KNOWLEDGE TRANSFER BEST PRACTICES AMONG APEC ECONOMIES

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MECHANISMS FOR KNOWLEDGE TRANSFER IN THE HEALTH SECTOR.

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What is knowledge transfer?

Knowledge transfer (KT) is a term used to encompass a very broad range of activities to support mutually beneficial collaborations between universities, businesses and the public sector.

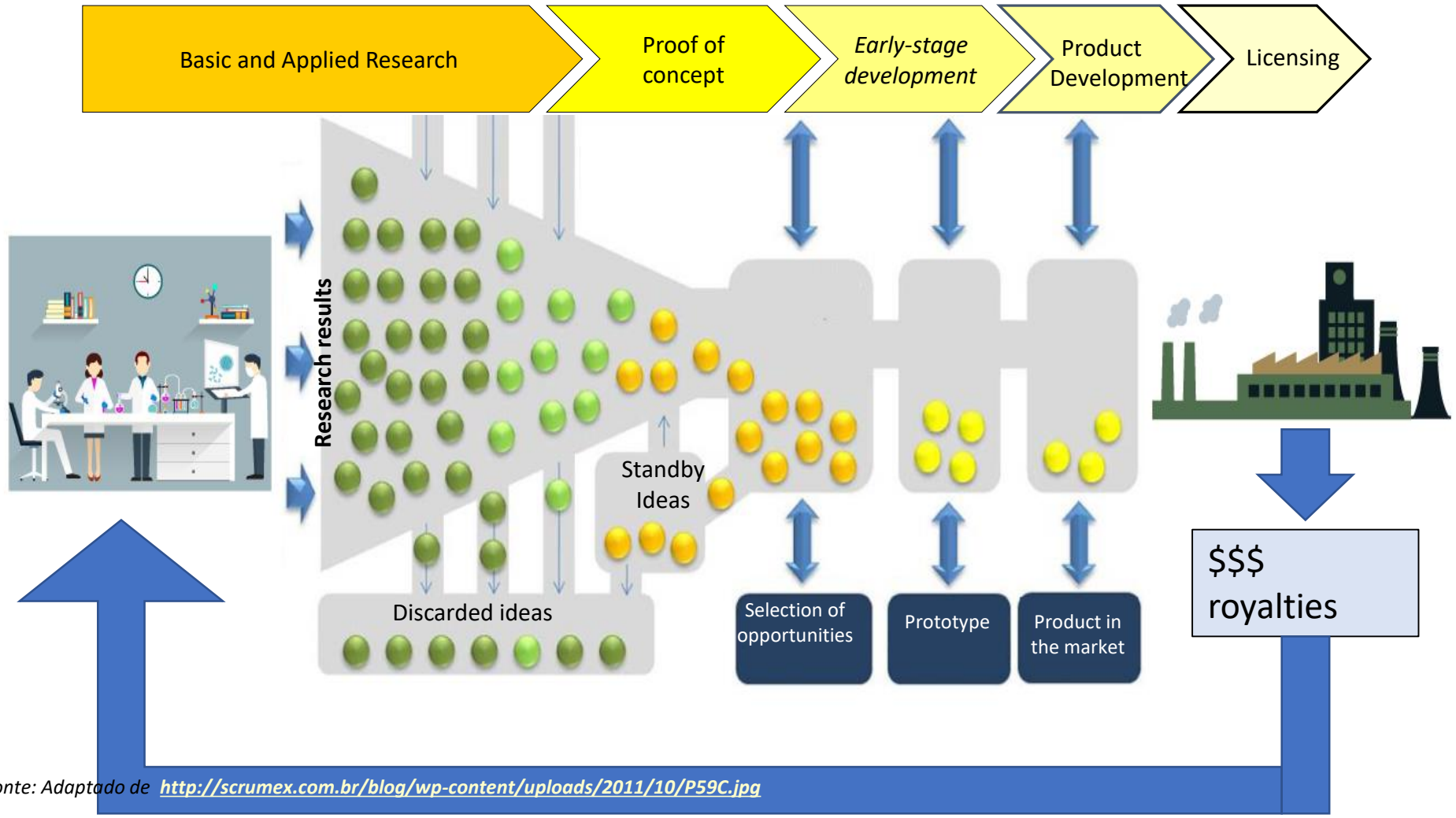
- It's all about the transfer of tangible and intellectual property, expertise, learning and skills between academia and the non-academic community.
- *"KT is a 'contact sport'; it works best when people meet to exchange ideas, sometimes serendipitiously, and spot new opportunities" (Tim Minshall).*
- For academics, KT can be a way of gaining new perspectives on possible directions and approaches for research. This two-way exchange element of KT is at the heart of successful and sustainable collaboration.
- Knowledge is transferred through publication of research output, and through events and networking.
- The KT that enables the company to put new products on the market and achieve commercial success is commonly referred to as technology transfer (TT), often used as a synonym for KT.

https://www.cam.ac.uk/research/news/what-is-knowledge-transfer

BENEFITS OF TECHNOLOGY TRANSFER

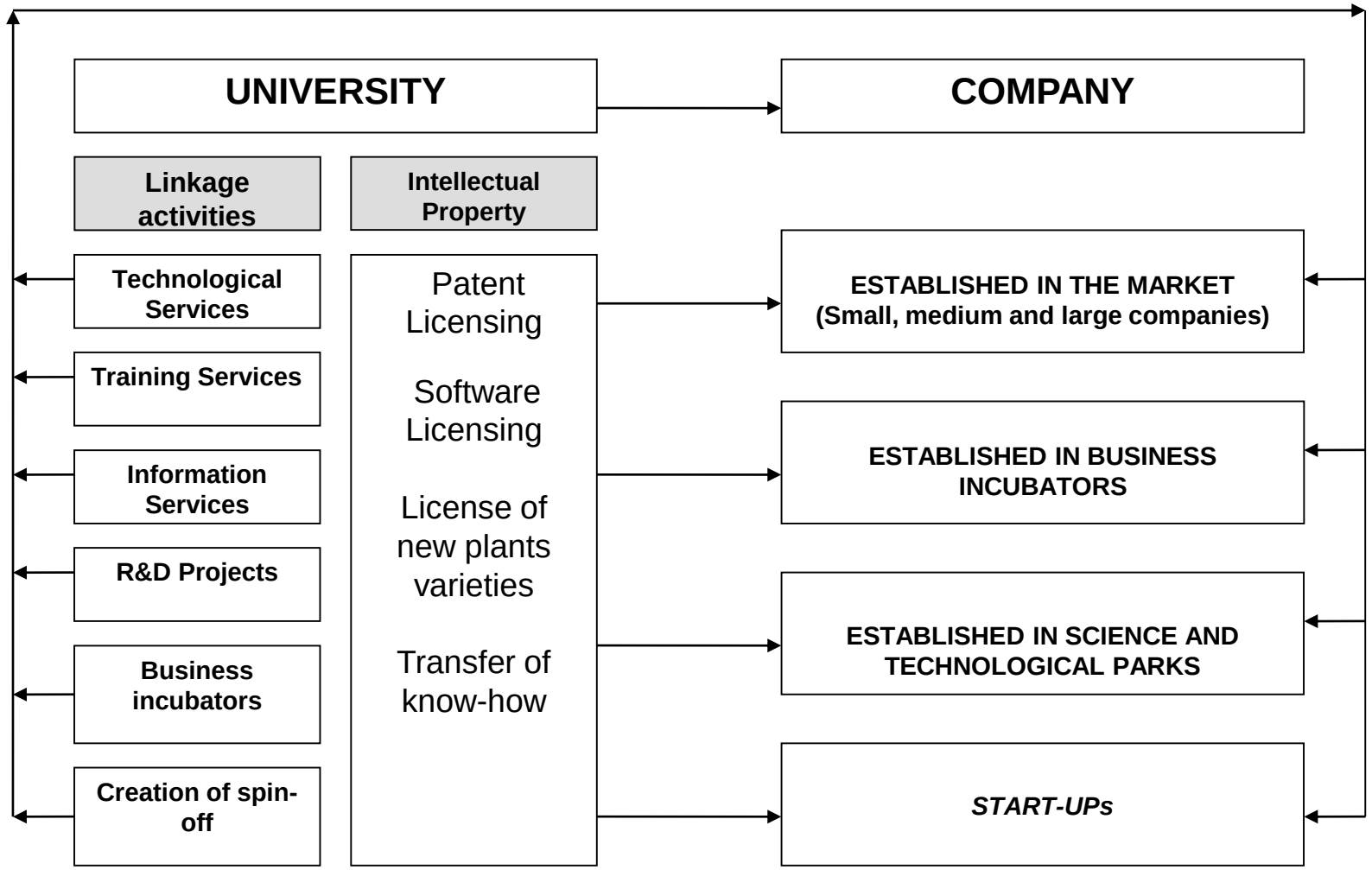
- Development of products and services that benefit the public
- Local economic development through job creation and new companies
- Attraction of corporate research support
- Licensing revenue for further research
- Attraction and retention of scientific talent

From the lab to the market: a virtuous circle



Fonte: Adaptado de ***http://scrumex.com.br/blog/wp-content/uploads/2011/10/P59C.jpg***

MECHANISMS FOR KNOWLEDGE TRANSFER



Technology Transfer – bridging death valley

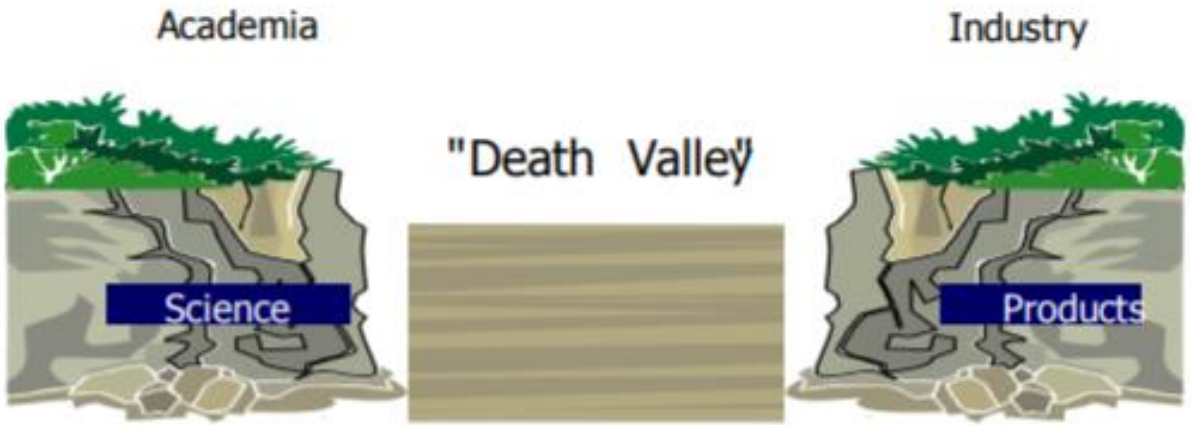
Source: wipo_pub_transition_2_ b_pdf

University

Social responsibilities
Basic research
Create new knowledge
Pure curiosity driven research
Publications & collaborations
Sharing of material

Corporate

Shareholder responsibilities
Applied research
Develop new products
Specific objectives, product focused
Ownership and secrecy
Control of material

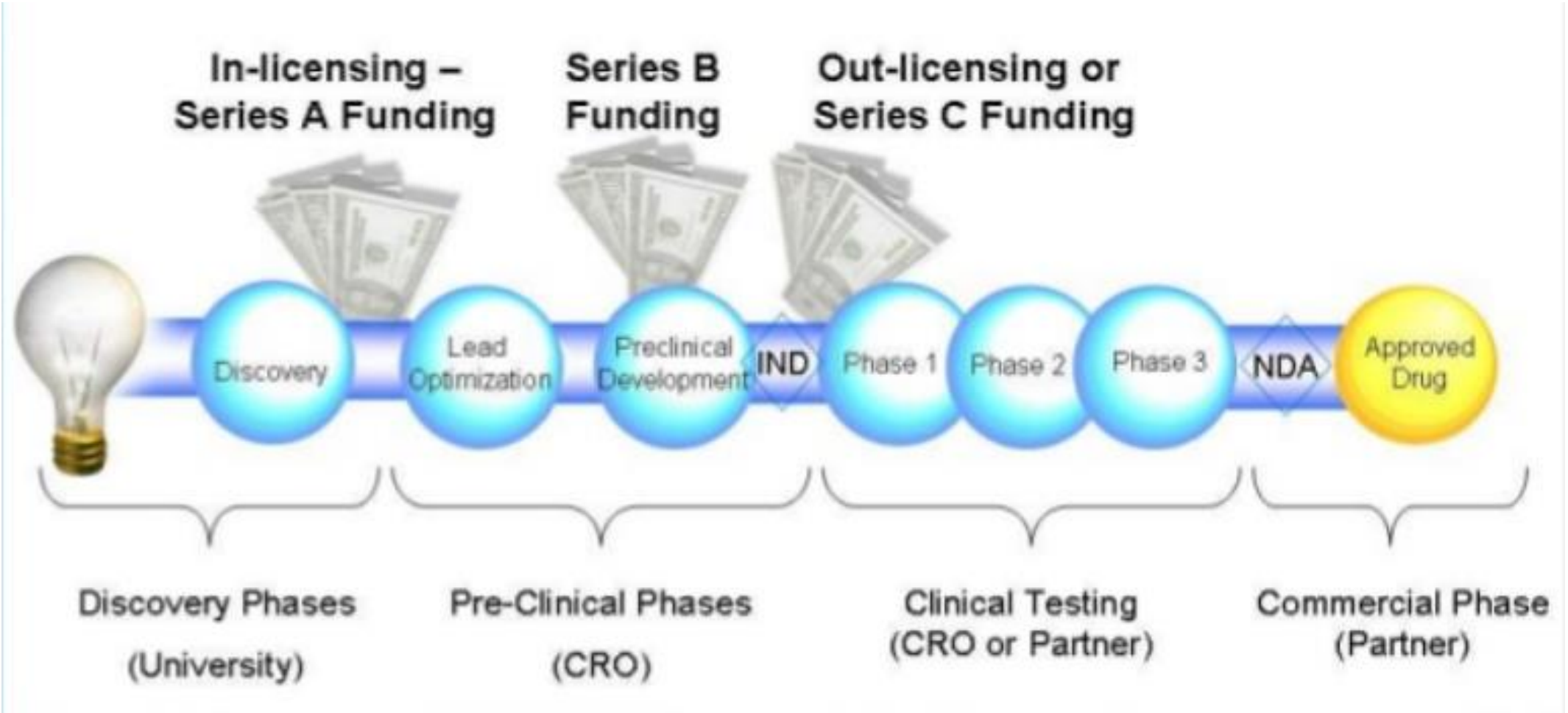


“Death valley” and the challenge of technology transfer.

From bench to bedside: translational research (TR) in health

- Bridging “death valley”, TR is considered an approach to speed up technological innovation and bring basic research results to effective applications on health demands.
- It is defined as “part of a unidirectional continuum in which research findings are moved from the researcher’s bench to the patient’s bedside and community” (Rubio et al., 2010).
- In the continuum, TR research is broken down into different stages from pre-clinical studies to clinical trials phase I, II and III.

Drug Development Pipeline



Source: Nasim Arshad https://pt.slideshare.net/nasimarshadi/drug-development-process-62544651i

Preclinical studies

- **Lab and animal testing to determine if the drug is safe enough for human testing.**
- To gain approval for general medical use, the **quality**, **safety** and **efficacy** of any product must be demonstrated.
- Regulatory authority approval to start clinical trials is based largely upon preclinical pharmacological and toxicological assessment of the potential new drug in animals.
- Such preclinical studies can **take up to 3 years to complete.**

Source: Nasim Arshad https://pt.slideshare.net/nasimarshadi/drug-development-process-62544651i

Clinical Phase – Testing in humans

- This is composed of **four successive phases** and only after all phases have been completed can the drug be released for marketing and made available for use by the population.

Phase I - Evaluates the safety of the investigated product. Tested in small groups (10-30 people), usually healthy volunteers.

Phase II - Number of patients is higher (70-100) and evaluates the effectiveness of the medication and obtains more detailed information on safety (toxicity).

Phase III – Number of patients from 100 to 1000. Studies in this phase are randomized: patients are divided into two groups - the control group and the investigational group.

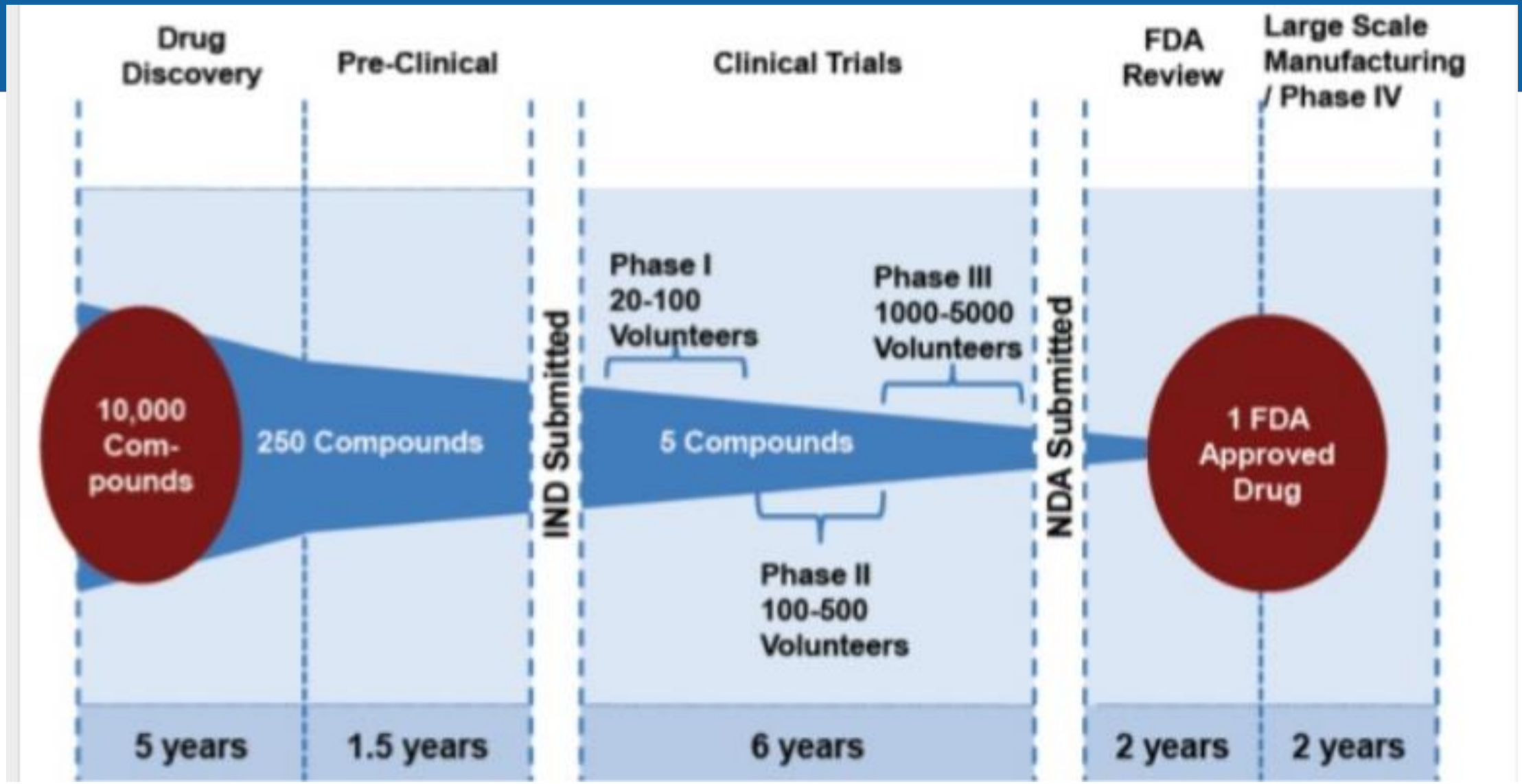
Phase IV - These studies are performed to confirm that the results obtained in the previous phase (III) are applicable in a large part of the sick population. At this stage, the drug has already been approved to be marketed.

Source: http://www.sbppc.org.br/portal/index.php?option=com_content&task=view&id=14&Itemid=37

Clinical Trials

Trial phase	*Evaluation undertaken (and usual number of patients)*	*Average duration (years)*
I	*Safety testing in healthy human volunteers (20–80)*	1
II	*Efficacy and safety testing in small number of patients (100–300)*	2
III	*Large-scale efficacy and safety testing in substantial numbers of patients (1000–3000)*	3
IV	*Post-marketing safety surveillance undertaken for some drugs that are administered over particularly long periods of time number of patients varies)*	*Several*

Source: Nasim Arshad https://pt.slideshare.net/nasimarshadi/drug-development-process-62544651i

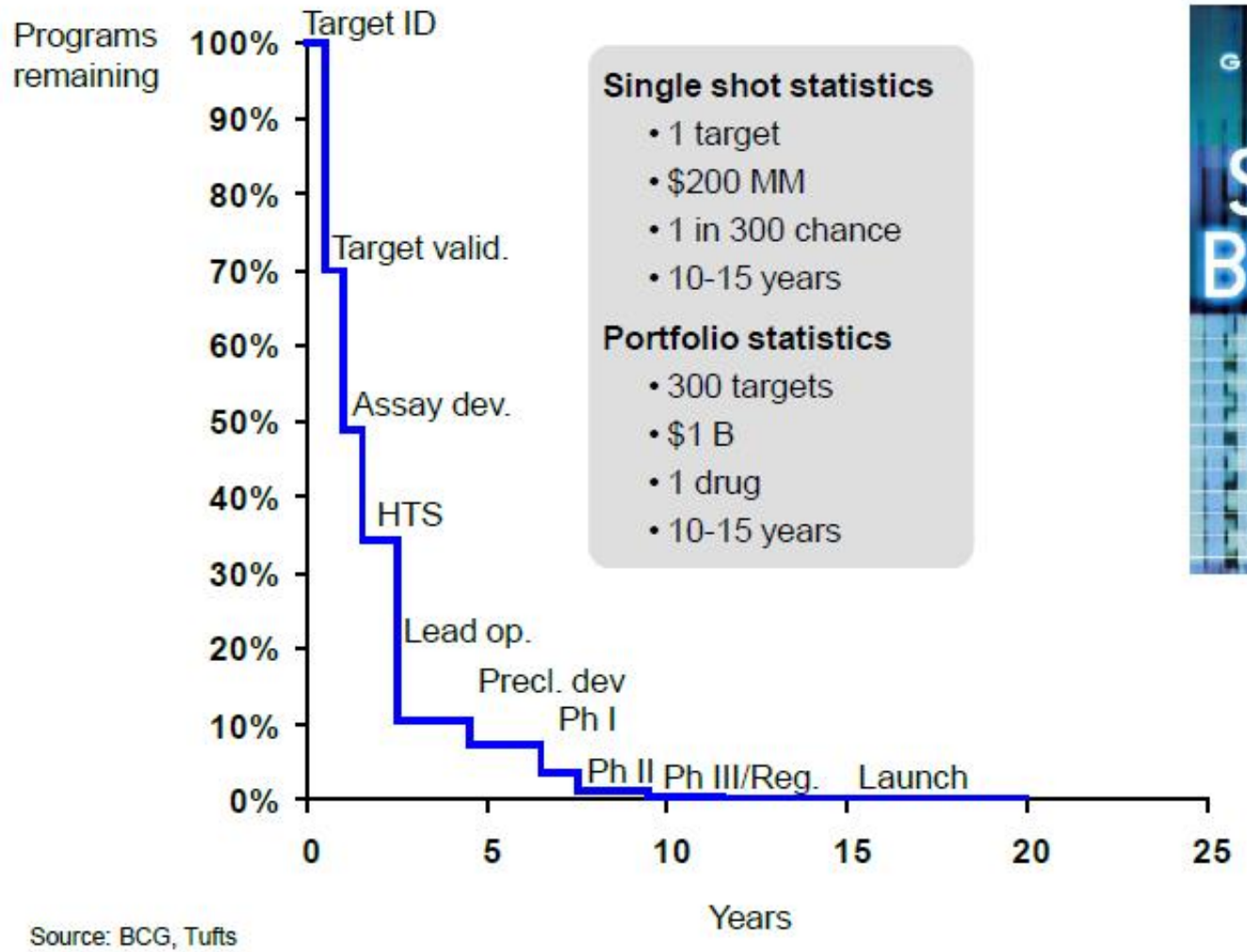


Source: Nasim Arshadi

*The average cost to research and develop each successful drug is estimated to be **$800 million** to **$ 1 billion***

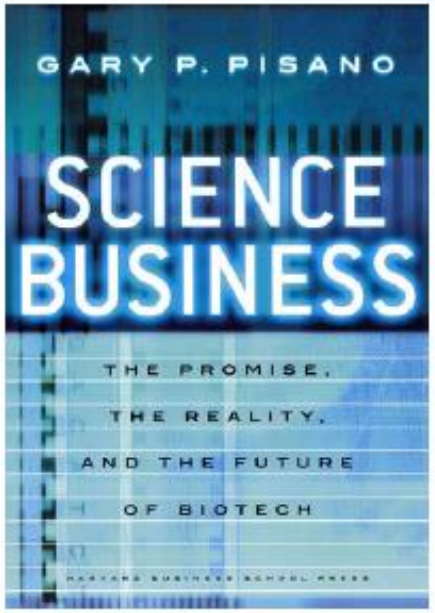
Drug development is long, expensive, and uncertain

Source: Camilo Ansarah Sobrinho, 2017



Single shot statistics
- 1 target
- $200 MM
- 1 in 300 chance
- 10-15 years

Portfolio statistics
- 300 targets
- $1 B
- 1 drug
- 10-15 years



BIOMED VALLEY DISCOVERIES

Mechanisms for Technology Transfer

TTO

- Evaluates researcher's invention disclosures and obtains and protects patent rights as needed to promote development and commercialization of the intellectual property.
- Negotiates patent and proprietary technology license agreements to transfer university patent rights, proprietary technologies, and materials to private-sector partners for development and commercialization.
- Supports the researcher in the creation of spinoff companies.

Accelerator

- Aims to increase the number of university technology transfer partnerships, including private firms, research organizations, and nonprofit entities.
- Enables professional staff to focus more on marketing and partnership development and engagement activities.
- Streamlines technology transfer partnership processes and procedures to maximize transfer effectiveness.
- Maintains close links with funding agencies for innovation.

Mechanisms for Technology Transfer

Spin-offs

- Bringing research output to market through the formation of a new business can be particularly appropriate when the application represents a 'disruption' to the current market or sector, or where there isn't any obvious external partner to whom the idea could be licensed.
- Create and utilize intellectual property
- Further progress of early stage projects to be visible for big pharma and investors
- Tech transfer to big pharma / or growing to become mid size or big pharma
- R&D services (e.g. non-clinical and clinical CRO, SMO, Phase 1 units, consultancy, regulatory, medical writing, etc.)
- Create jobs (social impact)

Mechanisms for Technology Transfer

Clinical research centers (CRCs)

- Refers to any designated medical facility used to conduct clinical research, such as at a hospital or a medical clinic. They have been used to perform clinical trials of various medical procedures.
- The center should aim at the patient, often without access to better treatment options. Through appropriately designed research protocols, the most modern treatments or procedures are made available, as well as cutting-edge health care.
- Ethical conduct is the master guide for all these projects and is ensured by prior approval of the research protocols by the Research Ethics Committees.
- Specialized labor and adequate technical-scientific training in Good Clinical Research Practices; ensure the appropriate infrastructure for the monitoring research protocols; and to meet the increasing demand for large clinical studies, as well as in national studies of priority in public health.

Arrangements for Technology Transfer

- Technology transfer of **biomedical technologies** to companies with the expectation that the recipients will actively exploit or develop the technology and share benefits with the academic inventors usually occurs under one of the following three types of arrangements:

  (*a*) licenses or assignments of preexisting technologies;
  (*b*) collaborative or sponsored research agreements to develop new information or technologies; and
  (*c*) formation of start-up companies, usually financed largely by private venture capital.

- Taken together, these methods constitute the technology transfer "system" between publicly supported research institutions and industry.

Source: Robert Kneller, 2001, http://clincancerres.aacrjournals.org/content/7/4/761

EXAMPLES OF KNOWLEDGE TRANSFER IN HEALTH

- Sharing of know-how through clinical trials training and management;
- Screening/sharing of compound libraries;
- Scientific knowledge transfers via research collaborations;
- Building public health capacity through training and education;
- Imparting management skills and expertise;
- Diffusing knowledge through direct investments;
- Raising local production quality through joint ventures and licensed manufacturing;
- Training in regulatory and quality standards;
- Education in supply chain/logistical management;
- Training of local health workforces;
- Communication and advocacy training;
- Sharing of intellectual property and other knowledge.

Source: International Fderation of Pharmaceutical Manufacturers & Associations (IFPMA),

EXAMPLES OF KNOWLEDGE TRANSFER IN HEALTH

- Drugs
- Vaccine
- Diagnostic Kit
- Detection Method
- Vector Viral
- Antibody
- Computer program
- Method of Protein Expression
- New Therapy
- Adjuvant
- Animal Model Courses / Trainings
- Database
- Medical Devices

Contracts and agreements for Technology Transfer

- Material Transfer Agreement (MTA)
- Confidentiality Agreement (CDA / NDA)
- Collaborative Research Contract (RCA)
- Sponsored Research Contract
- Licensing Agreement
- Start-Up Company Licenses
- Inter-institutional contracts (IIA)
  - Invention and ownership of two different institutions
- Distribution of Royalties
- ……

One Size Does NOT Fit All

Source: Camilo Ansarah Sobrinho, 2017

Strategy is tailored for every technology.

One Size Does NOT Fit All

Strategy is technology-dependent and licensing opportunity-dependent

- **Cost of developing the technology**
- **Regulatory Burden**
- **Epidemiology of disease**
- **Manufacturing Capabilities**
- **Strength of Country's Patent System**
- **Licensee's presence in certain countries**

Source: Camilo Ansarah Sobrinho, 2017

THANK YOU

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