

Anticipatory Assessment: A New Imperative for Responsible Biomedical Innovation

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September 28, 2026

Emerging technologies are redefining expectations for health and medicine and accelerating the pace of innovation. The radical novelty and convergence of platform technologies, including mRNA, gene editing, and artificial intelligence, are creating remarkable opportunities to prevent disease, personalize care, and transform health systems. For example, mRNA platform technology enabled rapid vaccine development during the COVID-19 pandemic and provided the foundation to explore promising new areas such as cancer vaccine therapies (Yang et al., 2025). Artificial intelligence and machine learning have supported massive developments in medical devices (Singh et al., 2025). Furthermore, advances in genetic research are pushing the frontiers of patient-tailored gene editing, with the first personalized CRISPR-based therapeutics now entering early clinical use (Musunuru et al., 2025).

Yet the same advances that hold such promise also introduce novel risks related to ethics, equity, biosecurity, affordability, and societal trust. The authors agree that as the pace of innovation increasingly outstrips the ability of regulatory, market, and academic institutions to respond, it becomes crucial to identify, analyze, and mitigate potential consequences of new technologies via anticipatory assessment before the technologies reach widespread use. Delaying the evaluation of emerging technologies until they are mature increases the risk that preventable harms become structurally embedded in the system of practice.

A call for a systematic assessment of technology is not new. In the 1970s, the US federal government recognized the need for an independent authority to guide the safe and responsible deployment of emerging technologies. Congress chartered the Office of Technology Assessment (OTA) in 1972 to provide policymakers with objective information about the potential impacts of technological applications (IOM, 1988). While the OTA proved to be an invaluable resource, many of its assessments primarily focused on evaluating technologies that had already been developed or were nearing deployment. The authors suggest that this emphasis may have limited the OTA's ability to influence technologies during earlier stages of development—precisely when the greatest opportunity exists to shape innovation trajectories and prevent downstream harm. Moreover, the OTA's reports were designed for policymakers, not innovators and technology developers, who have the most direct control over design decisions and early-stage outcomes.

After the OTA's closure in 1995, Congress sought to maintain analytic capacity through the US Government Accountability Office (GAO), which created the Science, Technology Assessment, and Analytics team (Persons, 2020). The work of the GAO largely mirrors the OTA's original mandate to provide impartial, retrospective assessments of technologies already on the cusp of deployment. In addition, GAO analyses tend to emphasize technical and regulatory considerations without

consistently evaluating the broader social, ethical, and political dimensions that shape how technologies function in practice.

Despite the valuable analyses produced by both the OTA and GAO, the authors believe that neither approach has fully achieved some important core aims of technology assessment: anticipating impacts early, guiding responsible design decisions, aligning innovation with societal values, and preventing downstream harm. When applied in the 21st century, the limitations of traditional technology assessment include purpose, timing, and intended audience. Evaluating emerging technologies solely for their safety, efficacy, and pricing is insufficient; ethics, equity, and alignment with societal values must also be treated as core assessment criteria. In addition, assessments that take place only as technologies approach market entry offer limited capacity to influence design, deployment models, and access pathways. Hence it is now important to pursue an anticipatory approach—one that applies foresight early and iteratively, enabling adaptations throughout the development process to prevent or mitigate potential harms before a technology reaches the market.

Meeting these mandates necessitates shifting greater accountability toward technology developers and enablers, who shape design decisions long before regulatory review. Because emerging technologies are increasingly developed across academic, commercial, clinical, and public health sectors, influence is distributed across a set of key decision makers who shape innovation trajectories. Therefore, assessments require the participation of stakeholders as technologies develop, and well before market entry. Effective technology assessment must be paired with a multisectoral governance process that ensures ethical integrity, coordinates responsible oversight, and confirms that new health technologies deliver real public benefit (Mathews et al., 2022).

In this commentary, the authors call on these actors to adopt the concept of anticipatory

technology assessment as a shared expectation of responsible biomedical innovation. Specifically, innovators could identify and develop strategies to mitigate foreseeable risks. Anticipatory, life cycle-based assessment applied iteratively from concept through development can inform design choices, surface tradeoffs, and proactively identify response strategies before risks become entrenched.

Rather than directing or constraining developers, such a system would generate structured, decision-relevant information that supports responsible choices throughout development. At a minimum, this modernized framework would: (1) initiate assessment at the concept or prototype stage; (2) provide structured, periodic touchpoints throughout the innovation life cycle; (3) produce actionable guidance on risk mitigation, design options, and societal considerations; and (4) support scenario-based analyses to explore plausible future consequences. Most critically, this tool could be applied repeatedly throughout the innovation life cycle, enabling early identification and mitigation of risks long before technologies reach widespread use. In addition to using anticipatory assessment as a tool for innovators to identify and address high-risk areas of their technologies, this approach can be used by funders, technology transfer officers, investors, and industry personnel to make decisions about financing, technology acquisition, and development. In the future, anticipatory assessment could be applied by new or existing national technology assessment entities analogous to the OTA and GAO to advise, guide, or govern the development of new innovations to increase accountability to the public and the communities the technologies are intended to serve.

International efforts, including those led by the Organisation for Economic Co-operation and Development (OECD), illustrate the feasibility and growing importance of anticipatory governance in an era of accelerating technological complexity

(OECD, 2024). The authors believe what is needed in the United States is a shared, practical approach that embeds such assessment into the norms and expectations of biomedical innovation. In this context, the US National Academy of Medicine (NAM) has recently established a public, private, and multisectoral initiative, the Action Collaborative on Translating Emerging Science, Technology, and Innovation (ACT-ESTI), to co-develop and steward a shared anticipatory assessment framework (NAM, n.d.). ACT-ESTI includes leadership from across academia, industry, and government to advance a framework of anticipatory assessment for responsible innovation in the biomedical field. ACT-ESTI's role is not to evaluate or approve individual technologies, but to convene funders, journals, industry, payers, patient groups, and researchers to align on shared expectations for responsible innovation; to develop a user-friendly framework that innovators and enablers can integrate into existing research and development processes; and to support learning across sectors by identifying common challenges, best practices, and opportunities for early intervention. This framework would operate alongside, not within, regulatory processes, generating decision-relevant information without constraining innovation or duplicating existing oversight mechanisms.

The authors agree that biomedical innovation is entering an era defined by speed, convergence, and scale. Technologies developed today can quickly diffuse globally, shaping health outcomes for decades to come. Oversight structures built for a slower and more linear innovation landscape can no longer keep pace with this reality. Embedding anticipatory assessment into the norms of biomedical research and development offers a pragmatic path forward, one that strengthens accountability to patients and communities while preserving the dynamism of scientific discovery. By aligning incentives early and across sectors, this approach can help ensure that emerging technologies are not only groundbreaking, but

also responsive to societal needs while mitigating unintended consequences. The future of patient care and the promise of emerging technologies depend on a shared commitment to advancing innovations that are not only pathbreaking, but safe, equitable, and trustworthy.

References

- IOM (Institute of Medicine). 1988. *Medical Technology Assessment Directory: A pilot reference to organizations, assessments, and information resources*. Washington, DC: National Academies Press. <https://doi.org/10.17226/1090>.
- Mathews, D. J. H., C. A. Balatbat, and V. J. Dzau. 2022. Governance of emerging technologies in health and medicine—Creating a new framework. *New England Journal of Medicine* 386:2239-2242. <https://www.nejm.org/doi/full/10.1056/NEJMms2200907>.
- Musunuru, K., S. A. Grandinette, X. Wang, T. R. Hudson, K. Briseno, A. M. Berry, J. L. Hacker, A. Hsu, R. A. Silverstein, L. T. Hille, A. N. Ogul, N. A. Robinson-Garvin, J. C. Small, S. McCague, S. M. Burke, C. M. Wright, S. Bick, V. Indurthi, S. Sharma, M. Jepperson, C. A. Vakulskas, M. Collingwood, K. Keogh, A. Jacobi, M. Sturgeon, C. Brommel, E. Schmaljohn, G. Kurgan, T. Osborne, H. Zhang, K. Kinney, G. Rettig, C. J. Barbosa, S. C. Semple, Y. K. Tam, C. Lutz, L. A. George, B. P. Kleinstiver, D. R. Liu, K. Ng, S. H. Kassim, P. Giannikopoulos, M. G. Alameh, F. D. Urnov, and R. C. Ahrens-Nicklas. 2025. Patient-specific in vivo gene editing to treat a rare genetic disease. *New England Journal of Medicine* 392(22):2235-2243. <https://doi.org/10.1056/NEJMoa2504747>.
- NAM (National Academy of Medicine). n.d. *Action Collaborative on Translating Emerging Science, Technology, and Innovation in Health and Medicine*. Available at: <https://nam.edu/our-work/programs/committee-on-emerging-science-technology-and-innovation-in-health-and-medicine/> (accessed July 22, 2026).

OECD (Organisation for Economic Co-operation and Development). 2024. *Framework for Anticipatory Governance of Emerging Technologies*. Paris: OECD Publishing. <https://doi.org/10.1787/0248ead5-en>.

Persons, T. 2020. The return of science and technology assessment for Congress. *Issues in Science and Technology* 37(1):23-25. Available at: <https://issues.org/the-return-of-science-and-technology-assessment-for-congress/> (accessed August 13, 2026).

Singh, R., M. Bapna, A. R. Diab, E. S. Ruiz, and W. Lotter. 2025. How AI is used in FDA-authorized medical devices: A taxonomy across 1,016 authorizations. *npj Digital Medicine* 8:388. <https://doi.org/10.1038/s41746-025-01800-1>.

Yang, Y., Y. Sun, X. Kang, and Y. Wang. 2025. mRNA vaccine platforms and novel delivery systems: From mechanistic principles to clinical translation. *Human Vaccines & Immunotherapeutics* 21(1):2597629. <https://doi.org/10.1080/21645515.2025.2597629>.

DOI

<https://doi.org/10.31478/202609c>

Suggested Citation

Dzau, V., M. Randhahn, M. H. Laitner, and E. Shambaugh. 2026. Anticipatory Assessment: A New Imperative for Responsible Biomedical Innovation. *NAM Perspectives*. Commentary,

National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/202609c>.

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Conflict-of-Interest Disclosures

None to disclose.

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