



December 20, 2024

Monica M. Bertagnolli, M.D.
Director, National Institutes of Health
Room 126, Building 1
One Center Drive
Bethesda, MD 20892-0148

Dear Director Bertagnolli:

On behalf of the National Center for Advancing Translational Sciences (NCATS) Alliance, a coalition of patient advocates, clinicians, academic medical centers, researchers, and biotechnology companies working to educate the public and policymakers on the important science being advanced by NCATS and ensuring Congress provides NCATS with the necessary funding to deliver on its scientific mission, we write to express our strong support for the recent recommendation by the NCATS Advisory Council to elevate the National Center for Advancing Translational Sciences (NCATS) to an Institute within the National Institutes of Health (NIH). This recommendation reflects NCATS' remarkable achievements, strategic vision, and its critical role in advancing translational science for the benefit of patients, healthcare providers, and the broader biomedical research community.

Since its inception in 2011, NCATS has demonstrated unparalleled leadership in tackling translational challenges, ensuring that scientific discoveries are efficiently translated into tangible health solutions. As a Center, NCATS has delivered significant outcomes, including:

- Supporting the development of 55 Investigational New Drugs (INDs) and contributing to 15 New Drug Approvals, a notable achievement that underscores its transformative role in therapy development.
- Spearheading the Clinical and Translational Science Awards (CTSA) program, which has grown to include 63 hubs nationwide, creating an unmatched infrastructure for translational research.
- Launching groundbreaking initiatives like the Rare Diseases Clinical Research Network (RDCRN), which has advanced research in over 200 rare diseases and contributed to the approval of 12 FDA-approved treatments for 11 rare diseases.
- Developing innovative models like the National Clinical Cohort Collaborative (N3C) Clinical Data Enclave, a premier resource for real-world data analytics that is foundational to emerging fields such as artificial intelligence and machine learning in biomedical research.

The case for NCATS' elevation to an Institute is compelling and aligns with established precedents at NIH, including the transitions of the National Human Genome Research Institute (NHGRI), the National Institute on Minority Health and Health Disparities (NIMHD), and the National Institute of Nursing Research (NINR). In each case, these transitions enhanced the respective organization's capacity to address emerging challenges and opportunities in their fields, broadened their scope, and empowered them to operate under legislative authorities comparable to those of other Institutes.

As the biomedical research landscape continues to evolve, NCATS is uniquely positioned to lead transformative advances in areas such as data science, gene therapy, and precision medicine. Elevating NCATS to an Institute will:

- Provide the structural and legislative framework needed to expand its scope and capabilities, enabling it to conduct clinical trials beyond Phase IIb and further its mission of delivering "more treatments, for all people, more quickly."
- Solidify its standing as a leader in translational science, enhancing its ability to forge critical public-private partnerships, leverage resources effectively, and catalyze innovation across the NIH and beyond.
- Reflect the significant scale, impact, and funding levels already comparable to a mid-sized NIH Institute, ensuring that NCATS can continue to address the most pressing translational challenges with the agility and authority it requires.

We applaud the NCATS Advisory Council for its foresight in recommending this transition and urge you to initiate the necessary steps to elevate NCATS to an Institute. This evolution is not only a recognition of NCATS' outstanding contributions but also a crucial investment in the future of translational science and its potential to improve health outcomes for all.

Thank you for your consideration of this important recommendation. We stand ready to assist in advancing this critical initiative and would welcome the opportunity to discuss this matter further.

Sincerely,

A handwritten signature in black ink, appearing to read 'JKB', followed by a horizontal line extending to the right.

J. Kevin Brennan
Executive Director, NCATS Alliance