Standardizing and harmonizing MRD assessment using ctDNA to enable clinical implementation to improve patient outcomes.

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Immunotherapy (IO) and IO combinations have revolutionized clinical outcomes and is a pillar in cancer care, with approvals for both metastatic and non-metastatic patients across multiple tumor types. Despite the benefits observed for non-metastatic patients receiving IO there is a desire to optimize the risk and benefit to maximize efficacy and minimizing adverse events. Utilizing biomarkers to identify patients who are at high risk of recurrence after surgery and need adjuvant treatment is an active area of research. Circulating tumor DNA (ctDNA) has emerged as a biomarker that could identify patients that are likely to recur and need adjuvant therapy. Clinical data across multiple indications demonstrates that patients that are positive for ctDNA have worse outcomes, clearly identifying patients that have a high unmet need. However, at present there are more than 10 different diagnostics that assess ctDNA and report on MRD, with different levels of analytical and clinical validation and limited global access. To implement prospective ctDNA assessment in interventional clinical trials testing new treatments, we need to understand and harmonize the technical, analytical, clinical, value and reimbursement. These efforts will be critical to clinical implementation and improved patient outcomes.