

At the IBD Biomarker Summit, Hosted by the Crohn's & Colitis Foundation, C-Path Shares the Case for formation of an IBD Biomarker Consortium

At the IBD Biomarkers Summit, hosted by the <u>Crohn's & Colitis Foundation</u> on October 17-18, 2018, in Newark, N.J., Critical Path Institute (C-Path) highlighted the need for an Inflammatory Bowel Disease (IBD) focused consortium with the goal to qualify biomarkers as tools to support IBD drug development programs.

The two-day participatory event featured presentations and breakout sessions with preeminent IBD thought leaders from academia, industry, foundations, and regulatory bodies. Discussions highlighted the need for biomarkers in early-stage clinical studies, later-stage trials and clinical practice, and opportunities to address biomarker needs through emerging technologies such as transcriptomics and big data analysis. Other areas of focus included biomarker fundamentals, mucosal healing, quantitative imaging and endoscopy, molecular biomarkers, data integration and decision modeling. Breakout sessions facilitated opportunities for networking and collaboration among the participants.

C-Path's Biomarkers Program Officer, John-Michael Sauer, Ph.D., served on the summit planning committee and co-chaired a session titled, "Toward an IBD Biomarker Consortium," with the Crohn's & Colitis Foundation's Senior Director of Translational Research, Andrés Hurtado-Lorenzo, Ph.D. Brian Feagan, Senior Scientific Officer Gastroenterology/Clinical Research, Robarts Clinical Trials, began the session by discussing the case for an IBD biomarker consortium. Joseph Menetski, Associate Vice President, Research Partnerships at the Foundation for the NIH (FNIH) provided an historical perspective on the impact of biomarker consortia in other disease areas. And Dr. Sauer then provided an overview of C-Path's approach to forming consortia which often focus on qualification of biomarkers for use as tools to support drug development programs. Subsequent breakout sessions, which included C-Path's Nicholas M.P. King, M.S., and Chandler Birch, MBA, focused on the case for formation of an IBD biomarker consortium and the steps required to form a consortium.

C-Path's Crohn's Disease Biomarker Pre-Consortium (CDBpC) is currently working to understand the biomarker landscape in Crohn's disease by identifying drug development needs, aligning with specific regulatory needs and identifying biomarkers that support these needs. Biomarkers identified through these efforts will be evaluated by working groups comprised of CDBpC members to lay the groundwork for formation of a regulatory science-based Crohn's disease biomarker consortium. Anyone interested in joining the CDBpC should contact John-Michael Sauer at jsauer@c-path.org.