WHITE PAPER

Going all in on precision medicine

Solutions to shape the ecosystem to effectively deliver n=1 healthcare

By Pavankumar Anne, Khushboo Garg, Anupurvi Jain and Nid Ramesh

Introduction

Precision medicine-based approaches for drug development and patient care have surged in the past decade, bolstered by evidence of superior patient outcomes, particularly within oncology. Recent studies have shown use of precision medicine resulted in improvements in patient lifespan. In one study, targeted therapies extended the life expectancy of pancreatic cancer patients by an average of one year. Based on a population-level study, researchers attributed the sharp decline in mortality in non-small cell lung cancer (NSCLC) patients to not only a reduction in incidence but also the approval and adoption of targeted therapies in the U.S.

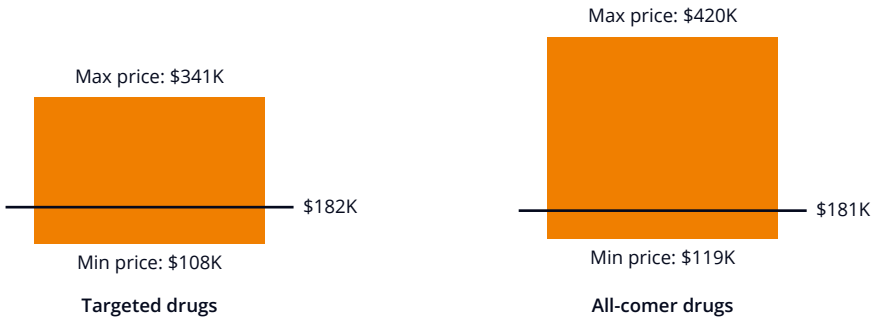
Traditional pharmaceutical manufacturers continue to invest in more targeted, biomarker-driven indications. Diagnostic and healthcare technology companies are investing resources to transform a surplus of patient data into more personalized, meaningful care that improves patients' lives in a financially sustainable manner. As a significant proportion of the oncology pipeline continues to target specific biomarkers and investments continue to pour in, treating each cancer patient as "n=1," or as a sample size of one, is within our reach and will eventually become the norm.

The oncology market is viewed as the greatest area of opportunity for precision medicine given its size, disease heterogeneity and the number of approved biomarkers. However, precision medicine has the potential to greatly impact other disease areas, including immunology, neurodegenerative diseases, chronic illnesses and more.

Unfortunately, innovation is slowing due to persistent challenges in discovery and development. Pharmaceutical companies face rising costs in drug discovery and commercialization with a diminishing ability to increase revenue, reinforcing the attractiveness of investing in "all-comer" indications and treatments for diseases with higher prevalence.

FIGURE 1:

No major difference in median price of targeted and all-comer branded cancer drugs



More importantly, the current application of precision medicine isn't always equitable. Certain populations, such as historically marginalized groups and people from lower socioeconomic backgrounds, are often left out of the latest research and therapeutic advancements. As a result, new precision medicine therapies and approaches may not adequately account for characteristics specific to these groups.

In this paper, we will explore what is and isn't currently working in precision medicine, challenges that hinder widespread adoption and five strategies pharma leaders can lead through collaboration with other key stakeholders in the precision medicine space. We've also included verbatim quotes throughout this paper, which were shared by key stakeholders in panel discussions with ZS.

The many interpretations of precision medicine

Despite recent advances, the term "precision medicine" still carries some degree of ambiguity, as it can encompass several different aspects and approaches to healthcare. The Obama administration's 2015 Precision Medicine Initiative described it as an approach that "takes into account individual differences in people's genes, environments and lifestyles" to improve healthcare and treat diseases. The American Cancer Society describes precision medicine as the "way healthcare providers can offer and plan specific care for their patients, based on particular genes, proteins and other substances in a person's body." These definitions revolve around the tailoring of medical interventions to a patient's specific characteristics, which often implies genetics but includes much more.

While precision medicine is often considered analogous to targeted therapies, it should be thought of as a way to deliver patient care, starting from when a person is born and continuing for the rest of their life. In general, the various applications of precision medicine fall into the four buckets described in Figure 2.

FIGURE 2:

Applications of precision medicine

Screening and prevention

Screening to learn about any predispositions can occur early in the patient journey with precision medicine. It can help determine behavioral or medical interventions that lower the risk of developing a disease.

Monitoring and prediction

Precision medicine can help proactively anticipate disease prognosis and response to treatment or other medical interventions, including any resistance. It can help monitor response to treatment and disease progression better than current practice.

Diagnosis and patient stratification

Precision medicine can help identify disease, severity and progression in patients, including patients that wouldn't be identified under clinical observation.

Treatment

Tailoring treatments and approach—including dosage, timing, duration of therapy and combinations—to patient needs and characteristics

Current applications of precision medicine are primarily informed by genomics, which can include using tumor genetics to assess risk of developing certain cancers. Genomic biomarkers can also be used to determine the appropriate treatment or monitor response. Although there are many uses for genomics yet to be explored, the future of precision medicine will go beyond genomics and consider other characteristics to inform medical interventions and clinical management. These characteristics include:

1. Other omics, such as transcriptomics (gene expression), proteomics (proteins), lipidomics (cellular lipid pathways and networks), circulating tumor cells or DNA (ctDNA) and more
2. Medical, family and social history
3. Environmental factors
4. Other observable patient data, such as lifestyle or behavioral information observed by physicians and collected from wearables, personal devices and other means

Forming a complete picture of the patient with an n=1 mindset

While each of these patient characteristics currently—or will eventually—inform the right medical intervention, the goal should be to integrate them into one holistic, individualized picture of the patient. This picture can be used to develop and deliver proactive care, rather than forcing providers to rely on several disparate pieces of the puzzle to provide reactive care. Patient management should be contextualized through the patient's entire clinical timeline, including physicians they've seen and treatments they've received. Every medically significant event and medical intervention should be factored into determining the most appropriate care.

Doing this can help shift the application of precision medicine from developing treatments that are more effective in a subset of patients, based on certain characteristics, to a more personalized and dynamic approach to patient care.

"Maybe this is the patient's second or third primary care doctor. Maybe they've already been treated with osimertinib and experienced resistance or adverse events to combination therapy. Clinical timeline contextualization is important in the overall delivery of precision medicine care."

—A diagnostics leader

Achieving n=1 in precision medicine has the potential to maximize quality of life, increase life expectancy, improve disease prognosis and decrease mortality. Precision medicine can also help lower costs by eliminating inefficiencies in the healthcare system. Preventing suboptimal applications of medicine—such as patients receiving suboptimal treatments or medical interventions—can save patients valuable time and improve cost-effectiveness within the healthcare system. Shifting the healthcare market towards this future is imperative and requires the close collaboration with major stakeholders, including pharmaceutical and diagnostic manufacturers, regulatory bodies and policymakers, payers and healthcare systems.

Defining the grand promise of precision medicine

In an ideal world, where precision medicine is optimized, we envision four defining characteristics.

1. All biomarkers are known and identifiable
Using the appropriate tools and techniques, all informative and actionable biomarkers and omics data that have the potential to impact clinical management are known and identifiable in patients.

2. All biomarkers are actionable
Healthcare professionals (HCPs) can prevent, diagnose, treat and predict outcomes related to clinical management based on every biomarker or piece of genetic information available in the patient data. These biomarkers may have varying utility but fit together to form one holistic picture of the patient.

3. All patients are cared for at the right time
The right patients get the right treatment or behavioral intervention with the appropriate specifications at the right time, with a shift from reactive care to more proactive patient management.

4. All stakeholders are incentivized appropriately
Misalignment of financial incentives translates to slower progress in patient care. In an ideal world, precision medicine applications are performed sustainably with a patient-centric approach, leading to continued advancement in discovery and delivery of precision medicine-based care.

A framework for understanding precision medicine's challenges

Numerous challenges stand in the way of progress in precision medicine. We've categorized these challenges into the following buckets as part of a framework for understanding what's holding precision medicine back.

- **Clinical advancement and technological innovation.** Challenges relating to the ability to collect and analyze enough patient data to identify and validate useful and actionable biomarkers and targeted therapies.
- **Care delivery.** Challenges relating to the ability of providers and patients to keep up with the fast pace of innovation in precision medicine and take advantage of the latest precision medicine has to offer.
- **Behavioral and social dynamics.** Challenges arising from factors that influence patient and HCP behaviors, such as emotional barriers, educational gaps and inherent beliefs that affect adoption and utilization.
- **Systemic factors, including regulatory, policy and economic factors.** These involve macro issues affecting the clinical and commercial aspects of precision medicine, including key regulations, policies and population-level factors such as demographics.

Using this framework, we've identified seven key challenges in precision medicine.

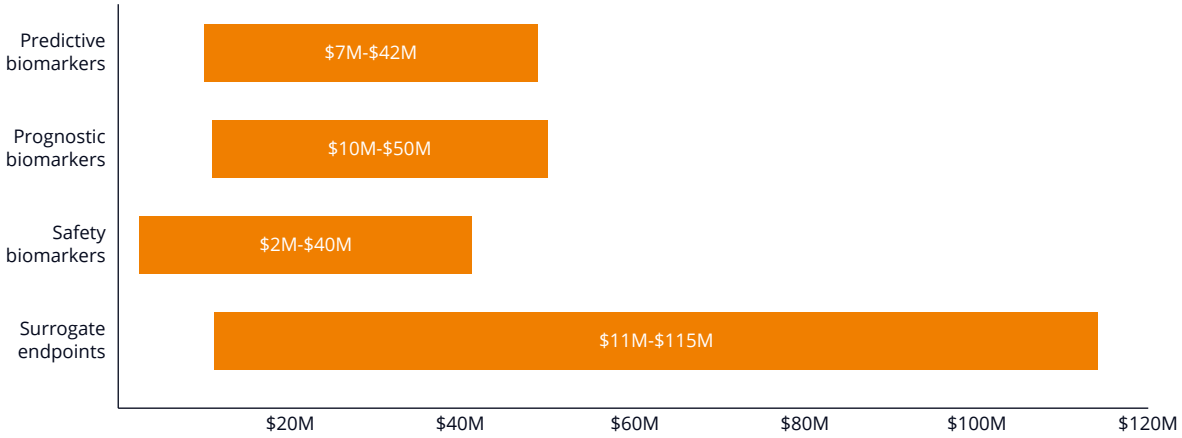
1. Siloed, unharmonized data and limitations to broader use
In precision medicine, the efficient collection and mining of patient data, from genomics to social and lifestyle behaviors, are crucial to future discoveries. However, gaps in data, inconsistent data collection methods and the absence of well-established standards result in interoperability issues and limited harmonization, particularly for unstructured or qualitative medical data. There are also difficulties associated with codifying and compiling electronic health records (EHRs) with imaging data and HCP notes about patient visits, especially when patients engage with numerous stakeholders in the healthcare ecosystem across several distinct sites of care.

Industry stakeholders also rely on acquisitions and partnerships with owners of proprietary databases and healthcare technology companies, including EHR and artificial intelligence (AI) platforms, to access and mine patient data for diagnostic and drug development, contributing to data that is siloed or inaccessible to most parties.

2. Promising yet clinically nonactionable biomarkers
Despite showing promise in lab studies, biomarkers may still be clinically nonactionable. They may have insufficient predictive value due to the low sensitivity or specificity of tests as well as low disease prevalence. Ultra-rare cancers require highly sensitive and specific tests, validated by large studies, for sufficient predictive value and utility. Additionally, clinical studies with poor design or execution—such as studies with biased patient selection and evaluation—result in highly expensive and irreproducible results.

FIGURE 3:

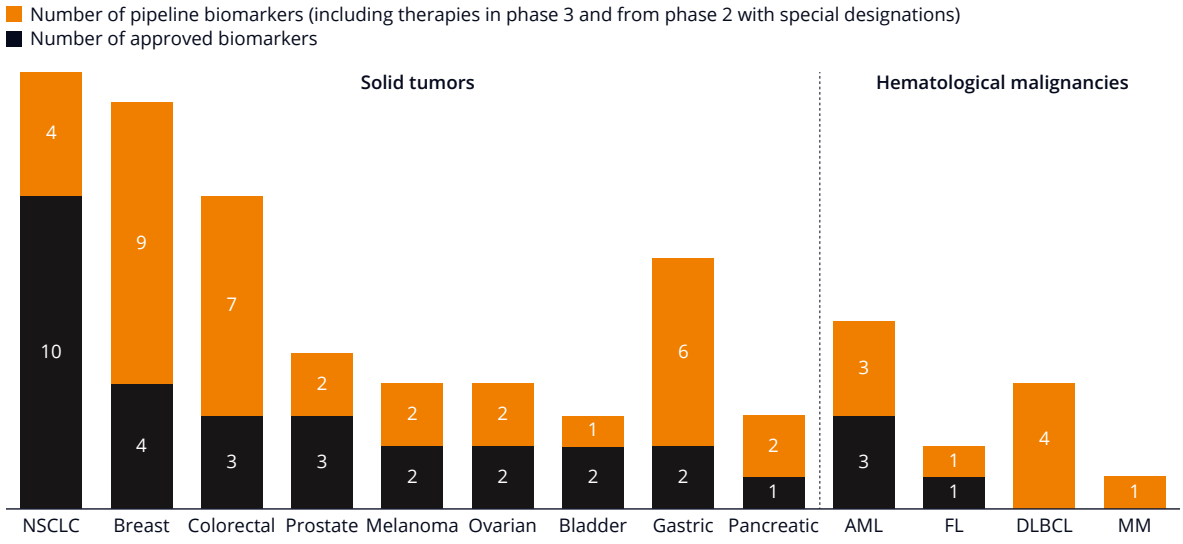
Estimated cost of identifying and validating biomarkers for drug development



Source: U.S. Dept of Health and Human Services report, "Cost Drivers in the Development and Validation of Biomarkers Used in Drug Development"

FIGURE 4:

Number of actionable biomarkers for select tumors



**NSCLC = Non-small cell lung cancer; AML = Acute myeloid leukemia; FL = Follicular lymphoma; DLBCL = Diffuse large B cell lymphoma; MM = Multiple myeloma*

Source: ZS internal repository based on FDA labels, as of January 2023.

A patient's tumor microenvironment will play a greater role in determining the optimal clinical management, particularly with the advancement of liquid biopsies. Today, however, tumor heterogeneity, such as those that are interpatient, intrapatient or intratumor, pose an obstacle to cancer biomarker discovery, making it difficult to validate effective genetic biomarkers.

Immunotherapy has also led to improved patient outcomes, but not for the vast majority of patients, leaving room for new biomarkers to help predict and improve treatment response.

3. Regulatory hurdles for diagnostics

Given the difficulties of qualifying new biomarkers, pharma and diagnostic stakeholders have mainly relied on including specific biomarkers in clinical trials and developing companion diagnostics (CDx) that require large upfront investments and close collaboration with the Food and Drug Administration (FDA). Most CDx assays face stringent requirements, due to falling under the FDA's class 3 (high risk) medical device classification. Most CDx assays also often result in indications that reference only specific therapeutic products, which even the FDA recognizes as being problematic and has sought to curb through industry guidance.

The FDA's biomarker qualification program would more efficiently enable biomarkers to be used for drug development and drug approval, but it requires the collaboration and advocacy of multiple academic and industry stakeholders, such as diagnostic manufacturers and drug developers that are willing to share data and methodologies to support approvals.

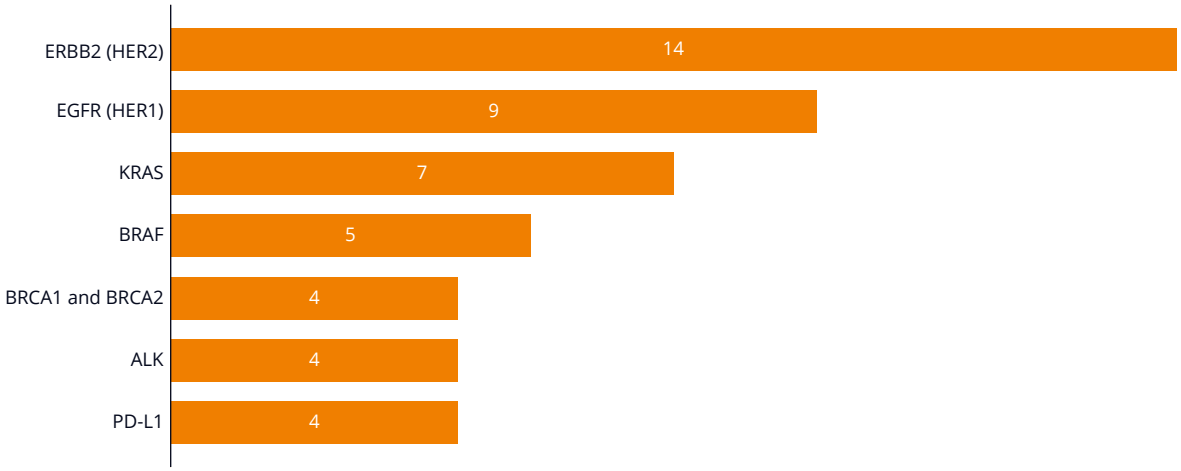
Lab developed tests (LDTs) have traditionally benefitted from more lax oversight of the FDA, causing a higher degree of variability among testing options for the same biomarker. However, policymakers are working on new regulations to increase LDT oversight.

4. Lack of standardization within the diagnostic landscape

The emergence of a multitude of diagnostic options for the same indication leaves HCPs confused on the right choice and payers confused on what to reimburse. Diagnostic options may differ on inclusion of biomarkers, sample requirements, testing methodologies or design features—such as cutoffs and filters—that impact accuracy, results reporting and interpretation. Compared to standard tissue biopsies, liquid biopsies are minimally invasive, allow for easy sample collection and resampling and have shorter turnaround times. However, questions about reliability, specificity and clinical utility remain.

FIGURE 5:

Number of approved CDx for select biomarkers



Source: FDA, List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools), as of October 2022.

The FDA has also been reluctant to provide broader use labels for commercially developed diagnostic products, despite acknowledging their advantage of reducing variability. LDTs, which are often developed to fit custom needs of hospitals and integrated delivery networks (IDNs), save on costs and reduce turnaround times for receiving results, but contribute to the issue of variability.

FIGURE 6:

Approved CDx for NSCLC EGFR Exon 19 deletion or Exon 21 L858R substitution

	Gilotrif (afatinib)	Vizimpro (dacomitinib)	Tarceva (erlotinib)	Iressa (gefitinib)	Tagrisso (osimertinib)
Cobas EGFR mutation test	X		X	X	X
FoundationOne CDx	X		X	X	X
Guardant360 CDx					X
ONCO/Reveal Dx lung and colon cancer assay	X	X	X	X	
Oncomine Dx target test				X	
Therascreen EGFR RGQ PCR kit	X	X		X	

Source: FDA, List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools), as of October 2022.

FIGURE 7:

Approved CDx for melanoma BRAF V600E or V600K

	Braftovi (encorafenib) + Mektovi (binimetinib	Cotellic (cobimetinib) + Zelboraf (vemurafenib)	Tafinlar (dabrafenib)	Mekinist (trametinib)	Tafinlar (dabrafenib) + Mekinist (trametinib)	Cotellic (cobimetinib) + Tecentriq (atezolizumab) + Zelboraf (vemurafenib)	Zelboraf (vemurafenib)
Cobas 4800 BRAF V600 Mutation Test		X					X
FoundationOne CDx	X	X	X	X	X	X	X
THXID BRAF kit	X		X	X			

Source: FDA.gov, List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Accessed October 2022.

Pharmaceutical companies are also increasingly joining forces with diagnostic companies to drive biomarker and therapeutic discoveries with the latest technology and patient data. These partnerships generate additional testing options that are more tailored to a specific pharmaceutical company's portfolio, rather than the market as a whole.

Examples of pharma-diagnostic CDx partnerships include:

- In May 2022, Janssen entered a long-term partnership with Illumina to codevelop CDx programs for precision oncology to deliver innovation at scale.
- In 2018, Pfizer entered a partnership with Foundation Medicine to develop and commercialize CDx for its precision oncology portfolio.
- In June 2022, AstraZeneca and GRAIL entered a strategic partnership to develop and commercialize CDx assays for high-risk, early-stage cancers.

5. Trial recruitment and design inefficiencies

Precision medicine interventions must be validated by recruiting enough eligible patients. However, biomarkers and diseases of low prevalence make it challenging to find and recruit enough patients in a timely, inexpensive way. Centralization of trials in academic or urban centers can add to a patient's logistical burden, making it even more difficult to recruit specific patient subtypes.

Innovative trial designs, including basket and umbrella trials, synthetic arms, "just-in-time" trials, decentralized or home-based trials and rolling trials, reduce some of these challenges. However, investigators must still contend with the need to maintain statistical validity and the difficulty of integrating biomarker testing into trial logistics. Researchers must ensure patients are tested correctly, adhere to sample requirements, avoid practices that unintentionally bias results and get timely results to minimize trial length and costs. Complex trial designs and small sample trial arms also lead to results that are not as easy to interpret for the purposes of regulatory approval and HCP treatment decision-making.

6. Constrained access and utilization of diagnostics and targeted therapies
The challenge of identifying the right patients at the right time is becoming increasingly complex with advances in precision medicine. The evolving field leaves oncologists overwhelmed with information and unable to keep up with the latest biomarkers, tests and therapeutic options and supporting evidence. Collaborative clinical management will continue to take root, with increased reliance on molecular tumor boards and pathologists. Pathologists play an increasingly important role in reducing testing barriers for oncologists, whether it's setting reflexive testing protocols, choosing third-party labs and tests or interpreting tests. However, current physician education and commercialization efforts may not adequately target or engage these other stakeholders.

"Until there's a disease modifying agent in the marketplace, the diagnostics tend to not take off. Even though they may be available, they're just not as readily available or reimbursed."

—A pharma leader

Depending on the tumor type and current patient stratification, it can take several years after the launch of the first targeted therapy to see consistently high testing rates for the indicated biomarker. Diagnostics adoption is influenced by physician knowledge, existing testing options and logistics, reimbursement and patient out-of-pocket costs. Physicians need to not only be aware of available testing options but also have sufficient access to tests at reliable and trusted labs. Pan-cancer tests can screen for multiple tumors in patients without defined risk factors, though test sensitivity needs improvement. Community settings also tend to have limited exposure to new technologies, driving reliance on external labs.

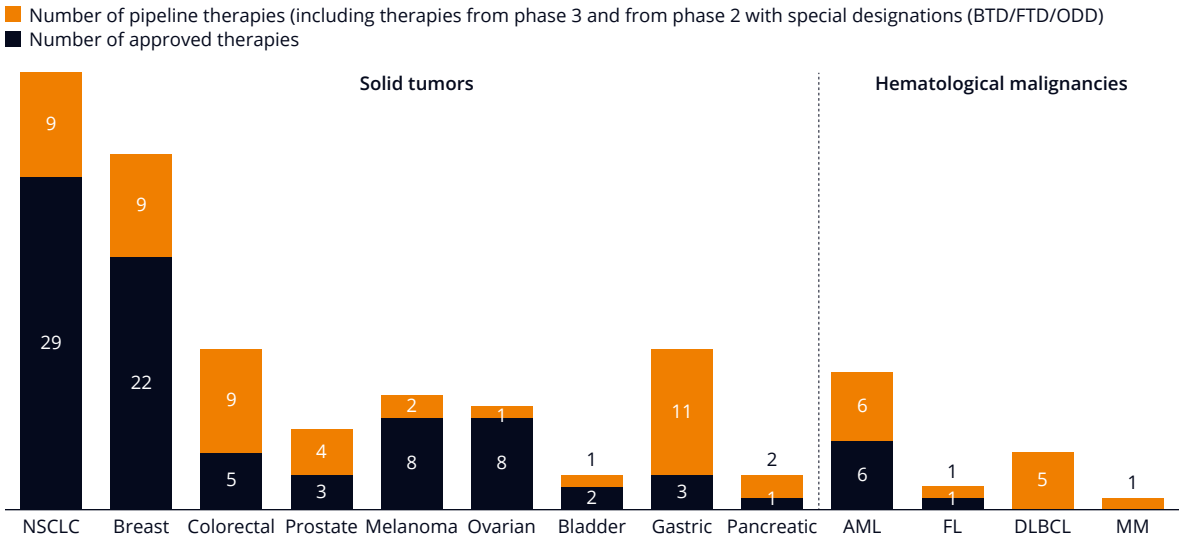
Oncologists rated the following as top factors that influence biomarker testing choice:

- Patient-relevant clinical pathways and guidelines
- The drug's label mandating CDx use
- Reimbursement and molecular tumor boards

Given the importance of cost and reimbursement in physician test utilization, payers also play a critical role, with commercial payers preferring single mutation and hotspot and next generation screening (NGS) testing to broader panels. Most payers cite clinical validity, as supported by clinical guidelines and study results, along with the drug's label mandating CDx use, as well as impact on patient management as key factors influencing coverage decisions for oncology biomarker tests. Conditions for reimbursement, including prior authorization, can be highly restrictive, cumbersome and inefficient for oncologists. Most oncologists find current reimbursement of NGS testing by commercial payers to be unsatisfactory.

FIGURE 8:

Number of approved targeted therapies for select tumors



**NSCLC = Non-small cell lung cancer; AML = Acute myeloid leukemia; FL = Follicular Lymphoma; DLBCL = Diffuse large B cell lymphoma; MM = Multiple myeloma*

Source: ZS internal repository based on FDA labels, as of January 2023.

Treatment adoption and utilization are similarly affected by factors that hinder diagnostic utilization, including lagging physician knowledge, low reimbursement and high patient out-of-pocket costs. After ordering biomarker testing, physicians may be unsure of the right treatment for patients due to difficulties in interpreting results, unclear treatment pathways or sequences or even lack of coverage. Although oncologists rely on molecular tumor boards, peer-reviewed journals and study results to inform targeted treatment decisions, many still face the immense difficulty of keeping up with the latest guidelines, at times leading to suboptimal care, particularly in community settings.

Payers report relying on clinical guidelines and Medicare decisions to inform their own coverage decisions, though they can be influenced by the availability and pricing of currently approved therapies. Both oncologists and payers seek sufficient data on patient outcomes to justify use of targeted therapies, but the data is not always easily accessible or is too limited to convince stakeholders. This is primarily due to nonstandardized testing options and highly variable treatment pathways and patient outcomes.

7. Gaps in patient trust, understanding and expectations

Patients are becoming more engaged in their medical journey, with more cancer patients requesting biomarker testing across tumor types, particularly in NSCLC and breast cancer, than before. Patient advocacy groups are also getting involved in the preclinical stage to guide research and development (R&D) decisions and push for regulatory approval. However, patients may have a limited understanding of or hold unreasonable expectations for currently available tests and therapies, especially with the rise of direct-to-consumer (DTC) marketing and frequent advances in precision medicine. It becomes more imperative for physicians to stay informed to help patients make the right decision.

Patients are also not only concerned about the confidentiality and security of the data they share but also its ownership and beneficiaries. A majority of patients expressed their unwillingness to share their data, with a sizeable majority expressing their unwillingness even when compensated, particularly with pharmaceutical firms.

As data from wearables, mobile apps, telehealth and other digital platforms are incorporated into developing new precision medicine innovations, adequate security, privacy measures and patient trust will be even more crucial.

Realizing the grand promise of precision medicine

All major stakeholders have an important role to play in bringing us closer to realizing the grand promise of precision medicine. Pharma cannot and should not do it alone. Stakeholder collaboration is necessary to not only address systemic challenges but also to solve for scale. However, given the financial strength and interconnectedness with other stakeholders, pharma is well positioned to take charge and lead others in the right direction.

> **"When everyone shares in the pain, that's when change happens. But we as pharma need to lead, based on the financials, resources, existing relationships and reach."**
>
> —A pharma leader

To achieve a more sustainable and efficient healthcare system that strives to deliver n=1 care, pharma should consider the following five strategies.

1. **Stay the course on using a flexible and proactive R&D approach, while collaborating with other pharma or diagnostics stakeholders on data sharing to push for regulatory flexibility.**
    - Continue relying on innovative trial designs and supplement them with adequate, well-sourced real-world evidence (RWE).
    - Work with regulatory agencies early on to ensure best practices are used to navigate logistical and design challenges, particularly with innovative trials. Build the necessary infrastructure for more efficient clinical trials, with the optimal number of arms and statistical design.
    - Collaborate with other industry stakeholders to eliminate data silos to establish standards for collecting and using RWE in drug discovery and to address payer demands for data to support coverage decisions. Ideally, this should be done through the construction of robust public data sets.

  - In January 2022, 23andMe and GSK extended their collaboration for a fifth year to discover and validate novel drug targets using 23andMe's proprietary genetic and health survey database.

- Engage with regulatory agencies to actively push for development of a more flexible approval process that increases reliance on RWE, so beneficial therapies can get to patients sooner.

2. **Continue pushing for higher reimbursement for diagnostics by empowering pathologists and using shared risk models for drug coverage.**

   - Capitalize on existing relationships with pathologists built through salesforce interactions by empowering them to play a larger role in influencing payers and public policy coverage decisions, as pathologists are closer to oncologists' decision-making.

   - Act on opportunities to execute innovative agreements that share the risk of innovation with payers. These can be focused on diagnostics or therapeutics. Value-based pricing and managed entry agreements that employ outcomes-based arrangements reduce payer uncertainty and drive more efficient use of therapies. It's also important for these value-based pricing contracts to adequately account for variable, uncertain outcomes, potentially using dynamic conditions or tailoring to specific patients.

3. **Work with diagnostic companies and payers to drive greater standardization of testing. Standardization may require working with payers or policymakers to make meaningful changes at a national level, but pharma can still lead cross-pharma and cross-stakeholder collaborations.**

   - Team up with other pharma companies to push diagnostic companies to adopt standards among testing methodologies that optimize accuracy and clinical significance along with timeliness of results. Ensure standardized testing is used for clinical trials.

   - Work with other pharma companies on education and marketing efforts for diagnostics and products that target the same biomarkers or possess similar indications. Cross-pharma collaborations can also push diagnostic companies to develop CDx indicated for multiple therapeutic products instead of a specific product.

   - Include laboratories in diagnostics strategy by encouraging adoption of testing standards for in-house, lab-developed tests.

   - Push for dedicated diagnostic codes and clear tracking of testing used to ensure payers have clear visibility into tests used and can make the best coverage decisions.

4. **Help HCPs achieve more consistent, optimal treatment and clinical management decisions.**

   - Integrate conventional data, such as claims data, and nonconventional data sets, such as electronic physician notes and CT scans. Offer actionable tools to providers that facilitate patient identification.
   - Push for availability of clinical decision support tools, including comparison of diagnostic tests and integration of diagnostic test results into EHRs that ensure patients are getting the right treatment or care at the right time.
     - In October 2022, Adaptive Biotechnologies partnered with Epic to integrate its clonoSEQ diagnostic test, used for detecting minimal residual disease in blood cancer patients, into Epic's EHR system.
   - Encourage use of virtual tumor boards, digital pathology and telemedicine to break barriers, particularly for community physicians and peer networks. Access to more experienced specialists would ensure patients receive the best care possible based on the latest data and practices.
   - Push for clinical guidelines that make clear recommendations on biomarker testing without overwhelming the oncologist and contributing to payer uncertainty.
   - Explore bold moves, such as leading a cross-pharma sponsored biomarker testing initiative for undertreated tumors or creation of community-curated data to reach underserved populations.

5. **Invest in establishing patient relationships that span a larger part of their journey to develop a holistic understanding of patients.**

   - Pharma should meaningfully balance investments in bringing a targeted therapy to market with investments offering a sophisticated provider toolkit that enables proactive risk assessment, including early-stage detection, treatment response and disease recurrence monitoring. Pursuing these "beyond treatment" aspects require partnerships with diagnostics and health technology players already scientifically and financially invested in these areas.
   - New testing options, particularly technologies that facilitate early cancer detection continue to evolve. Pan-tumor tests, such as GRAIL's Galleri or Exact Sciences' Thrive, which can detect multiple cancers, have the potential to be used as routine screens even in individuals who do not have any discernible risk factors. Pharma can bring unique learnings and best practices from running drug trials with screening and ongoing monitoring that can be very valuable to diagnostic stakeholders.

- Adopt and apply AI and machine learning capabilities to existing omics data for proactive and predictive care intervention.
  - Since June 2022, Paige has been collaborating with Janssen on its AI-powered screening tool to predict occurrence of actionable genomic alterations, including FGFR, for advanced bladder cancer.
- Use direct-to-consumer strategies to get patients to think holistically about health. Enable this by delivering holistic education that goes beyond the tumor and its treatment and focuses equally on preventative care.

The future of medicine is n=1

The time to pursue the grand promise of precision medicine is now, and these strategies are just the tip of the iceberg. We believe that the n=1 mindset of care delivery will become a dominant part of most pharma portfolios in the next decade. Strategic planning and foresight are required to successfully execute on the solutions we described but doing so will produce a more sustainable and profitable portfolio differentiator in the years to come.

Endnotes

U.S. Department of Health and Human Services report, "Cost Drivers in the Development and Validation of Biomarkers Used in Drug Development," https://aspe.hhs.gov/reports/cost-drivers-development-validation-biomarkers-used-drug-development

U.S. Food and Drug Administration, List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

About the authors

Pavankumar Anne is a principal in ZS's Boston office and supports biopharma and diagnostics companies across the full spectrum of marketing and sales opportunities. He is one of the leaders within ZS's pharma industry vertical and leads ZS's biomarker center of excellence with a focus on precision medicine. Pavan has 10-plus years of experience partnering with clients to identify gaps in their customer experience, developing commercialization strategies, gathering customer insights and designing forward-looking local and global go-to-market models. Pavan holds an MBA from Yale School of Management and a B.S. in mechanical engineering from the Indian Institute of Technology, Madras.

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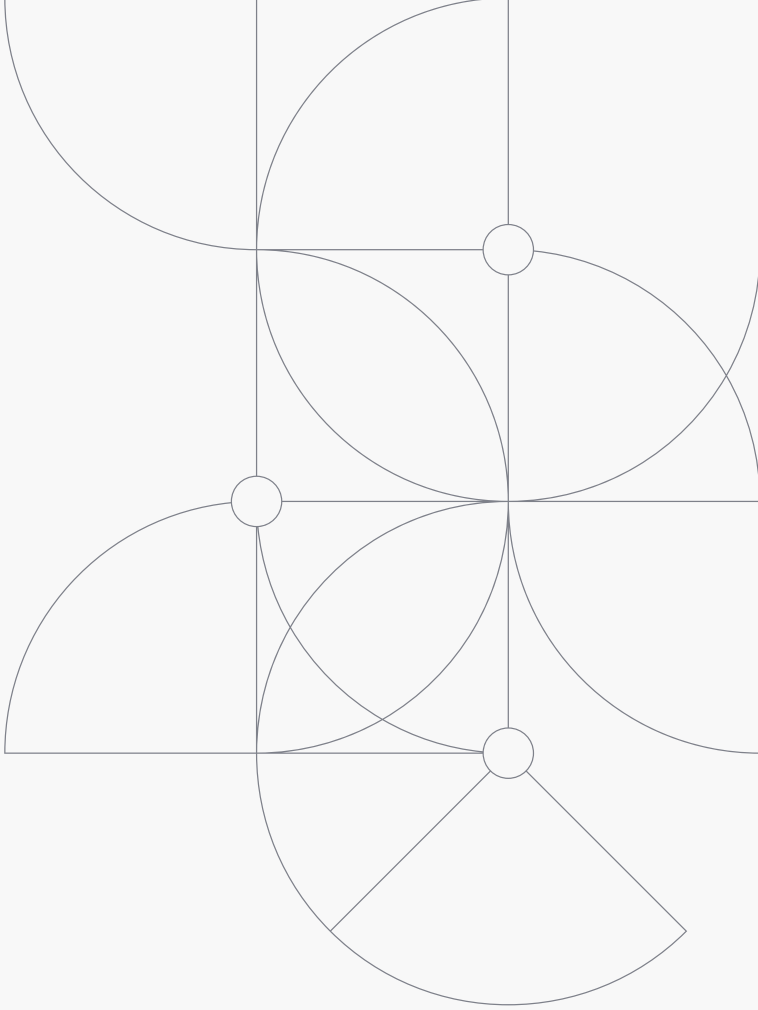

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