



Clinical Trials 101:

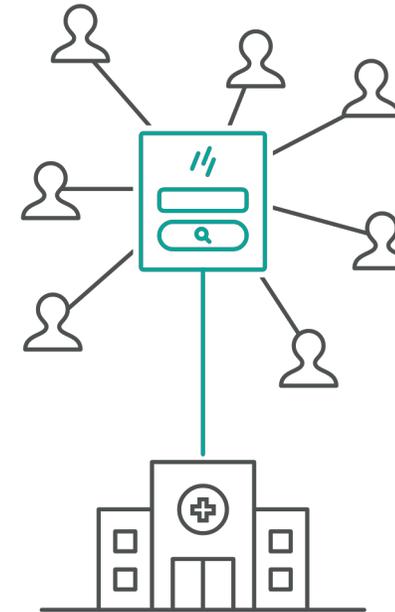
Understanding how clinical trials work to find the right fit for you



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# Antidote: Accelerating medical research

Antidote is a digital health company that aims to accelerate the development of new treatments by closing the gap between medical research and the people who need it.



# What is medical/clinical research?

“Research in which people, or data or samples of tissue from people, are studied to understand health and disease. Clinical research helps find new and better ways to detect, diagnose, treat, and prevent disease.”

- [National Cancer Institute](#)

Observational	Experimental (Intervention)
Cohort study (prospective)	Randomized control trial (prospective)
Case control study (retrospective)	
Case studies	

# Myositis Research

- Currently 56 trials recruiting or not yet recruiting in ClinicalTrials.gov looking for individuals with Myositis seeking 21,660 volunteers.
- 38 trials are intervention:
  - 25 drug/device
- 18 trials are observational

# Key terms

- Protocol
- Principal Investigator
- Institutional Review Board
- Informed consent
- Study phase
- Inclusion/Exclusion Criteria
- Blinding

## Good resources:

- <https://www.antidote.me/how-clinical-trials-work>
- <https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>

# Some notes on rare disease trials/treatments

- Smaller sample size requirements
- Less likely to be an RCT
- Less likely to be double blind
- Less likely to use new drug/device (active comparator)
- Orphan Drugs

## Good resources:

- <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5882124/>

I think medical research is great. I just  
don't want to partake.



# Why should you care?

**It's simple: Without you, there can be no new treatments or cures.**

80% of medical research is delayed or canceled due to difficulty enrolling participants.

# Here are a few other reasons to participate:

- Access to care
- Quality of care
- Advancing science
- Financial benefits (sometimes)

# But what if I...

- get a placebo? I don't want a sugar pill.
- don't have the time?
- don't want to switch physicians? I love my doctor!
- don't do well with the uncertainty? I don't want to be a guinea pig.
- don't trust doctors? I heard something once about Tuskegee.
- get really bad side effects from the new treatment?
- don't know how to find the right trial for me?
- heard they aren't paying me to participate? Am afraid of needles, MRIs and/or doctors?
- don't have transportation?
- haven't exhausted all other treatment options?
- change my mind after I sign a consent form?

What if it doesn't work?



But what if it does?



# How to find a trial

The screenshot shows a web browser at the URL <https://understandingmyositis.org/clinical-trials/>. The page features a navigation menu with links for UNDERSTANDING MYOSITIS, LIVING WITH MYOSITIS, NEWS & EVENTS, GET INVOLVED, and a prominent DONATE button. The main content area is titled "Clinical Trial Matching" and includes a list of features: "Access the latest clinical trials", "Get involved in research opportunities", and "Custom match based on your condition, location, and more". A large white "START" button is centered below the list. To the right, a sidebar contains a "Now Recruiting, DETERMINE Clinical Trial for Dermatomyositis" announcement dated January 23, 2019, and a "Helpful Resources" section with links to Clinical Trials, Explore Myositis, Find a Myositis Doctor, Mission and Vision, and Who is MSU?. A social sharing bar at the bottom right offers options to share on Facebook, Twitter, Pinterest, Messenger, Email, and Print. A note at the bottom states: "NOTE: All trials listed on ClinicalTrials.gov are included in the clinical trial matching tool above."

# How to find a trial

- Think about:
  - What kind of trial am I interested in?
  - What phase(s) of a trial am I interested in?
  - What time am I able to give?
  - Would I be okay if I had to stop taking the study drug after the trial ended, even if it was working well for me?
  - Do I need to be reimbursed for my time and travel?
  - What type of information do I want to receive during and after the trial (and ask the researchers if they will provide that information)?

I found a trial. Now what?



# What to expect before the trial

- Conversations with the researcher in charge of the trial (Study Coordinator or PI)
- In-person screening/site visit
- Informed consent
- Study run-in (sometimes)
- Randomization or screen failure

# What to expect during the trial

- Study visits
- Between study visits
- After the trial concludes

I didn't find a trial (or I wasn't eligible).  
Now what?



# Two potential avenues

- Expanded access: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5443564/>
  - “Provides a pathway for patients to gain access to investigational drugs, biologics, and medical devices used to diagnose, monitor, or treat patients with serious diseases or conditions for which there are no comparable or satisfactory therapy options available outside of clinical trials.”
    - Requires support of FDA, physician, drug company.
    - Speak with your physician about options
- Right to Try: <https://www.fda.gov/ForPatients/Other/ucm625115.htm>
  - A pathway through which terminally ill individuals can gain access to experimental treatment when they have exhausted approved treatment options and do not qualify for a clinical trial to gain access to the treatment.
    - Drugs are eligible when they have completed a Phase I trial, have an application filed with the FDA or are under investigation in a trial, whose active development or production is ongoing.



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