Many drug developers have examined new strategies for creating efficiencies in their development processes, including the adoption of genomics-based approaches. Genomic data can identify new drug targets for both common and rare diseases, can predict which patients are likely to respond to a specific treatment, and has the potential to significantly reduce the cost of clinical trials by reducing the number of patients that must be enrolled in order to demonstrate safety and efficacy. A key component of the approval of targeted therapeutics is the ability to identify the population of patients who will benefit from treatment, and this has largely hinged on the co-development and co-submission to the FDA of a companion diagnostic test.The co-development process, or the development of the test and drug for the simultaneous submission to FDA, has led to a major alteration in the way that drugs are being developed, with traditionally separate entities-pharmaceutical and diagnostic companies-now working in close collaboration. Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests is the summary of a workshop held by the Roundtable on Translating Genomic-Based Research for Health on February 27, 2013 to examine and discuss challenges and potential solutions for the codevelopment of targeted therapeutics and companion molecular tests for the prediction of drug response. Prior to the workshop, key stakeholders, including laboratory and medical professional societies, were individually asked to provide possible solutions to resolve the concerns raised about co-development of companion diagnostic tests and therapies. Workshop speakers were charged with addressing these solutions in their presentations by providing insight on (1) whether the proposed solutions address the problems described, (2) whether there are other solutions to propose, and (3) what steps could be taken to effectively implement the proposed solutions.

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