

[lupusinitiative.org/MIMICT](http://lupusinitiative.org/MIMICT)

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## MIMICT

Materials to Increase Minority  
Involvement in Clinical Trials

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African American Patients

# DISTRIBUTION GUIDE FOR CLINICAL TRIAL SITES



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# Acknowledgements

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*Our expert advisors include rheumatologists and health professionals, people living with lupus, and others. Throughout development of this project there has been communication, collaboration and transparency among all experts.*



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**KDH RESEARCH &  
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Materials to Increase Minority Involvement in Clinical Trials are presented by the American College of Rheumatology in collaboration with KDH Research & Communication. This project was supported by Grant Number 1 CPIMP171138 from the U.S. Department of Health and Human Services Office of Minority Health (HHS, OMH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the HHS or OMH.

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# INTRODUCTION

Robust clinical trial research leads to innovative treatment options, but minorities often lack awareness and access to these clinical trial opportunities.

Clinical trial sites can help increase minority involvement in clinical trials by building relationships with providers and encouraging them to raise patient awareness about clinical trial opportunities.

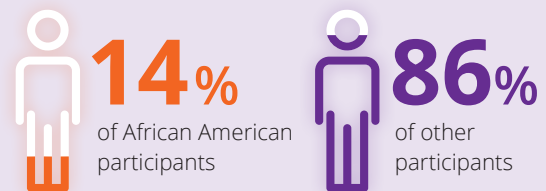
## The issue

### Low African American involvement in clinical trials.

Slow drug development over the past 56 years delays advancements in lupus treatments.

In 2011, the Food and Drug Administration approved belimumab, the *only* new drug for lupus since 1955.<sup>2</sup> Despite the disproportionate prevalence of lupus among African Americans, **only 14 percent of the belimumab clinical trial participants were African American.**

Advancements in lupus are slow and often lack conclusive results in minority populations.



The small sample size in the belimumab trials led to inconclusive results on the effectiveness of belimumab for African Americans.

## Why focus on African American patient involvement in lupus clinical trials?

### Lupus disproportionately affects minority populations, especially African Americans.

African American patients are disproportionately affected by lupus compared to non-Hispanic whites.<sup>2</sup>

Low African American involvement in lupus clinical trials results in a lack of data on the effectiveness and safety of treatments within a population that experiences the highest lupus incidence, prevalence, morbidity, and mortality.<sup>2,4</sup>

### Lupus Prevalence



Non-Hispanic Whites



African Americans

***Lupus prevalence among African Americans is 2-3 times greater than in non-Hispanic whites.<sup>1</sup>***

# Educate Providers About Clinical Trials

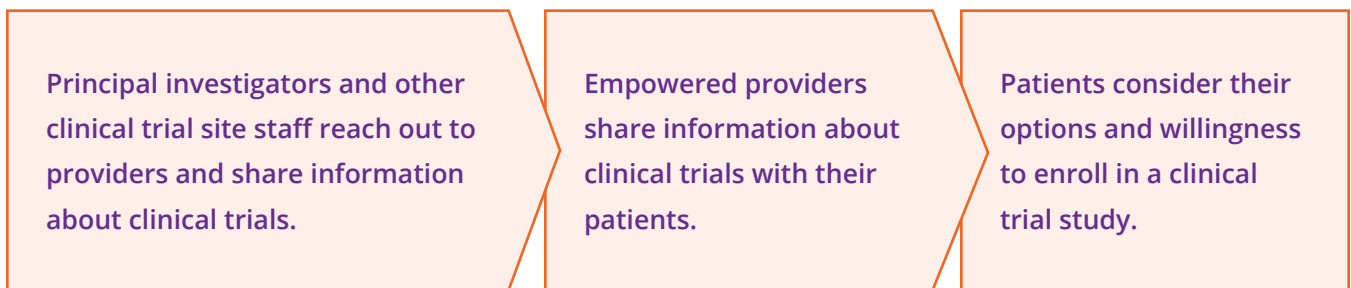


Patients prefer to learn about clinical trials from their doctors.

African American patients are more likely to receive information about clinical trials from television, radio, and print media.<sup>3</sup> Very few patients hear about clinical trial opportunities from their doctors. Patients who get information about clinical trials from their provider are more likely to participate in a trial.<sup>3</sup>

Unfortunately, many providers lack awareness about clinical trials and do not share clinical trial opportunities with patients. The relationship between clinical trial sites and providers is critical to increase minority involvement in clinical trials.

The Materials to Increase Minority Involvement in Clinical Trials (MIMICT) focuses on strengthening these relationships.



The distributional toolkit consists of this short guide and a few customizable materials to edit and share specific contact information about your clinical trial study to providers.



Add information about your clinical trial to this customizable document and distribute it to providers along with existing materials you use for outreach.

- Customizable Lupus Clinical Trials Flyer



Instruct providers to browse the education course modules and distribute the patient materials to equip them with tools to introduce their patients to clinical trials as part of a range of treatment options.

# Learn More About MIMICT



## Minority Involvement in Lupus Clinical Trials

Clinical trial research drives medical innovation and widens the range of treatment options providers may offer to patients with lupus. Thus, low minority involvement in lupus clinical trials significantly limits our knowledge about the effectiveness and safety of new lupus treatments among people from diverse backgrounds



## Why use the Materials to Increase Minority Involvement in Clinical Trials (MIMICT)?

Providers and patients may hesitate to discuss clinical trial opportunities and enroll in clinical trials. For providers, barriers to discussing clinical trials include lack of awareness about clinical trials, lack of knowledge about lupus clinical trials, and lack of time.

MIMICT aims to equip providers to overcome these barriers. Specifically, the materials are designed to facilitate communication between clinical trial sites and providers to address common concerns.

**Table 1. Common provider concerns**

Common provider concern	How to use MIMICT
<p>“I don’t have time to explain all details about clinical trials to patients.”</p> <p>“I don’t know how to make a clinical trial referral.”</p>	<p>Remind providers that if they lack time to explain all the details about clinical trials, they can handout MIMICTs online materials. Once providers introduce the information about clinical trials, patients can use the resources to go more in depth.</p> <p>List the steps in the referral process for your specific clinical trial in a simple document so providers clearly understand their expected tasks when referring patients to your trial.</p>
<p>“I don’t know much about clinical trials.”</p>	<p>Encourage providers to browse MIMICT’s brief educational modules to build their knowledge about clinical trials and ethical medical research.</p>
<p>“Encouraging patients to enroll in clinical trials feels unethical/coercive.”</p>	<p>Reinforce to providers that patients make the decision to participate. Providers should empower patients and raise awareness about informed decision-making.</p>
<p>“It’s difficult to find information about clinical trials.”</p> <p>“My patients don’t meet the eligibility criteria for clinical trials.”</p>	<p>Ensure that providers have a point-of-contact among the clinical trial site staff.</p> <p>Explain that to providers that it is not their role to assess a patient’s eligibility for a clinical trial. This responsibility lies with clinical trial site staff.</p>

## Works Cited

<sup>1</sup>Lupus Foundation of America. (2013). Benlysta: What you need to know. Retrieved from <http://bit.ly/2oxTnWv>

<sup>2</sup>Lim, S. S., Bayakly, A. R., Helmick, C. G., Gordon, C., Easley, K. A., & Drenkard, C. (2014). The Incidence and Prevalence of Systemic Lupus Erythematosus, 2002–2004: The Georgia Lupus Registry. *Arthritis & Rheumatology*, 66(2), 357-368. doi:10.1002/art.38239

<sup>3</sup>Baquet, C. R., Commiskey, P., Mullins, C. D., & Mishra, S. I. (2006). Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detection and Prevention*, 30(1), 24-33.

<sup>4</sup>The Society for Women’s Health Research. (2011). Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials. Washington, DC: Food and Drug Administration, Office of Women’s Health.

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