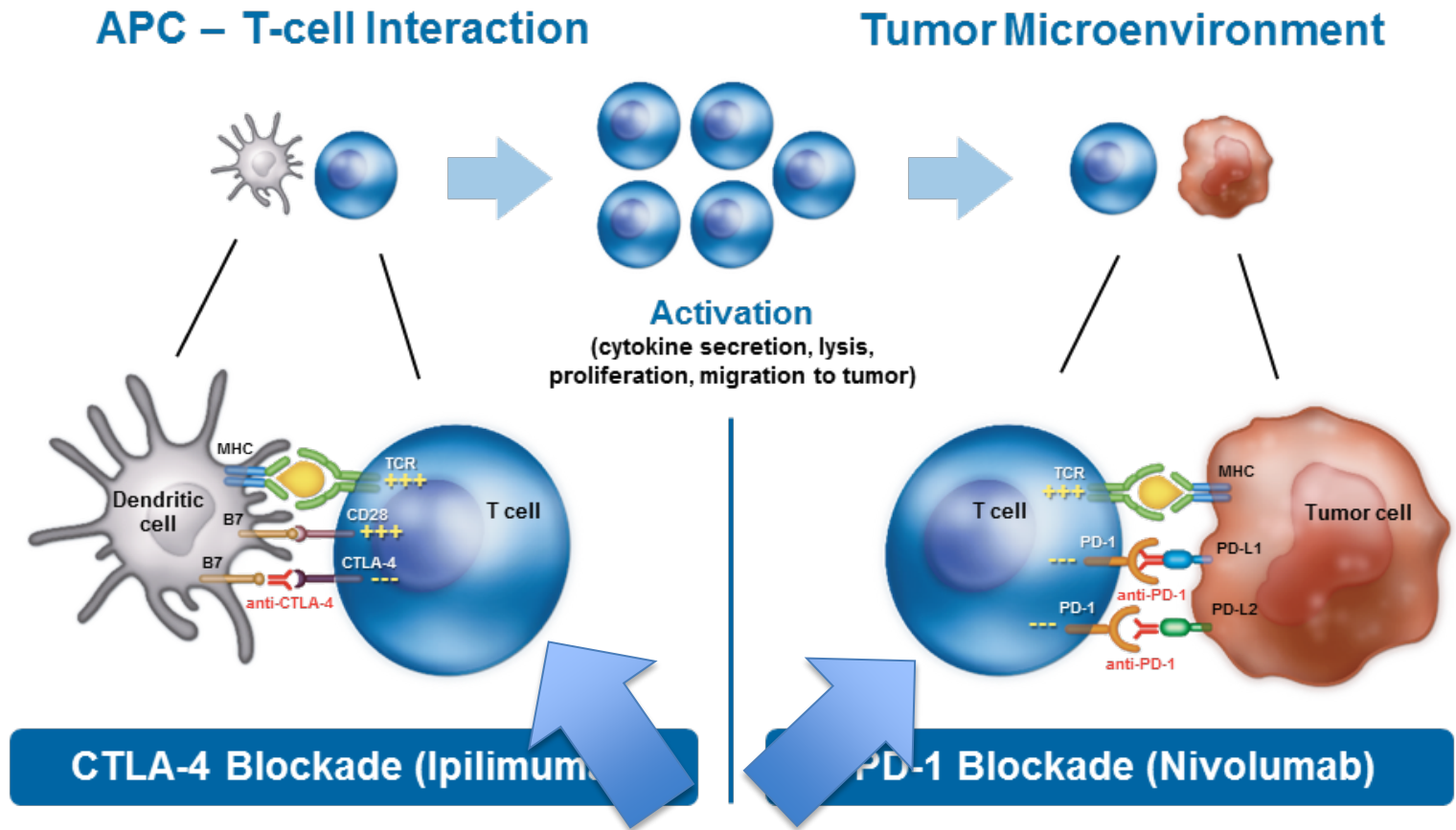


Eligibility Criteria for Immuno-Oncology Trials

**FDA Cardio-Oncology Symposium
December 1, 2017**

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Vanderbilt-Ingram Cancer Center
Nashville, TN**

Background



All about the T cells

Adapted from Wolchok J, ASCO 2015

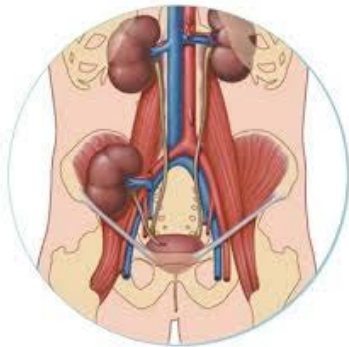
Inclusion/Exclusion Criteria

Anything that predisposes to immune toxicity

- Autoimmune disease
- Prior transplant



Rheumatoid Arthritis



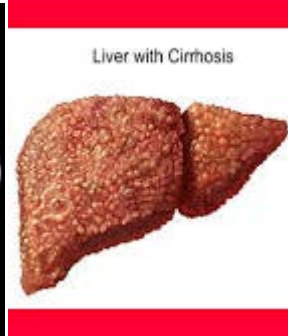
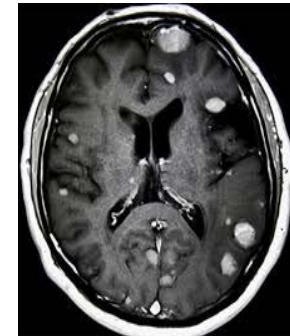
Anything that compromises immune efficacy

- Steroids
- Viral infections
- Prior anti-PD-1

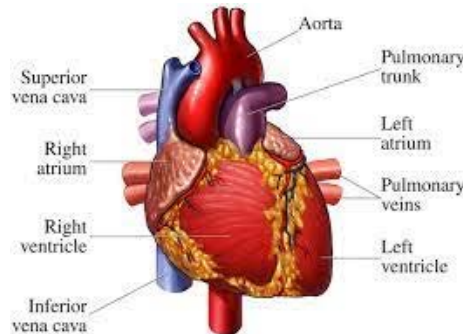


Difficulty in interpreting efficacy/toxicity

- Brain mets
- Organ dysfunction
- Poor performance status



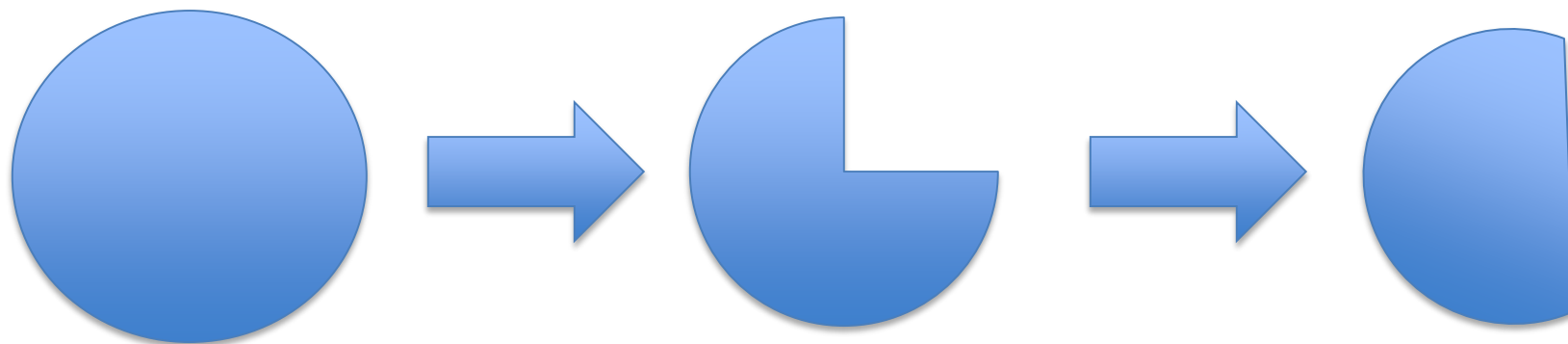
What is missing?



Inclusion/Exclusion Criteria

- Too restrictive?
 - Increasing inclusion/exclusion criteria in NSCLC trials
 - Between brain mets, autoimmunity, impaired organ function, prior cancers....

Missing a huge number of real-world patients!!!



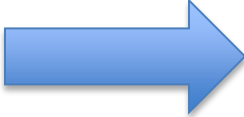
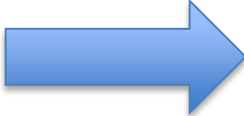
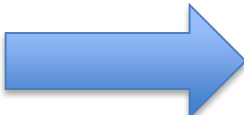
Inclusion/Exclusion Criteria

- **Too Restrictive?**
 - No difference in survival in NSCLC with prior cancer
 - Good tolerance of ipilimumab and anti-PD-1 in patients with autoimmune disease, hepatitis B/C
 - Good tolerance in organ dysfunction
 - Good activity of ipi/nivo in untreated brain mets

Johnson et al JAMA Onc 2016, Menzies et al Ann Onc 2017, Kanz et al JITC 2016, El-Khoueiry et al Lancet 2017, Long et al ASCO 2017, Tawbi et al ASCO 2017

Inclusion/Exclusion Criteria

Moving in the right direction?

- No prior cancers 
 - No autoimmunity 
 - No brain mets 
- No cancer requiring definitive treatment, or cancers that have not been treated in X years
 - Long list of exceptions or nothing requiring systemic therapy
 - Definitively treated brain mets or brain met specific trials

Cardiac specific criteria

- Largely absent
 - “other medical condition that could interfere”
 - Impaired performance status
 - Combination partner criteria (e.g. VEGF or BRAF/MEK immune combinations)