

Experts Urge Clinical Trials Network to Study Infectious Disease Therapies in Immunocompromised Patients

More than 6% of Americans are immunocompromised, yet most clinical trials exclude them.

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A coalition of leading infectious disease and cancer experts is urging for the creation of a clinical trials network to evaluate the safety and efficacy of existing and new therapies for immunocompromised people, a growing population that is at increased risk for infectious diseases.

“Immunocompromised patients are often excluded from clinical trials for new therapies to treat and prevent infections, which means we lack critical data to guide their care,” said [Josh Hill, MD](#), a physician-researcher at Fred Hutch Cancer Center, who together with [Michael Boeckh, MD, PhD](#), and [Steve Pergam, MD, MPH](#), is leading the effort to create the clinical trials network. “This network would fill a major gap in our research infrastructure and ensure clinicians can provide the best care possible to immunocompromised patients.”

A shared vision for creating the proposed clinical trials network, published in [JAMA Network Open](#), follows an interdisciplinary meeting held on September 10, 2024, in Bethesda, Maryland, where researchers, patient advocates, clinicians, government and industry leaders convened to address the urgent need for targeted clinical research. The meeting identified key gaps and opportunities in the current research landscape and laid the groundwork for a coordinated national effort to address the needs of these complex immunocompromised patient populations.

An overlooked population

Recent estimates indicate that at least 6.6% of the U.S. population, or more than 20 million Americans, are considered immunocompromised. The immunocompromised population includes patients with cancer, bone marrow transplant recipients, solid organ transplant recipients and people with autoimmune diseases, among others. Over time, the number of immunocompromised people has grown, as has the need for tailored treatment and prevention strategies for infectious diseases in these populations.

Clinical trials enrolling immunocompromised individuals could provide data around the optimal timing, dosing, duration, combination and effectiveness of preventive and therapeutic agents. For

example, recently developed vaccines and monoclonal agents targeting respiratory syncytial virus, or RSV, have been new additions in preventing outbreaks and serious disease in the general population. However, the lack of sufficient data on optimal administration in immunocompromised populations has led to delays in access to lifesaving therapies, all while leaving clinicians without clear guidance for how best to administer them in these patients.

“Similar to the scientific focus that has resulted in rapid advances in cancer immunotherapies and new ways to prevent and treat infectious diseases, we need to build a network that’s entirely focused on immunocompromised populations,” Hill said. “Immunocompromised patients have been overlooked for too long.”

Building a solution

Stakeholders called for public support, ideally integrated across multiple federal government agencies or institutes, to help ensure a robust framework for the network and opportunities for private industry to collaborate. National networks have proven successful in facilitating the study of bone marrow transplant, HIV vaccines and pediatric oncology.

The stakeholders highlighted three goals for the proposed network:

- Create a consortium of institutions to accelerate implementation of standardized clinical trials designed to assess therapies to prevent and treat infections in patients with moderate-to-high risk.
- Establish centralized statistical and data management, laboratory and operational cores to improve standardization and efficiency of network-sponsored studies.
- Identify and develop high-priority clinical trials.

The network structure also would include regional clinical hubs to ensure geographic and demographic representation, stakeholder and patient advisory panels for strategic guidance and flexible funding streams from public and private sources.

Encouraging participation and innovation

Through utilizing a participatory research model, the network would work with immunocompromised people and patient advocates to advise the network’s scientific agenda and contribute to advocacy and recruitment efforts.

Innovative approaches, such as AI, would be leveraged to enhance trial outcomes and efficiencies. Additionally, policy solutions, such as creating regulatory incentives to include immunocompromised people in clinical trials and label medications for their use, could help speed access to new therapies in this population.

“The most important step in creating a clinical trials network dedicated to studying therapies to

prevent and treat infections in immunocompromised people was to bring our committed community together,” Hill noted. “Now we’re taking concrete steps to realize this shared vision.”

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