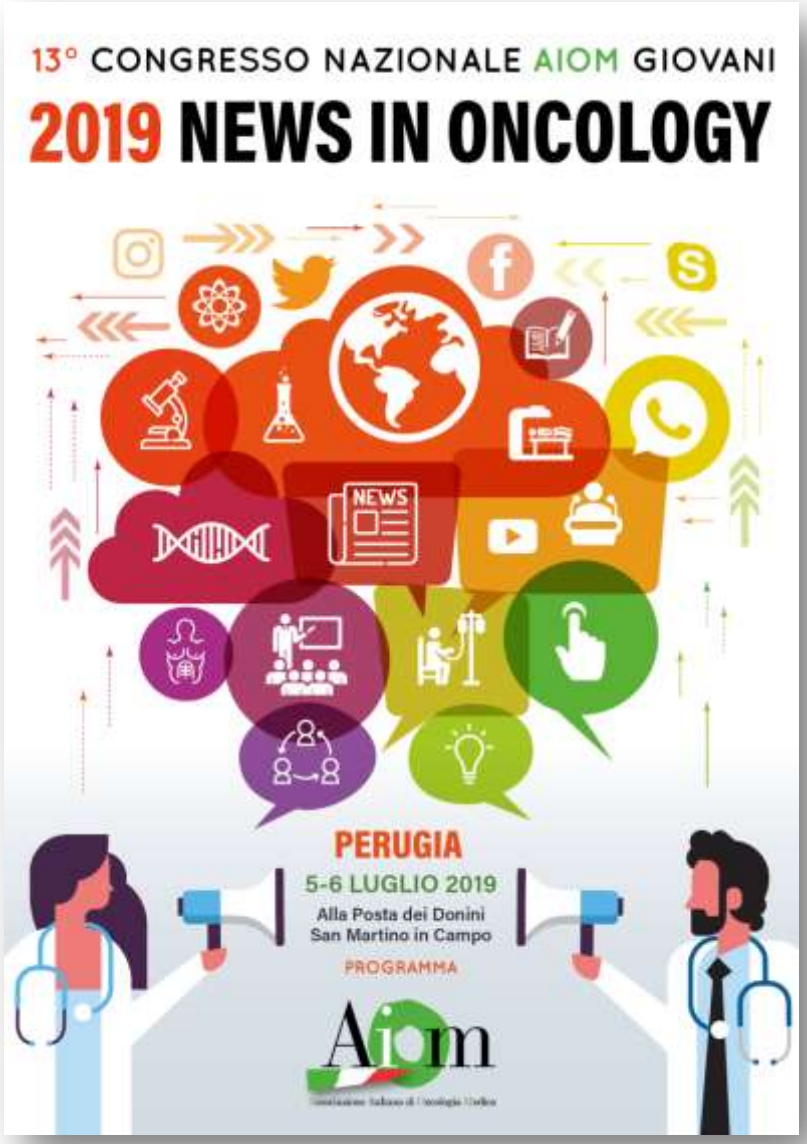

Il valore intrinseco delle terapie oncologiche: Quale framework?

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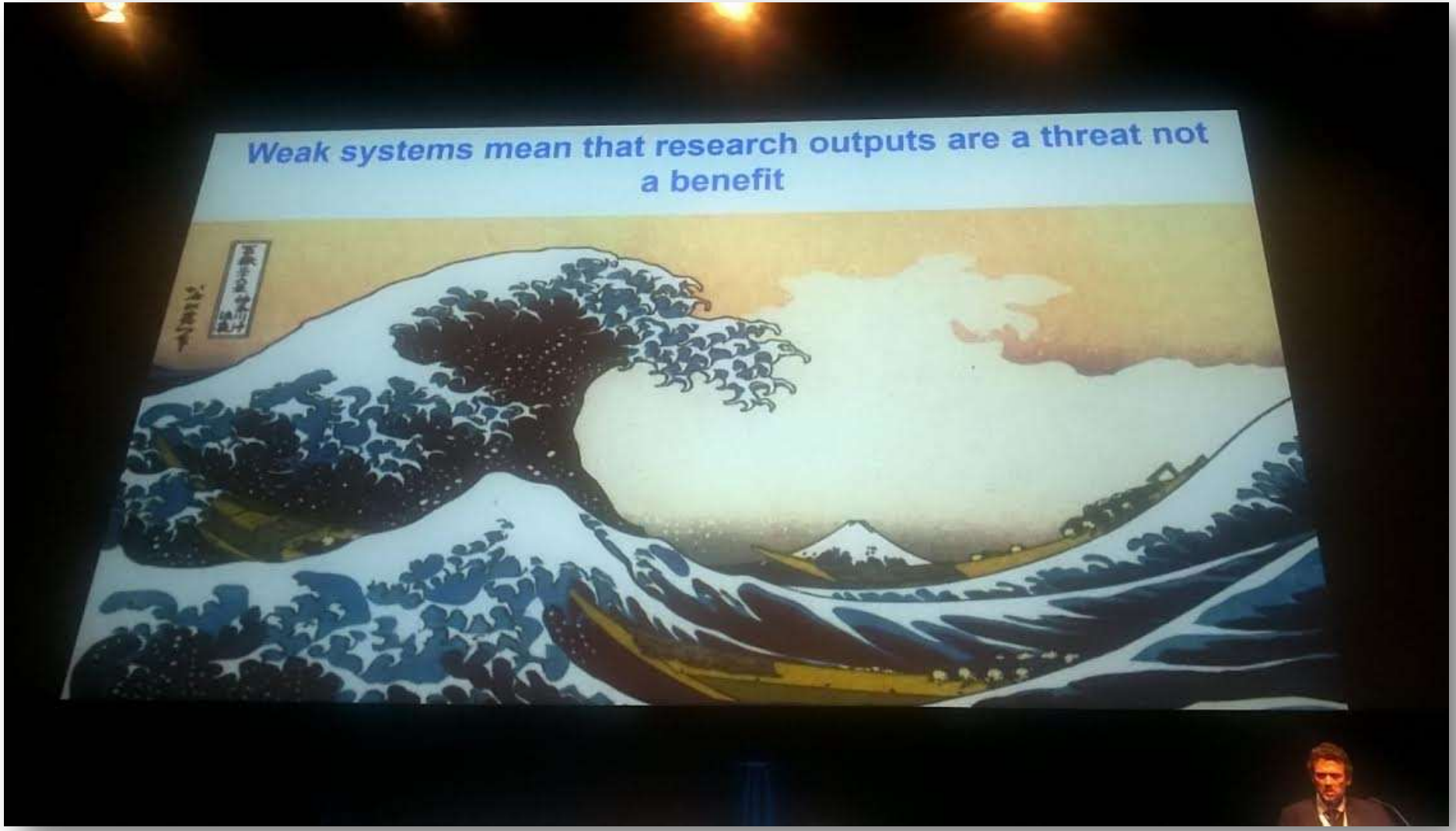
Disclosure
as of July 6, 2019

In the last 3 years I received:

- Personal honoraria from Bristol Myers Squibb, Takeda, Merck Sharp & Dohme, AstraZeneca, Janssen, Pfizer for acting as consultant or participating to advisory boards.

- Institutional research grant from Tesaro

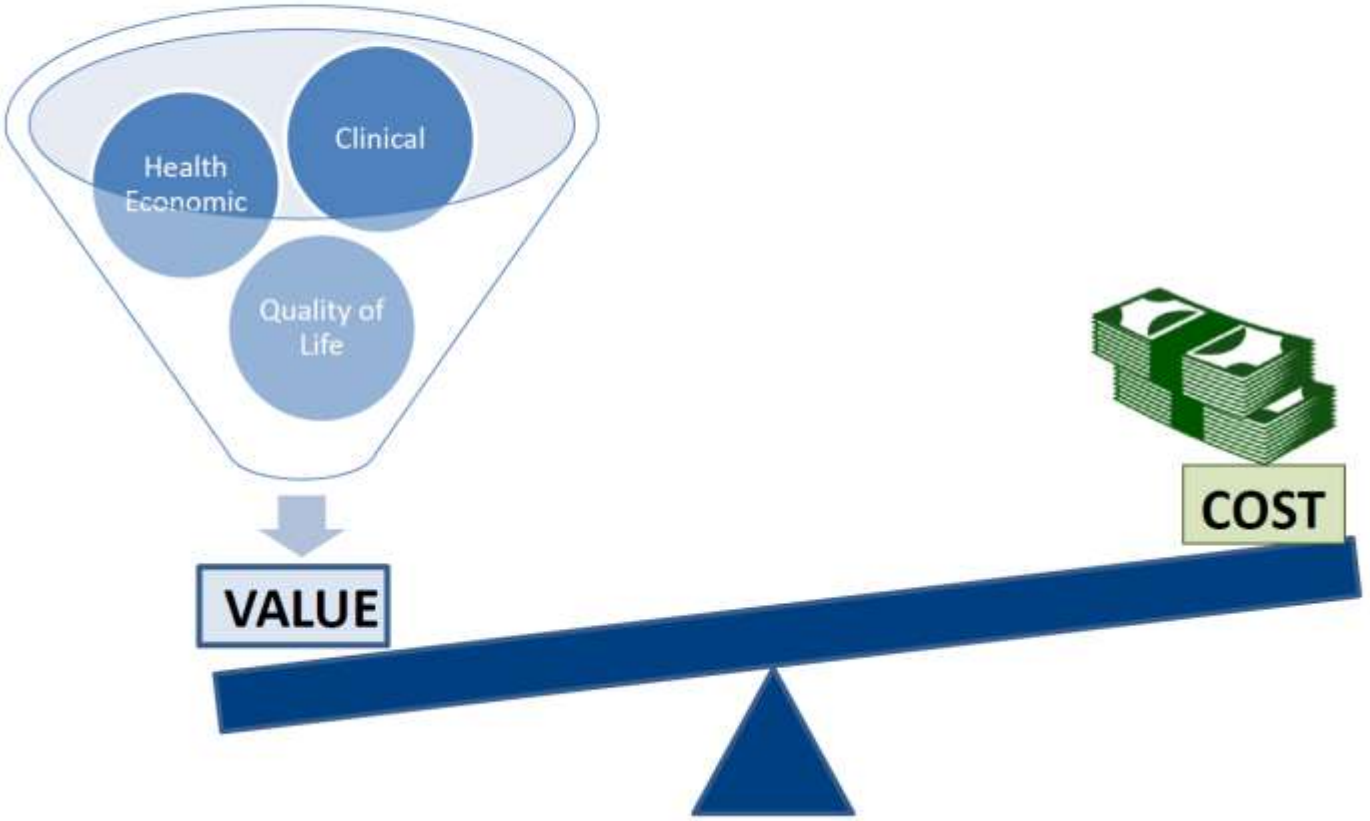


Richard Sullivan, ESMO meeting, October 10, 2016

Equitable and affordable cancer care: Is Europe a union for real?

Value Frameworks

A defined process or methodology for determining a product's or service's **relative value** compared to another treatment and its **cost or relative cost**:



MassBio. What is the value of value frameworks in making healthcare decisions? http://files.massbio.org/file/VALUE11302016.pdf

Cancer Center

Moving the Discussion to Value
it's far more than Cost

$$V = \frac{Q + S}{\$}$$

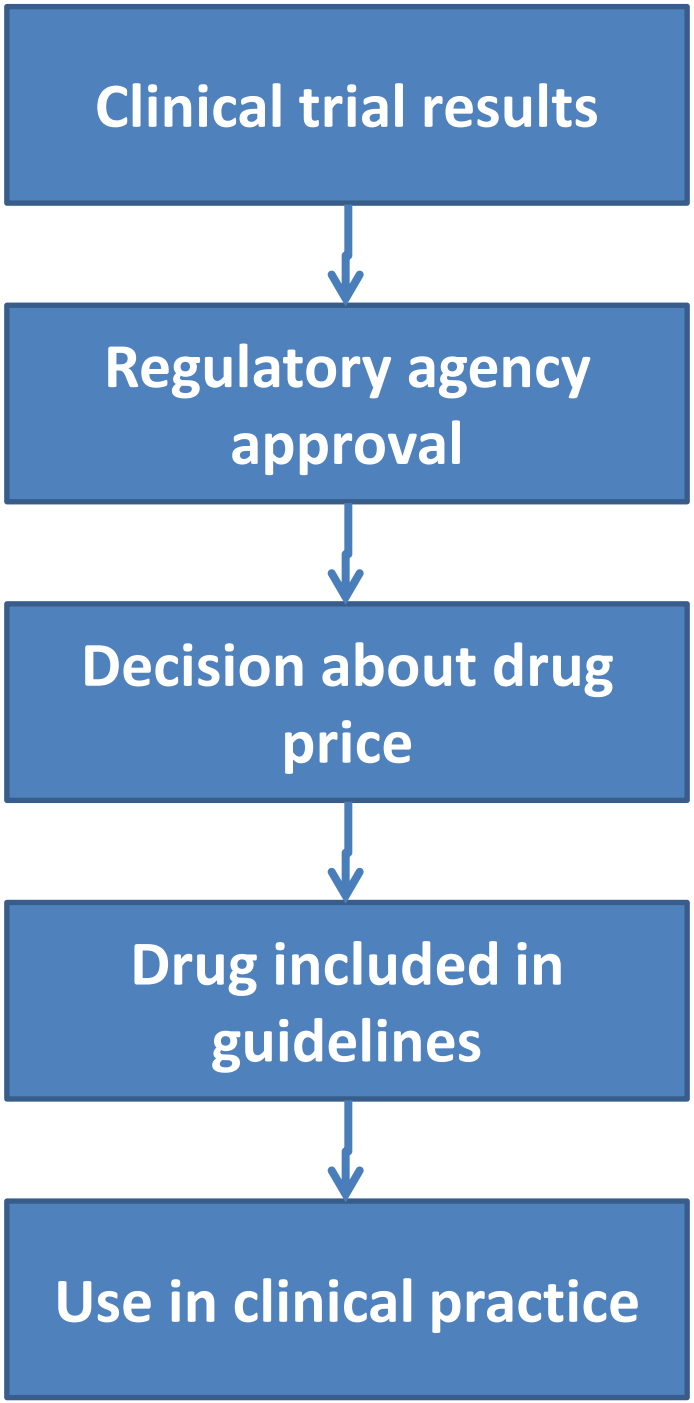
V (VALUE) = Q (QUALITY) + S (SERVICE) / $ (COST)

Beth Israel Deaconess Medical Center

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Il valore intrinseco delle terapie oncologiche: per chi?

- **Per gli sperimentatori,** che disegnano, conducono e interpretano i risultati di uno studio clinico
- **Per le società scientifiche e le riviste,** che dovrebbero pretendere una valutazione critica dei risultati
- **Per le agenzie regolatorie,** che devono decidere in merito all'autorizzazione all'impiego dei nuovi farmaci
- **Per i pagatori**, che devono decidere in merito al prezzo del trattamento
- **Per i clinici,** che, basandosi sui risultati degli studi, devono prendere decisioni per la pratica clinica
- **Per i pazienti,** candidati a ricevere il trattamento nella pratica clinica


Clinical trial results
Regulatory agency approval
Decision about drug price
Drug included in guidelines
Use in clinical practice

Cancer Center

ASCO's Value Initiative

- In spring 2013, ASCO Board of Directors engaged in a strategic discussion on value around the following statement:
  - *Increasingly, the desired care for oncology patients will be assessed on the VALUE of that care rather than the COST*
  - *It is critical to define VALUE and suggest how VALUE should be integrated into treatment decisions*

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Cancer Center

ASCO's Value Initiative

- Desired outcomes:
  - *A transparent, clinically driven, methodologically sound method for defining and assessing relative value of cancer care options*
  - *Oncology providers will have the skills and tools to assess relative value of therapies and use these in discussing treatment options with their patients.*
  - *Patients have ready access to information to help them understand the relative value of treatment options that meet their unique needs.*

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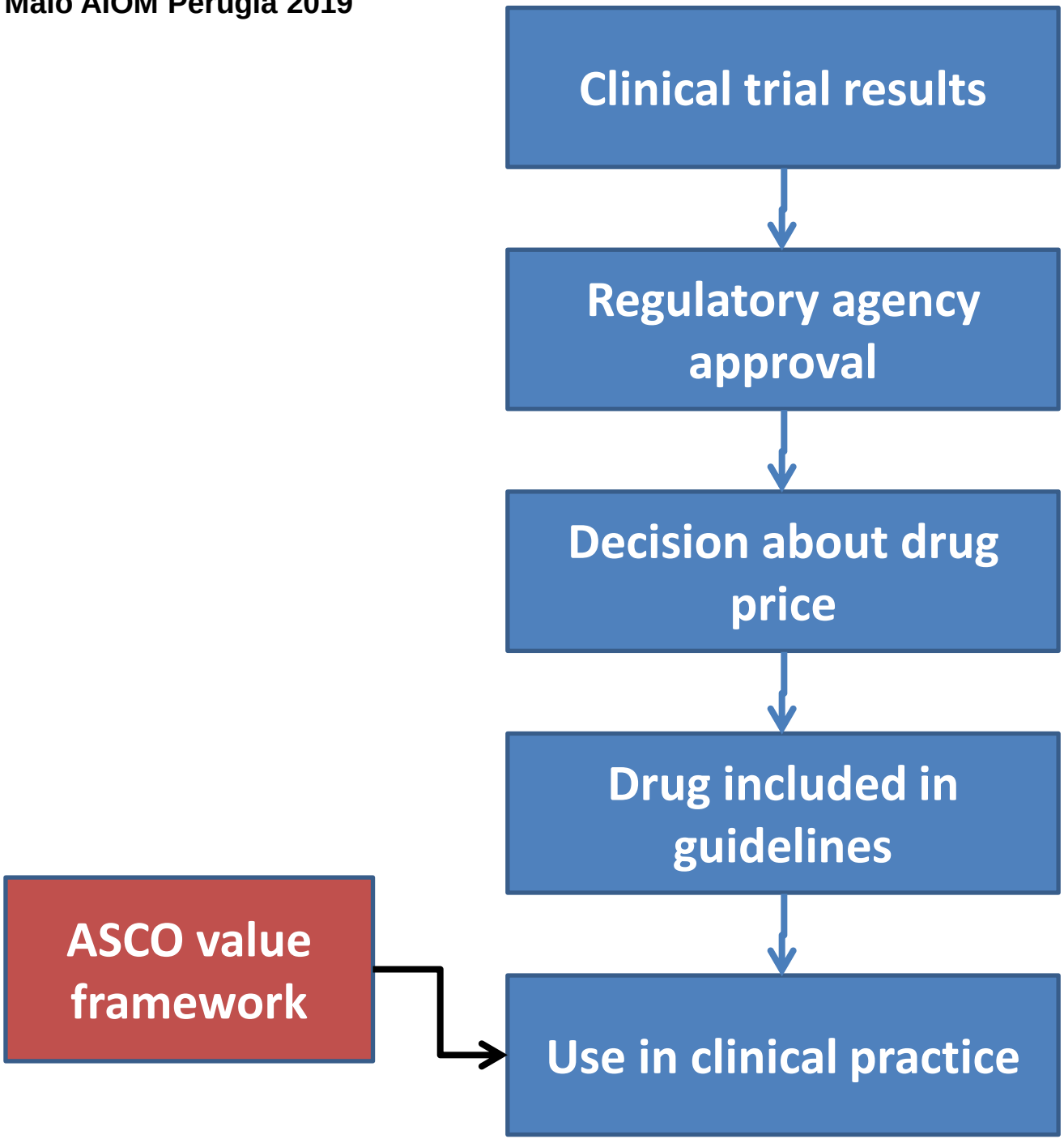
Clinical trial results
Regulatory agency approval
Decision about drug price
Drug included in guidelines
ASCO value framework
Use in clinical practice

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options

Lowell E. Schnipper, Nancy E. Davidson, Dana S. Wollins, Courtney Tyne, Douglas W. Blayney, Diane Blum, Adam P. Dicker, Patricia A. Ganz, J. Russell Hoverman, Robert Langdon, Gary H. Lyman, Neal J. Meropol, Therese Mulvey, Lee Newcomer, Jeffrey Peppercorn, Blase Polite, Derek Raghavan, Gregory Rossi, Leonard Saltz, Deborah Schrag, Thomas J. Smith, Peter P. Yu, Clifford A. Hudis, and Richard L. Schilsky

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received

Lowell E. Schnipper, Nancy E. Davidson, Dana S. Wollins, Douglas W. Blayney, Adam P. Dicker, Patricia A. Ganz, J. Russell Hoverman, Robert Langdon, Gary H. Lyman, Neal J. Meropol, Therese Mulvey, Lee Newcomer, Jeffrey Peppercorn, Blase Polite, Derek Raghavan, Gregory Rossi, Leonard Saltz, Deborah Schrag, Thomas J. Smith, Peter P. Yu, Clifford A. Hudis, Julie M. Vose, and Richard L. Schilsky

Schnipper LE, et al. *J Clin Oncol*. 2015;33(23):2563-2577.
Schnipper LE et al. *J Clin Oncol.* 2016; 34(24):2925-34.

Clinical benefit

Step 1: Determine the regimen's CLINICAL BENEFIT		
1.A. Is hazard ratio (HR) for death reported?	**YES.** Assign an HR Score for death by subtracting the HR from 1, and then multiplying the result by 100. Write this number in the box labeled "HR Score (death)." **Proceed to 1.F.**	**HR Score (death)**
	No. Proceed to 1B.	
1.B. If HR for death is not reported, is median overall survival (OS) reported?	**YES.** Assign an OS Score by calculating the percentage (ie, fractional) difference in median overall survival between the two regimens and multiply the result by 100. Write this number in the box labeled "OS Score." **Proceed to 1.F.**	**OS Score**
	NO. Proceed to 1.C.	
1.C. If OS data are not reported, is hazard ratio (HR) for disease progression reported?	**YES.** Assign an HR Score for disease progression by subtracting the HR from 1, multiplying the result by 100, and then multiplying this number by 0.8. Write this number in the box labeled "HR Score (progression)." **Proceed to 1.F.**	**HR Score (progression)**
	NO. Proceed to 1.D.	
1.D. If HR for disease progression is not reported, is median progression-free survival (PFS) reported?	**YES.** Assign a PFS Score by calculating the percentage (ie, fractional) difference in median progression-free survival between the two regimens and multiply the result by 100. Multiply this number by 0.8. Write this number in the box labeled "PFS Score." **Proceed to 1.F.**	**PFS Score**
	NO. Proceed to 1.E.	
1.E. If median PFS is not reported, is response rate (RR) reported?	**YES.** Assign an RR Score by adding the complete response (CR) and partial response (PR) rates, multiply by 100, then multiply this number by 0.7. Write this number in the box labeled "RR Score." **Proceed to 1.F.**	**RR Score**
1.F. Calculate the Clinical Benefit Score	Insert the score for HR death, HR PFS, median OS, or median PFS. **Note: You should have a score for only 1 of the clinical benefit scales above.** Write the total in the box labeled "Clinical Benefit Score." **Proceed to Step 2.**	**Clinical Benefit Score**

Schnipper LE et al. *J Clin Oncol.* 2016; 34(24):2925-34.

«Tail of the curve» bonus

3.A. TAIL OF THE CURVE. Identify the time point on the survival curve that is 2X the median OS (or PFS) of the comparator regimen. Is there a 50% or greater improvement in proportion of patients alive with the test regimen at this time point (assuming ≥ 20% surviving with standard)?	**YES.** If yes, award 20 points if the improvement is in OS, and 16 points (0.8 x 20) if the improvement is in PFS, and place this number in the box labeled "Tail of the Curve Bonus Points." **Proceed to Step 3.B.**	**Tail of the Curve Bonus Points**
	NO. No bonus points are awarded. **Proceed to Step 3.B.**	

Schnipper LE et al. *J Clin Oncol.* 2016; 34(24):2925-34.

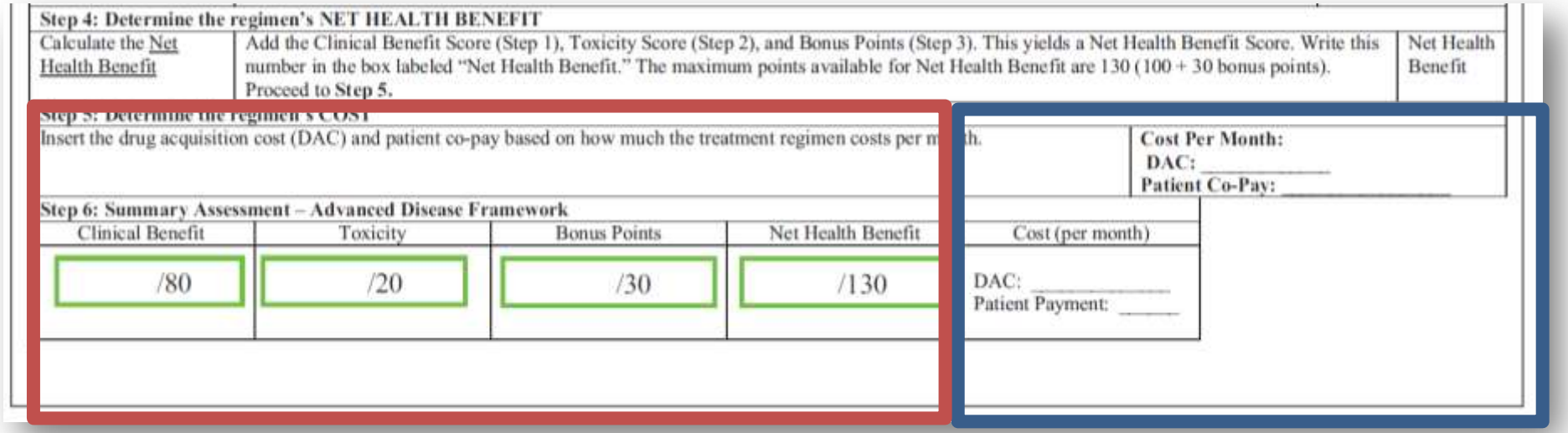
Toxicity

Step 2: Determine the regimen's TOXICITY		
Does the new regimen represent an improvement in toxicity over the standard of care/ comparator?	For each of the regimens being assessed, compare the number and frequency of clinically relevant toxicities, and assign a Toxicity Score) as shown below. Each clinically meaningful toxicity (ie, exclude laboratory results only) is assigned a score between 0.5 and 2.0 based on grade and frequency: For every grade 1 or 2 toxicity with a frequency < 10%, record 0.5 points. For every grade 1 or 2 toxicity with a frequency ≥ 10%, record 1.0 points. For every grade 3 or 4 toxicity with a frequency < 5%, record 1.5 points. For every grade 3 or 4 toxicity with a frequency ≥ 5%, record 2.0 points. Calculate the total number of toxicity points for each regimen. Calculate the percentage difference in total toxicity points between the two regimens, then multiply by 20 to obtain a toxicity score. If the regimen being evaluated is more toxic than the comparator, subtract the toxicity score of the regimen from the clinical benefit score. If the regimen is less toxic than the comparator, add the toxicity score of the regimen to the clinical benefit score. **If there are unresolved symptomatic treatment-related toxicities at 1 year after completion of treatment, subtract 5 additional points from the clinical benefit score.** The maximum points that can be awarded is 20. **Proceed to Step 3.**	**Toxicity Score**

Bonus points

3.B. PALLIATION BONUS. Is an improvement in cancer-related symptoms reported?	**YES.** If a statistically significant improvement in cancer-related symptoms is reported for the regimen being evaluated, award 10 points, and place this number in the box labeled "Palliation Bonus." **Proceed to Step 3.C.**	**Palliation Bonus**
	NO. No bonus points are awarded. **Proceed to Step 3.C.**	
3.C. QoL BONUS. Is an improvement in QoL reported?	**YES.** If a statistically significant improvement in QoL is reported for the regimen being evaluated, award 10 points, and place this number in the box labeled "QoL Bonus." **Proceed to Step 3.D.**	**QoL Bonus**
	NO. No bonus points are awarded. **Proceed to Step 3.D.**	
3.D. TREATMENT-FREE INTERVAL BONUS. Are data related to treatment-free interval reported?	**YES.** If a statistically significant improvement in treatment-free interval is reported for the regimen being evaluated, multiply the percentage improvement by 20 and award points. **Proceed to 3.E.**	**Treatment-Free Interval Bonus**
	NO. No bonus points are awarded. **Proceed to Step 3.E.**	

Schnipper LE et al. *J Clin Oncol.* 2016; 34(24):2925-34.



Step 4: Determine the regimen's NET HEALTH BENEFIT		
Calculate the Net Health Benefit	Add the Clinical Benefit Score (Step 1), Toxicity Score (Step 2), and Bonus Points (Step 3). This yields a Net Health Benefit Score. Write this number in the box labeled "Net Health Benefit." The maximum points available for Net Health Benefit are 130 (100 + 30 bonus points). Proceed to **Step 5.**	Net Health Benefit

Step 5: Determine the regimen's COST

Insert the drug acquisition cost (DAC) and patient co-pay based on how much the treatment regimen costs per m th.

Cost Per Month:
DAC: _____
Patient Co-Pay: _____

Step 6: Summary Assessment – Advanced Disease Framework

Clinical Benefit	Toxicity	Bonus Points	Net Health Benefit	Cost (per month)
/80	/20	/30	/130	DAC: _____ Patient Payment: _____

Schnipper LE, et al. *J Clin Oncol*. 2015;33(23):2563-2577.

ASCO value framework: l'esempio del CRPC

Table 2 Clinical benefit, toxicity, net health benefit (NHB) and cost of three regimens when compared with standard-of-care regimen used for first-line treatment of metastatic castration-resistant prostate cancer drugs [24, 25]

ASCO framework for assessing value in cancer care

Medication (new vs control)	Trial	Setting	Primary outcome	OS new med	OS control	Improvement	OS score	Clinical benefit score	Number of toxicities grade 3–5 new med	Number of toxicities grade 3–5 control	Regimen toxicity	Toxicity score	Palliation bonus	Treatment-free interva	NHB	Cost (drug acquisition cost)
Prednisone ± abiraterone	N Engl J Med 2011	Castration refractory after docetaxel	OS	14.8	10.9	36	2	32	37	34	9	0	10	0	42	7523.88$
Enzalutamide vs placebo	N Engl J Med 2012	Castration refractory after docetaxel	OS	18.4	13.6	35	2	32	8	6	33	0	0	0	32	8494.91$
Cabazitaxel + prednisone vs mitoxantrone + prednisone	Lancet 2010	Castration refractory after docetaxel	OS	15.1	12.7	19	1	16	21	19	11	0	0	0	16	10,699.43$

The value for the treatment option of radium 223 is not shown

Micó C, et al. This is a call to oncologists for action. Clin Transl Oncol. 2018 Dec;20(12):1493-1501.

Annals of Oncology

special articles

Annals of Oncology 26: 1547–1573, 2015
doi:10.1093/annonc/mdv249
Published online 30 May 2015

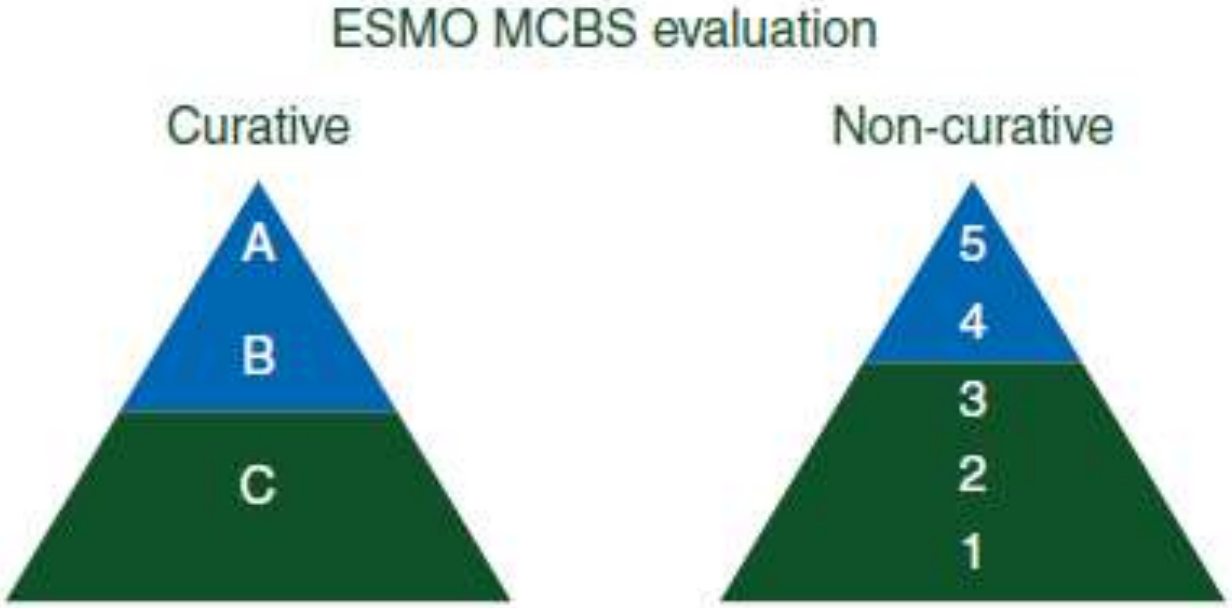
A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS)

N. I. Cherny[1*], R. Sullivan[2], U. Dafni[3], J. M. Kerst[4], A. Sobrero[5], C. Zielinski[6], E. G. E. de Vries[7] & M. J. Piccart[8,9]

[1]*Cancer Pain and Palliative Medicine Service, Department of Medical Oncology, Shaare Zedek Medical Center, Jerusalem, Israel;* [2]*Kings Health Partners Integrated Cancer Centre, King's College London, Institute of Cancer Policy, London, UK;* [3]*University of Athens and Frontiers of Science Foundation-Hellas, Athens, Greece;* [4]*Department of Medical Oncology, Antoni van Leeuwenhoek Hospital;* [5]*Department of Medical Oncology, IRCCS San Martino IST, Genova, Italy;* [6]*Division of Oncology, Medical University Vienna, Vienna, Austria;* [7]*Department of Medical Oncology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands;* [8]*Jules Bordet Institute, UniversitéLibre de Bruxelles, Brussels, Belgium;* [9]*Netherlands Cancer Institute, Amsterdam, The Netherlands*

Received 22 May 2015; accepted 22 May 2015

Cherny NI, et al. *Ann Oncol*. 2015;26:1547-1573.



Curative-Evaluation form 1: for new approaches to adjuvant therapy or new potentially curative therapies

Non-curative-Evaluation forms 2a, b or c: for therapies that are not likely to be curative

Figure 3. Visualisation of ESMO-MCB scores for curative and non-curative setting. A & B and 5 and 4 represent the grades with substantial improvement.

Cherny NI, et al. *Ann Oncol*. 2015;26:1547-1573.

IF median OS with the standard treatment >1 year

Grade 4	*Mark with X if relevant*
HR ≤0.70 AND Gain ≥5 months	
Increase in 3 year survival alone ≥10%	

Grade 3	
HR ≤0.70 AND Gain 3–4.9 months	
Increase in 3 year survival alone 5 - <10%	

Grade 2	
HR >0.70–0.75 OR Gain 1.5–2.9 months	
Increase in 3 year survival alone 3 - <5%	

Grade 1	
HR >0.75 OR Gain <1.5 months	
Increase in 3 year survival alone <3%	

Cherny NI, et al. *Ann Oncol*. 2015;26:1547-1573.

Quality of Life assessment /grade 3–4 toxicities assessment*

Does secondary endpoint quality of life show improvement	
Are there statistically significantly less grade 3–4 toxicities impacting on daily well-being*	

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

Adjustments

Upgrade 1 level if improved quality of life and/or less grade 3–4 toxicities impacting daily well-being are shown

Final adjusted magnitude of clinical benefit grade

5	4	3	2	1

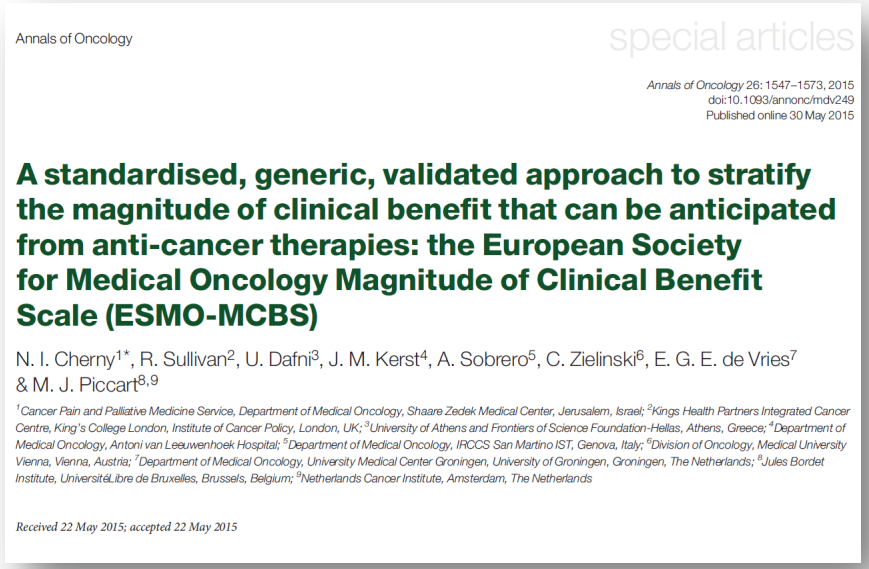
ESMO MCBS: l'esempio del CRPC

Table 1 The scores obtained for first-line treatment of metastatic castration-resistant prostate cancer therapies with the ESMO scale [22, 23]

Field testing ESMO–MCBS v 1.0/v 1.1.: prostate cancer

Medication (new vs control)	Trial	Setting	Primary outcome	OS gain	OS HR	QoL	ESMO/ MCBS v 1.0	ESMO/MCBS v 1.1
Abiraterone prednisone ± vs placebo prednisone	N Engl J Med 2011	Castration refractory after docetaxel	OS	3.9 months	0.65 (0.54–0.77) $p < 0.001$		4	4
Enzalutamide vs placebo	N Engl J Med 2012	Castration refractory after docetaxel	OS	4.8 months	0.63 (0.53–0.75)	Improved $p < 0.001$	4	4
Cabazitaxel + prednisone vs mitoxantrone + prednisone	Lancet 2010	Castration refractory after docetaxel	OS	2.4 months	0.70 (0.59–0.83) $p < 0.001$)		2	2
Radium 223 ± best SoC	N Engl J Med 2013	Castration refractory after or not docetaxel	OS	3.6 months	0.70 (0.55–0.88)	Improved $p < 0.001$	5	5

Micó C, et al. This is a call to oncologists for action. Clin Transl Oncol. 2018 Dec;20(12):1493-1501.



Annals of Oncology

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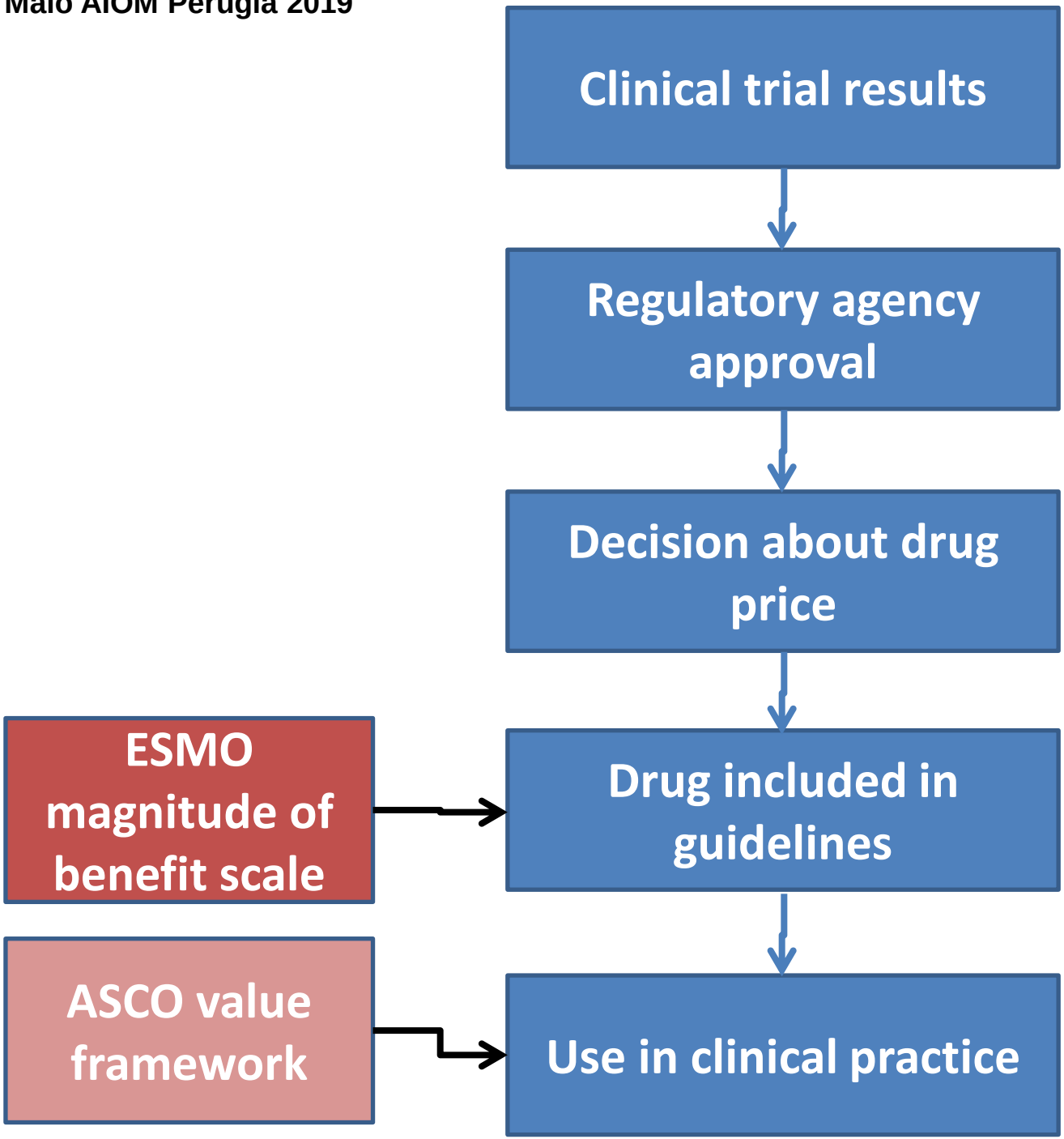
Received 22 May 2015; accepted 22 May 2015

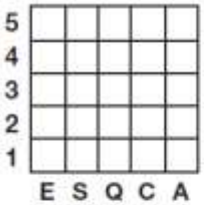
- *ESMO intends to apply this scale prospectively to each new anti-cancer drug/intervention that will be EMA approved.*
- *Drugs or treatment interventions that obtain the highest scores on the scale* ***will be emphasized in the ESMO guidelines****, with the hope that they will be rapidly endorsed by health authorities across the European Union.*

Cherny NI, et al. *Ann Oncol*. 2015;26:1547-1573.


Clinical trial results
Regulatory agency approval
Decision about drug price
ESMO magnitude of benefit scale
Drug included in guidelines
ASCO value framework
Use in clinical practice

NCCN Evidence Blocks™
User Guide

NCCN EVIDENCE BLOCKS™ CATEGORIES AND DEFINITIONS



E = Efficacy of Regimen/Agent
S = Safety of Regimen/Agent
Q = Quality of Evidence
C = Consistency of Evidence
A = Affordability of Regimen/Agent

Efficacy of Regimen/Agent

5	**Highly effective:** Cure likely and often provides long-term survival advantage
4	**Very effective:** Cure unlikely but sometimes provides long-term survival advantage
3	**Moderately effective:** Modest impact on survival, but often provides control of disease
2	**Minimally effective:** No, or unknown impact on survival, but sometimes provides control of disease
1	**Palliative:** Provides symptomatic benefit only

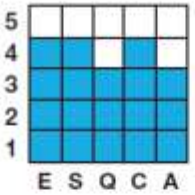
Safety of Regimen/Agent

5	**Usually no meaningful toxicity:** Uncommon or minimal toxicities; no interference with activities of daily living (ADLs)
4	**Occasionally toxic:** Rare significant toxicities or low-grade toxicities only; little interference with ADLs
3	**Mildly toxic:** Mild toxicity that interferes with ADLs
2	**Moderately toxic:** Significant toxicities often occur but life threatening/fatal toxicity is uncommon; interference with ADLs is frequent
1	**Highly toxic:** Significant toxicities or life threatening/fatal toxicity occurs often; interference with ADLs is usual and severe

Note: For significant chronic or long-term toxicities, score decreased by 1

NCCN.org/EvidenceBlocks

NCCN EVIDENCE BLOCKS™ EXAMPLE



E = 4
S = 4
Q = 3
C = 4
A = 3

Quality of Evidence

5	**High quality:** Multiple well-designed randomized trials and/or meta-analyses
4	**Good quality:** One or more well-designed randomized trials
3	**Average quality:** Low quality randomized trial(s) or well-designed non-randomized trial(s)
2	**Low quality:** Case reports or extensive clinical experience
1	**Poor quality:** Little or no evidence

Consistency of Evidence

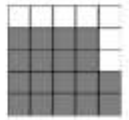
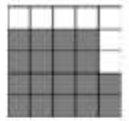
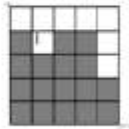
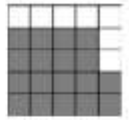
5	**Highly consistent:** Multiple trials with similar outcomes
4	**Mainly consistent:** Multiple trials with some variability in outcome
3	**May be consistent:** Few trials or only trials with few patients, whether randomized or not, with some variability in outcome
2	**Inconsistent:** Meaningful differences in direction of outcome between quality trials
1	**Anecdotal evidence only:** Evidence in humans based upon anecdotal experience

Affordability of Regimen/Agent (includes drug cost, supportive care, infusions, toxicity monitoring, management of toxicity)

5	**Very inexpensive**
4	**Inexpensive**
3	**Moderately expensive**
2	**Expensive**
1	**Very expensive**

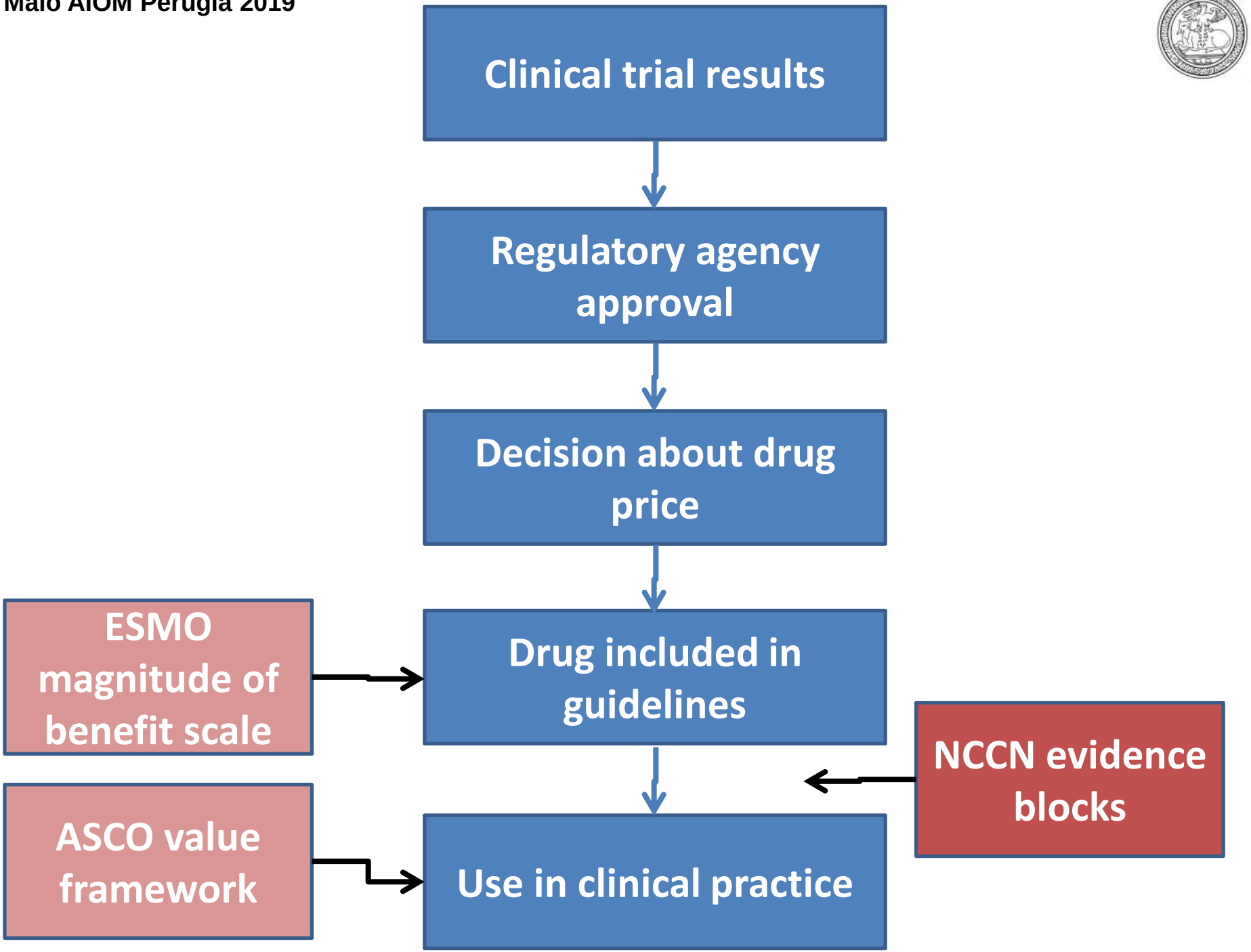
NCCN evidence blocks: l'esempio del CRPC

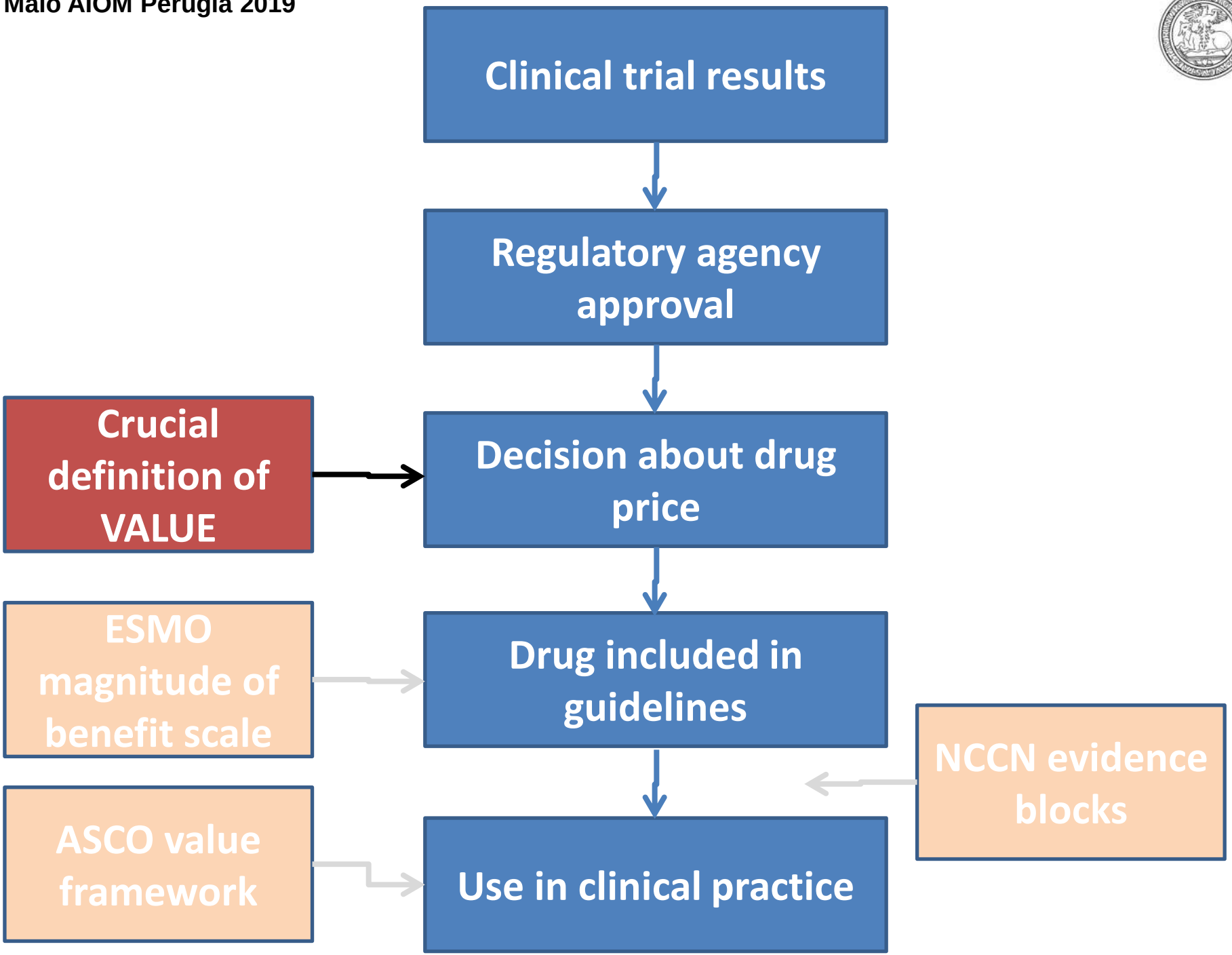
The NCCN value initiative: using NCCN evidence blocks in clinical decisions

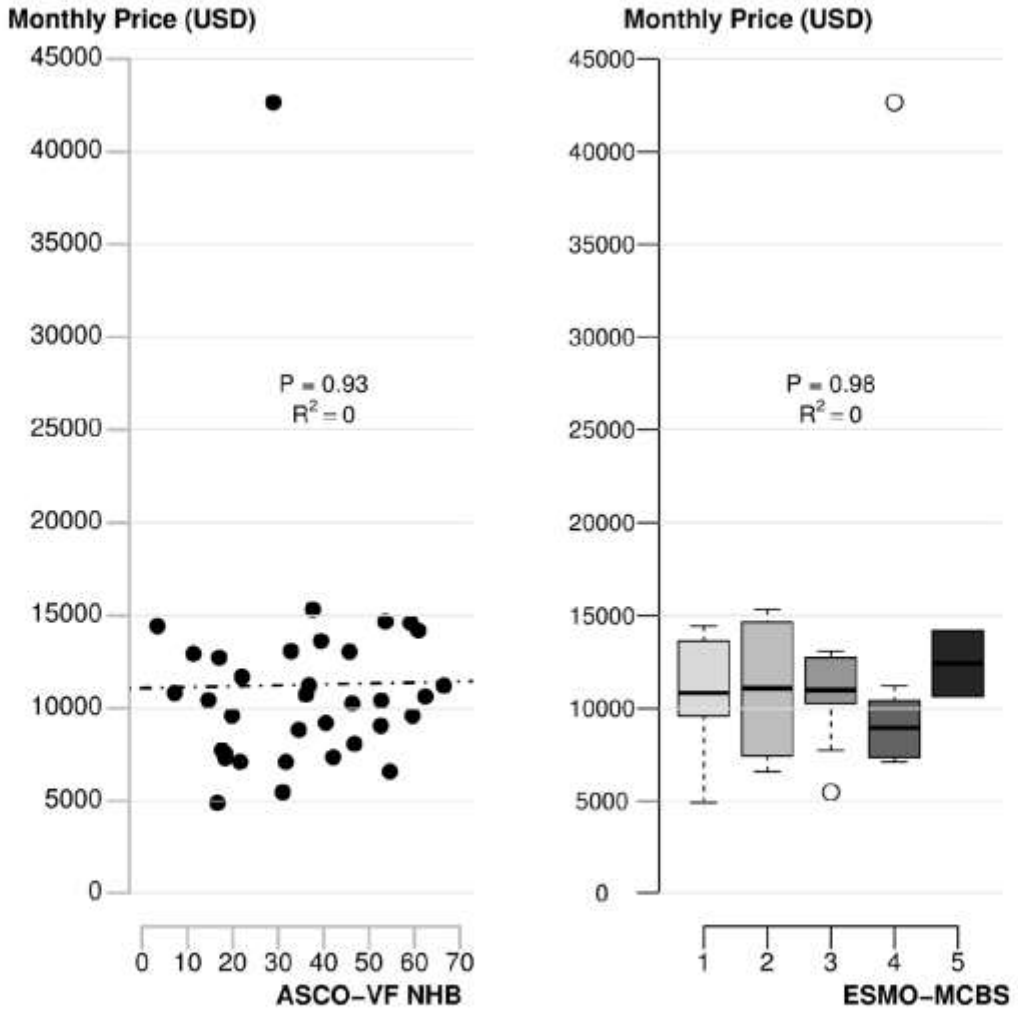
Medication (new vs control)	Efficacy	Safety	Quality and quantity of evidence	Consistency of evidence	Affordability	Block
Prednisone ± abiraterone	4	4	4	4	2	
Enzalutamide vs placebo	4	4	4	4	2	
Cabazitaxel + prednisone vs mitoxantrone + prednisone	4	3	4	4	2	
Radium 223 ± best SoC	4	4	4	4	2	

Efficacy: 4: very effective: sometimes provides long-term survival advantage or has curative potential. Safety: 4: occasionally toxic: rare significant toxicities or low-grade toxicities only. Little interference with activities of daily living (ADLs) 3: mildly toxic: mild toxicity that interferes with ADLs is common. Quality: 4: good quality: several well-designed randomized trials. Consistency of evidence: 4: mainly consistent: multiple trials with some variability in outcomes. Affordability: 2: expensive

Micó C, et al. This is a call to oncologists for action. Clin Transl Oncol. 2018 Dec;20(12):1493-1501.


Clinical trial results
Regulatory agency approval
Decision about drug price
Drug included in guidelines
Use in clinical practice
ESMO magnitude of benefit scale
ASCO value framework
NCCN evidence blocks


Clinical trial results
Regulatory agency approval
Crucial definition of VALUE
Decision about drug price
ESMO magnitude of benefit scale
Drug included in guidelines
NCCN evidence blocks
ASCO value framework
Use in clinical practice

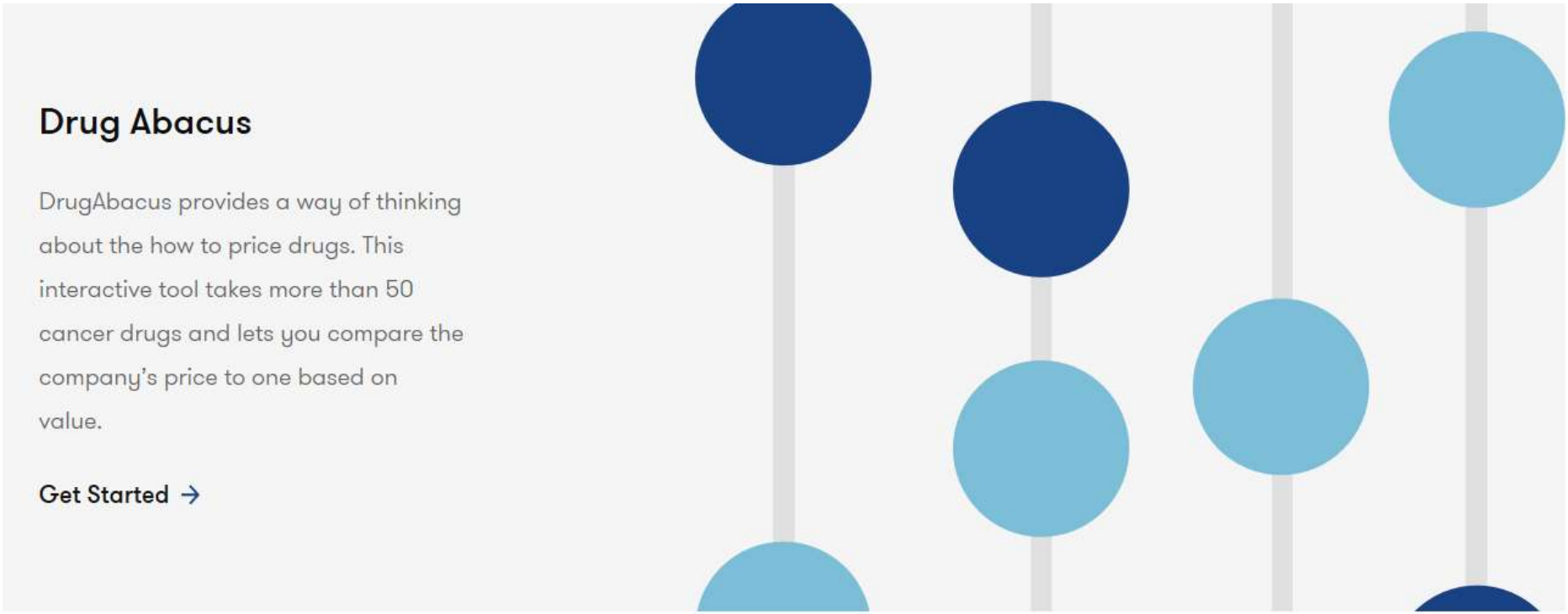


Relationship between the clinical benefit of the 37 anticancer drugs approved by the FDA from 2000 to 2015 as evaluated by the 2016 update of the ASCO-VF NHB and the ESMO-MCBS and the price according to US Medicare (data on prices retrieved from DrugAbascus).

Vivot A, et al. Ann Oncol. 2017 May 1;28(5):1111-1116.

Drug Abacus

Memorial Sloan Kettering Cancer Center



https://drugpricinglab.org/tools/

Drug Abacus

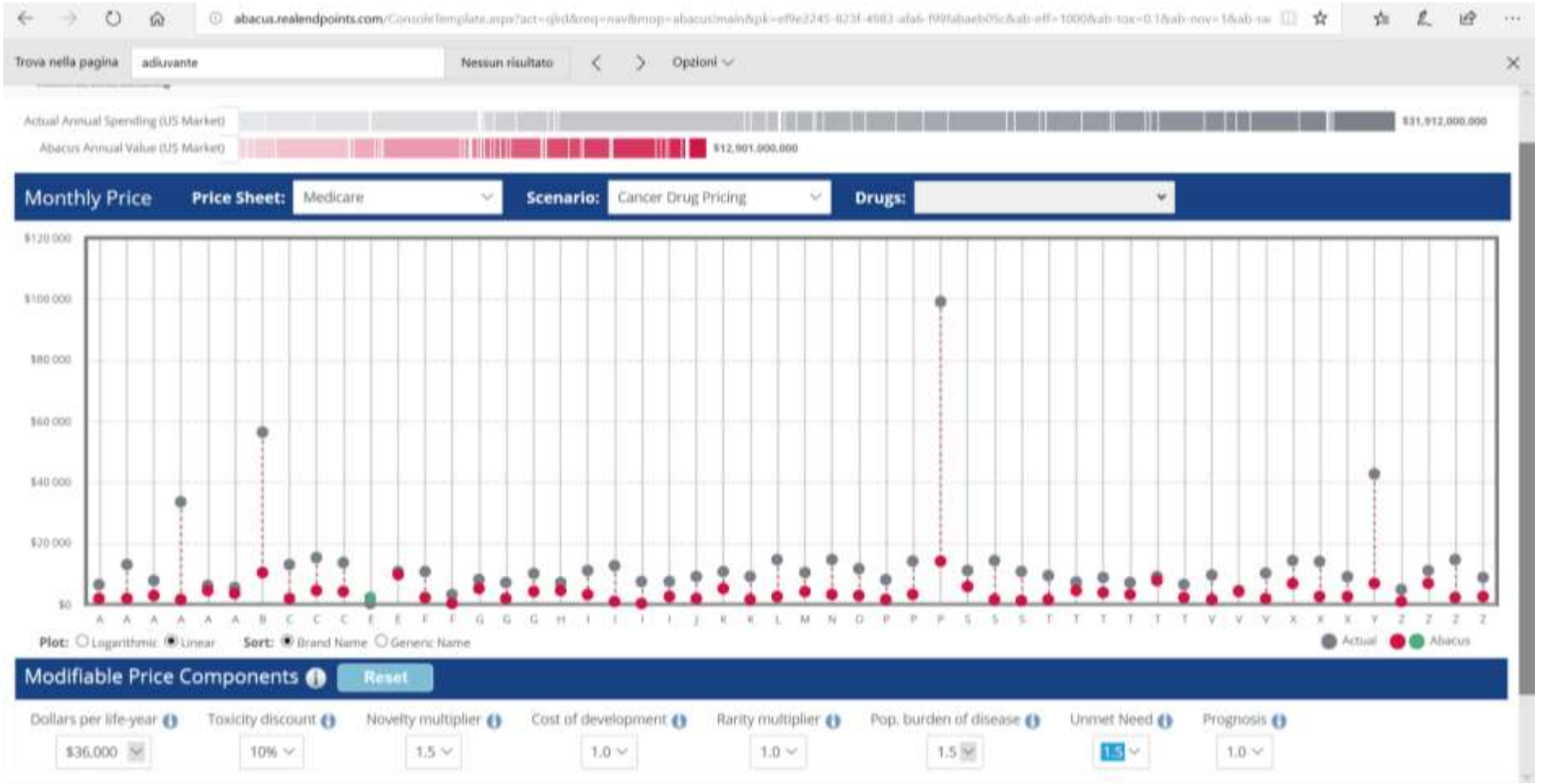
Memorial Sloan Kettering Cancer Center

Component	Weights
Price for a year of life	$12,000 to $300,000
Toxicity discount	0% to 30% in 5% increments
Novelty multiplier (premium)	1.0 to 3.0 in 0.5 increments
Rarity multiplier (premium)	1.0 to 3.0 in 0.5 increments
Population Burden of Disease (premium for large population burdens)	1.0 to 3.0 in 0.5 increments
Cost of development (premium for expensive R&D)	1.0 to 3.0 in 0.5 increments
Prognosis (premium for treatment of aggressive disease)	1.0 to 3.0 in 0.5 increments
Unmet need (premium for diseases with few/no treatment options)	1.0 to 3.0 in 0.5 increments

https://drugpricinglab.org/tools/

Drug Abacus

Memorial Sloan Kettering Cancer Center



https://drugpricinglab.org/tools/

Massimo Di Maio
@MassimoDiMaio75

#ASCO19 a plea to my colleagues: please be sober when reporting new results on social media... We are communicating science, not advertisements...

6:00 AM - 4 Jun 2019

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"Let's make innovation a benefit, not a threat"

Despite the ever increasing pressure on cancer and health care budgets, ***innovation*** *will and must continue.*

Value-based frameworks *offer one of the most rational approaches for policymakers committed to improving cancer outcomes through a public health approach.*

Shooting for the Moon or Flying Too Near the Sun? Crossing the Value Rubicon in Precision Cancer Care
Lawler M et al. Public Health Genomics 2016;19:132-136

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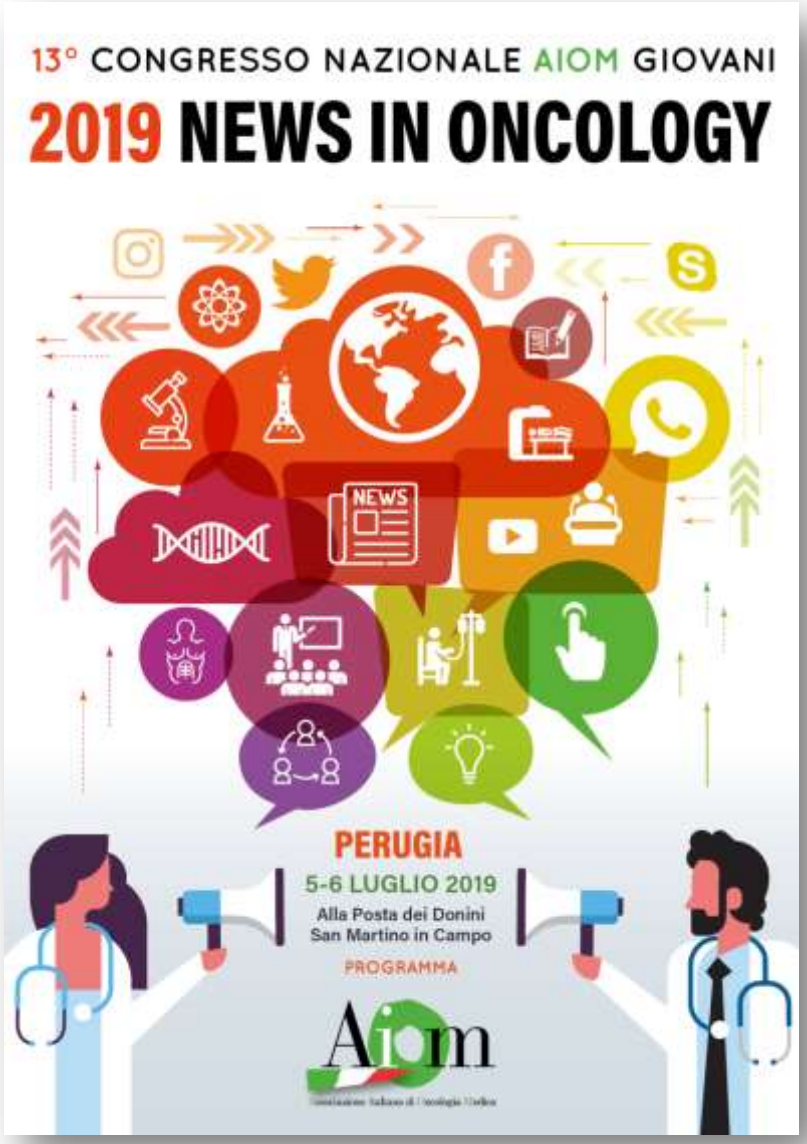
"Oggigiorno si conosce il prezzo di tutto, ma non si conosce il valore di niente."

Così rifletteva Oscar Wilde, oltre un secolo fa. Parole adatte a sottolineare l'utilità dell'analisi che ha stimato il valore dei farmaci oncologici approvati negli ultimi anni, ma che non evidenzia alcuna relazione tra il valore ed il prezzo...

Vivot, J. Jacot, J.-D. Zeitoun, P. Ravaud, P. Crequit, R. Porcher; Clinical Benefit, Price and Approval Characteristics of FDA-approved New Drugs for Treating Advanced Solid Cancer, 2000-2015. Ann Oncol 2017 mdx053. doi: 10.1093/annonc/mdx053



Il valore intrinseco delle terapie oncologiche: Quale framework?

Massimo Di Maio

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