ASOPROCÁNCER
Asociación Pro Congreso de Cancerología

XXII Congreso Colombiano de Cáncer

19, 20 y 21 de marzo de 2026

Inteligencia artificial en oncología
Atención integral centrada en el paciente

Centro de convenciones Neomundo
Bucaramanga

Con el aval de:

RADIOLIGANDOS EN Ca PRÓSTATA ¿A QUIÉN, CÓMO Y CUÁNDO MEDIR RESPUESTA?

Julián G. Rojas Camacho
Médico Nuclear
Fundación Santa Fe de Bogotá
Bucaramanga, 20 de marzo de 2026

XXII Congreso Colombiano de Cáncer

Declaración de conflictos de intereses

No tengo conflictos de interés en esta charla.

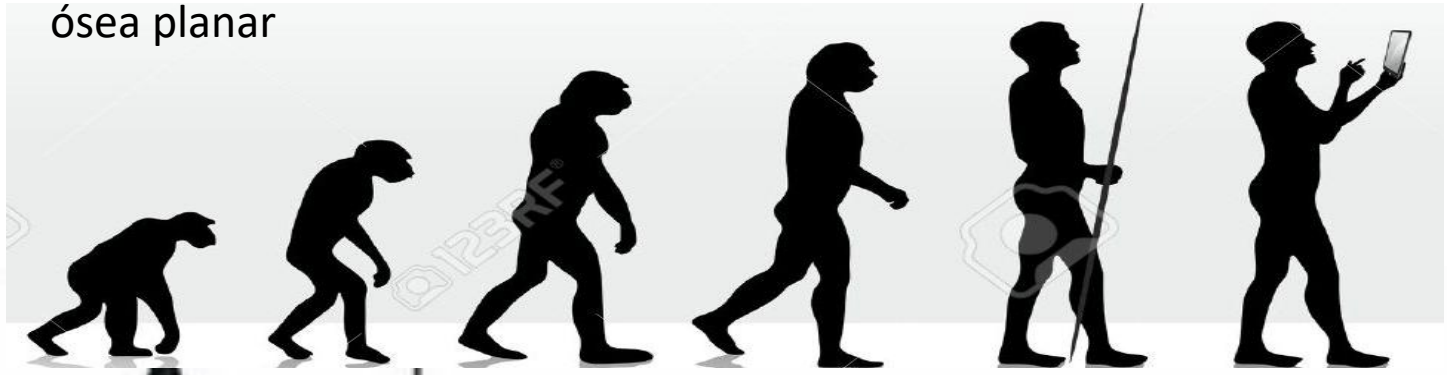
THERAGNOSTICS

Gammagrafía ósea planar

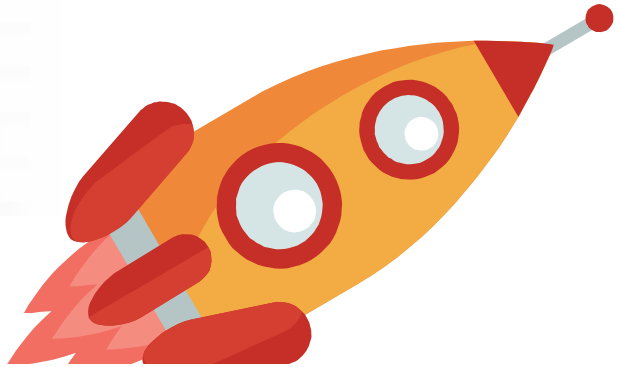
SPECT

SPECT-CT

PET-CT

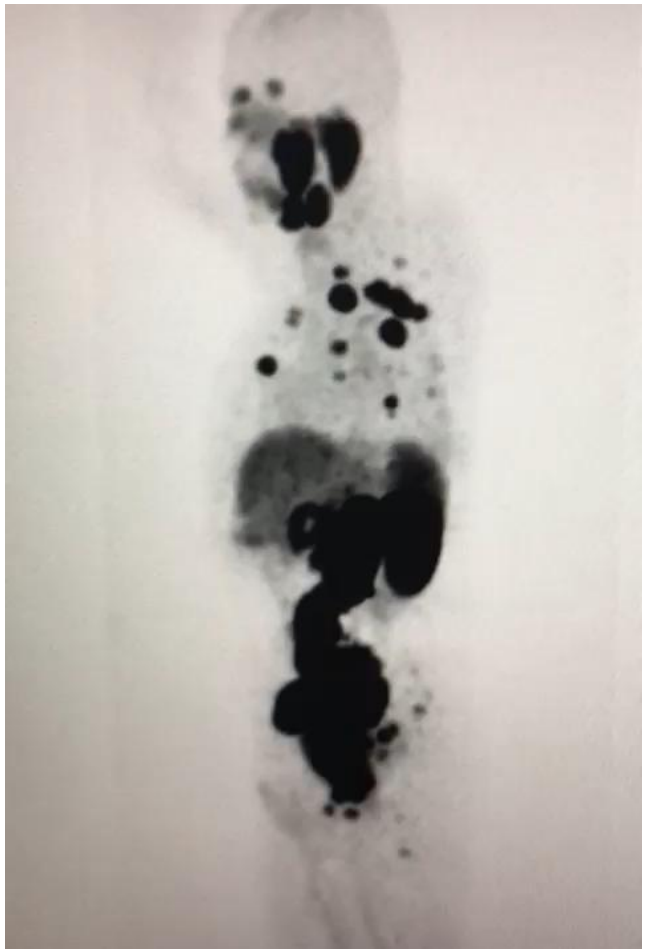


- **FDG**
- **Colina**
- **Fluciclovine**
- **PSMA**
- **FNa**
- **FAPI**



Basado en el conocimiento del autor

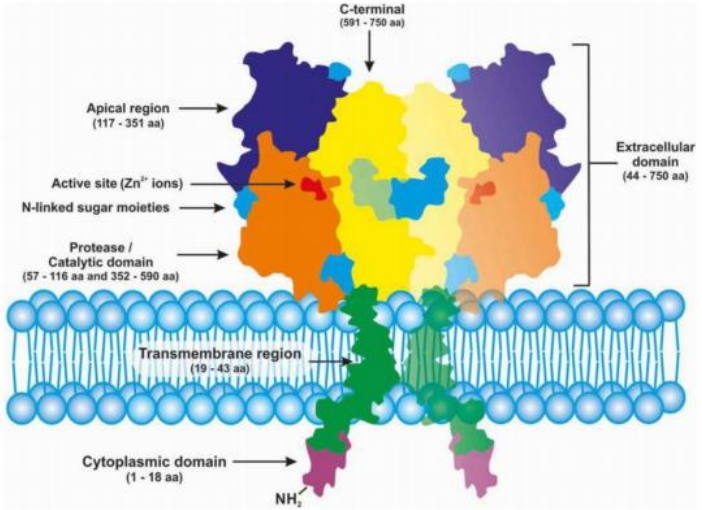
INC
Marzo 2018



PET-CT PSMA…

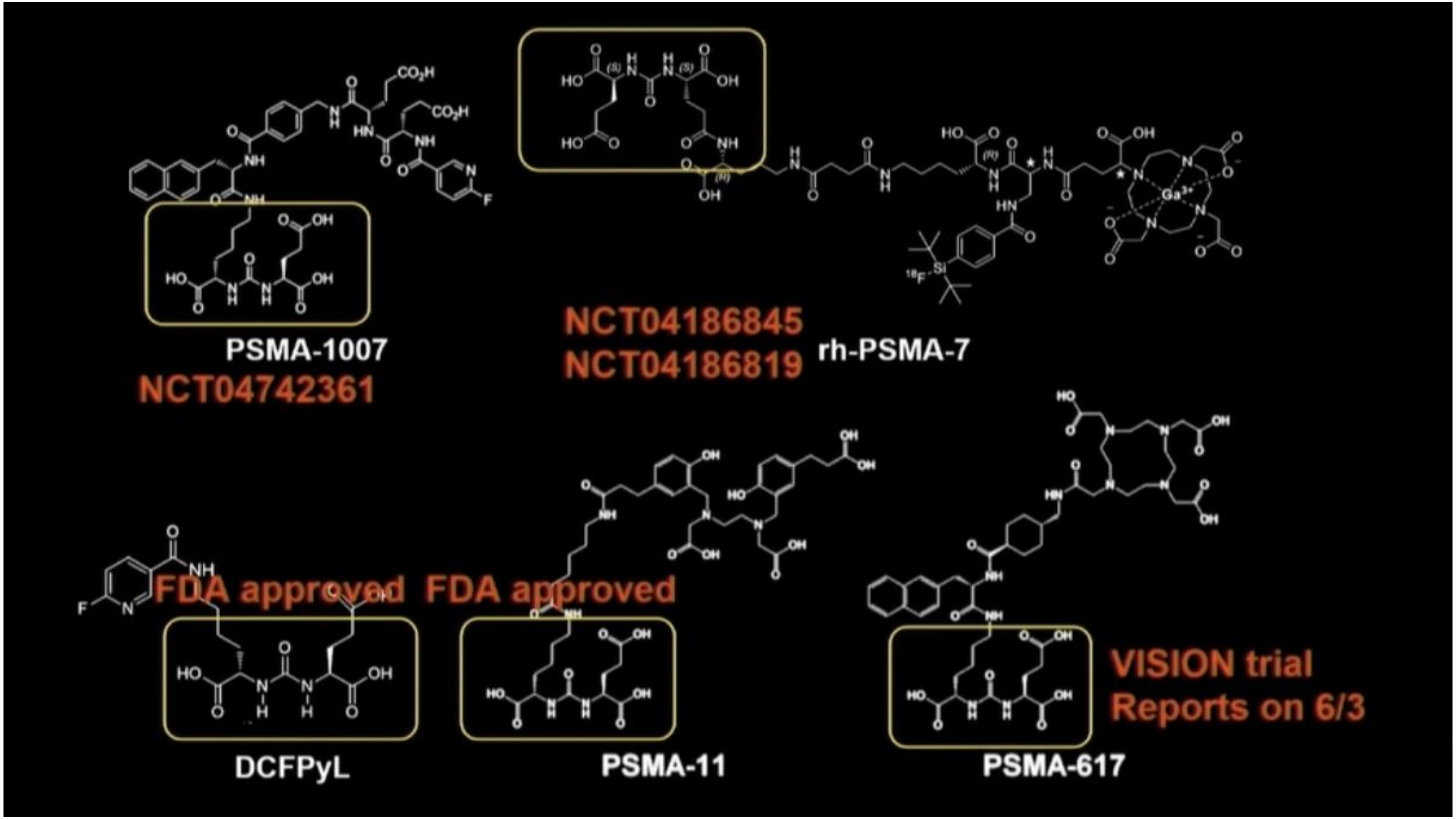
- Transmembrane glycoprotein
- Expression 100-1000 times higher in Prostate Ca. and increases with T and CPRC.
- 5 – 10 % of Prostate Ca. may be PSMA negative.

Theragnostics

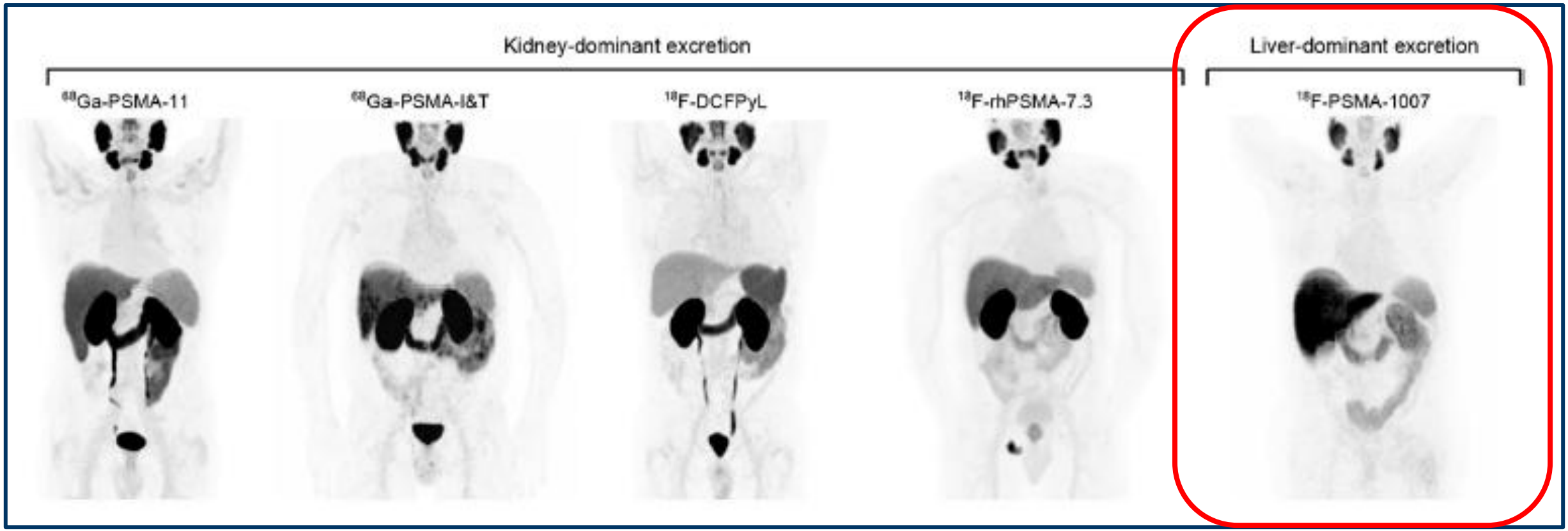


O'Driscott C et al, Br J Pharm 2016
doi:10.1111/bph.13576

Eur Urol. 2016 Mar;69(3):393-6.



Eur Urol. 2016 Mar;69(3):393-6.



> Disponibilidad de ligandos PET-CT PSMA
> Aprobación de teragnóstico PSMA

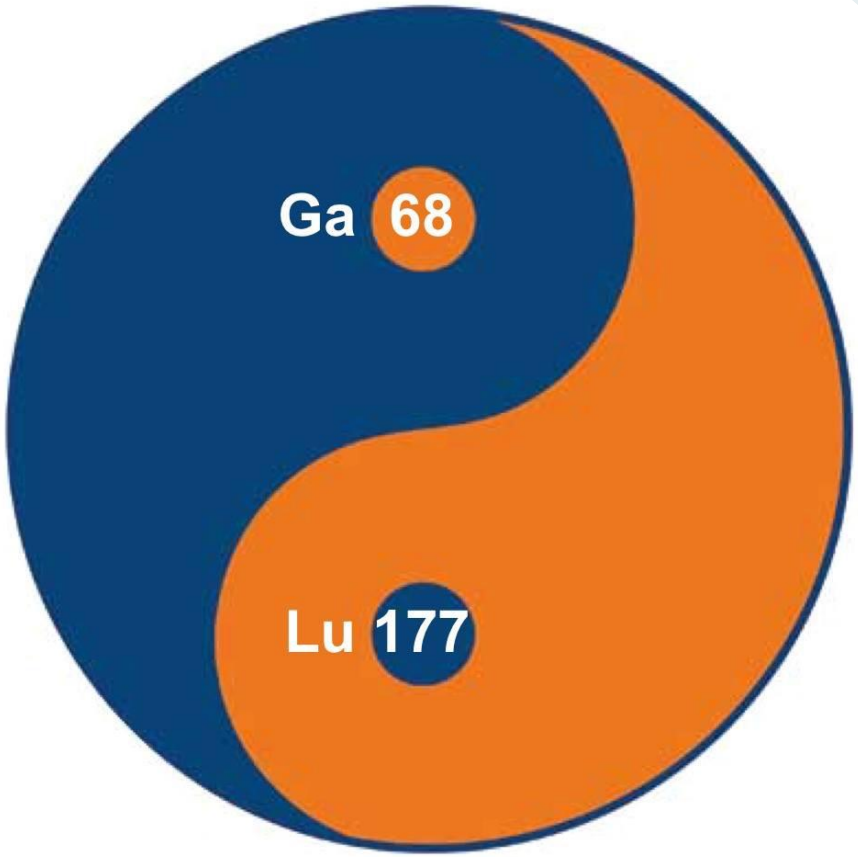
> Número de pacientes sometidos a PET-CT PSMA
¿Evaluación de respuesta?

Eur J Nucl Med Mol Imaging 50, 1466–1486 (2023)

Appropriate Use Criteria for Prostate-Specific Membrane Antigen PET Imaging

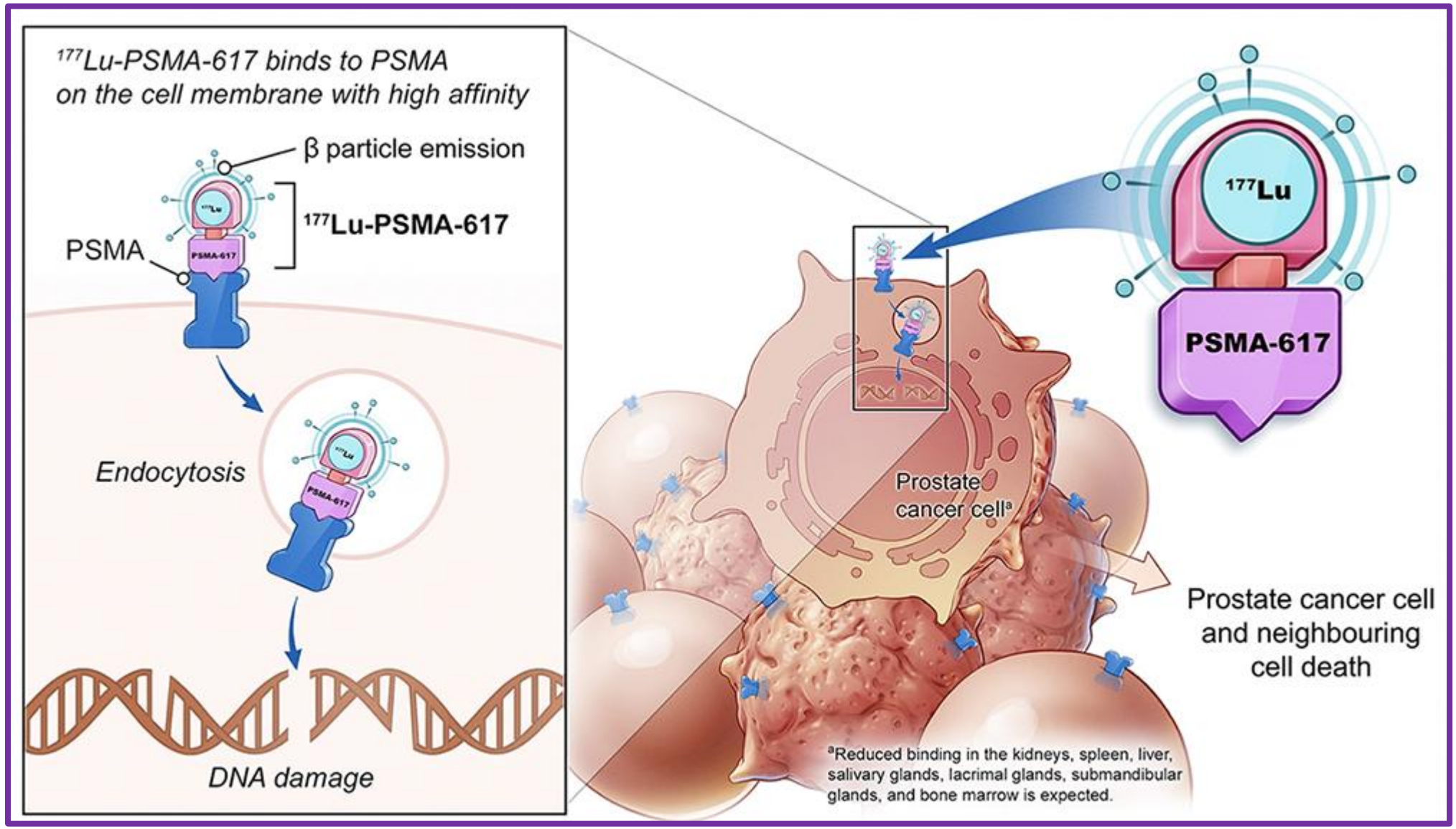
Scenario no.	Description	Appropriateness	Score
1	Patients with suspected prostate cancer (e.g., high/rising PSA levels, abnormal digital rectal examination results) evaluated for targeted biopsy and detection of intraprostatic tumor	Rarely appropriate	3
2	Patients with very-low, low-, and favorable intermediate-risk prostate cancer	Rarely appropriate	2
3	Newly diagnosed unfavorable intermediate-, high-risk, or very-high-risk prostate cancer	Appropriate	8
4	Newly diagnosed unfavorable intermediate-, high-risk, or very-high-risk prostate cancer with negative/equivocal or oligometastatic disease on conventional imaging	Appropriate	8
5	Newly diagnosed prostate cancer with widespread metastatic disease on conventional imaging	May be appropriate	4
6	PSA persistence or PSA rise from undetectable level after radical prostatectomy	Appropriate	9
7	PSA rise above nadir after definitive radiotherapy	Appropriate	9
8	PSA rise after focal therapy of the primary tumor	May be appropriate	5
9	nmCRPC (M0) on conventional imaging	Appropriate	7
10	Posttreatment PSA rise in the mCRPC setting	May be appropriate	6
11	Evaluation of response to therapy	May be appropriate	5

Journal of Nuclear Medicine January 2022, 63 (1) 59-68;
https://doi.org/10.2967/jnumed.121.263262

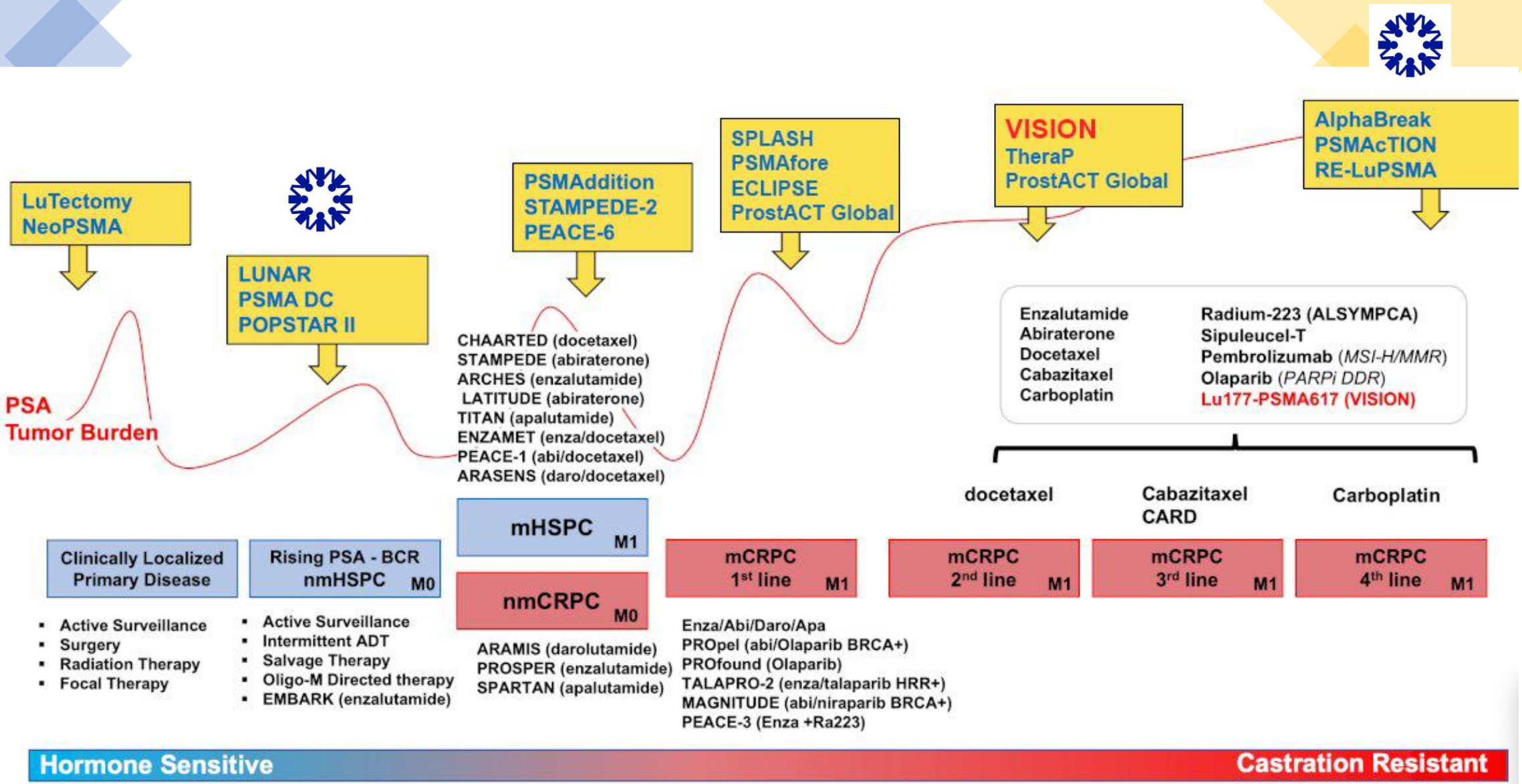


MEDICINA DE PRECISIÓN

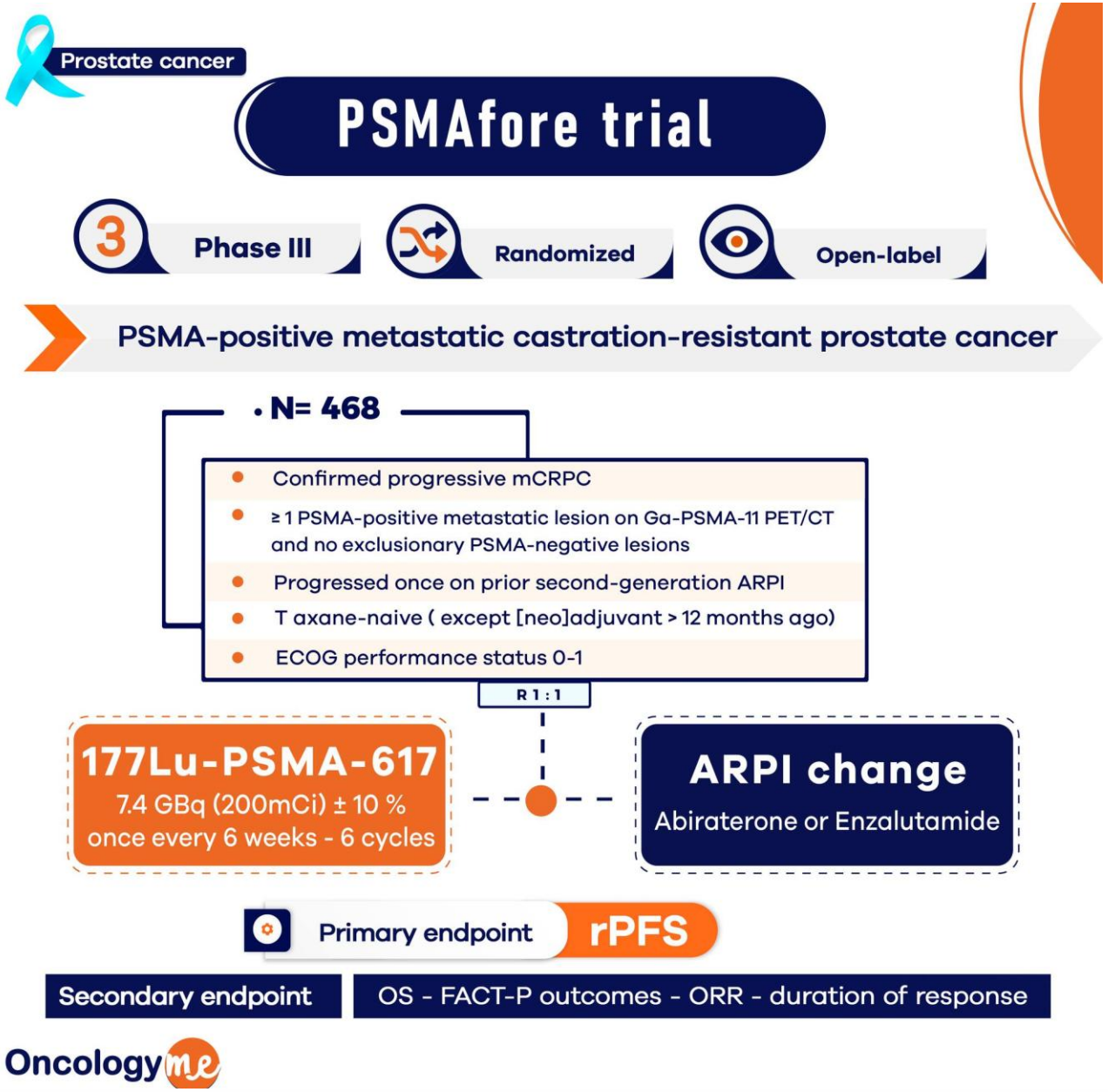
THERAGNOSTICS



N Engl J Med 2021 ; 385 : 1091 - 1103


LuTectomy
NeoPSMA
LUNAR
PSMA DC
POPSTAR II
PSMAddition
STAMPEDE-2
PEACE-6
SPLASH
PSMAfore
ECLIPSE
ProstACT Global
VISION
TheraP
ProstACT Global
AlphaBreak
PSMAcTION
RE-LuPSMA
PSA
Tumor Burden
CHAARTED (docetaxel)
STAMPEDE (abiraterone)
ARCHES (enzalutamide)
LATITUDE (abiraterone)
TITAN (apalutamide)
ENZAMET (enza/docetaxel)
PEACE-1 (abi/docetaxel)
ARASENS (daro/docetaxel)
Enzalutamide
Abiraterone
Docetaxel
Cabazitaxel
Carboplatin
Radium-223 (ALSYMPCA)
Sipuleucel-T
Pembrolizumab (MSI-H/MMR)
Olaparib (PARPi DDR)
Lu177-PSMA617 (VISION)
docetaxel
Cabazitaxel
CARD
Carboplatin
Clinically Localized
Primary Disease
Rising PSA - BCR
nmHSPC M0
mHSPC M1
nmCRPC M0
mCRPC
1st line M1
mCRPC
2nd line M1
mCRPC
3rd line M1
mCRPC
4th line M1
Active Surveillance
Surgery
Radiation Therapy
Focal Therapy
Active Surveillance
Intermittent ADT
Salvage Therapy
Oligo-M Directed therapy
EMBARK (enzalutamide)
ARAMIS (darolutamide)
PROSPER (enzalutamide)
SPARTAN (apalutamide)
Enza/Abi/Daro/Apa
PROpel (abi/Olaparib BRCA+)
PROfound (Olaparib)
TALAPRO-2 (enza/talaparib HRR+)
MAGNITUDE (abi/niraparib BRCA+)
PEACE-3 (Enza +Ra223)
Hormone Sensitive
Castration Resistant

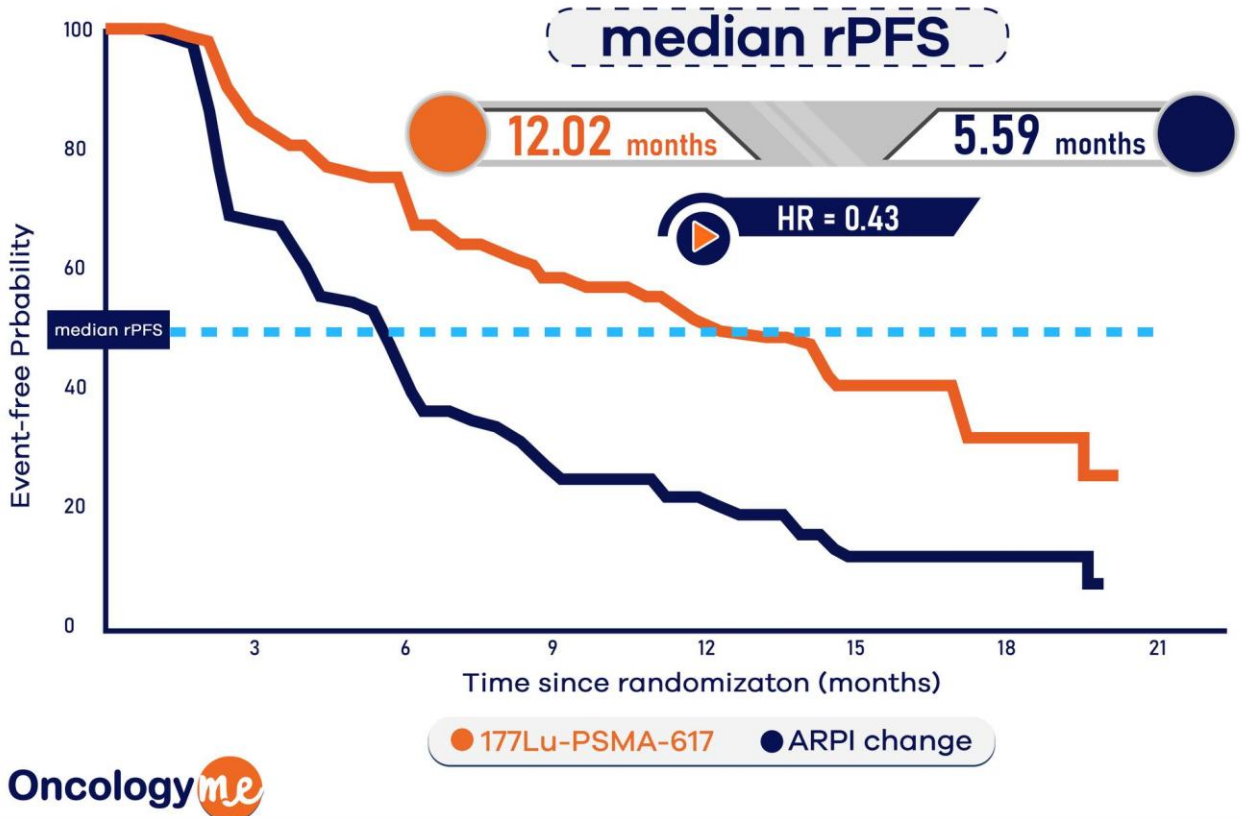
	TheraP (phase 2)	X	VISION (phase 3)
Population:	progressing mCRPC Pre Rx: taxane + ARPi		progressing mCRPC Pre Rx: taxane + ARPi
Imaging selection:	PSMA-PET **positive** (SUV>20) **FDG-PET: no discordant w/ PSMA** excl: 28%		PSMA-PET **positive** (SUV > liver) no FDG-PET excl: 12%
Intervention:	^{177}Lu-PSMA 8,5GBq – up to 6x	☢	^{177}Lu-PSMA 7,4GBq – 4-6x
Control Arm:	**Cabazitaxel** 20mg/m^2		**Standard of Care (SOC)** Excl: Chem, Immuno, ^{223}Ra
#1 Endpoint	PSA ≥ 50% response		rPFS and OS
rPFS:	12mo wo/ PD: 19% x 3% HR: 0.64		median: 8,7% x 3,4% HR: 0.40
OS:	immature in this analysis		median: 15,3% x 11,3% HR: 0.62
Toxicity (≥G3):	33% x 54%		37% x 5%
	Hofman *et al* ASCO GU21		Morris *et al* ASCO 21


Prostate cancer
PSMAfore trial
3
Phase III
Randomized
Open-label
PSMA-positive metastatic castration-resistant prostate cancer
N= 468
Confirmed progressive mCRPC
≥ 1 PSMA-positive metastatic lesion on Ga-PSMA-11 PET/CT and no exclusionary PSMA-negative lesions
Progressed once on prior second-generation ARPI
T axane-naive (except [neo]adjuvant > 12 months ago)
ECOG performance status 0-1
R 1 : 1
177Lu-PSMA-617
7.4 GBq (200mCi) ± 10 %
once every 6 weeks - 6 cycles
ARPI change
Abiraterone or Enzalutamide
Primary endpoint
rPFS
Secondary endpoint
OS - FACT-P outcomes - ORR - duration of response
Oncologyme

Prostate cancer

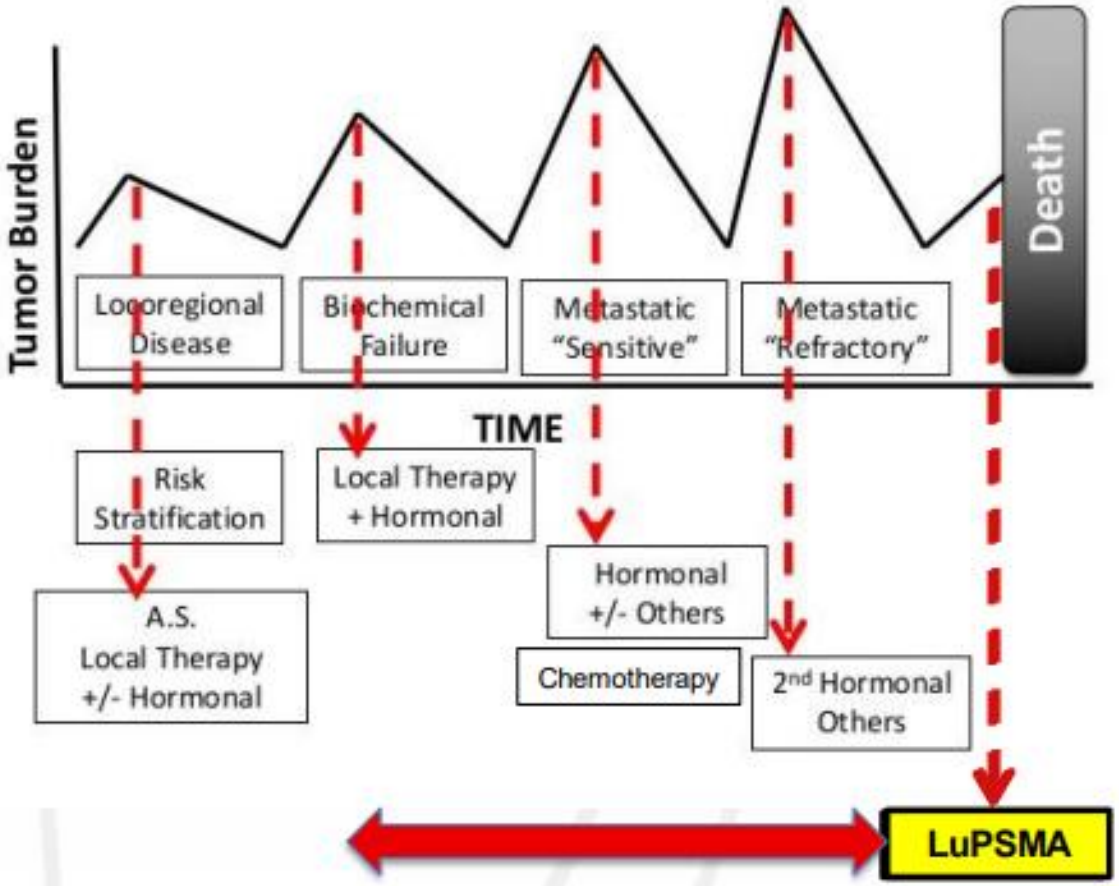
PSMAfore trial

Significant improvement in rPFS



OncologyMe

^{177}Lu-PSMA shows promise: can it be used earlier?



Cancers **2021**, 13, 4023. https://doi.org/10.3390/cancers13164023

BERLIN 2025 ESMO congress

Phase 3 trial of [^{177}Lu]Lu-PSMA-617 combined with ADT + ARPI in patients with PSMA-positive metastatic hormone-sensitive prostate cancer (PSMAddition)

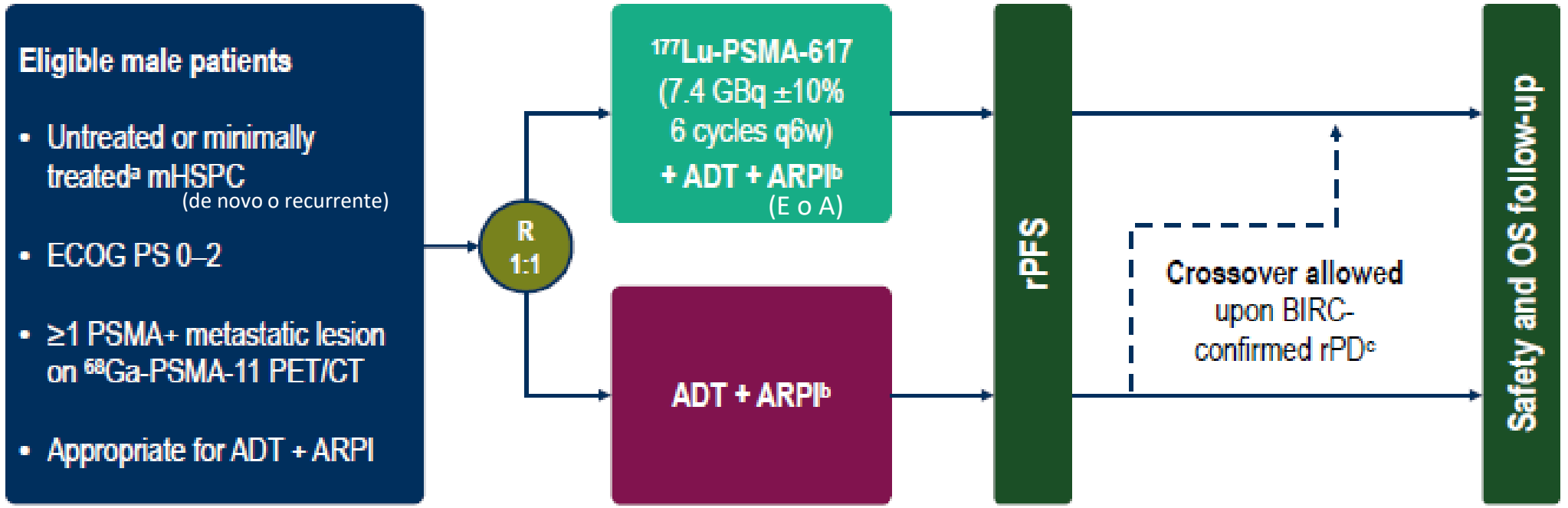
Presenter: Scott T Tagawa,* Weill Cornell Medicine, New York, NY, USA

Co-authors: Oliver Sartor,* Josep M Piulats, Fred Saad, Karim Fizazi, Alison Reid, Himisha Beltran, Gero Kramer, Hakim Mahammedi, Matthias Eiber, Shilpa Gupta, Daniel Castellano, Ralph Hauke, Hyun Kim, Cheol Kwak, See Tong Pang, Emmanuel Bouillaud, Angela Zhang, Olga Sakharova, Michael J Morris*, **on behalf of the PSMAddition investigators**

19 October 2025

*Equal contributors

PSMAddition: randomized phase 3 trial of ^{177}Lu-PSMA-617 in mHSPC



Stratification factors

- Disease volume (high/low) – per CHAARTED criteria[1]
- Age ≥ 70 years (yes/no)
- Previous or planned treatment of primary tumour by radiation or prostatectomy (yes/no)

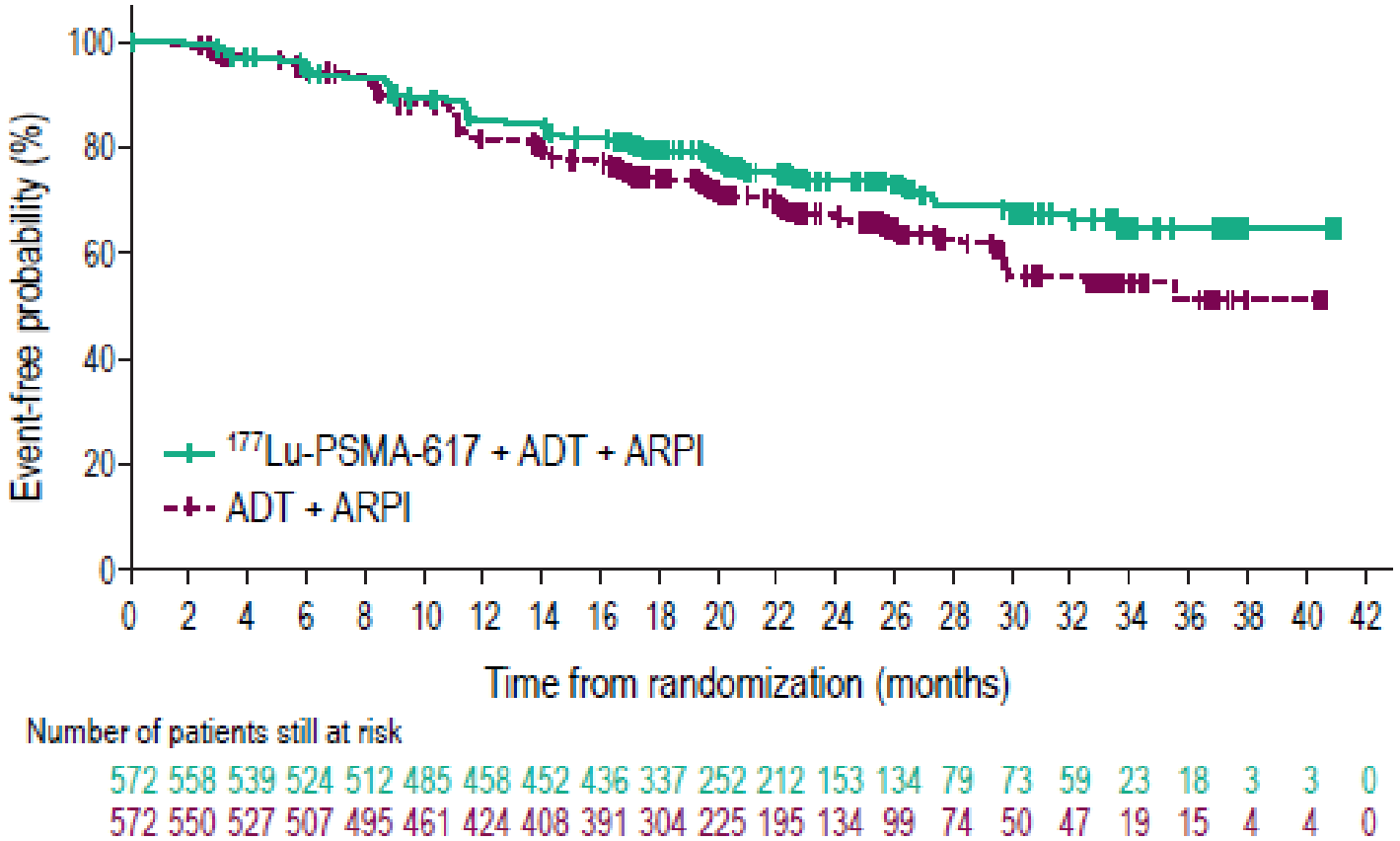
Follow-up periods

- rPFS: until event in all patients
- Safety: 30 days then 24 and 48 weeks after treatment discontinuation
- OS: every 90 days after last contact

[a] ADT in the neo-/adjuvant setting and/or up to 45 days of ADT/ARPI for metastatic disease was allowed before study entry | [b] Any ARPI with one switch allowed | [c] ADT/ARPI not mandatory after crossover
ADT, androgen deprivation therapy; BIRC, blinded independent review committee; ECOG PS, Eastern Cooperative Oncology Group performance status; OS, overall survival; PET/CT, positron-emission tomography/computed tomography; q6w, every 6 weeks; rPD, radiographic disease progression; rPFS, radiographic progression-free survival

1. Sweeney CT *et al. N Engl J Med* 2015;373:737–46

rPFS by BIRC – the primary endpoint was met



	^{177}Lu-PSMA-617 + ADT + ARPI (N = 572)	ADT + ARPI (N = 572)
Events – n (%) rPD Death without rPD	139 (24.3) 112 (19.6) 27 (4.7)	172 (30.1) 152 (26.6) 20 (3.5)
HR (95% CI)	0.72 (0.58, 0.90)	
p value	0.002[a]	
Median rPFS (95% CI) – months	NR (NE, NE)	NR (29.7, NE)

[a]Significance threshold at rPFS IA2: 0.009 (one-sided; stratified log-rank test); information fraction, 74.4%
CI, confidence interval; IA, interim analysis; NE, not estimable; NR, not reached

Puntos para Considerar

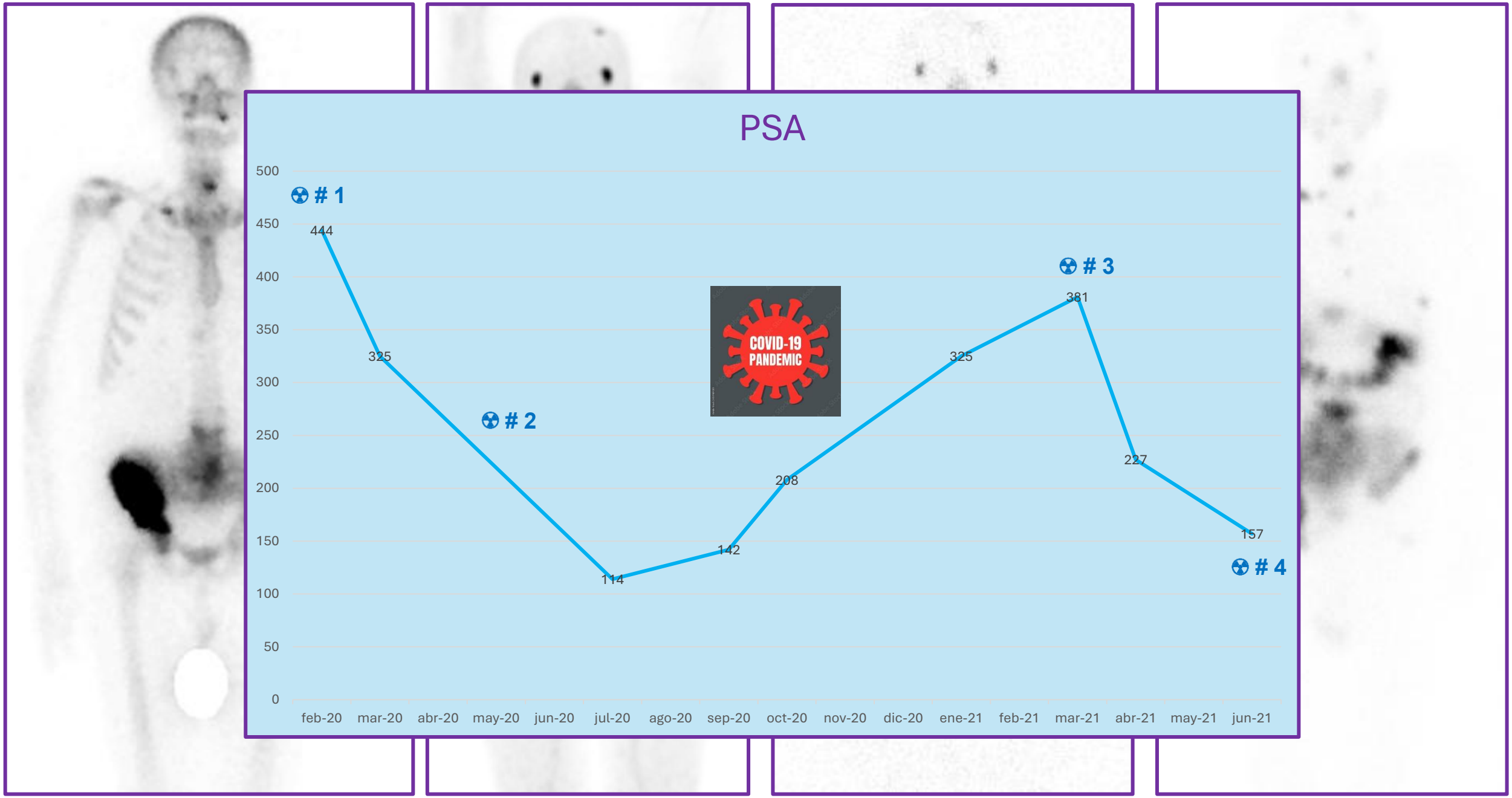
DISEÑO/METODOLOGÍA DEL ESTUDIO

- Endpoint rPFS: subrogado (retrasar un cambio visibles en las imágenes CT o GGO) no significa un beneficio tangible en el paciente.
- Datos más sólidos y a largo plazo (OS, calidad de vida) aun son datos inmaduros.
- Uso de Crossover (60 %).
- No es posible realizar un estudio doble ciego por la naturaleza y la complejidad logística del radiofármaco.
- FDA: podría aprobar rPFS, sin embargo, los pagadores exigen endpoints diferentes y más sólidos.

PERCEPCIÓN DEL PERFIL DE SEGURIDAD

- Perfil seguridad y calidad de vida no percibidos adecuadamente por fase temprana de la enfermedad. EA (on-target, off-tumor side effects)
- Dosis utilizada (6 ciclos fijos). Son necesarias las dosis fijas??
- Recordar que la respuesta puede ser muy rápida con la terapia ADT y ARPI, y se perciba poco beneficio antitumoral y si incremento de efectos secundarios.
- Imágenes de seguimiento interinas podrían tener utilidad, después de 2 ciclos para definir nuevas dosis. RECIP criterio 1.0 (dosificación adaptativa)

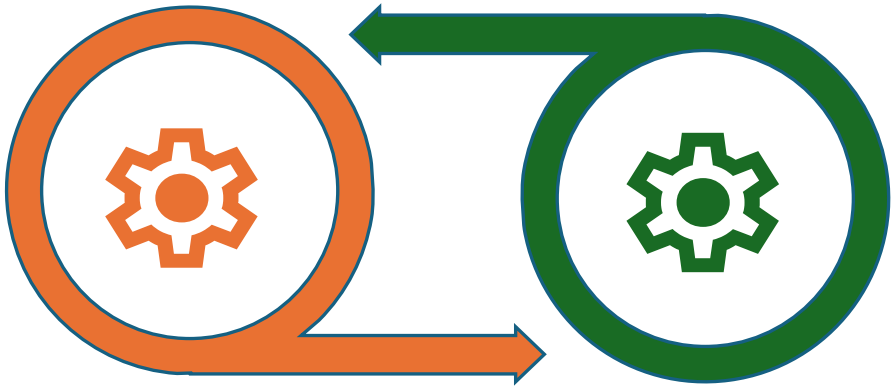
Imágenes correspondientes al archivo del autor



08/2019 01/2020 02/2020 07/2021

¿QUÉ ES RECIP?

VOLUMEN TUMOTAL TOTAL (TTV) DE LESIONES PET-CT PSMA POSITIVAS



SOFWARE DE EVALUACIÓN CUANTITATIVA

Total Tumor Burden Stats	
Max	33,73
Mean	8,65
Volume (mL)	243,58
TLA	2105,87
Uptake Time (hr)	1,54

mim SOFTWARE

Radiology 2023; 308(1):e222148

Análisis Multicéntrico Retrospectivo

RECIP combina:

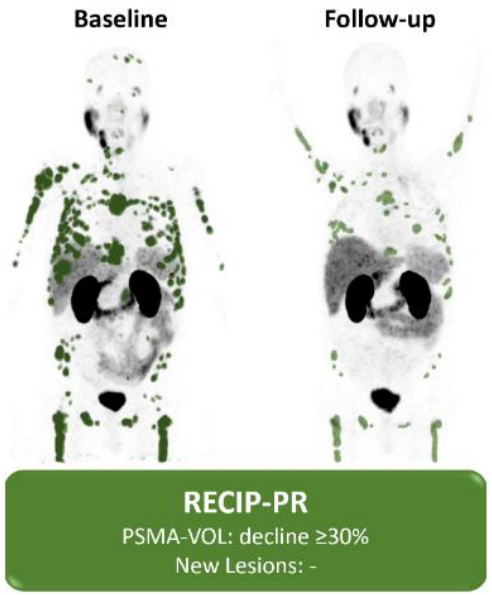
1. Cambios en el (TTV)
2. Estado de nuevas lesiones

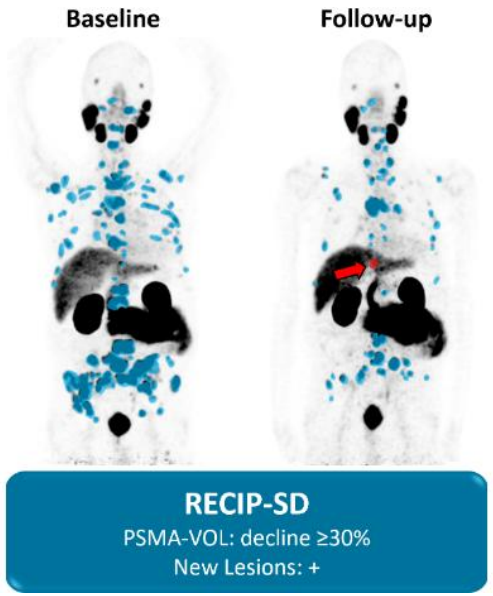
https://recip-criteria.com/

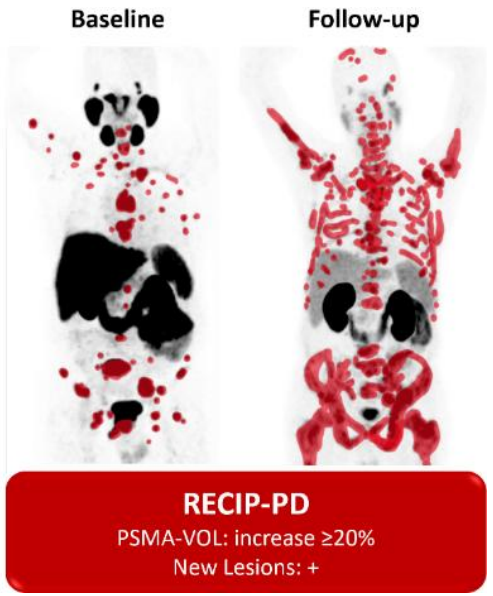
RECIP 1.0 Definition

RECIP integrates changes in total PSMA-positive tumor volume (PSMA-VOL) between baseline and follow-up scan and occurrence of new lesions.

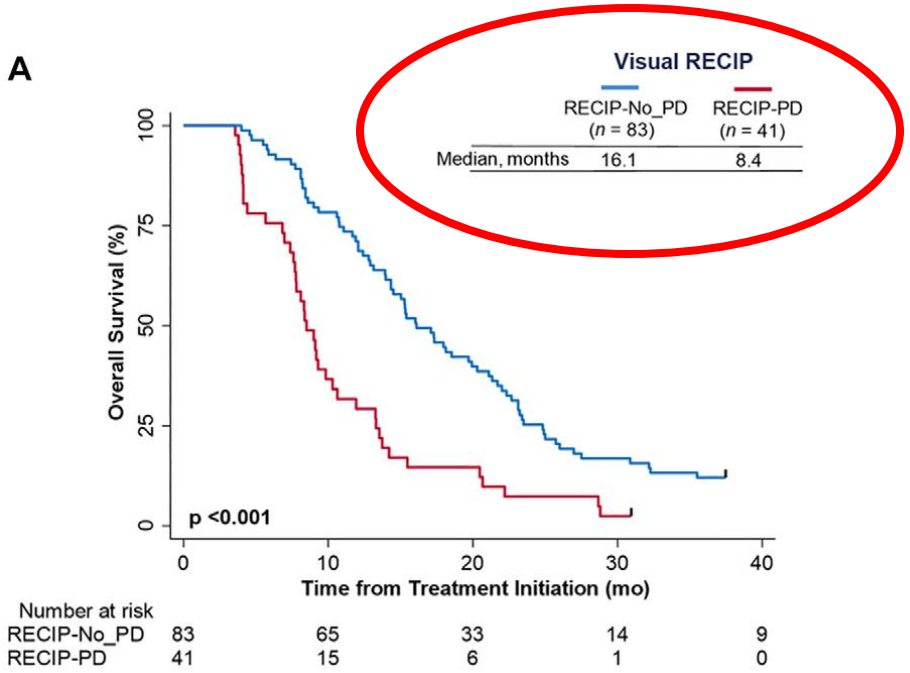
Complete Response	**RECIP-CR**	Absense of any PSMA-update on follow-up PET scan
Partial Response	**RECIP-PR**	≥30% decrease in PSMA-VOL without appearance of new lesions
Progressive Disease	**RECIP-PD**	≥20% increase in PSMA-VOL with appearance of new lesions
Stable Disease	**RECIP-SD**	<30% decrease in PSMA-VOL with/without appearance of new lesions *or* ≥30% decrease in PSMA-VOL with appearance of new lesions *or* <20% increase in PSMA-VOL with/without appearance of new lesions *or* ≥20% increase in PSMA-VOL without appearance of new lesions

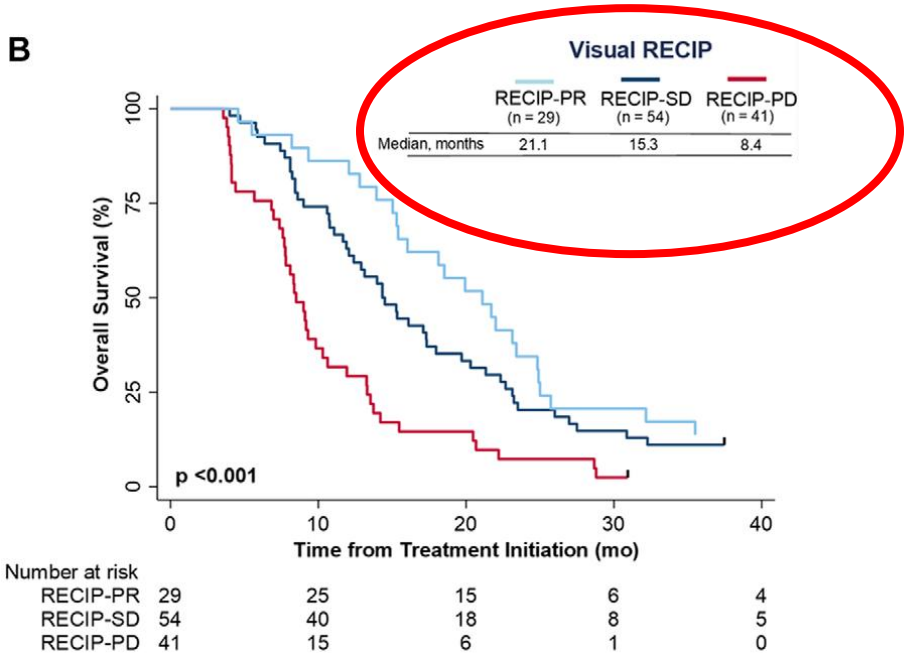


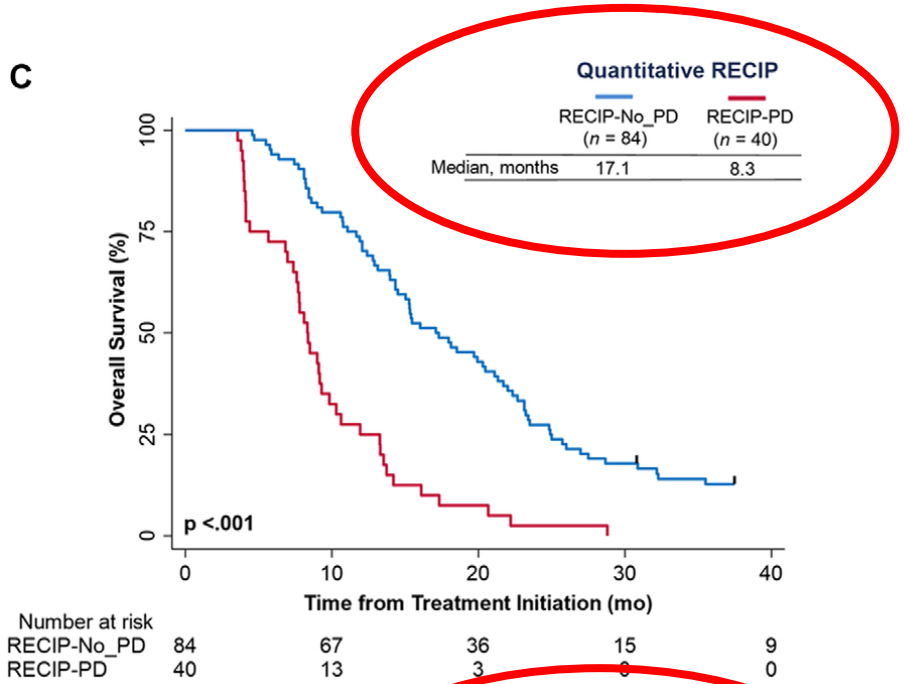


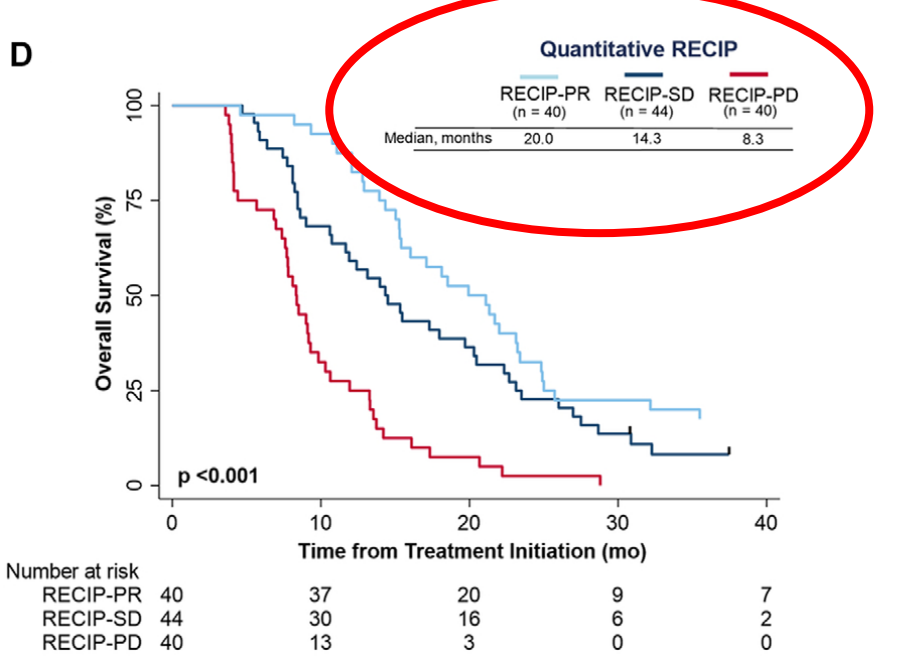


https://recip-criteria.com/

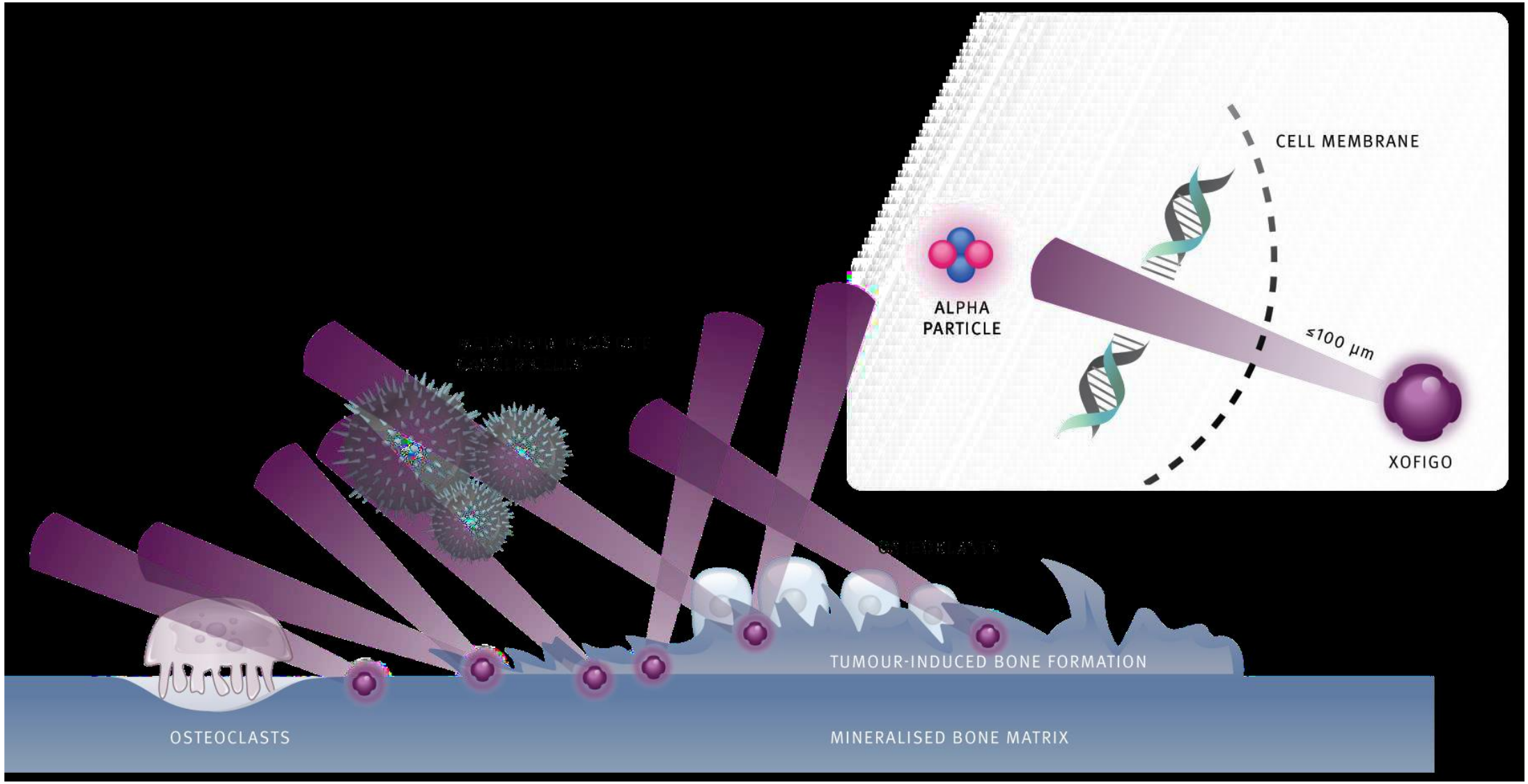




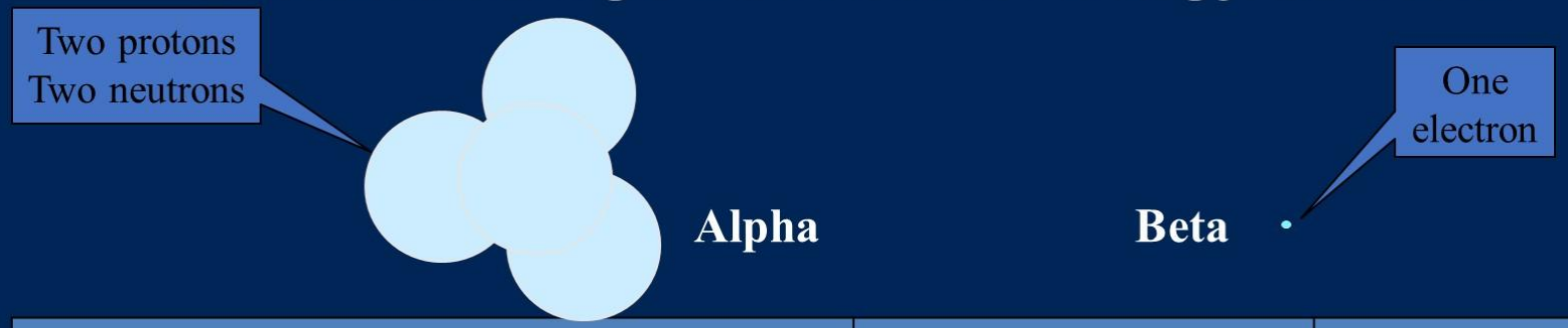




Radiology 2023; 308(1):e222148


CELL MEMBRANE
ALPHA PARTICLE
≤100 µm
XOFIGO
TUMOUR-INDUCED BONE FORMATION
OSTEOCLASTS
MINERALISED BONE MATRIX

Clinical Utility of α versus β Particles: Effective Range and Linear Energy Transfer



	α	β
Relative particle mass	7300	1
Speed of light	6%	98%
Initial energy (MeV) per particle	3–8	0.01–2.5
Range in tissue (μm)	40–100	50–5000
* LET (KeV/μm)	60–230	0.015–0.4
DNA hits to kill cells	1–10	100–1000

Courtesy of Oliver Sartor

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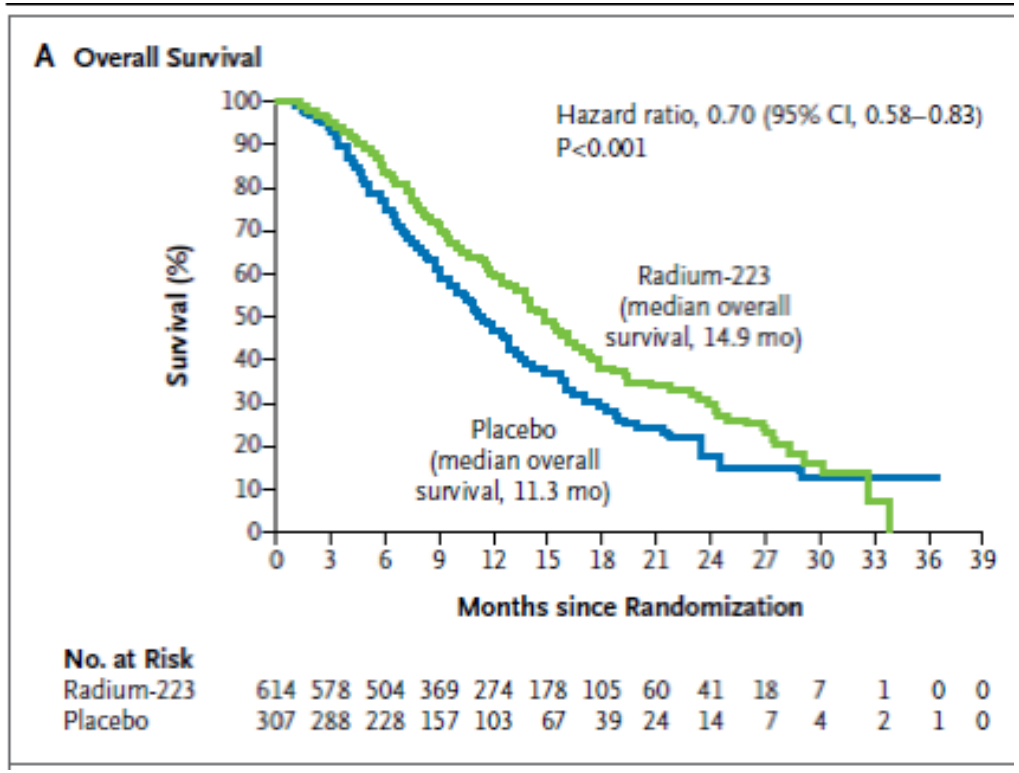
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 18, 2013 VOL. 369 NO. 3

Alpha Emitter Radium-223 and Survival in Metastatic Prostate Cancer

C. Parker, S. Nilsson, D. Heinrich, S.I. Helle, J.M. O'Sullivan, S.D. Fosså, A. Chodacki, P. Wiechno, J. Logue, M. Seke, A. Widmark, D.C. Johannessen, P. Hoskin, D. Bottomley, N.D. James, A. Solberg, I. Syndikus, J. Kliment, S. Wedel, S. Boehmer, [illegible] taudacher, J. Garci[illegible]tors*

ALSYMPCA



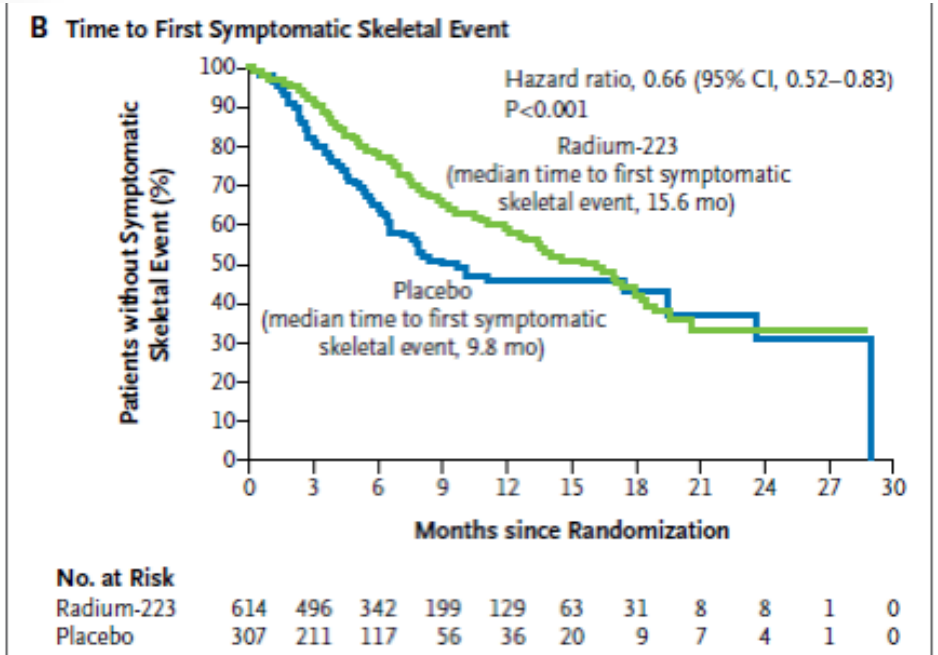
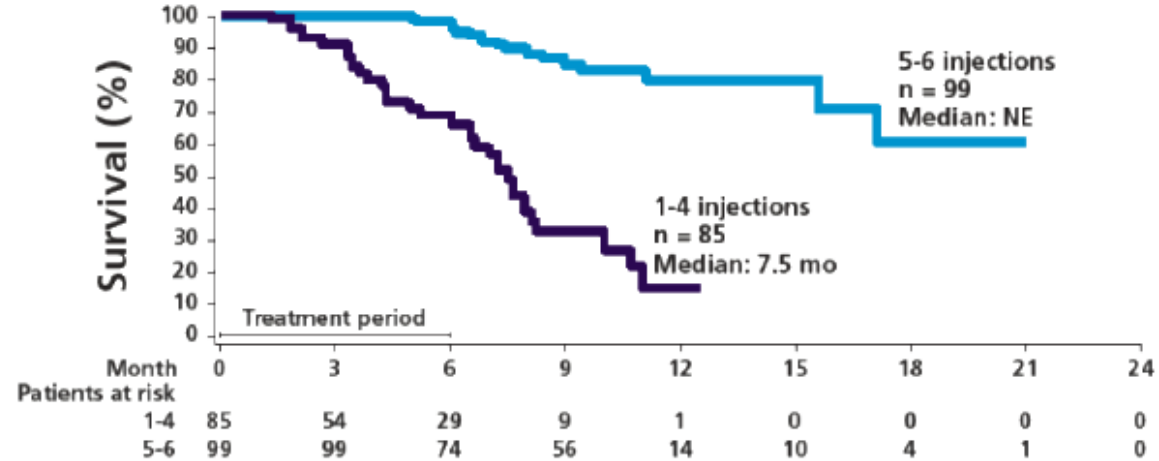


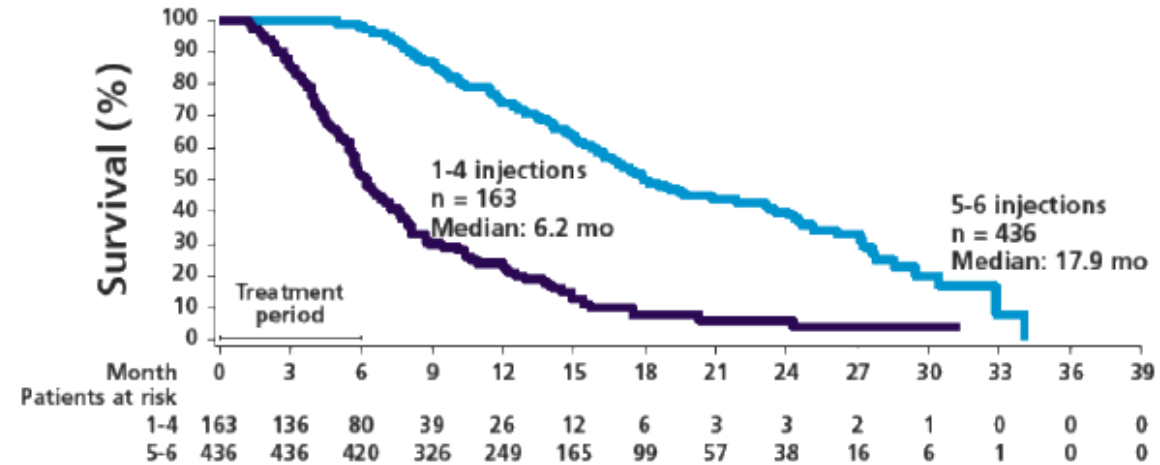
Figure 1. Kaplan–Meier Estimates of Overall Survival and the Time to the First Symptomatic Skeletal Event.

A. US EAP: Radium-223 Patients Received 1-4 Versus 5-6 Injections



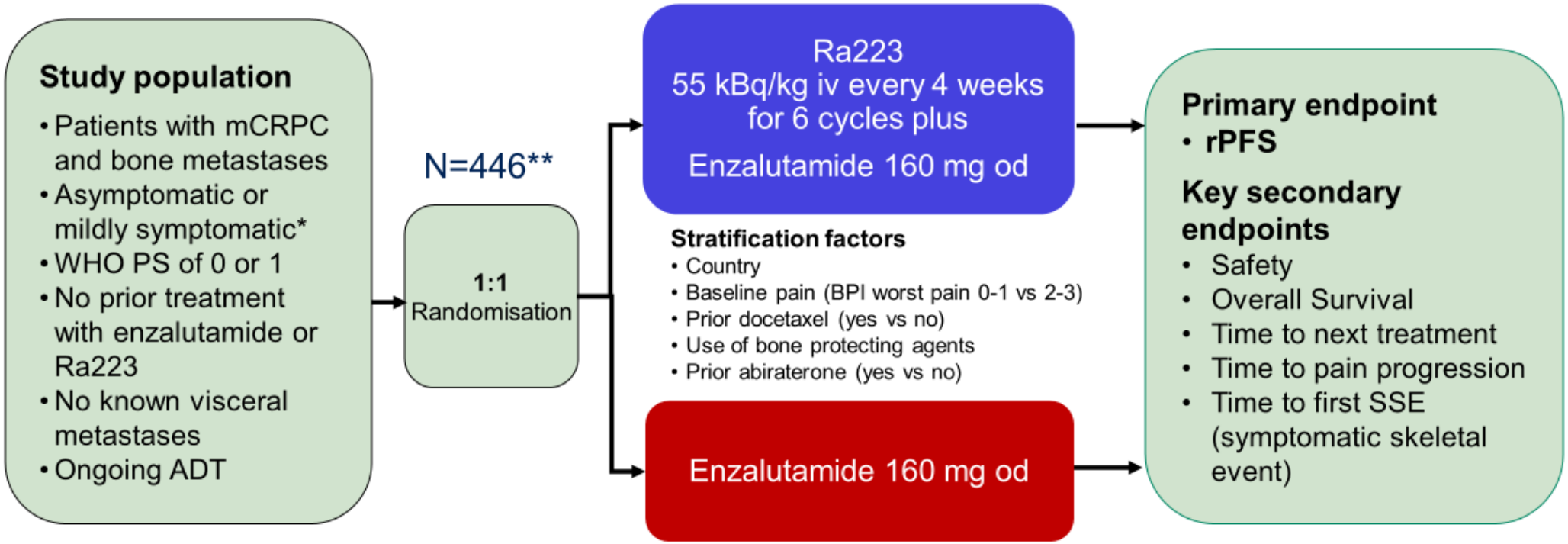
Month	0	3	6	9	12	15	18	21	24
Patients at risk									
1-4	85	54	29	9	1	0	0	0	0
5-6	99	99	74	56	14	10	4	1	0

B. ALSYMPCA: Radium-223 Patients Received 1-4 Versus 5-6 Injections



Month	0	3	6	9	12	15	18	21	24	27	30	33	36	39
Patients at risk														
1-4	163	136	80	39	26	12	6	3	3	2	1	0	0	0
5-6	436	436	420	326	249	165	99	57	38	16	6	1	0	0

EORTC-GUCG 1333 (PEACE-3)



*defined as brief pain inventory WP24 score < 4
** original target accrual N=560, adapted for slow accrual

Use of bone protecting agents (BPA) made mandatory
(after inclusion of 119 patients)

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EORTC

Final overall survival results from EORTC 1333/PEACE-3: Enzalutamide with or without Radium-223 in metastatic castration-resistant prostate cancer

Enrique Gallardo

(Parc Taulí Hospital Universitari, I3PT-CERCA, Universitat Autònoma de Barcelona, Sabadell, Spain)

On behalf of: Silke Gillessen, Ananya Choudhury, Fred Saad, Andrey Soares, Yohann Loriot, Raymond S. McDermott, Alejo Rodríguez-Vida, Pedro Isaacson Velho, Felipe J. Cruz, Thierry A. Roumeguere, Gedske Daugaard, Rosely Yamamura, Frederic Lecouvet, Corneel Coens, Coralie Poncet, Beatrice Fournier, Bertrand Tombal; and all the PEACE-3 investigators.

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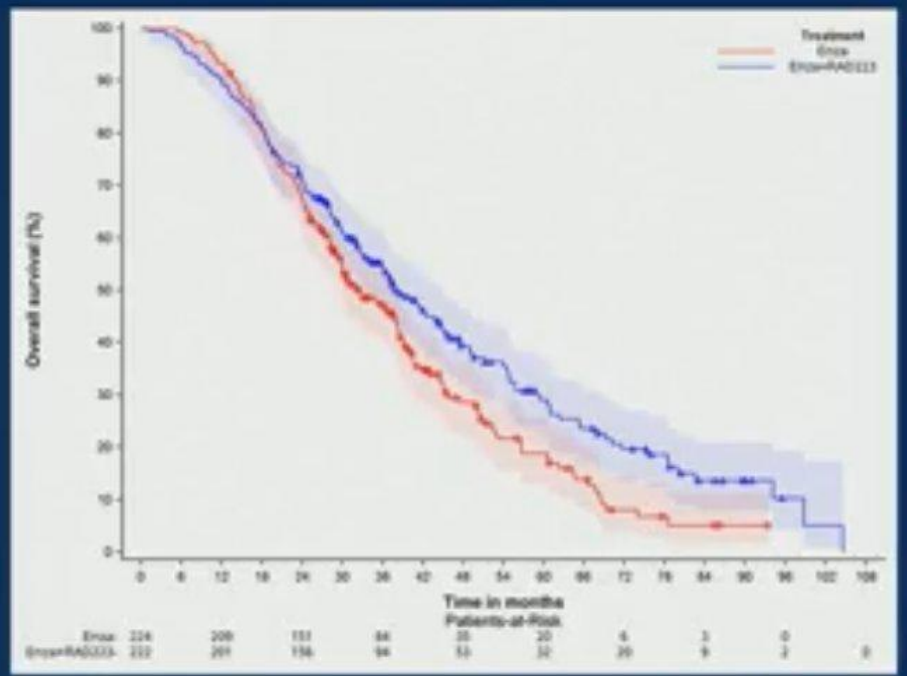
Final OS results



	Event/ Total	Median (95%CI) (months)[1]	Hazard Ratio (95% CI)[2]	1-sided P-value
Treatment				Logrank: 0.0096[3]
Enza	165/224	32.62 (29.31-38.24)	0.76 (0.60-0.96)	Permutation: 0.0105
Enza+Ra223	153/222	38.21 (33.08-44.75)		

[1]Kaplan-Meier method; [2]Cox model; [3]Stratified Logrank test

	Enza+Ra223 (N=222) (95% CI)	Enza (N=224) (95% CI)
6 mths	96.8 (93.5-98.5%)	99.1 (96.5-99.8%)
12 mths	90.5 (85.9-93.7%)	92.9 (88.6-95.6%)
18 mths	81.1 (75.3-85.6%)	80.8 (74.9-85.3%)
24 mths	71.1 (64.7-76.6%)	67.7 (61.2-73.4%)
36 mths	54.2 (47.1-60.6%)	47.4 (40.6-54.0%)

Preset level of significance at final analysis: <0.0248
Crossing of the curves (still) present at month 18
Only 3 patients censored < 24 months

Database locked on 12 January 2026 (cut off date: 01 May 2025)

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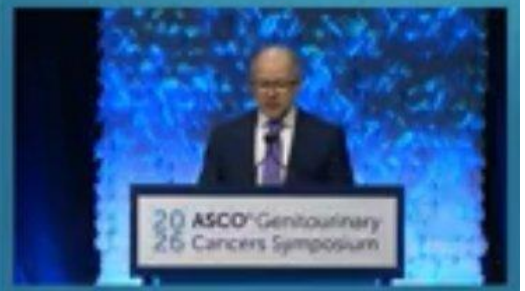


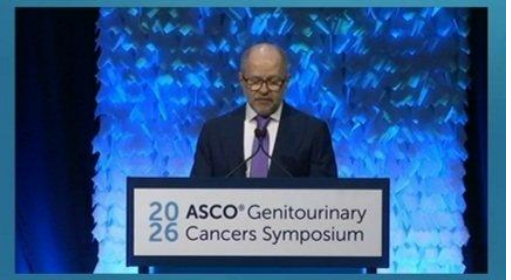
SUMMARY

- Final OS and updated safety based on database locked on 12 January 2026
  - Median follow-up duration: **58 months**

- Combination of enzalutamide and 6 cycles of Ra223 shows a **significant improvement in OS:**
  - HR 0.76 (0.60-0.96), **log-rank p-value=0.0096**
  - Median OS increased: **32.6** → **38.2** months with the combination
  - Crossing of the OS curves around 18 months is (still) observed.
    - Difference at month 12 = +6 deaths (16 vs 22).
    - Additional analyses are planned to further characterise the hazard ratios over time.

- Improvement in rPFS is confirmed with longer follow-up (**HR 0.71 (0.57-0.89**).
  Median rPFS = 16.4 → 19.2 months.

- Observed safety profile of the combination is consistent with results at primary completion: moderate increase in treatment-emergent adverse events with the combination.



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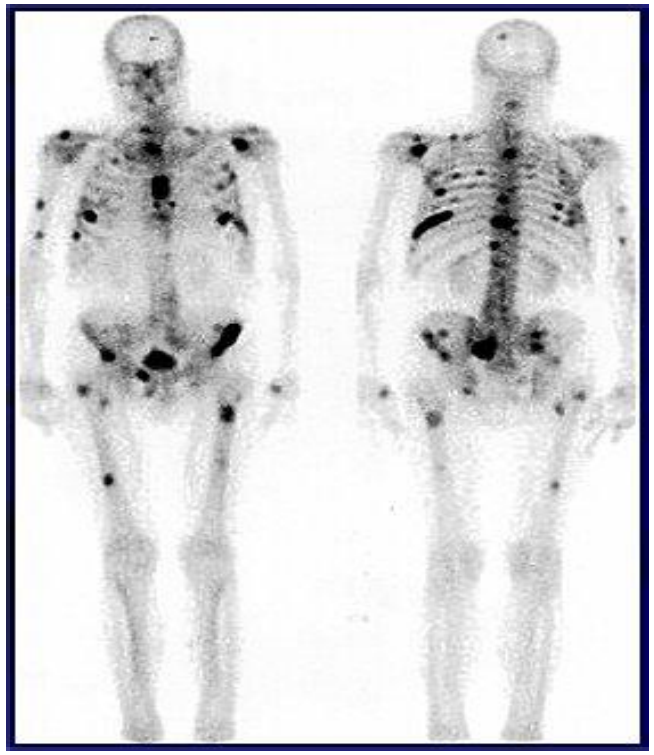
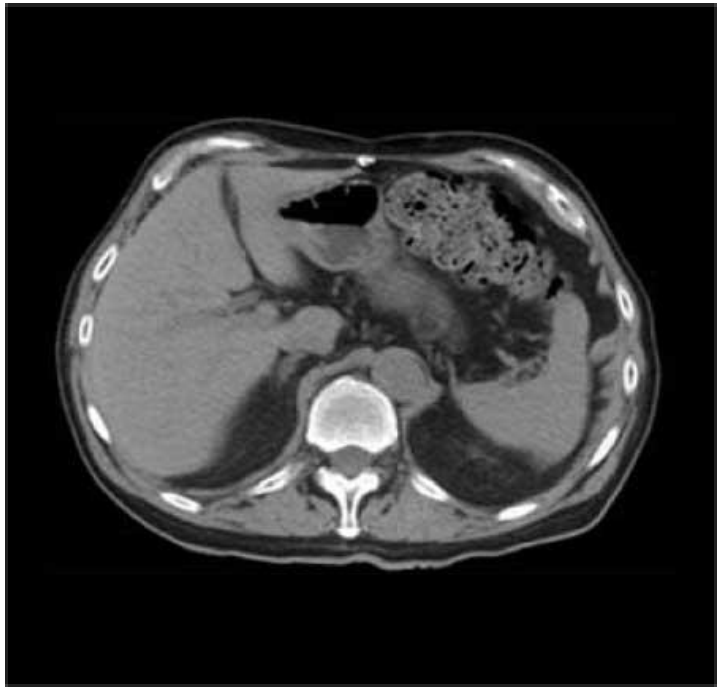
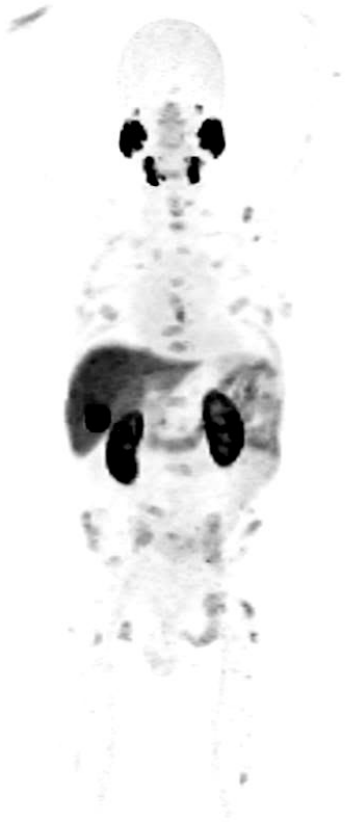
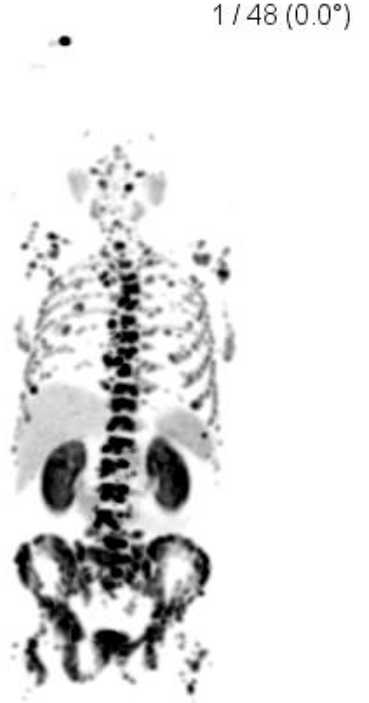
SELECCIÓN 2008-2011





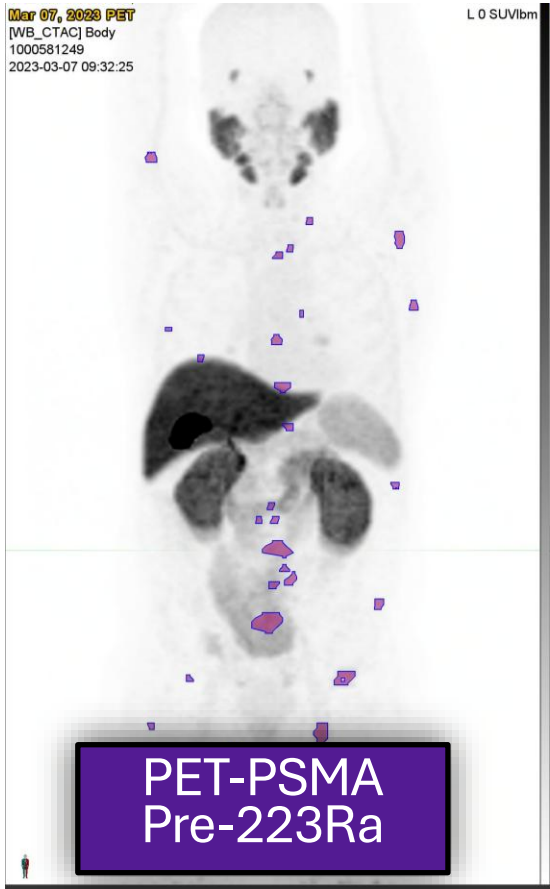


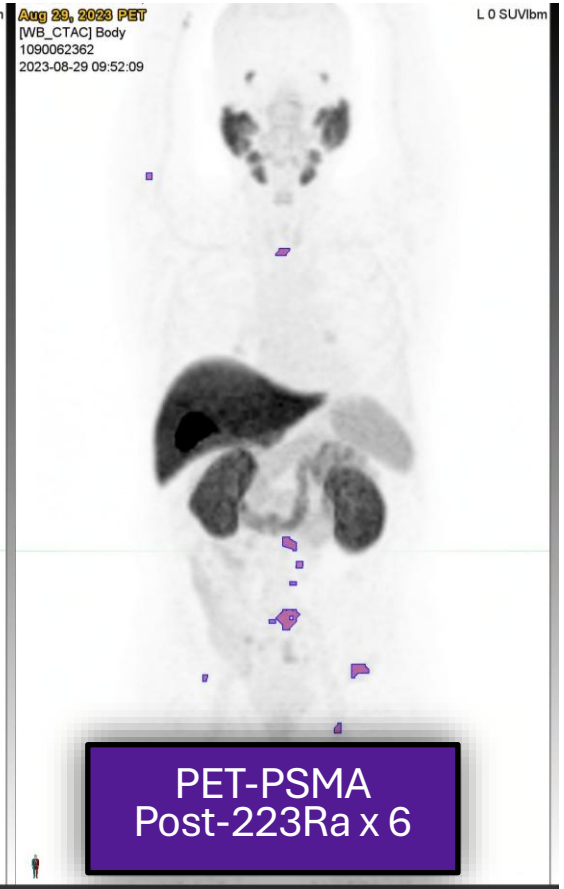
mCRPC



Tumor Burden Statistics	Nov 30, 2023
	Value
Max	9.93
Mean	4.09
Volume (ml)	367.27
TLA (mean*ml)	1501.44

Tumor Burden Summary	2023-07-27
	SUVlbm
Volume (ml)	547.8
Max	109.3
Mean	7.4
TLA (mean*ml)	4049.5



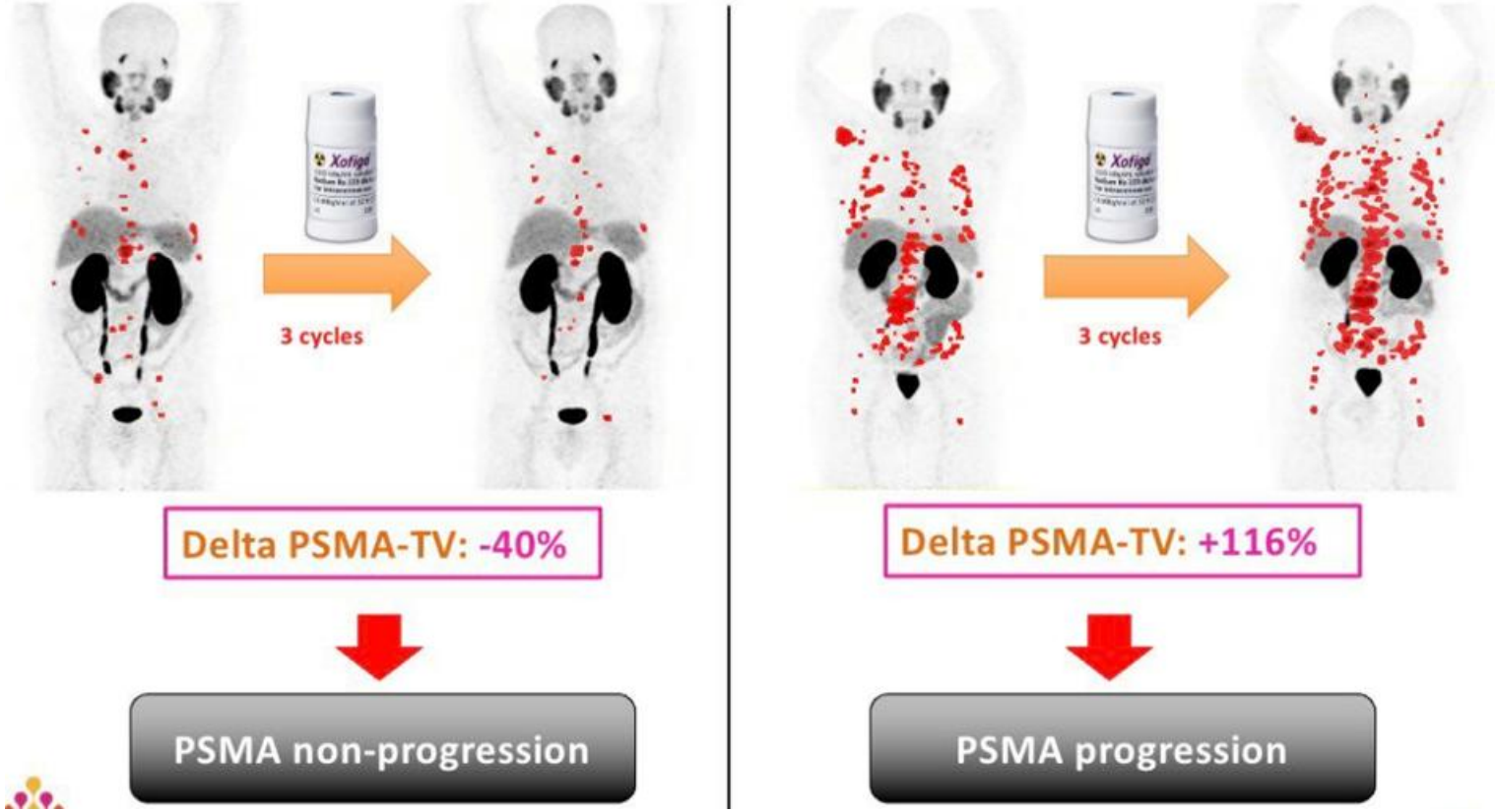


Tumor Burden Summary	2023-03-07	2023-08-29	
	SUVlbm	SUVlbm	Δ (%)
Uptake Time (hr)	1.1	1	*-6.5*
Volume (ml)	39.6	10	*-74.8*
Max	4.6	3.1	*-32.3*
Mean	2.4	2.2	*-7.6*
TLA (mean*ml)	94	21.9	*-76.7*
Bone Involvement (ml)	39.6	10	*-74.8*
Bone Involvement (%)	100	100	*0*

Interim ^{68}Ga-PSMA PET/CT for assessing progression and outcome prediction in metastatic castration-resistant prostate cancer patients receiving Radium-223

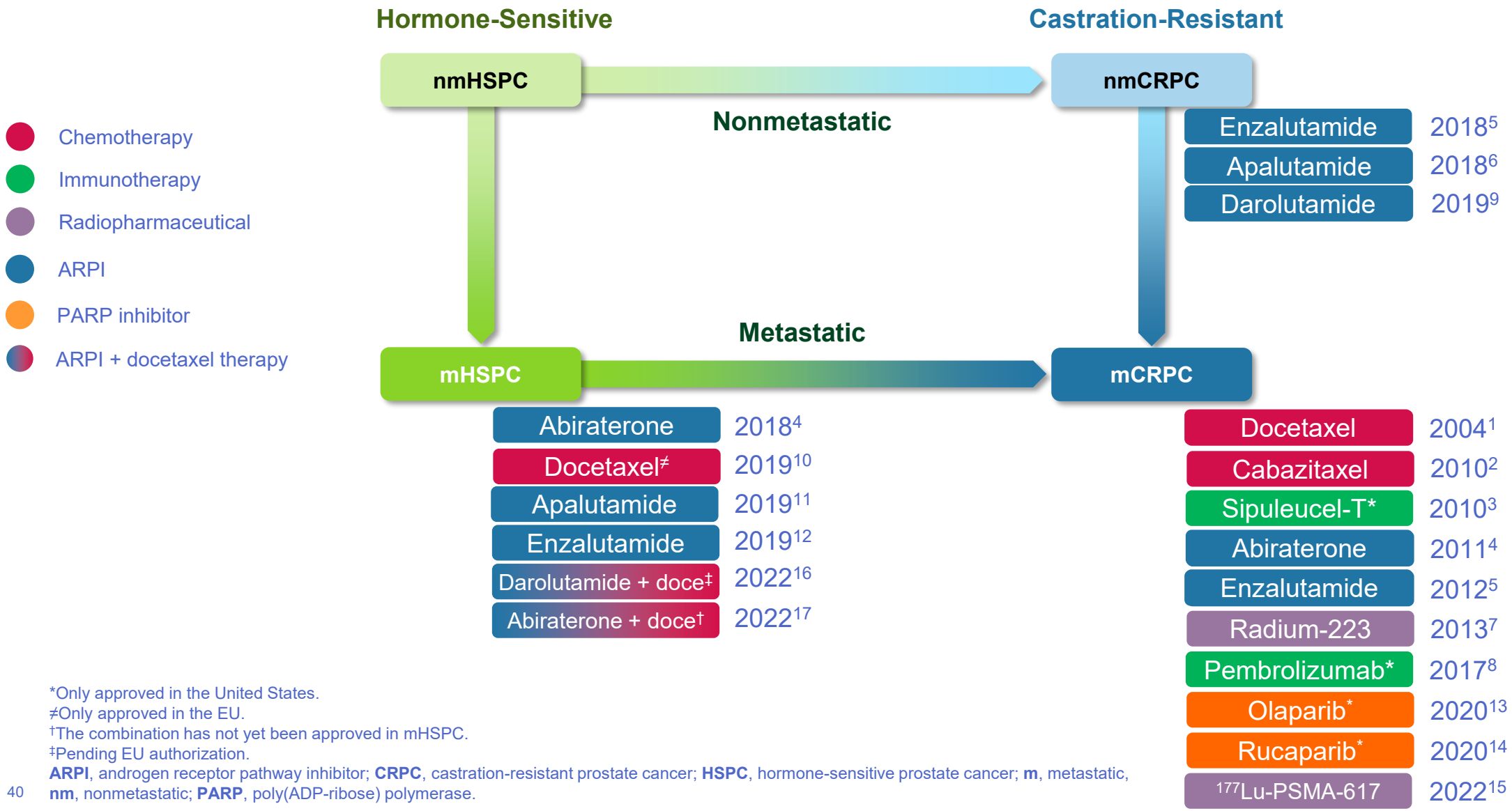
Qaid Ahmed Shagera, Carlos Artigas[1], Sideris Spyridon[2], Thierry Gil[2], Patrick Flamen[1]

PSMA response classification



Qaid Shagera et al. Interim 68GA-PSMAPET/CT for assessing progression and outcoe prediction in metastastic castrarion-resustant prostate cancer receiving Radium 223. SNMMI annual Meeting 2022

The Approval of Therapies in Earlier Stages of Prostate Cancer Provides New Opportunities for Sequencing Therapies to Benefit Patients



*Only approved in the United States.
≠Only approved in the EU.
†The combination has not yet been approved in mHSPC.
‡Pending EU authorization.
ARPI, androgen receptor pathway inhibitor; **CRPC**, castration-resistant prostate cancer; **HSPC**, hormone-sensitive prostate cancer; **m**, metastatic, **nm**, nonmetastatic; **PARP**, poly(ADP-ribose) polymerase.

No existe el mejor tratamiento universal, sino el mejor para cada paciente y para cada momento de su historia

La secuencia de manejo del cáncer de próstata metastásico resistente a castración no está definido

El Ra223 es una opción razonable con el paciente indicado

Definir "el mejor paciente" aun es una tarea pendiente.

El uso de terapia ósea (bifosfonatos/denosumab) debe ser una constante.

El manejo multidisciplinario debería ser una norma.

Definir criterios para suspensión del tratamiento con Ra223 Progresión

El uso de terapias combinadas es una opción biológicamente plausible

Evitar progresión de la enfermedad por ausencia del tratamiento.

Statistical pitfalls of personalized medicine.
Nature 2018 Nature 563, 619-621 (2018) doi: https://doi.org/10.1038/d41586-018-07535-2

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"Tratamos lo que vemos,
vemos lo que tratamos,
cuantificamos lo que tratamos"

GRACIAS

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