

Workshop Case: MemGen study

- The study is a randomized (1:1), double blind, placebo-controlled trial, testing a new drug, MemGen, to reverse memory loss in patients with mild-moderate Alzheimer's Disease.
- Study enrolls inpatients who are hospitalized for clinical dementia workup (per usual clinical care, not research). Subjects will be enrolled during the first two days of hospitalization.
- Intervention: a single IV infusion of 10 mg MemGen per kg/m² or Placebo while inpatient, with close safety monitoring throughout hospitalization, including daily collection/assessment of clinical events occurring during the course of inpatient clinical care that meet the definition of AEs.
- After discharge, subjects are followed for 4 visits over 3.5 months. Study visits assess for safety (lab testing, physical exam, querying the patient and caregiver on AEs) and efficacy (neuropsychological testing and Swiss AD scale completion).
- Data from the clinical workup for the hospitalization and several study-specific assessments will be used to determine eligibility.
- Primary objective: To evaluate the efficacy of MemGen as compared to placebo, for the reversal of memory loss in AD patients.

Instructions:

- Your breakout room will be assigned to discuss 2 of the lettered sections below. If your group finishes discussing these two sections you can move onto others.
- Assign someone to keep notes on the group discussion so some learnings, insights and observations from the group can be shared with other groups after we "break" from the breakout rooms.
- Approach the discussion by considering the MemGen case above.
 - o Think about the sources of the data (some from the EMR, some generated by study staff, etc.).
 - o Consider your data management strategy: CRFs, data collection forms, what source is directly entered into the CRF vs. on a data collection form, etc.
 - o Consider what data collection tools you need to develop to record the data.
 - o Consider also how you will design your Case Report Forms (CFRs) and data collection tools, including specific requirements for data collection forms and Case Report Forms (CRFs) in your strategy.
- Discuss strategies for developing your data collection forms and Case Report Forms for the sections below.

Remember that there is not one "right answer" and there are several strategies that are acceptable. With that in mind, consider what makes a strategy "acceptable".

A. Eligibility/Baseline:

- Physical exam (acceptable to come from medical record if done during the current hospitalization)
- Vital signs
- Research blood draw: CBC, metabolic panel, lipid panel
- Neuropsychological testing battery by certified study staff at baseline
- Swiss AD scale: Obtained in-person by a certified investigator at baseline

B. Informed Consent

C. Eligibility criteria:

Inclusion

1. Admitted as inpatient per clinical care indication for work-up of dementia
2. Probable mild-moderate Alzheimer's disease diagnosis via completion of Surity AD testing per standard clinical care during current hospitalization
3. MMSE 13-24 performed per standard clinical care during current hospitalization
4. Age 55-89 at time of Eligibility assessment

Exclusion

1. Clinically significant hypertension, anemia, liver disease or kidney disease according to guidelines provided in the MemGen Handbook
2. Current plasma creatinine ≥ 1.5 mg/dL
3. Concurrent use of systemic corticosteroids
4. Any condition that, in the opinion of the study physician, makes it medically inappropriate or risky for the participant to enroll in the trial

D. Demographics

- Gender
- Race/ethnicity
- DOB/Age

E. Infusion

- Height and weight should be measured and BMI calculated within two days of the infusion, as it is used to calculate MemGen dosing.
- Infusion should take place over at least 1 hour. First 30 minutes should be at a rate of 50 cc/hr, after which rate can be increased to 200 cc/hr.
- Vital signs taken every 15 minutes through the infusion and then hourly for 4 hours after infusion ends.

F. Hospitalization

- Daily check of medical record to document/assess AEs, from enrollment (pre-infusion) through discharge; assess: seriousness, severity, expected/unexpected, relatedness
- Daily vital signs

E. Post-discharge in-clinic Study visits x4 (Visit 1 two weeks after discharge and monthly x 3)

- Vital signs
- Blood draw: CBC, metabolic panel, lipid panel
- Physical exam
- Review and record current medications
- Querying for AEs/assessment of AEs (Seriousness, severity, expected/unexpected, relatedness)
- Neuropsychological testing battery by certified study staff
- Swiss AD scale: Obtained in-person by a certified investigator
- QOL survey of caregiver