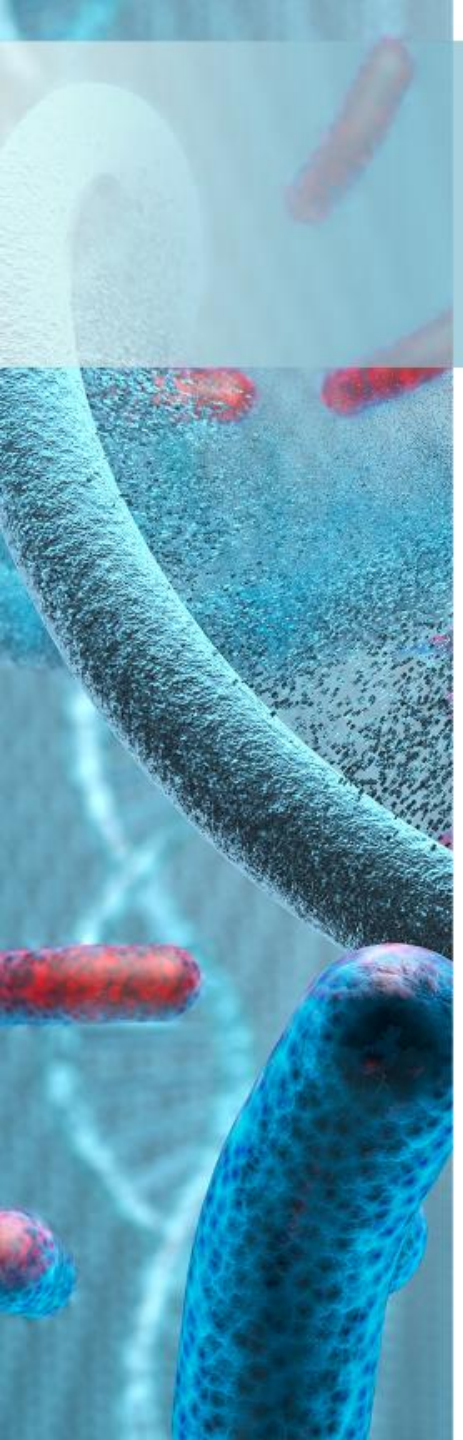
Improving Quality of Life for Patients on Immune Checkpoint Inhibitors

Listening to What They Have to Say



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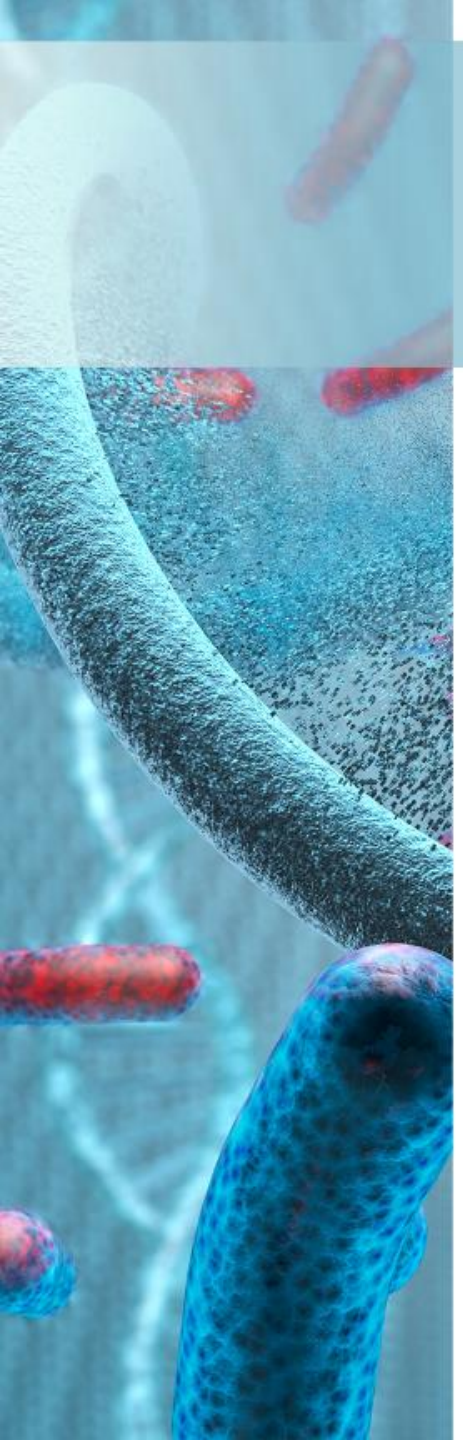
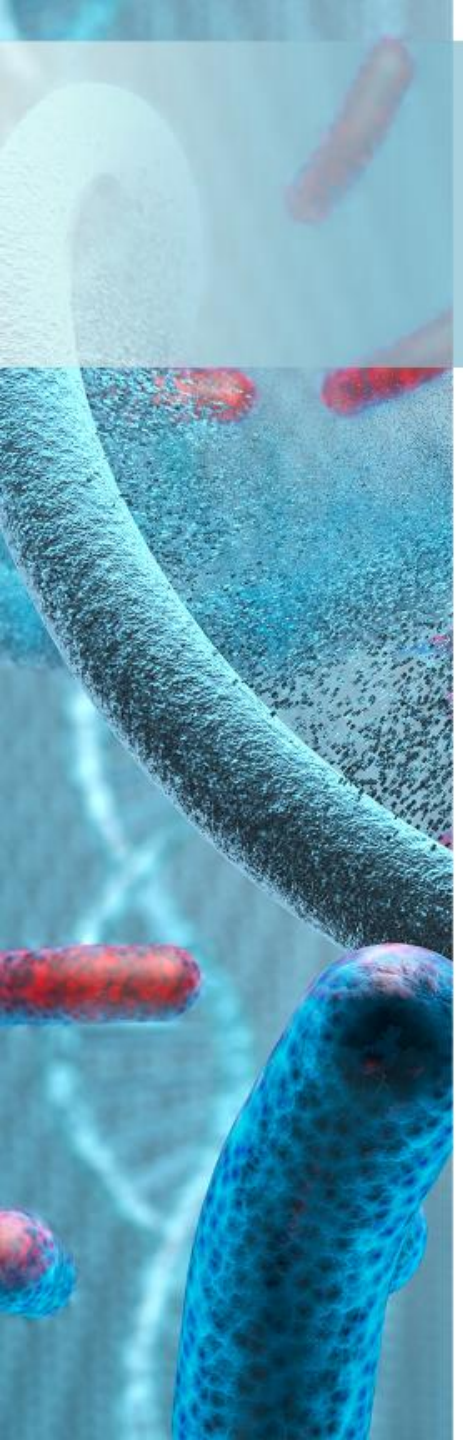


Faculty

Val R. Adams, PharmD, FCCP, BCOP

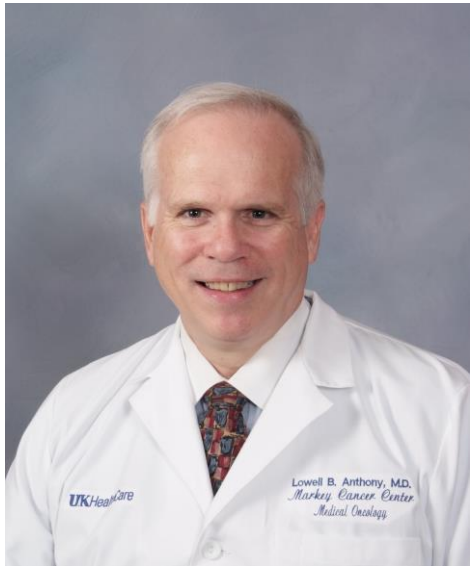
Associate Professor of Pharmacy Practice & Science
Markey Cancer Center at the University of Kentucky
Lexington, KY

Dr. Adams is an associate professor, Department of Pharmacy Practice and Science, in the College of Pharmacy at the University of Kentucky. He serves as graduate faculty, director of the hematology/oncology residency program, and member of the Markey Cancer Center, where he has a clinical practice site. Dr. Adams received his BS in Pharmacy from the University of Utah and his PharmD from the University of Texas at Austin. He completed a residency in hematology/oncology at the Audie L. Murphy Memorial VA Hospital in San Antonio and a 2-year fellowship in immunology and transplantation at the University of Florida.



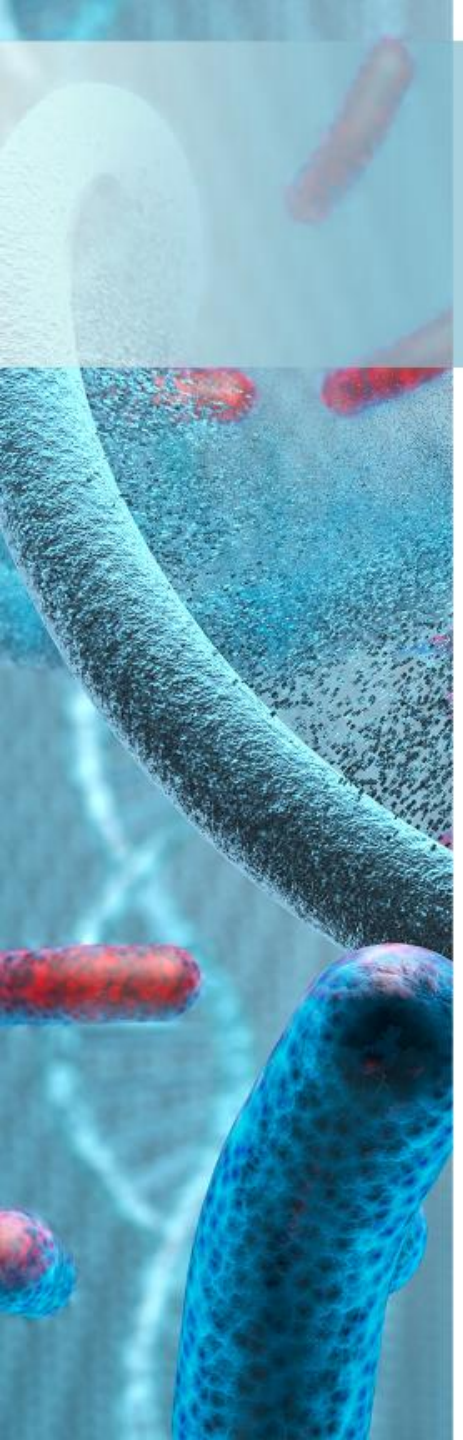
Faculty

Lowell B. Anthony, MD, FACP



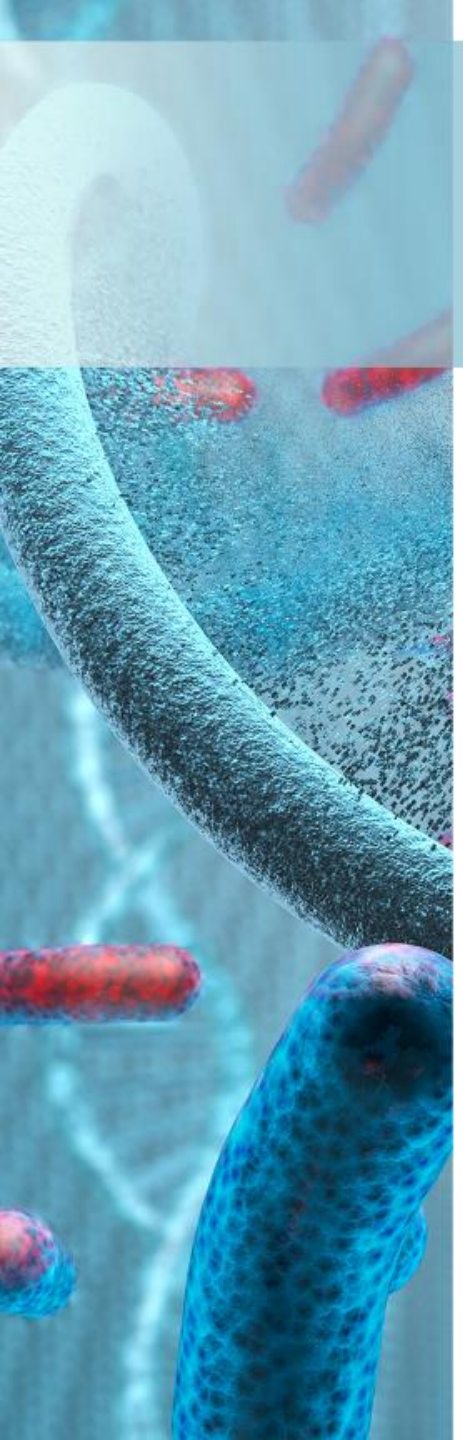
Professor of Medicine
Chief, Division of Medical Oncology
Markey Cancer Center at the University of Kentucky
Lexington, KY

Dr. Anthony is a medical oncologist with a focus on neuroendocrine neoplasms. He is Professor of Internal Medicine and Division Chief for Medical Oncology. Dr. Anthony received his undergraduate degree from King College in Bristol, Tennessee and his medical and postgraduate training in medical oncology and clinical pharmacology at Vanderbilt University Medical Center in Nashville. Dr. Anthony is board certified in Internal Medicine and Medical Oncology and is a Fellow of the American College of Physicians. Dr. Anthony is an active member of several professional organizations, including the American Society of Clinical Oncology, the American Federation for Medical Research, the American Association for Cancer Research, the Southwest Oncology Group, the Southern Society for Clinical Investigation, and the Multinational Association of Supportive Care in Cancer, and he was a founding member of the North American Neuroendocrine Tumor Society (NANETS).



Patient Faculty

- Gladys Evelyn Willey
- Jeffrey Wayne Smith



Disclosures

Dr. Adams has disclosed that he has no actual or potential conflict of interest in relation to this program.

Dr. Anthony has disclosed that he has no actual or potential conflict of interest in relation to this program.

Ms. Duvall, **Ms. Willey**, and **Mr. Smith** have disclosed that they have no actual or potential conflict of interest in relation to this program.

The clinical reviewer, **Megan May, PharmD, BCOP** has no actual or potential conflicts of interest in relation to this program.

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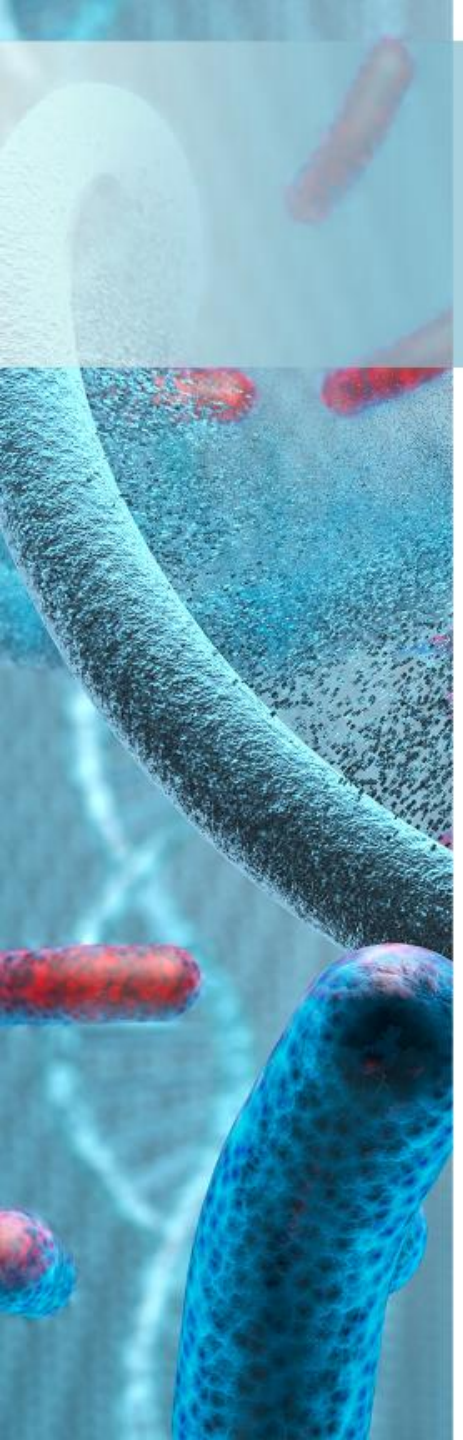

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Type of Activity: Application

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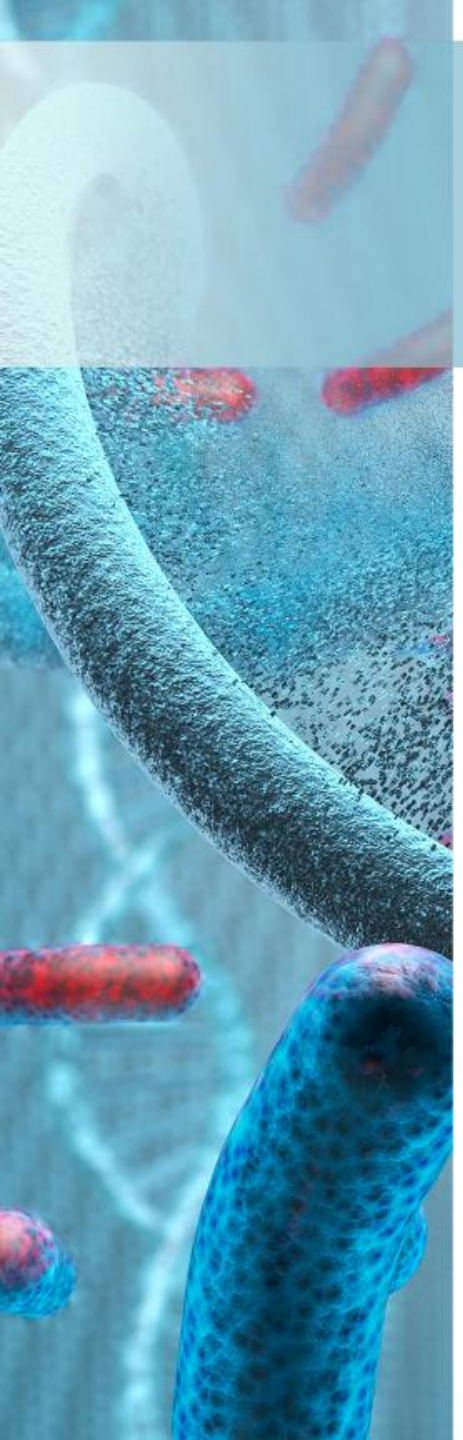
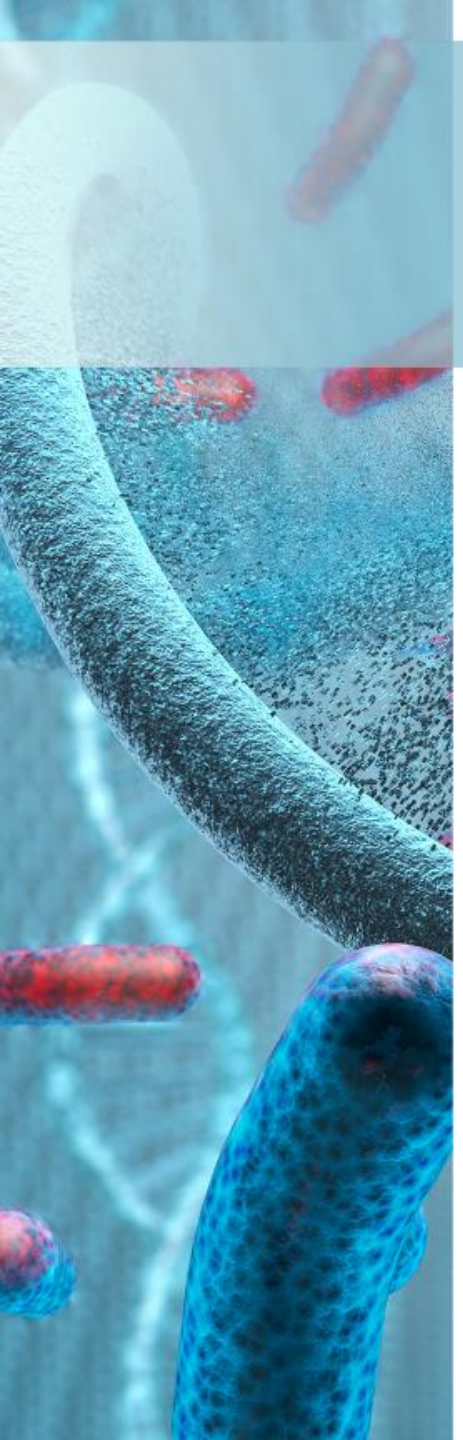


Learning Objectives

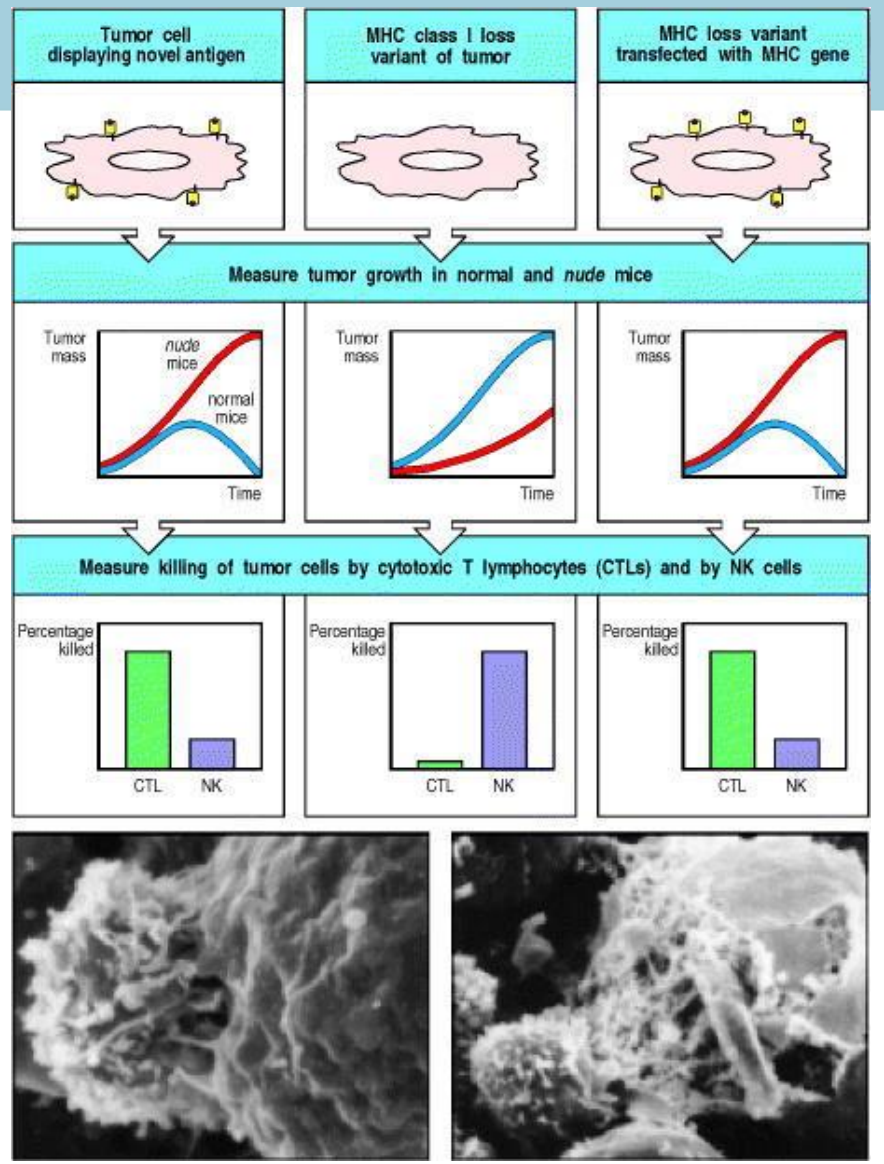
- **Assess** adverse events associated with immune checkpoint inhibitors and their unique management strategies
- **Identify** issues and strategies to improve the quality of life for patients on immune checkpoint inhibitors
- **Recognize** effective communication strategies and gaps in communication and the need for both upfront and follow-up communication to improve outcomes
- **Formulate** strategies to overcome barriers to treatment, including financial and access issues



The Next Chapter in Cancer Treatment

- Chapter 1 – Cytotoxic chemotherapy - non-specifically killed cells
  - Normal cells were more resistant and recovered faster from toxicity than tumor cells
  - Derived from natural products
- Chapter 2 – Targeted anti-tumor agents
  - Determine molecular drivers stimulating cancer growth and block with signaling pathway
- Chapter 3 – Immunotherapy
  - Augment the immune system’s ability to kill cancer cells

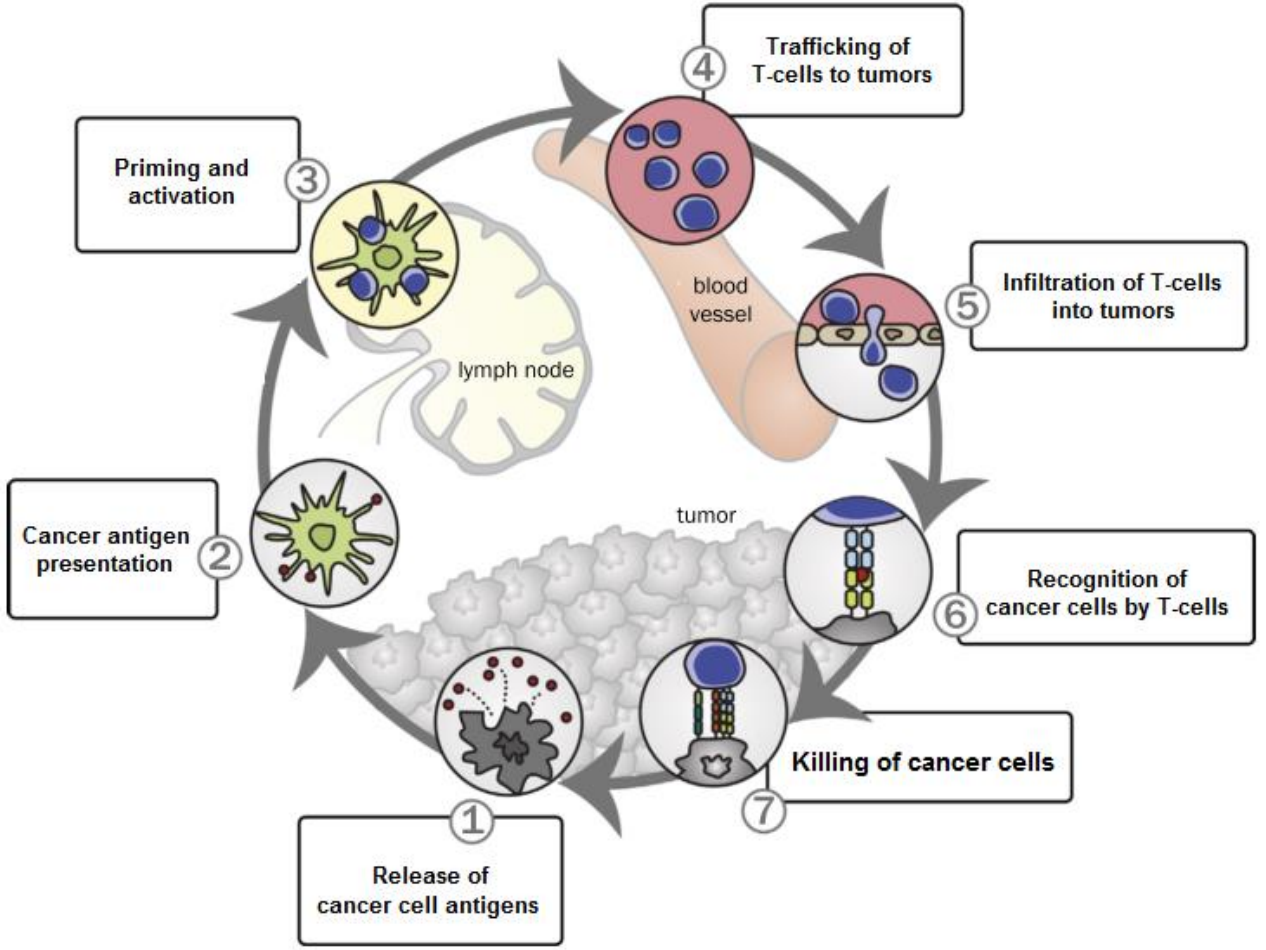
Cytotoxic T-cell and Tumor Cell Interactions



Janeway CA Jr, et al. *Immunobiology: The Immune System in Health and Disease.* 5th edition. New York: Garland Science; 2001.

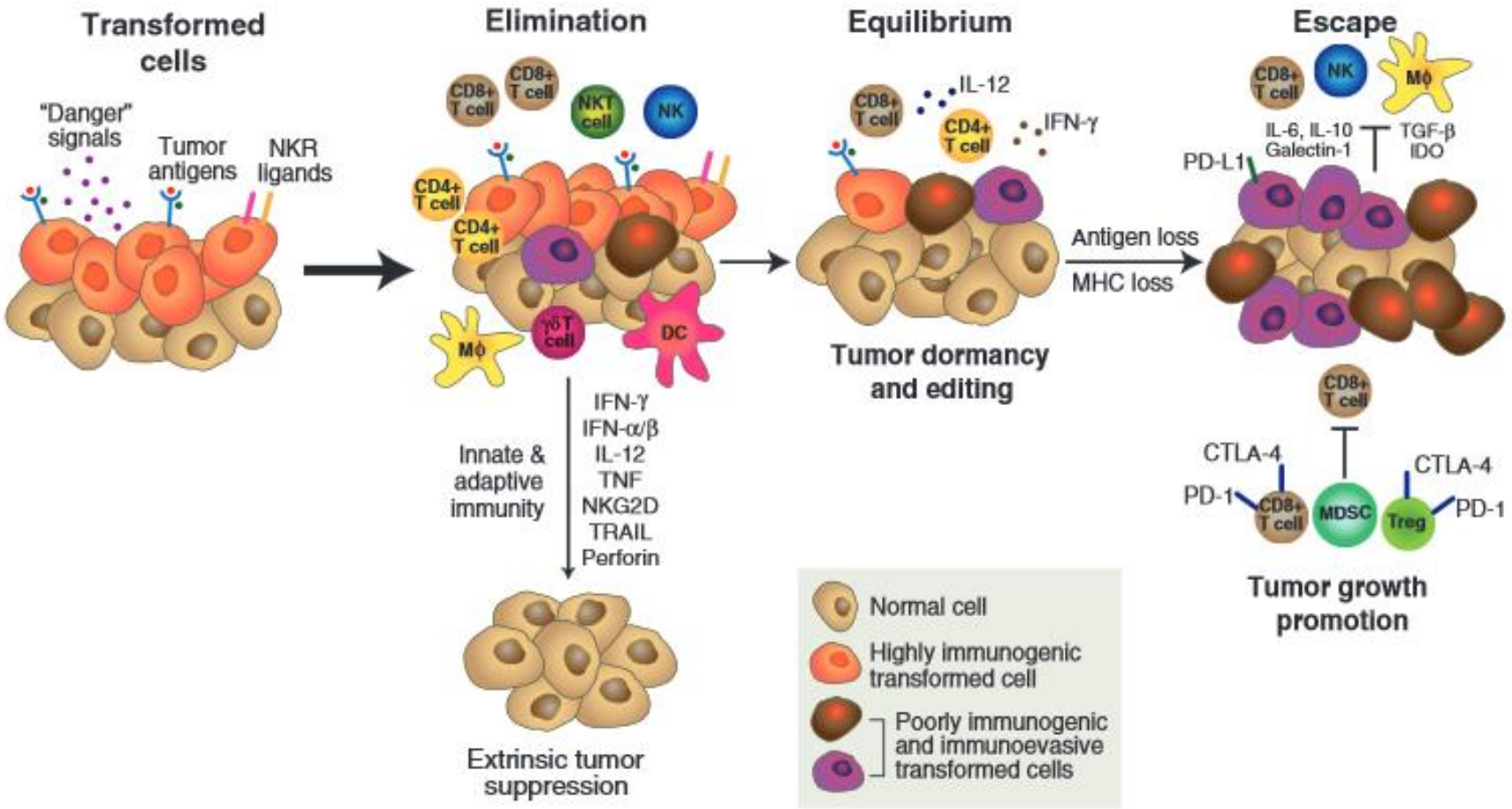
CTL, cytotoxic T-lymphocytes; MHC, major histocompatibility complex; NK, natural killer cells.

Immune System Recognition of Cancer



Daud A. *Semin Oncol.* 2015;42 Suppl 3:S3-S11.

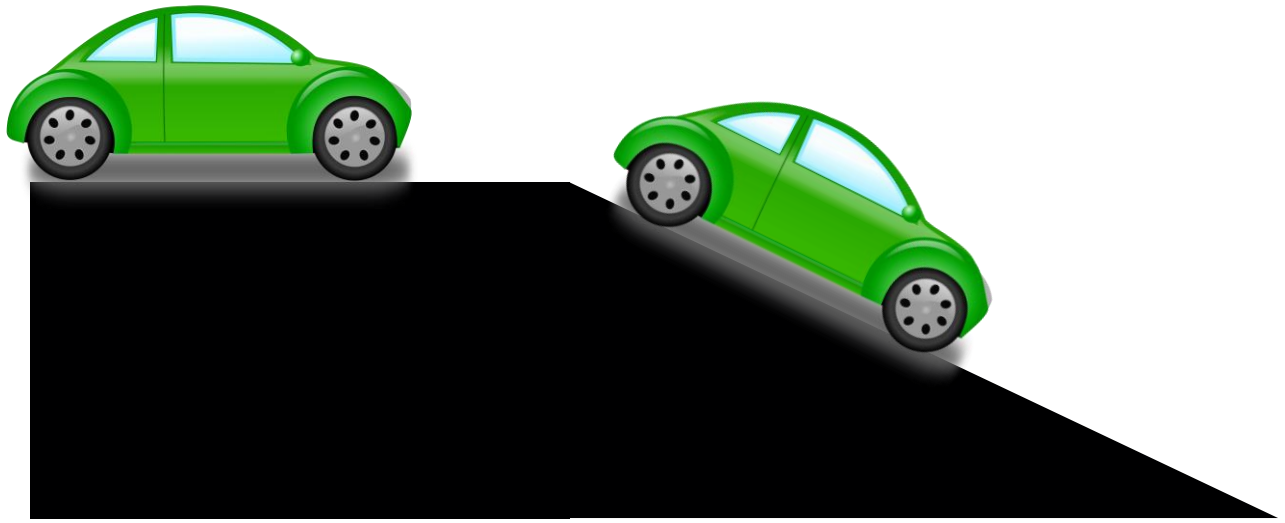
Avoiding Immune Surveillance



Schreiber RD, et al. *Science*. 2011;331(6024):1565-70.

Getting T-Cells Moving

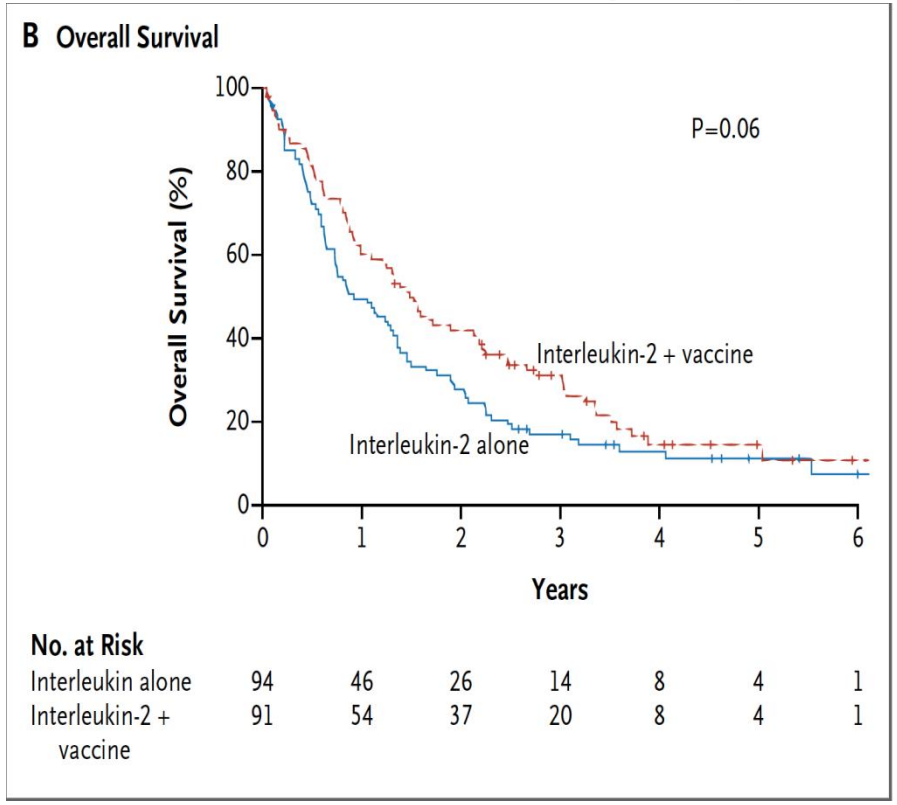
Put on the gas (activate)
or
Take off the brakes (checkpoint inhibitors)



Put on the Gas or Take off the Brakes?

Gas On

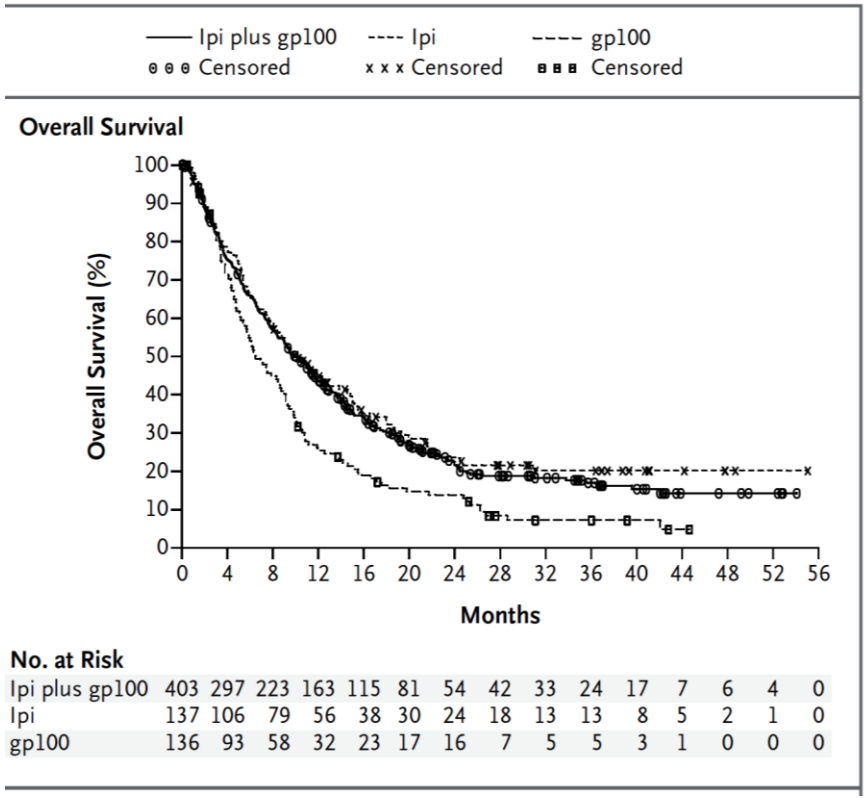
gp100 Peptide Vaccine and Interleukin-2 (IL-2)



Schwartzentruber DJ, et al. *N Engl J Med*. 2011;364(22):2119-27.

Brake Off

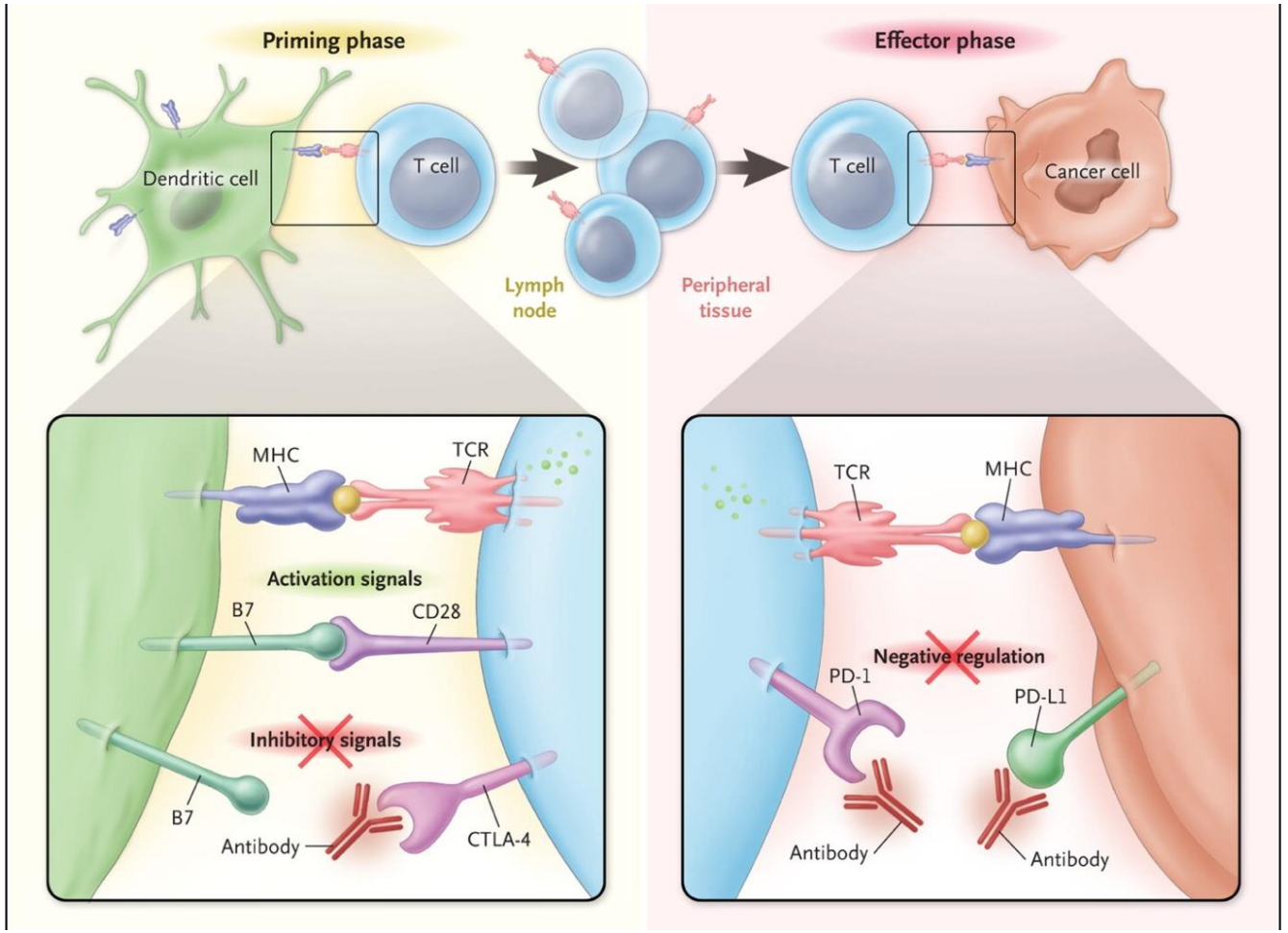
Ipilimumab (Ipi)



Hodi et al. *N Engl J Med*. 2010;363(8):711-23.

gp100, glycoprotein 100.

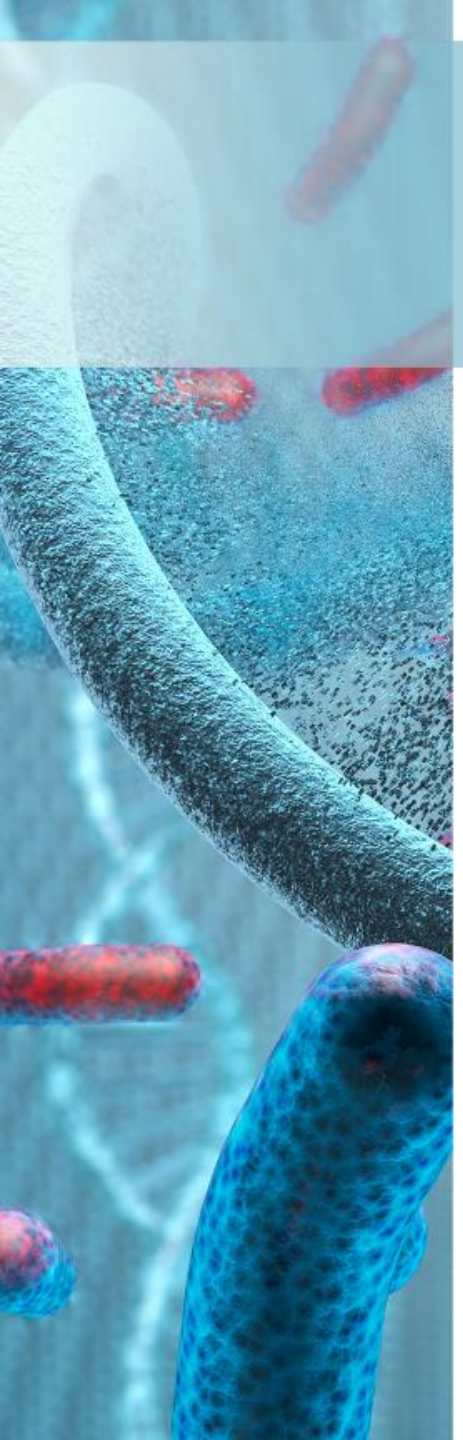
CTLA-4 and PD-1/L1 Checkpoint Blockade



Ribas A. *N Engl J Med.* 2012;366(26):2517-9.

The Goal of Checkpoint Inhibitors

Immuno-oncology is focused on “unleashing” T-cells that recognize cancer so they can “chase” it down

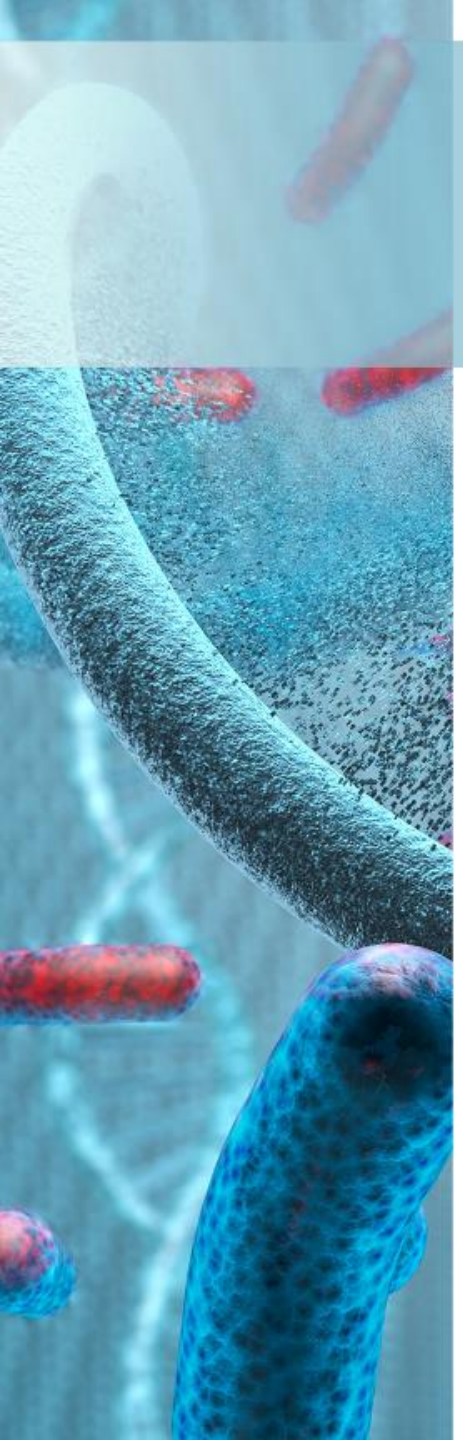


Checkpoint Inhibitors

Drug	Indications (see prescribing information for details)
Atezolizumab (PD-L1i)	NSCLC, **bladder CA**, SCLC, breast CA (TNBC), HCC
Avelumab (PD-L1i)	**Merkel cell carcinoma**, **bladder CA**, renal cell CA
Durvalumab (PD-L1i)	NSCLC, **bladder CA, SCLC**
Nivolumab (PD-1i)	Melanoma, NSCLC, SCLC, renal cell CA, Hodgkin lymphoma, head and neck CA, **bladder CA**, MSI-H/dMMR colorectal CA, hepatocellular CA
Pembrolizumab (PD-1i)	Melanoma, NSCLC, SCLC, Hodgkin lymphoma, head and neck CA, **bladder CA,** MSI-H/dMMR CA, gastric CA, NHL, esophageal CA, cervical CA, hepatocellular CA, **Merkel cell carcinoma**, renal cell CA, endometrial CA, TMB-H, HCC
Cemiplimab-rwlc (PD-1i)	Cutaneous squamous cell carcinoma
Ipilimumab (CTLA-4i)	Melanoma, renal cell CA, MSI-H/dMMR colorectal CA, HCC, NSCLC

CA, cancer; CTLA-4i, cytotoxic T-lymphocyte-associated protein 4 inhibitor; dMMR, mismatch repair deficient; HCC, hepatocellular carcinoma; IV, intravenously; MSI-H, microsatellite instability-high; NHL, non-Hodgkin lymphoma; NSCLC, non-small cell lung cancer; PD-1i, programmed cell death protein 1 inhibitor; PD-L1i, programmed death-ligand 1 inhibitor; SCLC, small cell lung cancer; TMB-H tumor mutation burden – high; TNBC, triple-negative breast cancer.

Bavencio [prescribing information]; 2020.; Imflinzi [prescribing information]; 2020.; Keytruda [prescribing information]; 2020.; Libtayo [prescribing information]; 2020.; Opdivo [prescribing information]; 2020.; Tecentriq [prescribing information]; 2020.; Yervoy [prescribing information]; 2020.

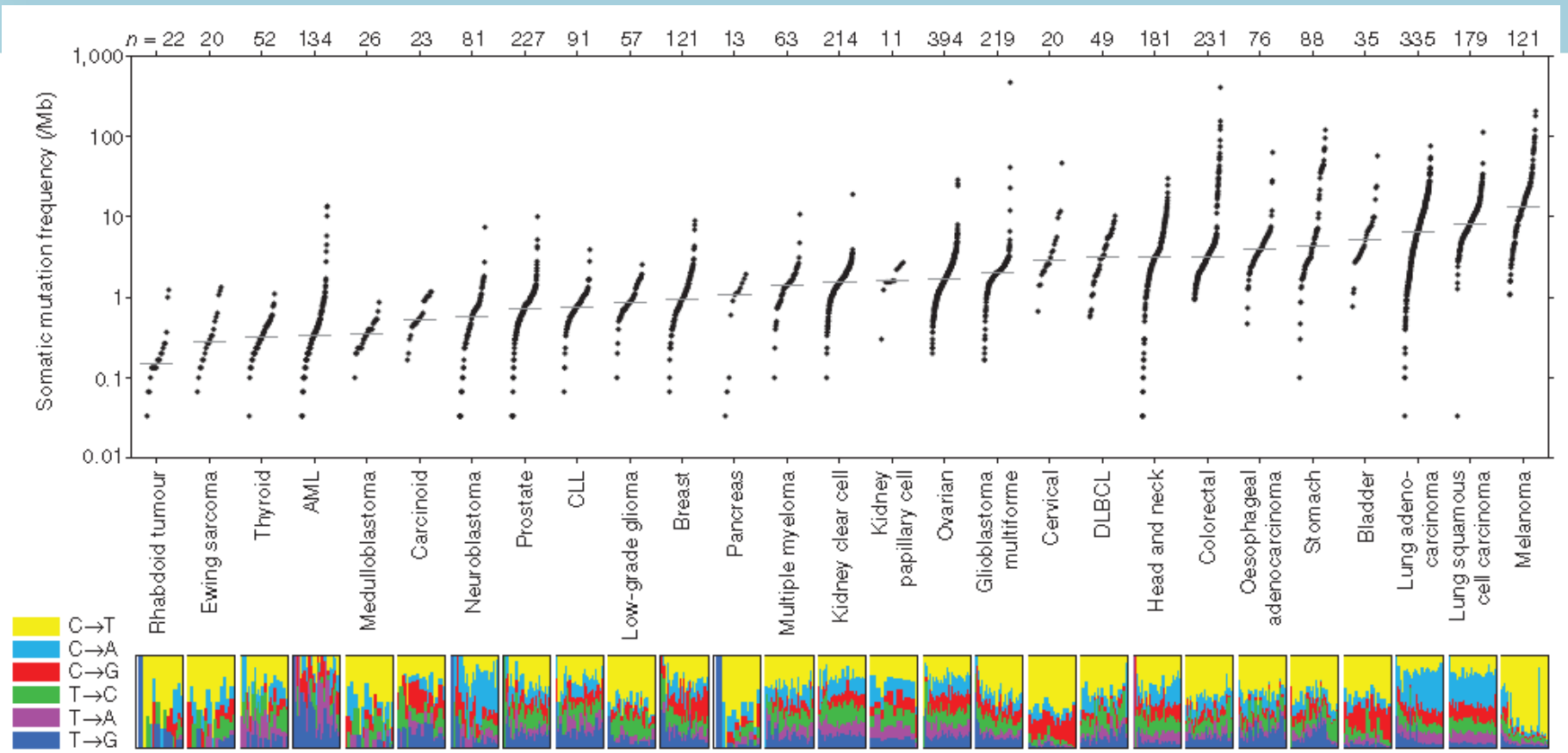


Contraindications to Checkpoint Inhibitors

- The prescribing information for all 7 agents list “NONE” under contraindications
- Essentially all studies excluded patients with autoimmune disease
- Real-world evidence suggests that the likelihood of exacerbating the underlying autoimmune condition (a flare) is common, but it is usually caught early and successfully managed
- Most trials prohibited baseline corticosteroids, and real-world evidence suggests that it impairs efficacy of treatment

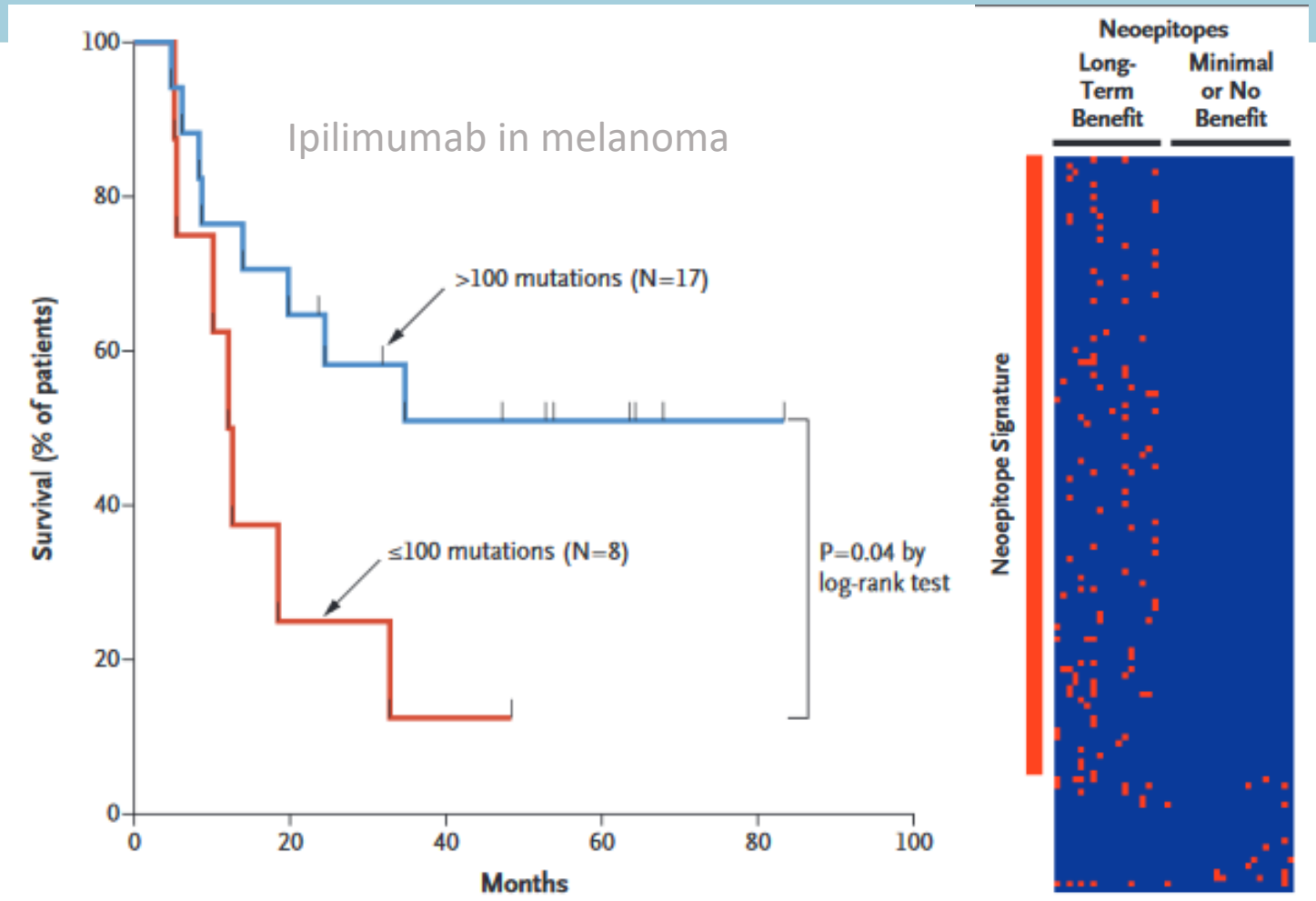
Arbour KC, et al. *J Clin Oncol*. 2018(28);36:2872-8.;
Coureau M, et al. *Front Med (Lausanne).* 2020;7:137.

Immunogenicity of Tumors



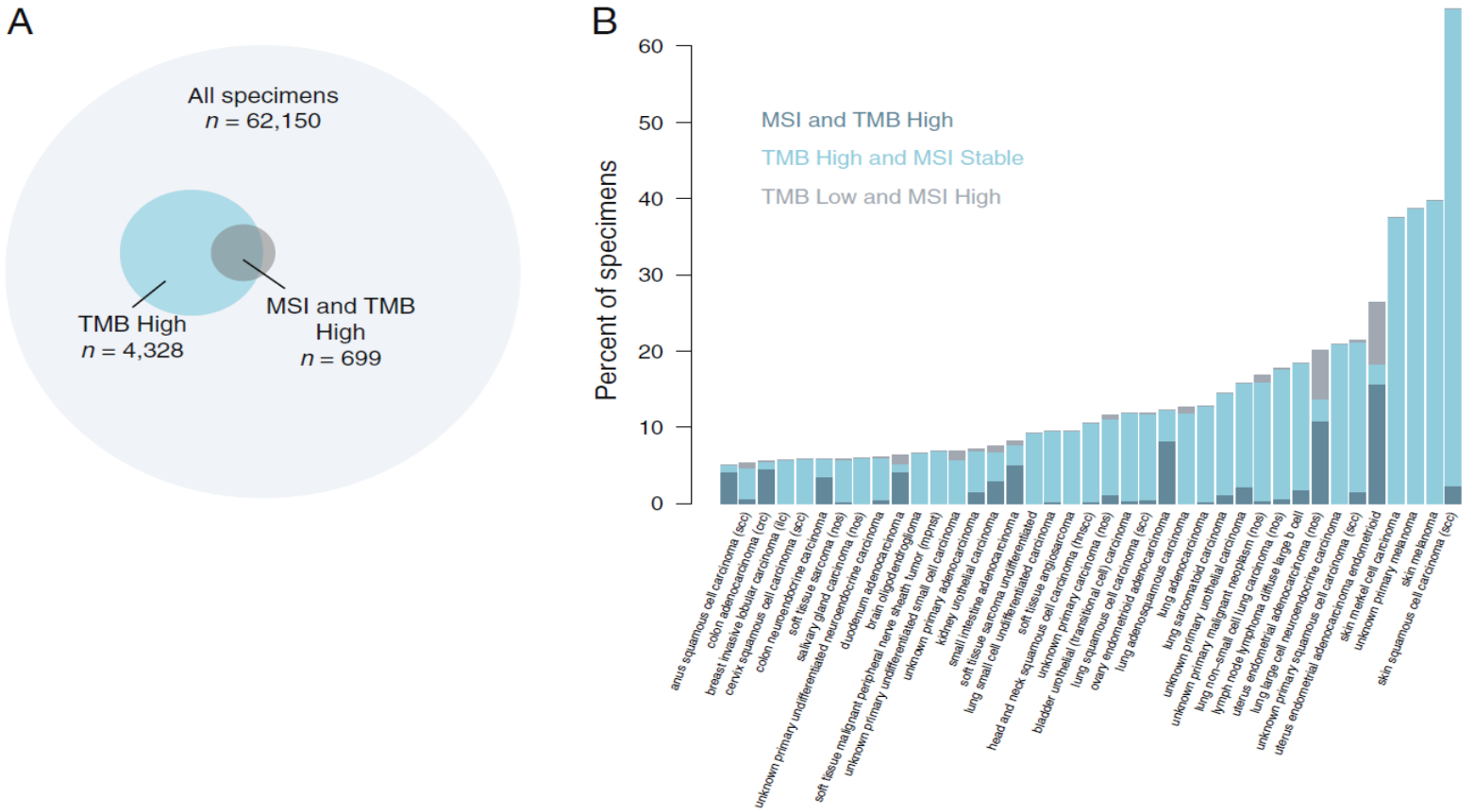
Lawrence MS, et al. *Nature.* 2013;499(7457):214-8.

Mutational Burden – Neoantigen



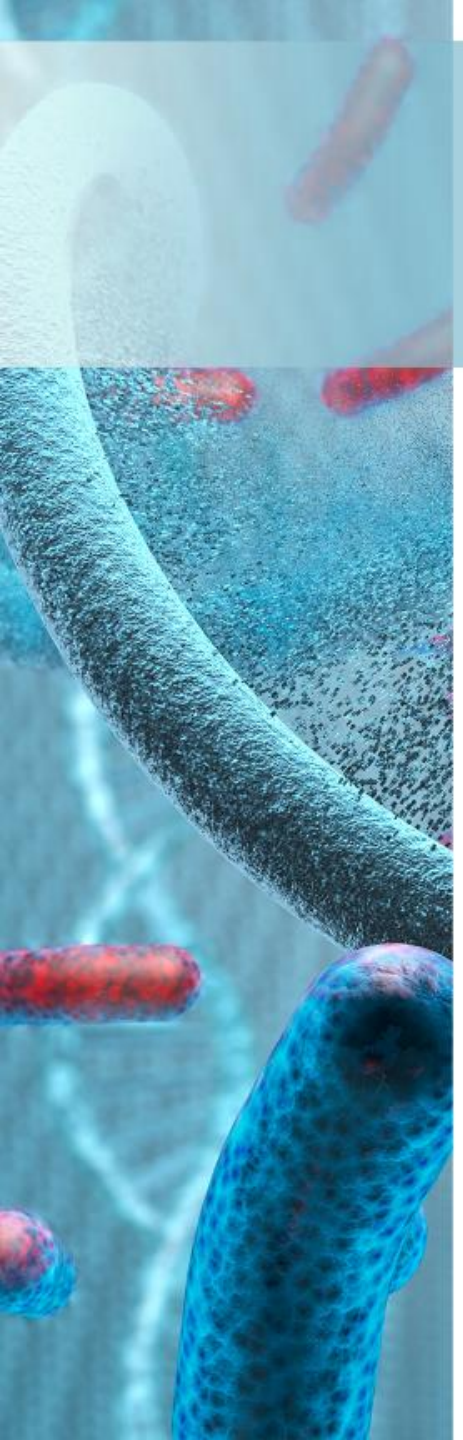
Snyder A, et al. *N Engl J Med*. 2014;371(23):2189-99.

Targeting Tumors on the Basis of Tumor Mutational Burden

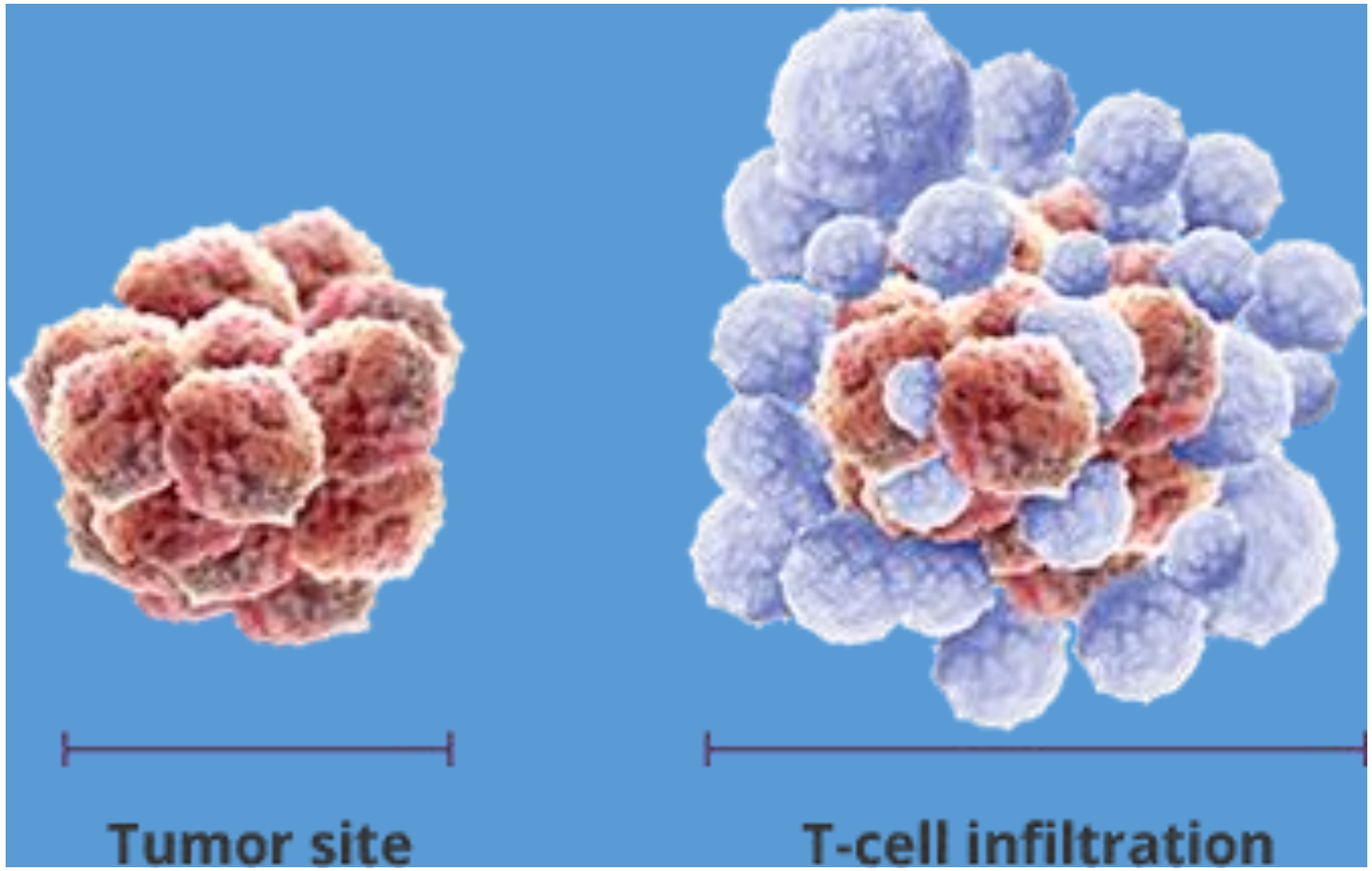


Chalmers ZR, et al. *Genome Med.* 2017;9(1):34.

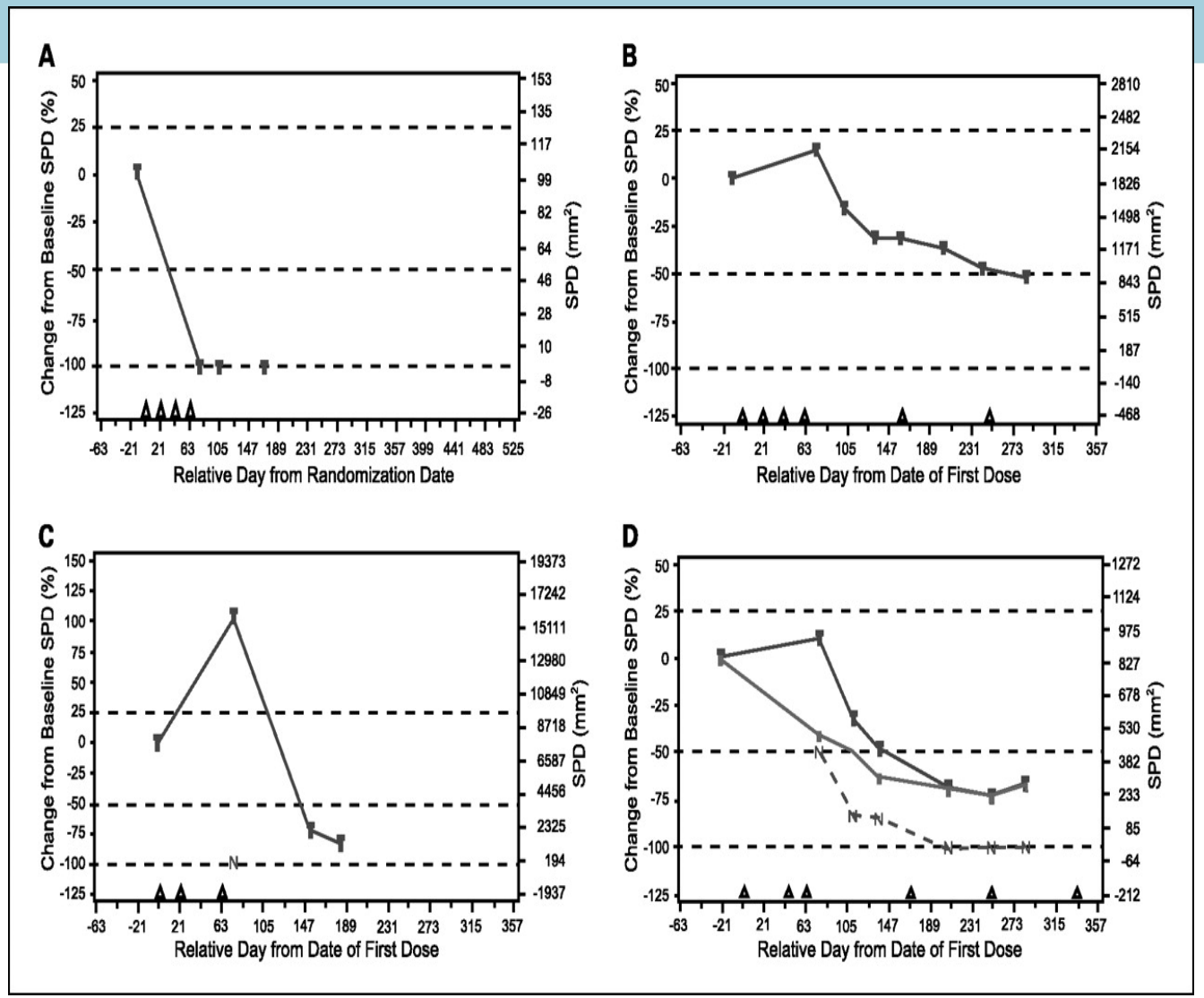
MSI, microsatellite instable;
TMB, tumor mutational burden.



Challenges: Pseudoprogression

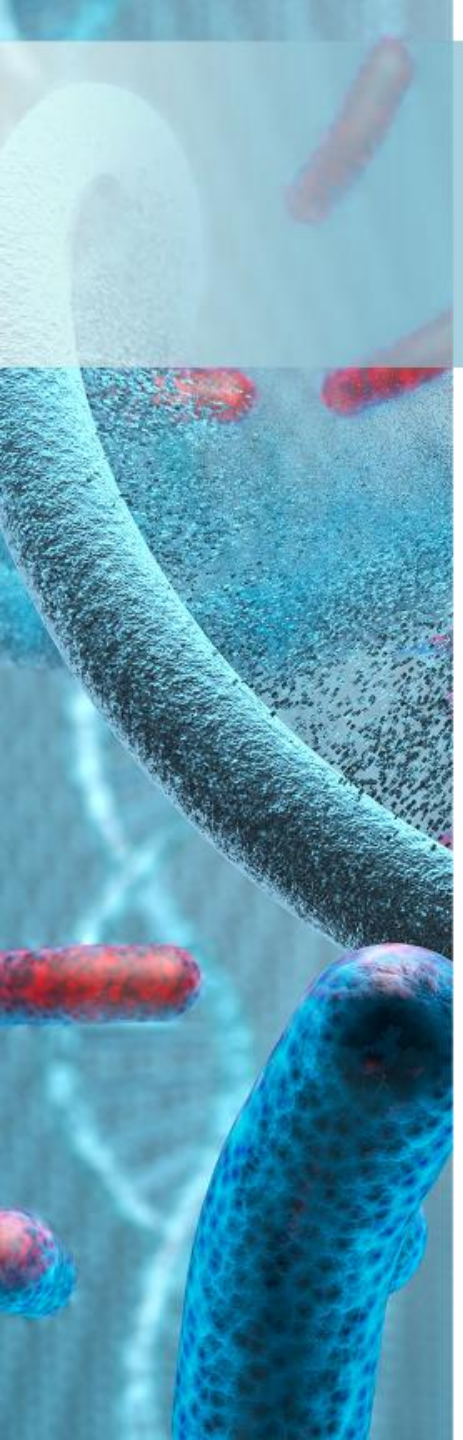


Patterns of Response to Ipilimumab Observed in Advanced Melanoma



Wolchok JD, et al. *Clin Cancer Res*. 2009;15(23):7412-20.
For educational purposes only.

SPD, sum of the product of perpendicular diameters.



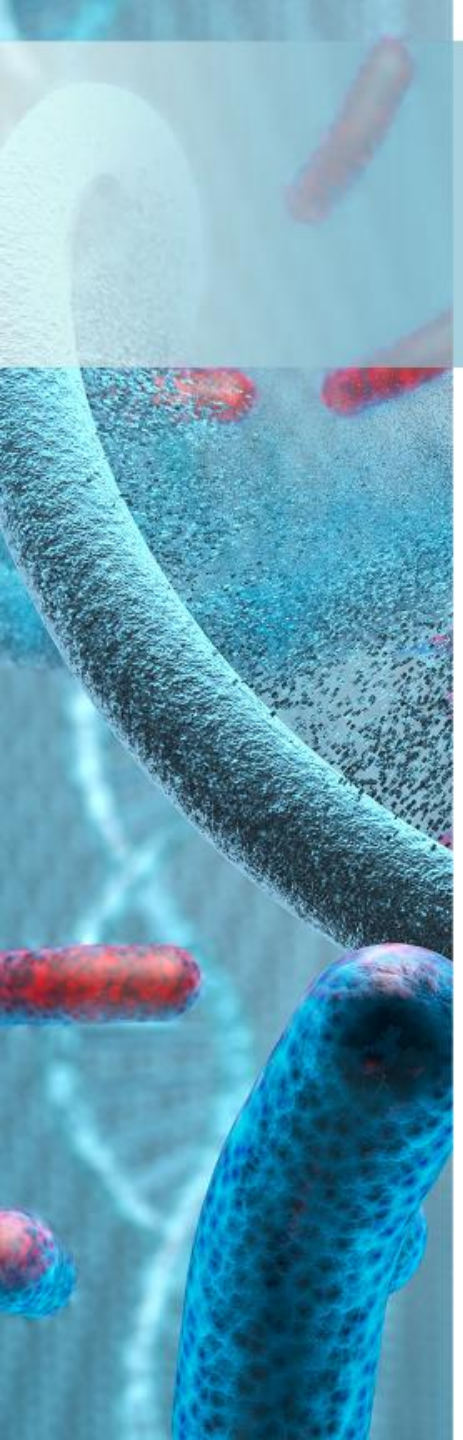
Immune-Related Response Criteria (iRECIST)

Comparison of RECIST 1.1 and iRECIST

	RECIST 1.1	iRECIST
Definitions of measurable and non-measurable disease; numbers and site of target disease	Measurable lesions are ≥10 mm in diameter (≥15 mm for nodal lesions); maximum of five lesions (two per organ); all other disease is considered non-target (must be ≥10 mm in short axis for nodal disease)	No change from RECIST 1.1; however, new lesions are assessed as per RECIST 1.1 but are recorded separately on the case report form (but not included in the sum of lesions for target lesions identified at baseline)
Complete response, partial response, or stable disease	Cannot have met criteria for progression before complete response, partial response, or stable disease	Can have had iUPD (one or more instances), but not iCPD, before iCR, iPR, or iSD
Confirmation of complete response or partial response	Only required for non-randomised trials	As per RECIST 1.1
Confirmation of stable disease	Not required	As per RECIST 1.1
New lesions	Result in progression; recorded but not measured	Results in iUPD but iCPD is only assigned on the basis of this category if at next assessment additional new lesions appear or an increase in size of new lesions is seen (≥5 mm for sum of new lesion target or any increase in new lesion non-target); the appearance of new lesions when none have previously been recorded, can also confirm iCPD
Independent blinded review and central collection of scans	Recommended in some circumstances —eg, in some trials with progression-based endpoints planned for marketing approval	Collection of scans (but not independent review) recommended for all trials
Confirmation of progression	Not required (unless equivocal)	Required
Consideration of clinical status	Not included in assessment	Clinical stability is considered when deciding whether treatment is continued after iUPD

"i" indicates immune responses assigned using iRECIST. RECIST=Response Evaluation Criteria in Solid Tumours. iUPD=unconfirmed progression. iCPD=confirmed progression. iCR=complete response. iPR=partial response. iSD=stable disease.

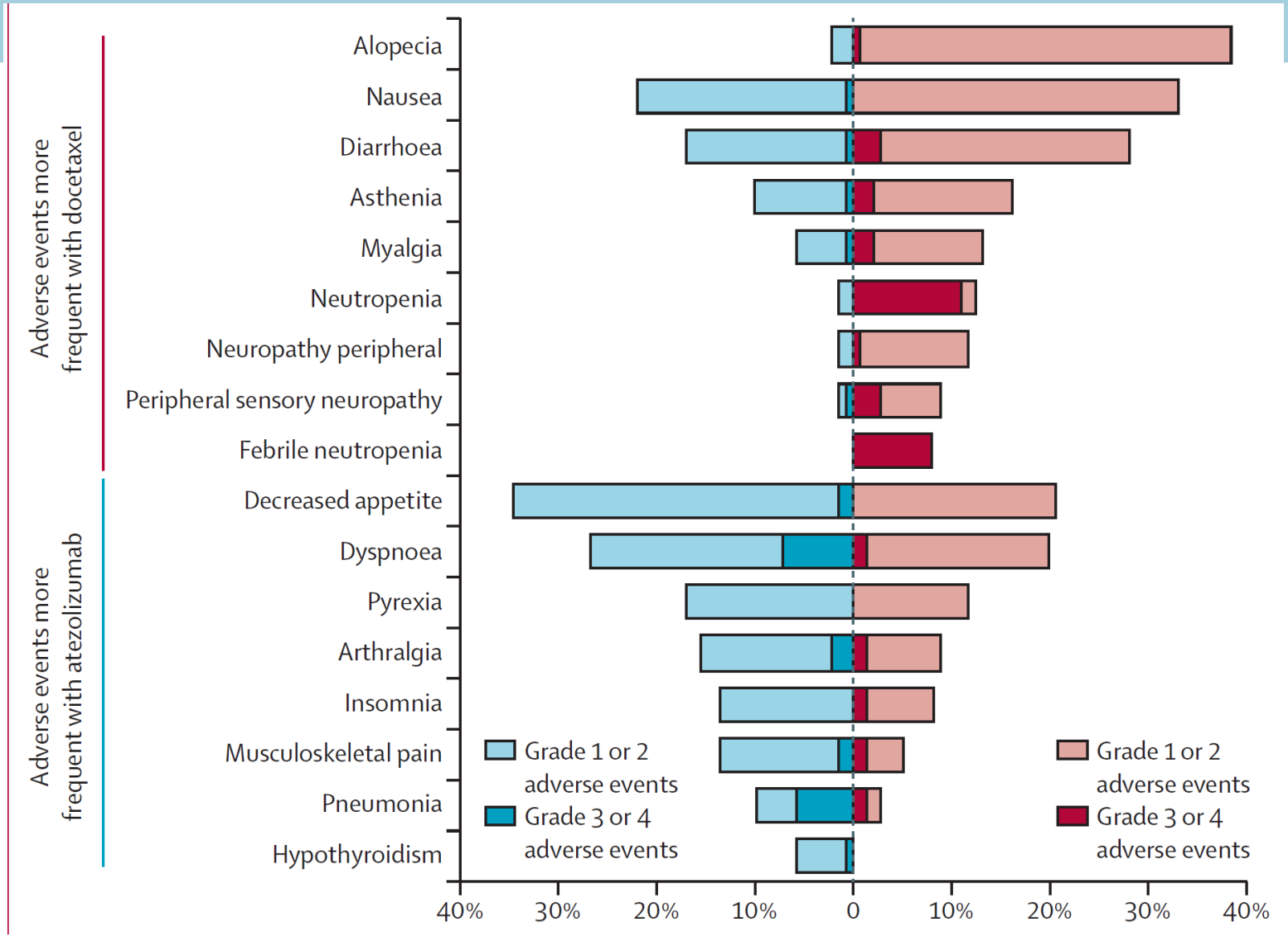
Seymour L, et al. *Lancet Oncol.* 2017;18(3):e143-52.



Altered Toxicity Profile

- Focus is immune-related adverse events (irAEs)
- Organs affected are similar
- Time relationship between immuno-oncology (IO) therapy and onset of toxicity is not apparent
- Delayed time to first toxic event
- Treat with steroids
- No dose reduction

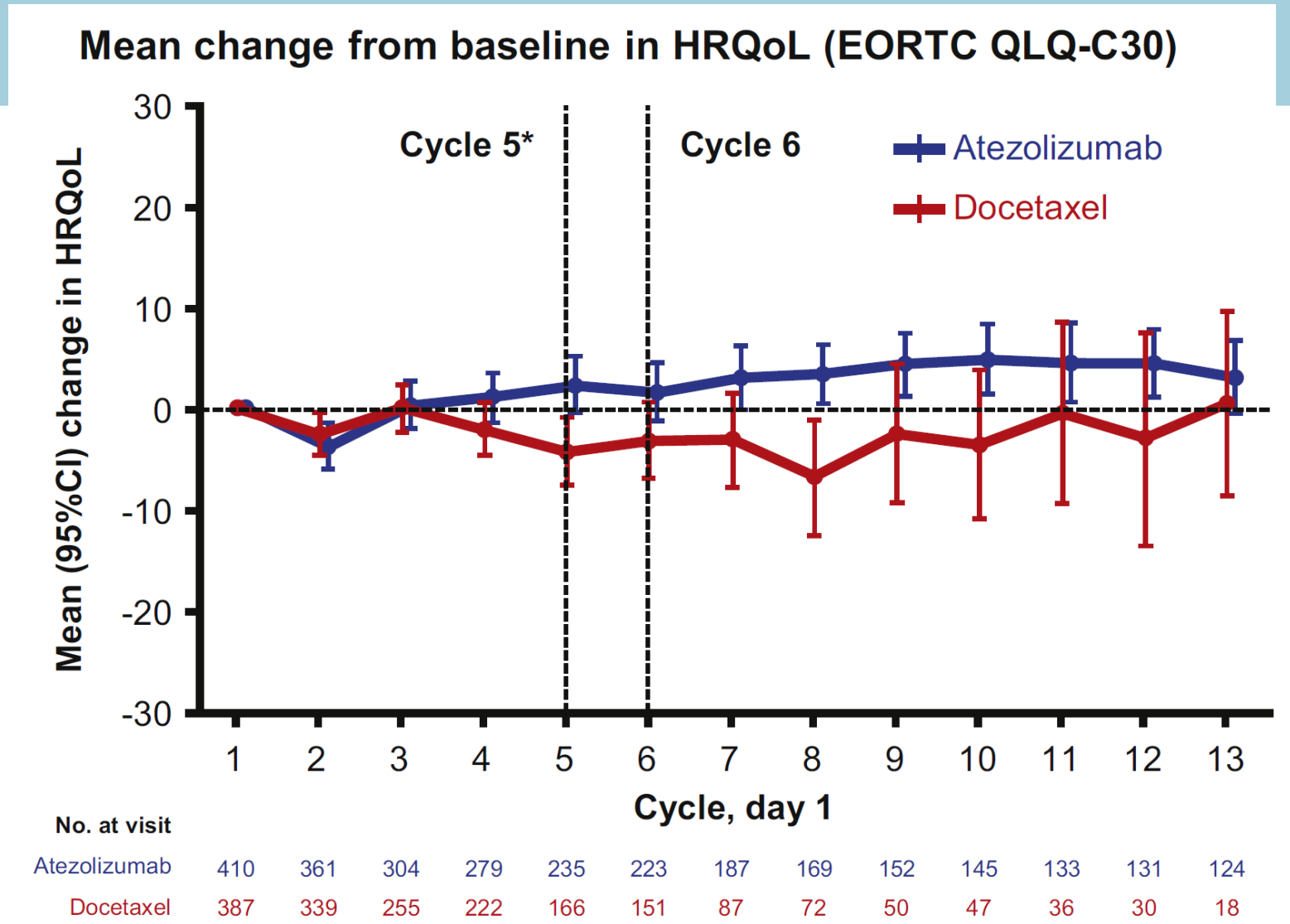
IO Toxicity Compared to Chemotherapy (NSCLC – Atezolizumab vs. Docetaxel)



Fehrenbacher L, et al. *Lancet*. 2016;387(10030):1837-46.

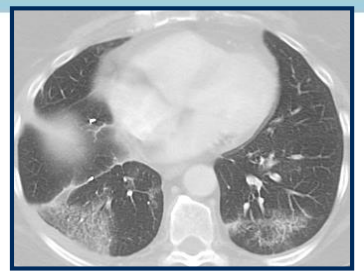
ALT, alanine aminotransferase;
AST, aspartate aminotransferase.

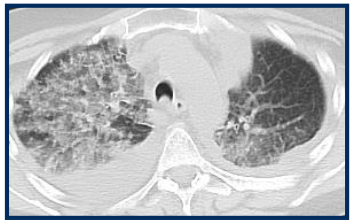
Health-Related Quality of Life vs. Chemotherapy

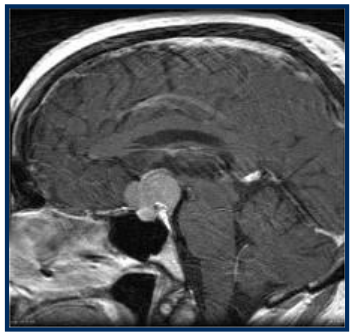


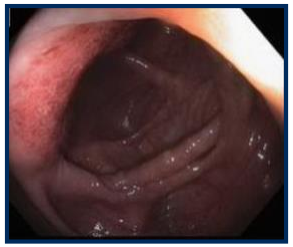
Bordoni R, et al. *Clin Lung Cancer.* 2018;19(5):441-9.

Immune-Related Adverse Events by System

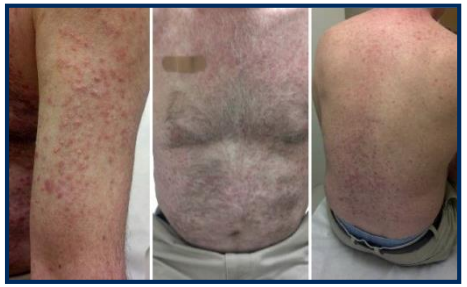


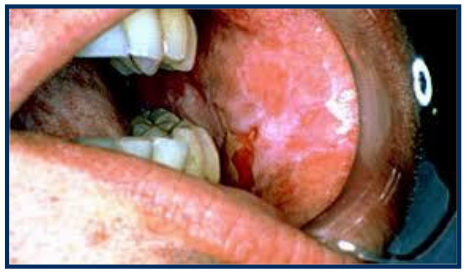


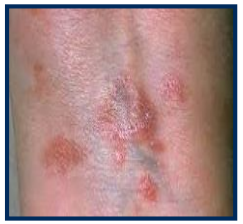


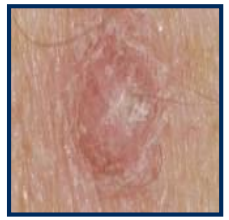


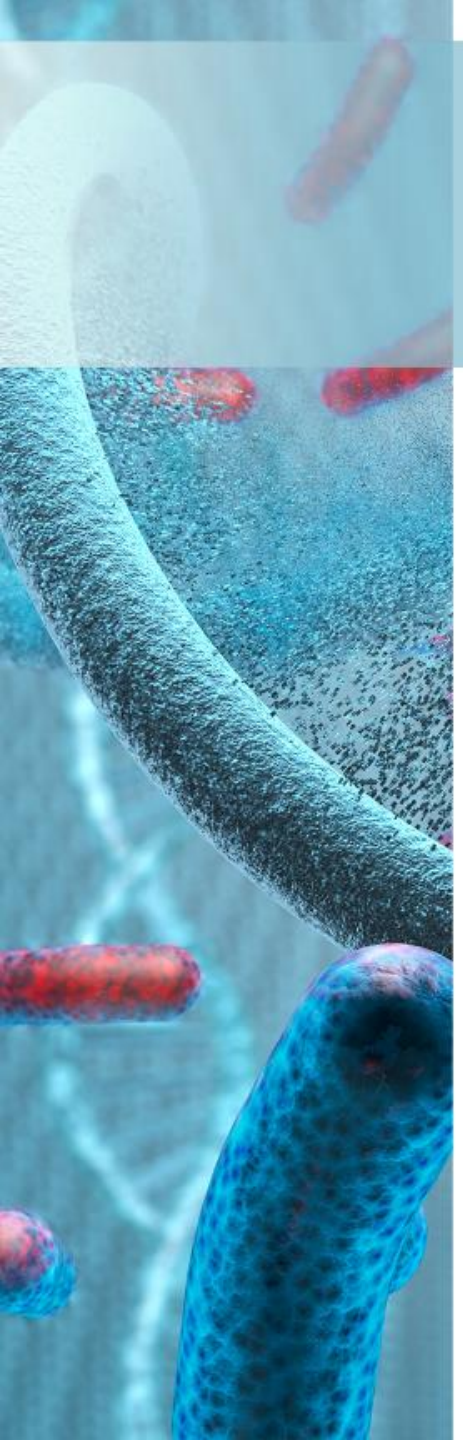
Pulmonary	Pneumonitis, respiratory failure
Endocrine	Thyroiditis, hypothyroidism, hyperthyroidism, hypophysitis, hypopituitarism, adrenal insufficiency
Cardiac	Pericarditis, myocarditis, vasculitis
GI	Nausea, colitis, perforation, pancreatitis
Heme	Red cell aplasia, pancytopenia, autoimmune neutropenia
Ocular	Uveitis, iritis, conjunctivitis, scleritis, blepharitis
Skin	Vitiligo, pruritus, rash, lichenoid deposits
Liver	Transaminitis, hepatitis
Kidney	Nephritis, renal insufficiency
Musculoskeletal	Arthralgias, myalgias
Neurologic	Neuropathy, meningitis, Guillain-Barré syndrome, myasthenia gravis, temporal arteritis











JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Clinical Practice Guideline

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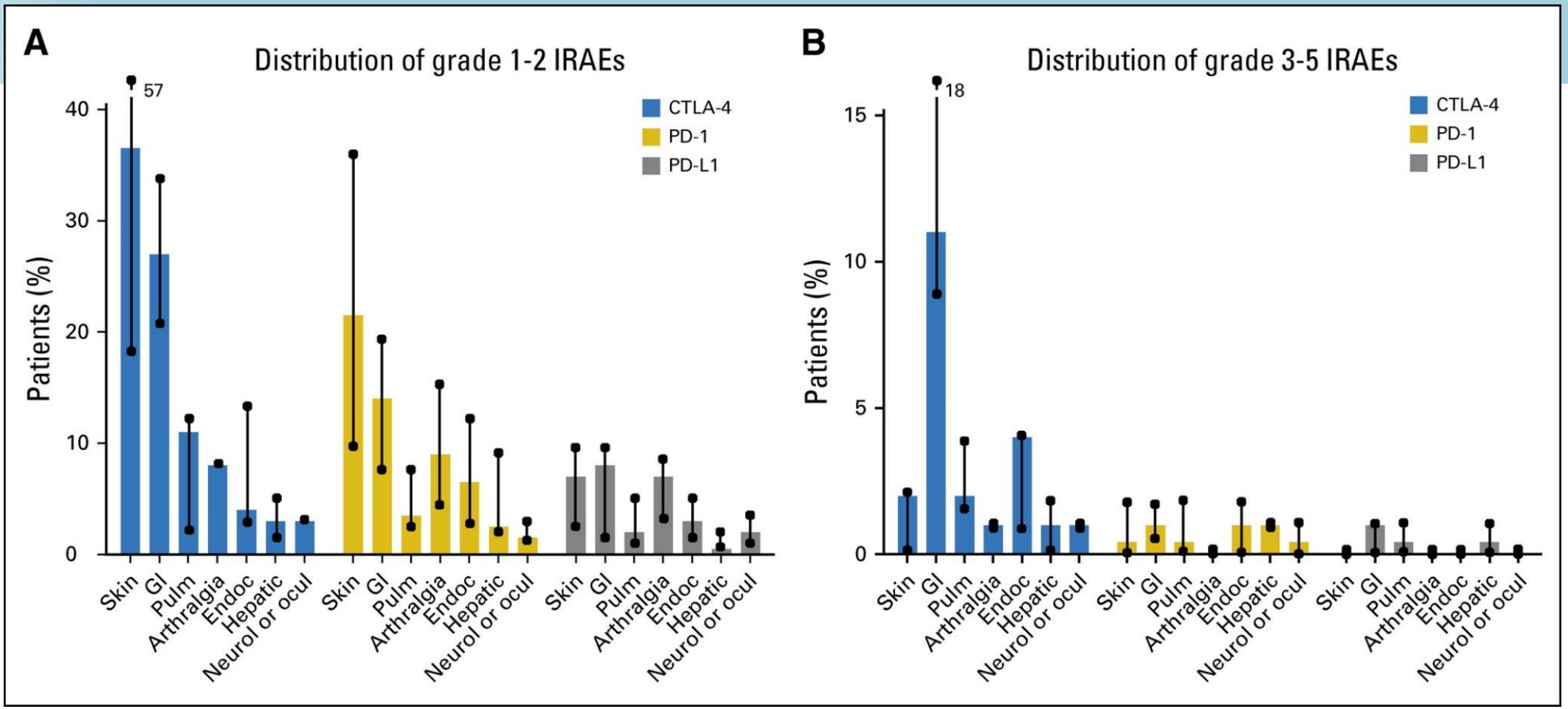
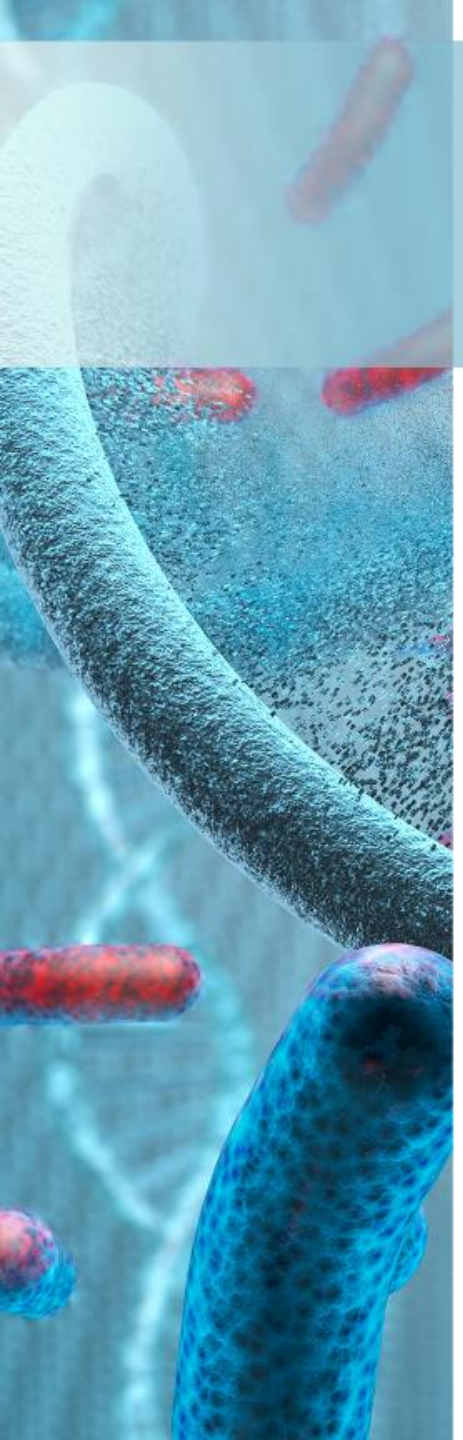
Checkpoint Inhibitor Toxicity

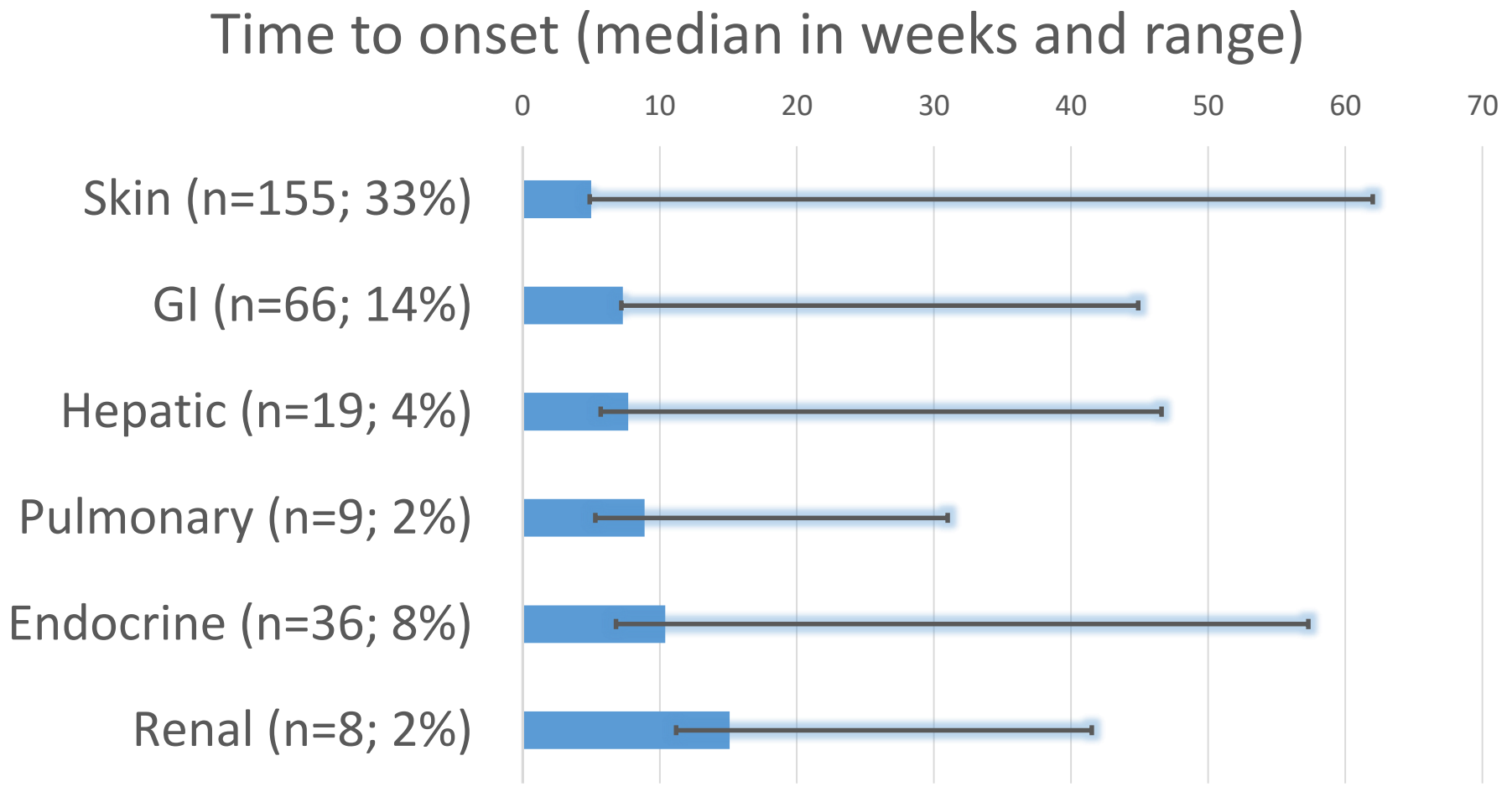


Distribution of (A) grade 1 to 2 and (B) grade 3 to 5 irAEs for all tumor types in the main clinical trials with anti–CTLA-4, anti-PD-1, or anti–PD-L1 antibodies as single therapies. The values quoted are the median (range) irAE rates for the set of clinical trials as a whole. Adapted from Michot JM, et al. Eur J Can. 2016;54:139-49.

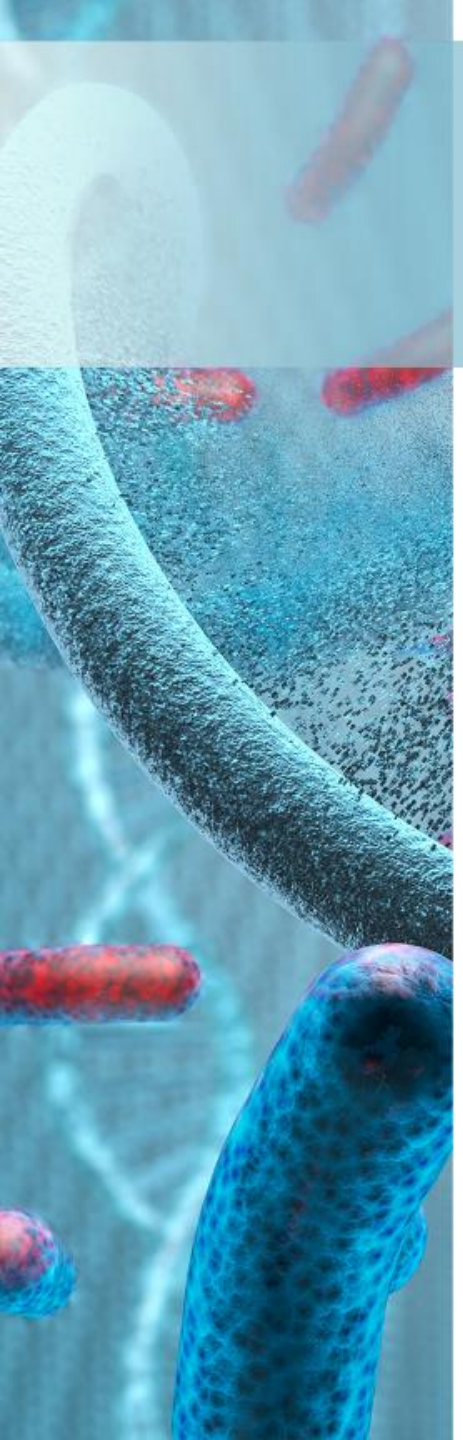
Endoc, endocrine; GI, gastrointestinal; Neurol, neurological; Ocul, ocular; Pulm, pulmonary.



Immune-Related Toxicity



Wolchok JD, et al. *J Clin Oncol*. 2015;33:Abst LBA1.



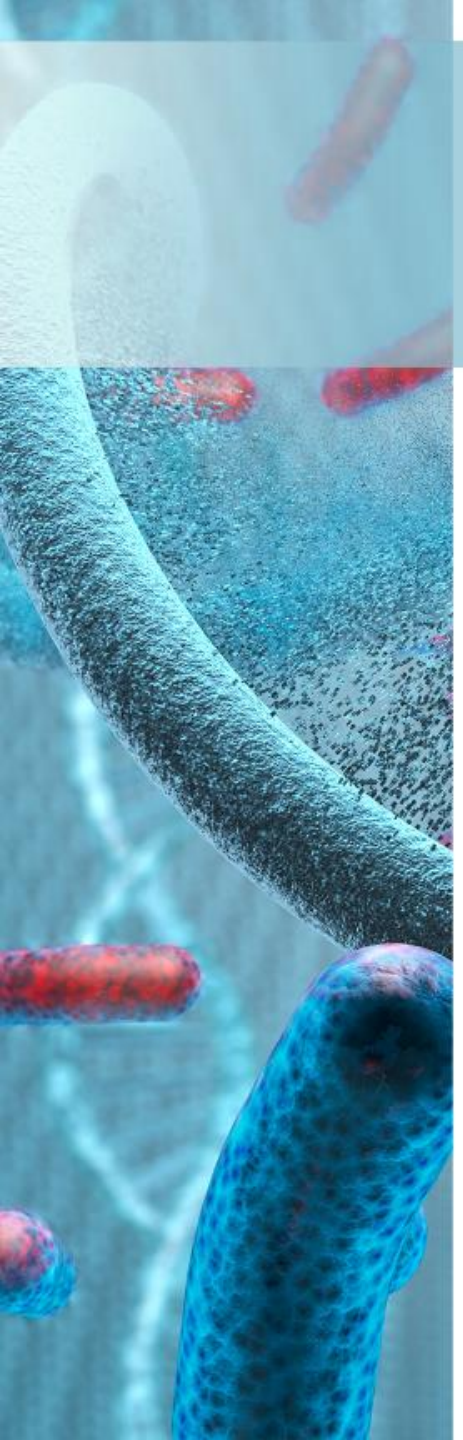
General Management

Grade 1	Grade 2	Grade 3	Grade 4
Contine ICPi Monitor for symptoms every 2-3 days	Suspend ICPi Consider restarting when grade 1 Corticosteroids may be started (Pred or MethylPred 0.5 mg/kg)	Suspend ICPi, Start high-dose corticosteroids (Pred or MethylPred 1-2 mg/kg; taper over 4-6 weeks) Additional immune suppression for refractory patients	Discontinue therapy Hospitalize Start high-dose corticosteroids (Pred or MethylPred 1-2 mg/kg; taper over 4-6 weeks) Additional immune suppression for refractory patients

See organ-specific recommendations

www.asco.org/supportive-care-guidelines. Accessed February 16, 2018.

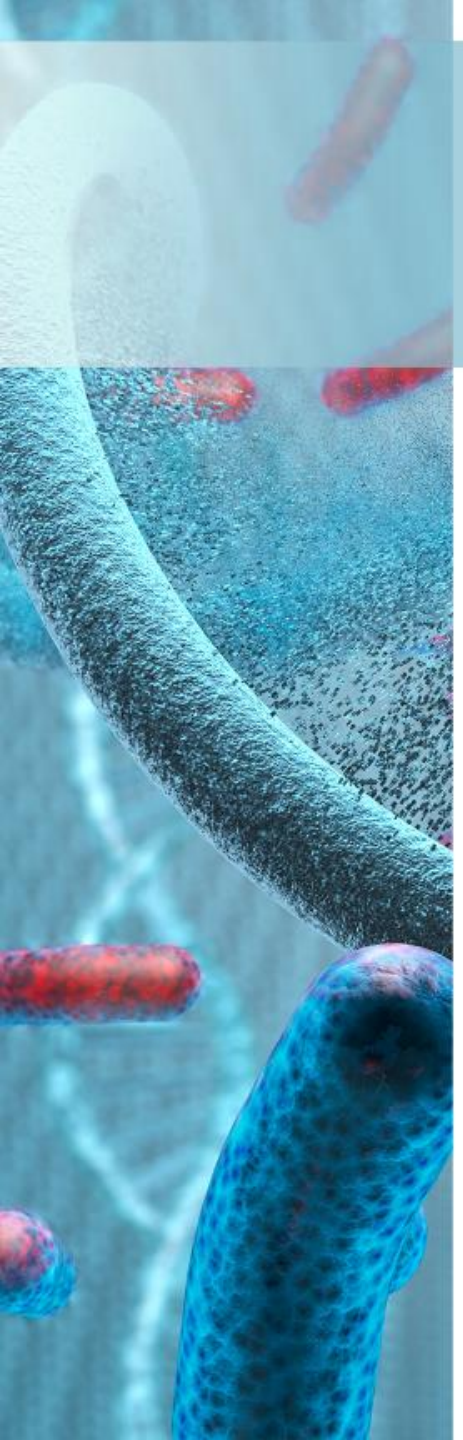
ICPi, immune checkpoint inhibitor; MethylPred, methylprednisolone; Pred, prednisone.



Financial Toxicity

- Survey study of 105 patients receiving immunotherapy
- 48% were aware of financial difficulty
- 34% had pre-treatment finance discussion
- Difficulties:
  - 35% high medical co-pay
  - 33% decrease in income
  - 21% high medication co-pay
- Addressing the difficulties
  - 39% used personal finances
  - 28% trimmed private expenses
  - 24% got help from family and friends

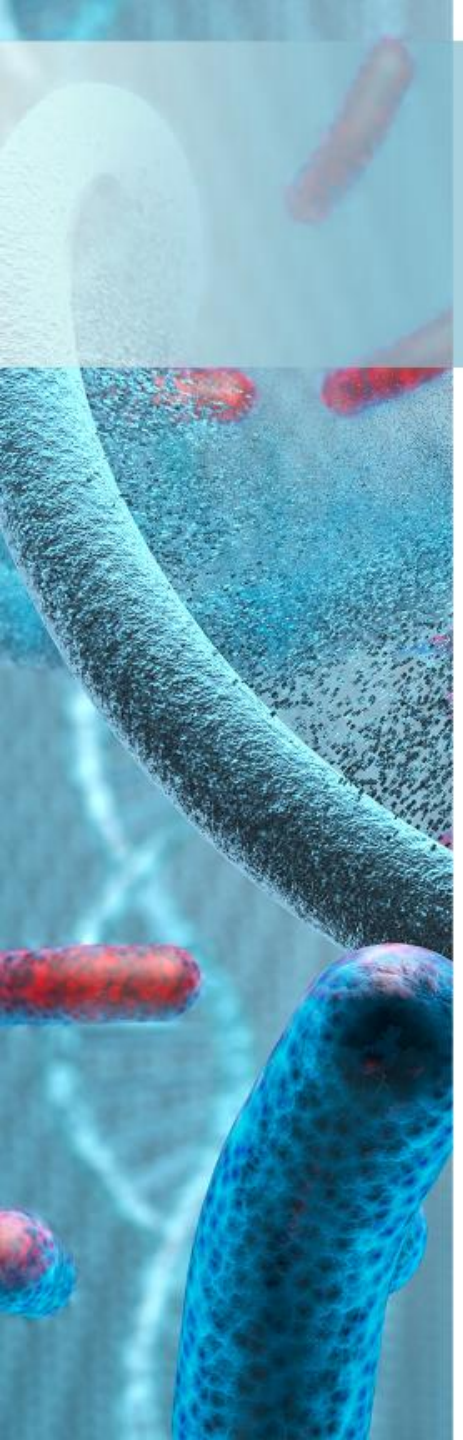
Vorobiof DA, et al. *J Clin Oncol*. 2020;38(suppl 5):abstr 90.



Patient and Family Education

- Time to response from checkpoint inhibitors differs from standard therapy
  - Response in baseline lesions
  - Stable disease with slow decline in tumor volume
  - Response following initial increase in tumor volume or new lesion
  - Patients may develop signs of disease progression after treatment
    - Sudden and painful increase in tumor size, rash, low-grade fever, bone pain
    - Treatment can continue through this disease “pseudoprogression”

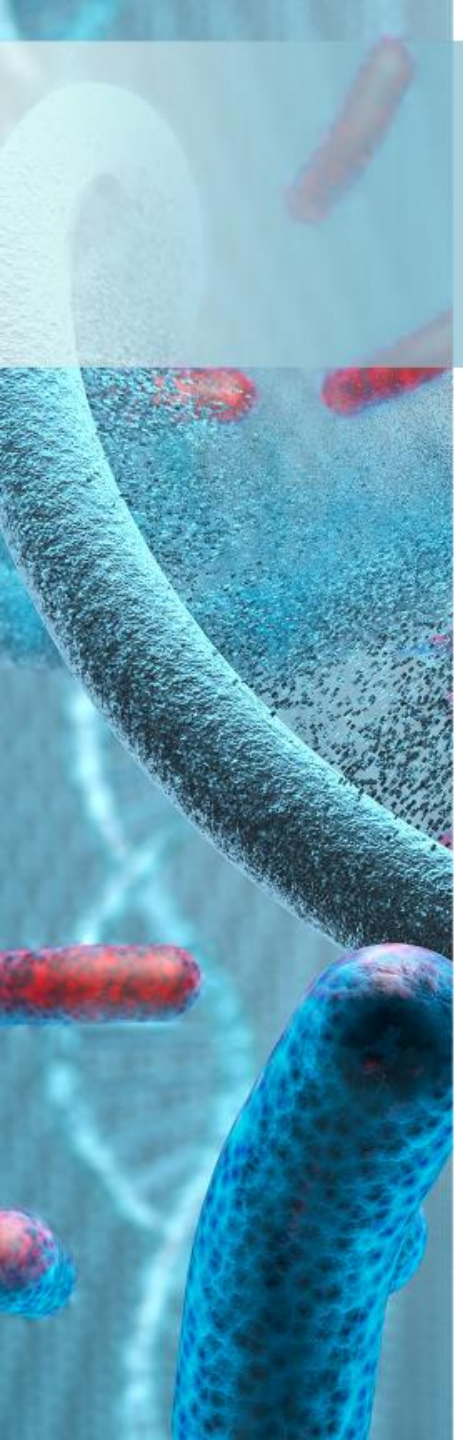
Wood LS, et al. *Clin J Oncol Nurs.* 2019;23(3):271-80.



Patient and Family Education

- Different AE profile than chemotherapy
- Early recognition of AEs is essential to effective treatment
- Patients must notify their care provider if symptoms develop or they are admitted to local facility
- irAEs are related to the mechanism of action of immunotherapies
- irAEs are treatable and respond well to steroids

AE, adverse event.



Communication Tool

IMMUNOTHERAPY WALLET CARD

NAME: _____

CANCER DX: _____

I-O AGENTS RCV'D: ☐ CHECKPOINT INHIBITOR(S)

☐ CAR-T ☐ VACCINES ☐ ONCOLYTIC VIRAL THERAPY

☐ MONOCLONAL ANTIBODIES

DRUG NAME(S): _____

IMMUNOTHERAPY TX START DATE: _____

OTHER CANCER MEDICATIONS: _____

*NOTE: IMMUNOTHERAPY AGENTS ARE **NOT** CHEMOTHERAPY AND SIDE EFFECTS MUST BE MANAGED DIFFERENTLY. (SEE BACK)*

ONS Oncology Nursing Society

IMMUNOTHERAPY CARD

IMMUNE-MEDIATED SIDE EFFECTS*, COMMON WITH CHECKPOINT INHIBITORS VARY IN SEVERITY AND MAY REQUIRE REFERRAL AND STEROIDS. PATIENTS HAVE A LIFETIME RISK OF IMMUNE-RELATED SIDE EFFECTS.

**MAY PRESENT AS RASH, DIARRHEA, ABDOMINAL PAIN, COUGH, FATIGUE, HEADACHES, VISION CHANGES, ETC.– CONFER WITH ONCOLOGY TEAM BEFORE CHANGING I-O REGIMEN OR STARTING SIDE EFFECT TREATMENT.*

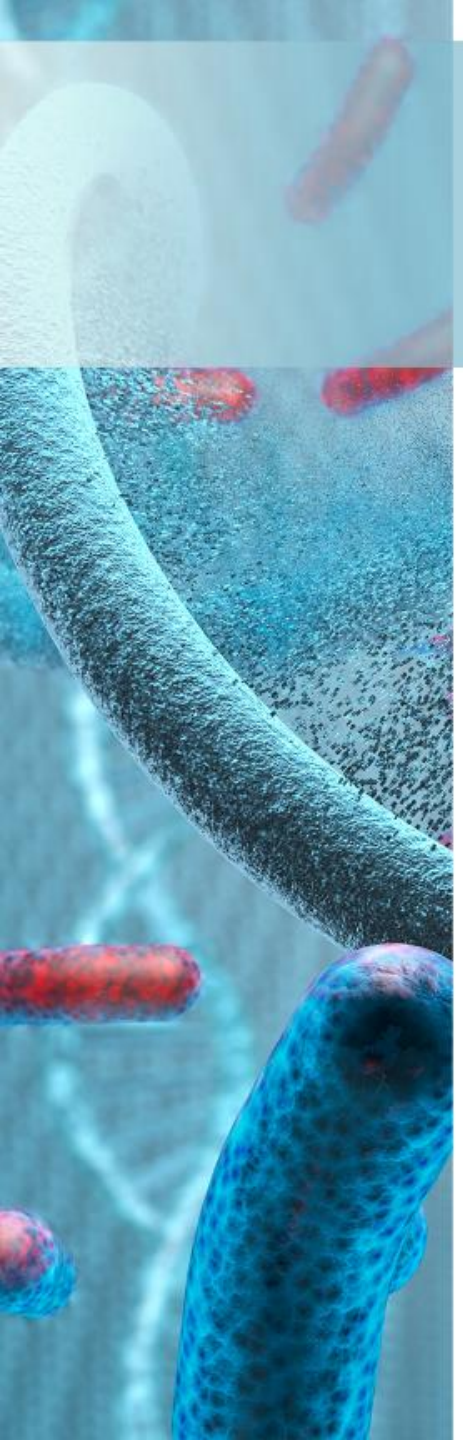
ONCOLOGY PROVIDER NAME _____

ONCOLOGY PROVIDER NO. _____

EMERGENCY CONTACT _____

CONTACT PHONE NO. _____

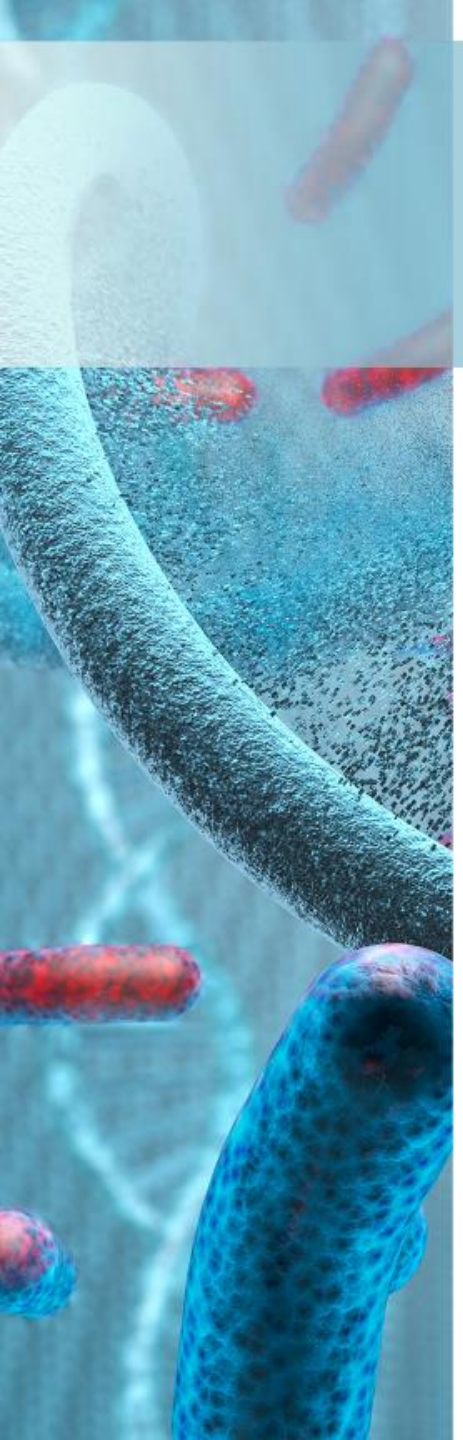
www.asco.org/supportive-care-guidelines. Accessed February 16, 2018.



Strategies to Manage IO Toxicity and Care Coordination

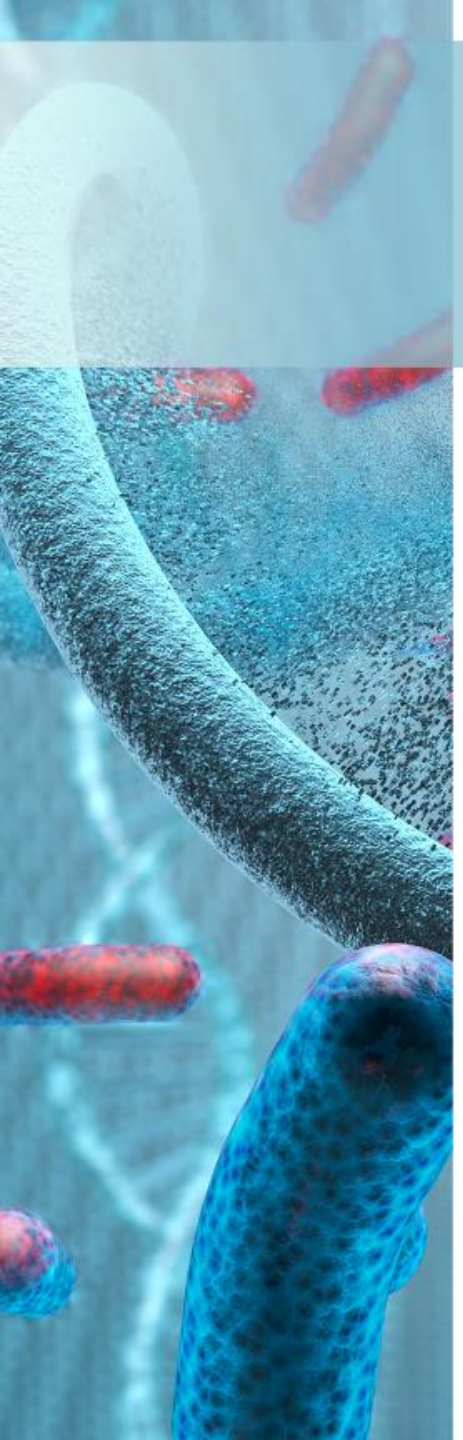
- Educate patients who have received or are receiving immunotherapy about who to call for toxicity issues
- Continuously educate providers, patients/caregivers, and non-clinical staff
- Triage patients on the basis of symptoms
- Developing same-day care models (e.g., via “quick clinics” or a symptom-management workspace)
- Establish standard of practice guidelines for irAE management

Association of Community Cancer Center 2017-2018: IMMUNO-ONCOLOGY: Transforming the Delivery of Cancer Care in the Community.



Finances of IO Therapy

- Typically injectables are under medical benefit
- Payers limited in ability to manage costs
- Tools commonly in place:
  - Prior authorization



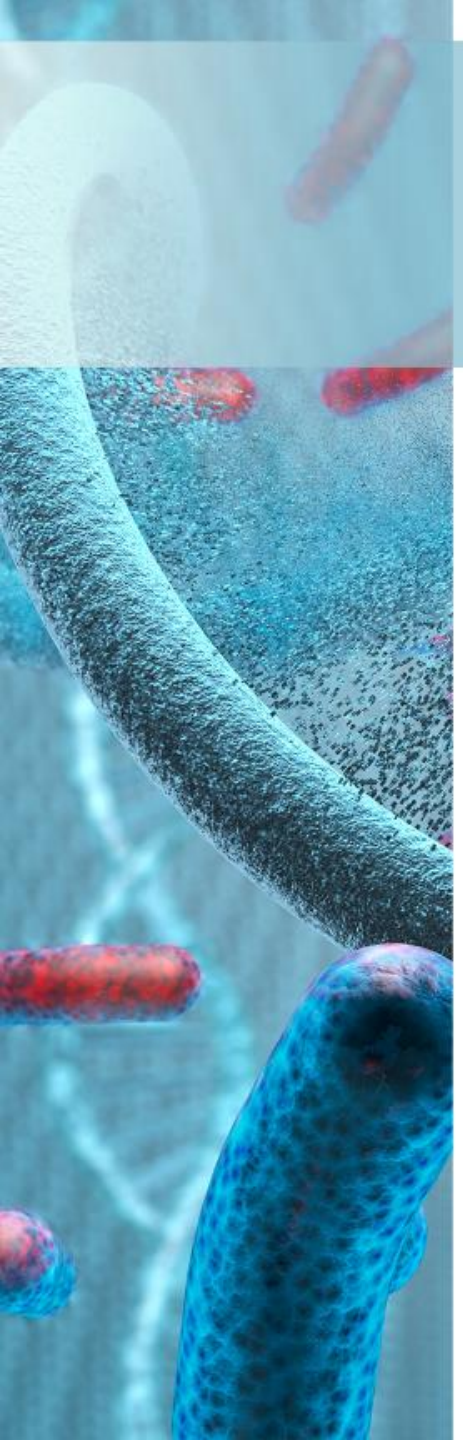
Patient G.W.

- 71 yo patient with metastatic bladder cancer who has received ~12 months of immunotherapy
- Current LABS:

142 | 104 | 12
---<100 Ca: 9.7
4.0 | 26 | 0.73

WBC: 7.17 / Hb: 12.6 / Hct: 39.3 / Plt: 233

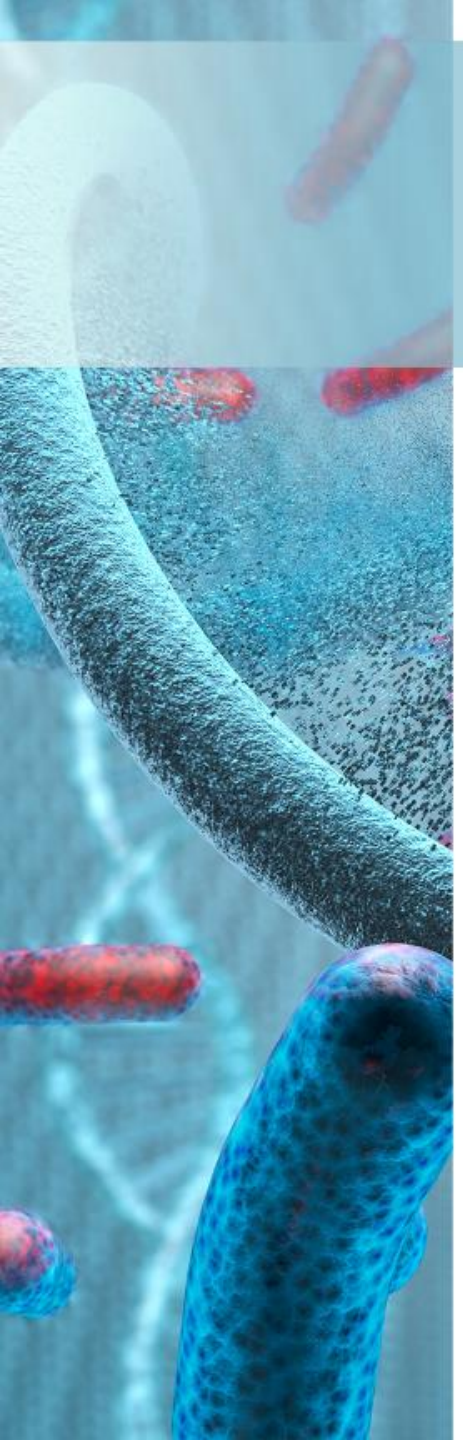
AST: 22 / ALT: 18 / AlkPhos: 97 / Bili: 0.3 / Prot: 6.5 / Alb: 3.3



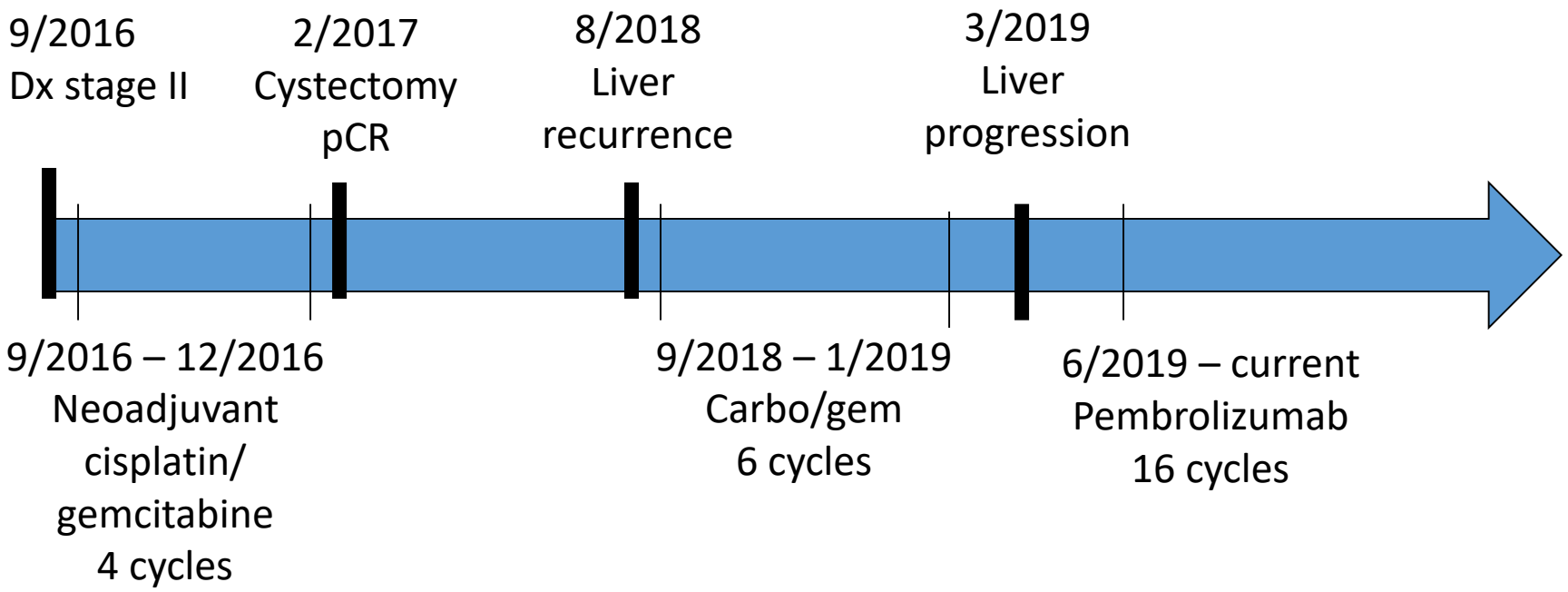
Patient G.W. – Medical History

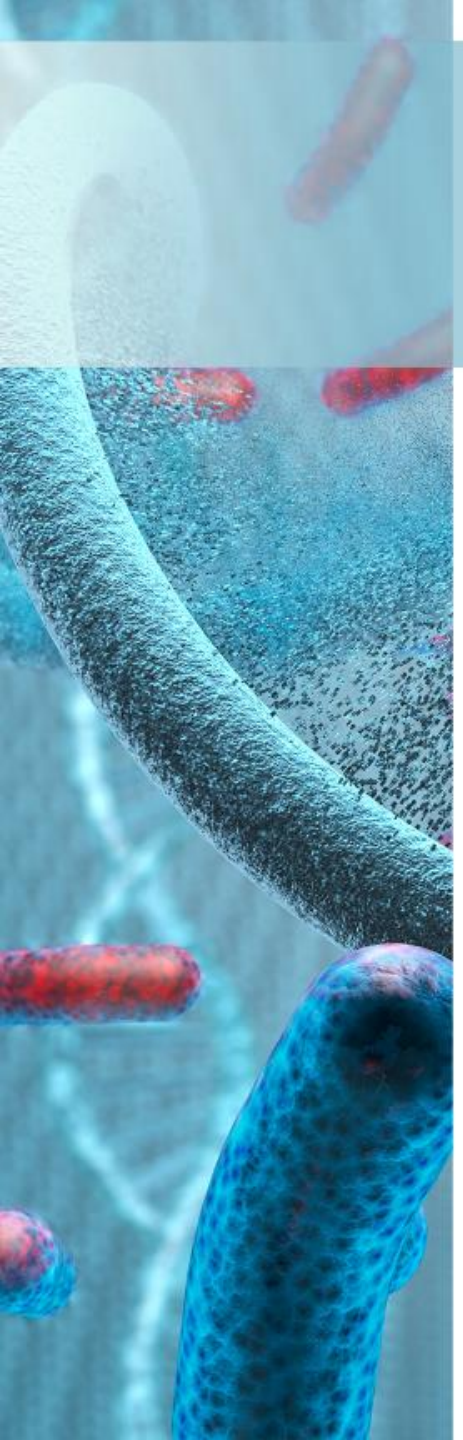
Problem	Status
Bladder cancer	Stable disease on pembrolizumab
Giant cell arteritis	Controlled on prednisone
Bilateral hip pain – trochanteric bursitis	Topical treatment, bedtime ibuprofen, past intrabursal injection of steroid – pain much better
Cancer-related pain	Taken off narcotics – pain resolved
Thyroid	TSH low, clinically euthyroid – f/u lab normal

TSH, thyroid-stimulating hormone.



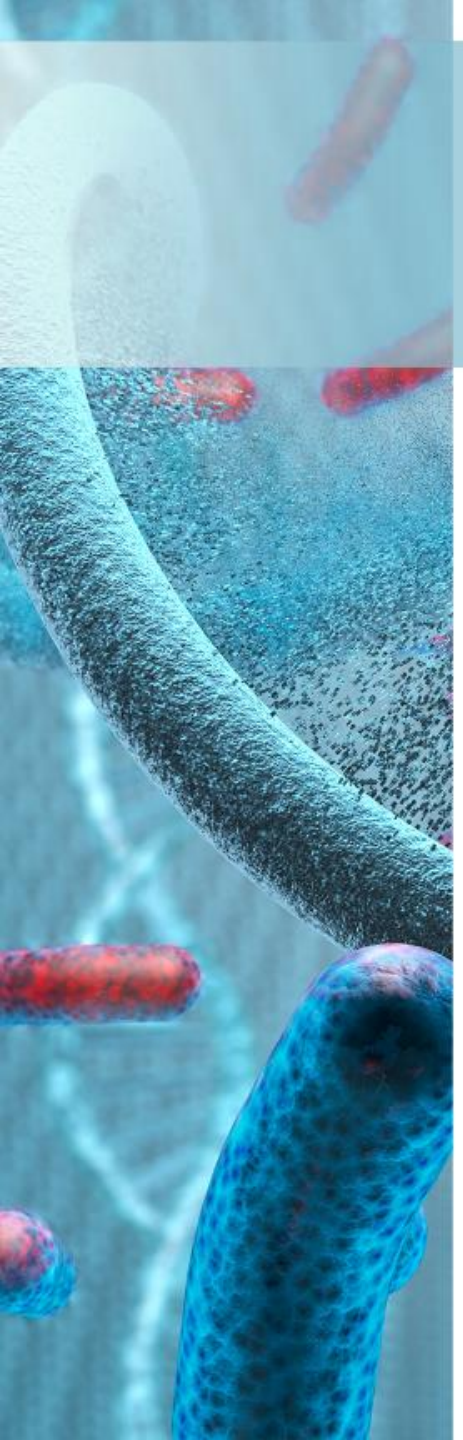
Patient G.W. – Cancer History



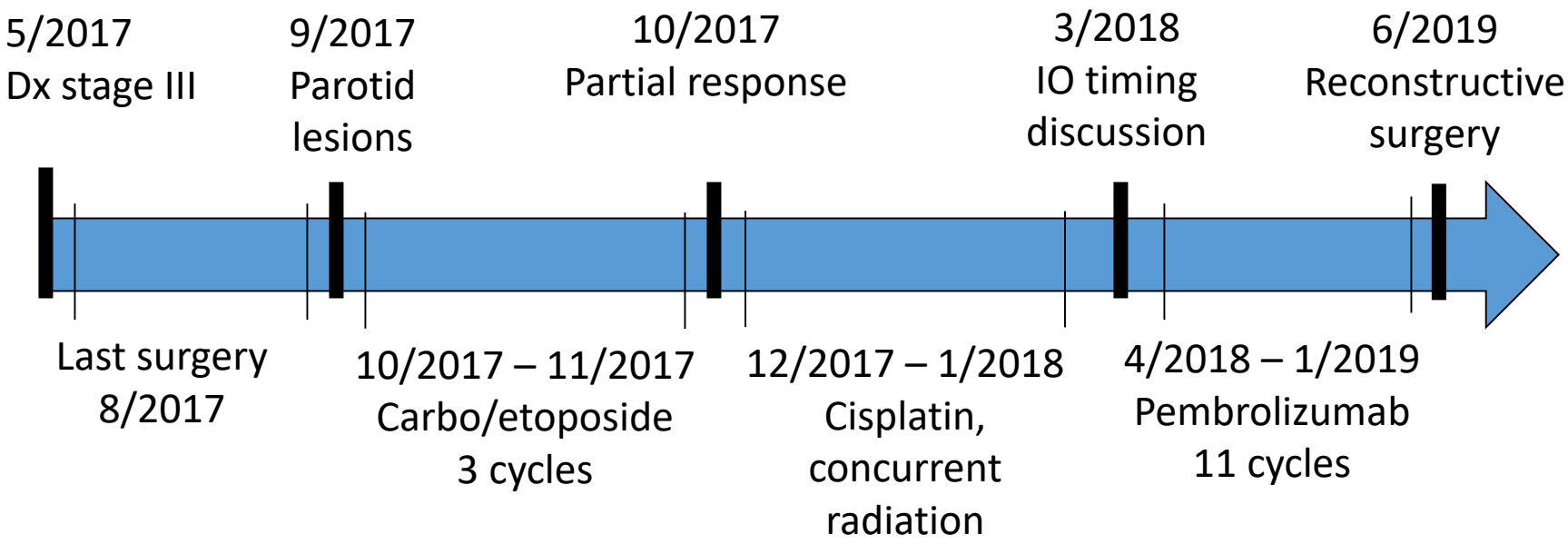


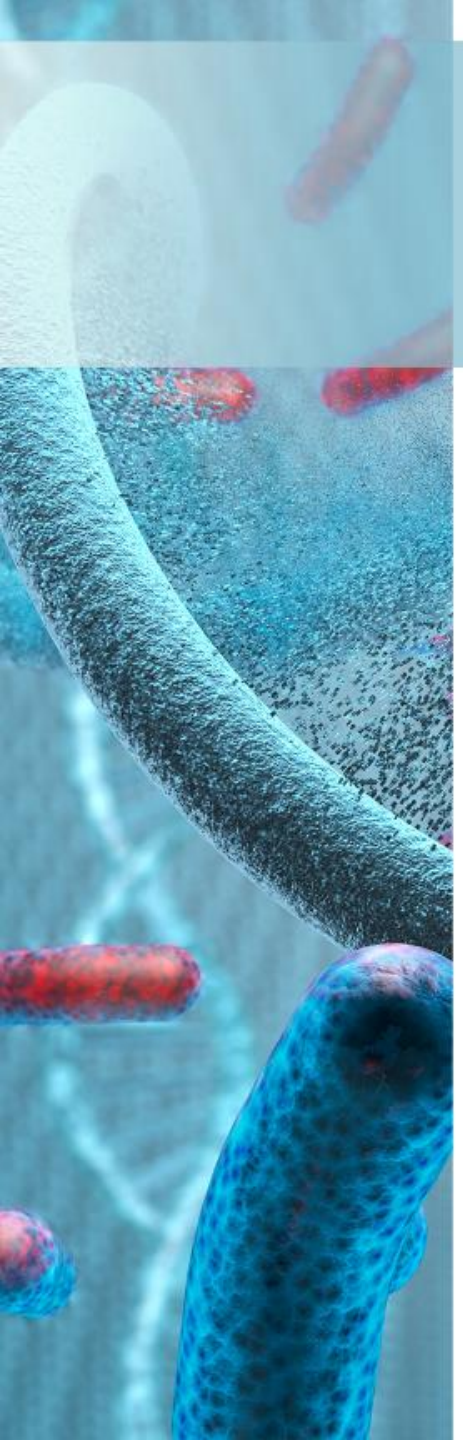
Patient J.S.

- 61 yo patient with Merkel Cell cancer who has received ~9 months of immunotherapy
- History: Initially started in his nasal passageway and submandibular mass that was surgically removed. Then, a month later, enlarged parotid glands represented new disease.



Patient J.S. – Cancer History





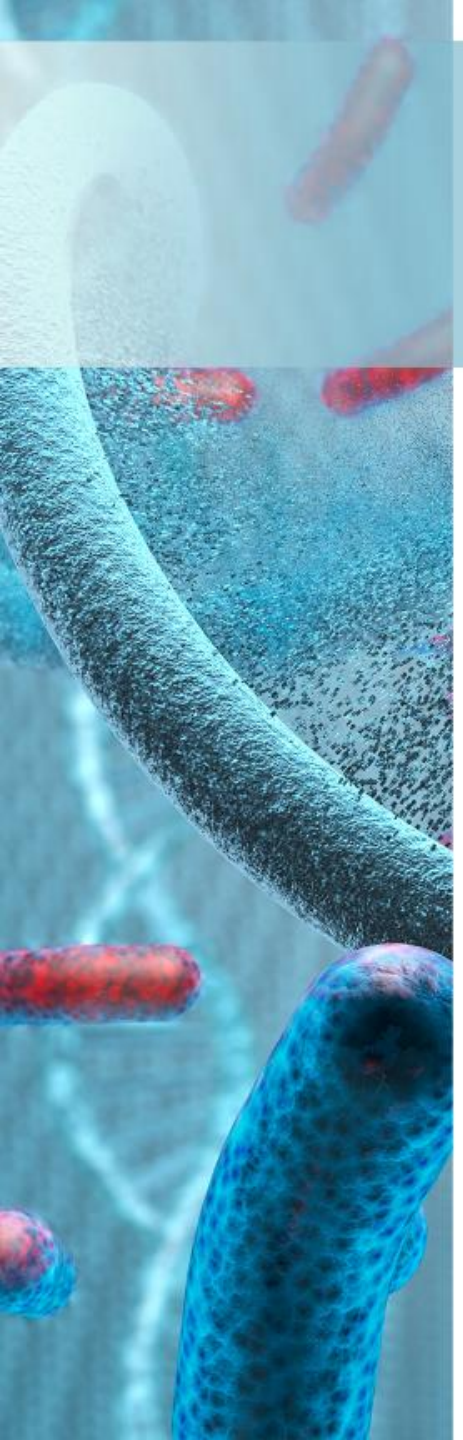
Patient J.S. – Current Medications

Outpatient Medication/Rx Writer:

PILOCARPINE HCL TABS 5MG: TAKE 1 TABLET THREE TIMES A DAY
ALPRAZolam 0.5 mg oral tablet: 1 tab(s) orally 2 times a day, As Needed -PRN anxiety
Atrovent 21 mcg/inh nasal spray: 2 spray(s) nasal once (at bedtime)
baclofen 10 mg oral tablet: 1 tab(s) orally 2 times a day
finasteride 5 mg oral tablet: 1 tab(s) orally once a day
traZODone 50 mg oral tablet: 1 orally once a day
Levitra 20 mg oral tablet: 1 tab(s) orally once a day
hydroCHLOROthiazide 25 mg oral tablet: 1 tab(s) orally once a day
salsalate 750 mg oral tablet: 1 tab(s) orally 2 times a day
amLODIPine 10 mg oral tablet: 0.5 tab(s) orally once a day

Allergy, Intolerance, Adverse Event:

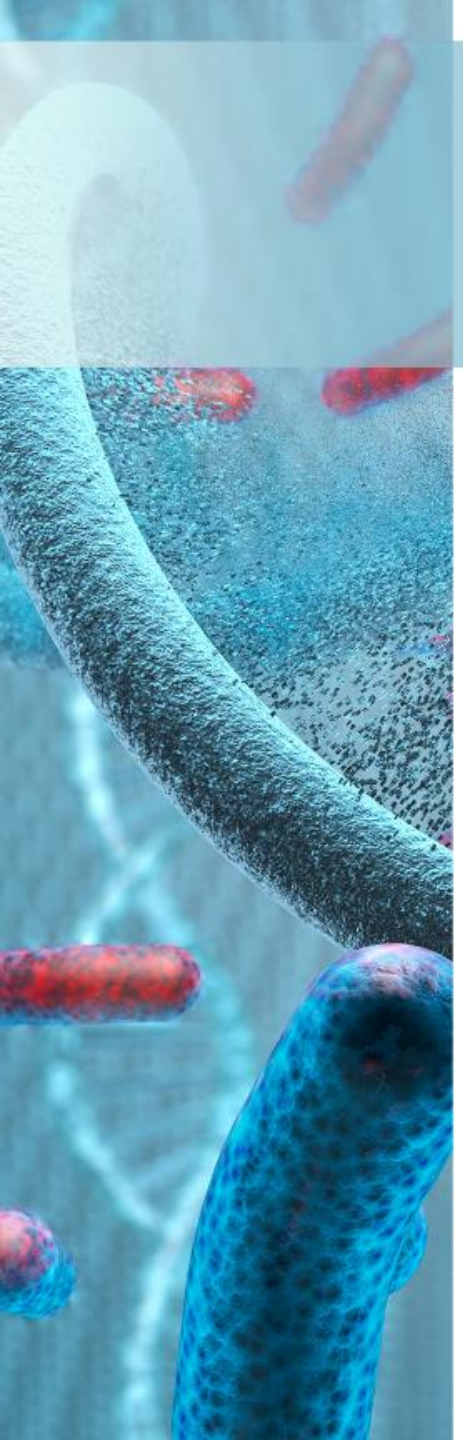
No Known Allergies:



Patient-Directed Questions

- Can you give us a summary of your cancer journey?
  - From an emotional standpoint, what has been the most challenging part of the journey?
  - What types of treatment have you had? Surgery, radiation, chemotherapy, immunotherapy?

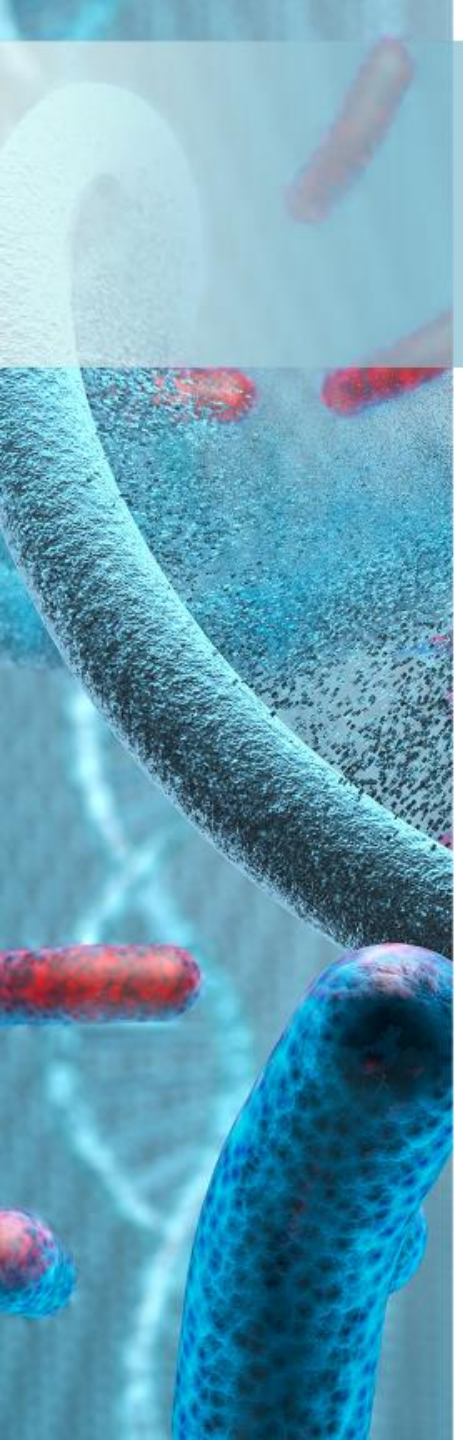
Both Patients



Patient-Directed Questions

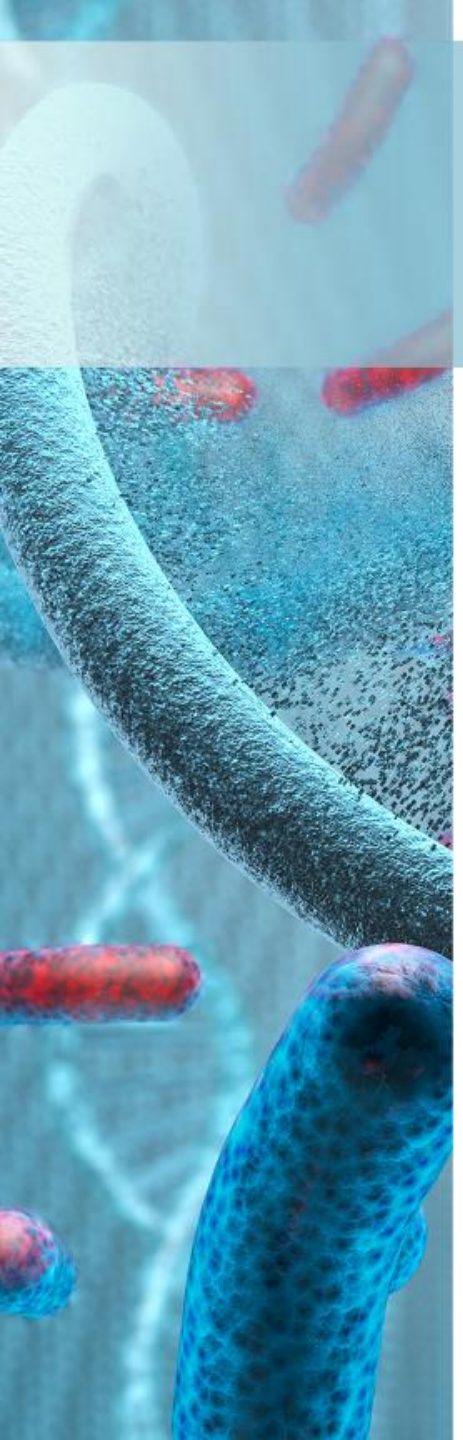
- Tell us about the early diagnostic process (e.g., surgery/biopsy).
  - Did you have any complications during the diagnostic work-up or initial treatment?
  - Who explained the potential toxicity you could experience with drug therapy?

Both Patients



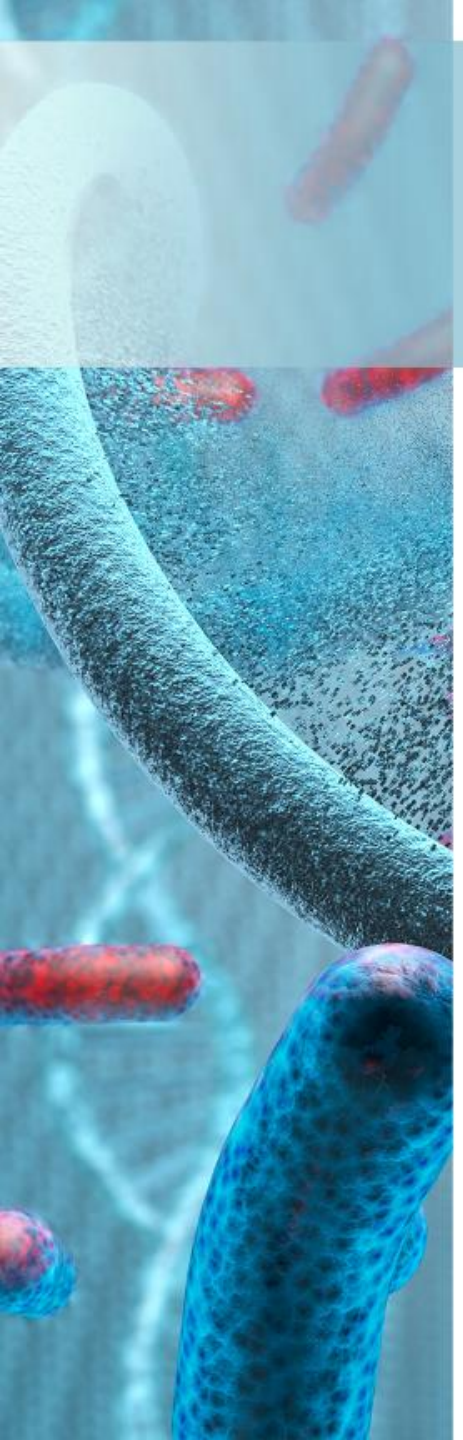
G.W. - Directed Questions

- How was the toxicity discussion about your first treatment (cisplatin and gemcitabine)?
  - Did you consent to treatment? Who went over the potential toxicity? Did you expect to have side effects? If so, what side effects?
  - How toxic would you say cisplatin and gemcitabine are (your first treatment)?



G.W. - Directed Questions

- How was the toxicity discussion about your second treatment regimen (carboplatin and gemcitabine)?
  - Did you consent to treatment? Who went over the potential toxicity? Did you expect to have side effects? If so, what side effects?
  - How toxic would you say carboplatin and gemcitabine are (your second regimen)? Tell us about your experience.



J.S. - Directed Questions

- How was the toxicity discussion about your first treatment (carboplatin and etoposide)?
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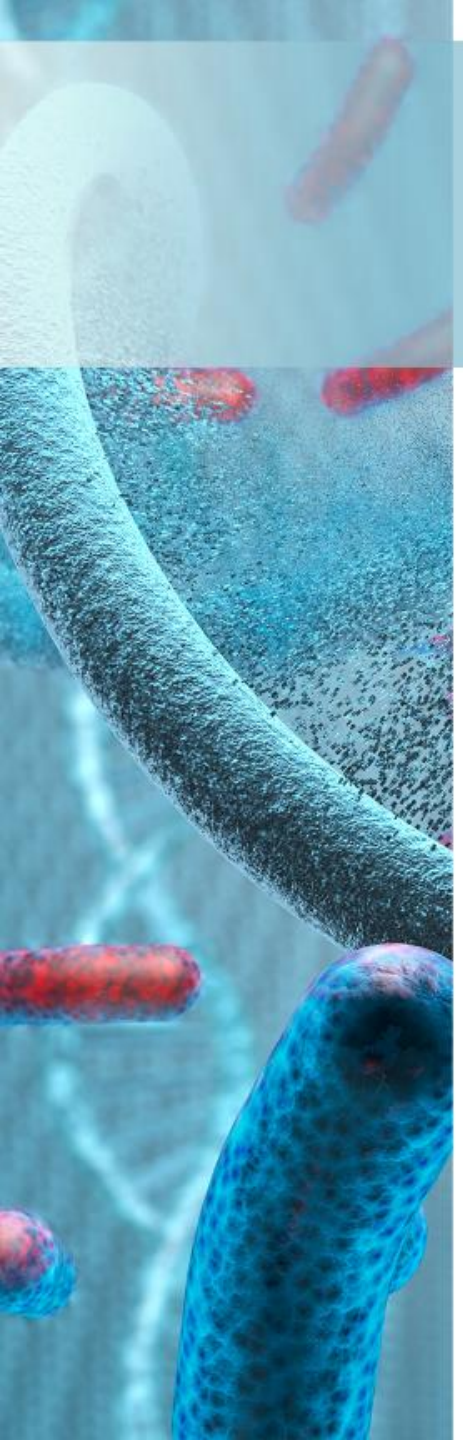
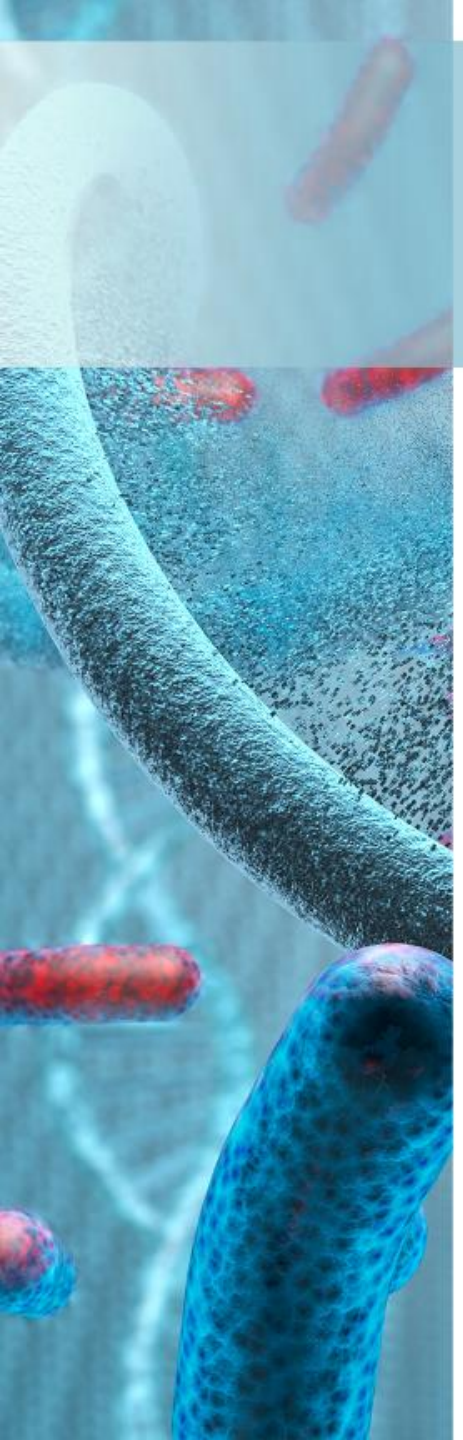


J.S. - Directed Questions

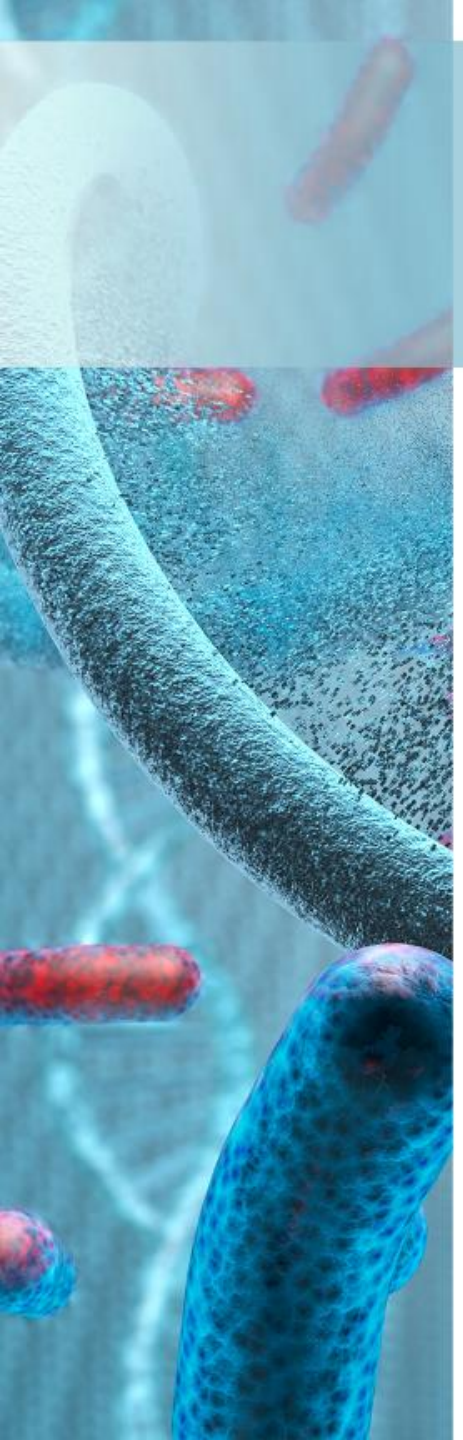
- How was the toxicity discussion about your second treatment regimen (cisplatin and radiation)?
  - Did you consent to treatment? Who went over the potential toxicity? Did you expect to have side effects? If so, what side effects?
  - How toxic would you say cisplatin and radiation are (your second regimen)? Tell us about your experience.



Patient-Directed Questions

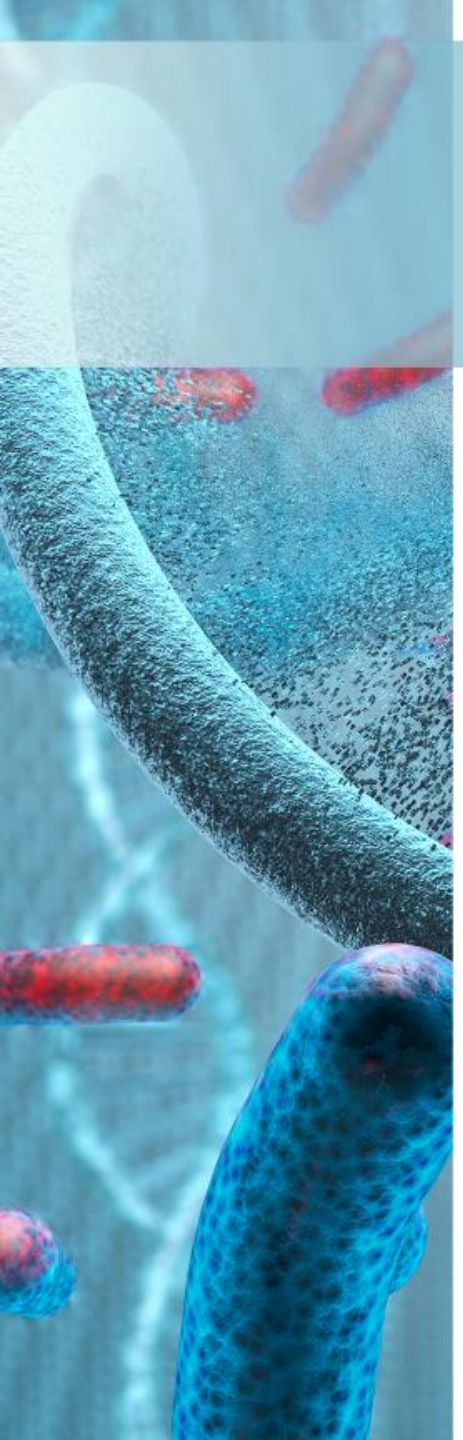
- How was the toxicity discussion about your third treatment regimen (pembrolizumab)?
  - Did you consent to treatment? Who went over the potential toxicity? Did you expect to have side effects? If so, what side effects?
  - How toxic would you say pembrolizumab is (your third and current regimen)? Tell us about your experience.

Both Patients



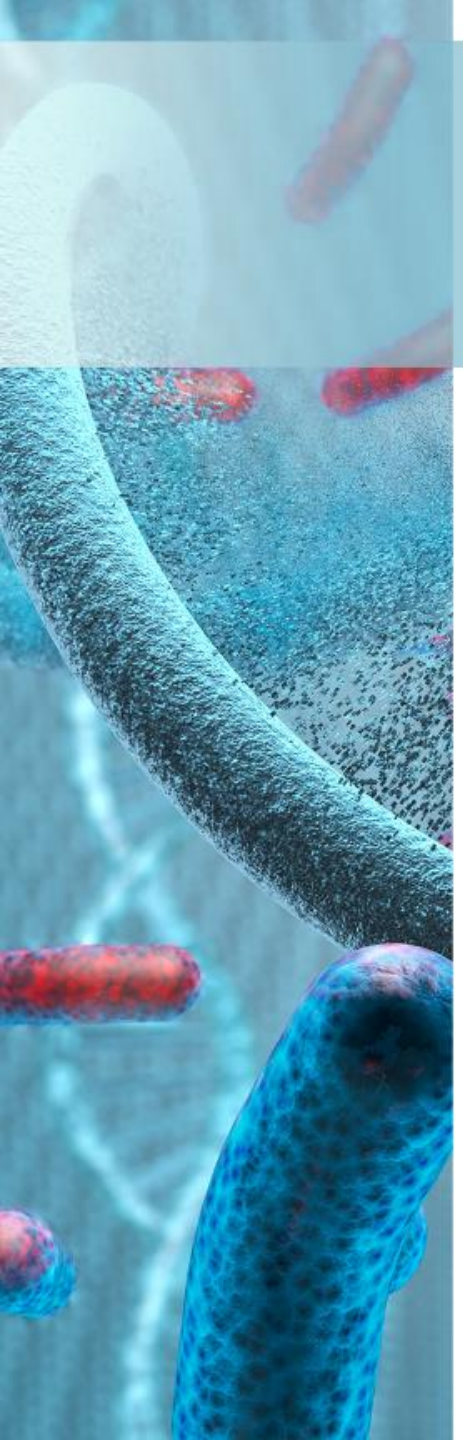
G.W. - Directed Questions

- After the first cycle of pembrolizumab, you had fevers that led to a hospitalization. From your perspective, how did that go?
  - Were you told they would restart treatment with pembrolizumab?
  - Did anyone talk to you about how restarting would impact toxicity or efficacy?



G.W. - Directed Questions

- Let’s talk about the logistics. Did you have any issues associated with getting cancer treatment?
  - You got a second opinion at MD Anderson. How did that go?
  - How did you get to the cancer center for treatment?
  - How and with whom were the finances discussed with you?
  - How were your interactions with the pharmacist?



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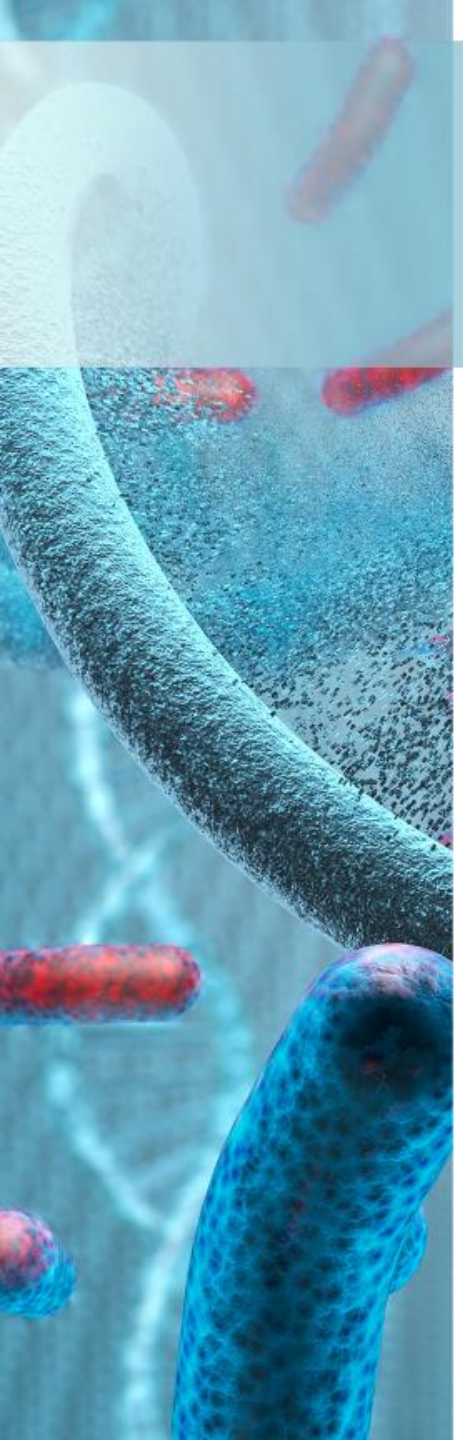
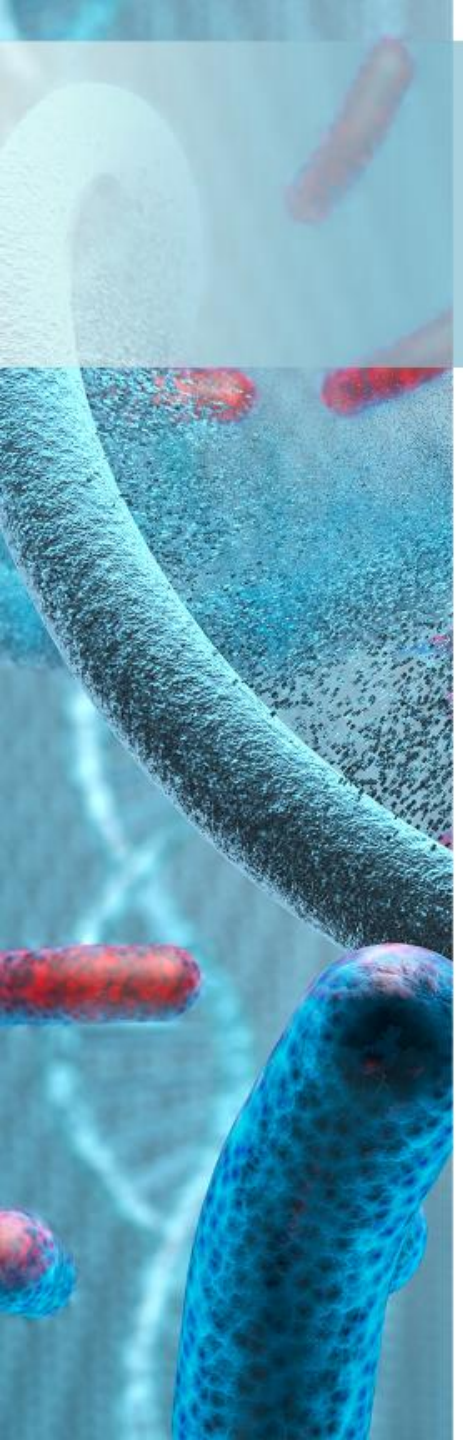


Patient-Directed Questions

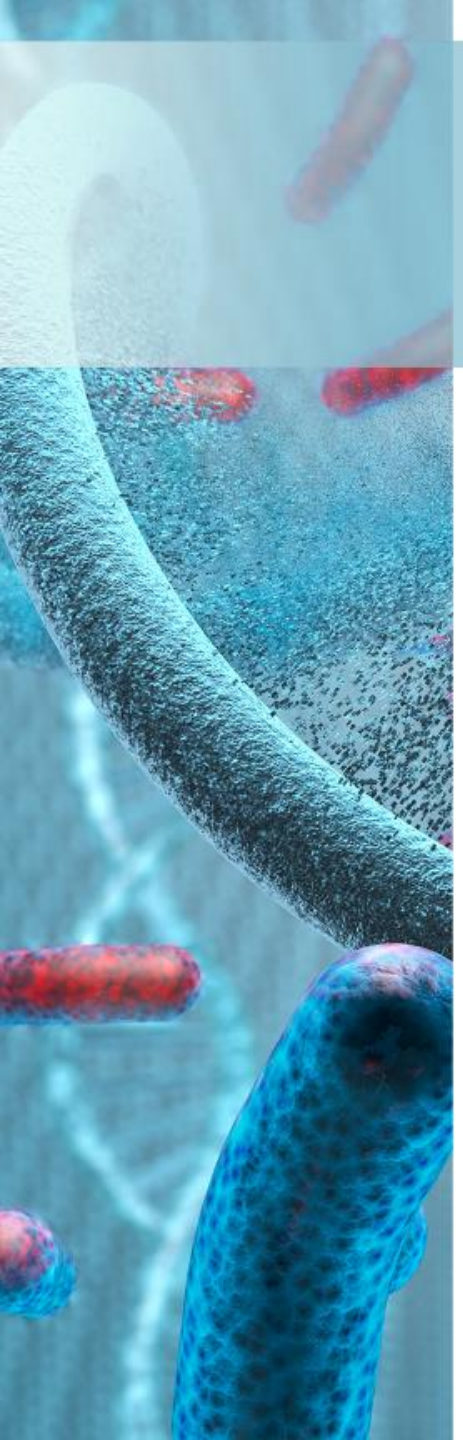
- More about the logistics:
  - Were you given instructions about what to do if you had problems (e.g., diarrhea, fatigue)?
  - Was the treatment team easy to contact for advice/information?
  - What could have been done differently by the healthcare team to make your journey easier?

Both Patients



J.S. - Directed Questions

- After a couple of cycles of pembrolizumab, you had vision changes that required additional work-up. From your perspective, how did that go?
  - Were you told they would restart treatment with pembrolizumab?
  - Did anyone talk to you about how restarting would impact toxicity or efficacy?



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Both Patients


Thank you!