



CANCER RESEARCH INSTITUTE

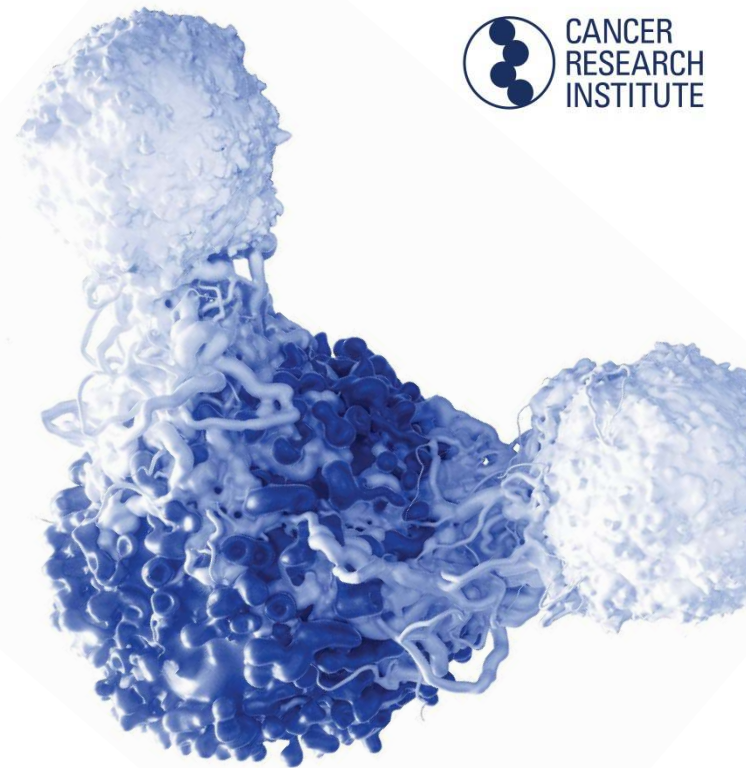
IMMUNOTHERAPY **PATIENT SUMMIT**

San Francisco • Chicago • New York • Houston • Tampa

Tampa December 9, 2017

Brian Brewer
Cancer Research Institute

WELCOME



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A special thank you to those who helped promote the summit

Addario Lung Cancer Foundation

BrainUp

Coalition for Clinical Trial Awareness

Colon Cancer Alliance

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Fight Colorectal Cancer

Focused Ultrasound Foundation

FORCE

GI Cancers Alliance

Imerman Angels

Immunotherapy Foundation

Let Life Happen

Melanoma Research Foundation

National Ovarian Cancer Coalition

Moffitt Cancer Center

Patient Empowerment Network

Scientific Experts

Scott Antonia, M.D., Ph.D.

Moffitt Cancer Center

Nina Bhardwaj, M.D., Ph.D.

Mount Sinai

Ezra Cohen, M.D.

UC San Diego

Philip Greenberg, M.D.

Fred Hutchinson Cancer Center

Patient Experts

Janie Ferling

Melanoma

Donna Fernandez

Lung Cancer

Karen Koehler

Leukemia

Johanna Sedman

Prostate Cancer (caregiver)

Schedule of Events



9:00am	Registration and networking
10:00am	Program commences Welcome Brian Brewer
10:15am	Hear from the experts Learn the basics of immunotherapy Philip Greenberg, M.D. Latest research update panel Moderator Philip Greenberg, M.D. Panelists Scott Antonia, M.D., Ph.D. Nina Bhardwaj, M.D., Ph.D. Ezra Cohen, M.D.
11:30am	Patient perspective Hear from a melanoma survivor Janie Ferling
12:00pm	Lunch and networking

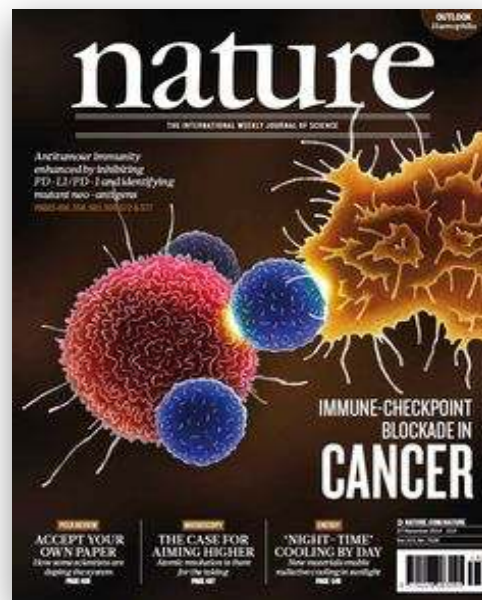
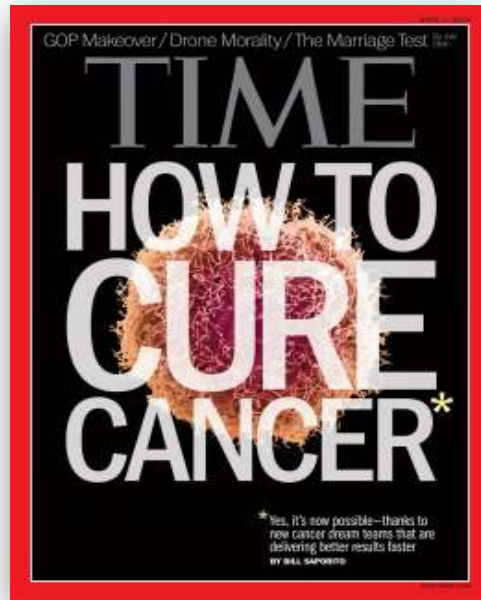
1:00pm	Demystifying clinical trials Learn about clinical trials and panel discussion Moderator Brian Brewer Panelists Donna Fernandez Karen Koehler Johanna Sedman
2:00pm	Refreshment break
2:15pm	Breakout sessions Your choice of moderated discussion with our experts or a general networking session Head and Neck Cancer Ezra Cohen, M.D. Melanoma Nina Bhardwaj, M.D., Ph.D. Lung Cancer Scott Antonia, M.D., Ph.D. General Immunotherapy & Networking Philip Greenberg, M.D.
3:15pm	Program closes
9:00am – 4:00pm	Clinical trial navigator appointments Appointments will be available all day. If you didn't pre-register, check with the registration desk.



Phil Greenberg, M.D.

Professor of Oncology and Immunology
Fred Hutchinson Cancer Research Center and
University of Washington

IMMUNOTHERAPY BASICS



The New York Times

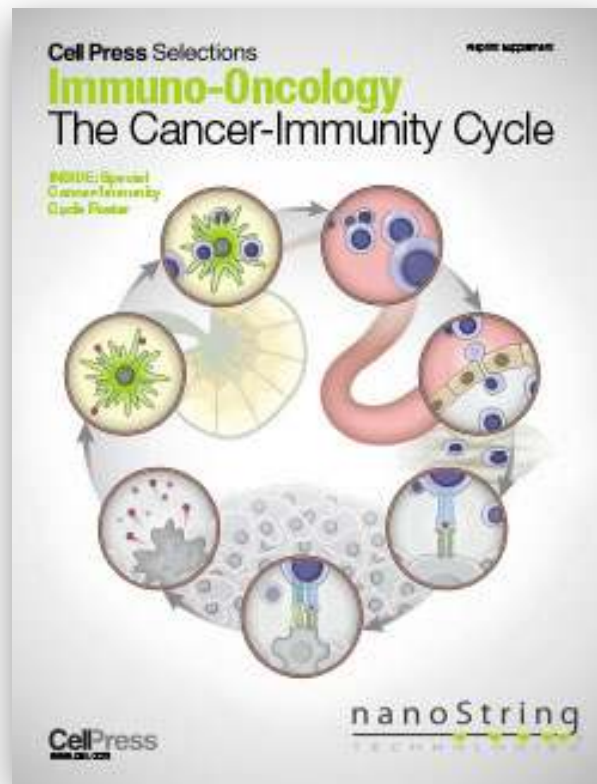
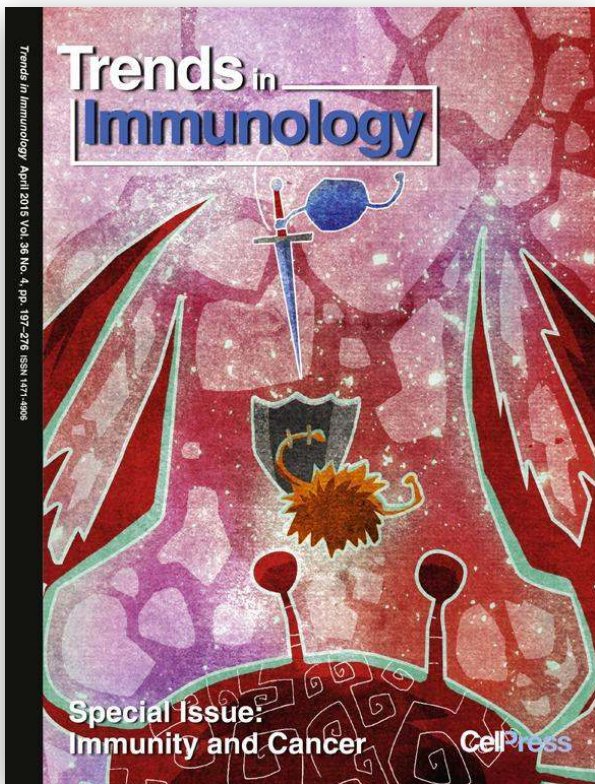
Patient's Cells Deployed to Attack Aggressive Cancer



The Washington Post

Health & Science

New therapies raise hope for a breakthrough in tackling cancer





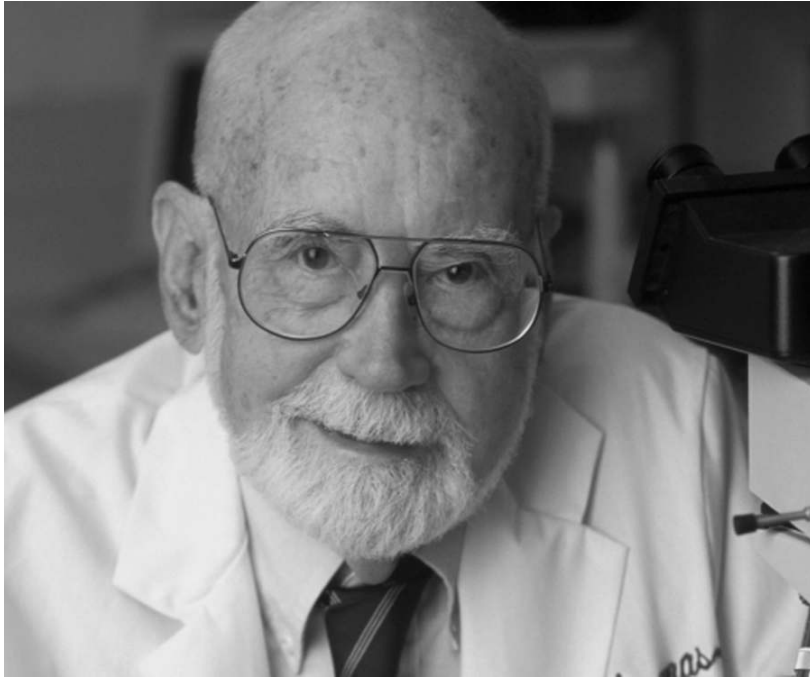
- Noted that some cancer patients experienced remissions following a severe bacterial infection
- In 1891, deliberately infected sarcoma patient with *Strep. pyogenes* and achieved a cure
- By 1893, had developed a mixture of bacterial toxins rather than live bacteria
- Considered the first immunologic therapy
- Results unpredictable, and enthusiasm shifted to newly developed radiation therapy



- Paul Ehrlich, Nobel Laureate, proposed in 1909 that the immune system recognizes and eliminates developing tumors

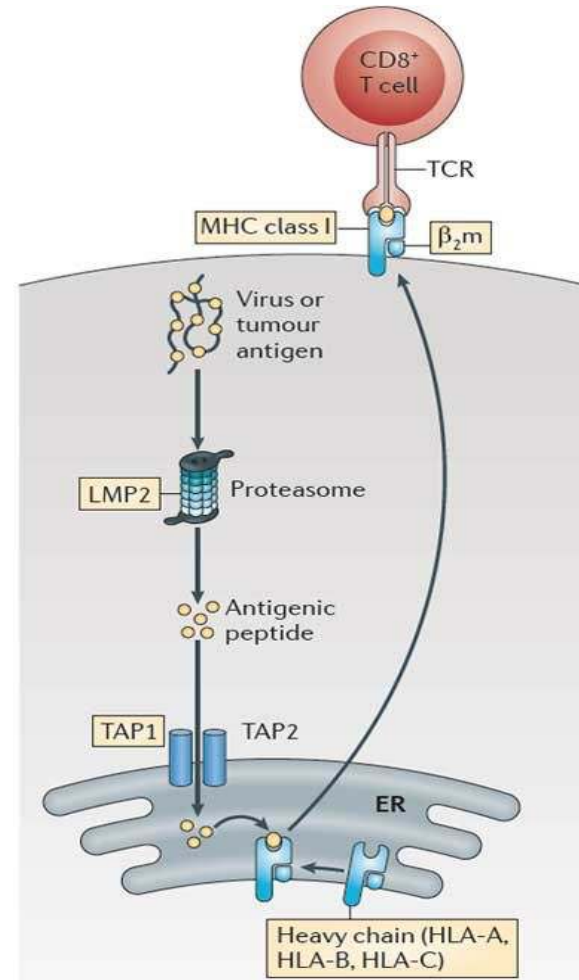
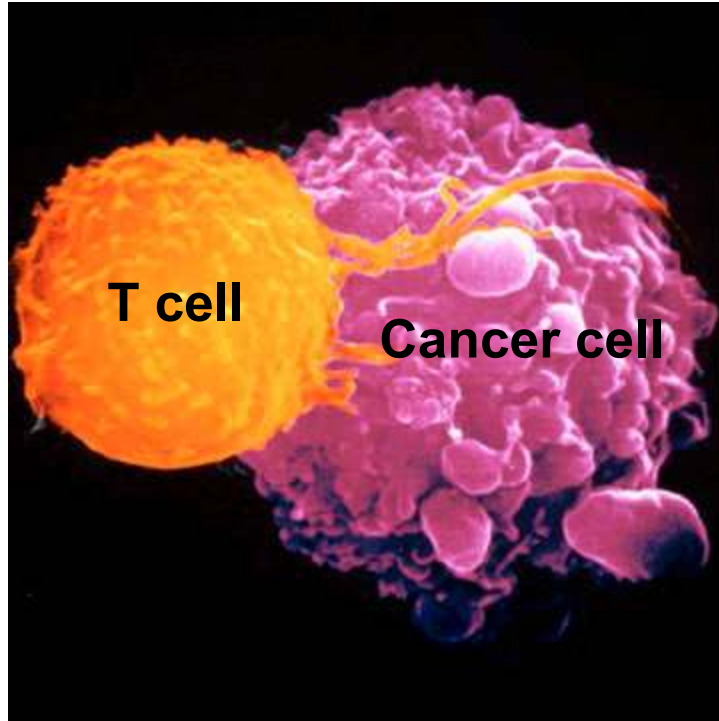


- Sir Macfarlane Burnet, Nobel Laureate, proposed in 1960's that tumors have genetic changes that should allow for recognition and elimination from surveillance by the immune system



- Don Thomas, Nobel Laureate for developing bone marrow transplantation, energized/validated the field by providing, in the 1970's, for the 1st time convincing evidence that human T cells can contribute to the eradication of a malignancy (donor T cells mediating a graft vs leukemia effect after allogeneic bone marrow transplant)

Immune Recognition of Cancer



Immunotherapy Strategy: Boosting the immune system's offense and/or overcoming cancer's defense

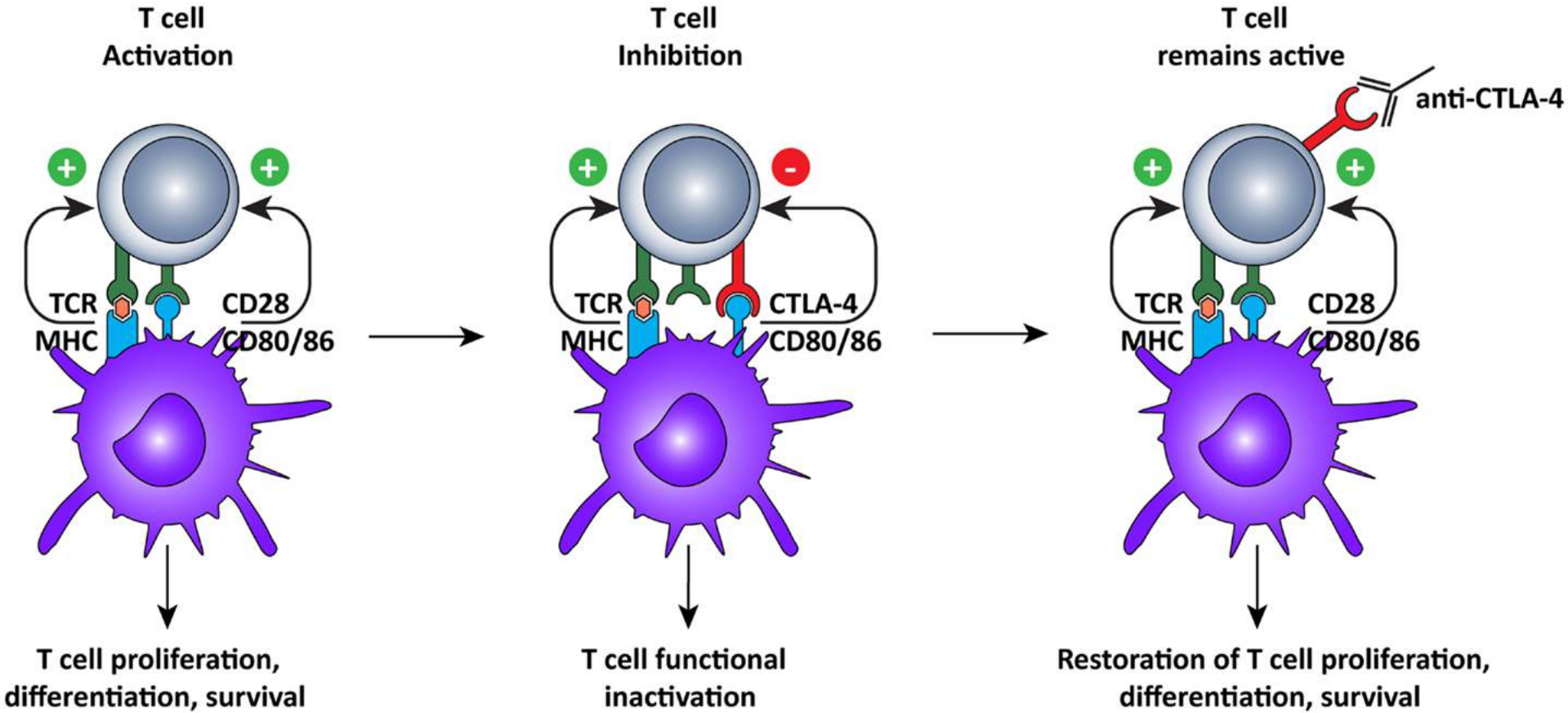


Two general strategies to promote the immune system to destroy cancer

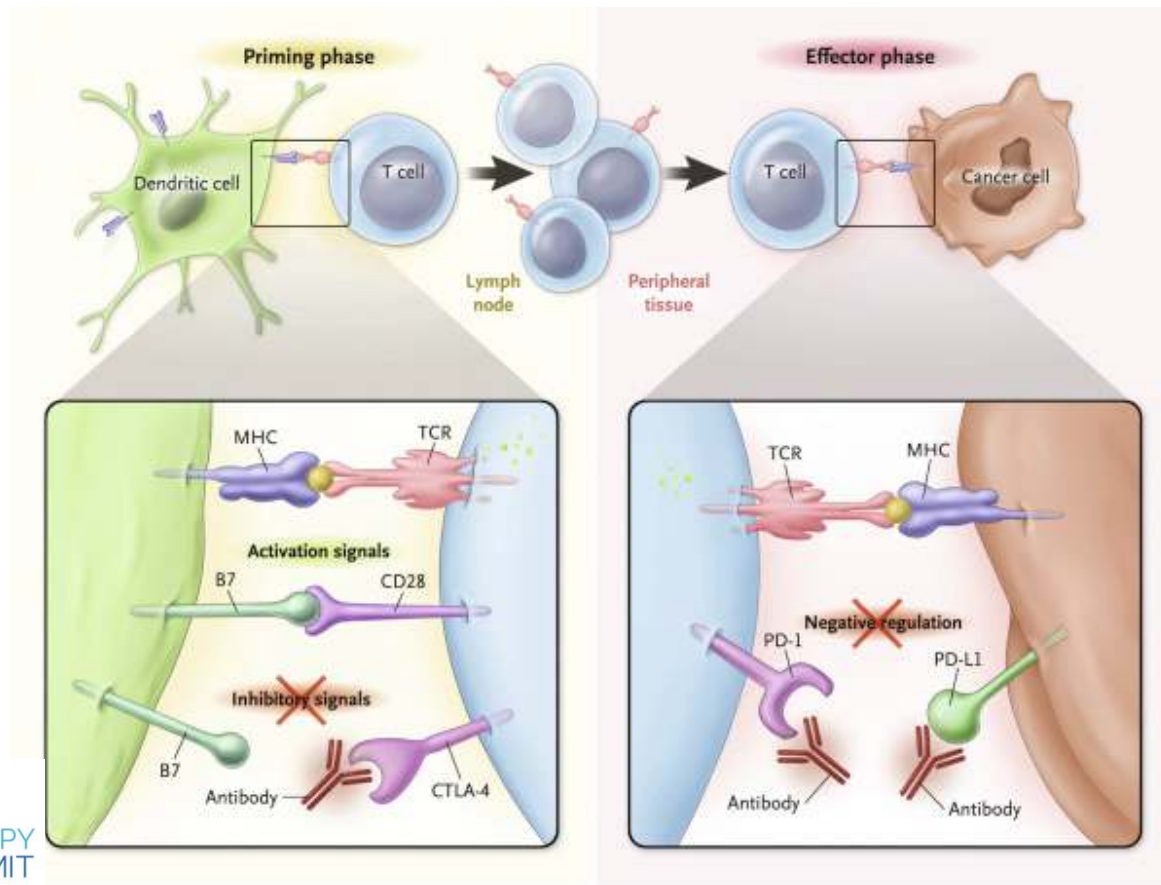


- Boost the offense
 - Increase the number and function of T cells capable of recognizing tumor cells
- Block the defense
 - Interfere with inhibitory pathways in the tumor site that resist T cell attack

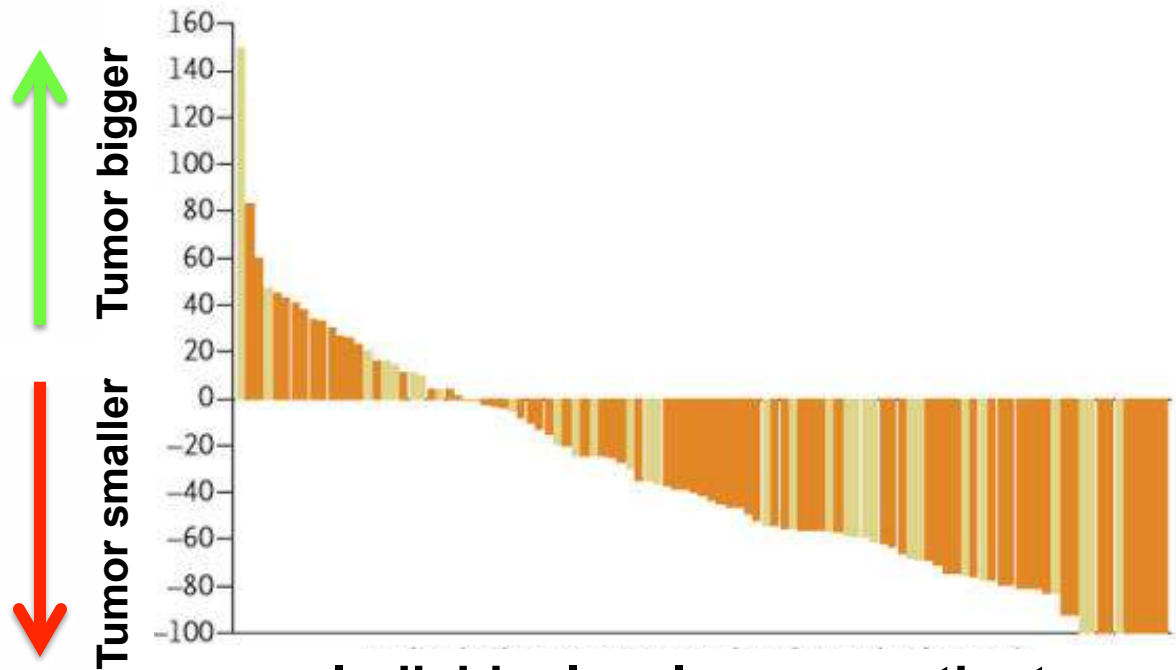
A Major Breakthrough: Blocking the inhibitory signal delivered through CTLA-4 on T cells (Checkpoint Blockade)



"The Wall" starts crumbling: Many more inhibitory checkpoints than CTLA-4 that can be blocked



Clinical activity of anti-PD-1 in metastatic melanoma



Individual melanoma patients

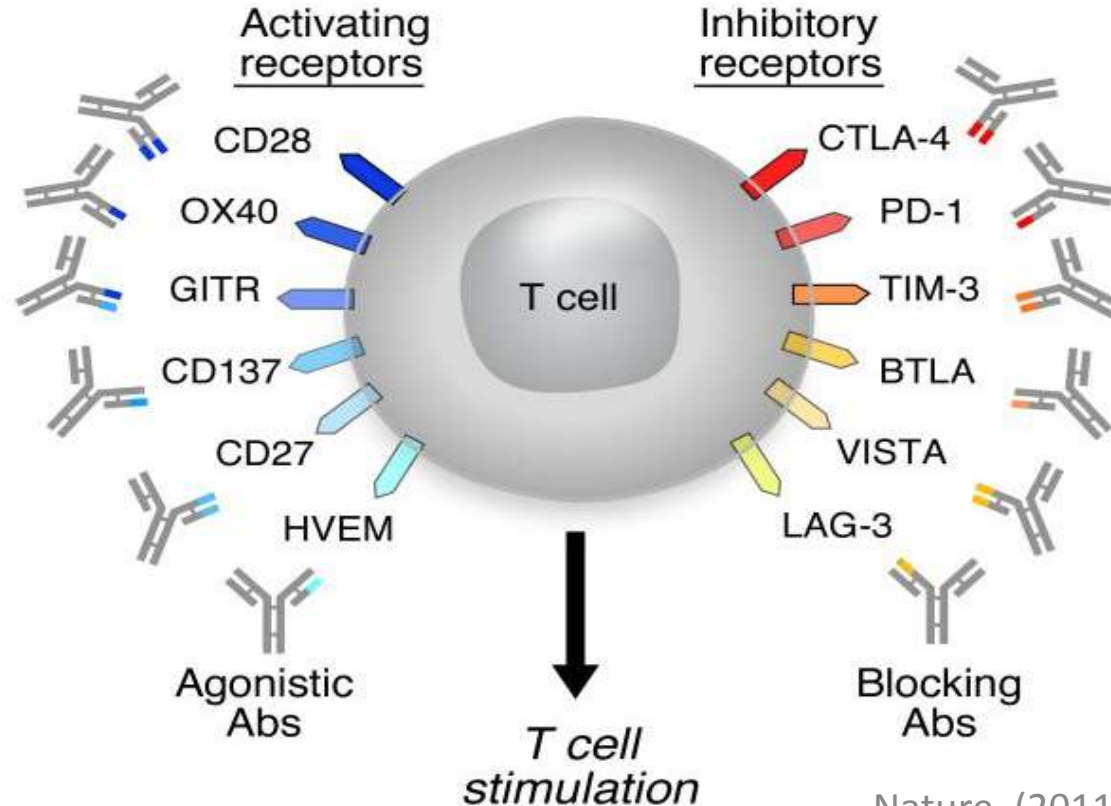
- FDA approved in 2014 for melanoma
- Now in 7 additional cancer entities, and counting

New immunotherapy drug behind Jimmy Carter's cancer cure

Former president given pembrolizumab, one of the most promising new drugs in the treatment of cancer

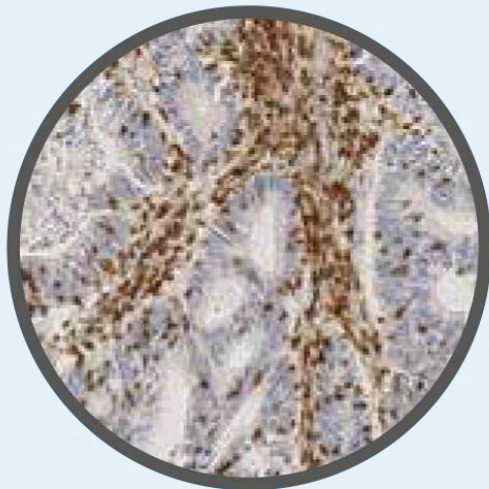


Many targets, and many combinations additive/synergistic,
so just getting started !



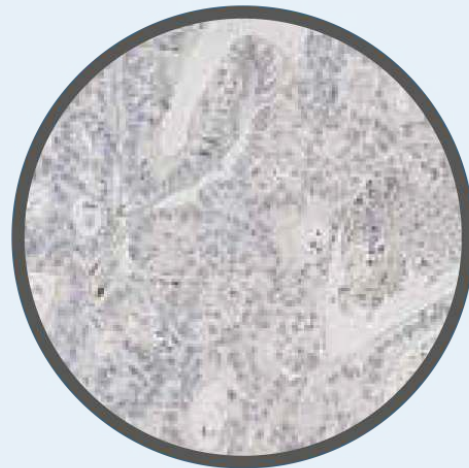
But only some patients respond to immune modulation:
Who does and who doesn't ?

INFLAMED OR HOT TUMOR



Activate Immunity

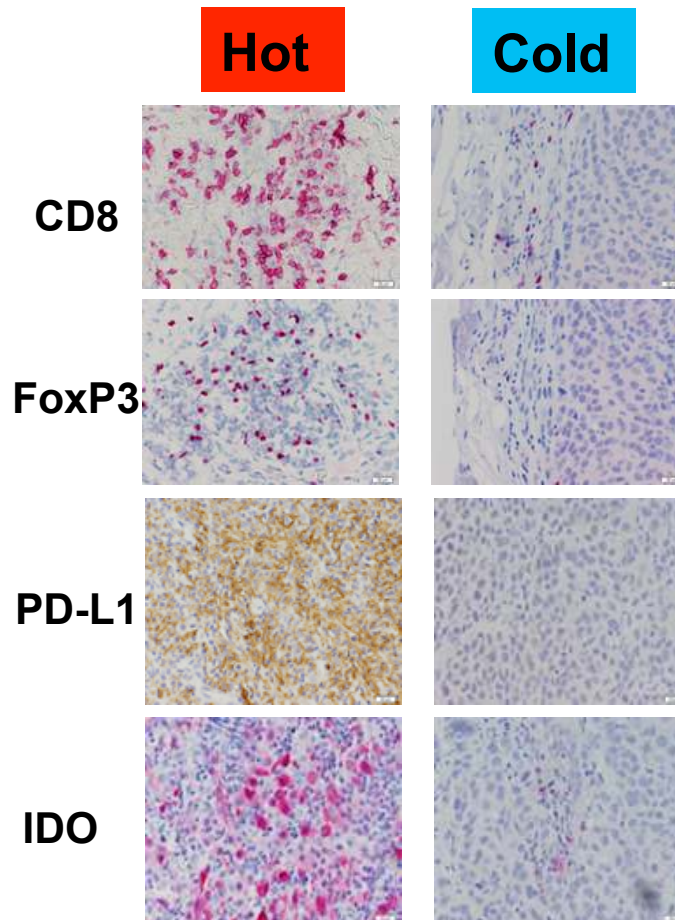
NON-INFLAMED COLD TUMOR



Create Immunogenicity

T cell-infiltrated (hot) tumors contain MULTIPLE inhibitory pathways

- Multiple “defense” pathways are co-opted in tumors once T cells enter
- Further supports concept that blocking two together might give superior outcomes



Inducing Immune Responses: Active Vaccination Against Virus-Induced Cancers



- Vaccine to feline leukemia virus for cats
- Vaccine to herpes virus (Marek's virus) in chickens
- Vaccine to hepatitis B in humans to prevent liver carcinoma
- Vaccination to HPV prevents cervical cancer
- With modern genomic technology that can define from a biopsy specimen all mutations in a tumor, major effort now to make **personalized vaccines** to each individual patient's tumor

NEWS

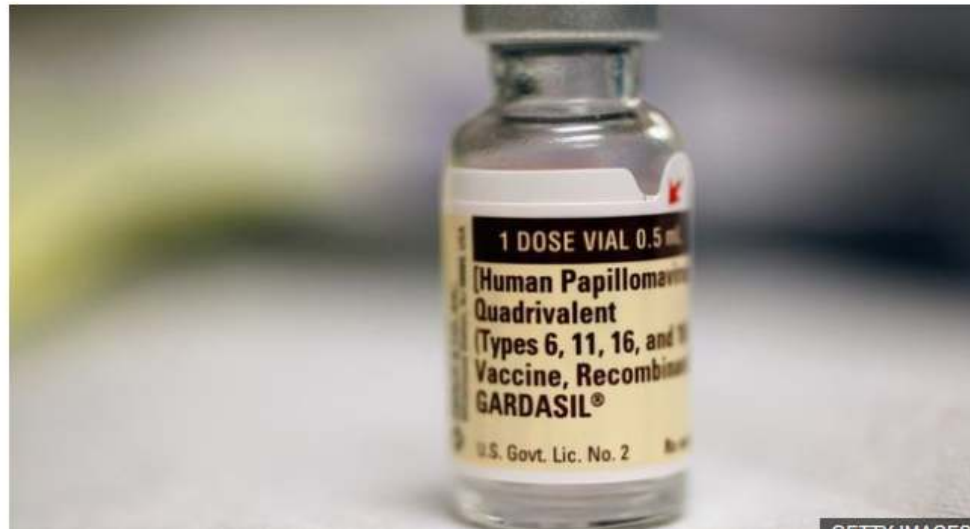
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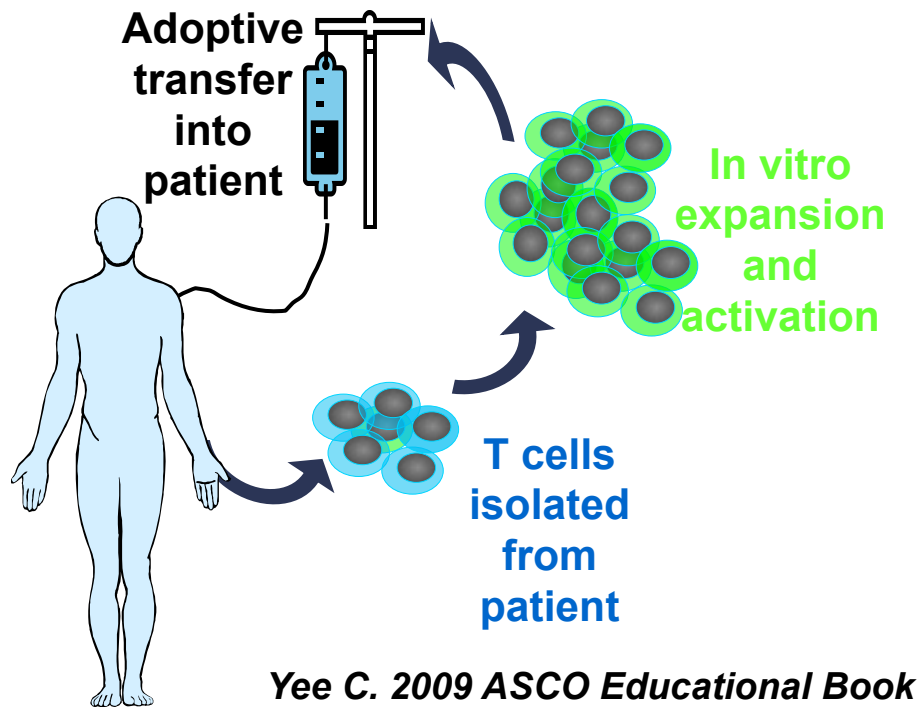
A decade on, vaccine has halved cervical cancer rate

🕒 29 August 2016 [Australia](#)



 Share





- T cells are isolated from tumor site or blood
- **Synthetic Biology**: Can engineer the T cells to recognize and better target tumor cells, function better, overcome obstacles posed by the tumor
- Expand T cells in laboratory
- Reintroduce T cells back into the patient

Using synthetic biology: Adoptive “CAR” T cell therapy

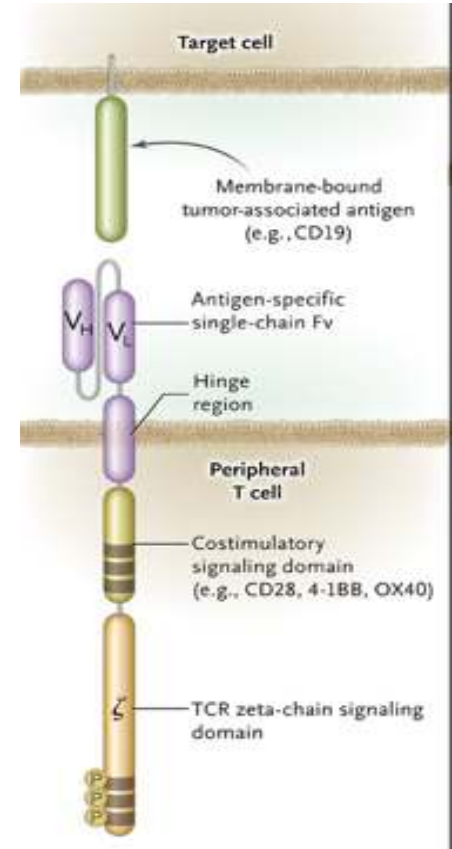
ORIGINAL ARTICLE

BRIEF REPORT

Chimeric Antigen Receptor–Modified T Cells in Chronic Lymphoid Leukemia

David L. Porter, M.D., Bruce L. Levine, Ph.D., Michael Kalos, Ph.D., Adam Bagg, M.D., and Carl H. June, M.D.
N Engl J Med 2011; 365:725-733 | August 25, 2011

- Isolate patient's peripheral blood T cells
- Lentivirus transduced with “CAR” (chimeric antigen receptor)
- CAR – anti-CD19 antibody fragment fused to intracellular domains of potent T cell signaling subunits
- Re-infuse “CAR”-modified T cells into patient
- Successful for treating children with B cell malignancies



HEALTH

In Girl's Last Hope, Altered Immune Cells Beat Leukemia

By DENISE GRADY DEC. 9, 2012



Emma Whitehead, with her mother, Kari. Last spring, Emma was near death from acute lymphoblastic leukemia but is now in remission after an experimental treatment at the Children's Hospital of Philadelphia.

Jeff Swensen for The New York Times

Additional Information: Useful resources about cancer immunotherapy



<https://www.cancerresearch.org/patients/what-is-immunotherapy>

<https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy.html>

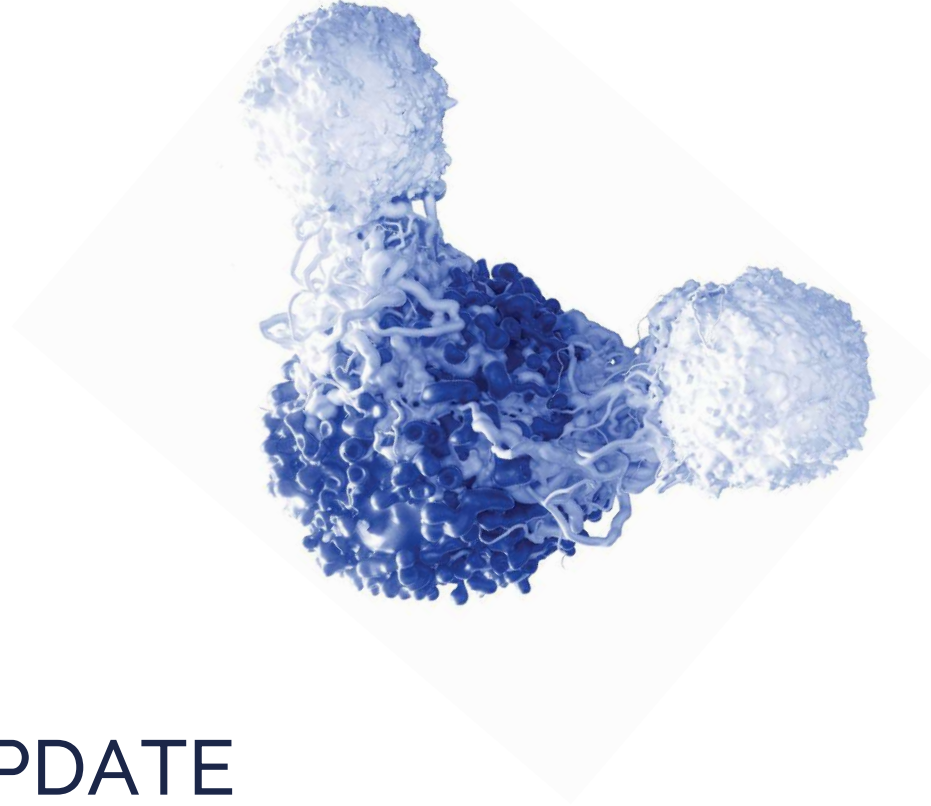
<https://www.cancer.gov/research/areas/treatment/immunotherapy-using-immune-system>

<https://www.sitcancer.org/patient>



Panel Discussion

LATEST RESEARCH UPDATE



Moderator

Philip Greenberg, M.D.

Panel

Scott Antonia, M.D., Ph.D.

Lung Cancer

Nina Bhardwaj, M.D., Ph.D.

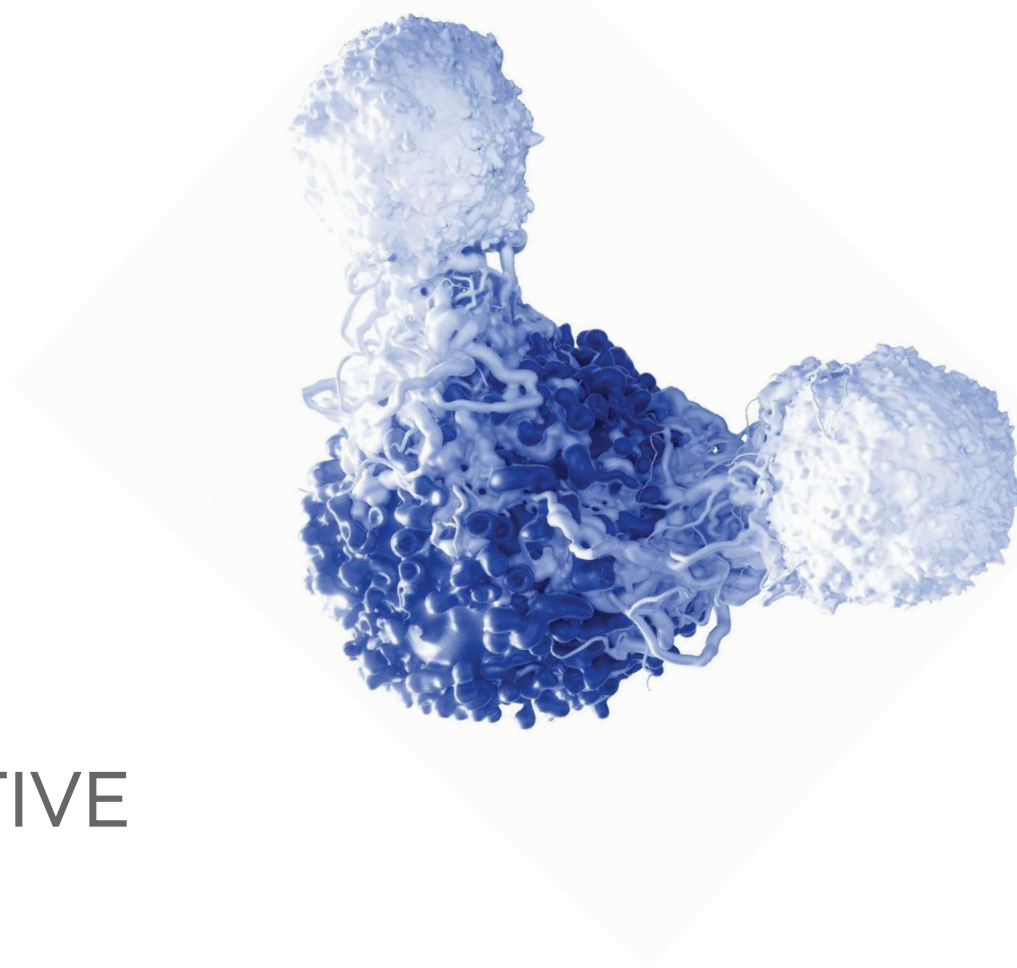
Melanoma

Ezra Cohen, M.D.

Head and Neck Cancer

Janie Ferling
Melanoma Survivor

PATIENT PERSPECTIVE



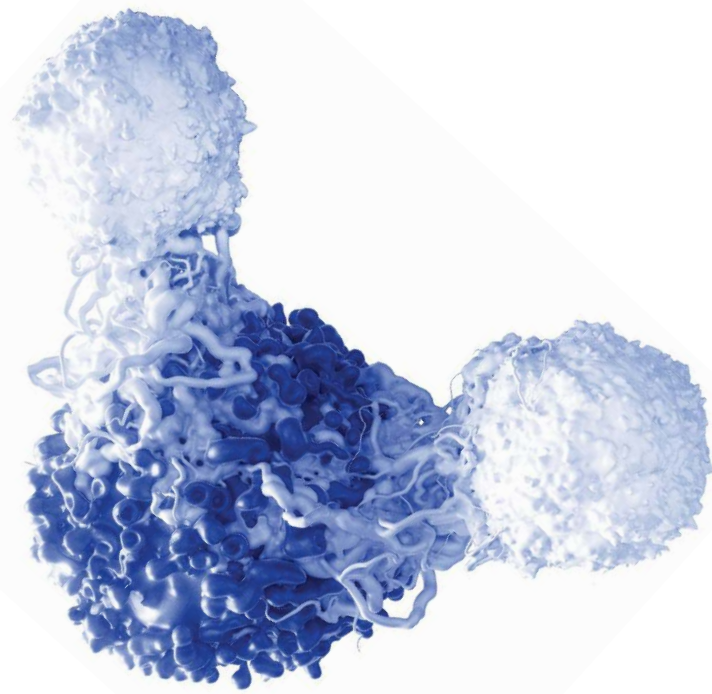


LUNCH AND NETWORKING

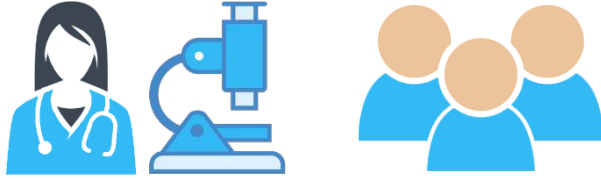
Brian Brewer

Cancer Research Institute

DEMYSTIFYING CLINICAL TRIALS

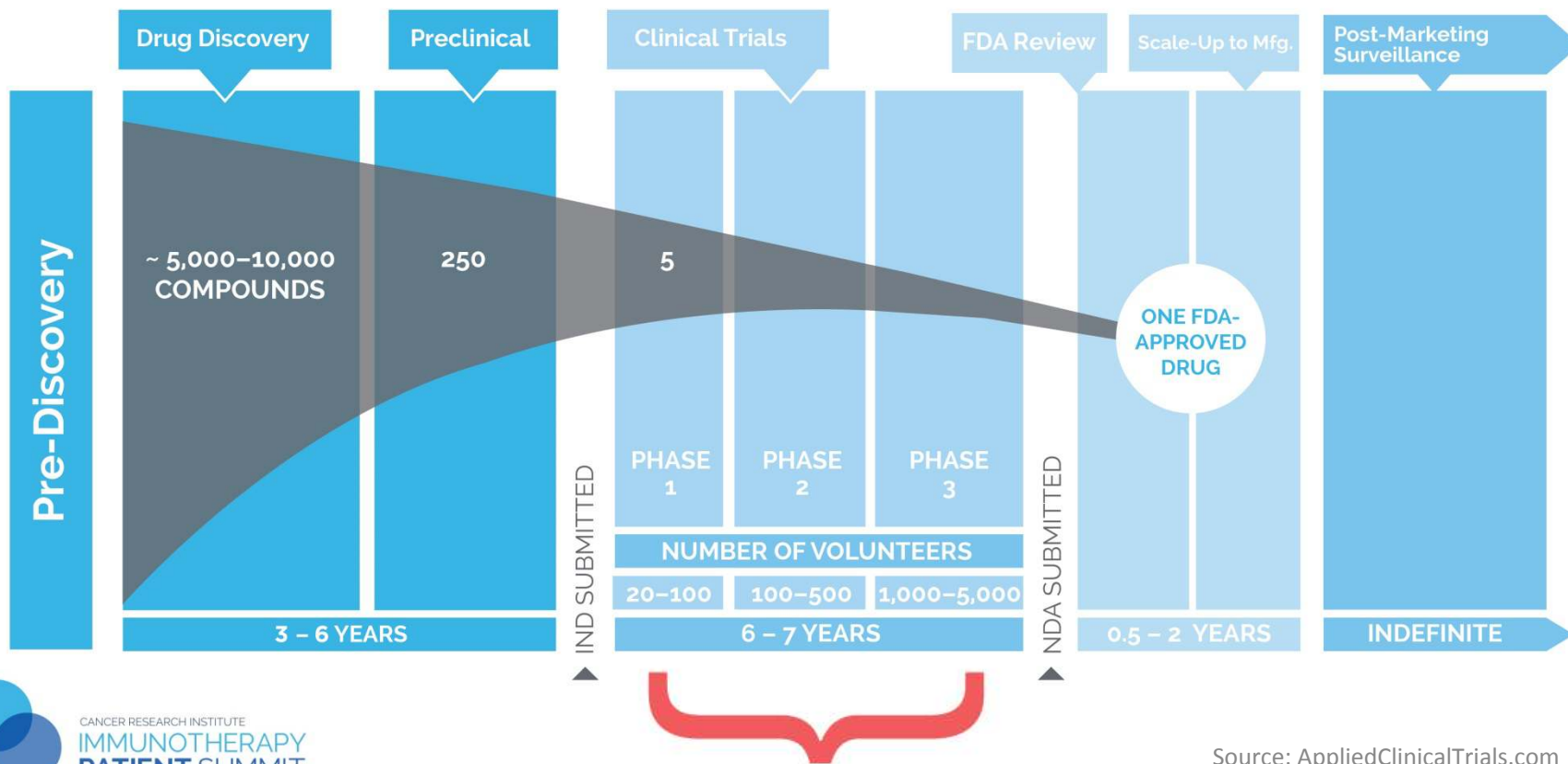


What Are Clinical Trials?



- Research studies that involve people
- Designed to answer specific questions about new and existing treatments
- Aim to improve treatments and the quality of life for people with disease

Getting from Discovery to Approval



What Are Clinical Trial Phases?

Phase
1



Is the treatment safe?

Purpose:

- First study in humans
- Find best dose, delivery method, and schedule
- Monitor for side effects
- Determine safety

Number of people: 20-100

Phase
2



Does it work?

Purpose:

- Look for effect on specific type(s) of cancer
- Continue monitoring for side effects and safety

Number of people: 100-500

Phase
3



Does it work better?

Purpose:

- Compare new treatment (or new use of a treatment) with current standard treatment
- Determine risk vs. benefit

Number of people: 1,000-5k+

Pros and Cons of Clinical Trials



Potential Advantages	Potential Disadvantages
Access to best possible care	Unknown side effects or risks
Receiving new drugs before they're widely available	Unknown benefits—drugs may not work as intended
Close monitoring by medical team	Not all patients may benefit
Chance to play active role in healthcare and research	Frequent tests and clinic visits
Help future generations	Possible need to travel to trial sites

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Questions to Ask Before Volunteering



- Why is this trial being done?
- Why is it believed that the treatment being studied may be better than the standard treatment?
- What are my other options (standard treatments, other trials)?
- How did patients do in any previous studies of this treatment?
- How will the doctor know if treatment is working?
- How long will the trial last?

Questions to Ask Before Volunteering



- Can I continue to receive this treatment after the trial ends?
- What kinds of procedures or tests are involved?
- What impact with the trial have on my daily life?
- Will I have to travel for treatment? Will I be compensated?
- How often will I need to travel to receive treatment?
- Will I be hospitalized as part of the trial?
- What costs (if any) will be my responsibility to pay?

Getting into a Clinical Trial Isn't Always a Given



Trials are designed to ask specific questions, and must adhere strictly to entry criteria to ensure data is accurate and meaningful.

This also helps ensure patients who could be made worse by treatment are not exposed to the risk.

Common criteria include:

- cancer type or stage
- treatment history
- genetic factors
- age
- medical history
- current health status

I might only get placebo
("sugar pill") instead of treatment.



Fact: Placebos are rarely used and never given in
the absence of some form of treatment.

Trials are only for people who have run out of treatment options (a “last resort”).



Fact: Clinical trials are designed for people with cancer of all types and stages.

I need to travel to a large hospital or cancer center to participate in a clinical trial.



Fact: Trials take place at local hospitals, cancer centers, and doctors' offices in all parts of the country, in both urban and rural areas.

My health insurance doesn't cover the cost of care in a clinical trial.



Fact: Doctor visits, hospital stays, and certain testing procedures may be covered by insurance. Research costs are typically covered by the trial sponsor.

Signing a consent form “locks” me into staying in a trial.



Fact: You are free to change your mind for any reason about participating in a trial anytime before or during a trial.

I will be made to feel like a
“guinea pig” experiment.



Fact: The overwhelming majority of trial participants say they were treated with dignity and respect, and report having had a positive experience in a trial.

Clinical trials aren't safe.



Fact: Safeguards including an Institutional Review Board, Data and Safety Monitoring Board, and an ongoing informed consent process ensure patients' rights and safety are protected.

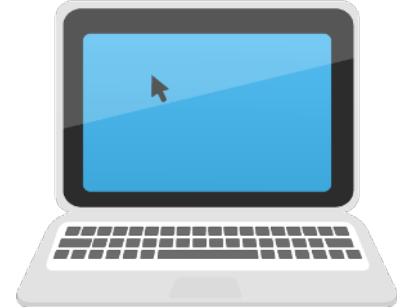
Informed consent = having all the facts before and during a trial

- Study purpose
- Length of time of the study
- Predictable risks
- Possible benefits
- Expectations
- Patient's rights
- Treatment alternatives
- Patient health monitoring
- Safeguards in place
- How to withdraw from study

Be bold in asking for details.
It's YOUR treatment plan.

How Can I Find a Clinical Trial?

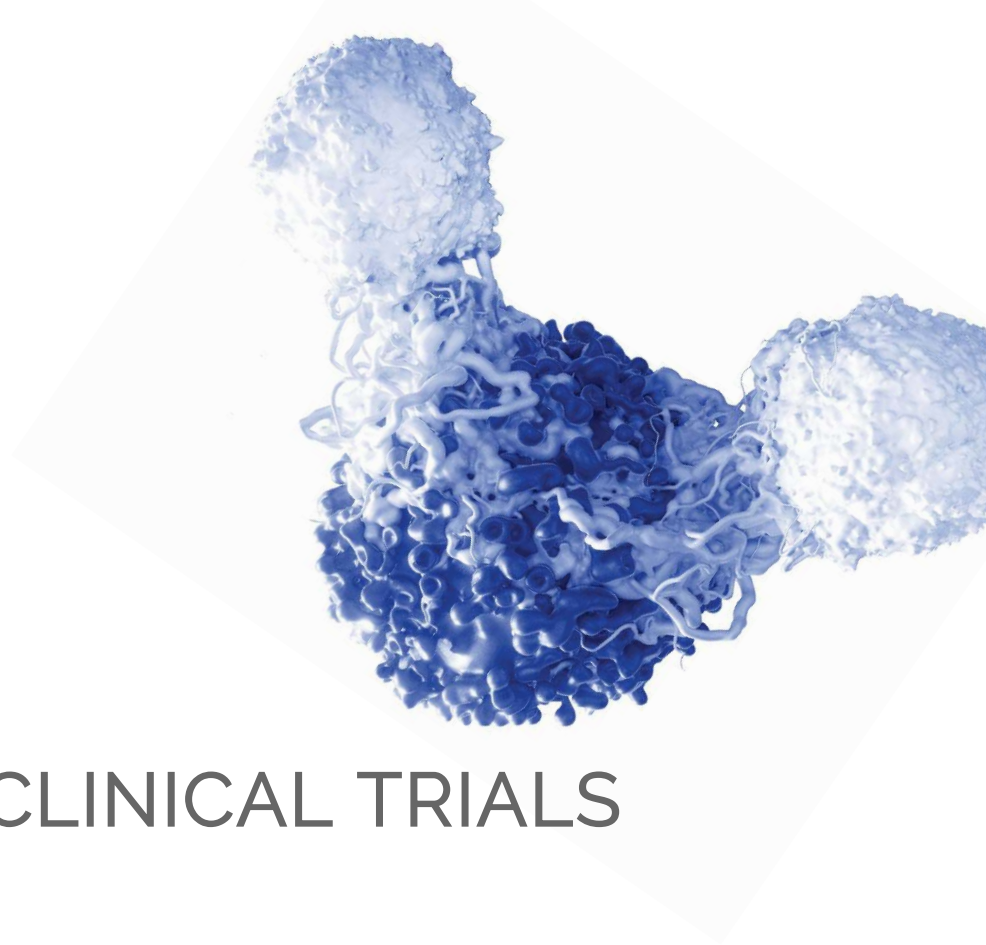
- Ask your doctor
- Ask another doctor if necessary...
- Contact a patient advocacy organization
 - Seek assistance from a clinical trial navigator, if offered
 - CRI Clinical Trial Finder: 1 (855) 216-0127
- Search online
 - <https://www.cancerresearch.org/patients/clinical-trials>
 - <https://clinicaltrials.gov/>





Panel Discussion

IMMUNOTHERAPY CLINICAL TRIALS



Moderator

Brian Brewer

Panel

Donna Fernandez

Lung Cancer

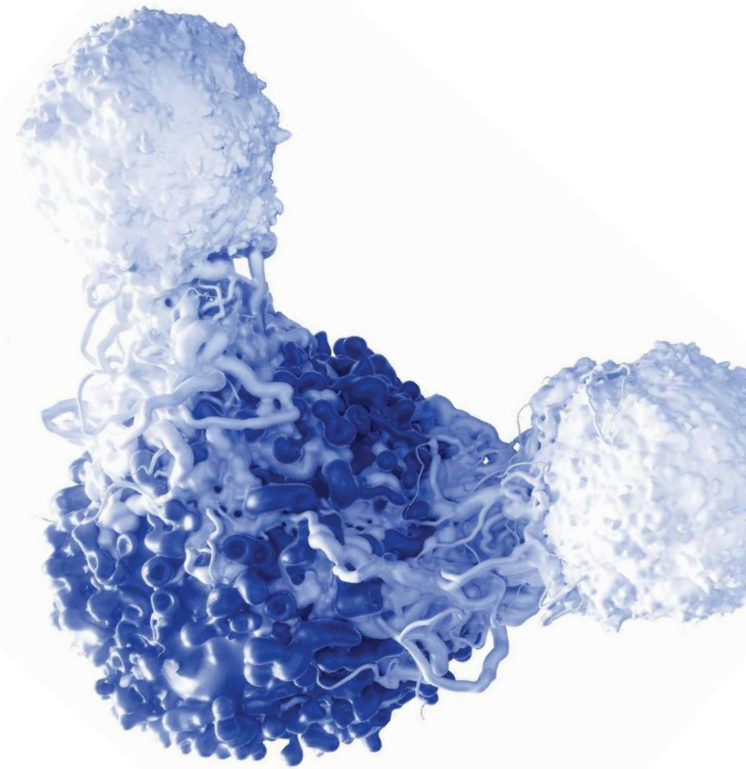
Karen Koehler

Leukemia

Johanna Sedman

Prostate Cancer (caregiver)

BREAKOUT SESSIONS



Breakout Rooms



Head and Neck Cancer

Ezra Cohen, M.D.

Pinewood

Melanoma

Nina Bhardwaj, M.D., Ph.D.

Birchwood

Lung Cancer

Scott Antonia, M.D., Ph.D.

Timberwood

General Immunotherapy

Philip Greenberg, M.D.

Cypress & Oakbrook (Here)

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