RESEARCH AND INNOVATION IN ITALY: FUTURE PERSPECTIVES ON POSSIBLE DEVELOPMENT

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AIFA Agenzia Italiana del Farmaco

Lilly

140 anni di impegno per migliorare la vita

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA/EMA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

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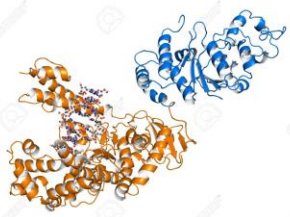
*Luca Pani, in accordance with the Revised Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts. .

N.B. For this talk I receive NO compensation



The value of biomedical research

The majority of resources invested in research does not lead to a substantial improvement of public health.

Correctable weaknesses in the design, conduct, and analysis of biomedical and public health research studies can produce misleading results and waste valuable resources.

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Macleod MR et al., Lancet 2014;383:101-1.

Innovation

"Innovation is the process of making improvement by introducing something new that should potentially yield a benefit for users".

"Innovation in the field of medicinal products consists of a completely or partially new active substance or biological entity or combinations acting against a disease, relieving symptoms or preventing a disease, that can improve the quality of patient management and outcomes".

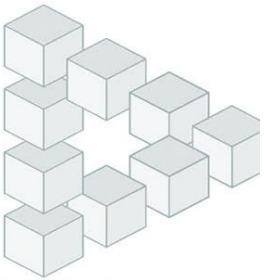
The Innovation Paradox in Health Care

The Costly Paradox of Health Care Technology

In every industry but one, technology makes things better and cheaper. Why is it that innovation increases the cost of health ca

By Jonathan S. Skinner on September 5, 2013

New England Genetics Collaborative



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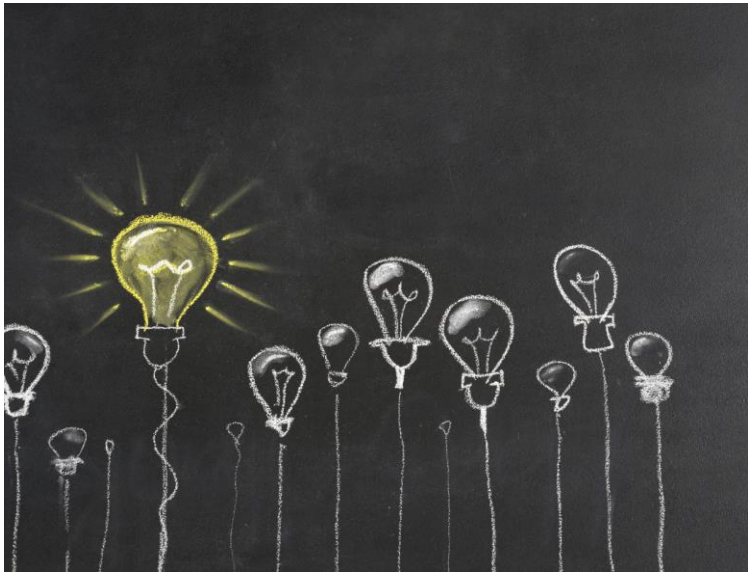
THE ITALIAN WAY

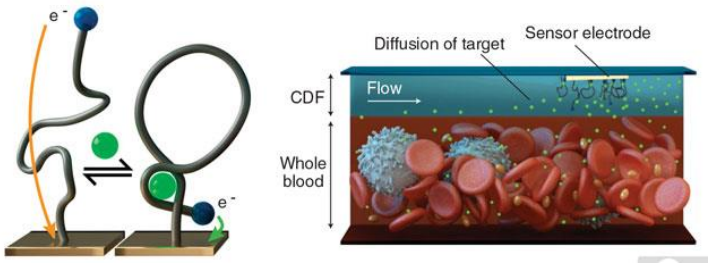
RESEARCH



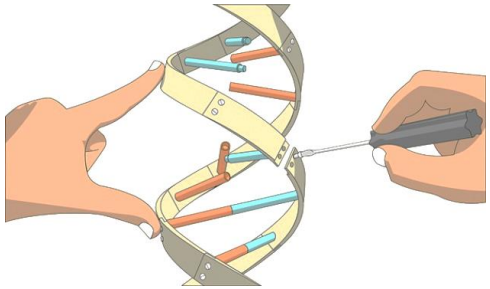
INNOVATION

Something innovative?

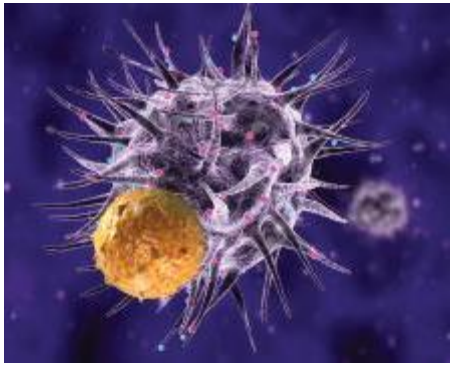
Sensor drugs



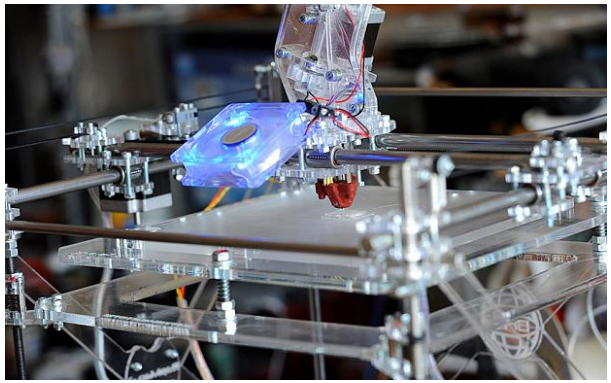
Genetic Editing



Immunotherapy



3D printed drugs

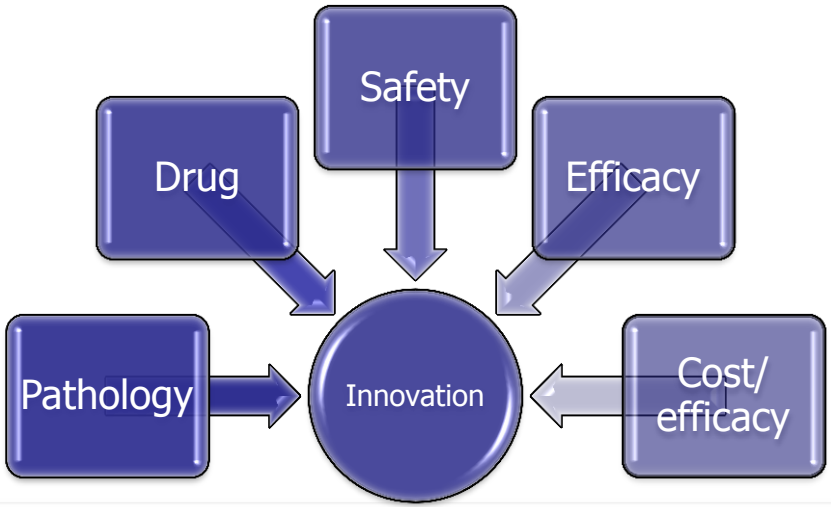


How to value innovation

A drug to be innovative must demonstrate an added therapeutic value (superior in terms of risk-benefit ratio) compared to the available alternative.

In any case, the favorable risk-benefit ratio must also be associated to a sustainable cost for the NHS.

from CTS 12 January 2015



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European context

NEW

Regulatory Agencies are working on possible collaborations and on valuable solutions to promote innovation in Europe.

The purpose is that of collaborating and exchanging information.

Some examples: The adaptive pathway;

NEW! New CTs regulation N. 536/2014;

Compassionate use programs;

NEW! PRIME.

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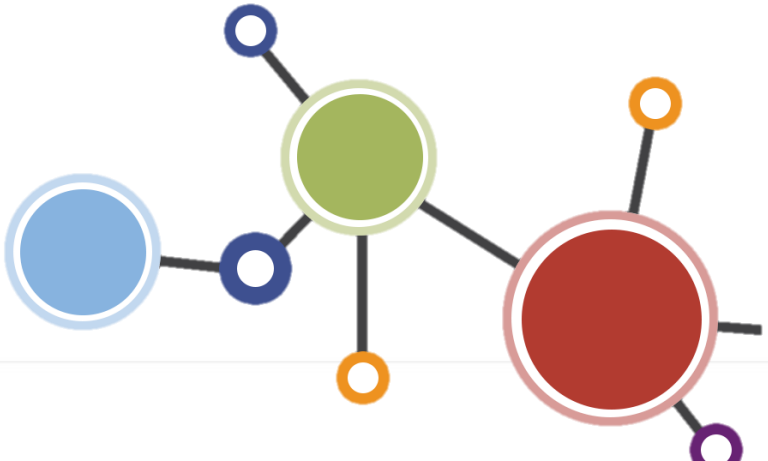
New CTs regulation N. 536/2014: what are the opportunities?

Italy can become the European hub for clinical research and the new Regulation on this subject is a great opportunity.

Ethichs Committees rationalization and reformation of the Agency will unable the institution of a unique scientific-economic committee.



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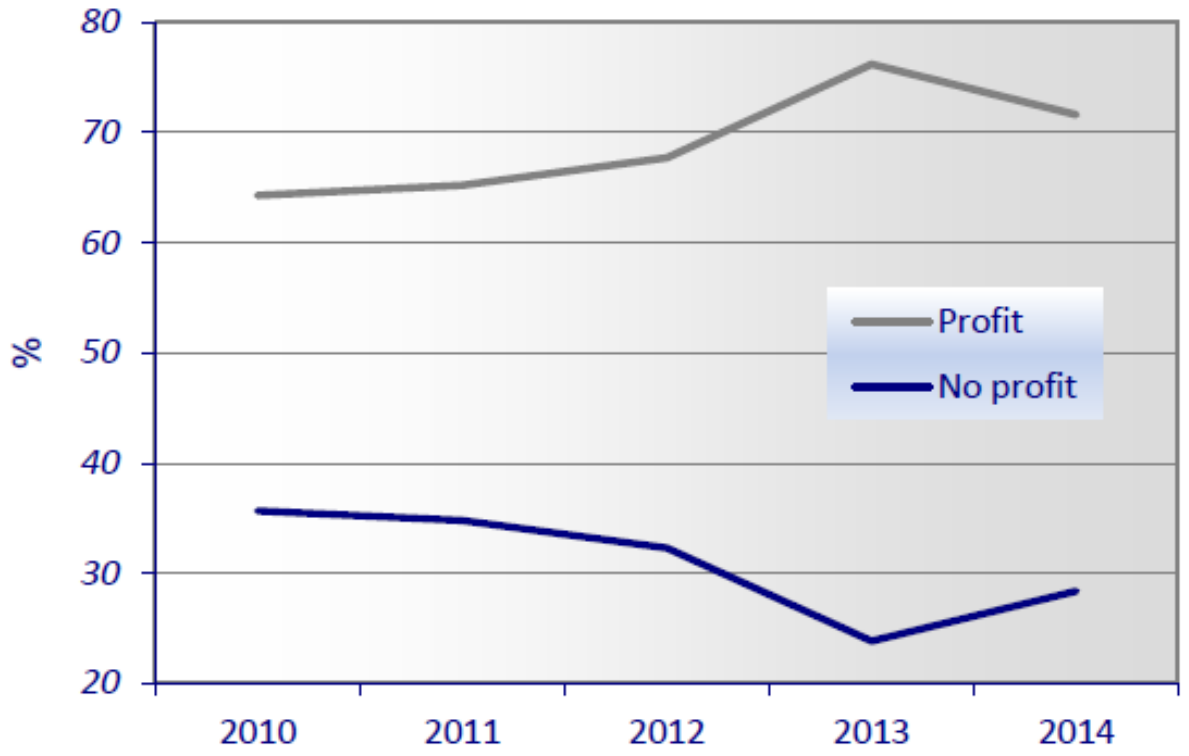
Our bet for the future?

In the new global competitive environment the weight of the emerging economies continues to grow also relating to investments in R&D.

- For new drugs find a "European " solution;
- "keep" research in our country;
- Studying specific actions to sustain research
- …also the indipendent ones;
- ad hoc funds?

Research in Italy



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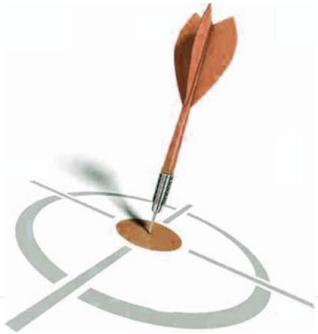
Promoting indipendent research: why?

- Studying populations of patients neglected by profit research;
- Solving doubts regarding on market drugs;

- Studying the incidence of adverse events on wider populations;

- Improving prescriptive appropriateness and adherence to therapy.



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Clinical trials on rare diseases

Clinical trials for rare diseases, considering Promotors profit vs no profit, National and International

CT authorized in 2014: 592 of which 139 (23,5%) on rare diseases

Promotor	**National SC (%)**	**International SC (%)**	**Total SC (%)**
Profit	5 (20,0)	99 (86,8)	**104 (74,8)**
No profit	20 (80,0)	15 (13,2)	**35 (25,2)**
Total	**25 (18,0)**	**114 (82,0)**	**139 (100,0)**

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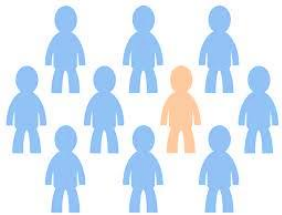

Role of the Agency for indipendent research

The AIFA fund (Art. 48, Legge 326/2003)

- The promotion of independent research on drugs represents one of the strategic tasks assigned to the Italian Medicines Agency by legislation.

- It is an *ad hoc* fund, where pharmaceutical companies contribute with 5% of their yearly expenditure devoted to promotional initiatives (e.g., seminars, workshops, etc.) aimed at physicians.

How AIFA uses the 5% fund

(Art. 48, Legge 326/2003)

- Orphan drugs for the treatment of rare diseases and drugs for non-responders.;
- Head to head comparison of drugs and therapeutic strategies;
- Strategies to improve the appropriateness of drug use and pharmacoepidemiology studies.
- Independent info center on drugs;
- Programme of active pharmacovigilance.

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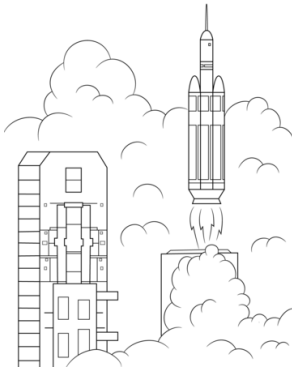
Launching Independent Research



- Selection process *top down*: one/two areas;
- One step procedure;
- Evaluation of the protocols by independent Italian and foreigner experts;
- Allocation of funding per area.

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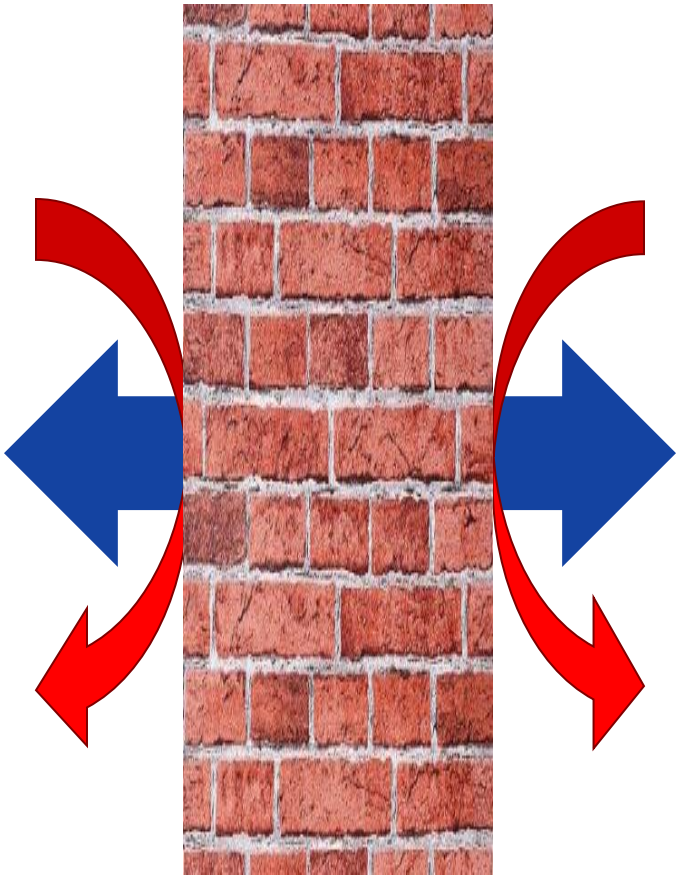
Public-private partnership

Regulatory Agency



Pharmaceutical companies

Sustainalbility should ensure innovation and balance between investments and costs

53 FDA approved new drugs (2014)

7.000 New drugs under development in the world

12 Potential blockbusters for the next 5 years

1,1 B$ Italian Innovative Drugs Funds for the year 2015 - 2016

A new ***Governance*** is deemed necessary!

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Source: AIFA, FDA, CEIS-TorVergata,

Conclusions

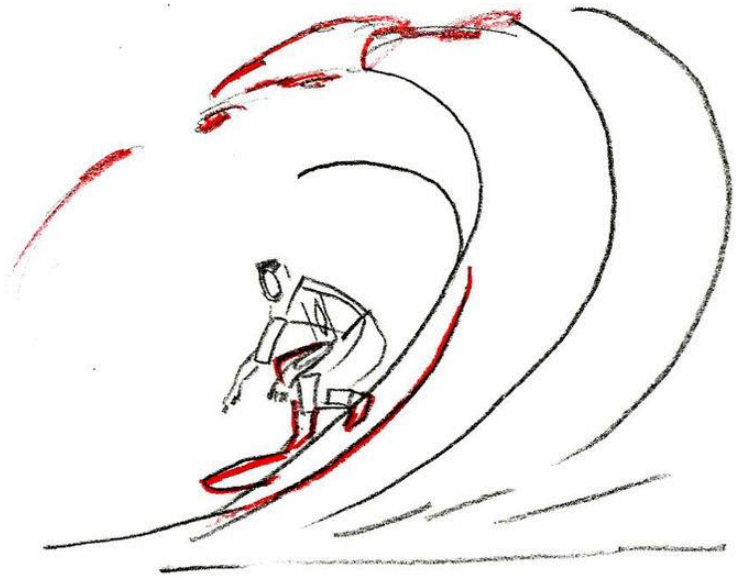
The challenge of Independent clinical research represents, in Italy, a great opportunity for development and a model for Europe.

Access to Innovation:

Universalism?

or

"Selective Universalism?"



Are we ready for the big one?

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