The Evolving Treatment Landscape for

Metastatic Castration-Resistant Prostate Cancer

Jointly provided by Potomac Center for Medical Education and Rockpointe Oncology

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Disclosures

Faculty and Steering Committee Disclosures

The faculty and steering committee reported the following relevant financial relationships that they or their spouse/partner have with commercial interests:

Daniel P. Petrylak, MD: *Consultant:* Bayer, Bellicum, Dendreon, Exelixis, Ferring, Johnson & Johnson, Medivation, Millennium, Roche Laboratories, Sanofi Aventis, Tyme Pharmaceuticals; *Grant/Research Support:* Agenysis, Celgene, Dendron, Eli Lilly, Johnson & Johnson, Millennium, Ocogenix, Progenies, Roche Laboratories, Sanofi Aventis

Oliver Sartor, MD: *Consultant:* Algela, Amgen, Bayer, Bellicum, Bristol-Myers Squibb, Celgene, Dendreon, Exelixis, GSK, Johnson & Johnson, Medivation, Oncogenex, Sanofi-Aventis; *Grant/Research Support:* Algeta, AstraZeneca, Cougar, GSK, Johnson & Johnson, Sanofi-Aventis

Non-faculty Disclosures

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Learning Objectives

At the conclusion of this activity, participants should be able to demonstrate the ability to:

- Review the current and emerging data regarding diagnosis and management of mCRPC
- Assess the safety and efficacy data of available therapies and the roles of biomarkers in personalizing the management of mCRPC
- Empower patients to become active participants in their treatment decisions and health management
- Discuss updated guidelines for systemic therapy and survivorship care planning

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Phase III trials in CRPC: Current status

TRIAL	PRE-DOCETAXEL	HR	Survival (months)
SWOG 9916	Docetaxel/estramustine vs Mitoxantrone/prednisone	0.80	17.5 vs 15.6
TAX 327	Docetaxel/prednisone vs mitoxantrone/prednisone	0.79	19.3 vs 16.3*
IMPACT	Sipuleucel-T vs Control	0.78	25.8 vs 21.7
COU-AA-302	Abiraterone/prednisone vs Placebo/prednisone	0.79	34.7 vs. 30.3*
PREVAIL	Enzalutamide vs Placebo	0.71	35.3 vs. 30.3*
	POST-DOCETAXEL		
TROPIC	Cabazitaxel/prednisone vs mitoxantrone/prednisone	0.70	15.1 vs 12.7
COU-AA-301	Abiraterone/prednisone vs placebo/prednisone	0.74	15.8 vs 11.2*
AFFIRM	Enzalutamide vs placebo	0.63	18.4 vs 13.6
	PRE- and POST-DOCETAXEL		
ALSYMPCA	Radium-223/supportive care vs placebo/BSC	0.70	14.9 vs 11.3*

*updated analysis

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What is "Bad" About the Current "State of the Art" in CRPC

- All effects to date are really quite modest
  - Oncologists are self-congratulatory, but patients need more
- Many approvals, but limited comparative data among any of the life-prolonging therapies
  - FIRSTANA was the first head-to-head comparison (cabazitaxel vs docetaxel)
- No practice-changing combination/sequential trials have been reported
- Everybody loves mom, apple pie, and "personalized" medicine; but, so far, nothing changes practice for clinicians
- Cost of drugs a huge ongoing concern

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Phase III Failures with Docetaxel +/- Design

- DN101 (calcitriol)
- GVAX (GM-CSF transduced PCa cell lines)
- Endothelin antagonists
  - Atrasentan
  - Zibotentan
- VEGF targeted
  - Bevacizumab
  - Aflibercept
- Dasatinib
- Lenalidomide

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Treatment Decision-making is Complex

- Drug availability? *Cost is a major issue*
- Clinical trial availability
- Performance status, age, comorbidities
- Laboratory assessments (WBC, platelets, liver fx)
- Symptomatic or asymptomatic? If so, where and how much?
- Response/resistance to prior therapies
- Tolerance/intolerance of prior therapies
- Burden of disease
- Location of disease (bone, liver, etc.)
- Pace of disease (rapid or slow)
- Systemic or focal progression?
- Phenotype (adeno/anaplastic/neuroendocrine)
- Patient preferences

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Which Drug for Which Patient?

- Biomarkers are the great hope
  - The AR variants/mutants
    - Shout out to JHMI
  - Germline and somatic DNA repair (BRCA1/2, ATM, etc.)
    - Love the PARP story here
  - Newer methods of CTC analysis
    - Epic Sciences gets a bravo
  - Immune signatures
- Individual laboratories need replacement by industrial processes!
- We identify poor prognosis with high degrees of certainty, but picking winners is harder to do

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Two Types of Biomarkers: Tumor and Host

Tumor focused	Triggered by host reaction to tumor
• Various proteins and isoforms: PSA, AR, and LDH • DNA mutations, deletions, CNV, translocations, methylation, etc. • RNA expression and/or alterations (big ones, little ones, coding, and non-coding) • CTCs, oncosomes, exosomes, and all their contents • Imaging galore	• Pain/performance status • Alkaline phosphatase • Albumin • Tc-99 MDP bone scans • Immune cell analysis • Hematopoietic cell function: hemoglobin, nucleated RBCs, etc.

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Case Report

- A 74-year-old relatively healthy man with CRPC (ECOG PS=1) is receiving abiraterone as a first-line CRPC therapy
- He has a slowly rising PSA and new onset of mild bone pain relieved with ibuprofen
- Restaging indicates 4 new bone lesions and 2.5 cm (new) retroperitoneal nodes
- No laboratory issues

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Discussion Question: Treatment Options to Consider

What is your preferred treatment for this patient?

1. Continue abiraterone
2. Switch to enzalutamide
3. Switch to radium-223
4. Switch to docetaxel
5. Focus on bone lesions: zoledronic acid/denosumab
6. Consider some combination therapy

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Discussion Question: Treatment Options to Consider

What is your preferred treatment for this patient?

1. Continue abiraterone
2. Switch to enzalutamide
3. Switch to radium-223
4. Switch to docetaxel
5. Focus on bone lesions: zoledronic acid/denosumab
6. Consider some combination therapy

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CRPC Prognostic Biomarkers: Baseline and Post-therapy Considerations

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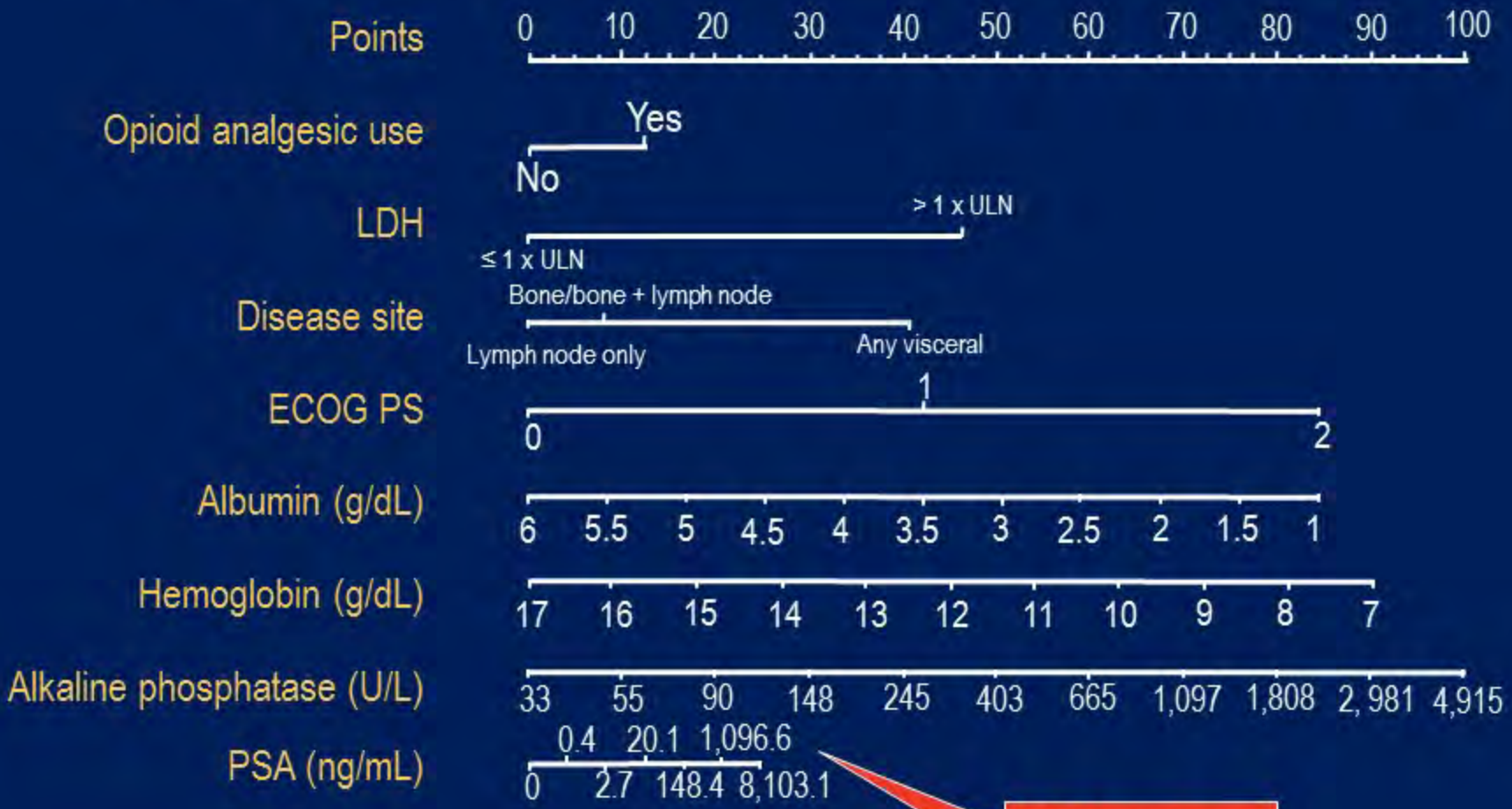
The Updated Halabi Data for mCRPC Patients Treated with Docetaxel



Halabi S et al. *J Clin Oncol.* 2014;32:671-677.

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Multivariate Analysis of Survival in COU-302

Parameter	Hazard ratio (95% CI)	*p* value
Treatment (abiraterone plus prednisone vs prednisone alone)	0.74 (0.61–0.89)	0.002
ECOG score (1 vs 0)	1.17 (0.94–1.45)	0.2
Log (baseline serum PSA, ng/ml)	1.18 (1.10–1.27)	<0.0001
Log (baseline lactate dehydrogenase, IU/l)	3.07 (2.11–4.48)	<0.0001
Log (baseline alkaline phosphatase, IU/l)	1.33 (1.14–1.56)	0.0003
Baseline haemoglobin, g/dl	0.92 (0.85–0.99)	0.02
Bone metastasis only at baseline, yes vs no	0.69 (0.57–0.85)	0.0003
Age	1.02 (1.01–1.03)	0.0006

Rathkopf DE et al. *Eur Urol.* 2014;66:815-825.

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Multivariate Analysis for Survival: Radium Phase III Trial

Baseline Variable	Hazard Ratio	*P* value
Radium-Rx	0.783	<0.01
Albumin	0.973	<0.01
Log LDH	3.476	<0.001
ECOG PS	1.612	0.001
Log PSA	1.401	<0.001
Log Alk Phos	2.046	<0.001
Age	1.014	<0.05

Sartor AO et al. Presented at: American Society of Clinical Oncology (ASCO) 2013.

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The PSA to LDH Transition in mCRPC

- Early in the disease, PSA is a wonderful marker
  - For men without a prostate, PSA is near perfect!!!
- Later in the disease, the reliability of PSA declines
- LDH and ALP emerge as more important
- The PSA to LDH transition escapes many docs and all patients!

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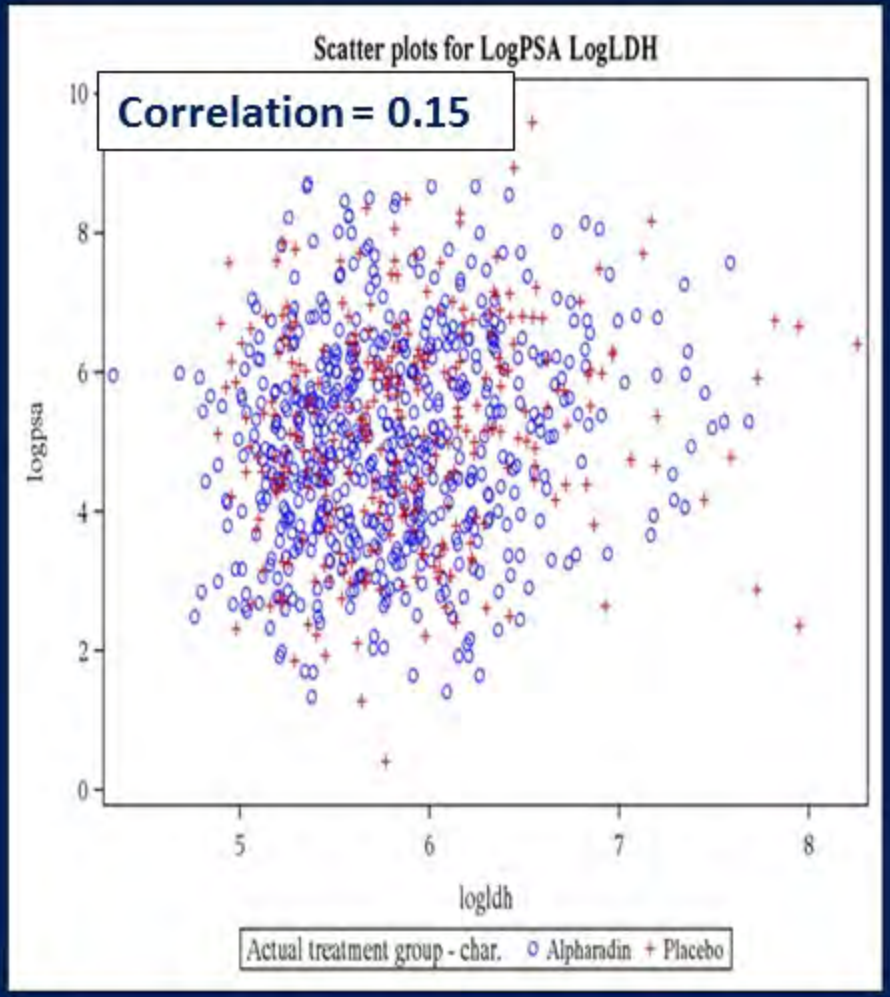
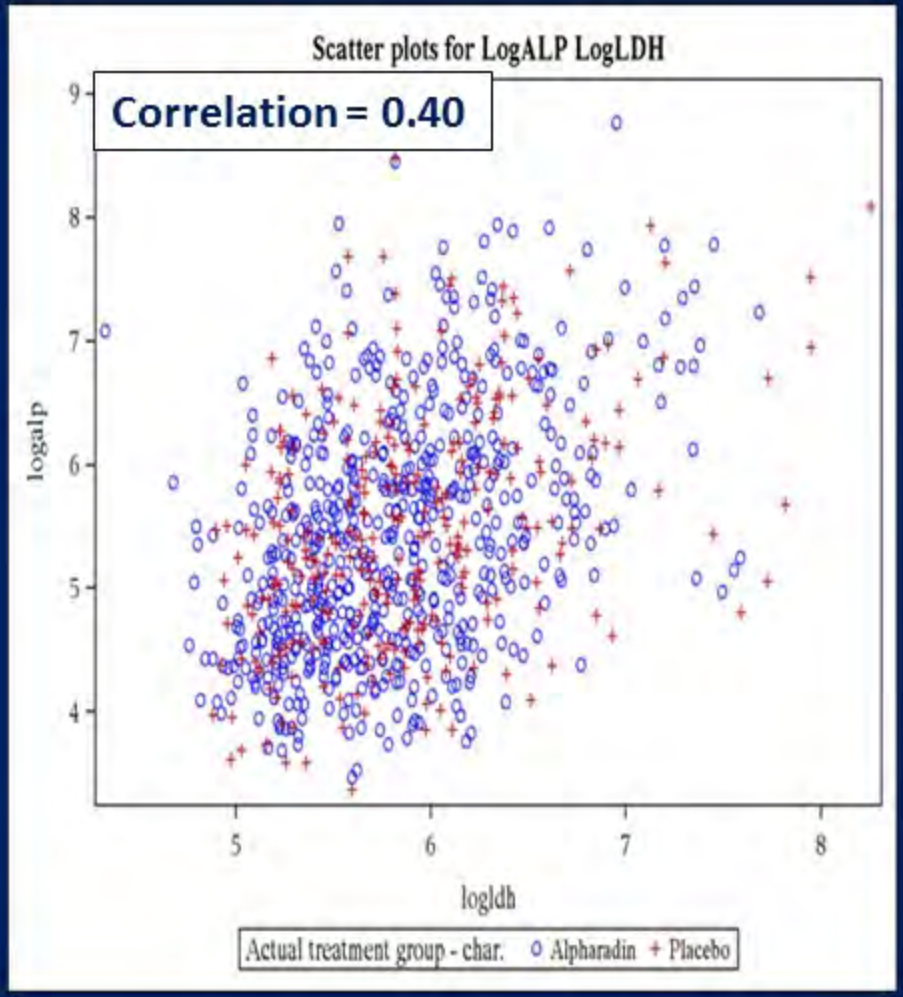
Scatter Plots Assessing Correlation Between Log PSA, Log ALP, and Log LDH from ALSYMPCA





Courtesy of Oliver Sartor, MD

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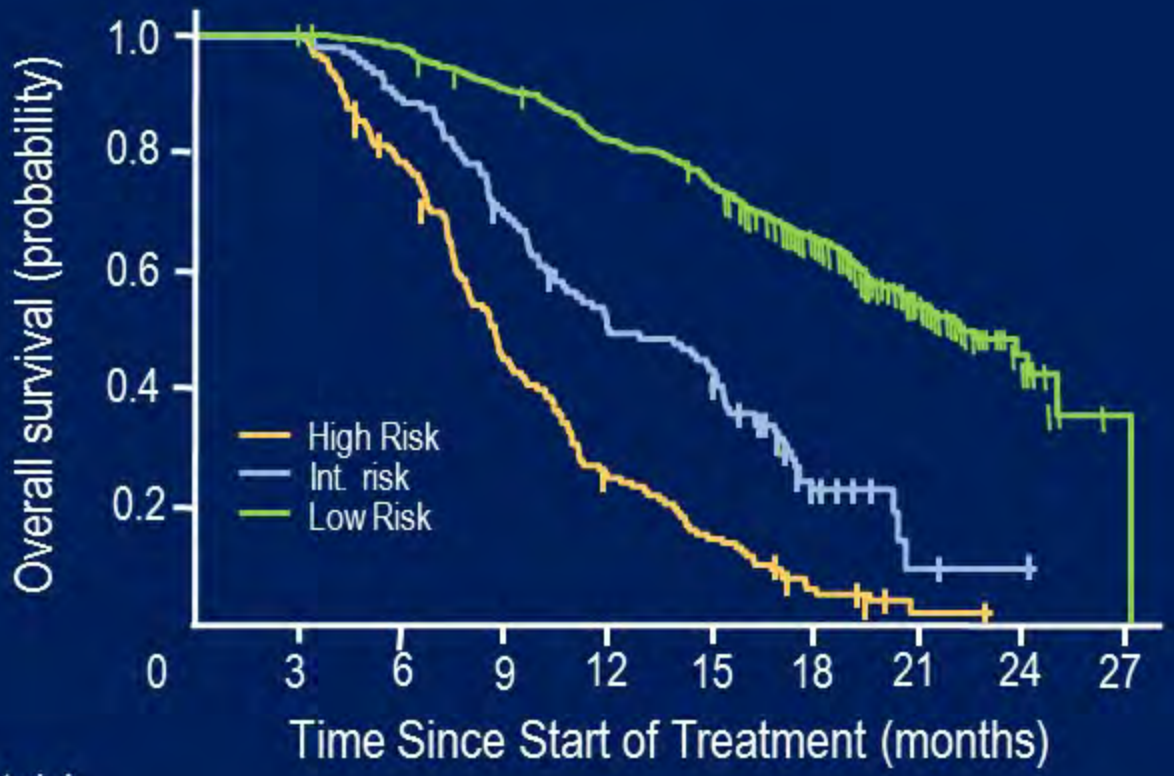
Surrogacy at 12 weeks in COU-AA-301

- CTC <4 (low)
- CTC >5 and LDH <250 (intermediate)
- CTC >5 and LDH >250 (high)



No. at risk										
High risk	145	145	112	63	35	20	7	1	0	0
Int. risk	116	116	104	80	57	49	17	2	1	0
Low risk	450	450	439	405	364	329	238	110	114	1

Scher HI et al. *J Clin Oncol.* 2015;33:1348-1355.

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Discussion Question

Which of the following biomarkers have emerged as a surrogate for overall survival in mCRPC, as demonstrated in the secondary analysis of the COU-AA-301 study?

1. Prostate-specific antigen (PSA) and lactate dehydrogenase (LDH)
2. Circulating tumor cells
3. PSA and alkaline phosphatase
4. A combination of CTCs and LDH

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Answer

Which of the following biomarkers have emerged as a surrogate for overall survival in mCRPC, as demonstrated in the secondary analysis of the COU-AA-301 study?

1. Prostate-specific antigen (PSA) and lactate dehydrogenase (LDH)
2. Circulating tumor cells
3. PSA and alkaline phosphatase
4. A combination of CTCs and LDH

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CRPC Predictive Biomarkers

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Ligand-independent AR Variants Derived from Splicing of Cryptic Exons Are Clearly Described

Hu R et al. *Cancer Res.* 2009;69:16-22.

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“Liquid” Biopsy

- How much DNA information can you extract from a peripheral blood sample?
- Are these actionable?
- How well do they reflect tumor heterogeneity?

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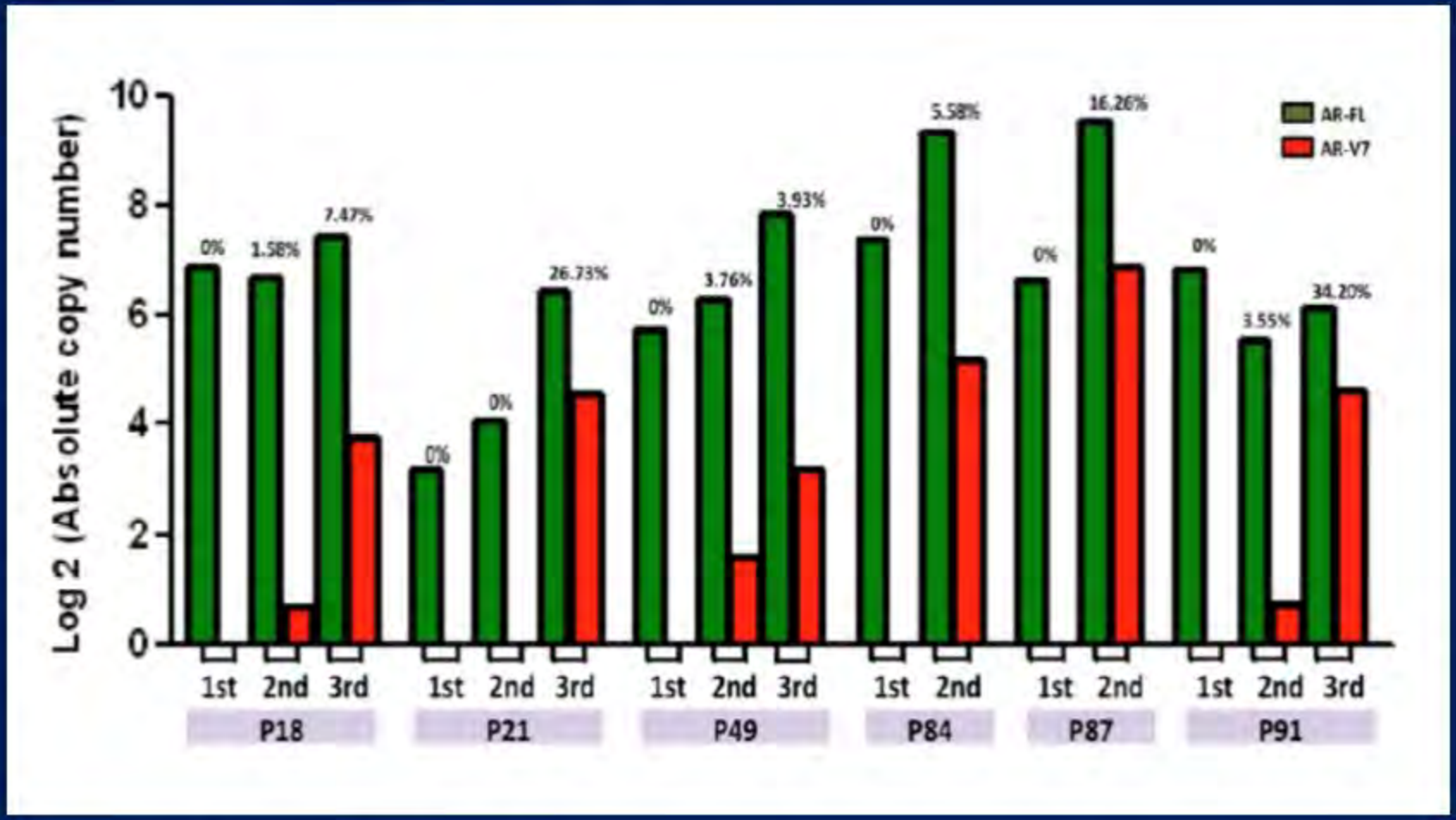
Induction of AR-V7 mRNA in CTCs Post-Abi/Enza Treatment



Antonarakis ES et al. *N Engl J Med*. 2014;371:1028-1038.

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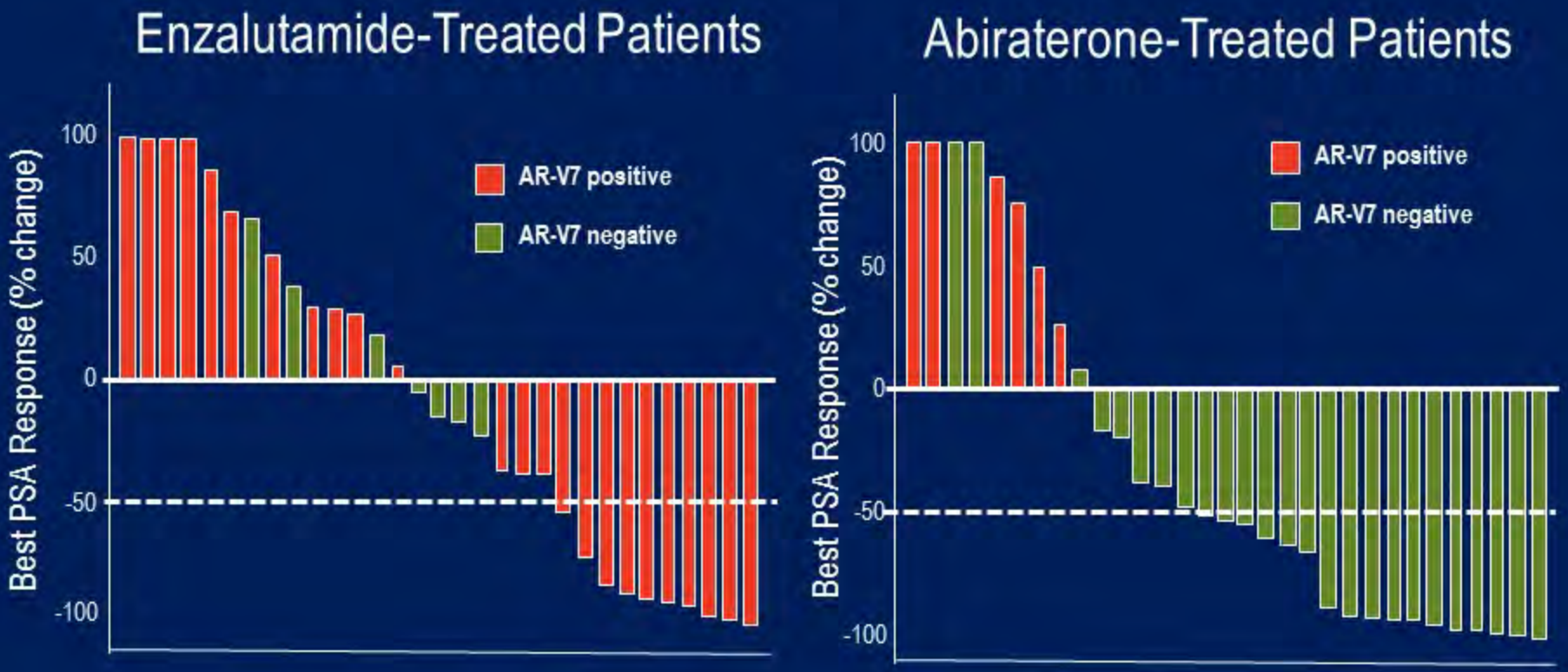
PSA Responses in Abi/Enza-treated Patients Stratified by AR-V7 RNA Status in CTCs



Antonarakis ES et al. *N Engl J Med.* 2014;371:1028-1038.

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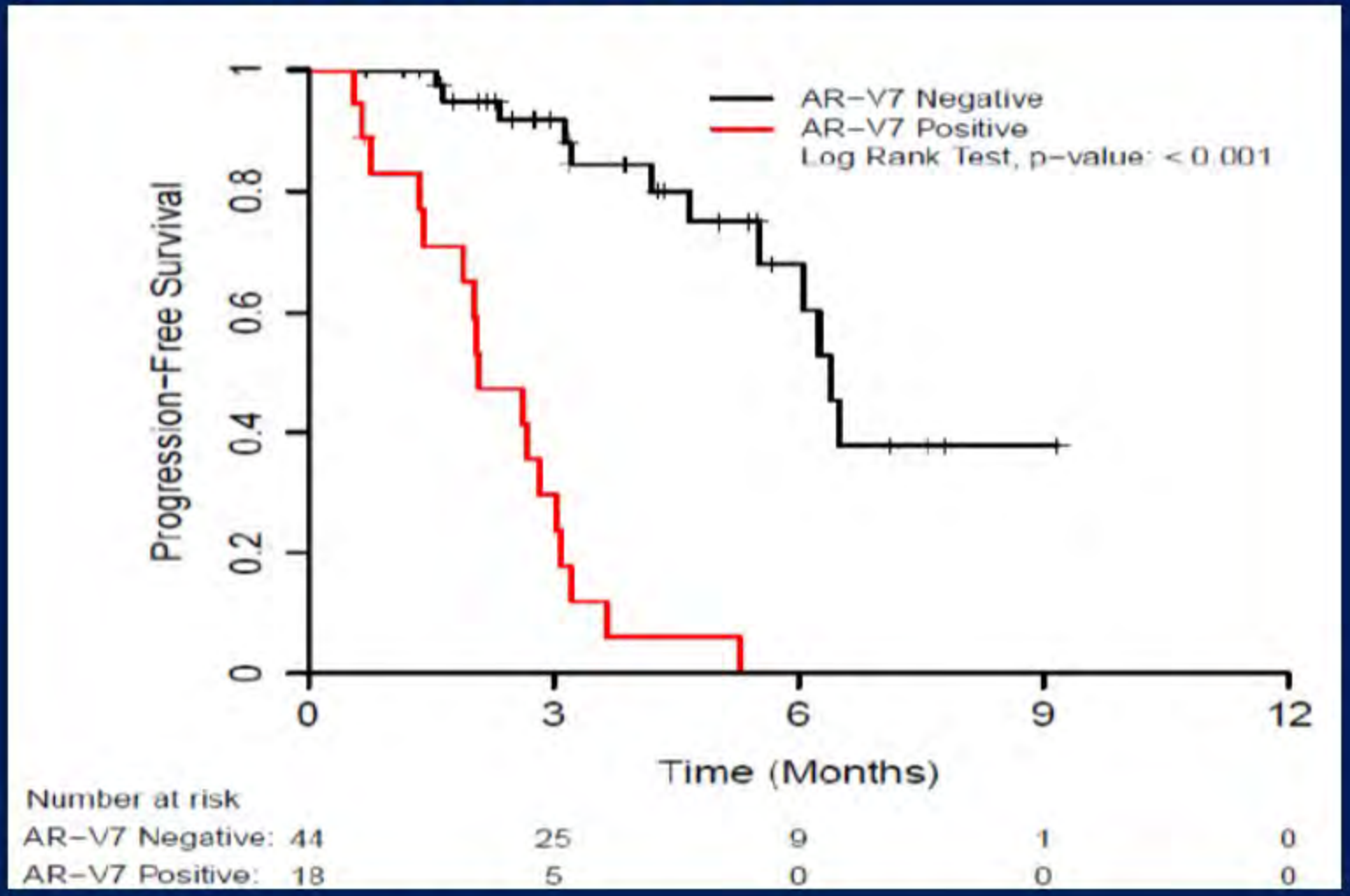
PFS in Abi/Enza-treated Patients Stratified by AR-V7 RNA Status in CTCs



Antonarakis ES et al. *N Engl J Med.* 2014;371:1028-1038.

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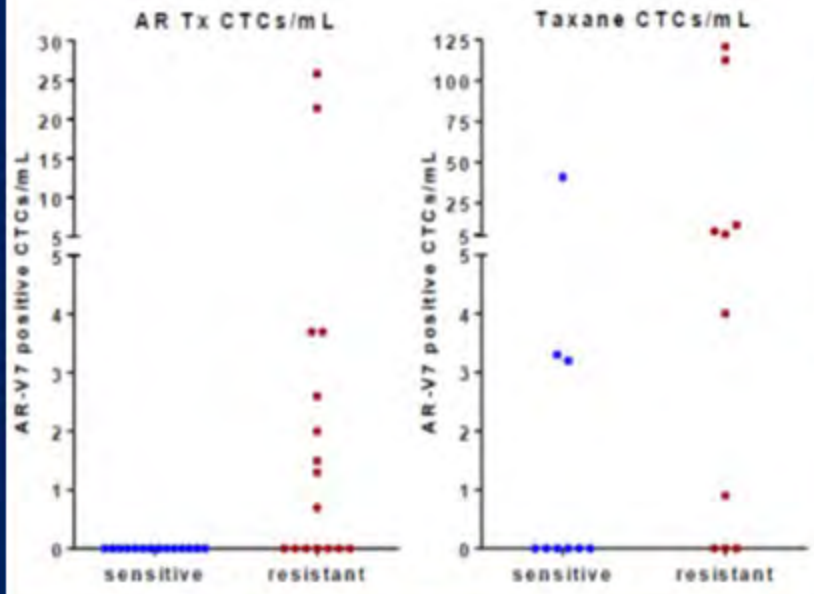
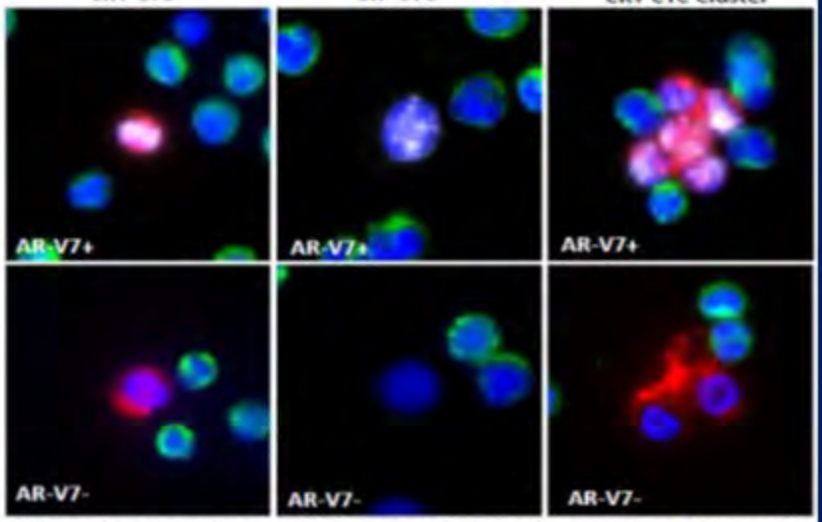
AR-V7 Detection in CTCs Using a Monoclonal Antibody

AR-V7 in CTCs Predicts Resistance to ARS Tx but not to Taxane Chemotherapy



Patients with AR-V7+ CTCs			Clinical Specificity/Sensitivity		
	Sensitive	Resistant	Specificity	Sensitivity	OR
ARS Tx	0/14 (0%)	9/16 (56%)	1.00	0.56	Inf.
Taxane Tx	3/9 (33%)	7/10 (70%)	0.67	0.70	4.7

Representative CTC images from a single 3+ Line patient demonstrating AR-V7 and CTC heterogeneity



AR-V7 positivity predicts resistance to AR-directed therapy. AR-V7 protein expression was found in CTCs from 9/16 patients resistant to ARS Tx. While CTCs were identified in 13/14 ARS Tx sensitive patients (range: 0-418, median: 4), 0/14 harbored AR-V7+ CTCs. Of all patients in the ARS Tx cohort that lacked AR-V7+ cells, 67% were sensitive to ARS Tx. AR-V7 prevalence does not predict resistance to Taxane chemotherapy: AR-V7+ CTCs were found in 3/9 and 7/10 Taxane-sensitive and resistant patients, respectively.

Kelvin J et al. Presented at: American Association for Cancer Research (AACR) 2015.

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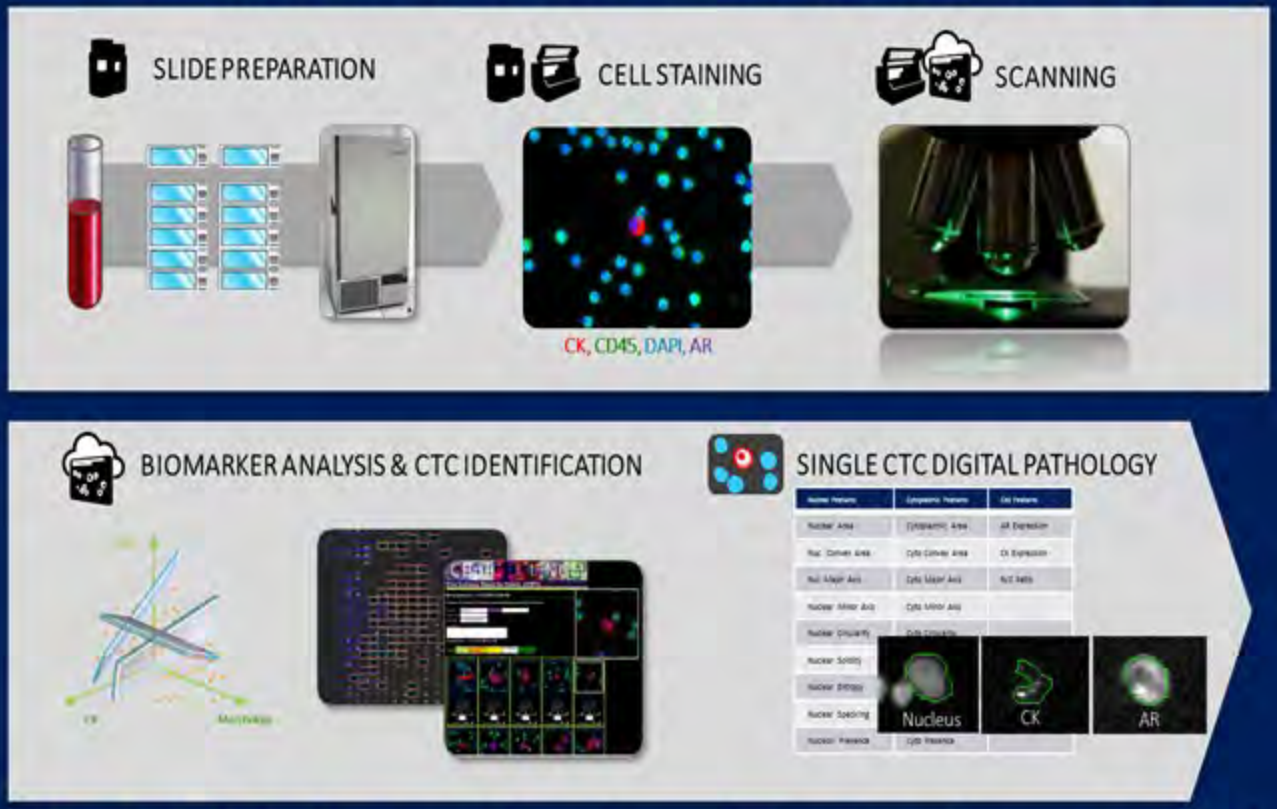
Epic Sciences Morphology Methods

- CTCs were isolated using a No Selection platform and analyzed at the single-cell level by morphology (facial recognition) and protein analysis



No Cell Selection enables characterization of any rare cell type: inclusive of CK-, small, apoptotic, and CTC clusters

Scher HI et al. Presented at: American Society of Clinical Oncology (ASCO) 2015.

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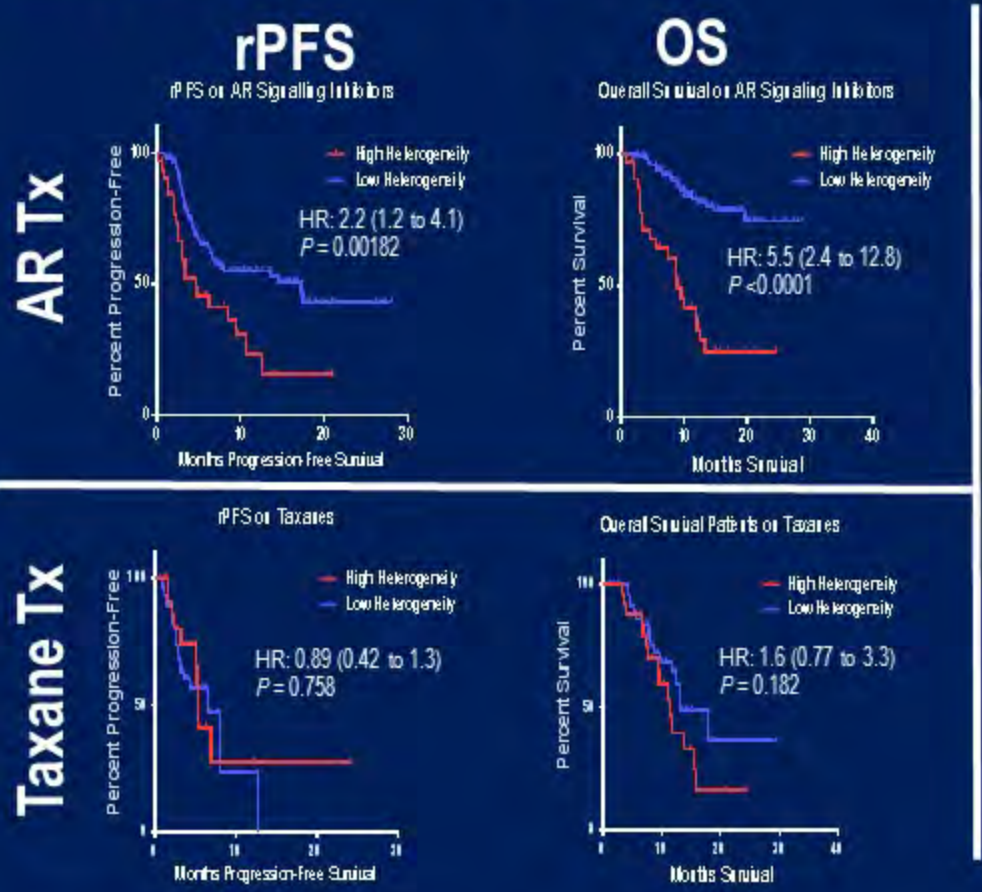
High CTC Phenotypic Heterogeneity Predicted for Shorter Progression and Survival Times on Newer AR Tx but not Taxane Tx*



Outcomes on AR Tx Based on Heterogeneity

AR Tx (n = 150)	High Heterogeneity	Low Heterogeneity
Median Survival	9 months	not reached
Hazard Ratio: OS	5.51	
logrank *P*-value OS	<0.0001	
Median rPFS	5 months	17 months
Hazard Ratio: rPFS	2.2	
logrank: rPFS	0.00182	

*Unadjusted for baseline factors

Scher HI et al. Presented at: American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium 2016.

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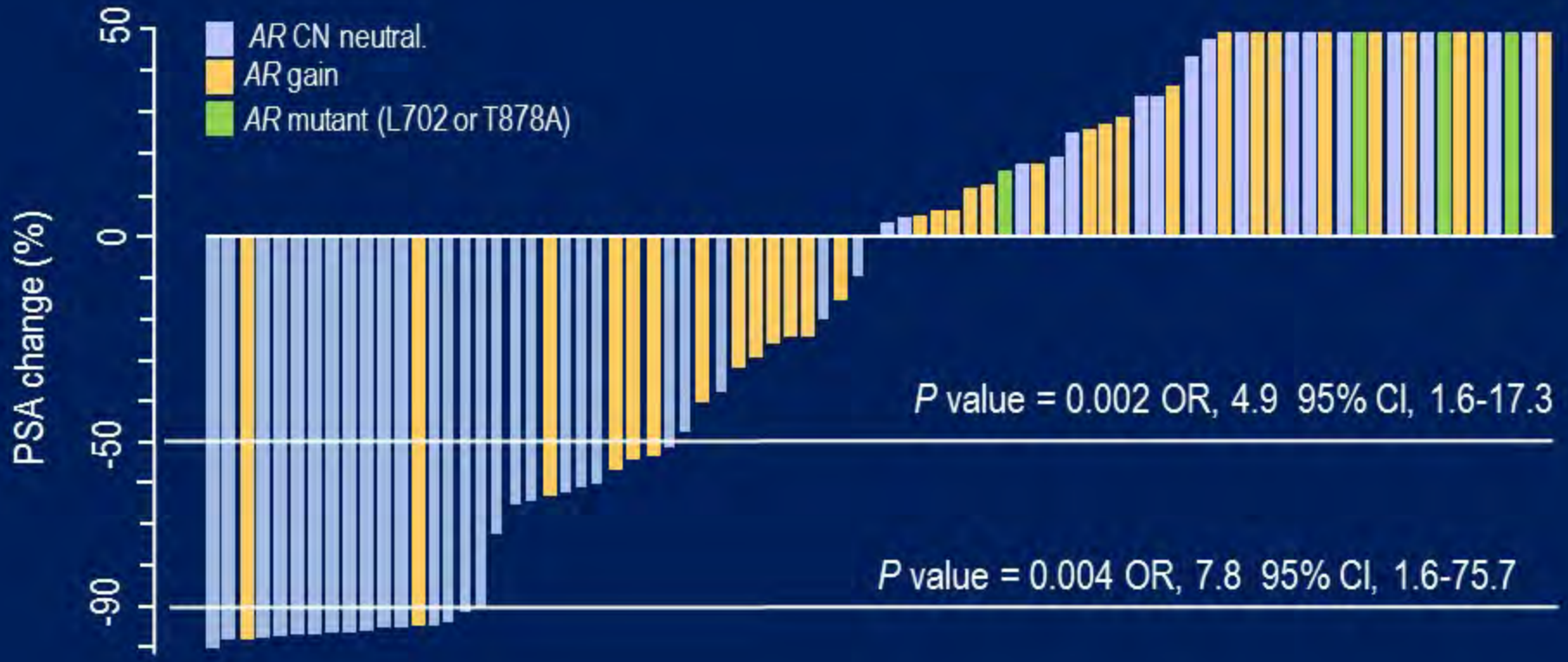
Free Plasma DNA: AR Copy Number Gain or Selected Mutations in Abiraterone Treated Patients



Romanel A et al. *Sci Transl Med.* 2015;7:312re10.

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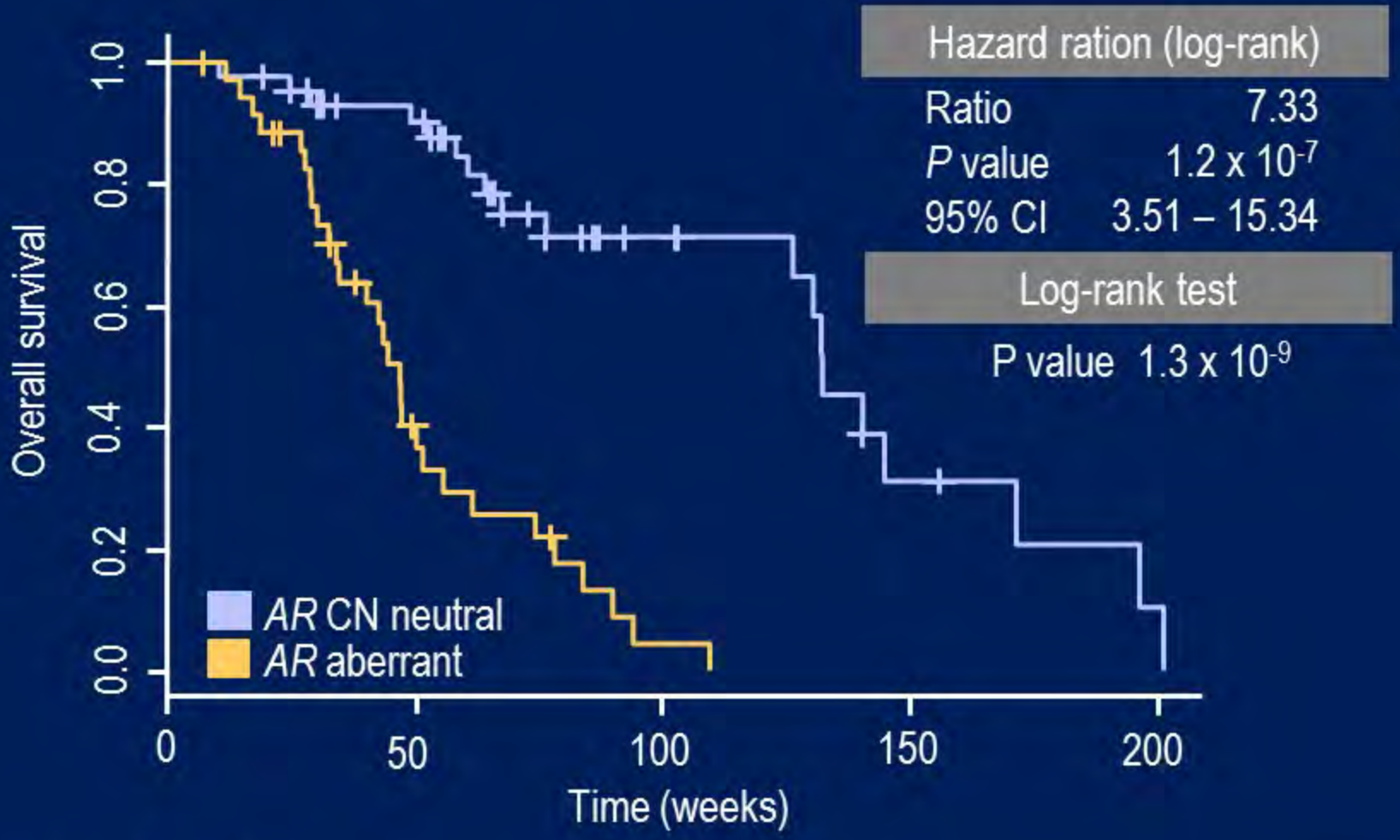
Overall Survival: *AR Copy Number Gain or Selected Mutations in Plasma Free DNA Prospectively Tested in Abiraterone Treated Patients*



Romanel A et al. *Sci Transl Med.* 2015;7:312re10.

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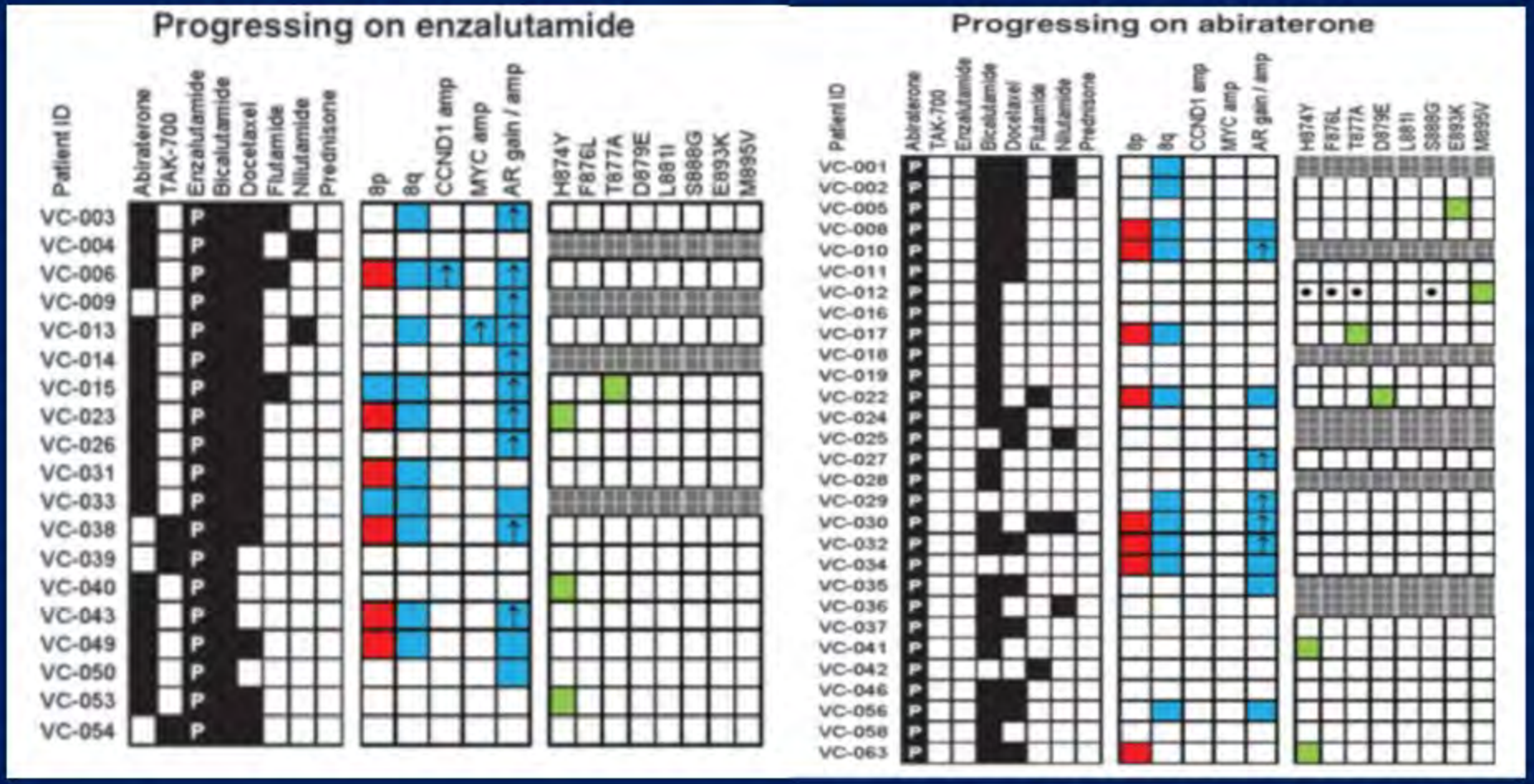
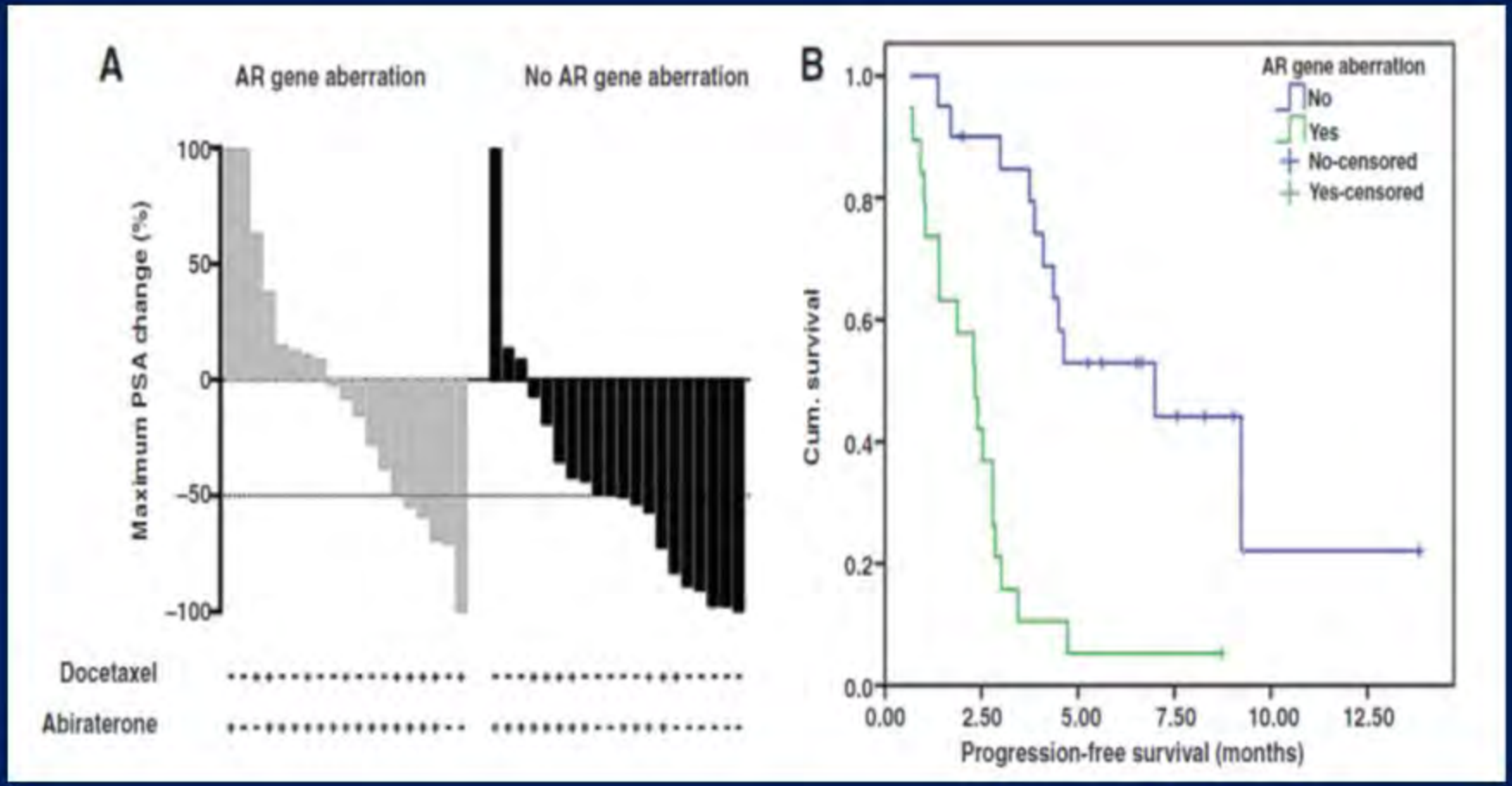
Cell-free DNA Alterations and Progression



Azad AA et al. *Clin Cancer Res.* 2015;21:2315-2324.

AR Gene Aberration (Copy # Increase or Various AR Exon 8 Mutations) Predicts Enzalutamide Resistance



Azad AA et al. *Clin Cancer Res.* 2015;21:2315-2324.

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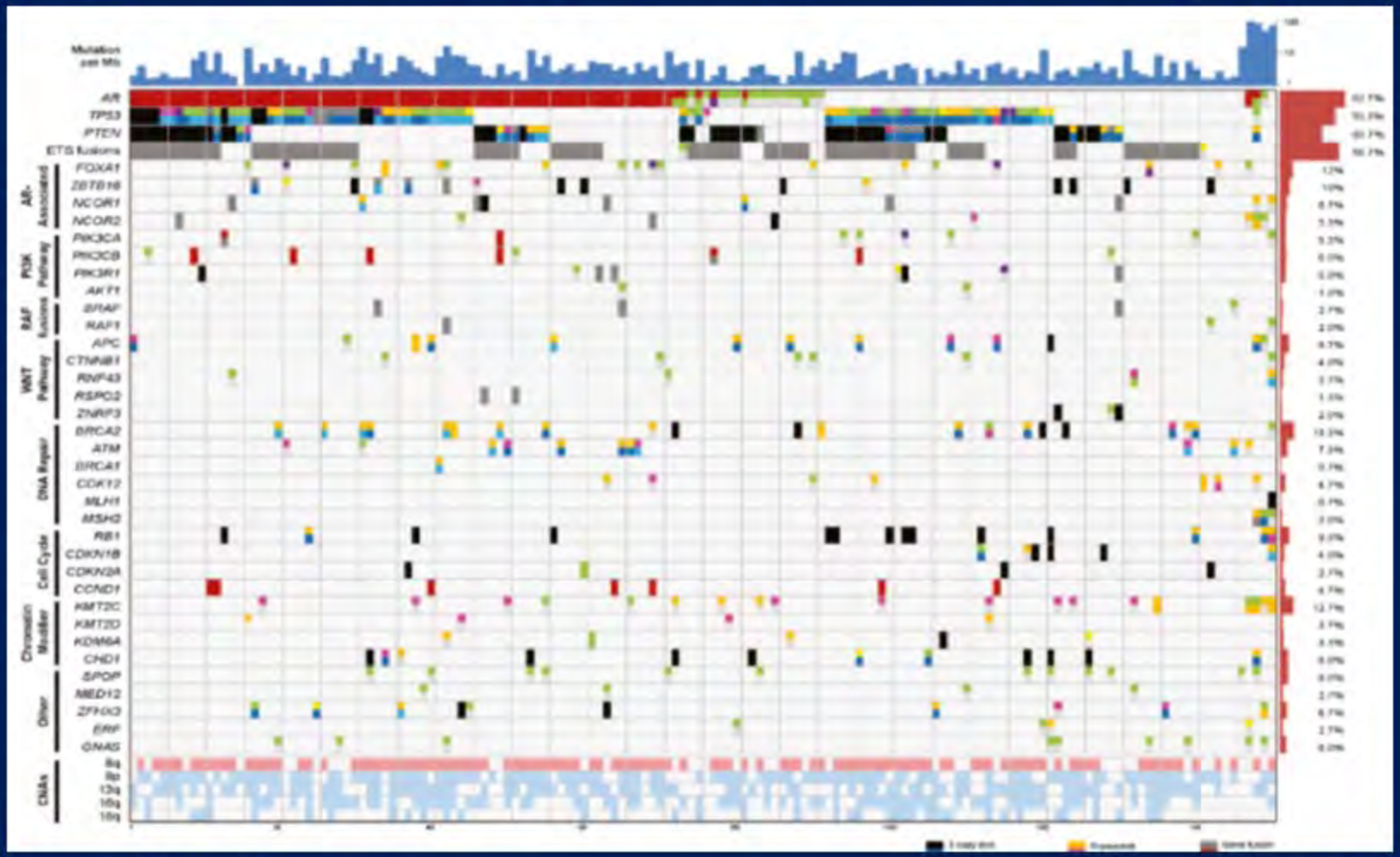
Challenges: Metastatic Prostate Cancer is a Heterogeneous Group of Diseases Filled with Targets, but Androgen Receptor Often Key



Robinson et al. Cell 161:1215, 2015

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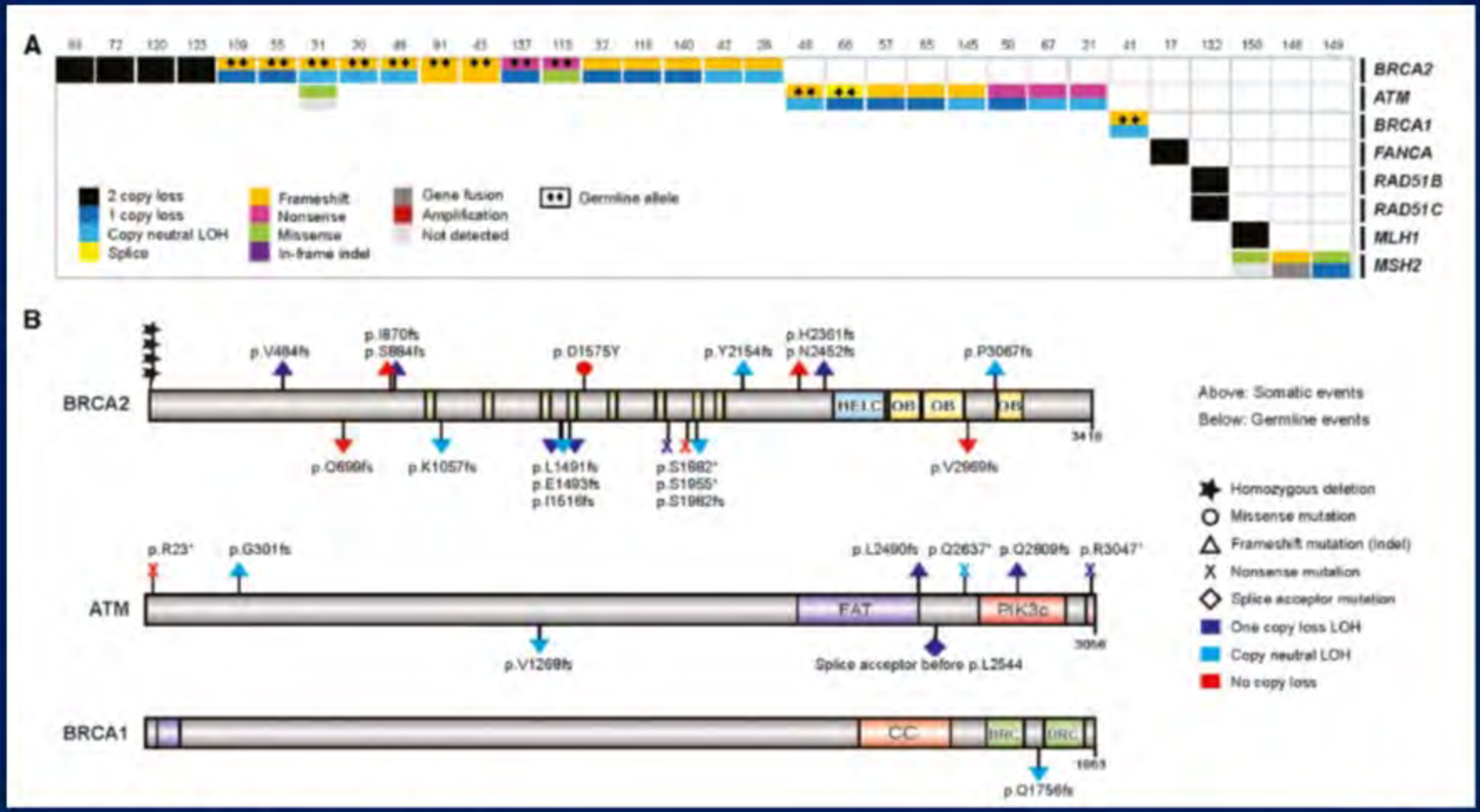
Tissue based studies: DNA Repair Defects are more Common than Appreciated



Robinson D et al. *Cell*. 2015;161:1215-1228.

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Inherited DNA-Repair Gene Mutations in Men with Metastatic Prostate Cancer Regardless of Family History

- 11.8% of men with metastatic prostate cancer
  - BRCA2 5.8%
  - CHEK2 1.9%
  - ATM 1.6%
  - BRCA1 0.9%
  - RAD51D and PALB2 0.4% each
- 4.6% of men with localized prostate cancer

Pritchard CC et al. *N Engl J Med*. 2016;375:443-453.

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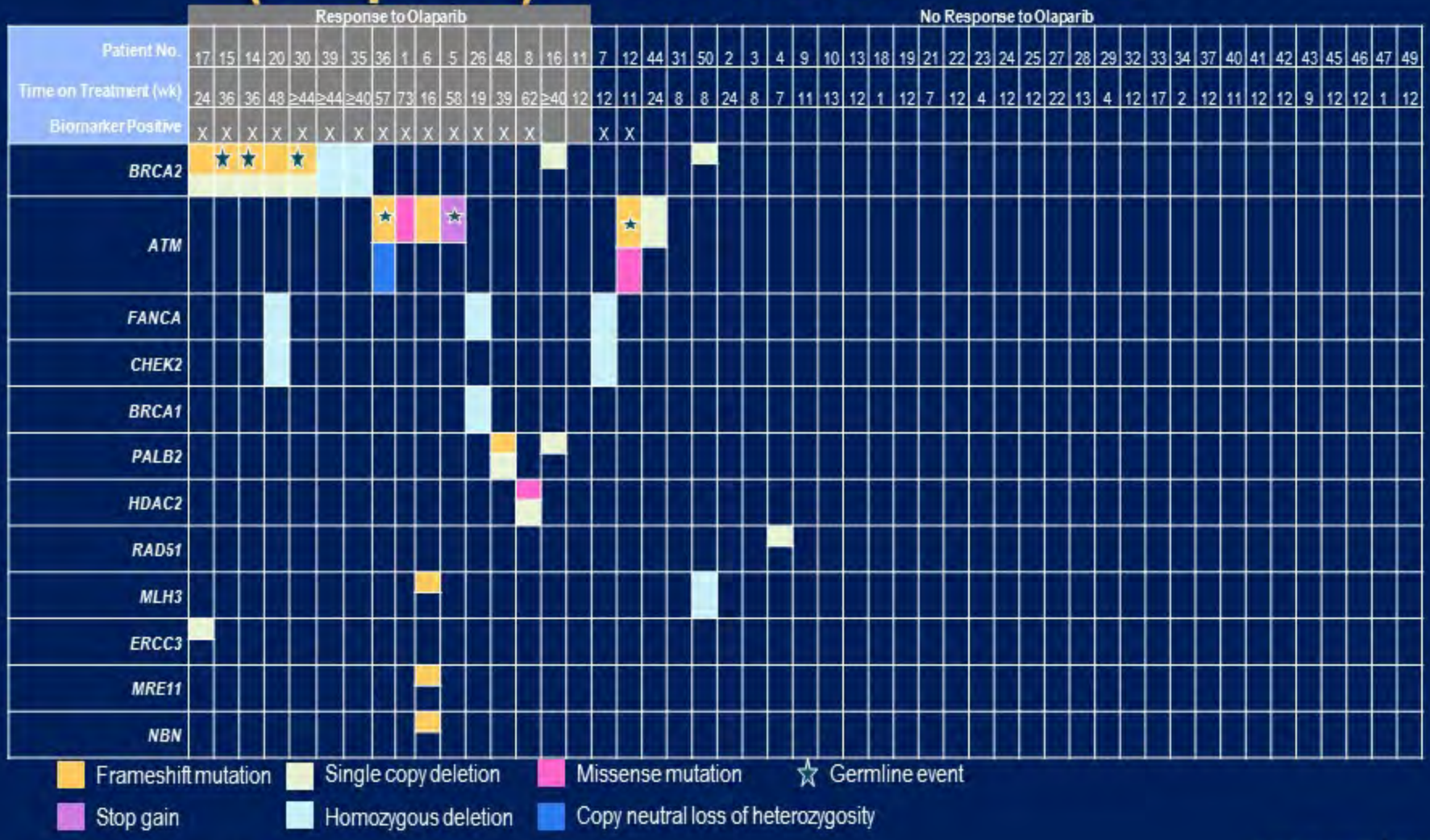
DNA-Repair Defects and a PARP inhibitor (Olaparib) in Metastatic CRPC



Mateo J et al. *N Engl J Med.* 2015;373:1697-1708.

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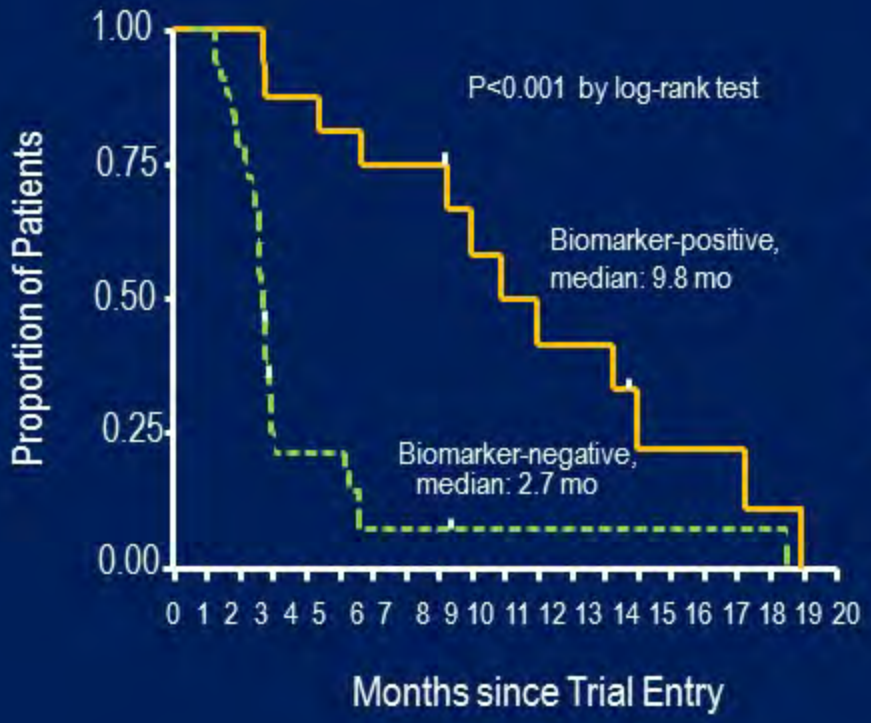
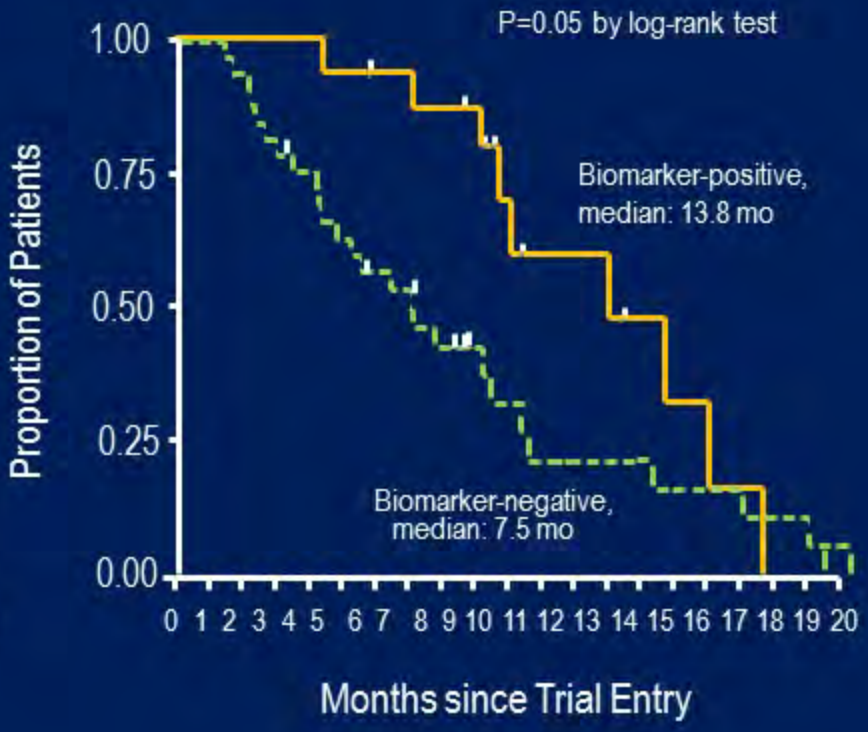
DNA-Repair Defects and Olaparib in Metastatic Prostate Cancer: PFS and OS

Radiologic Progression-free Survival



Overall Survival



Mateo J et al. *N Engl J Med.* 2015;373:1697-1708.

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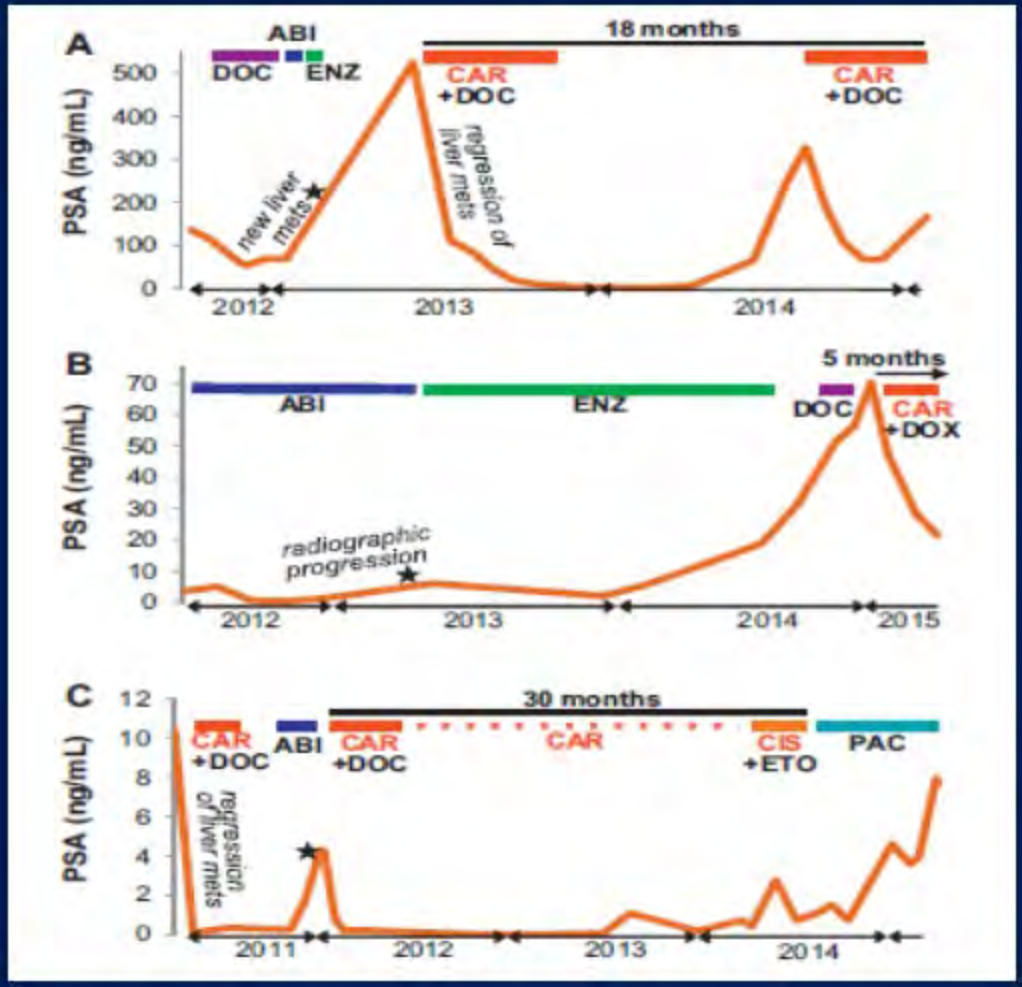
Platinum-Sensitive CRPC Correlates with Biallelic Inactivation of BRCA2



Cheng HH et al. *Eur Urol.* 2016;69:992-995.

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"Liquid" Biopsy: Beyond Androgen Receptor and DNA Repair

- How much DNA information can you extract from a peripheral blood sample?
- Are these actionable?
- How well do they reflect tumor heterogeneity?

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Cell-Free DNA: Patient with CRPC After Multiple Therapies

Alteration		% cfDNA	cfDNA Amplification	FDA Approved in Indication	Available for Use in Other Indications	Clinical Drug Trials
TP53	*R273H*	9.8		None	None	Trials Available
BRAF	*S36A*	2.3	The functional consequences and clinical significance of this gene variant are not established. The relevance of therapies targeting this alteration is uncertain. Similar to other alterations in circulating cfDNA, the monitoring of this variant may be reflective of disease progression or treatment; clinical correlation is advised.			
	AMP		+	None	Cobimetinib, Regorafenib, Sorafenib, Trametinib	Trials Available
MET	*D587E*	0.5	The functional consequences and clinical significance of this gene variant are not established. The relevance of therapies targeting this alteration is uncertain. Similar to other alterations in circulating cfDNA, the monitoring of this variant may be reflective of disease progression or treatment; clinical correlation is advised.			
	AMP		+	None	Cabozantinib, Crizotinib	Trials Available
BRCA2	*W2970**	0.2		None	Olaparib	Trials Available
NTRK1	*D412D‡*	0.1	There is no change in the amino acid at this position and it is not likely to be a therapeutic target. Similar to other alterations in circulating cfDNA, the monitoring of this variant may be reflective of disease progression or treatment; clinical correlation is advised.			
AR	*AMP*		+++	Abiraterone, Bicalutamide, Degarelix, Enzalutamide, Flutamide, More drugs available	None	Trials Available
MYC	*AMP*		++	None	None	Trials Available

Courtesy of Oliver Sartor, MD

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Progressive Metastatic Prostate Cancer after ADT + Docetaxel "Upfront"

1 Total Alteration(s) Detected

1 with Associated Therapy
0 Associated with Lack of Response
Multiple Clinical Trials Available

Summary of Alterations & Associated Treatment Options

The percentage, or allele frequency, of altered cell-free DNA (% cfDNA) circulating in blood is related to the unique tumor biology of this patient. Factors that may affect the amount/percentages of detected genomic alterations in circulating cell-free DNA in blood include tumor growth, turn-over, size, heterogeneity, vascularization, disease progression, or treatment.

Alteration		% cfDNA	cfDNA Amplification	FDA Approved in Indication	Available for Use in Other Indications	Clinical Drug Trials
BRAF	*K601E*	6.1		None	Cobimetinib, Regorafenib, Sorafenib, Trametinib, Vemurafenib	Trials Available

Courtesy of Oliver Sartor, MD

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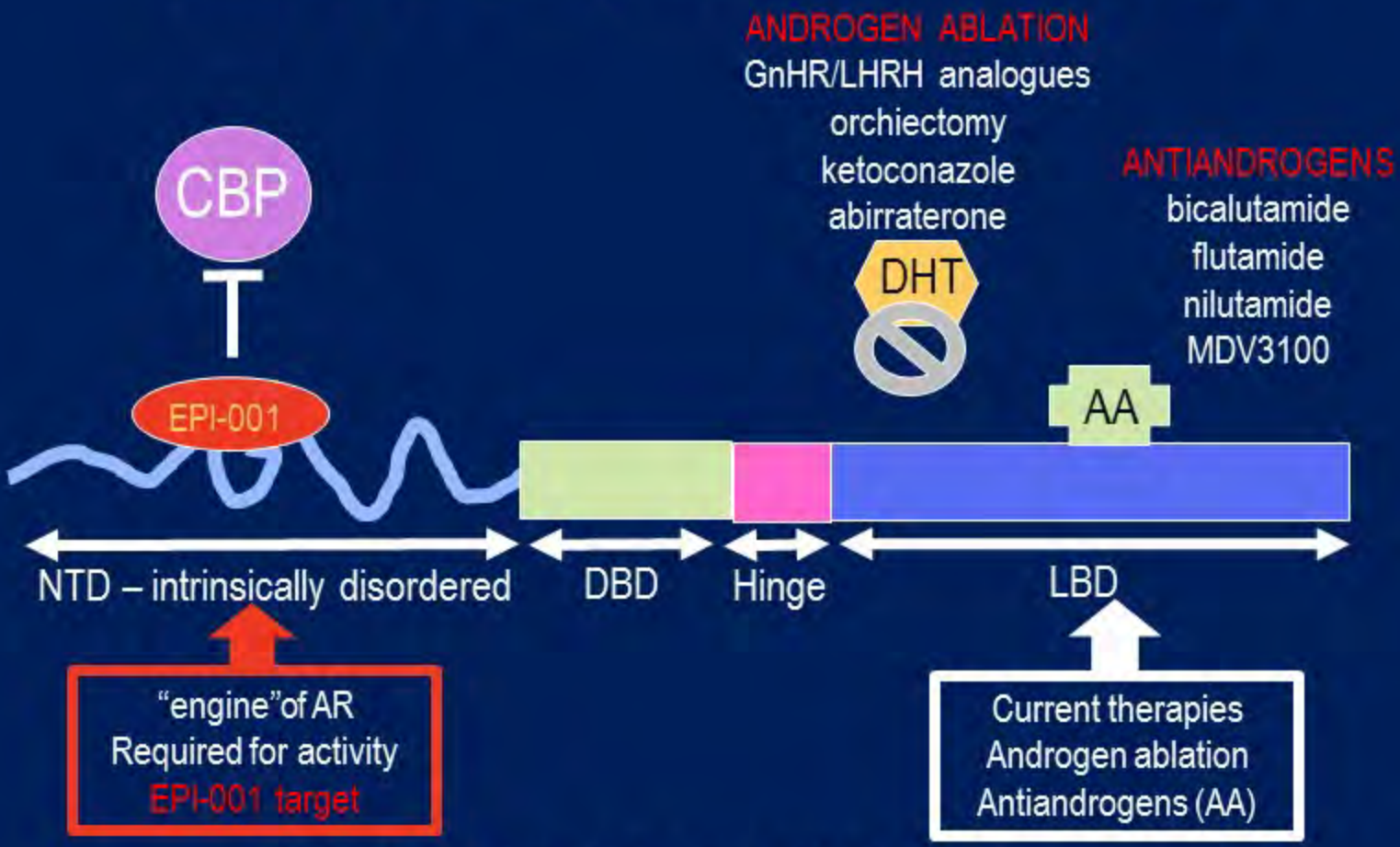
How Can We Make V7 or AR Amplification or AR Mutants Go Away?

or

How Can We Make V7 or AR Amplification or AR Mutants Irrelevant?

ROCKPOINTE Oncology

Small Molecule Inhibitors Targeting the 'Achilles' Heel of Androgen Receptor Activity



ESSA Pharmaceuticals has a trial in process now

Sadar MD. *Cancer Res.* 2011;71:1208-1213.

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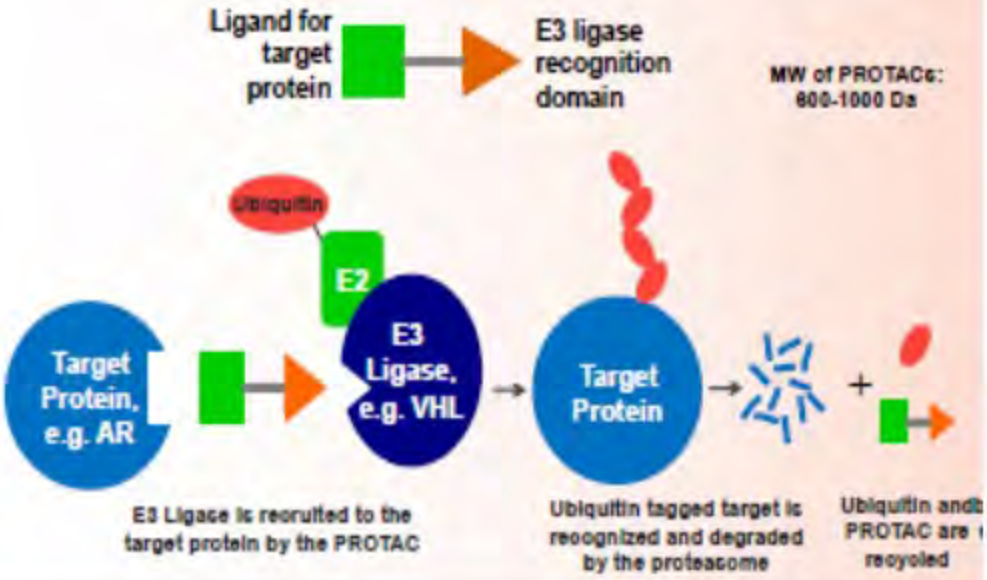
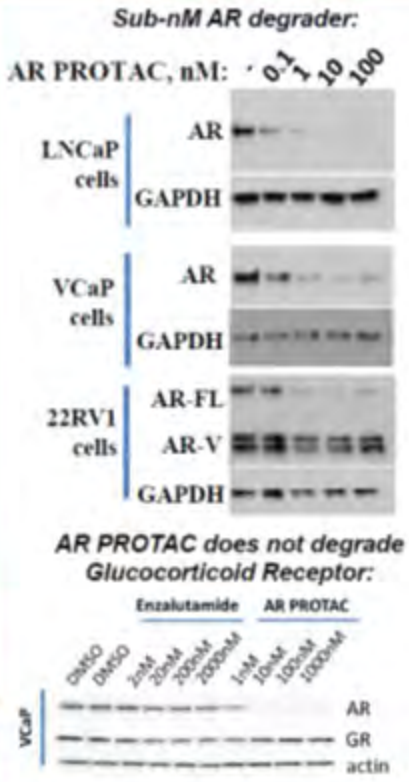
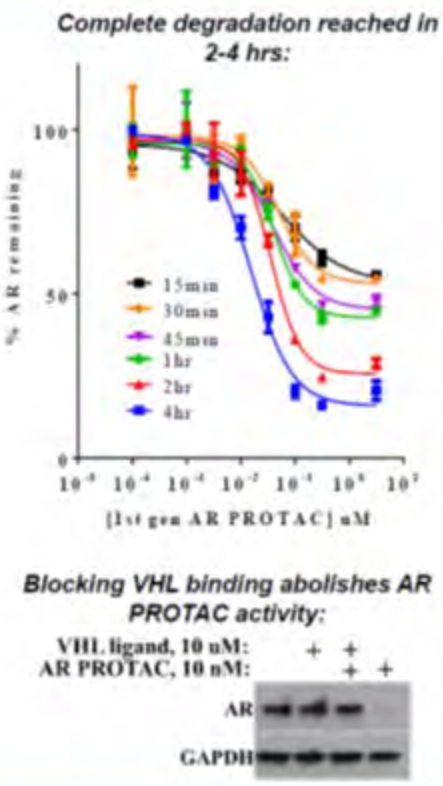
Promoting Degradation of AR-FL and Possibly ARVs via E3 Ligase

PROTAC: PROteolysis TArgeting Chimera

- Technology developed by Prof. Craig Crews, Yale University
- Platform licensed to Arvinas in 2013







Jin M et al. Presented at: American Association for Cancer Research (AACR) 2015.

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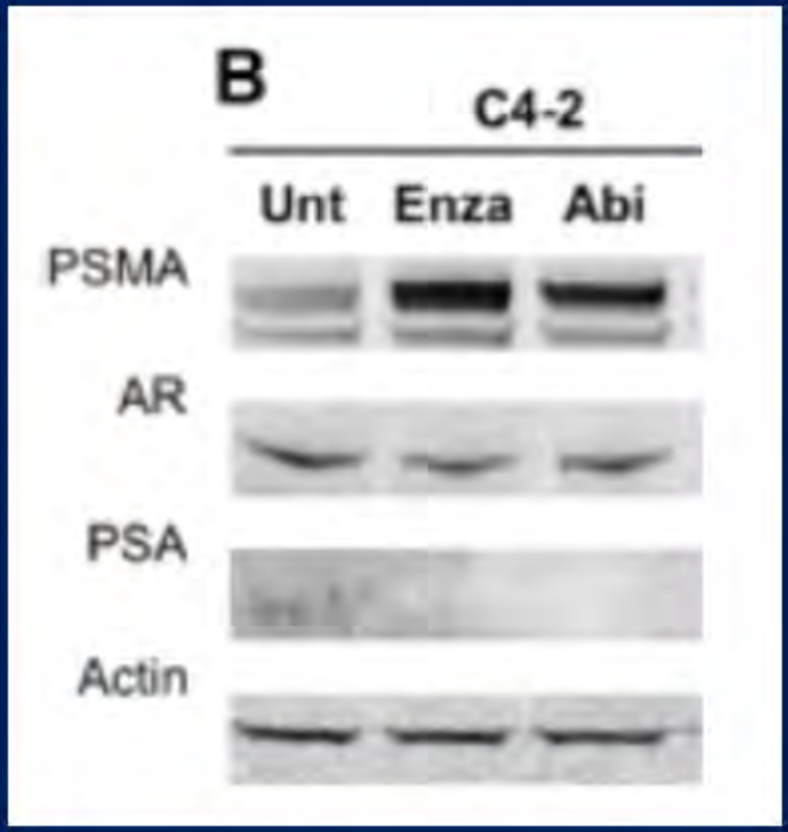
PSMA is Upregulated by Enza and Abi in Model Systems



Murga, et al. (2015). The Prostate, 75(3), 242-254. doi:10.1002/pros.22910

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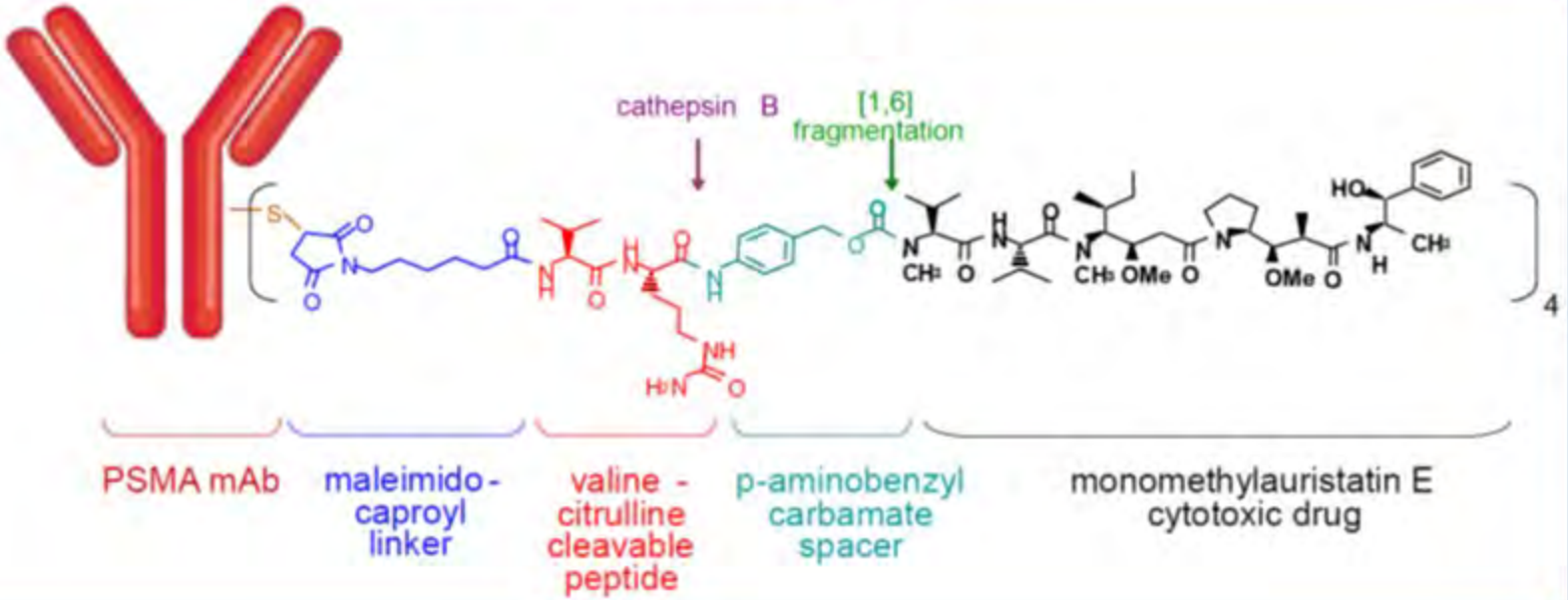
Antibody Drug Conjugates

PSMA: Target for ADC Therapy



Wang et al. Mol Cancer Ther. 2011 Sep;10(9):1728-39.

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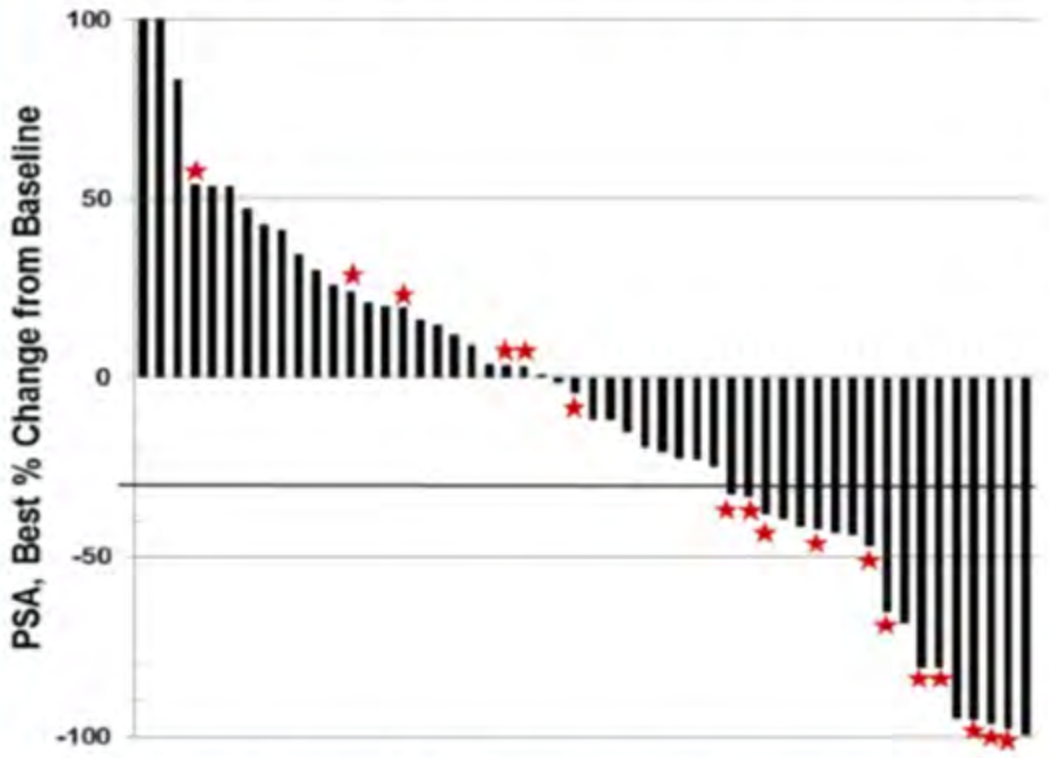
PSMA Targeted Chemotherapy

Study 2301

AR-V7 status does not confer resistance to PSMA ADC



- A total of 52 samples were analyzed for AR-V7
- 17/52 tested positive for N-term AR = AR+
- 35/52 were negative for N-term AR = AR-
- 17 proceeded to be tested for C-term AR
- All 17 had C-term loss to various degree, thus AR-V7+ (★)
- 11/17 responded to PSMA ADC (65%)

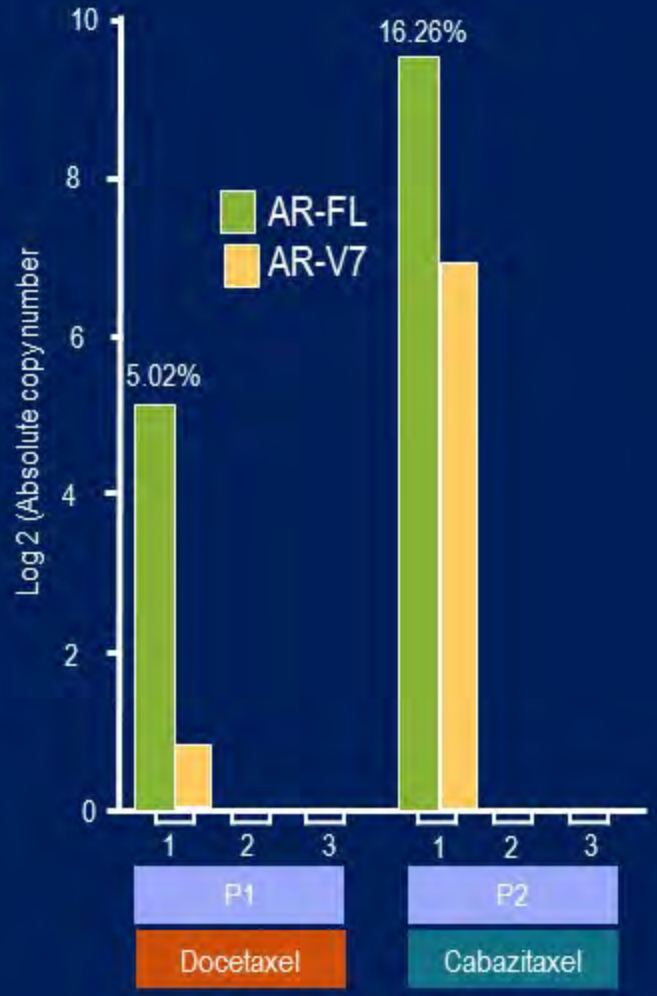
PSMA ADC can be effective in reducing PSA regardless of AR-V7 status

Petrylak et al, ESMO/ECCO 2015, Abstract 419.

ROCKPOINTE Oncology

Converting AR-V7 CTCs from Positive to Negative with Taxanes

Treatment	Remained AR-V7 positive	'Reversions' to AR-V7 negative	Unknown
First-line ADT (*n* = 0)	0	0	0
Abiraterone (*n* = 5)	4	0	1
Enzalutamide (*n* = 4)	4	0	0
Docetaxel (*n* = 9)	4	5	0
Cabazitaxel (*n* = 4)	1	1	2
Total (*n* = 22)	13	6	3



Taxanes can re-sensitize some men to AR inhibition!

Nakazawa M et al. *Ann Oncol.* 2015;26:1859-1865.

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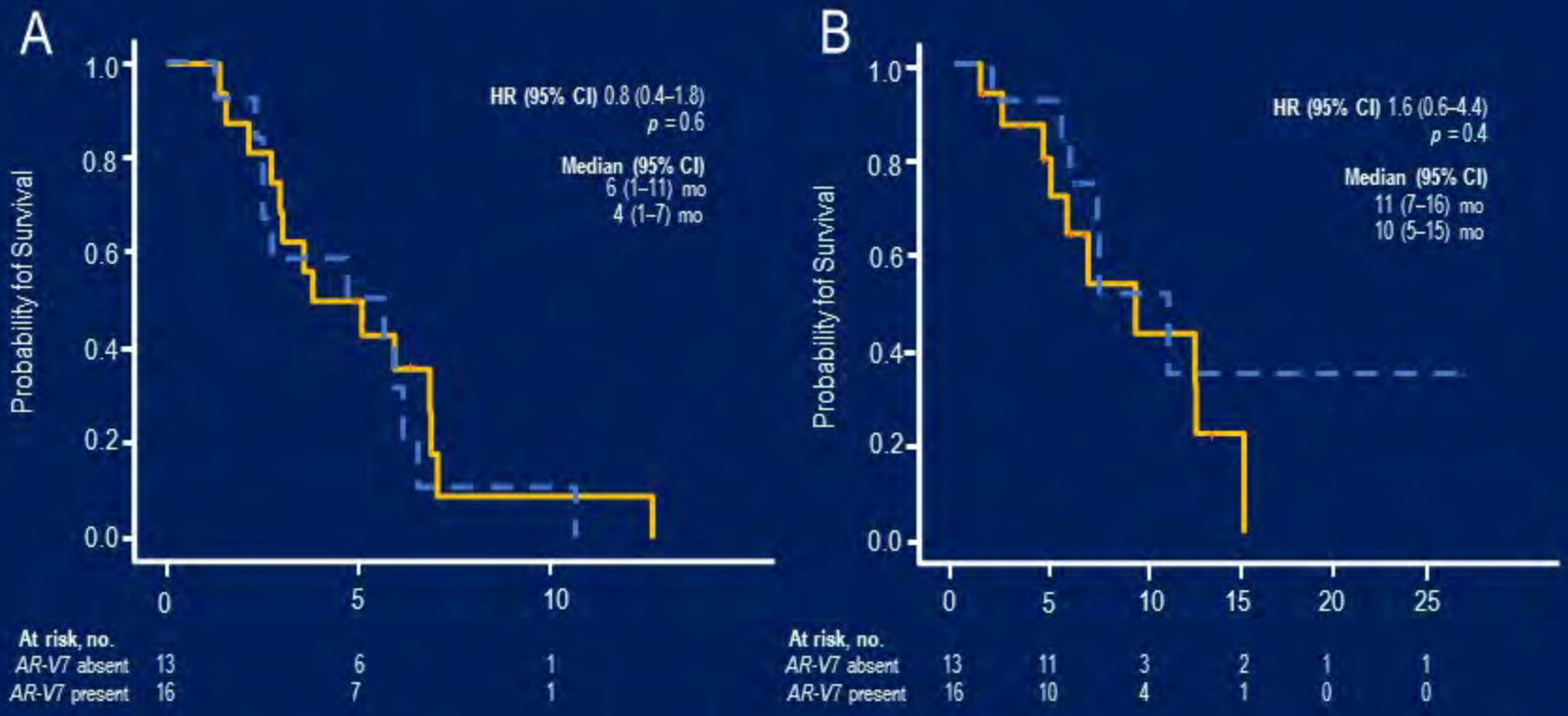
Efficacy of Cabazitaxel in CRPC Is Independent of the Presence of *AR-V7* in CTCs



(A) Progression-free survival and (B) overall survival as a function of *AR-V7* in circulating tumor cells at baseline. The reported *p* value is from a log-rank test.

AR-V7 = androgen receptor splice variant 7; CI = confidence interval; HR = hazard ratio.

Onstenk W et al. *Eur Urol.* 2015;68:939-945.

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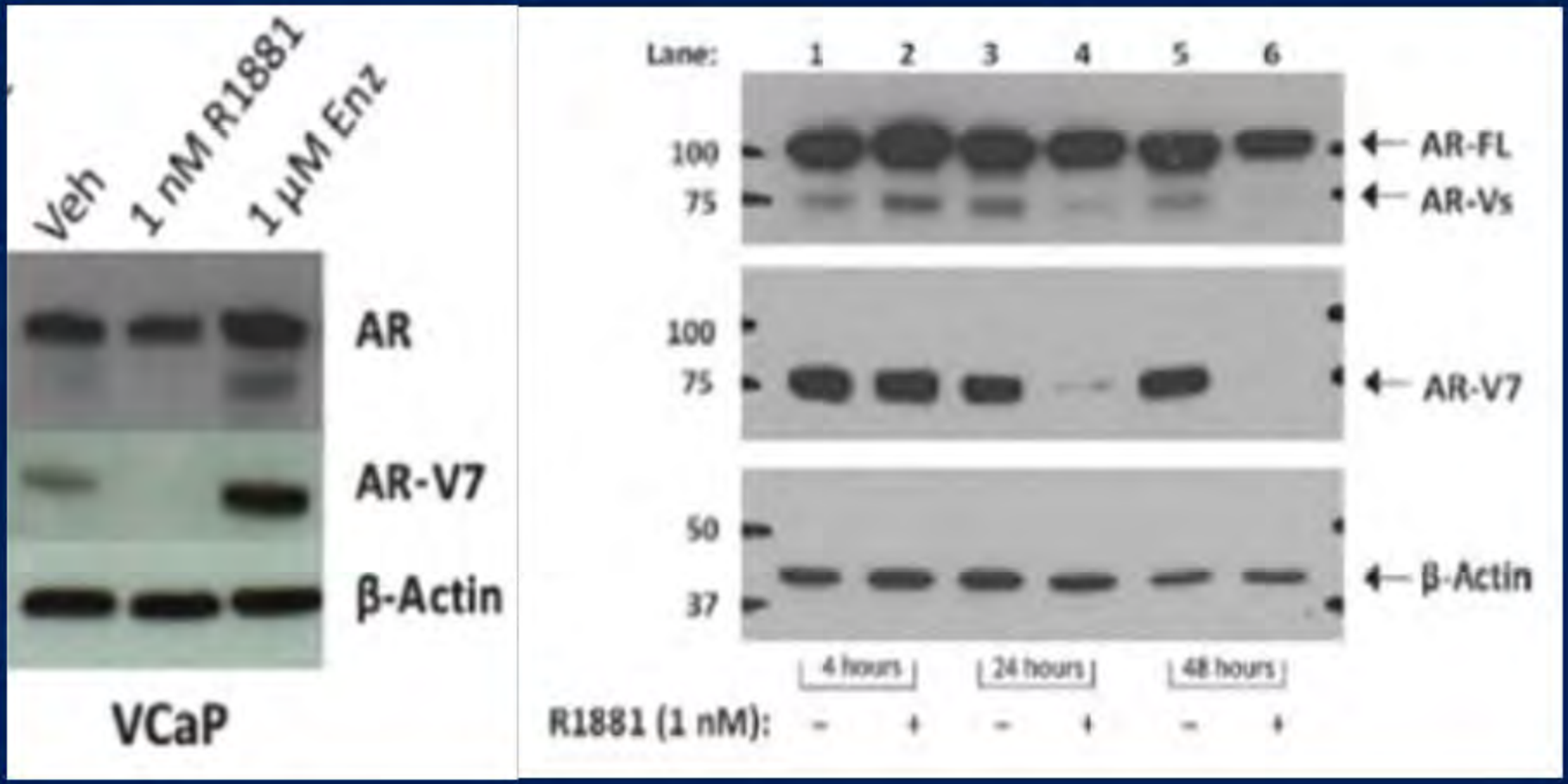
AR-V7 Suppression with Androgens and Upregulation with Enzalutamide



Denmeade and colleagues at Johns Hopkins.

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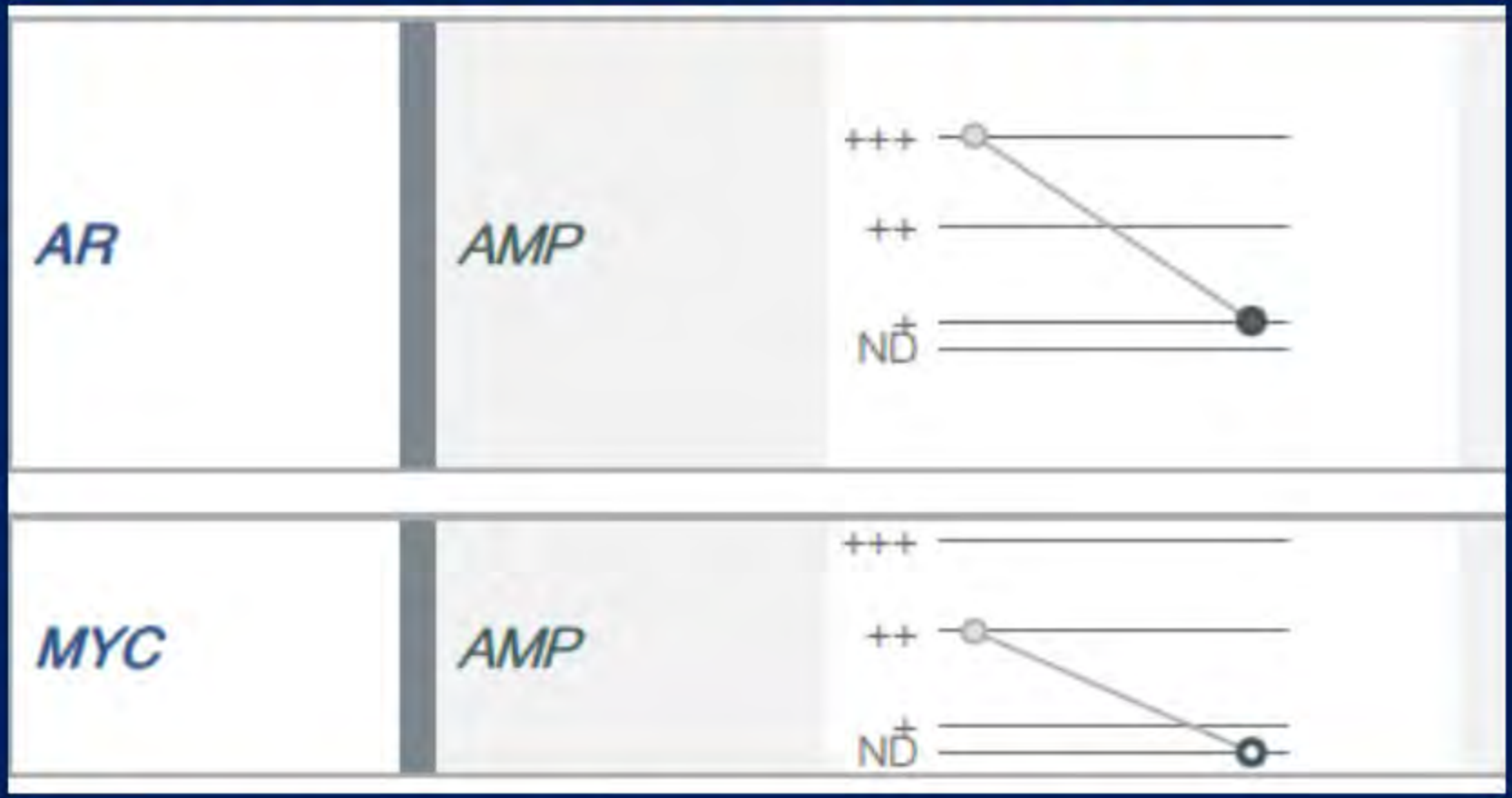
High Dose Testosterone: Suppression of AR Amplification (and Myc Amplification) in a CRPC Patients as Detected by cfDNA Assays



Pt was re-sensitized to abiraterone post-high dose T!

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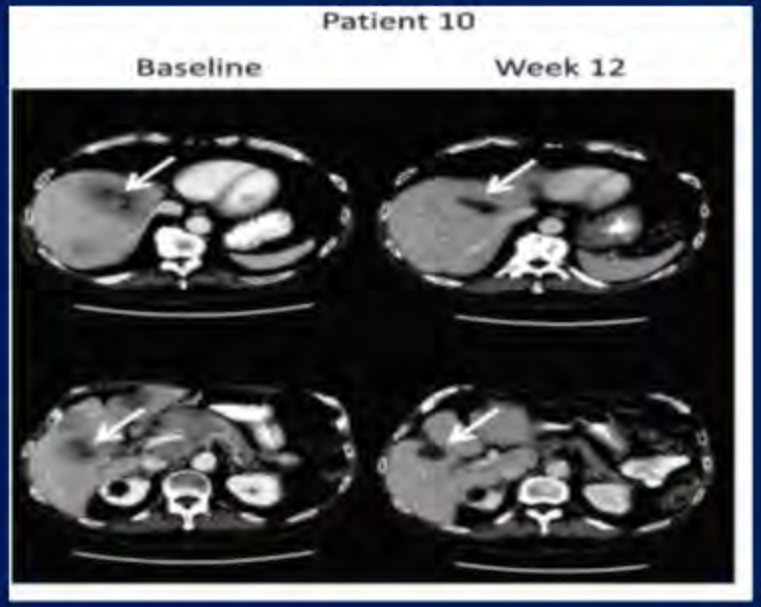
Bypassing AR: Pembrolizumab in CRPC

Table 2: Responding Patients*

Patient number	Date of cycle 1	PSA (ng/ml) baseline to nadir	Measurable Disease at Baseline	Best Radiologic Response	MSI	Prior Treatment for mCRPC
1	April 2015	70.65 → 0.08	Yes	PR	present	abi, enz
7	October 2015	46.09 → 0.02	No	N/A	n/a	abi, enz
10	January 2016	2502.75 → < 0.01	Yes	PR	absent	enz



Microsatellite instability noted

Graff et al. Oncotarget July, 2016 DOI10.18632/oncotarget.1047

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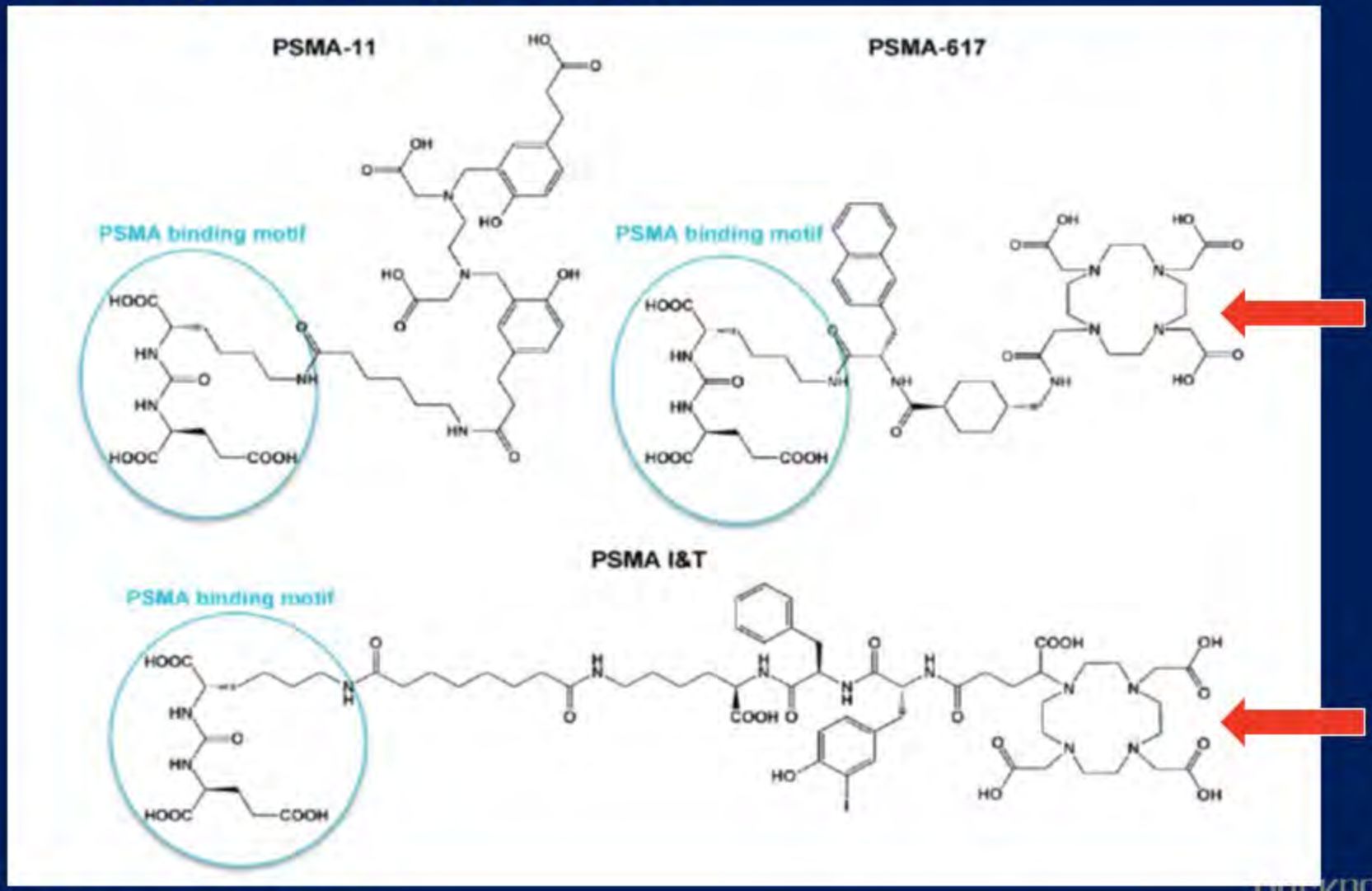
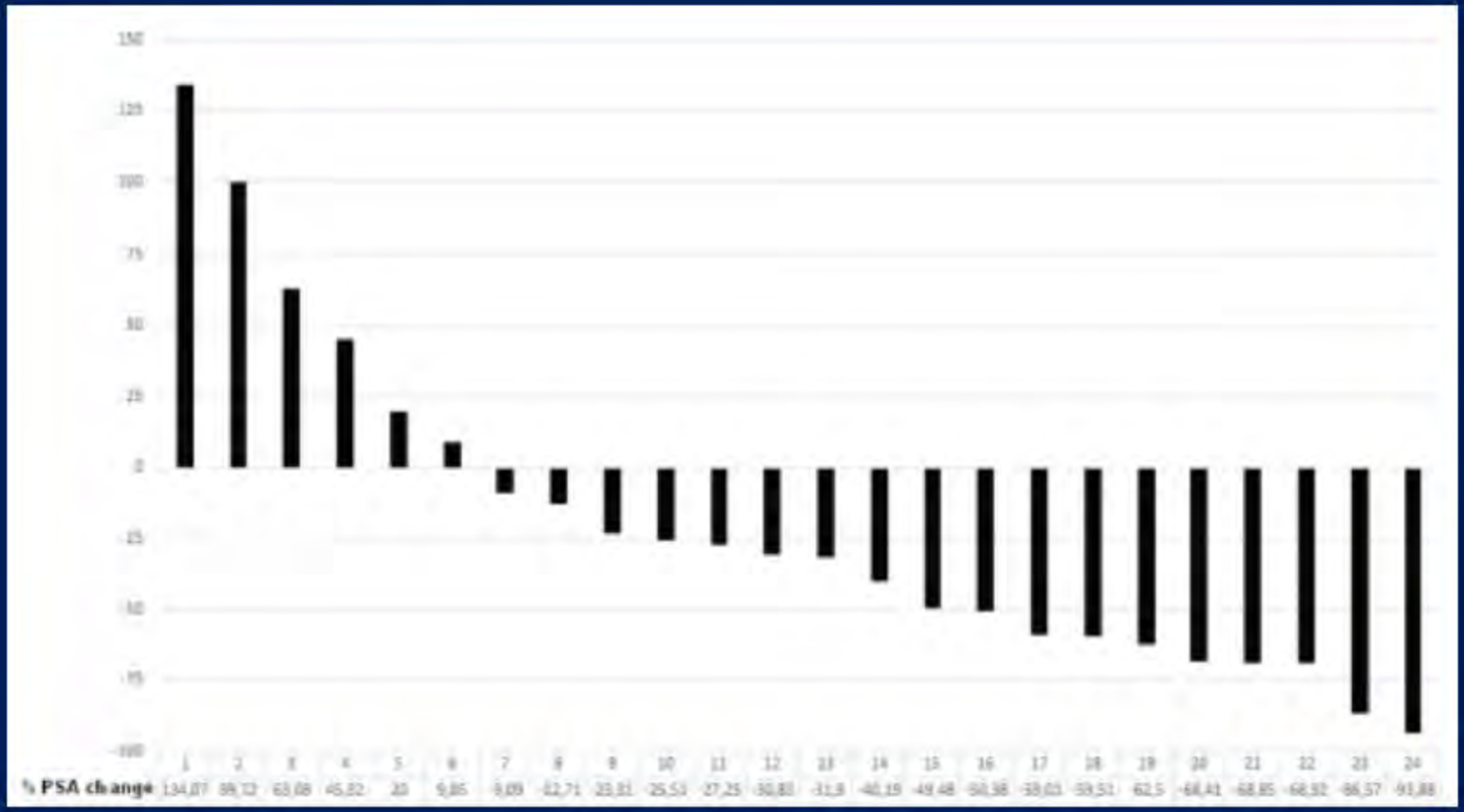
PSMA Binding Molecules can be linked to Therapeutic Agents, such as Lu-177, Sm-153,Y-90, Bi-213, Ac-225, or Th-229, by attaching a Chelator



Chatolic et al. Theragnostics 6:849, 2016

Rockpointe Oncology

PSA change 8 weeks after one cycle ^{177}Lu-DFKZ-PSMA-617



Amhadzadehfhar et al. Oncotarget 7:12477, 2016

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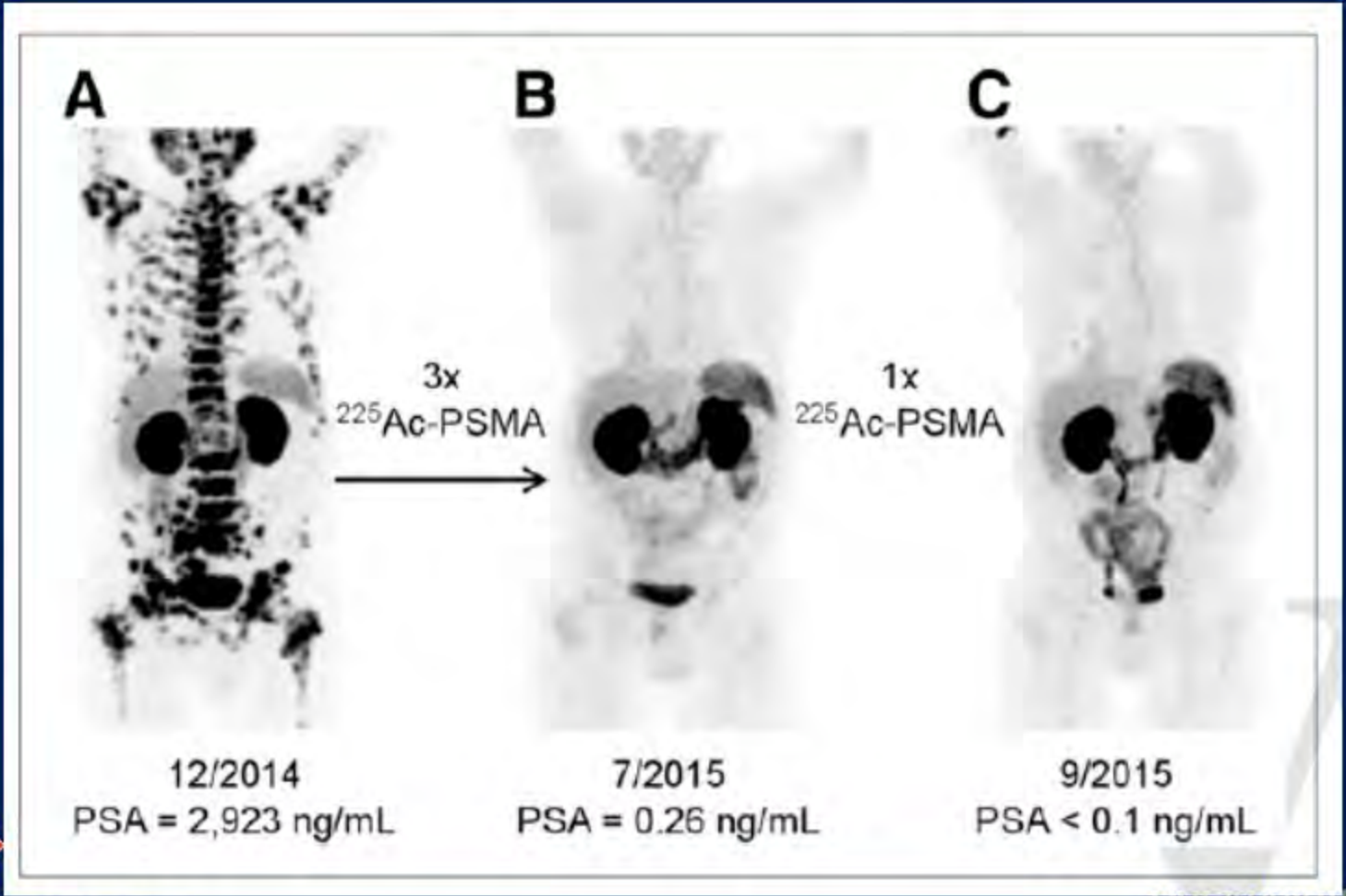
Radio-conjugates: PSMA targeted alpha emitters (Actinium-225) as 9th line treatment

Patient A
Leuprorelin
Zoledronate
Docetaxel (50 cycles)
Carmustine/epirubicin in hyperthermia
Abiraterone
Enzalutamide
^{223}Ra (6 cycles)
Abiraterone reexposition
Estramustine



Kratochwil et a. J Nuc Med 57: 1-4, 2016

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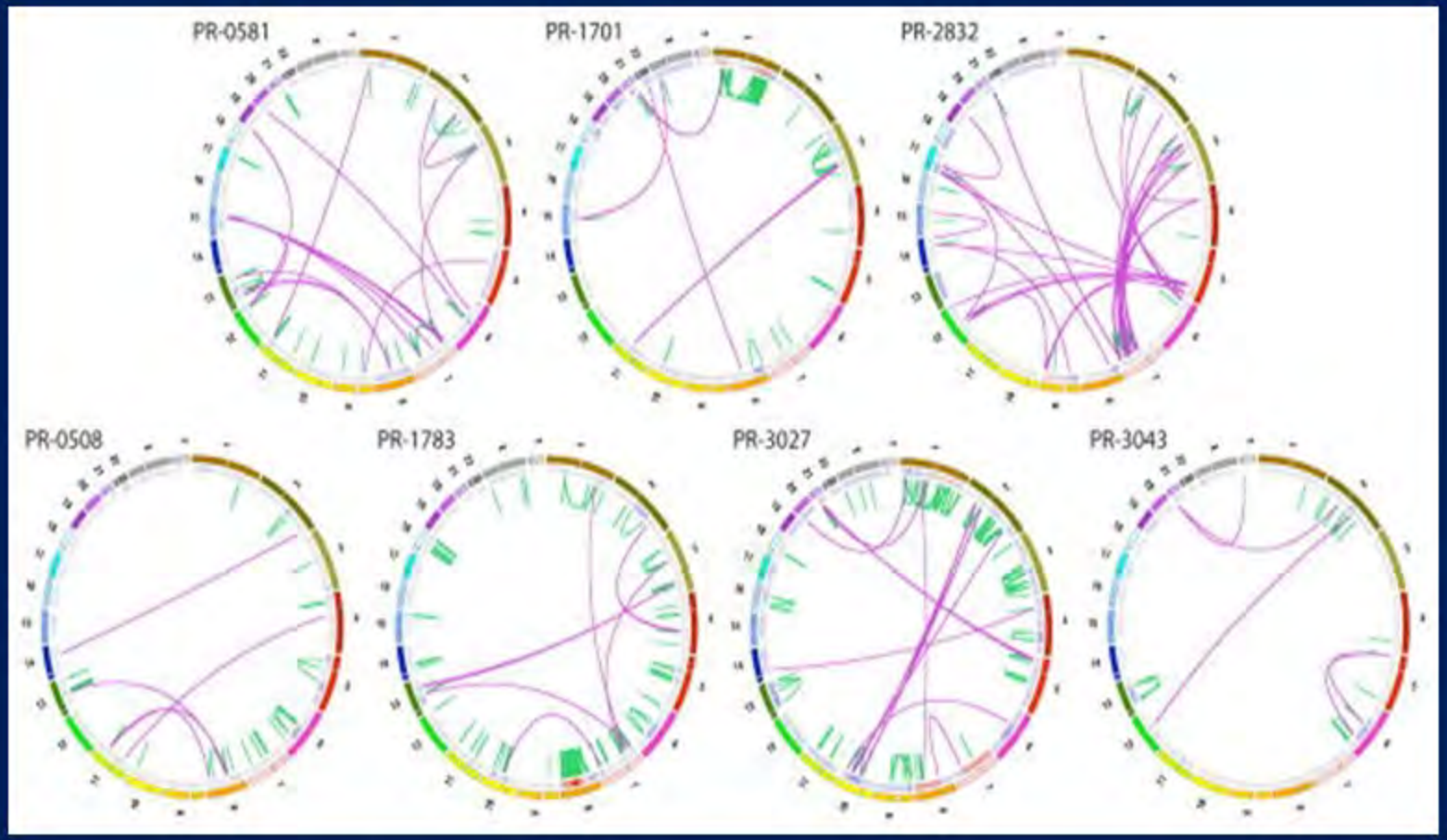
Genetically Heterogeneous Cancers Are a Challenge for "Molecularly Targeted" Therapy, but Radiation Kills Them All!



Berger ME et al. *Nature*. 2011;470:214-220.

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Discussion Question

Prognostic and predictive biomarkers offer clinical utility by facilitating optimal treatment selection. AR-V7 and cfDNA biomarkers are predictive of resistance for which of the following agents?

1. Docetaxel and radium-223
2. Enzalutamide and abiraterone
3. Enzalutamide and cabazitaxel
4. Abiraterone and docetaxel

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Answer

Prognostic and predictive biomarkers offer clinical utility by facilitating optimal treatment selection. AR-V7 and cfDNA biomarkers are predictive of resistance for which of the following agents?

1. Docetaxel and radium-223
2. Enzalutamide and abiraterone
3. Enzalutamide and cabazitaxel
4. Abiraterone and docetaxel

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Summary

- CRPC is rapidly evolving with biomarkers now promising clinical utility
- Targeted therapy is still evolving and proof of concept is getting closer
- Multiple mechanisms of targeting resistance are being investigated
- Right now taxanes, high dose T, PSMA targeting, and new immunotherapy interests me
- The only thing assured is that we will have change ahead!

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Survivorship Care Planning

- American Cancer Society prostate cancer survivorship guidelines (endorsed by ASCO) recommend planning for and monitoring:
  - Health promotion
  - Prostate cancer surveillance
  - Screening for new cancers
  - Long-term and late functional disease and treatment effects
  - Psychosocial issues
  - Coordination of care

Retrieved from www.asco.org/press-center/ascoendorses-american-cancer-society-prostatecancer-survivorship-care-guidelines.

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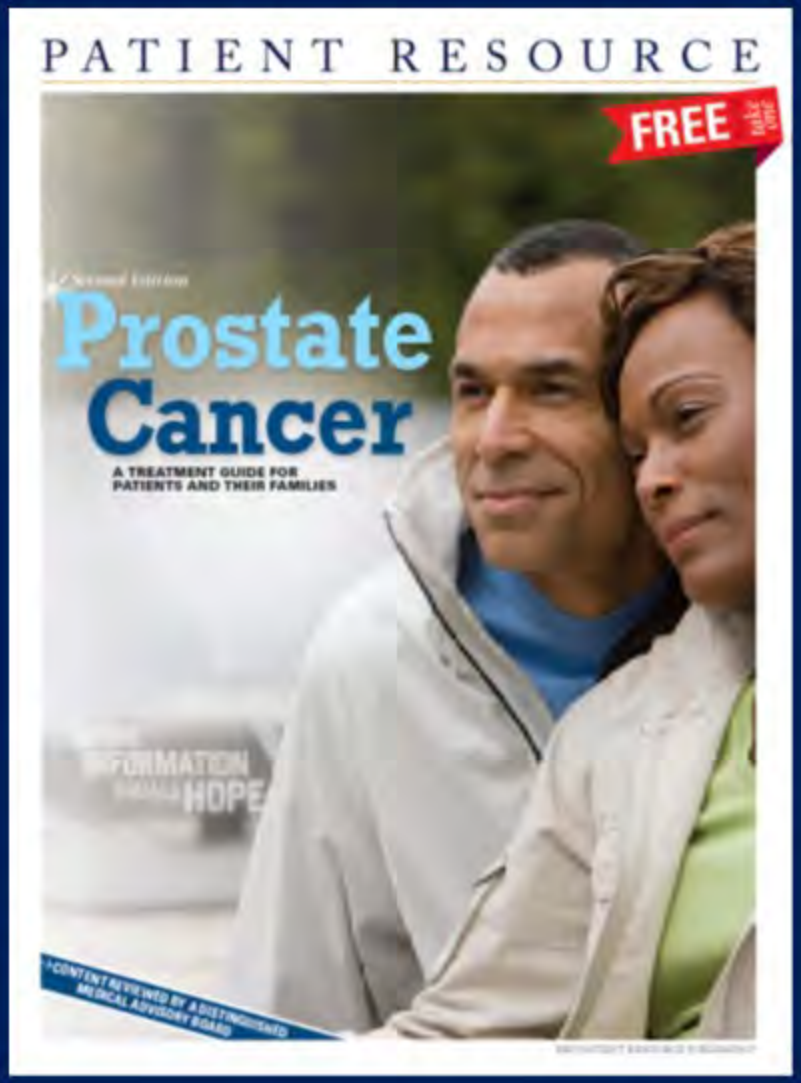
Patient Information Brochure from Patient Resource



- Excellent resource to educate and engage patients and families
- Can be shipped to your office (no charge for S&H)
- Available online with additional resources at: http://www.patientresource.com/Prostate_Cancer.aspx

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Additional Patient Resources

American Urological Association (AUA)

- Know Your Stats about Prostate Cancer®
  - Screening, Checklists, Treatment Options
    http://www.urologyhealth.org/knowyourstats/get-the-facts

American Society of Clinical Oncology (ASCO)

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Thank you for joining us today!

Please remember to complete the **POSTTEST** and **EVALUATION**.

Your participation will help shape future CME activities.