# Experiences with Immunotherapy from Denmark

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Århus Workshop in Breast Surgery
13.05.2025

# National Center for Cancer Immune Therapy (CCIT-DK)

- Established in October 2006. Led by Prof. Inge Marie Svane and Prof. Mads Hald Andersen
- ~ 100 employees including scientific and technical staff
- Appointed the national research and competence center for immunotherapy in 2017
- CCIT-DK has carried out numerous clinical trials and facilitates quick clinical implementation of new immunotherapies

**Inge Marie Svane, Director**

**Mads Hald Andersen, Director**

# Experiences with Immunotherapy - Outline

- Introduction: Cancer Immunotherapy
  - Rationale and historical development
  - Types of immunotherapy
  - Immune Checkpoint Inhibitors (ICI)
- Efficacy (in melanoma) and challenges in response evaluation
- Which patients benefit from treatment with immunotherapy?
- Immune related toxicity: why, which, when and who?
- Neoadjuvant immunotherapy – rationale and challenges
- Perspectives

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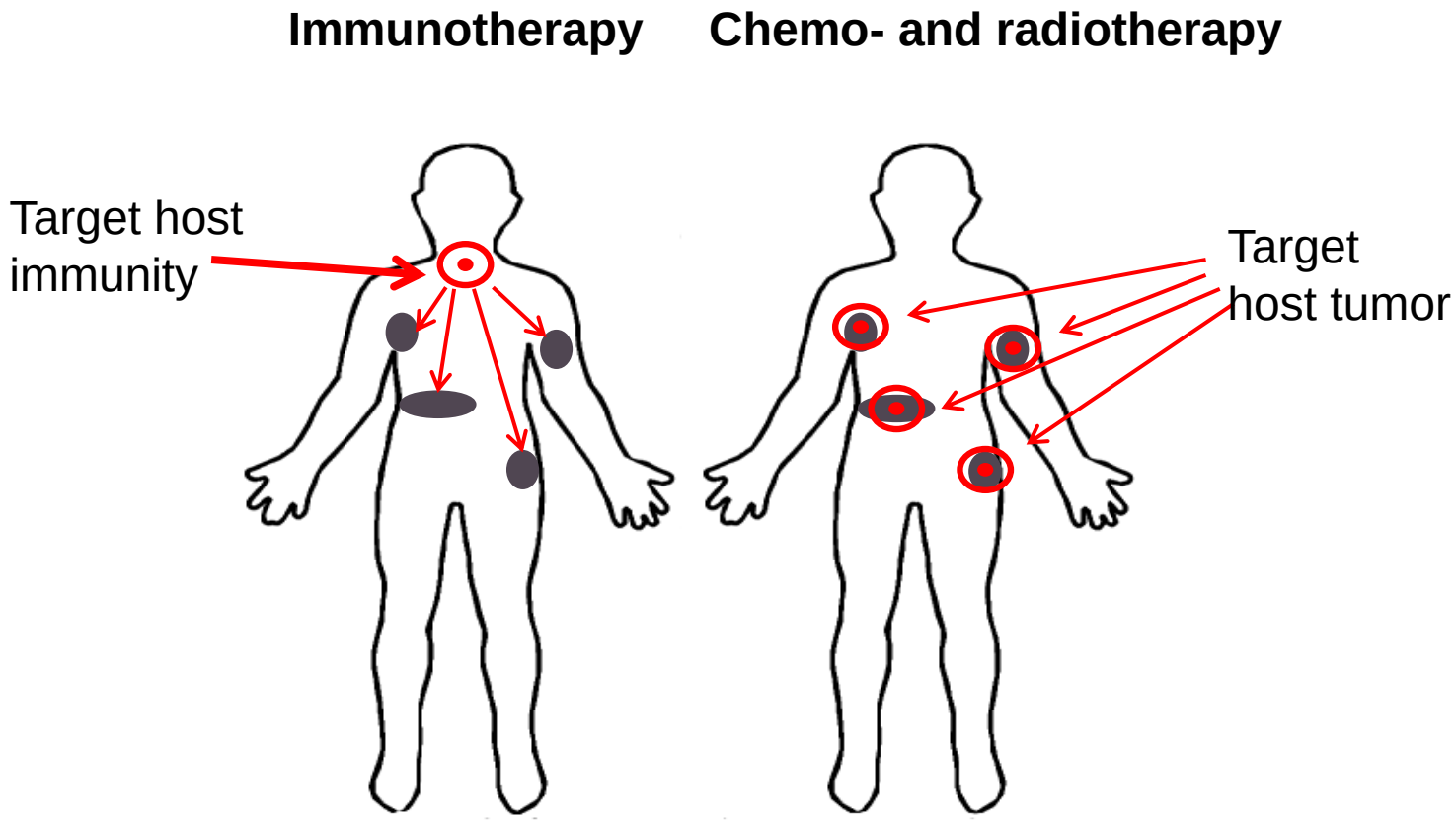
# Cancer Immunotherapy – A conceptual change in how to target cancer

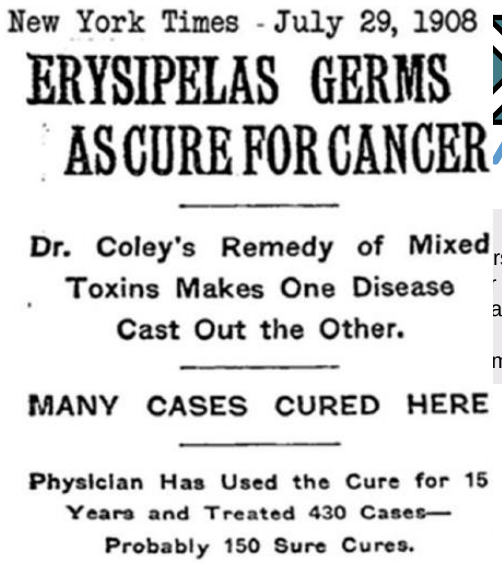


# Historical points of impact in the development of Immunotherapy

**1909**
Cancer occurs spontaneously: immune system recognizes and protects
(Paul Erlich)

**1891**
First cancer "vaccine" demonstrated (Coley bacterial toxin)

**Late 1950s**
Immunosurveillance theory introduced
(Thomas Burnet)


New York Times - July 29, 1908

ERYSIPELAS GERMS AS CURE FOR CANCER

Dr. Coley's Remedy of Mixed Toxins Makes One Disease Cast Out the Other.

MANY CASES CURED HERE

Physician Has Used the Cure for 15 Years and Treated 430 Cases—Probably 150 Sure Cures.

**1967**
The ... cel... rol... (Ja...

**1975**
The first ...

**1985**
Adoptive ...

**1987**
The frist immune ...

- Immunotherapy continues to expand to an increasing number of solid tumor types
- Surgeons will increasingly encounter patients treated with cancer immunotherapies
- Knowledge regarding mechanisms of action and adverse effects facilitates optimal pre-, peri and postoperative care

...rst ... vaccine ... and ... ms)

... some tumors

... immunotherapy

... for bladder cancer

**2010**
Sipuleucel-T approved as first ...

... approved for metastatic melanoma

**2019**
**Atezolizumab** (anti-PD-L1) approved for TNBC

... approved for metastatic melanoma

**2015**
The first oncolytic virus (**T-VEC**) approved for the treatment of metastatic melanoma

**2020**
Nobel prize, CRISPR-Cas9 technology (Charpentier and Doudna)

2020

**2022**
**Tebentafusp** approved as first bispecific T cell engager (uveal melanoma)

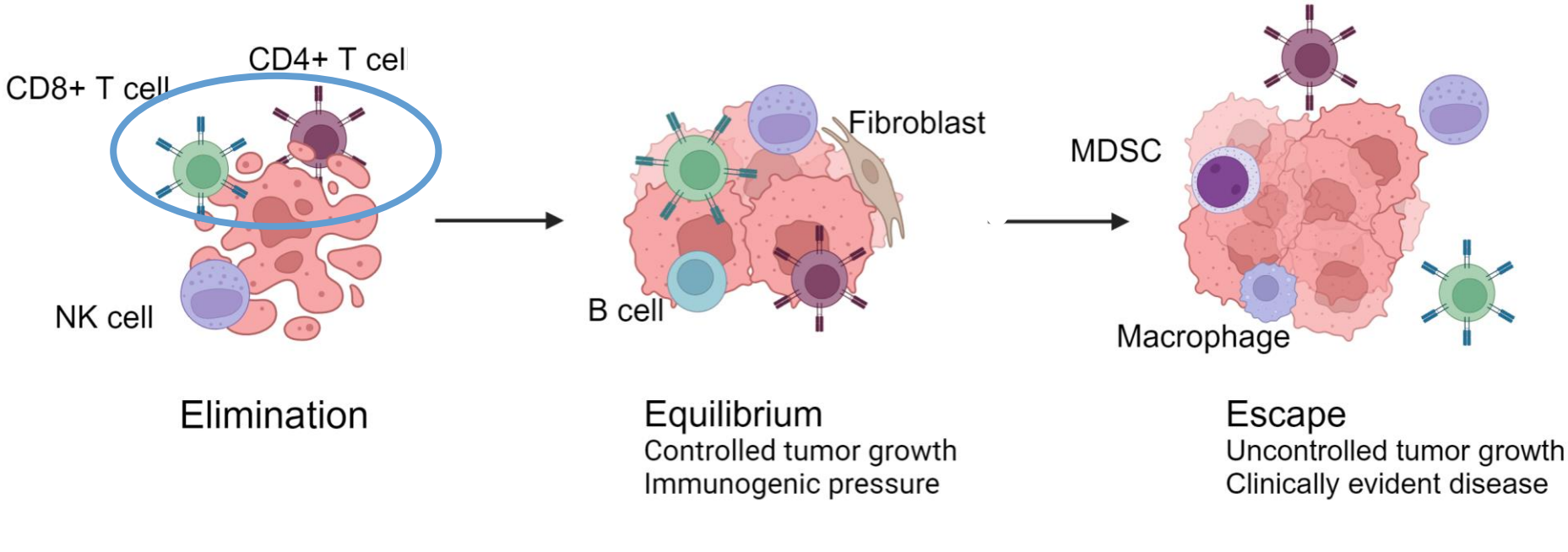
**2024**
ACT **with tumor infiltrating lymphocytes (TILs)** approved for metastatic melanoma

Unspecific agents

Precision agents

Oiseth, 2017

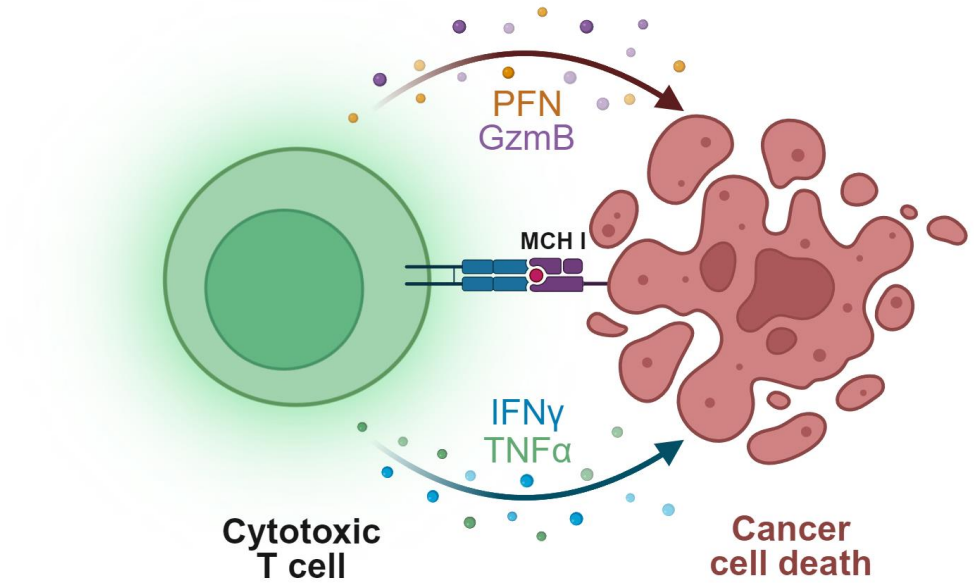
# Cancer: A result of failed immunity?




Created with Biorender.com

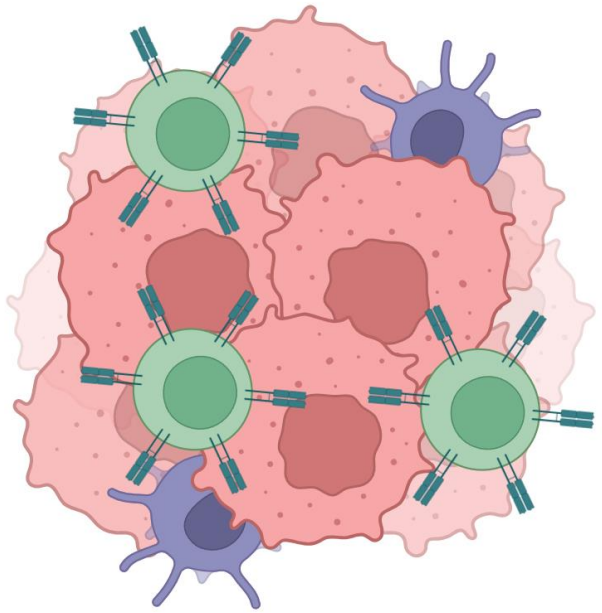
# T cells are crucial players in cancer elimination

## T cells can kill tumor cells in an antigen-dependent manner




Created with Biorender

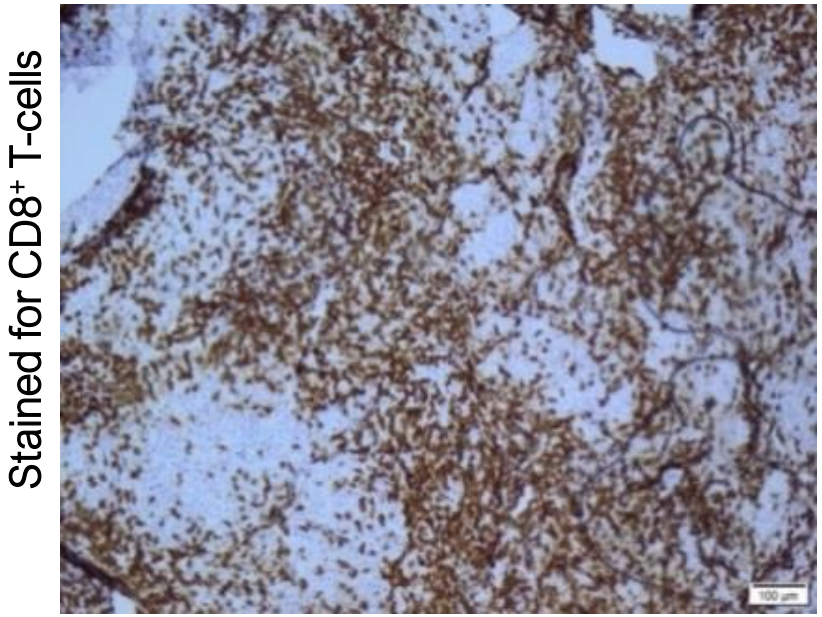
## Most solid tumors are infiltrated by T cells



Created with Biorender

# T cell infiltration – a good prognostic marker

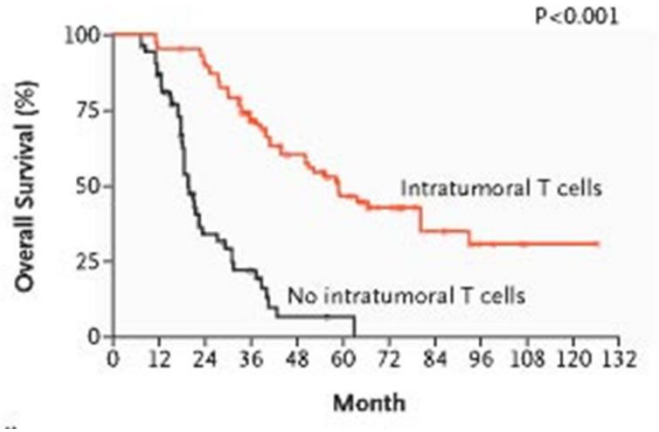
## Most tumors are infiltrated by T-cells




Andersen, Borch and Donia, Ann Oncol 2018

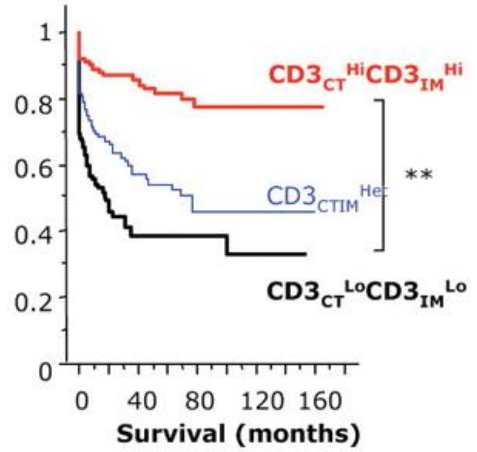
- T cell infiltration is a good prognostic marker across different cancer types

## …in Ovarian Cancer



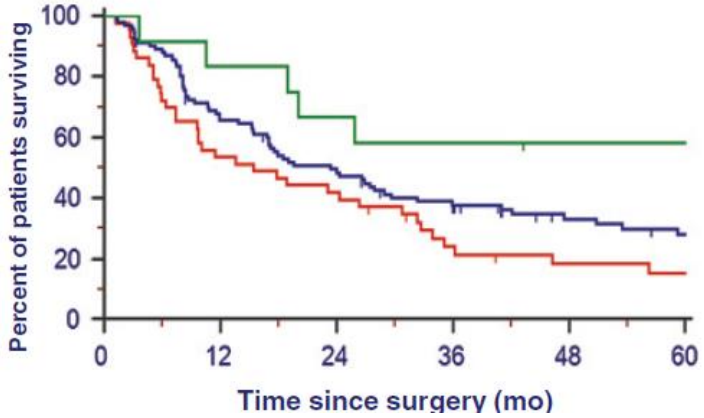

N Engl J Med 2003;348:203-13

## …in Gastrointestinal Cancer



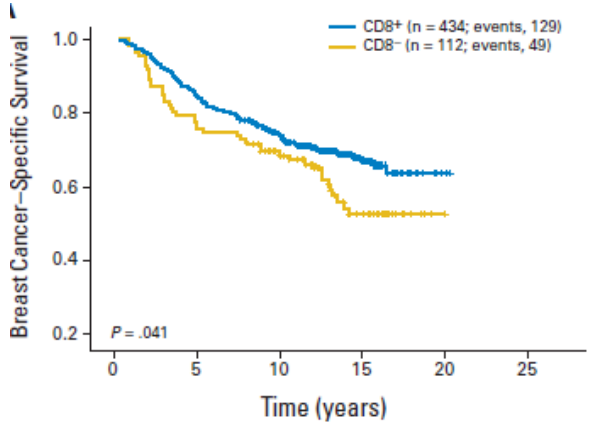

Galon J et al., Science 2006

## …in Melanoma




Erdag G et al., Cancer Res 2012

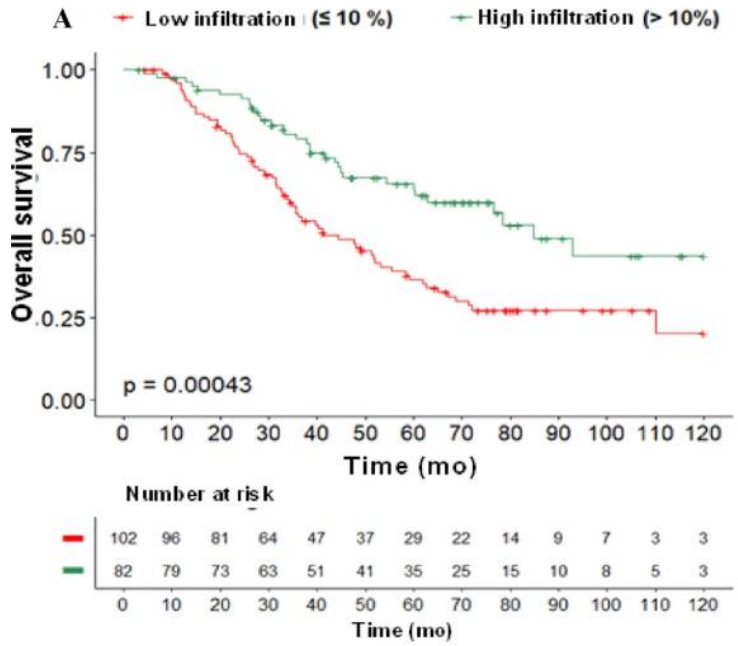
## …in Breast Cancer




Mahmoud SM et al., JCO 2011

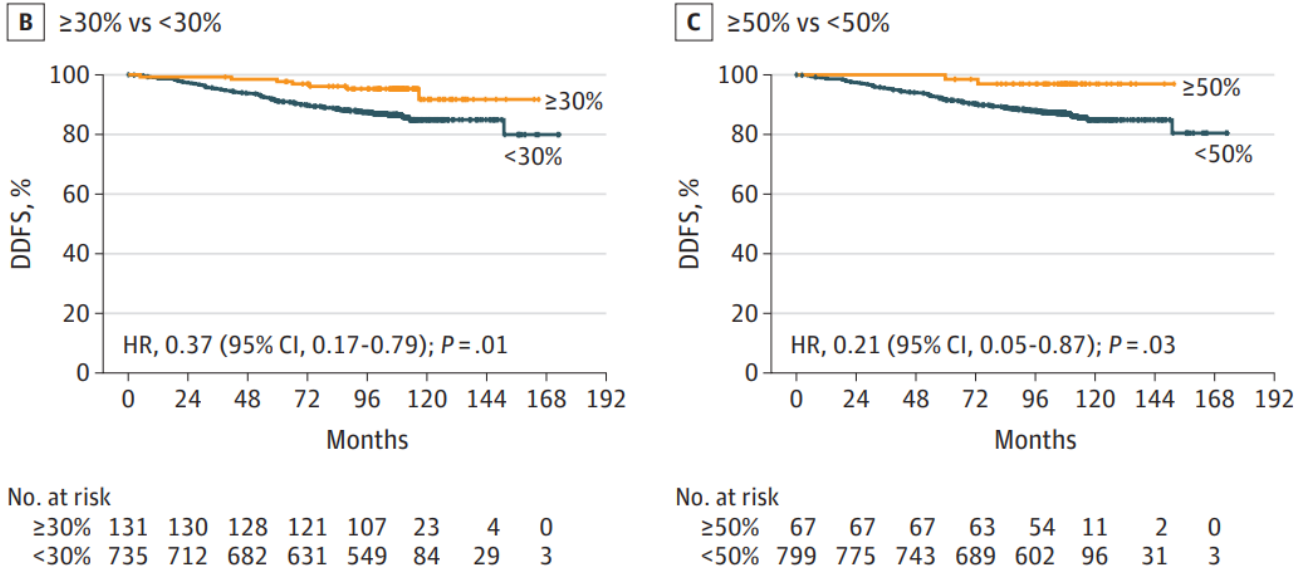
# TILs are associated with improved survival in breast cancer subtypes

TNBC




Huertas-Caro et al., 2023

HER2 positive BC

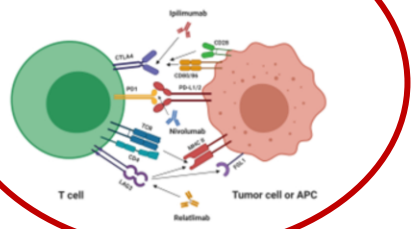



Dieci et al., JAMA Oncology, 2025

**HR+/HER2- breast cancer:** No prognostic value of TILs has been found. HR+/HER2- breast cancer is characterized by a low mean TIL count and a low tumor mutational burden.

# Cancer Immunotherapy

Monoclonal antibodies

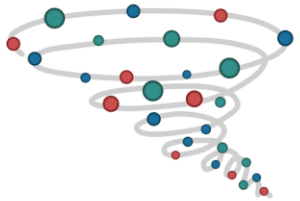



Conventional therapy

Vaccines

Cancer immunotherapy

Cytokine therapy



Oncolytic virus therapy

Adoptive Cell Therapy (ACT)

TILs CARs TCR

## FDA-approved immunotherapeutic drugs for solid tumors

### Non-cellular therapies

- Immune checkpoint inhibitors (PD-1/PD-L1, CTLA-4, LAG-3)
- Therapeutic cancer vaccines (for prostate cancer)
- Cytokines (IL-2, interferon-alpha)
- Oncolytic viruses (T-VEC)

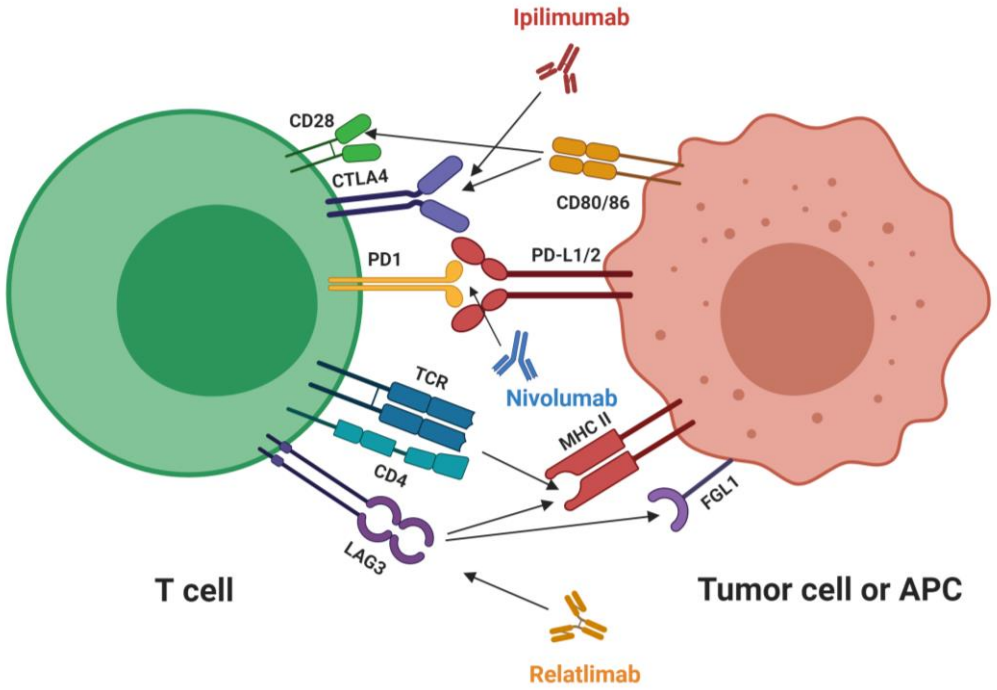
### Cellular therapies

- CAR-T therapy (B cell lymphoma/Myeloma)
- Tumor-infiltrating lymphocytes (TILs) (melanoma)
- TCR cell therapy (Sarcoma)

# Immune Escape

## Strategies to avoid immune detection

Infiltrating T cells are suppressed by the tumor microenvironment. Suppresive mechanisms are numerous.




Created with Biorender.com

### Immune checkpoints

Molecules on the surface of the T cell.
When activated, they inhibit the function of the T cell

- CTLA-4
- PD1
- LAG3

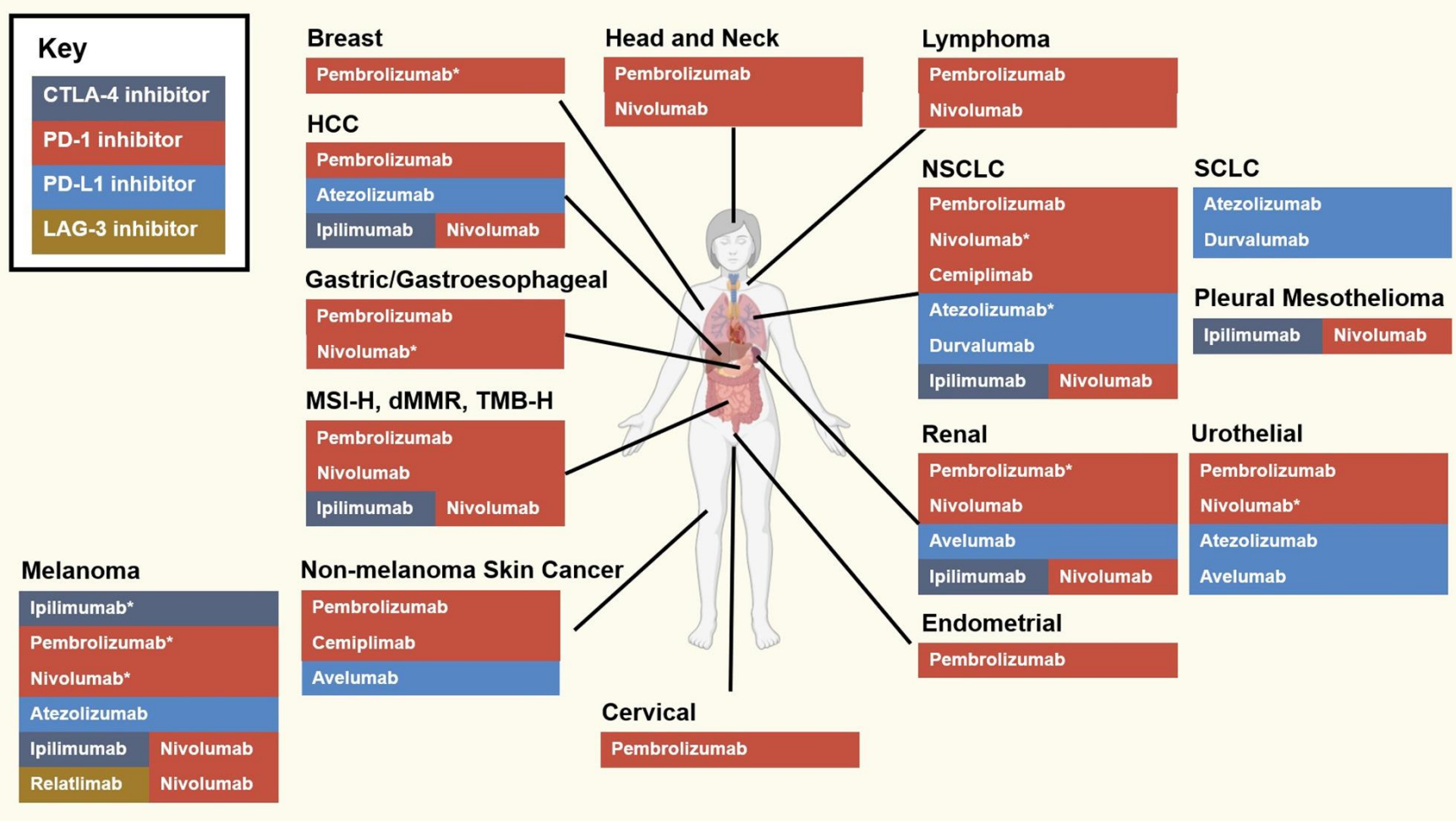
Cartromjapan.com

### Immune checkpoint inhibitors (ICI)

Drugs that block the inhibitory signal = activation

- Ipilimumab (CTLA4)
- Nivolumab/pembrolizumab ect. (PD1)
- Atezolizumab (PD-L1)
- Relatlimab (LAG3)

# Approved uses of Immune Checkpoint Inhibitors




* Also approved for adjuvant or neoadjuvant setting

Tan S et al, *JACC: CardioOncology*, 2022

## FDA approvals (2024)

- 11 drugs targeting 4 immune checkpoints
- More than 42 indications
- Many of these are also approved in Denmark

# Outline

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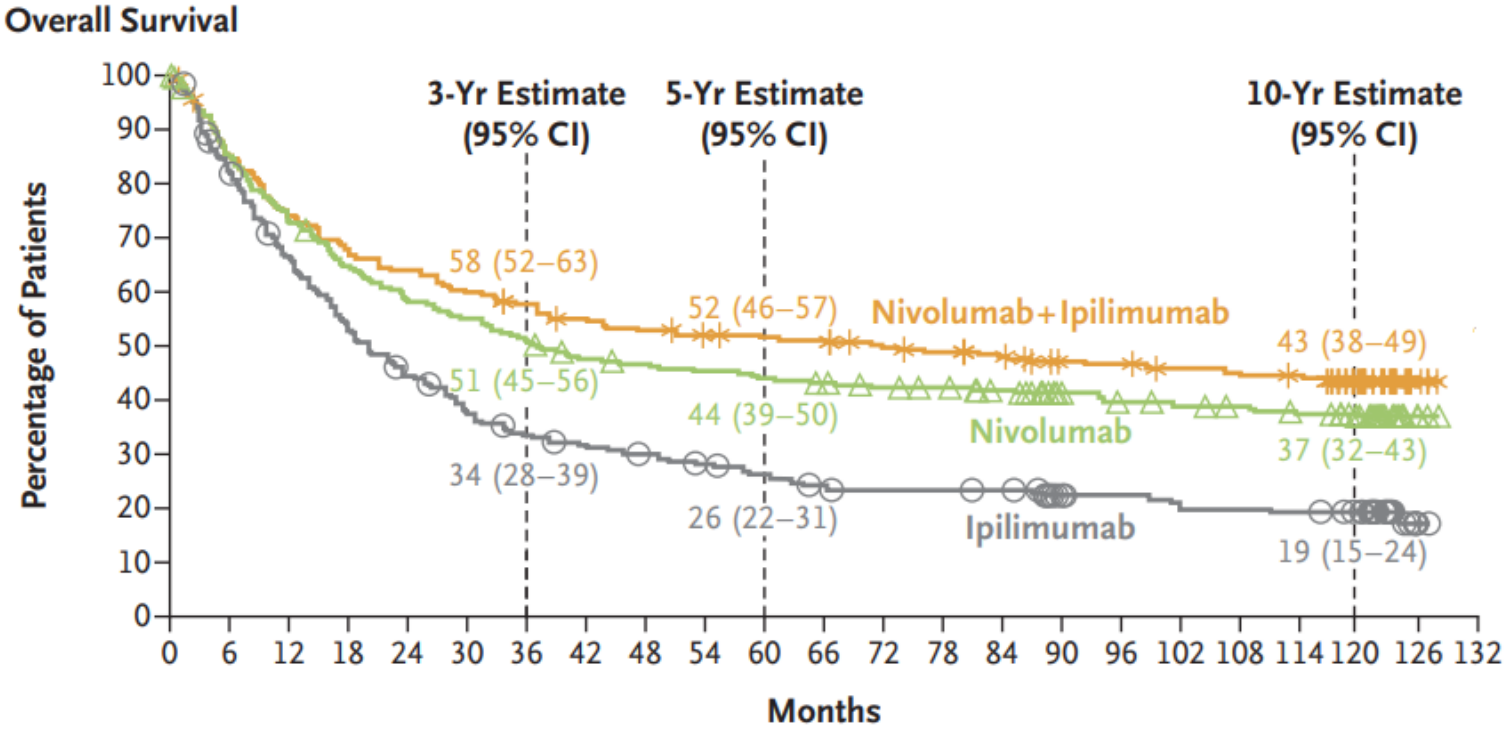
# Immune Checkpoint Inhibitors – A revolution in the treatment of metastatic melanoma




**No. at Risk**

| | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivo+ipi | 314 | 265 | 227 | 210 | 199 | 187 | 179 | 169 | 163 | 158 | 156 | 153 | 147 | 144 | 139 | 126 | 124 | 120 | 117 | 115 | 92 | 10 | 0 |
| Nivolumab | 316 | 265 | 231 | 201 | 181 | 171 | 158 | 145 | 141 | 137 | 134 | 130 | 126 | 123 | 118 | 107 | 102 | 98 | 96 | 92 | 77 | 4 | 0 |
| Ipilimumab | 315 | 253 | 203 | 163 | 135 | 113 | 100 | 94 | 87 | 81 | 75 | 68 | 64 | 64 | 63 | 50 | 49 | 44 | 43 | 42 | 35 | 3 | 0 |

Median overall survival in the 70ties: < 1 years

Median overall survival today: ~ 6 years

Wolchok et al., new England journal of med., 2024

# Clincal response rate to ICI therapy

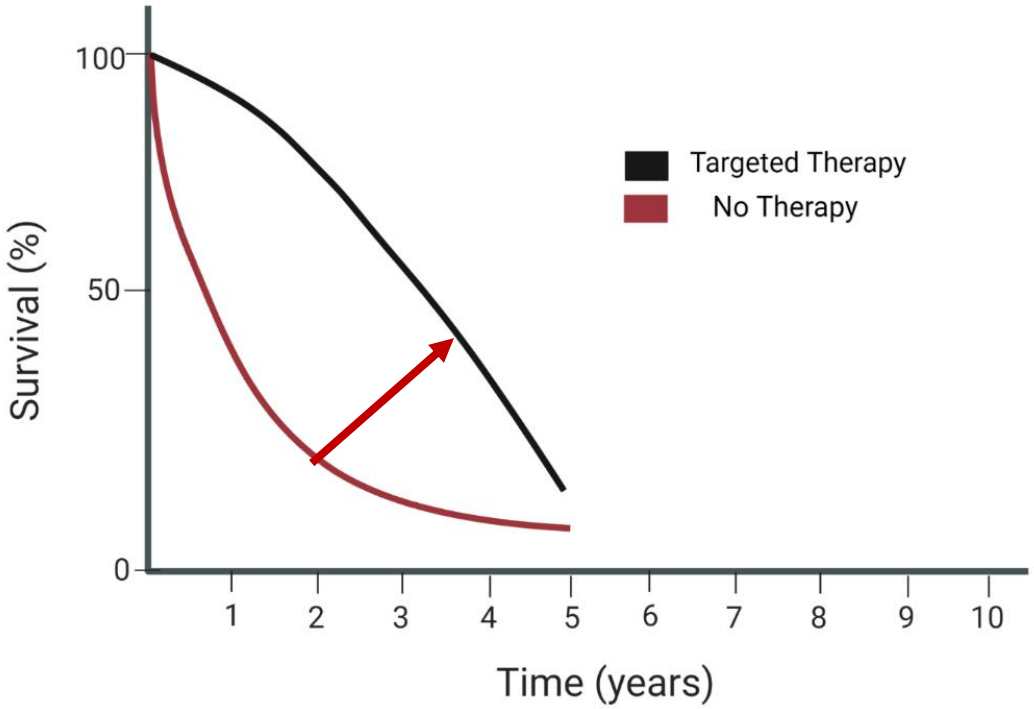
## Single agent:

| | |
|---|---|
| Melanoma | ~35% |
| Lung cancer | ~30% |
| Renal cancer | ~25% |
| Gastric cancer | ~15% |
| Bladder cancer | ~20% |
| Head and Neck cancer | ~20% |
| Colorectal cancer | <10% |
| Prostate cancer | <10% |

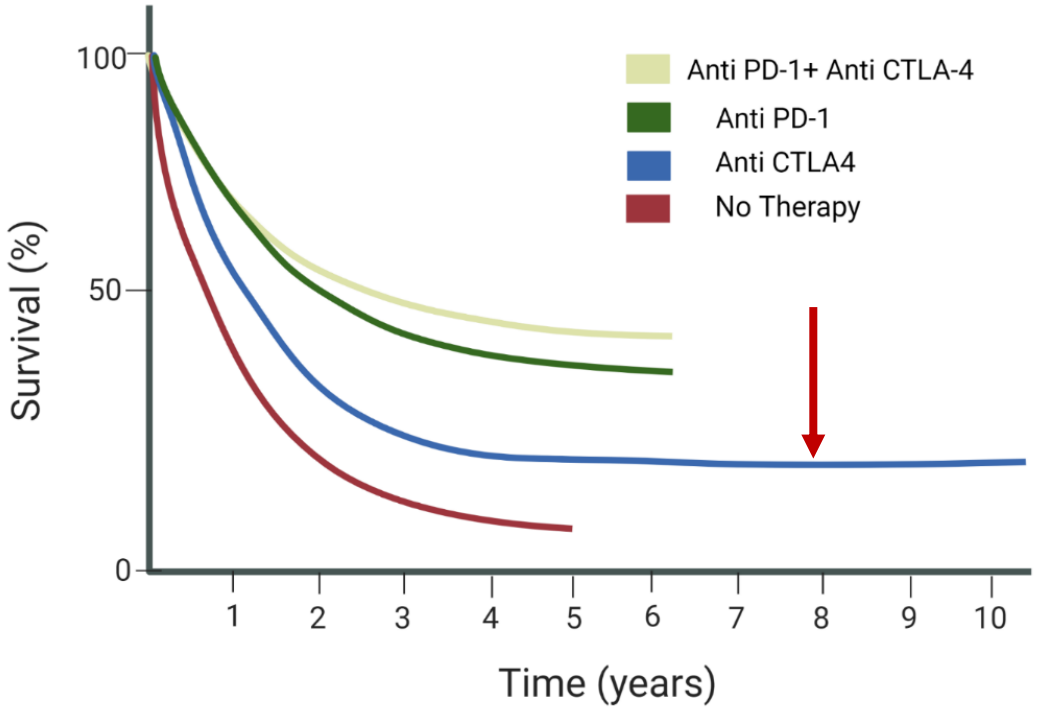
## Combination with αCTLA-4:

| | |
|---|---|
| Melanoma | >50% |
| Renal cell carcinoma | >40% |

# Reponse to immunotherapy – why the enthusiasm?




High percentage but short-term benefit




Moderate percentage but long-term benefit

Concept by G. Freeman, Harvard Medical School
Curves are hand-drawn with Biorender for didactic purposes, do not necessarily represent real results from clinical trials

# Responses to immunotherapy can…

## …develop fast

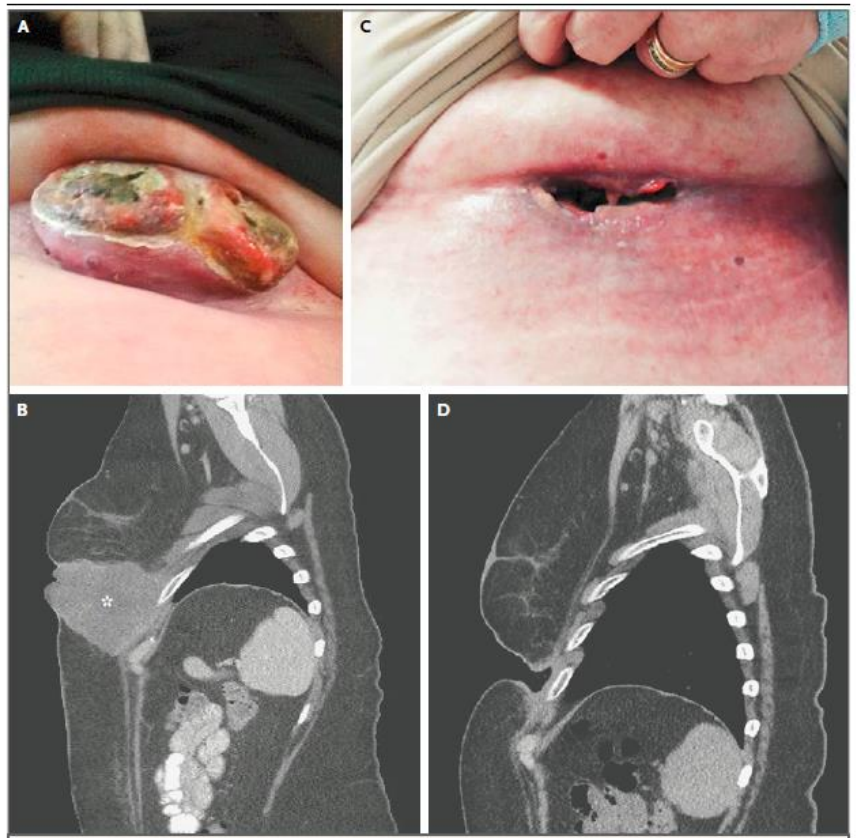
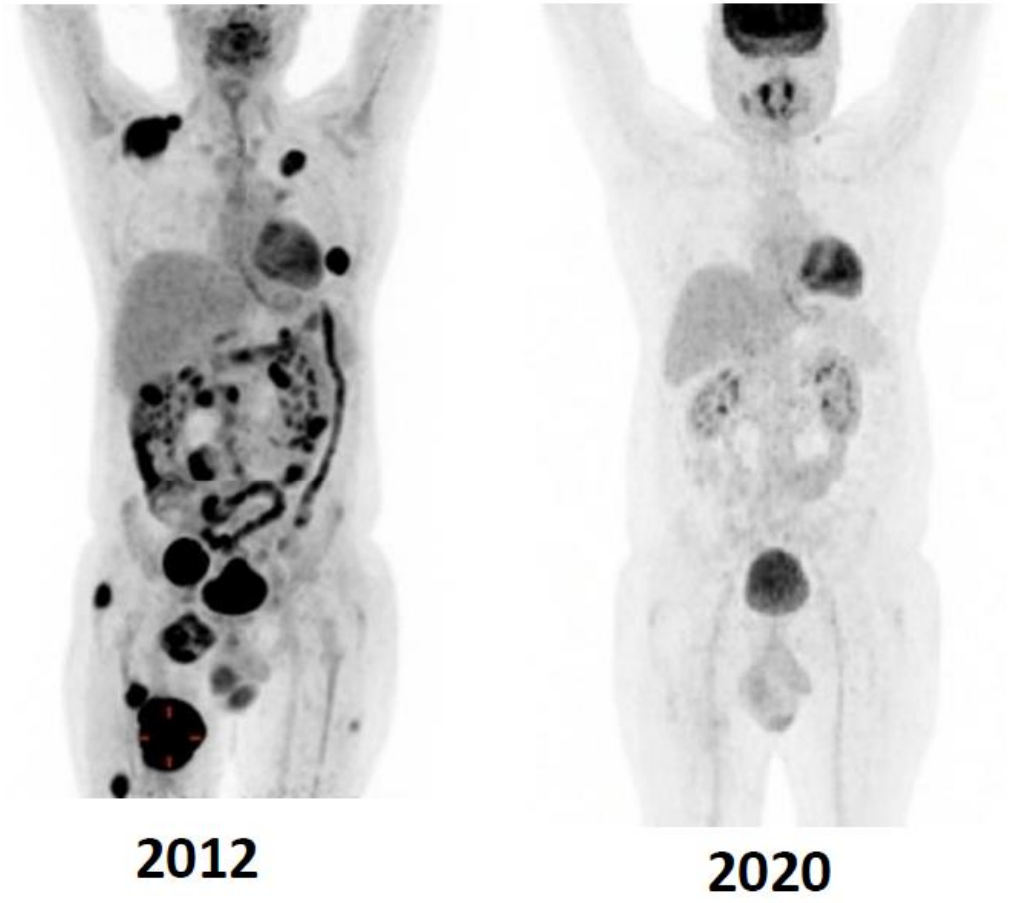



**Figure 1. Response of a Large Chest-Wall Melanoma Metastasis to One Dose of Ipilimumab plus Nivolumab.**

A pretreatment photograph (with the camera pointing upward from the patient's waist) (Panel A) and a pretreatment CT scan with soft-tissue windows (Panel B) show the chest-wall mass (asterisk). Three weeks after the first treatment, the tumor resolved, leaving a cavity (Panel C). Six weeks after the first treatment, a CT scan showed resolution of the chest-wall mass (Panel D).

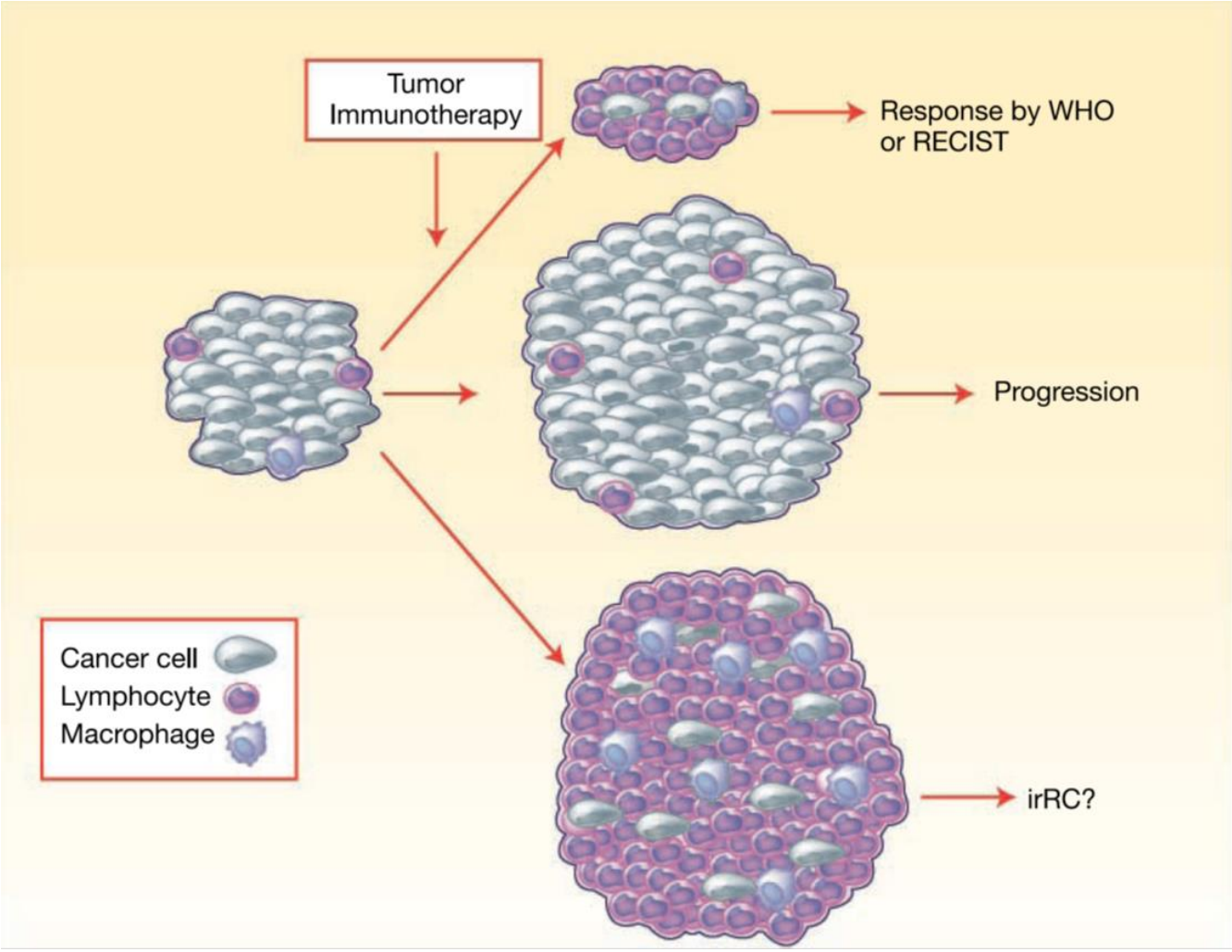
This letter was published on April 20, 2015, at NEJM.org.

## … be long-lasting




Updated from Andersen R, Donia M, Ellebaek E, et al. Clin Cancer Res. 2016. Response to TIL therapy.

# Response evaluation - pseudoprogression




Ribas A et al. Clin Cancer Res 2009

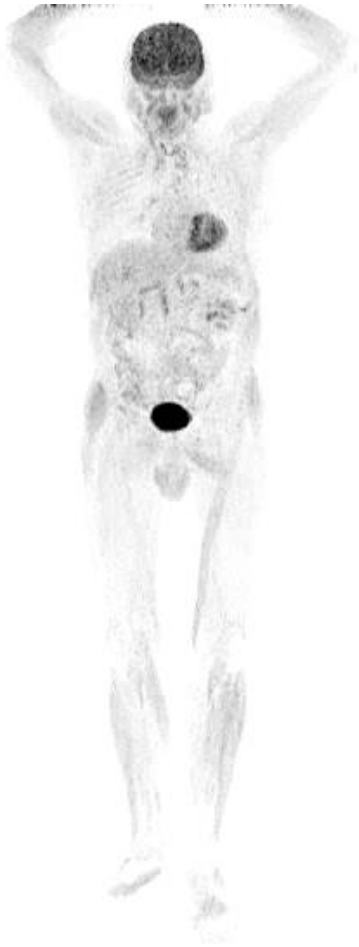
Pseudoprogression: A rare phenomenon which occurs in 1-10% of melanoma patients

Immune cells infiltrate the tumor, causing inflammation and swelling which can be mistaken for tumor growth

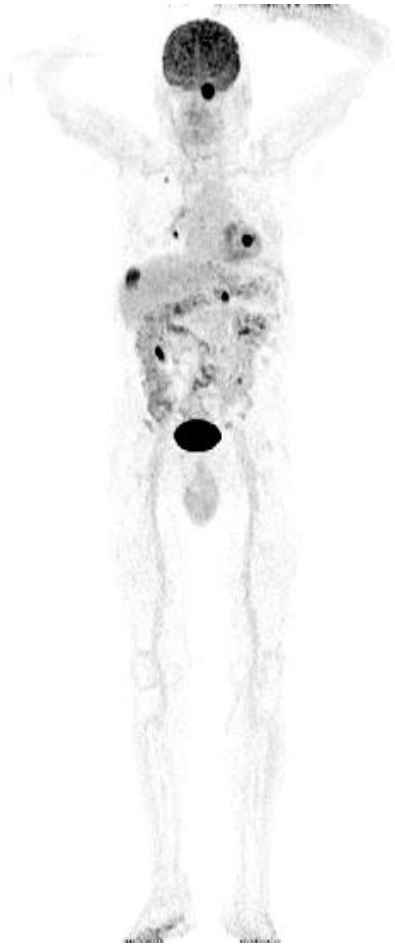
Pseudoprogression is most commonly seen within the first few months

Understanding pseudoprogression is crucial for clinicians to avoid prematurely discontinuing effective treatments

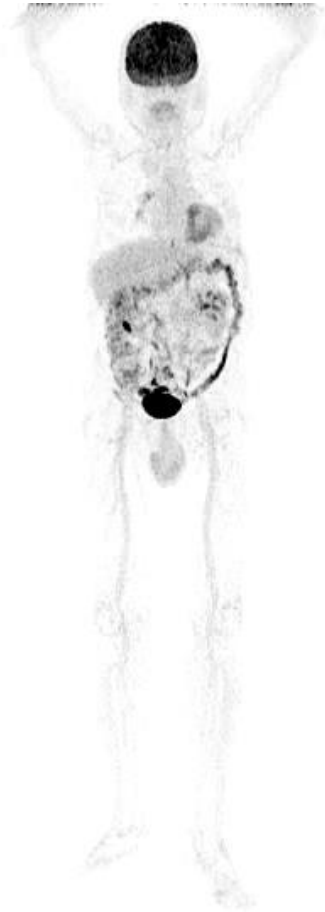
# Peudoprogression Melanoma (metastatic disease)



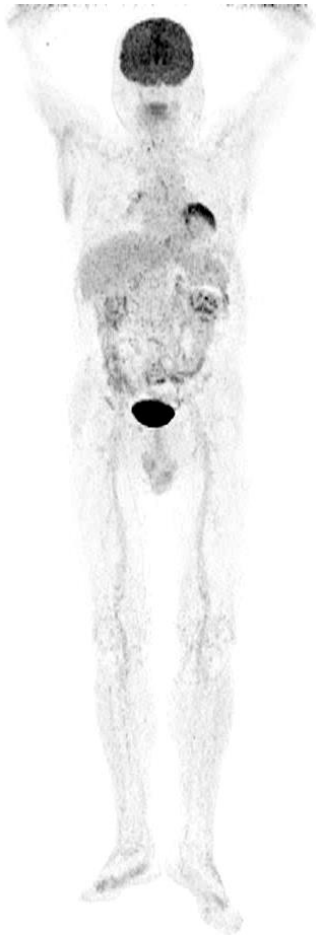
**November 2017**



**January 2018**

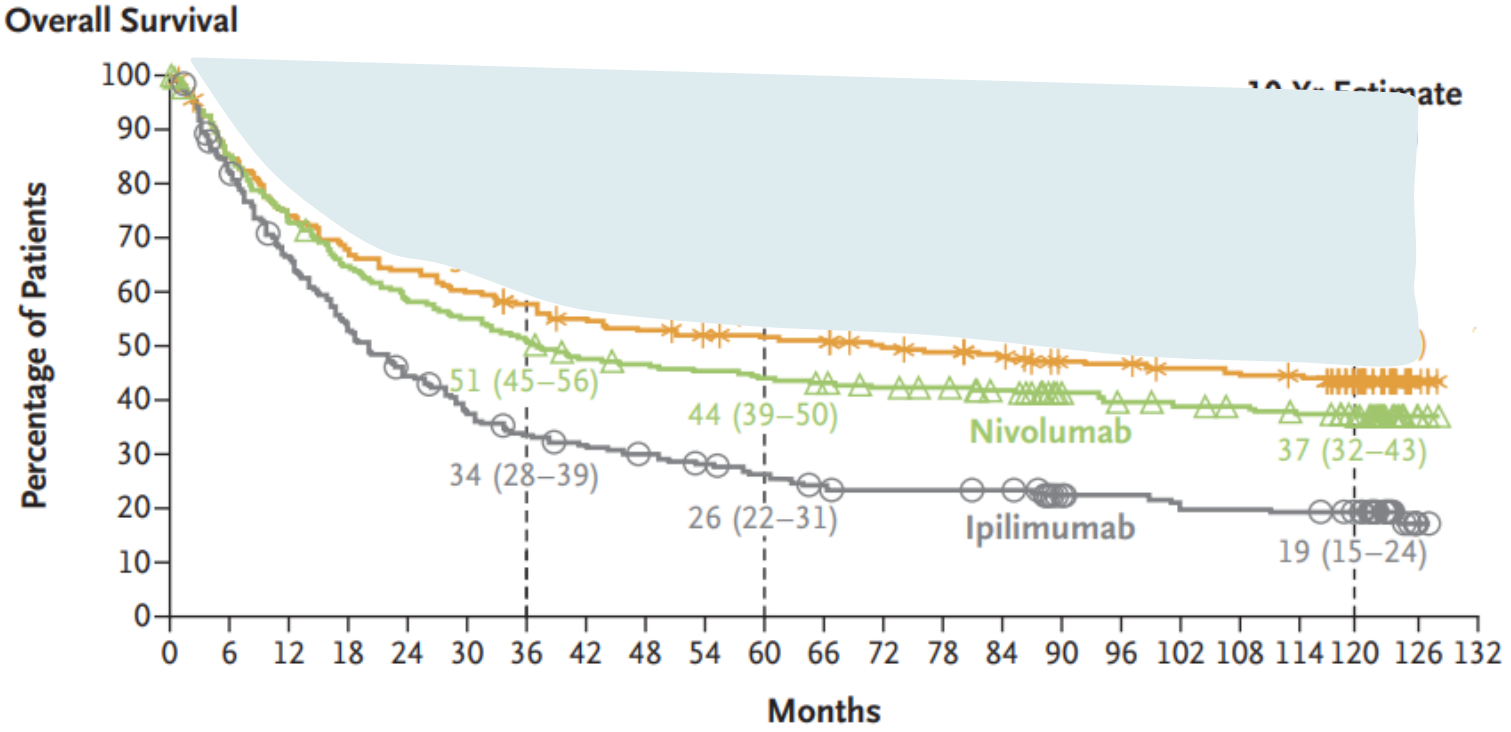


**February 2018**



**March 2019**

# Immune Checkpoint Inhibitors – A revolution in the treatment of metastatic melanoma

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Wolchok et al., new England journal of med., 2024

Despite great advances in the treatment of metastatic melanoma

- ~ 35 % of melanoma patients show **primary resistance** to therapy
- ~ 60 % of melanoma patients progress within three years on combination ICI

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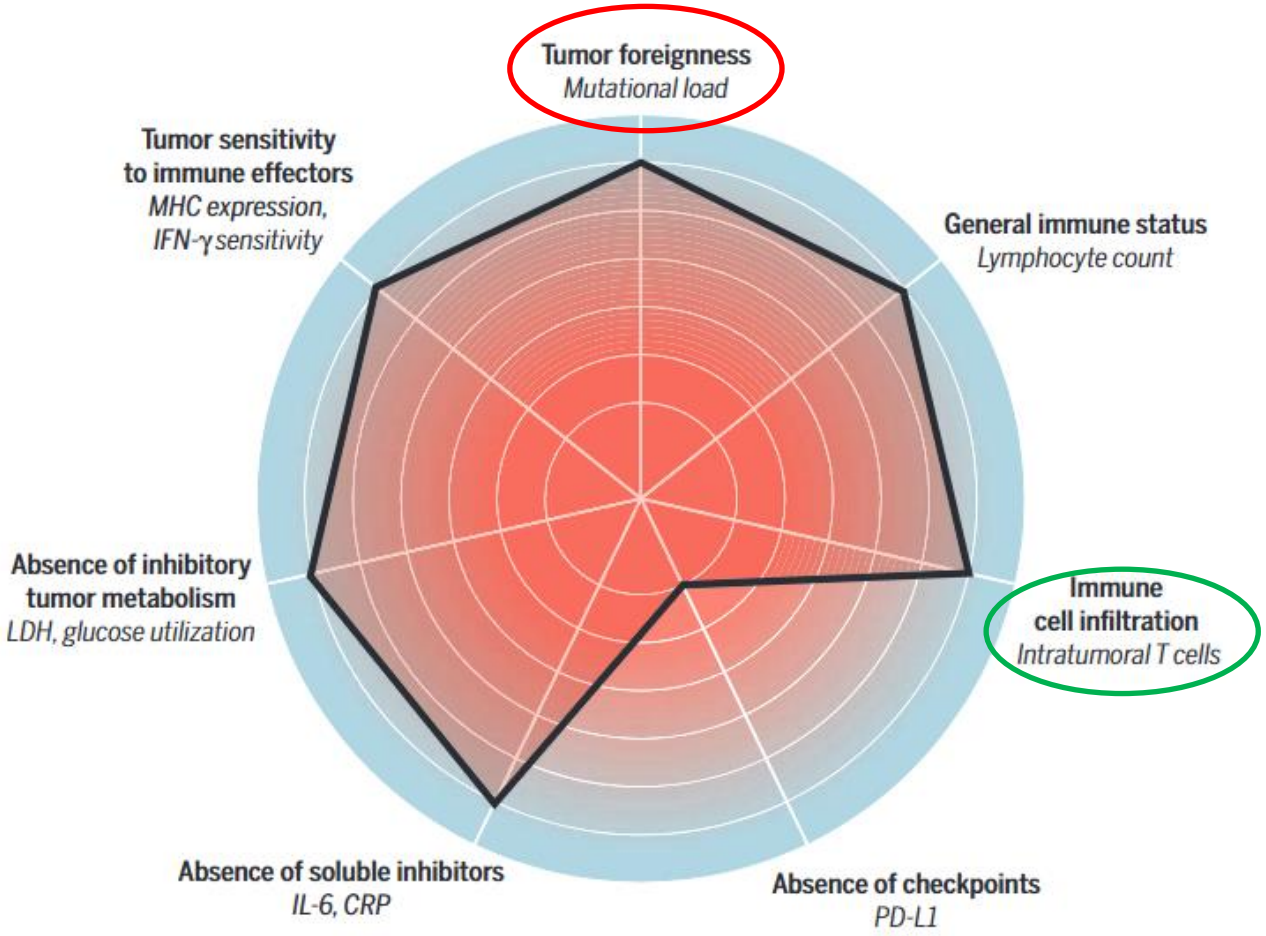
# Tumor immunogenicity - The cancer immunogram

## Which patients are most likely to benefit from immmunotherapy?

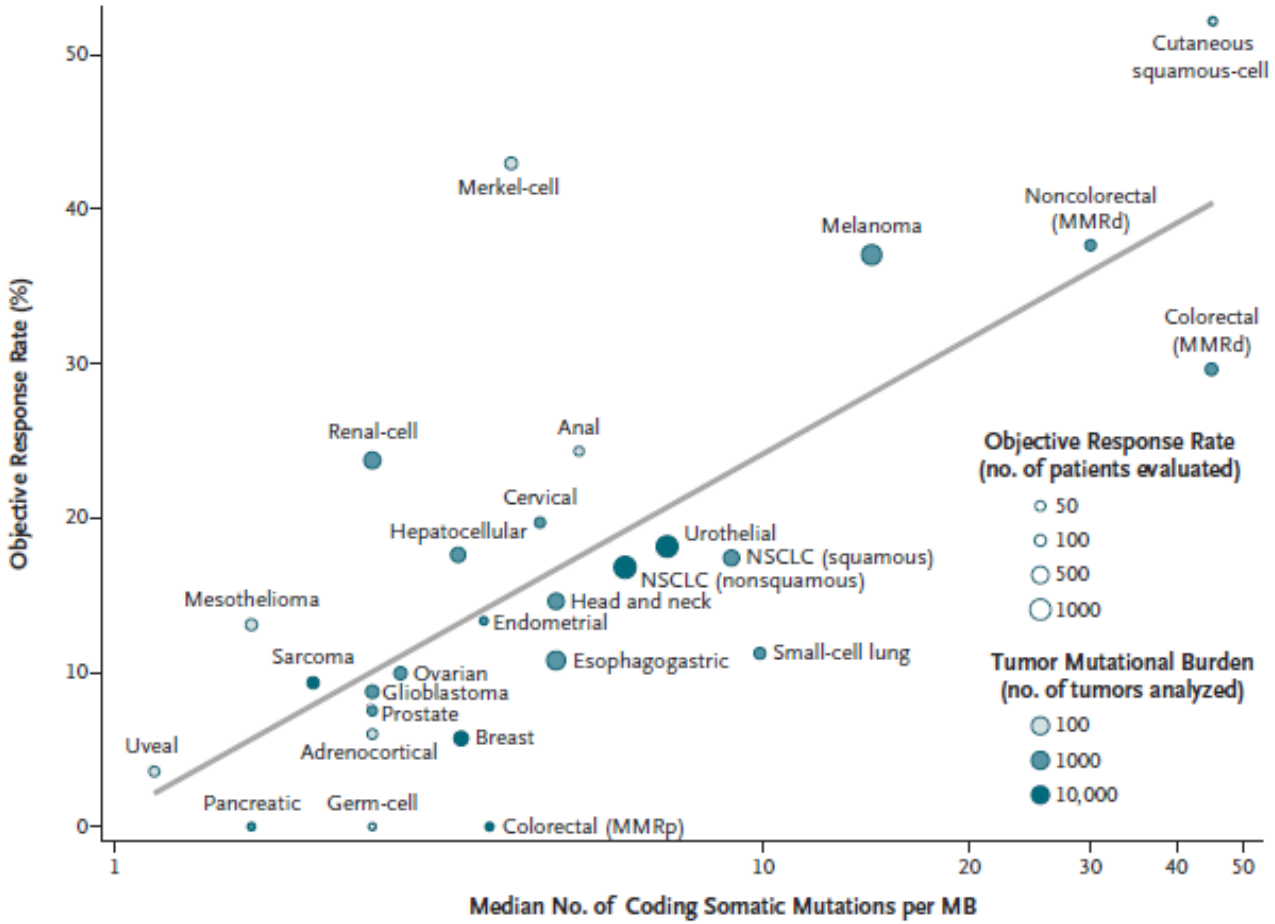



- Seven parameter that provide a framework to understand the immunogenicity of a cancer

- The “value” of these parameters can differ greatly between diagnoses and patients

Blank et al. Science 2016

# Correlation between tumor mutational burden (TMB) and objective response to anti-PD1/PDL1

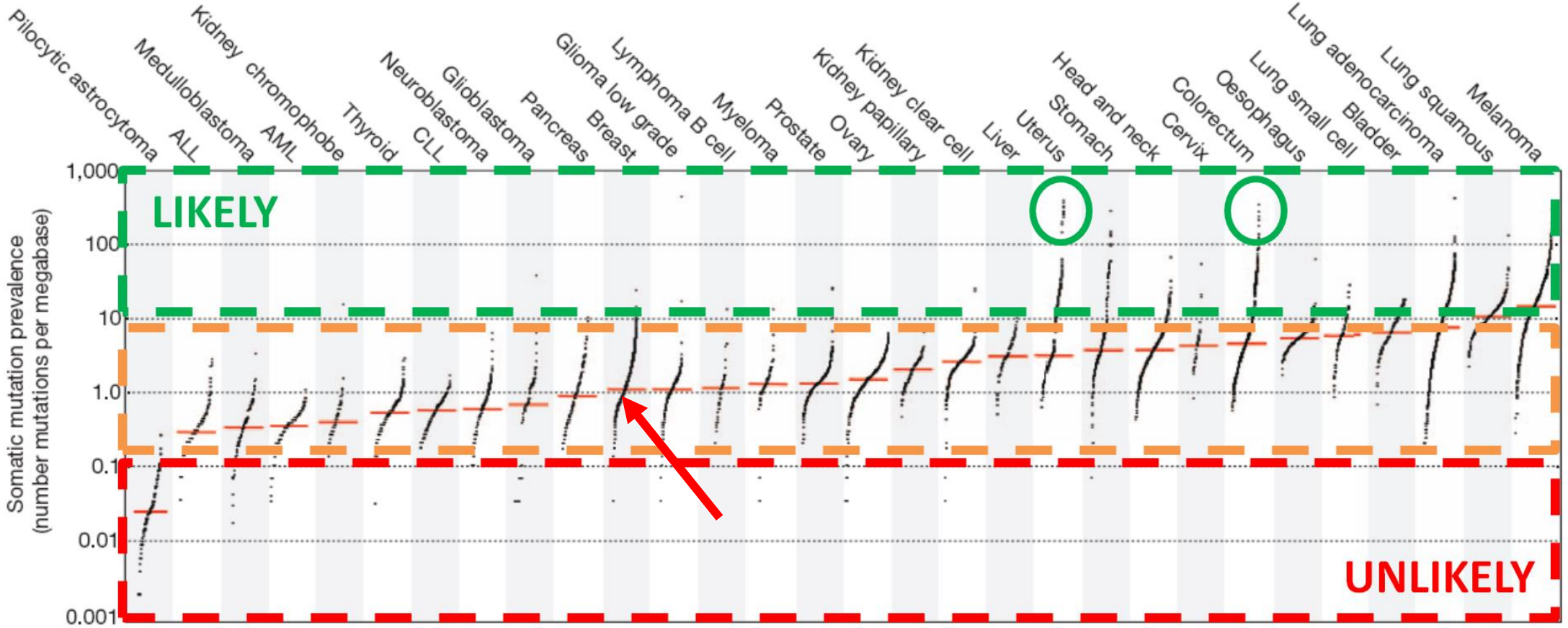



Yarchoan et al, NEJM 2017

TMB is the number of somatic mutations in the conding DNA sequence of the cancer genome

TMB does not take into account account self-antigen recognition

# Mutational burden of solid tumors




Schumacher et al. Sience 2017
Alexandrov et al, Nature 2013

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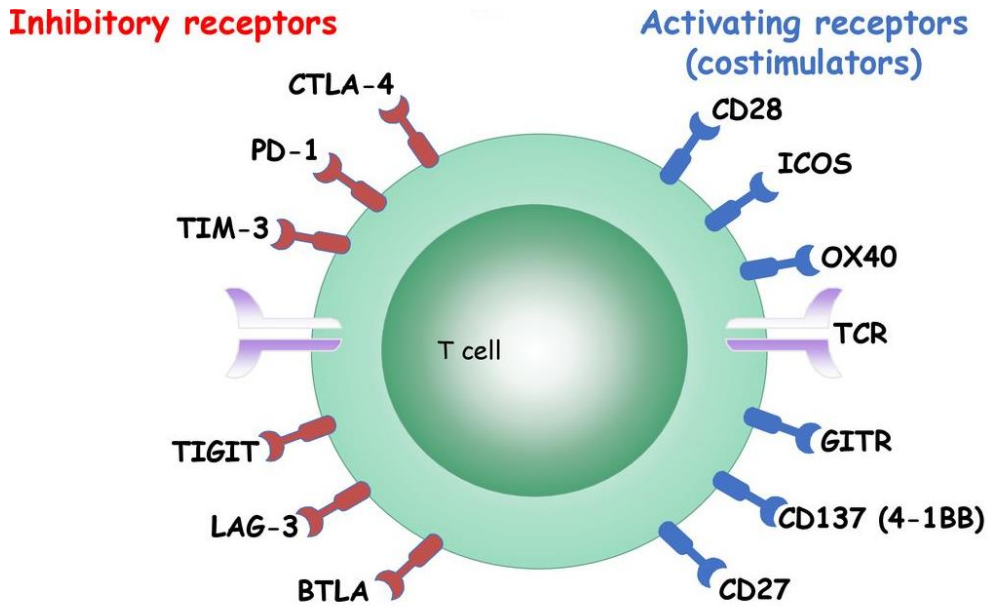
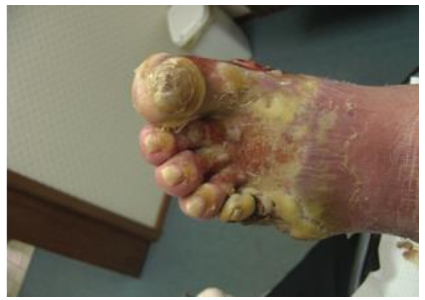
# Manipulation of the immune system comes with a risk



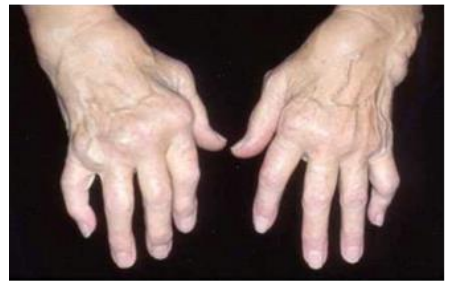

- Immunological balance:
  - Critical to maintain tolerance towards normal tissue
  - Prevents autoimmunity
- Immune regulating antibodies
  - Can potentially cause autoimmune reactions by interrupting the immune balance

→ Immune-related adverse events

Infections



Autoimmune diseases



# Immune-related Adverse Events (irAEs) – why?

**Potential mechanisms:**

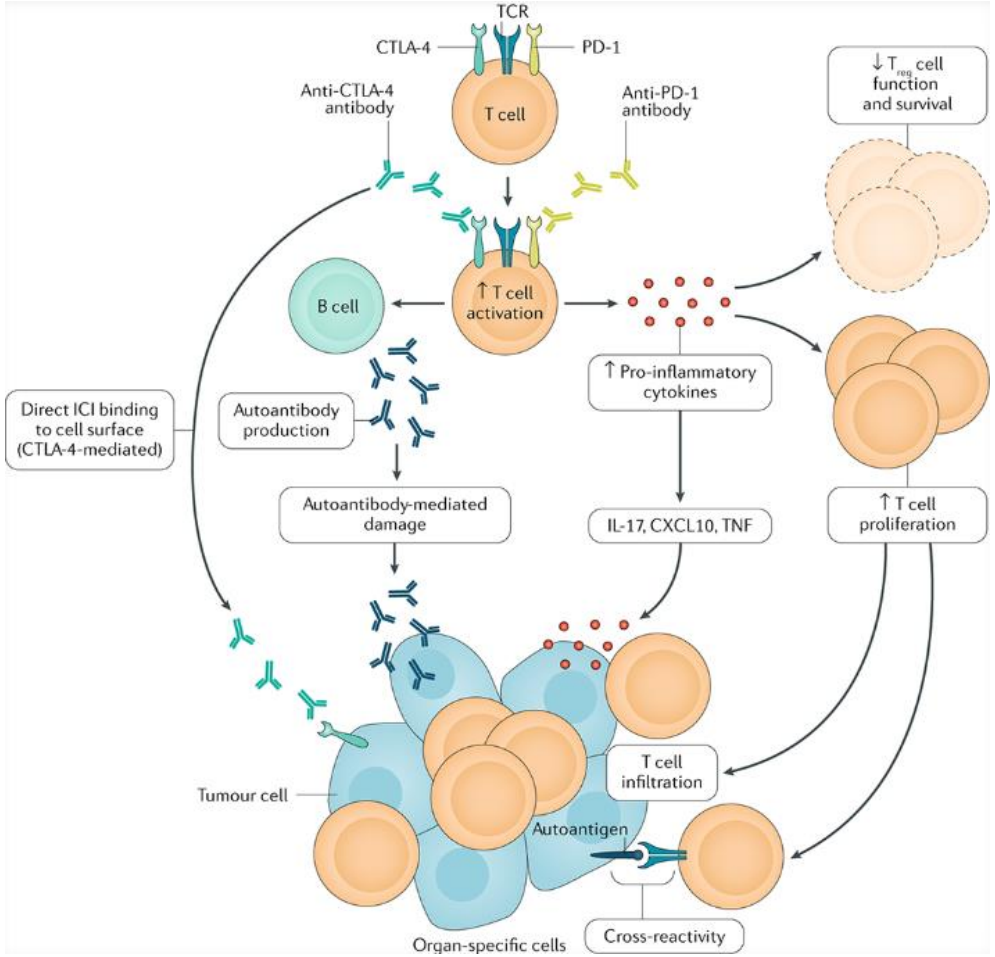
1) increasing T-cell activity against overlapping antigens in tumors and healthy tissue

2) increasing levels of preexisting autoantibodies

3) an increase in the level of inflammatory cytokines

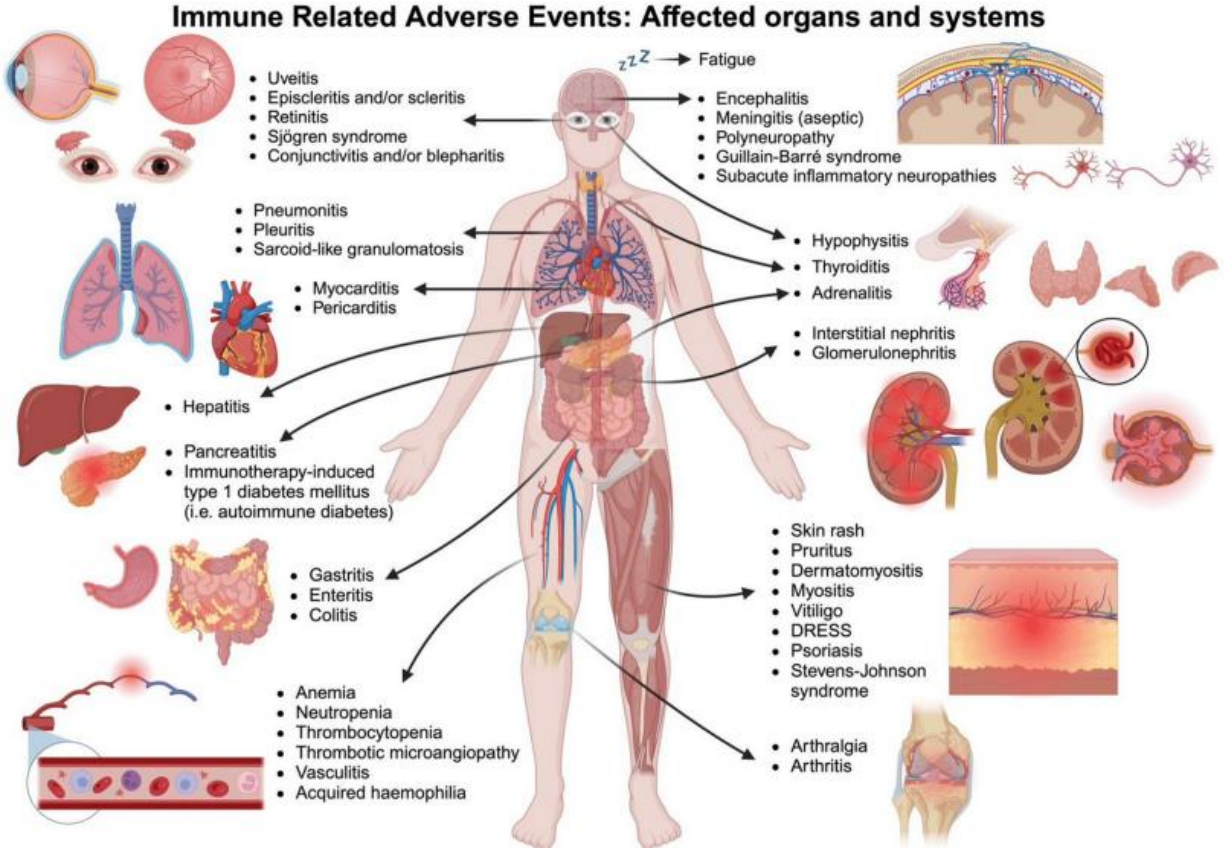
4) enhanced complement-mediated inflammation due to direct binding of drug antibody against immune checkpoint molecules (e.g. CTLA-4) expressed on normal tissue

5) Genetic susceptibility to Immunotox may also play an important role but has so far been poorly studied

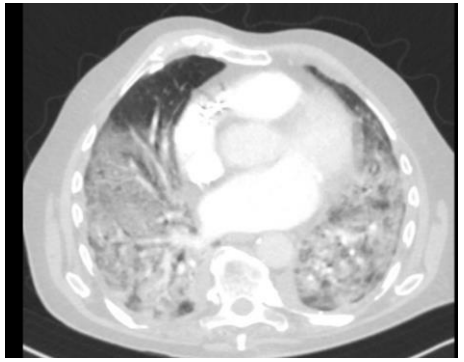


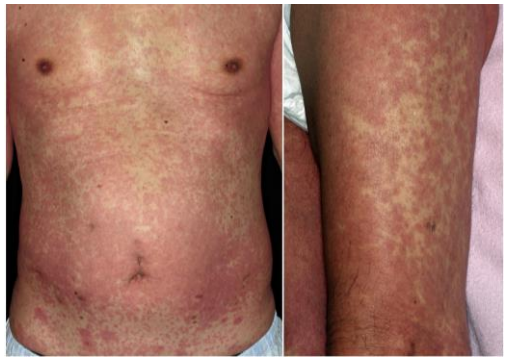

Ramos-Casals et. al-., Nature Rev Dis Primers 2020

# Immune-related Adverse Events – which?

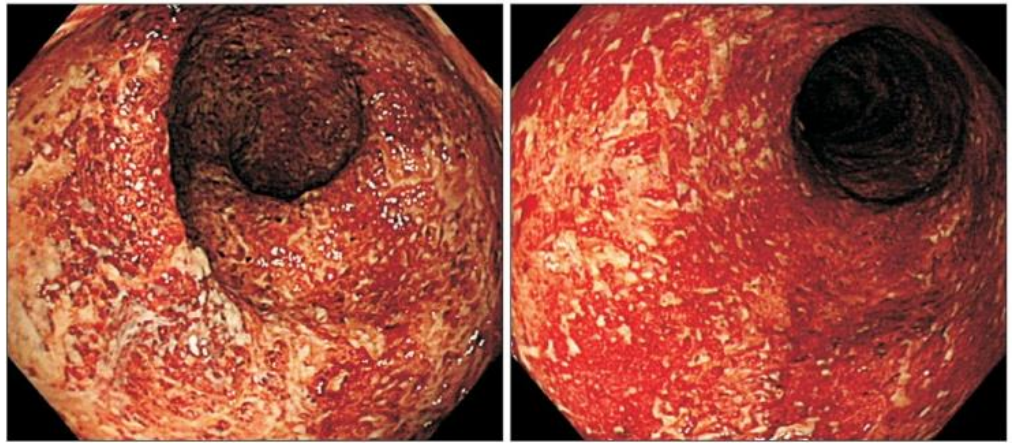



- ICIs are well-tolerated by most people
- irAEs are often mild, but they can be fatal
- Common irAEs are rash, colitis, endocrinopathies, and pneumonitis





Okiyama et al., Allergology Int., 2022



Lee et al., Intestinal Research 2018

# Immune-related Adverse Events – which?

- Mild irAEs are most often seen, while serious irAEs are less common.

CTCAE-grading

Grade 1: **Mild**; asymptomatic; clinical or diagnostic observations only; intervention not indicated.

Grade 2: **Moderate**; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL

Grade 3: **Severe** or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization; limiting self-care ADL.

Grade 4: **Life-threatening** consequences; urgent intervention indicated.

Grade 5: **Death**

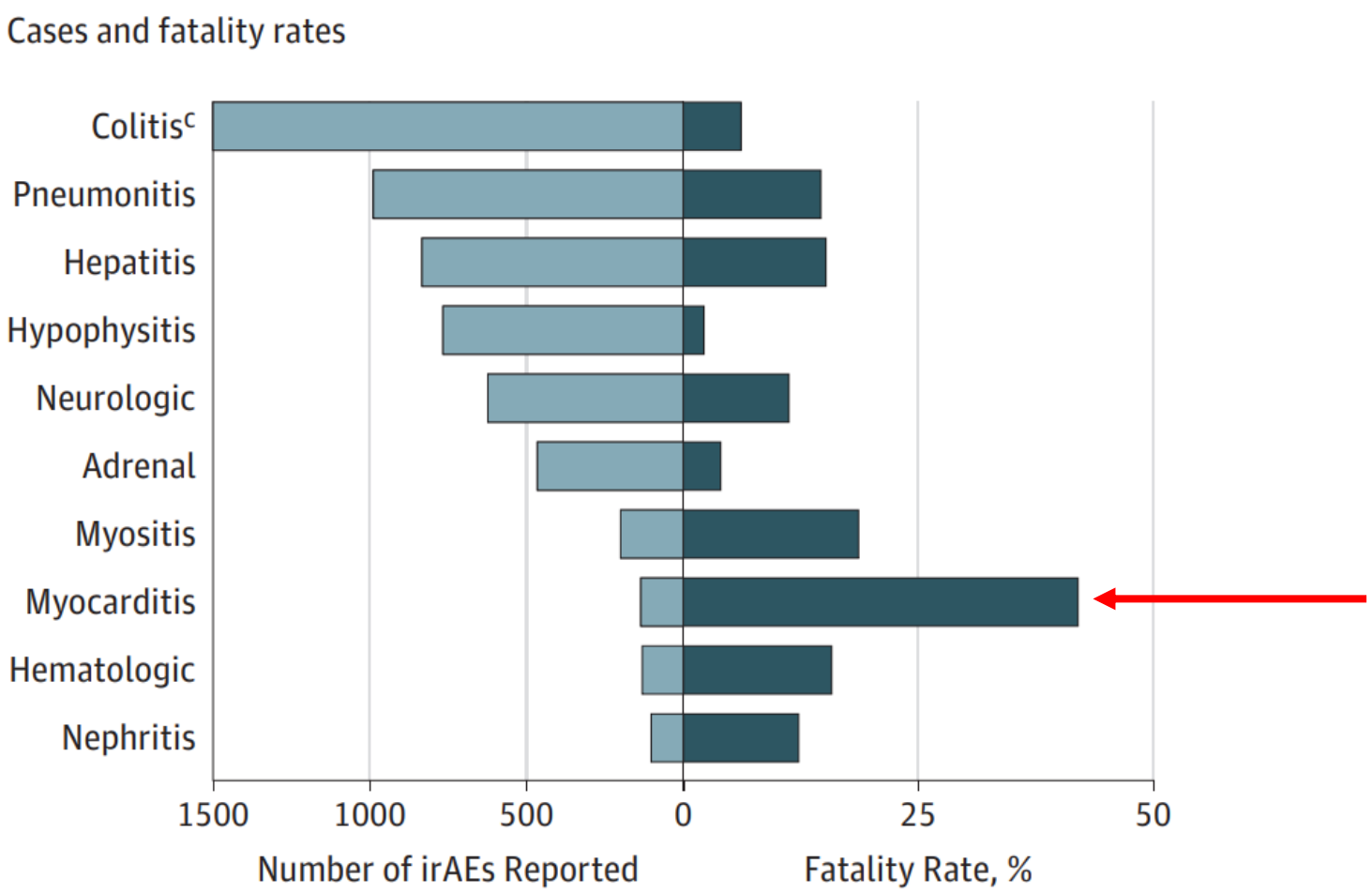
Common Terminology Criteria of Adverse Events

The type and severity of irAEs differ between the various antibodies

| | Grade 3-4 AEs % | % of Pts who permantely discontinued for any grade |
|---|---|---|
| Ipilimumab 3 mg/kg[1] | 27 | 15.4 |
| Ipilimumab 10 mg/kg[1] | 34 | 31 |
| Nivolumab[2] | 13 | 6 |
| Pembrolizumab 2 mg/kg[3] | 13.5 | 4.5 |
| Ipilimumab/Nivolumab[4] | 56.5 | 38.7 |

Modified from Ascierto P, ESMO 2017 Annual Meeting

# Incidence and fatality rate of immune related adverse events



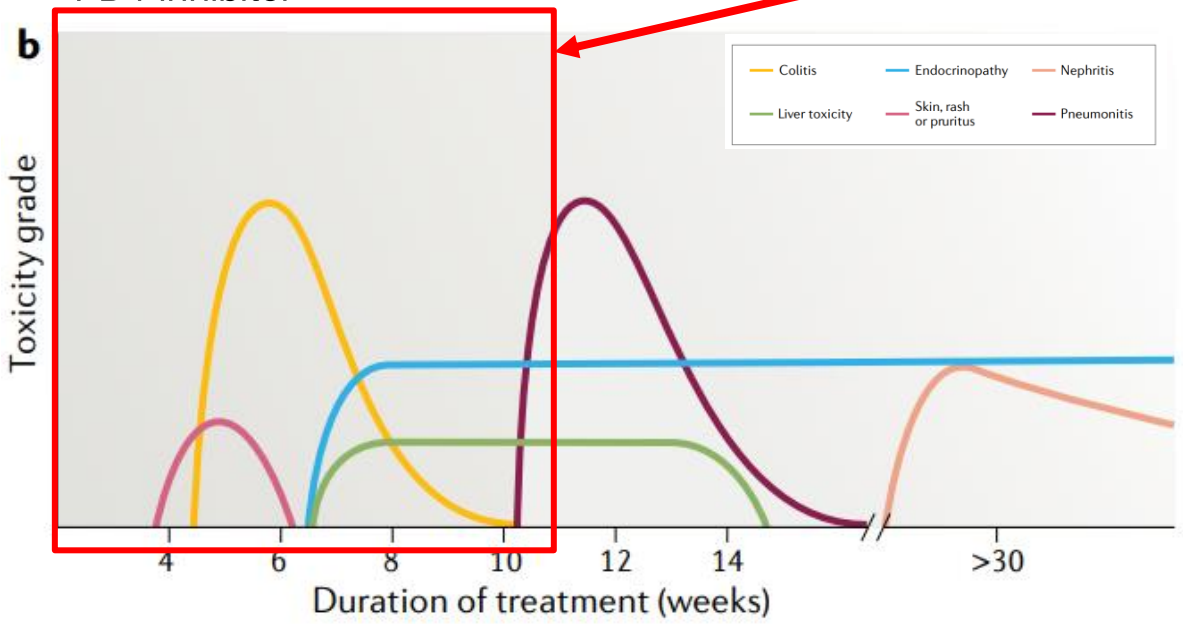

- Uncommon (<1%), but may be life-threatening (up to 50%)
- Highest incidence and fatality with combination treatment
- Median onset 1 month after therapy initiation

Wang et al., JAMA Oncology 2018

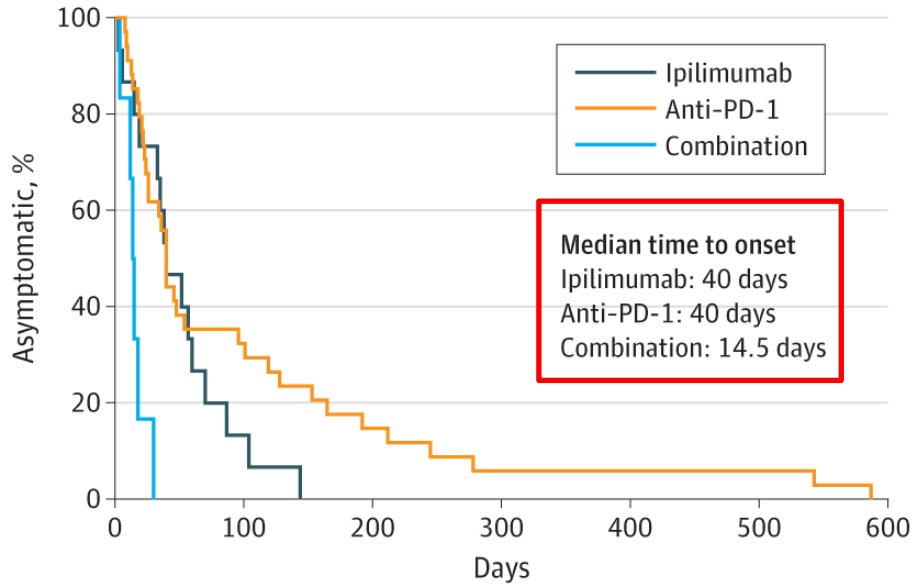
# Immune-related Adverse Events – when?

Pre-surgical period for patients receiving neoadjuvant therapy

PD1 inhibitor




Martins et al., Clinical Oncology 2019




No. at risk

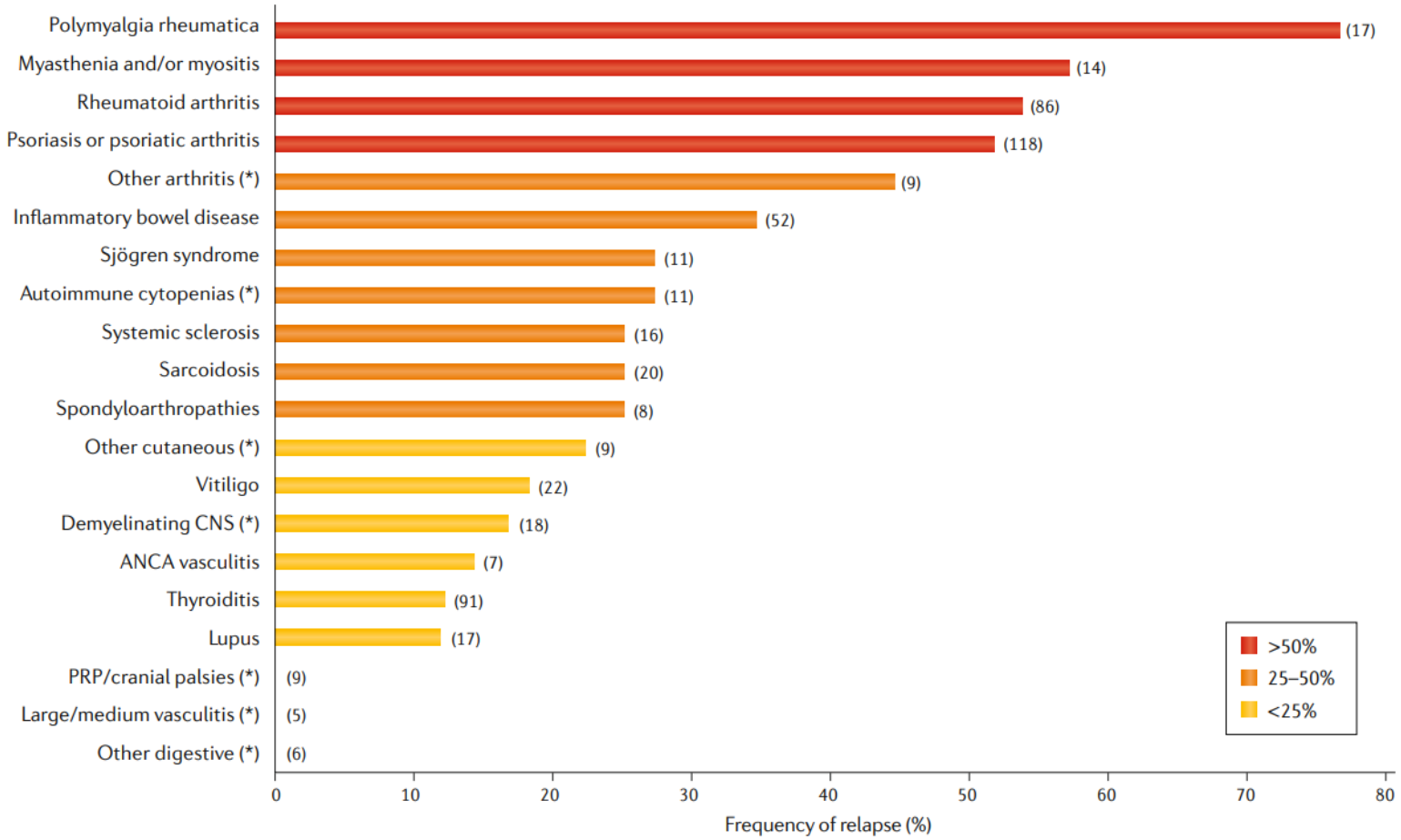
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Ipilimumab | 15 | 2 | 0 | 0 | 0 | 0 | 0 |
| Anti-PD-1 | 34 | 11 | 5 | 2 | 2 | 2 | 0 |
| Combination | 6 | 0 | 0 | 0 | 0 | 0 | 0 |

Wang et al. JAMA onc. 2018,

- Many irAEs develop within the first **4-12 weeks** from treatment initiation
- The onset is earlier for patients receiving combination therapy.
- irAEs that tend to develop late (>1 year): Kidney and haematological

Fatal irAEs develop early

# Immune-related Adverse Events – who?

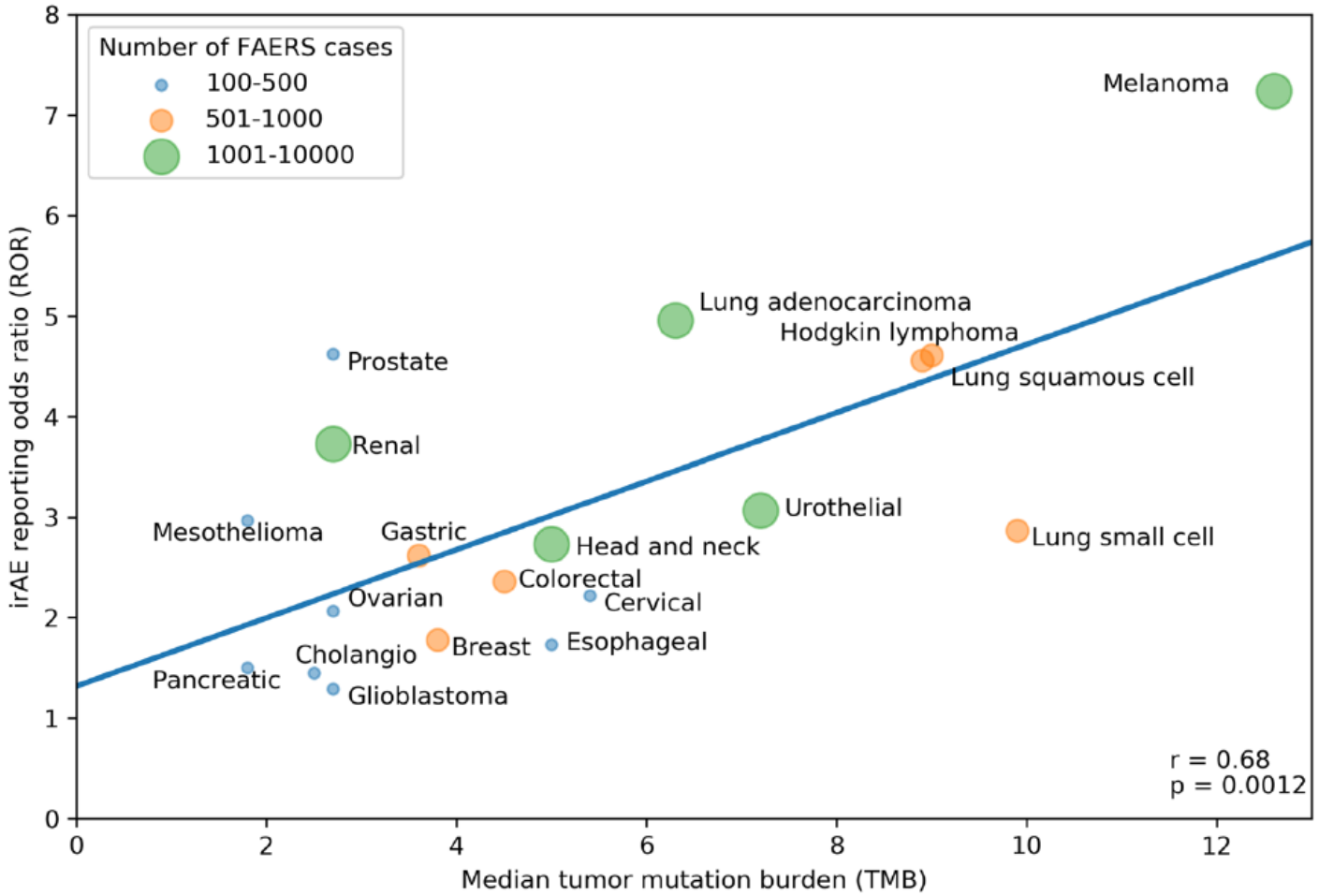



Ramos-Casals et al., Nature Rev Dis Primers 2020

Pre-existing autoimmune disease increases the risk of irAEs

~5% of the Danish population have an autoimmune disease

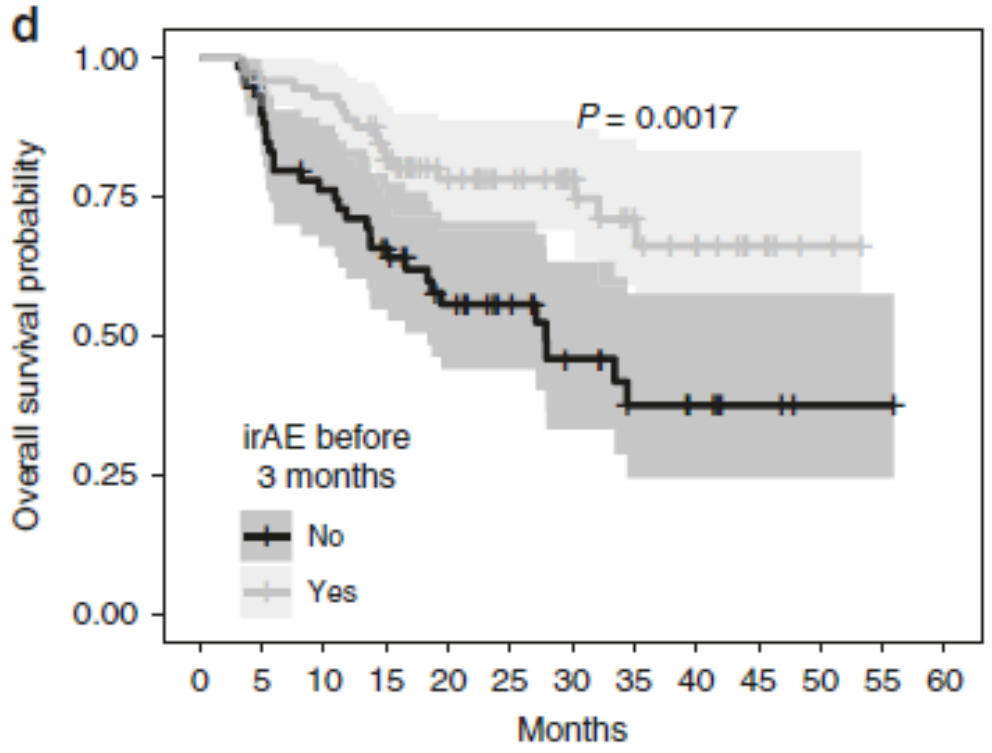
# Immune-related Adverse Events – who?




Cancer Immunology, Immunotherapy (2020)

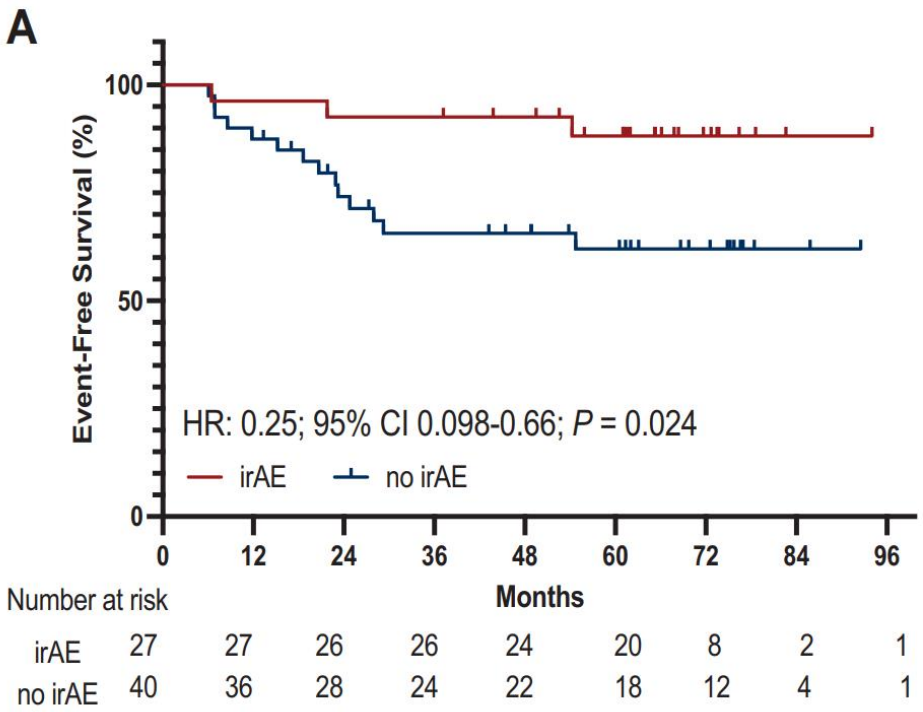
Immune-related adverse events are associated to tumor mutational burden in different solid cancers

# Immune Related Adverse Events are Related to Survival in Melanoma Patients




British Journal of Cancer (2021)

**Similar tendencies are reported in other solid cancers, including TNBC**




Rios-Hoyo et al., ESMO open, 2025

The development of irAE is associated with a significantly higher EFS in patients with TNBC treated with neoadjuvant immune checkpoint therapy plus chemotherapy

# Immune Related Adverse Events – increased risk in elderly?

## Safety Summary by Key Subgroups (CheckMate 067)

| Patients Reporting Event, % | NIVO+IPI (n=313) | | NIVO (n=313) | |
|---|---|---|---|---|
| | Any Grade | Grade 3–4 | Any Grade | Grade 3–4 |
| **Treatment-related AE** | 96 | 55 | 82 | 16 |
| Aged ≥65 and <75 years | 95 | 50 | 81 | 22 |
| Aged ≥75 and <85 years | 97 | 48 | 83 | 21 |
| M1c disease | 94 | 54 | 79 | 14 |
| PD-L1 expression ≥5% | 97 | 53 | 85 | 16 |
| Patients with complete response | 100 | 58 | 93 | 32 |
| **Treatment-related AE leading to discontinuation** | 36 | 29 | 8 | 5 |
| **Treatment-related death[a]** | 0 | | <1 | |

- Treatment-related AEs reported with IPI were consistent with prior experience

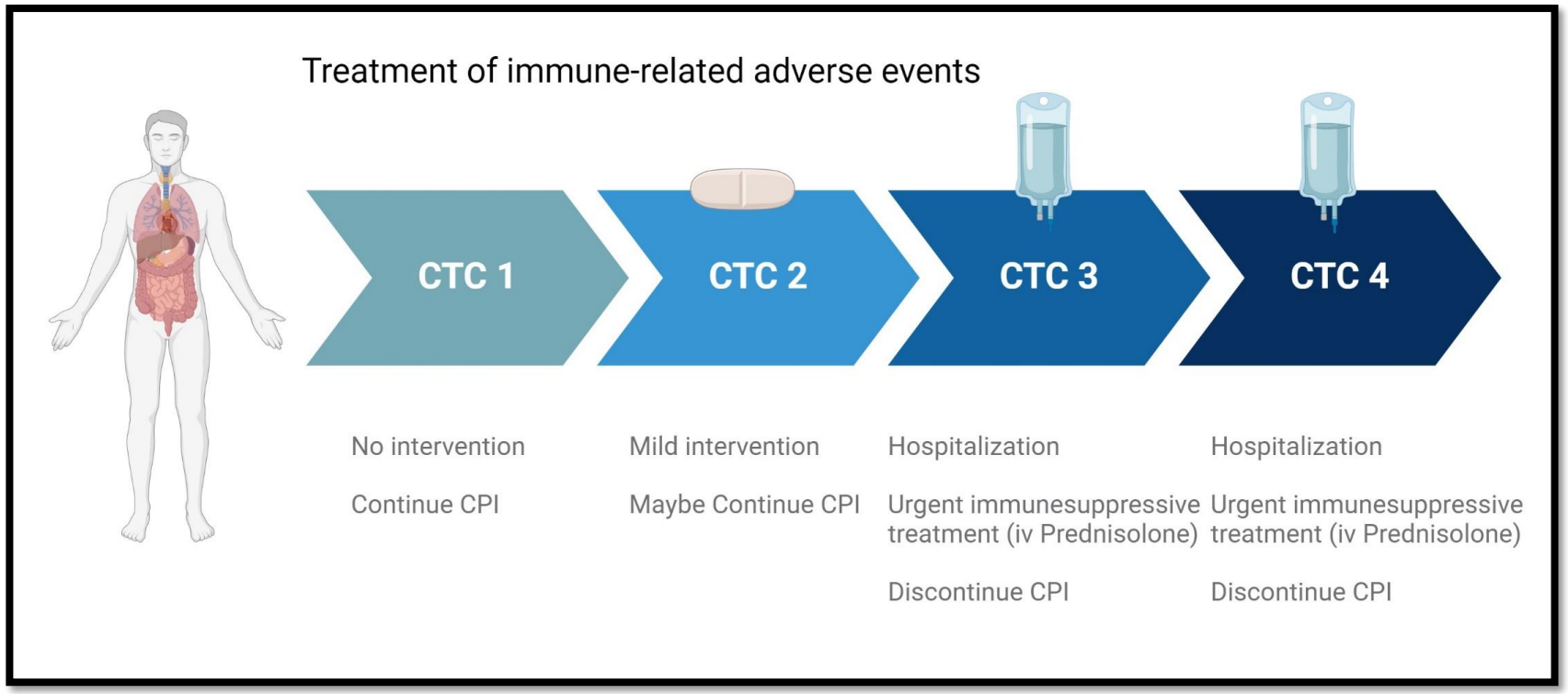
[a]One death in the NIVO group was reported as neutropenia.
Larkin J, et al. Presented at ECC 2015 abstract 3303.

- Chance of efficacy largely independent of age (data not shown)
- The risk of serious side effects is not increased with increasing age
- The tolerability of side effects can be reduced
- In DK we rarely treat patients above 80 with **combined** checkpoint inhibitors.

CCIT DENMARK

# How to handle irAEs – Key recommendations

**There should be a high level of suspicion that new symptoms are treatment-related**

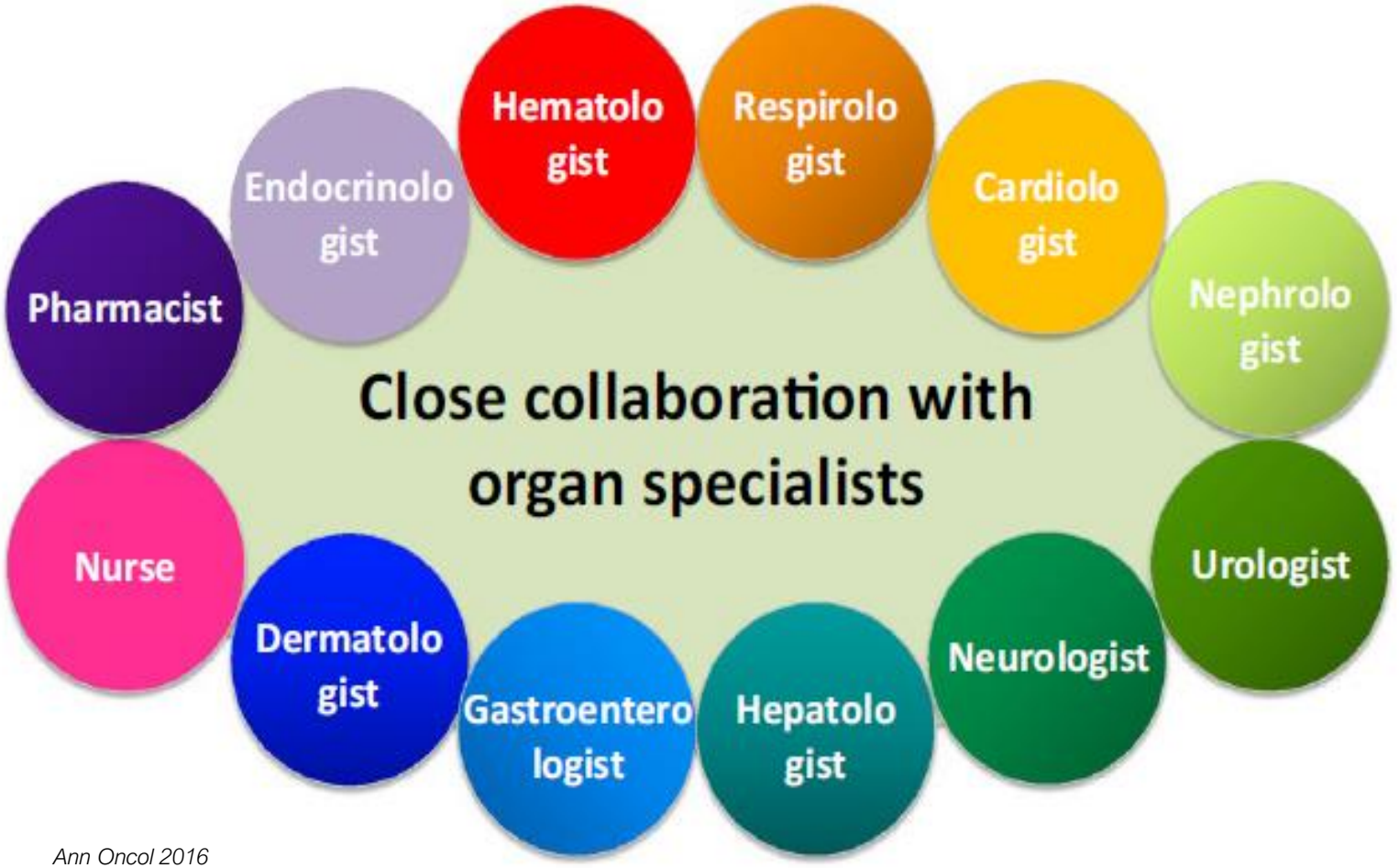



R. Jurlander, created with Biorender

When symptoms and/or laboratory values revert ≤ grade 1, rechallenging with ICIs may be offered

Grade 4 toxicities: Permanent discontinuation of ICIs (except for endocrinopathies)

# Multi-diciplinary management of immune toxicity

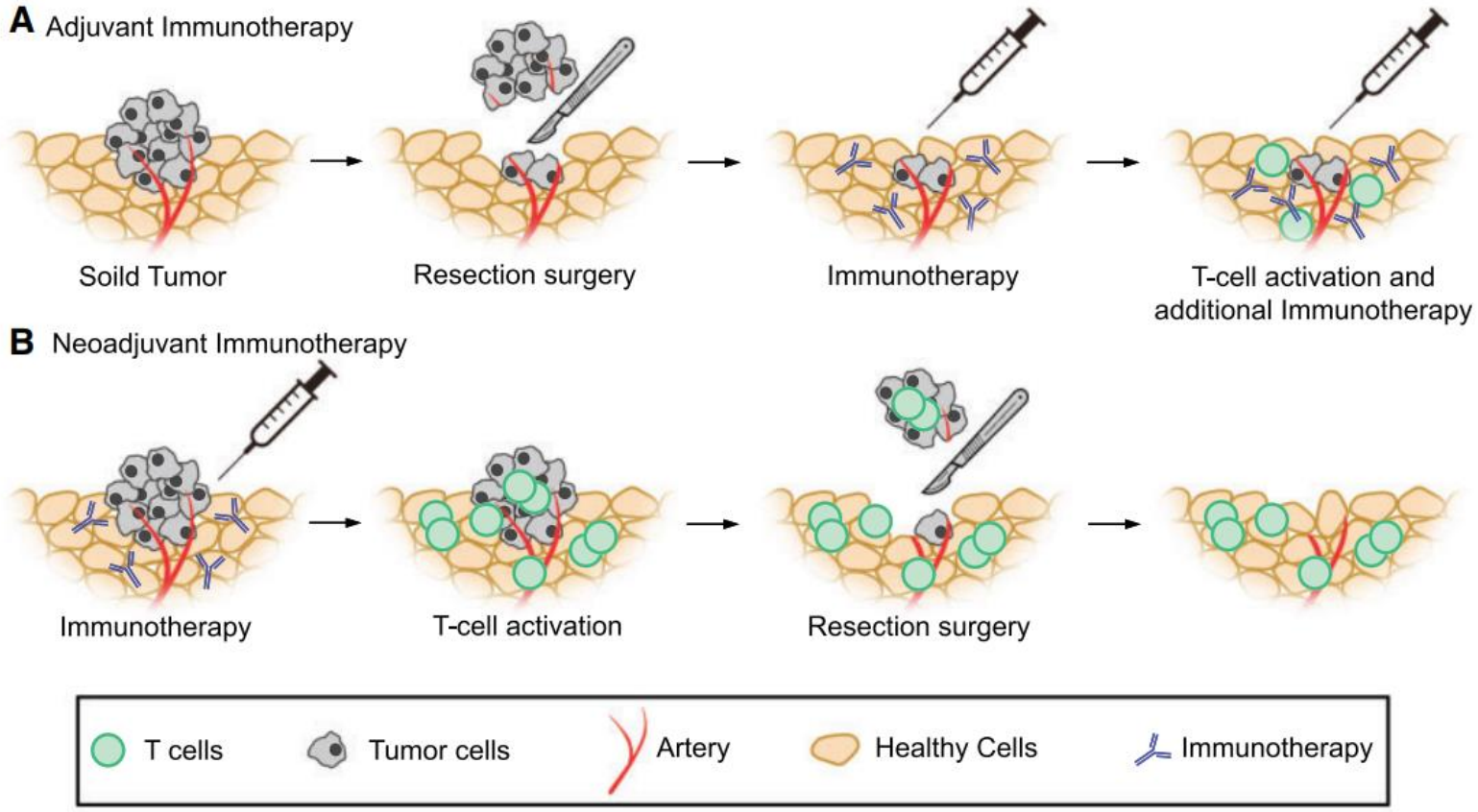



*Ann Oncol 2016*

# Outline

- Introduction: Cancer Immunotherapy
  - Rationale and historical development
  - Types of immunotherapy
  - Immune Checkpoint Inhibitors (ICI)
- Efficacy (in melanoma) and challenges in response evaluation
- Which patients benefit from treatment with immunotherapy?
- Immune related toxicity: why, which, when and who?
- Neoadjuvant immunotherapy – rationale and challenges
- Perspectives

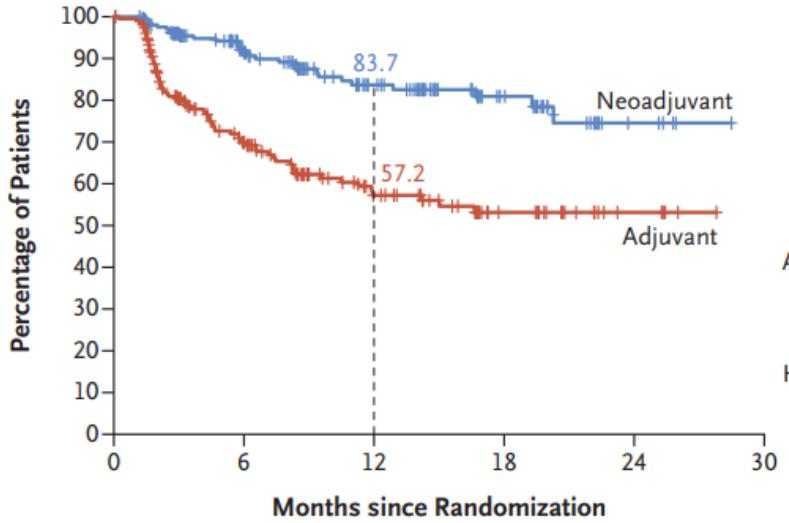
# Neoadjuvant immunotherapy – theoretically better than adjuvant therapy




The presence of the entire tumor, and therefore the complete neoantigen repertoire, at the time the immunotherapy is initiated induces a stronger and more diverse T cell response

Krishnamoorthy et al., JNCI J Natl Cancer Inst 2021

# Neoadjuvant ICI results in a better EFS compared to adjuvant ICI in melanoma




| No. at Risk (no. censored) | | | | | |
|---|---|---|---|---|---|
| Neoadjuvant | 212 (0) | 126 (71) | 77 (111) | 34 (152) | 5 (179) |
| Adjuvant | 211 (0) | 100 (57) | 53 (89) | 23 (116) | 6 (133) |

| | No. of Events/ Total No. of Patients |
|---|---|
| Neoadjuvant | 28/212 |
| Adjuvant | 72/211 |

Adjusted difference in restricted mean survival time, 8.00 mo (99.9% CI, 4.94–11.05); P<0.001

Hazard ratio for progression, recurrence, or death, 0.32 (99.9% CI, 0.15–0.66)

Table 3. Adverse Events.*

| Event | Neoadjuvant Group (N=212) | Adjuvant Group (N=208) |
|---|---|---|
| Any adverse event — no. (%) | 204 (96.2) | 194 (93.3) |
| Any grade ≥3 adverse event — no. (%) | 100 (47.2) | 71 (34.1) |
| Serious adverse event — no. (%) | 77 (36.3) | 49 (23.6) |
| Treatment-related adverse event — no. (%) | 196 (92.5) | 178 (85.6) |
| Treatment-related grade ≥3 adverse event — no. (%) | 82 (38.7) | 50 (24.0) |
| Surgery-related adverse event — no./total no. (%) | 120/198 (60.6) | 151/208 (72.6) |
| Surgery-related grade ≥3 adverse event — no./total no. (%) | 28/198 (14.1) | 30/208 (14.4) |
| Adverse event related to systemic treatment — no./total no. (%) | 181/212 (85.4) | 123/170 (72.4) |
| Grade ≥3 adverse event related to systemic treatment — no./total no. (%) | 63/212 (29.7) | 25/170 (14.7) |
| Discontinuation of treatment due to adverse event — no. (%) | 19 (9.0) | 30 (14.4) |
| Death due to treatment-related adverse event — no. (%) | 0 | 1 (0.5) |

Blank et al, New eng. J. Med., 2024

## Neoadjuvant immunoterapy in melanoma

- Does not incrase the rate of surgery-related adverse events
- Does not increase the duration of the surgery
- Does not increase specific morbidities (seroma, lymphodema ect.)

Kuijpers et al., Cancers, 2024

## Most trials does not include specific surgical endpoints

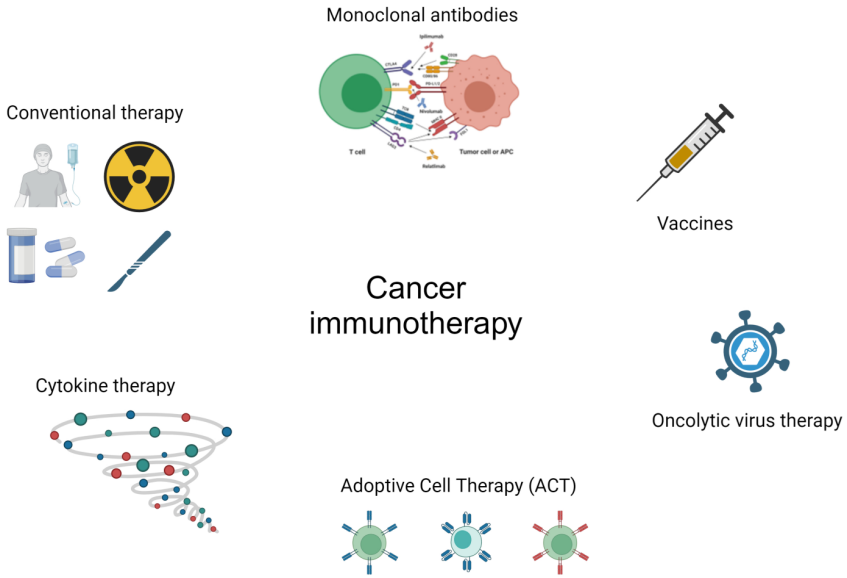
- Tissue fibrosis and its impact on surgery (only anectotal reports)?
- Difficulties in accurate determination of tumour margins?

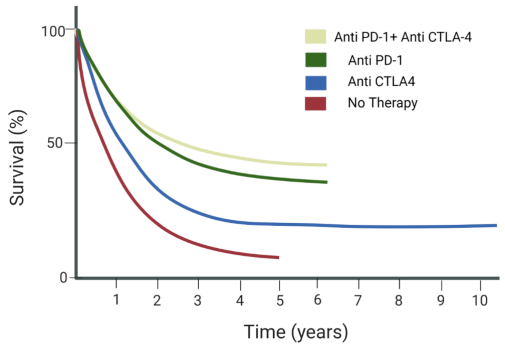
Kuijpers et al., Cancers, 2024, Leser et al., Ann. Of surgery, 2024

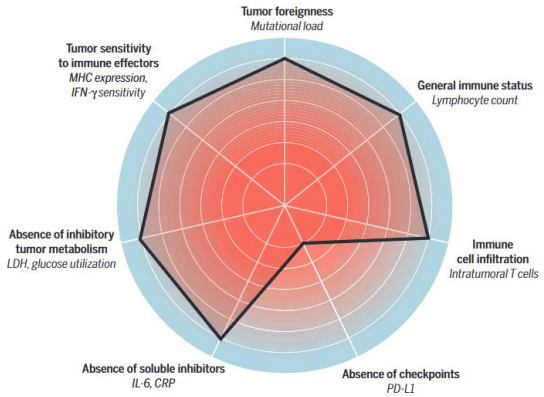
# Outline

- Introduction: Cancer Immunotherapy
  - Rationale and historical development
  - Types of immunotherapy
- Immune Checkpoint Inhibitors (ICI)
  - Mode of action and efficacy in and beyond malignant melanoma
  - Immune related toxicity: why, which, when and who?
- Neoadjuvant immunotherapy – rationale and status
- Perspectives and take-home-messages

# Immunotherapy – take home messages



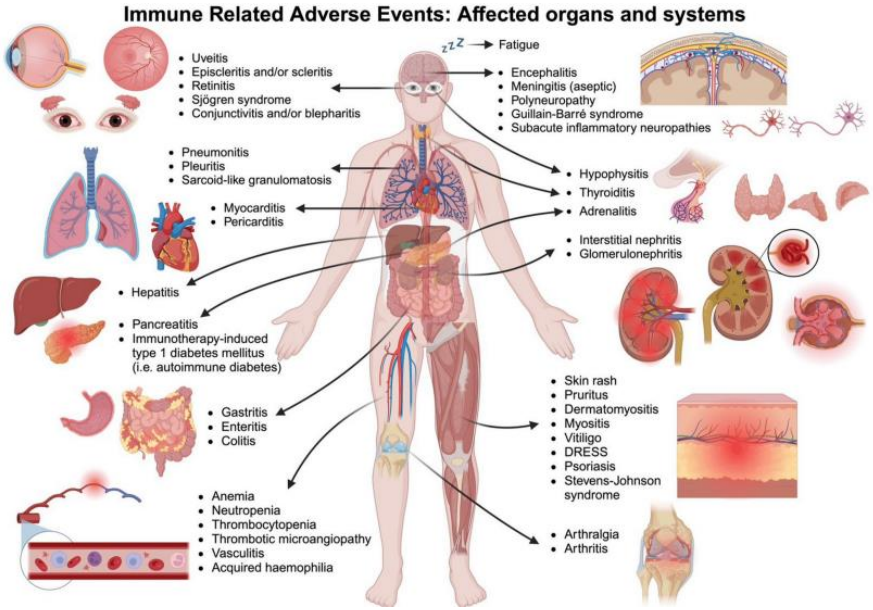




- The term immunotherapy covers a wide range of immune-activating approaches, with immune checkpoint inhibitors (ICIs) being the most widely used
- Immunotherapy continues to expand to an increasing number of solid tumor types
- Immunotherapy can result in durable, complete responses or long-lasting partial reponses/stable disease, however primary and secondary resistance is a major challenge
- Pseudoprogression is a rare phenomenon – but to understand and recognize it is important
- The chance of response depends on multiple factors (of which many are still not clear)

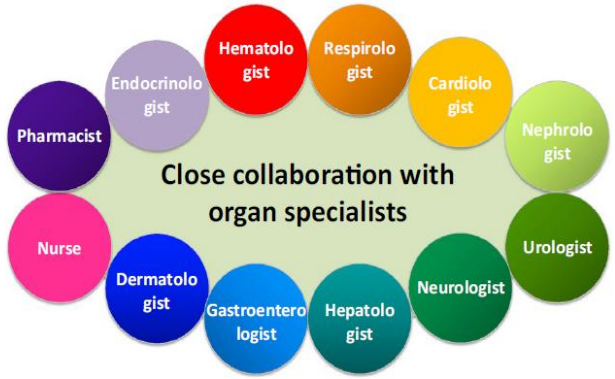
# Immunotherapy – take home messages

- Immune-related adverse events can affect almost any organ system
- Most immune-related adverse events develop early, but late onset (>1 year) is possible
- Immune-related adverse events can be fatal. Early recognition and treatment is crucial
- Handling of severe irAEs is a multidisciplinary task
- Immunotherapy is expanding to the neoadjuvant setting (melanoma, TNBC) demanding close collaboration with surgeons. The impact on surgical endpoints still needs further exploration.




**Session A, May 13, auditorium G206-145**

| | |
|---|---|
| **09.30-10.00** | **Registration, coffee and exhibition** |
| **10.00-10.15** | **Welcome**<br>Peer Christiansen |
| **10.15-12.00** | **Immunotherapy for patients with breast cancer**<br>Moderators: Niels Kroman and Hanne Melgaard Nielsen |
| 10.15-10.55 | Experiences with immunotherapy from Denmark<br>Tine Monberg |
| 10.55-11.15 | Indication for immunotherapy in breast cancer patients<br>Christina Bjerre |
| 11.15-11.35 | Sygepleje til patienter med brystkræft der får immunterapi<br>Karen Henneberg |
| 11.35-12.00 | Panel discussion |




Ann Oncol 2016

# Questions?

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