



Baltimore November 16, 2019



Speakers





Scientific Experts

Patient Experts

Marijo Bilusic, M.D., Ph.D.

National Cancer Institute

Elizabeth M. Jaffee, M.D.

Johns Hopkins Kimmel Cancer Center

Ranee Mehra, M.D.

University of Maryland Medical Center

Suzanne L. Topalian, M.D.

Johns Hopkins Kimmel Cancer Center

Vanessa Brandon

Colorectal cancer

Donna Lynch

Diffuse large B-cell (non-Hodgkin) lymphoma

John Ryan

Non-small cell lung cancer

Adrienne Skinner

Ampullary cancer

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Thank you to those who helped promote the summit

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- Colorectal Cancer Alliance
- Crush It For Curtis Foundation
- Esophageal Cancer Action Network
- Esophageal Cancer Awareness Association
- Fight Colorectal Cancer
- FORCE
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- HopeWell Cancer Care
- Johns Hopkins Sidney Kimmel Cancer Center
- Leukemia & Lymphoma Society
- Ludwig Cancer Research

- LUNGevity
- Melanoma Research Alliance
- Melanoma Research Foundation
- National Ovarian Cancer Coalition Baltimore
- Nueva Vida
- Pancreatic Cancer Action Network
- Patient Empowerment Network
- SHARE
- Us TOO
- Ulman Foundation
- University of Maryland Medical Center
- Young Survival Coalition

Summit Program



Morning Session	10:00 AM – 12:00 PM
Lunch	12:00 PM - 1:00 PM
Afternoon Session	1:00 PM – 2:15 PM
Breakout Sessions	2:15 PM – 3:15 PM

Clinical Trial Navigator Appointments are available from 9:00 AM to 4:00 PM. Please stop by the check-in desk near registration to learn more.



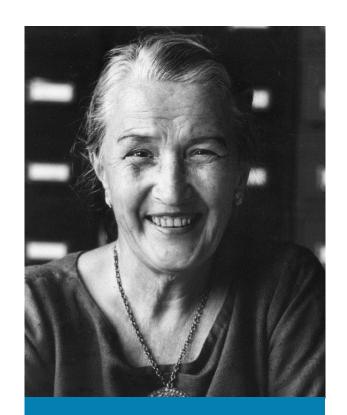
You will receive two emails after the summit:

- 1. A survey to share your feedback on the summit as well as insights into future programming.
- Information from the summit day, including this presentation and instructions on how to use our <u>Clinical Trial Finder service</u>.

Pioneering Immunotherapy







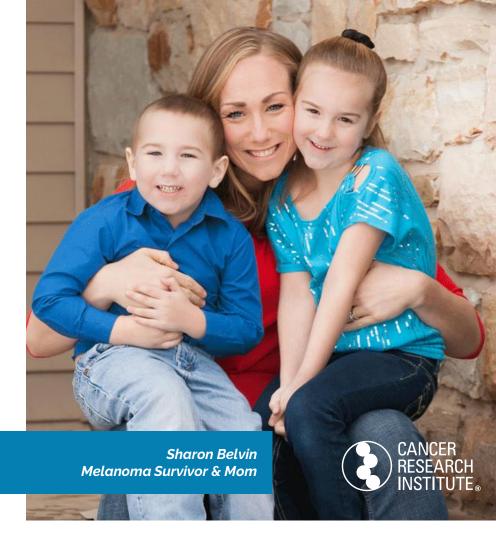
Helen Coley Nauts, D.Sc. (Hon.) Co-Founder, Cancer Research Institute 1907 - 2001

CRI Mission

SAVE MORE LIVES

by fueling the discovery and development of powerful immunotherapies for all types of cancer.





CRI Impact



FUNDED

3,300 scientists worldwide

INVESTED

\$420+ million

TRUSTED

Platinum, A+ charity





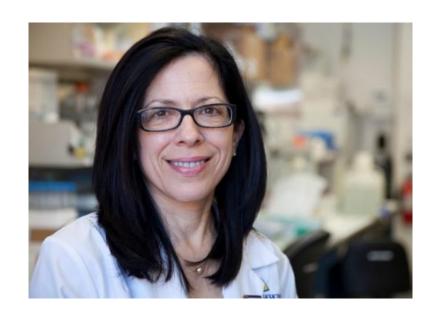






Immunotherapy 101









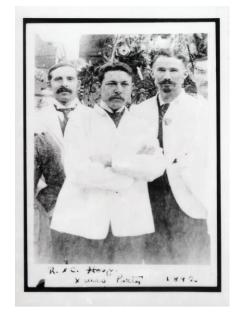
Elizabeth M. Jaffee, M.D.

Deputy Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Professor of Oncology

Origin & Revival of Immunotherapy



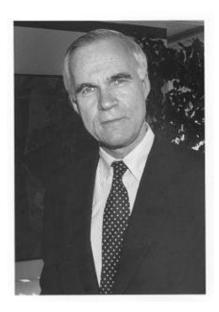








1900s: Paul Ehrlich

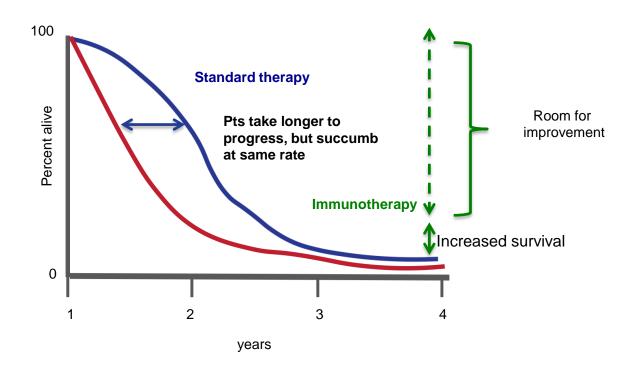


1960s: Lloyd J. Old

Immunotherapy: A Potential Cure?







The Immune System at a Glance: Our Natural Defense System





Nose

Hairs and mucus trap foreign particles and prevent them from entering the body

Thymus

Small organ located just behind the breastbone where T cells mature (the "T" is for thymus)

Bone Marrow

Tissue in the center of bones that is responsible for making blood cells, including white blood cells

White blood cells

White blood cells-including macrophages, dendritic cells, and lymphocytes-are the cellular actors of immunity

Tonsils

Structures at the back of the throat that sample bacteria and viruses that enter the body through the mouth or nose

Lymph nodes

Small, bean-shaped structures located throughout the body that filter lymph fluid; where immune cells are alerted to the presence of pathogens or cancer

Spleen

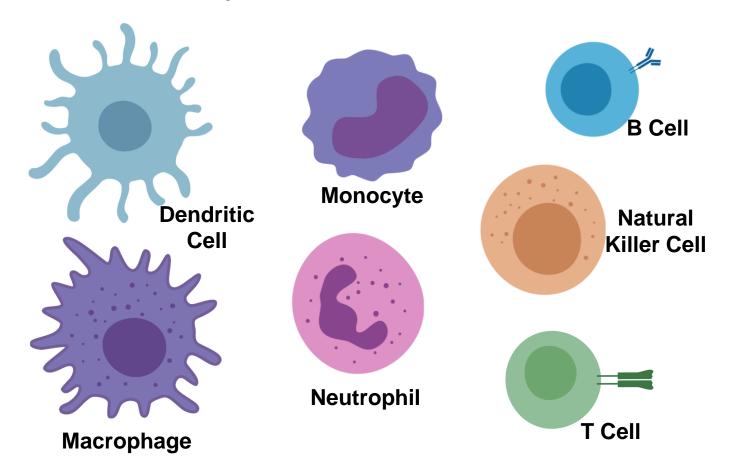
Fist-sized organ located in the upper-left part of the abdomen. containing white blood cells that fight infection and cancer

Lymphatic vessels

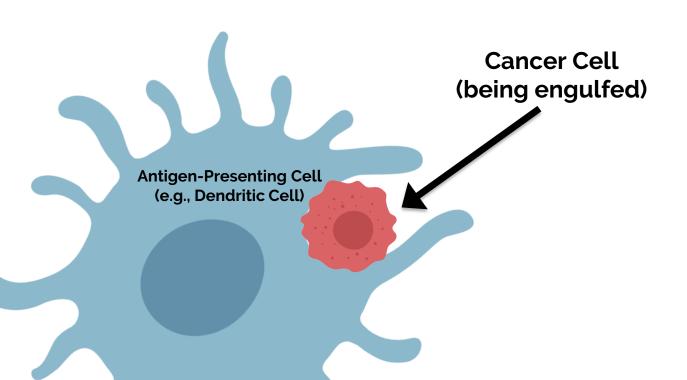
Thin-walled tubes that collect and transport lymph fluid throughout body

The Cells of the Immune System: The "Soldiers" in our Army

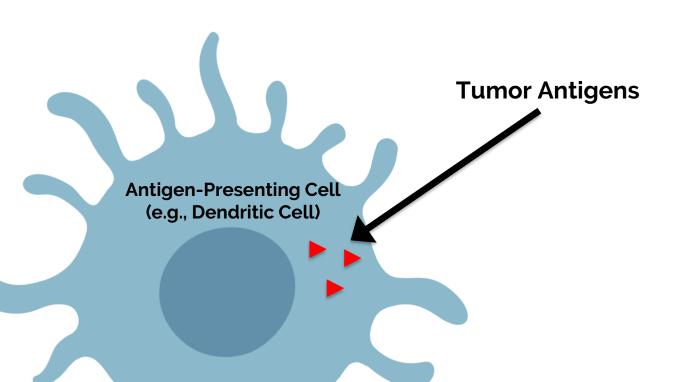




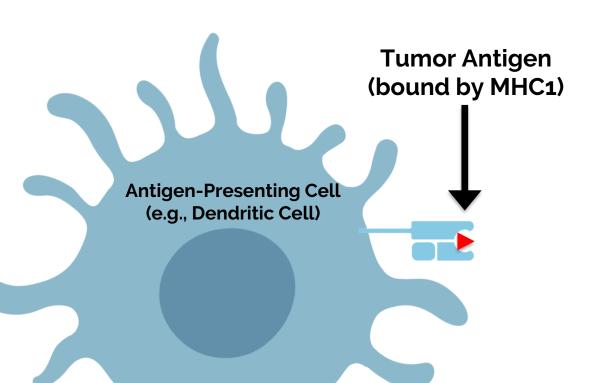




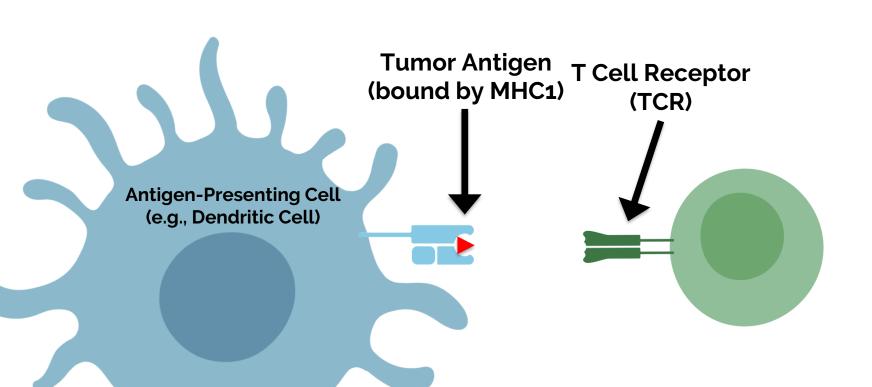




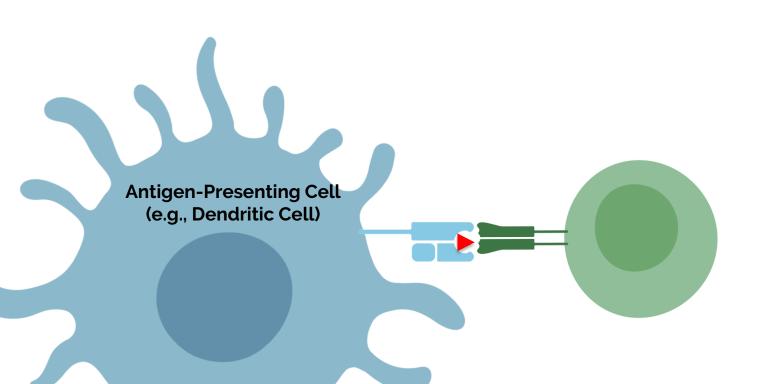




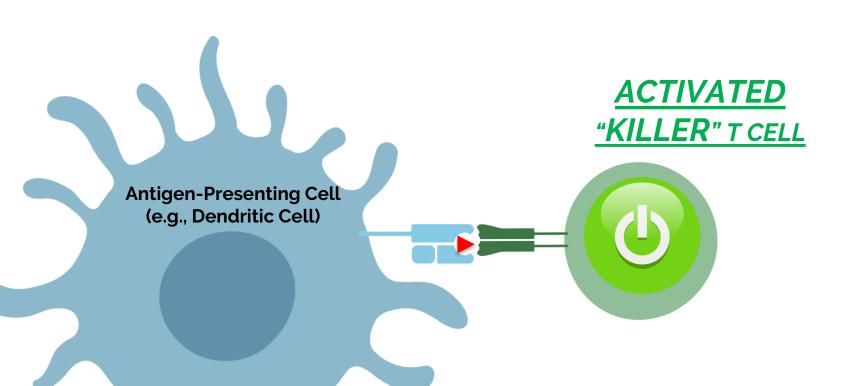




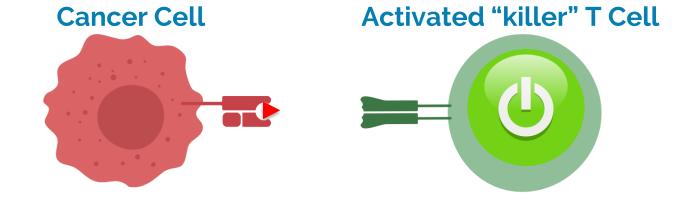






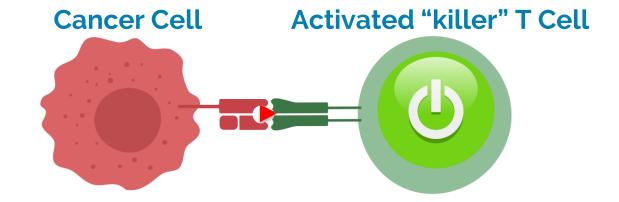






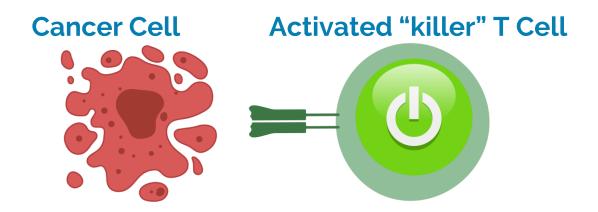










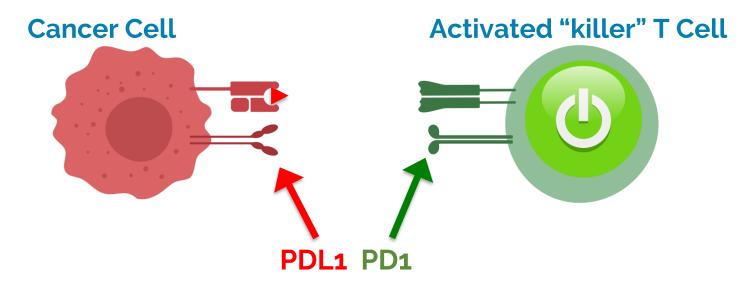


CANCER CELL ELIMINATED!



Immune Checkpoints Can Suppress Immune Responses

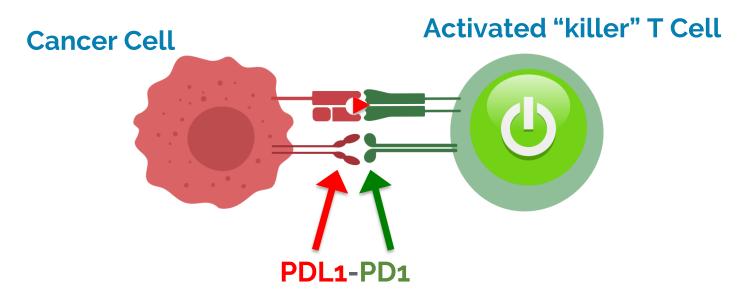






Immune Checkpoints Can Suppress Immune Responses

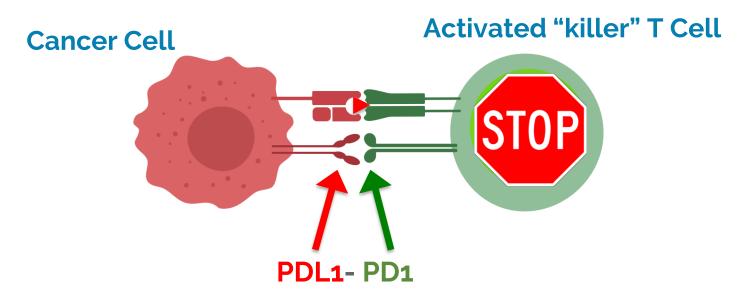






Immune Checkpoints Can Suppress Immune Responses

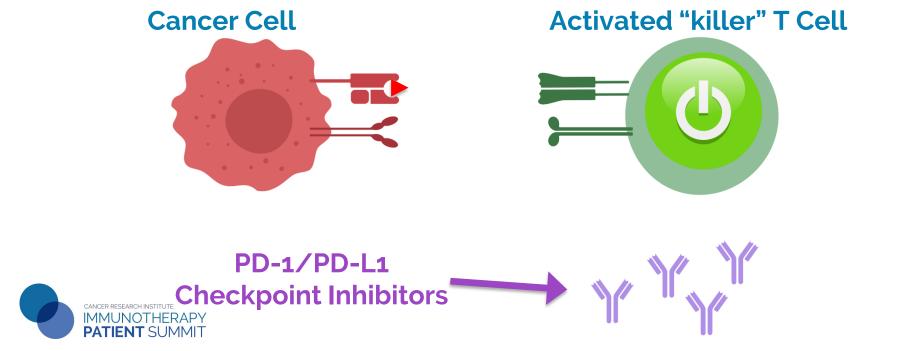




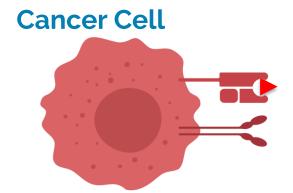


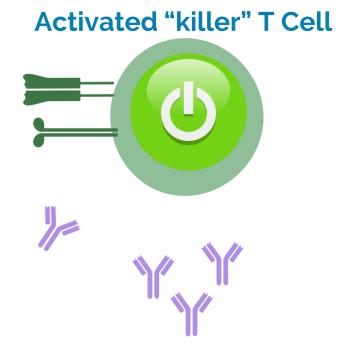
Normally, PDL1-PD1 leads to T cell "exhaustion"





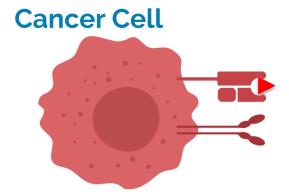




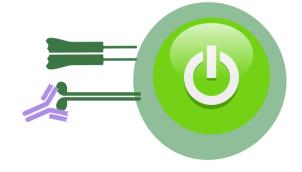




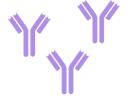




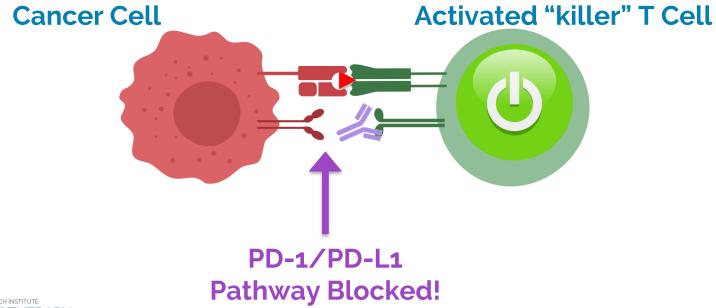






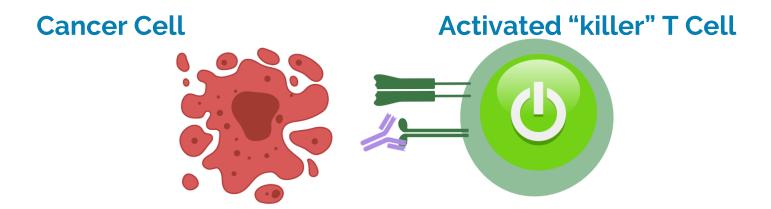










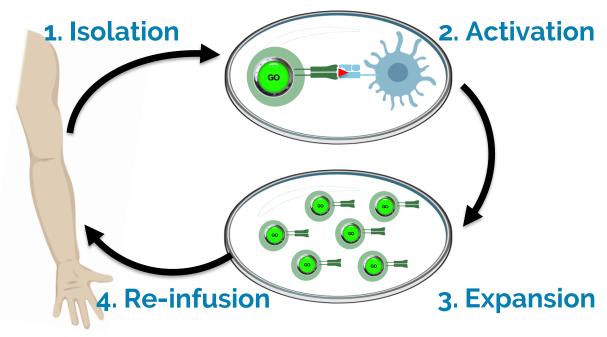


CANCER CELL ELIMINATED!



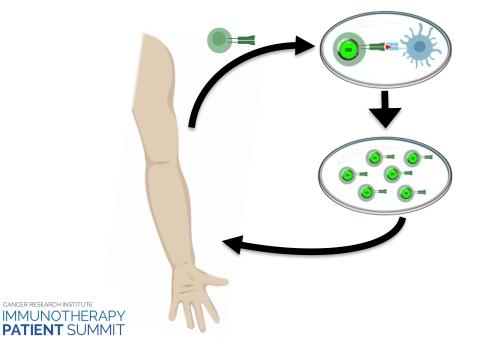
Adoptive T Cell Immunotherapy

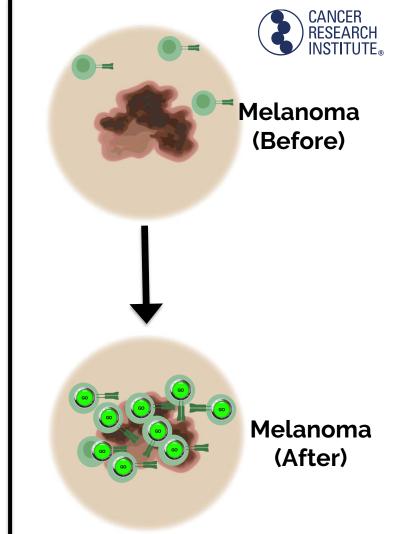






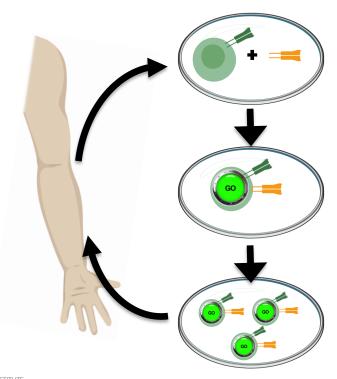
Adoptive T Cells In Action (Against Melanoma)





T Cell Receptor Engineering



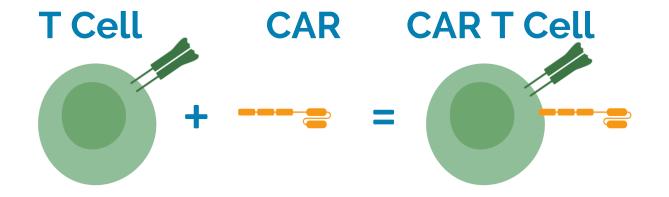


Equip T cells with new, cancer-targeting TCR



CAR T Cell Immunotherapy (Chimeric Antigen Receptor)

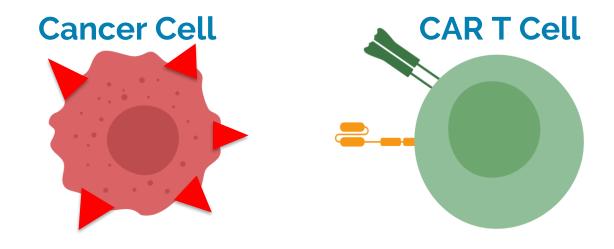






CAR T Cell Immunotherapy (Chimeric Antigen Receptor)



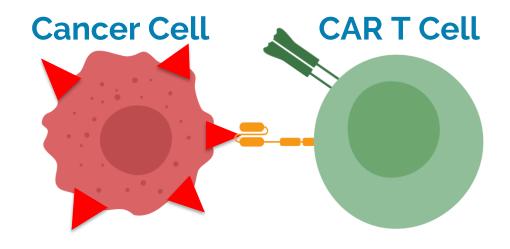


CARs enable MHC-independent targeting & killing!



CAR T Cell Immunotherapy (Chimeric Antigen Receptor)



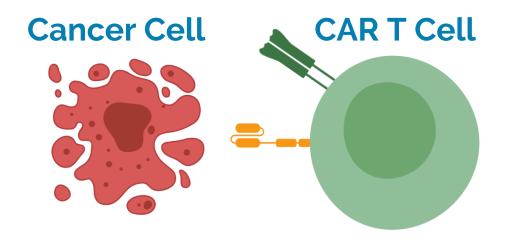


CARs enable MHC-independent targeting & killing!



CAR T Cell Immunotherapy (Chimeric Antigen Receptor)



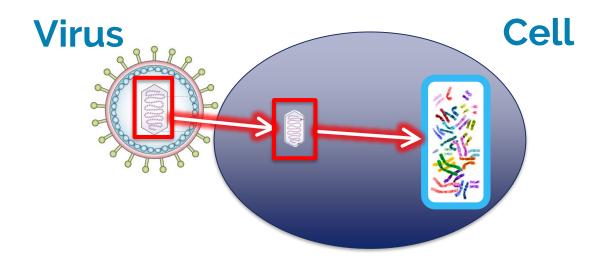


CARs enable MHC-independent targeting & killing!



Oncolytic Virus Immunotherapy



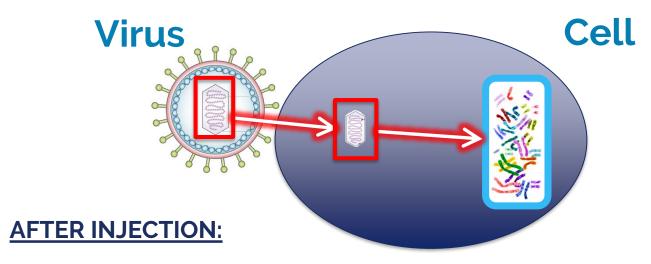


- Viruses can alter our cells' DNA, by inserting their own genetic material
- Impaired defenses make tumor cells more susceptible to infection



Oncolytic Virus Immunotherapy



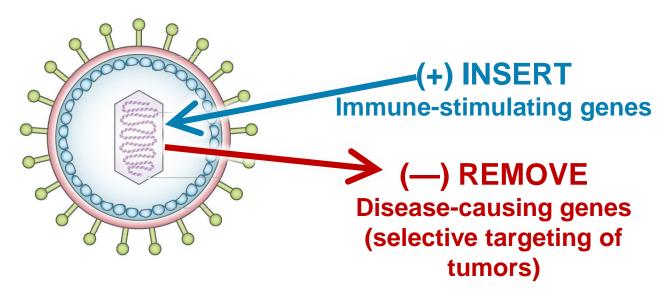


- 1) Viruses cause tumor cells to "burst" & release antigens
- 2) Immune cells uptake & present tumor antigens
- 3) Stimulates adaptive, and potentially systemic, immune responses



Reprogramming Oncolytic Viruses | To Enhance Anti-Tumor Activity





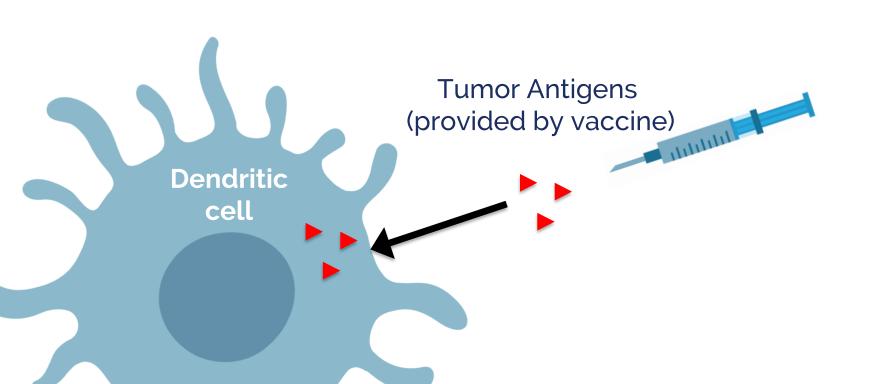




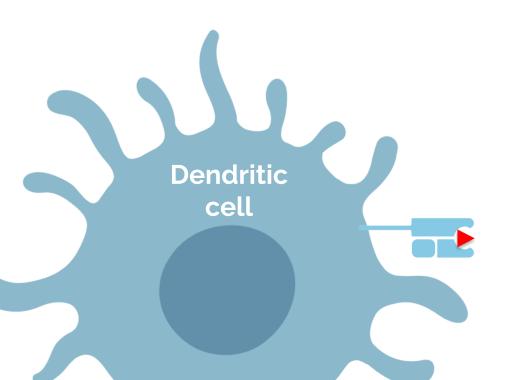
Tumor Antigens (provided by vaccine)



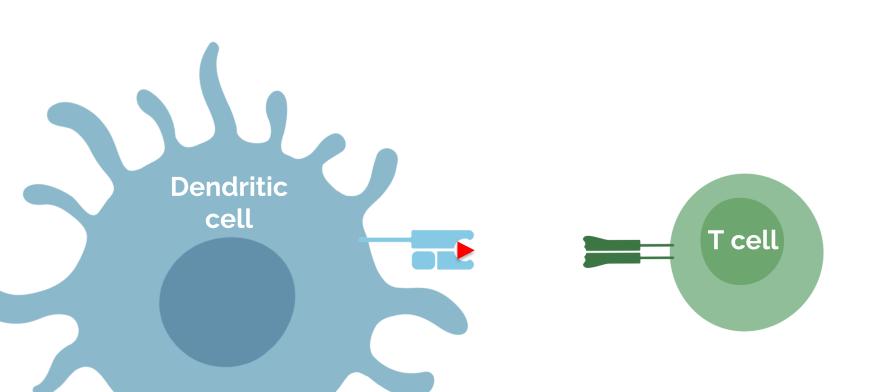




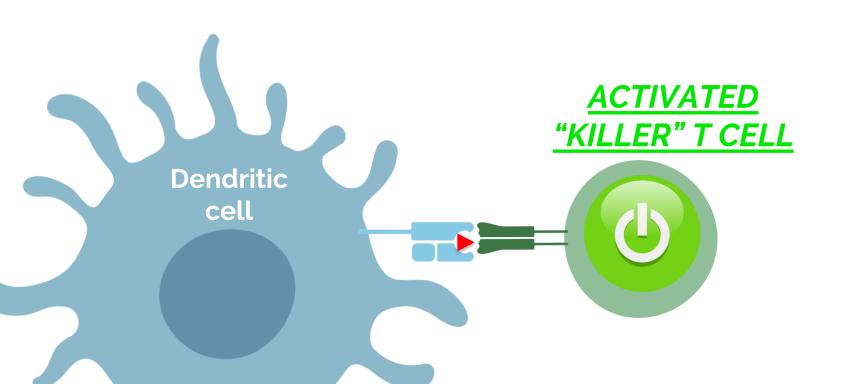








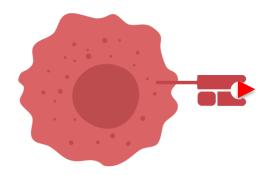




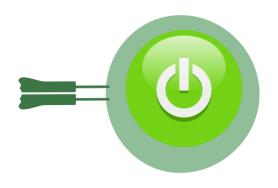
Vaccine-Induced Elimination of Cancer Cells



Cancer Cell



Activated "killer" T Cell





Vaccine-Induced Elimination of Cancer Cells

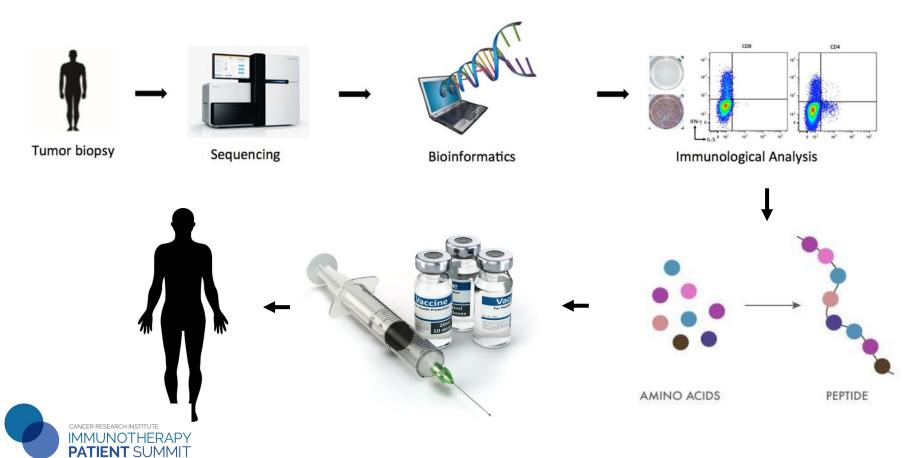


Cancer Cell Activated "killer" T Cell



Personalized Neoantigen Vaccine Trial





Challenges in Cancer Immunotherapy



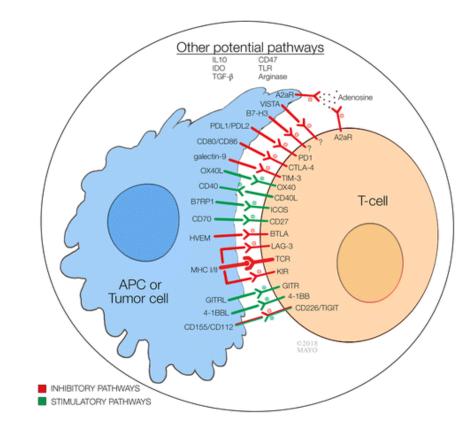
- Discovering and validating new biomarkers to help doctors predict which patients will respond to which immunotherapies
- Determining the best way to combine immunotherapies with each other as well other treatments to extend immunotherapy's benefits for more patients
- Learning how to decouple side effects of immunotherapy from benefit



Why have most responses been modest and why are some cancers refractory to immunotherapy?



 Cancers upregulate molecules to turn off immune cells

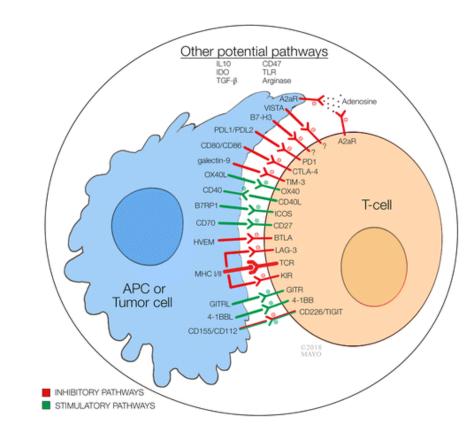




Why have most responses been modest and why are some cancers refractory to immunotherapy?



- Cancers upregulate molecules to turn off immune cells
- Cancers secrete chemicals to turn off the immune system



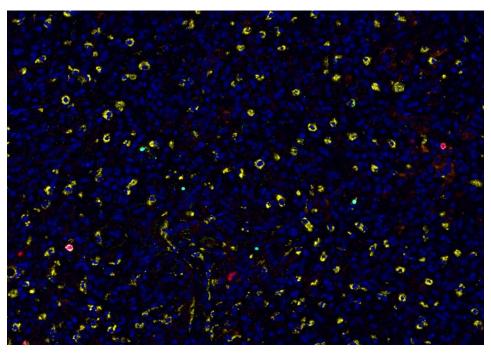


Why have most responses been modest and why are some cancers refractory to immunotherapy?



- Cancers upregulate molecules to turn off immune cells
- 2. Cancers secrete chemicals to turn off the immune system
- 3. Cancers recruit suppressive cells to inactivate/block the immune response



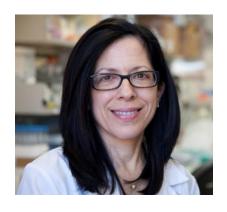




Panel Discussion



LATEST RESEARCH UPDATES



Moderator
Elizabeth M. Jaffee, M.D.
Pancreatic cancer



Panelist
Marijo Bilusic, M.D., Ph.D.
Genitourinary cancer



Panelist Ranee Mehra, M.D. Lung cancer



Panelist Suzanne L. Topalian, M.D. Melanoma

Immunotherapy Patient Perspective





Adrienne Skinner
Ampullary Cancer Veteran



Adrienne's Guidelines

- Clinical trials' success depends on specific characteristics for each trial:
 Find out what those are and be prepared to answer questions about your ability to meet them
- Cancer treatment is a journey: Make sure you are exploring all roads
- **Become educated:** However, trust but verify your sources
- Remember there are thousands of people who are working to help you: Your experience is important in ways you may never know. Help the process of improving results for all
- Persistence and positivity makes a difference
- Take control where you can
- Marshall your support team



Taking control of my hair loss in 2013.

Cancer makes you feel like your body is out of control.

Choosing when my hair would be gone felt better than waiting for it.



This is my 'fancy girl' wig. She came to work with me.

No one really knew I was sick unless I told them. How you behave is what people read. Make-up, wigs and false eyelashes hid the physical impact for me.



These are the amazing doctors who led the clinical trial for the immunotherapy solution that saved my life.

Dr. Luis Diaz and Dr. Yung Le, my heros!



Support from them was, and is, crucial. And for them, knowing there is a potential solution should they get cancer is a relief (three of them have Lynch Syndrome, too).

My four daughters



Support from family and friends is essential. Be open about what you need.

So lucky to have Joe in my life!



What a joy to be here for my first grandchild.

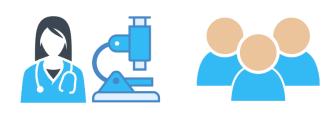
My newest team support member!





What Are Clinical Trials?









 Designed to answer specific questions about new and existing treatments

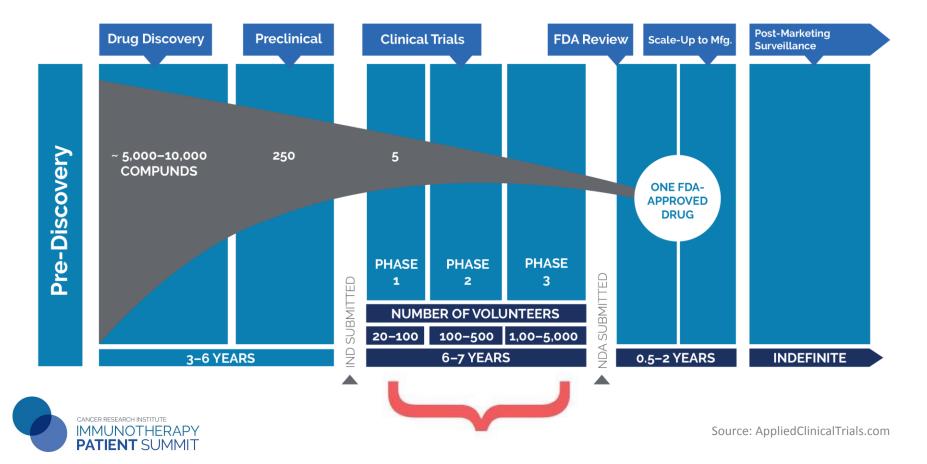


 Aim to improve treatments and the quality of life for people with disease



Getting from Discovery to Approval





What Are Clinical Trial Phases?





Phase 2
Does it work?



Purpose:

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

Number of people: 20-100

Purpose:

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

Number of people: 100-500

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:

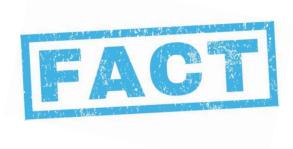
- cancer type or stage
- treatment history
- genetic factors
- age
- medical history
- current health status







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



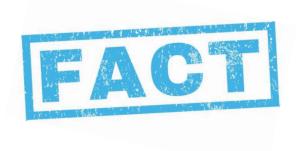
Placebos are rarely used and never given in the absence of some form of treatment.







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



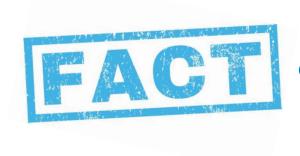
Clinical trials are designed for people with cancer of all types and stages.







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



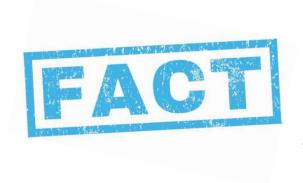
Trials take place at local hospitals, cancer centers, and doctors' offices in all parts of the country, in both urban and rural areas.







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



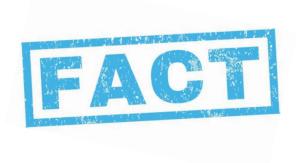
Doctor visits, hospital stays, and certain testing procedures may be covered by insurance. Research costs are typically covered by the trial sponsor.







Signing a consent form "locks" me into staying in a trial.



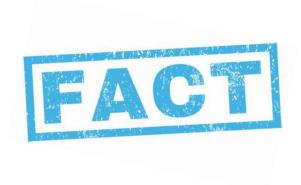
Fact: You are free to change your mind for any reason about participating in a trial anytime before or during a trial.







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



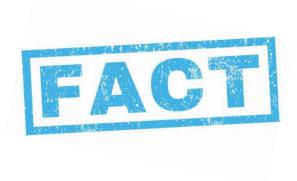
Fact: The overwhelming majority of trial participants say they were treated with dignity and respect, and report having had a positive experience in a trial.







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.



A Word About Informed Consent



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?

CANCER RESEARCH INSTITUTE®

- 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/







Immunotherapy Patient Panel



Moderator	ranet
Brian Brewer	Vanessa Brandon
	Colorectal cancer
	Donna Lynch
	Diffuse large B-cell (non-Hodgkin) lymphoma

Panel

John Ryan

Non-small cell lung cancer



Moderator



Breakout Session Rooms



General Immunotherapy Elizabeth M. Jaffee, M.D.	Level 1 Pullen Plaza
Melanoma	Level 2
Megan D. Schollenberger, MSN, CRNP	Room 200
Lung Cancer	Level 2
Ranee Mehra, M.D.	Room 202
Genitourinary Cancer	Level 3
Marijo Bilusic, M.D., Ph.D.	Mt. Washington Room



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