

NEW HORIZONS FOR PRECISION MEDICINE INNOVATION

THE FUTURE BEYOND ONCOLOGY

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Precision medicine has been an aspiration of the life sciences industry for the better part of two decades, since the global, publicly funded Human Genome Project concluded in 2003. In the years since, pharmaceutical organizations, diagnostics companies, academic institutions and technology giants have worked toward making more targeted treatment a reality.

Although [42% of 2018 drug approvals](#) by the U.S. Food and Drug Administration were classified as precision medicines, the runway for progress is vast, with most early milestones concentrated in the oncology space. Since the landmark regulatory approval of breast cancer treatment Herceptin in 1998, manufacturers — including Genentech, Novartis and others — have co-developed and implemented companion diagnostics to identify individuals whose cancers are more likely to respond to a given drug.

Ushering in the next phase of precision medicine will require organizations to expand beyond oncology into new therapeutic areas and navigate the accompanying clinical and commercial implications. To accelerate innovation and effective outcomes, organizations must make a deeper commitment to biomarker research and new diagnostic development — two important pathways to better stratify patient populations and tailor treatment approaches.

New Optimism and Opportunities for Precision Medicine

Despite historical challenges, there is growing potential for life sciences organizations to take innovative precision medicine approaches outside of oncology, in areas such as immune and inflammatory, central nervous system, metabolic and other diseases.

Recent biomarker studies and cross-industry collaboration around inflammatory bowel disease (IBD) highlight one new precision medicine frontier. Harvard and MIT scientists recently published a series of research findings on the [microbiome events](#) that trigger inflammatory reactions in people with IBD, as well as how microbiome composition may influence individual patient responses to existing biologic therapies. More granular insight into microbiome changes and markers may help identify targets and relevant patient subpopulations for future IBD treatments. Researchers are already considering more affordable, [on-demand approaches to microbiome analysis](#), with an eye toward potential future clinical applications.

Developments of this kind in other therapeutic areas have been slower to come to fruition, underscoring the need for continued diagnostic innovation. With Alzheimer's disease, for instance, myriad biological factors change before symptoms manifest, to the point where an individual may incur irreversible damage before ever consulting

with a healthcare provider. The slow onset of the disease and variability within patient populations also poses obstacles to conducting and interpreting clinical trials, which limits the efficacy of any one drug.

Failed biomarker-based Alzheimer's trials conducted by [Biogen, Eli Lilly, Merck and Pfizer](#) reinforce the importance of earlier — and more convenient — screening methods to both identify at-risk populations and develop effective treatments. Recently published data suggests that blood tests could be used to screen cognitively healthy individuals for current or future amyloid beta [protein levels associated with Alzheimer's disease](#), potentially providing a new tool for drug trial enrollment and longer-term patient identification for therapy.

The technology industry's push into life sciences could help extend the breadth of biomarker discovery and novel diagnostic possibilities. Progress by firms from Alphabet to IBM — along with platform businesses focused on molecular-, cell- or tissue-based analysis — signal that future diagnostics could be based on data-driven algorithms in addition to or instead of wet lab measurements. For example, Verily, Alphabet's life sciences research arm, unveiled a tool in 2019 that uses machine learning to profile proteins and uncover new biomarkers.

Overcoming Barriers to Diagnostic Success

Early wins in oncology have proven the many benefits that novel biomarkers and diagnostics can yield, from enabling smaller, more efficient clinical trials to achieving higher drug response rates. To facilitate precision medicine development in other disease areas, pharmaceutical and diagnostics organizations will need to:

- **Embrace complexity.** Cancer presents challenges with tumor detection and biopsy, as well as the need to target increasingly complex mechanisms for drug development. Other

therapeutic areas may present heightened challenges. For example, autoimmune or neurodegenerative conditions evolve over time, with key molecular and cellular changes occurring before symptoms manifest, and disease activity and symptoms that ebb and flow. They may also be correlated with an even wider array of candidate biomarkers to sort through. Life sciences organizations should prepare to segment patient populations earlier in the research process and manage increasingly diverse testing to identify relevant biomarkers.

- **Encourage more exploratory biomarker research.** Biomarker research is sometimes perceived as a supplemental (and complicated) investment that prolongs the drug development cycle and adds cost. Leaders should carefully weigh the costs against the potential reality that prioritizing human biomarker studies early can expedite later-stage clinical trials. Organizations may also consider how external partnerships (with academic research institutions and diagnostic companies, for example) might enhance and accelerate the process. In each case, the specific cost benefit of a biomarker program must be considered, but emerging discoveries suggest that the time for broader and more proactive approaches is now.
- **Pursue proactive commercialization planning.** With diagnostics, organizations face greater pressure to begin with the end in mind, outlining upfront how a diagnostic's value will be positioned in market if clinical studies demonstrate positive outcomes in a specific population. Downstream factors like benefits for target populations, feasibility of clinical implementation and competitive differentiators should inform initial development decisions. It is also important to consider that the clinical and commercial impact of precision medicine can extend across the entire diagnostic continuum, from screening and early diagnosis to monitoring.

- **Adapt to a new mix of stakeholders.** The uptake and impact of any diagnostic depends on drug manufacturers' partnerships with clinicians, pathologists, lab professionals and, increasingly, consumers. As brands like 23andMe and AncestryDNA bring genetics research into the mainstream, consumers who ask their providers the right questions can be valuable partners in biomarker research and diagnostic adoption. To operationalize this benefit, leaders need to outline new patient journeys in relation to diagnostic testing and determine the best opportunities for engagement. Organizations must also focus on provider education to demystify new test types and modalities that may be unfamiliar to specialists.
- **Envision tomorrow's organizational structure.** Innovation won't happen in a vacuum; it will require coordination between pharmaceutical organizations, diagnostics firms and academic institutions. Team structures and roles may need to shift to support a growing portfolio of partnerships, and leaders should assess how sales functions can evolve to accommodate a larger push into precision medicine. Unlike traditional drug sales targeted to providers, diagnostics are typically marketed to pathologists as well. In a constrained labor market, organizations must decide how and when to recruit new talent with expertise in diagnostics, and how to integrate it.

Prepare Today for a Rapidly Unfolding Future

The science and technology that underpin precision medicine continues to evolve rapidly. To successfully innovate, life sciences leaders must be ready to transform their operations and organizational structures.

Any strategic plans for broadening diagnostics capabilities should be flexible, knowing that novel analytics technologies and biomarkers continue

to emerge. Leaders should prepare by having defined decision criteria and planning mechanisms in place to guide partnership, development and commercialization investments once more data becomes available.

The future of precision medicine is unfolding in real time. In an unpredictable environment, organizations need a vision for expanding precision medicine beyond oncology – and the agility to act on it.

Key Takeaways

To advance precision medicine innovation beyond oncology, life sciences leaders must:

Think differently.

Shift attitudes around investment in early biomarker research by systematically evaluating and demonstrating how the benefits can drive success during later-stage clinical trials and commercialization.

Plan differently.

Reverse engineer standard drug and diagnostics lifecycles by using market insights and audience needs to guide biomarker research, diagnostic development and early commercial planning.

Act differently.

Align with a strategic mix of partners, from platform and technology firms to leading researchers and research institutions, to expand innovation potential and share risk.



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