White Paper

Achieving Oncology Launch Excellence

How to navigate harsh realities in a highly fluid environment

MARKUS GORES, Vice President, EMEA Thought Leadership, IQVIA
KIRSTIE SCOTT, Senior Consultant, EMEA Thought Leadership, IQVIA
PARMENDER DAHIYA, Associate Principal, Strategy Consulting, IQVIA

Table of contents

Introduction

For more than a decade, oncology has been the largest therapy area by value, and it continues to grow at a robust pace. The global market for innovative oncology products is forecast to grow at 6% CAGR through 2028,[1] considering net sales after rebates and discounts, driven by 100 new oncology treatments that are expected to launch in the next five years alone.[2] Globally, this could generate more than $61 billion in incremental net sales, bringing the total oncology market to $234 billion by 2028, again considering net sales after rebates and discounts.[1]

Fuelling this growth is a rich pipeline, with oncology trials representing 44% of total global R&D activity.[3] Novel oncology modalities, especially cell and gene therapies, antibody drug conjugates (ADCs) and multi-specific-antibodies, have risen to 25% of all oncology trials.[4]

Unsurprisingly, this opportunity attracts almost all of the top 20 pharma companies, as well as emerging biopharmaceutical companies which were responsible for 60% of new oncology trials in 2023.[4] Deals relating to antibody drug conjugates represented $90 billion in deal value in 2023, accounting for 45% of the total value of large deals (above $2 billion) in 2023, as companies like Pfizer, AbbVie, and Merck seek growth through new oncology platforms.[3]

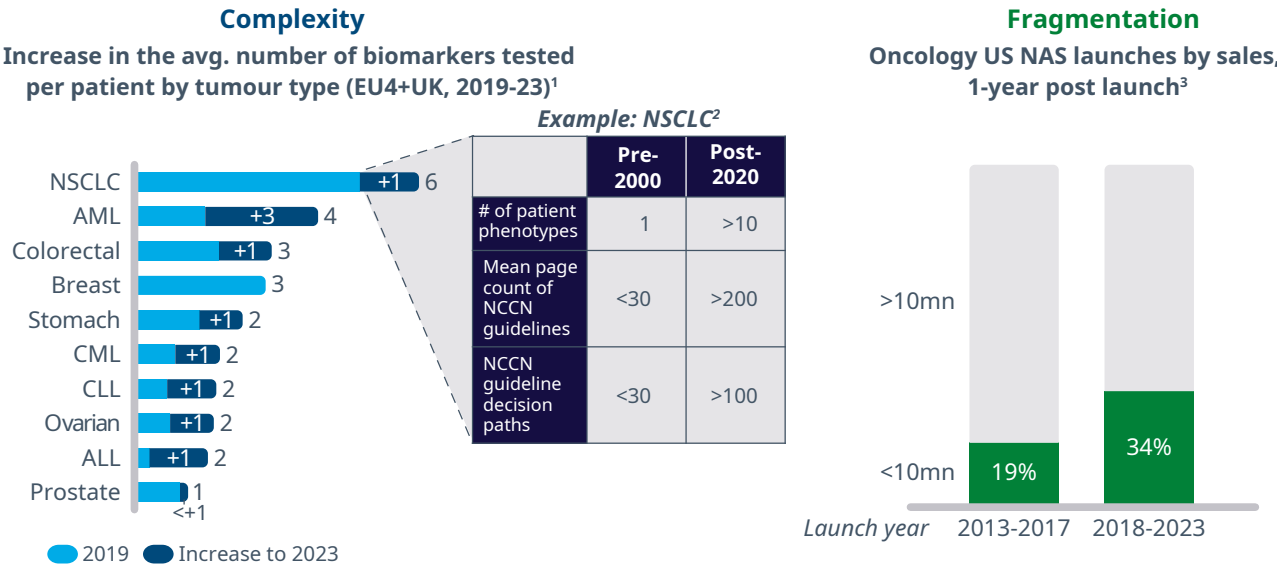
However, the rapid pace of innovation, fierce competition and struggling healthcare systems create considerable headwinds for companies launching oncology products, which are compounded by specific, often complex supply chain and manufacturing requirements for cutting-edge therapies.

Furthermore, the route to oncology launch success is built through a “marathon” of expanding labels, new indications and new regimens as products typically launch in multiple new sub-populations within a tumour type, often moving into earlier lines of therapy, and/or expanding into different tumour types.

Headwinds facing oncology launches

Oncology innovators face an unforgiving launch environment which presents a number of specific challenges (see Figure 1):

Figure 1: Innovators face increasing complexity and fragmentation



Source: IQVIA EMEA Thought Leadership; 1) IQVIA Oncology Dynamics 2023, EU4+UK; 2) IQVIA expertise and secondary research: Tang et al: The histologic phenotype of lung cancers is associated with transcriptomic features rather than genomic characteristics, Nat Commun 12, 2021; Kann et al. Changes in Length and Complexity of Clinical Practice Guidelines in Oncology, 1996-2019, JAMA Netw Open, 2020; 3) IQVIA MIDAS QTR March 2024

- **Opportunity fragmentation:** Innovation in oncology increasingly targets smaller, discrete patient sub-populations, often biomarker-defined. This limits the absolute size of each individual launch and requires a precision approach to identify those patients in routine practice and target the relevant prescribers who treat them, while limiting the P&L headroom for resourcing.
- **Overwhelming complexity:** Several trends converge to create an exceedingly complex oncology market for innovators to navigate. Firstly, frantic innovation activity has resulted in a very crowded therapeutic landscape, with numerous drugs used in different lines of therapy, for different patient subtypes, often in combination regimens. Secondly, the rise of precision therapies utilising biomarkers and companion diagnostics adds further complexity as patient populations are stratified even more finely. At the same time, innovators and HCPs need to master new diagnostic challenges, such as embedding novel biomarkers in routine practice to identify eligible patients, understanding resulting new treatment pathways or ensuring sufficient testing capacity. Finally, the fast pace of innovation means innovators operate in a highly fluid market environment with continuously moving goal posts.
- **Pressed for time:** Given the high level of unmet need, many oncology products benefit from accelerated approvals and breakthrough designations. However, this leaves less time for launch preparation and generating mature evidence ahead of market entry. Once on the market, de facto exclusivity periods get squeezed as follow-on competitors launch more rapidly, which accelerated approvals may only partially mitigate. Finally, cost containment measures such as the IRA may further compress an asset's economic lifespan, especially for small-molecule drugs with high exposure to Medicare. For example, in the case of multi-indication brands the first launch starts the clock on when price negotiations can begin, thus exposing later indications to relatively earlier impact of IRA measures in their respective lifecycle. This limits the time available for innovators to capture the full commercial opportunity.

- **Value scrutiny:** Increasingly, questions are being raised about how the high volume of oncology innovation translates into greater patient benefit. For example, one recent study found that 41% of drugs granted accelerated approval from 2013-2017 did not improve overall survival or quality of life in confirmatory trials after more than 5 years of follow-up.[5] Another study concluded that only 29% of FDA-approved, genome-targeted therapies demonstrated substantial clinical benefit using the ESMO-MCBS rating.[6] In a budget constrained environment, stakeholders will demand unambiguously compelling and robust evidence before granting full access and embracing new therapies in clinical practice.
- **Lagging health systems:** Innovation is moving faster than healthcare systems' ability to adopt new therapies, financially and especially operationally. For example, capacity constraints, including skilled staff shortages following pandemic burnout[7] or scarcity of accredited facilities for delivering highly specialised therapies, combined with mis-aligned or unprepared care pathways prevent the effective delivery of cutting-edge treatments such as CAR-T, radio-pharmaceuticals or biomarker-based precision therapies. Across innovative oncology products, the average delay between European regulatory approval and availability was more than a year in 75% of the 36 countries included in the 2023 Patient W.A.I.T. indicator study.[8] Alarmingly, 60% of these countries have oncology products which take more than 3 years to availability, and every country has oncology products which take more than a year to availability. This elevates health system readiness as a major bottleneck for achieving launch success.

These harsh realities define the launch context and in turn the critical success factors at which innovators now must excel to achieve oncology Launch Excellence.

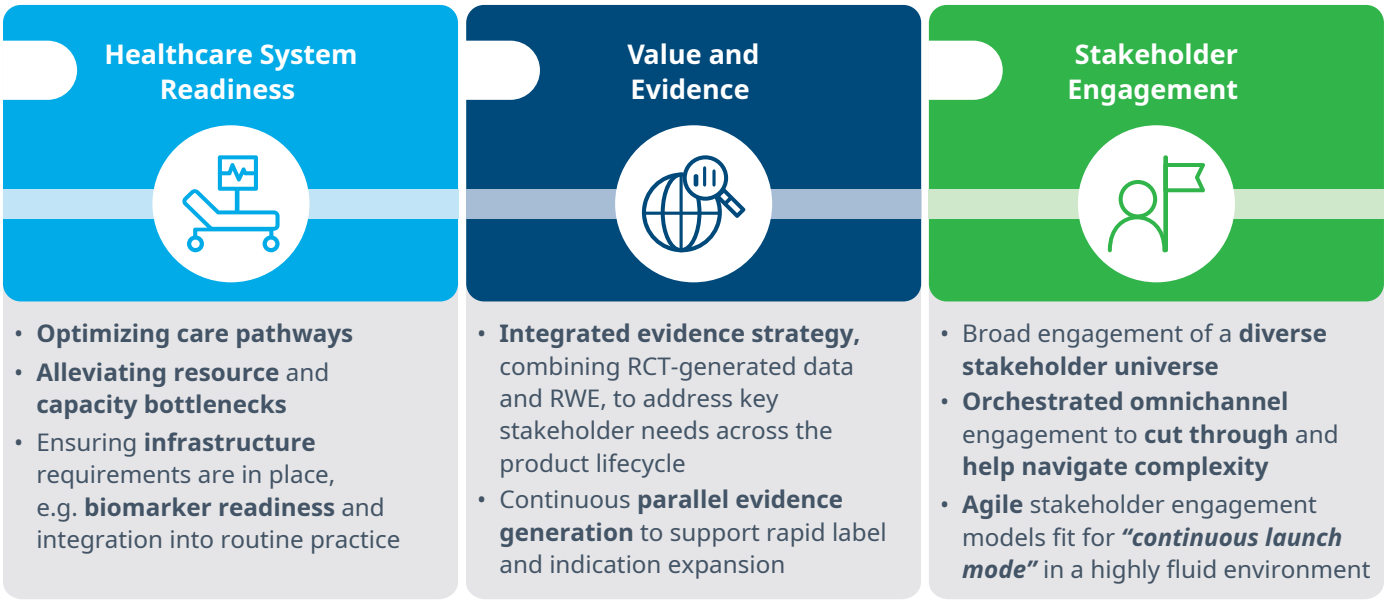
Achieving oncology Launch Excellence

We are building on the extensive learnings from IQVIA's reputable Launch Excellence series, our systematic study of the performance of launches of innovative products and underlying drivers of success, spanning over two decades.[9]

Oncology Launch Excellence rests on three strategic pillars as the critical foundations of launch success (see Figure 2):

Strained and constrained health systems must be supported to effectively adopt innovation.

Figure 2: The three pillars of oncology Launch Excellence



Source: IQVIA EMEA Thought Leadership

1. **Healthcare system readiness:** Strained and constrained health systems must be supported in the adoption of innovation and to accelerate its translation into change in clinical practice. This requires optimising care pathways and improving decision support, alleviating resource and capacity bottlenecks, and ensuring specific infrastructure requirements are in place, including upgrading both physical and digital infrastructure.

   Examples include biomarker readiness which sees a novel biomarker embedded in routine clinical practice supported by adequate testing capacity and fully trained HCPs, diagnostic support for interdisciplinary tumour boards, or supply chain readiness for complex, novel modalities such as CAR-Ts or radiopharmaceuticals combined with a network of accredited facilities for care delivery.

2. **Value and evidence:** An integrated evidence strategy, combining RCT-generated data and RWE, is critical to address the needs of all key stakeholders along the product lifecycle, to ensure approval, access and to facilitate the adoption of novel therapies. With regulatory approvals often being based on less mature evidence, e.g., from single arm trials, using surrogate endpoints, generating confirmatory evidence is critical to reassure stakeholders of long-term benefits, including real world effectiveness and safety. Furthermore, maximising the potential of oncology assets requires continuous, parallel evidence generation to support rapid label and indication expansion. Crucially, evidence also plays an important internal role as the insight foundation for informing key strategic decisions, e.g., defining the brand strategy.

3. **Stakeholder engagement:** Innovators must engage a diverse stakeholder universe, spanning payers, HTA bodies, providers/local health systems, HCPs, nurses, patient advocacy groups and patients. In the case of multi-indication assets, pan-tumour alignment across stakeholders is important to create brand equity and realise economies of scale at the asset level. Orchestrated omnichannel engagement is critical to efficiently deliver timely, relevant and succinct content, as well as value-add services. These must cut through and help stakeholders navigate complexity for a superior customer experience. Stakeholder engagement models need to be agile, as oncology innovators find themselves in 'continuous launch mode' as they roll out label and indication expansions in a highly fluid environment.

We will now systematically explore best practice for each strategic pillar of oncology Launch Excellence, illustrated through relevant case examples.

I. Health system readiness: beyond access to enablement

Addressing the health system 'innovation readiness gap' is a key prerequisite for achieving launch success, especially in oncology which is at the forefront of transformative biopharmaceutical innovation. It requires a fundamentally different approach focussed on partnering with healthcare systems on a broader agenda to remove barriers to the effective adoption of innovative therapies.

PATHWAY OPTIMISATION

Given the complexity of delivering cancer care, many health systems grapple with unwarranted pathway variations that result in sub-optimal patient outcomes and experiences. It further impacts productivity due to inefficient utilisation of healthcare resources and capacity, which limits systems' ability to embrace novel therapies.

Developing local solutions in partnership with health systems provides an opportunity for innovators to facilitate optimal care pathway configurations and to eliminate capacity bottlenecks. This in turn creates the conditions for innovation to flourish and deliver benefits to eligible patients.

For example, the UK lags behind other countries in patient outcomes in several cancers, e.g., having amongst the lowest lung cancer survival rates globally.[10] This has been linked to barriers in its cancer care pathways affecting the adoption of innovative therapies.[11]

A number of initiatives aim to address this situation, for example:

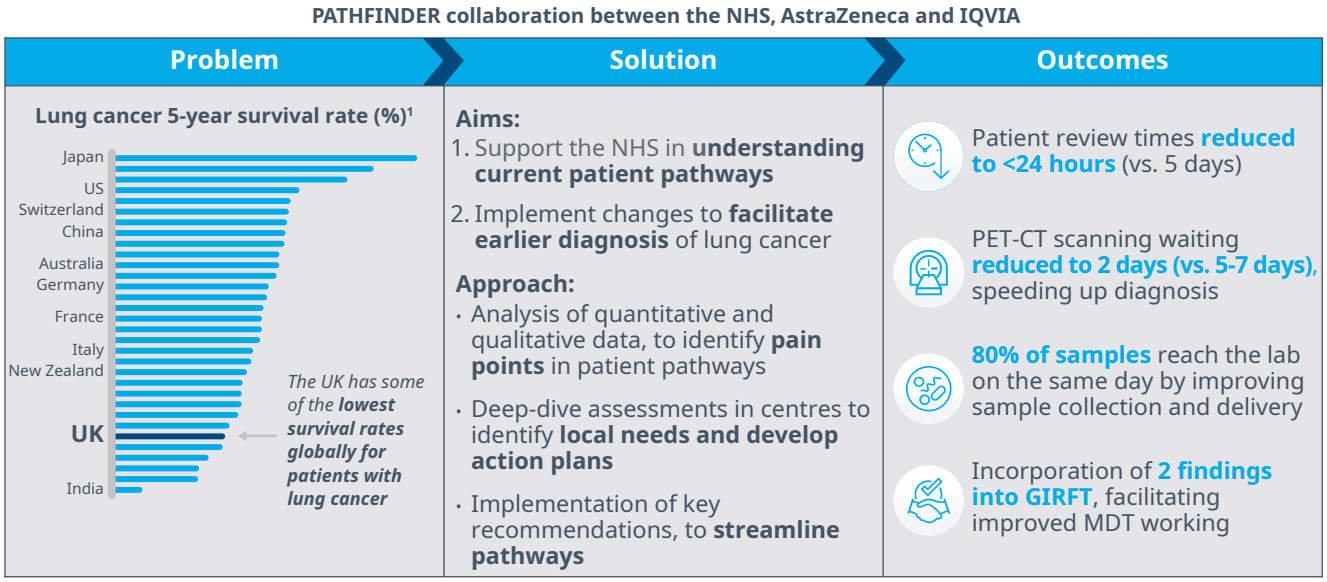
- A partnership between BMS, Macmillan and an NHS cancer trust that aims to combat the longstanding capacity challenges within the cancer workforce in the UK by developing a workforce and innovation forecasting model.[12]
- Roche's National Optimal Lung Cancer Pathway Analysis Model (NOLCP model), an automated excel-based tool to monitor performance of the NOLCP and identify areas for service development and improvement.[13]
- AstraZeneca's PATHFINDER[14, 15] collaboration with the NHS and IQVIA (see Figure 3), aimed at diagnosing patients earlier, accelerating navigation to treatment, and increasing curative intent treatment rates. In-depth audits identified pain points in care pathways to inform local action plans to streamline them. For example, this effort resulted in reduced patient review times (from 5 days to 24 hours), shorter waiting times for PET-CT scanning to speed up diagnosis (from 5-7 days to 2 days) and improved sample collection and delivery, meaning that 80% of samples reached the lab on the same day.

Excellent launches proactively identify systemic bottlenecks early during the pre-launch phase and use targeted initiatives to resolve them, as illustrated by the above examples, to create the headroom in stretched healthcare systems that is needed for innovative oncology launches to succeed and transform cancer care.

INFRASTRUCTURE READINESS

Transformative innovations, such as CAR-T or radioligand therapies (RLT), face unique challenges because existing care pathways are ill-suited to accommodate them.

Figure 3: Accelerating the lung cancer patient pathway in the UK



Source: IQVIA EMEA Strategy Consulting; 1) Data taken from Allemani C, Matsuda T, Di Carlo V, et al. Global surveillance of trends in cancer survival 2000-14 (CONCORD-3): analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries. Lancet. 2018;391(10125):1023-1075. Notes: GIRFT= Getting It Right First Time; MDT=Multi-Disciplinary Team

For example, radioligand therapy demands specialized facilities to ensure safe administration: shielded rooms are essential during treatment to protect healthcare workers and other patients from radiation exposure; patients remain radioactive post-treatment, necessitating isolation rooms and careful capacity planning. In addition, the short half-life of isotopes requires efficient manufacturing and supply chains to deliver RLTs promptly while they remain radioactive. Furthermore, staff across the supply chain must be trained on the proper handling, storage and disposal of radioactive materials, including waste generated during treatments.

The IQVIA Institute highlighted in its recent report[16] five major levers to address RLT capacity bottlenecks, which require a multi-stakeholder, collaborative approach: diagnostic capacity, patient referral processes, number of RLT centres/beds, regulatory and patient release frameworks and skilled workforce.

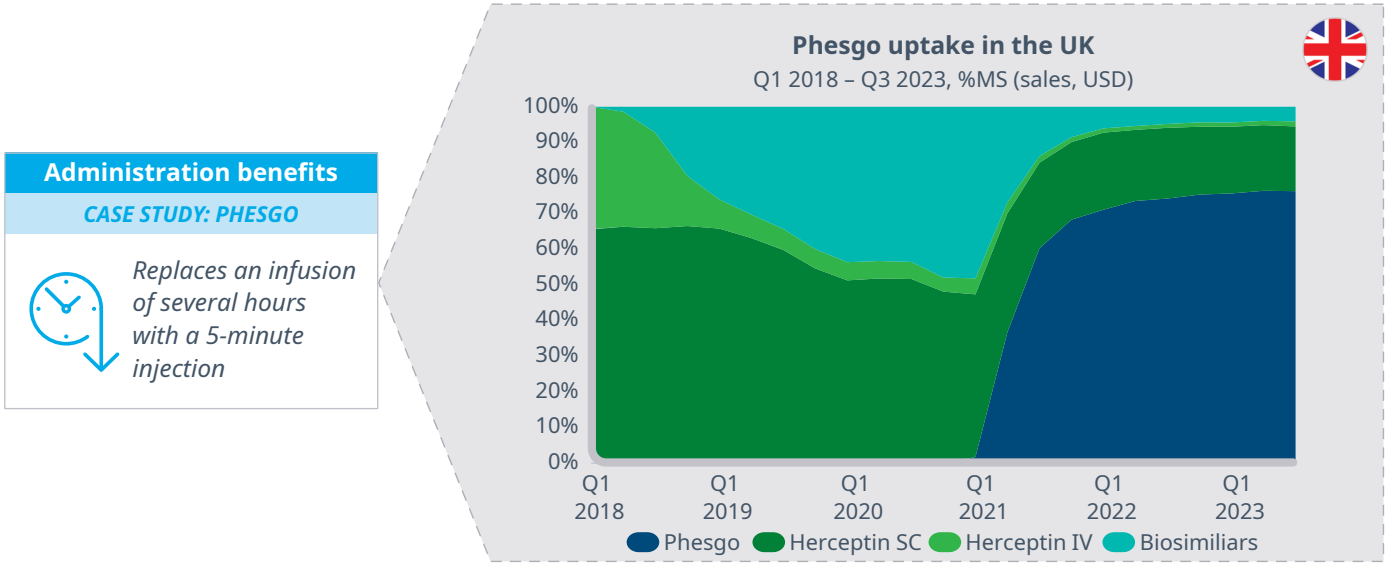
Achieving readiness to deliver highly innovative therapies creates major financial pressures for providers. For example, establishing fully equipped specialist centres, including capital-intensive diagnostics and treatment infrastructure, requires significant investment, which is a particular challenge for smaller, less well funded community centres compared to major academic centres of excellence. Private-public/manufacturer-provider partnerships could play an important role in expanding critical infrastructure, e.g., manufacturers providing financing solutions to help treatment centres manage cash flow challenges resulting from building out new, specialist capacity.

ALLEVIATING THE OPERATIONAL BURDEN

In addition to delivering optimal patient outcomes, differentiated innovative therapies also alleviate the operational burden on health systems, for example facilitating delivery of procedures in an outpatient setting. Novel formulations can make therapies less capacity-intensive, e.g., by enabling faster turnaround through shorter infusion times or substituting infusions with much quicker injections. For example, Darzalex Faspro, a subcutaneous formulation of intravenous multiple myeloma treatment Darzalex, reduces administration time from 7 hours to 2-3 minutes.

Another example, Phesgo, a subcutaneous, fixed-dose combination of Herceptin and Perjeta for the treatment of HER2+ breast cancer, replaces an intravenous infusion of its individual components that lasts 60-150 minutes with a 5-minute injection.[17] The beneficial impact on patients and health system capacity prompted NHS England to adopt Phesgo as the preferred therapy at the expense of lower cost Herceptin IV biosimilars (see Figure 4).[18] This example highlights how considerations of broader system benefits can outweigh a narrow focus on the budget impact of direct drug cost.

Figure 4: Alleviating the capacity burden on health systems



Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS Q3 2023

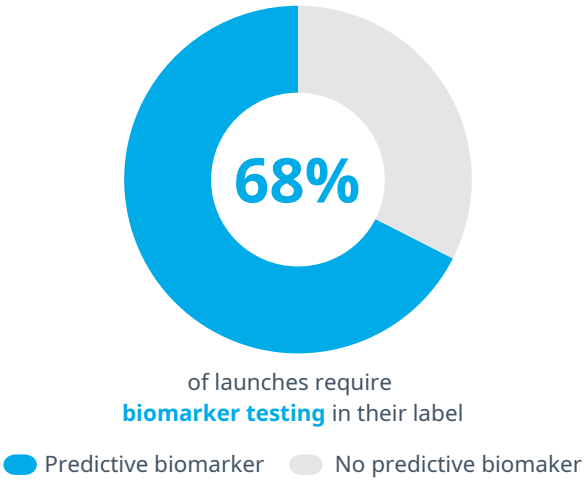
BIOMARKER READINESS

The rise of molecularly targeted, biomarker-based therapies elevates health systems' biomarker readiness as a critical success factor for oncology launches. Therapies with predictive biomarkers tend to achieve greater commercial success than those without, as health systems, payers and oncologists value higher certainty of favourable patient outcomes in the biomarker-defined population (see Figure 5).

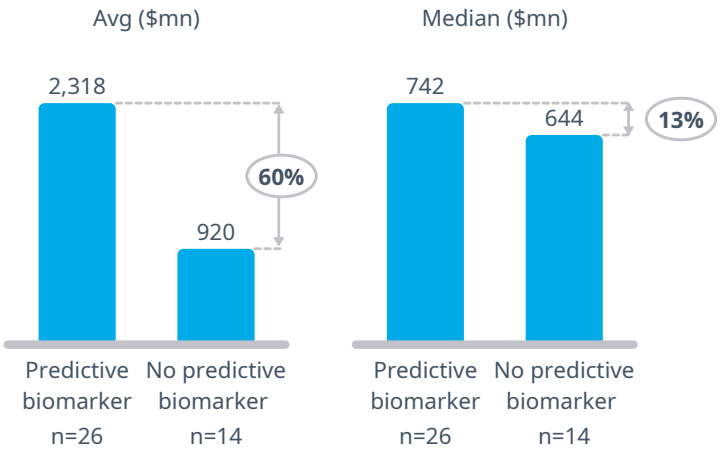
Therapies with predictive biomarkers tend to achieve greater commercial success, as stakeholders value higher certainty of favourable patient outcomes.

Figure 5: Predictive biomarkers aid commercial success

Label requirements for recent oncology NAS launches in US
(share of solid tumour NAS from 2019 to 2023)



Avg 5-year US sales for Oncology NAS with or without predictive biomarkers*
(solid tumour NAS 2013-19)

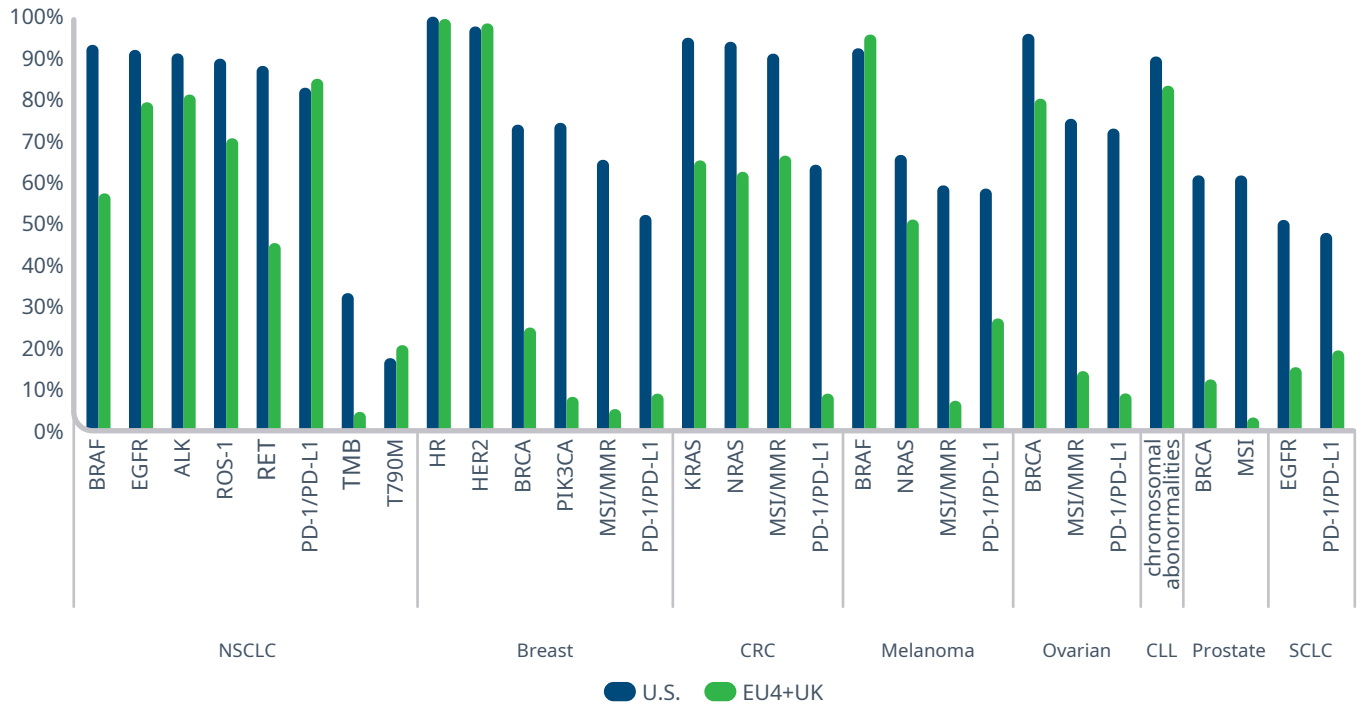


Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS QTR Mar 24; FDA labels; IQVIA Institute NAS dataset; Notes: Includes NAS for solid tumours launched in the US; *Sales are at a product level not an indication level, but predictive biomarker classification is based on the FDA label of the first indication approval

Novel therapies targeting biomarker-defined patient populations must overcome numerous barriers to ensure their wide and effective adoption in clinical practice:

- Wide variation in biomarker testing in routine practice across tumour types and geographies (see Figure 6)
- Low awareness of novel biomarkers as oncologists, and pathologists, struggle to keep abreast of the rapid evolution in cutting-edge disease management
- Delays in updated guidance from medical societies and lack of efficient reimbursement pathways for biomarker tests
- Bottlenecks in biomarker testing capacity and workflows, e.g., performing biopsies, shipment of samples to pathology lab, running the biomarker test and returning the result to HCPs

Figure 6: Testing rates by tumour, biomarker and geography, 2023



Source: IQVIA Oncology Dynamics, Dec 2023; IQVIA Institute; Global Oncology Trends 2024: Outlook to 2028

Excellent launches dedicate significant, early effort to ensure biomarker readiness.

Excellent launches therefore dedicate significant, early effort to ensure biomarker readiness, which must be seamlessly integrated into the broader launch readiness preparations.

This requires a multi-stakeholder approach starting at the clinical development stage. It involves embedding biomarkers in pivotal trials; defining clear testing protocols with scientific advisory boards and building advocacy with clinicians for the new biomarker's utility; engaging with guideline setting bodies to facilitate timely updates of testing guidance; embedding a new biomarker within existing workflows, both within clinics and diagnostic labs, and training oncologists, nurses and pathologists on the practicalities of testing; and engaging with payers to ensure coverage of biomarker tests.

For example, in preparation for the Keytruda launch, it was vital for Merck to train pathologists on interpreting the then novel, non-binary PD-L1 biomarker which involves translating levels of staining into % PD-L1 expression. Bayer and Loxo Oncology hired a diagnostic team with a mix of diagnostic-science liaisons to build awareness with oncologists and pathologists on NTRK mutation testing before the Vitrakvi launch.

Furthermore, partnering with diagnostics companies and establishing an effective Rx/Dx commercialisation framework plays an important role in building out the required biomarker testing infrastructure and developing a service and delivery model as a prerequisite for the adoption of molecularly targeted therapies.

Medical affairs is well placed for leading healthcare system engagement to facilitate system readiness, through dedicated roles with a broader remit beyond product-focused education, such as care pathway enablers or the aforementioned diagnostic science liaison.[19]

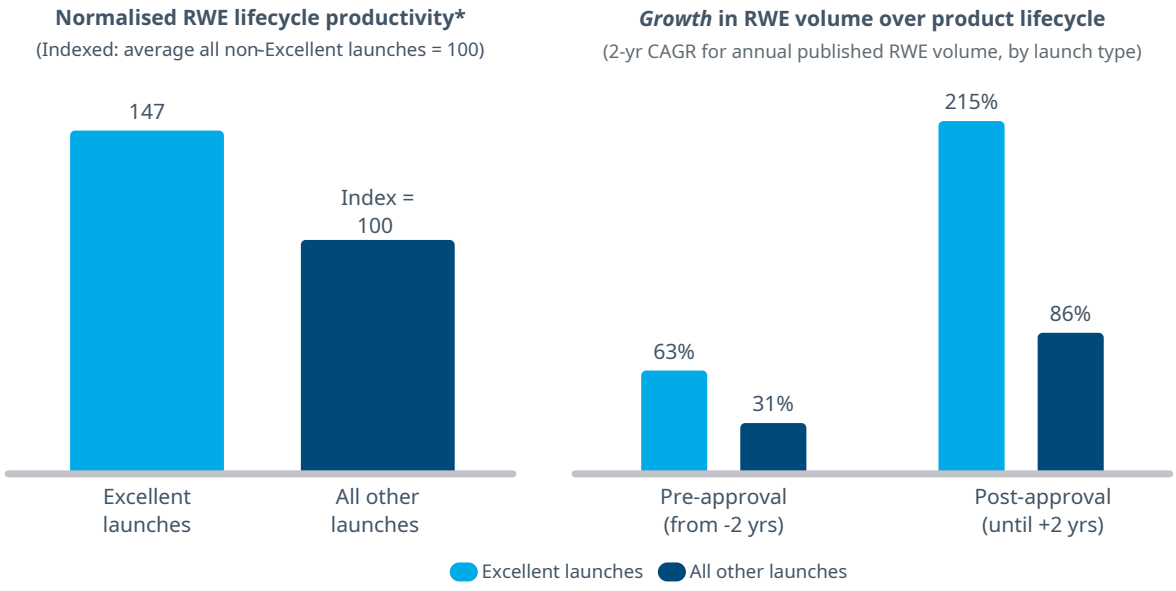
II. Value and evidence: bracing for the marathon

Data generated during clinical development is the basis for regulatory approval, and it typically forms the foundation of a product's value proposition. However, achieving commercial success in oncology requires comprehensive, integrated and continuous evidence generation, including clinical trials and RWE, to build the brand and address the needs of all key stakeholders in a timely manner, at all stages along the product lifecycle, for example:

- Generating disease awareness, highlighting unmet needs and potential benefits of novel MoAs during pre-launch market shaping, in particular where innovation aims to create new categories, e.g., HER2 low or ultra-low breast cancer patient segments who benefit from treatment with Enhertu.
- Pinpointing value in discrete patient populations to secure and expand market access by addressing two types of uncertainty payers face, around (i) clinical outcomes and (ii) budget impact, especially when regulatory approval was based on less mature evidence, e.g., accelerated approval using single-arm, phase 2 data.
- Demonstrating relative benefits vs. the standard of care or other competitors when entering crowded market segments through comparative evidence, such as head-to-head trials and comparative real-world effectiveness studies.
- Quantifying health system benefits, e.g., alleviating the capacity burden, more efficient healthcare resource utilisation or the avoidance of downstream impact on cost and resources due to disease progression and complications.
- Facilitating the adoption of innovation by changing clinical practice, e.g., helping HCPs navigate increasingly complex treatment algorithms, providing clarity and guidance for identifying the most suitable patients in routine practice for a novel therapy and how to use it for optimal disease management.
- Harnessing evidence, especially RWE, as strategic enabler of healthcare system engagement and for the co-development of solutions that underpin health system readiness, the first of our three strategic pillars of oncology Launch Excellence.

As we have shown elsewhere, Excellent launches generate more evidence over their lifecycle and start evidence generation earlier than non-Excellent ones (see Figure 7). They utilise evidence as a strategic differentiator to create a constant 'news flow' as a prerequisite for capturing top share of mind and creating more engagement opportunities with external stakeholders, e.g., payers, external experts and practising oncologists.[20]

Figure 7: Excellent launches generate more RWE, earlier and faster



Source: IQVIA EMEA Thought leadership; IQVIA White Paper "Excellent launches are winning the evidence battle"
* Total number of publications/number of indications approved >6month ago/normalised for time on market

For example, one oncology innovator was developing a novel, targeted therapy with the potential to re-define clinical practice in a biomarker-defined population. Extensive market shaping was critical to establish a new, meaningful patient segment and to set a new standard of care (SoC). The company developed and executed a comprehensive, integrated evidence programme, with shared objectives across functions (see Figure 8):

1. *Evidence priorities aligned to key levers of market shaping:* (i) Raising awareness of unmet need; (ii) demonstrating product differentiation to HCPs, patients and health systems, including clinical, patient-centric and health economic benefits; (iii) enabling optimal clinical practice, e.g., biomarker testing, patient identification, streamlined patient journeys and product positioning within treatment algorithm.
2. *Evidence phased over the asset lifecycle:* From pre-launch, peri-launch through post-launch, reflecting when specific stakeholder needs must be addressed and highlighting lead times for generating timely evidence.
3. *Clear, pragmatic tactical plans for evidence generation:* Identifying data needs (e.g., proactive data sourcing and establishing research networks); specifying the most suitable methodologies and study designs for fit-for-purpose evidence generation that balances robustness, speed and cost; defining clear timelines, resource/budget needs and responsibilities.

Figure 8: Integrated evidence programme for market shaping

Market shaping levers	Pre-launch	Launch	Launch + 2 yrs
Raise awareness of unmet need	Incidence, prevalence and mortality of biomarker XX positive tumour X SOC treatment and outcomes in biomarker XX positive population Background rates and management of AEs from current treatments in the real world Characterisation of subgroup of patients with poor outcomes based on molecular and clinical features	Patient preference on benefits vs. tolerability across lines of treatment Physician preference on benefits vs. tolerability across lines of treatment RW outcomes of patients that are being rechallenged/recycled with SoC	Resistance mechanisms of patients with disease progression at all lines of treatment
Show product differentiation	Correlation of endpoints in biomarker XX positive tumour X with OS Baseline HCRU inc. duration of hospitalization, cost of disease progression and AE management	Product X efficacy, safety in biomarker+ population, as per single-arm RCT Product X efficacy, safety in biomarker+ population: RCT vs. external comparator	Identification of long-term AEs in the real world (survivorship) Quality of life outcomes data (including PROs) in patients treated with product X RW outcomes products X in different, biomarker-defined sub-populations Long-term HCRU impact of product X, incl cost offsets from AE management
Enable optimal clinical practice	Patient journey (inc. diagnostics, treatment sequencing and outcomes) across geographies Patient identification, biomarker testing in clinical practice and trends over time Sequencing of existing regimens within and across different MoAs Identification of fast progressors on SoC	Biomarker XX testing: Best practice Incidence, prevalence and prognosis of patients with other biomarkers, incl. overlaps Identification of high-risk patients developing high-grade AEs Unwarranted variation in local care pathways, capacity and demand management	Prognostic value of biomarker XX mutant vs. wild type populations Sequencing of product X vs. existing regimens within and across different MoAs Product X efficacy impact of dose-reduction strategies

Source: IQVIA Real World Solutions

Powered by compelling evidence, this oncology innovator successfully created a new category in a market already served by several legacy therapy options, set a new SoC and delivered an outstanding oncology launch.

SMARTER STRATEGIC DECISIONS

Integrated evidence generation also plays a critical role in providing the insight foundation to internal teams and functions to inform strategic decisions, e.g., defining the target product profile (TPP) and brand strategy, including competitive positioning, patient and HCP segmentation or priority intervention points to target along the patient journey.

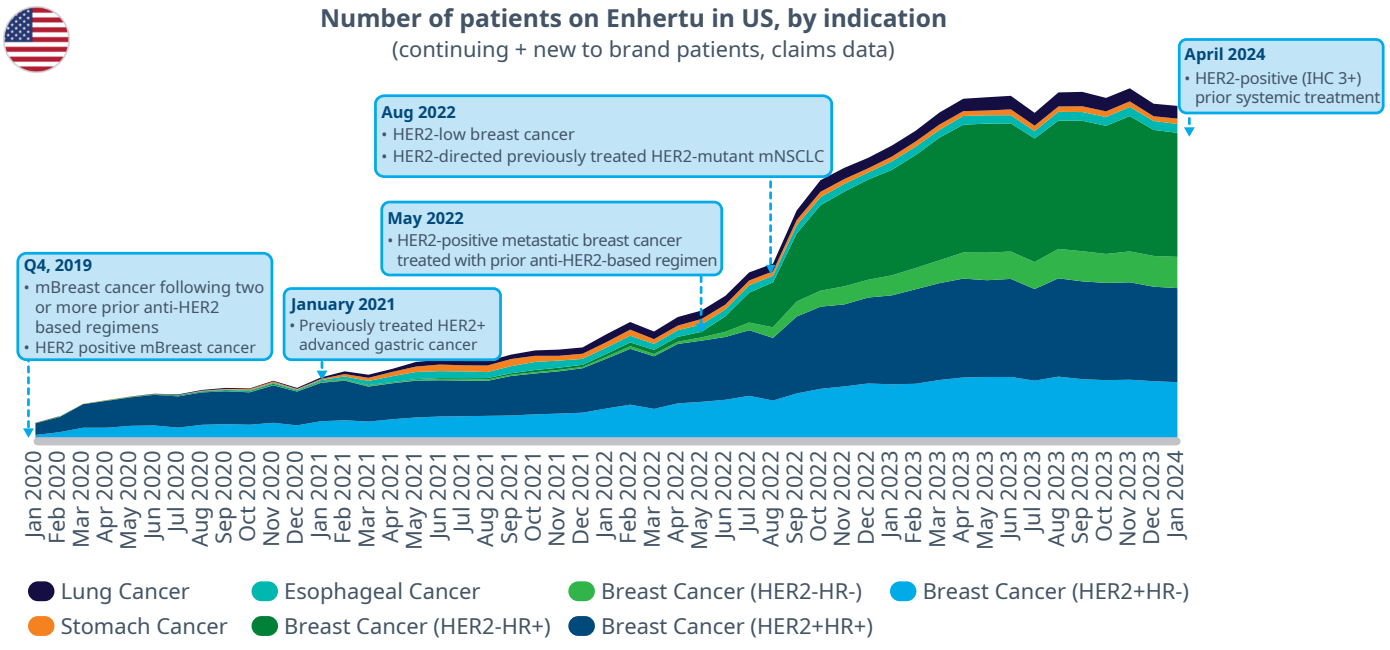
Leaders increasingly utilise structured, interactive disease mapping, which draws on a diverse range of clinical, behavioural, attitudinal data, e.g., RCT, EMR, registries, patient-generated data, claims, PMR/surveys, social feeds or literature. It serves as a powerful tool for cross-functional strategic planning, for example to identify and prioritise opportunities, such as underserved sub-populations or pathway bottlenecks, while allowing rapid scenario testing and impact assessment of different strategic options.[21]

PARALLEL EVIDENCE GENERATION

Maximising the potential of an oncology asset requires continuous, parallel evidence generation to accelerate label and indication expansion.

For example, supported by an extensive clinical development programme, Enhertu initially targeted patients with HER2+ metastatic breast cancer, before expanding into new patient populations within breast cancer (patients with HER2-low expression, and likely soon, patients with HER2-ultra low expression) as well as expanding across tumour types with new indications in gastric and lung cancer (see Figure 9). This set up Enhertu for rapid growth to become a major oncology blockbuster brand.

Figure 9: Enhertu example – extensive label and indication expansion



Source: IQVIA US Claims Data

III. Stakeholder engagement: cutting through the noise

Several factors determine the oncology-specific requirements for an effective stakeholder engagement model:

- **Need for precision:** Opportunity fragmentation leads to smaller launches and limits the P&L headroom for go-to-market investment. Innovators must therefore balance OPEX in support of adequate stakeholder education on novel, often complex therapies with opportunity potential. This requires deploying resources with great precision, targeted at key stakeholders and critical intervention/decision points along the patient journey for maximum spend effectiveness.
- **A franchise approach:** Maximising the value of an oncology asset requires ongoing label and indication expansion. Furthermore, faced with opportunity fragmentation, many innovators need to assemble a multi-asset, multi-indication oncology portfolio to achieve critical mass. An effective stakeholder engagement model therefore must reflect, and holistically balance, asset/indication-specific go-to-market requirements, customer overlap and opportunity potential at oncology franchise level.
- **Speed and multiple priorities:** Compressed economic lifespans demand accelerated commercialisation to maximise an asset's value. It also forces innovators to pursue parallel development of multiple indications, instead of a traditional, sequential approach. In turn, companies must be able to handle greater complexity and multiple priorities at the same time as they execute multiple, overlapping, possibly even simultaneous launches of new indications.
- **Agility:** Frantic innovation activity fuels a rapidly evolving therapeutic landscape in oncology and ever-changing competitive dynamics. Oncology innovators therefore need to be highly agile to swiftly pivot as the goal posts in the marketplace keep moving, e.g., adapting launch plans, re-allocating field resource or re-focusing engagement of external experts or evidence dissemination.

Successfully priming the market for innovative oncology therapies and removing health system barriers requires different frontline capabilities, beyond the traditional roles for customer engagement, such as care pathway enablers, with medical affairs playing an outsized role. These new profiles must be able to navigate the complexity of healthcare systems and successfully deliver collaborative initiatives. Depending on the extent of market preparation required, these activities must start early, for example 24-36 months before launch, when introducing highly innovative, transformational therapies.

PATIENT ENGAGEMENT

Early engagement with patient advocacy groups and patients to understand their unmet needs is crucial for launch success. In particular non-clinical unmet needs can present real barriers to access and adoption for innovative therapies. Our previous white paper "Planning to Engage: A Holistic Approach to Patient Inclusion" provides a comprehensive model to understand and address the wide-ranging needs of patients and their communities.[22]

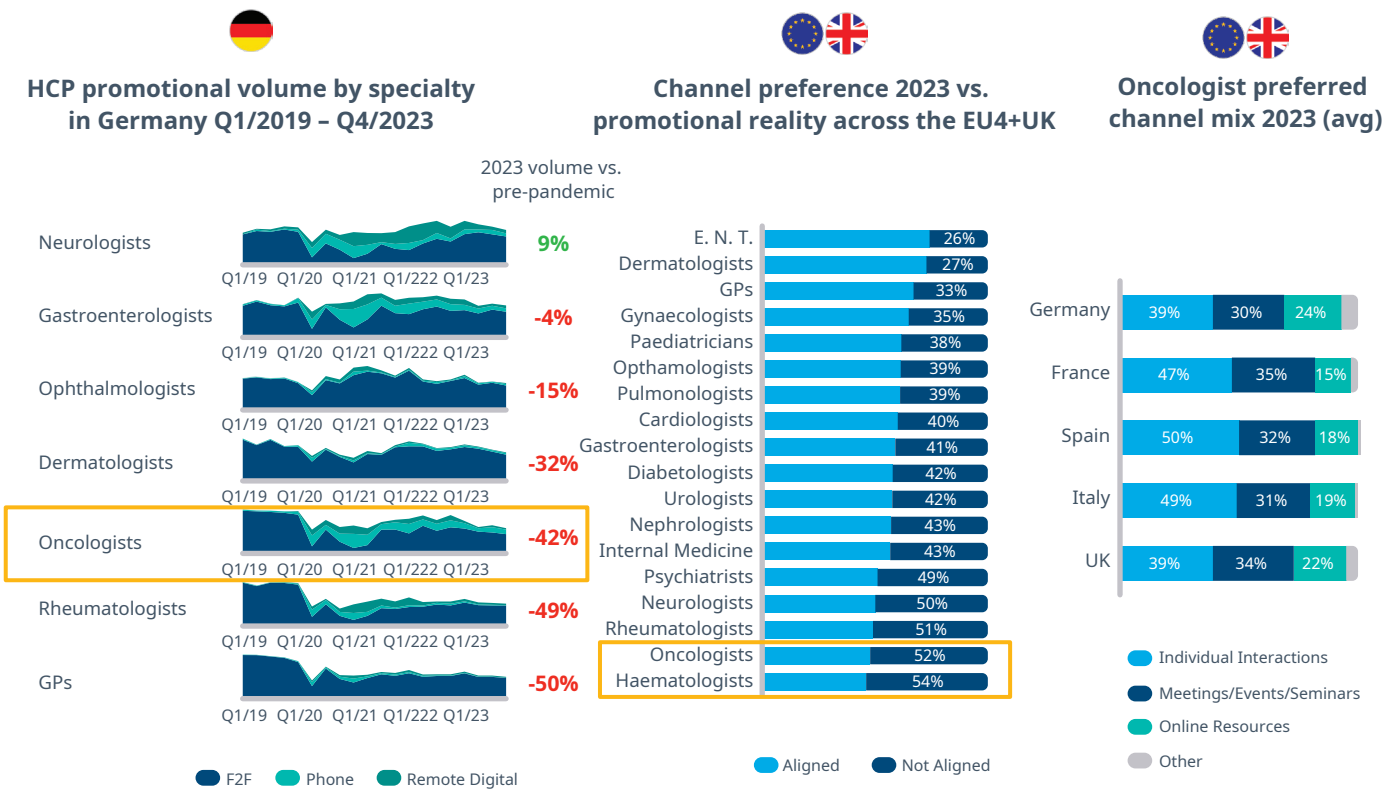
In the US market where direct-to-consumer (DTC) advertising is possible, several leading oncology brands utilise DTC advertising to stimulate demand. For example, DTC spend on Opdivo and Verzenio was $85-95 million in the first year alone.[23] However, DTC advertising is not a necessary requirement for achieving oncology Launch Excellence. Many leading oncology launches have a low DTC spend, reflecting their highly specialised nature and the complexity of the disease; more than half of Excellent oncology launches had less than $500 thousand spent on DTC in the first year post-launch.

OMNICHANNEL ENGAGEMENT

Many oncologists are time-poor which is reflected in the lowest access for sales reps among prescriber specialties, with call volumes in oncology still 20% or more below pre-pandemic levels in many countries.[23] Oncologists are also overwhelmed by information they receive from many directions, e.g., from different biopharma companies, different functions within those companies, their peers, professional networks or medical societies. Consequently, successful customer engagement must cut through this noise and deliver relevant, personalised content and services, via an orchestrated omnichannel approach that reflects oncologists' needs and their preferences.[24]

However, our analysis found a significant gap exists today, with oncologists and haematologists having the lowest alignment among all prescriber specialties between their channel preference and the promotional reality across EU4+UK markets (see Figure 10).

Figure 10: Oncologists' promotional reality in 2023



Source: IQVIA EMEA Thought Leadership; IQVIA ChannelDynamics™; 'F2F' includes detailing and meetings, 'Remote Digital' includes e-detailing & e-meetings; Channel Preference Survey 2023 matched with actual promotional data from the IQVIA daily diary study at an individual HCP level

As competition continues to intensify, oncology innovators must urgently close this gap to stand out, be heard and build deeper, lasting customer relationships. Crucially, an orchestrated, customer preference-led omnichannel approach must include engagement by both commercial and medical teams.[25]

A FRANCHISE-LEVEL APPROACH

Many innovators assemble multi-asset, multi-indication oncology portfolios to achieve critical mass and also to participate in different growth opportunities this TA offers. Commercialising a portfolio is more complex and requires an archetype approach for optimal capability and resource deployment.

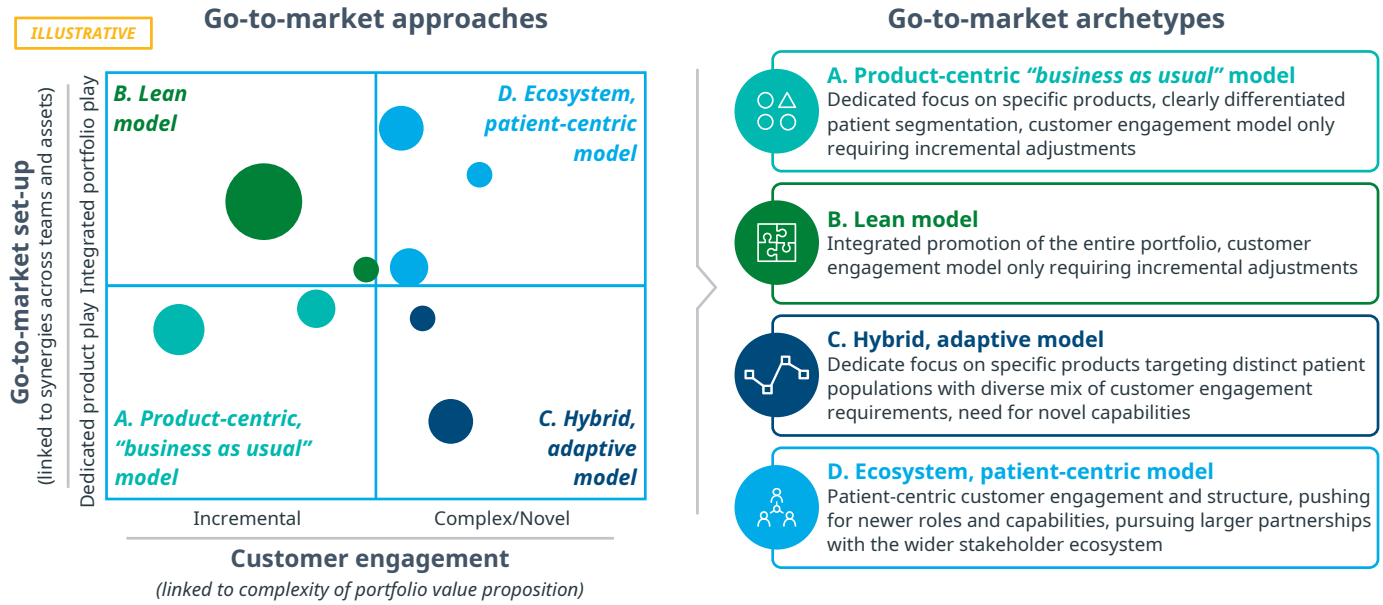
Innovators need to consider two dimensions to determine an optimal go-to-market (GtM) approach for each asset/indication across a complex portfolio (see Figure 11):

- The *customer engagement model*, defined by the complexity of the respective value proposition, e.g., the competitive intensity faced, level of innovation and resulting need for market shaping.[26]
- The *structural GtM setup*, balancing opportunity size and synergy potential across the portfolio, e.g., due to customer overlap and use of existing GtM infrastructure.

The resulting GtM model archetypes have specific, critical capability requirements derived from the intersect of portfolio and market needs.

Mapping their expanding portfolios against GtM archetypes provides innovators with a roadmap to guide capability development, resourcing plans and potential structural evolution to ensure optimal commercialisation as more assets/indications enter the market.

Figure 11: Go-to-market model archetypes for oncology commercialisation



Source: IQVIA EMEA Strategy Consulting

Organisational implications for oncology innovators

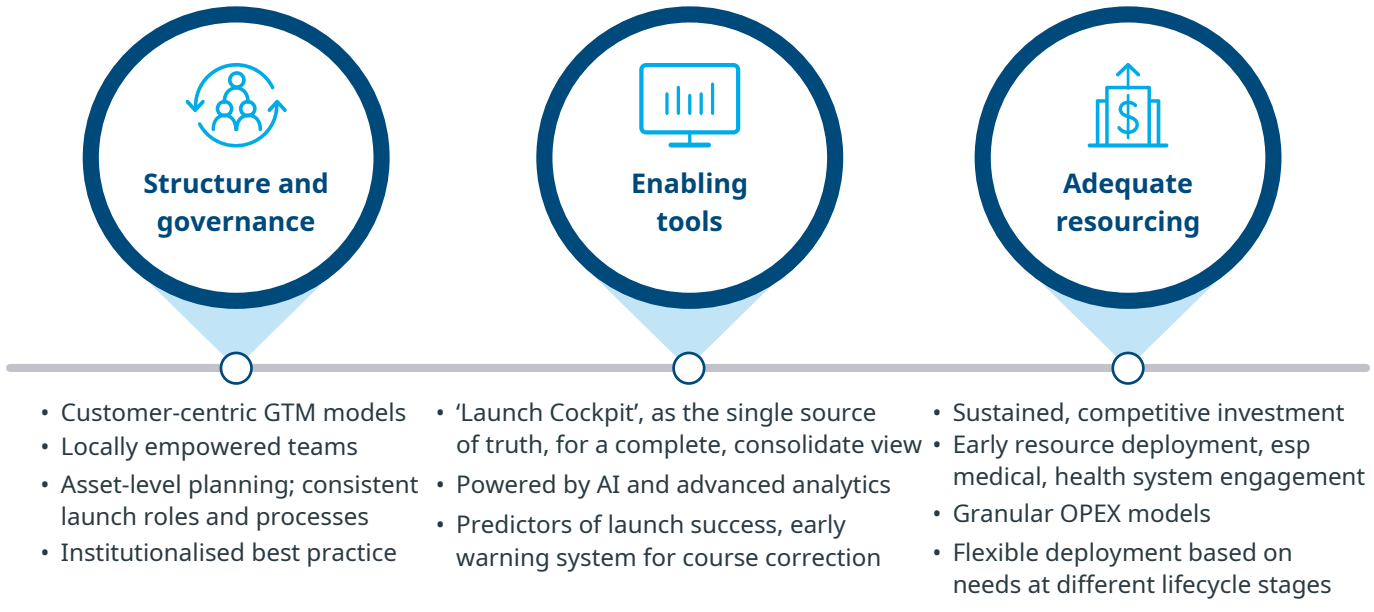
In the previous section we elaborated on the strategic pillars of oncology Launch Excellence, which are defined by external factors in the emerging launch environment. Here we focus on the organisational implications for oncology innovators to successfully deliver on those strategic pillars.

With the route to success in oncology resembling a "marathon" of expanding labels, new indications and new regimens, oncology innovators find themselves in permanent launch mode. As innovators accelerate label expansions and 'stack indications' to maximise asset value, the required parallel execution translates into greater intensity of workload, while a fluid launch environment demands organisational agility.

Thus maintaining organisational momentum and focus is the single biggest challenge as oncology innovators need to manage multiple, overlapping and sometimes conflicting priorities.[27]

Innovators therefore need to address three organisational priorities to achieve oncology Launch Excellence (see Figure 12):

Figure 12: Organisational implications for oncology innovators



Source: IQVIA EMEA Thought Leadership

1. **Structure and governance** serve as important vehicles to drive organisational focus. For example, customer-centric go-to-market models with locally empowered teams minimise distraction and create nimbler units, not unlike a start-up, with greater focus, customer intimacy and faster decision turnaround. Asset-level planning, as counterweight, combined with consistent launch roles and expectations across functions and countries ensures organisational alignment above indications and enables the consistent execution across multiple launches.[28]

2. **Enabling tools:** The highly dynamic oncology market environment demands adaptive launch strategies, with an agile and more proactive approach to launch management. Predictors of launch success play a critical role as enablers, for example using RWD and AIML-powered patient flow and market dynamics models to track performance in granular patient sub-segments using true leading indicators.[29] Leaders establish a 'Launch Cockpit', as the single source of truth, for a complete, consolidated view of all launch activities, KPIs, impact and performance data. Powered by AI and advanced analytics, it provides actionable insight to inform rapid decision making and acts as an alert system to flag issues and trigger swift course correction.[30]

3. **Adequate resourcing:** Oncology innovators must commit to competitive investment and resource levels to equip the organisation for an intense launch programme. This includes early resource deployment, especially medical field roles and health system readiness facilitators, and the initiation of RWE generation pre-launch. Competitive investment must be sustained across label expansions and the launches of additional indications. Budget planning should be informed by granular OPEX models that reflect indication- and market-specific dynamics and competitive intensity to determine optimal spend levels while capturing cross-indication/cross-portfolio synergies.[31]

A functionally defined matrix model increases organisational flexibility by creating a pool of resources that can be dynamically deployed, for example, to specific label expansions or new indication launches based on increasing or decreasing resourcing needs at different stages in an asset's lifecycle, and across a diverse oncology portfolio.

Achieving Excellence in oncology launches is becoming harder than ever, as innovators face unique and formidable challenges in an unforgiving environment.

It requires mastering three strategic pillars – healthcare system readiness, value and evidence, and stakeholder engagement. To successfully deliver on these, oncology innovators must prepare their organisations by committing adequate investment to build critical new capabilities and by embedding the organisational enablers for new ways of working. For those who get this right, the sizeable prize is theirs to seize.

References

1. IQVIA Analytics Link, company reported, analyst consensus, April 2024
2. Global Use of Medicines; IQVIA Institute report, January 2024: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicines-2024-outlook-to-2028/iqvia-institute-global-use-of-medicines-2024-forweb.pdf
3. Global trends in R&D 2024; IQVIA Institute report, February 2024: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2024
4. Global Oncology Trends 2024: Outlook to 2028; IQVIA Institute report, May 2024: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2024.
5. Liu ITT, Kesselheim AS, Cliff ERS. Clinical Benefit and Regulatory Outcomes of Cancer Drugs Receiving Accelerated Approval. JAMA. 2024;331(17):1471–1479. doi:10.1001/jama.2024.2396
6. Tibau A., et.al., Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies, JAMA Oncology, April 2024
7. Firestorm to Burnout: The Impact of the Pandemic on Healthcare Professionals, IQVIA white paper, April 2023: https://www.iqvia.com/library/white-papers/firestorm-to-burnout-the-impact-of-the-pandemic-on-healthcare-professionals
8. EFPIA Patient W.A.I.T. Indicator 2024: https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf
9. IQVIA Launch Excellence series, bi-annual publications I-VIII, 2007-2023
10. Allemani C, et al., CONCORD Working Group. Global surveillance of trends in cancer survival 2000-14 (CONCORD-3): analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries. Lancet. 2018 Mar 17;391(10125):1023-1075. doi: 10.1016/S0140-6736(17)33326-3.
11. UCL blog, 27 February 2024: UK cancer treatment falls behind other countries | UCL News - UCL – University College London
12. BMS-Macmillan collaboration, December 2022: DEC2022-updated-Executive-Summary-Macmillan-Prehabilitation-Collaborative-Working-Project-ONC-GB-2200786.pdf (bms.com)
13. National Optimal Lung Cancer Pathway Analysis Model, November 2023: Microsoft Word - Collaborative working executive summary- National Optimal Lung Cancer Pathway (NOLCP) Model_Nov_2023 (1).docx (roche.com)
14. PME Awards 2023, Excellence in Collaboration and Partnerships – Winner: NHS, AstraZeneca, IQVIA lung cancer PATHFINDER Collaborative; https://pmeaawards.com/results/pmea-awards-2023-results/excellence-in-collaboration-and-partnerships/
15. Accelerating the lung cancer patient pathway; IQVIA, 1 July 2024: https://www.iqvia.com/locations/united-kingdom/library/videos/accelerating-the-lung-cancer-patient-pathway
16. Succeeding with Innovation: The State of Radioligand Therapy Readiness in Europe, IQVIA Institute report, December 2024: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/succeeding-with-innovation-state-of-radioligand-therapy

17. Phesgo product website: https://www.phesgo.com/about-phesgo/what-is-it.html

18. NHS England, 4 April 2021: NHS England » Thousands of patients set to benefit from five-minute breast cancer treatment

19. In pursuit of Medical Launch Excellence, IQVIA white paper, November 2023: https://www.iqvia.com/library/white-papers/in-pursuit-of-medical-launch-excellence

20. Excellent launches are winning the evidence battle – Beyond necessity and nice to have: RWE as a true strategic differentiator; IQVIA white paper, 2020: https://www.iqvia.com/locations/united-kingdom/library/white-papers/excellent-launches-are-winning-the-evidence-battle

21. Map, model and act on key opportunities to transform care; IQVIA presentation by C. Alzaga-Chaudhry, at Reuters Pharma 2024

22. Planning to Engage: A Holistic Approach to Patient Inclusion; IQVIA white paper, February 2023: https://www.iqvia.com/library/white-papers/planning-to-engage-a-holistic-approach-to-patient-inclusion

23. IQVIA EMEA Thought Leadership analysis of IQVIA Channel Dynamics™ data, June 2024

24. Time to Take Omnichannel Action, IQVIA white paper, June 2024: https://www.iqvia.com/locations/emea/library/white-papers/time-to-take-omnichannel-action

25. Medical Affairs' Next Frontier: Unlocking Omnichannel Engagement, IQVIA white paper, December 2022: https://www.iqvia.com/library/white-papers/medical-affairs-next-frontier-unlocking-omnichannel-engagement

26. Transcending the Traditional Focus of Oncology Commercialisation, IQVIA white paper, January 2023: https://www.iqvia.com/library/white-papers/transcending-the-traditional-focus-of-oncology-commercialisation

27. Launch Excellence: Escaping the Complexity Trap, IQVIA white paper, September 2021: https://www.iqvia.com/library/white-papers/launch-excellence-escaping-the-complexity-trap

28. Success Multiplied: Launch Excellence for Multi-Indication Assets, IQVIA white paper, February 2023: https://www.iqvia.com/library/white-papers/success-multiplied-launch-excellence-for-multi-indication-assets

29. No More Surprises: Understanding Predictors of Launch Success, IQVIA white paper, June 2021: https://www.iqvia.com/library/white-papers/no-more-surprises-understanding-predictors-of-launch-success

30. IQVIA blog, April 2024: Powering Launch Excellence with Generative AI - IQVIA

31. Redefining OPEX modelling for a competitive future, IQVIA white paper, October 2022: https://www.iqvia.com/library/white-papers/redefining-opex-modelling-for-a-competitive-future

About the authors

MARKUS GORES
Vice President, EMEA Thought Leadership, IQVIA

Markus has over 20 years of experience in life sciences, advising clients in all major geographies on a broad range of topics, including real world evidence strategy, launch readiness, go-to-market models, brand and commercial strategies, and building enabling organisational capabilities. Markus is a frequent speaker on the latest industry trends and regularly engages with senior leadership teams of pharmaceutical companies. Prior to his current role in Thought Leadership, he has held leadership positions within IQVIA Real World Solutions and QuintilesIMS Consulting Services (formerly the IMS Consulting Group). Markus holds a PhD in Pharmaceutical Chemistry from the University of Hanover and has completed post-doctoral research at the University of California.

KIRSTIE SCOTT
Senior Consultant, EMEA Thought Leadership, IQVIA

Kirstie is a Senior Consultant in IQVIA's EMEA Thought Leadership team, based in London. She has experience writing white papers and delivering presentations across a range of priority healthcare topics such as Launch Excellence, the availability of medicines, and the impact of biosimilars in Europe. A particular recent focus is how companies with new launches can overcome the challenging post-pandemic environment to achieve launch success. Kirstie has over 5 years' experience in healthcare and life sciences, previously providing clinical and commercial competitive insights for pharmaceutical companies, and working to support industry associations to influence health policy. She holds a degree in Neuroscience from the University of Nottingham.

PARMENDER DAHIYA
Associate Principal, Strategy Consulting, IQVIA

Parmender is an Associate Principal in IQVIA's EMEA Strategy Consulting team, with over 18 years of experience advising senior leadership teams of Fortune 500 companies across EMEA, North America, and APAC regions. At IQVIA, he leads strategy engagements for pharmaceutical companies, focusing on go-to-market, commercial, launch strategy, digital, and marketing strategy. Parmender has a strong track record of leading large cross-functional and transformational programs. Previously, he has led life sciences and healthcare consulting teams at Monitor Deloitte in Southeast Asia and at ZS Associates, in Chicago, USA. Parmender holds an MBA from the Indian Institute of Management, Bangalore, and a Bachelor of Technology in Computer Science from RGPV, India.

Acknowledgements

The authors would like to thank Cristina Alzaga-Chaudhry and Sarah Rickwood for their generous support and valuable contributions to the development of this white paper.

CONTACT US

iqvia.com