

# **EUROPABIO WORKSHOP ON CLINICAL TRIALS - INTRODUCTION**

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# Introduction to EuropaBio

- EuropaBio is **the European Association for Bioindustries**;
- Brings together bioscience companies from all fields of **research and development, testing, manufacturing and distribution of biotechnology products**;
- Has 62 **corporate members** and 7 associate members, operating worldwide;
- Has 19 national biotechnology associations, representing some **1800 small and medium sized enterprises**;
- Has 2 Bioregions.
- Mission: **to promote an innovative and dynamic biotechnology-based industry in Europe.**



# A key technology platform

Today, biotechnology is a key platform providing solutions in three main sectors:



**Healthcare  
Biotechnology**



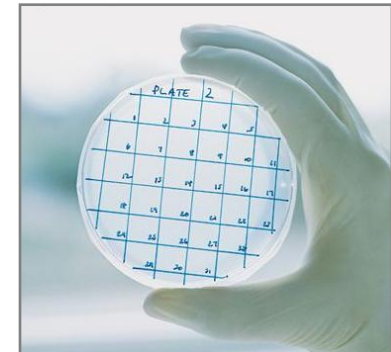
**Agri Food Biotechnology**



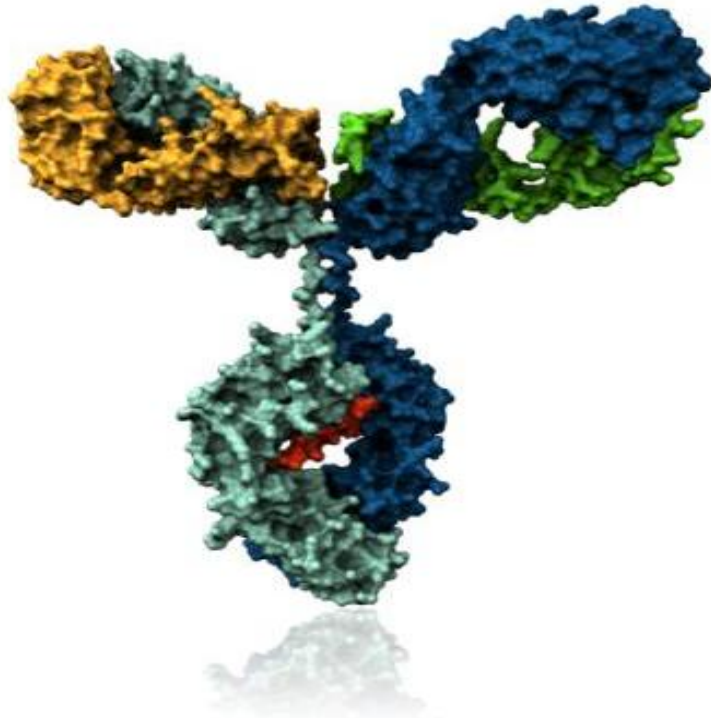
**Industrial Biotechnology**

Using biotechnology to develop medicinal products delivers medicines which:

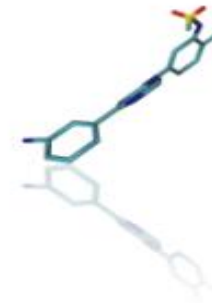
- Have **unique specificity for their target**;
- Are **identical to or mimick naturally occurring substances** with a powerful mode of action;
- Are directly influencing or interfering with **biological processes/pathways**:
  - Directly affecting disease mechanisms;
  - Reducing the risk of undesired pharmacological activity.



# Biotechnology medicines are complex products



**Antibody :**  
**Molecular weight 150'000 dalton**



**Small molecule medicine:**  
**Molecular weight 500 d.**

# The benefits of healthcare biotechnology in figures



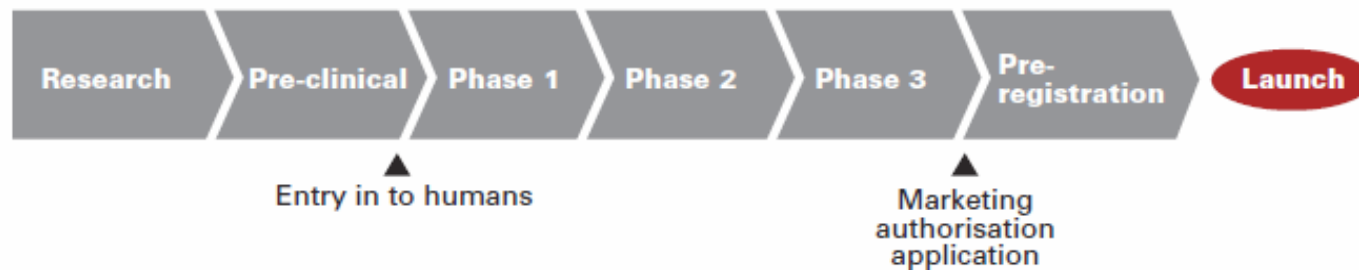
- More than **350 million patients** have already benefited from approved medicines manufactured through biotechnology and gene technology<sup>1</sup>
- **650 new biotechnology medicines and vaccines** are currently being tested for more than 100 diseases, including cancer, diabetes, Alzheimer's, AIDS, rare diseases
- Biotechnology in health care delivery has the **potential to cure** rather than treat numerous debilitating diseases
- **2.5 million** is the number of childhood deaths prevented worldwide each year by immunisation<sup>2</sup>
- **20 vaccines** for infectious diseases have been developed – many of them for children<sup>2</sup>

<sup>1</sup> Biotechnology Research Continues to Bolster Arsenal Against Disease with 633 Medicines in Development. PhRMA Report, 2008

<sup>2</sup> Zhou, et al, 2003.

# Medicines development takes time

## Medicines Development Timeline



Stage objectives	Research	Pre-clinical	Phase 1	Phase 2	Phase 3	Pre-registration
	<ul style="list-style-type: none"> <li>Understand disease mechanisms</li> <li>Identify targets and compounds against them</li> </ul>	<ul style="list-style-type: none"> <li>Test candidate drugs in laboratory and animals for toxicity, side-effects and therapeutic value</li> </ul>	<ul style="list-style-type: none"> <li>Test safety healthy volunteers (20-200 people)</li> </ul>	<ul style="list-style-type: none"> <li>Test efficacy in targeted disease (in 200-300 people)</li> <li>Determine appropriate dose</li> </ul>	<ul style="list-style-type: none"> <li>Confirm efficacy in larger patient populations (300-3,000 people)</li> <li>Monitor side-effects</li> </ul>	<ul style="list-style-type: none"> <li>FDA/EMA reviews 100,000 page application and decides whether to grant approval</li> </ul>
Probability of reaching launch*	0.1%	1%	5%	10%	50%	75%
Duration (Years)	3-5	1-2	1-2	1-2	2-3	1-2

Source: Parexel; PERI; industry averages

\*Source: Goldman Sachs Research estimates

# Revision of the Clinical Trials Directive

Important for healthcare biotechnology



- A very **timely subject** for the healthcare biotechnology industry
- Many biotechnology medicines are currently **in clinical development**
- Many biotechnology companies are **SMEs**, which feel even more acutely the **administrative burden** created by the uneven implementation of the Directive.
- **Multinational trials** are more frequent with biologicals and biotechnology-derived medicines (e.g. OMPs), a trend likely to increase with the emergence of personalised medicines.

# Today's objectives

1. Hear the views of all key stakeholders
2. Explore how to achieve a simplified and coherent framework for clinical trials across EU Member States
3. Raise awareness of the importance of clinical research in Europe