**Simsen personal – a personalized, tumor-guided sequencing platform for ultrasensitive ctdna detection in clinical trials**

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**Abstract**

Background

Detecting extremely rare variant alleles is increasingly recognized as a crucial biomarker in clinical trials for treatment response monitoring, minimal residual disease (MRD) detection, and patient stratification. However, the detection of rare circulating tumor DNA fragments (ctDNA) is challenged by low numbers of mutant DNA molecules and difficult sample types.

Objective

To develop a highly sensitive and specific method for detecting rare ctDNA mutations using personalized sequencing assays tailored to each patient's unique tumor mutational profile.

Methods

Simsen Personal employs a highly optimized workflow to create tumor-guided, personalized, ultrasensitive sequencing assays for ctDNA detection. This includes advanced in silico assay design using SiMSen-seq technology, optimized reaction chemistry, and a machine-learning enhanced variant calling algorithm. The flexibility of SiMSen-Seq assays enables rapid custom panel development, combining ultrasensitive personalized ctDNA monitoring optimized for MRD with bespoke sequence content, such as actionable and resistance variants.

Results

The enhancements significantly increase the dynamic range and sensitivity for detecting rare mutations and recovering target molecules. The high sensitivity and specificity of Simsen Personal were demonstrated using both reference materials and human plasma samples. Additionally, real-world data from clinical trials showed that Simsen Personal enables ultrasensitive ctDNA detection.

Conclusion

Simsen Personal, a tumor-informed, personalized sequencing platform, enables highly specific and sensitive ctDNA detection, far surpassing standard sequencing approaches.

**Do you have any conflicts of interest?**

Yes, I have a conflict of interest.

Company employment