

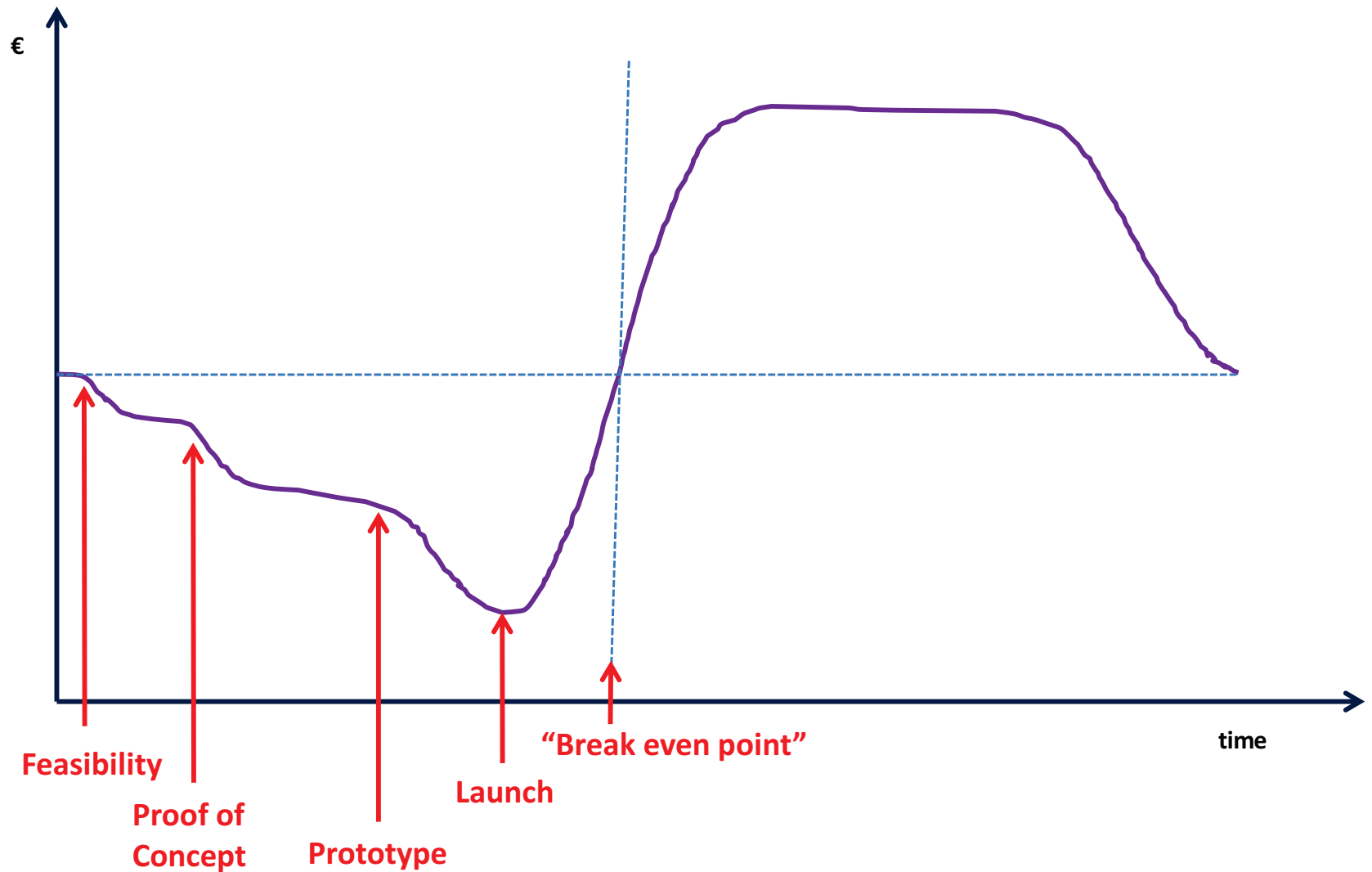


University Joins Industry: R&D

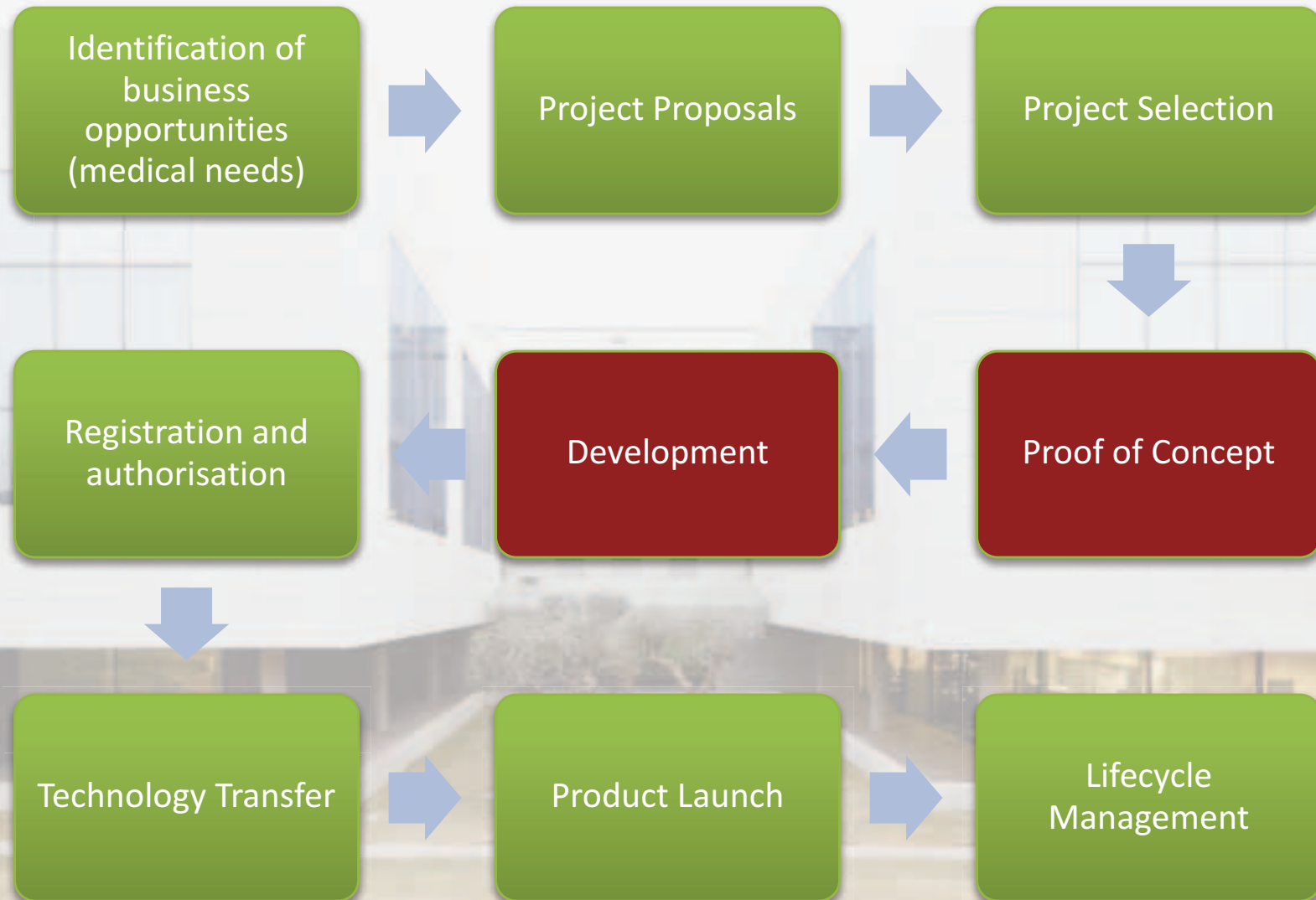
David Sanín
R&D Manager



R&D from a financial viewpoint



R&D in new medicines





R&D in the pharmaceutical industry

Mission: Development of New Medicines

Includes:

Discovery/ invention of new Active Ingredients (chemical substance with therapeutic uses)

Clinical and pre-clinical studies to demonstrate **Efficacy** (therapeutic benefit) and **Safety** (risk-benefit balance)

All development activities related to the Physical Product (Chemistry, Manufacturing and Controls). This includes all activities related to **Chemical Development** and **Pharmaceutical Development**.



Scope of Pharma R&D

“New Chemical/Biological Entities”

- Novel Active Ingredients
- Investment of hundreds of Million€
- 8-10 years long development

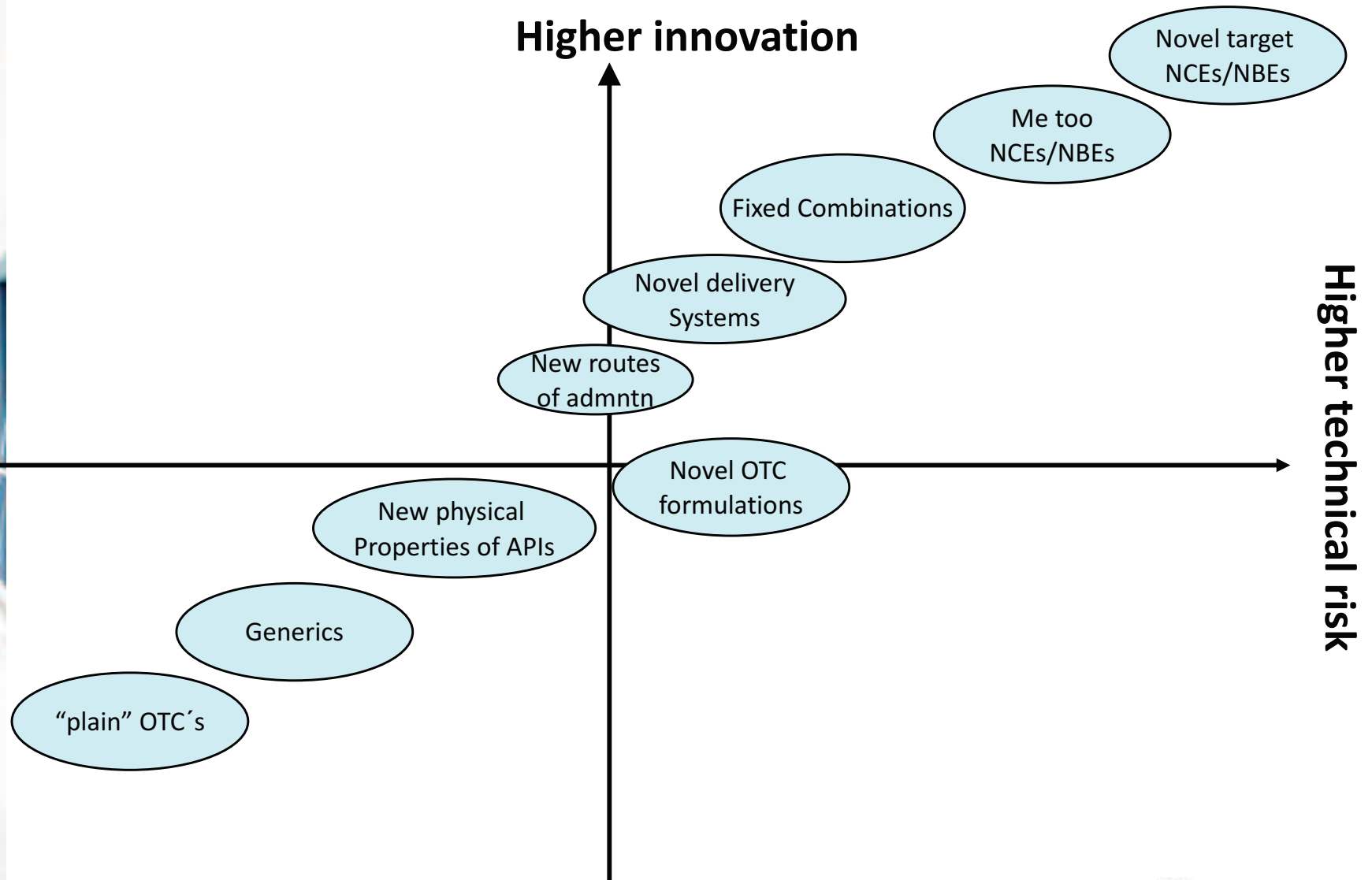
“New Therapeutical Entities”

- Existing Active Ingredients
- Efficacy improvements without detriment to Safety
- New dosage, route of administration, repositioning.
- Typical 4-8 years long development

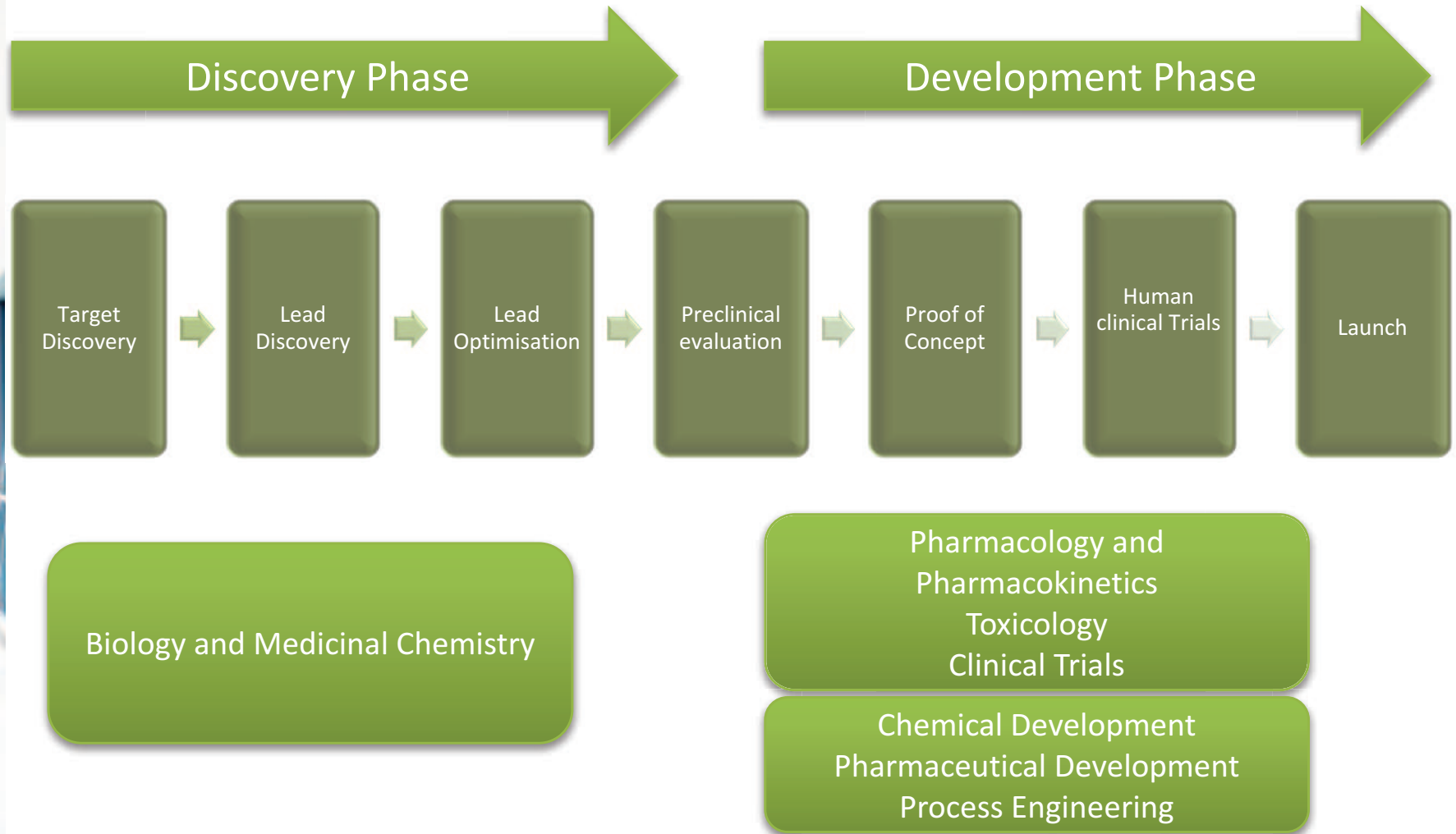
Generic and OTC drugs

- Existing Active Ingredients
- Same dosage and route of administration. Formulation can be different.
- 1,5-3 years long development

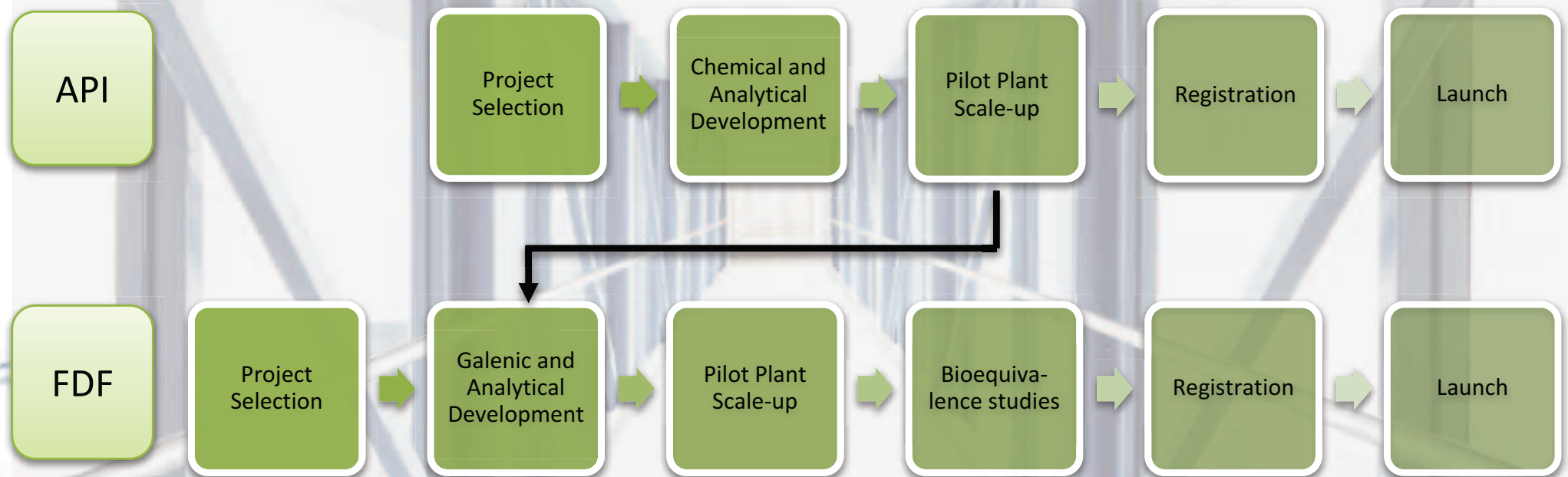
Innovation and risk in Pharma R&D



New Chemical Entities



Generics Drug Development



Not only Products...

.....also PROCESSES

In parallel to Product Development, the industrial processes need to be developed



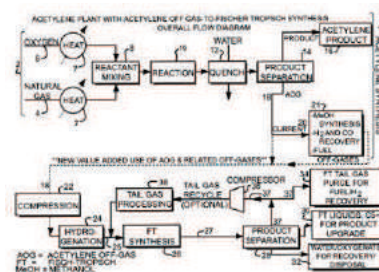
Products



Customers



R&D



Processes



Production

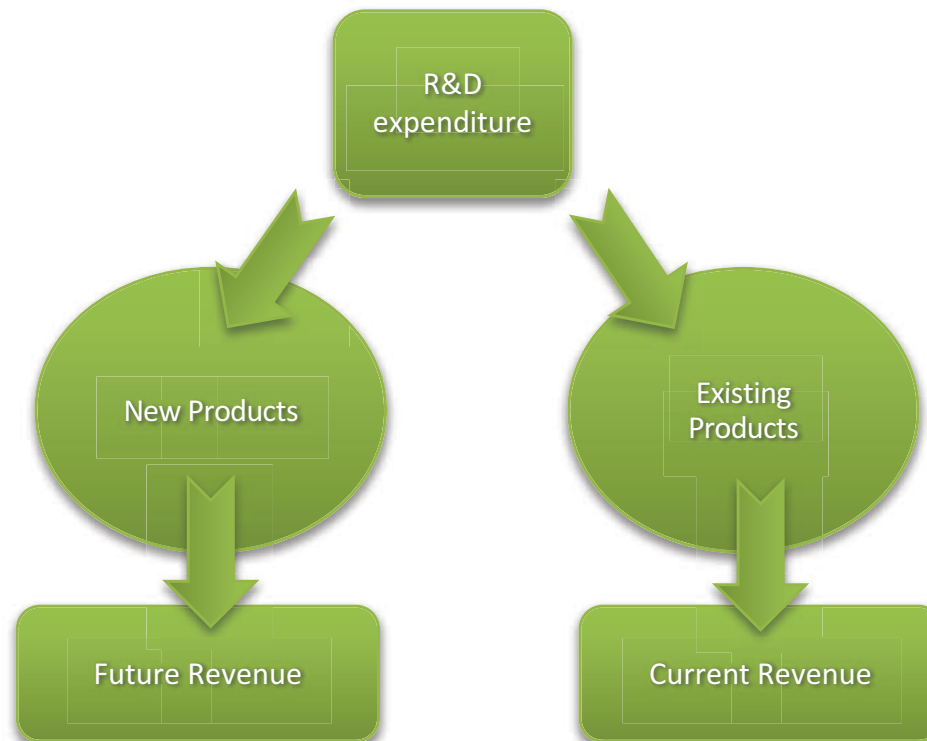
R&D role in Pharma Development

Main role:

- **Development of New Products**

Secondary Objectives:

- Improvement of existing products (Lifecycle Management)
- Supporting the organisation on scientific and technical aspects (marketing, regulatory, manufacturing, quality, etc).



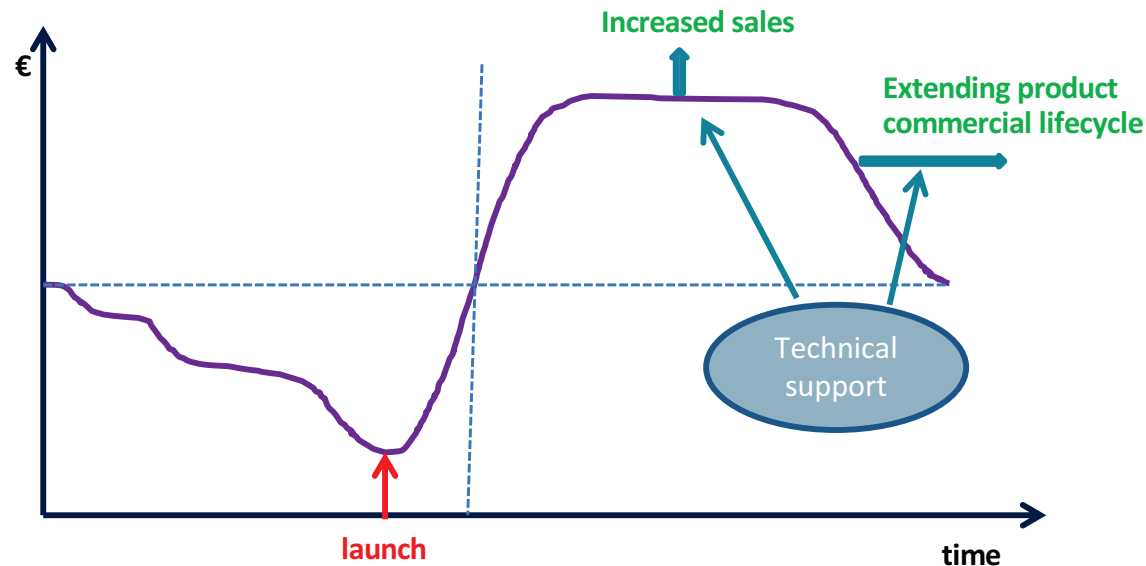
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R&D role in Pharma Development



R&D in the Pharmaceutical Industry

How important is R&D for Pharmaceutical companies

It depends.....

The relevance (and therefore the level of investment) in R&D is related to the intended level of innovation in the Company.

- Companies focused on the development of NCEs/NBEs spend in R&D approximately 12% of revenues.
- Generic Drug developers spend in R&D approximately 5-7% of revenues.

Is it possible for a Pharma Company to exist without R&D activities?

There are many Pharma Business models...

... so there are many ways to use R&D activities in Pharma companies.

- Only large multinationals carry out most R&D internally.
- There are companies specialising only in the Discovery phase to “sell” the projects before entering the costly Clinical Trials phase (license-out).
- There are companies very strong in marketing/sales “buying” the developed products (license-in).
- It is common that only the strategic R&D activities are carried out in-house, externalising the non-strategic activities to Contract Research Organisations.

....but the good news is that there is normally high profesional mobility within this business “ecosystem”. Scientists are recruited from pharma companies with different models and other companies with R&D and/or technical teams, such as other healthcare companies, scientific instrumentation makers, etc.

Professional profiles in Pharma R&D

The most common qualifications in Pharma R&D are degree holders from the following disciplines:

Biology
Chemistry
Pharmacy
Medicine

But recruitment from other backgrounds are also such as: maths (statistics), veterinary, computer science, process engineering.

And.... is it necessary to hold a PhD degree?



Professional profiles in Pharma R&D

what competencies make a competent scientist into a exceptional R&D professional?

- Team-work
- Attention to detail
- Problem Solving
- Personal development
- Communication Skills

And also....

...those other competencies and values that are specific to each company.

And Thank You for your attention!

