

Pharmaceuticals & Medical Products Practice

Playing to win in oncology: Key capabilities for success

Five key trends are driving growth in oncology. To be successful in oncology, a focus on capabilities is critical—both the ones in place today and the ones needed to stay competitive.

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The landscape

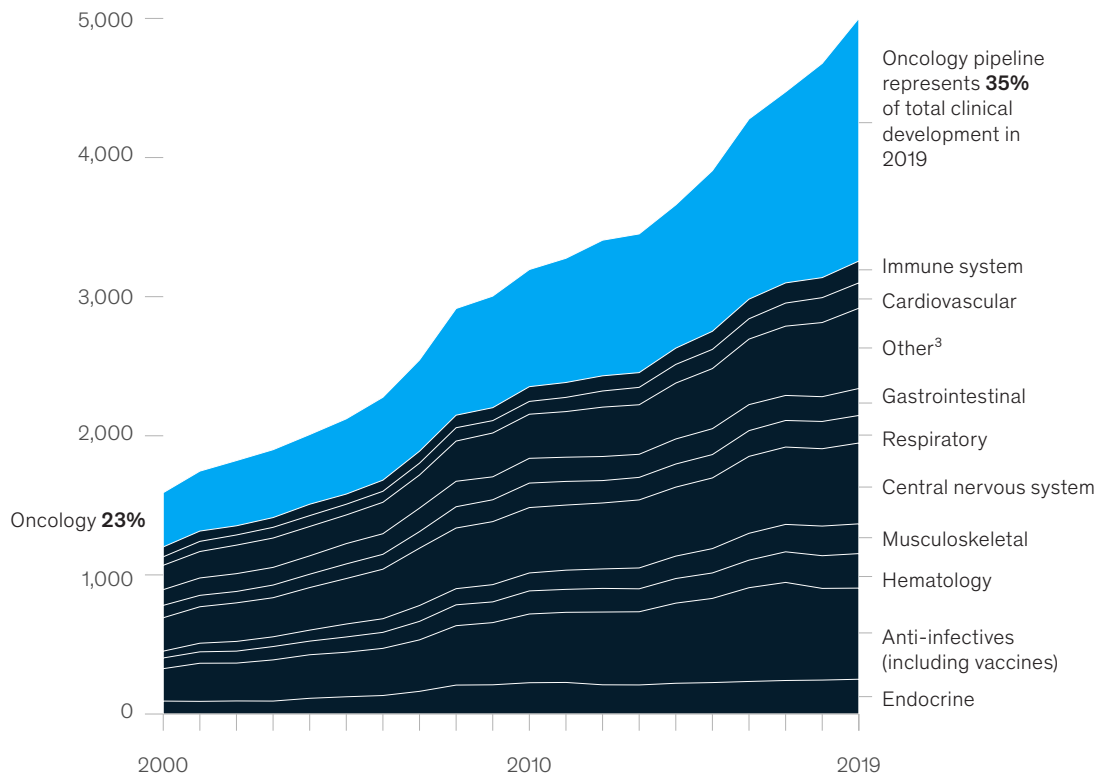
Today, oncology is one of the world's fastest-moving therapeutic areas (TAs); as the largest single TA, it is expected to represent 26 percent of pharmaceutical sales by 2022,¹ with 107 new drug approvals in 2018 alone.² The space is also highly competitive: 35 percent of the industry preclinical pipeline is now in oncology (Exhibit 1), and all top ten players have a commercial presence. Such interest and investment is partly aided by rapid development cycles.

High growth and unmet need have also attracted several new players to oncology—while making others double down. In 2000, 23 percent of all compounds in the visible preclinical pipeline were in oncology, increasing to 38 percent in 2019. This increases competition in terms of clinical-trial recruitment—for example, the number of breast-cancer patients required for active clinical trials exceeds the annual number of diagnoses twofold. In the commercial space, competition is intense, with multiple marketed and pipeline assets in key classes, such as CDK4, CDK6, or PD1.

Exhibit 1

In 2019, 35 percent of all compounds in the visible preclinical pipeline were in oncology, up from 23 percent in 2000.

Total number of compounds reported in trends data,¹ number reported in trends data²



¹ Excluding reformulations and biosimilars; smallest therapeutic areas (dermatology, sensory, genito-urinary, diagnostics and imaging, and other) are grouped as "Other."

² Years and phases missing in source data were added.

³ Including dermatology, diagnostics and imaging, and early-stage assets with no therapeutic-area information.

Source: Pharmaprojects, 2019; McKinsey analysis

¹ EvaluatePharma, June 1, 2018.

² Includes all cancer indication approvals (that is, including new indications for drugs previously approved); for more, see EvaluatePharma, September 17, 2019.

To strengthen positioning and win in this highly competitive and complex oncology space, it is important for pharmaceutical companies to focus on a set of core capabilities.

How to win in oncology

Broadly speaking, five key trends drive growth in the oncology space: democratized innovation, increased importance of precision medicine, increasing attention to value, complex and rapidly changing treatment paradigms, and the importance of stakeholder engagement amidst intense competition. Companies need specific capabilities to respond to these industry trends and to provide differentiated value.

Democratized innovation

Increasingly, the most innovative science sits outside of Big Pharma—the number of clinical trials initiated by non-top-ten players has increased from 4,500 in 2007 (72 percent in total) to 5,900 in 2018 (65 percent in total).³ The level of venture-capital (VC) investment has also continued to increase, with oncology experiencing 197 rounds of VC investment involving a corporate investor between 2009 and 2018 compared with an average of 24 rounds in other TAs.⁴ Therefore, to drive the next generation of growth, pharmaceutical companies are increasingly exploring collaborative and externally facing innovation models. The growth of combination therapies in oncology emphasizes such an approach, with 81 percent of immuno-oncology (IO) trials conducted as combination trials with two or more agents.⁵

A strong partnership group lies at the heart of this democratized innovation model. By maintaining a clear view of the external landscape and being able to rapidly and objectively assess a wide set of opportunities—including academic partnerships, VC investment, traditional business development, and

collaborations—partnership groups help identify the right partnering synergies and partnership opportunities customized to a company's stage of growth. For a large pharmaceutical company, the partnership group focuses on who the right companies are for partnering based on business goals or development needs, turning ideas—such as live-mapping opportunities and investment in capable business-development teams—into formal partnerships.

For smaller companies, the partnership group plays a somewhat different matchmaking role, with a focus on maximizing the portfolio value. This can include identifying potential investors or buyout opportunities. Partnership groups can also leverage their awareness of clinical-trial candidates at major biopharmas to help small companies forge research alliances where there are pipeline synergies or increase the opportunities for new combination-therapy partnerships.

Once a partnership is established, it is critical that progress is tracked clearly and that interventions are made where value is potentially at risk (for example, delays to clinical programs, misalignment in the development or commercialization strategy, and the attrition of key talent). Key performance indicators for a partnership group might include a breadth of external networks (across academia and industry), the success rate associated with securing partnerships, the top talent brought into the pharmaceutical company, the time to process the logistics of the partnership, the presence of a clear approach to track and manage the partnership, and ultimately, the value created through the efforts of this group.

Precision medicine

Oncology, supported by an explosion of data collection, represents the vanguard of precision medicine; this can be seen in the increasing number

³ Biocentury, BCIQ, August 2019.

⁴ Average includes central nervous system, gastrointestinal, cardiovascular, musculoskeletal, respiratory, endocrine, genito-urinary and dermatology; for more, see Philip Chong Edwin Elmhirst, and Jonathan Gardner, "Like the rest of biopharma investors, corporate VCs love oncology," Vantage, February 21, 2019.

⁵ Limited to registration potential and proof-of-concept trials. Data for 2019 is as of October 2019; for more, see McKinsey MIOSS.

of distinct cancer phenotypes, patient populations, and therapy choices available.⁶ Within this space, biomarkers are a requisite for drug development, with the number of biomarker-coupled therapies increasing by about threefold since 2010.⁷ Winning requires an ability to identify suitable biomarkers, demonstrate their prognostic ability, develop suitable companion diagnostics, and reach patients who will most benefit from this innovation.

Numerous oncogenes are already well established as biomarkers in major indications (for instance, ALK, EGFR, HER2, and ER⁸), with multiple targeted therapies and testing (through multigene panels) part of the standard practice in most major markets. As the field progresses, leaders will look for new types of biomarkers harnessing the potential of proteomic and immunological data to better target therapies (for example improving response rate of IO therapies by better targeting specific combinations). Further, there is significant opportunity to use liquid biopsies to gather “real time” data of biomarkers and their response throughout treatment. An example of this is Guardant Health’s partnership with AstraZeneca to develop blood-based companion-diagnostic tests that support commercialization of Tagrisso and Imfinzi based on Guardant’s liquid-biopsy platform.⁹

As patient populations become smaller, identifying those who may benefit most from innovative therapies will become more important. Pharmaceutical companies wishing to succeed in precision medicine can learn from the rare-diseases space, which combines engagement with patient-advocacy groups (for example, the role of ROS1der in the recruitment of patients for the entrectinib trial), the review of oncologists’ patient records, and partnership with testing companies to identify patients who may be suitable for therapies (both during clinical development and commercialization).

Increased focus on value

Efforts to manage drug spending have increased the focus on oncology products. This can be seen in Europe, where value-based health-technology assessments (HTAs) are common, as well as the United States (through oncology formulary restrictions and increased use of oncology pathways). This, combined with limited data at the time of accelerated approvals, means that pharmaceutical companies are working more closely with payers to establish the value proposition of a product. In addition, novel high-cost modalities are forcing a change to the value proposition, from one focused on pure drug provision to a personalized-service model, requiring a go-to-market (GTM) model redesign.

The combination of increased diversity in evidence packages and a growing focus on value elevates the importance of both health-economics-and-outcomes-research (HEOR) and pricing-and-market-access (P&MA) teams. HEOR teams are increasingly involved earlier in drug development to ensure that key end points and comparators are included in clinical trials, building a broader evidentiary strategy (including real-world evidence, patient-reported outcomes, meta-analyses, and registries) that demonstrates therapy value. Such diverse evidence packages can also be used to support indication expansion, such as Pfizer’s recent approval of Ibrance in male breast cancer based on real-world data.

More companies should also consider the key role that P&MA teams can play, particularly in oncology, in working with payers and HTA bodies well ahead of launch to ensure dossiers are optimized (for instance, through payer advisory boards). Further, more advanced companies may engage in launch-sequence modeling and value decisions to maximize therapy potential. Pharmaceutical companies

⁶ Jacob Aptekar, Nicholas Donoghoe, Edd Fleming, Meredith Reichert, Erika Stanzi, and Kevin Webster, “Precision medicine: Opening the aperture,” February 2019, McKinsey.com.

⁷ “Table of pharmacogenomic biomarkers in drug labeling,” US Food & Drug Administration, as of May 31, 2019, fda.gov.

⁸ ALK = anaplastic lymphoma kinase; EGFR = epidermal growth factor receptor; HER2 = human epidermal growth factor receptor 2; ER = estrogen receptor.

⁹ “Guardant Health partners with AstraZeneca to develop blood-based companion diagnostic tests for Tagrisso and Imfinzi,” Global Newswire, December 13, 2018, globenewswire.com.

As treatment paradigms become more complex and trial recruitment more competitive, patient centricity is also ever more important.

must be able to choose the right narrative to communicate product value, for example, through advanced and direct comparisons.

Within pricing and contracting, innovative schemes (for instance, around drug portfolios) and outcomes-based contracts are becoming important in product strategy given external pressures such as increased competition and greater focus on oncology pricing. As an example, the median annual cost of a new cancer drug launched in 2017 exceeded \$150,000,¹⁰ and the cost pressure is even higher for novel therapies (such as CAR-T-cell therapies), given the added challenge of determining a viable pricing model for one-time cures.

While there are complexities and challenges in setting up outcome-based payments schemes (for instance, price-reporting requirements in the United States¹¹), examples do exist in oncology, including Novartis's innovative contract for CAR-T-cell therapy, Kymriah, in Germany and the United States. As part of the agreement, Novartis shares the risk by partially reimbursing treatment costs if a patient dies of their illness within a given period. Earlier in 2019 in the United States, Novartis and Gilead Sciences obtained a new diagnosis-related group code with higher reimbursement amounts for Kymriah and Yescarta, respectively.¹²

Complex and rapidly changing treatment paradigm

Oncology is characterized by a rapidly evolving and globalized standard of care. In non-small-cell lung cancer, for example, the number of approved therapies was expected to increase from 14 in 2009 to 22 by the end of 2019.¹³

In this context, development plans (for instance, combination partners, indication sequencing, and approval strategy) must be strategically developed making complex trade-offs that include the ability to recruit for clinical trials, cost of comparator drugs for studies, time to market, and breadth of label. Such an approach requires deep competitive intelligence and war-gaming-type approach. Here, biopharmaceutical companies increasingly leverage adaptive trials and may increasingly explore the use of real-world evidence (RWE) to create synthetic control arms to reduce the overall size (and cost) of trials and ensure that as many patients as possible can receive the most-effective therapies in development.

As treatment paradigms become more complex and trial recruitment more competitive, patient centricity is also ever more important. For clinical trials, support centers that work to improve patient experiences can be a key differentiator in

¹⁰ *Global Oncology Trends 2019: Innovation, expansion, and disruption*, IQVIA Ltd Pharmadeals, May 24, 2018, iqvia.com.

¹¹ Toby AuWerter, Jeff Smith, Josh Sternberg, and Lydia The, "Unlocking market access for gene therapies in the United States," August 2019, McKinsey.com.

¹² Angus Liu, "Medicare's new CAR-T coverage rules could boost adoption of slow-growing meds," FiercePharma, August 8, 2019, fiercepharma.com.

¹³ EvaluatePharma, 2019.

competitive populations. From a patient perspective, best-in-class trials could include providing information that helps them choose between competing trials, giving access to planning tools to help with logistics and cost minimization, and remote monitoring to reduce the time in a hospital.

For in-market drugs, patient services are becoming more critical and expanding in scope, driven by novel modalities (such as CAR-T therapy) and complex modes of treatment. While historically, patient services have focused on reimbursement and access, companies are now increasing their focus on onboarding, disease management, and adherence through internal or outsourced capabilities. Best-in-class patient-service practices include a single point of contact for patients throughout the journey, seamless coordination between call-center and field-based resources, and the integration of digital and analytics into workflows to make the experience more individualized for patients and doctors. The provision of more holistic support beyond the brand is important and can include support with nutrition, general wellness, disease management, or the set-up of peer-to-peer communities.

Stakeholder engagement amidst intense competition

As a highly competitive field, oncology requires robust key-account-management capabilities. This includes building strong relationships with all key stakeholders (such as group purchasing organizations or “GPOs”, insurers, and hospital procurement departments) that create a partnership-style dynamic (rather than that of a buyer). The key account manager will always be thinking about what the stakeholder challenges are and will help them accordingly: engaging with hospitals at a population level to support pathway-based conversations, for instance, will help inform marketing strategies and refine the discourse of field teams. This is complemented by a sales force

with a deep understanding of complex therapies and changing landscapes. Accordingly, oncology sales reps are typically higher paid than those in other TAs and also heavily incentivized based on performance.

For the medical organization, the role of the medical-science liaison (MSL) is also important. They must be scientifically credible, cutting through a complex array of publications, changing pathways, and standards of care while supporting oncologists in understanding the latest innovations (in addition to supporting patients in accessing treatment). Further, the medical organization maintains its important relationship with physicians through investigator-initiated-trial (IIT) programs, high-quality continuing medical education, virtual advisory boards, and remote congress attendance, while also accessing key opinion leaders (key influencers of prescribing behavior).

Across both commercial and medical, sophisticated physician mapping can identify areas of unmet need as well as segment physicians to ensure, for example, that they receive the most-relevant information for their practice. This can be combined with digital engagement to build bespoke physician experiences and interactions across multiple channels. In the best cases, the physician journey will evolve as they engage with the field force and digital media. Where pharmaceutical companies have multiple therapies that are prescribed by a single physician, the go-to-market model deploys algorithms that can integrate and customize the information that a physician receives across multiple brands.

Finally, it is critical for commercial and medical organizations to seek feedback from the field and connect the insights back to the overall strategy (for instance, through customer-relationship-management data analysis and machine learning). Pharmaceutical companies must be able to respond rapidly to the feedback received from the field and adapt their strategy as needed. (Exhibit 2)

Exhibit 2

Pharmaceutical companies must identify which individual capabilities they need to excel in and where industry standard will suffice.

Overview of assessment against key capability areas, by dimension

Democratized innovation

Groups implicated	Average	Leading indicator	Best in class
● Partnership-management group	<ul style="list-style-type: none"> ● Partnership strategy aligned with corporate strategy ● Dedicated full-time equivalent to identify potential partners ● Proactive outreach to partners of interest 	<ul style="list-style-type: none"> ● Maintenance of live map of opportunities ● Membership of multiple consortia ● Active presence in innovation hubs 	<ul style="list-style-type: none"> ● Consistent appraisal framework allowing comparison of internal and external opportunities ● Dedicated partnership office with clear frameworks to track partner performance ● Range of partnership models, eg, build to buy, company creation, incubator programs, systematic academia programs

Precision medicine

Groups implicated	Average	Leading indicator	Best in class
<ul style="list-style-type: none"> ● Analytics team ● Companion diagnostics ● Precision medicine 	<ul style="list-style-type: none"> ● Target populations defined and sized during drug development ● Global biomarker and companion diagnostic (CDx) team in place 	<ul style="list-style-type: none"> ● Use of site-agnostic development approaches ● CDx teams in major markets to support test uptake ● Strategic partnerships with diagnostic providers 	<ul style="list-style-type: none"> ● Development capabilities across broad set of biomarkers, eg, proteomic, microbiome, liquid biopsies ● Biomarker strategy as key element of governance decisions prior to pivotal trial initiation ● Ongoing collaboration with patient advocacy groups to access patients as well as real-time patient ID (including prelaunch)

Increased focus on value

Groups implicated	Average	Leading indicator	Best in class
<ul style="list-style-type: none"> ● Health economics and outreach research/evidence generation ● Market access 	<ul style="list-style-type: none"> ● Integrated evidence plan in place ● Proactive mapping of patient pathways ● Clear value story with flexible go-to-market models ● Regulatory approach tailored by market 	<ul style="list-style-type: none"> ● Value demonstration as core element of evidence plan ● Proactive engagement with payers during pivotal trial design ● Market-specific value strategy, including value based payments as needed 	<ul style="list-style-type: none"> ● Innovative contracting strategies in place to share risk ● Differentiated trials by geography to meet market specific value need ● Integrated value and access team embedded in asset core team (beyond market access)

Complex and rapidly changing treatment paradigm

Groups implicated	Average	Leading indicator	Best in class
<ul style="list-style-type: none"> ● Clinical sciences ● Patient services 	<ul style="list-style-type: none"> ● Clear objective of accelerating timeline in development plans ● Patient programs in place for launched assets 	<ul style="list-style-type: none"> ● Trials consider individual innovative acceleration approaches (eg, synthetic control arm) ● Patient programs established prelaunch 	<ul style="list-style-type: none"> ● End-to-end redesign of trial design to accelerate and maximize value of data, and optimize patient insights/patient experience ● Best-in-class patient support established, including provision of anticipatory information, wraparound support, coordination of appointment booking, and creation of a 1-treatment team

Intense competition

Groups implicated	Average	Leading indicator	Best in class
<ul style="list-style-type: none"> ● Medical- and commercial-field organization 	<ul style="list-style-type: none"> ● Competitive-intelligence team in place ● Clear patient journey established ● Key-opinion-leader (KOL) mapping developed prelaunch 	<ul style="list-style-type: none"> ● Live competitor dashboard maintained and reviewed at governance ● KOL segmentation developed (including digital channels) ● Dedicated key-account-management team established 	<ul style="list-style-type: none"> ● Uncertainty around competitor outcomes included in portfolio modeling ● Personalized, dynamic multichannel strategy for multiple stakeholder groups ● Strategy for engaging broader healthcare team (eg, nurse practitioners)

A focus on capabilities

To be successful in oncology, a focus on capabilities is critical—not only on what is in place today, but also a plan for building the new capabilities that are essential for becoming a leader in key strategic areas. Capabilities span beyond individuals and can include supporting technology, processes, and ways of working; for example, access to data (across R&D and commercial), analytical engines, and oncology-specific governance to allow for fast decision making. The three steps to building best-in-class capabilities are:

1. *Create an integrated view.* By creating a single integrated view that describes the capabilities needed, this ensures an approach that is consistent across global and key markets (such as the United States, which represents 52 percent of all oncology sales,¹⁴ and China, which is a key growth market). Depending on a company's operating model, specific capabilities may be in global or local teams—regardless, access to capabilities around P&MA, patient engagement, commercial analytics, and medical is needed across major markets.
2. *Decide when to leverage resources outside the company.* Not all capabilities need to be built in-house. For certain capabilities, “talent beyond

the payroll” and partnerships—such as partnering on specific analytical capabilities or data sets—can be better solutions. Where capabilities are desired in-house, a clear value proposition must be developed and articulated to attract the best talent (likely combining compensation, career progression, and working environment).

3. *Focus on retention for top talent.* Given the extreme competition for talent in oncology, companies must develop a strategy on how they can attract (and retain) top players. Successful strategies often include a combination of competitive salaries and incentives, clear development opportunities and pathways, and an oncology vision and portfolio that motivates members of the organization.

Finally, having in place systems that consistently track talent, capabilities, and resource allocation are critical for planning and enable faster decision making, both at the region level and globally. Strategic workforce planning (hiring, partnerships, consortia, and acquisitions) should also be embedded into business-planning cycles. Companies that build these measures into their best practices will be successful in having the right capabilities in place and staying ahead in the fast-moving and competitive oncology arena.

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¹⁴ EvaluatePharma, September 2019.