

C-Path Program and Consortia Leaders Selected to Serve in Sr. Vice President and Vice President Roles

*Inish O’Doherty and Sudhir Sivakumaran will lead new programs;
Stephen Joel Coons and John-Michael Sauer move into Sr. VP roles.*

TUCSON Ariz., March 10, 2021 — Critical Path Institute (C-Path) today announced it has promoted Inish O’Doherty, Ph.D., to Vice President of the organization’s newly formed Immunology and Hematology Program and Sudhir Sivakumaran, Ph.D., to Vice President for its Neuroscience Program, effective immediately. Both Drs. O’Doherty and Sivakumaran currently serve as Executive Directors of multiple C-Path consortia. Additionally, current Program Officer Stephen Joel Coons, Ph.D., will now serve as Senior Vice President of the Clinical Outcome Assessment (COA) Program and John-Michael Sauer, Ph.D., as Senior Vice President of Translational and Safety Sciences Program.

The promotions and new program groups stem from a reorganization and optimization within C-Path after a year of strategic development planning.

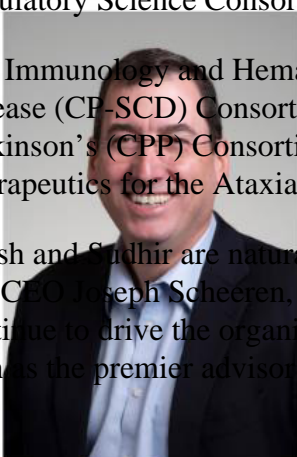
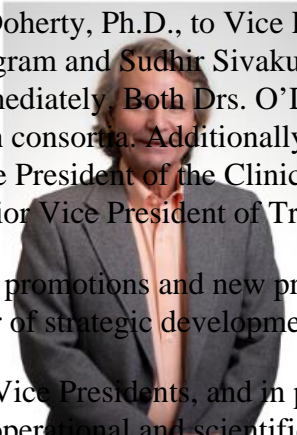
As Vice Presidents, and in partnership with senior leadership, Dr. O’Doherty and Dr. Sivakumaran will guide all operational and scientific activities for the Immunology and Hematology and Neuroscience Programs, respectively. These activities will include supporting and implementing strategic priorities for the various consortia in these programs, and individual working groups within them. Each will also work with key individuals at regulatory agencies worldwide, including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and the Pharmaceuticals and Medical Devices Agency (PMDA).

Dr. O’Doherty, a clinical development scientist, has been with C-Path for more than four years, as Executive Director of C-Path’s Type 1 Diabetes (T1D) Consortium and Transplant Therapeutic Consortium (TTC). His work focuses on the pre-competitive development of biomarkers and quantitative tools, which aim to optimize clinical trial design and minimize risk in regulatory decision-making.

Dr. Sivakumaran, a neuroscientist and research and development professional, has nearly 20 years combined experience in academic, pre-clinical and early clinical research and development, and business development. He has been with C-Path since July 2019 and serves as Executive Director of the Critical Path for Alzheimer’s Disease (CPAD) consortium and Interim Executive Director for the Huntington’s Disease Regulatory Science Consortium (HD-RSC).

The Immunology and Hematology Program will include T1D, TTC and the Critical Path for Sickle Cell Disease (CF-SCD) Consortium. The Neuroscience Program will consist of CPAD, HD-RSC, Critical Path for Parkinson’s (CPP) Consortium, Duchenne Regulatory Science Consortium (D-RSC) and the Critical Path to Therapeutics for the Ataxias (CPTA) Consortium.

“Inish and Sudhir are natural selections for these new leadership roles within C-Path,” said C-Path President and CEO Joseph Scheeren, Pharm. D. “They bring deep and insightful experience to the programs and will continue to drive the organization’s strategic leadership and business development initiatives in support of C-Path as the premier advisor to academia, industry, regulators and other partners in the ever-evolving medical



John-Michael Sauer, Ph.D.

product development and regulatory ecosystem.”

The Translational and Safety Sciences Program will focus on drug safety, nephrology, inflammatory bowel disease (IBD), drug repurposing and translational therapeutics, where the COA Program will continue its work on patient-reported outcome measures and other COAs, with an added emphasis on rare diseases.

For three decades, Dr. Coons has focused on incorporating the patient’s voice into the assessment of health and health care. Prior to C-Path, he was a professor in the College of Pharmacy and the Mel & Enid Zuckerman College of Public Health at the University of Arizona. Dr. Coons is a fellow in the American Association of Pharmaceutical Scientists and Professor Emeritus at the University of Arizona.

Dr. John-Michael Sauer is a toxicologist by training with more than 15 years’ experience in drug discovery and development. He has led multiple functional areas across pharmaceutical companies and is dedicated to bringing quantitative translational science approaches to safety assessment, as well as transforming the way we use nonclinical safety data to drive clinical study design and data interpretation. Dr. Sauer is a Research Professor, Department of Pharmacology, College of Medicine, Professor of Practice, James E. Rogers College of Law and Designated Campus Colleague, University of Arizona.

“John-Michael and Stephen are accomplished experts in their respective fields, and we’re honored to have them continue to lead these areas for C-Path,” said Scheeren. “As longstanding members of our leadership team, they have made significant contributions to the growth and success of the organization.”

Reporting directly to Dr. Scheeren, O’Doherty, Sivakumaran, Coons and Sauer will continue to serve on C-Path’s leadership team, “helping to shape the innovative and regulatory pathways to accelerate delivery of therapies for patients in need,” Scheeren said.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 55% funded by FDA/HHS, totaling \$14,575,306, and 45% funded by non-government source(s), totaling \$11,916,747. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government. For more information, please visit FDA.gov.



Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

Media Contact:

Kissy Black
C-Path
615.310.1894
kblack@c-path.org

