Translation of Biomedical Research from the Academy

Manuel Fresno
Centro de Biología Molecular Severo Ochoa CSIC-Universidad Autónoma de Madrid
DIOMUNE,
manuel.fresno@uam.es, mfresno@diomune.com

Traslation of Biomedical Research from the Academy: where do we stand?

- Types/mechanisms of translational research
- Factor affecting the translation
  - Professional
  - Social
  - Clinical
  - Industrial
  - Economic

Typesof translational research by Academia

- Technical assistance activities
- Specialized training and personnel training
- The Research (R) in Academia has applied potential (D)
- Patents , models and inventions
  - Sell, license to a company
  - **R+D Company**
- Join ventures (Open Innovation)
  - Important differences depending if the initial idea is coming from the Academia or from industry
  - **R+D Company+ Academia**
  - **Development (Company)**
- SpinOff
  - **R+D Inventor/Academia**

Academic Spin-Offs

- Agile instruments of knowledge transfer.
- Legal regulation is not well defined and does not favor the development of business initiatives as much as it should.
- There is no standard model of participation of the university and in the creation of Technology-Based Companies. Depend on each university, the business and social environment, as well as the support of Public Administrations.

Whycreate a spin-off?

- **Theentrepreneur**
  - ***Will be able to continue developing the technology that was her/his idea***and generated in the university until the final product,
  - Hire very valuable research personnel
  - obtaineconomicyields of theprocess.
- **University**
  - Will be able to promote its work of transfer of contracts with the spin off of investigations that if they do not reach the market will not bring you monetary benefits.
- **Society**
  - Will benefit from the skilled jobs that generate the spin off, the taxes they pay and the innovative products they develop.

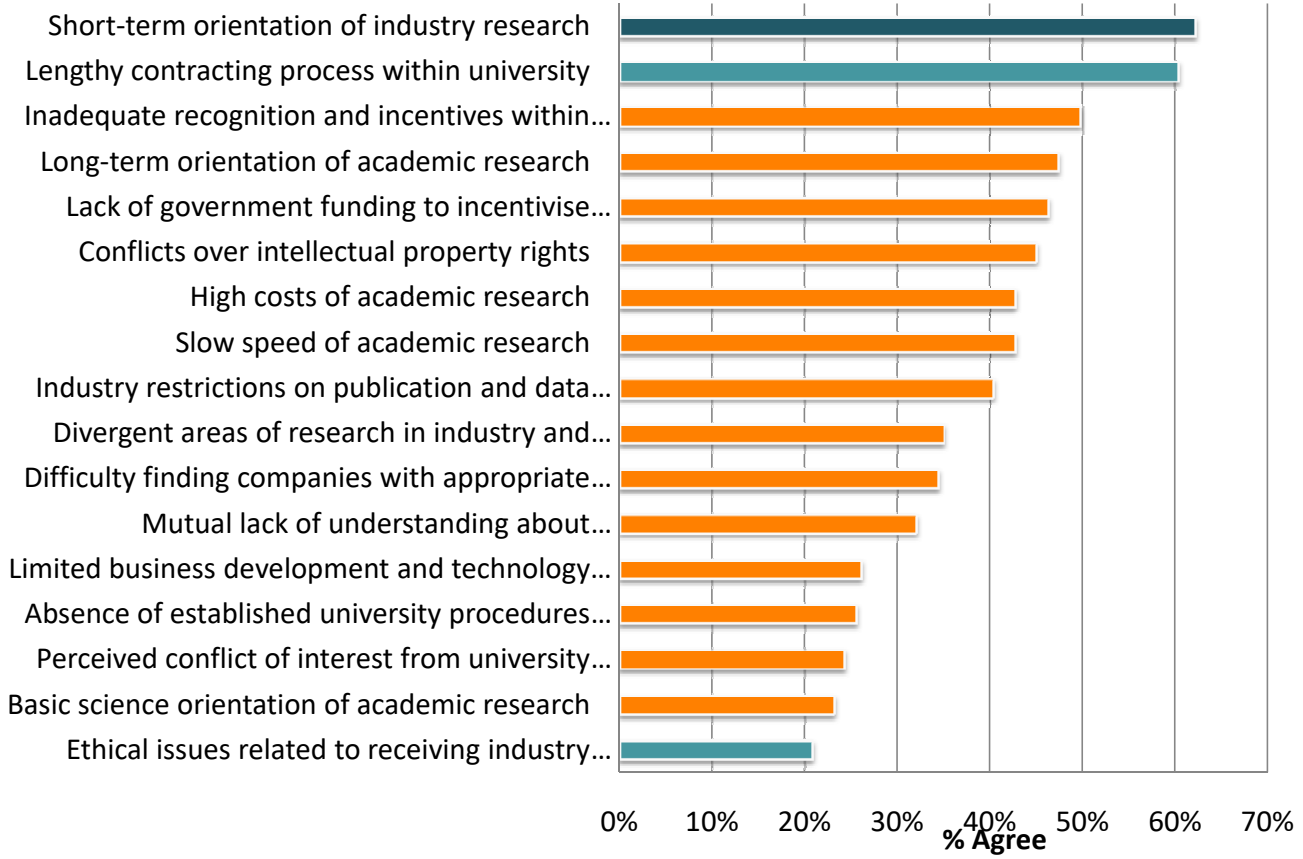
Factors affecting Academia Biomedical Translation

- Themacroeconomiccontext
- Access tofundingsources
- Thesocial context
- Thetechnologicalcontext
- Governmentsupportpolicies
- Therole of theuniversity

Factors affecting Academia Biomedical Translation

- Specific factors from Academia
  - Poorvalorization of this activity in the University, etc
  - Professional career pathways
  - Lack of culture of support for entrepreneurship
  - Possible conflict between remuneration for the publication of research results and compensation for the commercialization of research
  - Scientists need to be implicated in very high percentage in the subsequent development of the product/technology (i.e. to attract investors). This highly impacts in their Academic life
  - Clinician-Scientists (Lack of critical « bridge » scientists who understand basic research and experimental medicine)
  - Other cultural factors such as the "publish or die" view
- General factors from the clinical discovery process
  - Failure to reach goals. Longer times, more costly
  - Less Venture Capital , more valley of death
  - Unmet medical need is not the driving force.
    (Industrial, Economic, even social play a more determinant driving force)

What have you found to be the major barriers to collaboration with industry in academic translational research?



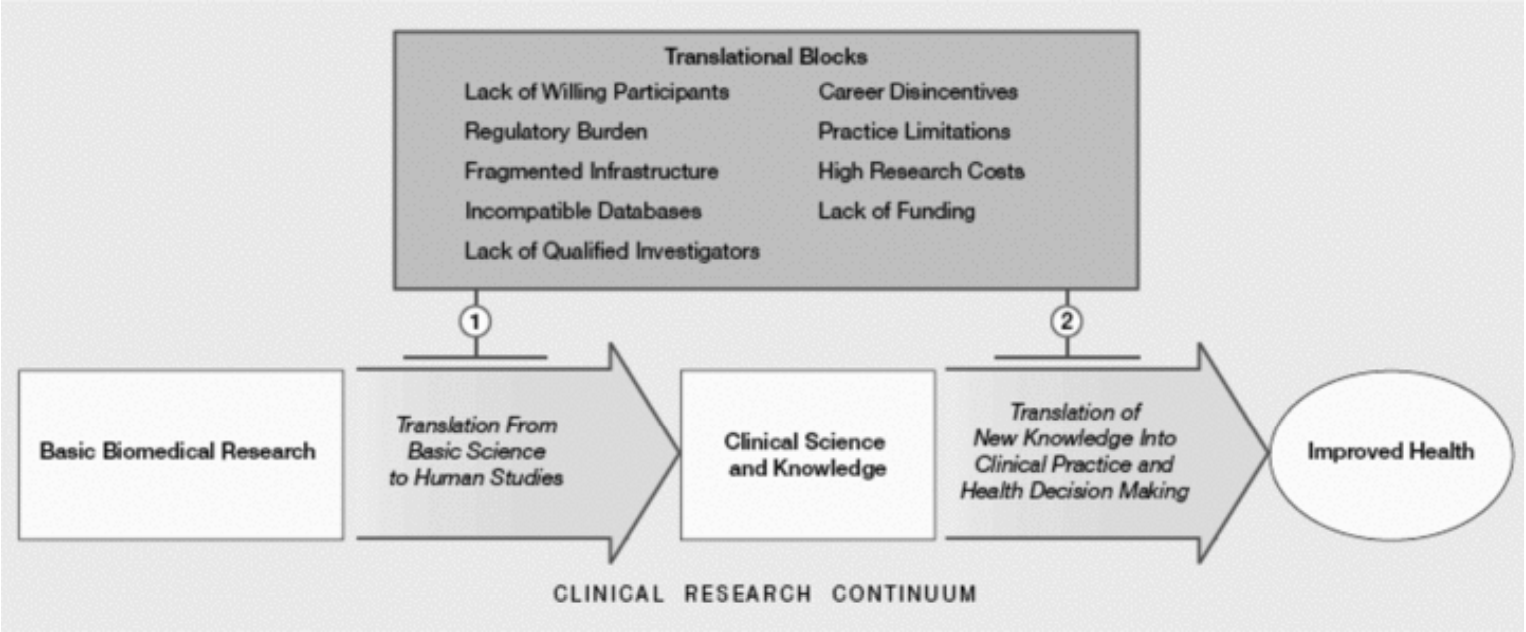
Natasha Davie
Translation in Healthcare – Exploring the Impact of Emerging Technologies, Oxford

Factorsthatimprovethetechnology transfer of universities

- Thesystem of economic incentives forteacherswhocarryouttechnology transfer activities
- Thelocation of theuniversity in a regionwith a highconcentration of high-techcompanies
- Themission of theuniversitywithclearsupportfortechnologytransfer
- Theexperience of thetechnology transfer office of theuniversity (OTRI)

Biomedical Translational Research

Problems at different stages of development



Evaluating Translational Research: A Process Marker Model, Volume: 4, Issue: 3, Pages: 153-162, First published: 27 June 2011, DOI: (10.1111/j.1752-8062.2011.00291.x)

A spectacular drop in worldwide R&D productivity in new therapies

- Clinical timelines increasing (+ 15% annually)
- NME approvals decrease (-26% annually)
- RD costs increase (+ 11% annually)

The Fundamental Drug Discovery problem

- The number of potential biological disease modifying targets has dramatically increased in latest years , thanks to progress made in the biomedical sciences
- However TRANSLATABILITY of those advances into tangible health benefits seems to have decreased
- Academia, Government and Industry need to implement more innovative solutions

Scientific Problems in Translational research in Drug Discovery

- Poor target selection*
  - Many targets, many cellular and animal models but low predictability to human disease
  - Poor animal models
    - Not mimicking human situation
    - Genetically inbred not reflecting human population (targets based on genetically deficient animals)
  - Heavy reliance on insufficient surrogate biology away from human biology
  - Discrepancies in the literature not taking into account

- NEED:
  - More systematic validation of published findings
  - Development of specific biomarkers related to hypothesized mode of action in humans

* Recentstudieshaveshown a substantialproportion (up to 60%) of publishedpreclinicalfindings are not reproducible whentaken up byindustry (Freedman LP, Cockburn IM, Simcoe TS. Theeconomics of reproducibility in preclinicalresearch. PLoSBiol 2015;13(6):e1002165)

Scientific Problems in Translational research in Drug Discovery

- Toxicity in animals is the largest cause of drug attrition during early research, when up to 70% of optimized leads never progress beyond dose range-finding or regulatory toxicology studies.
- During drug development, most failures occur during phase II (when up to 70% of drug candidates stop their progression) and phase III (when 50% stop their progression) clinical trials.

Economic/Industrial Problems in Translational research in Drug Discovery

- Drug discovery programs that pursue already established drug targets have at up to 20-fold higher probability of success than those that pursue novel drug targets
- They have a much higher probability of leading to a drug with few to no innovative advantages but easy to get into the market.
- However, this type of drugs, and not drugs with new MOA , are the drugs mostly approved

Translation of Biomedical Research from the Academy