The end of the beginning of personalized medicine

Soria and colleagues [1] have recently explained, thoroughly as usual, how the term ‘personalized medicine’ has become more than a ubiquitous refrain and they said that the expansion of targeted therapies will improve cancer survival if priorities of drug marketing converged with those of scientific research. This reading prompts us to speculate on the possible alternatives in drug approval process for targeted therapies without which it is impossible to achieve this dream. First, instead of RECIST-based response rate [2], a summary statistics such as incipient high survival rate could be sufficient for approval despite the paucity of the biomarker-positive patient subgroup. For instance, Fisher’s exact \textit{t}-test comparing the 6-month overall survival gain associated with the use of the targeted drug with respect to an expected literature-based survival rate in a hypothetical group of the same size and disease. Secondly, independent validation of biomarker tests should be paid by Public Health Systems. Lastly, to compensate for market shrinkage due to smallness of the biomarker-positive patient population, patent for personalized drugs should never expire [3]. In our opinion, such three points are profoundly intertwined. Since medicine is at crossroads, translational researchers and biostatisticians are to quicken this change.

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disclosure

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references


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