

Tavola Rotonda

Quali modelli di governance adottare a livello regionale per garantire una gestione sostenibile dell'innovazione in oncologia **A. Santoro**

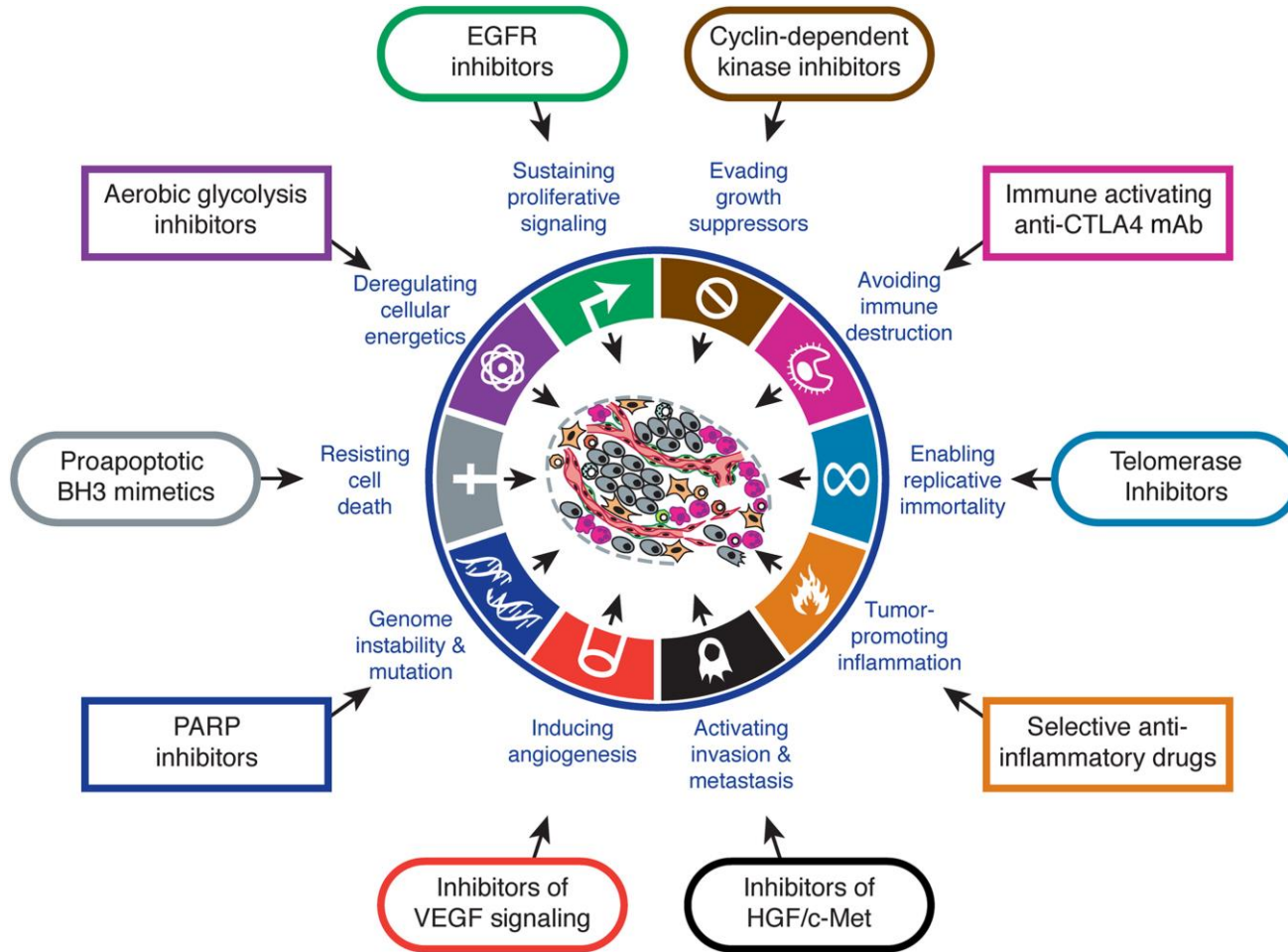
WOKSHOP:

**Il governo della innovazione farmaceutica :
Modelli di gestione sostenibile dei farmaci
oncologici innovativi ad alto costo**

Milano 10 Marzo,2017

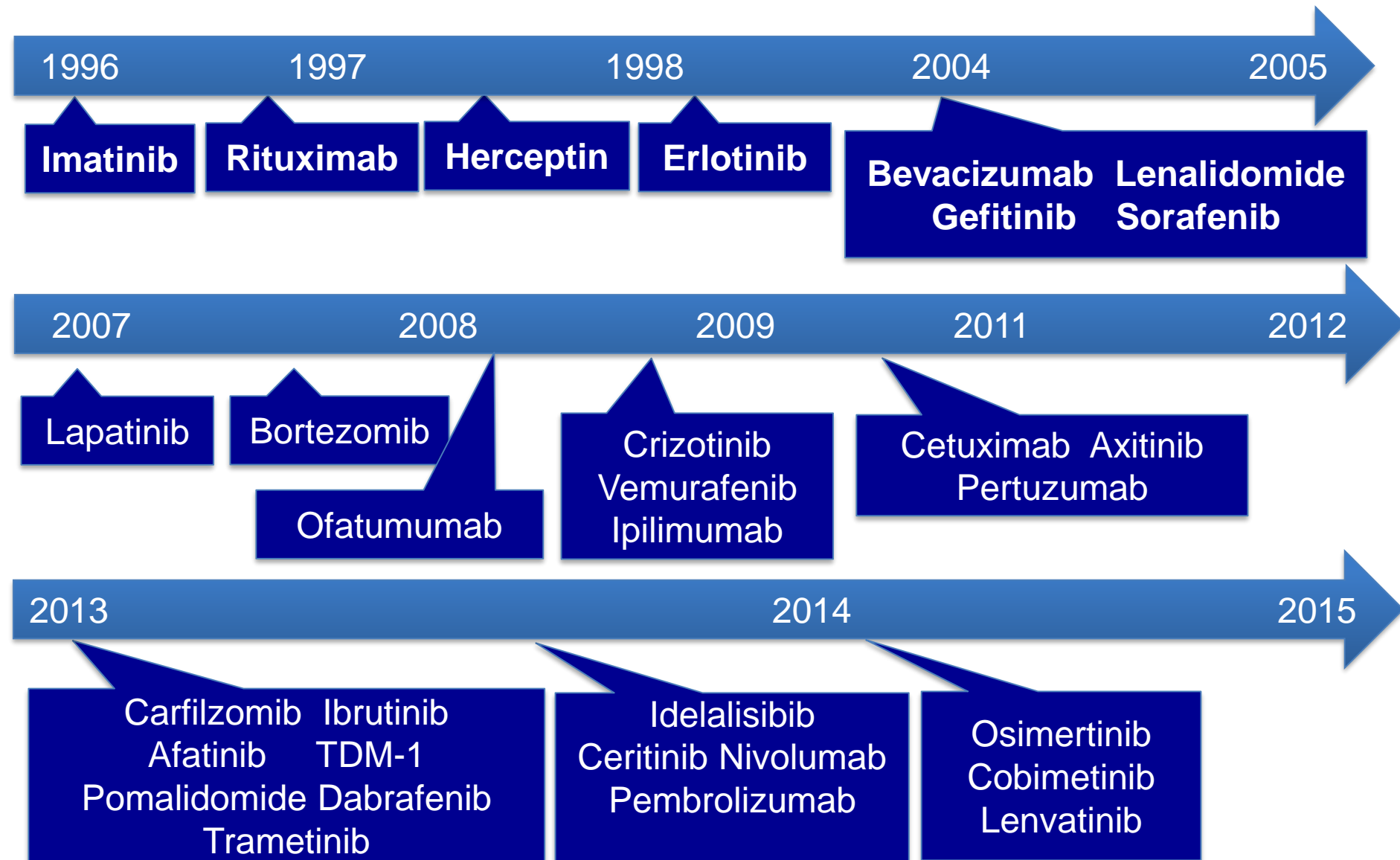


INNOVATIVE STRATEGIES



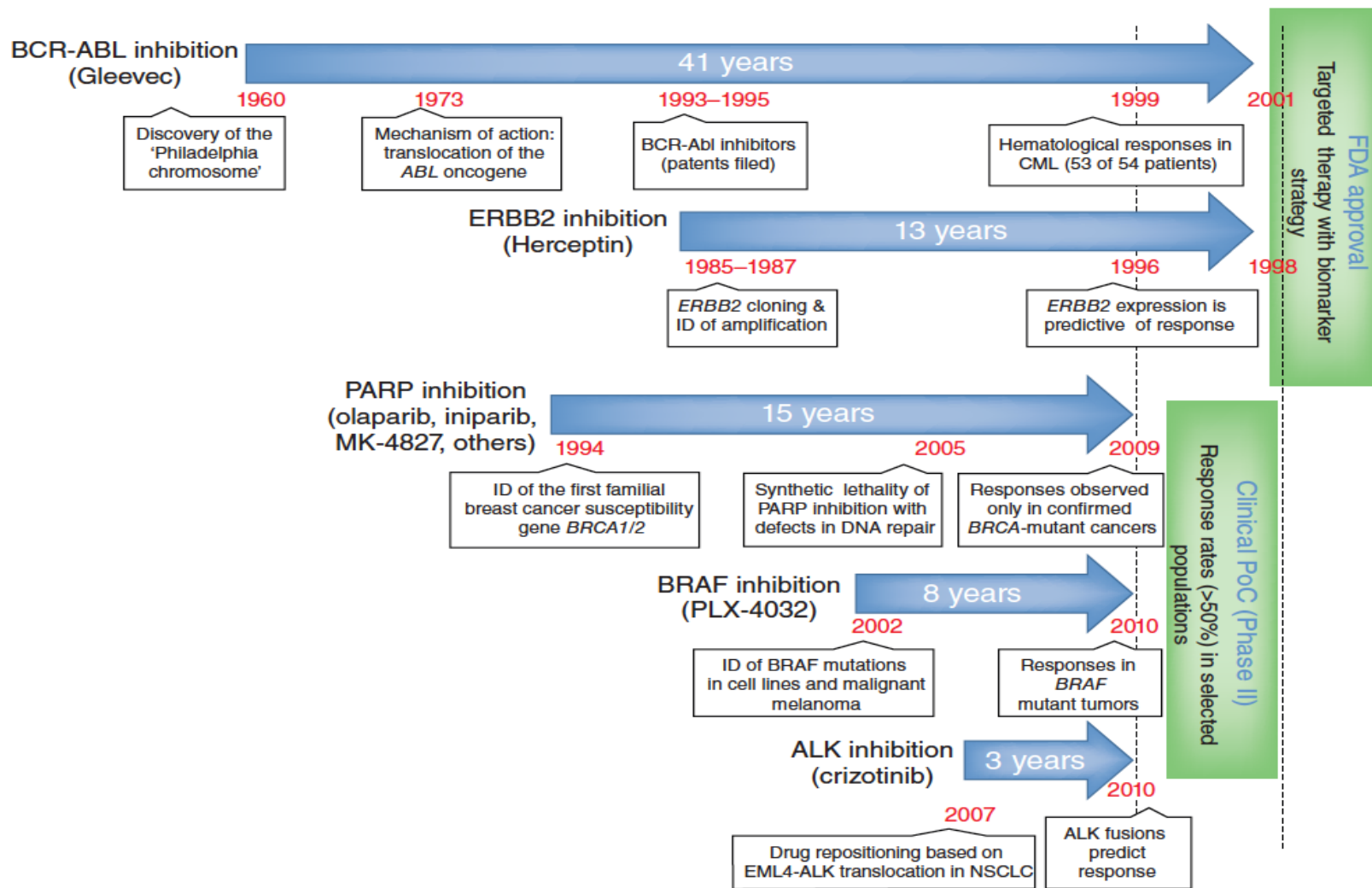
D Hanahan & B Weinberg, 2011

IL VALORE DELLA RICERCA CLINICA



TIMELINE OF FDA APPROVAL FOR NEW ANTICANCER DRUGS

Cancer genetics is accelerating the time of the approval of new drugs



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EVOLUTION VS REVOLUTION

VOLUME 26 · NUMBER 19 · JULY 1 2008

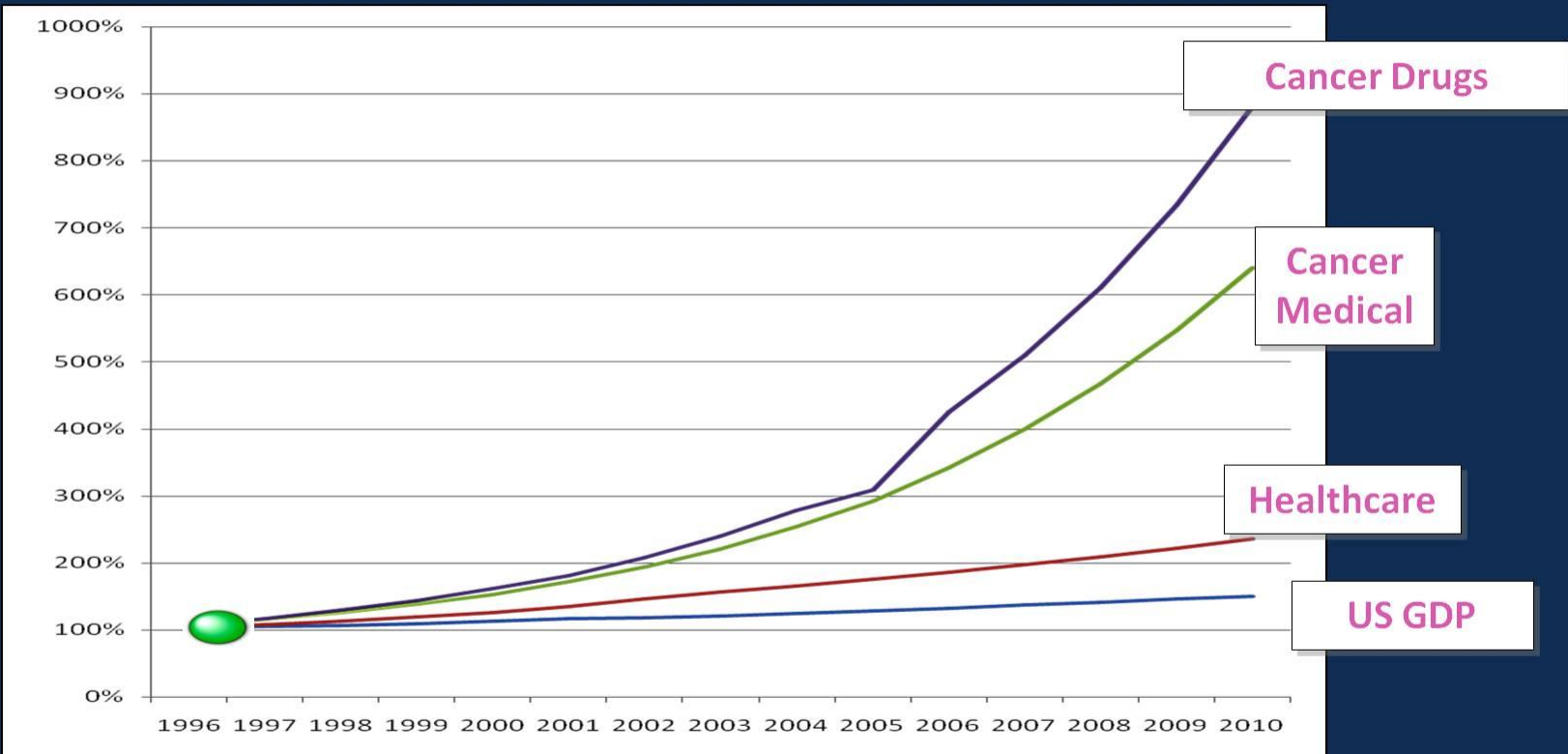
JOURNAL OF CLINICAL ONCOLOGY

CELEBRATING 25 YEARS OF JCO

Lessons From a Time Capsule: Evolution, Not Revolution, in Therapy for Advanced Non–Small-Cell Lung Cancer

Mark R. Green, *Network for Medical Communication and Research Analytics, Atlanta, GA; Medical University of South Carolina, Charleston, SC*

U.S. Cancer Care Spending

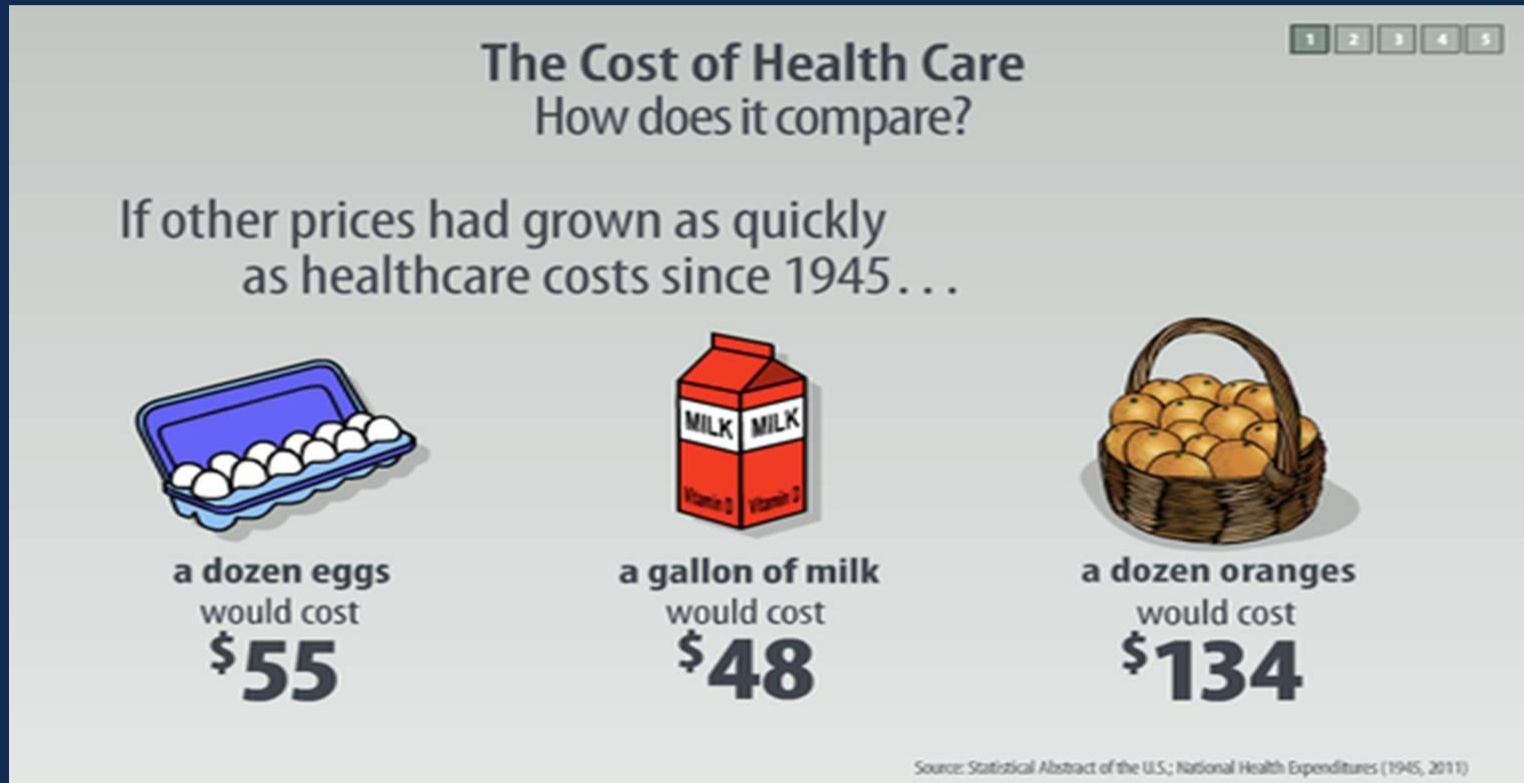


PRESENTED AT: **ASCO ANNUAL MEETING '16**

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Blue Cross Blue Shield Association

U.S. Healthcare Spending



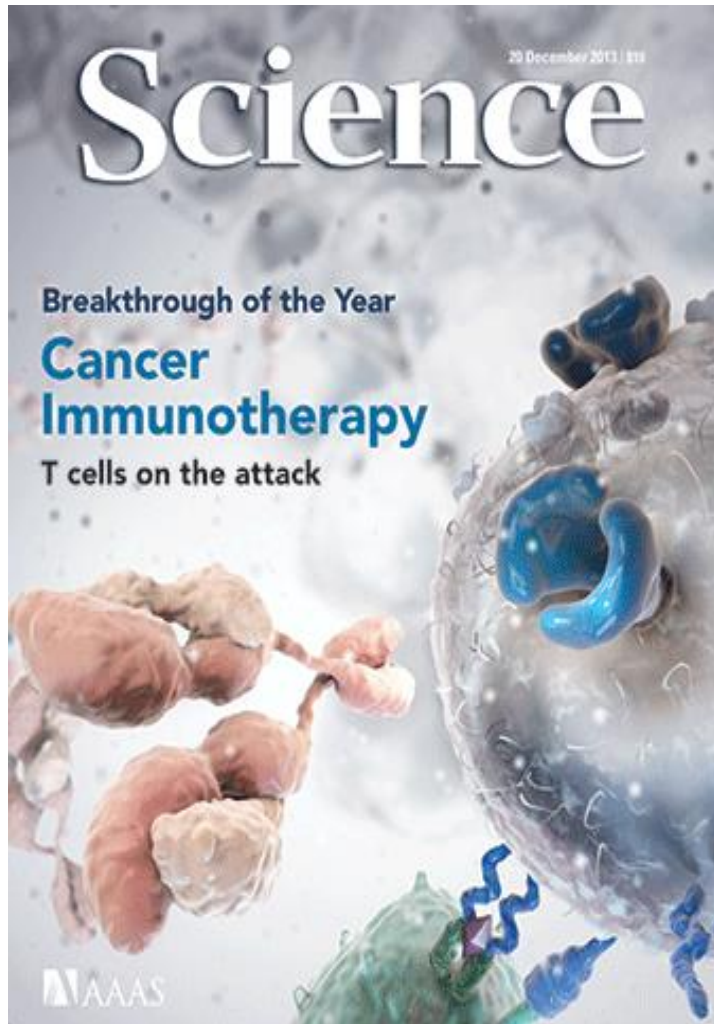
PRESENTED AT: **ASCO ANNUAL MEETING '16**

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Institute of Medicine Report. The Healthcare Imperative: Lowering Costs and Improving Outcomes. Feb 2011

THE KILLER WITHIN

The immune system can be a powerful weapon against cancer — but researchers are still grappling with how to control it.



**“THE GOOD NEWS —
AND THE BAD NEWS —
IS THAT THE IMMUNE
SYSTEM IS INCREDIBLY
POWERFUL.”**

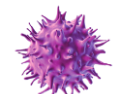
CANCER IMMUNOTHERAPY TODAY

TUMORS RESPONSIVE TO ANTI-PD1 OR ANTI-PD-L1 THERAPY

- ▶ **MELANOMA**
- ▶ **RCC**
- ▶ **NSCLC**
- ▶ **UROTHELIAL CANCER**
- ▶ **HEAD AND NECK CANCER**
- ▶ **MERKEL CELL CARCINOMA**



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



AFFORDABILITY

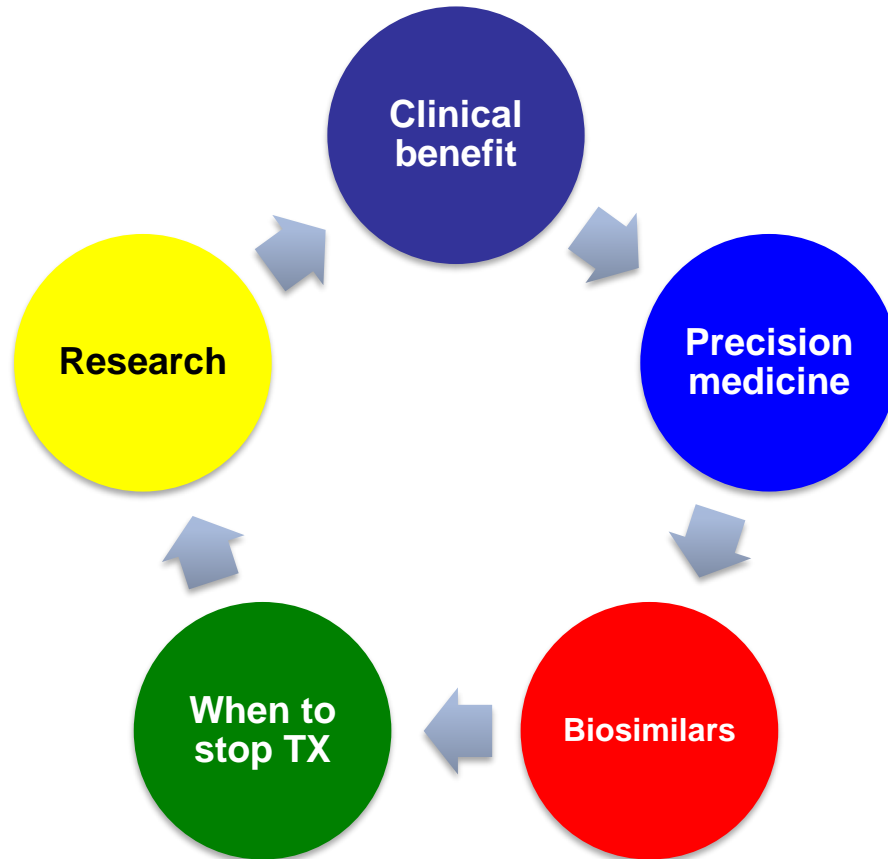


***WHAT
TO DO ?***

***WHICH
END-POINTS?***



HOW TO IMPROVE THE AFFORDABILITY?



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What Determines A Morally Justifiable “Just Price” For Cancer Drug ?

KANTARJIAN et al, Blood 2013

If drug price reflects value, then it should be proportional to the benefit in objective measures, such as survival prolongation, tumor shrinkage or improved quality of life



**American Society of Clinical Oncology Perspective:
Raising the Bar for Clinical Trials by Defining Clinically
Meaningful Outcomes**

Lee M. Ellis, David S. Bernstein, Emile E. Voest, Jordan D. Berlin, Daniel Sargent, Patricia Cortazar, Elizabeth Garrett-Mayer, Roy S. Herbst, Rogerio C. Lilenbaum, Camelia Sima, Alan P. Venook, Mithat Gonen, Richard L. Schilsky, Neal J. Meropol, and Lowell E. Schnipper

JCO 2014

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Delivering affordable cancer care in high-income countries

Sullivan et al, Lancet Oncology 2012

The cancer profession and industry should take responsibility and not accept a substandard evidence base and an ethos of very small benefit at whatever cost; rather, we need delivery of fair prices and real value from new technologies

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“the clinically valid comparison is between strategies of overall, not just primary treatment”

JM Connors NEJM, 2011



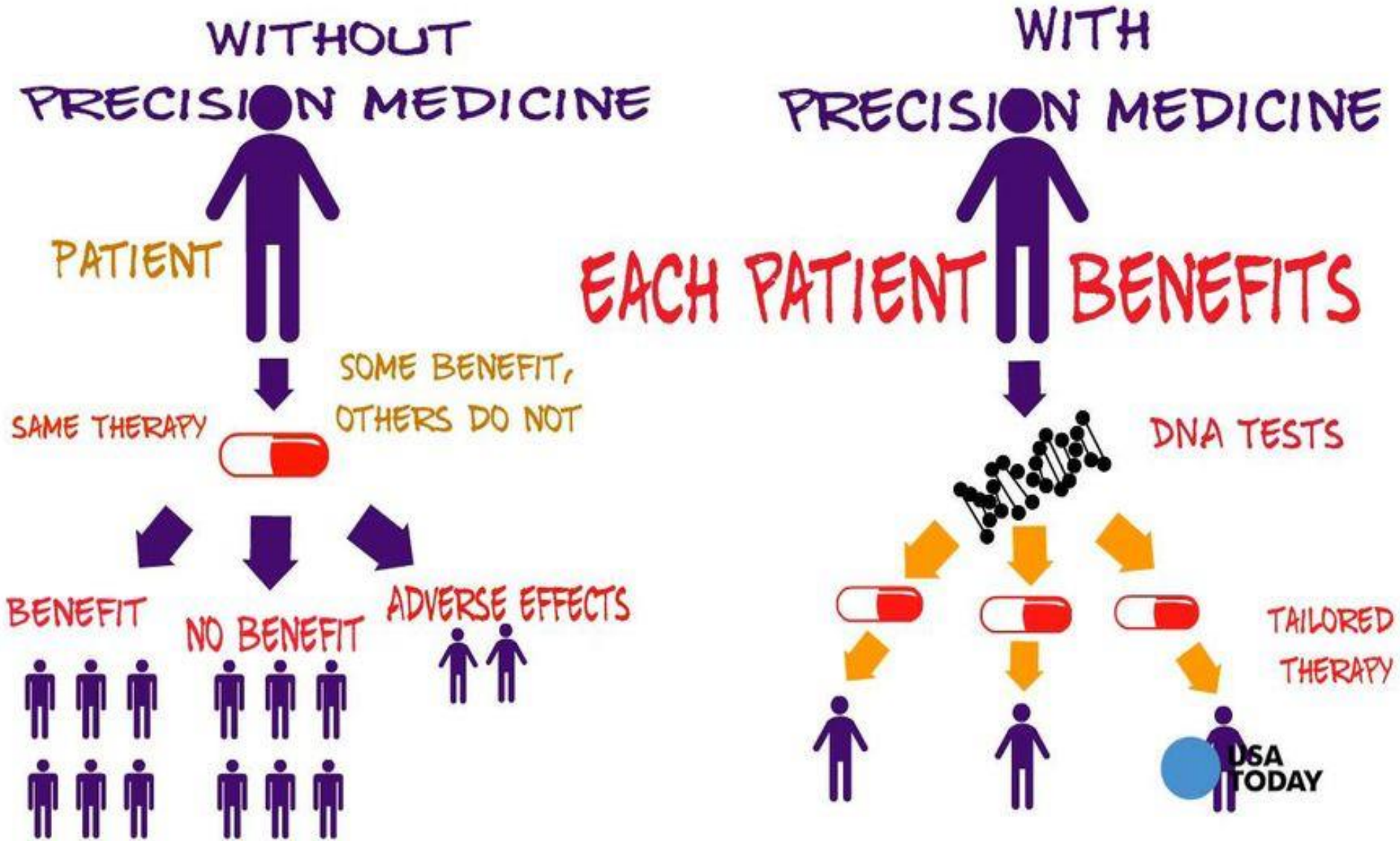
A New Initiative on Precision Medicine



PRESIDENT OBAMA'S PRECISION MEDICINE INITIATIVE WOULD
**HELP DEVELOP BETTER TREATMENTS
FOR DISEASES LIKE CANCER BY:**

- Accelerating the design and testing of effective **treatments tailored to individual patients**
- Expanding genetically based clinical cancer trials
- Establishing a national "**cancer knowledge network**" to guide treatment decisions

LOOKING FOR THE TARGET: WHERE WE ARE?



BIOSIMILARS :WHERE WE ARE?

Table 6 EF sales of biotech with patent expiring in the period 2013–2019 and potential savings induced early by biosimilar mABs, assuming that market availability of the biosimilar mABs occurs immediately after the expiry of biotech patent

Biotech drugs	Patent expiring	Sales 2011	Months of patent expiring per year		Potential savings per year	
			Years	Months		
Rituximab	02/11/2013	176,007,618	2013	2	12,320,533	2013
Rituximab			2014	10	84,415,495	2014
Trastuzumab	29/07/2014	222,483,457		5		
Infliximab	13/08/2014	134,510,848		4		
Cetuximab	15/09/2014	35,629,693		3		
Trastuzumab			2015	7	159,616,552	2015
Infliximab				8		
Cetuximab				9		
Etanercept	02/02/2015	311,865,813		10		
Etanercept			2018	2	15,593,291	2016
Adalimumab	16/04/2018	263,207,565		8	52,641,513	2018
Adalimumab			2020	4		2019
Bevacizumab	16/12/2019	124,042,200		12	63,533,416	2020
TOTAL		1,267,747,194			388,120,800	

WHEN TO STOP THERAPY?

Palliative chemotherapy leads to more deaths away from home

Terminally ill patients with cancer who receive chemotherapy in the last months of their lives are more likely to die in hospital than at home, say US researchers.

Findings from Alexi A Wright and colleagues' cohort study draw attention to the need for discussion between doctors, patients, and their families about the harms and benefits of palliative chemotherapy.

Previous studies have not examined whether the use of chemotherapy in the months leading up to a patient's death is associated with the need for intensive medical care and subsequently an increased risk of dying in an intensive-care unit.

Wright and colleagues examined data from the Coping with Cancer trial, which followed-up 386 terminally ill patients with cancer. 216 (56%)

patients were receiving chemotherapy for an average of 4 months before death.

Their findings showed that patients who were receiving palliative chemotherapy were more likely to die in an intensive-care unit (11% vs 2%; adjusted risk difference 6.1%, 95% CI 1.1 to 11.1; $p=0.02$) and less likely to die at home (47% vs 66%; -10.8% , -1.0 to -20.6 ; $p=0.03$), compared with patients who were not. Those receiving palliative chemotherapy were also less likely to die in their preferred place compared with those who were not (65% vs 80%; adjusted risk difference -9.4% , -0.8 to -18.1 ; $p=0.03$).

Jane Maher, from Macmillan Cancer Support (London, UK), said: "As more cancer patients have chemotherapy in the last months of life, it's become harder for oncologists to present infor-

mation to their patients in the right way to help them to make the right decisions. The impact of chemotherapy on the mode of death has been under-researched and this study is a helpful addition to the literature."

She continued: "early involvement of specialist palliative care at the same time as having chemotherapy can make a real difference to the chances of dying in the place of choice and avoiding inappropriate invasive procedures."

Martin Ledwick of Cancer Research UK (London, UK), added: "It raises interesting issues around having clear objectives for treating patients with terminal cancer and questions about whether patients receiving palliative chemotherapy truly understand the objectives of their treatment."

Sanjay Tandy



Lea Peterson/Science Photo Library

Published Online
March 7, 2014
[http://dx.doi.org/10.1016/S1470-2045\(14\)70111-1](http://dx.doi.org/10.1016/S1470-2045(14)70111-1)
For the **study** see *BMJ* 2014;
Published online March 4.
DOI:10.1136/bmj.g1219

