New Paper in Nature Reviews Drug Discovery Highlights How to Maximize the Regulatory Impact of Consortium-Based Projects

The paper, by authors from IHI and the Critical Path Institute, highlights the importance of a structured, strategic approach to regulatory issues from the beginning.

BRUSSELS and AMSTERDAM, June 16, 2025 — The Innovative Health Initiative (IHI) and Critical Path Institute® (C-Path) today announced the publication of a peer-reviewed paper in *Nature Reviews Drug Discovery*, highlighting insights from multistakeholder global consortia launched over the past two decades to address barriers in drug development. Titled "Delivering regulatory impact from consortium-based projects," the paper presents a joint approach to addressing key challenges in developing tools to support regulatory decision-making.

Drawing on the experience of cross-sector partnerships, the authors stress that collaboration alone is not enough to achieve meaningful impact on accelerating drug development. Key aspects to maximize regulatory impact include early regulatory engagement, clear evidentiary standards, and long-term planning for data access and sustainability.

"This work emphasizes the urgency—and feasibility—of building globally coordinated, cross-sector efforts to drive innovation for patients who have long been underserved," said C-Path Vice President of Global Affairs Cécile Ollivier. "By aligning stakeholders and lowering technical and regulatory barriers, we can reshape the drug development landscape."

As regulatory science becomes more central to translating innovation into patient benefit, the authors highlight the importance of taking a structured, strategic approach to regulatory issues, starting from the earliest stages of project planning and running right through to the post-project stage.

"We are collectively working to turn exciting advances in health research and innovation into real benefits for people and patients," said Nathalie Seigneuret, Senior Scientific Project Manager at IHI. "Regulatory science is key to making this happen, and we hope that this paper will help projects deliver results that meet regulators' needs."

Aligned with the IHI guide for applicants and project consortia on regulatory considerations for IMI and IHI projects, the paper outlines priorities for implementation:

• A clear regulatory strategy defined at project start

• A tailored data management plan aligned with regulatory goals

• A sustainability plan to ensure post-project data availability

• Early engagement with regulators led by experienced collaborators

This paper reflects growing momentum for innovative and sustainable research whose results strive to accelerate medical product development and inform regulatory decision-making.

Read the full paper, here, and supplementary material, here.

About IHI

The Innovative Health Initiative (IHI) aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

IHI is a partnership between the European Union and European industry associations representing the pharmaceutical, medical technology, biotechnology, digital health and vaccine industries, namely COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe. IHI's total budget is EUR 2.4 billion. Half of this comes from Horizon Europe, the EU's research and innovation programme. The IHI industry partners have committed EUR 1 billion to IHI, and a further EUR 200 million can be committed by other organisations that decide to become Contributing Partners.

IHI builds on the successes of the Innovative Medicines Initiative (IMI), and the IHI Programme Office continues to manage the IMI project portfolio. For more information visit ihi.europa.eu and follow IHI on LinkedIn, Bluesky and Mastodon.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the FDA's Critical Path Initiative, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org and follow C-Path on LinkedIn, X, Facebook, Instagram, BlueSky and YouTube.

Media Contacts:

Catherine Brett
External Relations Manager
+32 2 541 8214
Catherine.brett@ihi.europa.eu

Roxan Triolo Olivas
C-Path
520.954.1634
rolivas@c-path.org