C-Path Europe: A Global Vision of Success

TUCSON, Ariz. and **AMSTERDAM**, April 26, 2023 — As an organization that generates regulatory-endorsed solutions and methodologies to accelerate drug development, Critical Path Institute (C-Path) today shared a year-in-review of its European-focused activities to advance global regulatory science.

"We are pleased with the progress and continued development of our global efforts in the regulatory and data science spaces," said C-Path Europe's Managing Director Cécile Ollivier, M.S. "As our work builds on the successes of C-Path's 15-year presence in Europe, we look forward to strengthening partnerships in key areas with the greatest potential to accelerate global drug development in high unmet need areas and public health benefits."

In 2022, two Qualification Opinions were issued by EMA, one for the Type 1 Diabetes Consortium's enrichment biomarkers for T1D prevention clinical trials and one for the Transplant Therapeutics Consortium iBox Scoring System as a secondary efficacy endpoint in clinical trials investigating novel immunosuppressive medicines in kidney transplant patients.

Additionally, two Letters of Support were issued by EMA for the Critical Path for Parkinson's Consortium's Model-based Clinical Trial Simulation Platform for Parkinson's Disease and the Duchenne Regulatory Science Consortium's Model-based Clinical Trial Simulation Platform for Duchenne Muscular Dystrophy.

These Qualification Opinions and Letters of Support boost the continued transformation of trial design and drug development paradigms and bring C-Path's total number of EMA Qualification Opinions to nine, and an equal number of Letters of Support.

"It has been exciting to be a part of C-Path's growth in Europe," said C-Path Board member Tomas Salmonson, Ph.D., M.S., and former Chair of the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use. "Cécile and the teams at C-Path have done the hard work over the last year to ensure that C-Path is contributing advancements to EMA's Regulatory Science Strategy."

C-Path has always been committed to delivering the greatest opportunities for rapid improvement and global public health benefits. C-Path-led efforts to catalyze and accelerate tuberculosis drug development date back to 2010 and are currently concentrated in support of two programs under the Innovative Medicines Initiative's AMR Accelerator: European Regimen Accelerator for Tuberculosis (ERA4TB) and the Academia and Industry United Innovation and Treatment for Tuberculosis (UNITE4TB).

Additionally, as part of its International Neonatal Consortium, a C-Path global collaboration formed to forge a predictable regulatory path for evaluating the safety and effectiveness of therapies for neonates, C-Path has received fully anonymized electronic patient record (EPR) data from UK's National Neonatal Research Database (NNRD). It is NNRD's largest data transfer to date and the first time C-Path has received UK EPR data. This will contribute to a neonatal pilot project funded by a grant from the U.S. Food and Drug Administration to better understand and find treatments for bronchopulmonary dysplasia, a chronic lung disease which frequently affects premature infants.

Overall, C-Path's year-in-review highlights its continued commitment to advancing regulatory science and its efforts to optimize the drug development process through actionable tools and solutions. C-Path looks forward to continued partnerships and global efforts to fulfill its mission of accelerating the path to a

healthier world.

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, 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.

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