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Should Enthusiasm Surrounding Antibiotics Be Tempered?

- Declines in antibiotic research and development, and over-utilization of broad-spectrum anti-infectives have contributed to the rising public health concerns around bacterial antibiotic resistance.
- To address the diminishing antibiotic pipeline, the US government has been escalating its support for initiatives to address the innovation shortfalls through expedited development timelines, elongated market exclusivity, and improved reimbursement.
- While initiatives may encourage an increase in the number of antibiotic R&D programs, the commercial landscape has not yet evolved to adequately reward innovation due to the limited uptake in pathogen diagnostics and the contracting volume of patients addressable by novel agents.

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Introduction

The market for antibiotics has gained considerable attention over the past few years with an increasing number of development programs and an upturn in the number and value of antibiotic-driven deals (see Figure 1: RECENT NOTABLE ANTIBIOTIC DEALS). However, this activity may be viewed as overly optimistic as significant challenges for new antibiotic programs still persist—limited diagnostic adoption and an unfavorable reimbursement landscape. Several recent and proposed regulatory initiatives are intended to promote anti-infective innovation by reducing time to market, subsidizing development costs, and increasing reimbursement. However, these programs are expected to have limited impact on the return on investment (ROI) of antibiotic product development.

Technology advancements have allowed for more precise antibiotic therapy as increasingly targeted agents have been developed to address specific bacterial species and antibiotic-resistant strains. Although a more pathogen-specific treatment strategy will likely lead to improved patient outcomes, the diagnostic and reimbursement landscapes have not yet evolved to provide an environment to adequately reward this innovation. Frequently, hospitals and clinics utilize the diagnostic technologies developed decades ago (e.g., bacterial culture) which have contributed to the overutilization of broad-spectrum agents and the delay in targeted treatment. Additionally, modest improvements in the Diagnosis-Related Group (DRG) reimbursement for novel anti-infectives have failed to adequately cover the costs of serious and resistant infections. As a result, companies may not achieve the ROI levels previously generated by innovative antibiotics (e.g., Augmentin, Zyvox) or other therapeutic areas that have moved to a more targeted treatment approach (e.g., oncology).

Figure 1, Recent Notable Antibiotic Deals

Acquiring Company	Recent Deals/Acquisitions (Completion Date)	Primary Assets	Deal Type	Total Deal Value ($M)
Cubist	Trius	Tedizolid	Acquisition	$818
Cubist	Optimer (October 2013)	Dificid, (C. Diff.)	Acquisition	$806
The Medicines Co.	Rempex (December 2013)	Carbavance, Minocin IV, RPX-602, and preclinical developmental program	Acquisition	$474
Debiopharm	Affinium Pharmaceuticals (February 2014)	Research program with early stage development antibiotics assets	Acquisition	N/A
Actavis	Durata (November 2014)	Dalvance	Acquisition	$675
Merck	Cubist (January 2015)	Cubicin, Sivextro, Zerbaxa, Surotomycin, Bevenopran, CB-618	Acquisition	$9.5 B
Roche (licensing)	Meiji Seika Pharma & Fedora (January 2015)	PI beta - lactamase inhibitor	Licensing	$750

Regulatory Focus on Antibiotics

In an attempt to incentivize innovation in a market experiencing pricing pressure from increasing generic competition and limited reimbursement, several programs have been sponsored by US governmental and regulatory agencies. The Biomedical Advanced Research and Development Authority (BARDA) was established within the US Department of Health and Human Services in 2010 for the purpose of developing medical countermeasures to intentional or natural threats to public health, including emerging infectious disease. In addition to providing grants to private companies to support the development of novel antibiotics and antivirals, BARDA also supports partnerships across federal organizations, academia and industry to facilitate clinical development, manufacturing and regulatory activities. Over the past five years, several companies and organizations have taken advantage of these incentives in the development of antibiotics (see Figure 2: BARDA PARTNERSHIPS), however these programs have yet to complete clinical development.

A program that has demonstrated a more near-term impact on the late stage clinical development of antibiotics, is the Generating Antibiotics Incentives Now provision (GAIN Act) of the Food and Drug Administration Safety and Innovation Act (FDASIA). Signed into law in July 2012 to promote innovation in anti-infective drug development, the GAIN Act provides the opportunity for both additional market exclusivity (five years) and a pathway to an accelerated regulatory review (fast-track status) if approved for a Qualified Infectious Disease Product (QIDP) designation.

Figure 2, BARDA Public-Private Partnerships

BARDA Private Partner	Date Awarded	Grant Amount	Product	Phase of Development by Indication (Estimated Completion Date)
Achaogen	08/2010	$60M	Plazomicin	III (BSI, HABP, VABP: 01/2017; cUTI: 05/2017)
GSK	09/2011	$38.5M initial, Up to $94M	GSK2251052	Terminated in phase III (due to evolving resistance)
CUBRC/Tetraphase	01/2012	$67M	Eravacycline	III (cIAI, cUTI: unknown)
Cempra	05/2013	$58M	Solithromycin	III (CABP: Complete; UTI: unknown)
GSK (Joint BARDA-GSK Committees)	05/2013	$196M (contract)	Broad-Spectrum Portfolio	Phase Unknown (multiple broad-spectrum antibiotics)
Basilea	06/2013	$89M	BAL30072	I (UTI: 12/15)
Medicine's Company/ Rempex	02/2014	$90M	Carbavance	III (UTI: 03/2016)
AstraZeneca	09/2015	$220M (over 5 years)	Novel Antibiotic Portfolio (including combination of aztreonam/avibactam)	Phase Unknown

Source: US Department of Health and Human Services, Public Health Emergency, BARDA Procurements and Grants

BSI: bloodstream infection; CABP: community-acquired bacterial pneumonia; cIAI: complicated intra-abdominal infection; cUTI: chronic urinary tract infection; HABP: hospital-acquired bacterial pneumonia; UTI: urinary tract infection; VABP: ventilator-associated bacterial pneumonia

Between July 2012 and September 2014 alone, the FDA granted 39 QIDP designations[1]. Thus far, these designations have accelerated approval for several products, including Dalvance, the first QIDP designated drug approved. Three more products followed suit in 2014 (Orbactiv, Sivextro, Zerbaxa), of which, Orbactiv was the first QIDP product approved without an advisory committee.

In addition to BARDA grant funding and the GAIN Act, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act was included in the 21st Century Cures Act, approved by the House of Representatives in July 2015. Intended to incentivize the development of products addressing antibiotic resistance, the ADAPT Act established an approval pathway for antibiotics and antifungals targeting serious or life-threatening infections for which no suitable options exist. Due to the reduced size of the patient population impacted by these conditions, the Limited Population Antibacterial Drug (LPAD) pathway for approval would require smaller clinical trials than those for products addressing broader indications. The 21st Century Cures Act, is currently awaiting consideration by the Committee on Health, Education, Labor and Pensions, and has the potential to further accelerate the clinical development timeline for antibiotics targeting serious infections with a high level of unmet need.

While these inducements may promote innovation in anti-infectives for antibiotic resistant infections and other areas of unmet need, the programs have yet to make a significant impact on the realized antibiotic product revenue and development return—due to the small target patient populations, limited availability of pathogen identifying diagnostics, and reimbursement constraints.

Diminishing Returns

Despite increasing public awareness of the antibiotic resistance concerns and government incentives to promote antibiotic innovation, the ROI for novel antibiotic products has been declining since the 1980s. To illustrate this finding, antibiotic products launched since 1985 were graphed based on the ratio of their cumulative sales to the size of the patient population studied in clinical development (see Chart 1: DIMINISHING RETURNS). There is a clear downward trend demonstrated by approximately a ten-fold decline in the average ratio from 1985 to 2010, with fewer high producing outliers in the more recent years. It remains to be seen whether this trend will continue, or if it has reached a plateau. As therapeutics becomes more targeted, and their addressable patient population more limited, improved reimbursement and diagnostic adoption would be required to slow this decline.

[1] Woodcock, J. Three encouraging steps towards new antibiotics. Posted September 23, 2014 by FDA Voice.

Chart 1, Ratio of Cumulative Revenue 10 Years Post Launch to Number of Phase III Patients in Clinical Development

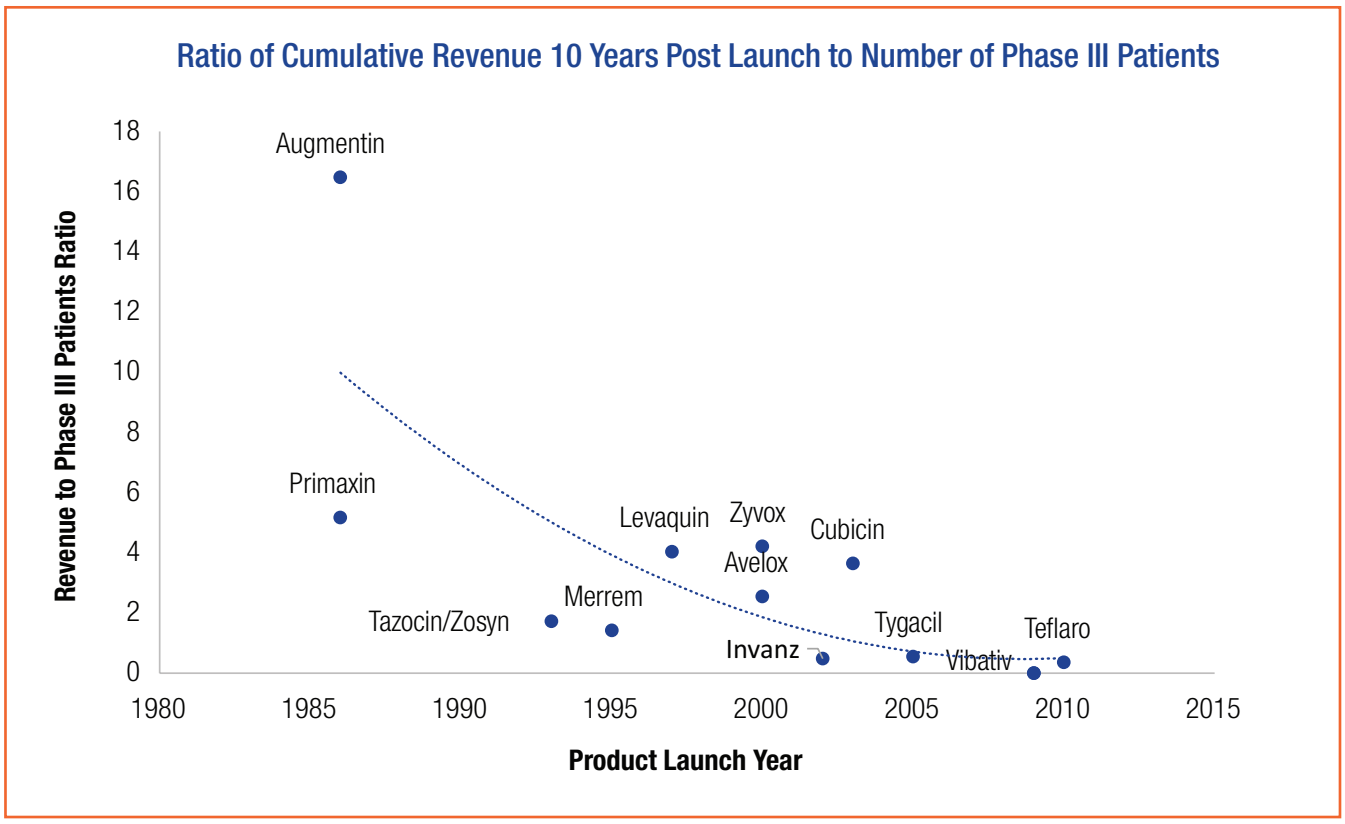

Chart 1. Key antibacterial drugs launched since 1985: Ratio of 10 year cumulative sales (in millions, adjusted to 2015 dollars) to number of patients studied in phase III trials included in the product label. For recent launches (i.e., Vibativ and Telfaro), forecasted peak sales are based on consensus analyst forecasts.

Adoption of Diagnostics for Pathogen Identification

As the market evolves towards a more targeted treatment approach, the adoption of rapid, point-of-care (POC) diagnostic tests will be required to diagnose and identify treatment-resistant pathogens before the selection of a first-line therapy. Currently, the empiric use of broad-spectrum antibiotics is recommended in clinical guidelines for initial infection treatment. The antibiotic is often administered until the results of culture-based assays are returned, typically after two to four days. Only after the pathogen species and antibiotic susceptibility has been determined, are patients transitioned to a more targeted antibacterial treatment option. The delay in pathogen identification often results in a lengthened hospital stay, elevating inpatient treatment costs, and increasing the risk of developing antibiotic resistance through the overuse of broad-spectrum agents.

The need for POC diagnostics was recently outlined by the federal government in 'The National Action Plan for Combating Antibiotic-Resistant Bacteria', published in March 2015[2]. This initiative aims to incentivize the development, dissemination, and use of POC diagnostics by 2020. The plan includes incentives and guidelines for private and public development in coordination with government organizations such as the FDA, BARDA, and the Centers for Disease Control and Prevention (CDC). Arguably, the most important aspect of the antibiotic national action plan is a directive to improve the Medicare reimbursement and coding related to diagnostic tests, which currently is a limiting factor to patient access to newer diagnostic techniques. Traditional bacterial cultures are reimbursed by Centers for Medicare & Medicaid Services (CMS) under the "CPT-4/HCPCS Codes Subject to CLIA Edits" rates that are reimbursed based on the methodology of the test performed (e.g., urine screen for bacteria is CPT code 81007). As clinical laboratories began to increase the use of next generation approaches, such as molecular diagnostics, payers voiced concerns due to the lack of transparency to the analytes included in complex testing panels. In response, CMS implemented analyte-specific molecular pathology codes (MoPath Codes) in January, 2013. This method handicaps the multi-analyte tests, such as molecular diagnostic panels[3]. The White House National Action Plan for Combating Antibiotic Resistant Bacteria (2015) recognizes the obstacles to diagnostic uptake

[2] President's Council of Advisors on Science and Technology, National Action Plan for Combating Antibiotic Resistant Bacter, 2015.
[3] American College of Medical Genetics and Genomics. (2013) Molecular Pathology Rate Setting Guide for Laboratories.

and has initiated a FDA-CMS Parallel Review program to reduce costs and develop clear diagnostic reimbursement policies to incentivize utilization.

The current POC diagnostic landscape includes testing platforms for rapid pathogen identification and sensitivity testing. While development is promising, there are several key limitations with these technologies including strict requirements for samples and type, as well as limited pathogen identification capabilities. These limitations not only impact the adoption of diagnostics, but also impede the utilization of targeted antibiotic agents.

Reimbursement Reform

A key obstacle to achieving greater commercial returns on antibiotic development is the current inpatient reimbursement landscape. The reimbursement structure for serious bacterial infections has not evolved to address the significant differences in cost and complexity associated with treating indications caused by resistant and non-resistant pathogens. One study indicated the cost of treating an antimicrobial resistant infection was, on average, 4.3 times greater than that of a non-resistant infection ($56,745 versus $13,210)[4]. However, in the inpatient setting, the typical DRG reimbursement does not take this discrepancy into account. For example, severe sepsis and septicemia codes (DRG 870-872) range from $7,990 - $46,192 (with or without mechanical ventilation, with or without major complications or comorbidities)[5], often resulting in a loss for the inpatient provider. In addition, the current infection rates for most resistant pathogens are relatively small, thus are under-represented in the average treatment costs. Recently launched, targeted antibiotic therapy is estimated to cost from $2,000 to $6,000 per course of therapy[6].

In order to address the potential limitations of DRG reimbursement on use of breakthrough technologies in the inpatient setting, the Centers for Medicare & Medicaid Services (CMS) implemented the New Technology Add-on Payment (NTAP) program. The program, which established initial criteria for NTAP qualification in 2001, provides an add-on payment for hospital discharges not to exceed either 50% of the amount by which the cost of the case exceeds the Medicare Severity-DRG (MS-DRG) payment or 50% of the cost of the new technology[7]. Not only does the reimbursement rate fail to incentivize utilization of new technologies, but the criteria requiring the applicants to demonstrate an advance in medical technology ("substantially improves, relative to technologies previously available") which meets the high cost threshold has been considered prohibitively restrictive. Since 2001, through reimbursement for federal fiscal year (FY) 2016, only 21 of the 62 NTAP applications were approved by CMS[8,9]. Recent rejections include Cresemba (an Astellas Pharma antifungal) and Dalvance, which were determined to fall short of substantial clinical improvement over existing technologies. Accumulated NTAP payments from FY 2002-2013 amount to less than $202M (less than $17M annually, on average)[8], approximately one-third of CMS projections. It is clear that the NTAP program alone, will not address the DRG reimbursement short-fall for novel antibiotics.

In order to supplement the NTAP program, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) provision of the 21st Century Cures Act (section 2123) has been proposed to provide add-on payments under Medicare's Hospital Inpatient Prospective Payment System (IPPS) reimbursement. If passed, an additional payment, in the current Medicare Part B reimbursement amount, would be provided to the treating hospital for the use of approved DISARM products in antimicrobial-resistant infections. Eligible products would include QIDP designated drugs and anti-infectives addressing infections associated with high mortality or morbidity and a high unmet medical need as determined by the FDA and the CDC. This provision would allow higher reimbursement for severe or antibiotic-resistant infections, if the use of more expensive, targeted agents are necessary.

In the case that the 21st Century Cures Act is not enacted with the DISARM provision, improved reimbursement may still be achieved if DRG codes were specific to not only the site of infection, but also the pathogen and resistance profile associated with the patient's infection. ICD-9/10 codes (International Statistical Classification of Diseases and Related Health Problems) have been recently transitioned to include specific pathogens but not resistance profiles. However, CMS DRG codes remain broad (see Figure 3: EXAMPLES OF REIMBURSEMENT DISCREPANCY). This reform would increase coverage for the high-cost, difficult to treat bacterial infections, potentially driving utilization of novel, targeted agents in severe infections. The improvement in patient outcomes resulting from this reimbursement approach may also provide additional incentives for the adoption of rapid, POC diagnostics for early pathogen characterization (see Inset: ADDITIONAL DRG REIMBURSEMENT CASE STUDY EXAMPLE: GENENTECH'S ACTIVASE).

[4] Roberts, et al., Hospital and Societal Costs of Antimicrobial Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship, Clin Infect Dis. (2009) 49(8): 1175-1184.
[5] Centers for Medicare and Medicaid Services. 2013 DRG Summary: Top 100 DRGs Based on Total Discharges by DRG.
[6] Truven Health Analytics. Red Book Drug Prices. Accessed November 2015.
[7] Centers for Medicare and Medicaid Services. New Medical Services and New Technologies. Application Information for FY 2017.
[8] Hernandez J, Machacz SF, Robinson JC. US Hospital Payment Adjustments For Innovative Technology Lag Behind Those In Germany, France, And Japan. Health Affairs. 2015 (34) 261-270.
[9] Department of Health and Human Services. Federal Register. Vol 80, No. 158. August 2015.

Figure 3, Examples of Reimbursement Discrepancy that Limit Novel Antibiotic Utilization

DRG Code & Definition	Total US Discharges (2013)	Average Covered Charges (2013)*	Average Total Payment (2013)†
177-Respiratory Infection and Inflammation with MCC	72,906	$52.7K	$14.2K
178- Respiratory Infection and Inflammation with CC	52,714	$37.6K	$10.1K
193- Simple Pneumonia and Pleurisy with MCC	145,391	$39.6K	$10.4K
194- Simple Pneumonia and Pleurisy with CC	182,388	$26.9K	$7.1K
193- Simple Pneumonia and Pleurisy without MCC/CC	71,357	$19.7K	$4.9K
602- Cellulitis with MCC (e.g., ABSSSI)	27,083	$38.8K	$10.7K
603- Cellulitis without MCC (e.g., ABSSSI)	134,288	$22.1K	$4.7K
853- Infectious and Parasitic Disease with OR Procedure with MCC	53,117	$146.3K	$41.0K
870- Septicemia or Severe Sepsis with MV 96+ Hours	33,180	$170.4K	$46.2K
871- Septicemia or Severe Sepsis without MV 96+ Hours with MCC	398,004	$51.6K	$14.0K
872- Septicemia or Severe Sepsis without MV 96+ Hours without MCC	127,832	$30.1K	$8.0K

ABSSSI: acute bacterial skin and skin structure infection; CC: complications and comorbidities; MCC: major complications and comorbidities; MV: mechanical ventilation

*The provider's average charge for services covered by Medicare for all discharges in the DRG. These will vary from hospital to hospital because of differences in hospital charge structures

†The average total payments to all providers for the MS-DRG including the MS-DRG amount, teaching, disproportionate share, capital, and outlier payments for all cases. Also included in average total payments are co-payment and deductible amounts that the patient is responsible for and any additional payments by third parties for coordination of benefits.

Additional DRG Reimbursement Case Study Example: Genentech's Activase

In 1996, the FDA approved Activase (alteplase), a recombinant tissue plasminogen activator (rtPA) for the management of acute ischemic stroke (AIS). The product had demonstrated improved neurological recovery and reduction in the incidence of disability when administered within three hours of the onset of stroke symptoms. Despite the demonstrated improved patient outcomes, the use of rtPA in the US inpatient setting remained low. In 2004, only 1.8% to 2.1% of AIS patients received rtPA[10] (approximately $2,000 per dose) due to reimbursement[11]. Based on an analysis of more than one million stroke patients from 1990-1991 and 2000-2001 and converted to 2008 dollars, one US study found the median hospitalization cost due to ischemic stroke to range from $8,000-$23,000[12]. This range is in stark contrast with the DRG reimbursement at that time of $5,700. With high efficacy and poor utilization data, Genentech lobbied CMS to introduce additional reimbursement for tissue plasminogen activators. The new DRG code (559, "Acute ischemic stroke with use of thrombolytic agent), approved in 2005 and effective in FY 2006, provided an additional $6,000 in reimbursement to cover the costs of both the therapeutic agent and additional treatment costs (e.g., testing, ICU stay) for patients receiving a tissue plasminogen activator[13]. This additional DRG had an immediate impact on product utilization. By 2009, 3.4% to 5.2% of AIS patients rtPA, approximately doubling utilization of a product which had already been marketed for eight years[10]. Genentech sales of Activase in the US increased from $195M to $379M in the same time period[14].

In order to promote the use of the more expensive, novel antibiotics in high priority bacterial infections, and the rtPA case should serve as a model for the impact of DRG reimbursement codes.

[10] Adeoye O, Hornung R, Khatri P, Dleindorfer D. Recombinant Tissue-Type Plasminogen Activator Use for Ischemic Stroke in the United States. Stroke. 2011; 42(7): 1952–1955.
[11] Arora S, Broderick JP, Frankel M et al. Acute stroke care in the US: results from 4 pilot prototypes of the Paul Coverdell National Acute Stroke Registry. Stroke 2005; 361232- 1240.
[12] Qureshi AI, et al. (2007) Changes in cost and outcome among US patients with stroke hospitalized in 1990-1991 and those hospitalized in 2000-2001.
[13] Bambauer, et al., Reasons why few patients with acute stroke receive tissue plasminogen activator, Arch Neurol. 2006; 63(5):661-664.
[14] Genentech, Inc. and Roche Holding AG. FY2004-2009 10K.

Conclusion

The path to blockbuster status for recent and future antibiotic launches in the US includes significant obstacles, such as the lack of adoption of rapid diagnostics to accompany pathogen-specific therapeutics and reimbursement limitations which do not account currently for the additional costs associated with severe and resistant infections. A transformation in inpatient reimbursement has the potential to benefit patient outcomes in the form of improved antibiotic stewardship, through early pathogen characterization and more precise treatment decisions. This market shift has the potential to incentivize future innovation in antibiotic and diagnostic development, increasing utilization of targeted agents and improving product development returns. However, even with reimbursement improvement the returns for next-generation antibiotics will be constrained due to the limited addressable patient population. Thus, the enthusiasm driving the high values of recent antibiotic deals should be tempered to reflect the challenges faced by novel antibiotics in this shifting landscape.

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.

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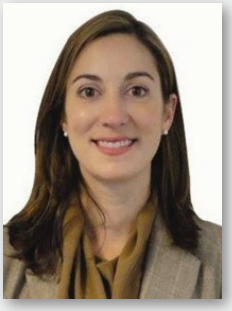
Recent by-lined articles have appeared in Pharmaceutical Executive, InVivo, Nature Biotech, RPM Report, and Scrip. In addition, Ben's case studies on the pharmaceutical industry have been used in graduate business programs.

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.