Clin Exp Pharmacol 2015, 5:4
http://dx.doi.org/10.4172/2161-1459.S1.008

OMICS International
conferenceseries.com

Improving the R&D process in the development of innovative medicines: New paradigm and the role of pharmacology and preclinical studies

Joao Rocha
University of Lisbon, Portugal

The drug discovery stage involves narrowing down thousands of compounds to a few hundred promising possibilities that are ready for preclinical testing. Although preclinical studies only account for about 10% of the overall cost of development of an approved product, they precede the clinical and regulatory lifecycle of a given product and comprise the riskiest phase of new product development. It is estimated that only about 3–5% of all products graduate from the initial preclinical testing into the advanced clinical testing phase. Therefore, preclinical testing is widely considered as one of the crucial points in drug discovery and development. It is the point of the R&D process that can prematurely identify drug candidates with the potential to become "winners" and eliminate the "losers" prior to any significant expenditure ("fail early and cheap"). Recent strategies are being developed to change the paradigm in drug development, in order for the preclinical R&D phase to reduce high attrition rates in drug development today that led to increasingly cost in drug development yet a decline in the approval of new molecular entities. Some of those strategies involve public-private partnerships initiatives; translational approaches bridging the gap between preclinical and human testing that consist in a better crosstalk between basic science and clinical setting, fast-tracking patients' access to innovative medicines. These include the concept of repurposing/recycling new therapeutic uses from existing drugs and the development of efficacy/toxicological biomarkers able to predict, at early stages of development, the confidence in mechanism and safety of the investigational drug.

jrocha@ff.ulisboa.pt

Notes: