NOVEL RNA-SEQ PLATFORM IMPROVE PATIENT OUTCOME IN CLINICAL ONCOLOGY AND ENABLE IMPLEMENTATION OF AI IN THE CLINIC

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Background Only 1 out of 4 cancer treatments prolongs life while expenditure for cancer treatment is greater than \$100 billion/year. RNA-sequencing has allowed researchers to gain insight into the transcriptome of human cancers. However, RNA-sequencing remains widely unused in clinical oncology. We address this issue through the development and CLIA validation of OneRNA—an RNA-sequencing platform for cancer diagnostics and the design of new treatments. The development of OneRNA had to overcome the two main hurdles for implementation of RNA sequencing in the clinic: 1) clinical samples are typically embedded in FFPE which results in highly fragmented RNA making sequencing of these samples difficult. 2) how to interpret aberrant gene expression events and translate these results into clinical action. We demonstrate how OneRNA® would enable the design of sophisticated combinatorial clinical studies. An example is combining immune targeting agents such as checkpoint inhibitors with mRNA vaccines. OneRNA also supports the integration of gene expression algorithms because of its ability to interrogate the entire sample transcriptome. OneRNA® has been CLIA certified using FFPE, FF, blood, and saliva samples. Furthermore, the sample preparation method has demonstrated >95% concordance between FF and FFPE and 5–10X the sensitivity compared to Truseq.

Methods This study aims to demonstrate the clinical utility of OneRNA in detecting aberrant gene expression events and connecting these to already approved drugs that targets these events to offer truly individualized treatment options.

Results We show that OneRNA has the ability to predict results for not only validated biomarkers used in standard of care such as ER, PR and HER2 in breast cancer, but also provide insight into biomarkers for response to already approved drugs independent of tissue type and with no standard test. Finally, we demonstrate the reproducibility of OneRNA in predicting IHC status in ER, PR and HER2.

Conclusions These results demonstrate that OneRNA has applications in both cancer research, drug discovery and development, development of companion diagnostic algorithms and implementation of truly individualized treatment.

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