

C-Path's Romero Appears on The BioCentury Show



The graphic features a large portrait of Klaus Romero, M.D., on the left. To the right, the show's logo 'THE BIOCENTURY SHOW' is displayed in red and white, with a play button icon. Below the logo, it says 'with Simone Fishburn, Ph.D., BioCentury' and includes a small circular portrait of Simone Fishburn. A red banner contains the date 'AUGUST 24, 2023'. Below this, the text reads 'A CONVERSATION WITH KLAUS ROMERO, M.D.' and 'CSO and Executive Director of Clinical Pharmacology, Critical Path Institute'. A red play button icon is at the bottom right.

[Klaus Romero, Chief Science Officer at Critical Path Institute](#), occupies a rare role in the industry, as the top scientist in an organization whose mission is to solve industry-wide bottlenecks in drug development, with a path that leads directly to endorsement by FDA and other regulatory bodies.

[On the latest episode of *The BioCentury Show*](#), Romero discussed how C-Path works with various stakeholders, and breaks down their various requirements into scientific questions that lead to regulatory solutions.

C-Path was formed out of an FDA plan presented in 2004. It was incorporated in 2005 to create a neutral environment where pharma companies, academics and regulatory agencies can share information they otherwise couldn't, and solve major hurdles. Those stakeholders often have widely different perspectives and interests, even around a common goal. The emphasis is on the "neutral" territory.

"We totally are diplomats, and for those of us with a clinical background, that comes in handy for these conversations because it's like establishing a diagnosis," said Romero.

The task is to listen to the "headaches" of patient advocacy groups, industry, regulators and academics, and articulate the perceived bottlenecks into regulatory science terminology. "A lot of times, what's being voiced are symptoms of the underlying problem, but not the problem itself," said Romero.

For example, the complaint of needing a biomarker might not be the lack of a biomarker itself, but a lack of understanding or pathway for how to implement a biomarker in a properly designed trial.

One example was in polycystic kidney disease, where there was no specifically approved therapy to slow or stop disease progression. Part of the problem was there was no metric that would answer questions such as which patients to enroll in a trial. Solving it required building a quantitative machinery that could link the baseline total kidney volume information to projections and predictions of what would happen later in the disease.

Romero discussed the path to approval of a biomarker for polycystic kidney disease, how the organization works to support and advance issues for rare disease drug development and the issues involved in regenerative diseases where interventions need to take place early in life, but the benefit is observable only years later. He also discussed how C-Path is building machine learning and AI into some of its long-established competencies, such as model-informed drug development, as well as the difference he thinks it can make in understanding and deployment of real-world evidence.

[You can watch this episode of *The BioCentury Show*, here.](#)

*The BioCentury Show is sponsored by the BioCentury-BayHelix [East-West BioPharma Summit](#), which takes place in Cambridge, Mass., Oct 2-4. For information on how to sponsor *The BioCentury Show* and the *BioCentury This Week* podcast, please contact Sarah Shoaff at sarah.shoaff@biocentury.com.*