

*Entrepreneurship in Life Sciences*  
*Rijeka, 25-26 April 2013*

***25<sup>th</sup> April 2013***  
***Rijeka Croatia***



Project funded by the EU

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# *Translational Medicine, Technology Transfer and IPR: Lessons from Europe (and beyond...)*

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T3I Ltd Oxford UK*



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# Over-view

- Translational medicine: 'bench to bedside' research
- Drivers of new models
- The emerging role of pre-competitive research and the PPP
- Examples of PPP initiatives in Europe and other countries
- The impact on IPR management
- The implications for TTOs and metrics





## “Translational medicine”

- An effort to carry scientific knowledge from 'bench to bedside'
- research where laboratory findings lead to the development of therapeutics for treating and preventing disease.
- Does this fit to a traditional model of Innovation?



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# Does translational medicine follow a pipeline model?

*The pipeline model of innovation assumes that reliance on high IPR enforcement and limited sharing are the best ways to facilitate further pharmaceutical innovation*

*TRUE?????*

Research

Development

Demonstration

Diffusion

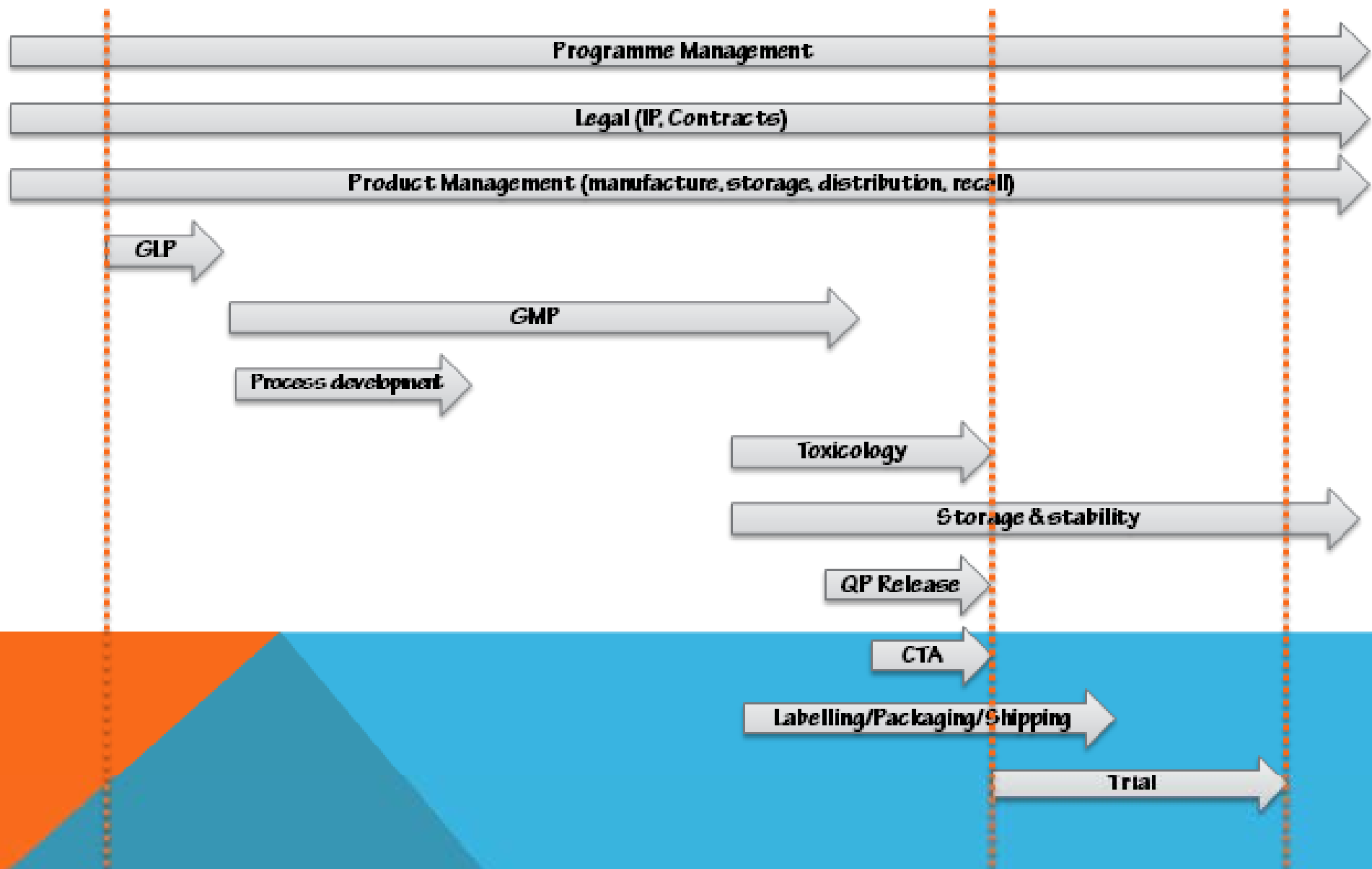


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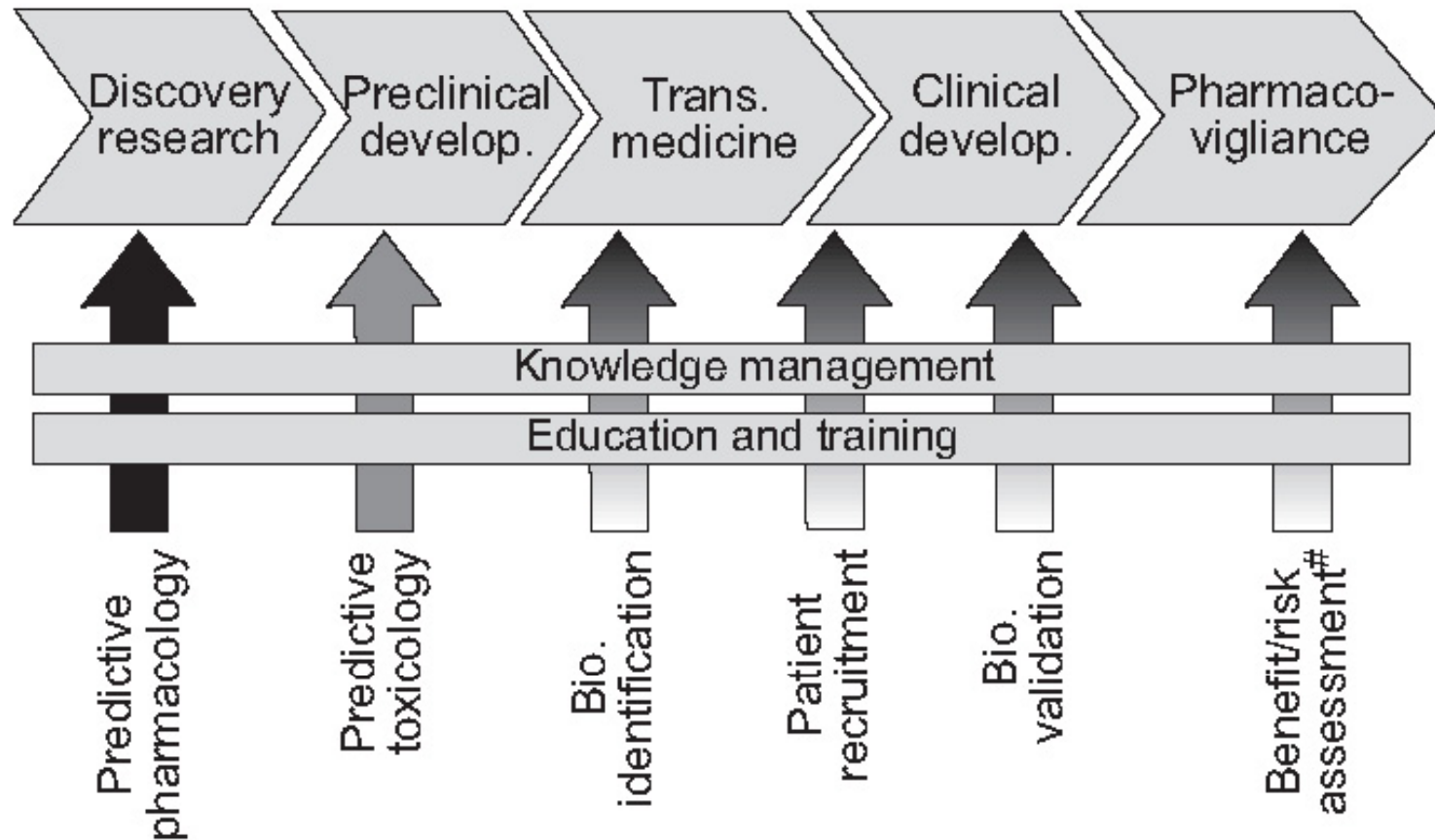
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# A ROADMAP FROM BENCH TO CLINIC





# Key bottlenecks in pharmaceutical and development process



*N. Kamet et al. 2012*



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# Center for Advanced Translational Science (USA) NCATS

*strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline in an effort to speed the delivery of new drugs, diagnostics and medical devices to patients.*



## *Policy issues*

- **Models for Precompetitive Collaboration**
- **Translational Research Policy**
- **Intellectual Property for Collaborative Projects**

<http://www.ncats.nih.gov>



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# Driving new models of innovation for drug discovery

## Drivers

- High costs
- Duplication of effort
- Diminishing levels of product development

## Collaborators

- Academia
- Industry
- Government
- Nongovernment organizations
- Patient organizations

*No single pharmaceutical company has the necessary breadth and depth of expertise and resource*

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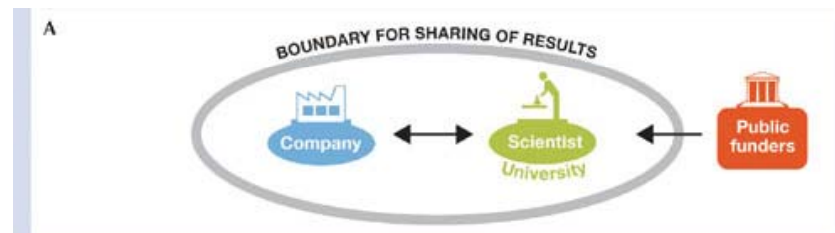
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# Pre-competitive research collaborations

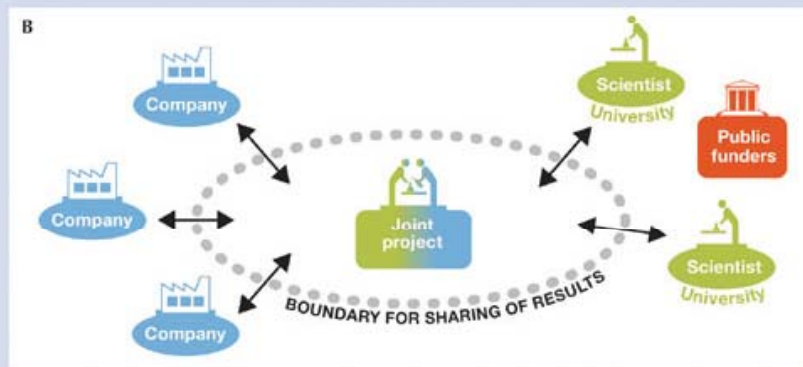
EMBOreports VOL10 | NO9 | 2009

Traditional model



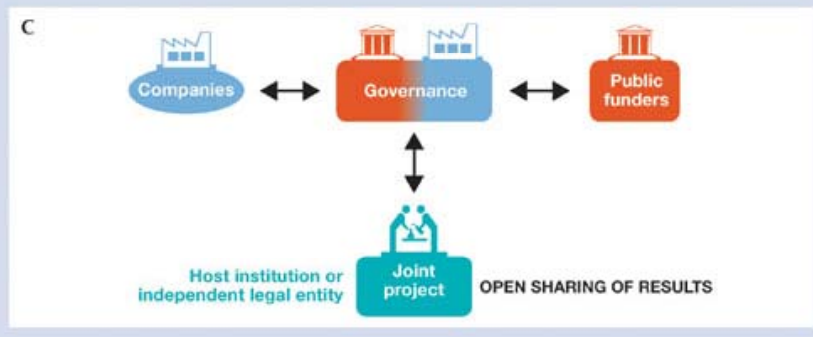
Closed collaboration between a company and an academic researcher. IPR owned typically by company.

Closed consortium model



Several parties contribute to a joint project. Results and/or intellectual property rights are normally retained by consortium members.

Open consortium model – public-private partnership



A joint project, governed by its funders, is carried out at a host institution or as a separate legal entity. Results are made freely ***available to allow research in the public domain.***



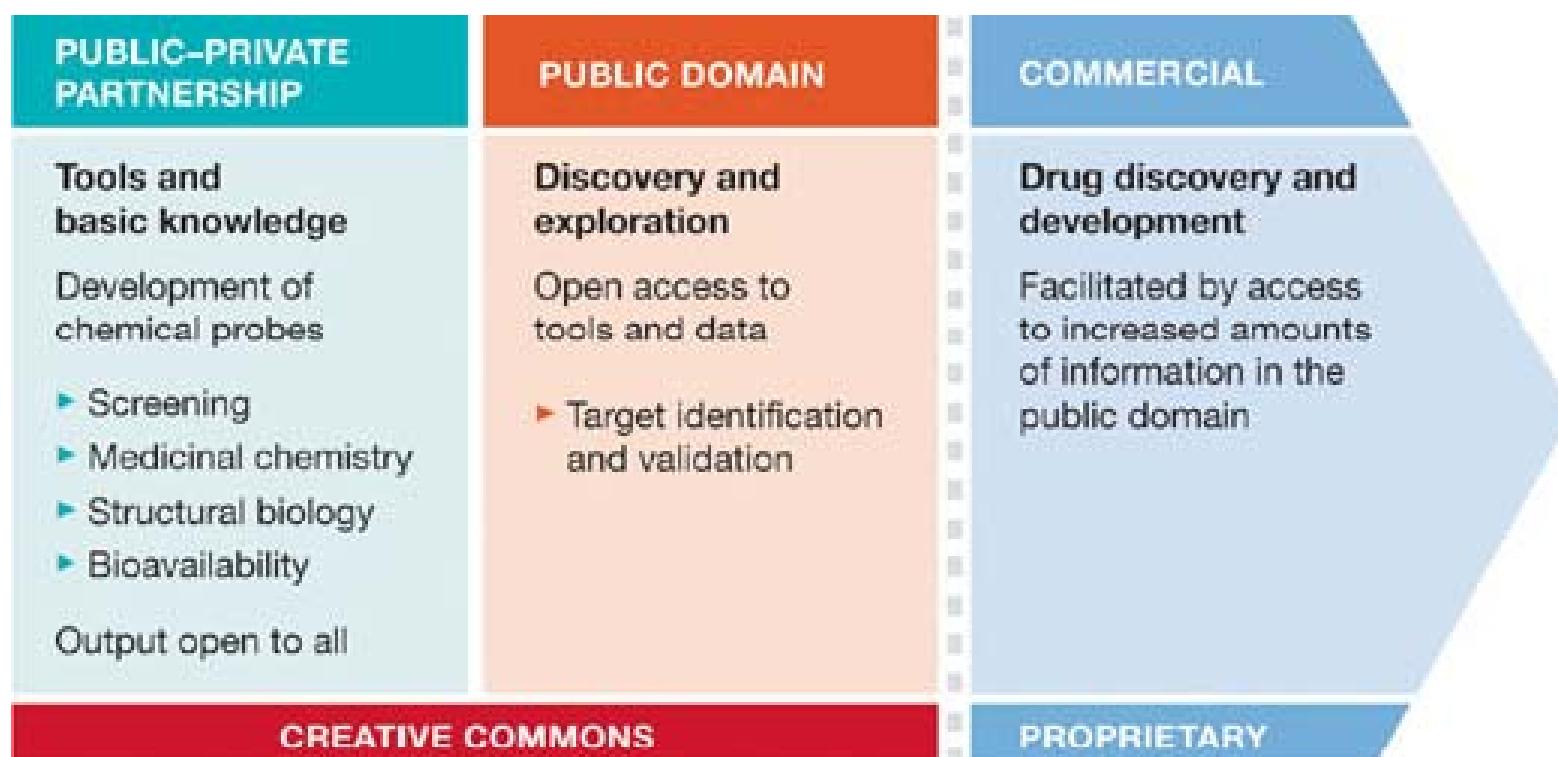
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# Pre-competitive research collaborations



Results—tools and data—are shared freely to facilitate further exploration and new discoveries.

Increased knowledge will allow commercial projects at a later stage with an increased chance of success.



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EMBOreports VOL10 | NO9 | 2009

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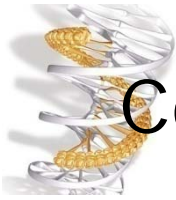
# Structural Genomics Consortium



- not-for-profit, public-private partnership
- engaged in pre-competitive research to facilitate the discovery of new medicines
- generating reagents and knowledge related to human proteins and proteins from human parasites
- Operates an **Open Access Model**



“The SGC and its scientists are committed to making their research outputs (materials and knowledge) available without restriction on use. This means that the SGC will promptly place its results in the public domain and will not agree to file for patent protection on any of its research outputs. It will seek the same commitment from any research collaborator.”



## Community resources: Jackson Laboratory JAX



JAX® Mice & Services  
**2013-14 Catalog**

Order today



*JAX ensures that donors accept a **research commons approach** for academics in return for JAX acting as a bridge between donors and industry*

*[www.jax.org](http://www.jax.org)*

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- TI Pharma is an non-profit organization
- provides governance for complex - often pre-competitive- partnership projects.

### **Independent research enabler:**

- transparency and reliability to collaborating partners
- fosters the realization of joint research goals.
- "Custodian of trust"





# Dutch research enabling group, Top Institute Pharma (TIP)

- “research projects are... focused on research that is difficult or impossible for individual companies to perform”
- PPP types:
  - (1) product development partnerships to develop products in areas of market failure, and
  - (2) knowledge development.



- <http://www.tipharma.com>



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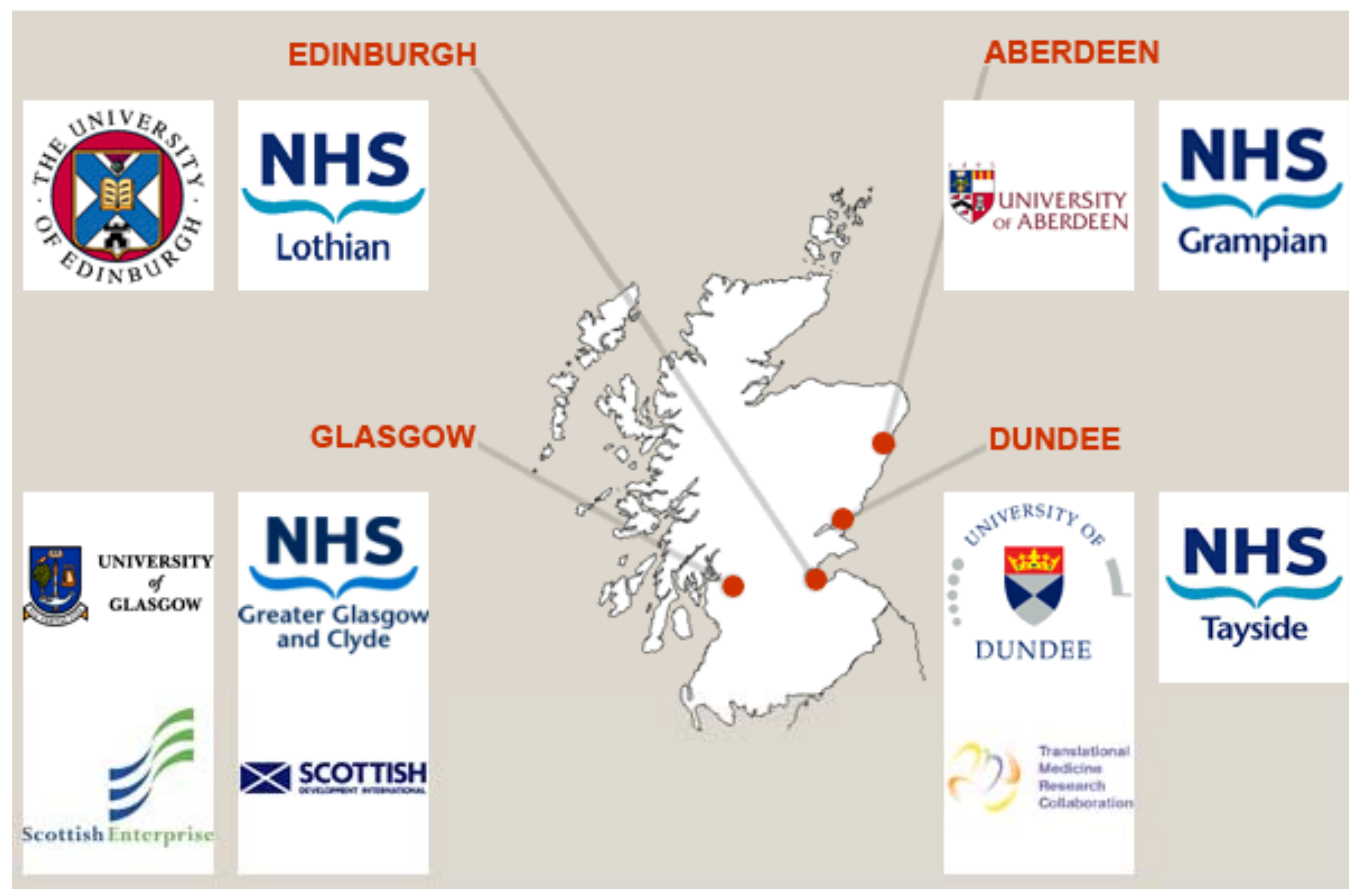
# TMRC Translational Medicine Research Collaboration



Translational  
Medicine  
Research  
Collaboration



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*Launched 2006*

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# TMRI

- Principal delivery and exploitation vehicle for the Scottish Translational Medicine Research Collaboration
- **Shared Goals, Shared Risks and ultimately Shared Rewards**



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# Innovative Medicines Initiative Europe



Innovative Medicines Initiative

- Europe's largest public-private initiative.
- Aiming to speed up the development of better and safer medicines for patients.
- Supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.
- A joint undertaking between the **European Union** and the pharmaceutical industry association **EFPIA**.



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# Innovative Medicines Initiative Europe



Innovative Medicines Initiative

- IMI The IMI Intellectual Property (IP) Policy governs the IP regime of all projects funded by the IMI
- To promote knowledge creation, together with its disclosure and exploitation
- To achieve fair allocation of rights
- To reward innovation
- To provide some scope of flexibility for participants to establish the most appropriate agreements serving the project objectives (-> Project Agreement, i.e. agreement between the participants)

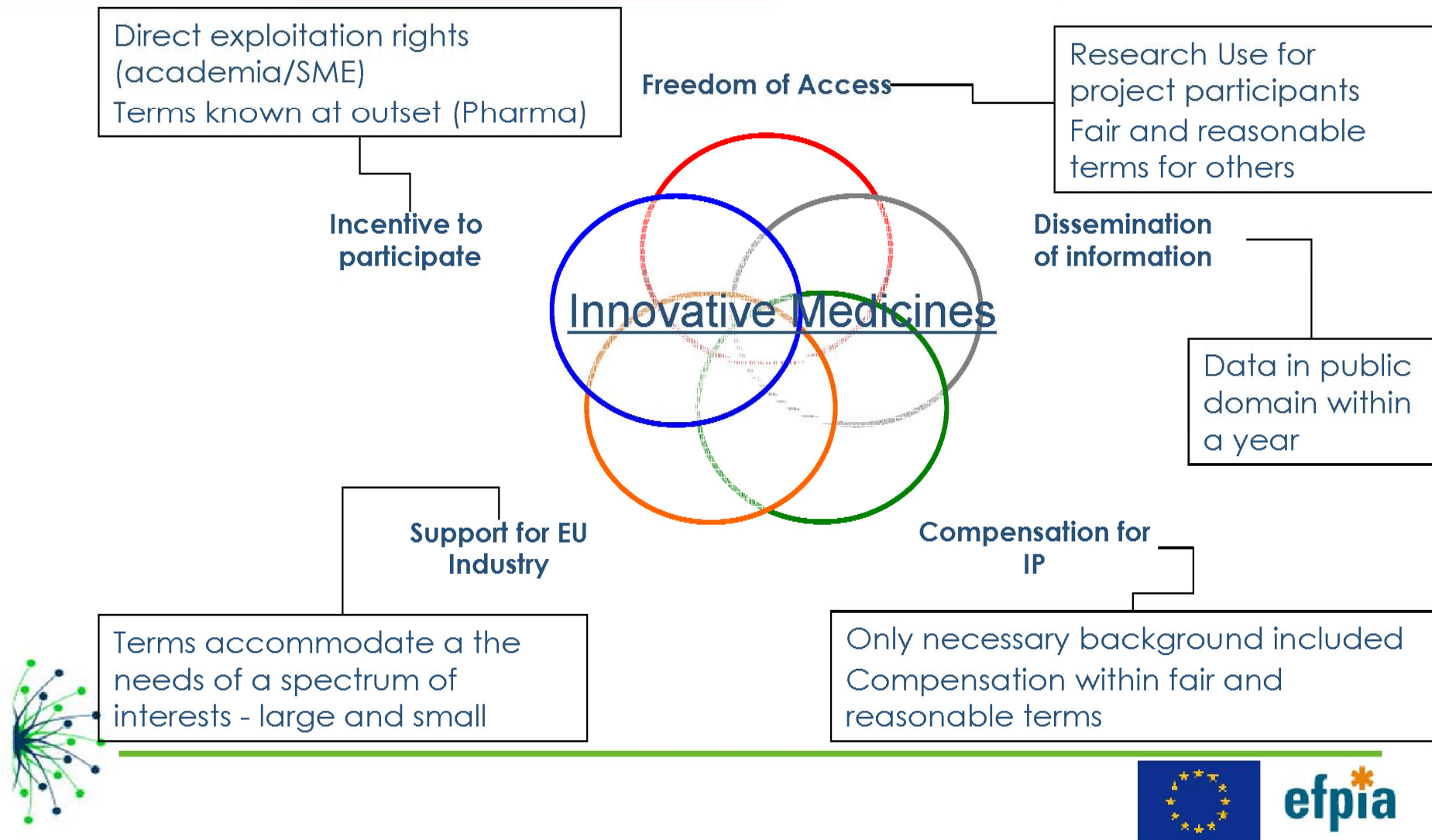


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# One policy, multiple interests





## Are PPPS the way forward?

- *It was once said that everything in life is a PPP  
'otherwise it is just an idea gathering dust on a shelf'  
Ruxandra Draghia-Akli*
- *There is a lot of value that PPPs can add; however **good governance** and the promotion of excellence is essential  
Willem De Laat*
- *The early achievements confirm that IMI is on track to achieve its goals Michel Goldman*
- *It is clear from what we have heard today that partnerships across regions and public-private initiatives are the way forward Lambert Van Nistelrooij*





# Enhancing Translational Research Collaborations - Rethinking IPR strategy?



Bubela et al *ScienceTranslationalMedicine.org* 22 February 2012 Vol 4 Issue 122



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<b>Knowledge system</b>	<b>Public domain</b>	<b>Common pool resources</b>	<b>Open source</b>	<b>Open access</b>	<b>Open innovation strategies</b>		<b>Closed innovation</b>
<b>Goal</b>	Access to knowledge; minimal transaction costs	Creation of resources of research tools and databases within a managed environment	Construction of a web of users who share knowledge and materials through legal agreements	Creation of norms to facilitate access to knowledge and collaboration	Facilitation of knowledge exchange about IPRs or trade in patents and other IPRs	Facilitation of Joint Research Partnerships	Maximal control over all stages of research through product development and marketing
<b>IP strategy/mechanism</b>	IPRs expired or ineligible. Specific public domain dedication	Licenses/simple agreements balance access with other considerations such as resource sustainability (such as cost recovery), sensitivity (animal welfare, safety, and confidentiality), and attribution	Viral licensing mainly for copyrighted material. Improvements shared under the same open terms as applied to original	Collaborators and funders create clear rules on how knowledge is produced and used and enforce those rules. Does not necessarily rely on IPRs	Internet communications platforms on licensing and partnerships; auctions; exchanges; patent pools; clearinghouses	Exchange programs, research alliances, public-private partnerships	Vertically integrated firms reliant on strong IPR protection, including patent, trademark, and data exclusivity
<b>Use</b>	Data/databases	Research tools/databases	Software and other copyrighted material	Research tools and data	Patented inventions available for licensing	Precompetitive research	Research, product development, and marketing
<b>Examples</b>	GenBank; Mouse Genomics Informatics (MGI)	JAX Mice; European Mutant Mouse Archive; International HapMap Project; SAGE Data Repository	Linux; BioBricks; BiOS	Structural Genomics Consortium	Flintbox; BIO Ventures for Health; Medicines Patent Pool; MPEG LA clearinghouse for molecular diagnostics	Innovative Medicines Initiative	Traditional pharmaceutical business model

*Bubela et al* **ScienceTranslationalMedicine.org** 22 February 2012 Vol 4 Issue 122



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## 'Technology transfer' metrics and KPIs

Intermediate input-output measures e.g.:

- # Invention disclosures
- # Patents filed and
- Licensing re
- # Spinout
- Encourage a ... and the treatment of T



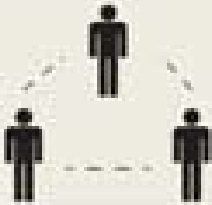
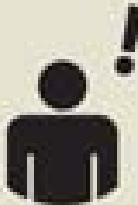


Research

Development

Demonstration

Diffusion



	Input	Process	Output	Outcome
<b>Networks</b> 	Number and diversity of partners	Exchange of information between partners	Number of projects continued after PPP funding	Number and size of new partnerships inspired by PPPs
<b>Know-how</b> 	Formal knowledge sharing; for example, background IP in consortia	Knowledge sharing through percentage of personnel exchanged and number of consortia meetings	Number and citation score for joint publications	Number of products in clinical development based (partially) on knowledge generated in PPPs
<b>Human capital</b> 	Number of experts involved, number of highly cited researchers	Percentage of researchers trained via PPP-specific courses	Number of completed PhDs and postdoctoral positions	Percentage of trained researchers working in R&D positions in the sector
<b>Financials and operations</b> 	Total research funding available in partnership	Percentage of researchers and staff using intranet on a regular basis	Percentage of milestones achieved in consortia	Return on investment after 5 years at industrial partners and in start-ups

*Nature Reviews Drug Discovery | AOP, published online 30 March 2012*



# Conclusions

- Translational medicine requires new models of innovation and IPR management for optimum operation
- Pre-competitive research collaborations require clear negotiations around IPRs as both inputs and outputs of the collaboration
- Harnessing the 'potential' of Public Private Partnerships (PPPs) can help put Europe at the forefront of pharmaceutical research and development.
- Focus on IPR Management and not IPR regimes
- Rethink associated metrics to measure impact





## *Comments and Questions?*

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