C-Path and IMI 2nd Annual Meeting

Accelerating the Development of Drugs, Diagnostics, and Devices: Partnerships to Expand the Precompetitive Space

Wednesday, December 3, 2014
Bethesda, MD, USA

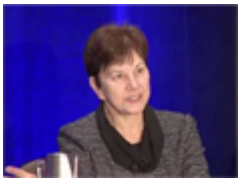
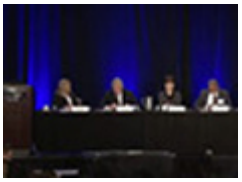
On December 3, 2014, the Critical Path Institute (C-Path) and Innovative Medicines Initiative (IMI) convened an international group of thought leaders to identify new ways to collaborate and achieve a common goal of a robust regulatory science infrastructure that better supports efficient and productive medical product development.

The meeting, Accelerating the Development of Drugs, Diagnostics and Devices: Partnerships to Expand the Precompetitive Space was the second annual meeting of C-Path and IMI, and explored key topics around public-private partnerships (PPPs) to advance regulatory science, data-sharing and patient safety biomarkers.

The organizations explored lessons learned from the PPP model and discussed the importance of leveraging resources and avoiding duplication of efforts. IMI and C-Path have been working together and sharing best practices for many years now, and, as IMI Executive Director Professor Michel Goldman characterized it, the event was “an excellent opportunity to discuss how open collaboration models can contribute to solving medicine’s greatest challenges.”

The ideas, goals, and progress discussed during the conference were subsequently featured in the January 15, 2015 issue of Biocentury Innovations in an article entitled “Consortium Crosstalk.”

Agenda	Event videos

8:45-9:00 am **Welcome with Martha Brumfield (C--Path) and Michel Goldman (IMI)**	 *Martha Brumfield* (C-Path)  *Michel Goldman* (IMI)
9:00-11:00 am **Session 1: Partnerships to Advance Regulatory Science and Leverage Global Biopharmaceutical Development** **Co-chair/Moderators:** *Martha Brumfield* (C--Path) and *Michel Goldman* (IMI) **Panelist:** *Janet Woodcock* (FDA), *Dalvir Gill* (TransCelerate BioPharma Inc), *David Wholley* (FNIH), *William Chin* (PhRMA) **Panel Discussion Topics:** • What have partnerships produced that could not have been accomplished by a single organization? • What metrics should be applied to evaluating partnerships? • What are the key challenges facing today's partnerships, and how can those challenges be optimally addressed? • What factors should be considered when partners prioritize projects? • How can newly formed partnerships leverage ongoing efforts of established partnerships? • How to ensure coordination?	 Session 1 – Introduction  *Janet Woodcock* (FDA)  *Dalvir Gill* (TransCelerate BioPharma Inc)  *David Wholley* (FNIH)  *William Chin* (PhRMA)  Session 1 – Panel Discussion

1:30-1:00 pm

Session 2: Safety Biomarkers: The PSTC and SAFE--T Collaboration

Co-chair/Moderators: *John--Michael Sauer* (C--Path) and *Michael Lawton* (Pfizer)

Panelist: *Denise Robinson--Gravatt* (formerly Pfizer), *Douglas Keller* (Sanofi), *John--Michael Sauer* (C--Path), *Michael Lawton* (Pfizer), *Ameeta Parekh* (FDA), *Maria Teresa De Magistris* (IMI SAFE--T), *Frank D. Sistare* (Merck), *Thorsten Vetter* (EMA)

Panel Presentations:

- The past: Key lessons learned from the SAFE--T/PSTC collaboration Denise Robinson--Gravatt (Pfizer)
- The present: benefits from the ongoing collaboration; preclinical and clinical qualification of markers for BSEP inhibition Douglas Keller (Sanofi)
- The future: How to build on a successful collaboration John--Michael Sauer (C--Path) and Michael Lawton (Pfizer)

Expert Opinion: *ShaAvhrée Buckman--Garner* (FDA)

Panel Discussion Topics:

- How has the SAFE--T/PSTC collaboration been set up?
- What has been achieved through this collaboration (e.g. Strategic benefits: capitalizing on synergies and improving regulatory interactions, a real--life example: preclinical and clinical qualification approaches of markers for BSEP inhibition)
- What are the key lessons learned from the SAFE--T/PSTC collaboration?
- What were major obstacles in setting up the collaborative agreement?
- What is needed to be more efficient in the future?
- How to build on a successful collaboration and what areas would benefit from more collaboration

Session 2 – Introduction

Denise Robinson--Gravatt (formerly Pfizer)

Douglas Keller (Sanofi)

John--Michael Sauer (C--Path)

Michael Lawton (Pfizer)

ShaAvhrée Buckman--Garner (FDA)

Session 2 – Panel Discussion

2:00-4:00 pm

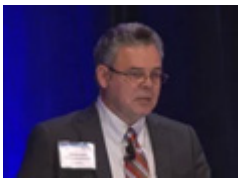
Session 3: Maximizing the value of data shared by multiple organizations

Co-chair/Moderators: *Enrique Avilés* (C--Path) and *Ann Martin* (IMI)

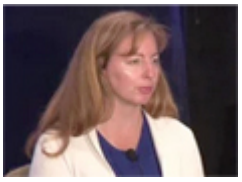
Panelist: *Sharon Hesterlee* (PPMD), *Kald Abdallah* (Project DataSphere), *Ed Bowen* (Pfizer, TransCelerate BioPharma Inc.), *Keith Elliston* (tranSMART Foundation), *Bron Kisler* (CDISC), *Mary Ann Slack* (FDA)

Panel Discussion Topics:

- What are the best methods to maximize the research utility of data contributed by multiple organizations to a collaborative effort?
- Success stories in analyzing & pooling data to yield new insights & tools
- Harmonization of approaches to data sharing/aggregating of data
- How to increase collaboration across existing data sharing initiatives
- Integrating Electronic Health Records into Clinical Trial databases

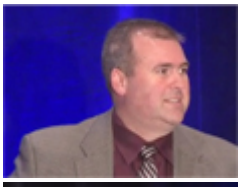


Session 3 – Introduction



Sharon Hesterlee (PPMD)

Kald Abdallah (Project DataSphere)



Ed Bowen (Pfizer, TransCelerate BioPharma Inc.)

Keith Elliston (tranSMART Foundation)

Bron Kisler (CDISC)

Mary Ann Slack (FDA)

Session 3 – Panel Discussion

4:00-4:30 pm

Closing Remarks: Identification of key next steps Michel Goldman and Martha Brumfield

Martha Brumfield (C-Path)

Michel Goldman (IMI)