Genomic Biomarkers for Pharmaceutical Development: Chapter 1. Application of Translational Science to Clinical Development (Japan Annual Reviews in Electronics, Computers and Telecommunications)

Koustubh Ranade, Brandon W. Higgs, Ruth March, Lorin Roskos, Bahija Jallal, Yihong Yao

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Despite the large and ever-growing investment in pharmaceutical R&D, the number of innovative new medicines that meet significant unmet medical needs has been stagnant, if not declining. There are many potential reasons for this low return on pharmaceutical R&D investment, but one likely cause is the low probability of the success of clinical trials, particularly in early clinical development. Translational science, which we define as identifying the ‘right’ patient for the ‘right’ drug at the ‘right’ dose, promises to improve not only the odds of success of clinical development, but perhaps more importantly, to get the right drug to the right patient, thereby sparing those patients who may be less likely to benefit from a new therapeutic. We believe that this goal can be achieved by putting the patient first, i.e., by investing in understanding of disease heterogeneity at the molecular level, and then tailoring new therapeutics to subsets of patients. Using examples from the literature and our own experience, we describe current and emerging translational approaches that employ genomic and genetic methods in the areas of cancer, inflammation, and metabolic and infectious disease to this end. We use simple simulations to demonstrate how such translational strategies can significantly reduce the size of clinical trials or increase the likelihood of success of early phase trials. We end by discussing genomic approaches to understand adverse drug reactions.

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