



Academia-Industry

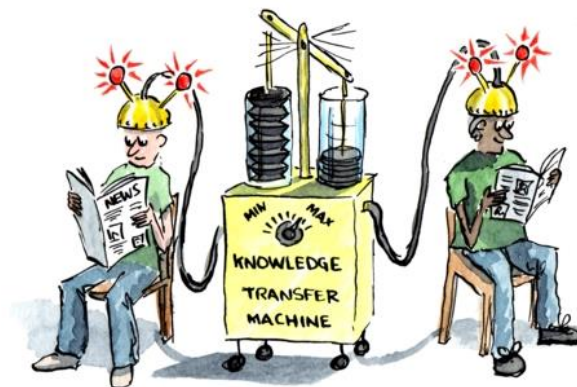
Linda van de Burgwal, PhD

23 January, 2020



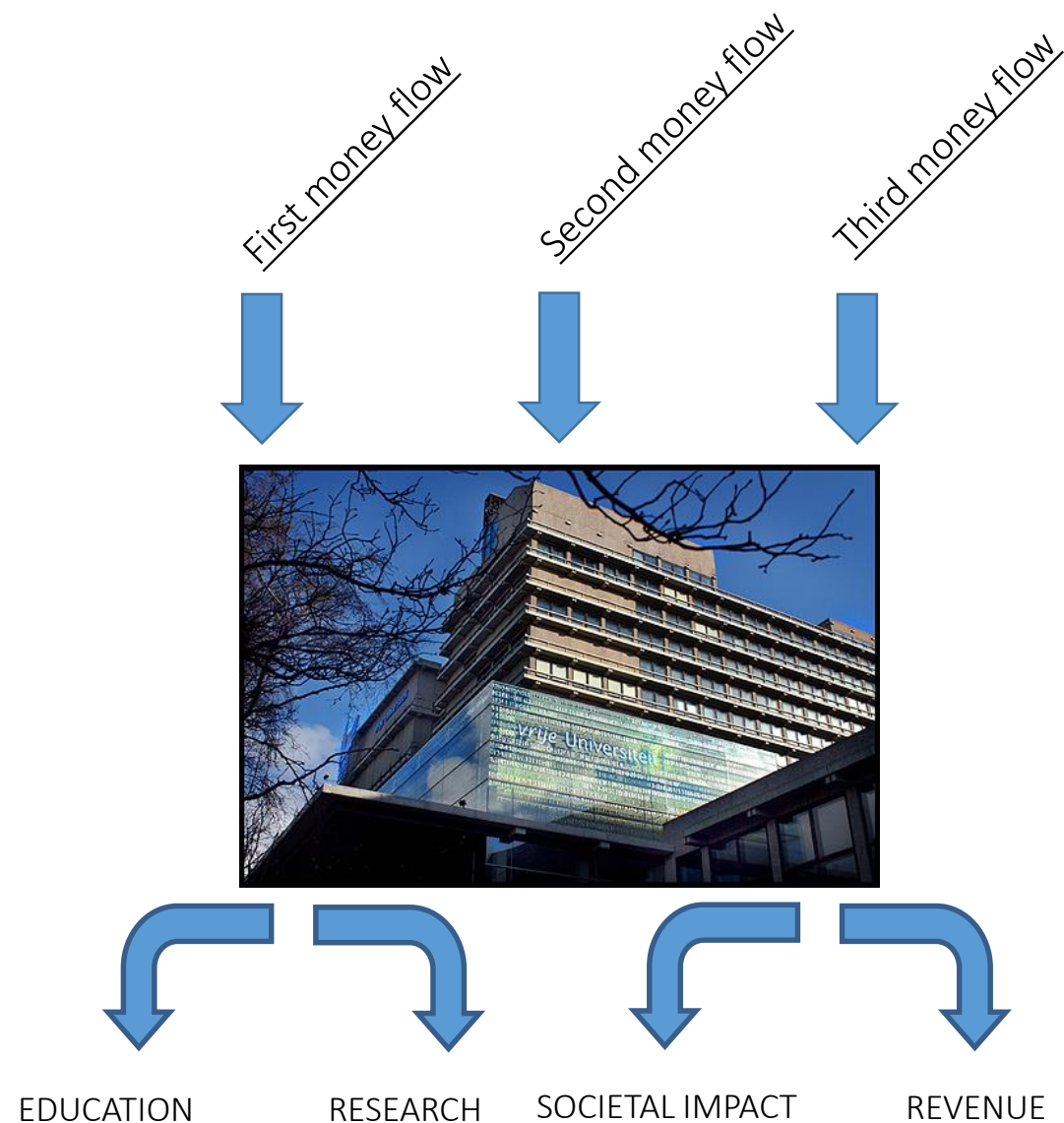
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 813343.

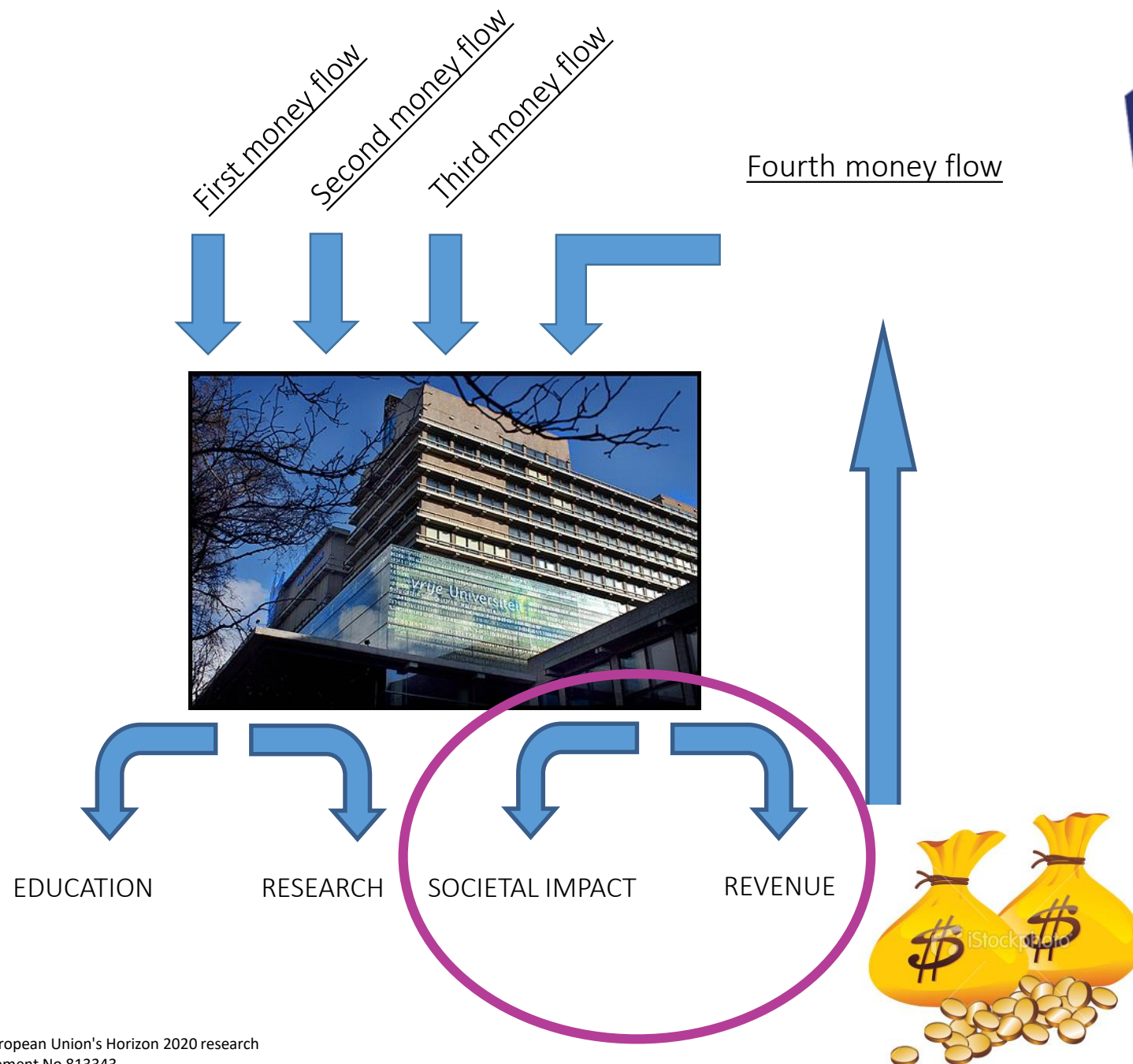
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VALORISATION







Definition of knowledge valorisation



- Whereas
- **knowledge transfer** highlights the formal transfer of academic knowledge to parties in the commercial sector for economic benefit,
- **knowledge valorisation** takes a broader scope and looks at “the creation of societal value from knowledge by translating research findings into innovative products, services, processes and/or business activities”.

Farming¹
(land)

Industrial age²
(labour)

Knowledge society³
(Innovation)



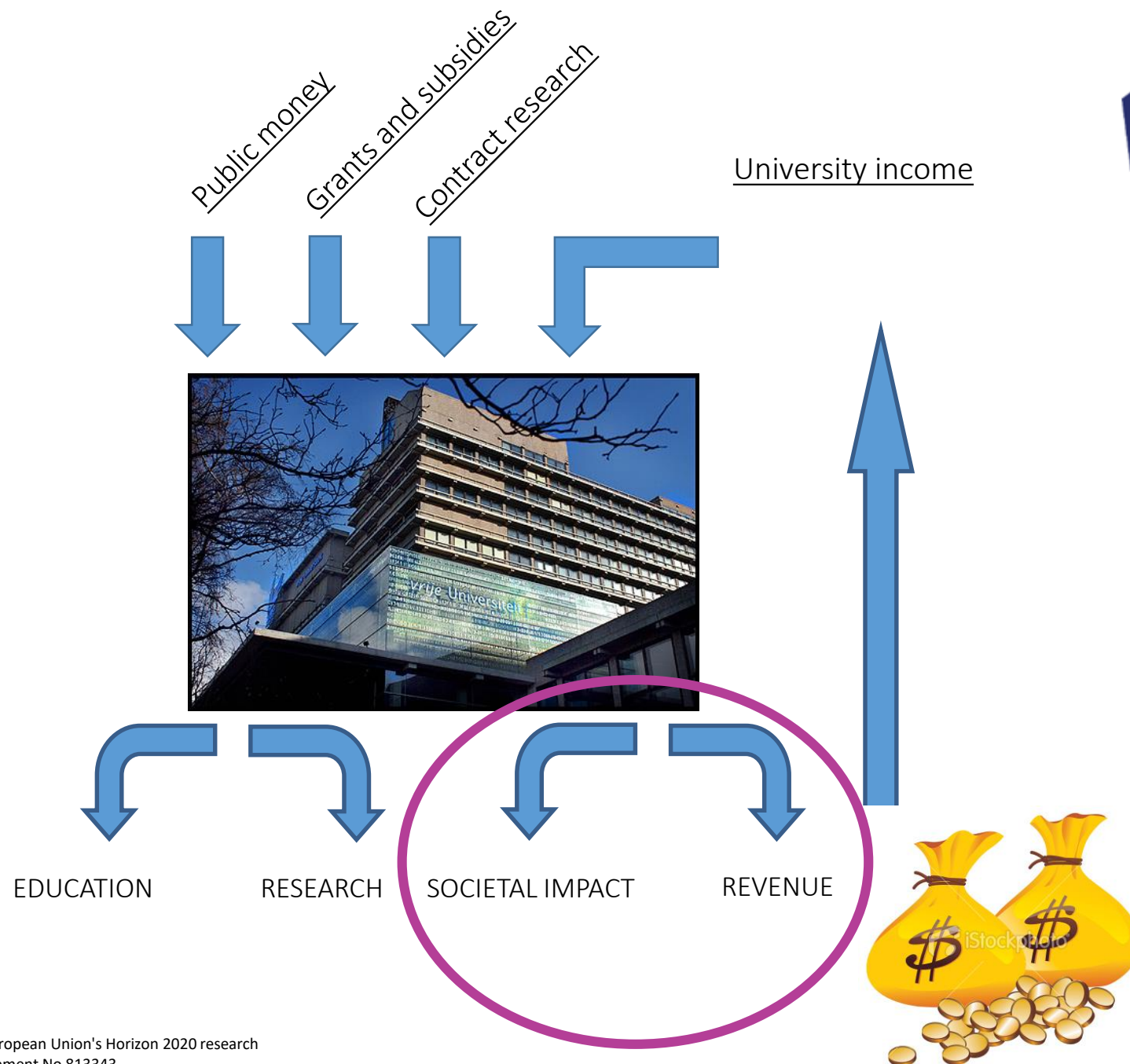
Societies are moving toward
the *(knowledge)* society

“Just as castles provided the source of strength for medieval towns, and factories provided prosperity in the industrial age,

universities are the source of strength in the knowledge-based economy of the twenty-first century.”



Lord Dearing (September 2002)



Societal Impact of Knowledge has Four Pillars



- Knowledge for knowledge
(scientific, curiosity-driven research)
- Knowledge for culture
(dissemination to and involvement of the general public)
- Knowledge for welfare (€)
(products or services)
- Knowledge for wellbeing
(policy advice, guidelines)

Societal Impact of Knowledge has Four Pillars



Table 1 Framework for a broad societal impact of knowledge with examples for knowledge production, exchange and use within each of the domains

	Academic orientation with an impact on knowledge	Civil society orientation with an impact on culture	Entrepreneurial orientation with an impact on economy	State-governmental orientation with an impact on wellbeing
Knowledge production	Scientific publications	Lay publications	Patents, products	Guideline development, professional publications
Knowledge exchange	Lectures, scientific consultations	Speeches, courses for general public	Consultancy, contract research	Membership of professional associations, participation in policy research
Knowledge use	Citations	Use of (school) books	Use of patents and products	Use of guidelines Implementation of advice

van de Burgwal, L. H., Dias, A., & Claassen, E. (2019).

The Journal of Technology Transfer, 44(1), 1-20.

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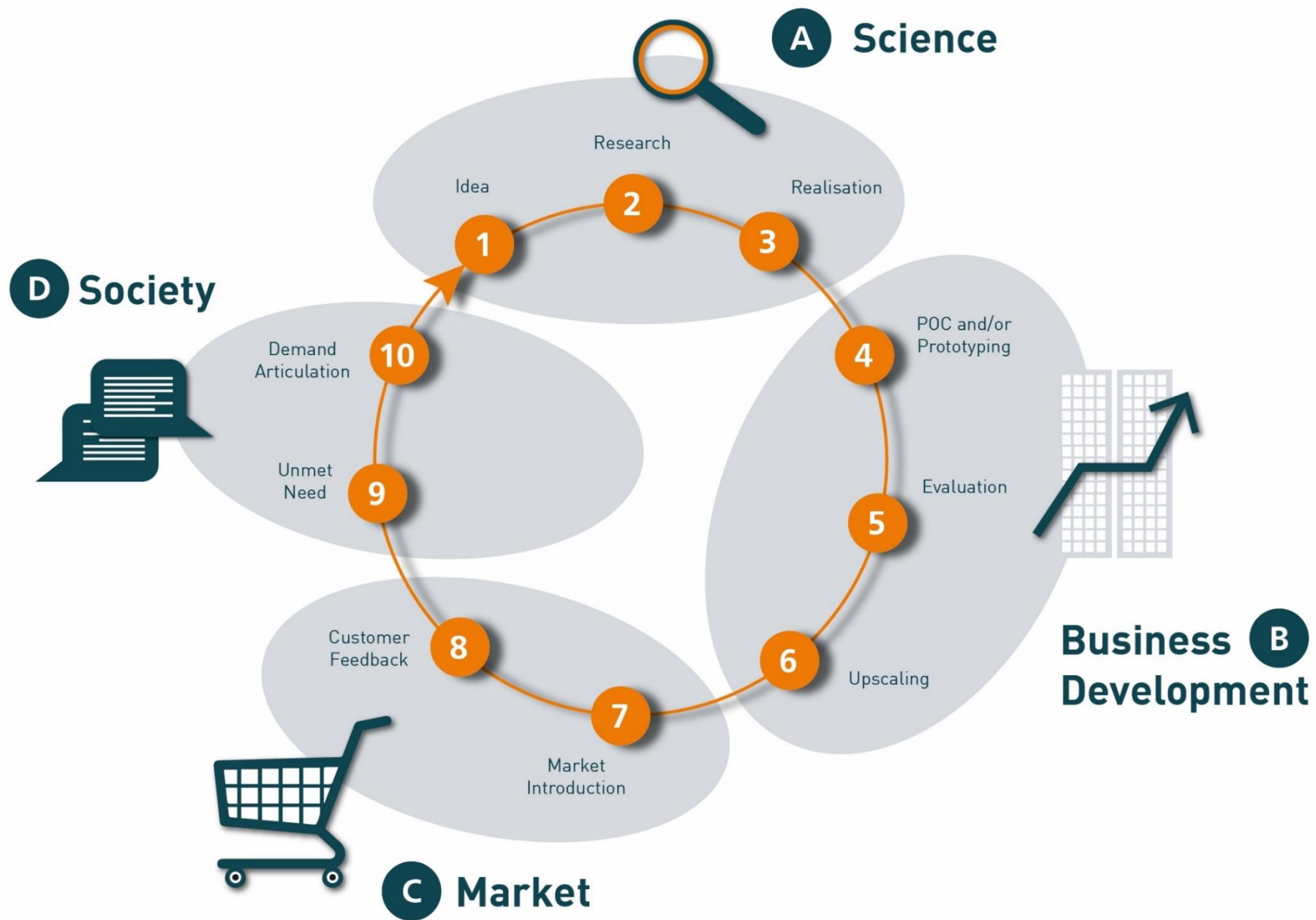


Societal Impact of Knowledge has Four Pillars

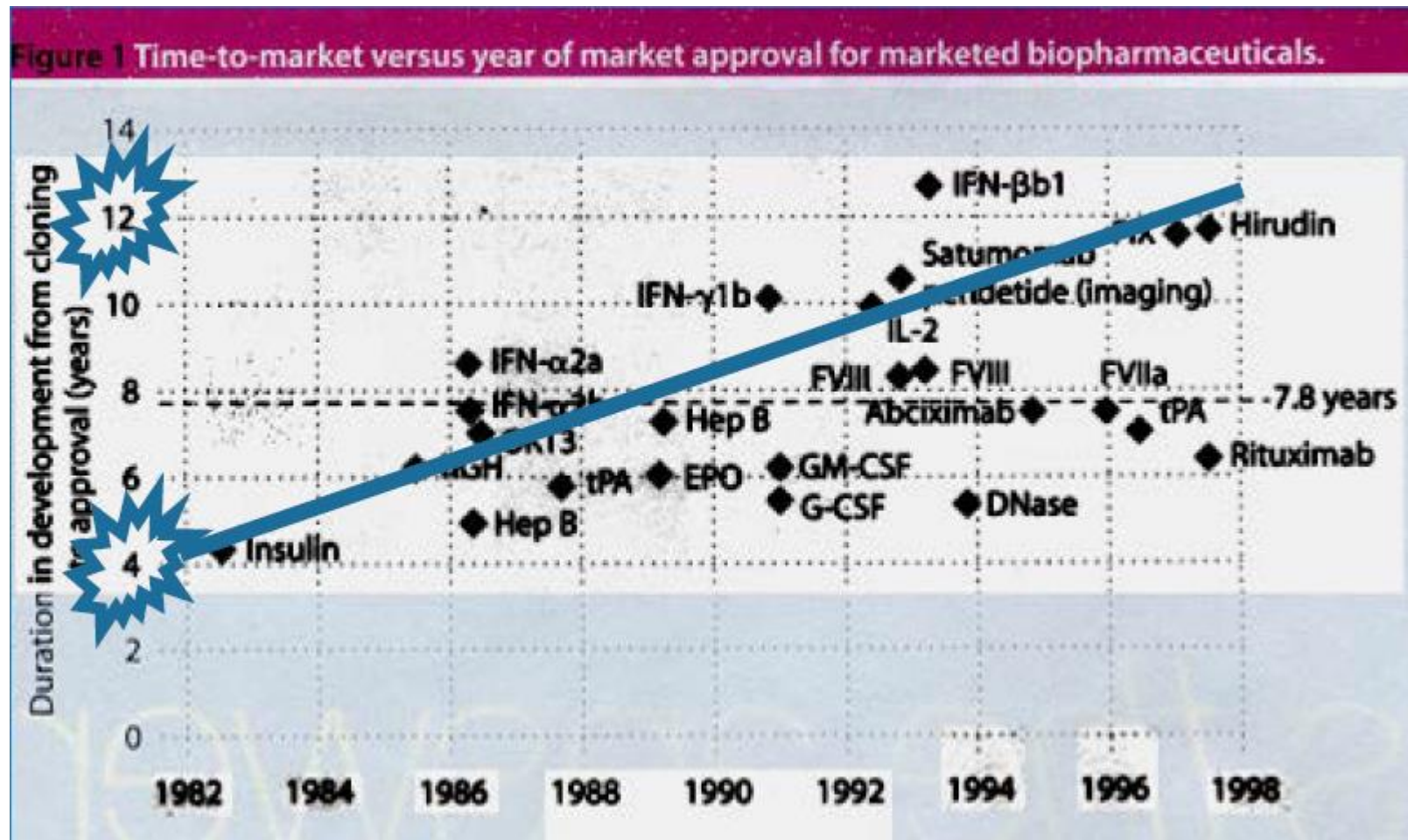
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Drug development takes a lot of time...



... money...

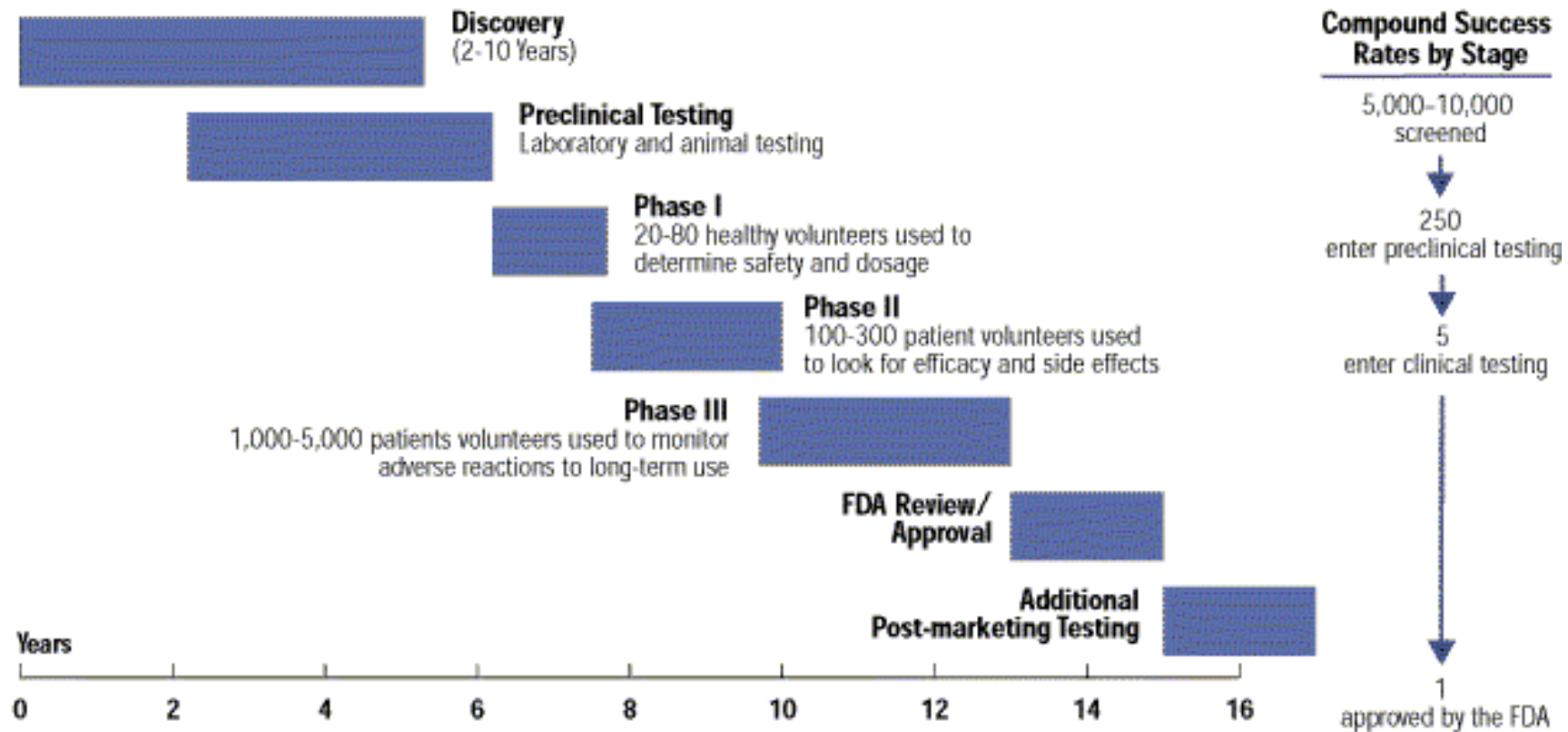


Figure 11: Increasing Cost to Develop One New Medicine



SOURCES: J. A. DiMasi and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics*, 2007; J. A. DiMasi, et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

... is risky...



Source: PhRMA, based on data from Center for the Study of Drug Development, Tufts University, 1995.

... and has become increasingly complex



K. D. S. FERNALD *ET AL.*

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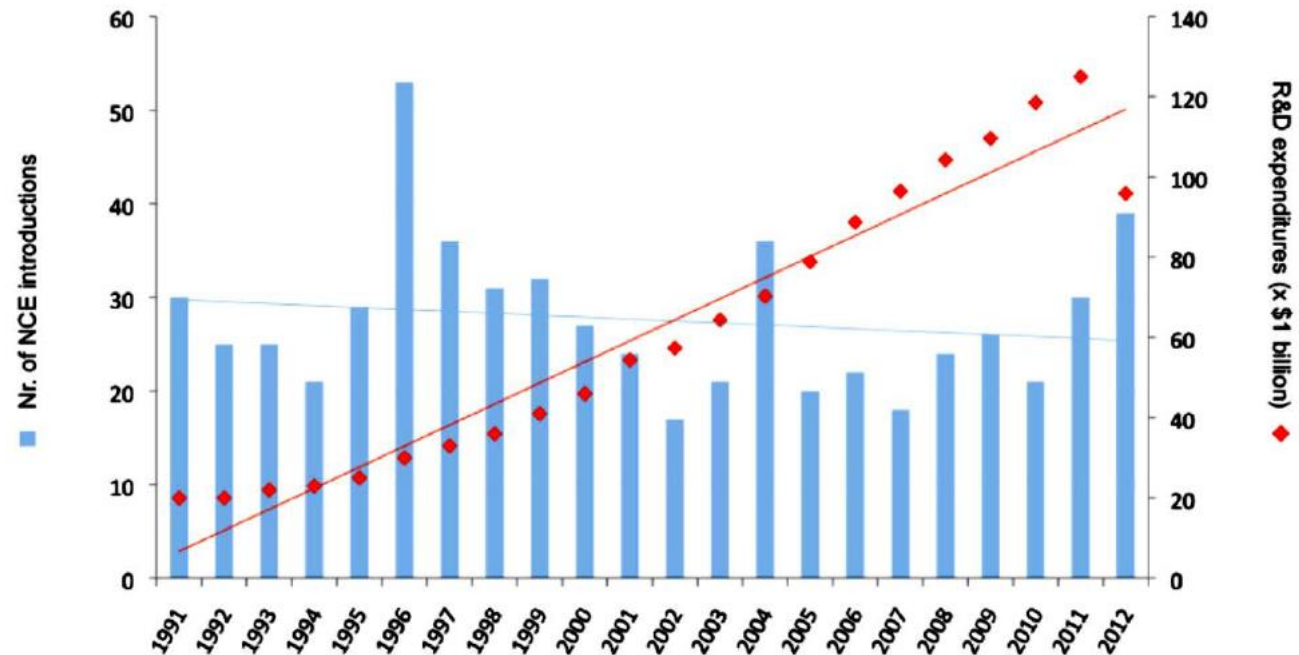
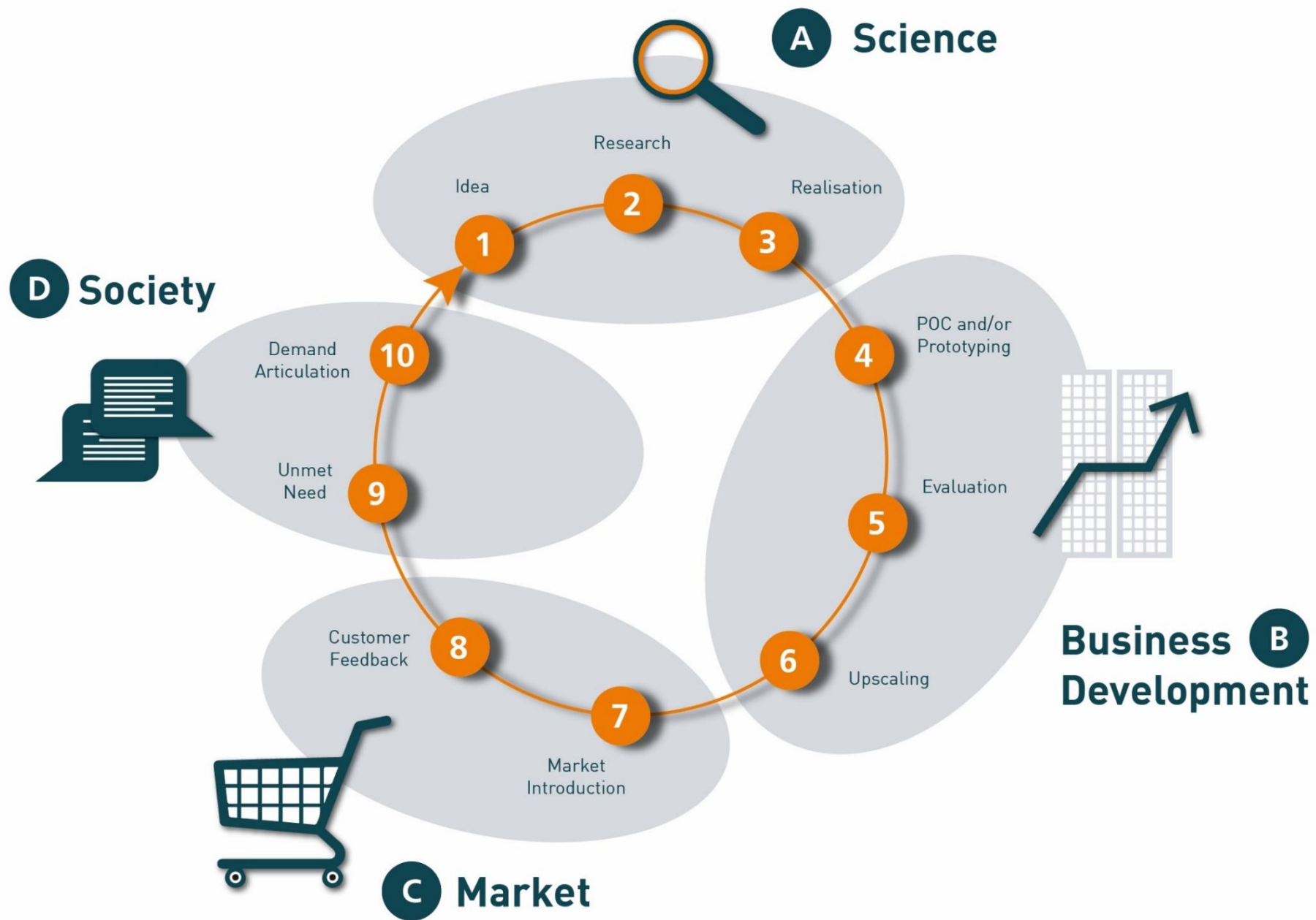


Figure 1. The pharmaceutical “productivity gap”; the considerable rise of R&D expenditures versus a stagnant pattern of New Chemical Entity (NCE) introductions (Data obtained from fda.gov, Medtrack and literature (Drews, 1998; EFPIA)).

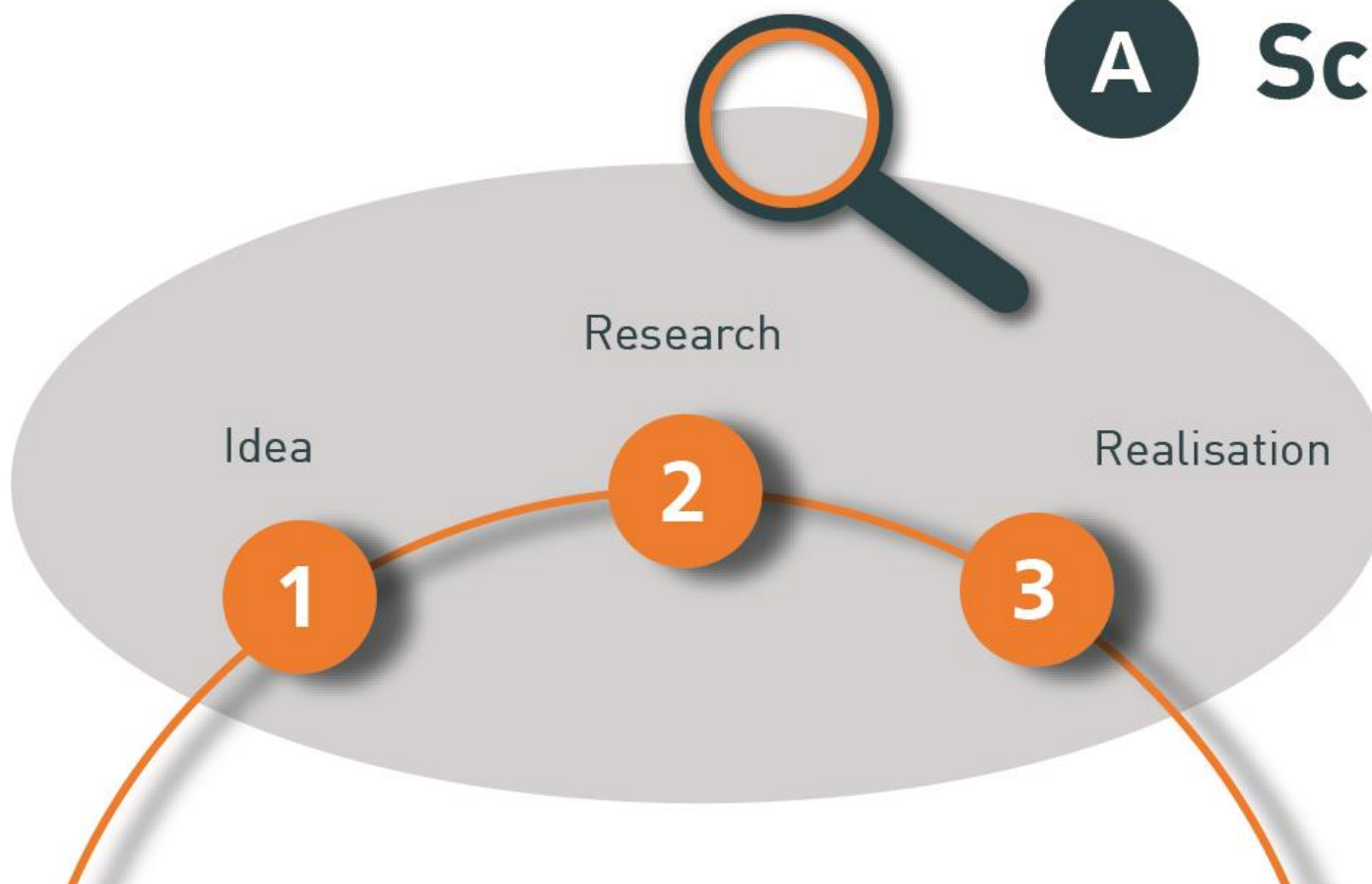
Now, consider your work at INITIATE.

How could you incorporate knowledge valorisation in your work?





A Science



Realization



publication (scientific / layman's / professional)

book

courses (MOOC)

report (policy / advisory)

guideline

database

instruments / tools

patent

designs

software

product

service

3b

REALIZATION

A Scientific Publication

B Oral Presentations /
Conf. Proceedings

C Report

D Courses

E Layman's Publication

F Social Media

G Instruments / Tools

H Database

I IP (see 3a A-F)

J Designs

K Software

L Product

M Serious Games

N Expert Role

O Contract Research

P Training

Q Consultancy

R Service for Fee

S Consortium Building

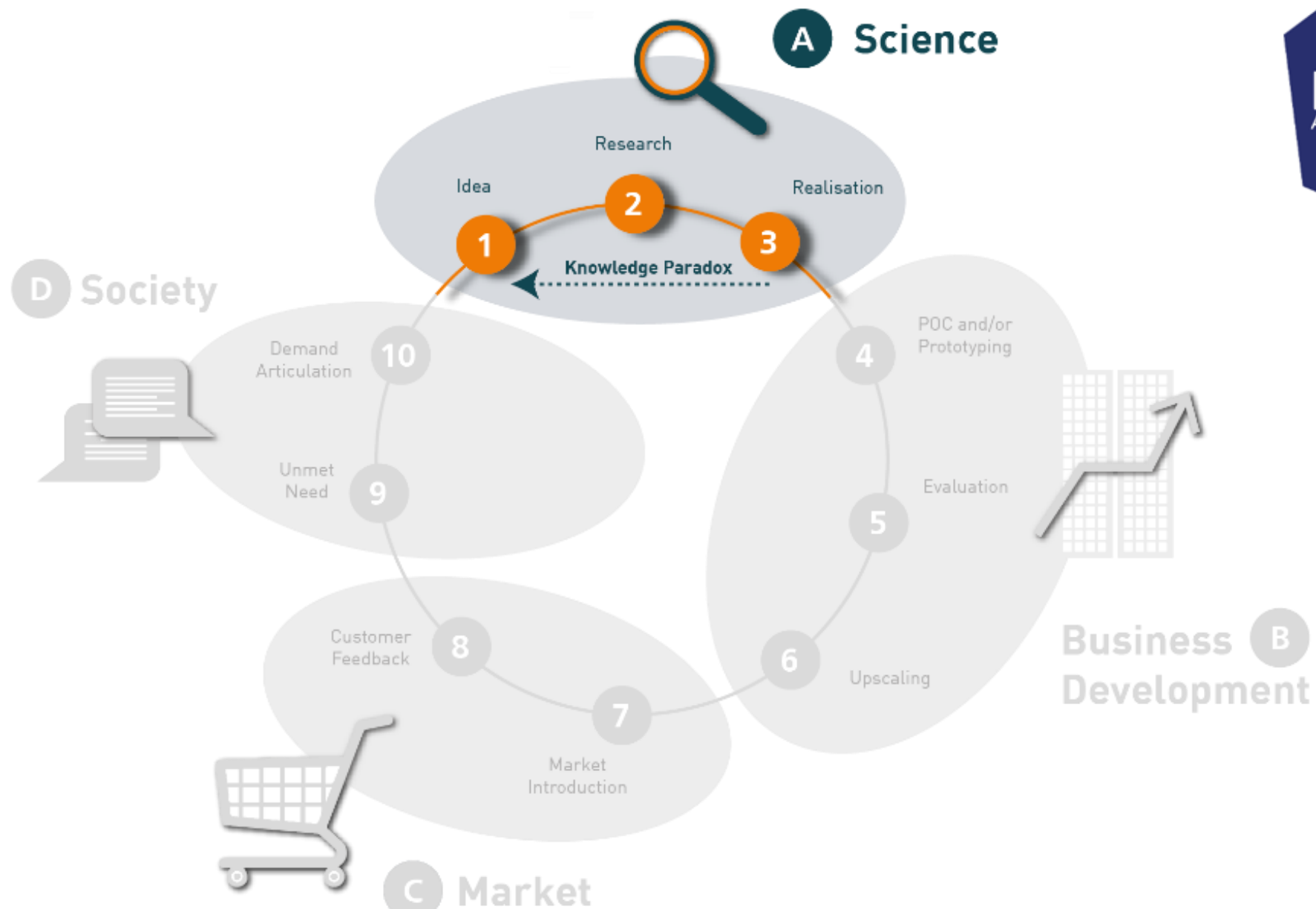
T IP Pool

U Guidelines

V Sale

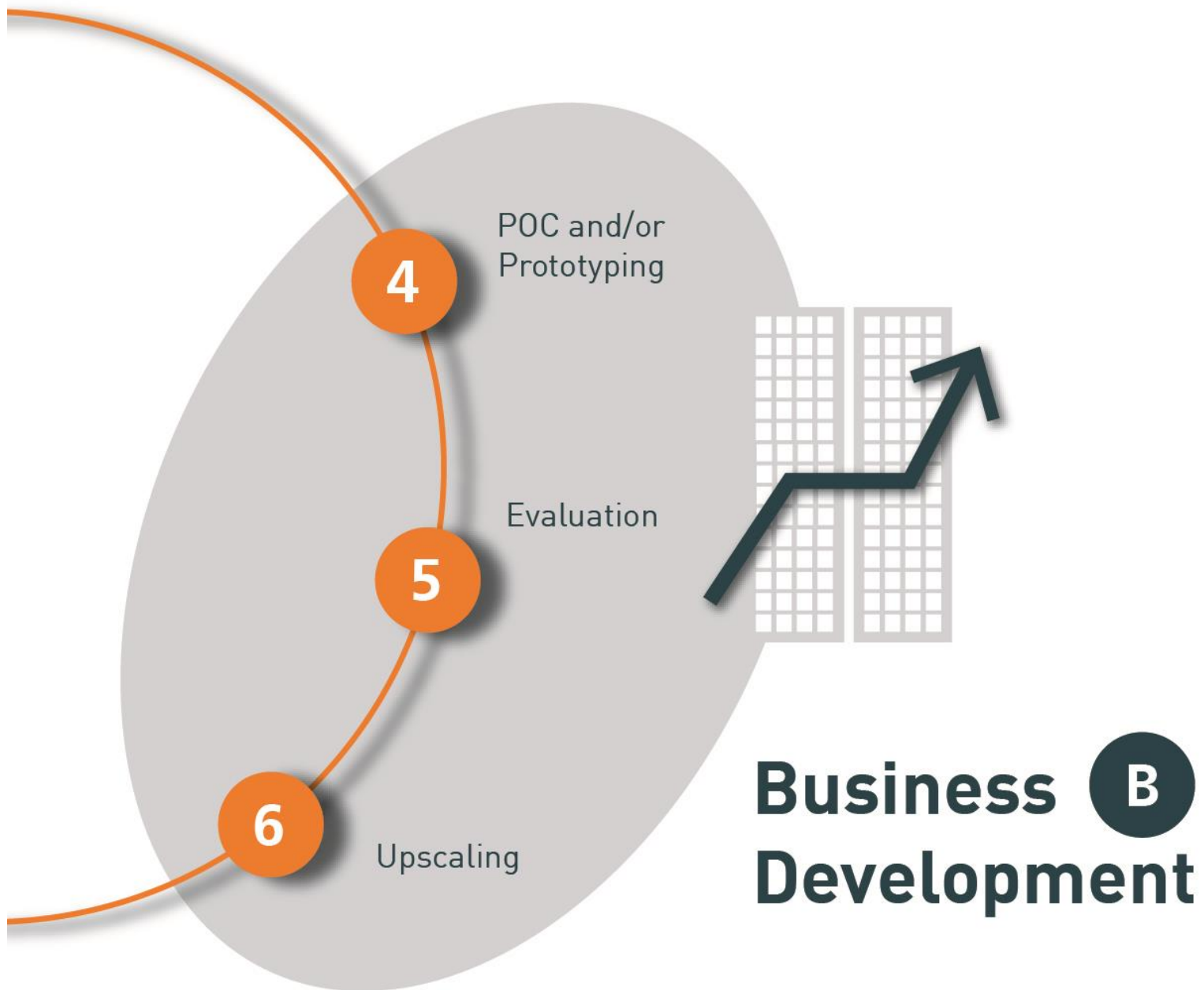
W Licence

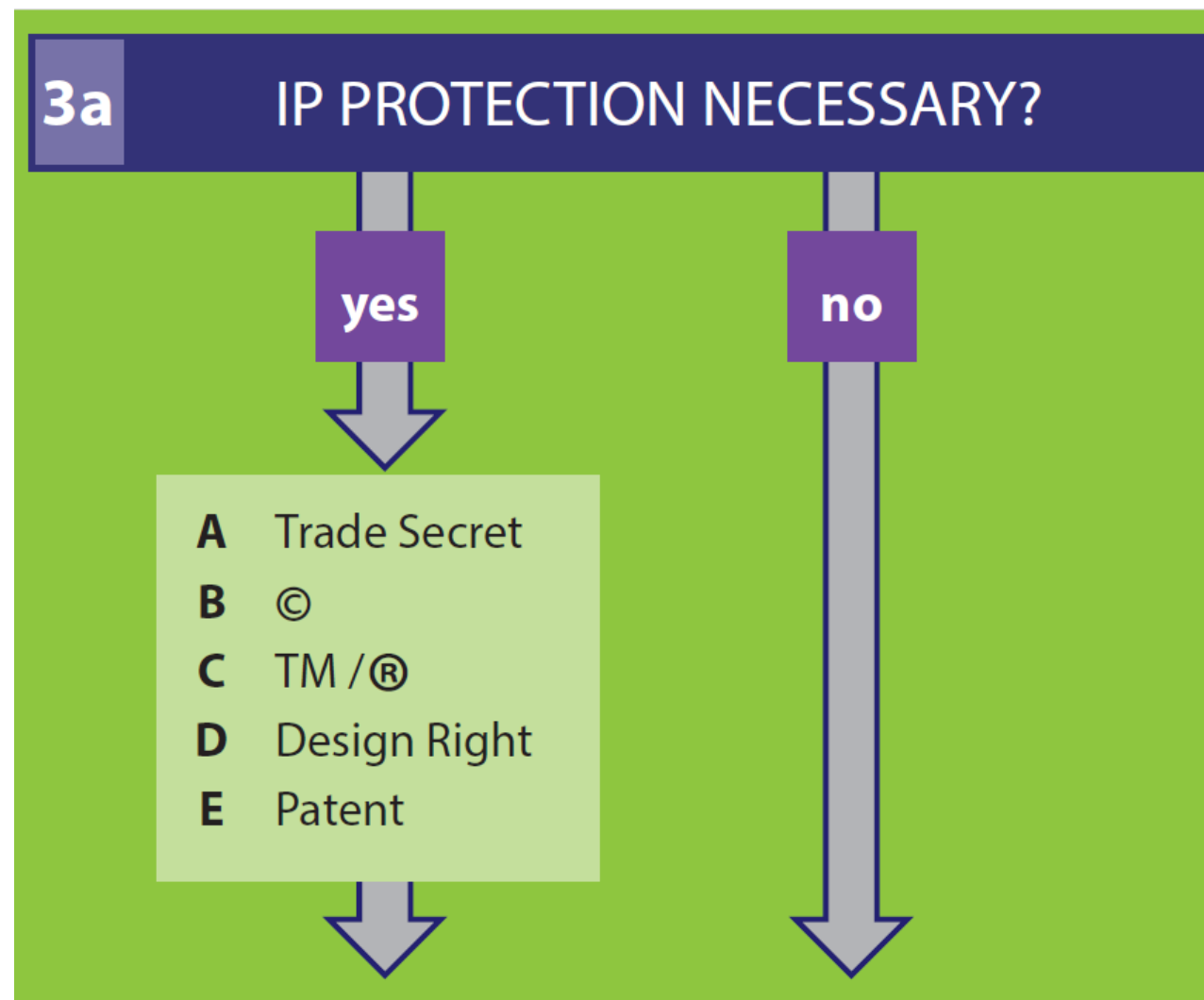
X Spin-out



Bridging the Knowledge Gap



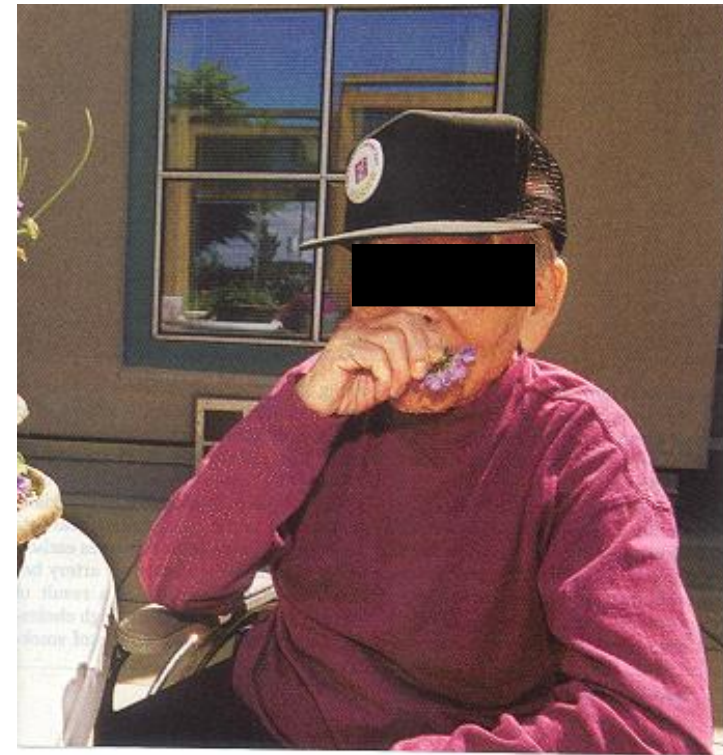




The patient's perspective



- No patent
- No exclusivity
- No price premium
- No profit
- No investment
- No product
- No cure or treatment



Intellectual property rights:

ipr

Industrial rights:
(registration with governments)

Patent law



Brands

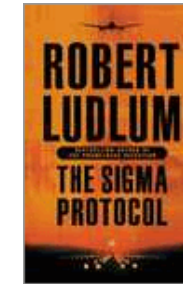


**Drawings and
Model rights**



Other rights:
(no registration necessary)

Copyright

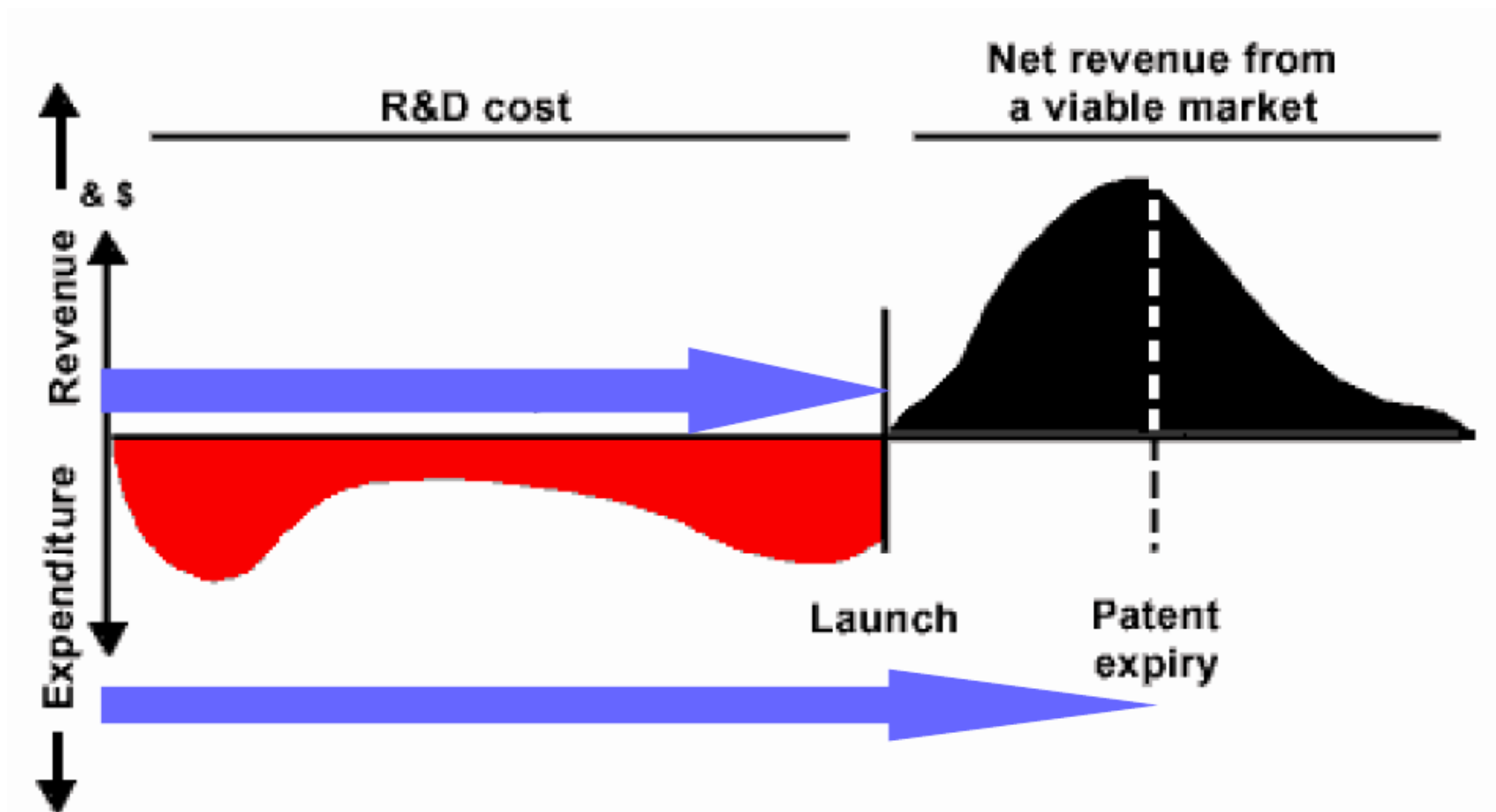


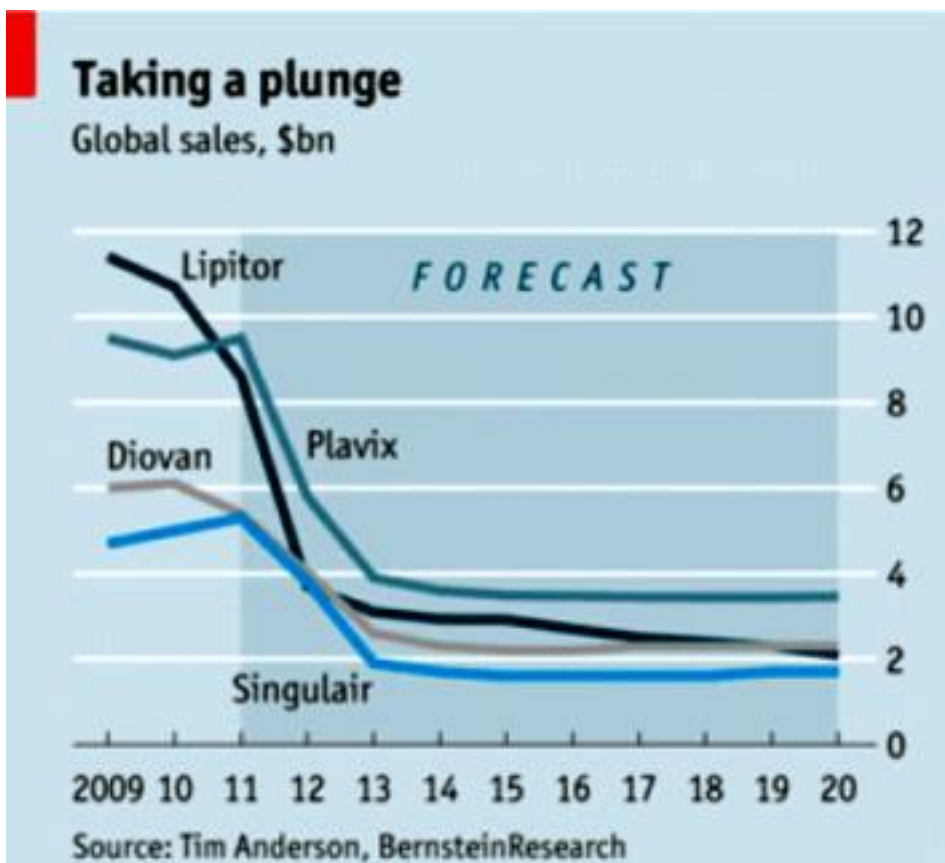
Databases

Trade secrets

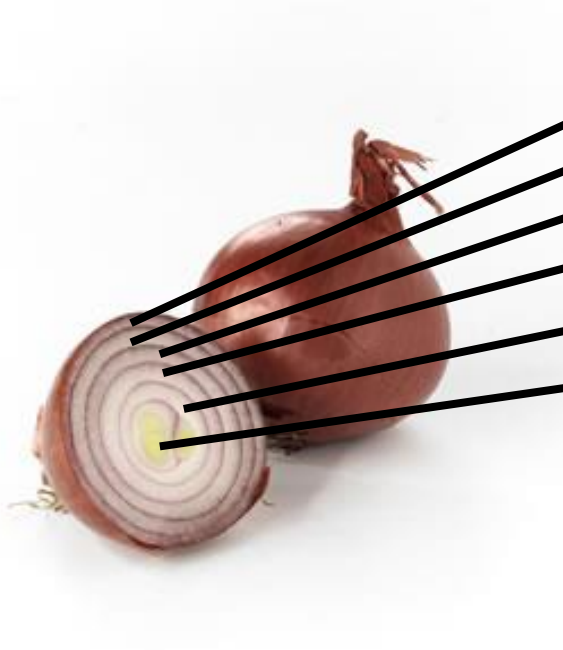








Intellectual property as layers around the core

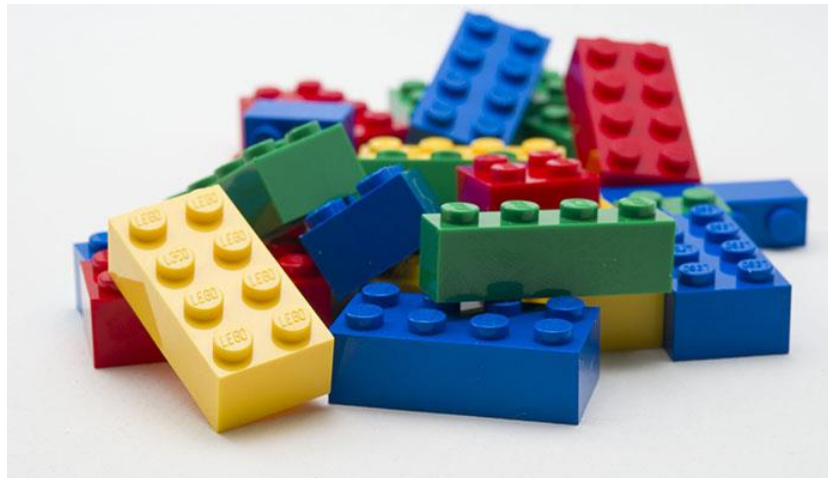
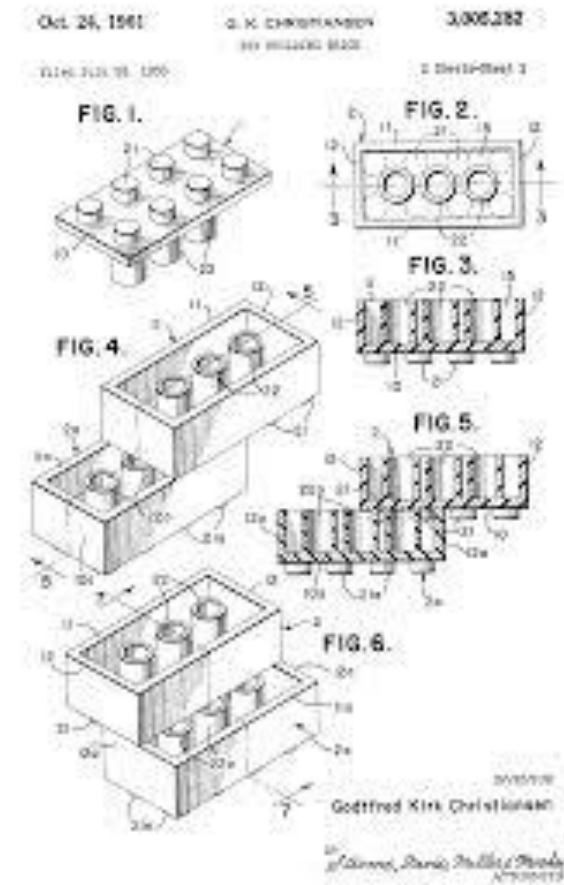


1. REGISTERED TRADE MARK
2. BRAND
3. COPYRIGHT
4. REGISTRATION (DOSSIER)
5. PATENT
6. COMMERCIAL INTANGIBLES
7. MARKETING INTANGIBLES
8. TRADE SECRET
9. TECHNICAL INTANGIBLES

One product, multiple layers of protection



- Trademark
- Patent
- Copyright
- Design



Famous anti-jet lag drug

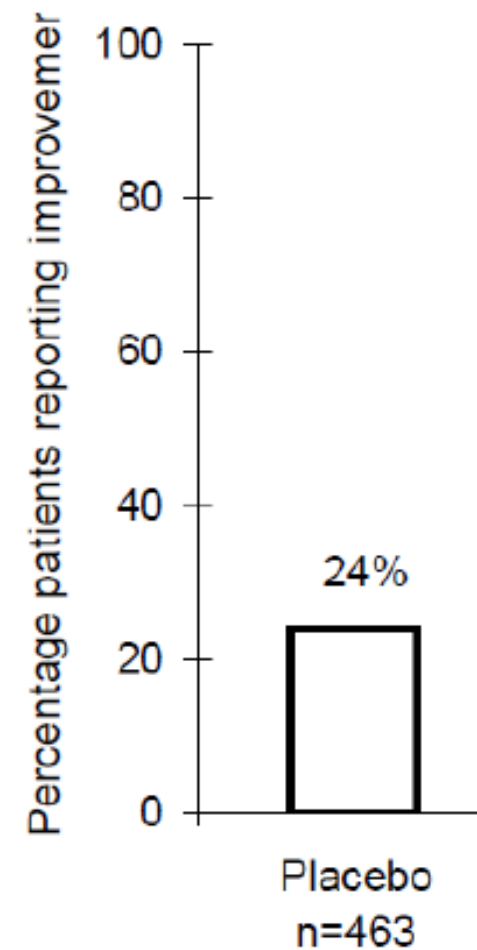
- Original patent on reducing high blood pressure
- “sildenafil”



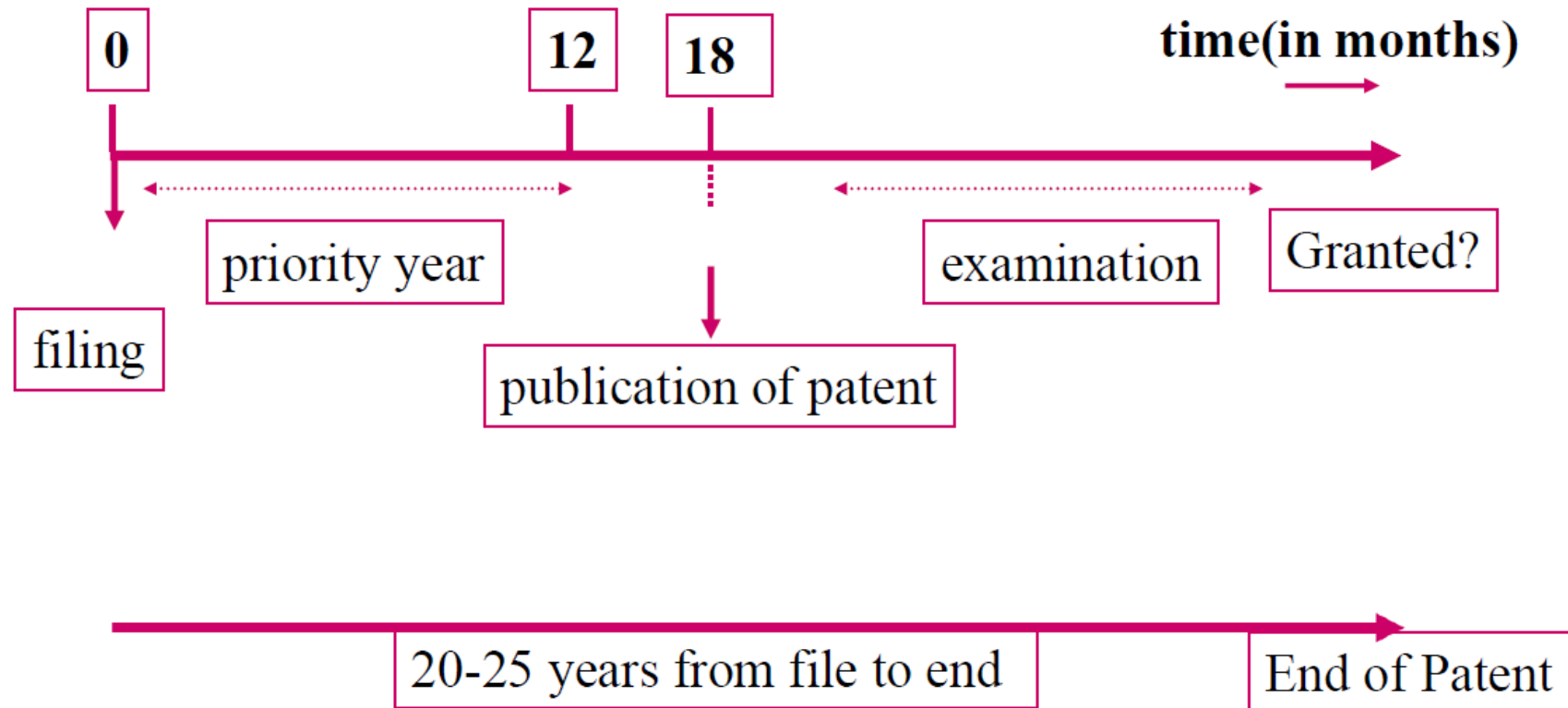


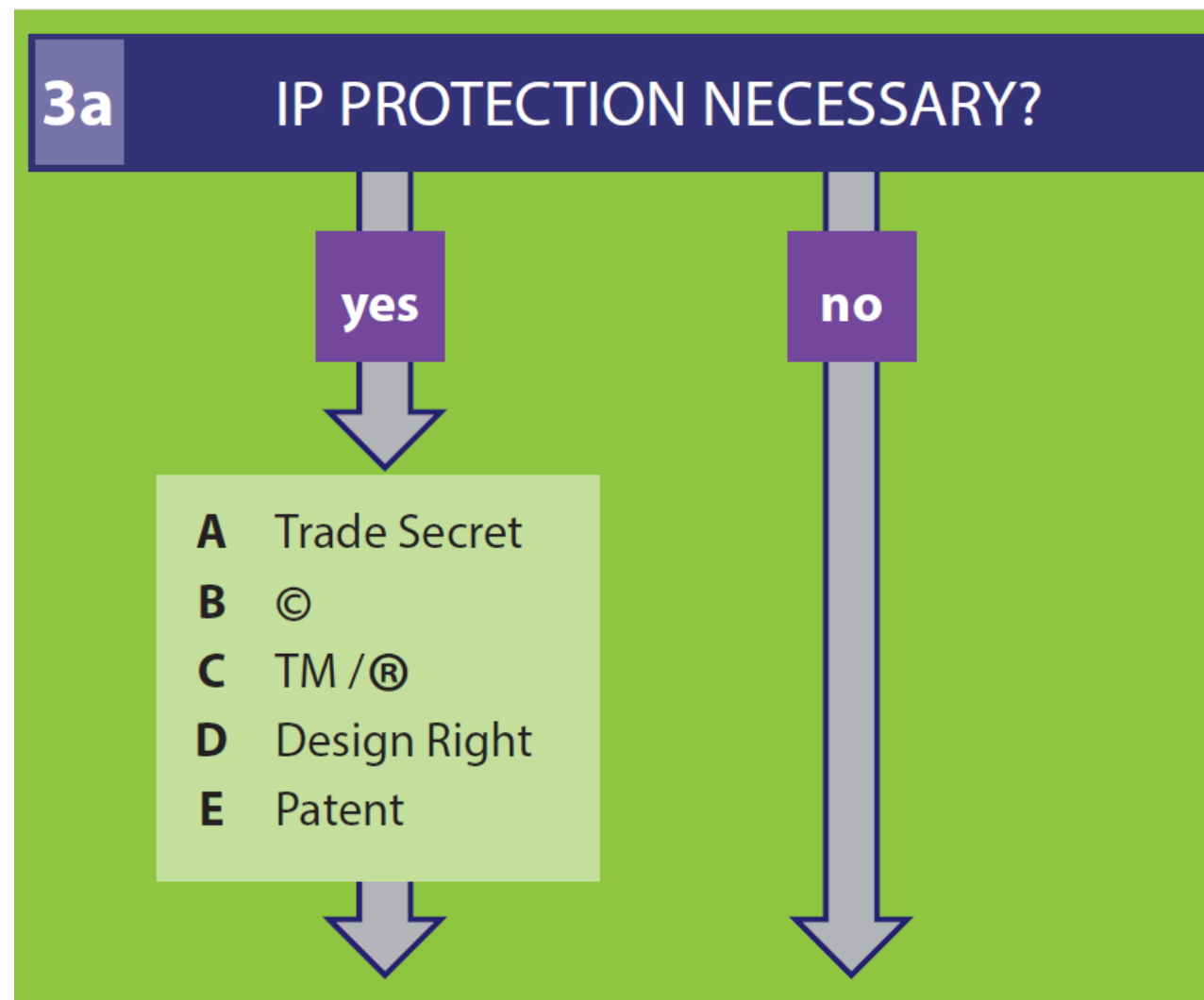


Placebo Effect: 24% report improvement on 'fake' Viagra



Patent procedure





Prior art



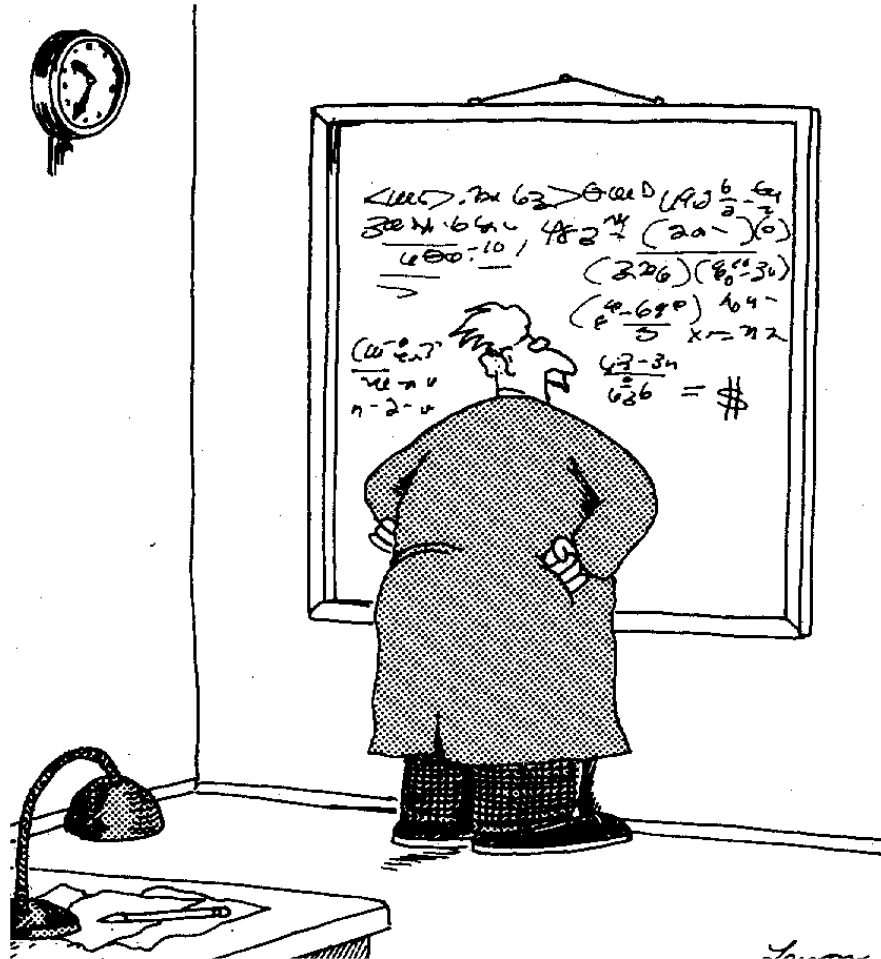
- Anything published on the day before filing a patent application
- First to invent (US) vs. First to file (ROW)
- Patent before you publish

In view of predetermined patent life



- In a small “blockbuster” market of 1 billion annual sales, a delay of one day has a huge impact
- Gross turnover loss almost 3 million daily!
- At royalty rate of 3%, that is 82.000 for licensor
- 100M market, 8.200
- 10M market, 820 or 24.600 per month!

Time is actually money

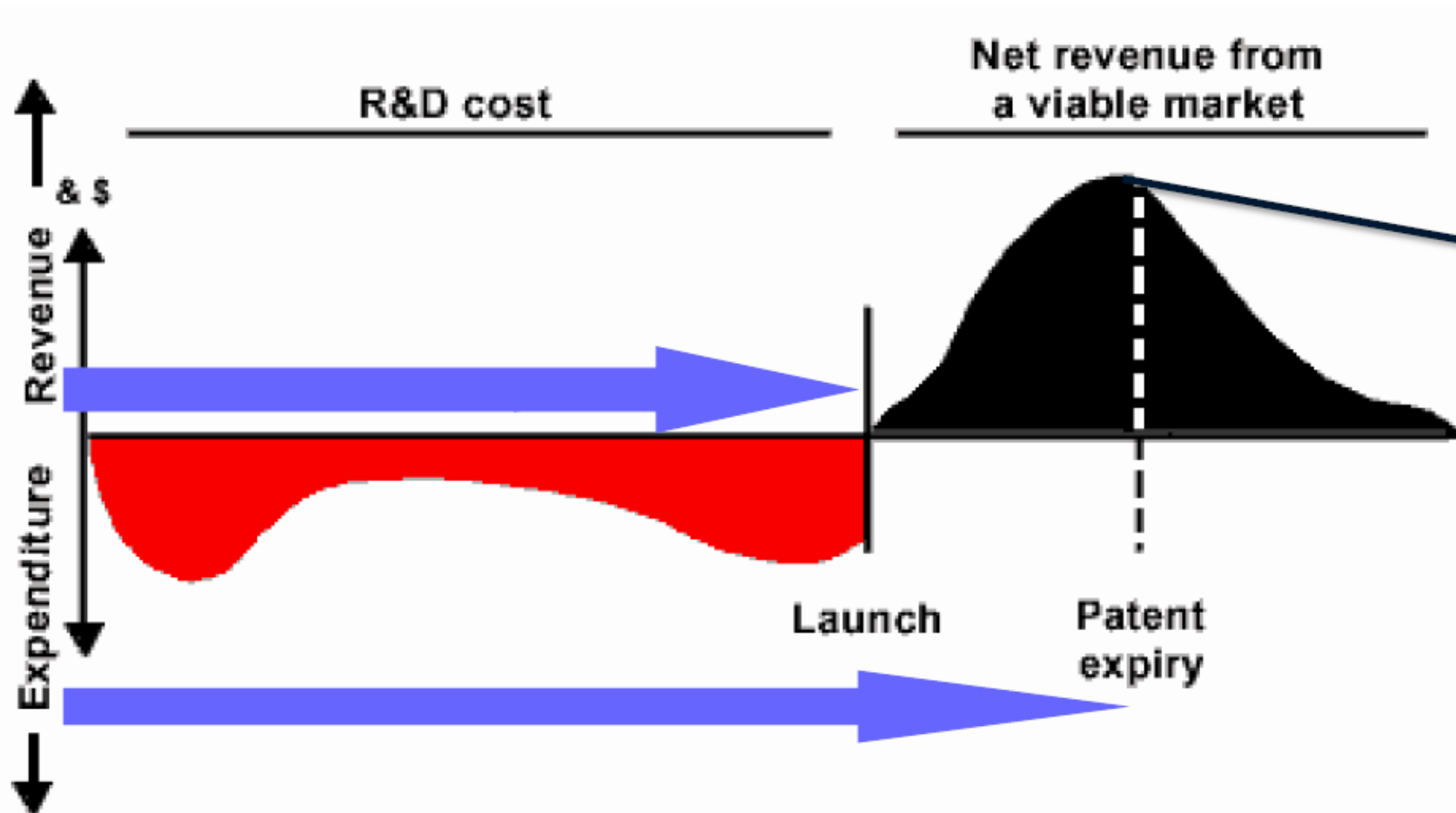


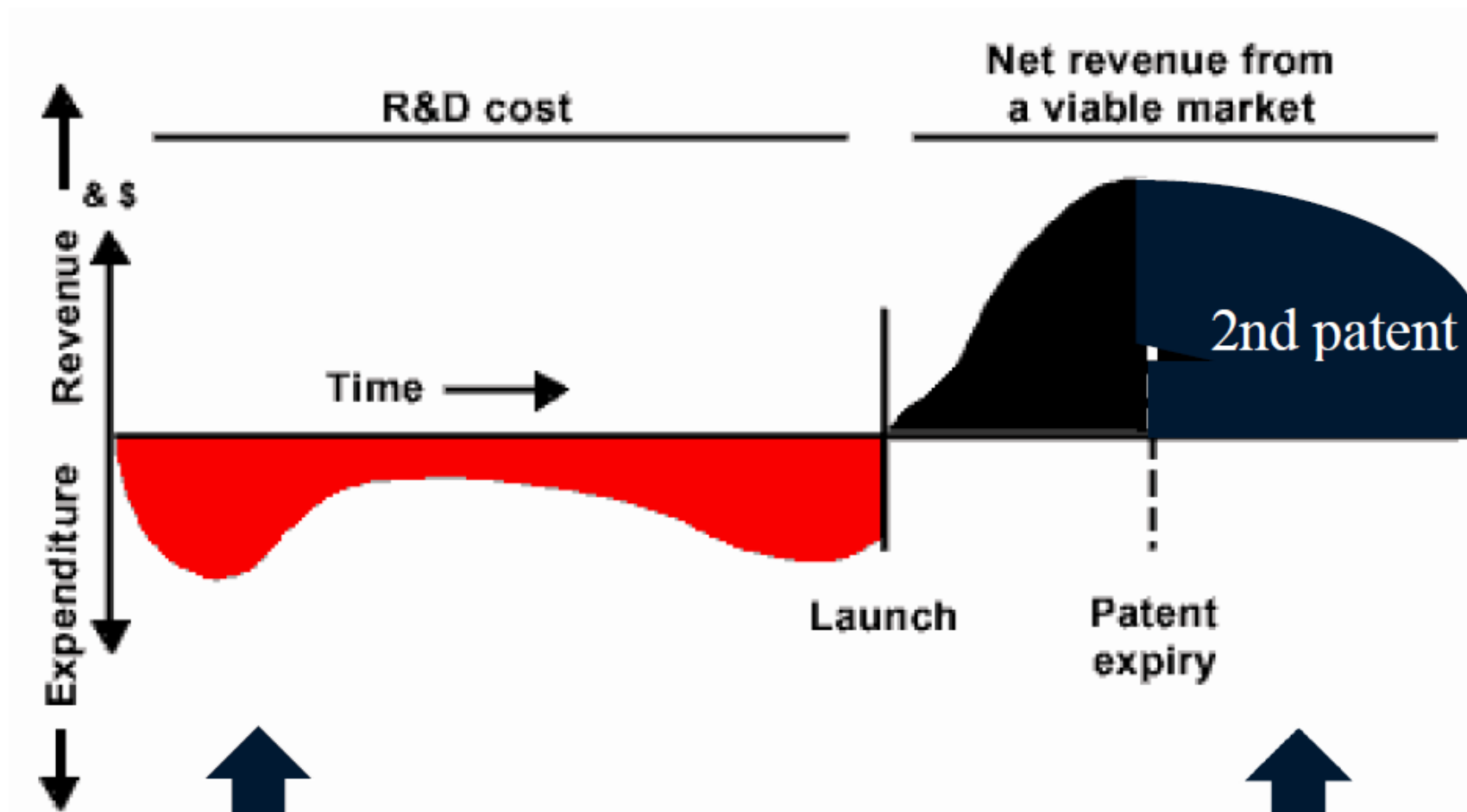
When to patent

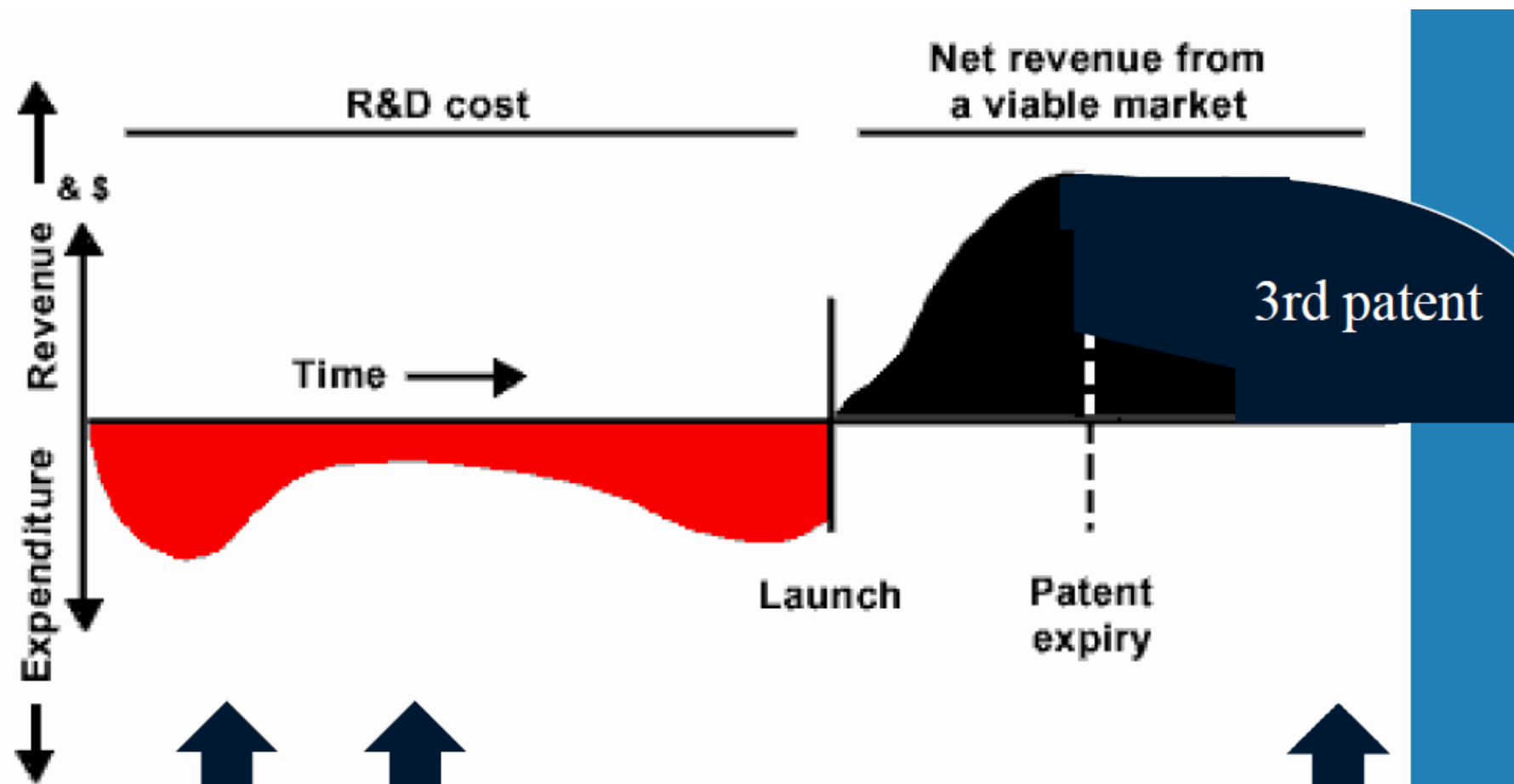


Earlier	Later
Risk of being too late	More evidence to prove 'utility'
	Better supported claims
	Longer (later) patent period

Evergreening







Extending market exclusivity

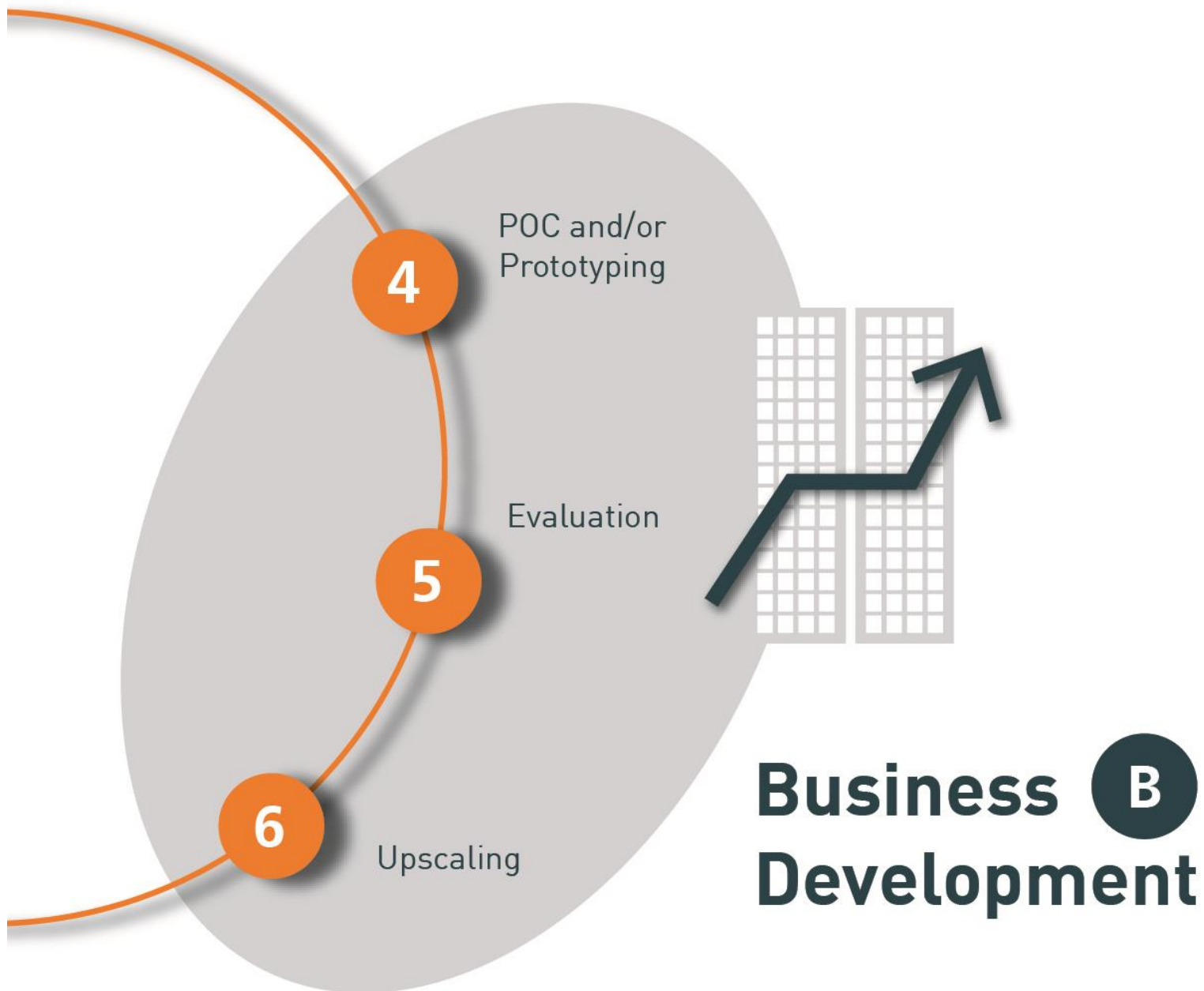
- Multiple patents
- Brands
- Trademarks
- Design rights
- Copyrights
- Dossier data protection (8 years in EU)



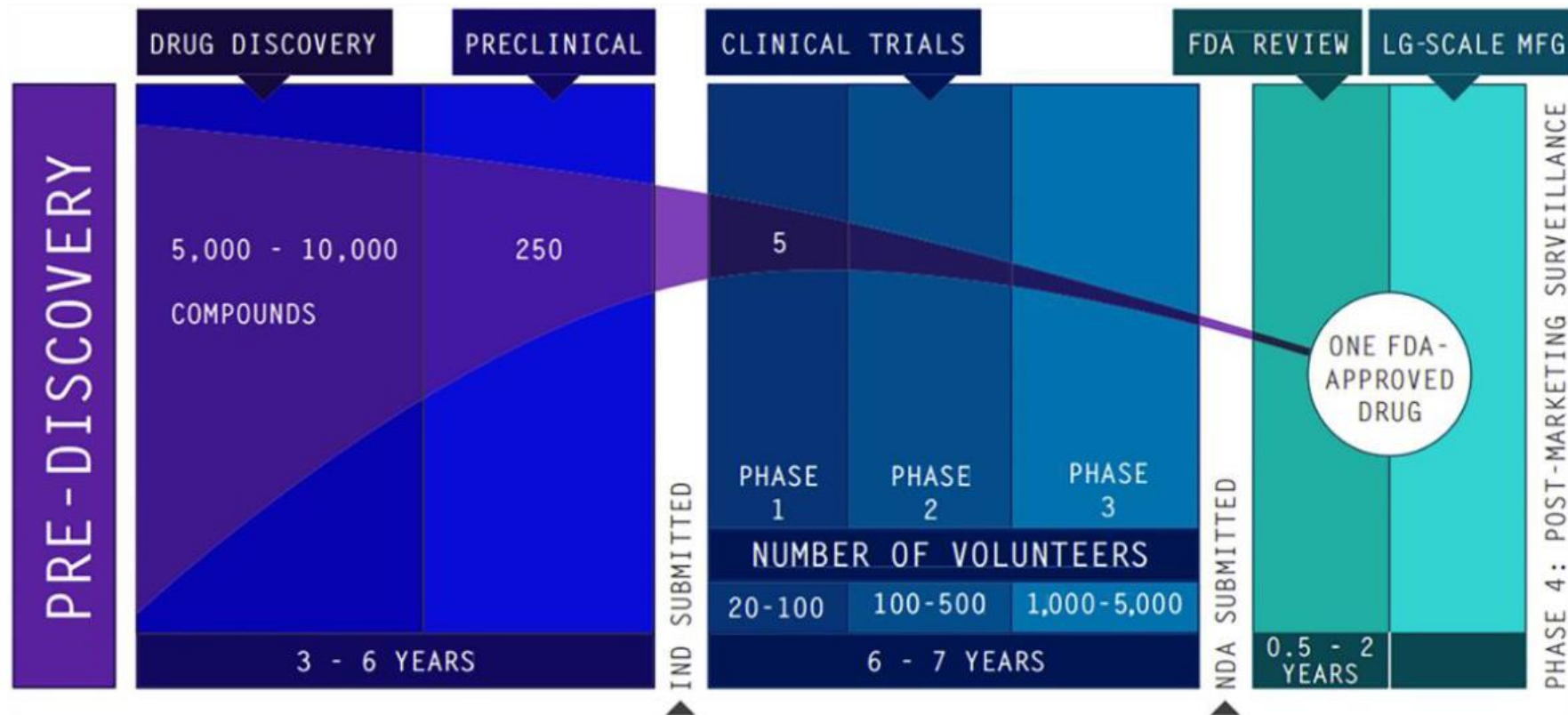
5

EVALUATION

- A** Pre-clinical
 - B** Clinical (Safety)
 - C** Clinical (Efficacy)
 - D** Quality
 - E** Regulatory
 - F** Ecological Impact
-
- G** Societal Impact
 - H** Accessibility
(Access Framework)



Life Sciences value chain



Example failure rates clinical trials in drug development

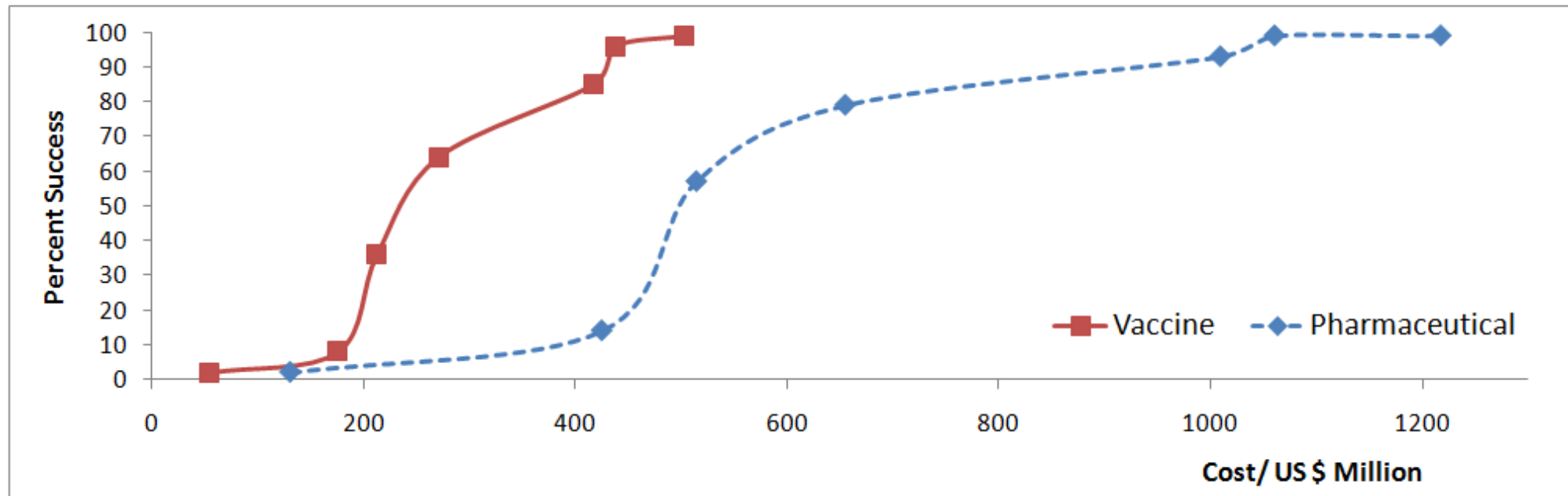


	# of subjects	Length	Purpose	% drugs successfully tested
Phase I	20 – 100	Several months	Mainly safety	60%
Phase II (exploratory / confirmatory)	Up to several 100s	Several months – 2 years	Short term safety; mainly effectiveness	30%
Phase III (confirmatory)	100s – to several 80.000	1 – 4 years	Safety, dosage & effectiveness	60%

Differences in risks between pharmaceuticals and vaccines



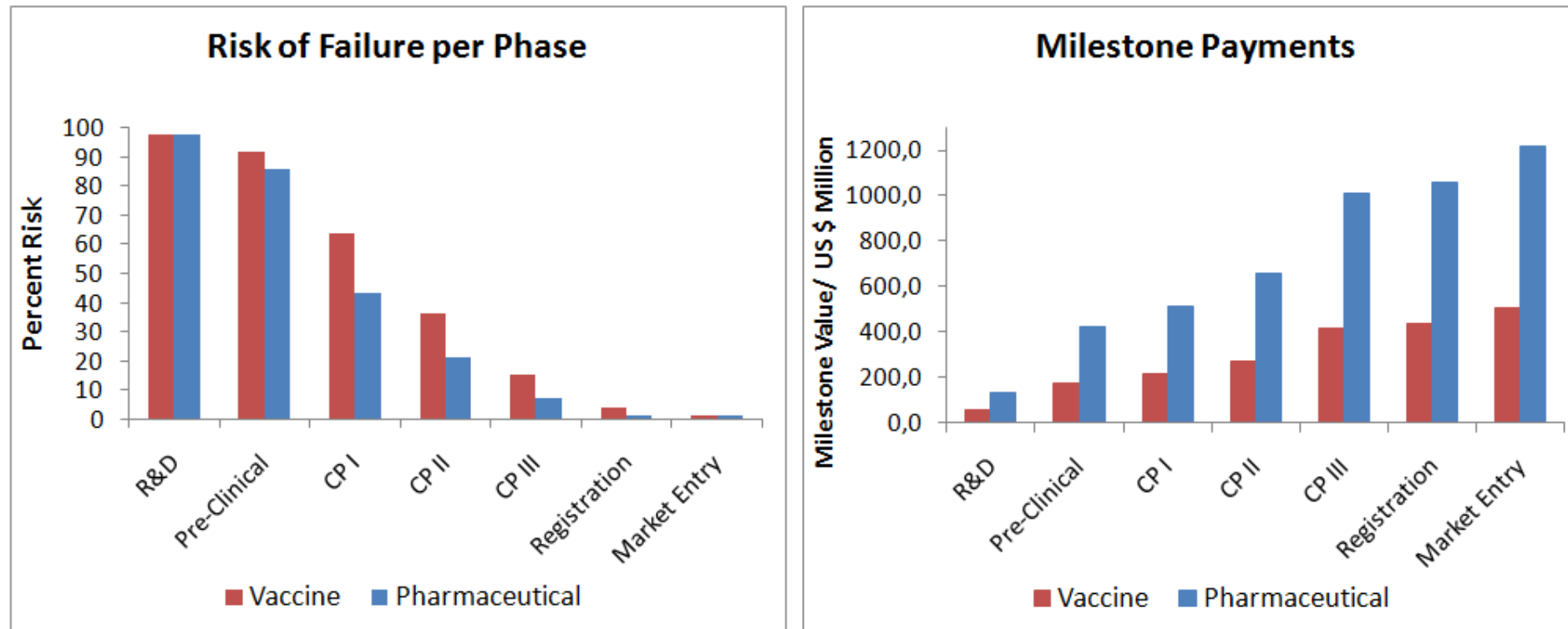
FIGURE PART B: Risk Profile of Vaccine and Pharmaceutical Products



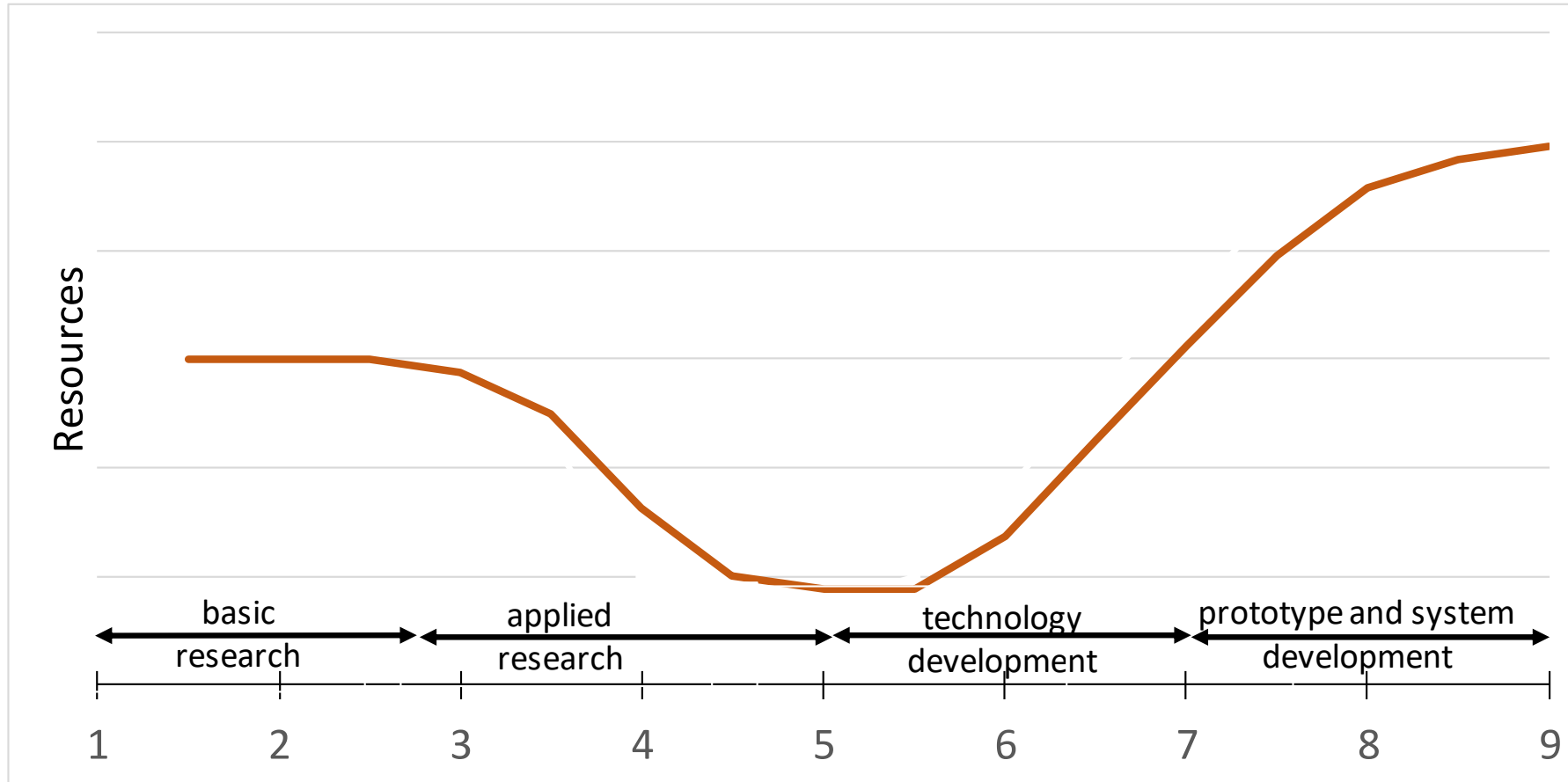
Lower risks correspond to lower milestone payments



FIGURE PART A: Risk and Milestone Payments



EU: Technology readiness levels



EU: Technology readiness levels



Proven
Technology

Commercialization Chasm

"Industry"

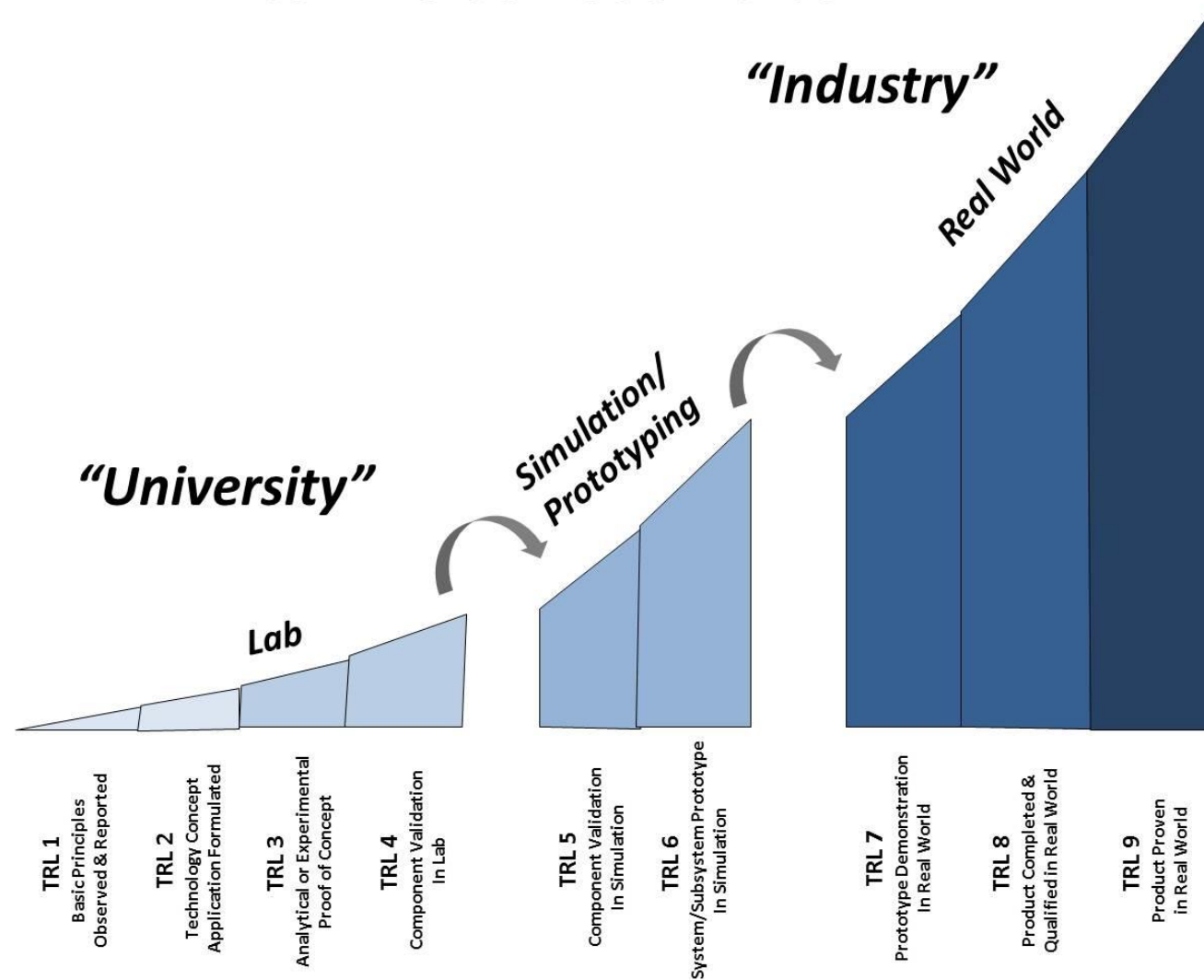
Real World

"University"

*Simulation/
Prototyping*

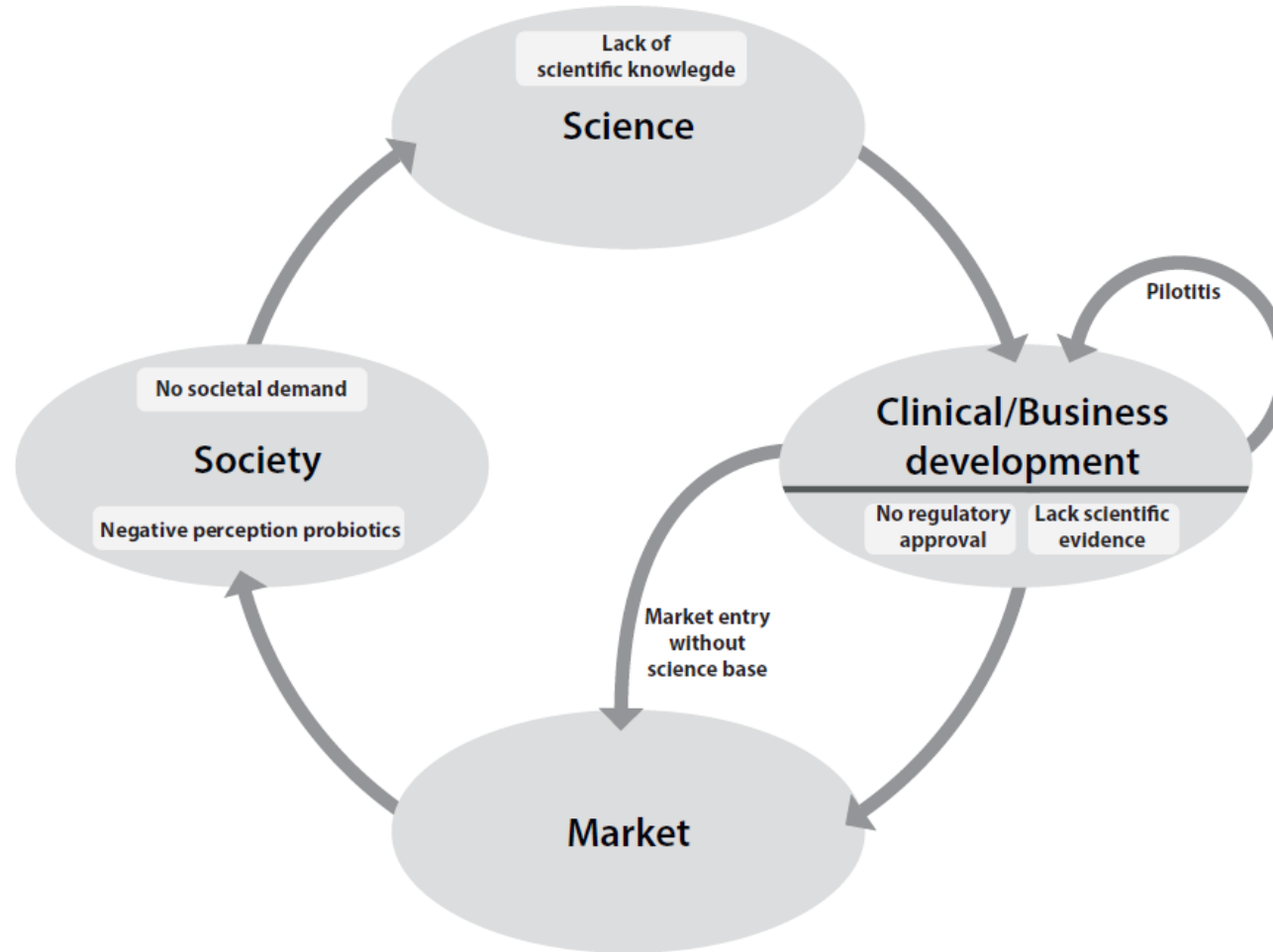
Lab

Basic
Principles





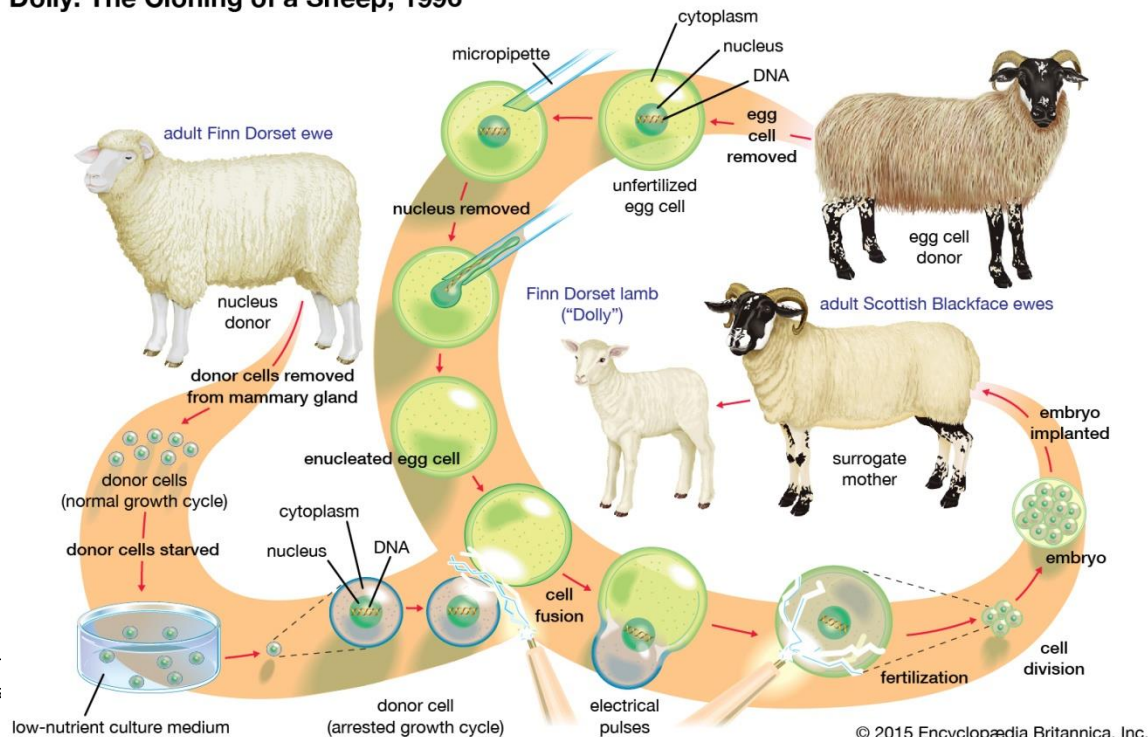
Rush to Market in Probiotics







Dolly: The Cloning of a Sheep, 1996



**Bull Herman alive in the museum
in Leiden, Naturalis**



D Society



Demand
Articulation

10

Unmet
Need

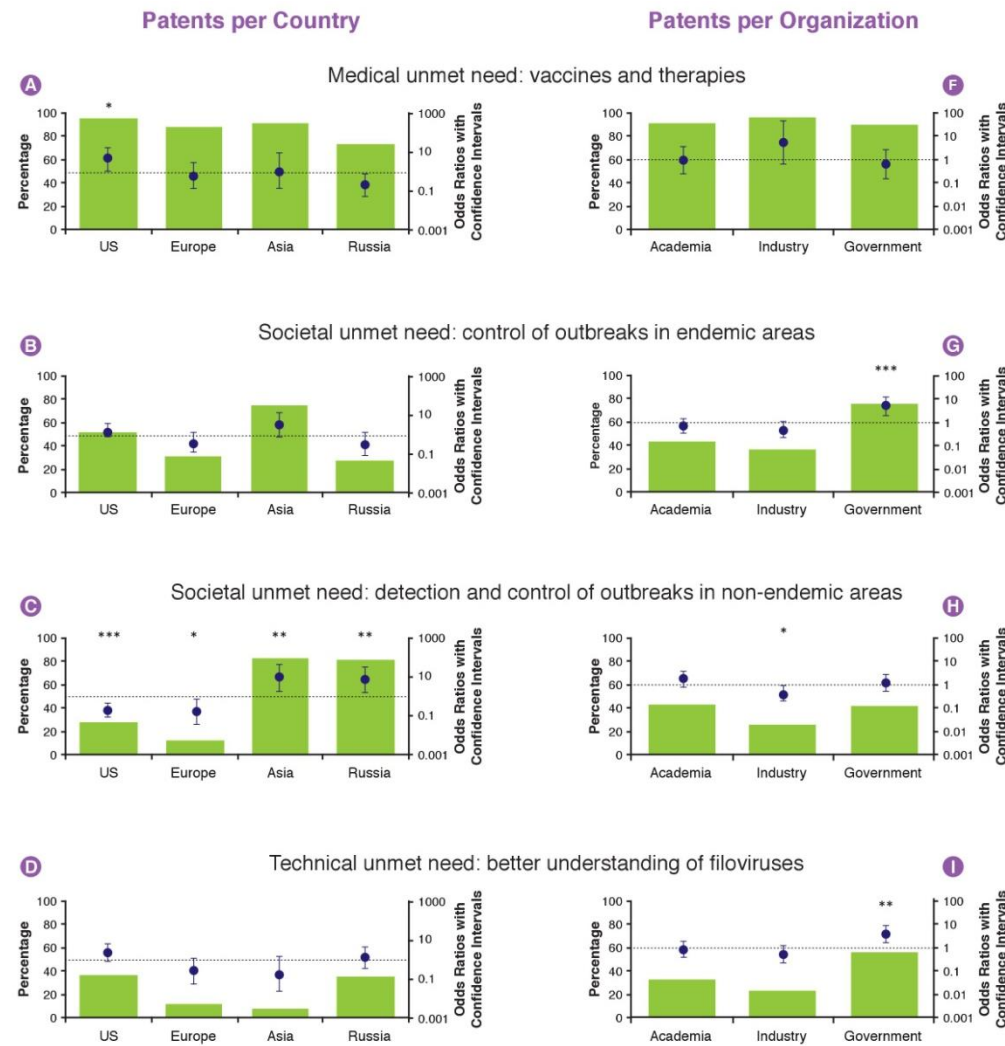
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10 DEMAND ARTICULATION

Agenda Setting

- A** Media
- B** Public
- C** Commercial
- D** Policy

Demand A

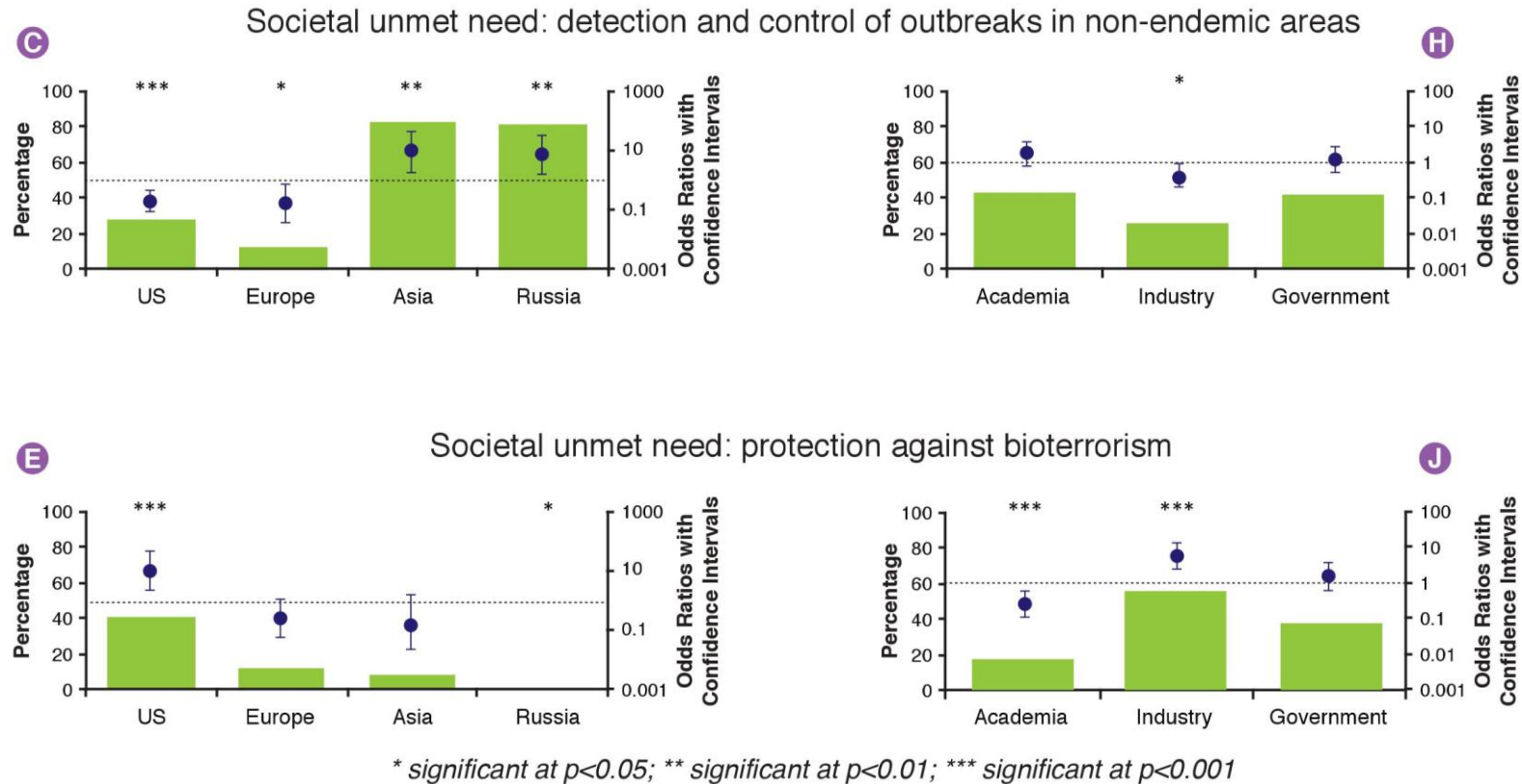


Self-Centric and Altruistic Unmet Needs for Ebola: Barriers to International Preparedness

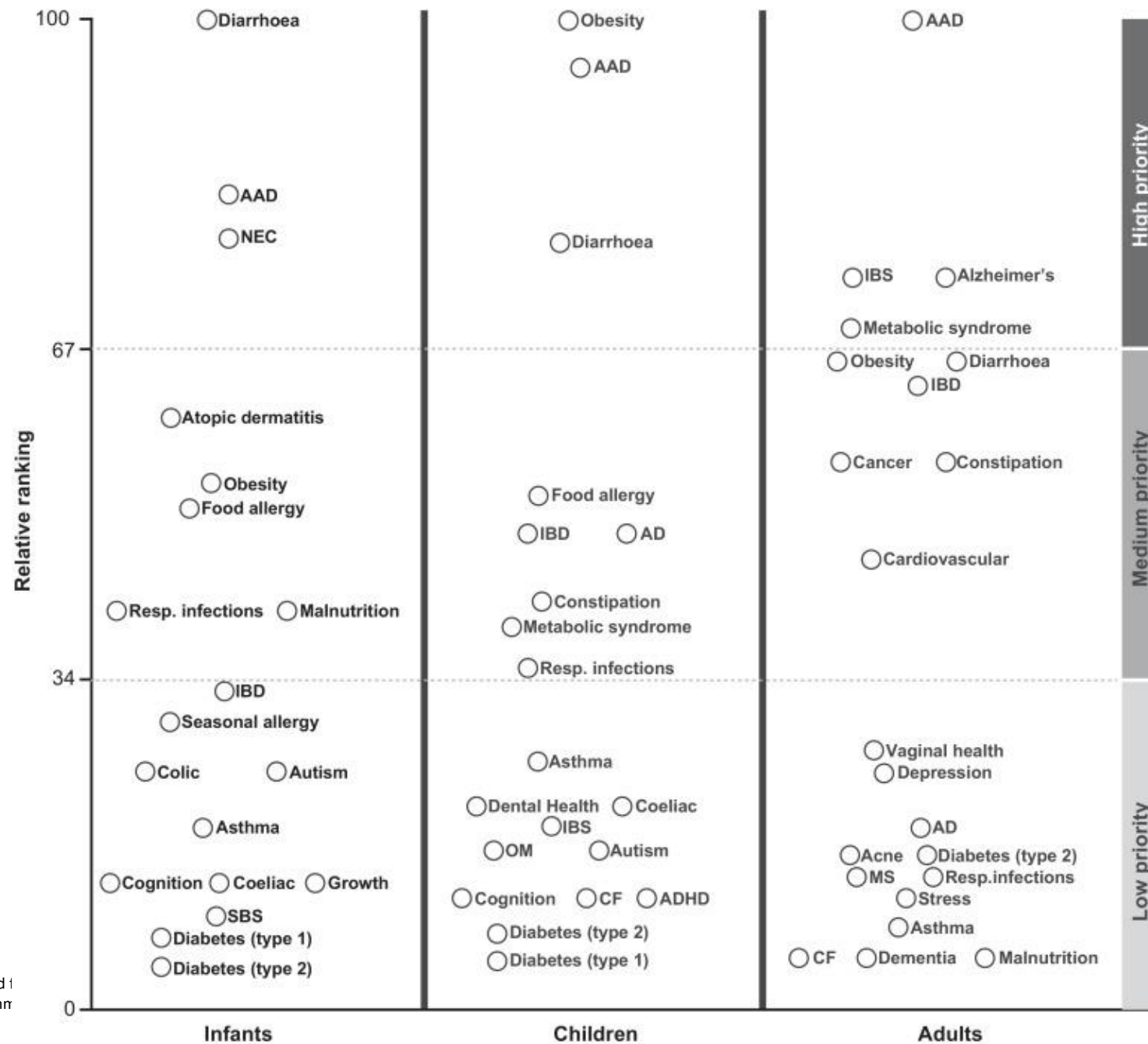
Linda H.M. Van de Burgwal, MSc; Leslie A. Reperant, PhD; Albert D.M.E. Osterhaus, Prof dr; Sorana C. Iancu, PhD; Esther S. Pronker, PhD; Eric Claassen, Prof dr

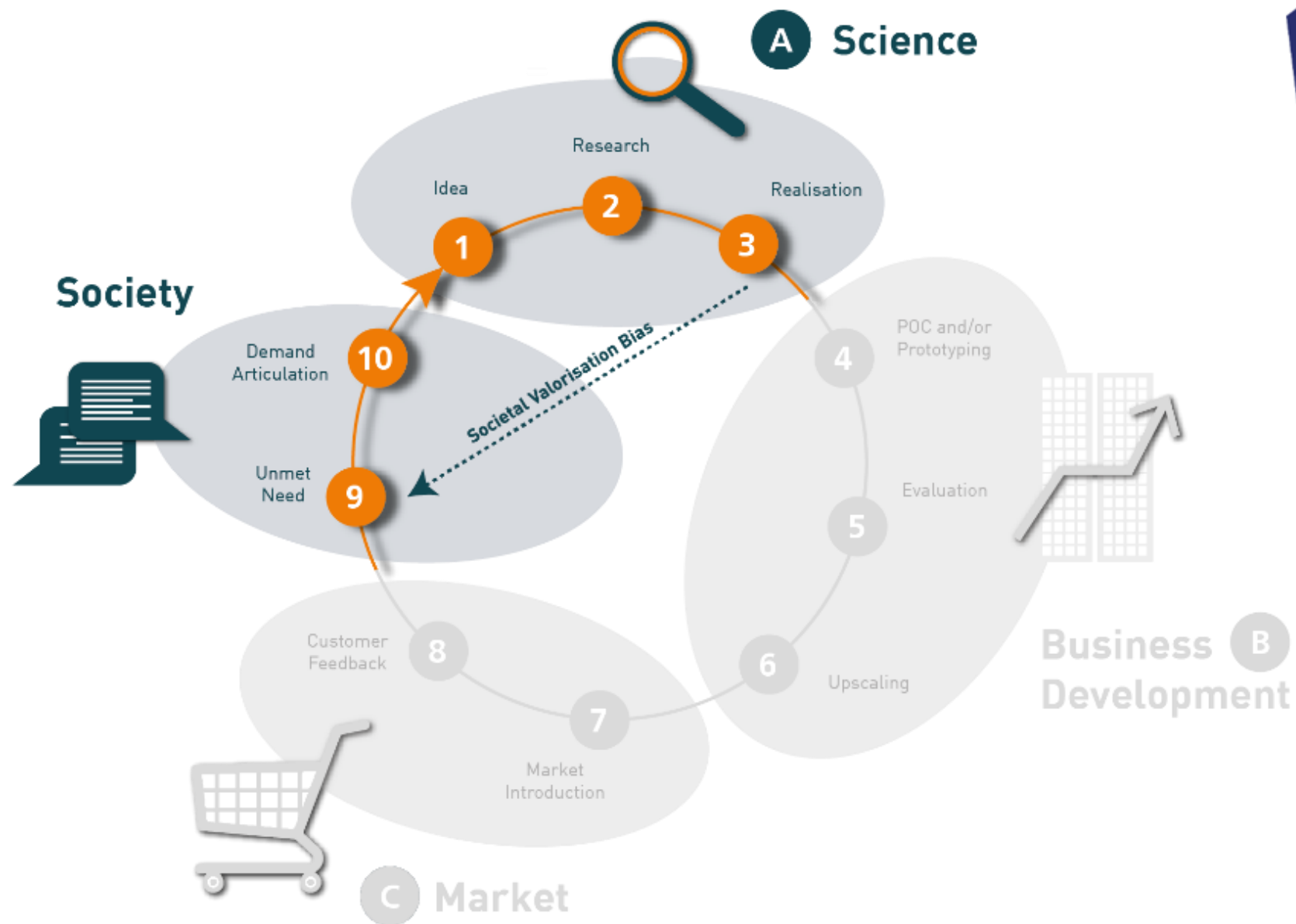
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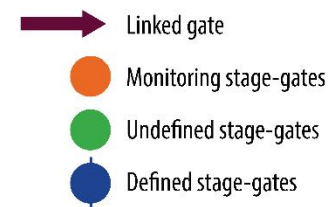
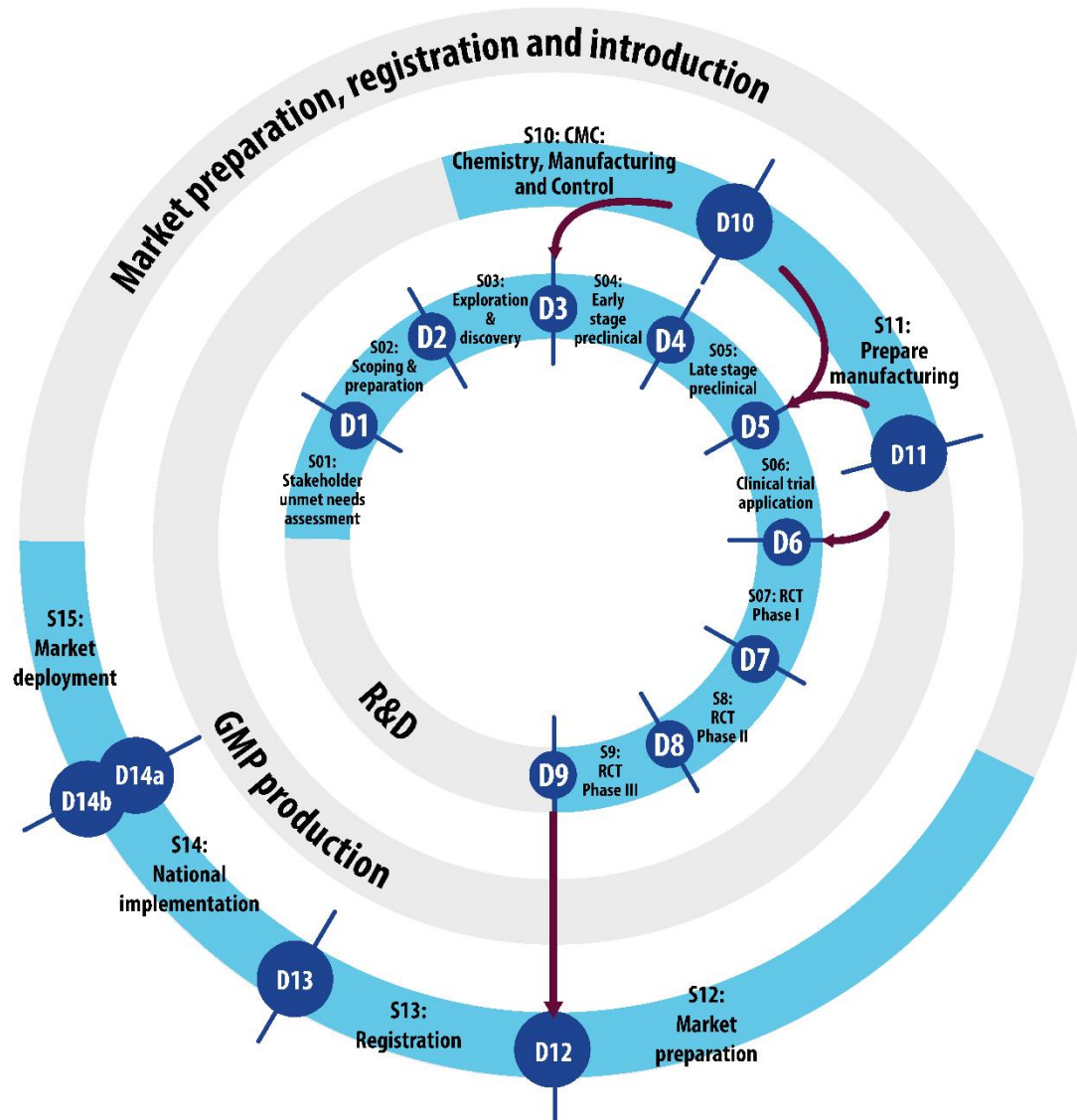
Demand Articulation



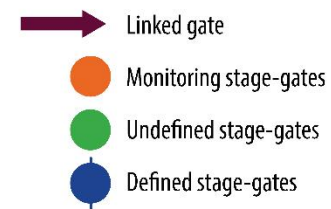
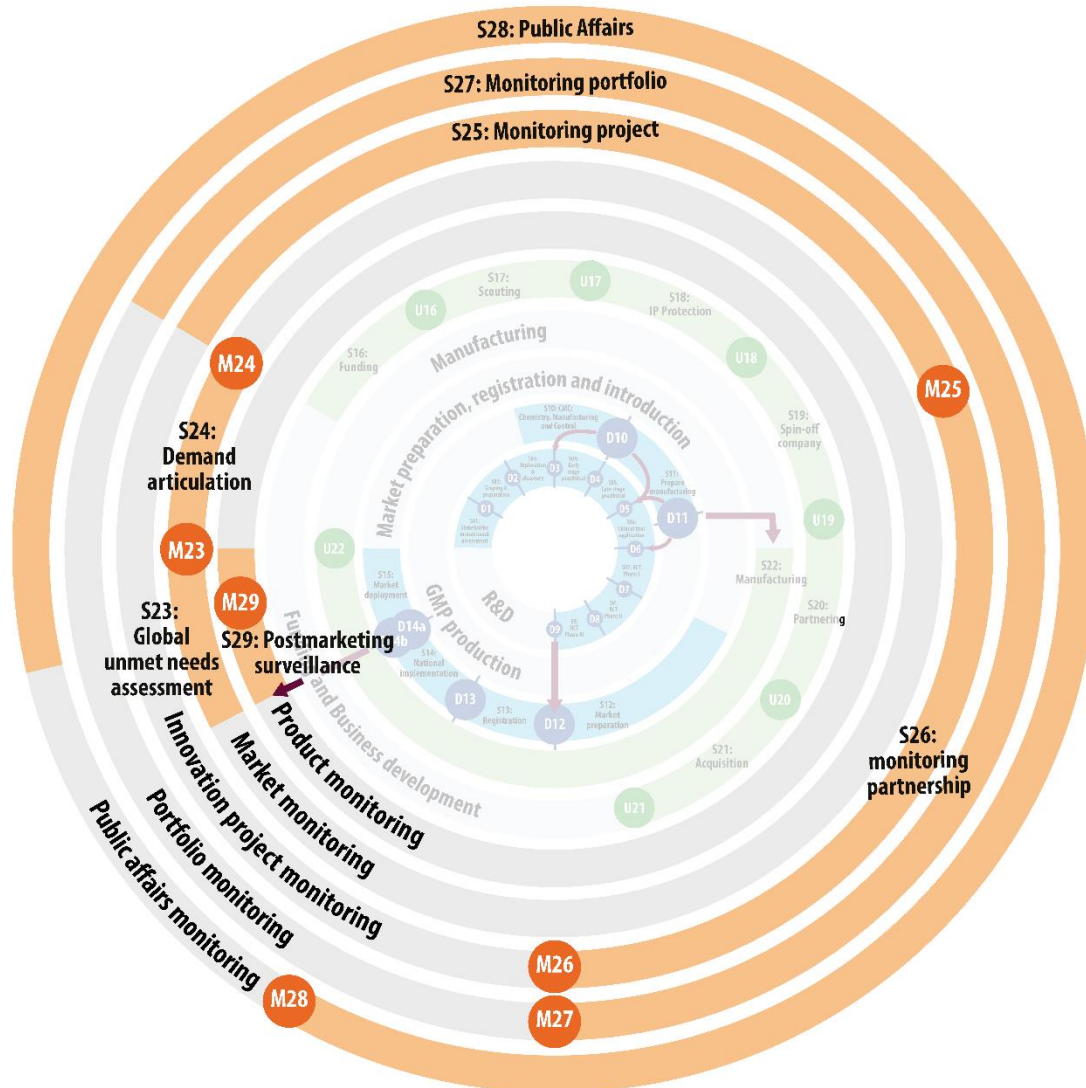
Clinical condition prioritization

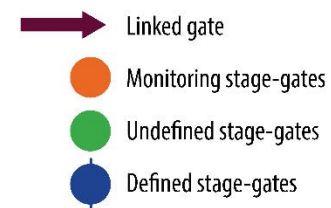
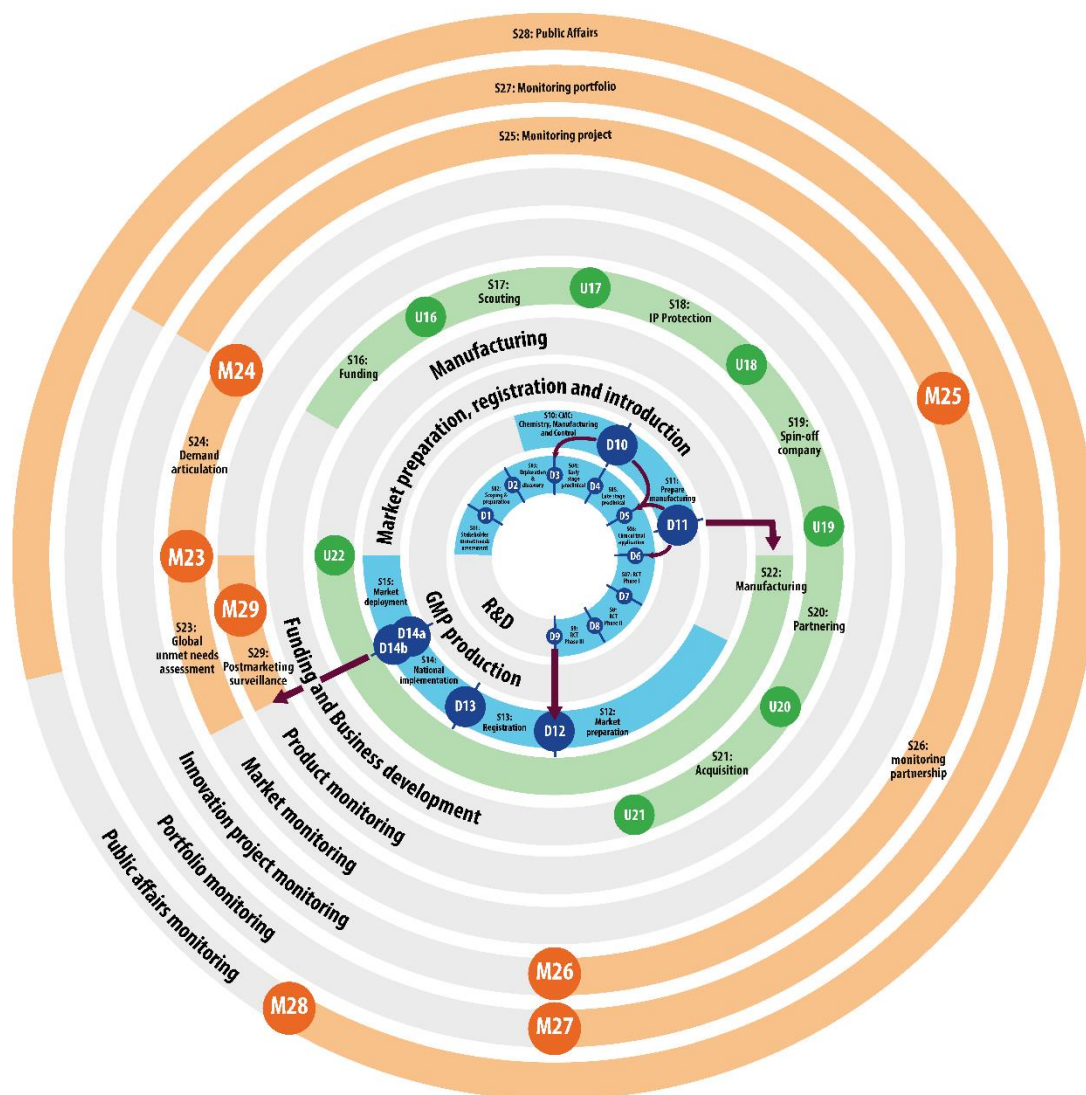


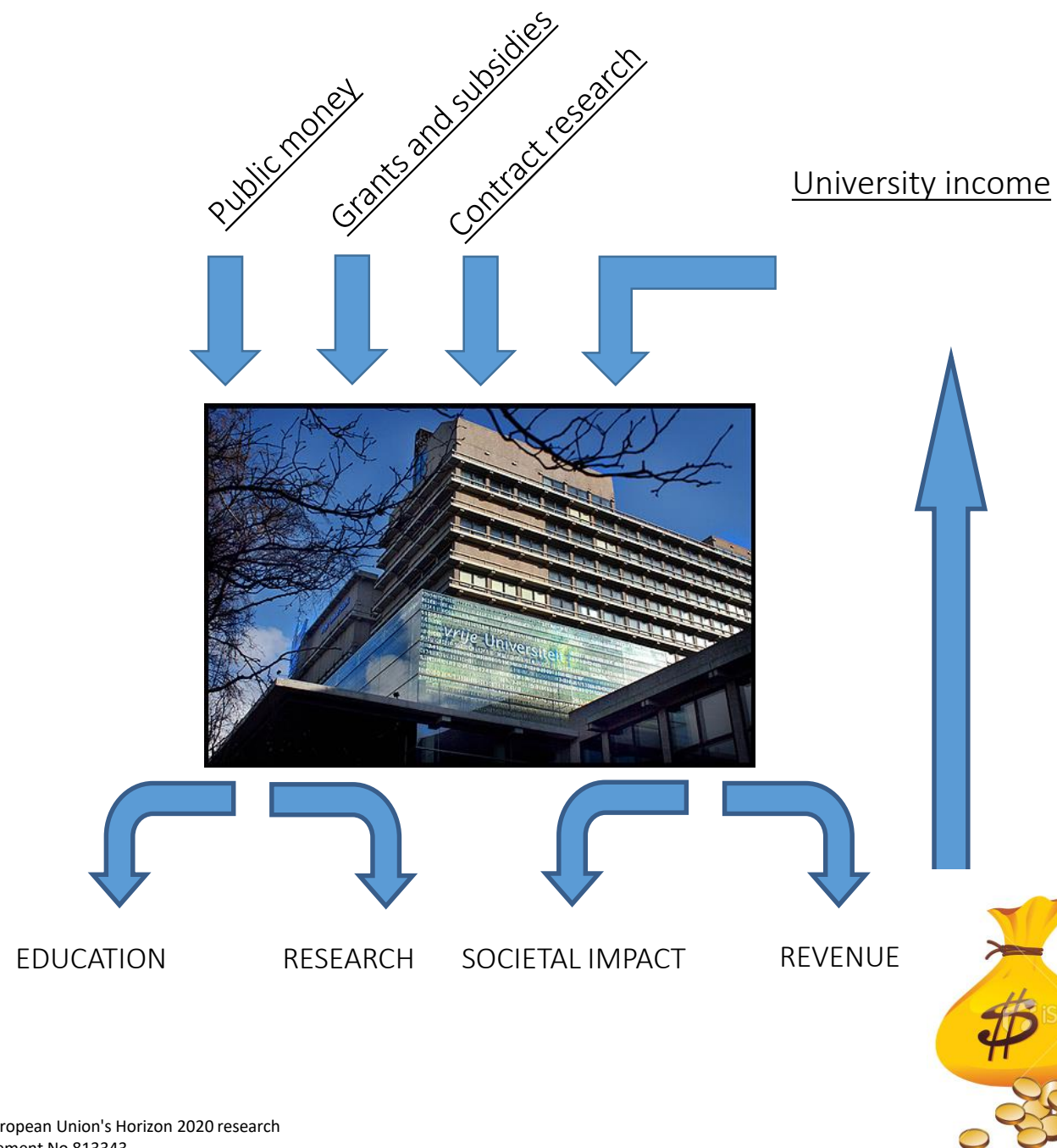


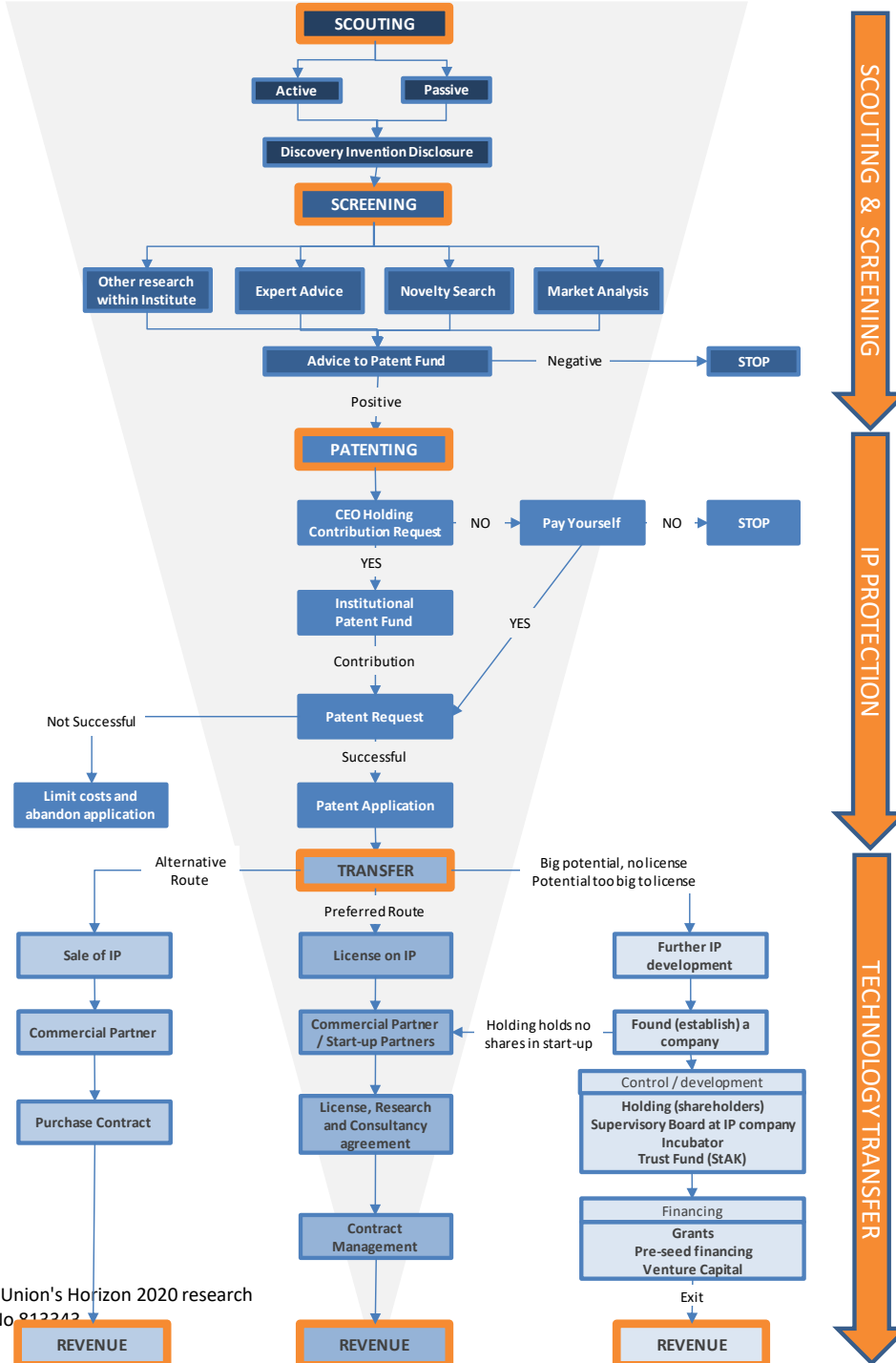


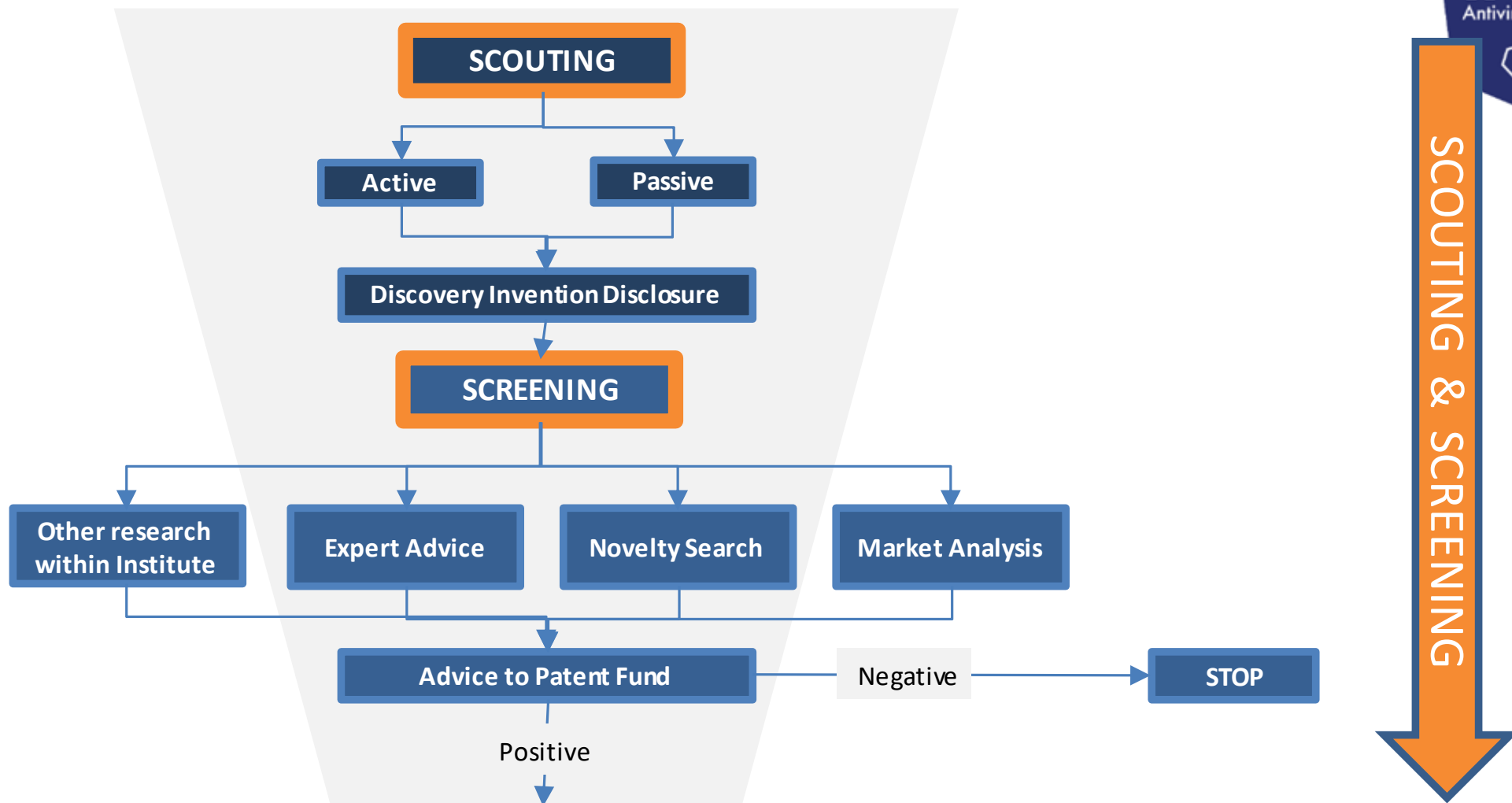












Probability of Success



10) High P.O.S.

- Currently have the capability
- Defined technology

- Have access to the channel
- Have demonstrated ability to realize value
- Strong evidence exists to support expected volume and margins

8)

- Partial proof of benefit or continual development required (e.g., hybridization)
- Strong related capabilities

- Have a “roadmap” and access to some portion of the channel

6)

- Requires additional development to prove viable cost-benefit
- Success is likely within 5 years

- Have proven related capabilities (e.g., have done it with x but not y)
- Proven benefit but consumer behavior changes requires (e.g., cholesterol reduction)

4)

- Significant technical hurdles exist
- Success will require time and resources (>5 years)

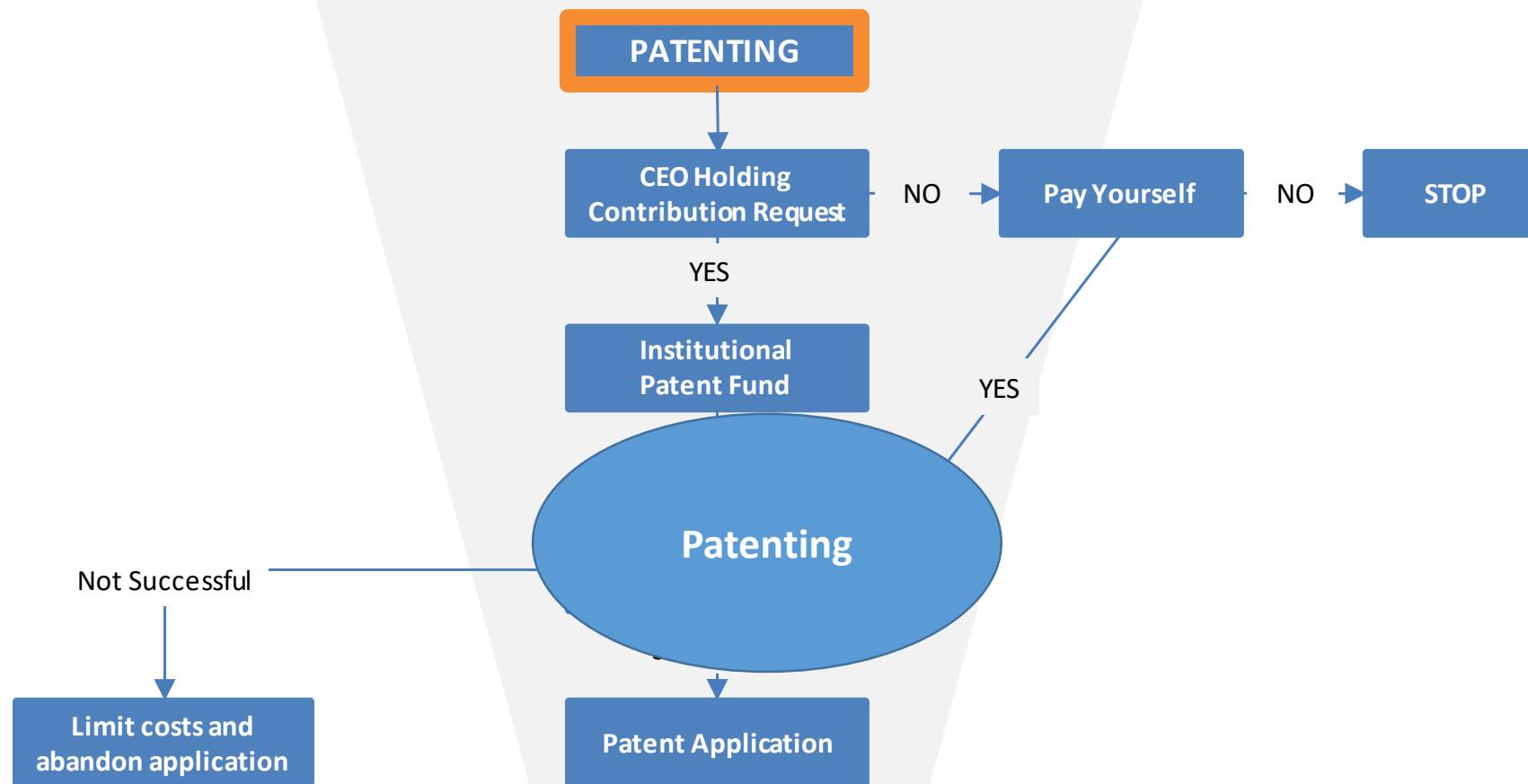
- Unproven value-capture mechanisms
- Undeveloped channel - will likely require JV/alliance
- Consumer behavior change required

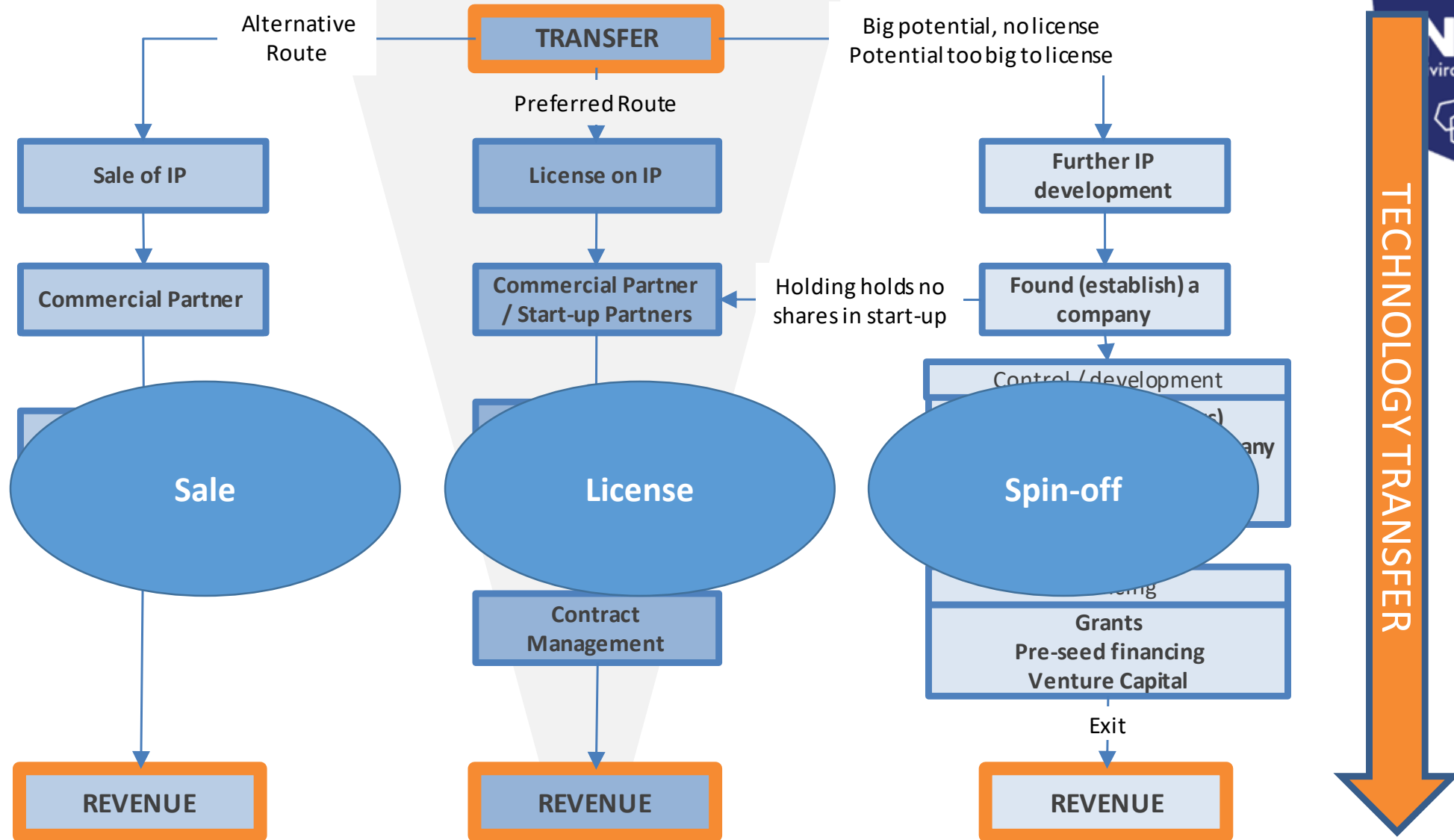
2) Low P.O.S.

- Significant technical hurdles exist
- Understand the “pathway” but unclear on ability to get there
- Other companies have patent real estate

- No current channel access
- Unproven value capture mechanism and unclear on ability to get there
- Significant regulatory hurdles









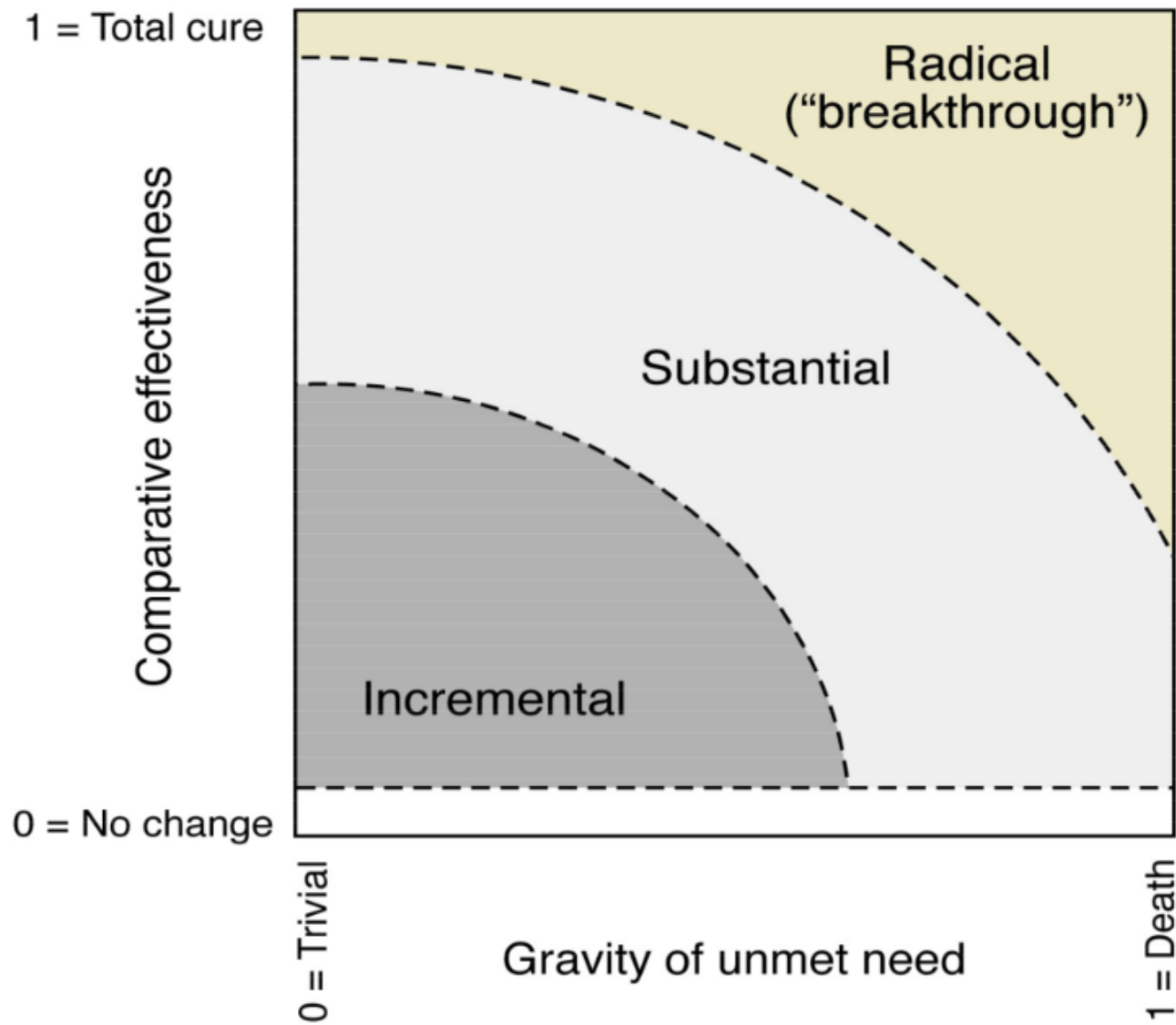
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KnowP – Societal Impact of Knowledge Projects



"Look what I found in the dumpster!
A perfectly good business plan!"



Societal Impact of Knowledge Projects



M	Webinar topic	Group assignment
12	The life science value chain	Charting the value chain
15	Patenting in life sciences	Patent analysis
18	Customer Segments & Value Proposition	Market analysis
21	Key resources & Key Partners	Competitor analysis
24	Key activities	Roadmapping development
27	Financial aspects of your business plan	Drafting budget for future development
30	Financial statements	Drafting financial statements for business plan
33	SWOT / Evaluating Business Models	Refining and finalizing business plan
36	<i>Presentation of Valorisation Projects</i>	

Business plan

- Entrepreneur
- Idea, mission & strategy
- External factors & liability
- IP, patents, trade secrets
- Marketing plan
- Production plan
- Personnel plan
- Management
- Financial plan





A simple business plan

- How do we look in 1, 3, 5, 10 years from now?
- Who are my customers?
- Who are my competitors?
- What are my products?
 - PMC, turnover, COG, price, value, etc.
- Why would the customer buy at my place?
- What do I do when I reach my goals?
- What do I need to do that?

Your KnowP projects



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