IMI Contact
Catherine Brett
+32 2 541 82 14
catherine.brett@imi.europa.eu

C-Path Contact:
Allison Schott
520 647 8380
aschott@c-path.org

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LEADING US AND EUROPEAN MEDICAL PUBLIC-PRIVATE PARTNERSHIPS ANNOUNCE AGREEMENT

Critical Path Institute and Innovative Medicines Initiative Collaborate on Development of Important New Drug Safety Tests

Tucson, AZ - The Predictive Safety Testing Consortium (PSTC) led by the Critical Path Institute (C-Path) and the Safer and Faster Evidence-based Translation (SAFE-T) consortium sponsored by the Innovative Medicines Initiative (IMI), announced today the signature of an agreement to work together in their efforts to improve drug safety.

Ensuring the safety of new medicines is a major challenge in drug development; too often, safety issues are only detected very late in development, when vast amounts of time and money have already been spent developing a potential drug. Sometimes, problems are only picked up after the medicine has been released to the market, and the drug has to be withdrawn. Both PSTC and SAFE-T are working on the development of new biomarkers to improve our ability to predict, diagnose, and monitor drug-induced injury to the liver, kidney, and vascular system.

“Increased collaboration between these leading consortia will create important synergies and lead to better results for both projects,” said Martha Brumfield, President and CEO for C-Path. “For example, work being done by both the PSTC and SAFE-T consortia will inevitably reduce duplication of work, synergize use of resources and expedite the development and regulatory qualification of new tools with key regulatory agencies, the U. S. Food & Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).”

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"The SAFE-T and PSTC consortia have already been collaborating informally for some time, and this formal agreement will allow the projects to enhance their cooperation, share expertise and resources, prevent the duplication of effort, and ultimately speed up the development of new tools to improve the safety of new medicines," said IMI Executive Director Michel Goldman.

Both consortia intend to qualify biomarkers that are more specific, more sensitive and more predictive than the currently available, traditional biomarkers and to gain regulatory acceptance for routine use of these biomarkers in preclinical and clinical drug development. These biomarkers show great promise in addressing deficiencies and gaps in drug development. Therefore, the two consortia decided to sign an agreement defining the framework and setting up an organization for further collaboration and exchange of information.

The proposed collaboration provides benefits and opportunities for the sponsors, stakeholders, and participants of PSTC and SAFE-T as follows:

- Cost sharing/cost reduction and greater speed/efficiency.
- Utilizing the complementary strengths of the 2 organizations. For example, leveraging the larger PSTC efforts in preclinical studies so that the clinical biomarkers being advanced by SAFE-T are adequately anchored with preclinical data.
- More effective and strengthened communication with the regulatory bodies with such benefits as coordinated submission of data for review by the regulatory agencies in US, EU and Japan, to assist in consistent decision making on the proposed safety biomarkers.
- Overall increase in scientific influence and awareness through joint communication efforts. Ability to cover a greater number of scientific meetings, joint publications,
- Generation of a more robust dataset with more rapid dissemination to clinical community and patient groups in US and Europe with the coordinated resources of both consortia.
- Increased likelihood of acceptance and application of these novel safety biomarkers.

In May, 2011, C-Path and IMI signed a Memorandum of Understanding (MoU) to further the missions of both organizations. IMI, based in the European Union, and C-Path, based in the United States, share similar objectives that accelerate the development of safer, more effective medicines for patients.

For more information please visit:

http://c-path.org/pstc.cfm
http://www.imi-safe-t.eu/

About The Innovative Medicine Initiative

The Innovative Medicines Initiative (IMI) is the world's largest public-private partnership in health care. IMI is improving the environment for pharmaceutical innovation in Europe by engaging and supporting networks of industrial and academic experts in collaborative research projects. The European Union contributes €1 billion to the IMI research programme, which is matched by in kind contributions worth at least another €1 billion from the member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative currently supports 40 projects, many of which are already producing impressive results. The projects are all working to address the biggest challenges in drug development, to accelerate the development of safer and more effective treatments for patients.

About Critical Path Institute

Established in 2005 as a non-profit organization, C-Path was formed with public and private philanthropic support from the University of Arizona, the US Food and Drug Administration (FDA), and the Tucson community. Additional funding has been provided by Science Foundation Arizona (SFAz). C-Path is committed to improving human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations around this mission, C-Path has established global, public- private partnerships that include more than 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and 41 major pharmaceutical companies. C-Path has headquarters in Tucson, AZ.

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