Meet The Professor

Optimizing the Management of Metastatic Castration-Resistant Prostate Cancer

Simon Chowdhury, MD, PhD
Consultant Medical Oncologist
London, United Kingdom

Commercial Support

These activities are 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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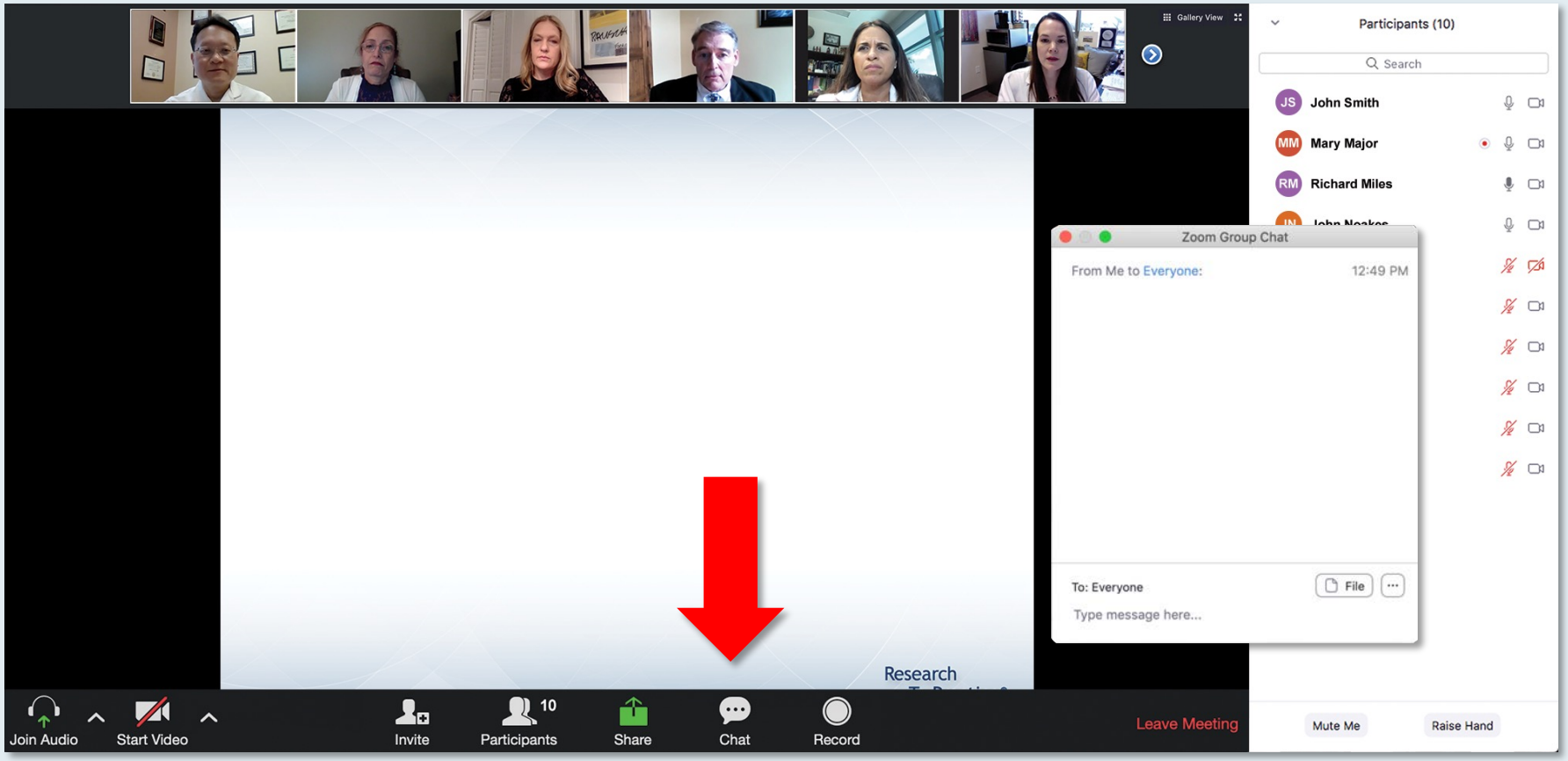
Prof Chowdhury — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



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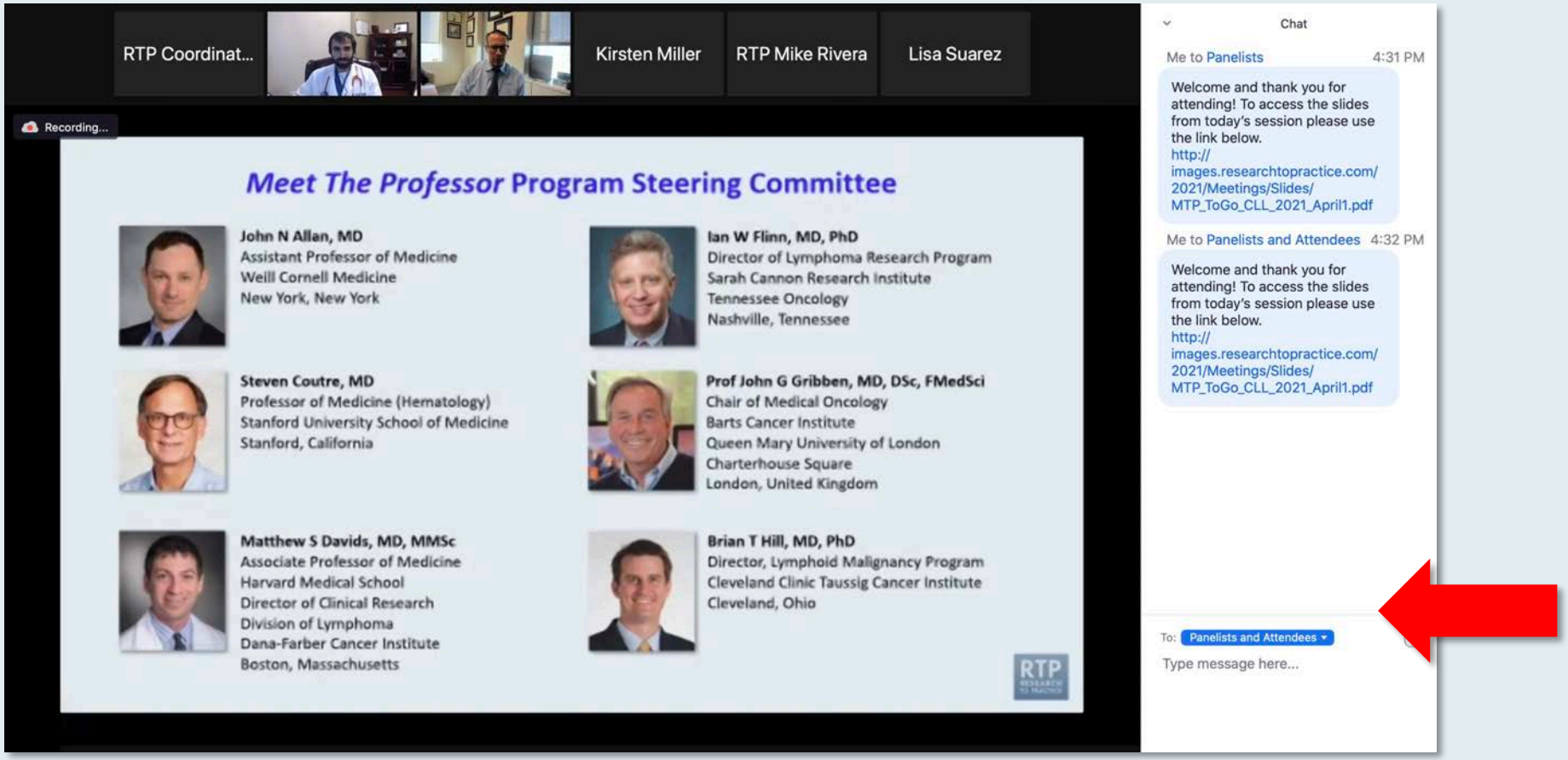

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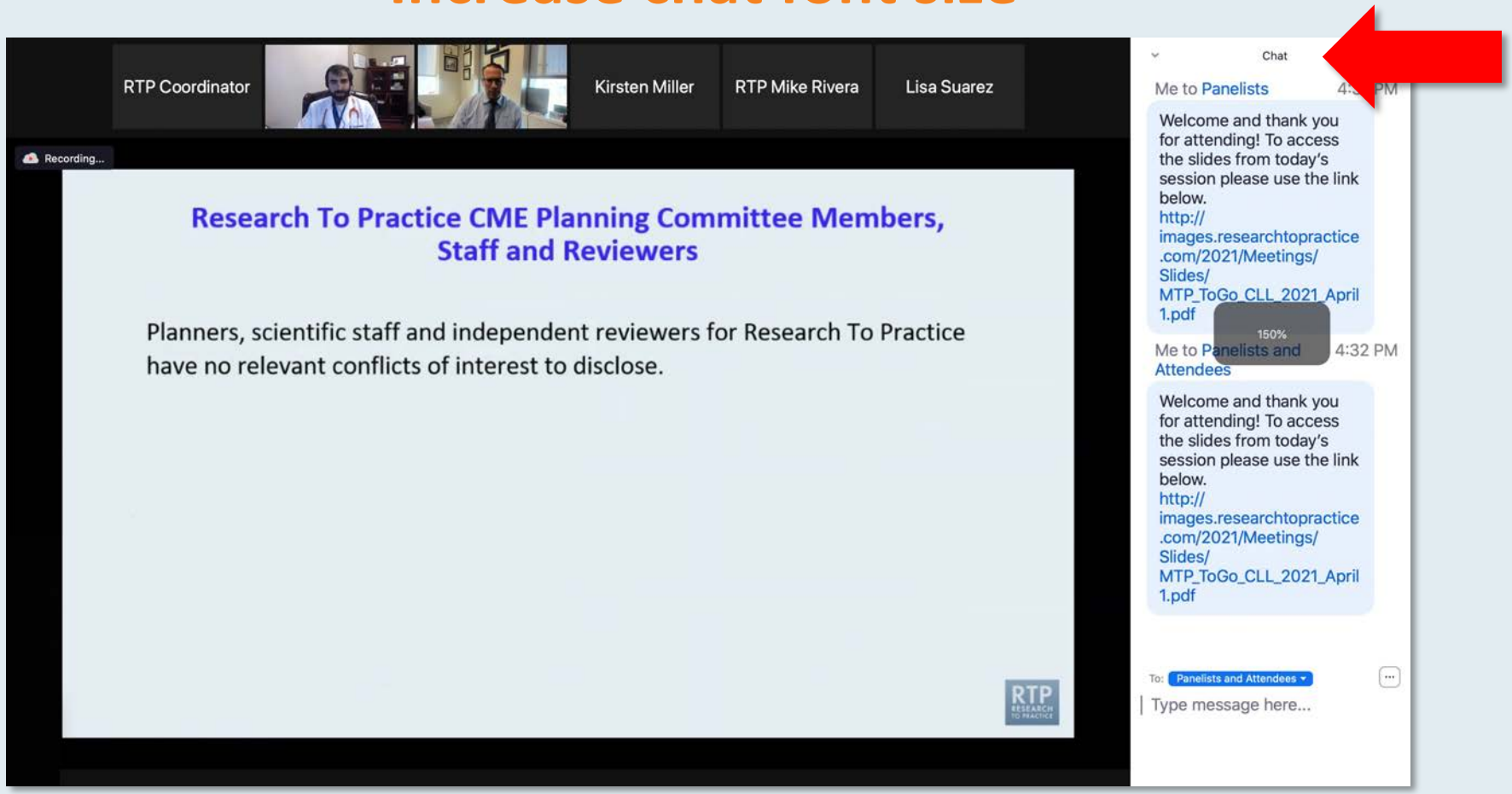

Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

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WITH DR NEIL LOVE

Side Effects of Hormonal Therapy in Prostate Cancer

DR ROBERTO IACOVELLI

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Optimizing Biomarker-Based Decision-Making for Patients with Non-Small Cell Lung Cancer with EGFR Mutations or with Other Oncogene-Addicted Lung Cancers

A 2-Part CME/MOC-Accredited Webinar Series

Thursday, November 11, 2021
5:00 PM – 6:00 PM ET

Faculty

Marc Ladanyi, MD
Andrew J McKenzie, PhD
Helena Yu, MD

Moderator

Neil Love, MD

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Meet The Professor

Optimizing the Clinical Management of Hodgkin and Non-Hodgkin Lymphomas

Monday, November 15, 2021
5:00 PM – 6:00 PM ET

Faculty

Christopher R Flowers, MD, MS

Moderator

Neil Love, MD

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Meet The Professor

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

Wednesday, November 17, 2021
5:00 PM – 6:00 PM ET

Faculty

Kevin Kalinsky, MD, MS

Moderator

Neil Love, MD

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Meet The Professor

Current and Future Role of Immunotherapy in the Management of Lung Cancer

Thursday, November 18, 2021
5:00 PM – 6:00 PM ET

Faculty

Stephen V Liu, MD

Moderator

Neil Love, MD

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Meet The Professor

Management of BRAF-Mutant Melanoma

Monday, November 29, 2021
5:00 PM – 6:00 PM ET

Faculty
Jason J Luke, MD

Moderator
Neil Love, MD

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Meet The Professor

Optimizing the Management of Metastatic Castration-Resistant Prostate Cancer

Tuesday, November 30, 2021
5:00 PM – 6:00 PM ET

Faculty

A Oliver Sartor, MD

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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Meet The Professor

Optimizing the Management of Metastatic Castration-Resistant Prostate Cancer

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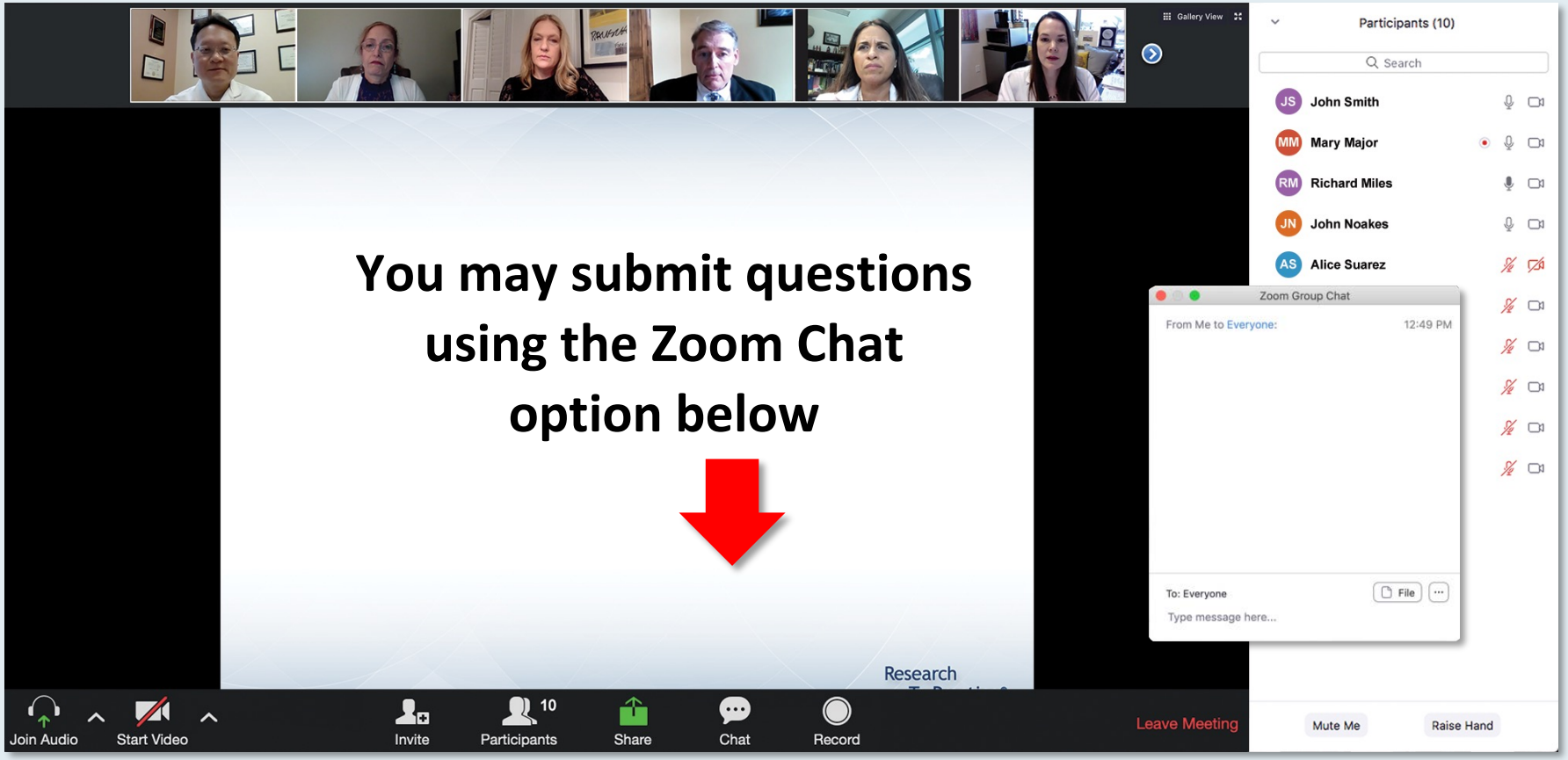

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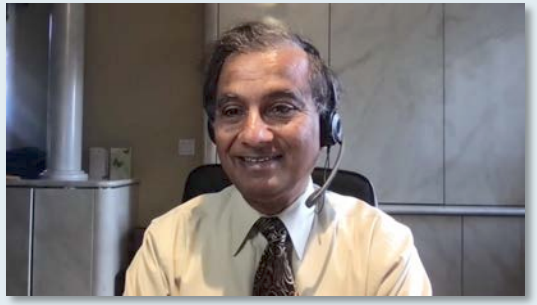
London, United Kingdom

Spencer Henick Bachow, MD
Lynn Cancer Institute
FAU Schmidt College of Medicine
Boca Raton, Florida



Sunil Gandhi, MD
Florida Cancer Specialists
and Research Institute
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Reid Health
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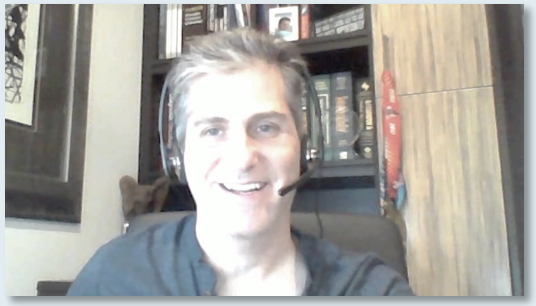
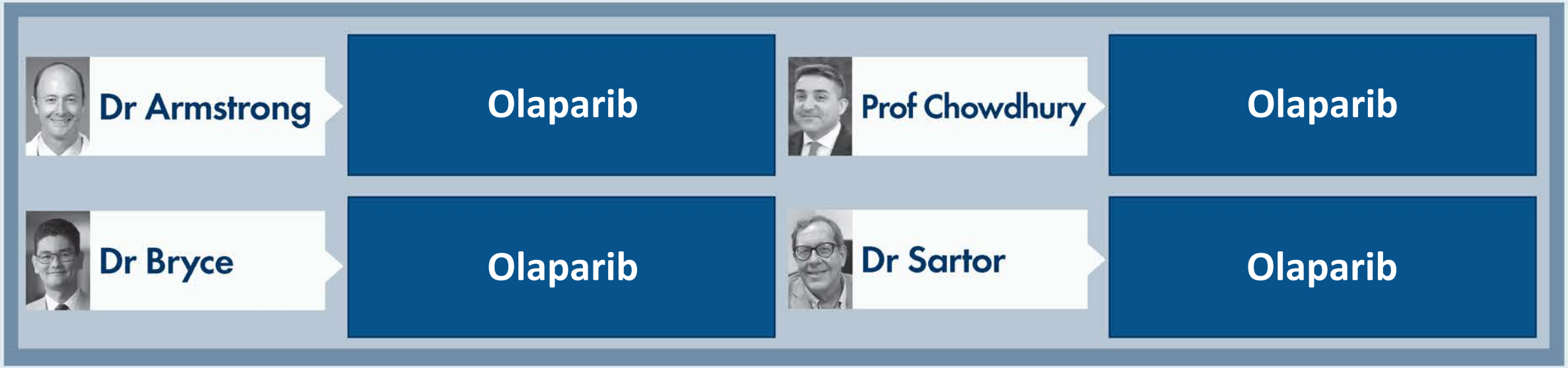


Shachar Peles, MD
Florida Cancer Specialists
and Research Institute
Lake Worth, Florida

Kelly Yap, MD
City of Hope
Arcadia, California

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

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?



Meet The Professor with Prof Chowdhury

MODULE 1: Prostate Cancer Genomic Landscape

MODULE 2: Lutetium-177-PSMA-617

MODULE 3: Case Presentations

- Dr Lamar: A 67-year-old man with metastatic castration-resistant prostate cancer (mCRPC) and a germline BRCA2 mutation
- Dr Yap: An 80-year-old man with mCRPC and a somatic BRCA2 mutation
- Dr Hafron: A 68-year-old man with BRCA1/2 wild-type mCRPC
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MODULE 4: Faculty Survey

MODULE 5: Journal Club with Prof Chowdhury

MODULE 6: Appendix of Key Data Sets

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EUROPEAN UROLOGY 79 (2021) 519–529

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

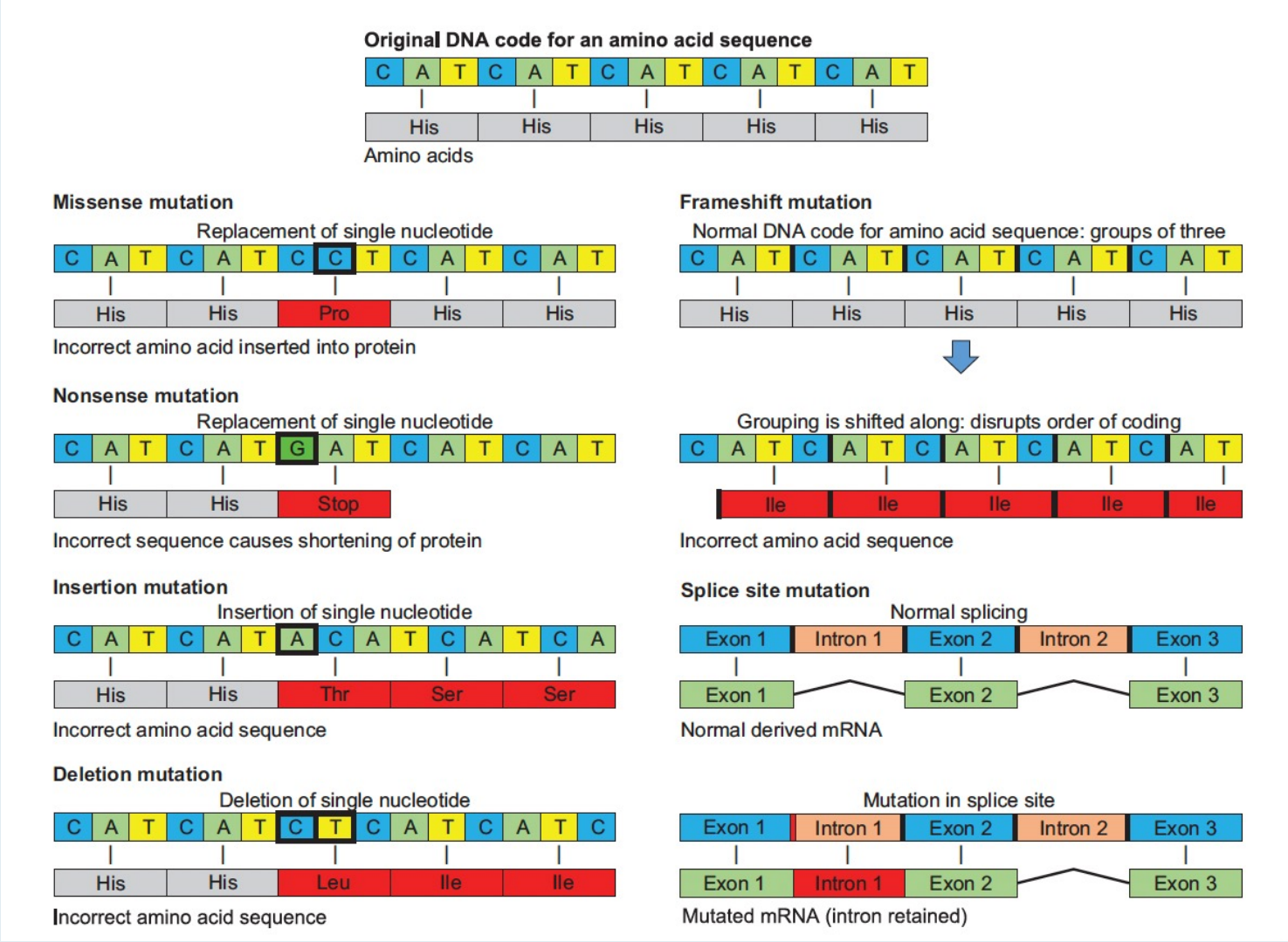
European Association of Urology

Review – Prostate Cancer

Genomic Testing in Patients with Metastatic Castration-resistant Prostate Cancer: A Pragmatic Guide for Clinicians

Axel S. Merseburger[a,†,*], *Nick Waldron*[b,†], *Maria J. Ribal*[c], *Axel Heidenreich*[d], *Sven Perner*[e,f], *Karim Fizazi*[g], *Cora N. Sternberg*[h], *Joaquin Mateo*[i], *Manfred P. Wirth*[j], *Elena Castro*[k,l], *David Olmos*[k,l], *Daniel P. Petrylak*[m], *Simon Chowdhury*[b,n]

Overview of Common Gene Mutations



Merseburger AS et al. *Eur Urol* 2021;79(4):519-29.

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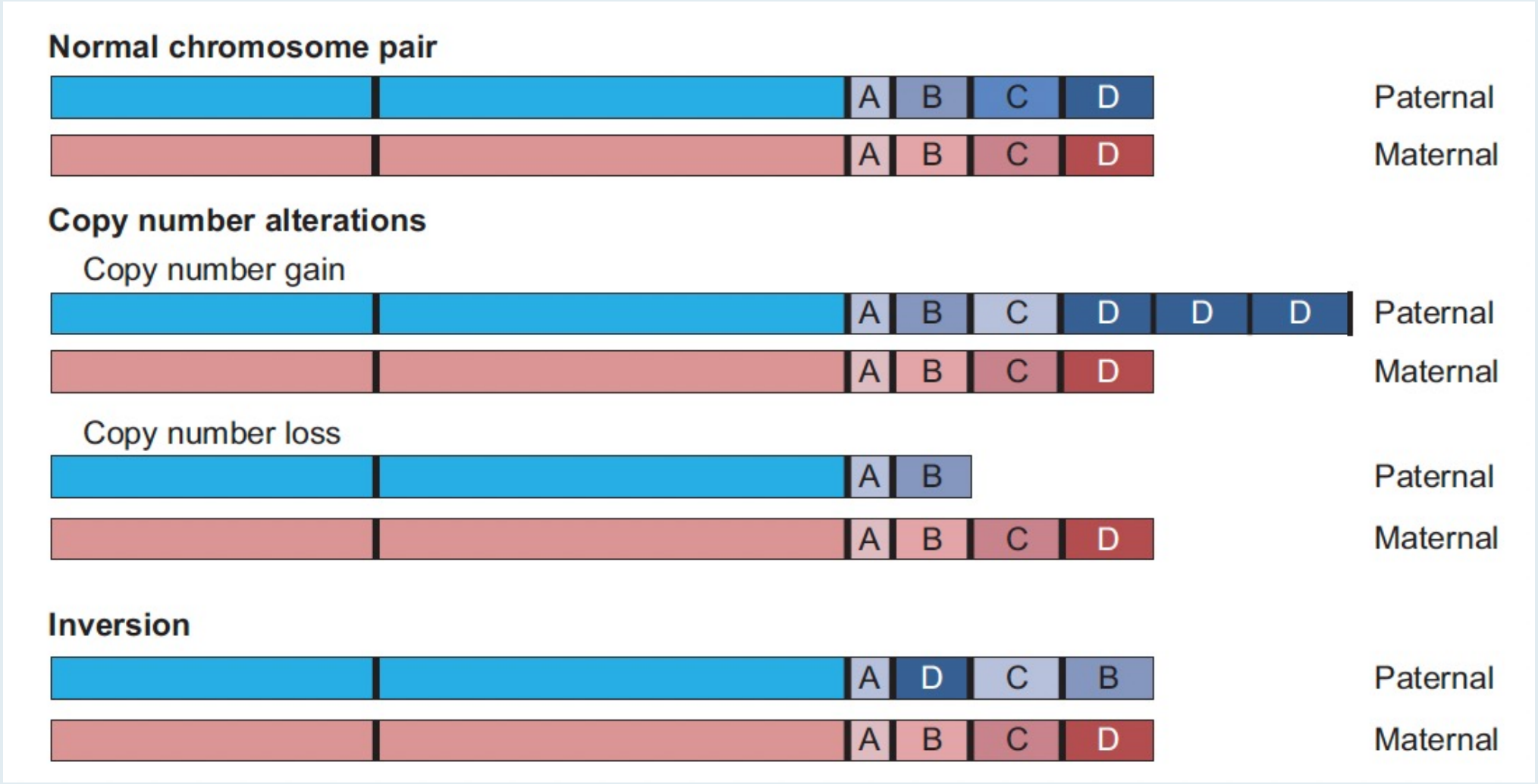
Overview of Common Large-Scale Alterations



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N Engl J Med 2021;385:1091-103

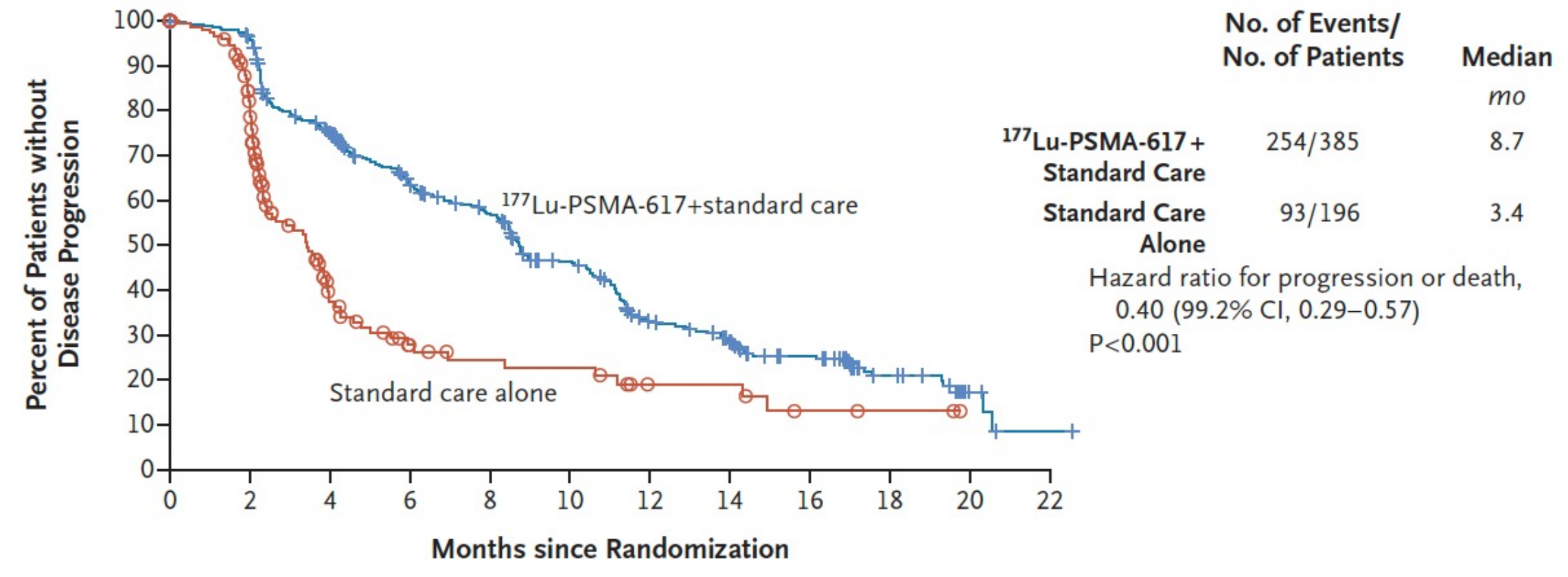
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

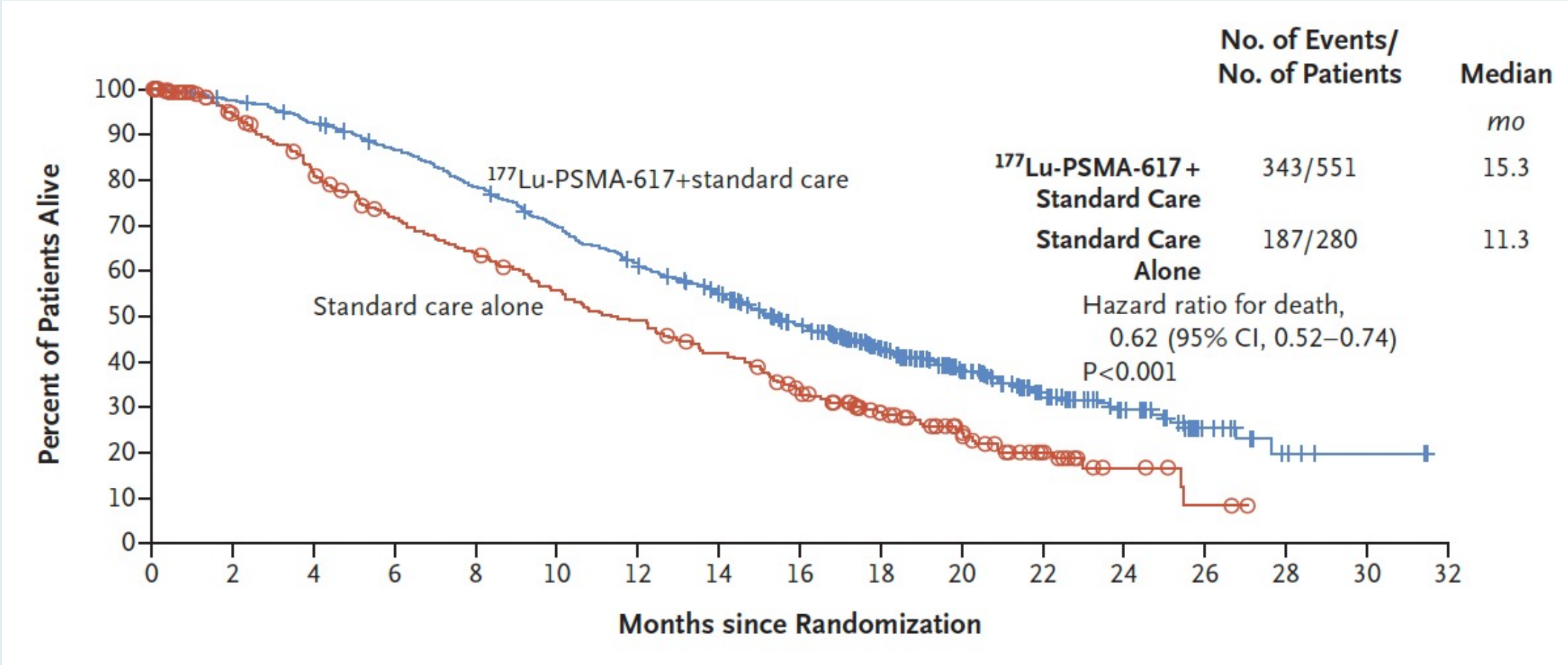
O. Sartor, J. de Bono, K.N. Chi, K. Fizazi, K. Herrmann, K. Rahbar, S.T. Tagawa, L.T. Nordquist, N. Vaishampayan, G. El-Haddad, C.H. Park, T.M. Beer, A. Armour, W.J. Pérez-Contreras, M. DeSilvio, E. Kpamegan, G. Gericke, R.A. Messmann, M.J. Morris, and B.J. Krause, for the VISION Investigators*

VISION: Imaging-Based Progression-Free Survival



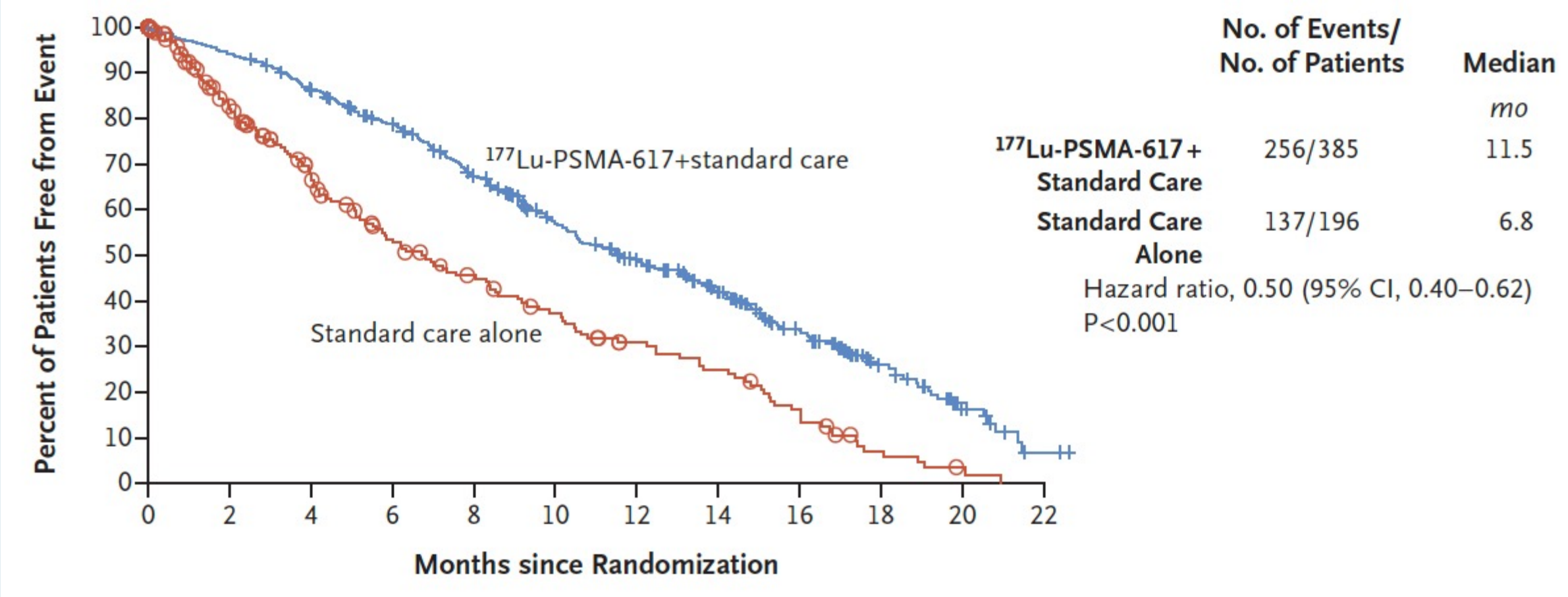
Sartor O et al. *N Engl J Med* 2021;385:1091-103.

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.

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Case Presentation – Dr Lamar: A 67-year-old man with mCRPC and a germline BRCA2 mutation

Dr Zanetta Lamar

- Sister died of ovarian cancer; patient and 4 offspring test positive for BRCA2 mutation
- 2005: Prostate cancer s/p prostatectomy, leuprolide/bicalutamide
- 2018: Abiraterone/prednisone
- 2019: Bone metastases

Questions

- In patients that are BRCA-positive with prostate cancer, what sequence do you give PARP inhibitors? Do you consider it first line? Second line? How do you go about thinking about treatment with these agents?

Case Presentation – Dr Lamar: A 67-year-old man with mCRPC and a germline BRCA2 mutation (continued)

Dr Zanetta Lamar

- Sister died of ovarian cancer; patient and 4 offspring test positive for BRCA2 mutation
- 2005: Prostate cancer s/p prostatectomy, leuprolide/bicalutamide
- 2018: Abiraterone/prednisone
- 2019: Bone metastases
- ***Olaparib x 9 months → PSA increase***
  - ***Severe fatigue addressed via dose adjustments***

Questions

- ***How do you manage toxicity with the PARP inhibitors? Do you agree with our approach to find a dose that he could tolerate and that would keep his PSA level under control? Would you consider switching to another PARP inhibitor?***
- ***Now that he has progressed, would you do anything differently besides going to chemotherapy? Would you consider a platinum agent?***

Case Presentation – Dr Yap: An 80-year-old man with mCRPC and a somatic BRCA2 mutation

Dr Kelly Yap

Dr KS Kumar

- Remote history of prostate cancer, with unknown clinicopathologic details
- Fifteen years later: High-volume bone and nodal metastases
- ADT/docetaxel, with discontinuation of docetaxel after 5 cycles due to toxicity
- Abiraterone/prednisone x 7 months → PD
- Liquid biopsy: Somatic BRCA2 mutation

Questions

- In a patient with symptomatic bone metastases and a somatic BRCA2 mutation, what would be the best treatment? Would it be a PARP inhibitor or radium-223 or the combination of PARP inhibitor with radium-223?
- In what situation would a PARP inhibitor be indicated in addition to a BRCA mutation?
- Which of the following markers of HRD – BRCA, ATM, PALB, etc – are indicative of best response to PARP inhibitors? For which ones would you still not consider using a PARP inhibitor?

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Case Presentation – Dr Hafron: A 68-year-old man with BRCA1/2 wild-type mCRPC

Dr Jason Hafron

- Presents with back pain and PSA 231 ng/dL
- Prostate biopsy: Grade group 4 adenocarcinoma of the prostate
- Germline and somatic testing: Negative for actionable mutations
- Imaging: Widespread osseous metastases
- Docetaxel x 6 → Abiraterone/prednisone, with PSA increase from nadir 1.42 to 92.3 ng/dL
- 68Ga-PSMA PET scan: Diffuse osseous metastases, positive lymph node, pulmonary nodules
- Expanded access program for Lutetium Lu 177 dotatate

Questions

- Would you have considered a second-line chemotherapy prior to lutetium 177 in this patient? How would you follow response following treatment with lutetium 177? Is PSMA adequate to follow these patients after treatment with lutetium?
- Would you consider repeat PSMA studies to evaluate response in this patient?

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Lutetium Lu 177 dotatate re-challenge

Dr Sulfi Ibrahim

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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

Questions

- Would you have chosen a different treatment than docetaxel?
- After docetaxel x 6, would you switch to enzalutamide or abiraterone/prednisone, or would you wait until disease progression to switch to another therapy?

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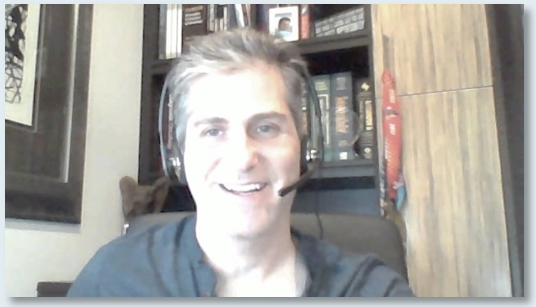
Case Presentation – Dr Peles: An 86-year-old man with M0 CRPC



Dr Shachar Peles

- 2009: Gleason 7 prostate cancer, s/p EBRT → GnRH agonist x 9 months
- 2017: PSA relapsed → Leuprolide/bicalutamide
- 6/2017: CABG/aortic valve replacement cb embolic stroke with left hemiparesis; warfarin anticoagulation
- 5/2018: Rising PSA (PSADT: 4 months); Imaging negative for metastases
- Apalutamide, with dose reduction due to HTN then discontinued 10/2020
- Darolutamide
- 2021: PSA progression to 30 ng/dL; Bone scan: No evidence of skeletal metastases; CT CAP: Negative

Question

- What would you do next?

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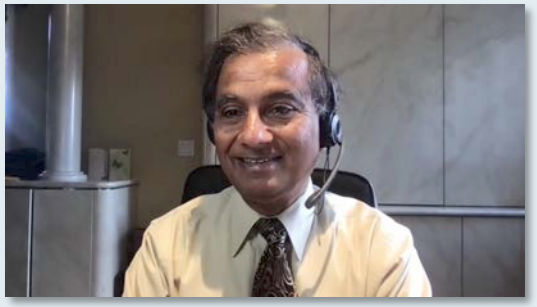
Case Presentation – Dr Gandhi: A 63-year-old man with BRCA1/2 wild-type mCRPC



Dr Sunil Gandhi

- 2014: Gleason 4 + 3 T2cN0 M0 prostate cancer with PSA 9.9 ng/dL, s/p LHRH agonist and RT
- 2018: PSA begins rising → LHRH agonist, with initial response followed by PSA increase
- 2/2019 CT and bone scan: Extensive retroperitoneal and pelvic LAD and widespread bone metastases
- Abiraterone, with initial PSA decline followed by increase
- Enzalutamide, without response and worsening pain
- Docetaxel x 9, with worsening PSA → Cabazitaxel, with stable disease but persistent pain requiring narcotics

Questions

- When should I consider administering radium-223? Does it cause myelosuppression?
- Why not give radium-223 to more patients like him?

RTP RESEARCH TO PRACTICE

Protocol and nonprotocol treatment approaches for oligometastatic prostate cancer

Dr David Morris

RTP
RESEARCH
TO PRACTICE

The oral GnRH receptor antagonist relugolix as an alternative to IV treatments

Dr Shachar Peles

RTP
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TO PRACTICE

Case Presentation – Dr Ibrahim: A 59-year-old man with mCRPC

Dr Sulfi Ibrahim

- Prostate cancer s/p radiation therapy and hormonal therapy
- Patient refuses leuprolide due to needle phobia
- Relugolix, well tolerated with PSA response but now subsequent PSA increase

Questions

- Can relugolix be safely combined with secondary hormonal agents, such as abiraterone or enzalutamide?

Oral relugolix in patients with preexisting cardiac issues

Dr Helen Moon

RTP
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TO PRACTICE

Case Presentation – Dr Bachow: A 62-year-old man with mCRPC and a somatic BRCA1 mutation, high tumor mutational 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 up front and then at progression give the PARP inhibitor?

RTP RESEARCH TO PRACTICE

Meet The Professor with Prof Chowdhury

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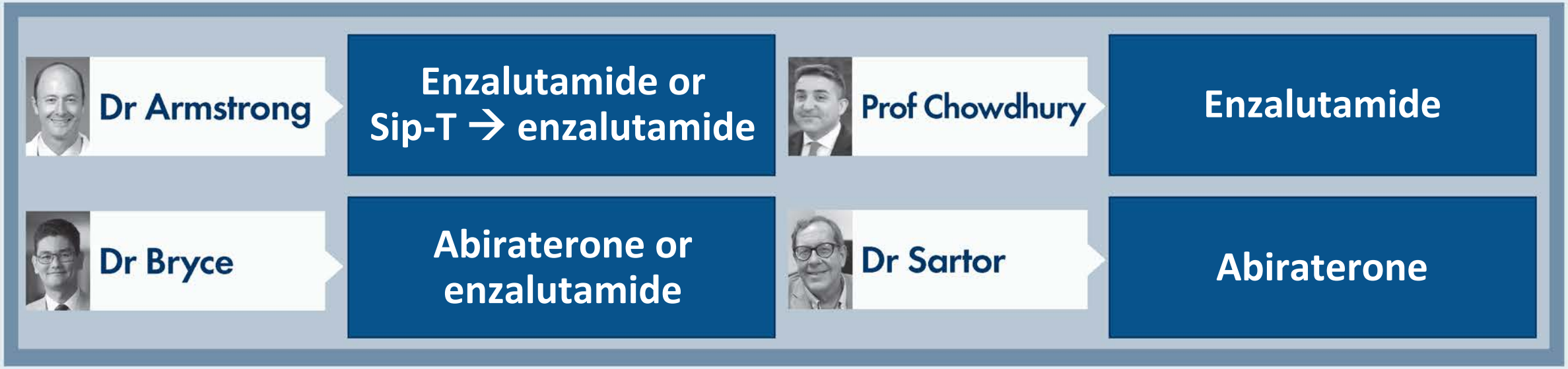
A 65-year-old man with BRCA wild-type, microsatellite stable (MSS) prostate cancer metastatic to the bone who is receiving an LHRH agonist alone for hormone-sensitive disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?



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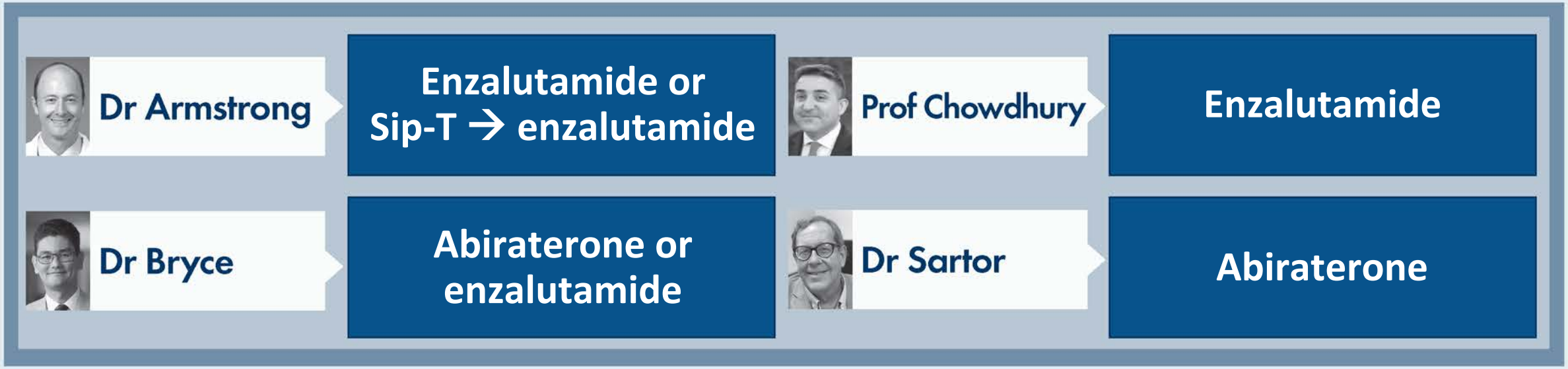
RTP RESEARCH TO PRACTICE

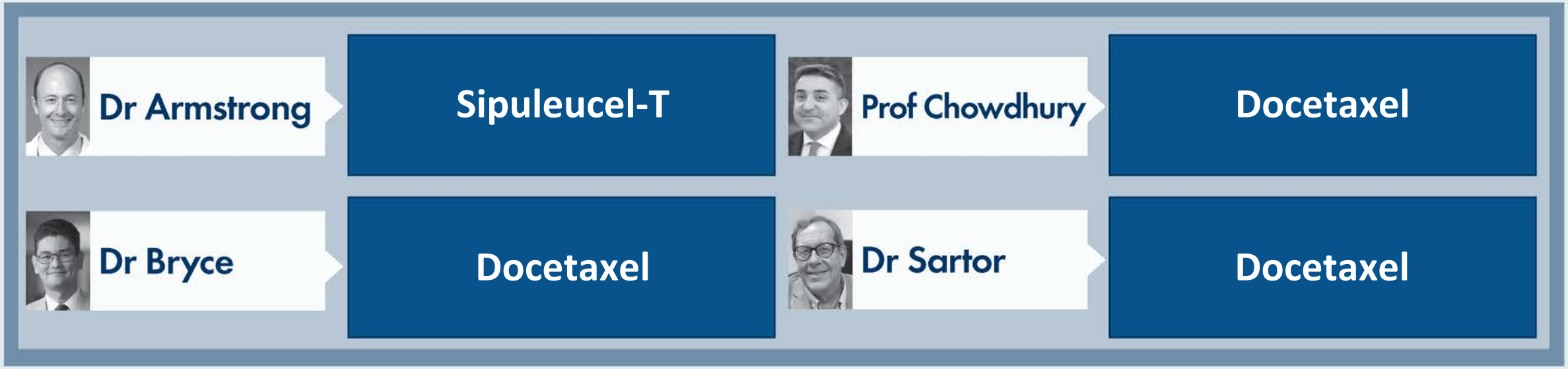
A 65-year-old man with MSS prostate cancer metastatic to the bone and a germline BRCA2 mutation who is receiving an LHRH agonist alone for hormone-sensitive disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?



A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone 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 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?



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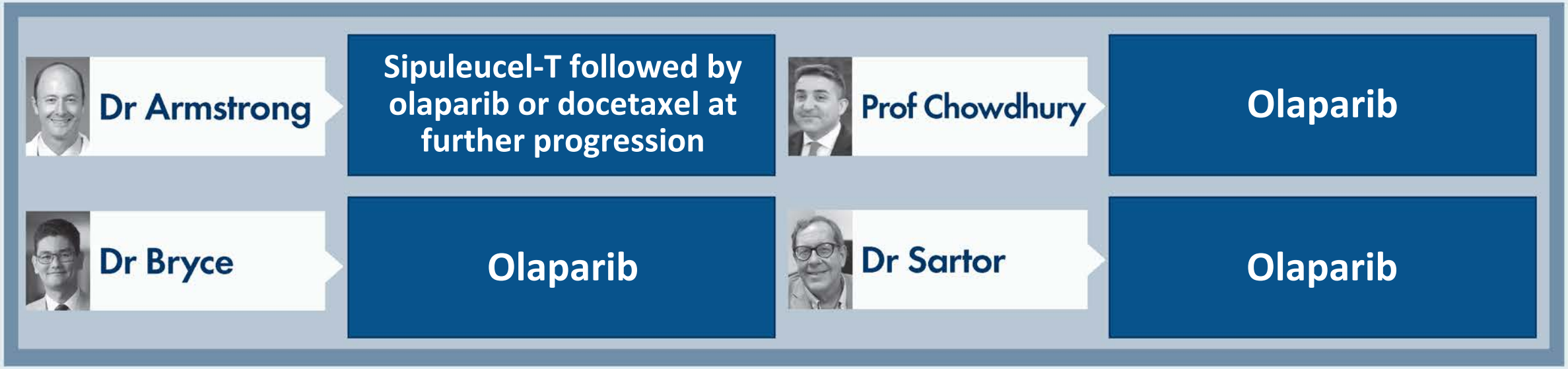

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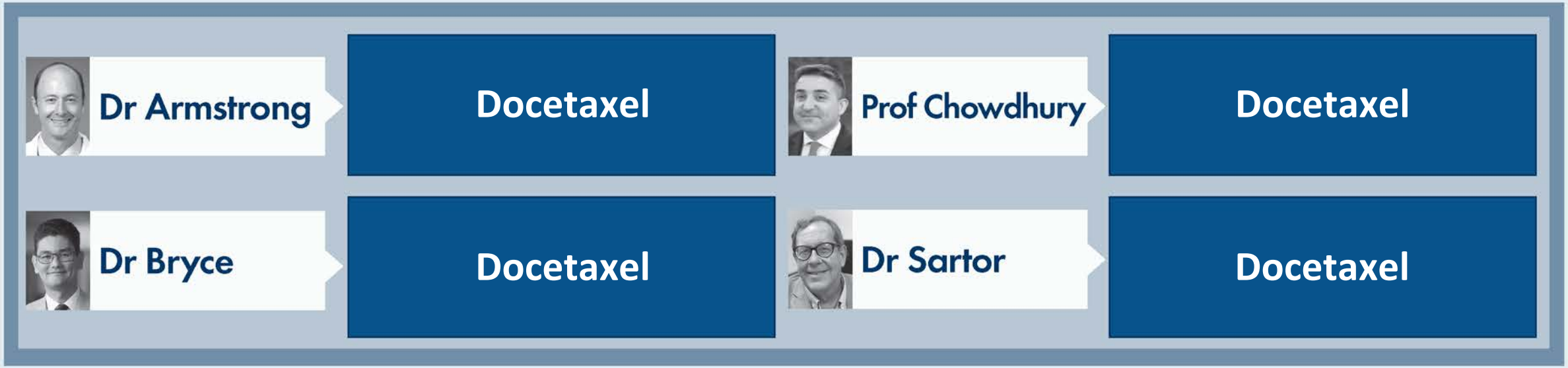

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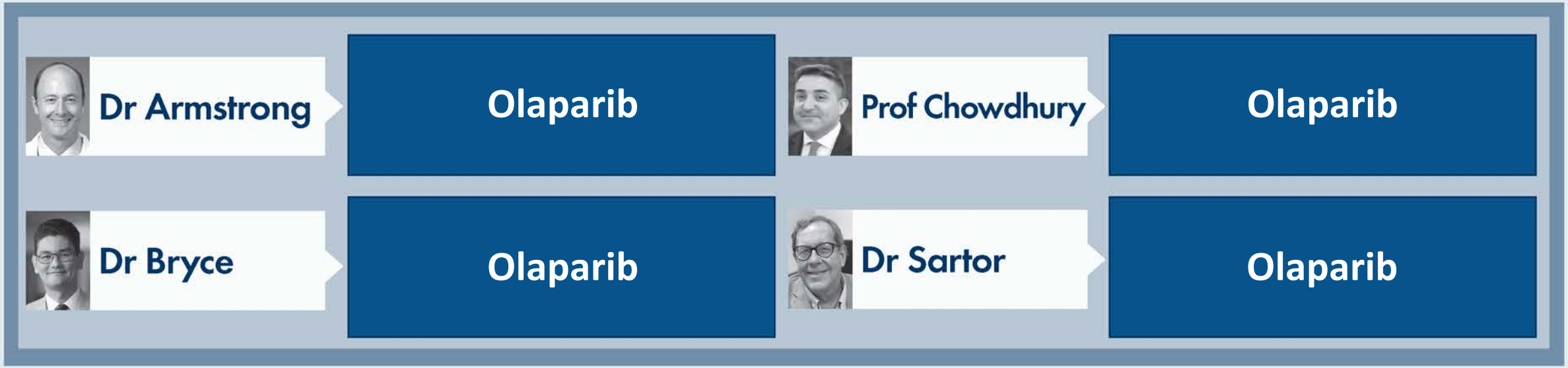
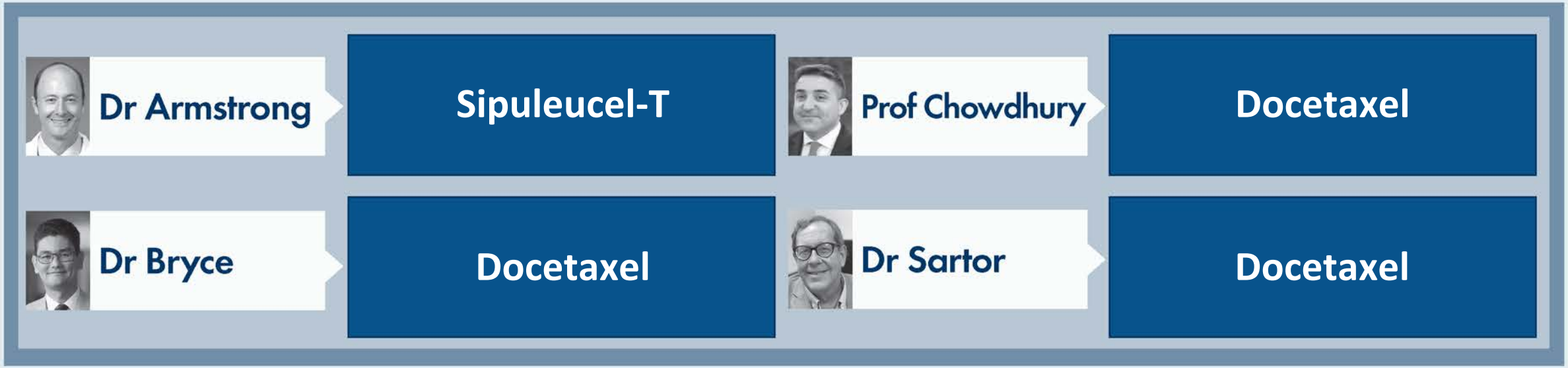
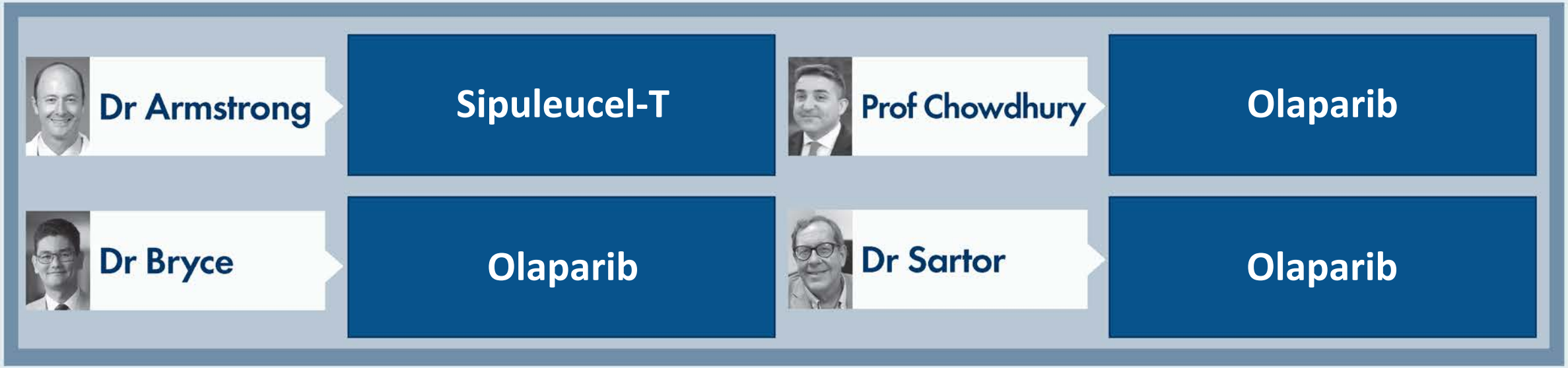


A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving enzalutamide for hormone-sensitive metastatic disease develops new low-volume asymptomatic bone metastases. Which systemic treatment would you most likely recommend?



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?

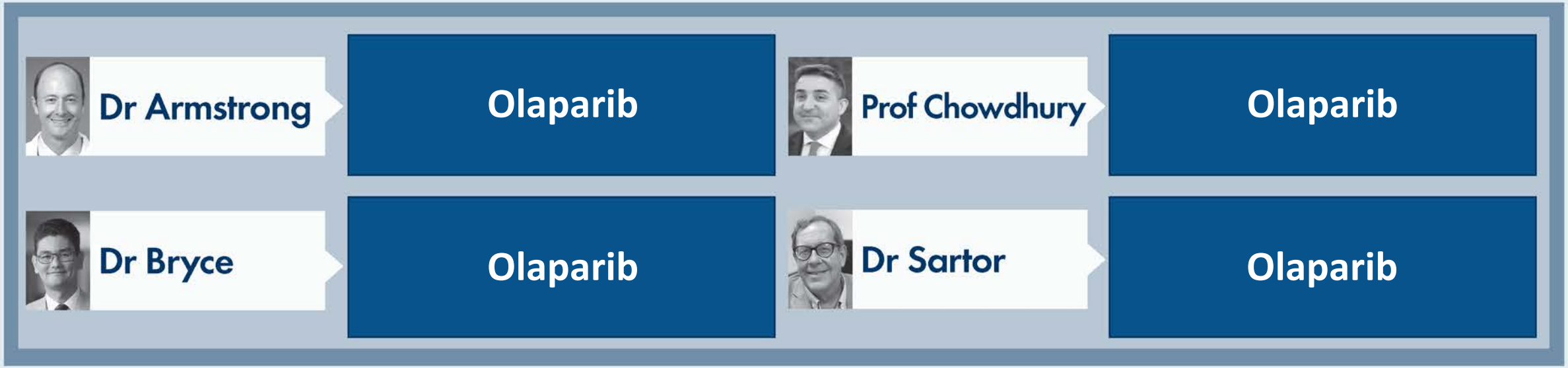


A 65-year-old man with BRCA wild-type, MSS prostate cancer metastatic to the bone who is receiving enzalutamide for hormone-sensitive disease develops new high-volume symptomatic bone metastases. Which systemic treatment would you most likely recommend?

 Dr Armstrong	Docetaxel	 Prof Chowdhury	Docetaxel
 Dr Bryce	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?



In general, at what point, if any, do you generally recommend radium-223 to a patient with bone-only mCRPC?

 Dr Armstrong	After at least 1 AR inhibitor and docetaxel or if a patient is unfit for or declines chemotherapy	 Prof Chowdhury	I generally would not administer radium-223
 Dr Bryce	After at least 1 line of both hormonal therapy and chemotherapy	 Dr Sartor	After 1 line of chemotherapy

RTP RESEARCH TO PRACTICE

Based on available data and your own clinical experience, do you believe that radium-223 is effective in alleviating bone pain?

RTP
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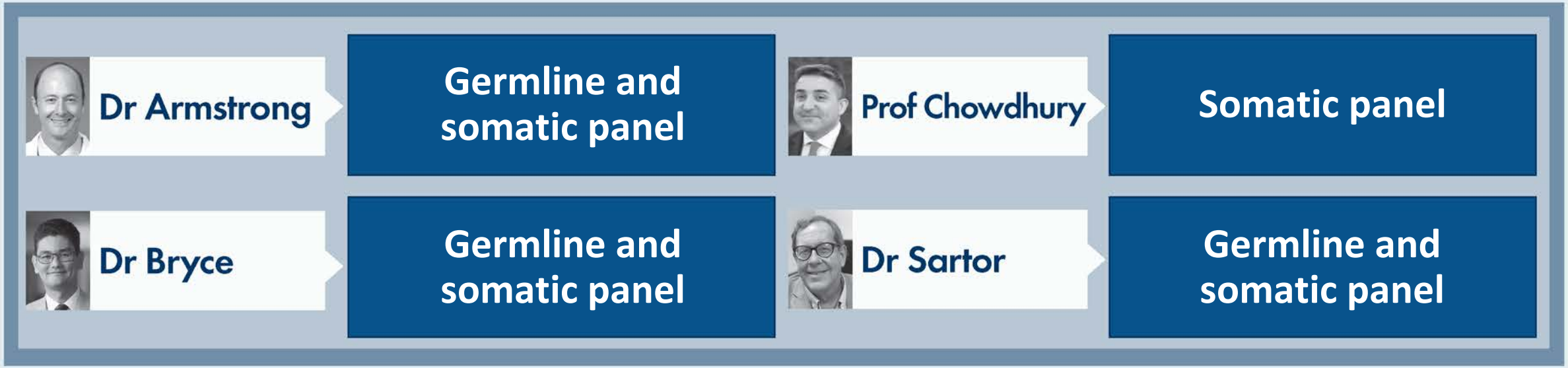
TO PRACTICE

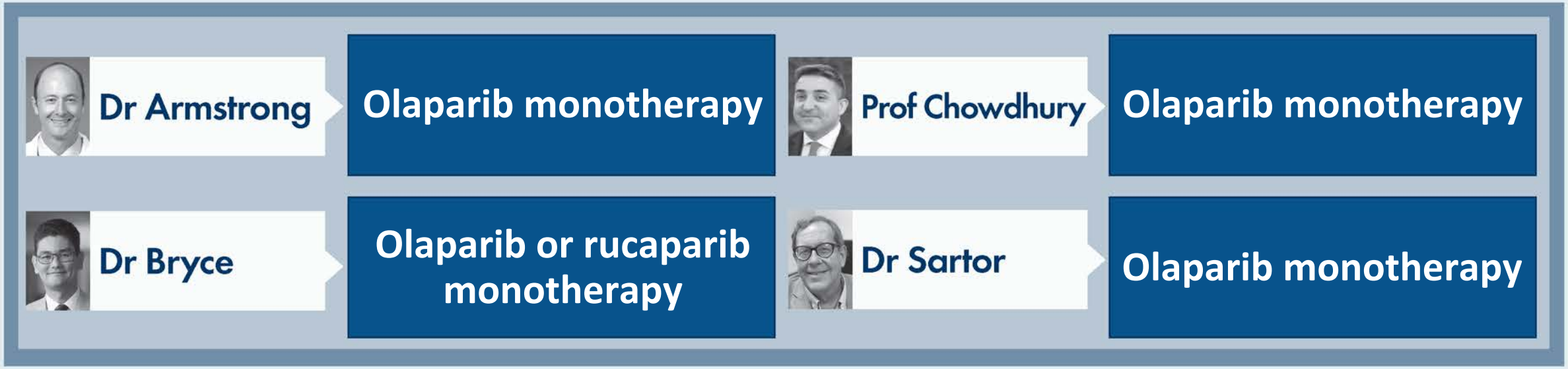
Which of the following genomic evaluations do you generally order for patients with mCRPC and no specific family history of cancer?



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 Chowdhury	After 1 line of hormonal therapy
 Dr Bryce	After 1 line of hormonal therapy	 Dr Sartor	After 1 line of hormonal therapy

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?



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

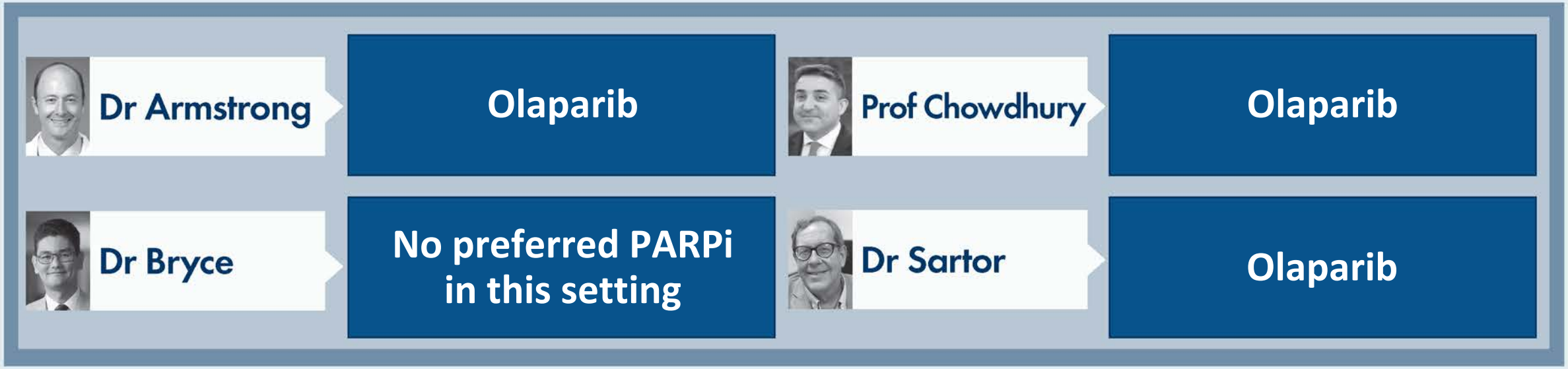
 Dr Armstrong	I have not and would not	 Prof Chowdhury	I have not and would not
 Dr Bryce	I have not but would for the right patient	 Dr Sartor	I have not and would not

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?

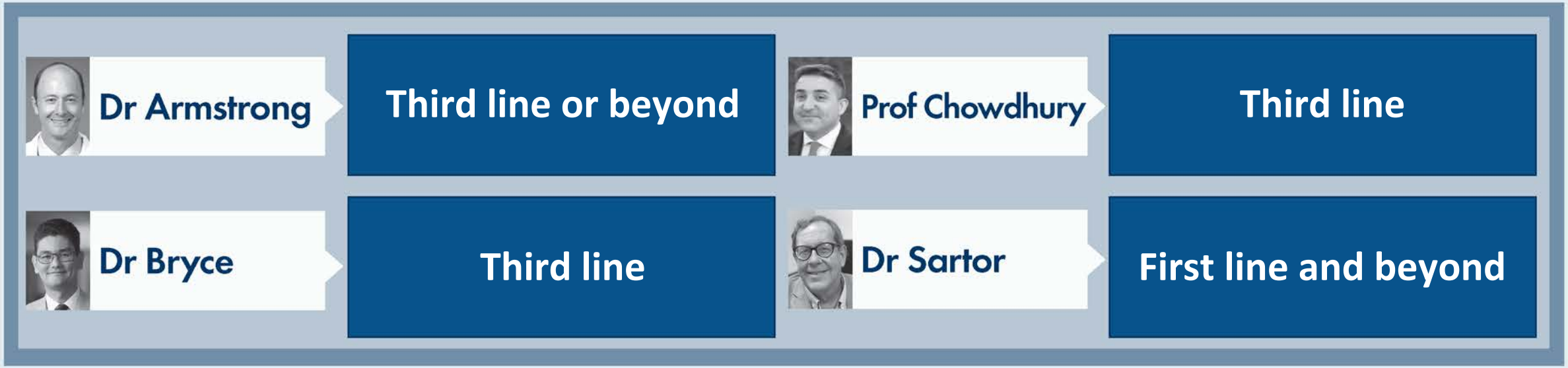
 Dr Armstrong	I have (mCRPC) I have not (mHSPC)	 Prof Chowdhury	I have not and would not
 Dr Bryce	I have not but would for the right patient	 Dr Sartor	I have

In general, which is your preferred PARP inhibitor for a patient with metastatic prostate cancer and a BRCA or BRCA-like mutation?



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

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



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 Chowdhury	Beyond third line
 Dr Bryce	Third line	 Dr Sartor	First line and beyond

RTP RESEARCH TO PRACTICE

Meet The Professor with Prof Chowdhury

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MODULE 6: Appendix of Key Data Sets

RTP
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TO PRACTICE

Journal Club with Prof Chowdhury

- Hanna Tukachinsky et al. **Genomic analysis of circulating tumor DNA in 3,334 patients with advanced prostate cancer to identify targetable BRCA alterations and AR resistance mechanisms.** Genitourinary Cancers Symposium 2021;Abstract 25.
- Tukachinsky H et al. **Genomic analysis of circulating tumor DNA in 3,334 patients with advanced prostate cancer identifies targetable BRCA alterations and AR resistance mechanisms.** *Clin Cancer Res* 2021;27(11):3094-105.
- Loehr A et al. **Response to rucaparib in BRCA-mutant metastatic castration-resistant prostate cancer identified by genomic testing in the TRITON2 study.** *Clin Cancer Res* 2021:[Online ahead of print].

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RESEARCH
TO PRACTICE

Journal Club with Prof Chowdhury

- Finelli A et al. **Comparison of joint and landmark modeling for predicting cancer progression in men with castration-resistant prostate cancer: A secondary post hoc analysis of the PREVAIL randomized clinical trial.** *JAMA Netw Open* 2021;4(6):e2112426.
- Attard G et al. **Abiraterone acetate plus prednisolone (AAP) with or without enzalutamide (ENZ) added to androgen deprivation therapy (ADT) compared to ADT alone for men with high-risk non-metastatic (M0) prostate cancer (PCa): Combined analysis from two comparisons in the STAMPEDE platform protocol.** ESMO 2021; Abstract LBA4_PR.
- Bjartell A et al. **Real-world safety and efficacy outcomes with abiraterone acetate plus prednisone or prednisolone as the first- or second-line treatment for metastatic castration-resistant prostate cancer: Data from the Prostate Cancer Registry.** *Target Oncol* 2021;16(3):357-67.

RTP RESEARCH TO PRACTICE

Journal Club with Prof Chowdhury (Cont)

- Feng FY et al. **Association of molecular subtypes with differential outcome to apalutamide treatment in nonmetastatic castration-resistant prostate cancer.** *JAMA Oncol* 2021:e211463.
- Sweeney CJ et al; ENZAMET Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). **Overall survival of men with metachronous metastatic hormone-sensitive prostate cancer treated with enzalutamide and androgen deprivation therapy.** *Eur Urol* 2021;80(3):275-9.

RTP RESEARCH TO PRACTICE

Meet The Professor with Prof Chowdhury

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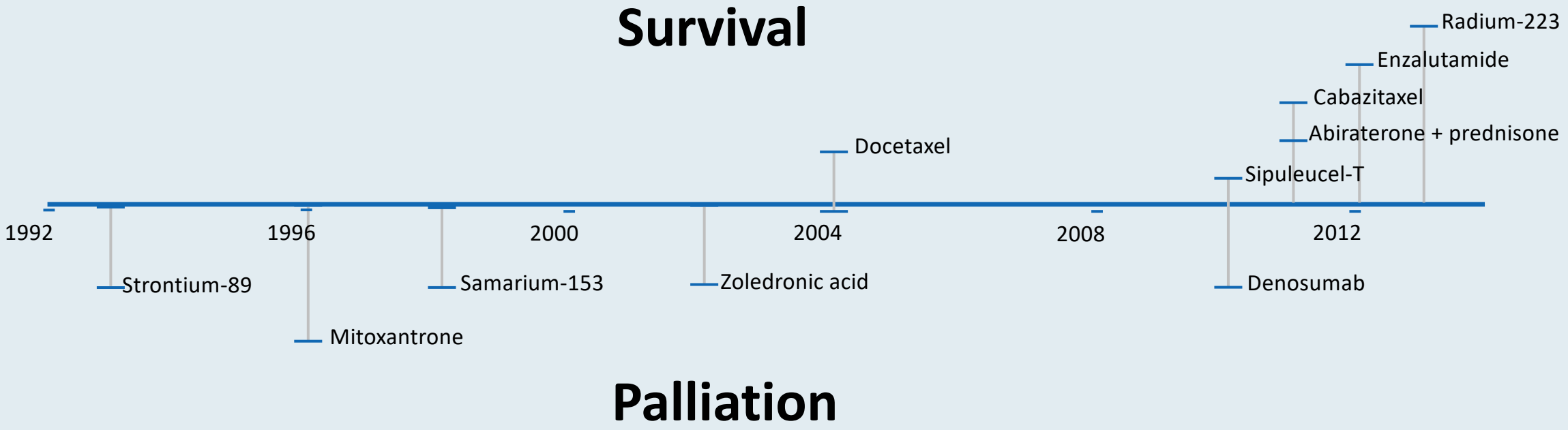
RTP RESEARCH TO PRACTICE

Selection and Sequencing of Therapy for Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Timeline of FDA Approvals in mCRPC



Metastatic disease was defined by conventional imaging (eg, bone scan, CT scans)

RTP RESEARCH TO PRACTICE

FDA Approves Relugolix for Advanced Prostate Cancer

Press Release: December 18, 2020

"On December 18, 2020, the US Food and Drug Administration approved the first oral gonadotropin-releasing hormone (GnRH) receptor antagonist, relugolix, for adult patients with advanced prostate cancer.

Efficacy was evaluated in HERO (NCT03085095), a randomized, open label trial in men requiring at least one year of androgen deprivation therapy with either prostate cancer recurrence following radiation or surgery or newly diagnosed castration-sensitive advanced prostate cancer.

Patients (N=934) were randomized (2:1) to receive relugolix 360 mg oral loading dose on the first day, followed by daily oral doses of 120 mg, or leuprolide acetate 22.5 mg injection subcutaneously every 3 months for 48 weeks."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-relugolix-advanced-prostate-cancer

RTP RESEARCH TO PRACTICE

HERO Phase III Trial: Results Comparing Relugolix, an Oral GnRH Receptor Antagonist, versus Leuprolide Acetate for Advanced Prostate Cancer[1]

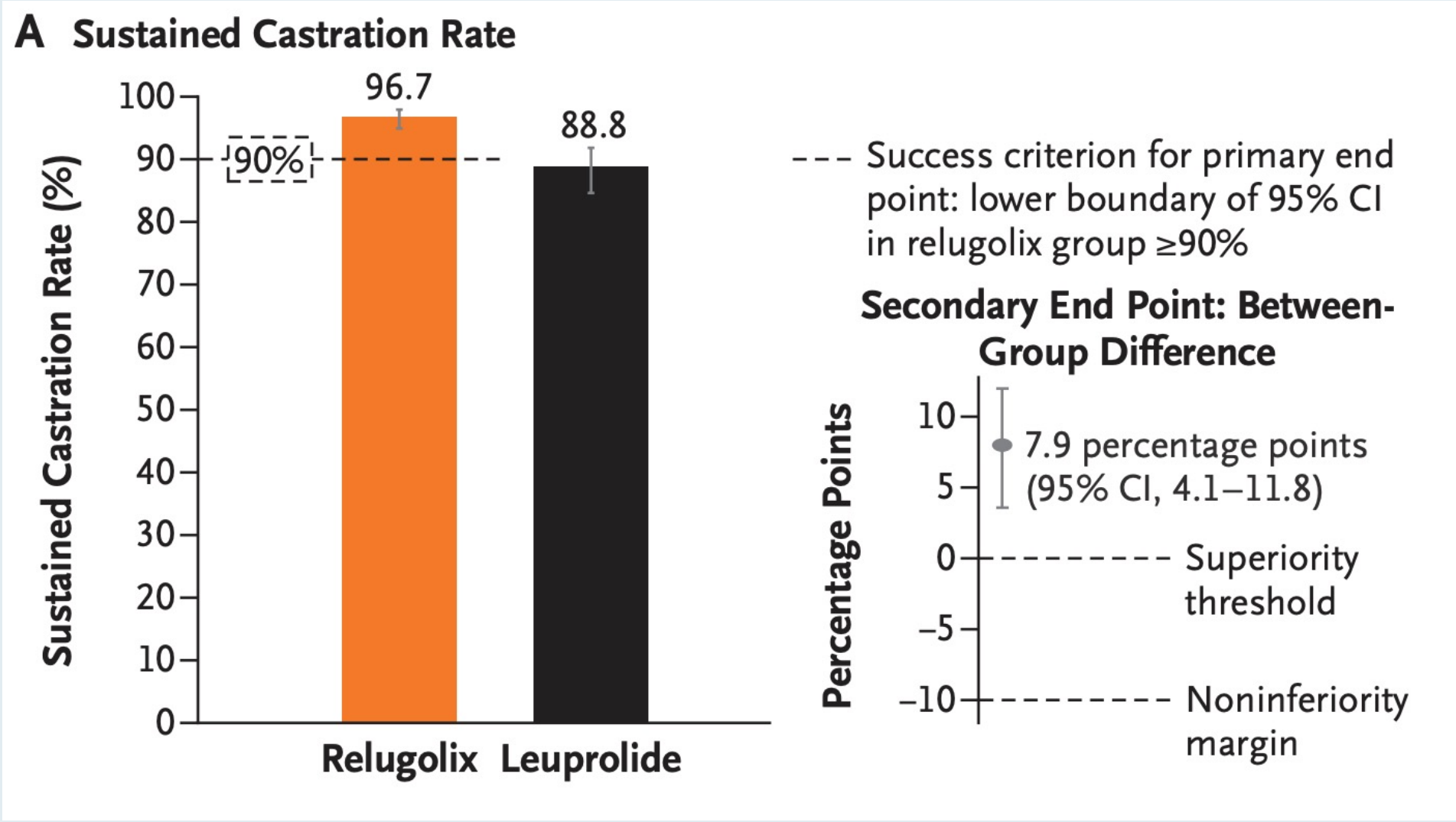
Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer[2]

[1] Shore N et al.
ASCO 2020;Abstract 5602.

[2] Shore ND et al.
N Engl J Med 2020;382(23):2187-96.

RTP RESEARCH TO PRACTICE

HERO Study: Oral Relugolix versus Leuprolide Acetate for Androgen-Deprivation Therapy



Shore ND et al. *N Engl J Med* 2020;382:2187-96.

RTP RESEARCH TO PRACTICE

Recent FDA Approvals of Next-Generation Antiandrogens in Nonmetastatic Castration-Resistant Prostate Cancer

Agent	Approval date	Pivotal study
Darolutamide	July 30, 2020	ARAMIS
Enzalutamide	July 12, 2018	PROSPER
Apalutamide	February 14, 2018	SPARTAN

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

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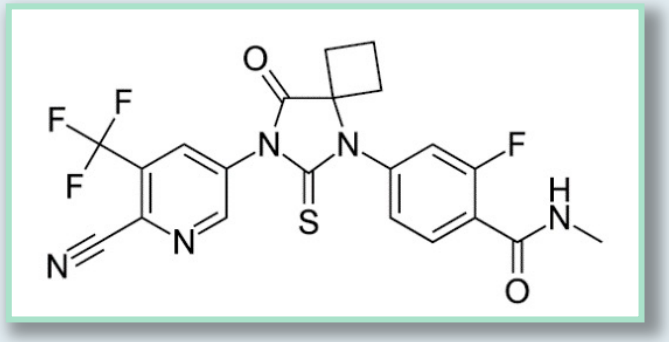
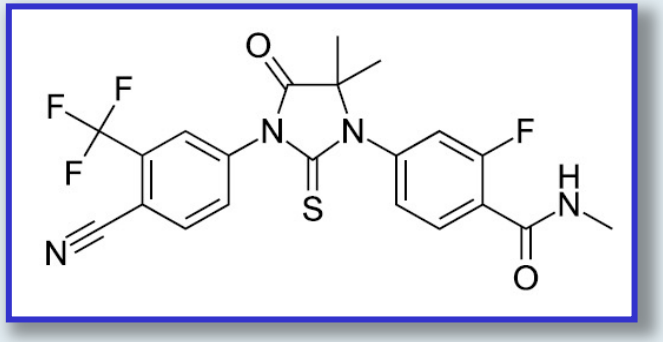
Next-Generation Androgen Receptor Inhibitors

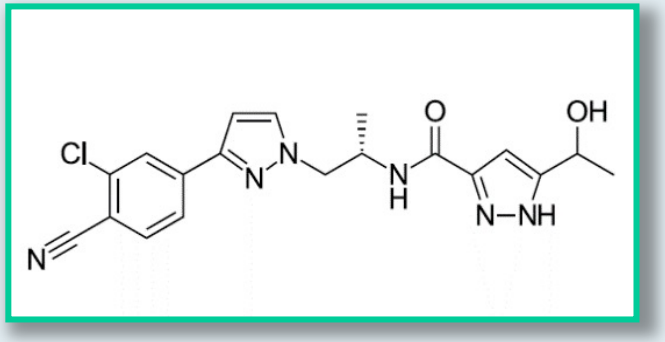
Apalutamide



Enzalutamide



Darolutamide

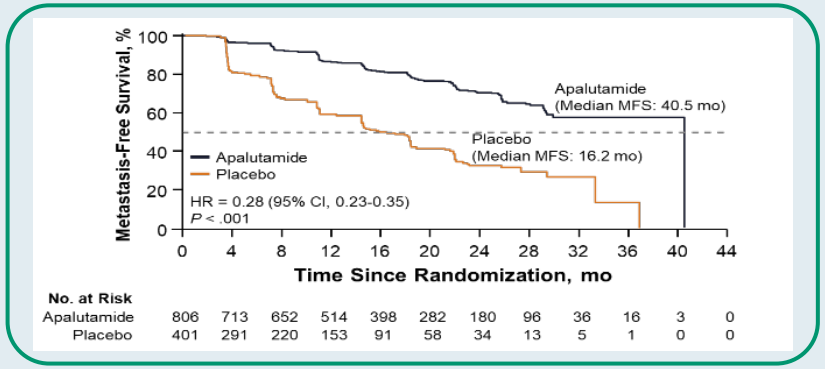


- Apalutamide and enzalutamide have similar structures
- Darolutamide is structurally distinct from apalutamide and enzalutamide, characterized by low blood–brain barrier penetration and may have improved tolerability

Zurth C et al. *J Clin Oncol* 2018;36(Suppl 6):Abstract 345; Sandmann S et al. Genitourinary Cancers Symposium 2019;Abstract 156.

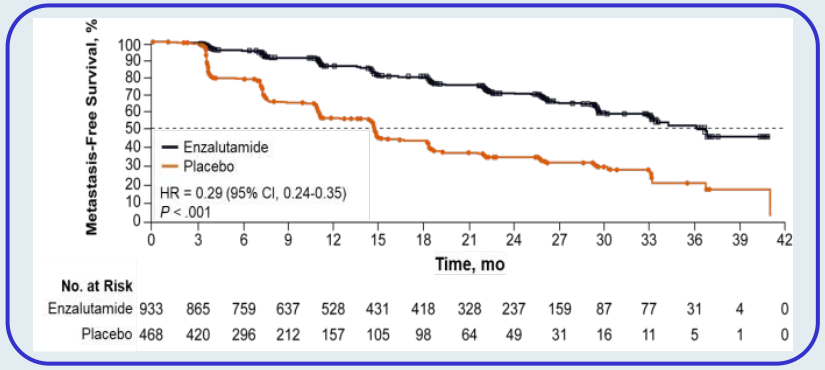
Primary Endpoint: Metastasis-Free Survival

SPARTAN[1]
Apalutamide



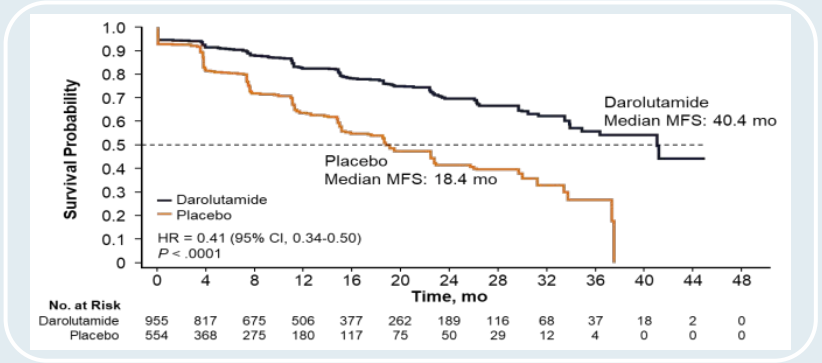
- 72% reduction of distant progression or death
- Median MFS: APA 40.5 vs PBO 16.2 months
- 24-month MFS benefit

PROSPER[2]
Enzalutamide



- 71% reduction of distant progression or death
- Median MFS: ENZA 36.6 vs PBO 14.7 months
- 22-month MFS benefit

ARAMIS[3]
Darolutamide



- 59% reduction of distant progression or death
- Median MFS: DARO 40.4 vs PBO 18.4 months
- 22-month MFS benefit

1. Smith MR et al. *NEJM* 2018;378:1408-18. 2. Hussain M et al. *NEJM* 2018;378:2465-74. 3. Fizazi K et al. *NEJM* 2019;380:1235-46.

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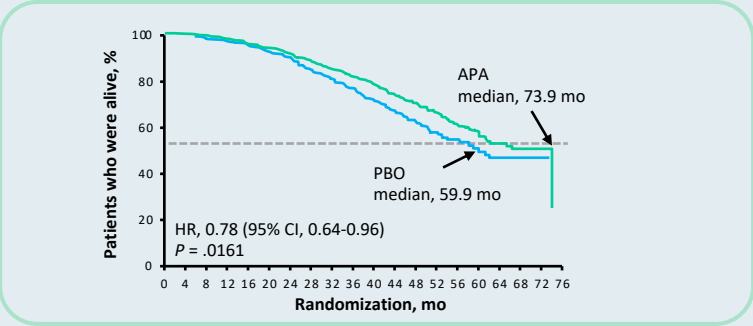
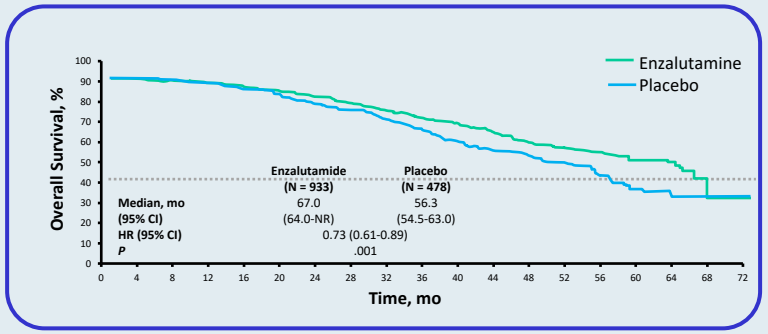
Secondary Endpoint: Overall Survival (OS)

SPARTAN1[1]
Apalutamide



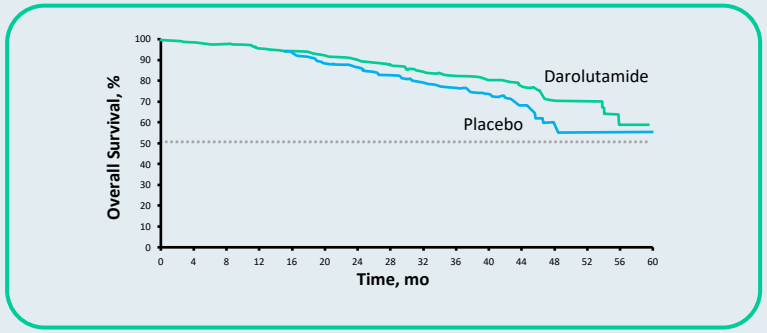
- 22% reduction in risk of death
- Median follow-up of 52.0 mo
- Median OS was significantly longer for apalutamide vs placebo
  - 73.9 mo vs 59.9 mo
  - **HR = 0.78 (95% CI 0.64-0.96); *p* = .016**

PROSPER[2]
Enzalutamide



- 27% reduction in risk of death
- Median follow-up of 48 mo
- Median OS was significantly longer for enzalutamide vs placebo
  - 67.0 mo vs 56.3 mo
  - **HR = 0.73 (95% CI 0.61-0.89); *p* = .001**

ARAMIS[3]
Darolutamide



- 31% reduction in risk of death
- Median follow-up of 29.0 mo
- Median OS was significantly longer for darolutamide vs placebo
  - **HR = 0.69 (95% CI, 0.53-0.88); *p* = .003**

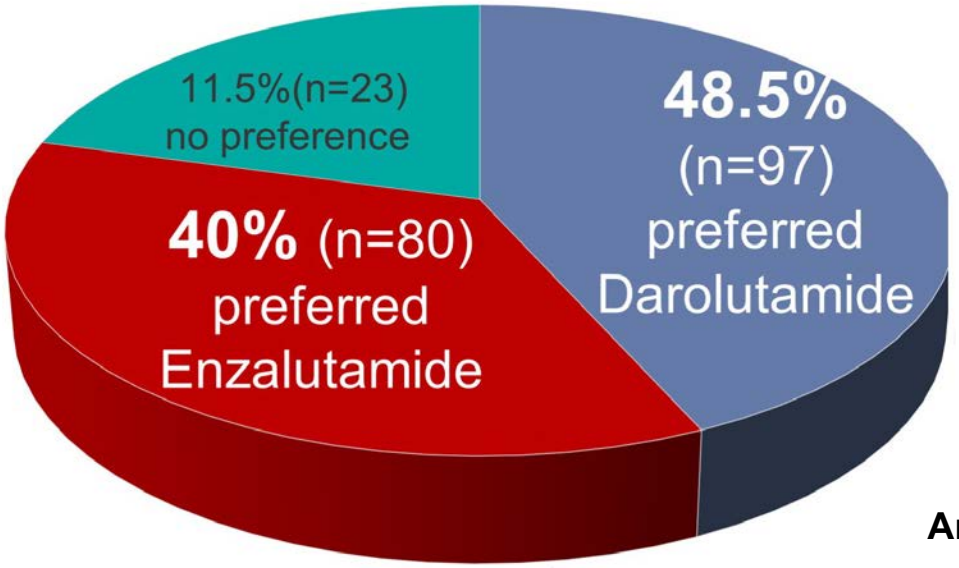
1. Smith MR et al. *Eur Urol* 2020;79:150-8. 2. Sternberg CN et al. *NEJM* 2020;382:2197-206. 3. Fizazi K et al. *NEJM* 2020;383:1040-9.

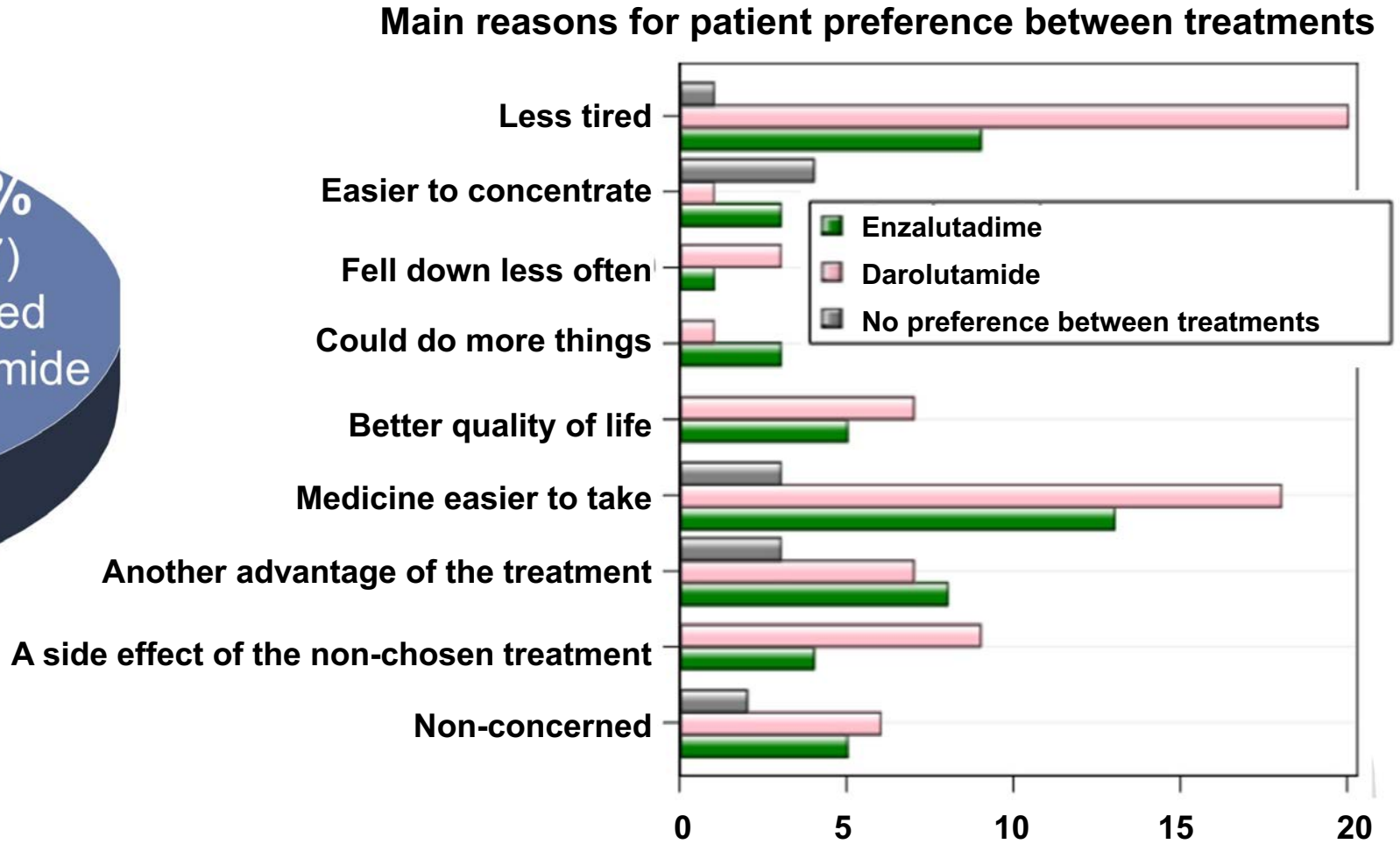
Comparison of Toxicities: Darolutamide, Enzalutamide, Apalutamide

Toxicity	ARAMIS		PROSPER		SPARTAN	
	Darolutamide	Placebo	Enzalutamide	Placebo	Apalutamide	Placebo
Fatigue/asthenia	16%	11%	33%	14%	30%	21%
Falling	4%	5%	11%	4%	16%	9%
Dizziness	5%	4%	10%	4%	9%	6%
Mental impairment	1%	2%	5%	2%	5%	3%

Sternberg CN et al; PROSPER Investigators. *N Engl J Med* 2020;382(23):2197-206.
Fizazi K et al; ARAMIS Investigators. *N Engl J Med* 2020;383:1040-9.
Small EJ et al; SPARTAN Investigators. ASCO 2020;Abstract 5516.

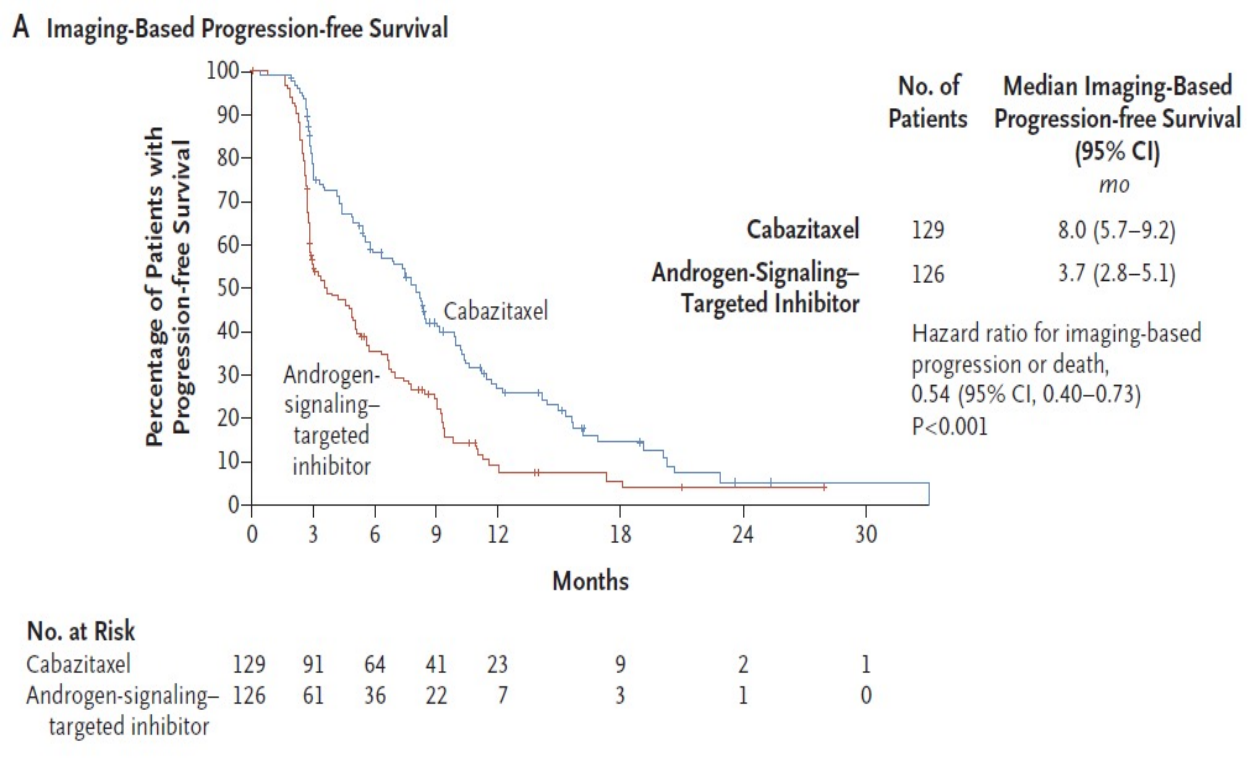
ODENZA: A Phase II Crossover Trial Evaluating Preference Between Darolutamide and Enzalutamide in Men with Asymptomatic or Mildly Symptomatic mCRPC

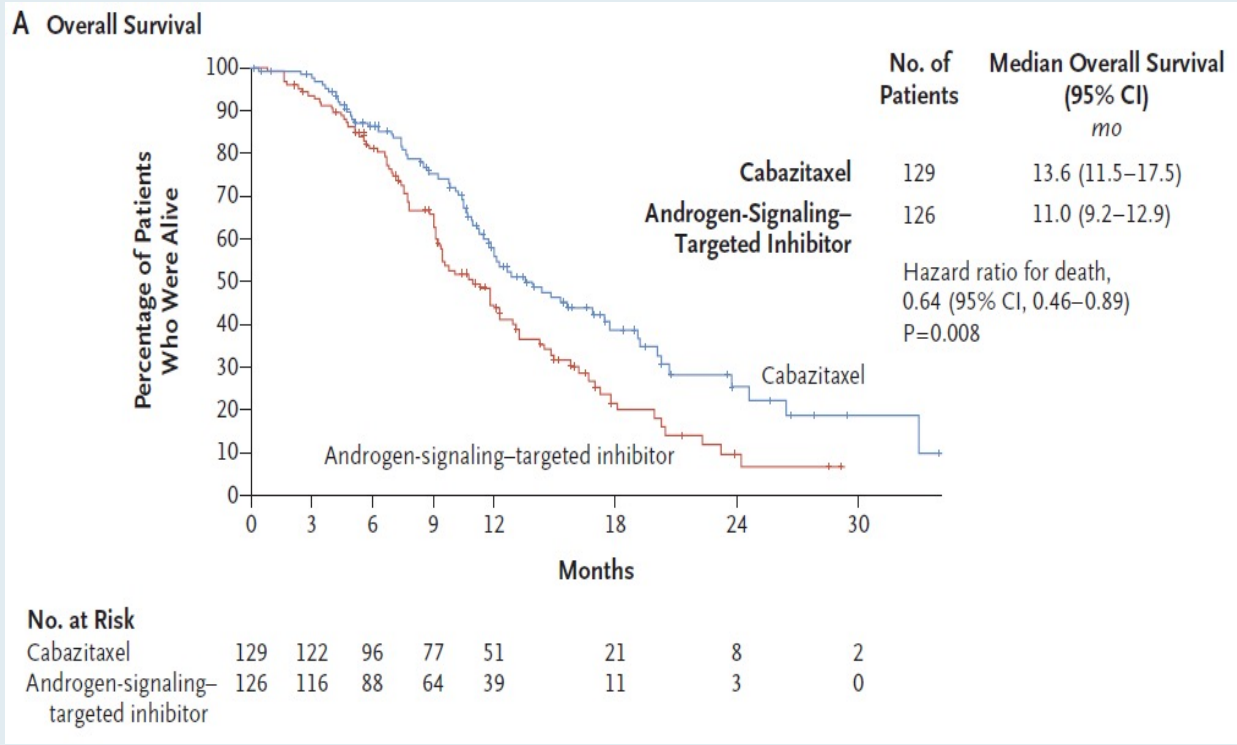




Colomba E et al. ASCO 2021;Abstract 5046.

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





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

RTP RESEARCH TO PRACTICE

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

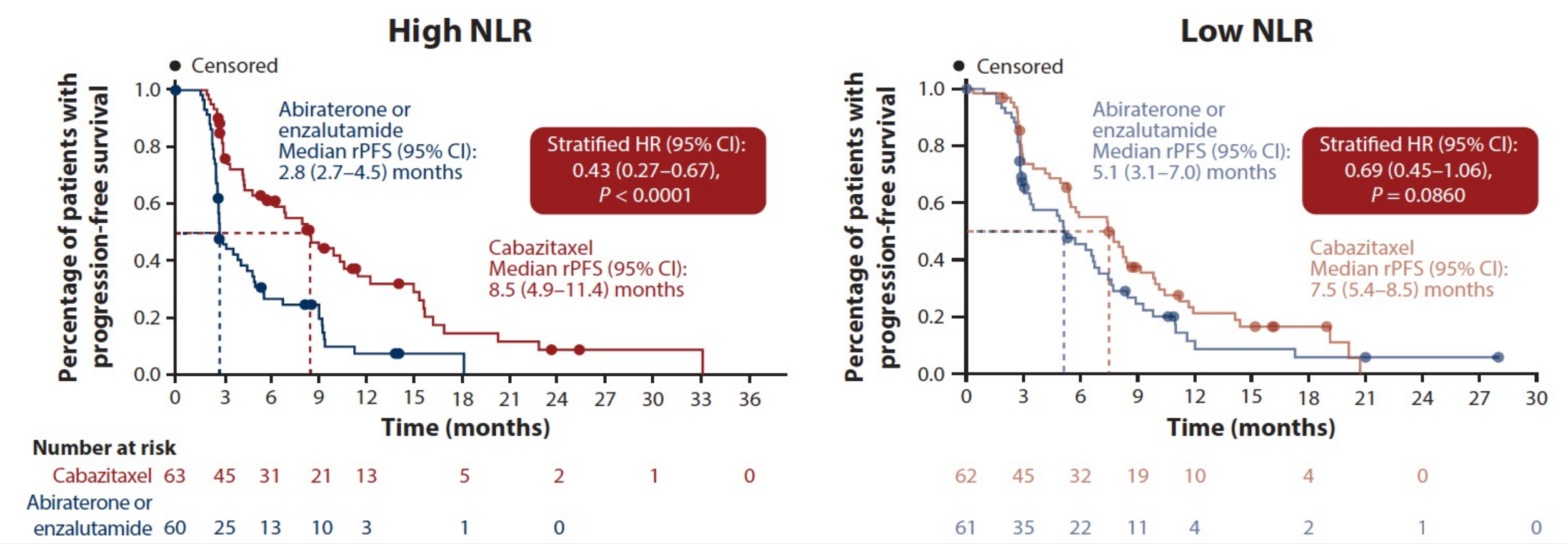
Baseline neutrophil-to-lymphocyte ratio as a predictive and prognostic biomarker in patients with metastatic castration-resistant prostate cancer treated with cabazitaxel versus abiraterone or enzalutamide in the CARD study

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].

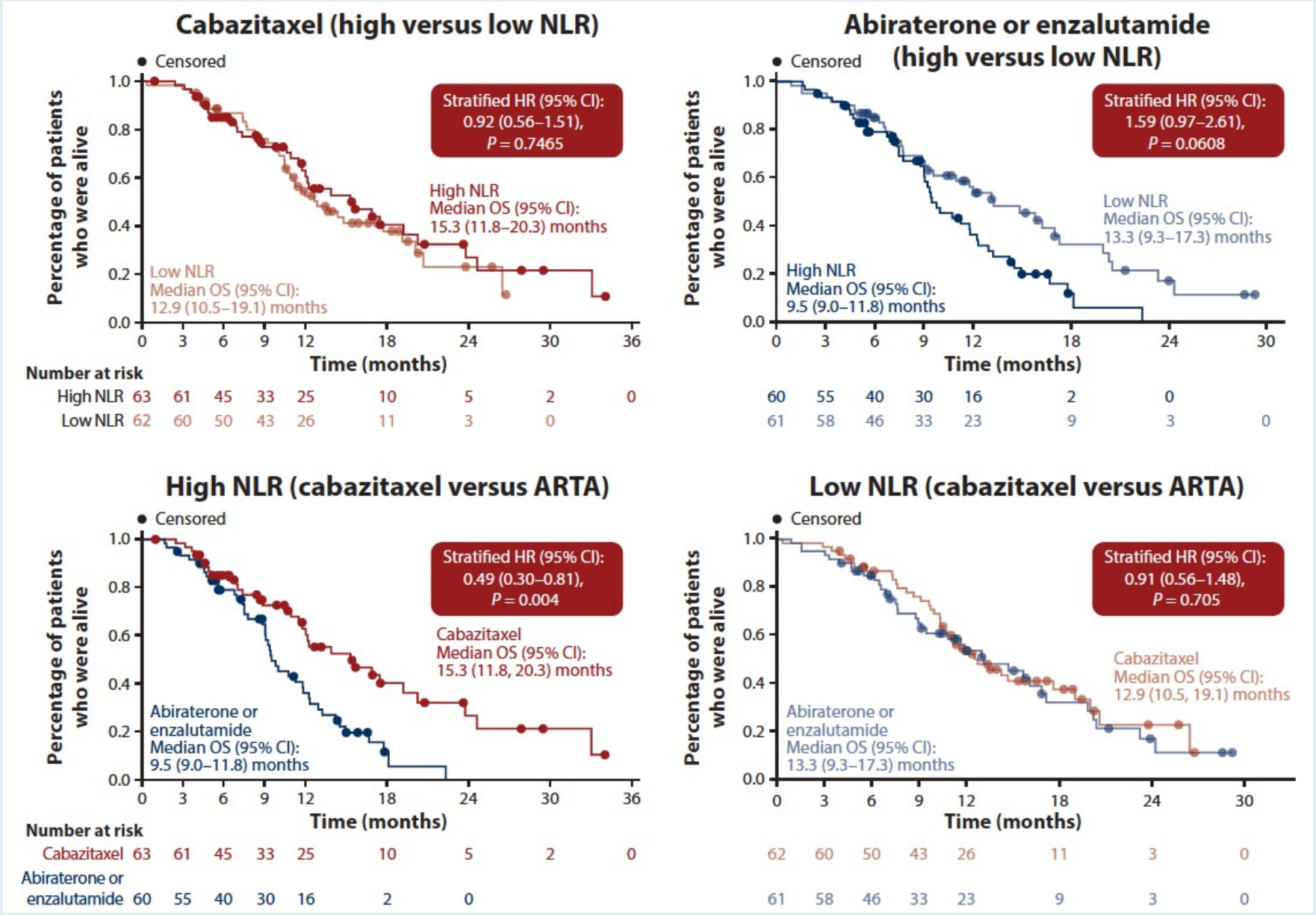
RTP RESEARCH TO PRACTICE

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].

RTP RESEARCH TO PRACTICE

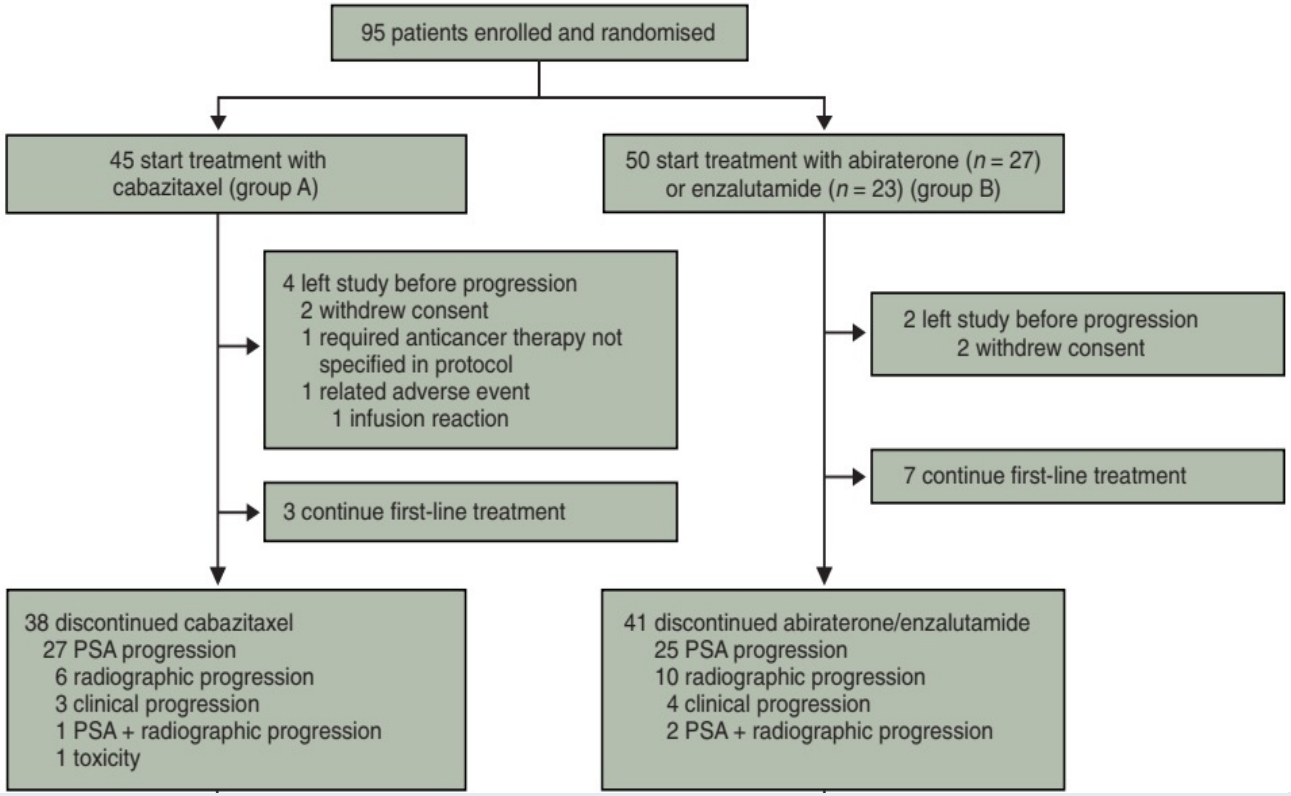
The Canadian Trial (Phase II OZM-054 Trial)

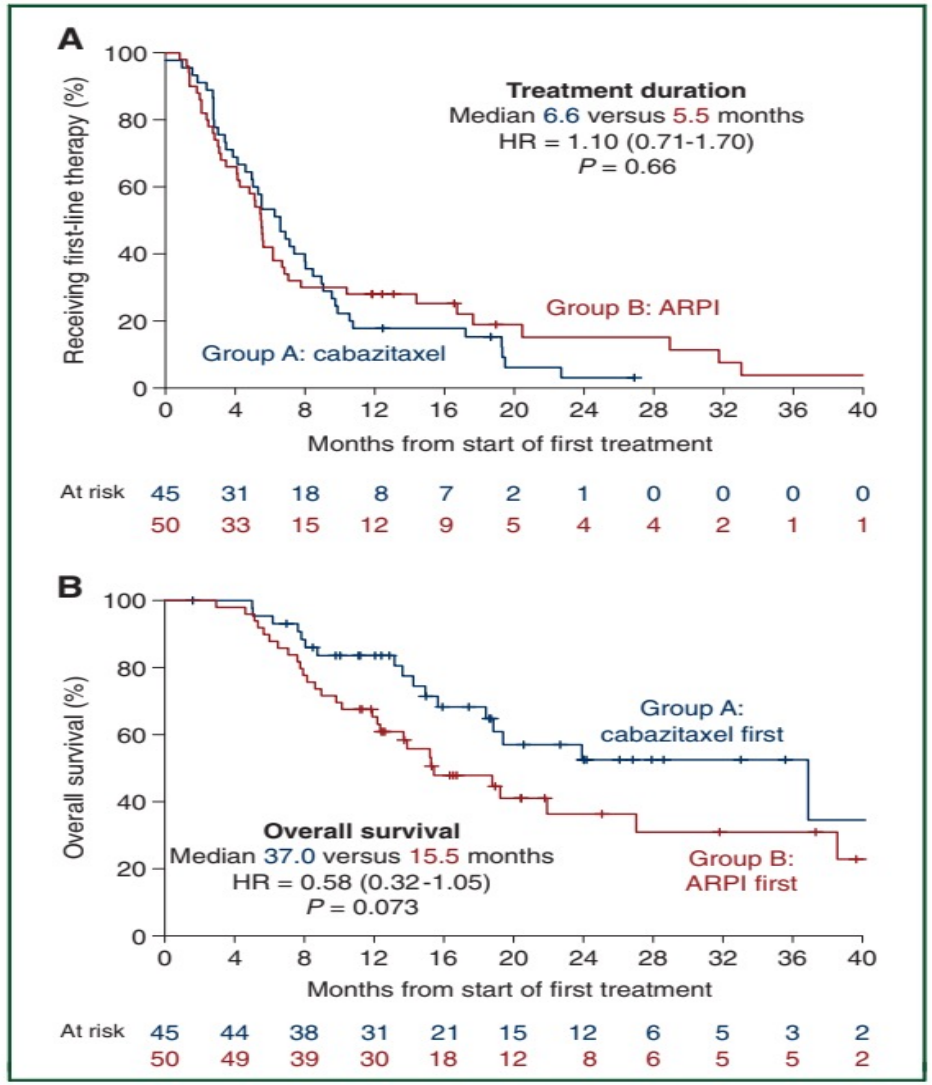
Poor prognosis:

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.

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

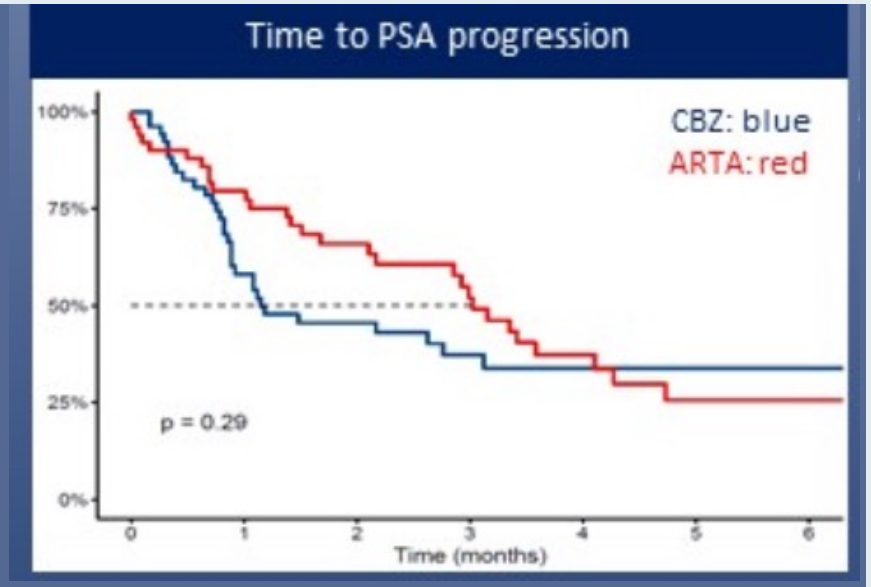
R

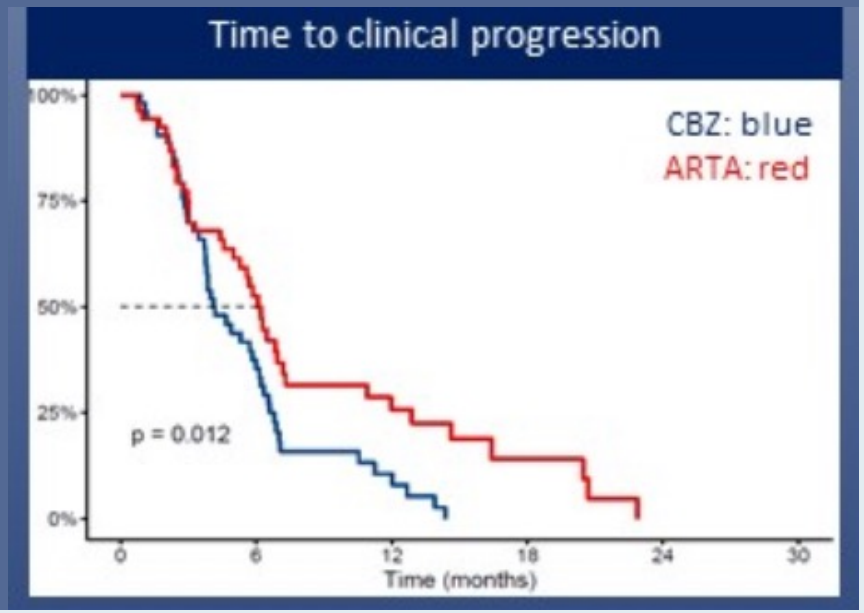
Cabazitaxel

Abiraterone/P OR enzalutamide

12 weeks CBR

Follow-up for secondary endpoints

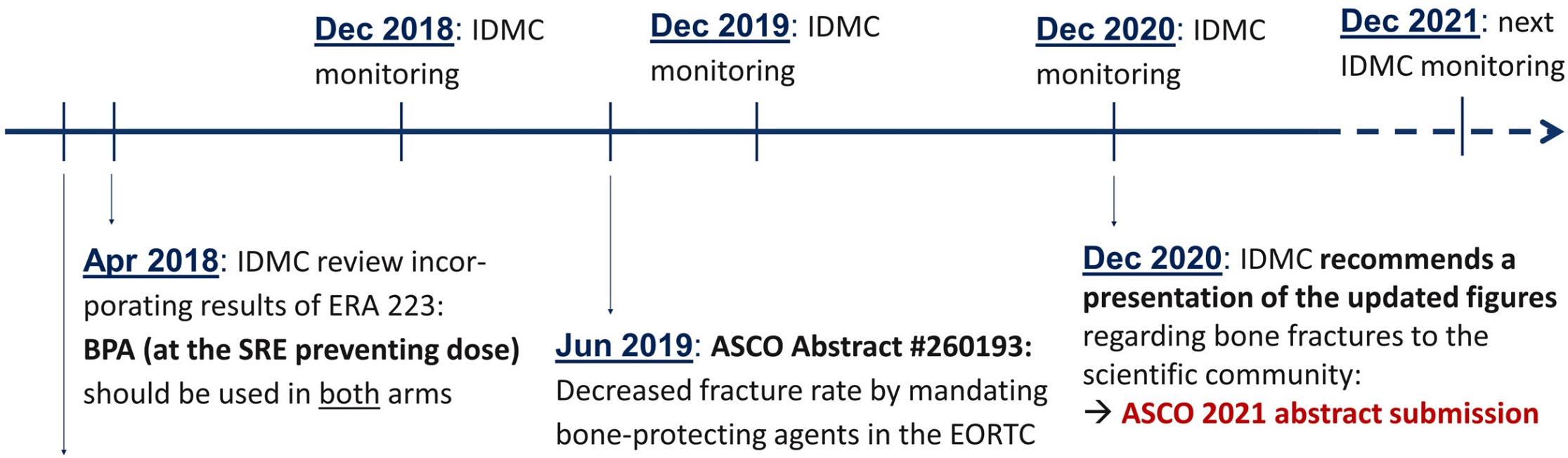




van der Zande K et al. *ASCO* 2021;Abstract 5059.

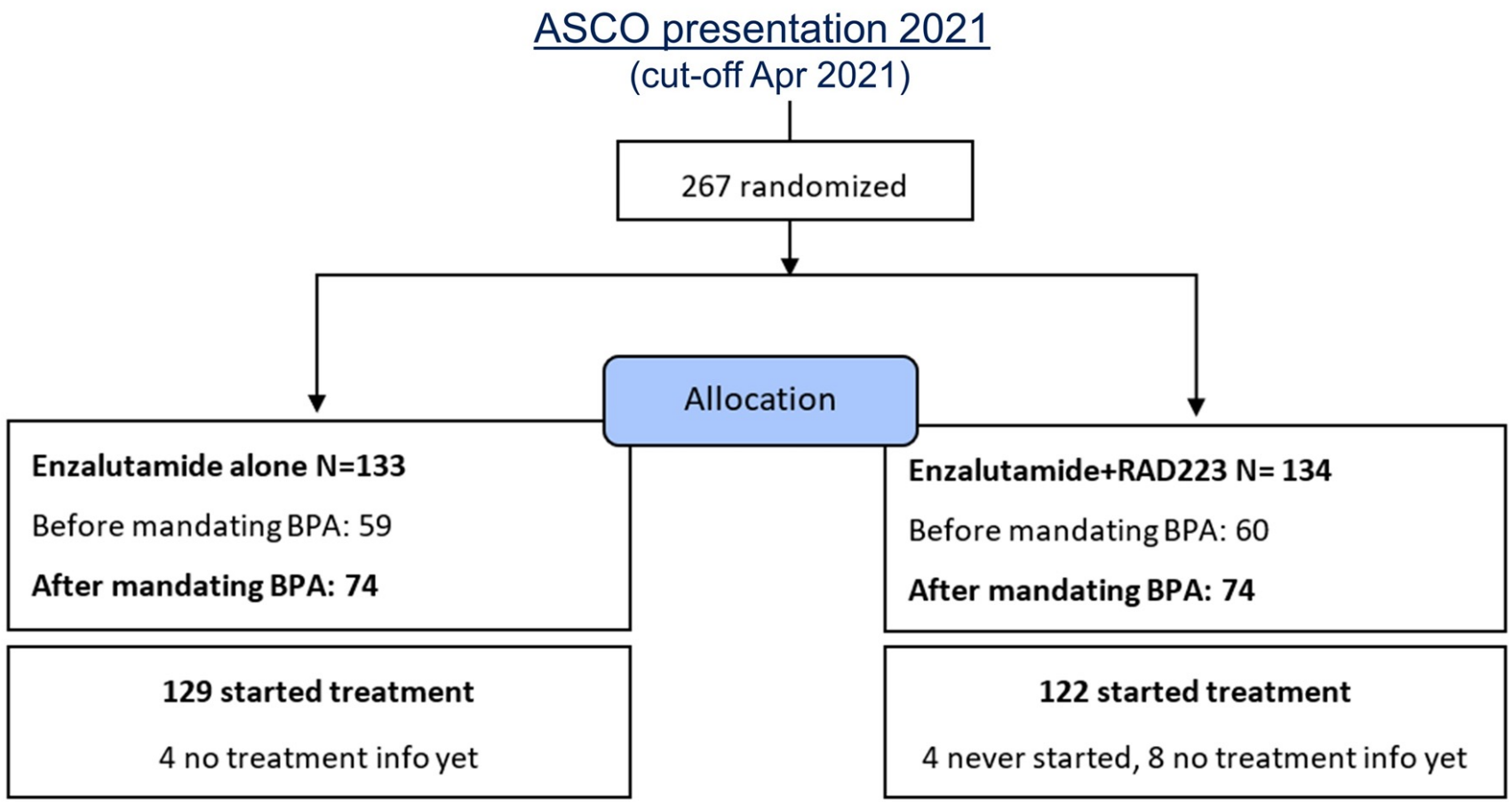
RTP RESEARCH TO PRACTICE

PEACE III: Timelines, Impact of the ERA 223 Trial and Role of IDMC



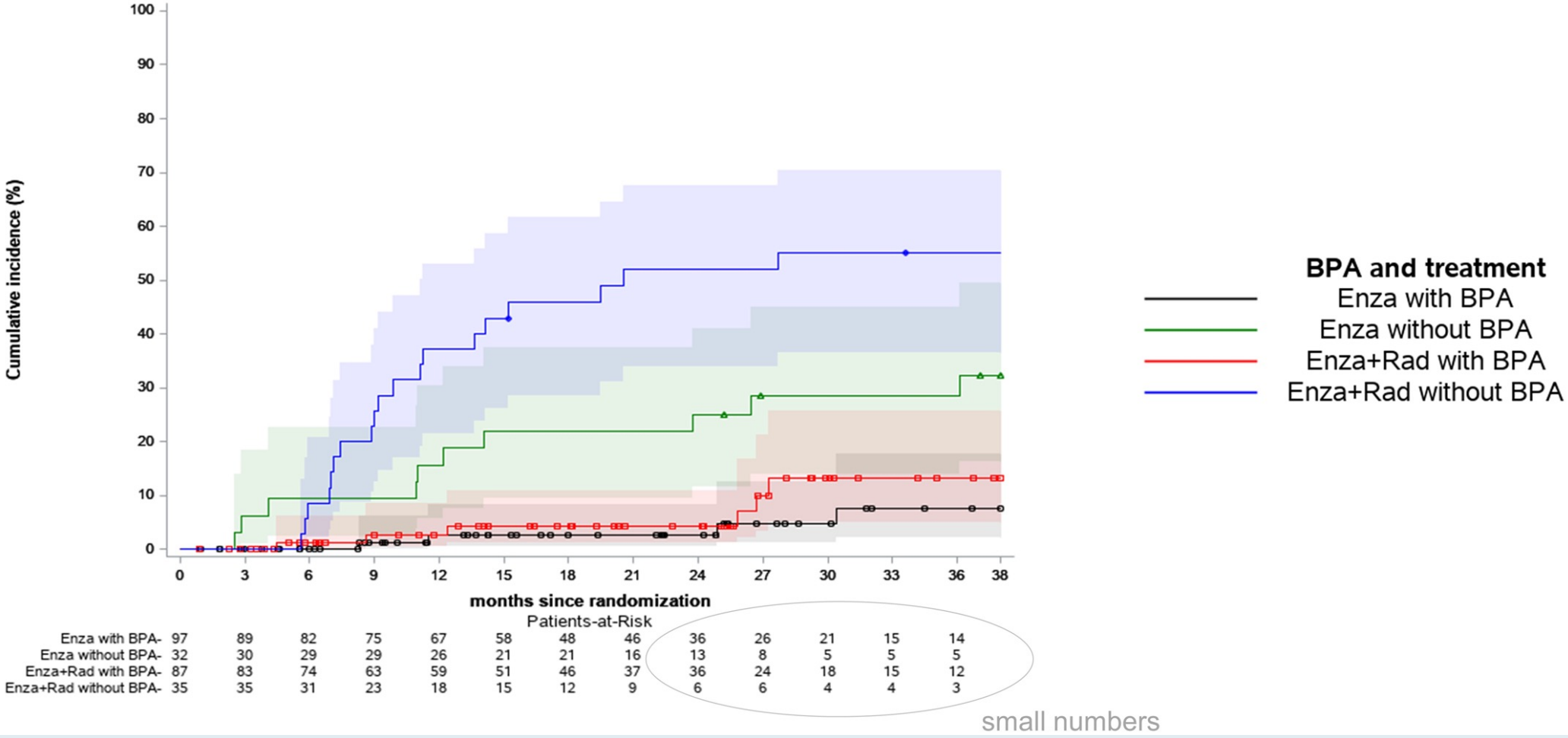
Gillessen S et al. ASCO 2021;Abstract 5002.

PEACE III: Impact of Bone-Protecting Agents (BPA) on Fracture Rates



Gillessen S et al. ASCO 2021;Abstract 5002.

PEACE III: Cumulative Incidence of Fractures by Treatment Arm and Use of BPA



Gillessen S et al. ASCO 2021;Abstract 5002.

RTP RESEARCH TO PRACTICE

PEACE III: Bone Fractures and Cumulative Incidence – Safety Population

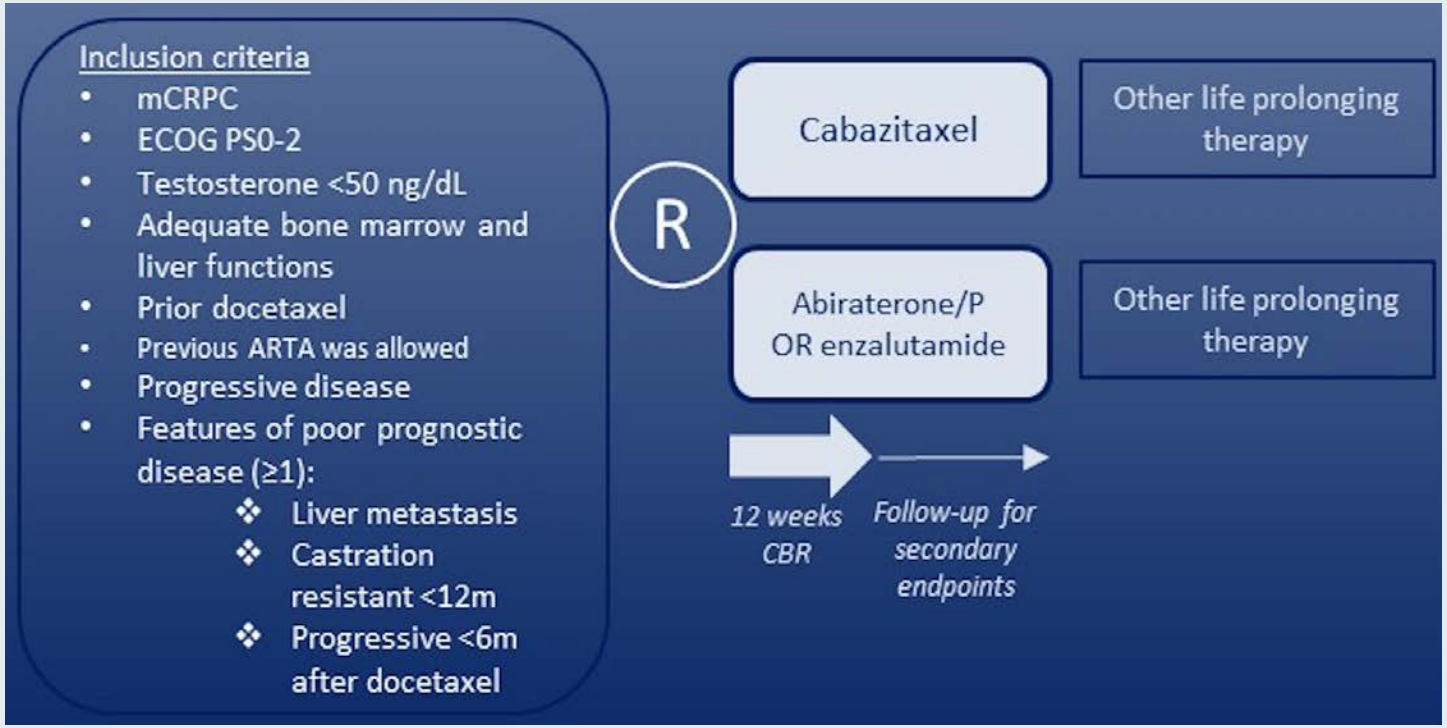
Time point	Without BPA		With BPA	
	Enza+Rad (N=35)	Enza (N=32)	Enza+Rad (N=87)	Enza (N=97)
	Cum Incidence (95% CI)	Cum Incidence (95% CI)	Cum Incidence (95% CI)	Cum Incidence (95% CI)
9 months	25.7 (12.6-41.0)	9.4 (2.3-22.5)	2.7 (0.5-8.5)	1.3 (0.1-6.1)
12 months	**37.1 (21.3-53.0)**	**15.6 (5.6-30.3)**	**2.7 (0.5-8.5)**	**2.6 (0.5-8.3)**
15 months	42.9 (26.1-58.6)	21.9 (9.5-37.5)	4.3 (1.1-10.9)	2.6 (0.5-8.3)
18 months	**45.9 (28.6-61.6)**	**21.9 (9.5-37.5)**	**4.3 (1.1-10.9)**	**2.6 (0.5-8.3)**
21 months	52.0 (33.8-67.5)	21.9 (9.5-37.5)	4.3 (1.1-10.9)	2.6 (0.5-8.3)

Gillessen S et al. ASCO 2021;Abstract 5002.

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.

OSTRICh: First Results with CBZ versus an ARTA for Patients with Poor-Prognosis mCRPC

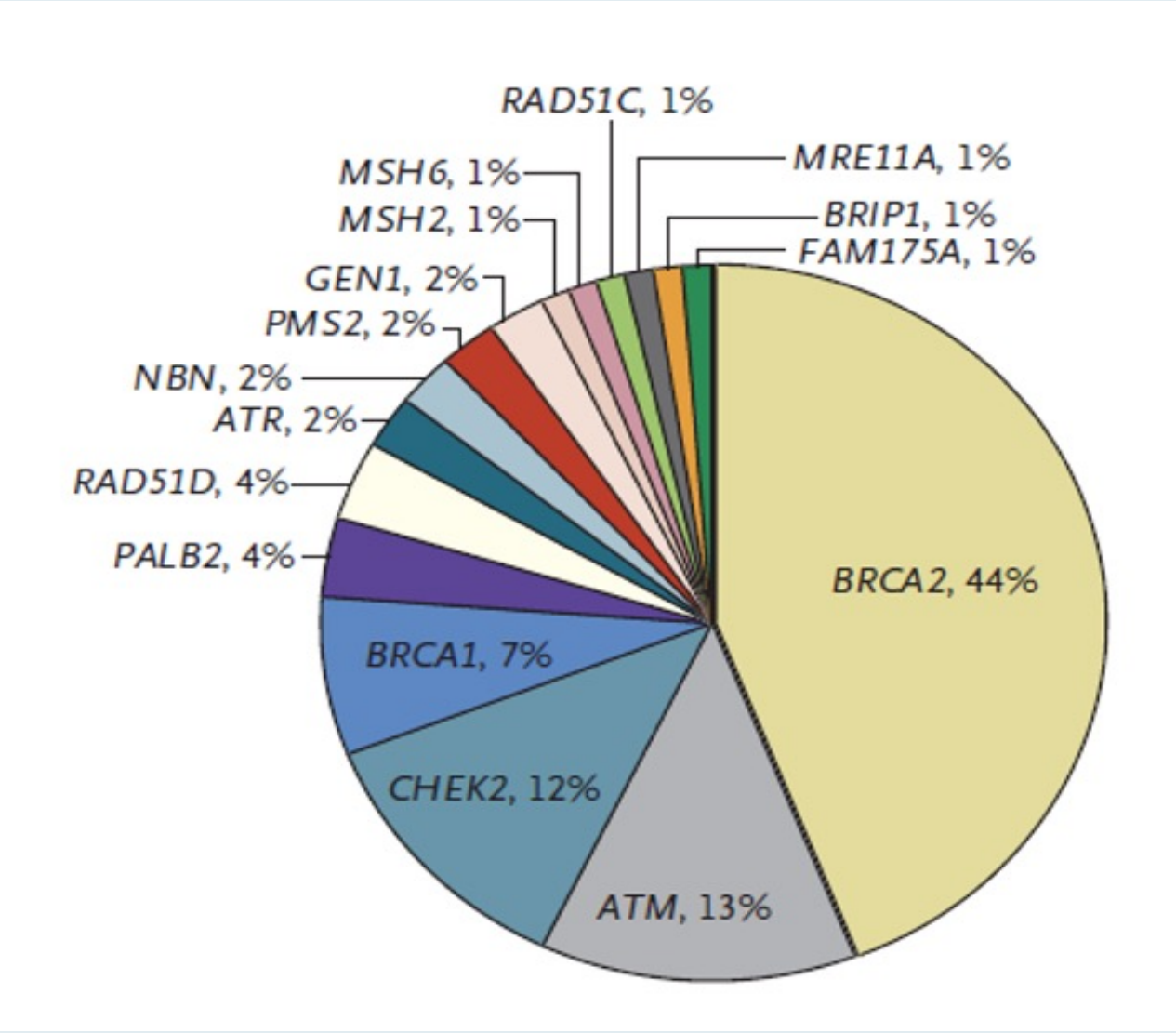


- No significant difference in CBR between CBZ and ARTA treated patients at 12 weeks
- Visceral metastases were more frequent in CBZ patients
- Radiological response and stable disease at 12 weeks was significantly higher in patients treated with CBZ than with ARTA
- Time to clinical progression was significantly prolonged in patients treated with ARTA
- Overall survival and rPFS was similar in both groups

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

Integration of PARP Inhibitors into the Management of mCRPC

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

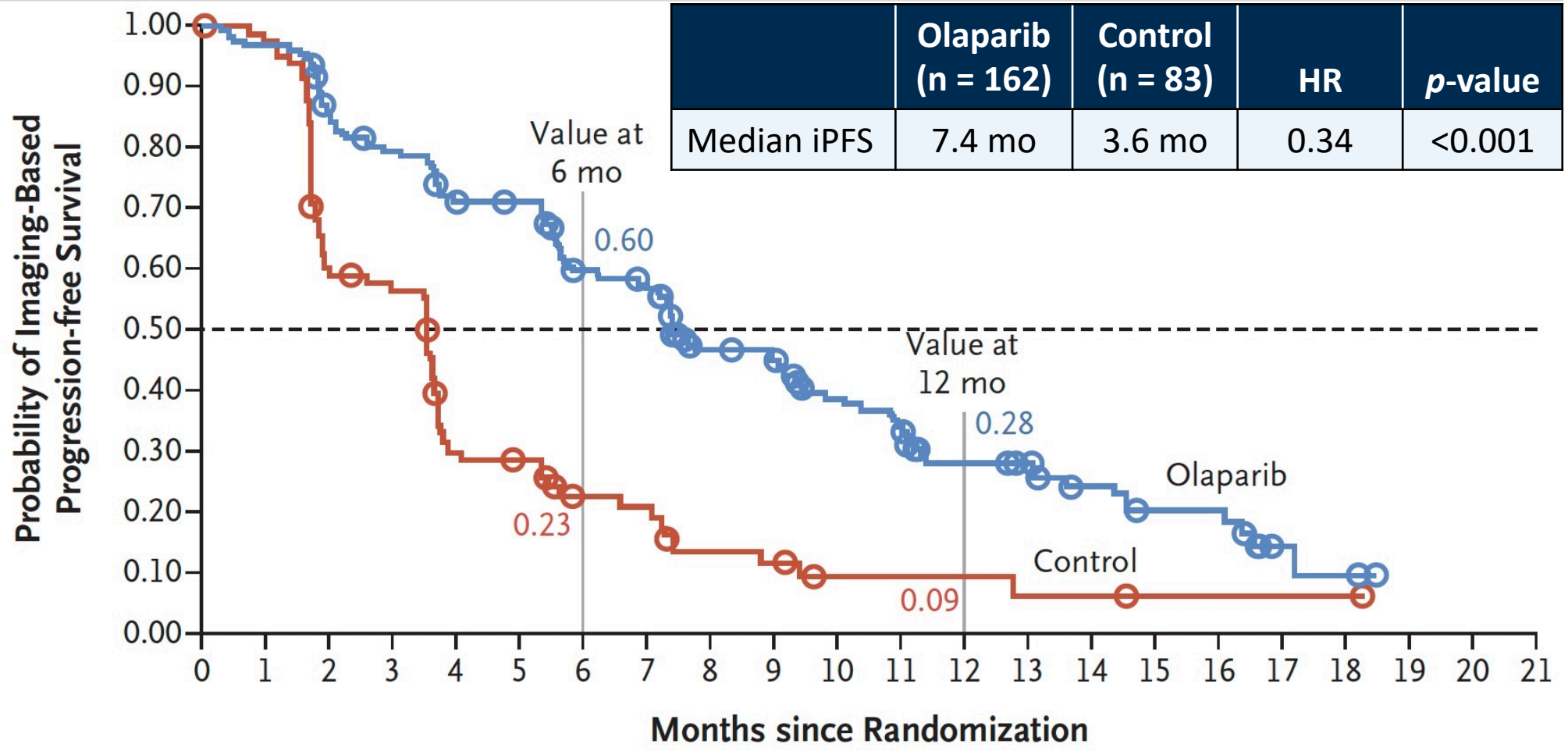
Olaparib for Metastatic Castration-Resistant Prostate Cancer

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

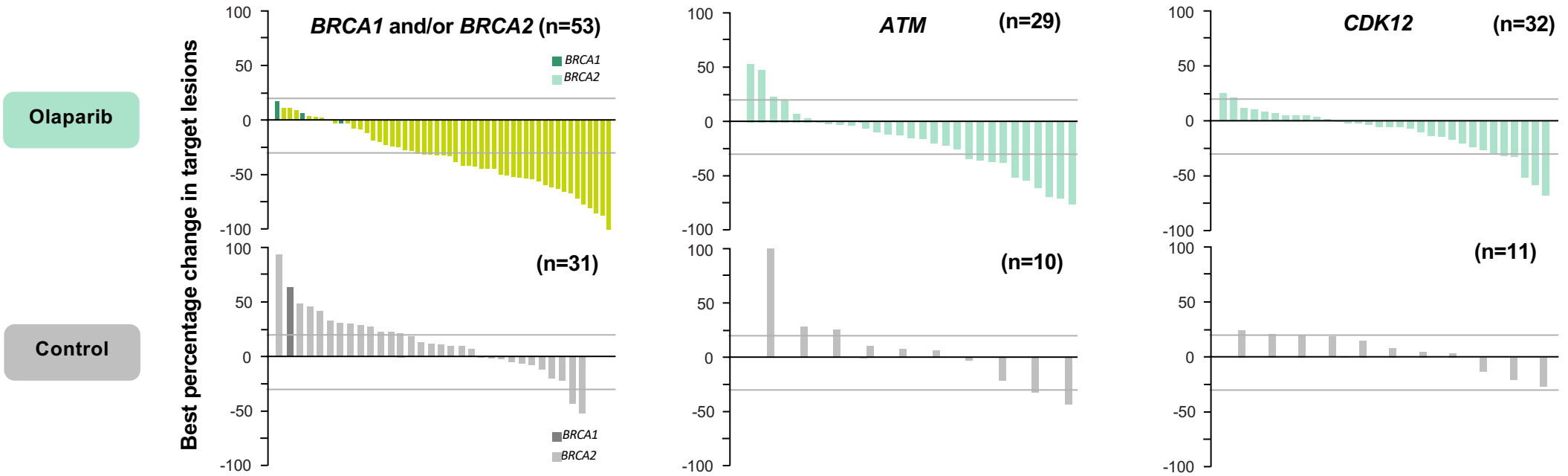


de Bono J et al; PROfound investigators. *N Engl J Med* 2020;382(22):2091-102.

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

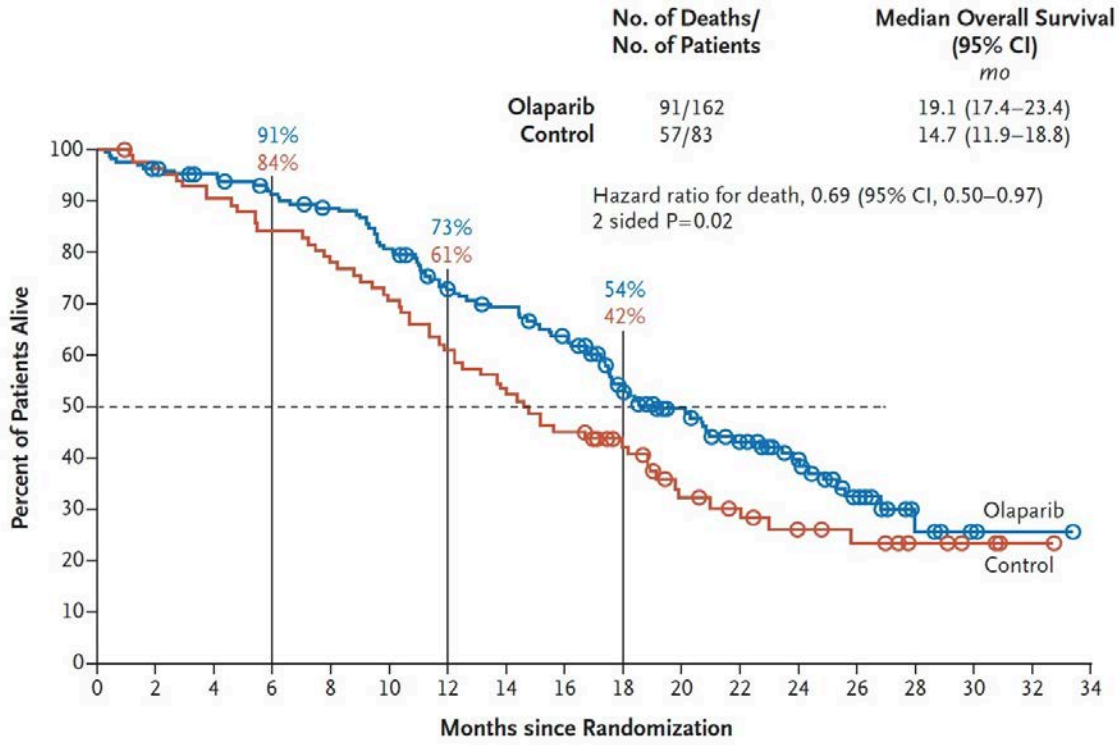
Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer

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*

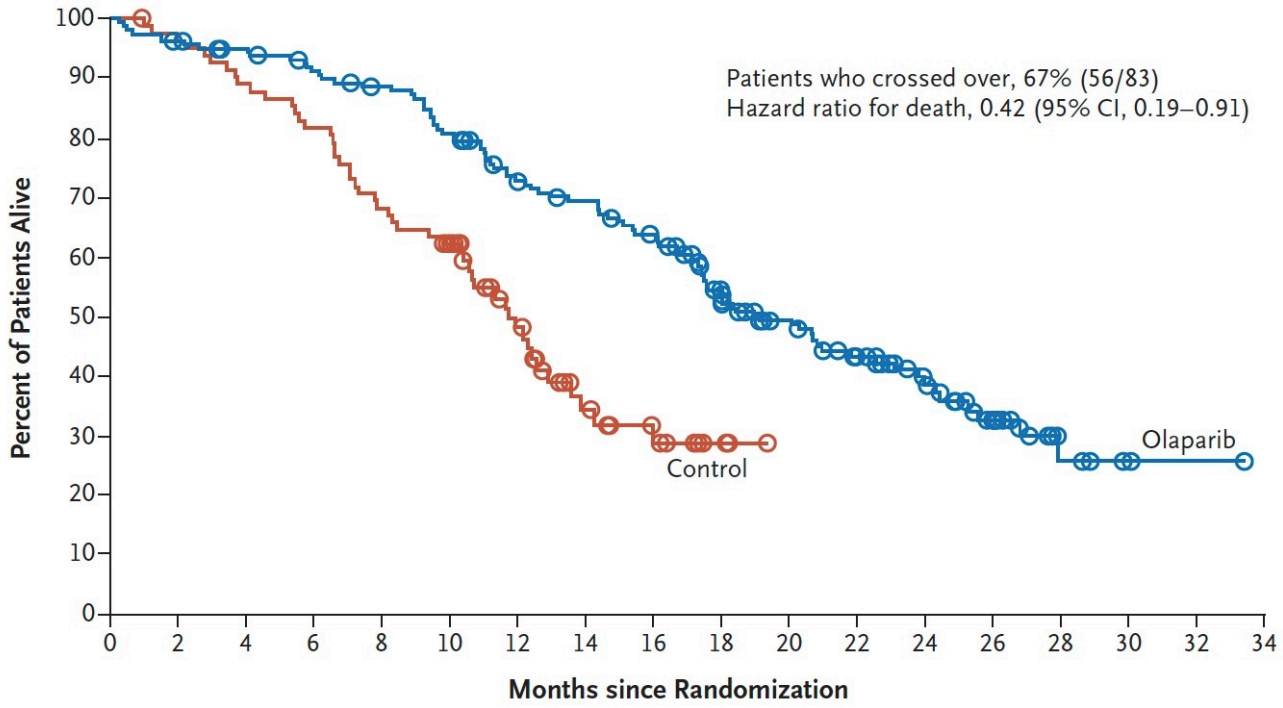
***N Engl J Med* 2020;383(24):2345-57.**

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

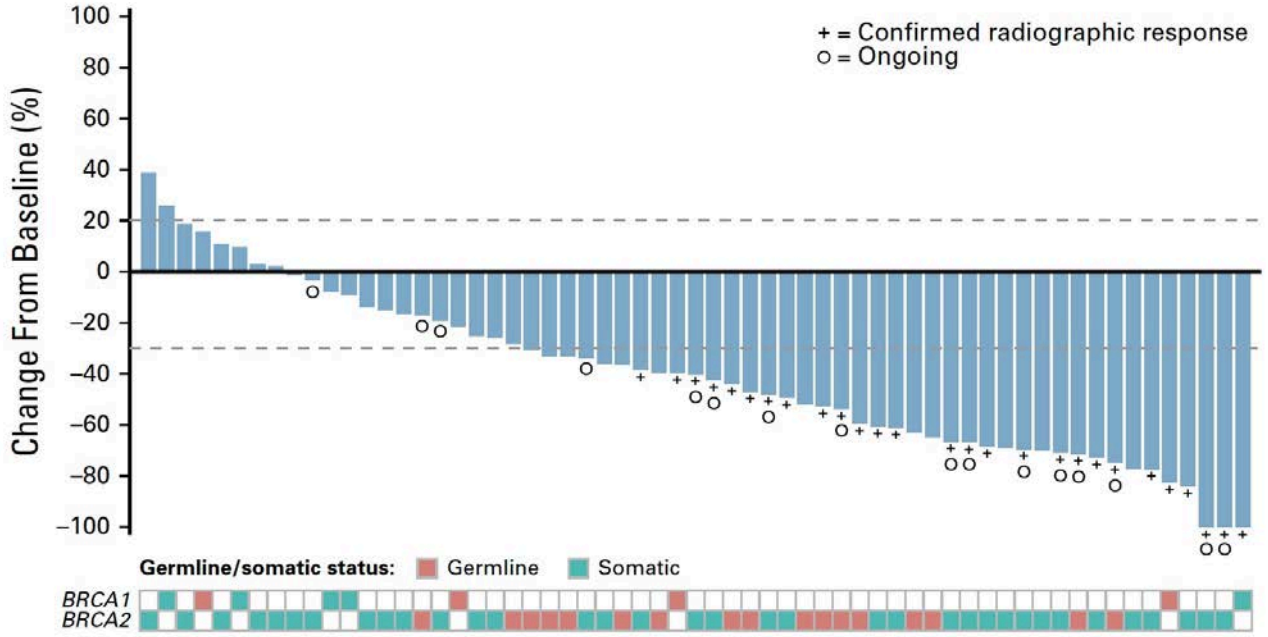
Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a *BRCA1* or *BRCA2* Gene Alteration

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

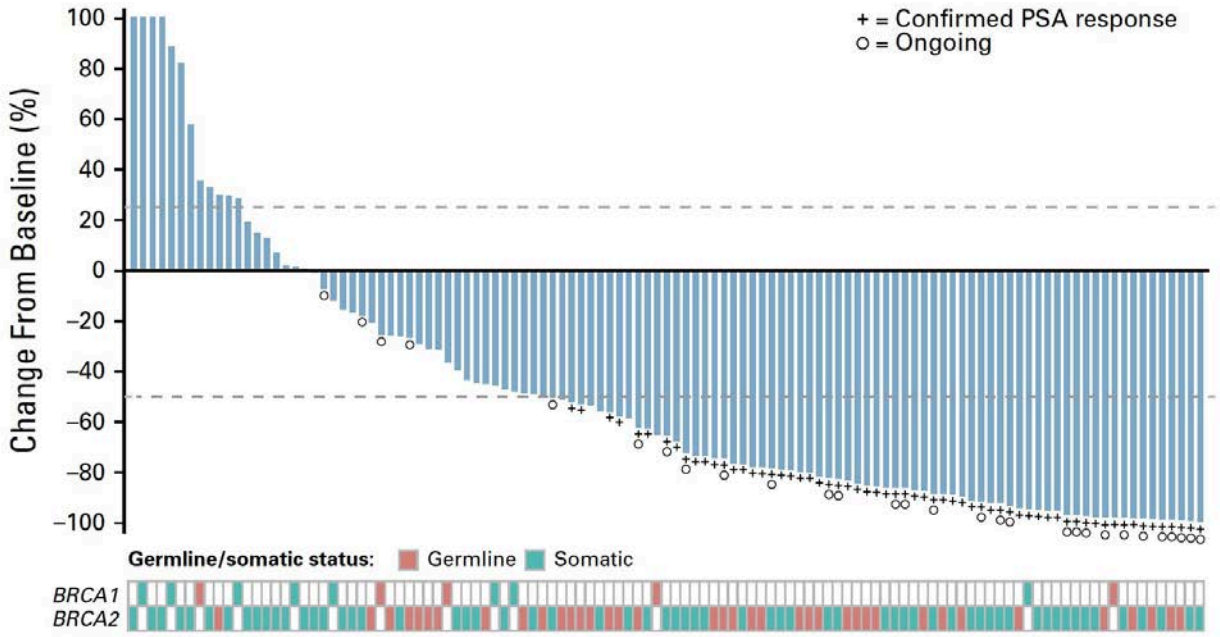
J Clin Oncol 2020;38(22):3763-72.

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%

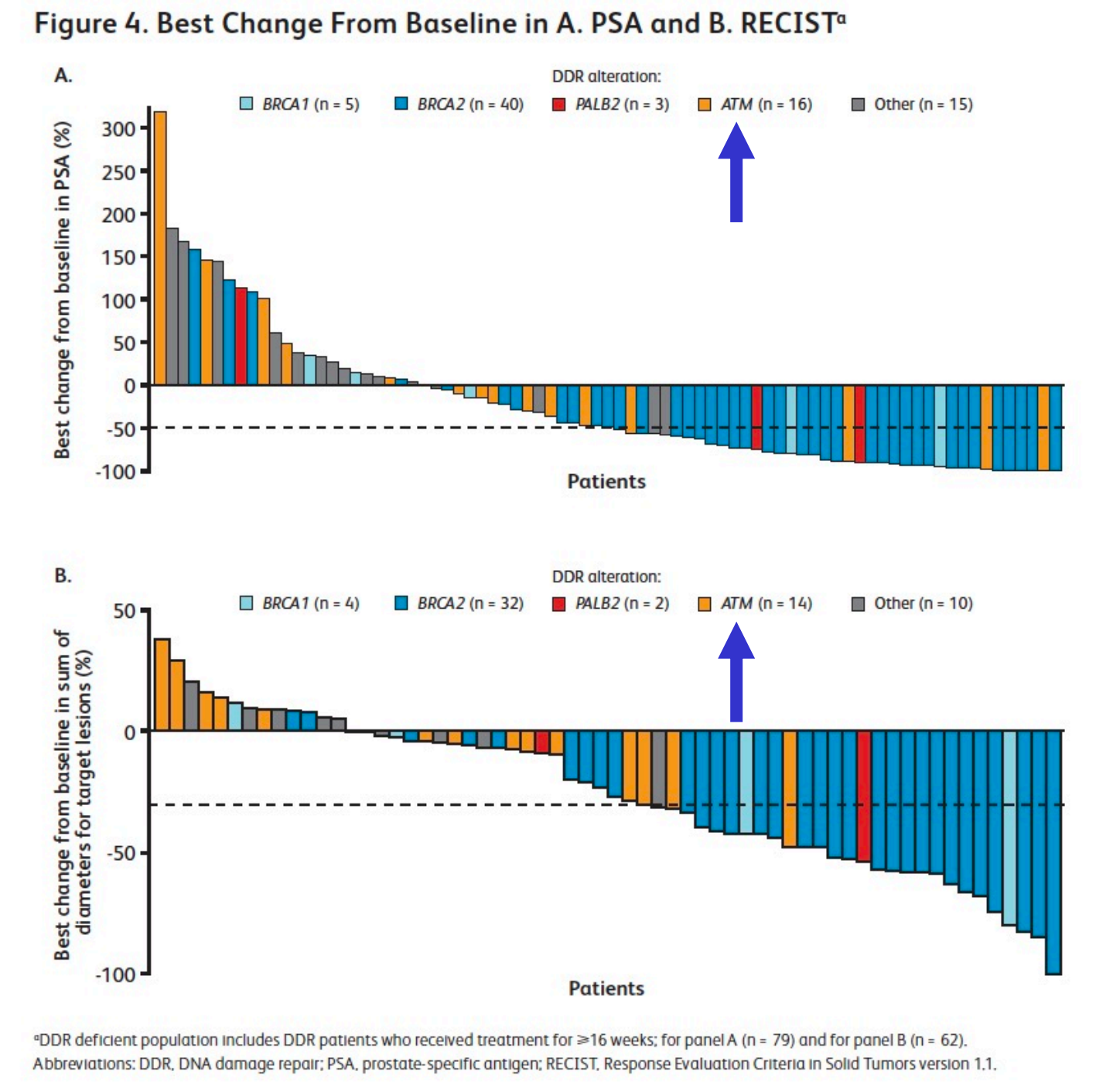


Abida W et al. TRITON2 investigators. *J Clin Oncol* 2020;38(32):3763-72.

RTP RESEARCH TO PRACTICE

Talazoparib in mCRPC (TALAPRO-1)

BRCA in blue
ATM loss in orange
PALB2 in red

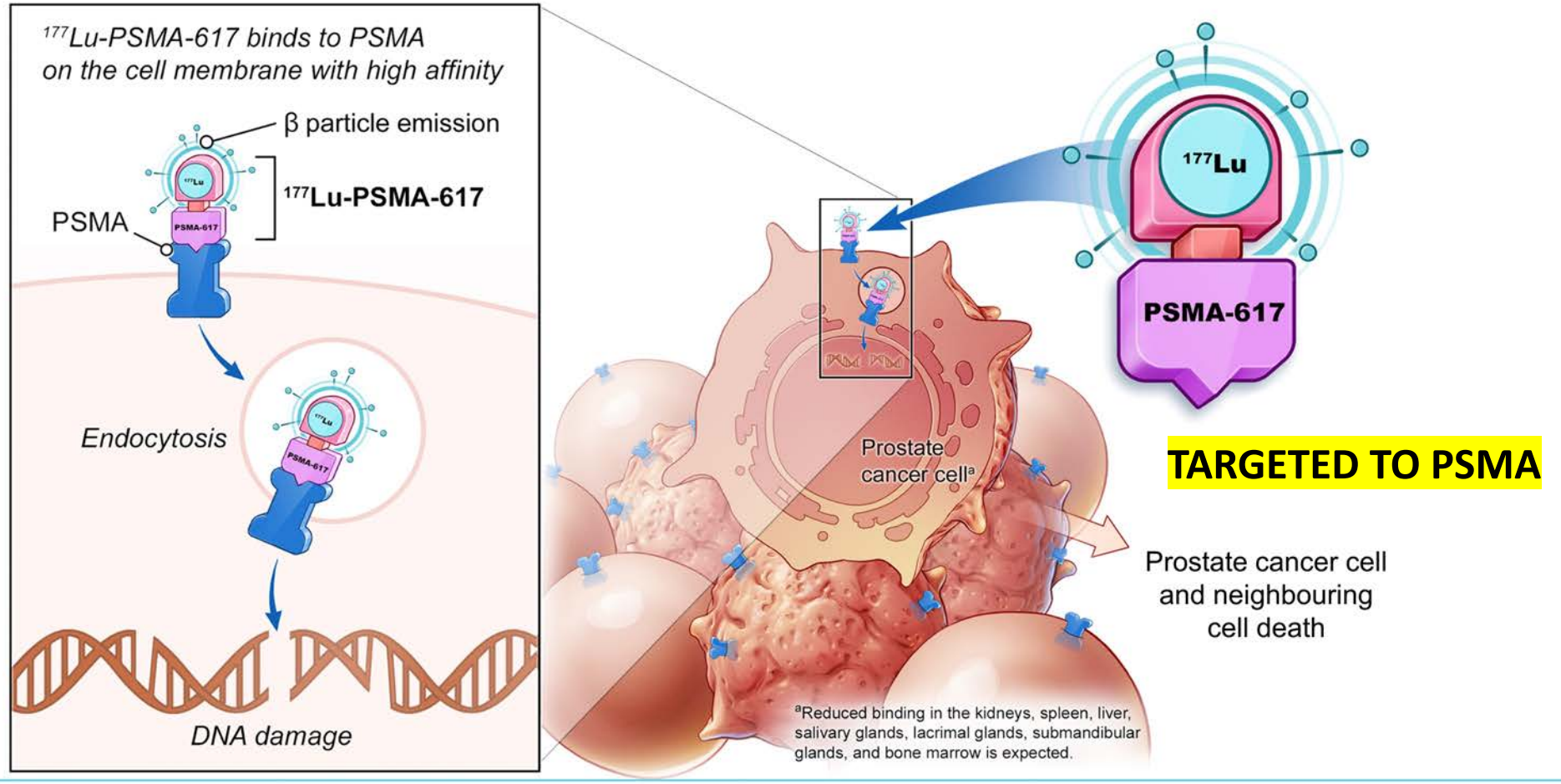


de Bono JS et al. *Lancet Oncol* 2021;22(9):1250-64.

RTP RESEARCH TO PRACTICE

Novel and Investigational Strategies for Patients with mCRPC

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

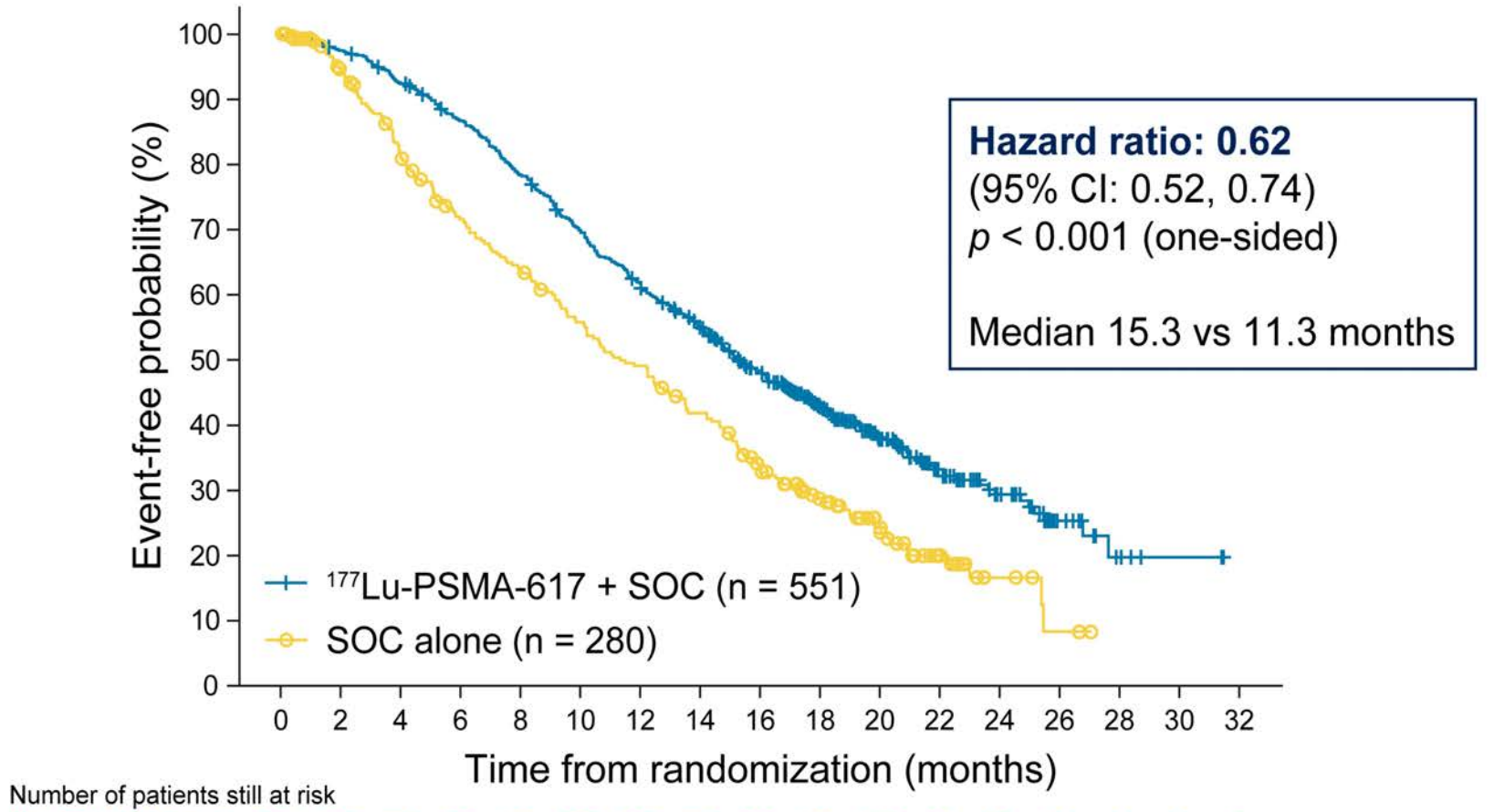


Morris MJ et al. ASCO 2021;Abstract LBA4.

VISION: OS with the Addition of ^{177}Lu-PSMA to Standard Therapy for mCRPC

Primary analysis

All randomized patients
(N = 831)



Number of patients still at risk

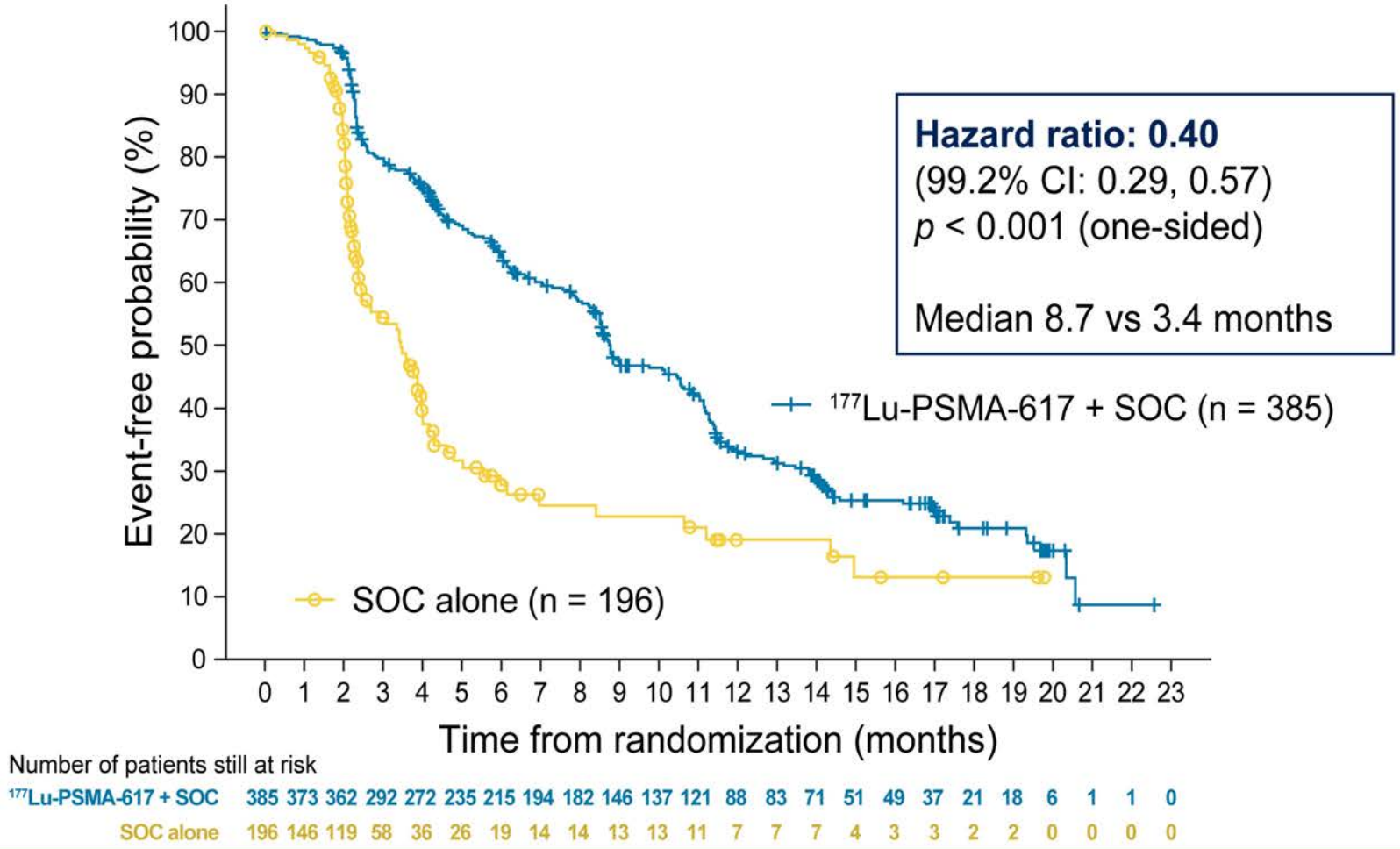
^{177}Lu-PSMA-617 + SOC	551	535	506	470	425	377	332	289	236	166	112	63	36	15	5	2	0
SOC alone	280	238	203	173	155	133	117	98	73	51	33	16	6	2	0	0	0

Morris MJ et al. ASCO 2021;Abstract LBA4.

VISION: rPFS with Addition of ^{177}Lu-PSMA to Standard Therapy for mCRPC

Primary analysis

rPFS analysis set (n = 581)



Morris MJ et al. ASCO 2021;Abstract LBA4.

RTP RESEARCH TO PRACTICE

VISION: Treatment-Related Adverse Events

Patients, n (%)	All grades		Grade 3–5	
	^{177}Lu-PSMA-617 + SOC (n = 529)	SOC alone (n = 205)	^{177}Lu-PSMA-617 + SOC (n = 529)	SOC alone (n = 205)
Fatigue	260 (49.1)	60 (29.3)	37 (7.0)	5 (2.4)
Bone marrow suppression	251 (47.4)	36 (17.6)	124 (23.4)	14 (6.8)
Leukopenia	66 (12.5)	4 (2.0)	13 (2.5)	1 (0.5)
Lymphopenia	75 (14.2)	8 (3.9)	41 (7.8)	1 (0.5)
Anemia	168 (31.8)	27 (13.2)	68 (12.9)	10 (4.9)
Thrombocytopenia	91 (17.2)	9 (4.4)	42 (7.9)	2 (1.0)
Dry mouth	208 (39.3)	2 (1.0)	0 (0.0)	0 (0.0)
Nausea and vomiting	208 (39.3)	35 (17.1)	8 (1.5)	1 (0.5)
Renal effects	46 (8.7)	12 (5.9)	18 (3.4)	6 (2.9)
Second primary malignancies	11 (2.1)	2 (1.0)	4 (0.8)	1 (0.5)
Intracranial hemorrhage	7 (1.3)	3 (1.5)	5 (0.9)	2 (1.0)

Morris MJ et al. ASCO 2021;Abstract LBA4.

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]

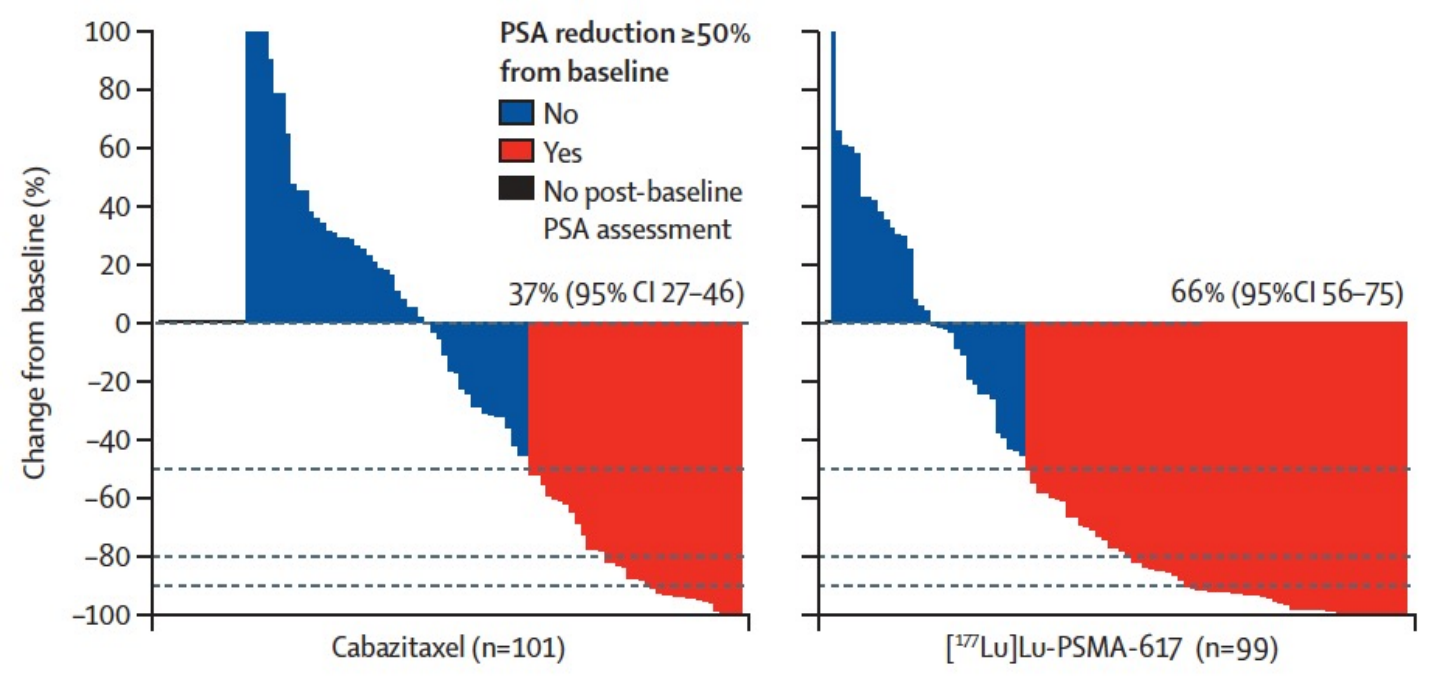
Michael S Hofman, Louise Emmett, Shahneen Sandhu, Amir Iravani, Anthony M Joshua, Jeffrey C Goh, David A Pattison, Thean Hsiang Tan, Ian D Kirkwood, Siobhan Ng, Roslyn J Francis, Craig Gedye, Natalie K Rutherford, Andrew Weickhardt , Andrew M Scott, Sze-Ting Lee, Edmond M Kwan, Arun A Azad, Shakher Ramdave, 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.

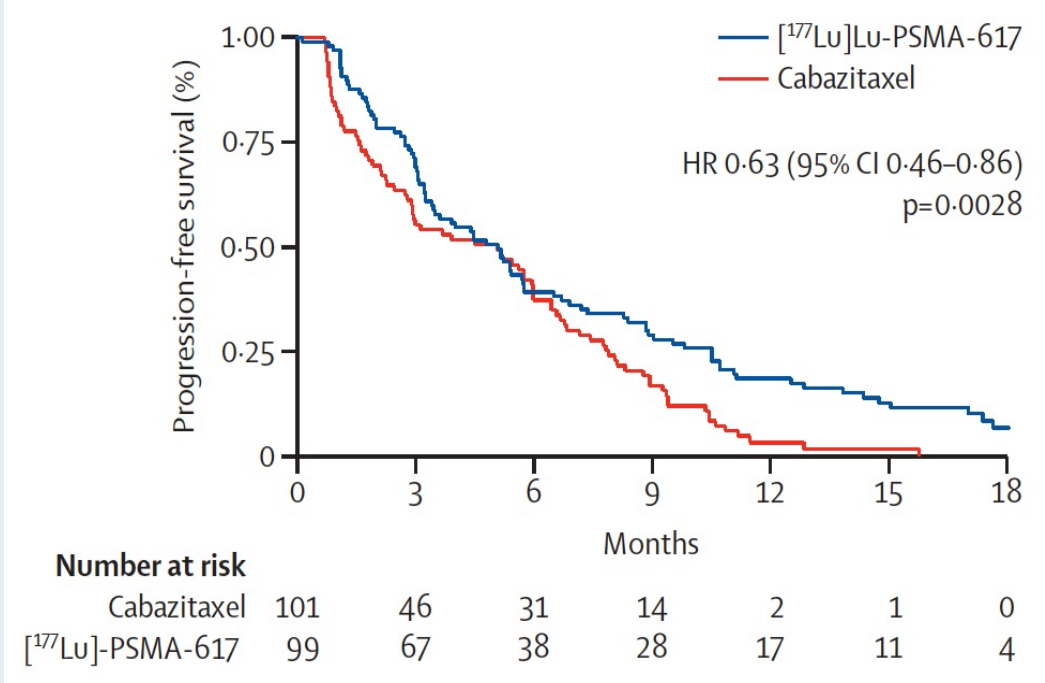
RTP RESEARCH TO PRACTICE

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

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*]

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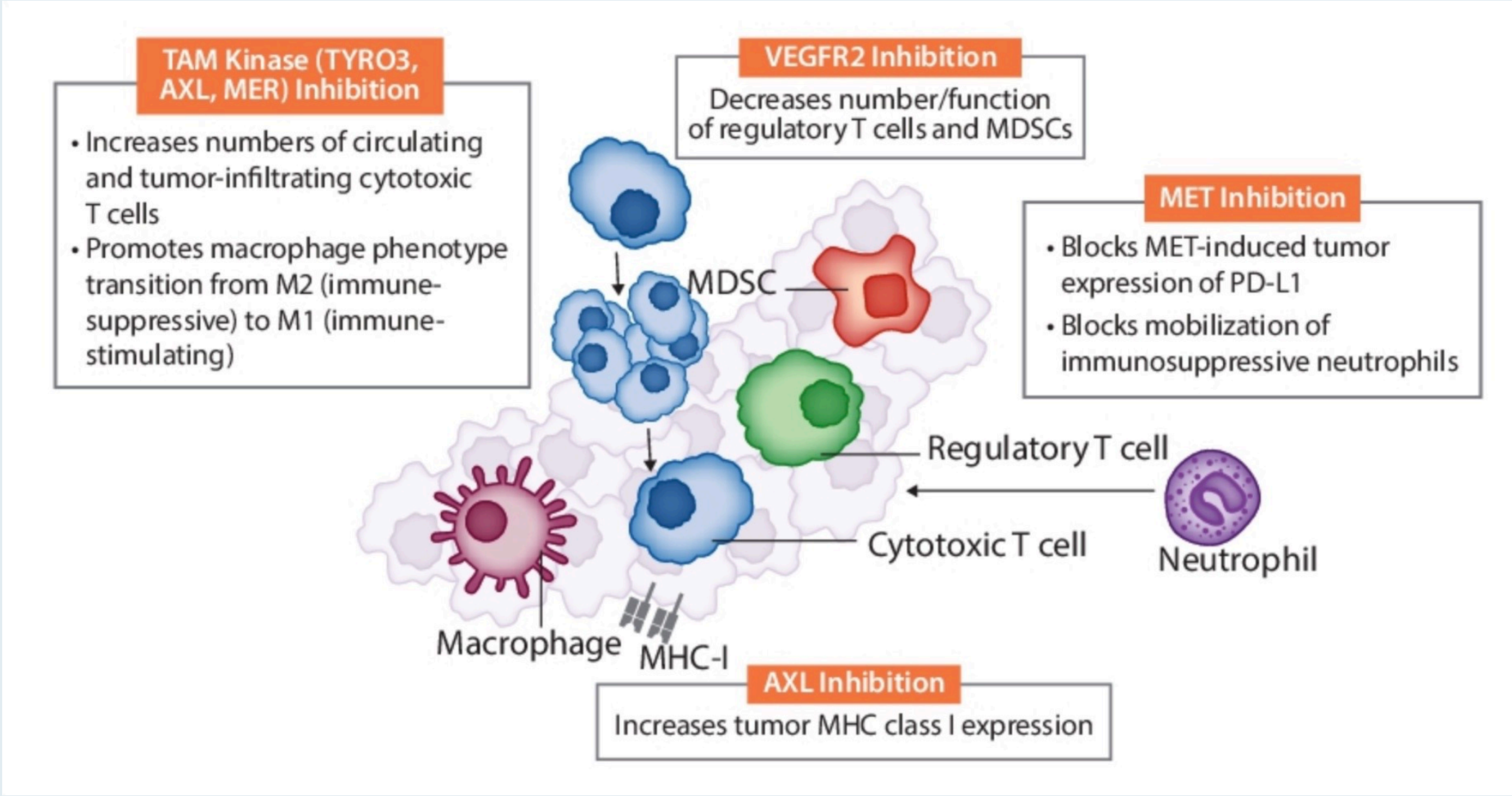
*Co-senior authors

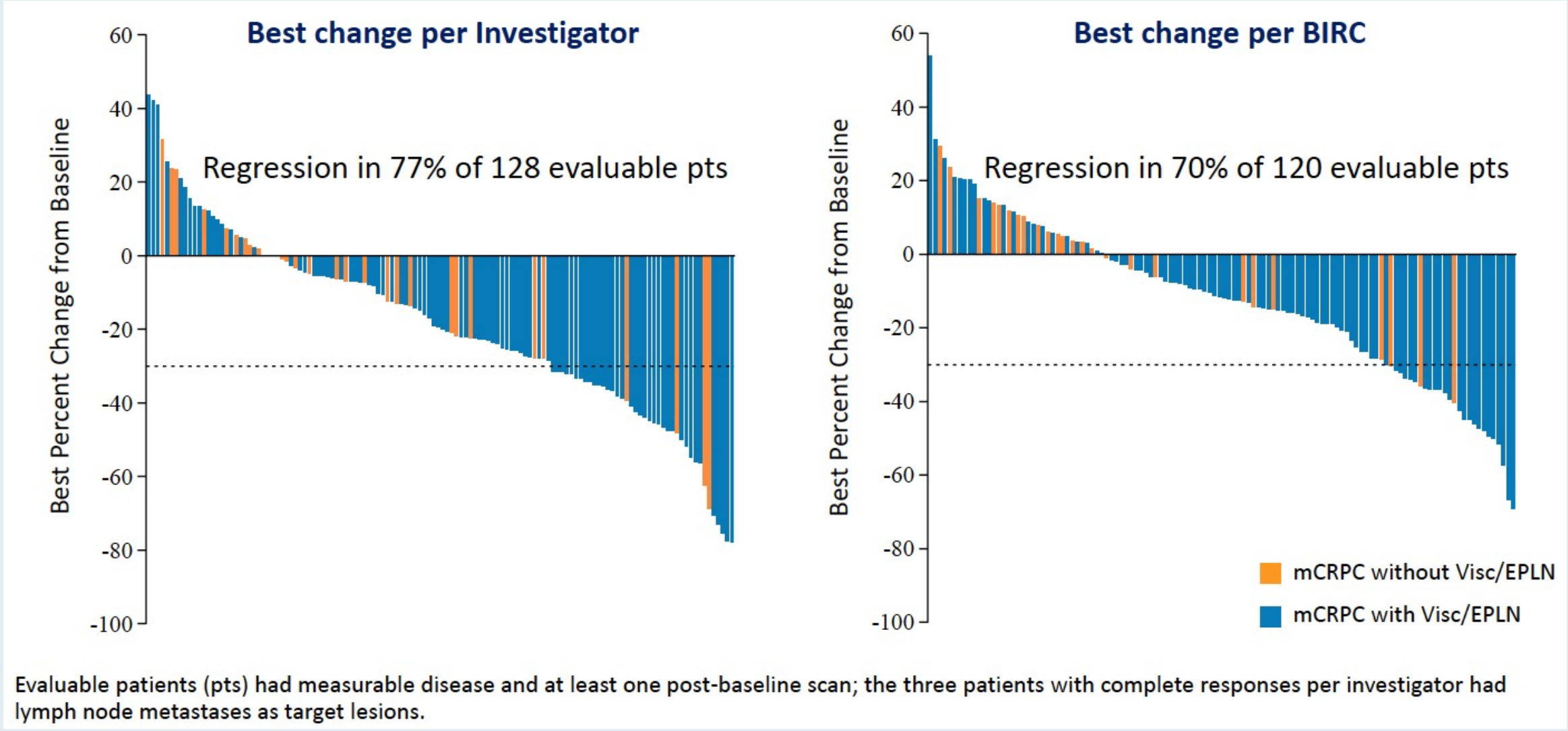
RTP RESEARCH TO PRACTICE

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.

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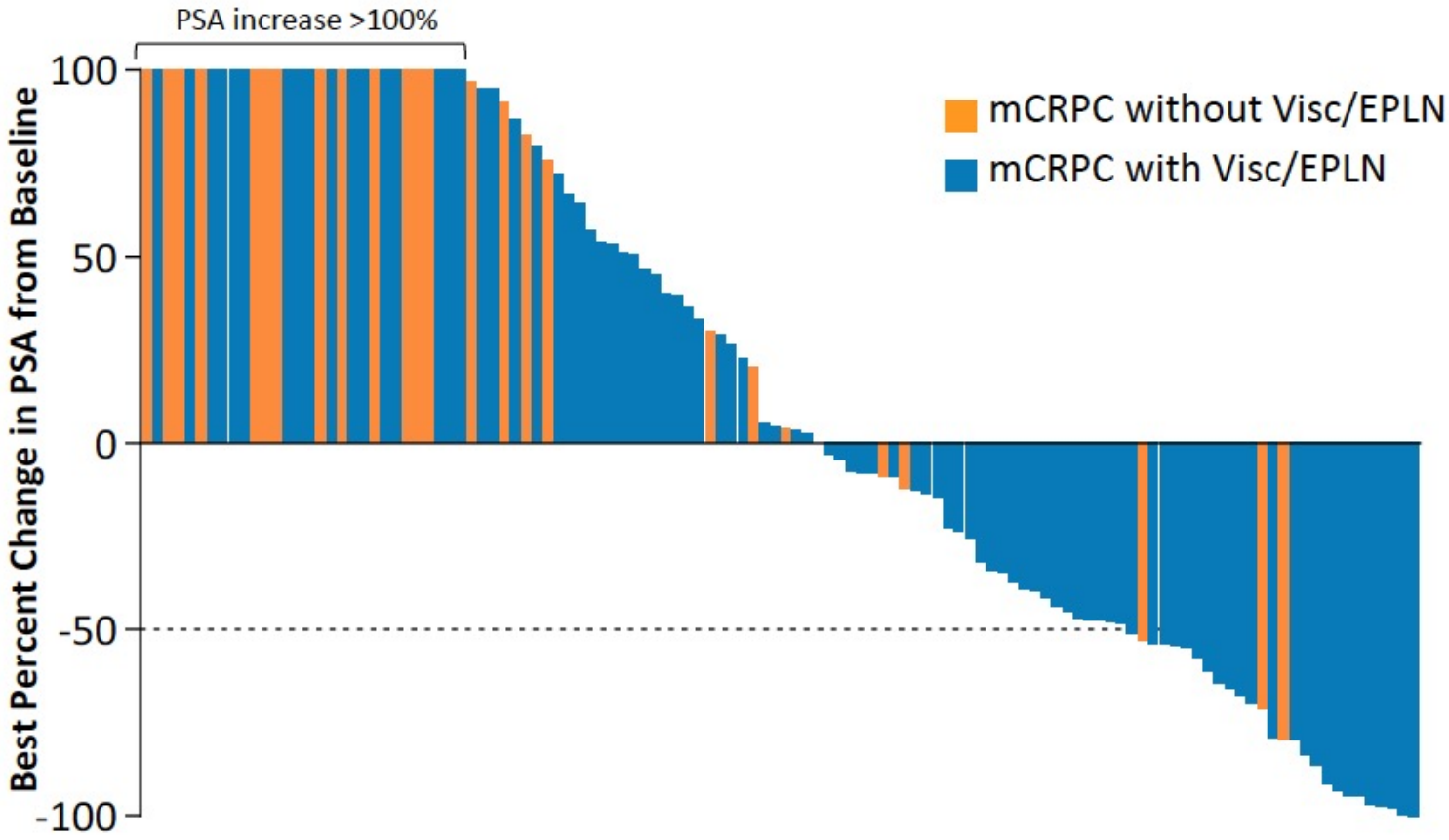
COSMIC-021: Best Change in PSA from Baseline



- 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%

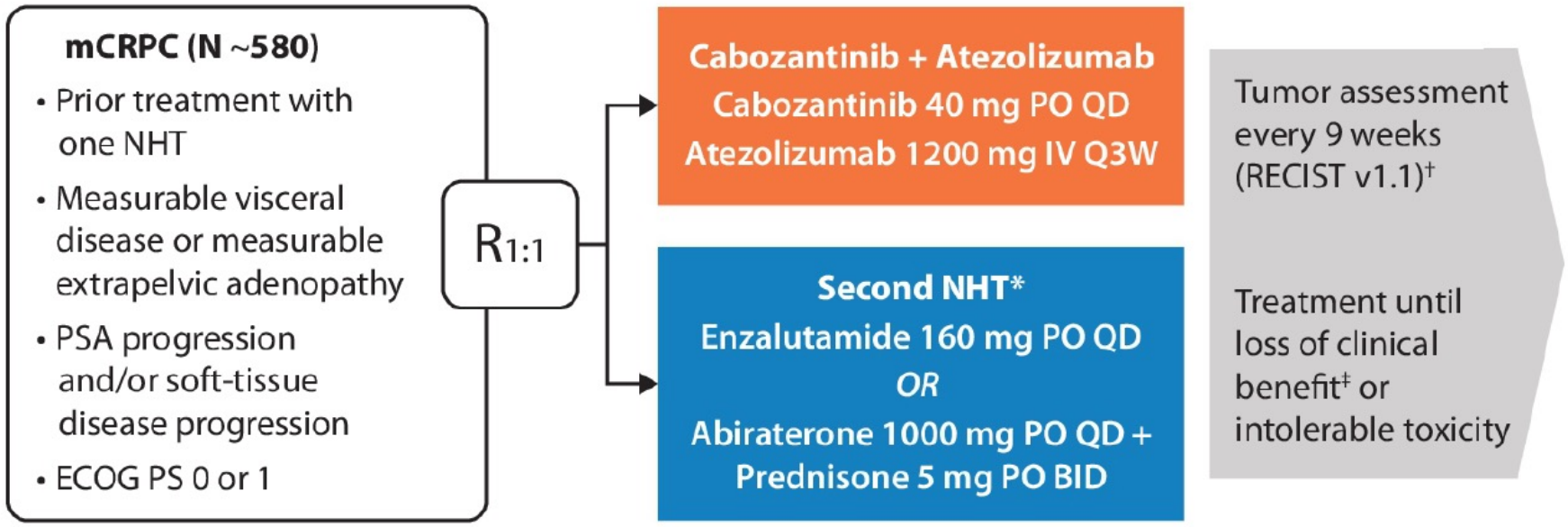
Agarwal et al. ESMO 2021;Abstract LBA24.

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)

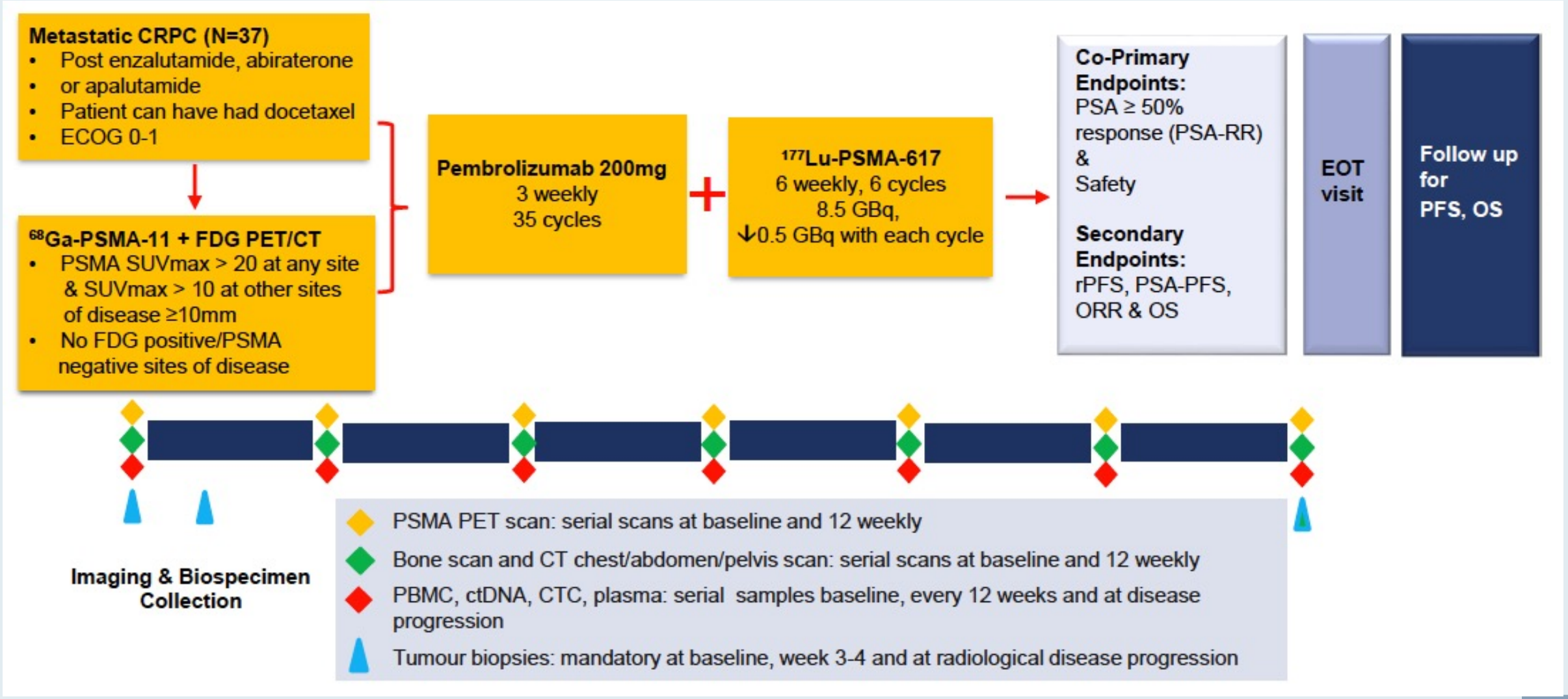
Shahneen Sandhu, Anthony M. Joshua, Louise Emmett, Lavinia Spain, Lisa G. Horvath, Megan Crumbaker, Arsha Anton, Roslyn Wallace, Anupama Pasam, Mathias Bressel, Erin Cassidy, Patricia Banks, Aravind Ravi Kumar, Ramin Alipour, Tim Akhurst, Grace Kong, Ian D. Davis, Scott Williams, Rod Hicks, Michael S.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

Abstract 577O

2021 ESMO congress

Presented by: Shahneen Sandhu

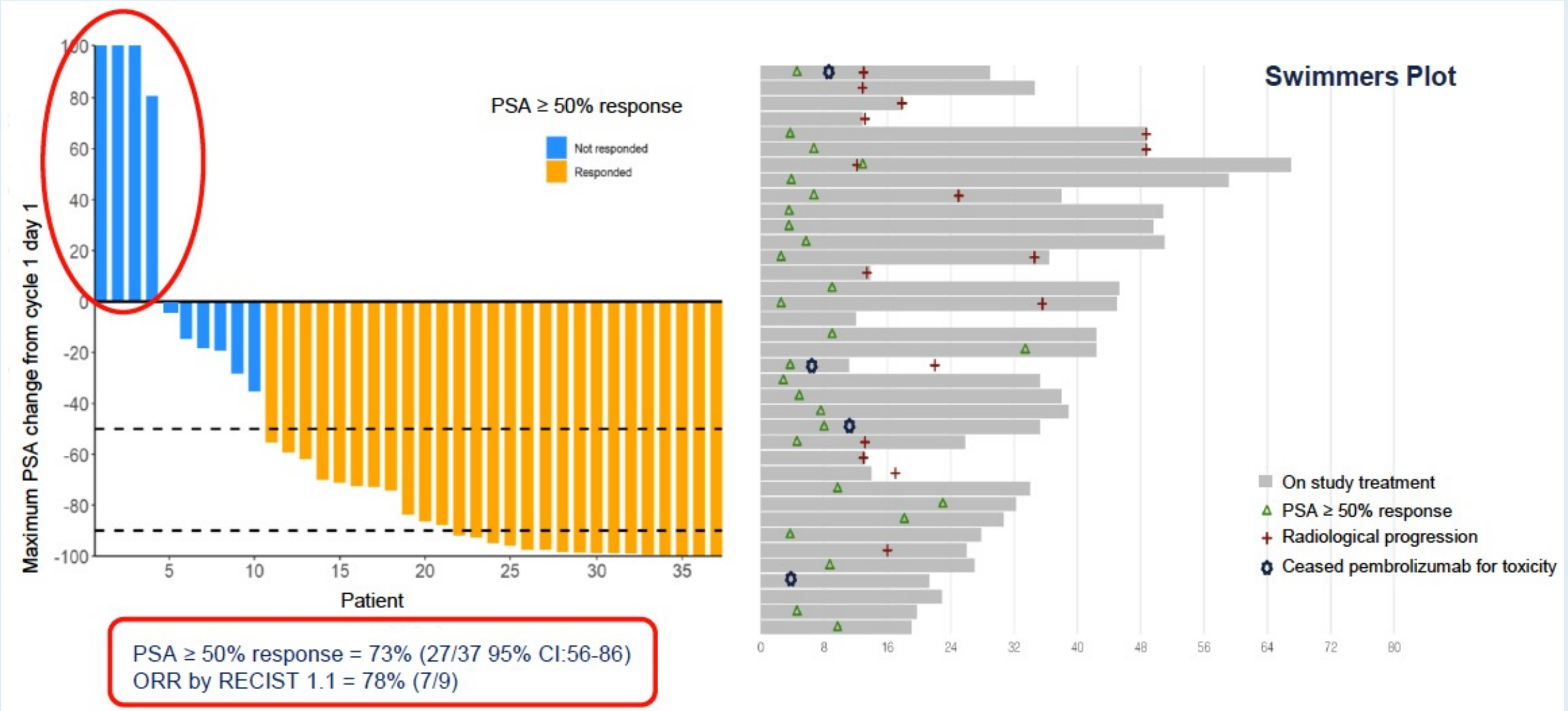
PSMA-Lutetium Radionuclide Therapy and ImmuNotherapy for Prostate CancEr (PRINCE) Trial Schema



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.

VIRTUAL MOLECULAR TUMOR BOARD
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