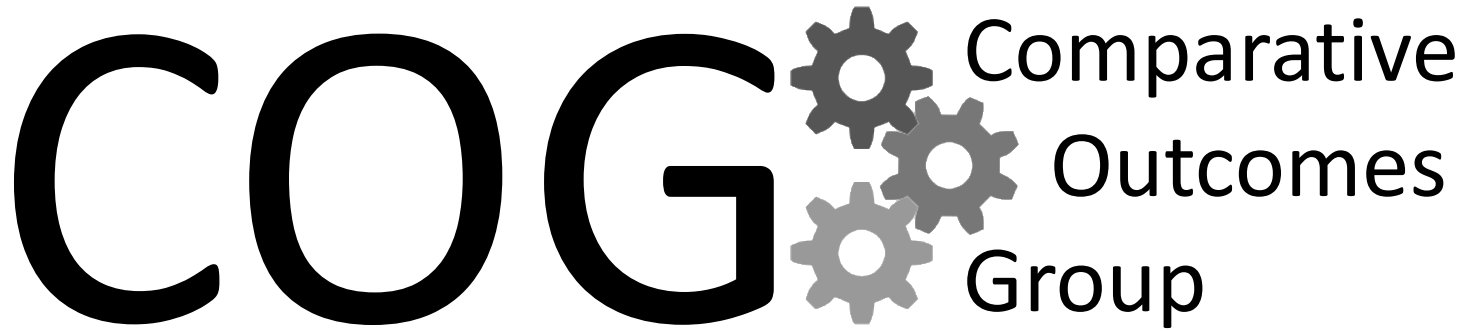
NATIONAL BIOSIMILARS FORUM
Dublin Thursday 25th October



NATIONAL BIOSIMILARS FORUM
Dublin Thursday 25th October

Comparative Outcomes Group

NATIONAL BIOSIMILARS FORUM

25th October, 2018

Proudly sponsored by:

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Overview:

This Biosimilars Forum will be a very balanced and holistic update on Biosimilars in Ireland with originators, biosimilar companies, the payer and clinicians all represented.

Format:

Each speaker will give a presentation, after which they will form a Q&A panel, with an opportunity for questions from the floor.

Agenda

	9.30	Registration
	10am	Welcome
	10.05am	**Bernard Duggan,** Senior Pharmacist – Medicines Management Programme *"Overview of Roadmap for Biosimilars Policy"*
	10.25am	**Dr Roisin Adams,** Chief Pharmacist – HSE *"Value in Drug Expenditure"*
	10.50am	**Dr Ginny Acha,** Executive Director Global Policy –MSD *Presentation title TBC*
	11.15am	**Dr Paul Cornes** – Consultant Oncologist *"Sustaining Affordable Cancer Care AND Healthcare Innovation"*
	11.40am	**Paul Harmon,** Senior Director, Europe… ology Biologics Lead – Mylan *"Sustainability of the Biosimilar Sector"*
	12.05am	**Dr Anthony O' Connor,** Consultant Gastroentologist - Tallaght University Hospital *"The view from the Clinic"*
	12.25pm	Q&A Session
	12.40pm	Lunch

- **"Sustaining Affordable Cancer Care & Healthcare Innovation"**
- **Dr Paul CORNES**
  - **Oncologist, Bristol UK**

Medical Representative – European Commission Biosimilars Stakeholders Meetings 2014-2018

Biosimilars Session Organizer - UICC/WHO World Cancer Congress 2018

Ref: [1]

Dr Paul Cornes

Disclosures October 2018

- **Salary received:**
  - **United Kingdom National Health Service**
- **Honoraria received:**
  - **Accord Healthcare**
  - **Amgen**
  - **Astro**
  - **Bernstein**
  - **Biogen**
  - **British Medical Journal**
  - **Drug Investigators Association**
  - **European Association for Hospital Pharmacists**
  - **European Commission**
  - **Global Academy of Health Sciences**
  - **IBC Life Sciences Asia/Informa**
  - **International Society of Oncology Pharmacy Practitioners**
  - **Janssen**
  - **Lilly**
  - **Medicines for Europe/European Generics Association**
  - **Merck Serono**
  - **Mylan**
  - **Napp**
  - **National Cancer Society Malaysia**
  - **Pfizer/Hospira**
  - **Pharmaceutical Association of Malaysia**
  - **Roche**
  - **Sandoz**
  - **Synsana EEIG**
  - **Teva**
  - **Vital_Transformation**

These slides and their content are the responsibility of Dr Paul Cornes.

Please let me know if there are errors or omissions…

…or you have a better way of explaining it

Why are we here?

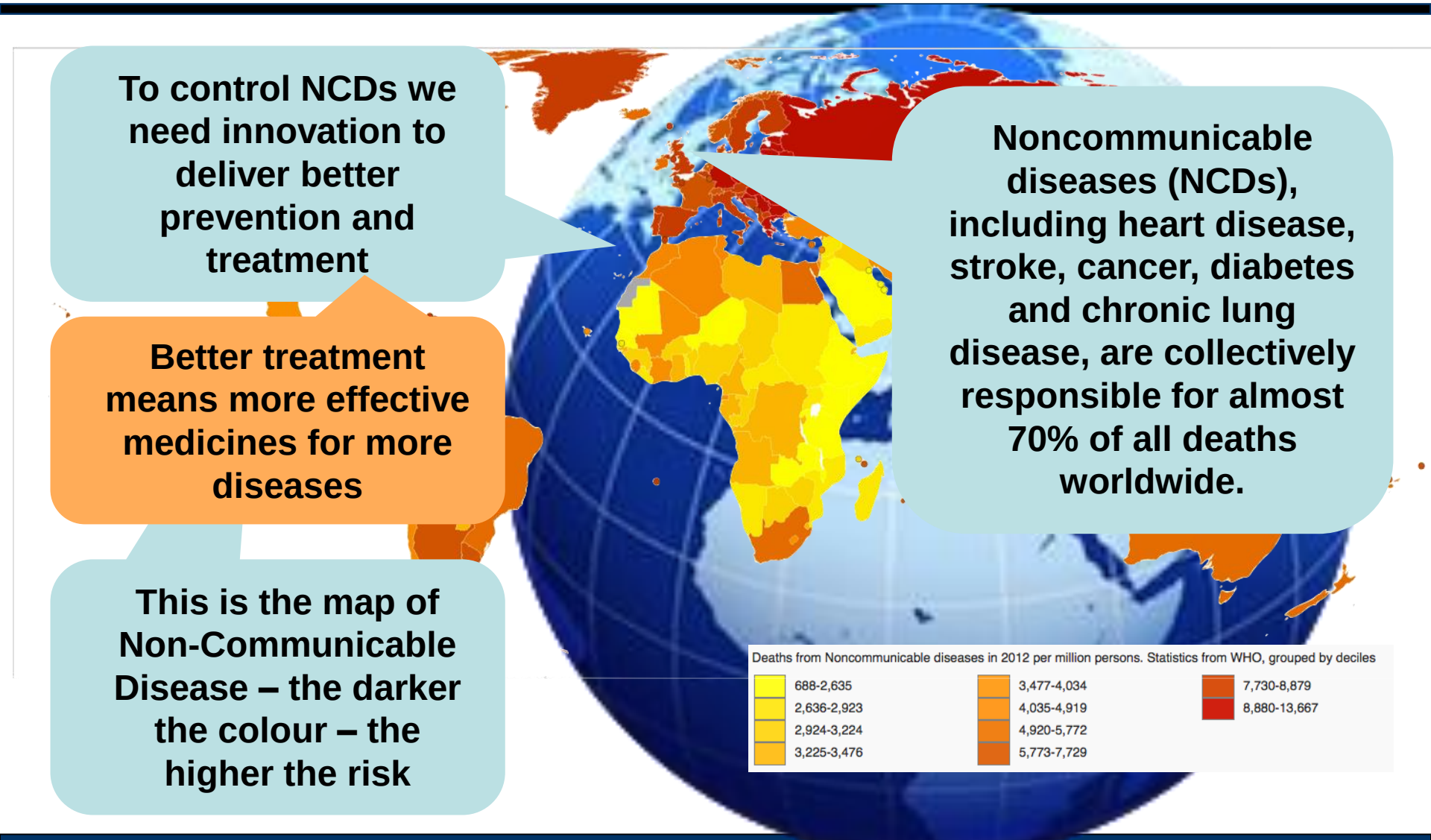
We live in a changing era of Disease

To control NCDs we need innovation to deliver better prevention and treatment

Better treatment means more effective medicines for more diseases

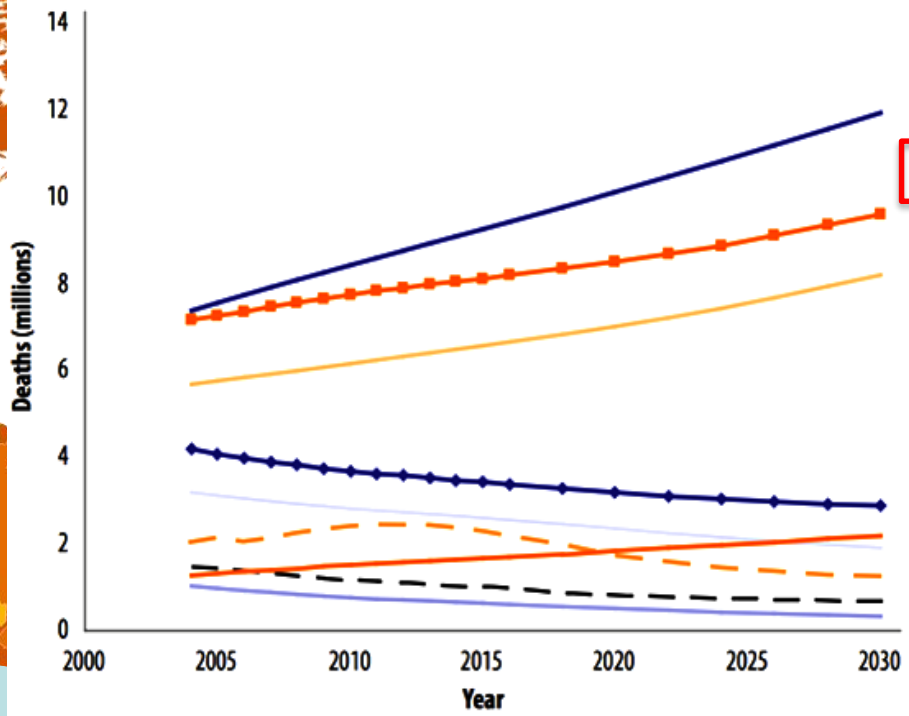
This is the map of Non-Communicable Disease – the darker the colour – the higher the risk

Noncommunicable diseases (NCDs), including heart disease, stroke, cancer, diabetes and chronic lung disease, are collectively responsible for almost 70% of all deaths worldwide.



Ref [1] https://upload.wikimedia.org/wikipedia/commons/thumb/c/c6/Noncommunicable_diseases_world_map-Deaths_per_million_persons-WHO2012.svg/2000px-Noncommunicable_diseases_world_map-Deaths_per_million_persons-WHO2012.svg.png. Accessed Nov 3, 2016 [2] Non-communicable diseases. The Kings Fund. https://www.kingsfund.org.uk/time-to-think-differently/trends/disease-and-disability/non-communicable-diseases. Accessed Nov 6, 2016

We live in the era of Non-Communicable Disease – with cancer the main threat



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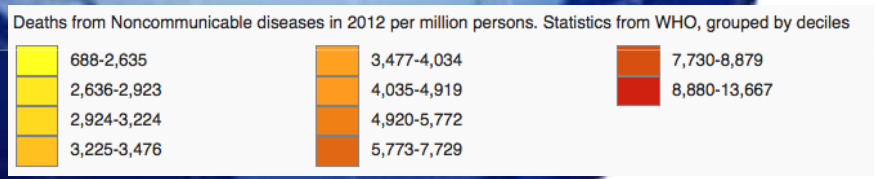

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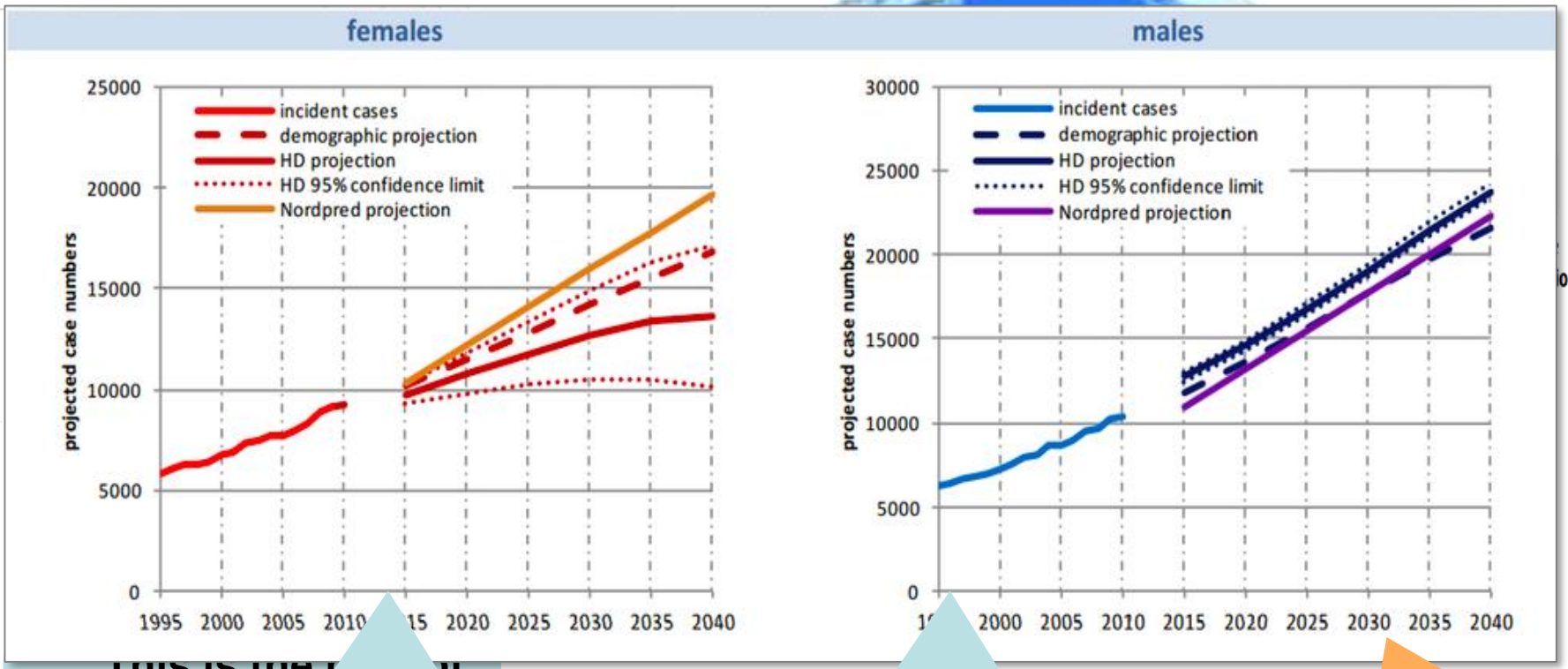


Ireland cannot escape this trend

Cancer rates will double by 2040 [2]

The majority of Irish Cancer Patients will be >70 years of age [2]

So who will pay for their cancer treatment?

Ref [1] https://upload.wikimedia.org/wikipedia/commons/thumb/c/c6/Noncommunicable_diseases_world_map-Deaths_per_million_persons-WHO2012.svg/2000px-Noncommunicable_diseases_world_map-Deaths_per_million_persons-WHO2012.svg.png. Accessed Nov 3, 2016 [2] Non-communicable diseases. The Kings Fund. https://www.kingsfund.org.uk/time-to-think-differently/trends/disease-and-disability/non-communicable-diseases. Accessed Nov 6, 2016

Future demographic trends threaten national finances even further

- **Workers paying for healthcare 20-64y** **vs. Population >65years**

- **1950**
  - 7.2:1

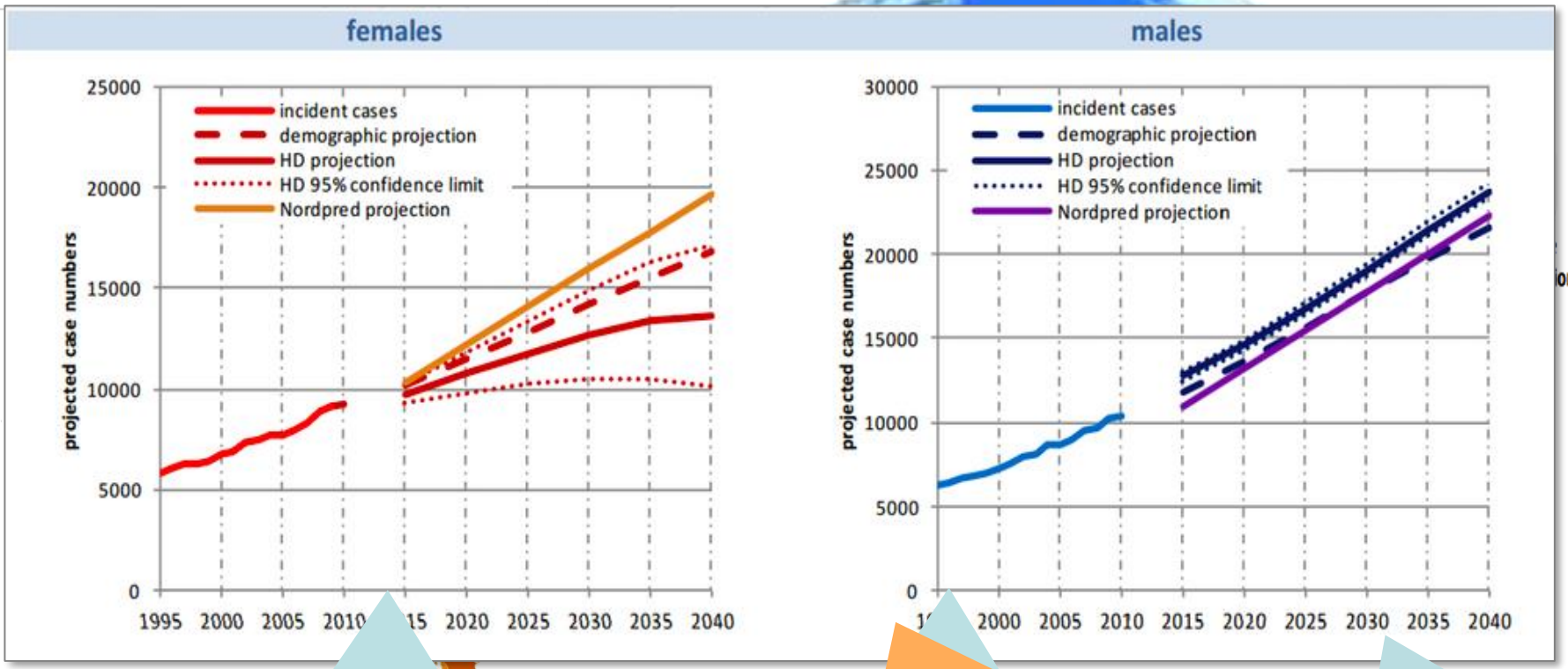
- **1980**
  - 5.1:1

- **2050**
  - 2.1:1

So who will pay for their cancer treatment?

Ref: [1] The Economist-Old Age Dependency Ratios-May 2009. http://www.economist.com/node/13611235. Accessed nov 7, 2016 [2] The Economist-Old Age Dependency Ratios-May 2009. http://www.economist.com/node/13611235. Accessed nov 7, 2016 [2] The Economist-Falling short. The trouble with pensions. Economist Jun 12th 2008, 13:09. http://www.economist.com/node/11529345. Accessed nov 7, 2016 [3] Map Image. CCO License. https://upload.wikimedia.org/wikipedia/commons/7/7a/United_Kingdom_Portugal_Locator.png. Accessed March 13, 2017

We live in the era of Non-Communicable Disease – with cancer the main threat



Ireland cannot escape this trend

Cancer rates will double by 2040 [2]

And how will we treat them?

So who will pay for their cancer treatment?

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The possibility at the millennium, 2000

Cell, Vol. 100, 57–70, January 7, 2000, Copyright ©2000 by Cell Press

The Hallmarks of Cancer

Douglas Hanahan* and Robert A. Weinberg†
*Department of Biochemistry and Biophysics and
Hormone Research Institute
University of California at San Francisco
San Francisco, California 94143
†Whitehead Institute for Biomedical Research and
Department of Biology
Massachusetts Institute of Technology
Cambridge, Massachusetts 02142

the complexity of 200 differe
may be explained by a few u
pathways

And how will we
them?

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Ref [1] Hanahan D, Weinberg RA (January 2000). "The Hallmarks of Cancer". Cell 100 (1): 57–70. [2] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg

Where were we?

I am sorry to report that you have breast cancer

Tell me doctor – what have I got?

Anatomic diagnosis

Malignant Neoplasm of Female Breast
ICD-10-CM (Category C50)
Nipple and areola – *right, left, unspecified*
Central portion – *right, left, unspecified*
Upper-inner quadrant – *right, left, unspecified*
Lower-inner quadrant – *right, left, unspecified*
Upper-outer q…nt – *right, left, unspecified*
Lower-outer q…nt – *right, left, unspecified*
Axillary tail – *rig…ft, unspec…*
Overlapping …d
Unspecifie…d

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015

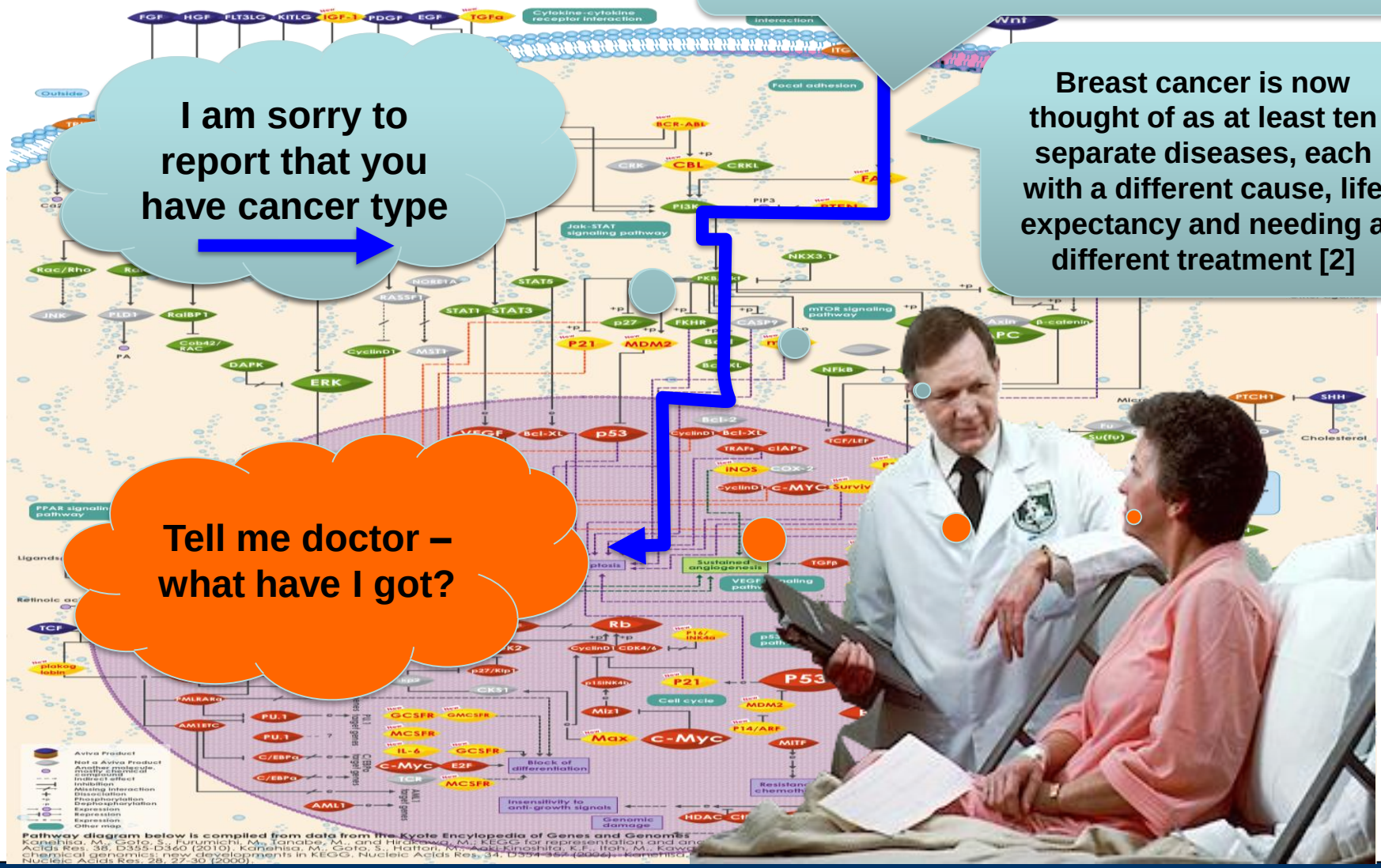
Where are we now?

Anatomic diagnosis with complex biomarkers

I am sorry to report that you have cancer type

Breast cancer is now thought of as at least ten separate diseases, each with a different cause, life expectancy and needing a different treatment [2]

Tell me doctor – what have I got?



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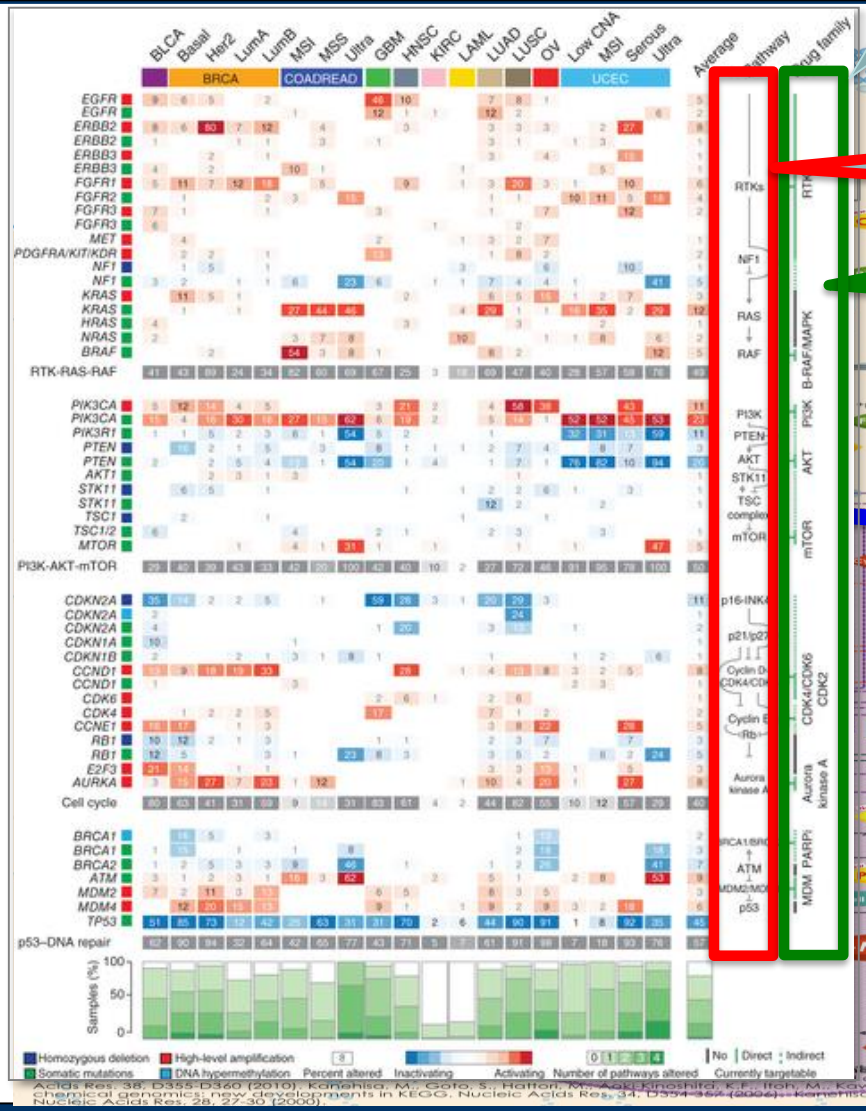
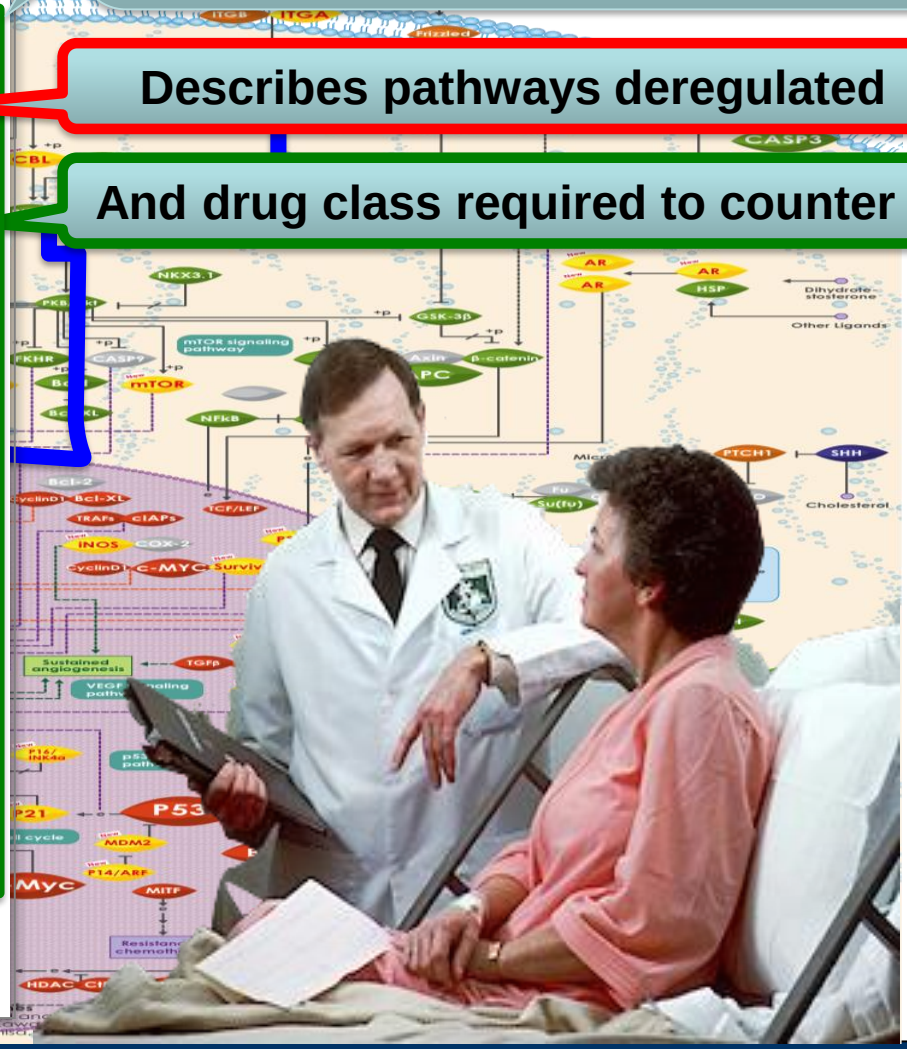
Where are we heading?

The Cancer Genome Atlas is a working Map of functional and actionable alterations across different tumour types [4]

Describes pathways deregulated

And drug class required to counter it





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Where are we heading?

2016: Targeting two deregulated pathways with lapatinib and trastuzumab - Tumours can be gone in as short as 11 days! [5]

Describes pathways deregulated

And drug class required to counter it

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NEWS *10 March 2016*

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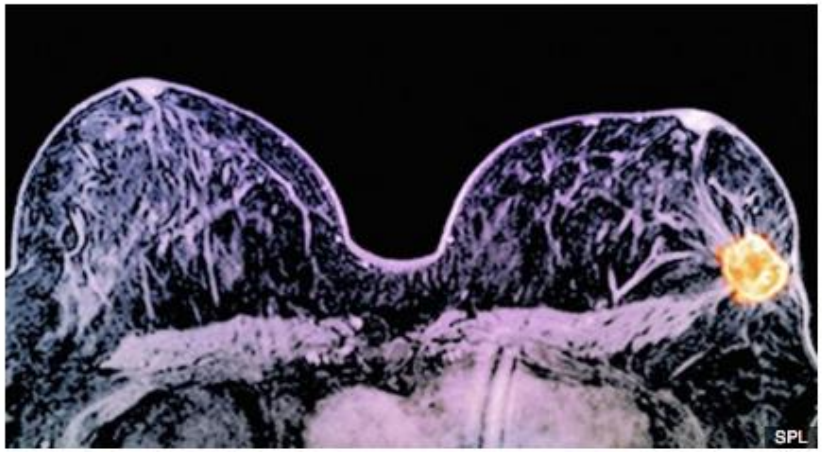
Health

Tumours shrunk 'dramatically' in 11 days

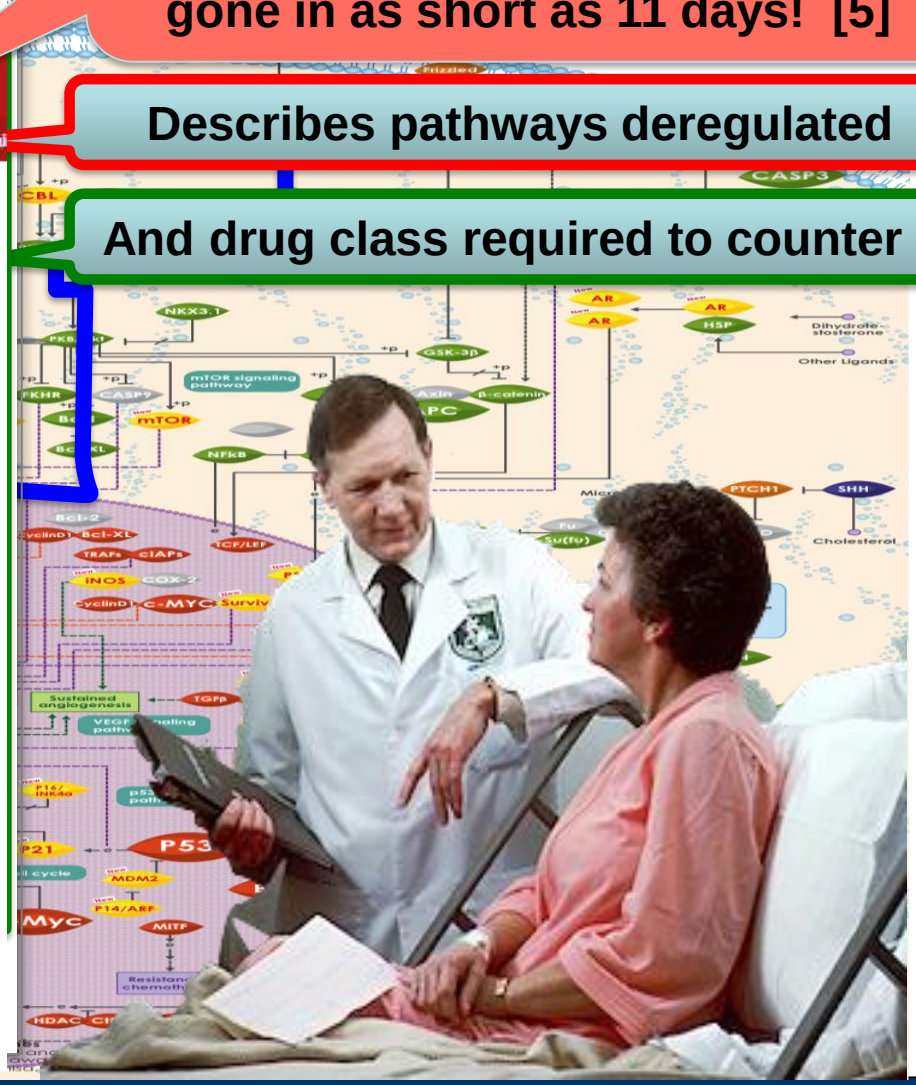
By James Gallagher
Health editor, BBC News website

10 March 2016 | Health



A pair of drugs can dramatically shrink and eliminate some breast cancers in just 11 days, UK doctors have shown.

They said the "surprise" findings, reported at the European Breast Cancer Conference, could mean some women no longer need chemotherapy.



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Where are we heading?

The Cancer Genome Atlas is a working Map of functional and actionable alterations across different tumour types [4]

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The cancer revolution: Personalised treatment that's 'six times better' than traditional methods at beating the disease

- The revolutionary approach tailors treatment to each cancer patient
- Experts have hailed the 'personalised medicine' as a huge breakthrough
- Research will show how the technique increases chances of survival

By SOPHIE BORLAND, HEALTH EDITOR IN CHICAGO FOR THE DAILY MAIL

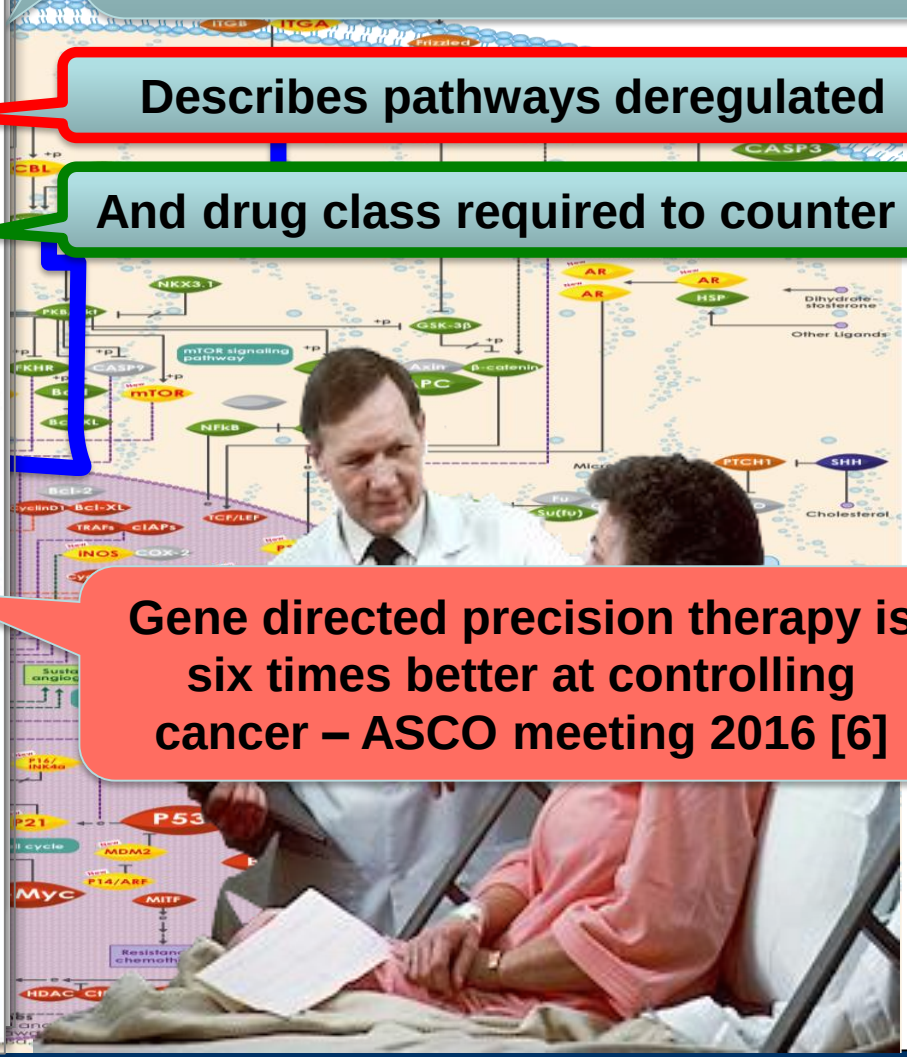
PUBLISHED: 00:12, 4 June 2016 | **UPDATED:** 01:39, 4 June 2016

A revolutionary approach to cancer which tailors treatment to each patient is six times as effective as traditional methods, a landmark study has found.

Experts have hailed the so-called 'personalised medicine' as the biggest breakthrough since chemotherapy.

The technique sees a patient's tumour genetically tested as soon as they are diagnosed. This allows doctors to determine whether the cancer is aggressive, whether chemotherapy is necessary and exactly which drugs are needed.

Research involving 13,203 patients, to be unveiled at the world's largest cancer conference next week, will show the technique drastically increases chances of survival and reduces the risk of the disease spreading and returning.

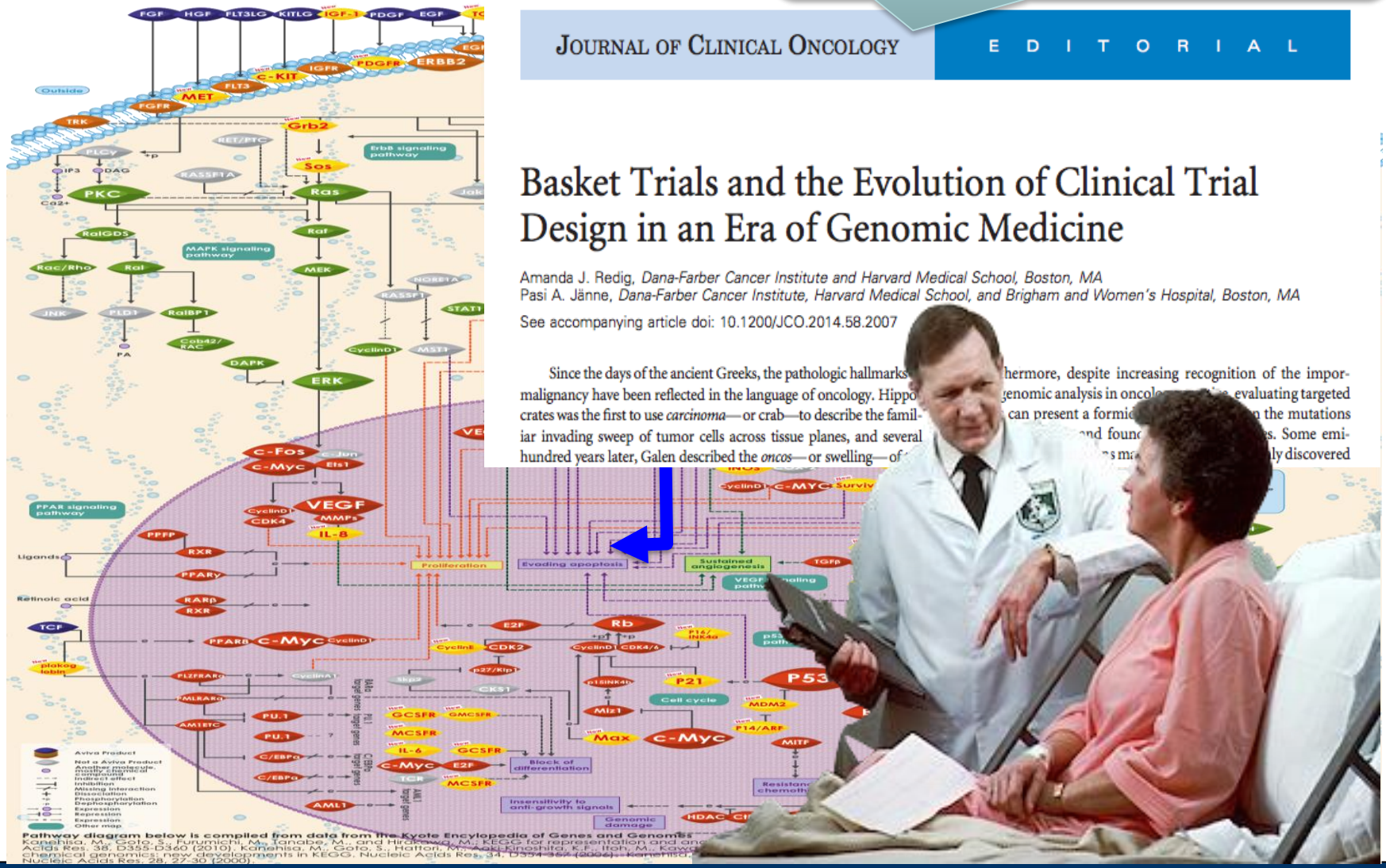


Gene directed precision therapy is six times better at controlling cancer – ASCO meeting 2016 [6]

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015. [3] Sharma, P et al. Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential. Cell 2015;161(2):205–214 [4] Giovanni Ciriello G et al. Emerging landscape of oncogenic signatures across human cancers. Nature Genetics 2013;45:1127–1133 doi:10.1038/ng.2762 [6] Borland S. The cancer revolution: Personalised treatment that's 'six times better' than traditional methods at beating the disease. DailyMail, Published: 00:12, 4 June 2016 | Updated: 01:39, 4 June 2016. http://www.dailymail.co.uk/news/article-3624700/The-cancer-revolution-Personalised-treatment-s-six-times-better-traditional-methods-beating-disease.html#ixzz4AnW443cO. Accessed June 6, 2016

Where are we heading?

"Basket trials" now mean we will treat cancers by genomic diagnosis, not anatomic site [4]



JOURNAL OF CLINICAL ONCOLOGY | E D I T O R I A L

Basket Trials and the Evolution of Clinical Trial Design in an Era of Genomic Medicine

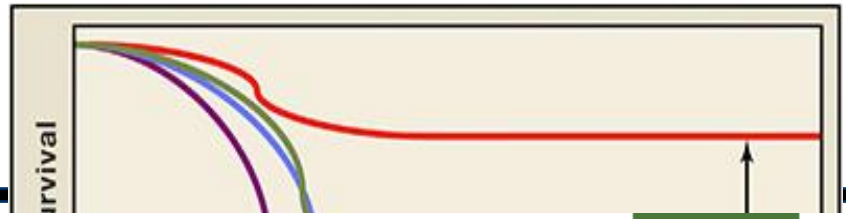
Amanda J. Redig, *Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA*
Pasi A. Jänne, *Dana-Farber Cancer Institute, Harvard Medical School, and Brigham and Women's Hospital, Boston, MA*

See accompanying article doi: 10.1200/JCO.2014.58.2007

Since the days of the ancient Greeks, the pathologic hallmarks … hermore, despite increasing recognition of the impor-
malignancy have been reflected in the language of oncology. Hippo… genomic analysis in oncolo… evaluating targeted
crates was the first to use *carcinoma*—or crab—to describe the famil- … can present a formi… the mutations
iar invading sweep of tumor cells across tissue planes, and several … nd found… s. Some emi-
hundred years later, Galen described the *oncos*—or swelling—of … s ma… ly discovered

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015. [3] Sharma, P et al. Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential. Cell 2015;161(2):205–214 [4] Redig, AJ et al. Basket Trials and the Evolution of Clinical Trial Design in an Era of Genomic Medicine. JCO February 9, 2015 JCO.2014.58.8432

Where are we heading?



With 3 key steps deregulated – we need 3 concurrent cancer therapies

How should we treat it?

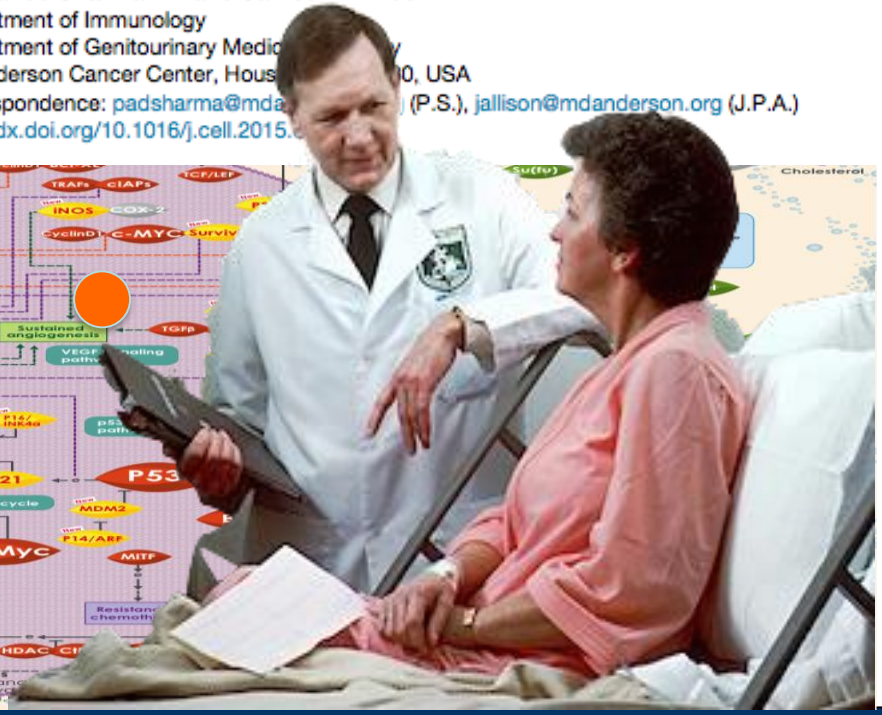
Leading Edge

Review

Cell

Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential

Padmanee Sharma[1,2,*] and James P. Allison[1,*]
[1]Department of Immunology
[2]Department of Genitourinary Medic
MD Anderson Cancer Center, Hous 0, USA
*Correspondence: padsharma@mda (P.S.), jallison@mdanderson.org (J.P.A.)
http://dx.doi.org/10.1016/j.cell.2015.



Pathway diagram below is compiled from data from the Kyoto Encyclopedia of Genes and Genomes

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September

Where are we heading?

With 3 key steps deregulated – we need 3 concurrent cancer therapies

Will my health insurance cover that?

the average cost per month for a branded oncology drug in the U.S. is now approximately $10,000 [2]

$10,000 x 3 x 12 = $360,000 a year

Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] IMS Health Study: Cancer Drug Innovation Surges As Cost Growth Moderates. URL: http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=19b381d71adc5410VgnVCM10000076192ca2RCRD&vgnextchannel=5ec1e590cb4dc310Vg

Where are we heading?

With 3 key steps deregulated – we need 3 concurrent cancer therapies

the average cost per month for a branded oncology drug in the U.S. is now approximately $10,000 [2]

$10,000 x 3 x 12 = $360,000 a year

$360,000 =
11 years earnings for the average Irish citizen!

On average individuals in the Republic of Ireland have an annual gross income of €26,800/$33,024 USD [3]

Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] IMS Health Study: Cancer Drug Innovation Surges As Cost Growth Moderates. URL: http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=19b381d71adc5410VgnVCM10000076192ca2RCRD&vgnextchannel=5ec1e590cb4dc310Vg

Where are we heading?

This is 7 times more than the Annual Per Capita Income in Austria

11 times for the Czech republic

14 times more for Hungary

19 times more for Bulgaria

the average cost per month for a branded oncology drug in the U.S. is now approximately $10,000 [2]

$10,000 x 3 x 12 = $360,000 a year

Most Healthcare Systems are struggling to afford monotherapy

Combination precision targeted therapy will be impossible to afford at current drug prices

4.78

Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] IMS Health Study: Cancer Drug Innovation Surges As Cost Growth Moderates. URL: http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=19b381d71adc5410VgnVCM10000076192ca2RCRD&vgnextchannel=5ec1e590cb4dc310Vg

We Have a Problem …

CAN WE AFFORD THE WAR ON CANCER?

Immunotherapy vaccines could extend survival in a handful of cancers. But personalizing treatment, payers argue, is not sustainable. Where should the line be drawn?

BY ED SILVERMAN

Two years ago, the U.S. Food and Drug Administration took a step that ld never leucel- e-stage me af- olving allegations of conflicts of interest among a pair of FDA advisory com- mittee members who reviewed the tending a life by 4.1 months is worth the price of Provenge. It has also prompted larger questions about the underlying technology and the need to develop more vaccines.

Provenge is made by culturing a patient's immune cells with a recombinant antigen. The individualized product is then infused back into the patient, activating the immune system to target and attack the cancer. This "immunotherapy" underscores the move toward personalized

Most Healthcare Systems are struggling to afford monotherapy

Combination precision targeted therapy will be impossible to afford at current drug prices

Ref: [1] Steven Brill. Bitter Pill: Why Medical Bills Are Killing Us. Time April 4, 2013 [2] Silverman E. *Biotechnol Healthc.* 2012;9(4):13-16.

Access to innovation has one key rule

"The only treatment that works is a one that we can afford to give"

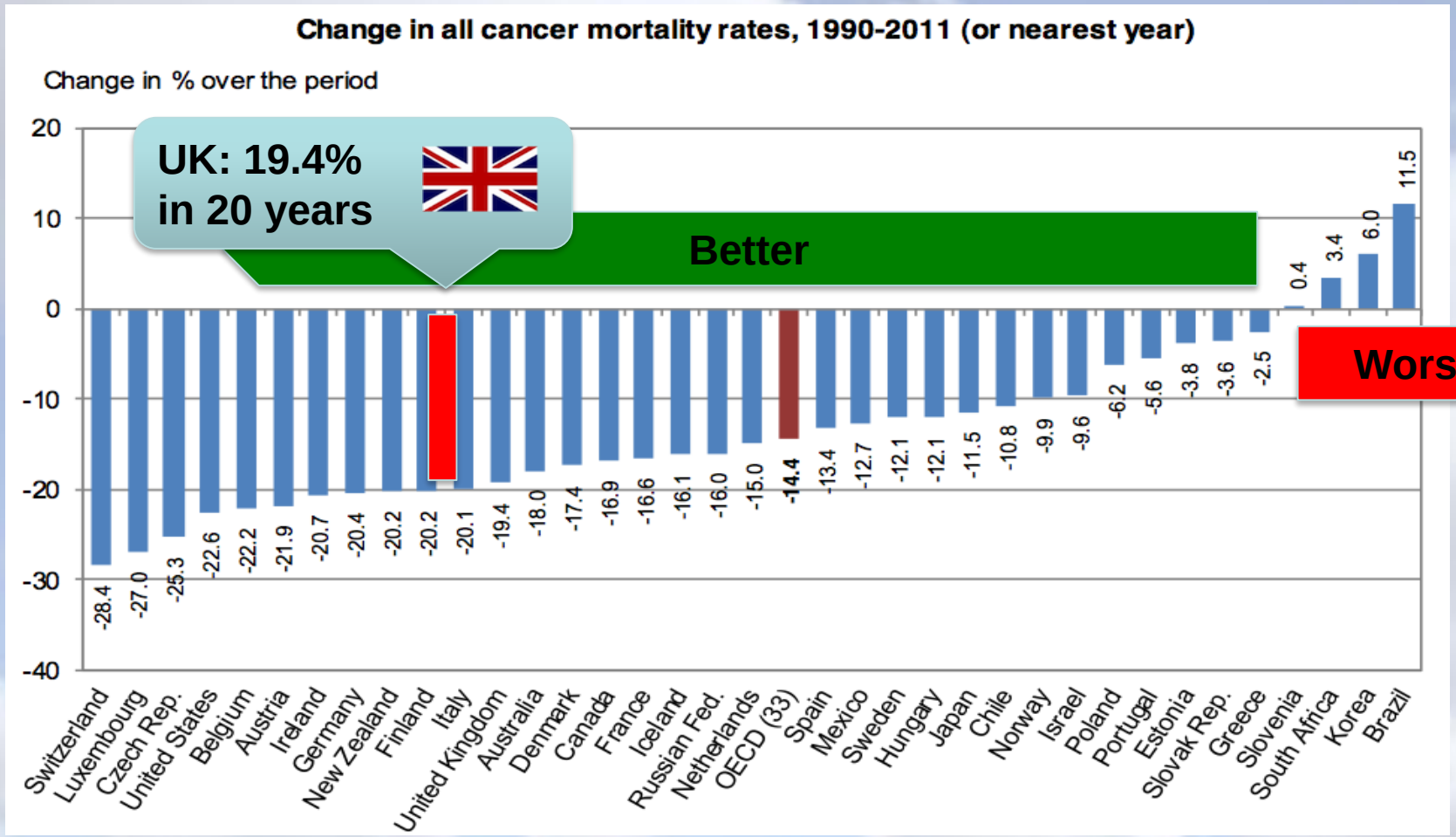
On our current spending patterns – healthcare is unsustainable

Especially for cancer

Ref: European Patients' Rights Day: 10 benefits the EU brings to patients. EC Memo Brussels, 12 May 2014. http://europa.eu/rapid/press-release_MEMO-14-341_en.htm. Accessed June 19, 2015 .

Do we really need innovation in cancer care?

- **Reduction in cancer deaths –**



Ref: [1] Cancer Care: Chart Set. www.oecd.org/health/health-systems/cancer-care.htm. Accessed March 21, 2016

The aspirations for personalised medicine are realistic – not just “blue sky” thinking

- **Reduction in cancer deaths –**

Ref: [1] Cancer Care: Chart Set. www.oecd.org/health/health-systems/cancer-care.htm. Accessed March 21, 2016 [2] Under-80 cancer deaths 'eliminated by 2050' claim. NHS Choices Jan 14, 2015. URL: http://www.nhs.uk/news/2015/01January/Pages/Under-80-cancer-deaths-eliminated-by-2050-claim.aspx . Accessed Sept 27, 2016 [3] Overcoming Cancer in the 21st Century. UCL. 14 JANUARY 2015. URL: http://www.ucl.ac.uk/pharmacy/departments/practice-policy/VF_Embargo.pdf. Accessed Sept 27, 2016

The reality of cancer care now

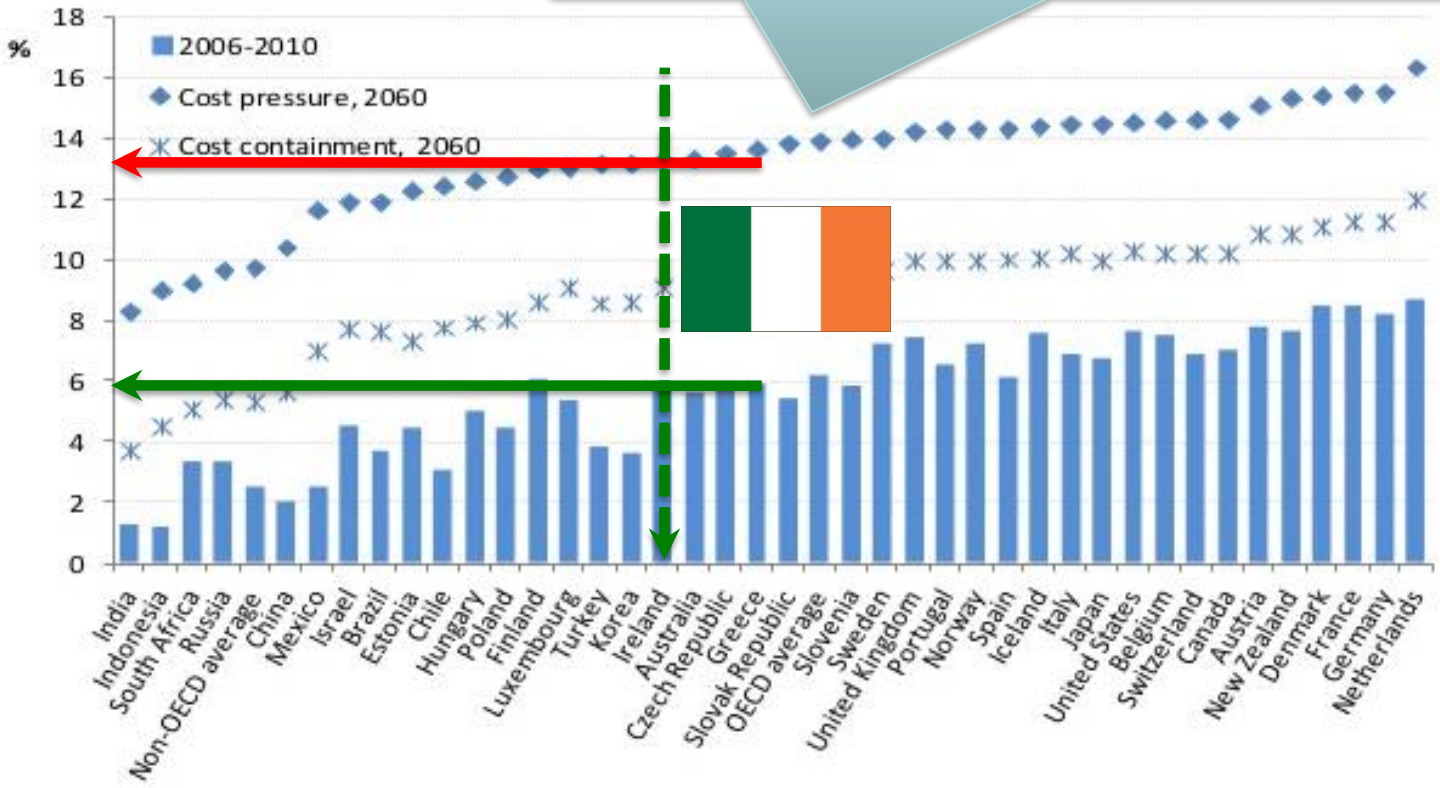
- ***"We must confront a stark reality: cancer care is not affordable for most patients, many payers, and nearly all governments. This is a real and immediate issue across the world"***

Ref: [1] Thomas R et al. Delivering affordable cancer care a value challenge to health systems. Report of the WISH Delivering Affordable Cancer Care Forum 2015. URL: www.wish.org.qa. Accessed Oct 17, 2016 [2] Image – CCO License - https://upload.wikimedia.org/wikipedia/commons/c/cc/Science_and_Mechanics_Nov_1931_cover.jpg. Accessed Nov 2, 2016

Health spending pressures – planning for 30 years ahead in Eire

- **2016 OECD projections: health and long term care projections as a % of GDP**

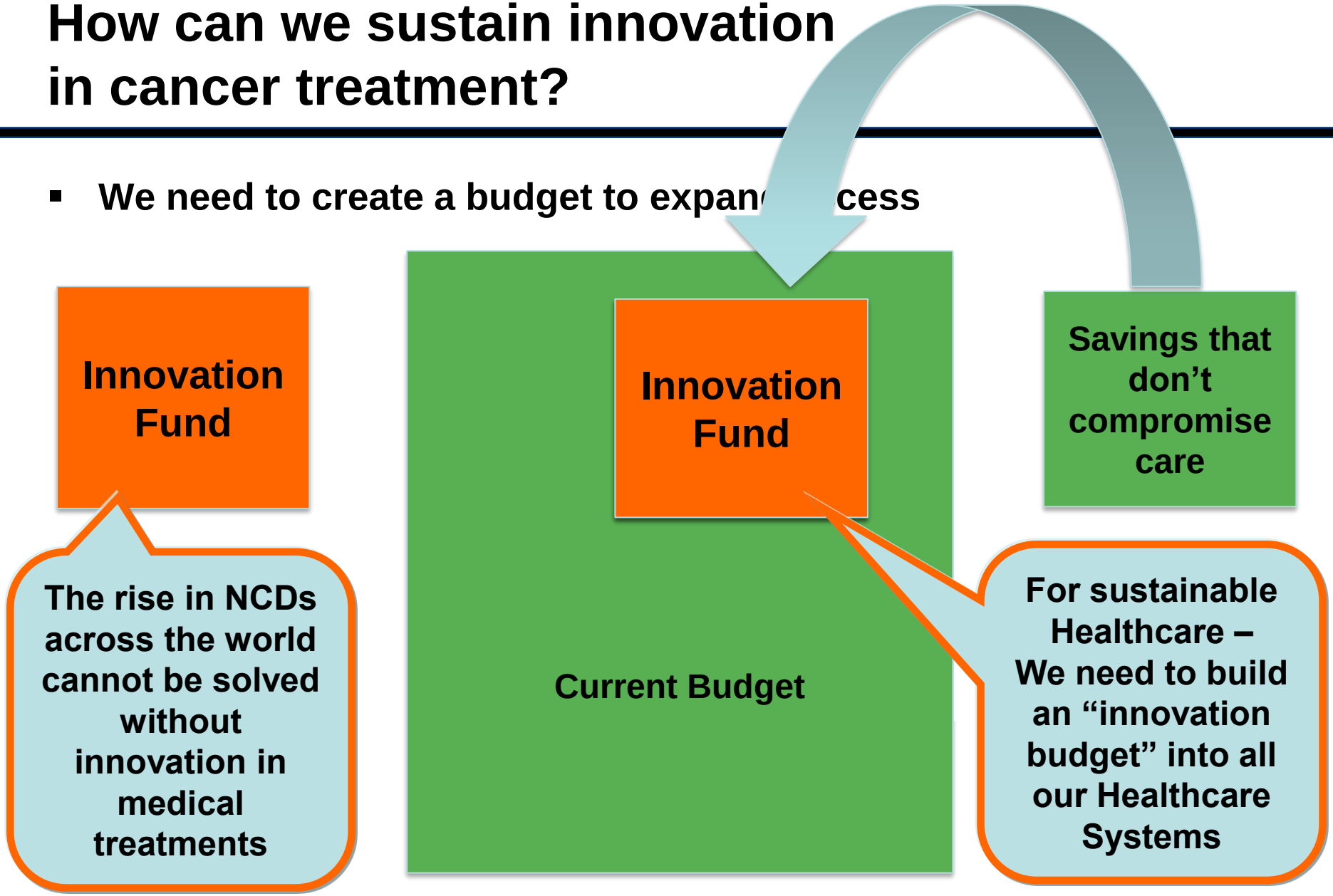
Without extra measures – health spending will double to 13-14% of national wealth



Ref: [1] Martins JO. The Drivers of Public Health Spending. OECD 4-5 Feb, 2016. http://www.slideshare.net/OECD-GOV/the-drivers-of-public-health-spending-integrating-policies-and-institutions. Accessed March 22, 2016 [2] alarm clock – clip art free apple macintosh Snow Leopard / Microsoft Office 2008 clip art set

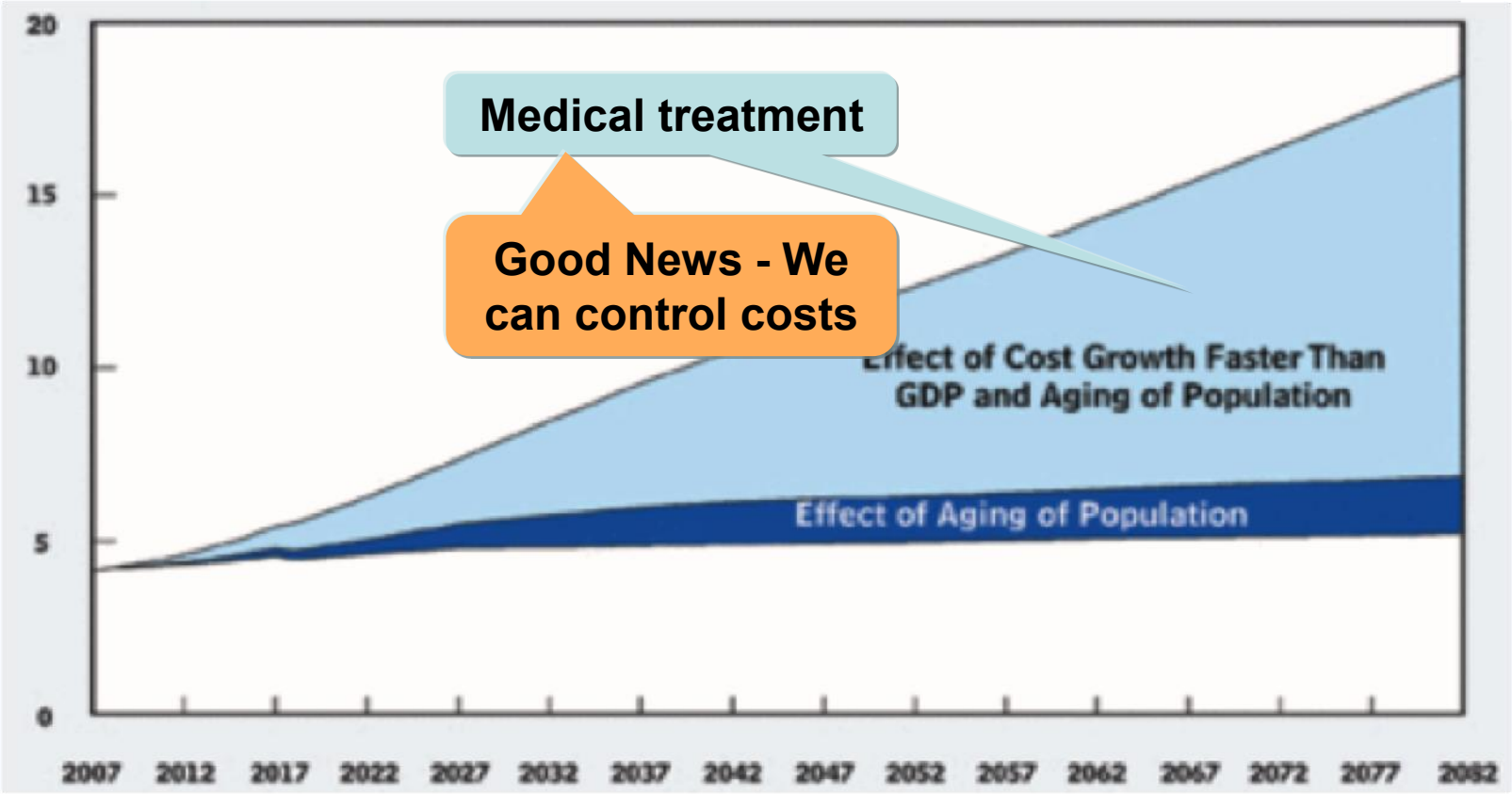
How can we sustain innovation in cancer treatment?

- We need to create a budget to expan[illegible]cess



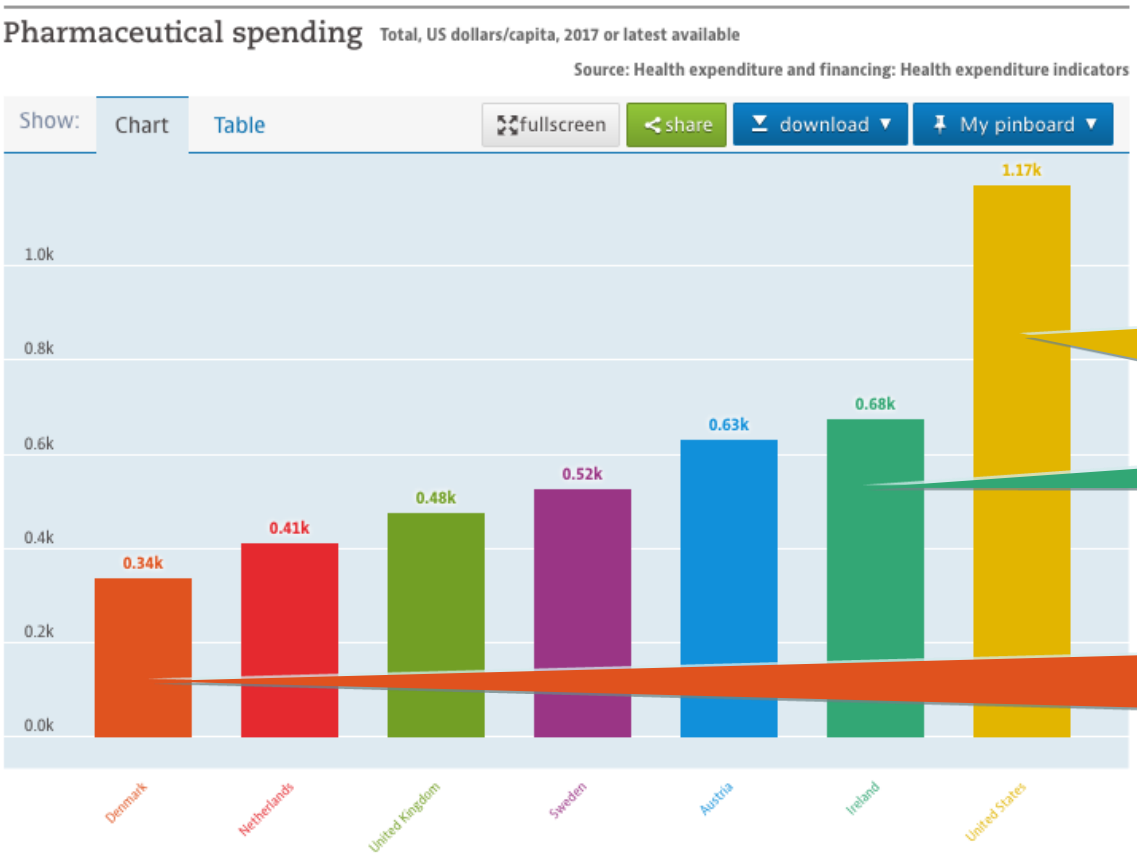
Planning for the future: what will happen to costs?

What is the driver for increased spending: ageing populations or medical treatment?



Planning for the future: what are costs now?

Ireland is one of the top world spenders on medicines per citizen

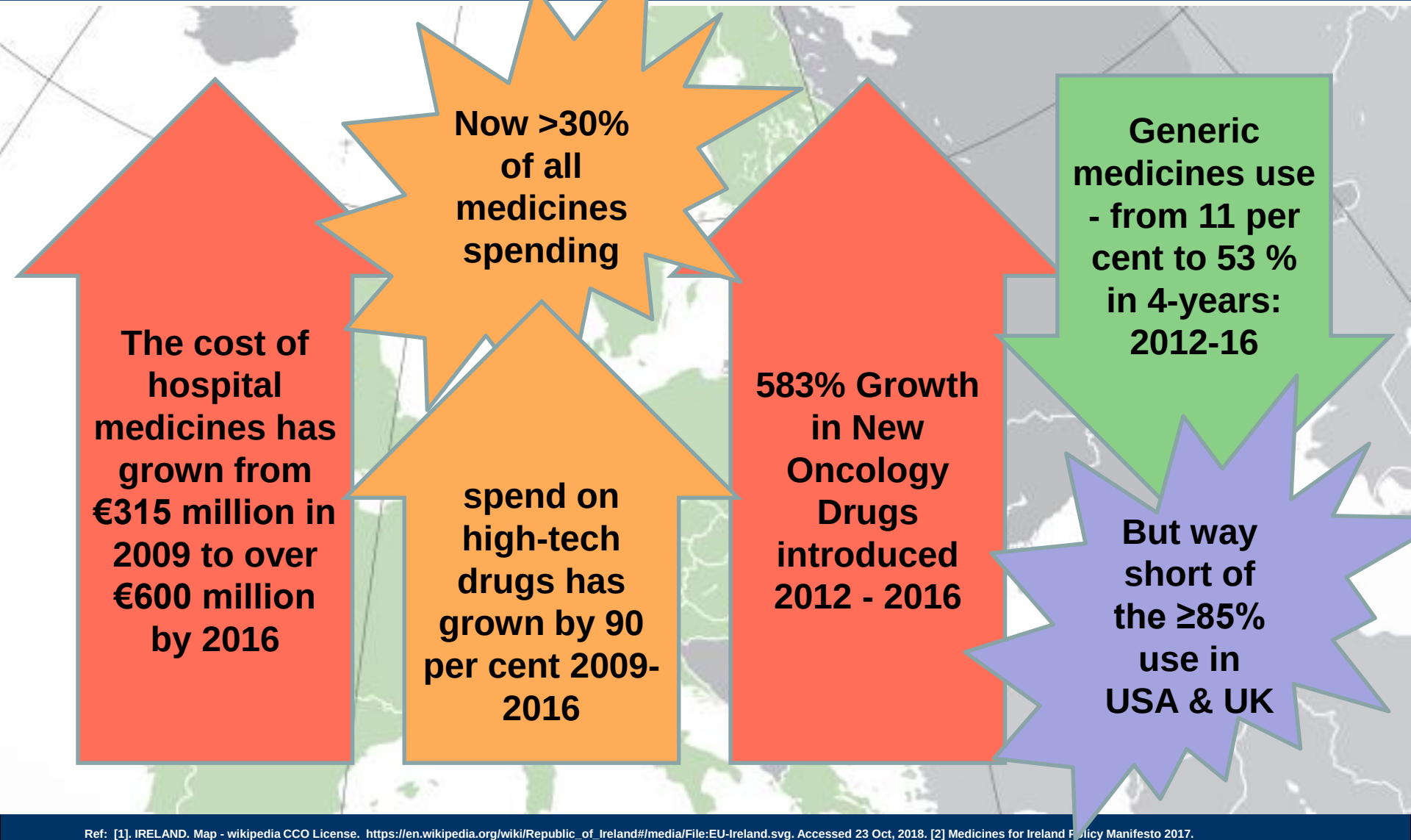


But still less than the USA

Ireland

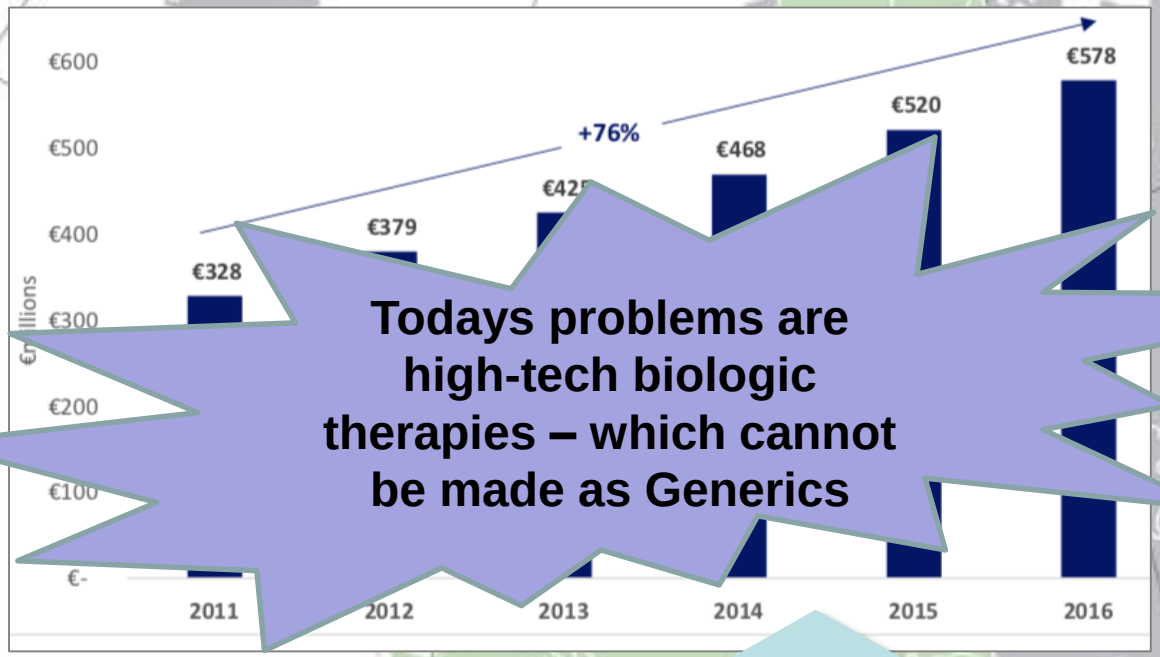
Higher for example than Denmark, Netherlands, UK, Sweden, Austria

Planning for the future: what are the trends now for Ireland?



Ref: [1]. IRELAND. Map - wikipedia CCO License. https://en.wikipedia.org/wiki/Republic_of_Ireland#/media/File:EU-Ireland.svg. Accessed 23 Oct, 2018. [2] Medicines for Ireland Policy Manifesto 2017. https://www.medicinesforireland.ie/wp-content/.../Medicines-for-Ireland-Manifesto.pdf. Accessed Oct 22, 2018. [3] Jenny Connors et al. Spending Review 2017 Spending Review 2017. Future Sustainability of Pharmaceutical Expenditure. Dept of Pub Expenditure & Reform; April, 2017 May, 2017. https://www.per.gov.ie/wp-content/uploads/Pharmaceutical-Expenditure.pdf. Accessed Oct 22, 2018

Medicines spending in Ireland - trends



Todays problems are high-tech biologic therapies – which cannot be made as Generics

Generic medicines use - from 11 per cent to 53 % in 4-years: 2012-16

But this only addresses yesterdays problems

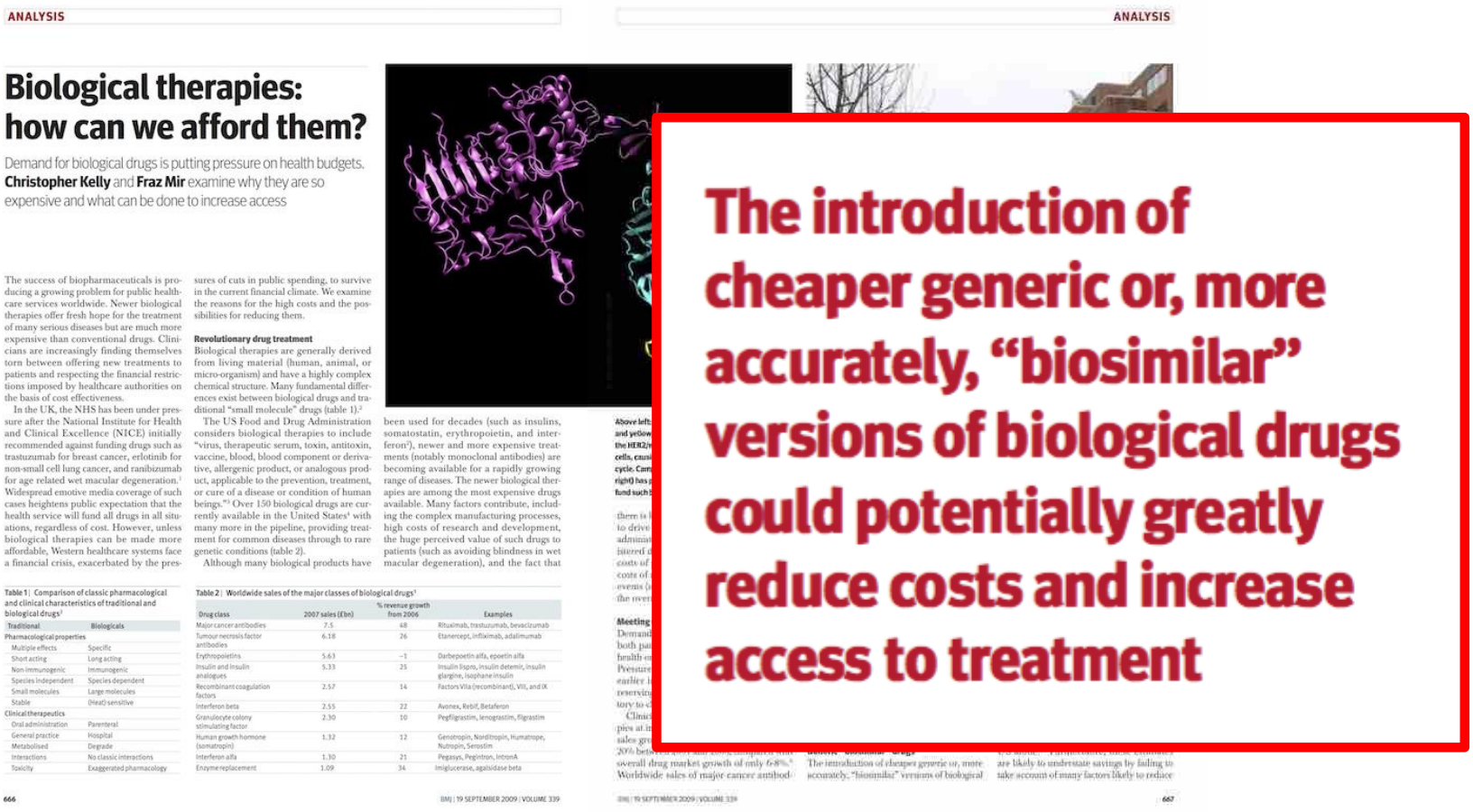
Increasing generic usage to the levels seen in the UK would save the Irish state €210 million each year [1]

But way short of the ≥85% use in USA & UK

Ref: [1] Jenny Connors. Spending Review 2017 - Future Sustainability of Pharmaceutical Expenditure May, 2017. Department of Public Expenditure & Reform. Eire.[2] Shane O'Sullivan. used to dread bringing an inhaler out to a patient and asking for €85,. TheJournal.ie. Mar 9th 2016, 10:08 AM . http://www.thejournal.ie/readme/medicine-costs-ireland-2649649-Mar2016/. Accessed Oct 22, 2018

Biological therapies – we want them but how can we afford them

- **British Medical Journal - September 2009**



ANALYSIS

Biological therapies: how can we afford them?

Demand for biological drugs is putting pressure on health budgets. **Christopher Kelly** and **Fraz Mir** examine why they are so expensive and what can be done to increase access

The success of biopharmaceuticals is producing a growing problem for public healthcare services worldwide. Newer biological therapies offer fresh hope for the treatment of many serious diseases but are much more expensive than conventional drugs. Clinicians are increasingly finding themselves torn between offering new treatments to patients and respecting the financial restrictions imposed by healthcare authorities on the basis of cost effectiveness.

In the UK, the NHS has been under pressure after the National Institute for Health and Clinical Excellence (NICE) initially recommended against funding drugs such as trastuzumab for breast cancer, erlotinib for non-small cell lung cancer, and ranibizumab for age related wet macular degeneration.[1] Widespread emotive media coverage of such cases heightens public expectation that the health service will fund all drugs in all situations, regardless of cost. However, unless biological therapies can be made more affordable, Western healthcare systems face a financial crisis, exacerbated by the pressures of cuts in public spending, to survive in the current financial climate. We examine the reasons for the high costs and the possibilities for reducing them.

Revolutionary drug treatment

Biological therapies are generally derived from living material (human, animal, or micro-organism) and have a highly complex chemical structure. Many fundamental differences exist between biological drugs and traditional "small molecule" drugs (table 1).[2]

The US Food and Drug Administration considers biological therapies to include "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings."[3] Over 150 biological drugs are currently available in the United States[4] with many more in the pipeline, providing treatment for common diseases through to rare genetic conditions (table 2).

Although many biological products have been used for decades (such as insulins, somatostatin, erythropoietin, and interferon[2]), newer and more expensive treatments (notably monoclonal antibodies) are becoming available for a rapidly growing range of diseases. The newer biological therapies are among the most expensive drugs available. Many factors contribute, including the complex manufacturing processes, high costs of research and development, the huge perceived value of such drugs to patients (such as avoiding blindness in wet macular degeneration), and the fact that

Table 1 | Comparison of classic pharmacological and clinical characteristics of traditional and biological drugs[2]

Traditional	Biologicals
Pharmacological properties	
Multiple effects	Specific
Short acting	Long acting
Non-immunogenic	Immunogenic
Species independent	Species-dependent
Small molecules	Large molecules
Stable	(Heat) sensitive
Clinical therapeutics	
Oral administration	Parenteral
General practice	Hospital
Metabolised	Degrade
Interactions	No classic interactions
Toxicity	Exaggerated pharmacology

Table 2 | Worldwide sales of the major classes of biological drugs[1]

Drug class	2007 sales (£bn)	% revenue growth from 2006	Examples
Major cancer antibodies	7.5	48	Rituximab, trastuzumab, bevacizumab
Tumour necrosis factor antibodies	6.18	26	Etanercept, infliximab, adalimumab
Erythropoietins	5.63	−1	Darbepoetin alfa, epoetin alfa
Insulin and insulin analogues	5.33	25	Insulin lispro, insulin detemir, insulin glargine, isophane insulin
Recombinant coagulation factors	2.57	14	Factors VIIa (recombinant), VIII, and IX
Interferon beta	2.55	22	Avonex, Rebif, Betaferon
Granulocyte colony stimulating factor	2.30	10	Pegfilgrastim, lenograstim, filgrastim
Human growth hormone (somatropin)	1.32	12	Genotropin, Norditropin, Humatrope, Nutropin, Saizen
Interferon alfa	1.30	21	Pegasys, Peginton, IntronA
Enzyme replacement	1.09	34	Imiglucerase, agalsidase beta

666

BMJ | 19 SEPTEMBER 2009 | VOLUME 339

ANALYSIS

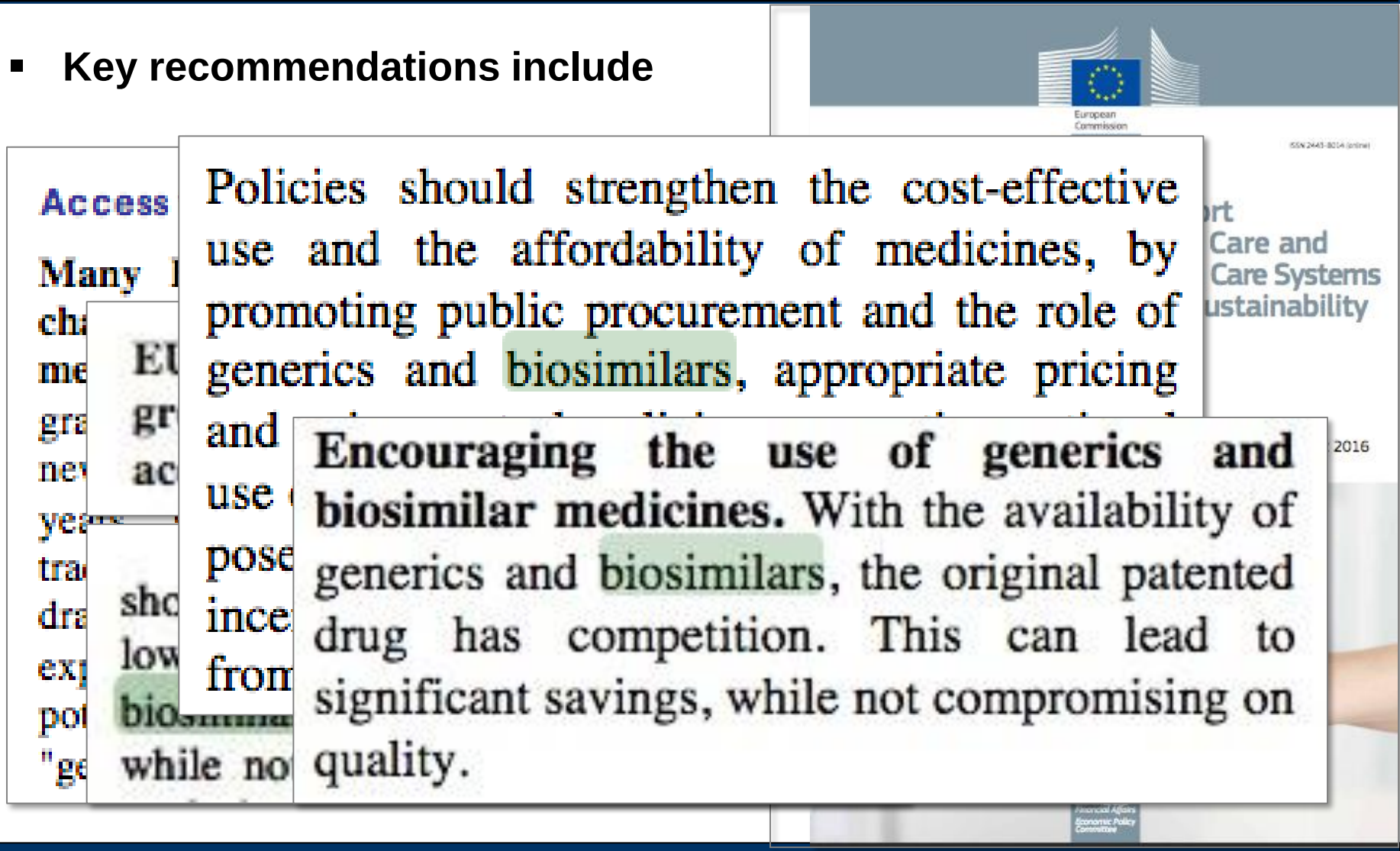
The introduction of cheaper generic or, more accurately, "biosimilar" versions of biological drugs could potentially greatly reduce costs and increase access to treatment

667

Refs [1] Kelly C, Mir F. Biological therapies: how can we afford them? BMJ 19 september 2009;339:666-669.

The EU reports on strategies for sustainable care place biosimilars as a central policy imperative

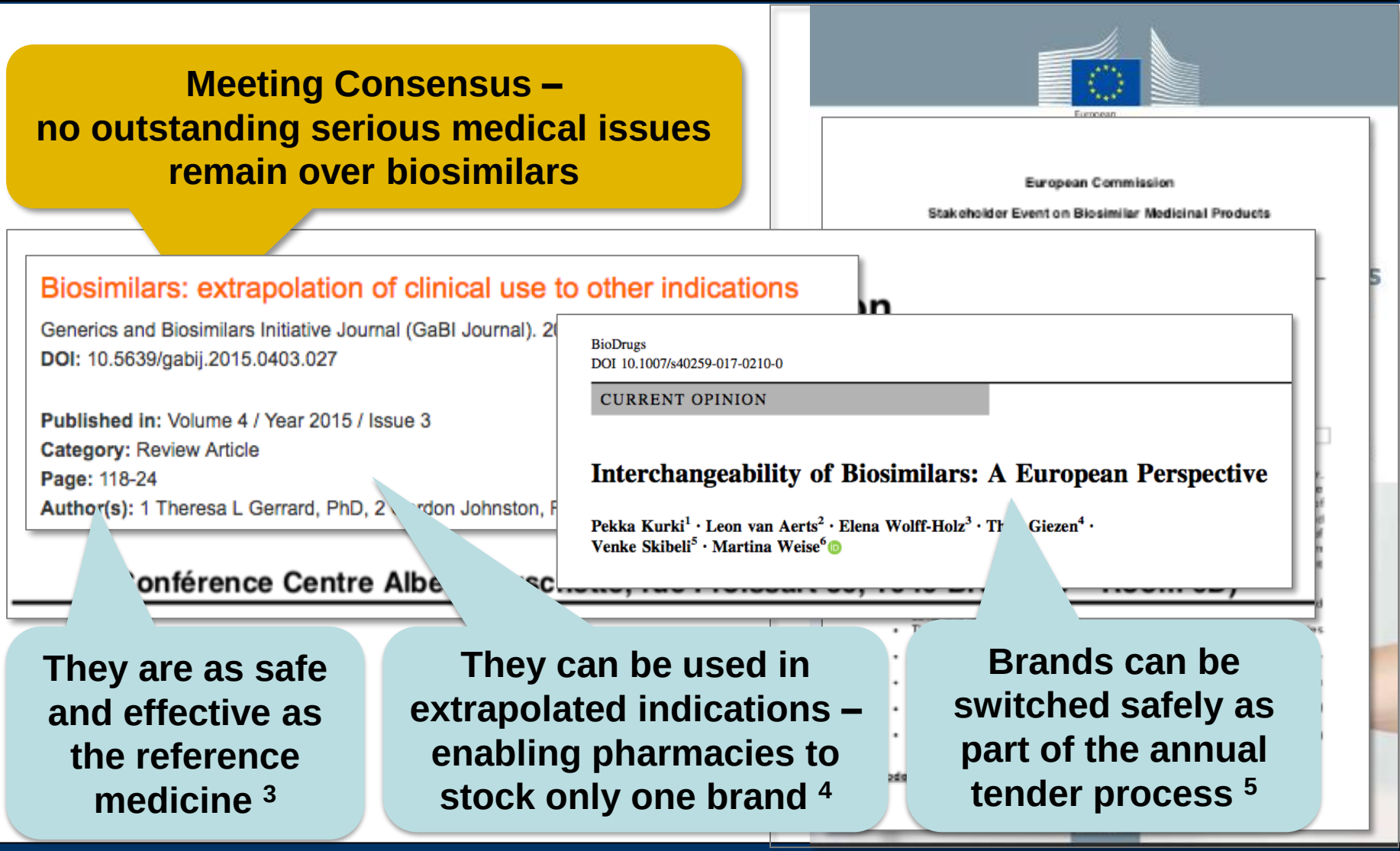
- **Key recommendations include**



Ref: [1] Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability, Volume 1, October 2016. EU. http://ec.europa.eu/economy_finance/publications/eeip/pdf/ip037_vol1_en.pdf. Accessed Nov 17, 2016

The EU reports on strategies for sustainable care place biosimilars as a central policy imperative

Meeting Consensus –
no outstanding serious medical issues remain over biosimilars



They are as safe and effective as the reference medicine [3]

They can be used in extrapolated indications – enabling pharmacies to stock only one brand [4]

Brands can be switched safely as part of the annual tender process [5]

Ref: [1] Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability, Volume 1, October 2016. EU. http://ec.europa.eu/economy_finance/publications/eeip/pdf/ip037_vol1_en.pdf. Accessed Nov 17, 2016. [2 4th European Commission Stakeholder Event on Biosimilar Medicinal Products. Brussels 14 Sep 2018. https://ec.europa.eu/docsroom/documents/31361/attachments/1/translations/.../native. Accessed Oct 22, 2018 [3] Biosimilars in the EU - Information guide for healthcare professionals. Prepared jointly by the European Medicines Agency and the European Commission. http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf. Accessed Aug 31, 2017 [4] Gerrard TL et al. Biosimilars: extrapolation of clinical use to other indications. Generics and Biosimilars Initiative Journal (GaBI Journal). 2015;4(3):118-24. DOI: 10.5639/gabij.2015.0403.027 [5] Pekka Kurki, et al. Interchangeability of Biosimilars: A European Perspective. BioDrugs DOI 10.1007/s40259-017-0210-0. accessed March 14, 2017

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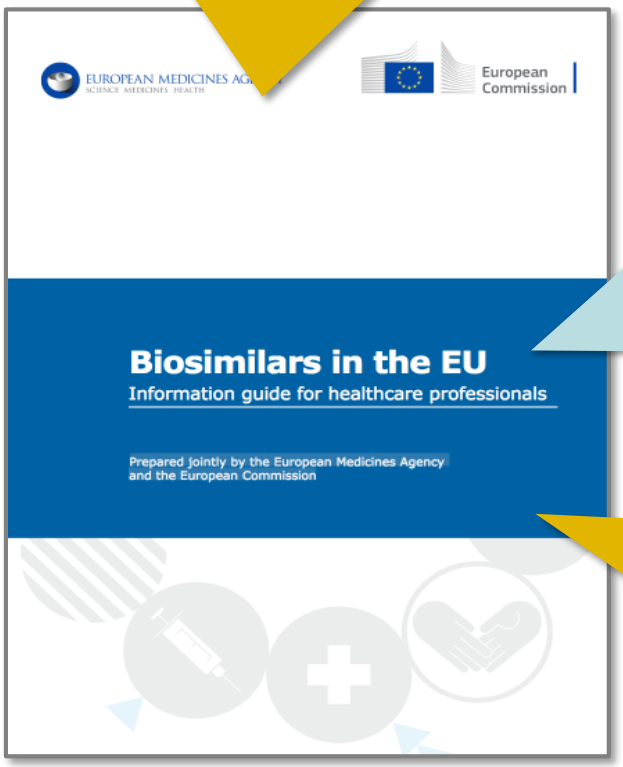
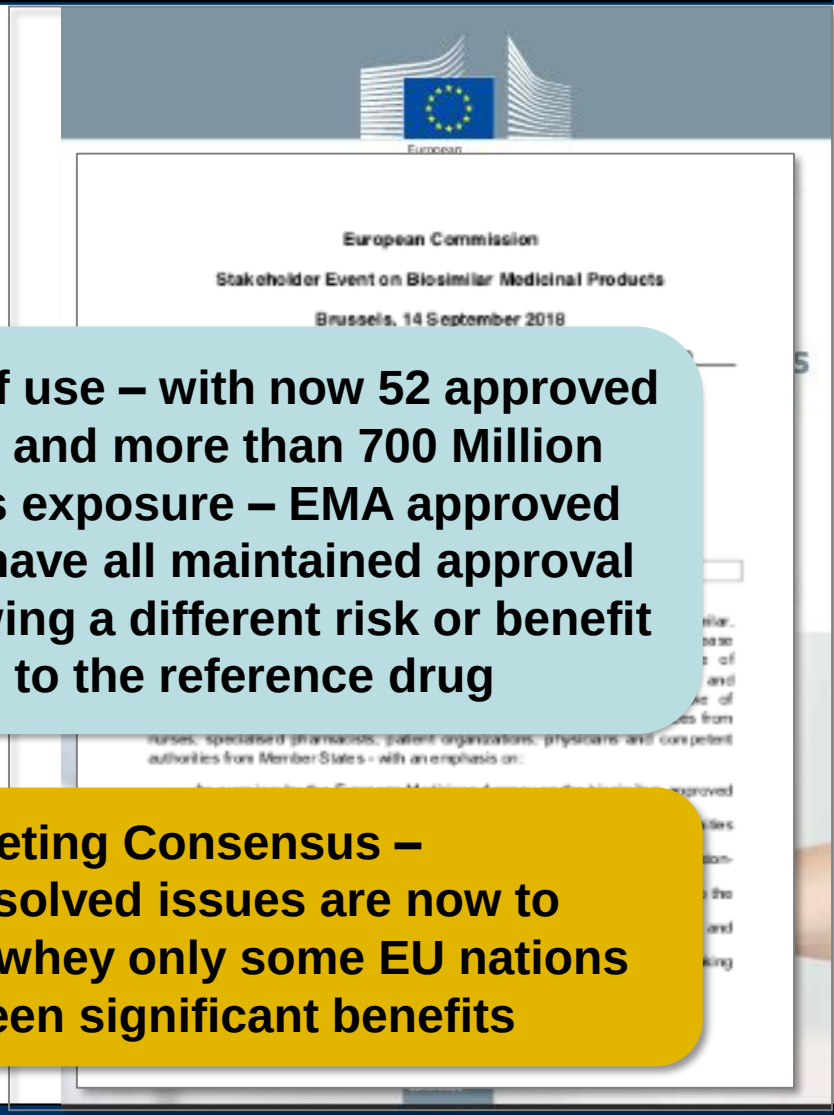




In a decade of use – with now 52 approved biosimilars and more than 700 Million patient days exposure – EMA approved biosimilars have all maintained approval without showing a different risk or benefit profile to the reference drug

Meeting Consensus –
The unresolved issues are now to understand whey only some EU nations have seen significant benefits

Ref: [1] 4th European Commission Stakeholder Event on Biosimilar Medicinal Products. Brussels 14 Sep 2018. https://ec.europa.eu/docsroom/documents/31361/attachments/1/translations/.../native. Accessed Oct 22, 2018 [2] Medicines for Europe - Biosimilars. http://www.medicinesforeurope.com/wp-content/uploads/2016/03/infographic-biosimilars.pdf accessed March 14, 2017 [3] Medicines for Europe information based on EMA Post-authorisation Safety Update Reports (PSURs) reported by Adrian van den Hoven. Biosimilar medicines clinical use: an experience based-EU perspective. FDA Presentation 13 July 2017, Washington D.C. ,USA. http://www.medicinesforeurope.com/docs/20170713%20-%20Biosimilar%20Medicines%20Group,%20EU%20experience-AVH-US%20FDA%20Adcom.pdf. Accessed Aug 31, 2017 [4] Biosimilars in the EU - Information guide for healthcare professionals. Prepared jointly by the European Medicines Agency and the European Commission. http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf. Accessed Aug 31, 2017

For a Payer – the budget impact of a biosimilar promotion policy can be significant

ASH | 59th Annual Meeting & Exposition
Atlanta, GA · December 9-12, 2017

4668 Budget Impact Analysis of Switching Chemotherapy Patients Using Granulocyte Colony-Stimulating Factors (G-CSFs) from Pegfilgrastim to Short-Acting G-CSFs in the United States

Program: Oral and Poster Abstracts
Session: 901. Health Services Research—Non-Malignant Conditions: Poster III

Monday, December 11, 2017, 6:00 PM-8:00 PM
Bldg A, Lvl 1, Hall A2 (Georgia World Congress Center)

Elizabeth James[1], Holly Trautman[1*], **Erika Szabo**[2*] and Boxiong Tang, MD, PhD[2]*

- **If a payer with a 1-million-member health plan**
  - **Could reduce pegfilgrastim use by just 10%**
  - **And replace it with short-acting filgrastim biosimilars**
    - Even if 60% needed home care help with administration
  - **This would generate annual cost savings of $5,533,259**

Ref: [1]

For a Country: the Budget Impact of a Biosimilar Promotion Policy Can Be Significant

- **Example: English National Health Service NHS**

NHS spending £1 billion on four drugs as bill soars

Oliver Wright, Policy Editor

December 5 2016, 12:01am, The Times

The NHS spends 15 per cent of its £116 billion budget on drugs

SUZANNE PLUNKETT/REUTERS

3 of these 4 drugs come from one class – anti-inflammatory biologic medicines

The amount of money that the NHS spends on drugs has surged by nearly 30 per cent in five years, with four treatments now costing the health service more than a billion pounds.

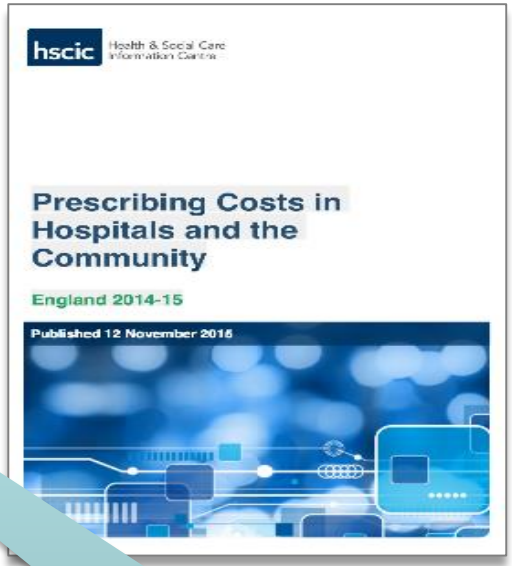
Ref: [1] Prescribing Costs in Hospitals and the Community England 2014-15. UK HSIC. Published Nov 12, 2015. http://www.hscic.gov.uk/catalogue/PUB18973/hosp-pres-eng-201415-report.pdf. Accessed April 19, 2016 [2] Oliver Wright, Policy Editor. NHS spending £1 billion on four drugs as bill soars. The Times, December 5 2016, 12:01am. https://www.thetimes.co.uk/article/nhs-spending-1-billion-on-four-drugs-as-bill-soars-m35805xfx. Accessed May 31, 2017

For a Country: the Budget Impact of a Biosimilar Promotion Policy Can Be Significant


NHS spending £1 billion on four

Fully qualified nurses start on salaries of **£21,692** rising to £28,180 on Band 5 of the NHS Agenda for Change Pay Rates. Salaries in London attract a high-cost area supplement. With experience, in positions such as nurse team leader on Band 6, salaries progress to £26,041 to £34,876.

Adult nurse job profile | Prospects.ac.uk
https://www.prospects.ac.uk/job-profiles/adult-nurse



£342 Million funds the salary of 15,766 new nurses for the NHS in England[2]

Every 1 patient added to the average hospital-wide nurse workload increases the risk of death following common surgical procedures by 7%[3]

90% biosimilar use at 50% discount offers £342 million / €391m to reinvest into healthcare

Ref: [1] UK HSIC. Prescribing Costs in Hospitals and the Community England 2014-15. Published 12 Nov 2015. http://www.hscic.gov.uk/catalogue/PUB18973/hosp-pres-eng-201415-report.pdf. Accessed 19 April 2016. [2] Wright O. NHS Spending £1 Billion on Four Drugs as Bill Soars. The Times, 5 Dec 2016. https://www.thetimes.co.uk/article/nhs-spending-1-billion-on-four-drugs-as-bill-soars-m35805xfx. Accessed 31 May 2017. [3] Prospects: Adult Nurse. https://www.prospects.ac.uk/job-profiles/adult-nurse. Accessed 19 April 2018. [4] Aiken LH et al. JAMA. 2002;288:1987-1993.

For Europe: The Budget Impact of a Biosimilar Promotion Policy Can Be Significant

Advances in Therapy
May 2017, Volume 34, Issue 5, pp 1128–1144 | Cite as

The Rituximab Biosimilar CT-P10 in Rheumatology and Cancer: A Budget Impact Analysis in 28 European Countries

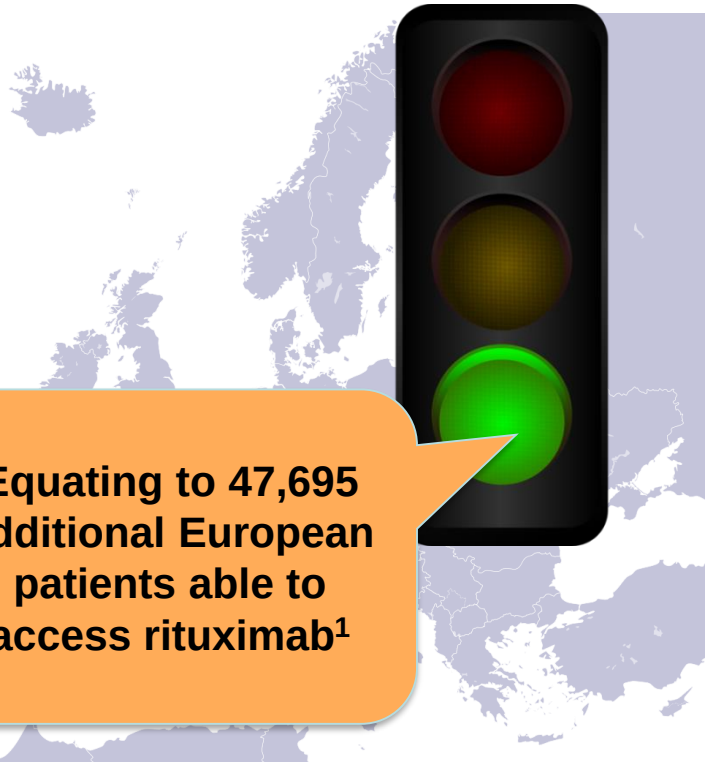
Authors | Authors and affiliations

László Gulácsi, Valentin Brodszky, Petra Baji, Fanni Rencz, Márta Péntek

Assuming 30% price discounts for rituximab[1]

And steady uptake of: 30% year 1 40% year 2 50% year 3[1]

Europe would save €570 million over 3 years[1]



Equating to 47,695 additional European patients able to access rituximab[1]

1. Gulácsi, L et al. *Adv Ther*. 2017;34:1128-1144.

For Europe: The Budget Impact of a Biosimilar Promotion Policy Can Be Significant

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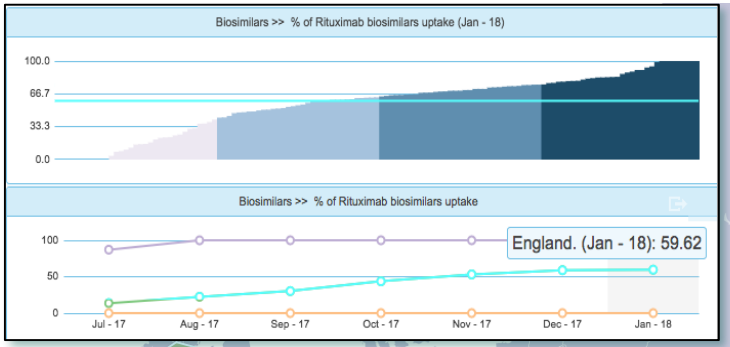

Assuming 30% price discounts for rituximab[1]

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Europe would save €570 million over 3 years[1]

THIS SAVING IS ACHIEVABLE: 6 months from launch – the English National Health Service had already reached 60% biosimilar rituximab use[2]

1. Gulácsi, L et al. *Adv Ther*. 2017;34:1128-1144. 2. NHS Medicines Optimisation Dashboard. https://apps.nhsbsa.nhs.uk/MOD/AtlasTrustsMedsOp/atlas.html. Accessed 14 June 2018.

For the World: The Budget Impact of a Biosimilar Promotion Policy Can Be Significant

- **The 3 bestselling cancer medicines in the world in 2015:**
  - **Rituximab - $7.10bn**
  - **Bevacizumab - $6.74bn**
  - **Trastuzumab - $6.59bn**

As of June 2018, Biosimilars of all 3 are beginning to be approved in Europe and the US

Current cost to world oncology: >$20bn/y

Even moderate 25% discount gives immediate return of $5bn/y for our healthcare systems

50% savings gives $10bn USD

REFS. [1] Pharmaceutical Technology The world's most sold cancer drugs in 2015. 31 Mar 2016. http://www.pharmaceutical-technology.com/features/featurethe-worlds-most-sold-cancer-drugs-in-2015-4852126/. Accessed 15 June 2018. US Food and Drug Administration (FDA). FDA-Approved Biosimilar Products. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm. Accessed 15 June 2018. [2] European Medicines Agency (EMA). Biosimilar Medicines. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_001832.jsp&mid=WC0b01ac0580bb8fda. Accessed 14 March 2018. PMLive Press Release. MSD launches EU's first biosimilar Herceptin in UK. http://www.pmlive.com/pharma_news/msd_launches_eus_first_biosimilar_herceptin_in_uk_1226749. Accessed 15 June 2018.

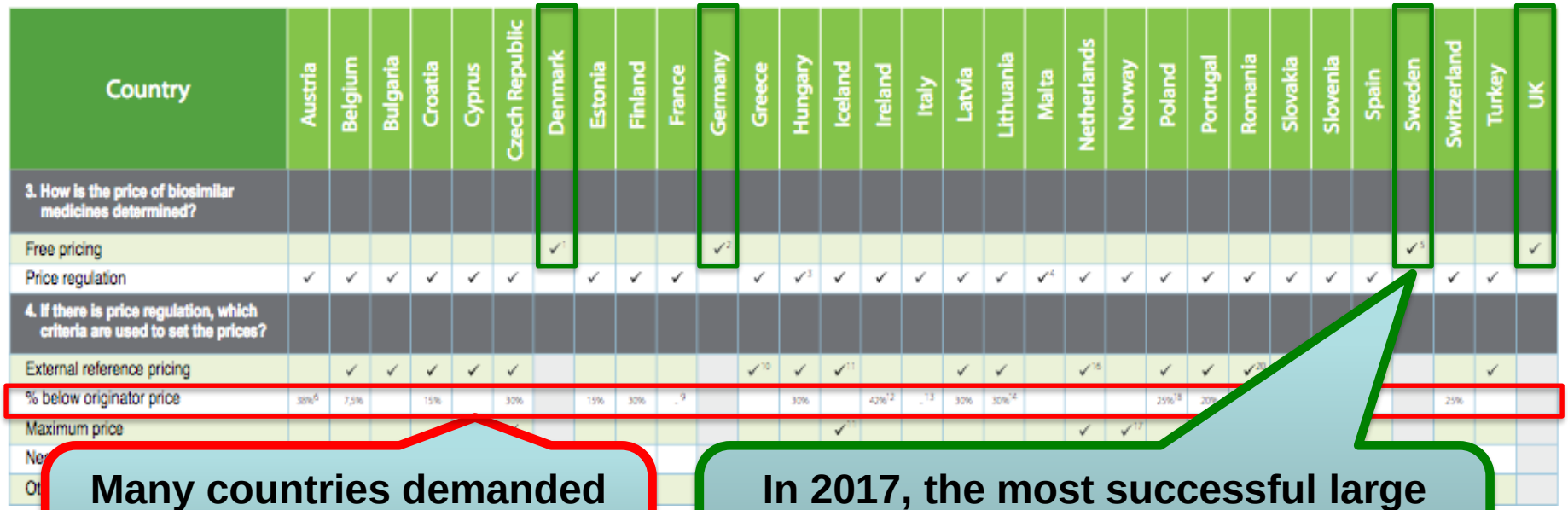
Benefit for Patients May Vary by Country

- **But crucially – every Health System can benefit**

Where there is full access	**Constraints on the drug budget will decline and headroom for innovation may be created**
Where there is partial access or with co-payment	**Reimbursement may become feasible; direct costs for patients may go down**
No access / biologics in general unaffordable	**Patients may get access to live-saving medicines with biosimilars**

Creating a market for biosimilars

- **While health service payers understand the value of biosimilars and all have some promotion of biosimilar use**
  - **European Nations have no uniform approach**



Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
3. How is the price of biosimilar medicines determined?																															
Free pricing							✓[1]				✓[2]																	✓[3]			✓
Price regulation	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓[3]	✓	✓	✓	✓	✓	✓[4]	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
4. If there is price regulation, which criteria are used to set the prices?																															
External reference pricing		✓	✓	✓	✓	✓						✓[10]	✓	✓[11]			✓	✓		✓[16]		✓	✓	✓[20]						✓	
% below originator price	38%[5]	7,5%		15%		30%		15%	30%	-[9]			30%		42%[12]	-[13]	30%	30%[14]				25%[18]	20%						25%		
Maximum price														✓[21]						✓	✓[17]										
Ne																															
Ot																															

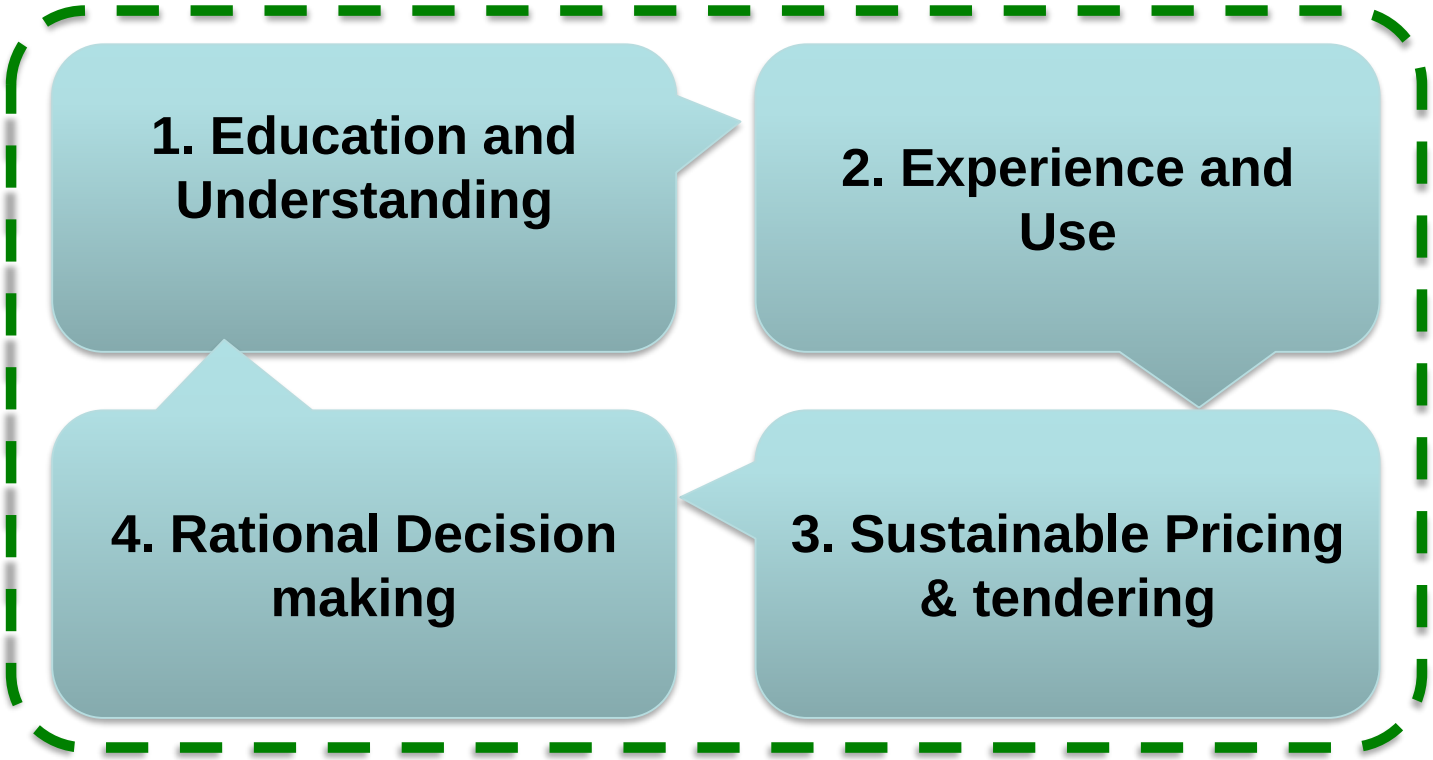
Many countries demanded reference price cuts of 7.5-42% (42% Ireland)

In 2017, the most successful large health systems for biosimilar uptake have used only tenders to set prices

Ref: [1] Market review – biosimilar medicines markets 2017. Medicines For Europe. http://www.medicinesforeurope.com/wp-content/uploads/2017/09/Market-Review-biosimilar-medicines-market-2017.pdf. Accessed April 18, 2018

Creating a market for biosimilars

- **Four elements, considered holistically, provide a "Sustainability Policy Framework" for the biosimilar medicines market:**

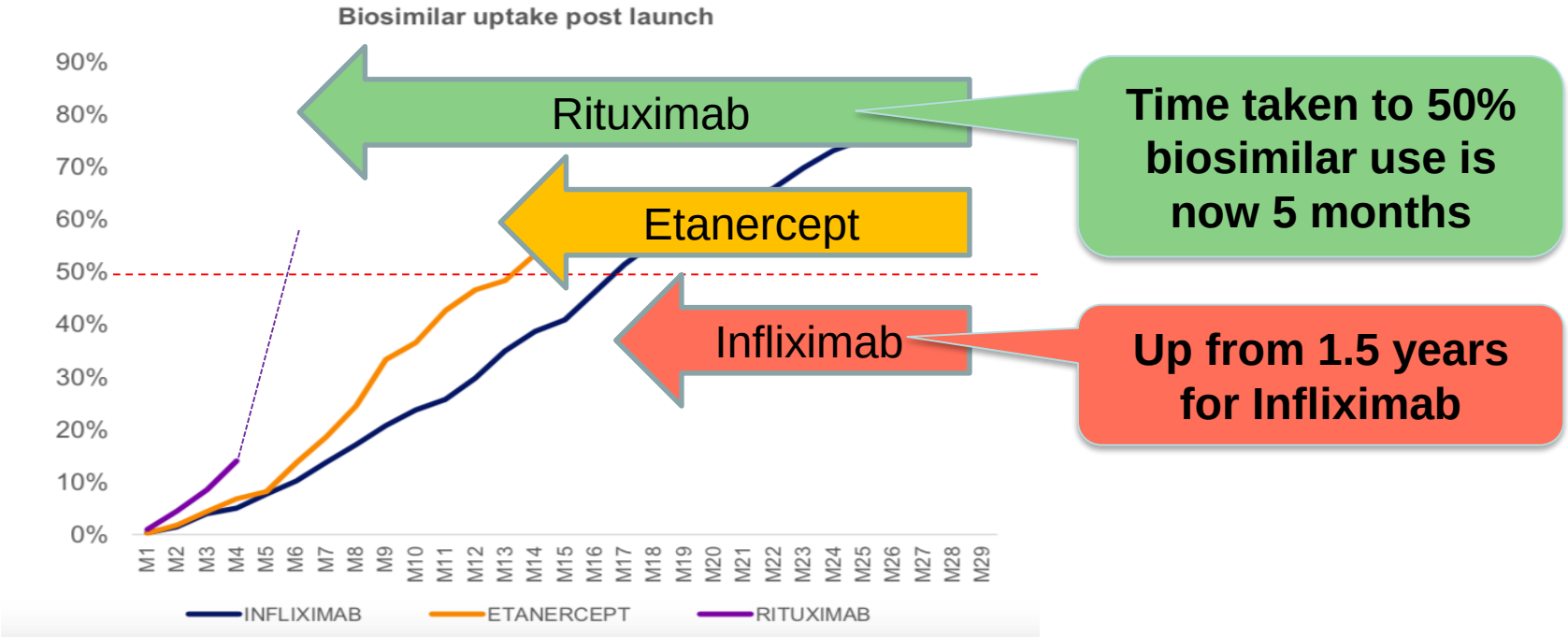


Ref: [1] GfK Market Access & the European Biosimilars Group. Report - Factors Supporting a Sustainable European Biosimilar Medicines Market,September 2014. www.medicinesforeurope.com/.../GfK_Final_Report-_Factors_Supporting_a_Sustaina... Accessed April 18, 2018

Enhanced Biosimilar use is safe and achieveable

- **IMS/IQ-VIA data now suggests that NHS England is the fastest adopting health system of the big European nations**

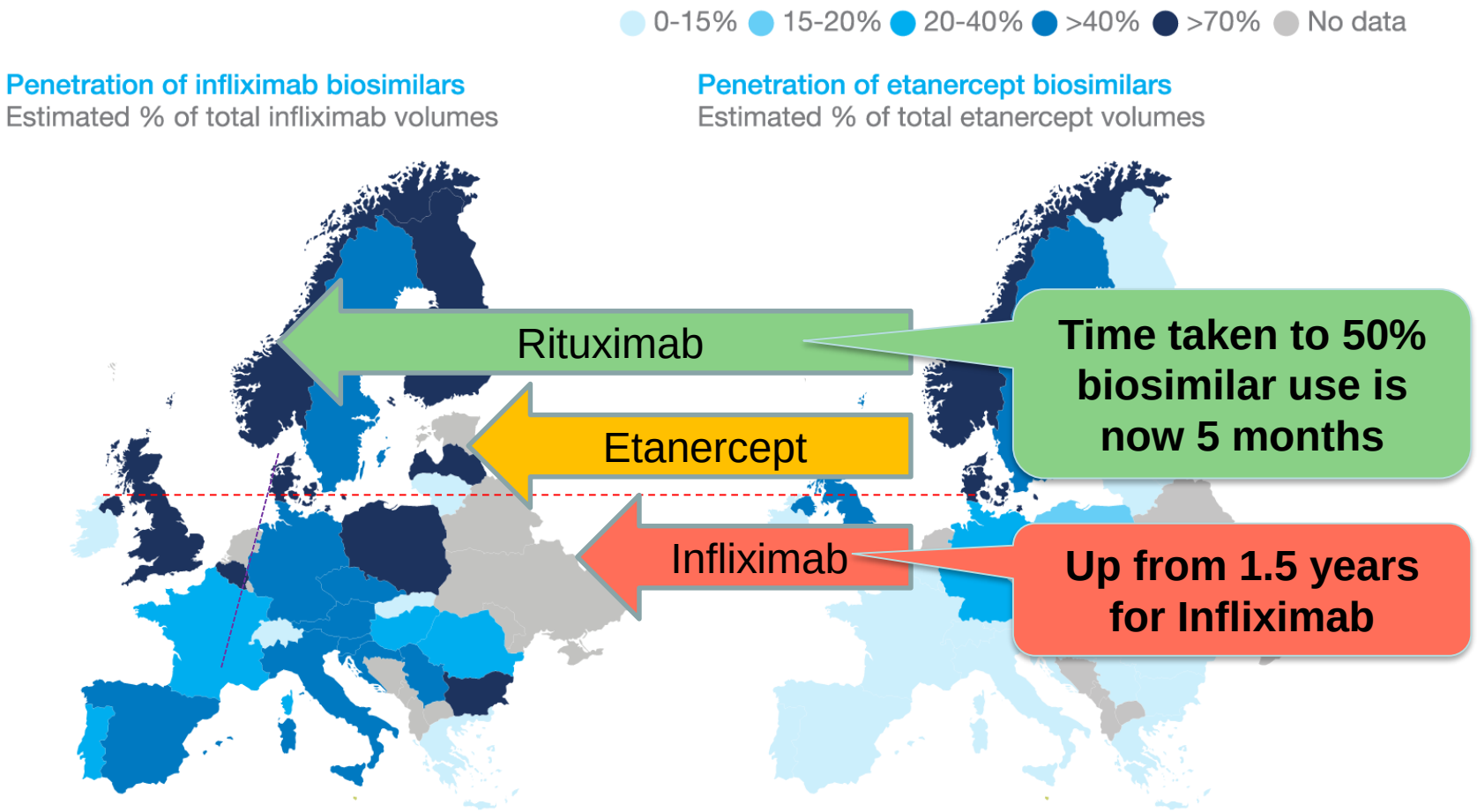
- **With each new class of biosimilars launch – the NHS has shown a learning cycle for implementation and access**



Ref: [1]. NHS England uptake data – from the NHS Medicines Optimisation Dashboard

Use of biosimilars shows striking geographic variation

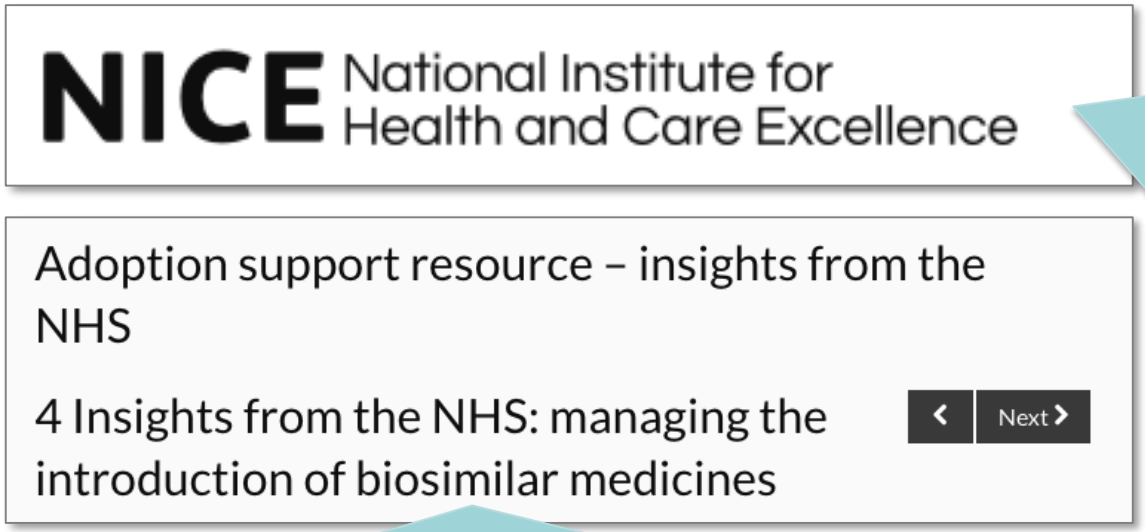
- **Example: Infliximab & etanercept Biosimilars in Europe, 2017**



Ref: [1]. Ying Chen et al. Five things to know about biosimilars right now. McKinsey July 2018. https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/five-things-to-know-about-biosimilars-right-now. Accessed Sept 13, 2018

UK National Health Service – Centralised Biosimilars strategy

- **Has evolved from experience of small regional programmes**
- **Now centralized into one National Strategy**



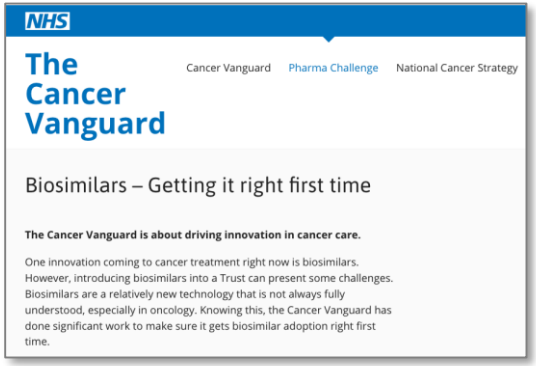
The costs of switching to a biosimilar for a hospital were offset by a "Gainshare Agreement"

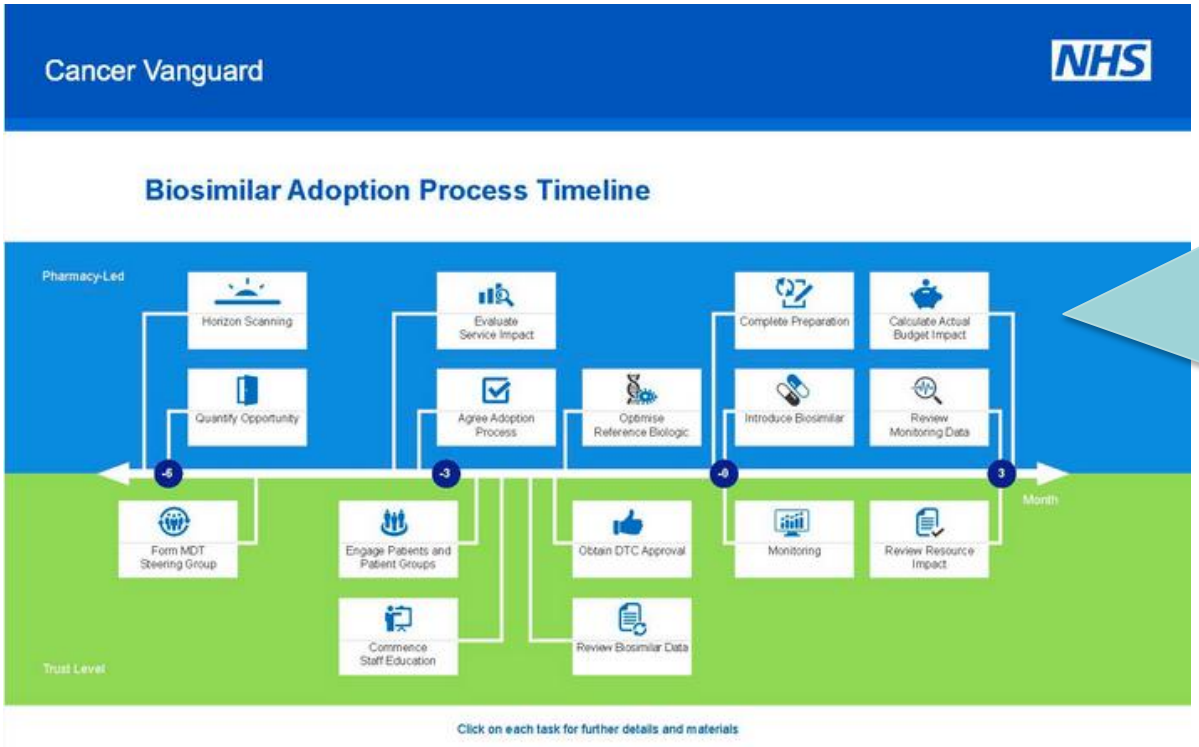
"Gainshare Agreement": Financial savings created by switching to a biosimilar were shared by the payer – funding additional hospital staff to manage the switch and reward cost-effective prescribing behaviour

Ref: [1]. Adoption support resource – insights from the NHS. 4 Insights from the NHS: managing the introduction of biosimilar medicines. https://www.nice.org.uk/guidance/ta329/resources/adoption-support-resource-insights-from-the-nhs-493818736/chapter/4-Insights-from-the-NHS-managing-the-introduction-of-biosimilar-medicines. Accessed Aug 20, 2018.

UK National Health Service – Centralised Biosimilars strategy for cancer

- NHS regards biosimilars as innovation
- Driven by a specific education and information strategy “Cancer Vanguard”





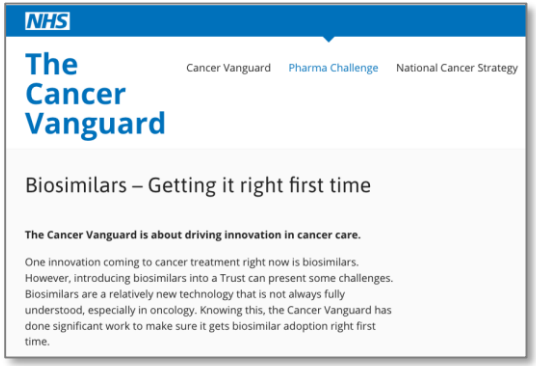
Interactive website to reach key resources:

- Slide Sets
- Audio
- Service Impact Study
- Key Documents

Ref: [1]. The Cancer Vanguard - Biosimilars – Getting it right first time. NHS. http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/. Accessed Aug 20, 2018

UK NHS

- **NHS regards biosimilars as innovation**
- **Driven by a specific education and information strategy “Cancer Vanguard”**


NHS

The Cancer Vanguard

Cancer Vanguard | Pharma Challenge | National Cancer Strategy

Biosimilars – Getting it right first time

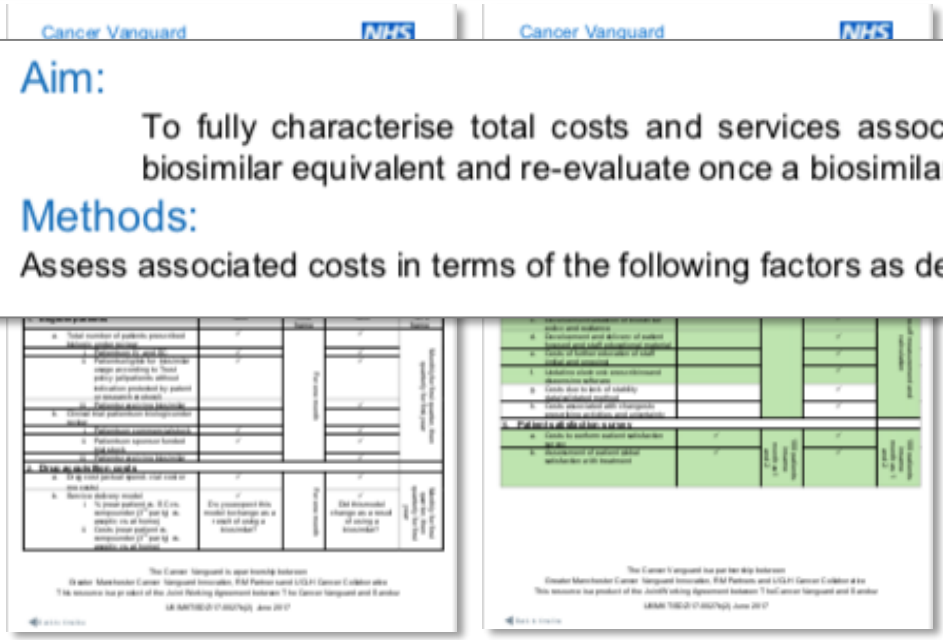
The Cancer Vanguard is about driving innovation in cancer care.

One innovation coming to cancer treatment right now is biosimilars. However, introducing biosimilars into a Trust can present some challenges. Biosimilars are a relatively new technology that is not always fully understood, especially in oncology. Knowing this, the Cancer Vanguard has done significant work to make sure it gets biosimilar adoption right first time.


Cancer Vanguard

NHS

Service Impact Research Study


Cancer Vanguard NHS

Cancer Vanguard NHS

Aim:

To fully characterise total costs and services associated with delivery of a cancer treatment with a biosimilar equivalent and re-evaluate once a biosimilar is in use.

Methods:

Assess associated costs in terms of the following factors as detailed below.

- **Audio**
- **Service Impact Study**
- **Key Documents**

Ref: [1]. The Cancer Vanguard - Biosimilars – Getting it right first time. NHS. http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/. Accessed Aug 20, 2018

UK NHS – Biosimilar Service Impact Studies

- **Record costs of switching brands – and outcomes before and after the change - Including**
  - **Service Costs**

3. Service costs	
a. Counsel +/- consent patients	✓
b. Preparation of patient materials and education	
c. Time associated with clerking patient	✓
d. Administration costs i. Chair time (Vs. total capacity) ii. Monitoring	✓ Is monitoring or chair time requirement expected to change?
e. Resources associated with ensuring reimbursement from commissioners	✓ Do you anticipate use of biosimilars changing your reimbursement process?
f. Costs associated with prescribing or administration errors	

Ref: [1]. The Cancer Vanguard - Biosimilars – Getting it right first time. NHS. http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/. Accessed Aug 20, 2018

UK NHS – Biosimilar Service Impact Studies

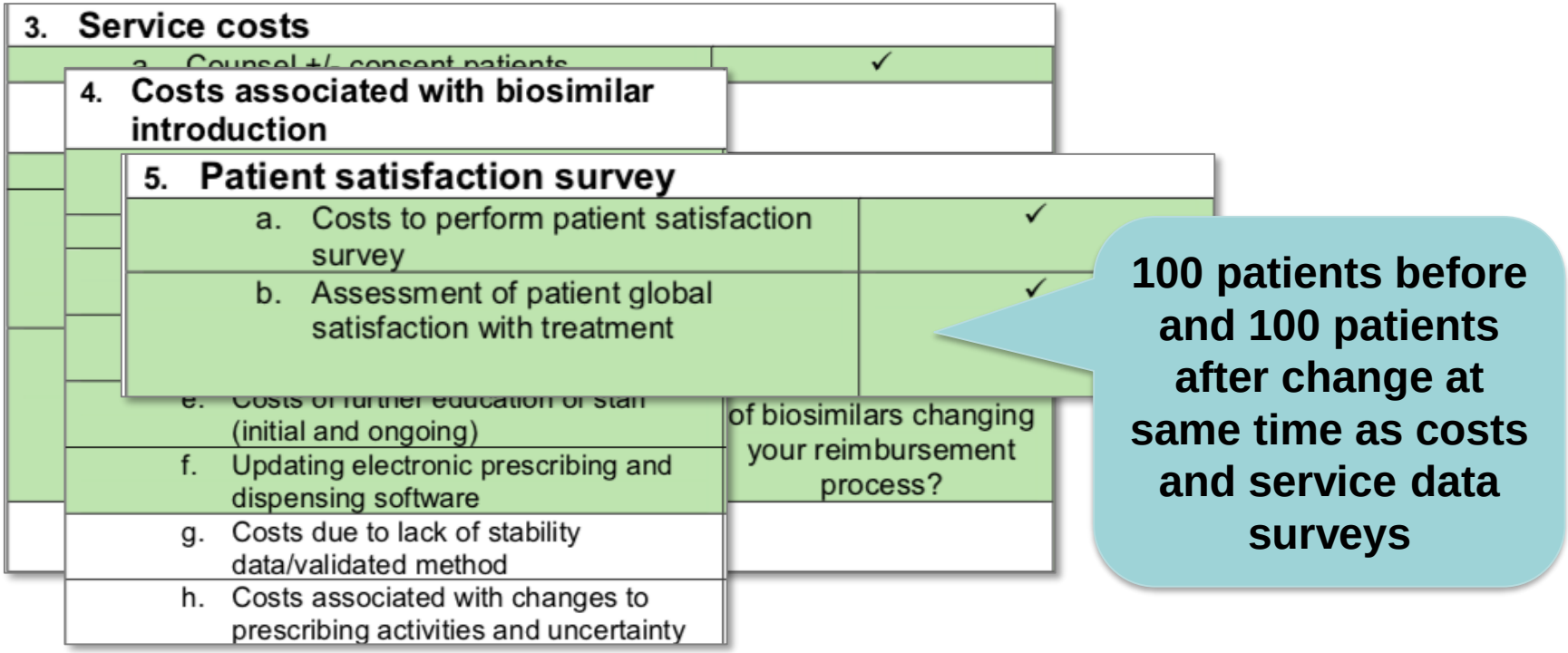
- **Record costs of switching brands – and outcomes before and after the change - Including**
  - **Service Costs, Switching costs**

3.	**Service costs**	
	a. Counsel +/- consent patients	✓
4.	**Costs associated with biosimilar introduction**	
	a. Preparation and validation of aseptic worksheet	✓
	b. Preparation for formulary application	✓
	c. Development/adaption of biosimilar policy and guidance	Is monitoring or chair time requirement expected to change?
	d. Development and delivery of patient focused and staff educational material	✓
	e. Costs of further education of staff (initial and ongoing)	Do you anticipate use of biosimilars changing your reimbursement process?
	f. Updating electronic prescribing and dispensing software	
	g. Costs due to lack of stability data/validated method	
	h. Costs associated with changes to prescribing activities and uncertainty	

Ref: [1]. The Cancer Vanguard - Biosimilars – Getting it right first time. NHS. http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/. Accessed Aug 20, 2018

UK NHS – Biosimilar Service Impact Studies

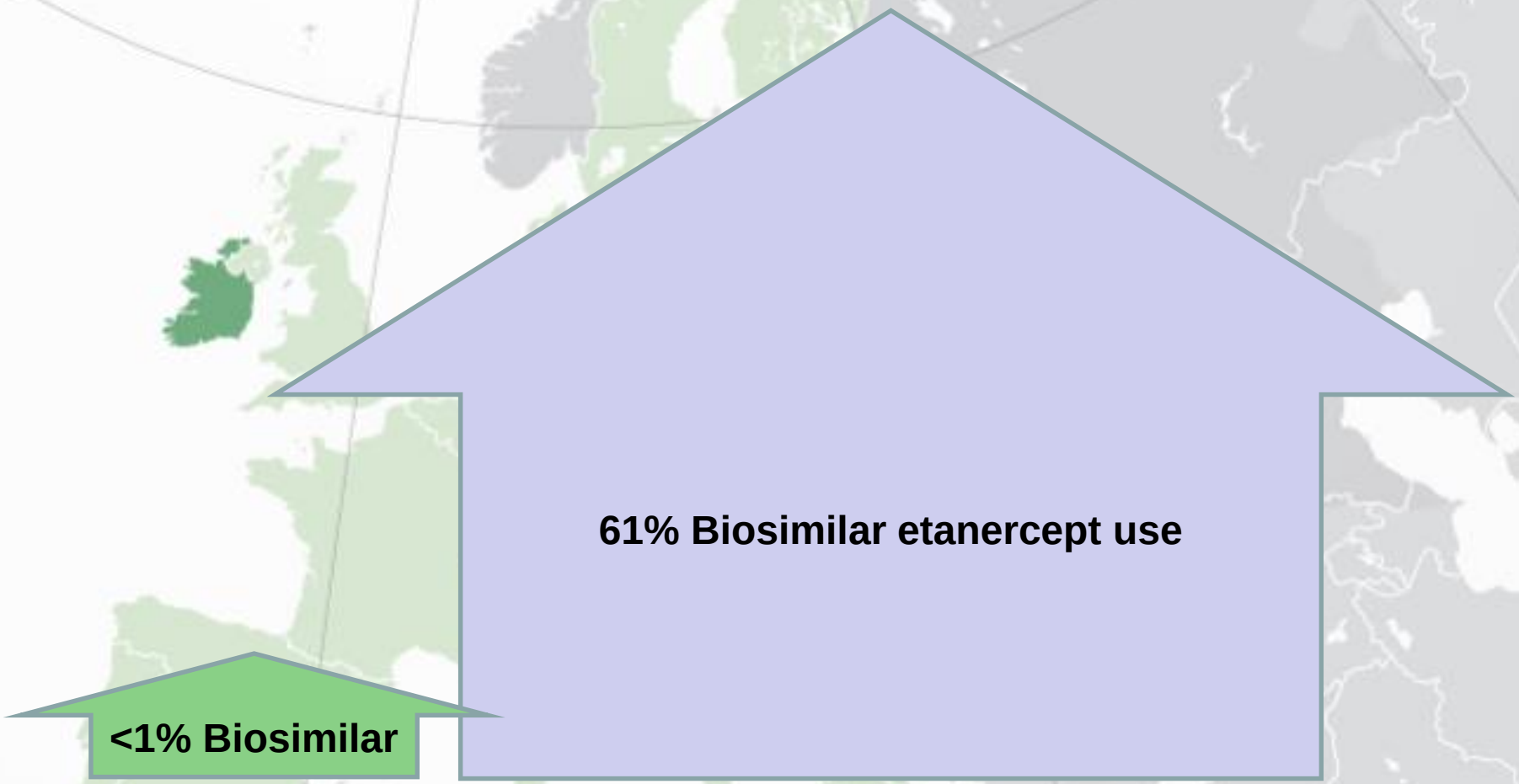
- **Record costs of switching brands – and outcomes before and after the change - Including**
  - **Service Costs, Switching costs, Patient Satisfaction**



Ref: [1]. The Cancer Vanguard - Biosimilars – Getting it right first time. NHS. http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/. Accessed Aug 20, 2018

Biosimilar access May 2017: example etanercept use

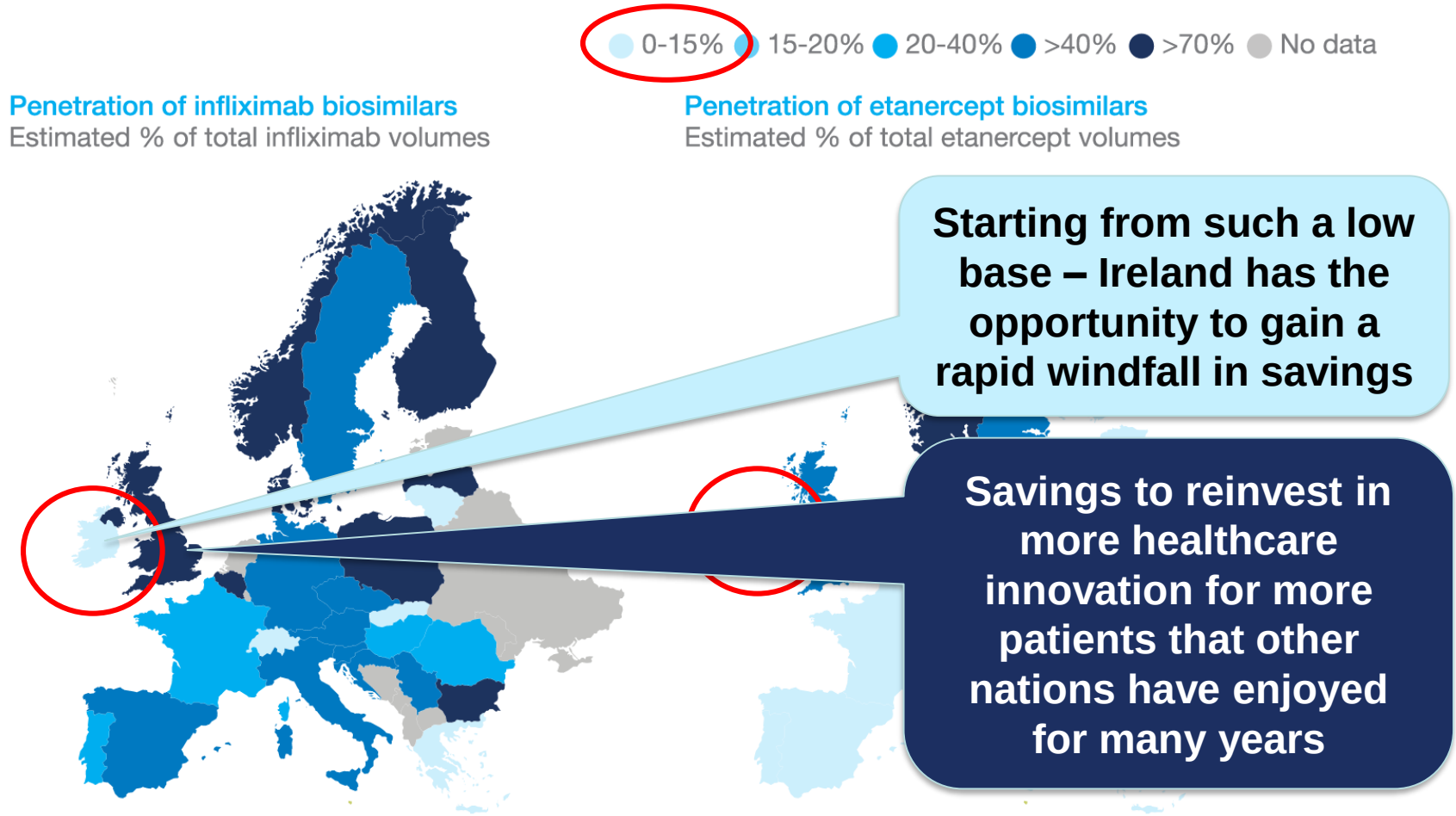
- HSE Ireland May 2017
- NHS England May 2017



Ref: [1]. IRELAND. Map - wikipedia CCO License. https://en.wikipedia.org/wiki/Republic_of_Ireland#/media/File:EU-Ireland.svg. Accessed 23 Oct, 2018. [2] NHS England Medicines Optimisation Dashboard; https://apps.nhsbsa.nhs.uk/MOD/AtlasTrustsMedsOp/atlas.html. Accessed Oct 22, 2018. [3] Medicines for Ireland Policy Manifesto 2017. https://www.medicinesforireland.ie/wp-content/.../Medicines-for-Ireland-Manifesto.pdf. Accessed Oct 22, 2018

Biosimilars for Ireland – the scale of the opportunity

- **Example: Infliximab & etanercept Biosimilars in Europe, 2017**



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Biosimilars for Ireland – the scale of the opportunity

- **Ireland has had historically lower levels of generic prescribing than other European Countries and the USA**
  - **The same is now evident for biosimilars [1]**
- **At 50% discount, optimizing biosimilar use could generate a more than 100 Million Euro annual health improvement budget for no more tax or insurance spend [1]**

Registered Nurse (RN) Salary (Ireland) - PayScale
https://www.payscale.com/research/IE/Job=Registered_Nurse_(RN)/Salary
A Registered **Nurse** (**RN**) earns an average **salary** of €30,784 per year. A skill in Hospice is associated with high **pay** for this job. Most people move on to other jobs if they have more than 20 years' experience in the career.

Sufficient to pay the salary of 3248 new nurses for Ireland [2]

Nurses save lives too - each additional patient per nurse increases hospital mortality 7%
30 day hospital mortality (odds ratio [OR], 1.07; 95% confidence interval [CI], 1.03-1.12) [2]

Ref: [1]. Irish Department of Health. Public Consultation Paper: National Biosimilar Medicines Policy. August 2017. Department of Health, Hawkins House, Hawkins Street, Dublin 2 Ireland. Website: http://health.gov.ie/consultations/. Accessed August 19, 2018. [2] Registered Nurse (RN) Salary (Ireland) - PayScale. https://www.payscale.com/research/IE/Job=Registered_Nurse_(RN)/Salary. Accessed August 19, 2018. [3] Aiken LH et al. Hospital nurse staffing and patient

Biosimilars for Ireland – the scale of the opportunity

- Ireland has had historically lower levels of g
  than other European Countries and the USA
  - The same is now evident for biosimilars [1]

This could be achieved 3 times over without needing *"significantly increased funding"*

The Budget in 2017 has highlighted again that the nursing situation in Ireland is still in crisis. Minister for Health Simon Harris has promised that an additional 1,000 nurses will be recruited using significantly increased funding for the health service. Liam Doran, the general secretary of the Irish Nurses and Midwives Organisa-

experience in th areer.

Sufficient to pay the salary of 3248 new nurses for Ireland [2]

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Biosimilars are needed to sustain affordable cancer care AND healthcare innovation

CONCLUSIONS

- **We need innovation - especially in cancer medicine to cope with disease trends**
  - **if we can sustain innovation at the current rate of improvement we can realistically eradicate cancer deaths in the under 80s by 2050**
- **Funding innovation is a challenge shared by all nations**
  - **All nations have an interest in shared solutions**
- **Ireland has more to gain than most European nations from promoting better value medicines**
  - **Delaying biosimilars policy initiatives risks both future innovation and the sustainability of even current levels of care in the face of Ireland's significant demographic challenges**

Ref: [1]