LIUC
Università Cattaneo

Innovazione e sviluppo del prodotto

Il settore farmaceutico (3)

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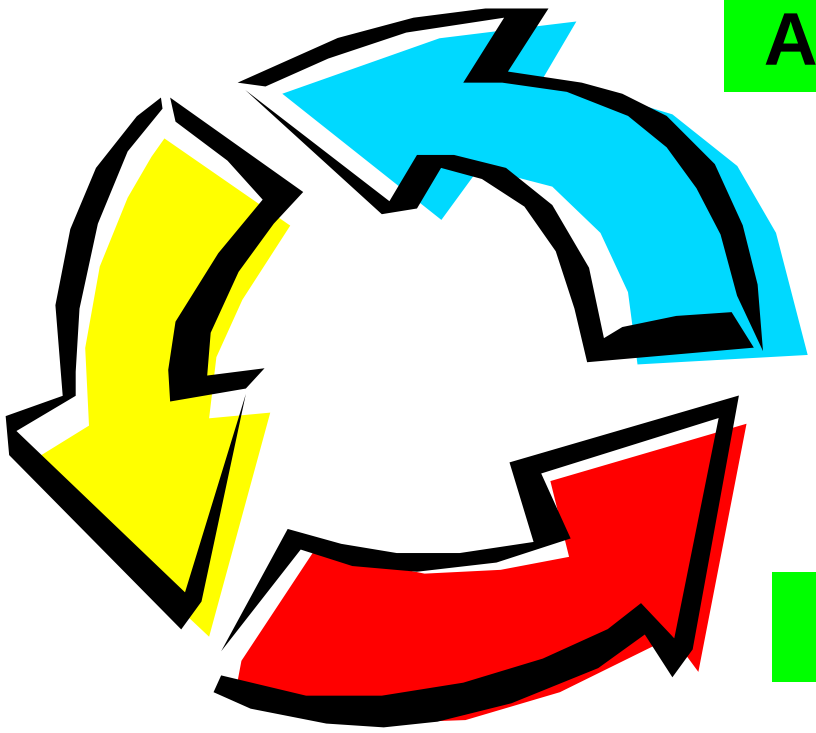
Substantial Utility “Wheel”

Probe for disease state e.g. cancer gene mutation

Assay for specific, substantial, credible use

Antibody



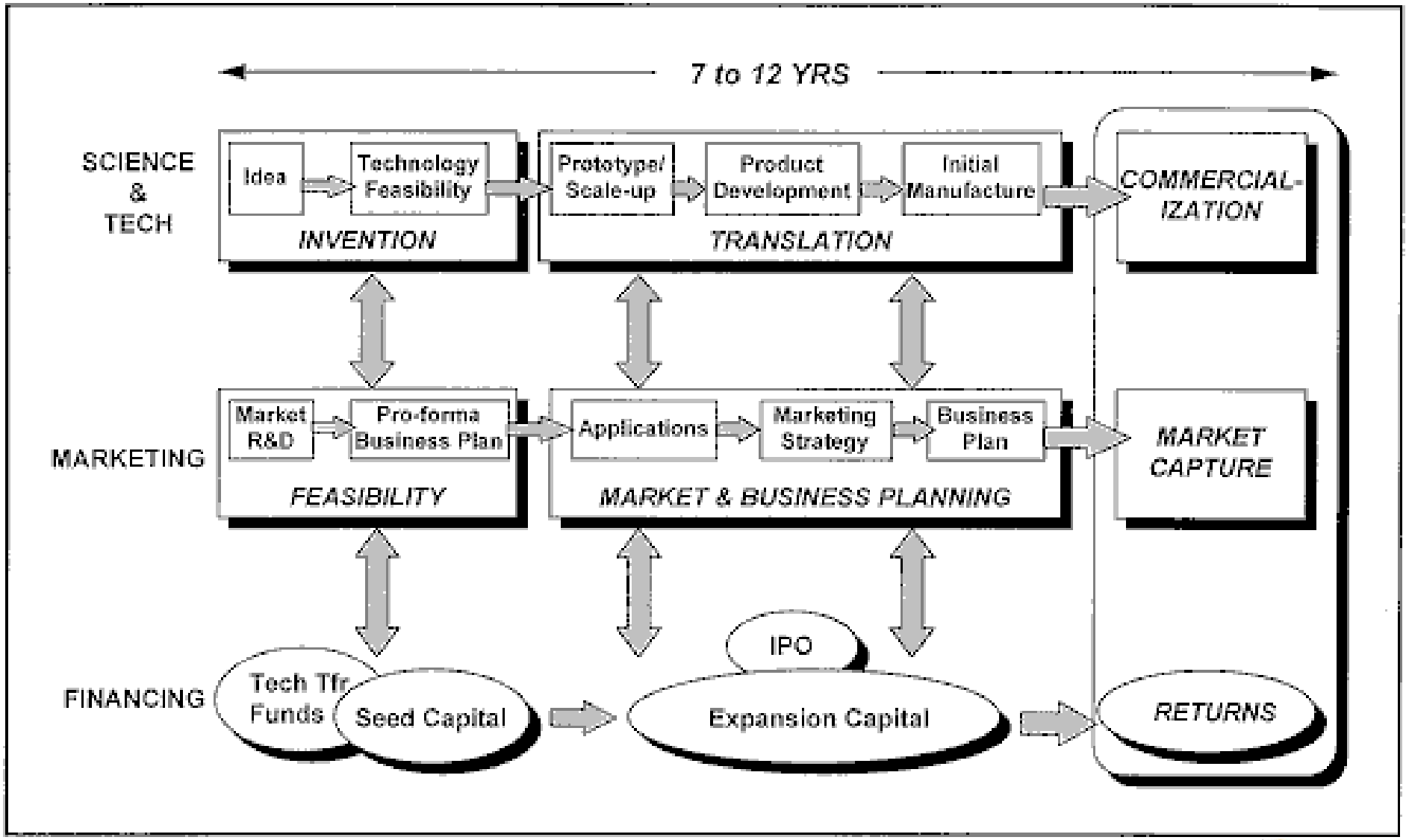
Nucleic Acid

Protein

What is important?

- Meeting Consumer demands
- Strong scientific basis for products
- Early access
- Exposure to a wide band width of technologies, ideas, and products
- Building a product pipeline
- Partnerships

The Technology Transfer flow chart



Patents

- **What is a ‘patentable invention’?**
  - Patents are issued by US Patent & Trademark Office, European Patent Office and patent offices of respective countries
  - Must show your idea is “novel **and** not obvious” & that it works (data)
  - When issued, confers the right to sue if an infringer sells a product in the marketplace based on your idea
- **What is intangible intellectual property that can be protected?**
  - Copyright – software, drawings
  - Know-how – protocols for synthesis of a small molecule drugs
  - Also known as trade secrets (“secret sauce”)
  - Almost always key to real value in the product, never disclosed in a patent application

Patents

- Generally last 20 years
- Since most companies file for patent during pre-clinical trials, usually the patent is only good for another 10 years or so after it gains FDA approval
- What can be patented
  - Product
  - Method
  - Use
- Examples
  - DNA and RNA sequences
  - Proteins, enzymes, antibiotics
  - Antibodies, antigens
  - Micro-organisms, cell lines, hybrids

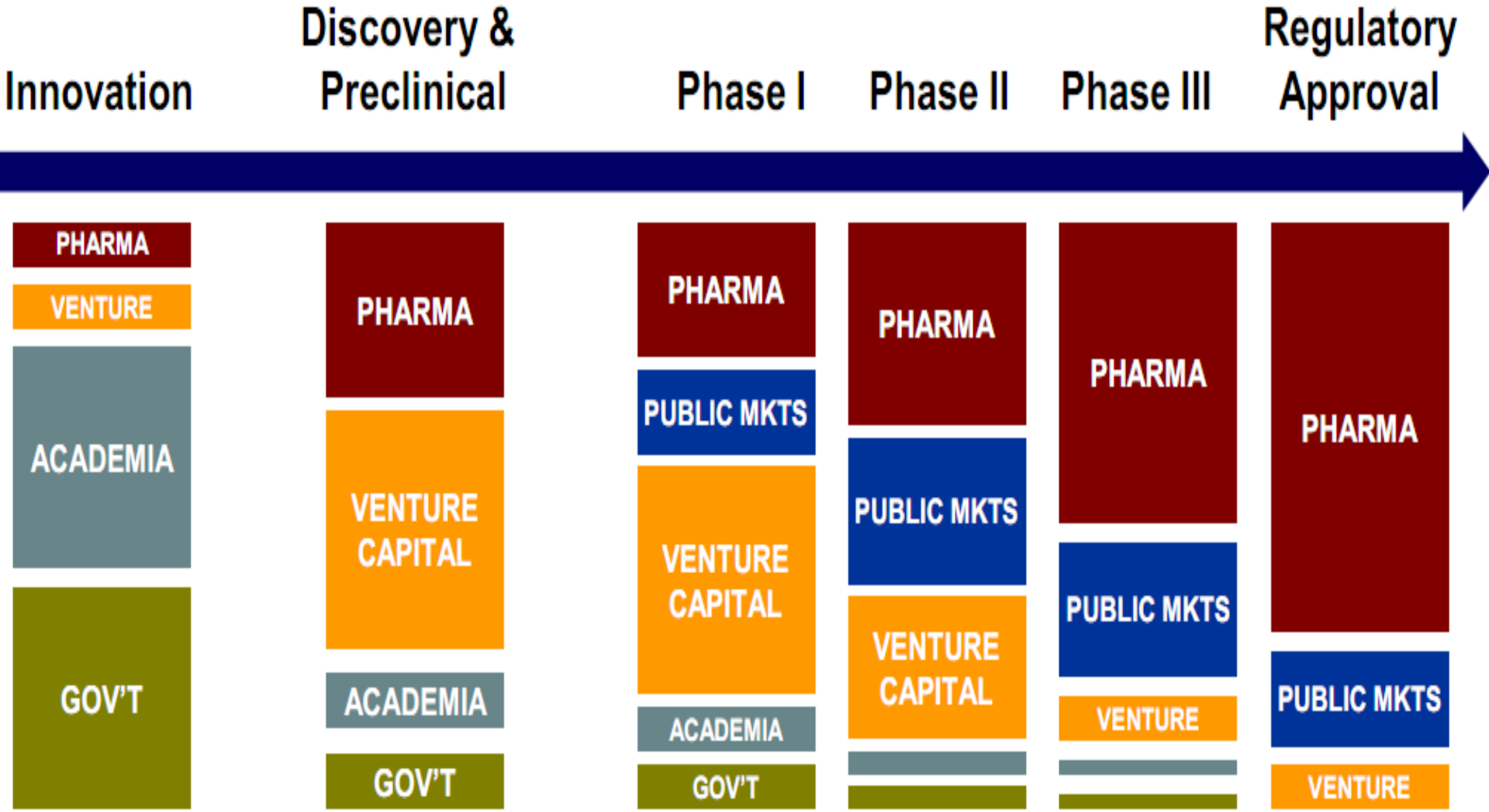
Patent protection

- However, drugs may have several patents
  - **Specific delivery method**
  - **Specific product/molecule**
  - **Specific manufacturing process**
  - **Specific medical indication**
    - How molecules react
  - **Specific Combination**
    - Fixed dose/combination of several molecules

Why patents are important?

- **Worthless unless a product made from it, sold & making €€**
  - Does not keep others from stealing your ideas
  - Just gives you the right to sue them if they do steal
  - Formidable barrier to entry if you succeed
  - In pharmaceuticals, can charge a premium price
- **Confers exclusivity**
  - Means you're the only one legally authorized to sell product
  - Can be US only, EU only, ROW only or combination
  - When patent expires for pharmaceuticals, generic drug makers take over & premium-priced drug revenues decline ~ 60% in one year post-expiry
  - Strong patents are enormously valuable to pharma, biotech and medtech companies

Collaboration required in pharmaceutical industry



The Industry-University interface is multifaceted

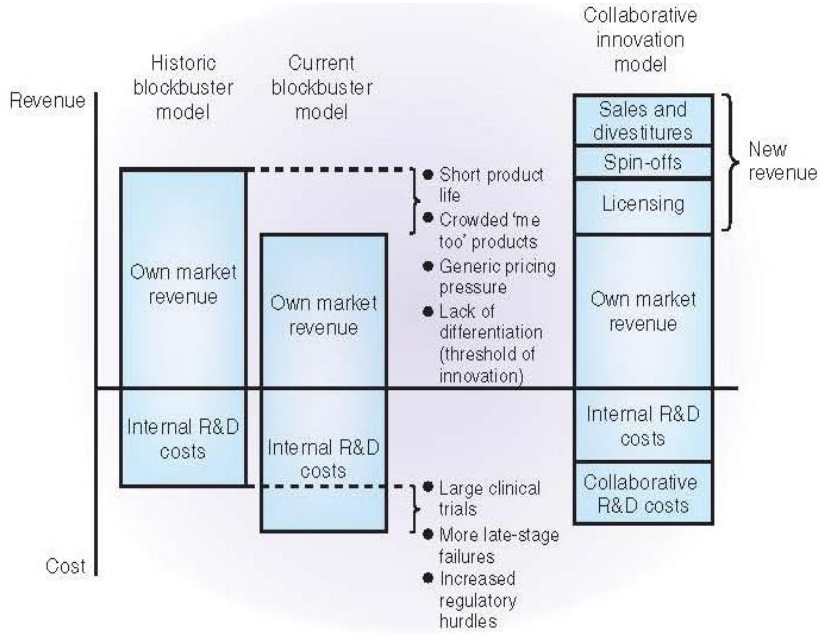
- Corporate sponsored research
- Corporate collaborations
- Material and knowledge transfer
- Consulting and other public service
- IP creation and licensing
- Gifts: cash, endowed chairs, equipment, sponsorship of graduate programs
- Graduate fellowships
- Industry consortia (memberships)
- Exchange of personnel, sharing of resources
- Investment in university employee-founded startups
- Networks of service providers and capital that support entrepreneurial activities

Open innovation networks between academia and industry: an imperative for breakthrough therapies

Teri Melese, Salima M Lin, Julia L Chang & Neal H Cohen

The demand to bring transformative therapeutics to patients and the escalating costs of doing so are driving the life science industry to seek collaborations with academia to stimulate innovation. Despite the opportunities afforded by working together, companies and universities lack a systematic approach for capturing the full potential of such relationships. Detailed here are a few suggested strategies to help these collaborations succeed.

The term 'open innovation' was coined by Henry Chesbrough to describe "how useful knowledge and technology was becoming increasingly widespread," such that newly developing technologies and products benefited from integrating knowledge and expertise from multiple sources[1]. He also made the case that the economics of innovation is a key driver for companies to open their innovation process[1,2]. Pharmaceutical and large biotechnology companies, as an example, increased their research and development (R&D) spend



The Open Innovation mindset

Closed Innovation

- We must discover, develop, manufacture and distribute innovations ourselves in a vertically integrated model
- The requisite expertise in R&D must exist inside of our company
- If we invent and fund everything internally we will win
- We must control and conceal our innovation processes, technologies and tools, so that our competitors don't profit from our ideas

Open Innovation

- Enormous value can be unlocked from external R&D and innovation networks
- Pharmaceutical R&D has become far too complex for us to employ all the expertise needed
- Creating a better business model for partnered innovation can trump internal invention
- We will profit from others' use of our innovations and knowledge, and we will leverage others' IP whenever it advances our own business model

[1] Adapted from ***Open Innovation***, by Henry Chesbrough Harvard Business School Press, 2006

Closed / Open Innovation

- ***Closed innovation*** - requires control

- ***Open innovation***
  - companies use external as well as internal ideas and both external and internal ways to market
  - internal ideas can be taken to the market through external channels to generate additional value

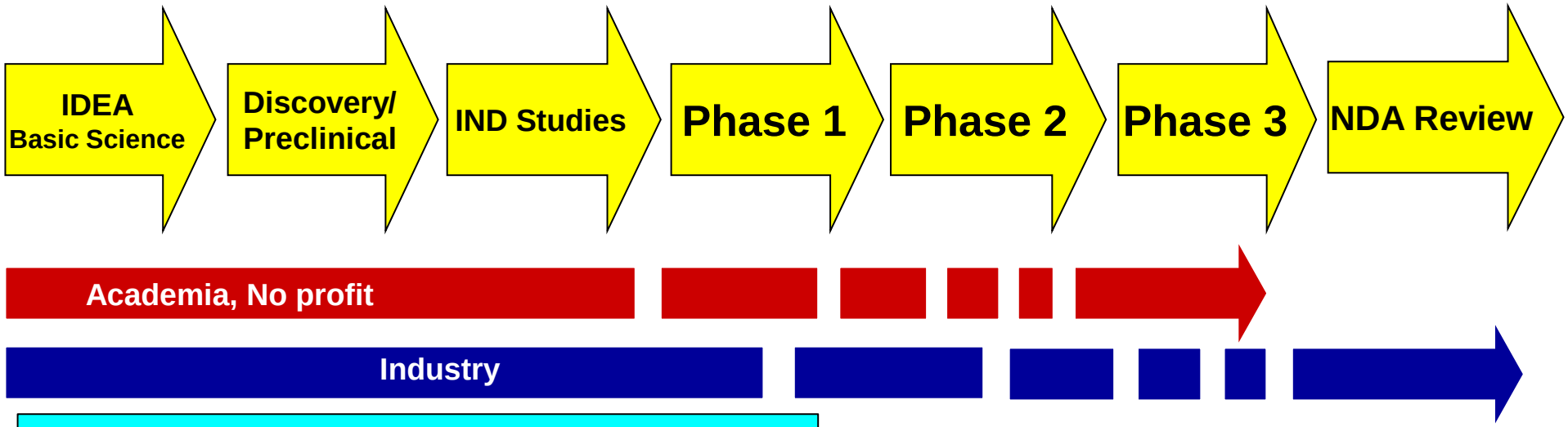
Source: Chesbrough, H., "Open Innovation", Harvard Business School Publishing, Boston MA, 2003

In marked contrast, an open innovation model — most recently embraced by open source software developers and information technology companies — is much more nimble and flexible and relies on both internal and external resources for product development and commercialization.
Much of this new activity is enabled *via* the web and a new vocabulary is emerging.

The open innovation business model is more commonly referred to as "crowdsourcing." And, as the name implies, it leverages the collective external expertise of a network of contributors (the "crowd") to help develop products, services, ideas or content that originated as internal ideas.

Crowdsourcing is beginning to take off despite the concern about Intellectual Property.

New paradigm for Drug Discovery & Development



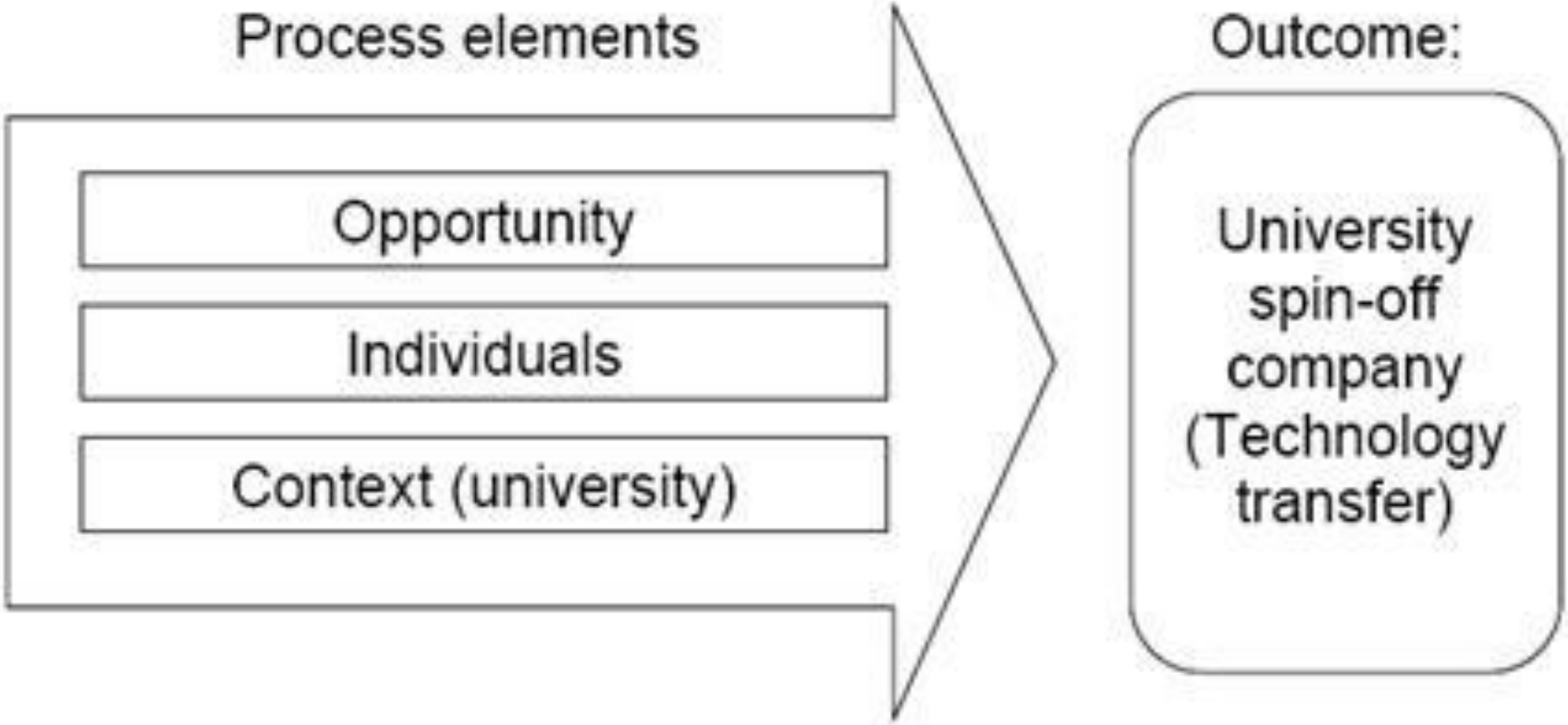
Future Role of Academia in D 3

- Partnering with industry in discovery and translation of specific products or therapeutic areas
- Research leading to new evaluative tools for predicting, understanding and assessing the effects of medical products in the relevant species (people)
- Hubs for clinical trial networks that incorporate community practitioners and also have the capacity for integration of sophisticated bench science

Pharmaceutical Sector Competencies

- Business attitude
- Medicinal chemistry
- High throughput screening
- Lead optimization
- Manufacturing and scale up
- Late phase development
- Marketing, PR and lobbying
- Distribution

The entrepreneurial process of a university spin off creation



How do Hi Tech companies form?

Two common ways:

1. **Scientist(s) in an academic or industrial position form a company to commercialize a novel idea**

2. **An established company or university forms a company to develop a potentially profitable technology**

Spin – Offs

- **Spin-offs are new companies start from a technology or product from a larger company or an university.**
- **Two separate organizations after the spin-off.**
- **The new company has access to other sources of funding and they can develop a team to develop the technology or product.**

Reasons for spinoffs

- Improved focus and reduction of negative synergies. Improved investment efficiency. Diversified firms allocate investment funds inefficiently.
- Ability to offer more effective incentive contracts to managers.
- A firm creates a subsidiary to hold a portion of its assets, distributes shares of its subsidiary to its employees to create an independent company.
- Tax and regulatory-related reasons.

Spinoffs are vital to implementation of innovative projects

Employees of large, established firms are a rich source of innovative project proposals

large firm's physical and organizational assets facilitate discoveries

Established firms often fail to implement promising project proposals

large portion of most important U.S. innovation based firms grew out of spin-offs

Spin-offs represent established firm finance failures: without spin-offs, highly promising project proposals would go to waste

Corporate Spin – Offs

- **Corporate spin-offs are more likely to succeed than university-based start-ups.**

- **They demonstrate higher growth rates, lower chance of failure and produce more innovations than independent or university based start-ups.**

- **Failure rate for *commercial* spin-offs *15%* versus *45%* for *university* spin-offs.**

Spin – Off

Best practices

- **Good qualities include greater business expertise, better access to capital and markets.**
- **They result from restructuring (when research does not match core business).**
- **Universities must deal with bureaucracy and a less entrepreneurial approach (pressure of frequent publication – patenting is used differently; not used to exclude competition).**

Technology spinoffs Success elements

Effective communications

Integration team in place early

- Technology
- Manufacturing engineering
- Manufacturing
- Marketing
- Finance
- Human resources
- Champion from large company to support integration

Aggressive training program

Small company flexible culture preserved where possible

Promote and fund synergy it just doesn't happen

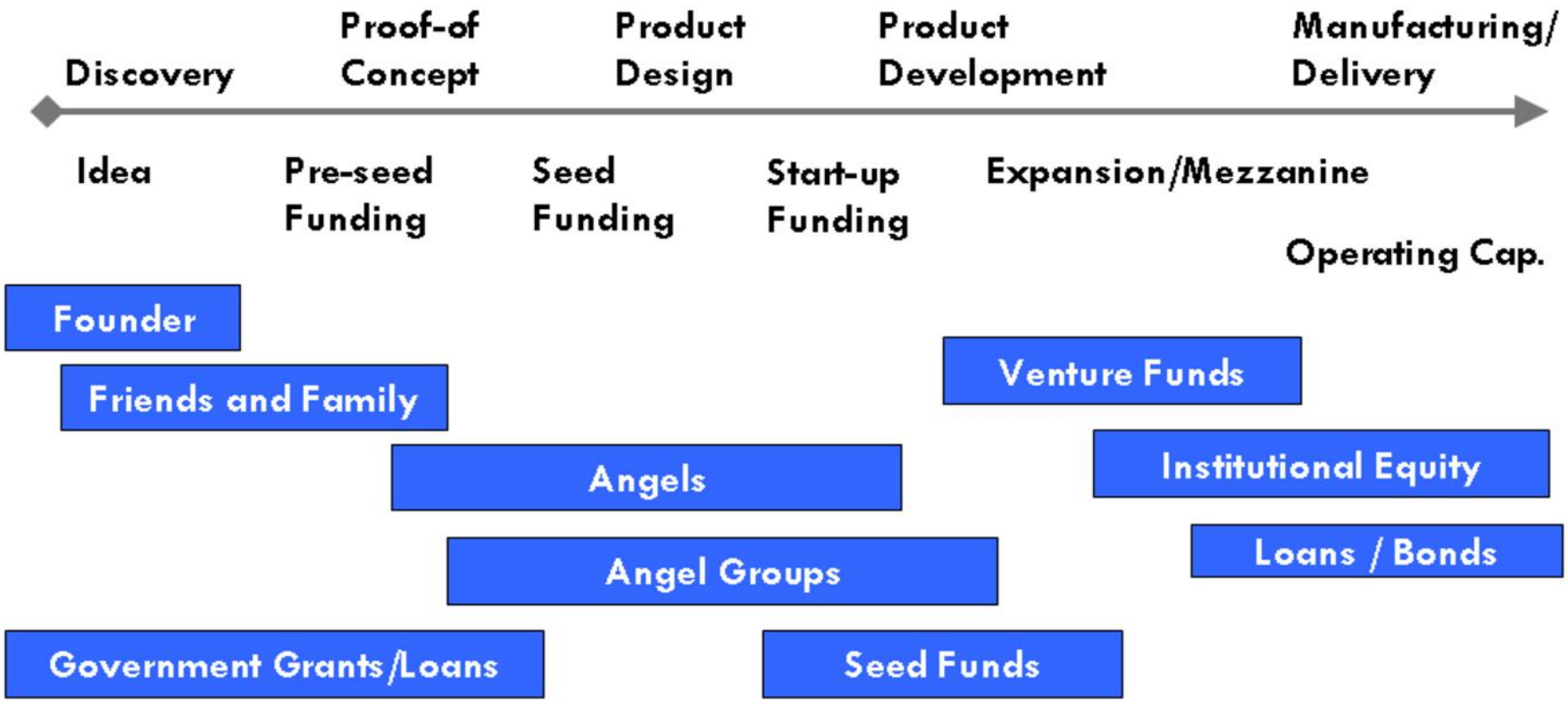
Graceful transition (Agilent Approach)

Start – Ups

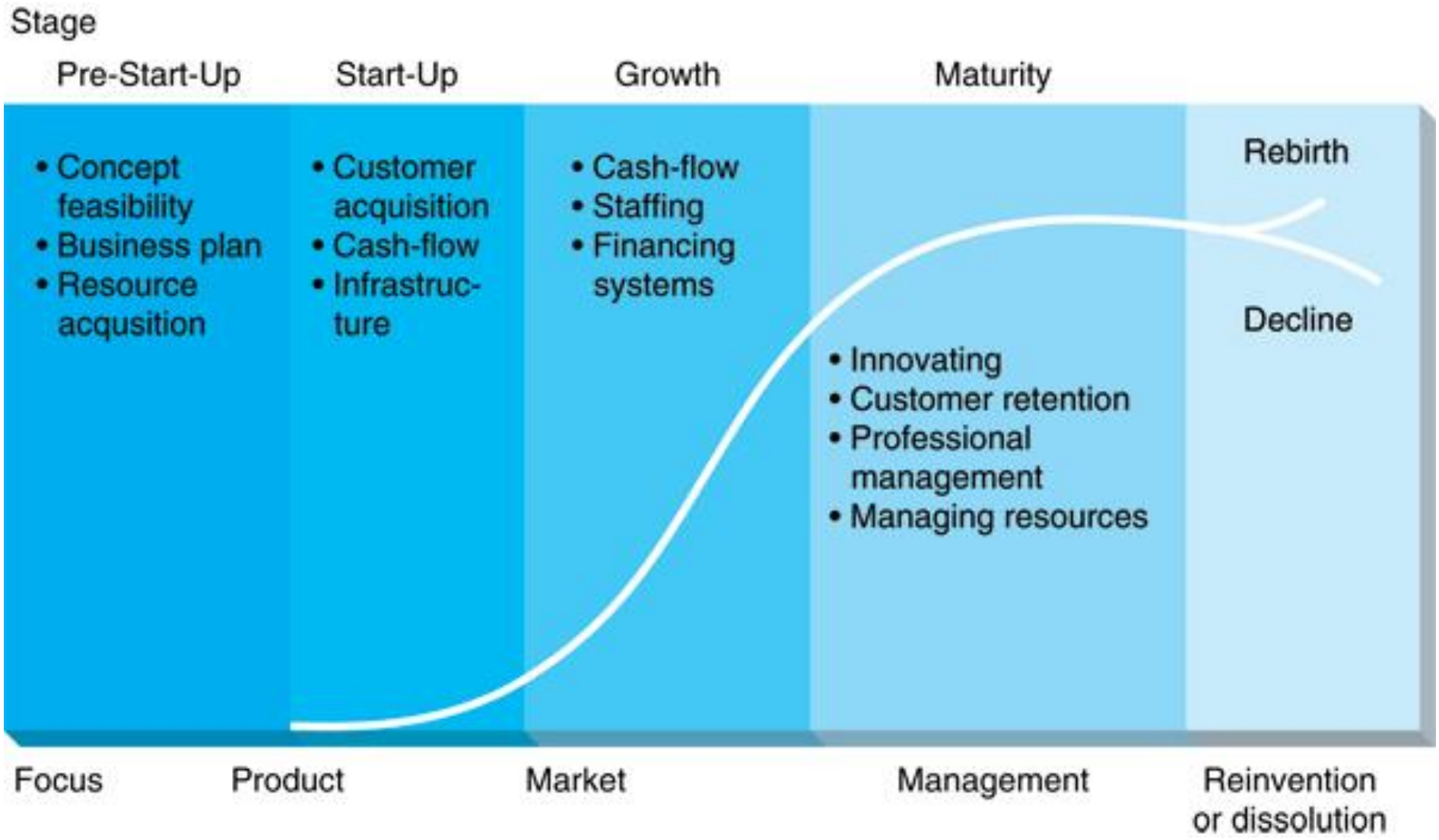
- **Independent start-ups emerge from a group of expert scientists with a vision to commercialize a new technology and financiers (lendors/investors) to fund their opportunity.**

- **The bulk of initial investment comes from venture capitalists and angel investors (affluent individuals who provide capital for business start-up in exchange for ownership equity)**

Financing life cycle



The life cycle of a Company



Caveats for successful start ups ....

- Be careful to select science with commercial potential
- Secure intellectual property
- Bet on the jockey, not on the horse
- Establish frequent and candid dialogue among investigators and stakeholders
- Avoid conflicts of interest, practice good business principles