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Current Alzheimer's Disease Clinical Research at SIU Medicine

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FORWARD. FOR YOU.

CURRENT TRIALS IN THE NEUROLOGY AND NEUROSURGERY DEPARTMENTS AT SIU MEDICINE

Alzheimer's Disease – 6 open (3 Pending)
Parkinson's Disease and Movement disorders – 4 open (2 Pending)
Neurocritical Care – 1 open (0 Pending)
Neurosurgery – 1 open (1 Pending)
Neuromuscular – 1 open (0 Pending)
Seizure – 4 open (4 Pending)
Stroke – 1 open (0 Pending)

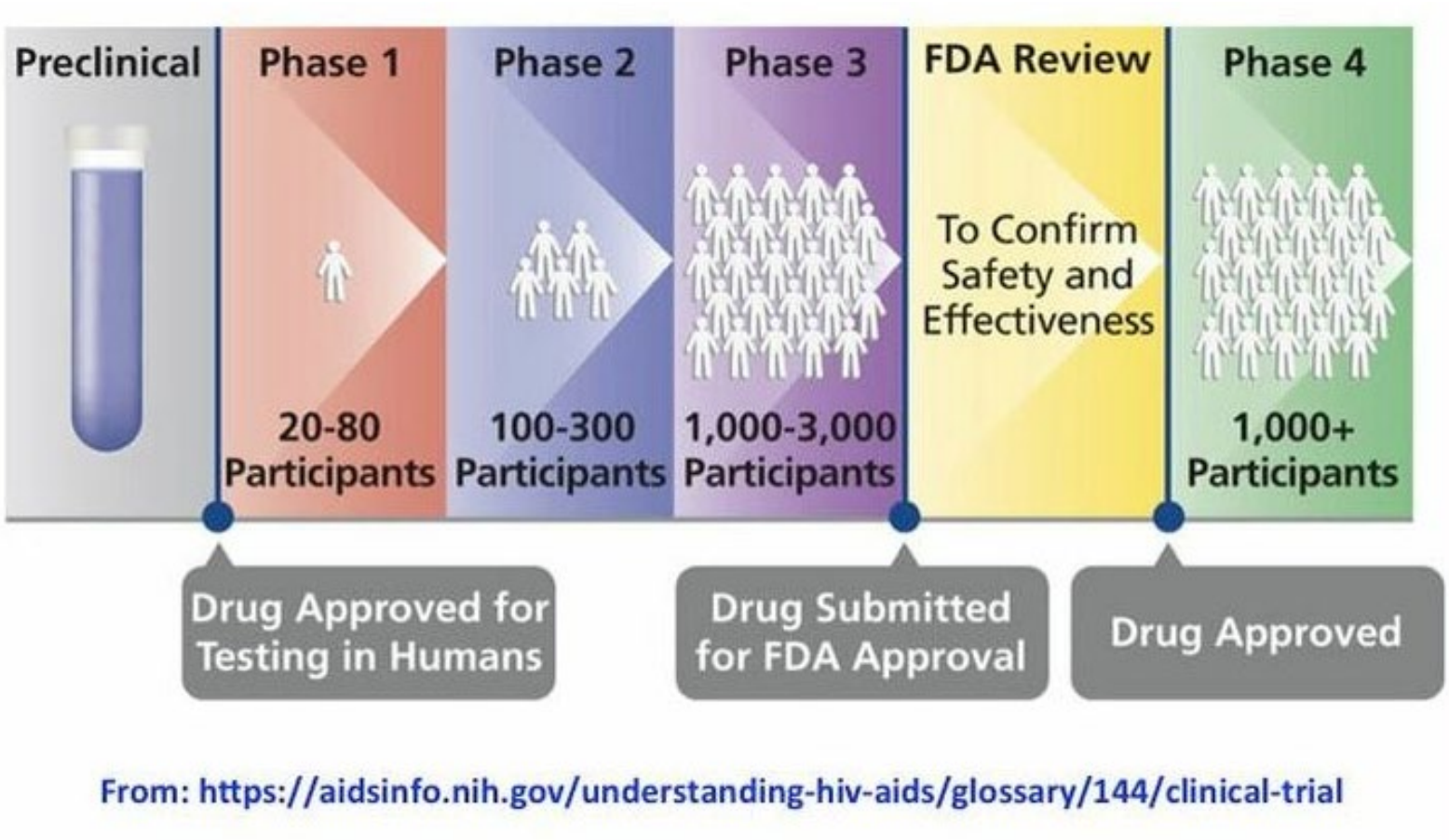
https://www.siumed.edu/neuro/research.html

If you would like to enroll in our clinical trials, please complete the patient survey located at: https://www.siumed.edu/ccr/enroll-clinical-trial

WHAT IS A CLINICAL TRIAL?

- A clinical trial is a research study that tests a medicine or therapy in people.
- Clinical research helps us answer questions about the medicine being studied.
- 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.

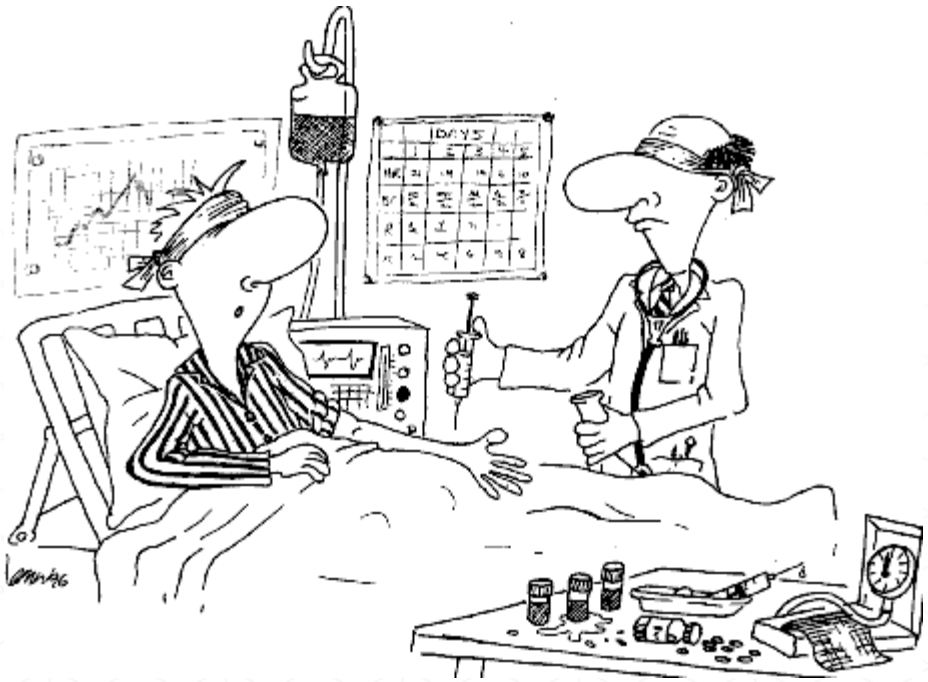
CLINICAL TRIAL PHASES



From: https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/144/clinical-trial

CLINICAL TRIAL TERMS

- Double-Blind – both the study team and the subject are "blinded" to the treatment that is being given
- Placebo-Controlled – compares a treatment to a look-alike substance that includes no active treatment or drug
- Open-Label – A trial in which treatment is known to the study team and to the subject
- Adverse Event (AE) – A change or medical event that occurs during a clinical trial. It may or may not be caused by the treatment received in the trial.



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THE CLINICAL RESEARCH TEAM

- Principal Investigator (PI)
- Sub-Investigator (Sub-I)
- Clinical Research Coordinator (CRC)
- Research Nurse

VALUE OF CLINICAL TRIALS

- New medical breakthroughs.
- Determine safety and effectiveness for the human body
- They may show that one treatment is effective over a previously used treatment
- Help reduce the burdens of disability and illness
- Developing cures!

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WHY DO PEOPLE PARTICIPATE?

- Advancement of science and treatments
- To help others with the same condition or disease as them
- To obtain treatments before it is available to others
- More attention from physicians (frequent visits)
- Etc.

IMPORTANT THINGS TO KNOW ABOUT CLINICAL TRIALS

- Everyone conducting a clinical trial has strict regulatory and ethical duties.
- There are independent reviewers that operate separate from the day-to-day conduct of research (Institutional Review Boards or Central IRBs)
- They are experiments.
- Risks and benefits are different for everyone.

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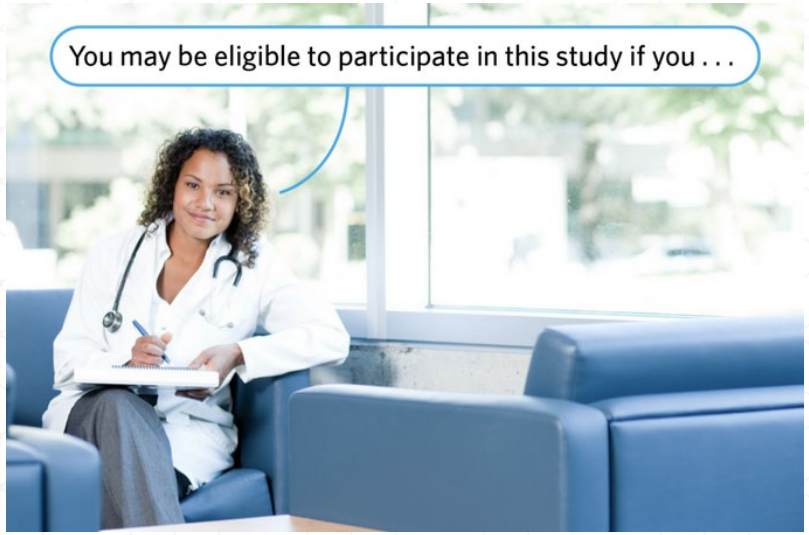
IS THERE PAYMENT FOR PARTICIPATION?

- For most 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.

INCLUSION/EXCLUSION CRITERIA

- Inclusion criteria – characteristics prospective subjects must have if they want to be included in a study
  - Demographics
  - Medical History
- Exclusion criteria – Additional criteria that may interfere with the success of the study or increase risks for unfavorable outcomes



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TYPICAL INCLUSION CRITERIA FOR ALZHEIMER'S TRIALS

- Age range (usually 55 to 85)
- Diagnosis of Alzheimer's disease or memory loss
- Generally in good health other than the illness being studied
- Caregiver is with the patient at least 10 hours a week and willing to accompany patients to all study visits
- Mini-Mental State Exam (MMSE) – score is 0 to 30 (more on this later)
  - Mild studies – score of 25-30
  - Moderate studies – score of 14-24
  - Severe studies – score of 0-13

EXCLUSION CRITERIA FOR ALZHEIMER'S TRIALS

- Inability to tolerate MRIs/PET scans
- BMI outside of range
- Poor venous access
- Serious medical conditions (that in the opinion of the PI preclude the patient's safe participation)
- Prohibited medications
- Recently alcohol and tobacco use

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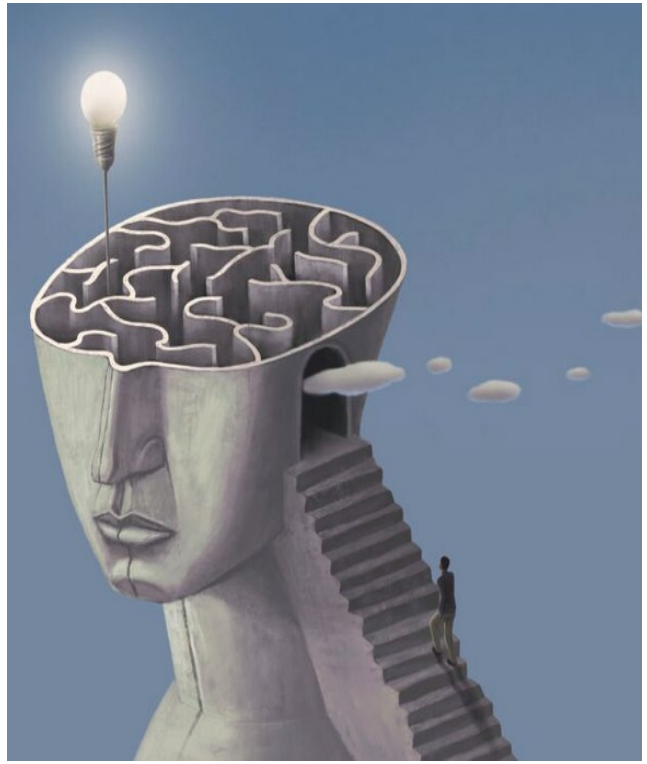
COGNITIVE TESTING

- Most clinical trials require the use of scales to help determine if the intervention being studied is effective.
- Scales commonly used in clinical trials:
  - Mini Mental State Exam (MMSE)
  - Alzheimer's Disease Assessment Scale (ADAS)
  - Montreal Cognitive Assessment (MoCA)
  - Repeatable Battery for Assessment of Neuropsychological Status (RBANS)
  - Clinical Dementia Rating (CDR)
- Caregiver Questionnaires
  - Neuropsychiatric Inventory (NPI)
  - Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL)
  - Etc.



MINI-MENTAL STATE EXAM (MMSE)

Mini-Mental State Examination (MMSE)

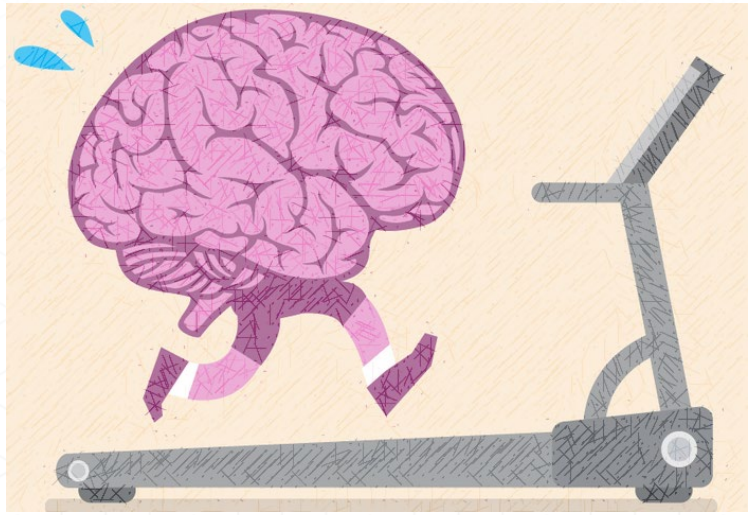
Patient's Name: _____ Date: _____

Instructions: ***Ask the questions in the order listed. Score one point for each correct response within each question or activity.***

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf



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THE MOST IMPORTANT THING YOU NEED TO KNOW ABOUT CLINICAL TRIALS

- Participants can withdraw from a clinical trial at any time for any reason.
  - Ongoing Consent
  - Keep subjects and caregivers updated on risks that may change their willingness to participate
  - Remind the patient and caregiver of the study goals and objectives

CURRENTLY ENROLLING-LIFT AD (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
- 375 participants – currently at >50% of target
- Now only enrolling those on no other drugs for treatment of Alzheimer's Disease
- to investigate the effectiveness of ATH-1017 at different doses compared to a placebo, for the treatment of Alzheimer's disease (AD) and determine the safety and tolerability of ATH-1017
- Sara Boarman, BS, is the Lead Coordinator for this study – you can reach her at sboarman93@siumed.edu or 217.545.6829.

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LIFT AD – DURING THE TRIAL

- Patients will undergo cognitive assessments, collection of laboratory samples, ECG monitoring, and a brain MRI
- Screening Period - (to confirm eligibility) can last up to 28 days.
- Treatment Period-you will receive your assigned study medication via a once daily subcutaneous injection that will last up to 26 weeks (approximately 6 months) and 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.
- There is no cost to the subject to participate and subjects and caregivers each receive $78 per visit that is completed.

CURRENTLY ENROLLING – LIFT AD OPEN-LABEL EXTENSION (ATH-1017-AD-0203)

- Open-Label Extension (OLE) – only subjects who complete the 26 week blinded portion of study may *roll-over* into the OLE.
- The OLE is not blinded – Open-Label means everyone gets the real drug – no more possibility of placebo.
- This period runs 18 months – it is run similar to the blinded period (less cognitive testing).
- Subjects will receive a daily subcutaneous injection.
- You do not have to enroll in the OLE – it is optional.
- Sara Boarman, BS, is the Lead Coordinator for this study – you can reach her at sboarman93@siumed.edu or 217.545.6829.

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CURRENTLY ENROLLING – NEW IDEAS: IMAGING DEMENTIA-EVIDENCE FOR AMYLOID SCANNING STUDY

- American College of Radiology is sponsoring
- A Study to Improve Precision in Amyloid PET Coverage and Patient Care
- For patients suspected of having Mild Cognitive Impairment or Dementia
- The doctor is actually being studied - 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

NEW iDEAS
Brain Imaging Study for Alzheimer's

NEW IDEAS

- **Currently only enrolling minorities of color** – this is not expected to change in the near future.
- Must be a Medicare recipient – Medicare is paying for scan.
- $75 check comes to subject's home directly from ACR.
- Contact Sara Boarman, BS, at 217.545.6829 or sboarman93@siumed.edu for more information.

NEW iDEAS
Brain Imaging Study for Alzheimer's

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CURRENTLY ENROLLING – CAREGIVER CHARACTERISTICS THAT MAY BE ASSOCIATED WITH THE OPTIMAL CARE OF PATIENTS WITH ALZHEIMER'S DISEASE (CAREGIVER STUDY)

- Investigating various characteristics that may predict changes in caregiving over the course of three years.
- Couples will have a one-time visit at the clinic where 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 depression screening.
- A total payment of $450 will be paid to couples who complete the full three years.
- Looking for couples over the age of 70-caregiver has to be spouse
- NOT A TREATMENT STUDY
- Contact Stephanie Kohlrus, BA, CCRP, at 217.545.3013 or skohlrus@siumed.edu for more information.

ONGOING – NOT ENROLLING
LILLY I5T-MC-AACI (TRAILBLAZER 2)

- Assessment of safety, tolerability, and efficacy of donanemab in early symptomatic Alzheimer's disease.
- Phase 3
- Infusion every four weeks at Simmons Cancer Institute
- 78 weeks blinded with the option to roll over into an open-label period
- June 2021 - Lilly's donanemab receives U.S. FDA's Breakthrough Therapy designation for treatment of Alzheimer's disease.

Lilly

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ONGOING – NOT ENROLLING GN40040 (ROCHE LAURIET)

- 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 Springfield Memorial Hospital.
- If it works, MTAU9937A may slow down how fast the disease progresses.

LOOKING FOR CLINICAL TRIALS

- http://clinicaltrials.gov or search Clinical Trials.gov
- This is a worldwide database of privately and publicly funded clinical trials.
- Currently there are over 400,000 research studies in all 50 states and 221 countries.
  - Search for Alzheimer's disease turned up nearly 3,000 results.
  - Search for Dementia turned up over 4,000 results.

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ALZHEIMER'S NEUROLOGY CLINICAL RESEARCH TEAM

Jennifer Arnold, MD, PhD – Principal Investigator
Tom Ala, MD – Principal Investigator/Sub-Investigator
Cindy Womack, DNP – Sub-Investigator
Amber Fifer, PharmD, ACRP-CP – Research Assistant Professor of Neurology and Psychiatry
Barbara Lokaitis, BA, CCRP – Senior Clinical Research Coordinator
Stephanie Kohlrus, BA, CCRP – Clinical Research Coordinator
Ann Jirmasek, BS, MA, LPC, NCC – Rater
Amy Richey, LPN – Rater
Sara Boarman, BS – Clinical Research Specialist
Rylee Manka, BA – Clinical Research Specialist
Stephanie Rasmussen, RN, BSN – Research Nurse
Mary (Missy) Cartwright, RN, BSN – Research Nurse
Andre Catalano, PharmD, MBA – Post-Doctoral Fellow
Megan Meinke, MD – Post-Doctoral Fellow

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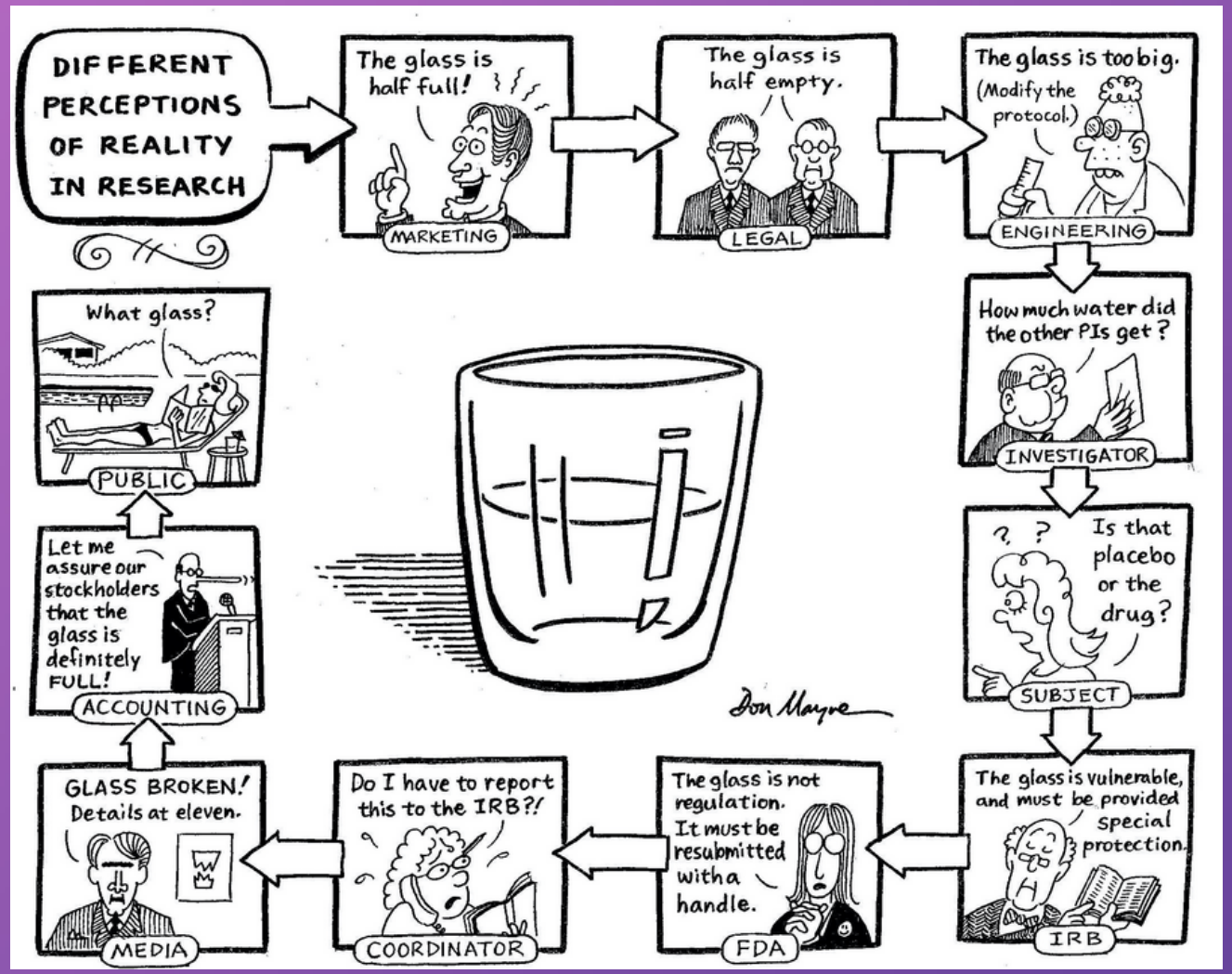
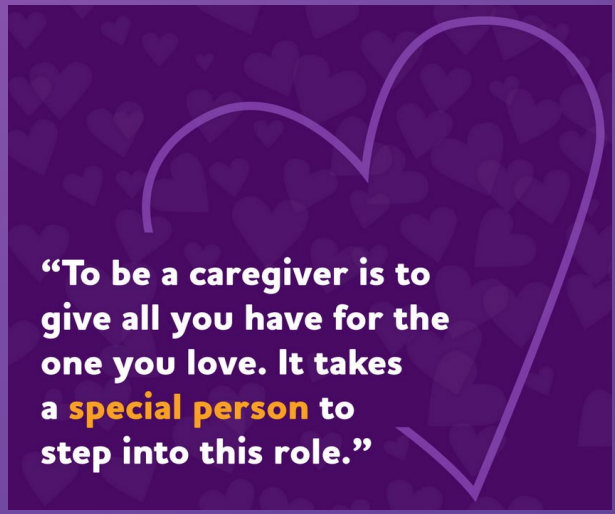
QUESTIONS?





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