C-Path and Tufts Medical Center Collaborate on EHR Data Transfer

The endeavor represents a major milestone for C-Path

TUCSON, Ariz., March 10, 2022 — Critical Path Institute (C-Path) and Tufts Medical Center have announced a collaboration to transfer electronic healthcare records (EHR) data to C-Path as part of the real-world data (RWD) effort to generate actionable real-world evidence (RWE) for neonatal drug development. This initiative, funded by a grant from the U.S. Food and Drug Administration (FDA), is being executed through a neonatal pilot project within C-Path's International Neonatal Consortium (INC). It is the first time C-Path has acquired EHR data.

The data contains more than 5,900 de-identified patient level datapoints and will be used to fulfill two clinical RWE aims of the effort. First is to generate generalizable reference ranges for neonatal laboratory values and second, to develop a disease progression model for bronchopulmonary dysplasia (BPD) — a chronic lung disease which frequently affects premature infants.

"C-Path and Tufts Medical Center have been collaborating on real-world data projects for years and it's beyond exciting to see the progress we've made as a team," said INC Executive Director Kanwaljit Singh, M.D., M.P.H. "Dr. Jonathan Davis has been at the forefront of this initiative and we're grateful for all he's done to prioritize EHR data as part of this endeavor. This event is a major milestone not just for INC but for C-Path as well. This is the first time ever an EHR dataset has been transferred and integrated by C-Path for creating drug development tools."

The generation of these RWE solutions will be led in partnership between INC and C-Path's Quantitative Medicine Program with support from its Data Collaboration Center. C-Path's Chief Science Officer and project Co-Principal Investigator Klaus Romero, M.D., M.S., F.C.P., added, "This project will accelerate addressing some of the most challenging unmet needs in the neonatal population by applying our core competencies in quantitative modeling, biomarkers, and regulatory science."

Patients and families of neonates will benefit from this project given that the data will enable use of laboratory values as actionable markers in neonatal trials. For BPD patients, it will help improve the understanding of the condition, how it progresses, what the risk factors are, and how these risk factors relate to long term outcomes such as the development of asthma. Importantly, it will lead to better and more focused patient enrollment for BPD trials — potentially leading to the development of novel drugs to treat this important condition.

The electronic health records shared by Tufts MC will be integrated with other patient-level RWD national registries and networks, as well as clinical trial datasets contributed by INC industry members. Each year in the U.S., 10 percent of neonates are born preterm, creating an urgent need to improve survival and outcome. However, there is minimal new drug development and most existing drugs have insufficient evidence to support safety, efficacy and dosage in this high-risk population.

In May of 2021, C-Path and Tufts MC announced a joint venture to integrate the first patient-level clinical trial data to generate actionable real-world evidence (RWE) for neonatal drug development, from real-world neonate data (RWD).

“This is the second data transfer between Tufts MC and C-Path and I applaud the team of scientists at C-Path that are making real advances in neonatology,” said Jonathan Davis, M.D., Chief of Newborn Medicine at Tufts Children’s Hospital, Associate Director of the Tufts Clinical and Translational Science Institute and Co-Principal Investigator. “Between EHR data and the previous clinical trial data transfer there is great promise to not only benefit the unmet needs of the neonatal population, but for other populations and therapeutic areas as well.”

C-Path’s INC will continue to partner with collaborators and new data contributors to integrate additional patient-level datasets. For more information on collaborating with INC, and how to contribute data, please email Christine Barry at cbarry@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.

CRITICAL PATH INSTITUTE

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 dozens of pharmaceutical and biotech companies. C-Path U.S. 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.

Contact:

Kissy Black
C-Path
615.310.1894
kblack@c-path.org