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Abstract #545848

SPOT-MAS Multi - cancer early detection

K-ACCELERATE: A Multicenter Prospective Trial Evaluating the Utility of a ctDNA-Based Assay for Accelerating Multi-Cancer Diagnosis in High-Risk Symptomatic Participants

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Background

- In low- and middle-income countries, cancers are often diagnosed only after symptom onset.
- Non-specific symptoms can complicate referral decisions, causing diagnosis delays and unnecessary investigations.
- We previously developed SPOT-MAS, a multi-cancer early detection test integrating epigenetic, genetic, and fragmentomic features of circulating tumor DNA (ctDNA).
- Here, we report K-ACCELERATE (NCT06391749), a prospective multicenter study evaluating SPOT-MAS as a cancer triage tool for symptomatic individuals.

Methods

- Adults with symptoms suggestive of colorectal, gastric, breast, liver, or lung cancer were prospectively recruited from 13 hospitals in Vietnam and assigned to symptom-based diagnostic pathways (Figure 1).
- SPOT-MAS testing was performed alongside standard-of-care diagnostics, with final diagnosis confirmed by imaging and/or biopsy and up to 12 months of follow-up.
- Among 972 eligible symptomatic participants, 862 completed diagnostic resolution and follow-up as of the January 2026 data cutoff.

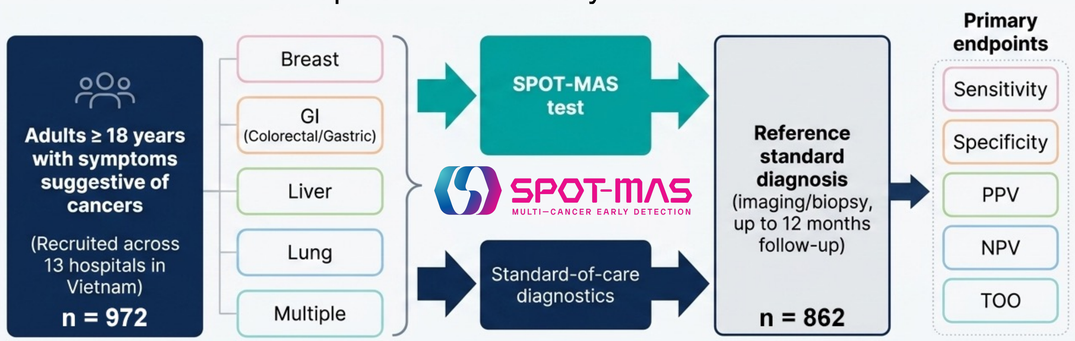
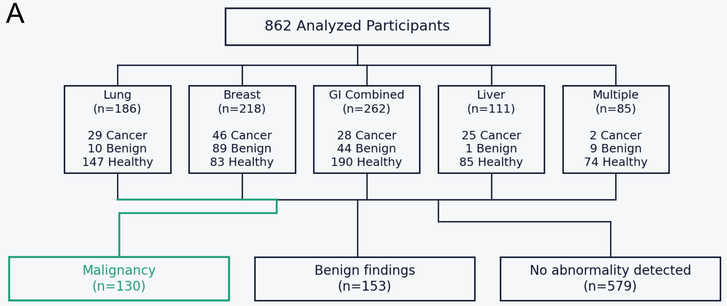


Figure 1. K-ACCELERATE study design and workflow

Results



B **Overall Diagnostic Performance**

65.4% Sensitivity (85/130)	**92.1%** Specificity (674/732)
59.4% PPV (85/143)	**93.7%** NPV (674/719)

	Lung	Breast	GI	Liver	Multiple
Sensitivity	62.1%	58.7%	64.3%	80.0%	100.0%
Specificity	91.7%	90.7%	92.3%	90.7%	96.4%
PPV	58.1%	62.8%	50.0%	71.4%	40.0%
NPV	92.9%	89.1%	95.6%	94.0%	100.0%

Figure 2. K-ACCELERATE: (A) participants distribution and (B) SPOT-MAS diagnostic performance across symptomatic cancer pathways

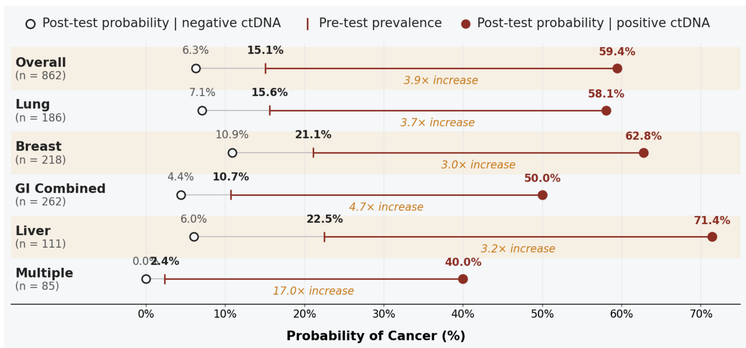


Figure 3. Shift in Cancer Risk Probability After ctDNA Testing, Stratified by Diagnostic Pathway

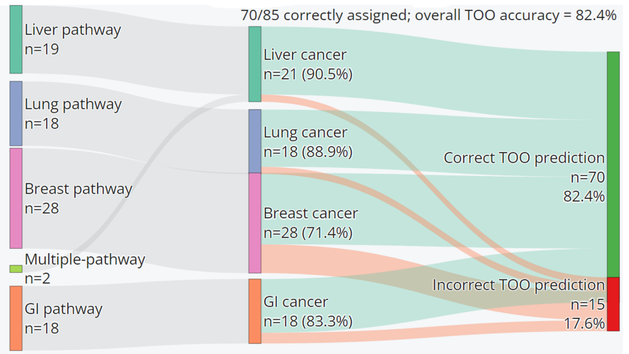


Figure 4. Tissue-of-Origin (TOO) Prediction Performance of SPOT-MAS

- ctDNA-based tissue-of-origin prediction achieved 82.4% accuracy.
- ctDNA-guided triage increased PPV from 15.1% to 59.4%, a nearly four-fold improvement, while maintaining high NPV (93.7%).

Conclusion

SPOT-MAS demonstrates clinical utility as a non-invasive auxiliary diagnostic tool for individuals presenting with cancer-related symptoms in low-resource settings.

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