DO ADVANCES IN SYSTEMIC THERAPIES REQUIRE PARTICULAR STANDARDS?

ESMO Frameworks and Tools

Prof. Andres Cervantes MD MSc PhD

Past-President - European Society for Medical Oncology (ESMO)

OECI NEW A&D STANDARDS: EXPERTS' CONSENSUS CONFERENCE

Brussels, 12.02.2025

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO MISSION & VISION

- Improve quality of prevention, diagnosis, treatment and care
- Advance the art and practice of oncology
- Disseminate knowledge to cancer patients and the public
- Educate and train oncology professionals
- Ensure a high standard of qualification
- Promote equal access to optimal cancer care

> **40,000**

a global community from **179** countries and territories

51% women

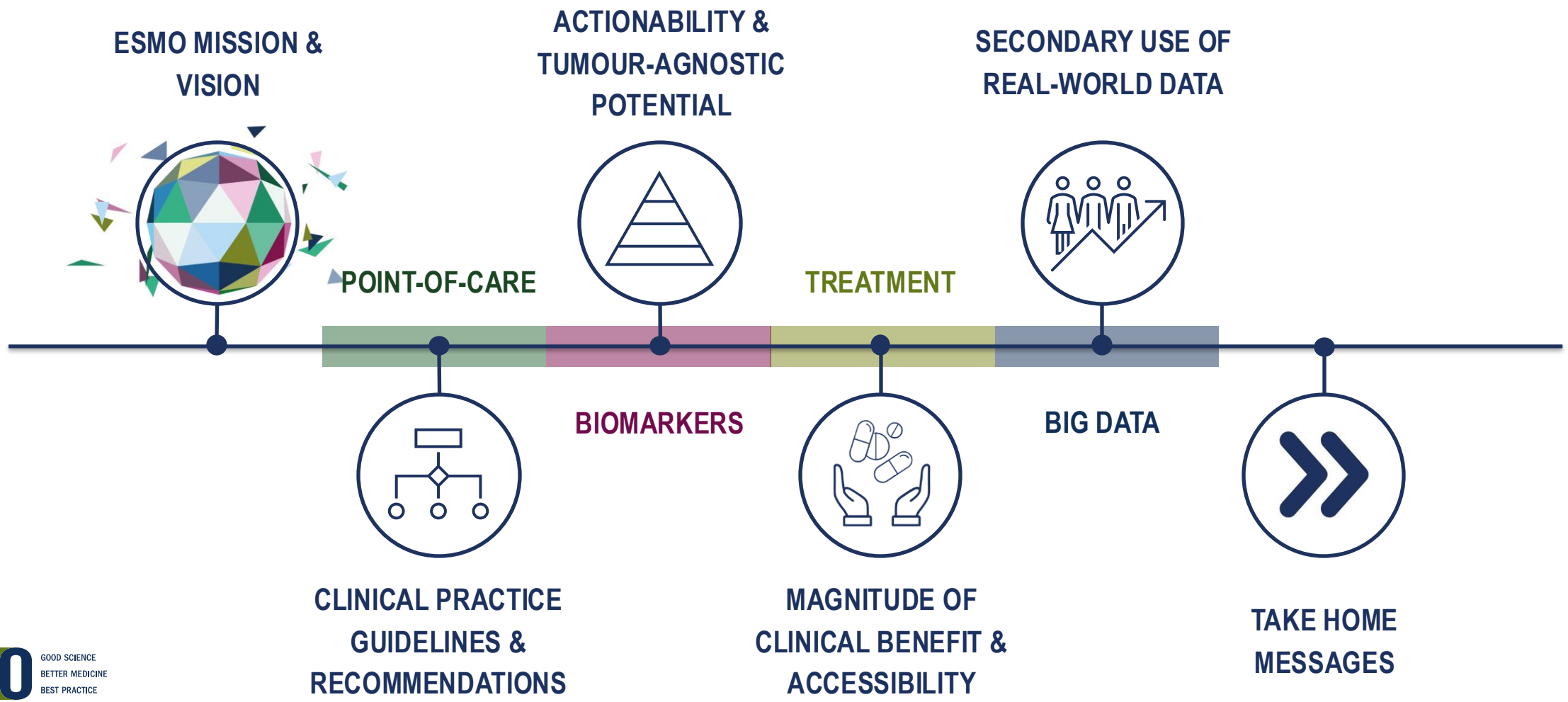
> 40 specialties

51% ≤ 40yrs old

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

DEFINING STANDARDS

ESMO Frameworks and Tools



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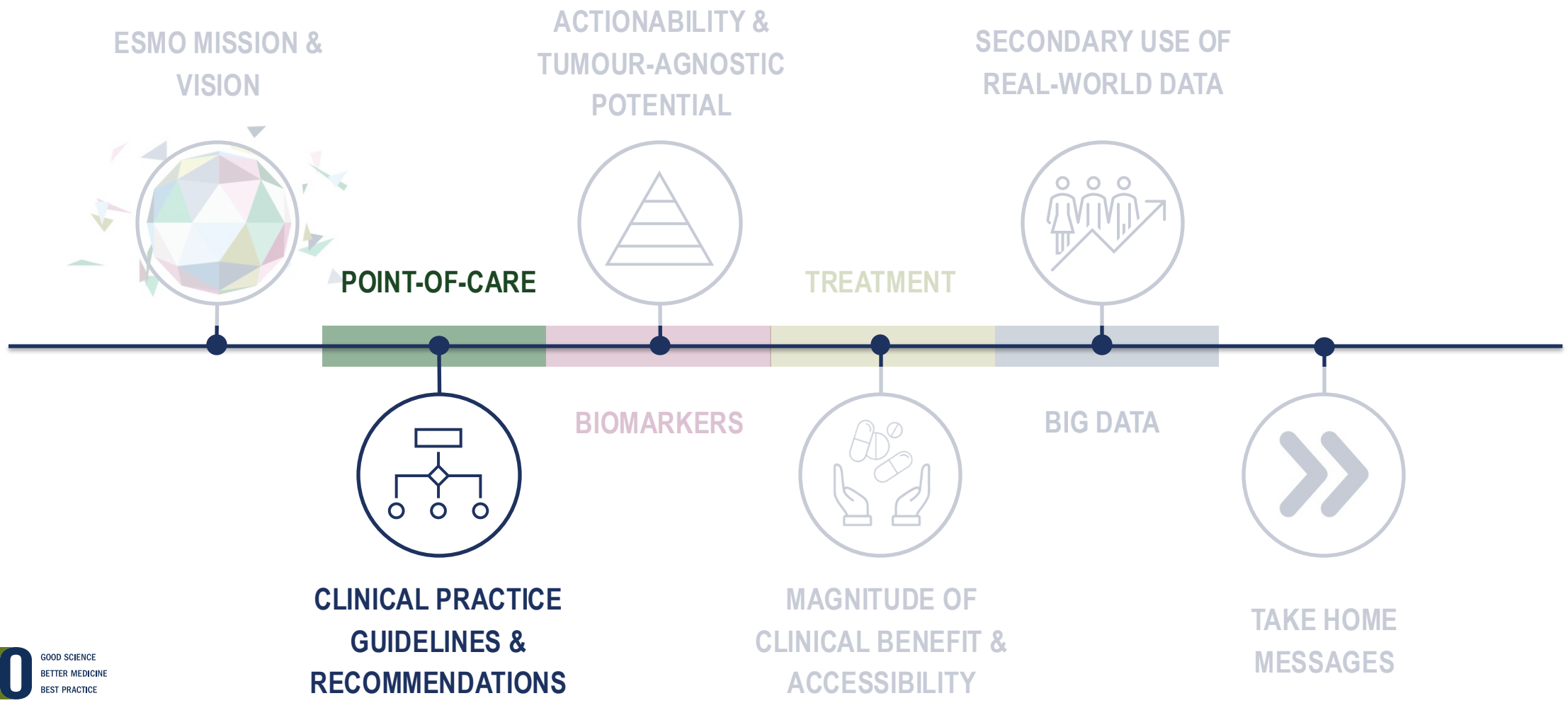

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

CLINICAL PRACTICE GUIDELINES

The ESMO Clinical Practice Guidelines, prepared and reviewed by leading experts and based on evidence-based medicine, provide you with a set of recommendations on state of the art care to help HCPs and patients.

Breast Cancer

Read more →

Gastrointestinal Cancers

Read more →

Lung and Chest Tumours

Read more →

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

Oncogene-addicted metastatic non-small-cell lung cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up

Ann Oncol. 2023;34(4):339-357.
Hendriks L E, Kerr K, Menis J, et al. on behalf of the ESMO Guidelines Committee

- This ESMO Clinical Practice Guideline provides key recommendations and algorithms for managing oncogene-addicted mNSCLC.
- The guideline covers diagnosis, staging, risk assessment, treatment and disease monitoring.
- ESMO-MCBS scores are given to describe the levels of evidence for treatment choices.
- ESCAT scores are given to describe the evidence level for genomic alterations as biomarkers for using targeted therapies.
- Recommendations are based on available scientific data and the authors'collective expert opinion.
- In clinical practice, all recommendations provided need to be discussed with patients in a shared decision-making approach.

Living Guideline

ESMO Oncogene-Addicted Non-Small Cell Lung Cancer Living Guideline

Related items

Read full article

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ESMO-MCBS Scorecards

Guidelines Webinar →

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

Oncogene-addicted metastatic non-small-cell lung cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up☆

L. E. Hendriks[1], K. M. Kerr[2], J. Menis[3], T. S. Mok[4], U. Nestle[5,6], A. Passaro[7], S. Peters[8], D. Planchard[9], E. F. Smit[10,11], B. J. Solomon[12], G. Veronesi[13,14] & M. Reck[15], on behalf of the ESMO Guidelines Committee*

ESMO Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer Living Guideline

To cite this living guideline, please include the original Clinical Practice Guideline citation "Ann Oncol. 2023;34(4):339-357" and this online publication, including date and version number: "ESMO Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer Living Guideline, v1.2 January 2025"
Export references (RIS)
This living guideline was prepared by L Hendriks, F Cortiula, E Mariamidze, D Martins-Branco, G Pentheroudakis and M Reck, on behalf of the Clinical Practice Guideline author group.
v1.2 was prepared by L Hendriks, F Cortiula, E Mariamidze, D Martins-Branco, M Reck and S. Popat, and has been peer reviewed.

Diagnosis, Pathology and Molecular Biology — More info →

Staging and Risk Assessment — More info →

Management of Advanced and Metastatic Disease — More info →

Follow-up, Long-term Implications and Survivorship — More info →

ESMO GUIDELINES: REAL WORLD CASES
ONCOGENE-ADDICTED NSCLC

ESMO WEBINAR SERIES

ESMO Guidelines: Real World Cases - Oncogene-Addicted Non-Small-Cell Lung Cancer

Chair: **Solange Peters**
Speakers: **Giuseppe Lo Russo, Lizza Hendriks, Jaafar Bennouna**

ESMO CPG @ POINT-OF-CARE

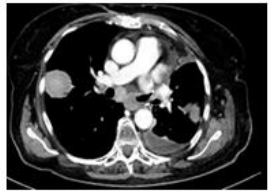
CASE PRESENTATION

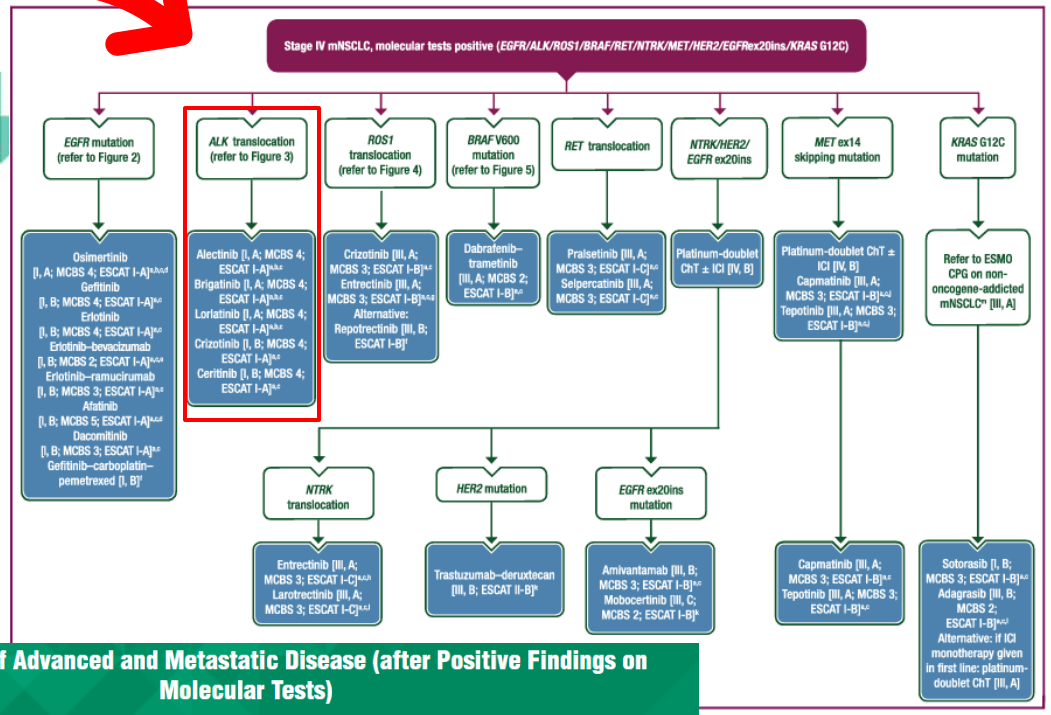
Female, 52 years, Never smoker
No co-morbidites; ECOG PS 0

- **Jul'15** persistent dry cough
- **Cest X-Ray:** bilateral lung opacities
- **TB CT scan**: bilateral lung nodules; pathologic mediastinal lymph nodes; pathologic abdominal lymph nodes
- **TB FDG-PET:** confirms the sites of disease of CT scan
- **FBS/TBNA:**

Lung adenocarcinoma
cT4 N2 M1c, IV stage (AJCC 8th edition)

ALK (IHC): **positive**
EGFR (PCR Hot spot) **wild-type**
ROS1 (FISH) **negative**
PD-L1 1-49%



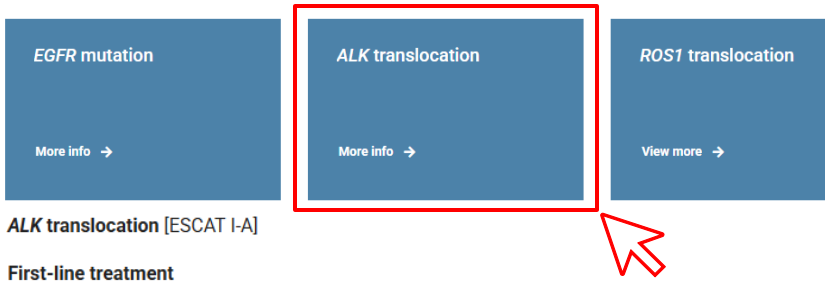


Management of Advanced and Metastatic Disease (after Positive Findings on Molecular Tests)

ESMO GUIDELINES: REAL WORLD CASES

Giuseppe Lo Russo MD;PHD

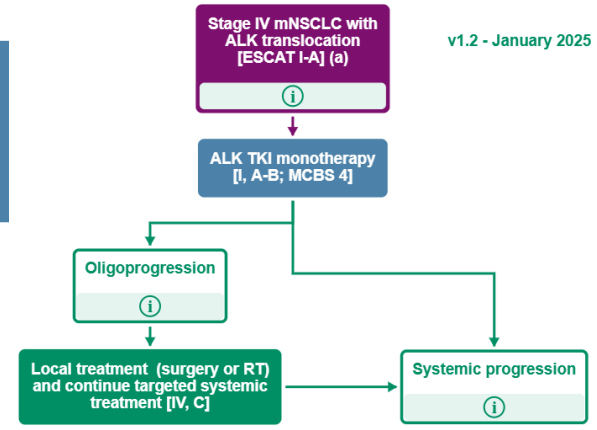
What if the patient had bone metastases with indication for palliative radiotherapy?



***ALK* translocation** [ESCAT I-A]

First-line treatment

- Patients should be treated in the first-line setting with alectinib [I, A; **ESMO-MCBS v1.1 score: 4**], brigatinib [I, A; **ESMO-MCBS v1.1 score: 4**] or lorlatinib [I, A; **ESMO-MCBS v1.1 score: 4**]. These options are preferred over crizotinib [I, B; **ESMO-MCBS v1.1 score: 4**] or ceritinib [I, B; **ESMO-MCBS v1.1 score: 4**].



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ESMO-ESTRO CONSENSUS RECOMMENDATIONS ON

SAFETY OF COMBINING TARGETED THERAPIES WITH RADIOTHERAPY

Disclaimer Preliminary data. Not for clinical use before reading the full publications.

Table 1. Delphi consensus recommendations for various drug class-radiotherapy combinations. The traffic light colors represent the recommended safety measure for each scenario.

GENERAL STATEMENTS												
Irradiated area	**Type of radiotherapy**	**CDK4/6**	**HER2**	**PARP**	**mTOR**	**EGFR**	**ALK**	**BRAF/ MEK**	**PD-(L)1**	**CTLA-4**	**VEGF**	**Multi target**
Skin	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											
Brain	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											
Head & neck	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											
Thorax	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											
Abdomen/pelvis	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											
Musculoskeletal tissues	Low-dose palliative											
	High-dose conventionally fractionated											
	High-dose stereotactic											

LEGEND			
Minor/no adaptation Clinically insignificant drug interruption/dosage reduction, a minor radiotherapy adaptation, or no adaptations.	**Major adaptation** Clinically relevant drug interruption/ dosage reduction or a major radiotherapy adaptation.	**Not combining** Protracted drug interruption or no radiotherapy, to avoid a drug-radiotherapy interaction.	**No agreement** Agreement rate below 75%.

DISCLAIMER
Preliminary results. Not for clinical use before reading the full publications.

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ESTRO European Society for Radiotherapy & Oncology


Collaborating
Asian
Societies
Malaysian Oncological Society
Taiwan Oncology Society
THAI SOCIETY OF CLINICAL ONCOLOGY
CSCO
Chinese Society of Clinical Oncology
Beijing Xisike Clinical Oncology Research Foundation
JSMO
Japanese Society of Medical Oncology
INDIAN SOCIETY OF MEDICAL & PAEDIATRIC ONCOLOGY
The Indonesian Society of Hematology Medical Oncology
ISHMO
KSMO
KOREAN SOCIETY OF MEDICAL ONCOLOGY
Singapore Society of Oncology
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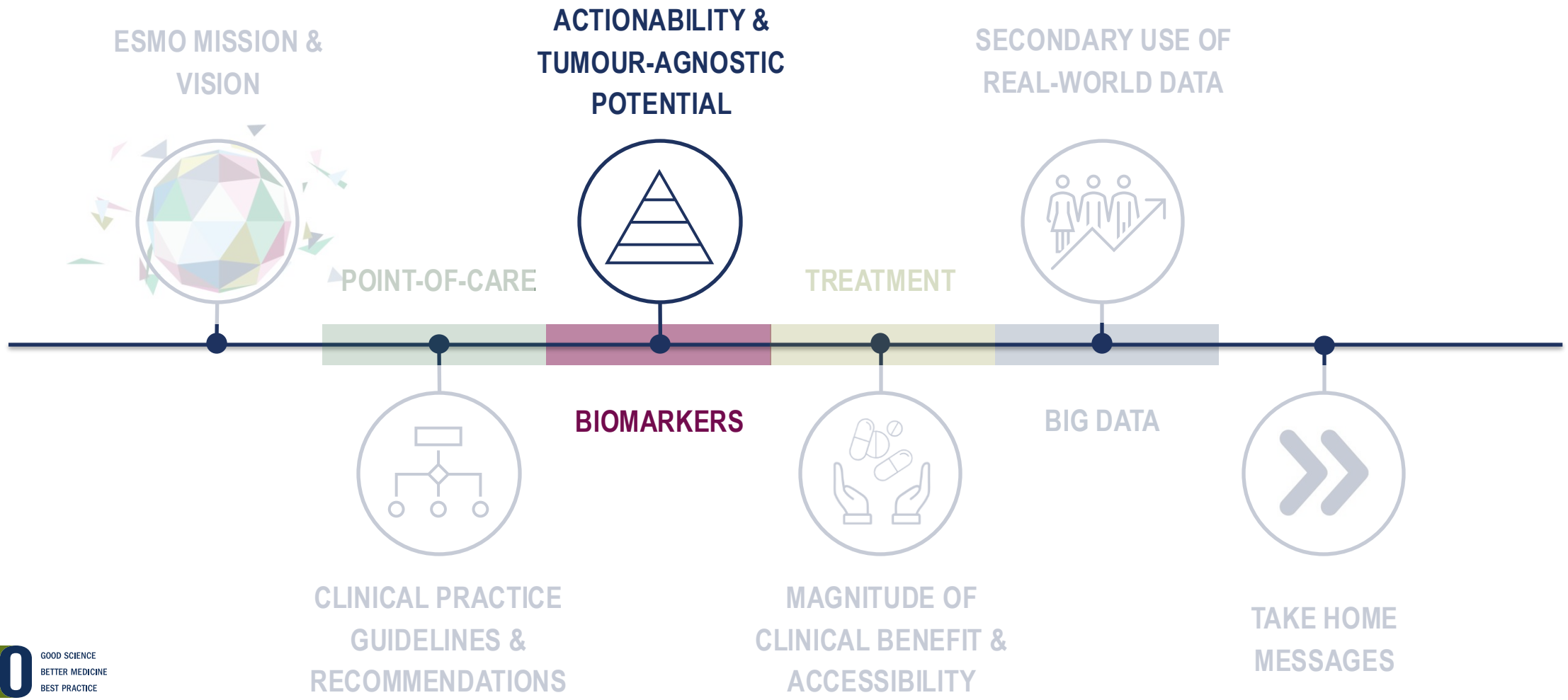
1969
ESMO PAGA
Pan-Asian Guidelines Adaptation

DEFINING STANDARDS

ESMO Frameworks and Tools



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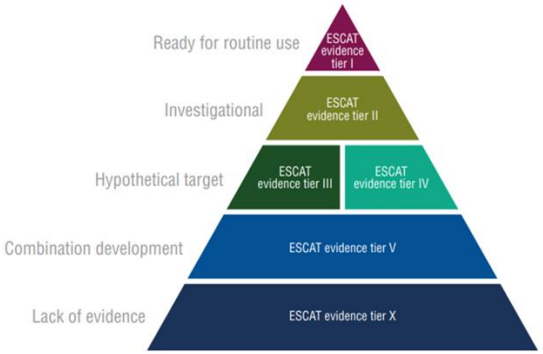
ESCAT: ESMO Scale of Clinical Actionability for molecular Targets

	ESCAT evidence tier		Required level of evidence	Clinical implication
Ready for routine use	I Alteration-drug match is associated with improved outcome in clinical trials	I-A	Prospective, randomised clinical trials show the alteration-drug match in a specific tumour type results in a clinically meaningful improvement of a survival end point	Access to the treatment should be considered standard of care
		I-B	Prospective, non-randomised clinical trials show that the alteration-drug match in a specific tumour type, results in clinically meaningful benefit as defined by ESMO MCBS 1.1	
		I-C	Clinical trials across tumour types or basket clinical trials show clinical benefit associated with the alteration-drug match, with similar benefit observed across tumour types	
Investigational	II Alteration-drug match is associated with antitumour activity, but magnitude of benefit is unknown	II-A	Retrospective studies show patients with the specific alteration in a specific tumour type experience clinically meaningful benefit with matched drug compared with alteration-negative patients	Treatment to be considered "preferable" in the context of evidence collection either as a prospective registry or as a prospective clinical trial
		II-B	Prospective clinical trial(s) show the alteration-drug match in a specific tumour type results in increased responsiveness when treated with a matched drug, however, no data currently available on survival end points	
Hypothetical target	III Alteration-drug match suspected to improve outcome based on clinical trial data in other tumour type(s) or with similar molecular alteration	III-A	Clinical benefit demonstrated in patients with the specific alteration (as tiers I and II above) but in a different tumour type. Limited/absence of clinical evidence available for the patient-specific cancer type or broadly across cancer types	Clinical trials to be discussed with patients
		III-B	An alteration that has a similar predicted functional impact as an already studied tier I abnormality in the same gene or pathway, but does not have associated supportive clinical data	
	IV Pre-clinical evidence of actionability	IV-A	Evidence that the alteration or a functionally similar alteration influences drug sensitivity in preclinical *in vitro* or *in vivo* models	Treatment should "only be considered" in the context of early clinical trials. Lack of clinical data should be stressed to patients
		IV-B	Actionability predicted *in silico*	
Combination development	V Alteration-drug match is associated with objective response, but without clinically meaningful benefit		Prospective studies show that targeted therapy is associated with objective responses, but this does not lead to improved outcome	Clinical trials assessing drug combination strategies could be considered
Lack of Evidence	X Lack of evidence for actionability		No evidence that the genomic alteration is therapeutically actionable	The finding should not be taken into account for clinical decision

To enquire or ask questions about the ESMO Scale for Clinical Actionability of molecular Targets, please send an email to education@esmo.org

Mateo J, *et al. Annals of Oncology* 2018;29(9):1895-1902.

A framework to rank genomic alterations as targets for precision oncology



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NEXT-GENERATION SEQUENCING IN ADVANCED CANCER

ESMO recommendations updated in 2024

Table 2. List of genomic alterations level I/II according to ESCAT in advanced non-squamous non-small-cell lung cancer

Gene	Alteration	Estimated prevalence	ESCAT score	Drug class matched	References
EGFR	Common mutations (deletion exon 19, p.L858R)	15% Caucasian 50% Asian 30% LATAM	IA	First-, second- and third-generation EGFR TKIs EGFR-MET bispecific antibodies + third-generation EGFR TKIs EGFR-MET bispecific antibodies + chemotherapy ± EGFR TKIs (after PD on third-generation EGFR TKIs)	Midha et al., *Am J Can Res* 2015[12] Arrieta et al., *J Thorac Oncol* 2015[13] Soria et al., *N Engl J Med* 2018[14] Ramalingam et al., *N Engl J Med* 2020[15] Cho et al., *Ann Oncol* 2023[16] Passaro et al., *Ann Oncol* 2024[17]
	Acquired p.T790M mutation in exon 20	60% after first- or second-generation EGFR TKIs	IA	Third-generation EGFR TKIs	Mok et al., *N Engl J Med* 2017[18] Papadimitrakopoulou et al., *Ann Oncol* 2020[19]
	Exon 20 insertions	2%	IA	EGFR-MET bispecific antibodies or TKIs	Park et al., *J Clin Oncol* 2021[20] Zhou et al., *N Engl J Med* 2023[21]
	Uncommon mutations (p.G719 variants in exon 18, p.L861Q in exon 21, p.S768I in exon 20)	10%	IB	Second- and third-generation EGFR TKIs	Cho et al., *J Clin Oncol* 2020[22] Yang et al., *Front Oncol* 2022[23]
ALK	Fusions	5%	IA	ALK TKIs	Mok et al., *Ann Oncol* 2020[24] Shaw et al., *N Engl J Med* 2020[25] Camidge et al., *J Thorac Oncol* 2021[26] Horn et al., *JAMA Oncol* 2021[27] Solomon et al., *Lancet Respir Med* 2023[28]
KRAS	Mutations (p. G12C)	12%	IA	KRAS ^{G12C} TKIs	Jänne et al., *N Engl J Med* 2022[29] de Langen et al., *Lancet*
RET	Fusions	1%-2%	IA	RET TKIs	Subbiah et al., *Clin Can* [31] Griesinger et al., *Ann On* 202 Drilon et al., *J Clin Oncol* 2023[33] Zhou et al., *N Engl J Med* 2023[34]
ROS1	Fusions	1%-2%	IB	ROS1 TKIs	Shaw et al., *Ann Oncol* 2019[35] Shaw et al., *Lancet Oncol* 2019[36] Drilon et al., *JTO Clin Res Rep* 2022[37]
BRAF	Mutations (p. V600E)	2%	IB	BRAF TKIs + MEK TKIs	Planchard et al., *J Thorac Oncol* 2022[38] Riely et al., *J Clin Oncol* 2023[39]
MET	Mutations exon 14 skipping	3%	IB	MET TKIs	Drilon et al., *Nat Med* 2020[40] Wolf et al., *J Clin Oncol* 2021[41] Lu et al., *Lancet Respir* 2021[42] Thomas et al., *J Thorac Oncol* 2022[43] Wolf et al., *Ann Oncol* 2022[44]
	Focal amplifications	5% as primary 15% as mechanism of acquired resistance on EGFR TKIs	IIB	MET TKIs + third-generation EGFR TKIs EGFR-MET bispecific antibodies + third-generation EGFR TKIs	Yu et al., *Ann Oncol* 2021[45] Bauml et al., *J Clin Oncol* 2021[46] Shu et al., *J Clin Oncol* 2022[47] Marmarelis et al., *J Thorac Oncol* 2022[48] Hartmaier et al., *Cancer Discov* 2023[49] Tan et al., *J Clin Oncol* 2023[50]
ERBB2	Hotspot mutations	3%	IIB	Pan-HER TKIs Anti-HER2 ADCs	Hyman et al., *Nature* 2018[51] Li et al., *N Engl J Med* 2022[52]
NRG1	Fusions	<1%	IIB	Anti-HER2/HER3 bispecific antibody	Schram et al., *JCO* 2022[53]

ESCAT Tier IA: *ALK* fusion - alectinib

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ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

Recommendations for the use of next-generation sequencing (NGS) for patients with advanced cancer in 2024: a report from the ESMO Precision Medicine Working Group

M. F. Mosele[1,2], C. B. Westphalen[3], A. Stenzinger[4], F. Barlesi[1,2,5], A. Bayle[5,6,7,8], I. Bièche[9], J. Bonastre[7,8], E. Castro[10], R. Dienstmann[11,12,13], A. Krämer[14,15], A. Czarnecka[16,17], F. Meric-Bernstam[18], S. Michiels[7,8], R. Miller[19,20], N. Normanno[21], J. Reis-Filho[22†], J. Remon[2], M. Robson[23], E. Rouleau[24], A. Scarpa[25], C. Serrano[11], J. Mateo[11] & F. André[1,2,5*]

- ✓ *Tumour-agnostic*
- ✓ Non-squamous NSCLC
- ✓ Breast cancer
- ✓ Colorectal cancer
- ✓ Prostate cancer
- ✓ Gastric cancer
- ✓ Pancreatic cancer
- ✓ *Ovarian cancer*
- ✓ Hepatocellular carcinoma
- ✓ Rare tumours: Cholangiocarcinoma, *GIST, Soft tissue sarcomas, Thyroid cancer, CUP*

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NEXT-GENERATION SEQUENCING IN ADVANCED CANCER

ESMO recommendations updated in 2024

Table 1. List of tumour-agnostic genomic alterations

Gene/Signature[a]	Alteration	Estimated prevalence (illustration of tumours with high prevalence of the alteration)	ESCAT score	Drug class matched	References
NTRK1/2/3	Fusions	80%-90% secretory breast cancer 15%-20% Spitzoid melanoma	IC	TRK inhibitors	Hong et al., *Lancet Oncol* 2020[2] Demetri et al., *Clin Can Res* 2022[3]
MSI-H/dMMR[a]	MSI-H/dMMR	15%-20% endometrial cancer 15%-20% gastric adenocarcinoma	IC	PD-1 checkpoint inhibitors	Marcus et al., *Clin Can Res* 2019[4]
RET	Fusions	7% thyroid papillary cancer 2% salivary gland cancer	IC	RET inhibitors	Subbiah et al., *Lancet Oncol* 2022[5] Subbiah et al., *Nat Med* 2022[6]
BRAF	Mutations (p.V600E)	40%-45% melanoma 5%-6% small intestinal adenocarcinoma	IC	BRAF inhibitors + MEK inhibitors	Subbiah et al., *Cancer Discov* 2020[7] Salama et al., *J Clin Oncol* 2020[8]
FGFR1/2/3	Fusions Mutations	20%-40% bladder cancer 3% glioblastoma multiforme 10%-20% urothelial carcinoma 10% endometrial cancer	IC	Pan-FGFR TKIs	Pant et al., *Lancet Oncol* 2023[9]
TMB-H[a]	TMB-H	40% small-cell lung cancer	IC	PD-1/PD-L1 checkpoint inhibitors	Valero et al., *JAMA Oncol* 2021[10] Friedman et al., *Cancer Discov* 2022[11]

dMMR, mismatch repair deficient; ESCAT, ESMO Scale for Clinical Actionability of molecular Targets; FGFR, fibroblast growth factor receptor; MSI-H, microsatellite instability-high; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; TKIs, tyrosine kinase inhibitors; TMB-H, tumor mutation burden-high; TRK, tropomyosin receptor kinase.
[a]Signature; TKIs, tyrosine kinase inhibitors.

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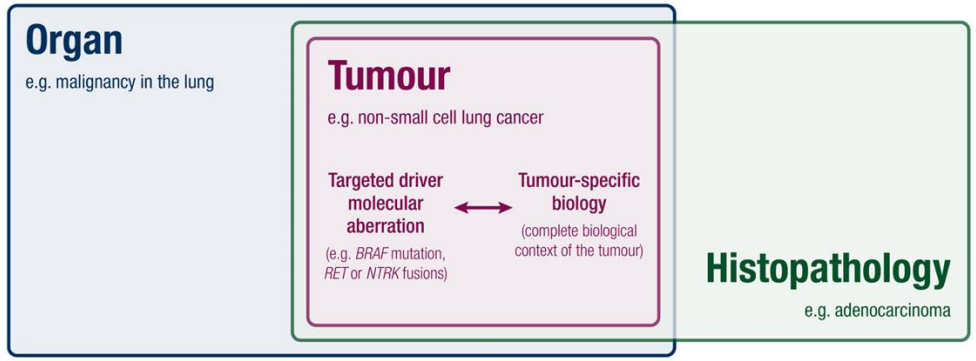
What makes a target alteration and a molecularly guided treatment option tumour-agnostic?



- ✓ ***Tumour-agnostic***
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- ✓ Hepatocellular carcinoma
- ✓ Rare tumours: Cholangiocarcinoma, ***GIST, Soft tissue sarcomas, Thyroid cancer, CUP***

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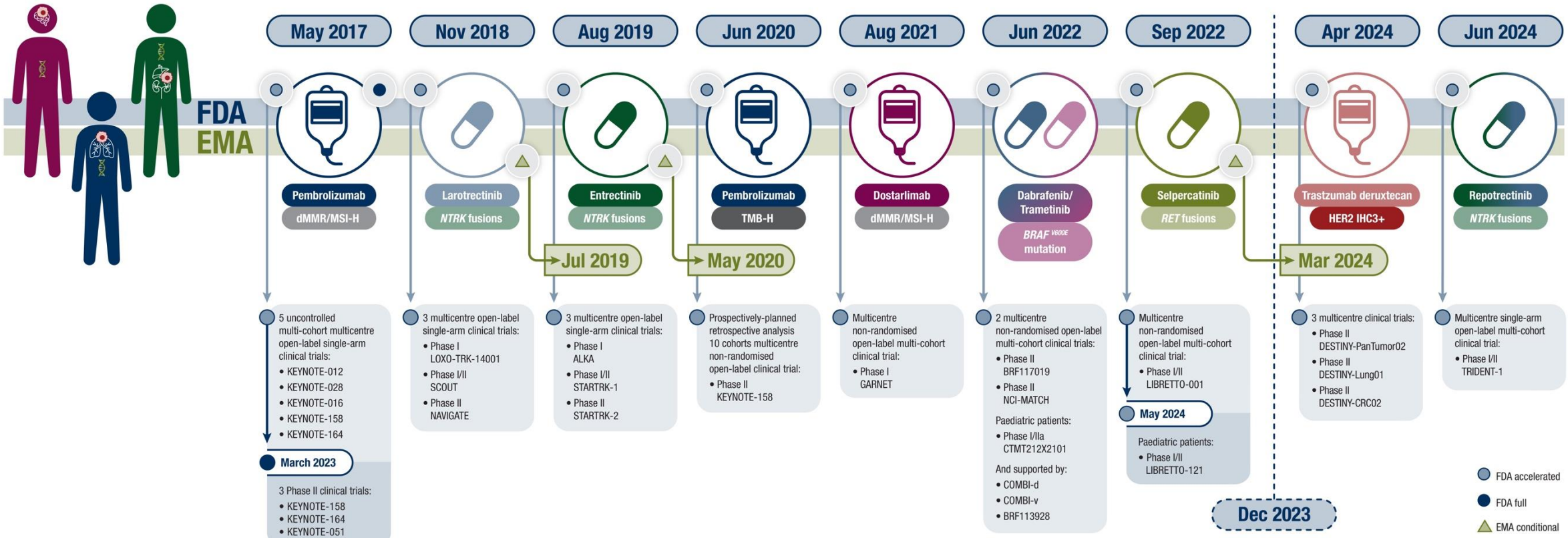
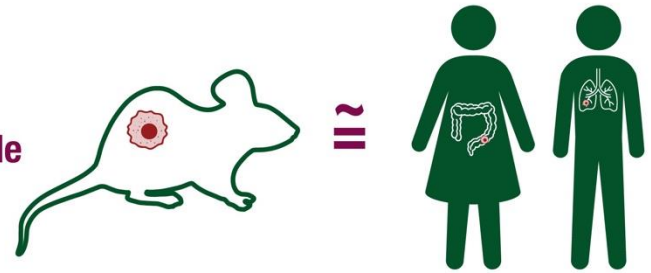
TUMOUR-AGNOSTIC APPROVED INDICATIONS



ETAC-S: ESMO TUMOUR-AGNOSTIC CLASSIFIER AND SCREENER

Minimum requirements for tumour-agnostic potential

Robust preclinical evidence of mechanistic/biological rationale



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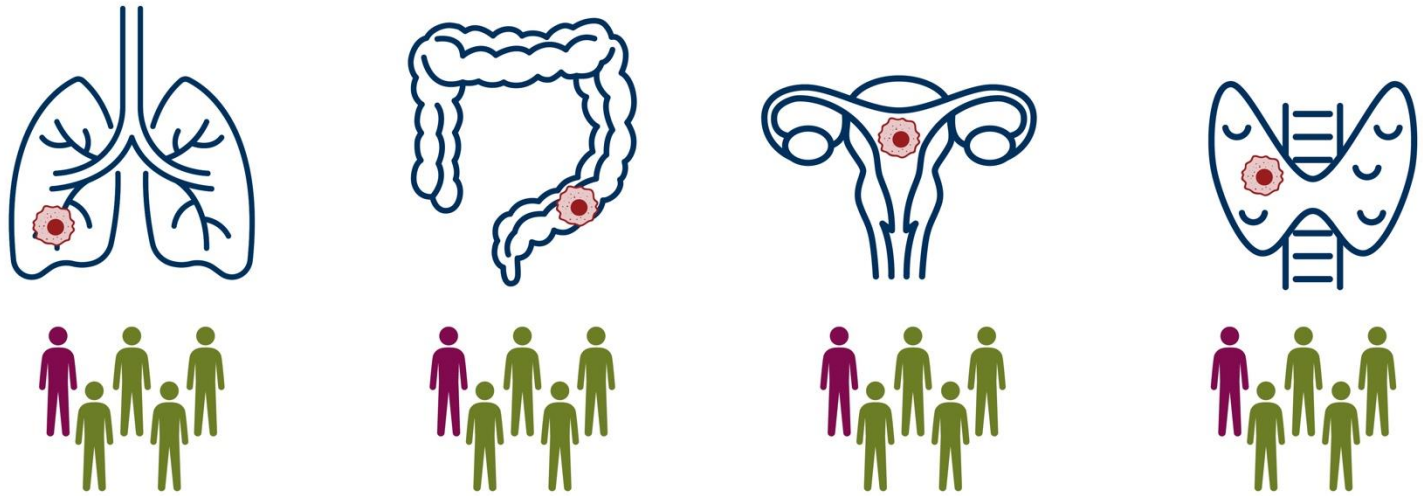
Phase I/II or Phase II trials

2/3 tumours investigated and ≥ 4 tumour types with

Minimum ORR≥20% in ≥ 5 evaluable patients with refractory disease



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

The ESMO Tumour-Agnostic Classifier and Screener (ETAC-S): a tool for assessing tumour-agnostic potential of molecularly guided therapies and for steering drug development

C. B. Westphalen[1,2*†], D. Martins-Branco[3†], J. R. Beal[4], C. Cardone[5], N. Coleman[6,7,8], A. M. Schram[9,10], S. Halabi[11,12], S. Michiels[13,14], C. Yap[15], F. André[16,17,18], F. Bibeau[19], G. Curigliano[20,21], E. Garralda[22], S. Kummar[23], R. Kurzrock[24], S. Limaye[25], S. Loges[26,27], A. Marabelle[28], C. Marchió[29,30], J. Mateo[22], J. Rodon[31], T. Spanic[32], G. Pentheroudakis[3†] & V. Subbiah[33‡]

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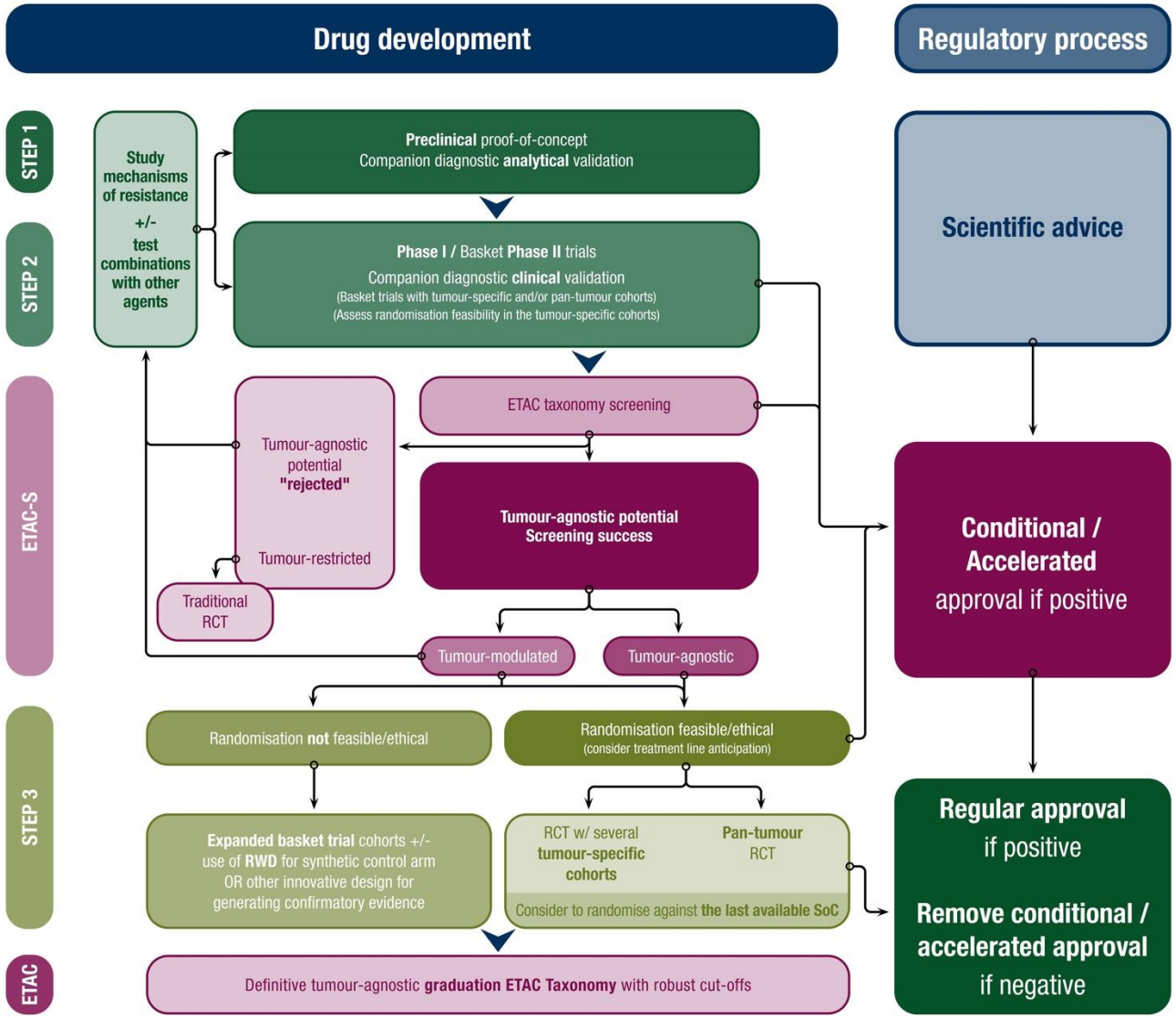
ETAC-S: ESMO TUMOUR-AGNOSTIC CLASSIFIER AND SCREENER



The ETAC-S is an easily applicable set of minimum requirements designed to identify molecularly guided treatment options eligible for tumour-agnostic potential.

Proposed tumour-agnostic **framework** allows to foster and accelerate **drug development** for patients with cancer.

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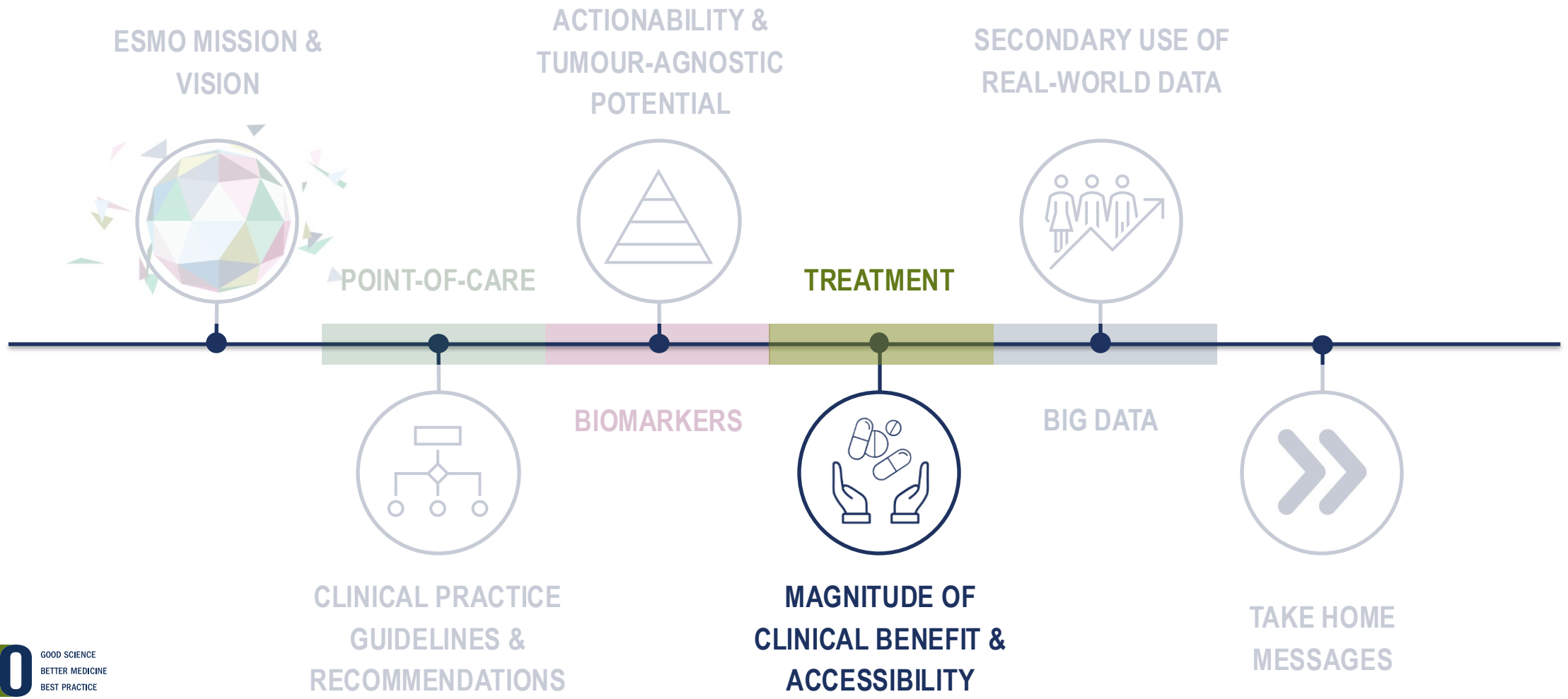
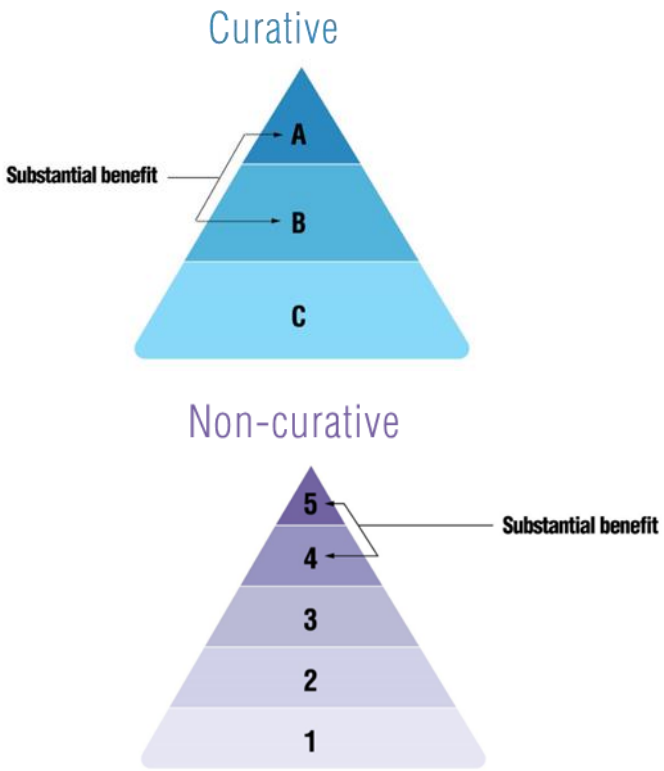
DEFINING STANDARDS

ESMO Frameworks and Tools



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE



Cherny et al, Ann Oncol 2015 & 2017

Curative intent:

- (Neo)adjuvant / curative therapy — Form 1

Non-curative intent:

- Primary outcome OS — Form 2A
- Primary outcome PFS — Form 2B
- Primary outcome RR / QoL / non-inferiority — Form 2C
- Single arm — Form 3

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE

Patient with mCRC RAS-wt/BRAF-wt/HER2-neg who have been previously treated with fluoropyrimidine-based ChT, an anti-VEGF therapy and an anti-EGFR therapy.

- Regorafenib [**ESMO-MCBS v1.1 score: 1**] is recommended in patients pre-treated with fluoropyrimidines, oxaliplatin, irinotecan and biologics, if available, or in earlier lines of therapy following oxaliplatin and irinotecan regimen failure, depending on local approvals [I, A].

Regorafenib

CORRECT

← Back

1

Score

Indication details

Reference

Grothey A, Cutsem EV, Sobrero A et al. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. Lancet 2013; 381:303-312

Hofheinz RD, Bruix J, Demetri GD, et al. Effect of Regorafenib in Delaying Definitive Deterioration in Health-Related Quality of Life in Patients with Advanced Cancer of Three Different Tumor Types. Cancer Manag Res. 2021;13:5523-5533

Primary Outcome(s)

Primary Outcome(s)	OS
Evaluated Outcome	OS
Form(s)	Form 2a

Outcome Data

OS Control	5 months
OS Gain	1.4 months
OS HR	0.77 (0.64-0.94)

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE

Patient with mCRC RAS-wt/BRAF-wt/HER2-neg who have been previously treated with fluoropyrimidine-based ChT, an anti-VEGF therapy and an anti-EGFR therapy.

- Trifluridine–tipiracil (TAS-102) **[ESMO-MCBS v1.1 score: 3]** is recommended in patients pretreated with fluoropyrimidines, oxaliplatin, irinotecan and biologics, if available, or in earlier lines of therapy following oxaliplatin and irinotecan regimen failure, depending on local approvals [I, A].

Trifluridine/Tipiracil (TAS-102)

RECOURSE

← Back

3

Score

Reference

Mayer RJ, Van Cutsem EV, Falcone A et al. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. N Engl J Med 2015; 372:1909-1919

Van Cutsem E, Mayer RJ, Laurent S et al. The subgroups of the phase III RECOURSE trial of trifluridine/tipiracil (TAS-102) versus placebo with best supportive care in patients with metastatic colorectal cancer. Eur J Cancer 2018;90:60-72

Indication details

Primary Outcome(s)

Primary Outcome(s)	OS
Evaluated Outcome	OS
Form(s)	Form 2a

Outcome Data

PFS Control	1.7 months
PFS Gain	0.3 months
PFS HR	0.48 (0.41-0.57)
OS Control	5.2 months
OS Gain	2.0 months
OS HR	0.69 (0.59-0.81)

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE

Patient with mCRC RAS-wt/BRAF-wt/HER2-neg who have been previously treated with fluoropyrimidine-based ChT, an anti-VEGF therapy and an anti-EGFR therapy.

- Trifluridine–tipiracil (TAS-102) **[ESMO-MCBS v1.1 score: 3]** is recommended in patients pretreated with fluoropyrimidines, oxaliplatin, irinotecan and biologics, if available, or in earlier lines of therapy following oxaliplatin and irinotecan regimen failure, depending on local approvals [I, A]. The addition of bevacizumab to third- or later-line trifluridine–tipiracil should be considered if available [I, A; trifluridine–tipiracil–bevacizumab: **ESMO-MCBS v1.1 score: 4**].

Trifluridine/Tipiracil (TAS-102)

SUNLIGHT

← Back

4

Score

Reference

Prager GW, Taieb J Fakih M et al. Trifluridine-Tipiracil and Bevacizumab in Refractory Metastatic Colorectal Cancer. N Engl J Med. 2023;388(18):1657-1667

Primary Outcome(s)

Primary Outcome(s)	OS
Evaluated Outcome	OS
Form(s)	Form 2a

Outcome Data

OS Control	7.5 months
OS Gain	3.3 months
OS HR	0.61 (0.49-0.77)

ESMO STUDY ON THE AVAILABILITY, OUT-OF-POCKET COSTS AND ACCESSIBILITY OF ANTINEOPLASTIC MEDICINES

SPECIAL ARTICLE

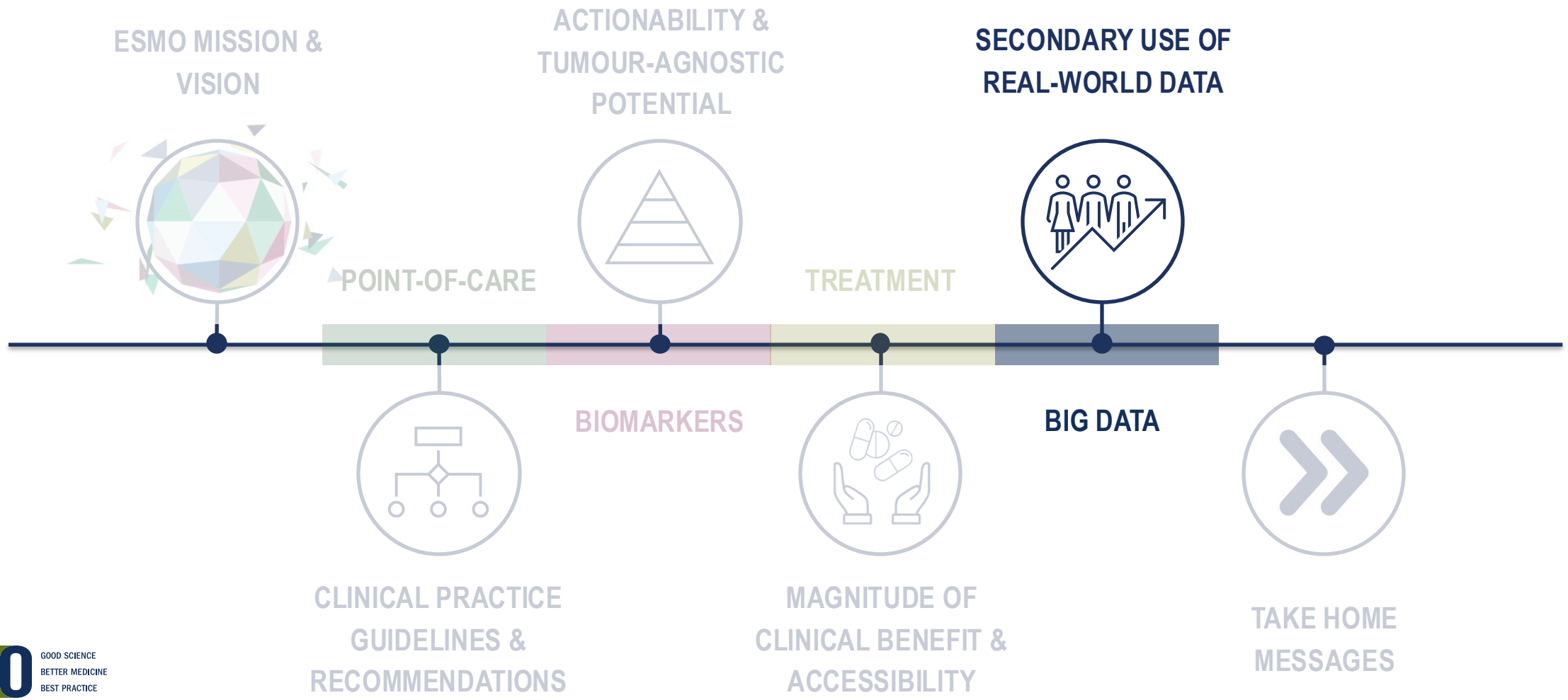
ESMO Global Consortium Study on the availability, out-of-pocket costs, and accessibility of cancer medicines: 2023 update

N. I. Cherny[1*†], D. Trapani[2,3†], M. Galotti[4], M. Saar[5,6], G. Bricalli[4], F. Roitberg[7,8], B. Gyawali[9], G. Curigliano[2,3], J.-Y. Blay[10], K. Meier[6,11], N. J. Latino[4] & E. G. E. de Vries[12]

Figure 3. New and expensive immune-mediated and targeted therapies on the 22nd WHO EML - formulary availability and out-of-pocket costs. (A) High- and upper middle-income countries. (B) Lower-middle- and low-income countries.

DEFINING STANDARDS

ESMO Frameworks and Tools



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

REVIEW

Characteristics and impact of real-world evidence studies in oncology: comprehensive mapping review of publications evaluating targeted therapies in solid tumours

A. Pellat[1,2†*], T. Grinda[3†], P. Cresta Morgado[4,5], A. Prelaj[6,7], V. Miskovic[6,7], A. Valachis[8], I. Zerdes[9,10], D. Martins-Branco[11], L. Provenzano[6,7], A. Spagnoletti[6], G. Nader-Marta[12], B. E. Wilson[13,14], Y.-H. Yang[15], G. Pentheroudakis[11], S. Delaloge[3], L. Castelo-Branco[16‡] & M. Koopman[17‡]

RWE studies published between 2020-2022

N = 1,251 studies, 50% took place in Asia

RWE reporting on TT is growing, nevertheless:

- 8% with international range, 41% unicentric, funding is unclear (at least 50% with no funding/not reported)

The scientific impact is still limited

- 3% of studies published in a journal with an IF > 10
- Studies with more centres (>10) and studies issued from Europe are both associated with higher IF

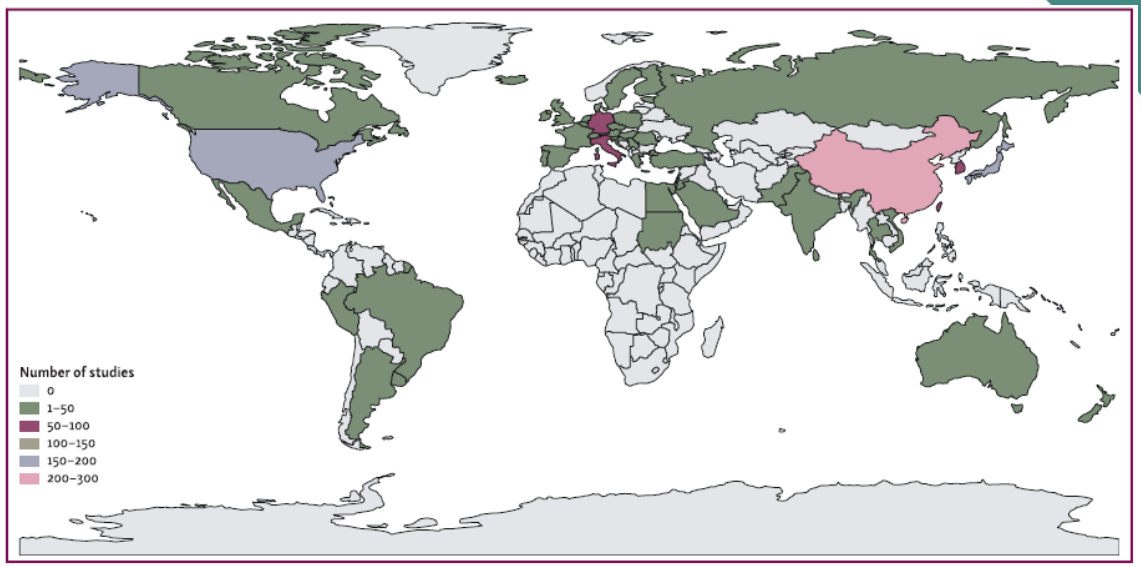
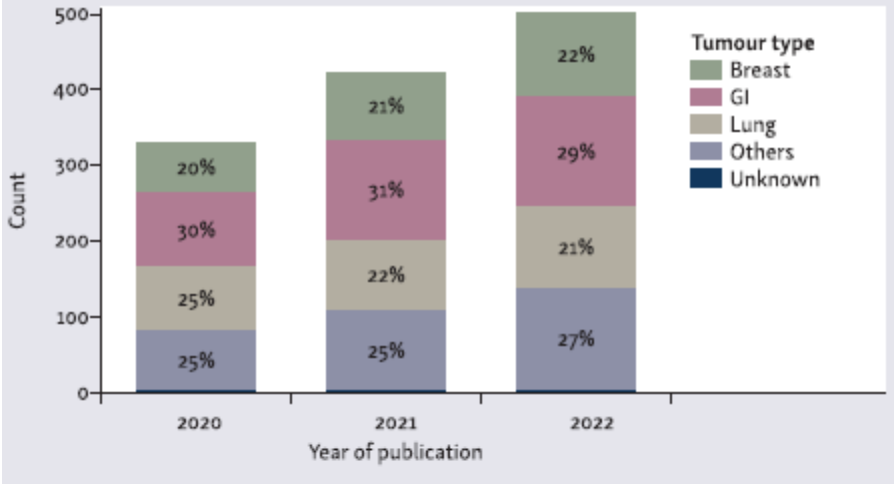


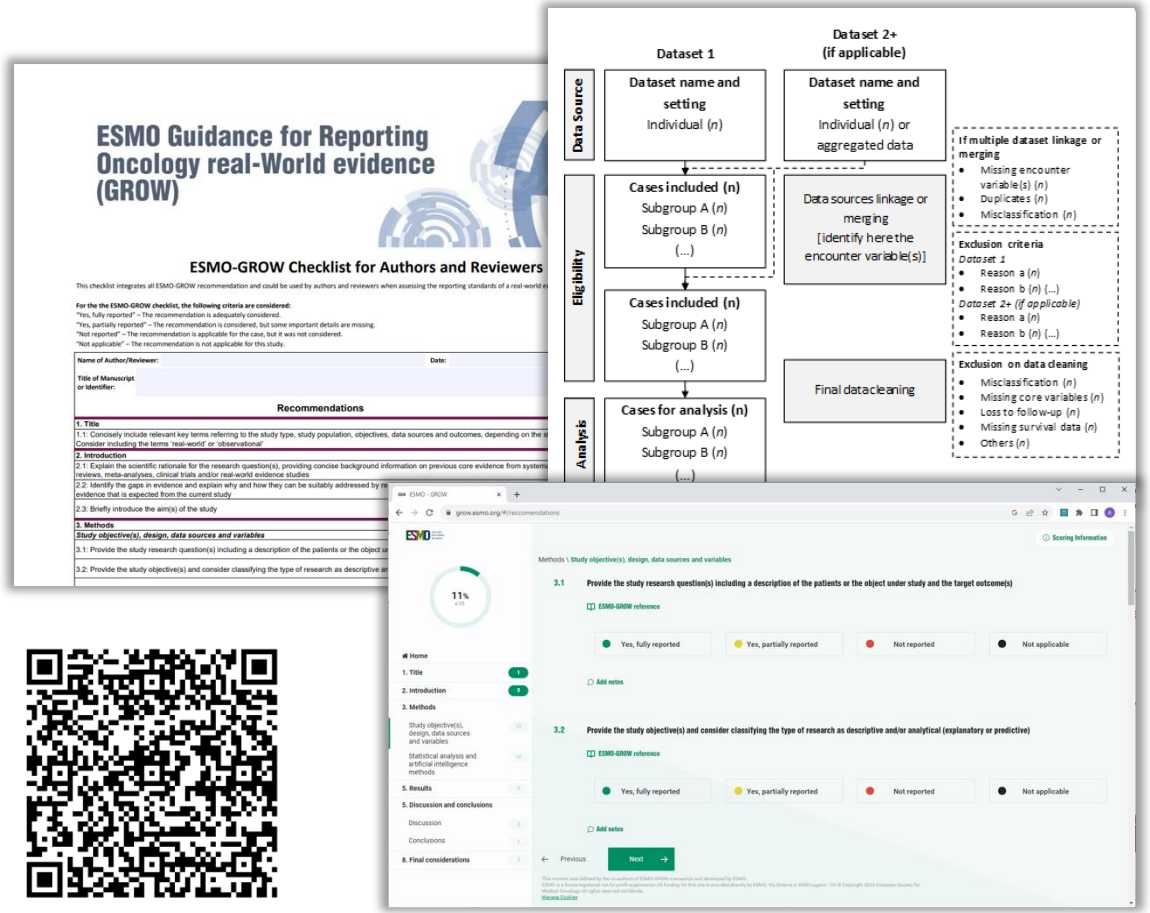
Figure 2. Number of publications per country.[a]
[a]The country of origin for each publication was derived from the corresponding author's affiliation (total of 54 countries).



ESMO GUIDANCE FOR REPORTING ONCOLOGY REAL-WORLD EVIDENCE (ESMO-GROW)

The first reporting guidance specifically developed for oncology RWE studies

- Detailed **list of recommendations** for authors and reviewers of RWE publications.
- Broad Scope: **Descriptive to Analytical**
- Addresses **new treatments**, **molecular-based epidemiology**, **oncology-specific variables**, and **tech-based RWE research** (AI, machine learning)
- Facilitates **harmonised interpretation** by all stakeholders
- **Related Materials:** Online Tool, Checklist, Flowchart



ESMO RWDD

Castelo-Branco L et al. "ESMO Guidance for Reporting Oncology real-World evidence (GROW)". **Ann Oncol** 2023; 34: 10.1016/j.annonc.2023.10.001 & **ESMO Real World Data & Digital Oncol** 2023; 1: 10.1016/j.esmorw.2023.10.001

ESMO GUIDANCE FOR REPORTING ONCOLOGY REAL-WORLD EVIDENCE (ESMO-GROW)

Reporting informative score

Observational Study > Future Oncol. 2024 Apr;20(12):761-780. doi: 10.2217/fon-2023-0858.
Epub 2024 Jan 17.

Real-world comparative effectiveness of palbociclib plus aromatase inhibitor in HR+/HER2- metastatic breast cancer

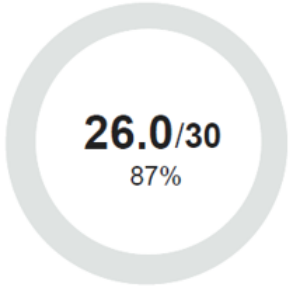
Nicholas Robert [1], Connie Chen [2], Sindy Kim [3], Zhe Zhang [3], Kathleen M Aguilar [1], Yunfei Wang [1], Benjamin Li [2], Michael Gaffney [2], Xin Huang [3], Lynn McRoy [2]

Affiliations + expand

PMID: 38231045 DOI: 10.2217/fon-2023-0858

Reporting informative score useful for:

- ✓ **authors** while drafting the manuscript
- ✓ **editors** and **peer-reviewers** after submission
- ✓ **readers** while critically appraising the report



ESMO-GROW informative Score

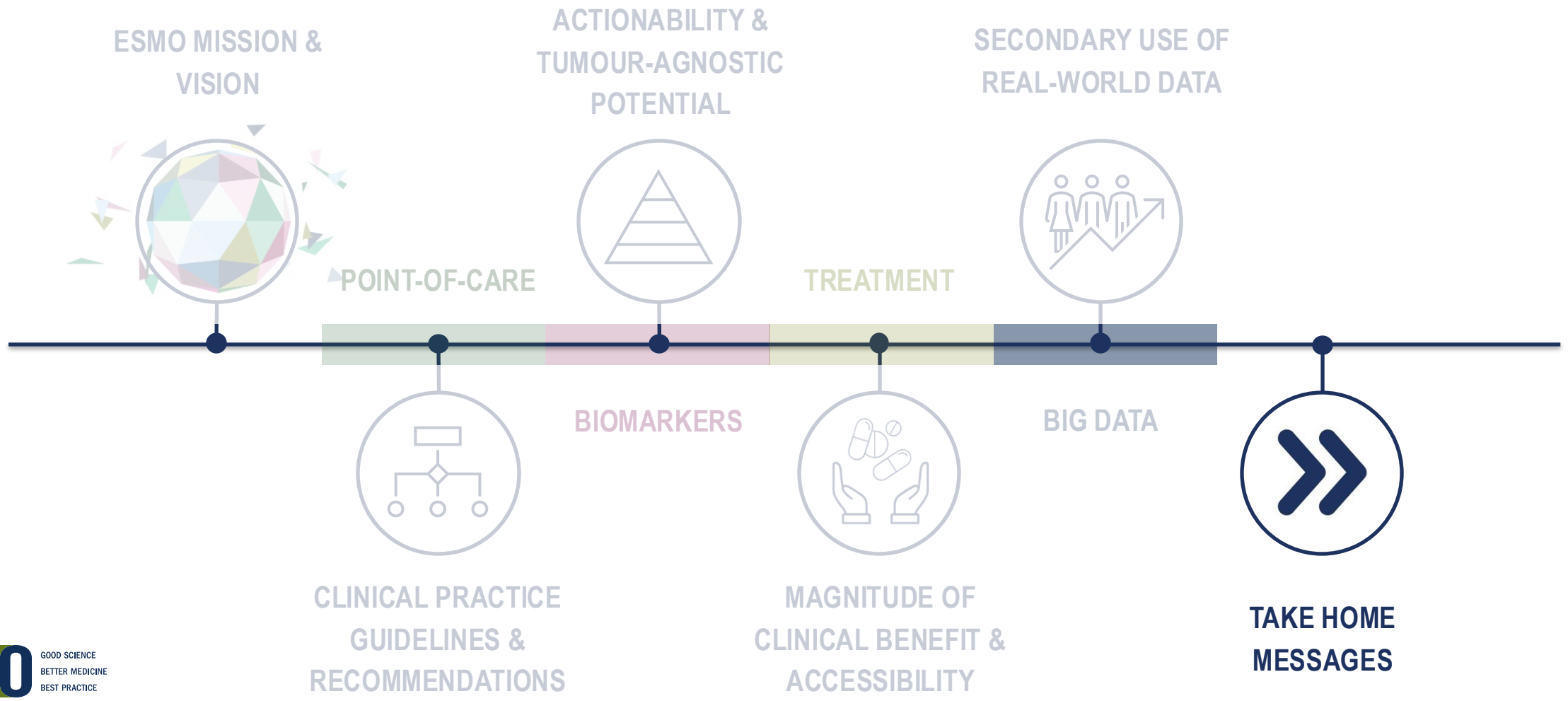
Detailed Scoring

- 23/35 Yes, fully reported
- 6/35 Yes, partially reported
- 1/35 Not reported
- 5/35 Not applicable

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

DEFINING STANDARDS THROUGH CANCER CARE PATHWAY

ESMO Frameworks and Tools



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO FRAMEWORKS AND TOOLS - TAKE HOME MESSAGES

CLINICAL PRACTICE GUIDELINES & RECOMMENDATIONS

- ✓ ESMO Clinical Practice Guidelines provide recommendations to help HCPs and patients with the best care options.
- ✓ ESMO-ESTRO statements describe the safety of combining radiotherapy with targeted agents or immunotherapy.

ACTIONABILITY & TUMOUR-AGNOSTIC POTENTIAL

- ✓ ESCAT is a systematic framework to rank molecular targets based on evidence available supporting their value as clinical targets.
- ✓ ESMO Tumour-Agnostic Classifier and Screener sets minimum requirements for treatments eligible for tumour-agnostic potential.

MAGNITUDE OF CLINICAL BENEFIT & ACCESSIBILITY

- ✓ ESMO-MCBS facilitates improved decision-making regarding the value of anti-cancer therapies, promotes accessibility and reduces iniquity of access to high value cancer treatments.

SECONDARY USE OF REAL-WORLD DATA

- ✓ ESMO-GROW recommendation checklist can be used by authors and reviewers for the reporting of RWE studies.

THANK YOU
FOR YOUR ATTENTION

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