



Clinical Research in MS

Ryan Dickerson, PhD
Clinical Research Coordinator

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What is clinical research?

- Medical research that studies people to understand health and disease
- Helps improve the way doctors treat and prevent illness.
- Clinical research findings help us learn:
 - How the body works
 - How illness develops in people and changes over time
 - How the body handles possible treatments
 - How lifestyle and life circumstances influence disease frequency and outcomes



Not all clinical research is the same

▪ *Observational Studies*

- Participants are not assigned to a test group (drug, device, procedure, etc.), though they may be self-electing to take/use a product.
- Identify associations between variables (e.g., drug X and health outcome Y) but cannot prove causation.
- Help researchers understand a situation and generate a hypothesis to be tested in a clinical trial
- Useful when clinical trials cannot be done (e.g., a study asking people to engage in known high risk behaviors, or long-term disease monitoring)

▪ *Clinical Trials*

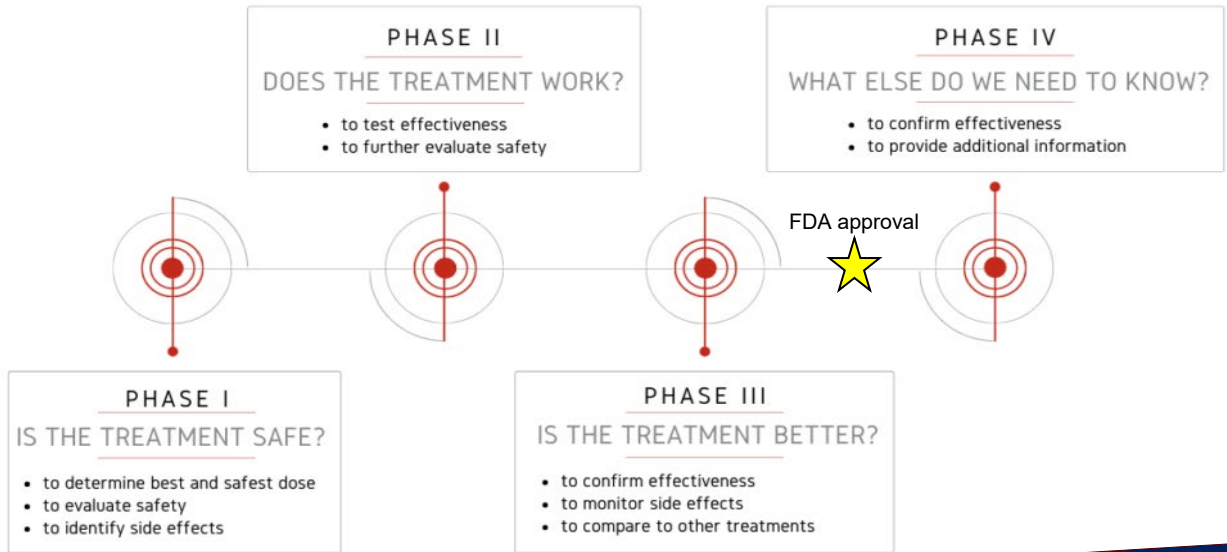
- Participants are assigned into test groups, often through a blinded randomization
- Often involve administration or use of products that have not yet received FDA approval
- Gold standard for proving that a new product or procedure works for the intended outcome
- Investigational products are often compared to either a product that is already on the market or to a placebo
- Participants and investigators are often blinded from knowing which intervention a volunteer receives and from seeing clinical results that could provide insight into group assignment

What is a clinical trial?



National Institutes of Health (NIH)

THE 4 PHASES IN CLINICAL TRIALS



Who can participate?

- Clinical research is conducted according to an Institutional Review Board (IRB) approved research protocol developed by the sponsor or lead investigator that details eligibility criteria, including:
 - Reason for conducting the study
 - Inclusion/Exclusion Criteria
 - How many participants are needed

Example Eligibility:

Inclusion Criteria

- Adults, ages 18-65
- Diagnosed with Progressive MS
- No evidence of relapse within 24 months
- Ability to walk at least 100 meters

Exclusion Criteria

- Any active or uncontrolled autoimmune disease other than MS
- Women who are pregnant or may become pregnant
- Use of anti-CD19/20 therapies within the last 12 months (e.g., Ocrevus)
- Use of systemic corticosteroids within the last 30 days

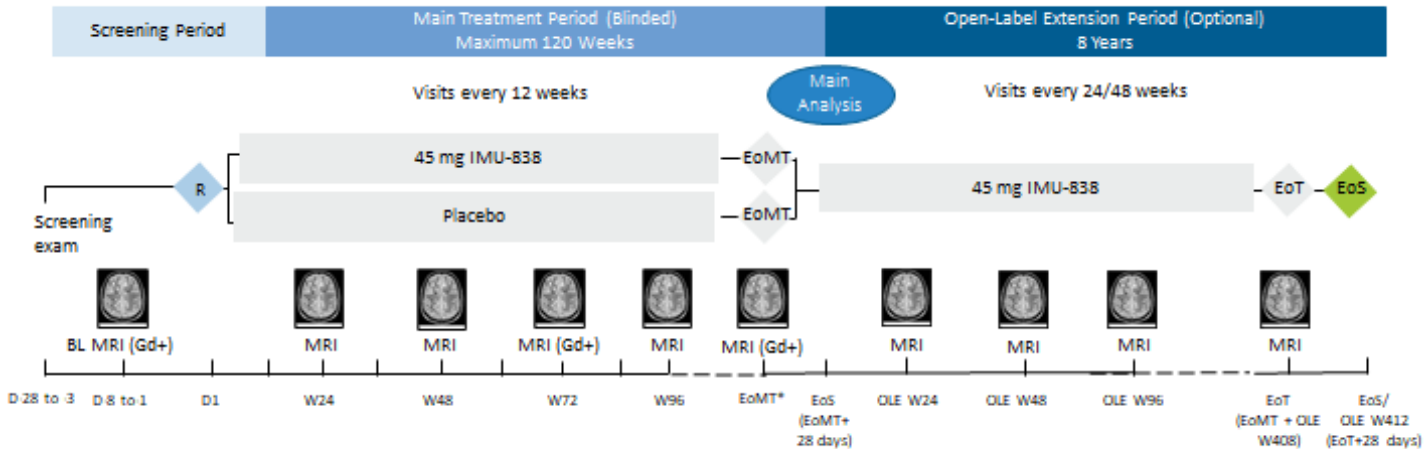
Informed Consent

- Detailed description of study rationale and design
 - Study duration and visit frequency
 - What will be asked of you at research visits
 - Risks and benefits associated with your participation
 - Data security
 - Other treatment options
 - Any costs associated with participation
 - Principal Investigator (PI) contact information
- Opportunity to ask questions
- Collect signatures



- **Your participation is completely voluntary and can be stopped at any time without impacting your relationship with your healthcare team.**

Example Study Schedule



How we collect data:

- Medical history
- Current medications
- Vitals
- Questionnaires
- Lab results (blood, urine, saliva, CSF, etc.)
- MRI images
- Functional Assessments
- Physical Exams

Different from your standard office visits

- Some visits are short and may piggyback off your standard clinic visits.
- Other study protocols may last several hours and require unique research visits
- Research activities with the whole team (multiple clinicians, research coordinators, imaging staff)
- You and your doctor may not have access to study-specific lab results (blinding)
- You may be asked to participate in additional diagnostics above and beyond the standard of care
- Sometimes, transportation and lodging reimbursement may be available



Current Studies

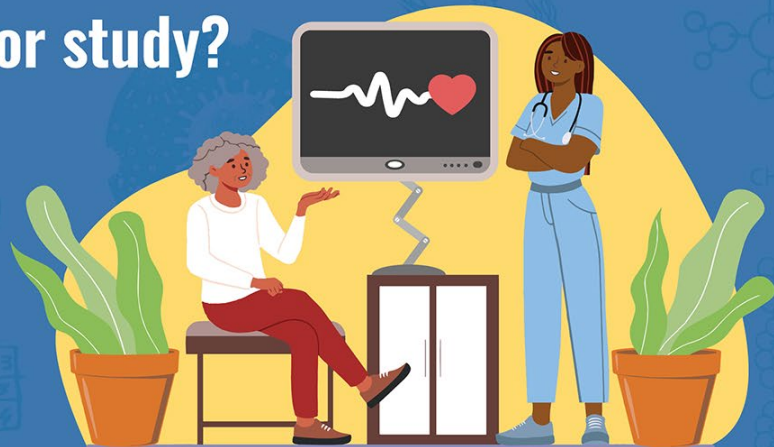
Status	Enrolling?	Type	Title	Sponsor
Ongoing	Yes	Clinical	A Phase-2b, Double-Blind, Randomized Controlled Trial to Evaluate the Activity and Safety of Inebilizumab in Anti-NMDA Receptor Encephalitis and Assess Biomarkers of Disease (EXTINGUISH)	NeuroNEXT
Ongoing	Yes	Observational	Markers of Biological Aging in Multiple Sclerosis	NIH
Ongoing	Yes	Observational	Neuroscience Research Institute Brain Bank and Biorepository (NRI-BBB)	OSU
Ongoing	No	Clinical	Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate Efficacy, Safety, and Tolerability of IMU-838 in Patients with Progressive Multiple Sclerosis (CALLIPER)	Immunic Therapeutics
Ongoing	No	Clinical	A Phase 3, randomized, double-blind efficacy and safety study comparing SAR442168 to teriflunomide (Aubagio®) in participants with relapsing forms of multiple sclerosis (GEMINI 1) (EFC16033)	Sanofi
Ongoing	No	Observational	COVID-19 Vaccine Efficacy in MS Patients: The Impact of Disease Modifying Therapies	OSU
Paused	No	Clinical	EFC16035-A Phase 3, randomized, double-blind, efficacy and safety study comparing SAR442168 to placebo in participants with primary progressive multiple sclerosis (PERSEUS) (ECG16035)	Sanofi
Upcoming	No	Observational	North American Registry for Care and Research in Multiple Sclerosis (NARCRMS)	CMSC

Additional clinical and observational studies coming soon!

Why join a clinical trial or study?

By participating, you can:

- Learn more about your disease or condition
- Feel like you're playing an active role in your health
- Help researchers find new ways to prevent or treat disease
- Benefit future generations through scientific advances



Major medical breakthroughs could not happen without the generosity of volunteers like you.

National Institutes of Health (NIH)

Clinical Research Staff



Kasturi Ganesh Barki



Marina Rodriguez



Ryan Dickerson



Emma Hill

Thank You

For more information, please contact:

MSresearch@osumc.edu

Or

Ryan.Dickerson@osumc.edu

Office: 614-688-9162