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Lupus Research Action Network (LRAN) Training 2022: Day 1

Meeting Agenda: Day 1

- Welcome and Introductions
- Goals and Objectives
- Background on IMPACT+ Project
- Introduction to Lupus Research Action Network (LRAN), Roles, Member Engagement
  - Research Accelerated by You (RAY)
- Clinical Trials 101
- History of Racism and Clinical Trials
- Clinical Trial: Barriers and Facilitators
- Lupus Patient Experience

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Goals and Objectives

- Increase Understanding and Importance of Lupus Research
  - What is research and what are clinical trials?
  - Historical context of racism in clinical trials
  - The Power of Your Voice
- Increase Participation in Lupus Research
  - Opportunities
    - What you can do, how you can do it
    - Research Accelerated by You (RAY)
- Help Solve the Cruel Mystery!

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IMPACT+ Project

Increasing Minority Participation and Awareness in Clinical Trials

- A program funded by the Office of Minority Health
- Built on the foundation of previous grants
- Program Intention: Demonstrate the effectiveness of interventions for increasing minority participation in lupus-related clinical trials to help to reduce lupus-related health disparities experienced by racial and ethnic minority populations.
- The LFA's IMPACT+ project seeks to increase the participation and retention of Black/African American participants in lupus clinical trials

IMPACT+ Program Goals

- Goal 1:

  Work with rheumatology nurses and people with lupus (PWL) to increase understanding of clinical trials and the barriers to enrollment, and best approaches to encourage racial and ethnic minority participation in clinical trials, with a focus on Black/African Americans with lupus

- Goal 2:

  Train PWL via LRAN program about clinical trials, the barriers to clinical trial enrollment, best approaches to support racial and ethnic minority participation in clinical trials and how to speak to their peers in the community, with a particular focus throughout the program on Black/African American PWL.

- Goal 3:

  Determine the feasibility of adding clinical trial outreach to the new patient navigator (PN) program.

Lupus Research Action Network

Overview

- What:
  The Lupus Research Action Network (LRAN) is a group of Individuals living with lupus who are committed and empowered to advance lupus research through advocacy, awareness and education.
- Goal:
  Increase knowledge about and participation in lupus research, including clinical trials, through a trusted peer network, including a focus to increase engagement in lupus research among racial and ethnic minority groups.
- Objective:
  Educate LRAN participants about research, clinical trials and provide best practices and opportunities to speak to others with lupus about participating in lupus research

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LRAN Member Role

What are We Looking for From LRAN Members?

- Knowledgeable about lupus and living with the disease
- Have an interest in lupus advocacy, research and clinical trials
- Willing to connect with people living lupus in their communities and networks
- Passionate about advancing lupus research and elevating the patient voice in research and clinical trials

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LRAN Member Engagement

- Attend the virtual LRAN training
- Sharing personal experiences with lupus research at a variety of lupus community events
- Represent the Foundation and lupus community on lupus research focused panel discussions, focus groups, etc.
- Connect one-on-one with people with lupus interested in lupus research
- Share the Foundation's research work among networks on social media
- Report outreach efforts to Regional/Chapter staff upon completion
- Share with other Lupus Warriors how they can learn more about lupus research and take a first step by enrolling in the Research Accelerated by You (RAY) registry

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RAY® - A First Step to Increase Participation in Lupus Trials

RAY®
LUPUS RESEARCH ACCELERATED by YOU
Lupus Foundation of America

- It's easy to do!
  - Can be done from the comfort of your own home!
- Learn more about research and engagement opportunities that will help advance lupus drug development
  - Clinical research and clinical trial opportunities
  - Focus group/listening session opportunities
    - FDA
    - Pharmaceutical companies

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Clinical Trials 101

Dr. Joan Merrill

What is Lupus?

- Lupus is a disease that affects the immune system, which protects the body from germs and infections. In a person with lupus, the immune system can't tell the difference between these germs and the body's healthy tissues and organs. So, the body attacks itself.
- Lupus can affect nearly every part of the body. If you have lupus, you may have some symptoms that are visible and others that are not. Lupus symptoms vary from person to person, can come and go, and can change over time.

What is Lupus?

Common Symptoms Include:

- Feeling very tired all the time, even when you've had enough sleep
- A butterfly-shaped red rash on your nose and cheeks
- Fingers or toes that turn white or blue in the cold or when you feel stressed
- Pain and swelling in your joints or muscles
- Feeling sick or getting a rash after being in the sun
- A low-grade fever

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Who is at risk?

- In the US, at least 1.5 million people have lupus - and about 16,000 new cases of lupus are reported each year.
- People of all ages, genders, and racial/ethnic groups can develop lupus. But certain people are at higher risk that others, including:
  - Women ages 15 to 44
  - Certain racial/ethnic groups - including people who are African American, Asian American, Hispanic/Latino, Native American, or Pacific Islander
  - People who have a family member with lupus or another autoimmune disease

Setting the Stage

Why Are We Having This Training?

- Clinical trials are an essential in developing new treatments.
- Lupus trials are difficult, time consuming and often fail
- Enrollment is a challenge

Setting the Stage

The Need for More Diverse Lupus Clinical Trials

- Lupus is a top 10 leading cause of death for Black and Hispanic women between the ages of 15 and 44.
- Mortality rates are more than three times higher in minority populations with lupus.
- The disparities that minorities with lupus, particularly African Americans, experience is strongly correlated to clinical trial participation

Source: Alarcon, G. S. (2008). Lessons from LUMINA: A multiethnic US cohort. Lupus, 17(11), 971-976. doi:10.1177/0961203308094359

We Need More Diverse Lupus Clinical Trials!

- Lupus is two to three times more prevalent among African American, Hispanic/Latina, Asian American, Native American, Alaska Native, Native Hawaiian and other Pacific Islander women than among White women.
- Minority women tend to develop lupus at a younger age, experience more serious complications, and have higher mortality rates.
- African American lupus patients are more likely to have organ system involvement, more active disease, and lower levels of social support compared with white lupus patients.

Challenges Experienced by PWL

Faced by all People Living with Lupus

- Delay to care and diagnosis
- Lack of coordination between primary and specialty care
- Financial/insurance coverage of appointments, tests, and medications.

Additional Challenges

Faced by Black/African American PWL

- Perpetuation of institutional racism and racial residential segregation
- Racial discrimination and unequal treatment
- Historical exploitation in research contribute to mistrust of the medical community and directly relate to poorer health outcomes.
- Providers may have implicit (unconscious) biases, may lack cultural competency, and may have time limitations to discuss complex issues with their patients. In addition, racial/ethnic diversity among lupus healthcare providers is currently limited.

Strategies to Mitigate Challenges

- Increase awareness of lupus in the context of cultural competency to reduce bias and minimize delays to diagnosis and high-quality care
- Improve communication between patients and providers to recognize and address the social, contextual, and historical issues voiced by Black/African American patients with lupus
- Promote efforts to diversify the healthcare workforce to bring additional understanding of these challenges to clinics and hospitals where lupus patient receives care.

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Why is Research Important?

- Research helps patients, physicians, and scientist gain important knowledge about the safety of new procedures, devices, or treatments
- Leads to new methods of preventing, diagnosing, treating, and finding the cures for diseases

What is Clinical Research

- Clinical research is medical research involving people.
- There are two types of clinical research:
  - Observational studies
  - Clinical trials

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Observational Studies

- Information gathering
- Volunteers grouped by broad characteristics
- Compare changes over time.
    - Example: Data collected through medical exams, tests, or questionnaires about a group of older adults over time to learn about the effects of different lifestyles on cognitive health. These studies may help identify new possibilities for clinical trials.

Clinical Trials

- Participants receive specific interventions according to the research plan or protocol created by the investigators.
- Interventions may be:
  - A medical product, like a drug or device
  - Procedures
  - changes to participants' behavior, such as diet
- Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or no intervention

Types of Clinical Trials

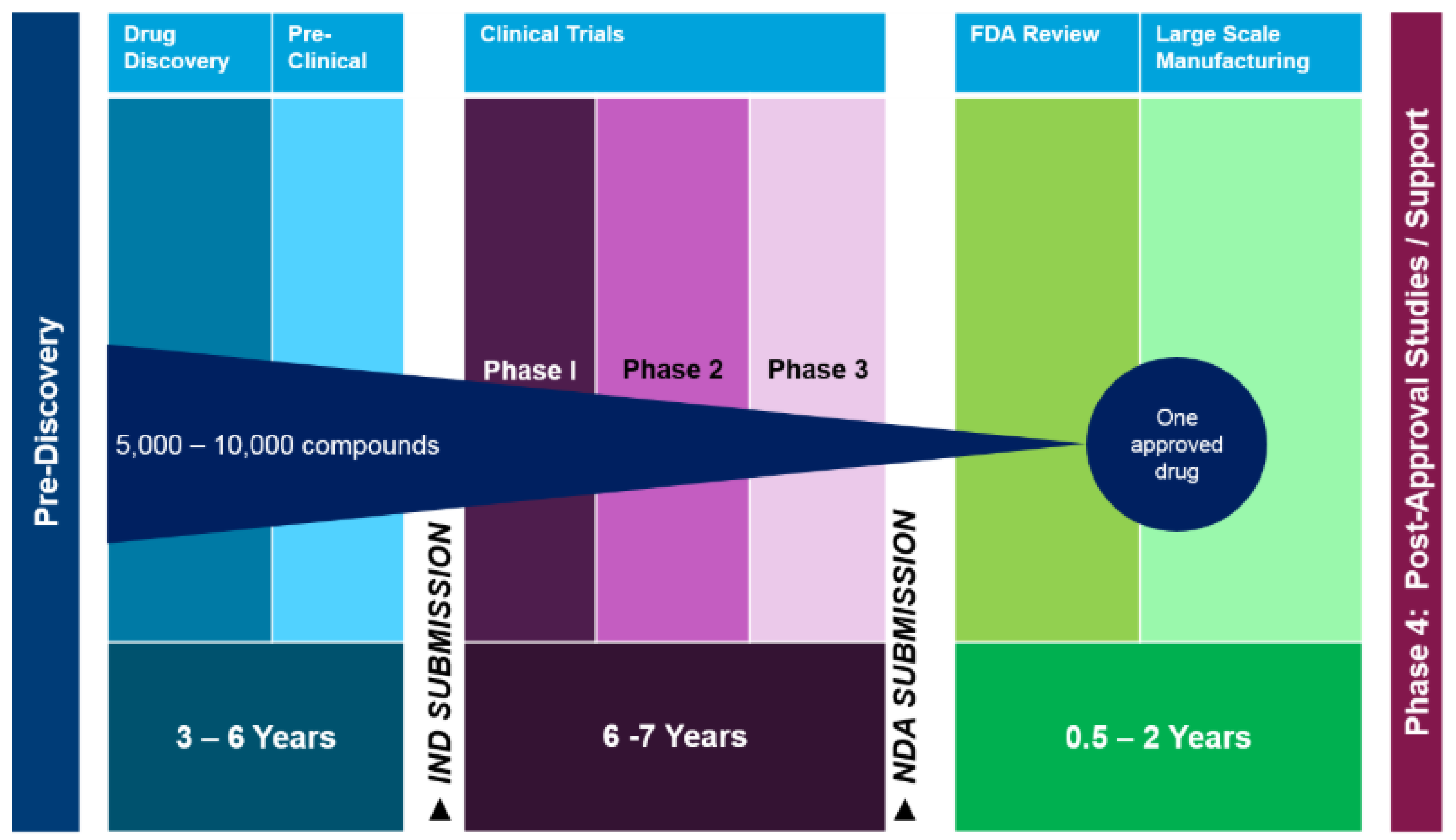
- Screening
- Diagnostic
- Prevention
- Treatment
- Quality-of-life trials

The First Clinical Trial

Source: Collier R. Legumes, lemons and streptomycin: A short history of the clinical trial. CMAJ. 2009;180:23–24.

- King Nebuchadnezzar believed that a diet of only meat and wine would keep his soldiers in the best physical condition. When he encountered objection from young men who preferred to eat vegetables, he set out to figure out which diet was better.
- The king allowed the young men to follow a diet of legumes and water —for 10 days.
- When the experiment ended, the vegetarians appeared better nourished than the meat-eaters, so the king permitted the young men to continue their diet.
- This may have been the first time that an open uncontrolled human experiment guided a decision about public health.

Drug Development Pipeline



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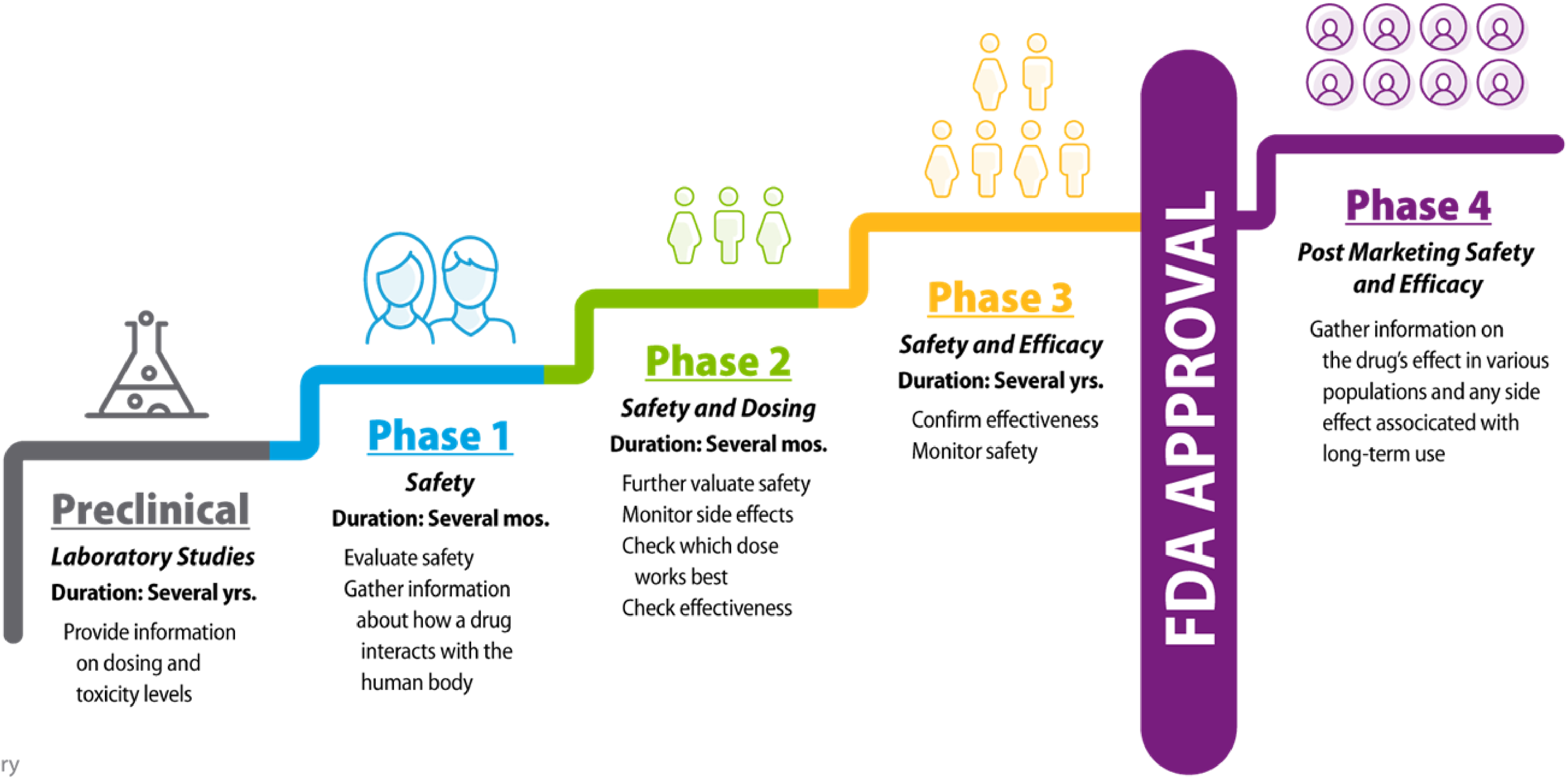
Phases of Clinical Trials



Preclinical

Laboratory Studies

Duration: Several yrs.

Provide information on dosing and toxicity levels

Phase 1

Safety

Duration: Several mos.

Evaluate safety

Gather information about how a drug interacts with the human body

Phase 2

Safety and Dosing

Duration: Several mos.

Further valuate safety

Monitor side effects

Check which dose works best

Check effectiveness

Phase 3

Safety and Efficacy

Duration: Several yrs.

Confirm effectiveness

Monitor safety

FDA APPROVAL

Phase 4

Post Marketing Safety and Efficacy

Gather information on the drug's effect in various populations and any side effect associated with long-term use

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Participating in Clinical Trials

Potential Benefits

- Gain access to new research treatments before they are widely available
- Obtain expert medical care during the trial
- Receive compensation, in some instances, for their participation
- Help others by contributing to medical research

Participating in Clinical Trials

Potential Risks

- There may be unpleasant, serious or even life-threatening side effects to the potential treatment
- The potential treatment may not be effective for the participant
- Participation may be time consuming and burdensome, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

Protecting Participants

- Patient safety is paramount in all clinical trials
- Ethical and legal codes that govern clinical trials
- Federally regulated with built-in safeguards to protect the participants
- Carefully designed protocol
- Individual participants’ names will remain private

Research is Highly Regulated To Protect Participants

- Institutional Review Board (IRB) ensure that the risks are reduced and risks are outweighed by the potential benefits.
  - An IRB is a committee that is responsible for reviewing research to protect the rights and safety of those under the research protocol.
- Ethical guidelines ensure that the clinical research increases medical understanding, while protecting participants
- Research has had a history of very questionable ethics, and as such there have been several regulations created to ensure only ethical treatment of participants under the guiding principles of Justice, Respect of Persons, and Beneficence

Research Ethics - A Timeline

Nuremberg Code (1948) “The voluntary informed consent of the human subject is absolutely essential.”

Tuskegee Syphilis Study (1932-72)

Declaration of Helsinki (1964) “This protocol should be submitted…to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence.”

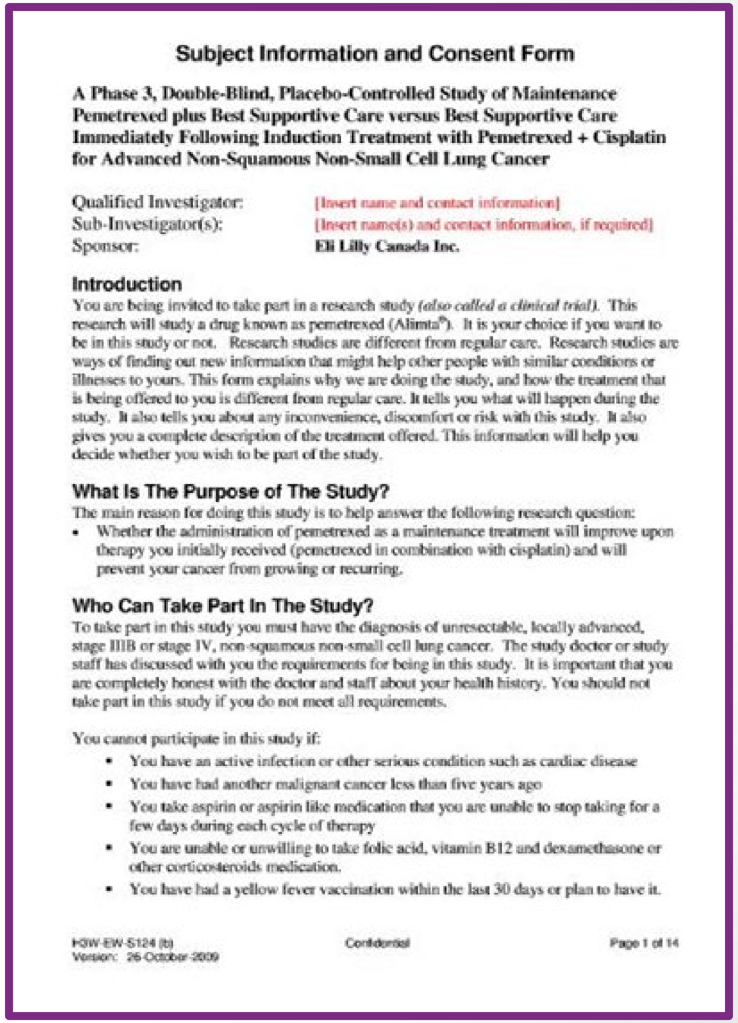
National Research Act (1974)

Protocols: Roadmap to Clinical Trials

- A research protocol is a detailed plan of how the study will be carried out. This includes:
  - Objectives
  - Background and Rationale
  - Subject Selection Criteria
  - Treatment Plan
  - Study Procedures
  - Response Evaluation Criteria
  - Statistical Section

Informed Consent

- The consent form and the process of consent helps to explain the protocol, and provide the potential participant with all the risks and benefits
- Even after signing consent form, participants reserve the right to withdraw at anytime.



Subject Information and Consent Form

A Phase 3, Double-Blind, Placebo-Controlled Study of Maintenance Pemetrexed plus Best Supportive Care versus Best Supportive Care Immediately Following Induction Treatment with Pemetrexed + Cisplatin for Advanced Non-Squamous Non-Small Cell Lung Cancer

Qualified Investigator:	[Insert name and contact information]
Sub-Investigator(s):	[Insert name(s) and contact information, if required]
Sponsor:	**Eli Lilly Canada Inc.**

Introduction

You are being invited to take part in a research study *(also called a clinical trial)*. This research will study a drug known as pemetrexed (Alimta®). It is your choice if you want to be in this study or not. Research studies are different from regular care. Research studies are ways of finding out new information that might help other people with similar conditions or illnesses to yours. This form explains why we are doing the study, and how the treatment that is being offered to you is different from regular care. It tells you what will happen during the study. It also tells you about any inconvenience, discomfort or risk with this study. It also gives you a complete description of the treatment offered. This information will help you decide whether you wish to be part of the study.

What Is The Purpose of The Study?

The main reason for doing this study is to help answer the following research question:

- Whether the administration of pemetrexed as a maintenance treatment will improve upon therapy you initially received (pemetrexed in combination with cisplatin) and will prevent your cancer from growing or recurring.

Who Can Take Part In The Study?

To take part in this study you must have the diagnosis of unresectable, locally advanced, stage IIIB or stage IV, non-squamous non-small cell lung cancer. The study doctor or study staff has discussed with you the requirements for being in this study. It is important that you are completely honest with the doctor and staff about your health history. You should not take part in this study if you do not meet all requirements.

You cannot participate in this study if:

- You have an active infection or other serious condition such as cardiac disease
- You have had another malignant cancer less than five years ago
- You take aspirin or aspirin like medication that you are unable to stop taking for a few days during each cycle of therapy
- You are unable or unwilling to take folic acid, vitamin B12 and dexamethasone or other corticosteroids medication.
- You have had a yellow fever vaccination within the last 30 days or plan to have it.

H3W-EW-S124 (b)
Version: 26-October-2009

Confidential

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Informed Consent

What to Look for…

- Study Safety:
  - What is the purpose of the study?
  - Why do the researchers think that their approach will be effective?
  - Who reviewed and approved the study?
  - Is patient safety monitored throughout the trial?
  - What happens if in the middle of the study, one group is doing much better (or worse) than the other?
  - What are the short- and long-term risks and benefits?
- Coordinating Care:
  - Will you be able to continue your normal medications and treatment during the trial?
  - Who will supervise your care, and where will the care occur?
  - Will your doctor know exactly what you are receiving and the results of any tests that are done?

Informed Consent (cont)

What to look for…

- Study Costs:
  - How will the study affect your daily life?
  - Will you have to pay for any portion of the trial, and how much will it cost?
  - Is your parking or transportation reimbursed?
  - How many extra visits will you have to make?
  - Who can help you answer questions from your insurance company or health plan about the trial?
- Confidentiality:
  - Who has access to your information?
  - How will this information be protected?
  - Will it be shared with anyone?
  - Who can you contact with any questions, concerns, or side effects?

Frequently Asked Questions

- What is a clinical trial?
- Who can participate in clinical trials?
- Why participate in a clinical trial?
- What happens during a clinical trial?
- What are the different types of clinical trials?
- What is informed consent?

Questions?

BREAK TIME!

We will re-group in 10 minutes

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History of Racism and Clinical Trials

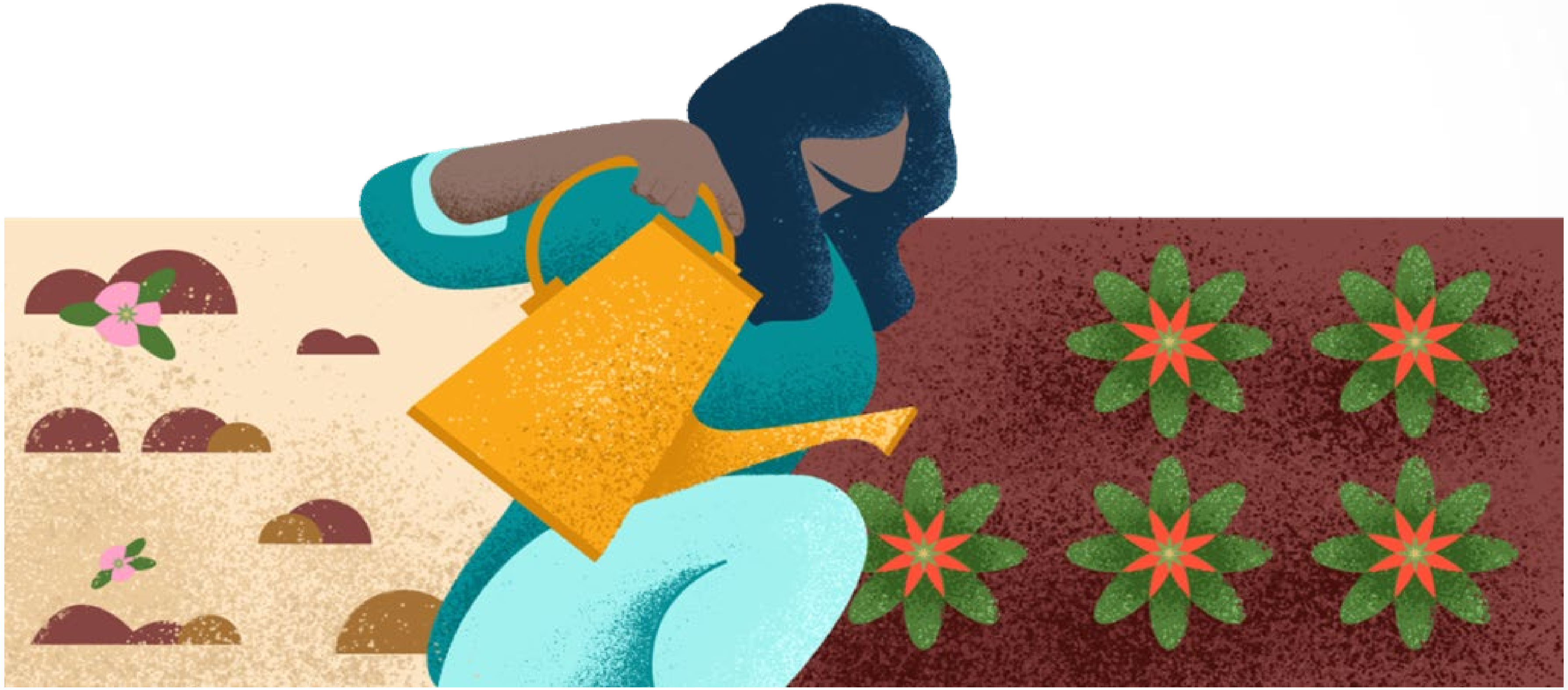
Dr. Rodlescia Sneed

What is Race and Ethnicity?

- Race is defined as “a category of humankind that shares certain distinctive physical traits.”
- The term ethnicities is more broadly defined as “large groups of people classed according to common racial, national, tribal, religious, linguistic, or cultural origin or background
  - Race is often determined by society and culture, rather than physical traits
  - Example “one drop rule”

Source: Blakemore, E. (2021, May 3). Race and ethnicity facts and information. Culture.

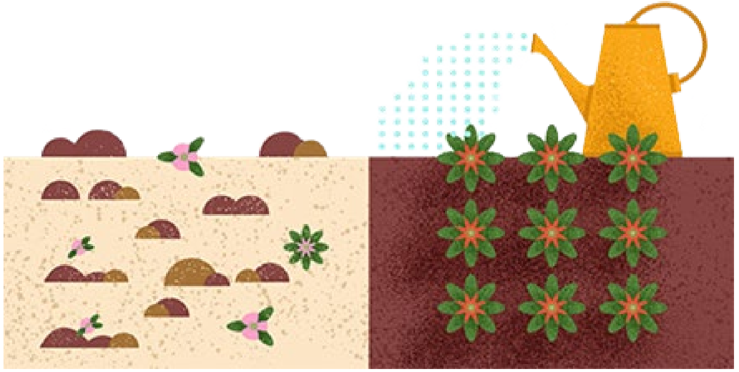
The Gardener's Tale: Allegory for Racism



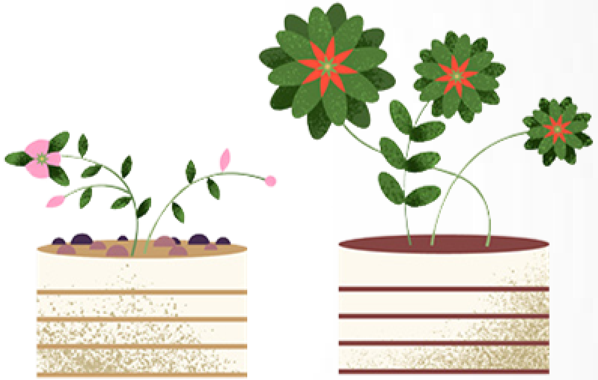
Source: Jones, C. P. "Levels of Racism: A Theoretic Framework and a Gardener's Tale," American Journal of Public Health 90 no. 8 (2000), 1212–1215.

The Gardener's Tale: Allegory for Racism

A gardener has two flower boxes, one that she knows is full of good soil and one that she knows is full of poor soil.



The gardener buys two packets of seeds for the same kind of flower — one packet for pink flowers and one for red flowers. She prefers the red over the pink, so she plants the red seeds in the good soil and leaves the pink flower seeds to be planted in the bad soil.



Of course, the red flowers flourish, but most of the pink flowers don't grow very high.

Jones C. Levels of Racism: A Theoretic Framework and a Gardener's Tale. AJPH 2000

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The Gardener’s Tale: Allegory for Racism

- After years, the gardener returns and believes that her preference for the red flowers over the pink flowers. Failing to see that she doomed the pink flowers from the beginning by planting them in the poor soil in the first place.
- Who is the gardener? The gardener is the racism that is endemic in the United States. This racism is deeply rooted in the day-to-day mechanisms of life, from neighborhood segregation, discriminatory employment practices, and even gaps in discipline in education and the criminal justice system. All these factors exacerbate health disparities and create challenges to achieving health equity.

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Does Racism Still Exist?

- Among Black women with lupus, unfair treatment and discrimination is associated with more severe disease
  - Discrimination may lead to increased stress which can increase inflammation and disease damage
- Black and Hispanic women with lupus who are pregnant have higher than expected rates of poor outcomes such as pre-term birth
  - Likely related to decreased access to care, social determinants of health, and differential treatment by health care providers
- Black and Hispanic patients presenting to the emergency department with pain are less likely to receive pain medications than White patients presenting with pain
  - Likely related to racial biases regarding pain tolerance and communication/language barriers

Historical Context of Racism in Medical Research

- Racism is a process rather than a sequence of events. Therefore, the following examples provide a snapshot into how racist research projects in the U.S. have caused harm.
- Tuskegee Syphilis Study:
  - 600 Black men were followed from 1932-1972
  - Men were followed to understand the natural process of syphilis; but were not told that they had syphilis and were not treated even after treatment was available.
  - It wasn’t until William Carter Jenkins, one of the first African Americans to be recruited to join the National Center for Health Statistics , a branch of the public health service, blew the whistle on the study with the help of fellow epidemiologist Peter Buxtun. They contacted the Associated Press which ran the story on the front page of the New York Times: “Syphilis Victims in US Study went Untreated for 40 Years”

Historical Context of Racism in Medical Research (cont)

- 31-year-old Black women whose cervical cancer were removed in 1951 without consent or compensation
- Her cells were used to create the first immortal cell line for medical research use.
- Some applications of the HeLa cells have been to study the effects of radiation, poison, drugs, hormones, and viruses.
- HeLa cells were used in the development of the polio and COVID19 vaccines.

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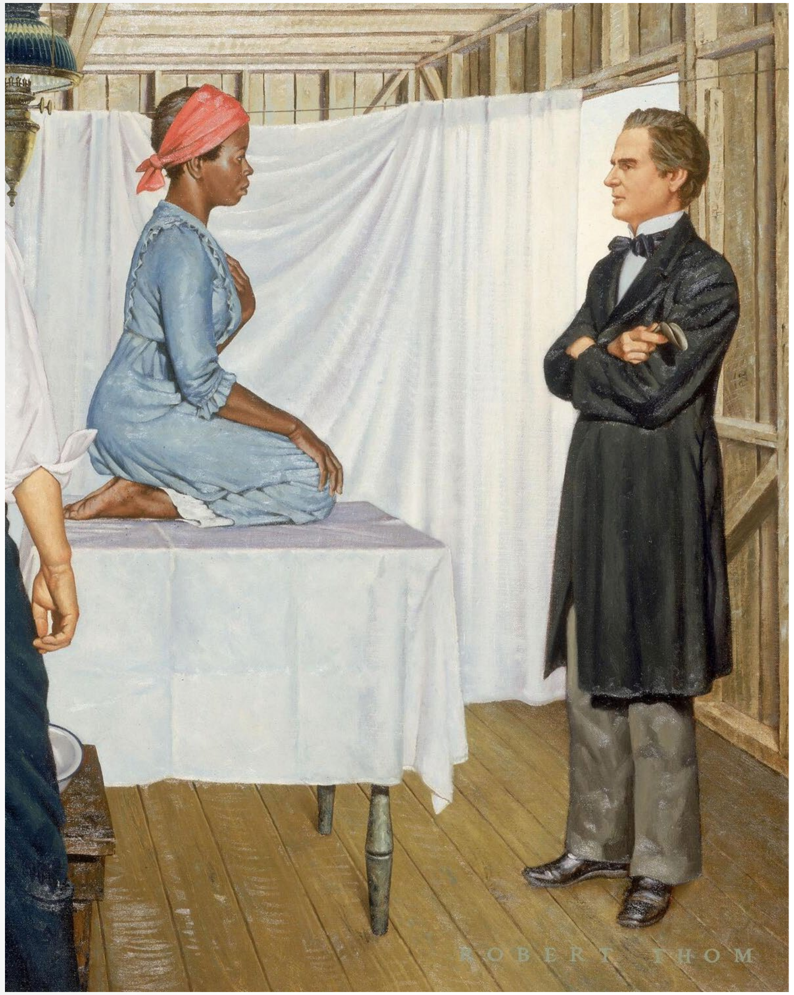

Historical Context of Racism in Medical Research (cont)

- J Marion Sims: born in 1813, this American physician became known as the father of gynecology.
- He is most well known for the surgical technique for the repair of vesicovaginal fistula, a severe complication of obstructed childbirth.
- Dr. Sims operated without anesthesia on enslaved black women. It was a common belief at the time that black people did not feel as much pain as white people.
- One enslaved woman, Anarcha, underwent at least 30 painful surgeries.

Clinical Trials Focus Groups: Thoughts on Race

“My friends always say “Don’t do it. Don’t forget your history…It haunts a lot of us…Any person of color.”

“A lot of the clinical trials, we would like to do them, but a lot of times, we don’t qualify…most of the time, with African American women, we don’t qualify for a lot of the studies unless you lie.”

“A lot of minorities, especially Black families, ‘cause we don’t go to the hospital, we wait until the very last minute, so when we do go to the hospital, we die. Then you’ll have people say, “Don’t go to the hospital. They kill you…”

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Clinical Trials Focus Groups

Thoughts on Race

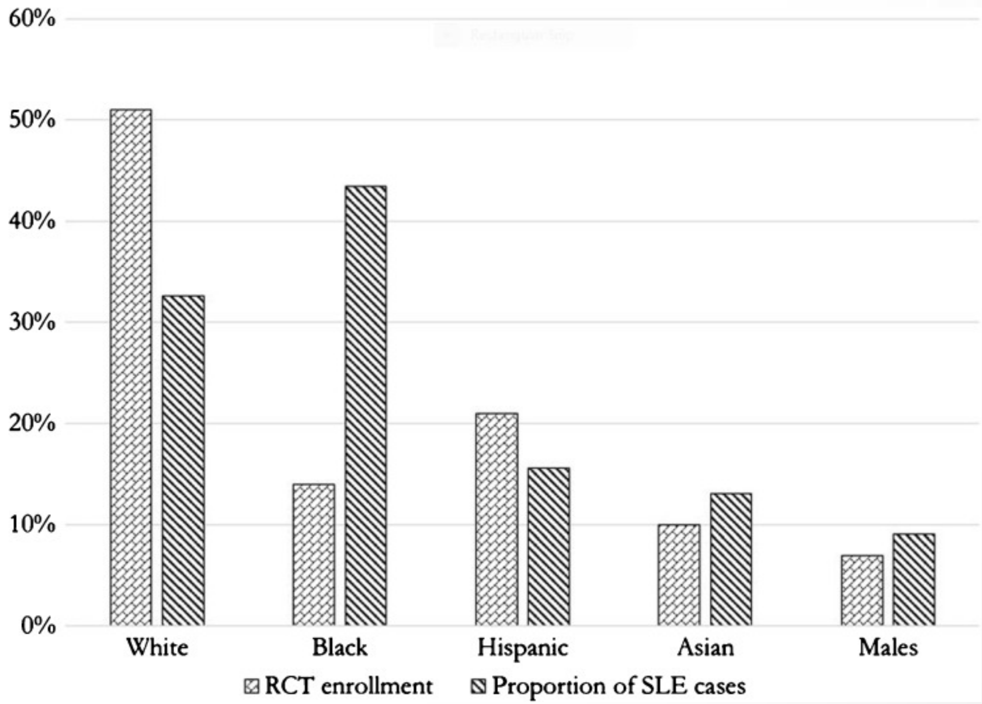
- "For me that [the race of the researcher] doesn't matter. I just want to know that the person is truthful…if the person seems truthful and open and whatever, that's fine."
- "It's needed. It's needed. It's needed. Because every time you look around, they're always doing cancer research. Lupus is just as prevalent out there as cancer. It's mainly in our community…the Black community."
- "It's a catch 22. We're more predominantly affected. If we don't participate in trials that benefit us, even more of us will be affected."

How to Prevent Racism in Clinical Trials

- 1974 National Research Act: Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - Voluntary informed consent must be obtained
  - Institutional Review Boards to maintain ethical standards
  - Federal Oversight: Presidential Commission for the Study of Biomedical Issues
- An Ethics Advisory Board was formed in the late 1970s to review ethical issues of biomedical research – resulting in the Belmont Report, which summarizes three ethical principles that should guide human research
  - Respect for Persons
  - Beneficence
  - Justice

What does this mean for clinical trials?

- Non-white people are under-represented in clinical trials
- 43% of people with lupus are Black, but only 14% of lupus clinical trial participants are Black
- Why is this the case?
  - Mistrust of physicians and researchers
  - Lack of authentic academic-community partnerships
  - Strict inclusion criteria



Falasinnu T et al, Curr Rheumatol Rep. 2018 Mar 17;20(4):20.
Lima K et al, Arthritis Care Res (Hoboken). 2019 Jul 26.

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Why is Racial Diversity Important in Clinical Trials?

- To study new interventions across all populations that they will be used to treat
  - If differences are found by race/ethnicity, the reason why must be investigated so that EVERYONE benefits
- Certain conditions, such as lupus, are more common in people of color. We want to make sure that the people who are most affected by a disease are the ones benefiting from clinical trials, in order to get patients more effective treatments more quickly
- Unequal enrollment in clinical trials perpetuates systemic racism in healthcare

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Questions?

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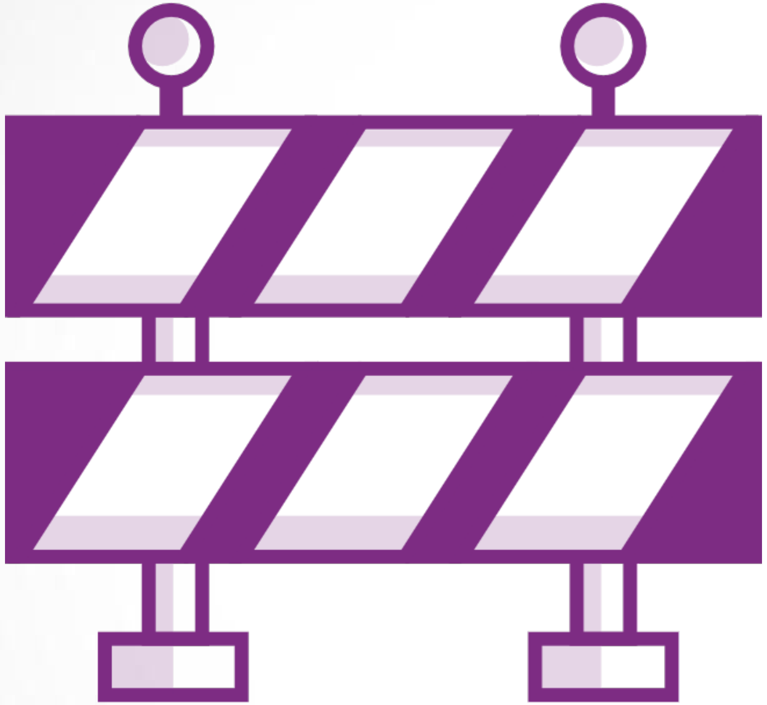
Clinical Trials: Barriers & Facilitators

Dr. Rosalind Ramsey Goldman

What are Clinical Trial Barriers and Facilitators?

- Barriers:
  - Things that make it more difficult for eligible participants to enroll or participate in a clinical trial
  - Decrease the chance that an eligible participant will want to enroll
- Facilitators:
  - Make it easier for participants to enroll or participate in a clinical trials
  - Increase the chance that an eligible participant will want to enroll
  - Facilitators are helpful that increase the likelihood of enrollment



Barriers to Clinical Trials Enrollment

- Health Status
  - Patient may be too sick.
  - Patient may not have a confirmed diagnosis of lupus
  - Patient may have a history of prior withdrawal due to medical complications through the course of prior clinical trials.
- Confusing Research Materials
  - Unclear and lengthy consent forms
  - Inaccessible recruitment documents
  - Confusing explanations of the study's protocol

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Barriers to Clinical Trials Enrollment

- Lack of peer or family support
  - Family and friends seeing clinical trials as "unsafe"
  - Confusion about what a clinical trial is and what enrollment will mean
- Historical Injustice and Racism
  - Past and present experiences of discrimination and racism in healthcare and every day life may contribute to mistrust and limit participation
- Health Literacy Challenges
  - Descriptions of study drug or study protocol in overly-medical terms.
  - Meeting the participant at their literacy level
  - Linguistically-competent translation and adaptation to culturally-related concepts
- Financial and Time Constraints
  - Patients may not be able to take time off of work to go to study visits or have competing obligations.
  - Financial burden of paying for childcare, transportation, or parking to attend study visits

Facilitators to Clinical Trials Enrollment

- Family, peer or partner support
  - Inclusion of patient's support network as part of the clinical trial recruitment process and allow time to address their questions
- Supportive relationship with Healthcare Provider
  - Patients and Providers should be able to discuss the risks and benefits of a clinical trial, both before the patient is enrolled and during the study
- Discuss clinical trials study findings with participants
- Comments: The patient motivation or compelling stage of the disease that leads into finding “other” treatment solutions.

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Facilitators to Clinical Trials Enrollment

- Clear Explanation of the Study's Purpose and Goals
- Participants should understand why the study is being conducted and why they are eligible
  - Allowing Time for Informed Consent
    - Patients should be given enough information about the risks and benefits of enrolling in a study to make the decision that is right for them
  - Open Communication Between Patients, PI, and Study Staff
    - Patients should feel comfortable asking the study staff and PI questions, which will most likely be answered with multiple conversations

Questions?

What’s coming up tomorrow?

Popular Opinion Leader Model: How you can effect change in your community

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Patient Perspective

Monique Gore- Massy

Thank You!

See you tomorrow!

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Lupus Research Action Network (LRAN) Training 2022: Day 2

Meeting Agenda: Day 2

- Review of Day 1 of Training
- Latest information on Lupus Drug Development/Clinical Trials
- Research Accelerated by You (RAY)
- The Power of your Voice - The Popular Opinion Leader Model
- How to Talk about Trials: What, Where When
- Breakout Sessions
- Next Steps and Resources for You
- LRAN Survey

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Latest Information on Lupus Drug Development and Clinical Trials

Dr. Joan Merrill

Lupus Studies

- ELEVATE Study
  - DxTerity Diagnostics, a Los Angeles based genomics company, is sponsoring an observational research study that uses participant's health information and a few drops of blood to better understand what it means to live with and manage lupus. They are looking to find a better, easier, and more convenient way for people living with lupus to track and manage their disease from home. Learn more at www.TheElevateStudy.com
- Mission Study
  - Kezar Life Sciences is evaluating an investigational medication in a clinical research study to determine whether it can help people living with lupus nephritis (LN). They are currently looking for participants with lupus nephritis to be enrolled into the Phase 2 portion of the study at multiple clinical trial sites in the United States. Learn more at www.mission-study.com
- CARE Study
  - Idorsia Pharmaceuticals is evaluating an investigational medication in a global phase 2 clinical research study for treating patients with lupus. The main aim of the study is to see whether this drug reduces the symptoms of lupus. In addition, the patient's quality of life and fatigue will also be assessed to fully understand the impact of the investigational treatment. Learn more at www.care4lupus.com

Lupus Studies

- TOPAZ Study
  - Biogen's TOPAZ Study is evaluating the safety and potential efficacy of an investigational medication in people with active systemic lupus erythematosus (SLE) who are still taking their current SLE non-biologic therapy. The TOPAZ Studies will last for a year and a half and include approximately 22 visits to the study site and are being conducted in over 25 countries. Learn more at www.topazlupusstudy.com
- PHOENYCS GO Study
  - UCB, a global biopharmaceutical company, in collaboration with Biogen, is evaluating an investigational drug in a global phase 3 clinical research study for treating patients with lupus. The purpose of the study is to evaluate the potential ability of the investigational drug as an add-on treatment to standard of care (SOC) medication to achieve clinically relevant long-term improvement of moderate to severe disease activity. Learn more at Lupus (clinlife.com)
- EQUALISE Study
  - Equillium, Inc. is evaluating an investigational medicine in a phase 1b clinical research study in patients with Systemic Lupus Erythematosus (SLE). They are looking for participants with active proliferative lupus nephritis to be enrolled in the second portion of the study at multiple clinical trial sites in the United States and India. Learn more at https://bit.ly/3qLN7g5

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Research Accelerated by You (RAY)

Dr.Joy Buie

RAY™

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Learn More and Register Today

Lupus.org/RAY

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What is RAY® Research Accelerated by You?

Lupus data platform for people with lupus & caregivers

- An online lupus registry (data platform) where people with lupus and caregivers can share information about their lupus experience
  - Help researchers accelerate the development of new treatments using PFDD approaches
  - Improve disease outcomes
  - Inform regulatory decision making
- To date: Over 1700+ registrants since October 2020
- Goal: over 50,000

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How Does RAY® Work?

LUPUS RESEARCH ACCELERATED by YOU
Lupus Foundation of America

- The RAY® database allows people with lupus to provide information about the following over time:
  - Demographic
  - Diagnosis experience
  - Treatments
  - Symptoms
  - Quality of Life
  - Treatment preferences (PFDD)
  - Clinical trial participation
  - Fatigue
- Information reported in RAY® stays 100% confidential
- Anonymous data can be shared with researchers to increase their understanding of lupus patient experiences

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Why Should You Join?

LUPUS RESEARCH ACCELERATED by YOU

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- Contribute to lupus research from your home
- Impact drug development without signing up for a drug based clinical trial
- Learn more about clinical trial and research information in your area
- See how your lived experience compares to others

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RAY® - A First Step to Increase Participation in Lupus Trials

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- It's easy to do!
  - Can be done from the comfort of your own home!
- Learn more about research and engagement opportunities that will help advance lupus drug development
  - Clinical research and clinical trial opportunities
  - Focus group/listening session opportunities
    - FDA
    - Pharmaceutical companies

Preview of Platform

BREAK TIME!

We will re-group in 10 minutes

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The Popular Opinion Leader Model

Dr. Rosalind Ramsey Goldman

Background and Introduction

- Improving Minority Participation and Awareness in Clinical Trials for Lupus (IMPACT+)
- Use of the Popular Opinion Leader (POL) Model to lead community education strategies
- Educate people living with lupus about clinical trials
  - In-person one-on-one interactions
  - Events
  - Social networks

Popular Opinion Leader (POL) Model

- What is a Popular Opinion Leader?
  - These are individuals who are typically respected, well-informed, and trusted members of a social group
- Popular Opinion Leader Model
  - Developed by the CDC for use in community prevention studies
  - Intervention designed to influence norms, behaviors, intentions and prompt actions at the community level

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LRAN Participants as Popular Opinion Leaders

How will the POL Model work?

- As a Popular Opinion Leader, you will be sharing information on clinical trials throughout your community:
  - Communicate trust
  - Increase knowledge and awareness of clinical trials
  - Change perceptions of clinical trials,
  - Increase participation in lupus clinical trials
- POL model is based on the social diffusion theory; behaviors change in a population can be initiated and will then diffuse to others if enough opinion leaders within the populations are known to adopt, endorse, and support the behavior

How Does a POL Influence Their Community?

- Social Network: a set of individuals or organizations who share common interests
- POLs can share information about health and scientific research through their social networks
  - Friends and Family
  - Fraternity/Sorority
  - Faith-based organizations
  - Social Media
  - Civic Group (Kiwanis club, Elks, Knights of Columbus)
  - Lupus support groups and other lupus events

How POLs Help Their Communities

- By spreading information, POLs help to…
  - Increase awareness and understanding of lupus in a community
  - Help lupus patients reach specialists to help care for their lupus
  - Spread positive messages about science-based research and clinical trials
  - Build partnerships between researchers and the surrounding community

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How do POLs Spread Information?

- POLs spread the information they know by speaking with communities, congregations, and their own social networks
- Participate in round-table discussions or community forums
- Conduct surveys or ask others about their knowledge of lupus, clinical trials, and healthcare, and spread the information they know
- Give out fact sheets, info-cards, or other tools as "conversation starters" and to remind people of the information they discussed

How is a POL's Success Measured?

- The POL model is often used in partnership with academic centers
- POL participation in studies is just as valued as professional input
- POLs record who they've spoken with and observations about meetings
- POL success if measured by the number of people they are able to engage and persuade with the intended message
- POLs demonstrate their influence by changing health seeking norms, in this case increasing the understanding of lupus clinical trials in their communities.

Questions?

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How to Talk about Trials: What, where, when

Pat Wildman

You ARE the Popular Opinion Leader

- What to communicate
- How to communicate
- Where to communicate
- Resources to help!

What to communicate

- Lupus trials need more diversity
  - Black/African Americans make up 43% of lupus cases nationally, yet only 14% of participants in lupus clinical trials
- Clinical trials are the only way to get new treatments
  - There are only 3 FDA approved treatments for lupus
- Research Accelerated by You (RAY)
  - Enrollment allows access to information on clinical trial opportunities
- Ask you Doctor for more information
  - Your doctor will be able to tell you about any trials available at their office, or a nearly location. They will also be able to tell you if you qualify for any clinical trials

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Where to Talk about Trials

- Lupus Walk
- Lupus and You Meetings
- Support Group Meetings
- At the doctor's office
- Cocktail Party
- Grocery Store
- Post Office

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How to Talk About Trials

Key Points:

- Start the conversion:
  - Ask questions: Do you know about RAY, are you happy with your current treatments, are you interested in learning more about what you can do?
  - Share your experience…with lupus, with quality of life, with treatments, with trials
- Briefly about trials:
  - need for people to participate, benefits, risks, your rights, share your experience if applicable
  - Communicate trust, freedom to make decisions (it’s their decision, not yours… share opportunities, don’t tell them what to do)
- How to learn more:
  - Enroll in RAY, Visit NRCL/Antidote

How to Talk About Trials

- Reminders:
  - Keep conversation focused:
    - Interactions with you and the person living with lupus are about them, not you
  - Keep your own story brief:
    - Stories should be short and have a purpose
    - Use your story to show empathy, illustrate an example, or decision point and its consequences
    - Your story should only be 2-3 sentences long

Ideas for Sharing on Social Media

- Personal experiences of being in a clinical trial or supporting a loved on who participated in a clinical trial
- A fact about clinical trials that you have learned about recently or want to highlight
- How clinical trials have impacted you
- Videos from trusted agencies about clinical trials
  - Center for Disease Control and Prevention - CDC
  - National Institutes of Health - NIH
  - Office of Minority Health - OMH

How to Talk about Trials

- Introduction:
  - Context: Who are you, what do you want to share?
- About You/Your Story:
  - What is your connection to lupus?
- Why this is Important:
  - Why did LRAN training appeal to you?
  - Why are you passionate about lupus clinical trials?
  - What is your Why?
- Action Steps:
  - What are you going to ask of them?

How to Talk About Trials

- YOUR Ideas!
  - Start the conversation/Introduction
  - About you
  - Why? Why important to you… and all people living with lupus
  - Action Steps - what they can do
- Breakout Rooms (4 Groups)
  - Group One Facilitator: Amy Yalden
  - Group Two Facilitator: Sue Gloor
  - Group Three Facilitator: Cindy Messerle
  - Group Four Facilitator: Stephanie Slan

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Breakout Groups

- As a group, brainstorm about the four key elements:
  - Introduction
  - Your story, who you are
  - Why research and trials are important to you and to all people with lupus
  - Action Steps
- 15 minutes
- Facilitated discussion
- Each group will share their ideas following the breakouts

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Breakout Groups

- Group 1
  - Scenario: You are at a Lupus Walk, you have just finished, and you and some other walkers have started chatting around the water cooler.
- Group 2
  - Scenario: You are at a support group meeting, and the group leader has just given you the floor to talk about LRAN
- Group 3
  - Scenario: You have been asked to present at a Lupus & You (L&Y) event, this will be a virtual event, and you will be using Zoom.
- Group 4
  - Scenario: You are at a celebration dinner with friends and family, you bump into a friend you haven't seen in years.

Opportunities to Talk about Trials

- Invitation to Speak at Lupus and You
  - lupus.org/resources/lupus-and-you
- Invitation to Speak at Support Group Meeting

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Next Steps For LRAN Members

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Post-survey

www.posttestlink.org/LRAN