WHITE PAPER

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# Accelerating oncology innovation:

## A CRO'S strategic role from IND to approval

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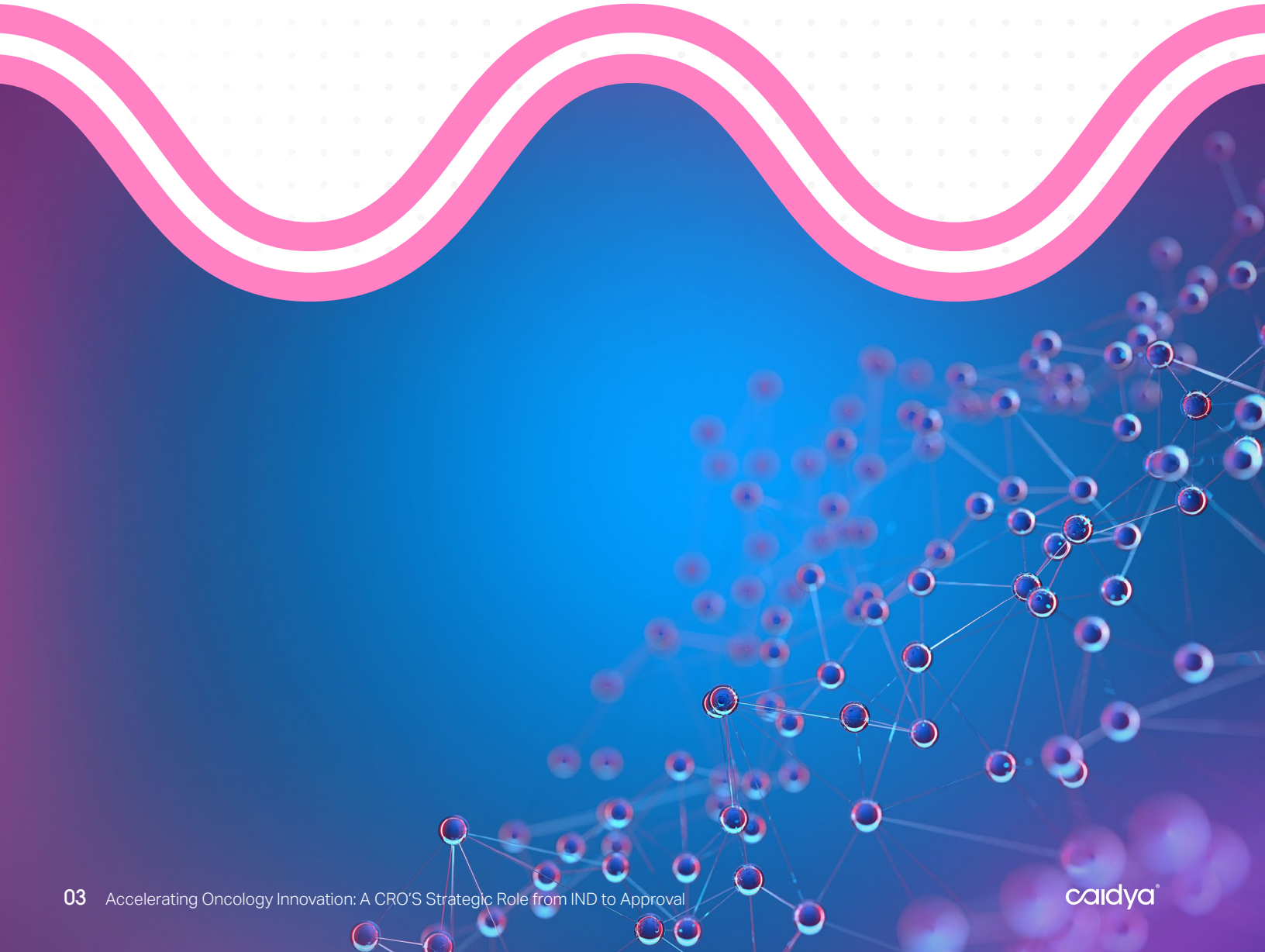
## Executive Summary

The oncology market is a dynamic, evolving segment within the pharmaceutical industry - one characterised by rapid advancements in treatment modalities and significant growth projections. As the market continues to expand, stakeholders are likely to focus on innovative therapies and personalised medicine to meet the increasing demand for effective cancer treatments.

This report offers a deep dive into the oncology research pipeline. It outlines current oncology market trends, highlights common sponsor challenges in trial design and execution, and shows how agile CROs drive success through subject matter expertise, operational excellence and a patient-centric approach.



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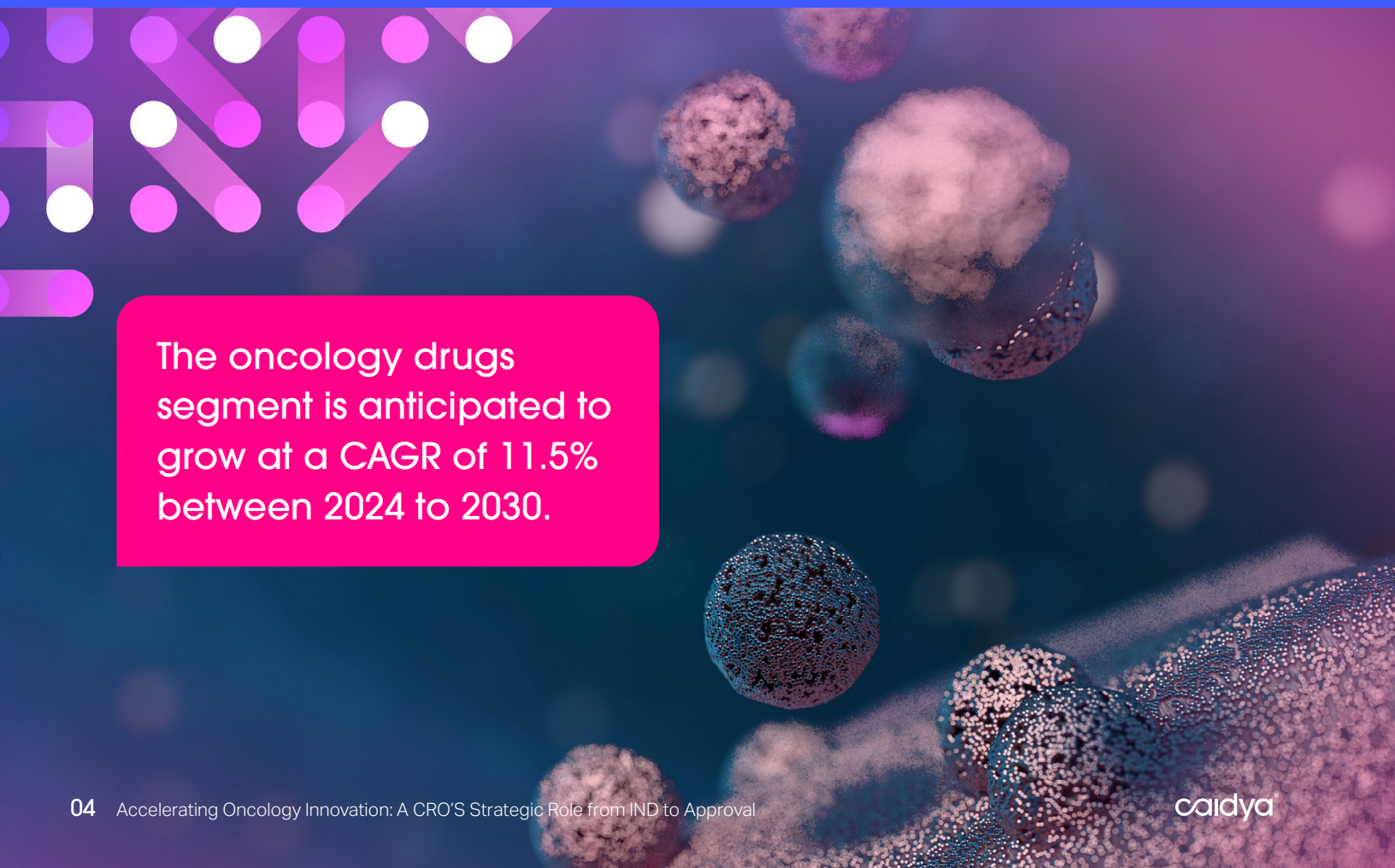
# Oncology market outlook: Innovation and opportunity

The oncology market is experiencing rapid growth. Driven by several key factors including the rising incidence of cancer due to lifestyle changes and an aging population, it is one of the most dynamic sections of the entire pharmaceutical industry. Its growth is particularly evident in advanced treatment modalities such as immunotherapies, CAR-T therapies, antibody drug conjugates (ADCs), and biomarker-driven drugs. These are making significant impacts across various cancer types, including non-small cell lung cancer (NSCLC), prostate cancer, bladder cancer, and other tumor types to improve long-term treatment outcomes.

However, according to GlobalData's *Likelihood of Approval* tool, only one in 10 oncology drugs entering development ultimately gain FDA approval - making it the most difficult therapy area for drug development. The low approval rate has led to a heavily skewed market dynamic, with oncology boasting the highest proportion of late development stage drugs compared to marketed drugs; 85% of innovator oncology drugs are still in clinical development (Phase I to Phase III)[i].

Despite these challenges, oncology is the leading therapy area by sales and has witnessed strong recovery post-Covid-19, fuelled by expanding frontiers in immunotherapy, targeted therapies helping redefine the standard, and early diagnostics. The sector is forecast to generate over twice the revenue of metabolic disorders, the next largest therapeutic area, and the oncology drugs segment is anticipated to grow at a CAGR of 11.5% between 2024 to 2030. This will see it reach $412 billion by 2030, with a market share of 29% of all global prescription drugs[ii].

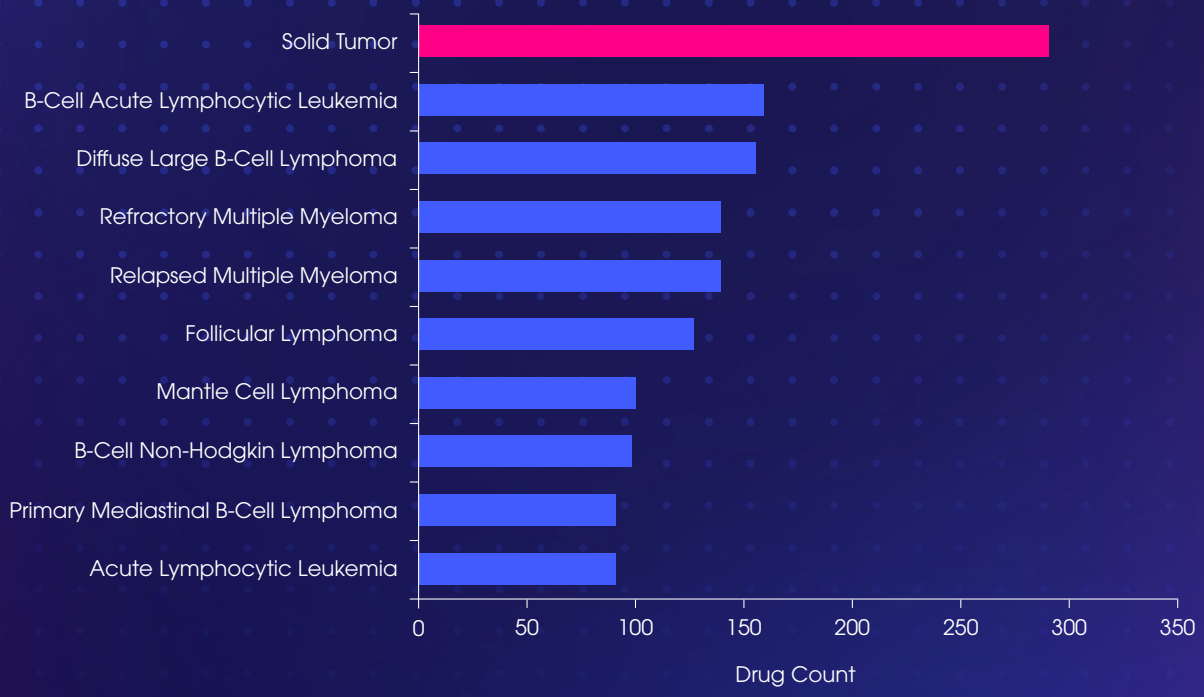


## Key drivers of growth

**Immunotherapies:** Immunotherapy has undergone profound changes to become a cornerstone in cancer treatment, leveraging the body's immune system to combat cancer cells. This includes immune checkpoint inhibitors and cancer vaccines, which have shown significant efficacy in various cancer types. The introduction of checkpoint inhibitors (ICIs), such as ipilimumab (Yervoy®), has marked a significant breakthrough, enabling dramatic and durable responses even in patients with otherwise incurable cancers. These therapies enhance the endogenous immune response rather than directly killing cancer cells, which allows for long-lasting tumour regressions, with data supporting earlier integration into earlier treatment lines and combinations regimens. However, many cancers still lack effective therapies.

**CAR-T therapies:** CAR-T cell therapy has demonstrated exceptional success in treating blood cancers. The first FDAapproved CAR-T therapies set a precedent for their use in oncology, and ongoing innovations are aimed at overcoming challenges associated with solid tumours. The market for CAR-T therapies is expected to see significant growth, with key products like Yescarta and Qartemi driving this trend[iii].

Figure 1: Pipeline drug count for CAR-Ts, per indication



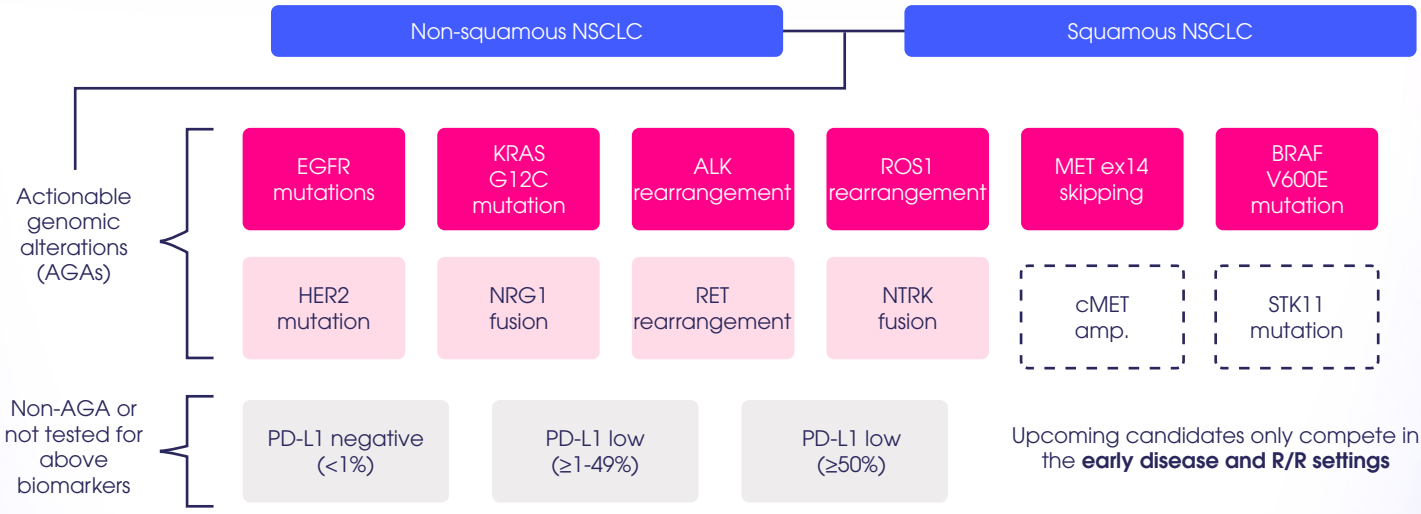

Note: Indications with a blue-highlighted bar refer to a blood cancer. An active pipeline stage refers to the development stages: discovery, preclinical, Phase I, Phase II, Phase III, and pre-registration.
Source: *GlobalData: Analyst Briefing: Blood Cancers Dominate CAR-T Pipeline, March 2025.*

**Biomarker-driven drugs:** The increasing popularity of biomarker testing is expanding the market for targeted therapies, especially in NSCLC. Advances in biomarker identification, and the presence of actionable biomarkers, allows for more personalised treatment approaches, addressing specific genetic alterations in patients. There are currently ten actionable genomic alterations (AGAs) that are addressed by targeted therapy agents across multiple lines of therapy.

**Technological innovations:** The integration of AI in diagnostics combined with advancements in biomarker identification are revolutionising cancer care. The result has helped facilitate better identification of candidates for HER2-targeted therapies and showing how patients can benefit from adjuvant chemotherapy to improve disease-free survival without additional therapy, thereby enhancing early diagnosis and improved treatment outcomes; success in these areas will only compound as technology continues to gather in sophistication.

**Regulatory support:** Significant challenges exist in securing regulatory approval compared to other therapeutic areas, despite the substantial investment flowing into cancer drug development. However, the emergence of expedited regulatory pathways is driving rapid market expansion for these therapies. For example, the US's FDA offers fast-track, breakthrough, Regenerative Medicine Advanced Therapy (RMAT) and Real-Time Oncology Review programmes to speed up reviews and approvals; the EU's EMA provides orphan drug and PRIME designations; and China's NMPA has introduced priority review and breakthrough therapy designations, enabling accelerated approval for therapies addressing unmet medical needs[iv].

## Figure 2: Existing and upcoming biomarkers for NSCLC targeted therapies across the 8MM




Targeted therapy in NSCLC is a highly competitive and differentiated space covering 10 different actionable biomarkers.
Source: GlobalData: *Current Trends in Targeted Therapies in Non-Small Cell Lung Cancer (NSCLC), April 2025.*

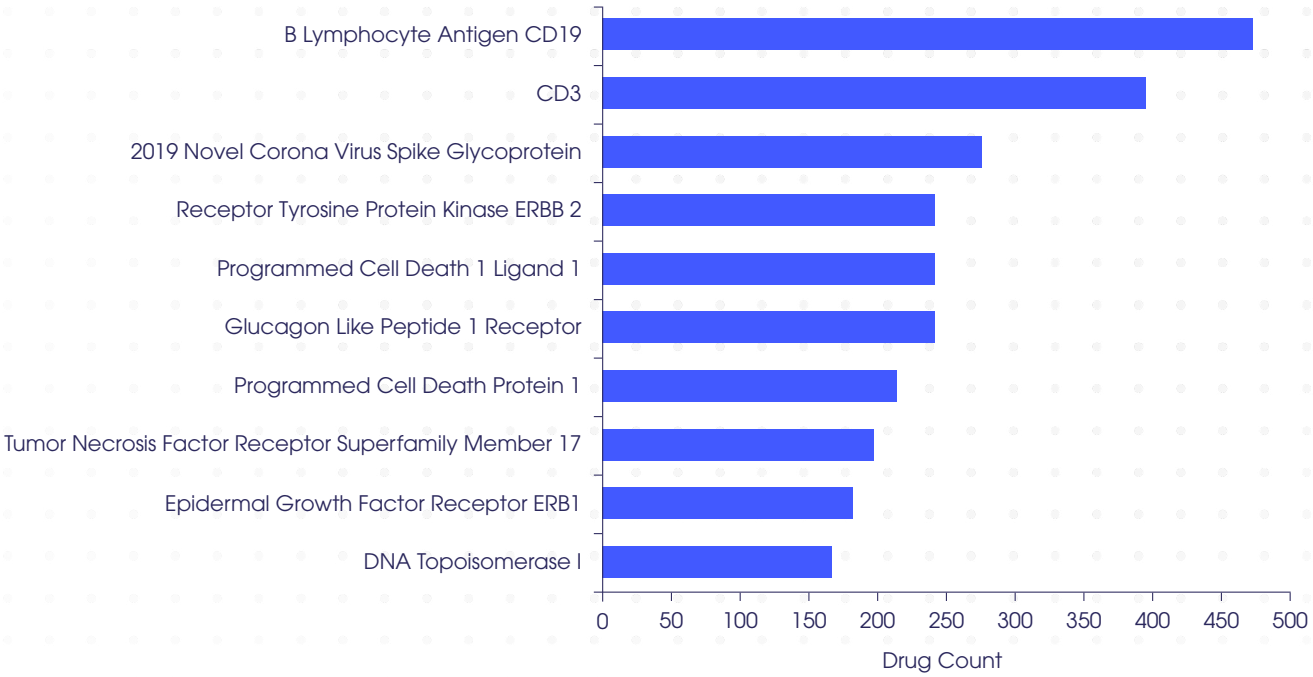
## The market for specific cancer types

**Non-small cell lung cancer (NSCLC):** The increasing incidence of NSCLC and the advent of new biomarker-driven therapies are key factors contributing to the growth of this segment.

**Bladder cancer:** The bladder cancer market is also seeing a significant influx of late-stage pipeline products, which are expected to reshape the treatment landscape.

**Prostate cancer:** Like NSCLC and bladder cancer, prostate cancer is poised for growth through the introduction of new therapies that leverage biomarker insights.

### Figure 3: Top 10 targets in the pipeline




Targeted therapy in NSCLC is a highly competitive and differentiated space covering 10 different actioFor the second year running, CD19 is the top biologic drug target. CD19 is implicated in blood cancers and is a key target for novel oncological technologies, such as CAR-T cell immunotherapy. Eight out of the top 10 targets for biologics are oncology-based, highlighting the focus on these products.
Source: *GlobalData: Looking Ahead to 2025 – the Future of Pharma, April 2025.*

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# Development lifecycle: Addressing sponsor challenges

Sponsors – especially smaller ones - often struggle with issues such as dose optimisation, regulatory alignment, and patient targeting, particularly in adaptive and global trial designs. However, effective collaboration with strategic CROs can help mitigate such issues, through their therapeutic and operational expertise, and enabling sponsors to navigate the complexities of clinical trials more efficiently.

## Key challenges faced by sponsors

**Dose optimisation**

Emerging sponsors often face challenges in dose optimisation due to constrained resources and technical expertise. This can result in inefficient dosing strategies that may not meet the specific needs of the trial population, impacting the success of the trial. The FDA's Project Optimus[v] now encourages more sophisticated dose optimisation, focusing on finding the minimum effective dose, minimal immunologically active dose, or optimal biological dose. Also, incorporating surrogate endpoints, such as progression-free survival or overall response rate as primary endpoints versus overall survival.

Such strategies rely on comprehensive data, including pharmacokinetics, pharmacodynamics, pharmacogenomics, and therapeutic drug monitoring, as well as patient-centric considerations such as dosing convenience and adherence. Experienced CROs can play a vital role in dose optimisation through their experience in more nuanced clinical trial designs that account for patient heterogeneity and long-term outcomes, while harnessing large datasets to tailor dosing strategies to specific patient populations, particularly in complex fields like oncology and rare diseases. Their expertise in trial execution ensures effective study design and implementation, while collaboration with academic research organisations further enriches the data available for informed dosing decisions.

**Regulatory alignment**

The dynamic nature of clinical research often requires rapid adaptations to regulatory guidance, which can be challenging for sponsors with less experience. In addition to helping companies meet evolving regulatory demands, particularly from agencies like the FDA and EMA, flexible CROs with regulatory and trial design expertise can also facilitate greater diversity in clinical trials. This is crucial in oncology due to varying patient responses to therapies based on genetic and demographic factors which CROs can facilitate through their operational expertise and understanding of regulatory landscapes.

CROs with a harmonised global framework can also manage submissions in multiple markets simultaneously. This strategy not only reduces development timelines but also maximises economic returns for biopharmaceutical companies.

**Patient targeting**

Identifying and targeting the right patient populations is increasingly complex, especially with the rise of personalised medicine. Emerging sponsors may lack access to the extensive data and technological resources to identify suitable patient populations. Without effective patient targeting, emerging sponsors risk recruiting insufficient or inappropriate participants, which can lead to trial failures or delays. By harnessing large datasets and advanced analytics, CROs with oncology experience and expertise can enhance patient targeting strategies, ensuring that emerging sponsors can efficiently identify and recruit suitable participants for their trials.

## Why an adaptive CROs is essential

CROs can play a pivotal role in alleviating pain points for emerging sponsors by leveraging their operational expertise and technological resources. CROs can also help facilitate adaptive trial designs that are responsive to emerging data and regulatory changes. This agility is essential for maintaining the relevance and competitiveness of clinical trials, while streamlining the process of implementing protocol changes, reduces delays associated with regulatory compliance and ensures that trials remain on track.

The integration of digital technologies and real-time data analytics is revolutionising clinical research, enhancing speed and accuracy, and CROs with a culture of agility are increasingly leveraging these innovations to support adaptive trial designs that allow for modifications based on incoming data - particularly advantageous in the dynamic field of oncology. This flexibility can lead to more efficient trial processes and improved patient outcomes.

Additionally, establishing clear roles and responsibilities from the outset of a study can improve oversight and accountability. This is vital as trials grow more complex, requiring ongoing communication between sponsors and CROs to ensure alignment and address challenges promptly. Partner-level collaboration is critical to success.

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# The CRO advantage: Patient centricity and operational precision

The right CRO can provide critical support and expertise that significantly enhance the oncology drug development process, offering expertise in regulatory compliance, operational efficiency, and innovative trial designs. Their role is vital in ensuring that promising therapies move swiftly from pre-IND to approval, benefiting patients in need of effective cancer treatments.

As the landscape of clinical trials evolves, designing trials with the needs and preferences of patients at the forefront is becoming increasingly important. The pharma and biotech industries is transitioning towards more personalized medicine and innovative trial designs; integration of patient-centric approaches with operational excellence will be key to thrive in a competitive and complex environment.

Technologies such as electronic data capture and teleconsultation tools allow drug developers to streamline operations and ensure compliance with regulatory standards, while also enhancing patient engagement. By focusing on what patients need and ensuring that operational processes are efficient, CROs improve trial outcomes and accelerate the development of new therapies. This dual focus not only enhances patient satisfaction but also optimises resources, ultimately leading to more successful trials.

## Comprehensive, expert-driven, globally integrated CRO support

Where can sponsors turn for a CRO that meets the many criteria presented by oncology research? Caidya is a global, full-service CRO, providing proactive risk management and agile trial design tailor-made for oncology and hematology development. The company engages early with clients to refine strategy, improve targeting and accelerate delivery, drawing on integrated medical, scientific, and operational teams experienced in navigating key development milestones. With 97% of project managers experienced in oncology research, Caidya is well positioned to deliver across all phases of development[vi].

Caidya leverages practical technology solutions to enhance patient recruitment and enrolment, achieving site activation to close times that are over 60% faster than the industry average in oncology trials. And by operating in more than 50 countries and regions, including significant expertise in China and the wider APAC region, Caidya can reach diverse patient populations.

From protocol design to regulatory approval, the company works as an extension of the client's team, maintaining transparent communication, reducing risk, and ensuring the delivery of highquality data to support timely and informed decision-making.

Sponsors need comprehensive support if they are to achieve critical milestones in preparing products for IND filing. This is exactly what Caidya provides. Their tailored approach guides the sponsor through every stage, from documentation and submission to dose selection, study design, pharmacokinetic analysis, and the preparation of final reports in support of the IND submission.

Caidya also collaborates closely with sponsors in first-in-human studies, assisting with patient and site selection, dose escalation, and optimising dosing strategies through pharmacokinetic and pharmacodynamic analysis. Their clinical pharmacology expertise supports rapid, accurate regulatory submissions and informed dose selection for market authorisation.

Offering a wide range of services to optimise early phase development, including conducting final pharmacokinetic analyses, preparing reports for IND submissions, examining PK/ PD relationships to ensure readiness for Phase III, and developing strategies for sampling and data analysis, Caidya's expertise ensures sponsors are well-prepared for regulatory submissions and market entry.

Additionally, Caidya's biostatistics and data science teams provide near real-time insights, robust data management, and full CDISC compliance, supporting informed decision-making and trial integrity. The company streamlines site, patient, and study team activities, while a wide range of services, including clinical monitoring, project management, feasibility, and patient concierge support, ensures efficient, high-quality trial execution and regulatory readiness.

**Caidya embed patient-first strategies into every stage of development - accelerating timelines and improving trial quality through global reach and tailored execution. Get in touch now to learn how they could turbocharge your oncology research productivity.**

# References


[i] GlobalData: Analyst Briefing: The Oncology Casino: High Stakes, Few Winners, January 2025.

[ii] GlobalData:  Analyst Briefing: The Oncology Casino: High Stakes, Few Winners, January 2025.

[iii] GlobalData: Analyst Briefing: Blood Cancers Dominate CAR-T Pipeline, March 2025.

[iv] GlobalData: Strategic Intelligence: Immuno-oncology (2025), July 2025.

[v] https://www.fda.gov/about-fda/oncology-center-excellence/projectoptimus

[vi] Caidya: Quick Guide: Oncology & Hematology; Expertise and adeptness for speed and certainty, May 2025.

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# Adapting at the Speed of Science

Caidya is a global, full-service CRO that brings expertise, agility to navigate complex trials, and global access to patients, that yields the high-quality data you need to make informed decisions.

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