

Pre-clinical animal research must improve

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Less than five percent of promising basic science discoveries that claim clinical relevance lead to approved drugs within a decade, partly because of flawed pre-clinical animal research. A number of recent initiatives seek to improve the quality of such studies, and an article published this week in *PLOS Medicine* identifies key experimental procedures believed to increase clinical generalizability.

The authors, led by Jonathan Kimmelman of McGill University in Montréal, did a systematic literature search and identified 26 guidelines with 55 different procedures that groups of scientists had proposed to improve the quality and usefulness of preclinical efficacy studies. They then summarized and prioritized the results.

The key recommendations are listed in the new STREAM (Studies of TRanslation, Ethics And Medicine) checklist, and include performance of a power calculation to determine sample size, randomized treatment allocation, and in-depth characterization of disease phenotype in the <u>animal model</u> prior to experimentation.

Preclinical <u>animal research</u> is a critical step in drug development. More rigorous attention to experimental procedures protects patients in subsequent clinical trials and redeems the use of animals. It also promises to reduce the cost and delay in developing drugs.

The researchers suggest that: "Investigators, institutional review boards, journals, and funding agencies should give our prioritized recommendations due consideration when designing, evaluating, and



sponsoring translational investigations."

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