C-Path Announces Successful Conclusion of the eCOA: Getting Better Together Initiative

Collaboration has culminated in meaningful, lasting changes for the benefit of stakeholders in the electronic collection of clinical outcome assessment data in clinical trials

TUCSON, Ariz., March 26, 2025 – Critical Path Institute® (C-Path) Patient-Reported Outcome (PRO) Consortium and Electronic Clinical Outcome Assessment (eCOA) Consortium are pleased to announce the successful conclusion of the *eCOA: Getting Better Together Initiative*. This initiative, driven by a shared commitment to advancing patient-focused drug development, has culminated in meaningful, lasting changes that will benefit all stakeholders across the eCOA ecosystem.

Beginning in 2019, this C-Path-led collaborative, pre-competitive initiative brought together clinical trial sponsors from the PRO Consortium, as well as eCOA technology and allied service providers from the eCOA Consortium. This partnership focuses on identifying and addressing the root cause of issues with eCOA implementation in clinical trials. As a public-private partnership, C-Path's consortia lead pre-competitive projects and working groups like the *eCOA: Getting Better Together Initiative* in which scientists from global regulatory agencies participate. Through in-depth analysis, stakeholder engagement, and the development of targeted solutions, the teams have produced key resources that include:

- Best practice recommendations published in peer-reviewed journals focusing on user acceptance testing for systems designed to collect clinical outcome assessment (COA) data electronically, dataset structure and standardization to support drug development, and eCOA data changes
- A common lexicon among eCOA providers, sponsors, and regulators designed to reduce miscommunication, comprehension errors, and inefficiencies with terminology
- Stakeholder alignment on patient-centric approaches, resulting in more intuitive and accessible eCOA tools that enhance patient engagement and data accuracy
- Collaborative efforts to address regulatory considerations and streamline the path to approval for clinical trials that use eCOA technologies.

While C-Path will continue to address the need for continued, authoritative leadership in the eCOA and DHT ecosystems by driving collaboration to address key and unmet needs, the completion of the *eCOA: Getting Better Together Initiative* allows all contributors to acknowledge the successes of the effort, and also allow us to reframe our ongoing and future collaborations to move beyond those with a specifically operational focus. Through these broad-reaching collaborations with our Consortium Members, C-Path remains steadfast in its commitment to advancing patient-focused drug development.

"One of the greatest successes of the *eCOA: Getting Better Together Initiative*, beyond the significant improvements to ways of working and guidance in COA data collection, was in breaking down barriers between the key actors in this space, including sponsors, eCOA partners, and linguistic validation partners," said Kate Zarzar, Principal PCOR Scientist, Study Execution Franchise Lead, Genentech, a Member of the Roche Group. "It created a more open, collaborative environment and fostered a sense of shared ownership and accountability for the success of the COA space in support of patients. This will continue to yield dividends in years to come for the collection of patient-relevant evidence."

Paul O'Donohoe, MSc, Senior Director, eCOA Product and Science, Medidata Solutions, stated, "The *eCOA: Getting Better Together Initiative* has been a crucial catalyst for sponsors, vendors and regulators to truly collaborate in addressing some of the shared challenges we face in maximizing the potential of eCOA technologies. The rising tide of successes the initiative has sparked benefits the entire industry and sets the scene for real technology-driven innovations in the years to come."

"As a sponsor, being part of the *eCOA: Getting Better Together Initiative* has been an invaluable experience," said Trish Delong, MS, Associate Director, Patient Reported Outcomes, Johnson and Johnson Innovative Medicine. "This collaboration has allowed us to gain insights and experience with technology providers and regulators, aligning on solutions that streamline eCOA implementation and improve data quality. The progress we've made together is a testament to the power of collective action and shared vision in advancing patient-centric innovation in clinical trials."

Kate Zarzar, Paul O'Donohoe, and Trish Delong all served as members of the eCOA Leadership Team, a cross-consortia group that oversees the execution of collaborative efforts such as the *eCOA: Getting Better Together Initiative*.

For more information about the *eCOA: Getting Better Together Initiative*, please see the Q4 2024 report.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the FDA's Critical Path Initiative, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. **C-Path's mission is to lead collaborations that advance better treatments for people worldwide**. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

Media Contacts:

Roxan Triolo Olivas
C-Path
520.954.1634
rolivas@c-path.org

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