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**BACKGROUND**

One of the major challenges to the successful development of therapies for Alzheimer's disease (AD) is the poor translation of preclinical efficacy from animal models to the clinic. Several key factors have been identified as contributors to the unsuccessful translation of therapeutic efficacy, these include:

- the failure of the models to fully recapitulate human AD,
- poor rigor, study design and data analysis, insufficient attention given to using a standard set of “best practices”,
- failure to match outcome measures used in preclinical animal studies and clinical studies,
- poor reproducibility of published data, and
- publication bias in favor of reporting positive findings.

To address this challenge and ameliorate some of the factors contributing to the preclinical to clinical gap in the development of AD therapies, several advisory meetings and workshops including the National Institutes of Health (NIH) AD Summits in 2012 and 2015 have created an open science knowledge portal – the Alzheimer’s Preclinical Efficacy Database or AlzPED. Through the following capabilities, AlzPED is intended to guide the development and implementation of strategies and recommendations for standardized best practices for the rigorous preclinical testing of AD candidate therapeutics:

**AlzPED has the following capabilities:**

- Provides researchers and information scientists with a facile way to survey existing AD preclinical therapy development literature and raise awareness about the elements of rigorous study design and requirements for transparent reporting.
- Currently hosts curated summaries from 917 preclinical efficacy studies published between 1996 and 2019.
- Influences the development and implementation of reproducibility strategies including guidelines for standardized best practices for the rigorous preclinical testing of AD candidate therapeutics.
- Provides search capability across relevant translational criteria data sets and external databases:
  - Therapeutic Agents
  - Animal Models
  - Targeted therapies
  - Therapeutic Targets (Open Targets and DrugBank.ca)
  - Therapeutic Targets (DrugBank.ca)
  - Animal Models (Open Targets and DrugBank.ca)
  - Clinical Trials (ClinicalTrials.gov)
  - Related Publications (Pubmed.gov and DrugBank.ca)
  - Funding Source
  - Related Grants (DrugBank.ca and DrugBank.ca)
  - Related Clinical Trials
  - Related Patents
- Provides a platform for creating citable reports/preprints of unpublished studies, including studies with negative data.
- Reports on this rigor of each study by summarizing the elements of experimental design.
- Provides a platform for creating citable reports/preprints of unpublished studies, including studies with negative data.
- Publishes available datasets of preclinical efficacy studies in PDF format.
- Provides funding agencies with a tool for enforcement of requirements for transparent reporting and rigorous study design.
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**A CURATED RECORD IN AlzPED: EXAMPLE OF RIGOROUS STUDY DESIGN**

**REPORTING TRENDS FOR THE 9 CORE ELEMENTS BASED ON JOURNAL IMPACT FACTOR AND NUMBER OF CITATIONS PER YEAR**

**SUMMARY**

In summary, AlzPED:

- It reviews the preclinical studies in AlzPED, demonstrating serious deficiencies in reporting critical elements of methodology such as power calculation, blinding for treatment/outcomes, randomization, sex of animal used and balancing for sex, animal genetic background and other.
- Poor reporting of critical elements of methodology diminish the scientific rigor, reproducibility and translational value of the preclinical studies.
- A standardized set of best practices is required for successful translation of therapeutic efficacy in AD research.