Natera's GALAXY Study: ctDNA Status Predicts CRC Outcomes

Natera's GALAXY study demonstrates circulating tumor DNA (ctDNA) status accurately predicts colorectal cancer recurrence risk and therapy response. The interim analysis, published in Nature Medicine, shows promising results for ctDNA-guided treatment decisions.

This Video Will Cover:

1. Study Design
2. MRD Window
3. Overall Survival Rates
4. Surveillance Window
5. Prognostic Factors

Study Design and Participants

1

Patient Cohort

2,240 individuals with stage II to IV or relapsed CRC following curative intent surgery.

2

Testing Method

Natera's Signatera ctDNA-based minimal residual disease (MRD) test used for evaluation.

3

Follow-up Period

Median follow-up period of 23 months.

MRD Window Analysis Results

Signatera-Positive

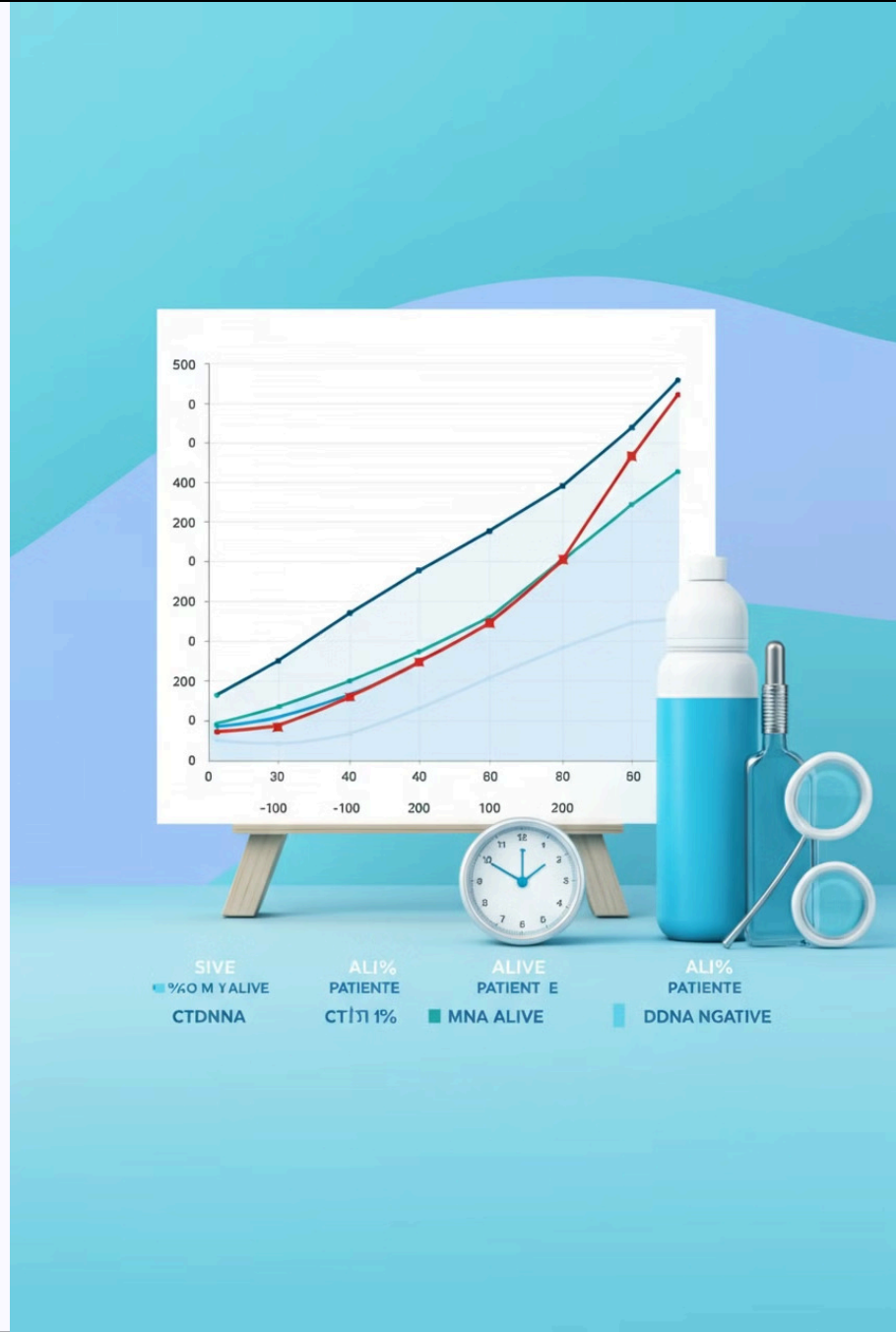
15.6% of patients positive. 78% experienced recurrence. 24-month DFS: 20%. 36-month DFS: 17%.

Signatera-Negative

84.4% of patients negative. 13% experienced recurrence. 24-month DFS: 85%. 36-month DFS: 84%.

Overall Survival Rates

Time Point	Signatera-Positive	Signatera-Negative
24 months	84%	99%
36 months	72%	96%



Surveillance Window Analysis

1 Patient Inclusion

1,791 patients for DFS analysis, 1,794 for OS analysis.

2 Recurrence Risk

Signatera-positive patients 34 times more likely to experience recurrence.

3 24-Month Outcomes

DFS: 9% for Signatera-positive vs 93% for Signatera-negative. OS: 83% vs 99%.

Prognostic Factors

ctDNA Status

Strongest prognostic factor for DFS and OS in multivariate analysis.

Genetic Mutations

BRAF V600E and RAS mutations associated with poor DFS and OS.

Lymph Node Status

Lymph node positivity prognostic of poor DFS and OS.

Clinical Implications

MRD-Negative Patients

Observation alone may be sufficient for positive outcomes.

MRD-Positive Patients

May benefit from adjuvant chemotherapy.

Treatment Guidance

ctDNA status could direct appropriate chemotherapy and monitor response.

Future Directions

1

Randomized Trials

Needed to confirm de-escalation or omission of chemotherapy in ctDNA-negative patients.

2

CIRCULATE-Japan Vega Protocol

Randomizing ctDNA-negative patients to adjuvant chemotherapy or observation only.

3

Drug Approval Endpoints

Potential for ctDNA as a surrogate endpoint in drug approval trials.