Conference Highlights Public Private Partnership Role in Medical Product Development

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Global organizations convene cross-sector thought leaders to discuss public-private partnerships

BETHESDA, MD, December 3, 2014—Today, the Critical Path Institute (C-Path) and Innovative Medicines Initiative (IMI) are convening an international group of thought leaders to identify new ways to collaborate and achieve a common goal of a robust regulatory science infrastructure that better supports efficient and productive medical product development. Accelerating the Development of Drugs, Diagnostics and Devices: Partnerships to Expand the Precompetitive Space is the second annual meeting of C-Path and IMI, and will explore key topics around partnerships to advance regulatory science, data-sharing and patient safety biomarkers.

“We are proud to partner with our colleagues at IMI to host a discussion on the role of public-private partnerships,” said Martha Brumfield, Ph.D., president and chief executive officer of C-Path. “No single entity has adequate resources, experience and data to tackle the complex issues in disease areas such as Alzheimer’s, Parkinson’s, schizophrenia, and diabetes. Global, collaborative efforts, along with the early engagement of regulatory authorities, advance innovation in these and other areas of unmet need.”

Public-private partnerships (PPPs) are at the forefront of a cross-sector effort to transform the expensive, time-consuming, high-risk and complicated process that delivers new treatment options. In its second annual conference, the two organizations will explore lessons learned with the PPP model and identify additional ways to leverage resources and avoid duplication of efforts.

“Collaboration is essential if we are to solve the biggest challenges in medicines development and to ensure patients gain rapid access to innovative therapies,” said Michel Goldman, M.D., Ph.D., executive director of IMI. “IMI and C-Path have been working together and sharing best practices for many years now, and this event represents an excellent opportunity to discuss how open collaboration models can contribute to solving medicine’s greatest challenges.”

Three separate panel discussions, moderated by C-Path and IMI, will draw on the perspective of government officials, researchers, regulators, and pharmaceutical industry representatives. The sessions include:

- Partnerships to Advance Regulatory Science and Leverage Global Biopharmaceutical Development will feature a discussion between Janet Woodcock of the U.S. Food and Drug Administration (FDA),

Dalvir Gill of TransCelerate BioPharma, William Chin of Pharmaceutical Research and Manufacturers of America (PhRMA) and David Wholley of the Foundation for the National Institutes of Health (FNIH).

- In session two, Safety Biomarkers: The Predictive Safety Testing Consortium (PSTC) and Safer and Faster Evidence-based Translation (SAFE-T) Collaboration conversation, John-Michael Sauer of C-Path and Michael Merz of Novartis will moderate a discussion with representatives from Merck, Sanofi, the FDA and European Medicines Agency.

- The third panel, Maximizing the Value of Data Shared by Multiple Organizations, brings together representatives from non-profit organizations and government to discuss ways to maximize the research utility of data.

PPPs have been successfully used to create new data standards and to identify biomarkers in several therapeutic areas, including pressing public health concerns such as Alzheimer's disease, tuberculosis and kidney safety. "These models are the future of drug development and while significant progress has been made, today's conversations will certainly push us forward," said Brumfield.

Michel Goldman added, "Public-private partnerships are now an established feature of the drug development landscape. Today's meeting will allow us to review what PPPs can do and how we can do even more to contribute to the development of the medicines of the future, for the benefit of patients and society."

Notes to Editors

The event will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814. It will also be possible to view the slides and hear the event audio via WebEx: https://pstcevent.webex.com/pstcevent/onstage/g.php?MTID=e6c6c0956270c0c4b7c3cc2d0f8ee970e

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About the Critical Path Institute

The Critical Path Institute (C-Path) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established seven global, public-private partnerships that currently include over 1,300 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org and at @cpathinstitute.

About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. It does this by facilitating collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators.

IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI has a budget of €3.3 billion for the period 2014-2024. Half of this comes from the EU's research and innovation programme, Horizon 2020. The other half comes from large companies, mostly from the pharmaceutical sector; these do not receive any EU funding, but contribute to the projects 'in kind', for example by donating their

researchers' time or providing access to research facilities or resources. For more information, visit www.imi.europa.eu and at @IMI_JU.

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