During the course of the next decade, the oncology market will continue to evolve. To examine the changes that will likely take place over the next 10 years, Campbell Alliance’s second-annual Oncology Index study is focused on the theme of maximizing value in oncology. Specifically, the study addresses the implications for the biopharmaceutical industry from the standpoint of identifying value, developing value, and delivering value.

This report is built on Campbell Alliance’s experience from more than 300 oncology projects in the past three years, during which time we worked with nearly all of the top oncology manufacturers globally and the vast majority of new oncology product launches. Our work covered a broad range of project types, from portfolio strategy to clinical development and commercialization. This report is also based on interviews with 10 highly published, internationally recognized oncology key opinion leaders and clinical investigators and is supported by Campbell Alliance’s proprietary Dealmakers’ Intentions Survey of 160 in-licensing and out-licensing professionals in the pharmaceutical and biotech industry. An additional pipeline analysis was conducted using a comprehensive oncology pipeline database that tabulates products by company, phase of development, mechanism of action, indication, and technology.

Identifying Value

As the industry looks to identify value in oncology over the next decade, genomic analysis and biomarker testing will become commonplace, specifying the eligible patient population for each drug. The next decade will also see newer classes of agents added to the treatment armamentarium. Cytotoxics will become smarter and more targeted, immunotherapies will produce the next wave of blockbusters as they leverage the human body’s own immune system to help combat cancer, and next-generation agents targeting cancer cell metabolism will have the potential for disruptive change in the oncology treatment paradigm.

During this time, the United States will continue to be the dominant oncology market in terms of revenue; however, emerging markets such as China and India provide important drivers for revenue growth. The innovation in oncology is not necessarily going to originate with big pharma; rather, innovation will continue to originate from smaller, clinical-stage companies. This means that big pharma is going to have to be smarter and faster on the in-licensing front, looking to earlier stages of development to find products. This also means big pharma companies must be willing to pay for assets that have been less de-risked than what they might have been comfortable with in the past.

Biomarkers, diagnostics, and personalized medicine

While considerable advances have been made in the development of novel treatments, unmet need still persists as targeted therapies and diagnostic techniques have not yet delivered a cure in most tumor types. Figure 1 graphs the common tumor types by incidence (number of patients) vs. survival. Tumors such as pancreatic cancer, liver cancer, lung cancer, and acute myeloid leukemia (AML) land in the upper box, representing lower survival or high unmet need. Even in the tumors that land closer to the bottom of the graph, the majority of late-stage patients do die from cancer, as most tumor types have no cure.
The future of oncology lies in finding treatments for specific patient populations within these traditional tumor-type boundaries. To that end, pharmaceutical manufacturers have increasingly adopted biomarkers for oncology agents on the market and in clinical development. In Figure 2, the charts on the left show that a number of tumor types, including breast cancer and colorectal cancer, have seen drugs approved for specific subpopulations. The chart on the right provides an overview of the tumor types with late-stage assets in development with biomarkers.

Based on an analysis of a comprehensive list of 158 unique oncology assets currently in phase III clinical studies for 20 different tumor types (13 solid and 7 hematological), Campbell Alliance concluded that in the next three to five years, both a greater number and a greater percentage of biomarker-driven agents will be produced for solid tumors than for hematological tumors. The full results of this study were published in the March 2012 issue of Oncology Business Review.

The broader use of biomarkers and diagnostics is enabled by the wider availability of genome sequencing, whose cost has declined at a rate faster than predicted by Moore’s Law (Figure 3). The cost of genome sequencing declined steadily in the past decade, and in the future, we expect individualized genome sequencing and analysis to become commonplace in cancer therapy.

Following this trend, while the current drug approval process is designed for specific tumor types, future drug approvals will likely be based on genomic analysis and will thus have broad applicability across multiple tumor types. Pfizer’s Xalkori® may be a good example, as the drug is being tested in multiple tumors with alterations in the ALK pathway—including lymphoma, renal cell carcinoma, and sarcoma—in addition to nonsmall cell lung cancer, which is the drug’s marketed indication.

**The rise of targeted cytotoxics, immunotherapies, and next-generation agents**

In most tumor types, targeted therapies based on signal transduction mechanisms have mostly offered incremental survival benefits. As a result, the need for potential cures will drive the search for newer classes of drugs, and the therapies available today will most likely be supplemented, or in some cases supplanted, by other classes of novel agents.

These novel agents will likely fall into three categories: smarter cytotoxics, immunotherapy, and next-generation agents targeting cancer stem cells, cancer cell metabolism, transcription and translation inhibition, and protein processing.
**Figure 2**

**Tumor Types With Approved Drugs for Specific Subpopulations**

- **Breast Cancer**
  - Breast cancers over-expressing HER2
  - 30% with Biomarkers
  - 70% Without Biomarkers

- **Metastatic Colorectal Carcinoma**
  - mCRC patients with mutated KRAS
  - 40% with Biomarkers
  - 60% Without Biomarkers

- **Non-Small Cell Lung Cancer**
  - Patients with ALK gene rearrangement
  - 5% with Biomarkers
  - 95% Without Biomarkers
  - Patients expressing high levels of EGFR
  - 25% with Biomarkers
  - 75% Without Biomarkers

- **Malignant Melanoma**
  - Patients with BRAFV600E gene
  - 30% with Biomarkers
  - 70% Without Biomarkers

**Phase III Oncology Assets With Biomarkers**

- Non-Hodgkin's Lymphoma
- Multiple Myeloma
- Hodgkin's Lymphoma
- Chronic Myeloid Leukemia
- Chronic Lymphocytic Leukemia
- Acute Myeloid Leukemia
- Acute Lymphocytic Leukemia
- Small Cell Lung Cancer
- Renal Cancer
- Prostate Cancer
- Pancreatic Cancer
- Ovarian Cancer
- Non-Small Cell Lung Cancer
- Melanoma
- Liver Cancer
- Head and Neck Cancer
- Glioblastoma
- Gastric Cancer
- Colorectal Cancer
- Breast Cancer

**Phase III Oncology Assets With Biomarkers**


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**Figure 3**

**Declining Cost of Genome Sequencing**

- Cost at which Steve Jobs had his genome sequenced in order to find treatment for his pancreatic cancer


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**Tumor Evaluation**

**Current Methods**
- Morphologic Features
- Flow Cytometric Analysis
- Cytogenic-FISH Analysis
- Molecular Studies

**Future Methods**
- Molecular Profiling
- Real-Time PCR
- Microarray Analysis
- Next-Generation Sequencing
Traditional cytotoxics are generally non-specific and will kill healthy human cells along with tumor cells. However, by using targeted, antibody-guided cytotoxics, the drug will be delivered specifically to the tumor, akin to using laser-guided bombs vs. carpet bombs. Targeted cytotoxics are quickly replacing non-specific cytotoxics in terms of revenue. In 2010, traditional cytotoxics accounted for 15% of sales revenue by therapy type for the top-10 oncology therapies (Figure 4). By 2020, however, targeted cytotoxics are expected to account for 12% of the pie, representing a partial replacement of the traditional cytotoxics in the next 10 years.

Beyond targeted cytotoxics, immunotherapy will offer curative potential in certain tumor types by activating the body’s immune system to fight tumors. In the next decade, immunotherapies will produce the next generation of blockbusters, primarily due to their unique mechanism, versatility in combination with other agents, and curative potential.

As an example of immunotherapy's potential, Figure 5 shows a Kaplan-Meier curve for Bristol-Myers Squibb’s immunotherapy Yervoy®. Whereas the overall survival rate for the control arm goes to zero within a relatively short period, Yervoy’s Kaplan-Meier curve reaches a survival floor in which 20% of patients are alive for at least four or five years.

The biggest potential in the treatment of cancer in the next 10 years may lie with next-generation technologies. Therapeutic options targeting cancer stem cells, transcription and translation inhibition, protein processing, and cancer cell metabolism are considered “next-generation agents” because of the potential for disruptive change in the oncology treatment paradigm.

Cancer stem cells are a phenotypically distinct subpopulation of cells with the ability to self-renew and drive tumorigenesis. The stem-cell platform includes drugs that act through the Notch, Wnt, and Hedgehog pathways and antibodies that target unique stem cell antigens to eliminate cancer stem cells. The transcription and translation inhibition platform includes antisense oligonucleotides, which knock down the expression of key genes involved in cancer. Drugs in the protein processing platform regulate proteins involved in cancer; this platform includes drugs that interfere with heat shock proteins and drugs that inhibit degradation of key proteins through proteasomes or ubiquitin ligases.

Among next-generation approaches, drugs affecting cell metabolism will most likely lead to transformational therapies. These drugs target the unique metabolic needs of cancer cells and prevent cancer cell energy production. The platform includes products that target key enzymes in critical metabolic pathways such as glycolysis or amino acid synthesis. Key opinion leaders interviewed by Campbell Alliance believe that targeting metabolic adaptation in tumors holds great potential because of its key role in tumorigenesis and adjacencies with tumor genomics and the microenvironment.
US dominance of oncology market

The next step in identifying value in oncology is to ascertain the geographical origin of value. While the emerging markets account for the majority of cancer patients, they contribute to only a small slice of the oncology market from a revenue perspective. The US market accounts for a disproportionate share of the global oncology market, and this trend is likely to continue, resulting in sustained focus on the US market by oncology manufacturers (Figure 6).

Additionally, the US Food and Drug Administration has approved more oncology drugs than the European Medicines Agency in the last decade and has been less stringent than EMA, particularly for indications with high unmet need. The FDA also tends to approve oncology drugs faster than the EMA. Among the drugs approved by both the FDA and EMA in the last decade, all were first approved by the FDA.

The potential for premium pricing in the US...
also supports its market dominance over Europe. As seen in Figure 7, oncology drug prices in the leading European markets are almost always lower than prices in the US, as much as 50% lower for some drugs.

Looking beyond the US and Europe, China and India show untapped revenue potential as the growth of the disease population far outpaces the treated population in both countries. Revenue projections for the oncology market are expected to increase at a compound annual growth rate of 13% in China and 11% in India.

China’s oncology market appears poised for growth as the introduction of targeted agents expands the market over the next decade. Challenges still remain with reimbursement of expensive targeted agents by public insurance schemes. For example, China’s National Reimbursed Drug List currently does not include any targeted cancer therapies. However, the increasing number of patients who can afford to pay out-of-pocket for cancer drugs will help drive market growth.

In India, meanwhile, conditions look promising on paper, but the country may not be a lucrative market due to reimbursement challenges and poor patent protection. Novartis’s difficulty in obtaining a patent for its innovative drug Gleevec® is a telling example. We believe India’s oncology market will continue to be dominated by generics, making it less attractive for global players.

**Value from early-stage deals**

In the next six years, most top oncology companies, with the notable exception of Roche, will rely on externally sourced products, which will contribute to more than 50% of their oncology revenue (Figure 8). Most oncology assets with phase III data are not available for licensing or acquisition; however, those that are available—such as Zelboraf® and Zytiga®—tend to command significant premiums.

The lack of licensable late-stage assets is reflected in the fact that, proportionally, more oncology deals have been signed for phase I and preclinical assets in the past five years (Figure 9). While companies are being forced to look at earlier stages of clinical development, these early-stage assets carry higher risk due to lack of proof-of-concept data and a lower probability of success.

In a Campbell Alliance survey of 160 licensing professionals in the first quarter of 2012, dealmakers on both sides of the negotiating table expected increases in the number of deals for preclinical and phase I assets in oncology. More than half of out-licensers and in-licensers believed that there would be more preclinical and phase I deals in 2012 than in 2011, while a negligible share (4%) of out-licensers and no in-licensers believed that there would be a decrease in deal activity for these early-stage assets.

The value of early-stage deals is also expected to rise as companies place their bets on nascent technology platforms that could transform the future treatment landscape.

**Developing Value**

Once companies have proactively gone about identifying value in oncology, they then must develop that value in well-designed clinical programs. Developing a successful oncol-

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**Figure 7**

US vs. EU Price Per Dose

<table>
<thead>
<tr>
<th>Drug</th>
<th>US Price</th>
<th>EU Average*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jevtana</td>
<td>$6,324</td>
<td>$6,356</td>
</tr>
<tr>
<td>Vectibix</td>
<td>$3,660</td>
<td>$2,818</td>
</tr>
<tr>
<td>Alimta</td>
<td>$2,818</td>
<td>$2,417</td>
</tr>
<tr>
<td>Avastin</td>
<td>$1,950</td>
<td>$1,590</td>
</tr>
<tr>
<td>Campath</td>
<td>$1,791</td>
<td>$1,583</td>
</tr>
<tr>
<td>Velcade</td>
<td>$1,490</td>
<td>$1,490</td>
</tr>
<tr>
<td>Torisel</td>
<td>$1,350</td>
<td>$1,060</td>
</tr>
<tr>
<td>Erbitux</td>
<td>$1,031</td>
<td>$500</td>
</tr>
</tbody>
</table>

*EU average consists of UK, Germany, and France prices.

Roche is an exception and has not been included in the analysis, as more than 90% of oncology revenues will come from products developed at Genentech. Source: Evaluate Pharma. Accessed July 2012.

Figure 9

Number of Deals by Stage at Signing 2007 to 2011*

Early Stage: Preclinical and Phase I; Late Stage: Phase III and beyond

*Oncology deals with a total potential value of $10M or more

ogy agent typically requires a large number of clinical trials in multiple tumor types that are carried out in parallel with each other. As a result, in-house clinical development will become insufficient for most manufacturers. The clinical development process will require more collaboration between manufacturers and non-industry groups such as the National Institutes of Health (NIH), universities, and cooperative groups.

Because standards of care are shifting rapidly, the clinical development process within oncology will need to become much faster than what the biopharma industry has traditionally been used to. This will require more global recruiting and greater use of adaptive and biomarker-driven trial design. In addition, therapeutic adjacencies such as supportive care, biosimilars, and diagnostics will be developed, as they represent additional revenue streams in oncology.

Parallel clinical trials

Developing successful oncology agents typically requires a large number of clinical trials and multiple shots on goal. As oncology clinical trials take a number of years to complete, companies do not have the luxury of patent life to work sequentially, targeting one indication at a time. Instead, today’s blockbuster oncology drugs have had a large number of clinical trials running in parallel. Each of the 10 top-selling oncology agents has benefited from between 300 and 1,100 clinical studies conducted by companies as well as academic and governmental bodies.

While conducting parallel trials involves risk, doing so increases the chance for approvals in multiple indications. In the case of Afinitor®, for example, Novartis conducted numerous phase II and phase III trials in parallel, targeting no fewer than 10 different tumor types, before the initial approval in renal cell carcinoma. The strategy has paid off, as Afinitor is currently indicated for five different tumor types, with a projected revenue potential of more than $2 billion by 2018.

As seen in Figure 10, more than 50% of the trials conducted with the top-10 oncology drugs are by non-industry groups such as the NIH, universities, and co-operative groups. In addition, co-op groups were responsible for the registrational studies of drugs including Rituxan®, Herceptin®, Temodar®, Gleevec, Avastin®, and Thalomid®.

Adaptive trials and diagnostic biomarker-driven trial design

The oncology treatment landscape is constantly evolving. With every new product

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**Figure 10**

Clinical Trials* by Funding Source (Top-10 Targeted Therapies)

*Currently active, interventional studies only; observational and expanded access studies excluded
launch, clinical and regulatory hurdles within oncology increase, making it difficult for subsequent products to demonstrate efficacy improvement and to secure approval. Meanwhile, a rich, late-stage clinical pipeline is leading to intense competition and shifting standards of care in some tumor types, forcing manufacturers to compress clinical development timelines. For example, when Bristol-Myers Squibb initiated clinical trials for Sprycel® in prostate cancer in 2008, the drug was added to docetaxel, which was considered the standard of care. By 2012, however, docetaxel was no longer the standard of care as Jevtana®, Provenge®, Zytiga®, and Xtandi® were launched in the intervening years. This has had significant implications for both patient recruitment for the Sprycel trial and eventual approval and marketing of Sprycel for prostate cancer.

Leveraging biomarkers in trial design could help reduce the size, length, and cost of clinical trials and increase the probability of success. Biomarkers can be used to identify patients most likely to benefit from therapy and predict response to therapy through the use of surrogate markers.

A proactive approach to identifying biomarkers resulted in the development of Xalkori, which was approved for a small subpopulation of non-small cell lung cancers after only three years of development. Within the biomarker-identified patient population, Xalkori achieved high response rates in two single-arm studies of approximately 250 patients, leading to regulatory approval. The approval of Xalkori may herald a new era of clinical trial design based on biomarkers.

Another option to expedite clinical trials could be adaptive trial design. Adaptive trial design refers to making planned, well-defined changes in trial design parameters during trial execution based on data from that trial in order to achieve goals of validity, scientific efficiency, and safety. Adaptive design relies on frequent interim analyses to modify the study design based on available data.

Adaptive clinical trials offer flexibility in clinical research as they truncate clinical development timelines and require smaller patient cohorts. On the other hand, adaptive trials are not without risks, requiring ongoing dialogue with the regulatory agencies to ensure eventual product approval. To date, no adaptive trials have resulted in product approvals. Nonetheless, adaptive trial design is worthy of exploration to improve the efficiency of clinical trials.

Worldwide patient recruitment

Due to the large number of clinical trials necessary for oncology drugs paired with limited patient populations, patient recruitment can be a bottleneck in oncology clinical development. As seen in Figure 11, the number of clinical trials per thousand patients in the US is greatest in oncology compared with other therapeutic areas. For every 100,000 patients, the industry conducts 135 clinical trials in oncology, compared with only 30 in CNS, 9 in respiratory, and 4 in cardiovascular diseases.

The solution may be worldwide, multicenter clinical trials. As patient recruitment is much faster in Brazil, Russia, India, and China as well as Eastern European countries, clinical trial sponsors are increasing the number of clinical trials for cancer drugs.
of trials conducted in these regions. There are benefits and risks to such a strategy that need to be carefully considered before conducting these trials. Conducting trials in emerging markets offers the advantage of faster recruitment, access to treatment-naive patient populations, and lower per-patient costs. However, companies are likely to face language and cultural barriers and drug supply and data collection challenges. Securing approval in developed markets based on data in emerging markets may present additional challenges.

**Therapeutic adjacencies representing additional revenue streams**

When doing portfolio planning, companies should not ignore supportive care agents, as they may represent low-risk, moderate-return investment opportunities. By 2016, blood cell factors and supportive care agents will contribute approximately 16% of the total oncology market (Figure 12). This revenue contribution of $16 billion could be a substantial addition to the bottom line.

Oncology biosimilars will represent significant revenue for companies with the right capabilities. Until this year, the EU5 markets have been driving growth in the biosimilar market. The US market is expected to experience a dramatic increase in biosimilar market size due to the patent expiry of products such as Erbitux®, Rituxan, and Neulasta® in 2015-2016.

Diagnostics are also fast becoming a valuable addition to oncology companies. Leading oncology players either have partnerships with or have acquired diagnostic companies to aid in drug development efforts. Many of the top companies have publicly stated their interest in developing companion diagnostics, as this could expedite clinical development and act as an incremental source of revenue.

**Delivering Value**

To ultimately deliver on the value of an oncology product, the future customer engagement model will have to address the needs of critical influencers of product utilization. Pharma companies will also require more robust medical affairs organizations to engage in dialogue with key opinion leaders, clinicians, advocacy groups, payers, and other stakeholders.

In the coming years, companies will broaden their focus to improve patient quality of life throughout the patient journey in oncology. Additional core functionalities, focused on such things as prevention and patient support, will be developed apart from a focus on therapeutics in order to address oncology as a chronic disease.

The concept of using multiple targeted therapies in combination is gaining traction with clinicians and regulatory agencies. In addition to a single company promoting combination therapies, companies are coming together to test approved or pipeline agents for combination therapy.

Finally, pharmaceutical companies are going to have to engage in partnerships with payers, as payers continue to exert more influence over treatment decisions. The use of payer partnerships is most advanced in Europe, especially in the UK and Italy.
Integrated sales, marketing, and medical affairs strategies

A movement toward niche markets in oncology will require customer-centric sales, marketing, and medical affairs strategies. Influencers of treatment will include not only physicians, but also patients, payers, pharmacies, distributors, governments, and the public. Oncology manufacturers will need to possess a comprehensive understanding of the dynamics and needs for each of the customer and stakeholder groups in the market. In addition, manufacturers will need to take into consideration macro-level trends relative to health policy, legal/regulatory requirements, technology, and competition.

The sophisticated oncology sales force will need to be proficient in clinical topics as well as non-clinical topics. Clinical data and supporting education will continue to be drivers for sales, but reimbursement services, patient assistance, complementary companion diagnostics, and clinical “wrap-around” services will also impact sales. In addition, patient-centric promotion will become increasingly important in oncology. This is reflected in growing direct-to-consumer spending by major oncology companies.

The commercial strategy will then need to be customized to local markets. Each local market—which may be defined as a state, a city, or a metropolitan area—has its own market dynamics due to different types and concentrations of providers and payers, as well as different local laws and regulations that govern the promotion and reimbursement of oncology drugs. Different types of local markets require different customer-facing roles and strategies, rather than a national one-size-fits-all approach.

An indispensable element of any oncology commercial model is medical affairs. As seen in Figure 13, oncology has a unique set of needs, such as the need for timely access to the latest research data, a strong interest in clinical trials and investigator-initiated studies, and need for rapid response to medical inquiries. The medical affairs organization is well-positioned to address these needs in ways that are frequently off-limits to the commercial organization. Leading oncology manufacturers deploy robust medical affairs teams that establish strong partnerships with opinion leaders, clinicians, advocacy groups, and payers.

**Impact throughout the patient journey**

Within the oncology value chain, pharmaceutical manufacturers are expanding their focus beyond the traditional area of drug therapy for metastatic disease. Potential business opportunities exist throughout the patient journey in oncology, and companies will broaden their focus to improve patient quality of life throughout that journey, from prevention and diagnosis all the way through treatment, supportive services and care, and provider/payer services.
As seen in Figure 14, apart from a focus on therapeutics, companies are developing additional core functionalities, such as patient support and provider/payer services, in order to address oncology as a chronic disease. Johnson & Johnson is a prime example of a manufacturer that focuses on different aspects of the cancer journey. The company has embraced a “Total Oncology” approach, leveraging its affiliates’ expertise throughout the cancer journey—from prevention, diagnosis, and treatment to supportive care and services.

Increased partnership among companies

The concept of using multiple targeted therapies in combination is gaining traction with regulatory agencies, as seen by the approval for Roche’s Perjeta® + Herceptin® despite initial concerns. In addition to a single company promoting combination therapies, big pharmaceutical players are coming together to test approved agents for combination therapy. For example, Bristol-Myers Squibb and Roche are pursuing combination studies for two approved agents—Yervoy and Zelboraf—for the treatment of metastatic melanoma.

Apart from testing combination options of approved agents, companies are also partnering in clinical stages to develop combination therapies. Bristol-Myers Squibb is partnering with Celgene on the phase III trials of Celgene’s Revlimid® with or without Bristol-Myers Squibb’s elotuzumab in multiple myeloma. Meanwhile, Merck’s MK-2206 is being tested in phase I alongside AstraZeneca’s AZD6244 for locally advanced or metastatic solid tumors.

With oncology drug prices continuing to increase and payers enforcing all available cost-containment measures, how to pay for combination targeted therapies will become a significant challenge in the oncology market.

Partnership with payers

Escalating healthcare spending continues to put pressure on government and private payers to contain drug costs. Payers are looking to ensure appropriate use and elimi-
nate waste while maintaining or improving outcomes.

In the US, utilization management of cancer therapeutics is a high priority for payers, who will most often restrict high-cost drugs, drugs with limited or no survival benefits, and drugs deemed to be at high risk for widespread off-label use, including failure to comply with step therapy. Payers are also looking toward the use of clinical pathways as a way to improve or maintain health outcomes while lowering costs. Clinical pathways are designed to address the limitations of prior authorization and of 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. Drug manufacturers will need to develop both a clinical and an economic value proposition to ensure pathway inclusion.

The oncology market access landscape is more challenging in the EU markets. Health technology assessments espoused by the National Institute for Health and Clinical Excellence (NICE) have long made the UK an inhospitable place for novel and expensive oncology agents, and the recent healthcare reform in Germany has greatly restricted pricing upside in this erstwhile free-pricing market. As European governments embrace austerity measures, the affordability of oncology drugs has come into question in some markets (Figure 15).

In the coming years, partnership with payers will continue to be an important lever for product access and uptake. With only so much money to allocate and new oncology agents coming to the market all the time, payers need to be judicious in what they choose to cover. Manufacturers need to start working with payers early on to form partnerships and gain a better understanding of what payer expectations are as a product is brought to the market.

The use of payer partnerships is most advanced in Europe, especially in the UK and Italy, where oncology drug manufacturers have adopted a number of payer partner-
ships to share risk on oncology drugs. Performance-based schemes generally involve payment or non-payment based on specific patient response or lack of response. Financially based schemes are more straightforward discounts or payment caps offered by manufacturers to payers.

In addition to direct payer partnerships, manufacturers have partnered with third-party advocates to secure reimbursement for oncology drugs. As an example, Pfizer engaged with multiple stakeholders to convince NICE to recommend Sutent® usage for the first-line treatment of renal cell carcinoma (RCC) in the UK. In its initial assessment in 2008, NICE rejected Sutent along with Avastin, Nexavar®, and Torisel® for RCC treatment. Pfizer then engaged with the Department of Health, promising that the company would provide the drug free of cost for the first cycle of treatment. Pfizer also engaged with other stakeholders—raising public awareness about the lack of access to Sutent, generating patient appeals for access, and eliciting support from key opinion leaders and academic medical centers. The result was that, in its final assessment in 2009, NICE recommended Sutent but still rejected Avastin, Nexavar, and Torisel for RCC treatment.

Conclusions and Implications

In the next 10 years, manufacturers will need to navigate a fast-evolving oncology landscape. Some of the top considerations for manufacturers include:

• The future of oncology will see an increasing number of drugs that are tailored to specific patient populations. Due to the growing importance of biomarkers in oncology drug development and commercialization, companies will need to develop robust biomarker capabilities and integrate such capabilities throughout the oncology value chain.

• Both established players and new entrants in oncology can benefit from a rigorous portfolio management approach, making decisions about whether or not to invest in oncology, as well as where to invest in oncology, in terms of tumor types, mechanisms of action, geographies, and sources of innovation.

• As the oncology market changes fundamentally, an innovative commercial model is needed to engage with a range of stakeholders and influencers on a variety of topics. Traditional sales forces will no longer suffice; medical affairs will play a more significant role.

• As global payers increase their management of oncology agents, manufacturers will need to develop a strong value proposition for the access and reimbursement of their products, incorporating both clinical and health economic arguments. Partnership with payers and payer influencers are also viable strategies.

Companies that can understand and proactively respond to these trends will be able to generate maximum value in this challenging market.
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.

Campbell Alliance: Strategy. Results.