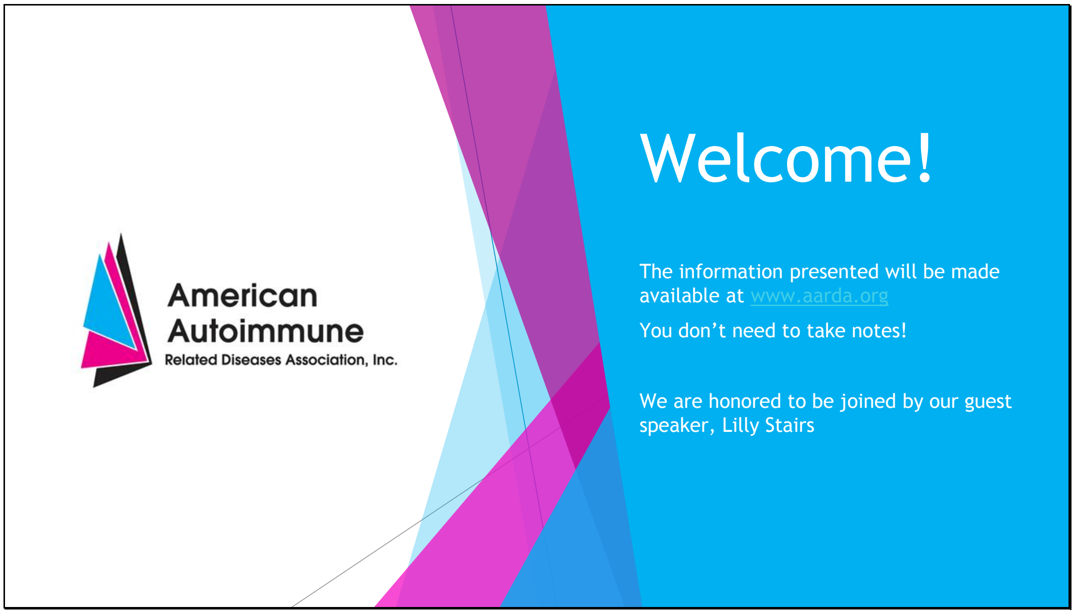
This webinar was held on November 15th, 2018.

Hosted by AARDA staff member Katie, assisted by Sandra, and questions were managed by Laura. Our featured guest speaker was Lilly Stairs.



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Welcome!

The information presented will be made available at www.aarda.org

You don't need to take notes!

We are honored to be joined by our guest speaker, Lilly Stairs

If you ever have any questions, comments, feedback, or anything else, please reach out to us! Email us at aarda@aarda.org or call our office at (586) 776-3900.

Lilly Stairs

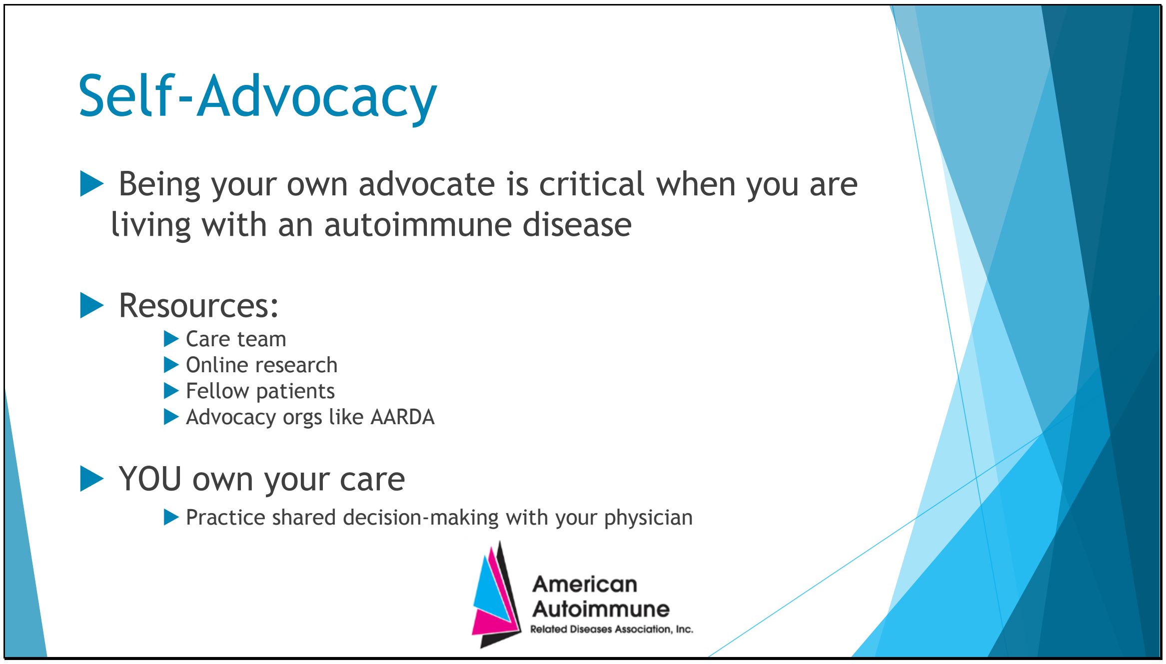
- Over 10 years experience in patient advocacy
- Head of Patient Advocacy at Clara Health
  - connecting patients to clinical trials and demystifying the experience
- Proud AARDA board member

Lilly Stairs is an amazing advocate for autoimmune disease patients. You can contact her at Clara Health by emailing lilly@clarahealth.com, or follow her on Twitter at @LillyStairs

Self-Advocacy

getting yourself the best possible care

The core of clinical trials is self-advocacy and getting yourself the best possible care.



Self-Advocacy

- Being your own advocate is critical when you are living with an autoimmune disease
- Resources:
  - Care team
  - Online research
  - Fellow patients
  - Advocacy orgs like AARDA
- YOU own your care
  - Practice shared decision-making with your physician

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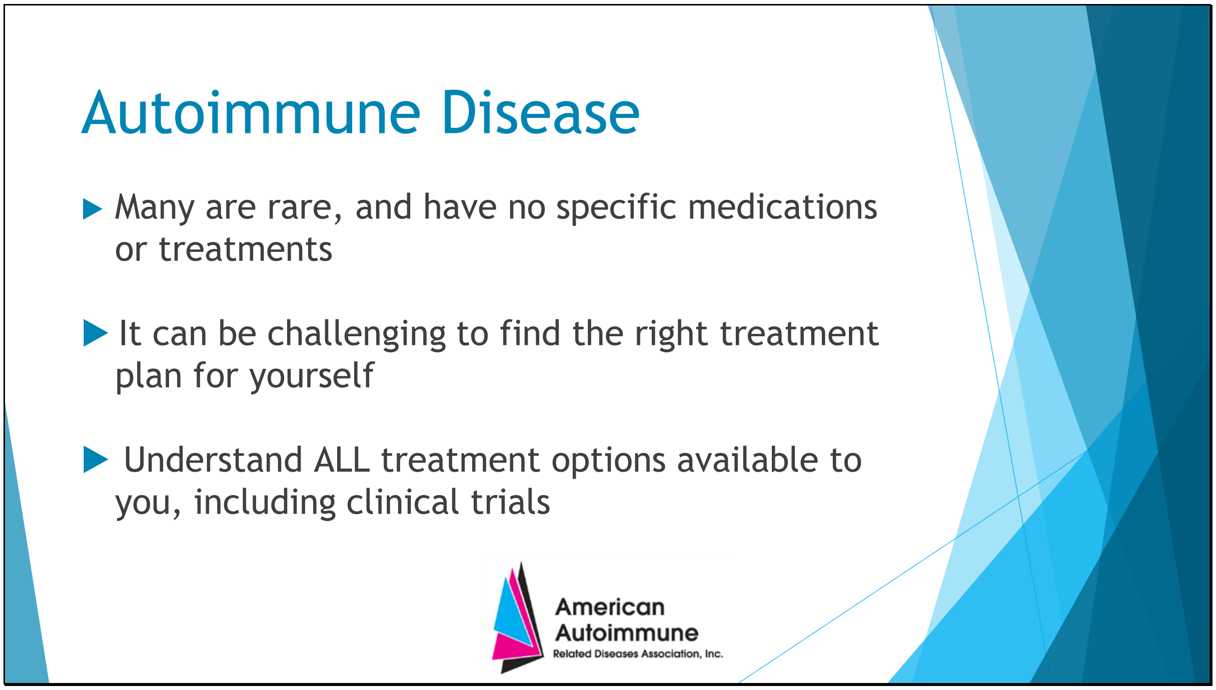
Managing everything that comes along with living with an autoimmune disease is stressful, but there are many different resources out there to help you and at the center of that is your care team. Online research can be a blessing and a curse, you can more easily connect with other patients but there is the danger of coming across information that has no validity, anyone can post anything online. Patients are a great resource, they've been in your shoes, they know what you're going through and can point you in a good direction and help you navigate your care.

You are the center of your care, you are the boss you are the CEO so make sure that when you are making decisions, you're practicing shared decision-making with your physician meaning that your physician isn't just telling you a list of things to do and you do them. It's a conversation so that you understand why you are doing those things and if you not feel comfortable with something you have every right to push back or just seek a second opinion about something. There have been many times in my journey living with Crohn's disease and psoriatic arthritis that I push back against my physician when they've said we'd like to try adding this medication or we'd like you to do this testing, and I said I'd like to understand why you'd like me to do because at this point I've done some of my own research and I don't think this is necessary and so it's really important to do that and don't be afraid to do that.



Autoimmune Disease

- Many are rare, and have no specific medications or treatments
- It can be challenging to find the right treatment plan for yourself
- Understand ALL treatment options available to you, including clinical trials

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There are many autoimmune diseases that currently have no specific medications or treatments and it can be very challenging to find the right treatment plan for yourself. Sometimes medications don't work, other times you find a good plan, and sometimes a medication works for a couple of years then it stops working. So, it's important living with an autoimmune disease to understand all of the treatment options that are available to you and that includes clinical trials. We say this because clinical trials are not really always a treatment option that gets discussed in an appointment that's not necessarily anyone's fault but physicians have ten minutes or less to see patients they're often double or triple booked and you feel like you're just trying to get all of these questions in, in the short amount of time that you have and so sometimes the idea of clinical trials can fall through the cracks, but they can really offer access to cutting edge therapies and can be a good fit for patients. I hope by the end of this webinar you feel more comfortable with the idea of clinical trials and empowered with the information provided.

Interested in political advocacy?

Sign up for VoterVoice to
receive action alerts

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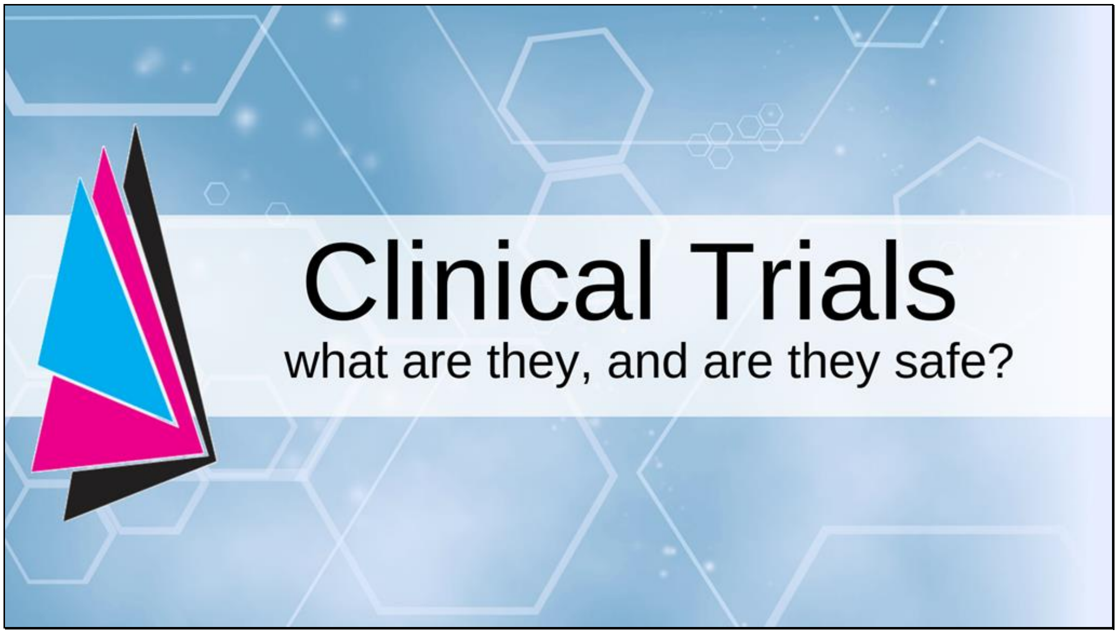
PART OF FiscalNote

https://www.aarda.org/get-involved/action/voter-voice/

If you’re interested in political advocacy, we recommend that you sign up with AARDA’s VoterVoice. Sign up and we will send you alerts when an advocacy issue comes up that you can take action on. You’ll get an email action alert to contact your representatives with information on the subject.

https://www.aarda.org/get-involved/action/voter-voice/



Clinical Trials
what are they, and are they safe?

One of the big questions that we often get is- are they safe? We will walk through the different phases of clinical trials, how they work, placebos, safety, all these different components we’re going to talk through in this webinar.

Clinical Trials:

What are they?

And what are they not?

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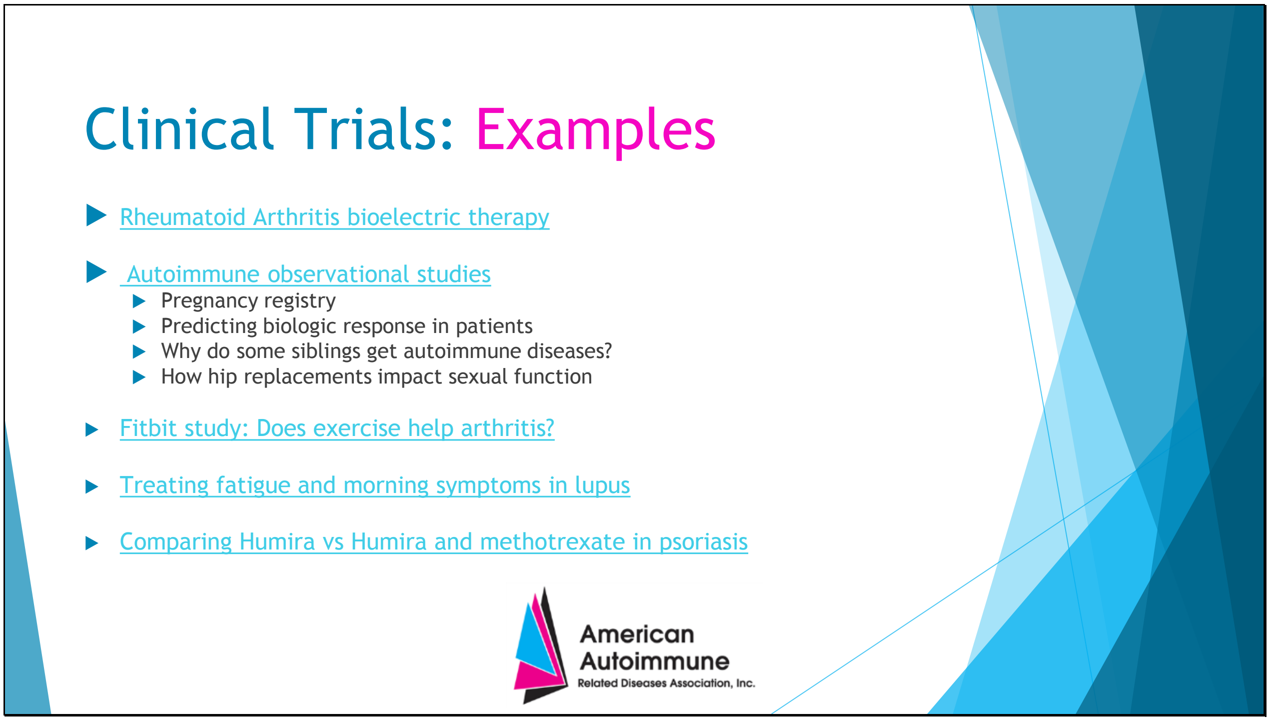
We’re going to start by going over some of the different clinical trials that exist for autoimmune disease patients. There are almost 300,000 clinical trials that are currently running just in the US and so that’s important to recognize that there are many options available.



Clinical Trials: Examples

- Rheumatoid Arthritis bioelectric therapy
- Autoimmune observational studies
  - Pregnancy registry
  - Predicting biologic response in patients
  - Why do some siblings get autoimmune diseases?
  - How hip replacements impact sexual function
- Fitbit study: Does exercise help arthritis?
- Treating fatigue and morning symptoms in lupus
- Comparing Humira vs Humira and methotrexate in psoriasis

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We have a vision of clinical trials that we have from pop culture of clinical trials of these really weird medications that are being tested in patients that are really experimental, and that's not the case. So, I wanted to talk about some really interesting clinical trials that could be beneficial for autoimmune disease (AD) patients. Rheumatoid Arthritis bioelectric therapy- this might be applicable to other AD patients. Normally one AD medication gets approved for one AD and later it is found to be beneficial for other AD's but still must go through the clinical trials process again. It's a little device that about the size of a penny and it gets implanted onto the vagus nerve which is in the neck, and it automatically delivers electrical stimulation on a set schedule and this kind of therapy can be used to trigger biochemical changes in the body which usually happens via a drug. That's really exciting to me as an autoimmune patient.

There are also observational studies; Autoimmune observational studies, one called the piano study in which thousands of women contribute to it over time if they're on a biologic. They give data while there pregnant and breast feeding to show the impact of biologics on the baby, and overwhelming it's been shown that there are no negative side effects. There is a clinical trial that's working to predict the biological response in patients, it'll help to determine which one to start with, the idea of precision medicine. Another study-why do some siblings get AD and others don't? There's nothing invasive and there's no medicine that's being given to patients its just observational, patients journal, take notes, maybe give blood, but no treatments given. There is also a study on how hip replacements impact sexual function. They very widely with an array of options.

Fitbit study: Does exercise help arthritis? Everyone who participates gets a fit bit and that gets tracked and sent to the study team and they keep an eye on symptoms.

Treating fatigue and morning symptoms in lupus is interesting because it's actually is for a drug that a lot of us know pretty well which prednisone and that's is looking at the difference between a delayed release vs an immediate release, so everyone's getting a treatment but it's just a timing difference.

Finally, there is Comparing Humira vs Humira and methotrexate in psoriasis again, everyone is getting a treatment of pretty well known drugs. It's the idea of trying to understand if patients should simply be on one drug, or the combination.

Clinical Trials

- Interventional Trials
  - Patients can access treatments not yet available through standard care.
  - These test new treatments, or new ways of using existing treatments.
- Observational trials
  - Allow researchers to follow a patient's health to learn more about a condition.
  - Patients generally continue their current treatment.

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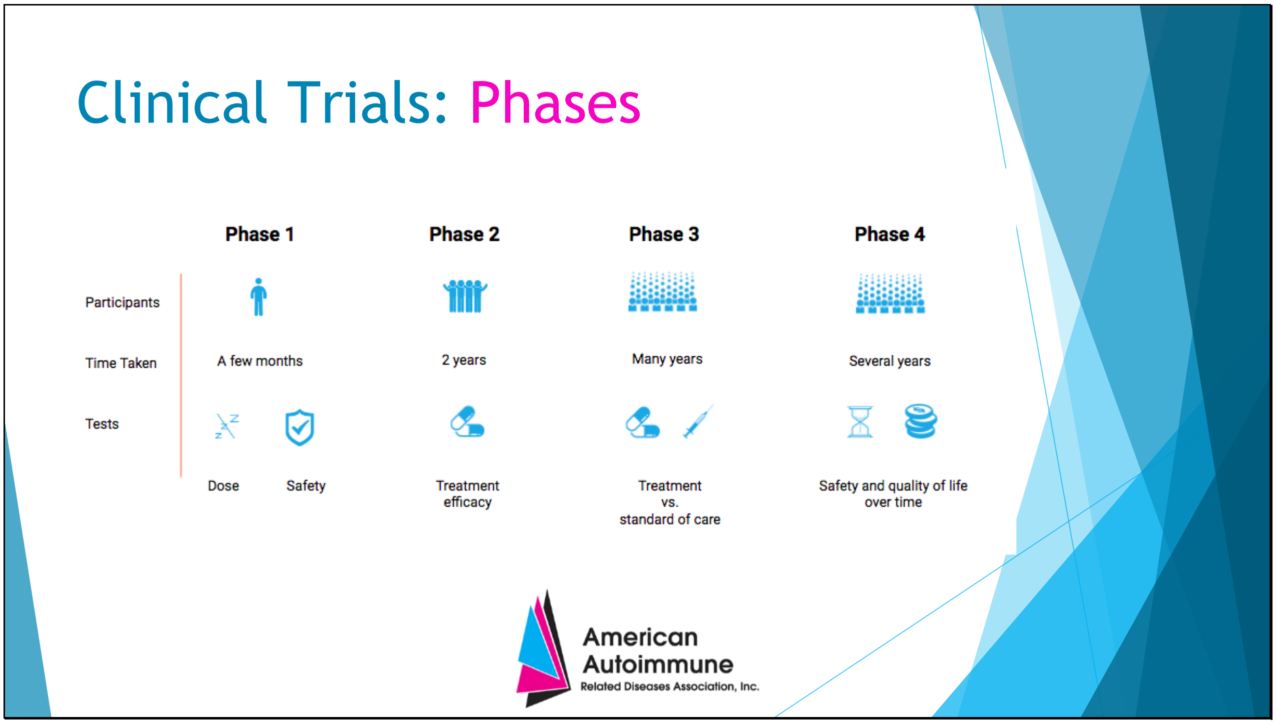
There are two different types of trials when you are looking at clinical trials. There's interventional trials, this is where patients can get access to new treatments that are not yet available via the standard care. You are getting an intervention, some sort of treatment. You can also test new ways of using existing treatments. Like with the biologic stimulation for RA patients, lets now test it for lupus, or any number of other drugs meant for one AD, now being tested for other ADs.

Observational trials are like the examples above. It allows researchers to study more about patient's experiences, and generally patients can continue on their current course of treatment if they are taking anything. It's mostly just tracking of certain items-tests, blood work, Fitbit, diet, etc.



Clinical Trials: Phases

	Phase 1	Phase 2	Phase 3	Phase 4
Participants				
Time Taken	A few months	2 years	Many years	Several years
Tests	Dose Safety	Treatment efficacy	Treatment vs. standard of care	Safety and quality of life over time

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There are a series of phases that clinical trials will go through before they reach approval, 4 phases. The first phase is generally a few months, with a small cohort of participants, who are healthy volunteers, so that means they aren't necessarily living with a condition. They are just measuring what a tolerable dose is and then the safety to make sure there's no sever safety risk.

Phase two will be about two years, a bigger population than phase one, at this point they will bring in patients with the conditions the dose and safety have been so now they are starting to look at treatment efficacy, while still monitoring dose and safety. But really focusing on how the treatment will work.

Phase three is many years, and many more participants. This is where you'll see the treatment getting put against the current standard of care. For example, with RA, the current standard of care is methotrexate, steroids, and/or biologics. Patients in the trial might get that current treatment and then half will get the new treatment. Everyone gets their condition treated.

Phase four this is when a treatment would be processed through the FDA at that point they'd make the decision to say yes, we'd like to approve this drug or no, it does not get approved. This phase happens after the drugs gets approved and looking at the safety and the quality over time, they're checking for adverse events and the long-term effects. They are typically observations by monitoring patients.

Clinical Trials:

Safety, and other concerns

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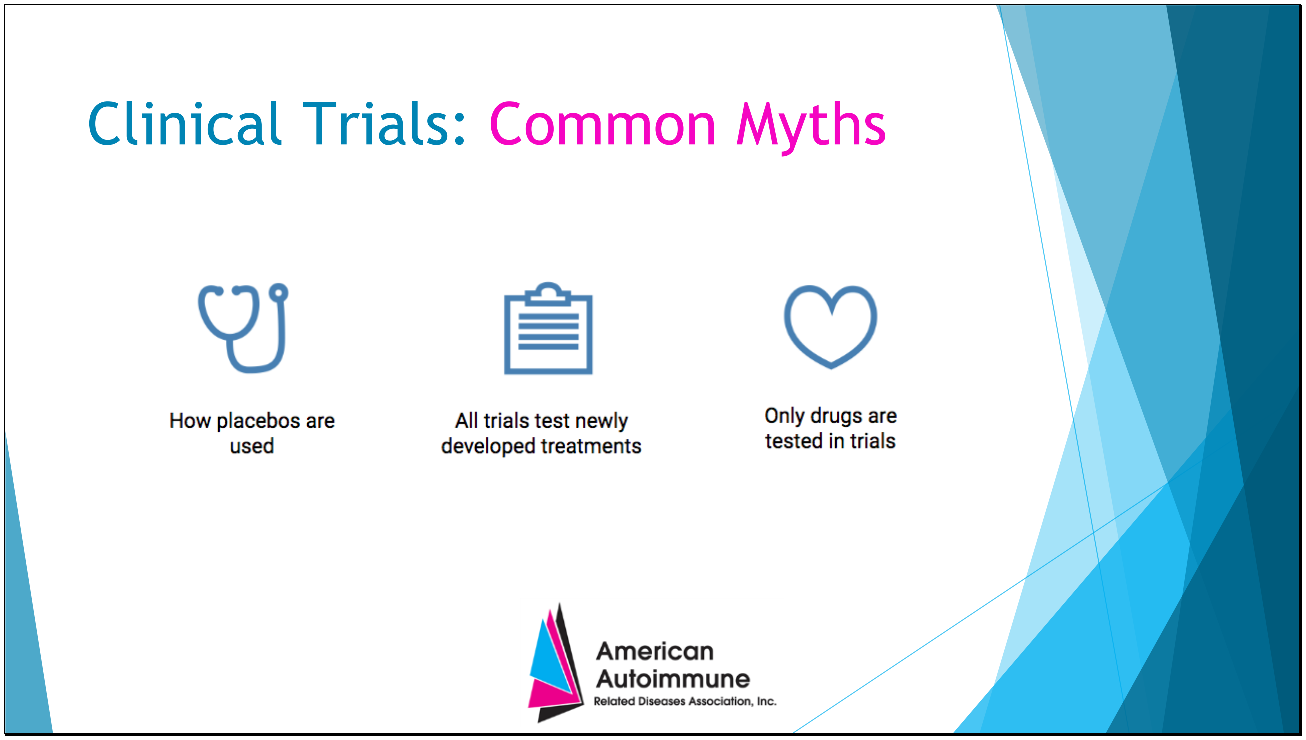
This is the biggest concern we hear about. “I don’t want to be a guinea pig”. We understand that, but clinical trials have changed drastically over the past decades. There are so many regulations in place to ensure the safety of clinical trial participants.



Clinical Trials: Common Myths

- How placebos are used
- All trials test newly developed treatments
- Only drugs are tested in trials

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How placebos are used, this is one of the things that I hear the most. We hear “I don’t want the sugar pill”, “I don’t want the placebo”. A lot of clinical trials now have a standard of care that don’t use a placebo- meaning that you don’t get treatment. A lot of clinical trials now, have the new treatment that they are testing, and it’s against the current standard of care. Only if it is absolutely necessary to the trial design will the patients have to get a placebo (no treatment). If a treatment is shown to work in clinical trials all the participants after a period of time will be switched over to be given that new treatment being tested. Often will get expanded access after the trial ends if its working well for them they will continue with it.

They study team when you’re looking applying for trials they can help you understand what the design of the trial is like. Be fully aware, nobody is going to lie to you and tell you that you’re getting treatment if you’re not. There is a process called informed consent, so you must understand everything about that trial before you actually sign on to it so there’s full transparency that’s happening.

Another common myth we hear is that all trials test newly developed treatments and a lot of trials do test newly developed treatments but a lot of them are testing medications that have already been approved by the FDA but there looking to approve it for the new condition. This often happens for biologics used to treat autoimmune conditions. The drugs are already proven to be safe and effective, just which diseases they can be used for.

Finally, the myth that only new drugs are tested in clinical trials. As mentioned before, the biologic device, or something like a diabetes pump or perhaps, or a surgery, so there are all kinds of different types of trials. It’s not always a certain kind of pill or injection that is getting tested.

Clinical Trials: Safety & Regulation

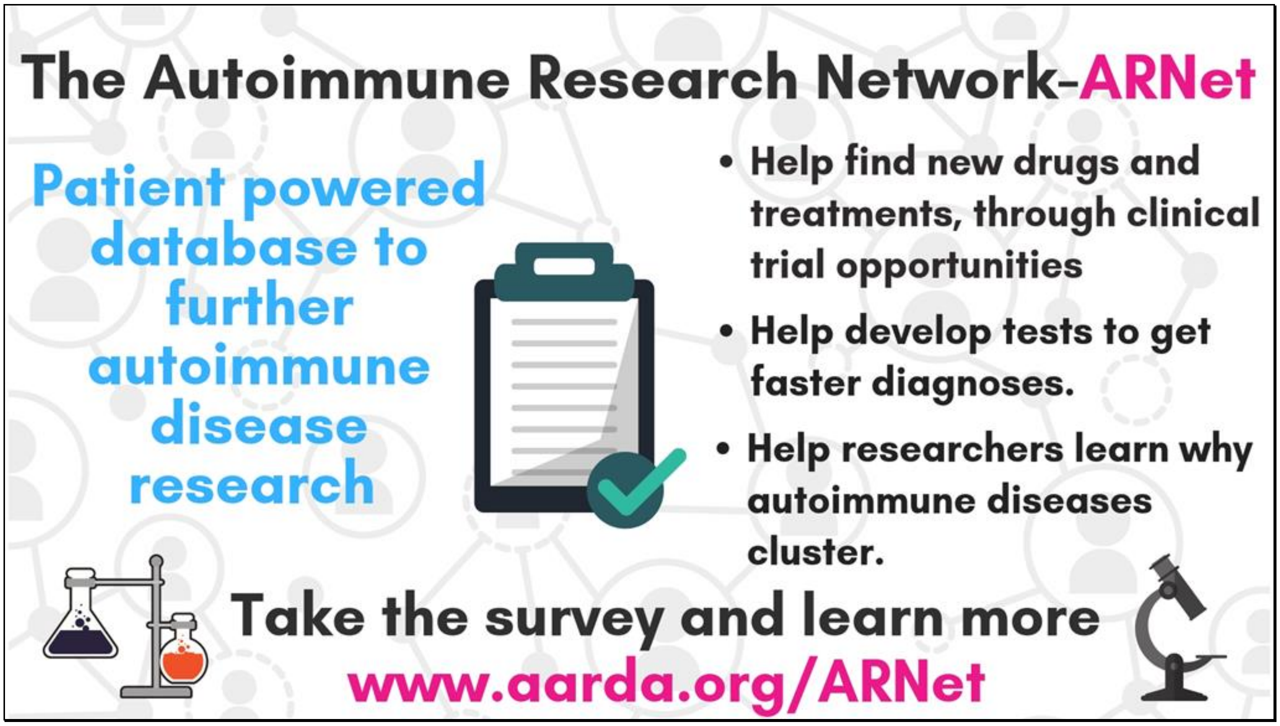
- Clinical trials are the last step in the 10-15 year research process to develop a new treatment for a condition
- **FDA:** The Food and Drug Administration, is a federal institution that protects participants throughout the clinical trial process by working closely with researchers to make sure that trials are safe
- **IRBs:** Before a clinical trial can be started, Institutional Review Boards (IRBs), a group of professionals with diverse experiences in research, medicine, and ethics, review and approve clinical trials before they are started
- There are state, national, and international regulations and policies in place to protect the rights and safety of people during and before they are even enrolled in a clinical trial

Learn more in Clara's Guide on how clinical trials are regulated for safety

There is so much to say on this topic. The guide at this link has a lot of useful information which was developed in collaboration with IBD physician Dr. Peter Higgins and it really gives a clear outline of how clinical trials are regulated for safety.

Learn more in Clara's Guide on how clinical trials are regulated for safety

Clinical trials are the last steps in a ten-fifteen-year development process. Before going to human trials, it spends a lot of time in the lab, its tested-on animals it's been tested in petri dishes. They've been worked on for quite a while. The FDA is a federal institution that protects the participants by working closely with the researches to make sure the clinical trials are safe. They must go through ever company that wants to go to clinical trials, they spend a lot of time talking back and forth to make sure that everything is good to go and that it's going to be safe for participants. The same with IRB's, or institutional review boards those are necessary for every single clinical trial. Everyone has to have their own institutional review board, and those are made up of a group of professionals with a diverse experience, and experience in research medicine ethics and they review and approve all clinical trials and all aspects from the marketing to the to the design of the trial they're looking at all of that and making sure that's its safe for the participants. Finally, there are state, federal, and internationals polices and regulations to protect the rights and safety of people during and before there are even involved in the trial- like the informed consent process. People sit down with a member of the study team and they really go through the nitty gritty details of what is going to be involved in participating in that clinical trials. There are a lot of check points and checks and balances in place to make sure that the trials are as safe as possible for the people who will be participating.



The Autoimmune Research Network-ARNet

Patient powered database to further autoimmune disease research

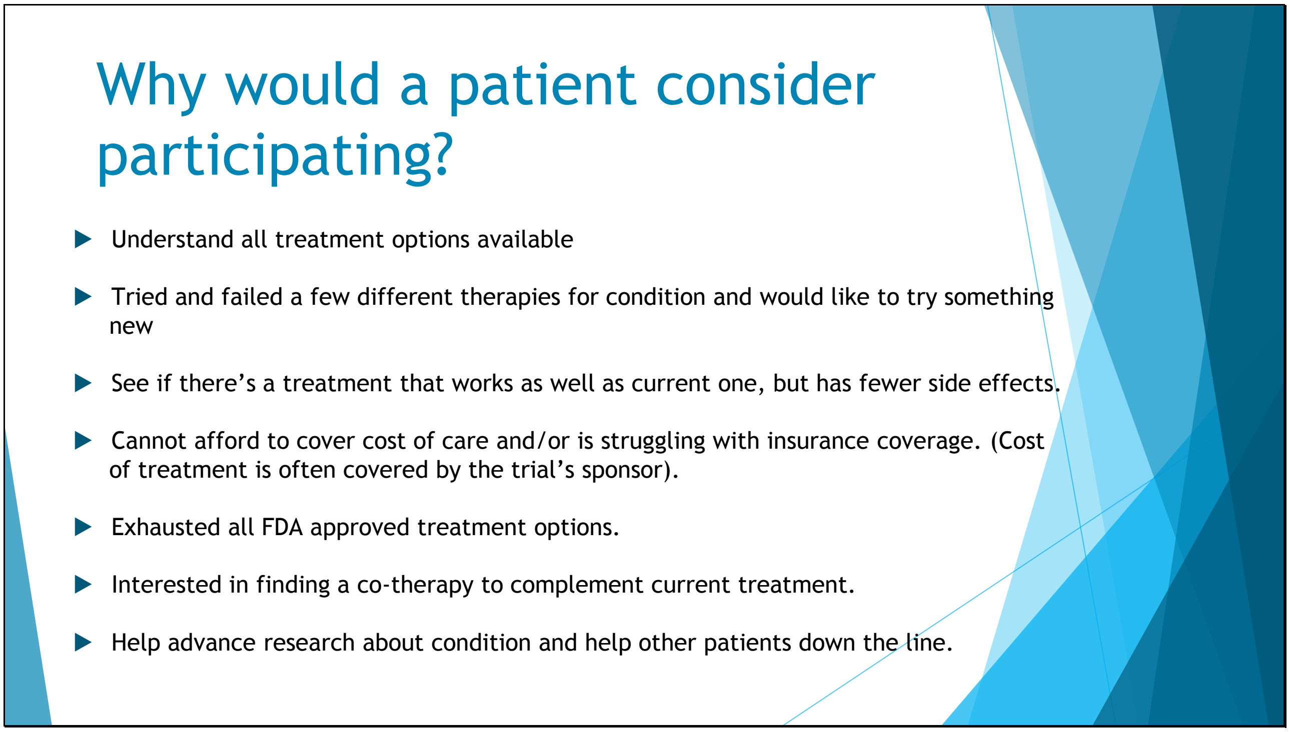
- Help find new drugs and treatments, through clinical trial opportunities
- Help develop tests to get faster diagnoses.
- Help researchers learn why autoimmune diseases cluster.

Take the survey and learn more

www.aarda.org/ARNet

You can help further AD research and be connected to these clinical trial opportunities. By filling out the simple ARNet survey, your data can be used to help researches get a better understanding of AD, and insights on where and what to research and study further. Additionally, researches will contact AARDA a with clinical trials or survey/study opportunities. All information is kept secure and your information is never shared without permission. For questions, please contact aarda@aarda.org.

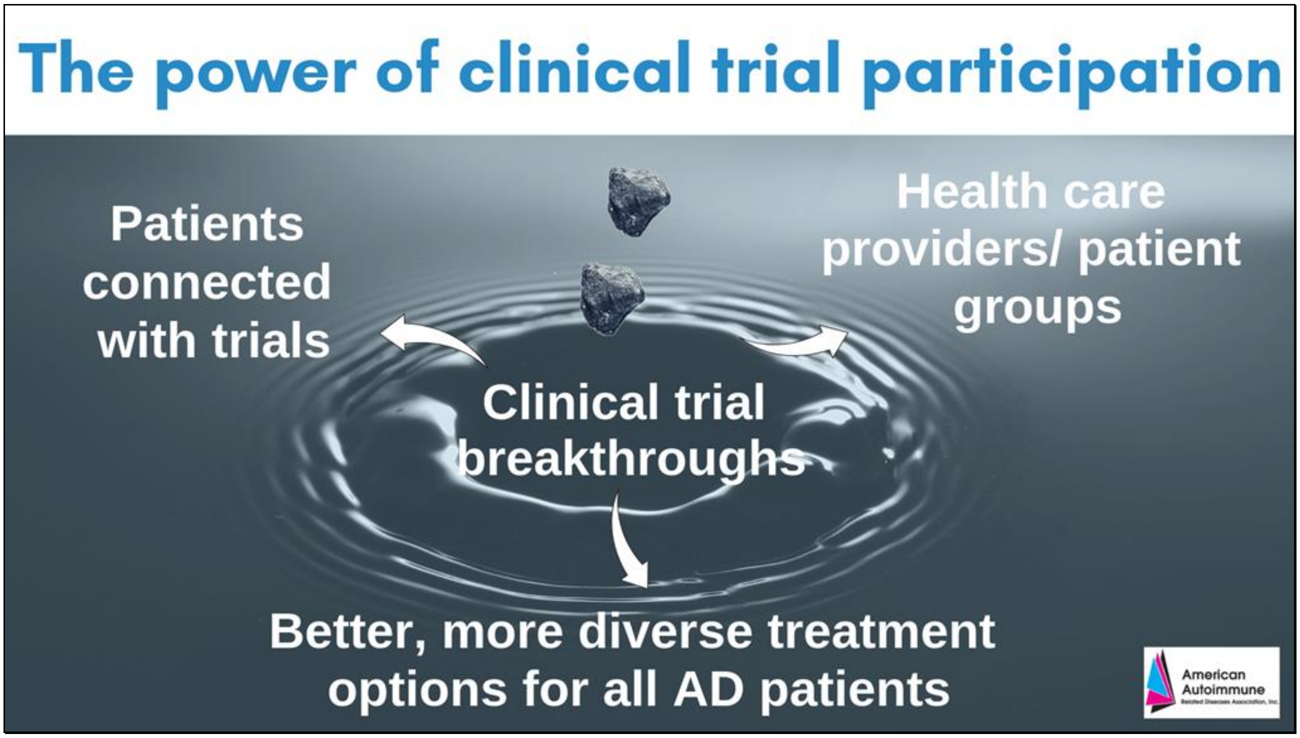
Click here to learn more and take the survey!



Why would a patient consider participating?

- Understand all treatment options available
- Tried and failed a few different therapies for condition and would like to try something new
- See if there’s a treatment that works as well as current one, but has fewer side effects.
- Cannot afford to cover cost of care and/or is struggling with insurance coverage. (Cost of treatment is often covered by the trial’s sponsor).
- Exhausted all FDA approved treatment options.
- Interested in finding a co-therapy to complement current treatment.
- Help advance research about condition and help other patients down the line.

It’s important to understand all the treatment options available. That can mean proved options, but that could also mean clinical trials. If your concerned about your condition and other medications or biologics haven’t worked, or you don’t want to go with a certain kind of treatment like biologics. Maybe you want to try a different approach like the stimulated that was discussed earlier, or just want to try something new, or something that might have fewer side effects. Maybe you are struggling to cover the cost of your care, or are having insurance issues, like step therapy, or a ridiculously high co-pay. One benefit of participating in a clinical trial is that often the treatment is covered by the trail sponsor and so it can offer you free care and that’s not a panacea that doesn’t count for every single trial, but it does for many of them, at least it covers the cost of care and treatment in the facilities. Some even cover travel costs to cover those expenses and the time it takes to get to those hospitals. Sometimes you exhaust your options with trying the available medication and clinical trials could really be the last resort option for you. Perhaps your interest in finding a co-therapy that could complement your current treatment, so you know maybe you are on some sort of medication that’s overall working but you are still experiencing some side-effects or symptoms. From an altruistic point of view, you may want to help other patients down the line, so you participate and when you do this you really are making a difference for so many patients now and in the future. If you think about it, every single medicine that we currently have that so many of us are on wouldn’t exist if it wasn’t for the patients who participated in clinical trials and that’s remarkable.



The power of clinical trial participation

Patients connected with trials

Health care providers/ patient groups

Clinical trial breakthroughs

Better, more diverse treatment options for all AD patients

American Autoimmune

Your participation in clinical trials has a ripple effect with an enormous potential to benefit the entire patient communities, for and beyond autoimmune disease patients and for all future patients.

Clinical Trials: How to Navigate the Process

- Talk to your doctor
- Visit clinicaltrials.gov or clarahealth.com
- Participate with ARNet and AARDA will connect you with opportunities

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It’s always great to talk to your physician about clinical trials. They can be a great resource for this. However, doctors don’t always have the time to cover trials during appointments. Clinicaltrials.gov, and Clara Health are both really great resources. Clara Health is user friendly and will walk you through the clinical trials process and can help answer your questions and additional resources and guides on the various aspects of clinical trials. www.guides.clarahealth.com

Clinical Trials: How Clara Can Help

Hand-picked trials
You can call, email, or instant message Clara's trial navigators and they will customize the options that best fit your needs.

Coordinating care
Clara will coordinate directly with the trial site and assist with sending medical records, filling out pre-screeners and scheduling initial appointments.

Insurance, travel, and beyond
Clara coordinates with insurance, helps schedule travel, and takes care of all the extra "to-dos" to make sure that no patient ever feels lost in the process.

Visit www.clarahealth.com to learn more and search for trials. You can also check out Clara Guides for in depth information on how clinical trials work.

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This is Clara's expertise, free of charge- you can plug in all of your information, if can call or instant message our trial navigators who are always on standby to help you customize the list of things you need to bring to your doctor to discuss. We'll coordinate care directly, we will set up a pre-screen that happens at a clinic site or hospital where the trial will be taking place. We help coordinate that, we even work with places like Uber to make sure you can get there. We work to make sure the process is easier for you so please feel free to get in touch with us at any time.

Questions?

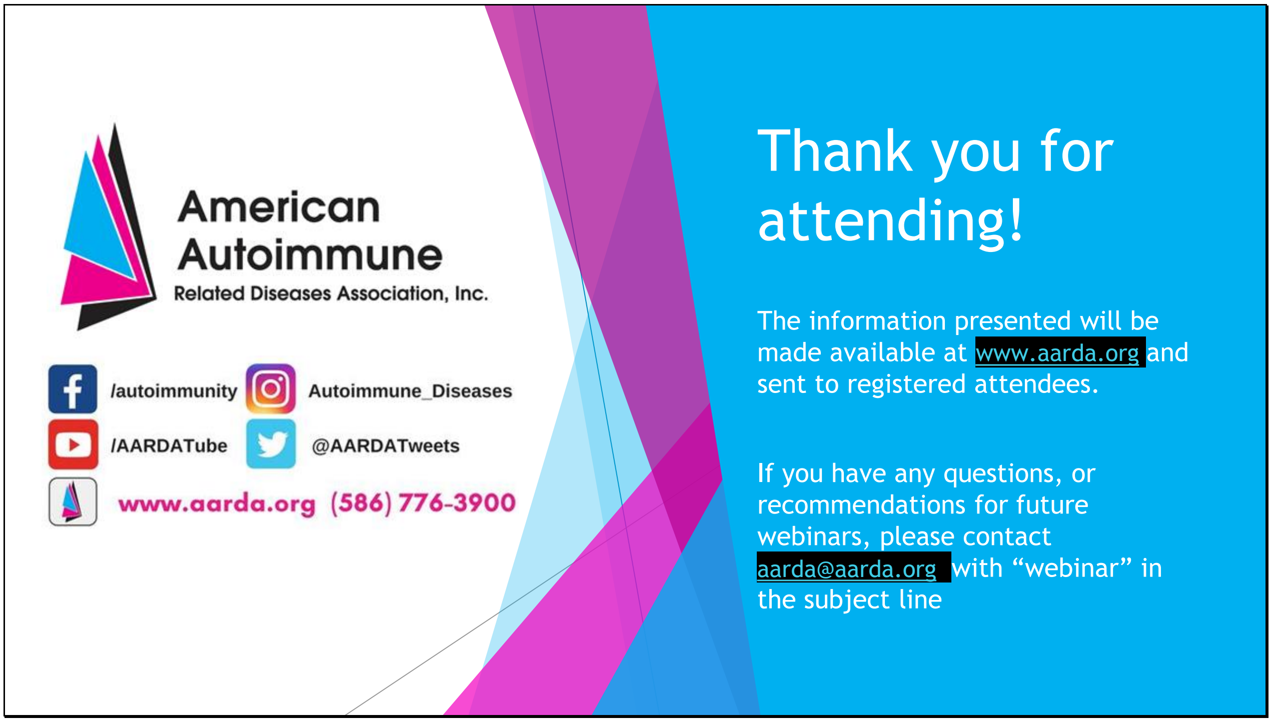
Do you know of trials for my disease/condition? Please visit Clara Health's website for the latest information https://www.clarahealth.com/

Can I share this information? Yes! Please do, we want to share and provide information to everyone who wants it.

Has there been an increase of people who want to participate in clinical trials? Yes! Especially with online patient communities, you can connect and see other experiences.

85% of trials fall behind because they do not have enough participants. Everyday millions of dollars are lost, and time wasted by not having enough people.

Is there any challenge in getting certain groups to participate with clinical trials? Unfortunately, yes, there is a sad truth in the history of clinical trials. There are differences in how different minorities, and different genders respond to medications. Unfortunately, clinical trials see a lot of white men participate, which doesn't encompass many groups. There has been a history where people were mistreated, like with Tuskegee and other events that have taken place. There are so many regulations in place now to prevent those things from happening again. You can trust your health care team, there are so many check points to make sure that participants are being kept safe and everything is being done by the book and done appropriately. There is a great podcast around MS and these issues that we will have soon. Click here for all of Clara Health's podcasts



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Thank you for attending!

The information presented will be made available at www.aarda.org and sent to registered attendees.

If you have any questions, or recommendations for future webinars, please contact aarda@aarda.org with “webinar” in the subject line

There is nothing more powerful than taking to a peer. Patients really hold the power in changing this landscape. We encourage you to have conversations with your peers and the public about these issues.

All the new advances are very encouraging, the stimulators, and new trials for diets and supplements. There is a lot of hope. If there is anything to take away from this is that **there is always hope**.