From Research to the Pharmaceutical Market

PERFORMANCE SYSTEMS

"Are there any appropriate systems?
What do they need to be more effective?"

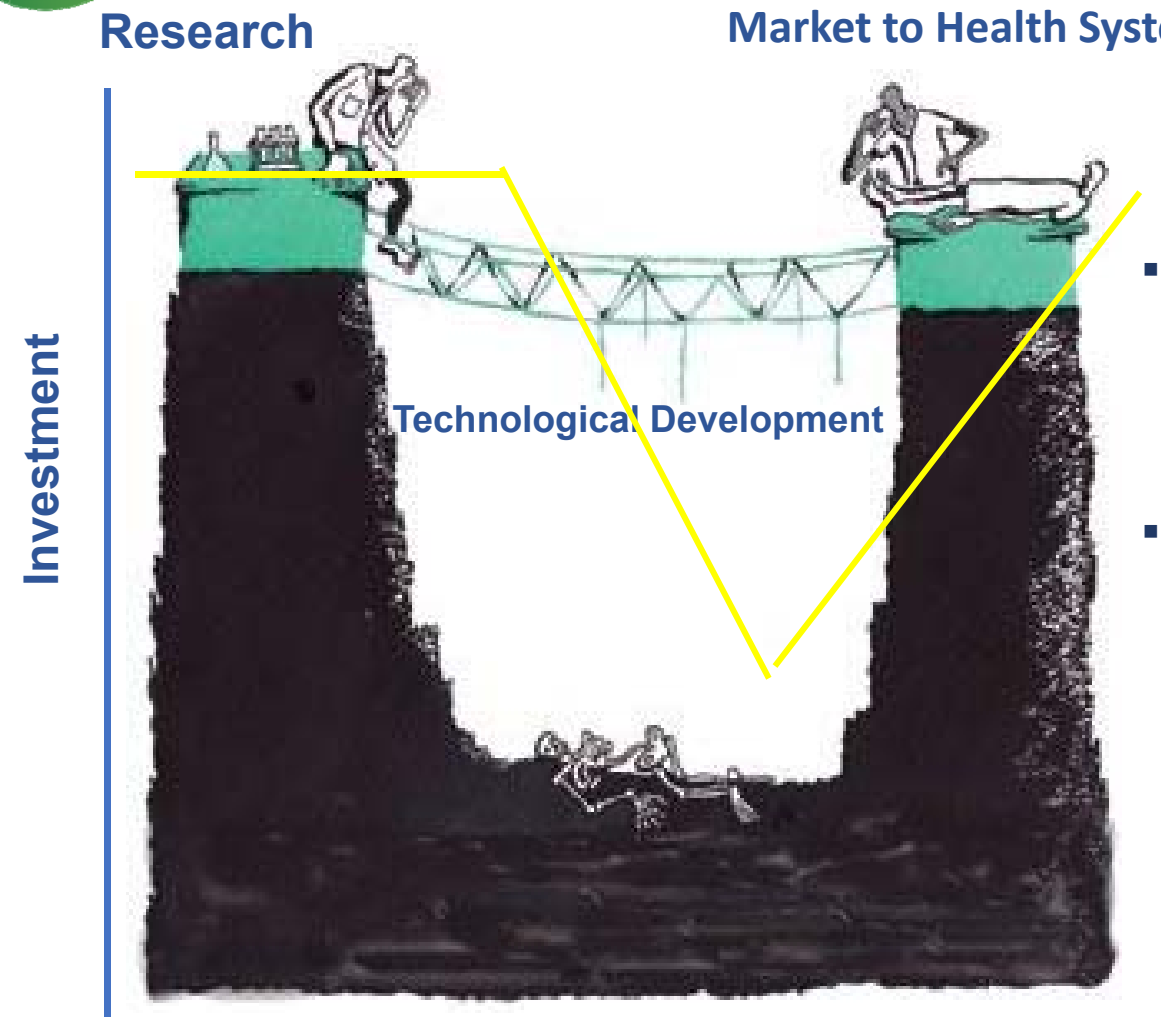
Francisca Vicente, PhD (Fundación MEDINA)

10 YEARS 2008-2018

FUNDACIÓN CENTRO DE EXCELENCIA EN INVESTIGACIÓN DE MEDICAMENTOS INNOVADORES EN ANDALUCÍA

26 September 2018

Crossing Valley of Death



- The process of translating basic research into a viable product is called "Valley of Death.
- NIH defines it as the period of transition when a developing technology is seen as promising, but is too new to validate its commercial potential and unable to attract the necessary funding for its continued development.

News Nature, 2008

Understanding Valorization

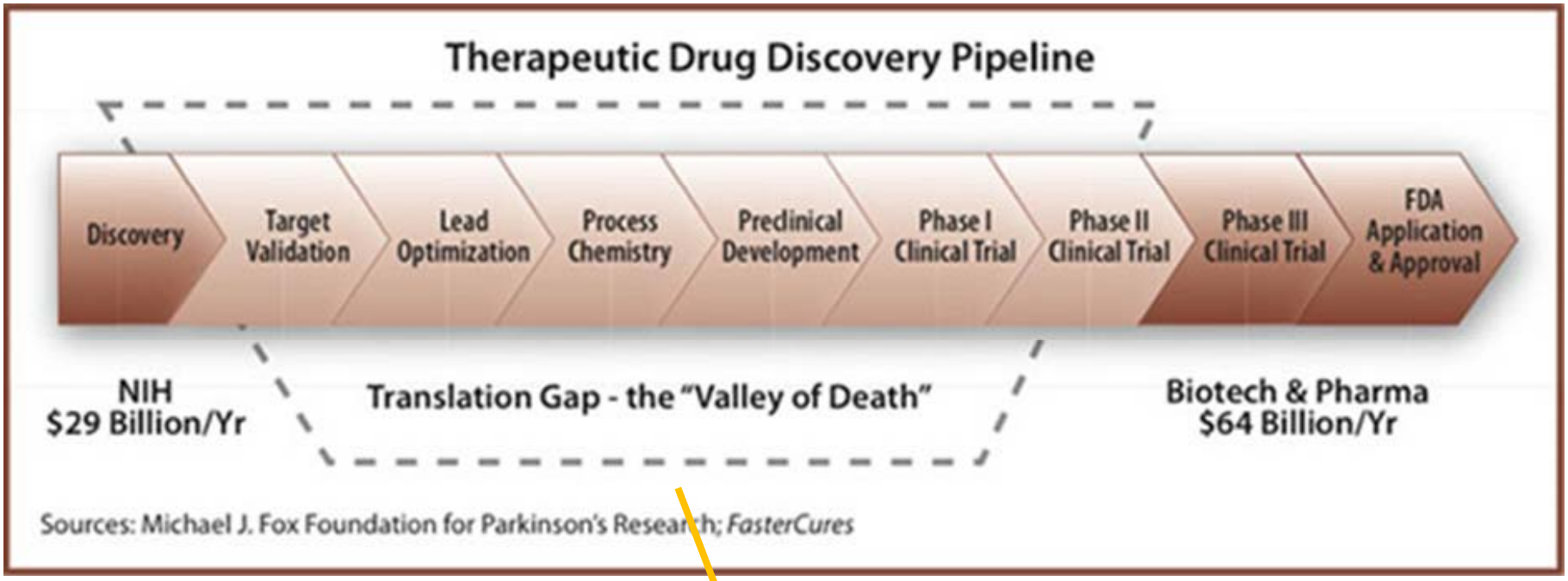
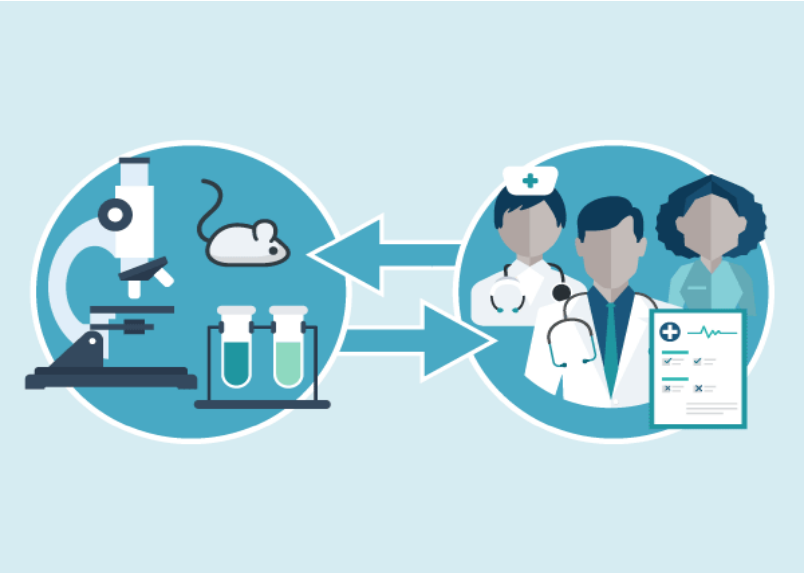


Illustration courtesy of FasterCures

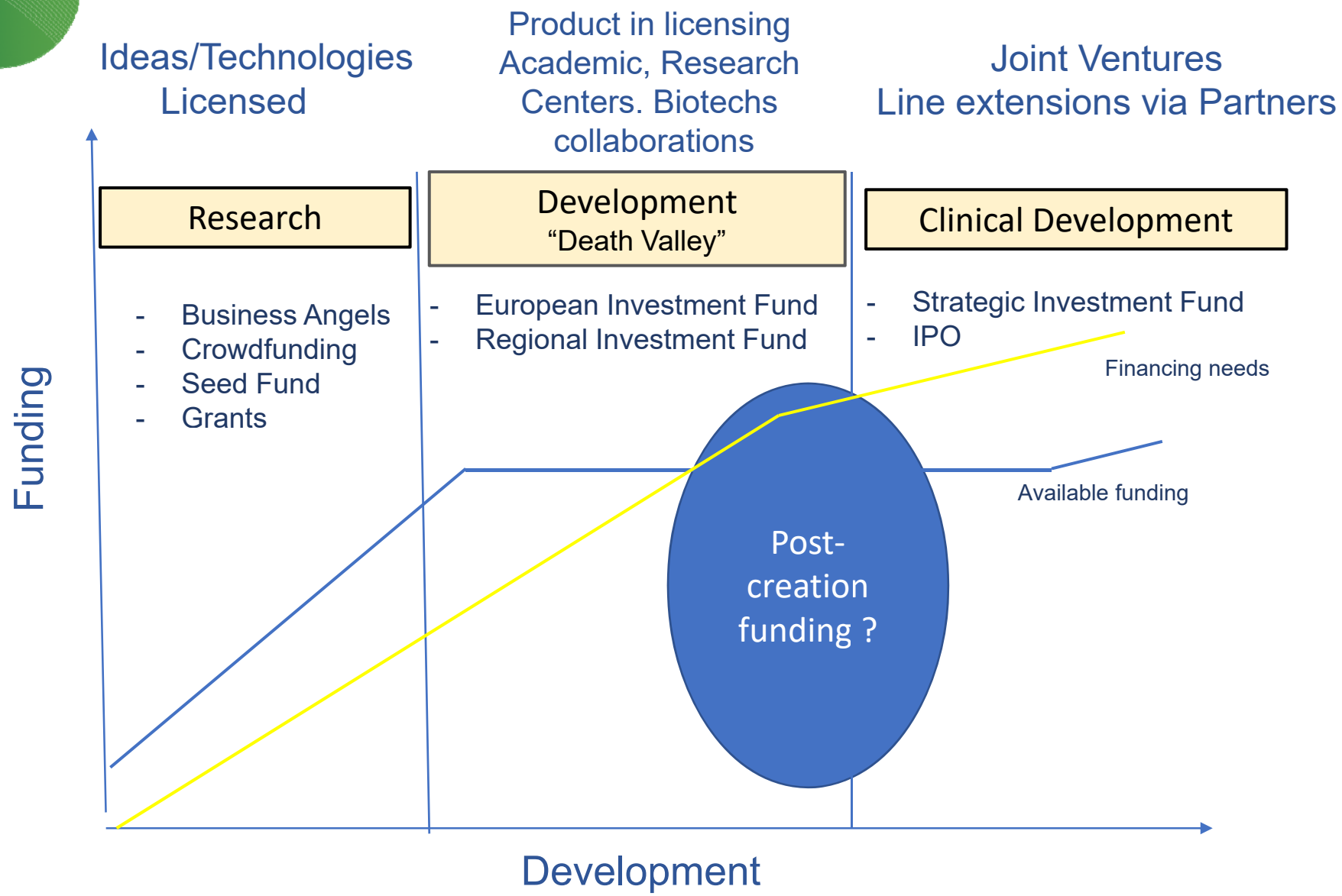
Attempt to bridge the gap with “Translational Research”.
It puts research findings to productive use for the benefit of human

Translational Research- Phases

- ✓ Developing new diseases treatments, drugs, and equipment based on basic science discoveries: “bench to bedside”
- ✓ Separate clinical research to clinical practice
- ✓ Clinical practice to broader community improvements



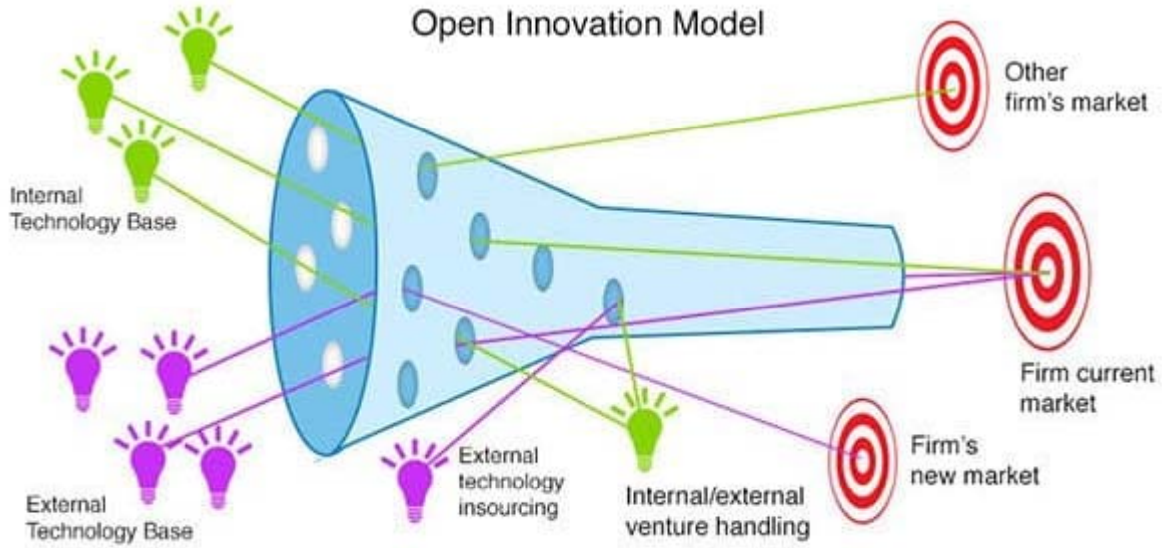
R&D Systems


Ideas/Technologies
Licensed
Product in licensing
Academic, Research
Centers. Biotechs
collaborations
Joint Ventures
Line extensions via Partners
Research
Development
"Death Valley"
Clinical Development
- Business Angels
- Crowdfunding
- Seed Fund
- Grants
- European Investment Fund
- Regional Investment Fund
- Strategic Investment Fund
- IPO
Financing needs
Available funding
Post-
creation
funding ?
Funding
Development

Current Research Infrastructures

Open innovation models & public-private partnership (PPP):

- ✓ Sharing capabilities
- ✓ Risks
- ✓ Funding
- ✓ Intellectual property
- ✓ Globalized environment
- ✓ Different co-development models

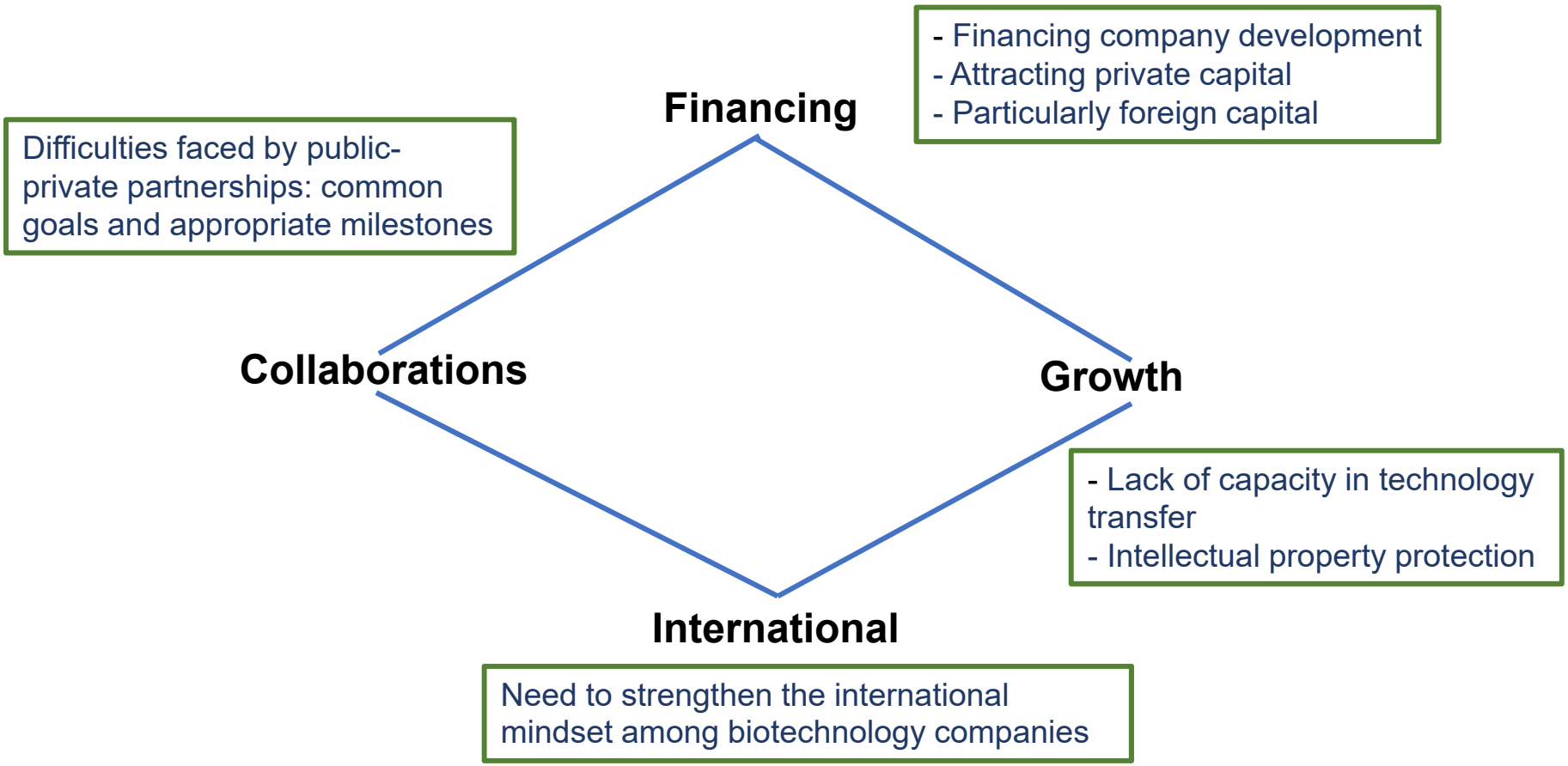


Translational Infrastructures

- US.- **NIH** - Clinical and Translational Science Centers (**CTSCs**)
- BRITAIN.- **Medical Research Council´s and National Institute for Health research with its NIHR** Office for Clinical Research Infrastructure (**NOCRI)**
- EUROPE.- **RIS, EATRIS, ECRIN -** Biomedical Translation Hubs across Europe

- **Avoid duplications**
- **Consolidate** global leadership through connection between **excellence and innovation**
- **Standardize processes**
- Pool **resources and synergize** efforts
- Drive **co-development models** in open Innovation for **advancing biomedical science** in the value chain

Identified Areas of Improvement



Challenges

- EU funding programmes should help **remove bottlenecks** in a coherent manner.
- Research funds should **support applied innovation projects**.
- **Private sector investment and new approaches** should be encouraged.
- Europe needs to **accelerate market access for new medical products**.

"Innovations can be realized with a more value-driven and market-oriented focus, so that regulations and costs are less important as barriers to change."

Guy Lebeau, chairman of the European Medical Technology Industry Association, EUCOMED

Finance-Improvements

- More direct public **investment in life science VC funds** is needed.
- Alternatively a new **life sciences 'fund of funds'** could be created with **European support**.
- The European Investment Bank could help to **leverage the investment of the LPs with specific financial instruments (e.g. guaranties).**
- Europe's institutional investors encouraged to allocate investments to life sciences VC **removing disincentives to investing in European healthcare VC.**
- **Venture philanthropy or public private partnerships** should be encouraged.
- **Increase awareness and advocacy** to bring more sources and types of investors into the sector.

EU Funds-Improvements

- **Simplification of framework programmes** to encourage SME involvement.
- More **experts evaluating** project proposals should have **industry experience**.
- More funding for '**applied innovation**' small projects.
- Funding **proof of concept projects, pre-commercial development, clinical trials..**
- **Funding lines** should be available to **single companies or universities**.
- **Collaborative projects** should enforce, making it **compulsory, exchanges and integration,** to magnify knowledge and skills transfer.
- **Enforce/improve/broaden public-private partnerships** (IMI), in fields where big pharma and VC money is not available but there is a clear medical need.

Technology Transfer

- **Training and capacity-building of Europe's** current technology transfer officers.
- **Recruiting and retaining professionals** with the right **mix of expertise**.
- **Secondments and exchanges** between **industry and technology** transfer **offices**.
- **Development of networks** within the **life sciences** sector and sustain/promote **incubators.**
- **Funding of IP** to protect European universities' and institutes' **intellectual property.**
- **Building on, and increasing**, current **European Investment Fund technology transfer funds.**

Clinical Development

- **Regulatory clinical trial** design should be better tailored to **personalized medicines**.
- **Reform finance support** systems to better **suit life-sciences and healthcare SMEs.**
- Take **advantage of scientific progress** (e.g. in diagnostics) to **rationalize healthcare spending**.

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Thank you !!!

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