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# Early Assessment of Efficacy Currently Requires Long-Term Assessment of Clinical Benefit

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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-tobedside efforts, rather than confronting a priori the need to increase the understanding of human pathophysiology.

## **Biological Impact**

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.

It is generally accepted that reactive oxygen species (ROS) scavenging molecules or antioxidants exert health-promoting effects and thus their consumption as food additives and nutraceuticals has been greatly encouraged. Antioxidants may be beneficial in situations of subclinical deficiency and increased demand or acutely upon high-dose infusion. However, to date, there is little clinical evidence for the long-term benefit of most antioxidants. Alarmingly, recent evidence points even to health risks, in particular for supplements of lipophilic antioxidants. The biological impact of ROS depends not only on their quantities

but also on their chemical nature, (sub) cellular and tissue location, and the rates of their formation and degradation. Moreover, ROS serve important physiological functions; thus, inappropriate removal of ROS may cause paradoxical reductive stress and thereby induce or promote disease. There is also a lack of sufficient priority placed on learning from failure so as to avoid the costly and common trap of repeating the same mistakes. This is because insufficient rigor is used to design clinical studies that should be aimed not only at the most important goal of improved survival but also at learning from the likely failures of treatment.

## **Exploratory Development**

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 Advancing translational research requires mechanisms. education and new sources of funding. This could be achieved

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through public and congressional education by a joint coalition of patients' advocacy groups, academia, drug regulatory agencies and industry.