D

Regulatory Science Symposium

Diversity in Clinical Trials in the Time of COVID-19

Friday, October 16, 2020 | 9:00am - 3:30pm PST

USC School of Pharmacy
International Center for Regulatory Science
SC CTSI

9:00 AM PST	**Introduction** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science
9:30 AM PST	**What Do We Mean by Diversity in Clinical Trials?** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science
10:00 AM PST	**Break**
10:15 AM PST	**FDA Initiatives to Address Diversity in Clinical Trials** *Nancy Pire-Smerkanich, DRSc* USC, SC-CTSI, School of Pharmacy I Assistant Professor, Dept. of Reg. & Quality Sciences
11:10 AM PST	**Clinical Trials Participation: Understanding the Needs and Importance of Diverse Populations** *Joan Chambers* Senior Director for Marketing and Outreach, Center for Information and Study on Clinical Research Participation
12:00 PM PST	**Lunch**
12:30 PM PST	**Diversity, Equity and Inclusion in Clinical Research** *Aman Khera* Global Head of Regulatory Strategy, Worldwide Clinical Trials
1:15 PM PST	**Populations on the Fringe of Clinical Trial Enrollment** *Terry David Church, DRSc, MA, MS* Assistant Professor, Dept. of Reg & Quality Sciences | Associate Director of Undergraduate Education
2:00 PM PST	**Break**
2:15 PM PST	**Ensuring Participant Diversity and Engagement During COVID-19** *Nicki Karimipour, PhD* USC, SC-CTSI, Associate Director, Communications I Program Manager, Clinical Research Support
3:00 PM PST	**Wrap-Up** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science

Please complete the course evaluation survey at the end of the symposium to receive a certificate of completion. Hours may be eligible for SoCRA and/or ACRP credit.

Series sponsored by The Greater LA CTSA Consortium

UCLA CTSI Grant #UL1TR001881 | SC CTSI | UC•IRVINE ICTS from lab to life.

SC CTSI is part of the Clinical and Translational Science Awards (CTSA) , a national network funded through the National Center for Advancing Translational Sciences (NCATS) at the NIH (Grant Number UL1TR001855). Under the mandate of "Translating Science into Solutions for Better Health," SC CTSI provides a wide range of services, funding, and education for researchers and promotes online collaboration tools such as USC Health Sciences Profiles .

Regulatory Science Symposium:

Diversity in Clinical Trials in the time of COVID-19

Speaker Bios

Eunjoo Pacifici, PharmD, PhD, is the Chair and Associate Professor of Regulatory and Quality Sciences and Associate Director of the International Center for Regulatory Science. Dr. Pacifici received a BS in Biochemistry from the University of California Los Angeles followed by a PharmD and PhD in Toxicology from the University of Southern California. She conducted her graduate research in the laboratory of Dr. Alex Sevanian in the Institute for Toxicology where she studied the mechanism of oxidative damage and repair in endothelial cell membrane. Before returning to USC as faculty, Dr. Pacifici worked at Amgen and gained experience in conducting clinical research with a special focus on the Asia Pacific and Latin America regions. She initially worked in the clinical development group managing U.S. investigational sites and central laboratories and then went on to work in the Asia Pacific / Latin America group interfacing with local clinical and regulatory staff in Japan, the People's Republic of China, Taiwan, and Mexico. She represented regional clinical and regulatory views on therapeutic product development teams and led satellite task forces in order to align local efforts with U.S. activities. Her additional professional experiences include community pharmacy practice in various settings and clinical pharmacy practice at the Hospital of the Good Samaritan in Los Angeles. Her current focus is on developing the next generation of regulatory scientists and pharmacy professionals with the knowledge, tools, and skills to expedite the development of innovative, safe, and effective biomedical products. epacific@usc.edu

Nancy Smerkanich, DRSc, **MS,** is an Assistant Professor in the Department of Regulatory and Quality Sciences, School of Pharmacy at the University of Southern California. Dr. Smerkanich holds a Doctorate and master's degree in Regulatory Science from USC and a Bachelor of Science Degree in Microbiology and a Bachelor of Arts in Russian from the University of Connecticut. Dr. Smerkanich received her faculty appointment after successfully completing her Doctoral Dissertation on "Benefits Risk Frameworks – Implementation in Industry" in 2015. In addition to teaching courses related to drug development and clinical trials, she provides regulatory guidance to industry peers. Nancy brings many years of practical regulatory knowledge and experience to academia where she participated in all regulatory aspects of product development, having served as Regulatory Liaison, US Agent, and Global Regulatory Lead across varied therapeutic areas. Known for her dedication to education and mentoring across industry, Nancy continues to be recognized for her ability to provide accurate, relevant and dynamic instruction on both the technical and strategic aspects of global regulatory affairs and for her service to professional organizations such as the Drug Information Association (DIA) and The Organization for Professionals in Regulatory Affairs (TOPRA). piresmer@usc.edu

Joan A. Chambers, is the Senior Director for Marketing and Outreach at he Center for Information & Study on Clinical Research Participation (CISCrP) and was on the CISCrP Advisory Board for over 10 years. Joan develops and executes strategic marketing, promotional and outreach campaigns to support the CISCRP mission of raising awareness and understanding about clinical research and the important role it plays in public health. Additionally, she directs, plans, and launches new initiatives for new growth opportunities. A well-known speaker at industry conferences, Joan has presented on a wide variety of topics specific to the clinical trials enterprise. Joan is on the Board of Directors for Greater Gift, the US PharmaTimes Steering Committee for Clinical Research of the Year (CROY), Steering Committee for Pharma Intelligence/ Informa Clinical & Research Excellence Awards (CARE), Steering Committee for PopUp Star, and is an active member of the Association of Clinical Research Professionals (ACRP) and the Drug Information Association (DIA). In the course of her career, she has published in clinical trade journals and was an instructor for Barnett International's CRA/CRC programs on the site identification/qualification process. Joan was formerly COO at CenterWatch. Her career included roles at ClinX, SCORR Marketing, CHI, Tufts CSDD and PAREXEL. Joan holds a B.S. in Marketing. jchambers@ciscrp.org

Aman Khera, is the Global Head of Regulatory Strategy at Worldwide Clinical Trials, a mid-size Clinical Research Organization (CRO). Aman joined Worldwide from a large global CRO, where during her 17 year tenure, she led and developed many functions and services within Regulatory, ranging from regulatory intelligence function to business development and streamlining the many initiatives to develop regulatory services, most recently holding the position of Head of Americas for the Regulatory Strategy and Agency Liaison team. She is an accomplished leader and expert in regulatory affairs with a 23-year track record of success within the CRO environment in providing global strategic direction in regulatory affairs. She has led a wide variety of regulatory projects providing regulatory strategy and development services for a variety of client sponsor companies ranging from virtual companies to large companies in many therapeutic indications. Her career is built on helping clients achieve their initiation to end regulatory strategies from study submission to commercialization.She is an active volunteer in regulatory associations; served on the editorial panel of the peer reviewed journal, the Regulatory Rapporteur as well as currently serving as Chair of the North American Chapter for The Organization for Professionals in Regulatory Affairs (TOPRA). Aman is also a member of the TOPRA Diversity Committee and has taken a special interest in diversity and inclusion within industry. aman.khera@worldwide.com

Terry Church, DRSc, MA, MS, is an Assistant Professor in Regulatory and Quality Sciences at the University of Southern California, School of Pharmacy. He is Associate Director of Undergraduate Education, and teaches in the undergraduate degree program, Pharmacology and Drug Development (PDD). Dr. Church's academic focus is on interdisciplinary applications of pharmaceutical regulation in relation to patterns of addiction, disaster management, and education and training. His areas of interest and expertise include biorepository regulation and ethics; drug addiction and regulation of controlled substances; regulatory practices for continuity and disaster planning; and policies and ethics of academic research. Dr. Church is an avid supporter of creative arts therapies and was involved in the initial set up of the Institute for Arts in Medicine at USC. Terry is a faculty fellow of the USC Center for Excellence in Teaching and co-chair of the educational committee of the Institute for Addiction Sciences. Dr. Church holds a Doctor of Science and Master of Science in Regulatory Science from the University of Southern California, a Master of Arts in Cultural Anthropology from Temple University, and a Bachelor of Arts in Social Sciences from the University of Pittsburgh. tdchurch@usc.edu

Nicki Karimipour, PhD, is an Associate Director of Communications and Clinical Research Support at SC CTSI. In her current role she establishes and maintains essential relationships with key stakeholders within and outside of the Institute for the purposes of furthering SC CTSI's reach, mission statement, and adoption of services among local investigators. In addition, she handles internal and external communications, oversees marketing efforts, branding, and media relations. In her role within the Clinical Research Support program, she oversees high-level clinical trial operations while planning and implementing strategic initiatives to promote effective, streamlined and compliant clinical research. She also assists investigators with the development of communication plans for maximizing participant recruitment and works with other SC CTSI core groups to leverage existing recruitment tools and collaboratively develop new tools. Prior to coming to SC CTSI, she worked as the Assistant to the Director of Strategy and Communications at the University of Florida CTSA hub. She has previous professional experience working in journalism, public relations, health-related strategic communications, and launching a digital health magazine for millennials. Additionally, she is a part-time faculty at California State University, Los Angeles in the Department of Public Health, where she educates the next generation of public health professionals at the graduate and undergraduate levels. Dr. Karimipour has a Ph.D. in Health Communications from the University of Florida and Master of Arts from the University of Florida. nicki.karimipour@med.usc.edu

Regulatory Science Virtual Symposium

"Diversity in Clinical Trials in the Time of COVID-19"

Introduction

Eunjoo Pacifici, PharmD, PhD
Chair and Associate Professor, Regulatory and Quality Sciences
Associate Director, DK Kim International Center for Regulatory Science
President, Pharmacy Faculty Council

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Symposium Log-In

Diversity in Clinical Trials in the Time of COVID-19
Friday October 16, 2020
9am – 3:30pm

Thank you for enrolling in the Regulatory Science Symposium. The Symposium digital binder and additional resource materials are available online now. Please download your materials prior to the start of the Symposium.

Please click the link below for Symposium materials:

Digital Binder Now Available

Please click the link below to enter the Symposium via Zoom:

Live Stream Link
Meeting ID: 985 9103 6143

One-tap mobile: US: +16699006833,,98591036143# or +13462487799,,98591036143#
Find your local number: https://usc.zoom.us/u/aYX7DcB5m
Join by SIP: 98591036143@zoomcrc.com

Presentations will start promptly at 9AM PST and we look forward to your virtual participation!

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SC CTSI Clinical Research Support (CRS)

A single stop for accessing all services an Investigator and research team needs to develop, activate, conduct, and report results for human subject research studies

Initial focus on investigator-initiated trials (non-cancer)

- **Services:**
  - Clinical research coordinators for hire
  - Research navigation
  - Recruitment support
  - Budget preparation support
- **Clinical Trials Unit (CTU)**:
  - Skilled research and nursing staff
  - Services to support highly-complexed human subjects research studies
  - Specimen processing lab
- **Voucher program:**
  - Awards up to $3,000 to generate new data for development of clinical and/or community research projects

https://sc-ctsi.org/about/groups/clinical-research-support

Nicki Karimipour, PhD
Program Manager, CRS

Tali Homsey, BA, CCRP
Clinical Research Supervisor, CRS

Contact Information:
crs@sc-ctsi.org

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Monitoring Module

1. Go to: https://uscregsci.remote-learner.net
2. Click ***create new account*** (right-hand side)
3. Type in your information and click ***Create my new account*** (bottom of page)
4. Open your email and click the link to confirm your account
5. Click ***courses*** (middle of page)
6. Scroll down and click ***Module 1 – Clinical Trial Monitoring***
7. Click ***Enroll me*** (middle of page)

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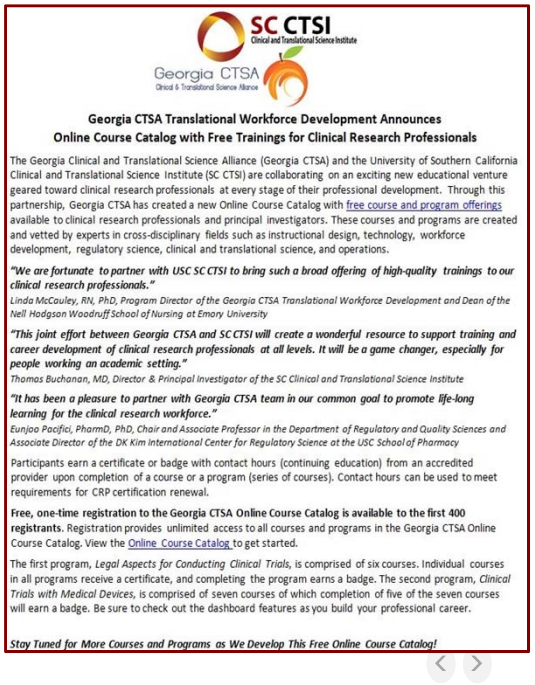
Georgia CTSA and SC CTSI: Online Course Catalog

- Free trainings for clinical research workforce
- Free, one-time registration to the first 400 registrants
- Registration provides unlimited access to all courses and programs in the Online Course Catalog
- Participants earn a certificate or badge with contact hours upon completion of a course or program
- Contact hours can be used for CRP certification renewal
- To get started: https://twd.ce.emorynursingexperience.com/



SC CTSI Clinical and Translational Science Institute

Georgia CTSA Clinical & Translational Science Alliance

Georgia CTSA Translational Workforce Development Announces Online Course Catalog with Free Trainings for Clinical Research Professionals

The Georgia Clinical and Translational Science Alliance (Georgia CTSA) and the University of Southern California Clinical and Translational Science Institute (SC CTSI) are collaborating on an exciting new educational venture geared toward clinical research professionals at every stage of their professional development. Through this partnership, Georgia CTSA has created a new Online Course Catalog with free course and program offerings available to clinical research professionals and principal investigators. These courses and programs are created and vetted by experts in cross-disciplinary fields such as instructional design, technology, workforce development, regulatory science, clinical and translational science, and operations.

"We are fortunate to partner with USC SC CTSI to bring such a broad offering of high-quality trainings to our clinical research professionals."

Linda McCauley, RN, PhD, Program Director of the Georgia CTSA Translational Workforce Development and Dean of the Nell Hodgson Woodruff School of Nursing at Emory University

"This joint effort between Georgia CTSA and SC CTSI will create a wonderful resource to support training and career development of clinical research professionals at all levels. It will be a game changer, especially for people working an academic setting."

Thomas Buchanan, MD, Director & Principal Investigator of the SC Clinical and Translational Science Institute

"It has been a pleasure to partner with Georgia CTSA team in our common goal to promote life-long learning for the clinical research workforce."

Eunjoo Pacifici, PharmD, PhD, Chair and Associate Professor in the Department of Regulatory and Quality Sciences and Associate Director of the DK Kim International Center for Regulatory Science at the USC School of Pharmacy

Participants earn a certificate or badge with contact hours (continuing education) from an accredited provider upon completion of a course or a program (series of courses). Contact hours can be used to meet requirements for CRP certification renewal.

Free, one-time registration to the Georgia CTSA Online Course Catalog is available to the first 400 registrants. Registration provides unlimited access to all courses and programs in the Georgia CTSA Online Course Catalog. View the Online Course Catalog to get started.

The first program, *Legal Aspects for Conducting Clinical Trials*, is comprised of six courses. Individual courses in all programs receive a certificate, and completing the program earns a badge. The second program, *Clinical Trials with Medical Devices*, is comprised of seven courses of which completion of five of the seven courses will earn a badge. Be sure to check out the dashboard features as you build your professional career.

Stay Tuned for More Courses and Programs as We Develop This Free Online Course Catalog!

http://regulatory.usc.edu

USC University of Southern California

REGULATORYSCIENCE

I'm looking for ...

PROGRAMS COURSES ADMISSIONS PROGRAM RESOURCES CONTACT D.K. KIM INTL CENTER FAQS ABOUT

Grow with our International Center

On May 2, 2019 we celebrated the naming of the D.K. Kim International Center for Regulatory Science in recognition of Mr. D.K. Kim's generous commitment to our Center.

Doctorate in Regulatory Science
A professional program that cultivates research, leadership and global capabilities for students in more advanced career stages.

MS in Regulatory Science
Designed to enhance the competencies of science-trained students to manage regulated medical products and foods.

MS in Medical Product Quality
Prepares students for careers as Quality professionals, providing the knowledge and skills required to ensure the safety of medical products worldwide.

MS in Management of Drug Development
Brings together skills and knowledge related to the formulation, quality management and testing of drugs in animals and people.

MS in Regulatory Management
Designed to provide post-doctoral scientists and clinicians with the knowledge and skills necessary to become leaders in regulatory and clinical research.

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Degree Programs

Five Graduate Streams

- DRSC
- **MS Regulatory Science**
- MS Regulatory Management
- MS Management of Drug Development
- MS Medical Product Quality

Certificates

- Food safety
- Regulatory Science
- Early Drug Development
- **Clinical Design and Management**
- Patient and Product Safety

Nancy Smerkanich
DRSc, MS
Assistant Professor
Department of Regulatory and Quality Sciences
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Symposiums

- **2015 -** Clinical Trial Hurdles
- **Spring 2016** - Clinical Trial Startup
- **Fall 2016** - Monitoring and Auditing
- **Spring 2017** - Clinical Trials in Special Populations
- **Fall 2017** - Clinical Trials in Era of Emerging Technologies and Treatments
- **Spring 2018** - Regulatory Aspects of Clinical Trial Design
- **Fall 2018** - Pharmacovigilance and Safety Reporting
- **Spring 2019** - Patient-Centered Drug Development and Real World Evidence/Data
- **Summer 2019** - Clinical Trials with Medical Devices
- **Fall 2019** - Legal Aspects of Conducting Clinical Trials
- **Spring 2020** - Quality by Design in Clinical Trials
- **Fall 2020 –** Diversity in Clinical Trials in the Time of COVID-19
- **Spring 2021** - TBD

Symposium recordings are easily accessible for viewing on the SC CTSI's online educational library
https://sc-ctsi.org/training-education/courses?audience=researchProfessionals

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Regulatory Science Virtual Symposium

Diversity in Clinical Trials in the Time of COVID-19

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Agenda

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3:00 PM PST	**Wrap-Up** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences I Associate Director, DK Kim International Center for Regulatory Science

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Presented by the USC School of Pharmacy International Center for Regulatory Science and the Southern California Clinical and Translational Science Institute

This certifies that

Before the end of todays Symposium you will receive a link to take the program evaluation.

Follow this link to the Survey:
Take the Survey

Please complete the program evaluation to receive a certificate of completion by Friday, October 30, 2020.

Eunjoo Pacifici, PharmD, PhD
Director
International Center for Regulatory Science

Thomas A. Buchanan, MD
Director
Southern California Clinical and Translational Science Institute

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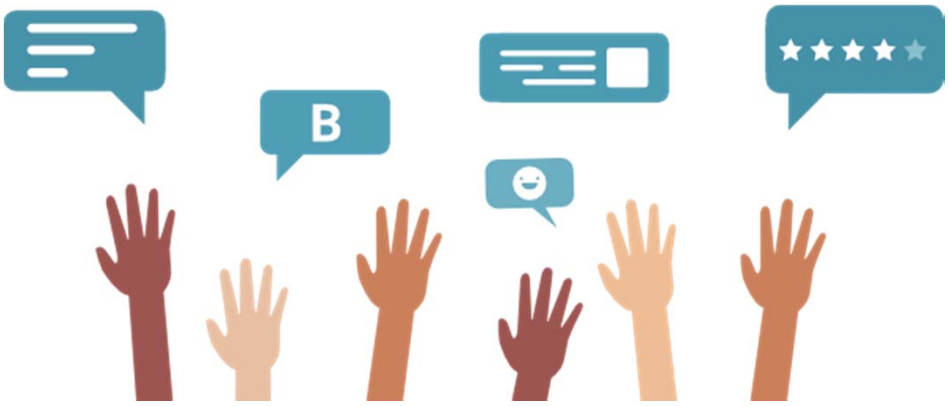
Time for Polls!



SC CTSI
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Twitter: @SoCalCTSI

USC School of Pharmacy
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Phone: (323) 442-3521
Email: regsci@usc.edu
Facebook: @RegSci

What Do We Mean by Diversity in Clinical Trials?

Eunjoo Pacifici, PharmD, PhD
epacific@usc.edu
Chair and Associate Professor, Regulatory and Quality Sciences
Associate Director, DK Kim International Center for Regulatory Science
President, Pharmacy Faculty Council

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Learning Objectives

01
Identify dimensions of diversity

02
Describe why diversity in clinical trials is important

03
Explain current landscape of diversity in clinical trials

04
Describe diversity in clinical trials of recently approved drugs

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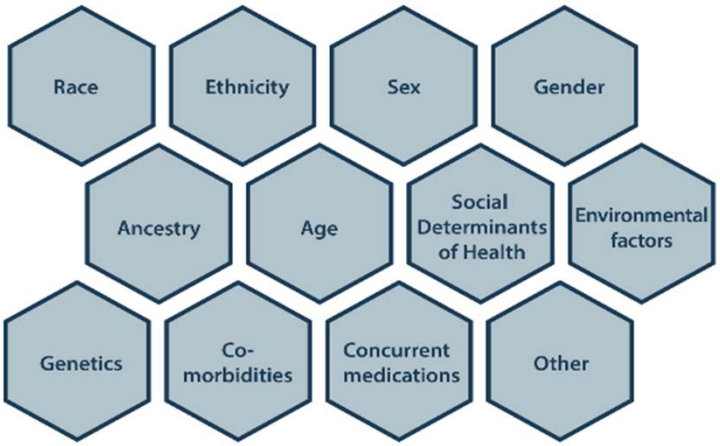
What is diversity?

Dimensions of Diversity



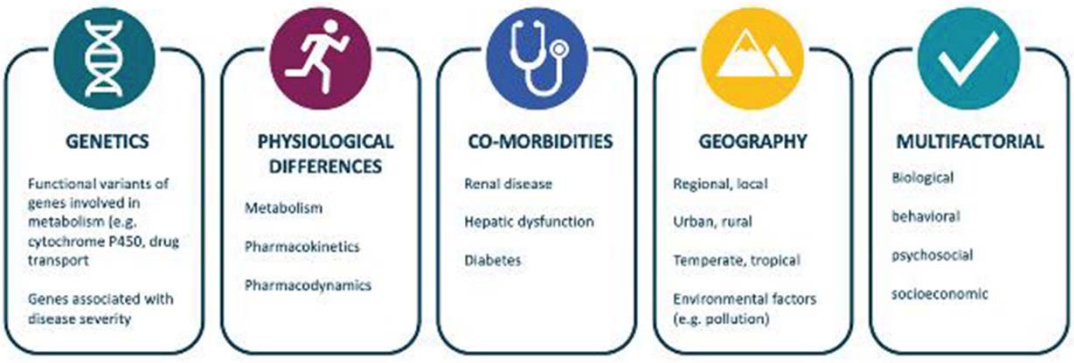
MRCT Center Diversity Guidance Document Version 1.0 – August 6, 2020

Intrinsic vs. Extrinsic Factors

INTRINSIC		EXTRINSIC
Genetic	Physiological and pathological conditions	Environmental
Gender	Age (children-elderly)	Climate Sunlight Pollution
Height Bodyweight		
	Liver Kidney Cardiovascular functions	**Culture** Socioeconomic factors Educational status Language
ADME Receptor sensitivity		
Race		Medical practice Disease definition/Diagnostic Therapeutic approach Drug compliance
Genetic polymorphism of the drug metabolism		
		Smoking Alcohol
		Food habits Stress
Genetic diseases	Diseases	Regulatory practice/GCP Methodology/Endpoints

https://database.ich.org/sites/default/files/E5_R1__Guideline.pdf

New products should be appropriate for patients who use them



MRCT Center Diversity Guidance Document Version 1.0 – August 6, 2020

Study populations in clinical research

- Should mirror the characteristics of the population affected by a particular illness or condition
- Reflect the characteristics of the population intended to use the product
- Inclusion of diverse populations is needed to understand
  - heterogeneity of treatment effect and safety
  - underlying biology
  - genetics, metabolism, or many other factors
  - interaction with concomitant drugs or biologics, compliance, comorbidities
- Prescribing information should be tailored for sub-populations

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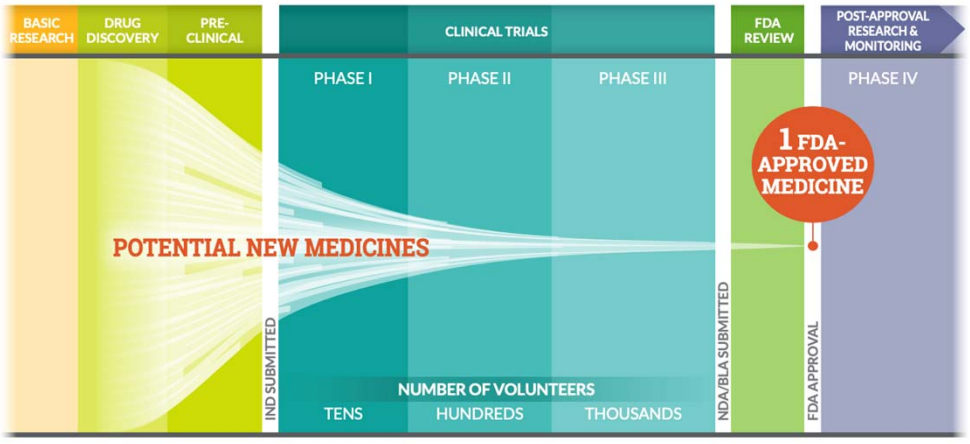
But developing a new product is challenging

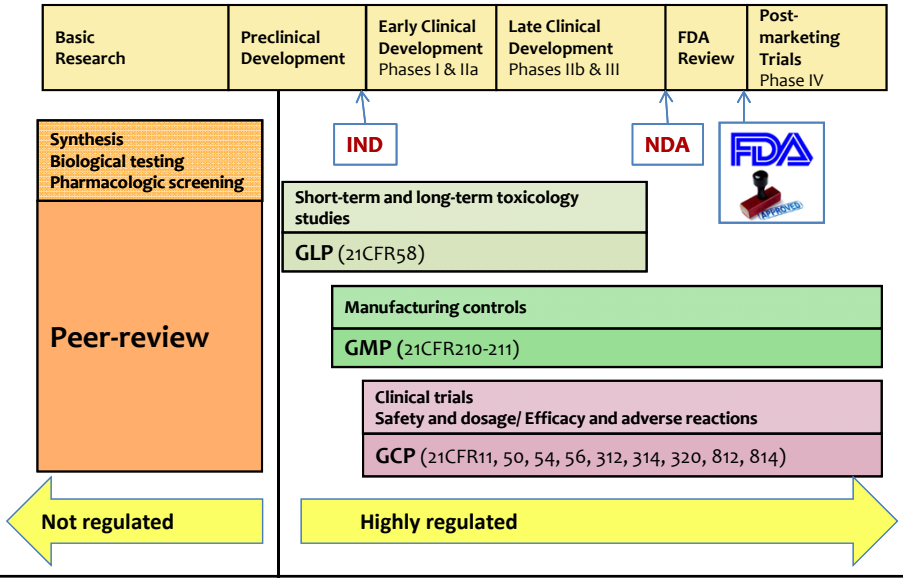


Key: IND=Investigational New Drug Application, NDA=New Drug Application, BLA=Biologics License Application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Sources: PhRMA adaptation of DiMasi JA et al.[12]; Tufts CSDD[13]; FDA[14]

The process is highly regulated



The goal: approved labeling

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use QINLOCK safely and effectively. See full prescribing information for QINLOCK.

QINLOCK™ (ripretinib) tablets, for oral use
Initial U.S. Approval: 2020

----------INDICATIONS AND USAGE----------
QINLOCK is a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. (1)

----------DOSAGE AND ADMINISTRATION----------
Recommended Dosage: 150 mg orally once daily with or without food. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets: 50 mg. (3)

----------CONTRAINDICATIONS----------
None. (4)

----------WARNINGS AND PRECAUTIONS----------
- Palmar-Plantar Erythrodysesthesia Syndrome: Based on severity, withhold QINLOCK and resume at same or reduced dose. (2.2, 5.1)
- New Primary Cutaneous Malignancies: Perform dermatologic evaluations when initiating QINLOCK and routinely during treatment. (5.2)
- Hypertension: Do not initiate QINLOCK in patients with uncontrolled hypertension and monitor blood pressure during treatment. Based on severity, withhold QINLOCK and then resume at same or reduced dose or permanently discontinue. (2.2, 5.3)
- Cardiac Dysfunction: Assess ejection fraction by echocardiogram or MUGA scan prior to initiating QINLOCK and during treatment, as clinically indicated. Permanently discontinue QINLOCK for Grade 3 or 4 left ventricular systolic dysfunction. (2.2, 5.4)
- Risk of Impaired Wound Healing: Withhold QINLOCK for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of QINLOCK after resolution of wound healing complications has not been established. (5.5)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.6, 8.1, 8.3)

----------ADVERSE REACTIONS----------
The most common adverse reactions (≥20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase and decreased phosphate. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Deciphera Pharmaceuticals, LLC, at 1-888-724-3274 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Strong CYP3A Inhibitors: Monitor more frequently for adverse reactions. (7.1)
- Strong CYP3A Inducers: Avoid concomitant use of strong CYP3A inducers. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 05/2020

Examples where differences exist

Clinical Pharmacology & Therapeutics

Review | Full Access

Racial/ethnic differences in drug disposition and response: Review of recently approved drugs

A Ramamoorthy, MA Pacanowski, J Bull, L Zhang

Clinical Pharmacology & Therapeutics, Volume: 97, Issue: 3, Pages: 263-273, First published: 13 December 2014, DOI: (10.1002/cpt.61)

DRUG	LABELING INFORMATION RELATED TO DIFFERENCES BY RACE/ETHNICITY	JUSTIFICATION
Angiotensin-converting enzyme inhibitor (ACE inhibitors) (e.g., captopril (Capoten®; enalapril (Vasotec®) and others)	A general statement in the labeling that states that ACE inhibitors are associated with a higher rate of angioedema in Black than in non-Black patients. First-line therapy in African-American/Black populations is often less effective than in non-Black patients due to lower renin profile in this population.	The risk of angioedema is ~5 times higher in African-Americans/Blacks. ACE Inhibitors, beta blockers and angiotensin receptor blockers are less effective as a class for hypertension in African-Americans/Blacks because renin-angiotensin-aldosterone is not dominant driver.

MRCT Center Diversity Guidance Document Version 1.0 – August 6, 2020

DRUG	LABELING INFORMATION RELATED TO DIFFERENCES BY RACE/ETHNICITY	JUSTIFICATION
Carbamazepine (Tegretol®)	A boxed warning in the drug label that describes the risk of serious and sometimes fatal dermatologic reactions (SJS/TEN), a risk higher in people of Asian ancestry. Patients of Asian ancestry should be tested for the presence of HLA-B*1502 allele prior to initiating treatment with this drug.	Studies in patients of Chinese ancestry have found a strong association between the risk of developing Stevens Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) and the presence of HLA-B*1502.

DRUG	LABELING INFORMATION RELATED TO DIFFERENCES BY RACE/ETHNICITY	JUSTIFICATION
Isosorbide dinitrate/hydralazine (Bidil®)	This treatment of heart failure was indicated as an adjunct therapy to standard therapy in self-identified Black patients to improve survival and improve patient-reported functional status.	Retrospective analyses suggested an effect on survival in Black patients but showing little evidence of an effect in White patients. Efficacy was confirmed by a trial enrolling only African-American/Black patients.
Rasburicase (Elitek®)	A boxed warning in the label indicating that patients at a higher risk of hemolysis if glucose-6-phosphate dehydrogenase (G6PD) deficient.	This product is contraindicated in patients with G6PD deficiency because of increased risk of hemolysis. G6PD deficiency is commonly seen in patients of African or Mediterranean ancestry.

Racial and ethnic differences across drugs

		Endpoint for observed interracial/ethnic differences[a]			
Generic name	Year of approval	PK	Safety	Efficacy	PMC/PMR
Ado-trastuzumab emtansine	2013		A		
Afatinib [O]	2013		A		
Alvimopan	2008	B, A, H	A		
Azilsartan medoxomil	2011	B		B	
Bedaquiline	2012	B			
Belimumab	2011			B	B
Bendamustine hydrochloride [O]	2008	A			
Crizotinib [O]	2011	A			
Crofelemer	2012			B	
Dronedarone hydrochloride	2009	A			
Eltrombopag [O]	2008	B, A	A [b,c]		
Everolimus	2009	B, A			
Fluticasone furoate & vilanterol	2013	A			
Ioflupane I-123	2011				NC
Lurasidone hydrochloride	2010	A			
Mirabegron	2012	A	A		
Pertuzumab	2012		A		
Pitavastatin calcium	2009	B			
Rivaroxaban	2011	A			
Roflumilast	2011	B, A, H			
Simeprevir	2013	A	A		A
Telaprevir	2011				B
Ticagrelor	2011	A			
Ulipristal acetate	2010	A			
Vandetanib [O]	2011	A			
Vigabatrin [O]	2009	A			

Need data to provide scientific evidence

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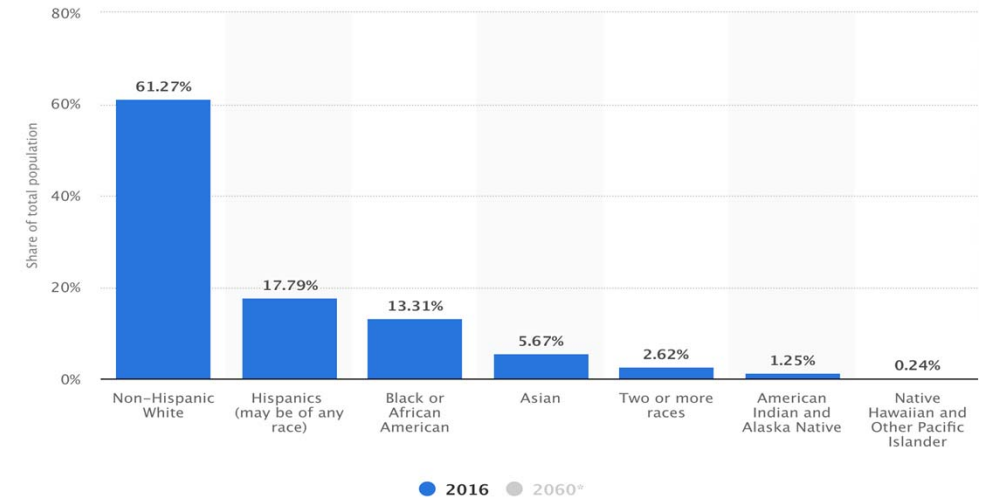
Demographics in U.S.



Details: United States; 2016

© Statista

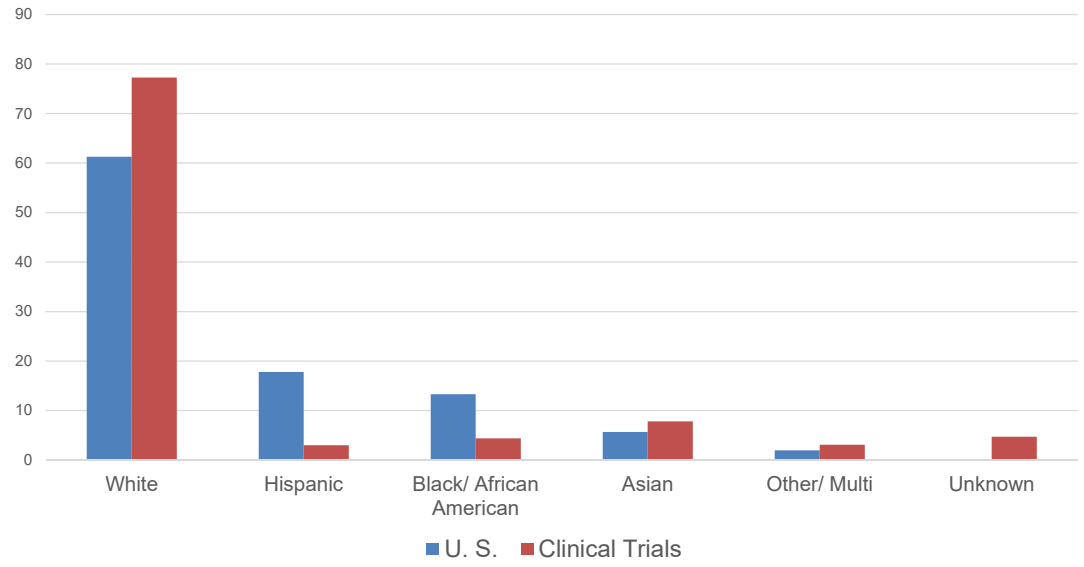
Demographics of Clinical Trials Participants in Pivotal Clinical Trials for New Molecular Entity Drugs and Biologics Approved by FDA From 2010 to 2012.

	2010	2011	2012	Overall
White	41,708 (79.5%)	83,551 (76.1%)	30,726 (76.7%)	155,985 (77.2%)
African American	1445 (2.7%)	3232 (2.9%)	4183 (10.4%)	8860 (4.4%)
Asian	2013 (3.8%)	11,266 (10.3%)	2418 (6.0%)	15,697 (7.8%)
Hispanic	2095 (4.0%)	1293 (1.2%)	2595 (6.5%)	5983 (3.0%)
Other	1353 (2.6%)	3532 (3.2%)	1366 (3.4%)	6251 (3.1%)
Unknown	5948 (11.3%)	3373 (3.1%)	251 (0.6%)	9572 (4.7%)

Eshera, Noha; Itana, Hawi; Zhang, Lei; Soon, Greg; Fadiran, Emmanuel

American Journal of Therapeutics. 22(6):435-455, November/December 2015.

Lack of diversity (%)



Need clinical trial data to include

- Race, ethnicity, sex, gender, age, and geographic ancestry
- Social, cultural, and economic factors, these factors
- To understand differences in
  - disease susceptibility and manifestation
  - treatment response, dose, schedule
  - adverse effects

Diversity and inclusion in clinical research

- Identify subpopulation variability in
  - diagnosis, treatment, and prevention
- Identify important group-specific efficacy and safety signals
- Help to develop effective treatments for those most likely to use them

This is complex…

- Some dimensions of diversity (age, sex) represent biological differences
- Others (race, ethnicity) represent social constructs
- But race and ethnicity may be related to other factors such as genetic allelic frequencies, environmental factors, and social conditions
- It is important to identify underrepresentation of subgroups
- And find ways to be inclusive of every demographic
- For justice, health equity, and trust

COVID-19 exposes differences in vulnerability

- Black
- Latinx
- Pacific Islander
- Homeless
- Incarcerated
- Aged
- Institutionalized
- With comorbidities (e.g., hypertension, diabetes, obesity)
- Potential genetic differences

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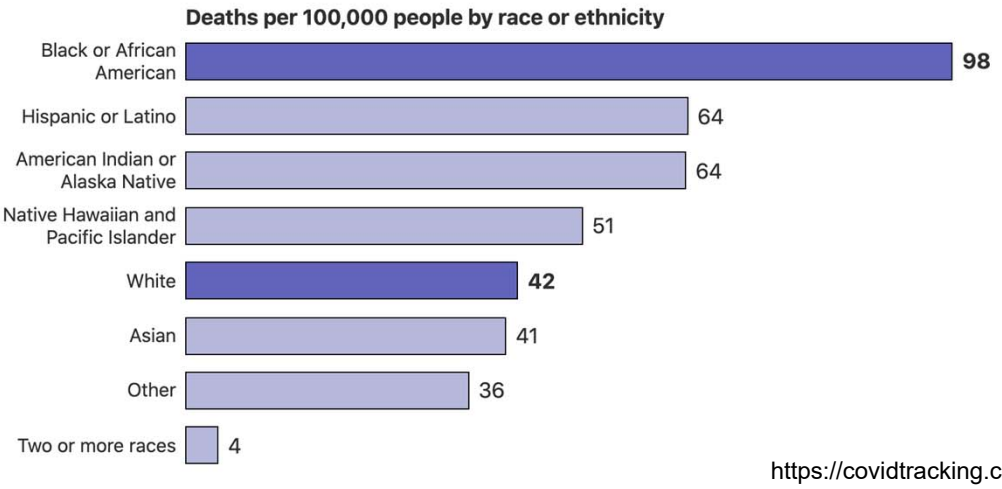
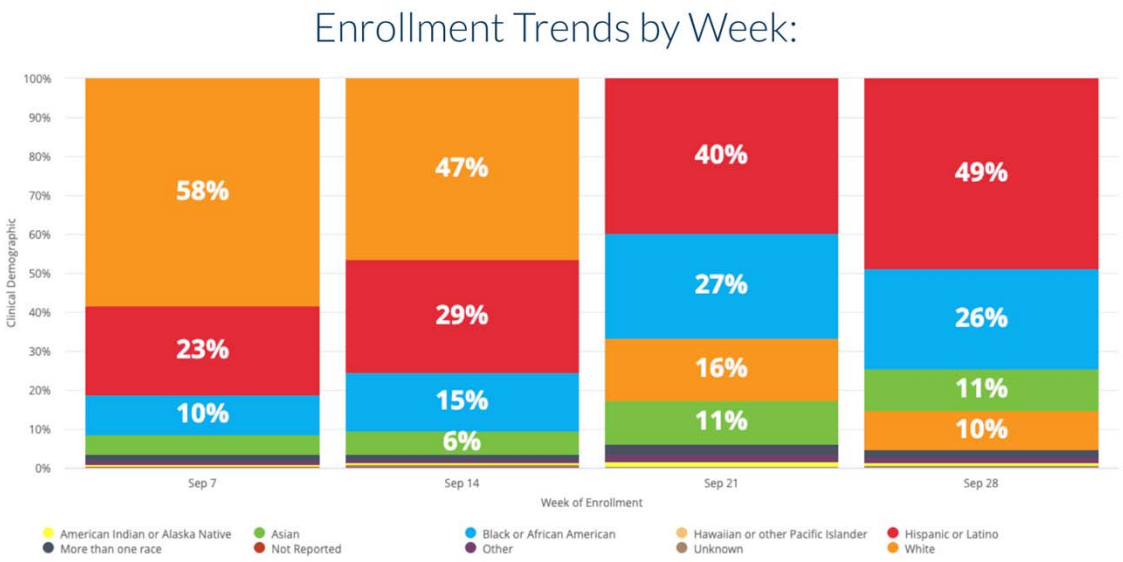
Nationwide, Black people are dying at 2.3 times the rate of white people.



https://covidtracking.com/

Inclusion efforts can be successful



https://www.modernatx.com/cove-study

Thank You

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FDA Initiatives to Address Diversity in Clinical Trials

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Assistant Professor, Regulatory and Quality Sciences

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Disclaimer

The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use.

- FDA does not develop new treatments or conduct clinical trials
  - FDA provides guidance to drug developers in academia (via NIH) and to industry sponsors who conduct the clinical trials

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FDA Guidance on Diversity

The FDA guidance on patient diversity does not specifically dictate what sponsors should do to make their trials more diverse.

- It does state trials should recruit patients that represent the population that has the burden of disease in the real world
- Failing to recruit a representative patient population may result in firms having to conduct additional research (e.g. clinical trials), which could delay the marketing application, approval and launch of a product

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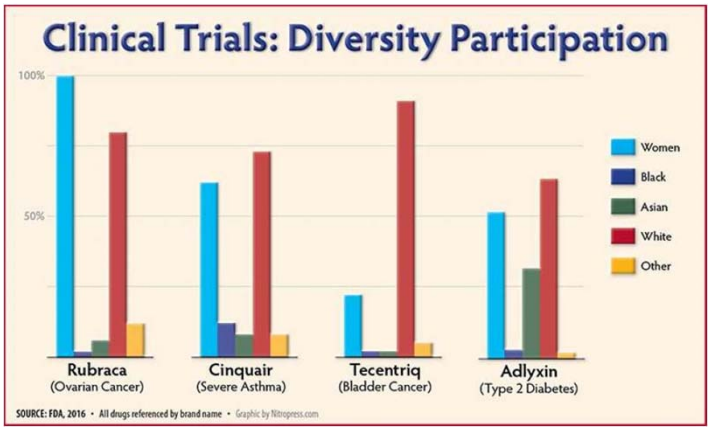
Clinical Trial Participation



FACT 1: Racial and ethnic minorities are underrepresented in clinical trials.

Fact 2: People of different ages, races, and ethnicities may react differently to medical products

For the products you see here it is known that these indications have different prevalence and possible drug effects in various subgroups which were not represented in the clinical trials for their therapeutic approvals

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Diversity in Sex/Gender

- Historically, females were excluded from clinical trials due to concerns about hormonal interference and child-bearing potential
- FDA Office of Women's Health (OWH) was established by Congressional mandate in 1994
  - One of their goals was to promote the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of sex/gender analysis
- Now women are in clinical trials in representative numbers (~51%)
  BUT women from **diverse backgrounds** still need to participate.
- Women of all ages, racial and ethnic groups, and women with disabilities or chronic health conditions are needed in clinical trials.

Office of Women's Health (OWH)

OWH recognizes Sex as a Biological Variable (SABV) that should be factored into research design, analysis, reporting and education.

Three scientific and educational projects:

Research and Development
https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research
Outreach and Communications
https://www.fda.gov/consumers/womens-health-topics/take-time-care-program
Medical initiatives and Scientific Engagement

FDA Office of Women's Health

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FDA Safety & Innovation Act (FDASIA - 2012)

Sec. 907 of FDASIA directed FDA to investigate how well demographic subgroups (sex, age, race and ethnicity) in applications for medical products – drugs, biologics and devices, submitted to the agency for marketing approval:

1) Are included in clinical trials; and
2) If subgroup-specific safety and effectiveness data are available.

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FDA Safety & Innovation Act (FDASIA - 2012)

- Section 907 also required the FDA to provide Congress with an **action plan** detailing "recommendations for improving the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data"
- Product labeling needs to include this data or note the lack of it!

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FDA Action Plan (2014)

Full title: FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data

- Priority One: Improve the completeness and quality of demographic subgroup data collection, reporting and analysis (**Quality**)
- Priority Two: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (**Participation**).
- Priority Three: Make demographic subgroup data more available and transparent (**Transparency**)

Available here: https://www.fda.gov/media/89307/download

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Priority 1

- 1.1. Reviewing and developing a work-plan for updating, and/or finalizing, relevant guidance on demographic subgroup data, including FDA staff training and outreach to external stakeholders, as needed, for implementation;
- 1.2. Working with sponsors to revise medical product applications to enhance information on demographic subgroups in medical product applications;
- 1.3. Strengthening FDA reviewer training by adding education/training around demographic inclusion, analysis, and communication of clinical data;
- 1.4. Enhancing FDA's systems for collecting, analyzing, and communicating diverse clinical information to optimize safe and effective use of medical products in diverse populations over the total product life cycle;
- 1.5. Conducting research on specific areas of public health concern related to demographic subgroups

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FDA Guidance

Contains Nonbinding Recommendations

Collection of Race and Ethnicity Data in Clinical Trials

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-5084 or omh@fda.hhs.gov.

U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Minority Health (OMH)
Office of Women's Health (OWH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)

October 2016
Clinical Medical

Race Data Standard

What is your race? (One or more categories may be selected)

a. ____White
b. ____Black or African American
c. ____American Indian or Alaska Native

These categories are part of the current OMB standard

d. ____Asian Indian
e. ____Chinese
f. ____Filipino
g. ____Japanese
h. ____Korean
i. ____Vietnamese
j. ____Other Asian

These categories roll up to the Asian category of the OMB standard

k. ____Native Hawaiian
l. ____Guamanian or Chamorro
m. ___ Samoan
n. ____Other Pacific Islander

These categories roll-up to the Native Hawaiian or Other Pacific Islander category of the OMB standard

Ethnicity Data Standard

Are you Hispanic, Latino/a, or of Spanish origin? (One or more categories may be selected)

a. ____No, not of Hispanic, Latino/a, or Spanish origin
b. ____Yes, Mexican, Mexican American, Chicano/a
c. ____Yes, Puerto Rican
d. ____Yes, Cuban
e. ____Yes, Another Hispanic, Latino/a or Spanish origin

These categories roll up to the Hispanic or Latino category of the OMB standard

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Priority 2

- 2.1 Seeking further clarity about barriers to subgroup participation rates;
- 2.2 Implementing efforts to enhance appropriate use of enrollment criteria in clinical trial protocols;
- 2.3 Collaborating with NIH, industry and other interested stakeholders to broaden diverse participation in clinical research;
- 2.4 Using FDA's communication channels to encourage clinical trial participation by demographic subgroups.

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Priority 3

- 3.1 Posting demographic composition and analysis by subgroup in pivotal clinical studies for FDA approved medical products;
- 3.2 Identifying potential methods to consistently communicate meaningful information on demographic subgroups in medical product labeling;
- 3.3 Implementing communication strategies that are sensitive to the needs of underrepresented subpopulations, with a focus on language access and health literacy; and
- 3.4 Establishing an internal FDA steering committee to oversee and track implementation of the action plan and serve as planning group for an FDA workshop on the action plan.

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Labeling and Literacy - Drug Trials Snapshots

- For new FDA approved products Drug Trials Snapshots are created to provide consumers with information about who participated in clinical trials that their registration.
- The information provided in these Snapshots also highlights whether there were any differences in the benefits and side effects among sex, race and age groups.
- Drug Trials Snapshots is part of an overall FDA effort to make demographic data more available and transparent

https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

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Drug Trials Snapshot - ADLYXIN (lixisenatide)

DRUG TRIALS SNAPSHOT SUMMARY:

What is the drug for?
ADLYXIN is a drug that improves blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise.

How is this drug used?
ADLYXIN is available as a liquid that comes in a prefilled pen. It is injected once daily under the skin (subcutaneously) before the first meal of the day.
ADLYXIN may be used alone or in combination with other FDA-approved diabetic medications such as metformin, sulfonylureas, pioglitazone and insulin.

What are the benefits of this drug?
In patients with type 2 diabetes, treatment with ADLYXIN can lower HbA1c (hemoglobin A1c, which is a measure of blood sugar control).

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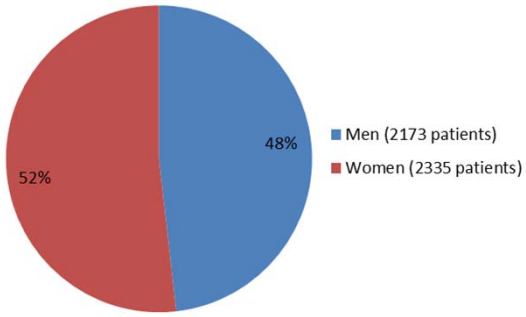
Drug Trials Snapshot - ADLYXIN (lixisenatide)

Were there any differences in how well the drug worked in clinical trials among sex, race and age?

- **Sex**: ADLYXIN worked similarly in men and women.



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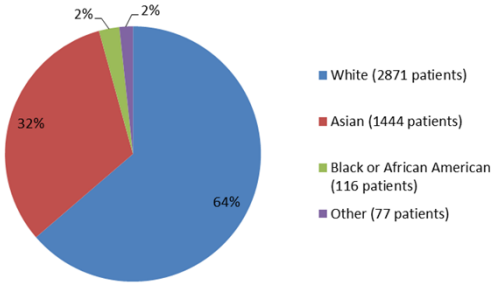
Drug Trials Snapshot - ADLYXIN (lixisenatide)

Were there any differences in how well the drug worked in clinical trials among sex, race and age?

- **Race**: The majority of patients were White and Asian. ADLYXIN worked slightly better in Asians than in White patients. The number of patients of other races were limited; therefore, differences in response among other races could not be determined



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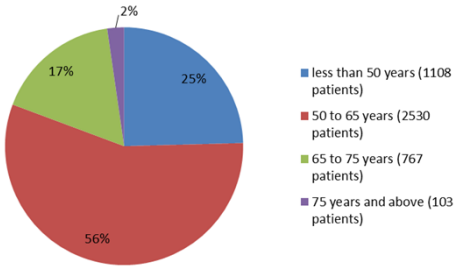
Drug Trials Snapshot - ADLYXIN (lixisenatide)

Were there any differences in how well the drug worked in clinical trials among sex, race and age?

- **Age**: ADLYXIN worked similarly in patients below and above 65 years of age.



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FDA Office of Minority Health and Health Equity (OMHHE)

- Established in 2010, the FDA OMHHE is the first office at FDA dedicated to protecting and promoting the health of diverse populations through research, outreach, and communication that works toward addressing health disparities, health equity, and ultimately strengthening FDA's ability to respond to minority health concerns
- OMHHE is leading groups made up of many FDA centers to develop actions that will reduce health disparities.
- 10th Anniversary video: https://www.fda.gov/consumers/minority-health-and-health-equity/fda-office-minority-health-and-health-equity-10-year-anniversary

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OMHHE – Diversity in Clinical Trials Initiative

Goal:
To raise awareness around racial and ethnic minority participation in clinical trials

Approach:
Ongoing multimedia campaign to raise awareness about the importance of diverse participation in clinical trials and includes multiple strategies that highlight the value, risks, and benefits of clinical trial participation

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OMHHE – Diversity in Clinical Trials Initiative

Tools:

- Educational materials like brochures, fact sheets, and post cards, in multiple languages
- Videos and public service announcements featuring diverse spokespersons sharing their unique perspectives on clinical trials
- Social media outreach encouraging different groups to participate in clinical trials, including tailored graphics that are representative of our communities
- Outreach to engage different communities and health professionals to raise awareness about the need for diverse participation in clinical trials
- Webinars, lectures, and podcasts
- Webpage with all resources and materials, including a communications toolkit

All materials can be found at www.fda.gov/healthequity

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Clinical Trials Transformation Initiative (CTTI)

CTTI is a Public (FDA)-Private (Membership) Organization
KEY PROJECT: The Value of Increasing Diversity in Clinical Trials

- The underrepresentation of diverse populations in clinical trials creates knowledge gaps about the risks and benefits of drugs and devices for the public.
- CTTI is addressing the value of including diverse patient populations in clinical trials throughout the development lifecycle of medical products—from early target identification through clinical trial conduct to increase research discoveries is vital.

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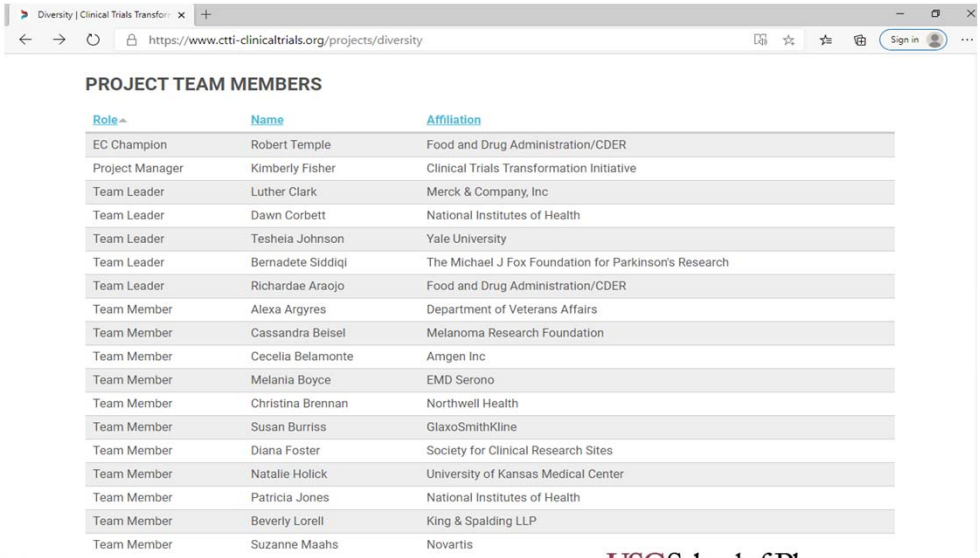
CTTI – Diversity Project



PROJECT TEAM MEMBERS

Role	Name	Affiliation
EC Champion	Robert Temple	Food and Drug Administration/CDER
Project Manager	Kimberly Fisher	Clinical Trials Transformation Initiative
Team Leader	Luther Clark	Merck & Company, Inc
Team Leader	Dawn Corbett	National Institutes of Health
Team Leader	Tesheia Johnson	Yale University
Team Leader	Bernadete Siddiqi	The Michael J Fox Foundation for Parkinson's Research
Team Leader	Richardae Araojo	Food and Drug Administration/CDER
Team Member	Alexa Argyres	Department of Veterans Affairs
Team Member	Cassandra Beisel	Melanoma Research Foundation
Team Member	Cecelia Belamonte	Amgen Inc
Team Member	Melania Boyce	EMD Serono
Team Member	Christina Brennan	Northwell Health
Team Member	Susan Burriss	GlaxoSmithKline
Team Member	Diana Foster	Society for Clinical Research Sites
Team Member	Natalie Holick	University of Kansas Medical Center
Team Member	Patricia Jones	National Institutes of Health
Team Member	Beverly Lorell	King & Spalding LLP
Team Member	Suzanne Maahs	Novartis

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CTTI Diversity Project

Scientific Rationale

- In women, these factors include, but are not limited to, sex hormones; changes in sex hormones due to menstruation, pregnancy, menopause, oral contraceptives; body fat composition; and environmental factors related to disparities in the practice of medicine between men and women
- In racial and ethnic minorities, disparities result from an interplay of *intrinsic* individual characteristics, such as the route of drug administration, and *extrinsic* factors such as culture, diet, the practice of medicine, and socioeconomic status
  - One example illustrating this issue is the African American atrial fibrillation (AF) "double paradox," which demonstrates how racial disparities in the practice of medicine impact overall population-level disease outcomes

CTTI Diversity Findings on Investigators/Sites

Research teams at sites face barriers

- lack of cultural competency,
- lack of resources and staffing to develop and implement accrual strategies targeted to underrepresented populations.

Common strategies used to address investigator-level barriers include

- cultural competency training
- intentional hiring practices that diversify research teams.

Case Study

TODAY (**T**reatment **O**ptions for type 2 **D**iabetes in **A**dolescents and **Y**outh) study.

- Native Americans have the highest prevalence of type 2 diabetes of any racial or ethnic group
- The University of Oklahoma included representative organizations from this key demographic and integrated the study into the health care ecosystem
- The result was a study that successfully engaged and retained Native American adolescents.

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Case Study

Patient Navigator Program

- The University of Alabama at Birmingham's Comprehensive Cancer Center
- UAB sought to increase the participation of African Americans in clinical trials by providing community education and conducting needs assessments to support patients.
- The result was a significant increase in African American enrollment and retention in clinical trials

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CTTI Diversity Findings on Sponsors

Sponsors can assist sites with

- aligning resources,
- provide incentives,
- accountability mechanisms to accrue underrepresented populations.

Some strategies involve

- specialized training programs for new minority investigators,
- intentional partnerships with sites that have proven success in the accrual of underrepresented populations,
- partnerships with community-based organizations.

Case Study

Lupus is two to three times more prevalent in women of color, which creates a sizeable health disparity.

- A recent lupus treatment that was approved by the FDA without robust data on efficacy in a diverse population.
- The company sponsoring those trials was required to conduct additional post-marketing research, which found mixed results on the treatment's efficacy in the African American population

NIH Initiatives

Legal basis:

The NIH is mandated by the Public Health Service Act to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study.

- The statute requires clinical trials to be designed to provide information about differences by sex/gender, race and/or ethnicity

Primary Goal:

- To ensure that research findings can be generalizable to the entire population

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Diversity in Covid19 Trials

COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
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)

May 2020
Clinical/Medical

- Clinical trials should include persons at high risk of complications such as the elderly, persons with underlying cardiovascular or respiratory disease, diabetes, chronic kidney disease, or other comorbidities, and immunocompromised persons (e.g., HIV-infected patients, organ transplant recipients, or patients receiving cancer chemotherapy).[11]
- COVID-19 disproportionately affects adults, including older individuals. The geriatric population should be appropriately represented in clinical trials.[12] Sponsors should consider conducting trials in nursing homes or other elder care facilities.
- Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.[13]

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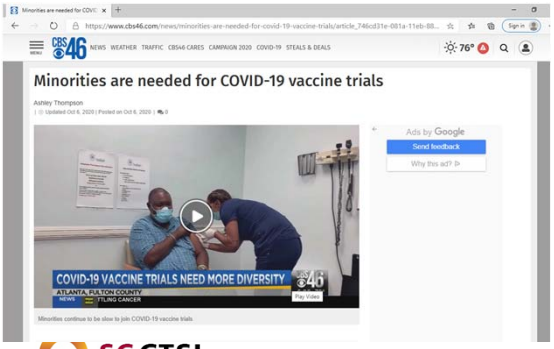
Diversity in Covid19 Trials

CORONAVIRUS
Published October 6
Moderna sees shortcomings in coronavirus trial minority enrollment, faces delays: report
The proportion of minority participants should reflect nationwide population to determine efficacy in these groups



THE CORONAVIRUS CRISIS
As COVID-19 Vaccine Trials Move At Warp Speed, Recruiting Black Volunteers Takes Time

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Final Thoughts

Addressing the barriers to under-represented populations and developing strategies to tackle them is critical.

Increasing diversity in clinical trials is something we must all do **together**!

QUESTIONS?

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Clinical Trial Participation:

Understanding the Needs & Importance of Diverse Populations

Joan A. Chambers
Senior Director, Marketing & Outreach

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Journey on Clinical Trial Participation

Decision Making

Participation Challenges

Convenience Enhancing Technologies & Support

Additional DtP Considerations

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Discussion Areas Through the Journey

- Understanding the importance of patient diversity in clinical trial participation
- Exploring different perceptions about clinical research among diverse demographics
- Ensuring patient safety and compliance through use of relevant technologies
- Simplifying the process for patients through exploring the potential for patient apps and video dosing
- Considering the concept of continuous data collection with wearables to remotely capture, transmit, and store data in a secure platform
- Exploring the future of patient centricity within clinical trials; how is this process likely to evolve over the next couple of years?

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Current State

- **Wide - acknowledgement of disparities that exist**
  - Clinical trials and beyond
- **Level of importance and need to address**
- **Work being done**
  - Using data in new, innovative ways
  - Industry collaborating with PAGs, community organizations
  - FDA Guidance

Source: Tufts CSDD, 2020

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Importance of Clinical Trial Research…

…in developing treatments and advancing healthcare is widely acknowledged.

- In 2019 alone,
  - 46,391 study volunteers contributed to clinical trials that resulted in the approval of 48 novel drugs.
  - Demographic subpopulations represented:
    - 9% of study volunteers were Black/African American
    - 9% Asian
    - 18% Hispanic
    - Highlights a lack of representation of diverse populations in clinical trial participation
  - FDA recommends broadening eligibility criteria to enhance diversity in clinical trials and to better reflect the patients who will be using a drug once it is approved.

Source: U.S. FDA (2019). Drug Trials Snapshots Summary Report. U.S. FDA (2019) Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry. *Draft Guidance Issued June.*

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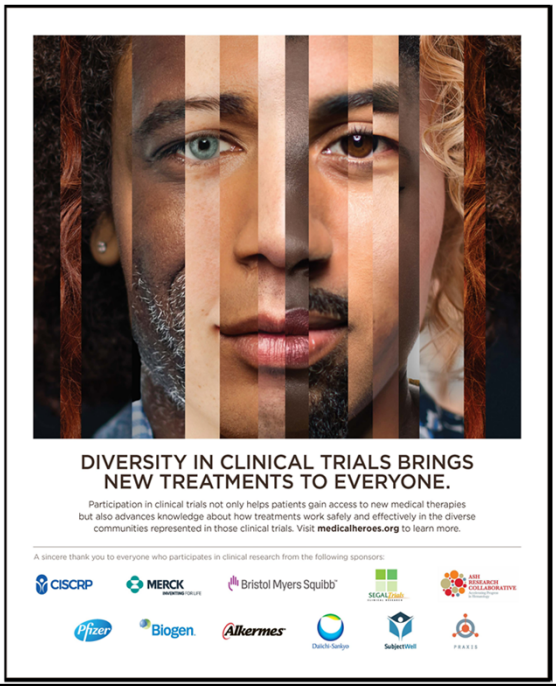

Deciding to Participate

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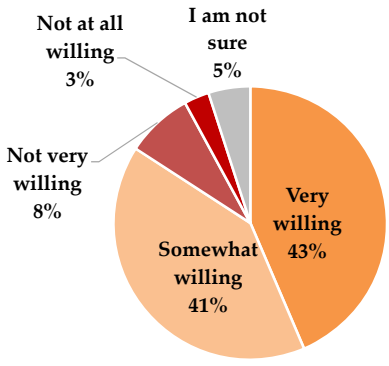
Willingness to Participate Does Not Always Translate into Participation

General willingness to participate in trial



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Participation in clinical trials

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Source: 2019 CISCRP Perceptions and Insights Study (n=12,451)

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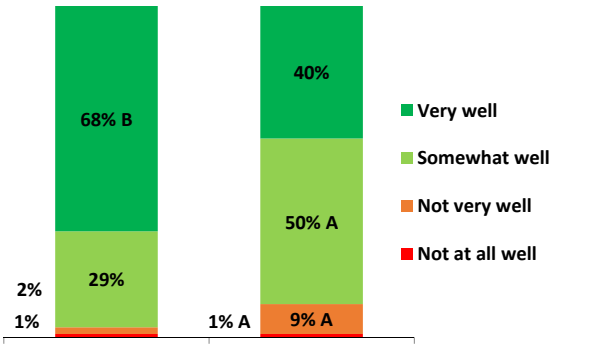
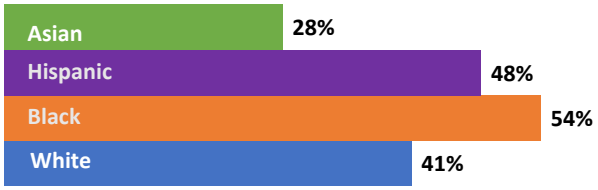
Black and Hispanic Populations More Confident in Knowledge, Asians Least Confident

How well do you understand what is meant by the term "clinical research study"?



% indicating understanding 'Very well'



Base: Those who never participated

SC CTSI Letters indicate statistical significance at 95%

Source: CISCRP 2019 Perceptions and Insights Study

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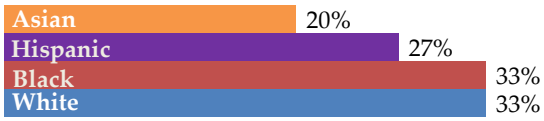
Mistrust of Pharma Companies Issue Among Both White and Black Populations

How much do you trust…? (n=12,451)	Not at all/ Not too much	Some	A lot
Pharmaceutical companies	32%	50%	18%
Research centers/clinics	11%	57%	31%
Regulatory agencies (FDA, EMA)	19%	54%	27%
Government research organizations (NIH, CDC)	18%	53%	29%

*% indicating trusting **pharmaceutical companies** "**Not at all/not too much**"*



Base: all respondents

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Source: CISCRP 2019 Perceptions and Insights Study

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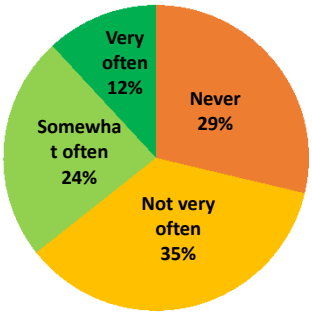
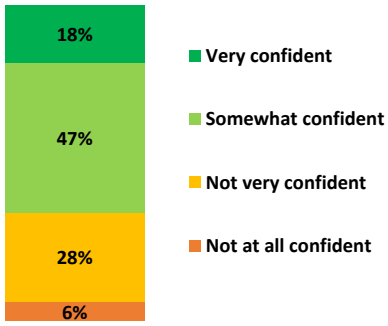
Clinical Trials Not Often Considered in HCP Discussions, but Patients can Advocate for Clinical Trials

When discussing treatment or medication options with your primary care physician (general practitioner) and/or specialist, how often do you consider clinical research studies as an option?



If your [doctor] was not interested in recommending a clinical research study as an option, how confident do you feel that you could convince him/her otherwise?



Sample Size = 12,451 Base: All respondents

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Source: CISCRP 2019 Perceptions and Insights Study

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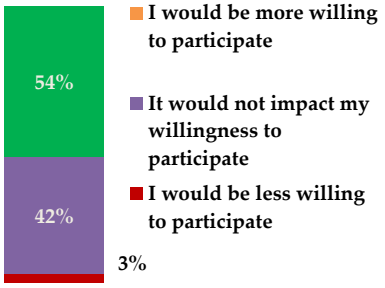
HCP Advice and Involvement Impact Willingness to Participate, Particularly Among Black Population

If you knew your primary care physician or specialist was conducting the clinical research study, how much of an impact, if any, would this have on your willingness to participate?



*% indicating '**more willing to participate**'*

Base: All respondents

Sample Size = 12,451 Base: All respondents

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Source: CISCRP 2019 Perceptions and Insights Study

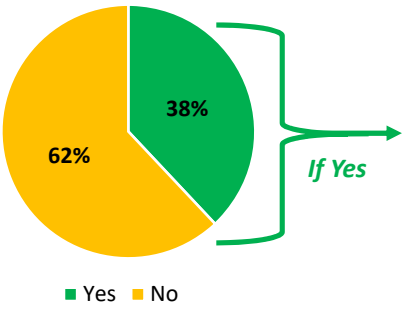
People would trust their **doctor's advice** the most when making a decision to participate in a clinical trial

However, Most Have Never Been Asked to Participate

Have you ever been asked to participate in a clinical research study?

✓ **Black/African Americans more likely to be asked than other races**

% Responding



Sample Size = 12,451 Base: All respondents

How were you asked to participate?

Top mentions:

- Through an email I received from a research study center or patient recruitment company (42%)
- Through a telephone call from a research study center or patient recruitment company (20%)
- Through my primary care physician (18%)

Sample Size = 4,750 Base: "Yes" asked to participate

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Source: CISCRP 2019 Perceptions and Insights Study

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Important Participation Considerations

If you were to participate in a clinical research study, how important are the following to your participation? *% indicating "Very important"*	White (n=9,671)	Black (n=691)	Hispanic (n=1,574)	Asian (n=1,427)
Provided with supporting information on managing my health condition in general	49%	**65%**	**64%**	47%
Provided with supporting information on the clinical research study (e.g., study guides, pamphlets)	48%	**62%**	**54%**	41%
Provided the opportunity to complete a satisfaction survey on your clinical research study experience	40%	51%	47%	35%
Concierge services	32%	**46%**	**44%**	35%
Clinical study medicine delivered to my home	30%	41%	43%	31%
Availability of clinical research study information designed specifically for caregivers	29%	42%	46%	34%
Availability of mobile applications (e.g., electronic surveys, visit reminders sent via text)	29%	**47%**	**41%**	29%
Review and sign documents in electronic format	27%	**42%**	**39%**	28%
Some/all study visits conducted at my home or my office	20%	33%	32%	26%

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Source: CISCRP 2019 Perceptions and Insights Study

(n= 12,451) Base: All respondents

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Key Information for Participation Decision

HIGH IMPORTANCE

Before making a decision to participate in a clinical research study, how important is it to you to know each of the following types of information? *% indicating "Very important"*	Base: All respondents (n=12,451)
Potential risks and benefits	81%
Purpose of the clinical research study	74%
Types of medical procedures required	71%
If my confidentiality would be protected	64%
Potential costs and reimbursements	**58%**
Physical location of the research study center	**57%**
If I would receive a summary of the study results after my participation ended	55%
Length of participation in the clinical research study	**54%**
Results and information from earlier phase studies on the study drug	52%
Duration of each study visit	**48%**
Number of study visits	**47%**
If time off from work is compensated	**40%**

CISCRP 2019 P&I Survey: n= 12,451 Base: All respondents

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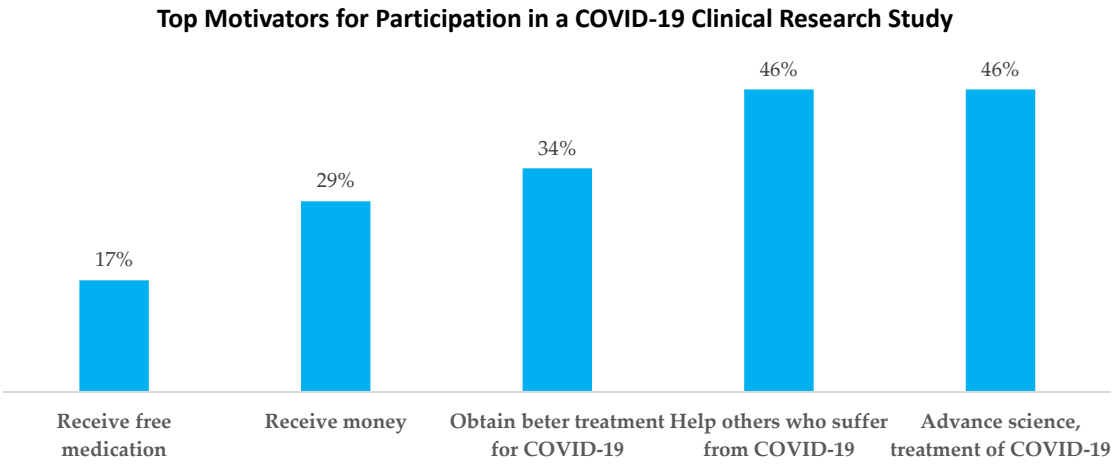
Top Participation Barriers Include Logistical Concerns

Motivations	Barriers
✓ Advance science/treatments (62%)	× Not wanting to risk health (49%)
✓ Help others with my disease (57%)	× Risks involved(46%)
✓ Better treatment (51%)	× Not knowing enough (25%)
✓ Education about disease/treatment (47%)	× Don't want to be treated as a test subject (22%)
✓ Compensation (42%)	× Risk of placebo (16%)
✓ Access to healthcare providers (29%)	× Too much time required (15%)
✓ Free medication/treatment (28%)	× Can't afford time off(14%)
✓ Information about the study influenced (23%)	× Too difficult to get to the research center (12%)
n=10,479 | Base: Those who said they would be 'Very' or 'Somewhat willing' to participate	n=1,974 | Base: Those who said they would be 'Not at all' or 'Not very willing' or were 'Unsure'

Participation in COVID-19 Clinical Trials



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Source: CISCRP April 2020 Survey; N=272| Base: Individuals indicating 'somewhat' or 'very willing' to participate

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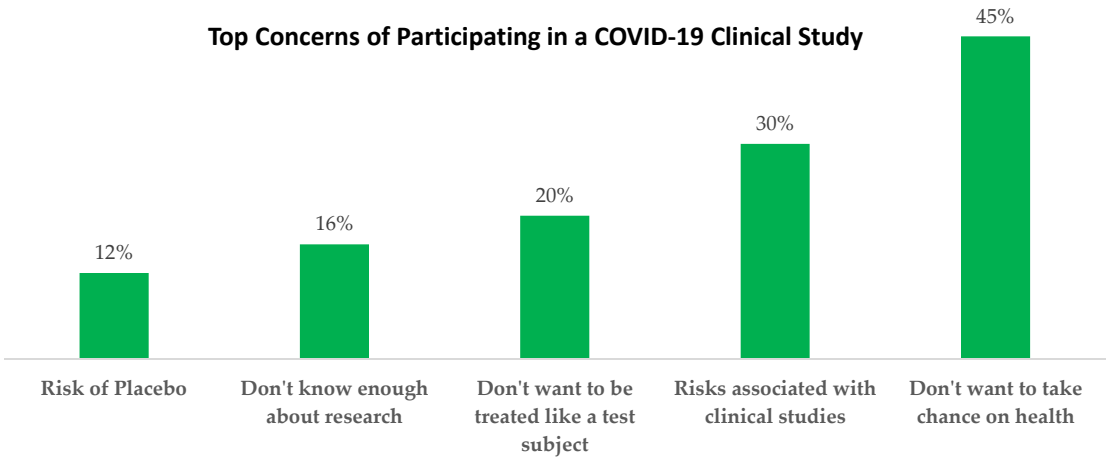
Concerns in Participating in COVID-19 Clinical Trials



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Source: CISCRP April 2020 Survey; N=228 | Base: Individuals indicating 'not sure', 'not at all' or 'not very' willing to participate

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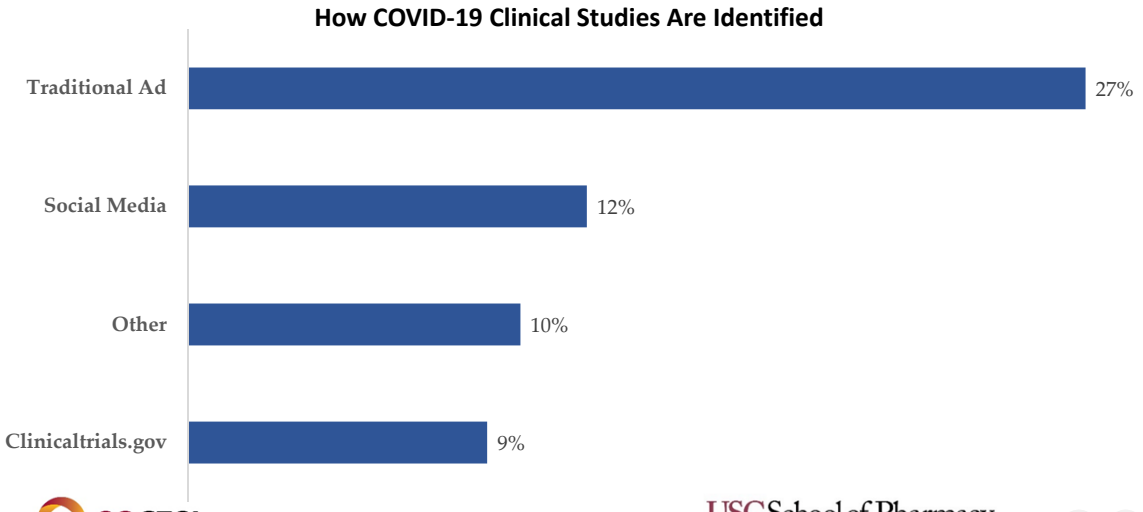
Awareness of COVID-19 Clinical Trials



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Source: CISCRP April 2020 Survey; N=184|Base: Individuals who knew of a COVID-19 clinical research study

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Seeking Advice When Deciding to Participate

Healthcare professionals are very influential during the decision-making process

If you knew your primary care physician or specialist was conducting the clinical research study, how much of an impact, if any, would this have on your willingness to participate?

More Willing	No Impact on Willingness
54%	42%

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CISCRP 2019 P&I Survey: n= 12,451 Base: All respondents

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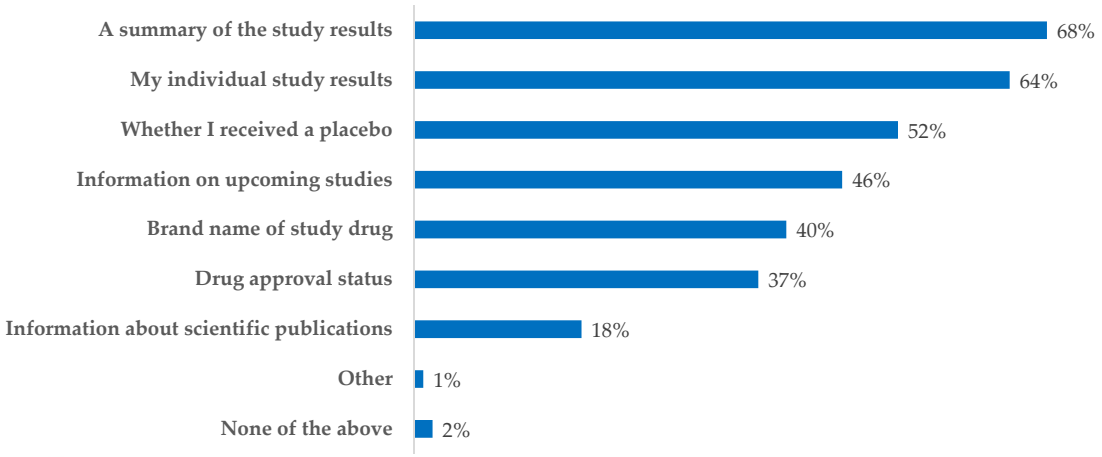
Receiving Information After Completing Study Participation



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Source: CISCRP April 2020 Survey; N=3,654|Base: Individuals who have participated in a clinical trial

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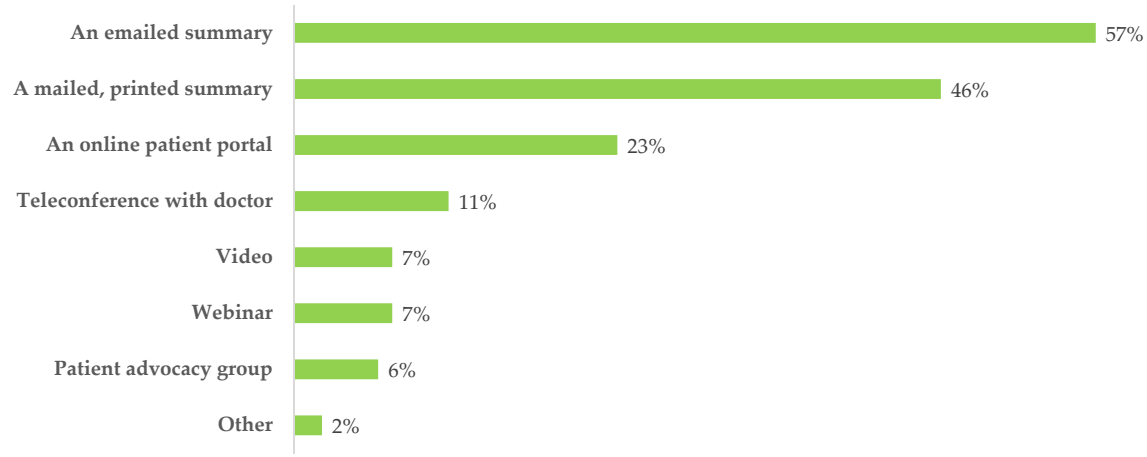
Preferences on Delivery of Clinical Trial Results



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Source: CISCRP April 2020 Survey; N=3,654|Base: Individuals who have participated in a clinical trial

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Participation Challenges

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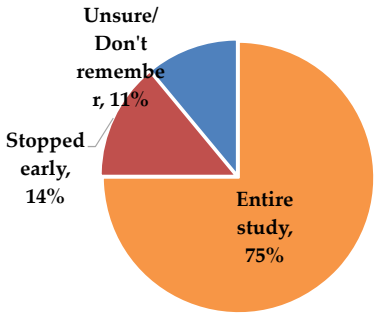
Participation for the Duration of the Study Depends on Several Factors

Did you participate in the entire research study or did you stop before your last scheduled study visit?



Sample Size = 3,654, Base: Those who have participated in a clinical trial

Top reasons for stopping participation

Voluntary Reasons:

- **Location of the study (13%)**
- Poor communication with study (11%)
- **Time commitment too much (11%)**

Involuntary Reasons:

- Side effects of study drug (14%)
- No longer qualified due to lab tests/other complications (20%)

Sample Size = 506, Base: Stopped participation in clinical trial

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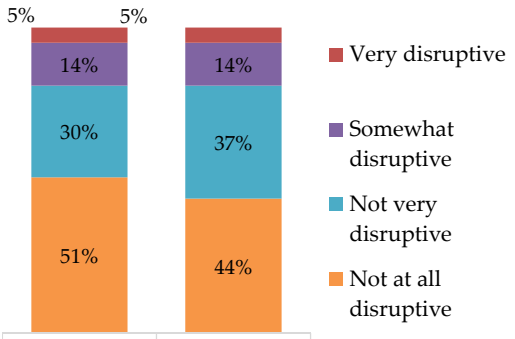
Travel, Length of Visits, Diagnostic Tests Among Top Burdens

How much did your participation affect your general daily routine?



How burdensome was each of the following?	% Somewhat or Very Burdensome
Traveling to the study clinic	**29%**
The length of the study visits	**21%**
Undergoing diagnostic tests (e.g. X-rays, MRIs)	21%
Completing health questionnaires	18%
Lab work (e.g. blood tests, urine)	17%
Taking the clinical study medicine	15%

Travel time to clinic (one way)*:

- Less than 30 minutes: 44%
- 30 minutes to 1 hour: 33%
- 1 to 2 hours: 16%
- 2 to 3 hours: 4%
- More than 3 hours: 2%

**Excludes those that did not travel and those that do not remember, (n=3,308)*

Sample Size = 3,654, Base: Those who have participated in a clinical trial

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Convenience Enhancing Technologies and Support

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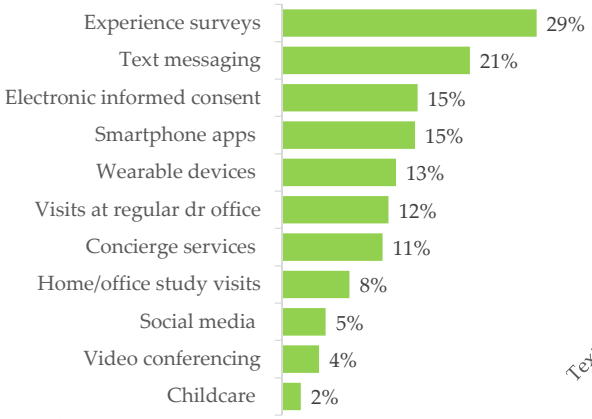
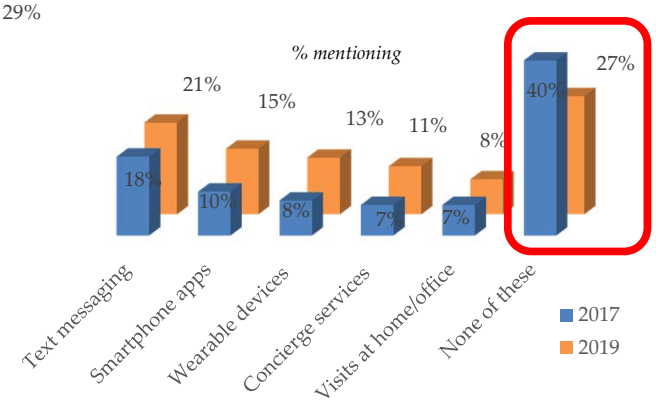
Areas of Growth in the Use of Convenience Enhancing Solutions Since 2017

Which of the following were used during your clinical research study?





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Sample Size = 3,654, Base: Those who have participated in a clinical trial

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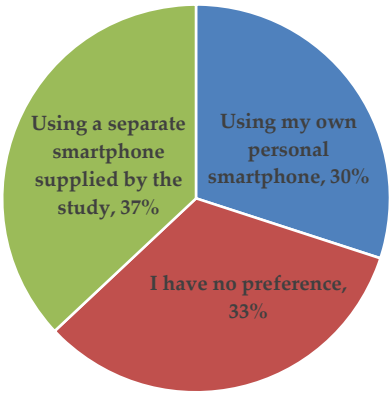
Participation in a Clinical Research Study May Require the Use of Smartphones



Individuals did not express a clear preference between using their own devices and the provision of an additional smartphone, once again emphasizing the need for flexibility and options.

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CISCRP 2019 P&I Survey: n= 12,451 Base: All respondents

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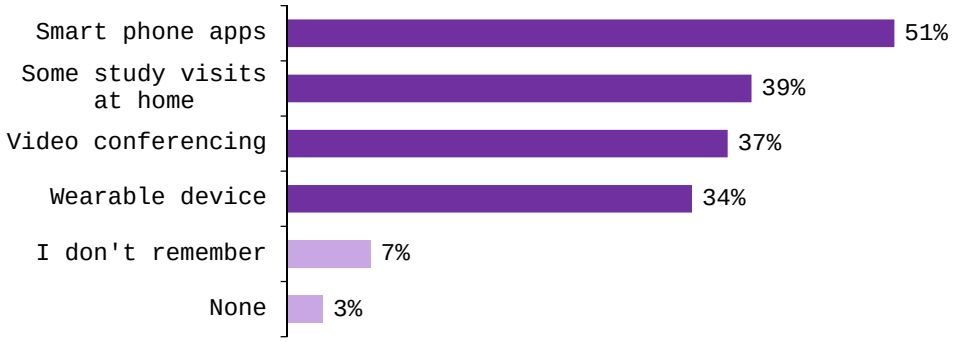
Most Children Used Smartphones and Other Technology During Participation

Which of the following were used during your clinical research study?



n=59 | Base: Children who self-report having participated in a clinical research study

2019 Perceptions & Insights

- Pediatric study participants report far more prevalent use of smartphone apps compared to adult participants, only 15% of whom said they used apps during participation (n=3,654).

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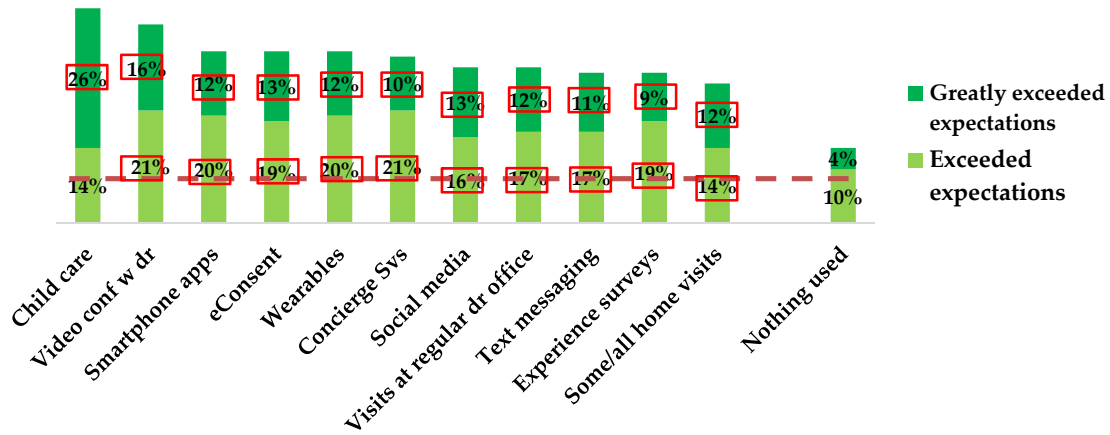
Study Volunteer Experiences are Improved with Supportive Services and Technology

How well did the clinical research study meet your overall expectations?



Statistically significant vs 'nothing used' at 95%CL, Child care significantly higher than all others

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Sample Size = 3,654, Base: Those who have participated in a clinical trial

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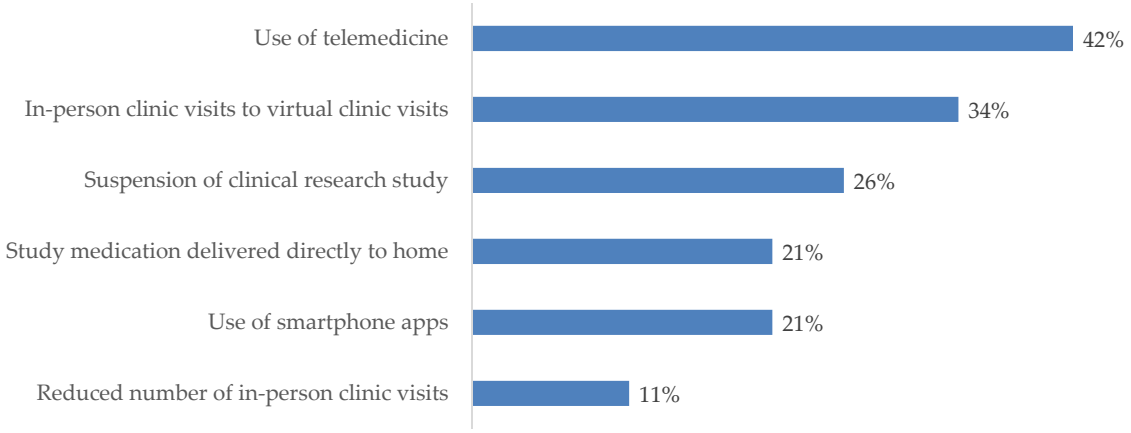
Current Clinical Trial Implications

Individuals enrolled in ongoing clinical trials for illnesses other than COVID-19 are being impacted by the pandemic



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CISCRP 2020 Survey: n= 38 | Base: Those currently enrolled in a clinical trial for a medical condition other than COVID-19, who have experienced changes

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Additional Direct to Patient Considerations

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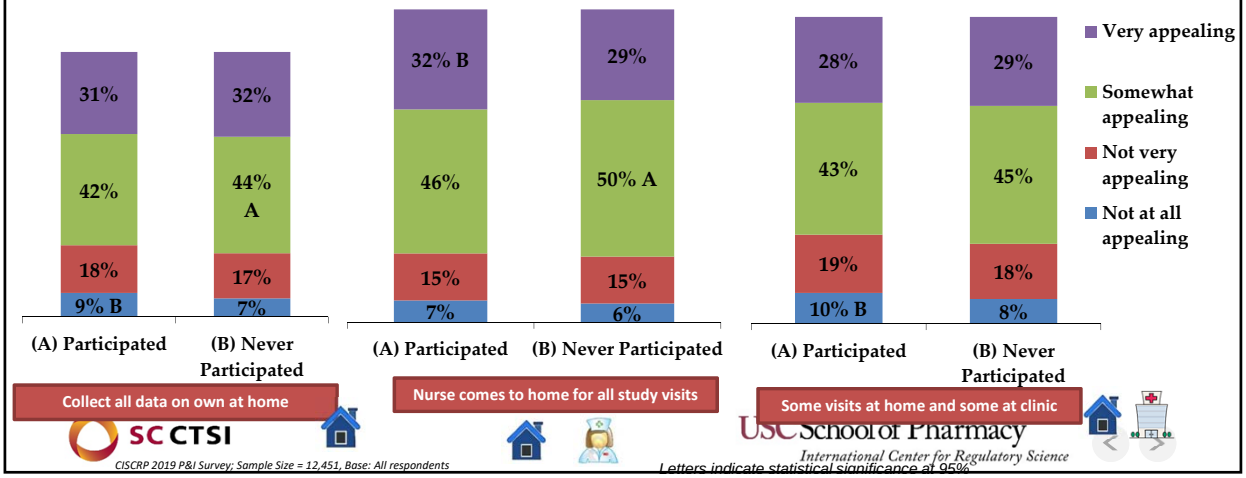
Which Model is Most Appealing? No One Size Fits All

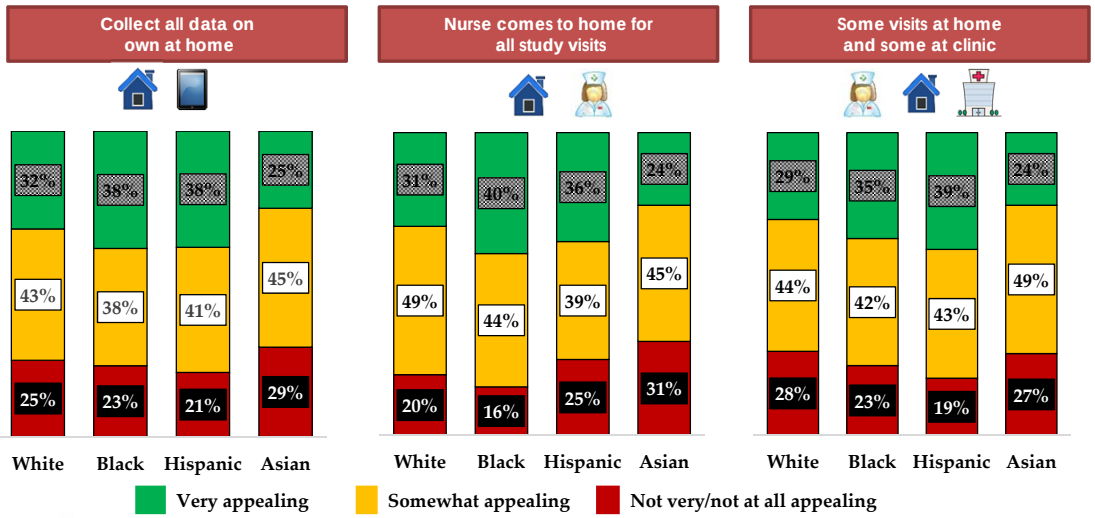
Compared to traveling to a study clinic/research center for all of your study visits, how appealing is each of the following options if you were to participate in a clinical research study?



CISCRP 2019 P&I Survey; Sample Size = 12,451, Base: All respondents

Letters indicate statistical significance at 95%

No One Size Fits All: Diverse Communities

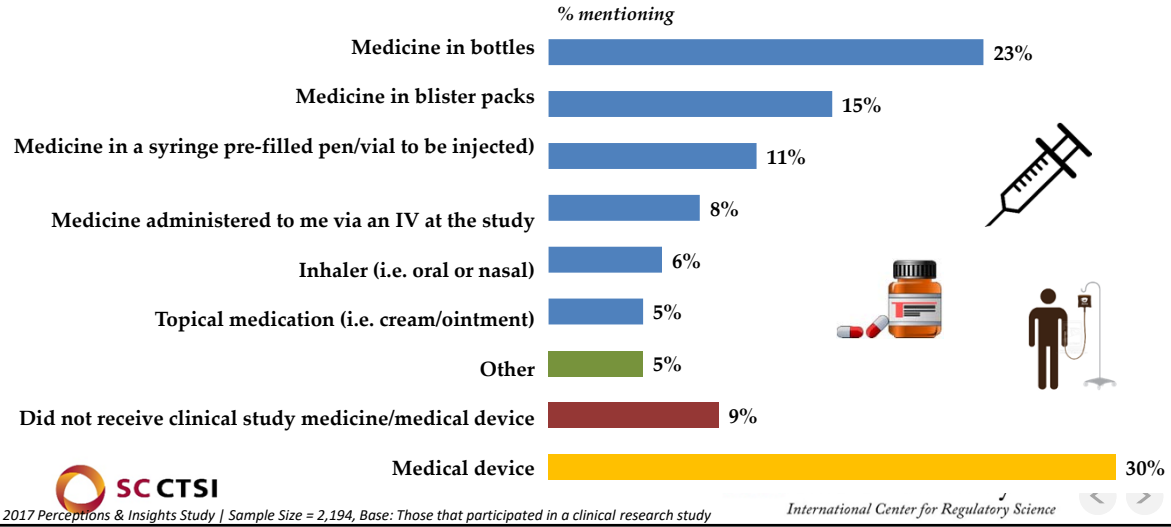


White (n=9,671); Black (n=691); Hispanic (n= 1,574), Asian (n= 1,427)

Source: CISCRP 2019 Perceptions and Insights Study

Investigational Medication Administration Methods

Medicine in bottles was the most commonly reported investigational medication



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2017 Perceptions & Insights Study | Sample Size = 2,194, Base: Those that participated in a clinical research study

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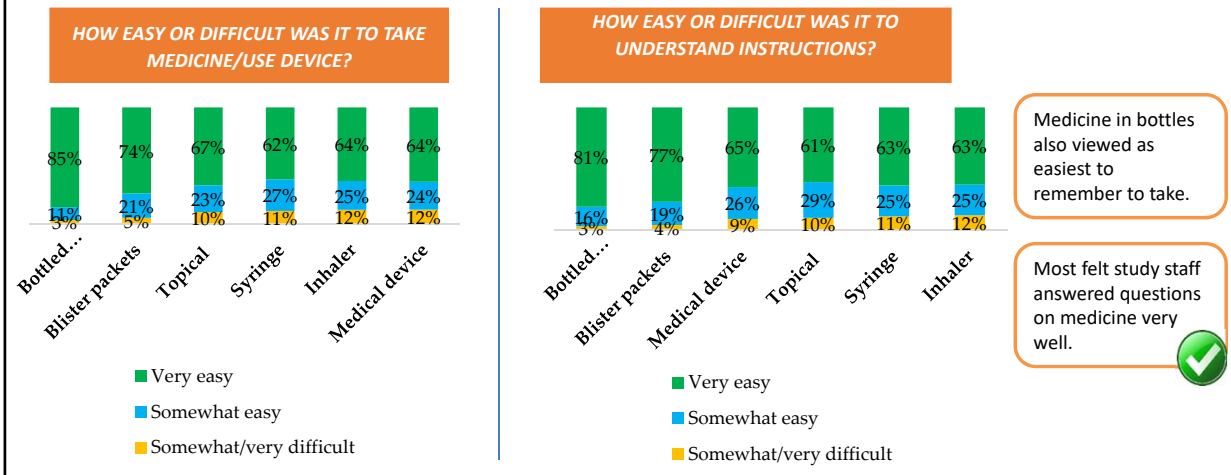
Medication: Ease of Use & Understanding of Instructions



Medicine in bottles also viewed as easiest to remember to take.

Most felt study staff answered questions on medicine very well.

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Source: 2017 CISCRP Perceptions & Insights Study; Sample Size = 1,215
Base: Those that received medicine/medical device, excludes "don't remember"

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Technology Advancements Impacting Clinical Research

- **Informed data decisions**
  - Electronic data capture has revolutionized the process
  - Technology is empowering clinical trial leaders with better insight into how certain patients will respond to a specific drug
- **Wearables empowering wellbeing**
  - Alongside the collection and analysis of significate amounts of data, technology can also be used to better enrich the clinical trial process
- **Entering the virtual world**
  - Technology has led to the introduction of virtual trials
- **Increased regulation**
  - Technology in clinical trials doesn't come without obstacles, especially when navigating the ever-changing regulatory environment
  - Patient safety comes first

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Source: February 13, 2020 article; Christian Hebenstreit

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Key Take-Aways

- Impact to daily life is critical for patients considering trials
- Many are willing to take part, but practical and logistical barriers exist
- Reported challenges of study volunteers highlight opportunity to provide more support
- Patients desire new technology and convenience-enhancing support
- COVID-19 Pandemic is impacting clinical trials and how they are being conducted
  - Industry is adapting to current healthcare environment; Use to technology

These new solutions help improve experiences!

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COVID-19 Impact on the Clinical Research Industry

- COVID-19 has the clinical research industry and all stakeholders in 5 fundamental ways:
  - There will be renewed interest in vaccines
  - There will be more adoption of artificial intelligence
  - There will be a rapid increase in automation
  - There will be more virtual and digital clinical trials
  - There will be increasing regulatory flexibility

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Source: April 24, 2020; Maggie L. Shaw

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Path Forward

- **Building trust with information and transparency**
- **Engaging and educating health care providers**
- **Reducing logistical barriers to participation**
- **Leveraging technologies and remote options**

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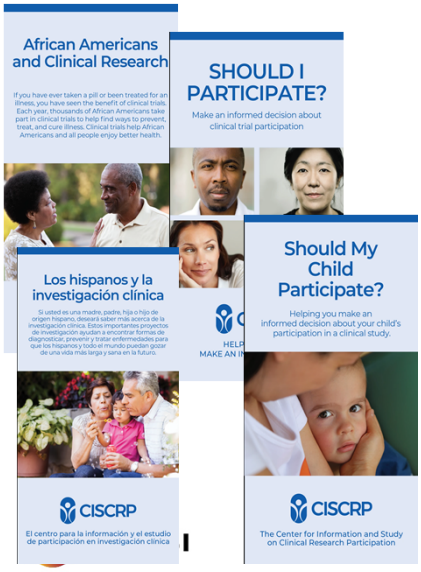
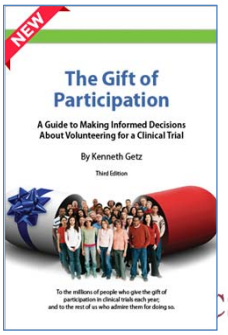
Clinical Research Educational Resources



Brochures
Videos, Posters
Gift of Participation Book
Webinars
Medical Hero Stories
FAQs
Questions to Ask Research Staff



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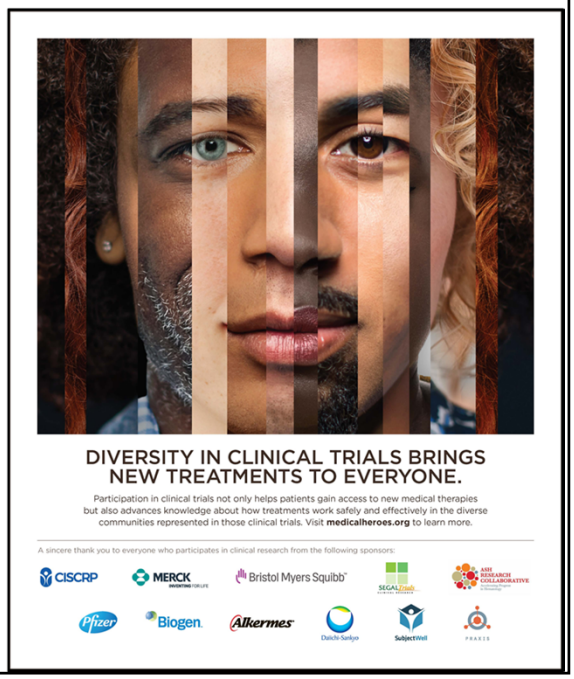

Thank You

Thank you.

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Senior Director, Marketing & Outreach

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Thank You

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Diversity, Equity and Inclusion in Clinical Research

Aman Khera
Global Head of Regulatory Strategy, Worldwide Clinical Trials
Rebel Regulator in Healthcare | Drug & Device Development | Digital Health & Privacy Geek | DEI Champion | Humanitarian | Innovation Lead |

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Key Learning Objectives

Upon completion of this session, participants should be able to:

- ✓ Review the importance of Diversity, Equity and Inclusion in Clinical Research
- ✓ Describe the obstacles at different levels in enrolling patients from diverse populations
- ✓ Understand the implications not enrolling patients from diverse populations into studies

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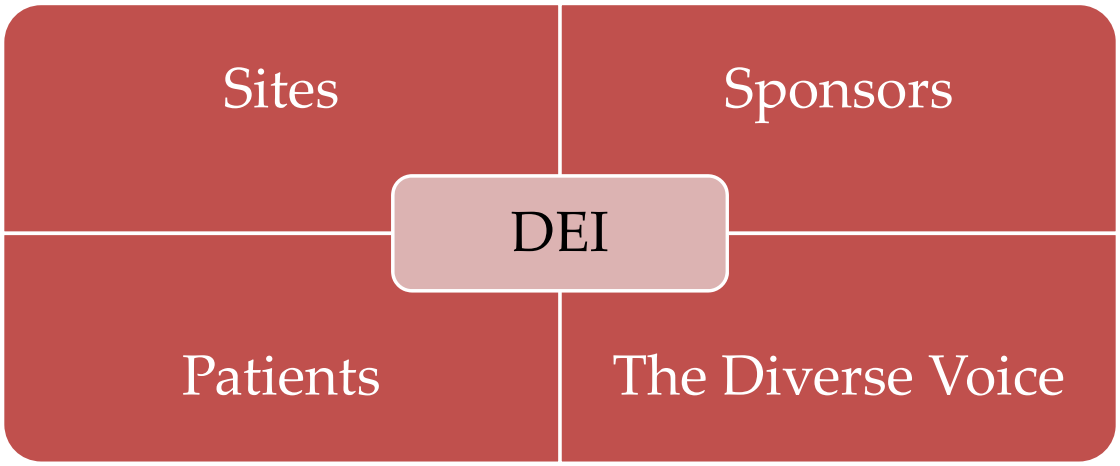
Introduction



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The importance of DEI

- Historically patient population diversity and inclusion initiatives have generally been considered a "nice to have" rather than an imperative.
- The issue has not had the momentum needed to bring about real change.
- There have been many worthy initiatives in this space, but they have been fragmented and fallen short.
- *Every year, the FDA issues a Drug Trials snapshot report. Last year only 26% of clinical trial participants were the age of 65 or older, 72% were White, 18% Hispanic, 9% Black or African American and 9% Asian. Last year, the FDA also introduced draft guidance to enhance the diversity of clinical trial populations, encouraging trial teams to broaden eligibility criteria, use adaptive clinical trial models and to consider enrollment challenges that potential participants may face.*

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The Why

- Disease and illness do not discriminate.
- However, our age, race and ethnicity DO play a part in determining how certain conditions and medical treatments affect us.
- If you fail to engage in diverse populations; you may well be undertaking clinical research in a patient population that is NOT representative of the treatment's true intended patient population in the market. If it's approved for market, you have a problem.
- There are many elements to diversity in clinical research: age, race, gender, ethnicity, genetics, comorbidities, concurrent medications, social determinants of health and environmental factors. These dimensions of diversity are not independent variables but rather have intersections.

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What if nothing changes?

- The variations in disease manifestation and treatment responses demonstrate why it is important to consider diverse populations.
- For example, racial differences in skin structure and physiology can affect responses to dermatologic and topically applied products.
- Another example is that the frequency of CYP2D6 poor metabolizers, which is important in beta blockers, antidepressants, antipsychotic beta blockers, is higher in Whites, Blacks and African Americans than the Asian population.
- The FDA has been looking at approved labelling that is related to specific races and ethnicities.
- Individuals of South Asian, African or African Caribbean descent in the UK are at higher risk of developing heart and circulatory diseases than white Europeans.

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Obstacles in reaching diverse populations

Sponsor and site level:

- lack of patient advocacy,
- a fear of delaying the trial
- or increasing the cost of the trial.

Investigator or clinical research staff perspective

- eligibility criteria limits enrollment.
- Typically, patients are recruited from the same sites repeatedly. Trial teams may not open research naïve sites in locations that may hold more diverse patient populations. Need to lessen institutional bias that directly results in a lack of diverse cultural understanding, paired with a lack of diverse staff at the site.

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Obstacles in reaching diverse populations

Community and patient perspective:

- Distrust of research and clinical trials overall
- Lack of awareness and limited health literate education and communications
- Logistical issues of trial conduct; study design and procedures are burdensome
- Payment and other financial concerns

- Also no harmonized requirements for data collection.
- An inherent lack of data standards that results in inconsistent data analysis.

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Engaging Communities

Sponsor companies must be open to change. Community and patient engagement are key.

Consider engaging with diverse patient communities even before having a protocol developed.

Reach out to research naïve sites and arm trial teams with training around inclusive language and behavior.

Consider offering translation or interpreter services.

Look at protocols with an assessment of the patient burden, to determine if steps can be taken to reduce the secondary and tertiary endpoints, potentially opening the pool of patients.

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The Diverse Voice

Is there a lack of "diverse" voices at sites and biopharma companies, if so how are you able to understand the lens of the very patients you wish to enroll and eventually treat?

Importance of both acknowledging and understanding cultural competencies.

- This doesn't just come from training courses but instead having those voices represented at sites and companies.

- In sites, we can all make an effort to support diverse teams that have the right intentions but may lack the experience.

- This is where we must work collaboratively to invest in clinical research sites for the present and for the future.

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Different Dimensions of Diversity

- When thinking about trial diversity and inclusivity, we need to think about the different dimensions of diversity: age, gender, ethnicity, socioeconomic status and many others
- Consider the intersectional ties

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Populations on the Fringe of Clinical Trial Enrollment

Terry David Church, DRSc, MA, MS
Assistant Professor, Regulatory and Quality Sciences
Associate Director, Undergraduate Education
Co-Chair Education Committee, Institute for Addiction Sciences
Faculty Fellow, Center for Excellence in Teaching

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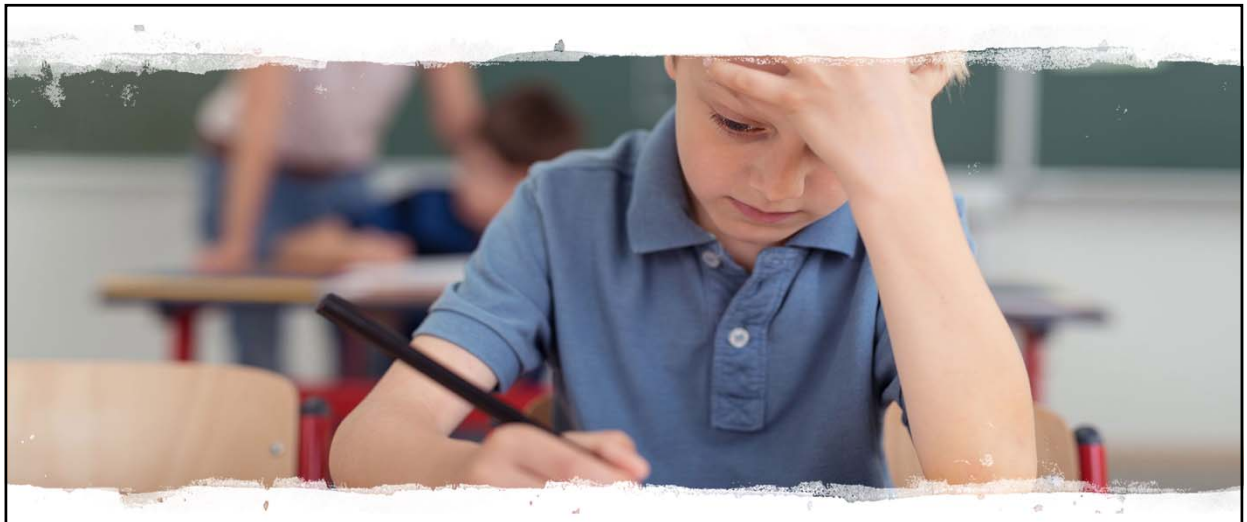

Surprise!!

It is test time…

What comes to mind when you hear the word "Clinical Trial"?

Start the presentation to see live content. For screen share software, share the entire screen. Get help at pollev.com/app

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Clinical Trials Are Crucial…

New Medical Treatments

Expanded or Refined Treatments

Identify Behavioral Changes

Activities to prolong and improve the lives of participants

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Clinical Trials Determine…

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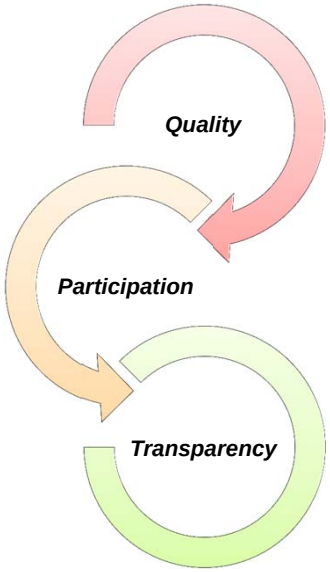
FDASIA Section 907

- In 2013, Sec 907 directed the FDA to investigate how well demographic subgroups (sex, age, race and ethnicity) in applications for medical products (drugs, biologics, and devices) submitted to the agency for marketing approval:
  1. Are represented in clinical trials; and
  2. If subgroup-specific safety and effectiveness data are available
- FDA recognizes it is important to test drugs and medical products in the people they are meant to help.

FDA's Action Plan

- In 2014, FDA issued an action plan to enhance the collection and availability of demographic subgroup data –

1. **Priority One:** Improve the completeness and quality of demographic subgroup data (*Quality*)
2. **Priority Two:** Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (*Participation*)
3. **Priority Three:** Making demographic subgroup data more available and transparent (*Transparency*)



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FDA – Drug Trial Snapshot 2019

Demographic Subgroups	Women	Caucasian	African American	Asian	Hispanic	Over 65	United States
Average	72%	72%	9%	9%	18%	35%	40%

- Overall 46,391 patients participated across 48 novel drugs
  - New Molecular Entities (NMEs)
    - New Drug Applications (NDAs)
    - Biologics License Applications (BLAs)

This represents 18,556 individuals for Drug Trials in 2019

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Diversity Metrics for Research in the US

- **Office of Management and Budget (OMB)**
  - OMB is responsible for setting several standards to assist in standardized and disciplined ways of collecting and reporting data across several industries and businesses in the United States
  - OMB guideline for the minimum set of categories to represent race and ethnicity
    - *Race* - American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White or Caucasian
    - *Ethnicity* – Hispanic or Latino and Not Hispanic or Latino

- **United States Census Bureau**
  - In addition to following OMB guidelines, the Census Bureau mandates self-identification in the categories of race and ethnicity

Updating the Federal Statistics

- The Census Bureau and the OMB worked together between 2015-2020 to review and evaluate current race and ethnicity statistics

  - OMB issued a Federal Register Notice, announcing the review in Sept 2016, which included:

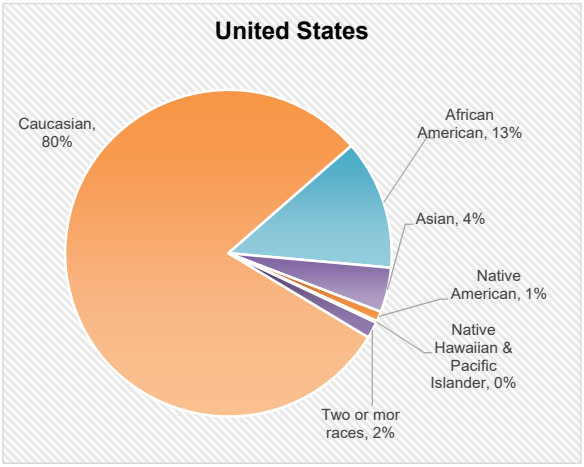
    a) the use of separate questions to measure race and ethnicity and question phrasing;

    b) the classification of a Middle Eastern and North African group and reporting category;

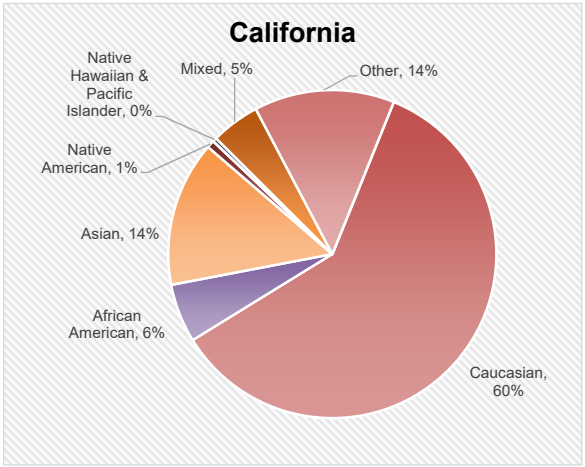
    c) the description of the intended use of minimum reporting categories; and

    d) terminology used for race and ethnicity classifications

Racial Composition



US Census 2020; N = 331,002,651 www.census.gov



US Census 2020; N = 38,654,206 www.census.gov

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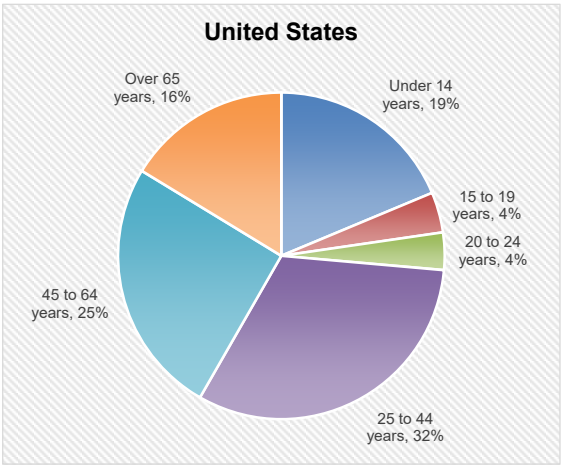
Age Composition



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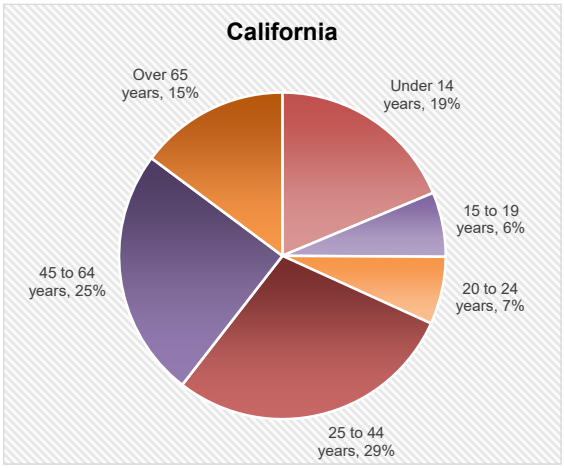

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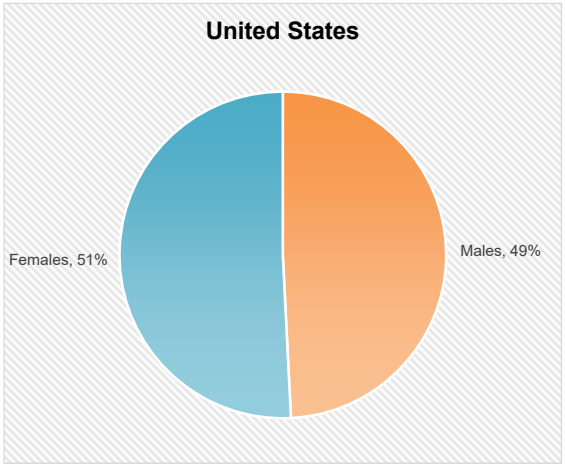
Gender Composition



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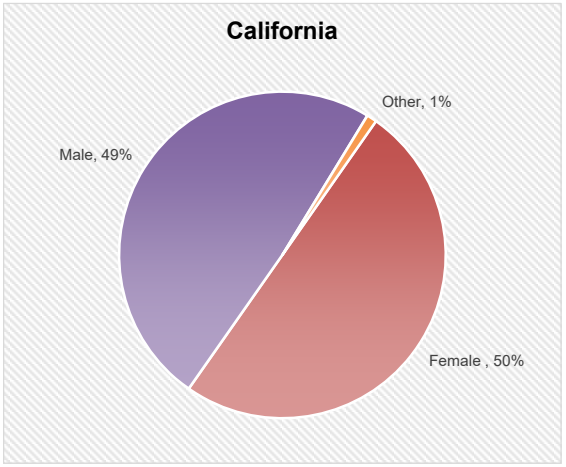

US Census 2020; N = 38,654,206 www.census.gov

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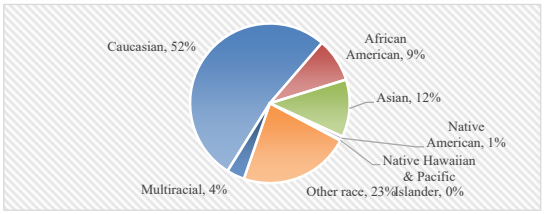
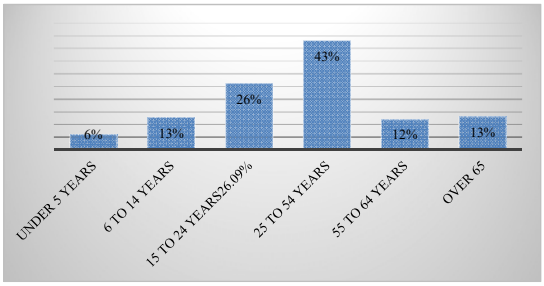
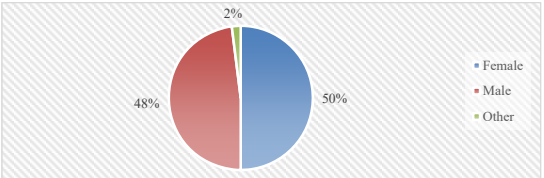
Los Angeles County

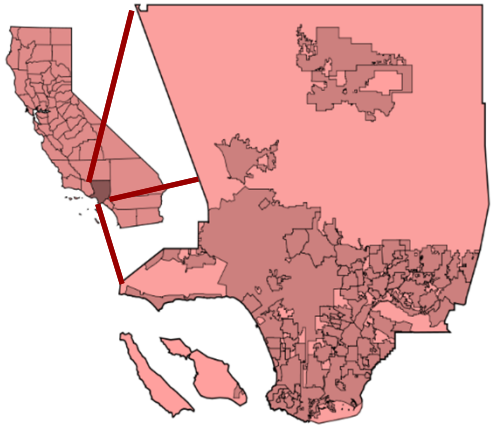
Data: census.gov/quickfacts/losangeles N = 10,039,107







Enumerating Los Angeles



- California Population: 38,654,206
- Los Angeles County Population: 10,039,107
- City of Los Angeles Population: 4,015,957
- Number of Inpatients 2019
  - LAC+USC: 35,635
  - Keck Medical: 12,905
  - Verdugo Hills: 6,750
  - USC Norris: 1,982
  - CHLA: 17,145
  - **Total USC System: 74,417**

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State, County, and City Census Facts – 2020 census:
https://worldpopulationreview.com/states/california-population/
Hospital Census: http://gis.oshpd.ca.gov/atlas/places/list-of-hospitals

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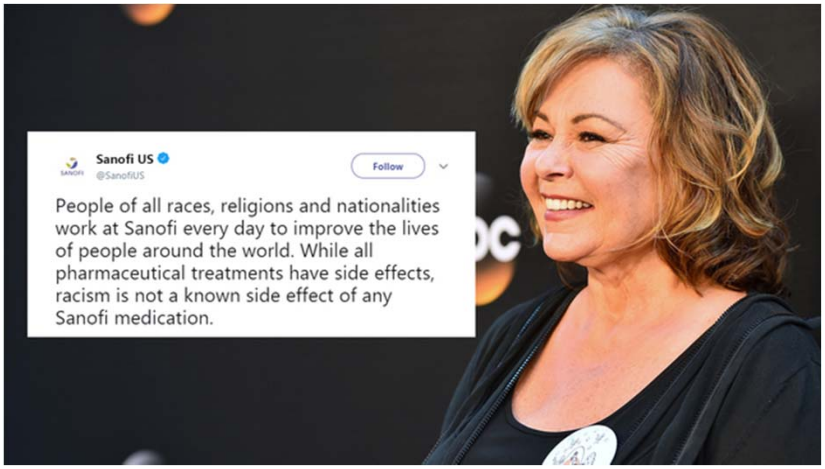
Zolpidem



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USC Undergraduate Research Associates Program

- "Underrepresented Populations in Clinical Trials"
  - Provost funded research program to understand underrepresented populations and cultural differences that impact health disparities
  - Selected students are given the opportunity to choose an underrepresented population of study
    - Students must dedicate to one-year of research
    - Must conduct minimum of 10-15 hours a week for research
- Research into topics related to pediatrics, diabetes, chronic diseases, and mental health
  - The results all point to a need for better inclusion

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Inclusion of Pediatric Participants in Clinical Trials

- In a study that looked at 26 drugs approved under the Best Pharmaceuticals for Children Act (BPCA) between 2016 and 2018, there were 135 studies conducted
- These studies brought to light –
  - A lack of standardization regarding which age constitutes specific pediatric sub-population, even where guidelines exist
  - A lack of pediatric representation in clinical trials (most involved adults and pediatrics)
- The main recommendation from this research –
  - Better pediatric representation in clinical trials
  - Improved safety, efficacy, and dosage information based on pediatric data for labeling and prescribing

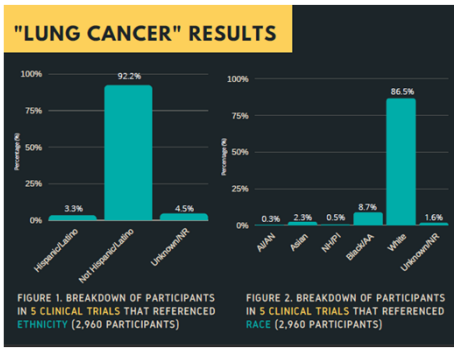
Ly, A., Uniyal, A., & Church, T. (2020). 4381 Examination of FDA Pediatric Regulations: Inclusion of Pediatric Populations in Clinical Trials, 2016-2018. *Journal of Clinical and Translational Science, 4*(s1), 131-131.

Low-Income Populations and Barriers to Diabetes Technology

- Access and successful use of continuous glucose monitors (CGMs) in low-income populations with Type 1 Diabetes (T1D)
  - Emphasis on California populations and public insurance programs
- Found several ways access could be improved
  - Many public and private insurers require patients to have a documented 4x/day self-monitoring of blood glucose
  - Paucity of clinical trials including socio-economic status as a criteria
- Some recommendations
  - Need for larger, US based clinical trials with T1D
  - Move to proactive rather than reactive healthcare systems for CGMs
    - Potential to save money for insurers and facilities
    - Potential improve quality of life for patients

Chronic Diseases in Los Angeles County

- This study looked at racial and ethnic group enrollments into chronic disease studies in LA County
  - Coronary heart disease, stroke, lung cancer, COPD, and Alzheimer's
  - Chronic disease accounts for over 75% of the US healthcare spending annually
- Implications of this research
  - Limited clinical trial data in LA County for many of these chronic diseases
  - Barriers to enrollment that limit enrollment
- Recommendations
  - Reconsider what clinical trials are being brought into LA County
  - Evaluate barriers to enrollment (system, individual, interpersonal levels)



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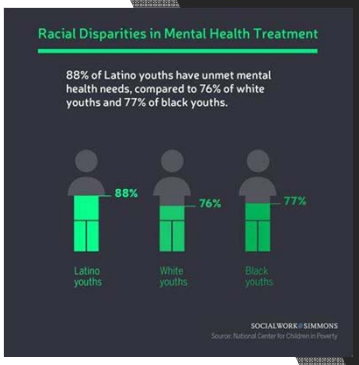
Race and Ethnicity in Mental Health Disorder Clinical Trials



- This study investigated the inclusion of race and ethnicity in clinical trials for mental health disorders
  - Anxiety, depression, bipolar disorder, Attention Deficit Hyperactivity Disorder (ADHD), and Post-Traumatic Stress Disorder (PTSD)
  - Adolescent and youth were the primary population of interest
- This study found
  - Unequal reporting of race and ethnicity within this study population
  - Unequal representation between racial and ethnic groups points to broader lack of minority enrollment
  - Consistent with known barriers to minority enrollment in pediatric mental health
- Future implications
  - Identify challenges and barriers within mental health among minorities
  - Increased inclusivity will result in improved mental health outcomes

Source: National Center for Children in Poverty – www.nccp.org

Antidepressants Among Special and Vulnerable Populations

- This study seeks to understand clinical trial enrollment in studies of clinical depression among vulnerable and special populations
  - Vulnerable populations: Pregnant women
  - Special populations: Risk of suicide; Individuals with diminished mental capacities
- Findings
  - Many antidepressant clinical trials only permit "healthy" individuals to enroll
  - Exclusion criteria prohibit pregnant women and those with mental health histories
- Recommendations
  - Better clinical trial representation of the depressed population will provide safety and efficacy information of commonly co-prescribed antidepressants

What Can We Do?

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Acknowledgements

Thank you to the amazing students, staff, and faculty – all part of our RegSci Family!

Additional thanks to the USC Provost's Office, who helped to fund the research presented.

FIGHT ON!

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Thank you for joining today's talk.

Any questions?

tdchurch@usc.edu

Ensuring Participant Diversity and Engagement during COVID-19

Nicki Karimipour, Ph.D.
Associate Director for Communications
Program Manager for Clinical Research Support
SC Clinical and Translational Science Institute

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What I'll cover today

Current issues in CT recruitment
Importance of diversity
Barriers associated with clinical research access
Strategies for engaging minority populations in research
How does COVID influence this?
Engagement strategies
Example
Takeaways for researchers
CTSI resources
Q&A

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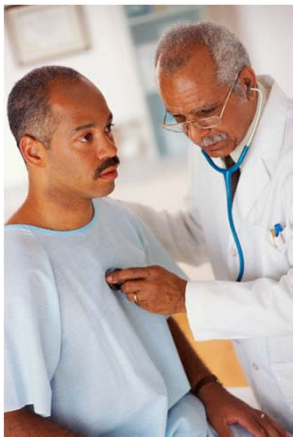
Current issues in CT recruitment

- Around 75% of investigators don't meet their enrollment goals, and 90% fail to meet recruitment goals within their estimated timeframe (Institute of Medicine Forum on Drug Discovery, Development, and Translation, 2010)
- The overwhelming majority of human studies involve white males – more inclusive enrollment can reveal more about certain diseases & diagnoses in various populations
  - Certain racial/ethnic populations may metabolize drugs differently (NIH)

Current issues in CT recruitment

- Lack of inclusivity
- Lack of efficiency
- Lack of focused approaches/strategies based on formative research
- Lack of proper engagement
- Lack of follow-up and return of results



Importance of diversity

- Diversity ensures accurate representation of ALL people in clinical research
  - Safer and more effective therapeutics, biologics, treatments, etc
- Not only is it the right thing to do – it's a requirement
- NIH Revitalization Act (1993) – amended Nov. 2017
- FDA launched a website called Drug Trials Snapshots to provide the public with information about the demographic composition of the data collected in clinical trials of newly approved medications (2014)
- NCI-designated cancer centers are required to identify and describe their Catchment Area (CA) and document ongoing research that specifically addresses the cancer burden, risk factors, incidence, morbidity, mortality, and inequities, in the CA (2012)

Despite her efforts, her son may have received treatments tailored to someone else. As with many diseases, the bulk of research on respiratory ailments in the U.S. has focused on white European-Americans, and Peete and her son are black. In May, a study in *Immunogenetics* out of the University of California, San Francisco, reported that only 5 percent of the genetic traits linked to asthma in European Americans applied to African Americans. Epidemiologist Esteban Burchard, who coauthored the paper, says other studies have also shown that different ethnicities have distinct genetic mutations that increase their risk for particular diseases and affect how they respond to medicine. Neglected by research, African American children have died from asthma at 10 times the rate of non-Hispanic white children.

To explain the lack of diversity in health studies and clinical trials, researchers sometimes blame recruiting difficulties. People of color—especially African Americans, the argument goes—harbor suspicion toward medical research and are less inclined to participate in it. Scientific papers, popular media, and advice for clinicians all have cited minority suspicion as a significant obstacle to recruitment. But several researchers who have conducted clinical trials with diverse participant pools say some studies just aren't making enough of an effort to be inclusive. People of color are often happy to help with experiments, they contend—and racial suspicion may just be a convenient scapegoat for lily-white studies.

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What prevents CT participation?

Technological Barriers

Geographic Barriers

Psychosocial Issues

Lack of knowledge about medical research

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Strategies for engaging minority populations in research

Meta-analysis of 20 health research studies that reported consent rates by race or ethnicity found that ethnic minority participants in the U.S. are as willing as non-Hispanic whites to take part in health research (Wendler et al., 2005)

- Ask about barriers
- Ask about how to make participation easier
- Ask about communication preferences/style

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How to ensure greater diversity

- Learn about your population
- Record what you learn
- Do cultural competency training
- Hire people of your target population
- Approach community stakeholders & key opinion leaders for help
- Course correct when needed
- Write up your findings/reflections

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How does COVID influence this?

- Distractions
- Scheduling issues
- Family obligations (or new obligations)
- Financial concerns

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Examples

Applied our successful models of CE in Latinx and African American communities to expand into Asian American communities.
Have begun delivering COVID-19 mitigation education to Korean Youth Community Center parent groups.

Employed a new place-based approach to CE and community-level interventions to promote health, provide linkage to care, and increase clinical trial participation.
Have hired a resident of Nickerson Gardens who is now on the CE team as a community health worker. She has organized focus groups with residents to discuss the impact of COVID-19 on residents.

Will offer CE's COVID-19 (4-session) education series to residents. Further explore barriers, facilitators and interventions to increase COVID-19 vaccine uptake.

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Takeaways

For researchers:

- Think critically about your participants' circumstances
- Try to be accommodating/flexible
- Harness the power of alternative communication methods
- Ask your target audience what their needs are and augment your recruitment strategies accordingly

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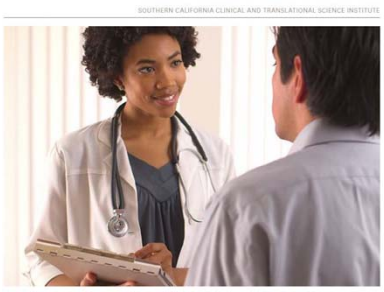
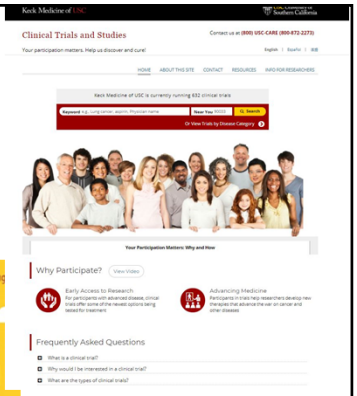
CTSI resources





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Regulatory Science Virtual Symposium

"Diversity in Clinical Trials in the Time of COVID-19"

Wrap-Up!

Eunjoo Pacifici, PharmD, PhD
Chair and Associate Professor, Regulatory and Quality Sciences
Associate Director, DK Kim International Center for Regulatory Science
President, Pharmacy Faculty Council

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SURVEY:
Plain Language Usage Among Regulatory Professionals

- Patient-focused drug development is an important aspect of clinical research.
- Dissemination of clinical trial results in plain language can increase patient engagement.
- We are asking you to take this short survey to help determine the usage of plain language within the regulatory environment.
- Please use this link: https://usc.qualtrics.com/jfe/form/SV_5n0GORPbf1549Hn

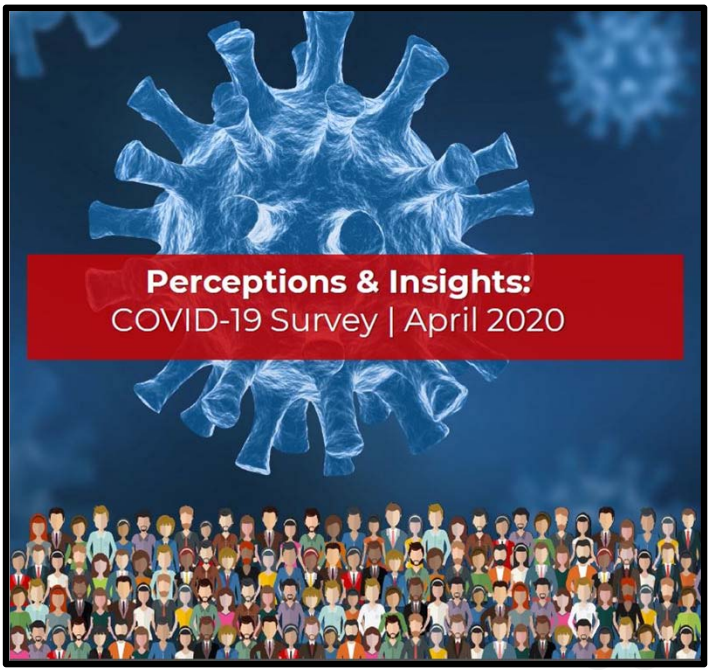
Resources

- To download the Research Report go to this link:

https://regulatory.usc.edu/files/2020/10/Fall-2020-Resource-COVID-19-Slide-Deck-FINAL-04MAY2020.pdf

- CISCRP Research Reports are available for free download.

https://www.ciscrp.org/education-center/resources/



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This certifies that

You should have received the link to take the program evaluation.

Follow this link to the Survey:
Take the Survey

Please complete the program evaluation to receive a certificate of completion by Friday, October 30, 2020.

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Thank You

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