

## C-Path European Nonprofit Established in Amsterdam

C-Path in Europe works seamlessly with its U.S. counterpart to advance the development of novel regulatory-endorsed methodologies to accelerate medical product development



**AMSTERDAM and TUCSON**, Ariz., March 23, 2022 — In support of <u>Critical Path Institute</u>'s (C-Path) mission to catalyze innovation that accelerates the path to a healthier world, C-Path is excited to announce the opening of its EU nonprofit headquarters in the Netherlands, which will focus on the development of existing and future activities in Europe.

C-Path is recognized globally as a leader in regulatory science, with extensive knowledge and experience in seeking and obtaining regulatory endorsement of drug development tools (DDTs) or novel methodologies in cooperation with the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). All C-Path regulatory-endorsed tools and methodologies are freely available to the broader scientific community.

The nonprofit's headquarters in Amsterdam will extend and complement C-Path's activities to improve public health, as well as share expertise, data, risks and costs to expedite advancements in global regulatory science by facilitating public-private partnerships with members from the biopharmaceutical industry, government regulatory agencies, academic institutions and patient groups in Europe.

"C-Path already has an established and longstanding presence in Europe," said C-Path Board Member, Tomas Salmonson, Ph.D., M.S., and former Chair of the EMA Committee for Medicinal Products for Human Use (CHMP). "We look forward to facilitating existing and new collaborations to productively support European Regulatory Science research programs and also contribute to the delivery of the EMA Regulatory Science Strategy to 2025."

Since its inception in 2005, C-Path has worked to forge relationships and collaborations in Europe in tandem with U.S. efforts to facilitate global collaboration. Since then, C-Path has received a significant number of <a href="Qualification Opinions and Letters of Support">Qualification Opinions and Letters of Support</a> from EMA and has a substantial track record of successful DDT and novel methodology endorsements by FDA, EMA and PMDA. These regulatory milestones have

contributed to addressing different unmet needs in medical product development, which have transformed drug development in different areas (among others, tuberculosis, polycystic kidney disease, Alzheimer's, Parkinson's, and irritable bowel syndrome).

"Advances in drug development are rapidly playing out on a global stage, and C-Path's extensive background in accelerating the drug development and regulatory processes will fuel innovation for the development of novel approaches that can be endorsed by regulators in many countries," said C-Path Chief Science Officer Klaus Romero, M.D., M.S., F.C.P. "Working together with European organizations remains a key C-Path priority. We're excited to have an office in Amsterdam, which we know will serve to enhance our collaborative efforts and speed the development of treatments for some of the world's most complex health issues."

An informative webinar, **C-Path in Europe: Moving Global Regulatory Science Forward**, is scheduled for April 20, 2022. Register here.

To learn more, visit: <a href="https://c-path.org/c-path-in-europe">https://c-path.org/c-path-in-europe</a>.



## **About C-Path**

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 hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, C-Path in Europe is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit c-path.org.

In the U.S., Critical Path Institute is supported by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) and is 54.2% funded by the FDA/HHS, totaling \$13,239,950, and 45.8% funded by non-government source(s), totaling \$11,196,634. 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.

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