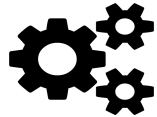


Paul Cornes:

The importance of Gastrointestinal Cancers in Europe – and why biosimilars matter.



**Comparative Outcomes Group,
Bristol, UK**



**ESO Task Force Advisory Board on
Access to Innovative Treatment in Europe**

European School of Oncology



Dr Paul Cornes

Disclosures

- Honoraria received:
 - Accord Healthcare
 - Amgen
 - Astro Pharma
 - Biogen
 - European Commission
 - Generics& Biosimilar Medicines Association Australia
 - Global Academy of Health Sciences
 - Medicines for Europe/European Generics Association
 - Merck Serono
 - Mylan
 - Napp
 - Pfizer/Hospira
 - Sandoz
 - Teva



Why are we here?



Centre Publications Countries Programmes Governance About WHO

Essential medicines and health products

Access to essential medicines as part of the right to health

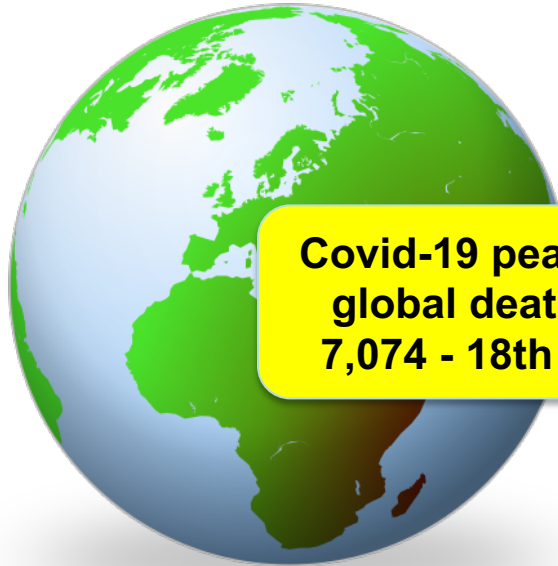
Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in international law. The right to health first emerged as a social right in the World Health Organization (WHO) Constitution (1946)* and in the Universal Declaration of Human Rights (1948)*. The binding International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966* details the progressive realization of the right to health through four concrete steps, including access to health facilities, goods and services.

“The States Parties to this Constitution declare...
The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”

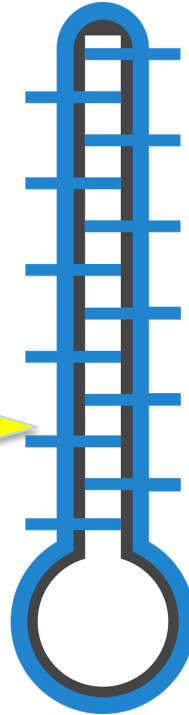
The authoritative General Comment 14 (2000)* further applies the principles of accessibility, availability, appropriateness and assured quality to goods and services

Why Cancer still matters today

- Even in the current crisis – cancer remains the greatest global threat to life

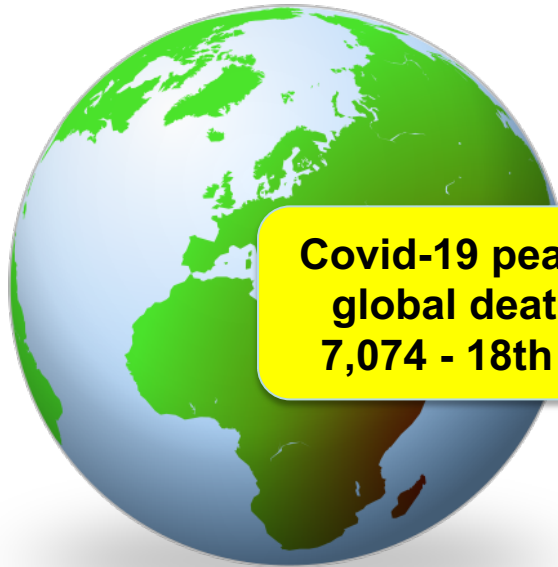


**Covid-19 peak mortality –
global deaths per day:
7,074 - 18th April 2020 ¹**

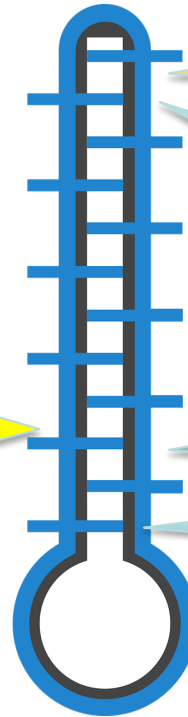


Why Cancer still matters today

- Even in the current crisis – cancer remains the greatest global threat to life



**Covid-19 peak mortality –
global deaths per day:
7,074 - 18th April 2020 ¹**



**Cancer - 26,040 global
deaths per day ²**

**Coronary heart disease -
25,840 deaths per day ²**

**Diabetes - 4,400 deaths
per day ²**

**Mosquito born infections
- 1,205 deaths per day ²**

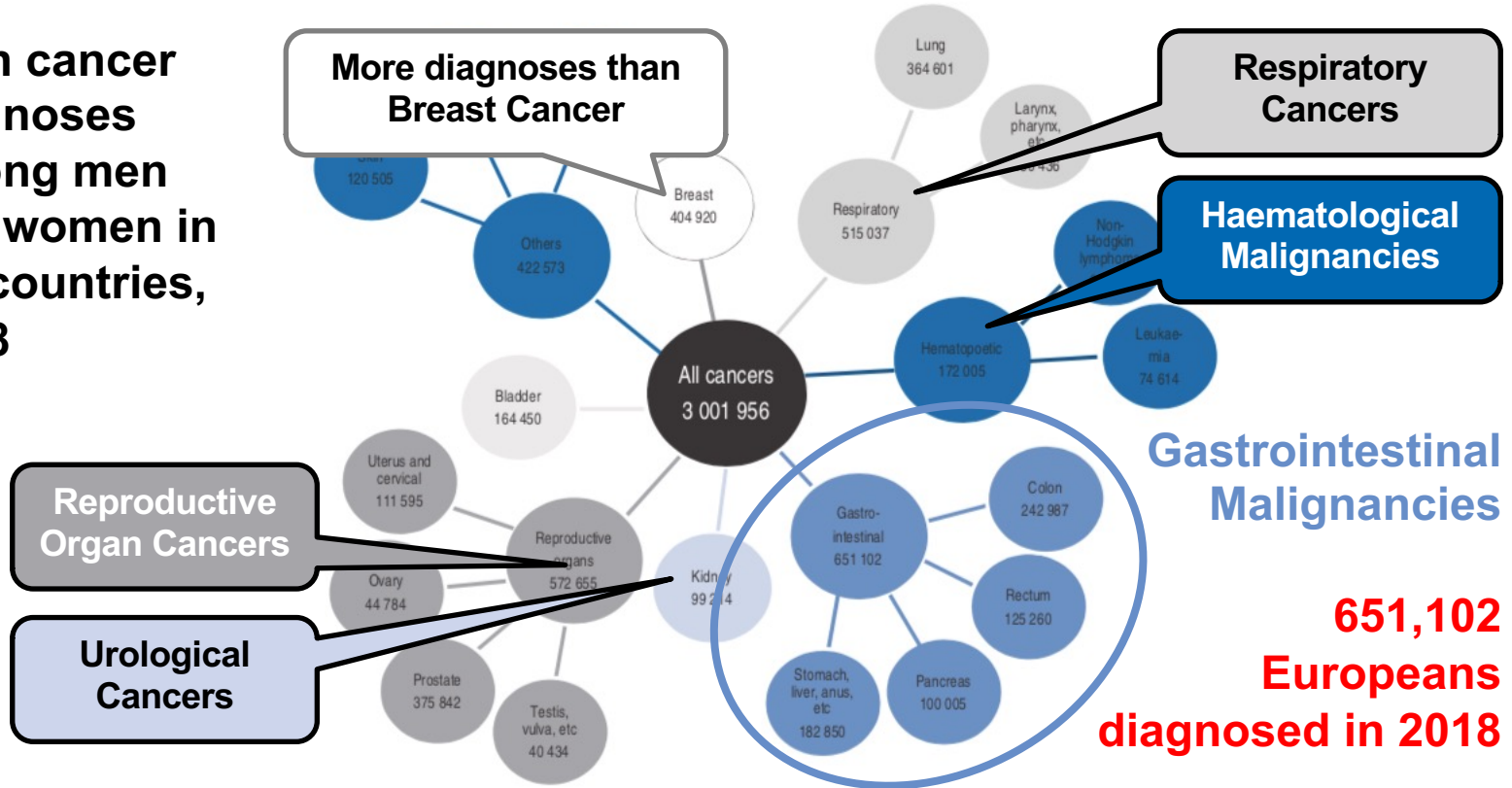
So – why the Economic Focus on GI cancers?





What's the ^{Human} cost of GI cancer in Europe?

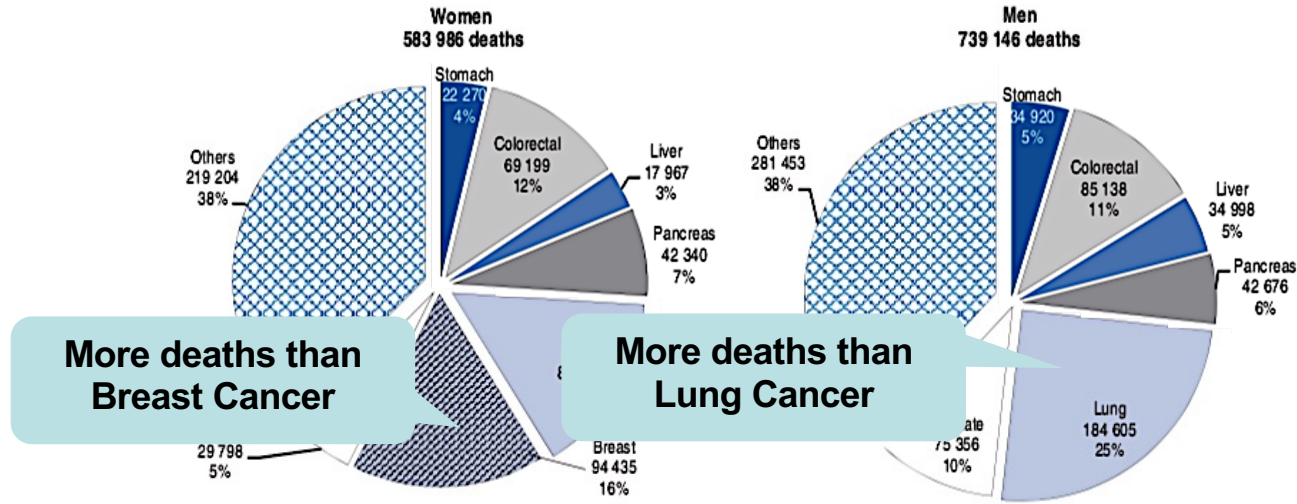
- Main cancer diagnoses among men and women in EU countries, 2018



What's the ^{Human} cost of GI cancer in Europe?



- European cancer mortality, 2015



Gastrointestinal Malignancies

349,508
Europeans died
in 2015

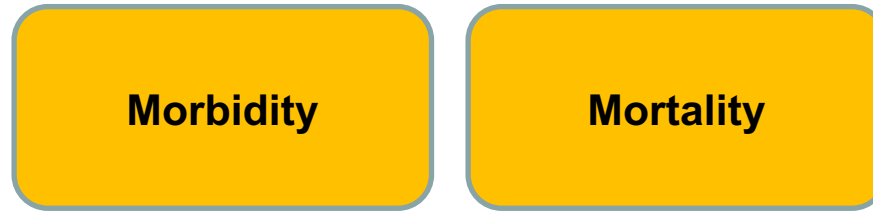
Source: Eurostat Database.

StatLink <http://dx.doi.org/10.1787/888933834509>

What's the ^{Human} cost of GI cancer in Europe?



Gastrointestinal Malignancies



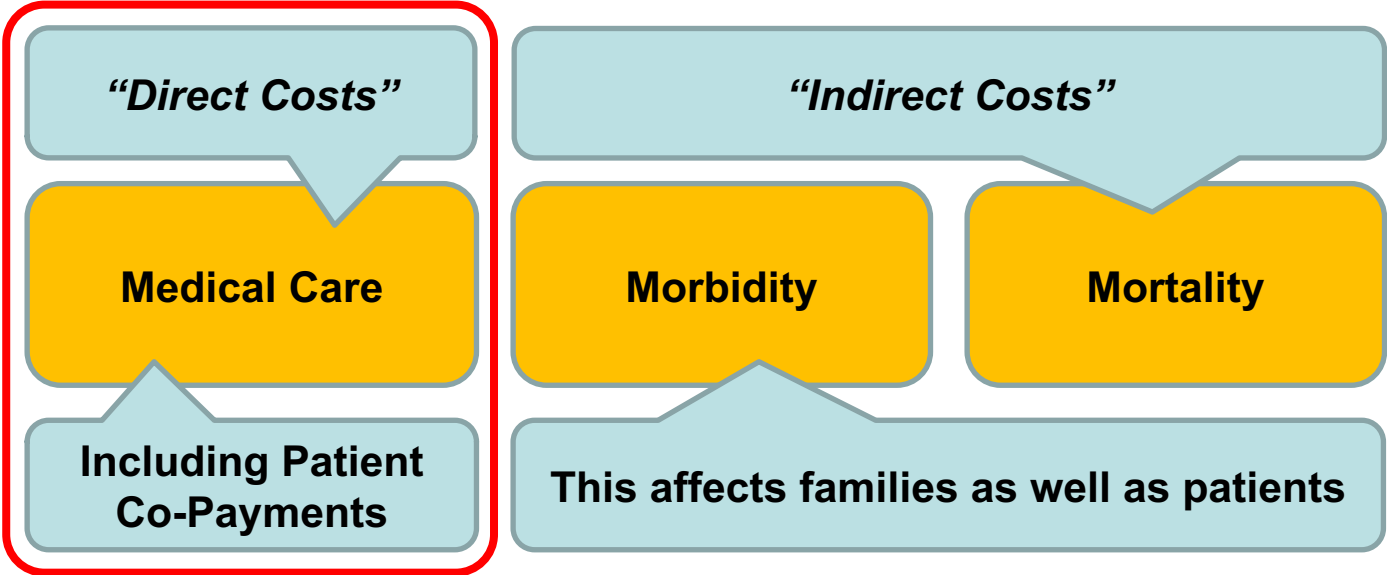
651,102
Europeans
diagnosed in
2018

349,508
Europeans died
in 2015



What's the cost of GI cancer in Europe?

- The Economic perspective**



Gastrointestinal Malignancies

651,102
Europeans
diagnosed in
2018

349,508
Europeans died
in 2015



What's the **Direct Cost** of GI cancer in Europe?

- The Economic perspective – NHS England Data ²

Gastrointestinal Malignancies

Direct Costs

Colorectal Cancer costs more over a decade than Breast, Prostate or Lung Cancer

	Colorectal (2010 £)		Breast (2010 £)		Prostate (2010 £)		Lung (2010 £)	
	18-64	≥65	18-64	≥65	18-64	≥65	18-64	≥65
1 Year prior	201	435	165	439	162	375	344	544
1 Year prior	471	471	183	398	224	517	310	542
1 Year prior	1023	1760	484	1126	715	1430	1337	1979
1 Year prior	17 241	14 776	11 109	7788	5171	4699	12 083	9061
1 Year prior	5014	4231	3676	2675	1965	2705	4540	4320
1 Year prior	3687	3403	2176	2270	1927	2598	4002	3945
1 Year prior	2927	2821	1782	2283	1484	2529	2671	3365
1 Year prior	2388	2769	1708	2186	1559	2593	2551	3043
1 Year prior	1823	2741	1646	2222	1584	2536	—	—
1 Year prior	1960	2341	1459	2121	1414	3770	—	—
1 Year prior	1688	2630	1432	2144	1501	2782	—	—
1 Year prior	1370	2236	1316	2277	1451	2596	—	—
Total (9 Years)	38 098	37 948	26 304	25 966	18 056	26 808	25 847	23 734

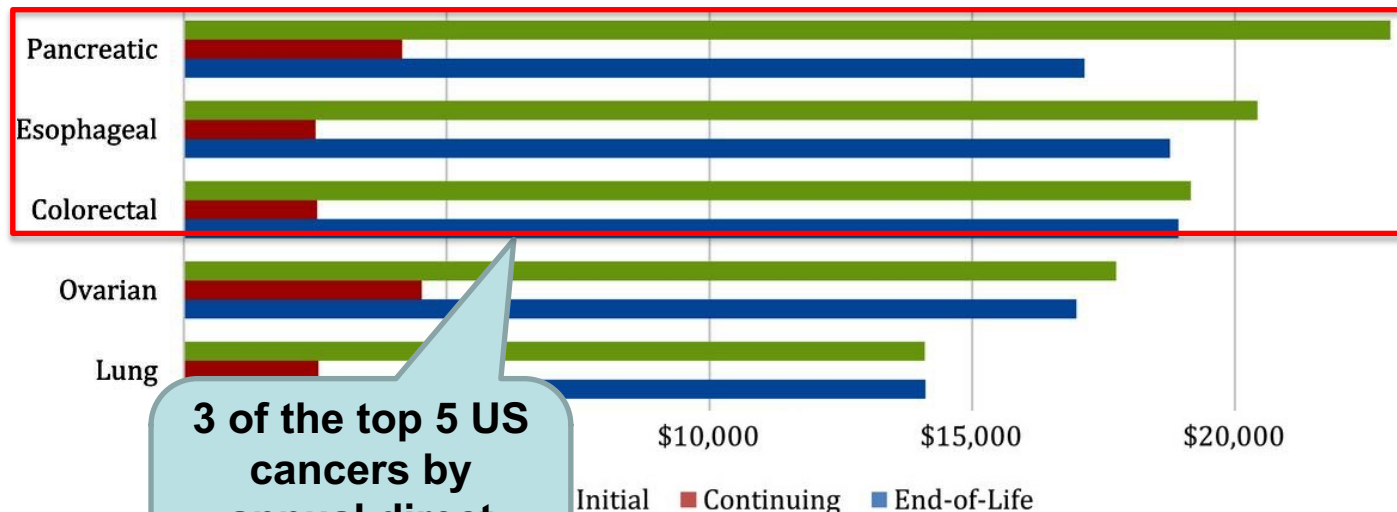
651,102
Europeans
diagnosed in
2018

349,508
Europeans died
in 2015

What's the **Direct Cost** of GI cancer in the USA?



▪ The Economic perspective – USA Data ²



3 of the top 5 US cancers by annual direct costs are Gastrointestinal ¹

Gastrointestinal Malignancies

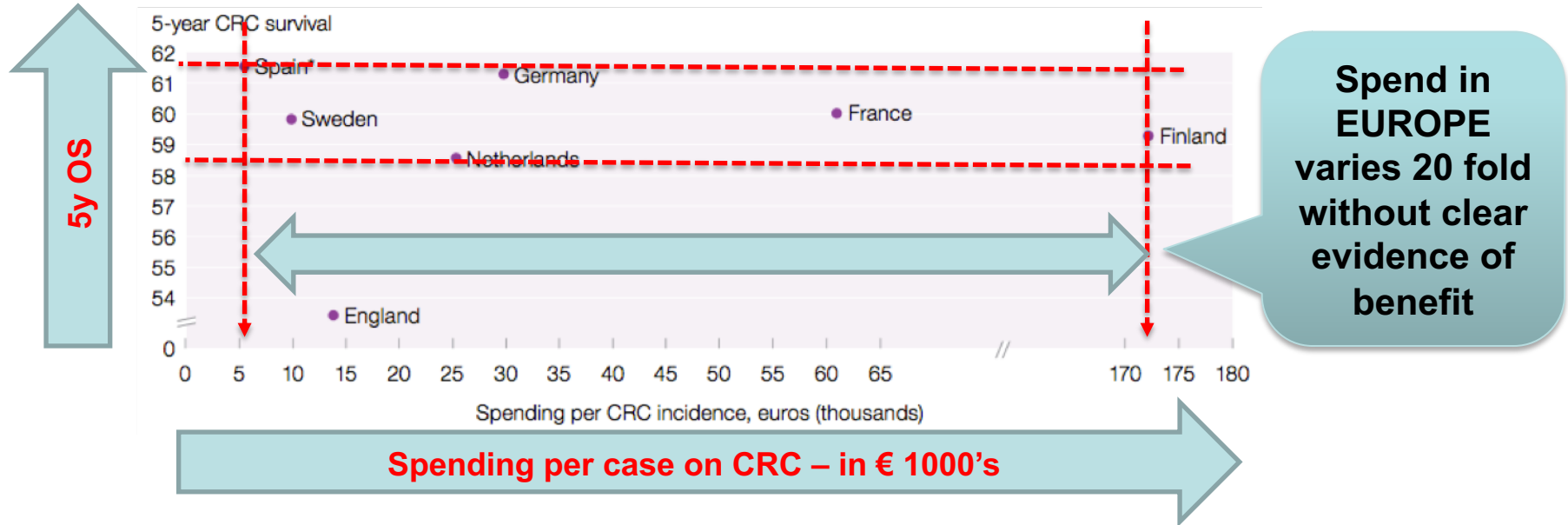
286,480 Americans diagnosed in 2018

147,090 Americans died in 2015

European Data shows very different performance between Health Systems



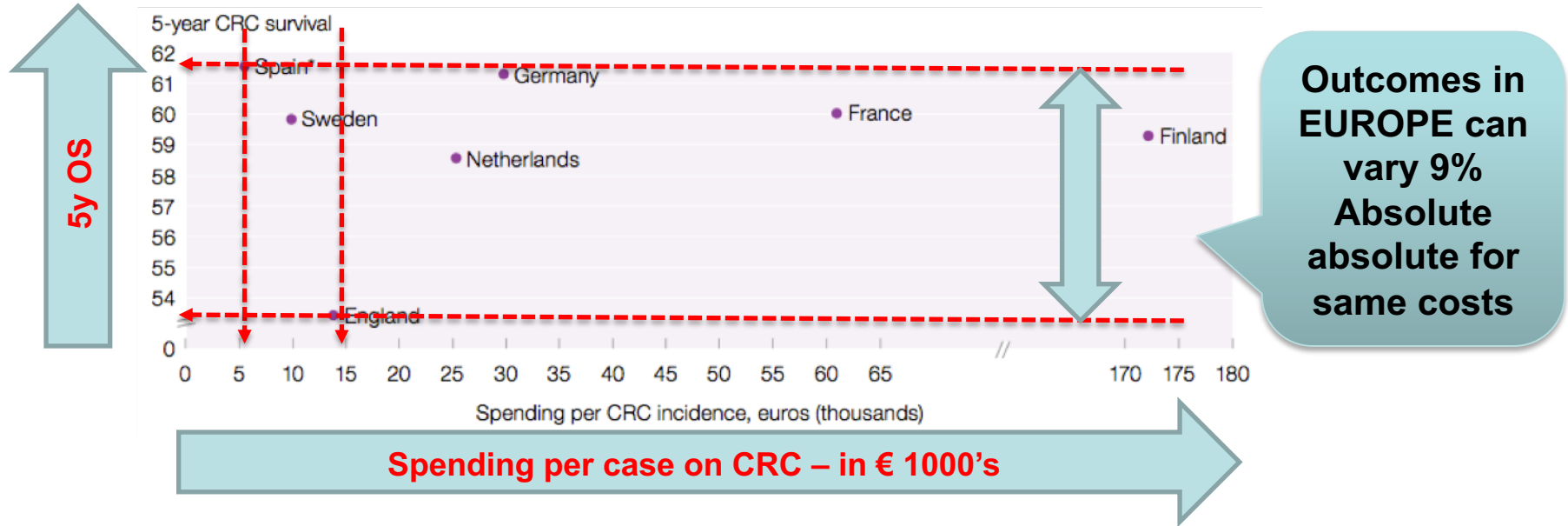
- Colorectal cancer (CRC) mortality rates vs spend in 7 European countries ¹



European Data shows very different performance between Health Systems



- Colorectal cancer (CRC) mortality rates vs spend in 7 European countries ¹



European Cancer Plan – Launched 3rd February 2021



Available languages: English



Press release | 3 February 2021 | Brussels

Europe's Beating Cancer Plan: A new EU approach to prevention, treatment and care

**Policy to
improve
outcomes is
simple**

1
**Prevention
through
lifestyle
changes &
medicines**

2
**Early
Diagnosis and
Screening**

3
**Improved
Cancer
Treatment**

The importance of cancer medicine:



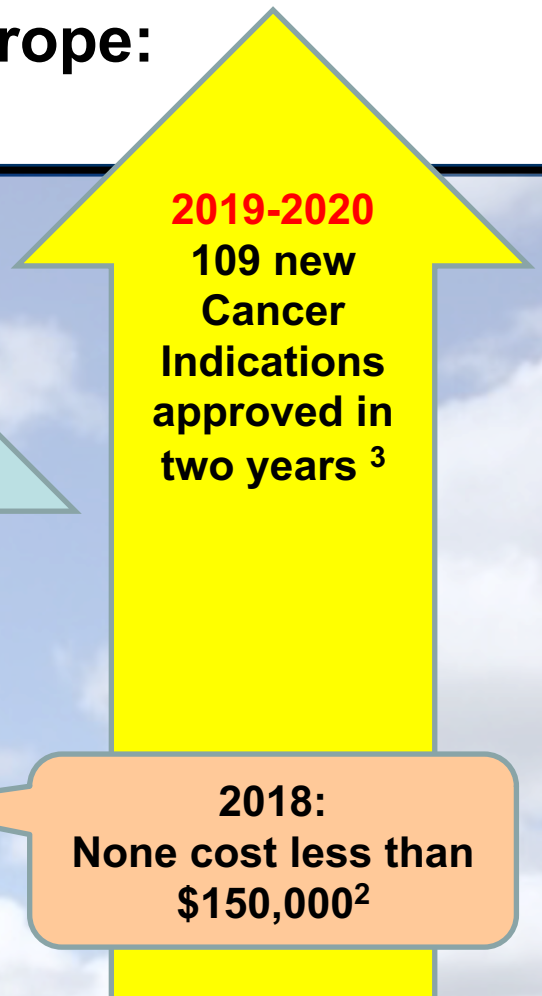
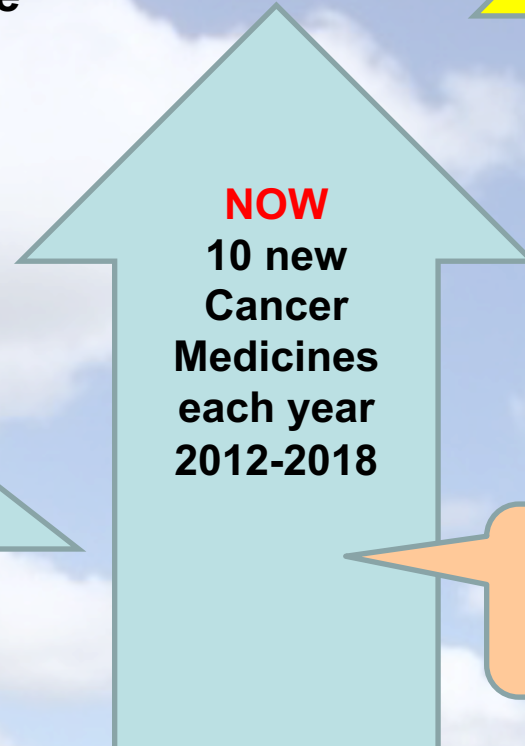
**Estimated –
new medicines have
accounted for 50-60 percent
of the increase in cancer
survival rates since 1975 ¹**

3

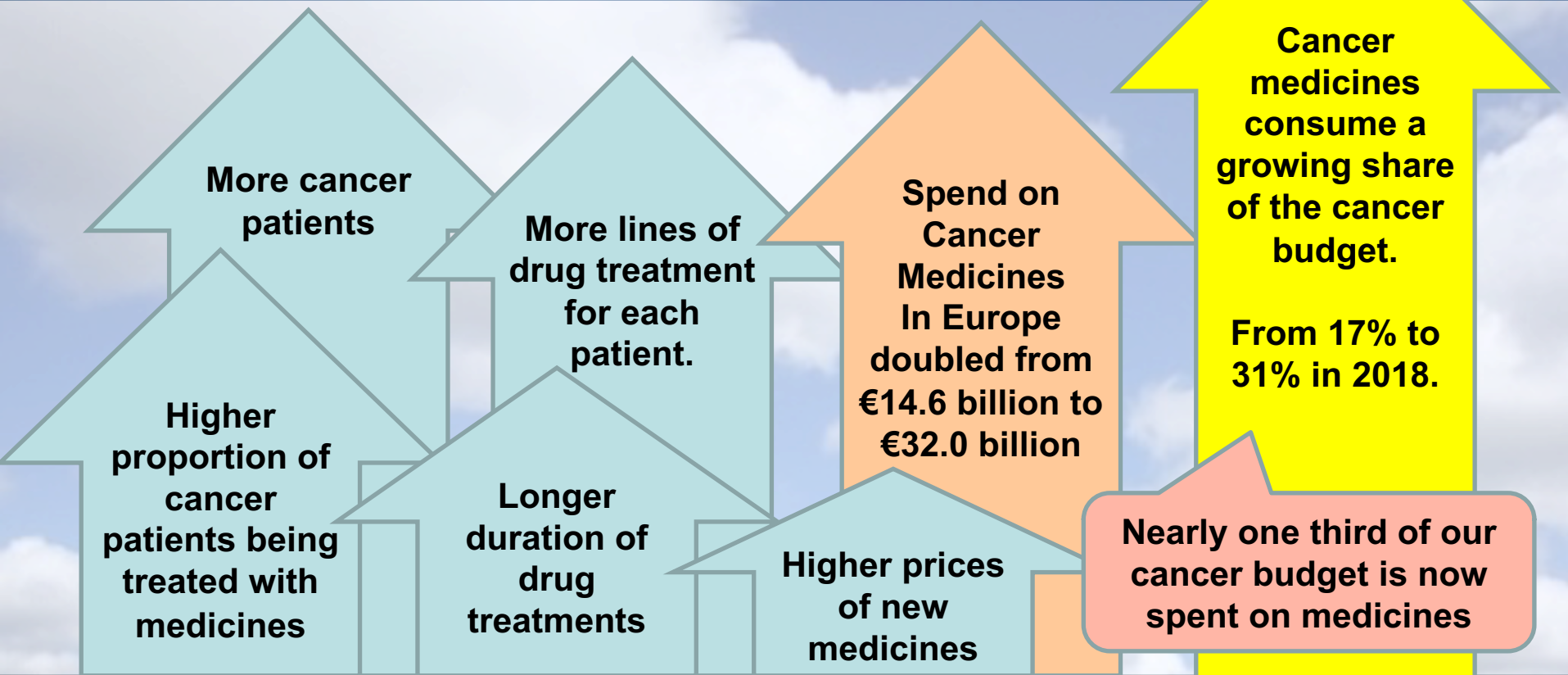
**Improved
Cancer
Treatment**

The cost of Innovation for Cancer in Europe: Trends 2008 to 2018

- Innovation in cancer medicine has accelerated
- New approvals by European Regulator ¹
 - 2002 - 2011
 - 2012 - 2018



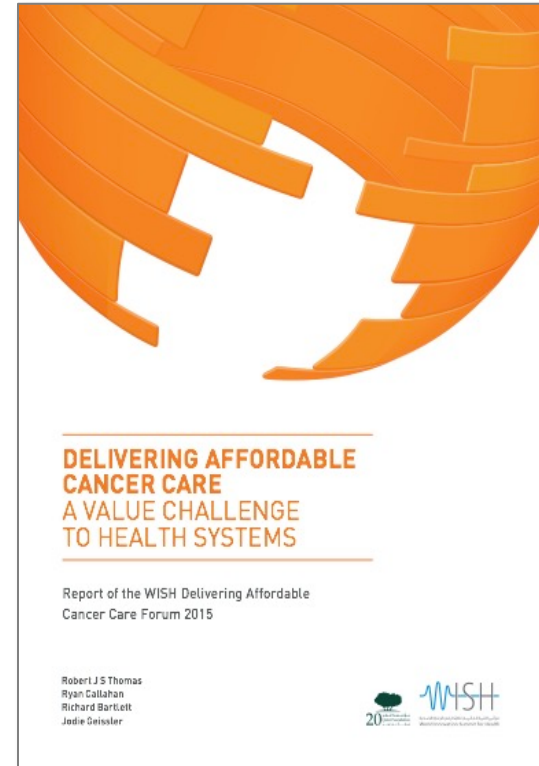
Cost pressures on cancer in Europe: Trends 2008 to 2018 ¹



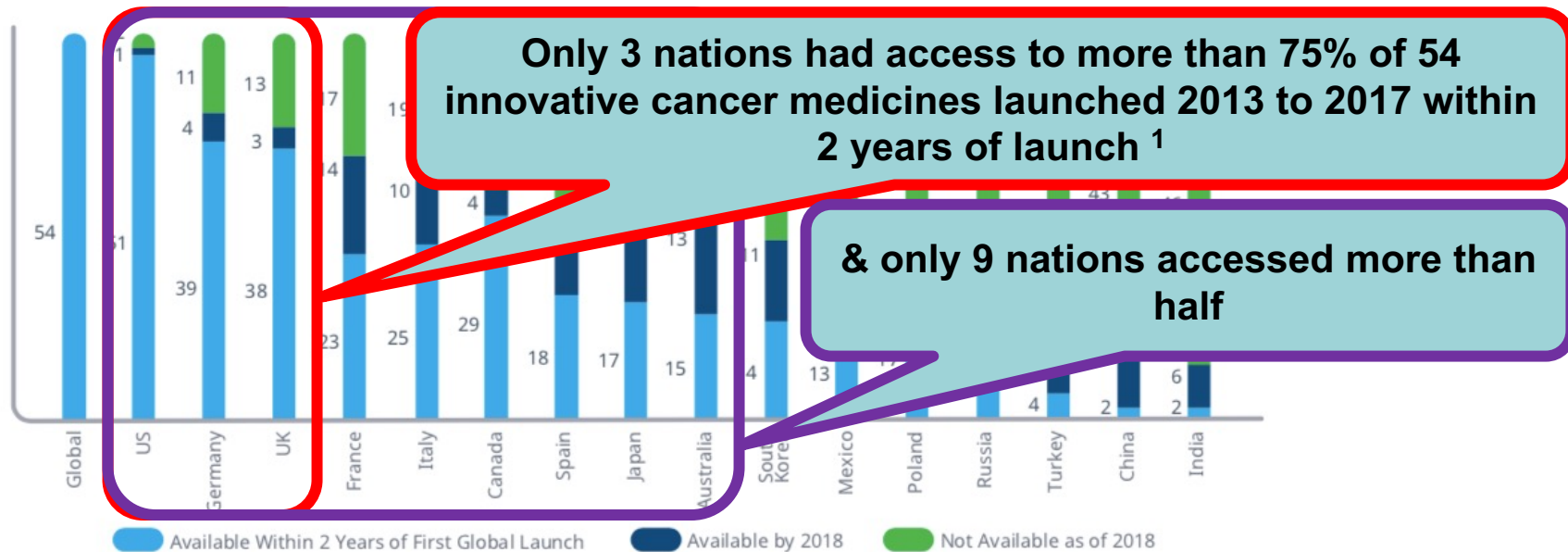
The reality of cancer care now

- ***“We must confront a stark reality: cancer care is not affordable for most patients, many payers, and nearly all governments. This is a real and immediate issue across the world”***

WISH foundation report



Access to innovative cancer medicines is a global problem:



Only patients in the United States, Germany and United Kingdom have access to more than 40 of the 54 oncology medicines initially launched between 2013 and 2017, due to manufacturers not filing for regulatory approval, delays or denials of approval, or manufacturers awaiting the results of reimbursement negotiations prior to launching the drug in the country

The EU reports on strategies for sustainable care



- Key recommendations include

The image shows a screenshot of a report page with several text boxes highlighting key recommendations. The background text is from a report titled "Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability".

Access to affordable medicines

Many EU Member States face a challenge to improve access to medicines. Public procurement and the role of generics and biosimilars, appropriate pricing and price-caps, and incentives for the use of medicines proposed by governments should see low price biosimilars while not compromising

Policies should strengthen the cost-effective use and the affordability of medicines, by promoting public procurement and the role of generics and biosimilars, appropriate pricing and price-caps, and incentives for the use of medicines proposed by governments should see low price biosimilars while not compromising

Encouraging the use of generics and biosimilar medicines. With the availability of generics and biosimilars, the original patented drug has competition. This can lead to significant savings, while not compromising on quality.

Report on Health Care and Long-Term Care Systems and Fiscal Sustainability

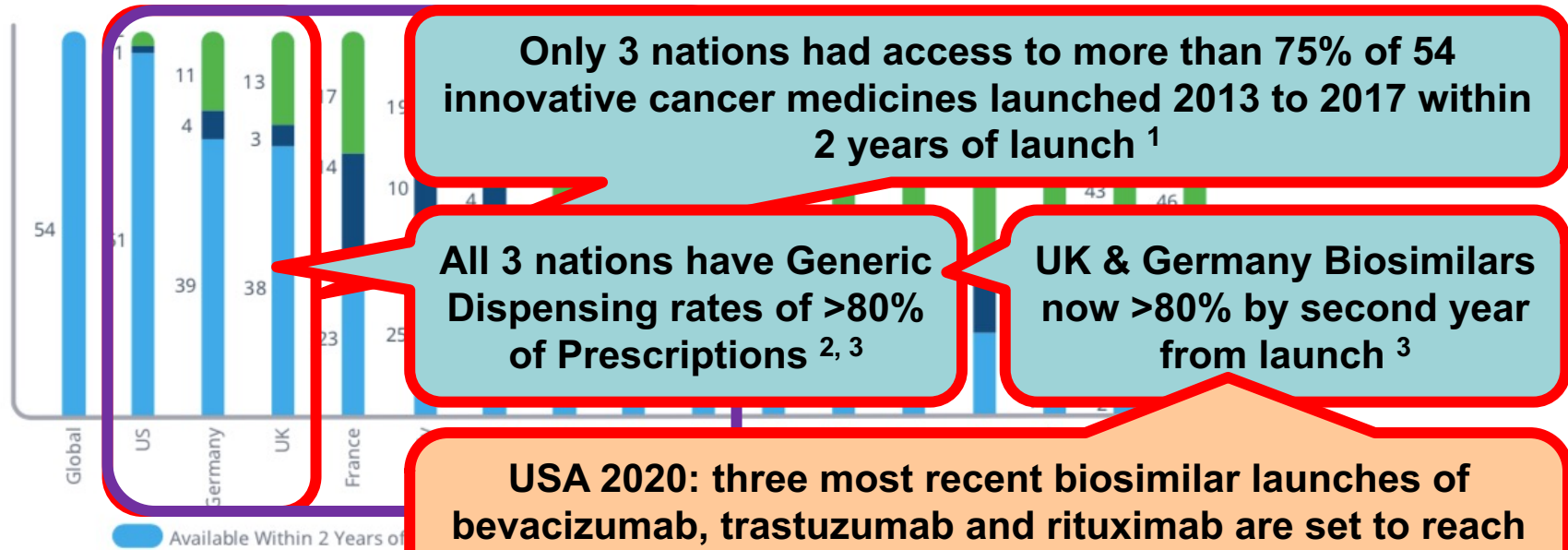
ISSN 2443-8034 (online)

Page 1

European Commission

Economic Policy Committee

Access to innovative cancer medicines is a global problem:



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54 oncology medicines initially la
regulatory approval, delays or deni
reimbursement negotiations prior to launching the drug in the country

Sustainable Innovation – funded through biosimilars

- **£320M Annual savings from UK Biosimilar and Generic programme for just ten medicines - €353M**
- **Annual Cost of the UK Cancer Drugs Fund to ensure access to innovative medicines £340M €375M**





Biologic drugs indicated in GI Cancers ¹

▪ Targeted Therapies

- Bevacizumab
- Ramucirumab
- Ziv-aflibercept
- Cetuximab
- Panitumumab
- Trastuzumab

▪ Immunotherapies

- Ipilimumab
- Nivolumab
- Pembrolizumab



Biologic drugs indicated in GI Cancers ¹

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▪ Immunotherapies

- Ipilimumab
- Nivolumab
- Pembrolizumab

European Patents expired before January 2021

Bevacizumab – 3 biosimilars already approved and 5 under review by European Regulators



Biologic drugs indicated in GI Cancers ¹

▪ Targeted Therapies

- **Bevacizumab**
- **Ramucirumab**
- **Ziv-aflibercept**
- **Cetuximab**
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- **Trastuzumab**



▪ Immunotherapies

- **Ipilimumab**
- **Nivolumab**
- **Pembrolizumab**

**European Patents expired or
expiring 2024**



Biologic drugs indicated in GI Cancers ¹

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- **Nivolumab**
- **Pembrolizumab**

**European Patents expired or
expiring 2026**

Biosimilar Bevacizumab – How similar is “similar enough” ?

- **What practical targets will a Hospital Pharmacist set for biosimilars?**

Biosimilar Bevacizumab – How similar is “similar enough” ?

- What practical targets will a Hospital Pharmacist set for biosimilars?

1. QSE

**Biosimilars must be
“similar enough” in
Quality, Safety and
Efficacy (QSE) to show
no clinically
meaningful differences
from the Original
Reference Product**

Biosimilar Bevacizumab – How similar is “similar enough” ?

- What practical targets will a Hospital Pharmacist set for biosimilars?

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Biosimilars must be “similar enough” in Quality, Safety and Efficacy (QSE) to show no clinically meaningful differences from the Original Reference Product

2. Switching

They must have no significant difference in immunogenicity – enabling brand switching with each new drug tender cycle

Biosimilar Bevacizumab – How similar is “similar enough” ?

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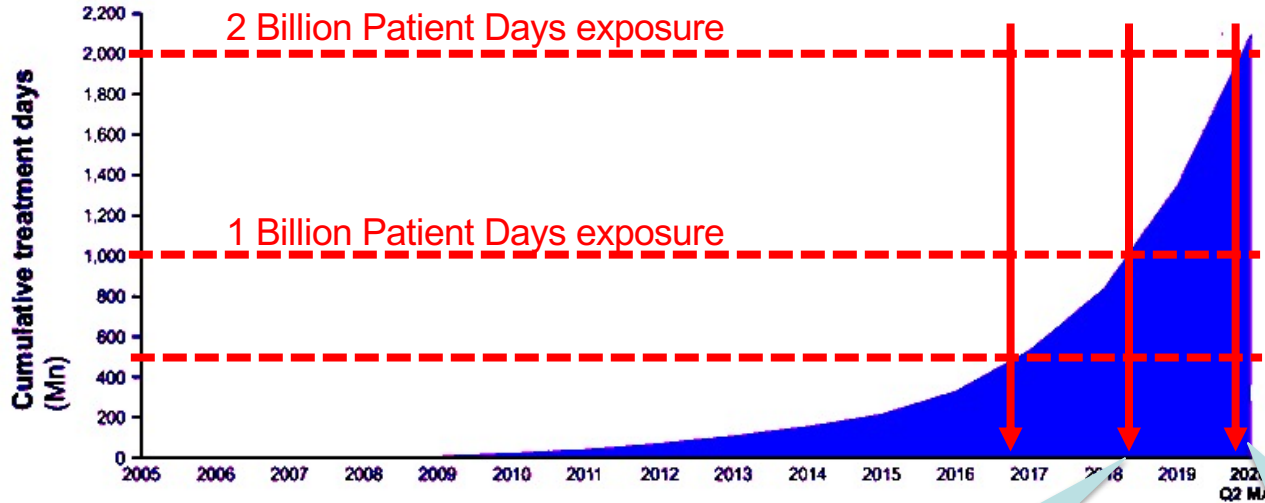
2. Switching

They must have no significant difference in immunogenicity – enabling brand switching with each new drug tender cycle

3. Extrapolation

They must match the potency of the Reference drug in all modes of action – enabling pharmacies to potentially stock only one brand for all approved indications

Real world experience with European Approved Biosimilars




**1 Billion Patient Days
Exposure reached 2018**

**2 Billion Patient Days
Exposure reached 2020**

What do we expect from European Approved Biosimilars?

- More than 14 years use in Europe ¹
- More than 70 Biosimilars approved & marketed
- More than 2 Billion documented Patient Days ²
Exposure
- Safety of switching to biosimilars has been validated in more than 170 clinical studies ³
- For many European Nations, biosimilar use now far outnumbers originator brand prescriptions each year ²
- European approved biosimilars have all maintained approval without showing a different risk or benefit profile to the reference drug ^{2,4}



Clinically
Similar



Economically
Different

What do we need for the optimal use of Biosimilars?

www.centerforbiosimilars.com › view › expert-opinion...

Expert Opinion Roundup: Overcoming Barriers to Biosimilar ...

7 Sept 2020 — Biosimilars
Emory has some of the
said that Emory educ

www.jmcp.org › doi › pdf › jmcp.2019.18412

Strategies for Overcoming Barriers to Adopting Biosimilars ...

by L Greene · 2019 · Cited by 12 · Related articles

8 Aug 2019 — overcoming
prescriber education
biosimilar product tha

www.frontiersin.org › articles ›

Overcoming Barriers to the Market Access of ... - Frontiers

by E Moorkens · 2016 · Cited by 59 · Related articles

29 Jun 2016 — We expect
that sponsor their me
developing the biosim

www.fda.gov › media › download › PDF

Biosimilar Adoption & Barriers to Success: Current and ... - FDA

Discuss challenges with biosimilar adoption within health systems. Describe ways ... Exhibit 22:

30-Day New-to-Brand Al
ti) ... around lack of bro
provider champion for bi

www.mdpi.com › pdf › PDF

Clinical and Regulatory Concerns of Biosimilars: A ... - MDPI

by V Halimi · 2020 · Cited by 1 · Related articles

11 Aug 2020 — reg
Medicines Agency
use worldwide [2].

pubmed.ncbi.nlm.nih.gov › ...

Strategies for Overcoming Barriers to Adopting Biosimilars ...

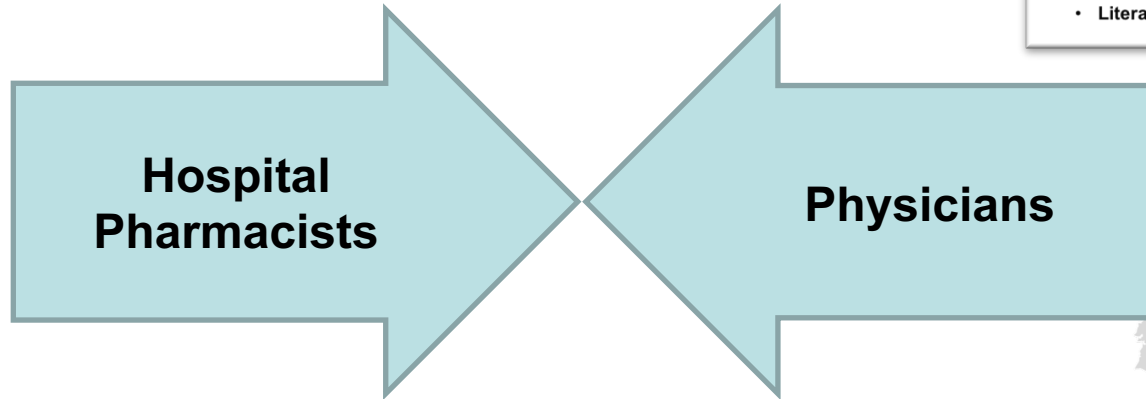
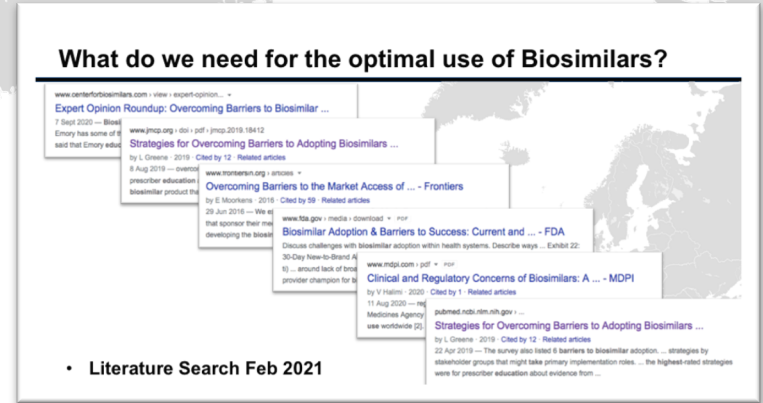
by L Greene · 2019 · Cited by 12 · Related articles

22 Apr 2019 — The survey also listed 6 barriers to biosimilar adoption. ... strategies by stakeholder groups that might take primary implementation roles. ... the highest-rated strategies were for prescriber education about evidence from ...

- Literature Search Feb 2021

What do we need for the optimal use of Biosimilars?

- In a recent survey of 300 specialty pharmacy professionals ¹
- The highest-rated strategies to overcome barriers to biosimilar adoption were for **prescriber education**

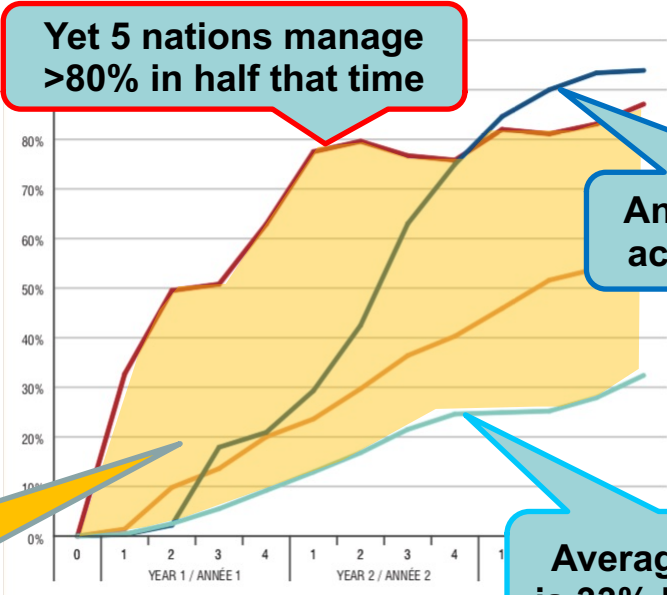


Biosimilar Infliximab – lessons learned from uptake in 37 developed countries

Scenario	OECD median biosimilar uptake	
Acute High uptake	95%	Five OECD countries with the highest uptake averaged across all acute treatment drugs.
Chronic High uptake		Three OECD countries with the highest uptake for an infliximab biosimilar.
Acute Average uptake	50%	All available OECD markets averaged across all acute treatment drugs.
Chronic Average uptake	30%	All available OECD markets with an infliximab biosimilar.

Yet 5 nations manage >80% in half that time

And another 3 nations achieve this by year 3

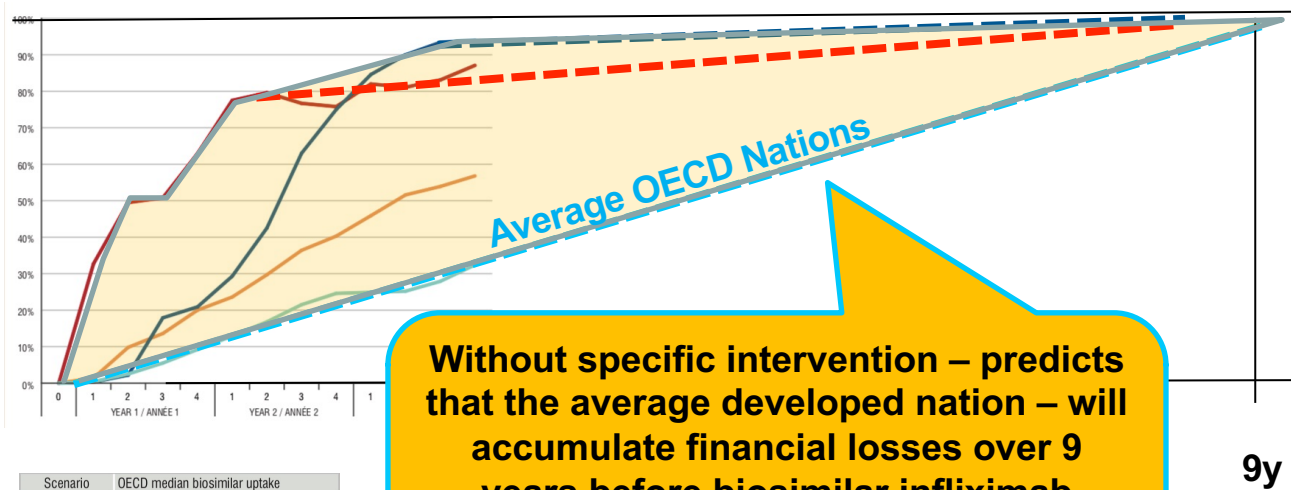


This represents financial losses to healthcare that can never be recovered

Average uptake is 33% by 3 years

OECD: The Organisation for Economic Co-operation and Development is an intergovernmental economic organisation with 37 member countries

Biosimilar Infliximab – lessons learned from uptake in 37 developed countries



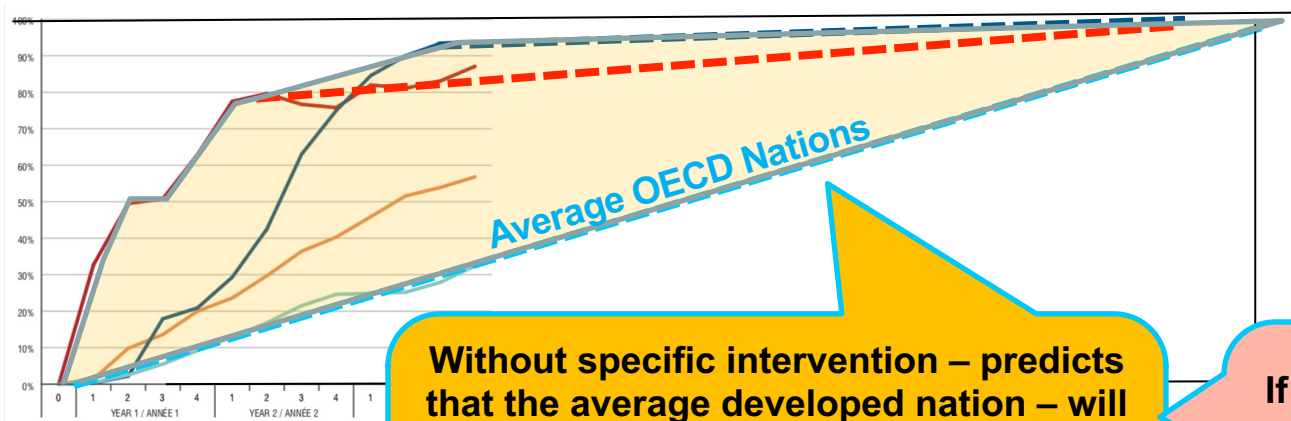
Without specific intervention – predicts that the average developed nation – will accumulate financial losses over 9 years before biosimilar infliximab uptake matches what can be achieved by other OECD health systems

9y

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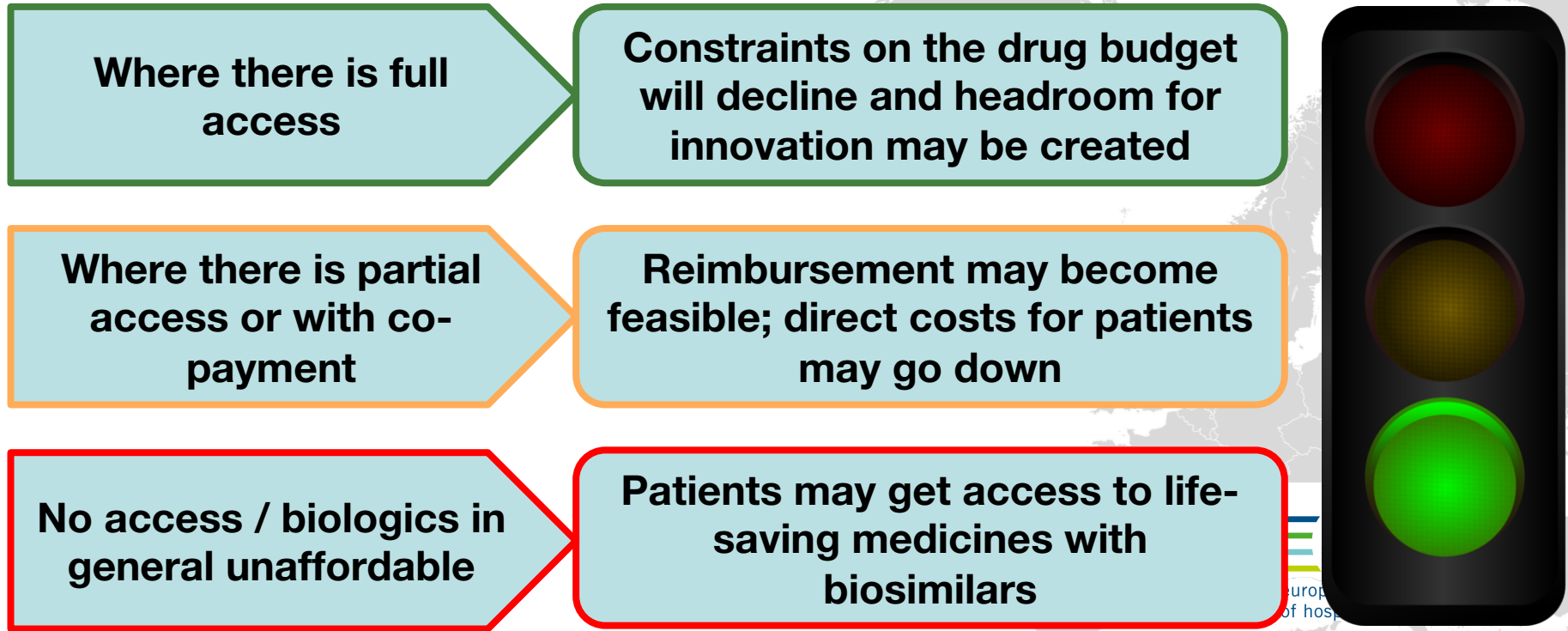
Without specific intervention – predicts that the average developed nation – will accumulate financial losses over 9 years before biosimilar infliximab uptake matches what can be achieved by other OECD health systems

If this represents the **average developed nation – then some will lose even more**

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Why every Healthcare system can benefit from biosimilars



Conclusions

Paul Cornes:

**The importance of Gastrointestinal Cancers in Europe –
and why biosimilars matter.**

**Cancer Care is
becoming
UNAFFORDABLE**

–
the treatment advances
we hear of at EAHP
2021 may be
implemented in just a
few wealthy nations

**GI Cancers Matter
the Human Cost and
Financial Cost is
significant**

--
Europe shows 20x
variation in costs for
no benefit & 9% OS
difference without cost

Patents expiring soon
-
mean that **Biosimilar
Brands of GI cancer
drugs** are set to deliver
significant savings that
we can reinvest into
improving cancer care