

# Cancer Medicines Forum

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## Rationale and Achievements

Denis Lacombe 5<sup>th</sup> April 2024

# We would not be here today without....

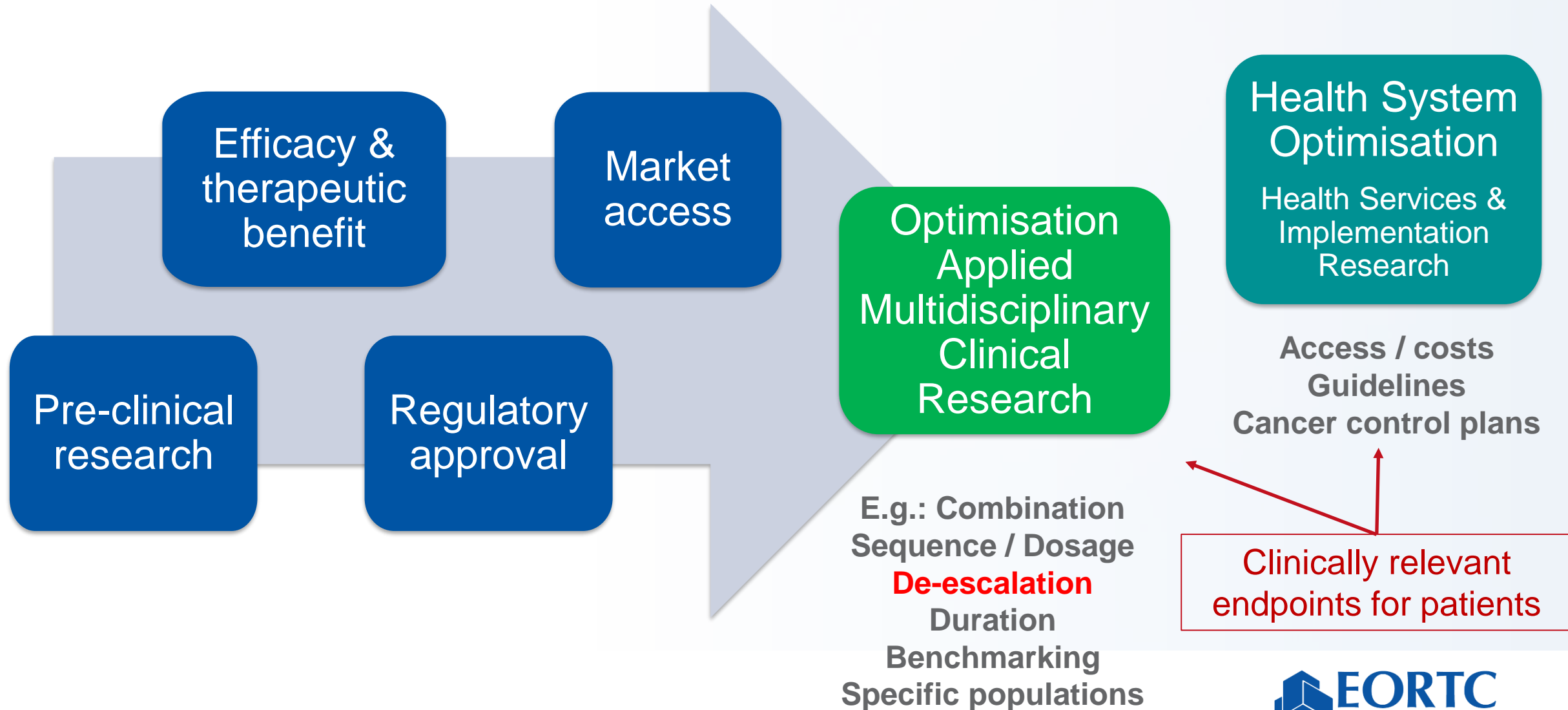
- EMA Management: Emer Cooke
  - Francesco Pignatti: Scientific Advisor for Oncology
  - Caroline Voltz: Scientific Lead, Haematology and Oncology Division
- Minister Vandembroucke: Vice Premier and Minister for Social Affairs and Public Health and his Cabinet: Anouk Waeytens, Anna Kubina, Gloria Ghequiere
- Representatives of the societies and organisations, members of the CMF
- The unconditional support of the EORTC Board of Directors represented by its president Prof W. van der Graaf
- Research Fellows: Robbe Saesen and Fabio Borges

# Why did the CMF get started?

Once upon a time in the late years 2000s....

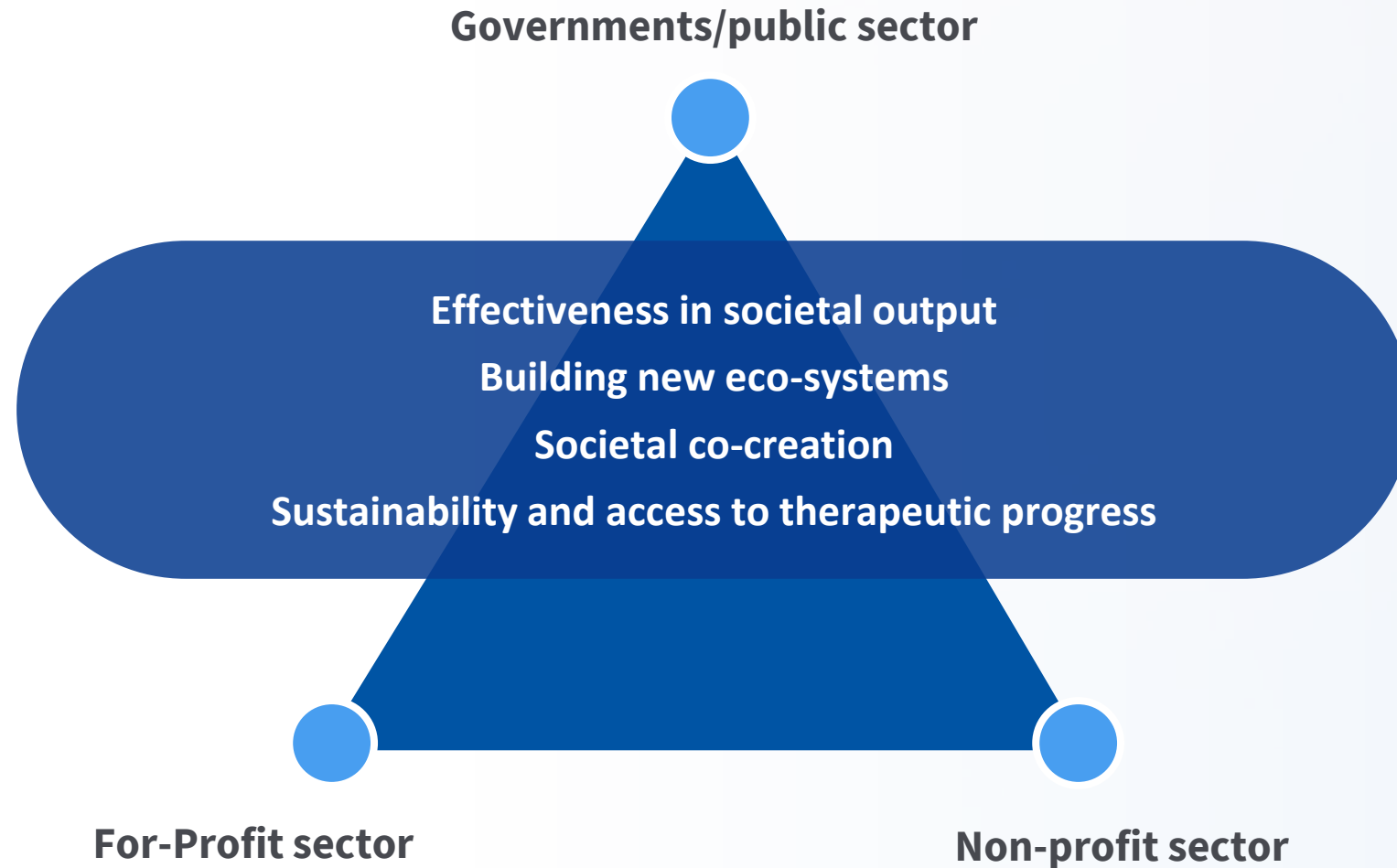


# When we needed to re-think why and how!





# Why EORTC stimulated the CMF?





# It has been a journey... today is an important milestone



### The Porto Declaration on Cancer Research

2021 PORTUGAL.EU

**2. Infrastructures for clinical and prevention trials:**

'Proof-of-concept' studies may serve as a starting point for further clinical and prevention research, with a practice-changing aim, including the assessment of its utility in healthcare or prevention, patients'/individuals' at risk, cure/survival and health-related quality of life. Well-developed clinical trial structures, and advanced diagnostic methods such as state-of-the-art molecular pathology, omics technologies, and pharmacology to stratify patients as well as innovative imaging are crucial. CCCs can play a role in this together with clinical research networks. The European Organisation for Research and Treatment of Cancer (EORTC) can facilitate this.

For prevention, infrastructures must include strong epidemiology closely connected to basic research, data acquisition capacity, and advanced computational capabilities, and both the International Agency for Research on Cancer (IARC) and Cancer Prevention Europe can play a prominent role in this, along with many other stakeholders. Again, it will be critical to establish funding mechanisms that stimulate these activities and guarantee sustainability. Funding should include resources for proof-of-concept trials initiated by academic investigators.

European Parliament  
2019 - 2024

Directorate-General for Internal Policies  
Special Committee on Beating Cancer

**SUMMARY**

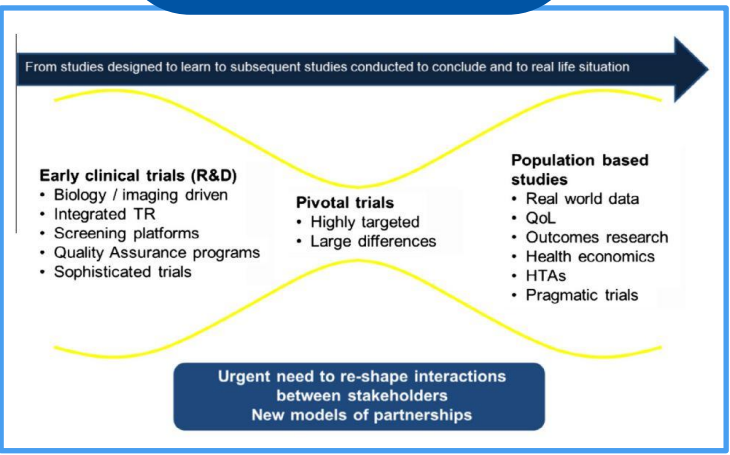
**BECA Hearing**  
"Mind the gap: For equal access to cancer medicines and treatments"  
Thursday 28 January 2021, 13:45 to 16:15 & 16:45 to 18:45  
(József Antall 4Q2 and with remote participation)

**In the Chair:** Bartosz ARLUKOWICZ, Chair

.....2013

2013-2019

2019-2024



**Manifesto**  
for a new approach for better medicine in Europe  
Establishing Treatment Optimization  
as part of personalized medicine development  
(version 29 May 2020)



Available online at [www.sciencedirect.com](http://www.sciencedirect.com)  
**ScienceDirect**  
journal homepage: [www.ejancer.com](http://www.ejancer.com)

Advancing academia-driven treatment optimisation in oncology: Launch of the EMA Cancer Medicines Forum

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Burock S, Meunier F, Lacombe D. How can innovative forms of clinical research contribute to deliver affordable cancer care in an evolving health care environment? Eur J Cancer 2013; 49:2777-2783.

# Key questions to the policy makers

- How to address the gap between supra-national versus national competences?
- If treatment optimisation is to be structured in the process: when, how and who?
- How do we re-engineer the sequence of questions from development into access?
- How do we prioritise questions and select the most appropriate methodology?
- Can Pragmatic clinical trials help structuring and addressing some of the issues?
- How do we structure independent multidisciplinary clinical research in the EU?



# Need for strategic intelligence approaches



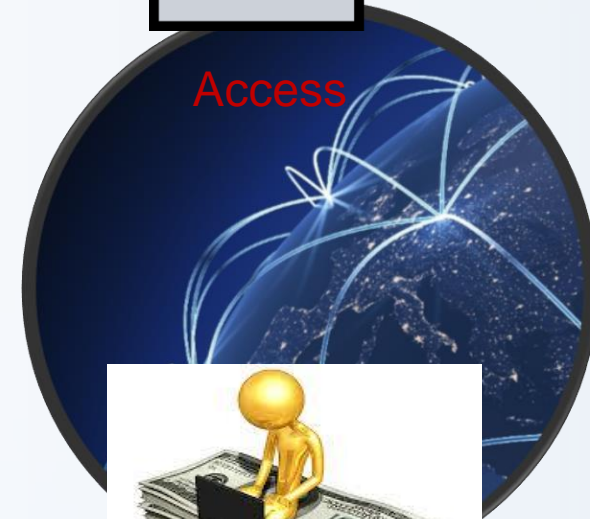
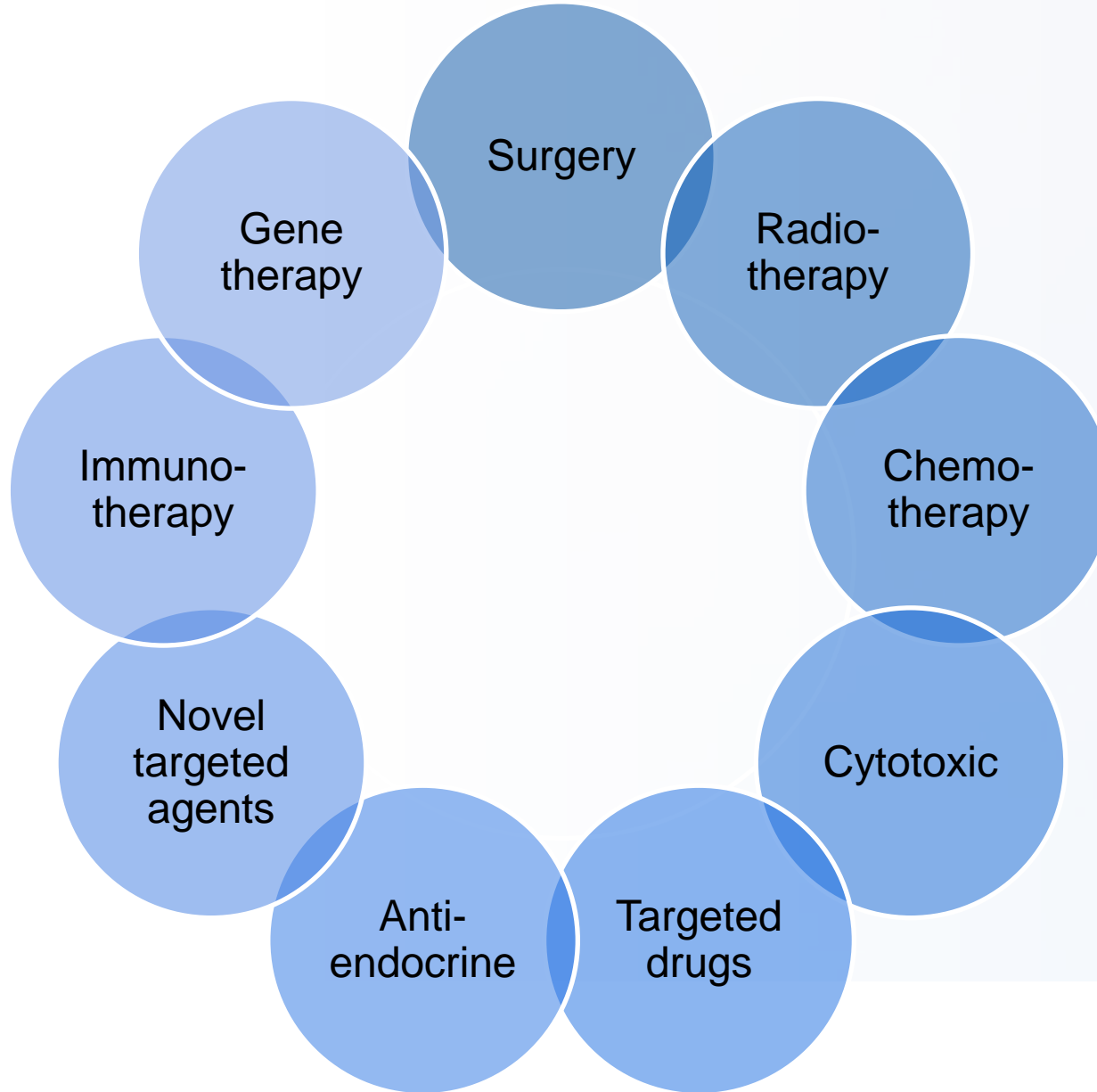
# The Future of Cancer Treatment is Combinatorial



Multidimensional data



Authorisation

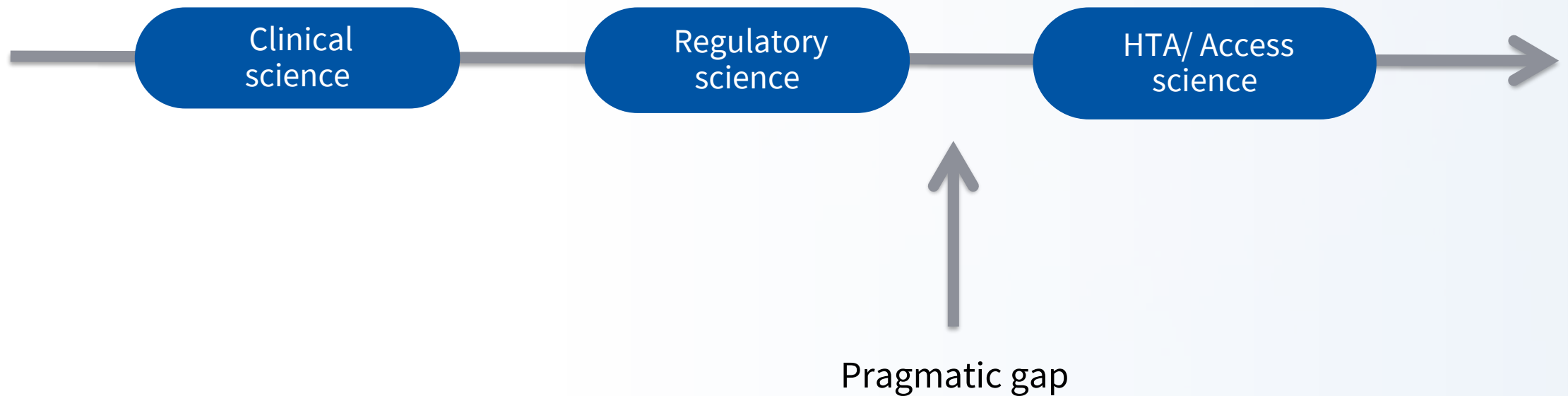


Access



Optimal access

# A new continuum to be set up ....Re-engineer....



# Objectives of the Cancer Medicines Forum



**To serve as a direct and official communication channel with the academic community in oncology**



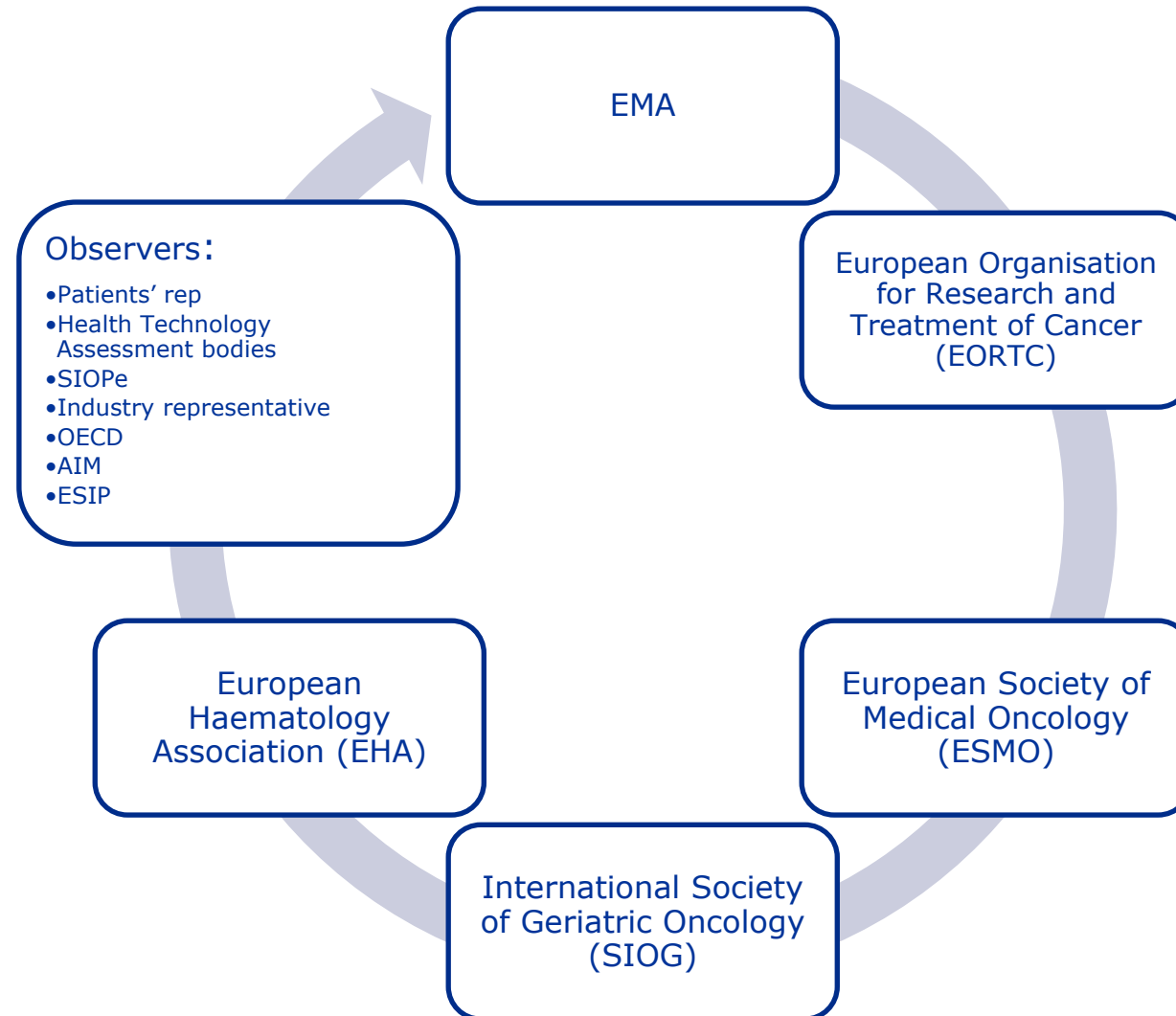
**To identify key research questions and best methodological approach to improve the clinical use of cancer medicines**

Treatment optimisation

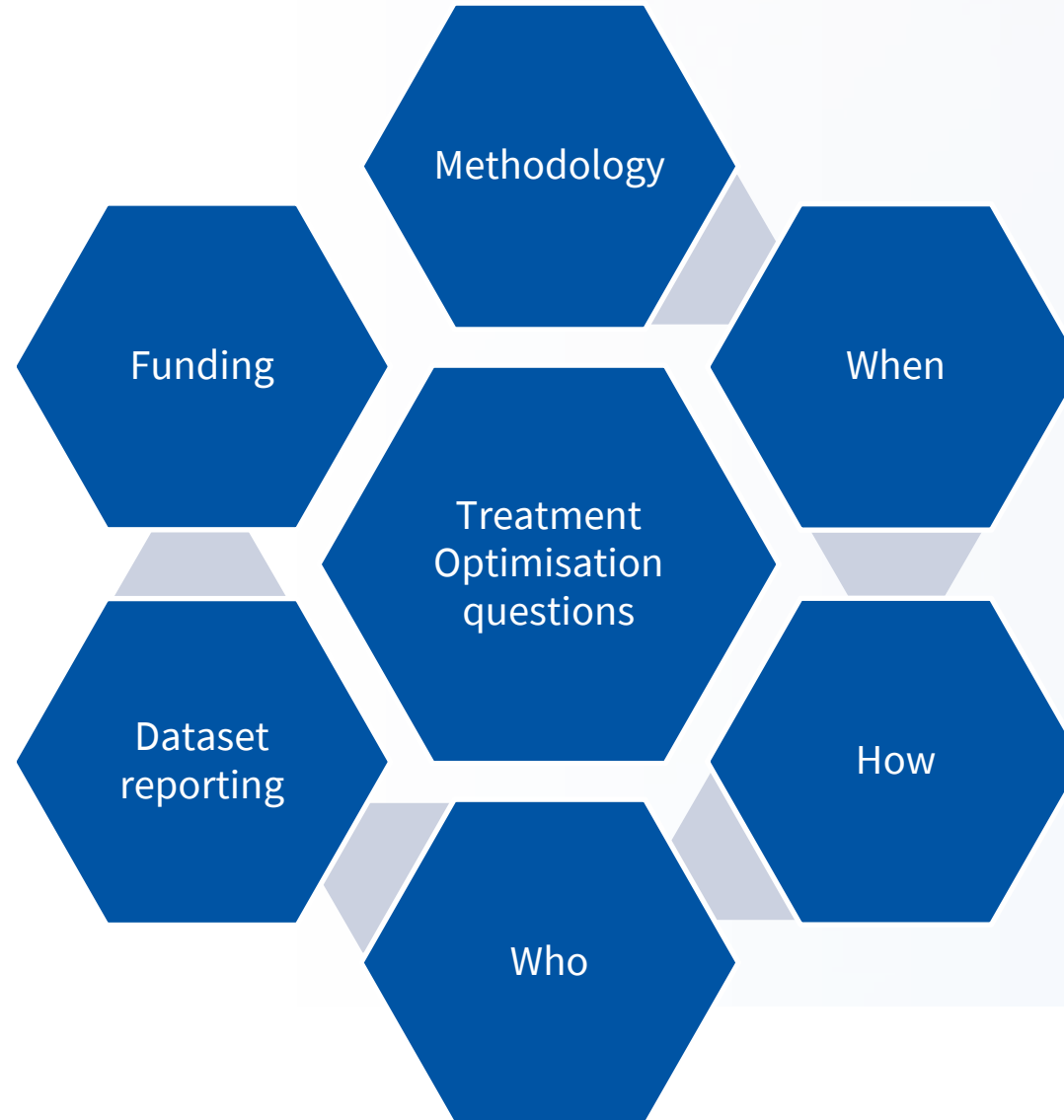


**To discuss the uptake of academic work in the wider context of regulatory decision-making in oncology**

# Focus on academia with other stakeholders

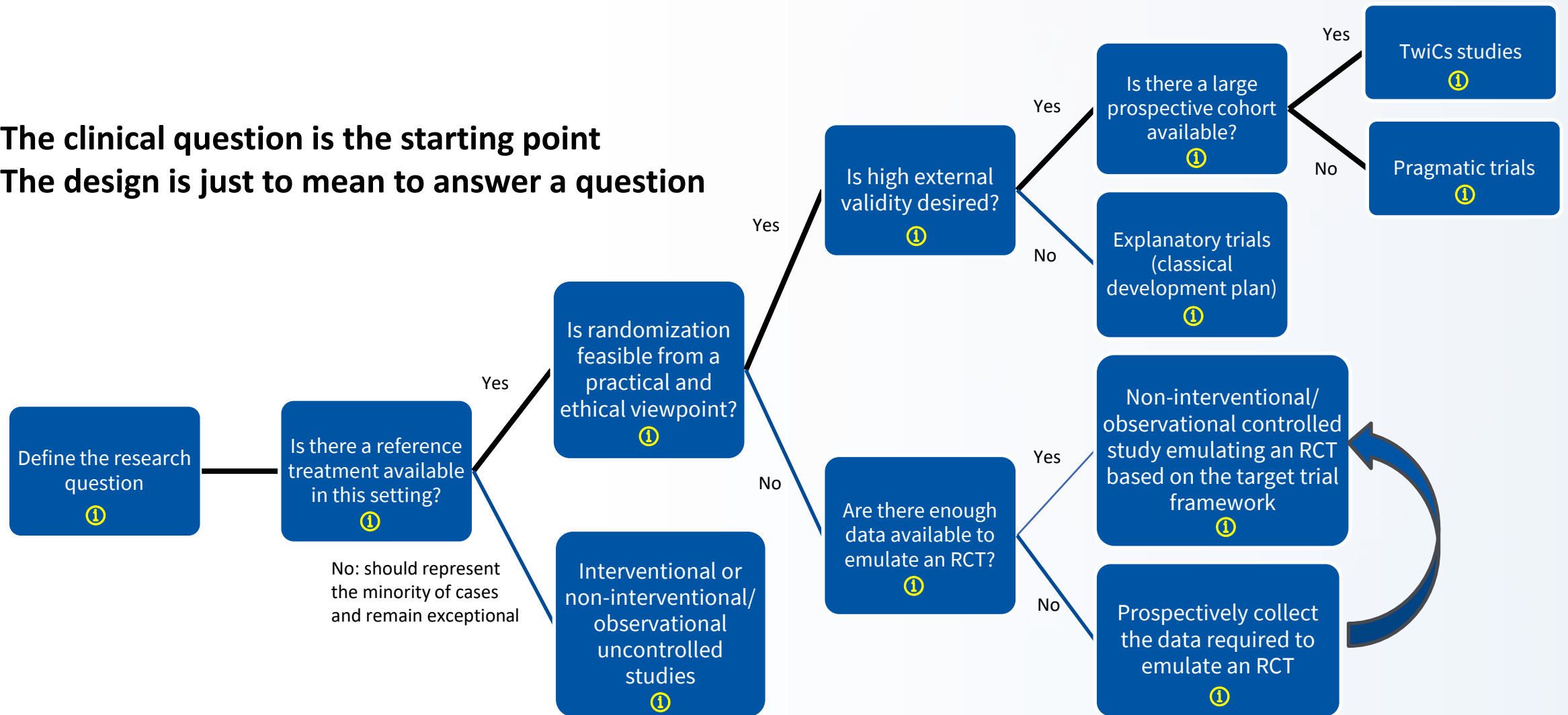


# Structuring Treatment Optimisation



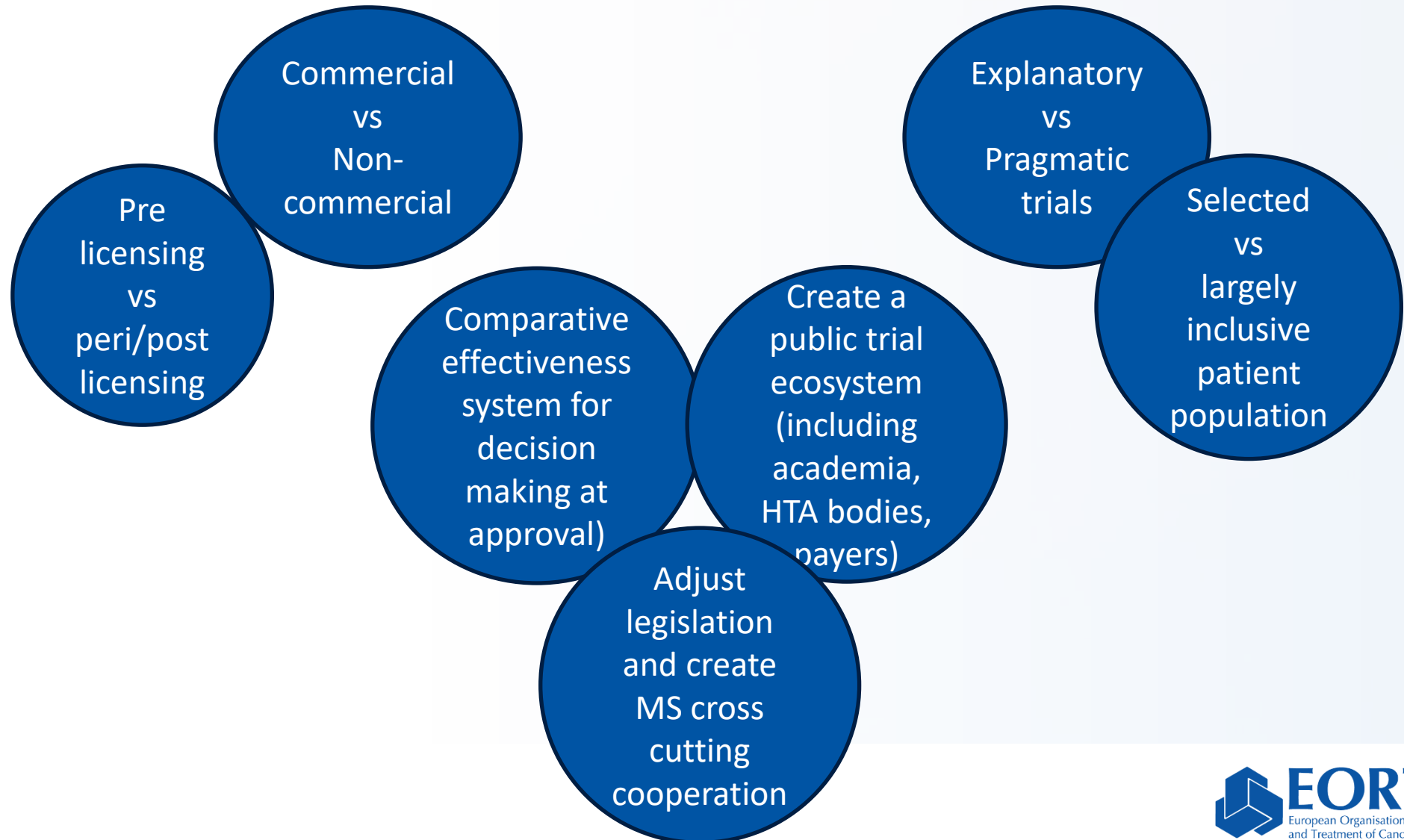


**The clinical question is the starting point**  
**The design is just to mean to answer a question**



Thick lines represent the default route to deliver evidence for trial design selection

# Addressing What-When-How-Who



# Treatment Optimisation is a spectrum

	What	Who	How	feasibility
Early stage Pre-licensing	Dose/safety R/B	Manufacturer	Regulatory process (i.e Optimus)	Explanatory trials
Late stage Post licensing	Combo, de-escalation, population, duration, schedule	Manufacturer academia	Public trial eco-system (adjust legislation)	Pragmatic trials Registry based trials Platform trials

# Operational challenges to implementation

Methodological research:  
Pragmatic trials, TwiCs...  
Recruitment and ethics

Adapt the clinical  
research environment  
Education of  
stakeholders

Reporting and access  
to datasets

Health economic  
dimension and  
funding

# Continued refinement of the pyramid of evidence-based medicine

