

C-Path Integrates European Offices to Optimize Global Operations and Collaborative Partnerships



AMSTERDAM and **TUCSON**, Ariz., July 18, 2023 — <u>Critical Path Institute (C-Path)</u> announced today the completion of the integration of C-Path Ltd. in Dublin, Ireland, into the C-Path nonprofit in Amsterdam, Netherlands. This integration will enable C-Path to increase its activity in Europe and broaden its global operations. C-Path operates in Europe as a nonprofit organisation that builds consensus among its stakeholders from around the world to improve public health. The organisation shares expertise, data, risks and costs to move regulatory science forward.

"We are thrilled to bring the talented European teams together as a unified organisation. Doing so allows us to expand our presence in Europe and strengthen our global operations. With this integration, we will continue to build consensus among stakeholders and share expertise driving global regulatory science and data science that are improving public health worldwide," said Cécile Ollivier, C-Path's Managing Director, Europe.

Shortly after it was founded in 2005, C-Path began forging relationships with European entities. In 2007, C-Path's <u>Predictive Safety Testing Consortium</u> was the first collaboration to submit through the pilot qualification procedures an evidence package for seven kidney safety biomarkers to the U.S. Food and Drug Administration, the European Medicines Agency (EMA) and the Pharmaceuticals and Medical Devices Agency in Japan. In May 2008, EMA issued a final conclusions statement for these nephrotoxicity biomarkers. To date, C-Path's total number of <u>EMA Qualification Opinions</u> is nine, with an equal number of Letters of Support.

As part of C-Path <u>Data Collaboration Center</u> (DCC), the team in Ireland is involved in global efforts. The DCC was founded to generate secure, large-scale data solutions for medical research, and provide unsurpassed expertise in curating, standardising, analysing and sharing medical data from around the world. DCC operates in a neutral space with a focus on accelerating clinical research and improved treatments by maximizing the utility of medical data.

Since 2019, C-Path's work in Ireland has been focused on two programs under the Innovative Medicines Initiative's (IMI) AMR Accelerator: The <u>European Regimen Accelerator for Tuberculosis (ERA4TB)</u> and the <u>Academia and Industry United Innovation and Treatment for Tuberculosis (UNITE4TB)</u>. C-Path is the lead partner for the data management work package for these projects, in which the Ireland-based data

management team are collaborating with partners, which has resulted in 124 standardised sources of data (93 preclinical and 31 clinical trial data sources) being made available to consortium partners to support their research requirements. In addition, to the project specific efforts on these TB initiatives, C-Path continues to maintain and expand the content of the TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS) which can be formally accessed and used by the global TB research community to support their ongoing research activities.

"We acknowledge and appreciate the outstanding contributions of Patrick O'Meara, Data Team Manager, and our Ireland-based Data Management team in advancing tuberculosis initiatives. Their collaborative efforts have played a pivotal role in supporting global regulatory strategies and driving advancements in drug development," said Richard Liwski, Chief Technology Officer for C-Path. "We extend our gratitude to Patrick and the team as we continue to make significant strides in these crucial endeavors. We are looking forward to remaining involved in C-Path European growth and activities."

C-Path celebrates the successful integration and expanded nonprofit operations in Europe. With this strengthened global presence, it remains committed to leading collaborations that accelerate drug development, advancing better treatments for people worldwide.



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

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