



Why We Do Research: Clinical Trials

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Objectives:

- Assess need for Research
- Define Clinical Trials
- Discuss Types of Clinical Trial
- Review History of Cancer Progress
- Explore recent and ongoing clinical trials

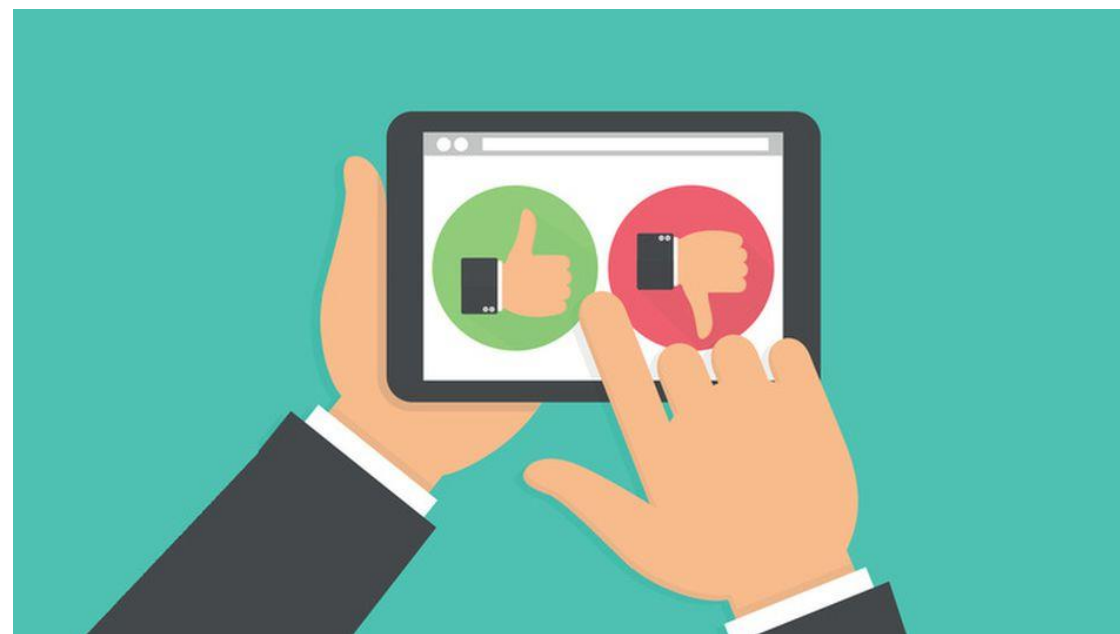




Have you ever ordered, educated about, infused, assessed, or treated any side effects for cancer treatment?

Yes

No







Definition of Clinical Trials

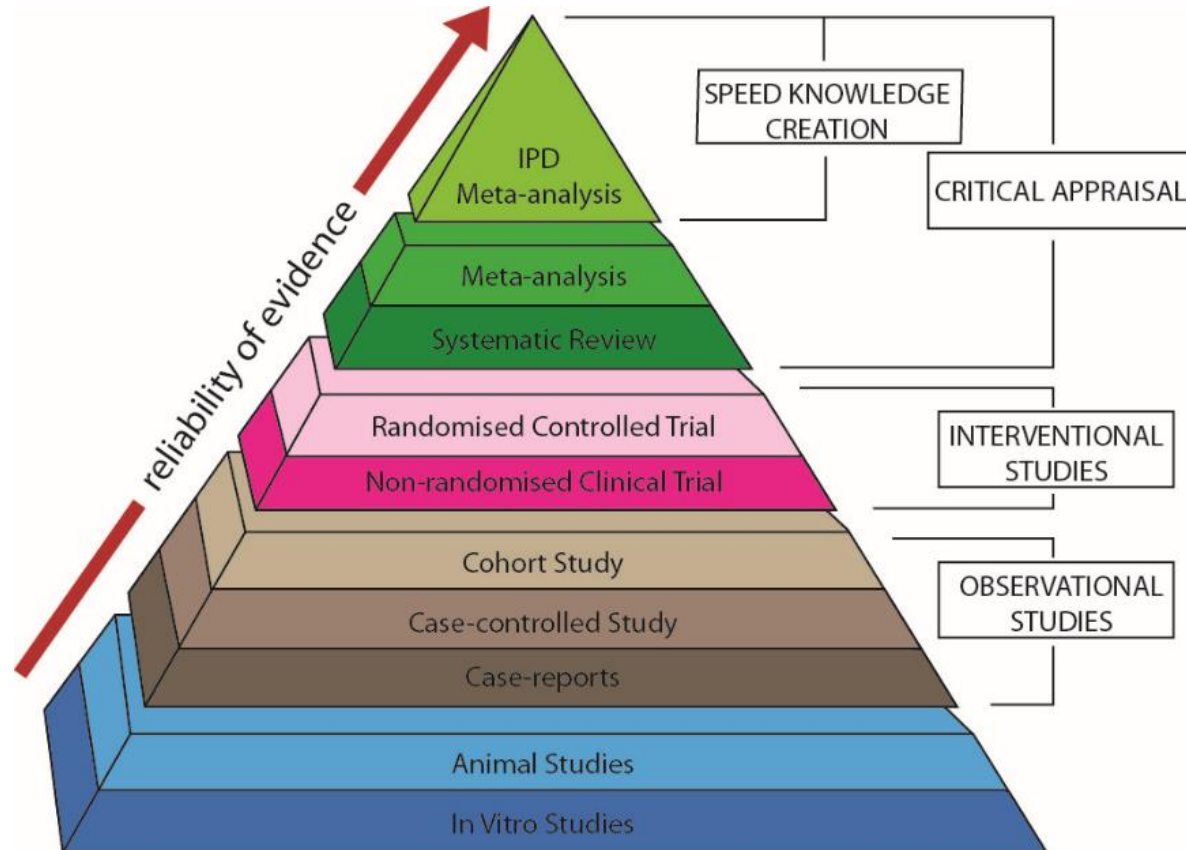
World Health Organization Definition-



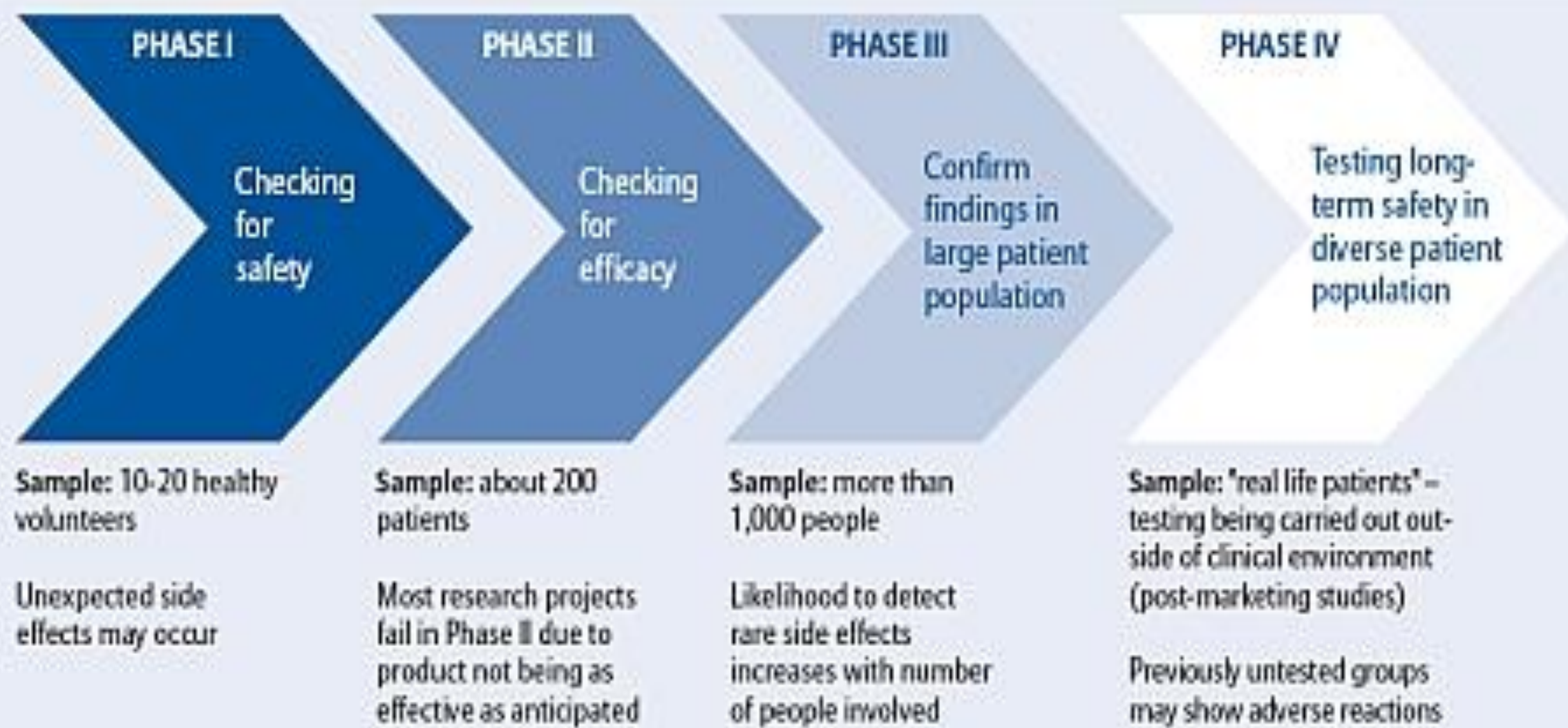
A **clinical trial** is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc.

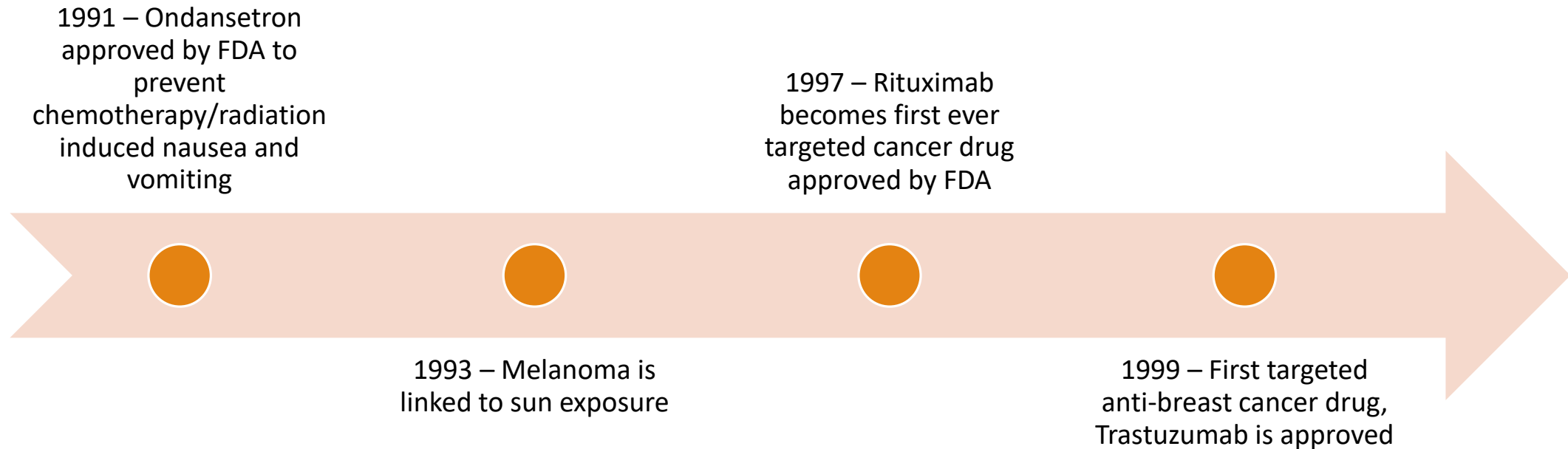
Types of Research



WATCHING YOUR STEP – THE DIFFERENT STAGES OF CLINICAL DEVELOPMENT AND WHAT THEY EXAMINE

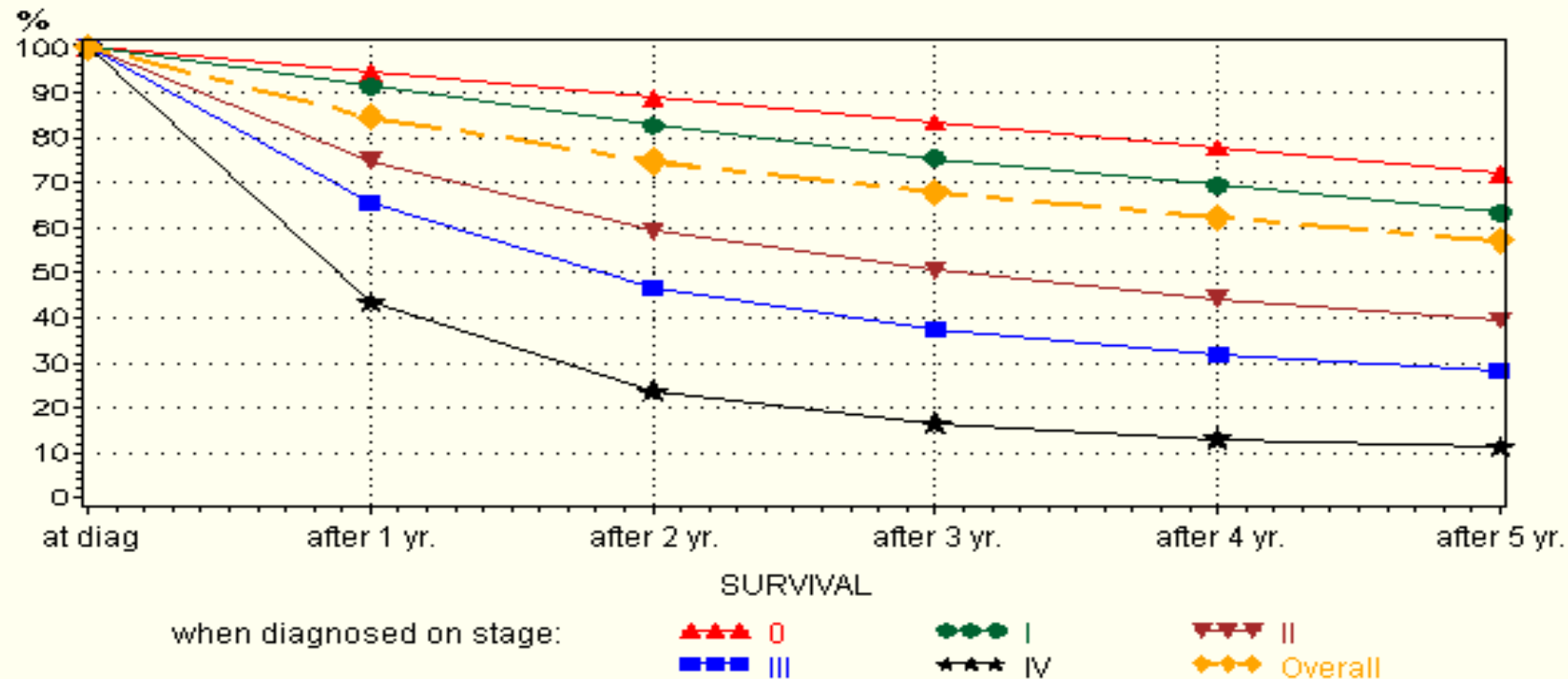


Cancer Progress 1990's:

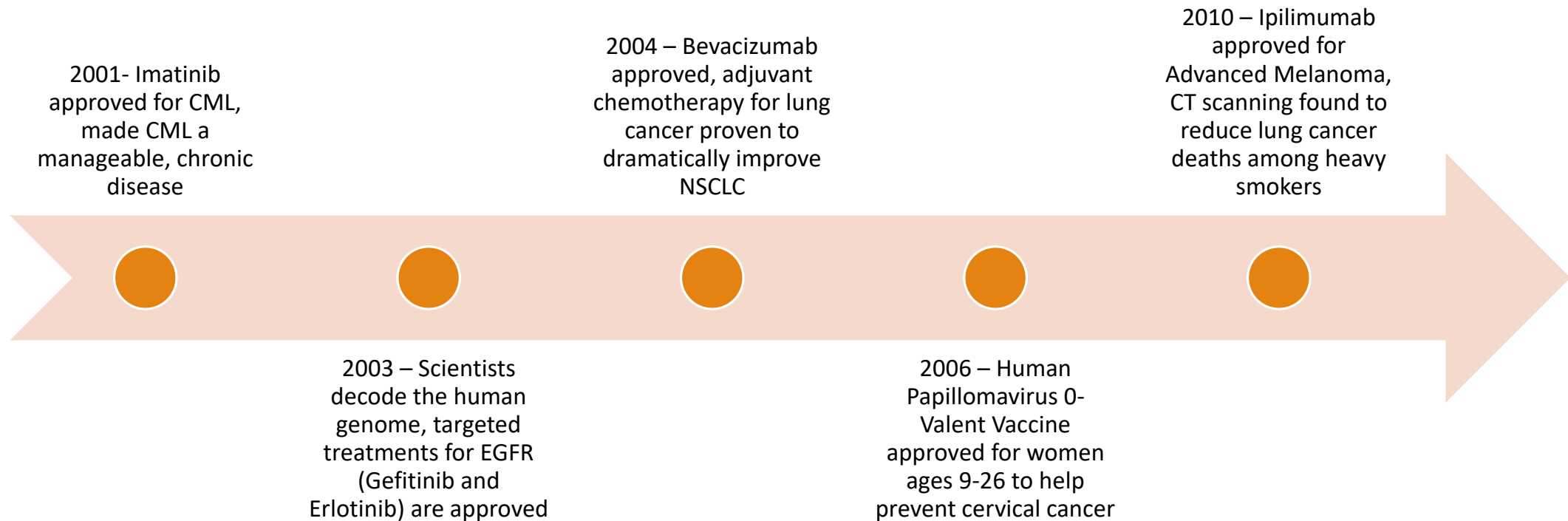


Bladder Cancer: aboutcancer.com

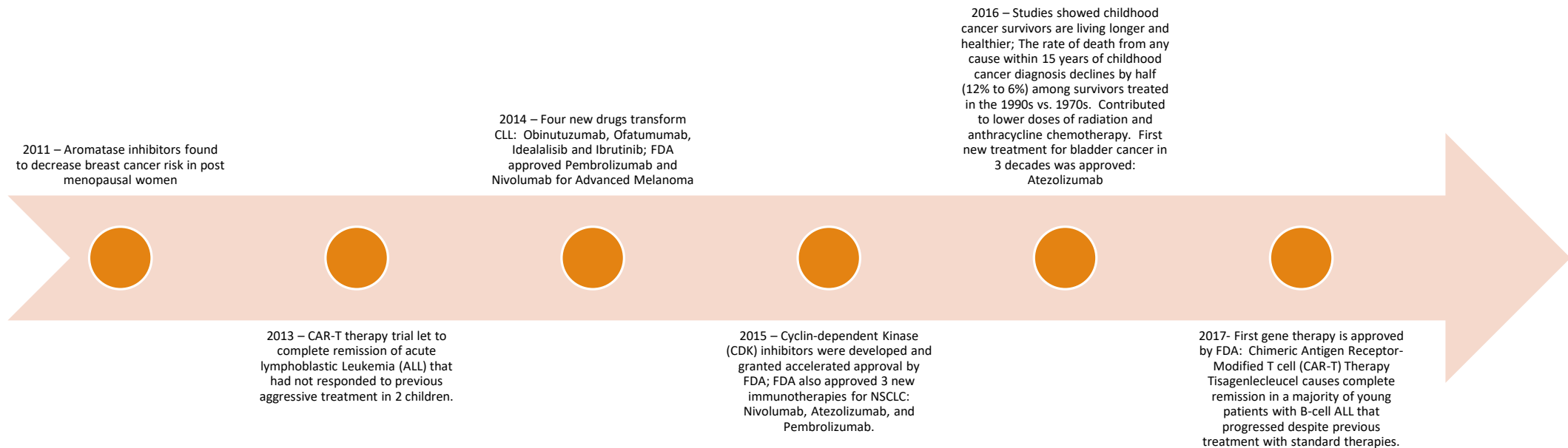
Five Year Surv. Rates for Bladder Cancer Cases Diagnosed in 1995 and 1996
All States / Data Reported from 1688 Hospitals
Hospitals of Type: All



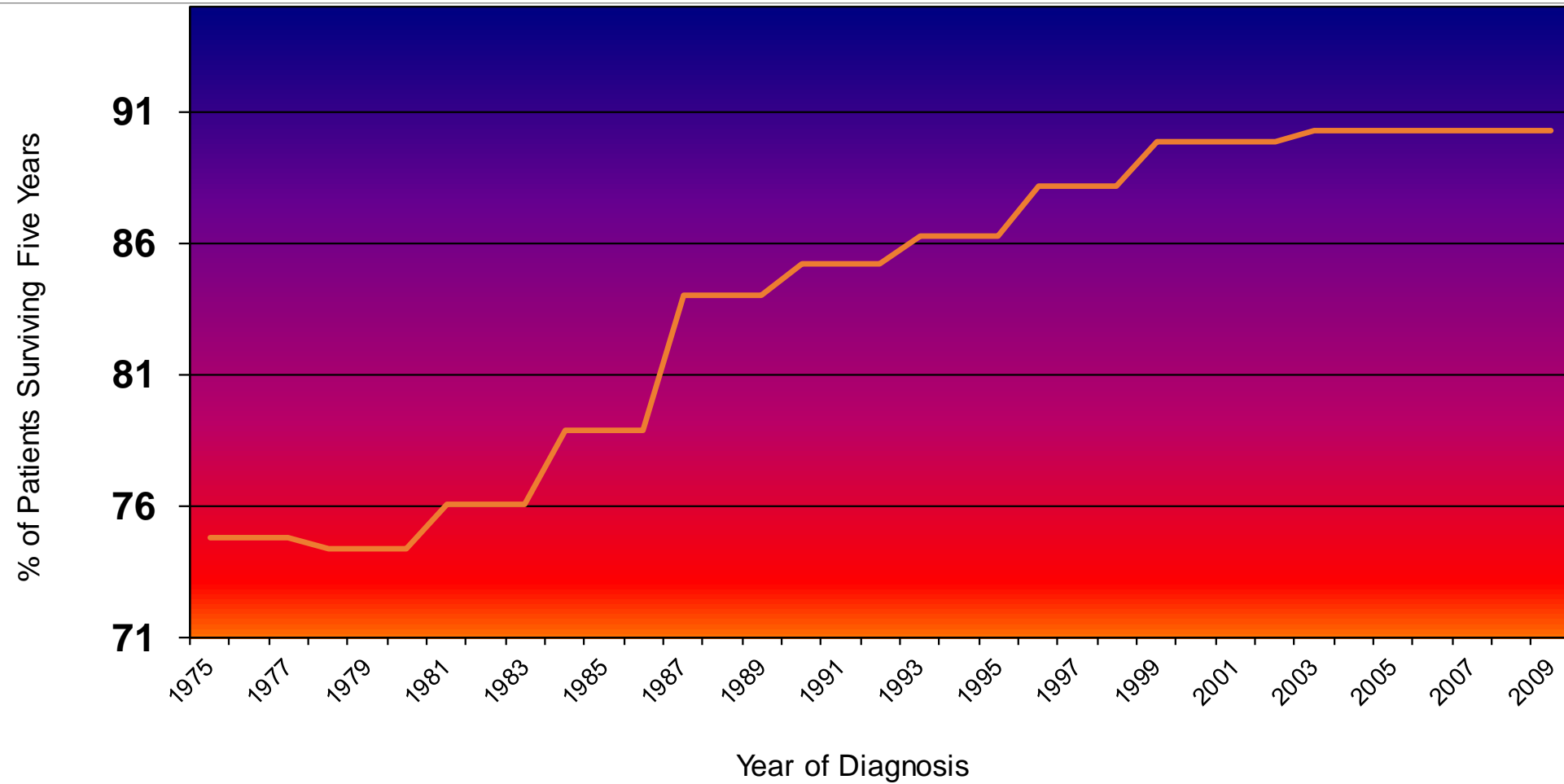
Cancer Progress Early 2000's:



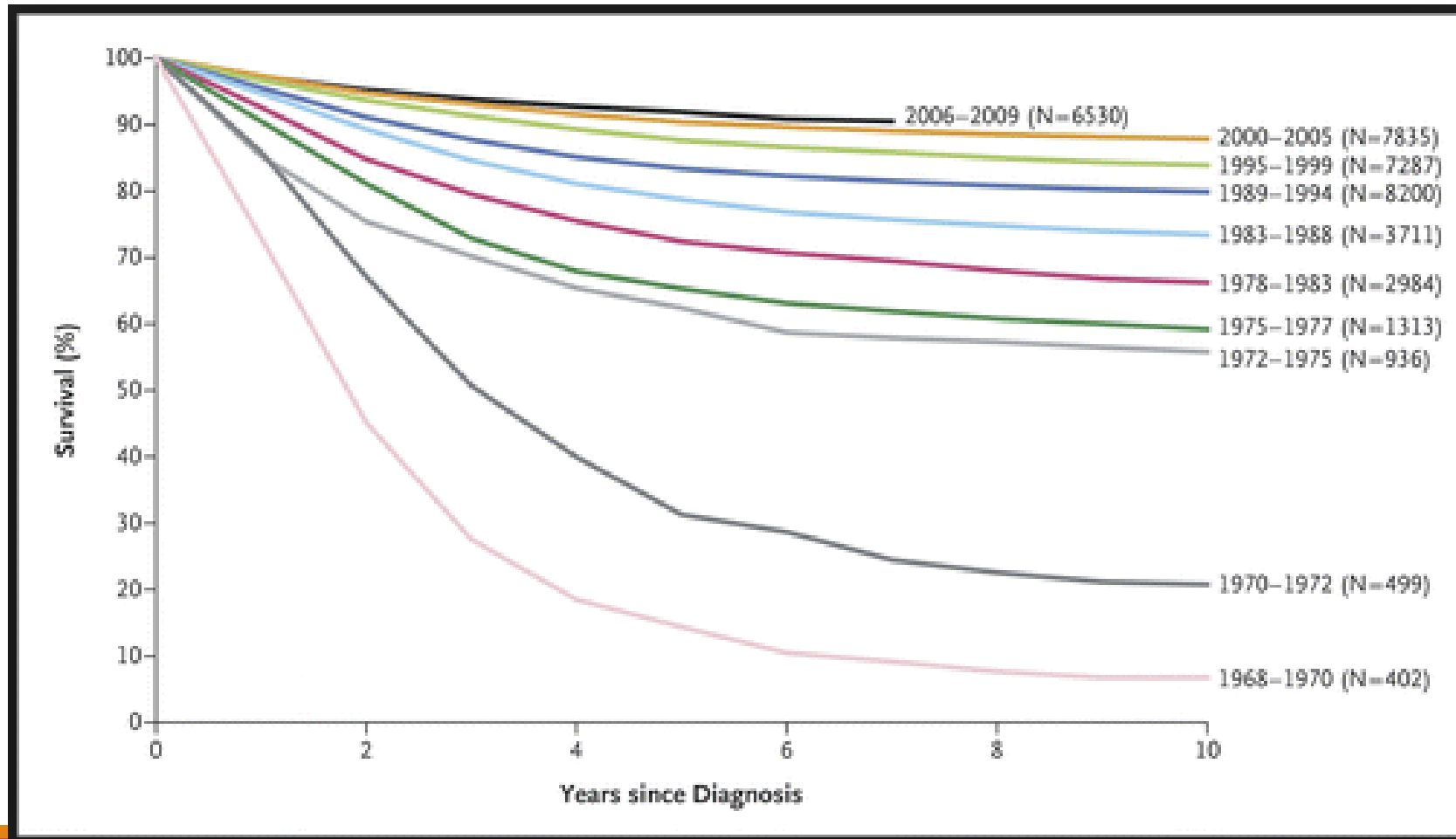
Cancer Progress 2011 and Beyond:



Breast Cancer



Childhood ALL

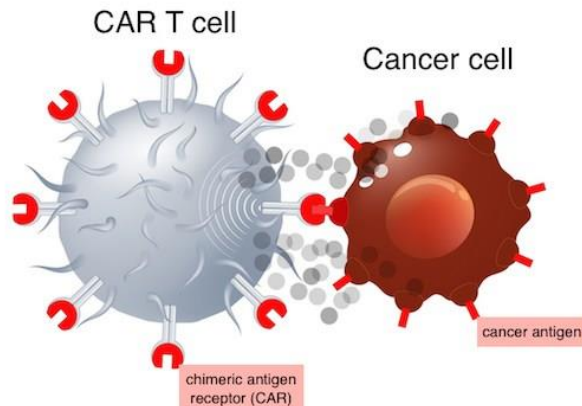


Learn Now

A 3D graphic featuring the words "Learn Now" in a blue, blocky font. To the right of the text is a large, bright yellow five-pointed star. A vibrant, multi-colored streak, resembling a comet or a meteor, originates from the bottom left and extends towards the star, displaying a gradient of red, orange, yellow, and green. The entire scene is set against a dark, starry background.

CAR-T Cell for ALL

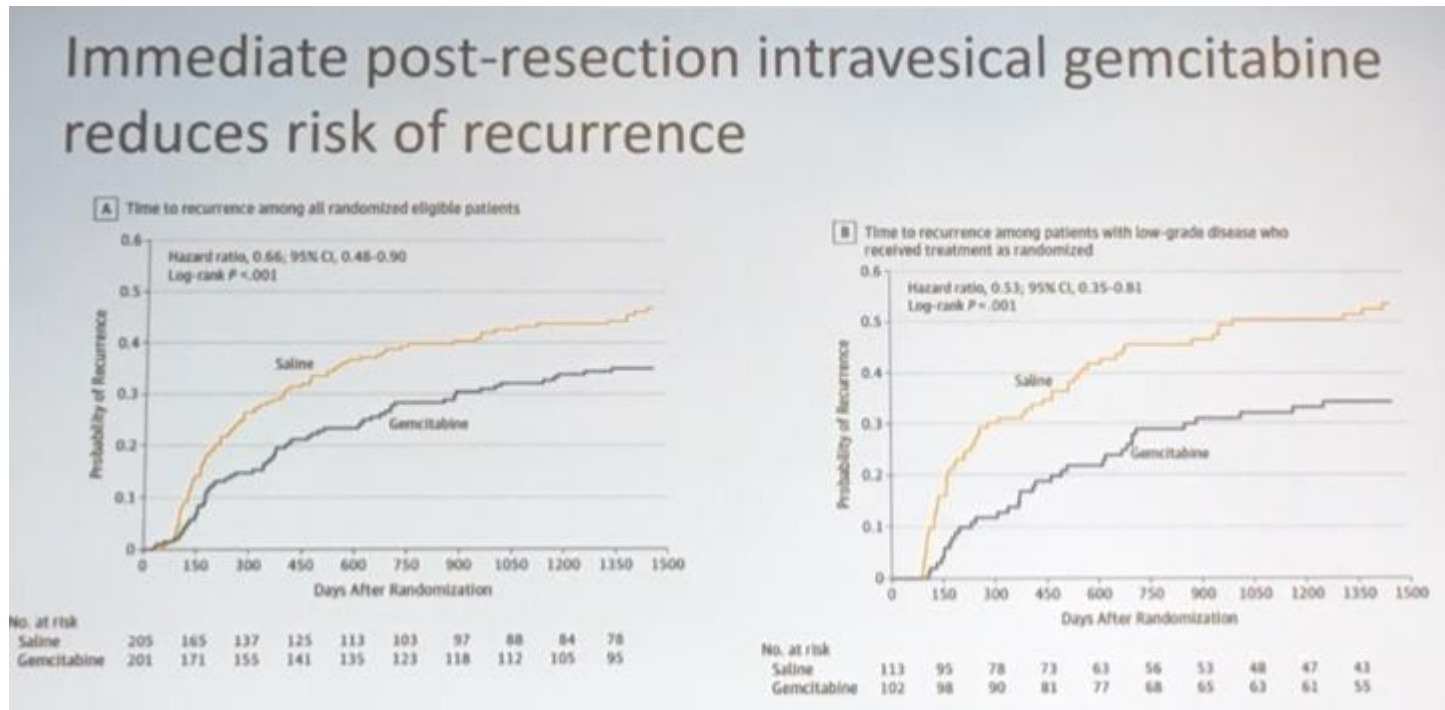
- 2 kids with relapsed and refractory B-Cell ALL received infusions of T cells transduced with anti-CD19 antibody and a T-cell signaling molecule
- In both patient's CTL019 T cells expanded to a level that was more than 1000 times as high as the initial engraftment.
- Cells were identified in the bone marrow and CSF
- Can cause Cytokine release syndrome, etanercept and tocilizumab helped to reverse symptoms and did not prevent expansion of the CAR-T cells or antileukemic efficacy
- CR was observed in both pts. And 1 is ongoing 11 months post tx. The 2nd had a relapse 2 months after treatment but with blast cells that no longer expressed CD19



Grupp, S.A., Kalos, M., Barrett, D., et. Al. (2013), *NEJM*; 368:1509-1518

SWOG 0337: Gemcitabine vs. Saline

The study looked at Gemcitabine vs. Saline in the prevention of bladder cancer recurrence in non-muscle invasive bladder cancer (NIMIBC), published by Dr. Messing in JAMA.



Demonstrated a significant decrease both in the intention to treat a population of patients suspected of having low-risk NIMIBC and an even greater benefit among the per protocol analysis of patients with pathologically proven low risk disease.

POLO Trial

Phase III Trial

Found that maintenance therapy with Olaparib significantly delayed the progression of metastatic pancreatic cancer in patients with BRCA gene mutations compared with placebo (median PFS was 7.4 months vs. 3.8 months respectively)

Given to patients who had not progressed after completion of initial platinum based chemotherapy and after 2 years 22.1% of people receiving Olaparib has no PD vs 9.6% for those treated with placebo

Pending mature survival data



KeyNote-001

Showed Pembrolizumab was safe and effective

Substantially increased overall survival for advances NSCLC

23.2% of people who had not previously been treated with chemotherapy and 15.5% of previously treated patients were alive after 5 years with the greatest benefit observed in patients with higher PD-L1 expression

Marked improvement over 5 year survival rates from pre immunotherapy which averaged 5.5% for NSCLC



Access to Therapies

August 8, 2019

CMS released a national coverage determination (NCD) on CAR-T cell Therapy that provides increased access to Medicare beneficiaries

Opened door to receive CAR-T cell therapy in an outpatient setting which will reduce the cost

Removes ambiguity around what CMS will cover

Still does not cover full cost



Rules to Research by:

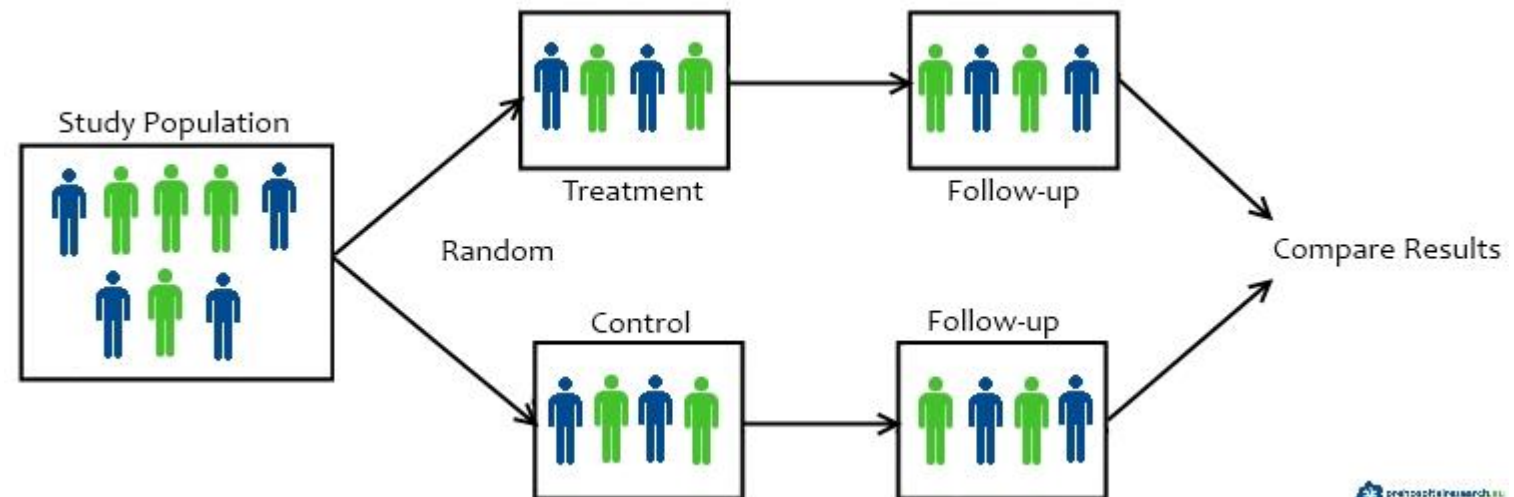


- Federal Code of Regulations 21
Part 11 compliant
- International Conference on Harmonization
(ICH 6) and Good Clinical Practice
- Institutional Review Board



Randomization / Open Label

- What does it mean
- Why is it done
- Terms: Control Arm vs. Study Arm



Recruiting Tips

- Present Research Early
- Use EMR's Effectively
 - Run Reports
 - View the reason for visit tab
- Prescreen Patients – targeting New Patients, Surgical referrals, Patient's post imaging,
- Keep list of potential patients – if on 1st line now and you have a 2nd line study start the conversation
- Perfecting your Approach

PARTICIPANTS NEEDED



EAP/Compassionate Use


Access to medication prior to FDA approval

- Sponsor needs to have a program for the compound
- Treating MD needs to write a letter of need
- Sponsor Approval/FDA Approval
- Must pass IRB approval



Resources:

<https://clinicaltrials.gov/>

 U.S. National Library of Medicine
ClinicalTrials.gov

[Find Studies](#) [About Studies](#) [Submit Studies](#) [Resources](#) [About Site](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 315,240 research studies in all 50 states and in 209 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Status ⓘ

☐ Recruiting and not yet recruiting studies

☒ All studies

Condition or disease ⓘ (For example: breast cancer)

Other terms ⓘ (For example: NCT number, drug name, investigator name)

Country ⓘ

[Search](#) [Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

Resources:

Common Terminology Criteria for Adverse Events (CTCAE)

Version 4.0

Published: May 28, 2009 (v4.03: June 14, 2010)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute



- Everyone with XYZ cancer will qualify for this study
- Everything is free for patient's on study
- Once you are on study you cannot get out
- Protocols are easy to write



- Everyone with XYZ cancer will qualify for this study
 - False– all studies have very specific inclusion/exclusion criteria for subjects to participate
- Everything is free for patient's on study
 - False– majority of the exams on study will align with standard of care and go through the patient's insurance, the sponsor is required to cover anything that is not approved or above the standard
- Once you are on study you cannot get out
 - False – subjects always have the option to stop the study, the treating physician can also take them off study if they feel there is a better option available
- Protocols are easy to write
 - True – most sites have a template and a team to help with this 😊

Questions

