CANCER RESEARCH INSTITUTE

IMMUNOTHERAPY PATIENT SUMMIT

San Francisco • Chicago • New York • Houston • Tampa

Chicago August 5, 2017

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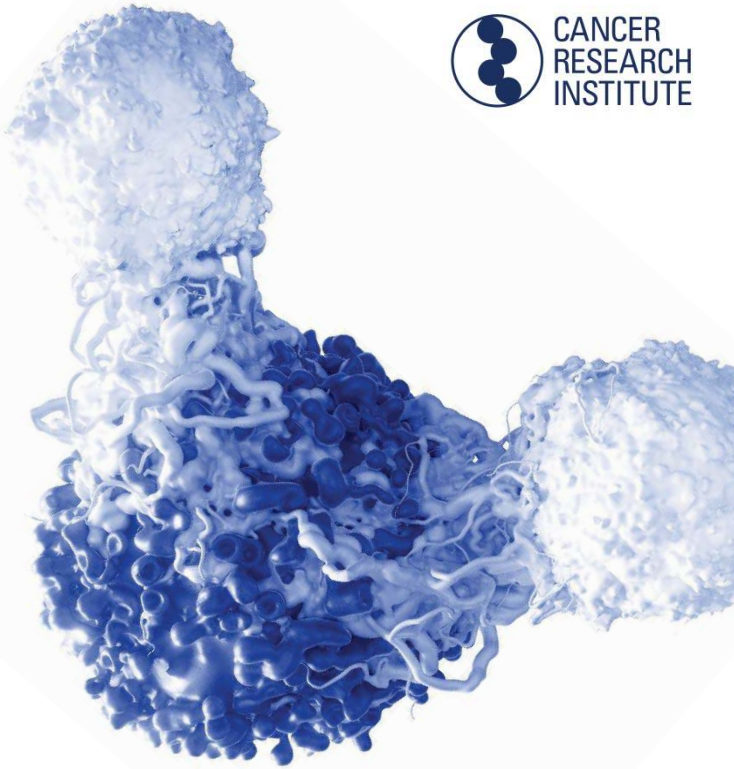

Brian Brewer

Cancer Research Institute

WELCOME

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PATIENT SUMMIT

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Let Life Happen
Melanoma Research Foundation
National Ovarian Cancer Coalition
Parker Institute for Cancer Immunotherapy
Patient Empowerment Network
University of Chicago Medicine Comprehensive Cancer Center

Our Guest Faculty

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Scientific Experts

Gavin Dunn, M.D., Ph.D.
Washington University

Thomas Gajewski, M.D., Ph.D.
University of Chicago

Kunle Odunsi, M.D., Ph.D.
Roswell Park Cancer Institute

Cassian Yee, M.D.
MD Anderson Cancer Center

Patient Experts

Janie Ferling
Melanoma

Donna Fernandez
Lung Cancer

Carol Roth
Brain Cancer

Schedule of Events

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9:00am	Registration and networking
10:00am	Program commences **Welcome** Brian Brewer **Introduction to the Cancer Research Institute** Jill O'Donnell-Tormey, Ph.D.
10:15am	**Hear from the experts** Learn the basics of immunotherapy Thomas Gajewski, M.D., Ph.D. Latest research update panel Moderator Thomas Gajewski, M.D., Ph.D. Panelists Gavin Dunn, M.D., Ph.D. Kunle Odunsi, M.D., Ph.D. Cassian Yee, 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 Janie Ferling Donna Fernandez Carol Roth
2:00pm	Refreshment break
2:15pm	**Breakout sessions** Your choice of moderated discussion with our experts or a general networking session Brain Cancer Gavin Dunn, M.D., Ph.D. Gynecologic Cancers Kunle Odunsi, M.D., Ph.D. Melanoma Cassian Yee, M.D. General Immunotherapy & Networking Thomas Gajewski, M.D., Ph.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.

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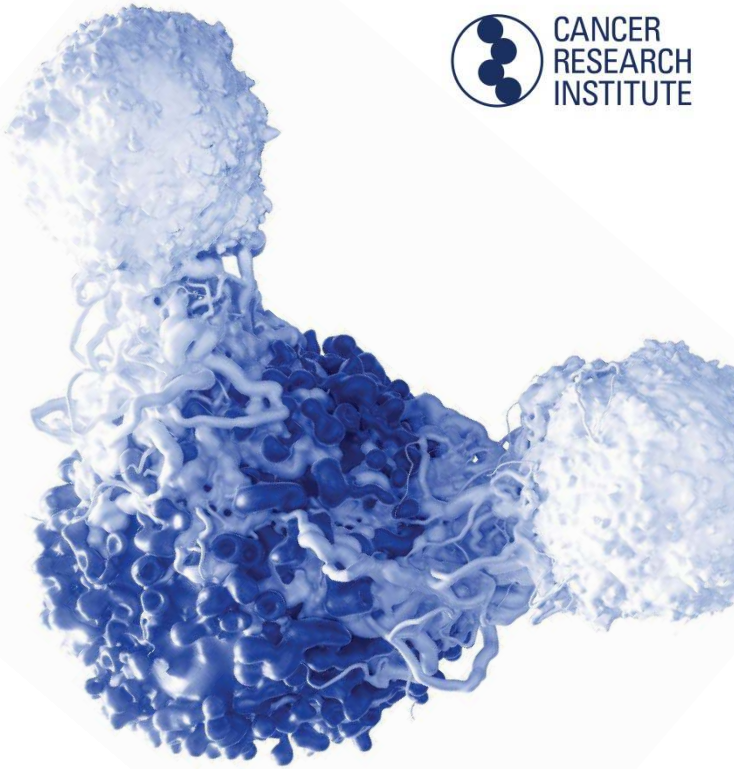

Jill O'Donnell-Tormey, Ph.D.

Cancer Research Institute

Introducing CRI

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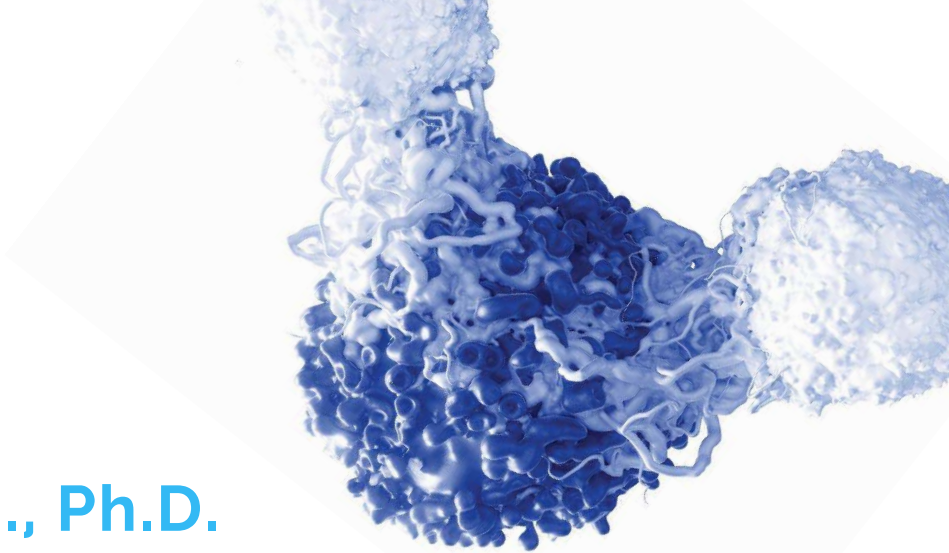

Thomas F. Gajewski, M.D., Ph.D.

AbbVie Foundation Professor of Cancer Immunotherapy

University of Chicago

IMMUNOTHERAPY BASICS

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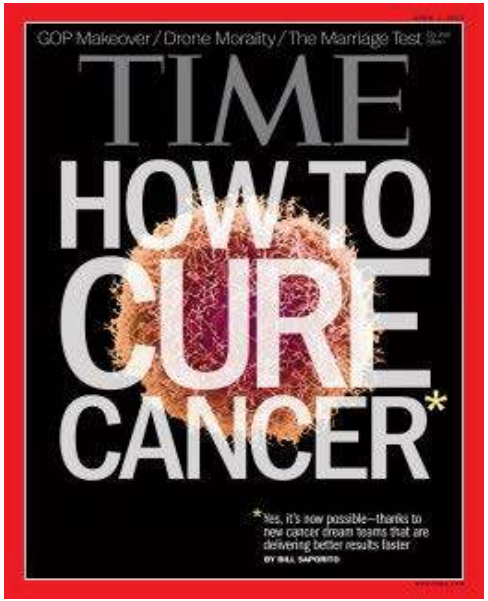

The New York Times

Patient's Cells Deployed to Attack Aggressive Cancer

The Washington Post

Health & Science

New therapies raise hope for a breakthrough in tackling cancer

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Dr. William Coley

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- Noted a case of sarcoma that became cured due to a bacterial infection
- In 1891, deliberately infected sarcoma patient with *Strep. pyogenes*
- By 1893, had developed a mixture of bacterial toxins rather than live bacteria
- Considered the first immunologic therapy

Immune Recognition of Cancer

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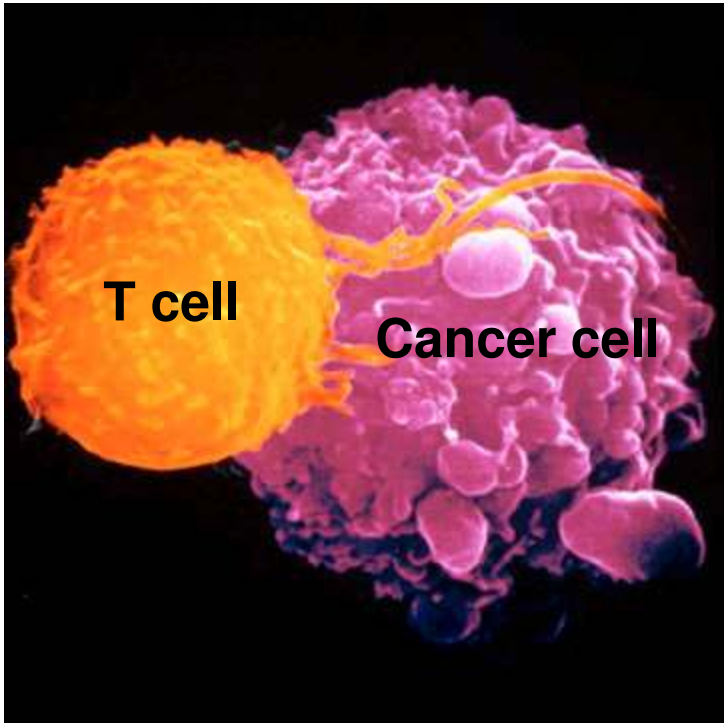

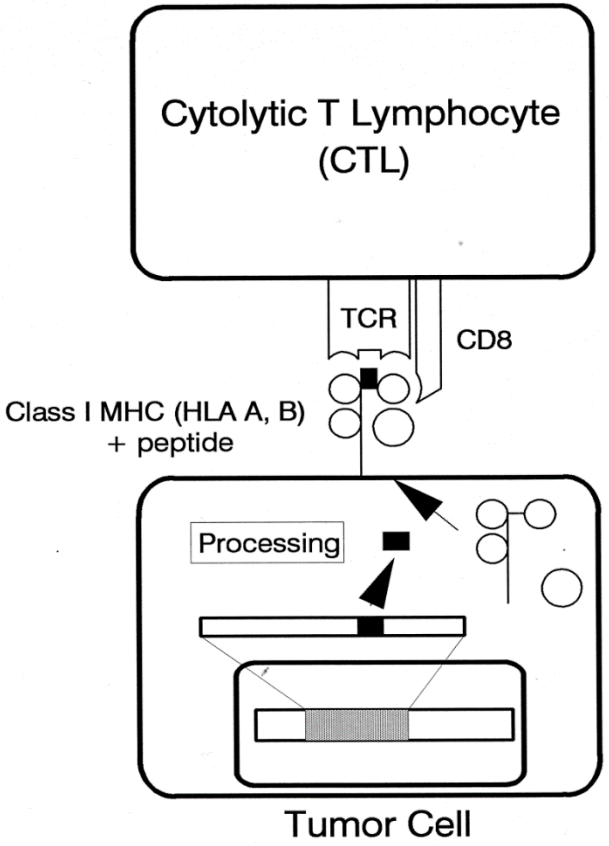

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Boosting immune system offense vs. overcoming cancer's defense

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Two general strategies to promote the immune system to destroy cancer

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- 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

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A decade on, vaccine has halved cervical cancer rate

29 August 2016 | Australia

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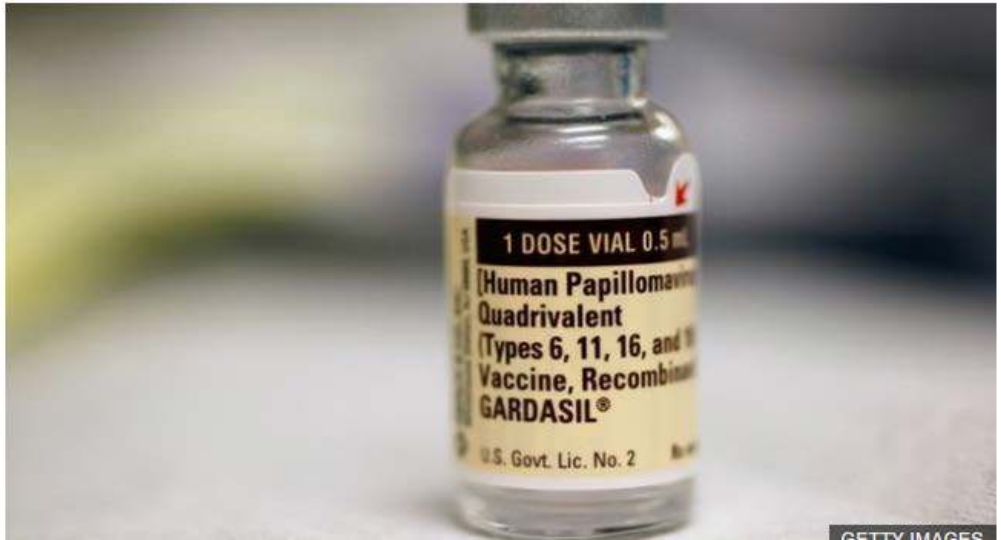

GETTY IMAGES

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Successful Active Vaccination Against Virus-Induced Cancers

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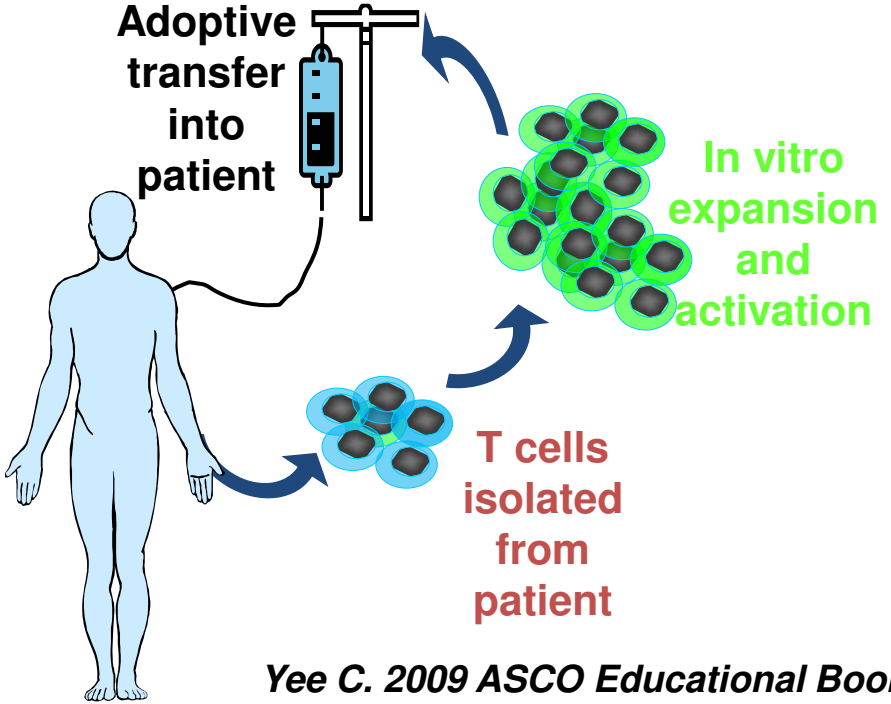
- Vaccine to feline leukemia virus for cats
- Vaccine to herpes virus (Marek's virus) in chickens

- Vaccine to hepatitis B in humans to prevent liver carcinoma
- Vaccination to HPV prevents cervical cancer

T cell adoptive transfer



Yee C. 2009 ASCO Educational Book

- T cells are isolated from tumor site or blood
- Expanded in laboratory
- Can be engineered to recognize new targets
- T cells are reintroduced back to the patient, usually with other agents

Adoptive "CAR" T cell therapy

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ORIGINAL ARTICLE

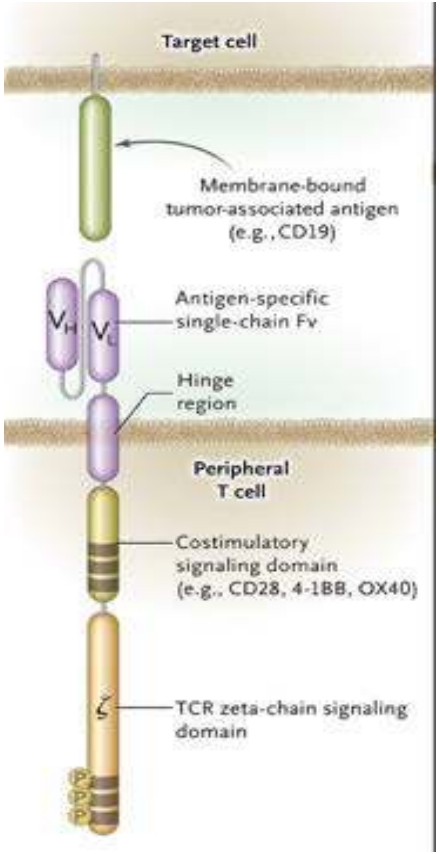
BRIEF REPORT

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



The New York Times

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

T cell-infiltrated tumors contain inhibitory pathways that turn the T cells back off: PD-L1/PD-1

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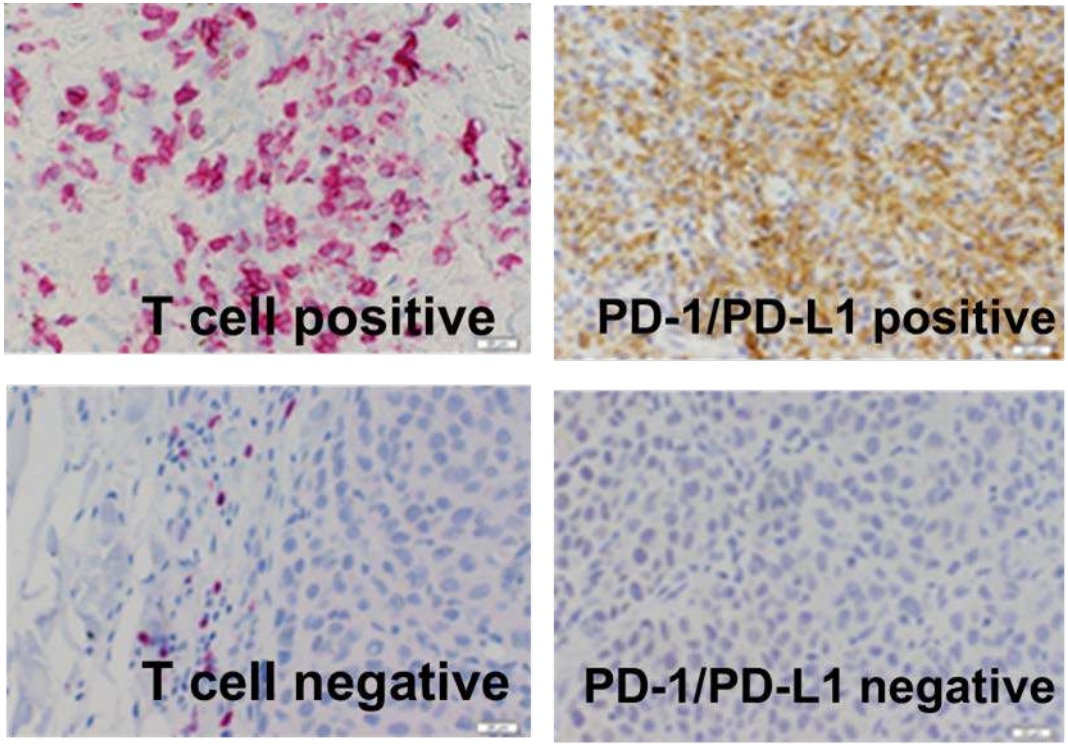
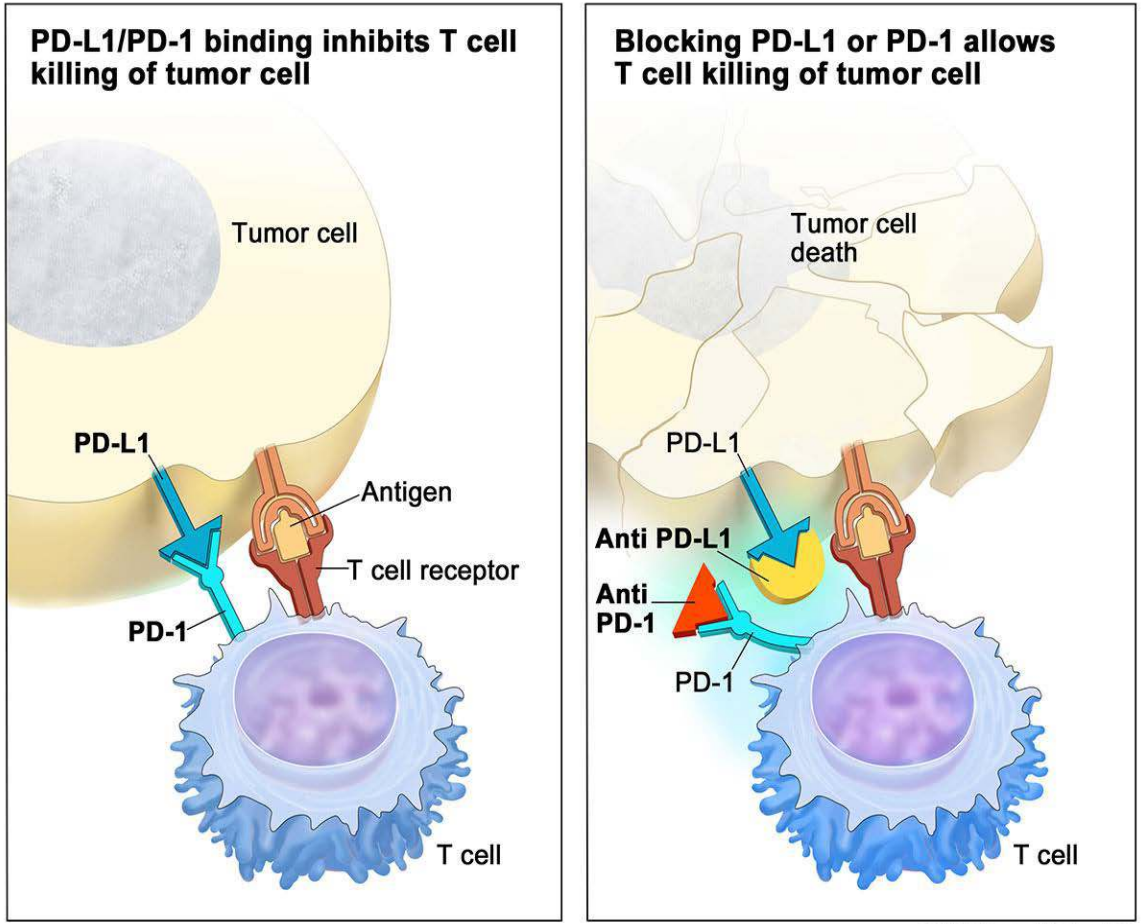


Checkpoint Inhibitors – Antibodies to Inhibitory PD-1 Receptor



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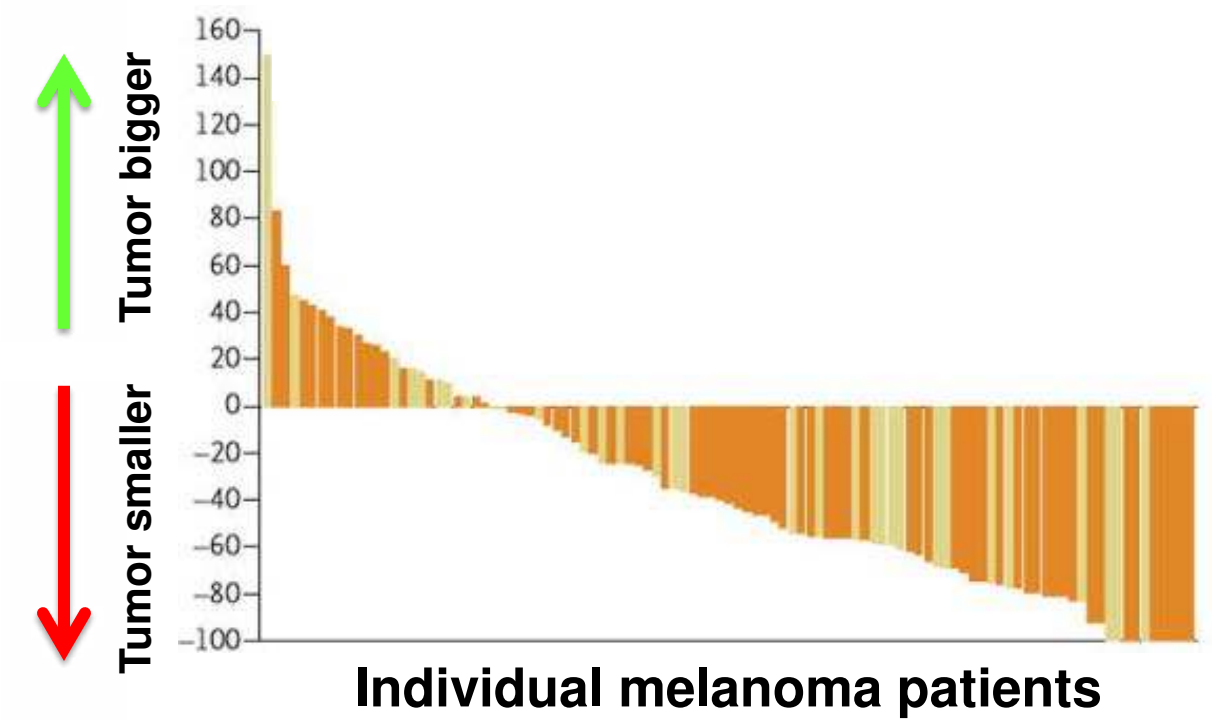
Clinical activity of anti-PD-1 in metastatic melanoma



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

Checkpoint Blockade Success!

T cell-infiltrated tumors contain MULTIPLE inhibitory pathways

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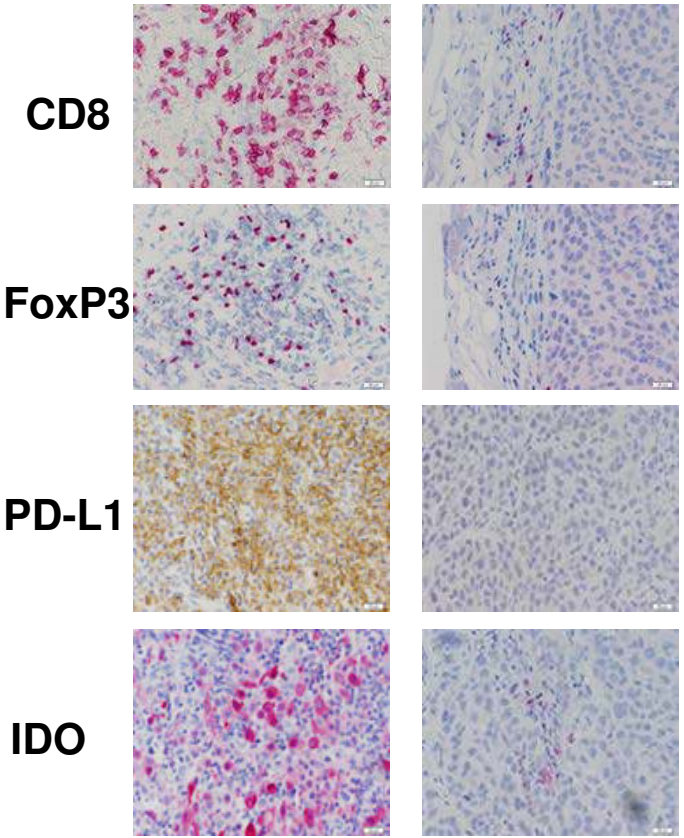
- Multiple “defense” pathways are co-opted in tumors once T cells enter
- Suggests the notion that blocking two together might be superior



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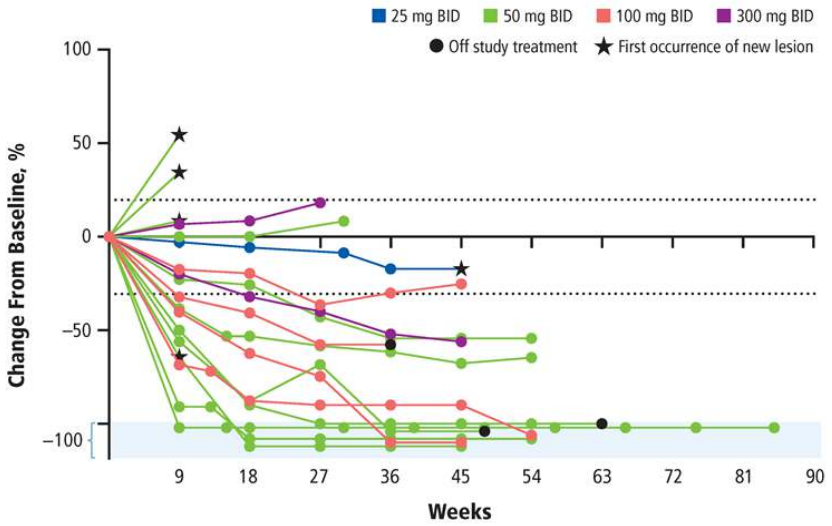
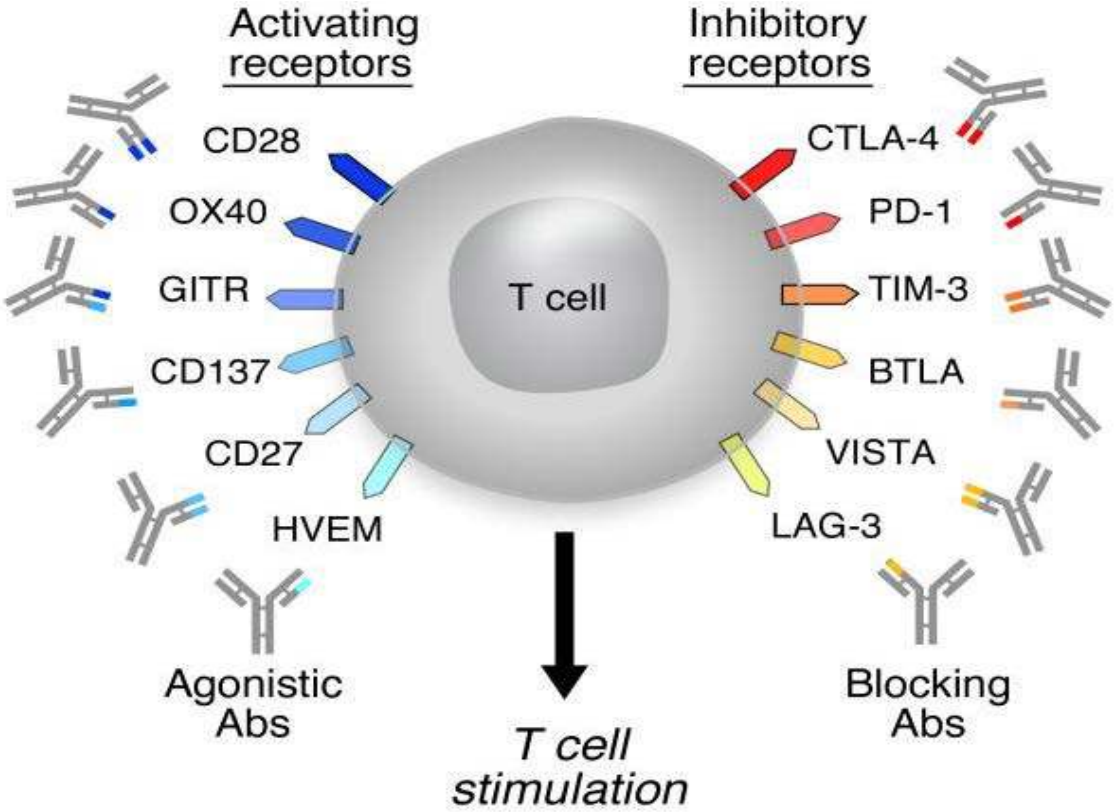
Combination anti-PD-1 + IDO inhibitor



Gangadhar et al. ESMO 2016

- Combination immunotherapy appears better than single drug
- This combo has entered late phase trials for melanoma and other cancers

So many targets, so little time!



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Nature. 2011 480:480-9

Additional Information

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Useful resources about cancer immunotherapy

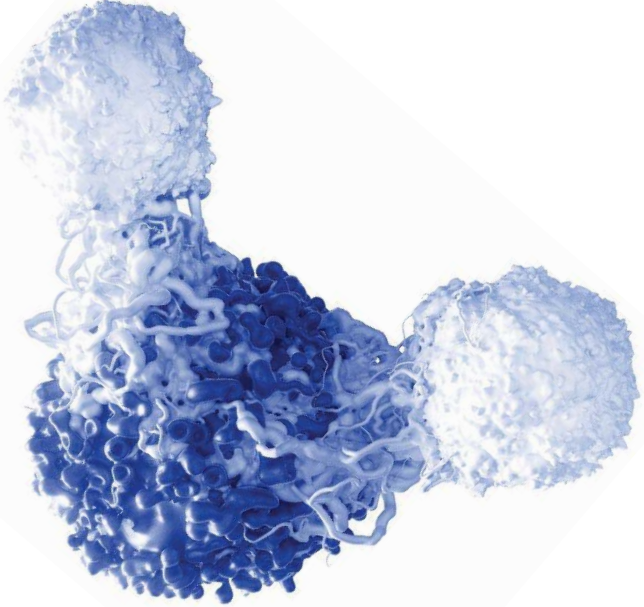
https://www.cancerresearch.org/patients/what-is-immunotherapy

https://cancer.uchicago.edu/research/highlights/immunotherapy/

https://www.roswellpark.org/immunotherapy

https://www.mdanderson.org/treatment-options/immunotherapy.html

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



Panel Discussion

LATEST RESEARCH UPDATE

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Scientific Panel

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Moderator

Thomas Gajewski, M.D., Ph.D.

Panel

Gavin Dunn, M.D., Ph.D.
Brain Cancer

Kunle Odunsi, M.D., Ph.D.
Gynecologic Cancers

Cassian Yee, M.D.
Melanoma

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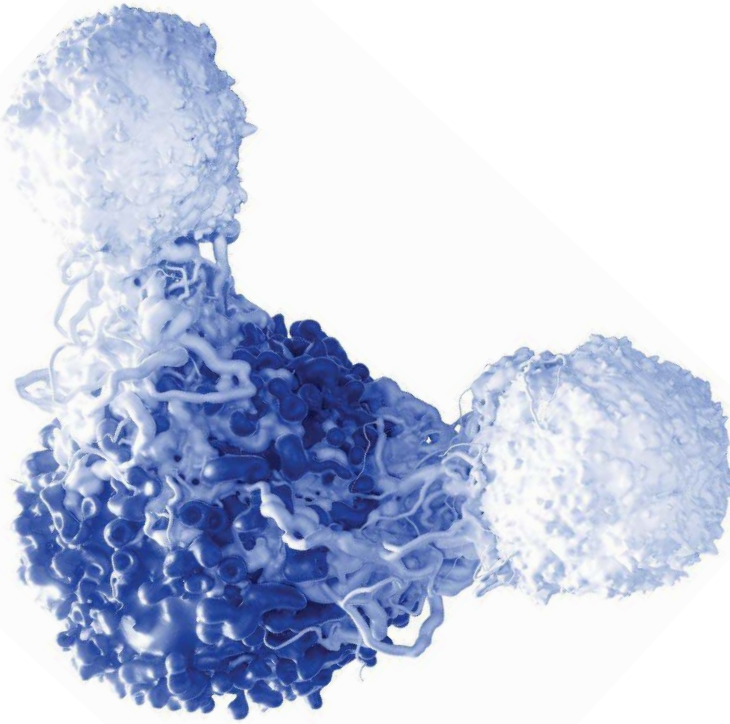

Janie Ferling

Melanoma Survivor

PATIENT PERSPECTIVE

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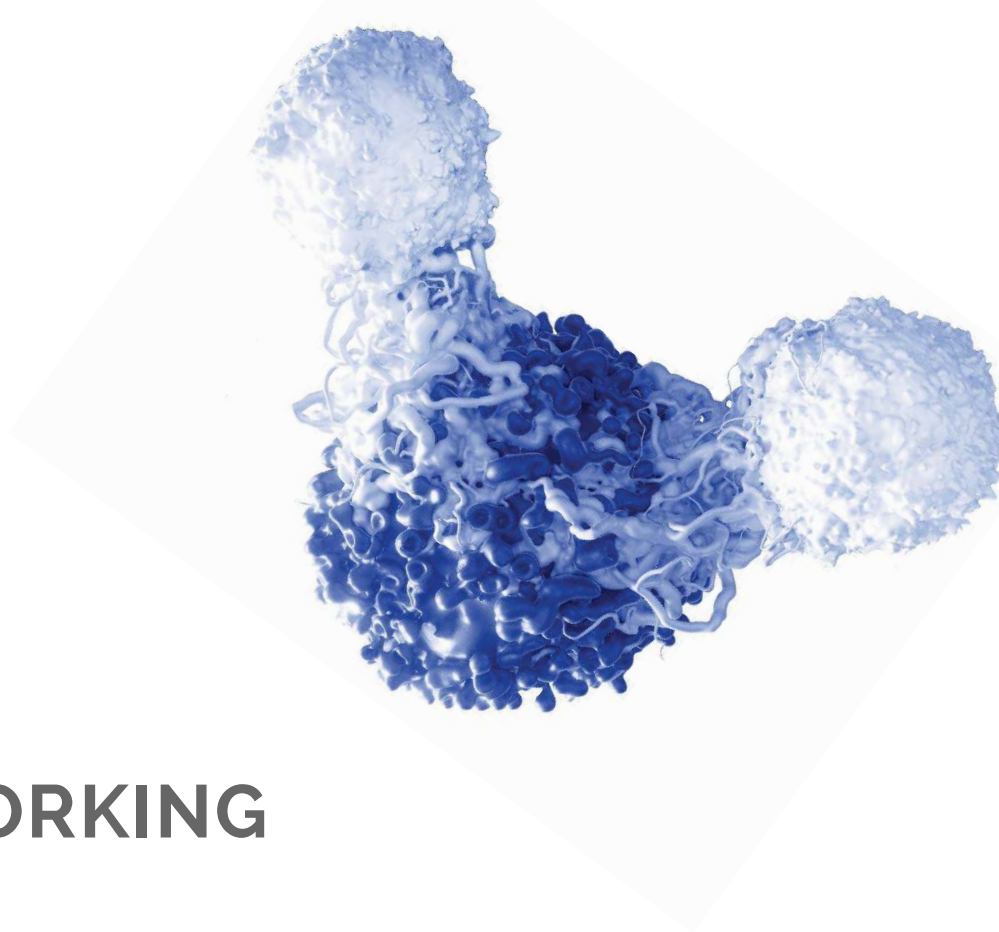

LUNCH AND NETWORKING

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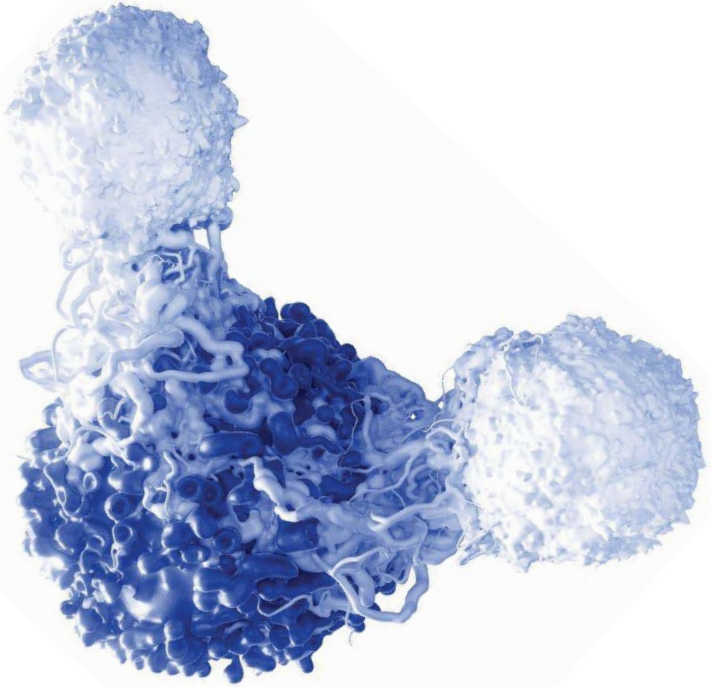

Brian Brewer

Cancer Research Institute

DEMYSTIFYING CLINICAL TRIALS

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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

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Source: AppliedClinicalTrials.com

Getting from Discovery to Approval

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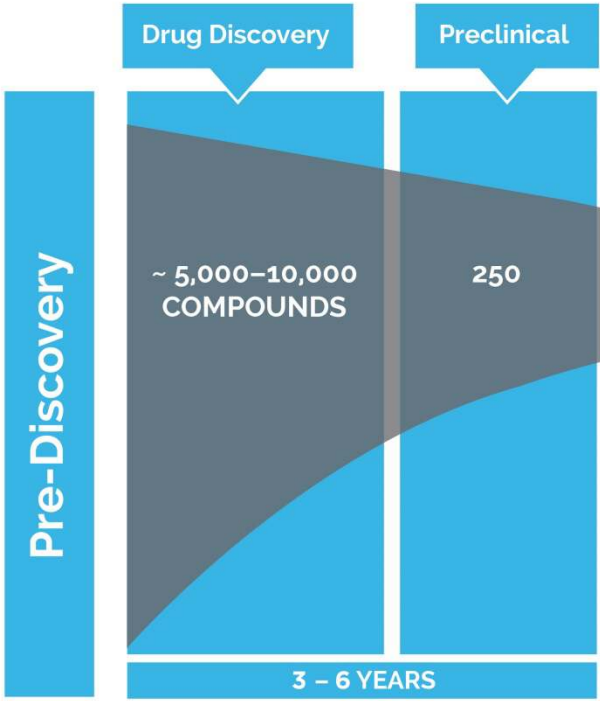

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Source: AppliedClinicalTrials.com

Getting from Discovery to Approval

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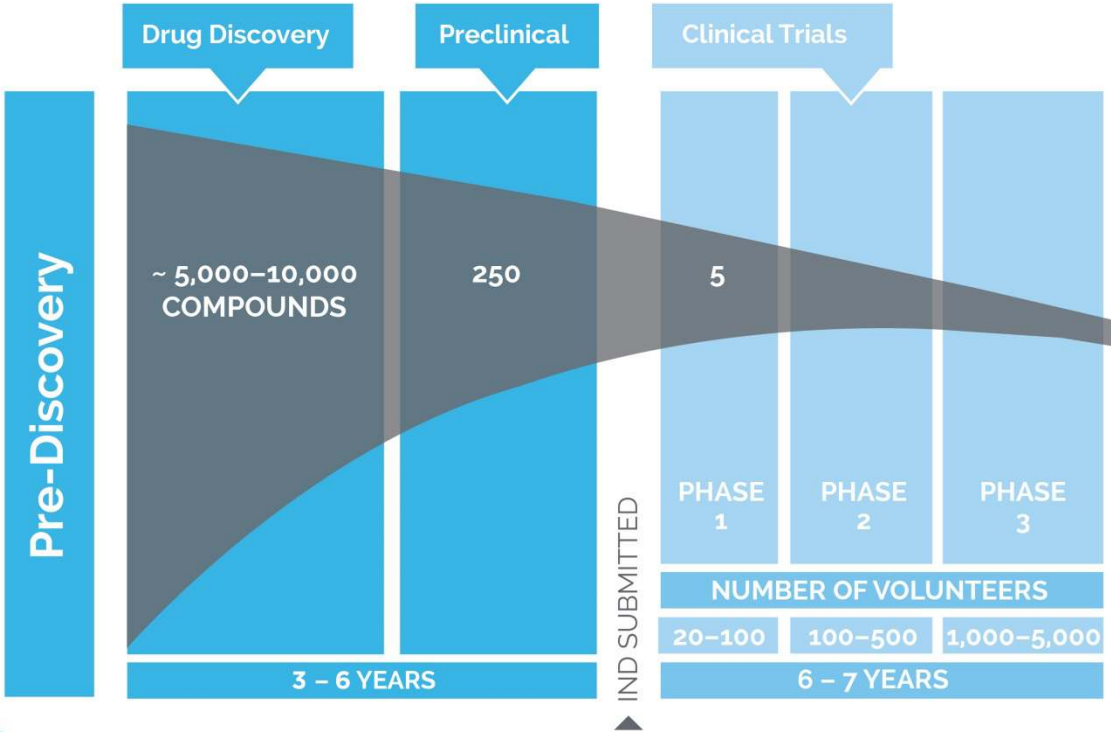

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Source: AppliedClinicalTrials.com

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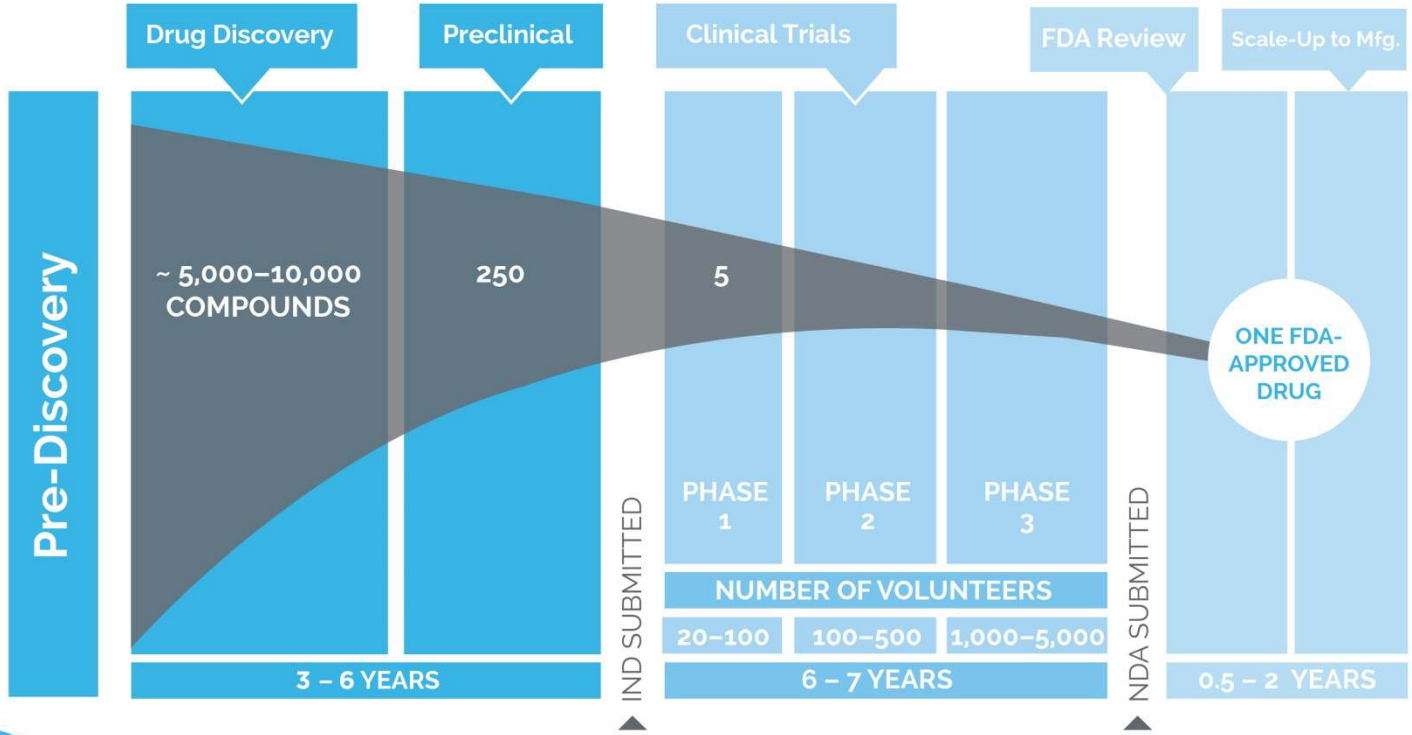

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Getting from Discovery to Approval

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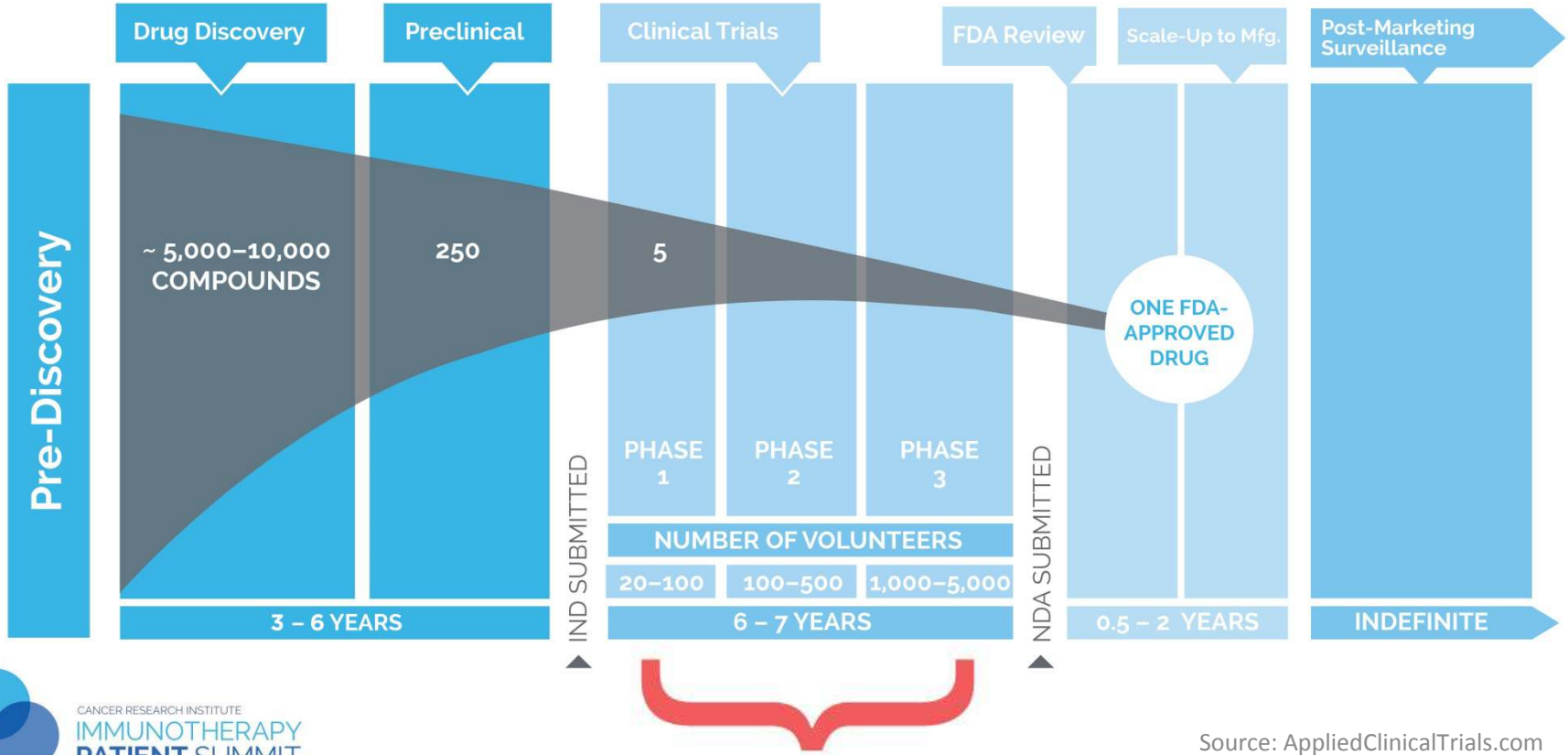

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Source: AppliedClinicalTrials.com

What Are Clinical Trial Phases?

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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+

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

Pros and Cons of Clinical Trials

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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

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- 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?

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

Questions to Ask Before Volunteering

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- 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?

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

Getting into a Clinical Trial Isn't Always a Given

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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

Clinical Trials: Myth versus Fact

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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.

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

Clinical Trials: Myth versus Fact

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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.

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

Clinical Trials: Myth versus Fact

CANCER RESEARCH INSTITUTE

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.

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

Clinical Trials: Myth versus Fact

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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.

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

Clinical Trials: Myth versus Fact

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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.

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Clinical Trials: Myth versus Fact

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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.

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

Clinical Trials: Myth versus Fact

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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.

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

A Word About Informed Consent

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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?

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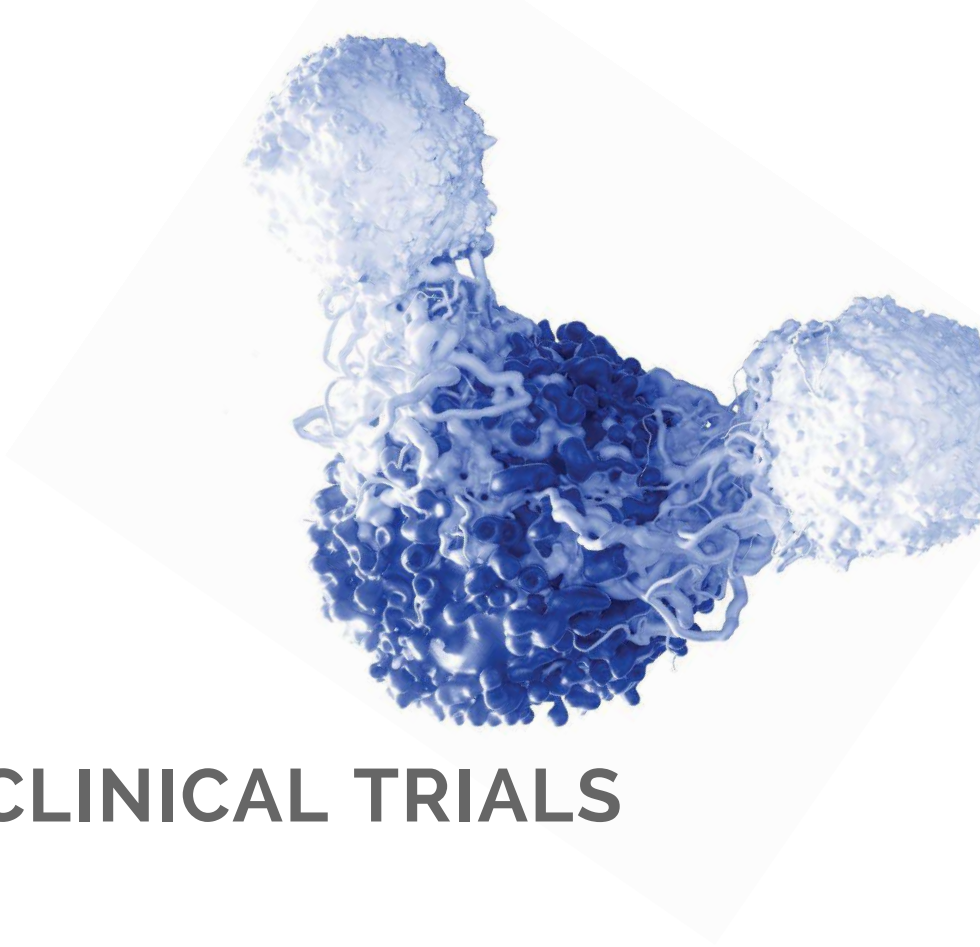
- Ask your doctor
- Ask another doctor if necessary…
- Contact a patient advocacy organization
  - Seek assistance from a clinical trial navigator, if offered
  - CRI Clinical Trial Finder: 1 (855) 216-0127
- Search online
  - https://www.cancerresearch.org/patients/clinical-trials
  - https://clinicaltrials.gov/



Panel Discussion

IMMUNOTHERAPY CLINICAL TRIALS

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Patient Panel

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Moderator

Brian Brewer

Panel

Janie Ferling
Melanoma

Donna Fernandez
Lung Cancer

Carol Roth
Brain Cancer

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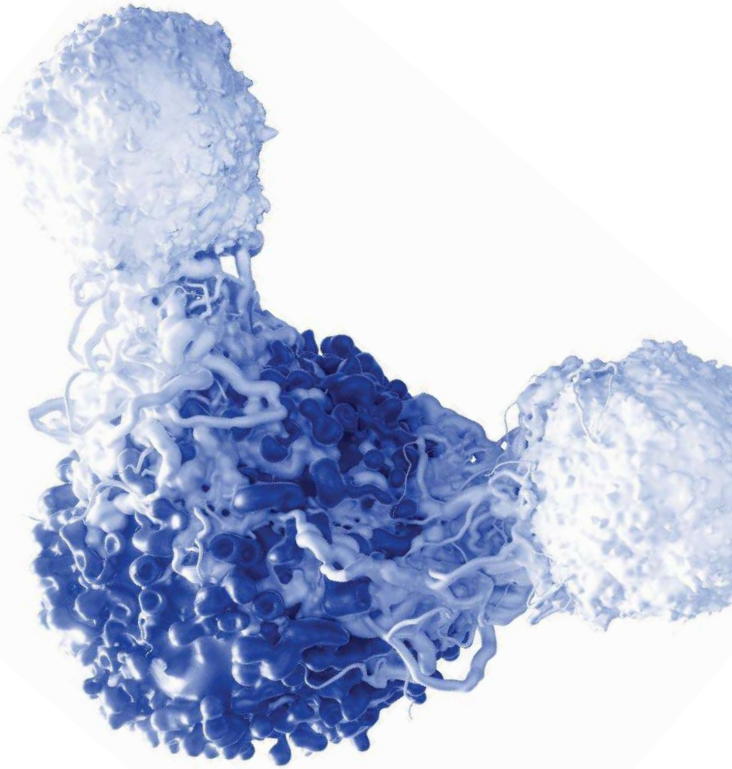

BREAKOUT SESSIONS

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Breakout Rooms

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Brain Cancer Gavin Dunn, M.D., Ph.D.	**State (3rd Floor)**
Gynecologic Cancers Kunle Odunsi, M.D., Ph.D.	**Grand Ballroom A (Next Door)**
Melanoma Cassian Yee, M.D.	**Van Buren (3rd Floor)**
General Immunotherapy Thomas Gajewski, M.D., Ph.D.	**Grand Ballroom BC (Here)**

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National Ovarian Cancer Coalition
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Chicago August 5, 2017