

C-Path Appoints Dr. Klaus Romero as Chief Science Officer



TUCSON, Ariz., March 12, 2020 — The Critical Path Institute (C-Path) today announced the appointment of Klaus Romero, M.D., M.S., F.C.P., as its new Chief Science Officer (CSO) effective April 1, 2020. Dr. Romero, a clinical pharmacologist and epidemiologist with more than 17 years combined experience in academic and pharmaceutical clinical research, translational sciences, pharmacometrics, modeling and simulation and pharmacoepidemiology, has been with C-Path since December 2007. His most recent role has been as Executive Director of Clinical Pharmacology and Quantitative Medicine. He will continue in dual roles as CSO and head of the Quantitative Medicine Program.

As CSO, Dr. Romero will spearhead innovations in research and science by delivering strategic and operational leadership of C-Path's data-driven nationally and internationally recognized programs in medical product development solutions. In collaboration with senior leadership, he will set the vision for C-Path's scientific endeavors and ensure that the focus of C-Path's public-private partnerships stay closely aligned with its mission to accelerate the pace and reduce the costs of medical product development, through innovation in data science, model-informed drug development, patient-centric drug development and precision medicine to optimize the scientific evaluation of the efficacy and safety of new therapies. This will be achieved through strengthening C-Path's pillars in quantitative medicine, data science, biomarkers, clinical outcome assessment tools and regulatory science.

“With more than 15 years of diverse experience in the drug development space, including demonstrated leadership abilities in heading large programs and cross-functional teams, there are few people who would be equally suited to lead C-Path's scientific initiatives than Klaus,” said C-Path President and CEO Joseph Scheeren, Pharm. D. “His combination of clinical pharmacology, epidemiology and model and simulation experience, plus his business development expertise and history of fostering meaningful interactions between regulatory agencies, industry, academia and patient groups will be key in enhancing signature C-Path consortia initiatives, while bringing strategic focus to data analytics to drive research and create efficiencies across all stages of drug development.”



During his tenure with C-Path, he has helped lead clinical pharmacology, pharmacoepidemiology and modeling and simulation projects in Alzheimer's disease, polycystic kidney disease (PKD), tuberculosis, type

1 diabetes, Parkinson's disease, Duchenne muscular dystrophy, kidney transplantation, Huntington's disease and cardiovascular drug safety. His work has helped to achieve major milestones, including the first regulatory endorsement by the U.S. Food and Drug Administration and European Medicines Agency of a clinical trial simulation tool for mild and moderate Alzheimer's disease and the regulatory qualification of the first imaging biomarker for PKD. Dr. Romero's scientific production with C-Path has resulted in more than 60 peer-reviewed publications related to his work with the Institute.

Reporting directly to Scheeren, Dr. Romero will serve as the Institute's spokesperson on all scientific matters.

"I am incredibly excited and honored to have been given the opportunity to further serve C-Path in this role. I am proud of our 15-year history, as we have grown from a small group of pioneers into a mature organization of innovators in solutions to expedite medical product development," said Dr. Romero. "I look forward to advancing and growing our pipeline of collaborative pre-competitive efforts. The era of knowledge management, decision science and personalized medicine represents the right time for C-Path to grow its leadership in transforming smart data into actionable cutting-edge knowledge to de-risk and expedite medical product development."

Dr. Romero is a fellow of the American College of Clinical Pharmacology, a founding member of the International Society of Pharmacometrics, as well as a member of the American Society for Clinical Pharmacology and Therapeutics, and the International Society for Pharmacoepidemiology. In addition to his duties at C-Path, he serves as Chairman of the Board of Directors for CredibleMeds®. He is fluent in English, Spanish, German and Portuguese, and has a passion for music, designing and playing innovative electric guitars. Dr. Romero is also a Research Associate Professor at the University of Arizona College of Medicine, Adjunct Professor at the College of Health Solutions at Arizona State University, Adjunct Professor at the University of Southern California's School of Pharmacy and serves on the Scientific Board of Pharos Dx. Dr. Romero received his medical degree from Pontifical Xavierian University, completed his training in Clinical Pharmacology at Columbia National University and holds an MS degree in Epidemiology from the Columbia School of Medicine.

Dr. Romero succeeds C-Path CSO Lynn Hudson, Ph.D., who will retire at the end of March; a position she has held since 2011. Under Hudson's leadership, C-Path's scientific consortia and programs have more than doubled.

"It has been an honor to serve as C-Path's scientific leader for the past decade," Hudson said. "C-Path continues to reach important milestones and achieve great progress in creating drug development efficiencies that have changed the time and expense it takes to get safe medical products to those who need them. I am incredibly proud of the work done here and I know Klaus will be a key player in C-Path's future success."



About Critical Path Institute

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.

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