

The Roadmap for Research to Improve Diagnosis, Part 1: Converting National Academy of Medicine Recommendations into Policy Action

A Report from the Society to Improve Diagnosis in Medicine

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Frontmatter/Acknowledgements

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Roadmap for Research to Improve Diagnosis (Policy Action)

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Foreword to the Roadmap for Research to Improve Diagnosis

A 19-year-old champion athlete whose stroke was missed in the emergency room... he can now only communicate by blinking; a 12-year-old girl whose fatal infection was mistaken for the flu and not caught in time; a new father whose malignant cancer pathology results were never communicated to the family, leading to his untimely death; a healthy 75-year-old woman who went blind from a rare but easily treatable disease that could have been diagnosed with a simple, inexpensive blood test—these are among the thousands of patients who suffer serious, preventable harms from diagnostic errors.

The US National Academy of Medicine (NAM) (formerly Institute of Medicine [IOM]), in its 2015 report, *Improving Diagnosis in Health Care*, called diagnostic errors, defined as the failure to make accurate and timely medical diagnoses or communicate these to patients, a "blind spot" for healthcare.¹ The report articulated that diagnostic errors are failures of our healthcare delivery system, rather than individuals¹ and called improving the diagnostic process a "moral, professional, and public health imperative."¹ The NAM report emphasized that lack of public funding for diagnostic quality and safety research is a critical and significant barrier to improving diagnosis for patients; they called for dedicated funding for research to develop, refine and fully implement solutions designed to reduce harms from diagnostic error.¹

The Society to Improve Diagnosis in Medicine ("SIDM"), with inputs from the Coalition to Improve Diagnosis (CID) has developed this *Roadmap for Research* to support implementation of NAM's urgent call for funding and cross-agency coordination of research efforts.¹ The Coalition is a confederation of more than 30 key national healthcare stakeholder organizations convened by SIDM who all share a vision to eliminate harms from medical diagnostic errors. Coalition members—representing patients, physicians, nurses, clinical educators, health systems, risk insurers, and others—have committed to taking both individual and collective action to address this critical public health problem. SIDM and Coalition members concur with the NAM that the science of diagnostic quality and safety is still young and many potential solutions are nascent or have not yet been tested or confirmed in actual clinical practice. Accordingly, *the Coalition has identified efforts to support investments in research focused on eliminating patient harms from diagnostic error as a top priority for collective action*.

Building directly on the NAM report, this Roadmap for Research (Part 1), focused on Policy Action, lays out the immediate and next steps that policymakers can take to support and facilitate research that will lead to tangible increases in accurate and timely diagnosis, thereby preventing death, disability, current wasteful spending on unnecessary tests, and downstream excess healthcare costs.

Focusing and scaling meaningful research to improve diagnosis will require direct patient engagement through influential patient advocacy organizations and a coordinated effort among policymakers, researchers, and funders. To facilitate this work, we will develop additional components of the Roadmap in consultation and collaboration with patients, the community of diagnostic researchers, and funding agencies, so that we can provide strategies and recommendations for these key stakeholders as well.

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EXECUTIVE SUMMARY

According to the 2015 US National Academy of Medicine (NAM)'s report, *Improving Diagnosis in Health Care*, diagnostic error represents a major public health problem likely to affect every one of us at least once in our lifetime, sometimes with devastating consequences.¹ More than 12 million Americans are affected each year,² with perhaps one-third of those suffering serious harms.³ Diagnostic errors are not only the most common and catastrophic of medical errors, but also the most costly, with aggregate costs to the healthcare system likely in excess of \$100 billion.⁴ The public health footprint of diagnostic error and its consequences likely dwarfs that of all other medical-related harms *combined*.

Despite the enormous toll of diagnostic error on lives and resources, funding for research to tackle this problem remains minimal, totaling just a few million dollars each year.⁵ This lack of research funding is directly responsible for limited progress in maturing the science of improving diagnostic quality and safety. Complicating matters, while diagnostic error research falls mostly in the category of health services research, a half-dozen federal health agencies have mission-congruent pieces of the diagnostic puzzle, and poor cross-agency coordination leaves major gaps in the research pipeline for diagnosis.

The 2015 NAM report powerfully declared that "improving the diagnostic process is not only possible, but it also represents a moral, professional, and public health imperative." Noting diagnostic error is "the bottom of the iceberg"⁴ of patient safety and improving diagnosis "the next frontier for patient safety,"⁶ the NAM strongly recommends dedicated federal funding to support a robust pipeline of diagnostic research and inter-agency coordination of research efforts.¹ A 2016 AHRQ Research Summit on Improving Diagnosis identified the need for core infrastructure and capacity investments to maximize the impact of new funding and catalyze research toward solutions.⁷ <u>These include strong research centers, a skilled diagnostic research workforce, and operational measures of diagnostic error</u>.

There is no single cause and no single solution to the problem of diagnostic errors; as both the NAM and AHRQ reports underscored, this issue must be solved in a scalable way through a systems improvement framework.^{1,7} Initial targets of research should focus on diseases for which the lack of timely, accurate, and duly communicated diagnoses frequently results in significant harm to patients (i.e., permanent disability or death) through missed opportunities for prompt treatment (i.e., before it is too late).¹

The '<u>Big Three</u>' are vascular events (e.g., stroke, heart attack, pulmonary embolus), infections (e.g., sepsis, meningitis, appendicitis), and cancers (e.g., lung, colon, breast). Together these three groups account for more than half of all the serious harms from diagnostic errors across healthcare settings.⁸ Providing the resources recommended by NAM and the AHRQ Summit to support research on strategies to improve the accuracy and timeliness of these diagnoses could have a profound impact on preventing death and disability from medical misdiagnosis. Simultaneously, improving diagnosis will lead to lower healthcare costs through decreased use of unnecessary advanced diagnostic tests, incorrect treatments, and treatment of dangerous conditions at a milder/earlier stage when they are less expensive to treat.⁹

PUBLIC HEALTH IMPACT: Diagnostic errors will likely touch every American in their lifetime, sometimes with devastating consequences.¹ Because research to improve diagnostic quality and safety is currently so underfunded,⁵ every dollar spent will produce huge returns on investment. Effective Congressional action to fund and assure coordinated research activities across federal agencies could potentially save hundreds of thousands of lives and reduce healthcare costs by more than \$100 billion per year.⁴

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Full Report

THE PUBLIC HEALTH IMPERATIVE – The Human Toll and Financial Costs of Diagnostic Error

Box 1. THE PROBLEM – A critical area of patient safety, healthcare quality, and cost savings that has not been adequately addressed by the healthcare sector is the issue of reducing diagnostic errors.

- Diagnostic errors affect more than 12 million Americans each year² and may seriously harm onethird of these patients,³ likely dwarfing all other causes of harm from medical errors combined.
- At a minimum, diagnostic errors cause more serious harms to patients than any other type of medical error,¹⁰ and 40,000-80,000 die each year from diagnostic failures in US hospitals alone.¹¹
- Costs are driven up by treating sicker patients (after the fact) in more advanced disease states, protracted "diagnostic journeys," and by the overuse of unnecessary, expensive diagnostic tests.⁹
- Improving the accuracy and timeliness of diagnosis will reduce costs from inappropriate testing, wrong treatments, and malpractice lawsuits, potentially saving over \$100 billion per year.⁴
- According to the National Academy of Medicine, "Improving the diagnostic process is not only possible, but also represents a moral, professional, and public health imperative."¹

According to the National Academy of Medicine (NAM), diagnostic errors represent a major public health problem likely to affect each of us in our lifetime.¹ The 2015 NAM report on *Improving Diagnosis in Health Care* calls us all to action with the powerful statement, "Improving the diagnostic process is not only possible, but it also represents a moral, professional, and public health imperative."¹

Annually in the US, there may be more than 12 million diagnostic errors² with one in three such errors causing serious patient harm.³ The aggregate annual costs to the US healthcare system could be as high as \$100 billion/year.⁴ Despite its enormous toll on human lives and massive drain on societal resources, opportunities to improve the diagnostic process have been largely ignored in prior patient safety and quality efforts.^{1,6} This is mostly because the problem remains largely hidden—diagnostic errors are rarely evident when they occur, and only surface at a later time when misdiagnosis-related harms have already occurred. Diagnostic errors represent the bottom of the iceberg of patient safety (Figure 1).



Figure 1. Diagnostic errors are the bottom of the iceberg of patient safety. Treatment (Rx) errors have a major public health impact, but diagnostic (Dx) errors have an even bigger one. Physician errors resulting in adverse events are more likely to be diagnostic than drug-related (14% vs. 9%); tort claims are nearly twice as common as claims for medication errors and result in the largest payouts; diagnostic errors are more likely to result in serious disability (47% vs. 14%).^{12,13} However, because diagnostic errors are discovered in hindsight and not routinely tracked, they remain hidden.

CAUSES AND SOLUTIONS FOR THE PROBLEM – The Need for More Research to Improve Diagnosis

Box 2. THE NEED FOR MORE RESEARCH – The science of improving diagnostic safety and quality is still nascent.⁶ The lack of research funding is directly responsible for limited progress. This underresourced area presents a dramatic opportunity for early return on investment.

- Diagnostic errors must be solved in a scalable way through a systems improvement framework.¹ Making progress will require significant investment to understand burden, causes, and solutions.
- Progress on these issues has been hampered by the lack of Federal research funding for this topic and a lack of research capacity (e.g., access to key data and adequately trained researchers).
- Relative to its public health footprint, diagnostic errors are likely the most underfunded research area in medicine, directly receiving only about \$7 million per year.⁵ Many individual diseases with smaller public health impact receive orders of magnitude more funding each year.¹⁴
- The National Institutes of Health (NIH) has a disease-oriented funding structure that serves research on disease mechanisms and treatments well, but research on diagnosis poorly.
- The Agency for Healthcare Research and Quality (AHRQ) has a strong mission-aligned interest in this area, but limited funding to accomplish ambitious and important quality and safety goals.

There is no single cause and no single solution to the problem of diagnostic errors.¹ **The NAM defines diagnostic error broadly as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.**" Missed, wrong, and delayed diagnoses often result from cognitive errors linked to knowledge gaps, provider inexperience with specific problems, or biased human reasoning.¹⁵ Others result from failures in care coordination, communication, or reporting of test results.¹⁶ These problems must be solved in a scalable way through a systems improvement framework, but achieving this requires a robust pipeline of diagnostic research.

Ultimately, diagnostic errors represent failures of our healthcare delivery system in the broadest sense.¹ While many of these "errors" are linked to individual physician actions, this does not imply negligence on the part of any specific provider, and fixing the diagnostic process requires a holistic view of the system. The "system" here refers to all of our healthcare delivery structures and processes, including the diagnostic education, training, and certification of providers; electronic tools supporting the delivery of day-to-day care; payment models that affect how we value and incentivize correct, timely diagnoses; and government research infrastructure and total funding dedicated to improving diagnosis. The diagnostic process must be addressed using multifaceted, transdisciplinary,¹⁷ team-oriented solutions developed within a systems science framework.^{18,19} As the NAM report articulated, because diagnostic quality and safety research remains underfunded and the science underdeveloped, improving diagnosis for patients requires critical further research to develop, refine, and fully implement such solutions.¹

There is now ample evidence that we are not yet doing enough research on this critical topic. A recent systematic review of the medical literature found many potential solutions, but almost none that have yet been studied in actual clinical practice to determine whether they improve patient outcomes.²⁰ The 2015 NAM report clearly identified the need for further research and called for "dedicated funding for research on the diagnostic process and diagnostic errors" as one of its eight final recommendations.¹ A 2017 study estimated that US Federal research spending targeted towards tackling the diagnostic error problem remains minimal, totaling just a few million dollars each year (Figure 2).⁵ It is notable that the total spent on diagnostic error-related research is substantially less than what we now spend each year for federally-sponsored research on individual diseases, most with much smaller public health impact.¹⁴



Figure 2. Diagnostic errors research funding is woefully inadequate. Treatment-related research (basic, translational, and clinical) receives the vast majority of federal healthcare research dollars. Even after the 2015 NAM Report *Improving Diagnosis in Health Care*, federal agencies involved in medical research spent just 0.02% (~\$7 million) of their aggregate budget (~\$35 billion) on issues related to improving diagnostic quality or safety.⁵

PRIORITY CONDITIONS - Focusing Research Efforts in Priority Areas (Tackling 'The Big Three')

The NAM outlined a broad palette of research topics in need of further study for the field to make robust progress on this complex topic (Appendix 1), but the report also clearly pointed the field towards early wins through an initial focus on "identifying the most common diagnostic errors, "don't miss" health conditions that may result in patient harm, [and] diagnostic errors that are relatively easy to address."¹ While the most frequent diagnostic errors are likely with common conditions such as asthma or migraine, malpractice and autopsy studies consistently find that roughly 50-80% of the serious harms resulting from missed or delayed diagnoses are linked to one of three key disease categories^{8,21-25}:

- 1. vascular events (e.g., stroke, heart attack, pulmonary embolus)
- 2. infections (e.g., sepsis, meningitis, appendicitis), and
- 3. cancers (e.g., lung cancer, colon cancer, breast cancer).

We refer to these major disease categories responsible for the lion's share of misdiagnosis-related harms as 'The Big Three.' The 'Big Three' are not evenly distributed across practice settings and patient populations—missed vascular events dominate in emergency care, missed infections are most common among children, and missed cancer diagnoses lead the way in primary care (Table 1). Nevertheless, 'Big Three' diseases account for at least 3 (and up to 5) of the 'top five' diseases across practice settings.⁸

•		•		-
Clinical Setting	Vascular Events	Infections	Cancers	TOTAL
Emergency medicine ²¹	~30%	~20%	~9%	~59%
Pediatrics ²⁵	-	~40%	~13%	~53%
Adult primary care ²²	~12%	~8%	~60%	~80%

Table 1. Proportion of serious harms attributed to "The Big Three" in frontline care settings

It is noteworthy that causes (and therefore solutions) likely differ substantially across the 'Big Three.' The Table below identifies one key disease example for each of the 'Big Three' categories (Table 2).

Table 2. Exemplars from each "Big Three" category with diagnostic error causes and possible solutions

Misdiagnosis	Principal Cause	Solution(s) in Need of Further Research
Stroke	No specialty expertise	Telemedicine & device-based decision support ²⁶
Sepsis	Overwhelmed by data	Big data visual analytics & machine learning algorithms ²⁷
Lung cancer	Results not communicated	Direct-to-patient reports & EHR triggers to close loops ²⁸

Exemplar diagnostic error stories for diseases from each of the "Big Three" can be found in Appendix 2.

THE PATH FORWARD – Laying the Groundwork for Maximal Impact of New Research Funding

A 2016 AHRQ Summit on Improving Diagnosis identified foundational needs to facilitate and catalyze research towards solutions, including the need to (1) create core diagnostic research services and teams to facilitate diagnostic research, (2) build capacity by training and developing a robust, highly-qualified diagnostic research workforce, and (3) establish valid operational measures of diagnostic error.⁷

Key Barrier	Key Facilitator	
Lack of research infrastructure	well-established centers around the country with strong leaders	
	and a track record of diagnostic research success	
Lack of research workforce	strong national mentorship network for trainees through SIDM	
	(https://www.improvediagnosis.org/page/SIDMFellowship)	
Lack of operational measures	2017 DHHS-funded National Quality Forum (NQF) report outlining a	
	conceptual framework for developing diagnostic error measures ²⁹	

SIDM supports a three-pronged approach to leverage key facilitators to overcome these key barriers, as suggested by the recent AHRQ⁷ and NQF²⁹ reports:

- 1. Establish Research Centers of Diagnostic Excellence (Appendix 3) These programs would create core resources and serve as central hubs for conducting critical diagnostic safety and quality research using transdisciplinary¹⁷ team science. Centers could be based on strategic partnerships that capitalize on capabilities of both academic research institutions and non-academic healthcare stakeholders to spark high-impact research on novel solutions to improve diagnosis. For example, an academic institution working on reducing emergency department missed vascular events and infections might partner with an emergency medicine professional society to implement and spread validated interventions; a health system with a unified electronic health record (EHR) that helps reduce diagnostic communication failures might partner with a standards-setting organization to disseminate new life-saving protocols; or an integrated healthcare provider/insurer might partner with a quality improvement organization on rapid-cycle operations improvement research in its network to apply learning health system principles to reducing harms from misdiagnosis.
- Support & Fund Diagnostic Fellowship Training Programs These programs would cultivate, train, and develop early career scientists to expand the currently limited pool of diagnostic quality and safety researchers. They would build on existing training programs for research methods (e.g., clinical, health services, dissemination/implementation) and add core content for diagnosis.
- 3. **Develop and Validate Operationally-Viable Measures** A rigorous measure development process should be fostered and supported for potentially high-value measure types <u>that matter to patients</u> and are promising but need further research to be validated, as identified by the NQF expert panel, including diagnostic outcomes and adequacy of diagnostic communication with patients.²⁹

RETURN ON INVESTMENT – Developing Core Resources and Building Capacity will Yield Excellent ROI

The projected net benefits (short, intermediate, and long term) of facilitating research to improve diagnosis are enormous. In the *short* term, the field is currently so underfunded that the marginal utility/value of each additional research dollar is likely to be substantial. In the *intermediate* term, there are promising solutions in the research pipeline for specific 'Big Three' problems that would eliminate low-value diagnostic care (low quality, high cost). For example, rectifying the known problem of stroke misdiagnosis in patients with dizziness/vertigo clinical presentations could eliminate 45,000-75,000 missed strokes, avert 15,000-25,000 serious patient harms, and save the healthcare system an estimated \$1 billion per year (currently wasted on unnecessary imaging and hospital admissions for patients with benign ear conditions that mimic strokes).^{30,31} Technology-based solutions are now being developed and tested, but need additional research to be ready for widespread dissemination.²⁶

In the *long* term, research which leads to improved diagnosis will not only be cost effective, but will almost always produce higher quality care <u>and</u> cost savings in situations where misdiagnoses are currently frequent.⁹ When we improve diagnosis, we realign resource use, increasing value (Figure 3).



Figure 3. Improving diagnosis saves both lives and money. Typical high-stakes diagnostic decisions are about differentiating dangerous diseases (in need of intensive diagnostic investigations or treatments) from benign diseases (*not* in need of intensive diagnostic investigations or treatments).^{32,33} The per-patient costs of care for dangerous diseases are generally greater than those for benign diseases, but there are many more patients with benign diseases. When we improve diagnosis beyond current practice (rather than merely trading off risks), we decrease both false negative and false positive classifications.⁹ Reducing false negatives for dangerous diseases saves lives (sometimes at added cost), while reducing false positives for benign diseases saves money (without harming patients). This combination results in high-value diagnosis that is both high quality *and* low cost.

POLICY ACTION PLAN – Coordinate Efforts between Policymakers, Funders, and Researchers

The diagnostic research pipeline is "leaky" with major gaps (Figure 4), so cross-agency coordination is essential. Policymakers can help by raising awareness of diagnostic errors as a priority topic, sparking cross-agency coordination, and infusing additional research funding for solving this critical public health

problem. This should include exploration of public-private partnerships (e.g., aligning efforts of private foundations in diagnostic research; identifying strategic partners within private industry willing and able to co-fund research and/or disseminate novel diagnostic technologies or best practices; and working closely with private safety and quality organizations to benchmark and improve performance).



Figure 4. There are major gaps in the diagnostic research pipeline. The NIH structure is poorly suited to fund most diagnostic research, because of its organ system and disease orientation (which is perfectly suited to treatment-related research). This is because the diagnostic process is often about differentiating disease A from disease B – if diseases A and B "belong" to two different NIH institutes, then studying that diagnostic process is aligned with neither institute's mission. As a result, there is a major funding gap in the early aspects of the translational research pipeline carrying new diagnostic discoveries forward. As a result, few diagnostic tests or approaches are ever directly studied for their impact on patient health, and many never reach clinical practice. For treatments, this gap is typically filled by industry-sponsored phase III clinical trials, but only rarely is this the case for diagnostic tests and devices. This is largely because pharmaceuticals are subjected to a more rigorous standard than diagnostics prior to FDA approval and use. Those marketing pharmaceutical treatments must demonstrate health benefits for patients in randomized trials; as a result, there is industry incentive to conduct such trials. By contrast, those marketing diagnostic tests or devices must only demonstrate that they measure what they claim to measure and that they are safe—there is no requirement that they benefit patient health. As a result, from the industry perspective, conducting studies to determine the health benefits of a diagnostic strategy is a risky proposition with little hope of meaningful return on investment. Accordingly, it is essential that the federal government play a key role in closing this gap. Abbreviations: Dx - Diagnosis; Rx - Treatment

Critical policy steps that key stakeholders can take include the following:

- 1. **Raising Awareness (SIDM/CID)** SIDM and the Coalition will lead efforts to raise public and policymaker awareness of the problem of diagnostic error by creating opportunities for Congress and other health policy stakeholders to hear from affected constituents, research scientists, and private organizations who want to solve it (e.g., Mont Fund, Gordon & Betty Moore Foundation).
- Cross-Agency Coordination (AHRQ) As requested by Congress in the Committee Report accompanying the FY18 Senate Labor, Health and Human Services, and Education Appropriations bill,³⁴ AHRQ should "convene a cross-agency working group that will propose a strategy to enhance scientific research to improve diagnosis in healthcare, as outlined in the 2015 [NAM] report."

In the short term (by early in fiscal year 2018), AHRQ should...

- a. <u>CATALOG</u> recent past and current research related to diagnostic safety and quality.
- b. <u>SOLICIT</u> information from other agencies on work they may be doing in this arena.
- c. <u>OUTLINE</u> a tactical plan to coordinate a cross-agency task force on diagnostic research.

In the *intermediate* term (by the end of fiscal year 2018), AHRQ should...

- d. <u>CONVENE</u> federal research funding agencies (e.g., AHRQ, NIH, PCORI, VA, CDC) and a broad range of other stakeholders, including patient advocates, outside the federal government.
- e. <u>ANALYZE</u> key gaps in research to improve diagnosis as identified by healthcare stakeholders, with an emphasis on clarifying needs across the diagnostic research continuum (Figure 4).
- f. <u>RECOMMEND</u> a multi-agency strategy that links specific agencies to particular aspects of research to improve diagnosis (e.g., implementing Centers of Diagnostic Excellence or research training programs might be priorities for AHRQ; developing a novel biomarker for sepsis might be a priority for NIH; studying closed-loop test results reporting might be a priority for the VA; and conducting large, pragmatic trials comparing current care to novel diagnostic strategies such as remote expert tele-diagnosis could be a priority for PCORI).

In the *longer* term (over the next decade), AHRQ should play an active coordinating role to...

- g. <u>DEPLOY</u> requests for proposals designed to address critical gaps (e.g., measurement), while maintaining a focus on funding implementation and application of diagnostic approaches that deliver improved patient outcomes and greater healthcare value.
- h. <u>CATALYZE</u> and coordinate cross-agency diagnostic research efforts as part of an "ACT to Improve Diagnosis" initiative designed to eliminate preventable harms from misdiagnosis.
- i. <u>MONITOR</u> progress and adjust these strategic plans as needed as the field evolves.
- 3. Funding (Congress) Congress should immediately appropriate new funds to AHRQ to overcome key barriers, as outlined above, by (a) establishing Research Centers of Diagnostic Excellence, (b) creating training opportunities through Diagnostic Fellowships, and (c) validating and deploying key operational measures of diagnostic quality & safety that matter to patients. We envision a one-time appropriation (\$10 million/year for 5 years) to fund at least 5 national centers to spark research, train researchers, and develop measures that enable and drive improvement. Simultaneously, Congress should provide sufficient resources for AHRQ to carry out the cross-agency coordination functions described above. We envision an additional \$1.5 million to support short-term planning and convening activities. In FY19, Congress should enact an ambitious "ACT to Improve Diagnosis" initiative to fund the cross-agency strategy developed through AHRQ's leadership at a level commensurate with the public health magnitude of the diagnostic error problem (\$100 million/year for 10 years).

CONCLUSIONS

SIDM and Coalition members concur with the NAM that improving diagnosis is a "moral, professional, and public health imperative."¹ To be sure, improving diagnosis and eliminating misdiagnosis-related harms will not be easy, simple, quick, or inexpensive. However, if policymakers embrace the steps above

to facilitate and enhance diagnostic research, we believe that this will result in transformational change for medical diagnosis that saves lives, prevents disability, and substantially reduces healthcare costs.

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