The Patient-Reported Outcome (PRO) Consortium at the Critical Path Institute (C-Path)

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The Asthma Working Group (WG) aims to obtain FDA qualification of a self-reported symptom diary for adults and adolescents with a diagnosis of mild to severe persistent asthma. The diary is intended for use as a co-primary or secondary endpoint in clinical trials aimed at establishing treatment benefit of asthma therapies. Participants in the WG include representatives from 11 PRO Consortium member firms, C-Path, and Adelphi Values. A panel of clinical experts provided advice at key points during the research process.

The WG completed a review of prior qualitative research which showed asthma was characterized by three core symptom domains: breathing symptoms (e.g., difficulty breathing, shortness of breath, wheezing), chest symptoms (e.g., tightness, pressure, pain), and cough-related symptoms (e.g., cough, mucus/phlegm).
The symptoms identified in the qualitative research are consistent with current guidelines for the diagnosis and management of asthma. A critical review of existing asthma symptom measures determined that none of them adequately assessed all of the core symptoms, which led to a decision to develop a new symptom diary.

To complement the findings from the literature, individual interviews were conducted with a sample of 55 participants to elicit both spontaneous and probed responses regarding their experience with asthma. Including a range of asthma severities, all participants had experienced asthma symptoms within three weeks of the interviews. Consistent with previous findings, the same core symptoms emerged. Based on these findings and input from clinical experts, draft items were developed and tested through three rounds of cognitive interviews.

The preliminary version of the measure, the Asthma Daily Symptom Diary (ADSD), includes nine items covering three symptom domains (i.e., breathing, chest, and cough). The ADSD is designed for completion in the morning and evening to capture variability of symptoms throughout a 24-hour period. Planned quantitative research will evaluate item function, test-retest reliability, and concurrent construct validity to inform further refinement of the ADSD prior to submission for initial FDA qualification as an exploratory endpoint measure.