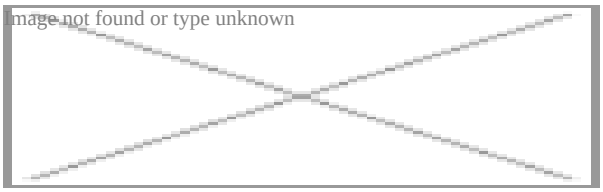
C-Path ePRO Consortium and PRO Consortium Announce COVID-19 Risk Assessment and Mitigation Strategies

Recommendations provided for sponsors and eCOA providers to facilitate the continued collection of PRO data in clinical trials.



TUCSON, Ariz., April 29, 2020 — In collaboration with Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium, the Electronic Patient-Reported Outcome (ePRO) Consortium announces "Coronavirus Disease 2019 (COVID-19): Risk Assessment and Mitigation Strategies for the Collection of Patient-Reported Outcome Data through Clinical Sites." The presentation focuses on the current challenges of capturing PRO data originally intended to be collected electronically (i.e., ePRO) from study participants during in-person visits to clinical trial sites. Recommended risk assessment and mitigation strategies are provided for consideration by trial sponsors and electronic clinical outcome assessment (eCOA) providers to facilitate the continued collection of PRO data in clinical trials.

Due to concerns surrounding COVID-19, many patients are either unable or unwilling to travel to sites for scheduled visits or sites have had to close due to social distancing measures. Representatives of ePRO Consortium and PRO Consortium member firms were invited by C-Path to collaborate on the development of recommendations aimed at lessening the impact of the disruption on PRO data collection at clinical trial sites. Over a one-month period, member representatives participated in a series of teleconferences to discuss and debate approaches to assessing the situation and effectively responding to it. The objective of the resulting presentation is to provide recommended risk assessment and mitigation strategies for consideration by sponsors and eCOA providers to facilitate the continued collection of PRO data in clinical trials. Topics include regulatory considerations, licensing considerations when altering the mode of administration of a PRO measure, and reporting protocol changes to the institutional review board.

"These mitigation strategies have led us to rethink traditional clinical trial data collection approaches and to recognize that technology, which has become increasingly important in clinical research, is available to support decentralized trials now and in the future," said Paul O'Donohoe, M.Sc., Scientific Lead, eCOA and Mobile Health at Medidata Solutions and Industry Vice Director of the ePRO Consortium.

"COVID-19 has impacted clinical trials in significant ways, and C-Path is proud to have supported the crucial conversations among eCOA providers and clinical trial sponsors that led to the roll out of strategies aimed to facilitate the continued collection of PRO data in clinical trials," said Sonya Eremenco, M.A., Acting Director, ePRO Consortium. "These strategies reflect the collective effort of both consortia to work together for the greater good, ensuring patient safety in these uncertain times."

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About C-Path's Electronic Patient-Reported Outcome Consortium

The Electronic Patient-Reported Outcome (ePRO) Consortium was established by Critical Path Institute in 2011. Along with C-Path, the members of the ePRO Consortium are firms that provide electronic data collection technologies and services for capturing patient-reported outcome (PRO) and other clinical outcome assessment (COA) data in clinical trials. The mission of the ePRO Consortium is to advance the science of clinical trial endpoint assessment by collaboratively supporting and conducting research, designing and delivering educational opportunities, and developing and disseminating best practice recommendations for electronic collection of clinical outcome data.

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About C-Path's Patient-Reported Outcome Consortium

The Patient-Reported Outcome (PRO) Consortium was formed in 2008 by Critical Path Institute in cooperation with the US Food and Drug Administration's Center for Drug Evaluation and Research and the pharmaceutical industry. The mission of the PRO Consortium is to establish and maintain a collaborative framework with appropriate stakeholders for the qualification of PRO measures and other clinical outcome assessment (COA) tools that will be publicly available for use in clinical trials where COA-based endpoints are used to support product labeling claims.

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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 dozens of pharmaceutical and biotech companies. C-Path US 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.

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