



CLINICAL TRIALS
for Better Health



HEALTH CARE PROVIDER TOOLKIT

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Welcome!

The **I'm In** campaign is an initiative to improve our nation's health by increasing clinical trial participation, particularly among traditionally underrepresented populations. Our goal is to involve key stakeholders — including physicians and other health care providers, advocacy organizations, policy makers and patients — to raise awareness about the importance of diversity in clinical trials. It's going to take all of us working together to make this difference.

Recognizing physicians play an important role in helping educate patients about clinical trials, we invite you to join this effort.

By becoming engaged with the campaign, either through a professional network or as an individual practitioner, you will have the opportunity to help improve the current clinical trials environment by engaging more diverse participants. From sharing information with your patients and colleagues and spreading the word about **I'm In** on social media to serving as a spokesperson, we welcome your involvement. No effort is too small. Let us know the ways in which you'd like to support the **I'm In** campaign by filling out and returning the Ways to Engage form on page 9. We've provided materials to share with your staff and patients, as well as resources for professional organizations to share with their members. For your convenience this toolkit, including the Ways to Engage form, is also available online at www.JoinImIn.org.

I'm In is a collaboration of the Pharmaceutical Research and Manufacturers of America (PhRMA) and National Minority Quality Forum. On behalf of the founders, we thank you for your support and participation. Without the patients who volunteer to participate in clinical trials, and the physicians who recommend participation and serve as clinical trial investigators, the development of new treatments would not be possible.



Resources for You and Your Staff

This toolkit includes information on the need for increased diversity in clinical trials, key messages you can use when sharing the campaign with others and an overview of ways you can engage with **I'm In**.

We look forward to your participation in the **I'm In** campaign!

- Why Get Involved?
- Key Messages
- Ways to Engage
- Website Article
- Social Media Cheat Sheet
- Website Banners
- Posters

Why Get Involved?

THE ISSUE

Clinical trials are used to evaluate the effectiveness and safety of medications or therapies by monitoring their effects in patients who volunteer to participate. The process used to test the effectiveness of new medicines should accurately reflect the patient population that will eventually take them.

Ethnically and racially diverse audiences are underrepresented in clinical trials. Despite representing 12 percent of the U.S. population, African Americans make up only 5 percent of clinical trials participants. Hispanics represent 16 percent of the U.S. population, but only 1 percent of clinical trials participants.¹

WHY IT MATTERS AS HEALTH CARE PROVIDERS

The findings of a May 2013 poll conducted by Research!America point to the important role of health care providers in talking to their patients about clinical trials. The study found more than two-thirds of Americans say it's likely they would participate in a clinical trial if recommended by their doctor, but only 22 percent say a doctor or other health care professional has ever talked to them about medical research.²

Respondents of the same survey believe health care providers should play a major role in raising awareness of clinical trials. In fact, 38 percent of Hispanics, 36 percent of Asians and 33 percent of African-Americans said providers have the greatest responsibility in educating the public about clinical trials, as did 42 percent of non-Hispanic whites.²

We hope the resources provided through the **I'm In** campaign will assist you in starting conversations with your patients to help them gain deeper knowledge of increasing participation in clinical trials so Americans can benefit from lifesaving treatments when medically appropriate.

WHY IT MATTERS TO PATIENTS

According to studies, there are biological differences in how people process drugs. For example, differences in genetic coding can make a cancer treatment react differently in one ethnic group than it would in another. These differences can also make drugs like antidepressants and blood-pressure medications less effective in one group than another.³

According to the FDA, increased diversity in clinical trials helps researchers find better treatments and better ways to fight diseases that disproportionately impact certain populations and may be important for safe and effective use of therapies.

- African American men are twice as likely to die from prostate cancer than Caucasians,⁴ but represent only 4 percent of prostate cancer clinical trials participants.⁵
- Suicide is one of the top three causes of death for Asian American women ages 15-45; however, only two percent of clinical trials participants for major depressive disorder were Asian American.⁶
- Mexican Americans and Puerto Ricans have more than double the prevalence of diabetes than Caucasians,⁷ but represented only 4 percent of clinical trials participants from 1998-2001.⁸

Participation in a clinical trial not only benefits the patient, it may also benefit future patients by helping to further medical innovations that can positively affect various ethnic and racial communities. Without the patients that volunteer to participate in clinical trials, the development of these treatments would not be possible.

THE SOLUTION

A coalition of partners including PhRMA and National Minority Quality Forum have teamed up to launch **I'm In**, a campaign to encourage greater diversity in clinical trials. Through strategic outreach and partnerships, the goal is to provide insight and assist in raising awareness about this important health care issue.

I'm In will include the Clinical Trial Engagement Network, the only online resource designed to accelerate the inclusion of underrepresented populations in clinical trials and will:

- Allow patients to connect to clinical trials in which they may be eligible to participate.
- Provide industry members, physicians, researchers and academic institutions with on-demand access to zip code level data that identifies different population groups by disease status and shows where recruitment efforts should take place in a cost-effective manner.

REFERENCES:

1. The Society for Women's Health Research United States Food and Drug Administration Office of Women's Health. "Dialogues on Diversifying Clinical Trials." 2011. Available from: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf> [Accessed 2013 Oct 10].
2. Research!America, An Alliance for Discoveries in Health. "Clinical Trials: Poll Data of Minority Populations." 2013. Available from: <http://www.researchamerica.org/uploads/clinicaltrialsminorities.pdf> [Accessed 14 Nov 2013].
3. The Food and Drug Administration. "Clinical Trials Shed Light on Minority Health." Available from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm349063.htm> [Accessed 18 Oct 2013].
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6. Centers for Disease Control. "Leading Causes of Death by Race/Ethnicity, All Females-United States, 2009." Available from: http://www.cdc.gov/women/lcod/2009/09_race_women.pdf. [Accessed 28 Oct 2013].
7. American Diabetes Association. "2011 National Diabetes Fact Sheet." 2011. Available from: "<http://www.diabetes.org/diabetes-basics/diabetes-statistics/>" [Accessed 2013 Oct 10].
8. Evelyn B, Gray K, Rothwell R (Office of Special Health Issues US FDA). US Black participation in clinical trials: a review of selected new molecular identities approved 1998-2001. Presented at the NMA meeting, 2002, Honolulu, Hawaii.

Key Messages

These key messages can be used when educating your patients and staff about the importance of increasing diversity in clinical trials.

I'm In is a campaign designed to accelerate participation of diverse populations in clinical trials. By increasing diversity in clinical trials, we can help ensure the process used to test the safety and effectiveness of potential new medicines accurately reflects the individuals who will eventually take them and increase scientific knowledge that may result in medical innovations for future patients. A cooperative effort of local, regional and national partners, **I'm In** was founded by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the National Minority Quality Forum.

Are you in? Visit www.JoinImIn.org.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study designed to carefully assess the safety and effectiveness of a therapy to prevent, detect or treat disease. By the time a potential new medicine makes it to a clinical trial in which you might be eligible to participate, it's typically gone through a minimum of three to six years of preclinical testing.

WHY SHOULD I PARTICIPATE IN A CLINICAL TRIAL?

Participation in a clinical trial often provides patients access to potential new treatments and expert health care at leading institutions. By participating in a clinical trial, you play an active role in your health and the health of others by contributing to scientific knowledge that may lead to innovative medical treatments for future patients.

WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

You don't have to be sick to take part in a clinical trial. Healthy individuals are also needed as participants. Sign up for the patient registry at [**www.JoinImIn.org**](http://www.JoinImIn.org) and learn about clinical trials in your area.

The I'm In Website

Designed as a user-friendly tool to empower individuals to learn more about clinical trials and the benefits of participating in clinical research, the **I'm In** website provides a variety of tools for patients, their friends and family, physicians, advocacy organizations and clinical trials sponsors and investigators.

THE I'M IN WEBSITE:

- Provides an overview of the clinical trial process and why it's important for current and future patients
- Explains why diversity in clinical trials is critical to finding the best treatment options
- Features toolkits with robust materials for various audiences available for download (advocacy organizations, physicians and media)
- Provides up-to-date clinical trial news and resources
- Provides users with the opportunity to join the campaign in multiple ways:
 - Sign up to be contacted about clinical trials in which they may be eligible to participate
 - Share the **I'm In** campaign with family and friends through social media
 - Shares background on the founding members and their role in the **I'm In** campaign



THE CLINICAL TRIAL ENGAGEMENT NETWORK:

The Clinical Trial Engagement Network provides a secure internet-based environment connecting patients, clinical trial sponsors, clinical investigators, health care professionals, their institutions and advocacy organizations across the nation. Here's how individuals and organizations can get involved:

- **Patients:** Both volunteers with health challenges and healthy participants are needed for clinical trials. Signing up as a patient in the Clinical Trial Engagement Network allows individuals to search for clinical trials as well as to enter a volunteer pool to be considered for participation in future clinical trials.
- **Advocates:** Patient advocacy organizations that would like to get involved with the campaign can download a customized advocate toolkit, become official **I'm In** Champions, and engage with **I'm In** on social media.
- **Physicians:** Physicians who are not clinical trial investigators but are interested in becoming one can register as an investigator in the Clinical Trial Engagement Network. A free physician toolkit is also available for download and provides more information about how to get involved with **I'm In**.
- **Clinical Trial Sponsors:** The Clinical Trial Recruitment Center is a new tool available to qualified clinical trial sponsors. Sponsors will have access to a secure Patient Registry, National Research Directory, Investigator Registry, Clinical Site Reporter and the National Health Index.
- **Clinical Trial Investigators:** Current clinical trial investigators, physicians and other health care professionals who want to become investigators can sign up for the Clinical Trial Engagement Network as an investigator and complete a profile to make their information available to clinical trial sponsors.
- **Friends and Family:** Patients often rely on family and friends for support and care during health challenges. Free resources are available to educate loved ones about clinical trials.

Ways to Engage

Health care providers are critical to raise awareness about the need for greater diversity in clinical trials and there are many ways you can help spread the word.

DISTRIBUTE INFORMATION TO YOUR PATIENTS AND COLLEAGUES

HAVE POSTERS AND/OR BROCHURES AVAILABLE IN YOUR OFFICE

- Posters Quantity: _____ Brochures Quantity: _____ Address: _____

HOST AN I'M IN REPRESENTATIVE AT AN UPCOMING MEETING/EVENT

- Name of event: _____ Date: _____ Time: _____
- Tell us about the event: _____

PARTICIPATE IN LOCAL I'M IN ENGAGEMENT EVENTS

BECOME AN I'M IN MEDIA SPOKESPERSON

ASSIST WITH OUTREACH TO ELECTED OFFICIALS

SUBMIT AN OPINION EDITORIAL OR LETTER TO THE EDITOR ABOUT I'M IN TO YOUR LOCAL NEWSPAPER

SUPPORT I'M IN ON DIGITAL MEDIA AS AN INDIVIDUAL/AS AN ORGANIZATION (CIRCLE ONE OR BOTH)

We will have a variety of ways for you to promote I'm In on social media. Please let us know if you'd be interested in spreading the word as an individual and/or organization by placing a check by the platforms you plan to use to promote I'm In and filling out the information below.

- Organization website: _____
- Individual website: _____
- Organization Facebook: _____
- Individual Facebook: _____
- Organization Twitter: _____
- Individual Twitter: _____
- Organization blog: _____
- Individual blog: _____
- Other (please list): _____

BECOME A CLINICAL TRIAL INVESTIGATOR (PHYSICIANS ONLY)

Are there other ways you'd like to promote I'm In that aren't listed? _____

This form can be found at JoinImIn.org, or you can simply return a hard copy to Emily Read at emilyr@moorecommgroup.com or fax to (850) 224-9286. For questions call (850) 224-0174.

We look forward to working with you throughout this campaign and thank you again for your commitment to advance clinical trial research among underrepresented populations by sharing news about I'm In with those in your community.

Your Name: _____ Organization: _____

Email: _____ Phone: _____

Website Article

THE FOLLOWING IS A SAMPLE ARTICLE FOR YOUR WEBSITE, NEWSLETTER OR OTHER PATIENT COMMUNICATION. WE WOULD BE GLAD TO HELP YOU CUSTOMIZE IT FOR YOUR AUDIENCE.

Clinical trials are used to evaluate the safety and effectiveness of medications by monitoring their effects in patients who volunteer to participate. This process should accurately take into account the patient populations that will eventually take them. According to the FDA, African Americans represent 12 percent of the U.S. population but only 5 percent of clinical trial participants and Hispanics make up 16 percent of the population but only 1 percent of clinical trials participants.

I'm In is a campaign created to raise awareness about the importance of clinical research and to encourage greater diversity in clinical trials, particularly among traditionally underrepresented populations. A collaboration of the Pharmaceutical Research and Manufacturers of America (PhRMA) and National Minority Quality Forum, **I'm In** is a fully integrated advocacy, media relations and digital media campaign designed to encourage participation in clinical trials.

I'm In is a contributor and supporter of the Clinical Trial Engagement Network, which provides a secure internet-based environment connecting patients, clinical trial sponsors, clinical investigators, health care professionals, their institutions and advocacy organizations across the nation. The Clinical Trial Engagement Network will give authorized users the capacity to simply and quickly identify (by both demographic and geographic characteristics) potential clinical study participants who meet specific protocol requirements, while simultaneously identifying points of care and community resources that can assist with site locations, investigator and patient recruitment. The result is more comprehensive clinical trials and in turn, better health.

It's always best to discuss with your physician whether a clinical trial is right for you. To learn more about **I'm In** and how you can get involved, visit [**JoinImIn.org**](http://JoinImIn.org).

Social Media Cheat Sheet: I'm In Campaign Launch

Below are simple tools to help promote the **I'm In** campaign launch on your social media networks, including hashtags and sample social media posts.

ONLINE:

Website: www.JoinImIn.org

Facebook: facebook.com/joinimin

Twitter: [@Join_ImIn](https://twitter.com/Join_ImIn)

YouTube: www.youtube.com/joinimin

CAMPAIGN HASHTAG:

- [#ImIn4Health](https://twitter.com/hashtag/ImIn4Health)

TOPICAL HASHTAGS

- [#clinicaltrials](https://twitter.com/hashtag/clinicaltrials)
- [#health](https://twitter.com/hashtag/health)
- [#healthdisparities](https://twitter.com/hashtag/healthdisparities)

SAMPLE FACEBOOK POST:

New medicines cannot be developed without clinical trials. Clinical trials cannot happen without volunteers. The goal of **I'm In** is to increase clinical trial participation among traditionally underrepresented populations. <Insert your organization name> is in. Learn more at www.JoinImIn.org.

The process used to test the effectiveness of potential new medicines should accurately take into account the patient populations that will eventually take them. Learn how <insert your organization name> is helping **I'm In** meet this challenge. www.JoinImIn.org.

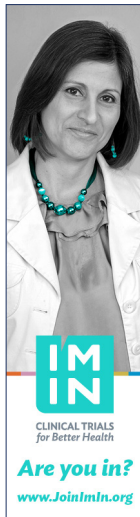
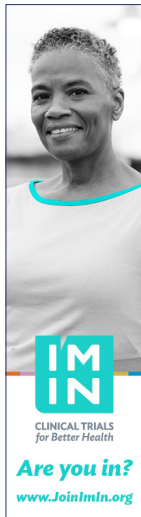
SAMPLE TWEETS:

1. We're in! Help us and [@Join_ImIn](https://twitter.com/Join_ImIn) spread the word about the importance of diversity in [#clinicaltrials](https://twitter.com/hashtag/clinicaltrials). [#ImIn4Health](https://twitter.com/hashtag/ImIn4Health)
2. Diversity in [#clinicaltrials](https://twitter.com/hashtag/clinicaltrials) is important to <Insert your organization name>. Follow [@Join_ImIn](https://twitter.com/Join_ImIn) as we work to make it happen. [#ImIn4Health](https://twitter.com/hashtag/ImIn4Health)

If you are planning any social media activities, including TweetChats and blog posts about diversity in clinical trials, please let us know. Please feel free to contact Emily Read at (850) 224-0174 or emilyr@moorecommgroup.com with any questions.

Website Banners

Please use these web banners on your website to promote **I'm In** and link them to our website at www.JoinImIn.org.



Posters



Resources for Your Patients

This toolkit includes information on the need for increased diversity in clinical trials, key messages you can use when sharing the campaign with patients and an overview of ways you can engage with **I'm In.**

We look forward to you joining the **I'm In** campaign!

- Fact Sheet: Did You Know?
- Clinical Trials Myth vs. Fact
- Patient FAQs
- Website Promo Card
- Brochure

Fact Sheet: Did You Know?

Medical innovations and new, effective treatments have the power to change lives, but these breakthroughs don't happen on their own. The research that goes into each new way to treat an illness or condition is comprehensive and involves various steps to ensure treatments truly work.

By evaluating the safety and efficacy of potential new medicines, clinical trials help improve health.

ABOUT CLINICAL TRIALS

Clinical trials are used to evaluate the safety and effectiveness of medications by monitoring their effects in patients who volunteer to participate. By the time the potential new medicine makes it to a clinical trial in which you might be eligible to participate, it's typically gone through at least three to six years of preclinical testing.

THE PHASES OF CLINICAL TRIALS¹



Clinical trials are important for the development of new medical treatments. If you or a loved one gets sick, you want the best treatment. Without the patients who volunteer to participate in clinical trials, the development of new treatments would not be possible.

WHY IS DIVERSITY IMPORTANT?

It's important for individuals of varied races, ethnicities, ages, gender and sexual orientation to participate in clinical trials. We know that some medicines impact people differently. For example, certain blood pressure medications are less effective in African Americans than other races. Inclusion of participants from diverse backgrounds furthers research and helps find better ways to fight diseases that disproportionately impact these populations.

However, ethnically and racially diverse audiences are underrepresented in clinical trials. Despite comprising 12 percent of the U.S. population, African Americans make up only 5 percent of clinical trial participants. Hispanics represent 16 percent of the U.S. population, but only 1 percent of clinical trial participants.²

REFERENCES:

1. PhRMA. Clinical Trials: The Phases of Drug Testing and Approval. Available from: <http://www.phrma.org/innovation/clinical-trials>. [Accessed 2013 Oct 11].
2. The Society for Women's Health Research United States Food and Drug Administration Office of Women's Health. "Dialogues on Diversifying Clinical Trials." 2011. Available from: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf> [Accessed 2013 Oct 10].

According to the FDA, increased diversity in clinical trials helps researchers find better treatments and better ways to fight diseases that disproportionately impact certain populations.

- African American men are twice as likely to die from prostate cancer than Caucasians³ but represent only 4 percent of prostate cancer clinical trial participants⁴
- Suicide is one of the top three causes of death for Asian American women ages 15-45⁵; however, they represent only 2 percent of participants in clinical trials for major depressive disorder⁴
- Mexican Americans and Puerto Ricans have more than double the prevalence of diabetes than Caucasians,⁶ but represented only 4 percent of clinical trial participants from 1998-2001⁵

You don't have to be sick to take part in a clinical trial. Healthy individuals are also needed as participants.

HERE'S HOW YOU CAN HELP

- ✓ Go to www.JoinImIn.org to be part of the campaign to increase diversity in clinical trials. You can sign up to be contacted about clinical trials in which you might be eligible to participate and learn more about research taking place in your city
- ✓ Encourage your friends and family to join I'm In. Visit www.JoinImIn.org to find materials you can share to help educate your community about the importance of diversity in clinical trials
- ✓ Have you participated in a clinical trial? Go to www.JoinImIn.org to share your story with us

Are you in?

To learn more about I'm In and how you can get involved and spread the word, visit www.JoinImIn.org.

REFERENCES:

3. National Cancer Institute at the National Institutes of Health. "Cancer Health Disparities" Fact Sheet. 2008. <http://www.cancer.gov/cancertopics/factsheet/disparities/cancer-health-disparities>. [Accessed 2013 Sept 19].
4. Food and Drug Administration. "FDA Report: Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products, August 2013." Available from: "<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/UCM365544.pdf> [Accessed 2013 Aug 20].
5. Evelyn B, Gray K, Rothwell R (Office of Special Health Issues US FDA). US Black participation in clinical trials: a review of selected new molecular identities approved 1998-2001. Presented at the NMA meeting, 2002, Honolulu, Hawaii.
6. American Diabetes Association. "2011 National Diabetes Fact Sheet." 2011. Available from: "<http://www.diabetes.org/diabetes-basics/diabetes-statistics/>." [Accessed 2013 Oct 10].

Clinical Trials Myth vs. Fact

MYTH: CLINICAL TRIALS DON'T HELP ANYONE.

FACT: Clinical trials are scientific studies used to evaluate potential new treatments and advance modern medicine by monitoring their effects on patients. It is important to test how individuals react to these therapies in order to gauge their safety and effectiveness. Clinical trials often lead to medical innovations that greatly improve health outcomes of patients.

MYTH: A CLINICAL TRIAL IS FOR YOU ONLY IF YOU HAVE NO OTHER TREATMENT OPTION.

FACT: Some clinical trials are meant for those who have exhausted all treatment options, while others are meant to test ways to prevent recurrence. Some are designed for healthy participants to test ways to prevent the illness in the first place. Clinical trials need participants such as:

- Healthy participants
- Patients in remission
- Newly diagnosed patients
- Patients with no other treatment options

It's always best to discuss with your physician whether a clinical trial is the right choice for you.

MYTH: CLINICAL TRIALS ARE ONLY FOR SICK PEOPLE.

FACT: Some clinical trials are meant to determine how a treatment works for a specific condition. Others are meant to track disease prevention and therefore require healthy participants. Most individuals can find a clinical trial in which they are eligible to participate.

MYTH: IF I'M RECEIVING A PLACEBO, I'M NOT GETTING TREATMENT.

FACT: Patients participating in a clinical trial receive the standard treatment of care - along with the option of a potential new treatment. Patients receiving a placebo still receive the standard treatment of care they would otherwise receive to treat their condition. For example, if a patient is participating in a cancer clinical trial and the standard of care is chemotherapy, the individual will receive chemotherapy, with the possibility of a potential new treatment.

MYTH: THERE ARE NO CLINICAL TRIALS IN MY AREA.

FACT: With thousands of clinical trials taking place in the U.S., there may be one near you. Registered users can visit www.JoinImIn.org, to use the Clinical Trial Locator to see the clinical trials currently underway in your area.

MYTH: THE ONLY WAY I CAN FIND OUT ABOUT A CLINICAL TRIAL IS THROUGH MY DOCTOR.

FACT: While physicians are often the way that many people learn about clinical trials in which they may be eligible, there are a number of tools that can help you find a clinical trial in your area. Registered users can visit www.JoinImIn.org to view our Clinical Trial Locator and find the clinical trials taking place near you.

MYTH: PARTICIPATING IN A CLINICAL TRIAL COSTS A LOT OF MONEY.

FACT: Most of the treatment costs associated with a clinical trial are covered by the researcher and sponsor. If not, many health insurance companies may cover the cost of treatment. Before participating in a clinical trial, you can ask the researchers about any potential costs for participation.

MYTH: I DON'T HAVE TIME TO FIND A CLINICAL TRIAL IN WHICH I MIGHT BE ELIGIBLE TO PARTICIPATE.

FACT: It's true that it can take some time to find a clinical trial. Through the Clinical Trial Engagement Network, you can sign up to enter a volunteer pool to be considered for participation in future clinical trials. Go to www.JoinImIn.org to sign up.

MYTH: CLINICAL TRIAL PARTICIPANTS ARE GUINEA PIGS.

FACT: Clinical trials are tightly regulated to ensure maximum safety for participants. All clinical trials involving human participants are monitored by an Institutional Review Board (IRB) to ensure high safety standards and processes are followed. IRBs are comprised of at least five members with a wide range of backgrounds, including at least one scientist, at least one non-scientist (such as a lawyer or professor) and at least one member of the community who is not connected to the institution or sponsor of the trial. Additionally, federal agencies such as the Office of Human Subjects Research Protection and Food and Drug Administration oversee clinical trials to ensure patient safety.

By the time a potential new treatment is allowed to be tested in patients, it has been in development for at least three to six years, meaning it's already been through rigorous preclinical testing. A treatment has to be backed by valid scientific evidence that shows it is likely to be safe and effective before it can be administered to patients in a clinical trial.

Researchers conducting clinical trials will clearly explain the potential benefits and risks, so you can feel confident about making the best decision in consultation with your doctor. Participants always have the right to end their participation at any time, even if the study is not over. According to the Center for Information and Study on Clinical Research Participation, most clinical trials participants indicate they would participate again.

Frequently Asked Questions for Patients

Q. WHAT ARE CLINICAL TRIALS AND WHY ARE THEY IMPORTANT?

- A.** Clinical trials are scientific studies in which researchers evaluate potential new treatments by monitoring their effects on people. It is important to test how individuals react to potential new therapies in order to gauge their safety and effectiveness. Even if at the end of the research period a therapy is not approved for lack of safety or effectiveness, clinical trials contribute greatly to the overall base of knowledge, and may help researchers develop new treatments in the future.

Q. WHO CONDUCTS CLINICAL TRIALS?

- A.** Clinical trials are conducted by physicians, investigators and researchers at various organizations including local research institutions, hospitals and universities.

Q. WHY SHOULD I PARTICIPATE IN A CLINICAL TRIAL?

- A.** Participation in a clinical trial often provides patients access to potential new treatments and to expert health care at leading institutions. By participating in a clinical trial, you play an active role in your health and the health of others by contributing to scientific knowledge that may lead to potential new medical treatments for future patients.

Q. ARE CLINICAL TRIALS SAFE?

- A.** As with any medical treatment, participation in a clinical trial offers benefits and risks. Researchers conducting these trials will clearly explain the potential benefits and risks so you can feel confident about making the best decision. Participants always reserve the right to end their participation at any time, even if the study is not complete.

All clinical trials must be approved by an Institutional Review Board (IRB). An IRB is made up of physicians, researchers and members of the local community. Its role is to make sure that the study is ethical and the rights and welfare of participants are protected. This includes ensuring high safety standards and processes are followed, and that risks are minimized and reasonable in relation to potential benefits.

The Food and Drug Administration (FDA) also plays an important role in the clinical trials process, ensuring the safety of participants, qualifications of researchers and the safety and efficacy of the studies.

It's always best to discuss with your physician whether a clinical trial is right for you.

Q. WHY DO CLINICAL TRIALS LACK PARTICIPATION FROM DIVERSE PATIENT POPULATIONS?

- A.** Reasons certain populations are underrepresented in clinical trials vary and may include lack of understanding of the clinical trial process, lack of awareness of which clinical trials are available to them, or lack of clinical trials in underserved areas.

Q. WHY IS IT IMPORTANT FOR DIVERSE PATIENT POPULATIONS TO PARTICIPATE IN CLINICAL TRIALS?

- A.** It's important for individuals of varied races, ethnicities, ages, gender and sexual orientation to participate in clinical trials. We know that some medicines impact people differently. For example, certain blood pressure medications are less effective in African Americans than other races. Inclusion of participants from diverse backgrounds furthers research and helps find better ways to fight diseases that disproportionately impact these populations.

The current clinical trial system faces many challenges in recruiting and retaining eligible participants. According to the Center for Information and Study on Clinical Research Participation, only 6 percent of clinical trials are completed on time and 50 percent of clinical research sites enroll one or no patients in their study. Delays in trial completion lead to delays in regulatory review and approval processes - which ultimately delays patient access to new, potentially life-saving medicines.

Q. HOW WOULD MY PARTICIPATION IN A CLINICAL TRIAL HELP MY COMMUNITY?

- A.** By increasing participation of populations typically underrepresented in clinical trials, not only can researchers gain knowledge of how a comprehensive participant pool reacts to medications and treatment, but they can learn more about how to address specific diseases that disproportionately affect certain ethnic or racial groups.

Q. WHAT IS I'M IN?

- A.** To enhance participation in clinical trials, the Pharmaceutical Research and Manufacturers of America (PhRMA) and National Minority Quality Forum have joined together to launch **I'm In**, a campaign to encourage greater diversity of patients who volunteer to participate in clinical trials. **I'm In** will be a contributor and supporter of the Clinical Trial Engagement Network. This resource will allow patients to connect to clinical trials in which they may be eligible to participate and provide industry members, physicians, researchers and academic institutions with on-demand access to zip code level data that identifies different population groups by disease status and validates where recruitment efforts should take place in a cost-effective manner.

Through strategic outreach and partnerships, **I'm In** will raise awareness about participation in clinical trials in historically underrepresented populations.

Q. HOW DOES THE CLINICAL TRIALS ENGAGEMENT NETWORK WORK?

- A.** The Clinical Trial Engagement Network provides a secure internet-based environment connecting patients, clinical trial sponsors, clinical investigators, health care professionals, their institutions and advocacy organizations across the nation. Here's how individuals and organizations can get involved:
 - **Patients:** Both volunteers with health challenges and healthy participants are needed for clinical trials. Signing up as a patient in the Clinical Trial Engagement Network allows individuals to search for clinical trials as well as to enter a volunteer pool to be considered for participation in future clinical trials.
 - **Advocacy Organizations:** Patient advocacy organizations that would like to get involved with the campaign can download a customized advocate toolkit, become official **I'm In** champions, and engage with **I'm In** on social media.
 - **Physicians:** Physicians who are not clinical trial investigators but are interested in becoming one can register as an investigator in the Clinical Trial Engagement Network. A free physician toolkit is also available for download and provides more information about how to get involved with **I'm In**.
 - **Clinical Trial Sponsors:** The Clinical Trial Recruitment Center is a new tool available to qualified clinical trial sponsors. Sponsors will have access to a secure Patient Registry, National Research Directory, Investigator Registry, Clinical Site Reporter and the National Health Index.
 - **Clinical Trial Investigators:** Current clinical trial investigators, physicians and other health care professionals who want to become investigators can sign up for the Clinical Trial Engagement Network as an investigator and complete a profile to make their information available to clinical trial sponsors.
 - **Family and Friends:** Patients often rely on family and friends for support and care during health challenges. Free resources are available to educate loved ones about clinical trials.

Q. HOW CAN I GET INVOLVED?

- A. I'm In** Champions are encouraged to get involved and share news about the campaign with their own communities. The first step is to visit [**www.JoinImIn.org**](http://www.JoinImIn.org) and register.

There are other ways you can get involved in providing news to your community about the importance of clinical trials. From sharing information through social media to scheduling speaking engagements, there are effective ways you can truly make a difference. Visit [**www.JoinImIn.org**](http://www.JoinImIn.org) to learn more about ways to get involved and for additional resources that will assist you in your outreach. Together, we can make a difference.

Website Promo Card

IM IN
CLINICAL TRIALS
for Better Health

Join us in celebrating the launch of I'm In.

I'm In is a campaign designed to improve health by increasing clinical trial participation among traditionally underrepresented populations, including African Americans, Asian Americans and Hispanics.

Together we can make a difference.

Are you in?

Visit our website to find out how you can get involved.

JoinImIn.org f t You Tube

Brochure

Why Clinical Trials Matter

Medical innovations and new, effective treatments have the power to change lives. But these breakthroughs don't happen on their own. The research that goes into each new way to treat an illness or condition is comprehensive and involves multiple steps to ensure treatments truly work.

That's why clinical trials exist - to evaluate the safety and effectiveness of treatments. Clinical trials help improve medical care. But something is missing. **YOU.**

What's I'm In?

I'm In is a campaign designed to improve health by increasing clinical trial participation among traditionally underrepresented populations, including African Americans, Asian Americans and Hispanics.

By increasing diversity in clinical trials, we can help ensure that the process used to test the effectiveness of new potential medicines accurately takes into account the patient populations that will eventually take them and helps increase scientific knowledge that may result in medical innovations and more effective treatments. I'm In was founded by the Pharmaceutical Research and Manufacturers of America (PhRMA) and National Minority Quality Forum.

Together we can make a difference.

Are you in?

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for Better Health

Thank you for your participation in the **I'm In** campaign. These resources have been provided for the direct promotion of the **I'm In** campaign to increase participation in clinical trials and may not be reproduced, copied, shared, distributed or used in any manner other than for the promotion of **I'm In**. If you have any questions or would like to inquire about other resources available, please contact Emily Read at (850) 224-0174 or emilyr@moorecommgroup.com.