

Biomedical Research into Useful Therapeutics

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Description

Increasingly more reports in the literature are reflecting on the hurdles of effective translation from promising results of biomedical research into useful therapeutics. A recurrent theme is that good intentions are frustrated by extrinsic factors upon which 'translation lists' have little control. It is possible that the problem resides, at least in part, within the translational community itself, which has failed to prioritize the steps required to approach the problem systematically. Most importantly, there is disproportionate emphasis on bench-to-bedside efforts, rather than confronting a priori the need to increase the understanding of human pathophysiology.

Human Genetics

Thus, therapeutic concepts based on experimental conditions that may not and indeed often do not represent the nature of human genetics lead to drug development that is not sufficiently applicable to the human condition. The damage is then amplified when these ill-fated concepts are tested in clinical trials at great cost. The use of surrogate biomarkers that could allow early assessment of efficacy currently requires long-term assessment of clinical benefit. Thus, therapeutic concepts based on experimental conditions that may not and indeed often do not represent the nature of human genetics lead to drug development that is not sufficiently applicable to the human condition. The damage is then amplified when these ill-fated concepts are tested in clinical trials at great cost. The use of surrogate biomarkers that could allow early assessment of efficacy currently requires long-term assessment of clinical benefit.

Translational Research

Translational medicine is the integrated application of innovative pharmacology tools, biomarkers, clinical methods,

clinical technologies and study designs to improve disease understanding, confidence in human drug targets and increase confidence in drug candidates, understand the therapeutic index in humans, enhance cost-effective decision making in exploratory development and increase phase II success. Translational research is one of the most important activities of translational medicine as it supports predictions about probable drug activities across species and is especially important when compounds with unprecedented drug targets are brought to humans for the first time. Translational research has the potential to deliver many practical benefits for patients and justify the extensive investments placed by the private and public sector in biomedical research. Translational research encompasses a complexity of scientific, financial, ethical, regulatory, legislative and practical hurdles that need to be addressed at several levels to make the process efficient. Several have resisted the idea of supporting translational research because of its high costs and the fear that it may re-direct funds from other biomedical disciplines. Resistance also comes from those more familiar with traditional clinical research methods. In this review, we argue that translational research should be seen as enabled by ongoing efforts in basic and clinical research and not competing with them. Translational research provides the knowledge necessary to draw important conclusions from clinical testing regarding disease and the viability of novel drug mechanisms. Advancing translational research requires education and new sources of funding. This could be achieved through public and congressional education by a joint coalition of patients' advocacy groups, academia, drug regulatory agencies and industry.