

# Immunotherapy, Bringing It All Together: The Next Generation of Approaches & Combinations

**Moderator:** Axel Hoos, MD, Vice President, Oncology Research and Development, GlaxoSmithKline

## **Panelists:**

- Neil Berinstein, MD, Affiliate Scientist, Sunnybrook Research Institute
- Paul Higham, Chief Executive Officer, Immatics
- Sara Zaknoen, MD, CMO, Polynoma, LLC
- Dennis L. Panicali, Ph.D, Vice President, Technical Operations Bavarian Nordic ImmunoTherapeutics
- Charles J. Link, Jr. MD, Chairman, Chief Executive & Scientific Officer at NewLink Genetics Corp

The logo features the words "CANCER" and "PROGRESS" in a bold, black, sans-serif font. "CANCER" is positioned above "PROGRESS". Below "PROGRESS" is the tagline "by Defined Health" in a smaller, italicized, black font. The entire text is overlaid on a large, light blue, irregular oval shape that is tilted diagonally.

**CANCER**  
**PROGRESS**  
*by Defined Health*



Frank, 80

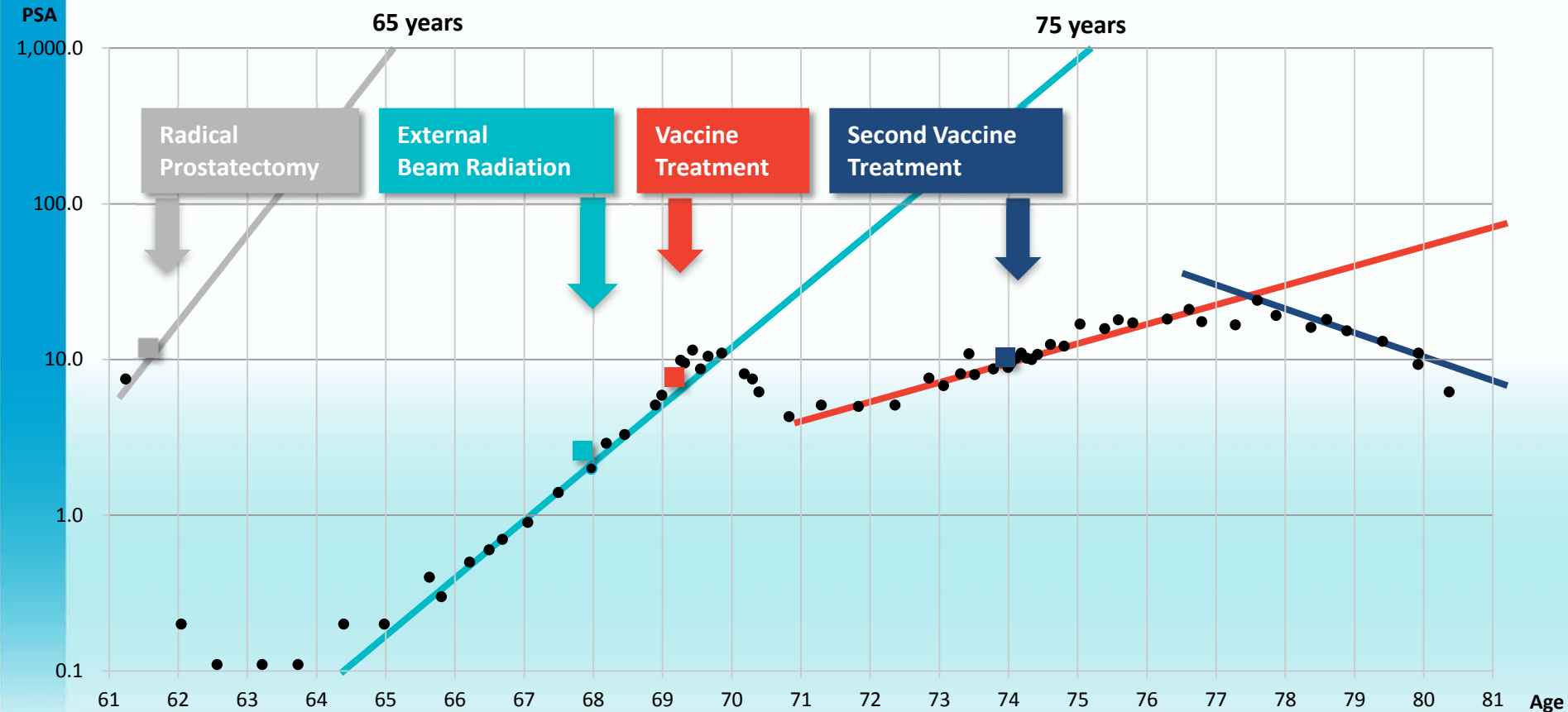
*Prostate cancer survivor*

FOXFIRE



# PROSTVAC<sup>®</sup> – Interesting Case History

Patient was never treated with hormones



Gleason grade: 4 + 3 = 7

Doubling time

Age at which PSA would equal 1000

- Trend before radical prostatectomy ( )
- Trend after radical prostatectomy. External beam radiation ( )
- Trend after first vaccine trial ( )
- Trend after second vaccine trial ( )

5.8 months      65 years  
 9.6 months      75 years  
 28.6 months      90 years



NCI Ph2 study

# PROSTVAC<sup>®</sup> Extends Survival in Patients with Less Advanced Disease

Open-Label Phase 2 in 32 mCRPC patients<sup>1</sup>

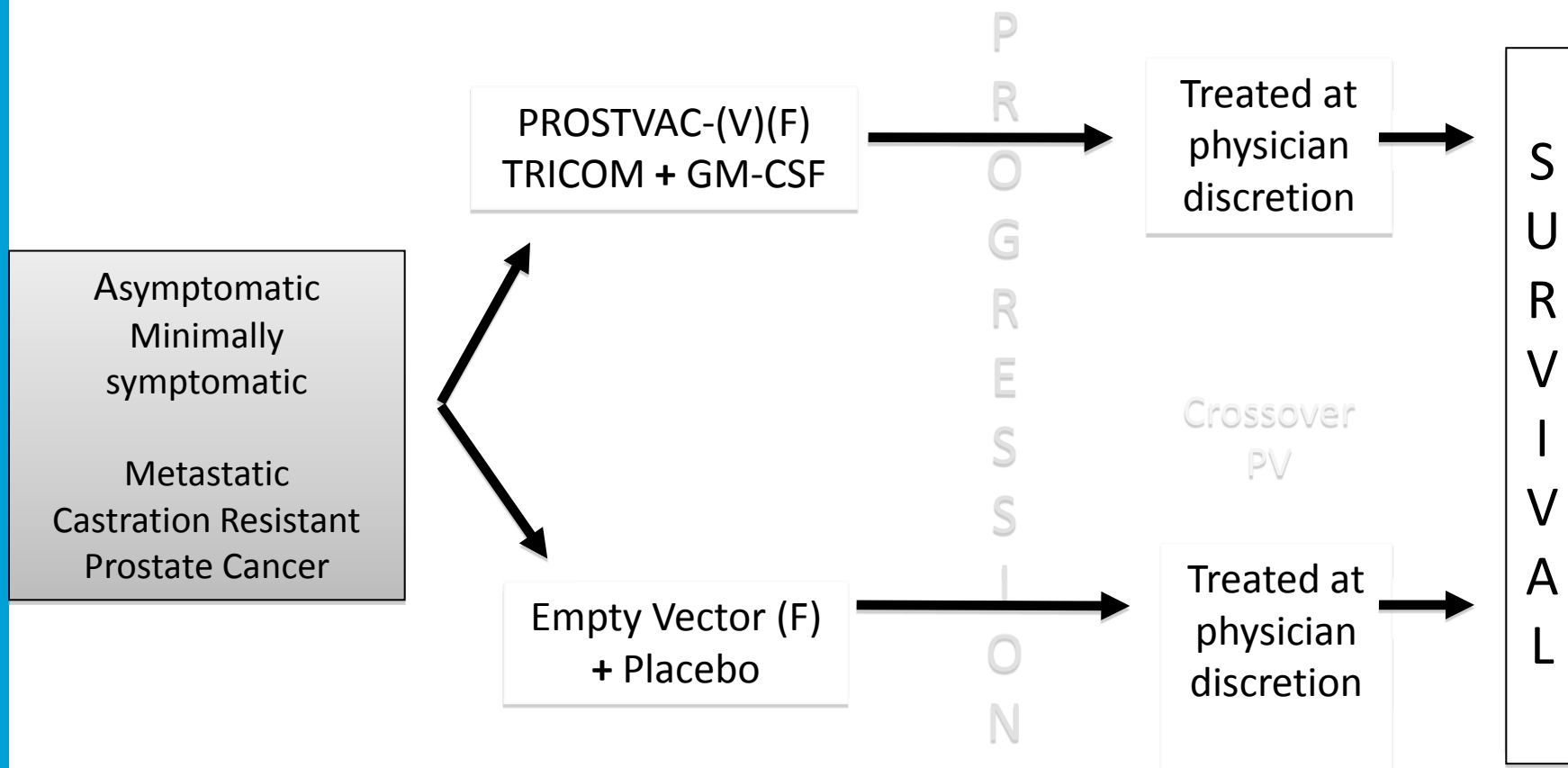
## Median survival (months)

	All patients	Patients with Halabi-predicted survival <18 months	Patients with Halabi-predicted survival ≥18 months
Predicted by Halabi model	17.4	12.3	20.9
With PROSTVAC <sup>®</sup> (n=32)	26.6	14.6	≥37.3 (not yet reached)
	<b>Δ 9.2 months</b>	<b>Δ 2.3 months</b>	<b>Δ ≥16.4 months</b>
Patients surviving longer than predicted	22 of 32 (69%)	10 of 17 (59%)	12 of 15 (80%)

<sup>1</sup>Gulley et al., Cancer Immunol Immunother. 2010



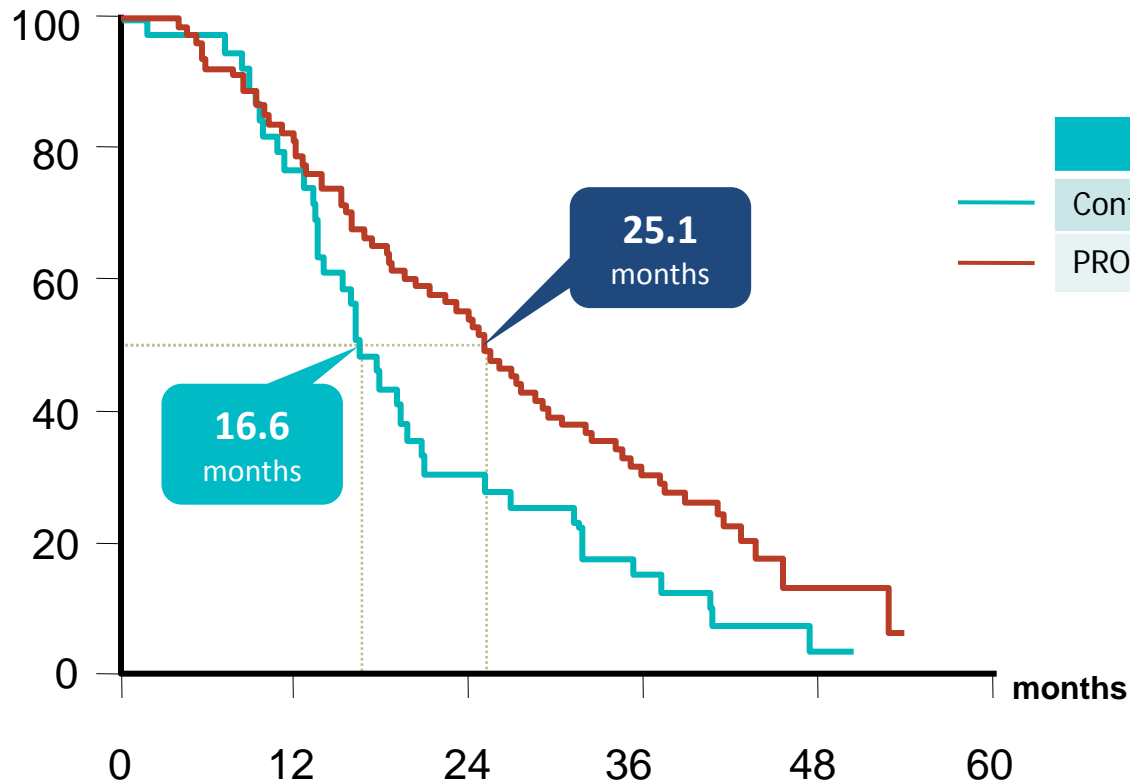
# Phase 2 Randomized Controlled Trial Design



***Two arms with crossover possible upon progression***

# PROSTVAC<sup>®</sup> Phase 2 Results

**Overall survival**  
(% of patients)



**Significantly extended overall survival**

	N	Deaths	Median
Control	40	37	16.6
PROSTVAC <sup>®</sup>	82	65	25.1

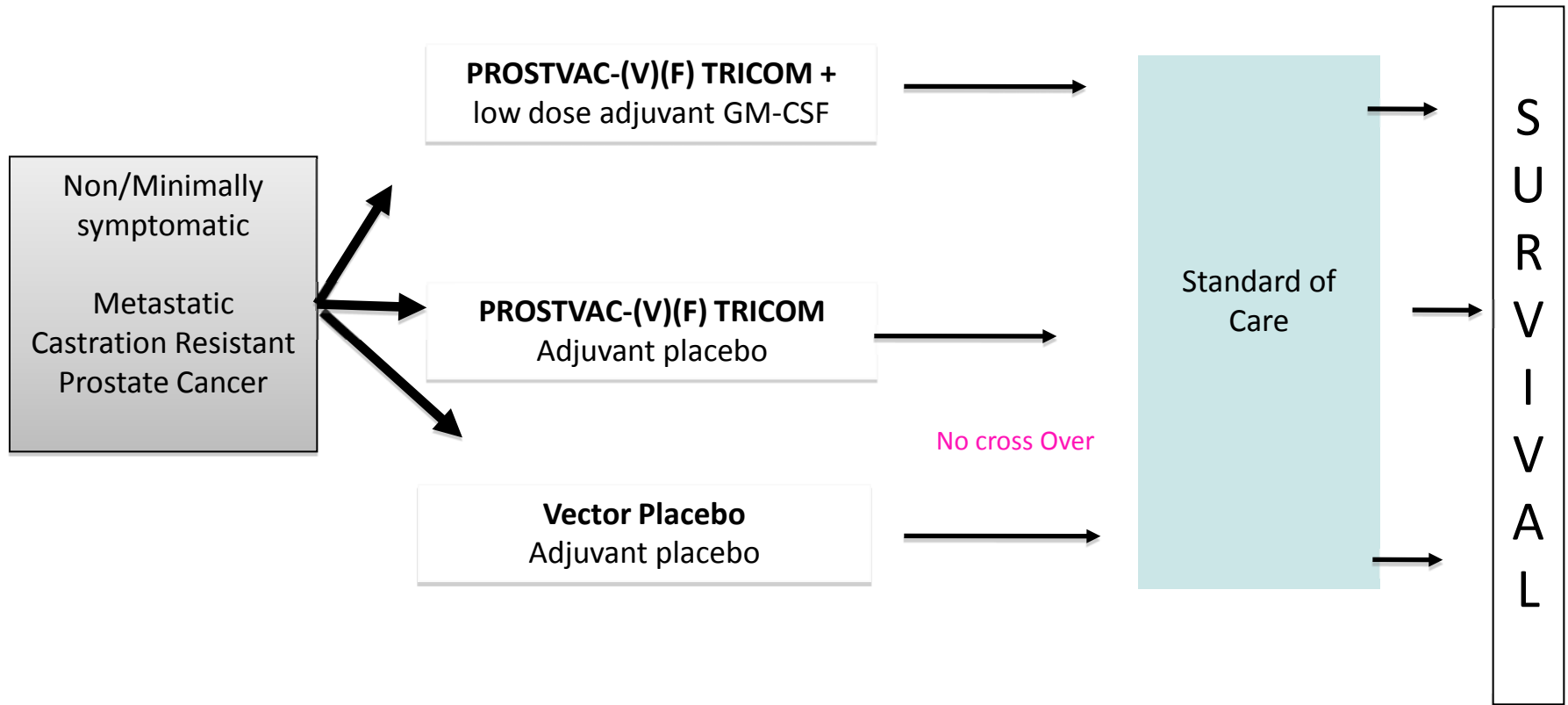
**Δ 8.5 months**

**Hazard ratio**  
**0.56 (95% CI 0.37–0.85)**

**p=0.0061**

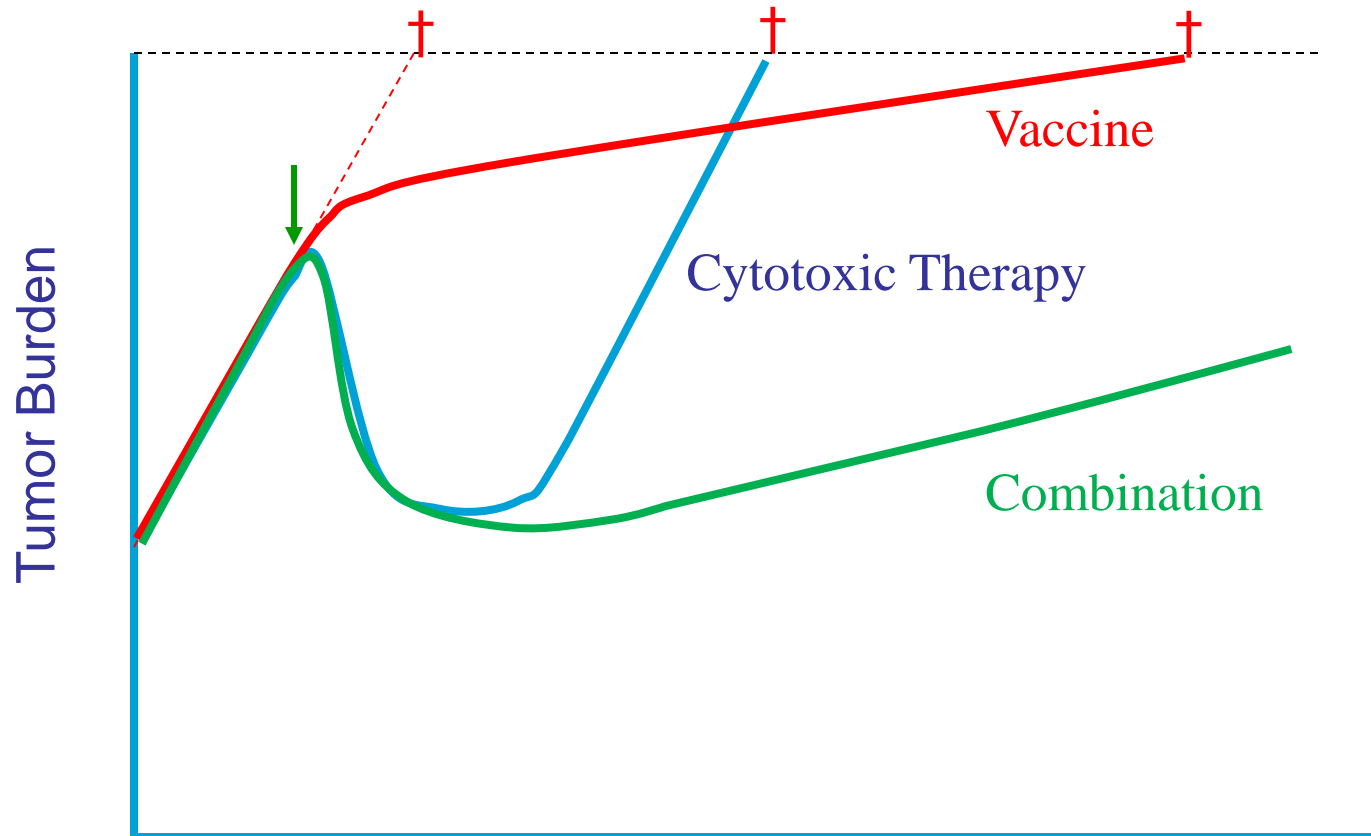
# Phase 3 Trial Design

## PROSPECT Study



*Three arms with no crossover*

# Tumor Growth Rate



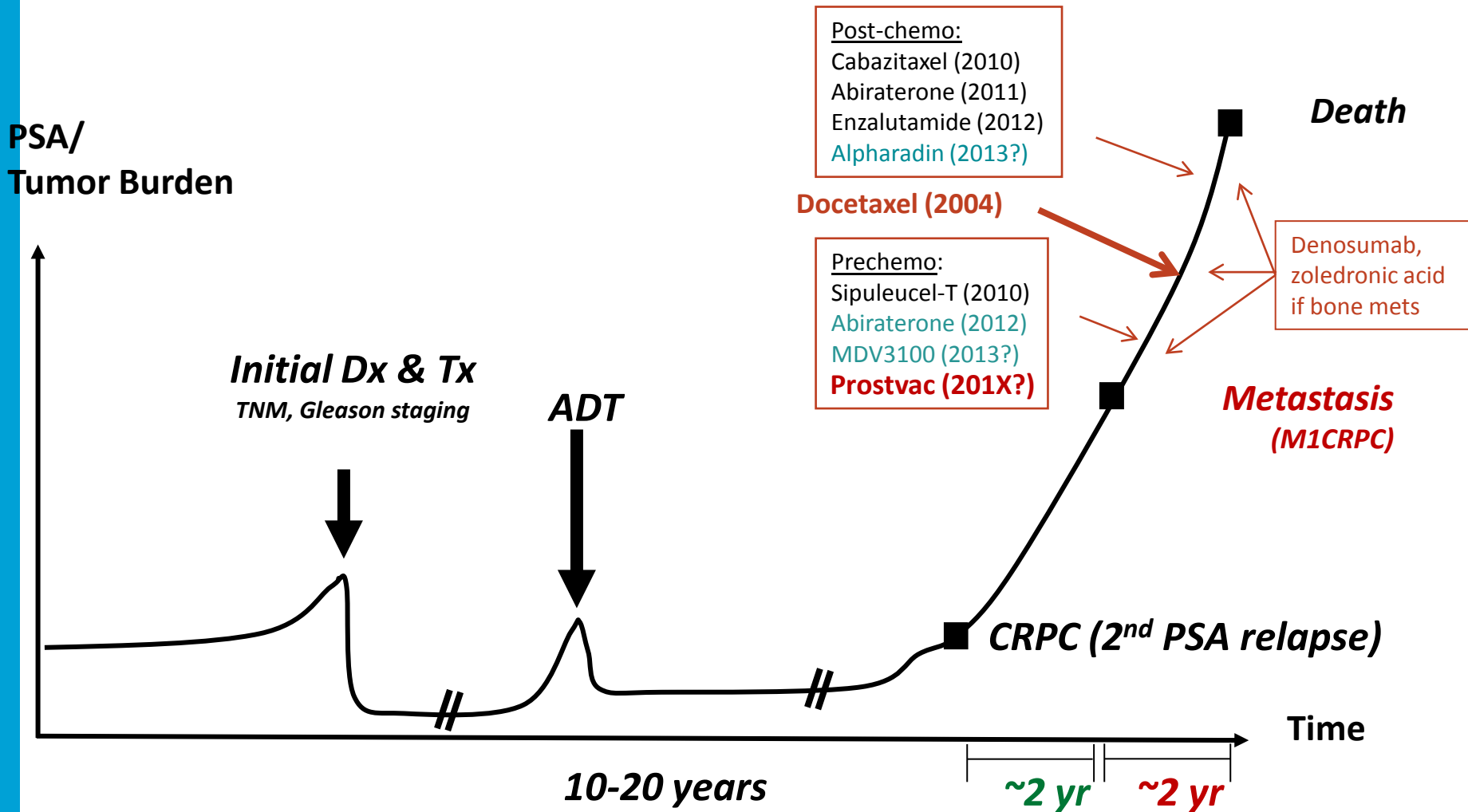
Stein W, Gulley JL, et al. *Clin Cancer Res*, 2011

Time





# Typical Disease History Prostate Cancer



# Immunotherapy, Bringing It All Together: The Next Generation of Approaches & Combinations

**Moderator:** Axel Hoos, MD, Vice President, Oncology Research and Development, GlaxoSmithKline

## **Panelists:**

- Neil Berinstein, MD, Affiliate Scientist, Sunnybrook Research Institute
- Paul Higham, Chief Executive Officer, Immatics
- Sara Zaknoen, MD, CMO, Polynoma, LLC
- Dennis L. Panicali, Ph.D, Vice President, Technical Operations Bavarian Nordic ImmunoTherapeutics
- Charles J. Link, Jr. MD, Chairman, Chief Executive & Scientific Officer at NewLink Genetics Corp

The logo features the words "CANCER" and "PROGRESS" in a bold, black, sans-serif font. "CANCER" is positioned above "PROGRESS". Below "PROGRESS" is the tagline "by Defined Health" in a smaller, italicized, black font. The text is overlaid on a large, light blue, irregular oval shape that tapers to the right.

**CANCER**  
**PROGRESS**  
*by Defined Health*