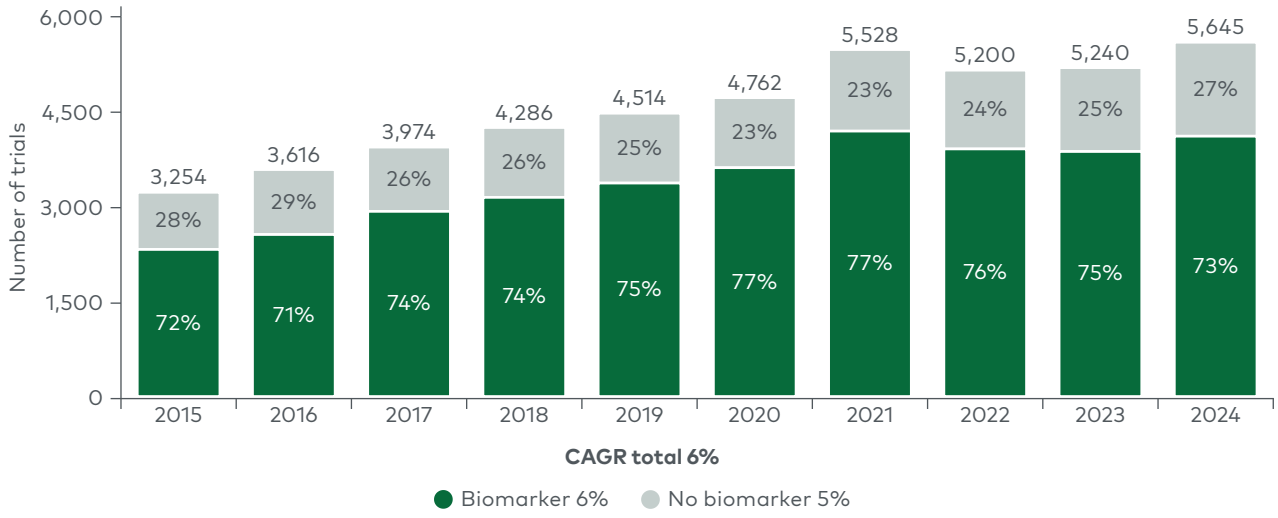
EXECUTIVE INSIGHTS

Launching Novel CDx for Oncology: 7 Strategies for Biopharma Companies

Early genetic screening, targeted therapies and other precision medicine (PM) offerings in recent years have transformed care and significantly improved outcomes for oncology patients while delivering substantial value creation that drives increased pharma investment. PM leverages biomarker (BM) strategies to successfully develop, commercialize and differentiate therapeutics by improving R&D efficiency and optionality, supporting regulatory filings, and enabling smaller and more productive clinical trials. To achieve commercial success for an oncology PM therapeutic, however, biopharma companies must also accomplish the effective launch of a companion diagnostic (CDx) that identifies eligible patients and informs ongoing treatment decisions.

Over the past decade, the proportion of oncology trials using BMs has steadily tracked overall trial growth except for a slight post-pandemic decline amid tough U.S. and Chinese macroeconomic conditions. In 2024, three-fourths of all oncology clinical trials included the use of a BM (see Figure 1).

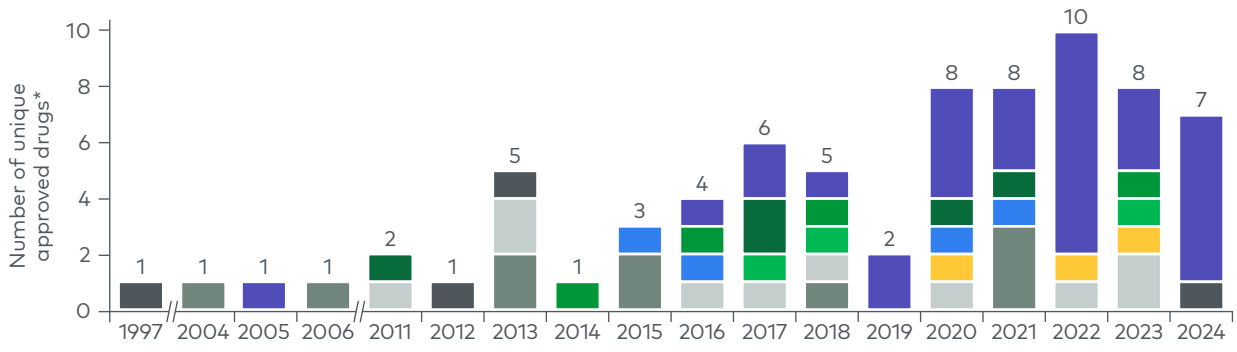
Figure 1
Biomarker use in oncology trials, by year (2015-24)



Note: CAGR=compound annual growth rate
Source: TrialTrove; L.E.K. research and analysis

Rising BM use in trials has predictably had an impact on product launches, with the U.S. Food and Drug Administration (FDA) approving seven to 10 oncology therapeutics with CDx annually since 2020 — and with an increasing focus on novel biomarkers rather than traditional ones (see Figure 2).

Figure 2
FDA-approved therapeutics with CDx, including novel oncological therapies (1997-2024)



	1997	2004	2005	2006	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Cumulative therapies	1	2	3	4	6	7	12	13	16	20	26	31	33	41	49	59	67	74
Cumulative indications**	1	2	3	4	7	8	14	15	20	26	32	42	49	69	82	100	116	132

*Count of unique companion diagnostic-therapy combination approvals
**Indication refers to broad cancer type and sample type (e.g., breast cancer or non-small cell lung cancer) rather than particular label indication, which may include factors such as age, line of therapy, other mutations or other patient/cancer characteristics
***Includes the following types of mutations or mutations in the following genes/gene classes: BCR-ABL, C-kit, dMMR, ESR1, EZH2, FGFR2, FGFR3, FOLR1, HLA, IDH1, IDH2, Ki-67, KRAS, MET, NTRK, PDGFRA, PI3KCA, ROS1, TP53
Note: FDA=Food & Drug Administration
Source: FDA list of approved companion diagnostic devices (accessed February 2025); L.E.K. research and analysis

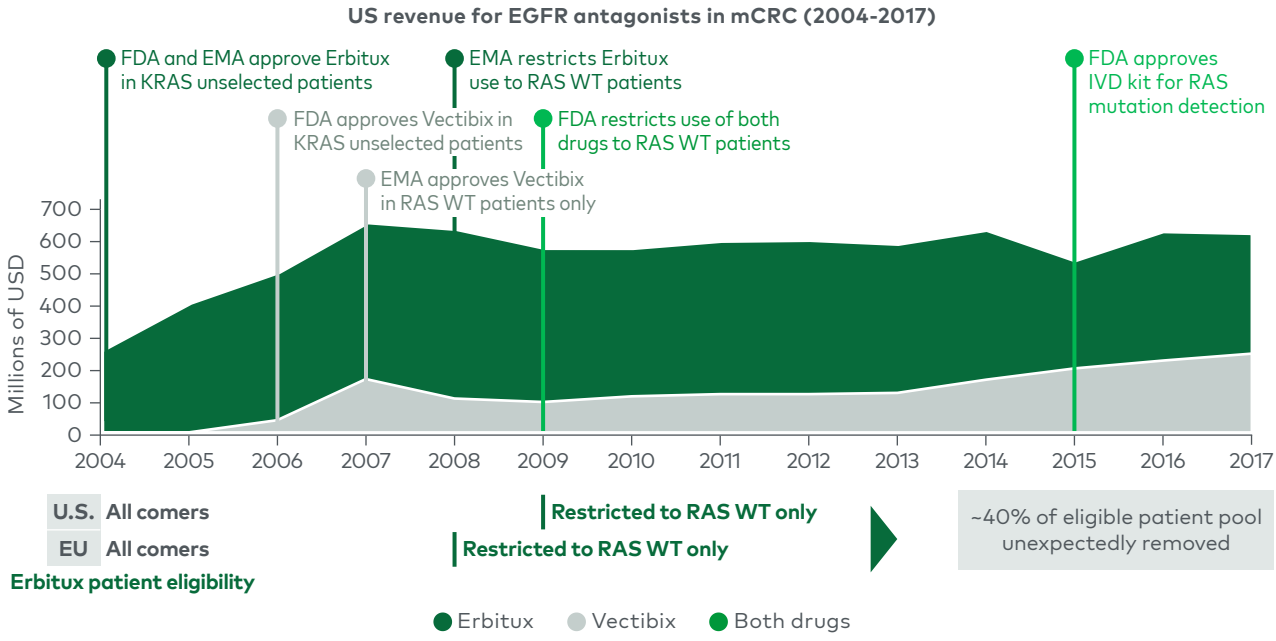
Given the advantages of launching a diagnostic (Dx) — and the many complexities involved — preparing to launch novel CDx in concert with the therapy itself is imperative. In working with biopharma companies to launch novel CDx for oncology therapeutics, L.E.K. Consulting has uncovered seven critical strategies to share.

1. Adopt an 'opt out' mentality.

Leaders in PM follow an opt-out approach: All new oncology programs start with a Dx component, consistently assessing needs and planning for them across the development life cycle. This mindset leads PM leaders to integrate Dx and therapeutic development through established Dx resources and capabilities. All-comers therapeutics can still be pursued, but this requires an active decision by leadership supported by clinical evidence.

The alternative "opt in" mindset — the assumption that an all-comers approach will work and BM development will follow — limits a company's ability to build Dx capabilities and processes, and disadvantages PM programs that require early and frequent collaboration between Dx and therapeutic teams. For example, in 2009 (after five years on the market), the FDA restricted Lilly's EGFR inhibitor Erbitux to KRAS wild-type patients (who comprise approximately 60% of colorectal cancers) based on data from a competitor's product. U.S. market adoption stagnated after the decision, and the cumulative revenue impact over the next decade reached hundreds of millions of dollars (see Figure 3).

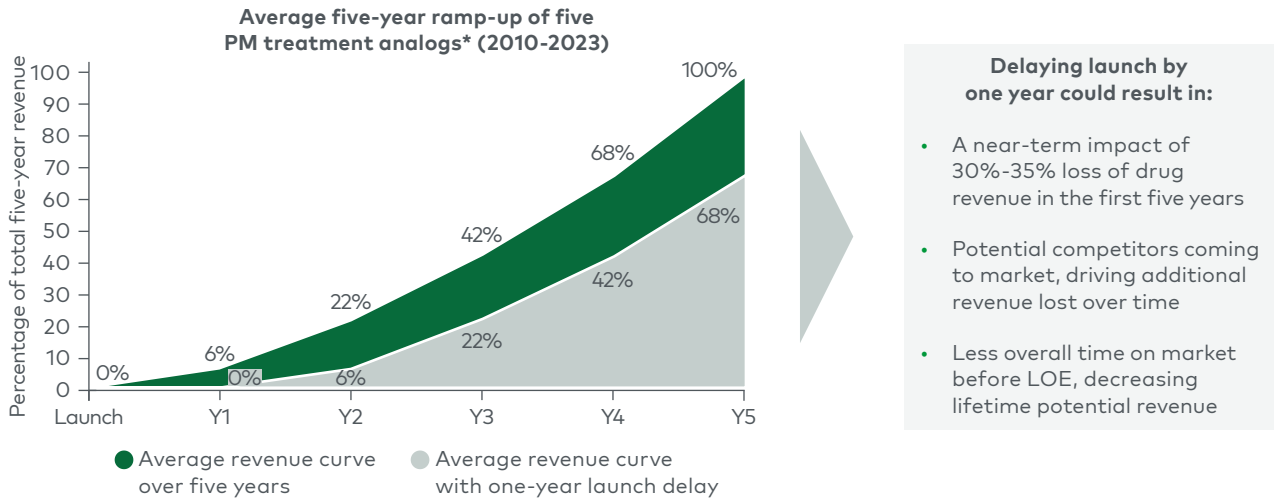
Figure 3
Case study: Erbitux in mCRC



Note: mCRC=metastatic colorectal cancer; FDA=Food & Drug Administration; EMA=European Medicines Agency; IVD=in vitro diagnostic
Source: Evaluate Pharma; FDA list of approved companion diagnostic devices; L.E.K. research and analysis

Indeed, historical averages suggest a one-year delay in launching a BM-directed drug could reduce the initial five-year cumulative revenues by 30%-35%, owing to the typical adoption ramp curve (Figure 4).

Figure 4
Revenue loss from launch delays in PM technology



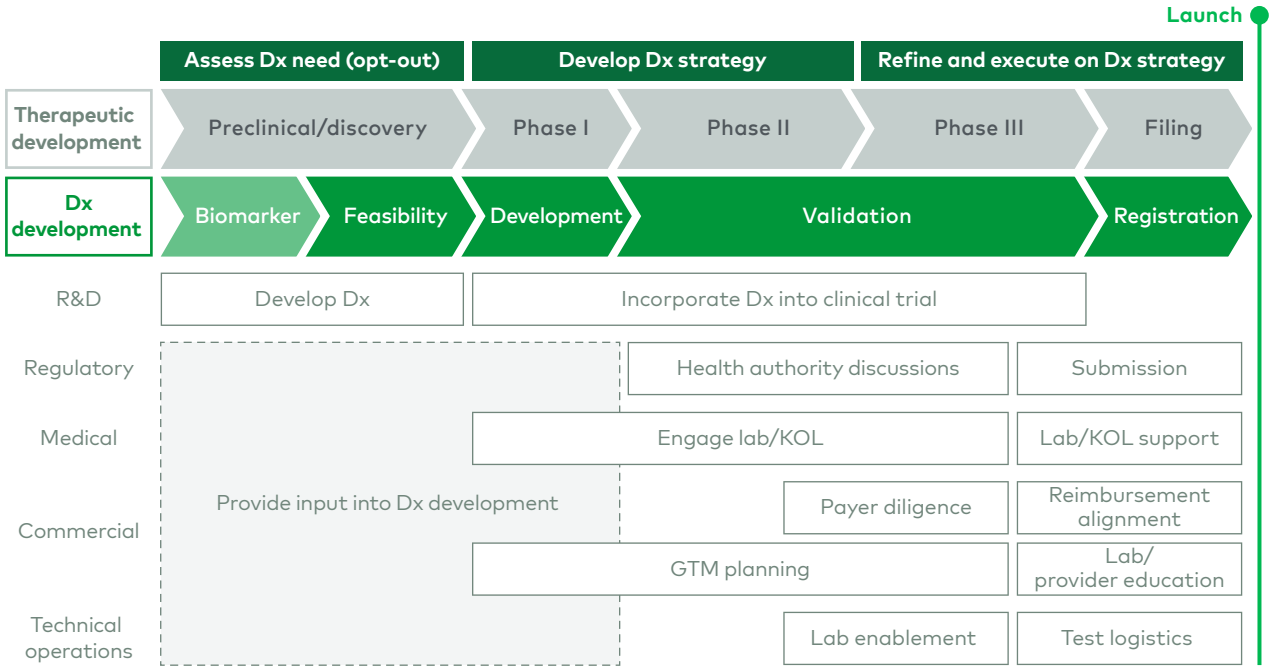
*Includes Lynparza (2015-20), Rydapt (2017-22), Vitrakvi (2020-25F), Xalkori (2011-16), Zelboraf (2011-16)
Note: PM=precision medicine; LOE=loss of exclusivity
Source: L.E.K. interviews, research and analysis; Evaluate Pharma

Dx leaders codify the opt-out mentality in their processes, requiring teams to consider Dx needs early and to continually reassess those needs throughout development — whether by adopting a proactive approach to BM discovery through comprehensive patient profiling, banking multiple bio samples and so forth; focusing on post hoc analysis to identify predictors of response; or continually optimizing by, for example, tracking molecular origins of resistance. Furthermore, they tend to organize personnel in ways that encourage dedicated focus on individual programs while maintaining centralized leadership and integrating functions and programs at the therapeutic area and enterprise levels. Embedding strategic Dx planning throughout the program drives preemptive discussion and collaboration and ensures organizationwide sharing of lessons and resources, thus increasing efficiency and institutional knowledge.

2. Start planning for CDx launch in preclinical development.

A successful Dx launch requires multifunctional support across the value chain, and companies should start planning as early as the preclinical stage. Dx development occurs parallel to therapeutic development, with key Dx launch readiness activities stage-gated by both therapeutic and Dx milestones (see Figure 5).

Figure 5
Key Dx activities by function throughout the value chain



Note: Dx=diagnostic; KOL=key opinion leader; GTM=go-to-market
Source: L.E.K. research and analysis

To drive efficiencies, R&D must incorporate cross-functional input from commercial and medical functions during preclinical development. This approach ensures that Dx addresses patient needs and that clinical endpoints support its commercialization. Commercial and medical readiness activities should focus on understanding and educating the market, developing a Dx-specific strategy and preparing the organization for Dx launch.

3. Address the unique operational challenges of adding CDx.

Companies must consider how the specific complexities of a Dx test should inform the commercial and go-to-market strategy. During development, an individual Dx faces specific commercial obstacles that differ from challenges with therapeutics — surrounding the analyte, such as protein or DNA; the testing technology, e.g., PCR or NGS; validated instrumentation such as 510(k) clearance; and the testing format, whether an in vitro diagnostic (IVD) or a laboratory-developed test (LDT) (see Figure 6). Pharma companies looking to develop a therapeutic with CDx should first understand the BM requirements for their indication. Next steps include determining whether they can support a decentralized testing model and building a robust payer strategy.

Figure 6
Considerations for Dx approach

Dx technology		
Immunohistochemistry	**PCR**	**NGS**
• Test for single protein marker/receptor • Lowest cost and fastest turnaround • Less-straightforward interpretation	• Targeted test for one to four or more genes • Medium cost and moderate turnaround • Binary result with minimal interpretation	• Broad test for 10+ genes • High cost and lengthy turnaround • Binary result with minimal interpretation

Test modality		
	In vitro diagnostic kit	**Laboratory-developed test**
Test content	**Lower complexity** Typically single analyte	**Higher complexity** Typically complex, multi-analyte
Flexibility	**Locked in** Assay is designed, developed and regulated "as is"	**Evolutionary** Can evolve as needed
Location	**Decentralized** Can be run on IVD-cleared instruments in any CLIA lab	**Centralized, single site** Site-specific assays that require extensive validation to set up
Regulatory	**FDA-regulated/CE marked (EU)** Highly regulated content/devices	**FDA (+ CE mark, until recently) not required** May operate without regulatory clearance in U.S.
Access	**Higher rate of successful reimbursement** Often inherently better trusted to provide reliable results	**Lower rates of successful reimbursement** Reimbursement may depend on the reputation of the lab

Note: Dx=diagnostic; PCR=polymerase chain reaction; NGS=next-generation sequencing; IVD=in vitro diagnostic; CLIA=Clinical Laboratory Improvement Amendments; FDA=Food & Drug Administration; EU=European Union
Source: L.E.K. research and analysis

For example, LDTs may face reimbursement issues and require extensive lab validation, yet in the U.S. they often are faster to market and support more numerous and complex BMs because regulatory clearance is not required. Alternatively, IVD kits are FDA regulated, do not support all analytes and face greater competition from other diagnostics, but any CLIA laboratory with the correct instrumentation can run them — and typically enjoy a higher rate of reimbursement. For some companies, launching and supporting, for example, both LDT and IVD versions of the same Dx adds further complexity and requires additional readiness planning and resources.

4. Build a separate Dx launch strategy.

PM leaders treat Dx launch and therapeutic launch as interconnected yet distinct processes, with different stakeholders and challenges. Because key CDx stakeholders are a diverse group that shares little overlap with therapeutics stakeholders — think pathologists versus prescribing oncologists — targeted outreach is the best way to build awareness and willingness to prescribe. Given the intricacy involved in effective testing (particularly with novel CDx), a launch strategy needs to address the necessary instrumentation or other technology; consider laboratory needs, such as LDT support and sample prep guidance; and take market access into account.

Ideally, companies should consider the interplay between Dx and therapeutic launch strategies when planning for launch. For instance, typical sales incentive structures based on the number of patients on a therapy may be unsuitable in a PM setting, where the number of patients screened for a therapy is potentially a more meaningful measure. Developing a Dx-specific launch strategy can enable widespread adoption and enhance the overall PM opportunity.

5. Leverage partner capabilities purposefully while developing internal expertise.

When empowering critical partners (internal and external) for their expertise in developing, filing and manufacturing Dx tests, biopharma companies should be intentional about expanding specific activities and achieving sufficient oversight. Depending on the organization's size and capabilities, tasks such as BM selection, test development, study result interpretation or Dx sales may be beyond internal capacity. On the other hand, activities that require close interaction with the therapeutic team (e.g., sample collection and banking) or that are strategic in nature (e.g., market access) may be better managed in-house.

Even when leveraging a partner, launching a Dx requires dedicated internal resources with Dx-specific expertise across the value chain. Specialists who understand both Dx and PM therapeutics are rare and in high demand, requiring early planning and strong retention efforts. Finding the right balance between external expertise and internal foundational knowledge will be crucial to overseeing Dx partners, who may lack the broader in-house context or may not be incentivized to optimize tests or fully invest in launch activities (see Figure 7).

Figure 7
Key development activities ownership: Dx partner vs. pharmacy team

Dx launch

Dx development	Biomarker discovery	Biomarker feasibility	Biomarker development	Clinical validation	Filing	Commercial-ization

Activities owned or co-owned by Dx partner or pharma	Dx partner vetting and selection	Determination of detection method	Test development	Stakeholder training/education and test marketing	Filing for regulatory approval
Expected role of Dx partner	• Engage with pharma and provide relevant information	• Determine detection method for use in Dx test	• Develop pilot assay and validate assay in clinical studies	• Support IVD kit field sales and stakeholder training/education	• File for Dx regulatory approval according to strategy set by pharma
Expected role of pharma Dx team	• Engage Dx partner and gather relevant input from functions	• Determine detection method for use in Dx test/coordinate supply chain	• Define strategy and manage sample collection, banking and analysis	• Drive stakeholder awareness and manage marketing for LDT	• Drive global regulatory filing strategy and ensure alignment with Dx partner
Expected role of pharma Tx team	• Provide input on Dx partner selection process	• No role	• Run clinical trials	• Tx sales represen-tatives to share basic Dx test information during detailing of oncologists • Tx MSLs to address basic Dx questions if pathologists/on-cologists contact pharma	• In market, Tx FTEs to support local filing as needed

Note: Dx=diagnostic; IVD=in vitro diagnostic; LDT=laboratory-developed test; Tx=treatment; MSL=medical science liaison; FTE=full-time equivalent
Source: L.E.K. research and analysis

Scaling a Dx ecosystem appropriately can prevent delays in Dx launch planning and execution. Overall, costs incurred when empowering an external partner or developing in-house talent should be viewed as imperative for product success — a strategic investment into that asset franchise rather than just a necessary evil to be minimized.

6. Infuse dedicated Dx expertise throughout the organization.

Successful Dx launch planning requires an environment where Dx needs are supported, integrated across functions, scaled appropriately and prioritized across the value chain. Essential strategies such as adopting an opt-out Dx mindset and investing in early Dx development and launch planning (as discussed earlier) can be up against an inertial mindset around an all-comers approach. Overcoming pushback from various levels of the company and other headwinds — such as the high costs associated with Dx development and the relatively low direct revenue from Dx versus therapeutic investment — will require unequivocal and sustained support from leadership. In prioritizing Dx investment, savvy PM leaders must also

expedite alignment of activities and incentives across Dx and therapeutic teams to generate the cross-functional collaboration needed for a successful launch.

7. Incorporate a thoughtful LCM strategy.

To become leaders in the PM space, companies must adopt a dedicated life cycle management (LCM) strategy that supports continuous evolution and improvement. Early and proactive planning is crucial for a biopharma company's ability to create sustained impact of BM oncology therapies, but Dx strategy does not end at launch. A meaningful LCM strategy will empower the organization to anticipate next-generation technologies, expanding indications, real-world evidence planning and continuous engagement with key stakeholders — all of which advances the ultimate goal of maximizing therapeutic potential.

L.E.K. continuously monitors pressing issues throughout the biopharma industry landscape in order to deliver innovative lessons, cutting-edge insights and actionable support and strategies that enhance our clients' ability to achieve their goals.

For more information, or to explore strategies that can unlock new possibilities for your biopharma business, please contact us.

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