

Diary for Irritable Bowel Syndrome Symptoms-Constipation is the First Patient-Reported Outcome Consortium Measure Used to Support an FDA-approved Label Claim



TUCSON, Ariz., January 7, 2021 — Critical Path Institute’s (C-Path) Patient-Reported Outcome (PRO) Consortium announces that clinical study results using the Consortium’s *Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C)* were recently included in the expanded label for the drug LINZESS® (linaclotide). The *DIBSS-C* was developed by the PRO Consortium’s Irritable Bowel Syndrome (IBS) Working Group to support the evaluation of both primary and key secondary endpoints related to improvements in IBS-C signs and symptoms within the context of clinical trials and is currently in FDA’s Clinical Outcome Assessment Qualification Program. Although the *DIBSS-C* was not specifically mentioned, results from its abdominal symptom scale were included in the updated label for LINZESS®. This is the first time a PRO Consortium measure has been used to support a label claim.

“The multi-stakeholder collaboration within the Critical Path Institute’s PRO Consortium, inclusive of sponsors, patients, measurement experts and FDA has been critical in being able to incorporate the patient’s voice into a development program and product labeling. This is a huge win for patients to understand the impact of treatment on symptoms that matter to them and inform 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. The component of the *DIBSS-C* used to support the expanded LINZESS® label was the abdominal symptom scale, which assesses abdominal pain, abdominal discomfort, and bloating.

“The use of patient-reported outcomes to support a treatment’s label expansion reinforces 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.”

Further information about the *DIBSS-C* is available by contacting proadmin@c-path.org.

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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.



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 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.

Contact:

Kissy Black
C-Path
615.298.1144 x500
kblack@c-path.org