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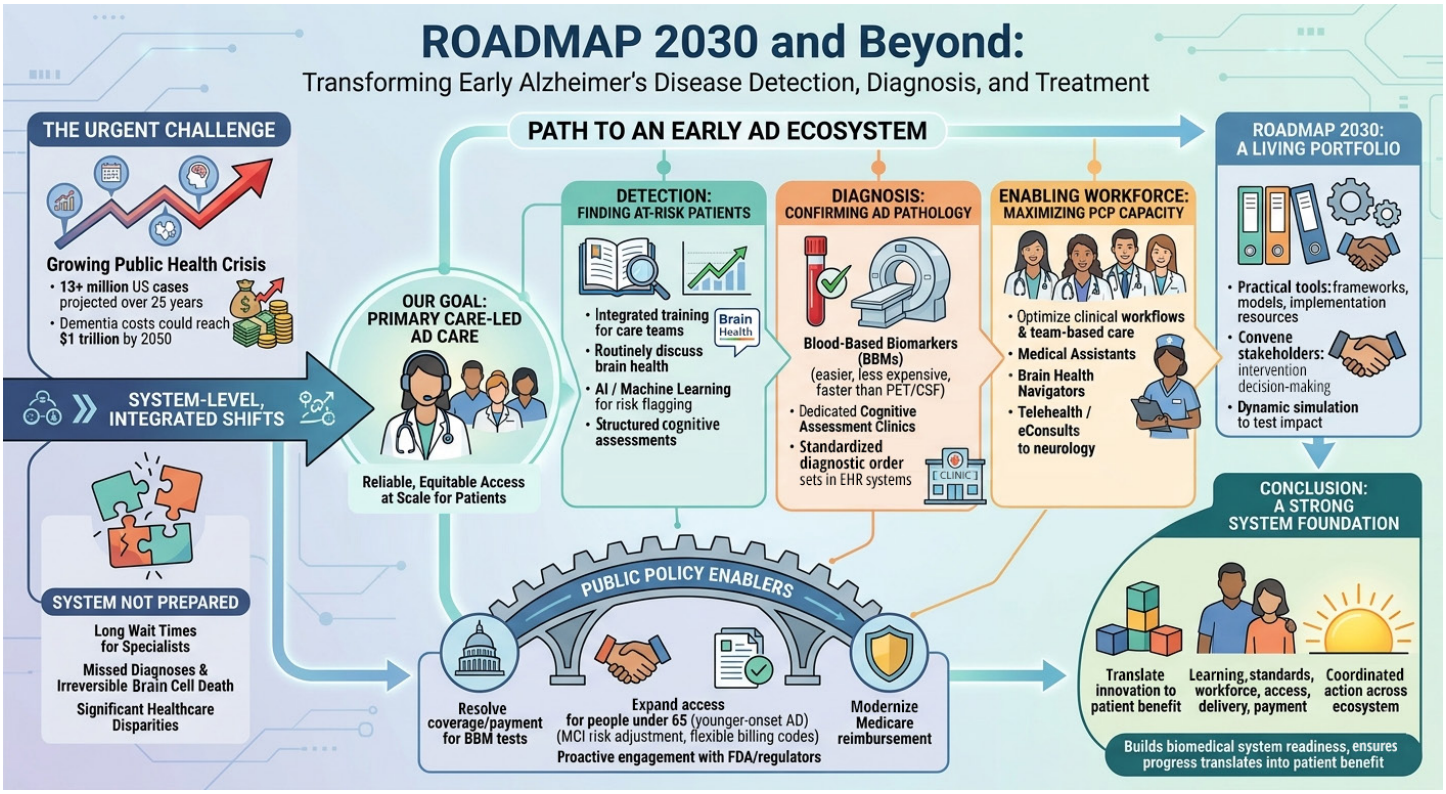
Roadmap 2030 and beyond: Transforming early Alzheimer's disease detection, diagnosis, and treatment

May 2026

Tufts Medical Center Institute for Clinical Research and Health Policy
Center for Biomedical System Design

Executive summary

Roadmap 2030 is a strategic initiative of the Tufts Center for Biomedical System Design (CBSD), developed through the NEWDIGS Consortium—a global, multi-stakeholder collaboration with a proven track record of accelerating impact from biomedical innovation. This initiative aims to transform early Alzheimer's disease (AD) care by enabling healthcare systems to deliver emerging therapies and diagnostics reliably, equitably, and at scale through a primary care-led model.



The urgent challenge

- **Access bottleneck:** Most eligible patients are **diagnosed too late to benefit** from FDA-approved disease-modifying therapies—a gap to close with biomedical system readiness.
- **Public health crisis**: Over the next 25 years, more than **13 million U.S. adults** are expected to be diagnosed with AD or dementia.
- **Economic impact**: Annual dementia care costs currently total **$384 billion** (plus $413 billion in unpaid care) and are projected to reach **$1 trillion by 2050**.
- **Systemic failure**: The current system relies on specialists—who comprise only **2.5% of U.S. physicians**—leading to wait times projected to exceed 18 months.

Strategic interventions for early AD care

Roadmap 2030 identifies three critical pillars to enable primary care professionals (PCPs) to manage early AD care:

- **Detection**: Improving screening rates through integrated care team training, the use of **structured cognitive assessments** (e.g., MoCA, SLUMS), and **AI/machine learning tools** to flag high-risk patients.
- **Diagnosis**: Streamlining the diagnostic process by adopting **blood-based biomarker (BBM) tests**, which are less invasive and can increase diagnostic accuracy from 61% to 91%. Other solutions include dedicated cognitive assessment clinics and standardized diagnostic order sets in EHR systems.
- **Workforce enabling**: Maximizing PCP capacity through **team-based care**, utilizing medical assistants for screenings, employing **brain health navigators** (registered nurses) for coordination, and leveraging **telehealth eConsults** to reduce specialist wait times by 12–24%.

Policy and system barriers

To achieve "biomedical system readiness," several structural hurdles must be addressed:

- **Coverage gaps**: Resolving the **24-month Medicare waiting period** for those with younger-onset AD and establishing clear reimbursement pathways for BBM tests and digital assessments.
- **Modernizing reimbursement**: Updating the Medicare Advantage Risk Adjustment Model to include incentives for diagnosing patients at the **Mild Cognitive Impairment (MCI)** stage.
- **Regulatory frameworks**: Proactively engaging with the FDA to ensure regulatory oversight for AI-driven clinical decision support software keeps pace with innovation.

Conclusion

Roadmap 2030 is a "living portfolio" of tools designed to move beyond design and into real-world implementation. The document emphasizes that without coordinated action across coverage, delivery, and payment policies, even the most promising scientific innovations will fail to reach patients effectively or equitably.

About NEWDIGS

NEW Drug Development ParadIGmS (NEWDIGS), founded at MIT in 2009, is a global "think and do" tank dedicated to improving patient outcomes by accelerating timely, appropriate access to biomedical innovations. NEWDIGS is the flagship program of the Center for Biomedical System Design (CBSD) at Tufts Medical Center's Institute for Clinical Research and Health Policy Studies. CBSD and NEWDIGS design, evaluate, and catalyze solutions that help the healthcare system keep pace with biomedical science — drawing on leaders from patient advocacy, payers, industry, regulators, clinicians, researchers, and investors.

Roadmap 2030 and beyond: Transforming early Alzheimer's disease detection, diagnosis, and treatment

Over the next 25 years, more than 13 million adults in the United States will be diagnosed with Alzheimer's disease (AD) and other forms of dementia. This wave of disease will profoundly impact families, communities, the healthcare system, and the broader economy.

AD is a growing public health crisis that the healthcare system must address. It is the 6th leading cause of death in the U.S. and among the most expensive and burdensome conditions—with dementia costing the healthcare system $384 billion annually, not including the $413 billion in care provided by 12 million unpaid care partners. Costs are anticipated to rise as AD prevalence increases in the U.S., with the Alzheimer's Association projecting that spending could reach $1 trillion by 2050 (inflation adjusted).

Biomedical innovation is advancing rapidly, yet the healthcare ecosystem is not yet prepared to deliver these advances to patients reliably and at scale. Biomedical and technological advancements provide a unique opportunity to delay and reduce many of the personal, societal, and economic costs of AD. However, system-level challenges result in delays to AD detection, diagnosis, and treatment. For a progressive disease like AD, the elapsed time too often results in irreversible loss of function due to nerve cell death and tissue loss in the brain—loss that impact the daily lives of people with AD and those who care for them. To realize the opportunities made possible by innovation, AD must be detected, diagnosed, and treated earlier. Achieving this will require system-level, integrated shifts across the healthcare system. Collaboratively, we can build an AD ecosystem that meets the needs of patients and enables the healthcare system to deliver biomedical advances reliably, equitably, and at scale.

Roadmap 2030: Transforming the Detection, Diagnosis, and Treatment of Early Alzheimer's Disease (called *Roadmap 2030* hereafter) outlines a vision for a next-generation healthcare system designed to ensure appropriate, timely and equitable access to therapies for patients with early AD, which includes individuals who have AD biomarkers and are either cognitively unimpaired or have mild symptoms. It assumes that within the next few years advances in diagnostics, therapeutics, and the management and prevention of side effects will be available for early AD, enabling primary care to play a more significant role in AD care.

Despite its name, *Roadmap 2030* is not a fixed blueprint. It is a living portfolio of materials —including frameworks, tools, models, and implementation resources— designed to support ongoing experimentation, learning, and changes to help prioritize and implement solutions to reduce the burden of early AD on the healthcare system and the patients who depend on these systems for care. Rather than a prescriptive set of solutions, *Roadmap 2030* is envisioned to convene stakeholders to determine, prioritize and implement context-specific interventions that best fit their needs, resources, and goals.

Roadmap 2030 was developed by a multistakeholder collaborative participating in the Alzheimer's Disease Project, led by the Center for Biomedical System Design (CBSD) and its NEWDIGS consortium at Tufts Medical Center. CBSD is dedicated to improving patient outcomes through equitable access to biomedical innovations, in ways that work for all stakeholders. CBSD takes a systems approach to designing, evaluating, and catalyzing advancements whose complex and cross-cutting nature cannot be addressed by a single organization or market sector. The CBSD Alzheimer's Disease Project has been working since 2024 to improve US healthcare system's readiness to treat the anticipated surge in people with AD and availability of new treatment options by articulating system-wide challenges in AD care and designing and pressure testing comprehensive solutions.

Facing reality: The system is not prepared and patients pay the price

The prevalence of AD already exceeds healthcare infrastructure capacity resulting in long wait times, delayed or missed diagnoses, and devastating disparities in access to care. Despite two FDA-approved disease-modifying therapies (DMTs) being commercially available to slow the progression of early AD, system-level barriers constrain the healthcare system's ability to identify efficiently people who are eligible for DMTs and inform them of this treatment option before they progress too far in their disease to be eligible.

Access to care for early AD is constrained by the unwieldy clinical journey involved in patient detection, diagnosis, treatment, and monitoring. Additionally, for certain populations inadequate insurance coverage creates considerable roadblocks to access. This is particularly applies to people with younger-onset AD (e.g., younger than age 65) who face a mandatory 24-month Medicare waiting period after Social Security Disability Insurance qualification. Coverage gaps during the critical early intervention window present a significant structural barrier.

With a robust AD drug development pipeline for new therapies and the anticipated surge in the prevalence of AD as Baby Boomers age, the field is at a critical point for developing and advancing system-level solutions before more people suffer the irreversible changes associated with the disease.

We need new care models to meet the challenge

Current care models typically rely on specialists to diagnose and prescribe treatment for AD. However, the number of specialists with expertise in Alzheimer's is woefully inadequate, creating significant access challenges for patients. Neurologists, geriatricians, and geriatric psychiatrists make up only about 2.5% of all U.S. physicians, and few new physicians choose to enter these specialties. Comparatively lower salaries, lack of mentorship, heavy workloads, high burnout risk, and limited career advancement opportunities may mean even choosing to enter these specialties. Additionally, many of these specialists do not have expertise in AD or treat AD patients. Consequently, patients referred to a specialist after signs and symptoms of AD are detected face long wait times or may never be seen at all. An analysis of Medicare beneficiaries found that only 36% of those who received a preliminary dementia diagnosis were seen by a specialist within 5 years. Another study projected patient average wait times for specialists to rise to more than 18 months

in the coming years. Dependence on specialists is unsustainable and has led to calls for primary care professionals (PCPs) to play a larger role in AD detection, diagnosis, treatment, and monitoring. For PCPs to assume an expanded role, they must be equipped with the necessary tools, education, and system structures to achieve and sustain success. *Roadmap 2030* proposes possible solutions to enable PCPs to take on this role and a dynamic simulation model to test the impact of a subset of these to aid in decision making.

A systems approach is necessary: Maximizing relationships between components and avoiding unintended consequences

Taking a systems approach involves considering how all aspects of a healthcare system interact. Healthcare system components are highly interconnected and generate patterns of behavior over time. Rather than focusing on isolated parts or static conditions, a system approach evaluates how relationships among components shape outcomes over time.

The behavior of complex systems often is counterintuitive, and well-intentioned interventions can produce unexpected negative consequences. By using system tools such as dynamic scenario planning models, we can explore these dynamics and identify potential leverage points—such as changes in care settings or incentives—that could improve overall system performance.

Additionally, there are many possible points of intervention along the AD care pathway. In a world of limited resources, stakeholders must decide where to intervene first—often without clear evidence about which strategies will have the greatest impact. Dynamic scenario planning models allow stakeholders to explore alternative strategies prior to real world implementation, helping identify leverage points and evaluate where coordinated actions across the system may be needed.

Designing interventions: Focusing on key roadblocks in early AD care

NEWDIGS consortium participants developed an extensive list of potential interventions for enabling PCP detection, diagnosis, treatment, and monitoring of early AD during the September 2025 Design Lab. Interventions were prioritized to ameliorate key roadblocks in early AD care: improving detection rates by increasing cognitive assessment rates, streamlining the diagnostic process, and enabling the PCP workforce. These are not the only possible interventions, but they represent the types of pilot activities that were considered mission-critical, credible, and feasible within the next few years.

Detection

First, knowledge gaps must be addressed through education and training for PCPs and their teams. PCPs often report lacking the knowledge and tools needed to evaluate cognitive concerns. To address this gap, education is needed for entire primary care teams—including physicians, physician assistants (PAs), nurse practitioners (NPs), care navigators, and others—on how to identify cognitive issues and understand the evidence behind available treatments that slow disease progression. Such education could increase clinician confidence and encourage more

routine brain health discussions with patients. Pilot programs, such as the University of Washington healthcare system's Cognition in Primary Care intervention, demonstrate that providing integrated education to care teams combined with in-exam room cognitive assessment tools led to significant increases in cognitive assessments (from 2.8 to 19.8 per month per PCP) and new AD diagnoses (from 6.2 to 14.6 per month per PCP).

The use of structured cognitive assessments is crucial in early detection and diagnosis of clinical AD. Using and documenting standardized tools (e.g., MoCA, SLUMS) to pinpoint specific affected cognitive domains (memory, language, attention) provides objective data beyond subjective clinical impressions. The use of structured cognitive assessments has been shown to improve detection rates and increase the number of patients flagged for further evaluation compared to unstructured clinical judgement.

Increasing the use of algorithms that apply artificial intelligence and machine learning and flag patients at risk for AD help prioritize patients for biomarker testing or cognitive assessment. This optimizes primary care resources by focusing on those at higher risk of developing AD. These tools integrate clinical, genetic, laboratory, imaging, and proteomic data, as well as information from passive digital markers such as wearable sensors and device cameras. Machine learning algorithms are applied to predict risk and guide AD testing with validated instruments. Such methods have demonstrated the ability to detect AD pathology or predict dementia diagnosis years before symptoms appear. Running in the background, these tools can detect subtle changes, trigger additional testing, and catalyze PCP action. In one pilot program, algorithm-generated flags led to improvements of 7.7 to 8.9 points over baseline in the use of cognitive assessments.

Diagnosis

Once cognitive impairment is detected, a diagnostic workup needs to be completed for the patient. This creates significant leakage in the system, with 73% of patients flagged never receiving a differential diagnosis. There are many system-related reasons for this including the shortage of AD specialists, cumbersome referral pathways, the complex, multi-step diagnosis process, as well as patient factors such as fear and stigma and the misattribution of symptoms as a normal part of aging.

The advent of blood-based biomarker (BBM) tests, which approximate the presence and burden of amyloid plaques in the brain, are an easier, less expensive, faster way to detect AD pathology compared to the traditional diagnostics methods of positron emission tomography (PET) scans or cerebrospinal fluid (CSF) testing. AD BBM tests in primary care have the potential to improve access to care, provide highly accurate information for clinical decision making, and reduce unnecessary specialty referral and advanced testing. Additionally, BBMs are not subject to the same false positive (Type 1) and false negative (Type 2) errors that can occur with cognitive assessment tests in less educated or those from non-dominant cultures or in women due to higher verbal memory skills which can mask symptoms of cognitive decline. One study found that the PCPs' diagnostic accuracy for AD pathology increased from 61% to 91% with the addition of BBMs. Expanding the use of BBMs is a minimally invasive way to streamline the diagnostic process and help identify patients with probable AD without the resource-intensive steps currently required when using PET scans or CSF testing.

However, realizing the potential of BBMs at scale will require resolution of outstanding coverage and reimbursement questions. The classification of BBM tests under Medicare, including whether

they are treated as clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule or as physician services under the Physician Fee Schedule, has direct implications for reimbursement adequacy, ordering flexibility, and patient access in primary care settings. Establishing clear, predictable coverage pathways and adequate payment rates for BBM testing is a prerequisite for the primary-care-led detection model *Roadmap 2030* envisions.

The development of dedicated cognitive assessment clinics that provide full-service clinical evaluation as well as any needed imaging and biomarker testing can reduce the chasm between cognitive assessments and diagnosis—essential to patients who may be eligible for DMTs getting to the offer of treatment. One pilot intervention found that dedicated cognitive assessment clinics increased diagnostic completion rates for patients flagged as positive for cognitive concerns from a baseline of 29% to 79%.

Use of diagnostic order sets may increase the number of patients who complete a full diagnostic evaluation. Order sets, predefined, evidence-based templates embedded in electronic health record (EHR) software provide decision support to PCPs on next steps while allowing physician flexibility. Diagnostic order sets generally improve appropriateness and efficiency of test ordering without increasing diagnostic errors. Studies have demonstrated that use of diagnostic orders sets resulted in 3-6 times improvement in the completion of full diagnostic evaluation over baseline rates. The effectiveness of diagnostic order sets and streamlined clinical pathways depends in part on the coverage environment in which they operate. National Coverage Determinations (NCDs) and Local Coverage Determinations govern Medicare coverage for many diagnostic tests used in the AD workup, including amyloid PET imaging and emerging blood-based biomarkers. Where NCDs impose conditions of coverage that limit testing to certain clinical settings or require specialist involvement, the goal of PCP-led diagnosis is structurally constrained. Advocacy for NCD reconsideration and modernization of coverage criteria to reflect current clinical evidence should be considered a systems-level intervention alongside the clinical workflow changes described here.

Enabling the PCP workforce for success

PCP capacity constraints must be overcome to increase their ability to deliver AD care. These pressures can be lessened by optimizing clinical workflows, implementing team-based care, and incorporating patient navigators. Team-based models that utilize PAs, NPs, and non-clinicians to handle parts of the assessment and diagnostic process can increase capacity and reduce the time burden on PCPs. For example, trained staff (such as medical assistants) can administer, score, and interpret brief cognitive assessments, freeing physician time and enabling higher screening rates. One pilot study found that the use of team care increased the rate of cognitive screening by 100% over baseline.

The use of brain health navigators—specially trained professionals (often registered nurses)—can provide support to patients, care partners, and primary and specialty healthcare providers throughout the AD journey. Brain health navigators increase the percentage of patients who complete a full diagnostic workup and serve as a personalized point of contact, help investigate cognitive concerns, coordinate care, and connect patients and families to resources and services.

Telehealth services also are an increasingly useful supplement or adjunct to PCP capabilities. Virtual specialist consultations can expedite accurate interpretation of cognitive assessment and oth-

er elements of neuropsychological consulting, and many elements of neuropsychological testing can be administered over telehealth platforms. Another way to use telehealth services is through eConsults—asynchronous specialist opinions requested by primary care or other clinicians. Neurology eConsults support PCP-led AD care, triaging patients who require in-person specialty evaluation and reducing patient travel burden. Access to neurology eConsults are estimated to reduce specialist visits by 25% and shorten the specialist visit wait time for patients by 12-24%.

Practice guidelines are needed for AD detection, diagnosis, treatment, and monitoring. Clinical pathways would give primary care teams a structured and flexible process to navigate shared decision-making for this complex condition and are integral to the development of meaningful quality measures. Initially, guidelines should be developed to help primary care providers conduct cognitive assessments, including specific recommendations for follow-up care when indicated. These guidelines could help improve the current estimates that only 1 out of 3 patients who screen positive on brief cognitive assessments receive any follow-up action, such as more detailed diagnostic workups, such as a referral for neuropsychological testing, neuroimaging orders placed, or referral to a dementia subspecialty clinic.

Although beyond the scope of *Roadmap 2030*, we recognize that shifting AD care towards greater primary care involvement must also address the existing workforce crisis, increased administrative burden, widespread burnout, and inadequate reimbursement.

Public policy

Several of the interventions described above could be advanced via key policy changes. We list here several areas that we believe deserve immediate policy focus, but as other interventions are deployed, need for additional policy changes will inevitably emerge.

For people under 65 who have younger-onset AD, insurance coverage gaps during the critical early intervention window remain a significant structural barrier because they face a mandatory 24-month Medicare waiting period after Social Security Disability Insurance qualification. Legislation has now been introduced in Congress that aims to address this gap. An even larger number of people under 65 would be eligible for future therapies demonstrated to work in cognitively unimpaired people with AD biomarkers, yet Medicare's current coverage policies exclude this indication and, if unchanged, private insurers would likely follow suit.

Early diagnosis is currently hampered by a number of policies. For instance, while digital cognitive assessments that can be administered in as little as three minutes have shown promise, using them currently does not qualify for Medicare reimbursement because Medicare's billing code requires a provider to conduct at least two tests and spend at least 16 minutes doing so. Additionally, many Medicare Advantage plans require prior authorization before billing for that code. Also, the Medicare Advantage Risk Adjustment Model disincentivizes diagnosis in the MCI stage by including an extra payment for dementia diagnoses but not for MCI. It is critical to modernize reimbursement to match the advances in Alzheimer's science.

As AI and machine learning tools for cognitive risk prediction move toward clinical deployment, regulatory and coverage frameworks will need to keep pace. Questions around FDA oversight of clinical decision support software, coverage of algorithm-driven services under Medicare, and

the intersection of AI regulation at the state and federal level will shape whether these tools can be practically integrated into primary care workflows. Proactive engagement with regulatory and payment policy development is essential to avoid delays in access to advanced tools.

Roadmaps set direction; Implementation creates change

Within *Roadmap 2030's* living portfolio, frameworks serve as practical tools to support the adoption of pilot innovation activities by providing a structured way to represent healthcare system components, measure intervention impact, and engage relevant stakeholders while accounting for context-specific implementation challenges.

However, implementation—not design—is where progress is ultimately determined. Attempts to implement innovations face their own barriers including misalignment of objectives, insufficient leadership, inertia, and a lack of financial resources. Biomedical innovations also face inefficiencies due to the time required for clinical practice integration. Delays are unfavorable for the developers of innovations, as well as healthcare organizations, policymakers and wider society, who do not benefit from the innovation and returns on their investment.

In this context, frameworks are most valuable when they are used to support implementation—not as ends in themselves. They can enable more iterative approaches, support learning across settings, and help stakeholders make informed decisions as new evidence emerges. When applied consistently, they can also facilitate knowledge-sharing and reduce the need to "reinvent the wheel," helping to accelerate implementation over time.

Conclusion

AD care is evolving rapidly, making it essential to implement innovations that improve how patients are identified, managed, and treated in real-world primary care settings. These advances have the potential to enhance clinical decision-making and quality of life for people living with AD—while improving affordability, effectiveness, and sustainability. But as therapies, diagnostics, and other tools accelerate, integrating them into routine care will become increasingly difficult without deliberate preparation. Failure to do so risks outdated care, rising costs, and widening inequities.

A strong system foundation is critical to translating innovation into patient benefit. Health systems must have policies, infrastructure, and processes in place to adapt quickly as new advances emerge. This is the essence of biomedical system readiness. Without it, even the most promising innovations will struggle to reach patients efficiently or equitably. Progress will depend on coordinated action across coverage, coding, and payment policy—areas that can either enable or constrain adoption at scale. Policymakers, regulators, and payers must therefore play an active role alongside providers and innovators. Advancing key domains of system maturity—learning, standards, workforce, access, delivery, and payment—in a coordinated way will be essential. Building biomedical system readiness is both an urgent priority and a shared opportunity to ensure that scientific progress translates into patient benefit at scale.

About NEWDIGS

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