

C-Path's Translational Therapeutics Accelerator Announces \$200,000 Grant for Drug Development Project in Inflammatory Bowel Disease

University Hospitals Cleveland Medical Center physician awarded funding to advance novel therapy for IBD.

TUCSON, Ariz., and **CLEVELAND**, July 16, 2025 — Critical Path Institute's® (C-Path) Translational Therapeutics Accelerator (TRxA) proudly announced today a \$200,000 grant to Carlos Subauste, M.D., an internist and infectious disease specialist at University Hospitals Cleveland Medical Center and professor at Case Western Reserve University, to advance a promising new therapy for inflammatory bowel disease (IBD).

IBD — a chronic and often debilitating condition affecting more than 2.4 million Americans, with approximately 70,000 new diagnoses each year — causes ongoing inflammation of the gastrointestinal tract, resulting in severe abdominal pain, weight loss, and irreversible damage to intestinal tissue.

In addressing the inflammation associated with IBD, many current and investigational treatments suppress the immune system, leaving patients vulnerable to serious, sometimes life-threatening infections. Dr. Subauste's work represents a first-in-class approach, selectively disrupting a pro-inflammatory signaling branch that helps determine specific types of immune responses, involving a protein known as CD40. This innovative approach modulates the inflammatory response without affecting immune-protective pathways. This strategy aims to maximize therapeutic impact while minimizing infection risk — a key limitation of current IBD therapies.

"CD40 is a major driver of inflammation in IBD," said Dr. Subauste. "By selectively blocking the CD40–TRAF2 pathway, we can suppress harmful inflammation while preserving the body's natural defense against infection."



Carlos Subauste, M.D.

Dr. Subauste's team has already identified potent small-molecule inhibitors with promising potency (at the nanomolar level) in cells and is currently progressing through early-stage drug lead optimization. The next stage of the project will refine these leads and prepare for preclinical development with the ultimate goal of bringing a safer, more effective therapy for IBD to patients in need. This therapeutic approach also has the potential for application to other CD40-driven diseases, such as multiple sclerosis, lupus, Sjogren's syndrome and diabetes.

The project is being supported by TRxA, a C-Path program that provides targeted funding and strategic support to help academic researchers advance high-potential therapeutic candidates into the clinic.

"C-Path is proud to support Dr. Subauste's innovative work targeting CD40–TRAF2 signaling," said Maaike Everts, Ph.D., Executive Director of TRxA. "This program represents the kind of science that TRxA was created to advance, addressing validated disease targets with smarter, safer mechanisms that can improve

outcomes for patients."

For more information on C-Path, TRxA and its initiatives, please visit c-path.org/trxa.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the <u>FDA's Critical Path Initiative</u>, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

About TRxA

Critical Path Institute's Translational Therapeutics Accelerator (TRxA) is a global drug accelerator focused on supporting academic scientists in advancing novel therapeutics from university-based labs to drug development pipelines of pharmaceutical companies and, ultimately, the clinic. As a nonprofit neutral convener of patient groups, academia, pharmaceutical companies and regulatory agencies, C-Path brings a breadth of scientific and drug development planning not available in other accelerator programs. TRxA is uniquely situated to leverage the expertise available through C-Path's >20 disease-based consortia, as well as regulatory expertise and project management, to empower academic investigators to succeed in bringing safe and effective treatments to patients. For more information, visit c-path.org/trxa or email trxa@c-path.org.

About University Hospitals / Cleveland, Ohio

Founded in 1866, University Hospitals serves the needs of patients through an integrated network of more than 20 hospitals (including five joint ventures), more than 50 health centers and outpatient facilities, and over 200 physician offices in 16 counties throughout northern Ohio. The system's flagship quaternary care, academic medical center, University Hospitals Cleveland Medical Center, is affiliated



with Case Western Reserve University School of Medicine, Northeast Ohio Medical University, Oxford University, Taiwan National University College of Medicine and the Technion Israel Institute of Technology. The main campus also includes the UH Rainbow Babies & Children's Hospital, ranked among the top children's hospitals in the nation; UH MacDonald Women's Hospital, Ohio's only hospital for women; and UH Seidman Cancer Center, part of the NCI-designated Case Comprehensive Cancer Center. UH is home to some of the most prestigious clinical and research programs in the nation, with more than 3,000 active clinical trials and research studies underway. UH Cleveland Medical Center is perennially among the highest performers in national ranking surveys, including "America's Best Hospitals" from U.S. News & World Report. UH is also home to 19 Clinical Care Delivery and Research Institutes. UH is one of the largest employers in Northeast Ohio with more than 30,000 employees. Follow UH on LinkedIn, Facebook and Twitter. For more information, visit here.

About Case Western Reserve University

At Case Western Reserve, one of the nation's leading research universities, we're driven to seek knowledge and find solutions to some of the world's most pressing problems. Nearly 6,200



undergraduate and 6,100 graduate students from across 96 countries study in our more than 250 degree programs across arts, dental medicine, engineering, law, management, medicine, nursing, science and social work. Our location in Cleveland, Ohio—a hub of cultural, business and healthcare activity—gives students unparalleled access to engaging academic, research, clinical, entrepreneurial and volunteer opportunities and prepares them to join our network of 125,000+ alumni making an impact worldwide. Visit case.edu to learn more.

Media Contacts:

Roxan Triolo Olivas C-Path 520.954.1634 rolivas@c-path.org

Ansley Kelm University Hospitals 678.313.6525 Ansley.Kelm@UHhospitals.org

William Lubinger Case Western Reserve University 216.368.4443 william.lubinger@case.edu