

2019 NEWS IN ONCOLOGY – 13° CONGRESSO NAZIONALE AIOM GIOVANI

PERUGIA, 5 – 6 Luglio

L'ACCESSO ALL'INNOVAZIONE IN ONCOLOGIA: QUALI MECCANISMI?

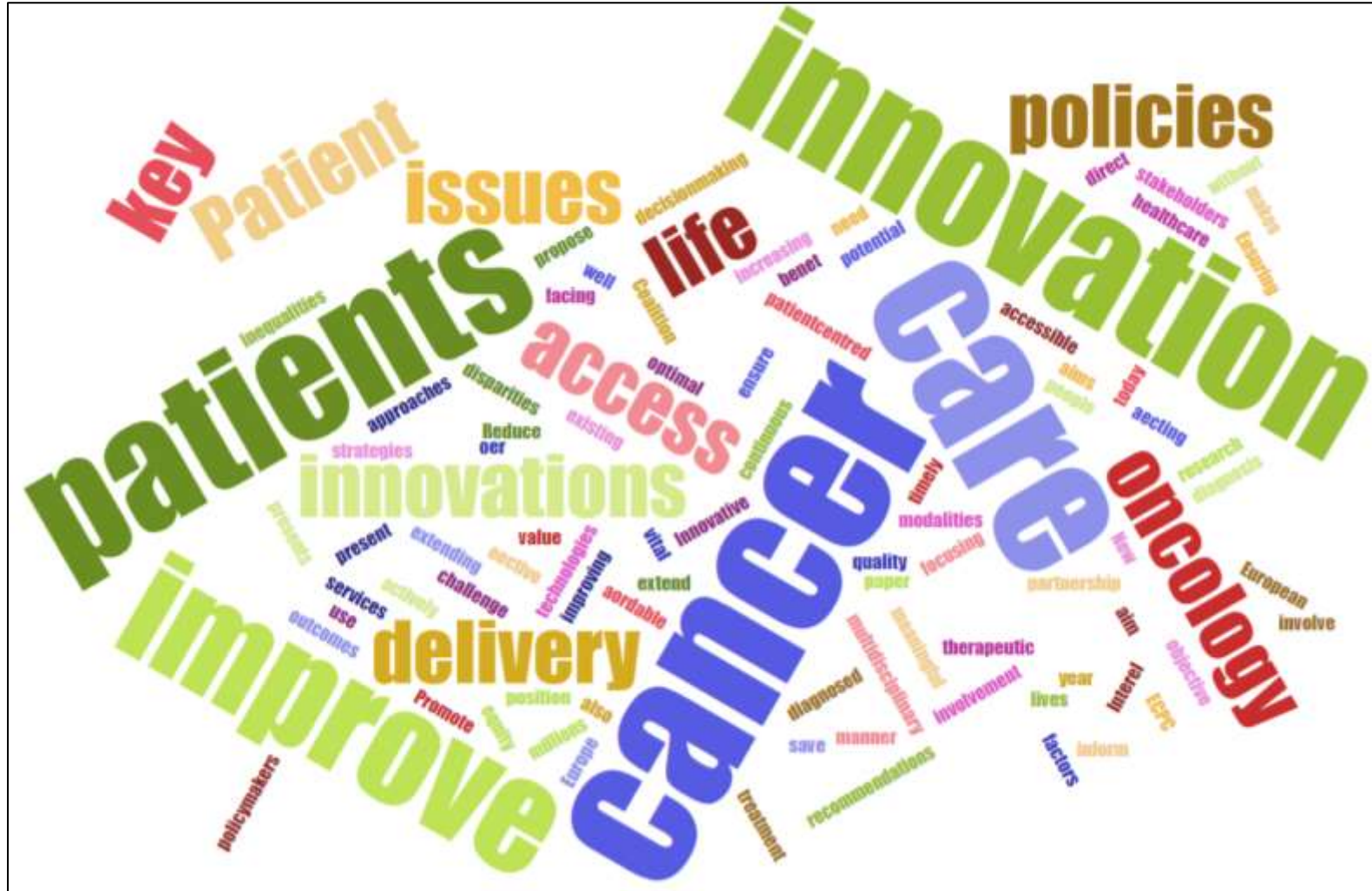
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WHAT'S THE INNOVATION IN ONCOLOGY?



Cloud based on «The value of innovation in Oncology – European Cancer Patient Coalition»

THE VALUE OF INNOVATION IN ONCOLOGY –

Innovative healthcare technologies, strategies and services offer the potential **to save, improve and extend the lives** of millions of people diagnosed with cancer each year.

Ensuring that effective innovations are **accessible** in a **timely and affordable** manner to all patients is a challenge facing all stakeholders in cancer care.

New approaches to both **cancer policies and care delivery** issues will be vital to ensure that innovations improve patient outcomes without increasing disparities.

As we have continuous innovation in cancer research, diagnosis and treatment, so we also need **innovation in cancer policies and care delivery**

WHAT IS **NOT** ACCESS TO INNOVATION IN ONCOLOGY?

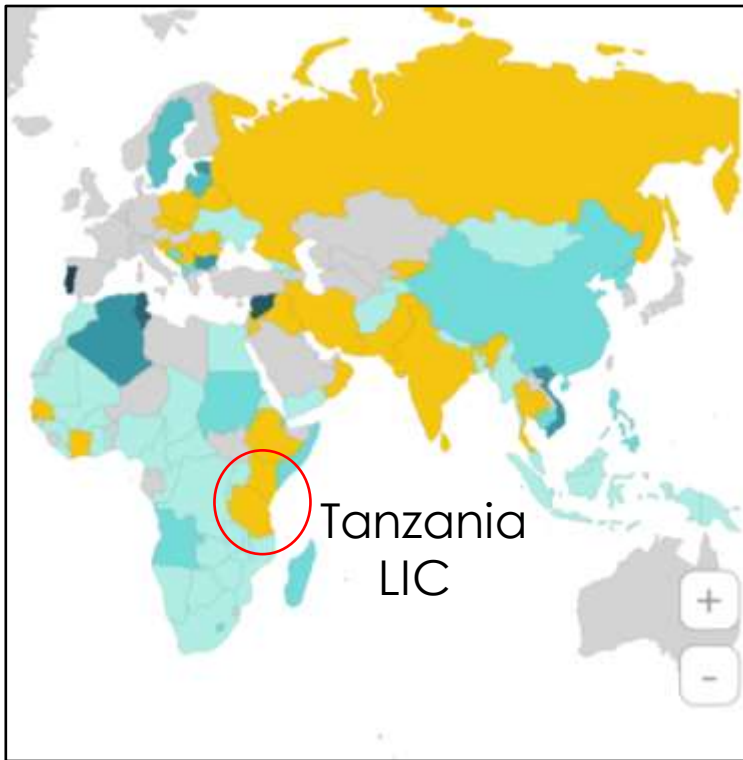


VALUE IN REAL WORLD CANCER POLICY

#1 Prioritise «new» drugs regardless their intrinsic value

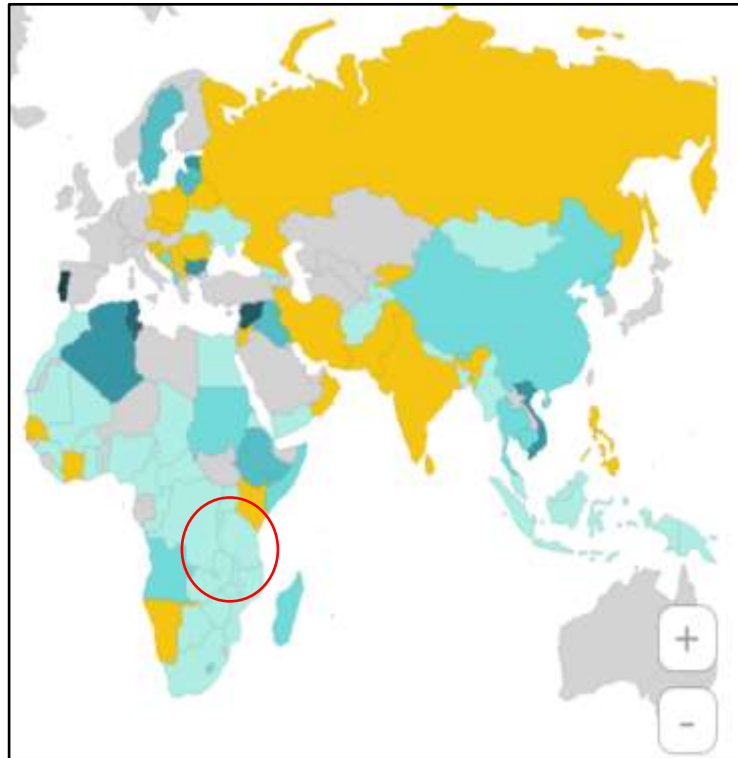
Non EML

Bevacizumab



EML

Trastuzumab



EML

Imatinib



EML, WHO essential medicine
essentialmeds.org

RECENT TRENDS IN BENEFITS OF MEDICINES APPROVED BY REGULATORY AGENCIES

#2 Hype in Oncology

- Overall Survival
- Progression-free
- ORR
- Tumor markers
- Mets-free
- Δ SUV

- ITT
- Subgroup (stratified)
- Subgroup (exploratory)

Δ HR

48 cancer medicines*

2009 - 2013

68 indications

57% of approved indications: evidence from pivotal registration trials showed **no benefits** for either overall survival or quality of life.



All approved medicines

2002 - 2014 #

Cancer indication

mOS: **+2,1 mo**

mPFS: **+2,5 mo**

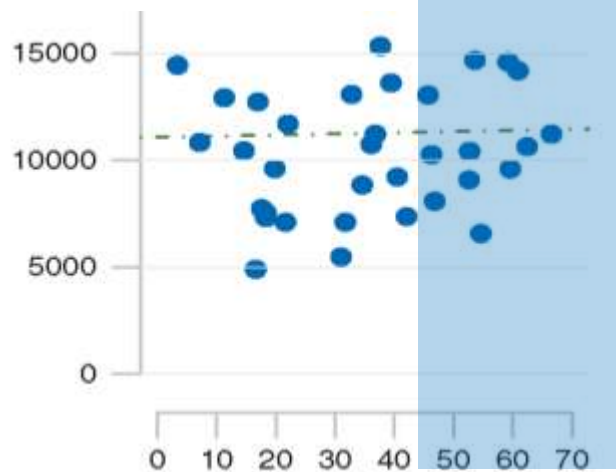


* EMA # FDA

THE GREATEST VALUE IS IN CLARITY

#3 Unrealistic optimism

ASCO- VF NHB



USD/month
DrugAbascus

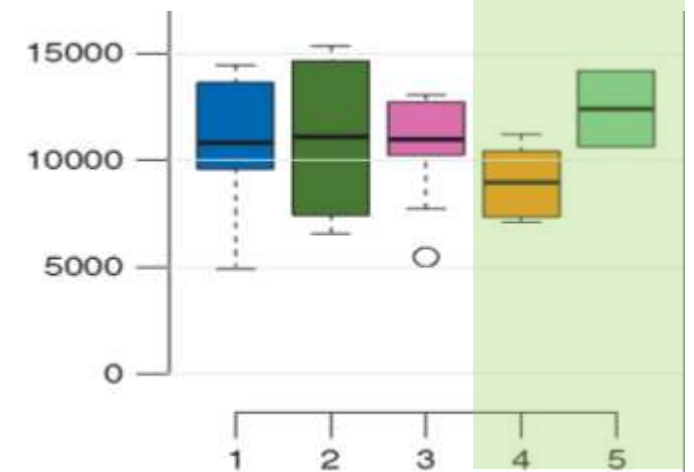
$[R^2 = 0, P = 0.93]$

New cancer
medicines
FDA approved
(2000-2015)

Advanced solid tumours

N=37

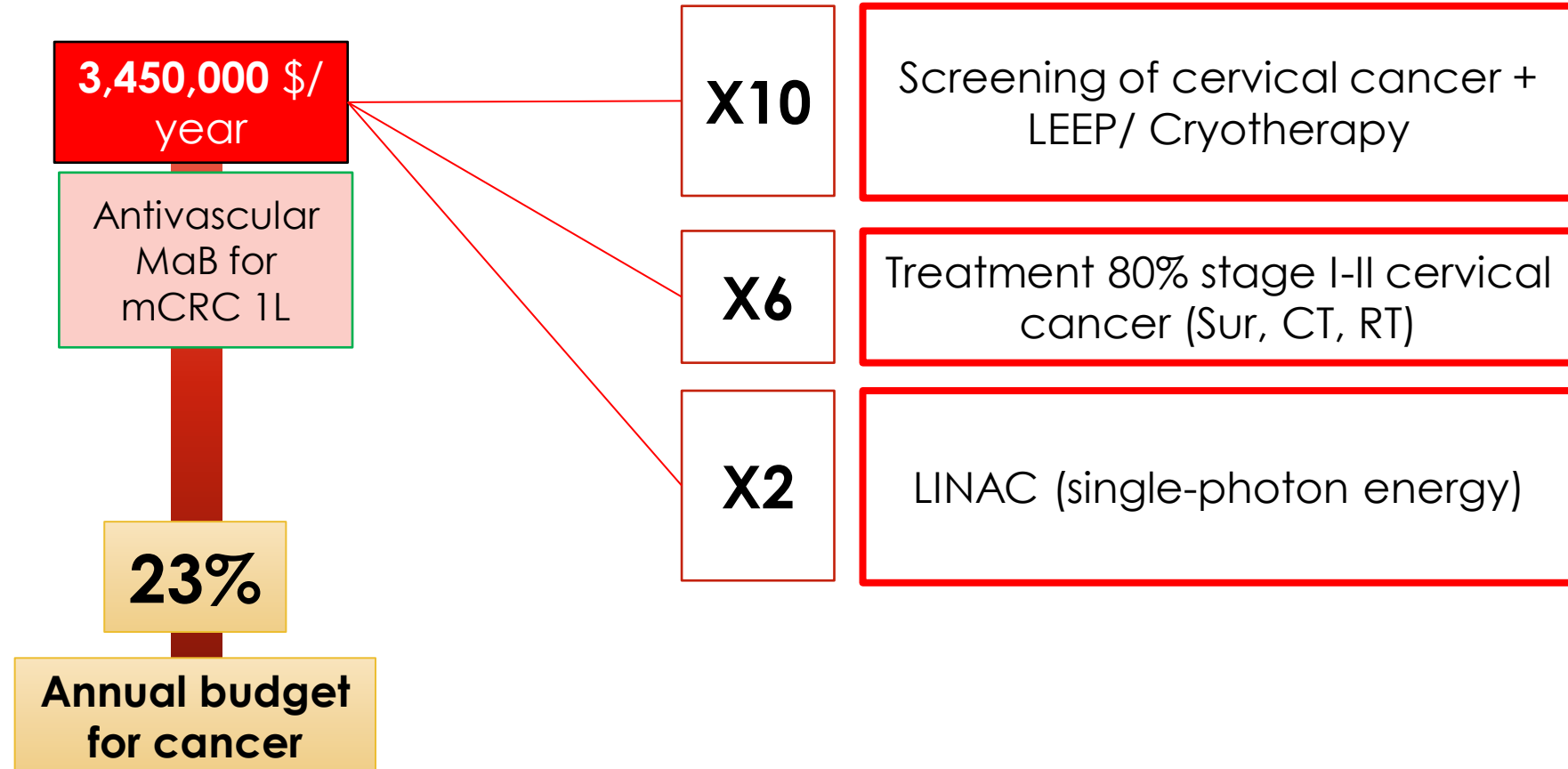
ESMO MCBS



USD/month
DrugAbascus

$[R^2 = 0, P = 0.98]$

PUTTING AL TOGETHER: EXERCICES DE STYLE



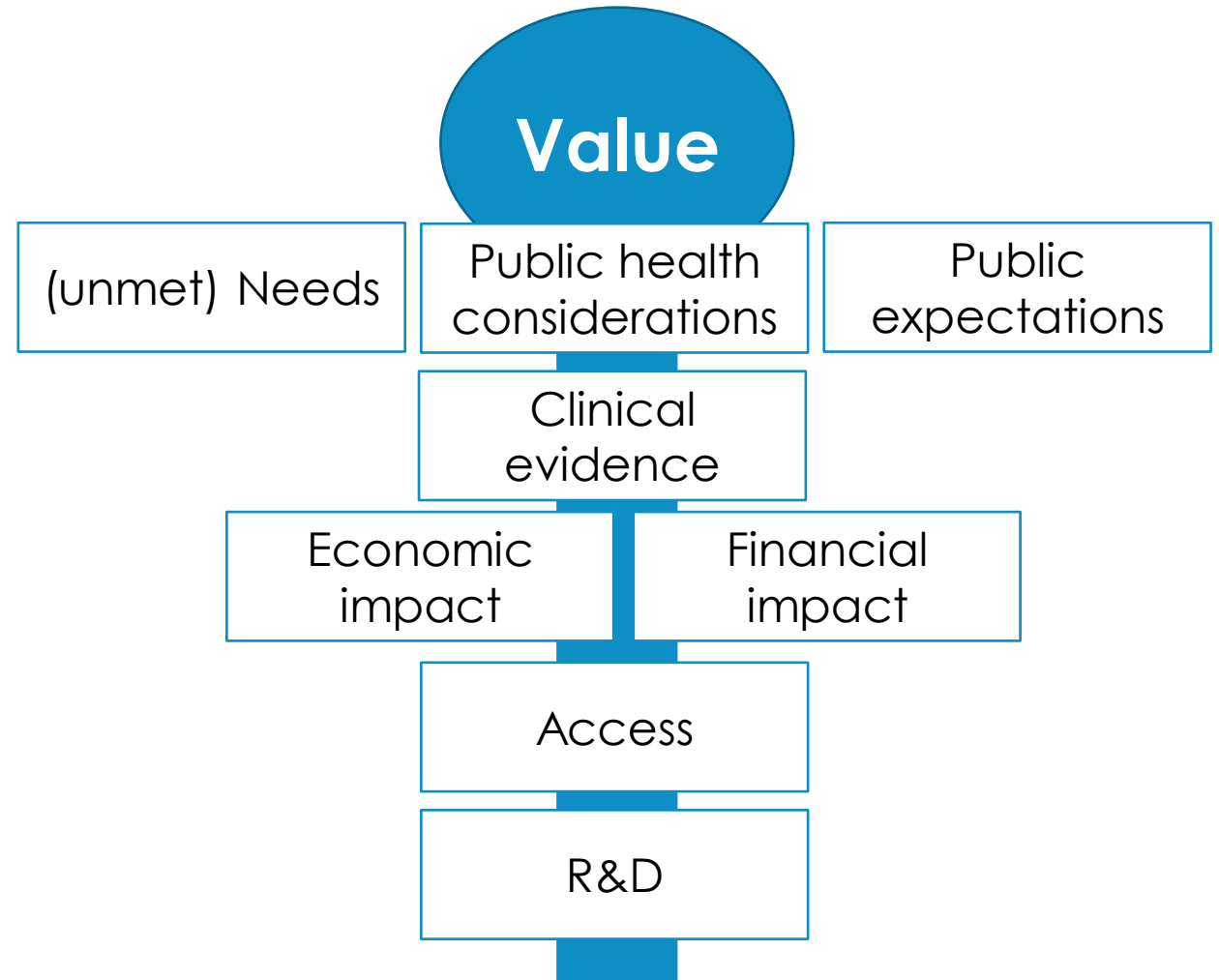
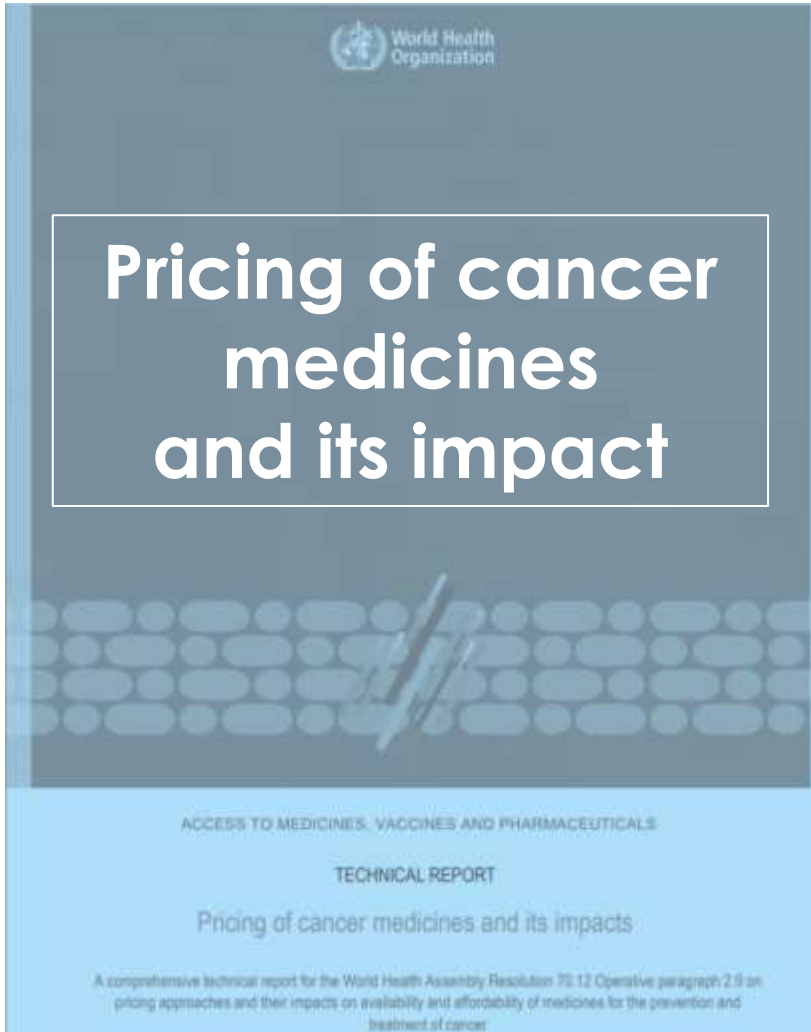
**cost assumptions from NCCP of comparable countries of the same subregion per income, corrected per population size
www.iccp-portal.org
(East Africa)

WHAT IS **VALUE- BASED** PRIORITIZATION OF INNOVATION IN ONCOLOGY?



What is Value?

WHO multi-dimensions of value of medicines

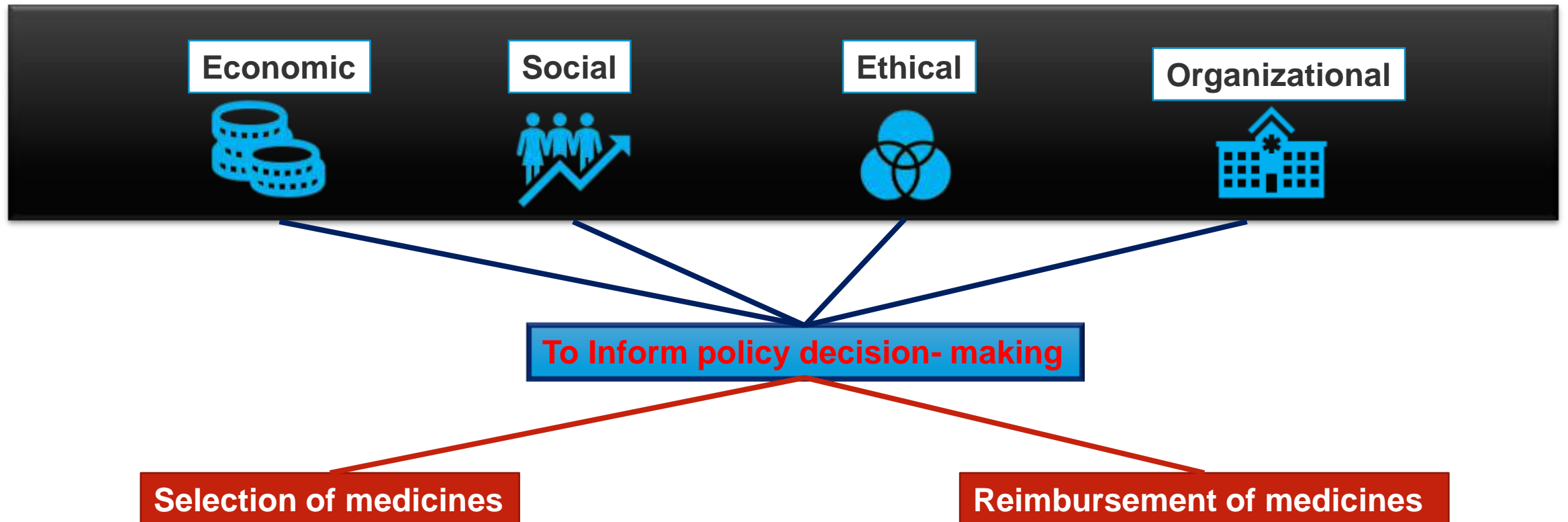




A HTA- APPROACH

Health technology assesment (HTA) is:

systematic evaluation of properties, effects, and/or impacts of health technology (WHO)



HTA IN EUROPE: WHAT CAPACITY?



All **HIC** had a HTA or were developing it

≈50% of **low- and middle** European countries have no functioning HTA: *low capacity to develop and sustain, to inform the policy of reimbursement of medicines*

Global situation (WHO):
>50% have no HTA

Map based on: <http://www.euro.who.int> (2019)

HTA IN EUROPE: WHAT CAPACITY?



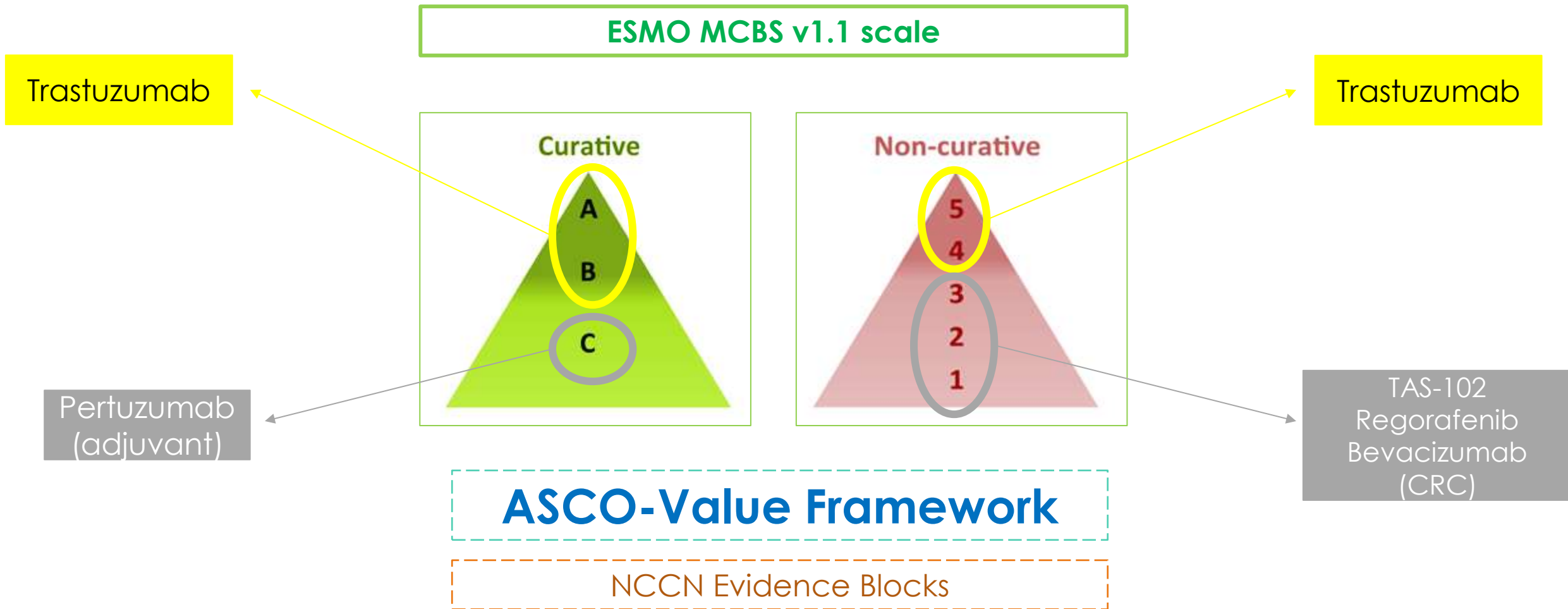
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“HTA is the setting of priority- setting and evaluation of innovative therapies... In the context of value- based prioritization and sustainability of resilient health systems, the HTA approach has been complemented by the development of frameworks and tools...”

EST MODUS IN REBUS: THE ESTIMATORS OF VALUE



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ESMO MCBS v1.1 scale

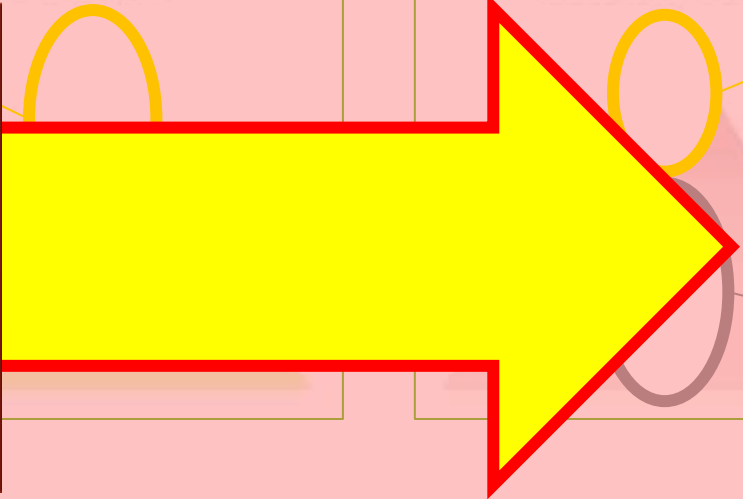
Trastuzumab

Trastuzumab

Curative

Non-curative

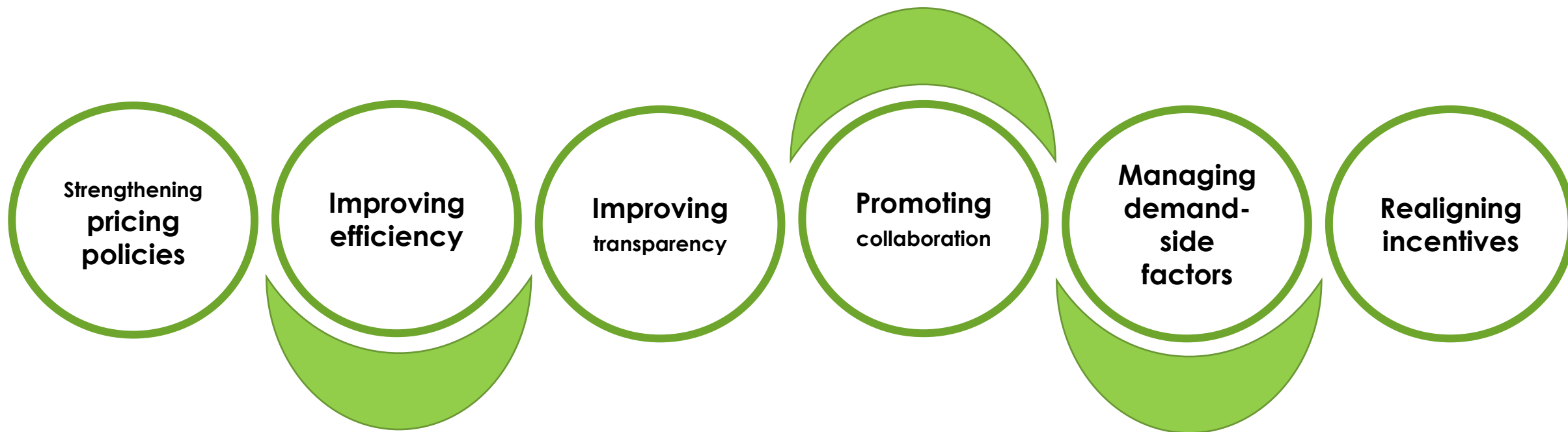
**4 more
“Valore
intrinseco”**



Prof di Maio, h 9.15

Value-based options to enhance the affordability & accessibility of cancer medicines

Sharing information on HTA



Prioritizing the selection of medicine with high(er) clinical Value

Correct mis-perceptions of inferior quality of generics/ biosimilars



IS THIS RELEVANT IN ITALY?

Early Access in Oncology: Why Is It Needed?

Value-based
priority-
setting of
innovative
therapies

VALUE

Evidence-based

Effect size

Safety/ QoL

Strength of the **Recommendations** of the Italian Association of Medical Oncology GLs (**AIOM**)

European Society for Medical Oncology (**ESMO**)
Magnitude of Clinical Benefit Scale

POLICY

SELECTION

REIMBURSEMENT

Priorities for early **access** (to innovation)
Conditional **reimbursement** within 60 days

TAKE-HOME POINTS

- **Value-based prioritization** is a priority in oncology
- Value can be determined by estimators & tools
- Non-Value-based policy results in a possible increase of overall cancer mortality & harm for all patients
- HTA framework is the setting to shape & adapt **Value-based decision-making**
- **Value-based policy-making** is relevant to all cancer interventions across the cancer continuum

Value is the determinant of prioritization of
Innovation in Oncology!