基因篩檢對抗癌新藥臨床試驗的影響

Impact of the Next-Generation Sequencing in Oncology Clinical Trials

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Genomic testing enables clinical management to be tailored to individual cancer patients based on the molecular alterations present within cancer cells. Genomic sequencing results can be applied to target therapies.
Next-generation sequencing has revolutionized the field of cancer genomics by enabling rapid and cost effective sequencing of large portions of the genome. Next-generation sequencing (NGS) influenced oncology clinical trials in many ways. First, NGS facilitated several tumor type-specific umbrella trials. For example, the National Lung Matrix Trial (NLMT) is a trial where patients with previously treated non-small cell lung cancer are assigned to personalized therapy based on the results of a 28-gene next-generation sequencing panel test. The Lung Cancer Master Protocol (Lung-MAP; S1400) is the first biomarker-driven master protocol initiated with the US National Cancer Institute and designed to address an unmet need for better therapies for squamous non-small-cell lung cancer. Second, it is unlikely complete clinical trials of the tumor type-agnostic targeted therapies (e.g. larotrectinib for fusion positive cancers) and immunotherapies (e.g. pembrolizumab for MSI-H or dMMR cancers) in a timely manner without applying NGS-based tumor molecular profiling. Third, clinical research centers developed multigene sequencing as a tool to screen patients eligible for clinical trials and to accelerate drug development. For example, a universal NGS-based tumor molecular profiling initiative at Memorial Sloan Kettering Cancer Center (MSK-IMPACT) was implemented for comprehensive genomic characterization of all patients with solid tumors who require systemic treatment. 11% were matched to genome-directed clinical trials.