

[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

# A QUICK -START GUIDE



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# Acknowledgements

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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.

As a provider, you can increase minority involvement in clinical trials **by referring patients to clinical trials as part of their treatment options.**

## 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>1</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>1,4</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>*

# Get Involved in Clinical Trial Referrals

Patients prefer to learn about clinical trials from you.

38%

Surveyed patients who get general information about clinical trials from the media.<sup>5</sup>

51%

Surveyed patients who prefer learning about clinical trial opportunities directly from providers.<sup>5</sup>

Patients want to explore options that will help them live healthier lives. A clinical trial is one of those options.

***Patients shouldn't have to wait to hear about clinical trial opportunities from a specialist.*** All providers, including primary care providers, nurses, physician assistants, nurse practitioners, and any non-specialists who engage patients with lupus, can raise awareness about lupus clinical trial opportunities.



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

### Step 1:

Strengthen your knowledge to easily respond to patient questions about clinical trials.

Browse these modules for more information about lupus, lupus health disparities, and minority clinical trial recruitment. Feel free to share the information with other members of your healthcare team!

- Clinical Trials Basics and Barriers to Recruiting African American Patients into Clinical Trials
- Lupus Health Disparities and Clinical Trials
- Referring Patients to Clinical Trials
- Impact of the Provider-Patient Relationship on Clinical Trial Referrals

### Step 2:

Provide resources for your patients to learn more details about clinical trials.

Print out these fliers to place in your exam rooms or waiting areas for patients and their families.

- Lupus Clinical Trials Factsheet
- Lupus Clinical Trials Informational Booklet

These modules are available in several formats. Learn about these topics while on-the-go!



# Why use Materials to Increase Minority Involvement in Clinical Trials?

Providers and patients face apprehension about discussing clinical trial opportunities and enrolling in clinical trials. MIMICT engages and equips providers to overcome barriers to making clinical trial referrals. Table 1 describes how MIMICT addresses common barriers to making a clinical trial referral.

**Table 1. Common barriers to making clinical trial referrals**

 <b>Barriers to making a clinical trial referral</b>	 <b>How MIMICT can help</b>
<p><b>“I don’t have time to explain all details about clinical trials to patients.”</b></p> <p><b>“Encouraging patients to enroll in clinical trials feels unethical/coercive.”</b></p>	<p>Keep copies of the patient materials in your waiting areas or exam rooms to save time explaining clinical trials. They contain more details for patients to review.</p> <p>Ultimately, patients make the decision to enroll. Browse MIMICT’s brief educational modules to build your knowledge about clinical trials</p>
<p><b>“I don’t know how to make a clinical trial referral.”</b></p> <p><b>“It’s difficult to find information about clinical trials.”</b></p> <p><b>“I don’t know anything about lupus clinical trials.”</b></p> <p><b>“I don’t know anybody conducting clinical trials.”</b></p>	<p>Browse MIMICT’s educational modules that explain the referral process, lupus clinical trials, and how to seek information about lupus clinical trials.</p> <p>Navigate to the MIMICT website “Resources” page for easy-to-find information about lupus clinical trials.</p>
<p><b>“I don’t know if my patients meet the eligibility criteria for clinical trials.”</b></p>	<p>Criteria differ by clinical trial site. Clinical trial site staff usually determine a patient’s eligibility for a trial.</p> <p>Browse MIMICT’s module on the clinical trial referral process to clearly see what is expected of providers during a referral.</p>
<p><b>“I rarely come across patients with lupus.”</b></p>	<p>Browse the educational modules to be prepared for when you encounter a patient with lupus who may want to talk with you about clinical trials.</p>
<p><b>“We know about the history of unethical research practices with minority communities. This makes conversations about clinical trial research more difficult. Minority patients may not be receptive to willing to discuss clinical trials.”</b></p>	<p>This misconception often prevents providers from discussing clinical trials with African American patients.</p> <p>Some patients may be apprehensive, but studies show that many minority patients are interested in learning more about clinical trials. Browse MIMICT’s module on the history of medical research and learn more about legal protections for research participants.</p>

## Works Cited

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

<sup>3</sup>Mitka, M. (2011). Treatment for lupus, first in 50 years, offers modest benefits, hope to patients. *JAMA*, 305(17), 1754-1755.

<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.

<sup>5</sup>Harper, B., & Reuter, S. (2009). Paying Fees to referring physicians: Ethical or Not Ethical? *Monitor*, 29-34.

<sup>6</sup>Yen, E. Y., Shaheen, M., Woo, J. P., & et al. (2017). 46-year trends in systemic lupus erythematosus mortality in the united states, 1968 to 2013: A nationwide population-based study. *Annals of Internal Medicine*. doi:10.7326/M17-0102

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