

SOCIETAL CHALLENGE: MICROBIAL INFECTIONS

- » Terminate every 4th human life
- » 13 million deaths per year in developing countries
- » The major killers: AIDS, TB, Malaria, AI, Diarrhea
- » Pandemic influenza
- » Multi-drug resistant microbes
- » Novel emerging pathogens
- » Microbe-induced chronic diseases and Cancer

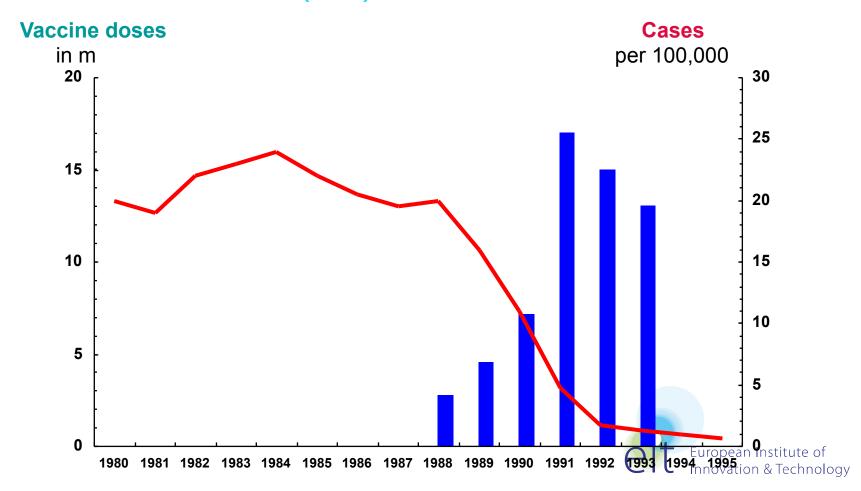


- Globally estim.: 250.000 to 500,000
 people killed by the seasonal flu epidemic
- Estimated 50,000,000 people killed by pandemic flu 1918



Vaccination is the most successful intervention to specifically control infectious diseases

HIB MENINGITIS CASES (USA) AFTER VACCINE LAUNCH



Novel vaccines: Great opportunities facing gigantic challenges

The utterly complex and biological nature of the products requires

- » Extremely high manufacturing skills
- » Extremely high quality measures
- » Extreme assurance of reproducibility from batch to batch

The prophylactic nature of the products requires

» Extremely low and acceptable levels of side-effects

The registration pathway is very difficult in the light

» To demonstrate disease prevention, as opposed to disease reduction for therapeutic pharma products

The customers are difficult to motivate due to

- » Reluctance to accept a medical intrusion as healthy individual
- » Lack to see the danger of diseases that are already controlled by vaccines

The fear of vaccines — a story as old as the first small pox immunzation 250 years ago





FURTHER SPECIFIC CHALLENGES OF THE VACCINE FIELD

- Extend the short list of less than 20 registered products towards desperately needed novel vaccine targets; e. g. HIV, TB, Malaria & nosocomial infectants, like Staph aureus
- Identify the right target populations regarding geography, exposure age, travel habits & risk
- Determine throughout the life cycle the best age window opportunities for immunization and booster vaccinations
- Improve existing vaccines and novel vaccines to function in the most critical human cohorts, the elderly and neonates
- Determine genetic and environmental factors that prevent protective immunity upon vaccination



INNOVATION MAY COME TO RESCUE, BUT DO WE UNDERSTAND ITS NATURE?

1

Discovery:

Finding out something not yet known

2

Invention:

creating or designing something not existing before

3

Translation:

processing discoveries and/or invention into innovation



Innovation:

making changes with societal impact based on discoveries and/or invention



DISCOVERY VERSUS INNOVATION RE-VISITING: ALEXANDER FLEMMING

- Isolated an antibacterial product of mold by serendipity 1929, coined it penicillin, but gave up working on that substance 1931, because believed – amongst others it would not last long enough in the body to kill bacteria
- But was not in charge of developing the antibacterial drug entering clinical trials 14 years later, not even in contact with the chemical, pharmaceutical & medical team transforming penicillin into a usable drug with acceptable side-effects [*]

^{*} Dufour, A., Carroll, S.B. (2013), 'Great myths die hard', Nature, October 2013, 502



EUROPE'S UNLOCKED POTENTIALS TO SUPPORT WORLD-CLASS INNOVATION

- High level of education & solid academic base
- Historical power houses of research & science
- Increasing number of centers of excellence
- Impressive corporations and SMEs
- Long tradition of product development

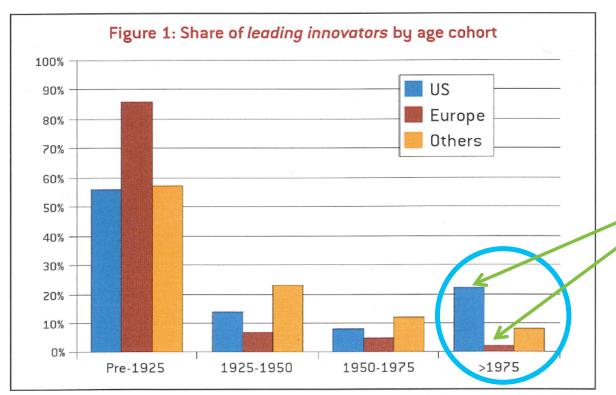


Growing European interactions between national R&D players





THE SMOKING GUN; AGE DISTRIBUTION OF INNOVATIVE COMPANIES



New firms set-up in the last 25 years

US: approx. 21%

EU: approx. 2%

Source: author's calculations. Note: Figure based on a sample of 226 companies, obtained from matching firms in the FT Global 500 from 2007 with the 2007 EC-IPTS Top 1000 EU and non-EU R&D scoreboard companies. Leading innovators are thus defined both by their market capitalisation and R&D expenditures. The US has 80 companies in this sample, Europe 86 and other countries 60.

Bruegel policy brief 2009 Reinhilde Veugelers



ENTRENEURSHIP AS DRIVER OF INNOVATION

Our horizon needs to be reshaped



Joseph Schumpeter:

"The entrepreneur drives economy by combining assets, including technologies, in new ways, creating new opportunities, new markets, new economic values and [...] the eagerness of million of people as customers seeking to improve their lives...."



HOW TO ENCOURAGE THE GROWTH OF YOUNG VENTURES IN EUROPE?





THE CORE OF INNOVATION IS THE KNOWLEDGE TRIANGLE



Actors within the knowledge triangle are at the core of the **innovation web** beyond the traditional collaborative R&D consortia

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RESUME: HOW TO STEP UP INNOVATION IN EUROPE

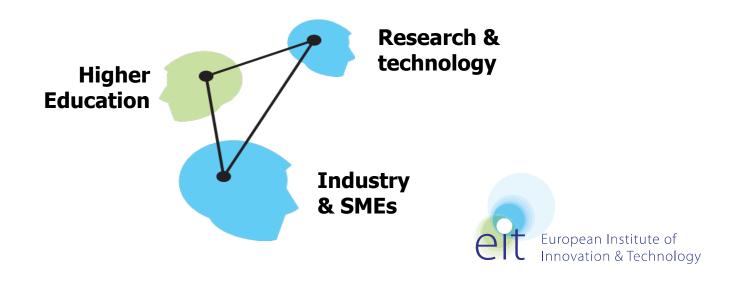
Seed trans-European ecosystems where research, business and education come together on topics of societal challenges:

- to build interconnected knowledge hubs,
- to breed entre- and intrepreneurs and,
- to create trust of venture capital and other investors



EUROPEAN INSTITUTE OF INNOVATION & TECHNOLOGY (EIT)

- EIT was set up in 2008 to unlock the European innovation landscape through a **new agenda at EU level**.
- EIT is the first initiative of the EU bringing together the three sides of the knowledge triangle.
- With the **entrepreneur** in the driver's seat to form the necessary links between higher education, business and research.



THE EIT STRATEGY

Place ownership, accountability & entrepreneurship into the centre of innovation

Overcome the silo mentality of the players within and between Member States

Create innovative ecosystems with global impact, targeting societal challenges

Seed-fund & catalyse the integration of the innovation triangle



THE EIT's "INNOVATION FACTORIES" Knowledge and Innovation Communities (KICs)

- highly integrated, creative and excellence-driven autonomous long-term partnerships
- internationally distributed but thematically convergent partners
- driven by societal challenges and fostering the emergence of entrepreneurs



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THE KICs: INNOVATION FACTORIES AROUND A COMMON THEME

- High degree of integration: e.g. independent corporation
- Long-term strategic approach: minimum 7 years
- **Effective governance:** CEO and management team at central and co-location level
- **Seed funding:** max. 25% budget from the EIT, over 75% to be attracted from partners & other public and private sources.
- **Co-location model:** 4-6 interconnected innovation hotspots leveraging on existing European capacities.
- Culture: KICs shaped by strong entrepreneurial culture
- High impact oriented activities based on a business plan: measurable deliverables & results
- Financial Sustainability: out of own income sources

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THE FIRST 3 KICs

Designated in December 2009 by the EIT Governing Board with their governance and management set up in 2010

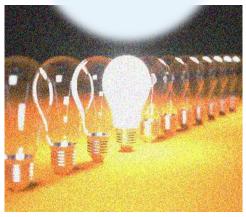










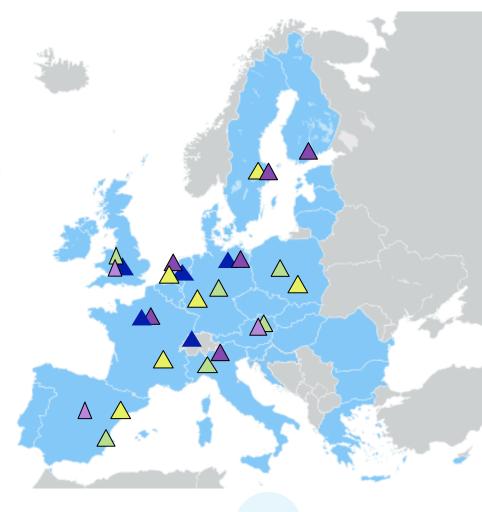




KICs' INTERCONNECTED ECOSYSTEMS THROUGH CLCs

Climate-KIC:

- ▲ Co-location Centre
- A RIC (Regional Implementation Innovation Centre)
- EIT ICT Labs:
 - ▲ Co-location Centre
 - Associate Partner
- KIC InnoEnergy
 - △ Co-location Centre





EIT ICT Labs

- **Mission:** EIT ICT Labs intends to turn Europe into the global leader in ICT innovation by establishing a new type of partnership between leading companies, research centres and universities in Europe.
- Thematic Focus Area: smart spaces, smart energy systems, health and wellbeing, digital cities of the future, future media and content delivery and intelligent mobility and transportation systems
- **Governance:** CEO Willem Jonker , Chairman Henning Kagermann
- **Partners** inc. Alcatel Lucent, Fraunhofer, KTH, Nokia, Aalto University, Ericsson, INRIA, Philips, Orange, SAP, Siemens, TRENTO Rise, Universite Paris Sud, Telecom Italia, VTT,...

KIC InnoEnergy

- **Mission:** To become the leading engine of innovation in the field of sustainable energy.
- Thematic Focus Area: energy from chemical fuels, renewables, clean coal technologies, sustainable nuclear and renewable energy convergence, intelligent, energy efficient buildings and cities and European smart electric grid and electric storage
- Governance: CEO Diego Pavia, Chairman Karl-Friedrich Ziegahn
- **Partners** inc. EnBW, Vattenfall, Karlsruhe Institute of Technology (KIT), Grenoble Ecole de Management, CEA, EDF, VITO, ESADE, Gas Natural Fenosa, TNE, K.U. Leuven, ABB, KTH, AGH University of Technology, Central Mining Institute,...

EXAMPLE: CLIMATE-KIC

- **Mission:** to accelerate significantly the innovation required for a transformation to a low-carbon economy, and to ensure Europe benefits from new technologies, company growth and jobs
- Thematic Focus Area: assessing climate change and managing its drivers, transitioning to resilient, low-carbon cities, advancing adaptive water management and developing zero carbon production systems
- Governance: CEO Mary Ritter, Chairman John Schellnhuber
- **Partners** inc. Bayer, EDF, GDF Suez, DSM, Schipol Airport ETH Zurich, Imperial College London, Potsdam Institute for Climate Impact Research PIK, Technische Universität Berlin, Forschungszentrum Jülich GmbH, l'Institut national de la recherche agronomique INRA, Delft University of Technology & Utrecht University,...

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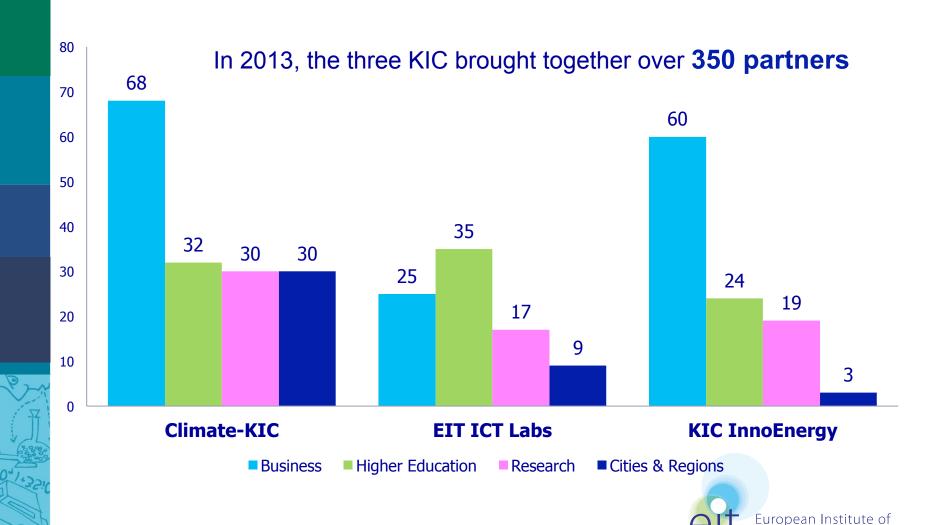
Sheltered innovation at Climate KIC: Partnership with Sainsbury

- Sainsbury's
 - Reduced carbon footprint of stores
 - Carbon neutral products at low prices
 - Want innovators to work with them and their suppliers, e.g. farmers (sheltered innovation)
 - Offer stores as a test bed
 - Host student masters and PhD project
- Large cascade effect via suppliers
- Model for other businesses



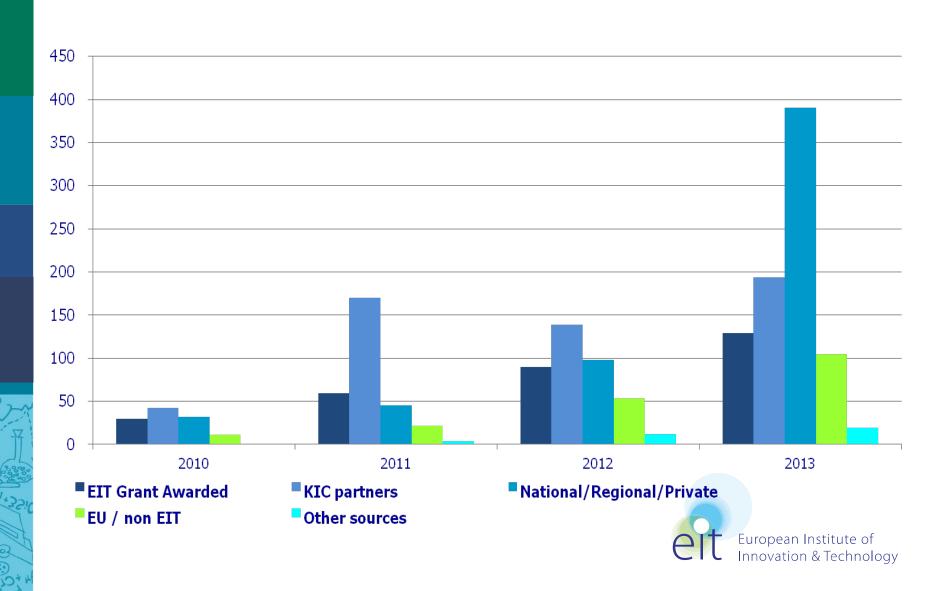


KIC PARTNERS: 2010-2013



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EIT FUNDING: 2010-2013 Leverage impact and sources of funding



KIC ACHIEVEMENTS SINCE THEIR IMPLEMENATION IN 2010

- 17 innovation hotspots spread across Europe
- More than 350 partners from business, higher education and research and other relevant institutions
- Approx. 300 million € EIT investment into the existing three
 KICs with more than 1.1 billion € leveraged from external sources
- KICs have recruited more than 1000 students into about 20 specific educational programmes integrating interdisciplinary innovation and entrepreneurship
- Approx. **90** innovation projects initiated by the KICs, **108** start-up companies, 400 business ideas incubated.

MILESTONES TO DATE

December 2009: 1st 3 KICs designated

September 2008: 1st meeting of the EIT GB

> April 2009: 1st Call for KICs launched

April 2010: EIT
Headquarters
open in
Budapest

2013: EIT budget of 2.7 billion € for 2014-2020 approved

2011-2012: Consolidation of EIT and KIC activities

March 2008: EIT set up by Council and EP



2014: Next KIC

call opened

THE FUTURE AND CURRENT KIC CALLS

Themes for future KICs

2014 2016 2018













FOCUS OF THE KIC SELECTION PROCESS

- Economic and social impact
- The business model and financial plan
- Demonstrating commitment, including financial commitment
- Strong and diverse partnership





EARLY LEARNING FROM THE EIT AND KICS

- Focus on a societal challenge
- Use public money to seed only
- Overcome silo mentality
- Intregrate all players
- Change mindset through light towers
- Create ownership and accountibility
- Establish corporate governance structures
- Allow failing and encourage restart
- Participate players at all levels and outside of the streamline
- Outreach globally



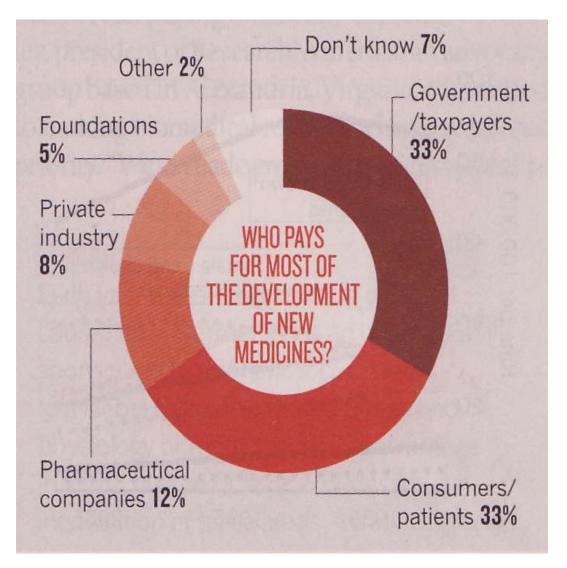
PHARMA INNOVATION IS COMPLEX, TAKES TIME, NEEDS INVESTMENTS AND IS RISKY

Example: development of new pharmaceuticals

	Research	Developmen (pre-clinical)	nt) Phase I	Phase II	νηαςρ	Submission of license	Product licensing
Likelihood of success (percent)	5	10	10 - 20	20 - 50	50 - 90	90 - 95	99
Cost (m US\$)	10 - 40	20 - 225	20 - 200	50 - 175	100 - 125	10 - 15	5 - 10
				γ	J		
Time (years)	4 - 6	1 - 2		4 - 6		1	



Who pays the bill for pharma development: Public misperception prevails.

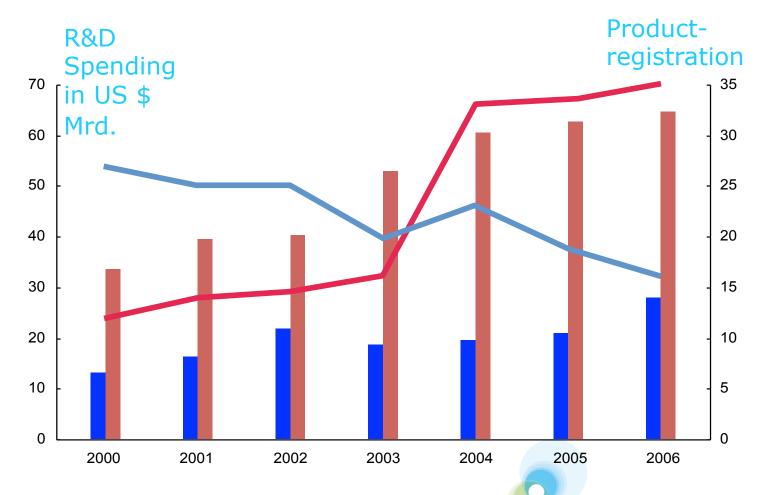


Source: Nature, 478, S18, 2011



Approvals of novel drugs stagnate, in spite biotech feeding pipeline

- Biotech R&D spending
- Pharma R&D spending
- Productregistration from Biotech
- Productregistration from established Pharma



Source: Ernst & Young

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ADDITIONAL CHALLENGES AHEAD FOR PHARMA DEVELOPMENT IN THE USA, JAPAN & EUROPE

- Public deficits and austerity policy add an extra layer of risk to the intrinsic R&D risk of drug development
- It will negatively impact public spending in healthcare, as well as, in research and education
- Rigidity, hurdles and diversity of regulatory and patent processes will make today's high income countries more difficult hubs for drug development, than in the past



Learning from the EIT: Tips for pharma & biotech industry

- overcome old paradigms, like striving for blockbusters only, NIH syndrome and rigid, sometimes, arrogant attitudes, to improve competitiveness for global challenges
- Intensify interactions with public and private stakeholders in healthcare
- o invent new ways to improve efficiency of drug development
- reach out to other innovation players; e.g. venture capital, universities and emerging countries
- create novel open innovation spaces to compensate for the lack of innovation and the contrains of available capital
- thus, pharma business will profit from optimization of the innovation knowledge triangle driven by entre- and intrapreneurship





Concrete steps:

- Create of innovative partnerships and webs including key players
- » Academia, SMEs and big pharma, Charity trusts, Governments, WHO and NGOs, Health insurances and regulatory bodies, like FDA, Centers of disease control
- Encourage interdisciplinary approach
- » Including scientists of all disciplines, engineers, manufacturing specialists medics, nurses, regulatory experts, but also MBAs, financiers, economists, sociologists, PR specialists, marketing analysts
- Educate the participants cross-faculties
- » To understand the principles of the topic and to enable cross-talk amongst all involved disciplines
- » Build global supply chains for rich & emerging countries, non-profit public & charity demand
- Place entrepreneurship, ownership and accountability into the center
- Attract people to bet their private money on innovation





Setting an example: Merck-Serono initiating a "KIC" in Geneva

- Merck KGaA restructuring after its acquisition of Serono
- Cost-cutting by closing HQ in Geneva, but keeping key personnel and assets
- But establishing Entrepreneur Partnership Program at the Geneva Campus
- Breeding three types of sin-offs:
 - Companies developing shelved assets
 - Companies providing Services and support
 - Consultancies focusing on marketing, reimbursement or regulatory affairs
- Providing corporate venture capital
- Wyss & Bertarelli families) forming at Campus consortium with UNIGE & EPLF



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"Betting money on technology, scientists and human beings is the key of succeeding in innovation"



Moshe Alafi, seed investor in Cetus, Biogen, Applied Biosystem, Qiagen & Amgen

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PREPARE FOR THE FUTURE: TAKE THE CUSTOMERS AND INNOVATORS OF TOMORROW INTO THE BOAT

