COLLABORATING FOR CURES:
Leveraging global public-private partnerships to accelerate biopharmaceuticals development

First Joint IMI – C-Path meeting
Brussels 7 March 2013
Collaborating for Cures
Leveraging Global Public-Private Partnerships to Accelerate Biopharmaceuticals Development

Martha A. Brumfield, Ph.D.,
CEO and President
Critical Path Institute (C-Path)

7 March 2013 Bruxelles
C-Path: A Public-Private Partnership

- Act as a trusted, neutral third party
- Convene scientific consortia of industry, academia, and government for pre-competitive sharing of data/expertise
  - The best science
  - The broadest experience
  - Active consensus building
- Shared risk and costs
- Enable iterative EMA/FDA/PMDA participation in developing new methods to assess the safety and efficacy of medical products
- Official regulatory recognition through “qualification” of Novel Methodologies and Drug Development Tools and acceptance of data standards
Individual Companies or Research Institutions Will Not Solve Challenges to Medicine’s Future Alone

- No single entity has the answer
- De-risking development and regulatory pathways is critical

Different Model for Partnering is Needed

- Expertise from all sectors must be involved
- International participation is necessary
- Willingness to share critical information/data is required
Factors Impacting Future Success

- Resource constraints at all levels
- Consortia fatigue
- Organizational Structure and Governance
- Data Sharing and Learning from failures
- Communication among partners
- Culture
- Financing
- Incentives
- Risk Mitigation
- Respect for confidentiality
Shared learning can shorten the timeline

- Data Standardization and Sharing
- Biomarker Development and Qualification
- Outcome Assessment Measures
- Modeling and Simulation

Clinical Development Phase

- Phase I: safety; 20-80 healthy individuals ~ 1-2 years
- Phase II: efficacy, safety; 100-300 patients ~ 1-2 years
- Phase III: efficacy, safety; 1,000-3,000 patients ~ 1-2 years

Approval Phase

- Regulatory Agency Review and Approval ~ 1-2 years
- Post Approval

Safety Biomarkers and in vitro tools

Enrichment Biomarkers, Outcome Assessment Measures, and Modeling & Simulation Tools

Biggest impact on compressing the timeline when implementing all proposed initiatives
C-Path Consortia

Seven global consortia collaborating with 1,000+ scientists and 41 companies

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- Biomarkers
- Clinical Outcome Assessment Instruments
- Clinical Trial Simulation Tools
- Data Standards
C-Path Collaborators

Consortia Members

Partners
THANK YOU

C-Path gratefully acknowledges the support of
The Innovative Medicines Initiative: A driving force in the quest for new therapies

Michel Goldman, MD, PhD
Executive Director, Innovative Medicines Initiative
Innovative Medicines Initiative: Joining forces in the healthcare sector
Key concepts underlying IMI

“Non-competitive” collaborative research for EFPIA companies

Competitive calls to select partners of EFPIA companies (IMI beneficiaries)

Open collaboration in public-private consortia (data sharing, wide dissemination of results)
How IMI works – Project architecture

A Typical IMI Consortium

Private Investment

*in kind* (£ 1 billion)

EU Public Funding

*cash* (£ 1 billion)

EFPIA

Pharma 1

Pharma 2

Pharma 3

Pharma 4

Pharma 5

Pharma 6

ACADEMIA

SMALL AND MEDIUM-SIZED ENTERPRISES

PATIENTS’ ORGANISATIONS

HOSPITALS

REGULATORS
Ongoing IMI Projects
Key figures of ongoing IMI Projects

- 594 Academic & research teams
- 109 SMEs
- 363 EFPIA teams
- 9 patient orgs
- ~4500 researchers

Increased probability of success
Earlier patient access

€580.7 mln IMI JU cash contribution
€587.5 mln EFPIA ‘n kind contribution
Key challenges addressed

- Disease heterogeneity
- Lack of predictive biomarkers and tools
- Outdated clinical designs and regulatory processes
- Insufficient incentives for pharma industry and biotech companies
- Need for mindset shift in stakeholder communities
THANK YOU