Practical Management Pearls for Immunotherapy for the Treatment of Lung Cancer and Mesothelioma

August 23, 2022

12:30 – 1:30 p.m. ET

sitc Society for Immunotherapy of Cancer
Cancer Immunotherapy GUIDELINES

AMGEN MERCK

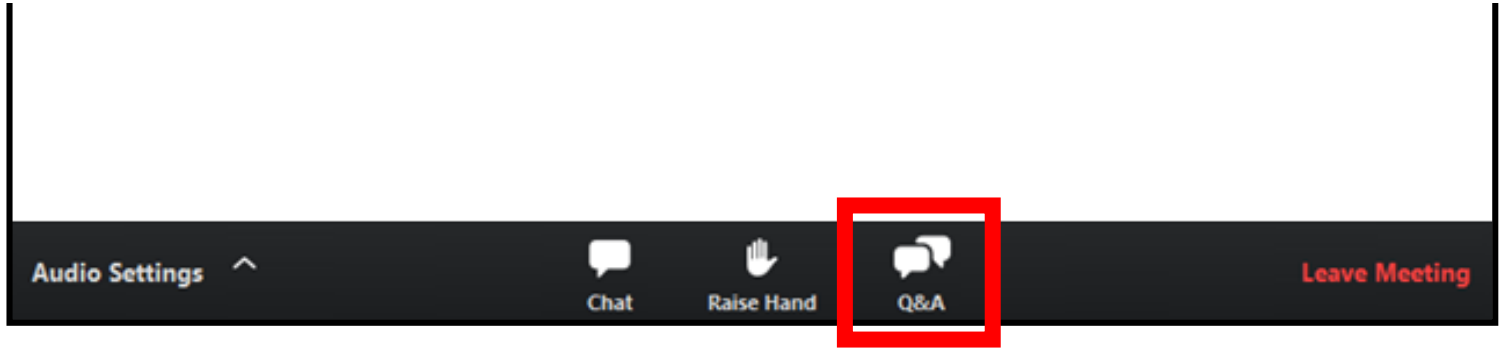
The Practical Management Pearls and Case Studies Webinars are part of the Cancer Immunotherapy Clinical Practice Guidelines Advanced Webinar Series supported, in part, by grants from Amgen and Merck & Co., Inc. (as of 9/15/2021)

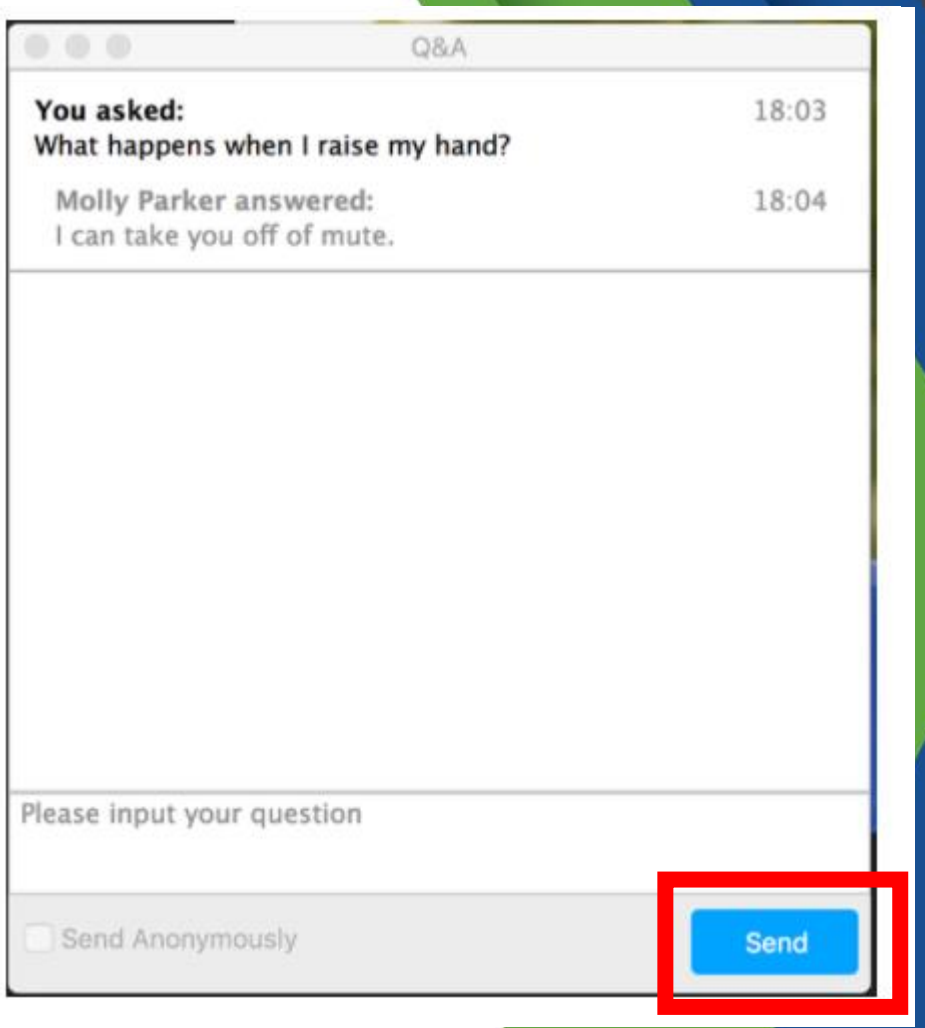
Webinar Agenda

12:30 - 12:35 p.m. ET	Overview: Welcome and Introductions
12:35 - 1:15 p.m. ET	Presentation and Discussion
1:15 - 1:25 p.m. ET	Question and Answer Session
1:25 - 1:30 p.m. ET	Closing Remarks

How to Submit Questions

- Click the “Q&A” icon located on at the bottom of your Zoom control panel
- Type your question in the Q&A box, then click “Send”
- Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)





Webinar faculty

Moderator: Ramaswamy Govindan, MD
Expert Panel Chair
Washington University School of Medicine

Sarah B. Goldberg, MD, MPH
Expert Panel Member
Yale Cancer Center

Jyoti D. Patel, MD
Expert Panel Member
Northwestern University

Learning objectives

- Outline practical considerations for diagnostic testing and classification in Lung Cancer and Mesothelioma and the implications for immunotherapy treatment planning
- Appropriately manage challenging and/or uncommon toxicities/irAEs associated with immunotherapy in Lung Cancer and Mesothelioma
- Determine optimal sequencing of immunotherapies in all stages of Lung Cancer and Mesothelioma treatment, including treatment for persistent or relapsed/refractory disease after initial therapy

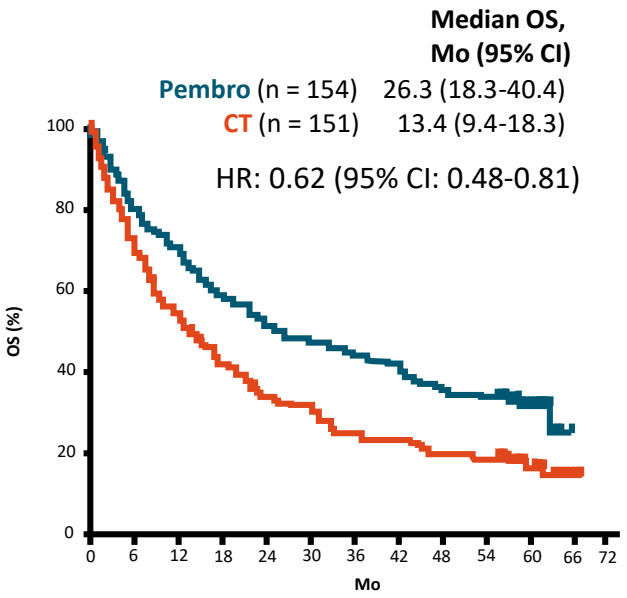
Poll question

What is your preferred regimen for 1st line treatment of advanced non-squamous NSCLC with PD-L1 1-49%?

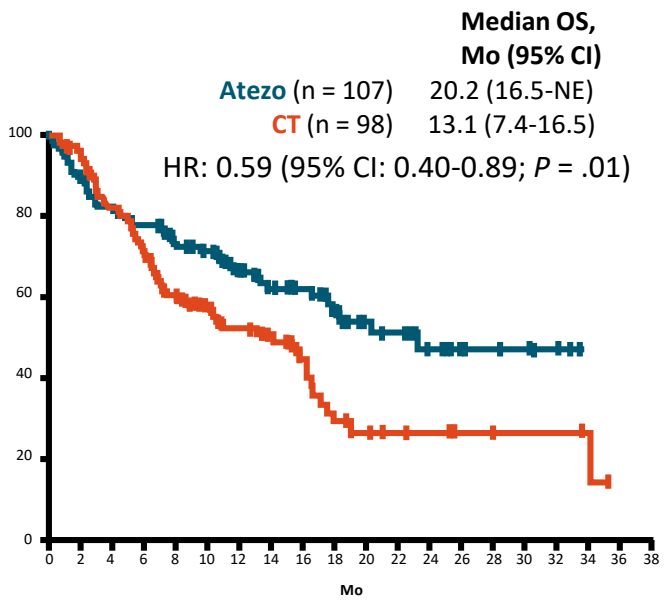
A. Pembrolizumab
B. Carboplatin/pemetrexed/pembrolizumab
C. Nivolumab/ipilimumab
D. Carboplatin/pemetrexed/nivolumab/ipilimumab
E. Carboplatin/paclitaxel/atezolizumab/bevacizumab

Single-agent PD-(L)1 inhibitor therapy for advanced NSCLC with PD-L1 ≥ 50%

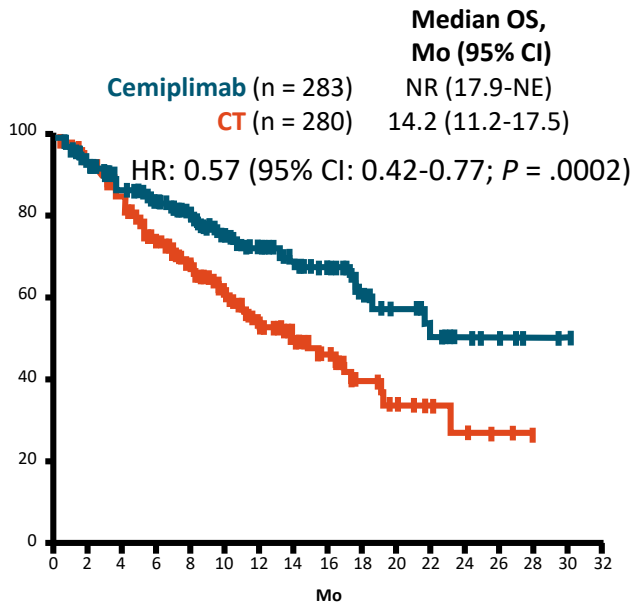
Pembrolizumab (KEYNOTE-024)



Atezolizumab (IMpower110)



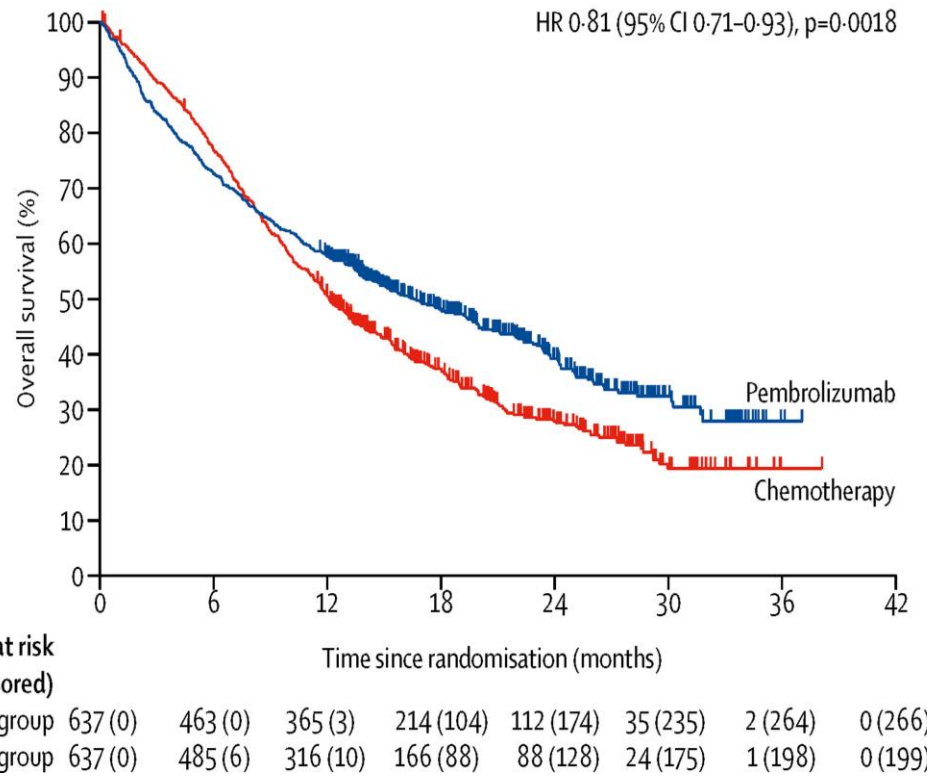
Cemiplimab (EMPOWER-Lung 1)



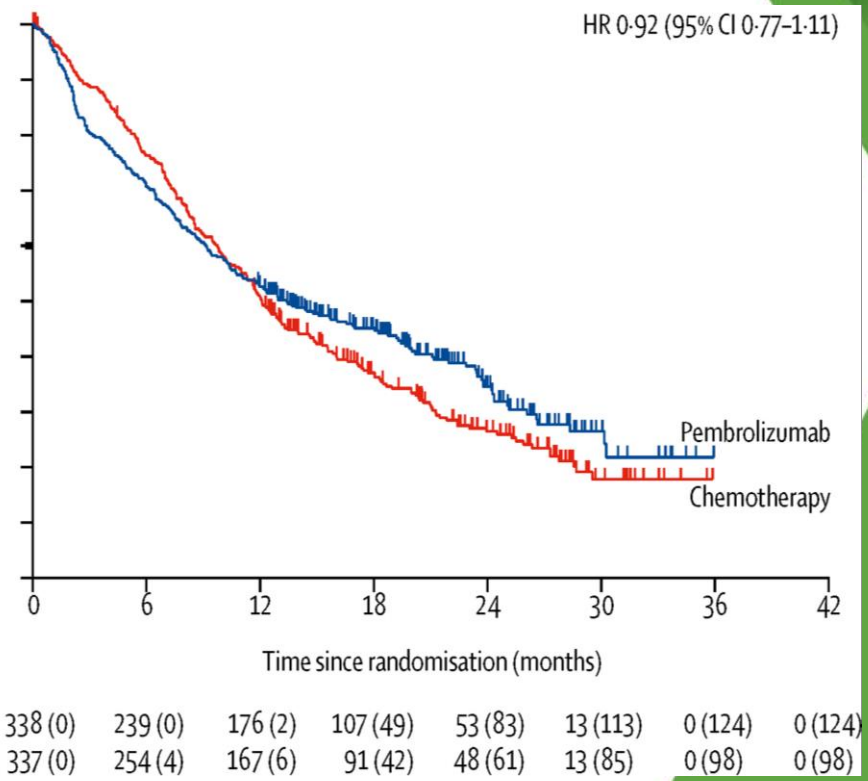
Reck. JCO. 2021;39:2339.
Herbst. NEJM. 2020;383:1328.
Sezer. Lancet. 2021;397:592.
Mok. Lancet. 2019;393:1819.
Cho. WCLC 2020. Abstr FP13.04.

Pembrolizumab for advanced NSCLC with PD-L1 ≥ 1%

Tumor PD-L1 1%-49%
(Exploratory Analysis)



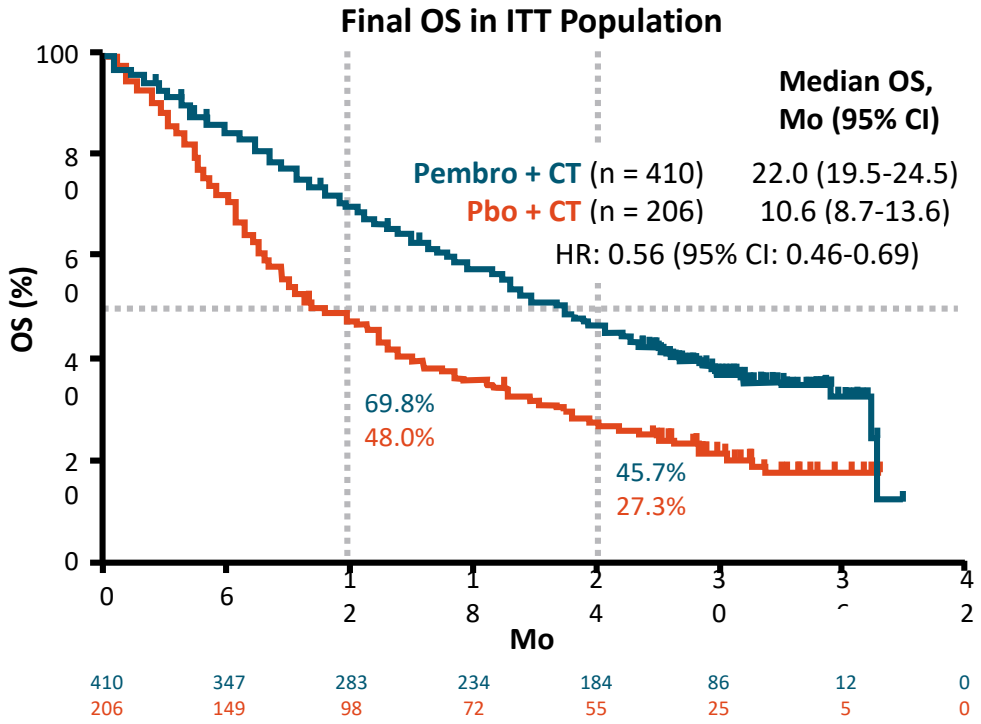
Number at risk (censored)								
Pembrolizumab group	637 (0)	463 (0)	365 (3)	214 (104)	112 (174)	35 (235)	2 (264)	0 (266)
Chemotherapy group	637 (0)	485 (6)	316 (10)	166 (88)	88 (128)	24 (175)	1 (198)	0 (199)

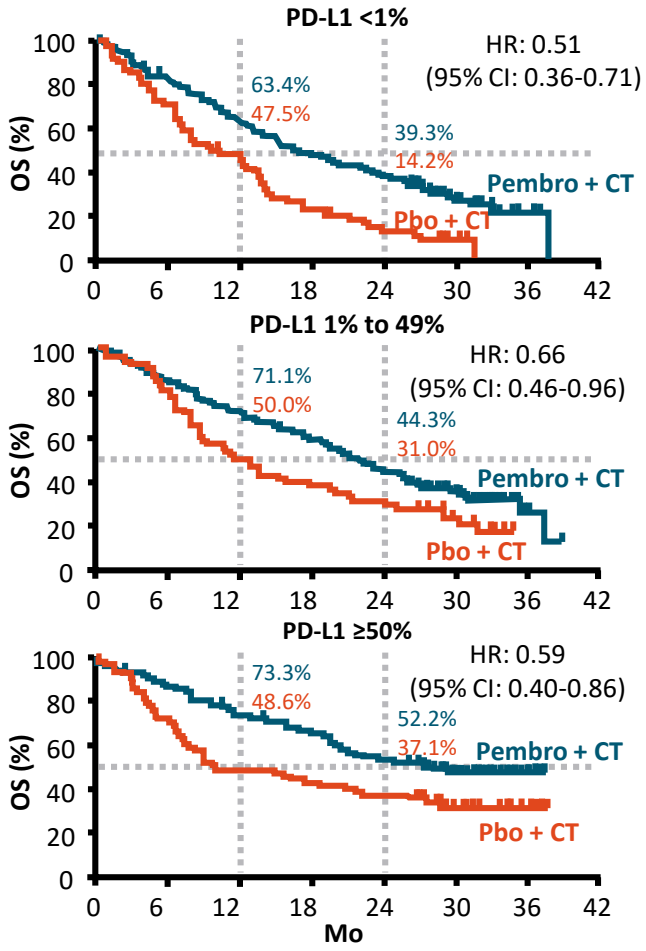


	338 (0)	239 (0)	176 (2)	107 (49)	53 (83)	13 (113)	0 (124)	0 (124)
	337 (0)	254 (4)	167 (6)	91 (42)	48 (61)	13 (85)	0 (98)	0 (98)

Mok TSK, et al. Lancet 2019

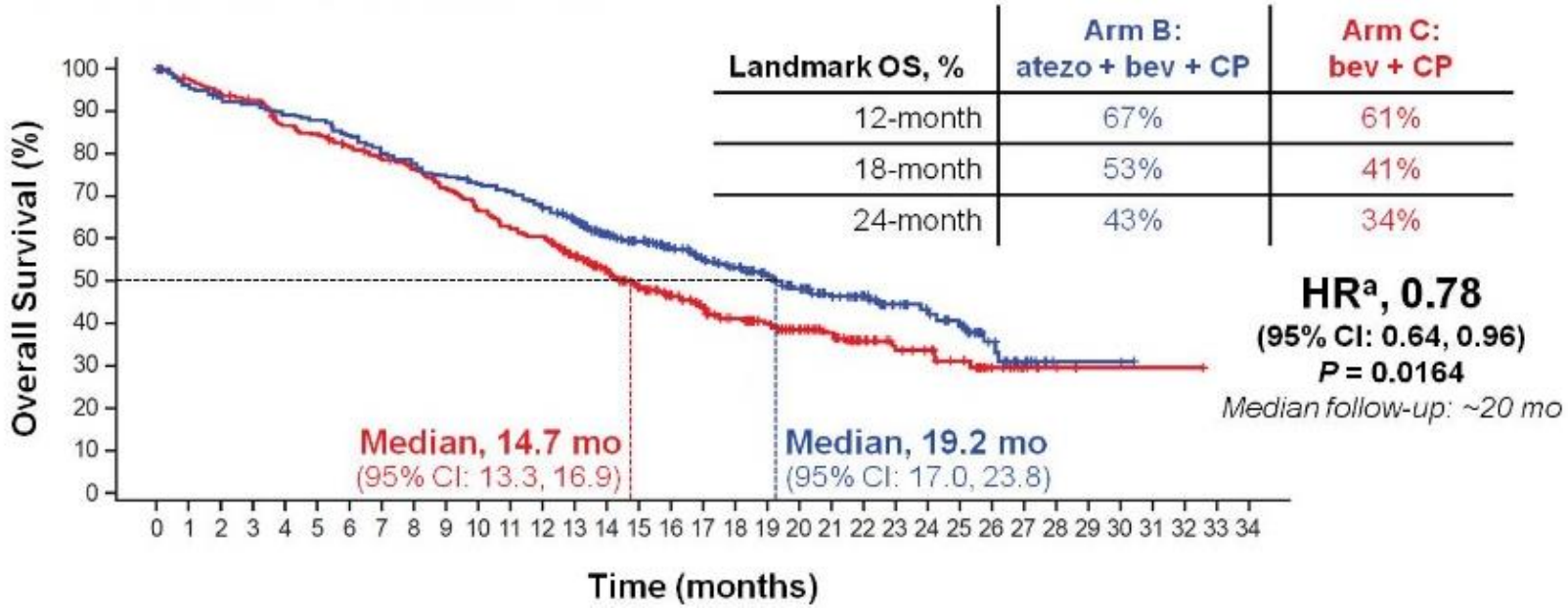
Pembrolizumab plus chemotherapy for advanced non-squamous NSCLC





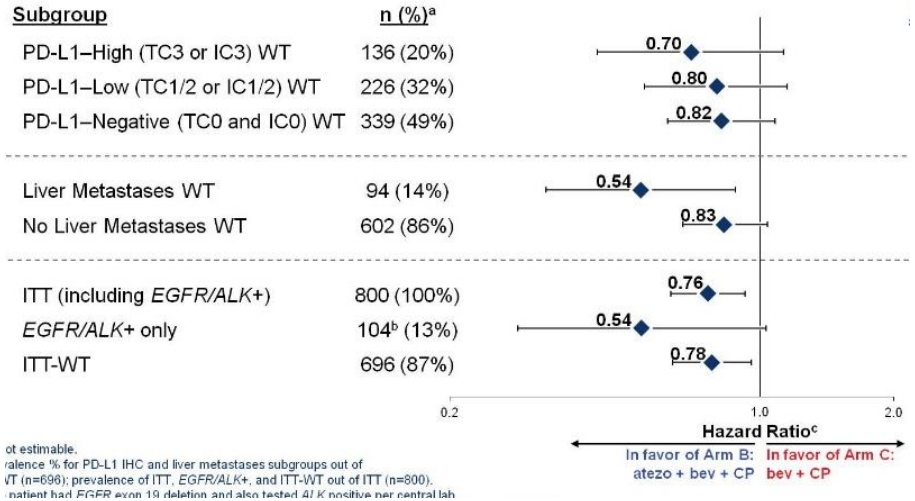
Rodríguez-Abreu. Ann Oncol. 2021;32:881.

Chemo/IO/VEGF inhibition for advanced non-squamous NSCLC



Landmark OS, %	Arm B: atezo + bev + CP	Arm C: bev + CP
12-month	67%	61%
18-month	53%	41%
24-month	43%	34%

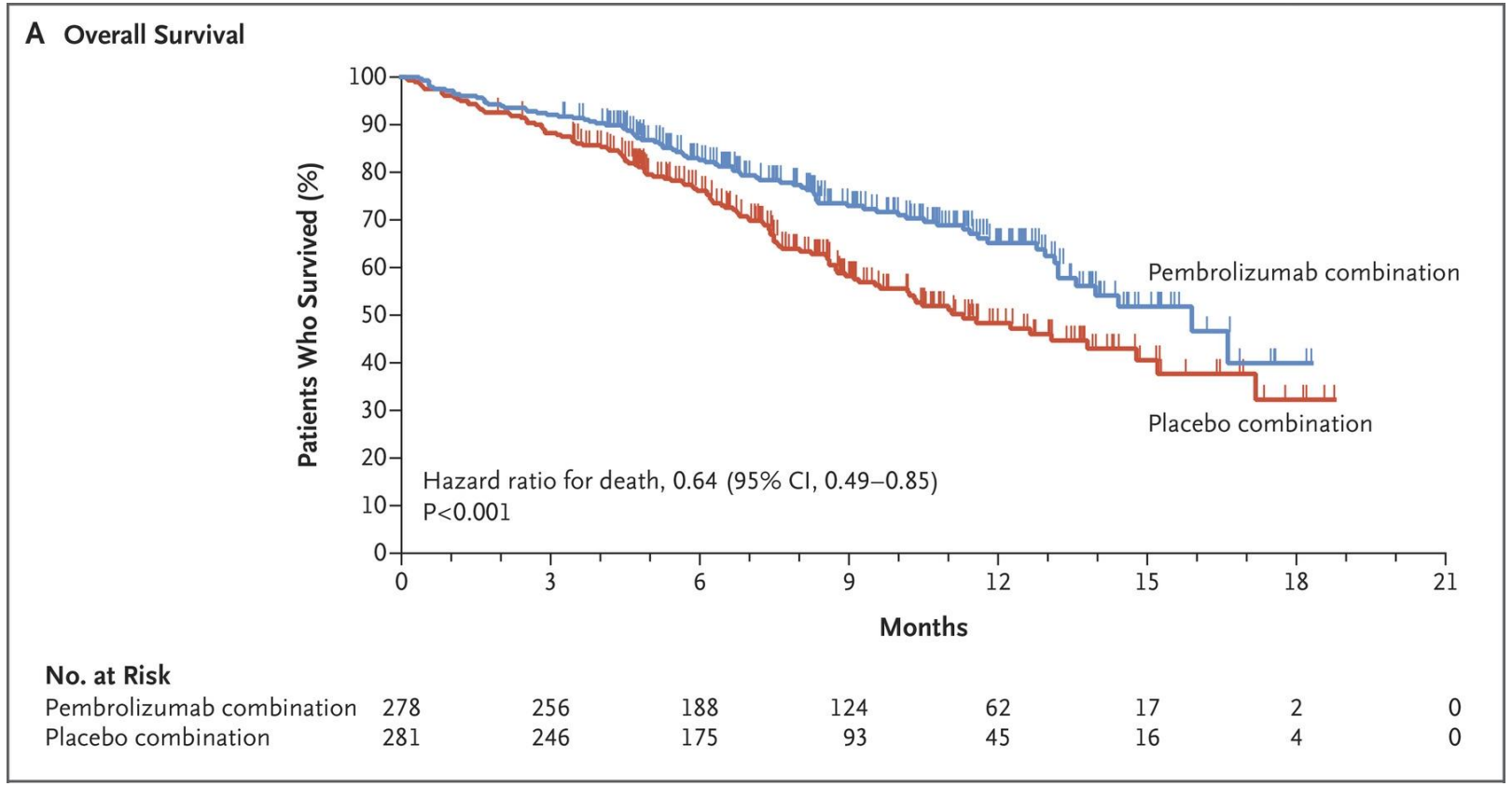
HR[a], 0.78
(95% CI: 0.64, 0.96)
***P* = 0.0164**
Median follow-up: ~20 mo



ot estimable.
valence % for PD-L1 IHC and liver metastases subgroups out of
/T (n=696); prevalence of ITT, *EGFR/ALK*+, and ITT-WT out of ITT (n=800).
patient had *EGFR* exon 19 deletion and also tested *ALK* positive per central lab

Socinski et al, NEJM 2018

Pembrolizumab plus chemotherapy for advanced squamous NSCLC



Paz-Ares et al, N Engl J Med 2018.

Pooled analysis of PD-(L)1 therapy +/- chemo in advanced NSCLC with PD-L1 ≥ 50%

	Chemo-IO	IO-only	
OS (median)	25.0 mos	20.9 mos	HR 0.82 (0.62, 1.08)
PFS (median)	9.6 mos	7.1 mos	HR 0.69 (0.55, 0.87)
ORR	61%	45%	OR 1.2 (1.1, 1.3)

	Subgroup	N[1]	OS		PFS		ORR	
			Median, months	HR (95% CI)	Median, months	HR (95% CI)	%	Odds ratio (95% CI)
Age, years	<65	898	25.0 vs 23.3	0.67 (0.46, 0.99)	9.4 vs 7.7	0.54 (0.39, 0.75)	62 vs 43	2.2 (1.3, 3.7)
	65-74	642	22.2 vs 18.6	0.83 (0.54, 1.28)	9.7 vs 6.8	0.80 (0.56, 1.13)	62 vs 43	1.9 (1.1, 3.4)
	≥75	185	NE vs 18.9	1.68 (0.69, 4.06)	11.8 vs 7.2	1.22 (0.58, 2.57)	52 vs 45	1.2 (0.4, 3.8)
ECOG	0	602	NE vs 31.8	0.70 (0.40, 1.21)	13.7 vs 8.5	0.61 (0.40, 0.92)	66 vs 47	2.6 (1.5, 4.7)
	1+	1148	17.7 vs 18.0	0.87 (0.64, 1.19)	8.2 vs 6.3	0.75 (0.57, 0.98)	58 vs 41	1.7 (1.1, 2.6)
Smoking	Never	197	NE vs 14.4	0.39 (0.15, 0.98)	10.2 vs 3.7	0.46 (0.23, 0.92)	69 vs 28	4.6 (1.5, 14.5)
	Ever	1549	23.0 vs 22.1	0.92 (0.69, 1.22)	9.3 vs 8.2	0.75 (0.59, 0.95)	60 vs 45	1.7 (1.2, 2.5)

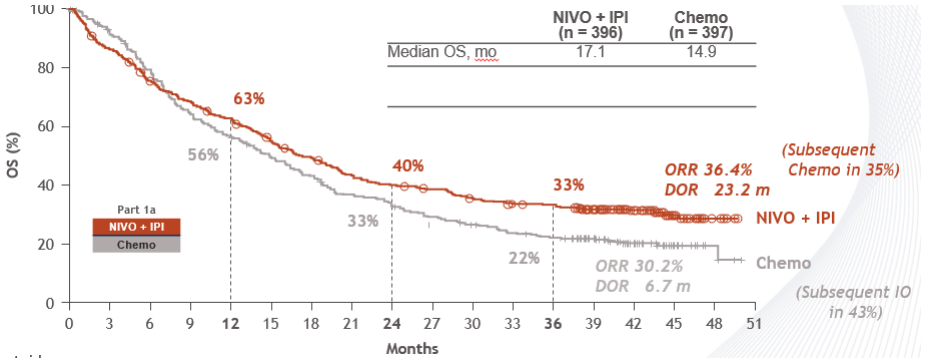
[1] Patients in the pooled chemo-IO and IO-only arms.

Akinboro O, et al. ASCO 2022.

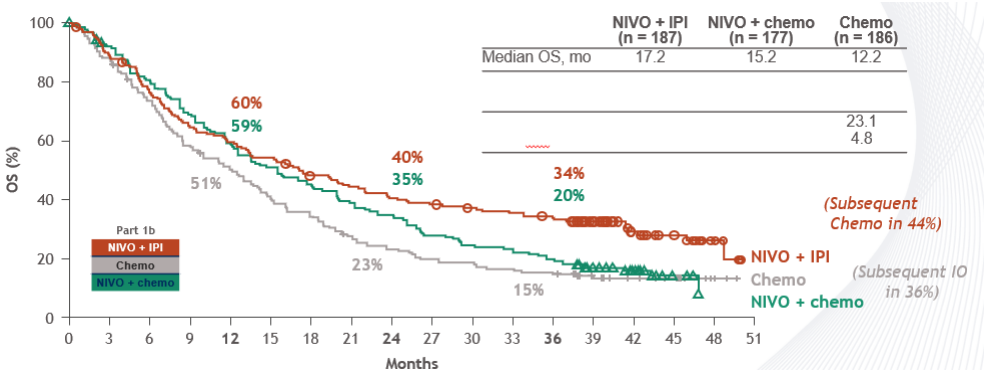
Combination immunotherapy for advanced NSCLC

Nivo/Ipi (Checkmate-227)

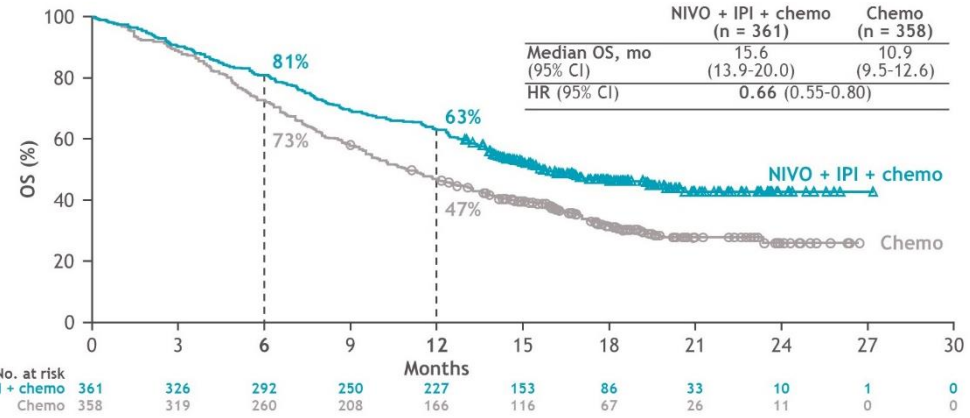
PD-L1 ≥ 1%



PD-L1 < 1%



Nivo/Ipi/Chemo (Checkmate-9LA)



Ramalingham et al, ASCO 2020.
Reck M et al, ASCO 2020.

Non-immunotherapy-based strategy

- Should be considered in the following situations:
  - Severe autoimmune disease
  - History of organ transplant
  - EGFR/ALK/other molecular subsets associated with non-response to immunotherapy
- Typically platinum-based doublet (+/- bevacizumab for non-squamous NSCLC)

Summary of first-line immunotherapy strategies in advanced NSCLC

- Single-agent pembrolizumab, atezolizumab and cemiplimab are more effective than chemotherapy in PD-L1 high NSCLC
- Pembrolizumab is superior to chemotherapy in NSCLC with PD-L1 >1%, however the benefit was driven by the patients with PD-L1 high tumors
- Chemo plus IO (with or without bevacizumab) can be an effective strategy regardless of PD-L1 status, however its role in PD-L1 high tumors is less clear
- Combination IO with ipi/nivo or ipi/nivo/chemo is superior to chemotherapy but has not been sufficiently compared to other IO-containing regimens

Polling Questions – Discussion

No live questions – a review of answers

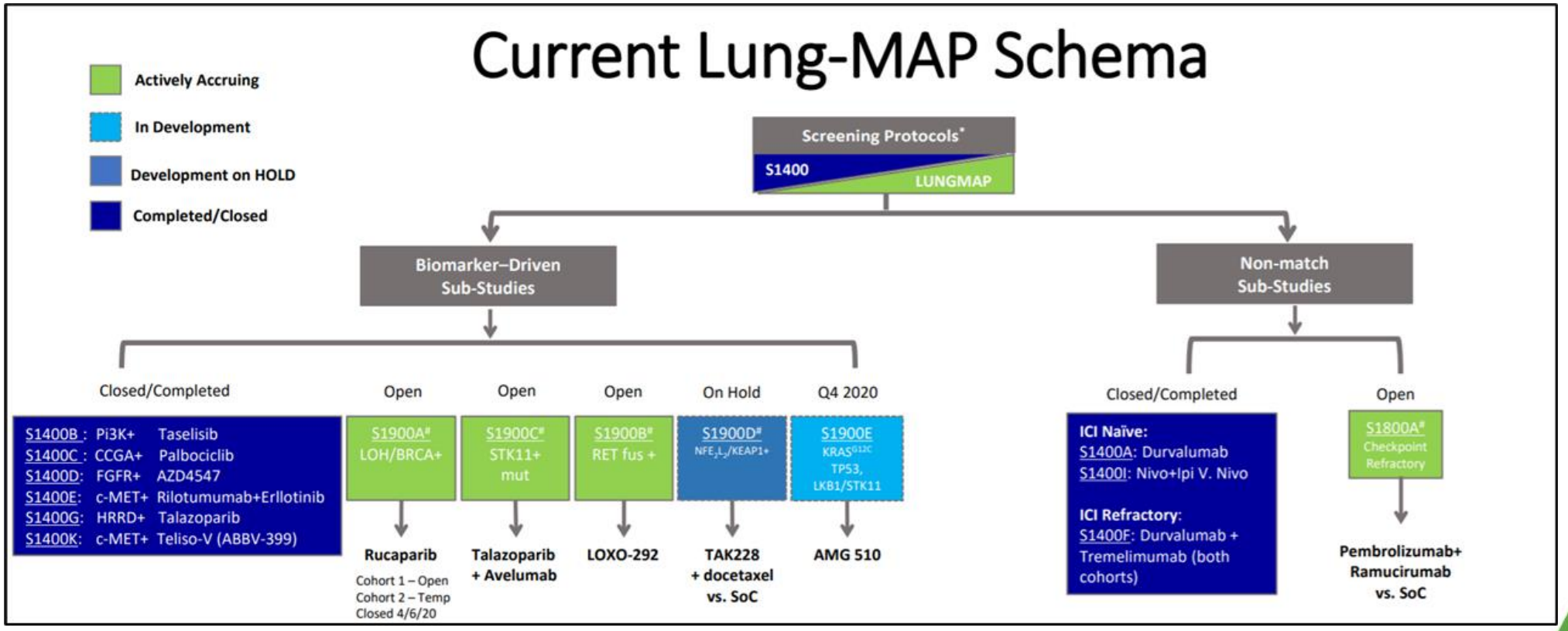
What treatment strategy would you consider for a patient with no significant co-morbidities and a good performance status who has stage IIIA non-squamous NSCLC with PD-L1 80% and multi-station mediastinal lymph node involvement (N2+)?

A. Neoadjuvant chemotherapy plus nivolumab followed by resection
B. Upfront resection followed by adjuvant chemotherapy and atezolizumab
C. Definitive concurrent chemoradiation followed by durvalumab
D. A or C
E. I would consider any of the above

Post-immunotherapy treatment strategies

- Platinum-based doublet if immunotherapy was given as first-line treatment
- Docetaxel +/- ramucirumab after chemotherapy and immunotherapy
- Local therapy for oligoprogression
- Clinical trials!

Novel strategies in development



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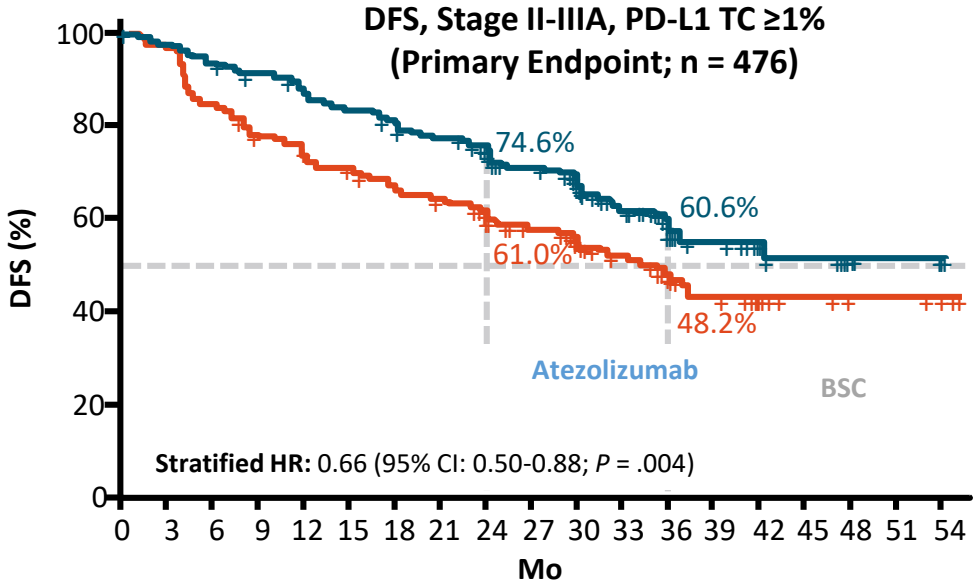
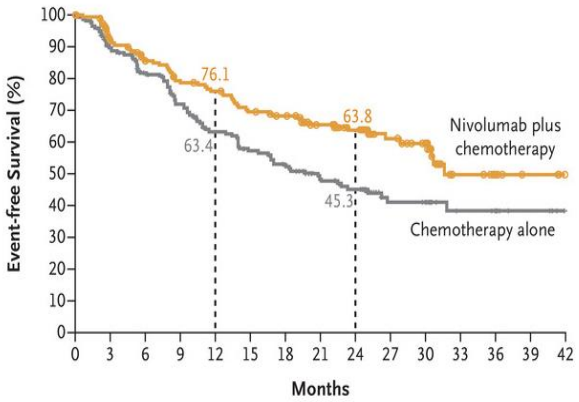
Early-stage NSCLC

Adjuvant atezolizumab



- DFS benefit by PD-L1 status: HR (95% CI)
  - TC ≥50%: 0.43 (0.27-0.68)
  - TC ≥1%: 0.66 (0.49-0.87)
  - TC <1%: 0.97 (0.72-1.31)

Neoadjuvant nivolumab/chemotherapy



	No. of Patients	Median Event-free Survival (95% CI) mo
Nivolumab plus Chemotherapy	179	31.6 (30.2–NR)
Chemotherapy Alone	179	20.8 (14.0–26.7)

Hazard ratio for disease progression, disease recurrence, or death, 0.63 (97.38% CI, 0.43–0.91)
P=0.005

No. at Risk

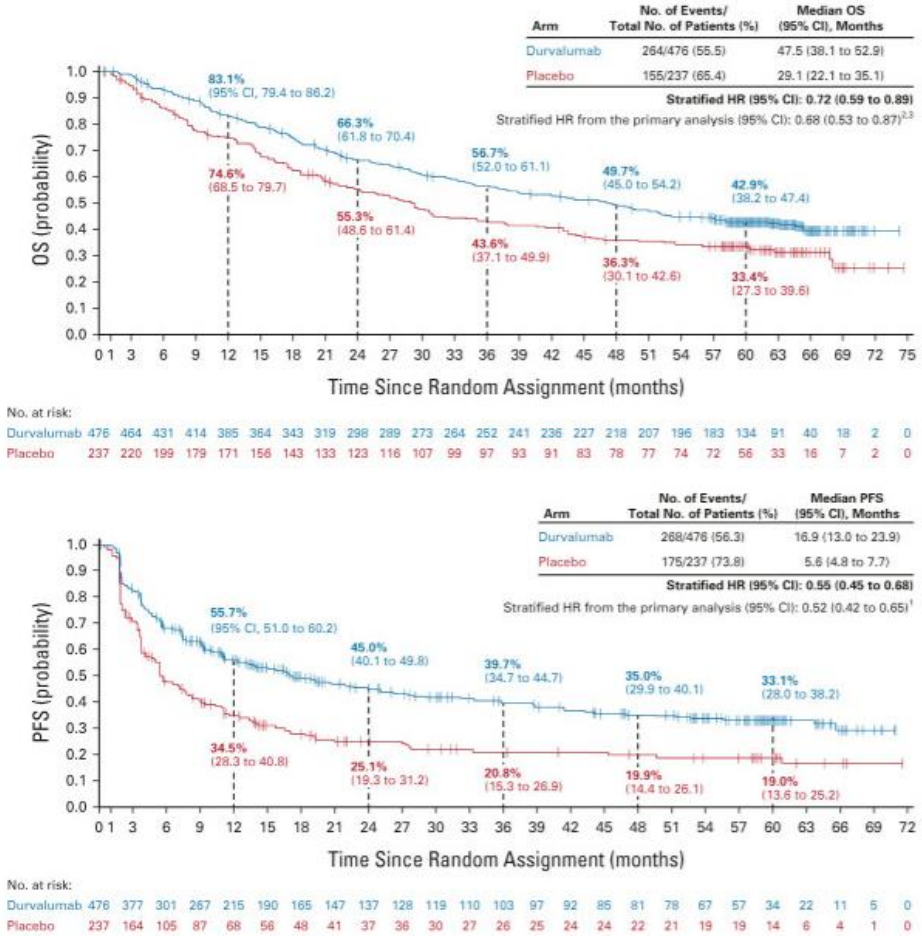
Nivolumab plus chemotherapy	179	151	136	124	118	107	102	87	74	41	34	13	6	3	0
Chemotherapy alone	179	144	126	109	94	83	75	61	52	26	24	13	11	4	0

Disease stage at baseline				
IB or II	127	NR (27.8–NR)	NR (16.8–NR)	0.87 (0.48–1.56)
IIIA	228	31.6 (26.6–NR)	15.7 (10.8–22.7)	0.54 (0.37–0.80)
Histologic type of tumor				
Squamous	182	30.6 (20.0–NR)	22.7 (11.5–NR)	0.77 (0.49–1.22)
Nonsquamous	176	NR (27.8–NR)	19.6 (13.8–26.2)	0.50 (0.32–0.79)
Smoking status				
Current or former smoker	318	31.6 (30.2–NR)	22.4 (15.7–NR)	0.68 (0.48–0.96)
Never smoked	39	NR (5.6–NR)	10.4 (7.7–20.8)	0.33 (0.13–0.87)
PD-L1 expression level				
<1%	155	25.1 (14.6–NR)	18.4 (13.9–26.2)	0.85 (0.54–1.32)
≥1%	178	NR (NR–NR)	21.1 (11.5–NR)	0.41 (0.24–0.70)
1–49%	98	NR (27.8–NR)	26.7 (11.5–NR)	0.58 (0.30–1.12)
≥50%	80	NR (NR–NR)	19.6 (8.2–NR)	0.24 (0.10–0.61)

Wakelee H, et al. Lancet. 2021.
Forde P, et al. NEJM 2022

Locally advanced unresectable NSCLC

PACIFIC: Consolidation durvalumab after definitive concurrent chemoradiation



Spigel DR, et al. JCO 2022.

Polling Questions – Discussion

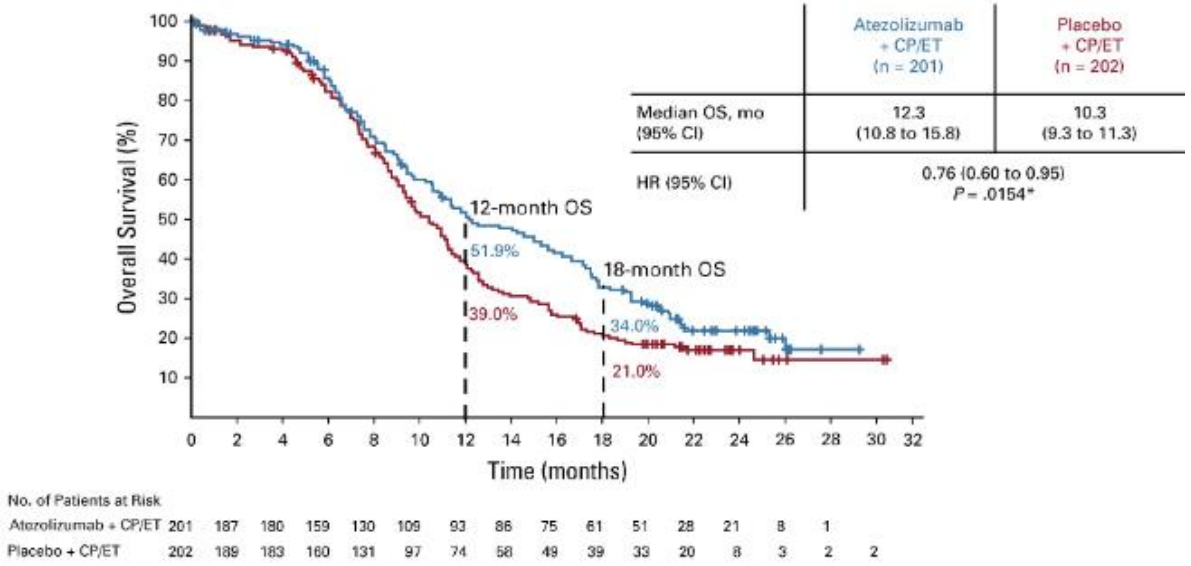
No live questions – a review of answers

What is your preferred regimen for 1st line treatment of advanced non-squamous NSCLC with PD-L1 1-49%?

A. Pembrolizumab
B. Carboplatin/pemetrexed/pembrolizumab
C. Nivolumab/ipilimumab
D. Carboplatin/pemetrexed/nivolumab/ipilimumab
E. Carboplatin/paclitaxel/atezolizumab/bevacizumab

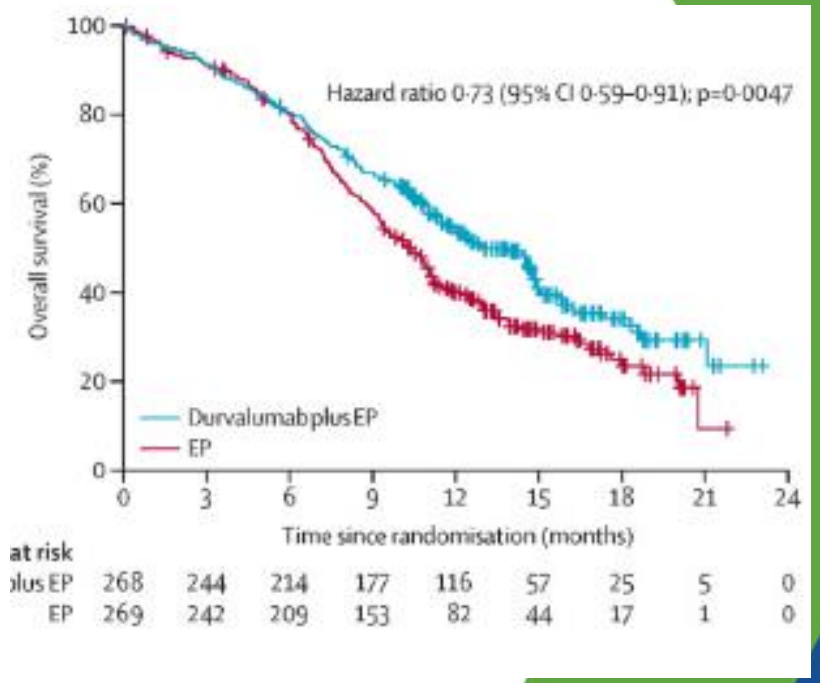
Immunotherapy for extensive-stage SCLC

Carbo/etoposide +/- atezolizumab (IMpower 133)



	Atezolizumab + CP/ET (n = 201)	Placebo + CP/ET (n = 202)
Median OS, mo (95% CI)	12.3 (10.8 to 15.8)	10.3 (9.3 to 11.3)
HR (95% CI)	0.76 (0.60 to 0.95) P = .0154*	

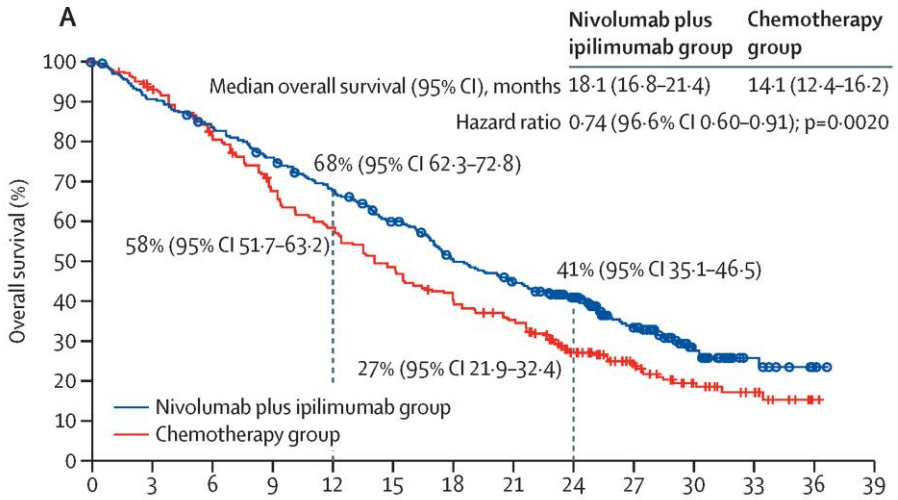
Carbo/etoposide +/- durvalumab (CASPIAN)



Liu SV, et al. JCO 2022
Paz-Ares L, et al Lancet 2019

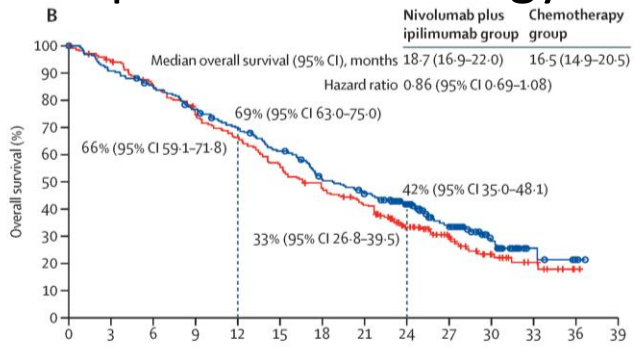
Immunotherapy for mesothelioma

All patients



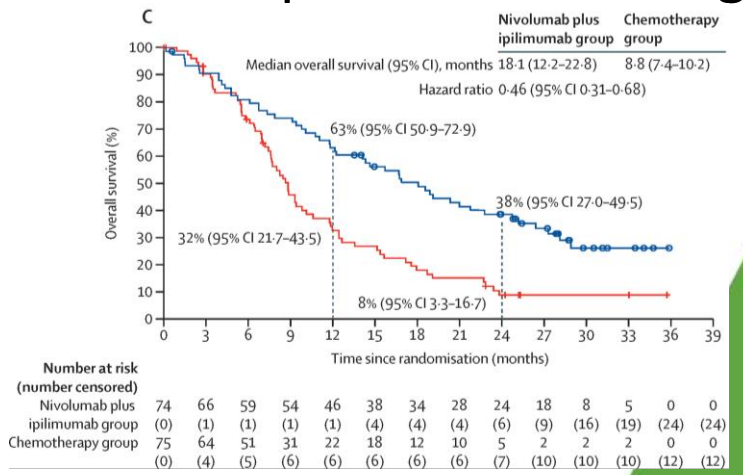
Number at risk (number censored)														
Nivolumab plus ipilimumab group	303 (0)	273 (2)	251 (4)	226 (5)	200 (7)	173 (11)	143 (14)	124 (16)	101 (29)	65 (49)	30 (76)	11 (93)	2 (101)	0 (103)
Chemotherapy group	302 (0)	268 (15)	233 (18)	190 (20)	162 (20)	136 (20)	113 (21)	95 (23)	62 (36)	38 (55)	20 (66)	11 (73)	1 (82)	0 (83)

Epithelioid histology



Number at risk (number censored)														
Nivolumab plus ipilimumab group	229 (0)	207 (1)	192 (3)	172 (4)	154 (6)	135 (7)	109 (10)	96 (12)	77 (23)	47 (40)	22 (60)	6 (74)	2 (77)	0 (79)
Chemotherapy group	227 (0)	204 (11)	182 (13)	159 (14)	140 (14)	118 (14)	101 (15)	85 (17)	57 (29)	36 (45)	18 (56)	9 (63)	1 (70)	0 (71)

Non-epithelioid histology



Number at risk (number censored)														
Nivolumab plus ipilimumab group	74 (0)	66 (1)	59 (1)	54 (1)	46 (1)	38 (4)	34 (4)	28 (4)	24 (6)	18 (9)	8 (16)	5 (19)	0 (24)	0 (24)
Chemotherapy group	75 (0)	64 (4)	51 (5)	31 (6)	22 (6)	18 (6)	12 (6)	10 (6)	5 (7)	2 (10)	2 (10)	2 (10)	0 (12)	0 (12)

Bass P, et al Lancet Oncology 2021

Summary

- Immunotherapy now has a role in nearly all patients with NSCLC, SCLC, and mesothelioma, including:
  - First-line treatment in patients with:
    - Advanced NSCLC
    - Extensive-stage SCLC
    - Mesothelioma
  - Consolidation in unresectable locally advanced NSCLC after chemoradiation
  - Neoadjuvant or adjuvant therapy in stage 2-3 NSCLC

Webinar outline

- Key Principles of Immune Mediated Adverse Events (irAE)
  - Mechanisms
  - Onset and Recognition
  - Management

Immunotherapy after ChemoRT:
How often can I start durvalumab within 14 days of completion?

1. <10%
2. 20%
3. 50%
4. >50%

Immune Related AEs (irAEs)

- Subset of patients develop irAEs
- Wide range of manifestation
  - Co-localize around “barrier” (gut, lungs, skin) or endocrine tissues
  - Up to 85% of patients treated with CTLA-4
  - 24-37% of patients treated with anti-PD-L1 or anti-PD-1
- Variable timing
  - Skin often earlier
  - Gut and endocrinopathies later
- Dual blockade of CTLA-4 and PD-1 pathway leads to both increased frequency and severity of irAEs

Postulated Mechanisms of irAEs

1. Pre-existing susceptibility to autoimmunity
2. Aberrant presentation of “self” by the tumor
3. Increasing level of inflammatory cytokines
4. Enhanced complement-mediated inflammation

Postow, NEJM 2018
Burke, Jour of Exper Med, 2020

Spectrum of Organs Affected by ICIs

Most common- thyroid, skin, and colitis

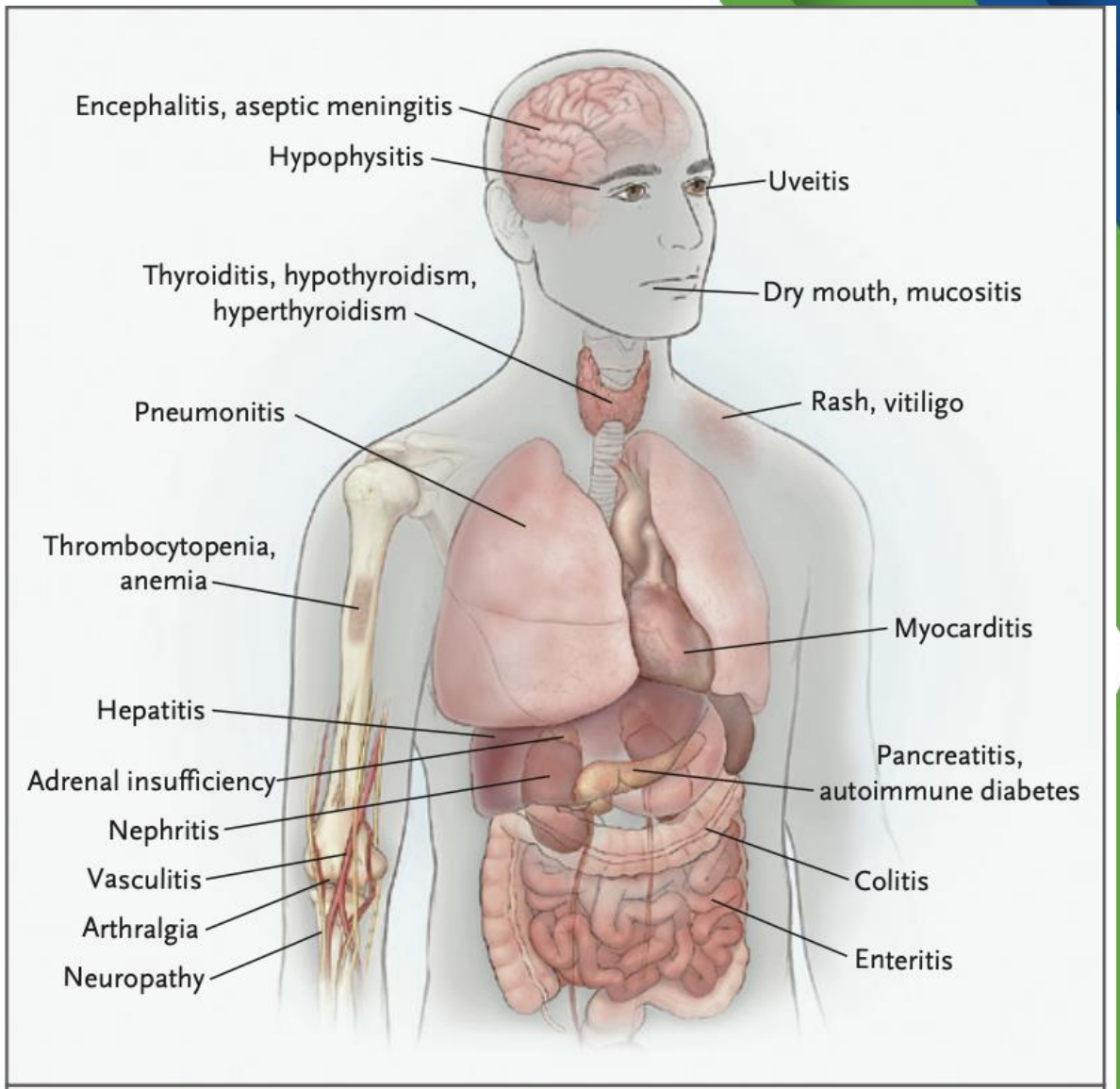


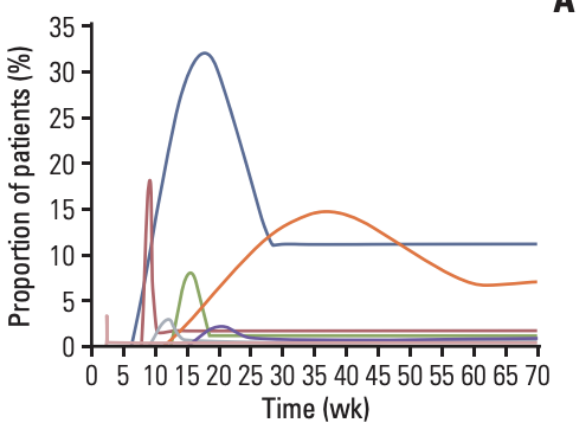
Figure 1. Organs Affected by Immune Checkpoint Blockade.

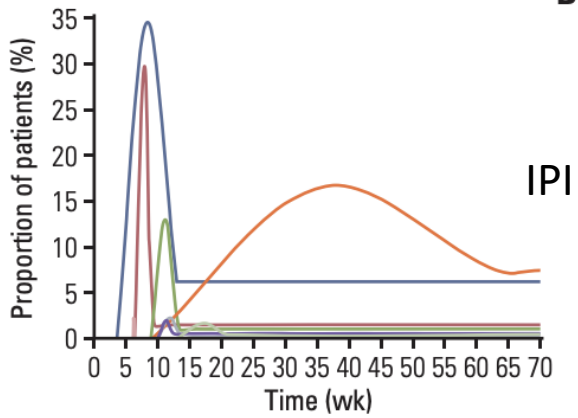
Immune checkpoint blockade can result in inflammation of any organ. Shown are the most common immune-related adverse events that clinicians encounter in patients treated with immune checkpoint blockade.

Postow, NEJM 2018

Kinetics of irAEs

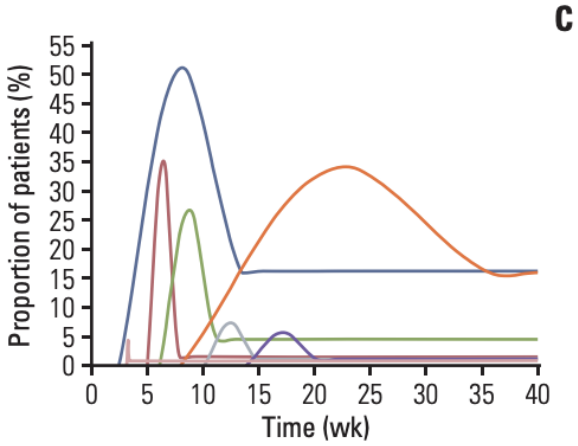
NIVO





IPI

NIVO + IPI



D

	Ranking of onset			Ranking of resolution		
	1	2	3	1	2	3
All categories	NIV+IPI (6.0)[a]	IPI (6.1)[b]	NIV (8.2)[a, b]	IPI (4.0)	NIV+IPI (5.1)	NIV (10.1)
Skin	NIV+IPI (2.4)[a]	IPI (3.6)[b]	NIV (6.1)[a, b]	IPI (9.3)	NIV+IPI (10.9)	NIV (22.1)
Gastrointestinal	NIV+IPI (4.9)	IPI (6.3)	NIV (7.7)	NIV (2.4)	NIV+IPI (2.9)	IPI (3.1)
Hepatic	NIV+IPI (6.1)[a, c]	IPI (8.9)[c]	NIV (12.3)[a]	IPI (4.4)	NIV+IPI (5.1)	NIV (6.1)
Endocrine	NIV+IPI (8.0)[a]	IPI (9.1)[b]	NIV (11.2)[a, b]	NIV+IPI (27.6)[a, c]	NIV (48.1)[a]	IPI (54.3)[c]
Pulmonary	NIV (8.9)	IPI (10.0)	NIV+IPI (10.1)	IPI (3.7)	NIV+IPI (4.5)	NIV (5.9)
Renal	IPI (10.0)[c]	NIV+IPI (13.9)[c]	NIV (14.8)	IPI (2.5)	NIV+IPI (6.3)	NIV (10.5)
Hypersensitivity/ Infusion reaction	NIV (2.2)[b]	NIV+IPI (3.1)[c]	IPI (6.1)[b, c]	IPI (0.1)	NIV (0.1)[a]	NIV+IPI (0.2)[a]
Neurologic	NA (-)			NA (-)		

Pooled analysis of 23 Clinical Trials/8436 Patients
-Tang, Cancer Res Treat 2021

irAEs and Efficacy of ICIs

- Conflicting but intriguing data
- Challenges in adjudication, attribution, and immortal time bias
- Diagnostic challenges
- Impact of treatment with immunosuppression

Using ICI Agents in Clinic

- Medical history
  - Specific questions on organ function-ie, shortness of breath on exertion, bowel function, previous history of autoimmune disease?
- Physical Examination
  - Vitals signs (with oximetry), weight, other significant findings
- Laboratory investigations
  - CBC, CMP, LFTs, TSH, other endocrine function evaluation when appropriate

Common Terminology Criteria of Adverse Events (CTCAE)

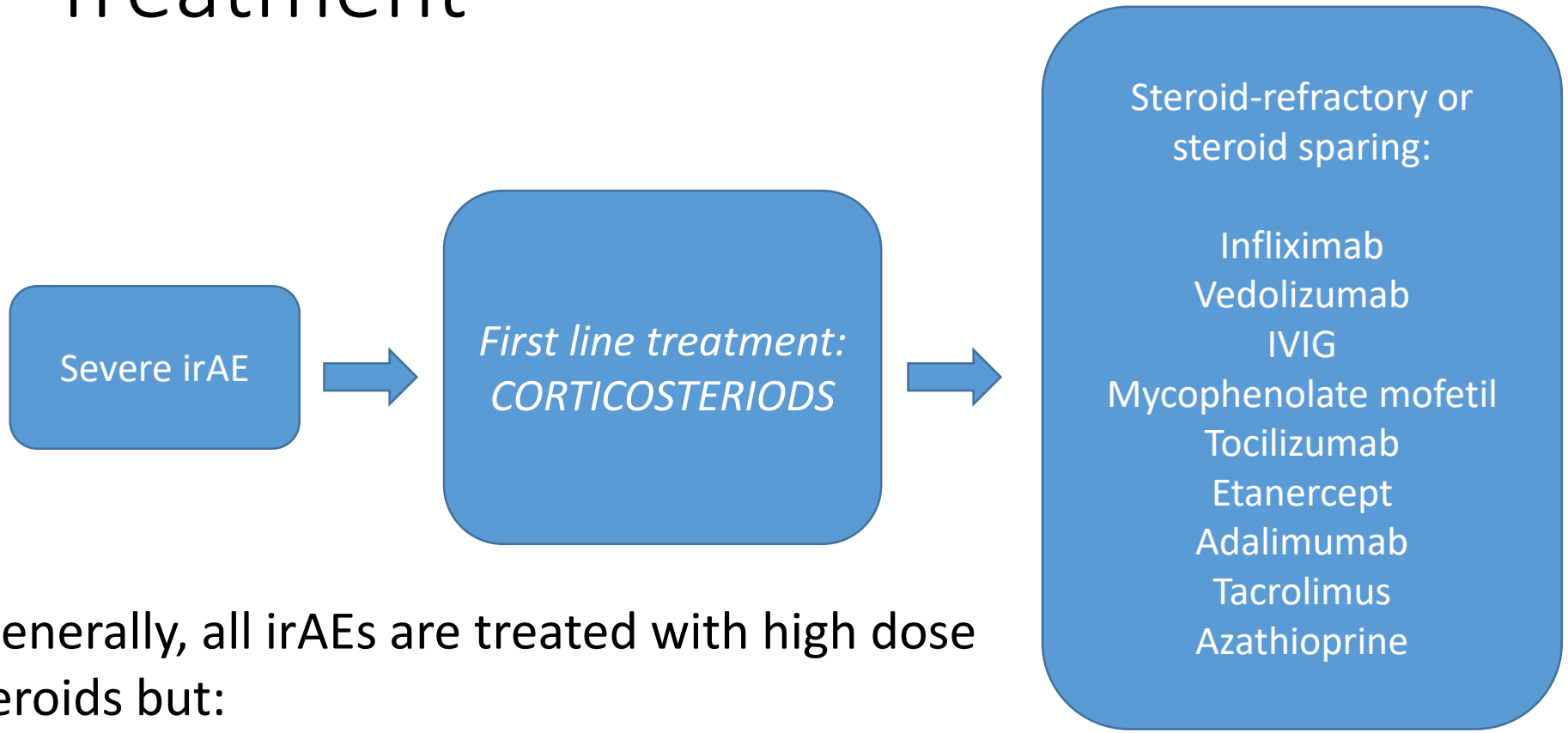
CTCAE grade	Clinical description
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2	Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated, disabling; limiting self-care ADL
4	Life-threatening consequences; urgent intervention indicated
5	Dearth related to adverse event

General Approach to Using IO in Clinic

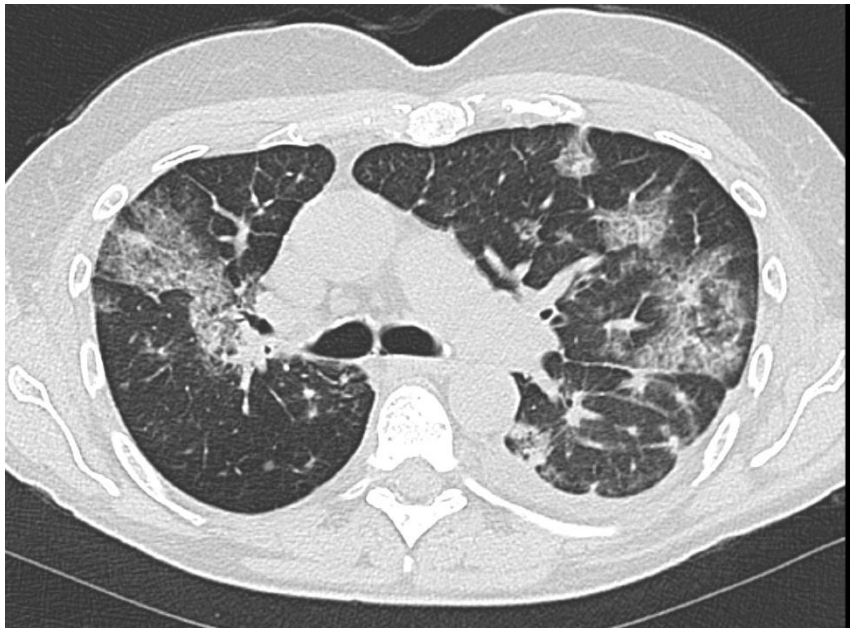
Grade	Management	Continuation of Drug?
Grade 1-LOW	Monitor closely	Continue (*watch pneumonitis if risk factors)
Grade 2-MODERATE	Symptomatic management Monitor closely Oral corticosteroids	Delay dose Resume IO when AEs to grade ≤1 or baseline
Grade 3/4-HIGH	Administer high dose iv corticosteroids Symptomatic management Monitor closely Involve consultants	Discontinue drug, usually permanently (skin, diarrhea can be exceptions)

STEROID TAPER IS USUALLY AT LEAST 4-6 WEEKS MINIMUM

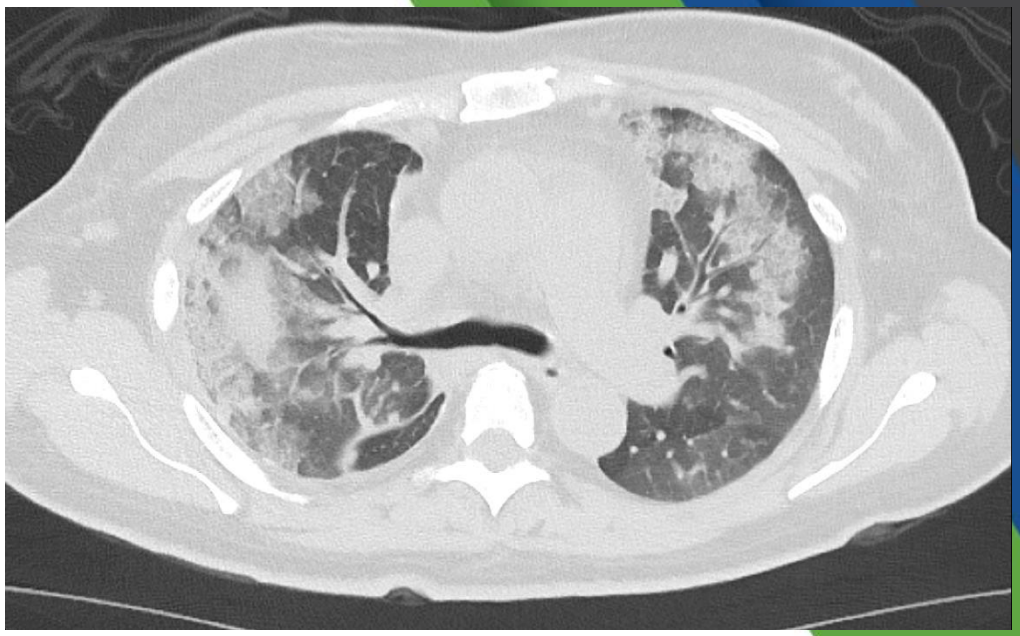
Types of Immunosuppressive Treatment



- Generally, all irAEs are treated with high dose steroids but:
  - ***Endocrine toxicities generally are simply treated with replacement of hormonal deficit in most situations except in specific situations***

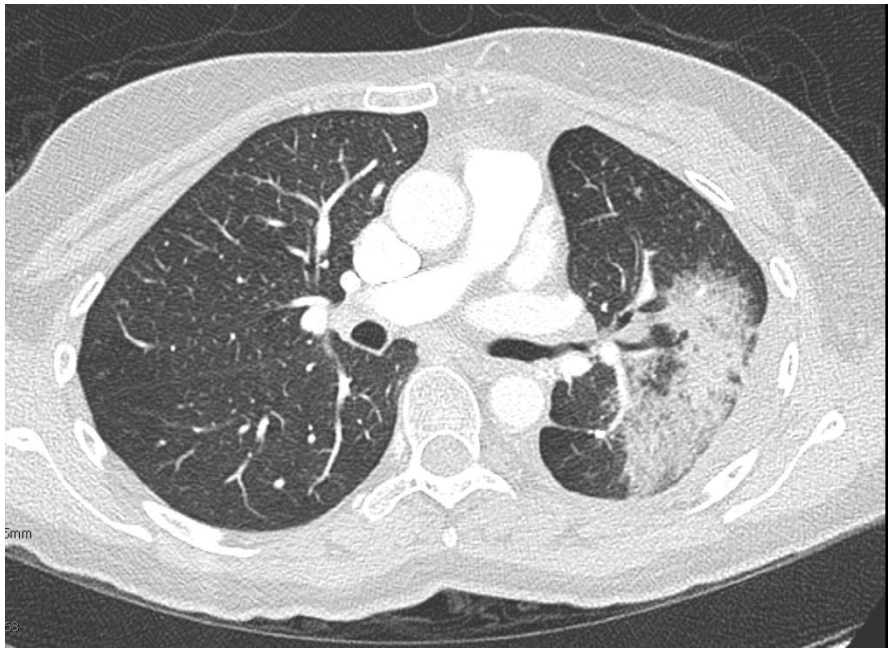


COVID



PD-1 inhibitor

All presented with mild cough, flu like symptoms with low grade fever, desaturation only with ambulation



Radiation Pneumonitis

Polling Questions – Discussion Cont'd

No live questions – a review of answers

- Immunotherapy after ChemoRT:
  How often can I start durvalumab within 14 days of completion?
  - <10%
  - 20%
  - 50%
  - >50%

Autoimmune Diseases (AD) and ICIs

- 14-25% of patients diagnosed with lung cancer will have pre-existing AD
- In patients with no (>80%) or low dose immunosuppression, ICI use[1]:
  - 20-40% of patients with exacerbation of ADs
  - <15% of patients with permanent discontinuation
- In patients on pre-existing steroids, inferior outcomes, but may reflect co-morbidity[2]

Patients with Preexisting Autoimmune Disease and Cancer	
ICIs May Be Considered	***Avoid ICIs***
1. Consult with appropriate specialists	1. Autoimmune neurologic or neuromuscular disorder
2. Low level or no immunosuppression with good control of AD	2. Life threatening autoimmune disease
3. Patient informed consent	3. Patients with poor control of AD OR requiring high doses of immunosuppressants for control

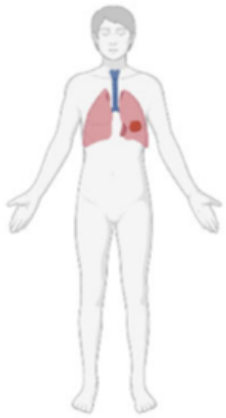
1. Leonardi, JCO, 2018; Kennedy, JNCCN, 2019
2. Arbour, JCO, 2019

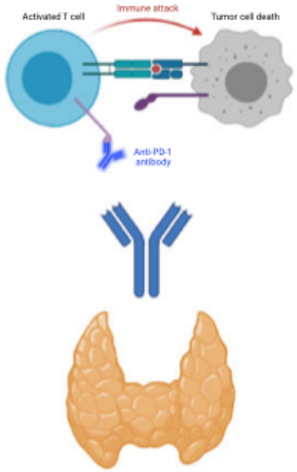
Rechallenge after irAEs

- 11-16% of patients develop Gr 3-5 irAEs[1]
- At rechallenge, incidence of Gr 3-4 irAE < than initial treatment (HR 0.44)[2]
- At rechallenge, GI > endocrine irAE
- Rechallenge after Gr 4 irAE should always be undertaken with CAUTION

1. Pillai, Cancer, 2018
2. Xu, JTO Clin and Res Reports, 2022

Innovation in irAEs





Preclinical setting	irAE prevention	irAE diagnosis	irAE treatment
Improved preclinical irAE models	Genetic biomarkers of irAE risk	Biomarkers of irAEs	Prospective irAE clinical trials
Improved mechanisms of irAEs in preclinical models	Microbial biomarkers of irAE risk	Imaging of irAEs	
Identification of novel biomarkers of irAE	Interventions to mitigate irAE risk e.g. microbial manipulation	Improved diagnostic pathways e.g. Multidisciplinary IR-Tox team	Refined treatment algorithms based on irAE mechanisms

Conroy, Nature Communications, 2022

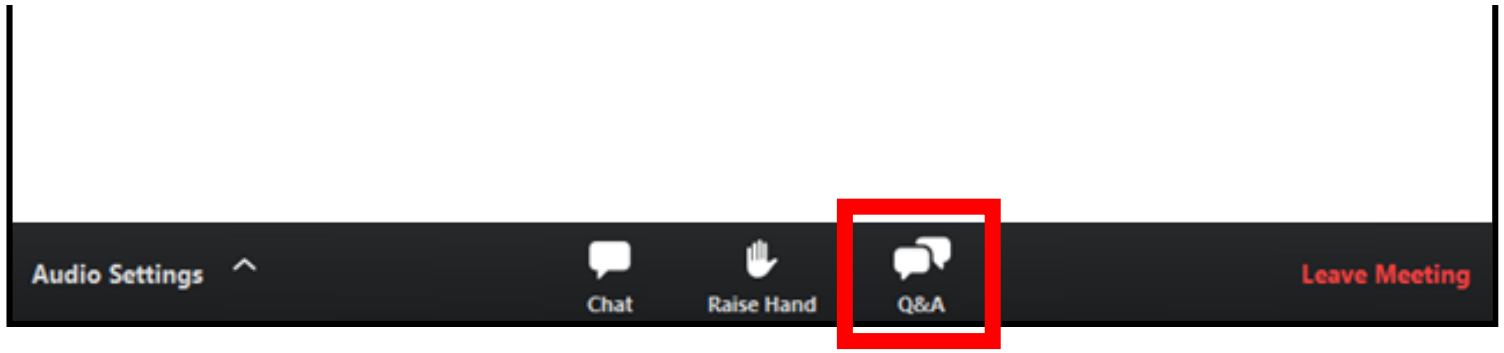
irAEs-Conclusions

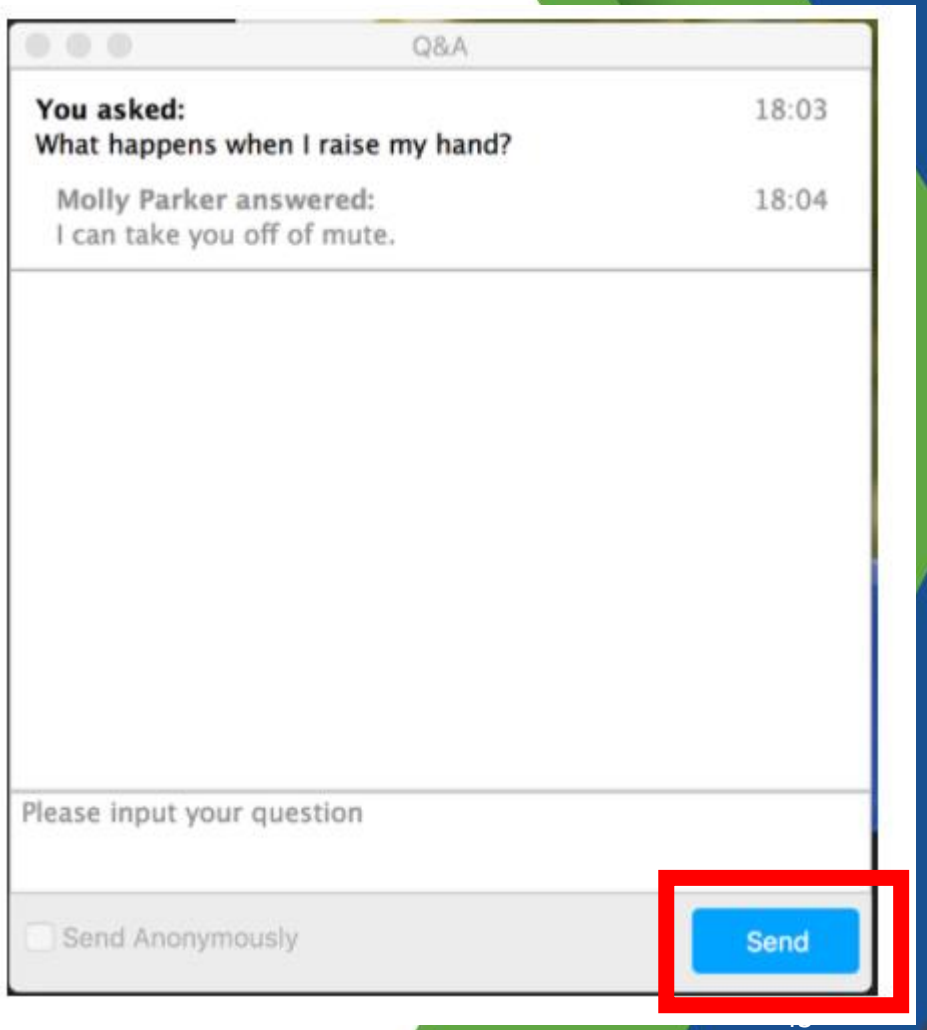
- Careful ongoing clinical assessment is necessary for early identification
- Can be life threatening when not identified early
- irAEs can occur at any time
- Toxicity does not equal response
- Consider all symptoms and signs as potential irAEs
- Refer to SITC organ-specific algorithms for management of irAEs

Q&A

How to Submit Questions

- Click the “Q&A” icon located on at the bottom of your Zoom control panel
- Type your question in the Q&A box, then click “Send”
- Questions will be answered in the Question & Answer





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Case Studies in Immunotherapy for the Treatment of Nonmelanoma Skin Cancer

October 28, 2022: 3:30 p.m.-4:30 p.m. ET

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Sept. 15, 2022: 1 p.m. – 3 p.m. ET

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PIM Postgraduate Institute for Medicine · sitc Society for Immunotherapy of Cancer · ACCC Association of Community Cancer Centers · APSHO Advanced Practitioner Society for Hematology and Oncology · HOPA Hematology/Oncology Pharmacy Association

The 2021-2022 Advances in Cancer Immunotherapy™ educational series is supported, in part, by independent medical education grants from AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Exelixis, Inc., Genentech, a Member of the Roche Group, Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc. (MSD), Novartis Pharmaceuticals Corporation, and Regeneron Pharmaceuticals Inc. (as of 10/25/2021)

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Questions or comments: connectED@sitcancer.org

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