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Early Oncology Trials and Biomarker Strategy: New Directions in Europe's Evolving Ecosystem

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Early Oncology Trials and Biomarker Strategy: New Directions in Europe's Evolving Ecosystem

Explore how evolving oncology study models, biomarker-driven strategies, and Europe's In Vitro Diagnostic Regulation (IVDR) are reshaping early development, and why collaboration across ecosystems is key to advancing innovation for patients.

The oncology development playbook is changing. Companies are moving beyond the traditional approach of testing novel agents first in 'end-stage' patients—those who have exhausted all lines of standard of care—and then proving the concept in later advanced disease settings.

Instead, they are designing studies that target pre-surgical settings, including both curative-intent and select metastatic patients, as well as first-line advanced indications, earlier in the development pathway. This shift builds on the successes of genomically targeted agents such as osimertinib and immune-modulatory therapies like nivolumab and pembrolizumab, both of which rapidly advanced into perioperative and first-line indications following early-phase success.

Recent examples demonstrating this shift include:

- SynOx Therapeutics performed their early clinical studies of emactuzumab (a humanized monoclonal antibody directed against colony-stimulating factor 1 receptor) primarily in patients with the rare diffuse-type tenosynovial giant cell tumor who were not amenable to or would not benefit from surgery, representing locally advanced or unresectable disease and often treated in a second-line setting. Having demonstrated robust efficacy with high objective response rates, they accelerated into Phase III and have completed global enrollment.[1]

- Early on in the development of Akeso's ivonescimab (a mAb targeting both programmed cell death protein 1 and vascular endothelial growth factor), the molecule showed an acceptable safety profile and promising antitumor activity both in the immunotherapy-resistant and first-line settings, supporting expansion into additional lung cancer populations. Following further positive data, Akeso has rapidly initiated a multicenter, randomized, double-blind Phase III study (AK112-311/HARMONi-9) of ivonescimab as consolidation therapy for limited-stage small cell lung cancer patients without progression after concurrent chemoradiotherapy.[2]

- IDEAYA Biosciences advanced *darovasertib* (a protein kinase C inhibitor) into registration-enabling trials for uveal melanoma in both first-line advanced and neoadjuvant settings, following promising Phase I outcomes that supported expansion into curative-intent cohorts.[3]

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> Success now requires navigating both scientific opportunity and regulatory complexity.

In addition, the 2025 ASCO and EHA meetings showcased multiple further examples of neoadjuvant and biomarker-driven approaches, reflecting the broader industry momentum toward earlier intervention.[4]

However, this strategic pivot coincides with the implementation of Europe's IVDR, which raised validation requirements for biomarker-based patient selection. In effect since May 2022, the IVDR has created significant challenges for clinical research in Europe, delaying studies, increasing costs, and affecting patient access, even as it aims to improve safety and diagnostic quality.[5-7] Success now requires navigating both scientific opportunity and regulatory complexity.

Limitations Of Traditional Development Approaches

Typically, the conventional oncology clinical development pathway for novel agents begins with patients with end-stage disease, who have been heavily pretreated and have exhausted standard-of-care options. While this approach prioritizes safety, it creates significant challenges for exploring pharmacodynamic activity, optimizing dose selection, and demonstrating meaningful therapeutic benefit.

In addition, these patients represent a highly selected population—survivors who have endured multiple treatment lines. The biological implications of this are profound:

- Their tumors have evolved significantly from their original disease state, becoming more heterogeneous through exposure to successive therapies.
- The multiple prior lines of therapy may have impacted the functions of various organ systems, particularly bone marrow and immune function, potentially putting the patient more at risk of the clinical manifestations of 'on target' toxicity in non-malignant tissues, as well as reducing anti-tumour activity if the novel agent is directed at the immune system.

The tumor evolution pattern means companies could spend years attempting to study the impact of their novel treatment on targets in disease states that differ substantially from those in which the therapeutic targets were initially identified. Meanwhile, settings where interventions could achieve curative outcomes—such as adjuvant or neoadjuvant treatment—remain unexplored until much later in development.

The evidence for earlier intervention continues to grow. "When we look at the way that treatments have been developed, you move from very advanced disease into the first line setting, into the adjuvant setting, to the neoadjuvant setting, and that's been the traditional paradigm," said Glen Clack, MD, oncology drug developer, advisor, and former AZ Global Clinical Leader. "We then find that a lot of these drugs are very successful in that neoadjuvant and adjuvant setting."

Immunotherapy development exemplifies this pattern. In earlier disease settings, there are clear advantages for immune-based approaches, with very early intervention providing "the ability to potentially increase your cure rate," said Dr. Clack, because treatment occurs when the patient isn't immunosuppressed from prior lines of cytotoxic therapy and the disease has a low burden and is not more heterogeneous from multiple interventions.

Recent approvals in head and neck cancer demonstrate the clinical validation of this approach. For example, Keytruda was approved by the FDA on June 12, 2025, for adults with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (Combined Positive Score ≥1), as determined by an FDA-approved test, as both neoadjuvant and adjuvant therapy.[8,9]

The approval was based on the pivotal Phase III KEYNOTE-689 study, where perioperative pembrolizumab significantly improved event-free survival and rates of substantial tumor shrinkage before surgery compared to standard of care. This regimen marks the first perioperative immunotherapy approval for locally advanced HNSCC in several years and represents a substantial shift in treatment protocol.

Emerging Models For Earlier-Stage Development

Forward-thinking companies are designing first-in-human studies that incorporate earlier-stage populations from the outset, supported by increasingly receptive regulatory guidance such as the FDA's Project FrontRunner, which encourages sponsors to prioritize earlier clinical settings for oncology drugs rather than starting in late-line disease. While the EMA does not have a direct equivalent, recent initiatives like Cancer as a Pathfinder echo similar priorities in the European context.

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Impression of Plus Ultra Manchester Laboratory

However, earlier-stage development requires different study designs and endpoint strategies. In the neoadjuvant setting, not only can a more in-depth assessment of proof of mechanism and proof of principle endpoints be performed, but complete pathological response rate is a well-recognized clinical endpoint (showing strong correlation with survival outcomes in lung cancer at least). This is supported by major pathologic response, residual cancer burden, as well as kinetic assessment of circulating tumor DNA, all reflecting anti-tumor activity. Time-to-event survival endpoints, such as event-free survival, disease-free survival / recurrence-free survival, however, tend to require larger, randomized studies rather than single-arm proof-of-concept experiments. If the intervention is a 'combination' approach, as it often is, an understanding of the potential impact of the combination agent on these endpoints should be understood and taken into account.

In addition, there are further layers of risk management in earlier settings, balancing the potential benefit (which may be completely unknown) against the risk of toxicities that could delay or complicate standard-of-care interventions such as surgery and the anesthesia associated with it.

The biotech sector is embracing this shift, according to Qaisar Rafiq, Senior Director of Business Development, Europe, at Kadans Science Partner (Kadans), and noted that "we need to see more biotechs taking this approach by designing their studies to incorporate patients earlier in their disease course, earlier in the development pathway, if the mechanism of action of their novel therapy suggests this approach." He has observed industry evolving toward "more precise biomarker-driven development strategies and pushing to demonstrate early signs of efficacy and differentiation in increasingly competitive indications."

The Role Of Integrated Ecosystems

Companies succeeding in earlier-stage development often share a common characteristic: proximity to clinical centers of excellence that enable rapid iteration between preclinical research, biomarker development, and clinical study design. A strategic location offers tangible advantages in terms of development, speed, and quality.

"Our strategic innovation hub at The Hive in Villejuif, Paris, sits on the same campus as Gustave Roussy, which is one of Europe's top cancer research hospitals," Rafiq explained. This proximity enables companies to "engage early with their clinical and transnational experts and access patient populations crucial for early-stage study designs and biomarker validation". Rafiq continued, highlighting Kadans' flagship development, Plus Ultra Manchester, which is located in close proximity to The Christie, another world-renowned oncology centre of excellence. Purpose-built to support innovative biotech and medtech companies, facilities such as Plus Ultra Manchester provide a unique opportunity to partner with clinical leaders and accelerate early-phase research.

The infrastructure requirements extend beyond basic laboratory space. Effective ecosystems provide flexible R&D environments and translational expertise that can accelerate development timelines. "By creating physical and strategic links between biotechs and Europe's most influential cancer research hubs, we at Kadans are enabling earlier, smarter, and more collaborative study developments," he added.

Clinical integration from the outset of development proves particularly valuable. Successful studies require involvement of front-line clinical staff to ensure that assays, imaging methodologies, and novel technologies can be delivered without significantly impacting patient care or quality of life.

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IVDR Implementation: New Requirements For Biomarker Validation

Europe's implementation of the IVDR has fundamentally altered the regulatory landscape for companion diagnostics and biomarker-based patient selection. The May 2025 deadline stipulates that only legacy IVD devices with proper transitional documentation can remain on the market, while all new diagnostic tests must comply with full IVDR requirements.[10]

The June 2025 MDCG 2025-5 guidance provided additional clarity on IVD performance studies, including requirements for ethics committee submissions and definitions of substantial modifications.[11] However, the practical impact on smaller companies developing targeted therapies remains significant.

"I completely understand the philosophy behind the introduction of the IVDR," Dr. Clack said, "[but] it is causing problems in developing agents against novel targets, particularly for small companies, because there is not an insignificant amount of work that needs to go into validating these assays."

For precision medicine development, this creates strategic tension. The optimal approach would involve enriching early-stage studies for biomarker-positive patients to establish proof of concept rapidly. "If you're developing a targeted agent, then essentially you should be studying it in that selected patient population at as early a time point as possible," Dr. Clack noted. Without this focused approach, companies risk developing drugs based on flawed hypotheses.

Instead, IVDR requirements often force suboptimal development strategies. Companies find themselves studying broader patient populations and retrospectively analyzing biomarker status—an approach that particularly disadvantages resource-constrained organizations. For smaller companies, this means recruiting patients who may only provide safety and PK data rather than the biomarker and efficacy signals needed for go/no-go decisions.

Industry surveys indicate that IVDR implementation has contributed to delays in dozens of early-stage trials, affecting tens of thousands of patients and delaying the launch of multiple innovative therapies. Compliance and validation requirements have also increased development costs substantially, particularly for smaller companies conducting biomarker-driven studies.[5-7] These constraints can slow proof-of-concept studies and complicate strategic decision-making.

The contrast with established pharmaceutical companies becomes stark in this context. AstraZeneca's osimertinib development in T790M mutant populations exemplifies the advantage of conducting definitive proof-of-concept studies in biomarker-selected patients early in the development phases.[12]

"A positive-go decision is positive for the company and for the patients," Dr. Clack observed, "while a positive-negative, a kill decision, is important for the investors, but it's also important for patients because it means that that drug is not needlessly being taken forward."

Strategies For Navigating IVDR Requirements

Despite increased regulatory complexity, companies are developing more sophisticated approaches to biomarker validation through collaborative strategies and ecosystem partnerships.

Growing industry awareness is driving more innovative approaches to regulatory constraints, particularly in oncology, where companion diagnostics and biomarkers play pivotal roles. "What's really encouraging is the increasing adoption of ecosystem thinking," Rafiq said. "Companies are embedding themselves in multidisciplinary environments where they can engage early with key stakeholders, whether that's translational scientists or regulatory advisors."

This integrated approach addresses core challenges in biomarker development, including validation, standardization, and access to high-quality samples.

Practical examples are emerging across Europe's innovation hubs. At the London Innovation Centre,

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companies like Myricx Bio and Cytospire Therapeutics are "working at the forefront of oncology innovation and are actively engaging with the ecosystem around them," Rafiq noted, "whether that's connecting with the nearby clinical institutions, building strategic partnerships or accessing shared expertise within the Kadans network."

These companies demonstrate the collaborative mindset that is becoming essential in the current regulatory and scientific landscape. The key insight is that IVDR compliance becomes more manageable when approached as an ecosystem challenge rather than an individual company problem. Shared expertise, collaborative validation studies, and integrated regulatory strategy can help smaller companies navigate requirements that might otherwise prove prohibitive.

A further example is One North Quay in Canary Wharf, where the proximity to the UK regulator, the MHRA, provides companies with instant access for testing and offers regulator a direct window into emerging industry challenges. This two-way interaction not only accelerates regulatory innovation but also ensures that companies and regulators are aligned early, reducing delays and uncertainty.

Dr. Clack argued for regulatory flexibility during exploratory phases: "There needs to be a simple way, during the exploratory phase of the study, to understand and explore the assay in parallel to your clinical study and refine that rather than essentially, as might be perceived by some investors, 'wasting your funding' on a patient population that was never going to deliver you a robust go/no-go decision."

> "While regulatory adaptation is essential, successful early development also hinges on incorporating patient perspectives."

While regulatory adaptation is essential, successful early development also hinges on incorporating patient perspectives. Engaging patients in study design not only improves study execution but also ensures that endpoints reflect real-world needs, complementing regulatory and biomarker strategies.

Incorporating Patient Perspectives Into Development Strategy

Patient engagement in study design represents both a regulatory expectation and a strategic opportunity to improve study execution and relevance.

"We should be engaging patients' representatives for their input into clinical study design at a much earlier time point… [and] thinking about including patient-oriented endpoints in clinical studies much earlier than we currently do," Dr. Clack said. "There are endpoints in clinical studies that are much more important to the patient than some of those we might prioritize."

The methodology involves early and transparent engagement, even before a clinical study has been submitted to the authorities or regulators. For example, protocol review with patient groups can identify practical modifications that significantly improve study completion rates. The process typically involves a focus group-like environment, where sponsors invite patients and their representatives, according to Rafiq.

The impact on study success can be substantial. High dropout rates plague many oncology studies; however, patient engagement can help address this challenge. "Through these focus groups, you can engage with the patient population to really understand what would be acceptable to them," Rafiq said. "Often, one small tweak here and there in the protocol makes the world's difference in terms of their compliance."

Yet even when protocols align with both regulators and patients, systemic infrastructure barriers can still slow progress. European healthcare systems vary widely in their ability to support precision oncology approaches, particularly in data consistency and disease characterization.

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Infrastructure Challenges In European Healthcare Systems

Beyond regulatory and patient considerations, European healthcare infrastructure presents challenges for implementing precision medicine approaches at scale.

Disease characterization remains inconsistent across centers and countries. "For targeted agents, we should be trying to understand the nature of the patient's disease," said Dr. Clack. "A good example of this is triple-negative breast cancer. The term triple-negative breast cancer doesn't tell me anything other than what the disease is not."

Even within national healthcare systems, consistency proves elusive. "You will find that some centers will have a greater understanding of the qualitative nature of the patient's disease, not just at the beginning of that process, but at various time points," he added. Data sharing between institutions also remains problematic. The staff involved with a clinical study often experience difficulties in obtaining patient information from other hospitals, even basic information such as prior tumour scan results.

Addressing these challenges requires a systematic approach to standardizing data collection and sharing. The goal, as Dr. Clack described, is to gain a better understanding of the patient's disease, enabling more precise therapeutic approaches.

These infrastructure gaps underline why regulatory bodies are increasingly viewed as partners in driving innovation. By working collaboratively with developers, agencies can help bridge inconsistencies across systems while maintaining patient safety.

Regulatory Engagement And Collaboration

Despite infrastructure challenges, regulatory agencies are demonstrating increased flexibility in their approach to innovative development strategies.

Dr. Clack reported encouraging signs from the MHRA. "It's very clear that aside from maintaining those ethical boundaries and the patient safety boundaries that they're beholden to do so, they are very open to discussing novel ways of delivering clinical studies that will benefit patients and would also encourage companies to perform their clinical studies in the UK."

This openness extends to other major agencies. The key is to approach regulators as collaborative partners in the development process, rather than as barriers to approval.

Staying current with regulatory precedents becomes increasingly essential. Dr. Clack advised that " any company just needs to be aware of what other people are doing, not just within their own academic network but with their colleagues within the Regulatory Authorities and Ethics Committees."

Early and substantive regulatory engagement can help companies navigate novel development approaches while maintaining appropriate safety standards.

Building Pan-European Networks For Innovation

The future of European oncology development lies in integrated networks that connect distributed centers of excellence across the continent.

Creating environments where clinicians, academics, and regulators can collaborate represents a fundamental shift from traditional development models. Rather than operating in isolation, successful companies are embedding themselves within ecosystems that combine academic research, clinical practice, diagnostics, talent availability, capital flow and industry expertise.

This approach extends beyond traditional incubator models toward integrated platforms that span multiple countries and specialties. The vision involves continental-scale network effects where a company developing an early-stage oncology asset in Amsterdam could seamlessly access clinical collaborators in Paris, translational experts in London, and manufacturing partners in Cambridge.

However, proximity alone is insufficient for creating value. "What really does stand out most is the importance of intentional connectivity, not just co-location," Rafiq said. Physical co-location of infrastructure, diagnostics, and clinical expertise must be complemented by deliberate integration that accelerates decision-making and reduces collaboration barriers.

For oncology development specifically, this means ensuring companies have early and ongoing access to translational science, clinicians who understand patient

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journeys, and diagnostic partners who can guide biomarker strategy from the outset of development. The infrastructure requirements are evolving beyond basic laboratory space to include GMP-ready facilities and modular clean rooms that enable rapid iteration from discovery through early phase studies.

Evidence of impact is already emerging from proximity-based models. Centers of excellence in Paris, Amsterdam, Cambridge, and Manchester are demonstrating how a strategic location "dramatically increases a company's ability to engage in meaningful, timely dialogue with clinical and research leaders early and often," Rafiq noted, explaining that this "shortens the feedback loop and allows biotech innovators to make smarter and faster decisions."

Examples include:

- **The Hive Campus Grand Parc, Paris**, adjacent to Gustave Roussy Hospital and driven by the Paris Saclay Cancer Cluster, uniting l'Université Paris Saclay, Institut Polytechnique de Paris, healthcare leaders, and companies like Sanofi.
- **Plus Ultra Utrecht, Netherlands**, at Utrecht Science Park, connecting Utrecht University, UMC Utrecht, Princess Máxima Centre for Pediatric Oncology, Hubrecht Institute, and companies like Genmab and Merus.
- **Mayde, King's Cross, London**, embedded in London's Knowledge Quarter, providing GMP manufacturing alongside laboratory and office space for oncology-focused startups, scale-ups, and collaborators.

Just as critical is the cultural and strategic framework surrounding the ecosystem. "When you create spaces where startups, academics, investors, and service providers are not only co-located but actively engaged, sharing insights, validating ideas, and forming partnerships, you create a multiplier effect. This is what we're striving for in places like our London Innovation Centre and our upcoming developments across the UK and Europe, such as the Clesa project in Madrid, and Merlin Place in Cambridge, UK," Rafiq said.

Taken together, these trends—earlier intervention, ecosystem integration, and cross-border connectivity—point toward a new strategic reality for oncology developers.

The Strategic Imperative

The convergence of earlier intervention opportunities, IVDR requirements, and ecosystem capabilities is reshaping competitive dynamics across the oncology development landscape. This transformation demands new approaches to development strategy, regulatory engagement, and collaborative partnerships.

Emerging biotechs face a particularly complex challenge. IVDR compliance can no longer be treated as an afterthought—it must be integrated into development planning from the outset. The traditional startup approach of lean teams and minimal external partnerships is becoming untenable when biomarker validation requires specialized regulatory expertise, clinical collaborators, and diagnostic partners. Companies that embrace ecosystem participation early are finding pathways through regulatory complexity that would otherwise consume disproportionate resources.

Established pharmaceutical companies aren't immune. Competitive advantage increasingly flows to organizations that can move rapidly into earlier disease settings without compromising biomarker validation rigor. Strategic partnerships within innovation ecosystems provide access to clinical populations and regulatory precedents that can significantly accelerate timelines.

Impression of Plus Ultra Utrecht

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The investment landscape is adapting accordingly. Due diligence processes now routinely examine biomarker validation strategies, regulatory pathway planning, and ecosystem access as core value-drivers. Portfolio companies embedded in collaborative networks with proximity to clinical excellence are demonstrating faster development timelines and higher success rates—a performance differential too significant for investors to ignore.

Regulatory agencies are also showing increasing flexibility, particularly in early-stage development settings where the potential patient benefit justifies modified risk-benefit calculations. The MHRA's approval of neoadjuvant first-in-human studies represents just one example of evolving regulatory thinking. Continued dialogue between agencies and innovative companies is refining frameworks that maintain safety standards while enabling faster access to breakthrough therapies.

The European oncology ecosystem is at an inflection point. Companies that adapt their strategies accordingly are positioning themselves not just for commercial success, but for the ability to deliver meaningful patient outcomes faster than ever before. Those clinging to traditional approaches risk being outpaced by competitors adopting the collaborative, ecosystem-driven model that increasingly defines successful development.

For oncology innovators, the mandate is clear: Embed biomarker strategy and regulatory foresight from the earliest stages, work within an integrated ecosystem of collaborators, and treat patient engagement as a core component of study design rather than an afterthought. Investors should prioritize companies that demonstrate ecosystem connectivity and IVDR readiness as key predictors of long-term success. Regulators, for their part, can continue to shape this future by maintaining flexible, collaborative approaches that enable innovation without compromising safety. The companies that act on these imperatives today will be the ones driving the next wave of curative oncology breakthroughs in Europe.

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Kadans Science Partner brings the perspective of an ecosystem operator supporting 500+ life sciences companies across six European countries, many in oncology and advanced therapies. Its pan-European network speeds collaboration across biotechs, academics, CROs, regulators, and diagnostics innovators; enables rapid trial and biomarker strategy iteration through a living laboratory model; and offers a clear path from preclinical discovery to clinical translation and commercialization. This white paper calls for a faster, smarter, and more patient-focused oncology development paradigm.

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