Clinical Research Webinar Series:

Patient Recruitment and Retention

Moderator:

ELENA RIOS, MD, MSPH, MACP

President,
National Hispanic
Health Foundation
Washington, DC

October 4, 2023

7 - 8 p.m. (ET)

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1.0 CME CREDIT PROVIDED

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AMGEN

Speakers:

MARCELO CORREIA, MD, MSC, PHD

Clinical Assistant Professor of Internal Medicine-
Endocrinology and Metabolism
University of Iowa
Iowa City, IA

JULIETA ARGÜELLES , MD

Research Head & Neck Cancer
MD Anderson Cancer Center
Houston, TX

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.

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INTERPROFESSIONAL CONTINUING EDUCATION

Objectives

- Describe how Hispanic physicians in private practice and academia have developed successful clinical research with targeted recruitment and retention strategies that can improve health care quality in the U.S.

- Review clinical research principles including patient recruitment, retention and community engagement.

- 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.

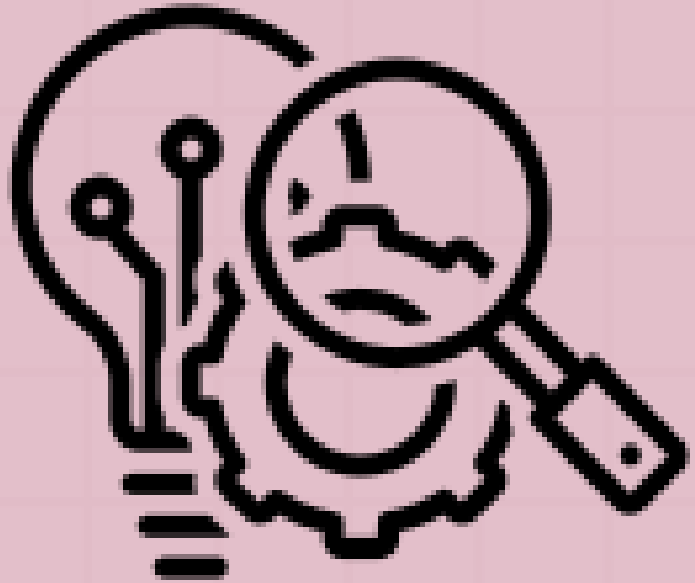
CLINICAL TRIALS CURRENT DIVERSITY PATIENT PARTICIPATION

Dr. Julieta Arguelles Hdz

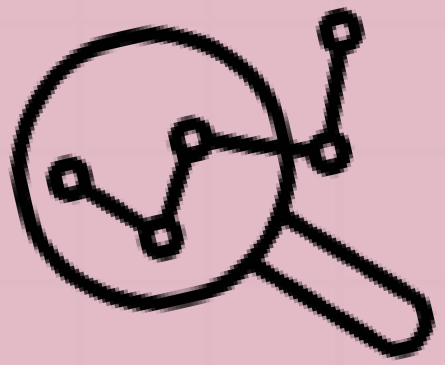
October 2023

AGENDA

- INTRODUCTION
  Industry experience
- MINORITY PARTICIPATION
- FUTURE OF CLINICAL TRIALS
- Q&A



INTRODUCTION



•The validity of clinical research studies depend on:
  - Adequate recruitment of subjects in a population of patients
  - Retention of the participants in the study
  - Adherence to protocol

•Once selected researchers and clinical research center, the recruitment and retention of patients ultimately determine if clinical studies adhere to the specified times.

•The recruitment of researchers, research center, and patients is a constant concern in the course of any sponsored clinical trial

PROBLEM

•At least 80% of clinical trials fail to meet the deadlines for registration of patients resulting in a loss of $1.3 million a day.

•Principal Reasons:

- Contract negotiation
- Slow regulatory clearance and by ethics committees
- Poor recruiting and patient retention

•Approximately 20% of researchers fail to include a single patient, and 30% below the enrollment in a trial.

WHY DOING GLOBAL RESEARCH?

Broad spectrum of diseases
Possible new markets

Competent and motivated researchers

Multiracial or ethnic groups

Large populations of patients with diseases of the developed countries and developing countries

Advanced science

Lower or underrepresented minority patient/physician participation in the US

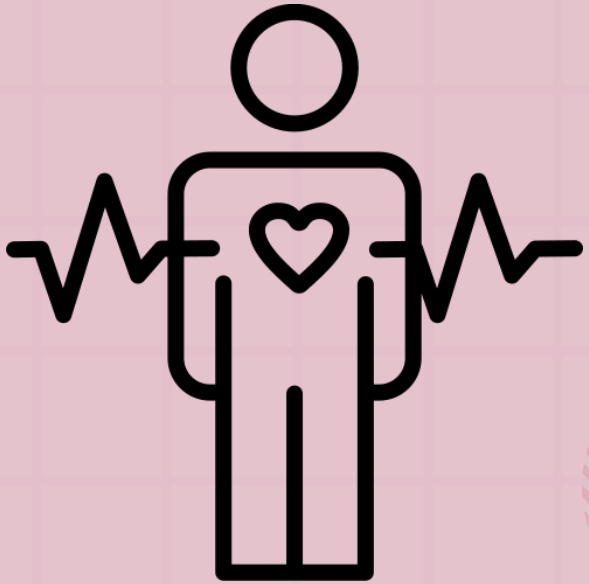
Business opportunity

EFFECTS OF POOR RECRUITMENT

SPONSOR	•Potentially biased statistical results •Loss of position and income by product •Decrease in confidence in researchers
RESEARCH SITE	•Potential loss of income due to lack of meeting goals •Risk of future involvement with sponsor •Loss in confidence of the patient

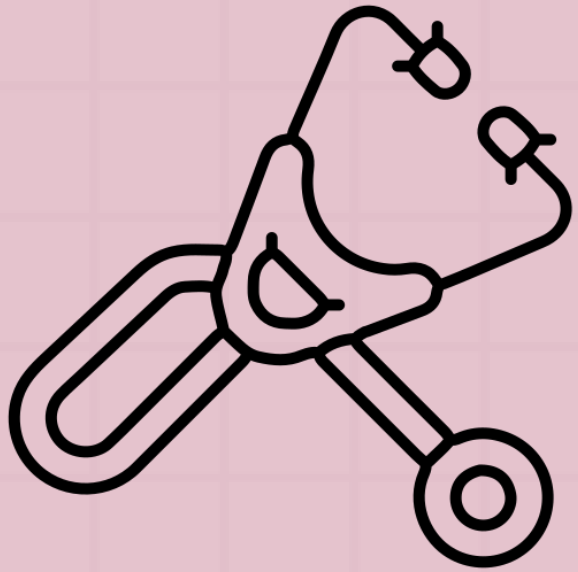
PATIENTS REFUSE TO PARTICIPATE FOR THE FOLLOWING REASONS

- Treatment of clinical trial would be less effective than the standard treatment
- Not find a clinical trial
- Insufficient information
- Time Inconvenience
- Might get placebo
- They would be treated as a "Guinea pig“
- Distance
- Cost



THAT IS WHAT THE PATIENT DEMANDS?

- Information about their health, medical condition, and progress of the study
- Feel that they have a contact in case of questions during the study
- Engage clinical staff
- Results are sent to medical GP
- Feel appreciated for their contribution
- Transport and support in their care
- Follow up



Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry U.S.

Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) November 2020

MINORITIES PATIENT/INVESTIGATOR DIVERSITY

- Minorities patients account for less than 10% of patients enrolled in clinical trials, according to the National Institute on Minority Health and Health Disparities.
- Recruiting diverse patient populations can be challenging, especially at the site level.
- Racial disparities among INVESTIGATORS are often a major reason why minority patients are underrepresented in clinical trials, not drawn a wider number of minority patients.
- Low incidence (4%) of participation in clinical research among minority physicians is observed with regards to U.S. Food & Drug Administration-regulated clinical trials with the industry.
- Call for Increase Diversity Among Clinical Researchers

FUTURE DEVELOPMENTS

FUTURE DEVELOPMENTS

- Identify potential investigators in the US region by specialty that works with minotity patient population (Experienced or Not) – Qualify to participate
- Develop training programs on GCP/ICH Guidelines – No need to be Certified (Optional)
  - Investigators
  - Clinical teams
    - Study Coordinators
    - Research Assistants
    - Pharmacists
    - Regulatory personnel
    - Others
- Prepare research sites with proper infrastructure to conduct clinical trials – must qualify to participate
- Sites must have proper study personnel – Qualified
- Sites/Investigators develop Procedure Manual

DEVELOPMENT

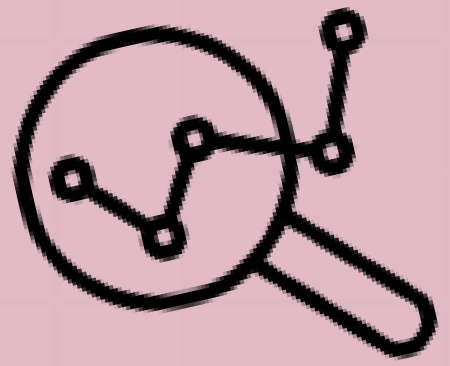
••Increase regional and global participation to intensify cultural presence among diversity patient population

•Increase minority investigator participation

- Academic
- Non-academic - Independent

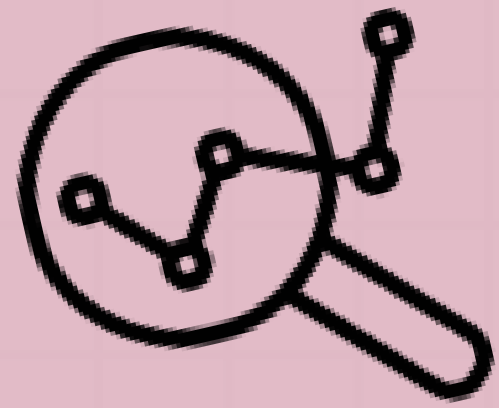
• Develop and Implement Business Development activities among research sites

- Increase presence of industry locally
- Increase access to trials
- Increase global representation



DEVELOPMENT

- Develop regional networks for stronger presence in the industry
  - Biopharma groups
  - CROs
  - Professional Associations
  - Regulators
- Participate on industry scientific networks
  - Speaker
  - Exhibits
  - Publications



REINFORCE COMMUNICATION

•Recruitment of Minorites is a complex process that involves not only patients, but also to the doctors, sponsors, and research staff.

•With set times and often fragmented communications, recruitment rates can be disappointingly low

QUESTIONS?

THANK YOU!

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THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

LatIMGs

Best Practices for Promoting Patient Retention in Clinical Trials

Marcelo Correia, MD MSc PhD DABOM
Division of Endocrinology
Preventive Intervention Center
University of Iowa Health Care and VAMC
Iowa City, IA

Disclosures: Dr. Correia receives research grants from Novartis, Novonordisk, Lilly and Stead Family.

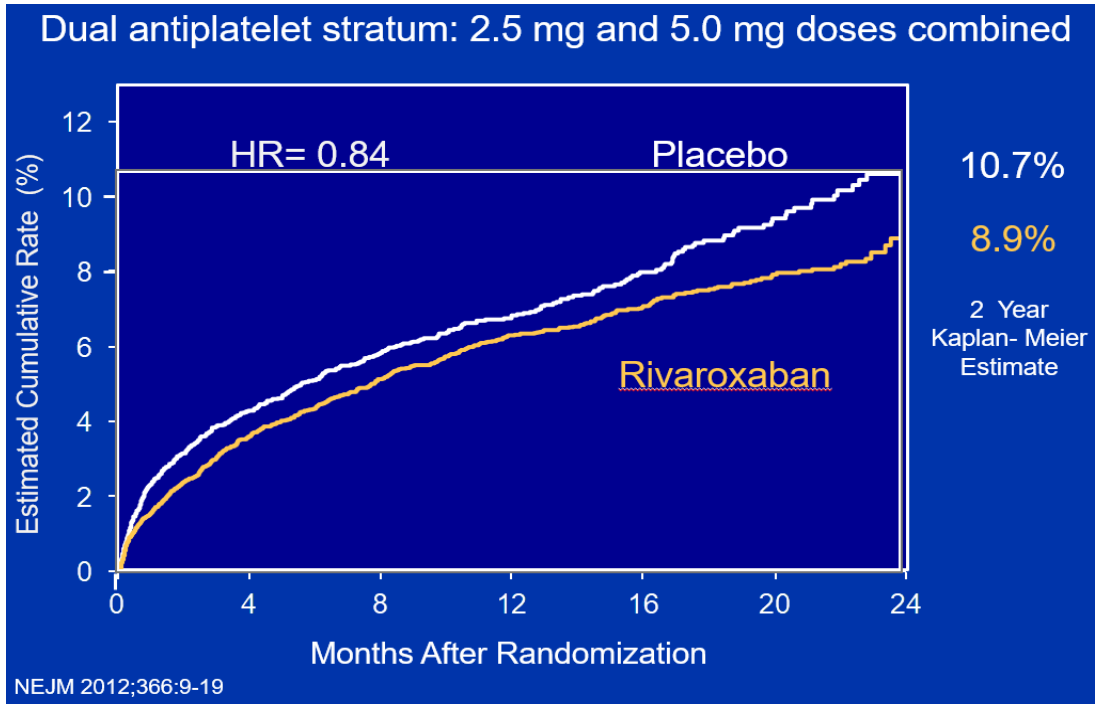
Clinical Research Webinar Series

Outline

- Case study: why patient retention matters?
- Patient relationship
- Patient experiences and site environment
- Patient education
- Patient support
- Retention risks and mitigation strategies
- Take home message

ATLAS Acute Coronary Syndrome 2 TIMI 51 Trial

Effect of Rivaroxaban on Primary Endpoint and Number of Patients with Missing Data



Courtesy: Dr. Steven Nissen

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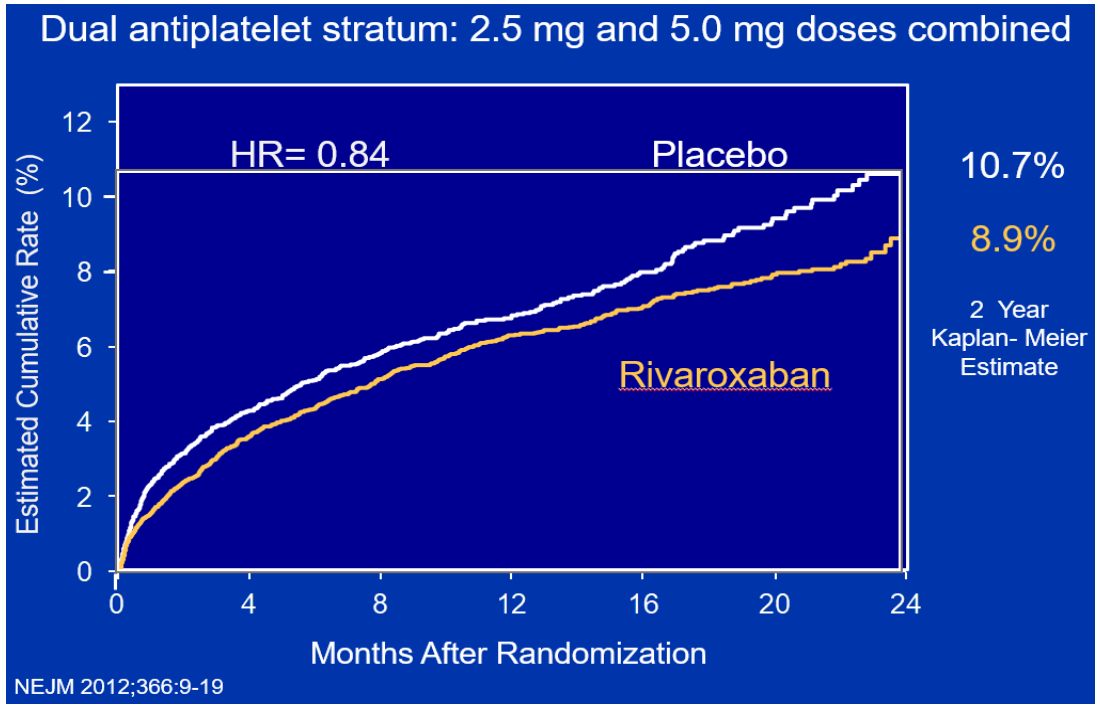

	Rivaroxaban 2.5 mg	Placebo	Difference
Consent Withdrawn	441	396	45
Lost to Follow-up	8	13	-5
Other	132	129	3
Total Premature Withdrawals	581 (11.4%)	538 (10.5%)	43

- 1,294 subjects discontinued the trial prematurely.
- The sponsor was only able to contact 183 (177 were alive).

Courtesy: Dr. Steven Nissen

Missing Data Led FDA to Vote Against Rivaroxaban for ACS

On May 23, 2012, the missing data plaguing the ATLAS trial led the FDA Cardiovascular and Renal Drugs Advisory Committee to vote 6 to 4 (with 1 abstention) against recommending rivaroxaban for reducing the risk of MACE in patients with acute coronary syndrome.

Dr. Tom Marciniak, a former FDA medical teal leader, was adamant that the trial **results are not interpretable because 12% of the patients had incomplete follow-up, far higher than the 1% to 1.5% differences in the end-point rates between rivaroxaban and placebo**.

Courtesy: Dr. Steven Nissen

Patient Relationship

- Principal investigator must actively interact with patients.
- Develop trust with the patient, spouse, family and friends.
- Know the patient's life outside the study because personal connections are key to engagement.
- Strive for dedicated study staff to ensure continuity of care, as patients enjoy interacting with the same staff.
- Listen, express understanding, and address concerns by the patient.
- Resolve concerns and check ongoing solutions.

Patient Experiences and Site Environment

- Identify circumstances ask for feedback (transportation, parking, check-in, wait time, mobility, special needs).
- Offer flexible scheduling to accommodate work and transportation.
- Consider holidays, vacation (patient and site staff), seasonal relocation, scheduling conflicts, and unexpected events (inclement weather).
  BE PREPARED TO ADJUST!
- Visits should be efficient but not rushed.
- Thank patients at every visit.

Patient Education

- Ensure that patients understand the study and encourage questions.
- Explain the study drug, dosing, potential adverse effects.
- Describe the purpose of visits and what will happen to ensure patient preparedness.
- Ask questions about the patient's ability to adhere to study intervention.
- Understand obstacles preventing adherence to study intervention.

Patient Support

- Be part of the patient's support network.
- Identify impediments to study compliance (transportation, travel time or cost to patient) and find solutions. Sponsor might help with extra costs.
- Communicate with the patient's health care providers and family to gain support.
- Discuss the time, date, and duration of next scheduled visit and confirm availability.
- Appointment cards and phone, text, email reminders are helpful.
- Be aware of unplanned hospitalizations, relocation, and impactful life events (divorce, pregnancy) and take a supportive approach.

Common Retention Risks and Mitigation Strategies

- **Problem:** Change in patients' mood or behavior.
- **Solution:** Try to understand the cause of their behavior address concerns.

- **Problem:** Change in patient contact information.
- **Solution:** Review contact information at every visit. Remind the patient to notify the site if information changes.

- **Problem:** Extended vacation or seasonal relocation.
- **Solution:** Schedule visits according to the patient's calendar. Visits in other sites can be possible.

Common Retention Risks and Mitigation Strategies

- **Problem:** Patient is uncertain about availability for future visits.
- **Solution:** Try to understand the cause and discuss possible benefits of being in a study (health monitoring, use of effective study drugs).

- **Problem:** Difficulty remembering visits.
- **Solution:** Provide reminder card, phone calls, text, email.

- **Problem:** Temporary interruption or permanent discontinuation of study intervention.
- **Solution:** Determine if rechallenge is allowable and, if applicable, discuss rechallenge.

Common Retention Risks and Mitigation Strategies

- **Problem:** Patient is concerned that the intervention is not effective.
- **Solution:** Explain about placebo if applicable. Discuss disease management and agree on a plan. Involve PCP.

- **Problem:** Hospitalization or SAE.
- **Solution:** Assess if it is possible to resume intervention and plan for rechallenge. Engage patient, family, and PCP during and after hospitalization/SAE.

- **Problem:** Patient is not compliant with intervention.
- **Solution:** Discuss compliance at every visit and track progress. Engage family and caretakers to increase compliance.

Common Retention Risks and Mitigation Strategies

- **Problem:** Life event (relative death, divorce, birth, job change).
- **Solution:** Allow time for the patient to recover and remain in contact.

- **Problem:** Patient advised by family member or PCP to stop participation.
- **Solution:** Engage family or PCP to understand the rationale for interruption and allow time to consider options.

- **Problem:** Turnover in site staff.
- **Solution:** Inform patients of staff changes in advance.

Take Home Message

- Assess the patients view of the clinical study throughout the trial.
- Patients always have the right to discontinue intervention or participation but must understand the consequences.
- Evaluate patients experiences on a frequent basis.
- Regular involvement by the **Principal Investigator** is essential!

Thanks for your attention!

marcelo-correia@uiowa.edu

Q&A

NHHF Programs Updates

Post-webinar Survey

- Please support and submit

Next Clinical Research Webinar

- January 24, 2024
- More details to come!

2023 Annual Hispanic Health Professional Student Scholarship

- If interested in Sponsorship opportunities please email us at nhhf@nhmafoundation.org
- **Upcoming Annual Gala Dates:**
  - Los Angeles, CA – November 17, 2023
  - Manhattan, NY – November 30, 2023
  - Scholarship Receptions in Washington D.C. (October TBD), Chicago (November 29), and San Antonio (February 22)!

Please visit our website for:

- Sponsorship opportunities
- Mentorship questions
- Programs
- Donations to NHHF

Visit our website at ***nhmafoundation.org***

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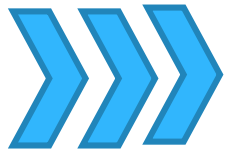
Complete our post-webinar survey!



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

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Thank you!