Problems in attempting to have novel devices and therapies reaching the patients and the market
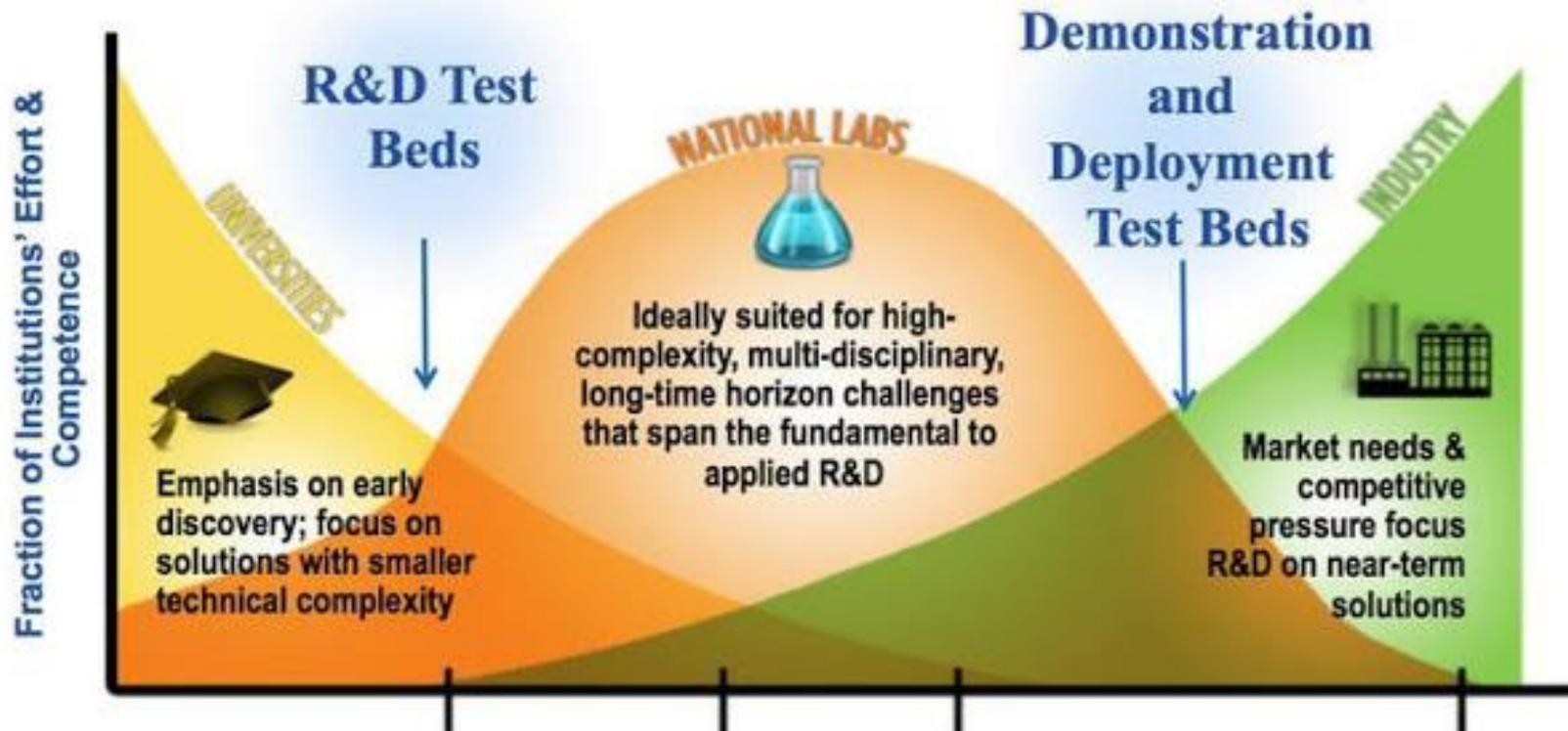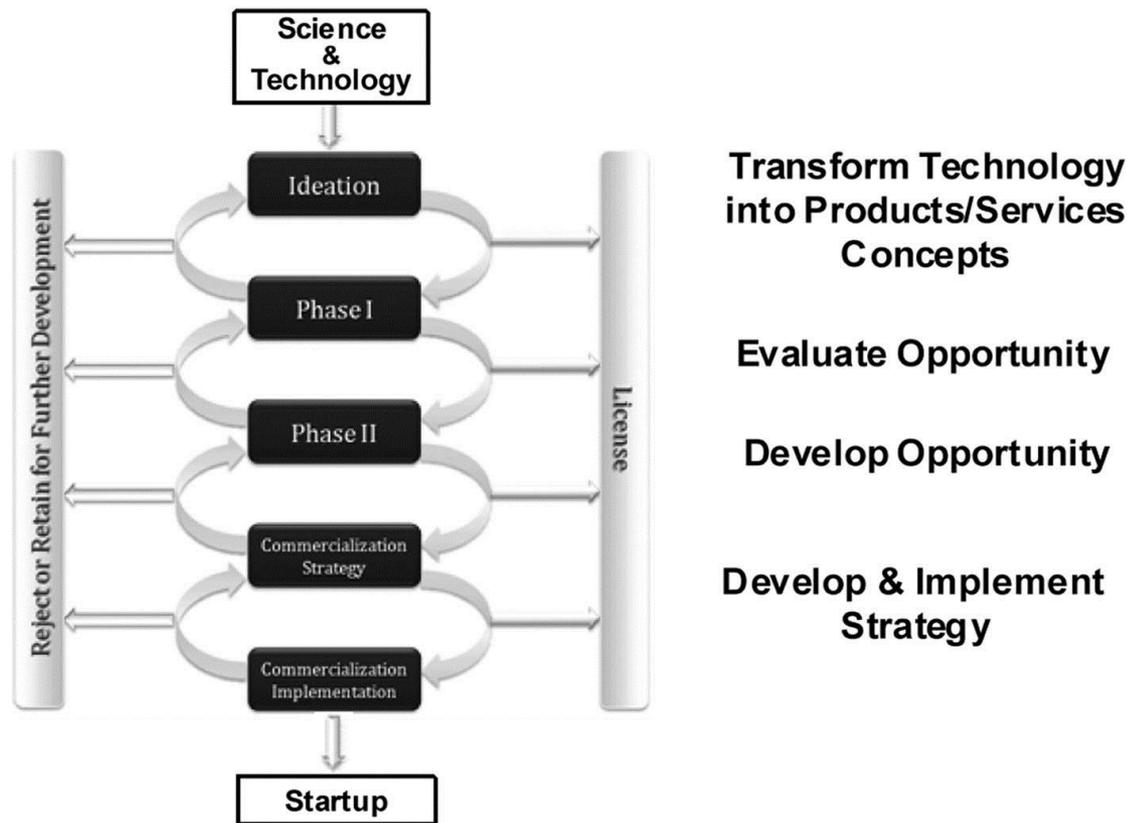
Fernando J. Monteiro

University of Porto

31st October 2017

Bridging the "*Valleys of Death*"

valleyofdeathreactors.jpg

A long and difficult pathway

"Valley of dead" and "using opportunities"

"There is a growing perception that the enormous resources being put into biomedical research, and the huge strides made in understanding disease mechanisms, are not resulting in commensurate gains in new treatments, diagnostics and prevention. "

"We are not seeing the breakthrough therapies that people can rightly expect,"
(Schechter, NIH Bethesda).

Ask ten people what translational research means and you're likely to get ten different answers.

For basic researchers clutching a new prospective drug, **translational research** might involve medicinal chemistry along with the animal tests and reams of paperwork required to enter a first clinical trial.

For groups wanting to develop diagnostics, imaging tools, or screening and prevention methods the route would be different.

In some sense much translational research is just rebranding **clinical R&D** by a different name.

But it also involves investing in training, research and infrastructure to help researchers engage in clinical research — and cross the valley of death.

Measuring the outcomes of translational research is notoriously difficult, as they do not lend themselves to the simplistic bean counting of publications.

"Go see the human beings who are suffering, and then ask yourself, is the work I did today relevant to human suffering? Did I do something that is going to help to change somebody's life, maybe not today but sometime soon?"
Christopher Reeve

Academia-industry synergies are needed

Large biopharmaceutical companies employ contractors or staff to address and meet many of the administrative and regulatory requirements necessary to develop, test and bring a product to market.

But most academic institutions do not provide appropriate regulatory support or the facilities necessary to meet the standards for clinical product preparation.

It makes sense to encourage the involvement of the private sector earlier in the progression of the translational research process

Academia-industry synergies are needed

Bench-to-bedside translational research is expensive and requires a level of infrastructure that transcends the laboratory.

Compliance with the regulatory, administrative and ethical requirements associated with the design and conduct of clinical trials necessitates dedicated and specialized financial and human resources.

Academic institutions, on their own, are not in a position to fully support clinical research.

But bedside-to-bench research can be both relatively less expensive and highly productive if samples are collected appropriately and questions are designed well.

TRYING TO OVERCOME KNOWLEDGE TRANSFER CONSTRAINS

At U. Porto we recently have a program, still very small in size but with interesting results up to now, named RE**SOLVE.**

Mainly the intention is to help to establish Proof of Concept (PoC) for projects in the health research and innovation sector that show potential to move into the market

It is a Program designed to capacitate teams, based on a set of specific tools and complemented by **PoC funding**

KNOWLEDGE TRANSFER CONSTRAINS

- ✓ Not knowing the key licensing contacts
- ✓ Unawareness of the market needs
- ✓ Low access to funding in early stages

- ✓ Excessive burocracy in regulatory affairs
- ✓ Lack of management skills
- ✓ Low efficiency of the open innovation platforms

resolve

University and
Research Labs

Companies

Valley of Death

| DISCOVERY | BASIC RESEARCH | APPLIED RESEARCH | PRODUCT DEVELOPMENT | COMMERCIALIZATION |

TOOLBOX

Validation of Prototypes and Proofs of Concept

End-users Forum

Fast Track for Clinical Studies

Team Building with MBAs
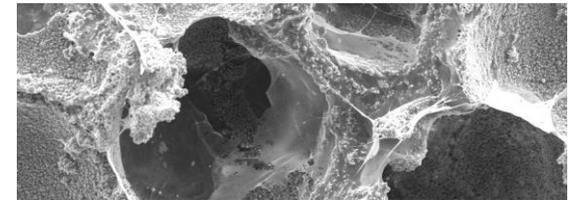
Observatory of Open Innovation Platforms

Licensing Contact List

Meeting with investors

RESOLVE 1st Edition Teams

Thank You for your kind attention

Thanks to **BIN**@SHEFFIELD