

Driving Inclusion in Clinical Research

Second Wednesday monthly
11AM – 12PM ET



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

LEARNING IN: A WEBINAR SERIES

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Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM -12noon ET



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LEANING IN: A WEBINAR SERIES

PREVIOUS WEBINAR
RECORDINGS AND SLIDES
AVAILABLE TO DOWNLOAD
[HERE](#)

Community Awareness, Access, Knowledge

Workforce Development

Study Design, Eligibility, Site Selection & Feasibility

Study Conduct (Recruitment, Retention)

Data Standards and Analysis

Stakeholder Roles and Responsibilities

Role of Data in Diversity: Genetics & Real World Data



Today's topic

Driving Inclusion in Clinical Research: How to Begin

April 14, 2021
11AM -12PM EDT



Barbara Bierer, MD
Moderator
Faculty Director,
MRCT Center



Anya Harry, MD, PhD
Guest Speaker
Head, Global Demographics
& Diversity
GlaxoSmithKline



Christopher Romero,
MD, PhD, FACP
Guest Speaker
Medical Director, USA
PanAmerican Clinical Research



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The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.





ACHIEVING DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

Guidance Document and Supplementary Toolkit

Barbara E. Bierer, MD
Sarah A. White, MPH
Laura G. Meloney, MPH, MS
Hayat R. Ahmed, MS
David H. Strauss, MD
Luther T. Clark, MD

Achieving Diversity, Inclusion, and Equity In Clinical Research

Guidance and Toolkit

Released 6 August 2020

mrctcenter.org/diversity-in-clinical-research



Leadership

- RADM Richardae Araujo, PharmD, MS, U.S. FDA
- Barbara E. Bierer, MD, MRCT Center
- Luther T. Clark, MD, Merck & Co., Inc.
- Milena Lolic, MD, U.S. FDA
- David H. Strauss, MD, Columbia University
- Sarah White, MPH, MRCT Center

MRCT Center staff:

- Carmen Aldinger, PhD, MPH
- Hayat Ahmed, MS
- Laura Meloney, MS, MPH
- Joshua Smith-Sreen, MPH

And the invaluable contributions of >50 workgroup members, representing:

- Patients, Patient Advocates
- Academia
- Pharmaceutical companies
- CROs
- Non-profit organizations
- Trade associations
- Government agencies
- Research institutes

Each serving in their individual capacity.

Guidance Document

- Multi-stakeholder contributions and consensus
- Practical and actionable recommendations
- Accountability section considers how each stakeholder can change the paradigm
- Toolkit provides adaptable resources not easily found elsewhere



<https://mrctcenter.org/diversity-in-clinical-research>


Diversity in Clinical Research Website: mrctcenter.org/diversity-in-clinical-research

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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

[ABOUT](#) | [GUIDANCE](#) | [TOOLS](#) | [CASE STUDIES](#) | [NEWS & EVENTS](#)



Improve Diversity in Clinical Research

The MRCT Center aims to inspire innovation and forward momentum to improve diversity in clinical research. Change and corrective action are challenging and will only occur with the commitment of the entire clinical research enterprise.

- Explore the **Achieving Diversity, Inclusion, and Equity in Clinical Research** Guidance Document.
- Use our **dynamic tools**, read our **case studies** and join us at our **Leaning In Webinars**. We invite you to **engage with us** to expand and enhance the document, tools and resources.

[DOWNLOAD THE GUIDANCE DOCUMENT](#) | [ORDER THE HARD COPY GUIDANCE DOCUMENT](#) | [EXPLORE THE TOOLKIT](#)

**New
Updates
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Upcoming Learning In Webinars

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LEANING IN: A WEBINAR SERIES

Driving Inclusion: How To Begin?

- How can institutions, sites and organizations plan, resource, and develop a program to address diversity and inclusion in clinical research?
- What strategies can be used with leadership to commit to and set expectations for diversity initiatives?
- What are some examples and experiences of organizations that are building and maintaining momentum toward inclusion in clinical research?



Today's speaker



Anya Harry, MD, PhD
Head, Global Demographics & Diversity
GlaxoSmithKline



do more
feel better
live longer

Approaching Diverse Representation in Clinical Research

How to Begin

Anya Harry MD, PhD
Head, Global Demographics &
Diversity

Indra

Corporate secretariat
UK

How to begin



Transformation at the grassroots and enterprise levels

Advocacy & Team

- ✓ Identify the gaps and unmet needs
- ✓ Seek and align with key stakeholders and advocates within the organization

Business Case

- ✓ Develop a narrative summarizing the current landscape, rationale (scientific, regulatory, patient) future recommendations, business impact, risks and implementation plan, including milestones
- ✓ Helpful: lean canvas as well as a logic model to understand key partners, activities, resources, etc.

Cross Functional Framework

- ✓ Prepare transformation with impacted teams
- ✓ Organize the effort into focused workstreams e.g., supportive data systems, study site engagement, community and professional organization engagement and policy

Training & Implementation

- ✓ Build internal awareness and seek input, understand the drivers for the audiences
 - ✓ Drive to embed the change within the culture for sustained impact
 - ✓ Communication plan for implementation
-

How to begin



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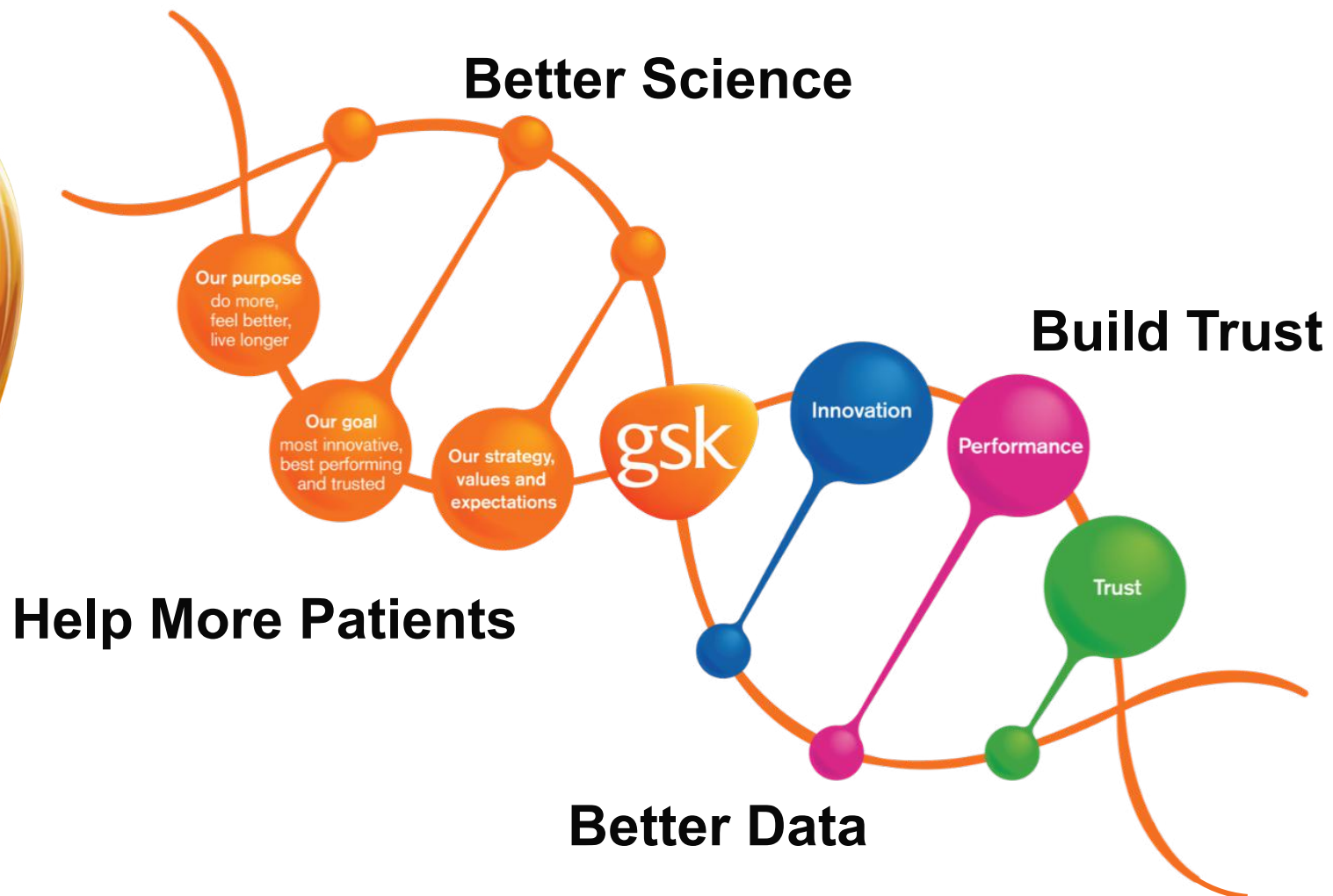
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 - ✓ **Drive to embed the change within the culture for sustained impact**
 - ✓ **Communication plan for implementation**
-

Thank You



Today's speaker



Christopher Romero, MD, PhD, FACP
Medical Director, USA
PanAmerican Clinical Research



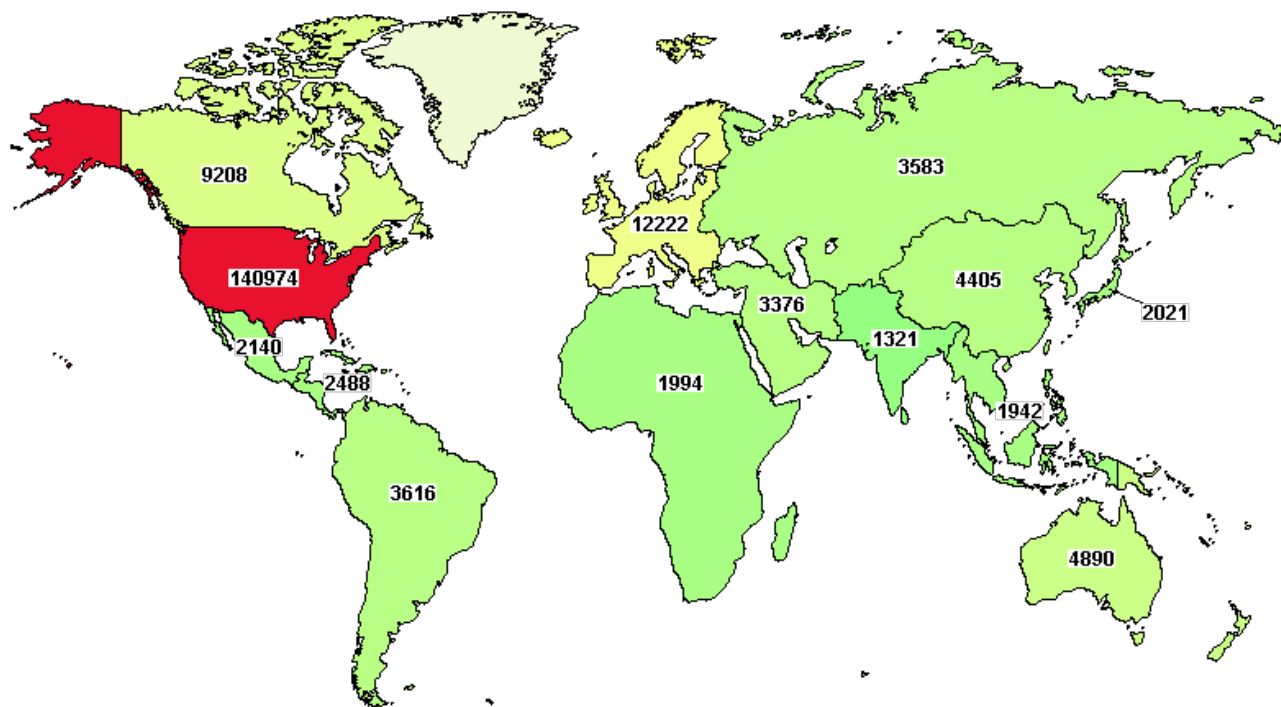
DRIVING INCLUSION IN CLINICAL RESEARCH. *HOW TO BEGIN*

PanAmerican Clinical Research, LLC

Christopher Romero, MD/PhD FACP

Medical Director, USA

USA LEADERSHIP IN CLINICAL TRIALS



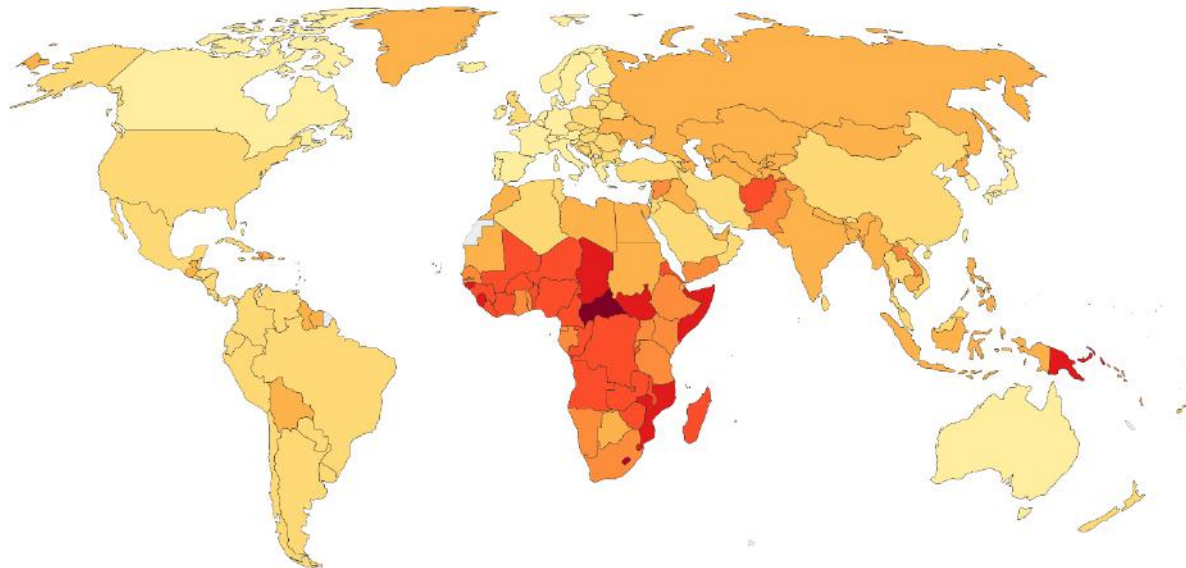
DISPARITIES IN GLOBAL DISEASE BURDEN

Burden of disease, 2017

Disability-Adjusted Life Years (DALYs) per 100,000 individuals from all causes.

DALYs measure the total burden of disease – both from years of life lost due to premature death and years lived with a disability.
One DALY equals one lost year of healthy life.

Our World
in Data



Source: IHME, Global Burden of Disease

Note: To allow comparisons between countries and over time this metric is age-standardized.

OurWorldInData.org/burden-of-disease • CC BY

FDA DRUG TRIALS SNAPSHOT

Table 1. Demographic Subgroups in 2018

DEMOGRAPHIC SUBGROUPS	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	69%	11%	10%	14%	15%	47%

*Data presented in this report are from 60 snapshots as one drug was approved for two indications.

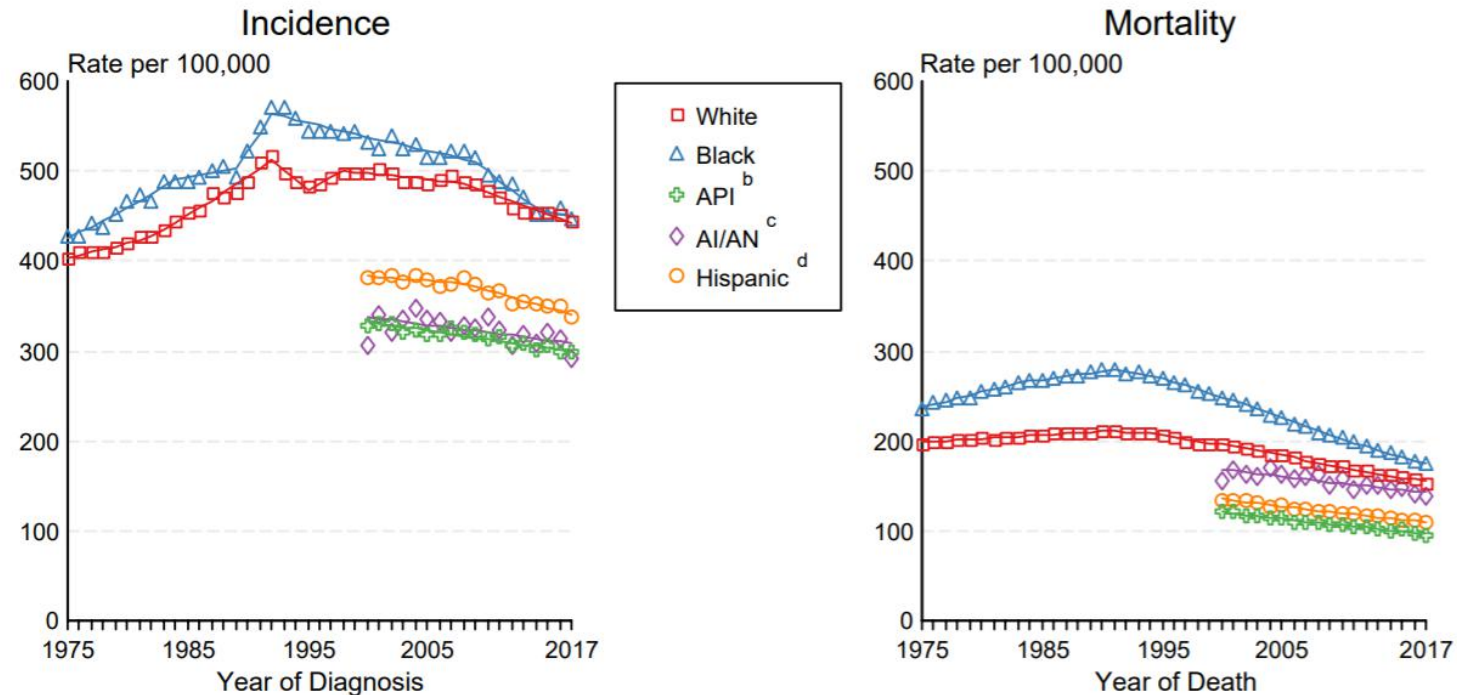
Table 1. Percent Participation in Clinical Trials by Subpopulation* for New Molecular Entities and Therapeutic Biologics Approved in 2020

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%

* The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific islander, Other, Unknown/Unreported) makes up to 100% of race category.

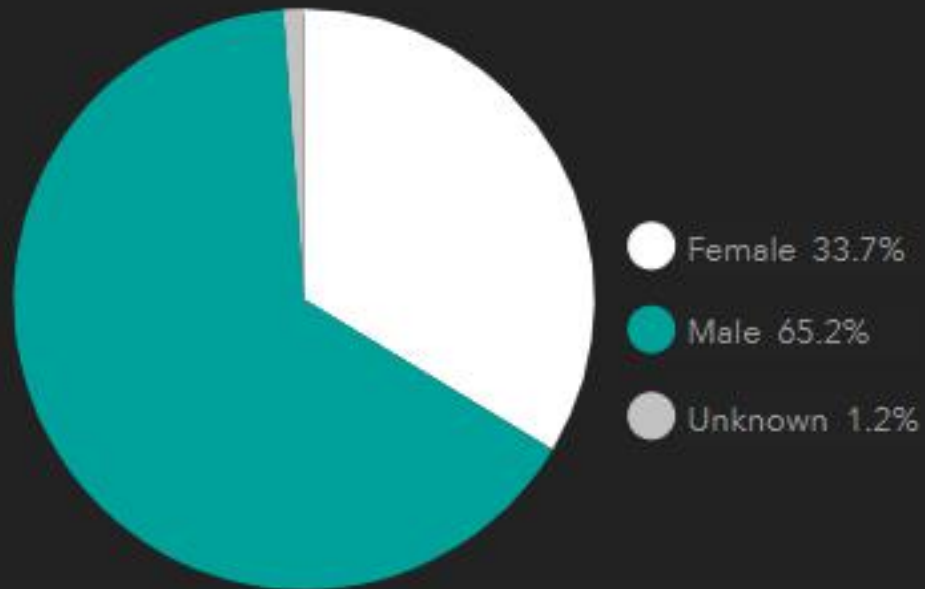
DISEASE INCIDENCE MISREPRESENTED IN CLINICAL TRIALS

SEER Incidence and US Death Rates^a
All Cancer Sites, Both Sexes
Joinpoint Analyses for Whites and Blacks from 1975-2017
and for Asian/Pacific Islanders, American Indians/Alaska Natives and Hispanics from 2000-2017

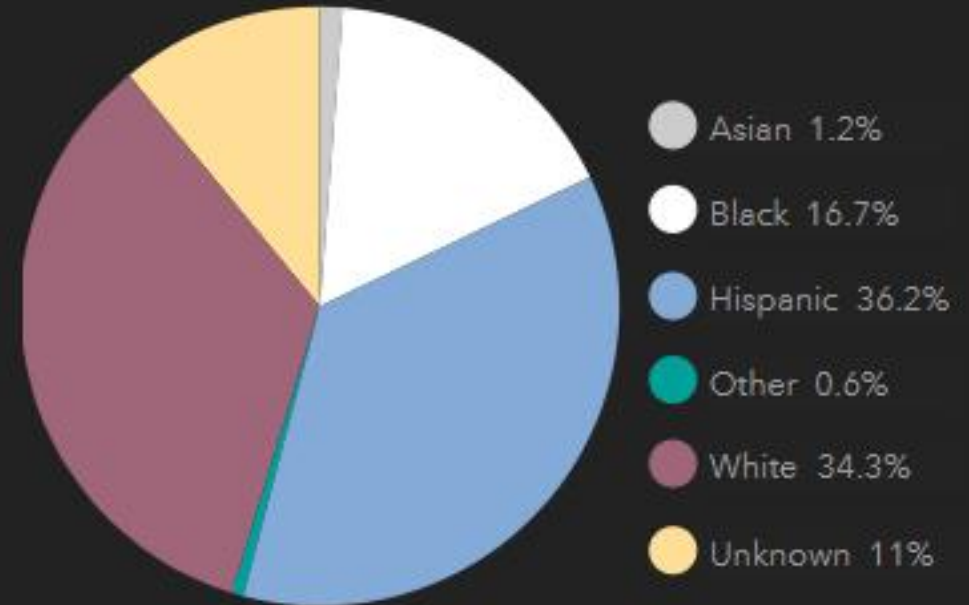


TEXAS COVID-19 DEMOGRAPHICS: CONFIRMED CASES

Sex

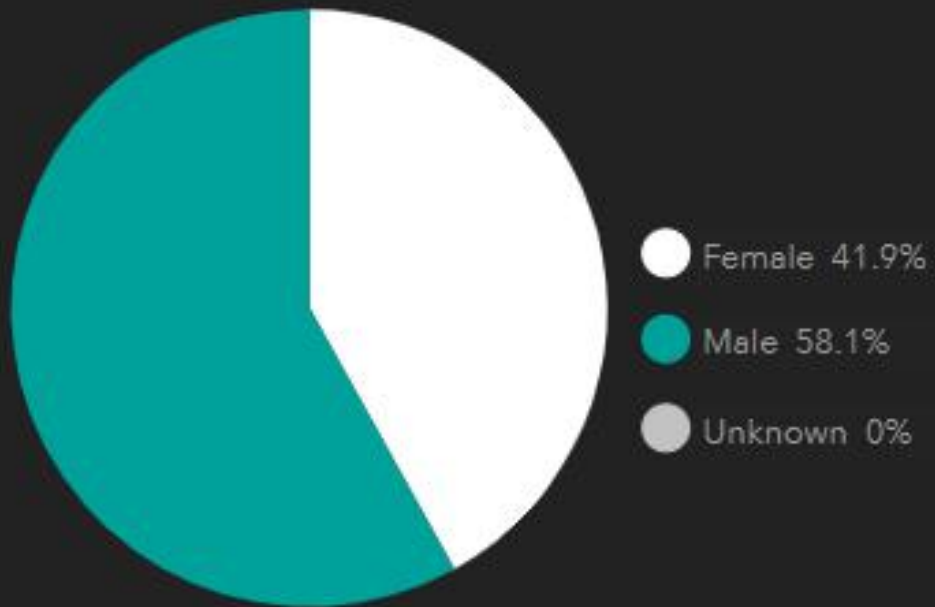


Race/Ethnicity

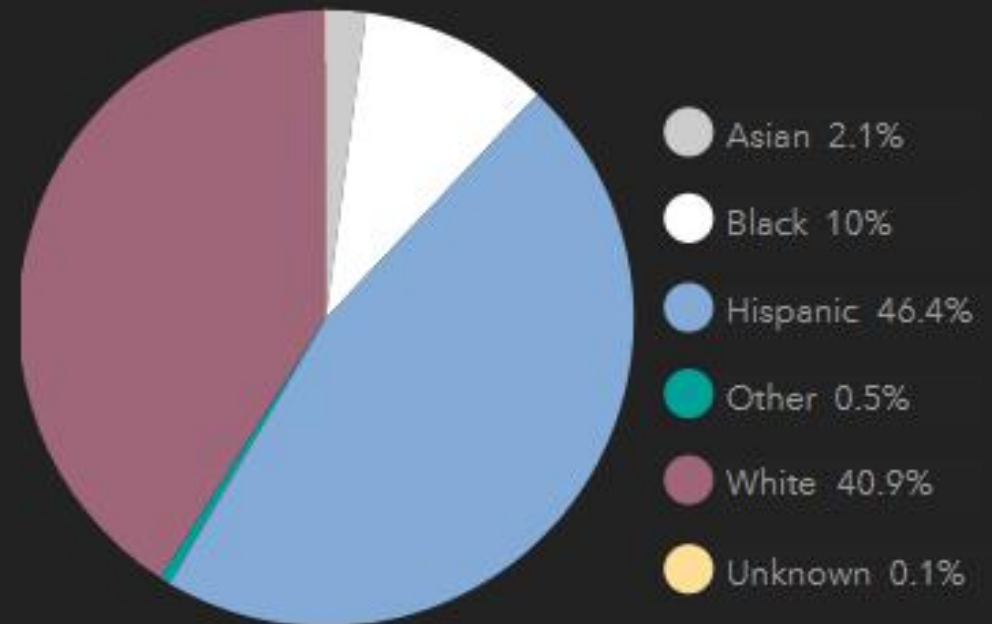


TEXAS COVID-19 DEMOGRAPHICS: MORTALITY

Sex



Race/Ethnicity



PANAMERICAN CLINICAL RESEARCH MISSION:

- PanAmerican's community-oriented and patient-centric approach produces unparalleled patient recruitment & retention and the highest quality data. **With experienced research physicians in major clinics and limited-resource communities, PanAmerican delivers results while providing health resources and education to underserved populations.**

Driving research outcomes and building healthier communities.



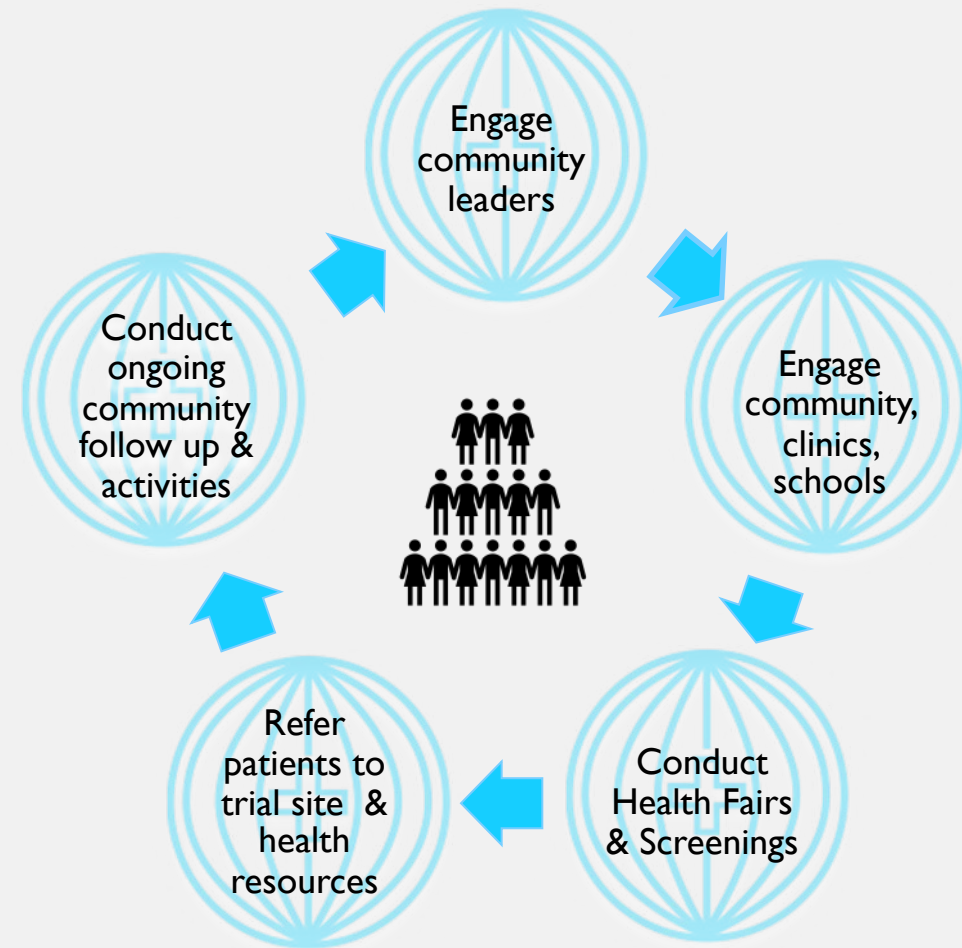
PANAMERICAN CLINICAL RESEARCH

- **Over 16 years of Clinical Research Experience in the U.S. and Latin America (LATAM).**
- **1200+ site network throughout Latin America.**
- **Physician & GCP trained Study Specialist at each site performs community education, outreach & recruitment.**
- **PanAmerican employs epidemiologists & physicians with research experience throughout Latin America who track disease trends & use local knowledge to identify communities for trials.**
- **Coordinating with LATAM sites on projects and public health efforts.**



HOW WE SERVE

Physician & GCP trained Study Specialist at each site performs community education, outreach & recruitment, & establishes referrals from physician specialists.



SUPPORT FOR LIMITED-RESOURCE COMMUNITIES

You have to have the respect and the trust of the community to approach, enroll, and retain patients. PanAmerican continues its support of communities through:



Health fairs & education



Disease screening & resource referrals



Organized access to rare disease trials



Community medicine supply coordination

Figure 11: Application of patient engagement strategies across four different stages of research

PRIORITY SETTING

- Participant and community relationship-building
- Essential research questions of importance for target population
- Relevant and meaningful outcomes
- Methods of decision making

STUDY DESIGN

- Novel study designs that support diverse enrollment
- Informed consent review processes, and outcome measures
- Aid in study recruitment through social networks and representative patient imagery

DISSEMINATION

- Understandable dissemination materials available at a health literacy level and in the multiple languages relevant to the target population.
- Review materials for inclusion of representative participant imagery
- Interpretation of study results for patients from diverse backgrounds
- Outreach to additional audiences
- Sharing results, including through social media

CONDUCT

- Understandable, health-literate research materials available
- Materials provided in health-literate multiple languages relevant to the target population
- Nurture patient and researcher/study team relationship

RIO GRANDE VALLEY, TEXAS

- 4 county region along Southern US Border
- 1.3 million inhabitants
- >90% Hispanic population
- >34% living below the poverty line
- 1/3 adults have <9th grade education
- McAllen, TX: highest % obesity and lowest rates of physical activity



THE TRUE BURDEN OF DISEASE



Texas Observer, 2019.

THE FORGOTTEN AMERICANS: THE LOWER RIO GRANDE VALLEY COLONIAS



THE FRONTLINE OF IMMIGRATION



SUCCESS IN A CHALLENGING ENVIRONMENT

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Tocilizumab in Patients Hospitalized with Covid-19 Pneumonia

Carlos Salama, M.D., Jian Han, Ph.D., Linda Yau, Ph.D., William G. Reiss, Pharm.D., Benjamin Kramer, M.D., Jeffrey D. Neidhart, M.D., Gerard J. Criner, M.D., Emma Kaplan-Lewis, M.D., Rachel Baden, M.D., Lavannya Pandit, M.D., Miriam L. Cameron, M.D., Julia Garcia-Diaz, M.D., Victoria Chávez, M.D., Martha Mekebe-Reuter, M.D., Ferdinando Lima de Menezes, M.D., Reena Shah, F.R.C.P., Maria F. González-Lara, M.D., Beverly Assman, M.S., Jamie Freedman, M.D., Ph.D., and Shalini V. Mohan, M.D.

ABSTRACT

BACKGROUND

Coronavirus disease 2019 (Covid-19) pneumonia is often associated with hyperinflammation. Despite the disproportionate incidence of Covid-19 among underserved and racial and ethnic minority populations, the safety and efficacy of the anti-interleukin-6 receptor antibody tocilizumab in patients from these populations who are hospitalized with Covid-19 pneumonia are unclear.

METHODS

We randomly assigned (in a 2:1 ratio) patients hospitalized with Covid-19 pneumonia who were not receiving mechanical ventilation to receive standard care plus one or two doses of either tocilizumab (8 mg per kilogram of body weight intravenously) or placebo. Site selection was focused on the inclusion of sites enrolling high-risk and minority populations. The primary outcome was mechanical ventilation or death by day 28.

RESULTS

A total of 389 patients underwent randomization, and the modified intention-to-treat population included 249 patients in the tocilizumab group and 128 patients in the placebo group. 56.0% were Hispanic or Latino, 14.9% were Black, 12.7% were American Indian or Alaska Native, 12.7% were non-Hispanic White, and 3.7% were of other or unknown race or ethnic group. The cumulative percentage of patients who had received mechanical ventilation or who had died by day 28 was 12.0% (95% confidence interval [CI], 8.5 to 16.9) in the tocilizumab group and 19.3% (95% CI, 13.3 to 27.4) in the placebo group (hazard ratio for mechanical ventilation or death, 0.56; 95% CI, 0.33 to 0.97; $P=0.04$ by the log-rank test). Clinical failure as assessed in a time-to-event analysis favored tocilizumab over placebo (hazard ratio, 0.55; 95% CI, 0.33 to 0.93). Death from any cause by day 28 occurred in 10.4% of the patients in the tocilizumab group and 8.6% of those in the placebo group (weighted difference, 2.0 percentage points; 95% CI, -5.2 to 7.8). In the safety population, serious adverse events occurred in 38 of 250 patients (15.2%) in the tocilizumab group and 25 of 127 patients (19.7%) in the placebo group.

CONCLUSIONS

In hospitalized patients with Covid-19 pneumonia who were not receiving mechanical ventilation, tocilizumab reduced the likelihood of progression to the composite outcome of mechanical ventilation or death, but it did not improve survival. No new safety signals were identified. (Funded by Genentech; EMPACTA ClinicalTrials.gov number, NCT04372186.)

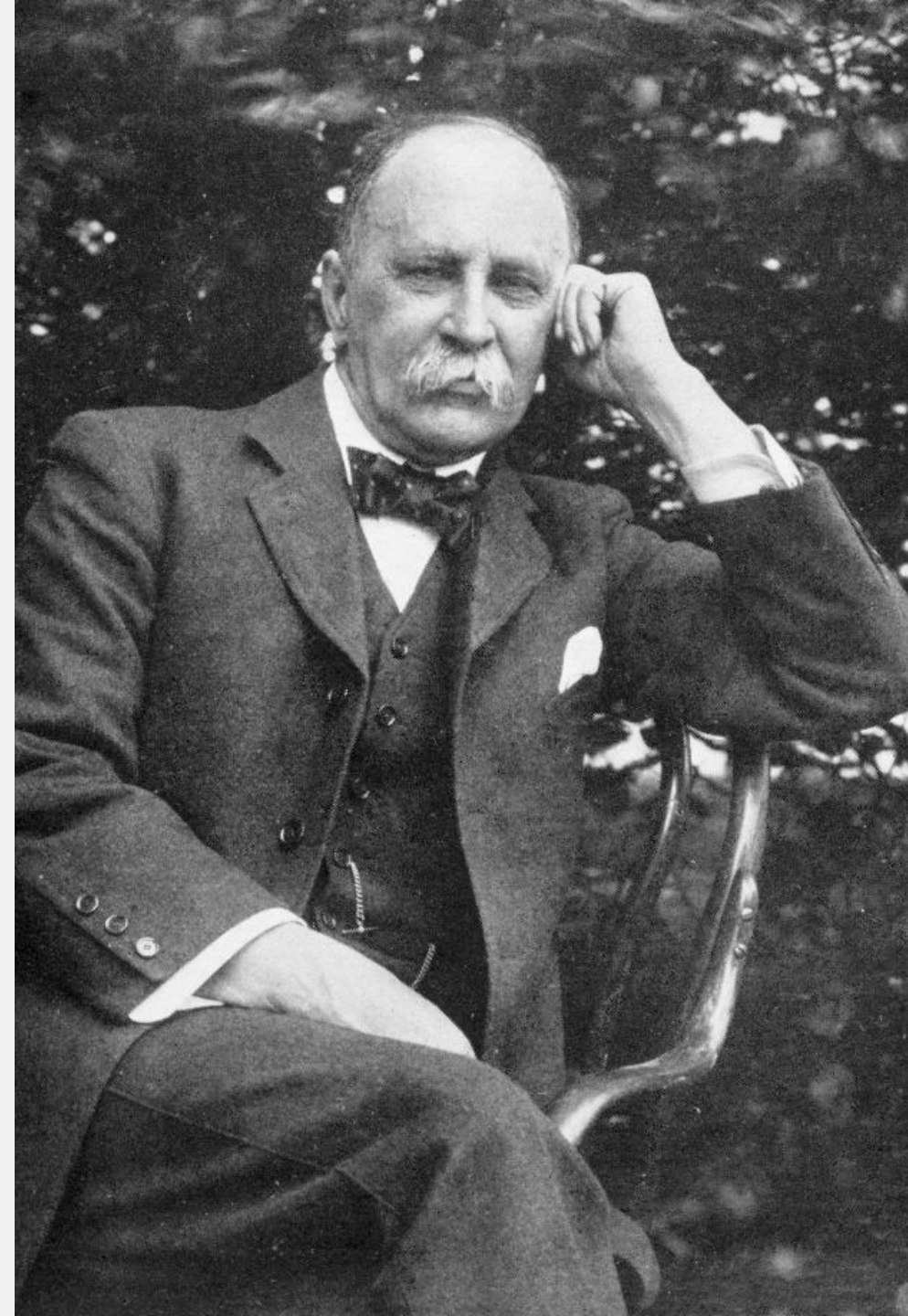
From Elmhurst Hospital Center-Icahn School of Medicine at Mount Sinai Hospital (C.S.), and Elmhurst Hospital Center-New York City Health and Hospitals (E.K.-L.) — both in New York; Genentech, South San Francisco (J.H., L.Y., W.G.R., B.K., B.A., J.F., S.V.M.), and Highland Hospital, Oakland (R.B.) — both in California; San Juan Oncology Associates, Farmington, NM (J.D.N.); Lewis Katz School of Medicine at Temple University, Philadelphia (G.J.C.); Michael E. DeBakey Houston VA Medical Center, Houston (L.P.); Holy Cross Health, Silver Spring, MD (M.L.C.); Ochsner Clinic Foundation, New Orleans (J.G.-D.); Central Military Hospital, Lima, Peru (V.C.); Stellenbosch University, Cape Town, South Africa (M.M.-R.); BR Trials—Clinical Research, São Paulo (F.L.M.); Aga Khan University Hospital, Nairobi (R.S.); and Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City (M.F.G.-L.). Address reprint requests to Dr. Mohan at Genentech, 1 DNA Way, South San Francisco, CA 94080, or at mohan.shalini@gene.com.

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DOI: 10.1056/NEJMoa2030340
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COMMUNITY RELATIONSHIP KEYS

- Local talent, local knowledge.
- Service to the community is paramount.
- Trust is earned and lost, not purchased and sold.
- Relationships take time to build.
- One on one, face to face interaction is the standard.



REPRESENTATIVE STAFFING

- Research staff recruited from local community and trained in GCP and clinical research.
- Culturally sensitive research personnel are able to relate and understand nuances of local population.
- “Hire the smile, train the skill” approach resulting in highly personable research team.
- Staff connections to community fosters trust.
- Familiarity with the medical community enables collaboration.



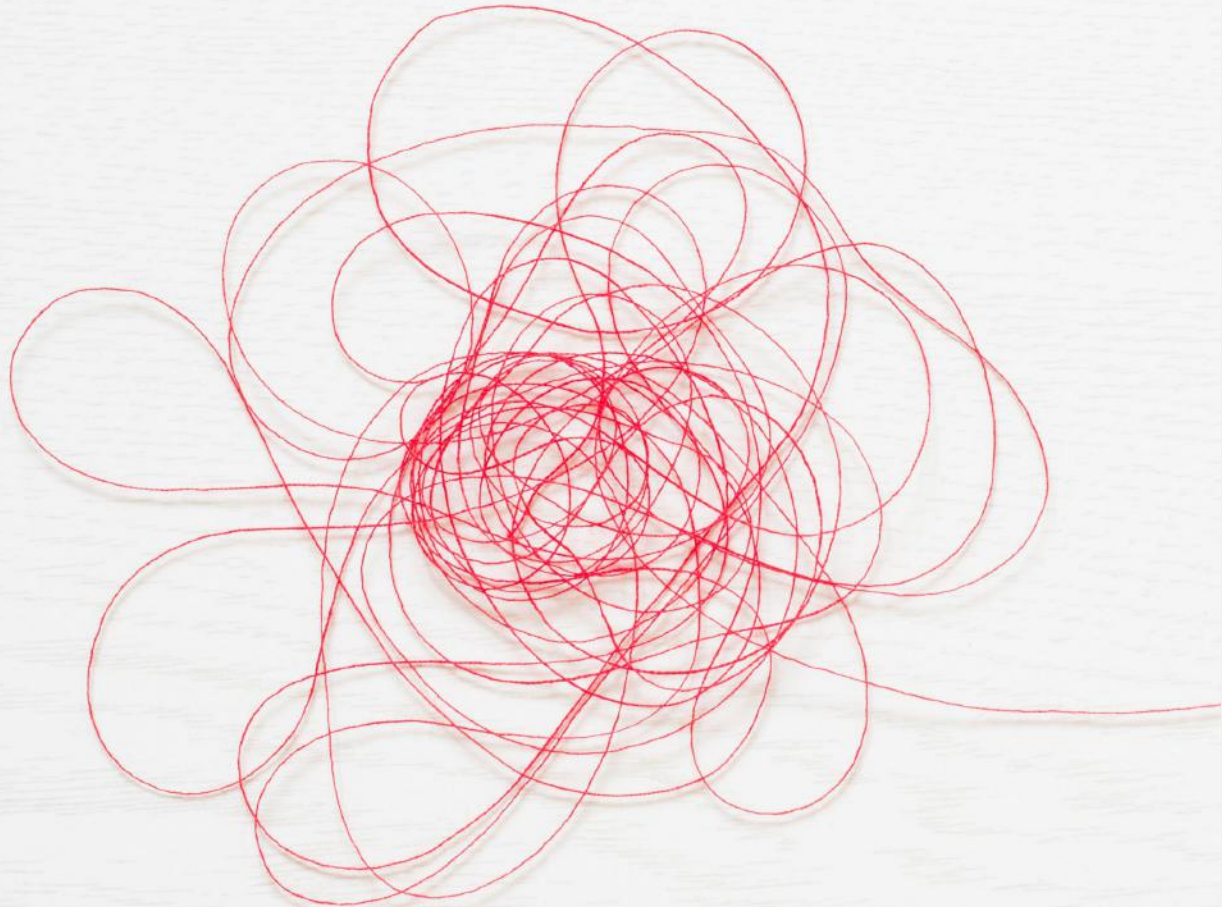
COMMUNITY SERVICE

- Traditional activities: health fair and community events.
- Pandemic activities: Supporting COVID-19 testing and vaccination efforts.
- Partner with patient advocacy groups to promote health literacy.
- Partner with non-profits to promote health and wellness in underserved communities.
- Partner with City and County Health Departments to facilitate their missions.
- Collaborate with local University researchers to promote their research endeavors.



ACTION ITEMS





BARRIERS TO CLINICAL TRIAL INCLUSIVITY

- Variations in regulatory environments in Lat Am. hinder participation compared to US Sites.
- Translated study material availability at startup.
- Community awareness and acceptance of clinical trials.
- Medical community acceptance of clinical trials.
- Decentralized trial technical barriers.
- Uninsured participants and newly diagnosed disease or adverse events.
- Migrant populations and timelines for retention.
- Trained / experienced research personnel shortage.

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Discussion and Questions