**Animal Studies Questionnaire**

**For proposals that include studies in animals, provide responses to all of the questions.** Please see [Snyder et al](http://www.alzheimersanddementia.com/article/S1552-5260%2816%2932676-0/fulltext) and [Shineman et al](https://alzres.biomedcentral.com/articles/10.1186/alzrt90) for recommendations on your animal study design.

1. Provide justification for the animal model selected based on the mechanism of action for the therapeutic agent. Does the model exhibit pathologies relevant to the mode of action (e.g. if the target is the immune system, does the model show elevated neuroinflammation)? Has the model been extensively characterized? (Genotype and phenotype should be confirmed throughout the duration of the study.)
2. Describe or reference pharmacokinetics (PK) data showing that your therapeutic agent reaches its intended target at a sufficient concentration to ensure that your hypothesis is being tested. PK should inform dose selection and should be performed with the same route of administration and formulation intended for use in your efficacy study.
3. What are your primary evaluation criteria? Describe how these outcomes are relevant to your compound’s mechanism of action and human disease symptoms.
4. What is your pharmacodynamic readout of target engagement?
5. How do you expect efficacy readouts in your animal study to translate into human clinical outcomes? Is a translatable biomarker for your target or mechanism of interest available?
6. Provide a statistical analysis plan. Include a power analysis to justify your sample size. Has your power analysis accounted for previously observed variability in your outcome measures?
7. Do you plan to use both males and females? If not, provide justification. Will the results be analyzed separately?
8. If your study is negative, do you still intend to publish the findings?
9. Include a flow chart of your animals through the treatment plan of the study.