
C-Path CEO Klaus Romero Talks One to Millions on The BioCentury Show

In a new interview, Romero explains why the real bottleneck in individualized medicine isn't science anymore — it's the system needed to scale it.

Critical Path Institute (C-Path) CEO Klaus Romero, M.D., MS, FCP, joined The BioCentury Show to discuss how the One to Millions Initiative is working to scale individualized therapies for rare and genetically defined diseases.

As Romero explained, designing a therapy for an individual patient is no longer the hard part, science has already proven that's possible. The real bottleneck is the absence of a standardized regulatory and development system that can translate a single success into a repeatable pathway for many.

"We're not reinventing the wheel," Romero said. "We are trying to maximize what has been done into a joint movement that can meet the vision of what FDA laid out in the guidance."

One to Millions is working to give shape to FDA's Plausible Mechanism Framework, bringing together companies, academic institutions, patient groups, and regulators to standardize how evidence and methods are generated, shared, and reused across programs. It will begin with antisense oligonucleotides (ASOs), a relatively mature genetic modality with enough experience across programs to support cross-program learning, with a shared safety database among its first planned deliverables. The goal is to cut down on repeated preclinical studies, shortening timelines and lowering costs enough to make individualized medicine economically viable.

While rare diseases stand to benefit first, Romero said the long-term vision extends further, to any condition defined by a druggable genetic mutation rather than how common it is, pointing to Parkinson's disease, which is increasingly being segmented into mutation-based subtypes facing "a similar rare disease situation." Listen to the full episode via The BioCentury Show's YouTube channel below: