

Clinical Trials 101 For Promotores / Community Health Workers



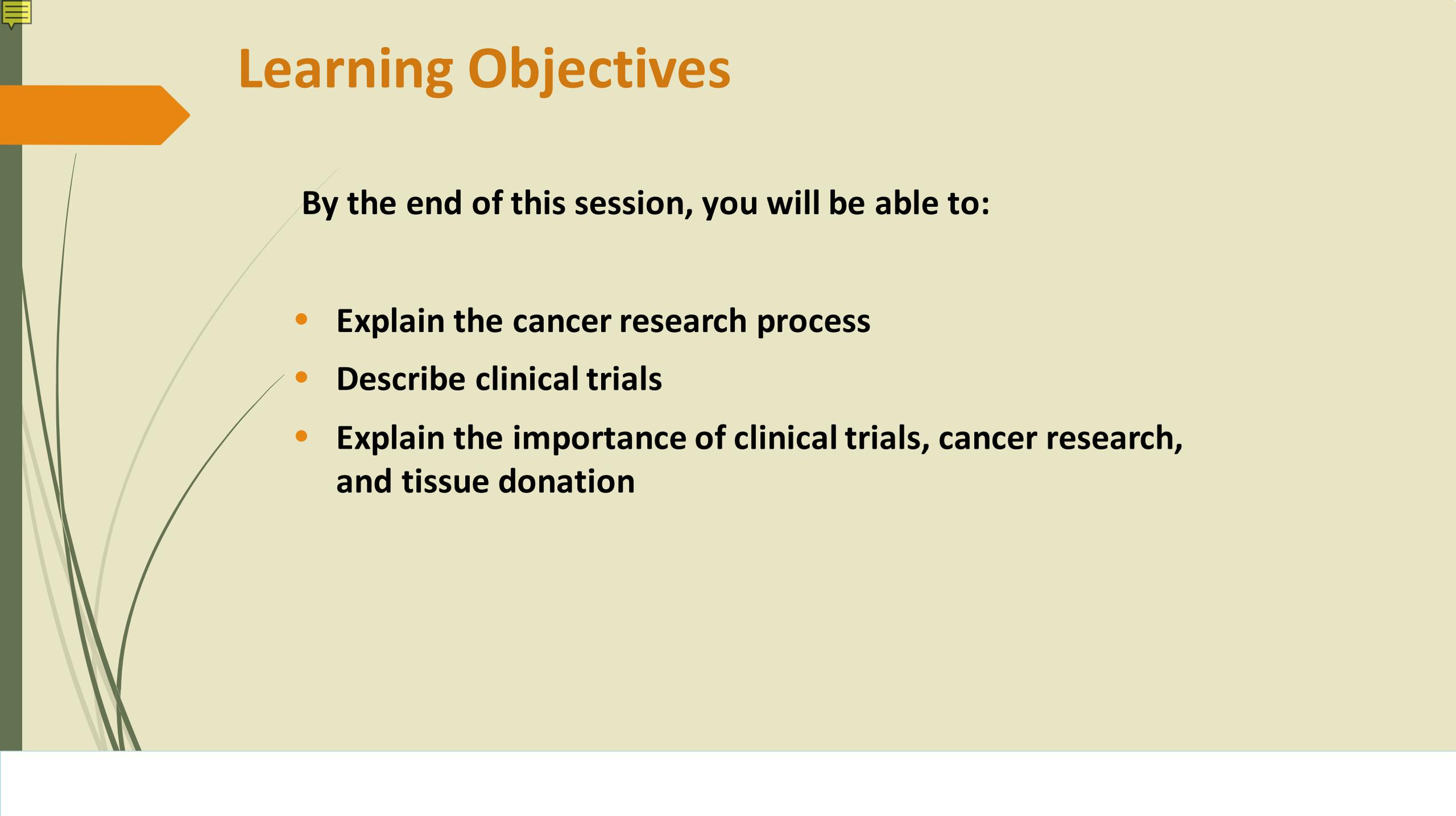
**Developed By Cancer Information & Support Network
& Día de la Mujer Latina**

WELCOME

Please feel free to ask questions

Remember we are not doctors so we are not making recommendations but rather providing information for you to help your patients





Learning Objectives

By the end of this session, you will be able to:

- **Explain the cancer research process**
- **Describe clinical trials**
- **Explain the importance of clinical trials, cancer research, and tissue donation**



Training Overview



- **Barriers to Enrollment in Clinical Trials**
- **The Research Process**
- **Clinical Trials 101**
- **Summary**



Barriers to Enrollment

Trust Issues

Past problems

- Track record of minority abuse – Tuskegee

Current Issues

- Distrust of Institutions
- Many may believe more in faith than in science
- Need for family involvement during all phases of decision
- Language and culturally appropriate delivery of information is lacking



Latinos and Clinical Trials

Latinos are less informed about clinical trials

- You can help inform your patients
- The hope is that participation will increase if patients are more informed

Only 2-3% of participants are Latinos

- New drugs need to be tested in the groups that will receive them



<http://www.cancer.org/acs/groups/cid/documents/webcontent/003005-pdf.pdf>

Other Issues

Financial difficulties and concerns that may affect a person's ability/decision to participate in clinical trials



Transportation Problems



Limited understanding about a clinical trial



Protections now in place: patient safety first

Federal laws

- National Commission for the Protection of Human Subjects
- Nuremberg
- Belmont Report
- National Research Act

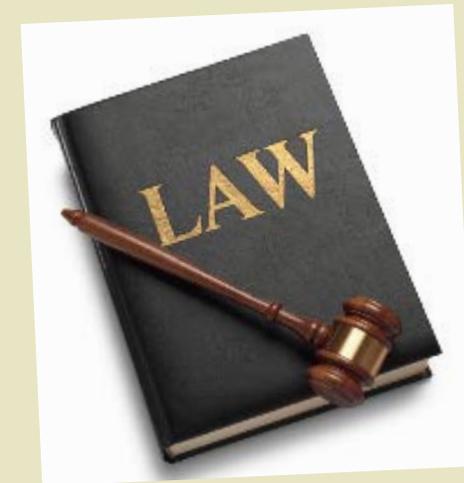
Before a study starts

Institutional Review Board (IRB)

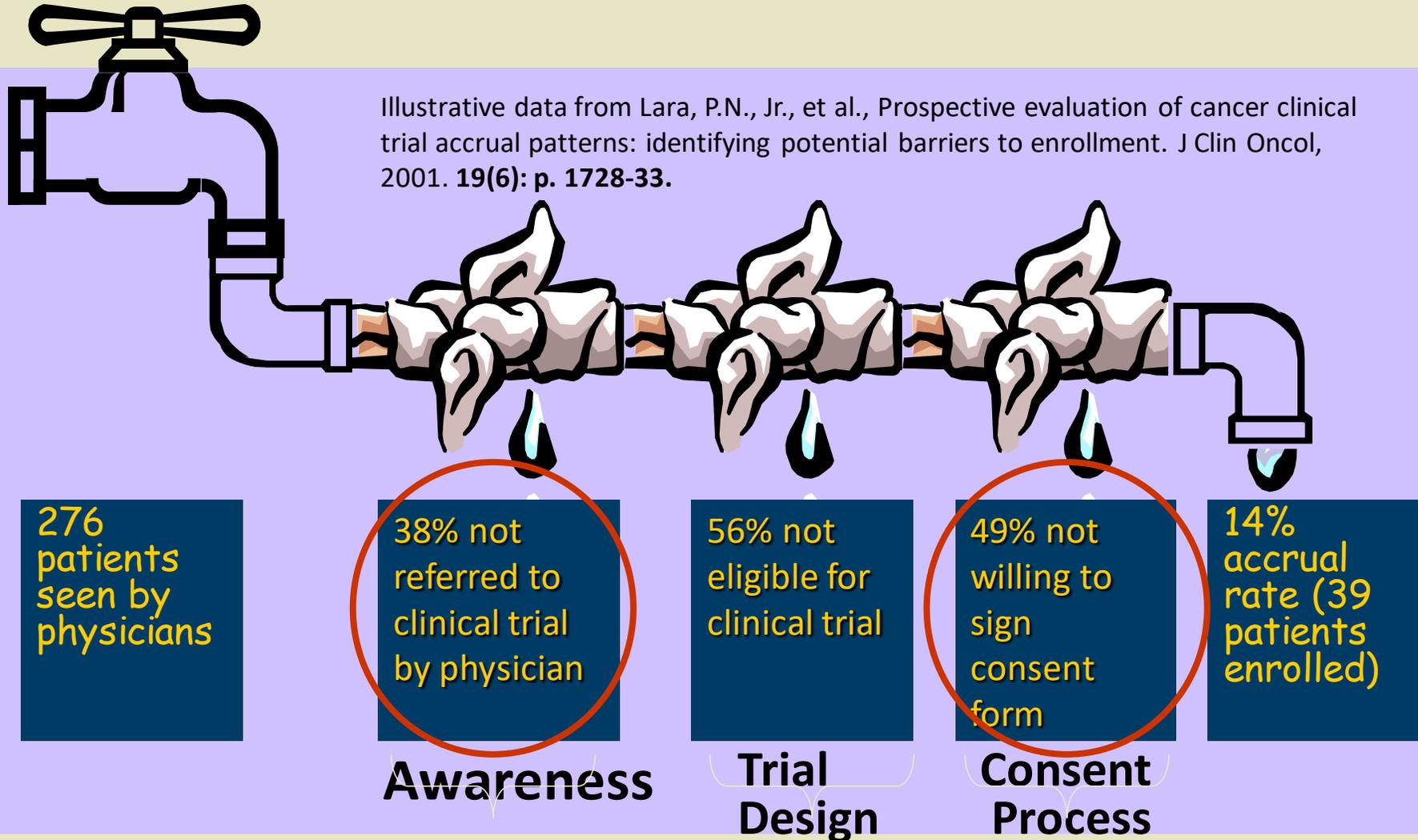
During the study

Institutional Review Board (IRB)

Data Safety Monitor Board (DSMB)



The Leaky Pipe of Clinical Trial Participation



Barriers To Participation

Physicians

Physicians

- Be unwilling to lose the patient to trial institution
- Worry about patients care or costs
- Do not inform their patients about clinical trials

Patients

- May be unaware of clinical trials
- Face too many decisions to think through
 - Communication issues
 - Cultural issues + MISTRUST
- Have cost or time constraints





Understanding The Research Process

Drug and device testing begins with extensive laboratory research which can involve years of experiments in animals and human cells.

If the initial laboratory research is successful, researchers send the data to the Food and Drug Administration (FDA) for approval to continue research and testing in humans.

2. Animal Studies: translational



3. Clinical Trials



1. Bench: basic laboratory bench

The Translational Research Process



4. Bedside

and back

Drug development begins with an idea and moves through the entire research process beginning with basic research, moving into translational (preclinical) studies, and finally resulting in a clinical trial.

Then the drug must navigate through the regulatory process before it is available to patients/participants.

Then the process circles back again.

Changes In Care Due to Research

Lets compare the 1960's with today using breast cancer

- **Early detection**
- **Treatment**
 - **Surgery**
 - **Chemotherapy**
 - **Hormone therapy**
- **Follow-up**



Early Detection

Early 1960's

- No screening Mammography
- No needle biopsy

Today

- Routine Screening
- Routine needle biopsy
- Digital mammography
- 3D mammography
- MRI
- Improved ultrasound
- Breast density

Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer – Institute of Medicine report, 2001

2016 American Society of Clinical Oncology (ASCO) – CancerProgress.net – Progress & Timeline

Surgery

Early 1960's

- Excisional biopsy
- Radical mastectomy



- Full lymph node dissection
- Hospital stay 7-10 days

Today

- Needle biopsy
- Modified radical mastectomy with improved reconstruction



- Tumor ablation
- Lumpectomy
- Sentinel node dissection
- Hospital stay 2-3 days

Chemotherapy

1960's

- Cytotoxic drugs –
Kills all fast growing cells
- Adjuvant chemo only
choice

Today

- Cytotoxic drugs –
Still the most prevalent
- Targeted agent - Only kills cancer cells
- Example - Herceptin
- Neoadjuvant chemo – Before surgery
- New metastatic agents approved

Hormone Therapy

Early 1960's

- None

Today

- 1998 Tamoxifen was approved
- 2004 Letrozole was approved
 - Other aromatase inhibitors – only for post-menopausal women

Clinical Cancer Research, The Estrogen Receptor
A Model for Molecular Medicine, Elwood V. Jensen and V. Craig Jordan
Published 1 June 2003

Timeline: Milestones in Cancer Treatment, CURE, Lacey Meyer, Oct 3, 2008

Radiation

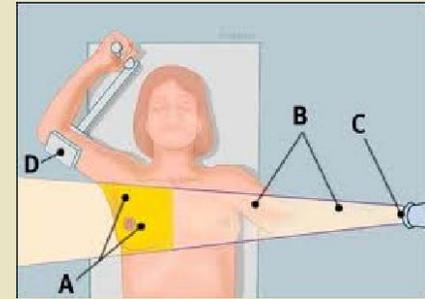
1960's

- Whole breast



Today

- Whole breast or just chest wall
- Choice for no radiation
- Partial breast radiation
- Other advances
- Computer controlled delivery
- Safer levels used



Follow-up

1960's

- Mammograms
- Wait for symptoms
- Who will metastasize

(i.e. have their cancer return in another body part)

The incidence of women diagnosed with advanced breast cancer has not changed since 1975

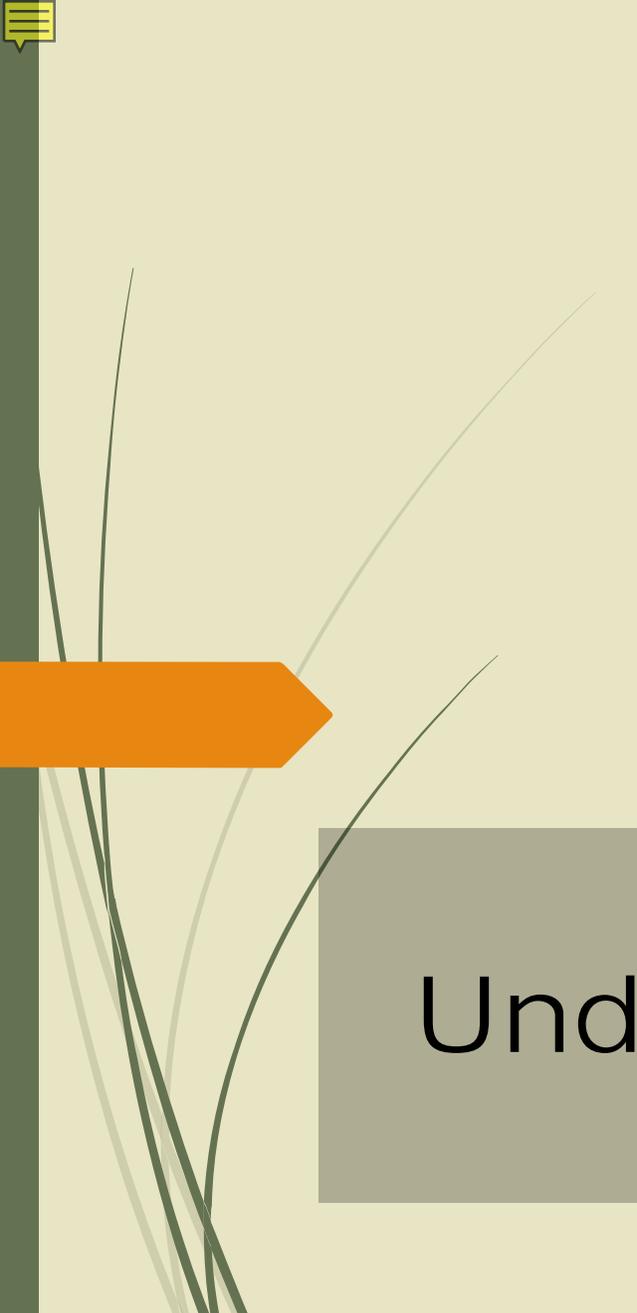
Today

- Mammograms, MRI, ultrasound
- Sometimes biomarkers
- Wait for symptoms



THE PROMISE OF RESEARCH

- **True early detection – before it has been there 10-20 years**
- **Genomic signatures – leading to more targeted therapy**
- **Biomarkers for follow-up**
- **Continued improvements in surgery & reconstruction**
- **Continued improvements in radiation**



Understanding Clinical Trials

Definition of Clinical Trials

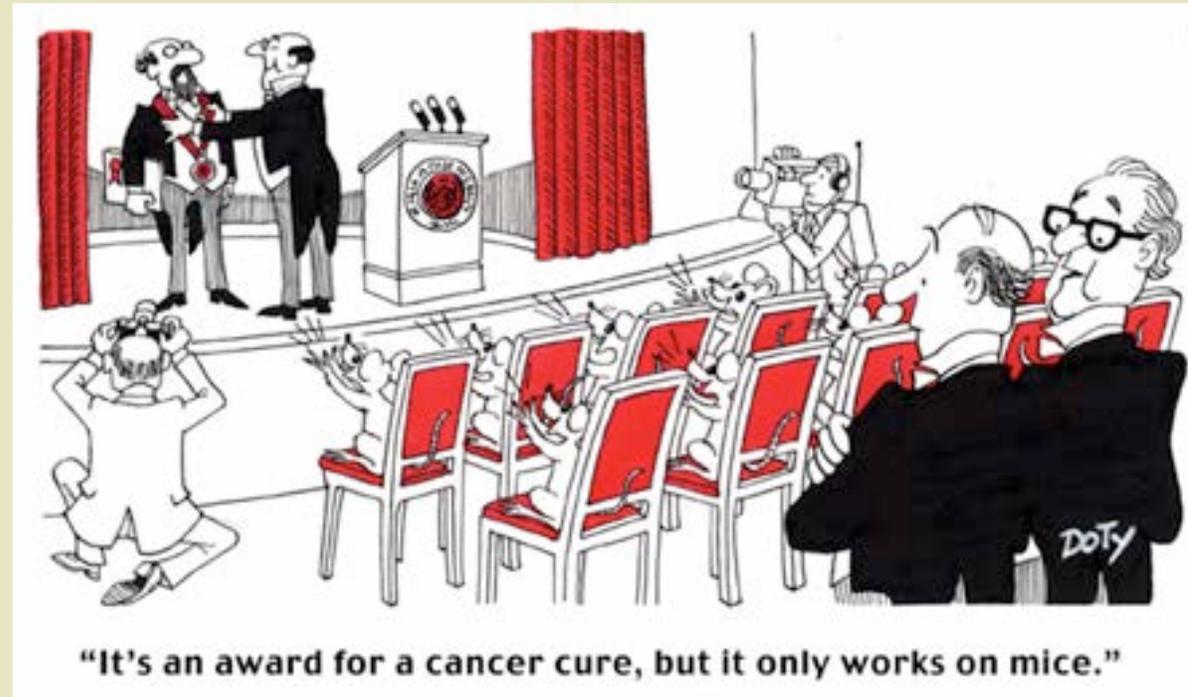
Clinical trials are research studies involving people



They try to answer scientific questions and find better ways to prevent, diagnose, or treat cancer.

- **Clinical trials are done to enhance current treatments or develop a new more efficient treatment.**

Need to Test Drugs In Humans



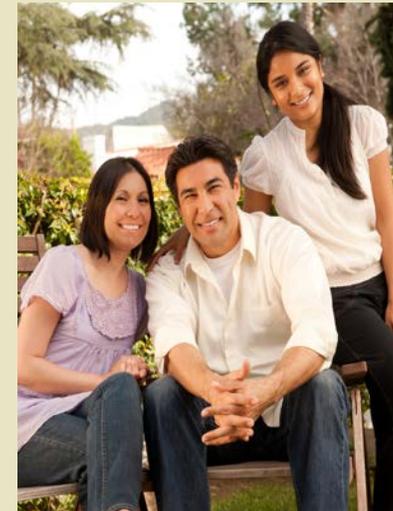
Many drugs work in animal models but not in people

Why Clinical Trials Are Important

Cancer affects all of us: 1 in 2 men / 1 in 3 women will get cancer during their lifetime

- **Clinical trials test new treatment options**
- **The more people participate –**
 - **the faster we can find better treatments**

Zosia Chustecka. Cancer Strikes 1 in 2 Men and 1 in 3 Women. *Medscape*. Feb 09, 2007.



Types of Clinical Trials

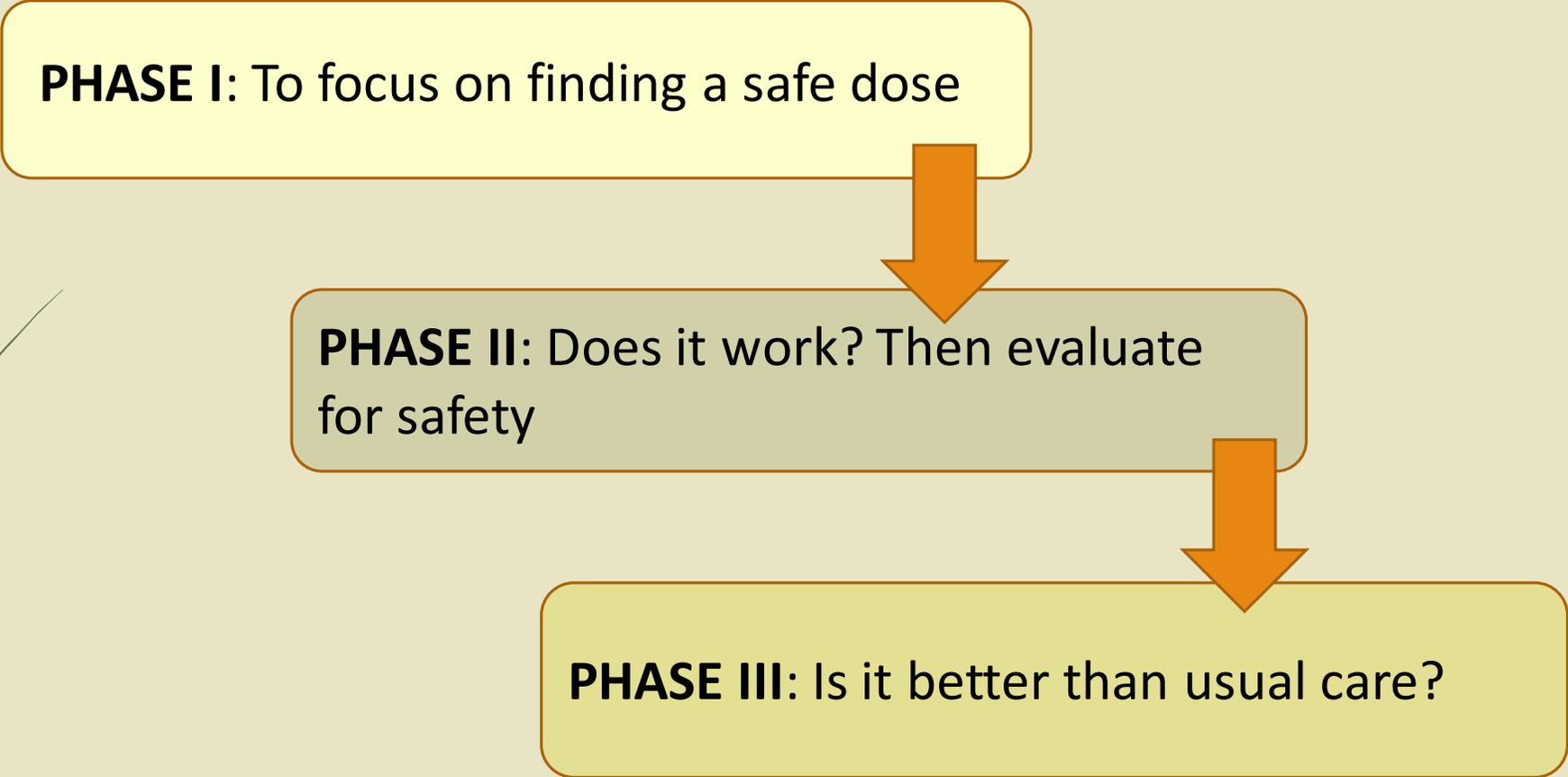
Prevention: life style interventions

Screening & Early Detection: find in general public

Treatment: new intervention

- ▶ **Test new chemotherapy drugs or targeted therapies**
- ▶ **Surgical procedures**
- ▶ **Radiation**
- ▶ **Comparisons of existing drugs – which is better**
- ▶ **Which order or dose of drug is the best**

Phases Of Clinical Trials



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graph TD; A[PHASE I: To focus on finding a safe dose] --> B[PHASE II: Does it work? Then evaluate for safety]; B --> C[PHASE III: Is it better than usual care?];
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PHASE I: To focus on finding a safe dose

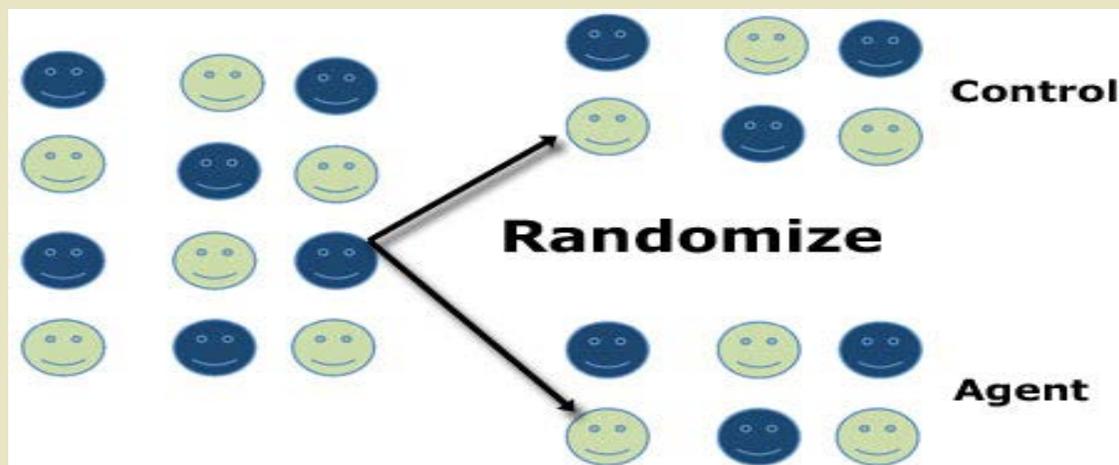
PHASE II: Does it work? Then evaluate for safety

PHASE III: Is it better than usual care?

Trial Designs

Randomized Controlled Trial (RCT)

- Patients are separated into 2 groups
 - One group gets the new agent (perhaps medicine)
 - The other called the control (gets standard care)



Benefits vs. Harms

Benefits

- May be first to receive best new treatment if drug works
- Will receive closer medical supervision than usual
- Will have the opportunity to help future patients

Harms

- May not be as good as 'usual care'
- May have unknown side effects
- May have extra cost and office visits



The Consent Form

The decision to participate is the patients

Informed Consent is more than a signature - it is a process

- All the facts about a study must be given before the patient decides to participate
- Always compare trial to standard options
- Rights should be fully explained



Explaining Patients Rights

Understanding the clinical trial is key

- **It is a research study / experiment**
- **All the facts about a study must be explained**
- **Always compare trial to standard options**
- **A patient can withdraw any time and their care will not be affected**
- **Benefits and harms must be understood**



The Role of Promotores/Community Health Workers To:

- ▶ Encourage members of their community to consider a cancer clinical trial.
- ▶ Encourage members of their community to talk to their doctors about what their risk is of getting a particular cancer based on their individual or family history and if there is a clinical trial specifically for genetics.
- ▶ Encourage an individual with a cancer concern to seek out advice from a healthcare provider and to get second opinions.
- ▶ Provide information about resources available in that community.
- ▶ Help connect one cancer survivor with another survivor and one who is participating in a clinical trial.
- ▶ Provide information that could dispel myths about cancer and clinical trials.

Questions To Get Answered:

Why is this study being done?

Who is doing this study?

Where is the trial being conducted?

What will I benefit from this study?

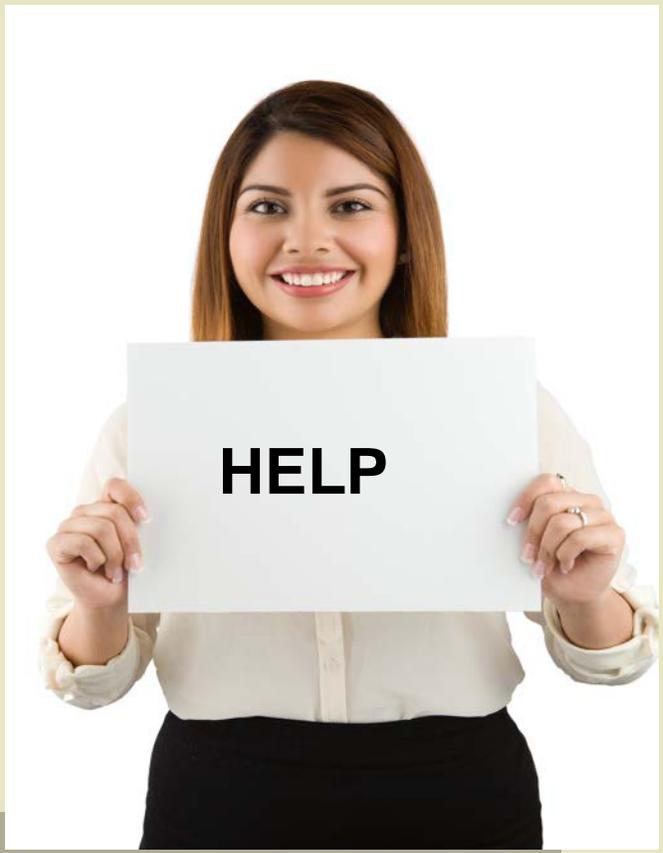
What are the risks?

- **Make sure patients understand they may not benefit from the new drug but will also get standard of care**

How long will the study last?

What extra tests/visits are involved?





How to Find a Clinical Trial

WHO CONDUCTS CLINICAL TRIALS?

- **The National Cancer Institute - www.cancer.gov**
- **The National Clinical Trials Network (NCTN)**
- **Cancer Therapy & Research Center (CTRC) – www.ctrc.net**
- **Academic centers, Community hospitals, Your own healthcare provider**
- **Pharmaceutical and Biotech companies**
- **<https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial>.**

How to Find Clinical Trials

The Internet

- Trial Check[®] : www.cancertrialshelp.org
- The NCI: www.clinicaltrials.gov

Ask Your Doctor About Clinical Trials



Resources

- ▶ **The National Cancer Institute - www.cancer.gov**
- ▶ **American Cancer Society – www.cancer.org**
- ▶ **Cancer Therapy & Research Center (CTRC) – www.ctrc.net**
- ▶ **<http://www.medscape.com/viewarticle/815141>**
- ▶ **Challenging Assumptions About Minority Participation in US Clinical Research <https://www.ncbi.nlm.nih.gov/pubmed/21805372>**
- ▶ **Trial Check® : www.cancertrialshelp.org**
- ▶ **The NCI: www.clinicaltrials.gov**
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