

Clinical Research Webinar Series **How to Plan Successful Clinical Trials:**

Moderator:

ELENA RIOS, MD, MSPH, MACP

President,
National Hispanic
Health Foundation
Washington, DC

Speaker:

**JOSE D. BURGOS, MD,
MBA, FACP, FHM**

Chief Medical Officer,
Internal Medicine
El Paso Medical Research
Institute
El Paso, TX

Speaker:

JOSEPH R. MARTEL, M.D.

Assistant Dean of Graduate Medical Education
Chair, Department of Ophthalmology
California Northstate College of Medicine
Elk Grove, CA

**Writing Proposals, Data Collection,
IRB, and Patient Safety**

Register Now: bit.ly/clinical2023

1.0 CME CREDIT PROVIDED



June 27



7 - 8 pm (EST)

Welcome

Elena Rios, MD, MSPH, MACP

President

National Hispanic Health Foundation

Washington, DC

Housekeeping

- All participant microphones will be muted, but please feel free to type your question into the Q & A box for the panelists to address during our Q & A session at the end.
- Please fill out the short post-webinar survey that will be emailed out after the event and also shown as a QR code at the end.
- Recording will be housed on NHHF website (nhmafoundation.org) and sent out one week after the event.

Joint Accreditation Statement

- In support of improving patient care, this activity has been planned and implemented by Amedco LLC and National Hispanic Health Foundation. Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Physicians (ACCME) Credit Designation

- Amedco LLC designates this live activity for a maximum of 1.00 AMA PRA Category I Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.



Objectives

- Describe how physicians in private practice have developed successful clinical research with large panels of Hispanic patients that can improve health care quality in the U.S.
- Review clinical research principles including how to write a successful proposal for sponsor or investigator initiated proposals, how to collect data, and how to write IRBs for patient safety.
- Increase awareness about the National Hispanic Health Foundation National Center for Hispanic Health Research that serves as a network for Hispanic and Hispanic-serving physicians and residents to provide opportunities to advance clinical research careers.

Safety and IRB

Jose D. Burgos, MD, MBA, FACP, FHM

Chief Medical Officer of Internal Medicine

El Paso Medical Research Institute

An Adverse Event is:

- Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment
- An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether considered related to the medicinal product or not
- Exacerbations of a chronic or intermittent pre-existing condition, including either an increase in frequency and/or intensity of the condition, are to be considered Aes

Reference: ICH E2A

A Serious Adverse Event:

Characterizations:

- Death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is of medical importance

Hospitalization does not include:

- Rehabilitation facility
- Hospice facility
- Nursing facility
- Emergency Room
- Same day surgery
- Admission for pre-existing condition not associated with AE
- Protocol-specified admission
- Pre-planned admission

When should you and your clinical research site collect AEs and SAEs?

- AEs & SAEs should be collected following the signing of the Informed Consent until end of study
- An AE reported after Informed Consent but before study drug administration will be considered a pretreatment AE

How long should your clinical research site follow AEs?

- AEs and SAEs, particularly causally related, are to be followed until the event or sequelae resolve, are determined to be medically stable, are otherwise explained, or if the participant is lost to follow-up

Study Discontinuation:

- In case of participant discontinuation, if applicable, it is important to identify the AE primarily responsible for discontinuation from the study

All SAEs must be reported

Information sponsors and IRBs may need are

- Medical history
- Concomitant medications
- Relevant laboratory & diagnostic tests
- Any treatment that the patient received
- Any other information felt necessary to characterize the SAE

Principal Considerations & Reporting

Institutional Review Boards typically require reporting of the following events:

- Unanticipated adverse device effect
- New or increased risk
- Protocol deviation that harmed a subject or placed subject at risk of harm
- Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- Audit, inspection, or inquiry by a federal agency
- Written reports of federal agencies (e.g., FDA Form 483)
- Allegation of Noncompliance or Finding of Noncompliance
- Breach of confidentiality
- Unresolved subject complaint
- Suspension or premature termination by the sponsor, investigator, or institution
- Incarceration of a subject in a research study not approved to involve prisoners
- State medical board actions against physician researchers
- Information where the sponsor requires prompt reporting to the IRB
- **Note that adverse event reporting requirements may vary across IRBs; so, be sure to check with the IRB of record for your protocol to determine what must be reported.**

Thank you!



Investigator Initiated Trials (IIT)

Joseph Martel, MD

Assistant Dean, Department of Graduate Medical Education

California Northstate College of Medicine

DISCLOSURES

Genentech, Alcon, Allergan, Novartis, Regeneron, Kala, Bausch & Lomb,
Santen, Aerie, Glaukos, Abbvie

IIT

1. Relationship between Primary Investigator and Sponsors
2. What is an Investigator Initiated Clinical Trial?
3. What can you contribute to a clinical trial, expertise, patient demographics?
4. Identifying a need or possible new application
5. Preparing a proposal
6. Identifying possible sponsors
7. The SoloKiko Advanced Research Program

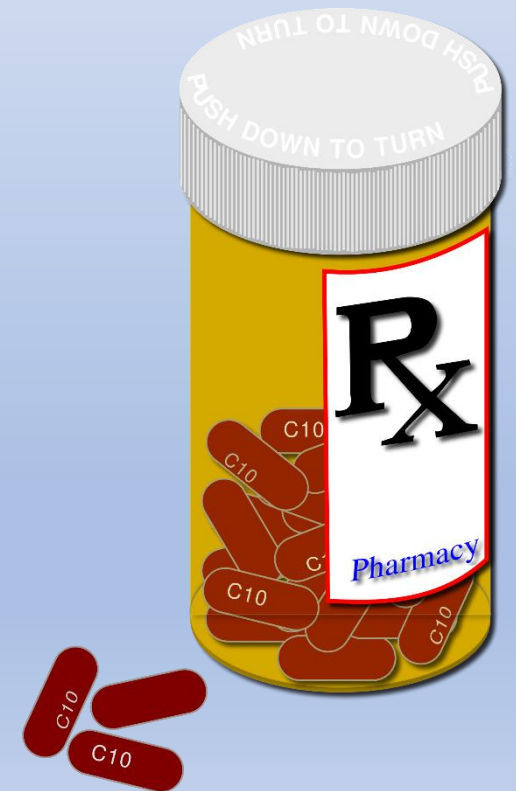
Relationship between Primary Investigator and Sponsors



- A partnership to improve patient care through the development and improvement of treatment modalities
- The gold standard for doing this is through clinical trials
- The clinician is uniquely positioned to determine the effectiveness as well as the side effects of a treatment
- Side effects can be negative or positive and can expand or restrict the use of a medication

What is an Investigator Initiated Clinical Trial (IIT)?

- I. An **Independent** study initiated by an **Independent** investigator, group or institution
- II. Benefits:
 - a. Independent determination of efficacy and side effects of a product
 - b. Obtain “real clinical world” information
 - c. Restrict or expand uses of the product
 - d. Obtain non industry independent information about the product
 - e. Generate new ideas





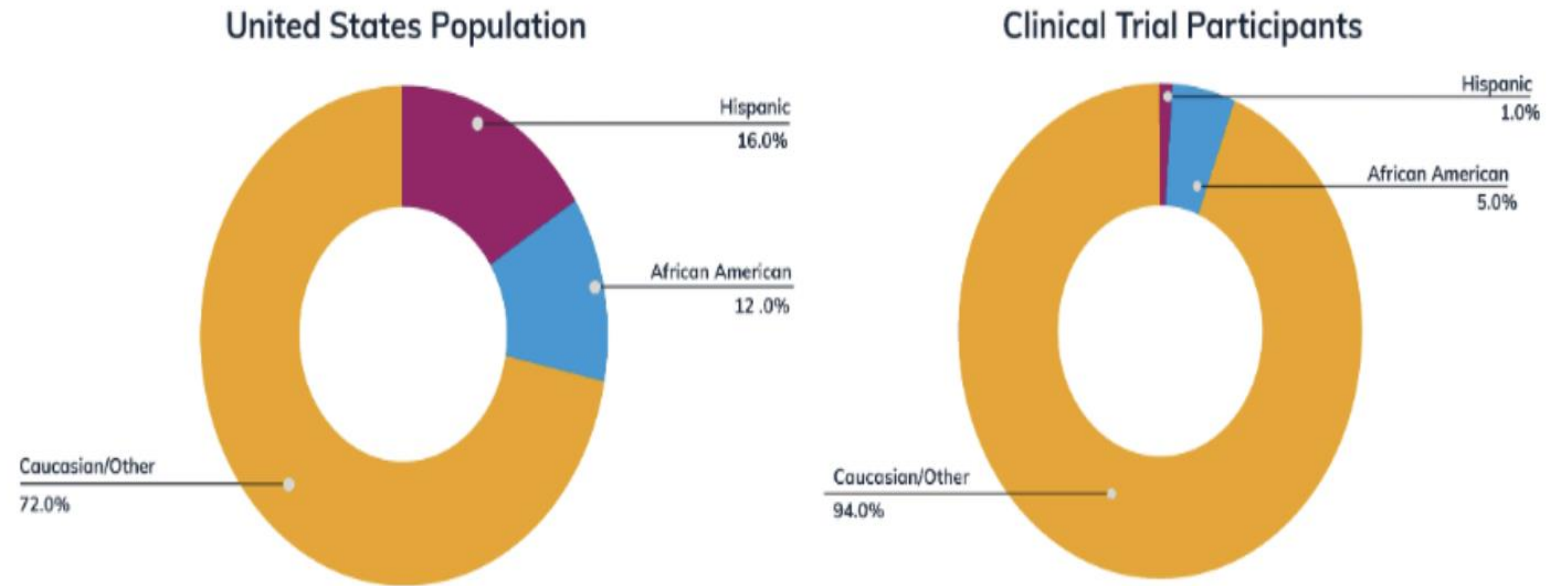
What can you contribute to a clinical trial?

- Clinical expertise
- Your experience
- Cultural and linguistic competence
- Observations and novel ideas
- Your office research staff and facility
- Your diverse patient population and effects of products on more diverse patient population

Latinx underrepresentation in clinical trials

- Minorities have historically been underrepresented in clinical trials.
- In 2011, African Americans and Hispanics comprised 12% and 16% of the US population, respectively, but only 5% and 1% of trial participants were African Americans and Hispanics, respectively.
- As a PI you can improve diversity in clinical trials

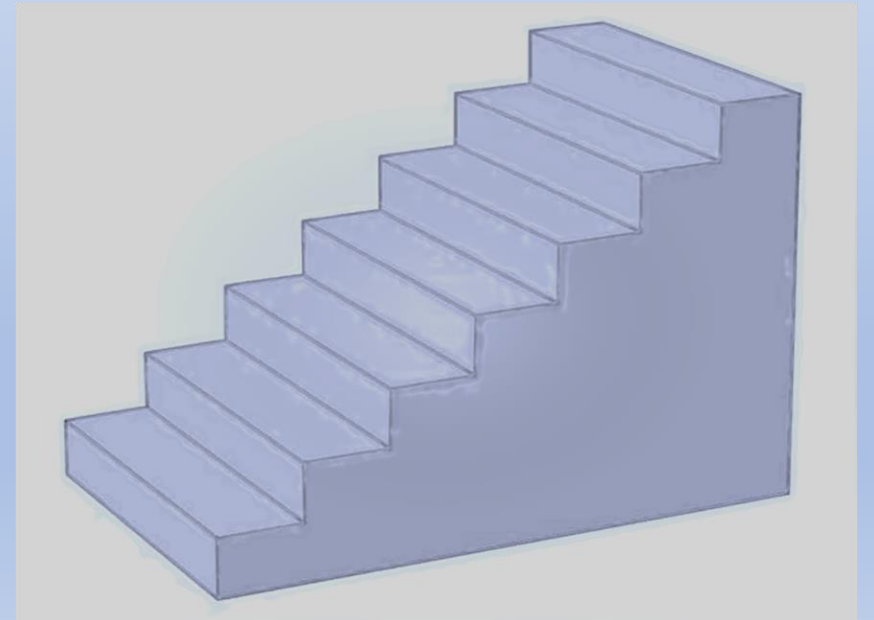
Underrepresentation in Clinical Trials



*Sourced from <https://www.sciencedirect.com/science/article/pii/S0146280618301889>

Steps to IIT

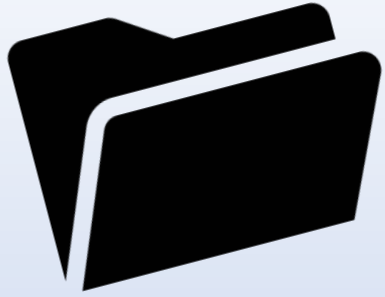
- Your observations and creativity will first drive your study
- Determine a hypothesis and what is required to prove or disprove it
- Create a Protocol - you can get help with this
- Do an internal feasibility study
- Approach sponsors to obtain funding
- Perform your study
- Analyze your Results and write a report



Identify a need or possibly off label use of a medication or product

- Use what you do in your daily clinical observations to identify beneficial or harmful effects of a treatment
- Formulate a plan to use your observations to benefit your patients
- Determine how you can prove or disprove your hypothesis
- Put this on paper
- The Pilocarpine example



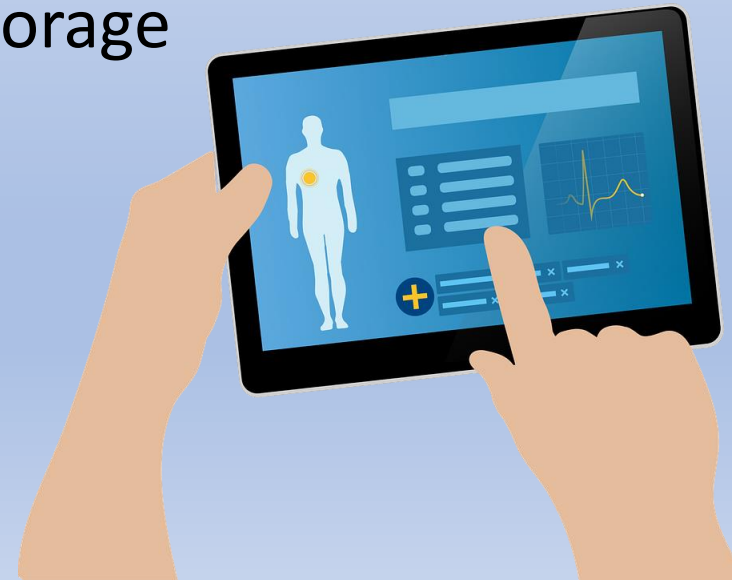


Developing a Study Protocol

- Do not hesitate to use help from potential sponsors – medical liaison
- Establish your hypothesis
- Determine Inclusion and Exclusion criteria
- Establish "end points" - what determines your proof
- Consider "one symptom and one sign"
- Determine order of medication administration and what tests will be used to determine efficacy
- Determine if you will have a control group

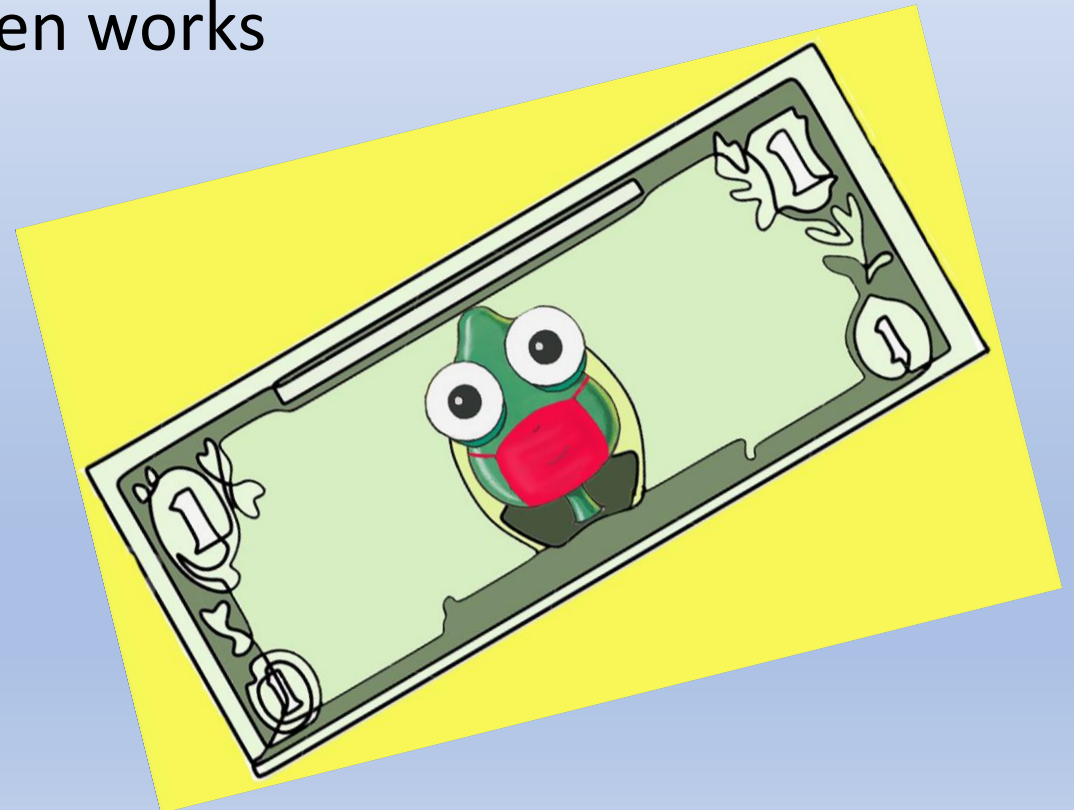
Feasibility study

- Use your electronic medical records
- What do you treat most and how frequently do you see it?
- Patient demographics
- Office equipment
- Secure and temperature-appropriate medication storage
- Secure medical record storage



Evaluating and approaching sponsors

- Most pharmaceutical companies welcome new ideas about their products, so approaching them first often works
- If new product or idea
 - a. look for sponsors with similar products
 - b. innovative companies



Your Study

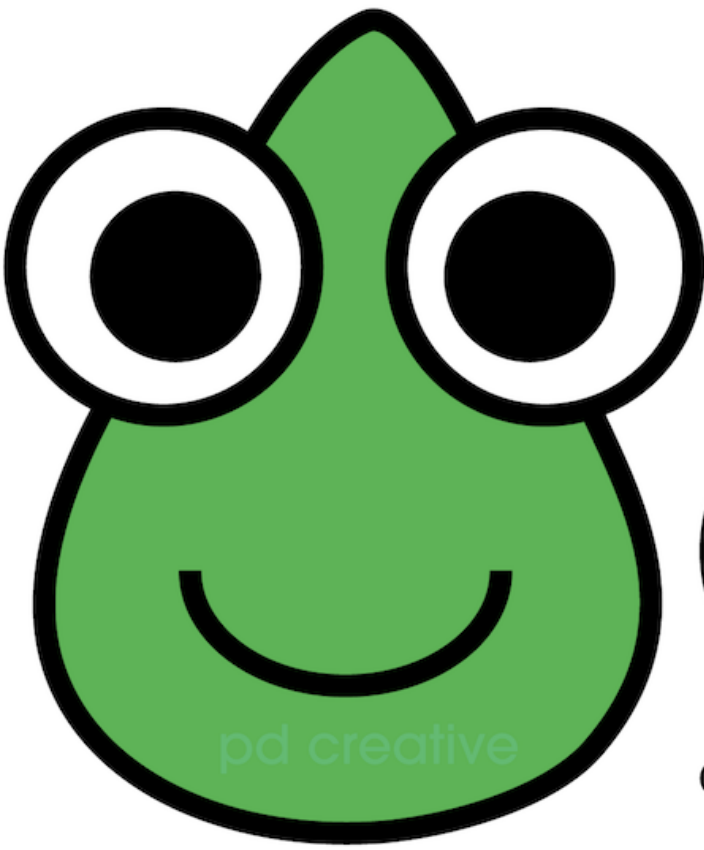
- Get GCP certified if you are not
- Establish study controls using GPC
- Establish and keep strictly the data you collect for analysis
- Analyze your data and consider a publication



Principal Investigator Role

1. Above all protect your patient
2. Responsible for all aspects of the study, including the storage of all records
3. Decide who meets inclusion and exclusion criteria
4. Determine and evaluate adverse events
5. Determine if patient needs to be withdrawn
6. Ultimately determine the effectiveness of treatment

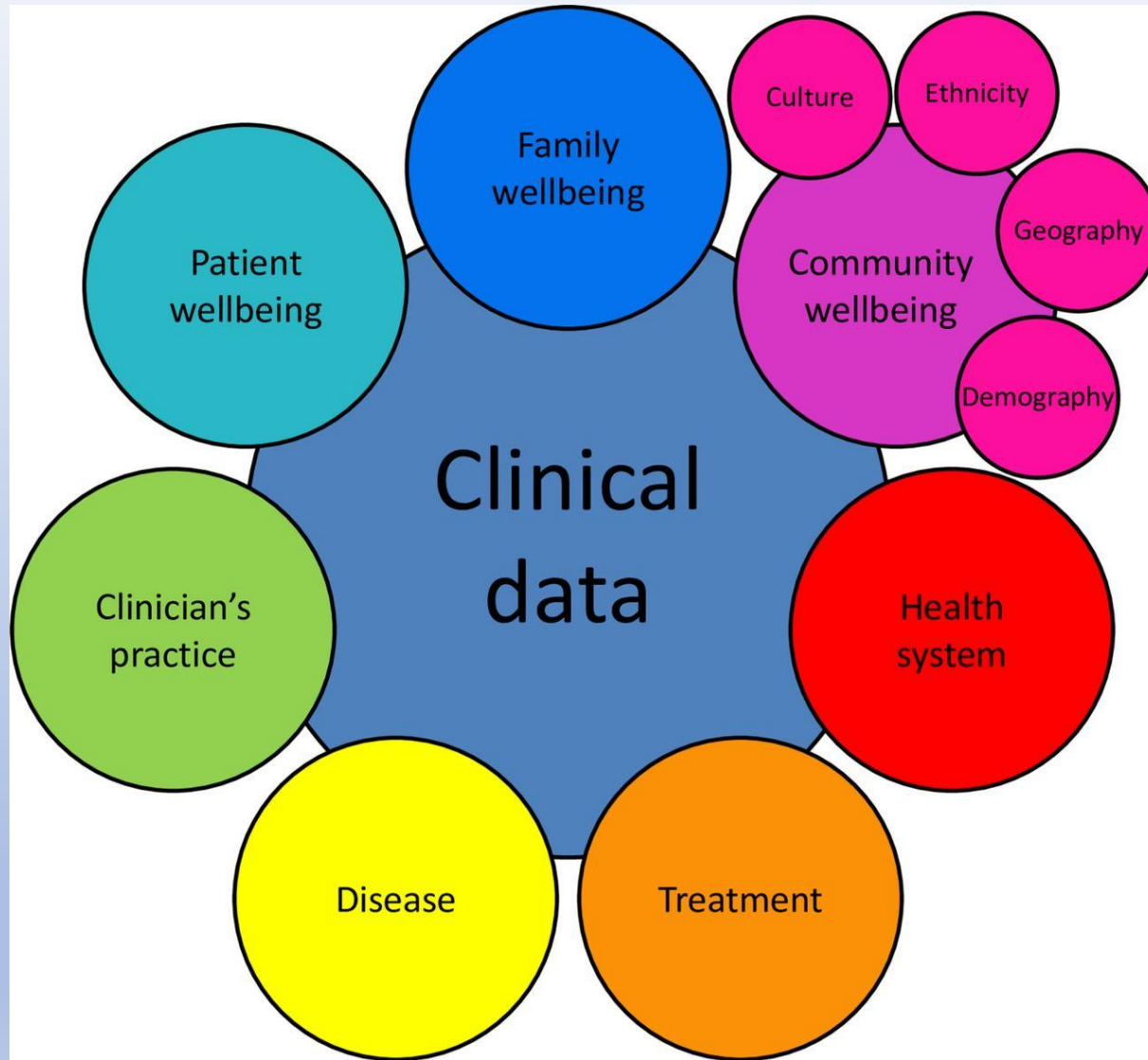




SOLOKIKO

Advanced Clinical Research Program
and
National Hispanic Health Foundation

1. A Program to train the next generation of diverse clinical Investigators
2. Improve diversity in clinical trials



Help Develop the clinical research skills beginning in the first three years of medical school



California Northstate College of Medicine Program Highlights

- The development of a clinical research program for medical students that will eventually be offered nation wide
- A highly selective program that will teach aspects of clinical research inclusive IIT
 - Identifying an unmet need
 - Development of a protocol
 - IRB
 - Performing the study
 - Evaluating the data and preparing a publishable paper
 - Submitting for a publication




Our First Year Results

- Successful Diabetic Retinopathy Project sponsored by Genentech
- 10 students
- Submitted for publication to JNHMS

SOLOKIKO Advanced Research Future Goals

- The Expansion into a national program
- Promote clinical cultural competence and sensitivity
- Train future diverse research clinicians
- Improve diversity in clinical trials
- Use program to generate publications for diverse applicants to residencies, making them more competitive

A hand holding a blue marker is shown writing the word "GOAL" in large, blue, capital letters on a whiteboard. The word is underlined with a single blue horizontal line. The background of the whiteboard is white, and the hand is positioned at the bottom right of the frame.

Thank You!

Q&A

NHHF Programs Updates

Post-webinar Survey

- Please support and submit

2023 Annual Hispanic Health Professional Student Scholarship

- If interested in Sponsorship opportunities please email us at nhhf@nhmafoundation.org
- **Deadline:** for sponsor name in invite is Friday, September 22, 2023
- **Upcoming Annual Gala Dates:**
 - Los Angeles, CA – November 17, 2023
 - Manhattan, NY – November 30, 2023
 - Scholarship Receptions in D.C, Chicago, and San Antonio! Dates TBD.

Please visit our website for:

- Sponsorship opportunities
- Mentorship questions
- Donations to NHHF



Visit our website at nhmafoundation.org

NHHF Programs Updates

Complete our
post-webinar
survey!



If you have any questions about our programs or events, please email us at nhhf@nhmafoundation.org.

Thank you!