

The thought about bioscience translation into drug development progress

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Steardo A. The thought about bioscience translation into drug development progress. *J Prev Emerging Disease*. 2023; 6(2): 4-3.

ABSTRACT

Nowadays, the scientific community is divided into pro-animal testing supporters, and scientists argue that animal testing is lacking in efficacy. I'm strongly against the development of animal houses for animal medical experiments. Experiments on animals reproduce artificially a condition of disease or injury. Several transgenic models are available for cancer drug testing. Many

times, the experiments are brutal. They involve laboratory animals in unethical procedures. Moreover, animal testing often has a low scientific power to esteem a medicine's effectiveness and safety.

Key Words: *Preclinical research; Drug development; Translational bioscience efficacy; Animal models; Model target*

INTRODUCTION

In the first instance, it is necessary to consider the following. The pro-animal testing scientific community argue that preclinical studies are important and necessary because, during animal studies, scientists evaluate the safety and efficacy of a novel molecule candidate for clinical assessment

Preclinical research in drug development

Although, clinical studies are the most meaningful part of drug evaluation because during phases I, II and, III the investigators can evaluate the effects of the therapeutic agent and balance its dose, risks, benefits, and harms, respectively. Nevertheless, during the past decade, bioscience has created gaps in translation bioscience in practical benefits for patients and society [1].

My point of view

The first item the reader needs to consider is: according to Plato, a Greek philosopher, life is a divine gift, and its destiny is decided by divinity. For ethical reasons, human beings cannot manipulate life like an object. Animal testing causes severe suffering to animals that participate in the experiment. Most of them are rodents, dogs, birds, and monkeys. Behind the sufferance grows a big economic interest and arises a big conflict of interests. In addition, several pieces of evidence emerge in literature criticizing animal testing [2]. Most of the clinical studies find unsafety and ineffective the data collected during

preclinical studies [3]. Only 11% of molecules tested enter clinical studies and only 5% of these are labelled [4]. 80 % of animal studies are ineffective [5], and are largely harmful to individuals participating in the trial [3]. Although, preclinical studies seem to be necessary to develop the safety and efficacy tests on molecules that will be evaluated in phase I on human beings. Anyhow, bias threatens its validity result. This type of experimental system can characterise the phenomena in the wrong way. Some animal model systems don't comply with the response of patients. Transgenic models mouse can create unforeseen reactions in the phase I trial. It means a failure of the preclinical research as it has been documented by "Monoclonal antibody TGN1412 trial failure explained by species differences in CD28 expression on CD4+ effector memory T-cells" in which immune toxicity emerged during phase I trial. Other mistakes emerge from the data reporting, and these are due to poor experimental design. Often a critical and methodical approach to data is necessary [5-8].

Question marks on animal models

Some question marks arose about the efficacy of animal models of disease to test human disease. The complexity of the human disease isn't easily applicable to an animal model, and it limits reproducibility. It also affects the translation of the results into useful data to put up clinical experimentation. No doubt, the disparity between the animal module and human disease jeopardises the drug

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Received: 19-April-2023, Manuscript No. *puljedpm-23-6526*; Editor assigned: 22-April-2023, PreQC No. *puljedpm-23-6526 (PQ)*; Reviewed: 27-April-2023, QC No. *puljedpm-23-6526 (Q)*; Revised: 29-April-2023, Manuscript No. *puljedpm-23-6526 (R)*; Published: 08-May-2023, DOI: [10.37532/PULJEDPM.2023;6\(2\):4-5](https://doi.org/10.37532/PULJEDPM.2023;6(2):4-5).



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development process because it causes the failure of clinical experimentation. Stroke is a clear example of what I have just mentioned. The use of invalid models could lead the industry to the wrong research direction and be a waste of money. The opportunity to create human organs grown by the laboratory, in silico screening models and 3D printing of human tissues is an important alternative to evaluate the parameter assessed during preclinical studies. The benefit of these new types of models is based on human biology. They could eliminate the physio-pathological gap between animals and human beings; so, they offer data about safety and efficacy parameters, deriving directly from predictive human models [7]. In this way they can reach the same scientific aim, enhance the efficacy of the experiment, and reduce animal suffering.

Animal translational bioscience efficacy

Some animal tests lack efficacy, but more could be done if scientific methodology could avoid bias in the design, research poor reporting, research invalidity, and qualitative research evaluation [4]. Their appearance in literature could fake the data and create a misunderstanding. For this reason, it is necessary to translate properly animal data into clinical experimentation [8]. Although, no doubt, evidence-based medicine data are more effective to evaluate the efficacy of a drug than preclinical studies [7]. On the other hand personalized medicine could improve the benefits and reduce the cost of clinical experimentation. It would reduce animal sacrifice. Indeed, animal targets don't manage to estimate properly novel molecules during the early phases of drug development.

CONCLUSION

In conclusion, animal testing isn't enough predictive, and it often causes mistakes. This inaccuracy involves trial participants in further suffering. More could be done if the scientific community would improve the use of different experimental models to reproduce injury and disease status directly on human biological models. In a way this way, scientists could test the effectiveness and the safety of a new molecule candidate for human beings' tests. It could reduce the use of animals in experimental therapeutic and so tests could also be more predictive by reducing severe side effects, especially during Phase I clinical trials. From my point of view, animals aren't an appropriate target to test molecules and start experimentation on humans.

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