

The European perspective of academic research: The way to move forward

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An odyssey through times...

- The past: where do we come from?
- The present: the evolving landscape of clinical research
- The future: where are we heading to?

Let's get started and turn back the clock

Chapter 1: the past



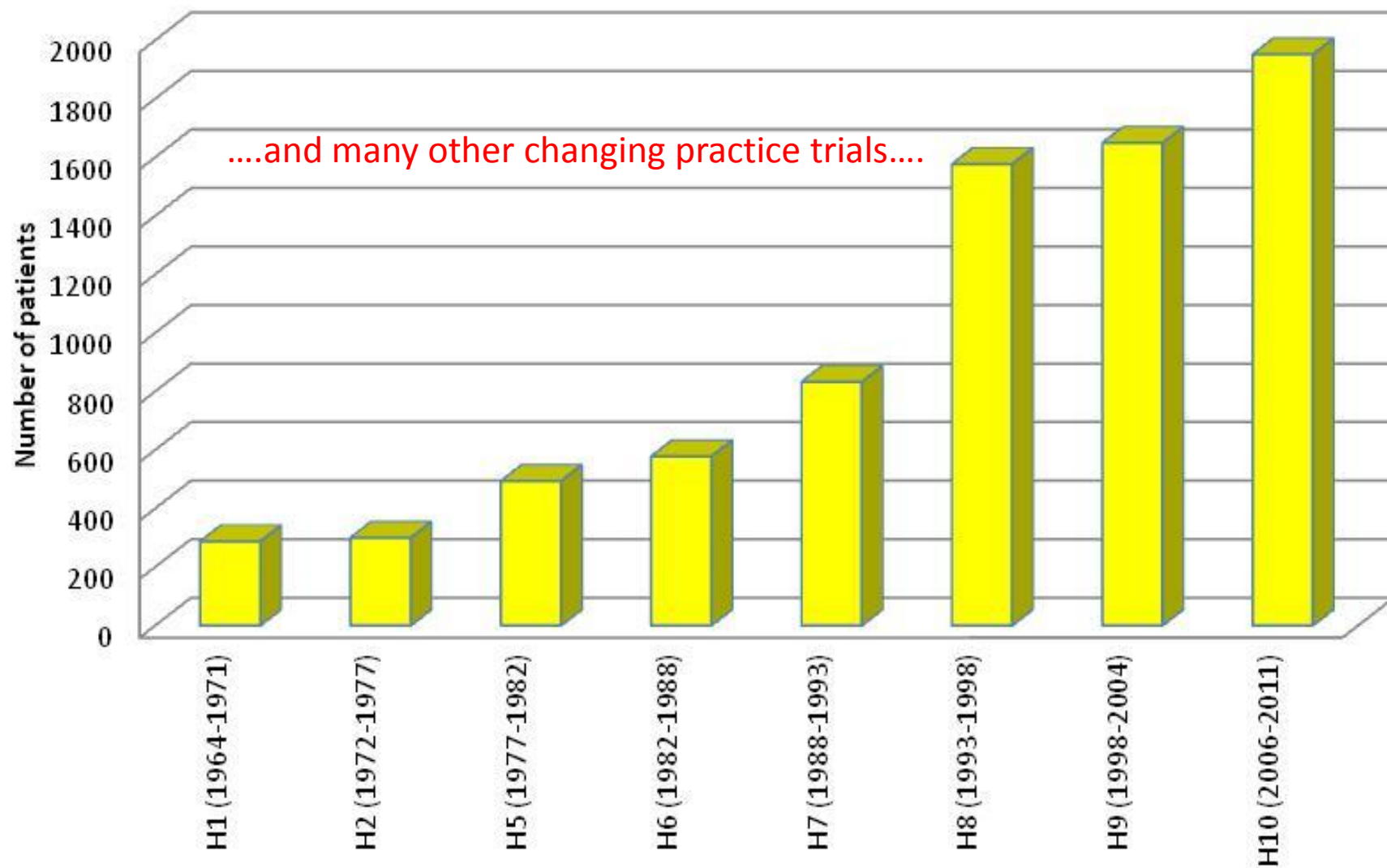
Treaty of Rome:1957
 EORTC created in 1962
 Nixon Cancer act: 1973

In 1991 EORTC:

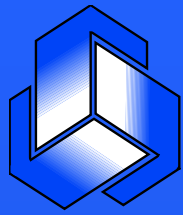
- 5-7000 new patients /year
- Headquarters staff less than 30
- Data management and statistics

We had a vision.....

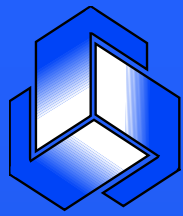
EORTC trials on Early Stage Hodgkin Lymphoma



.....and in 2004.....



**THERE ARE FEW
GOOD NEWS**



How to improve the quality and effectiveness of clinical cancer research?

- To train health care professionals in the methodology of clinical research
 - MDs, Nurses, Pharmacists, Directors of hospitals, Health authorities
- To promote independence of investigators (increasing funding for strategy trials and academic research networks)
- To harmonize national & international regulations
- To promote interaction and cooperation between Member States, authorities and academic networks



Missions of non-commercial research organizations

- Extending the use of drug (s)
- Establish treatments for rare diseases
- Therapeutic strategies (State of the Art) :
 - Comparing new therapies to existing standards
 - Comparing and developing multi-modality treatments



For the benefit of patients

.....and a new journey has started

Chapter 2: the present

Our missions remains the same

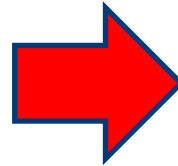
To improve the treatment and quality of life of cancer patients during and beyond the disease

But

The forms and the methods to reach the goal are evolving and we need to adapt to a constantly evolving environment:

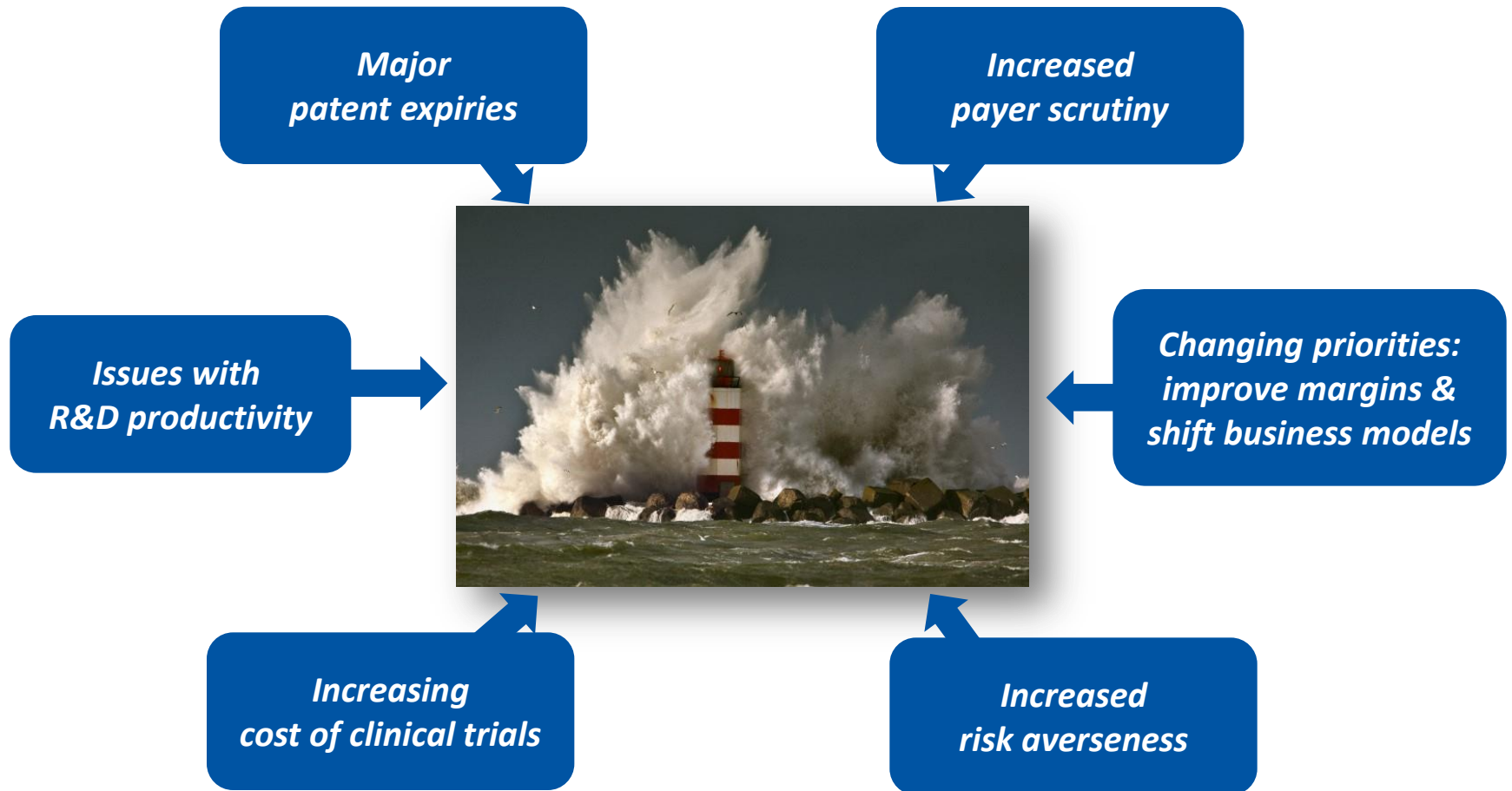
- scientific,
- regulatory
- and economical

A wake up call...



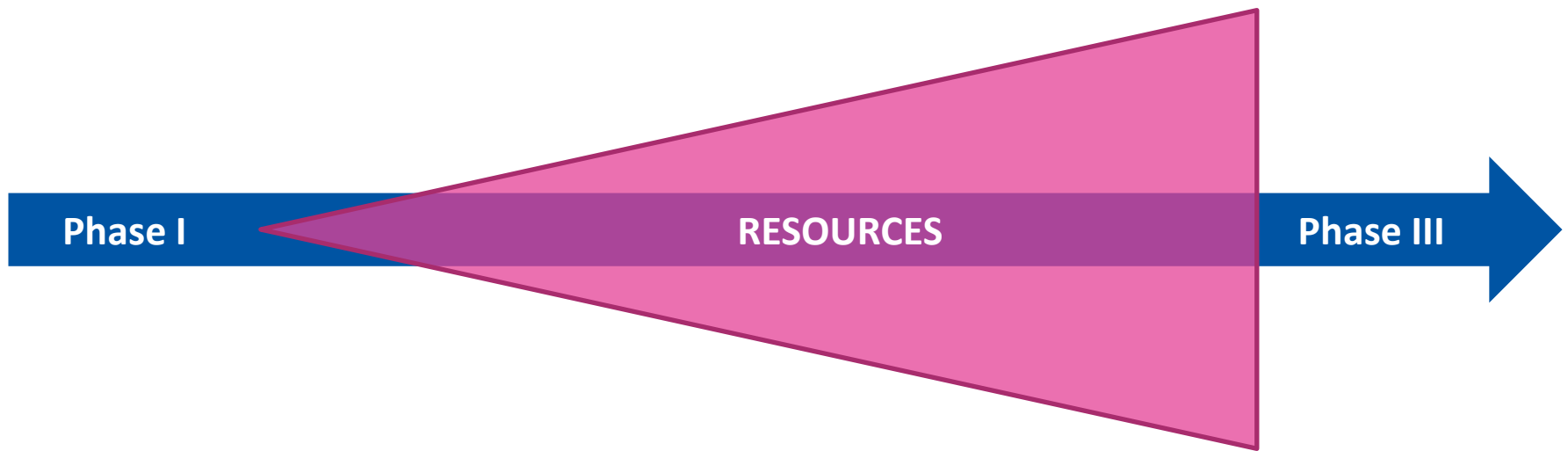
- All stakeholders are facing major challenges
- Unaffordable drug development and treatments
- Pay for performance
- Disease fragmentation
- High-tech clinical trials

As a community, we are experiencing a perfect storm



Changing clinical research pathway (I)

The classical model does no longer fit disease heterogeneity



The regulatory pathway is evolving towards

- Either document for sub groups at the end of all comers approach
- Or apply subgroup selection at start of development

Burock et al. Eur.J.Cancer (2013), <http://dx.doi.org/10.1016/j.ejca,2013.05.016>

Chapter 3: the way forward

4 main areas will shape the future

...omics

Technology and
data science

Outcomes

Partnerships
and
collaborations

The changing clinical research pathway (II)

From trials “designed to learn” to real life situation

Early clinical trials (R&D)

- Biology / imaging driven
- Integrated TR
- Screening platforms
- Collection of high quality data from various sources

Pivotal trials

- Highly targeted
- Large differences

Population-based studies

- Real world data
- Quality of life
- Health economics
- HTA
- Pragmatic trials

Burock et al. Eur.J.Cancer (2013), <http://dx.doi.org/10.1016/j.ejca,2013.05.016>

A wealth of emerging opportunities and the big data challenge

Dream? Reality? Necessity!

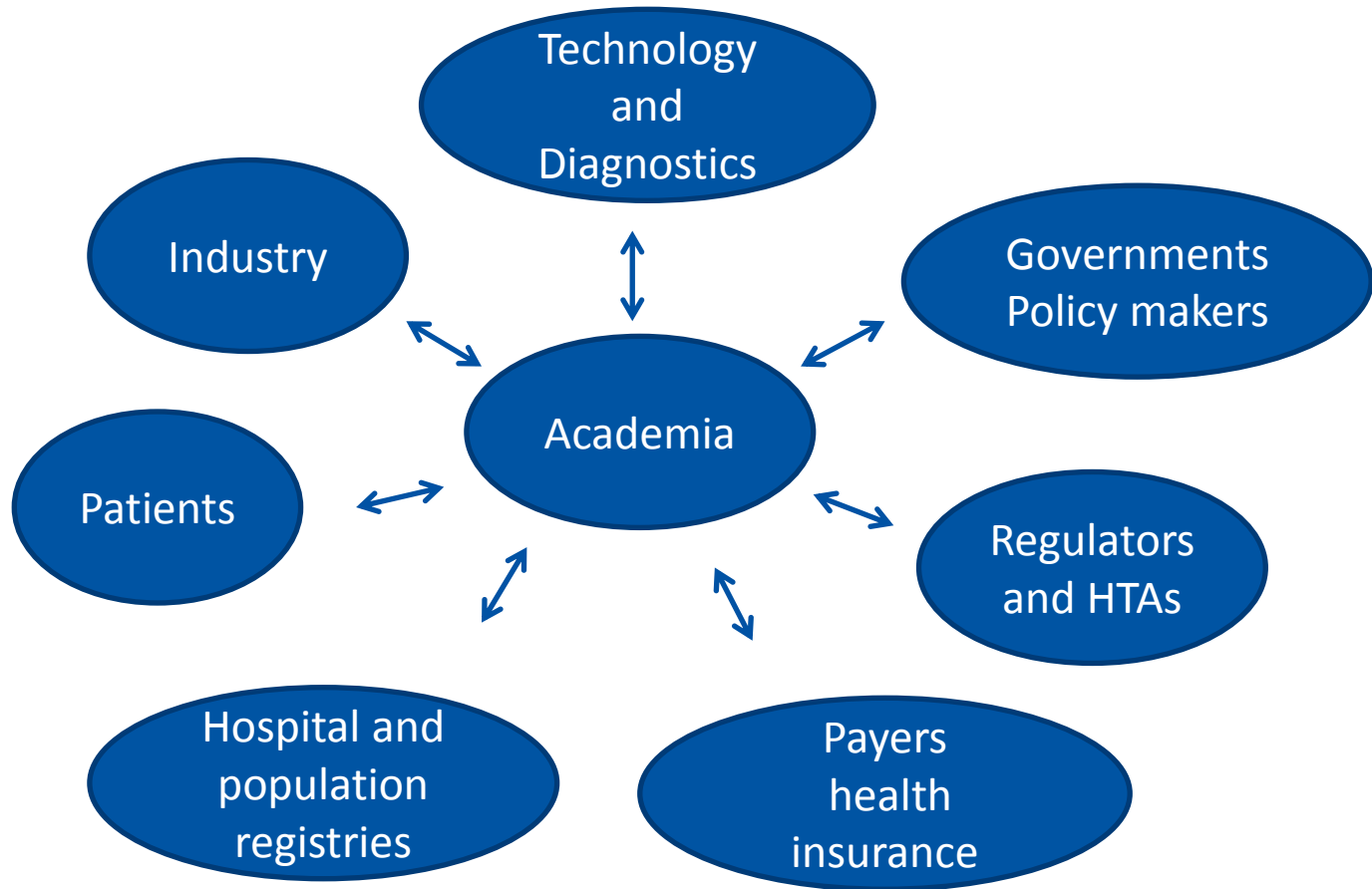
.....leaving the comfort zone....

.....from efficacy to effectiveness.....

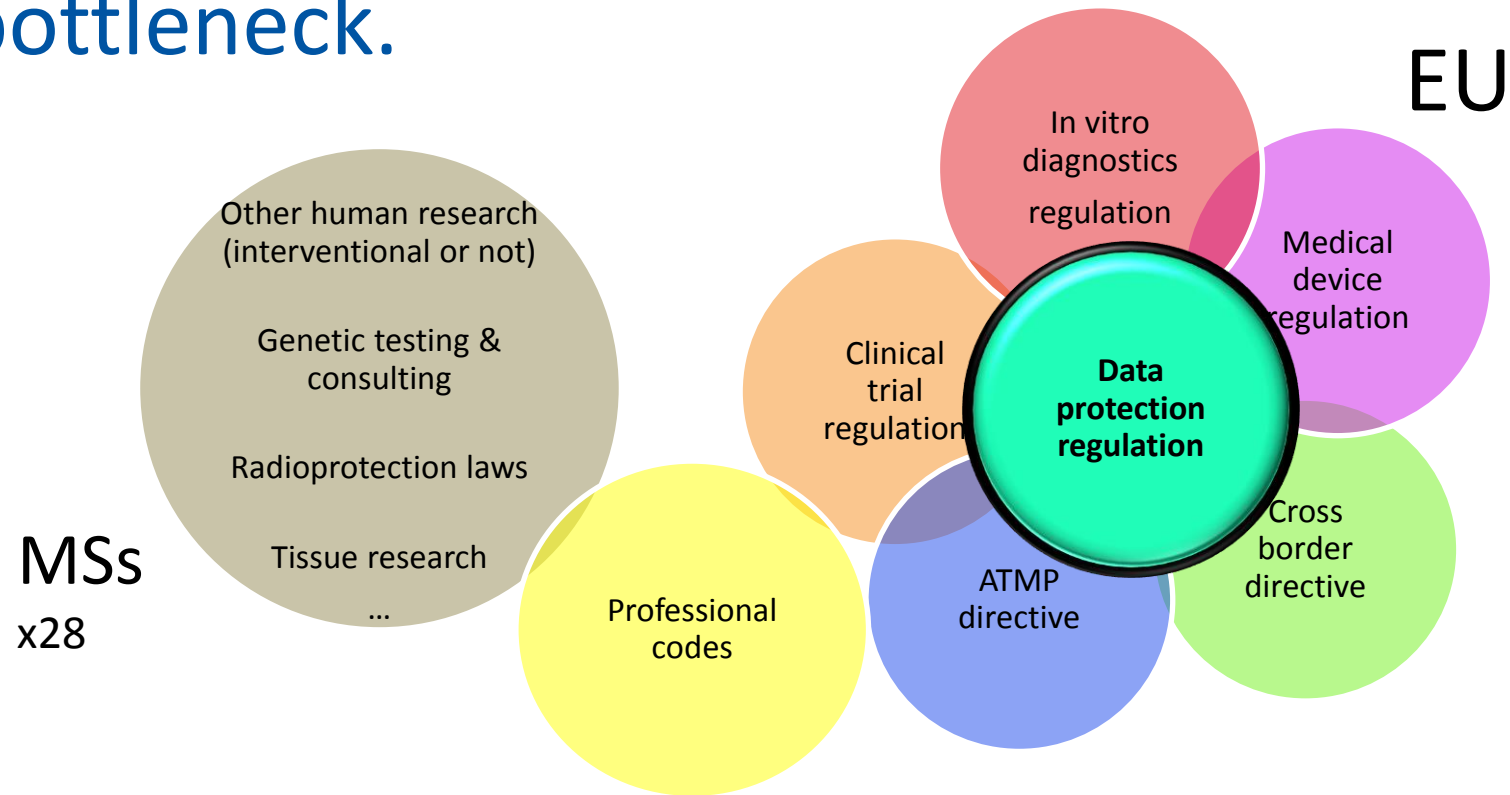
.....new models of partnerships.....



Innovative partnerships will shape clinical research



Regulatory framework in Europe: a major bottleneck.



⇒ *Streamline - Simplify - Harmonize*

Europe must build an integrated and harmonized legal and ethical framework to foster relevant international cancer clinical research

SAVE THE DATE

3 - 4 December 2015
Brussels, Belgium

Innovation and Biomarkers in Cancer Drug Development

A Joint Meeting by EORTC, NCI and EMA

The European Medicines Agency (EMA) and the United States National Cancer Institute (NCI) will join the EORTC to host the Innovation and Biomarkers in Cancer Drug Development on 3 - 4 December 2015 in Brussels, Belgium (EU).

Never before has cancer drug and biomarker development been so complex and required so much expertise, and this EORTC - NCI - EMA symposium is a much needed signpost along the path towards improved cancer treatments.

