

Advanced Anal Cancer in 2026

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Disclosures

- **Cathy Eng, MD, FACP, FASCO:** Consultant – AbbVie, Amgen, Arcus, BMS, Boehringer, EMD Serono, Gilead, GSK, Incyte, Merck, Merus, Novartis, Revolution Medicines, Takeda; Institutional Grants – Agenus, Amgen, Arcus, BBOT, Exelixis, Gritstone, Hutchmed, J&J, Merck, Pfizer, Sumitomo

Learning Objectives

- Summarize the clinical evidence that has established chemo-IO as the new standard of care for SCAC
- Describe strategies for sequencing chemo-IO across the disease continuum (eg, induction, continuation, and relapse settings), in accordance with the latest data and clinical guidelines
- Evaluate key considerations for patient selection, monitoring, and management of adverse events when using chemo-IO in diverse clinical scenarios, including special populations and multidisciplinary care contexts

The Incidence of Anal Cancer

At a Glance

Estimated New Cases in 2025

% of All New Cancer Cases

0.5%

Estimated Deaths in 2025

2,030

% of All Cancer Deaths

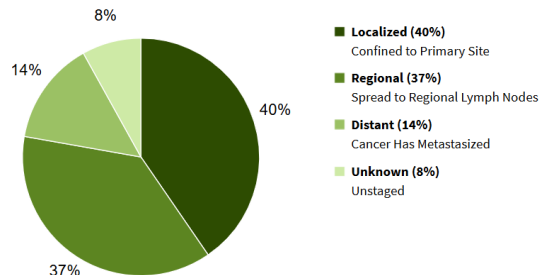
0.3%

2026:
11,270

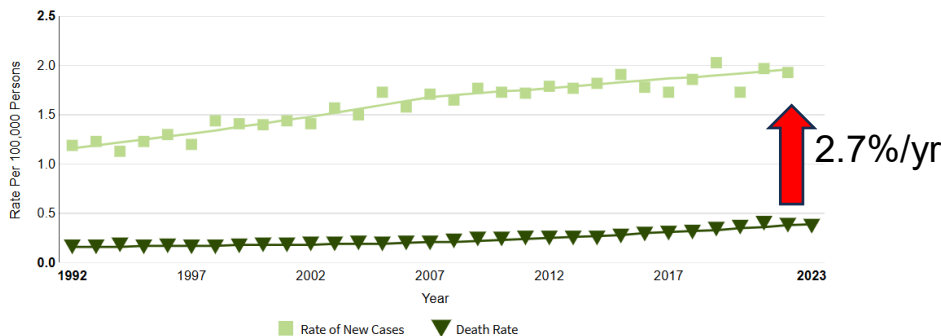
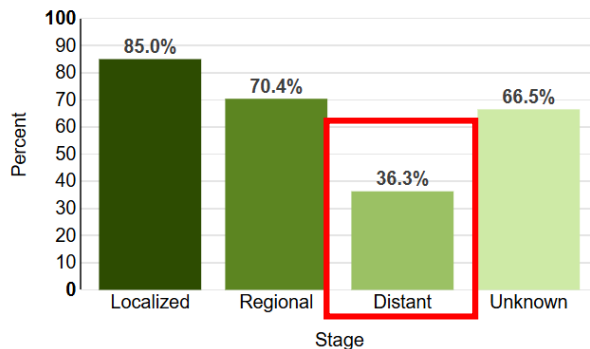
5-Year
Relative Survival
71.3%

2015–2021

Percent of Cases by Stage



5-Year Relative Survival



New cases come from SEER 12. Deaths come from U.S. Mortality.
All Races, Both Sexes. Rates are Age-Adjusted.

Surveillance, Epidemiology, and End Results (SEER). Accessed March 12, 2026. <https://seer.cancer.gov/statfacts/html/anus.html>. American Cancer Society. Updated January 13, 2026. Accessed March 12, 2026. <https://www.cancer.org/cancer/types/anal-cancer/what-is-key-statistics.html>. Siegel RL, et al. *CA Cancer J Clin*. 2026;76(2):e70067.

Global Incidence

International Agency for Research on Cancer



**GLOBAL CANCER
OBSERVATORY**

**CANCER
TODAY**

GLOBOCAN 2022



ANUS

Incidence

Rank	Cases	ASR (World)
30	54 306	0.54

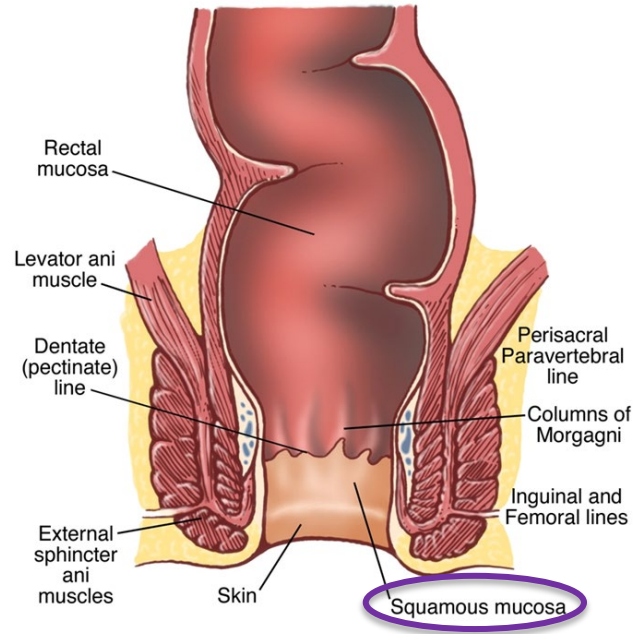
Mortality

Rank	Deaths	ASR (World)
30	22 035	0.21

Global Cancer Observatory. February 8, 2024. Accessed March 12, 2026.
<https://gco.iarc.who.int/media/globocan/factsheets/cancers/10-anus-fact-sheet.pdf>.

Anatomy and Risk Factors

Anatomy of the Anal Canal



Risk Factors for Anal CA

- >50 years of age
- >10 sexual partners
- HPV or other STD(s)
- Chronic immunosuppressed states
 - Pts with organ transplant, HIV/AIDS
 - *Not considered an AIDS-defining illness
- Receptive anal intercourse
- History of gynecological malignancies
- Tobacco use

HPV = human papillomavirus; STD = sexually transmitted disease.
Eng C, et al. *J Clin Oncol*. 2022;40(24):2774-2788.

Chlamydia, gonorrhea, and syphilis cases are all up from a decade ago.

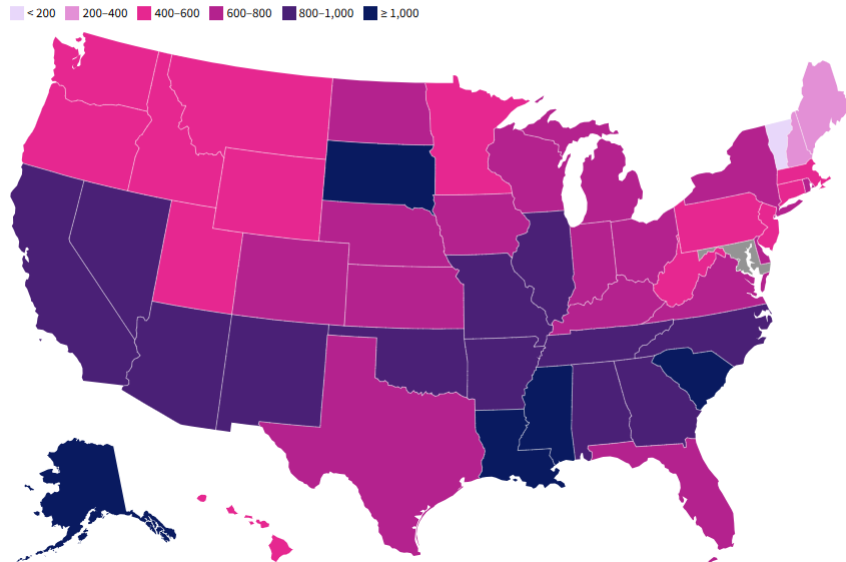
The chart displays the annual number of total syphilis, chlamydia, and gonorrhea cases in the United States from 2012 to 2021. The y-axis represents the number of cases, ranging from 0 to 1.8M. The x-axis represents the years. Chlamydia cases (dark blue line) are the highest, starting at approximately 1.4M in 2012, peaking at about 1.8M in 2019, and ending at approximately 1.65M in 2021. Gonorrhea cases (light blue line) start at about 350K in 2012 and rise steadily to approximately 700K in 2021. Syphilis cases (pink line) are the lowest, starting at about 50K in 2012 and increasing to approximately 180K in 2021.

Year	Total syphilis cases	Total chlamydia cases	Total gonorrhea cases
2012	~50K	~1.4M	~350K
2013	~60K	~1.4M	~330K
2014	~70K	~1.45M	~350K
2015	~80K	~1.55M	~400K
2016	~100K	~1.6M	~480K
2017	~120K	~1.75M	~550K
2018	~140K	~1.78M	~600K
2019	~160K	~1.8M	~620K
2020	~150K	~1.6M	~680K
2021	~180K	~1.65M	~700K

It's also worth noting that HIV data is collected in a separate CDC Surveillance Report. There were 36,136 cases reported in 2021.

Mississippi, Louisiana, Alaska, South Carolina, and South Dakota had the highest rates of reported STDs in 2021.

Cumulative reported STD rates for chlamydia, gonorrhea, and syphilis, per 100,00 people, 2021



USA Facts. Updated September 1, 2023. Accessed March 12, 2026. <https://usafacts.org/articles/how-common-are-stds-in-the-us/>.

HPV Vaccination/HIV/Tobacco Use and Risk

- HPV vaccination is underutilized in the catchment area
- TN and KY among the highest-risk states for HPV-related cancers, including anal cancer
- Expected continued rise in squamous cell carcinoma of the anal canal (SCCA) due to HIV/AIDS and tobacco abuse (2001-2005 vs 2014-2018)
 - Mortality (≥ 2 -fold) for persons age ≥ 50 years concentrated in the Midwestern and Southeastern states
 - Incidence
 - Men: TN, KY, and AL (RR: 1.53-1.92)
 - Women: TN (RR: 1.78)
 - Incidence rates correlate ($r=0.47$, $P<.001$) with AIDS and smoking ($r=0.49$, $P<.001$) prevalence patterns for men and women, respectively

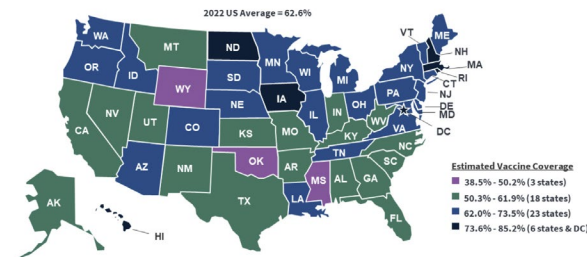
RR = rate ratio.

KFF. Updated October 8, 2024. Accessed March 12, 2026. <https://www.kff.org/womens-health-policy/fact-sheet/the-hpv-vaccine-access-and-use-in-the-u-s/>. Damgacioglu H, et al. *J Clin Oncol*. 2023;41(6):1228-1238.

Figure 3

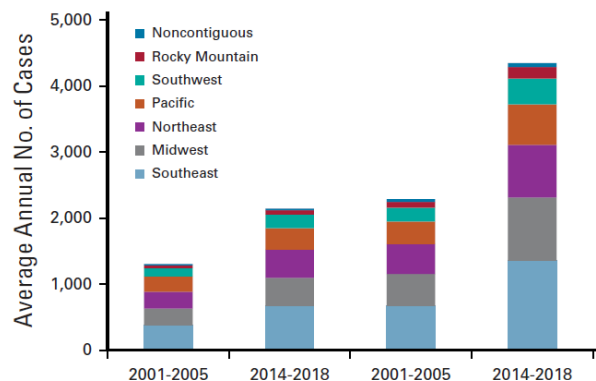
HPV Vaccination Rates of Adolescents by State

Adolescents Ages 13-17 with Up-to-Date (UTD) HPV Vaccination Series, 2022



NOTE: HPV UTD includes those with ≥ 3 doses, and those with 2 doses when the first HPV vaccine dose was initiated before age 15 years and there was at least 5 months minus 4 days between the first and second dose.
SOURCE: CDC, Vaccination Coverage Among Adolescents Age 13-17 Years - National Immunization Survey - Teen, United States, 2022. MMWR 72(34).

KFF



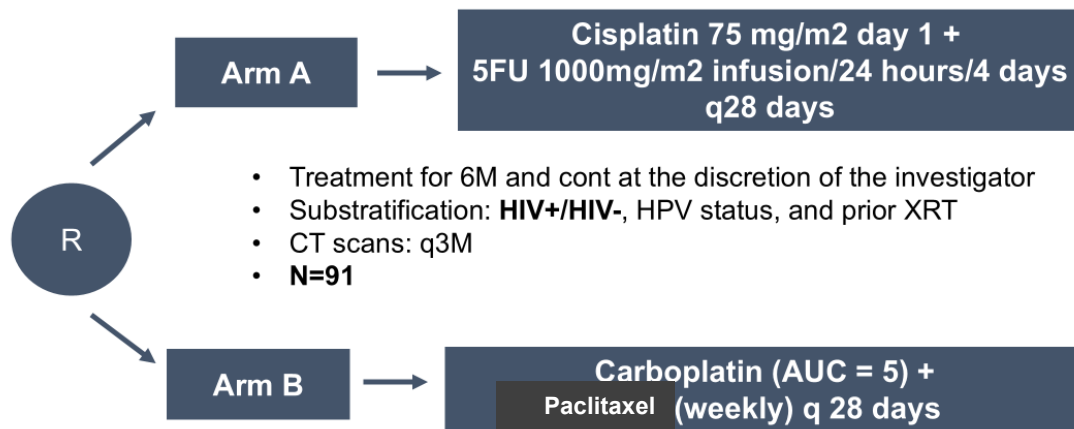
Historical Trials

Historical Cohorts in Metastatic SCCA

Author	N	Agents	ORR	Med PFS (months)	Med OS (months)
Wilking 1985	15	Vincristine, bleomycin & high-dose methotrexate	3/12 (25%)	2M	NR
Ajani 1989	3	5-FU/cisplatin	NA	17M (2 of 3)	NA
Faivre 1999	18	5-FU/cisplatin	65% (CR=15%)	4M	NA
Hainsworth 2001	60 (4 with anal cancer)	Docetaxel, cisplatin, 5-FU (TPF) (max = 4 cycles)	65% (CR = 25%)	26M	NR
Jhawer 2006	20	Mitomycin C, doxorubicin, cisplatin, bleomycin-lomustine	12/20 (60%)	8M	15
Alcindor 2008	5	Paclitaxel (1 st and 2 nd line)	60%	Range: 3-8M	Range: 4-20M
Abbas 2011	7	Paclitaxel (2 nd line)	57%	Range: 2-8M	Range: 5-14M
Kim 2013	8	Docetaxel, cisplatin, and 5-FU (DCF)	CR: 50% (3/4 resected)	19-88M	1 yr: 62.53M%
Eng, 2014 (retro)	77	Carboplatin/paclitaxel and 5-FU/cisplatin	33% - 57%	7M (5M vs. 16M)	22M (17M vs. 53M)
Kim, 2018	69	Phase II: Docetaxel, cisplatin, and 5-FU (DCF)	89%	11M	NR
Rogers, Eng (retro), 2020	56	Cetuximab or Panitumumab	41%	13.8M	16M
Morris, 2021	20	Atezolizumab + Bevacizumab	10%	4.1M	11.6M
*Gulley 2021	75 (9 anal CA)	Bintrafusp alfa (TGF- β + IO)	28% (Delayed 32%) for all pts [Anal CA: 1 PR + 1 CR (RR = 22%)]	3.2M	21.3M
*Lonardi, 2021	60	Phase II: Avelumab +/- cetuximab	10% vs. 17%	2.0M vs. 3.9M	13.9M vs. 7.8M

SCCA = squamous cell carcinoma of the anus; ORR = objective response rate; PFS = progression-free survival; OS = overall survival.

International Rare Cancers Initiative (IRCI)/ECOG EA2133 InterAACT: Tx-Naïve Met SCC of the Anal Canal



Objective: Identify best chemotherapy backbone for development

- 1) Primary endpoint: RR
- 2) Secondary endpoints: PFS, OS, correlatives, and QOL, etc.

Study PI's – S Rao, US PI: C Eng

FU = fluorouracil; XRT = external beam radiation therapy; AUC = area under the curve; RR = response rate; QOL = quality of life.

Rao S, et al. *J Clin Oncol*. 2020;38(22):2510-2518.

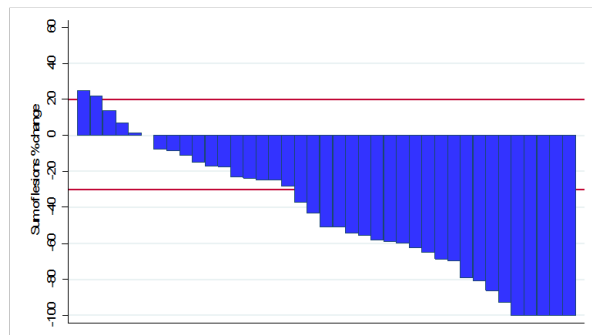
Primary Endpoint: InterAACT/EA2133

Response (RECIST)	Carboplatin-Paclitaxel		Cisplatin-5FU	
	N=39		N=35	
	N	(%) CI	N	(%)
CR	5	12.8	5	14.3
PR	18	46.2	15	42.9
SD	10	25.6	7	20.0
PD	6	15.4	8	22.9
CR/PR	23	59	20	57
		95% CI: [42.1-74.4]		95% CI: [39.4-73.7]

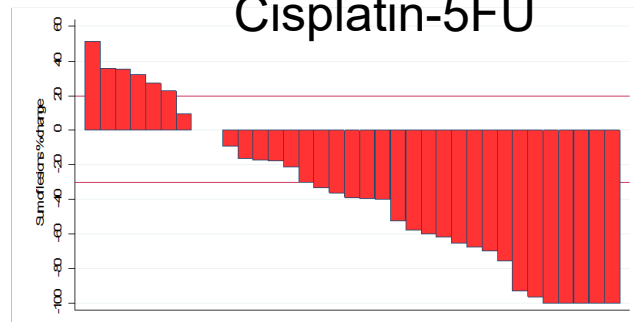
CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; CI = confidence interval.

Rao S, et al. *J Clin Oncol*. 2020;38(22):2510-2518.

Carboplatin-Paclitaxel

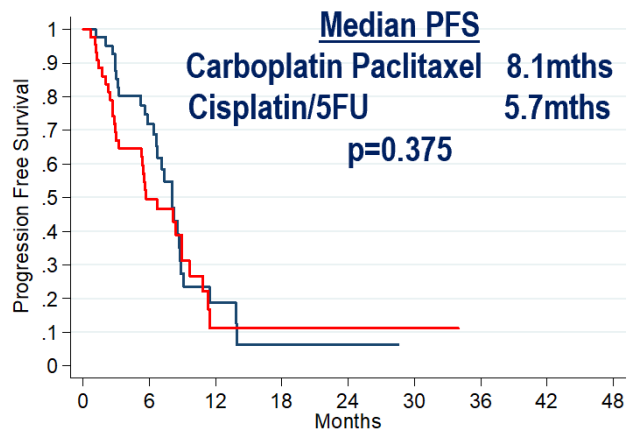


Cisplatin-5FU



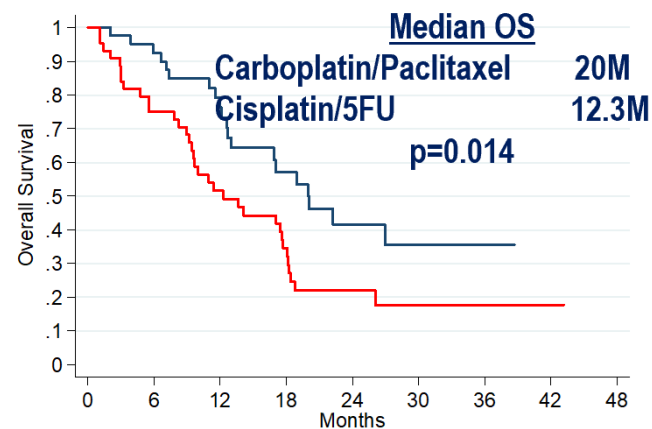
Secondary Endpoints: PFS and OS

Median follow-up of 25.3 M



Number at risk									
Carboplatin-Paclitax	45	25	3	1	1	0	0	0	0
Cisplatin-5FU	46	19	1	1	1	1	0	0	0

— Carboplatin-Paclitaxel — Cisplatin-5FU



Number at risk									
Carboplatin-Paclitax	45	36	27	16	9	4	2	0	0
Cisplatin-5FU	46	33	21	14	6	3	1	1	0

— Carboplatin-Paclitaxel — Cisplatin-5FU

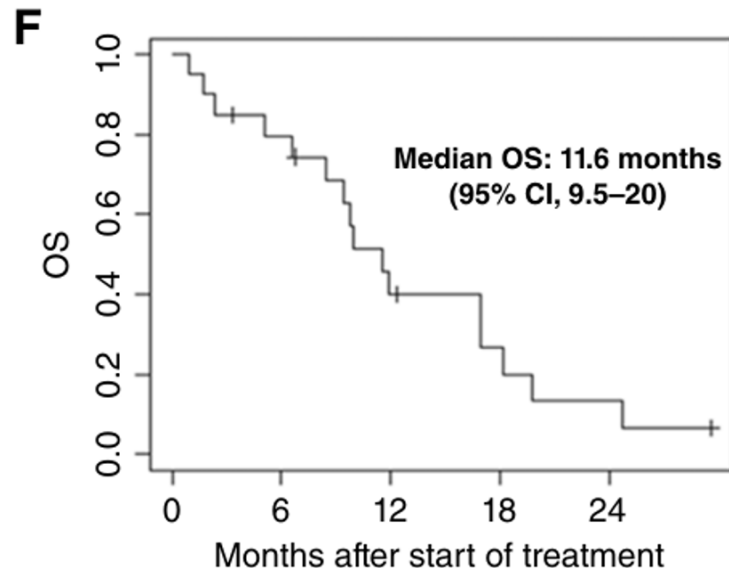
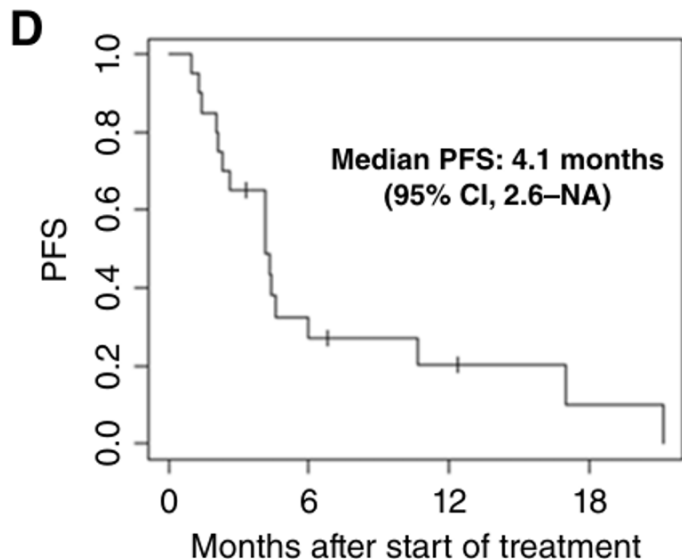
Role of Immunotherapy in Refractory Metastatic Anal Cancer

Drug	Phase	N	Dose	Primary endpoint	Secondary Endpoints
NCI9673: Nivolumab (Part A)	II	34	3 mg/kg IV q2 wks	ORR: 24% (2CR's)	PFS: 4.1M OS: 11.5M
Pembrolizumab (KN 158)	I/II	112	200 mg IV q3 wks	ORR:11% (No CR's)	PFS: 2.0M OS: 11.9M
Retifanlimab (POD1UM-202)	II	94	500 mg IV q 4 wks	ORR: 14% (1CR)	PFS: 2.3M OS:10.1M

Morris VK, et al. *Lancet Oncol.* 2017;18(4):446-453. Marabelle A, et al. *Lancet Gastroenterol Hepatol.* 2022;7(5):446-454. Rao S, et al. *Ann Oncol.* 2020;31(Suppl 4):S1170-S1171.

Recent Trial Results

Phase II Trial of Atezolizumab and Bevacizumab for the Treatment of HPV-Positive Unresectable or Metastatic Squamous Cell Carcinoma of the Anal Canal



NCI9673 (Part B): Randomized Phase II ETCTN Study of Nivolumab +/- Ipilimumab in Metastatic SCC of the Anal Canal

Patients with metastatic squamous cell carcinoma of the anal canal

- Treated with ≥ 1 prior therapy for metastatic disease
- No prior immune therapies received as part of cancer treatment

1:1

PI: C. Eng
Co-PI: V. Morris

Nivolumab
(480 mg IV q4 weeks)

Nivolumab + Ipilimumab
(1 mg/kg IV q8 weeks)

Primary endpoint: PFS

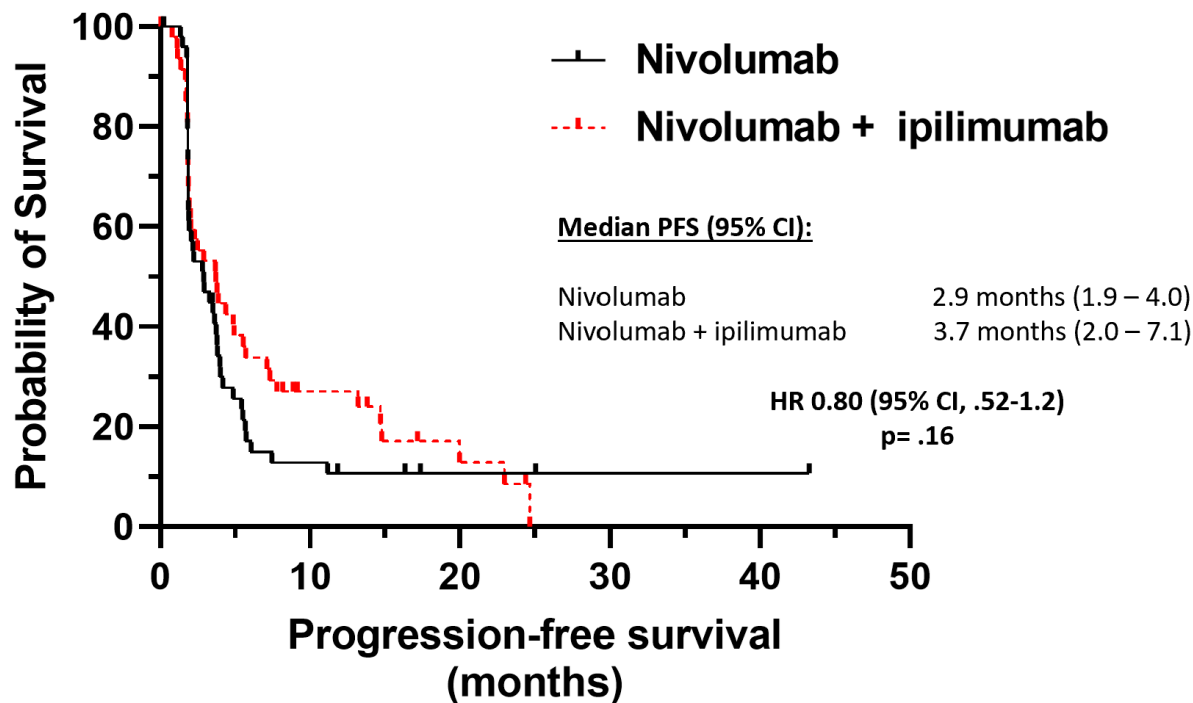
Secondary endpoints: OS, RR, and SAE's

Exploratory correlatives to be collected

SAE = serious adverse event.

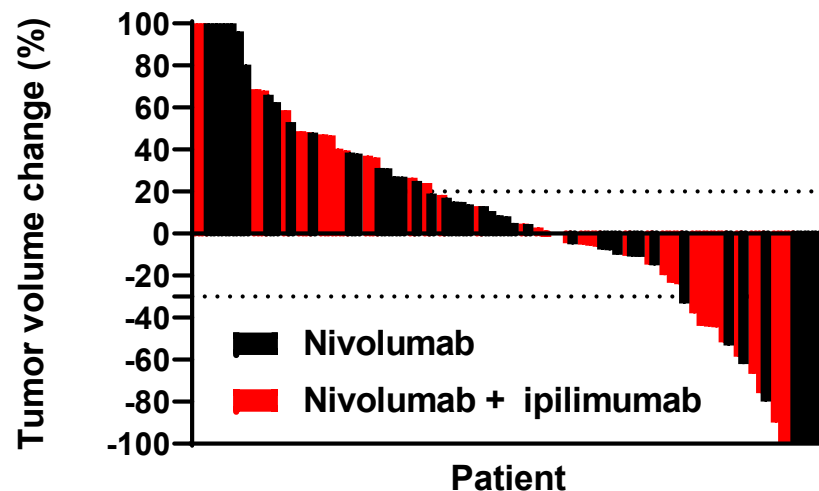
Morris VK...Eng C, et al. *J Clin Oncol.* 2026;44(6):497-507.

NCI 9673 Part B: Primary Endpoint



HR = hazard ratio.
Morris VK...Eng C, et al. *J Clin Oncol.* 2026;44(6):497-507.

NCI 9673 (Part B): ORR



- **Overall response rate (95% CI)**

Nivolumab

17.4% (9.1-31)

Nivolumab + ipilimumab

21.5% (12-36)

- **Disease control rate (95% CI)**

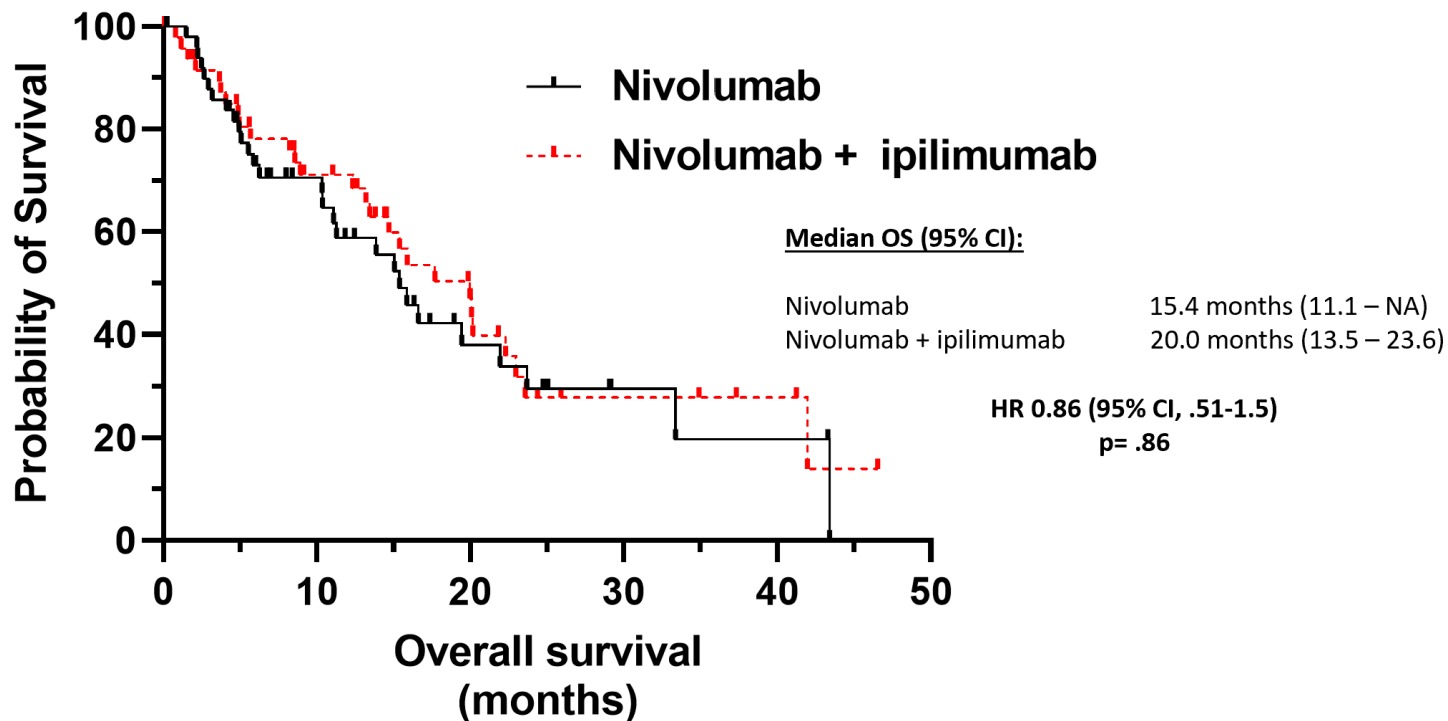
Nivolumab

43.5% (30-58)

Nivolumab + ipilimumab

47.6% (33-62)

NCI 9673 (Part B)



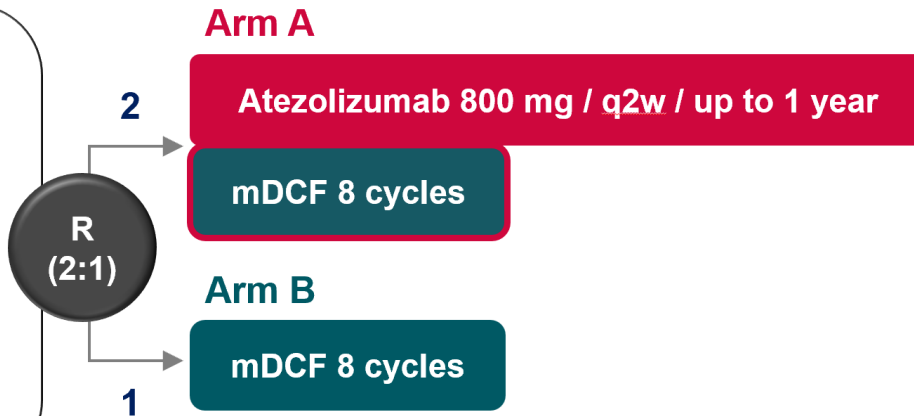
Chemo + IO Combination Therapy

SCARCE C17-02 PRODIGE 60

Study Design

Key eligibility criteria

- Advanced SCCA
 - Metastatic
 - Non-resectable local recurrence
- Treatment naïve
- Age ≥ 18 years
- ECOG PS 0-1
- Evaluable disease



Primary endpoint

- 1-year PFS rate by mITT

Secondary endpoints

- Median PFS
- OS
- ORR
- Safety
- HRQoL
- Biomarkers

Stratification: age (<65 vs ≥ 65 years), stage (synchronous metastatic vs metachronous metastatic vs locally advanced unresectable disease without metastasis)

ECOG PS = Eastern Cooperative Oncology Group Performance Status; mDCF = modified docetaxel, cisplatin, and fluorouracil; mITT = modified intention-to-treat; HRQoL = health-related quality of life.

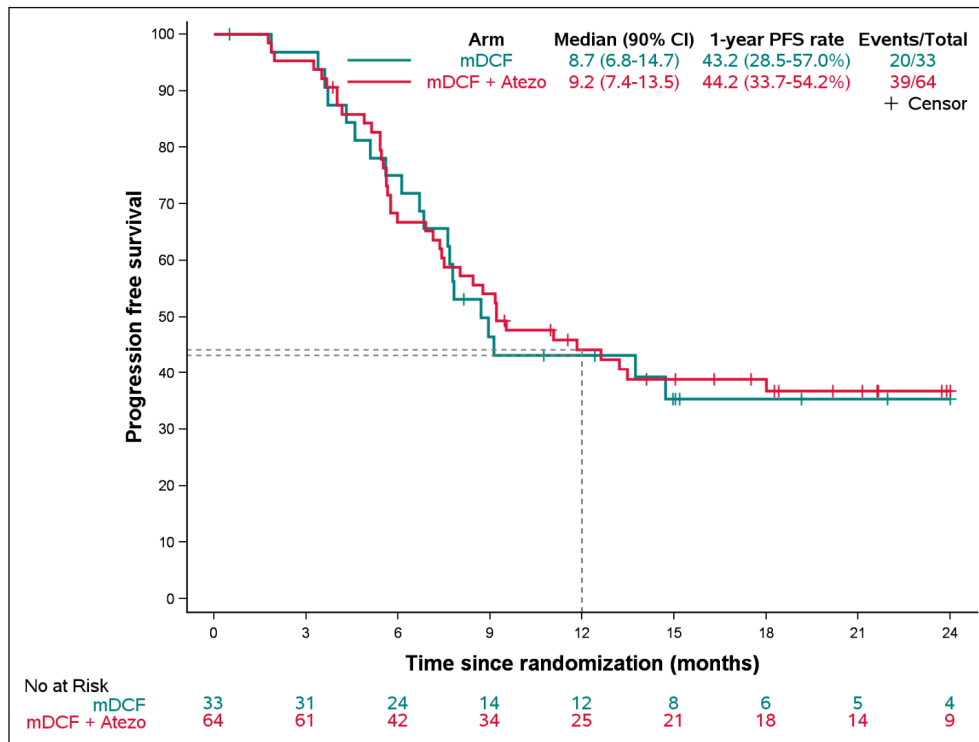
Kim S, et al. *Lancet Oncol.* 2024;25(4):518-528.

SCARCE C17-02 PRODIGE 60 Study Design



Arm A

1-year PFS rate: 44.2%
(90% CI 31.7-56.0)

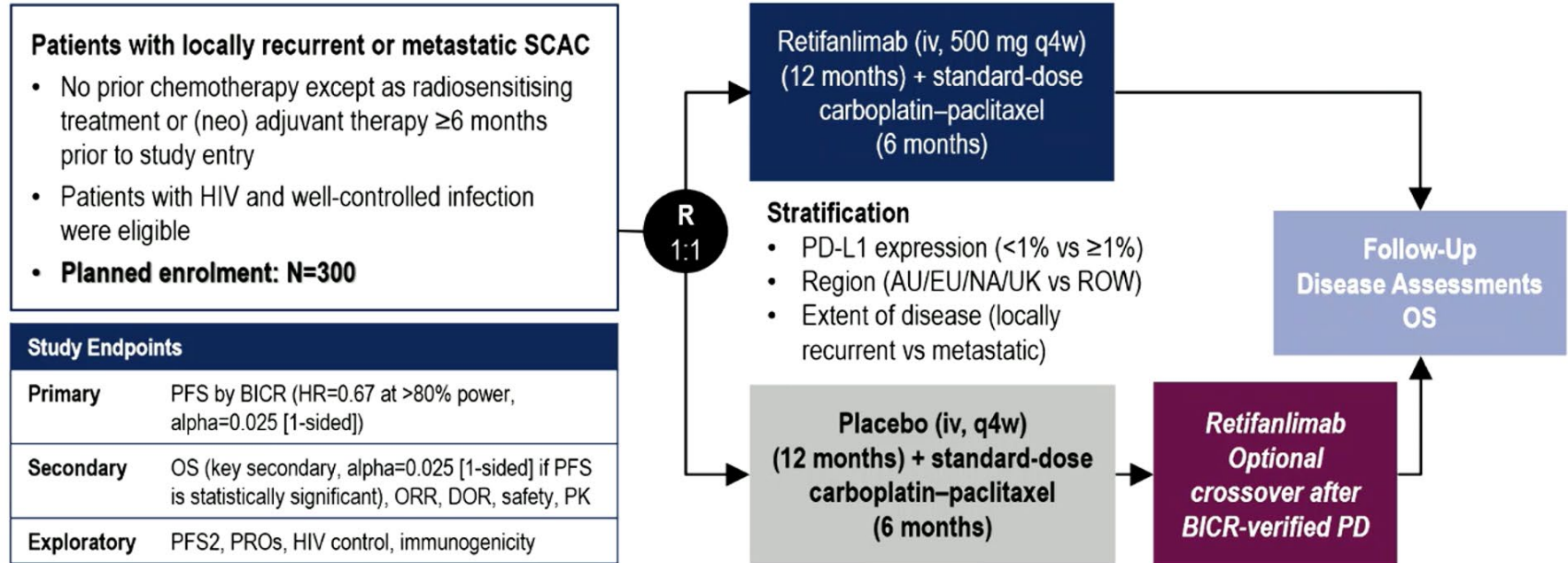


Arm B

1-year PFS rate: 43.2%
(90% CI 25.8-59.4)

Phase III: POD1UM-303

POD1UM-303/InterAACT-2 Study Design



BICR = blinded independent central review; DOR = duration of response; PK = pharmacokinetics; PROs = patient-reported outcomes.

Rao S, et al. *Lancet*. 2025;405(10495):2144-2152.

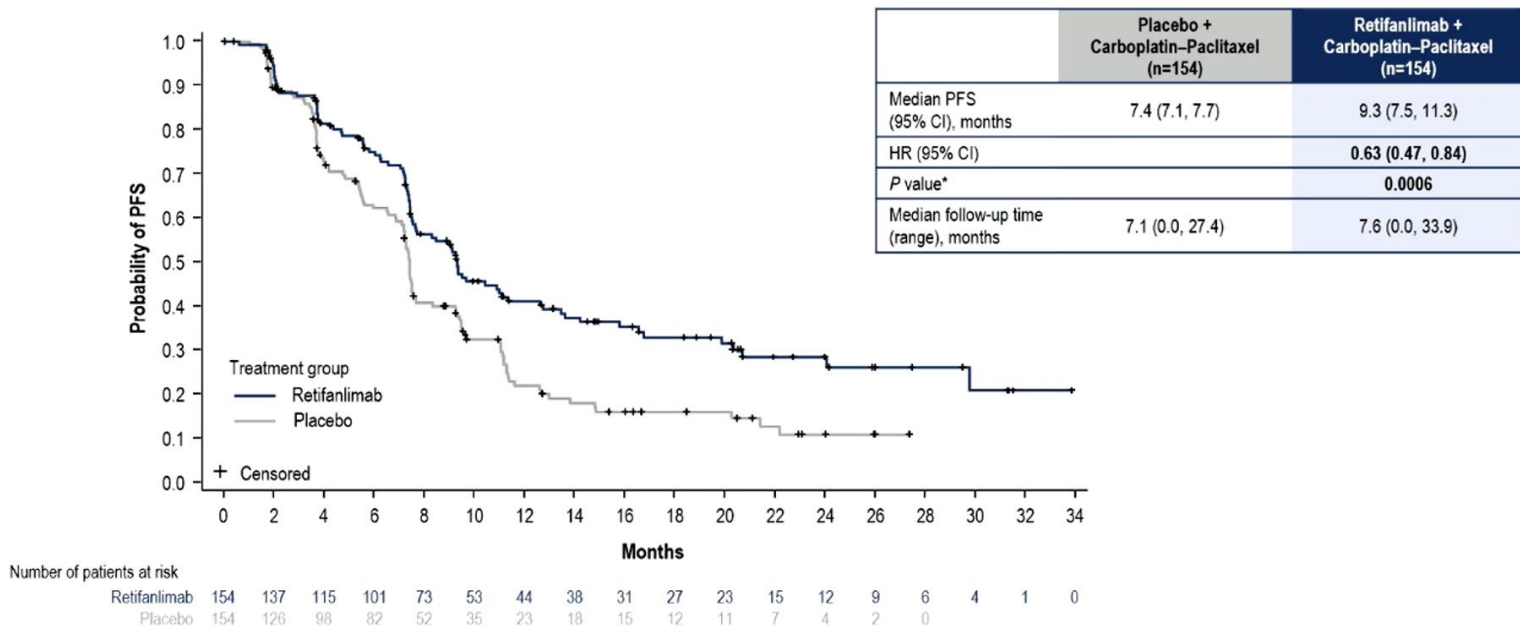
POD1UM-303: Demographics

	Retifanlimab plus carboplatin- paclitaxel (n=154)	Placebo plus carboplatin- paclitaxel (n=154)
Age, years	62 (29–86)	61 (35–84)
Sex		
Female	104 (68%)	118 (77%)
Male	50 (32%)	36 (23%)
Race		
White	132 (86%)	137 (89%)
Black or African American	3 (2%)	2 (1%)
Asian	10 (6%)	8 (5%)
Other	3 (2%)	2 (1%)
Geographical location		
Australia, the EU, North America, or the UK	146 (95%)	146 (95%)
Rest of the world	8 (5%)	8 (5%)
Previous radiotherapy	104 (68%)	113 (73%)
Locally recurrent disease	28 (18%)	27 (18%)
Metastatic disease*	126 (82%)	127 (82%)
Liver	55 (36%)	56 (36%)
ECOG PS 0	82 (53%)	86 (56%)
HIV positive	6 (4%)	5 (3%)
HPV status†		
Positive	29 (19%)	28 (18%)
Negative	3 (2%)	4 (3%)
Unknown or missing	122 (79%)	122 (79%)
P16 status‡		
Positive	76 (49%)	74 (48%)
Negative	16 (10%)	15 (10%)
Indeterminate or missing	62 (40%)	65 (42%)
PD-L1 expression status ≥1*§	139 (91%)	140 (91%)

Rao S, et al. *Lancet*. 2025;405(10495):2144-2152.



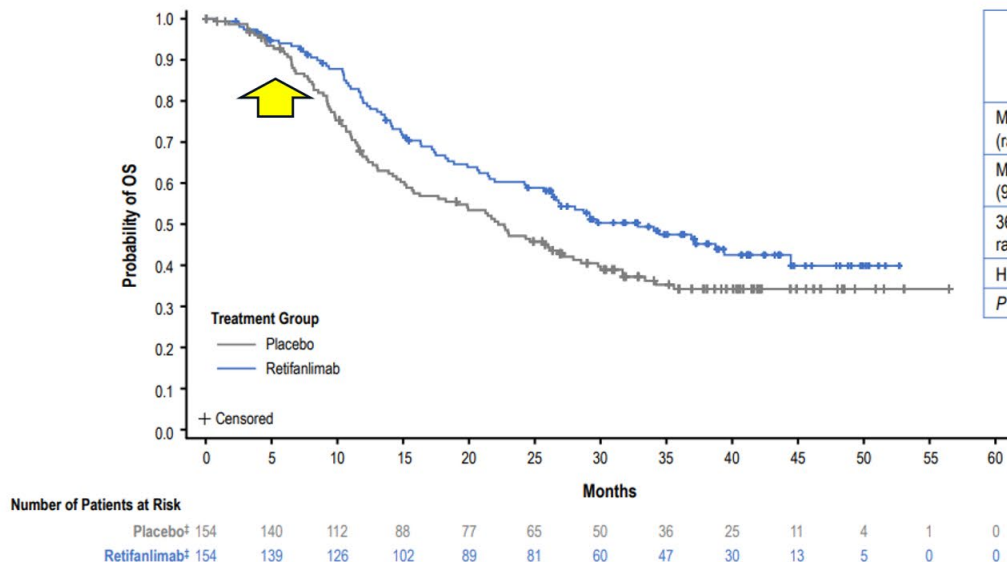
Primary Endpoint: PFS



POD1UM-303: Updated OS



OS (Key Secondary Endpoint)



	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
Median follow-up (range), months*	20.6 (0.0, 56.5)	26.3 (0.6, 52.7)
Median OS (95% CI), months	22.2 (15.7, 27.2)	32.8 (25.7, 44.5)
36-month OS rate (95% CI)	34.3 (26.4, 42.3)	47.5 (38.8, 55.6)
HR (95% CI)	0.75 (0.55, 1.01)	
P value [†]	0.0305	

POD1UM-303: ORR

	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
ORR (95% CI), %	44 (36, 52)	56 (48, 64)
CR, %	14	22 <i>P=0.0129†</i>
Median DOR (95% CI), months	7.2 (5.6, 9.3)	14.0 (8.6, 22.2)
DCR (95% CI), %	80 (73, 86)	87 (81, 92)

Safety Summary



Variable	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Median treatment duration, months	6.8	7.4	7.2
Patients with any TEAEs, n (%)	152 (100)	154 (100)	306 (100)
Patients with ≥ grade 3 TEAEs, n (%)	114 (75.0)	128 (83.1)	242 (79.1)
Patients with grade 5 TEAEs, n (%)	1 (0.7)*	4 (2.6)†	5 (1.6)
Patients with SAEs, n (%)	59 (38.8)	73 (47.4)	132 (43.1)
Treatment-related SAEs, n (%)	10 (6.6)	25 (16.2)	35 (11.4)
Immune-related AEs, n (%)	36 (23.7)	71 (46.1)	107 (35.0)
AEs leading to discontinuation, n (%)	4 (2.6)	17 (11.0)	21 (6.9)

- Safety of retifanlimab plus chemotherapy consistent with prior phase 2 data and known CPI literature in SCAC
- No loss of HIV control/viral load observed in patients with HIV
- At data cutoff, 90 patients (58.4%) in the retifanlimab arm remained on study

TEAEs = treatment-emergent adverse events.

Rao S, et al. Presented at: ESMO Immuno-Oncology Annual Congress; December 10-12, 2025; London, UK.

TEAEs

Most Common ($\geq 3\%$) Grade 3 or Higher TEAEs

MedRA Preferred Term	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Neutropenia	45 (29.6)	54 (35.1)	99 (32.4)
Anaemia	31 (20.4)	30 (19.5)	61 (19.9)
Neutrophil count decreased	13 (8.6)	26 (16.9)	39 (12.7)
White blood cell count decreased	13 (8.6)	14 (9.1)	27 (8.8)
Diarrhoea	9 (5.9)	8 (5.2)	17 (5.6)
Leukopenia	6 (3.9)	6 (3.9)	12 (3.9)
Asthenia	5 (3.3)	6 (3.9)	11 (3.6)
Sepsis	6 (3.9)	5 (3.2)	11 (3.6)
Pulmonary embolism	5 (3.3)	5 (3.2)	10 (3.3)
Vomiting	6 (3.9)	4 (2.6)	10 (3.3)

Most Common ($\geq 2\%$) Immune-Related TEAEs

MedRA Preferred Term	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Peripheral sensory neuropathy	15 (9.9)	17 (11.0)	32 (10.5)
Hypothyroidism	5 (3.3)	22 (14.3)	27 (8.8)
Hyperthyroidism	1 (0.7)	13 (8.4)	14 (4.6)
Pruritus	3 (2.0)	11 (7.1)	14 (4.6)
Adrenal insufficiency	0	8 (5.2)	8 (2.6)
Rash maculo-papular	3 (2.0)	3 (1.9)	6 (2.0)

Current National Comprehensive Cancer Network® (NCCN®) Guidelines (January 2026)



- CAPEOX⁶ *
 - Oxaliplatin 130 mg/m² IV Day 1
 - Capecitabine 1000 mg/m² twice Daily for 14 Days
 - Repeat every 3 Weeks
 - Carboplatin/Paclitaxel
 - Carboplatin AUC 5 IV Day 1
 - Paclitaxel 175 mg/m² IV Day 1
 - Repeat every 21 Days⁷
 - or
 - Carboplatin AUC 5 IV Day 1
 - Paclitaxel 80 mg/m² IV Days 1, 8, 15
 - Repeat every 28 Days⁸
 - FOLFICIS⁹
 - Cisplatin 40 mg/m² IV over 30 Minutes on Day 1*
 - Leucovorin 400 mg/m² IV Day 1*
 - Fluorouracil 400 mg/m² IV bolus Day 1, then 1000 mg/m²/day x 2 Days (total 2000 mg/m² over 46–48 Hours)
 - IV continuous infusion
 - Repeat every 2 Weeks

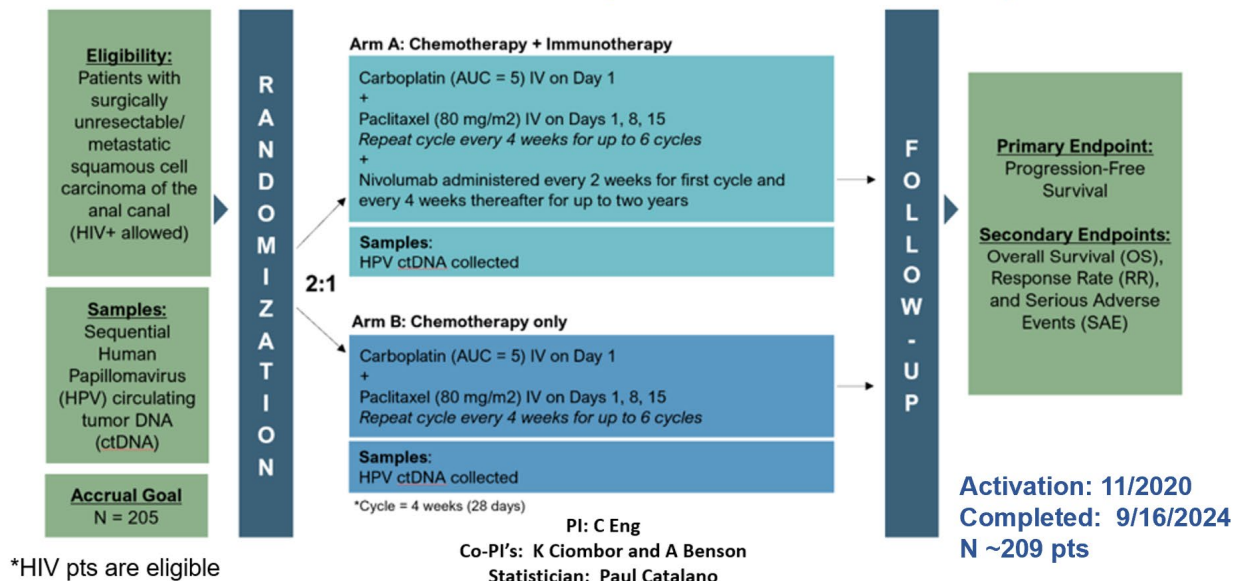
*Cisplatin and Leucovorin are given concurrently
 - FOLFOX¹⁰ *
 - Oxaliplatin 85 mg/m² IV Day 1
 - Leucovorin 400 mg/m² IV Day 1
 - Fluorouracil 400 mg/m² IV bolus Day 1, then 1200 mg/m²/day x 2 Days (total 2400 mg/m² over 46–48 Hours)
 - IV continuous infusion
 - Repeat every 2 Weeks
 - Carboplatin/Paclitaxel + Retifanlimab-dlwr¹³
 - Carboplatin AUC 5 IV Day 1
 - Paclitaxel 80 mg/m² IV Days 1, 8, and 15
 - Retifanlimab-dlwr 500 mg IV Day 1
 - Repeat every 28 Days for 6 cycles
 - Followed by Retifanlimab-dlwr 500 mg IV Day 1
 - Repeat every 28 Days for up to 7 cycles
 - Modified DCF¹⁴
 - Docetaxel 40 mg/m² IV Day 1
 - Cisplatin 40 mg/m² IV Day 1
 - Fluorouracil 1200 mg/m²/day x 2 Days (total 2400 mg/m² over 46–48 Hours)
 - Repeat every 2 Weeks
 - Cemiplimab-rwlc^{15,16} *
 - 350 mg IV Day 1
 - Repeat every 3 Weeks
 - Dostarlimab-gxly¹⁷
 - Dostarlimab-gxly 500 mg IV every 3 Weeks for 4 doses followed by 1000 mg IV every 6 Weeks
 - Nivolumab¹⁸
 - Nivolumab 240 mg IV every 2 Weeks
 - or Nivolumab 3 mg/kg IV every 2 Weeks
 - or Nivolumab 480 mg IV every 4 Weeks
 - or Nivolumab 6 mg/kg IV every 4 Weeks
 - Pembrolizumab¹⁹
 - Pembrolizumab 200 mg IV every 3 Weeks
 - or Pembrolizumab 2 mg/kg IV every 3 Weeks
 - or Pembrolizumab 400 mg IV every 6 Weeks
 - or Pembrolizumab 4 mg/kg IV every 6 Weeks
 - Retifanlimab-dlwr²¹
 - 500 mg IV Day 1
 - Repeat every 4 Weeks
 - Tislelizumab-jsgr²²⁻²⁵ *
 - 200 mg IV Day 1
 - Repeat every 3 Weeks
 - Toripalimab-tpzi²⁶ *
 - 3 mg/kg IV Day 1
 - Repeat every 2 Weeks
- Chemo/RT
- Fluorouracil + RT
 - Fluorouracil 225 mg/m² IV over 24 Hours (continuous infusion) daily on Days 1–5 or 1–7 for 5 Weeks with RT²⁷⁻²⁹
 - Capecitabine + RT
 - Capecitabine 825 mg/m² PO twice Daily Monday–Friday, on days of radiation treatment only, throughout the duration of RT (typically 28–30 treatment days)³⁰⁻³²

*Never tested in met anal cancer

Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Anal Carcinoma V.1.2026.
 © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed March 12, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

Pending Results

EA2176: Phase 3 Clinical Trial of Carboplatin and Paclitaxel +/- Nivolumab in Treatment-Naïve Metastatic Anal Cancer Patients (NCT04444921)



Bifunctional EGFR/TGF- β Inhibitor Ficerafusp Alfa (BCA-101) with Pembrolizumab

Figure 2. Waterfall Plot of Best Overall Response to Therapy (Investigator Assessed According to RECIST 1.1) and Color Coded by Liver Metastases Status (Efficacy-Evaluable Set; n=27)

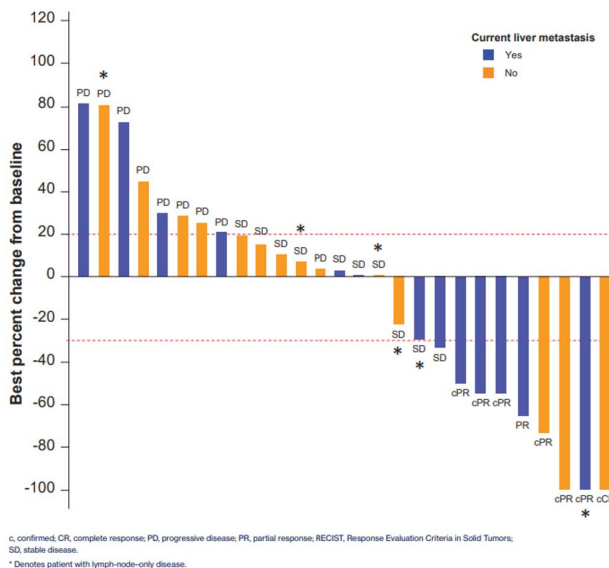
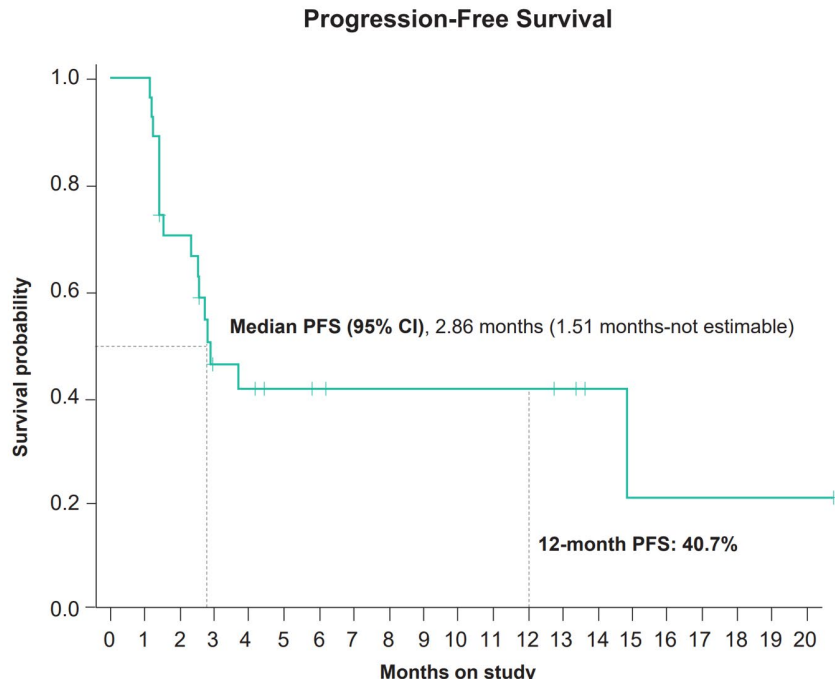


Figure 5. Progression-Free Survival (Efficacy-Evaluable Set; n=27)



Ongoing Trials in the US

	MOA	Phase	NCT #
SMP-3124LP	CHK-1	I	NCT06526819
TROP2 ADC LCB84	Trop-2	I	NCT05941507

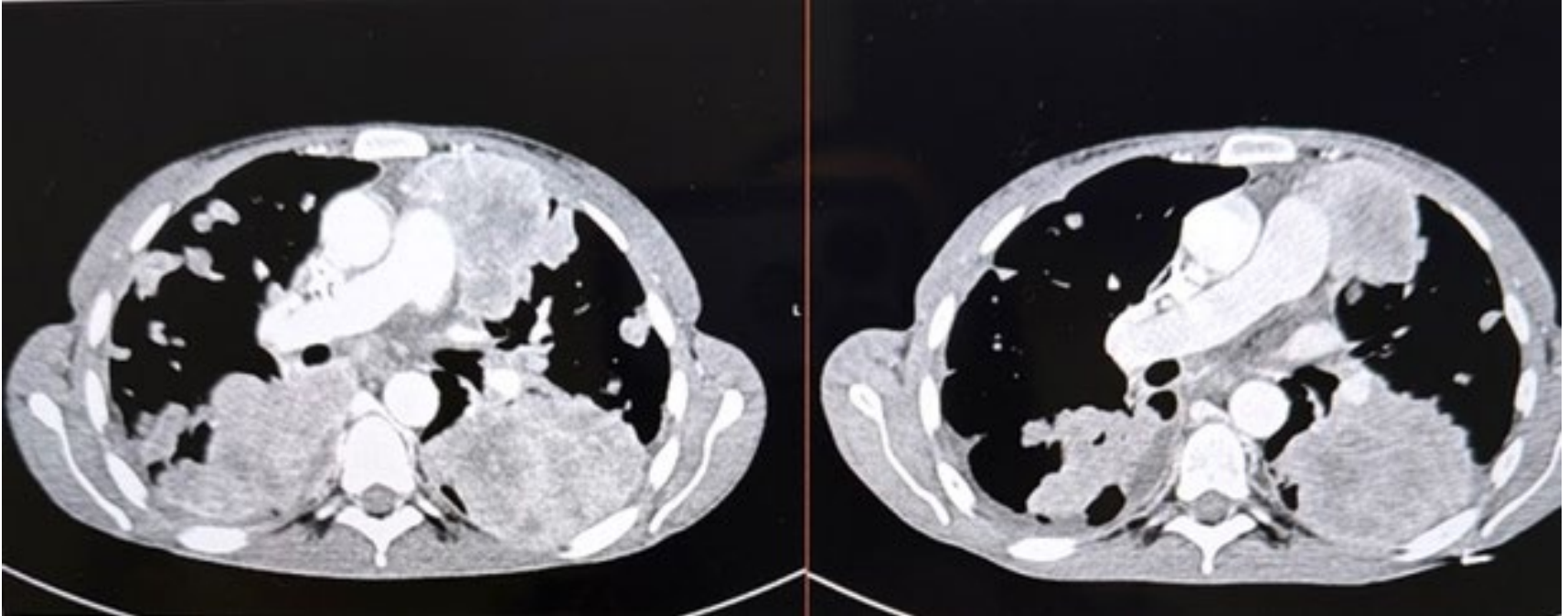
Of 84 currently enrolling trials, only 2 actively enrolling phase I trials in the US

MOA = mechanism of action.

ClinicalTrials.gov. Accessed March 12, 2026. <https://clinicaltrials.gov/study/NCT06526819>;

<https://clinicaltrials.gov/study/NCT05941507>.

Unmet Need: Phase I Trial with a Focus on SCCA



Courtesy of Eng C.

Education Session

Updates on Management of Anal Cancer: A New Era Has Begun

Gastrointestinal Cancer—Colorectal and Anal

🕒 Jun 1st 1:15 - 2:30 PM CDT

📍 E451 | On Demand

Jun 1st 1:30 - 1:45 PM CDT

Treatment Beyond First-Line Chemoimmunotherapy for Metastatic Anal Cancer

Van K. Morris, MD

Jun 1st 1:15 - 1:30 PM CDT

Latest Options for First-Line Treatment for Metastatic Anal Cancer

Sheela Rao, MD, MBBS

Jun 1st 1:45 - 2:00 PM CDT

Current Landscape of Curative-Intent Anal Cancer Management

Cathy Eng, MD, FACP, FASCO



Key Learning Points

- Combined chemotherapy + IO therapy is the standard of care for tx-naïve met anal Ca
 - Combined IO therapy was NS
- Continued cancer research in refractory met anal CA is an unmet need
- ALWAYS enroll to a clinical trial whenever possible to make greater and faster advances in a rare cancer