Meet The Professor

Optimizing the Management of Metastatic Castration-Resistant Prostate Cancer

A Oliver Sartor, MD
Laborde Professor for Cancer Research
Medical Director, Tulane Cancer Center
Assistant Dean for Oncology
Tulane Medical School
New Orleans, Louisiana

Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Exelixis Inc, Merck, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, and Sanofi Genzyme.

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Dr Love — Disclosures

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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

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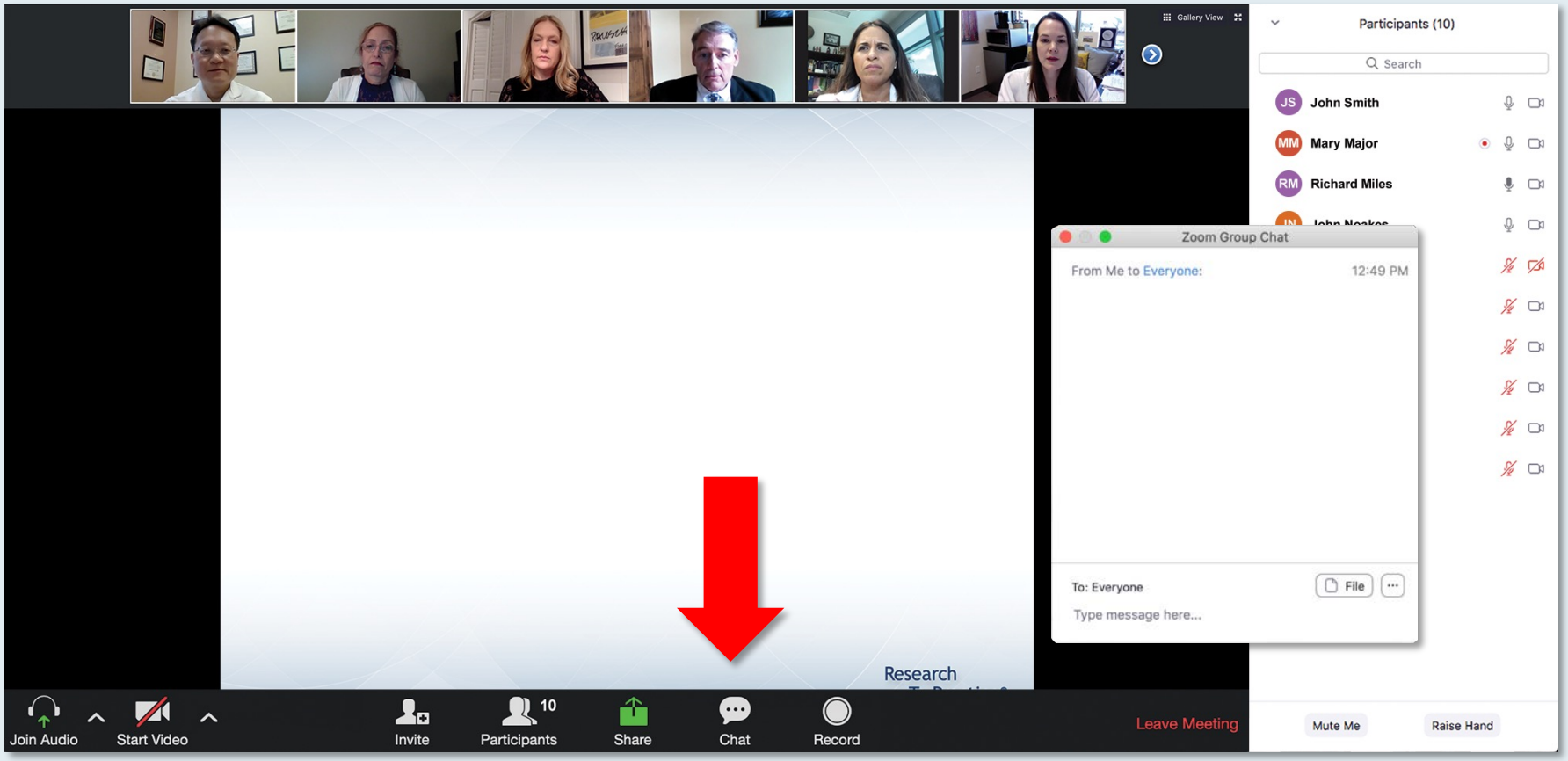
Contracted Research	Advanced Accelerator Applications, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Constellation Pharmaceuticals, Endocyte Inc, Invitae, Janssen Biotech Inc, Lantheus, Merck, Progenics Pharmaceuticals Inc, TeneoBio
Data and Safety Monitoring Board/Committee	AstraZeneca Pharmaceuticals LP, Janssen Biotech Inc, Pfizer Inc, Myovant Sciences

We Encourage Clinicians in Practice to Submit Questions



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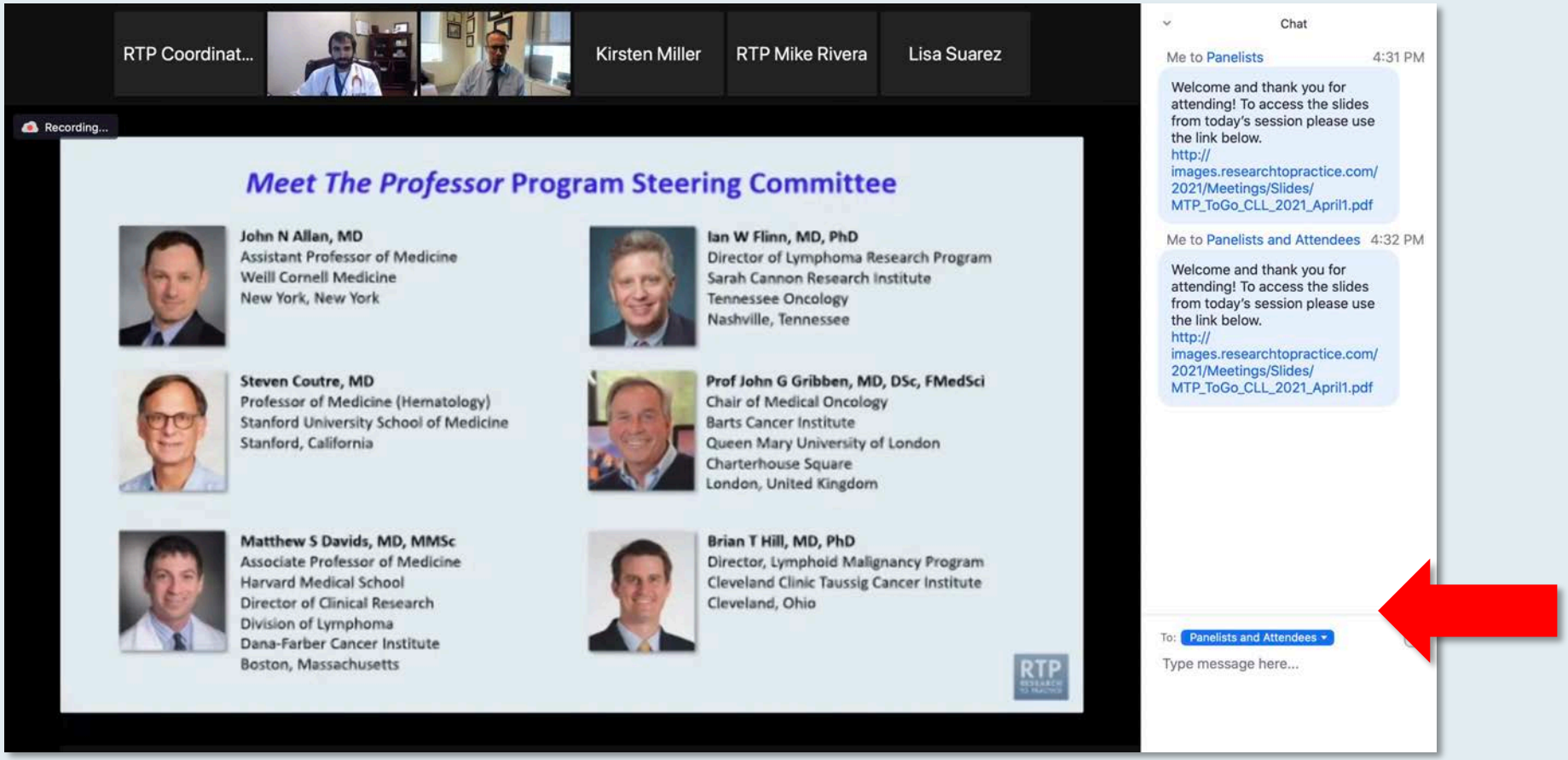

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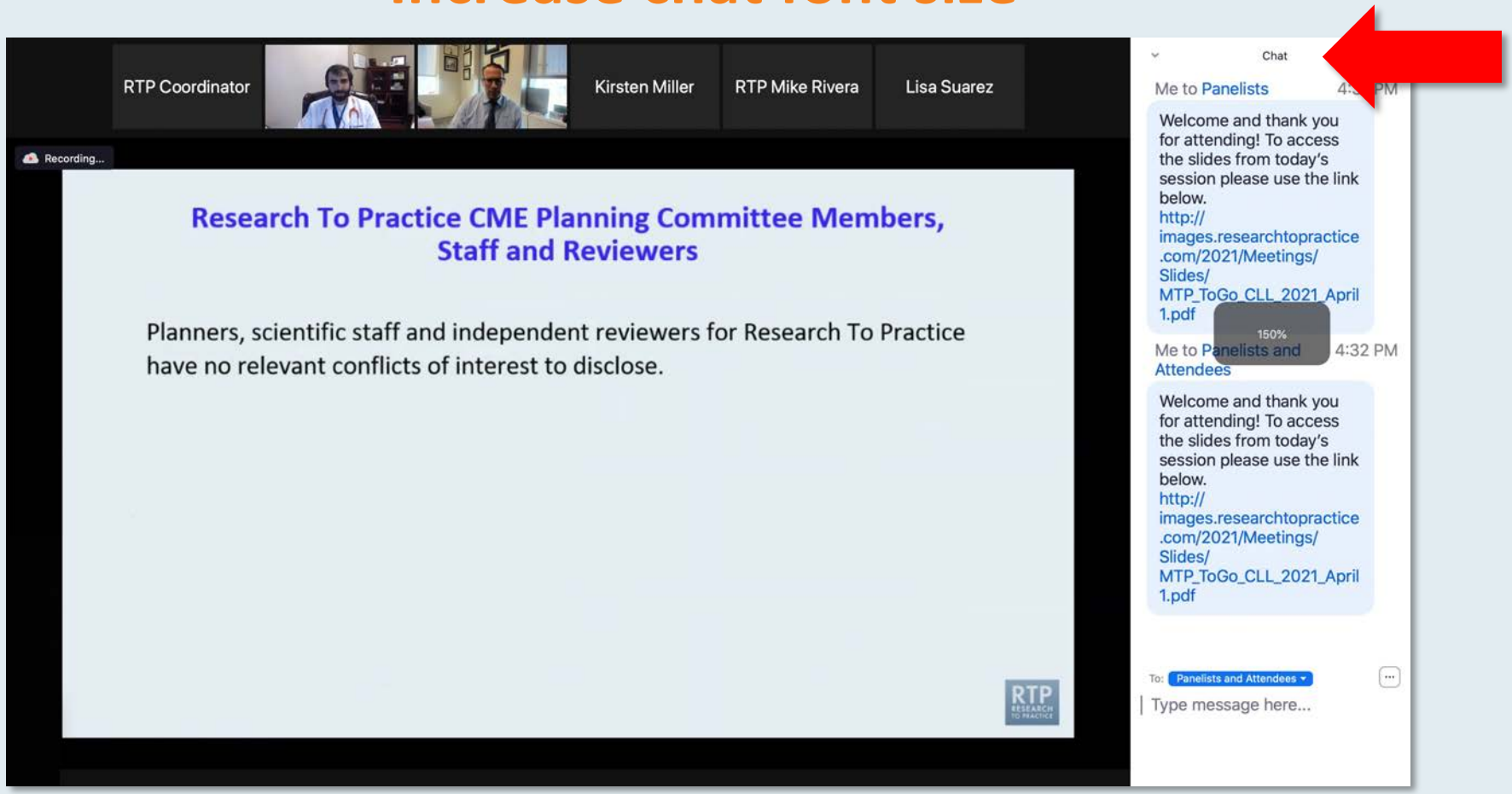

Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

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WITH DR NEIL LOVE

Side Effects of Hormonal Therapy in Prostate Cancer

DR ROBERTO IACOVELLI

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Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia

Wednesday, December 1, 2021
5:00 PM – 6:00 PM ET

Faculty

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

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Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with HER2-Positive Breast Cancer

Thursday, December 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Hope S Rugo, MD

Moderator

Neil Love, MD

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of ER-Positive Breast Cancer

Tuesday, December 7, 2021
8:00 PM – 9:45 PM ET

Faculty

Aditya Bardia, MD, MPH
Joyce O'Shaughnessy, MD
Kevin Kalinsky, MD, MS

Moderator

Erika Hamilton, MD

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Virginia F Borges, MD, MMSc
Sara Hurvitz, MD
Ian E Krop, MD, PhD

Moderator

Lisa Carey, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Triple-Negative Breast Cancer

Thursday, December 9, 2021
8:00 PM – 9:45 PM ET

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Rita Nanda, MD
Peter Schmid, FRCP, MD, PhD
Melinda Telli, MD

Moderator

Hope S Rugo, MD

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Chronic Lymphocytic Leukemia

Friday, December 10, 2021
7:30 AM – 9:30 AM ET

Faculty

Nitin Jain, MD
Anthony R Mato, MD, MSCE
John M Pagel, MD, PhD
Jennifer Woyach, MD

Moderator

John N Allan, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Hodgkin and Non-Hodgkin Lymphoma

Friday, December 10, 2021
11:30 AM – 1:30 PM ET

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Jeremy Abramson, MD
Martin Dreyling, MD, PhD
Loretta J Nastoupil, MD
Gilles Salles, MD, PhD

Moderator

Ann S LaCasce, MD, MMSc

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Multiple Myeloma

Friday, December 10, 2021
3:15 PM – 5:15 PM ET

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Larry D Anderson Jr, MD, PhD
Morie A Gertz, MD, MACP
Irene M Ghobrial, MD
Peter Voorhees, MD

Moderator

Robert Z Orlowski, MD, PhD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Acute Myeloid Leukemia and Myelodysplastic Syndromes

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Alexander Perl, MD
Richard M Stone, MD
Geoffrey L Uy, MD

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Harry Paul Erba, MD, PhD

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Optimizing the Management of Acute Myeloid Leukemia

Tuesday, December 14, 2021
5:00 PM – 6:00 PM ET

Faculty

Naval Daver, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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New Orleans, Louisiana

Meet The Professor Program Participating Faculty

Andrew J Armstrong, MD, ScM
Professor of Medicine, Surgery, Pharmacology and Cancer Biology
Director of Research
Duke Cancer Institute Center for Prostate and Urologic Cancers
Divisions of Medical Oncology and Urology
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Consultant Medical Oncologist
London, United Kingdom

Alan H Bryce, MD
Chair, Division of Hematology and Medical Oncology
Chair, Genitourinary Disease Group
Mayo Clinic
Phoenix, Arizona

Prof Karim Fizazi, MD, PhD
Head of Service and Full Professor
Institut Gustave Roussy
University of Paris Saclay
Villejuif, France

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Alicia K Morgans, MD, MPH
Genitourinary Medical Oncologist
Medical Director, Survivorship Program
Dana-Farber Cancer Institute
Boston, Massachusetts

Moderator
Neil Love, MD
Research To Practice
Miami, Florida

A Oliver Sartor, MD
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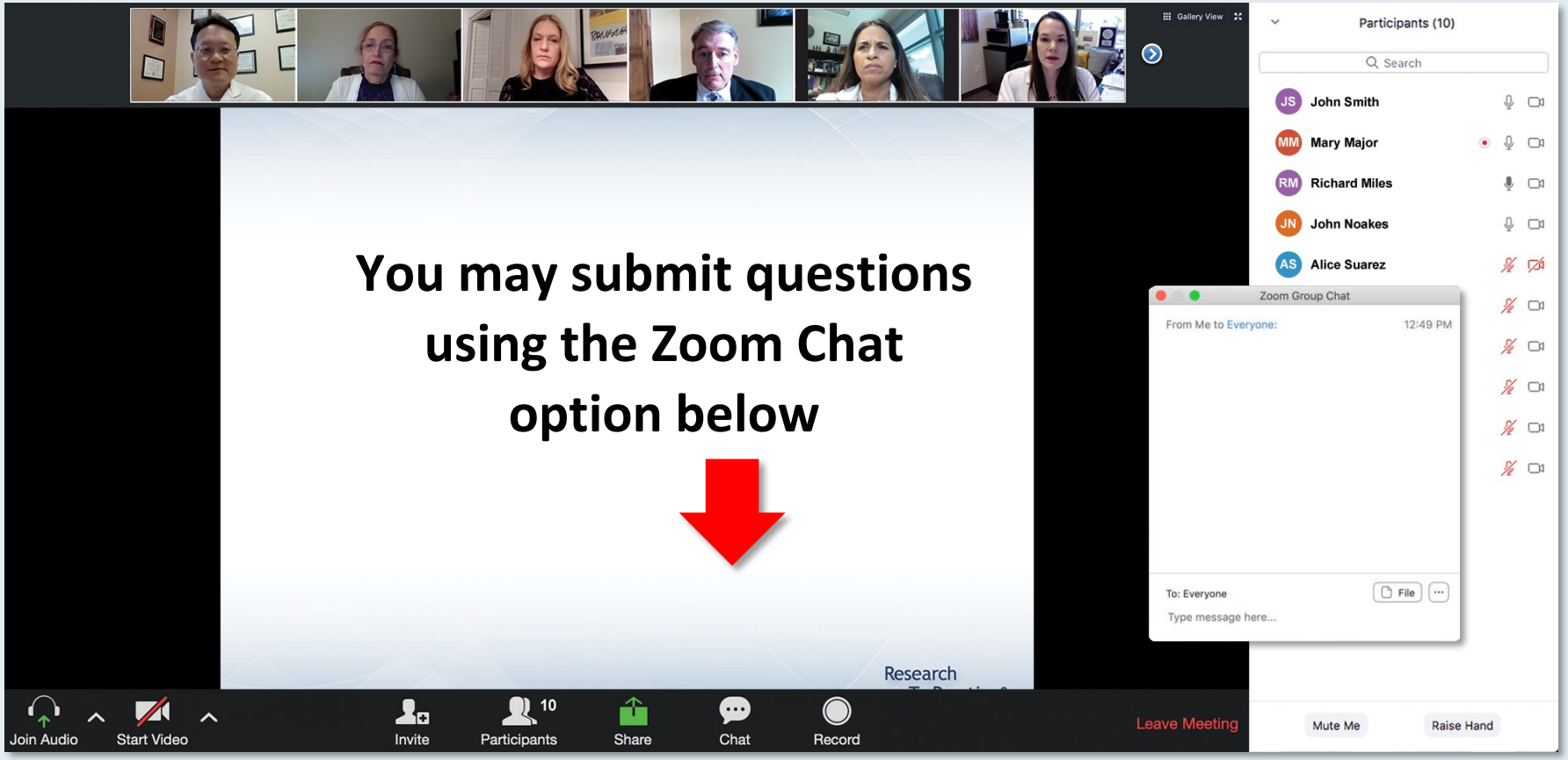

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Lynn Cancer Institute
FAU Schmidt College of Medicine
Boca Raton, Florida

David S Morris, MD
Advanced Therapeutics Center
Urology Associates
Nashville, Tennessee

Sulfi Ibrahim, MD
Reid Health
Richmond, Indiana

Syed F Zafar, MD
Florida Cancer Specialists and
Research Institute
Lee Health
Fort Myers, Florida

Nataliya Mar, MD
University of California, Irvine
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A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving abiraterone/dexamethasone for hormone-sensitive metastatic disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Olaparib	 Prof Fizazi	Olaparib
 Dr Bryce	Olaparib	 Dr Morgans	Radium-223
 Prof Chowdhury	Olaparib	 Dr Sartor	Olaparib

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Meet The Professor with Dr Sartor

MODULE 1: Overview of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- Dr Mar: A 75-year-old man with mCRPC

MODULE 2: BRCA/HRD-Negative mCRPC

- Dr Bachow: An 81-year-old man with mCRPC – LOH and AR-V7 splice site mutation
- Dr Ibrahim: A 74-year-old man with mCRPC – Enrolled on the VISION trial
- Key Relevant Data Sets

MODULE 3: BRCA/HRD-Positive mCRPC

- Dr Zafar: A 68-year-old man with metastatic hormone-sensitive prostate cancer and an ARID1A mutation
- Dr Morris: A 72-year-old man with mCRPC and a germline RAD51c mutation
- Dr Bachow: A 62-year-old man with mCRPC and a somatic BRCA1 mutation – High TMB
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MODULE 4: Other Novel Agents and Strategies Under Investigation

MODULE 5 Journal Club with Dr Sartor

MODULE 6: Faculty Survey

MODULE 7: Appendix

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Case Presentation – Dr Mar: A 75-year-old man with mCRPC

Dr Nataliya Mar

- Progressively worsening LUTS x 6 months, with PSA 1035 ng/mL
- CT CAP and bone scan: Blastic bone lesions and pulmonary nodules – biopsy-proven prostate cancer
- ADT and apalutamide, with PSA response
- Eighteen months later: PSA rising, pelvic pain
- Restaging imaging: Progression of bony disease

Questions

- What would be your next step in treatment?
- Besides BRCA1 and BRCA2, how do you feel about using PARP inhibitors in the other mutations, like, for example, the ATM mutation and other ones in a DDR pathway?
- What is the risk of developing MDS or AML in patients receiving PARP inhibitors?

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Case Presentation – Dr Bachow: An 81-year-old man with mCRPC – LOH and AR-V7 splice site mutation

Dr Spencer Bachow

- PMH: CAD, CABG, TN
- 8/2020: De novo osseous metastatic hormone-sensitive prostate cancer
  - TURP, with biopsies: Gleason 5 + 5 = 10, PSA 2.7 ng/dL prostate cancer
- EBRT → Docetaxel + ADT
  - 2 months after therapy, PSA increased to 6 ng/dL
  - NGS: LOH 21%, AR-V7 splice site mutation

Question

- Would you ever consider using abiraterone, enzalutamide, or apalutamide in a patient with mCRPC that harbors an AR-V7 splice site mutation?

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Case Presentation – Dr Ibrahim: A 74-year-old man with mCRPC – Enrolled on the VISION trial

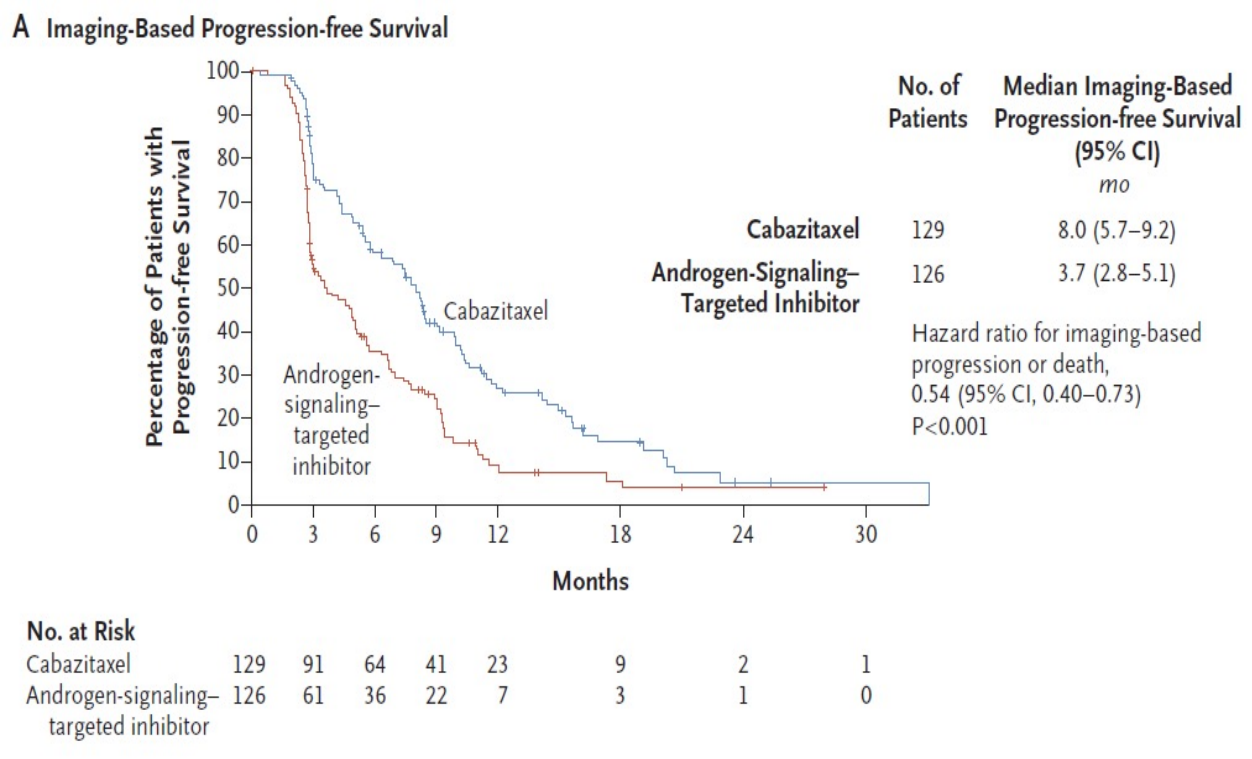
Dr Sulfi Ibrahim

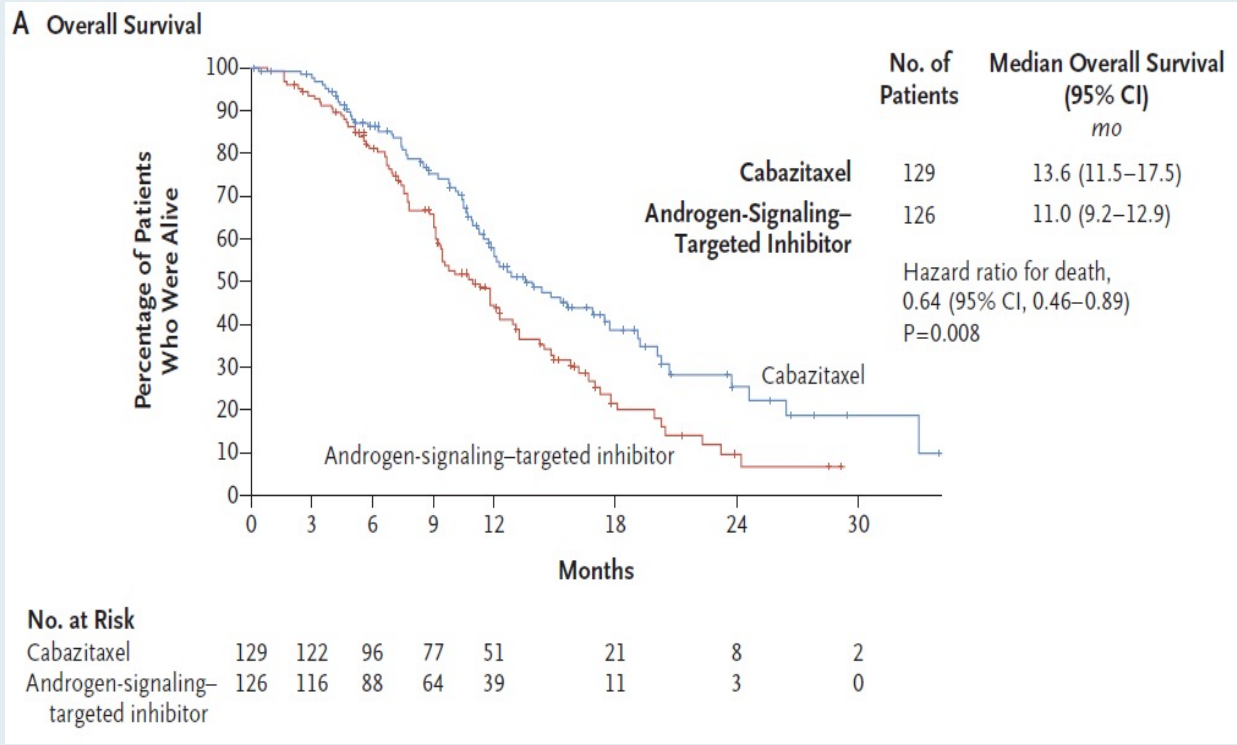
- Previous treatments: Leuprolide, abiraterone, enzalutamide and docetaxel
- Liquid biopsy: BRCA2 mutation
  - Olaparib with initial response but rising PSA at 4 months, asymptomatic
- Enrolled on the VISION study
  - Received 6 doses of 177Lu-PSMA-617
  - PSA progression: Trial of pembrolizumab in combination with investigational agent

Question

- For a patient who responds to 177Lu-PSMA-617 with good tolerance can you rechallenge the patient?

CARD: Imaging-Based PFS and OS with Cabazitaxel versus Abiraterone or Enzalutamide for mCRPC





de Wit R. et al. *NEJM* 2019;381:2506-18.

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CARD: Select Adverse Events

Table 2. Adverse Events (Safety Population).

Event	Cabazitaxel (N = 126)		Androgen-Signaling–Targeted Inhibitor (N = 124)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any adverse event — no. (%)	124 (98.4)	—	117 (94.4)	—
Any grade ≥3 adverse event — no. (%)	—	71 (56.3)	—	65 (52.4)
Any serious adverse event — no. (%)	49 (38.9)	—	48 (38.7)	—
Any adverse event leading to permanent discontinuation of treatment — no. (%)	25 (19.8)	—	11 (8.9)	—
Any adverse event leading to death — no. (%)*	7 (5.6)	—	14 (11.3)	—
Common adverse events — no. (%)†				
Asthenia or fatigue	67 (53.2)	5 (4.0)	45 (36.3)	3 (2.4)
Diarrhea	50 (39.7)	4 (3.2)	8 (6.5)	0
Infection	40 (31.7)	10 (7.9)	25 (20.2)	9 (7.3)
Musculoskeletal pain or discomfort‡	34 (27.0)	2 (1.6)	49 (39.5)	7 (5.6)
Nausea or vomiting	33 (26.2)	0	29 (23.4)	2 (1.6)
Peripheral neuropathy	25 (19.8)	4 (3.2)	4 (3.2)	0
Constipation	19 (15.1)	0	13 (10.5)	0
Hematuria	19 (15.1)	1 (0.8)	7 (5.6)	2 (1.6)
Laboratory abnormalities — no./total no. (%)††				
Anemia	124/125 (99.2)	10/125 (8.0)	118/124 (95.2)	6/124 (4.8)
Leukopenia	93/125 (74.4)	40/125 (32.0)	39/124 (31.5)	2/124 (1.6)
Neutropenia	81/123 (65.9)	55/123 (44.7)	8/124 (6.5)	4/124 (3.2)
Thrombocytopenia	51/125 (40.8)	4/125 (3.2)	20/124 (16.1)	2/124 (1.6)
Aspartate aminotransferase increased	27/124 (21.8)	4/124 (3.2)	35/124 (28.2)	0/124
Alanine aminotransferase increased	24/124 (19.4)	1/124 (0.8)	11/124 (8.9)	0/124
Hypokalemia	15/125 (12.0)	1/125 (0.8)	19/124 (15.3)	1/124 (0.8)

de Wit R et al. *NEJM* 2019;381:2506-18.

ORIGINAL RESEARCH

Baseline neutrophil-to-lymphocyte ratio as a predictive and prognostic biomarker in patients with metastatic castration-resistant prostate cancer treated with cabazitaxel versus abiraterone or enzalutamide in the CARD study

R. de Wit[1*], C. Wülfing[2], D. Castellano[3], G. Kramer[4], J.-C. Eymard[5], C. N. Sternberg[6], K. Fizazi[7,8], B. Tombal[9], A. Bamias[10], J. Carles[11], R. Iacovelli[12,13], B. Melichar[14], Á. Sverrisdóttir[15], C. Theodore[16], S. Feyerabend[17], C. Helissey[18], M. C. Foster[19], A. Ozatilgan[19], C. Geffriaud-Ricouard[20] & J. de Bono[21,22]

ESMO Open 2021;[Online ahead of print].

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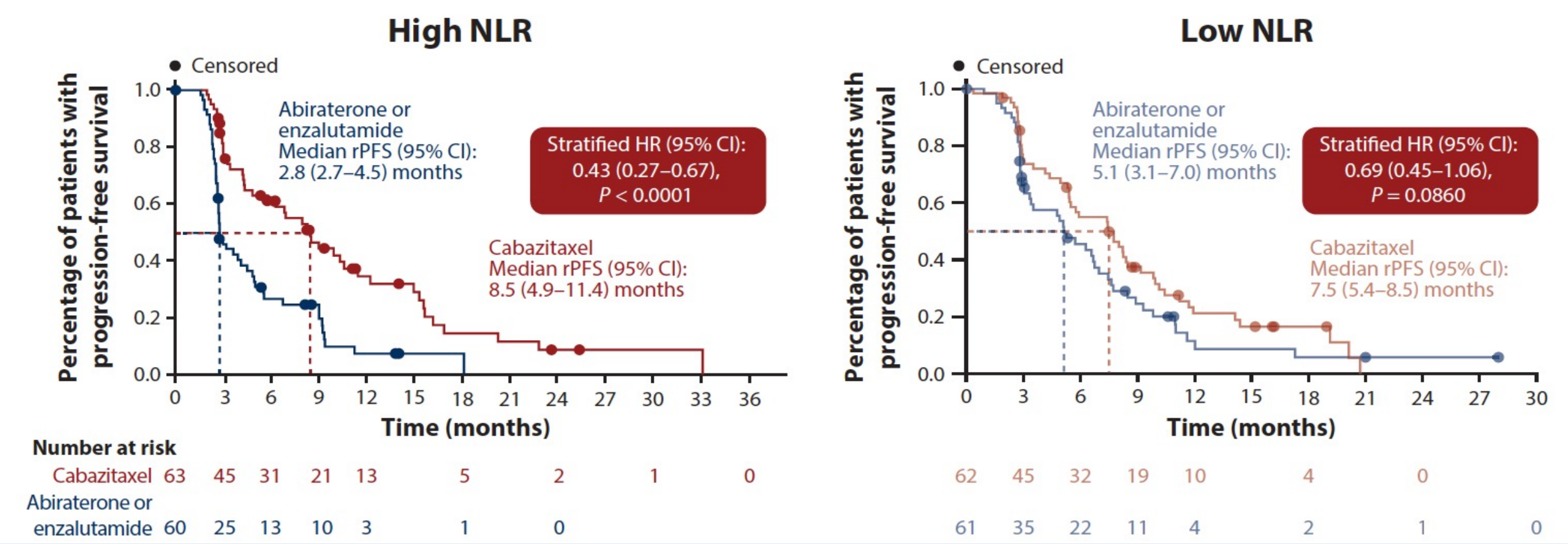
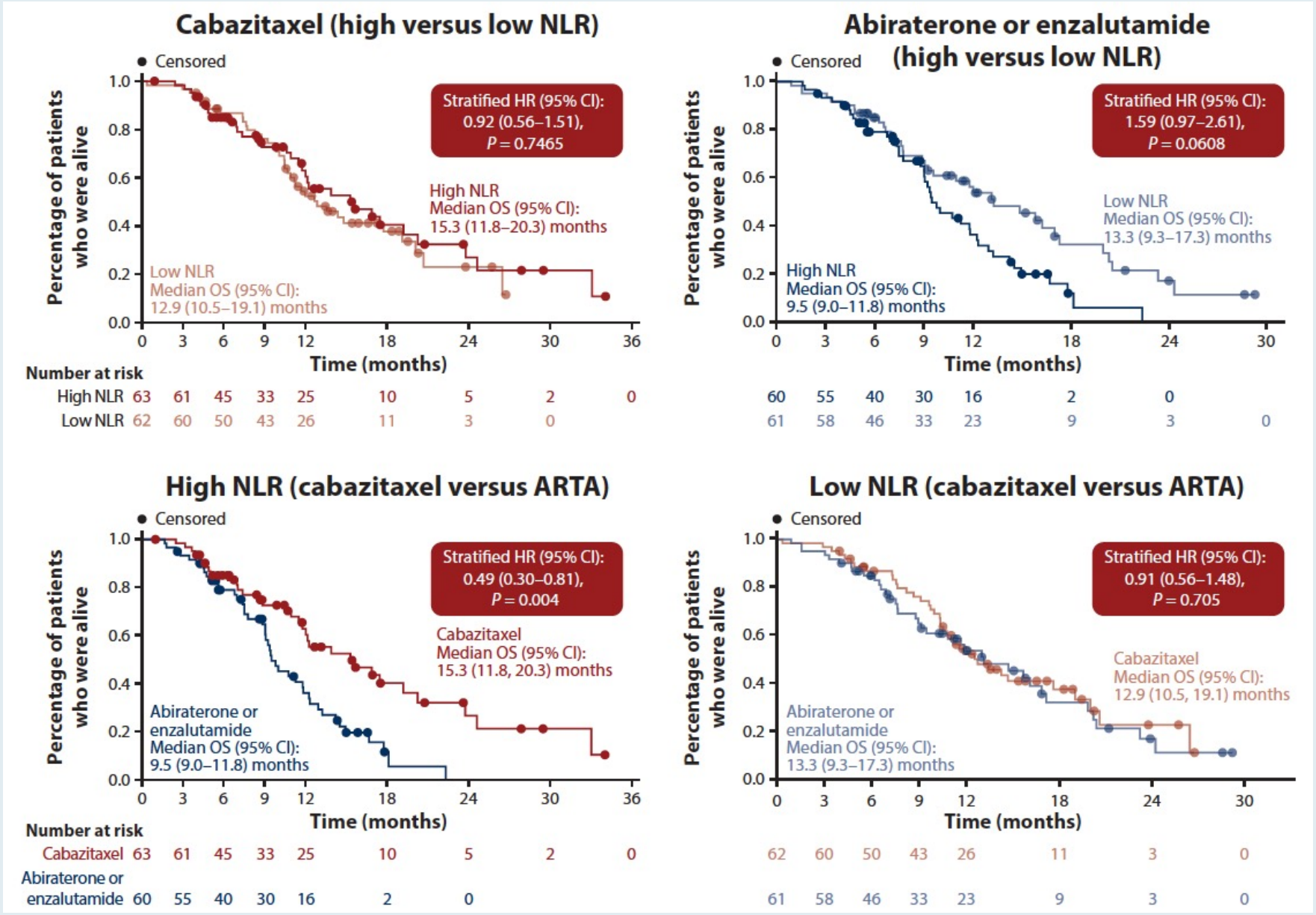
CARD: Radiographic PFS (rPFS) by Baseline Neutrophil-to-Lymphocyte Ratio (NLR)



de Wit R et al. *ESMO Open* 2021;[Online ahead of print].

CARD: OS by Baseline NLR



de Wit R et al. *ESMO Open* 2021;[Online ahead of print].

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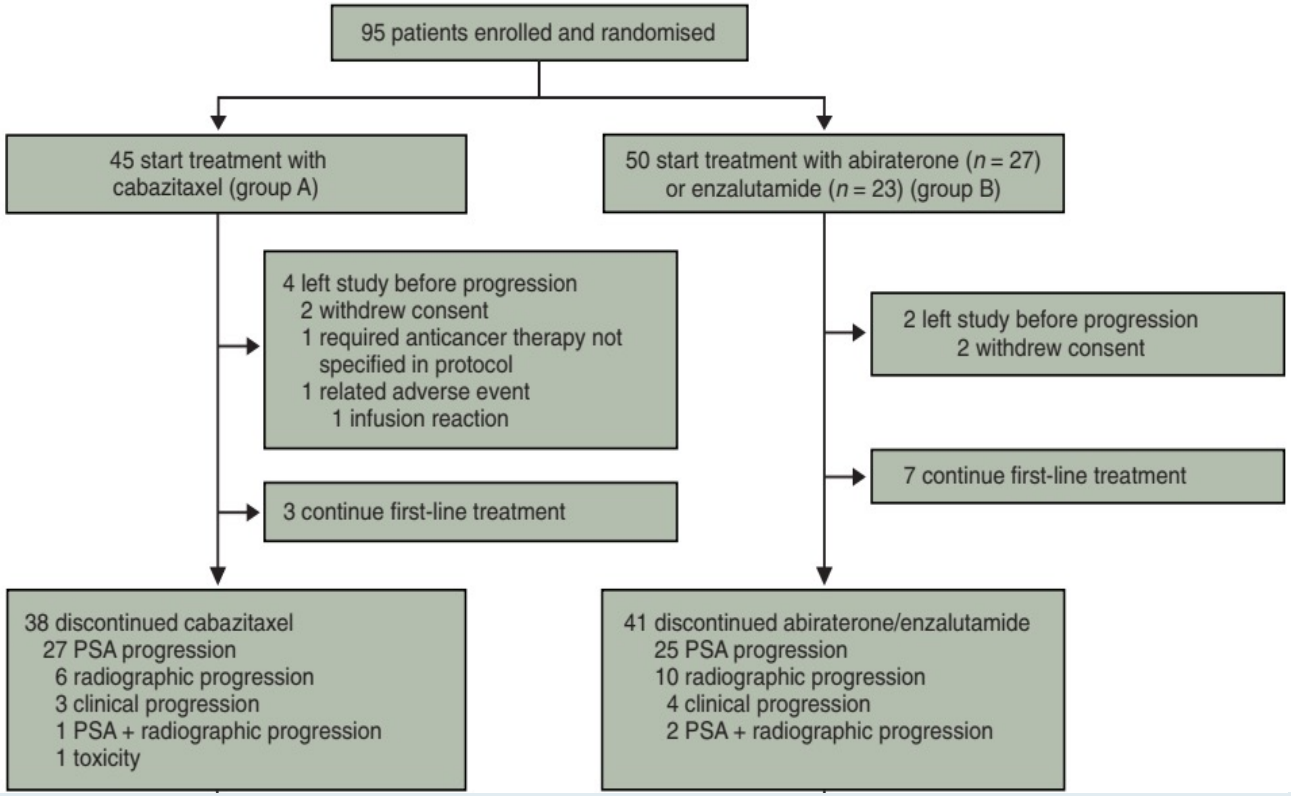
The Canadian Trial (Phase II OZM-054 Trial)

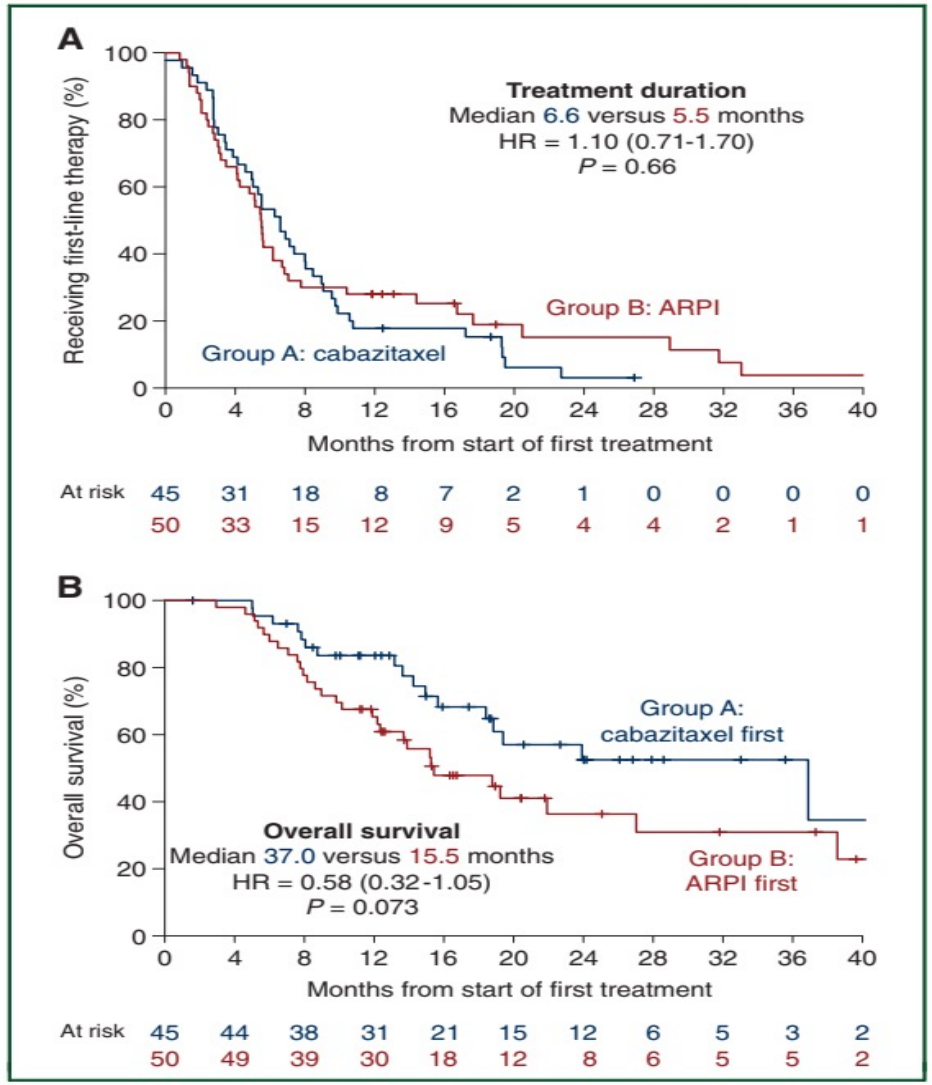
Poor prognosis:

liver mets,

CRPC <12 months,

or >3 of 6 (LDH, ECOG, visceral, albumin, ALP, <36 mo from Dx)





Annala M et al. *Ann Oncol* 2021;32:896-905.

First Results from a Randomized Phase II Study of Cabazitaxel (CBZ) versus an Androgen Receptor Targeted Agent (ARTA) in Patients with Poor-Prognosis Castration-Resistant Prostate Cancer (mCRPC)

van der Zande K et al.
ASCO 2021;Abstract 5059.

The Dutch Trial (Phase II OSTRICh Trial)

Inclusion criteria
- mCRPC
- ECOG PS0-2
- Testosterone <50 ng/dL
- Adequate bone marrow and liver functions
- Prior docetaxel
- Previous ARTA was allowed
- Progressive disease
- Features of poor prognostic disease (≥1):
  - Liver metastasis
  - Castration resistant <12m
  - Progressive <6m after docetaxel

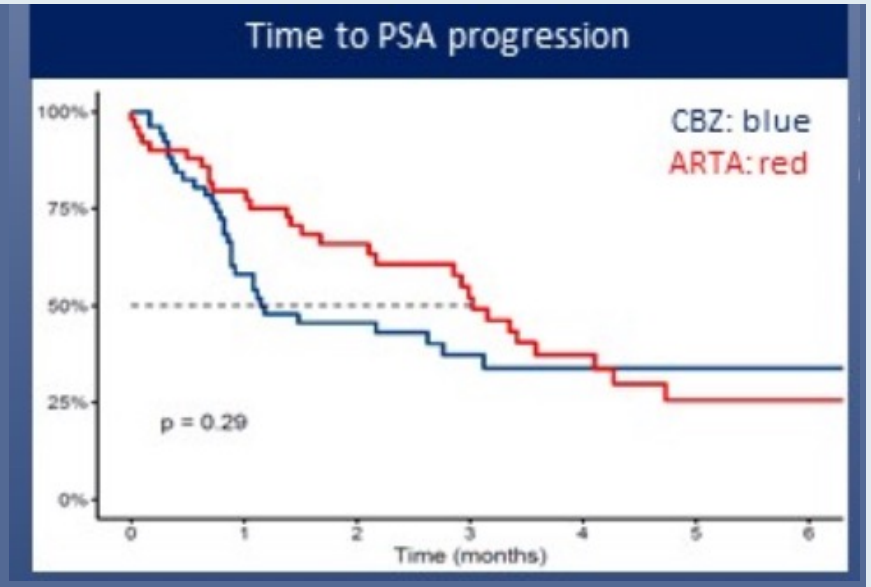
R

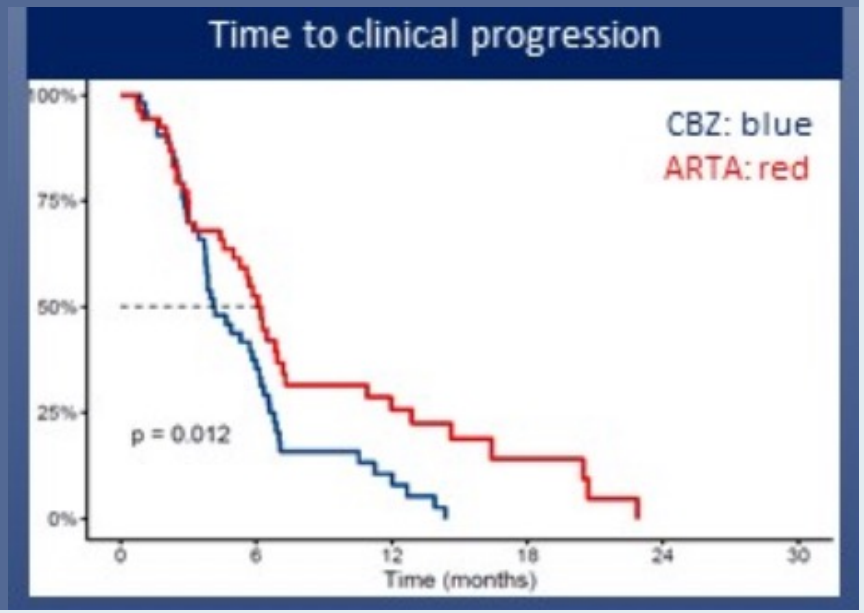
Cabazitaxel

Abiraterone/P OR enzalutamide

12 weeks CBR

Follow-up for secondary endpoints

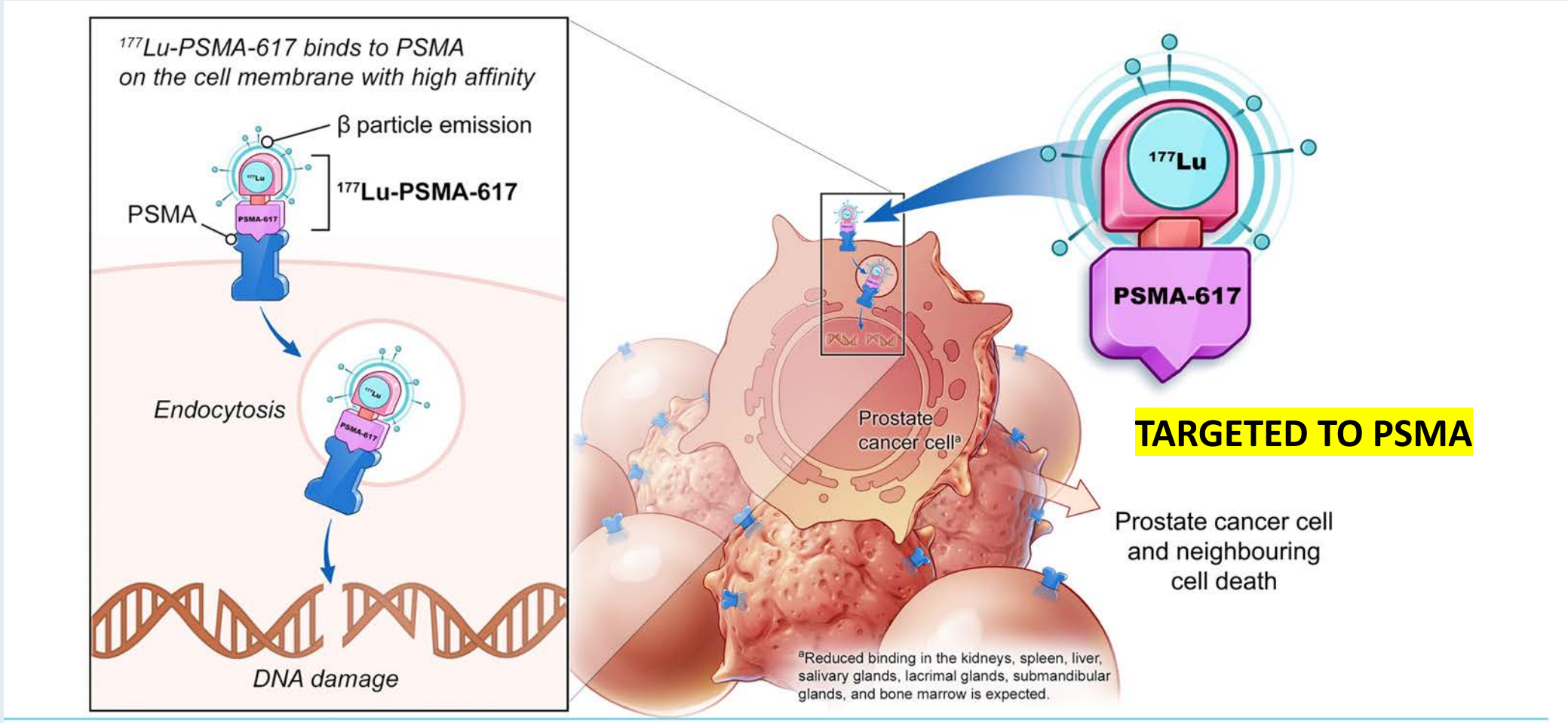




van der Zande K et al. *ASCO* 2021;Abstract 5059.

RTP RESEARCH TO PRACTICE

^{177}Lu-PSMA-617: Mechanism of Action



Morris MJ et al. ASCO 2021;Abstract LBA4.

RTP RESEARCH TO PRACTICE

N Engl J Med 2021;385:1091-103

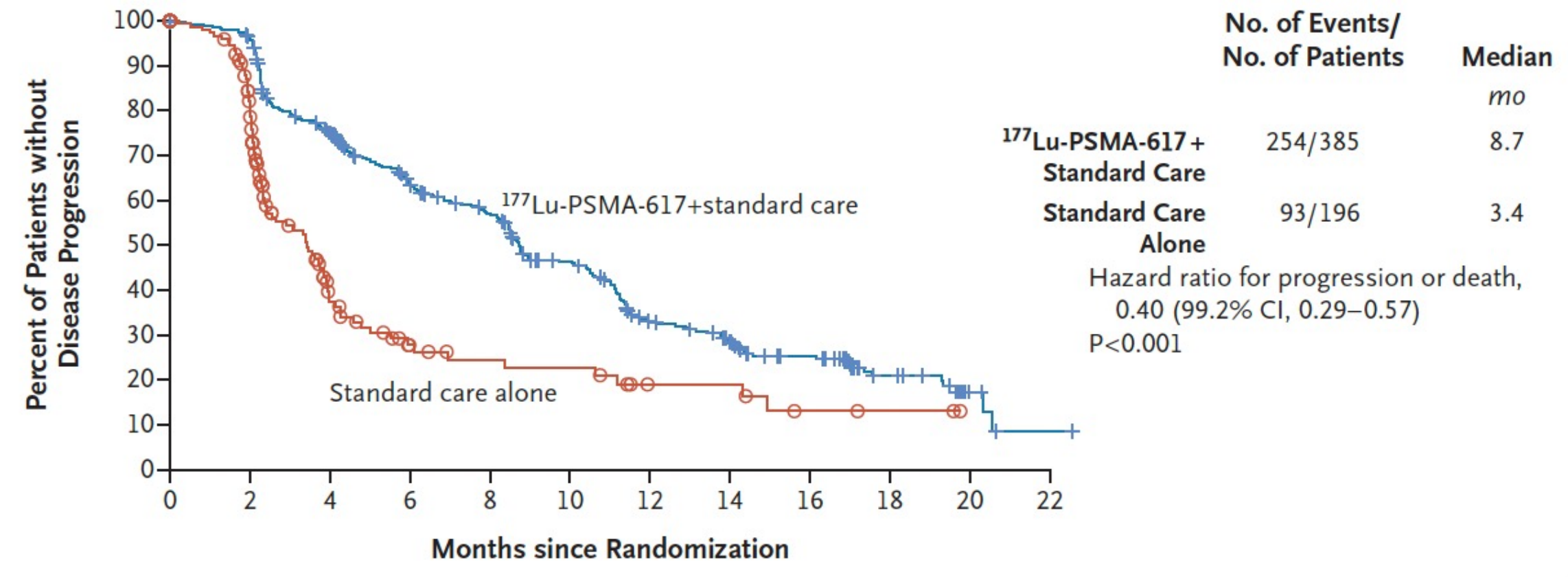
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Lutetium-177–PSMA-617 for Metastatic Castration-Resistant Prostate Cancer

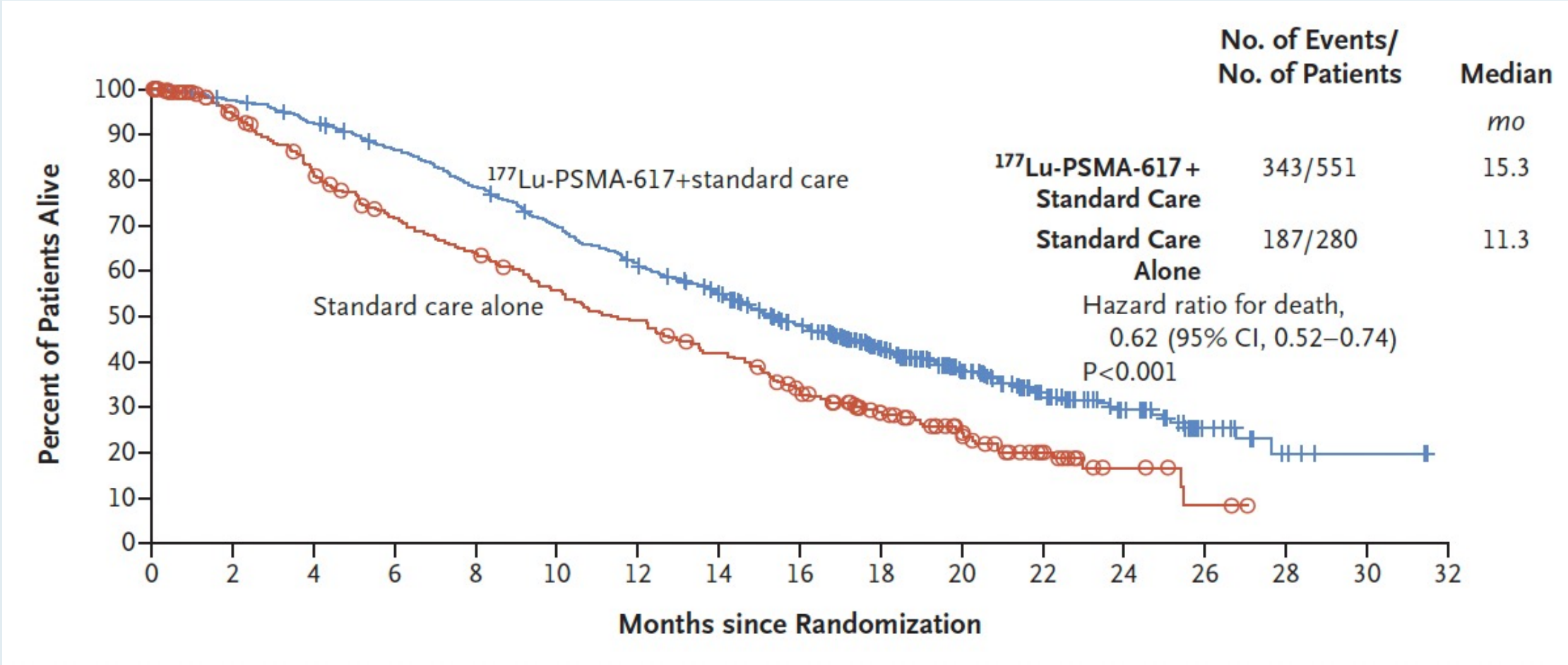
O. Sartor, J. de Bono, K.N. Chi, K. Fizazi, K. Herrmann, K. Rahbar, S.T. Tagawa, L.T. Nordquist, N. Vaishampayan, G. El-Haddad, C.H. Park, T.M. Beer, A. Armour, W.J. Pérez-Contreras, M. DeSilvio, E. Kpamegan, G. Gericke, R.A. Messmann, M.J. Morris, and B.J. Krause, for the VISION Investigators*

VISION: Imaging-Based Progression-Free Survival



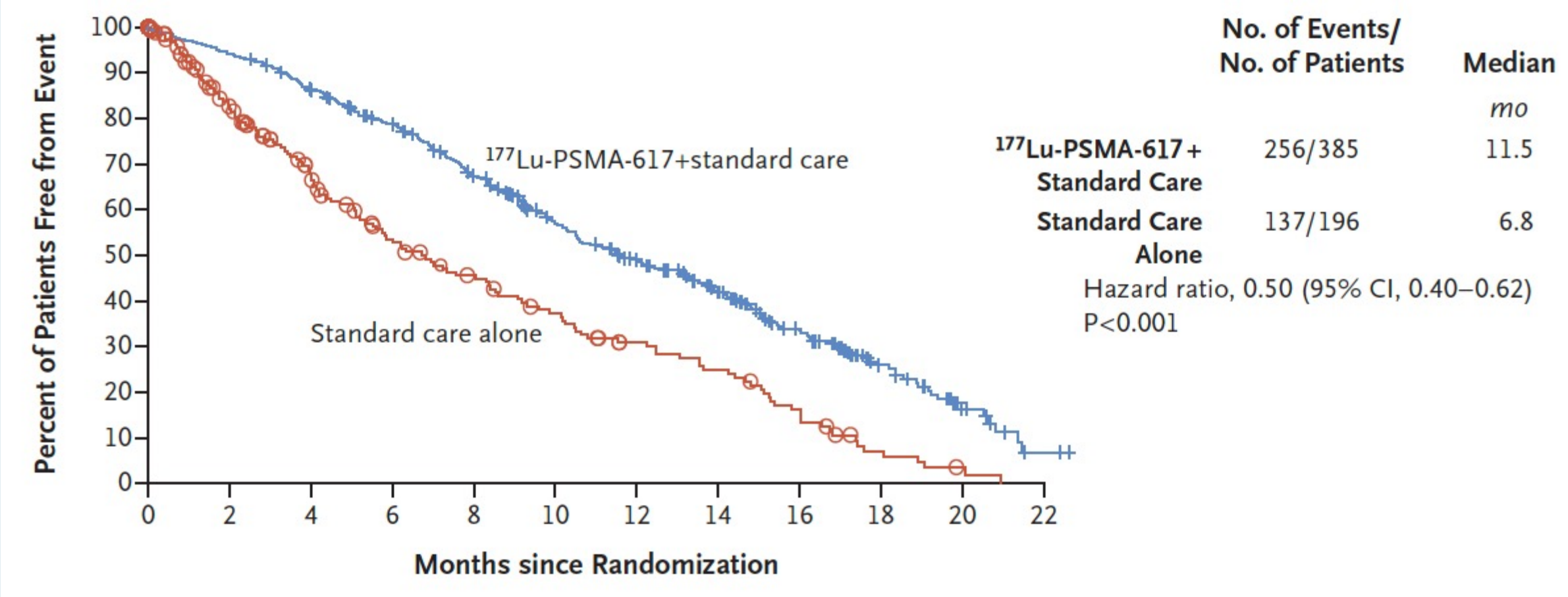
Sartor O et al. *N Engl J Med* 2021;385:1091-103.

VISION: Overall Survival



Sartor O et al. *N Engl J Med* 2021;385:1091-103.

VISION: Time to First Symptomatic Skeletal Event



Sartor O et al. *N Engl J Med* 2021;385:1091-103.

VISION: Selected Adverse Events

Event	^{177}Lu-PSMA-617 plus Standard Care (N = 529)		Standard Care Alone (N = 205)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
	number of patients (percent)			
Any adverse event	519 (98.1)	279 (52.7)	170 (82.9)	78 (38.0)
Fatigue	228 (43.1)	31 (5.9)	47 (22.9)	3 (1.5)
Thrombocytopenia	91 (17.2)	42 (7.9)	9 (4.4)	2 (1.0)
Lymphopenia	75 (14.2)	41 (7.8)	8 (3.9)	1 (0.5)
Leukopenia	66 (12.5)	13 (2.5)	4 (2.0)	1 (0.5)
Adverse event that led to reduction in ^{177}Lu-PSMA-617 dose	30 (5.7)	10 (1.9)	NA	NA
Adverse event that led to interruption of ^{177}Lu-PSMA-617†	85 (16.1)	42 (7.9)	NA	NA
Adverse event that led to discontinuation of ^{177}Lu-PSMA-617†	63 (11.9)	37 (7.0)	NA	NA
Adverse event that led to death‡	19 (3.6)	19 (3.6)	6 (2.9)	6 (2.9)

Sartor O et al. *N Engl J Med* 2021;385:1091-103.

RTP RESEARCH TO PRACTICE

177Lu-PSMA-617 (LuPSMA) versus Cabazitaxel in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Progressing After Docetaxel: Updated Results Including Progression-Free Survival (PFS) and Patient-Reported Outcomes (PROs) (TheraP ANZUP 1603)[1]

[^{177}Lu]Lu-PSMA-617 versus cabazitaxel in patients with metastatic castration-resistant prostate cancer (TheraP): a randomised, open-label, phase 2 trial [2]

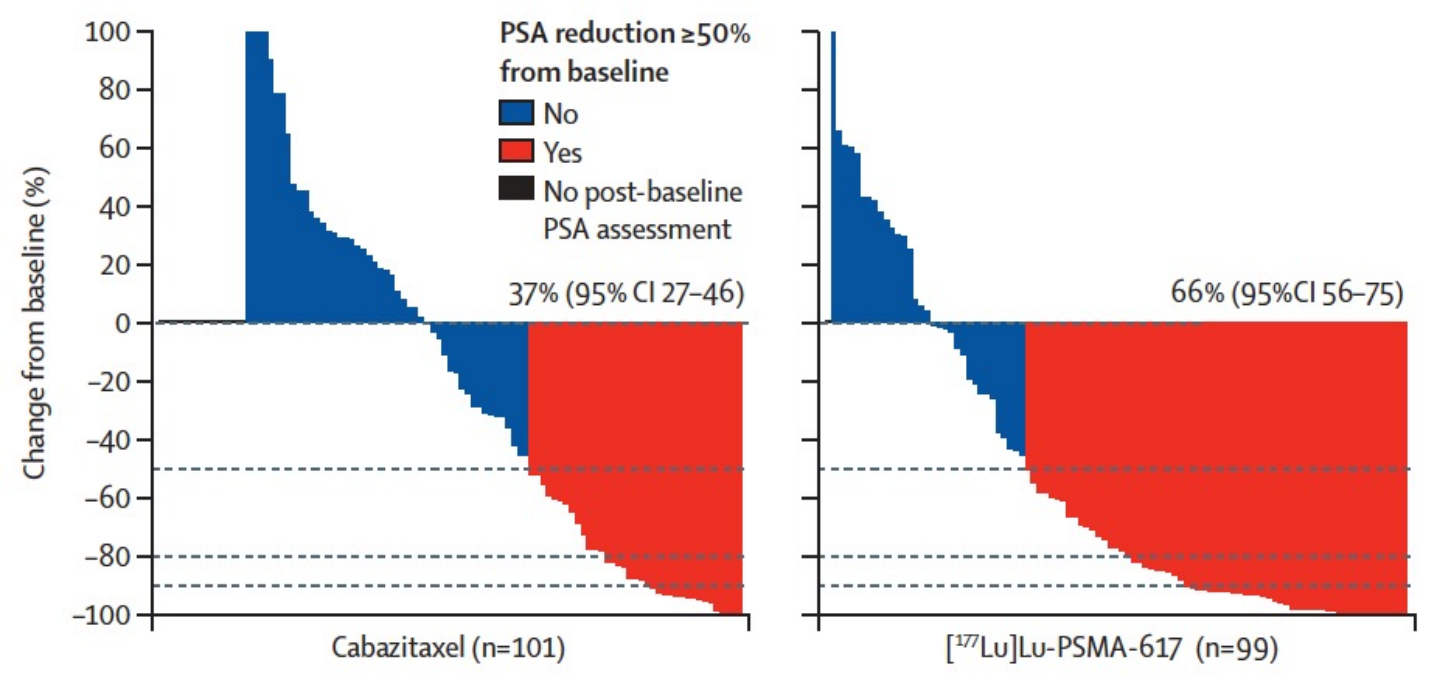
Michael S Hofman, Louise Emmett, Shahneen Sandhu, Amir Iravani, Anthony M Joshua, Jeffrey C Goh, David A Pattison, Thean Hsiang Tan, Ian D Kirkwood, Siobhan Ng, Roslyn J Francis, Craig Gedye, Natalie K Rutherford, Andrew Weickhardt , Andrew M Scott, Sze-Ting Lee, Edmond M Kwan, Arun A Azad, Shakher Ramdave, Andrew D Redfern, William Macdonald, Alex Guminski, Edward Hsiao, Wei Chua, Peter Lin, Alison Y Zhang, Margaret M McJannett, Martin R Stockler, John A Violet, Scott G Williams, Andrew J Martin, Ian D Davis, for the TheraP Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group†*

[1] Hofman MS et al. Genitourinary Cancers Symposium 2021;Abstract 6.
[2] Hofman MS et al. *Lancet* 2021;397(10276):797-804.

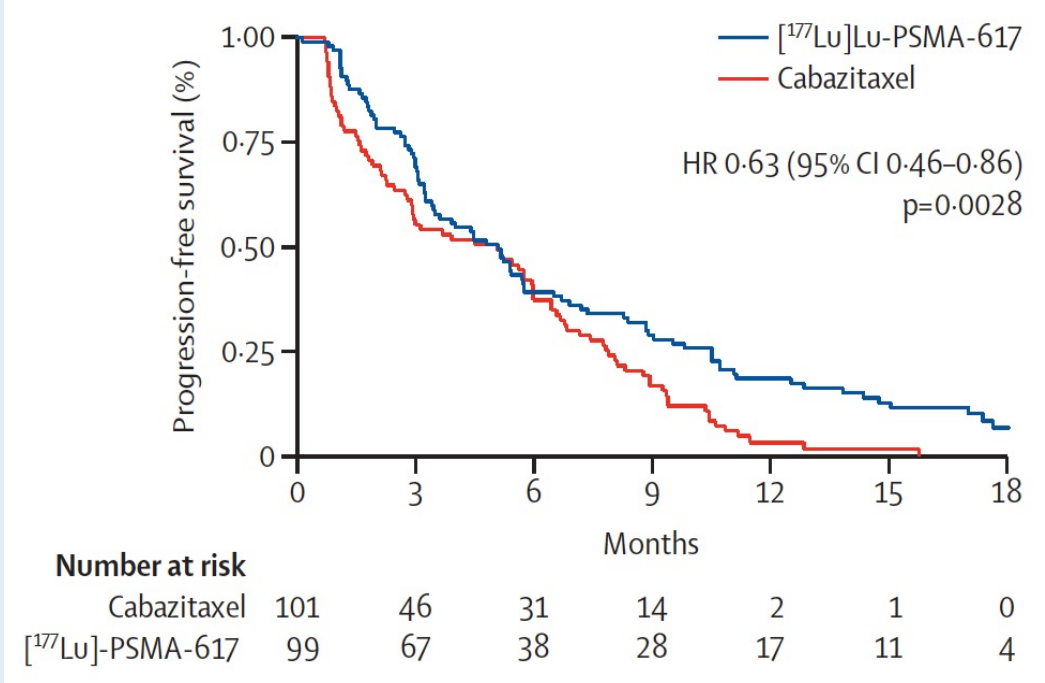
RTP RESEARCH TO PRACTICE

TheraP ANZUP 1603: PSA Response and PFS

PSA response



Radiographic or PSA progression-free survival



Hofman MS et al. Genitourinary Cancers Symposium 2021;Abstract 6; Hofman MS et al. *Lancet* 2021;397(10276):797-804.

TheraP ANZUP 1603: Adverse Events

	[^{177}Lu]Lu-PSMA-617 (n=98)		Cabazitaxel (n=85)	
	Grade 1–2	Grade 3–4	Grade 1–2	Grade 3–4
Fatigue	69 (70%)	5 (5%)	61 (72%)	3 (4%)
Pain*	60 (61%)	11 (11%)	52 (61%)	4 (5%)
Dry mouth	59 (60%)	0	18 (21%)	0
Diarrhoea	18 (18%)	1 (1%)	44 (52%)	4 (5%)
Nausea	39 (40%)	1 (1%)	29 (34%)	0
Thrombocytopenia	18 (18%)	11 (11%)	4 (5%)	0
Dry eyes	29 (30%)	0	3 (4%)	0
Anaemia	19 (19%)	8 (8%)	11 (13%)	7 (8%)
Neuropathy†	10 (10%)	0	22 (26%)	1 (1%)
Dysgeusia	12 (12%)	0	23 (27%)	0
Haematuria	3 (3%)	1 (1%)	12 (14%)	5 (6%)
Neutropenia‡	7 (7%)	4 (4%)	4 (5%)	11 (13%)
Insomnia	9 (9%)	0	12 (14%)	1 (1%)
Vomiting	12 (12%)	1 (1%)	10 (12%)	2 (2%)
Dizziness	4 (4%)	0	11 (13%)	0
Leukopenia	10 (10%)	1 (1%)	5 (6%)	1 (1%)
Any adverse event	53 (54%)	32 (33%)	34 (40%)	45 (53%)

Hofman MS et al. Genitourinary Cancers Symposium 2021;Abstract 6; Hofman MS et al. *Lancet* 2021;397(10276):797-804.

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Sartor

MODULE 1: Overview of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- Dr Mar: A 75-year-old man with mCRPC

MODULE 2: BRCA/HRD-Negative mCRPC

- Dr Bachow: An 81-year-old man with mCRPC – LOH and AR-V7 splice site mutation
- Dr Ibrahim: A 74-year-old man with mCRPC – Enrolled on the VISION trial
- Key Relevant Data Sets

MODULE 3: BRCA/HRD-Positive mCRPC

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- Dr Morris: A 72-year-old man with mCRPC and a germline RAD51c mutation
- Dr Bachow: A 62-year-old man with mCRPC and a somatic BRCA1 mutation – High TMB
- Key Relevant Data Sets

MODULE 4: Other Novel Agents and Strategies Under Investigation

MODULE 5 Journal Club with Dr Sartor

MODULE 6: Faculty Survey

MODULE 7: Appendix

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Zafar: A 68-year-old man with metastatic hormone-sensitive prostate cancer and an ARID1A mutation

Dr Syed Zafar

- 2012: Gleason 4 + 3 prostate cancer, PSA 1.8 ng/dL, s/p definitive RT
- 2020: PSA 1.8 ng/dL, abnormal LFTs → Staging: multifocal, biopsy-proven osseous and hepatic metastases
- Docetaxel, with improvement in LFTs, PSA undetectable
- NGS: ARID1A mutation
- Olaparib

Case Presentation – Dr Morris: A 72-year-old man with mCRPC and a germline RAD51c mutation

Dr David Morris

- 7/2015: Gleason 4 + 3, Decipher® low risk prostate cancer, s/p RALP
- 6/2016: Recurrence → RT
- 1/2019: PSA increased to 7.3 → ADT → PSA undetectable → 0.03 → 0.8 → 1.0 → 1.6 → 7 → 19
  - Imaging: No evidence of metastatic disease
- Fluciclovine uptake in nodes → Sipuleucel-T x 1 month → Continued PSA increase
  - Germline testing: Rad51c mutation
- Abiraterone/prednisone, with PSA decrease from 22 to 6.9

Questions

- How long would you continue with abiraterone/prednisone before trying a PARP inhibitor? Would you wait for imaging progression, or would you try a PARP inhibitor when the PSA is rising even if imaging is stable?

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Bachow: A 62-year-old man with mCRPC and a somatic BRCA1 mutation – High tumor mutation burden (TMB)

Dr Spencer Bachow

- 9/2010: Gleason 4 + 3 = 7, PSA 3 ng/dL prostate cancer, s/p RALP, zoledronic acid, EBRT, orchiectomy, bicalutamide/leuprolide, abiraterone/prednisone
- 3/2017: Left supraclavicular lymph node positive for prostate cancer
- Testing: BRCA1 mutation (presumed somatic)
- Docetaxel → Clinical trial of rucaparib, with continued ADT
- 2021: Bladder metastases, PSA 0.84 ng/dL w/ castrate testosterone levels
- NGS: TMB 11.5 mut/mB (high) → Pembrolizumab

Questions

- In treatment-naïve patients with mHSPC or mCRPC that harbor both germline and/or somatic BRCA mutations, how do you sequence therapies? Are you giving PARP inhibitors up front followed by either abiraterone, enzalutamide, apalutamide or docetaxel?
- Do you ever give the hormonal therapies or docetaxel upfront and then at progression give the PARP inhibitor? What's your preferred sequence?
- Which PARP inhibitor do you prefer? Does germline or somatic mutation make a difference?
- What is your experience with immune checkpoint inhibitors in patients with mCRPC with a high TMB?

RTP RESEARCH TO PRACTICE

Positive Results Announced for the PROpel Phase III Trial of Olaparib with Abiraterone as First-Line Treatment for mCRPC

Press Release: September 24, 2021

"Positive high-level results from the PROpel Phase III trial showed that olaparib in combination with abiraterone demonstrated a statistically significant and clinically meaningful improvement in radiographic progression-free survival (rPFS) versus standard-of-care abiraterone as a 1st-line treatment for men with metastatic castration-resistant prostate cancer (mCRPC) with or without homologous recombination repair (HRR) gene mutations.

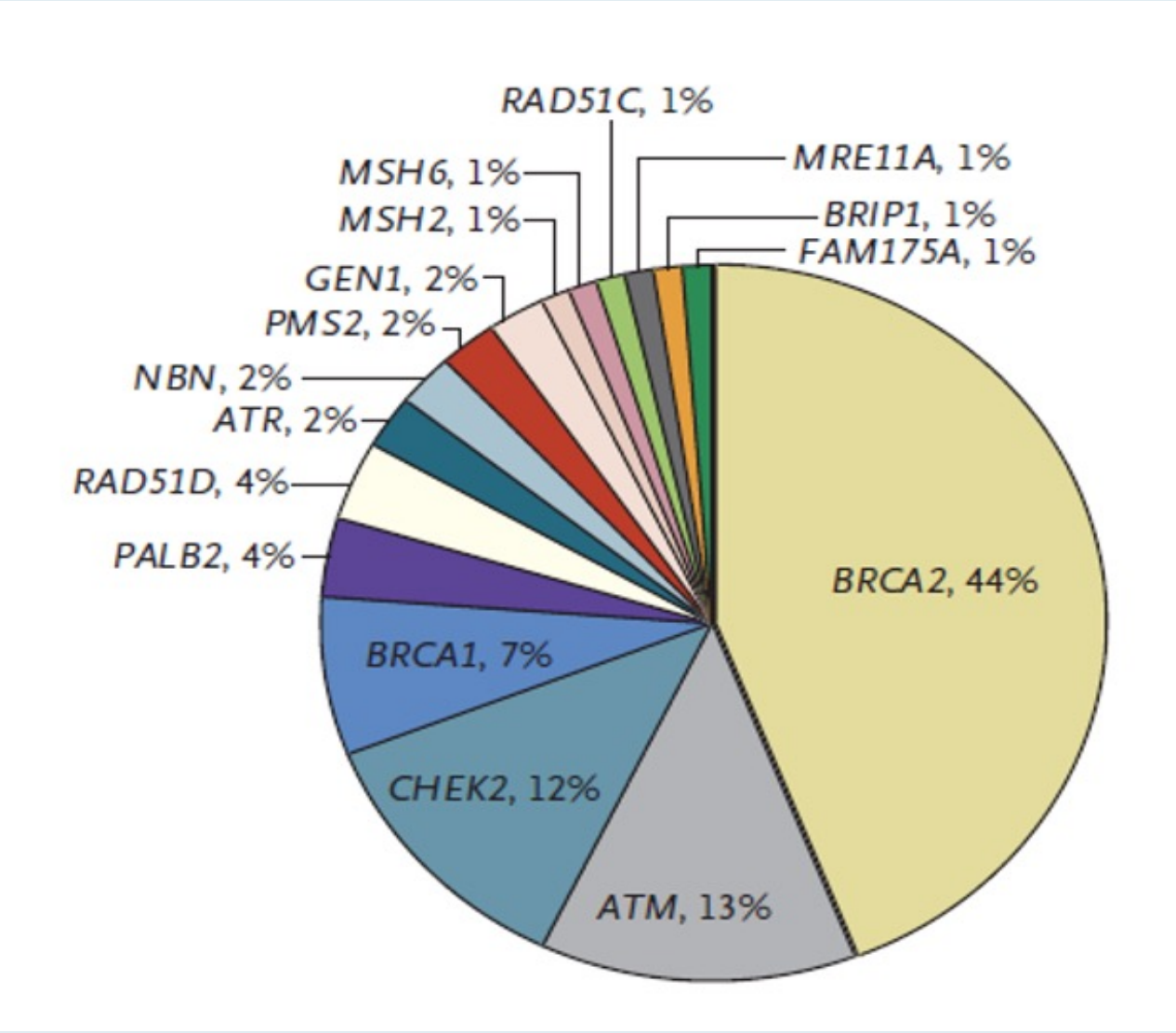
At a planned interim analysis, the Independent Data Monitoring Committee concluded that the trial met the primary endpoint of rPFS in men with mCRPC who had not received treatment in the 1st-line setting including with new hormonal agents or chemotherapy.

The data will be presented at an upcoming medical meeting."

https://www.astrazeneca.com/media-centre/press-releases/2021/lynparza-propel-trial-meets-primary-endpoint.html

RTP RESEARCH TO PRACTICE

Inherited DNA Repair Gene Mutations in Men with Metastatic Prostate Cancer



- Multicenter study of 692 men
- Deleterious mutations were found in 82 men (11.8%) in 16 genes
- Observed rate exceeded that associated with localized prostate cancer (4.6%) and general population without cancer (2.7%)

Courtesy of Matthew Smith, MD, PhD.

RTP RESEARCH TO PRACTICE

Recent FDA Approvals of PARP Inhibitors for mCRPC

PARP inhibitor	Approval date	Pivotal study
Olaparib	May 19, 2020	PROfound
Rucaparib	May 15, 2020	TRITON2

https://www.fda.gov/drugs/resources-information-approved-drugs/

RTP RESEARCH TO PRACTICE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

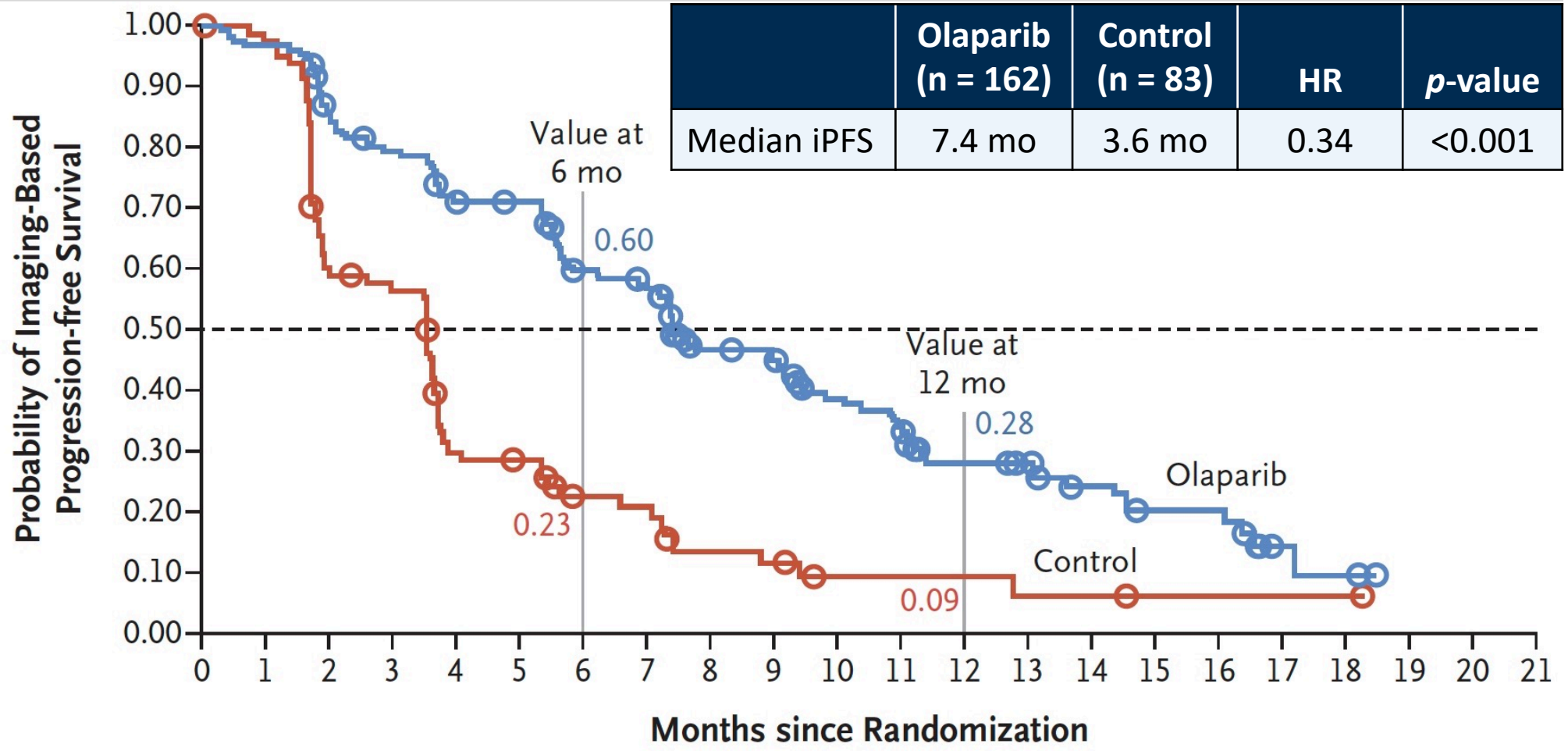
Olaparib for Metastatic Castration-Resistant Prostate Cancer

J. de Bono, J. Mateo, K. Fizazi, F. Saad, N. Shore, S. Sandhu, K.N. Chi, O. Sartor, N. Agarwal, D. Olmos, A. Thiery-Vuillemin, P. Twardowski, N. Mehra, C. Goessl, J. Kang, J. Burgents, W. Wu, A. Kohlmann, C.A. Adelman, and M. Hussain

***N Engl J Med* 2020;382:2091-102**

PROfound Primary Endpoint: Imaging-Based PFS with Olaparib for Patients with mCRPC Who Had at Least 1 Alteration in BRCA1, BRCA2 or ATM (Cohort A)

	Olaparib (n = 162)	Control (n = 83)	HR	*p*-value
Median iPFS	7.4 mo	3.6 mo	0.34	<0.001

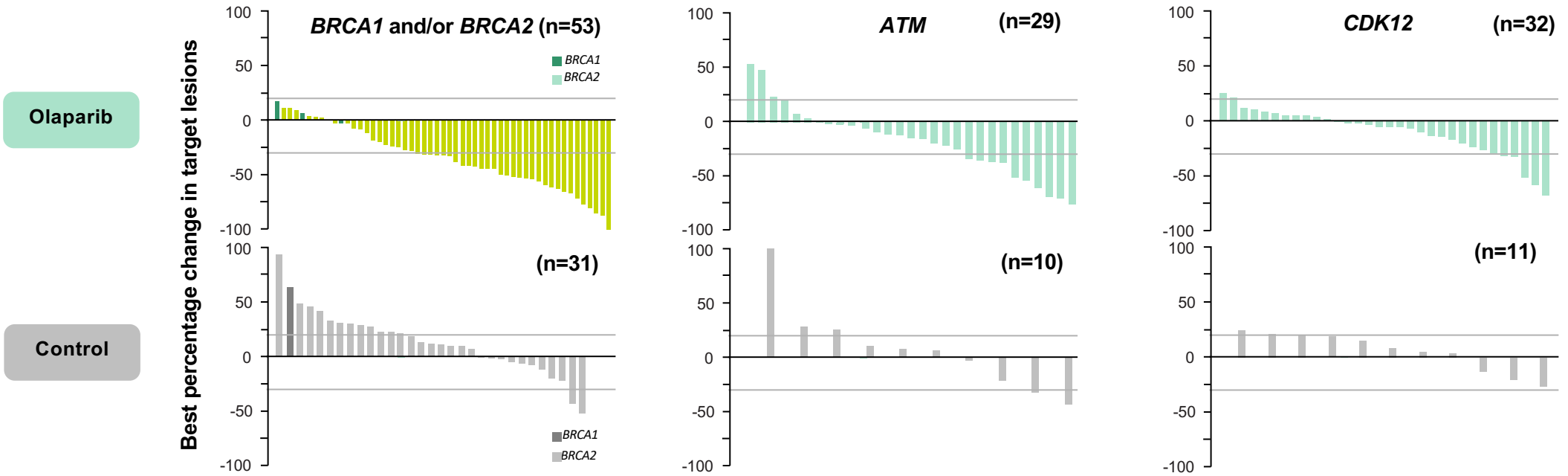


de Bono J et al; PROfound investigators. *N Engl J Med* 2020;382(22):2091-102.

RTP RESEARCH TO PRACTICE

Olaparib Antitumor Activity in PROfound

		Cohort A		Cohorts A+B		*BRCA1* and/or *BRCA2*		*ATM*		*CDK12*	
		Olaparib (N=162)	Control (N=83)	Olaparib (N=256)	Control (N=131)	Olaparib (N=102)	Control (N=58)	Olaparib (N=62)	Control (N=24)	Olaparib (N=61)	Control (N=28)
rPFS	Median, months	7.4	3.6	5.8	3.5	9.8	3.0	5.4	4.7	5.1	2.2
	HR (95% CI)	0.34 (0.25–0.47)		0.49 (0.38–0.63)		0.22 (0.15–0.32)		1.04 (0.61–1.87)		0.74 (0.44–1.31)	
OS	Median OS, months	19.1	14.7	17.3	14.0	20.1	14.4	18.0	15.6	14.1	11.5
	HR (95% CI)	0.69 (0.50–0.97)		0.79 (0.61–1.03)		0.63 (0.42–0.95)		0.93 (0.53–1.75)		0.97 (0.57–1.71)	
ORR	Evaluable patients, n	84	43	138	67	57	33	30	10	34	12
	ORR, %	33.3	2.3	21.7	4.5	43.9	0	10.0	10.0	5.9	0
PSA	Evaluable patients, n	153	77	243	123	94	54	61	22	58	27
	Confirmed response, %	43.1	7.8	30.0	9.8	61.7	0	13.1	22.7	5.2	3.7
CTC	Evaluable patients, n	52	22	78	32	29	17	25	3	14	5
	Conversion, %	55.8	22.7	52.6	21.9	69.0	23.5	40.0	33.3	50.0	40.0



de Bono et al. NEJM 2020

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

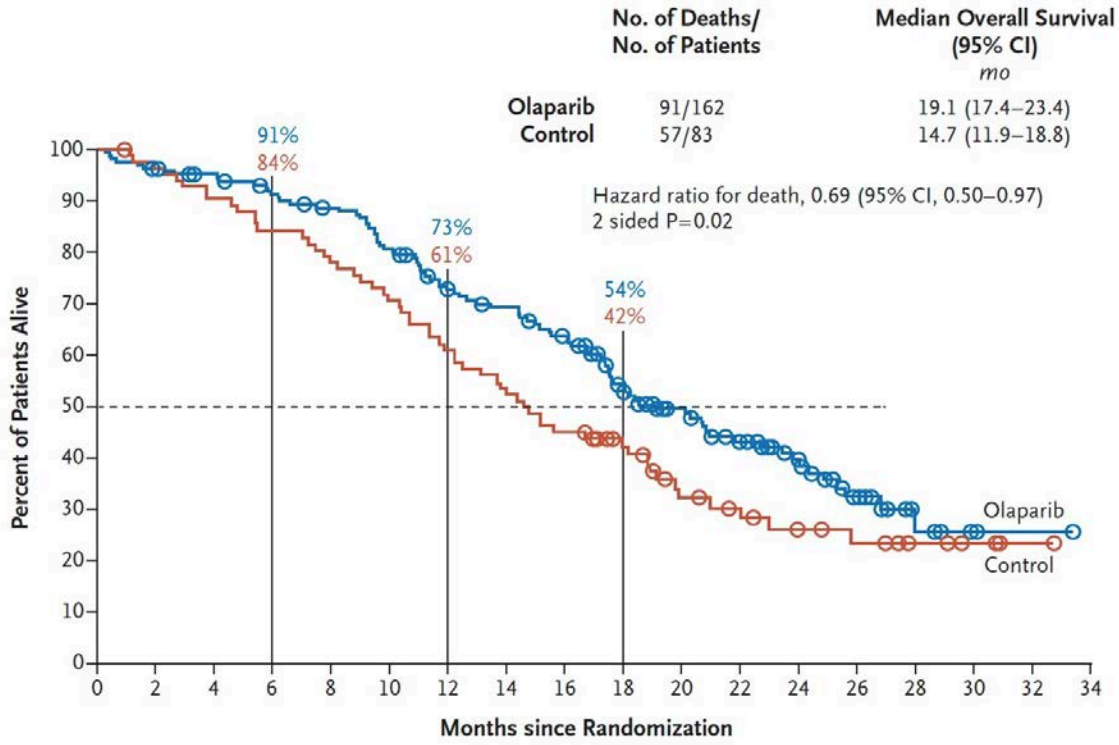
Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer

M. Hussain, J. Mateo, K. Fizazi, F. Saad, N. Shore, S. Sandhu, K.N. Chi, O. Sartor, N. Agarwal, D. Olmos, A. Thiery-Vuillemin, P. Twardowski, G. Roubaud, M. Özgüroğlu, J. Kang, J. Burgents, C. Gresty, C. Corcoran, C.A. Adelman, and J. de Bono, for the PROfound Trial Investigators*

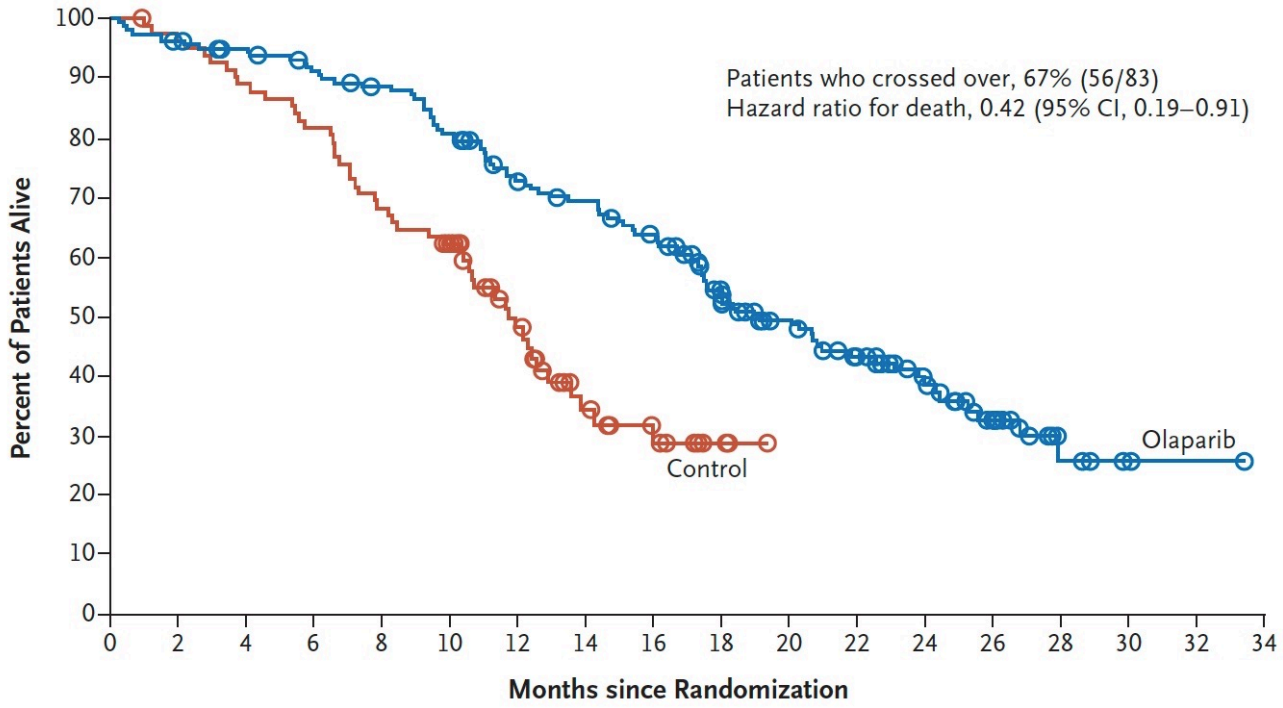
***N Engl J Med* 2020;383(24):2345-57.**

PROfound: OS with Olaparib in Patients with mCRPC Who Had at Least 1 Alteration in BRCA1, BRCA2 or ATM (Cohort A)

Overall survival



Cross-over adjusted overall survival



Hussain M et al; PROfound investigators. *N Engl J Med* 2020;383(24):2345-57.

rapid communications

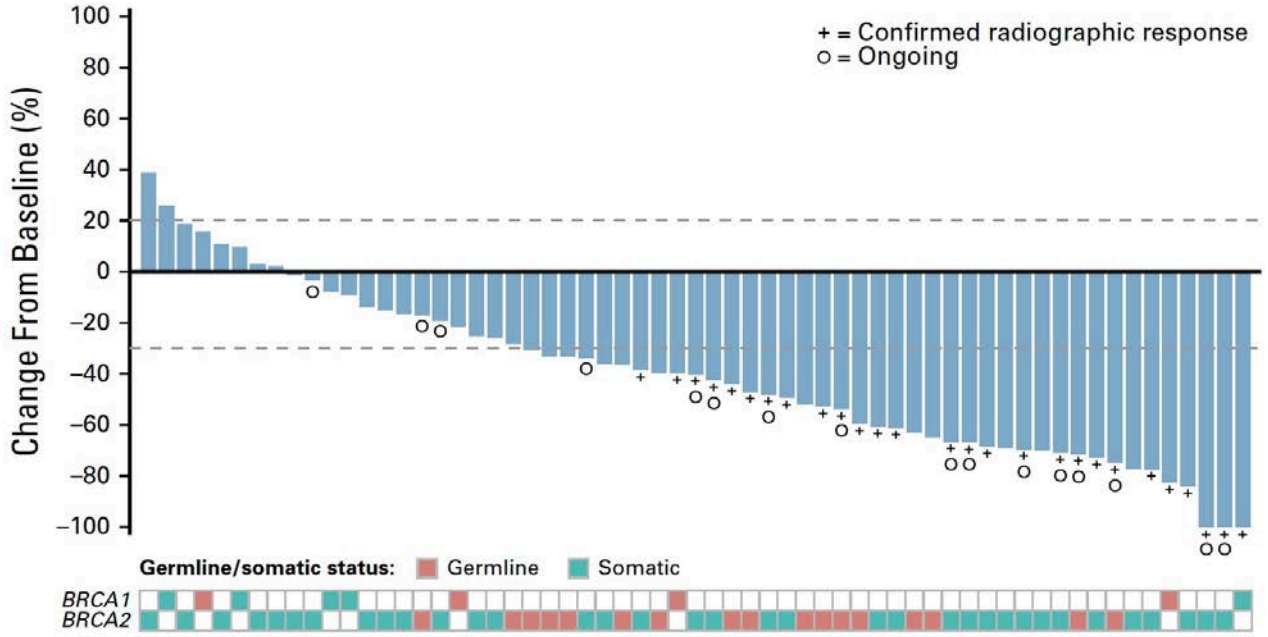
Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a *BRCA1* or *BRCA2* Gene Alteration

Wassim Abida, MD, PhD[1]; Akash Patnaik, MD, PhD, MMSc[2]; David Campbell, MBBS[3]; Jeremy Shapiro, MBBS[4]; Alan H. Bryce, MD[5]; Ray McDermott, MD, PhD, MBA[6]; Brieuc Sautois, MD, PhD[7]; Nicholas J. Vogelzang, MD[8]; Richard M. Bambury, MD[9]; Eric Voog, MD[10]; Jingsong Zhang, MD, PhD[11]; Josep M. Piulats, MD[12]; Charles J. Ryan, MD[13]; Axel S. Merseburger, PhD[14]; Gedske Daugaard, DMSc[15]; Axel Heidenreich, MD[16]; Karim Fizazi, MD, PhD[17]; Celestia S. Higano, MD[18]; Laurence E. Krieger, MBChB[19]; Cora N. Sternberg, MD[20]; Simon P. Watkins, PhD[21]; Darrin Despain, MStat[22]; Andrew D. Simmons, PhD[23]; Andrea Loehr, PhD[23]; Melanie Dowson, BA[24]; Tony Golsorkhi, MD[25]; and Simon Chowdhury, MD, PhD[26,27]; on behalf of the TRITON2 investigators

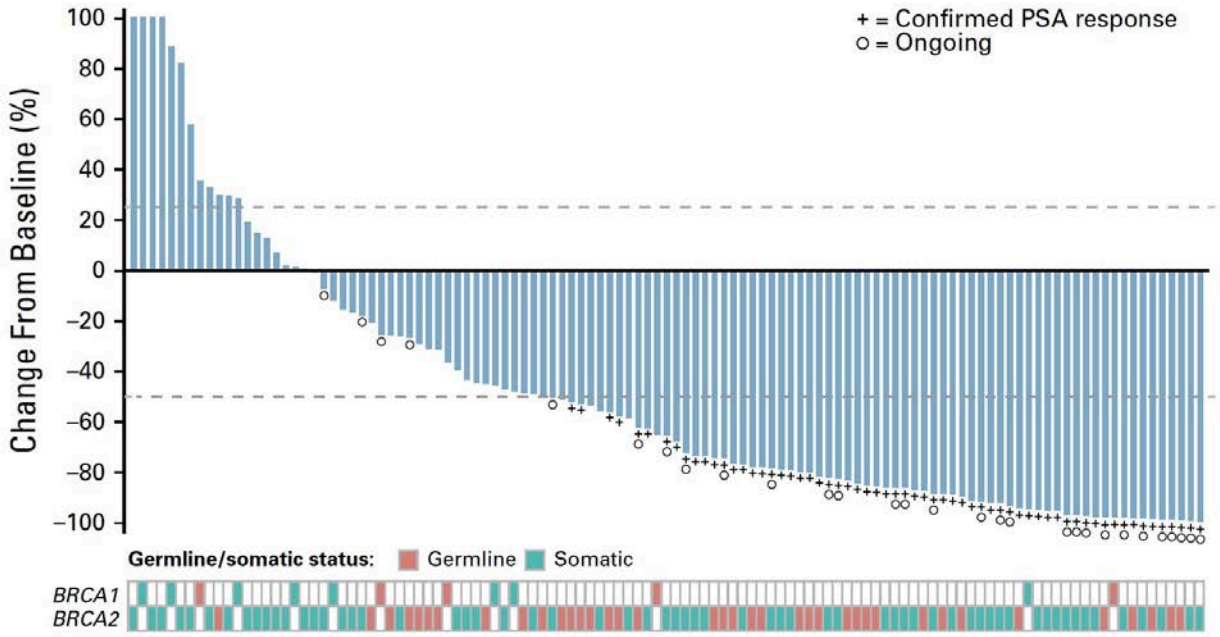
J Clin Oncol 2020;38(22):3763-72.

TRITON2: Response to Rucaparib in Patients with mCRPC Harboring a BRCA1 or BRCA2 Gene Alteration

ORR per independent radiology review: 43.5%



Confirmed PSA response rate: 54.8%

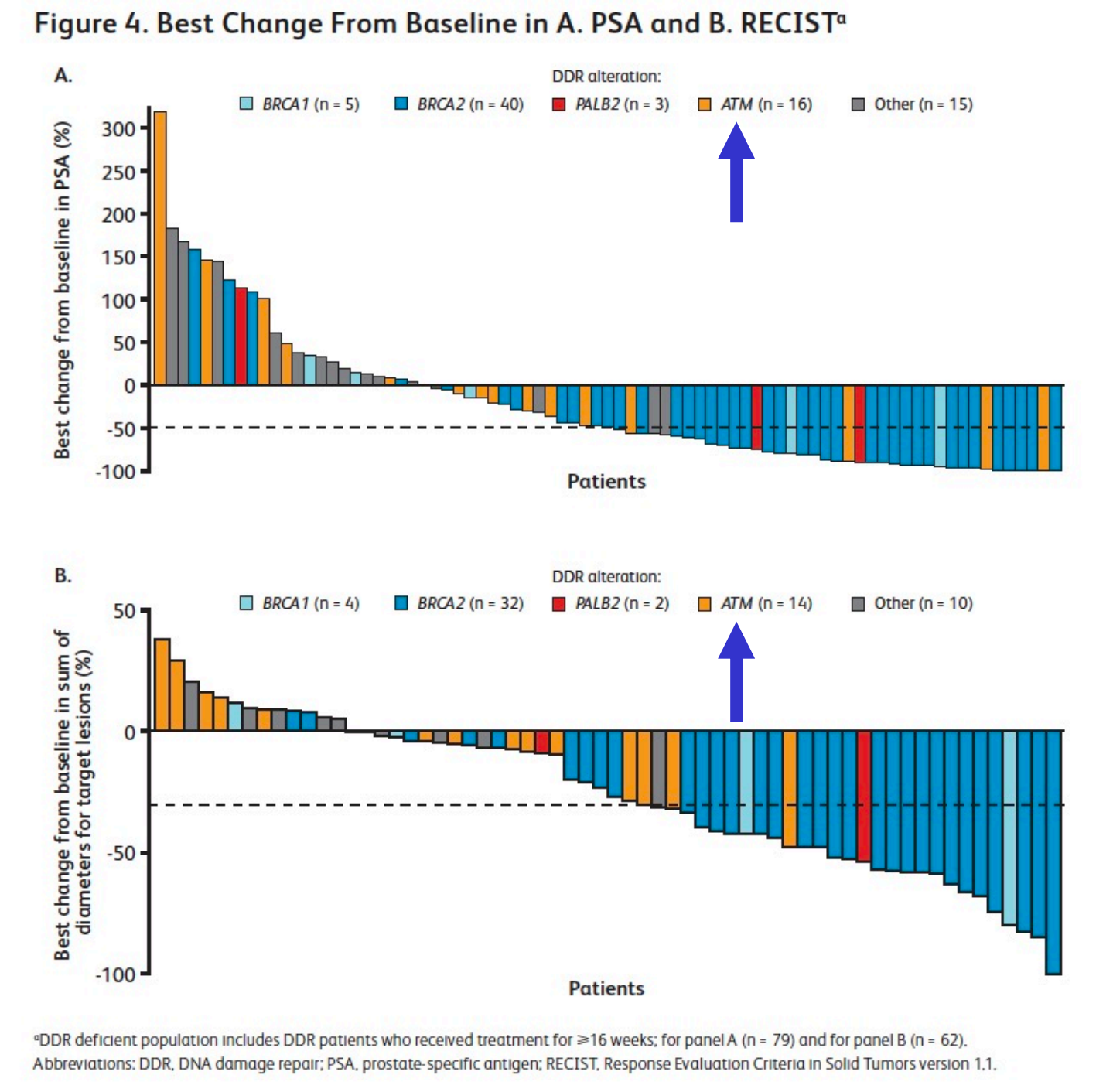


Abida W et al. TRITON2 investigators. *J Clin Oncol* 2020;38(32):3763-72.

RTP RESEARCH TO PRACTICE

Talazoparib in mCRPC (TALAPRO-1)

BRCA in blue
ATM loss in orange
PALB2 in red



de Bono JS et al. *Lancet Oncol* 2021;22(9):1250-64.

RTP RESEARCH TO PRACTICE

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RTP
RESEARCH
TO PRACTICE

Immune Checkpoint Inhibitors in mCRPC

Therapy	Disease State	Disease Response
Pembrolizumab monotherapy[a]	Post-chemotherapy	ORR 9% PSA RR 14%
Pembrolizumab + enzalutamide[b]	Pre-chemotherapy progressing on enzalutamide	ORR 12% PSA RR 14%
Atezolizumab + enzalutamide[c]	Pre- and post-chemotherapy, s/p abiraterone	ORR 14% PSA RR 26%
Atezolizumab + cabozantinib[d]	Pre-chemotherapy s/p enzalutamide or abiraterone	ORR 34% PSA RR 29%

[a]JCO 2020: 38(5) 395-405. [b]Presented at the 2021 ASCO Annual Meeting – Virtual; June 4-8, 2021. [c]Sweeney C. AACR 2020. IMbassador250. [d]Agarwal ASCO 2020. COSMIC-021

2021 ESMO congress

Abstract LBA24

Cabozantinib in combination with atezolizumab in patients with metastatic castration-resistant prostate cancer (mCRPC): results of expanded cohort 6 of the COSMIC-021 Study

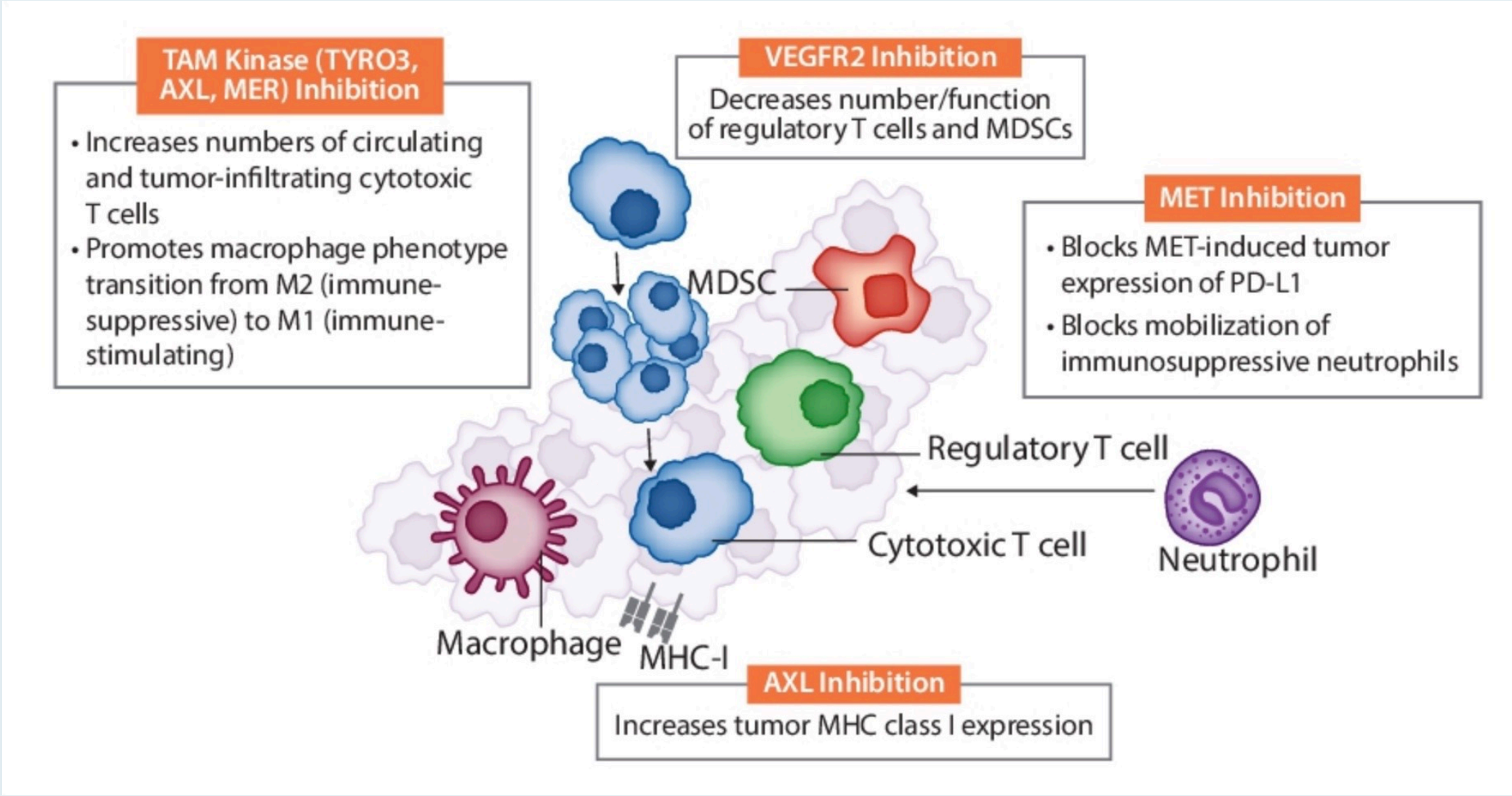
Neeraj Agarwal,[1] Bradley McGregor,[2] Benjamin L. Maughan,[1] Tanya B. Dorff,[3] William Kelly,[4] Bruno Fang,[5] Rana R. McKay,[6] Parminder Singh,[7] Lance Pagliaro,[8] Robert Dreicer,[9] Sandy Srinivas,[10] Yohann Loriot,[11] Ulka Vaishampayan,[12] Sanjay Goel,[13] Dominic Curran,[14] Ashok Panneerselvam,[14] Li-Fen Liu,[14] Toni K. Choueiri,[2*] Sumanta Pal[3*]

[1]Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; [2]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [3]City of Hope Comprehensive Cancer Center, Duarte, CA, USA; [4]Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA, USA; [5]Regional Cancer Care Associates, East Brunswick, NJ, USA; [6]University of California San Diego, San Diego, CA, USA; [7]Department of Oncology, Mayo Clinic, Scottsdale, AZ, USA; [8]Department of Oncology, Mayo Clinic, Rochester, MN, USA; [9]University of Virginia Cancer Center, Charlottesville, VA, USA; [10]Division of Medical Oncology, Stanford University Medical Center, Stanford, CA, USA; [11]Department of Cancer Medicine, Gustave Roussy Institute, INSERM 981, University Paris-Saclay, Villejuif, France; [12]Karmanos Cancer Center, Wayne State University, Detroit, MI, USA (Current affiliation: Division of Hematology/Oncology, University of Michigan, Ann Arbor, MI, USA); [13]Department of Medical Oncology, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA; [14]Exelixis, Inc., Alameda, CA, USA

*Co-senior authors

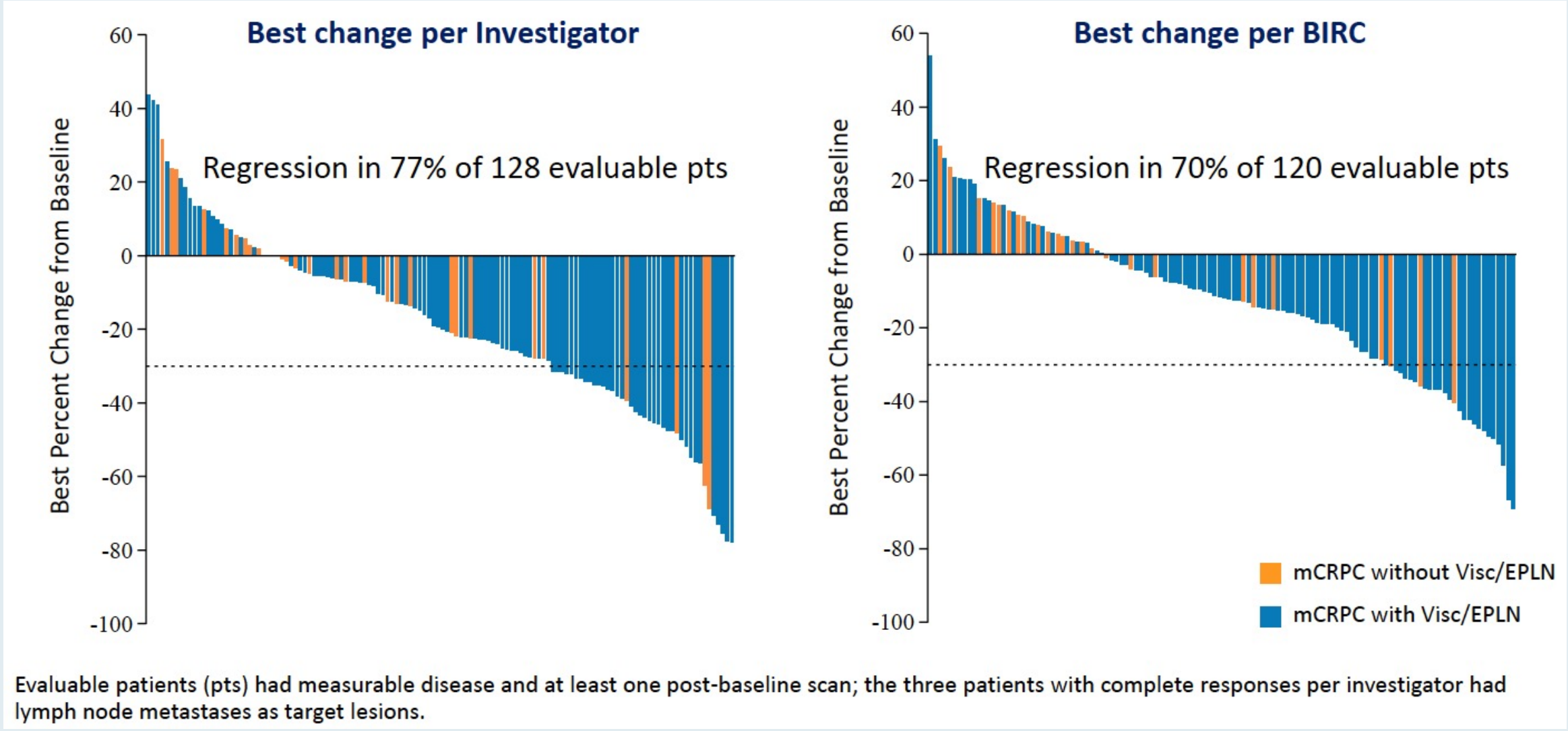
RTP RESEARCH TO PRACTICE

Cabozantinib Targets Pathways Associated with Tumor Immune Suppression



Agarwal N et al. ASCO 2020;Abstract 5564.

COSMIC-021: Best Change from Baseline in Sum of Target Lesions

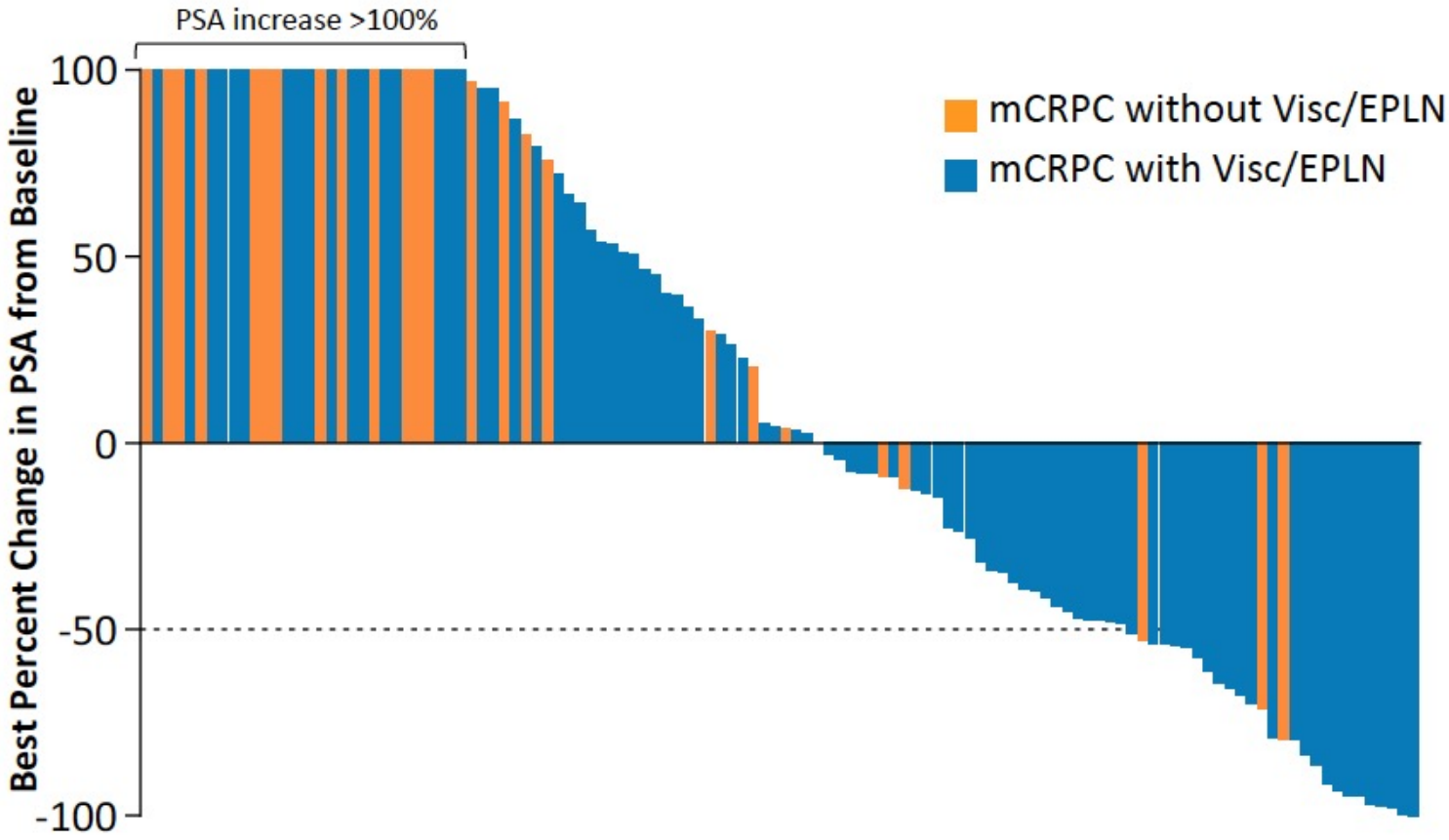


Evaluable patients (pts) had measurable disease and at least one post-baseline scan; the three patients with complete responses per investigator had lymph node metastases as target lesions.

Agarwal et al. ESMO 2021;Abstract LBA24.

RTP RESEARCH TO PRACTICE

COSMIC-021: Best Change in PSA from Baseline



- In 118 patients with post-baseline assessments, 55 (47%) had a decrease in PSA, and 27 (23%) had a decrease ≥50%
- In 92 patients with Visc/EPLN, 50 (54%) had a decrease in PSA, and 24 (26%) had a decrease ≥50%

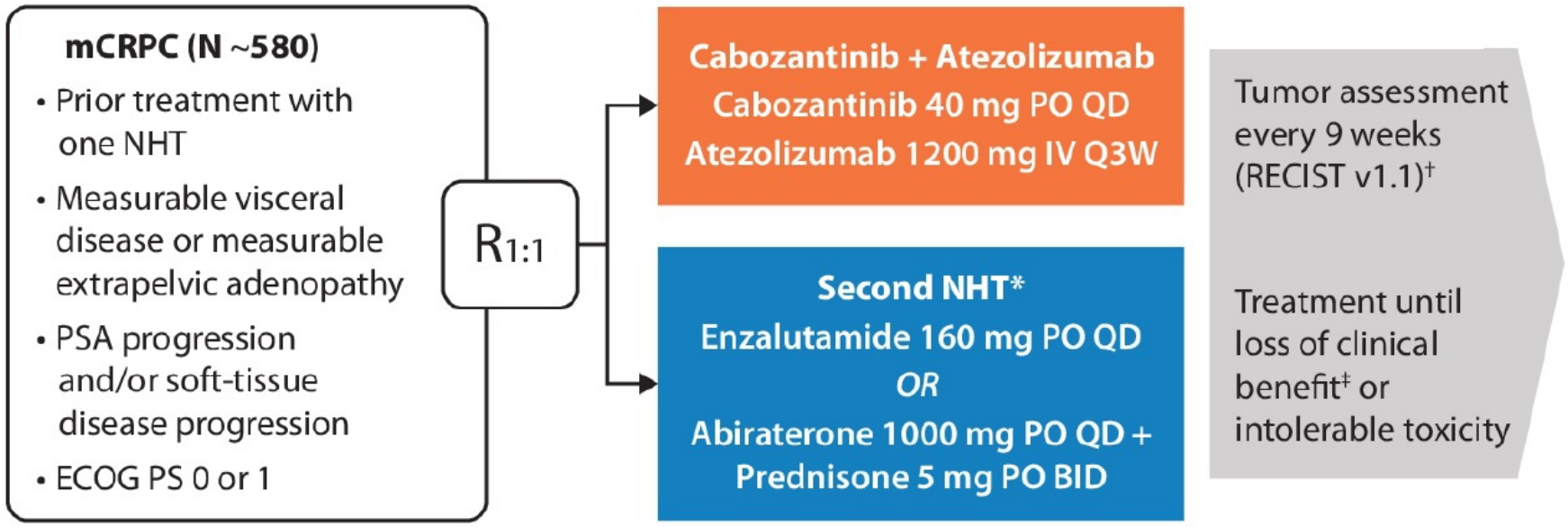
Agarwal et al. ESMO 2021;Abstract LBA24.

COSMIC-021: Select Treatment-Related Adverse Events

	mCRPC (N=132)	
	Any Grade	Grade 3/4
Any AE, %	95	55
Diarrhea	55	6.8
Fatigue	43	6.8
Nausea	42	0.8
Decreased appetite	34	1.5
Dysgeusia	27	0
Palmar-plantar erythrodysesthesia	25	2.3
Vomiting	23	1.5
Weight decreased	23	1.5
Aspartate aminotransferase increased	20	3.0
Stomatitis	16	0.8
Hypertension	14	6.8
Alanine aminotransferase increased	14	3
Dysphonia	13	0
Hypothyroidism	12	0
Pulmonary embolism	11	8.3

Agarwal et al. ESMO 2021;Abstract LBA24.

CONTACT-02: Phase III Trial Schema



Stratification

- Liver metastasis (yes, no)
- Prior docetaxel treatment for mCSPC (yes, no)
- Disease stage for which the first NHT was given (mCSPC, M0 CRPC, mCRPC)

Primary Endpoints:

- PFS per RECIST v1.1 by BIRC
- OS

Secondary Endpoint:

- ORR per RECIST v1.1 by BIRC

*Second NHT must differ from previous NHT taken
†Tumor assessment (RECIST v1.1) every 9 weeks for the first 28 weeks then every 12 weeks thereafter
‡Patients may be treated beyond progression if there is a clinical benefit in the opinion of the investigator

Agarwal N et al. Genitourinary Cancers Symposium 2021;Abstract TPS190.

RTP RESEARCH TO PRACTICE

PRINCE: Interim Analysis of the Phase Ib Study of ^{177}Lu-PSMA-617 in Combination with Pembrolizumab for Metastatic Castration Resistant Prostate Cancer (mCRPC)

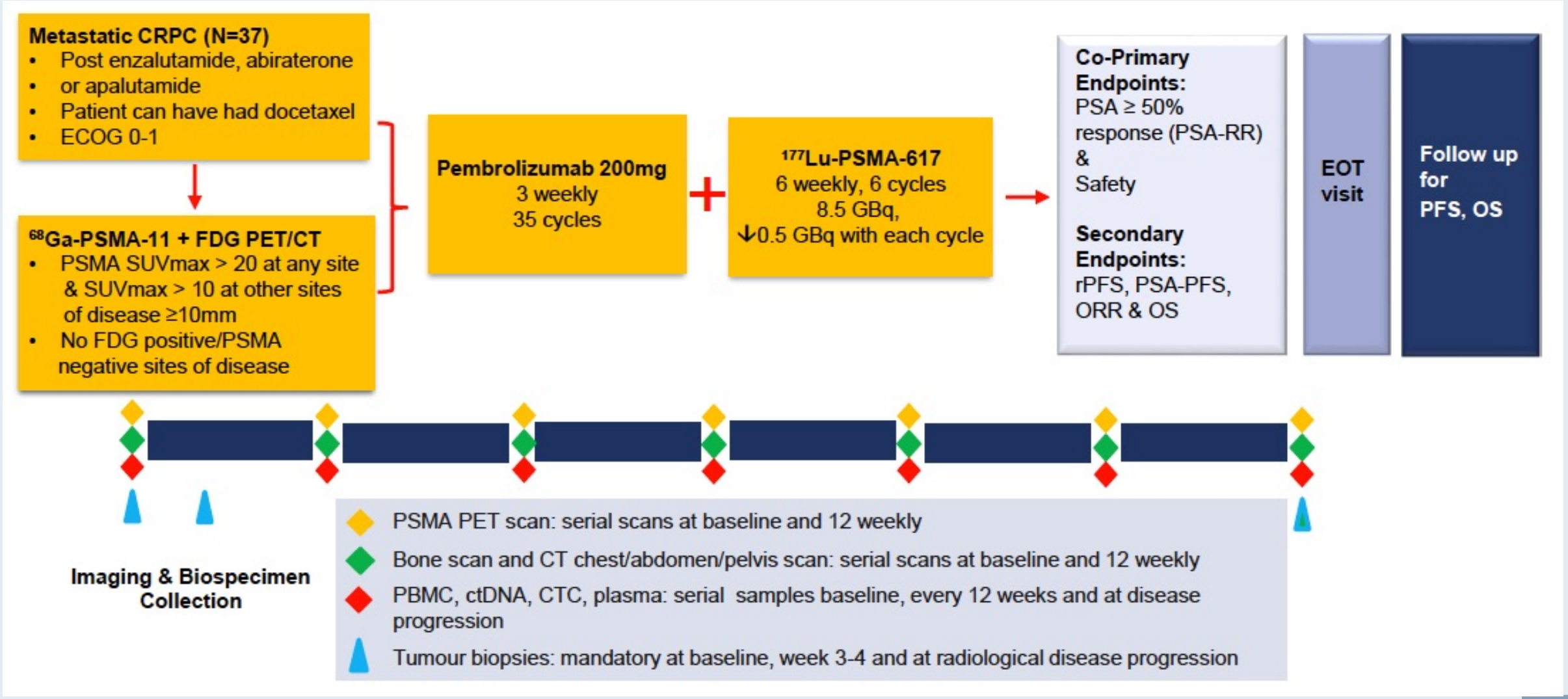
Shahneen Sandhu, Anthony M. Joshua, Louise Emmett, Lavinia Spain, Lisa G. Horvath, Megan Crumbaker, Arsha Anton, Roslyn Wallace, Anupama Pasam, Mathias Bressel, Erin Cassidy, Patricia Banks, Aravind Ravi Kumar, Ramin Alipour, Tim Akhurst, Grace Kong, Ian D. Davis, Scott Williams, Rod Hicks, Michael S. Hofman

Abstract 577O

2021 ESMO congress

Presented by: Shahneen Sandhu

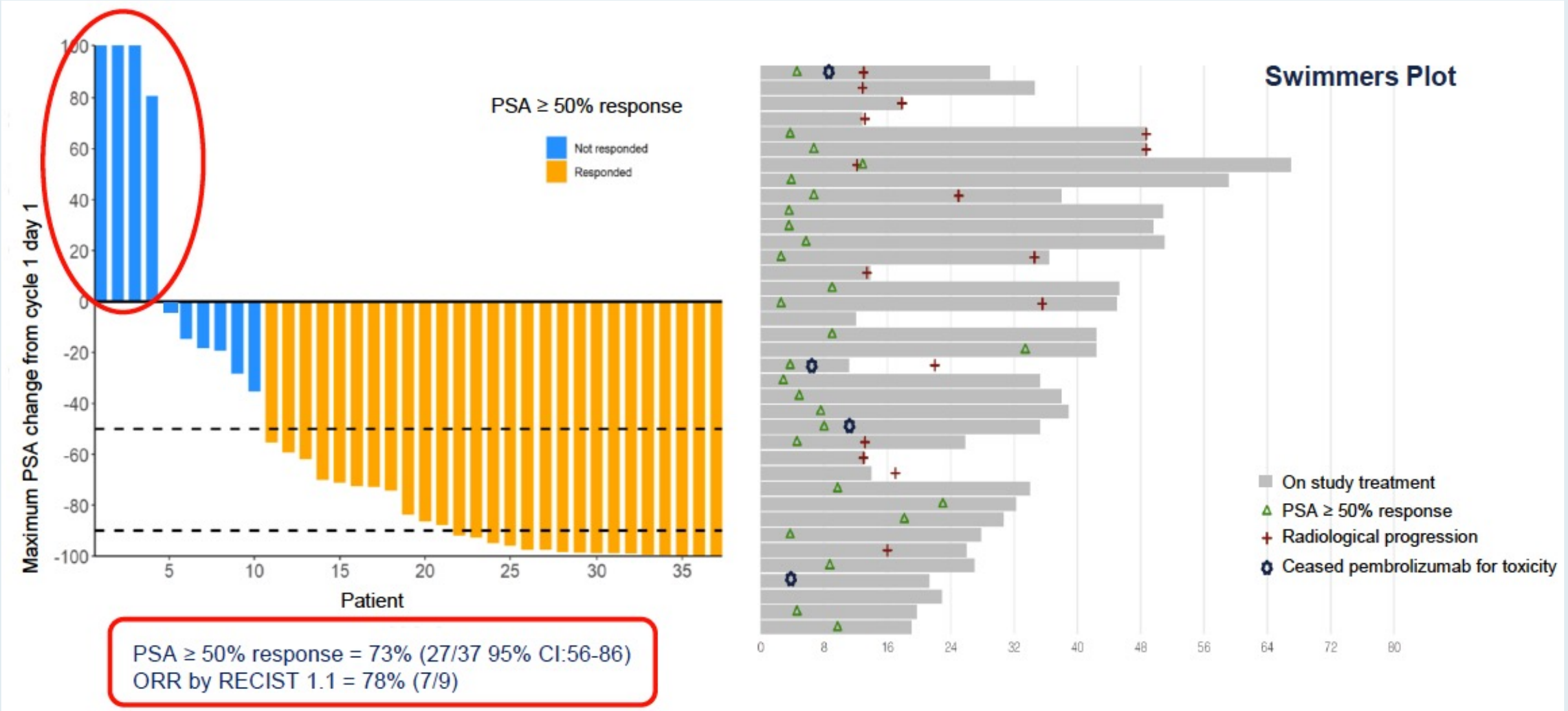
PSMA-Lutetium Radionuclide Therapy and ImmuNotherapy for Prostate CancEr (PRINCE) Trial Schema



Sandhu S et al. ESMO 2021;Abstract 577O.

RTP RESEARCH TO PRACTICE

PRINCE: PSA Response Rate (Primary Endpoint)



Sandhu S et al. ESMO 2021;Abstract 577O.

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PRINCE: Treatment-Related Adverse Events

TRAE term	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	N=37 (%)
Xerostomia	21 (57%)	7 (19%)	-	28 (76%)
Fatigue	11 (29 %)	3 (8%)	2 (5%)	16 (43%)
Rash	5 (14%)	4 (11%)		9 (25%)
Nausea	8 (21%)	1 (3%)	-	9 (24%)
Pruritis	6 (16%)	1 (3%)	-	7 (19%)
Anorexia	3 (8%)	3 (8%)	-	6 (16%)
Thrombocytopenia	4 (11%)	1(3%)	-	5 (14%)
Bone pain (flare)	4 (11%)	-	-	4 (11%)
Aspartate aminotransferase elevation	2 (5%)	2 (5%)	-	4 (11%)
Dry eye	3 (8%)	-	-	3 (8%)
Dysgeusia	2 (5%)	1 (3%)	-	3 (8%)
Weight loss	2 (5%)	1 (3%)		3 (8%)
Anemia	-	2 (5%)	1(3%)	3 (8%)
Alanine aminotransferase elevation	2 (5%)	1(3%)	-	3 (8%)
Amylase elevation	1 (3%)	1 (3%)	1 (3%)	3 (8%)
Arthralgia	3 (8%)	-	-	3 (8%)
Neutropenia	1 (3%)	-	-	1 (3%)

Pembrolizumab cycles: Median (range)	8 (1 - 22)
^{177}Lu-PSMA-617 cycles: Median (range)	4 (2 - 6)
Discontinuation for toxicity:	
Pembrolizumab, n (%)	4 (11%)
^{177}Lu-PSMA-617, n (%)	0 (0%)

- Treatment related adverse events (TRAEs) in by worst grade affecting > 5% and all hematological toxicity
- There were no grade 4 TRAEs or treatment related deaths

Sandhu S et al. ESMO 2021;Abstract 577O.

Meet The Professor with Dr Sartor

MODULE 1: Overview of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

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MODULE 2: BRCA/HRD-Negative mCRPC

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RESEARCH
TO PRACTICE

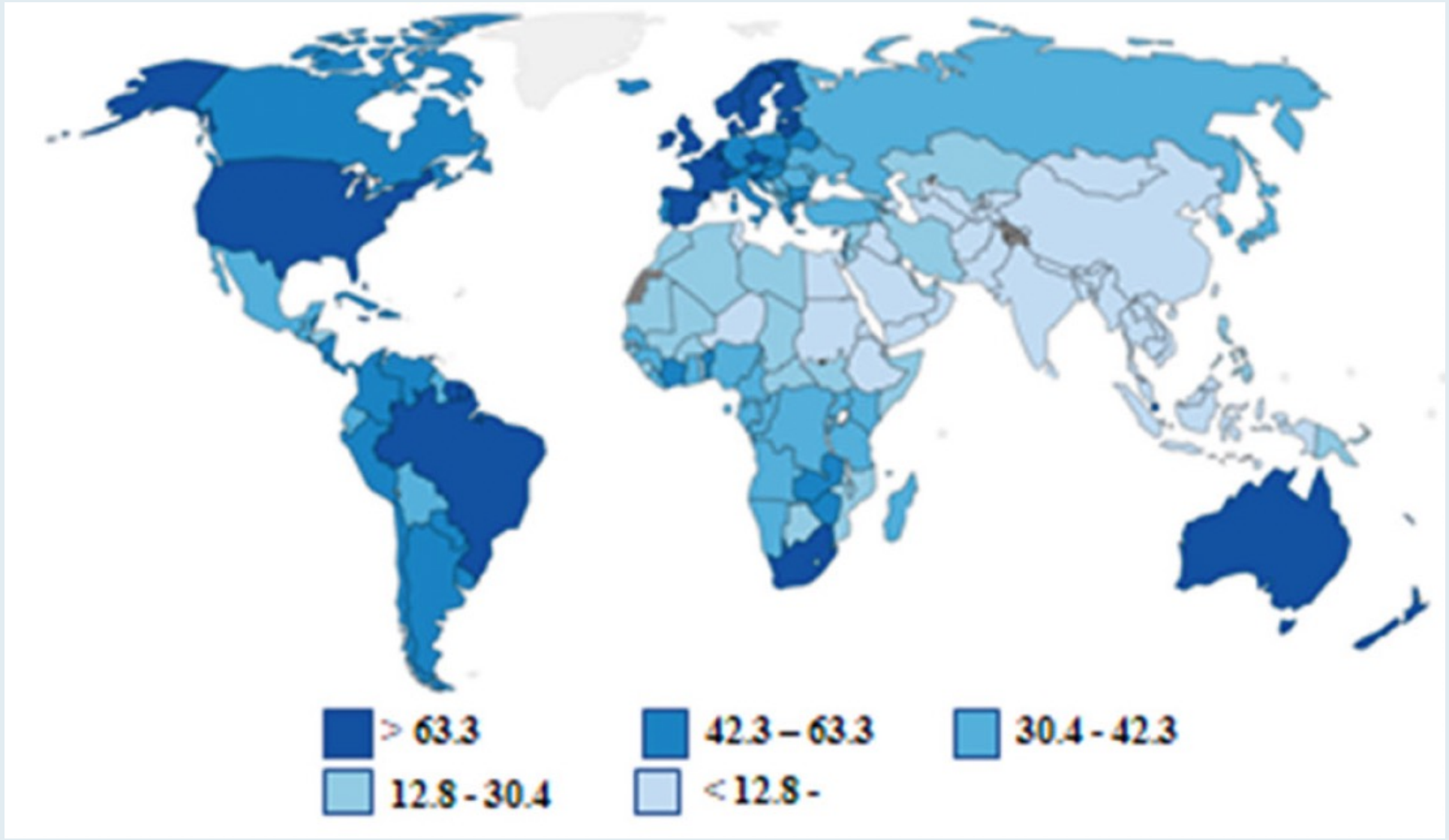
Am J Cancer Res 2021;11(4):1012-1030
www.ajcr.us /ISSN:2156-6976/ajcr0123963

Review Article

Prostate cancer racial, socioeconomic, geographic disparities: targeting the genomic landscape and splicing events in search for diagnostic, prognostic and therapeutic targets

Rahaba Marima[1], Rodney Hull[1], Kgomotso Mathabe[2], Botle Setlai[3], Jyotsna Batra[4,5], Oliver Sartor[1,6], Ravi Mehrotra[1,7], Zodwa Dlamini[1]

Worldwide Age Standardized Rate per 100,000 Men for Incidence



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

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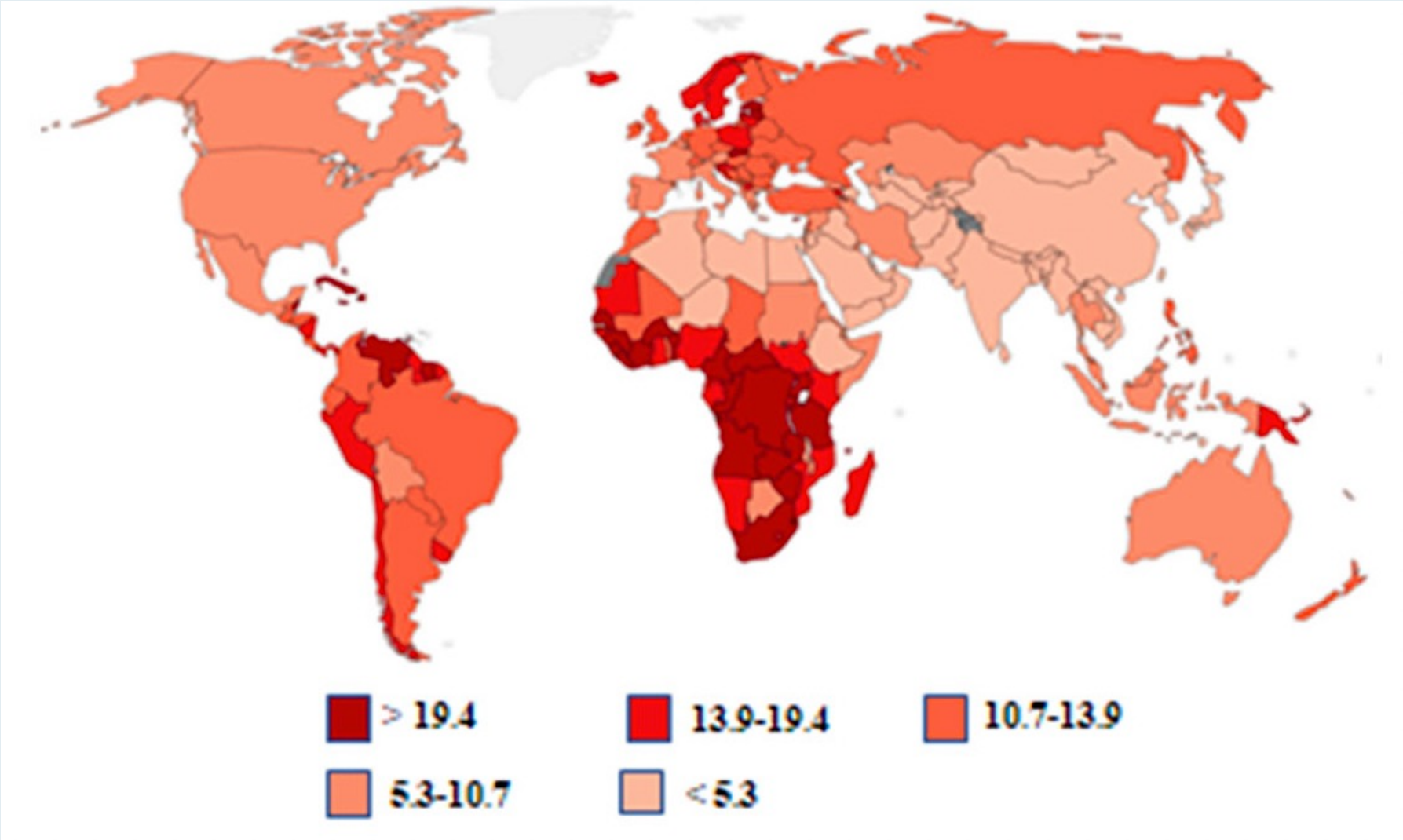
Worldwide Age Standardized Rate per 100,000 Men for Mortality



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

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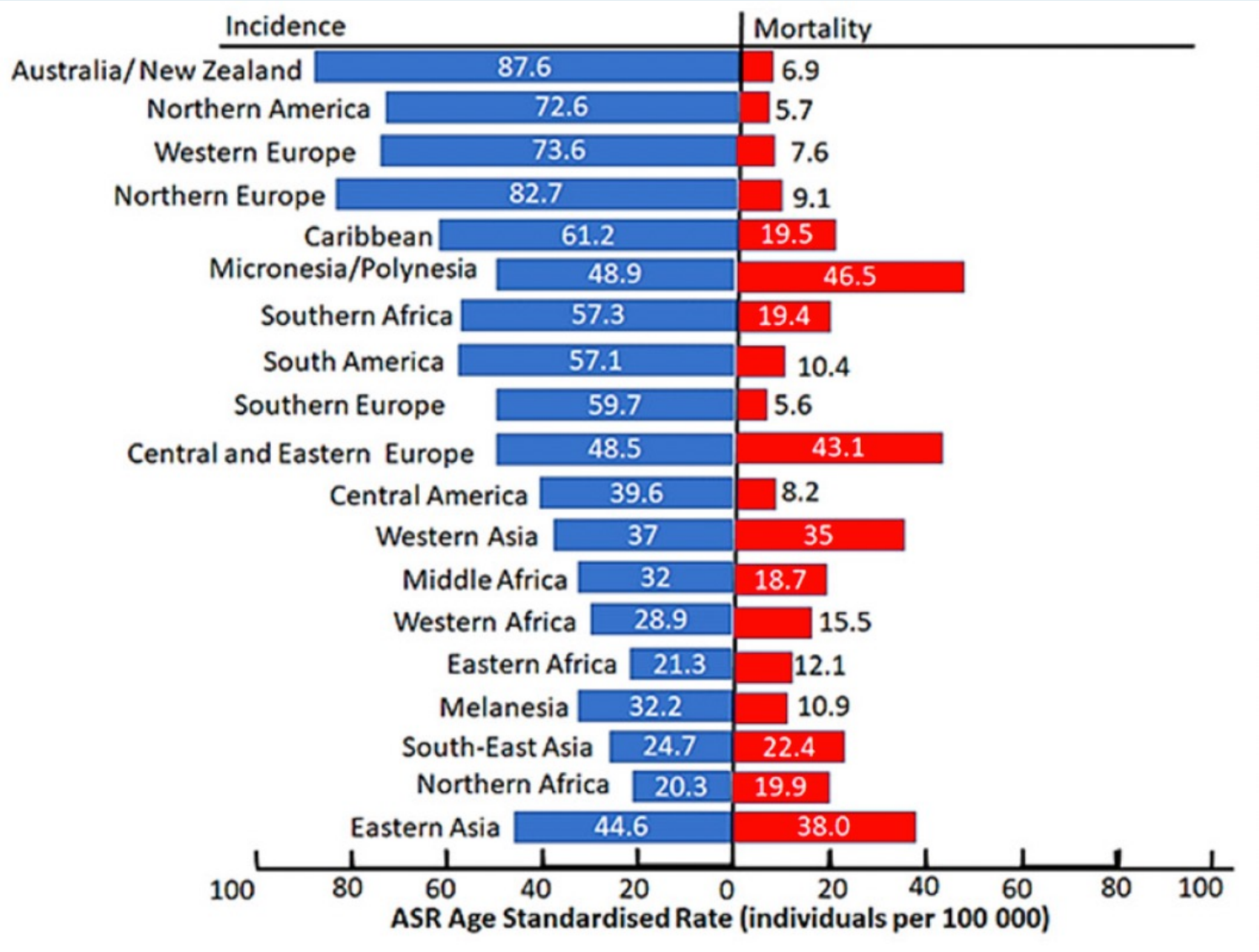
Incidence and Mortality Rates Based on Geographic Location



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

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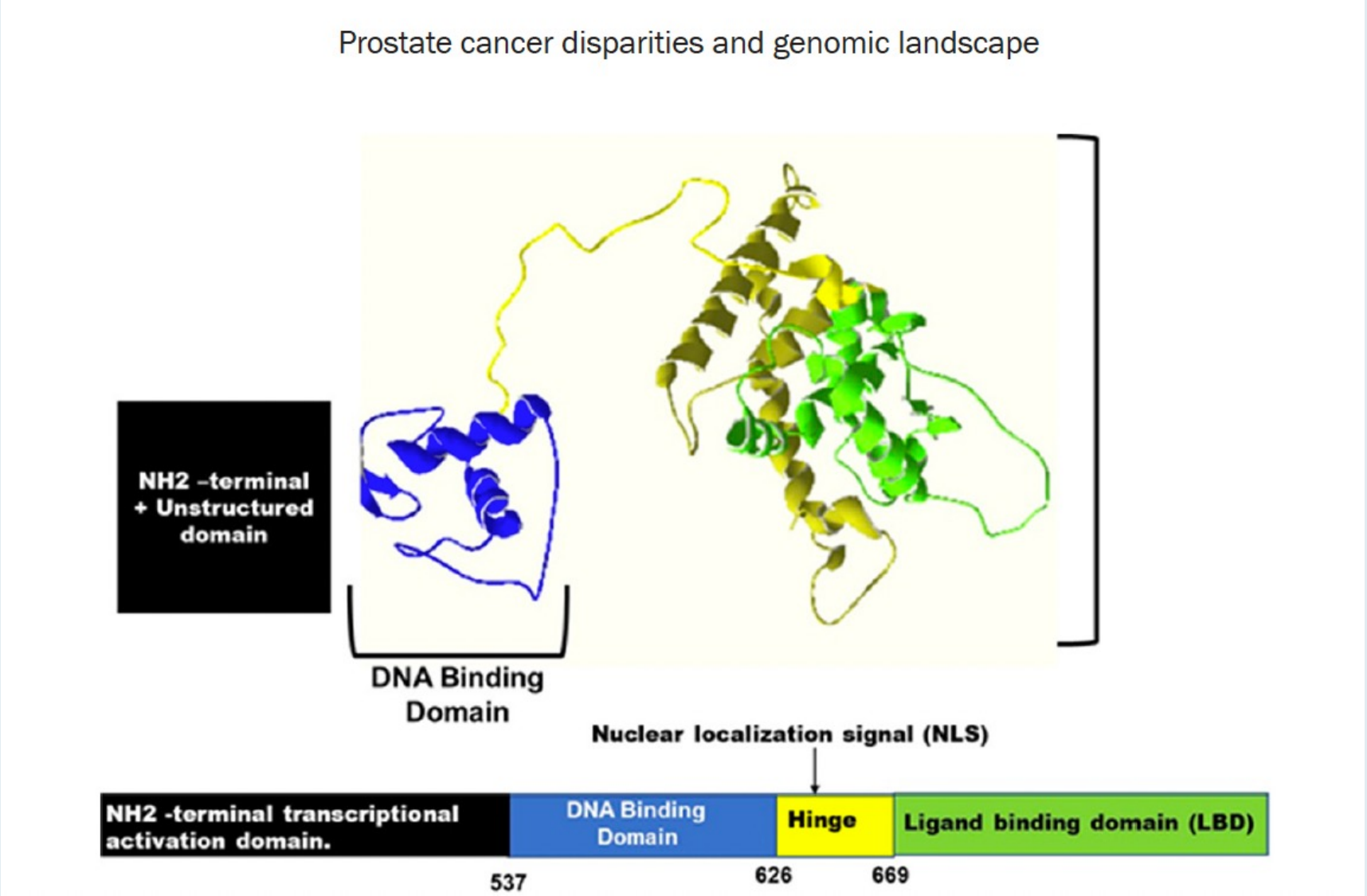
Structure of the Androgen Receptor



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

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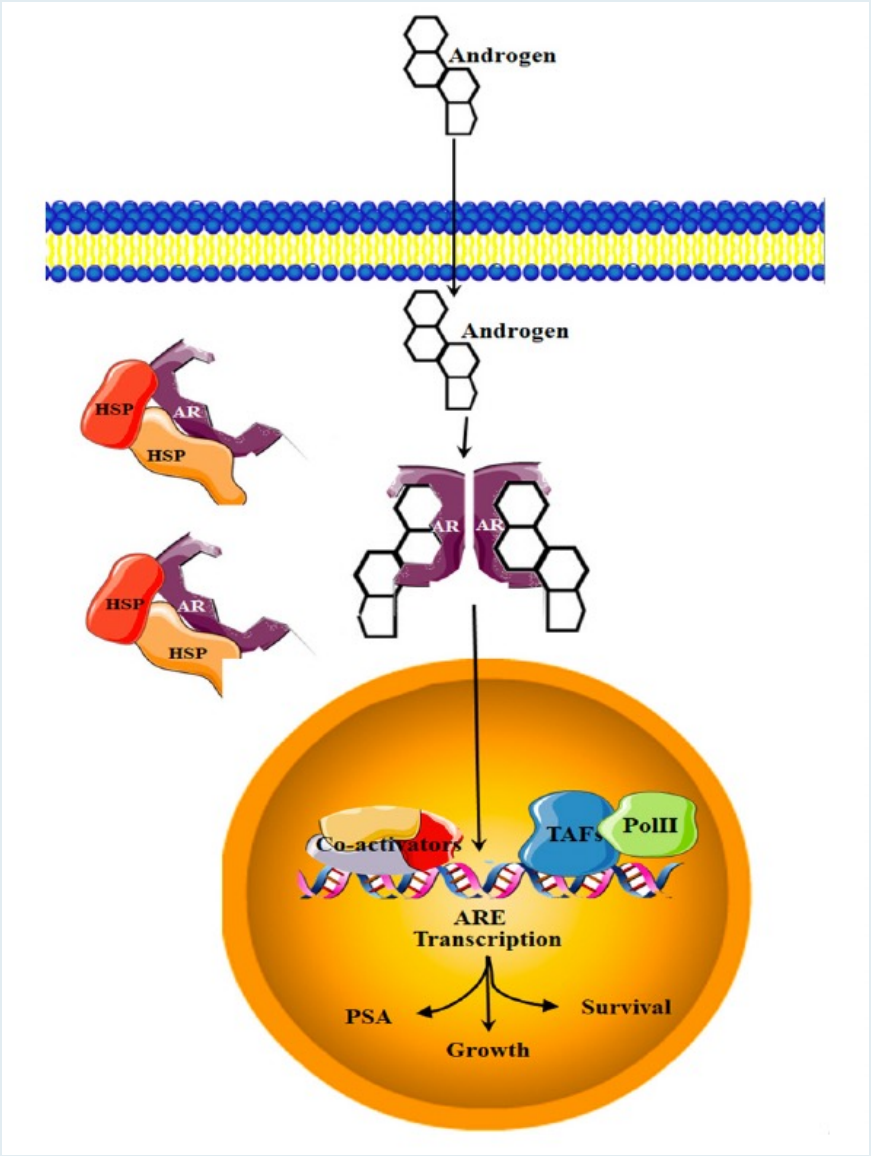
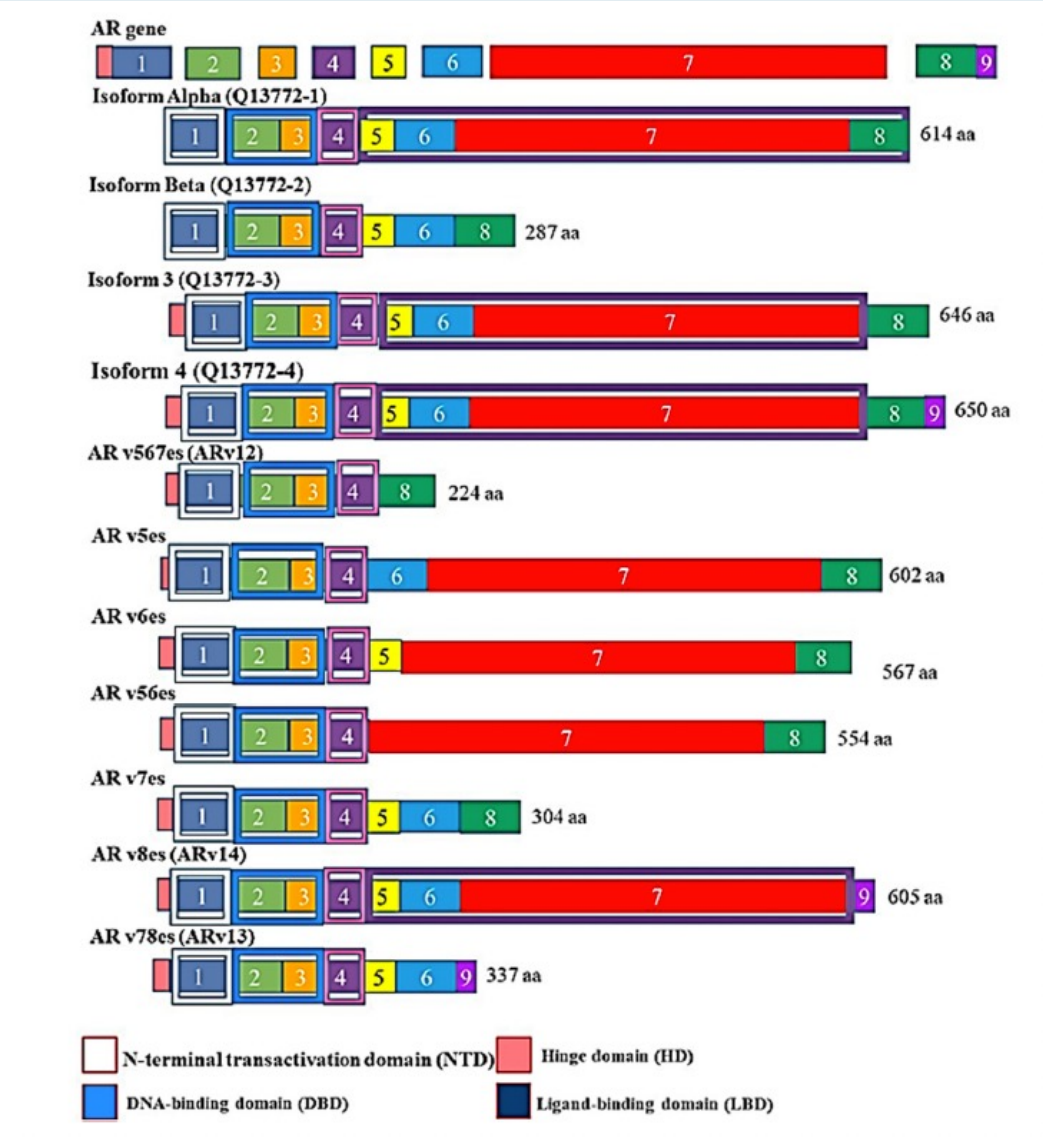
Androgen Receptor Signaling



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

Human Androgen Receptor Full Length with Splice Variants



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

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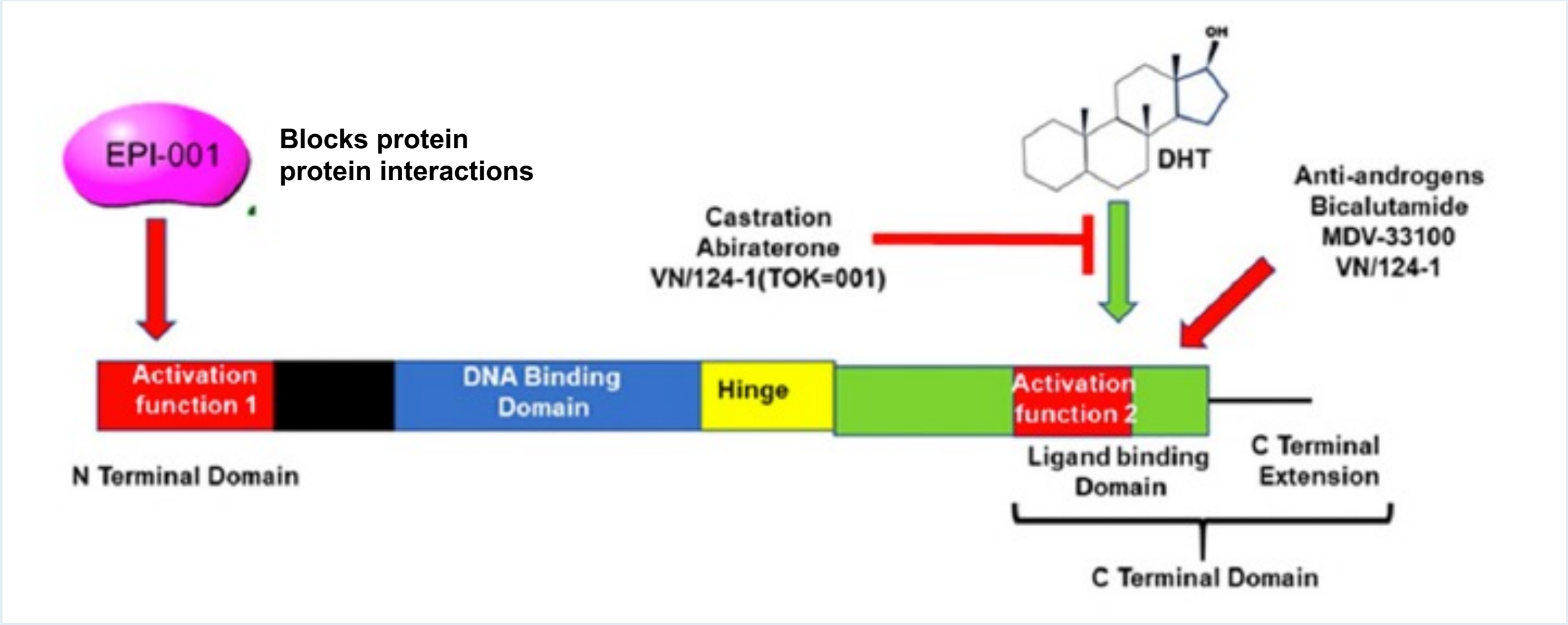
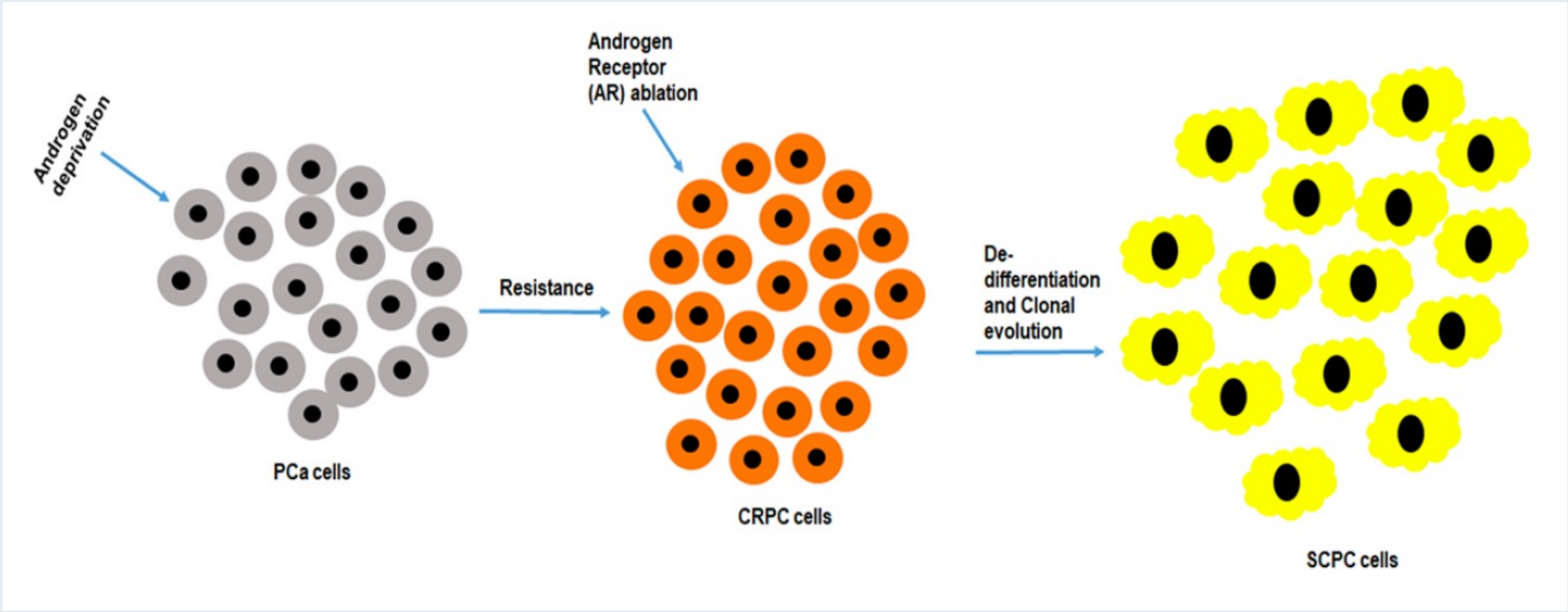
Structure of the Androgen Receptor (AR) Showing Binding Sites of Inhibitors and Activators of AR Signaling



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

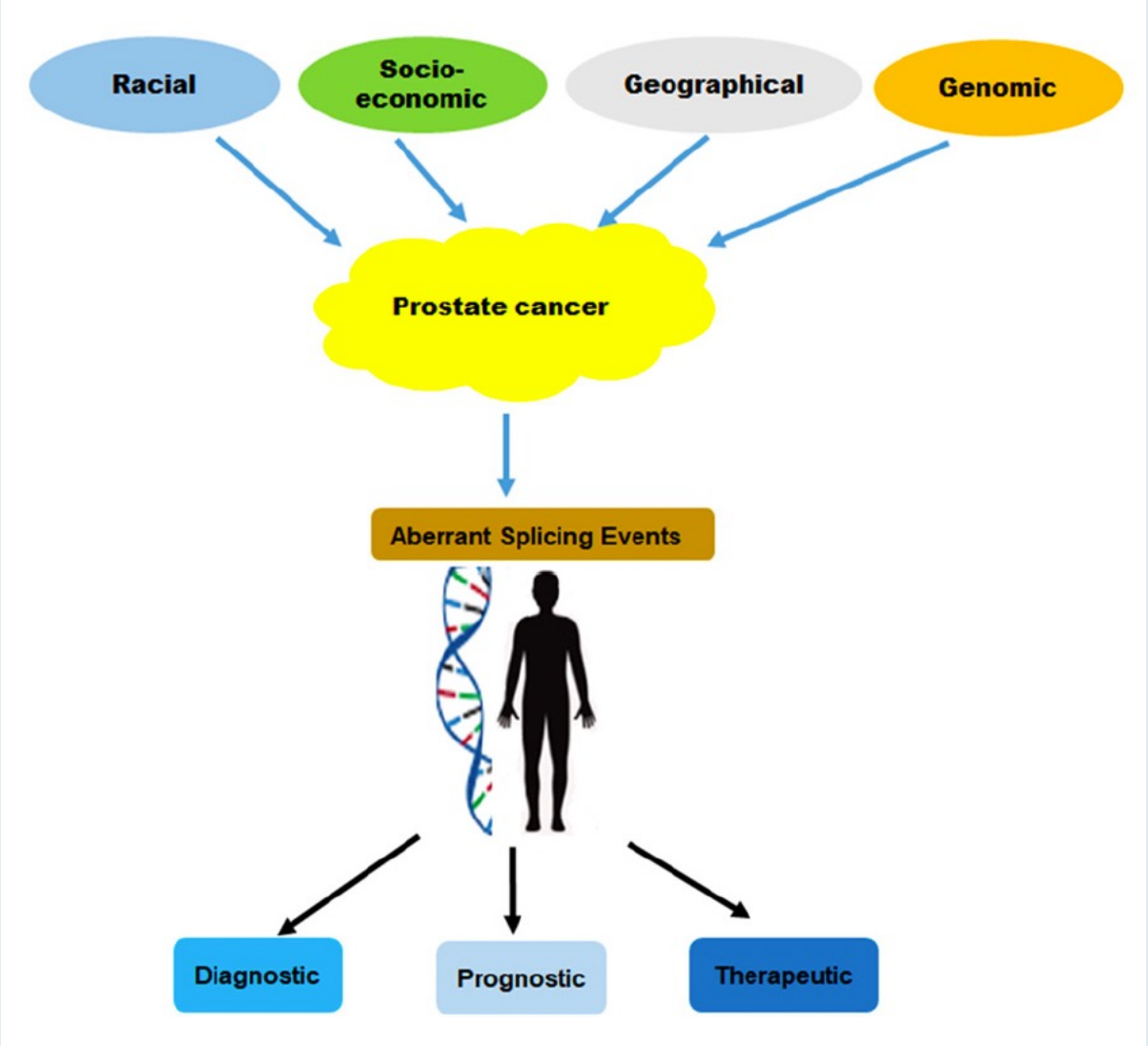
Dedifferentiation and Clonal Evolution of Prostate Cancer Cells



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

RTP RESEARCH TO PRACTICE

Genetic and Nongenetic Factors Contributing to Prostate Cancer Development and Progression



Marima R et al. *Am J Cancer Res* 2021;11(4):1012-30.

RTP RESEARCH TO PRACTICE

Journal Club with Dr Sartor (Continued)

- Jaeger E et al. **ctDNA pathogenic variants (PVs) in homologous recombination repair (HRR) genes in patients with metastatic CRPC.** Genitourinary Cancers Symposium 2021;Abstract 138.

- Ledet EM et al. **Comparison of germline mutations in African American and Caucasian men with metastatic prostate cancer.** *Prostate* 2021;81(7):433-9.

- Lin E et al. **Identification of somatic gene signatures in circulating cell-free DNA associated with disease progression in metastatic prostate cancer by a novel machine learning platform.** *Oncologist* 2021;26(9):751-60.

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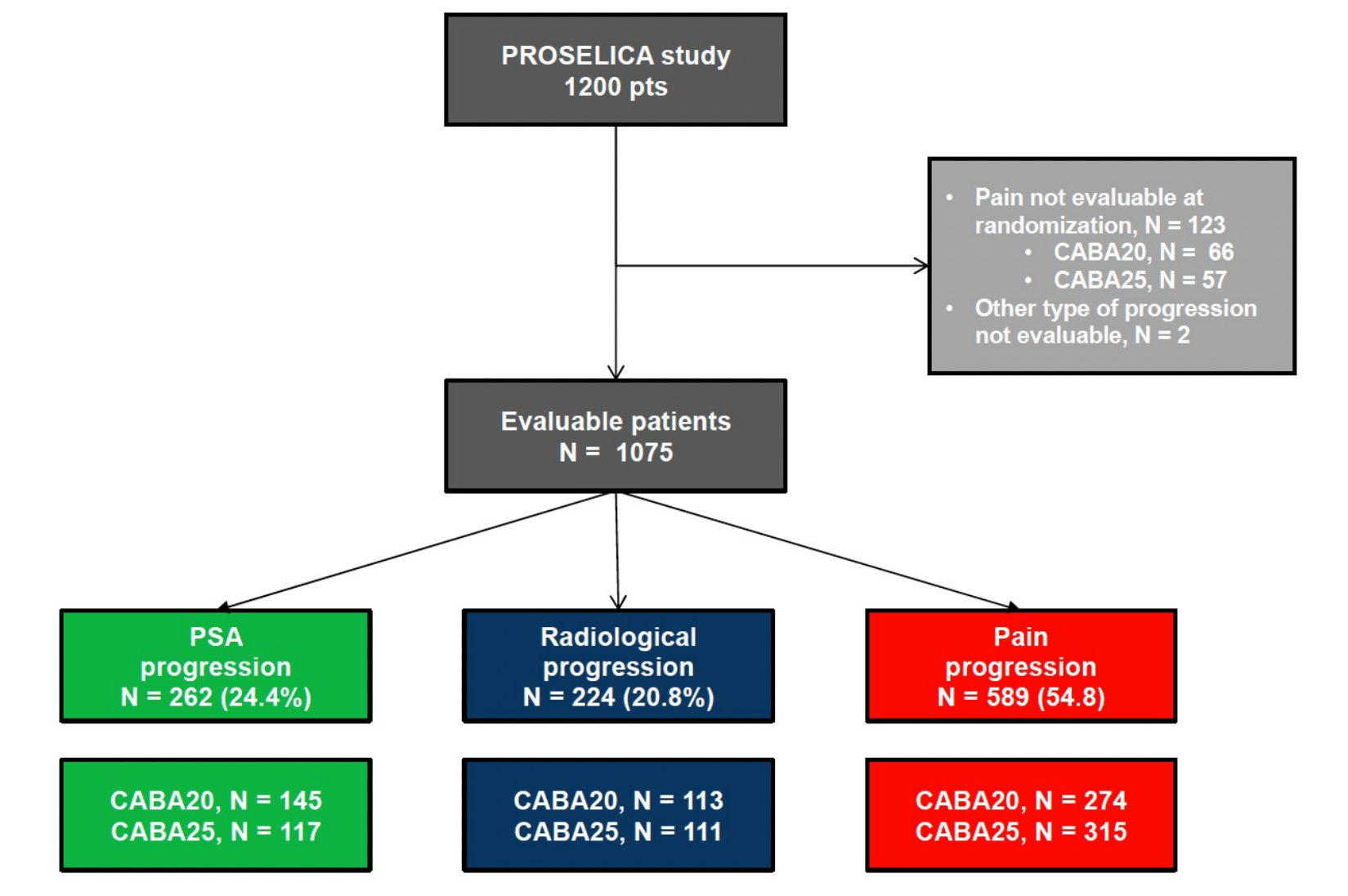
Journal Club with Dr Sartor (Continued)

- Sokolova AO et al. **Efficacy of systemic therapies in men with metastatic castration resistant prostate cancer harboring germline ATM versus BRCA2 mutations.** *Prostate* 2021;81(16):1382-9.

- Delanoy N et al. **Pain progression at initiation of cabazitaxel in metastatic castration-resistant prostate cancer (mCRPC): A post hoc analysis of the PROSELICA study.** *Cancers* (Basel) 2021;13(6):1284.

- Thiery-Vuillemin A et al. **Post hoc health-related quality of life analysis according to response among patients with prostate cancer in the PROSELICA and FIRSTANA studies.** *Oncologist* 2021;26(7):e1179-88.

PROSELICA Flow Chart



Delanoy N et al. *Cancers* (Basel) 2021;13(6):1284.

Journal Club with Dr Sartor (Continued)

- Sartor O et al. **Lutetium-177–PSMA-617 for metastatic castration-resistant prostate cancer.** *N Engl J Med* 2021;385(12):1091-103.

- Sartor AO et al. **A multicenter, randomized, controlled phase II study: Efficacy and safety of PSMA-targeted radioligand therapy I-131-1095 (1095) plus enzalutamide (enza) in 18F-DCFPyL PSMA scan avid, metastatic castration-resistant prostate cancer (mCRPC) patients post-abiraterone (abi) progression (ARROW).** Genitourinary Cancers Symposium 2021;Abstract TPS187.

- Sartor AO. **PSMA-targeted radiotherapy in metastatic castration-resistant prostate cancer.** *Clin Adv Hematol Oncol* 2021;19(8):494-6.

- Chi KN et al. **Study evaluating metastatic castrate resistant prostate cancer (mCRPC) treatment using 177Lu-PNT2002 PSMA therapy after second-line hormonal treatment (SPLASH).** ASCO 2021;Abstract TPS5087.

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Journal Club with Dr Sartor (Continued)

- Fizazi K et al. **Health-related quality of life (HRQoL), pain and safety outcomes in the phase 3 VISION study of 177Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer.** ESMO 2021;Abstract 576MO.

- Tagawa ST et al. **Final results of phase I/II trial of fractionated dose 177Lu-PSMA-617 for metastatic castration-resistant prostate cancer (mCRPC).** ESMO 2021;Abstract 600P.

Journal Club with Dr Sartor (Continued)

- Denmeade SR et al. **TRANSFORMER: A randomized phase II study comparing bipolar androgen therapy versus enzalutamide in asymptomatic men with castration-resistant metastatic prostate cancer.** *J Clin Oncol* 2021;39(12):1371-82.

- Buelow B et al. **TNB585.001: A multicenter, phase 1, open-label, dose-escalation and expansion study of tnb-585, a bispecific T-cell engager targeting PSMA in subjects with metastatic castrate resistant prostate cancer.** ASCO 2021;Abstract TPS5092.

- Fong L et al. **A Phase Ib study of atezolizumab with radium-223 dichloride in men with metastatic castration-resistant prostate cancer.** *Clin Cancer Res* 2021;27(17):4746-56.

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TO PRACTICE

Journal Club with Dr Sartor (Continued)

- Marshall CH et al. **Randomized phase II trial of sipuleucel-T with or without radium-223 in men with bone-metastatic castration-resistant prostate cancer.** *Clin Cancer Res* 2021;27(6):1623-30.

- Sartor O et al. **Clinical outcomes, management, and treatment patterns in patients with metastatic castration-resistant prostate cancer treated with radium-223 in community compared to academic settings.** *Prostate* 2021;81(10):657-66.

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TO PRACTICE

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RTP RESEARCH TO PRACTICE

A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving an LHRH agonist alone for hormone-sensitive disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?

Sip-T = sipuleucel-T

RTP RESEARCH TO PRACTICE

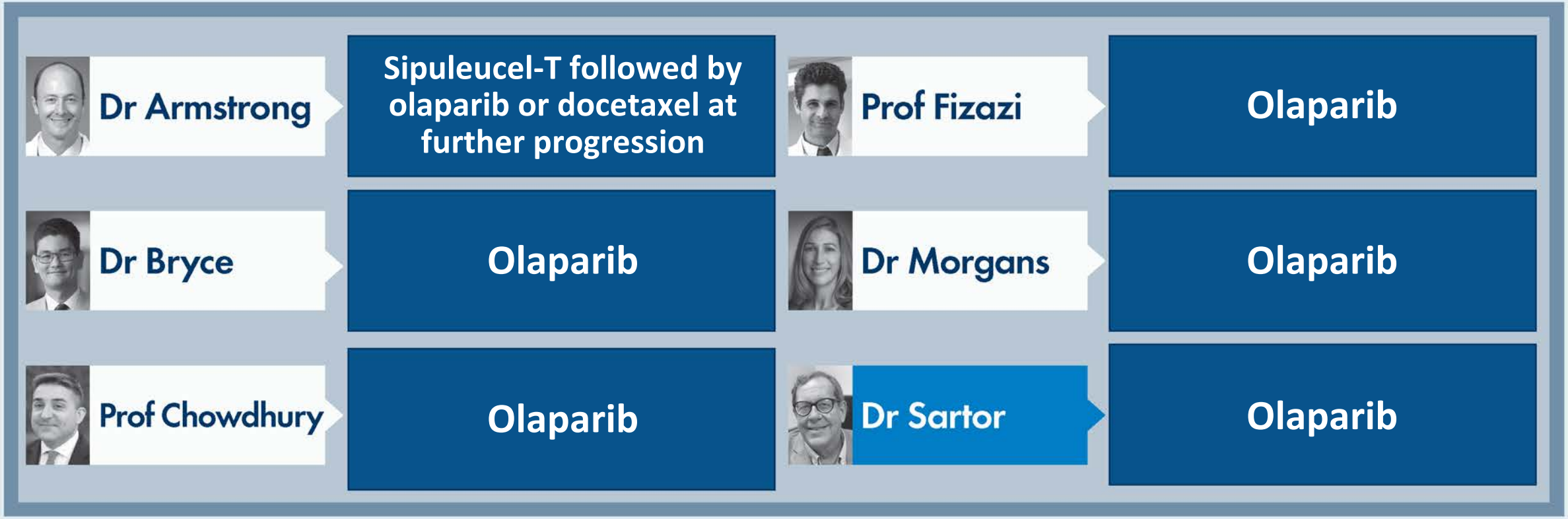
A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving an LHRH agonist alone for hormone-sensitive disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving abiraterone/dexamethasone for hormone-sensitive metastatic disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Sipuleucel-T	 Prof Fizazi	Docetaxel
 Dr Bryce	Docetaxel	 Dr Morgans	Sipuleucel-T
 Prof Chowdhury	Docetaxel	 Dr Sartor	Docetaxel

RTP RESEARCH TO PRACTICE

A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving abiraterone/dexamethasone for hormone-sensitive metastatic disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?



RTP RESEARCH TO PRACTICE

A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving abiraterone/dexamethasone for hormone-sensitive metastatic disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Docetaxel	 Prof Fizazi	Docetaxel
 Dr Bryce	Docetaxel	 Dr Morgans	Radium-223
 Prof Chowdhury	Docetaxel	 Dr Sartor	Docetaxel

RTP RESEARCH TO PRACTICE

A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving abiraterone/dexamethasone for hormone-sensitive metastatic disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Olaparib	 Prof Fizazi	Olaparib
 Dr Bryce	Olaparib	 Dr Morgans	Radium-223
 Prof Chowdhury	Olaparib	 Dr Sartor	Olaparib

RTP RESEARCH TO PRACTICE

A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving enzalutamide for hormone-sensitive metastatic disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Sipuleucel-T	 Prof Fizazi	Docetaxel
 Dr Bryce	Docetaxel	 Dr Morgans	Sipuleucel-T
 Prof Chowdhury	Docetaxel	 Dr Sartor	Docetaxel

RTP RESEARCH TO PRACTICE

A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving enzalutamide for hormone-sensitive metastatic disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Sipuleucel-T	 Prof Fizazi	Olaparib
 Dr Bryce	Olaparib	 Dr Morgans	Olaparib
 Prof Chowdhury	Olaparib	 Dr Sartor	Olaparib

RTP RESEARCH TO PRACTICE

A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving enzalutamide for hormone-sensitive disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Docetaxel	 Prof Fizazi	Docetaxel
 Dr Bryce	Docetaxel	 Dr Morgans	Radium-223
 Prof Chowdhury	Docetaxel	 Dr Sartor	Docetaxel

RTP RESEARCH TO PRACTICE

A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving enzalutamide for hormone-sensitive disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Olaparib	 Prof Fizazi	Olaparib
 Dr Bryce	Olaparib	 Dr Morgans	Radium-223
 Prof Chowdhury	Olaparib	 Dr Sartor	Olaparib

RTP RESEARCH TO PRACTICE

Which of the following genomic evaluations do you generally order for patients with mCRPC and no specific family history of cancer?

 Dr Armstrong	Germline and somatic panel	 Prof Fizazi	Germline and somatic panel
 Dr Bryce	Germline and somatic panel	 Dr Morgans	BRCA germline and somatic
 Prof Chowdhury	Somatic panel	 Dr Sartor	Germline and somatic panel

RTP RESEARCH TO PRACTICE

At what point, if any, do you generally recommend a PARP inhibitor to a patient with metastatic prostate cancer and a germline BRCA mutation?

 Dr Armstrong	After at least 1 line of both hormonal therapy and chemotherapy	 Prof Fizazi	After 1 line of hormonal therapy
 Dr Bryce	After 1 line of hormonal therapy	 Dr Morgans	After 1 line of hormonal therapy
 Prof Chowdhury	After 1 line of hormonal therapy	 Dr Sartor	After 1 line of hormonal therapy

RTP RESEARCH TO PRACTICE

For a patient with metastatic prostate cancer and a germline BRCA mutation to whom you would administer a PARP inhibitor, which treatment strategy would you likely use?

 Dr Armstrong	Olaparib monotherapy	 Prof Fizazi	Olaparib monotherapy
 Dr Bryce	Olaparib or rucaparib monotherapy	 Dr Morgans	Olaparib monotherapy
 Prof Chowdhury	Olaparib monotherapy	 Dr Sartor	Olaparib monotherapy

RTP RESEARCH TO PRACTICE

Have you administered or would you administer a PARP inhibitor to a patient with metastatic prostate cancer and a high LOH score?

 Dr Armstrong	I have not and would not	 Prof Fizazi	I have not and would not
 Dr Bryce	I have not but would for the right patient	 Dr Morgans	I have not and would not
 Prof Chowdhury	I have not and would not	 Dr Sartor	I have not and would not

RTP RESEARCH TO PRACTICE

Have you administered or would you administer a PARP inhibitor to a patient with metastatic prostate cancer that is HRD (homologous recombination deficiency) positive?

 Dr Armstrong	I have (mCRPC) I have not (mHSPC)	 Prof Fizazi	I have not and would not
 Dr Bryce	I have not but would for the right patient	 Dr Morgans	I have not and would not
 Prof Chowdhury	I have not and would not	 Dr Sartor	I have

RTP RESEARCH TO PRACTICE

In general, when administering a PARP inhibitor to a patient with metastatic prostate cancer, do you discuss the risk of developing myelodysplastic syndromes?

 Dr Armstrong	Yes	 Prof Fizazi	No
 Dr Bryce	Yes	 Dr Morgans	No
 Prof Chowdhury	Yes	 Dr Sartor	No

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, in which line of therapy would you administer 177Lu-PSMA-617 for patients with metastatic prostate cancer?

 Dr Armstrong	Third line or beyond	 Prof Fizazi	Third line
 Dr Bryce	Third line	 Dr Morgans	Third line
 Prof Chowdhury	Third line	 Dr Sartor	First line and beyond

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, in which line of therapy would you administer 177Lu-PSMA-617 for a patient with metastatic prostate cancer and a germline BRCA mutation?

 Dr Armstrong	Third line and beyond	 Prof Fizazi	Third line
 Dr Bryce	Third line	 Dr Morgans	Third line
 Prof Chowdhury	Beyond third line	 Dr Sartor	First line and beyond

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Sartor

MODULE 1: Overview of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- Dr Mar: A 75-year-old man with mCRPC

MODULE 2: BRCA/HRD-Negative mCRPC

- Dr Bachow: An 81-year-old man with mCRPC – LOH and AR-V7 splice site mutation
- Dr Ibrahim: A 74-year-old man with mCRPC – Enrolled on the VISION trial
- Key Relevant Data Sets

MODULE 3: BRCA/HRD-Positive mCRPC

- Dr Zafar: A 68-year-old man with metastatic hormone-sensitive prostate cancer and an ARID1A mutation
- Dr Morris: A 72-year-old man with mCRPC and a germline RAD51c mutation
- Dr Bachow: A 62-year-old man with mCRPC and a somatic BRCA1 mutation – High TMB
- Key Relevant Data Sets

MODULE 4: Other Novel Agents and Strategies Under Investigation

MODULE 5 Journal Club with Dr Sartor

MODULE 6: Faculty Survey

MODULE 7: Appendix

RTP RESEARCH TO PRACTICE

Abiraterone acetate plus prednisolone with or without enzalutamide added to androgen deprivation therapy compared to ADT alone for men with high-risk nonmetastatic prostate cancer: primary combined analysis from two comparisons in the STAMPEDE platform protocol

Gerhardt Attard, Louise Brown, Noel Clarke, Laura Murphy, William Cross, Rob Jones, Silke Gillessen, J.Martin Russell, Adrian Cook, Jo Bowen, Anna Lydon, Ian Pedley, Omi Parikh, Simon Chowdhury, Zafar Malik, David Matheson, Chris Parker, Matthew Sydes, Mahesh Parmar, Nicholas James **on behalf of the STAMPEDE investigators***

Conducted by Medical Research Council Trials Unit at University College London, U.K.

ClinicalTrials.gov number, NCT00268476 & Current Controlled Trials number, ISRCTN78818544

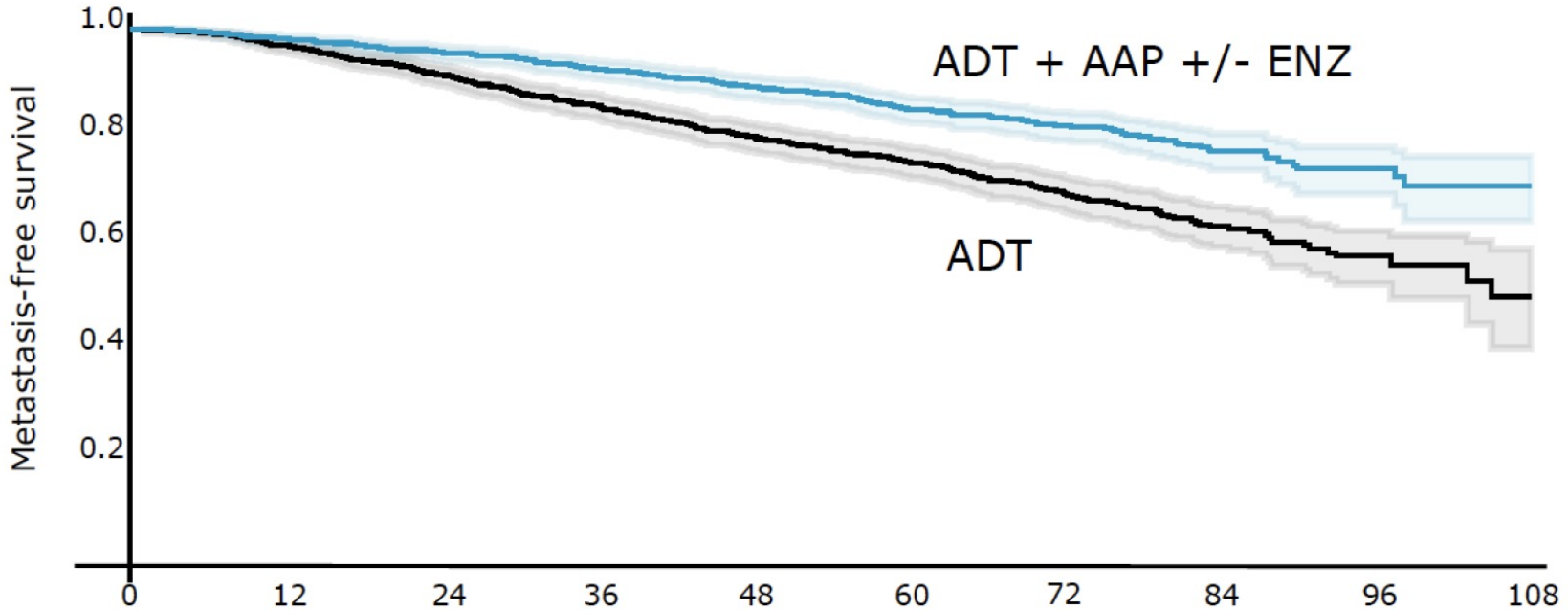
*113 U.K. and Swiss sites: list of investigators and collaborators at www.stampedetrial.org

www.stampedetrial.org

2021 ESMO congress

ESMO 2021;Abstract LBA4_PR.

Metastasis-Free Survival with the Addition of Abiraterone Acetate and Prednisolone with or without Enzalutamide to ADT for High-Risk M0 Prostate Cancer



ADT										
At-risk	988	950	894	836	767	550	329	172	53	9
Censored	0	8	11	14	26	201	387	522	632	673
Event	0	30	83	138	195	237	272	294	303	306
ADT+AAP+/-ENZ										
At-risk	986	948	917	884	839	622	369	198	71	14
Censored	0	21	28	31	45	225	460	615	737	792
Event	0	17	41	71	102	139	157	173	178	180

Events
180 ADT+ AAP +/- ENZ
306 ADT

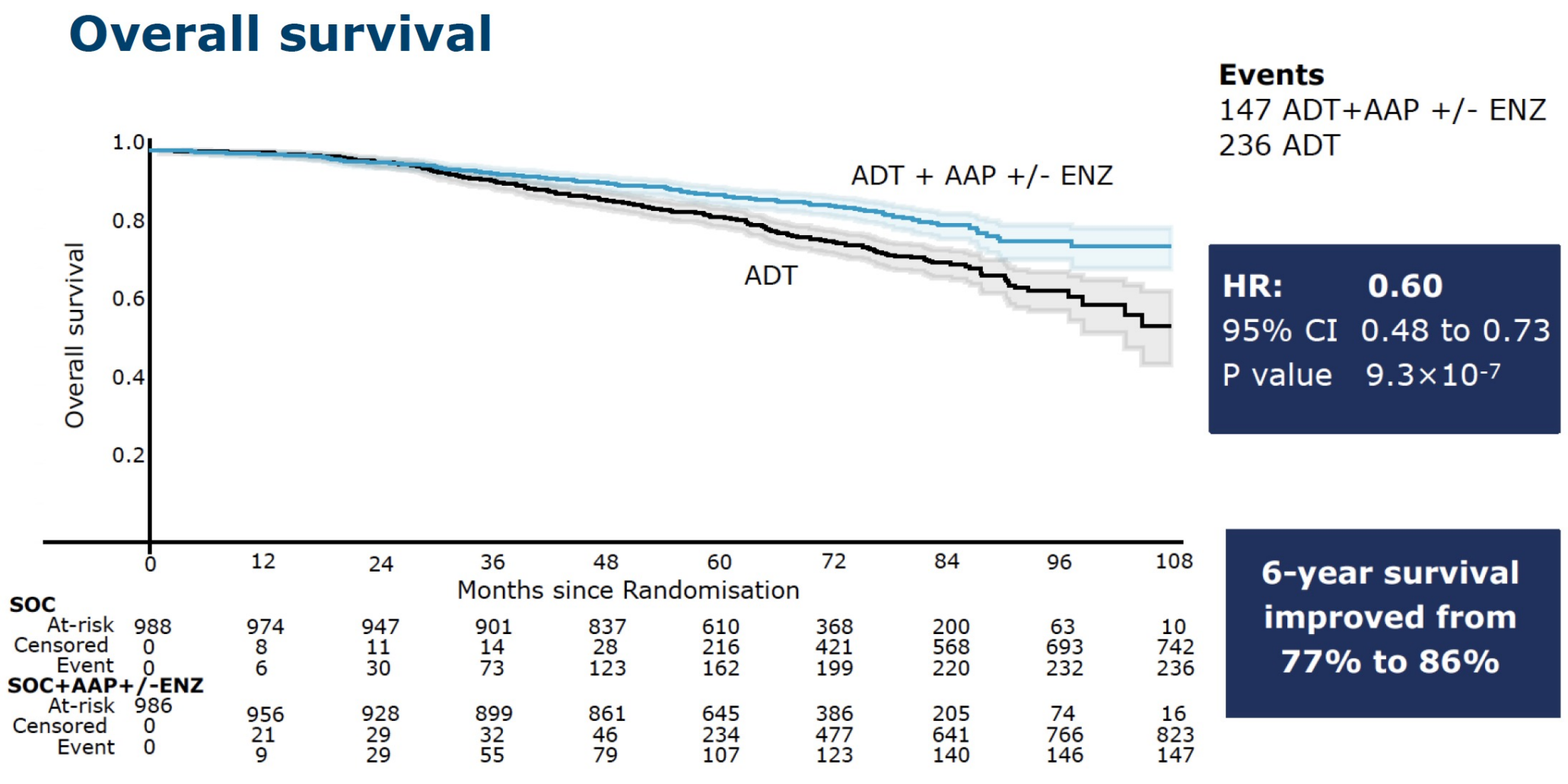
HR:	**0.53**
95% CI:	0.44-0.64
P value	2.9×10^{-11}

6-year MFS improved from 69% to 82%

Attard G et al. ESMO 2021;Abstract LBA4_PR.

RTP RESEARCH TO PRACTICE

Overall Survival with the Addition of Abiraterone Acetate and Prednisolone with or without Enzalutamide to ADT for High-Risk M0 Prostate Cancer



Attard G et al. ESMO 2021;Abstract LBA4_PR.

Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia

Wednesday, December 1, 2021
5:00 PM – 6:00 PM ET

Faculty

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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