



FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

PAVIA, ITALY
25 > 27 OCTOBER
2018

XI FORESIGHT TRAINING COURSE

CHANGES IN REGULATORY SCIENCES IN THE EU

how to move from a reactive
to a multi-stakeholder proactive attitude

ISTITUTI CLINICI SCIENTIFICI MAUGERI
Via Salvatore Maugeri, 6

Presentation of a COST proposal

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Regulatory sciences: a challenge

+ awareness on
regulatory
sciences

+ attention to
Health

New 'actors' (patients, healthcare professionals and researchers) **recently make the scene of regulatory sciences** as the public relevance of this sector is increasing...

Now healthcare professionals and researchers are also included in scientific committees (Ethics Committees, CHMP, PDCO, COMP, CAT, PRAC, HMPC)

they should build their expertise in the field
⇒ to make them able to play their role in evaluating processes and to bring their points of view and interests into the decisional process

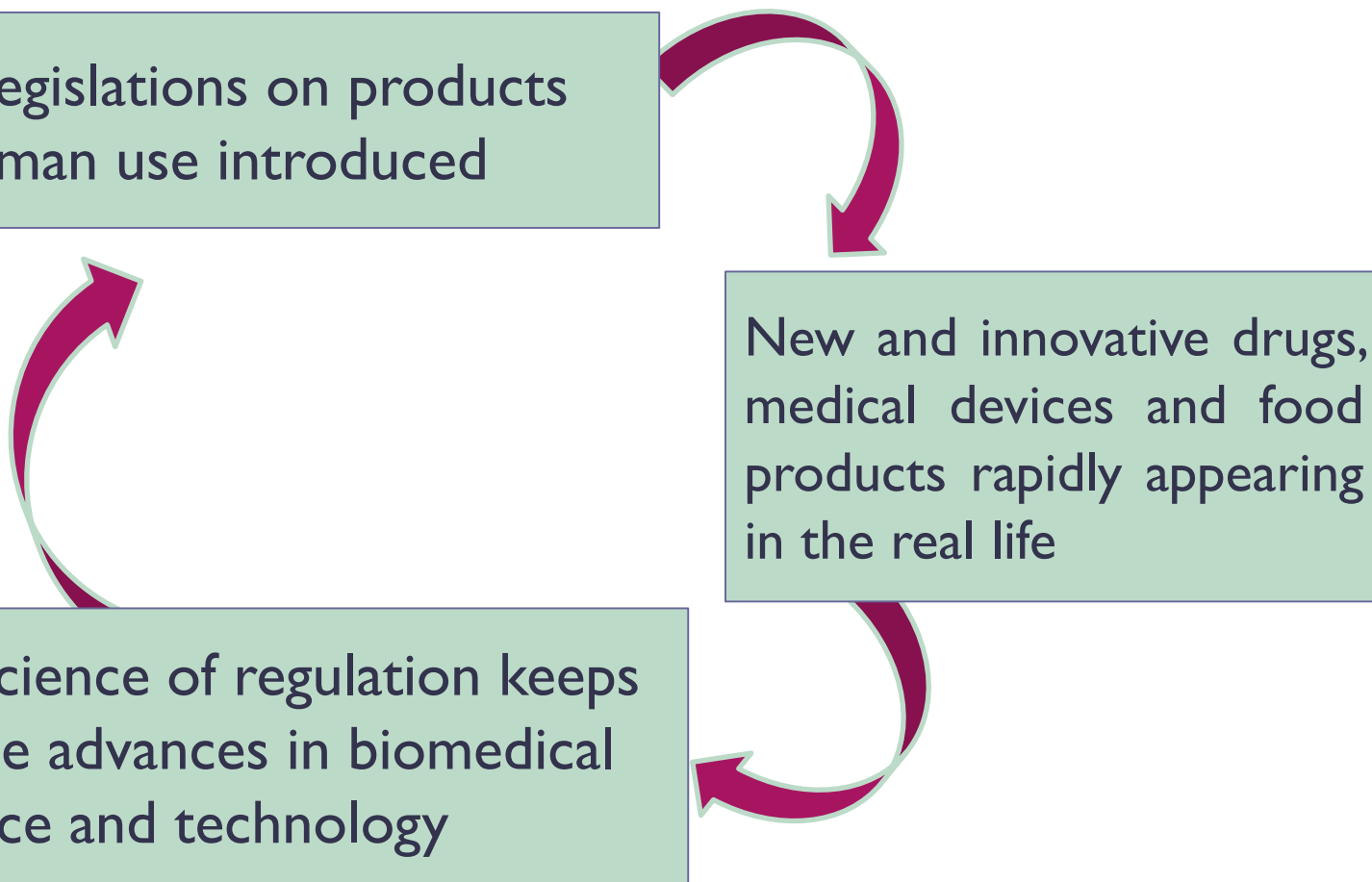


Regulatory sciences: need for continuous updates

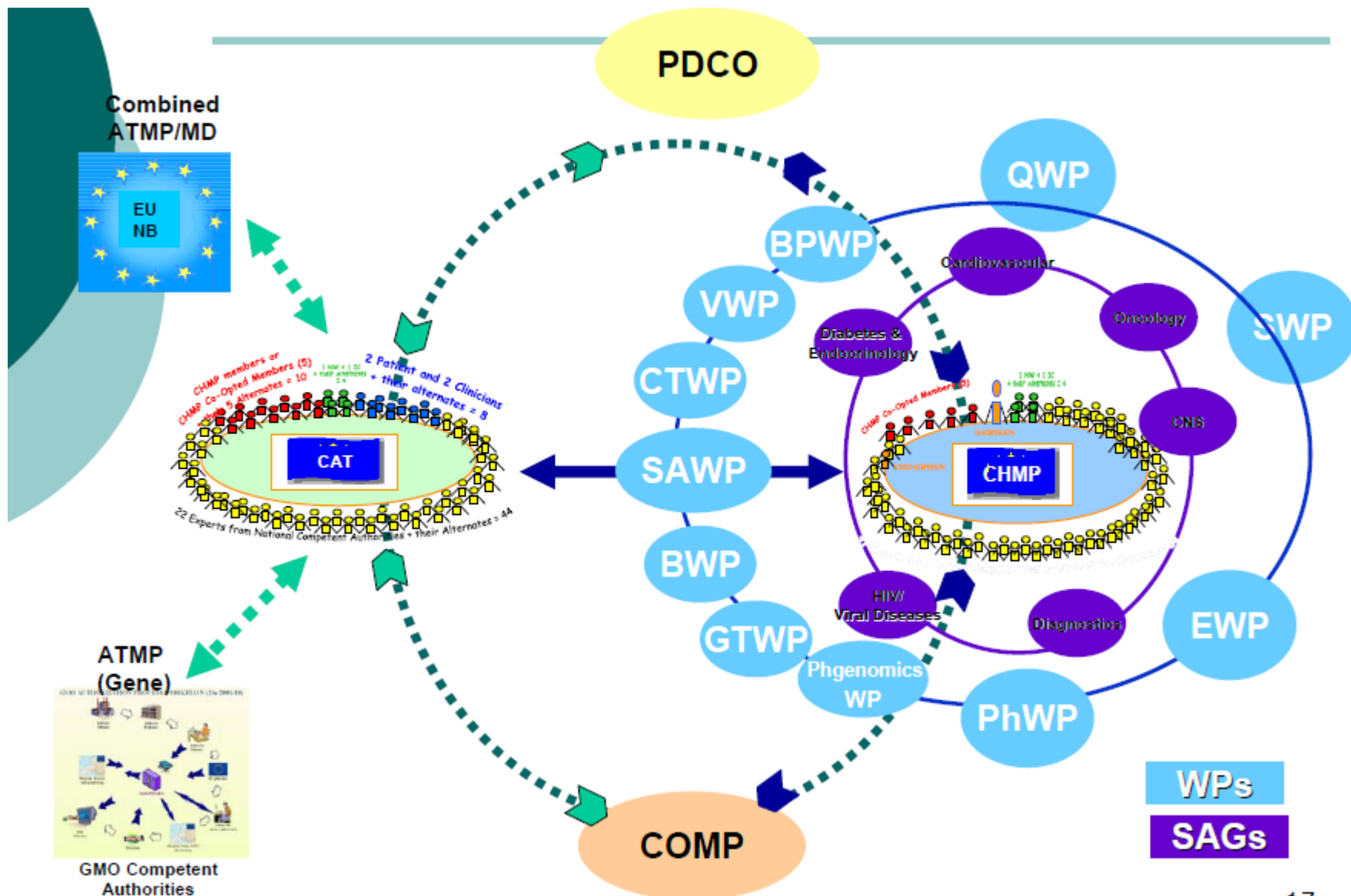
New legislations on products for human use introduced

New and innovative drugs, medical devices and food products rapidly appearing in the real life

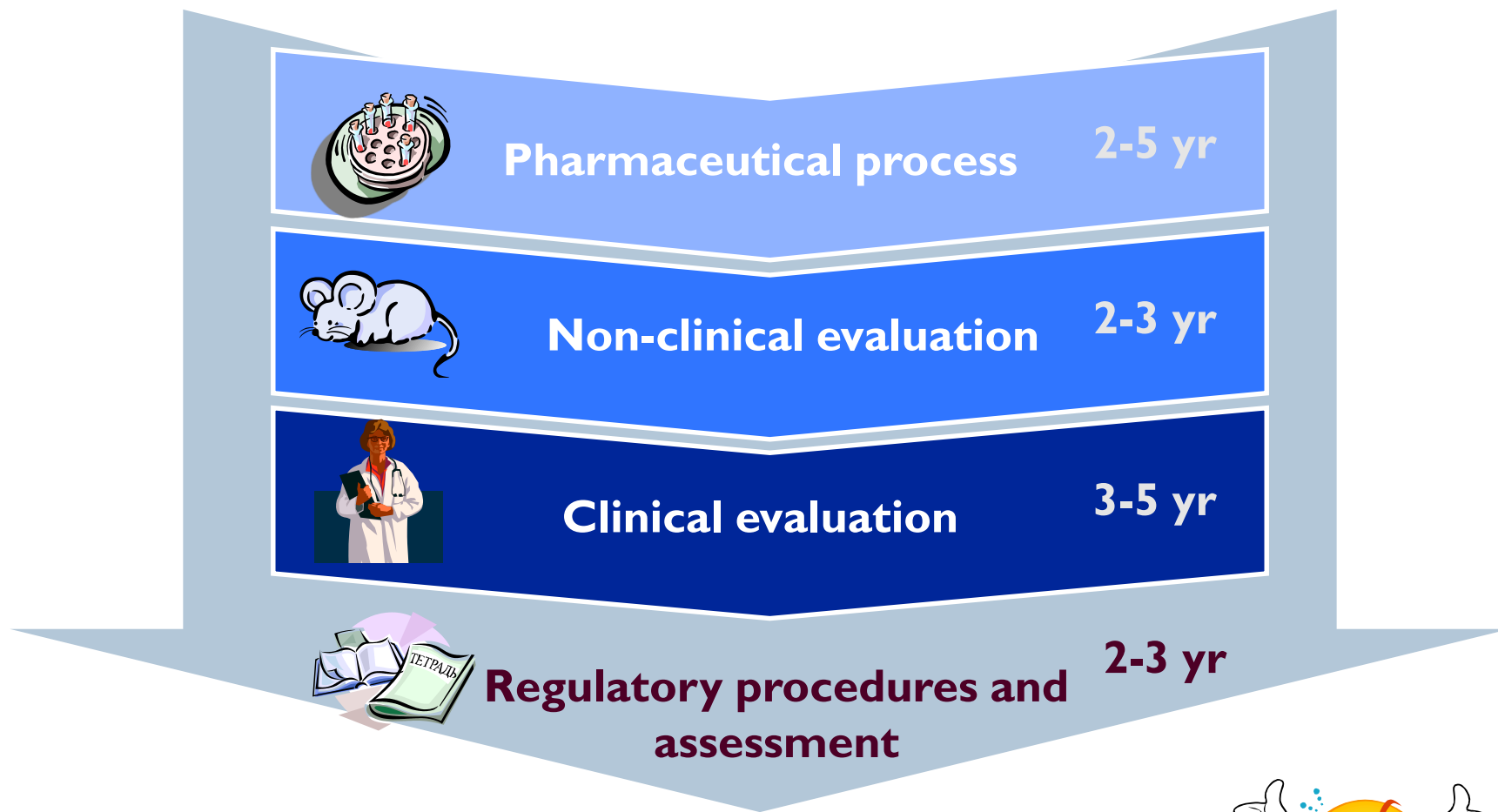
the science of regulation keeps up the advances in biomedical science and technology



Regulatory sciences: a matter of interactions



Regulatory sciences: need for comply with rules along the R&D



MA and MP market availability



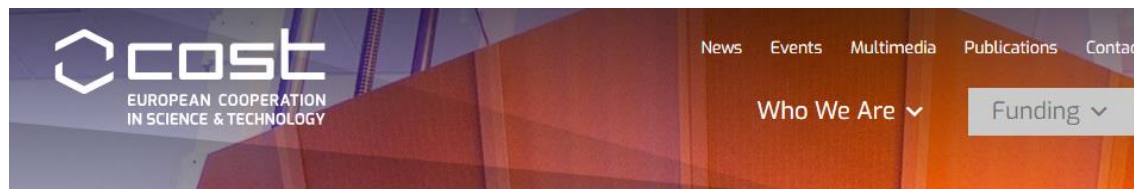


- ✓ *To share knowledge, needs and expertise*
- ✓ *To train and update a new generation of scientists in regulatory sciences*



To create common instruments

COST CALL



Open Call: A simple one-step application process

Home > Funding > How to get funding > Open Call

To enable breakthrough scientific developments leading to new concepts and products and contributes to strengthening Europe's research and innovation capacities



Regulatory sciences: a challenge to address through COST

*a relative newly recognised
scientific discipline,
international for its own nature*

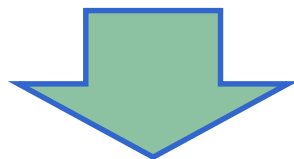


Extracted from Carolyn A.W 2013 presentation

- ✓ multi-disciplinary
- ✓ huge innovative content
- ✓ need for networking

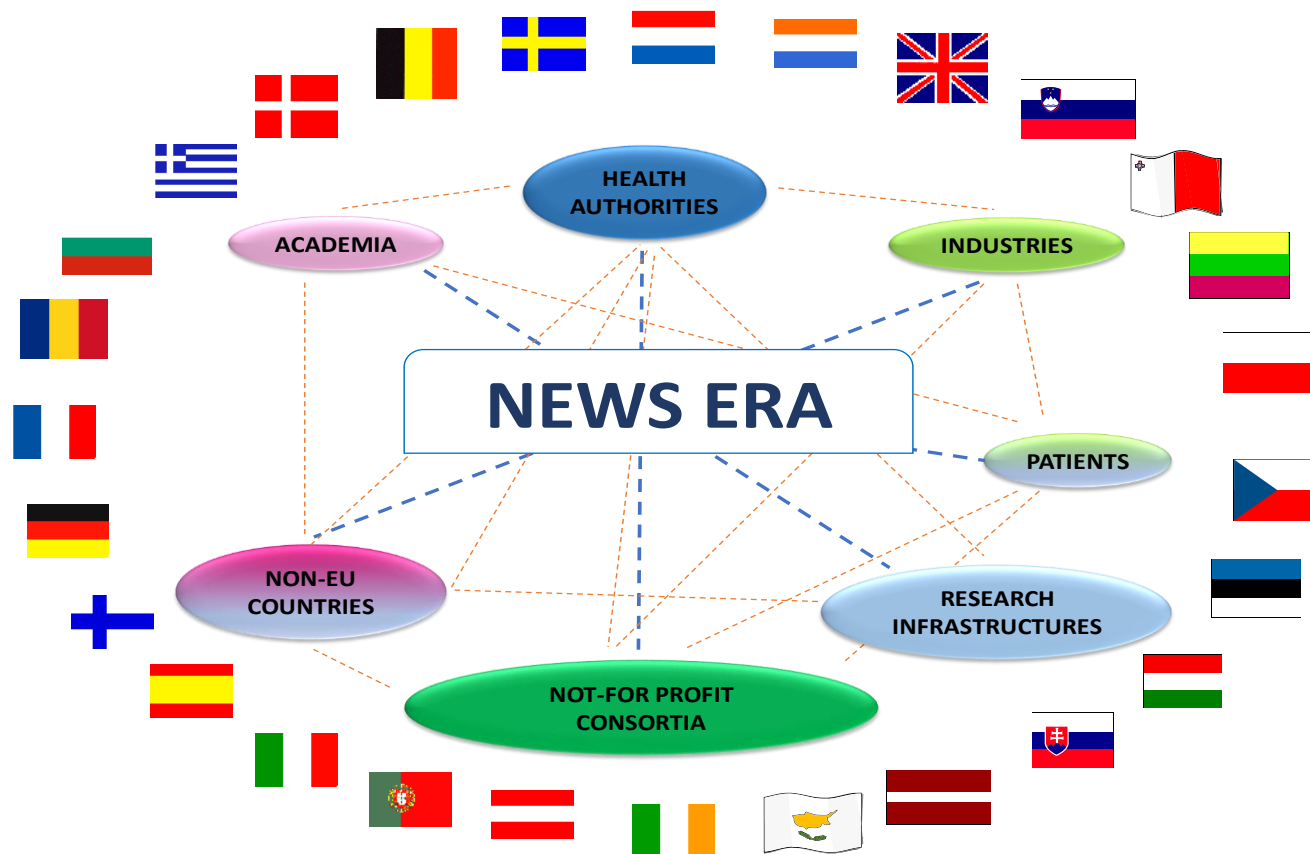
WHY THIS NETWORK?

Today no regulatory network of stakeholders exists in the EU!



moving from **REACTIVE REGULATION** to **PROACTIVE INVOLVEMENT** and **EARLY INTERACTION**

NEtWorking Science for European Regulatory Activities





- *To create a network linking EU researchers and the other stakeholders involved in the medicines lifecycle*
- *To share knowledge and develop common practices*
- *To provide inputs to drug legislation*
- *To increase the researchers' regulatory contents to develop and evaluate innovative products for human use*
- *To bridge the existing gap between the research-oriented programming and the current regulatory standards*

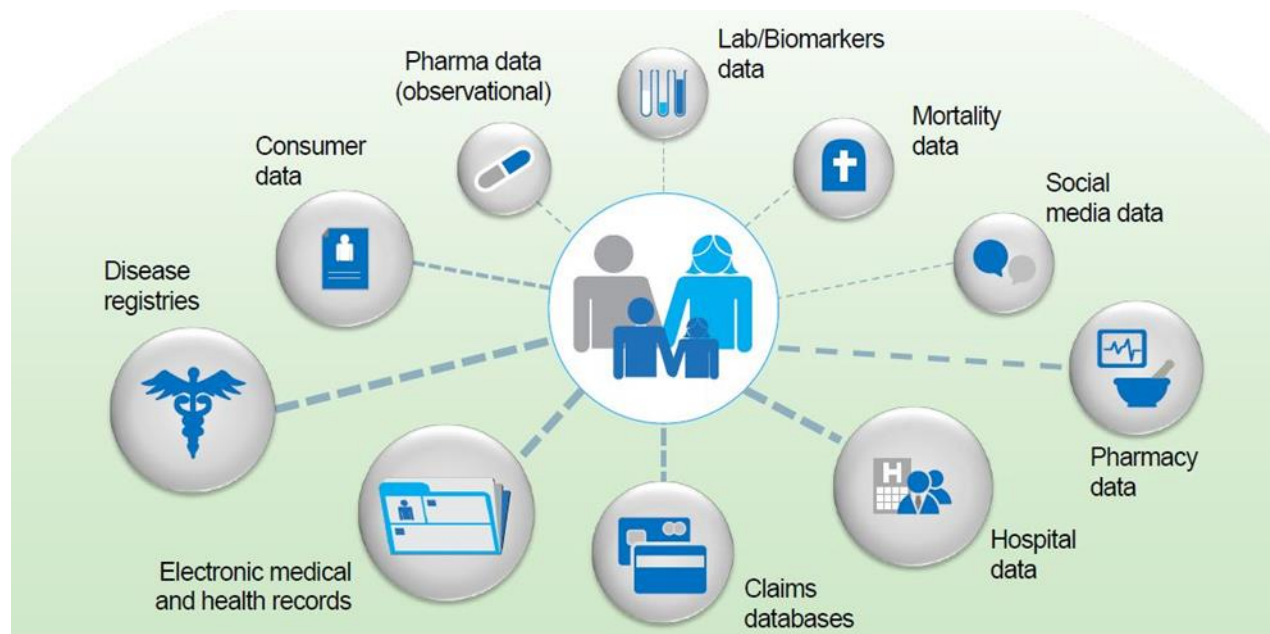


TOPICS:

- ❖ *Health data and secondary use*
- ❖ *Health Technology Assessment (HTA) and access policies*
- ❖ *Orphans and rare diseases*

Health data and secondary use

- A very current topic requiring a strong collaboration
- Secondary use of health data more and more included in regulatory procedures



HTA and access policies

- Need for harmonising the policies of access to drugs, pricing and reimbursement

- Proposal for a EU Regulation

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

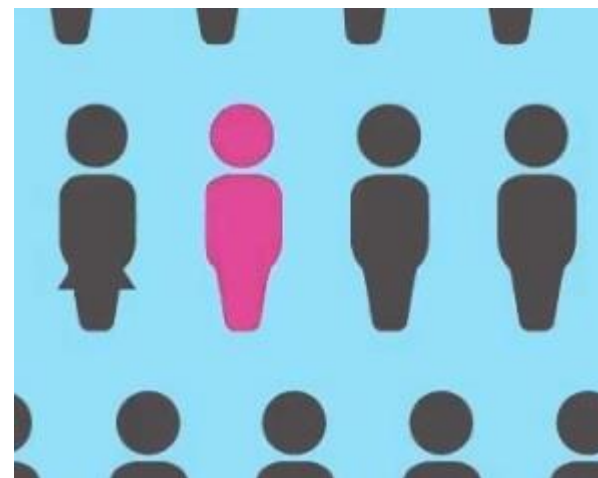
on health technology assessment and amending Directive 2011/24/EU

- Need for joining efforts to provide EU institutions with comments to better address the provisions providing the point of view of academia, patients, and healthcare professionals

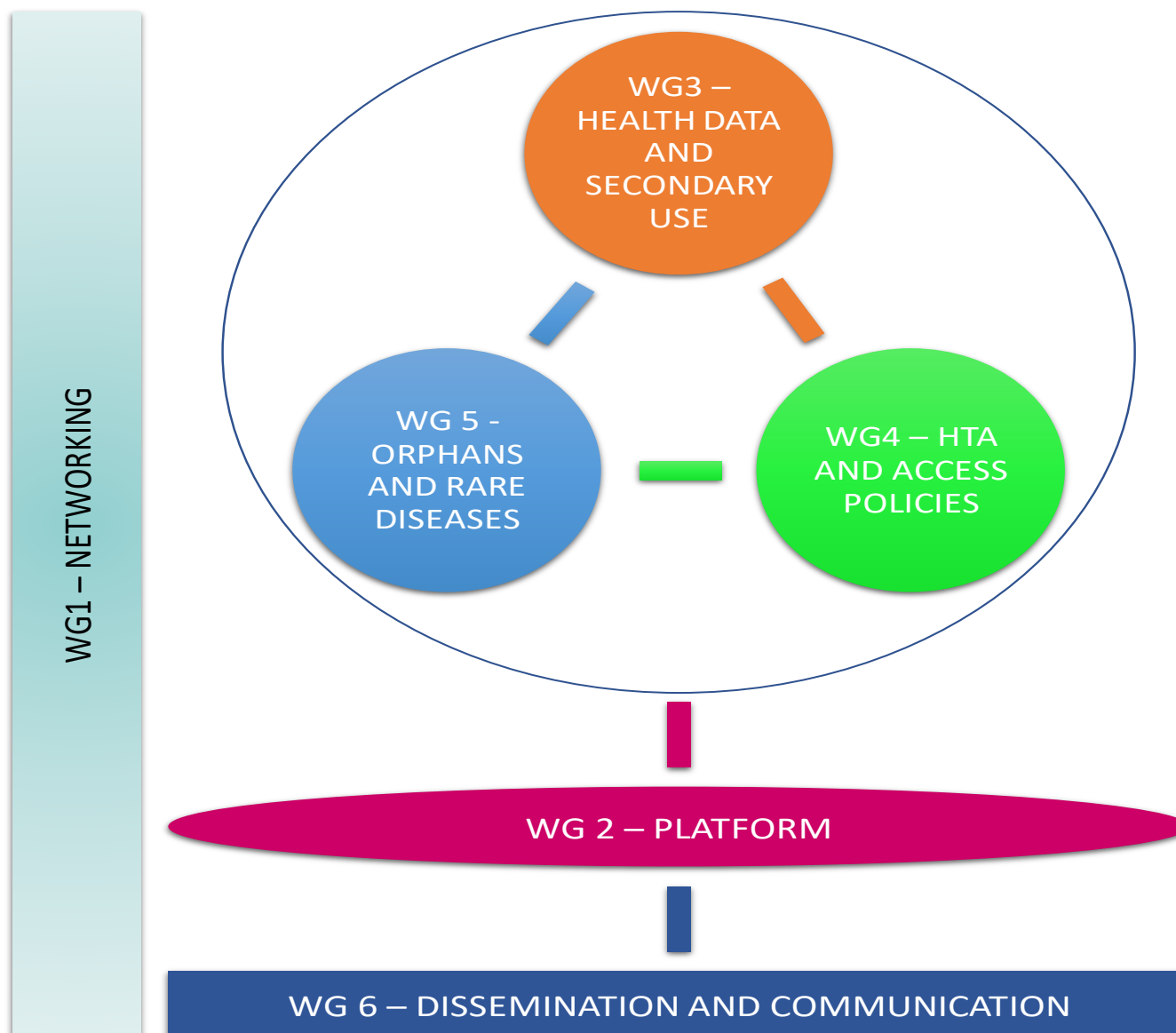


Orphans and rare diseases

- Orphans and rare diseases represent cases that will benefit from the dissemination of new knowledge
- Revision of Regulation (EC) 141/2000 is expected soon
- Need for networking and sharing



WORKING GROUPS



WGI - NETWORKING

Objective:

*To create the **regulatory network** with scientific and regulatory expertise*



Network set up



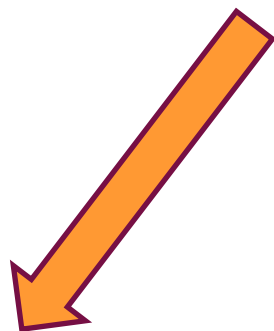
Enlarging the Network



WG2 - PLATFORM

Objective:

*To set up and implement the **ICT platform** to facilitate the exchange of information, store and make available training material*



Platform set up



Platform management
and contents upload



WGs on specific topics

Objective: *To set up groups of experts to address the topics*

WG3

**Health data and
secondary use**



WG4

**HTA and
access policies**



WG5

**Orphans and
rare diseases**



Expert Group
set up

Expert Group
periodical activities
(TCs, meetings)

Educational content
for the platform

Training School
organisation

Training schools

- to focus on the most innovative advancements
- to involve experts in regulatory sciences and in other fields linked, e.g. healthcare, economics, ethics, law, politics
- to train young researchers able to satisfy the requirements of the EU Pharmaceutical System
- to debate on the main current issues
- to involve young researchers in a multi-disciplinary network



WG6 - DISSEMINATION AND COMMUNICATION

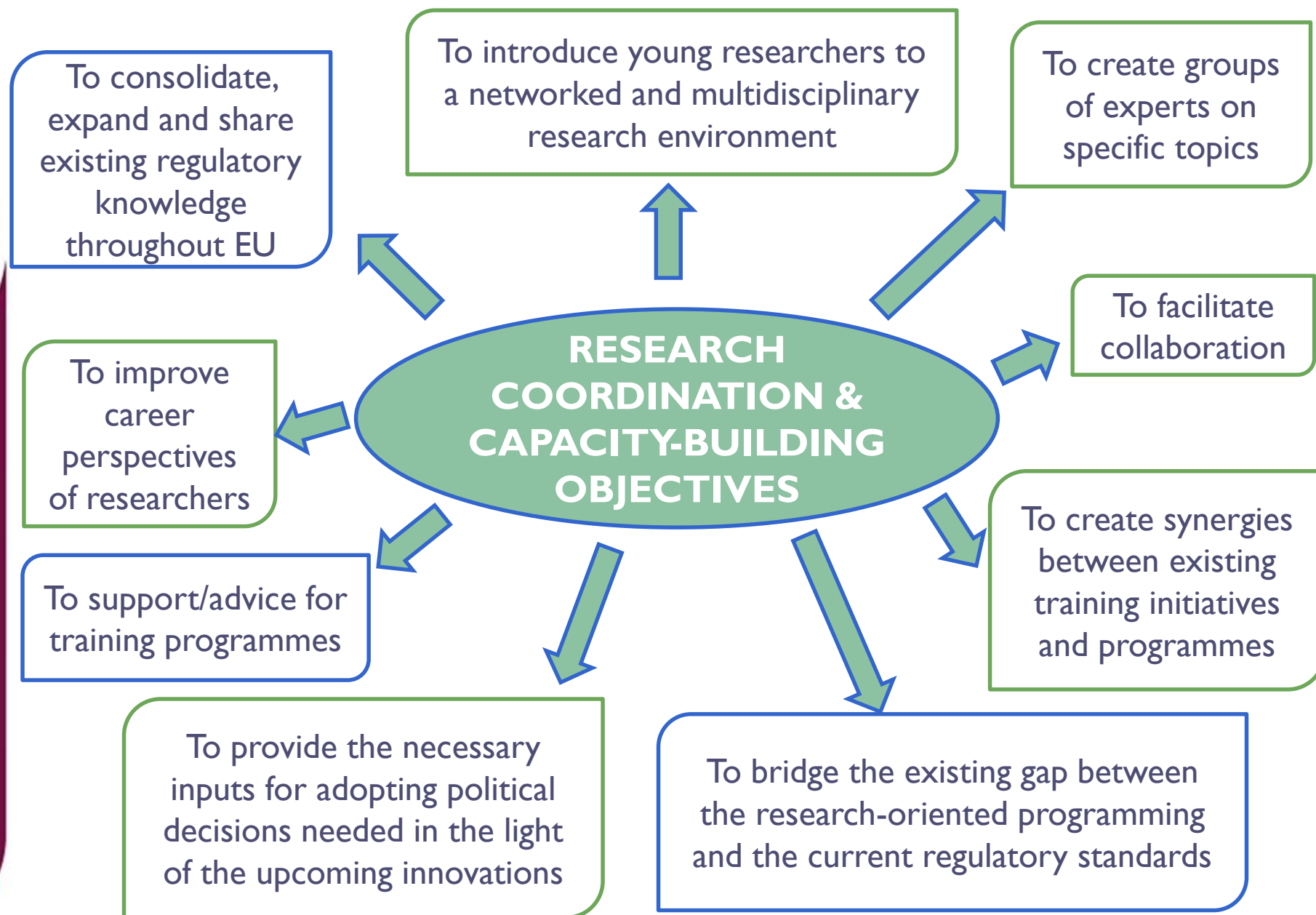


Objective: *To use, disseminate and exploit research results from NEWS ERA within and outside the network, supporting the Action's scientific and networking activities*

Development of communication
and dissemination tools

External meetings and
conferences

Managing intellectual
property rights, data
protection and
confidentiality



People joining

COST Country Institutions (14) : Albania  , Austria  , Belgium  , Cyprus  , France  , Germany  , Greece  , Italy  , Lithuania  , Netherlands  , Portugal  , Romania  , Spain  , United Kingdom 

- Viviana Giannuzzi
- Annagrazia Altavilla
- Enrico Bosone
- Helena Fonseca
- Josep Torrent
- Giovanni Migliaccio
- Fidelie Kalambayi
- Maurizio Scarpa
- Tanja Stamm
- George Papanikolaou
- Fedele Bonifazi
- Verena Stühlinger
- Dimitrios Athanasiou
- Mariagrazia Felisi
- Maurizia Dossena
- Petra Schnell- Inderst
- Hugo Tavares
- François Houÿez
- Cristina Enache
- Silvia Asan
- Catherine Turner
- Jean-Marc Van Gyseghem
- Marina Kleanthous
- Anila Godo
- Sarunas Narbutas

- ❖ *Gender Distribution: 44% Males and 56% Females*
- ❖ *Number of Early Career Investigators: 12*
- ❖ *Core expertise: clinical medicine, health sciences, law, basic medicine*



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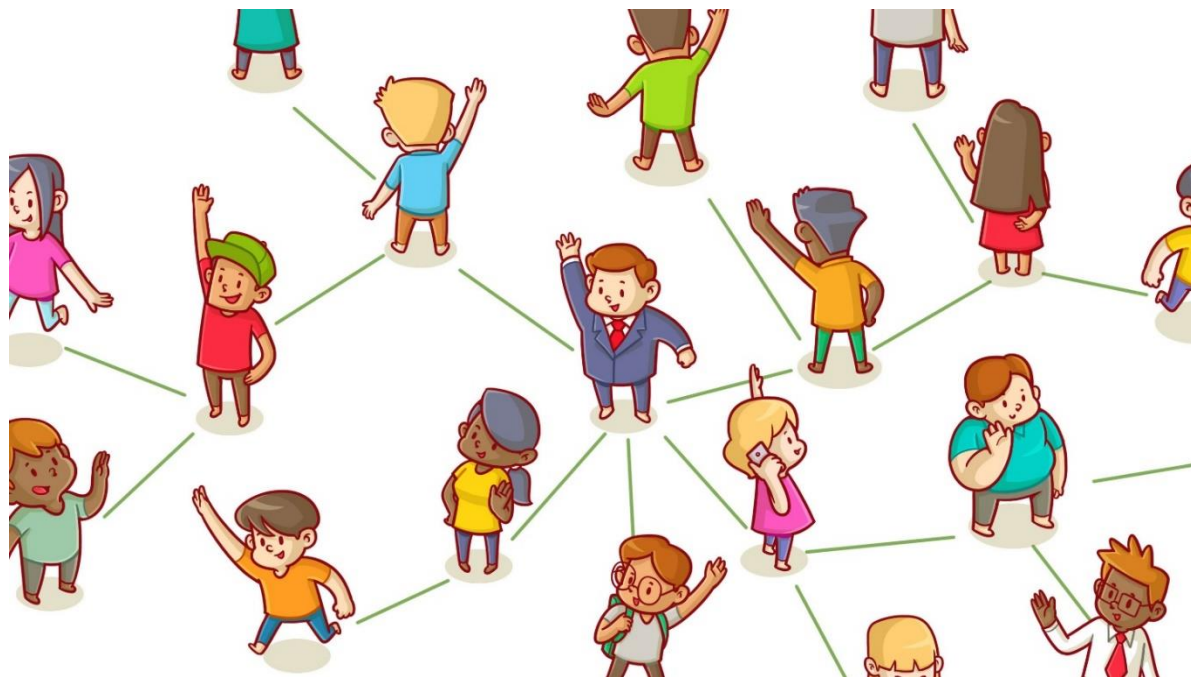
PharmD, PhD

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PDCO and EnprEMA WG 4 member

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**THANK
you!**



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