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THE CHANGING LANDSCAPE OF ONCOLOGY DRUG DEVELOPMENT:

Bringing novel lifesaving therapies to patients

THE PATH: STRATEGIC INSIGHTS THAT GUIDE VALUE

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THE CHANGING LANDSCAPE OF ONCOLOGY DRUG DEVELOPMENT: BRINGING NOVEL LIFESAVING THERAPIES TO PATIENTS

EXECUTIVE SUMMARY

The pharmaceutical oncology landscape looks very different today than it did just a decade ago. As the fastest-growing, most active sector of drug development, oncology has benefited from breakthroughs in science and technology that have advanced researchers' understanding of the biology, immunology, and genetics of cancer.

This growing body of knowledge has led to the development of new therapeutic strategies that increase treatment options and improve outcomes for patients. Many patient populations that previously were treated with nonselective chemotherapies are now receiving targeted agents and cancer immunotherapies that are tailored to the molecular and clinical features of their disease.

In addition to widening the oncology playing field, this shift toward precision medicine has intensified the competition. The past decade has seen 169 launches of novel active substances in oncology, including new immunotherapies, next-generation biotherapeutics, and treatments for rare cancers.[1] In 2021, there were nearly 7,000 anticancer drugs in the R&D pipeline, representing a 7% increase over 2020 and outpacing the overall rate of pipeline growth.[2] And almost all of this pipeline is geared toward precision oncology, including therapies such as small molecule angiogenesis inhibitors, immune checkpoint modulators, T cell–engaging antibodies, antibody–drug conjugates, and chimeric antigen receptor (CAR-T) therapies, among others.

From a manufacturing perspective, the implications are significant. Matching drug products to clinical and commercial needs for such a robust pipeline is inherently challenging and doing so in the shadow of a global pandemic increases the complexity by an order of magnitude.

Above and beyond these considerations, targeted cancer therapies are more complex than conventional chemotherapies, making their formulation more challenging, and many are highly potent compounds that require specialized facilities, equipment, and handling. Similarly, biologics must be handled, stored, and shipped at low temperatures to ensure the physical integrity of the doses and cell-based immunotherapies have unique logistical obstacles.

Coupled with quickly evolving standards of care across cancer types, accelerated approval pathways, lower production volumes, shorter product lifecycles, and a crowded development field, these considerations add multiple layers of intricacy to an already complex development model. This whitepaper provides strategic guidance for successfully navigating such complexities, focusing specifically on:

- Unique formulation and handling requirements
- Novel trial designs and the supply chain implications
- Regulatory and clinical strategies to support product approvals

By design, precision oncology requires a drug development framework that can bend to the specific needs of cancer patients and the unique genetic and molecular characteristics of their tumors. The inherent heterogeneity means the path from laboratory to finished product and commercial launch will be different for every therapy. Building an optimal road map for each requires a deep understanding of those differences and careful integration of best practices to meet patients' needs and more quickly bring novel therapies to market.

Matching drug products to clinical and commercial needs for such a robust pipeline is inherently challenging and doing so in the shadow of a global pandemic increases the complexity by an order of magnitude.

6,961	Therapies in the oncology R&D pipeline in 2021*
37.5%	Of overall pharma pipeline in development for cancer*
15,400+	Ongoing trials in oncology*
930	Products under development for rare cancers in 2021**

*Pharmaprojects, 2021
**IQVIA, 2021

INTRODUCTION

In 2020, approximately 10 million people worldwide died of cancer and 19.3 million people received a new cancer diagnosis, according to the International Agency for Research on Cancer. By 2040, the number of new cancer cases per year is expected to rise to 29.5 million and the number of cancer-related deaths to 16.4 million.[4]

On their own, these numbers seem to paint a grim picture, but the reality is that scientific breakthroughs in drug research and development, along with advanced screening and diagnostic capabilities, have improved outcomes for patients with many types of cancer. The most recent Annual Report to the Nation from the National Institutes of Health shows an average annual decrease in age-adjusted rates of new cancer cases and age-adjusted death rates of 1.0% and 1.8%, respectively, from 2009 to 2019.[5]

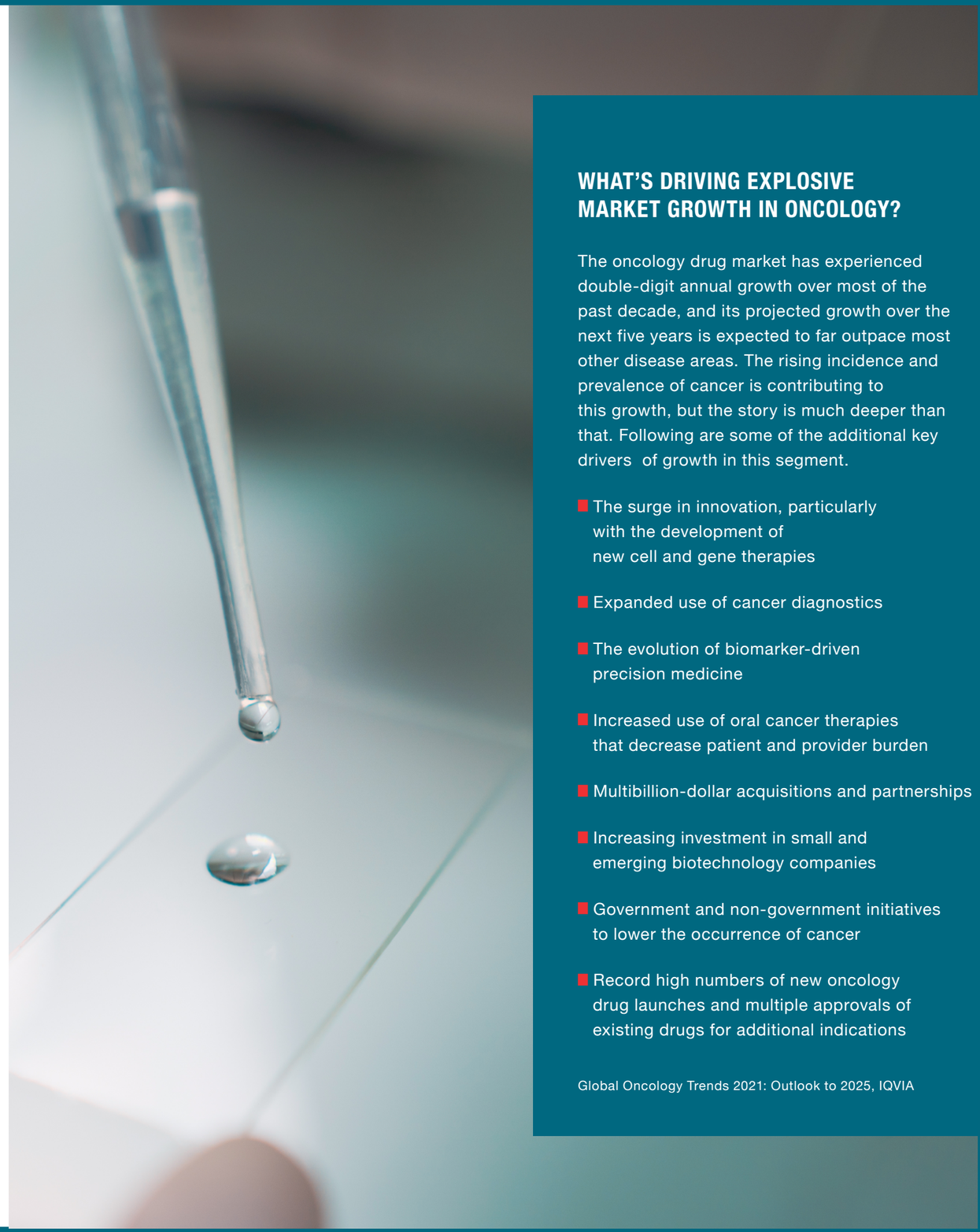
New drug targets, novel classes of therapy, and a trend toward smarter, more strategic treatment regimens have improved the standard of care for many cancers. Included among the groundbreaking advances are targeted and immune therapies, combination therapies, and next-generation biotherapeutics (gene editing, CAR-T and RNA therapeutics). There are, however, many tumor types that remain poorly addressed by current therapies. While a good number of these cancers are less common or rare, some cancers with large patient populations have persistent unmet needs despite the availability of targeted drugs.

Given the number of people living with cancer, the high degree of unmet need, and the intense focus on discovering and developing precision oncology medicines, analysts project the global oncology pharmaceutical market will increase from $177.4 billion in 2021 to $313.7 billion by 2026, at a compound annual growth rate (CAGR) of 12.1% for the period. Within the oncology drug pipeline, which currently makes up more than a third of the pharma pipeline overall, the projected CAGRs for the targeted therapy and immunotherapy markets, respectively, are 11.8% and 16.4%.[6] Multiple drivers are contributing to this growth (see “What’s driving explosive market growth in oncology?”).

With the growth in the oncology segment, the market dynamics are also changing. Following are some of the major forces contributing to the shifting environment:

- **The scope and speed of innovation.** The rapid pace of innovation that has led to precise diagnostics and novel drug classes and treatment strategies has contributed to intense competition for key targets which in turn has led to accelerated development times, shorter drug lifecycles, and more financial risk.

- **Advances in the understanding of disease biology.** The growing body of knowledge about the molecular basis of cancer cell behavior has opened the door for precision oncology. This shift means greater segmentation of patient populations and more complex therapies, thus lower volume production of drugs that are more complicated to produce and increased competition for a smaller pool of clinical trial participants.



WHAT’S DRIVING EXPLOSIVE MARKET GROWTH IN ONCOLOGY?

The oncology drug market has experienced double-digit annual growth over most of the past decade, and its projected growth over the next five years is expected to far outpace most other disease areas. The rising incidence and prevalence of cancer is contributing to this growth, but the story is much deeper than that. Following are some of the additional key drivers of growth in this segment.

- The surge in innovation, particularly with the development of new cell and gene therapies
- Expanded use of cancer diagnostics
- The evolution of biomarker-driven precision medicine
- Increased use of oral cancer therapies that decrease patient and provider burden
- Multibillion-dollar acquisitions and partnerships
- Increasing investment in small and emerging biotechnology companies
- Government and non-government initiatives to lower the occurrence of cancer
- Record high numbers of new oncology drug launches and multiple approvals of existing drugs for additional indications

Global Oncology Trends 2021: Outlook to 2025, IQVIA

- **Growing presence of biopharma across all stages of the oncology R&D pipeline.** Nearly 80% of the early-stage oncology pipeline and approximately two-thirds of the late-stage pipeline is controlled by emerging biopharma companies.[7] With increased access to capital, many biopharma companies are opting to hold onto their molecules through clinical development and even commercialization rather than selling or licensing their assets before launch. This shift is changing the dynamics of strategic partnerships in the industry. Emerging biopharma companies are heavily reliant on partnerships with service providers to match the manufacturing and regulatory expertise, scale, and reach of big pharma. Further, because of the deep investments, the need to consistently demonstrate value for all stakeholders is paramount.

- **The development of new pathways to regulatory approval.** New active substances in oncology increasingly qualify for expedited regulatory reviews or breakthrough designations, and many receive accelerated approval based on phase I or phase II data alone. Approval via this accelerated pathway is granted based on "substantial evidence that a surrogate or intermediate endpoint is reasonably likely to predict clinical benefit," and it is conditional, pending the results of mandated post-approval confirmatory trials.[8] From a development perspective, the fast-tracked process means that sponsors must have the capacity and expertise to scale up quickly and adjust to product demand.

With the pace of innovation and the changing landscape of oncology drug development, sponsors face unique challenges in their quest to bring new drugs to market. This report discusses some of the most critical formulation, handling, logistics, and regulatory considerations.

ONCOLOGY APIS: RISING TO FORMULATION CHALLENGES

Active pharmaceutical ingredients (APIs) for targeted oncology treatments are highly diverse in terms of their mechanisms of action, physiologic effect, and chemical structure. Today's arsenal comprises small molecules and biological compounds — each of which has unique formulation and manufacturing considerations that must be taken into account during development planning.[9]

Whereas with conventional, broad-spectrum chemotherapy agents which are associated with significant toxicity and side effects because of their inability to distinguish between cancerous and normal cells, targeted drugs can make that distinction. These drugs specifically target cancer cells, reducing toxicity and side effects. Small and large molecule targeted therapies achieve this end in different manners. Small molecule drugs permeate plasma membranes and act on targets from within the cell, while large molecule compounds bind to their targets on cell surfaces.

Regardless of the drug substance modality, formulation development is integral to successful drug product development.

TARGETED SMALL MOLECULE DRUGS

Currently, targeted small molecules make up more than 40% of the global oncology pipeline. From 2001 to 2020, the FDA granted market approval to 89 targeted small molecule drugs for treating various types of cancer. These drugs act by targeting various proteins, enzymes, factors, and receptors, such as JAK3, EGFR, CDK-4, CDK-6, and PARP.[10]

Because of their size, small molecules can translocate through plasma membranes and interact with targeted molecules inside of cells. In novel anticancer drugs, small molecule compounds interrupt certain protein pathways, decreasing cancer cell development and proliferation. Small molecule compounds have the advantage of being easy to synthesize by chemical reactions, making them easier to manufacture than biologics and less costly to produce. Because they are chemically and thermally stable, they have less restrictive storage and transportation requirements than biologics, and they are generally associated with better patient compliance due to their mainly oral route of administration.[11]

Among the notable disadvantages of small molecule cancer drugs are their relatively poor selectivity which can lead to off-target effects, low response rates, and drug resistance.[12] Some small molecules have a short half-life in the body, requiring more frequent dosing. Further, small molecules can only act on "druggable" targets, meaning they require access to a part of the molecule that is critical to its function and then bind strongly enough to influence its behavior. Some important antitumor targets are considered "undruggable," because small molecule inhibitors are not able to bind to the molecular targets.[13]

The complexity of some of these newer small molecule compounds makes formulation challenging. For example, the druggability of tumor targets only matters if the molecular compound can achieve therapeutically relevant bioavailability via the chosen drug delivery mechanism. From a formulation standpoint, multiple oral drug delivery technologies supported by versatile excipients are available for improving the solubility, permeability, and stability of the drug in the gastrointestinal tract, including micronization of the drug substance, lipid-based formulations, use of surfactants, drug substance nanoparticles, and solid dispersions of the drug.

More information about small molecule API development is available in our resource library.

LARGE MOLECULE THERAPEUTICS

Large molecule, or biological, therapies include a wide range of entities, such as large peptides, recombinant proteins, monoclonal antibodies, nanobodies, soluble receptors, recombinant DNA, antibody drug conjugates, fusion proteins, immunotherapeutics, and synthetic vaccines. Unlike small molecules, which are chemically synthesized, biologics are recombinantly produced by engineered cells. Rather than penetrating cell membranes, they induce responses through external, site-specific cellular binding. Because they are highly specific to their targets and don't interfere with healthy cells, they are generally considered to be less toxic than small molecules. However, they are capable of inducing an immune response in the patient, which can affect the safety and efficacy of the treatment.[14]

Biologics are inherently fragile, making them vulnerable at every stage of the development process. They are sensitive to heat and easily degraded. Together with their high molecular mass, this intrinsic instability renders nearly all biologics orally inactive, introduces substantial formulation and delivery challenges, and makes the manufacturing process incredibly complex—particularly in terms of scale-up and maintaining batch-to-batch equivalence.[15] Exposure to oxidation and agitation, drastic pressure changes, and temperatures outside the window of accessibility can change the analytical and stability profile of the molecule, potentially compromising the safety and efficacy of the drug—which could be fatal for a patient suffering from a life-threatening cancer.

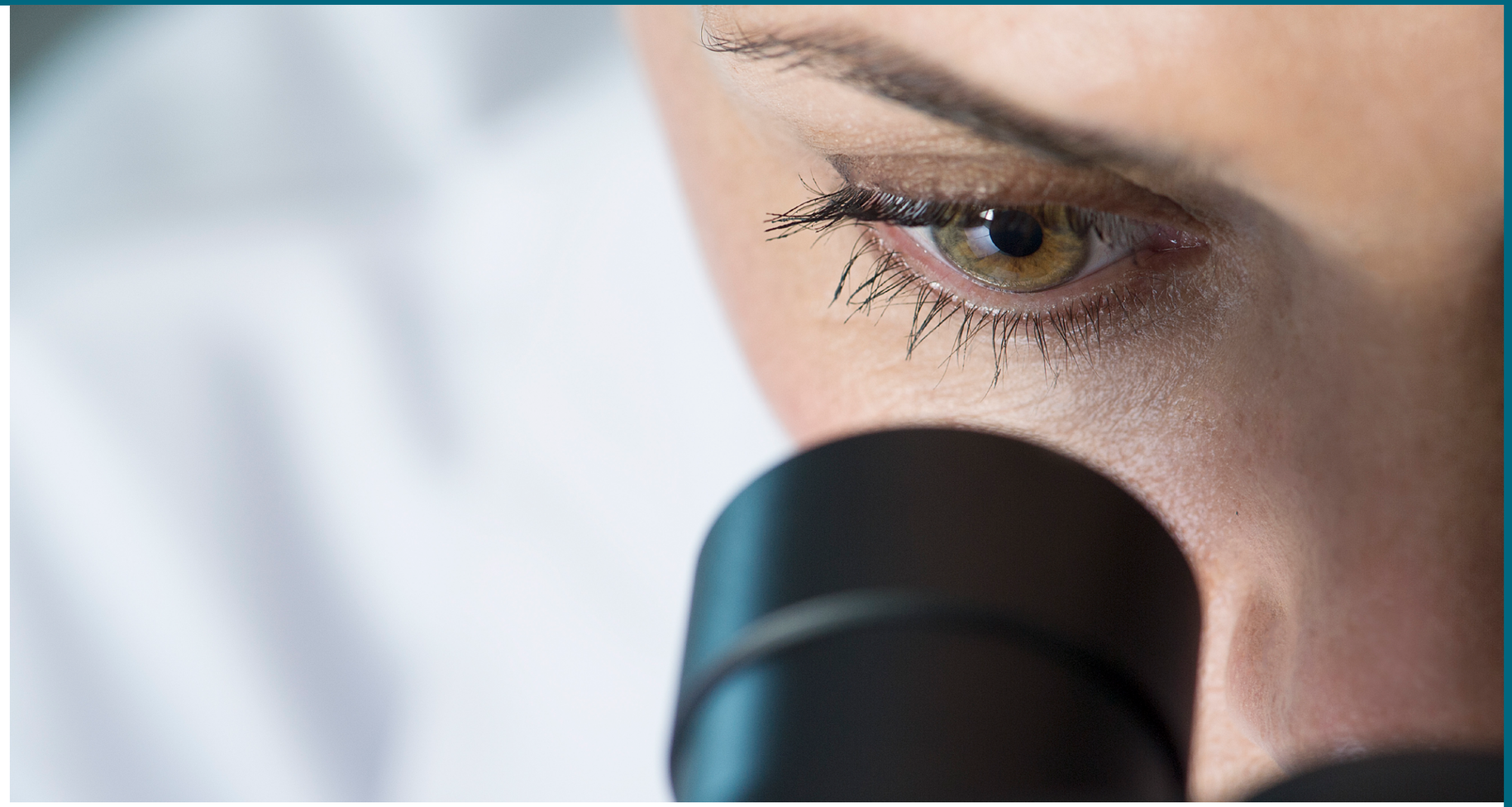
Additionally, because biologics are mainly administered by injection or infusion, their formulation must be compatible with the intended drug delivery system and potential contamination via leachables and extractables must be mitigated.

Advances in formulation and delivery strategies in recent years are helping to optimize biologics development. Examples include microsphere-based controlled-release technologies, protein modification methods that make use of polyethylene glycol and other polymers, and genetic manipulation of biopharmaceutical drugs. Efforts to generate more stable biologics are also under development. One example is the generation of d-amino acid analogues of FDA-approved drugs to limit degradation of protease.[17]

BEGIN WITH THE END IN MIND

Designing formulations for targeted oncology therapies—both small molecules and biologics—presents several challenges related to the complexity of the substances, the need for novel and sophisticated delivery routes and production methods, new regulatory pathways, and accelerated timelines for getting these products to market.

To reduce the risk that underperforming formulations will slow development programs at any point along the development continuum, formulations must be designed from the outset to align with the final container and drug-delivery method to avoid discordancy between active ingredients and production materials. In addition sponsors and strategic partners should always begin with the end goal in mind: development of a safe, effective medication that meets the needs of the patients who will be receiving it. Understanding patient and commercialization needs is critical for defining strategies for stabilization, concentration, and delivery.



In addition to the well-established principles of formulation noted above, the use of creative and often proprietary formulation technologies enables development teams to overcome unique formulation challenges. Patheon™ The Quadrant 2™ computational modeling platform is an example. It is an integrated drug formulation program that encompasses *in silico* tools, high-throughput screening, and predictive tools that can integrate with the commercialization process.

The program analyzes the specific molecular structure and chemical characteristics of compounds in combination with the unique target product profile to predict the optimal solubility enhancement technology and excipient combination at the earliest stage of development. Further modeling can predict stability outcomes for shelf life and component compatibility, blending and compression performance, and even product pharmacokinetic behavior to accelerate formulation and process development.

Capabilities such as these streamline development time and mitigate the inherent risks associated with trial-and-error experimental approaches. With the increasing competition in the oncology drug development space, creative formulation technologies such as this are becoming crucial differentiators.

Sponsors and strategic partners should always begin with the end goal in mind: development of a safe, effective medication that meets the needs of the patients who will be receiving it.

Learn how to get large molecule formulation right from the start.

HANDLING HIGHLY POTENT APIS

An additional differentiator in oncology drug development is the ability to safely work with these highly potent, life-saving drug substances. The increased focus on targeted therapy and precision oncology has led to an increase in the manufacture of highly potent active pharmaceutical ingredients (HPAPIs). In fact, highly potent drugs constitute a majority of the oncology pipeline. In 2020, 75% of the drugs in the oncology pipeline contained highly potent ingredients.[18]

There are two key objectives for the development of HPAPI formulations:

- Proper handling and containment of the substances to ensure the safety of the environment and protection of individuals involved in their manufacture
- Maintaining the purity and quality of the drug product when scaling up from drug substance to drug product manufacturing

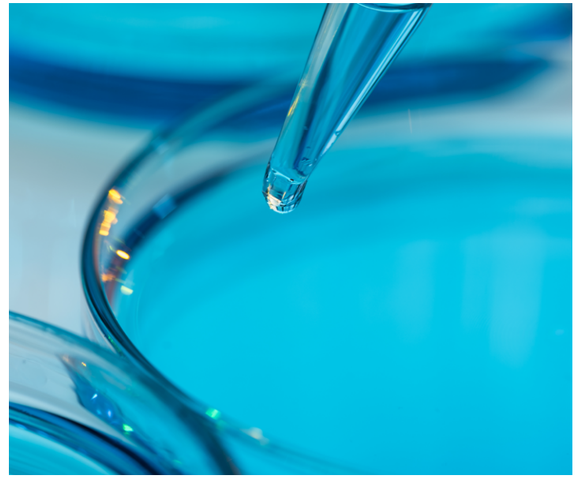
Rising to this challenge requires specialized expertise, engineering controls, and containment strategies. An optimal strategy for high-potency drug development should be built on deep knowledge of the global regulatory controls and guidance concerning HPAPI manufacturing, including Occupational Health and Safety Management System HPAPI processing standards; applicable GMP guidelines; FDA guidance on aseptic processing; relevant International Organization for Standardization (ISO) standards; and HPI handling guidance from the International Council for Harmonisation document.

The first and most important requirement for dealing with high-potency compounds is a comprehensive assessment to determine the safety and health parameters of the compound, including occupational exposure limits and characteristics such as mutagenicity, teratogenicity, and carcinogenicity. Drug classification in the categorization banding system is based on this assessment. The safety assessment, together with an understanding of the chemical process, provides input for defining a best practice for all critical operations in the chemical process, particularly those involving the handling of wet and dry powders. Critical operations should be defined for standard and emergency procedures.

Facility design is another essential consideration. Specifically, the facility must be equipped to support all operations on the highly potent compound, such as weighing, performing reactions, isolation, and drying. The primary control measures include engineering controls, such as local exhaust ventilation, containment within equipment, and isolators. Containment solutions that keep the material in the process equipment provide the most effective control for minimizing the risk of employee exposure or cross-contamination. Containment also improves yield and process efficiency. Secondary controls include local ventilation, room ventilation, air changes, air locks, and personal protective equipment.

Additional priority considerations include expertise in high-potency handling, including operators with competencies across occupational health and safety, toxicology, chemistry, and chemical technology; the development, implementation, and monitoring of training programs for all staff with access to high-potency compounds; and combustible dust testing and control procedures.

The increased importance of HPAPI containment and avoidance of cross-contamination, particularly when manufacturing takes place in a shared facility, has given rise to single-use technologies and systems. Single-use containment systems use qualified plastic materials that have been developed for high strength and meet regulatory requirements for containment control. As the capacity needs of oncology drugs in development change—in particular, the continued transition toward small volume highly potent drugs—the flexibility and cost-effectiveness of single-use systems will be in strong demand. Advances in single use technology, such as the development of more closed systems, new film chemistries, smart technologies, and automation will accelerate timelines for safely developing consistent-quality drugs for clinical trials and commercial launch.



To learn more strategies for developing highly potent drugs, from early development to commercialization, view this on-demand webinar.

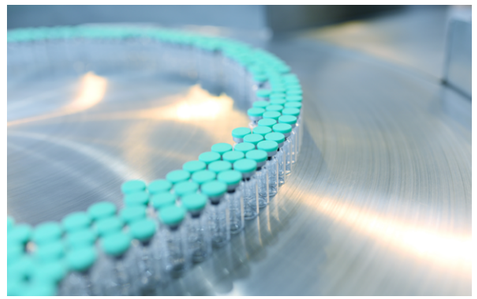
RISING TO THE SUPPLY CHAIN CHALLENGES OF INNOVATIVE CLINICAL TRIAL DESIGNS

As the development of novel and more targeted oncology therapies continues to climb, the challenge of designing and supplying clinical trials is becoming more complicated.[19] Because drugs are being developed to target specific molecular subtypes, criteria for trial participation are becoming increasingly selective, exacerbating an already challenging recruitment landscape Additionally, trials of investigative oncology drugs—many of which are on accelerated development pathways—have more complex designs than conventional trials, characterized by evolving endpoints, multiple protocol deviations, larger data collection activity, and more substantial amendments. The complexity and sensitivity of many of the drug products themselves require intricate choreography to manage temperature-controlled logistics, including packaging, storage, and distribution across sites and countries.

To streamline development of investigational oncology drugs, sponsors are increasingly adopting innovative approaches. Adaptive designs, master protocols, and decentralized trials are changing the nature of clinical development programs in oncology. Adaptive trials are a departure from conventional, inflexible trials in which patients receive a predetermined therapy for a fixed period oftime. Adaptive designs allow protocol modifications based on patient responses to treatment while the trial progresses. The adaptation schedule and process are defined in the trial protocol and may allow for modifications to dosage, sample size, patient selection criteria, and novel drug combinations.

Master protocol trials offer a different kind of clinical development flexibility. These are intended to simultaneously evaluate more than one investigational drug and/or more than one cancer type within the same overall trial structure. This approach enables the investigation of multiple biomarker targets across multiple tumor types. It also saves time by allowing investigators to test hypotheses and evaluate and compare drug combinations more quickly and enabling faster activation of new studies using existing infrastructures and cohorts. It can reduce trial start up, recruitment, and administration costs.

It supports the sharing of real-world evidence, and it offers patients more personalized treatment protocols based on their genetic subtypes and biomarkers.[20] However, master protocol trials are highly complex with multiple moving pieces, and can be resource intensive and require extensive planning and collaboration.



Clinical trials of investigative oncology drugs have complex designs characterized by evolving endpoints, multiple protocol deviations, larger data collection activity, and more substantial amendments.

Adaptive designs and master protocols can be especially impactful in the early stages of trials when decisions about dose selection and target indications are made. The flexible nature of these trial models introduces unique packaging, forecasting, and logistical complexities that must be considered at the earliest stages of protocol development.

Finally, decentralized clinical trials are also poised to fundamentally alter the dynamics of oncology development programs. Decentralized trials are essentially siteless studies in which patient recruitment is done electronically through various methods (e.g. patient portals, telemedicine applications, and remote electronic document access); some trial activities are virtual via video or through in-home visits; lab specimens are collected by local clinics or in-home phlebotomist visits; data is collected through digital health devices; and drugs are shipped directly to patients.[21]

The nature of oncology trials precludes fully virtual engagement in most cases, particularly when intravenous drugs must be administered, medical imaging is required, or toxicity surveillance is needed. However, decentralizing some elements—such as in-home assessments and drug delivery—is both feasible and valuable, particularly in terms of patient engagement and retention, both of which are more essential than ever given the smaller patient cohorts and the potentially devastating impact of even a handful of dropouts. While each of these trial innovations adds tremendous value to oncology clinical research efforts, they also present challenges to drug supply chain management. For example, for adaptive designs and master protocols, the challenges include the uncertainty of maximum drug supply needed, shifting supply requirements, and the need for rapid availability of new supply at trial decision points.[22] For decentralized trials, the direct-to-patient supply chain increases the complexities surrounding global distribution of time- and temperature-sensitive clinical trial materials exponentially.

All of these trial models require a new level of supply-chain flexibility to provide the right volume of the right drug at the right dose to the right location, whether to support mid-study changes due to protocol amendments or study adaptions or direct shipments to patients directly from sites, pharmacies, or depots. Add to this the competitive importance of meeting all critical clinical trial milestones in the crowded oncology space, and the need for innovative, comprehensive strategies for supply chain planning and management is evident.

In addition to flexibility, successful clinical supply strategies for today's oncology trials require access to an extensive global network of GMP/DGP facilities and partner depots; advanced technologies for forecasting, logistics, packaging, and tracking; extensive industry-certified transport solutions; and a clinical supply optimization team with deep expertise in end-to-end clinical supply chain management.

The flexible nature of new clinical trial models for oncology introduces unique packaging, forecasting, and logistical complexities that must be considered at the earliest stages of protocol development.

For more information about the impact of evolving clinical trial logistics on drug development programs, read our whitepaper

"What clinical teams should know about changing trial logistics and how they will affect development."

REGULATORY PATHWAYS TO QUICKER APPROVALS

Innovation in oncology drug development is not only happening in the lab. Regulatory agencies are also making changes that are contributing to a robust oncology pipeline.

Regulatory agencies globally have developed accelerated approval programs that aim to address unmet medical need in the treatment of a serious or life-threatening condition, and many of these programs are used for oncology candidates. In the United States, the FDA has four regulatory pathways to help get potentially life-saving drugs to patients more quickly than would be possible through conventional channels: priority review, breakthrough therapy, accelerated approval, and fast track. Similar pathways have been established by regulatory agencies globally.

From 2012 to 2020, 94% of all approved oncology drugs in the United States used at least one of these expedited pathways, and more than half received breakthrough therapy designation in particular.[23] Many of these drugs were approved based on Phase I or Phase II data, relying on evidence of beneficial effects on surrogate measures or intermediate endpoints that would predict a real clinical benefit. The accelerated approvals are conditional, however, requiring confirmation of their clinical benefits via post-approval confirmatory studies to evaluate their actual clinical benefits.

Sponsors who are able to successfully navigate the regulatory requirements for accelerated review and approval are able to launch products into the market sooner than they would be able to otherwise, meaning some very sick patients are able to receive early access to novel therapies and sponsors are able to gain first-mover advantage in an extremely competitive environment. Additionally, the accelerated approval programs provide sponsors the opportunity to consult with regulatory bodies frequently throughout the development process.

To realize the most benefit from accelerated approval programs, sponsors should take advantage of resources designed to streamline development from preclinical to commercial stages.

This helps ensure all requirements are being met in the Chemistry Manufacturing & Controls (CMC) package for the New Drug Application (NDA) or the Biologics License Application (BLA), as well as post-approval requirements. It also provides opportunities for identifying areas where there may be flexibility or alternate reporting solutions, particularly for rare cancers and those where there is significant unmet need due to a lack of effective treatments.

There are downsides to approval through accelerated channels. Chief among these is the possibility that post-approval studies fail to confirm the clinical benefit or identify safety issues that didn't emerge in the early-phase trials. If this happens, approval may be withdrawn, requiring the drug to be removed from the market. Another possibility is that product labels will need to be revised based on the new safety and efficacy data, which could have a significant influence on commercial and medical affairs activities.

Advancement of targeted oncology drugs through accelerated approval pathways, particularly traditional biologics and cell and gene therapies, is complicated by the potential for supply chain and cold chain bottlenecks. Careful planning is required to ensure the availability of resources for temperature-controlled shipment and storage in alignment with the faster pace of approval. To this end, sponsors and strategic partners should work together to map the cold chain supply during early development, including the unique chain-of-custody and chain-of-condition considerations for cell and gene therapies.

To realize the most benefit from accelerated review and approval programs, sponsors should take advantage of resources designed specifically to streamline development from preclinical to commercial stages, including comprehensive programs that integrate manufacturing and supply chain services.

CONCLUSION

Advances in the molecular understanding of cancer, the increased focus on developing targeted therapies based on that understanding, and regulatory support for getting novel treatments to market quickly have changed the clinical development paradigm for oncology drugs and introduced unique challenges. The success of oncology drug development programs in this new environment depends on sponsors' ability to overcome bioavailability challenges, handle high-potency materials, optimize the supply chain, and navigate a complex regulatory environment. To shepherd oncology molecules efficiently from formulation design to commercialization pharmaceutical and biotechnology companies must chart a new course for rapid clinical innovation and commercialization. The road map should include resources and strategic partnerships that provide the following:

- Scientific and analytical expertise to manage complex formulation and delivery challenges
- Equipment, facilities, and capacity to contain HPAPIs
- A flexible manufacturing and supply platform to meet the demands of innovative trial design
- Supply chain models that leverage advanced technology solutions, including process and analytical tools to accelerate scale-up to commercial production and drive resource efficiency
- Regulatory experts who work in lockstep with development teams from the outset to ensure that submission documents will meet all requirements

These considerations are integral across the drug development life cycle, as is a shared commitment among stakeholders to the development of safe, effective therapeutics that meet the unique needs of all cancer patients.

Explore innovative solutions for accelerating the development new therapies.

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