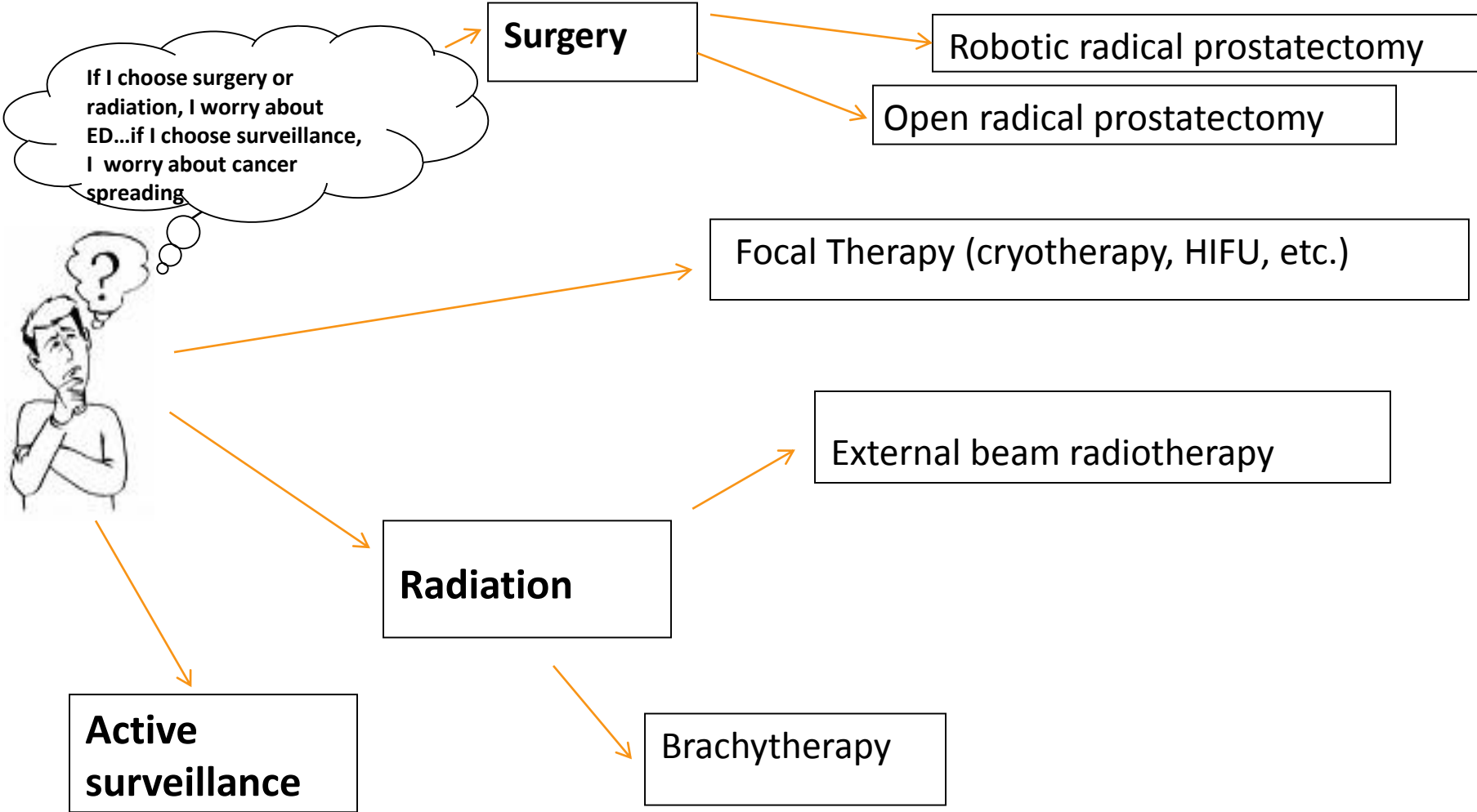


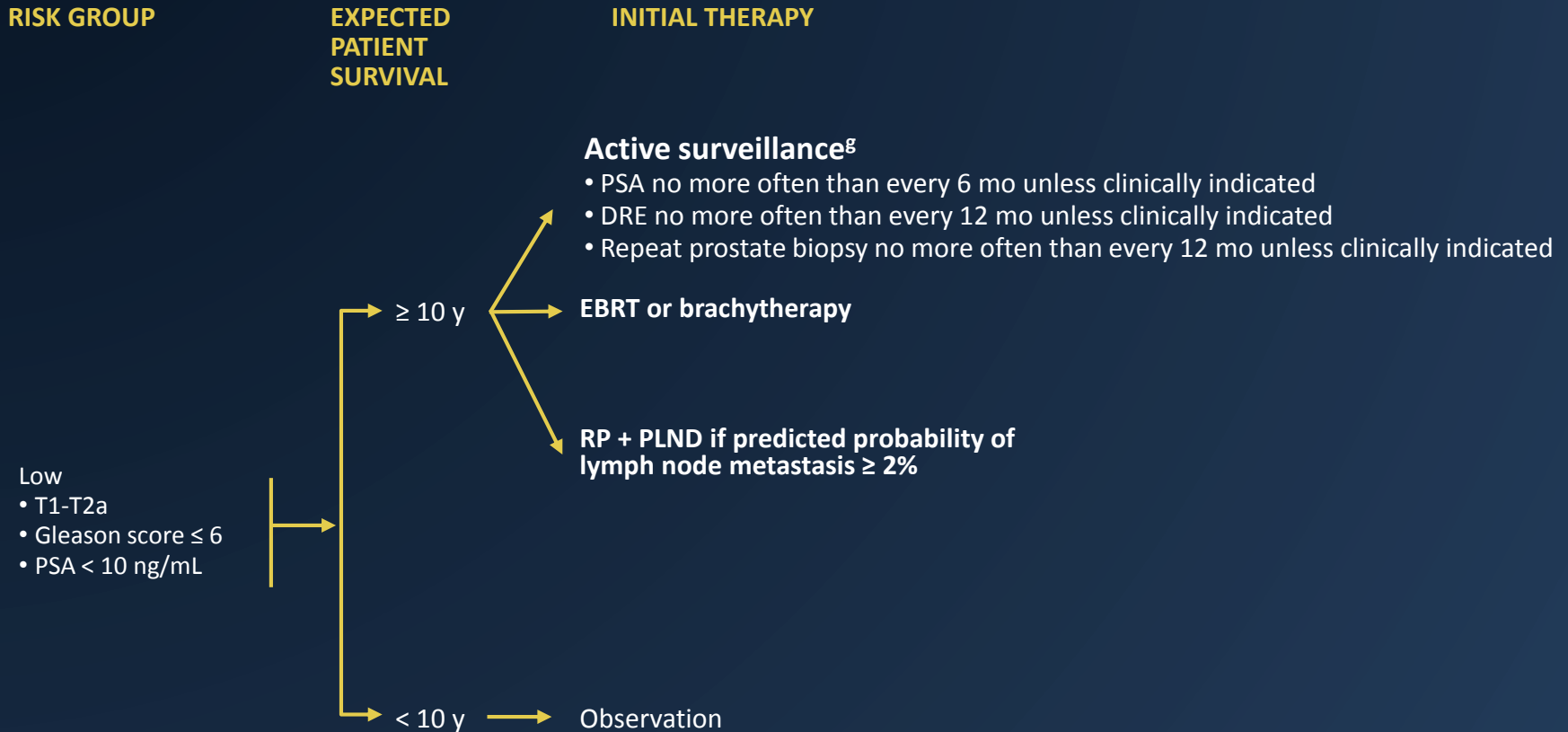
A Tale of Two Cancers or How Genomics Can Guide Treatment Decisions

Bela S. Denes, MD, FACS
Genomic Health, Inc.
Redwood City, CA

Decisions for a Man with Clinically Low Risk Prostate Cancer

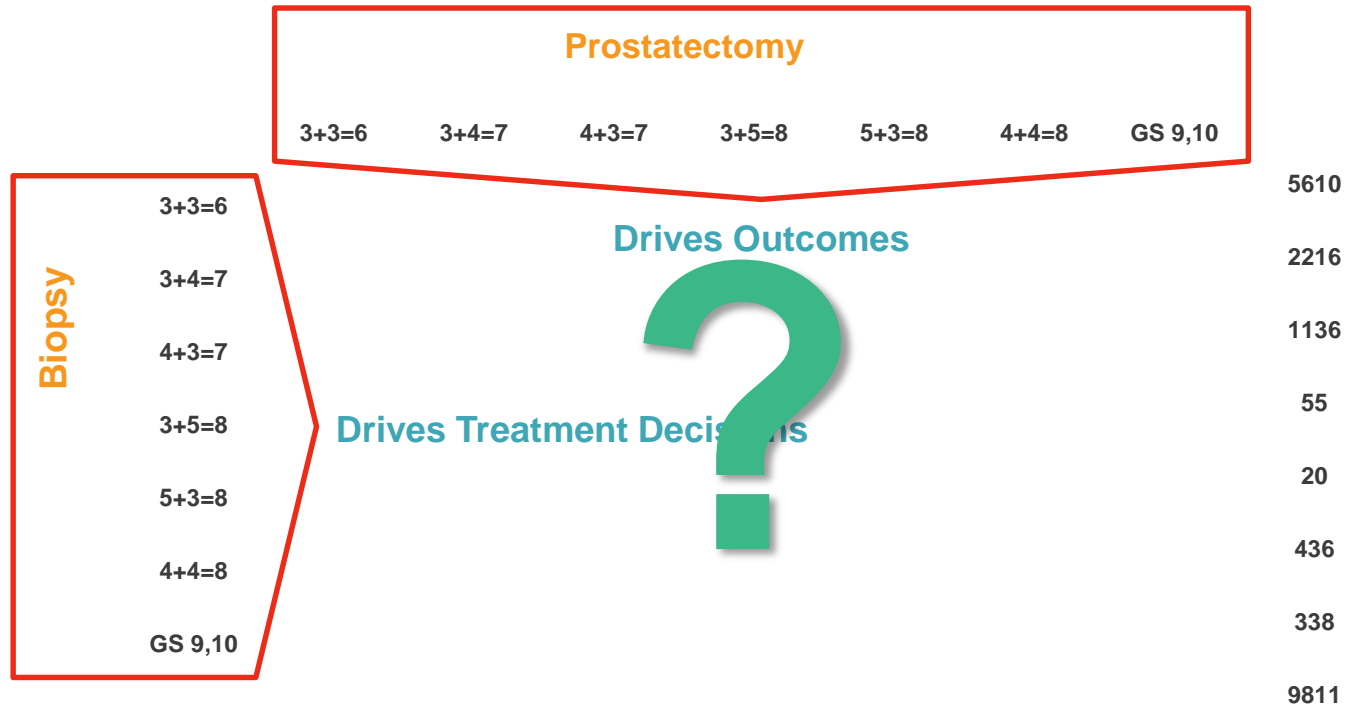


NCCN Guideline for Management of LOW RISK CaP



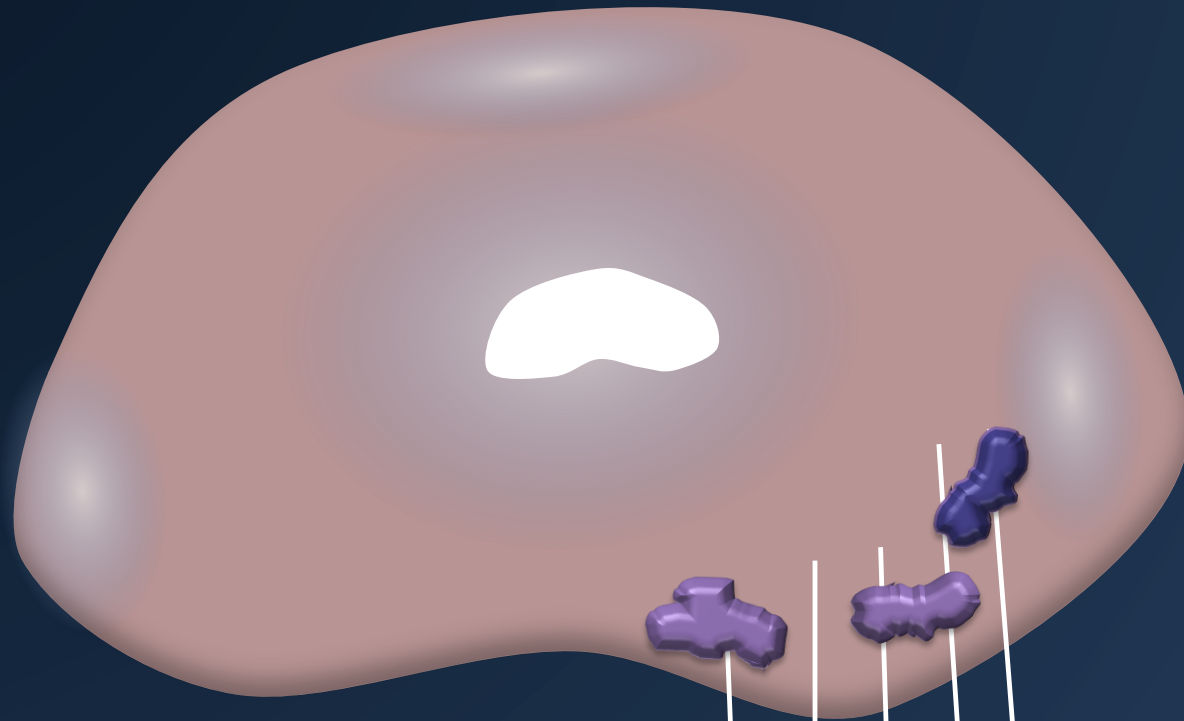
[§]Active surveillance involves actively monitoring the course of disease with the expectation to intervene with potentially curative therapy if the cancer progresses. See Principles of Active Surveillance and Observation (PROS-C).

Why All the Confusion?????



- Single Institution Experience (JHH) Matched Bx & RP 2004-2014; J. Epstein 9-13-15

The Challenge of Random Biopsies



Final Pathology – GS 7 (3 + 4)

3
+
3

(-)

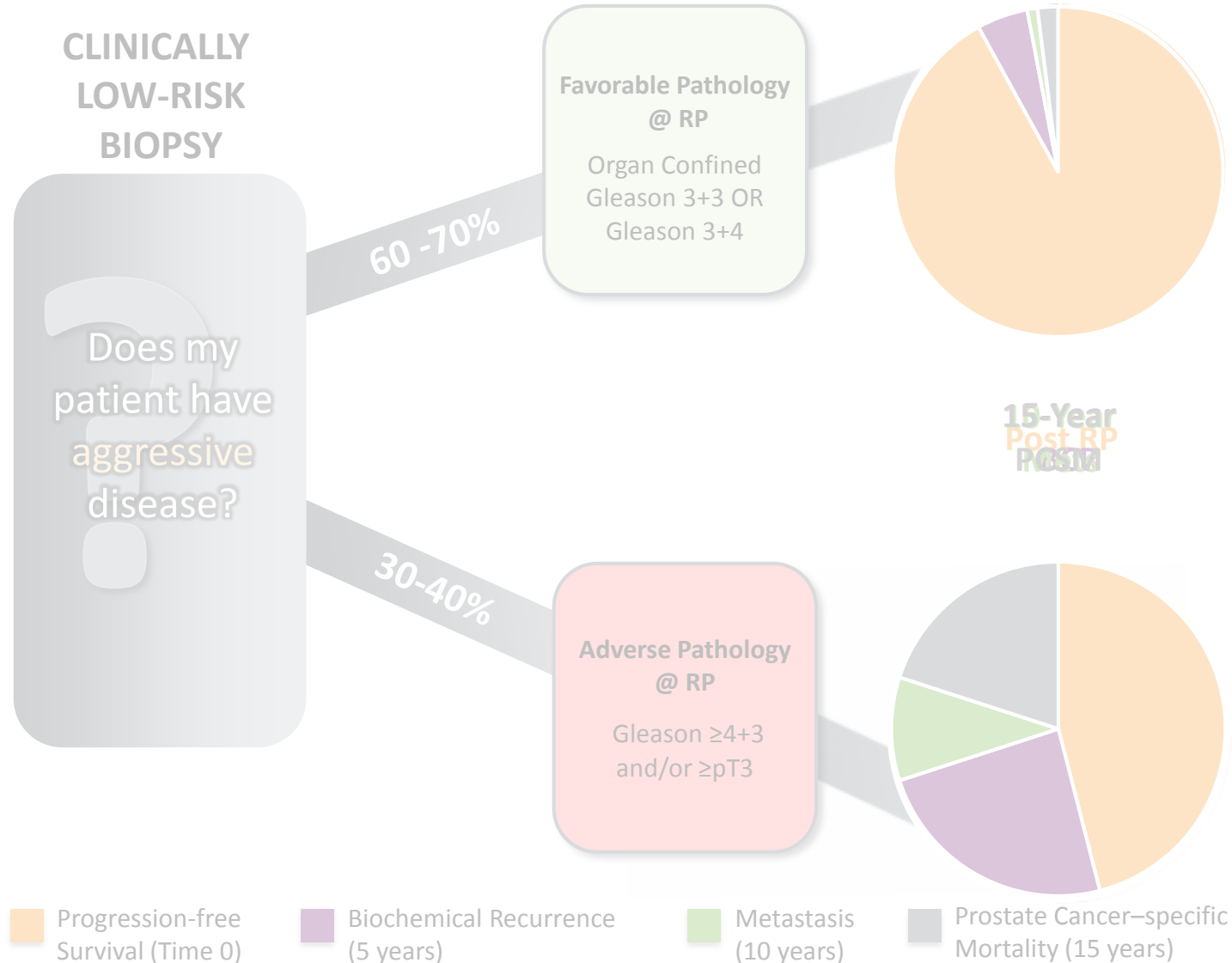
3
+
3

3
+
4

4
+
4

5

The Importance of Getting It Right



Michael is NCCN Low Risk has Been Advised to Have Radiation

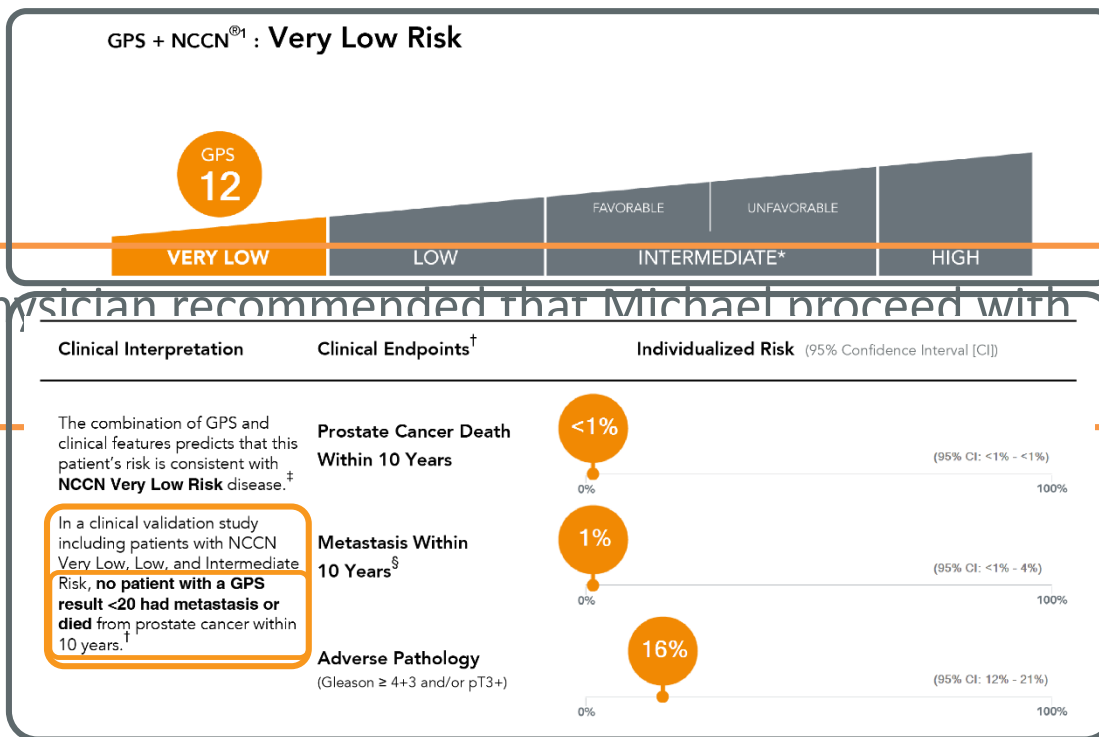
- PSA of 6.0
- PSAD of 0.30 ng/mL
- Prostate Volume of 20cc
- Biopsy revealed Gleason score 6 (3+3), 1/12 positive cores
- By NCCN[®] clinical factors alone he has NCCN[®] low-risk cancer and is interested in Active Surveillance
- His physician ordered GPS to assess the risk of occult higher-risk disease



Michael
68-year-old
healthy man;
Positive family
hx

Patient names, images, and pathology photos are illustrative.
American Society of Clinical Oncology (ASCO) and ASCO are registered trademarks of ASCO; National Comprehensive Cancer Network (NCCN) and NCCN are registered trademarks of NCCN. ASCO and NCCN do not endorse any product or therapy.

Michael's Oncotype DX GPS Report



No patients with GPS < 20 in the validation study experienced metastasis or prostate cancer death

This phrase appears only in reports with GPS < 20

George is NCCN Risk and has Been Advised to Pursue Active Surveillance

- PSA of 5.4
- PSAD of 0.18 ng/mL
- Prostate Volume of 30cc
- Biopsy revealed Gleason score 6 (3+3), 2/12 positive cores
- By NCCN[®] clinical factors alone he has NCCN[®] low-risk cancer and is not sure what to do next
- His physician ordered Oncotype DX GPS to assess the risk of occult higher-risk disease

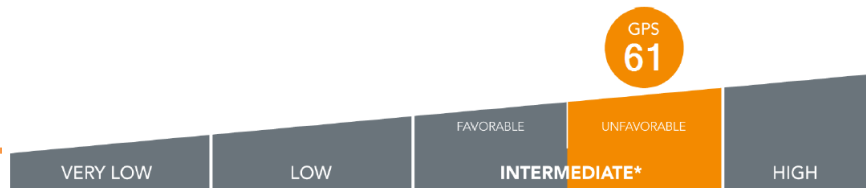


George
58-year-old
healthy man;
Negative
family hx.

Patient names, images, and pathology photos are illustrative.
American Society of Clinical Oncology (ASCO) and ASCO are registered trademarks of ASCO; National Comprehensive Cancer Network (NCCN) and NCCN are registered trademarks of NCCN. ASCO and NCCN do not endorse any product or therapy.

George's GPS Results

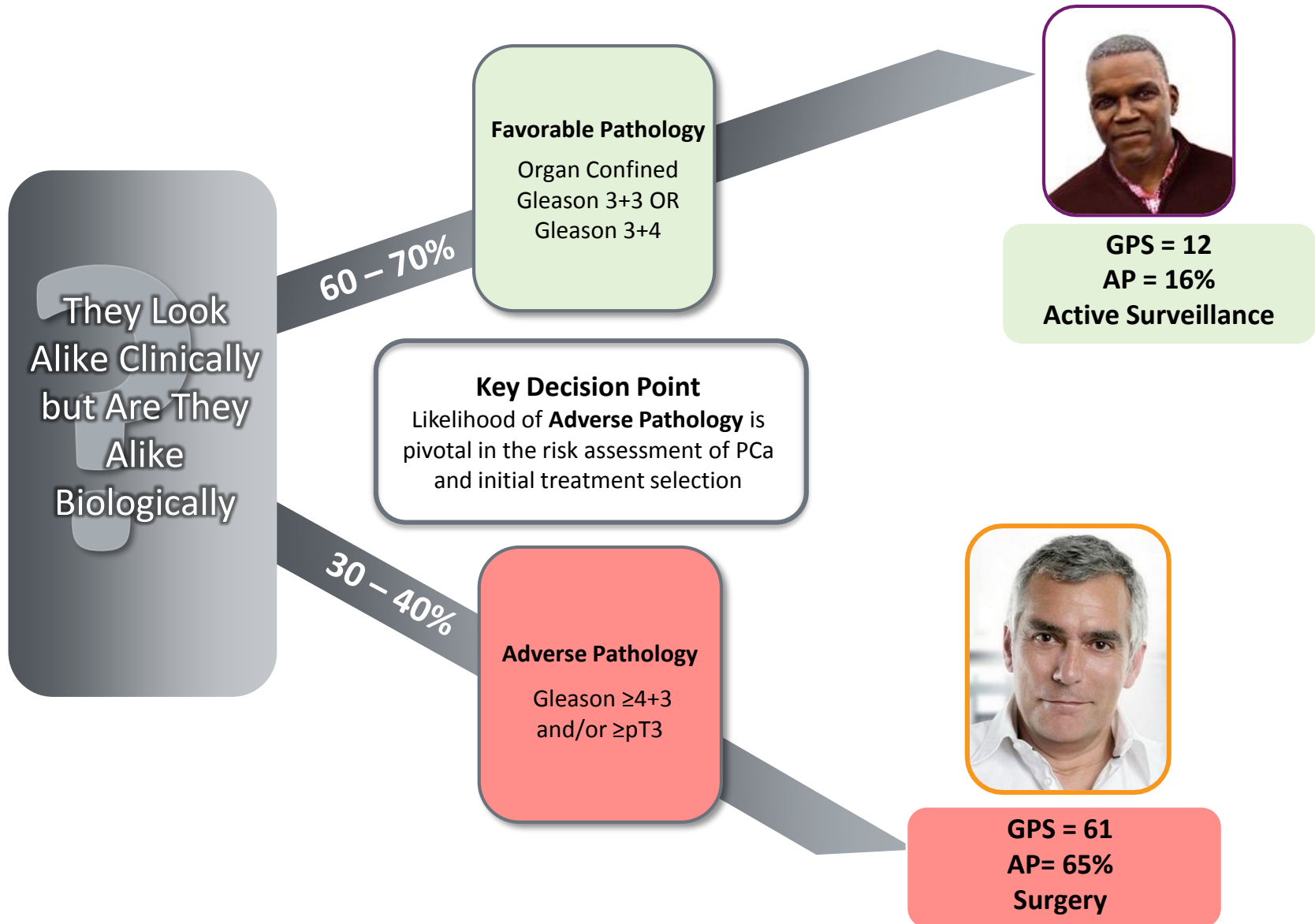
GPS + NCCN^{®1}: Unfavorable Intermediate Risk



- His physician recommended that George proceed with a prostatectomy
- Final pathology

Clinical Interpretation	Clinical Endpoints [†]	Individualized Risk (95% Confidence Interval [CI])
The combination of GPS and clinical features predicts that this patient's risk is consistent with NCCN Unfavorable Intermediate Risk disease. [‡]	Prostate Cancer Death Within 10 Years	<1% (95% CI: <1% - <1%)
	Metastasis Within 10 Years[§]	4% (95% CI: 1% - 28%)
	Adverse Pathology (Gleason ≥ 4+3 and/or pT3+)	65% (95% CI: 52% - 77%)

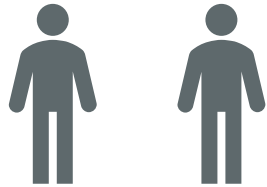
How Oncotype DX[®] GPS Can Help Decision Making



Endpoints Driving Treatment decisions

GPS + NCCN^{®1}: **Very Low Risk**

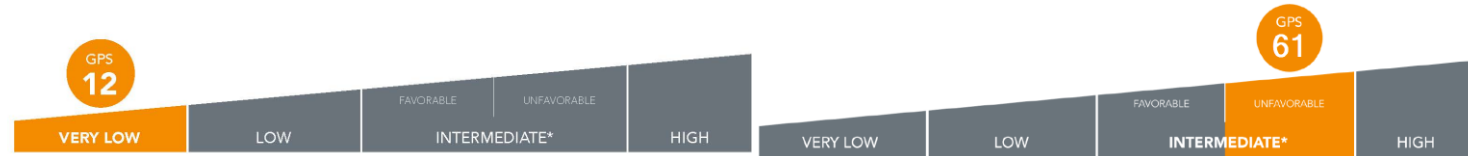
GPS + NCCN^{®1}: **Unfavorable Intermediate Risk**



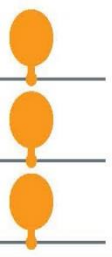
Michael

George

- Clinically Low Risk
- PSA of 6.0
- PSAD of 0.30 ng/mL
- Volume of 20cc
- 1 – 2 Cores Positive



GPS CAN HELP GUIDE TREATMENT DECISIONS BASED ON CANCER BIOLOGY



Do We Follow Conventional Wisdom in 2017?

Don't get into a car with a stranger



Keep bi

oncotype **DX**[®]



ONLY p

US President

Genomic Prostate Score



Gleason Score accurately stages CaP



Thank You

- bdenes@genomichealth.com