

## Building trust in oncology biosimilars: clinical practice Perspective from an oncology clinician

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ESMO Director of Public Policy

*The views expressed are the personal views of the presenter and may not be understood or quoted as being made on behalf of or reflecting the position of others*



# DECLARATION OF INTERESTS

Speaker, consultancy, advisory role (non remunerated)

Apogen, Roche, Mylan, Lilly, Pfizer, Novartis, Medicines for Europe, mAbxience, European Access Academy

Research funding paid to Institution: MSD; Novartis

ESMO Board member 2020-2022

Director of the ESMO Public Policy 2020-2022

Chair of the ESMO Global Policy Committee

Member of the ESMO EU Policy Committee

Member of the ESMO Cancer Medicine Committee

Member of WHO-DECIDE health hub

Former stakeholder pool HTA (EC)

EUnetHTA stakeholder pool

Co-chair of the Healthcare Professional Working Party of the European Medicines Agency (EMA)

Former core member of the EMA Scientific Advisory Group-Oncology (2012-2021)

Member of the EMA Cancer Medicine Forum



**1**

**WHY BIOSIMILARS ARE RELEVANT TO MY PRACTICE**

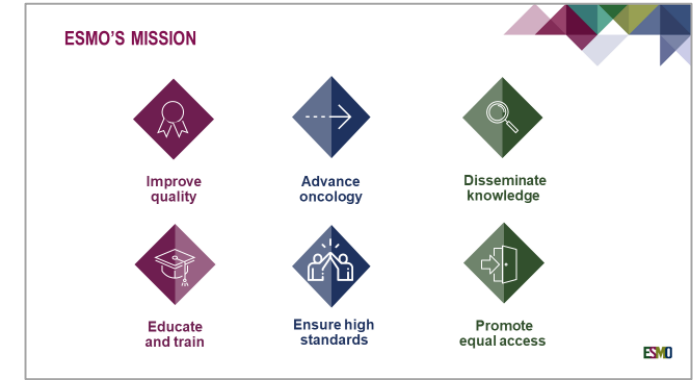
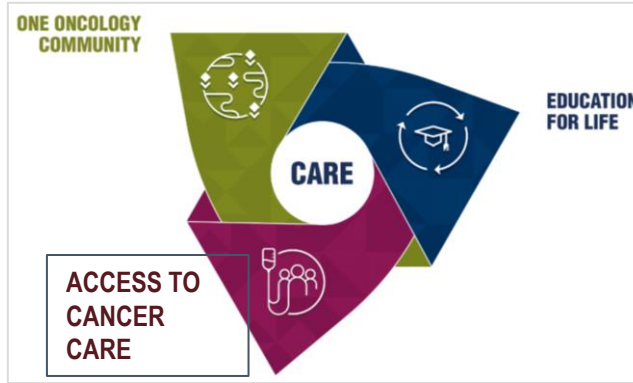
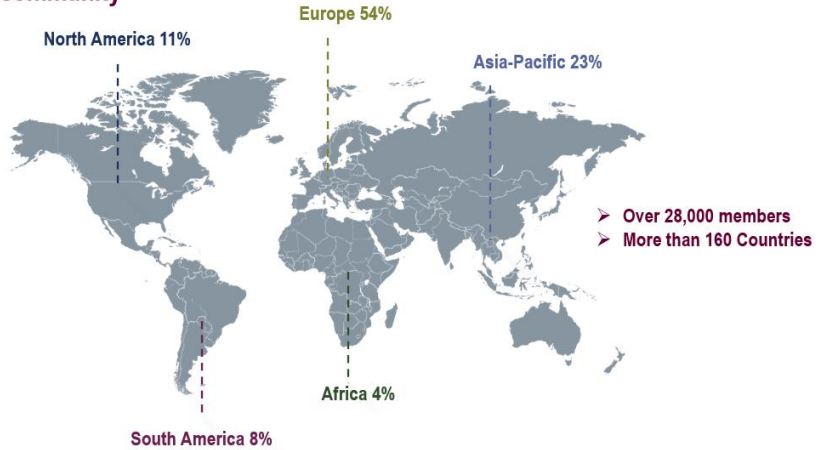
**2**

**HOW DID I BUILD CONFIDENCE**


**3**

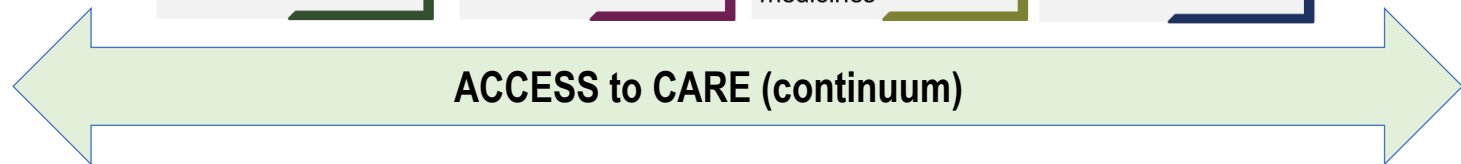
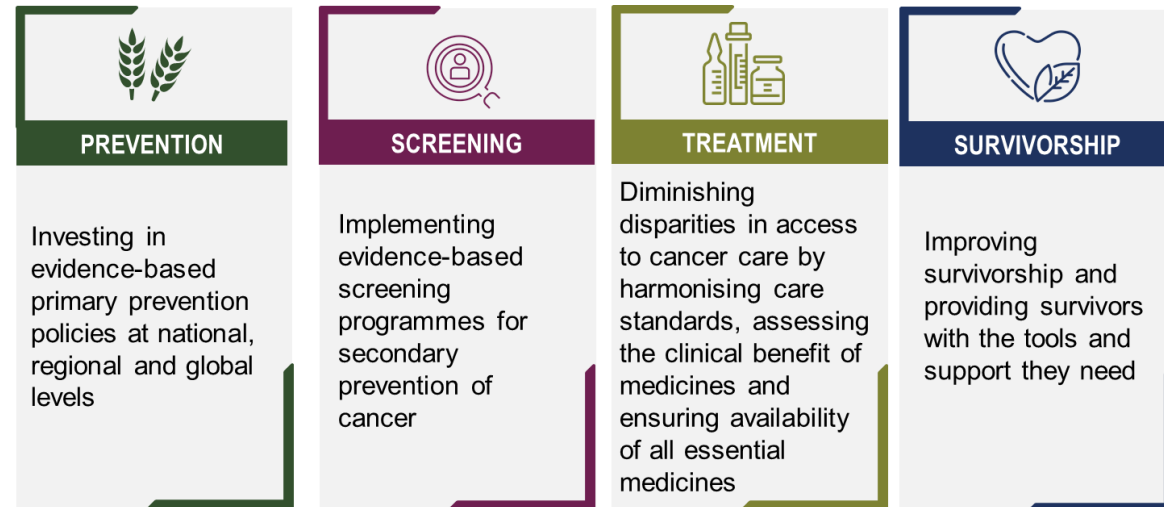
**NEXT STEPS**

**ESMO Members**  
A global community



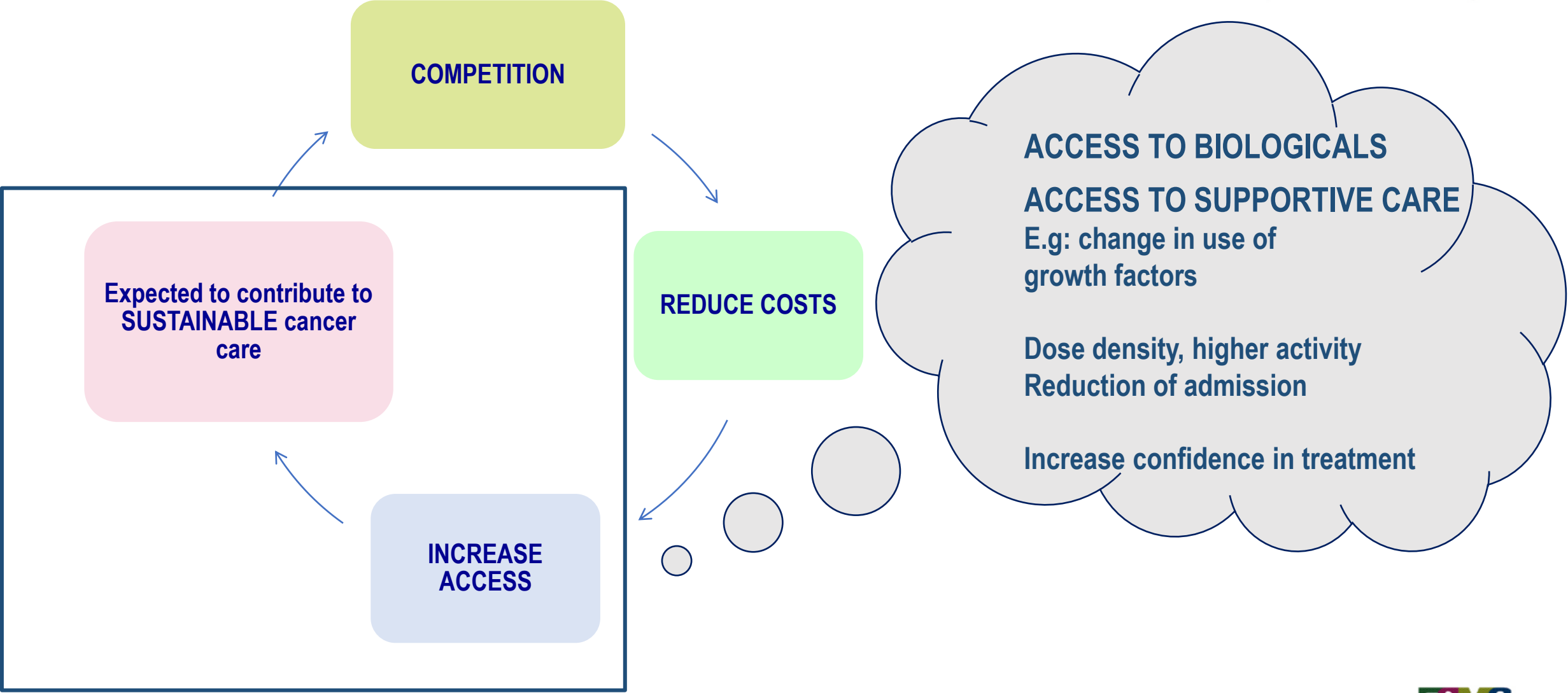
**THE ESMO BLUEPRINT TO TACKLE CANCER**

-  **Optimal Cancer Care**
-  **Universal Health Coverage**
-  **Sustainable Health Systems**



~~**INEQUITIES**~~

HCPs perspective: BIOSIMILARS & ACCESS & SUSTAINABILITY



# UNDERSTANDING BIOSIMILARS is the RESULT OF SHARING KNOWLEDGE



SCIENCE

REGULATORY EXPERTISE

LEARNED SOCIETIES






# The KEY role of learned societies: ESMO in action



Open Access Review

**ESMO** *Open* **Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers** 2017

Cancer Horizons


 CrossMark

**POSITION  
PAPER**

Open access Review

**ESMO** *Open* **Preparing for the incoming wave of biosimilars in oncology** 2018

Cancer Horizons


 Check for updates

ESMO Special session @  
ESMO 2017 in Madrid  
"The incoming wave of biosimilars  
in oncology"

Open access Original research

**ESMO** *Open* **Knowledge and use of biosimilars in oncology: a survey by the European Society for Medical Oncology** 2019

Cancer Horizons

 Check for updates

ESMO survey on awareness on  
Biosimilars launched  
during ESMO2017 in Madrid.  
Presented @ ESMO colloquium  
(ESMO 2018, Munich)



# ESMO BIOSIMILARS PORTAL



**Biosimilars promote access to innovative cancer medicines**

**Elisabeth de Vries**  
Chair of ESMO Cancer Medicines Committee

**and the sustainability of health systems**

**Josep Tabernero**  
ESMO Past President



**Welcome to the ESMO Biosimilars Portal**



## Science

A collection of resources to understand the science behind biosimilars.



## Education

ESMO education material to help stakeholders to better understand biosimilars.



## Regulation

Visit this section to understand how the EMA, the US FDA, and the WHO regulate biosimilars.



## Patient Resources

A series of resources produced by ESMO and independent sources to address patient concerns regarding biosimilars.


<https://www.esmo.org/Policy/ESMO-Biosimilars-Portal>



# Patients' support

**ESMO**

## UNDERSTANDING BIOSIMILARS For Cancer Patients



This infographic explains what 'biosimilars' are and what kind of opportunities they may bring for cancer patients and their treatment.

Please note that this infographic is only for educational purposes. It does not replace the advice of your doctor.

**PATIENT ADVOCACY**  
An ESMO Priority

### What are the opportunities?

Biosimilars **improve access** to much needed **cancer treatments**<sup>3</sup> by:

- Providing additional treatment options
- Decreasing prices of biological medicines
- Creating savings that may be redistributed to continue financing the healthcare systems

Even more biosimilars will reach cancer patients as of 2020...  
...because more existing biological medicines will **come off patent**.<sup>3</sup>

\*Off patent medicines are no longer subject to intellectual property exclusivity and can therefore be produced by an unlimited number of companies.

### Are they safe?

**EUROPEAN MEDICINES AGENCY** **WORLD HEALTH ORGANISATION**

Biosimilars are safe and work just as well as originator biological medicines, as they go through a rigorous assessment prior to being approved by healthcare authorities.<sup>4</sup>

The European Union is a pioneer in approving biosimilars. Between April 2006 and October 2018, the European Medicines Agency has approved 47 biosimilars, including rituximab and trastuzumab.<sup>5</sup>

The authorisation of biosimilars requires an extensive set of preclinical and clinical tests. These tests are aimed to demonstrate there are **no meaningful differences between the biosimilar and the originator biological medicine**.

You may not be aware, but these **minimal differences** already exist among the various batches of the originator biological medicine.<sup>6</sup>

The label of a biosimilar reflects the label of the originator product. You and your doctor can find all necessary information about the product, its safety and efficacy on the label.<sup>6</sup>



### You should know about...

- Immune reactions and other side-effects**  
All biological medicines, as they are made from living organisms, could cause your body to have an immune response, e.g. a high fever. Biosimilars have similar side-effects to their biologic counterparts, except for slight potential differences in immunogenicity (see definition below). Your treating physician will inform you about that. All potential immune responses and other side-effects are **closely studied and analysed** during the approval process for all biological medicines, including biosimilars.<sup>7</sup>  
Your nurse and medical staff will closely monitor any immune reactions that might occur during your treatment. As with any other medicine, your role in monitoring your reaction to the medicine is also crucial.
- Switching**  
Switching refers to exchanging a biological medicine with a biosimilar (or vice versa), following your doctor's decision.  
Your doctor should discuss this with you, provide you with all the necessary information and, together with you and the nurse's support, carefully oversee the transition.<sup>8</sup>

**Automatic substitution**  
Automatic substitution occurs when **one medicine is dispensed instead of another at pharmacy level, without consulting the doctor**.<sup>9</sup>  
Until now, this practice is **not recommended** for biological medicines. Currently in the European Union 21 countries forbid automatic substitution at pharmacy level.<sup>10</sup>

### 3 Indications

As long as a biosimilar has been proven to work as well as the biological medicine, it can be **used for all the indications** listed on the label of the originator, even those it has not been tested for itself (extrapolation).<sup>11</sup>


E.g. biosimilars of the originator trastuzumab, a biological medicine used in breast cancer treatment, can also be used for metastatic and early breast cancer, even if biosimilars have not been clinically tested for these indications. This is because the originator trastuzumab has gone through the whole process of clinical development, and the biosimilar has proven to have the same mechanism of action, safety and efficacy profile as the originator.<sup>12</sup>

### Speak to your doctor

Interaction and collaboration between patients, nurses, doctors and other medical staff, are essential elements for the successful use of biosimilars in cancer treatment.

**It is your right to be informed about any treatment you receive.** If you have any questions or concerns about biosimilars or other treatments, you should ask your doctor.

### What are biosimilar medicines?



**Biologics**: Biological medicines are complex medicines made from living organisms such as human and animal cells, yeast or bacteria. Hormones, vaccines, and monoclonal antibodies used in cancer therapies are examples of biological medicines.<sup>1</sup>

**Biosimilars**: Biosimilar medicines are highly similar copies of existing biological medicines (originators) that work in the same way.<sup>2</sup>

**Generics**: Generic medicines are identical copies of simple medicines. Paracetamol and ibuprofen are examples of generic medicines.<sup>2</sup>

**i** You may have heard of generics or biomarkers – these are not biosimilars!

### Frequently used terms you may want to know

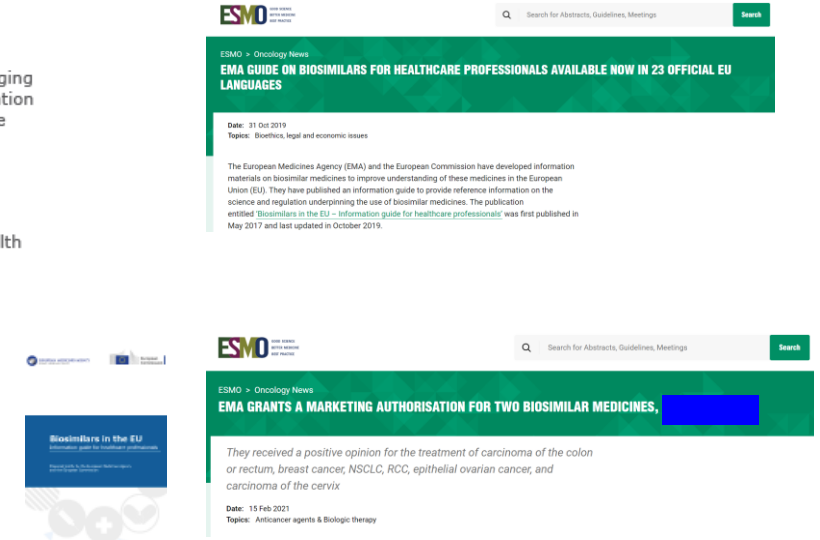
**Efficacy**: Ability of a medicine to produce an effect (e.g. reduce tumor size).<sup>11</sup>

**Extrapolation**: Extending safety and efficacy data for treatment indications from an originator biological medicine to a biosimilar, where the biosimilar has not undergone comparative clinical testing for this indication (see the section *Indications* above).<sup>9</sup>

**Immunogenicity**: Ability of a substance (e.g. protein) to cause an immune reaction (see the section *Immune reactions and other side effects* above).<sup>7</sup>

**Monoclonal antibodies**: Type of proteins made in the laboratory that can bind to substances in your body, including cancer cells. They are being used to treat some types of cancer.<sup>12</sup>

# COOPERATION with EU BODIES



## Promote the availability and support uptake of biosimilars in healthcare systems

Further develop strategic communication campaigns to healthcare providers and patient organisations to reinforce trust and confidence;

Enhance training of non-EU regulators in the evaluation of biosimilars

Address regulatory challenges in manufacturing e.g., statistical assessment of CQAs in the comparability exercise and the evolution of multisource biologicals/biosimilars;

Further develop the biosimilar framework, adapting the clinical part of the development to the latest scientific knowledge concerning the comparability assessment.

**And now confidence is at the extent that...**  
*v. personal position*



**WHY are we still discussing the role of biosimilars and how to build confidence?**  
Biosimilars (as their originator) changed the natural history of many cancers

**SCIENCE**

**Is the phase III trial validation needed?**  
Regulatory experience and technological advances  
(high performing analytical tools)

**SCIENCE**

Phase III trials never added crucial information about

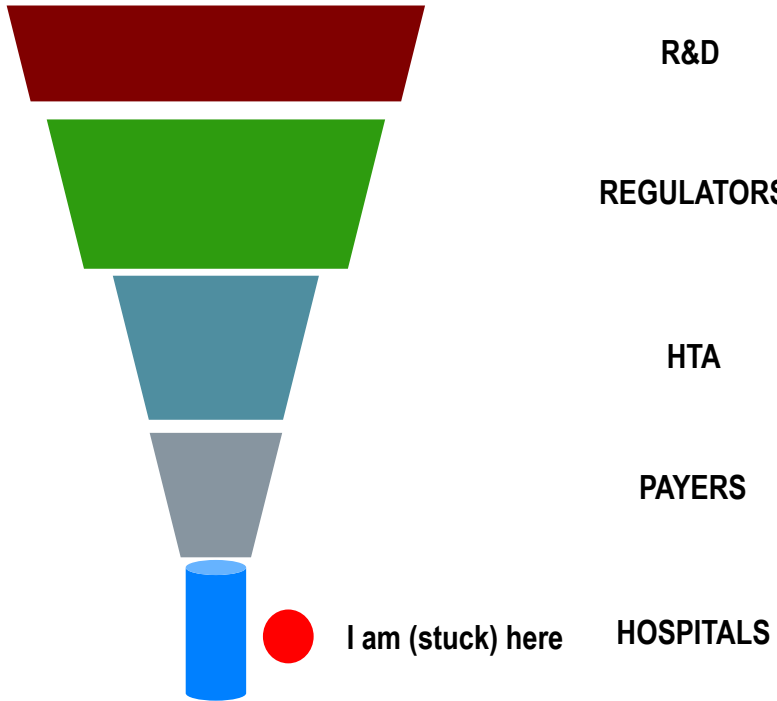
**The most impressive enabler: equal access**

**FAIRNESS**

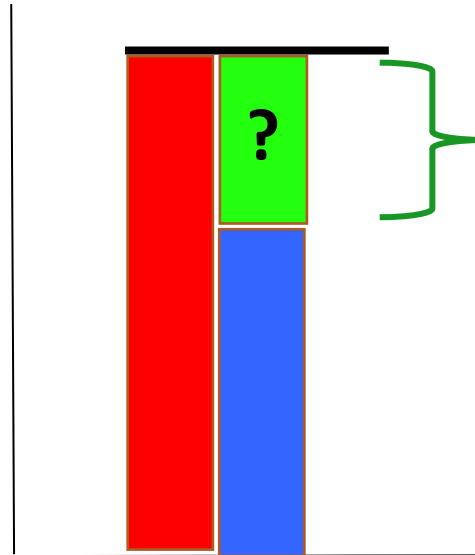
**Transparency in benefit sharing plans may play as enabler**  
Beneficiary: patients and consumers

# TRANSPARENT Re-ALLOCATION of RESOURCES

## The "FUNNEL" effect



Before Biosimilars    After Biosimilars








*Adapted from Steinar Madsen, Biosimilar Medicines Conference 2017*

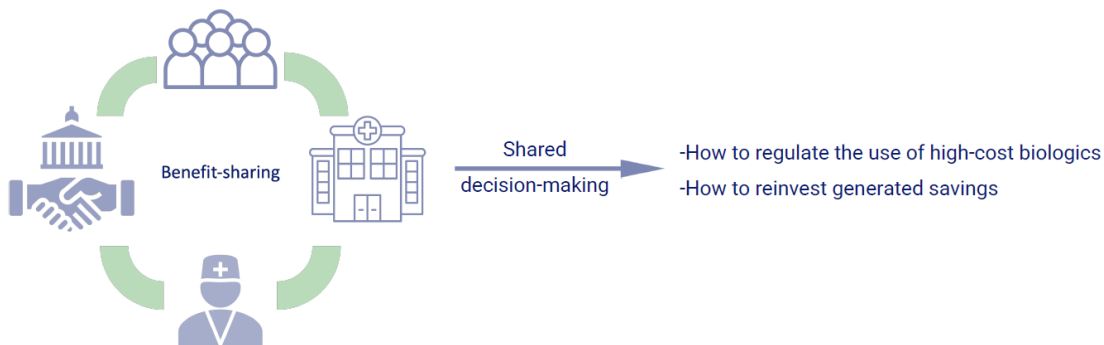
Cancer services?  
Cancer Drugs?  
Healthcare system more in general?  
Workforce?



# Qualitative Analysis of the Design and Implementation of Benefit-Sharing Programs for Biologics Across Europe

Biodrugs, 2022

Teresa Barcina Lacosta<sup>1</sup>  · Arnold G. Vulto<sup>1,2</sup>  · Adina Turcu-Stiolică<sup>3</sup>  · Isabelle Huys<sup>1</sup>  · Steven Simoens<sup>1</sup> 



**TRANSPARENCY** at the beginning and during the whole process

## Potential outcomes to be achieved via the implementation of benefit-sharing strategies:

1. Improved value for money
2. Aligned interests for stakeholders in health care
3. Active engagement of HCPs and patients
4. Transparent redistribution and reinvestment of savings
5. Leveraged resources to: (1) address the needs of health care systems and societies at large and (2) improve patients' outcomes

## Overview of recommendations

### Pre-implementation phase—design

→ To present a strong benefit-sharing proposal/business case including:

A comprehensive estimation of the savings potential over the years. This estimation would depend on the evolution of prices and the number of eligible patients

A detailed analysis of resource needs to be covered by the benefit-sharing agreement

→ To establish a reasonable time frame for the agreement based on savings potential, resource needs and the future market availability of other molecules within the therapeutic area

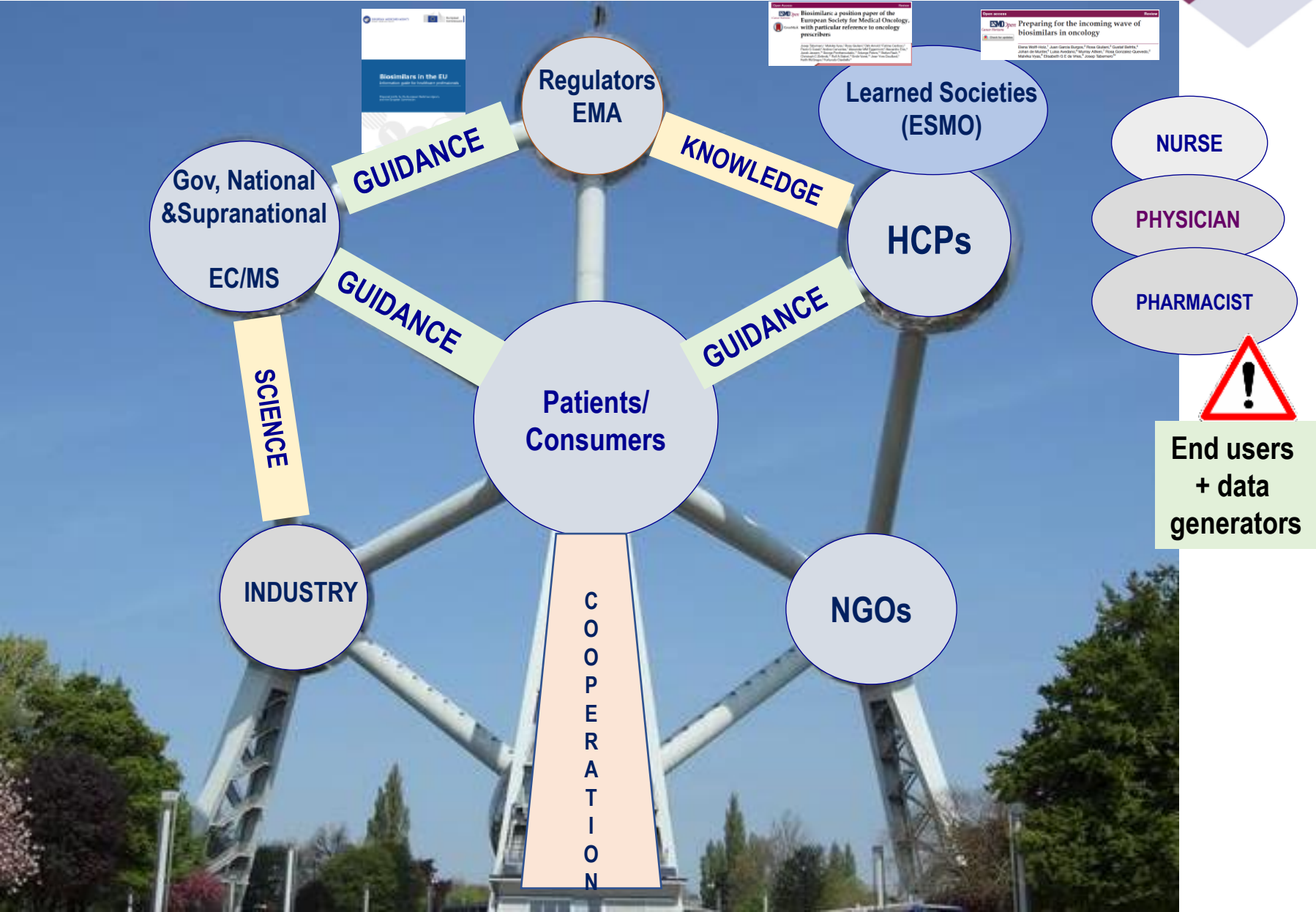
→ To clearly define (in advance) the scope of the benefit-sharing program in terms of uptake and savings objectives, resources reinvestment and expected outcomes

→ To clearly specify (in advance) who would be the direct/indirect beneficiaries of the savings reinvestment process and to establish clear pathways for the redistribution of savings

Experts recommend that a proportion of savings flows back to the clinical departments that participated in the savings generation. These departments should provide a proposal for the reinvestment of savings that is impactful for the clinical service and the patients

→ To establish mechanisms able to identify factors that may affect the continuity of benefit-sharing strategies

# The Biosimilar Atomium: maintaining confidence







# THANK YOU FOR ATTENDING TODAY!

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Thank you for attending this session,  
please do not hesitate to send any questions you may have to

[esmo@esmo.org](mailto:esmo@esmo.org)

and we will be happy to answer them.