

LRAN Lupus Research Action Network

by **Lupus Foundation of America**

A large, stylized, light purple letter 'P' is positioned on the left side of the slide. It has a thick, rounded top and a vertical stem that ends in a small square at the bottom.

Welcome to Clinical Trials 101

Today's Agenda

- LRAN Resources
- The Importance of Clinical Trials
- How to Find Clinical Trials
- The State of Lupus Clinical Trials

Help Us Solve
The Cruel Mystery

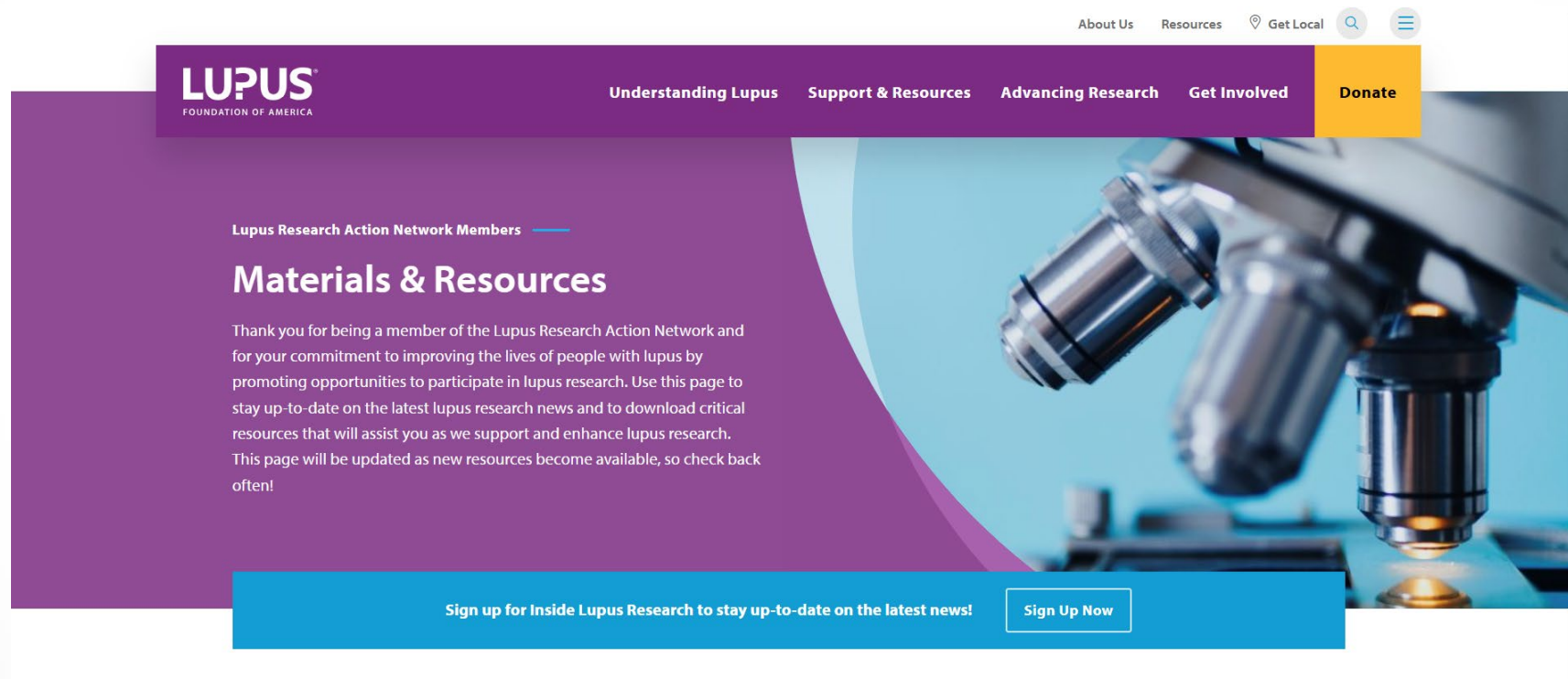
LUPUSTM

FOUNDATION OF AMERICA

LRAN Resources

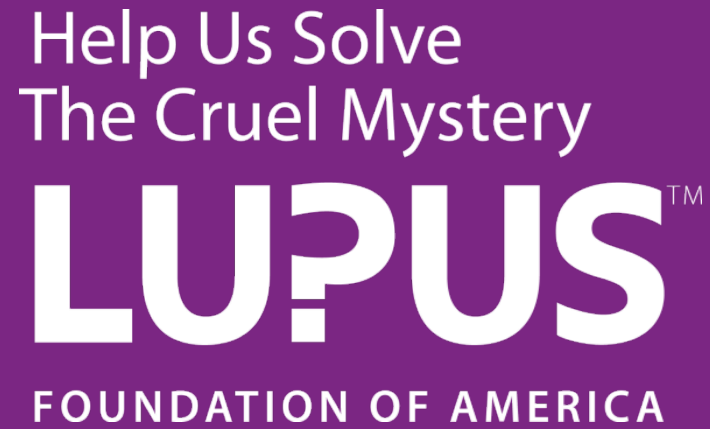
Where to Find LRAN Resources

- [Lupus.org/LRAN](https://lupus.org/LRAN)



LRAN Resources

- Review the latest LRAN training presentations
 - [2025 LRAN Training Presentations](#)
 - Lupus 101 Video Recording and Presentation Slides
- Provide someone with information on clinical trials
 - [General Resources](#)
 - [The Expert Series](#)
 - [Additional Resources](#)
- Provide someone with information about RAY
- Connect with my fellow LRAN members
 - [Join the Facebook Group](#)



The Importance of Clinical Trials

Stephanie Slan, MBA, ACRP-CP
Project Director, LFA

What is Clinical Research?



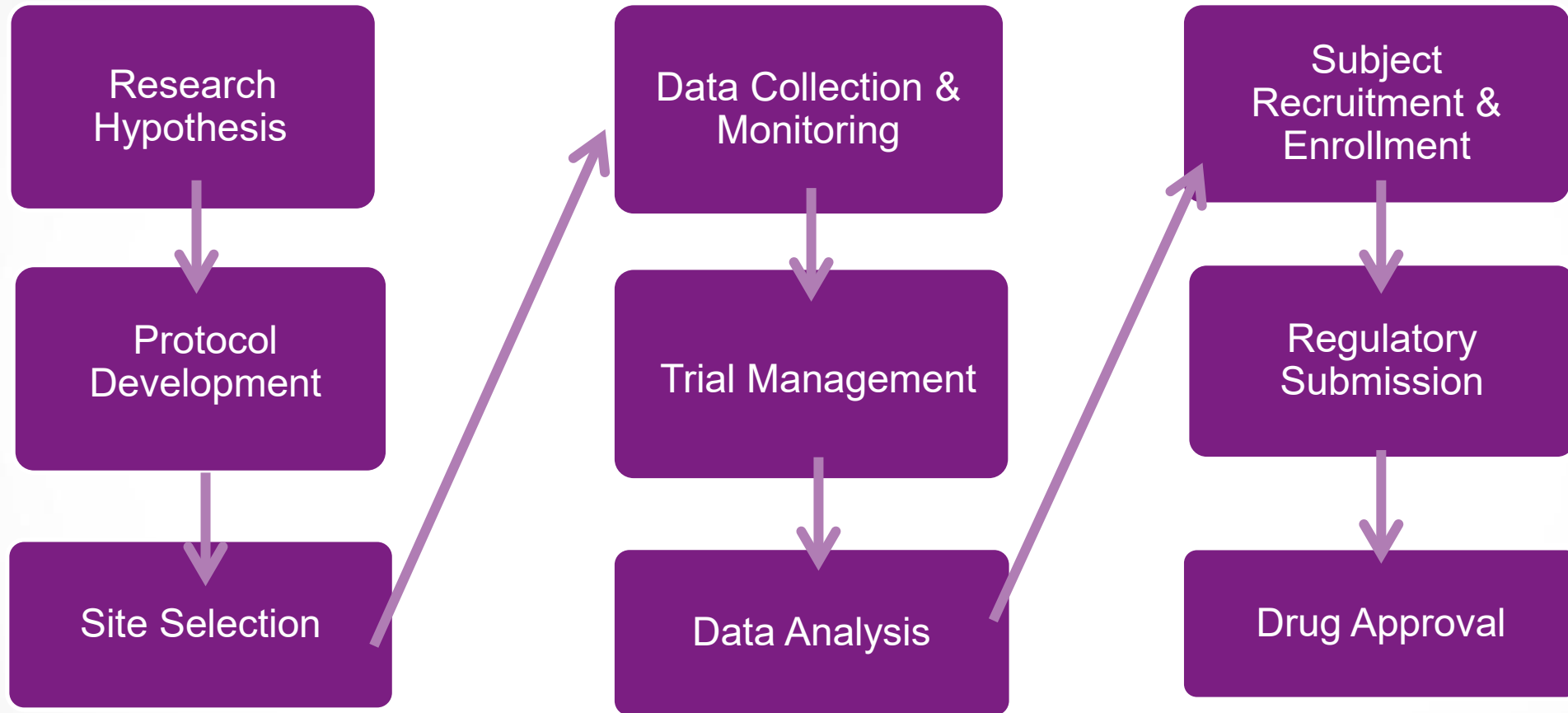
- Clinical research is the study of health and illness in people. The goal is to determine the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for use in people.
- There are two primary types of clinical research:
 - [Observational Studies](#)
 - [Clinical Trials](#)

Types of Clinical Research



- Observational Studies
 - Gather information over time, under normal settings
 - Case Control
 - Cohort
 - Prospective
 - Cross Sectional
 - Retrospective
- Clinical Trials
 - Research studies that test medical, surgical, or behavioral intervention
 - Open Label
 - Placebo Controlled + Blinded
 - Randomized

Clinical Trials Process



Phases of Clinical Trials

- This type of research is conducted in the lab
 - Typically looking at the dosing and toxicity of the medical approach (drug, diagnostic test, device) under study
 - Often includes the use of animal models



Preclinical

Laboratory Studies

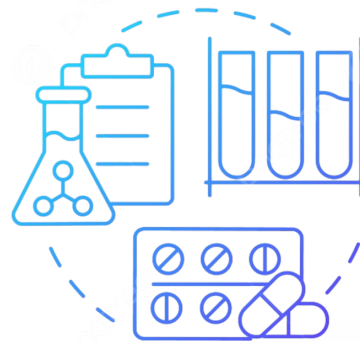
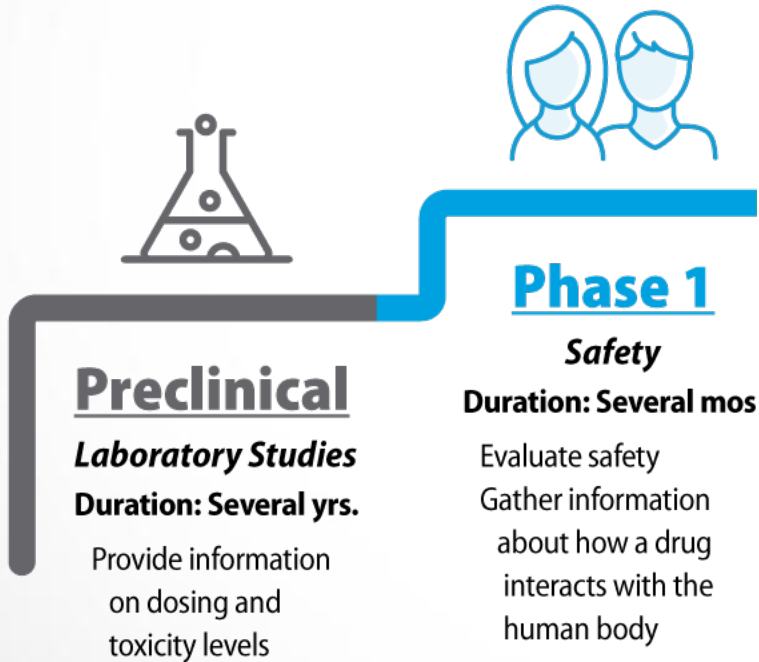
Duration: Several yrs.

Provide information
on dosing and
toxicity levels

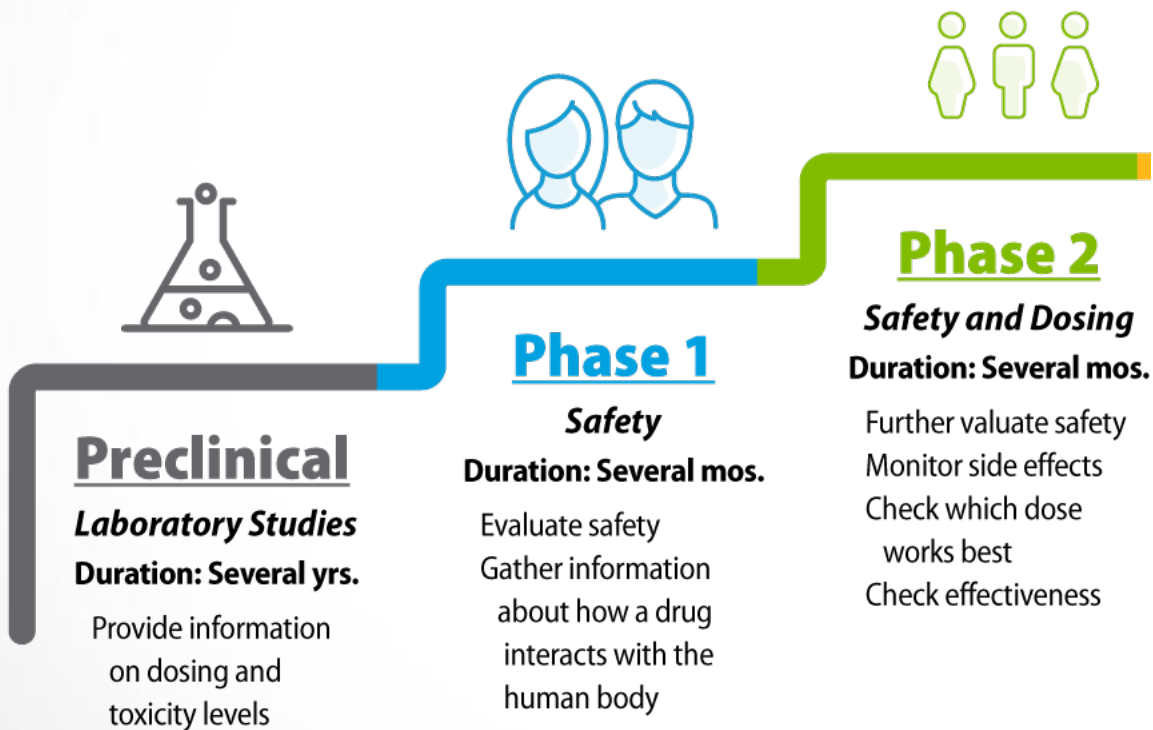


Phases of Clinical Trials

- Safety is the primary goal
 - Is the medical approach safe?
 - Identify side effects
 - Determine safe dosage
 - Typically, fewer than 100 participants



Phases of Clinical Trials

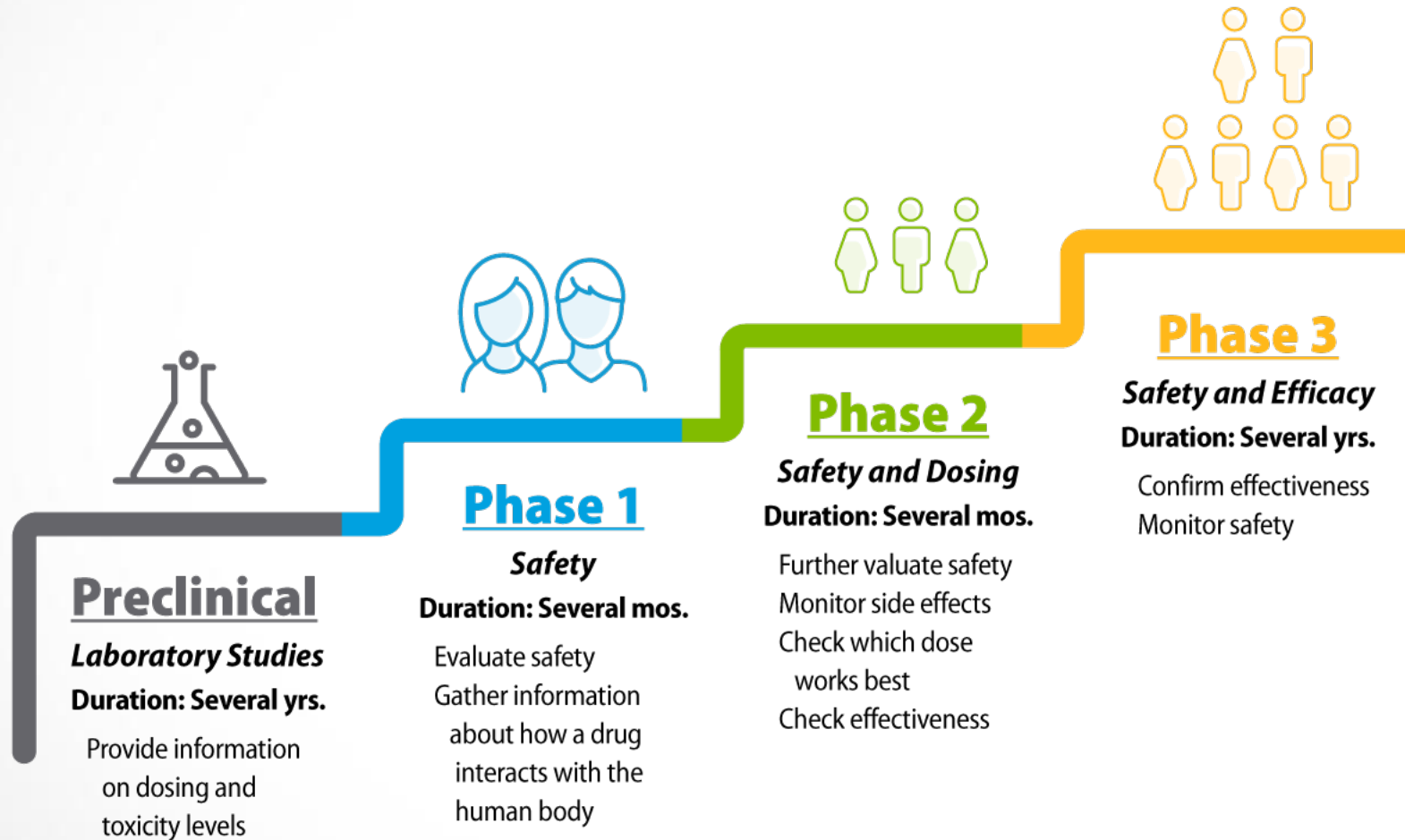


- Safety and Dosage are focus
 - Does the medical approach work?
 - Are there side effects?
 - Typically, 100- 300 participants

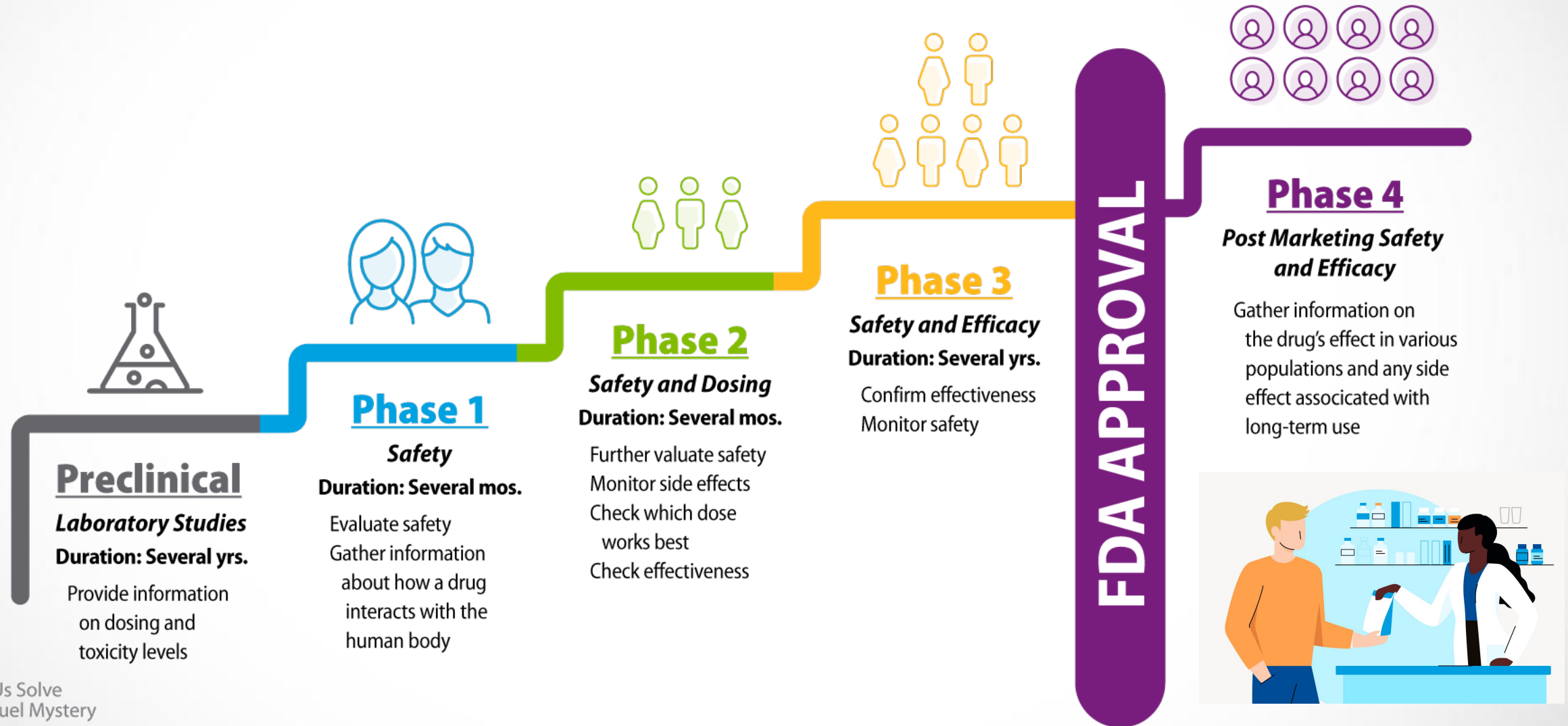


Phases of Clinical Trials

- Proof of Efficacy
 - Continue to monitor side effects
 - 1000 participants



Phases of Clinical Trials



Who runs Clinical Trials?

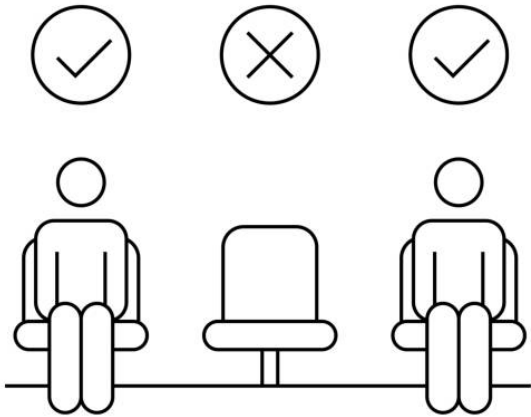
- Clinical trials are conducted under the guidance of a principal investigator (PI), the person(s) who oversee the clinical trial
 - Study design and protocol development
 - Regulatory Compliance
 - Participant Recruitment
 - Informed Consent Process
 - Study Implementation
 - Data Collection and Safety Monitoring
 - Data Analysis and Interpretation



How are Clinical Trials Conducted?

- **Clinical trial protocols** are detailed documents that provide a framework for conducting research studies to ensure consistency, accuracy and ethical treatment of participants.
- **Informed consent documents** are crucial for protecting the rights of participants and ensuring ethical treatment.
 - Informed consent is to be reviewed by participant and study staff to ensure that participant understands and agrees to study procedures

Who can participate in trials?



- To determine who is eligible, researchers rely on inclusion and exclusion criteria:
- Inclusion criteria:
 - Characteristics that individuals must possess to be considered eligible for participation in the clinical trial
- Exclusion criteria:
 - Characteristics or conditions that disqualify individuals from participating in the clinical trial

Why Participate in Clinical Trials?

What are reasons to enroll in a clinical trial:

- Contribute to new understandings of treatment that will help others in the future
- Participation in research allows you to be an active role in your healthcare
- Opportunity to try new treatments for health conditions, providing the chance for better control of your disease

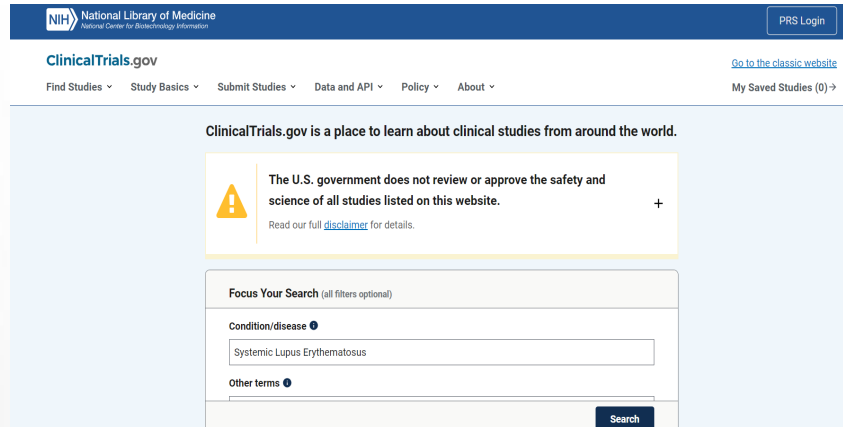
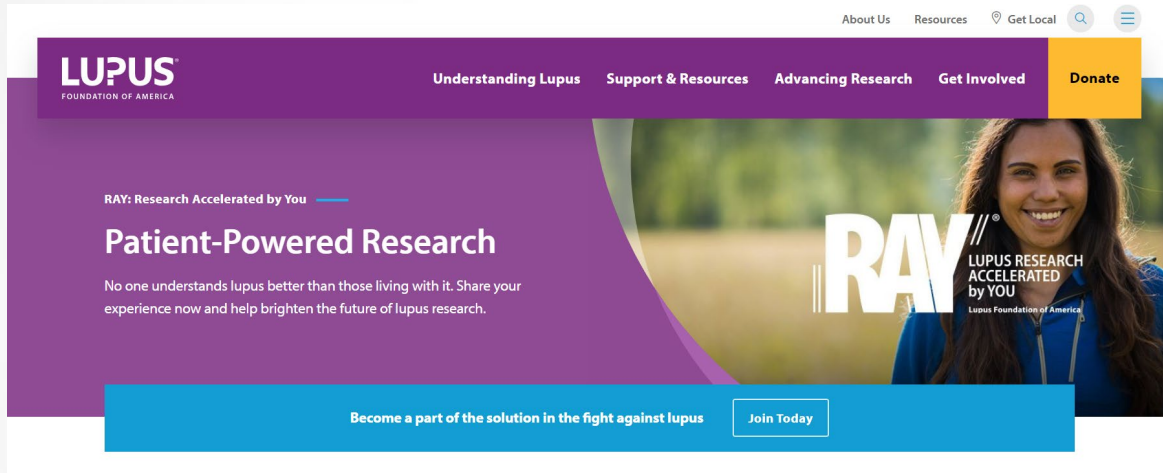


Help Us Solve
The Cruel Mystery
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Locating Clinical Trials

Safoah Agyemang, MS
Health Outcomes and Research Manager

How Do I Find Out About Trials?



1. The Lupus Foundation of America

- Research Accelerated by You (RAY®) Registry
- Local Advocacy Groups

2. ClinicalTrials.gov

- Largest database for ongoing clinical trials
- Filter by condition (lupus), location, and status

3. Antidote Match (antidote.me)

4. CenterWatch.com

5. Local Hospitals

How to Use ClinicalTrials.gov

Step 1: Go to **ClinicalTrials.gov**

Step 2: Enter “**Lupus**” in the search bar

Step 3: Use filters (e.g., location, phase, recruitment status)

The screenshot shows the ClinicalTrials.gov search results page for the query 'LUPUS'. The browser address bar shows 'clinicaltrials.gov/search?cond=LUPUS'. The left sidebar contains filters: 'Focus Your Search' with 'LUPUS' in the search bar, 'Other terms', 'Intervention/treatment', 'Location' (set to 'USA'), and 'Study Status' (set to 'Recruiting (256)'). The right sidebar shows 'Search Results' with 'Viewing 1-50 out of 1,253 studies' and 'Showing results for: LUPUS'. The main content area displays a list of studies, including 'Anti-CD19 Chimeric / ceptor T Cells for Refractory Systemic Lupus Erythematosus', 'Open-label Single-Arm Study to Evaluate the Safety and Efficacy of Combining Rituximab and AB-101 in B-cell Autoimmune Diseases', and 'A Study of Rapcaba...'. The 'Apply Filters' button is highlighted.

How to Use ClinicalTrials.gov



Search Results




Viewing 1-50 out of 86 studies

Showing results for: **lupus** | Recruiting studies | Phase: 2, 3

Sort studies by Newest First

None Selected



 RSS   Manage

<input type="checkbox"/>	Study Title	Status	Phase	Study Type	Sponsor	Locations
<input type="checkbox"/> 1	A Study of Rapcabtagene Autolucel in Systemic Lupus Erythematosus (SLE) Patients With Active, Refractory Lupus Nephritis (LN) NEW	Recruiting	Phase 2	Interventional	Novartis Pharmaceuticals	<ul style="list-style-type: none">NorthwestUniversityNovartis Ir

Step 4: Review **trial details** including eligibility criteria, trial purpose, location, contact info

Understanding Eligibility Criteria

- Read through **inclusion** and **exclusion** criteria carefully
 - Age, Gender, Specific Lupus Diagnosis, and Prior Treatments
- Reach out to trial coordinators to ask questions

Ask your doctor about trials



- Your doctor may know of trials in your area
- There may be trials enrolling at your clinic or hospital
- Discuss any trials that you are interested in participating in
- Ask how the trial fits with your current treatment plan
- Understand potential risks and benefits

Is a lupus clinical trial right for me?

What should I consider?

- Gather Information
- Assess Eligibility
- Weigh Potential Benefits and Risks
- Consider Alternatives
- Make an Informed Decision
- Legal and Ethical Protections
- Consider Logistics
- Seek Second Opinion

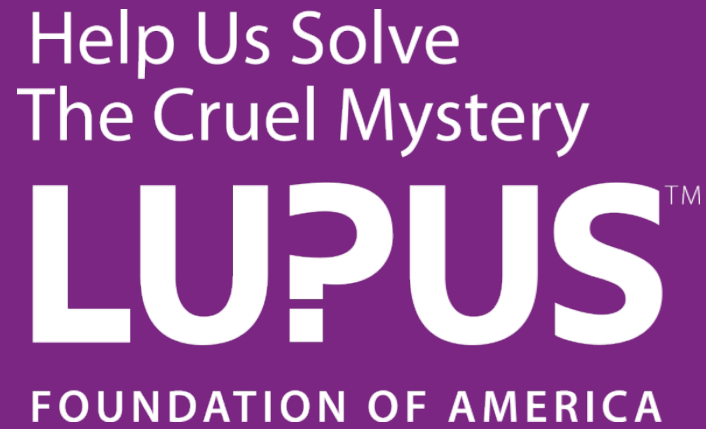
Informed Consent and Safety



- Know your rights as a participant (voluntary participation)
- Trials are regulated for safety, but some risks may still exist

Questions?





LRAN: The State of Lupus Clinical Trials

Joan T Merrill, M.D.

Oklahoma Medical Research Foundation

Co-Fellow with Sharon Kolasinski

Consultant: AbbVie, Alexion, Alumis, Amgen, Astra Zeneca, Aurinia, Biogen, Bristol Myers Squibb, EMD Serono, Genentech, Gilead, GlaxoSmithKline, Lilly, Merck, Pfizer, Provention, Remegen, Sanofi, Takeda, UCB, and Zenas.

Research support: Astra Zeneca, Bristol Myers Squibb, and GlaxoSmithKline.

No one Knows Why The Pharma Companies Did Not Run Away



What is Lupus? Consult Respected Authorities

Lupus - Symptoms & causes - Mayo Clinic



<https://www.mayoclinic.org/diseases-conditions/lupus> ▼

Lupus is a disease that occurs when your immune system attacks your own tissues and organs. Symptoms may include **fatigue, fever, joint pain, skin lesions, butterfly-**



CDC

<https://www.cdc.gov/lupus/facts/detailed.html> ▼

Systemic Lupus Erythematosus (SLE) | CDC

Web Systemic **lupus** erythematosus (SLE), is the most common type of **lupus**. SLE is an autoimmune disease in which the **immune system attacks** its own tissues, causing ...



Johns Hopkins Medicine

<https://www.hopkinsmedicine.org/health/conditions-and-diseases/lupus> ▼

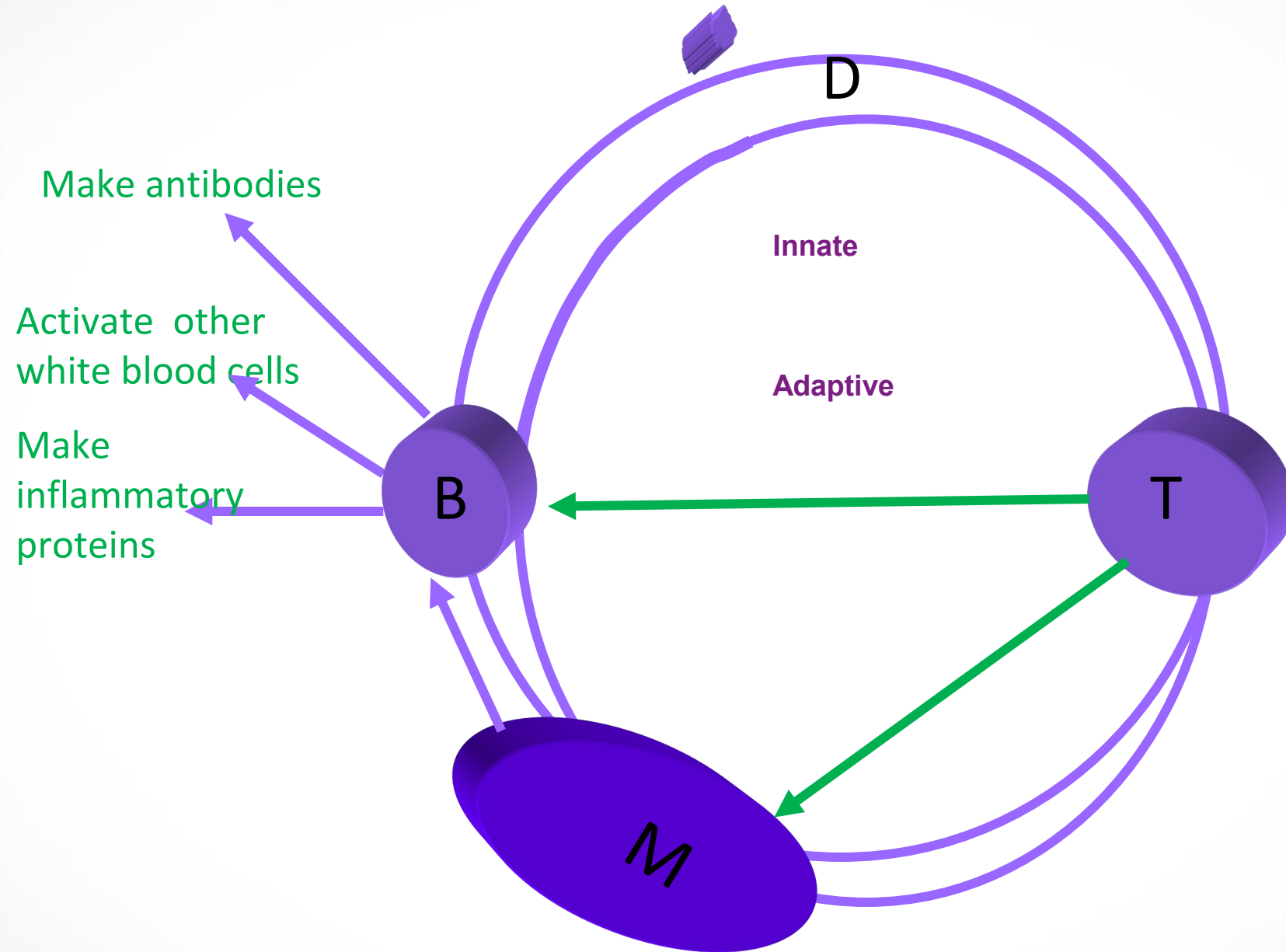
Lupus | Johns Hopkins Medicine



Web Systemic **lupus** erythematosus (**lupus**) is a disease that causes your body's **immune system** to **attack** its own cells and tissues. It causes periods of inflammation to various parts of ...

Why Do People Have Lupus?





LUPUS IMMUNE RESPONSE

Central and Peripheral Nervous System

Seizures, Psychosis, Headaches,
Cognitive Dysfunction,
Neuropathies, Depression,
Low Grade Fever

Eyes and Mucous Membranes

Ulcers in the Eyes, Nose,
Mouth or Vagina,
Sjögren's Syndrome

Heart, Lungs

Pericarditis, Myocarditis,
Endocarditis, Pleuritis,
Pneumonitis

Kidneys

Edema, Hypertension,
Proteinuria, Cell Casts,
Renal Failure

Gastrointestinal

Nausea, Vomiting, Diarrhea,
Weight Changes

Reproductive System

Pregnancy Complications,
Miscarriages,
Menstrual Cycle Irregularities

Musculoskeletal

Extreme Fatigue, Arthralgia,
Myalgia, Arthritis, Myositis

Blood

Anemia, Thrombocytopenia,
Leukopenia, Thrombosis,
Circulating Autoantibodies and
Immune Complexes

Skin

Butterfly Rash, Cutaneous
Lesions, Photosensitivity,
Alopecia, Vasculitis,
Raynaud's Phenomenon



Wallace DJ. In: Koopman DJ, ed. *Arthritis and Allied Conditions*. 13th ed. Vol 2 :1319.

Central and Peripheral Nervous System

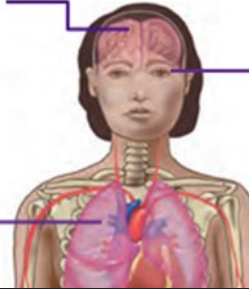
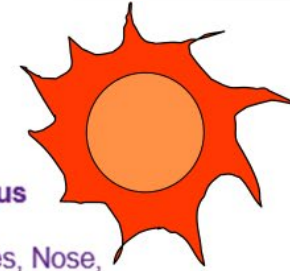
Seizures, Psychosis, Headaches,
Cognitive Dysfunction,
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Heart, Lungs

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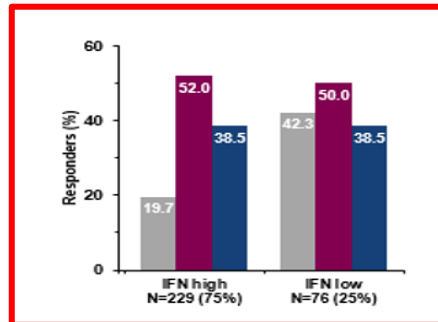
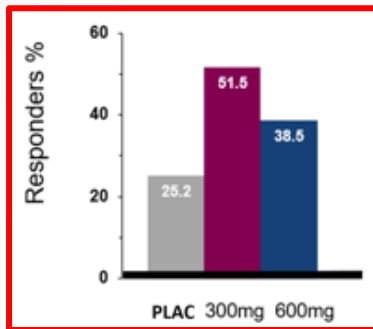
The Good News

Treatment	Target	Improved Treatment Effect Size with		Reference
		Sicker Subset	Less Polypharmacy	
Atacicept	BLyS/April		X	Isenberg ann rheu dis 2013 205067
Blisibimod	BLyS*	X		Furie ann rheu dis 2015 74:1667
Tabalumab	BLyS*	X		Merrill ann rheu dis 2016 15:332
Belimumab	BLys	X	X	VanVollenhoven ann rheu dis 2013 71:1343
Epratuzumab	CD22		X	Wallace ann rheu dis 2014 73:183
Rituximab	CD20	X	X	Merrill arth rheum 2010 62:222
Abatacept	B7	X	X	Furie arth rheum 2014 66:379
Ocrelizumab	CD20		X	Mysler arth rheum 2013 65:2368
PF-04236921	IL6	X	X	Wallace ACR 2014 (abstract)
Sifalimumab	IFN α	X		Khamashta ann rheu dis 2016 (epub)

Merrill Lupus Sci Med 2018 5:e000258

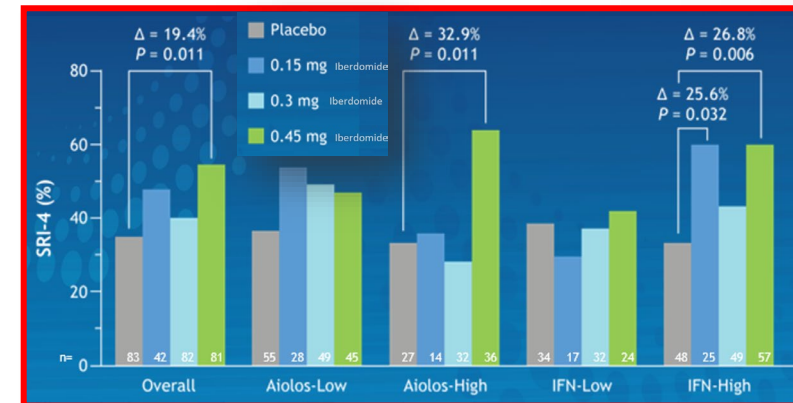
.....THEN WE LOOKED AT THE DATA

Anifrolumab



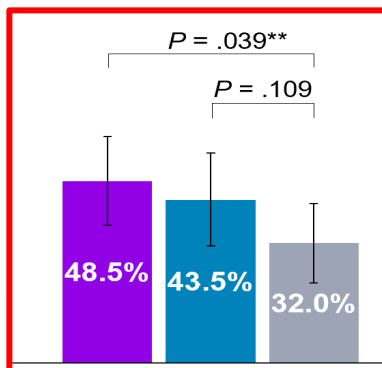
Furie Arth Rheum 2017 69:276

Iberdomide



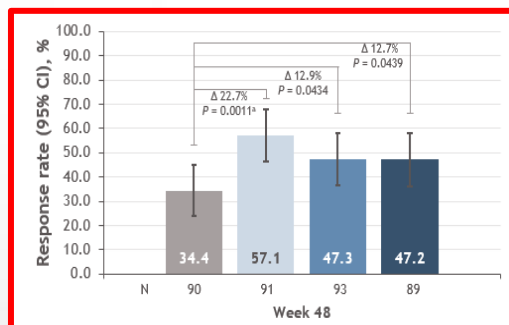
Merrill N Engl J Med 2022 386:1034

Upadacitinib +/-



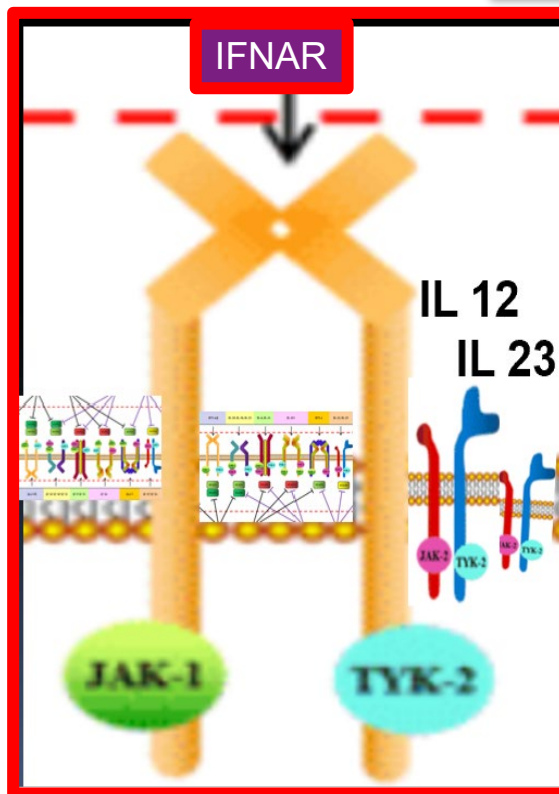
Merrill ACR 2023

Deucravacitinib



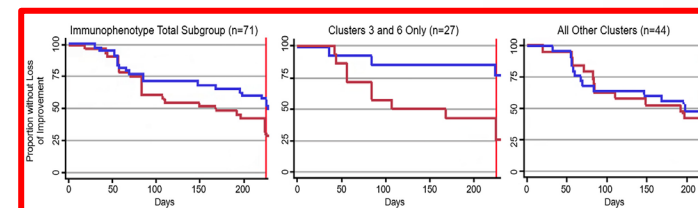
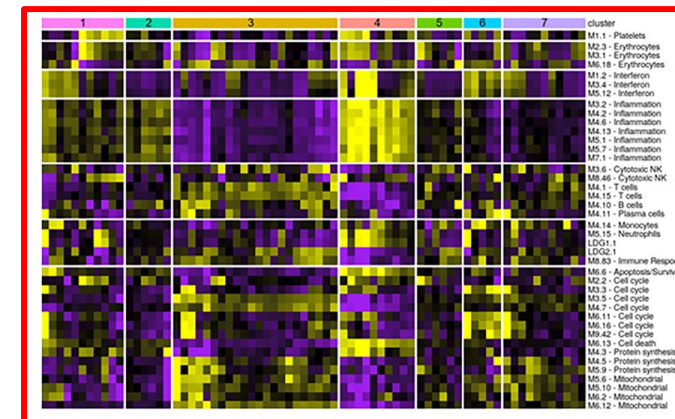
Morand Arth Rheum 2023 75:242

Elsubrutinib



IFI27, IFI44, IFI44L, and RSAD2

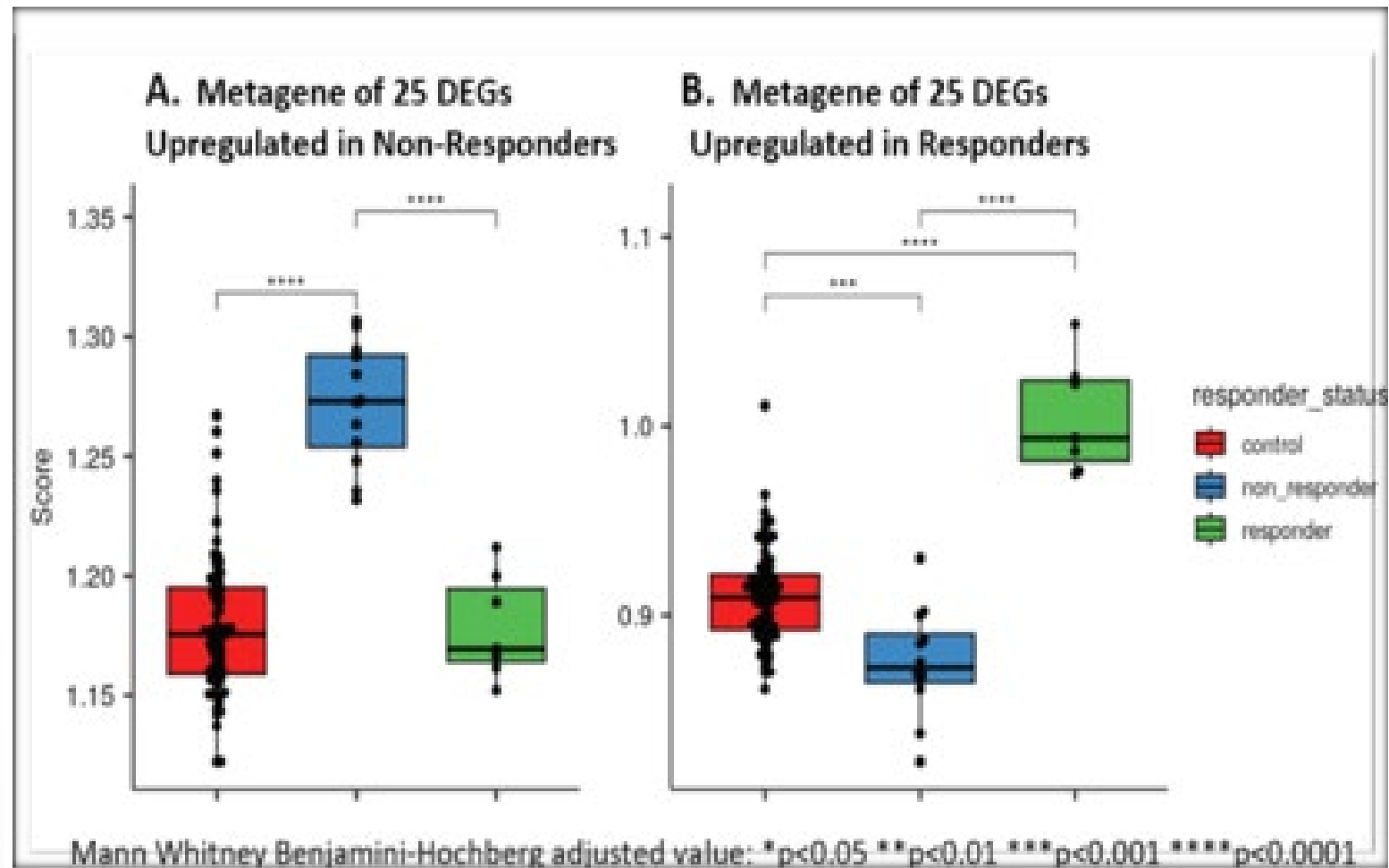
Obexelimab



Guthridge EClinicalMedicine 2020 4;20:100291

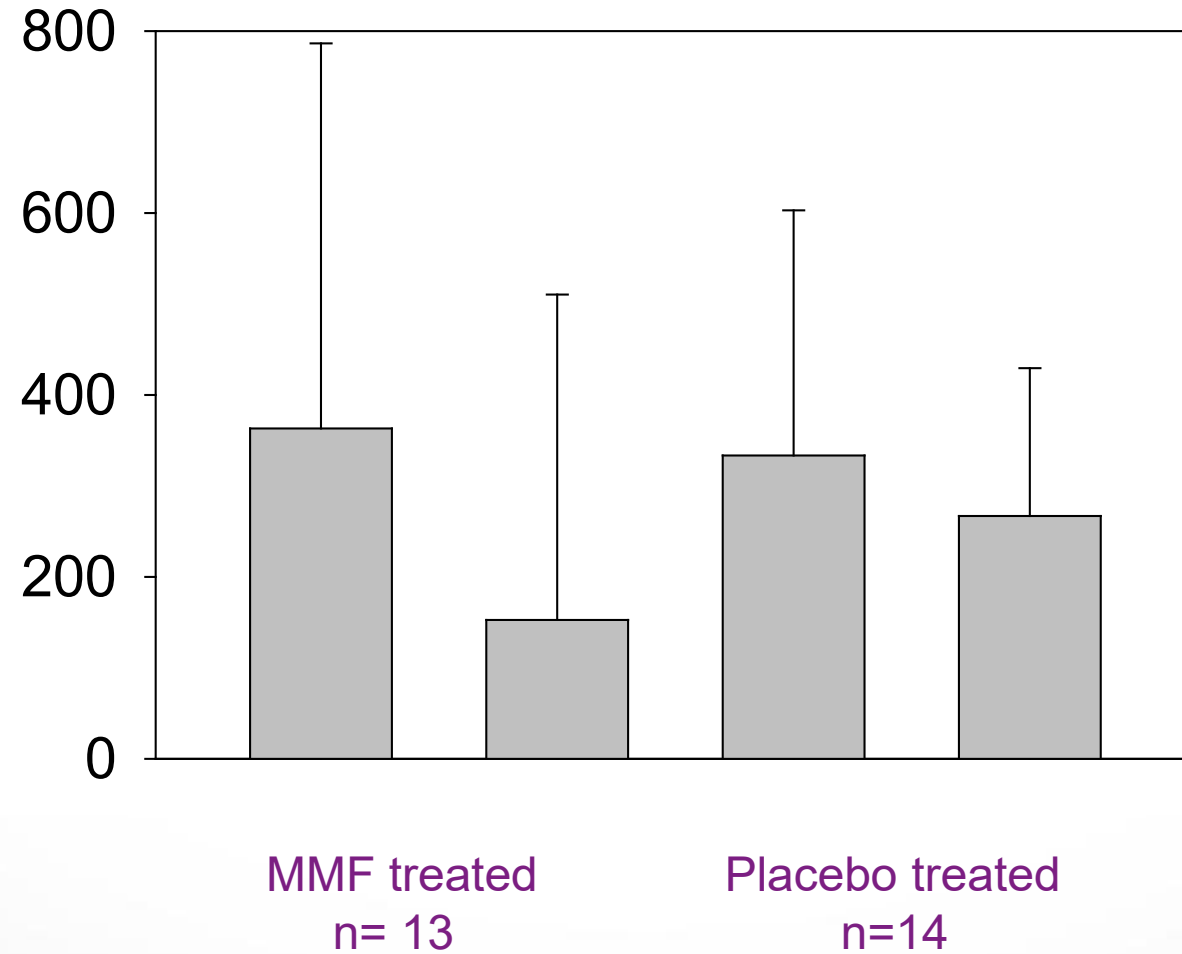
Merrill Arth Rheum 2023 75:2185

BLyS ACTIVITY SIGNATURE TEST: The BLAST STUDY



MMF Decreases CR3 Expression on Neutrophils

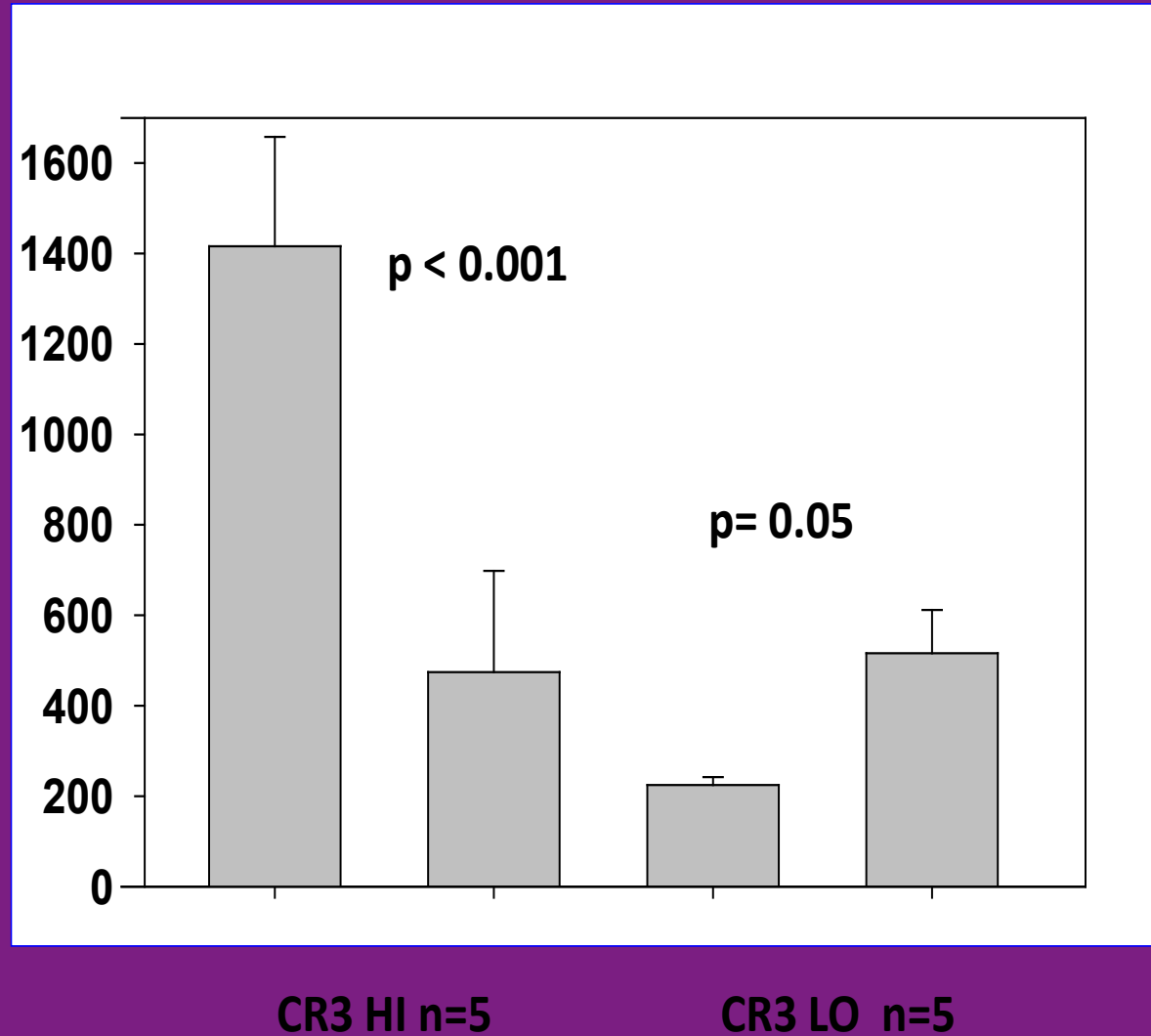
Surface Expression of CR3 on Neutrophils in MMF vs Placebo Groups
(Day 0 vs 12 Weeks, All Patients)



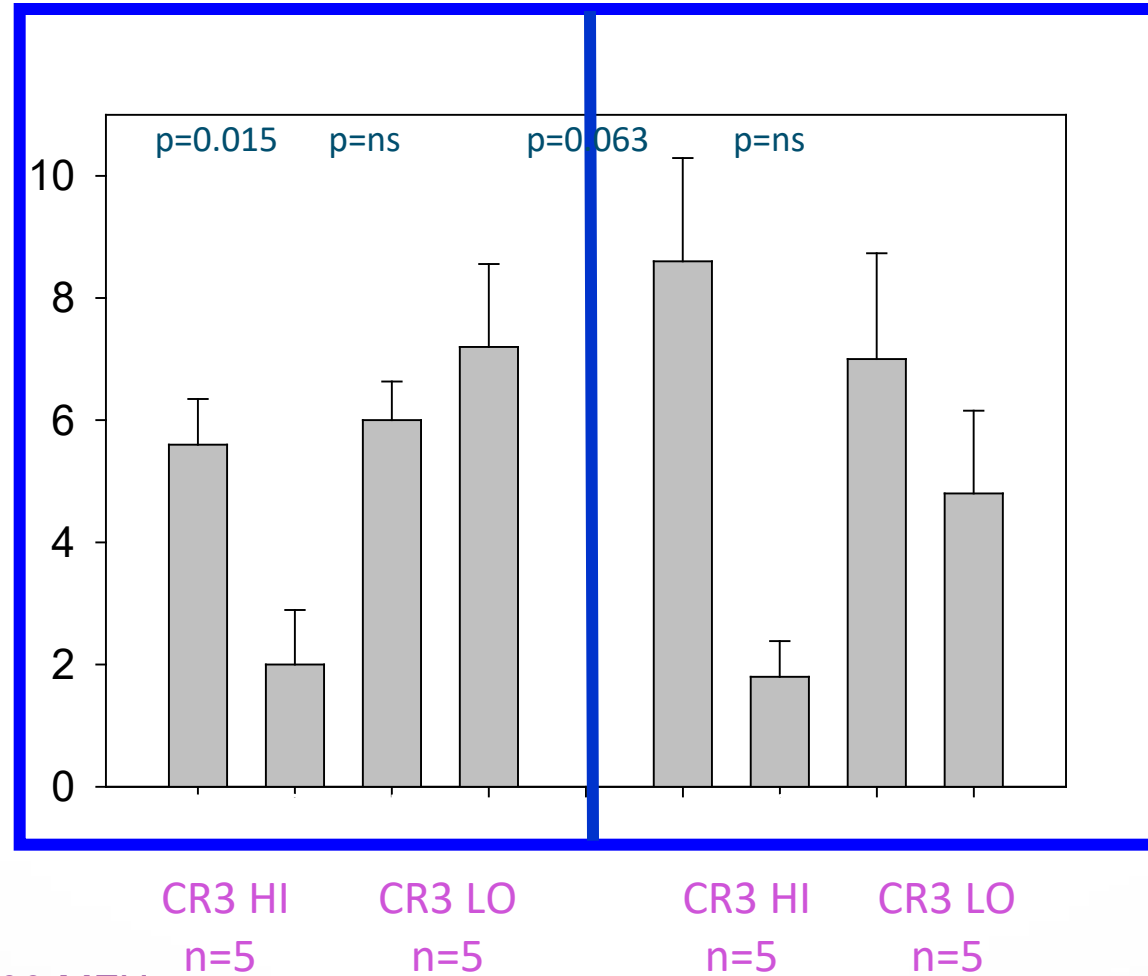
Surface Expression of CR3 Before and After Rx with MMF

by Baseline Expression (HI=>1,000 MFU, LO=<300MFU)

Mean Fluorescence Units



Global Disease Activity Improves More After MMF Rx in Subjects with High Neutrophil CR3 at Baseline: Support For Better Biologic Characterization of Responders to Improve Patient Selection



CR3 HI = > 1,000 MFU
CR3 LO = < 300 MFU

Flow cytometry with fluorescent immunostain for CD11b

How to Get to Precision Medicine
Quality of Samples from Trials
Strategic Science
Validation in More Trials

High Quality Clinical Data
Minimize Background Treatment



A large, light purple, stylized letter 'P' is positioned on the left side of the image, partially overlapping the text.

Thank you Dr. Merrill!

Don't Forget to Complete the Feedback Survey!



- LINK: https://lupus.Qualtrics.com/jfe/form/SV_cAzefJDCSjM6vcy