

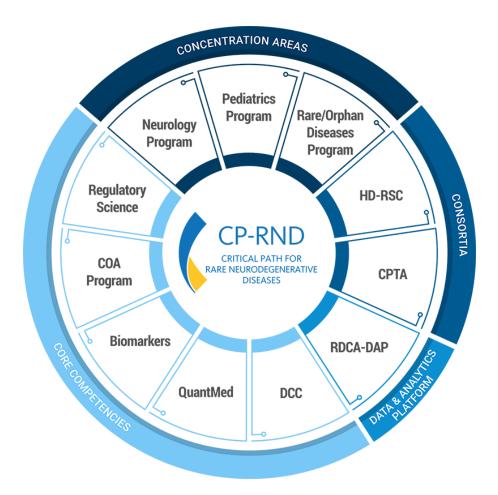
C-Path Awarded FDA Grant to Establish Public-Private Partnership to Advance Treatments for Rare Neurodegenerative Diseases



TUCSON, Ariz., Sept. 14, 2022 — <u>Critical Path Institute (C-Path)</u> has announced it will serve as the convener of the Critical Path for Rare Neurodegenerative Diseases (CP-RND), a new public-private partnership (PPP) to benefit people across multiple rare neurodegenerative diseases, supported by a grant from the U.S. Food and Drug Administration (FDA). The Agency announced the PPP today in a <u>press release</u>

"These innovative and collaborative approaches are needed to accelerate medical product development for the benefit of individuals living with these rare diseases, and their families," said Wainwright Fishburn, C-Path Board Chair. "I am thrilled about this partnership that will strengthen collaborations between C-Path, FDA and NIH, and bring together a diverse group of stakeholders."

C-Path's proven proficiencies will be leveraged to ensure the success of this effort, specifically the organization's track record in generating tangible solutions that have accelerated drug development in numerous diseases. This, together with the capabilities of its Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP ®) to integrate multiple patient-level data sources across rare diseases, will provide the foundation for leveraging advances in basic and clinical sciences, supported by NIH, and innovative regulatory science, supported by FDA.



In June, the FDA unveiled its <u>Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis (ALS)</u> — a five-year strategy for improving and extending the lives of people with rare neurodegenerative diseases, including ALS, by advancing the development of safe and effective medical products and facilitating patient access to novel treatments. The plan was developed in accordance with the provisions of the <u>Accelerating Access to Critical Therapies for ALS Act</u>, including the requirement to establish a public-private partnership this fiscal year.

"It is an honor for C-Path to be part of this transformative partnership with FDA and NIH. CP-RND will leverage all five of C-Path's <u>core competencies</u> — data management and standards, quantitative analytics and modeling, biomarkers, clinical outcome assessments and regulatory science — as well as C-Path's concentration areas from its <u>neuroscience/neurology</u>, <u>pediatrics</u>, and <u>rare disease programs</u>," explained Klaus Romero, M.D., M.S., F.C.P., C-Path's Chief Science Officer and Executive Director of Clinical Pharmacology. "This partnership with FDA and NIH will positively transform medical product development and make CP-RND a template for comprehensive and meaningful collaborative science."

As with previous PPPs at C-Path, CP-RND will provide a neutral environment for pre-competitive collaboration including, but not limited to industry, patients, advocacy groups, academia, non-profit organizations, and others, to come together and actively contribute to advance promising solutions for the benefit of these communities. To learn more about C-Path's CP-RND, visit https://c-path.org/programs/cp-rnd and contact the team at CP-RND@c-path.org.



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.

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 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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