C-Path Receives FDA Qualification for the *Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C)*

TUCSON, Ariz., March 9, 2021 — Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium announces the qualification of the *Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C)* by the U.S. Food and Drug Administration (FDA). The *DIBSS-C* was developed by the PRO Consortium's Irritable Bowel Syndrome (IBS) Working Group to support symptom-based efficacy endpoints in clinical trials for products intended to treat constipation-predominant IBS (IBS-C) in adults. Qualification of the *DIBSS-C* represents a major milestone for the IBS Working Group and is the PRO Consortium's fourth clinical outcome assessment (COA) to be qualified through the COA Qualification Program within FDA's Center for Drug Evaluation and Research.

"The multi-stakeholder collaboration within the Critical Path Institute's PRO Consortium, inclusive of sponsors, patients, measurement experts and FDA has been critical in enabling the incorporation of the patient's voice in IBS drug development and product labeling. The availability of the *DIBSS-C* for use in IBS-C trials is a huge win for patients since it is aimed assessing the impact of treatment on symptoms that matter to them and informing their treatment decision-making for this burdensome condition," stated Robyn T. Carson, MPH, Vice President, Patient-Centered Outcomes Research, at AbbVie and co-chair of the PRO Consortium's IBS Working Group.

IBS is a chronic functional bowel disorder characterized by recurrent episodes of abdominal pain associated with alterations in bowel movements. Diagnosis of functional bowel disorders, like IBS, is based on symptom criteria because there are no consistent and reliable diagnostic biomarkers. Because these symptoms are subject to natural variability, the *DIBSS-C* was developed as a daily and event-based diary to facilitate the collection of reliable data in clinical trials evaluating treatments for this condition.

"The qualification of the *DIBSS-C* exemplifies FDA's commitment to the needs of the gastrointestinal illness community," noted Ceciel T. Rooker, President of International Foundation for Gastrointestinal Disorders and a participant in the IBS Working Group. "It is a clear indication that patient voices are being heard and a huge win for the community as a whole. IFFGD is proud to be a part of the PRO Consortium's IBS Working Group and we are excited to see the continued emphasis on meeting true patient needs by listening to patient voices."

The *DIBSS-C* signifies an important advancement in PRO assessment in drug development for IBS-C and reflects FDA's commitment to patient-focused drug development through qualification of COAs that capture valid, reliable, and meaningful data. Stephen Joel Coons, Ph.D., the PRO Consortium's Executive Director, affirmed that, "The qualification of the *DIBSS-C* is an incredibly gratifying achievement for the PRO Consortium. It is the result of a substantial amount of time and effort invested by C-Path, our industry partners, clinical and measurement consultants, FDA, and the patients who participated in this very

worthwhile project. The *DIBSS-C* has the potential to change the current measurement paradigm for assessing clinical benefit in treatment trials for IBS-C."

The IBS Working Group acknowledges the crucial contributions of its research partner, RTI Health Solutions, throughout all aspects of this process.

When available for licensing, further information will be available via c-pathcoas.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 55% funded by FDA/HHS, totaling $14,575,306, and 45% funded by non-government source(s), totaling $11,916,747. 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. For more information, please visit FDA.gov.

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.

The **Patient-Reported Outcome (PRO) Consortium** was formed in 2008 by Critical Path Institute in cooperation with the U.S. 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 assessments (COAs) that will be publicly available for use in clinical trials where COA-based endpoints are used to support product labeling claims.

Media Contact:

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