Introduction

What pharma leaders fear most is uncertainty in today’s coverage and reimbursement environment. Government and private payers are under significant pressure to contain drug costs as healthcare spending continues to escalate. As a result, the high cost of cancer care presents unique challenges to market access. Among specialty therapeutic categories, cancer drug costs account for the highest per member per month spend. As cancer disproportionately affects the elderly, the aging baby boomer population will accelerate the demand for treatment. Consequently, payers are looking for game-changing ways to ensure appropriate use and eliminate waste while maintaining or improving outcomes.

To better understand the market access challenges within the oncology space, Campbell Alliance conducted an in-depth analysis of three market trends:

- Provider Consolidation and Site-of-Care Shifts
- Advent of Oral Oncolytics
- Payer Management and Clinical Pathway Experimentation

Based on in-depth primary research with key stakeholders, ongoing marketplace surveillance through secondary research, and hands-on industry experience, this paper outlines the key drivers and barriers associated with each of these trends.

Summary Results From the Trends in Oncology Market Access

Provider Consolidation and Site-of-Care Shifts
- The increasing shift in cancer drug spending to hospitals, many of which have access to 340B pricing, is negatively impacting cancer drugmaker profitability.
- For pharmaceutical marketers, hospitals represent a very different sales channel in terms of the system structure, stakeholder incentives, and selling messages.
- Drugmakers will need to look for ways to mitigate site-of-care shifts by addressing the financial concerns of community oncologists.

Advent of Oral Oncolytics
- The increased use of oral oncolytics confers different advantages and disadvantages to patients, providers, and payers.
- Drugmakers will need to optimize their investment in patient assistance programs, help physicians maintain their economic viability, and consider payer contracting strategies to defend or improve access.

Payer Management and Clinical Pathway Experimentation
- Payers are looking for game-changers to save them a meaningful amount of money. This has led them to evaluate payment reform and the use of clinical pathways as a means to restrict choice.
- Drugmakers must ensure their target product profile does not inadvertently lead to a label that incurs highly restrictive payer management, and they must develop a compelling economic value proposition to ensure pathway inclusion.
Provider Consolidation and Site-of-Care Shifts

The Trend

Office-based practices and hospitals represent two distinct customer segments with differing business models and support needs. Hospitals have greater leverage against payers in local markets with provider fragmentation than do office-based practices. In addition, whereas office-based practices rely heavily on buy-and-bill profits, hospitals rely more on diversified service lines and have access to 340B pricing if eligible. The 340B Drug Pricing Program resulted from the enactment of section 340B of the Public Health Service Act, which limits the cost of drugs to federal purchasers and to certain grantees of federal agencies, such as hospitals that serve a disproportionate share of low-income patients, children’s hospitals, freestanding cancer hospitals, critical access hospitals, and federally qualified health centers, among others.

Hospitals’ share of cancer drug spending is growing, making them an increasingly important customer segment. As institutions, hospital stakeholders have the power to influence access. The implication for cancer drugmakers is more restricted access to prescribers, who may themselves face restricted product selection due to the use of hospital formularies and institutional guidelines. Cancer drugmaker profitability also declines considerably when patients are referred to 340B institutions. Meanwhile, economic pressures have made it difficult for oncology practices to operate independently, resulting in provider consolidation. Growing hospital shares and provider consolidation both lead to greater bargaining power against payers and cancer drugmakers.

The Drivers

Provider consolidation and site-of-care shifts are being driven by a number of factors. Declining reimbursement and increasing administrative burdens have led large physician groups to acquire smaller practices to achieve economies of scale and gain bargaining power against payers and cancer drug manufacturers. Meanwhile, many cancer patients face significant affordability issues due to the high cost of drugs. When cancer strikes, the co-pay/coinsurance burden is not as likely to be anticipated as premiums or deductibles. Nevertheless, community providers prefer to keep patients in-house and will first look to foundations and other patient financial assistance before referring patients out.

The expansion of 340B discounts and other price concessions is also driving the trend. Cancer drugmakers are required to provide outpatient drugs to 340B hospitals at savings equal to the Medicaid drug rebate rate. Practices acquired by 340B hospitals are able to purchase drugs under 340B if they are an integral part of the hospital and operate/bill as a hospital outpatient department. Because the acquisition of community practices extends 340B pricing to a larger patient base and thus increases profits, 340B participation incentivizes hospitals to acquire community practices.
The increased use of oral oncolytics confers different advantages and disadvantages to each of three stakeholder groups: patients, providers, and payers. With oral drugs, payers see savings from the elimination of infusion costs. In addition, oral oncolytics are more easily managed under the pharmacy benefit, and product waste can be reduced through quantity limits and short cycle dispensing. Nevertheless, for payers, oral oncolytics represent a source of rapidly increasing spend.

The convenience of taking an oral medication is a benefit to the patient, but out-of-pocket costs for oral oncolytics can be overwhelming and lead to non-adherence. From the provider perspective, oral therapeutics eliminate the buy-and-sell profits that practices rely upon and result in uncompensated care for prior authorization, patient education, and side-effect management. Furthermore, oral medications take the provider out of the patient feedback loop, leading to less compliance control and making the management of treatment side effects more difficult.
Patient Affordability

With the high cost of cancer drugs and the prevalence of comorbid conditions, Medicare cancer patients fall in the Part D “donut hole” quickly. Although manufacturer discounts for standard benefit plans provide a subsidy that by 2020 will reduce the beneficiary’s contribution in the donut hole to 25%, this still represents a significant cost burden for Medicare patients prescribed branded oral cancer therapies.

When Part D benefits are determined by the use of a formulary tier, Medicare enrollees also face a high cost-share burden for oral cancer therapies. While oral oncolytics are most commonly placed on Tier 2 or Tier 3 for commercial lives, for Medicare lives they are most often placed on the specialty tier where the beneficiary is liable for 25% or 33% coinsurance (Figure 2).

Oral oncolytics are covered under the pharmacy benefit for 94% of lives in this study. Under the pharmacy benefit, commercial lives are most commonly liable for a flat co-pay for oral drugs, but they typically do not have an out-of-pocket maximum to limit their cost-share burden. In addition, cancer patients must pay their cost-share for oral medicines at the point of fill, whereas infused patients are invoiced sometime after treatment has been administered. Oral cancer drugs with patient cost-sharing greater than $500 on the initial claim are four times more likely to be abandoned than those with cost-sharing of $100 or less (Figure 3).

Distribution Strategy

Today, nearly half the volume of oral oncolytics is dispensed through specialty pharmacies (SPs), which focus on therapeutic categories with complex management issues, greater potential for adverse events, and significant expense. Payers primarily utilize SPs for managing waste, ensuring appropriate use, and monitoring patient compliance and adherence.

A range of specialty distribution models exist. Exclusive distribution networks offer a high level of control to drug manufacturers, but they limit patient access and impose supply chain risk. Alternatively, open networks offer a high level of accessibility and convenience to patients and providers but limited supply chain control to drug manufacturers. Cancer drugmakers should consider the provider and patient needs as well as other implications when deciding on a specialty pharmacy distribution model. For example, oral therapies with an exclusive distribution network may be able to avoid 340B discounting when the prescriptions are filled by pharmacies outside the 340B institution’s services.

The specialty hub, a variation of the SP model, has become increasingly popular as a means of simplifying distribution for patients and practices while maintaining a broad SP network. In the specialty hub model, the manufacturer’s hub determines the appropriate SP according to the patient’s insurance carrier and can direct the provider to that SP. Cancer drugmakers employing a hub can

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**Figure 2**

Where on formulary are most branded oral oncology products for the majority of commercial and Medicare lives? What is the flat co-pay dollar amount or coinsurance percentage for drugs on the specialty tier for the majority of lives within your organization?

**Most Common Formulary Status for Oral Oncolytics**

*(n=36 managed care payers; percentage of health plans)*

<table>
<thead>
<tr>
<th>Commercial Lives</th>
<th>Medicare Lives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average $78 co-pay (range $35-$100)</td>
<td>Tier 4/ Specialty 28%</td>
</tr>
<tr>
<td>Tier 4/ Specialty 28%</td>
<td>Tier 4/ Specialty 71%</td>
</tr>
<tr>
<td>Tier 3 36%</td>
<td>Tier 2 15%</td>
</tr>
<tr>
<td>Tier 3 36%</td>
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<td>Tier 2 15%</td>
</tr>
<tr>
<td>Tier 3 36%</td>
<td>Tier 3 15%</td>
</tr>
</tbody>
</table>

Source: Campbell Alliance Oncology Market Access Trends 2012.
increase control of the patient experience but at higher costs and with slower delivery times to patients.

While payers often require oral medicines be distributed through SPs, some physician groups have added on-site dispensing as a means to diversify their revenue stream and get paid for otherwise uncompensated care. Physician groups can leverage “Any Willing Provider” state laws to participate in pharmacy networks that otherwise seek to exclude on-site provider pharmacies. Today, 23 states have laws in place that require payers to allow any provider, from physicians to hospitals and pharmacies, to fill a prescription if the provider is willing to accept the terms and conditions set forth for an SP.

**Payer Management**

Health plans have been slow to adjust to the advent of oral oncolytics and patient affordability. Coverage disparities between oral and IV cancer treatments have led to a groundswell of advocacy for access parity laws. Today, 19 states and Washington DC have enacted oral parity laws to cover oral chemotherapy under terms no less favorable than those offered for IV treatments. Recently enacted oral/infused parity laws are raising costs for most payers, and health plans are increasingly turning to other cost-control strategies.

For oral cancer therapies in particular, health plans are focusing on eliminating wastage to better contain costs. Often, patients do not complete a full month of oral cancer therapy due to side effects or disease progression. “Split-fill dispensing” fills only half of the first month’s supply of oral medication initially and is becoming a popular cost-control strategy. This enables health plans to determine if the patient is responding to a treatment before dispensing a 30-day supply of medication. Walgreens Specialty Pharmacy’s cycle management program for oral oncolytics reportedly saved more than $3 million during the first three months of therapy among 1,740 patients.

As cancer evolves into a more chronic condition, competitive categories covered largely under the pharmacy benefit are likely to be more tightly managed. Indications such as renal cell carcinoma and chronic myelogenous leukemia are dominated by the use of oral cancer therapies with long treatment durations. In the absence of meaningful clinical differentiation, price will become the impetus for payer restrictions.

**Patients must share the cost for orals at the point of fill, whereas infusion patients receive bills after treatment. Oral drugs with patient cost sharing >$500 are four times more likely to be abandoned than those with cost sharing ≤$100.**

**Oral Oncolytic Abandonment Rate at Varying Cost-Sharing Amounts**

<table>
<thead>
<tr>
<th>Cost-Sharing Amount</th>
<th>Abandonment Rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤$100</td>
<td>6.7%</td>
<td></td>
</tr>
<tr>
<td>$101-$200</td>
<td>10.0%</td>
<td></td>
</tr>
<tr>
<td>$201-$500</td>
<td>13.4%</td>
<td></td>
</tr>
<tr>
<td>&gt;$500</td>
<td>24.7%</td>
<td></td>
</tr>
</tbody>
</table>

Only 11% of commercially insured patients paid more than $500 versus 46% of Medicare patients.

**Patient Cost-Sharing Amount for Initial Claim**

Notes  • Patients with claims defined as abandoned had reversed the newly initiated oncolytic but did not have a paid oncolytic claim within 90 days of submission date of the reversed claim.
  • Study includes patients prescribed Xeloda (capecitabine), Gleevec (imatinib), Nexavar (sorafenib), Revlimid (lenalidomide), Sutent (sunitinib), Tarceva (erlotinib), Temodar (temozolomide), or Tykerb (lapatinib).


**Recommendations for Cancer Drugmakers**

Key considerations for commercialization of oral oncolytics include program design for patient assistance, distribution strategy, and a compelling payer value proposition. As the patient’s cost burden continues to drive treatment abandonment, manufacturers should optimize the design of patient assistance programs to address the significant patient cost burden.

Trade strategies and distribution structure can be refined to determine the optimal...
level of supply chain control and provider/patient access. Although payers prefer the use of specialty pharmacies to distribute oral oncology drugs, on-site dispensing by community physician groups may improve practice economics as well as the patient experience. When evaluating distribution strategies, drug manufacturers should consider physician preferences for on-site dispensing.

Health plans are able to manage oral oncology more aggressively than infused therapies, so it is important to develop strategies to communicate clinical and economic value to payers. In categories with high competitive intensity, cancer drugmakers should consider developing contracting strategies to improve or defend access as the market matures.

RainTree Strives to Help Community Practices Improve Quality of Care

RainTree Oncology is a group purchasing organization (GPO) that is building a network to focus on oral oncology drug acquisition and management. RainTree strives to help community practices improve quality of care and enhance the economics of their business model for sustainability. This GPO is leveraging its vast network, which currently consists of 549 oncologists (including Florida Cancer Specialists and Tennessee Oncology, two of the nation’s largest physician groups’), to negotiate lower drug prices from drug manufacturers.

RainTree aims to help community oncology practices:
- Establish or enhance cost-effective pharmacy operations for oral dispensing
- Enable diversification of revenue stream and reduce reliance on buy-and-bill profits
- Achieve critical mass for partnering with drugmakers and payers
- Improve fulfillment rates and achieve more compliance control
- Monitor practice prescribing patterns and improve outcomes

1 RainTree press release, April 24, 2012

Payer Management and Clinical Pathway Experimentation

Utilization Management on the Rise

Utilization management of cancer therapeutics is a high priority for payers, but the level of management varies by product. Payers will most often restrict high-cost drugs, biomarker-indicated therapies, and drugs deemed to be at high risk for widespread off-label use, including failure to comply with step therapy.

Moving forward, commercial health plans expect to increase their use of utilization management tactics, but the range of tactics they employ is limited. According to Campbell Alliance’s survey, the vast majority of payers plan to increase their use of utilization management tactics, such as prior authorization, increased patient cost-sharing, prior therapy requirements, and the mandated use of specialty pharmacies to exclude buy-and-bill (i.e., white bagging).

Prior Authorization

Management tactics such as prior authorizations are a preferred tool, but the specific criteria and requirements for a given drug may vary by payer. Oncology practices navigate a wide range of prior authorization requirements to limit reimbursement risk. Successfully securing prior authorization does not guarantee payment, however.

Challenges exist in securing prior authorization. Payer policies that encourage conformity to label may limit flexibility with oncologists’ ability to modify regimens, for instance. A patient who skips a cycle of Avastin may be denied coverage when the payer considers the next cycle of Avastin use as a new line of therapy (second line) rather than a continuation of therapy within the same (i.e., first) line. Further, payers may require full medical records at the time of prior authorization for a number of cancer therapeutics, increasing practice administrative hassles.

In addition, payers often require step edits in categories where they perceive drug interchangeability to be high. The most notable examples are supportive care categories such as antiemetics, erythropoietin-stimulating agents (ESAs), and granulocyte-colony stimulating factors (G-CSFs). Here, payers may restrict the use of Neulasta to cancer patients with high risk of neutropenia or the use of Aloxi and Emend to patients on highly emetogenic regimens.

Most commercial health plans require prior authorization re-certification and often ask for documentation of patient response to therapy at the time of re-certification. Nearly all payers surveyed require documentation of
Figure 4
Which utilization management tools for IV and other office-administered cancer therapeutics do you expect to increase or decrease use of by 2014?

**Anticipated Change in Utilization Management for IV Drugs by 2014**
(n=38 managed care payers)

<table>
<thead>
<tr>
<th>Percentage of Plans in Sample</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomarkers/diagnostic tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Clinical pathways</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior authorization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased patient cost-sharing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior therapy requirement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mandated use of specialty pharmacy (to exclude buy-and-bill)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compendia listing/guideline requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shift of coverage from medical to pharmacy benefit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Campbell Alliance Oncology Market Access Trends 2012.

Figure 5
How much importance does your organization place on each of the following resources when determining formulary placement or restrictions for cancer products?

**Importance of Resources in Determining Coverage**
(n=38 managed care payers; average weight on a scale from 1 to 7, where 1 = “not at all important” and 7 = “extremely important”)

Source: Campbell Alliance Oncology Market Access Trends 2012.
patient response to therapy. Payers sometimes also request lab or imaging results as evidence of response, furthering the administrative burden for practices.

Adherence to treatment guidelines is encouraged and often enforced through prior authorization. Among payers surveyed, NCCN Guidelines® and peer-reviewed medical literature rank as the most important determiners of formulary placement or restrictions for cancer products (Figure 5). Although practices drive NCCN or internally developed guideline adherence with varying levels of sophistication (e.g., via electronic medical records), most payers surveyed allow for exceptions and none employ financial incentives for compliance.

**Clinical Pathways**

Whereas guidelines expand the set of available treatment options, pathways seek to restrict choice. The goal of a clinical pathway is to improve or maintain health outcomes while lowering costs by reducing treatment variability. Pathway inclusion is based on a hierarchy of efficacy, safety, and cost, in that order of priority.

Clinical pathways are designed to address the limitations of prior authorization and reducing fee schedules, offering more durable cost containment to payers. Pathways may lead to cost savings by encouraging the use of generics, streamlining treatment choices, and reducing side effects while maintaining outcomes.

Only 29% of commercial health plans surveyed by Campbell Alliance have implemented the use of clinical pathways to date, either as pilot programs or as fully implemented programs across all physician practices. But nearly half of commercial health plans surveyed perceive the use of clinical pathways to be of high or very high benefit. Currently, clinical pathway programs focus on the largest cancers, but the majority of payers surveyed anticipate expanding their use of clinical pathways to such tumor types as prostate, lymphoma, myeloma, and renal cell carcinoma (Figure 6). Some surveyed payers also expect to expand their clinical pathway programs to new geographical areas.

One way pathways may demonstrate cost savings is through adherence to established protocols. A study published by US Oncology shows evidence-based care for patients with NSCLC resulted in 35% cost savings while demonstrating equivalent health outcomes.7 However, many practice managers interviewed by Campbell Alliance do not find this data to be credible.

Despite this skepticism, some payers have begun implementing clinical pathways, which are mostly developed internally or with local health systems. Payers face significant barriers to pathway implementation, though, including lack of competition in a given provider market, lack of physician buy-in, and difficulty linking pathways to health outcomes (Figure 7). Payers must also design and implement a system of financial incentives for compliance.

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**Figure 6**

Do you expect your organization’s use of clinical pathways to increase by 2014, and if so, to what extent? For which tumor types are you employing these pathway-based programs in 2012? How is your organization expanding the use of clinical pathways? Which tumor types?

**Table: Anticipated Expansion of Clinical Pathways**

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>2012</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myeloma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ovarian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CML</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancreatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GBM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head/neck</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In addition to additional tumor types, ~40% of payers plan to expand clinical pathway program use geographically.
Campbell Alliance: Strategy. Results.

incentives to secure physician participation and motivate continued adherence.

Practices, meanwhile, question the value of clinical pathway programs, believing they lead to a loss of autonomy in treatment decision making. As a result, many physicians and practices interviewed for this study are resistant to clinical pathway program adoption. However, if pathways are implemented on the payer side, some practices recognize they may have to comply as a condition of reimbursement.

Recommendations for Cancer Drugmakers

Payers will increasingly use blunt tools (e.g., prior authorizations) and case management of high-cost patients as means of ensuring appropriate use and controlling costs. Drugmakers should ensure their target product profile does not inadvertently lead to a label that incurs highly restrictive payer management. In the case of Dendreon’s Provenge®, for example, commercial health plans looked to clinical trial exclusions to define coverage policy exclusions. The product’s indication statement allows some room for physician interpretation of terms such as “asymptomatic or minimally symptomatic,” therefore Provenge is typically not authorized for patients who use opioid analgesics for cancer-related pain.

As payers view clinical pathways as a potential game changer (relative to the use of blunt tools), drugmakers need to develop an economic value proposition that considers the total cost of therapy to ensure pathway inclusion. They can identify opportunities to engage regional stakeholders contributing to pathway development and/or driving pathway utilization. Cancer drugmakers can also increase physician awareness of their drug’s presence on pathways and keep clinicians apprised of their drug’s latest clinical developments, as pathways may not always be updated in a timely fashion.

Pathways are gaining traction, but only with a limited number of regional plans and in geographic markets conducive to pathway adoption. While adoption will likely be a slow process due to physician skepticism and resistance, it is important for drugmakers to monitor pathway adoption on a regional basis.

Clinical data will remain the primary driver for whether a particular drug is right for a particular patient. But practical, economic considerations may be the ultimate barrier to utilization.

Turnaround Tides: Trends in Oncology Market Access

Methodology

Primary Research

Figure A

Campbell Alliance fielded an online survey in April 2012 to gather perspectives on oncology trends from respondents representing 38 managed care health plans and 181 million covered lives in the US.

Participating Payers

National Plans (9)

Midwest (4)

Northeast (11)

South (7)

One (1) anonymous state

Participation Mix

(n=38)

Pharmacy Directors 39%

Medical Directors 61%

Organization Size

(n=38); self-reported

<750,000 Covered Lives

>5,000,000 Covered Lives

Small 14

Midsize 17

Large 7
Additional research

Campbell Alliance supplemented the payer survey and practice manager interviews with additional primary and secondary research:

- Primary research with managed care payers (n=5) from national and regional plans
- Primary research with community oncologists (n=100) representing community practices, private and academic hospitals, and health systems
- Secondary research with a variety of sources, including analyst reports, conference presentations, published studies, third-party data (e.g., Wolters-Kluwer and EvaluatePharma), and trade journals

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RESULTS.

It’s a pretty simple word that’s used a lot in the business world, but what does it really mean?

When you cut through all the clutter, “results” means performing beyond expectations, eradicating challenges, and achieving your business goals. It means not just dreaming it. But actually doing it.

Campbell Alliance is purpose-built to help biopharmaceutical and medical technology companies achieve results. Whether it’s seizing the leadership position in a new market, solving seemingly impossible challenges, or developing innovative approaches for success, we don’t quit until the desired results are delivered.

We offer the insight to help leaders develop powerful strategies, as well as the knowledge to ensure they’ll work in the real world. And through our relationship with inVentiv Health, we bring the global implementation capabilities needed to put even the most ambitious plans into action.

Delivering results is what we do. Let’s get to it.