



KCRS22

**Kidney Cancer  
Research Summit**

Phase 2 trial of Cabozantinib with Nivolumab and  
Ipilimumab in advanced RCC with variant Histology  
**CaNI (NCT04413123)**

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6-7 OCTOBER • PHILADELPHIA, PA

# RCC with variant Histology an Unmet Need

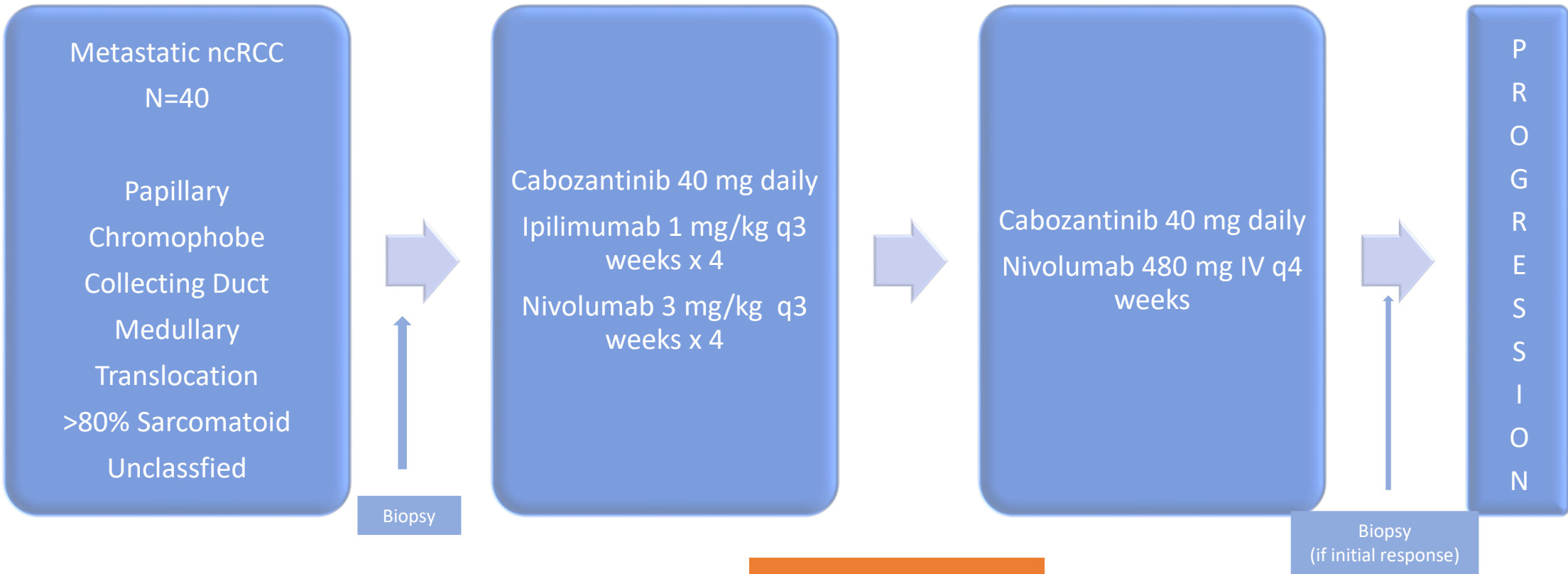
	Study	N	Objective Response Rate
<b>Cabozantinib<sup>1</sup></b>	Retrospective	112	27%
<b>Cabozantinib (papillary)<sup>2</sup></b>	Phase 2	46	23%
<b>Pembrolizumab<sup>3</sup></b>	Phase 2	165	26%
<b>Nivolumab/Ipilimumab<sup>4</sup></b>	Phase 3b/4	52	19.6%
<b>Atezolizumab/Bevacizumab<sup>5</sup></b>	Phase 2	40	26%
<b>Cabozantinib/Atezolizumab<sup>6</sup></b>	Phase 1	30	33%
<b>Cabozantinib/Nivolumab<sup>7</sup></b>	Phase 2	40	47.5%
<b>Lenvatinib/Pembrolizumab<sup>8</sup></b>	Phase 2	82	47.6%

1. Martinez Chanza et al, Lancet Oncology 2019  
 2. Pal et al, Lancet 2021  
 3. McDermott et al, Journal of Clinical Oncology 2021

4. Tykodi et al, ASCO GU 2021  
 5. McGregor et al, Journal Clinical Oncology 2020  
 6. Pal et al, Lancet Oncology 2021

7. Lee et al, Journal of Clinical Oncology 2022  
 8. Albiges et al, ESMO 2022

# CaN-I in Variant Histology RCC



**37 enrolled!**

Primary Objective  
ORR

Secondary Objectives  
Toxicities  
Duration of responses

# Toxicities

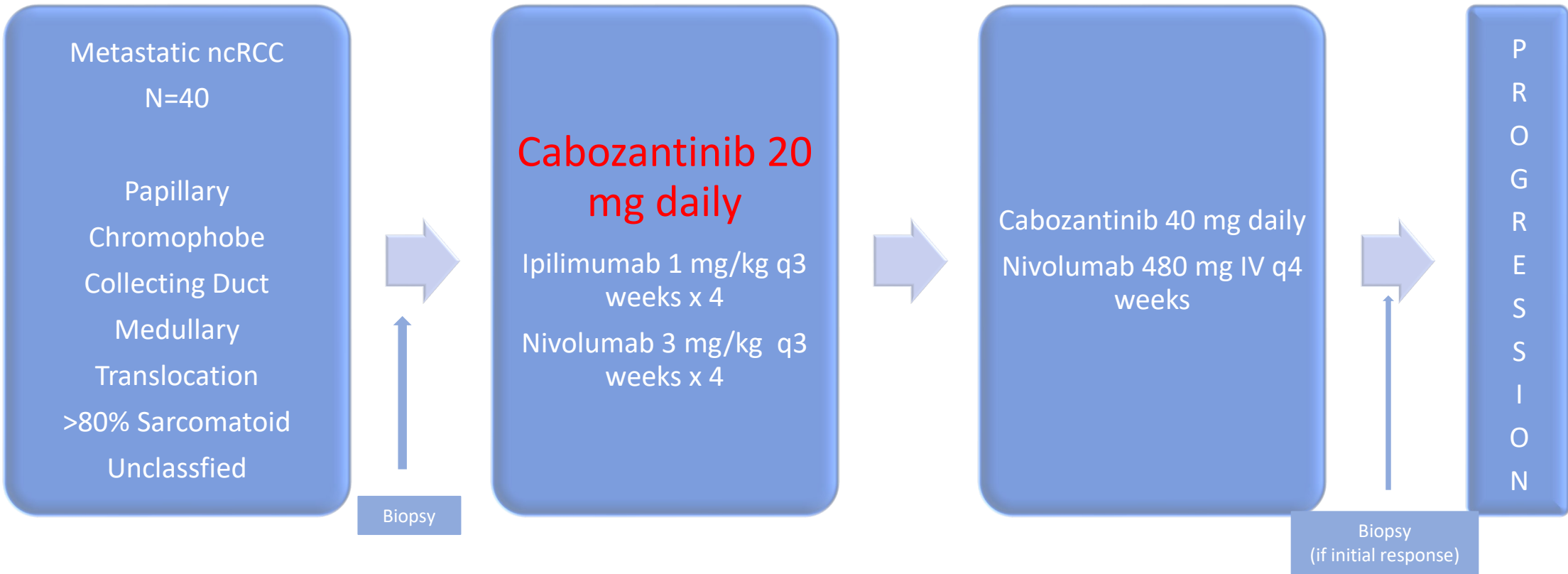
## Summary of Adverse Events (Safety Population)

	Cabo+Nivo+Ipi (N=426)		Pbo+Nivo+Ipi (N=424)	
	Any Grade	Grade 3–4	Any Grade	Grade 3–4
<b>Treatment-related adverse events</b>				
Any event,* %	99	73	91	41
Alanine aminotransferase increased	46	26	17	6
Aspartate aminotransferase increased	44	20	16	5
Diarrhea	41	4	18	3
Palmar-plantar erythrodysesthesia	28	3	4	0
Hypothyroidism	24	<1	15	0
Hypertension	23	8	5	2
Fatigue	22	2	21	1
Lipase increased	22	9	13	6
Amylase increased	20	5	12	2
Rash	20	2	20	1
Pruritus	20	0	26	<1

Only 58% received  
all 4 doses of  
ipilimumab

- Grade 5 TRAEs occurred in 3 patients (1%) with Cabo+Nivo+Ipi (gastrointestinal hemorrhage, hepatic failure, and respiratory failure) and 3 patients (1%) with Pbo+Nivo+Ipi
- 10 patients had grade 5 TRAEs with Cabo+Nivo+Ipi (immune-mediated hepatitis and acute hepatic failure) and one additional patient with Pbo+Nivo+Ipi (perforated ulcer)
- Use of high-dose corticosteroids 40% with Cabo+Nivo+Ipi and 35% with Pbo+Nivo+Ipi

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