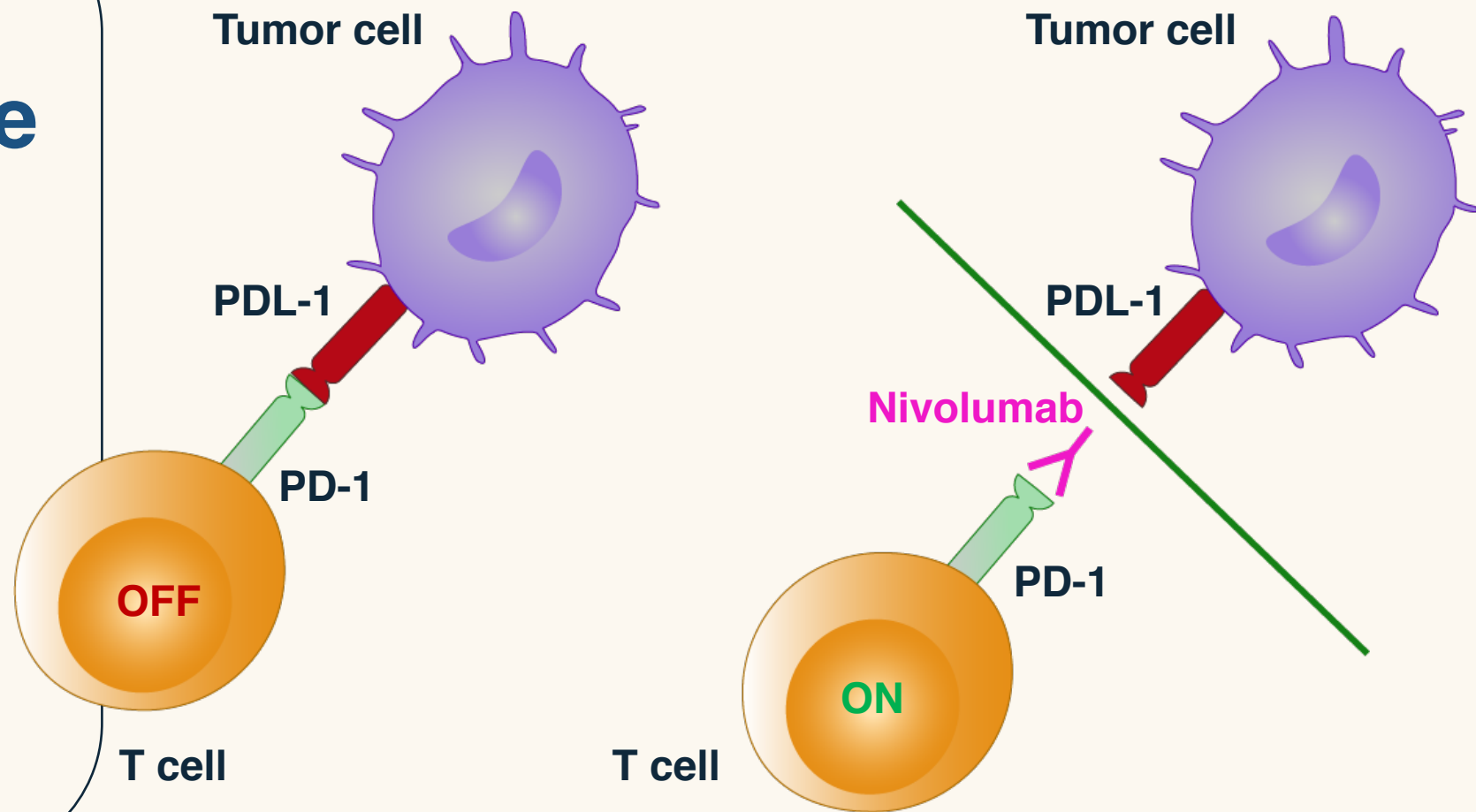
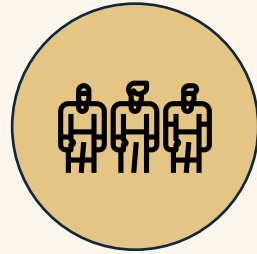


Nivolumab is safe and effective against advanced renal cell carcinoma (aRCC) in Japanese patients



How does nivolumab compare with everolimus against aRCC in Japanese patients?

Why compare nivolumab with everolimus?



Phase 3
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025 study



**Nivolumab is
safer and more
effective than
everolimus
against aRCC**

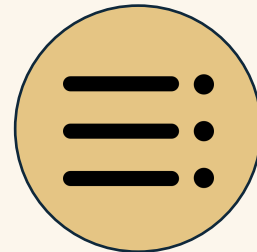
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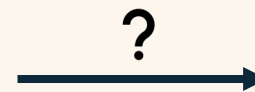


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Why Japanese patients?



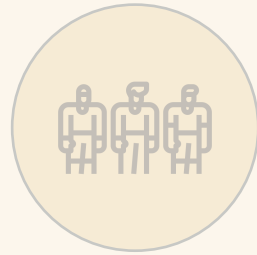
Environment
Genes
Treatment



Nivolumab is safer and more effective than everolimus against aRCC

How does nivolumab compare with everolimus against aRCC in Japanese patients?

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Phase 3
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Why Japanese patients?



Environment
Genes
Treatment

What did we do?



Compared
nivolumab &
everolimus in
global vs
Japanese
patients

Nivolumab is safer and more effective than everolimus against aRCC

How does nivolumab compare with everolimus against aRCC in Japanese patients?

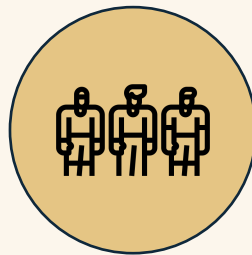
Why compare nivolumab with everolimus?

Nivolumab	Everolimus
Novel immunotherapy	Standard-of-care therapy
PD-1 checkpoint inhibitor	mTOR inhibitor

How does nivolumab compare with everolimus against aRCC in Japanese patients?

Why compare nivolumab with everolimus?

Phase 3
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Nivolumab improved overall survival and overall response rate in aRCC patients



Nivolumab is safer and more effective than everolimus against aRCC

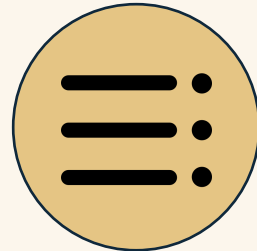
How does nivolumab compare with everolimus for aRCC treatment in Japanese patients?

Why compare nivolumab with everolimus?

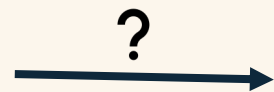


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025 study

Why Japanese patients?



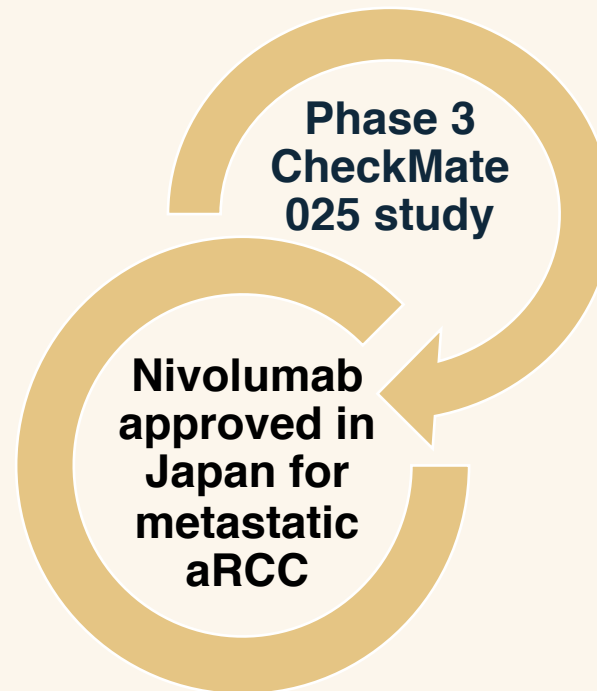
Environment
Genes
Treatment



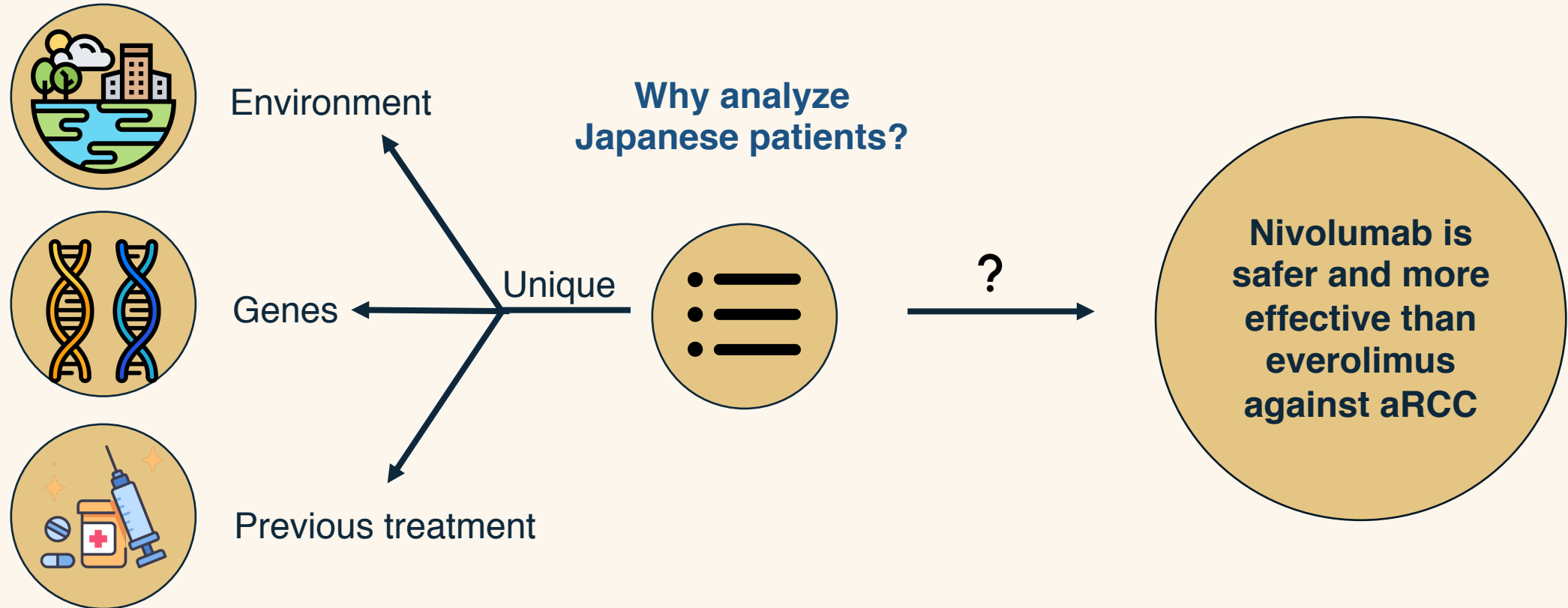
Nivolumab is safer and more effective than everolimus against aRCC

How does nivolumab compare with everolimus against aRCC in Japanese patients?

Why analyze
Japanese patients?



How does nivolumab compare with everolimus against aRCC in Japanese patients?



How does nivolumab compare with everolimus for aRCC treatment in Japanese patients?

Why compare nivolumab with everolimus?



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025 study

Why Japanese patients?

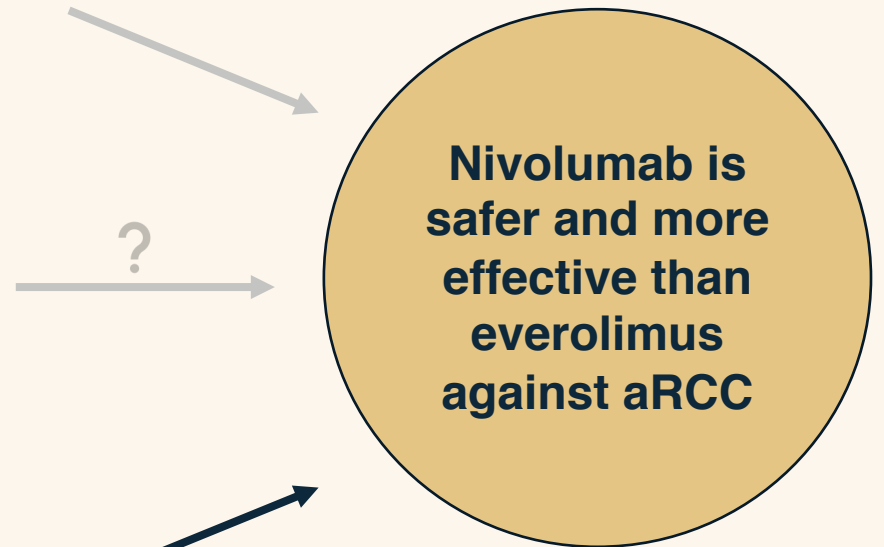


Environment
Genes
Treatment

What did we do?



Compared
nivolumab in
global vs
Japanese
patients



Study Design and Methods

Patients were randomized 1:1 to receive nivolumab or everolimus

PATIENTS

	Global (n)	Japanese (n)
Nivolumab	410	37
Everolimus	411	26

TREATMENT

Nivolumab dose: 3mg/kg intravenously every 2 weeks

Everolimus dose: 10-mg tablet orally once daily

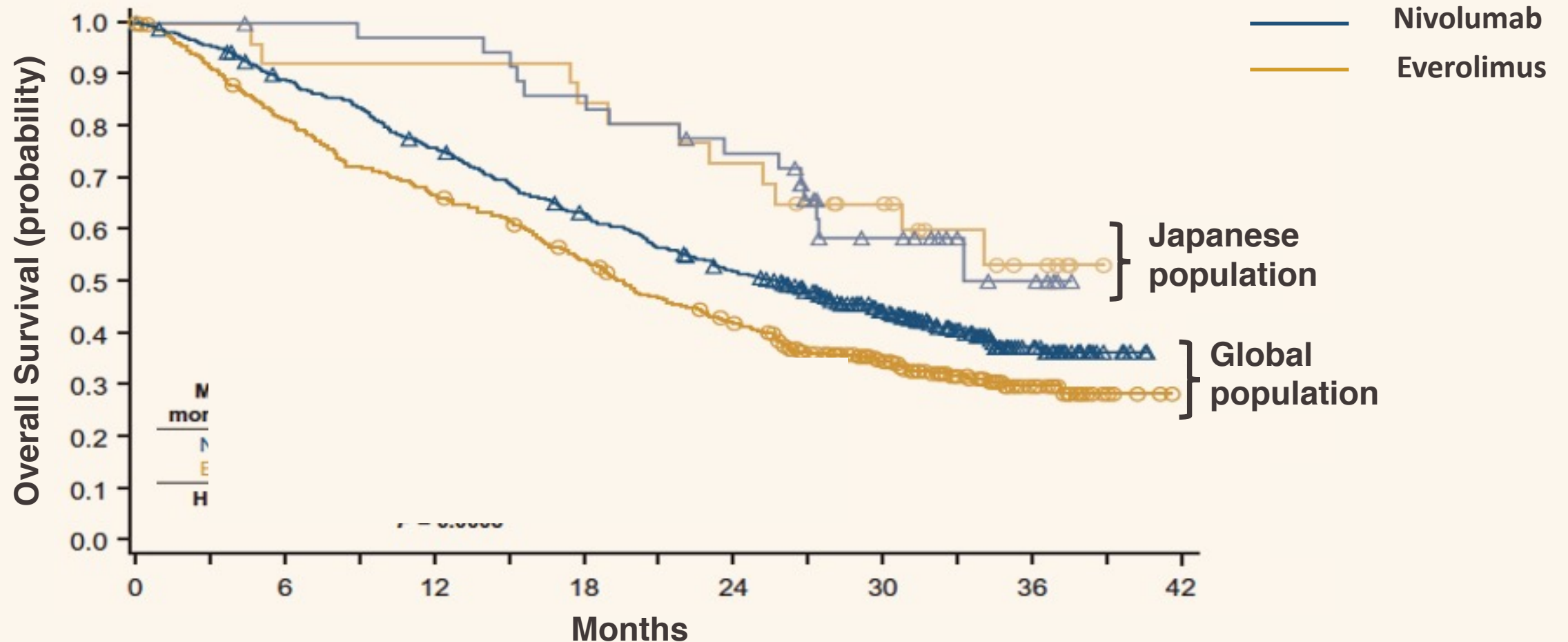
Study Design and Methods

PRIMARY ENDPOINT	SECONDARY ENDPOINTS
<ul style="list-style-type: none">• Overall Survival (OS)	<ul style="list-style-type: none">• Objective Response Rate (ORR)• Progression-free Survival (PFS)• Safety

Study Design and Methods



Nivolumab improved overall survival as compared to everolimus



Nivolumab was more effective than everolimus against aRCC

27%↑

Overall survival of global patient population

$P \leq .005$

513%↑

Overall response rate in global patient population

814%↑

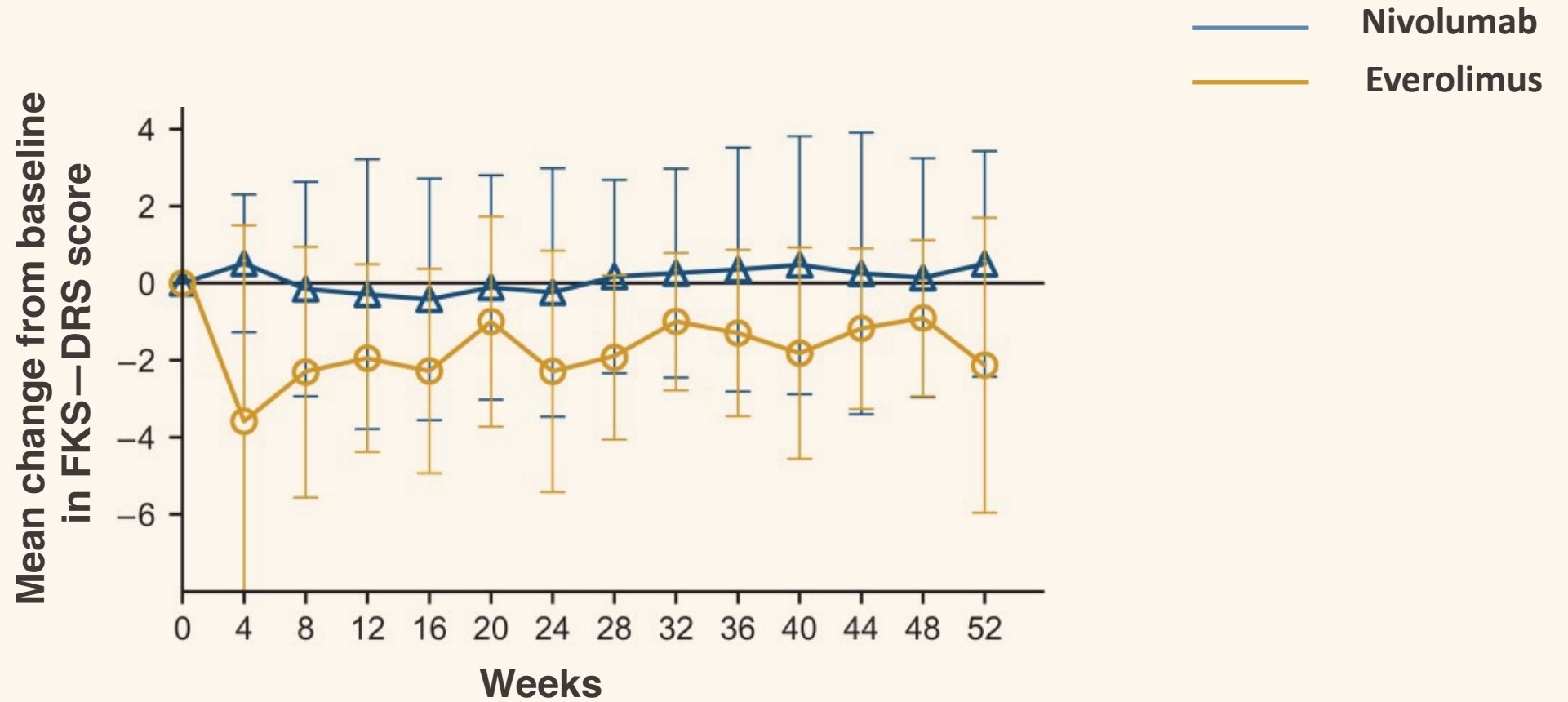
Overall response rate in Japanese patient population

Nivolumab was safer than everolimus against aRCC in Japanese patients

**Nivolumab has lower
treatment-related adverse events**

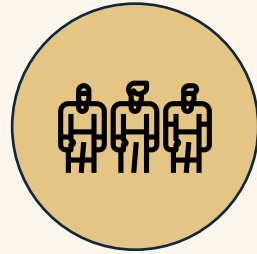
	% of patients with treatment-related adverse events	
	Any grade	Grade 3-4
Nivolumab	78	19
Everolimus	100	58

Quality of life was stable with nivolumab in Japanese patients



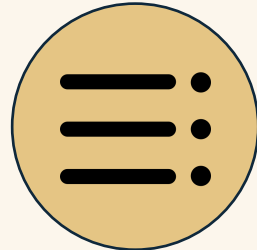
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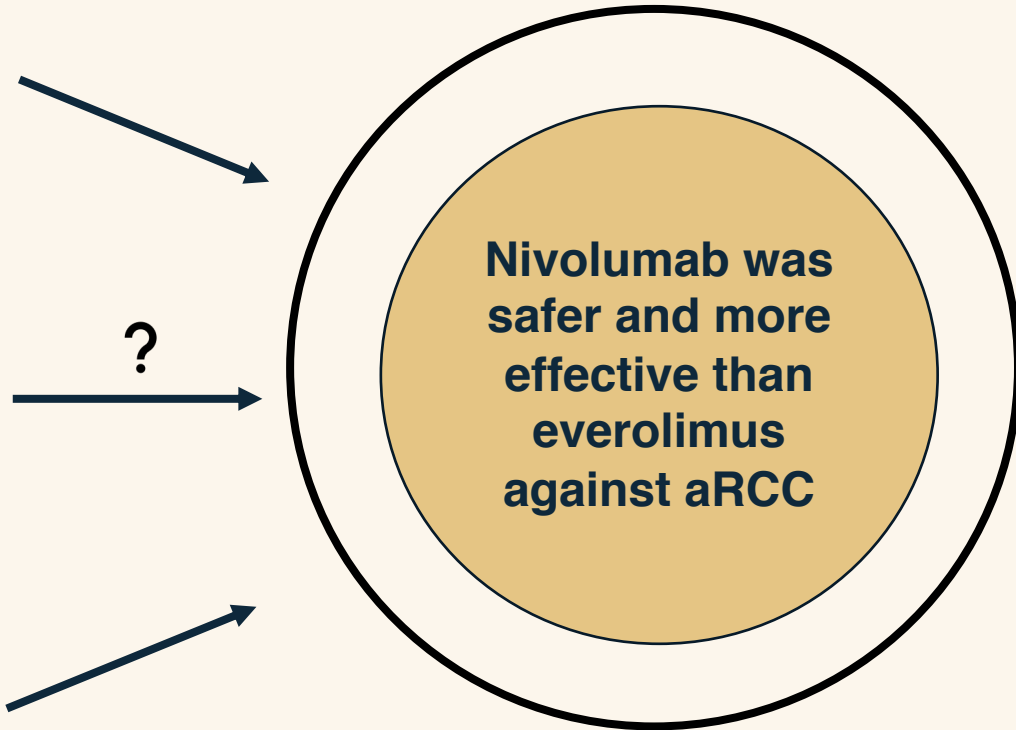


Environment
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What did we do?



Compared
nivolumab &
everolimus in
global vs
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patients



**Nivolumab was
safer and more
effective than
everolimus
against aRCC**

**This study supports the approval of
Nivolumab for metastatic aRCC in Japan.**

