

# When Rheumatologist and Patient Fight Lupus Together

Roberto Caricchio, MD  
Chief, Division of Rheumatology  
Director, Temple Lupus Program

# Disclosure

---

Dr. Caricchio consulted for:  
J&J, Aurinia and GSK

Dr. Caricchio is site PI for Clinical Trials with:  
AstraZeneca, Lilly, SOBI, Resolve, Novartis and LuCIN

Dr. Caricchio has no financial relationships with any other company whose products or services in any way relate to the practice of medicine, medical education or research.

# Learning Objectives

---

- 1) Introduction to Clinical Trials
- 2) Trials and Lupus
- 3) The Future of clinical trials

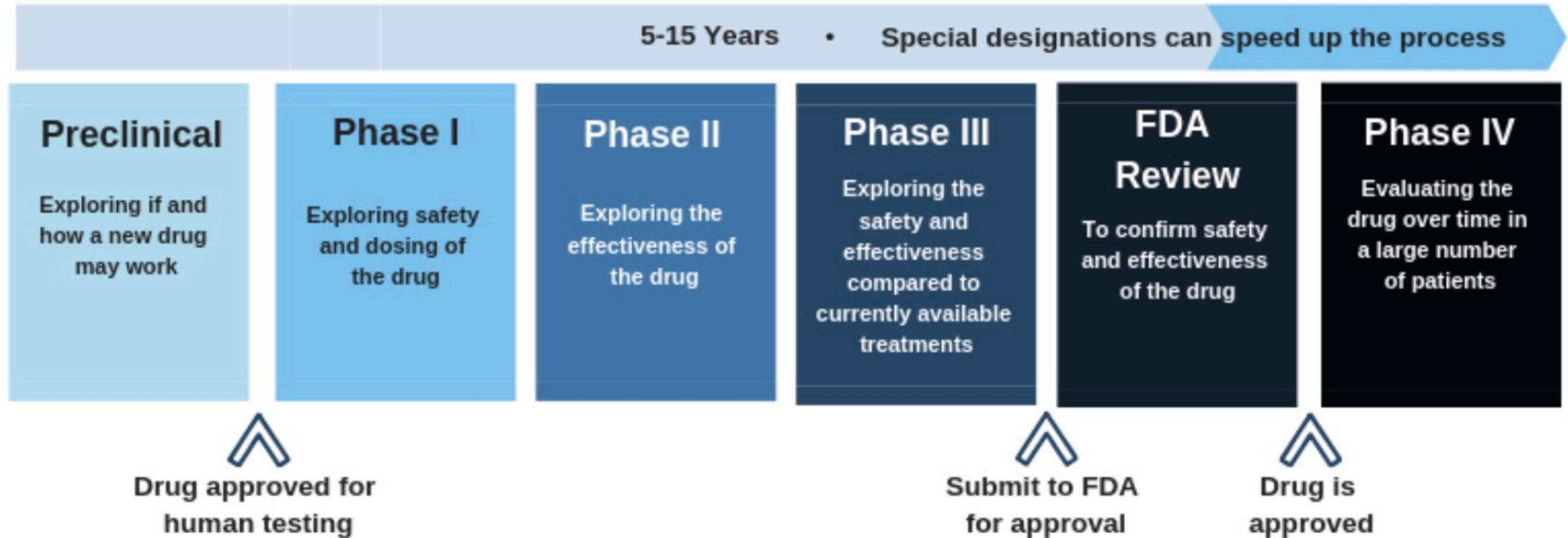
# Definition of a Clinical Trial

---

A **research study** in which one or more human subjects are **prospectively assigned** to one or more **interventions** (which may include **placebo** or other control) to evaluate the **effects** of those interventions on health-related biomedical or behavioral **outcomes**.

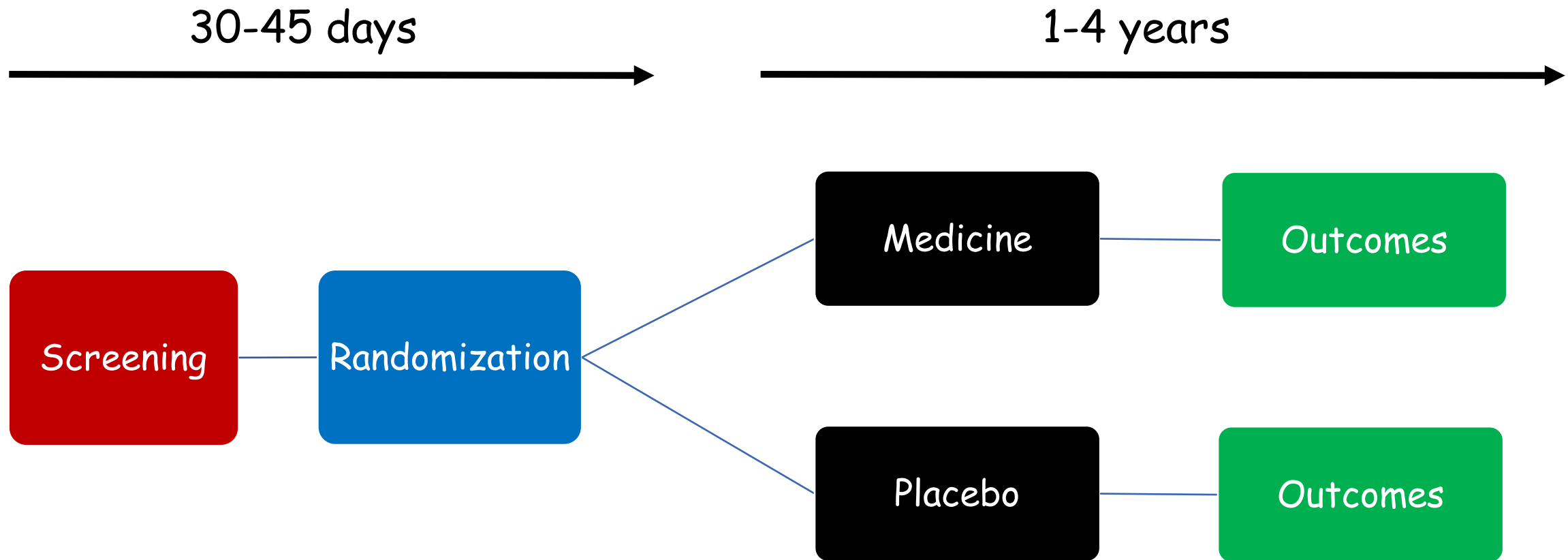
National Institute of Health

# The Phases of Clinical Trials



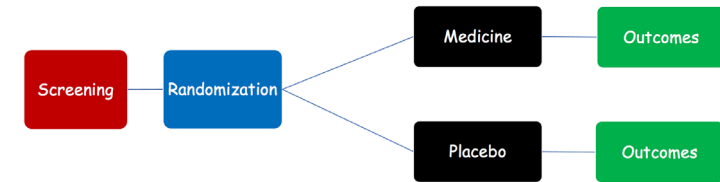
# The Design of a Clinical Trial

---



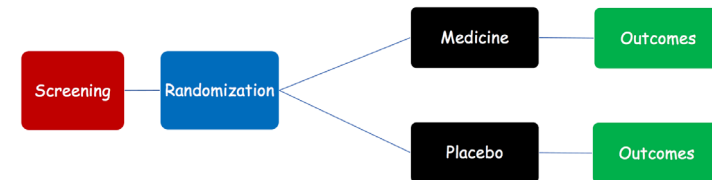
# Part I:

# The Informed consent



1. **Research** - statement that study involves research, its purpose, duration, procedures, & identification of experimental procedures
2. **Risks** - or discomforts, that are reasonably foreseeable
3. **Benefits** - to subject or others, that are reasonably expected
4. **Alternative** - procedures or treatments available, if any
5. **Confidentiality** - of records identifying subject, though may be inspected by authorized entities (*i.e.*, FDA, IRB, UCD/UCH, Sponsor)
6. **Research-Related Injury** - available treatment & compensation (if study is greater than minimal risk)
7. **Contact** - person for questions regarding the study, subject's rights, or research-related injury
8. **Voluntary** - no penalty or loss of benefits for choosing not to participate & may discontinue at any time

# Part I: Screening



## Inclusion Criteria (All)

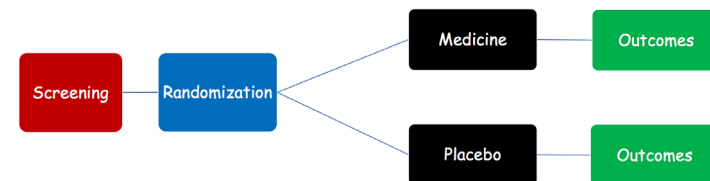
- At least 18 years of age.
- Clinical diagnosis of Systemic Lupus Erythematosus (SLE) by SLICC criteria.
- **Active SLE disease.**
- Autoantibody-positive.
- On **stable SLE treatment** regimen which may include corticosteroids (prednisone), antimalarial (hydroxychloroquine) and/or immunosuppressants (azathioprine, methotrexate, mycophenolate, etc.)

## Exclusion Criteria (Just one)

- **Pregnant or nursing.**
- Have received treatment with an investigational biological agent in the past year.
- Have **severe active lupus kidney disease.**
- Have **severe active central nervous system (CNS) lupus.**
- Have **active infections**
- Have a history of hypersensitivity reactions to contrast agents or biological medicines.

# Part I:

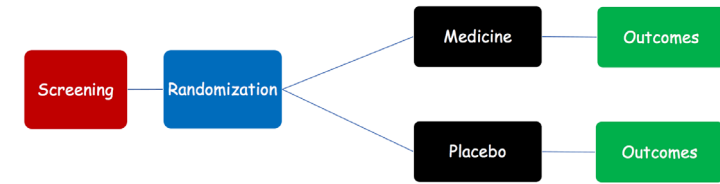
# Screening Lupus Activity



- **BICLA** = BILAG-based Combined Lupus Assessment
- **SRI 4** = Systemic Lupus Erythematosus Responder Index 4
- **CLASI** = Cutaneous Lupus Erythematosus Disease Area and Severity Index
- **SLEDAI-2K** = Systemic Lupus Erythematosus Disease Activity Index 2000
- **LFA-REAL** = Lupus Foundation of America Rapid Evaluation of Activity in Lupus
- **SFI** = SELENA-SLEDAI Flare Index
- **SLAM** = Systemic Lupus Activity Measure
- **SLAQ** = Systemic's Lupus Activity Questionnaire
- **SDI** = Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index
- **MCS** = Mental Component Summary
- **MOS SF** = 20-item Medical Outcomes Study Short Form
- **SF-36** = 36-item Short Form Health Survey
- **FACIT-F** = Functional Assessment of Chronic Illness Therapy-Fatigue
- **PGA** = Physician Global Assessment

# Part I: The First Day

---

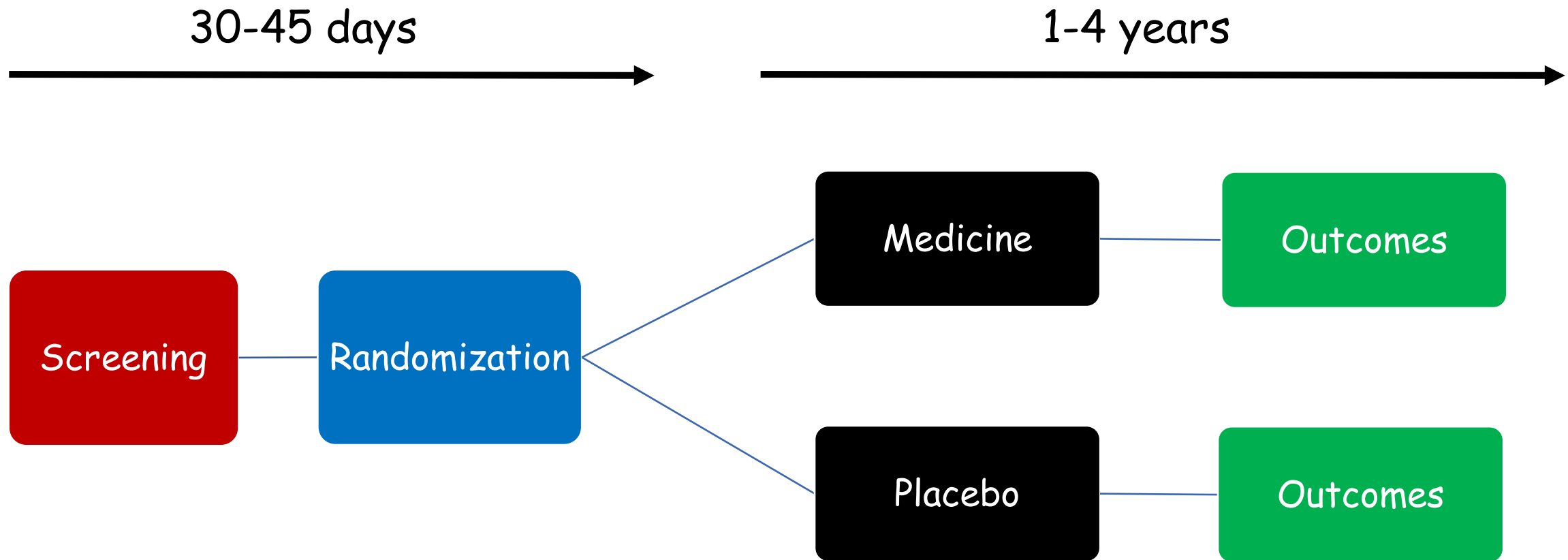


atory tests<sup>k</sup>

X

# The Design of a Clinical Trial

---



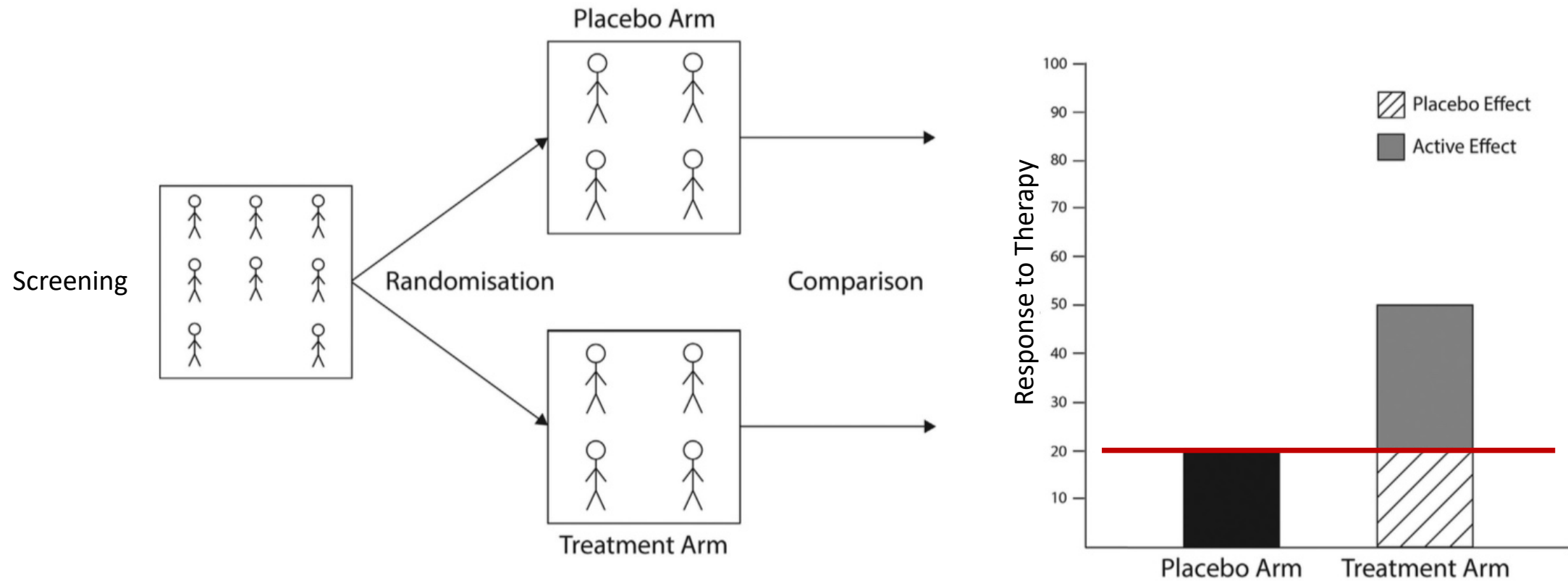
# The Placebo

---

**The Placebo:** a substance that has no therapeutic effect, used as a control in testing new drugs

**The Placebo Effect:** a beneficial effect which cannot be attributed to the properties of the placebo itself, and must therefore be due to the patient's belief in that treatment

# The Placebo Effect



<https://doi.org/10.1016/bs.irn.2018.07.021>

# Randomized Double-Blind Placebo-Controlled Trial

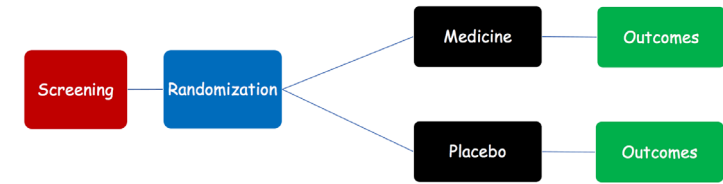
---



The Gold Standard of Clinical Trials

# Part II: Medicine/Placebo

---



Oral

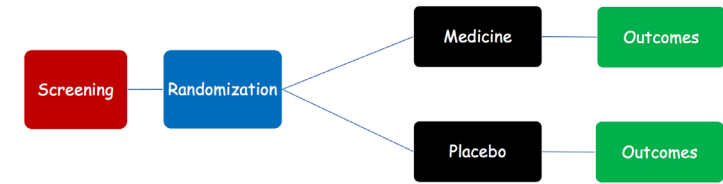
Intravenous

Subcutaneous

Transdermal

# Part I: Outcomes

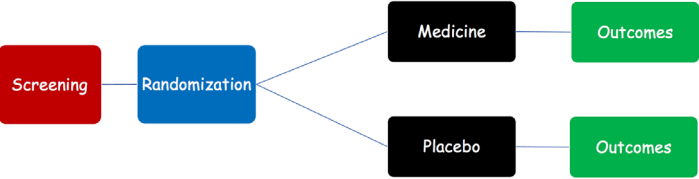
---



X X X X X X X X X X

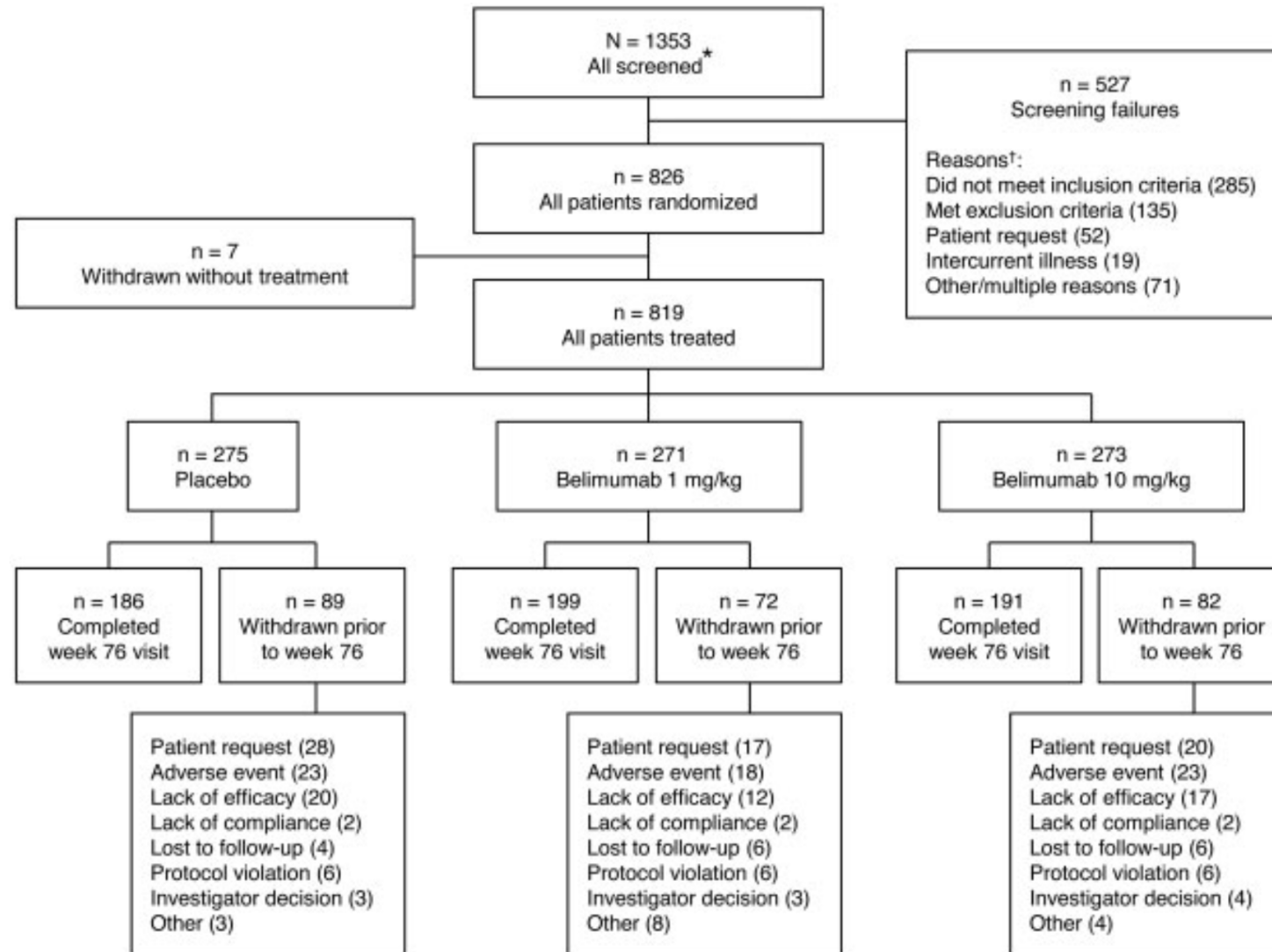
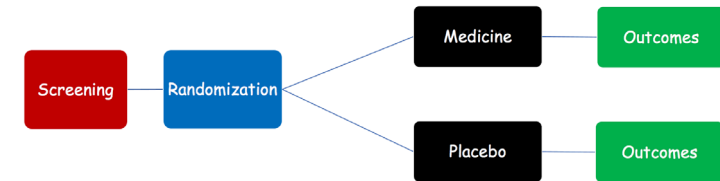
# Part I: Outcomes

---



atory tests<sup>k</sup>      X      X      X      X      X      X      X      X      X      X      X      X      X      X

# Part I: Outcomes



# Clinical Trials

---

## UPs

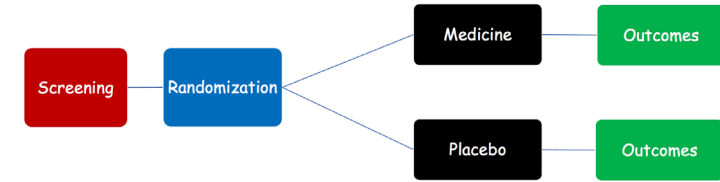
- Contribute to the development of better treatments
- Extensive clinical evaluation
- More frequent regular follow ups
- Better understanding of the disease

## DOWNs

- Frequent blood drawing and Visits
- Time consuming
- Anxiety for unknowns

# Part III: Lupus Clinical Trials

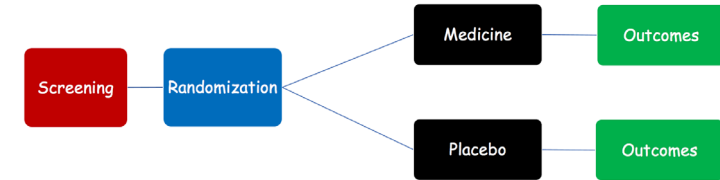
---



How do I find  
and enroll in one ?

- Ask your Rheumatologist
- Ask your Local or National Foundation
- Search on [clinicaltrials.gov](https://clinicaltrials.gov)

# Part III: Lupus Clinical Trials



NIH U.S. National Library of Medicine

*ClinicalTrials.gov*

Find Studies ▾

About Studies ▾

Submit Studies ▾

Resources ▾

About Site ▾

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 359,682 research studies in all 50 states and in 219 countries.

See [listed clinical studies](#) related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

## Find a study (all fields optional)

Saved St

### Status ⓘ

- ☐ Recruiting and not yet recruiting studies
- ☒ All studies

### Condition or disease ⓘ (For example: breast cancer)

X

### Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

### Country ⓘ

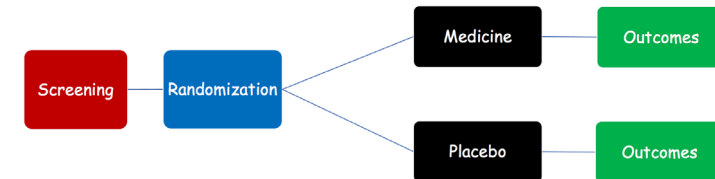
X

Search

[Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

# Part III: Lupus Clinical Trials



Showing: 1-10 of 67 studies 10 studies per page

Show/Hide Columns

NIH U.S. National Library of Medicine

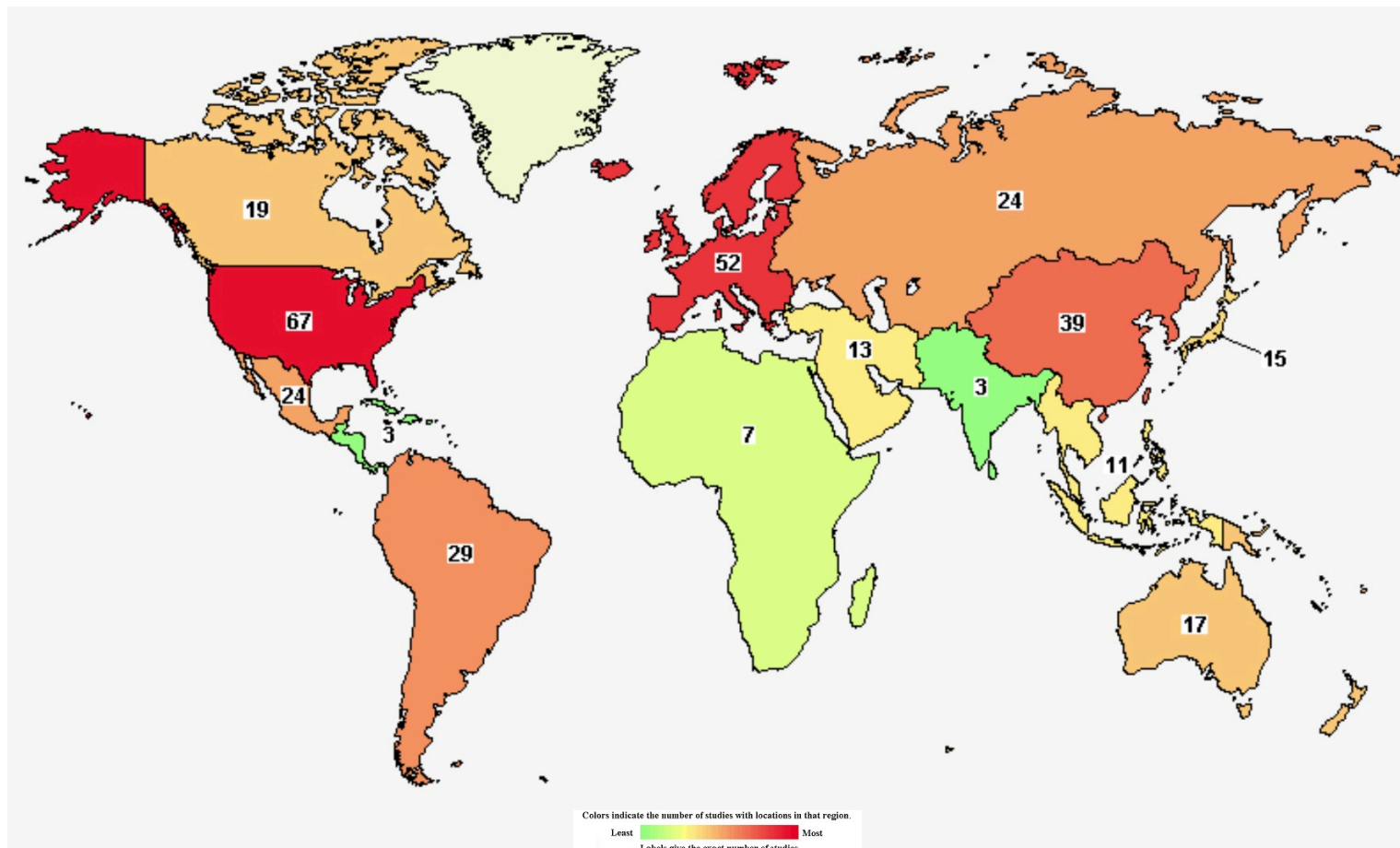
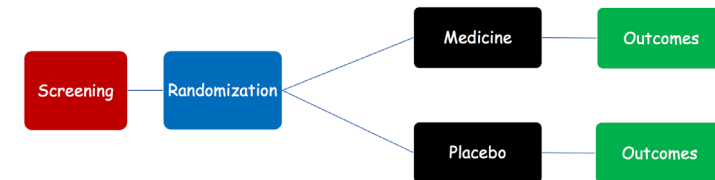
*ClinicalTrials.gov*

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	<a href="#">A Study to Assess the Safety and Efficacy of Secukinumab in Alleviating Symptoms of Discoid Lupus Erythematosus</a>	• Discoid <b>Lupus Erythematosus</b>	• Drug: Secukinumab	• CURTIS (Massachusetts General Hospital) Boston, Massachusetts, <b>United States</b>
2	<input type="checkbox"/>	Recruiting	<a href="#">Effect of Curcumin on Systemic Lupus Erythematosus</a>	• Systemic <b>Lupus Erythematosus</b>	• Drug: Curcumin supplement	• Loma Linda University Loma Linda, California, <b>United States</b>
3	<input type="checkbox"/>	Recruiting	<a href="#">Oral Tofacitinib in Adult Subjects With Discoid Lupus Erythematosus (DLE) and Systemic Lupus Erythematosus (SLE)</a>	• Discoid <b>Lupus Erythematosus</b> • Systemic <b>Lupus Erythematosus</b>	• Biological: Tofacitinib citrate	• Tufts Medical Center Boston, Massachusetts, <b>United States</b>
4	<input type="checkbox"/>	Recruiting	<a href="#">Study of AC0058TA in Patients With Systemic Lupus Erythematosus (SLE)</a>	• Systemic <b>Lupus Erythematosus</b>	• Drug: AC0058TA • Drug: Placebo AC0058TA	• Metroplex Clinical Research Center Dallas, Texas, <b>United States</b>
5	<input type="checkbox"/>	Active, not recruiting	<a href="#">Memantine for the Treatment of Cognitive Impairment in Systemic Lupus Erythematosus</a>	• <b>Lupus Erythematosus</b> , Systemic	• Drug: Memantine • Drug: Placebo	• Vanderbilt University Medical Center Nashville, Tennessee, <b>United States</b>
6	<input type="checkbox"/>	Active, not recruiting	<a href="#">Interactive Digital Technology to Assess and Improve Cognitive Dysfunction in Patients With Systemic Lupus Erythematosus</a>	• <b>Lupus Erythematosus</b> , Systemic	• Device: Project EVO Multi-Treatment	• Natinal Jewish Health Denver, Colorado, <b>United States</b>
7	<input type="checkbox"/>	Not yet recruiting	<a href="#">Treatment of Systemic Lupus Erythematosus (SLE) With N-acetylcysteine</a>	• Systemic <b>Lupus Erythematosus</b>	• Drug: N-acetylcysteine • Drug: Placebo	• SUNY Upstate Medical University Syracuse, New York, <b>United States</b> • SUNY Upstate Medical University Syracuse, New York, <b>United States</b>
8	<input type="checkbox"/>	Recruiting	<a href="#">Individual Patient Exposure and Response in Pediatric Lupus</a>	• Systemic <b>Lupus Erythematosus</b>	• Behavioral: Pillsy	• Duke Clinical Research Institute Durham, North Carolina, <b>United States</b>
9	<input type="checkbox"/>	Recruiting	<a href="#">Trial of Belimumab in Early Lupus</a>	• <b>Lupus Erythematosus</b> , Systemic • <b>Lupus Erythematosus</b>	• Biological: Belimumab • Biological: Belimumab/Placebo • Other: Placebo	• Feinstein Institute Manhasset, New York, <b>United States</b>
10	<input type="checkbox"/>	Recruiting	<a href="#">Aerobic Exercise in Women With Systemic Lupus Erythematosus</a>	• Systemic <b>Lupus Erythematosus</b> • <b>Lupus</b> • Autoimmune Disease • Rheumatic Disease	• Other: Treadmill exercise training	• National Institutes of Health Clinical Center Bethesda, Maryland, <b>United States</b>

Showing: 1-10 of 67 studies 10 studies per page

Paging: < > >>

# Part III: Lupus Clinical Trials

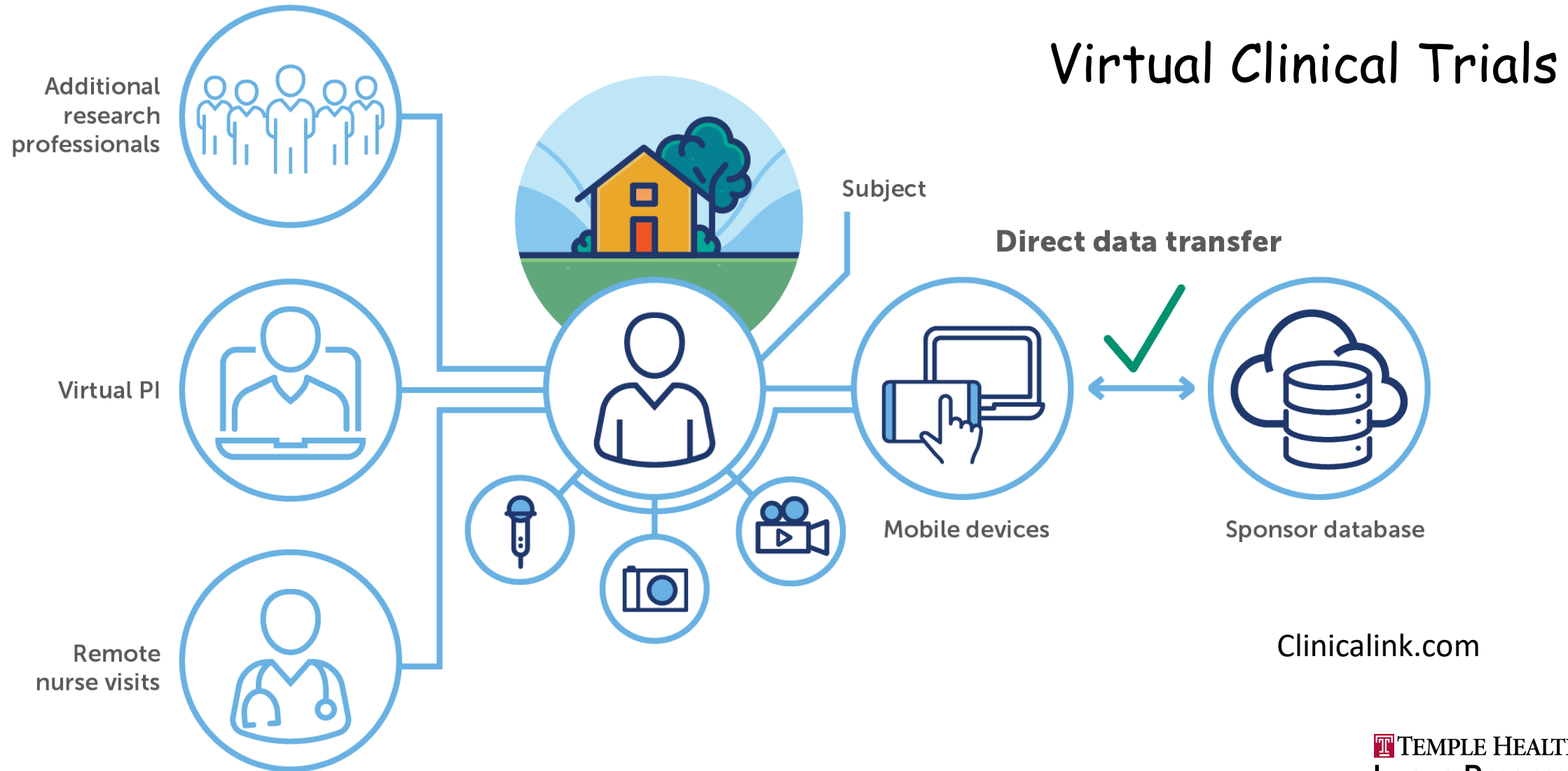


NIH U.S. National Library of Medicine  
*ClinicalTrials.gov*

130 Studies found for: **Recruiting, Not yet recruiting, Active, not recruiting Studies | Interventional Studies | Lupus Erythematosus**

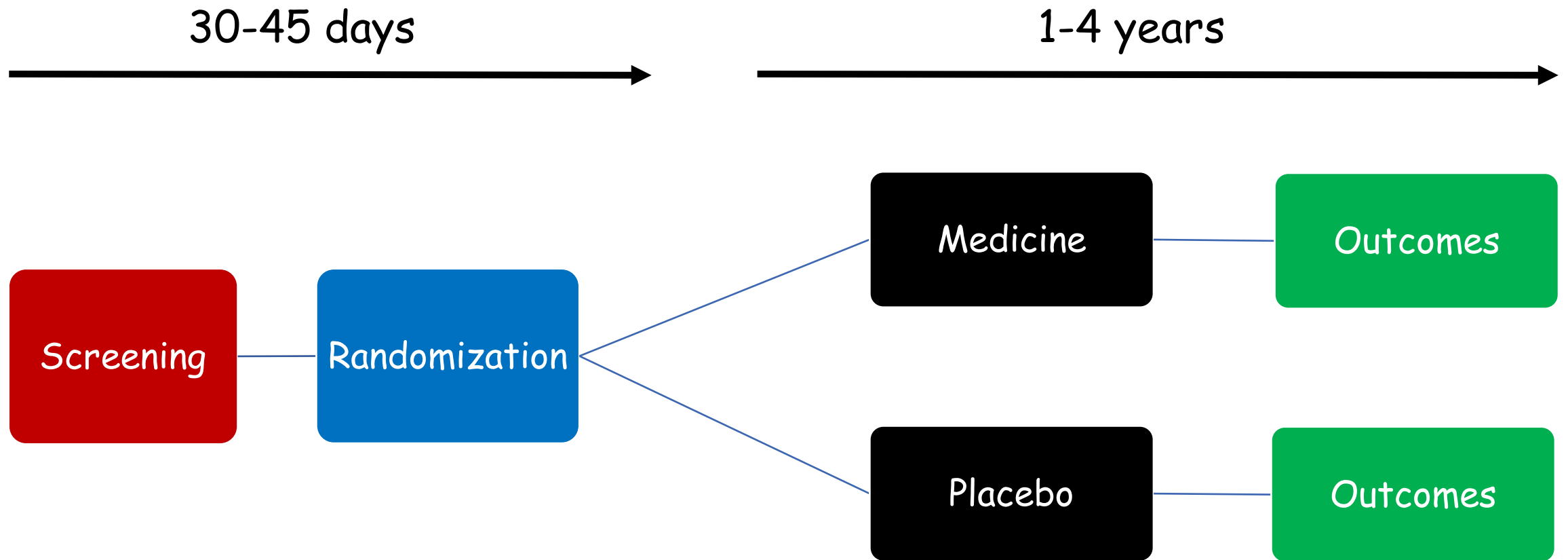
Applied Filters: ☒ Recruiting ☒ Not yet recruiting ☒ Active not recruiting ☒ Interventional

# The Future of Clinical Trials



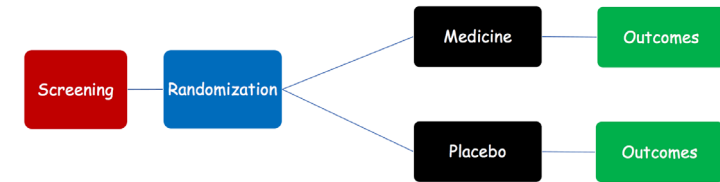
# The Design of a Clinical Trial

---



# Final thoughts of Clinical Trials

---



Save lives and give us better options

Are based on the generosity of patients

## The Dream of Every Lupologist



*“Your grandma and I have decided to live together.”*