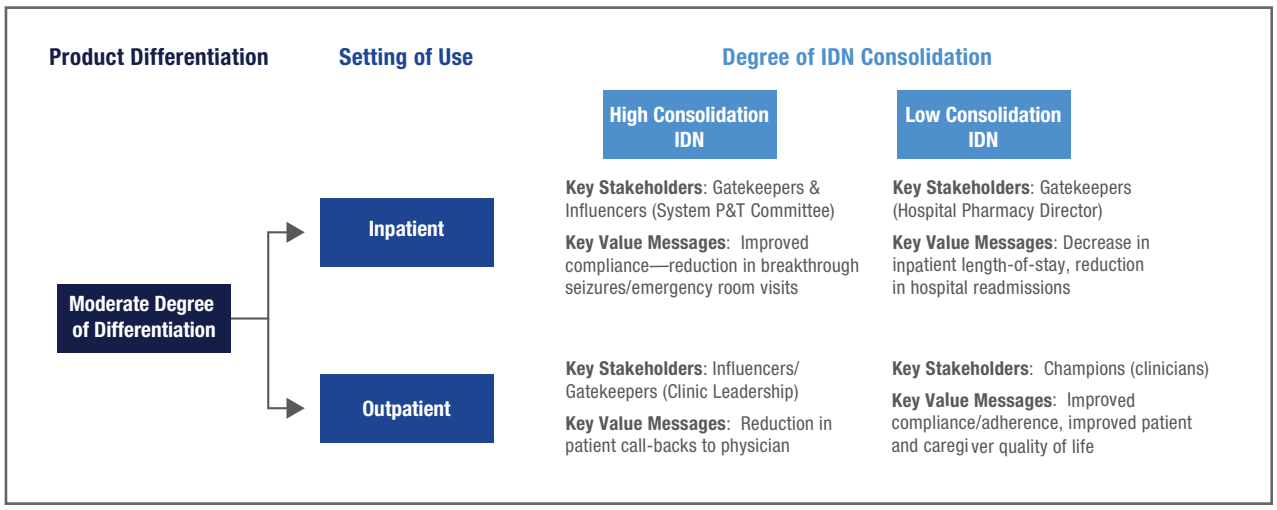
Given the evaluation of product-specific factors (e.g., Setting, Differentiation), IDN stakeholders most aligned with the Product E value proposition can be identified [see Figure 5: Product E— IDN Commercial Considerations Framework].

Figure 4: Triangle Insights Group IDN Commercial Considerations



Source: Triangle Insights Group Analysis

Figure 5: Product E—IDN Commercial Considerations Framework



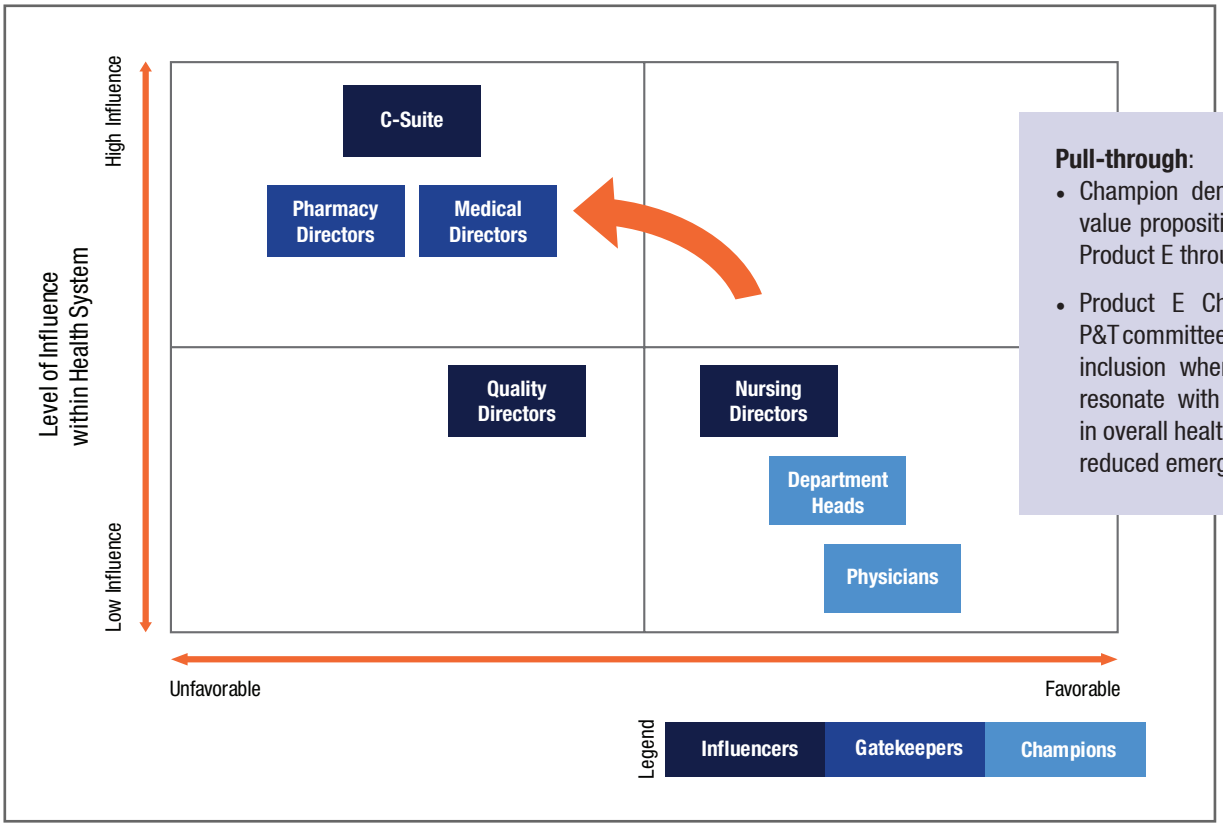
Source: Triangle Insights Group Analysis

Given the limited novelty and the availability of generic products, we would expect that inpatient formulary access for Product E is likely to be restricted by the Gatekeepers on the Pharmacy and Therapeutics committee. This could be problematic for the manufacturer given the expectation of new patient starts in the inpatient or ambulatory setting. The stakeholders that may be more receptive to the value proposition of reduced somnolence and drooling are likely to be the clinicians, in this case the treating neurologists, who may perceive the benefit of improved patient compliance due to improved tolerability. By cultivating these clinical Champions, a message for improved compliance leading to reduced breakthrough seizures and therefore reduced emergency room visits may become an attractive message to an Influencer. This "Pull-through" approach requires favorable receptivity to the product by influential Champions [see Figure 6: Product E in a Low Consolidation System—"Pull-through Srategy"]. This may be most effective in IDNs with limited consolidation, where individual hospitals and clinics determine product use. However, targeting these stakeholders may be more costly than a focused effort on key stakeholders in systems where decision-making is centralized. Conversely, a "Push-through" strategy targeting Influencers and Gatekeepers may be a more cost-effective targeting approach, but it typically requires a clear economic message. In addition to communicating a short-term system benefit (e.g., reduction in length of stay, improvements in CMS quality metrics), long-term clinical outcome improvements may also be necessary. This approach is likely more feasible for products with a high degree of differentiation.

This high-level framework enables manufacturers to take the first steps in crafting a sustainable IDN strategy by evaluating the key product factors (Product Setting and Product Differentiation) and IDN-specific considerations (IDN Level of Consolidation). With these factors outlined, the framework illuminates the relevant stakeholders and their incentives within the network to target product messaging across various settings of care and degrees of product novelty to drive successful commercialization.

In conclusion, the privately-owned or single institution hospital is a care model of times past. Network integration and consolidation of provider systems will continue to be a defining factor of the US healthcare landscape as economic pressures escalate and threaten the profitability of the hospital industry. The sphere of

Figure 6: Product E in a Low Consolidation System – "Pull-through Strategy"



Source: Triangle Insights Group Analysis

influence for these highly-consolidated systems will continually be magnified and will include utilization of traditionally retail-focused pharmaceuticals. While the IDN engagement approach and example presented here are simplified, they begin to demonstrate the considerations pharmaceutical manufacturers should contemplate as they prepare to engage with integrated delivery networks. Utilizing these tools to target key decision-makers and better understand their incentives in the IDN will allow for the improved communication of therapeutic product value to these key IDN stakeholders to drive commercial success.

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3. Evans, M (2014) Modern Healthcare, Consolidation creating giant hospital systems
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7. Centers for Medicare and Medicaid Services, Accountable Care Organizations;
8. Leavitt Partners; Accountable Care Learning Collaborative; Growth of ACOs and Alternative Payment Models in 2017, Health Affairs.
9. Center for Healthcare Quality and Payment Reform, Physician-Focused Payment Models

About Triangle Insights Group

Headquartered in Research Triangle Park, Triangle Insights Group, LLC is a strategy consulting firm providing guidance on the most critical business issues to leaders in life sciences organizations. The firm's approach combines deep knowledge of the industry across therapeutic areas and functional groups, with a dedication to creativity and disciplined critical thinking. Recommendations from Triangle Insights Group are original, relevant to the industry environment, and supported by rigorous analytics. Clients of Triangle Insights Group include large pharmaceutical companies, emerging biotechnology firms, diagnostics manufacturers, medical device companies, and private equity investors.

For more information about Triangle Insights Group, visit www.triangleinsights.com or call (919) 813-6079.

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Has thirteen years of pharmaceutical and consulting experience. Gautam focuses on providing strategic guidance to clients within life sciences organizations. His recent engagements have involved commercial assessment, indication prioritization, white-space strategy, commercial model design and in-licensing/out-licensing support.

Gautam has provided strategic advice to a wide range of clients, spanning Top-5 pharmaceutical manufacturers, emerging biotechnology manufacturers, bio-pharmaceutical investors, and service providers to bio-pharmaceutical companies. He has spoken at several industry conferences (LES, CED, EBD, BIO-Windhover, CHLA, Banff Venture Forum) and has published a peer-reviewed article on deal timing.

His previous employers have included GlaxoSmithKline, Boston Consulting Group and Campbell Alliance, where he was a Senior Practice Executive and led business/corporate development efforts for the central region. Gautam received his M.B.A. from the Fuqua School of Business at Duke. He holds an M.S. and a B.S. in Bio-Statistics from UNC-Chapel Hill.

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Chris has worked as a Senior Practice Executive with Campbell Alliance where he led the company's Business/Corporate Development efforts for the NY and NJ region. His recent management consulting experience has centered on corporate strategy and market opportunity assessments for life science companies and investors.

While at GlaxoSmithKline, Chris's scientific accomplishments led to multiple patent authorships and peer-reviewed publications, as well as discoveries resulting in over $30 million in company cost savings. In business development roles, Chris was responsible for corporate strategy and reviewing in-licensing and out-licensing opportunities. Chris earned an M.B.A. from the University of North Carolina Kenan-Flagler Business School as a member of Beta Gamma Sigma academic honor society. He has an M.S. from the University of Buffalo and a B.S. in Biochemistry from the University of Rochester.

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Recent by-lined articles have appeared in Pharmaceutical Executive, InVivo, Nature Biotech, RPM Report, and Scrip. In addition, Ben's case studies on the pharmaceutical industry have been used in graduate business programs.

Ben is the chairman of the Life Sciences Sector of the Licensing Executive Society. He has also been a member of the program committee for the BIO International Convention. Prior to the founding of Triangle Insights Group, Ben was the leader of the Business Development Practice at Campbell Alliance and a partner in the Strategy practice at Oliver Wyman (formerly Mercer Management Consulting/Strategic Planning Associates). Ben earned an M.B.A. from the Stanford Graduate School of Business and a B.S. from Duke University.

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Kate's previous strategic consulting experience includes: Platform Advisors, Campbell Alliance, and Deloitte. Kate also has research experience in discovery and development at AlphaVax, Inc., Research Triangle Institute, and Walter Reed Army Institute of Research.

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Barrett's previous management consulting positions in the life sciences industry were with Campbell Alliance and Boston Healthcare Associates. He also founded an independent life sciences consulting firm prior to the founding of Triangle Insights.

His background also includes client-side experience within the pharmaceutical industry. For plasma manufacturer Grifols Therapeutics (previously Talecris), Barrett led market intelligence for the pulmonary franchise including Prolastin-C, an orphan drug indicated for alpha-1 antitrypsin deficiency. Barrett received his M.B.A. from the Tuck School of Business at Dartmouth College. He holds a B.A. from the University of Virginia. He has been a lecturer at several life science industry conferences.