Current Alzheimer's Disease Clinical Research at SIU Medicine

Barbara Cray Lokaitis, BA, CCRP
Senior Clinical Research Coordinator
Center for Clinical Research
blokaitis@siumed.edu
217.545.9737

SIU MEDICINE
FORWARD. FOR YOU.

WHAT IS A CLINICAL TRIAL?

- A clinical trial is a research study that tests a medicine or therapy in people.
- Clinical trials can also be called clinical studies or clinical research.
- Clinical research helps us answer questions about the medicine being studied, like does the medicine work and is it safe.
- The medicines inside your medicine cabinet have one big thing in common; before reaching you, they went through years of research studies to ensure that they were safe for you to take.

THINGS YOU NEED TO KNOW ABOUT CLINICAL TRIALS

People participate for different reasons. Some common reasons for study volunteers to join a clinical trial include:

- to advance science and treatments
- to help others with the same condition or disease as them
- to potentially obtain better treatment

THINGS YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- Everyone conducting a clinical trial has strict regulatory and ethical duties.
- Institutional Review Board (IRB) or Central IRB, operate independently from the day-to-day conduct of research.
- The purpose of IRB is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research.

THINGS YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- Clinical trials are experiments, so the exact risks and benefits can be difficult to predict.
- Researchers only move forward with clinical trials when they are optimistic about the potential benefits and believe any risks for participants are acceptable.
- The risks and benefits are different for everyone.

THINGS YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- For each trial, this set of criteria is needed to prove whether a medicine works or not in a specific patient population.
- Trial criteria are based on things like age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

THINGS YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- For most clinical trials, the study medicine is provided and visits are conducted at no cost to the participant.
- Some clinical trials pay or reimburse participants.
- Payment for participation is not meant to entice subjects to participate.

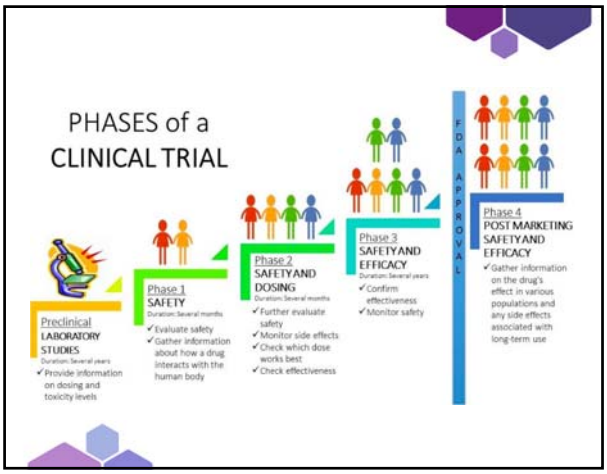
THE MOST IMPORTANT THING YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- Participants can withdraw from a clinical trial at any time, for any reason.
- No matter the stage of the trial, participants have the right to change their mind.
- If a study volunteer decides to leave the study, the Principal Investigator will remove them from the trial in a safe manner.

CURRENTLY ENROLLING – LIFT-AD

- Athira Pharma, Inc., Bothell, WA
- ATH-1017-AD-0201

- A Randomized, Placebo-Controlled, Double-Blind Study of ATH-1017 Treatment in Subjects with Mild to Moderate Alzheimer's Disease
- Phase 2
- 55 Centers in USA (might open in Australia)
- 300 participants (we currently have four enrolled) – currently at 75% of target



CURRENTLY ENROLLING –
LIFT AD

The main purpose of this study is to investigate the effectiveness of ATH-1017 at different doses compared to a placebo, for the treatment of Alzheimer's disease (AD) and to determine the safety and tolerability (whether side effects of a medicine can be handled by study subjects) of ATH-1017 compared to a placebo, when administered once a day for up to 26 weeks.

CURRENTLY ENROLLING –
LIFT AD

This is a Phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study comparing ATH-1017 40 mg/day and ATH-1017 70 mg/day with placebo in subjects with a clinical diagnosis of mild to moderate Alzheimer's disease (AD), diagnosed on a 'probable' level according to McKhann, 2011.

CURRENTLY ENROLLING –

LIFT AD

- Subjects and their trial partners will be required to sign an informed consent document and will be evaluated against the inclusion/exclusion criteria during a screening period.
- Those who meet all inclusion/exclusion criteria will be randomized in a ratio of 1:1:1 to three parallel arms, either to active treatment (ATH-1017 40 mg/day or ATH-1017 70 mg/day) or placebo.

CURRENTLY ENROLLING –

LIFT AD

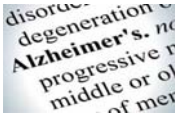
- During the study, patients will undergo cognitive assessments, collection of laboratory samples, ECG monitoring, and brain MRIs.

- The Screening Period (to confirm that you are suitable for the study) can last up to 28 days.
- The Treatment Period (where you will receive your assigned study medication) will last up to 26 weeks (approximately 6 months).
- The Post-treatment Follow-up Period (to check your overall health) may last up to 4 weeks or you may choose to go into the OPEN-LABEL EXTENSION period (more on that later).

CURRENTLY ENROLLING –

LIFT AD

- Study drugs will be administered by subcutaneous injection once-daily preferably during the daytime.
- The study partner will need to document all injections in a dosing diary.
- Subjects may experience risks and/or possible side effects while in the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effects that may happen.



CURRENTLY ENROLLING –

LIFT AD

- There is no cost to the subject to participate – all study related visits, tests, etc. are covered by Athira.
- Subjects do receive $78 for each visit that is completed. This is distributed via a check mailed to their home. Bad news, this is income according to the IRS.
- Sara Boarman, BS, in the Leader Coordinator for this study – you can reach her at sboarman93@siumed.edu or 217.545.6829.

CURRENTLY ENROLLING –

LIFT AD

- Open-Label Extension (OLE) – only subjects who complete the 26 week blinded portion of study may *roll-over* in the OLE.
- The OLE is not blinded – Open-Label means everyone gets the real drug – no more possibility of placebo.
- This is also 26 weeks – it is run very similar to the blinded period.
- You do not have to enroll in the OLE – it is optional.

CURRENTLY ENROLLING –

NEW IDEAS

- American College of Radiology
- New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study
- A Study to Improve Precision in Amyloid PET Coverage and Patient Care
- Mild Cognitive Impairment or Dementia
- 7,000 persons may be enrolled – United States
- Will having the results of an amyloid PET scan change your doctors treatment plan?
- Radioactive tracer injected via IV – wait 45 minutes, then PET scan of brain completed.
- **Currently only enrolling minorities of color** – this is expected to change in September 2022.
- Must be a Medicare recipient – Medicare is paying for scan.
- $75 check comes to subject's home directly from ACR.
- NOT A TREATMENT STUDY.
- Contact Stephanie Kohlrus, BA, CCRP, at 217.545.3013 or skohlrus@siumed.edu for more information.

NEW iDEAS
Brain Imaging Study for Alzheimer's

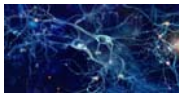
CURRENTLY ENROLLING –
CAREGIVER STUDY

- Caregiver Characteristics that may be associated with the optimal care of patients with Alzheimer's disease.
- Investigating various characteristics and features that may predict changes in caregiving over the course of three years. Couples will have a one-time visit at the clinic. During the one-time visit, the couple will be administered questionnaires, assessments, and physical measurements. After this visit, the caregiver will have a phone-call interview every two months, spanning three years. The caregiver will also complete two mail-in questionnaires every six months and a telephone depression screening.
- We hope to enroll 217 couples.
- Tom Ala, MD, is principal investigator.
- Each enrolled couple that completes the one-time visit and mail-in questionnaires will be paid $150. An additional payment of $100 will be given each succeeding 12 months for the phone-call interviews and for completing and returning the two questionnaires. A total payment of $450 will be paid to couples who complete the full three years. Payment will be given as a check mailed to your home address.
- Contact Stephanie Kohlrus, BA, CCRP, at 217.545.3013 or skohlrus@siumed.edu for more information.

ONGOING – NOT ENROLLING
TRAILBLAZER-2

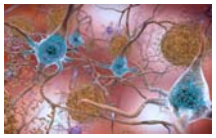
Lilly I5T-MC-AACI

- Assessment of safety, tolerability, and efficacy of donanemab in early symptomatic Alzheimer's disease.
- Phase 3
- Infusion every four weeks at SCI
- 1800 subjects world-wide
- Six subjects enrolled locally
- 78 weeks blinded
- 78 week OLE – all subjects are in OLE



ONGOING – NOT ENROLLING
TRAILBLAZER-2

During the study, patients will undergo cognitive assessments, collection of laboratory samples, ECG monitoring, brain magnetic resonance imaging (MRI) and positron emission tomography (PET) scans, and you will receive either the study drug or placebo by intravenous (IV) infusion once every 4 weeks. An IV infusion is when the drug or placebo is given through a needle into your vein.



ONGOING – NOT ENROLLING

TRAILBLAZER-2

- 24 Jun 2021 - Lilly's donanemab receives U.S. FDA's Breakthrough Therapy designation for treatment of Alzheimer's disease.
- The Breakthrough Therapy designation aims to expedite the development and review of drugs that are intended to treat a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over already available therapies that have received full FDA approval.

ONGOING – NOT ENROLLING

POST GRAD

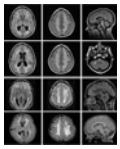
Hoffman-LaRoche WN42171

- An open-label, multicenter, rollover study to evaluate the safety, tolerability and efficacy of long-term gantenerumab administration in participants with Alzheimer's disease.
- Phase 3
- Injection every two weeks – in clinic.
- 2032 people enrolled world-wide.
- Four subjects enrolled locally (one still in GRADUATE).
- 18 month study

ONGOING – NOT ENROLLING

POST GRAD

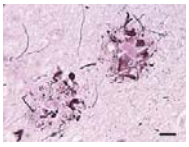
- Includes biosample repository plus tau and amyloid PET scan substudies.
- During the duration of the study, participants will undergo cognitive assessments, collection of laboratory samples, optional cerebral spinal fluid sampling, ECG monitoring, amyloid and tau PET assessments, and brain MRIs.



ONGOING – NOT ENROLLING

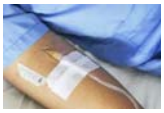
POST GRAD

- In **October 2021**, the FDA designated subcutaneous gantenerumab a Breakthrough Therapy, offering an accelerated review and approval process.
- The decision is based on promising results from the ongoing open-label extension trials, showing a significant reduction in brain amyloid plaque in Alzheimer's patients.



ONGOING – NOT ENROLLING

LAURIET

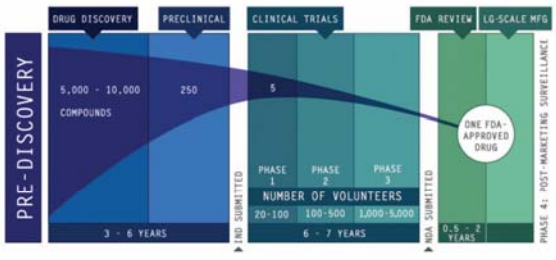


Genentech GN40040

- A Phase II, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy, and safety study of MTAU9937A in patients with moderate Alzheimer's disease.
- 260 subjects – 50 study centers
- One subject enrolled locally – currently in the OLE portion of the study
- 3.5 year study
- Infusion administered every four weeks – at SMH (aka MMC)
- If it works, MTAU9937A may slow down how fast the disease progresses.

Pathway to Your Medicine Cabinet

Drug Discovery and Development: A LONG, RISKY ROAD



PhRMA 2012 Annual Report
26

alzheimer's association

OUR CLINICAL RESEARCH TEAM

Tom Ala, MD – Principal Investigator
Jennifer Arnold, MD, PhD – Co-Investigator
Cindy Womack, DNP – Sub-Investigator
Charlene Young, FNP-BC – Sub-Investigator
Barbara Lokaitis, BA, CCRP – Senior Clinical Research Coordinator
Stephanie Kohlrus, BA, CCRP – Clinical Research Coordinator
Ann Jirmasek, MS, LPC – Rater
Amy Richey, LPN - Rater

OUR CLINICAL RESEARCH TEAM

Sara Boarman, BS – Clinical Research Specialist
Rylee Manka, BA – Clinical Research Specialist
April Murrey – Data Manager
Stephanie Rasmussen, BSN, RN – Research Nurse
Karin Newhall, BSN, RN – Research Nurse
Missy Cartwright, BSN, RN – Research Nurse
Andre Catalano, PharmD, MBA – Post Doc
Megan Meinke, MD – Clinical Research Specialist

SIU Medicine
Neuroscience Institute
Dale and Deborah Smith Center for Alzheimer's Research and Treatment
751 North Rutledge Street, Suite 3100
Springfield, IL 62702
217.545.9737