

Principles of Translational Science in Medicine: From Bench to Bedside



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Despite advancements in the cloning of the total human genome, biomedical innovations at the patient level are becoming rare events. However, translational medicine is a burgeoning science that shows the potential to reverse the trend. This textbook will comprise a state-of-the-art survey of translational medicine, with emphasis on its emerging scientific backbone, its strengths, and its weaknesses. It explores all aspects of preclinical and clinical issues that are relevant to the success of translational pharmaceutical or medical device or diagnostic innovations, including target risk assessment, biomarker evaluation, and predictivity grading for both efficacy and toxicity; early human trial designs that are adequate to guide stop or go decisions on the grounds of biomarker panels; and biostatistical methods to analyze multiple readout situations and quantify risk projections. The book provides guidance to design smart profiling strategies for new approaches aimed at cutting timelines and concentrating on the comparison of quality issues of early developmental processes for pharmaceutical and biotechnology research. By furthering the substantiation of translational medicine, creating awareness about its potential to promote innovations into clinical practice, and examining the terminology surrounding current biotechnologies, this book hopes to create a dialogue about translational science and what this will mean for patient care in the near future.

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