



Genomic Biomarker Testing in Advanced Prostate Cancer: A Primer for Clinicians

Thank you for joining us!

The webinar will begin shortly

August 13, 2026 | 3:00 – 4:00 PM ET



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American Cancer Society
National Prostate Cancer Roundtable
Webinar:

Genomic Biomarker Testing in Advanced Prostate Cancer: A Primer for Clinicians



August 13, 2026 | 3:00 PM

Thank You to Our Sponsors!

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 NOVARTIS

Pfizer has provided funding to ACS in support of the launch of "Change the Odds: Uniting to Improve Cancer Outcomes™," a new initiative to start creating change where it is most urgently needed: in communities disproportionately impacted by breast and prostate cancer.



Ground Rules



1 **Nonpartisan Commitment & Discussion Guidelines**

ACS/ACS CAN is a nonprofit, nonpartisan organization. We believe everyone should have a fair and just opportunity to prevent, detect, treat, and survive cancer. We therefore ask that you avoid partisan topics and opinions today.

2 **ACS National Roundtable Rules for Engagement**

Rules for engagement clarify the expectations for participation by members and representatives of the ACS NPCRT. Members are expected to respect and comply with these Rules and all other applicable ACS policies.

3 **Confidentiality**

This webinar is being recorded. Please be mindful of our conversation and respectful of others' privacy. Do not identify or discuss specific patients by name.

General Webinar Housekeeping



This webinar will be recorded and archived on the ACS NPCRT website.



You will be muted with your video turned off when you join the webinar.



This webinar takes place on the Zoom platform. To review Zoom's privacy policy, please visit <https://www.zoom.com/en/trust/terms/>



Questions? Type them in the Question-and-Answer box at the bottom of your screen. We also encourage you to ask questions as they arise in the chat.

Previously on ACS NPCRT...



The March 5, 2026, ***Managing Special Care Considerations in the Treatment of Advanced Prostate Cancer*** archived webinar, participants explored current standards of care and practical, patient-centered strategies for managing older or frail patients, preserving bone health, and addressing cardiac side effects associated with systemic therapy.



WEBINAR

Managing Special Care Considerations in the Treatment of Advanced Prostate Cancer

<https://npcrt.org/event/webinar-managing-special-care-considerations-in-the-treatment-of-advanced-prostate-cancer/>

1) Educate clinicians on the recent developments that have brought genomic biomarker testing to bear in advanced prostate cancer.

2) Review the different genomic and biomarker tests available for advanced PCa, what they test for, and how to help patients decide whether to pursue these tests.

3) Discuss the implementation of biomarker testing in this setting, barriers to access, and how to bridge the gap to generate real world impact.



Learning Objectives

ACS NPCRT Team Members



**Sarah Shafir, MPH
VP, National Roundtables
and Coalitions**



**Shannon Griffen-Blake,
PhD
Senior Director, National
Roundtables Programs**



**Lucas Brand, PhD
Strategic Director,
ACS NPCRT**



**Michelle Chappell, MS
Program Manager,
National Roundtables and
Coalitions**

Meet The Experts



Jerry S.H. Lee, BS, PhD

Chief Science and Innovation Officer, Ellison Medical Institute
Associate Professor of Clinical Medicine and Chemical Engineering and Material Sciences, and Quantitative and Computational Biology, and Health Innovation, USC

Meet The Experts



Peter Nelson, MD
Vice President of Clinical Oncology
Fred Hutch Cancer Center

Genomic Biomarker Testing in Advanced Prostate Cancer: A Primer for Clinicians

Engineer's Perspective

Jerry S.H. Lee, Ph.D.

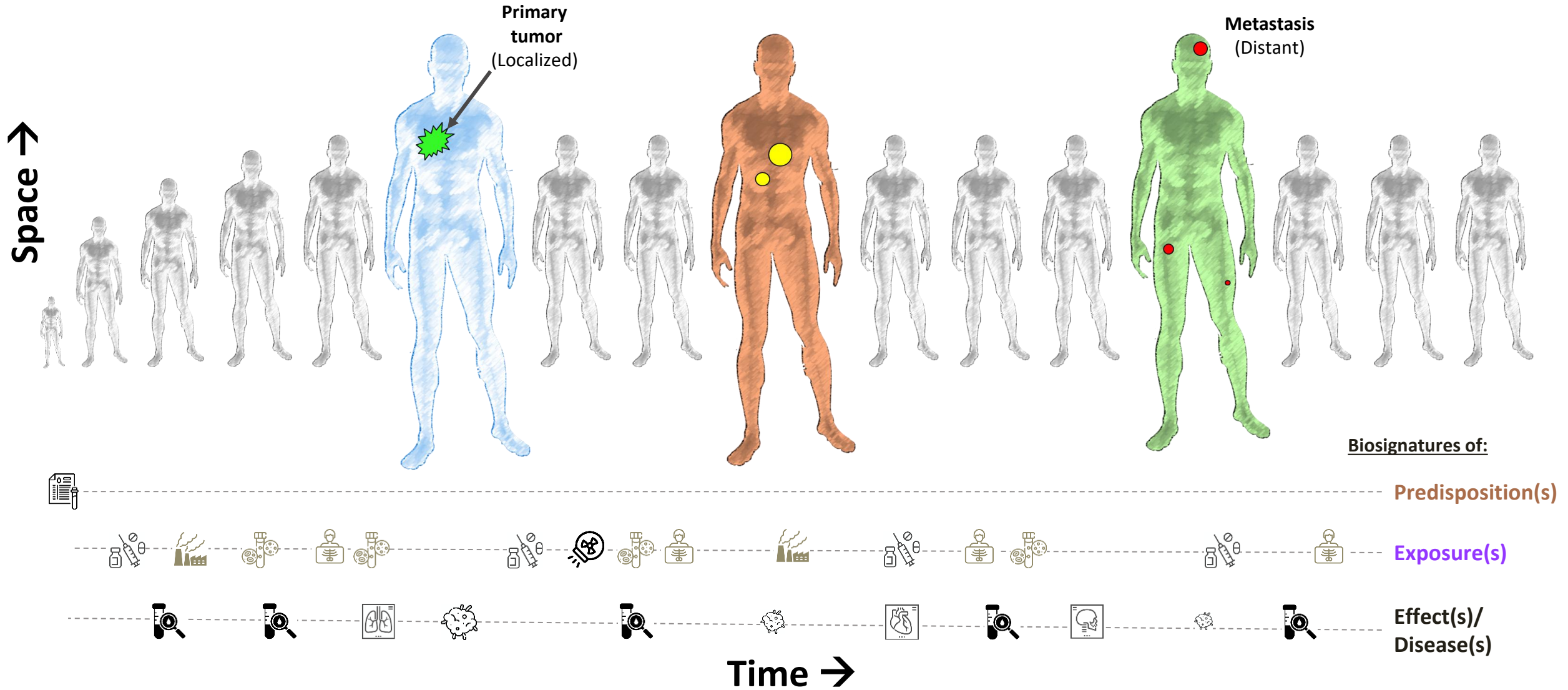
August 13, 2026

Jerry S.H. Lee, BS, PhD

Disclosure Statement

- Consultant to Murtha Cancer Center Director, Henry M. Jackson Foundation
- Member, Board of Directors, Lumea, Inc.
- Member, Scientific Advisory Board, AtlasXomics, Inc.
- Member, Scientific Advisory Board, miRoncol, Inc.
- Member, Advisory Board, Center for Computational Science Research, Inc.
- Co-founder, Blood Profiling Atlas in Cancer (BloodPAC) Consortium

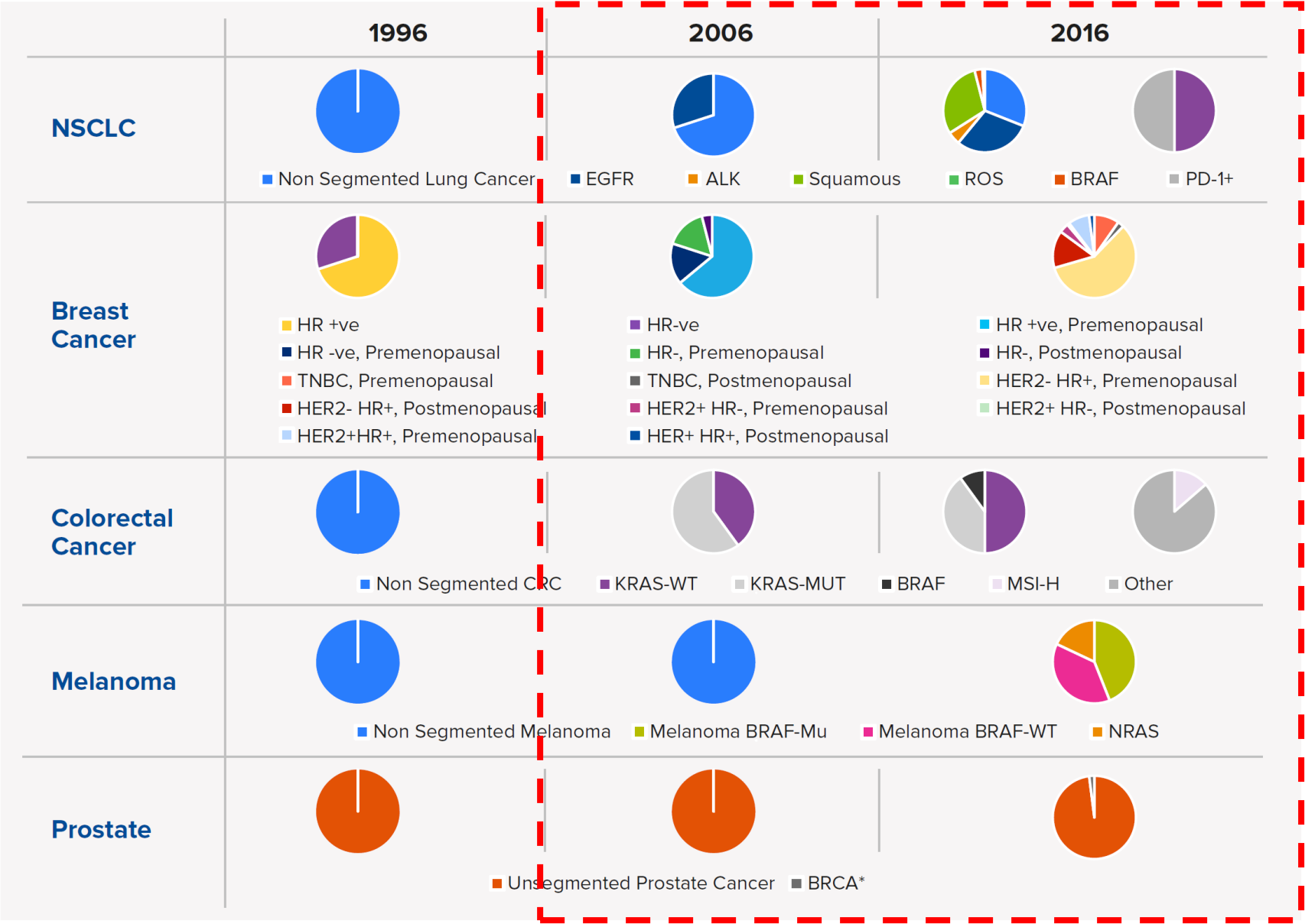
Engineer's Dream: Develop A Continuum





"Here's my DNA sequence."

Cancer has been progressively redefined over the past 20 years



9/28/2006

NIH Announces Two Integral Components of The Cancer Genome Atlas Pilot Project



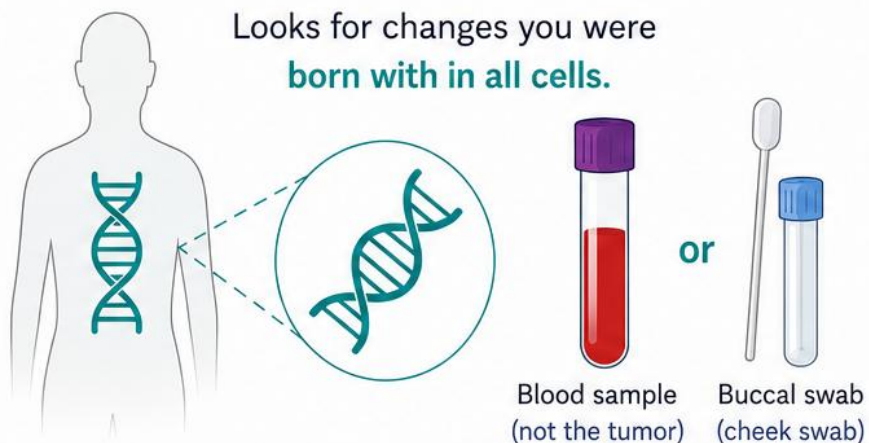
The National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI), both parts of the National Institutes of Health (NIH), today announced another two of the components of The Cancer Genome Atlas (TCGA) Pilot Project, a three-year, \$100 million collaboration to test the feasibility of using large-scale genome analysis technologies to identify important genetic changes involved in cancer. Lung, brain (glioblastoma), and ovarian cancers have been chosen as the tumors for study by TCGA Pilot Project.

“...the Data Coordinating Center will make TCGA data publicly accessible...and access to all TCGA data will be provided in a manner that meets the highest standards for protection and respect of the research participants....”

Germline vs. Somatic Sequencing

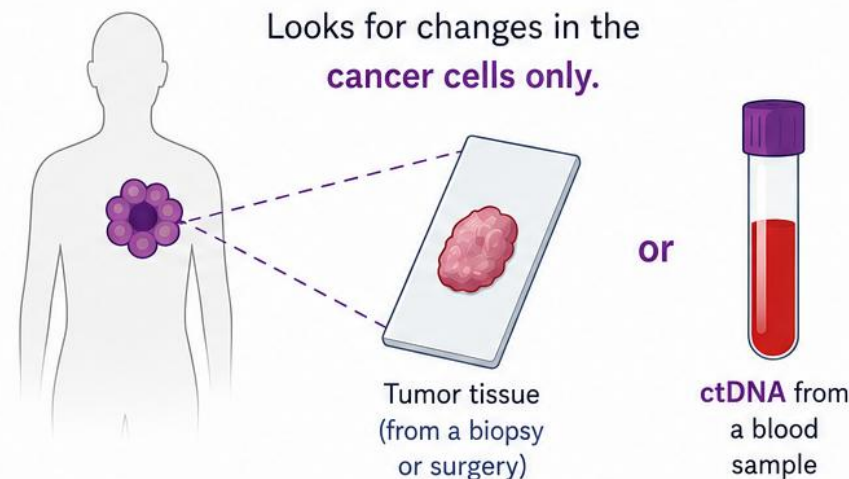
Two types of genetic testing that answer different questions

GERMLINE SEQUENCING



Helps find inherited changes that may affect your cancer risk and can be passed to family members.

SOMATIC SEQUENCING



Helps find genetic changes driving the cancer to guide treatment choices.



What is ctDNA?

ctDNA (circulating tumor DNA) is small pieces of DNA shed by cancer cells into the blood.



Can be used for somatic sequencing when a biopsy isn't possible



May help track treatment response and detect changes over time



A simple blood test



Your care team will recommend the right test based on your situation and what information will best help guide your treatment and care.

Created with ChatGPT by Dr. Jillian P. Infusino in 2026.

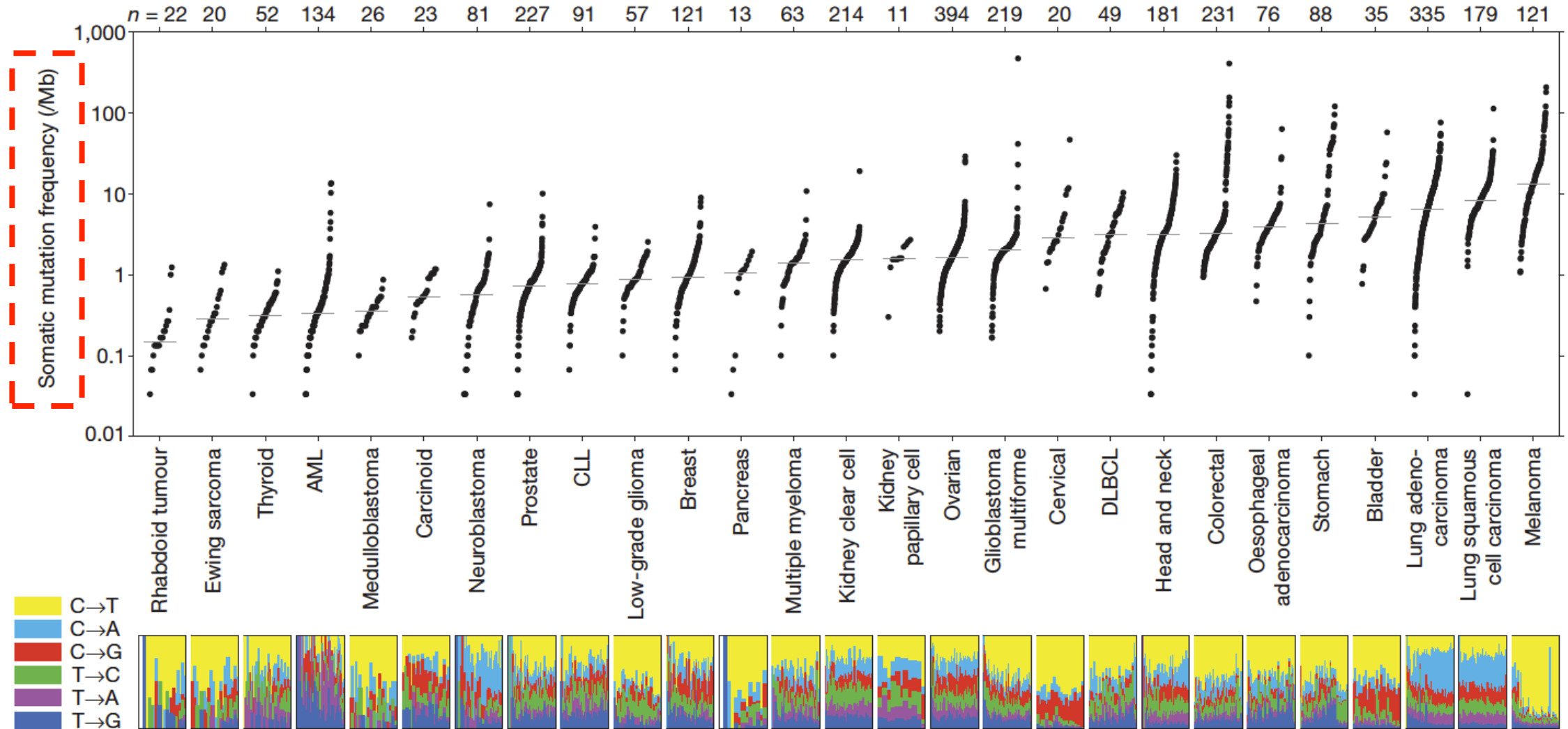
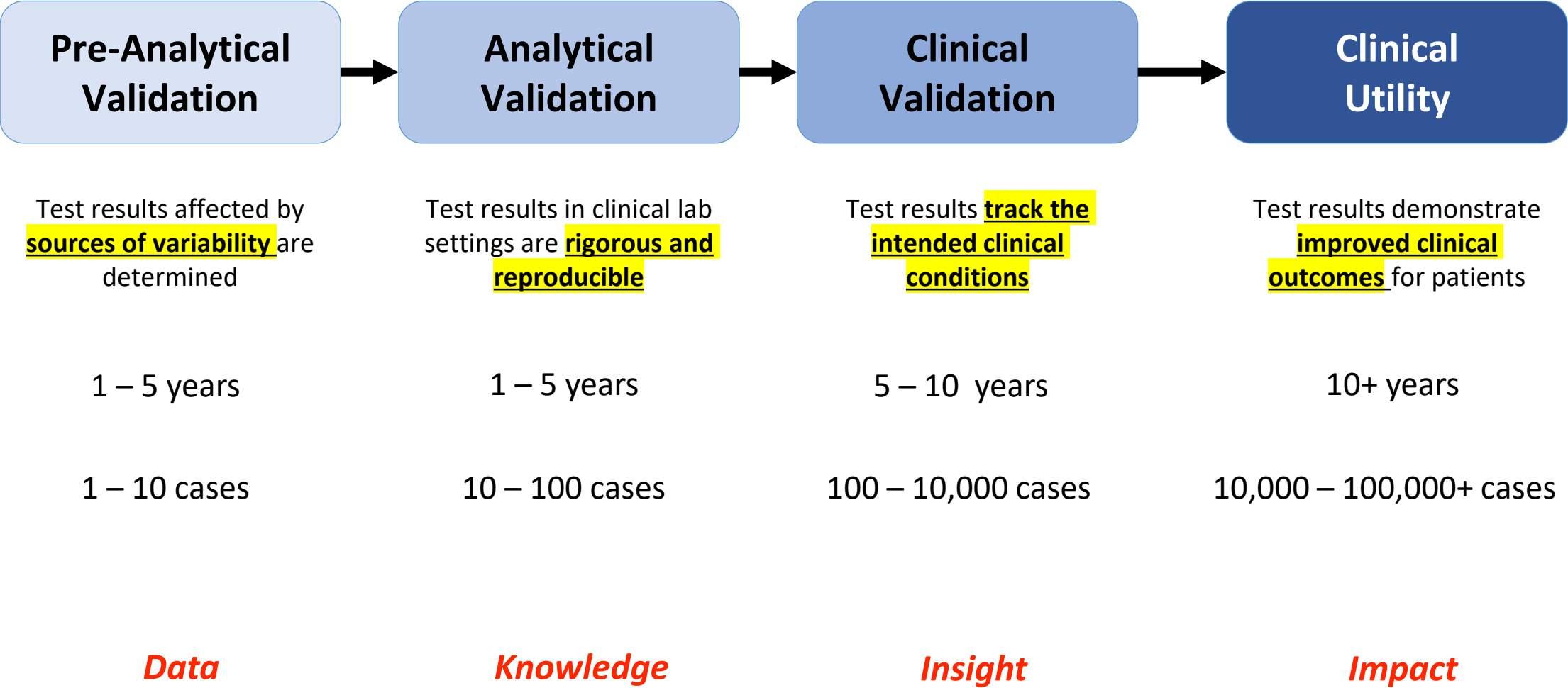


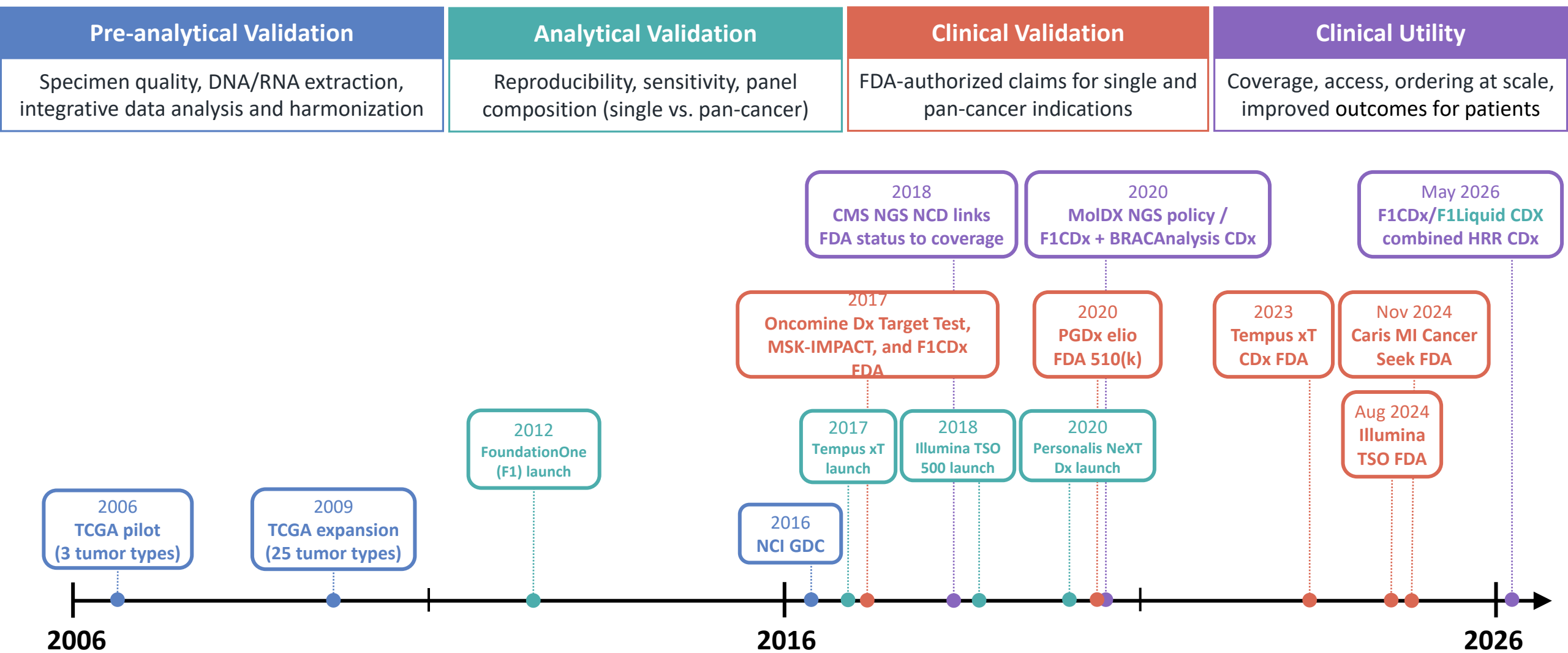
Figure 1 | Somatic mutation frequencies observed in exomes from 3,083 tumour-normal pairs. Each dot corresponds to a tumour-normal pair, with

such as tobacco smoke and ultraviolet light. Mutation frequencies vary more than 1,000-fold between lowest and highest across different cancers and also

Clear Context of Use Is Essential



Tissue-based Cancer Genomics Evolution: 2006 - 2026



“Pre-competitive collaboration aims to bring together multiple stakeholders that share a **common pain point**, and encourage them to develop **common solution(s)** that they can **all benefit from**, without giving any one of them a competitive advantage over another.

In this manner a **whole industry sector** can move forward as one, overcoming an operational hurdle or lowering a barrier to innovation that enables all to make progress, often including those who did not directly participate in the **creation of the solution(s)**.”

Tissue-based Cancer Genomics Evolution: 2006 - 2026

Pre-analytical Validation

Analytical Validation

Clinical Validation

Clinical Utility

PPP consortia and pragmatic trials that moved sequencing toward routine care

1 NCI TCGA 2006 - 2014

- Standardized biospecimen pre-analytical requirements
- Harmonized multi-center and multi-platform data generation **at scale**.

2 AACR GENIE 2015

- Aggregation and analysis of **real-world clinical sequencing** with **linked clinical data** from member institutions

3 NCI MATCH 2015

- Clinical trial entry evolved from **central testing** toward acceptance of **qualified clinical-grade sequencing**

4 ASCO TAPUR 2016

- Pragmatic trial using genomic results to **match patients to off-label targeted therapies** and **collect outcomes**

5 DoW/VA/NCI APOLLO 2016

- **National discovery to care learning health system** integrating genomics, proteomics, imaging, and outcomes across DoW and VA hospitals

2006

2016

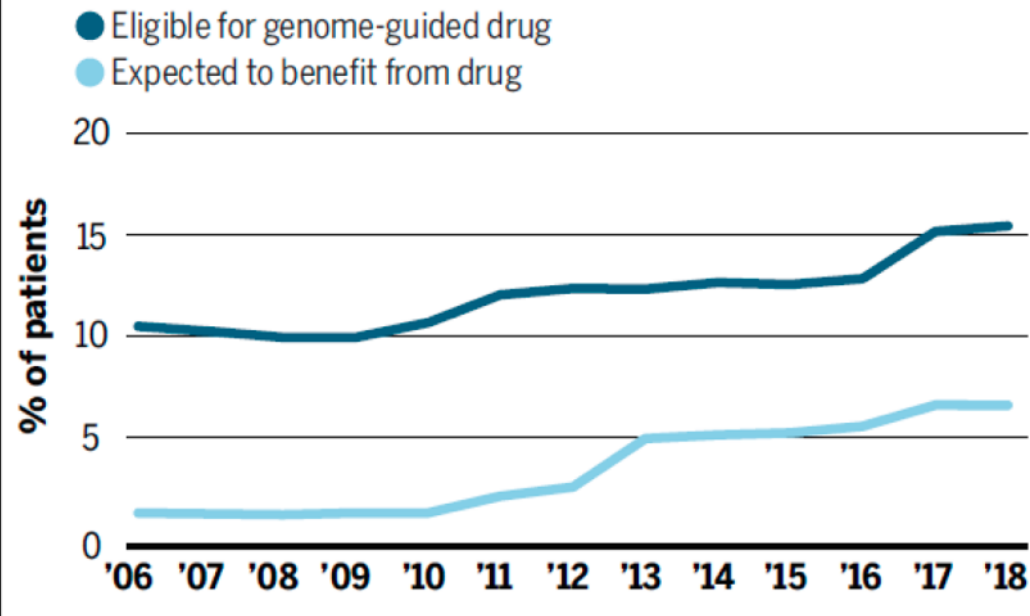
2026

Precision Medicine

2018

A lucky few

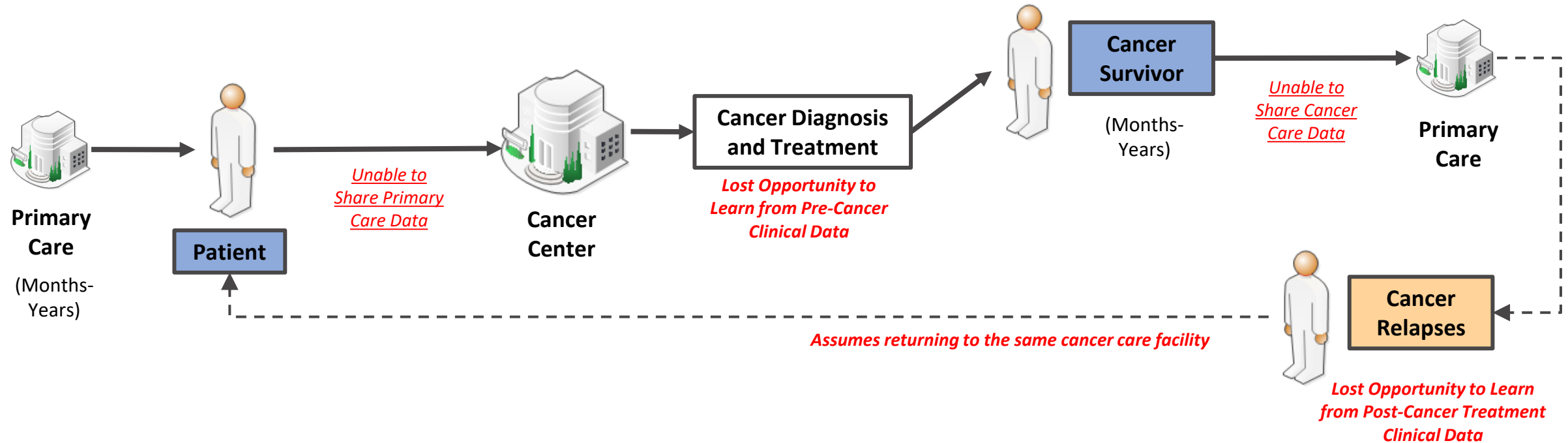
The portion of U.S. advanced cancer patients who can be matched with a Food and Drug Administration–approved drug based on their tumor’s genome is growing slowly, and only some will see their cancer shrink.



SCIENCE, 27 APRIL 2018 • VOL 360 ISSUE 6387

- Not what we expected
- 84 FDA-approved targeted therapies
- But only 15% of cancer patients have a biomarker that matches an FDA-approved drug (and only 6% benefit)
- Took 10 years to increase from 10% to 15% matched
- Growth rate expected to slow down (we found the easy cancer mutations)

Without a National Learning Healthcare System for Cancer

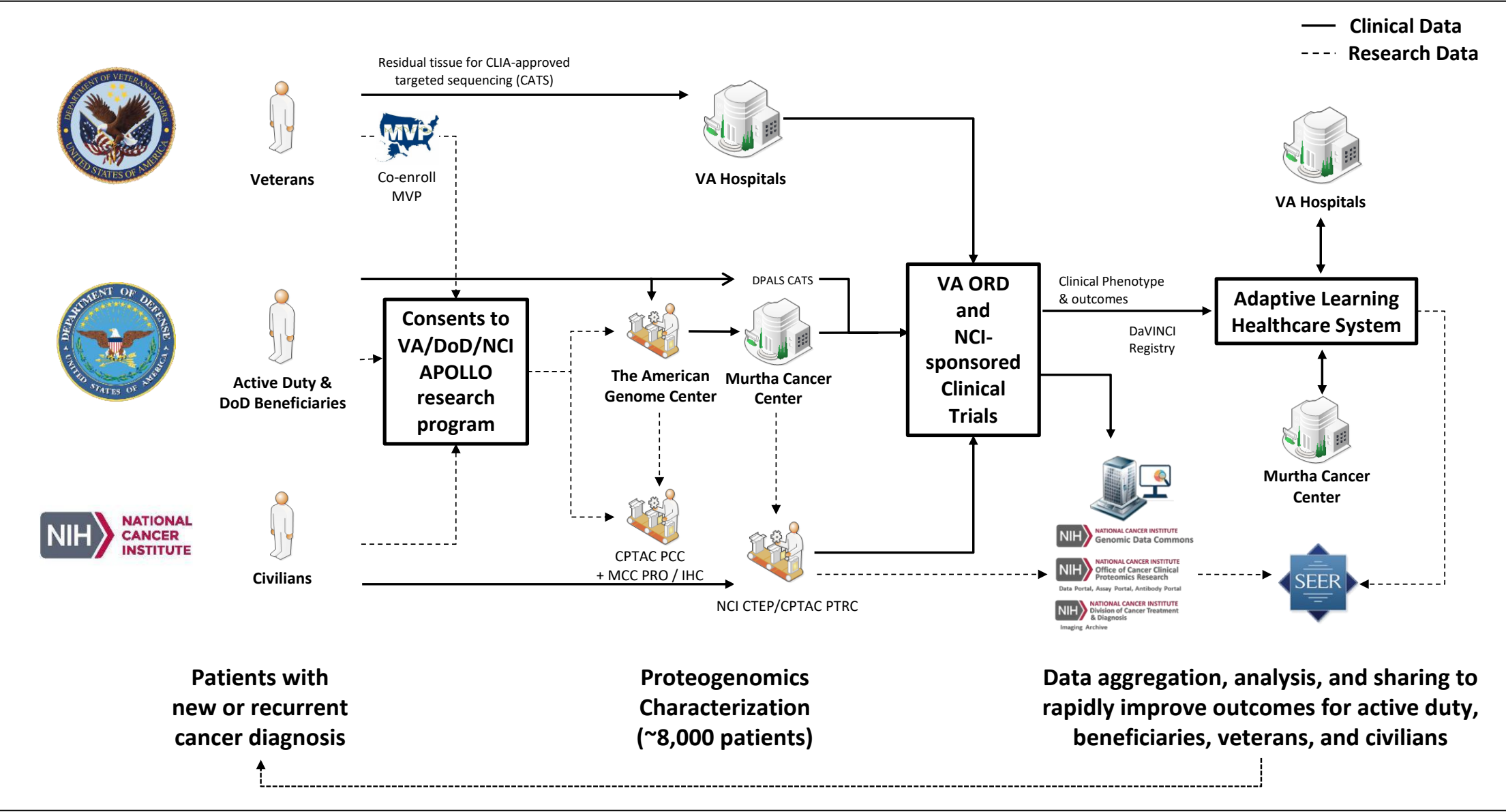


“~85% of cancer patients are first diagnosed and treated in community setting”

Copur et. al. J. Onc. Practice, 2015

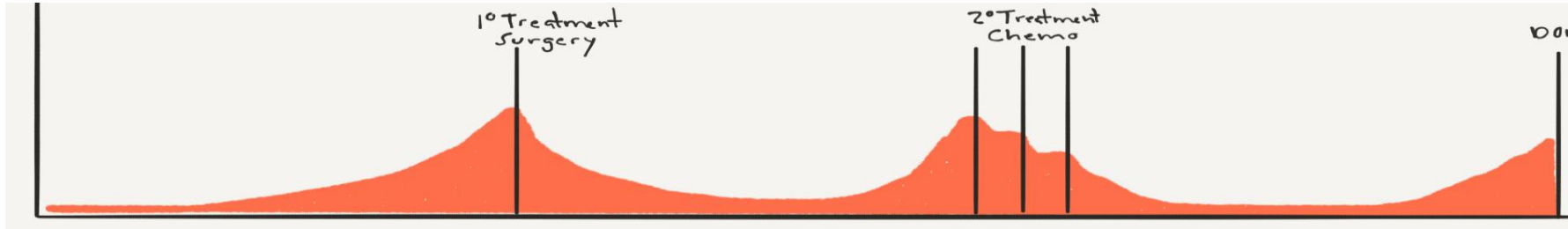


APOLLO: Applied Proteogenomics Organizational Learning and Outcomes Network

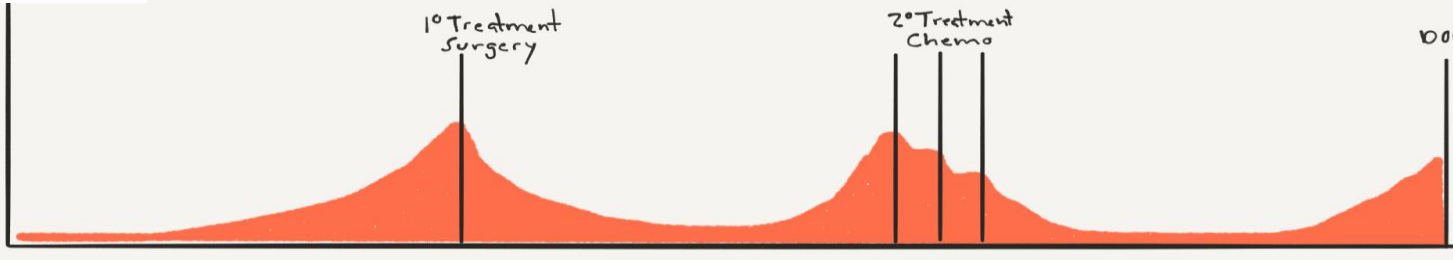


We Need Data Trajectories: Cancer + Health Factors

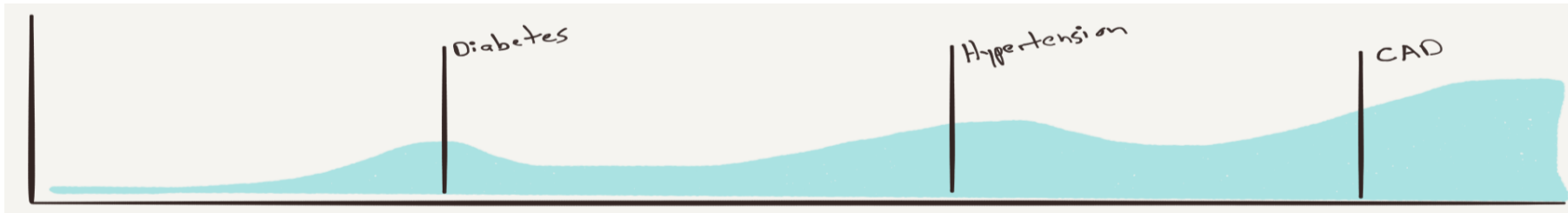
Cancer Case #1 Trajectory



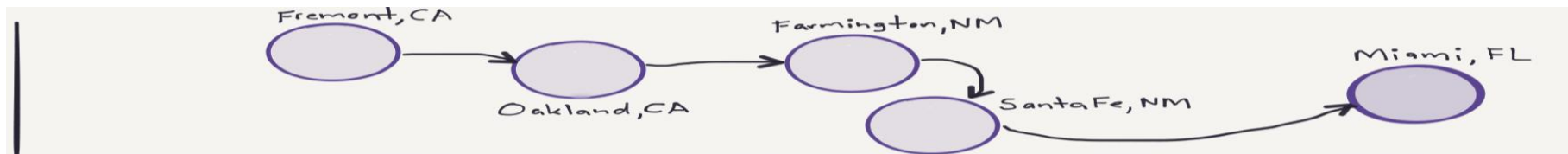
Cancer Case #2 Trajectory



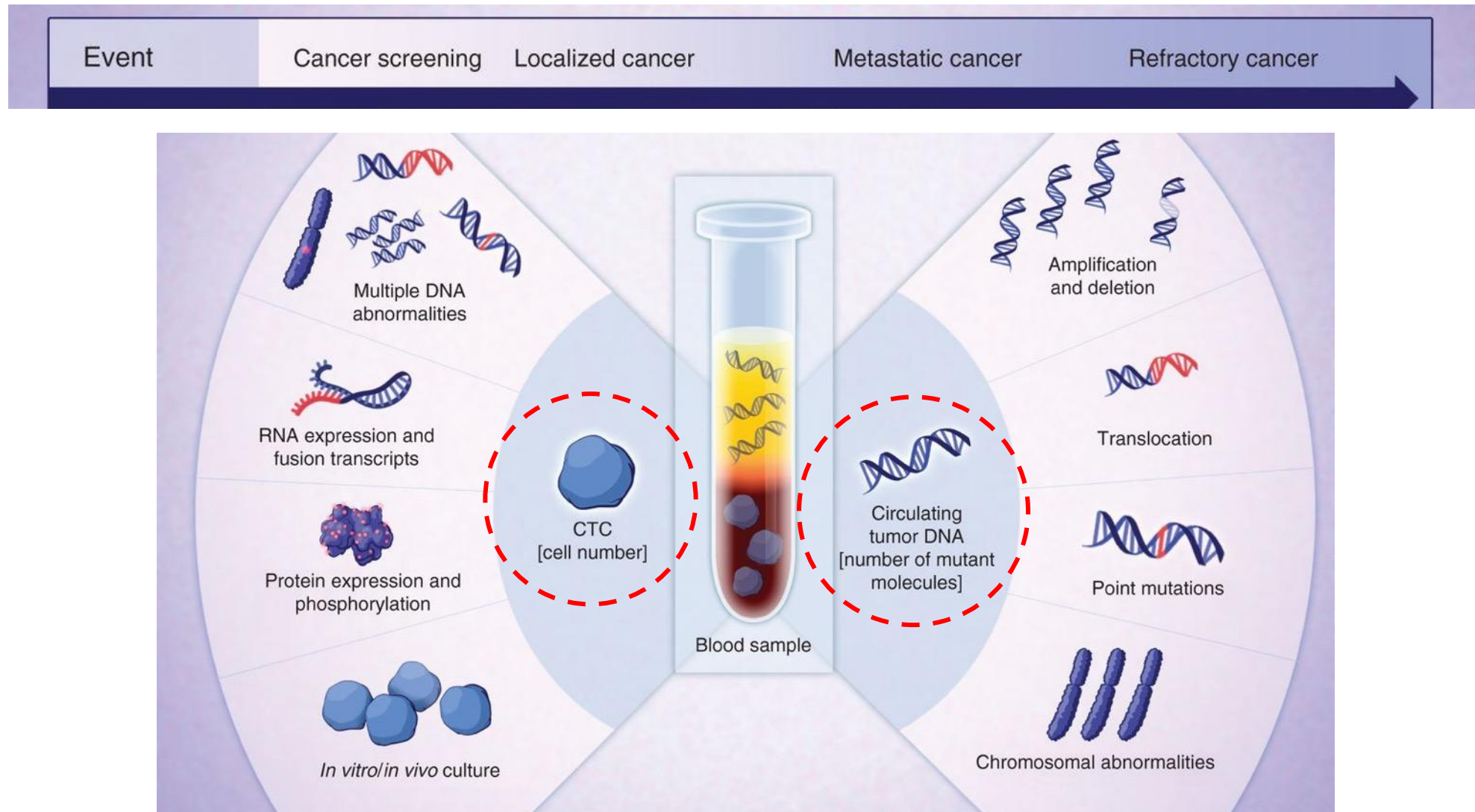
Comorbidity Cofactor Trajectory



Residence / Geospatial Cofactor Trajectory



What about blood profiling technologies?



Our Community: Collaboration is Key

Academics



Private
Payers



Diagnostic
Developers



76+

**GLOBAL
COLLABORATORS**

Government
Agencies



Non-Profits



Pharmaceutical
Companies



“Only a multi-stakeholder collaboration could develop consensus standards and best practices in evidence development necessary to enable clinical implementation of liquid biopsies” (Clarke CA, 2022)

<https://www.bloodpac.org/bloodpac-portal>

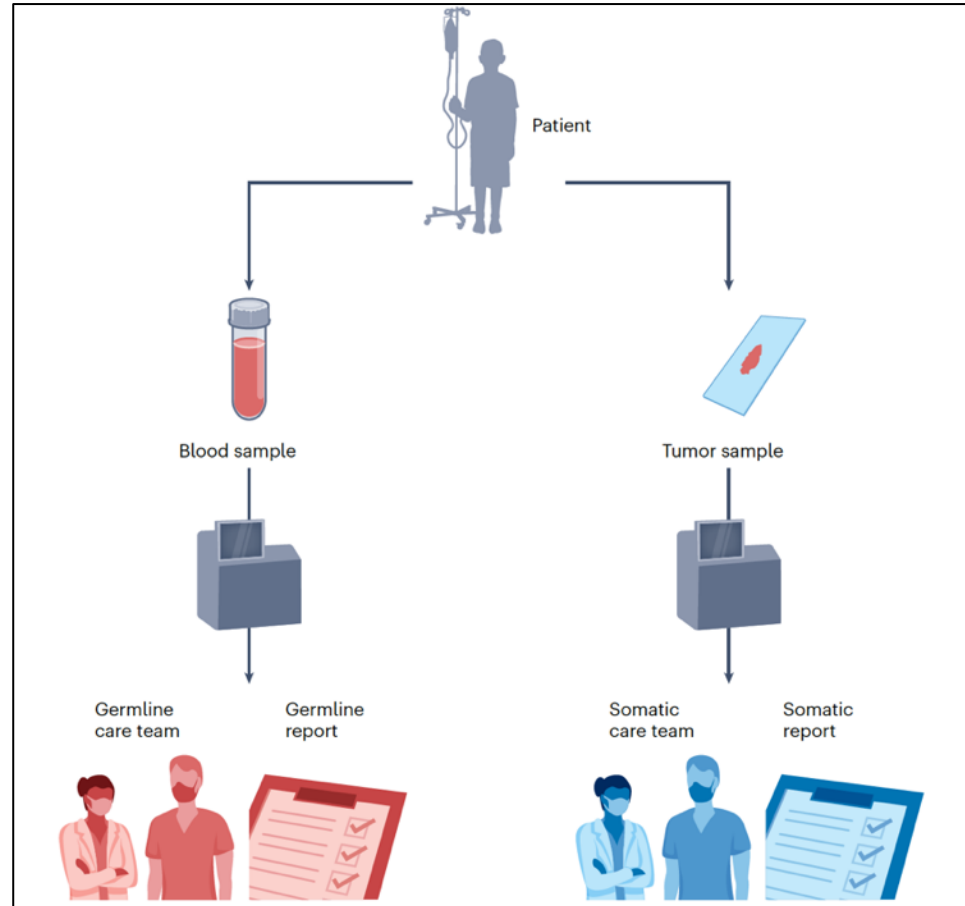


lauren@bloodPAC.org

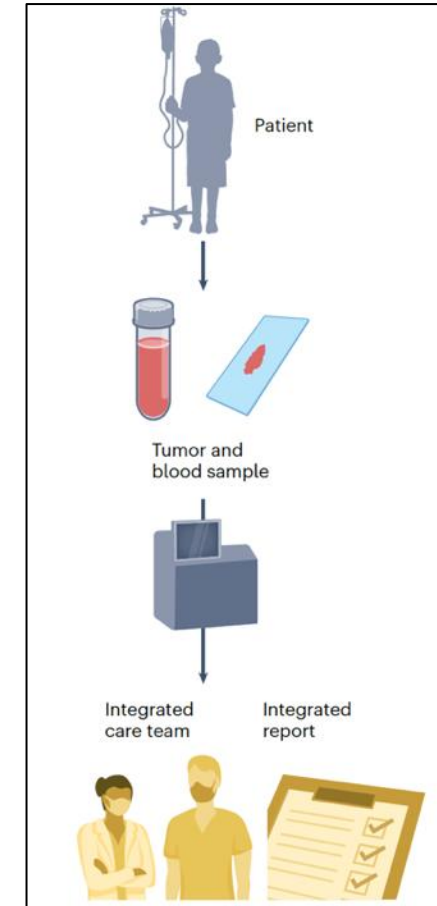
Patient-centered integration of tumor and germline genetic results can improve cancer care

nature medicine

05/25/2025



Current Siloed Model



Integrated Patient-Centered Model

Original Investigation | Health Policy

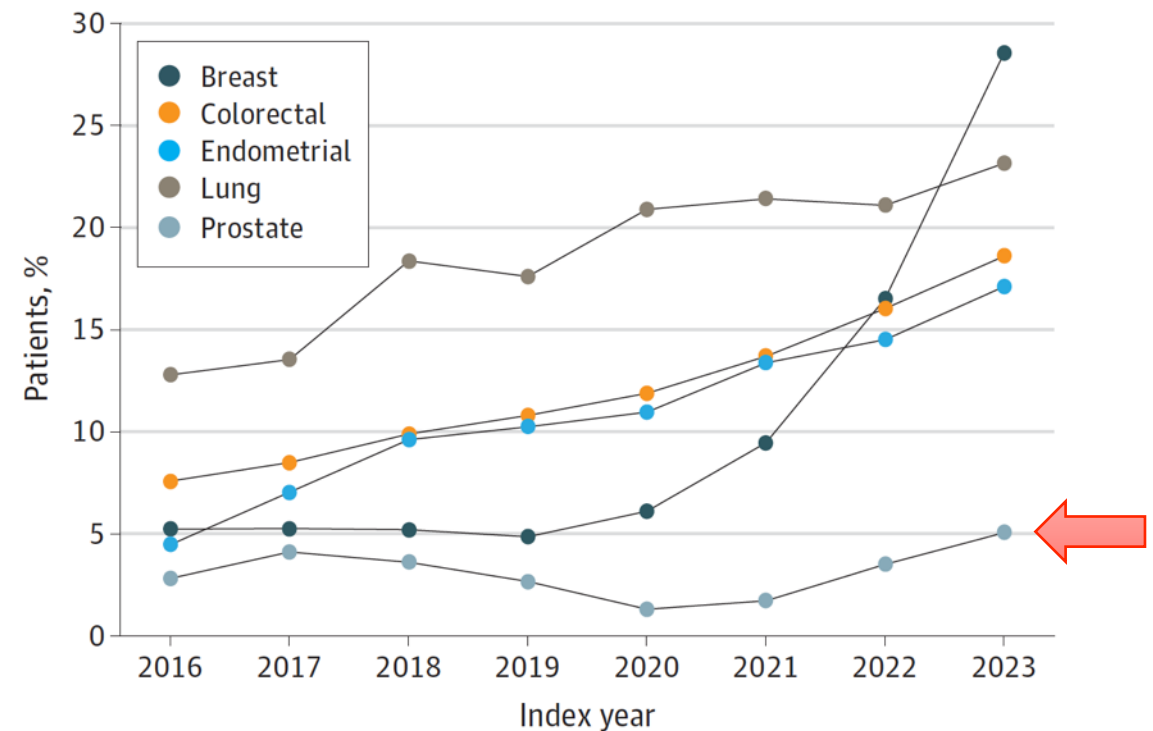
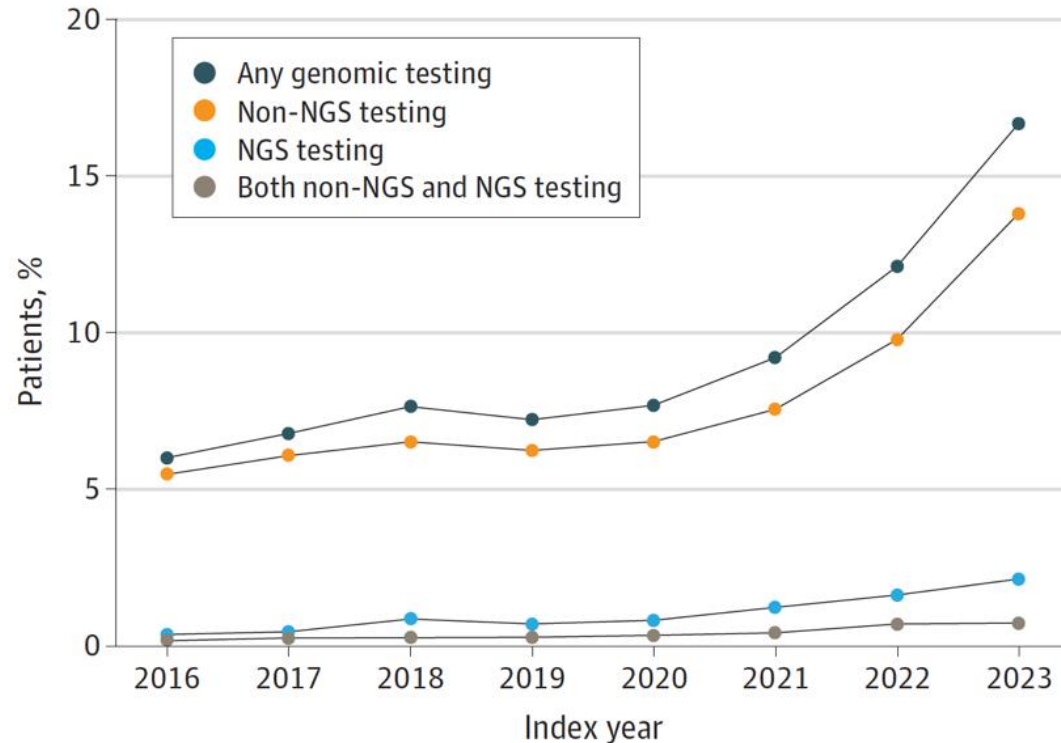
Genomic Testing Uptake Among Medicare Beneficiaries With Cancer

So-Yeon Kang, PhD, MBA, MPH; Rui Zhang, MS; Chul Kim, MD; Marc D. Schwartz, PhD; Jaeil Ahn, PhD; Arnold L. Potosky, PhD; Carole Roan Gresenz, PhD

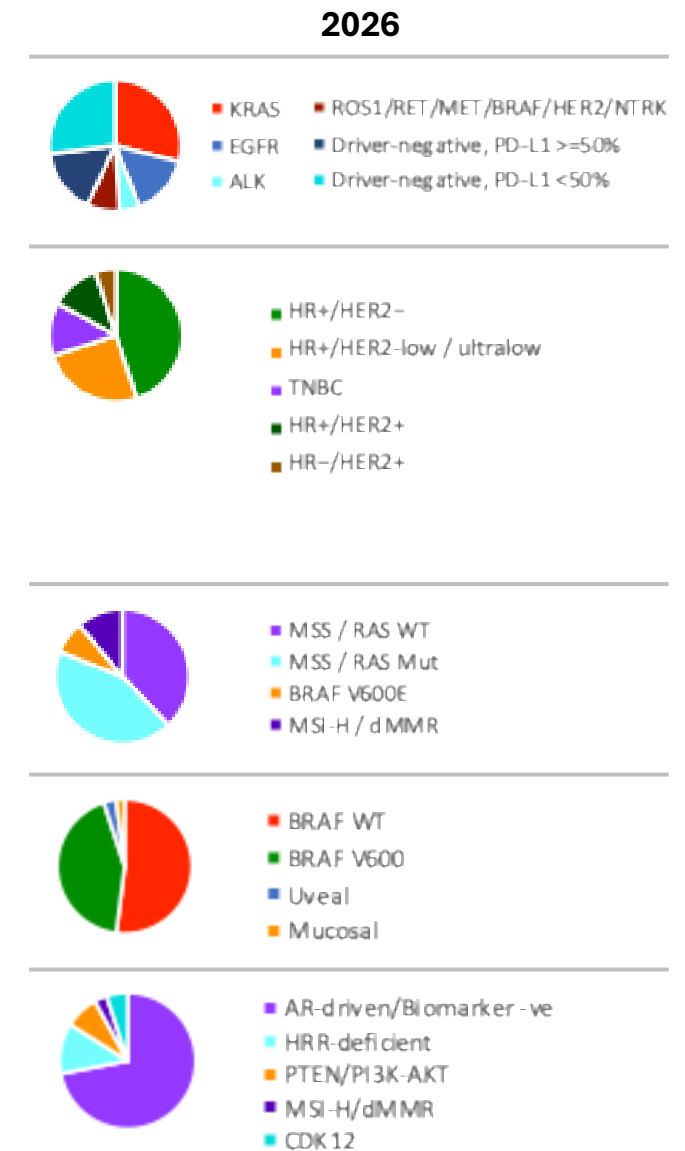
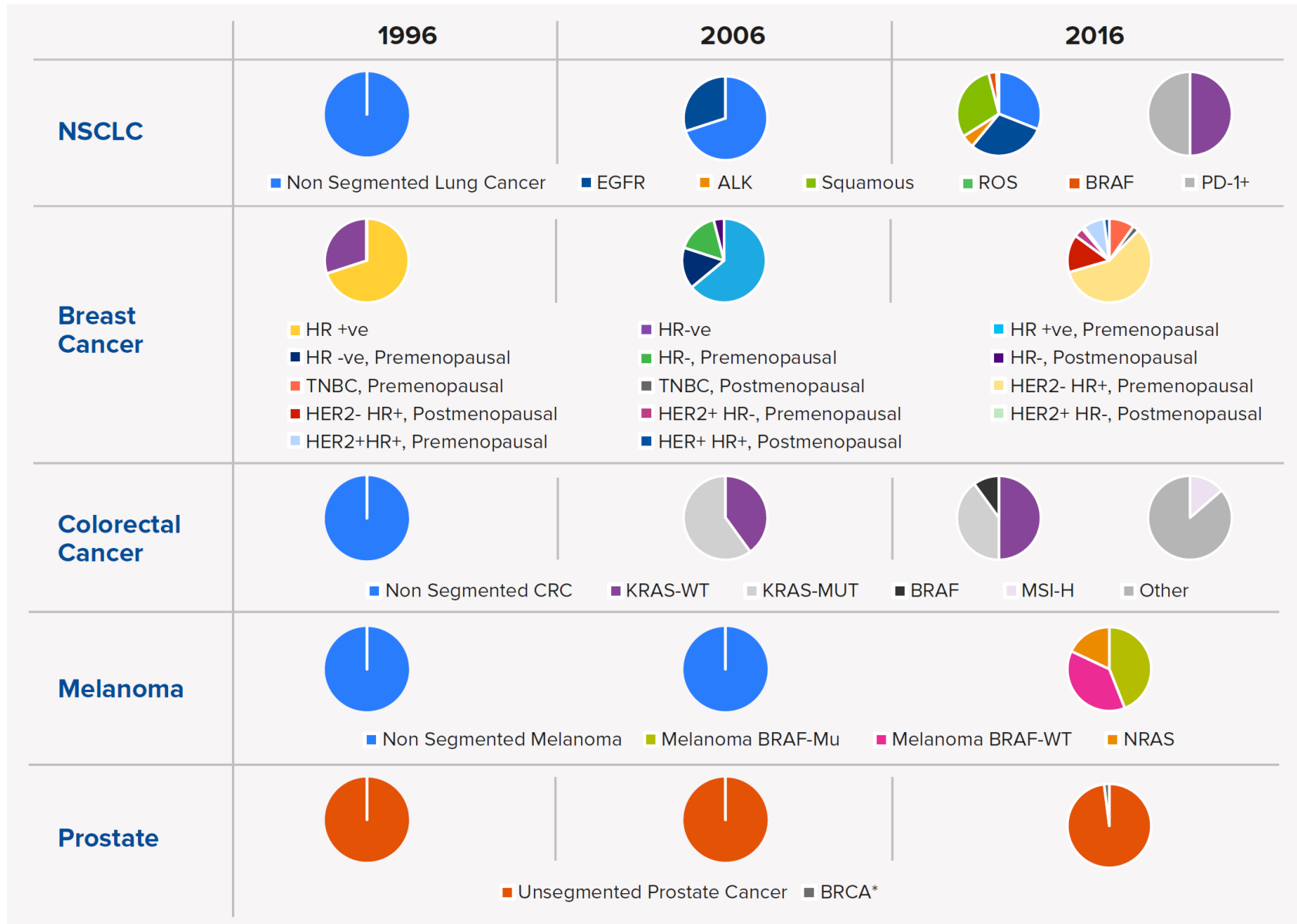
“RESULTS Of **391,151** Medicare beneficiaries with cancer (50.6% were female; 31.7% were older than 75 years), **7.0%** received **non-NGS testing** only, **1.2%** **NGS only**, **0.5%** **both**, and **91.4% no genomic testing**...beneficiaries with lung cancer had the highest NGS uptake (1.6%in 2016 vs 9.2%in 2023; $P < .001$)...

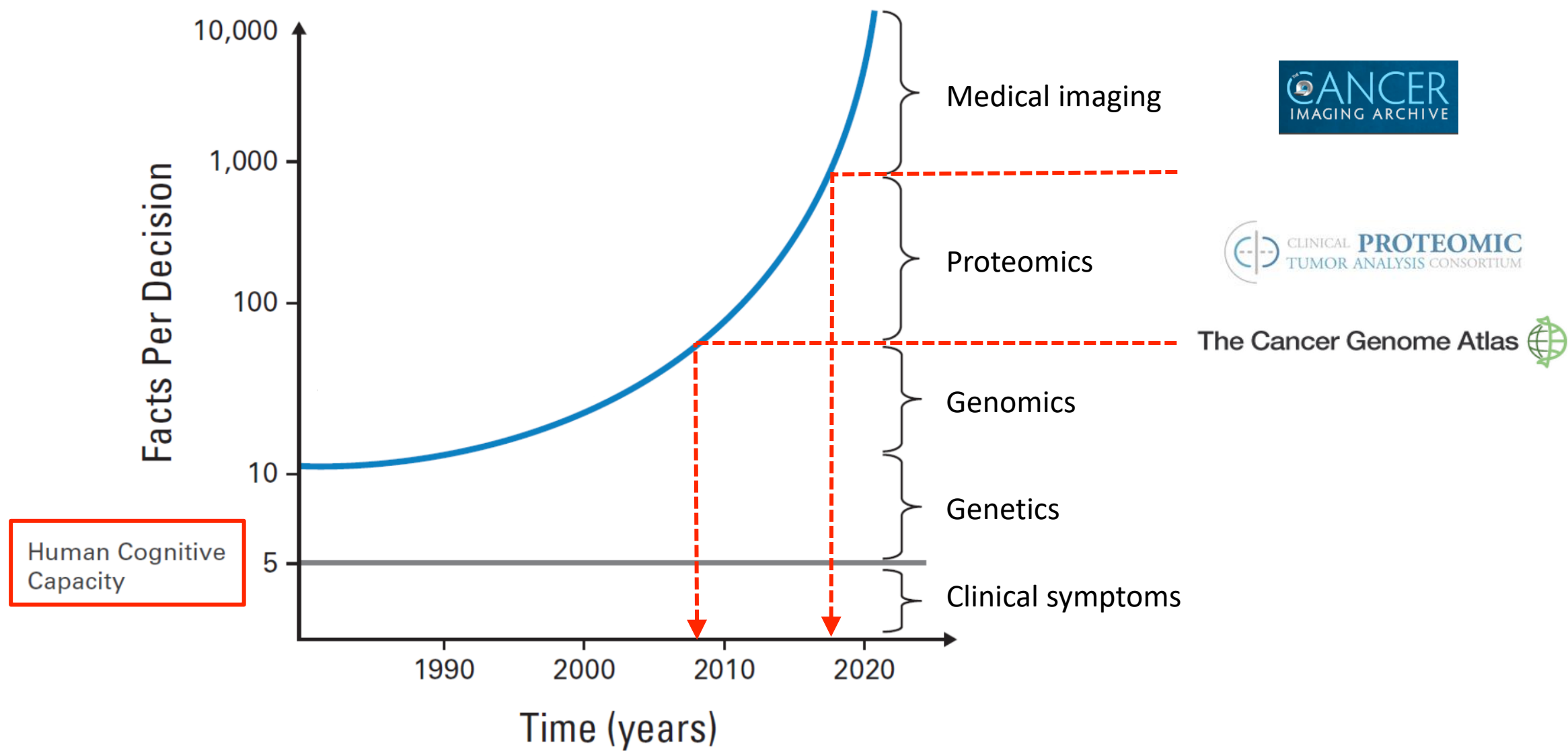
Beneficiaries with colorectal or endometrial cancer showed a moderate increase, whereas beneficiaries with **prostate cancer** had the **lowest uptake for any genomic testing**.

CONCLUSIONS In this cohort study of Medicare beneficiaries with cancer, genomic testing increased after NCD implementation, with increases driven by NGS among beneficiaries with lung cancer and non-NGS among beneficiaries with breast cancer. Overall, NGS uptake remained modest, **highlighting persistent gaps in access to precision oncology testing.**”



Cancer has been progressively redefined over the past **30** years





Thank you

Peter Nelson, MD
Vice President of Clinical Oncology
Fred Hutch Cancer Center

Genomic Biomarker Testing in Advanced Prostate Cancer: A Primer for Clinicians

August 2026

American Cancer Society
National Prostate Cancer Roundtable



Peter Nelson, MD
Fred Hutchinson Cancer Center
University of Washington
Seattle, Washington



DISCLOSURES

- Consultant: Genentech, Janssen, Vesto,
- Research support: Janssen, Genentech



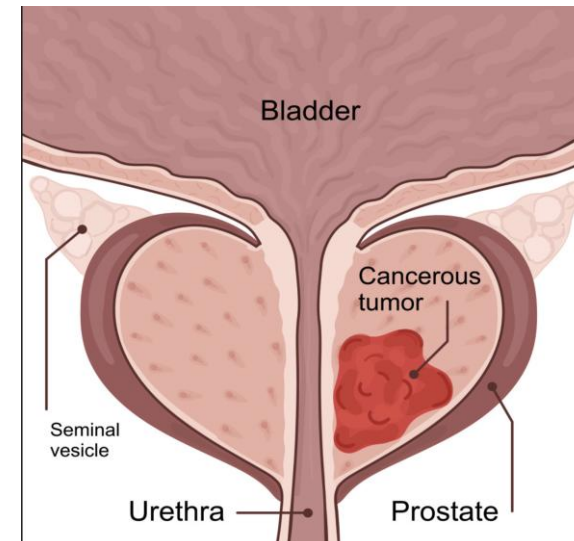
Fred Hutch
Cancer Center

DISCUSSION

- Advanced Prostate Cancer: Molecular Subtypes
- Prognostic and Predictive Biomarkers: Why Test?
- Therapeutics and Relevant Genomic Biomarkers
- Testing Options – Practical Guides
 - Types of Testing
 - Who and When to Test?
- Problems, Pitfalls, and Additional Information
- Conclusions/Closing

Prostate Cancer

- Extra-ordinarily common
- Heritable
- Indolence
- Metastatic Tropism
- Immune Recalcitrant
- Plasticity and Phenotypes
- AR Dependence
- *Molecular Heterogeneity*



Precision Medicine – Precision Oncology

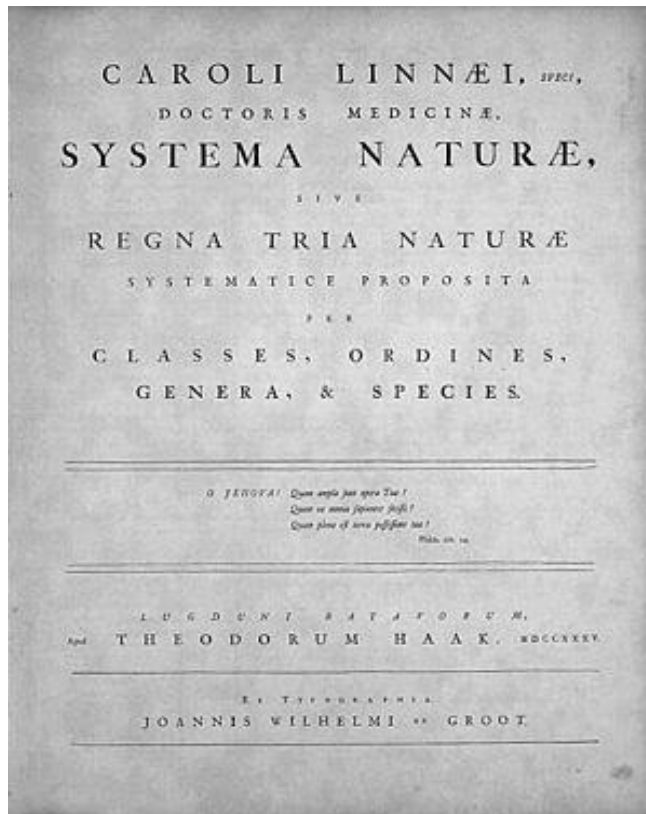
People are different...cancers are different...

Substantial variation in cancer risk and cancer behavior in the population....applying an understanding of this variation has important implications:

- Cancer Risk
- Cancer Screening
- Cancer Prevention
- **Cancer Treatment** (Specific Tumor Vulnerabilities)
- Treatment Side-Effects (Metabolism, etc)

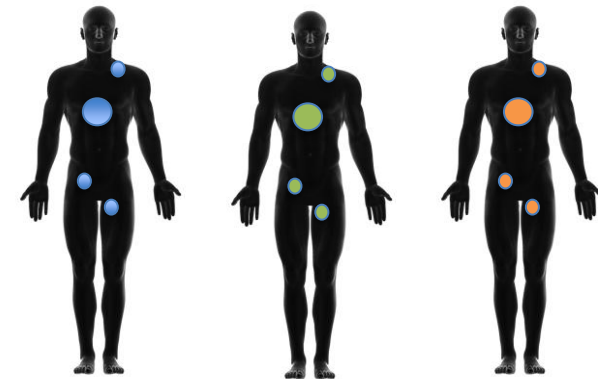
Precision Oncology (PO): Molecular Subtypes

Classification: Taxonomy



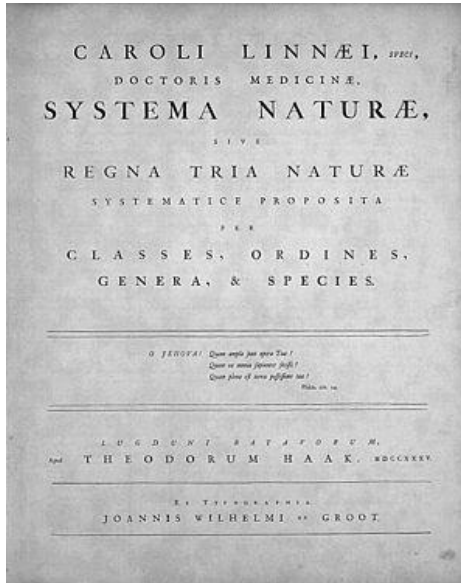
- Kingdom
- Phylum
- Class
- Order
- Family
- Genus
- Species

*PO is based on
the premise of
inter-individual
heterogeneity*



Precision Oncology: Molecular Subtypes

Classification: Taxonomy



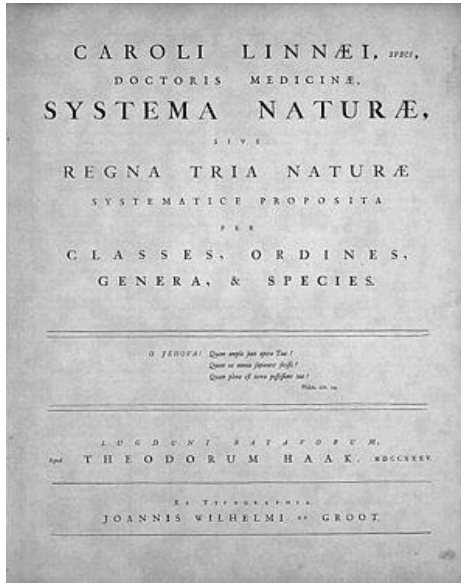
- Kingdom
- Phylum
- Class
- Order
- Family
- Genus
- Species

Prostate Cancer Classification

- 👉 Germline Variation
- 👉 Tumor (Somatic) Variation
 - ❖ Genomic
 - ❖ Transcriptomic
 - ❖ Epigenetic
 - ❖ Protein

Precision Oncology: Molecular Subtypes

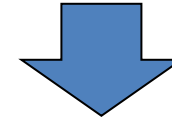
Classification: Taxonomy



- Kingdom
- Phylum
- Class
- Order
- Family
- Genus
- Species

Predict Behavior

Identify Vulnerabilities



Specify Therapy

resistance

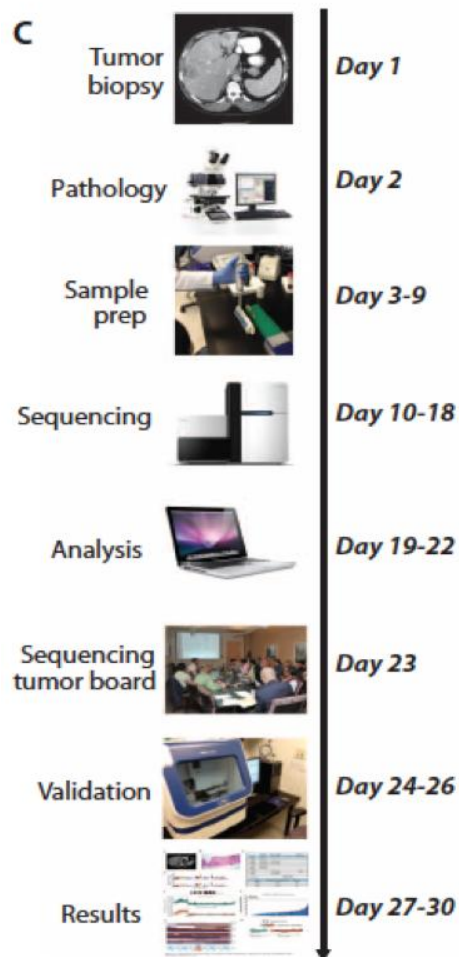


Emergence of New Subtypes

- ✓ Loss of traits
- ✓ Gain of traits

Genomics: PC Molecular Classification

Resource

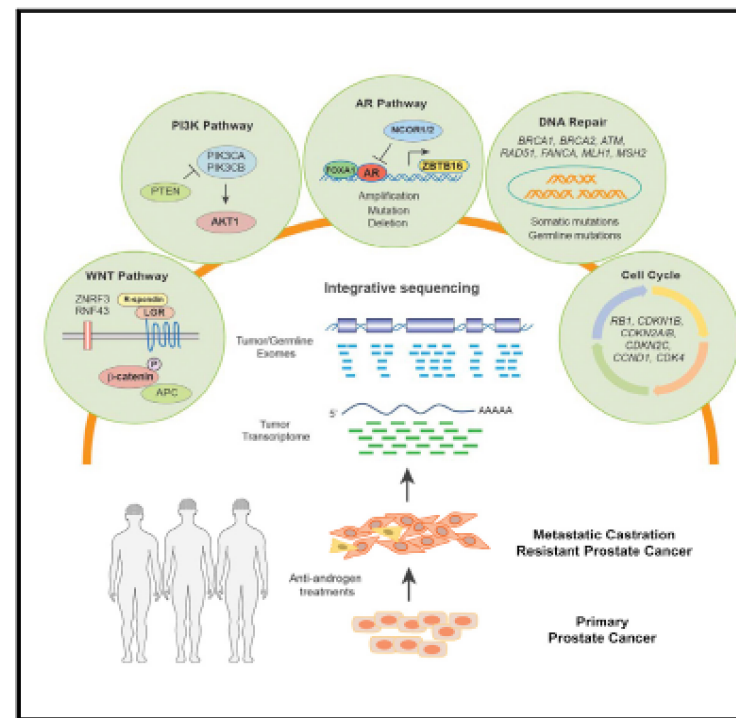


Roychowdhury et al (2011)

Cell

Integrative Clinical Genomics of Advanced Prostate Cancer

Graphical Abstract



Robinson et al (2015)

Authors

Dan Robinson, Eliezer M. Van Allen, ..., Charles L. Sawyers, Arul M. Chinnaiyan

Correspondence

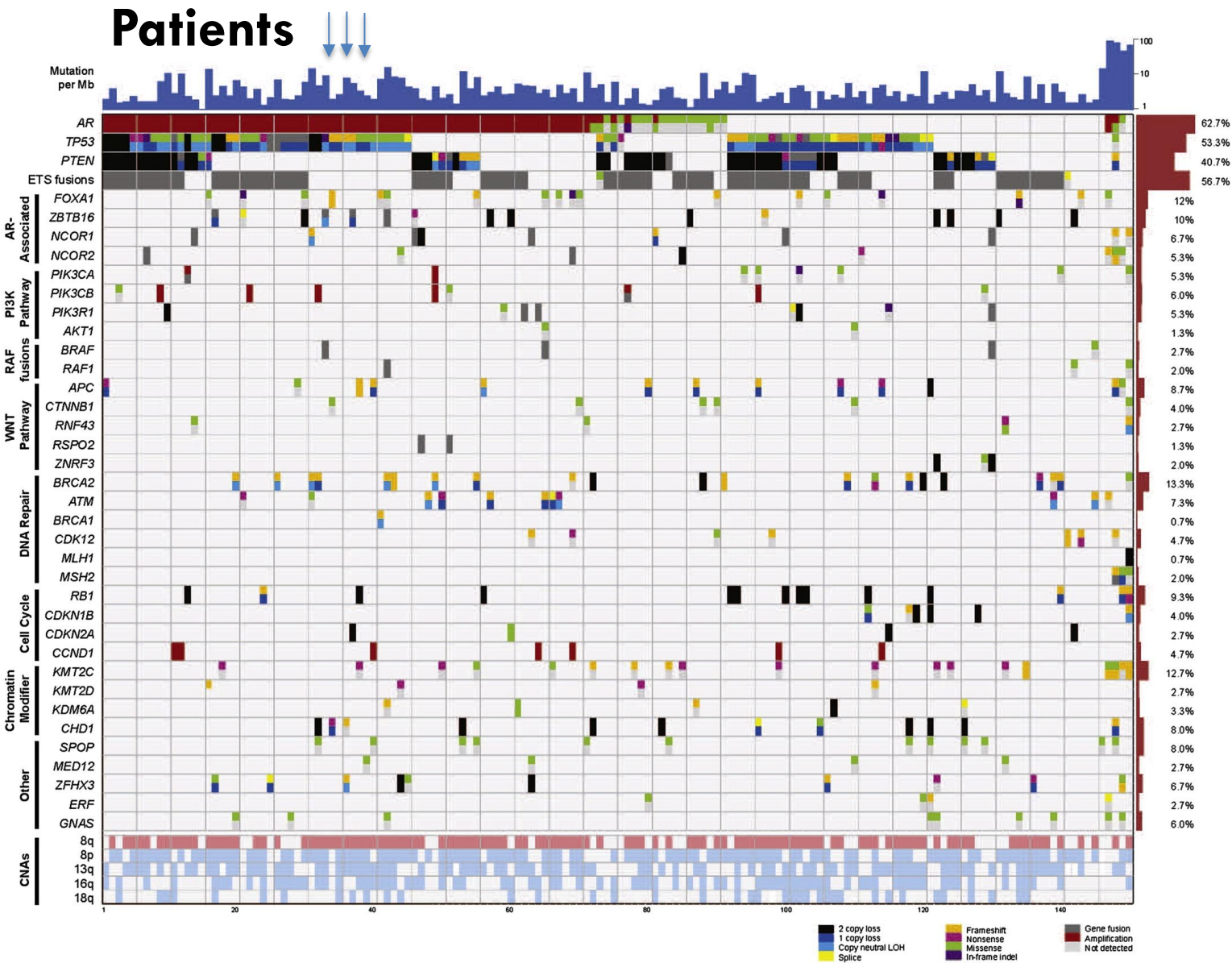
sawyersc@mskcc.org (C.L.S.), arul@umich.edu (A.M.C.)

In Brief

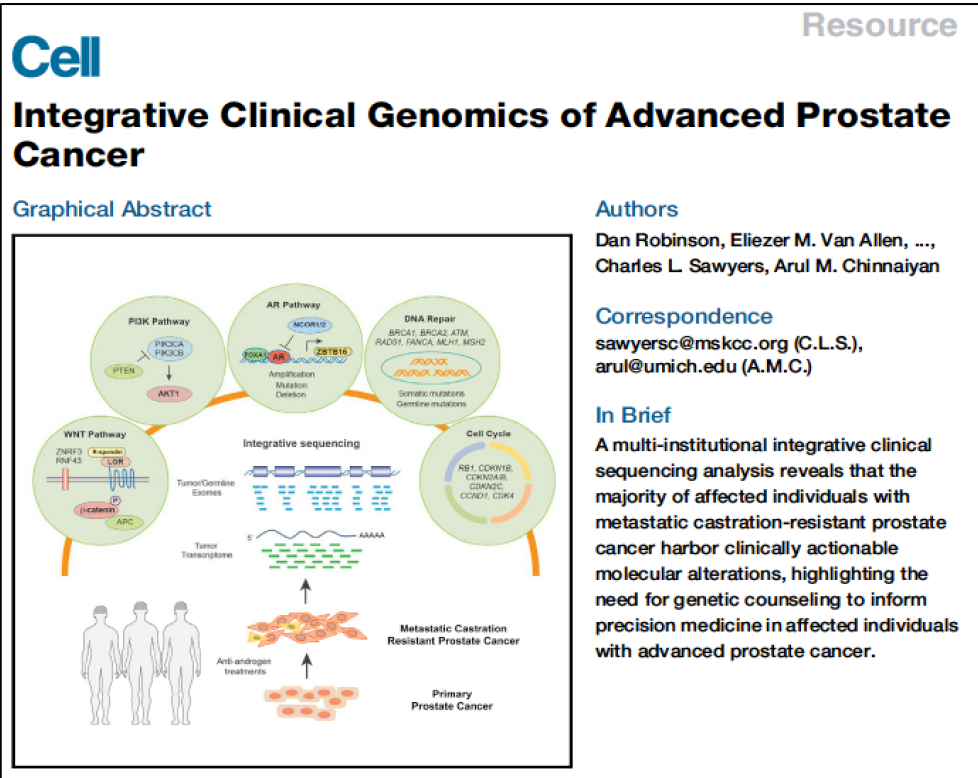
A multi-institutional integrative clinical sequencing analysis reveals that the majority of affected individuals with metastatic castration-resistant prostate cancer harbor clinically actionable molecular alterations, highlighting the need for genetic counseling to inform precision medicine in affected individuals with advanced prostate cancer.

Genomics: PC Molecular Classification

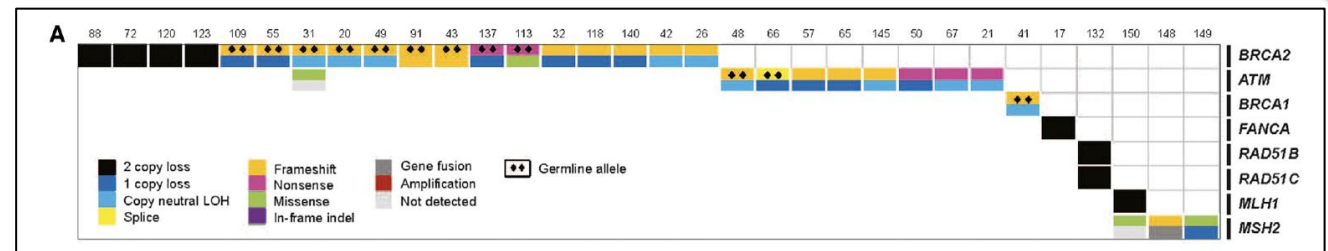
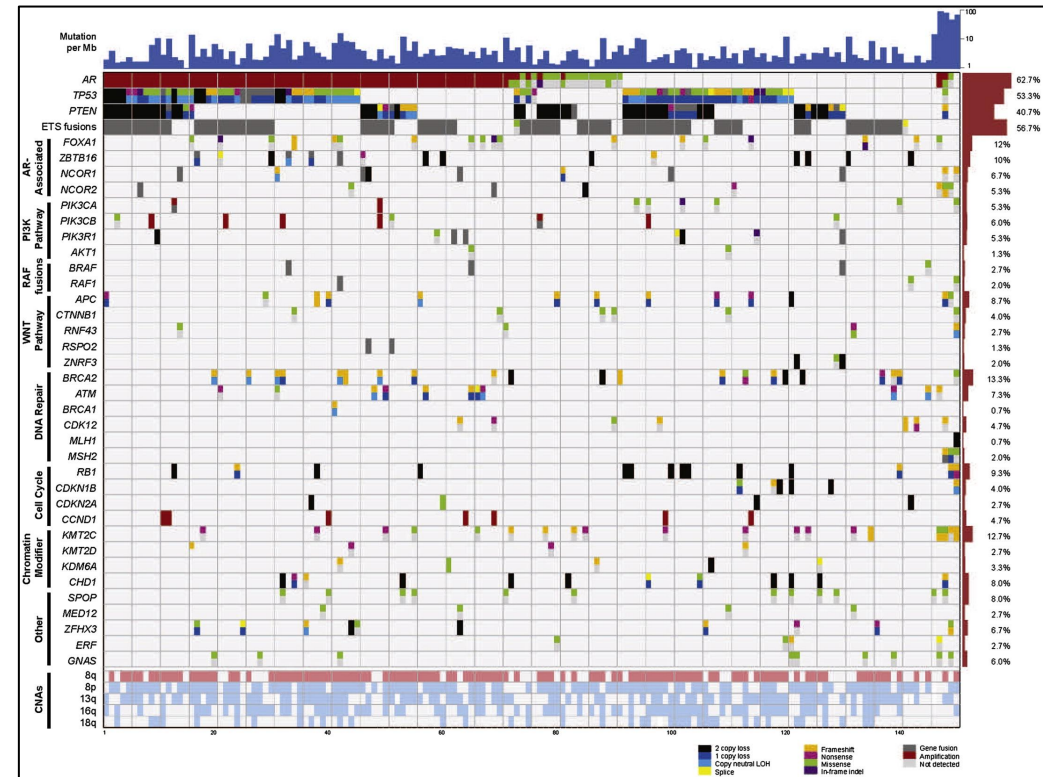
Genomic Alteration



Molecular Subtypes of Prostate Cancer



Robinson et al 2015



~20% of mCRPCs with mutations in DNA repair associated genes (SU2C: Robinson et al 2015 Cell)

Germline Alterations in DNA Repair Genes

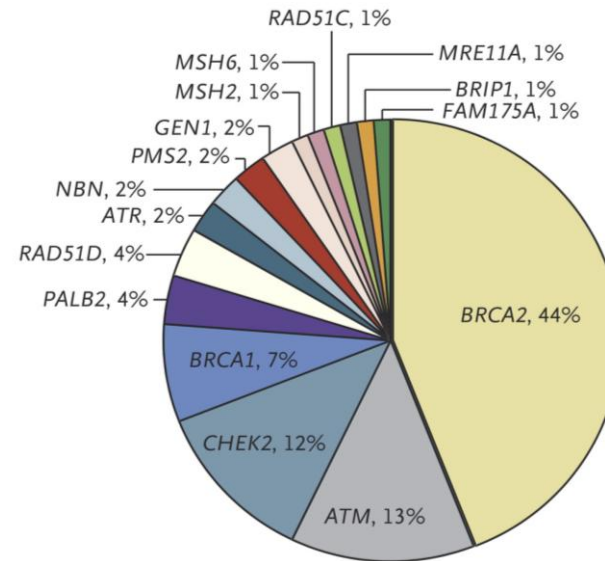
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

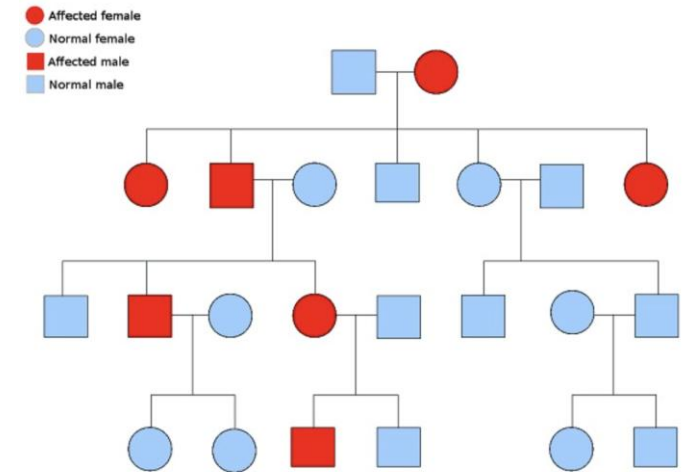
Inherited DNA-Repair Gene Mutations in Men with Metastatic Prostate Cancer

C.C. Pritchard, J. Mateo, M.F. Walsh, N. De Sarkar, W. Abida, H. Beltran, A. Garofalo, R. Gulati, S. Carreira, R. Eeles, O. Elemento, M.A. Rubin, D. Robinson, R. Lonigro, M. Hussain, A. Chinnaiyan, J. Vinson, J. Filipenko, L. Garraway, M.-E. Taplin, S. AlDubayan, G.C. Han, M. Beightol, C. Morrissey, B. Nghiem, H.H. Cheng, B. Montgomery, T. Walsh, S. Casadei, M. Berger, L. Zhang, A. Zehir, J. Vijai, H.I. Scher, C. Sawyers, N. Schultz, P.W. Kantoff, D. Solit, M. Robson, E.M. Van Allen, K. Offit, J. de Bono, and P.S. Nelson

Pritchard et al 2016



11.8% (82/692) with deleterious germline mutations in 16 DNA repair genes



**Prostate
Breast
Ovary
Pancreas**

PC Molecular Classification –

Genotypes

(Somatic)

- ETS-Rearrangement+
- HR-defective
- AR-mutant
- MMR-defective
- TP53/RB1 loss
- WNT/CTNNB1
- ATM
- CDK12
- PI3K/PTEN
- MAPK
- SPOP/CHD1
- Epigenetic Reg

Phenotypes

- AR-active
- Neuroendocrine/Small Cell
- Other
 - ☞ *Cell surface targets*
 - ☞ *Proliferation*

Precision Oncology:

Prognostic and Predictive Biomarkers

Medical Biomarkers — 4 major classes: molecular, physiologic, histologic and radiographic

PROGNOSTIC: Provides information about the patients overall outcome, regardless of any treatment or therapeutic intervention*.

PREDICTIVE: Provides information indicating the likelihood of benefiting from a specific therapy*.

*Oldenhuis CN, Oosting SF, Gietema JA, de Vries EG (May 2008). "Prognostic versus predictive value of biomarkers in oncology". *European Journal of Cancer*. **44** (7): 946–953. [doi:10.1016/j.ejca.2008.03.006](https://doi.org/10.1016/j.ejca.2008.03.006). [PMID 18396036](https://pubmed.ncbi.nlm.nih.gov/18396036/).

Classification for Therapy - Today

Genotypes

(Somatic)

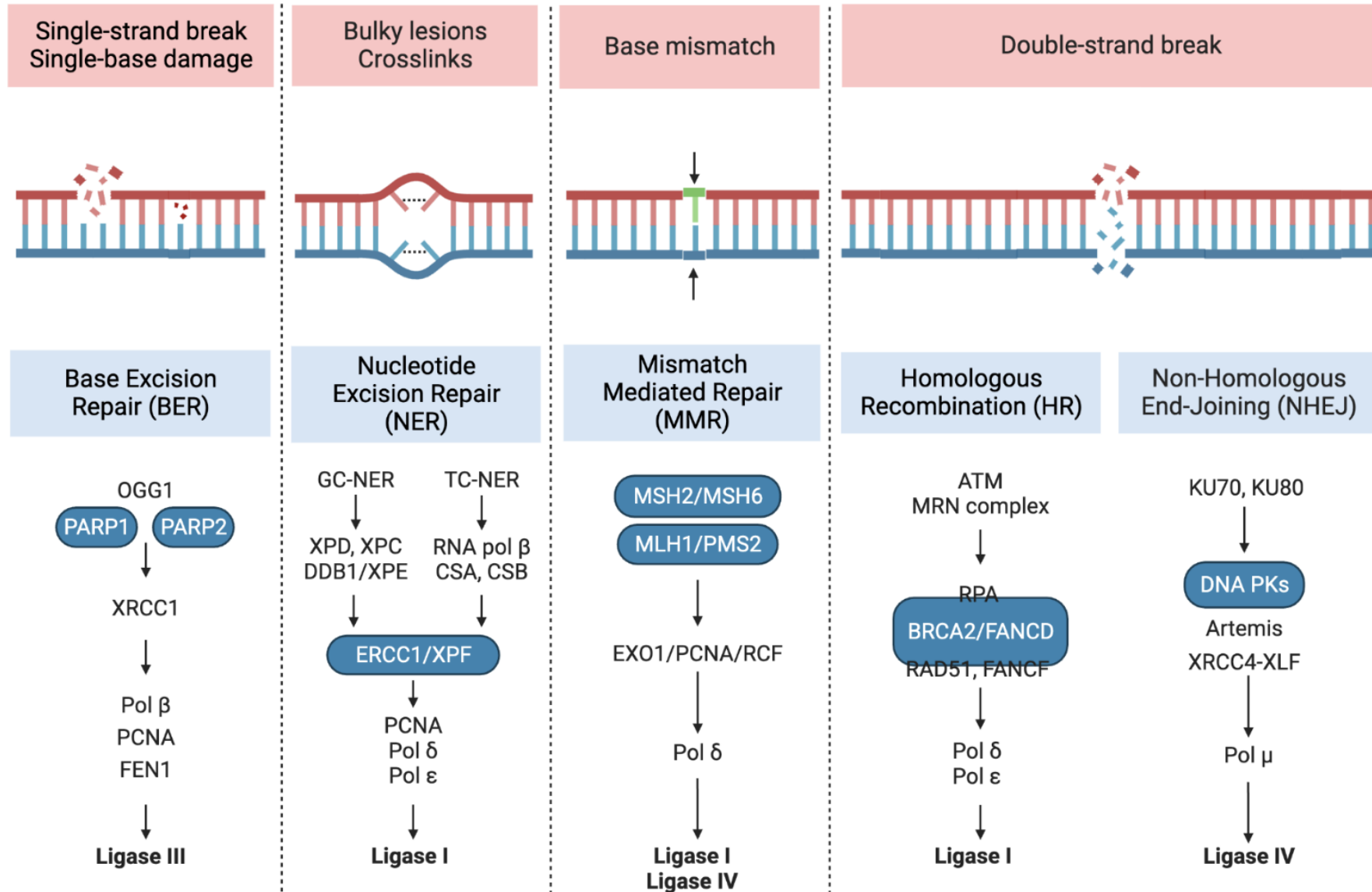
Treatment

• ETS-Rearrangement+	----->	?
• AR altered (GOF)	----->	AR degrader
• HR-defective	----->	PARPi
• MMR-defective	----->	ICB (PD1/PD-L1)
• TP53/RB1 loss	----->	Platinum/Cabazitaxel ATRi ?
• WNT/CTNNB1	----->	?
• CDK12	----->	PARPi/ICB (PD1/PD-L1)
• PI3K/PTEN	----->	AKTi
• MAPK	----->	MEKi/FGFRi
• SPOP/CHD1	----->	PARPi/PLAT ?
• Epigenetic Reg	----->	EZH2i/LSD1i/HDACi

Classification for Therapy - Today

<u>Molecular Subtype</u>		<u>Predictive Biomarker</u>		<u>Treatment</u>
• HR-defective	→	HR Gene Mutations	→	PARPi/(Platinum)
• MMR-defective	→	MMR Gene Mutations; MSI; TMB	→	ICB (PD1/PD-L1)
• PTEN-deficient	→	PTEN IHC	→	AKTi

DNA Damage and Repair



So many acronyms and synonyms...

Homologous Recombination (HR)

Homologous Recombination Deficiency (HRD)

Homology Directed Repair (HDR)

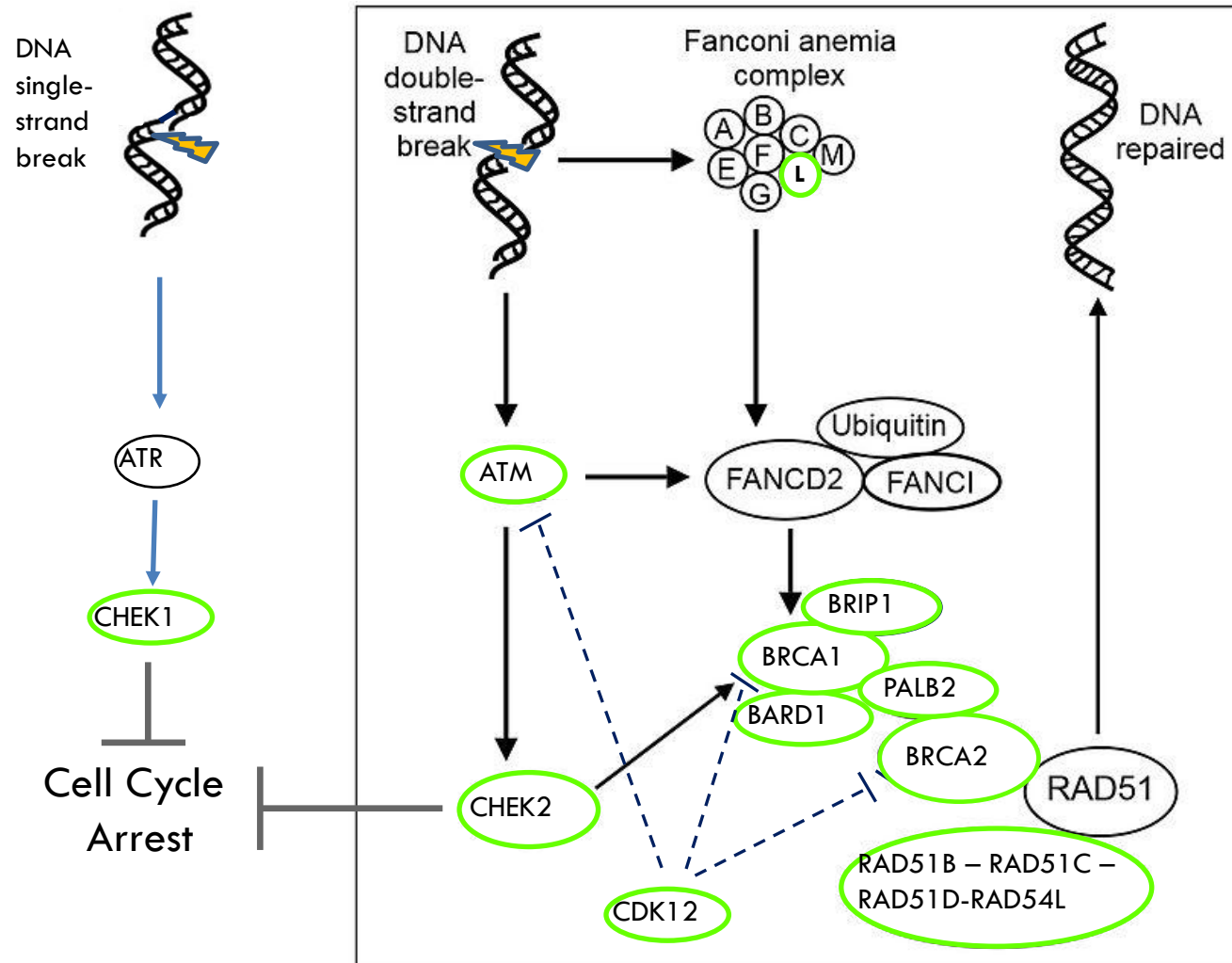
Homology Directed Repair Deficiency (HRd)

Homologous Recombination Repair (HRR)

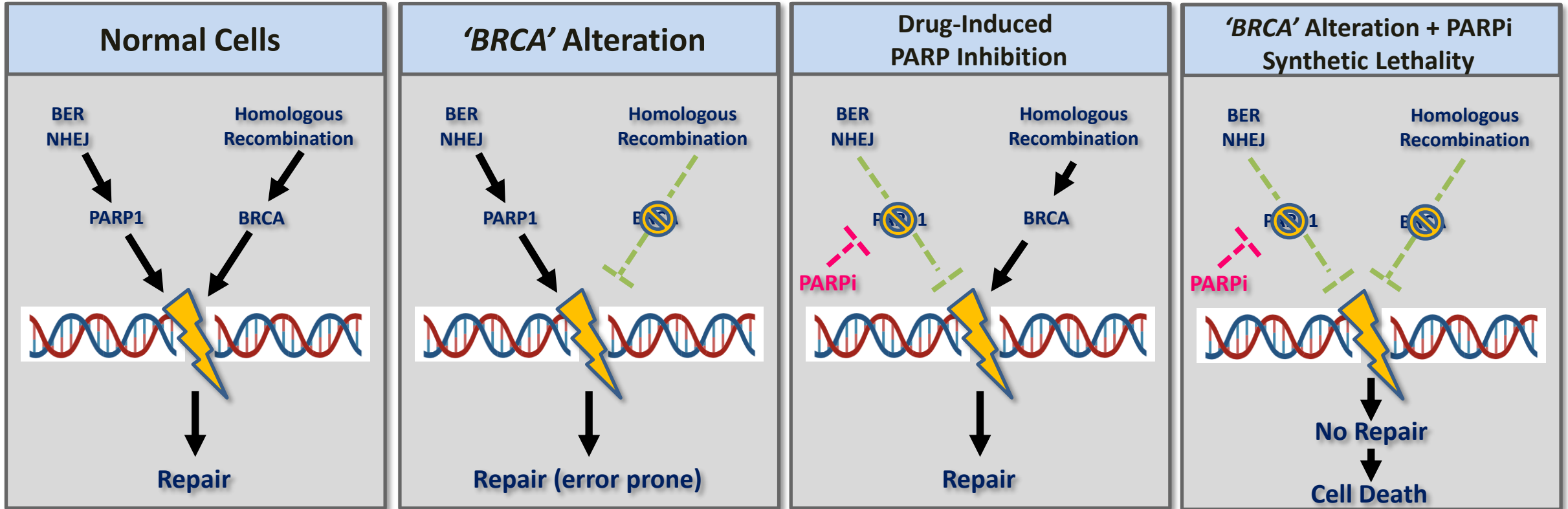
Homologous Recombination Repair Deficiency (HRRd)

Homologous Recombination Repair Mutated (HRRm)

Genes Involved in HR Repair Pathway



Synthetic Lethality: PARPi/Platinum



Hartwell LH, Szankasi P, Roberts CJ, Murray AW, Friend SH. Integrating genetic approaches into the discovery of anticancer drugs. *Science* 1997;278:1064-8.

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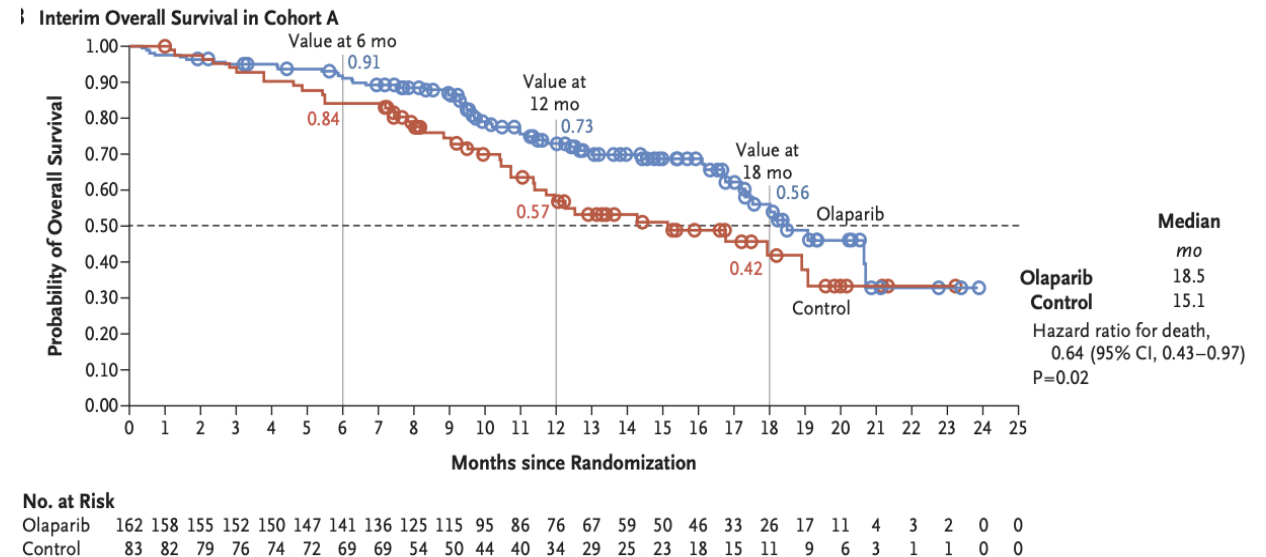
HRR Gene Mutations: Predictive Biomarker for PARPi

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



👉 In PROfound's BRCA subgroup, men on olaparib had median overall survival of 20.1 versus 14.4 months with enzalutamide or abiraterone.

(de Bono et al., New England Journal of Medicine, 2020; PROfound BRCA subgroup analysis, Journal of Clinical Oncology, 2023.)

The Trials

PROfound^(P3: Post ARSI)

	OLA	ENZ/ABI	HR
rPFS	7.4	3.6	0.34 (0.25-0.47) p<0.0001
OS	19.1	14.7	0.69 (0.50-0.97) p=0.02

TRITON2^(P2: Post ARSI+DOC)

	RUC	BRCA1; BRCA2
ORR	43% (31-57)	
rPFS	9 months (95% CI 8.3-13.5)	

Abida W et al. Rucaparib in Men with Metastatic Castration Resistant Prostate Cancer Harboring a BRCA1 or BRCA2 Gene Alteration. JCO 2020;3763-3772.

Abida W et al Non-BRCA DNA Damage Repair Gene Alterations and Response to the PARP Inhibitor Rucaparib in Metastatic Castration-Resistant Prostate Cancer: Analysis From the Phase II TRITON2 Study. Clin Can Res 2020 2487-

deBono J et al Olaparib for Metastatic Castration Resistant Prostate Cancer. NEJM 2020; 382(22):2091-2102.

Hussain M et al Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer. NEJM 2020 383(24):2345-2357.

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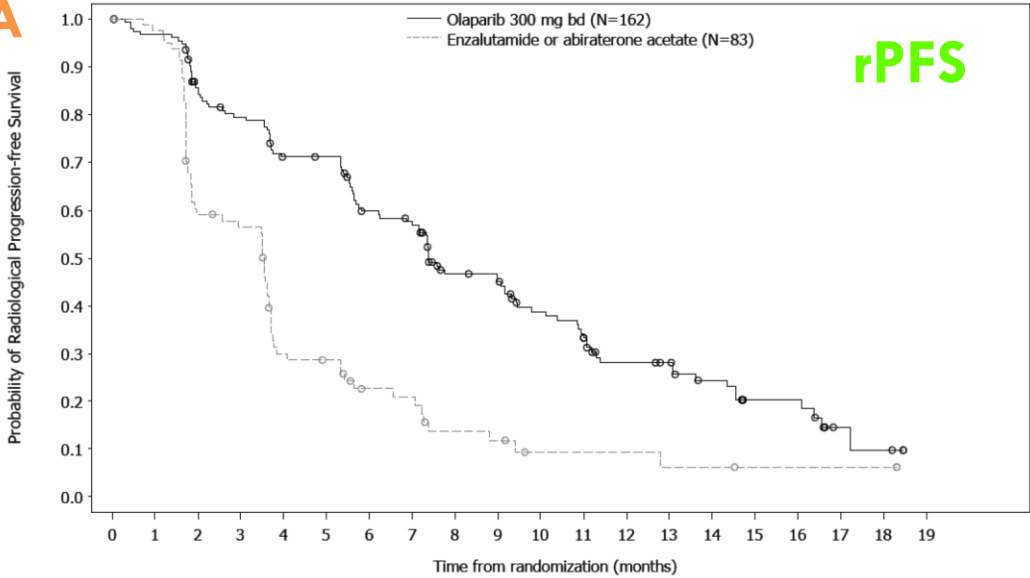
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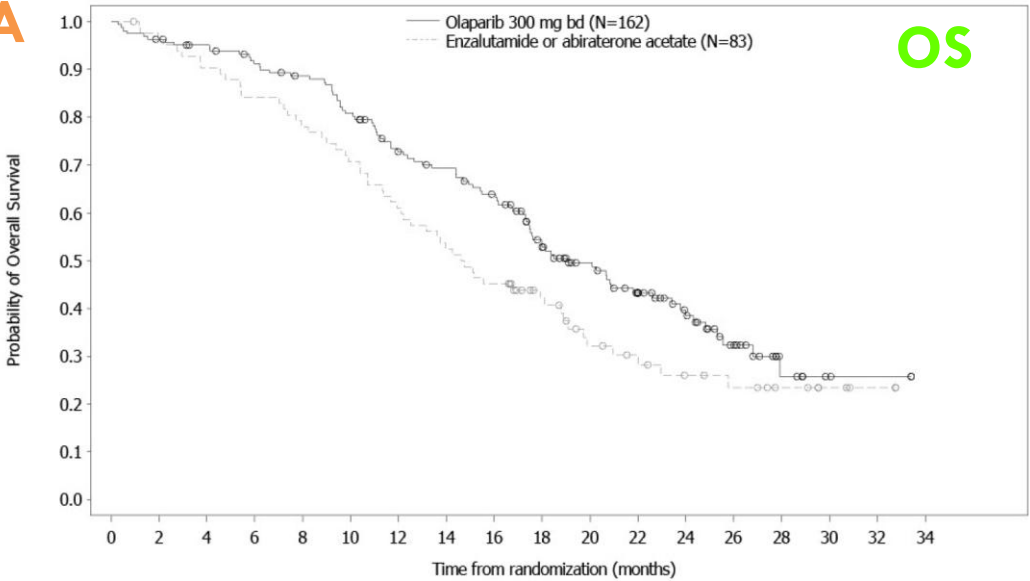
CA



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

Waxlin Abida, MD, PhD¹, Akash Patnaik, MD, PhD, MSc², David Campbell, MBBS³, Jeremy Shapiro, MBBS⁴, Alan H. Bryce, MD⁵, Ray McDermott, MD, PhD, MBA⁶, Brian Scatena, MD, PhD⁷, Nicholas J. Vogelzang, MD⁸, Richard M. Bambury, MD⁹, Eric Yong, MD¹⁰, Jingrong Zhang, MD, PhD¹¹, Josep M. Pujals, MD¹², Charles J. Ryan, MD¹³, Axel S. Merseburger, PhD¹⁴, Godefridus Daignault, DMSc¹⁵, Axel Hohenkammer, MD¹⁶, Karim Fizazi, MD, PhD¹⁷, Celeste S. Higgins, MD¹⁸, Laurence E. Klinger, MSc¹⁹, Cora H. Stenlund, MD²⁰, Simon P. Watkins, PhD²¹, Darin Despain, MStat²², Andrew D. Simmons, PhD²³, Andrea Lohr, PhD²⁴, Melanie Dowsan, BA²⁵, Tony Golubski, MD²⁶, and Simon Chowdhury, MD, PhD²⁷; on behalf of the TRITON2 Investigators

CA



Precision and Accuracy:

Problems with Approved Biomarkers

Table 1 Biomarker Testing for Patient Selection* (cont'd)

Indication	Biomarker	Sample type		
		Tumor	Blood	Plasma (ctDNA)
Maintenance treatment of recurrent ovarian cancer	No requirement for biomarker testing			
Advanced gBRCAm ovarian cancer	gBRCA1m, gBRCA2m		X	
gBRCAm HER2-negative metastatic breast cancer	gBRCA1m, gBRCA2m		X	
First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma	gBRCA1m, gBRCA2m		X	
Germline or somatic HRR gene-mutated metastatic castration-resistant prostate cancer	ATMm, BRCA1m, BRCA2m, BARD1m, BRIP1m, CDK12m, CHEK1m, CHEK2m, FANCLm, PALB2m, RAD51Bm, RAD51Cm, RAD51Dm, RAD54Lm	X		
	gBRCA1m, gBRCA2m		X	
	ATMm, BRCA1m, BRCA2m			X

* Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test, if available.

⚠ Nothing about biallelic loss

⚠ Several markers never tested

⚠ Several markers: low response



⚠ **ATM: <10% ORR***

⚠ **CDK12: 6% ORR***

⚠ **FANCL/RAD51C: Not Enrolled !**

PARPi + ARSI (Abiraterone)

Special Articles



FDA Approval Summary: Olaparib in Combination With Abiraterone for Treatment of Patients With *BRCA*-Mutated Metastatic Castration-Resistant Prostate Cancer

Jaleh Fallah, MD¹ ; Jianjin Xu, PhD¹ ; Chana Weinstock, MD¹; Michael H. Brave, MD¹; Erik Bloomquist, PhD¹ ; Mallorie H. Fiero, PhD¹; Timothy Schaefer, PhD²; Anand Pathak, MD, MPH, PhD²; Abdelrahman Abukhdeir, MD²; Vishal Bhatnagar, MD^{1,2}; Haw-Jyh Chiu, PhD¹; Tiffany Ricks, PhD¹; Christy John, PhD¹; Salaheldin Hamed, PhD¹; Christal Lee, PharmD¹; William F. Pierce, PharmD, MPH¹ ; Shyam Kalavar, PhD²; Reena Philip, PhD²; Shenghui Tang, PhD¹ ; Laleh Amiri-Kordestani, MD^{1,2} ; Richard Pazdur, MD^{1,2} ; Paul G. Kluetz, MD^{1,2}; and Daniel Suzman, MD¹

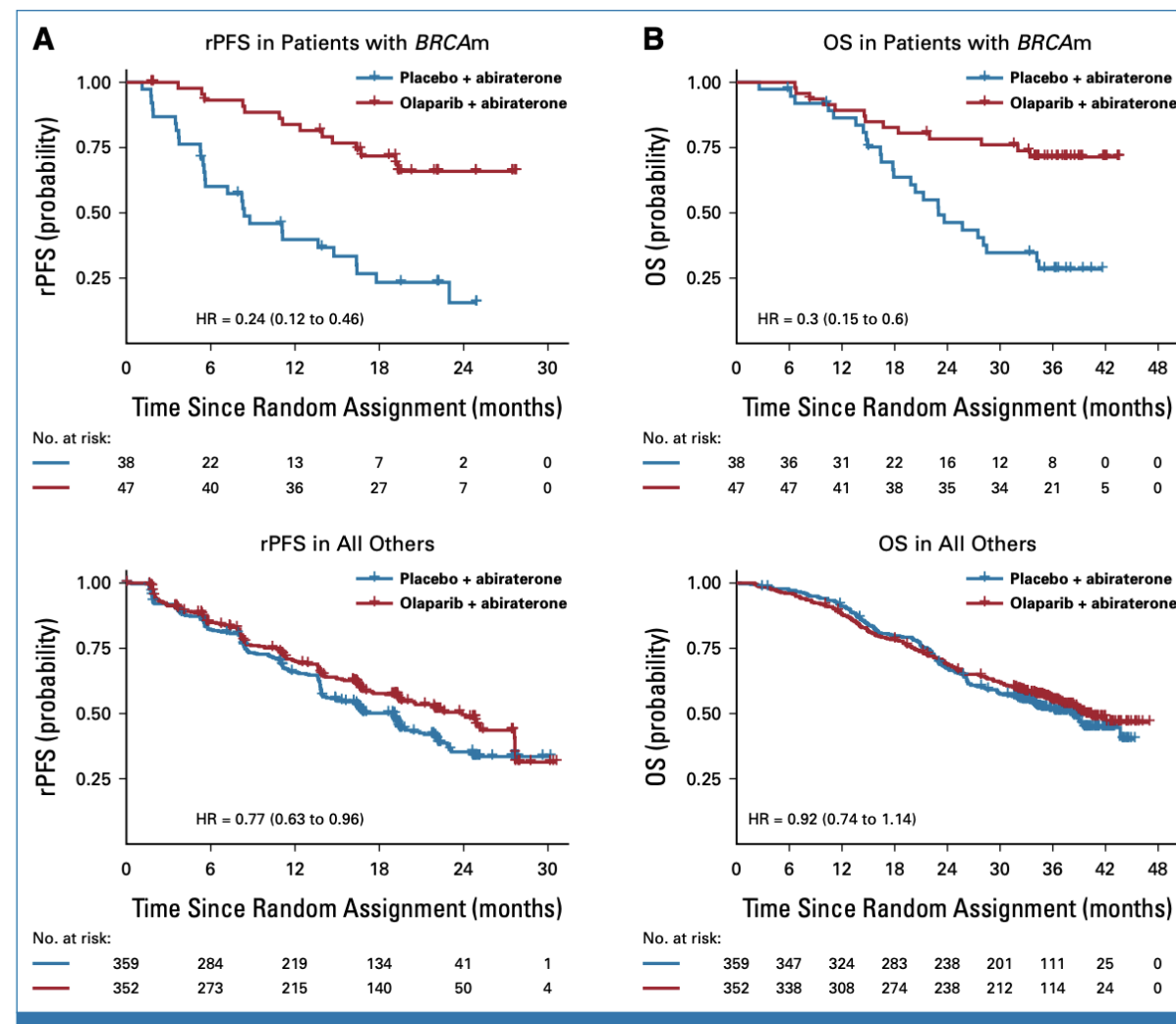


FIG 2. Kaplan-Meier estimates in PROpel of (A) rPFS in patients with *BRCAm*, (B) OS in patients with *BRCAm*, (C) rPFS in all others, and (D) OS in all others. HR, hazard ratio; OS, overall survival; rPFS, radiographic progression-free survival.

PARPi Approvals and Indications: Different Biomarkers and Context of Use...

- 👉 **Olaparib (Lynparza)** and **Rucaparib (Rubraca)** are approved as single agents;
- 👉 **Talazoparib (Talzenna)** and **Niraparib** are approved in combinations.
- 👉 **Niraparib** in 'CSPC' with Abiraterone

Drug (brand)	Partner therapy	Eligible mutation	Best for (setting)
Olaparib (Lynparza)	Used alone	Several HRR genes, incl. BRCA	mCRPC after enzalutamide or abiraterone
Olaparib (Lynparza)	Abiraterone + prednisone	BRCA	First-line mCRPC
Rucaparib (Rubraca)	Used alone	BRCA	mCRPC after a hormone agent and chemotherapy
Talazoparib (Talzenna)	Enzalutamide	HRR genes	First-line mCRPC
Niraparib (Akeega)	Abiraterone + prednisone	BRCA (mCRPC); BRCA2 (hormone-sensitive)	First-line mCRPC; 2025 option for BRCA2 hormone-sensitive disease

PARPi Approvals and Indications: Different Biomarkers and Context of Use...

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AKEEGA safely and effectively. See full prescribing information for AKEEGA.

AKEEGA® (niraparib and abiraterone acetate) tablets, for oral use
Initial U.S. Approval: 2023

-----RECENT MAJOR CHANGES-----	
Indications and Usage (1)	12/2025
Dosage and Administration (2.1, 2.2)	12/2025
Warnings and Precautions (5.1, 5.2, 5.3, 5.4)	12/2025

-----INDICATIONS AND USAGE-----

AKEEGA is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with:

- deleterious or suspected deleterious *BRCA2*-mutated (*BRCA2m*) metastatic castration-sensitive prostate cancer (mCSPC).
- deleterious or suspected deleterious *BRCA*-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC).
- Select patients for therapy based on an FDA-approved test for AKEEGA. (1, 2.1)

-----DOSAGE AND ADMINISTRATION-----

BRCA2m mCSPC:

- The recommended dosage of AKEEGA is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 5 mg prednisone daily until disease progression or unacceptable toxicity. (2.2)

BRCAm mCRPC:

- The recommended dosage of AKEEGA is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone daily until disease progression or unacceptable toxicity. (2.2)
- Patients receiving AKEEGA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. (2.2)
- Take AKEEGA on an empty stomach at least one hour before or two hours after food. (2.2)
- For adverse reactions, consider interruption of treatment, dose reduction, or dose discontinuation. (2.3)

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AKEEGA with prednisone is indicated for the treatment of adult patients with deleterious or suspected deleterious *BRCA2*-mutated (*BRCA2m*) metastatic castration-sensitive prostate cancer (mCSPC).

AKEEGA with prednisone is indicated for the treatment of adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC).

Select patients for therapy based on an FDA-approved test for AKEEGA [see *Dosage and Administration* (2.1)].

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Select patients for the treatment of mCSPC with AKEEGA based on the presence of a *BRCA2* gene alteration [see *Clinical Studies* (14.1)].

Select patients for the treatment of mCRPC with AKEEGA based on the presence of a *BRCA* gene alteration [see *Clinical Studies* (14.2)].

Information on FDA-approved tests is available at: <http://www.fda.gov/CompanionDiagnostics>.

2.2 Recommended Dosage

BRCA2-mutated (*BRCA2m*) Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

- The recommended dosage of AKEEGA is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 5 mg prednisone once daily until disease progression or unacceptable toxicity.

BRCA-mutated (*BRCAm*) Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- The recommended dosage of AKEEGA is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone once daily until disease progression or unacceptable toxicity.

Mismatch DNA Repair (MMR): Biomarkers = TMB; MSI; MMR Gene Mutation

FDA Approves Keytruda (pembrolizumab) as First Cancer Treatment for any Solid Tumor with a Specific Genetic Feature

 Add Drugs.com on Google

May 23, 2017 -- The U.S. Food and Drug Administration today granted accelerated approval to a treatment for patients whose cancers have a specific genetic feature (biomarker). This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.

[Keytruda \(pembrolizumab\)](#) is indicated for the treatment of adult and pediatric patients with unresectable or metastatic [solid tumors](#) that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). This indication covers patients with solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options and patients with colorectal cancer that has progressed following treatment with certain chemotherapy drugs.

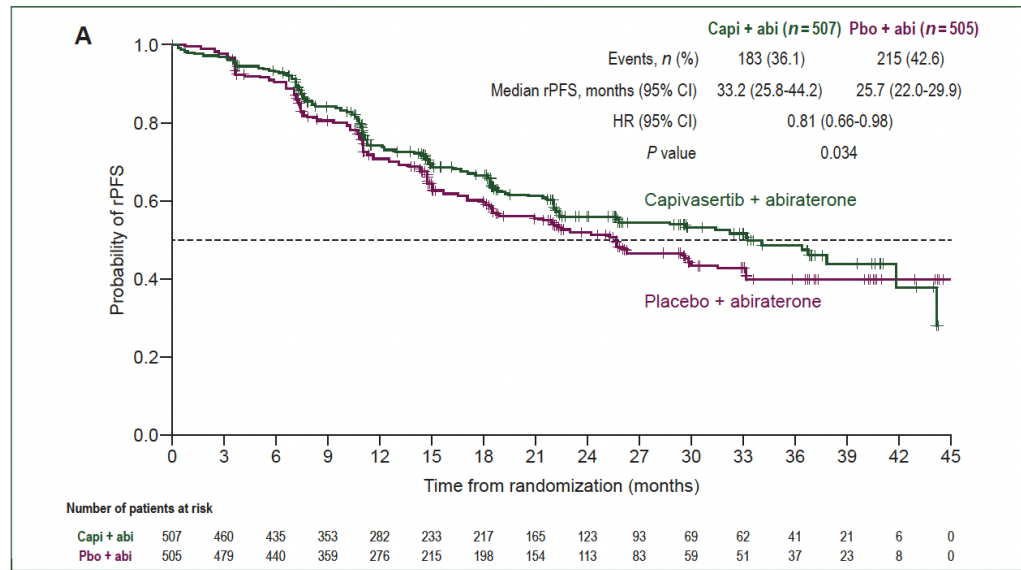
PTEN Tumor Suppressor Loss Biomarkers = PTEN IHC



ORIGINAL ARTICLE

Capivasertib plus abiraterone in PTEN-deficient metastatic hormone-sensitive prostate cancer: CAPItello-281 phase III study★

K. Fizazi^{1*}, N. W. Clarke², M. De Santis^{3,4}, H. Uemura⁵, A. P. Fay⁶, N. Karadurmus⁷, M. Kwiatkowski⁸, C. Alvarez-Fernandez^{9,10}, S. Jiang¹¹, M. Sotelo¹², D. Parslow¹³, N. Oliveira^{14,15}, T. G. Kwon¹⁶, D. Ye¹⁷, S. Boudewijns¹⁸, P. Danchaivijitr¹⁹, C. Rooney²⁰, C. Gresty²⁰, M. Yeste-Velasco²¹, J. Logan²² & D. J. George²³, for the CAPItello-281 Study Group†



Of 6201 patients, 6003 (96.8%) had valid IHC PTEN test results and 1519 (25.3% of the 6003) PTEN-deficient tumors at the $\geq 90\%$ threshold.

CAPItello-281, a randomized, double-blind, placebo-controlled, multicenter Phase 3 trial that enrolled 1,012 adults with newly diagnosed, PTEN-deficient metastatic androgen pathway modulation-naïve or -sensitive prostate cancer

Tumor PTEN deficiency: IHC VENTANA PTEN (SP218) RxDxAssay: at least 90% of viable malignant cells showing no specific cytoplasmic staining.

Patients were randomized 1:1 to receive either capivasertib plus abiraterone or placebo plus abiraterone.

Statistically significant improvement in RPFS: 33.2 mo capivasertib plus abiraterone compared to 25.7 months 19% reduction in the risk of radiographic disease progression or death.

DISCUSSION

- Advanced Prostate Cancer: Molecular Subtypes
- Prognostic and Predictive Biomarkers: Why Test?
- Therapeutics and Relevant Genomic Biomarkers
- Testing Options – Practical Guides
 - Types of Testing
 - Who and When to Test?
- Problems, Pitfalls, and Additional Information
- Conclusions/Closing

TYPES of TESTING

- Multiple somatic alterations that are predictive...so
- Panel Based “Comprehensive Genomic Profiling” - CGP
- Multiple Vendors: Some FDA/Some LDT
- In order of preference:
 - 👉 Metastatic Biopsy
 - 👉 Circulating tumor DNA (ctDNA)
 - 👉 Primary (archived) tissue/tumor

Circulating Tumor DNA

👉 ~1/3 tumor tissue testing failed in Phase 3 trials of patients with mCRPC – insufficient tumor; poor DNA quality/quantity; DNA extraction issues

👉 The majority of patients with mCRPC have ctDNA (70%)

👉 ctDNA testing is accurate – 81-93% mutations concordant between tissue biopsy and ctDNA

👉 Convenient and repeatable

ctDNA TESTING

SAMPLE TYPES	SAMPLE PREPARATION	ALTERATION TYPES DETECTED	SAMPLE QUALITY	POTENTIAL ADVANTAGES	POTENTIAL LIMITATIONS	TURNAROUND TIME
•Whole blood	Ethylenediaminetetraacetic acid (EDTA) tubes or cfDNA-stabilizing tubes	•Somatic •Germline	•DNA quantity: low •DNA quality: variable	•Easy to obtain •Represents tumor heterogeneity •Minimally invasive •Easily repeatable •Tool for monitoring resistance and clonal evolution	•Early-stage disease may have low concentrations of ctDNA •Potential for false positive if HRR genes affected by CHIP •Some platforms may have limited ability to detect copy number alterations	~ 1-3 weeks

TISSUE TESTING

SAMPLE TYPES	SAMPLE PREPARATION	ALTERATION TYPES DETECTED	SAMPLE QUALITY	POTENTIAL ADVANTAGES	POTENTIAL LIMITATIONS	TURNAROUND TIME
•Biopsies •Surgical specimens •Metastatic deposits	Formalin-fixed, paraffin-embedded (FFPE) slides	•Somatic •Germline	•DNA quantity: medium •DNA quality: low	•Considered the “gold” standard •Can use archival tissue	•Bone biopsies difficult to collect •Bone may not have enough quality DNA for sequencing •May not show tumor heterogeneity	2+ weeks

✓ <https://www.hrrmtesting.com/assets/pdfs/ctdna-hrrm-testing.pdf>

✓ Schweizer MT, Sivakumar S, Tukachinsky H, et al. Concordance of DNA repair gene mutations in paired primary prostate cancer samples and metastatic tissue or cell-free DNA. JAMA Oncol 2021;7(9):1378-82

TYPES of TESTING: Vendors

Example HRRm Commercial Laboratory Options*

Example HRRm Commercial Laboratory Options*					HRR Gene Mutation Coverage															
Commercial Laboratories	Example Tests*	Sample	Somatic HRRm?	Germline HRRm?	ATM	BRCA1	BRCA2	CDK12	CHEK2	PALB2	RAD51C	FANCL	BARD1	RAD51D	ATR	FANCA	MLH1	MRE11A	NBN	
Ambry	CancerNext Expanded**1	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●			●			
BioReference*	OnkoSight Advanced™*2,3	Tissue	Yes	Incidental ^b	●	●		●	●	●	●	●	●	●	●	●	●	●	●	
	OnkoRisk™ Hereditary Oncology Plus Panel ^{4,5}	Blood	No	Yes	●	●	●		●	●	●	●	●	●		●	●	●	●	
Caris® Life Sciences	MI Cancer Seek™*6	Tissue	Yes	No	●	●	●	●	●	●	●	●	●	●		●	●	●	●	
	Assure Liquid™*7	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Exact Sciences	Riskguard®*8,9	Blood/Saliva	No	Yes	●	●	●		●											
	OncoExTra®*10,11	Tissue	Yes	No	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Foundation	FoundationOne® Liquid CDx ¹²	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
	FoundationOne® CDx ¹³	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
GoPath®	ProstateNOW™*14,15	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●	●	●	●	●	●	
	OncoTarget®500™*16	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Guardant™	Guardant360® CDx ¹⁷	Blood	Yes	Incidental ^b	●	●	●	●									●			
	Guardant360®*18	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Labcorp	Multi-Cancer (Invitae)™*19	Blood/Saliva/ Buccal Cells	No	Yes	●	●	●		●	●	●		●	●			●			
	OmniSeq® Insight™*20,21	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
	VistaSeq® Hereditary*22	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●			●		●	
Myriad	MyRisk®*23	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●			●			
	Precise Tumor®*24	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Neogenomics	NeoTYPE® HRR Profile™*25	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Quest	Solid Tumor Expanded™*26,27	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
	Comp Hereditary Cancer®*28	Blood/Saliva/ Buccal Cells	No	Yes	●	●	●		●	●	●		●	●		●	●		●	
Tempus	Tempus xT Tissue®*29	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
	Tempus xF ³⁰	Blood	Yes	Incidental ^b	●	●	●			●	●				●		●			
	Tempus xF+ Liquid®*31	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	

- ✓ Insurance coverage varies
- ✓ Copay varies
- ✓ Somatic+Germline

Reports:

- ✓ Biallelic not often called
- ✓ Benign vs VUS vs Pathogenic
- ✓ ?PTEN by Genomics ≠ IHC
- ✓ Treatment recommendations

DISCUSSION

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Who and when to test ?

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend:

- 👉 **ALL** patients with mPC: multi-gene test for HRR and MMR somatic and germline gene alterations
- 👉 Patients with mCSPC: IHC for PTEN
- 👉 Consider retesting upon progression to mCRPC
(or after progression on PARPi if considering Platinum)
- 👉 Testing for germline mutations in all prostate cancer patients with a positive family history of certain cancers or familial cancer risk mutation and in all patients with very high-risk or high-risk localized, regional (node-positive), or mPC

DISCUSSION

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Problems, Pitfalls, and Additional Information

- ☞ Germline variants may be reported in somatic testing – counseling
- ☞ Good rationale for performing both Somatic and Germline testing
- ☞ Cascade testing of family members if gDNA repair alterations ID'd

- ☞ Be aware of Clonal Hematopoiesis of Indeterminate Potential (CHIP)
- ☞ VUS/Pathogenic variants are under continual revision
- ☞ Not all HR mutations confer the same PARPi response rates...
- ☞ Caution regarding treatment application based on current guidance..

Biomarker Assays: Be Aware

SPECIMEN TYPE Blood
DATE OF COLLECTION
SPECIMEN RECEIVED
SAMPLE COVERAGE 3,288x

PATIENT
DISEASE Prostate acinar adenocarcinoma

BIOMARKER FINDINGS			ACTIONABILITY	
MSI Status Undetermined				
GENOMIC FINDINGS		MAF %	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
ATM -	E834fs*9	0.29%	Olaparib	Niraparib
			Rucaparib	Talazoparib
10 Trials see p. 6				

NCCN category

1. ATM (poor overall response rates)
2. Misclassification due to partial vs complete loss
3. Misclassification due to CHIP

Research

JAMA Oncology | Brief Report
Association of Clonal Hematopoiesis in DNA Repair Genes
With Prostate Cancer Plasma Cell-free DNA Testing Interference

Kendal Jensen, MD, PhD; Eric Q. Konnick, MD; Michael T. Schweizer, MD; Alexandra O. Sokolova, MD; Petros Grivas, MD, PhD; Heather H. Cheng, MD, PhD; Nola M. Klemfuss, MHA; Mallory Beightol, BS, MB; Evan Y. Yu, MD; Peter S. Nelson, MD; Bruce Montgomery, MD; Colin C. Pritchard, MD, PhD

Problems, Pitfalls, and Additional Information

- 👉 Repeat testing: reversion mutations and PARPi/Platinum resistance
- 👉 Primary tumor testing may 'miss' index lesion for metastasis
- 👉 Metastases are generally concordant with respect to genomic events
- 👉 Somatic and Tumor testing is vastly under-utilized...

Under-Utilization of Genomic Testing

Research Article

For reprint orders, please contact: reprints@futuremedicine.com

Real-world homologous recombination repair mutation testing in metastatic castration-resistant prostate cancer in the USA, Europe and Japan

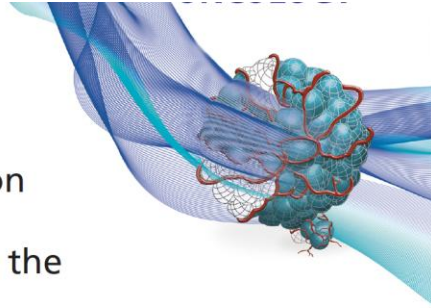
Andrea Leith¹, Amanda Ribbands¹, Jeri Kim², Matthew Last¹, Sophie Barlow¹, Lingfeng Yang^{2,3} & Sameer R Ghatge^{*,2}

¹Adelphi Real World, Bollington, UK

²Merck & Co., Inc., Kenilworth, NJ, USA

³Employee at the time the study was conducted

*Author for correspondence: sameer.ghatge@merck.com



Aim: To assess homologous recombination repair mutation (HRRm) testing patterns in mCRPC

Methods: A point-in-time, international survey conducted January–August 2020.

Results: Three-quarters of physicians (oncologists, urologists, specialist surgeons) globally reported access to genetic/genomic testing and just over half were HRRm testers. Surveyed physicians reported HRRm testing and positivity rates for 1913 patients, which were **18.1%** and 33.7%, respectively.

Of patients tested ($n = 347$), the most common HRR genes tested were BRCA (91.6%) and ATM (47.3%).

Conclusion: Overall testing rates were low, with physicians mostly testing patients they considered higher risk. Increased awareness and education are needed to encourage broader testing, to understand familial risk and to ID patients with worse outcomes or those eligible for life-prolonging treatments.

PC Molecular Classification – Beyond Genomics

Genotypes

(Germline/Somatic)

- ETS-Rearrangement+
- HR-defective
- MMR-defective
- TP53/RB1 loss
- WNT/CTNNB1
- CDK12
- PI3K/PTEN
- MAPK
- SPOP/CHD1
- Epigenetic Reg

Phenotypes

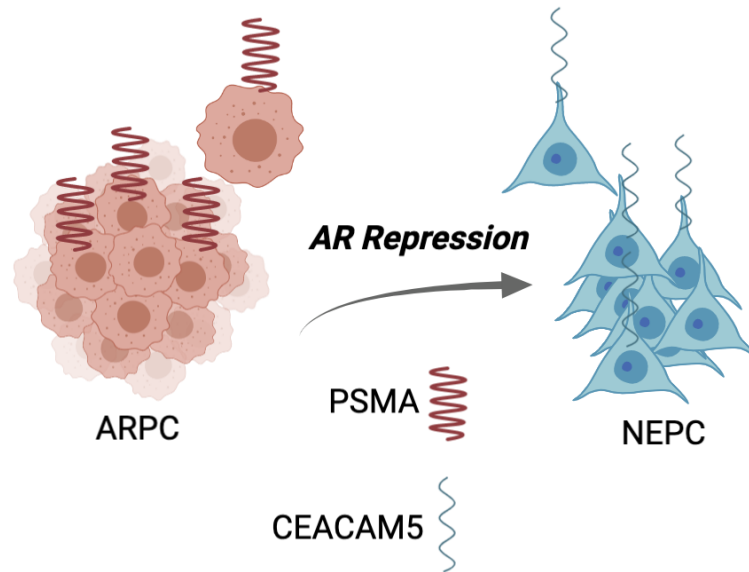
- AR-active
- Neuroendocrine
- Neural
- Small Cell
- Mixed (Amphicrine)
- Double-Negative
- Other' (Squamous...)
- PAM50 Classifications
 - ✓ LumA; LumB; Basal

Classification for Therapy - Future

GENOTYPE

(Germline/Somatic)

- ETS-Rearrangement+
- AR altered (GOF)
- HR-defective
- MMR-defective
- TP53/RB1 loss
- WNT/CTNNB1
- CDK12
- PI3K/PTEN
- MAPK
- SPOP/CHD1
- Epigenetic Reg



PHENOTYPE

(Cell Surface Protein)

- ✓ PSMA
- ✓ B7-H3
- ✓ TROP2
- ✓ CEACAM5
- ✓ DLL3
- ✓ PSCA
- ✓ L1CAM
- ✓ NCAM

↓
? Combinations....

Summary + Future Directions

- 👉 Prostate Cancer is comprised of distinct Molecular Subtypes
- 👉 Several PC Subtypes have specific treatment pathways
 - 👉 HRd – PARPi/Platinum
 - 👉 MMR – ICB
 - 👉 PTEN - AKTi
- 👉 Current Subtypes are Defined by Somatic Genomic Features
- 👉 Panel-based CGP is recommended (tissue/ctDNA)
- 👉 Current Subtypes are also Defined by Germline Alterations
- 👉 Additional tumor/somatic biomarkers in localized disease..(another talk)
- 👉 The future: Phenotype Profiling...(integrated with Genotype)

Thanks



Prostate Cancer
Foundation
Curing Together.



American
Cancer
Society®



Fred Hutch
Cancer Center



Q&A

Strategic Roadmap Published



<http://npcrt.org/strategic-roadmap-2026-2029/>

LEARNING OPPORTUNITY

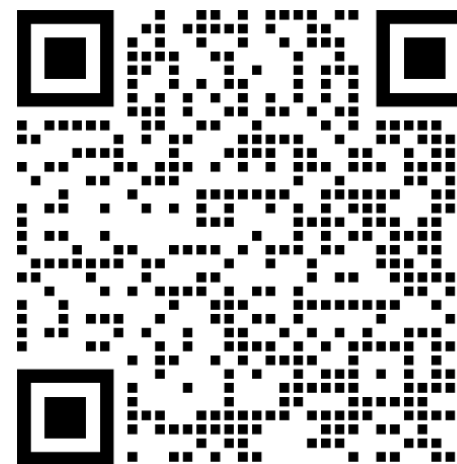
Improving Treatment in Localized Prostate Cancer ECHO

This ECHO will focus on discussing best practices for managing low-grade and/or localized prostate cancers including evidence-based care in the contexts of harm reduction, survivorship, treatment selection, shared decision-making, and patient support.



Launching August 18

- 6 sessions running from August 2026 – January 2027
- **CME credits will be offered for course completion**



<https://iecho.org/public/program/PRGM1782762598703U3QZA7MDHM>

If you're an MD, DO, NP, or PA in oncology or urology who cares for prostate cancer patients, this program is for you.

Upcoming Webinar

Introducing the ACS NPCRT Risk Assessment & Screening Toolkit for Primary Care Clinicians

This webinar will provide an overview of the forthcoming toolkit: its development, contents, use cases, and how it can help health systems/practices and physicians to overcome challenges associated with prostate cancer screening.



September 24, 3:30–4:30 PM ET



https://zoom.us/webinar/register/WN_NHACbcW7ScqkoVULb43_ww#/registration

If you're an MD, DO, NP, or PA in primary care or urology who orders or interprets screening tests for prostate cancer, this webinar and toolkit are for you!

Stay Connected with ACS NPCRT

- **Website:** npcrt.org
- **LinkedIn:** American Cancer Society National Prostate Cancer Roundtable
- **Newsletter:** Sign up at npcrt.org/about-us/





Thank You

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