

Connecting the Dots: Advancing Drug Development on a Global Scale

This latest Critical Path Institute® (C-Path) podcast episode centers on the global strategy and impact of C-Path's regulatory science efforts. C-Path CEO and podcast host Klaus Romero welcomes C-Path Vice President of Global Affairs Cécile Ollivier. Cécile leads C-Path's global regulatory science initiatives from the organization's European headquarters in Amsterdam. The discussion highlights the importance of a worldwide presence to navigate diverse regulatory ecosystems, drive alignment between major agencies like the FDA and EMA and develop innovative drug development tools.

C-Path's collaborative approach includes regulators as partners early in drug development, to redefine the evidence-generation enterprise for the 21st century. This conversation addresses the strategic design of regulatory pathways tailored to the context of use and clinical impact, emphasizing incremental development stages for high-impact tools like the quantitative models used as external controls. Initiatives in global health illustrate how C-Path leverages its regional presence to coordinate data sharing and address heterogeneous populations with innovative methods, optimizing drug development timelines and outcomes. Cecile also discusses emerging plans, including the newly launched Disease Modeling Coalition dedicated to pediatric disease characterization and leveraging quantitative methods to reduce delays in pediatric drug approvals.



Highlights:

- C-Path's strategic global presence enables understanding of regional regulatory needs and facilitates global alignment.
- The importance of scientific alignment between FDA and EMA, despite jurisdictional differences.
- How Context of Use statements maintain consistent scientific foundations but adapt to regional regulatory requirements.
- How regulators act as enablers and collaborators, contributing to tool design and validation from inception.
- A rundown of the tailored regulatory strategies and staged pathway selection.

Listen Now: