

# The Alzheimer's Disease Preclinical Efficacy Database –Improving the Rigor, Reproducibility and Translatability of Preclinical Research for Alzheimer's Disease:

**AizPED**

## Challenge that Needs to be Addressed:

- Failure of Alzheimer's therapies in the clinic due to poor translational validity of drug trials in AD animal models.

## Key Contributing Factors:

- AD animal models do not accurately recapitulate human AD
- Lack of reliable preclinical markers and outcome measures that translate to the clinic
- Lack of rigor in study design and methodology
- Publication bias in favor of reporting positive findings and under reporting negative findings
- Poor reproducibility of published data

NIH AD Summits in 2012 & 2015



## Recommendations Aimed at Increasing Predictive Power of Preclinical Testing in AD Animal Models:

1

House experimental details relating to the preclinical testing of candidate therapeutic agents in AD animal models.

2

Identify critical elements of design and methodology missing from studies

3

House experimental details of positive and negative data to overcome publication bias.



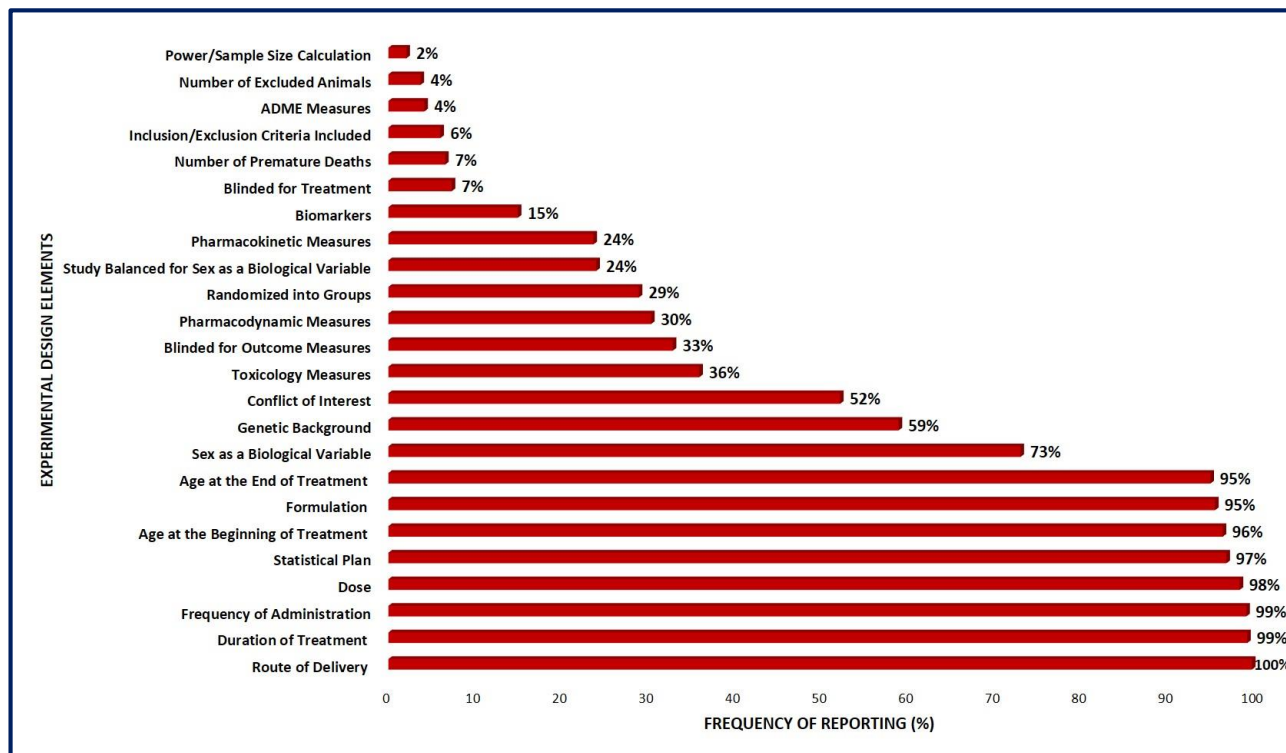
# Elements of Rigorous Experimental Design and Analysis of Reporting Trends

## Report on the rigor of a study curated in AlzPED: Summary of experimental design and methodology.

### Experimental Design

#### Is the following information reported in the study?:

- |   |   |
|---|---|
| ✓ Power/Sample Size Calculation               | ✓ Randomized into Groups                          |
| ✓ Blinded for Treatment                       | ✓ Blinded for Outcome Measures                    |
| ✗ Pharmacokinetic Measures                    | ✗ Pharmacodynamic Measures                        |
| ✗ Toxicology Measures                         | ✗ ADME Measures                                   |
| ✗ Biomarkers                                  | ✓ Dose  |
| ✓ Formulation                                 | ✓ Route of Delivery                               |
| ✓ Duration of Treatment                       | ✓ Frequency of Administration                     |
| ✓ Age of Animal at the Beginning of Treatment | ✓ Age of Animal at the End of Treatment           |
| ✓ Sex as a Biological Variable                | ✓ Study Balanced for Sex as a Biological Variable |
| ✗ Number of Premature Deaths                  | ✓ Number of Excluded Animals                      |
| ✓ Statistical Plan                            | ✓ Genetic Background                              |
| ✓ Inclusion/Exclusion Criteria Included       | ✓ Conflict of Interest                            |



**Reporting trends for the 24 recommended experimental design elements that improve reproducibility and translational value of preclinical studies. Data are presented as percentages calculated from 917 curated preclinical efficacy studies published between 1996 and 2019.**

Join **AlzPED** at Poster No. 4  
on Wednesday, March 4<sup>th</sup> from 5:00PM – 7:00PM

Detailed analytics available at: <https://alzped.nia.nih.gov/alzped-analytics>



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## Partner Organizations

