Burning Rock Biotech Limited

4Q 2025 results

12 March 2026

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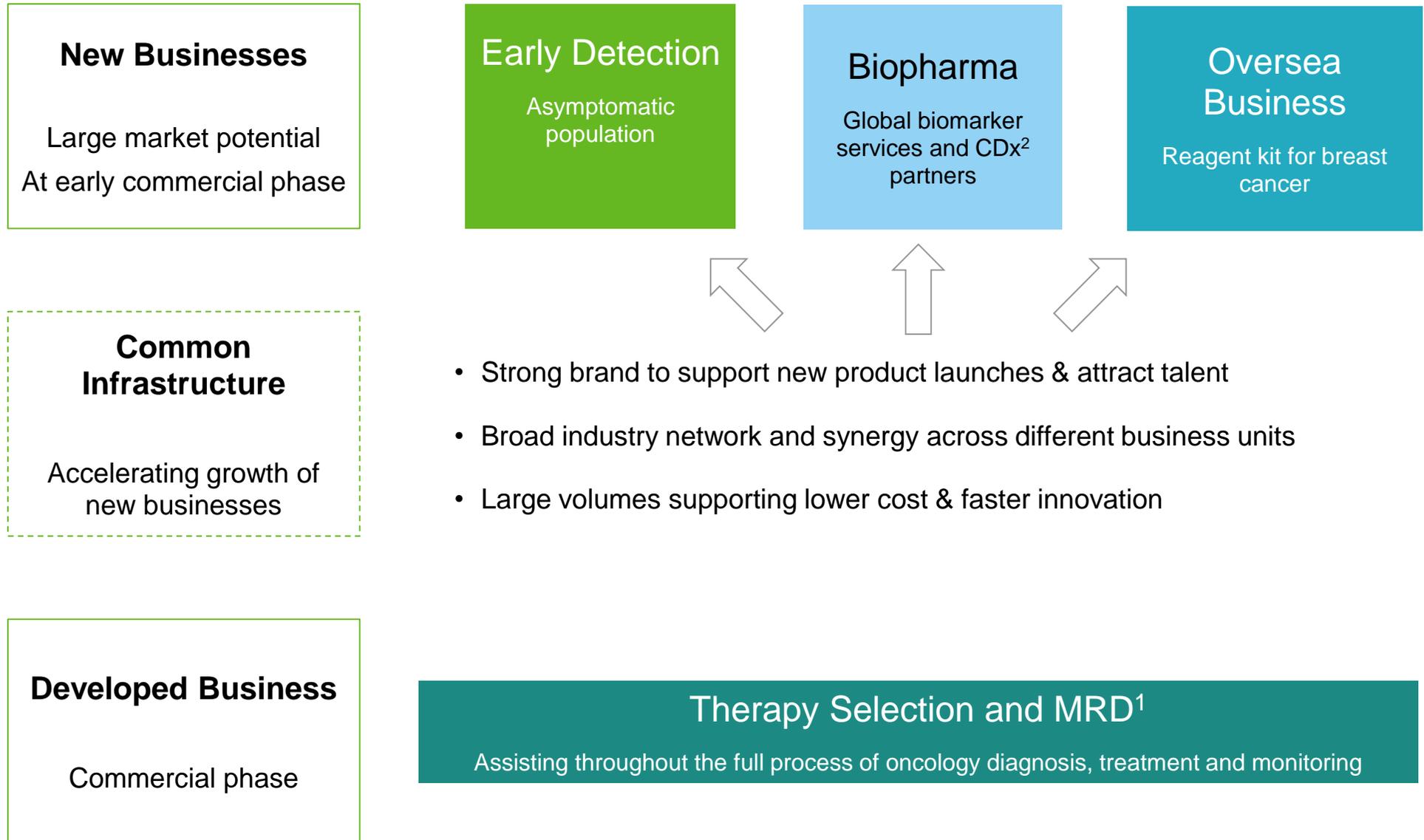
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Our value-building blocks

Extending leadership in NGS-based precision oncology from late-stage to earlier stage patients

New Businesses

Large market potential

At early commercial phase

Early Detection

Asymptomatic population

Biopharma

Global biomarker services and CDx[2] partners

Oversea Business

Reagent kit for breast cancer

Common Infrastructure

Accelerating growth of new businesses

- Strong brand to support new product launches & attract talent

- Broad industry network and synergy across different business units

- Large volumes supporting lower cost & faster innovation

Developed Business

Commercial phase

Therapy Selection and MRD[1]

Assisting throughout the full process of oncology diagnosis, treatment and monitoring

3

Notes:
[1] Minimal residual disease of solid tumors
[2] Companion diagnostics

Recent regulatory and academic progress

Therapy selection and MRD

- Presented study results at *Annals of Surgery* in December 2025. "ctDNA-based MRD detected by CanCatch® Custom associates with recurrence in CRC. Day 7 is an effective alternative landmark to Day 30 for MRD assessment and CanCatch® Custom outperforms TIFP and TNFP in the association of DFS. "

- OncoScreen® BCMatch Tissue Kit has officially entered the Priority Review Channel of the Center for Medical Device Evaluation (CMDE) under the NMPA.

- Published validation data of a novel method that integrated genomic and epigenomic profiling in the same DNA molecules (SPIRAL) on 2025 AMP (November 2025)

Early detection

- The core patent related to Burning Rock's proprietary ultrasensitive detection technology, ELSA-seq (Patent No.: US 12460202 B2), has officially been granted by the United States Patent and Trademark Office (USPTO).

Recent Operating progress
Continued efficiency gains, driving towards profitability

1 **Decreasing cash outflow**

- Positive operating cash flow in 4Q25 (23.0 RMB million)

- Significant decrease in cash outflow of FY25 (vs prior periods' negative trends)

2 **Increasing revenues from biopharma**

- Overseas revenues remained stable vs FY24

- Pharma revenues +34% vs FY24 (backed by >200 biopharma partnerships)

3 **Driving operating efficiency**

- Gross profit margin: 78% in 4Q25, +7% YoY, reflecting optimized product mix and cost control

- Significant improvement in net loss, adjusted EBITDA achieved profitability (4Q25: 0.4 RMB million, vs 4Q24's (23.7) RMB million)

4 **Reducing operating expenses**

- Total opex: -35% YoY in 4Q25, with R&D (-33% YoY), S&M (-6% YoY), and G&A (-15% YoY) all seeing disciplined cuts

- Cutting overhead, improving sales efficiency, and maintaining disciplined R&D investment

## 1 Cash Flow

Positive operating cash flow in 4Q25

RMB millions	25Q4	24Q4	FY25	FY24
Operating cash inflow (outflow)[1]	23.0	19.1	(28.4)	(92.3)
Capex[2]	(1.0)	(0.7)	(5.2)	(6.0)
Sum	**22.0**	**18.4**	**(33.6)**	**(98.3)**
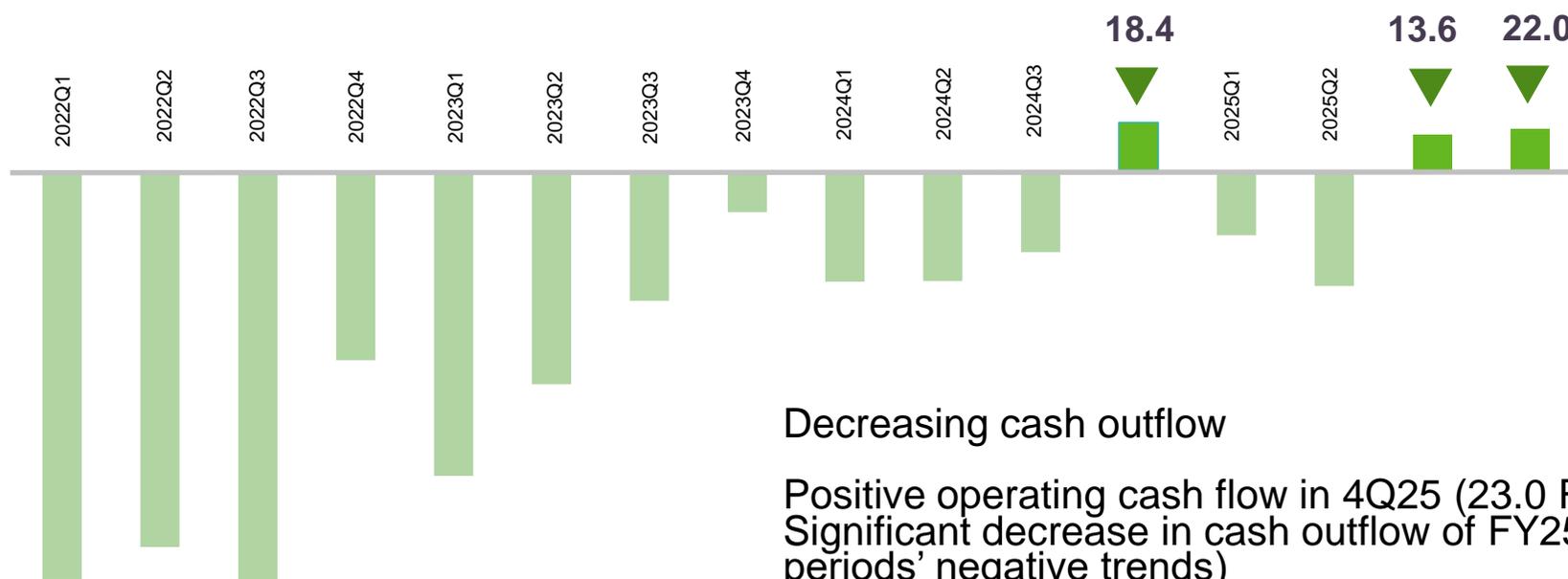
Decreasing cash outflow

Positive operating cash flow in 4Q25 (23.0 RMB million)
Significant decrease in cash outflow of FY25 (vs prior periods' negative trends)

② Revenues by contracting client's location

RMB millions	25Q4	24Q4	YoY	FY25	FY24	YoY
Revenues from overseas	21.8	40.5	-46%	100.9	100.0	1%
Revenues from mainland China	104.5	85.5	22%	438.7	415.8	6%
Total revenues	**126.3**	**126.0**	**0%**	**539.6**	**515.8**	**5%**
Total gross profit margin	**78%**	**71%**	**7%**	**75%**	**70%**	**5%**

19%

FY24

19%
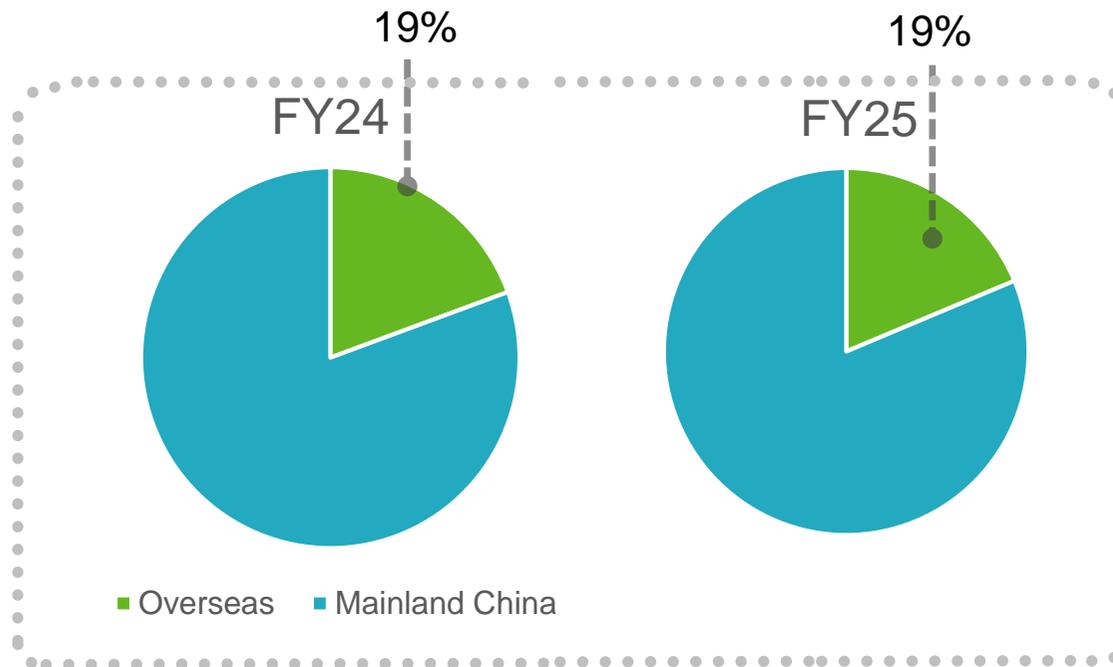
FY25

Overseas revenue remaining stable as 19% for FY25

■ Overseas ■ Mainland China

2 Revenues by channel

RMB millions	25Q4	24Q4	YoY	FY25	FY24	YoY
Revenues from central lab	44.0	39.3	12%	160.0	175.6	-9%
Revenues from in-hospital	51.0	43.4	18%	224.0	224.5	0%
Revenues from pharma R&D	31.3	43.3	-28%	155.6	115.7	34%
Total revenues	**126.3**	**126.0**	**0%**	**539.6**	**515.8**	**5%**
Total gross profit margin	**78%**	**71%**	**7%**	**75%**	**70%**	**5%**

FY24

FY25

% of revenue

% of revenue

34% 44% 22%

29% 41% 30%

■ Central lab ■ In-hospital ■ Pharma R&D
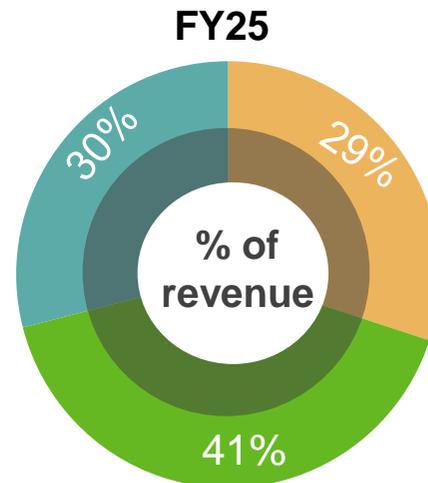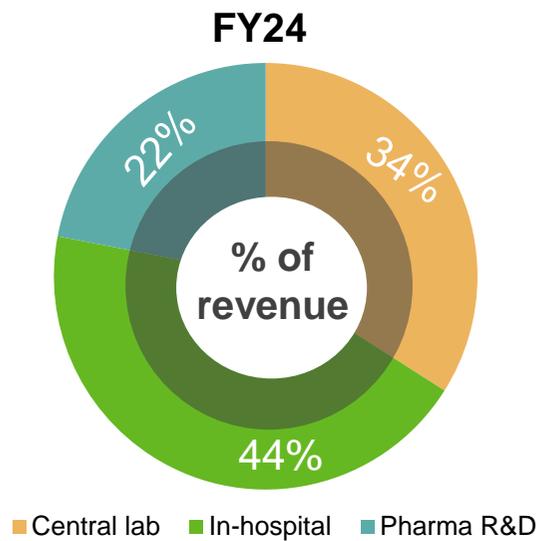
Increasing proportion of revenues from pharma R&D: 22% in FY24 to 30% in FY25

3 Adjusted EBITDA* executing on track towards breakeven

RMB millions	25Q4	24Q4	YoY	FY25	FY24	YoY
Gross profit	98.6	89.4	10%	402.9	362.4	11%
Operating expenses	(110.6)	(171.3)	-35%	(457.8)	(720.0)	-36%
Net loss	**(15.4)**	**(81.3)**	**-81%**	**(55.3)**	**(346.6)**	**-84%**
EBITDA (Non-GAAP)	(10.9)	(69.2)	-84%	(40.2)	(302.6)	-87%
Adjusted EBITDA (Non-GAAP)	**0.4**	**(23.7)**	**-101%**	**(8.8)**	**(101.3)**	**-91%**

Significant improvement in net loss, adjusted EBITDA achieved profitability in 25Q4
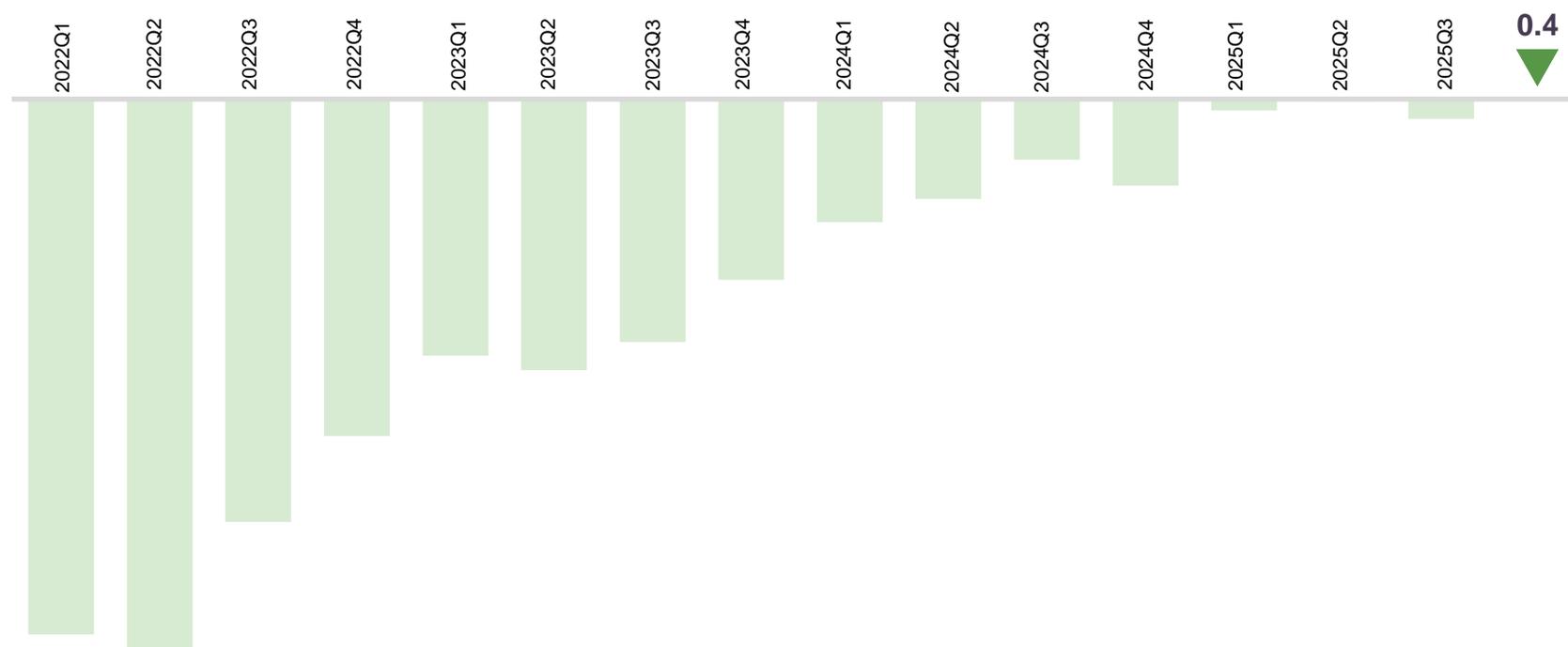
Notes:
*Defined as EBITDA adjusted to exclude impairment of accounts receivables and contract assets, impairment of long-lived assets and share-based compensation.

Reducing operating expenses

Expect cost savings going forward

% of revenues	25Q4	24Q4	YoY	FY25	FY24	YoY
R&D expense	28%	41%	-13%	31%	45%	-14%
S&M expense	35%	37%	-2%	31%	37%	-6%
G&A expense	25%	30%	-5%	23%	51%	-28%
Total expense	**88%**	**108%**	**-20%**	**85%**	**133%**	**-48%**

Driven by budget control measures, improving sales efficiency and disciplined investment of R&D, operating expenses had decreased significantly
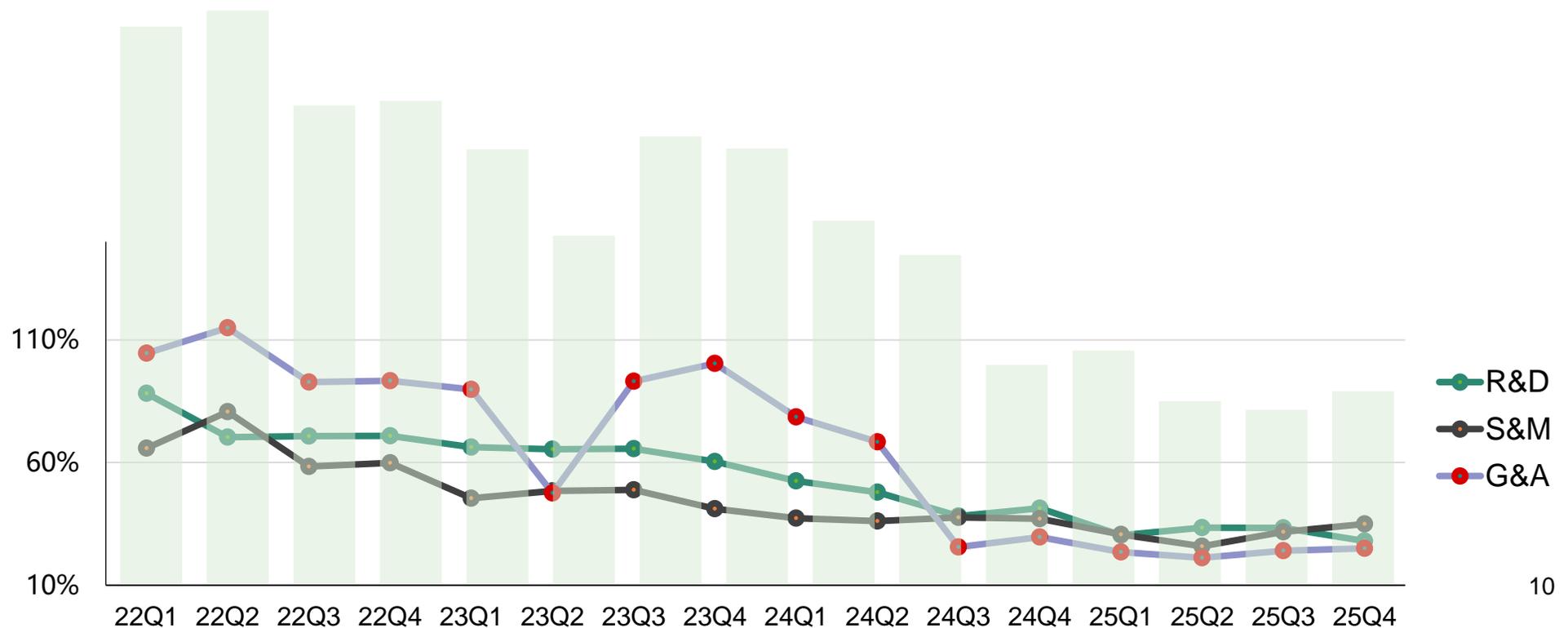
Financials
Steady progress of improving margins, profitability and reducing cash outflows

RMB millions	4Q25	3Q25	2Q25	1Q25	4Q25 YoY	4Q25 QoQ	4Q24	3Q24	2Q24	1Q24	2024	2025	FY25 YoY
Revenues	**126.3**	**131.6**	**148.6**	**133.1**	*0%*	*-4%*	**126.0**	**128.7**	**135.6**	**125.6**	**515.8**	**539.6**	*5%*
Central lab	44.0	36.8	40.9	38.3	12%	20%	39.3	40.0	48.8	47.6	175.6	160.0	-9%
In-hospital[1]	51.0	52.8	62.5	57.7	18%	-3%	43.4	63.8	59.9	57.4	224.5	224.0	0%
Pharma	31.3	42.0	45.2	37.1	-28%	-25%	43.3	24.9	26.9	20.6	115.7	155.6	34%
Gross profit	**98.6**	**98.8**	**108.1**	**97.4**	*10%*	*0%*	**89.4**	**91.8**	**95.4**	**85.7**	**362.4**	**402.9**	*11%*
Total opex	**110.6**	**115.0**	**119.6**	**112.6**	*-35%*	*-4%*	**171.3**	**130.5**	**206.7**	**211.6**	**720.0**	**457.8**	*-36%*
R&D[2]	34.2	40.3	48.9	38.0	-28%	-15%	47.6	43.7	50.8	49.0	191.1	161.4	-16%
S&M[2]	42.3	40.0	36.8	38.7	-2%	6%	43.2	44.2	45.3	43.7	176.4	157.8	-11%
G&A[2]	29.1	28.2	28.6	29.1	-13%	3%	33.5	28.4	37.9	37.5	137.3	115.0	-16%
SBC	2.8	3.5	2.1	4.2			7.5	9.8	67.6	68.8	153.7	12.6	
D&A	2.2	3.0	3.2	2.6			4.4	4.4	5.1	12.6	26.5	11.0	
Impairment	-	-	-	-			35.1	-	-	-	35.1	-	
Adjusted EBITDA[3]	**0.4**	**(5.4)**	**(0.6)**	**(3.1)**			**(23.7)**	**(16.6)**	**(27.3)**	**(33.7)**	**(101.3)**	**(8.8)**	
Operating profit	**(12.0)**	**(16.1)**	**(11.5)**	**(15.2)**			**(81.9)**	**(38.6)**	**(111.2)**	**(125.8)**	**(357.5)**	**(54.8)**	
Net operating cash flows	**23.0**	**16.4**	**(44.3)**	**(23.5)**			**19.1**	**(30.3)**	**(40.8)**	**(40.2)**	**(92.3)**	**(28.4)**	
Gross profit margin	78%	75%	73%	73%			71%	71%	70%	68%	70%	75%	

Notes:
[1] Within in-hospital segment, over 95% revenues are kit revenues, which are recurring in nature; the remaining are instrument revenues. In-hospital primarily through direct-sales model
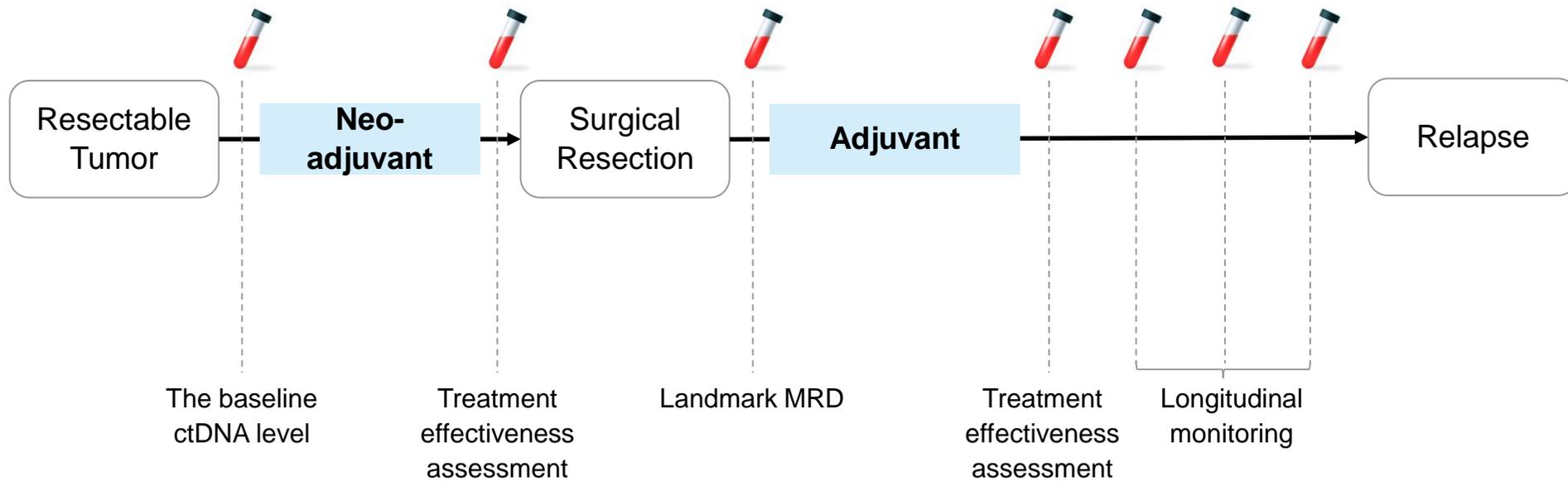[2] Excluding share based compensation (SBC) and depreciation and amortization (D&A)
[3] Defined as net income (loss) adjusted to exclude interest income (expense), income tax expense, depreciation and amortization, impairment of accounts receivables and contract assets, impairment of long-lived assets and share-based compensation.

Minimal Residual Disease (MRD)

Burning Rock's MRD clinical publications
Covering adjuvant and relapse settings in lung, colorectal, gastric and other cancers

| Resectable Tumor | → | **Neo-adjuvant** | → | Surgical Resection | **Adjuvant** | → | Relapse |

The baseline ctDNA level · Treatment effectiveness assessment · Landmark MRD · Treatment effectiveness assessment · Longitudinal monitoring

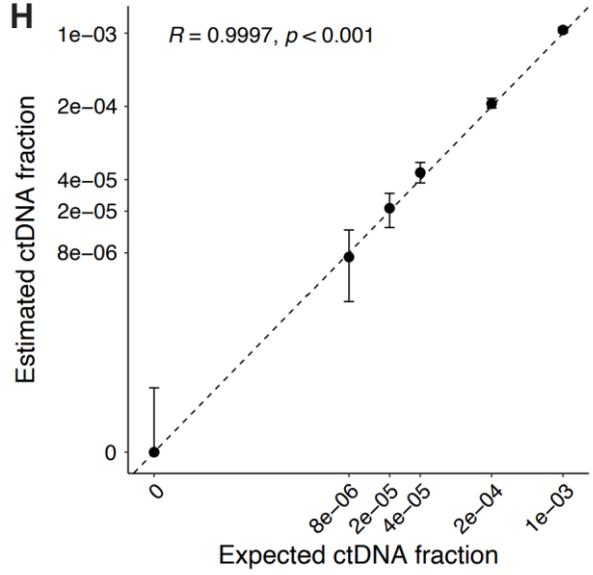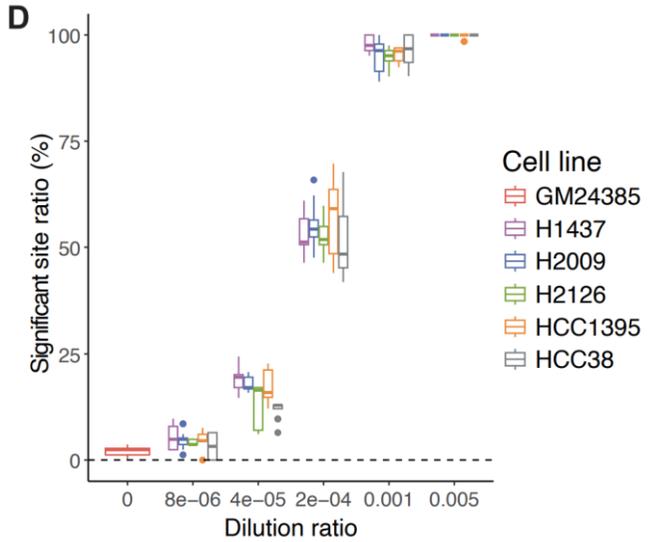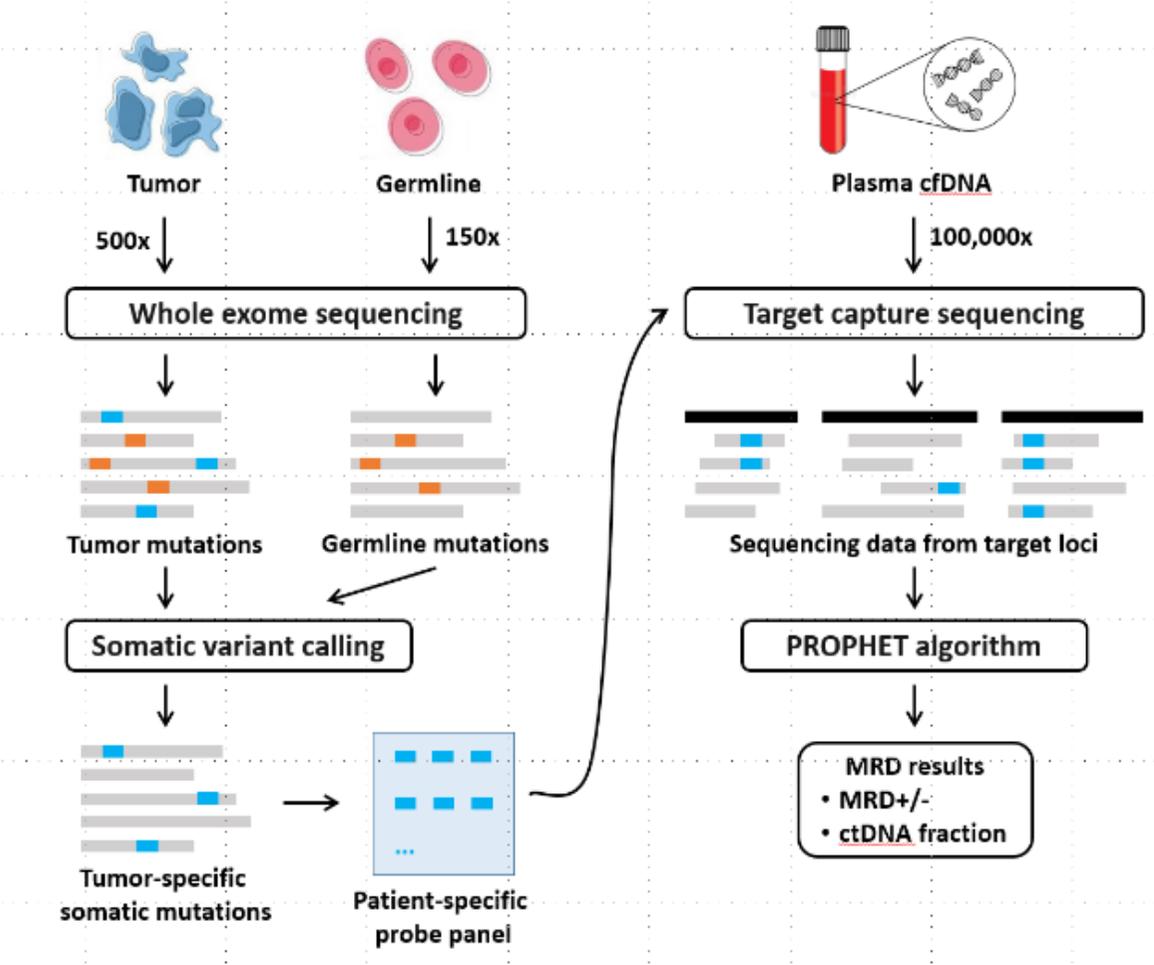| Cancer type	Publications	
Non-small-cell lung cancer	Baseline, landmark and longitudinal monitoring timepoints completed AACR 2022 Abstract 5916, AACR 2023 Abstract 1039, MEDAL study publication	**Cancer Cell**
Colorectal cancer	Baseline, landmark timepoints and longitudinal monitoring AACR 2022 Abstract 5917, ASCO GI 2023 Abstract 213, PRECARE study publication	**ANNALS OF SURGERY**
Esophageal cancer	Baseline, post-neoadjuvant therapy, landmark and longitudinal monitoring timepoints completed preSINO study publication	**Cell Reports Medicine**
Gastric cancer	Baseline and landmark timepoints AACR 2023 Abstract 6682	
Pancreatic cancer	Baseline, landmark and longitudinal monitoring timepoints completed ASCO GI 2023 Abstract 744	
Biliary tract cancer	Baseline and landmark timepoints AACR 2023 Abstract 6682	

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Overview of CanCatch® Custom (Previously named brPROPHET)
An ultrasensitive and quantitative MRD assay

Article

Cancer Cell

Individualized tumor-informed circulating tumor DNA analysis for postoperative monitoring of non-small cell lung cancer
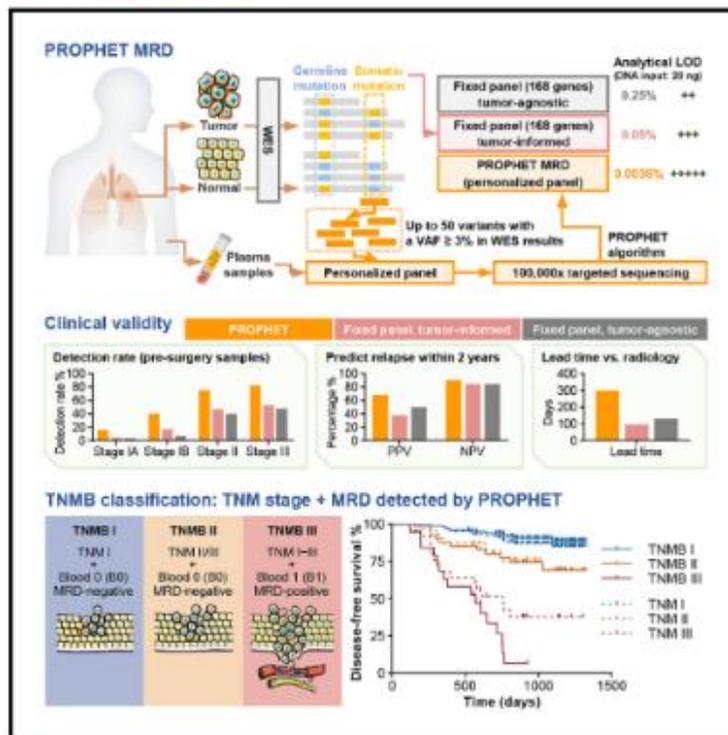
Graphical abstract

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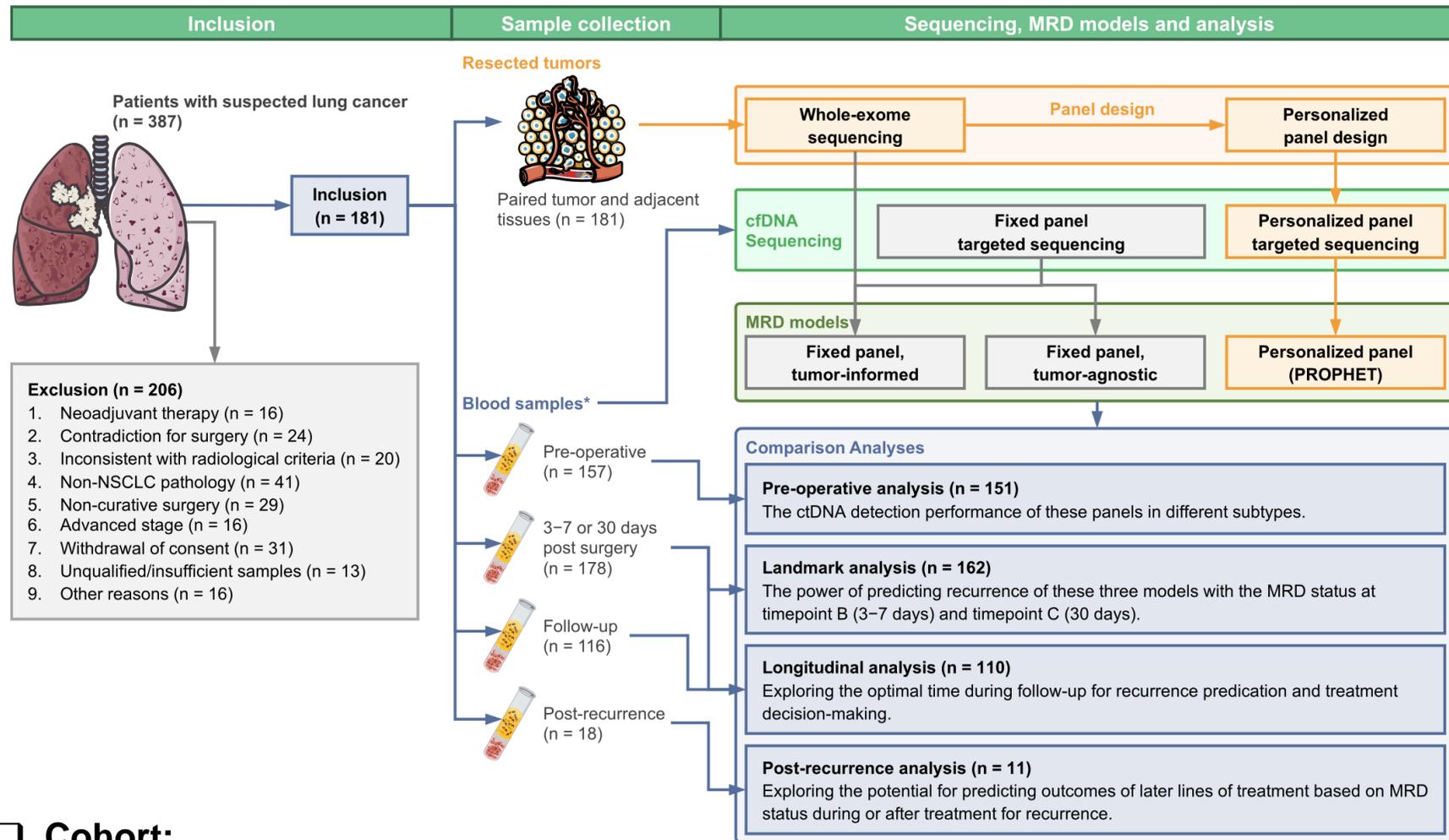
In brief

Chen et al. introduced personalized Patient-specific pROgnostic and Potential tHErapeutic marker Tracking (PROPHET) for detecting molecular residual disease (MRD) in NSCLC, featuring a notably low limit of detection (LOD). It exhibits elevated sensitivity and extended lead time than radiologically confirmed recurrence. It also facilitates prognostic accuracy and postoperative treatment evaluation.

Highlights

- PROPHET outperforms fixed-panel MRD assays in head-to-head comparison in NSCLC
- TNMB stage, integrating landmark ctDNA MRD and TNM, improves prognosis prediction
- PROPHET illustrates a median lead time of 299 days to radiological recurrence
- Post-relapse ctDNA status facilitates decision on later lines of treatment

Chen et al., 2023, Cancer Cell 41, 1–14
October 9, 2023 © 2023 Published by Elsevier Inc.
https://doi.org/10.1016/j.ccell.2023.08.010

Source: Chen et al., Individualized tumor-informed circulating tumor DNA analysis for postoperative monitoring of non-small cell lung cancer, Cancer Cell, Sep 2023

Study design

☐ **Cohort:**
  ▪ 181 patients enrolled Stage I (63%), II (19%), and III (18%)
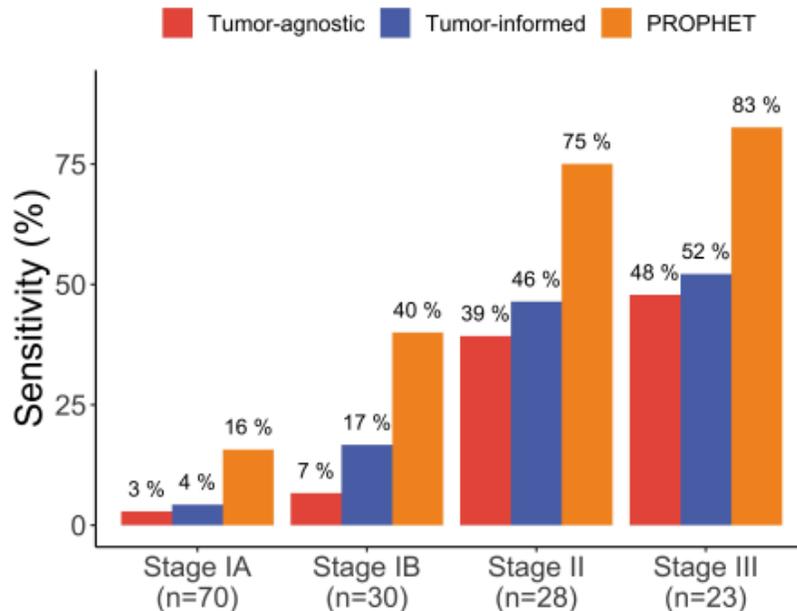☐ **Sampling Time:**
  ▪ Tumor and adjacent paired tissue collected at surgery
  ▪ Blood samples collected at Pre-operative, 3 days, and 30 days post-surgery
  ▪ Median Follow-up Time: 30 months

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CanCatch® Custom demonstrates superior sensitivity in ctDNA detection

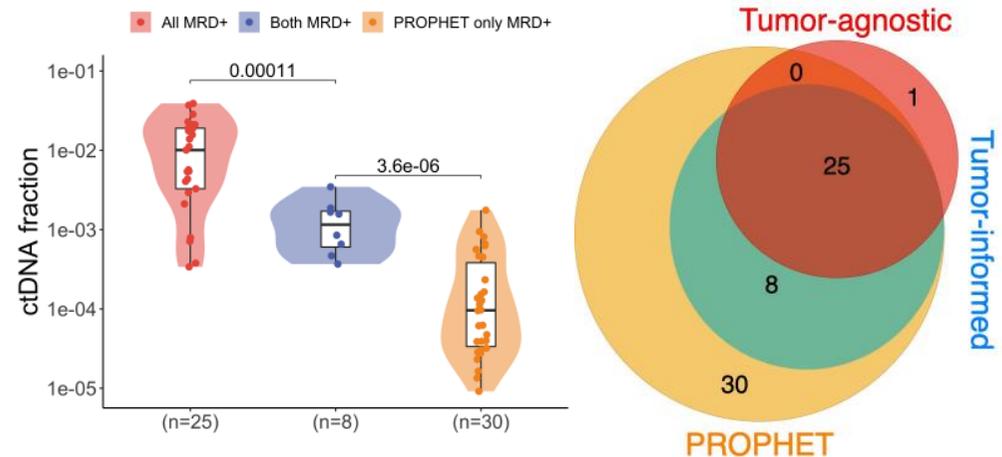## Clinical validation with pre-operative plasma samples

(a) Sensitivity of pre-operative plasma

(b) ctDNA fraction distribution of MRD (+) samples detected by different methods

- For pre-operative plasma from patients with different clinical stages, CanCatch® Custom has a higher sensitivity than the other two methods
- The median ctDNA fraction of the 30 patients detected by CanCatch® Custom alone was significantly lower than the 25 patients detected by all three MRD assays

The patient-specific CanCatch® Custom has a higher sensitivity than the two fixed panel detection methods

CanCatch® shows strong prognostic value in post-surgery NSCLC patients
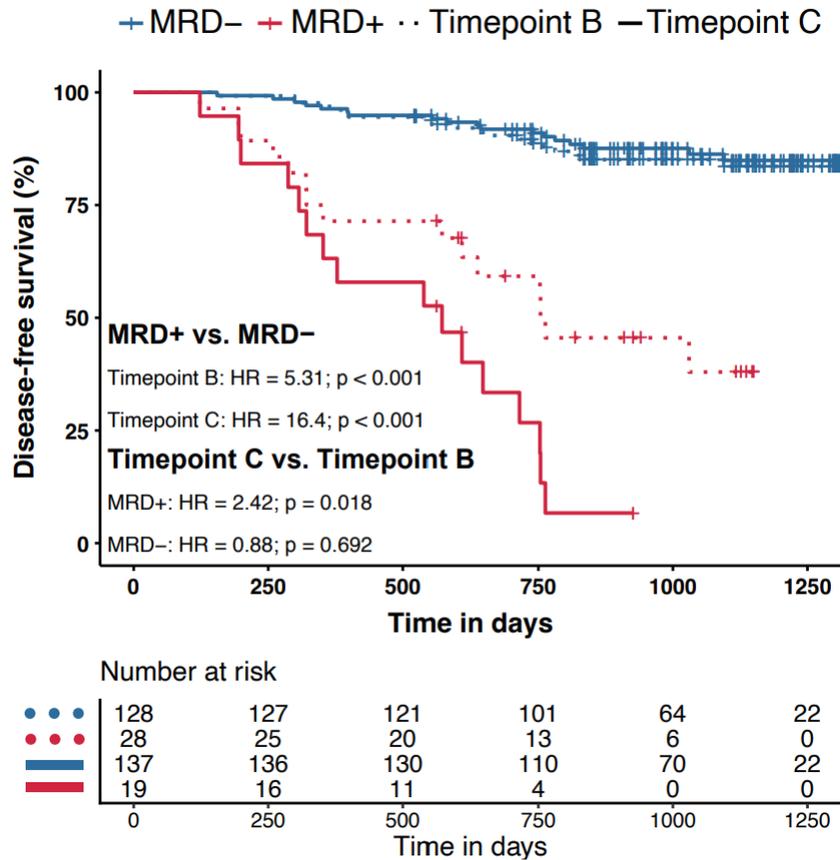
Prognostic analysis at Landmark time points
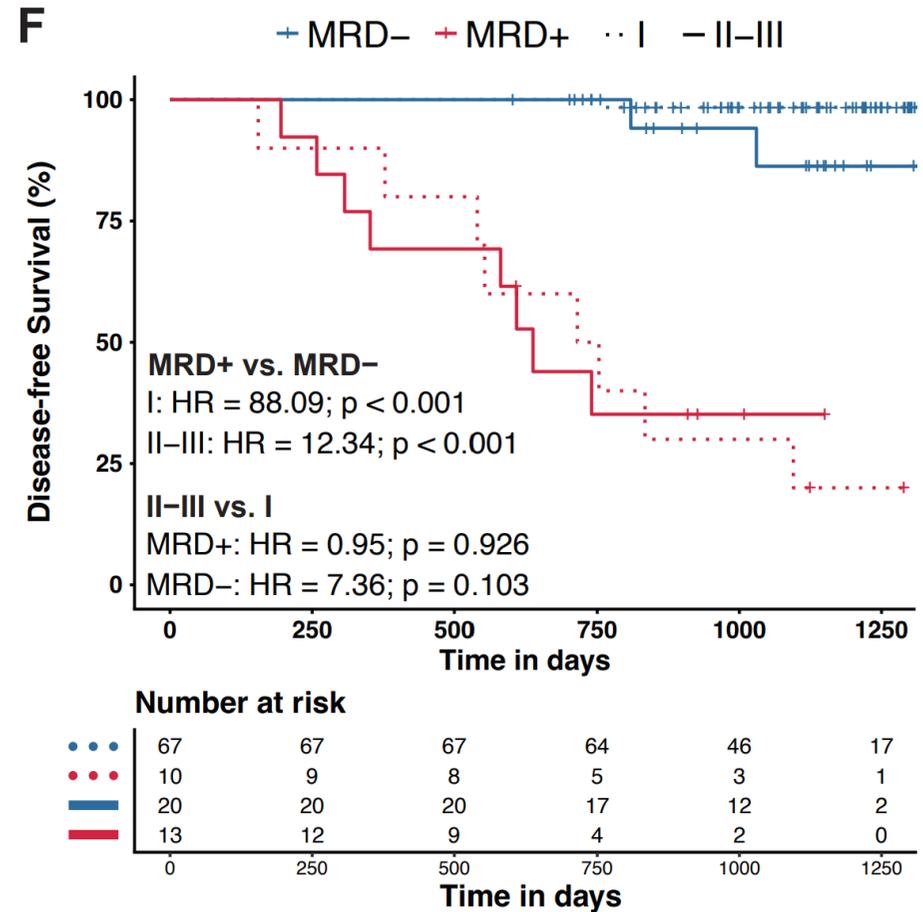
Longitudinal MRD analysis

Source: Liu et al. ctDNA detects residual disease after neoadjuvant chemoradiotherapy and guides adjuvant therapy in esophageal squamous cell carcinoma. Cell Rep Med. 2025.

Study design

Source: Liu et al. ctDNA detects residual disease after neoadjuvant chemoradiotherapy and guides adjuvant therapy in esophageal squamous cell carcinoma. Cell Rep Med. 2025.

CanCatch® Custom demonstrates superior sensitivity in ctDNA detection

- For baseline (before neoadjuvant therapy) plasma from patients with different clinical stages, CanCatch® Custom has a higher sensitivity than the other two methods
- The median ctDNA fraction of the 9 patients detected by CanCatch® Custom alone was significantly lower than the 76 patients detected by all three MRD assays

The patient-specific CanCatch® Custom has a higher sensitivity than the two fixed panel detection methods

CanCatch® can predict residual disease after neoadjuvant therapy in esophageal cancer
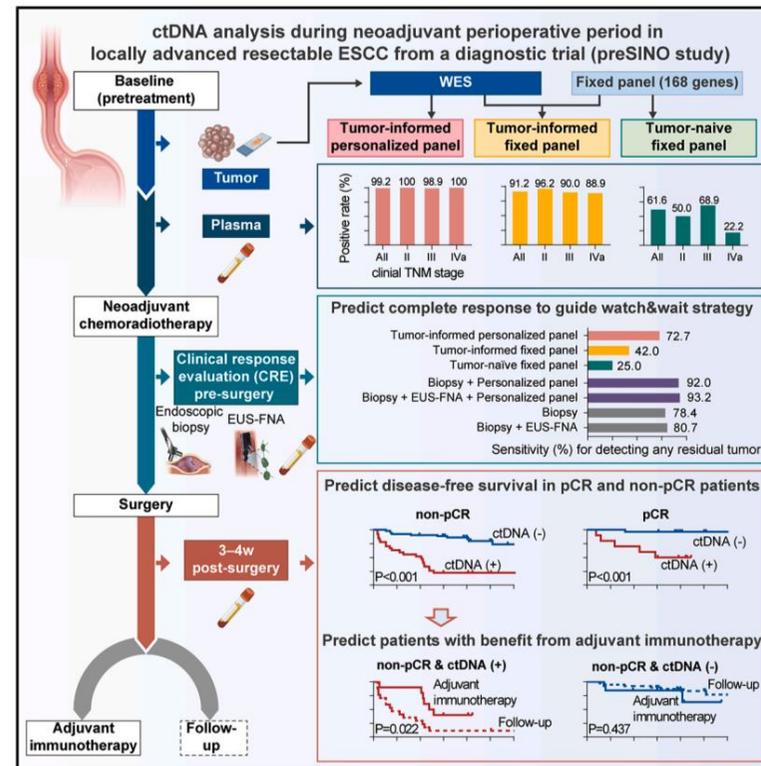
- CanCatch® Custom deceases the false negative rate of predicting residual disease by 11.3%-13.6% when combined with clinical response evaluation (biopsy or biopsy+fine needle aspiration)

Source: Liu et al. ctDNA detects residual disease after neoadjuvant chemoradiotherapy and guides adjuvant therapy in esophageal squamous cell carcinoma. Cell Rep Med. 2025.
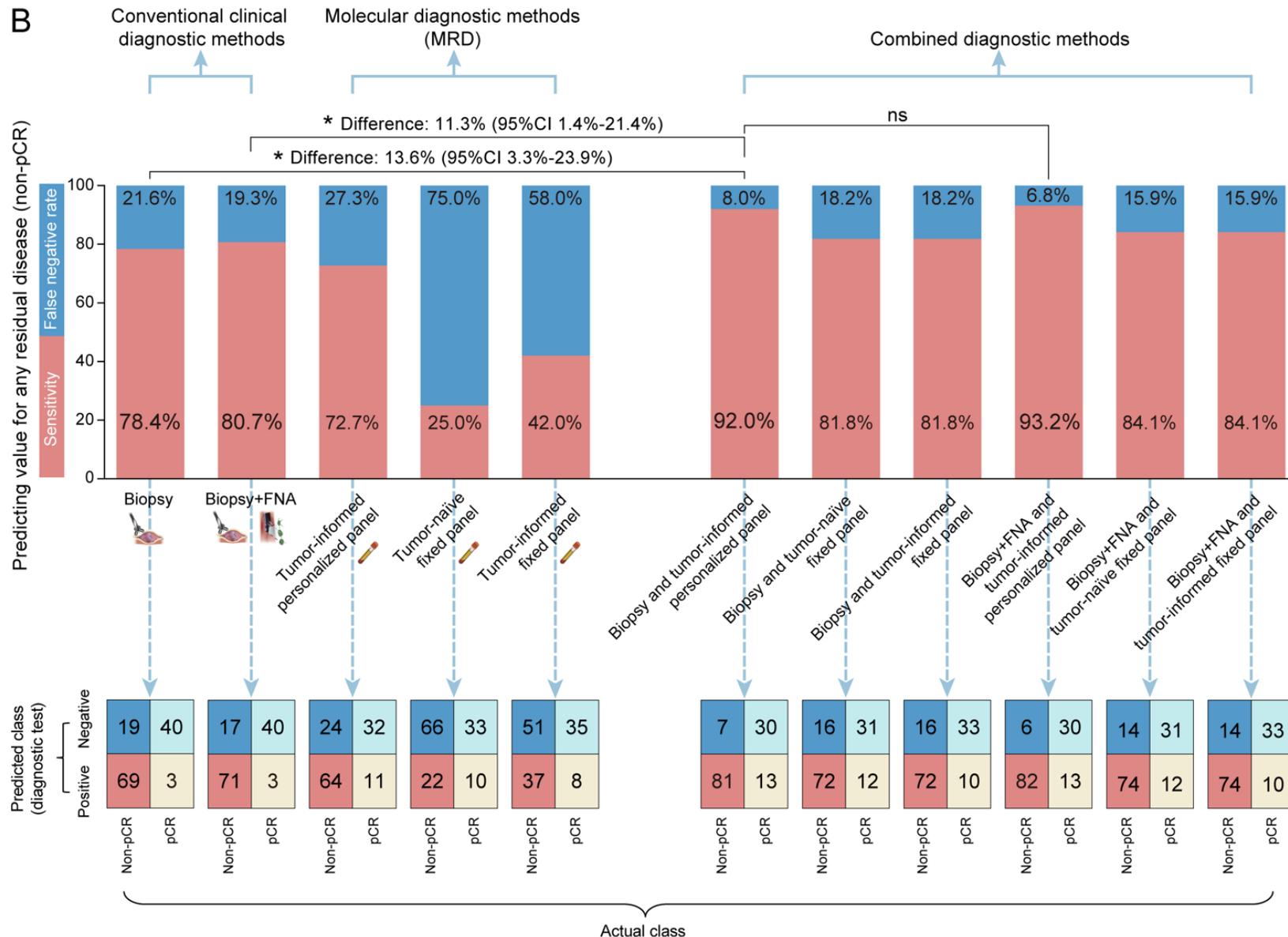
CanCatch® shows strong prognostic value in post-surgery esophageal cancer

- The ctDNA (+) detected by CanCatch® Custom at 3-4 weeks post-surgery was associated with poor disease-free survival.

- In patients with ctDNA (+) post-surgery, non-pCR patients treated with adjuvant immunotherapy had better disease-free survival than those without adjuvant immunotherapy, which was not observed in patients with ctDNA (-), suggesting that the ctDNA status post-surgery can guide adjuvant immunotherapy in patients with esophageal cancer.

Early detection

Burning Rock's multi-cancer early detection technology

Competitive technology

Methylation + machine learning to overcome challenges of low ctDNA abundance
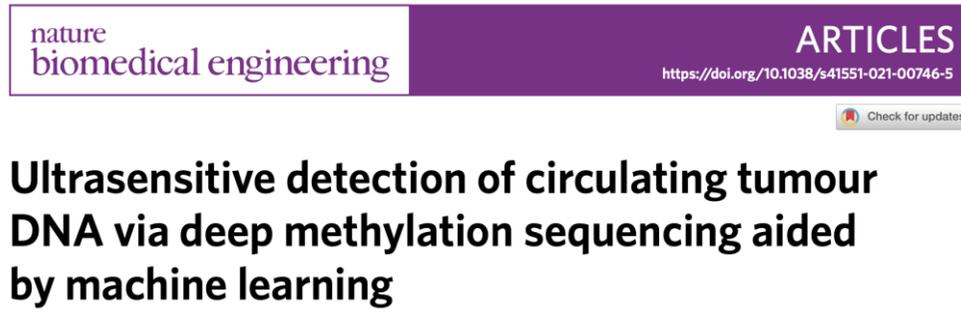
nature biomedical engineering

ARTICLES
https://doi.org/10.1038/s41551-021-00746-5

Check for updates

Ultrasensitive detection of circulating tumour DNA via deep methylation sequencing aided by machine learning

Multi-cancer validation data

ELSEVIER

Annals of Oncology
Available online 26 February 2023
In Press, Journal Pre-proof ? What's this? ↗

Original Article

Unintrusive multi-cancer detection by circulating cell-free DNA methylation sequencing (THUNDER): development and independent validation studies

AACR 2022

Session OPO.CL11.01 - Biomarkers
5116 - Analytical performance of ELSA-seq, a blood-based test for early detection of multiple cancers

Session OPO.CL11.01 - Biomarkers
5109 - Development of cfDNA reference standards for methylation-sequencing tests

ESMO 2022

A multi-cancer early detection model based on liquid biopsy of multi-omics biomarkers: A proof of concept study (PROMISE study)

Regulatory breakthrough

FDA breakthrough device designation granted

国家药品监督管理局
National Medical Products Administration
China NMPA breakthrough designation granted

Product development roadmap

Proof-of-concept
2016 – 2019

- Proof of concept on our methylation based, machine learning aided technology platform
- Results published on *Nature Biomedical Engineering*, "Ultrasensitive detection of circulating tumour DNA via deep methylation sequencing aided by machine learning"

3-cancer
2017 – 2020

- Lung, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC)

6-cancer
2018 – 2020

- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- THUNDER study (N=2,385) completed, 98.9% specificity and 69.1% sensitivity, top-2 predicted origin accuracy of 91.7% (independent validation cohort)
- PREVENT study (prospective and interventional, IU population) ongoing

22-cancer
2019 – Ongoing

- Covering 88% of China's cancer incidence
- PROMISE study (N=2,035) completed, improved performance vs. 6-cancer test
- PREDICT and PRESCIENT studies ongoing

Running the largest clinical programs in China supported by top physicians

PREDICT

Leading site: Shanghai Zhongshan Hospital

- One of China's largest comprehensive academic hospitals
- Performs c.104,000 operations and serves c.169,000 inpatients and over 4,236,000 outpatients on an annual basis[1]
- Ranked top 5 in the 2019 China's general hospital rankings[2]

Principal Investigator: Prof. Jia Fan

- Fellow of the Chinese Academy of Sciences
- President of Shanghai Zhongshan Hospital

PRESCIENT

Leading site: Cancer Hospital of the Chinese Academy of Medical Sciences[3]

- The first and top cancer-specialist hospital in China
- The National Clinical Center for Cancer Research, the National Center for Quality Control on Standardized Cancer Treatment and Diagnosis, the National Clinical Center for Drug Research

Principal Investigators

Prof. Jie He   Prof. Jie Wang

- Fellow of the Chinese Academy of Sciences
- President of CHCAMS

Head of the Dept. of Medicine, CHCAMS

PREVENT

Leading site: West China Hospital

- One of the largest hospitals in China, performed 196,000 surgeries and 7.8 million out-patient services in 2021
- Ranked #2 in the Fudan Best Hospital in China Rankings (2009-2020)

Principal Investigator: Prof. Weiming Li

- President of West China Hospital

Appendix 1

Early detection

Product Development Roadmap

Proof-of-concept
2016 – 2019

- Proof of concept on our methylation based, machine learning aided technology platform
- Results published on *Nature Biomedical Engineering*, "Ultrasensitive detection of circulating tumour DNA via deep methylation sequencing aided by machine learning"

3-cancer
2017 – 2020

- Lung, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC)

6-cancer
2018 – 2020
CE Mark, FDA BDD

- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- THUNDER study (N=2,385) completed, 98.9% specificity and 69.1% sensitivity, top-2 predicted origin accuracy of 91.7% (independent validation cohort)
- PREVENT study (prospective and interventional, IU population) ongoing

22-cancer
2019 – Ongoing

- Covering 88% of China's cancer incidence
- PROMISE study (N=2,035) completed, improved performance vs. 6-cancer test
- PREDICT/PRESCIENT studies ongoing

6-cancer test marker discovery and model training
The THUNDER study, 2395 participants

Marker discovery and panel validation

Marker discovery

~450,000 CpG sites
1. TCGA tissue samples
COAD/READ, ESCA, LIHC, LUAD/LUSC, OV, PAAD (cancer = 2,018, non-cancer = 195)
2. GEO white blood cell samples
(n = 656)

161,984 CpG sites

Panel validation

In-house tissue samples
(cancer = 249, adjacent/benign = 288)

Model training and validation (retrospective)

Plasma samples
(cancer = 735, non-cancer = 958)

Unconfirmed status (n = 23)

Failed lab QC (n = 30)

Failed bioinformatic QC (n = 26)

Plasma samples
(cancer = 700, non-cancer = 914)

Cancers were divided as pre-specified and controls were age-matched

Unmatched non-cancer (n = 165)

Training set
(cancer = 399, non-cancer = 626)

Validation set
(cancer = 301, non-cancer = 123)

Model lock

Independent validation (prospective)

Plasma samples were prospectively collected
(cancer = 1,433, non-cancer = 1,075)

Cancer and non-cancer samples were age-matched with a ratio of 1:1

The rest was remained for future analysis (n = 1,498)

Age-matched plasma samples
(cancer = 505, non-cancer = 505)

Failed lab QC (n = 51)

Failed bioinformatic QC (n = 13)

Independent validation set
(cancer = 473, non-cancer = 473)

A customized panel of 161,984 CpG sites was constructed and validated by public and in-house (cancer: n = 249; non-cancer: n = 288) methylome data, respectively. The cfDNA samples from 1,693 participants (cancer: n = 735; non-cancer: n = 958) were retrospectively collected and divided into training and validation sets to establish and test two multi-cancer detection blood test (MCDBT-1/2) models. Both models was blindly validated on a prospectively enrolled, independent validation cohort of age-matched 1,010 participants (cancer: n = 505; non-cancer: n = 505).

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6-cancer test, detection-of-cancer performance in case-control cohorts
The THUNDER study

Fig 3. Performance of the MCDBT-1/2 models. A. Sensitivity, specificity, accuracy of top predicted origin, and accuracy of top two predicted origins. **B.** The overall sensitivity, accuracy of top predicted origin, and sensitivity stratified by cancer types reported by tumor stage.

Data set	Specificity (%)	Sensitivity (%)	Accuracy of top predicted origin (%)	Accuracy of top two predicted origins (%)
Training set	99.7 (98.9-100.0)	75.2 (70.6-79.4)	89.7 (85.7-92.9)	94.7 (91.5-96.9)
Validation set	100.0 (97.0-100.0)	69.4 (63.9-74.6)	82.8 (77.0-87.6)	89.4 (84.5-93.3)
Independent validation set	**98.9 (97.6-99.7)**	**69.1 (64.8-73.3)**	**83.2 (78.7-87.1)**	**91.7 (88.2-94.5)**

Fig 4. Top predicted origin for the MCBDT-1 model. Confusion matrices representing the predicted origin in the training, the validation, and the independent validation sets.
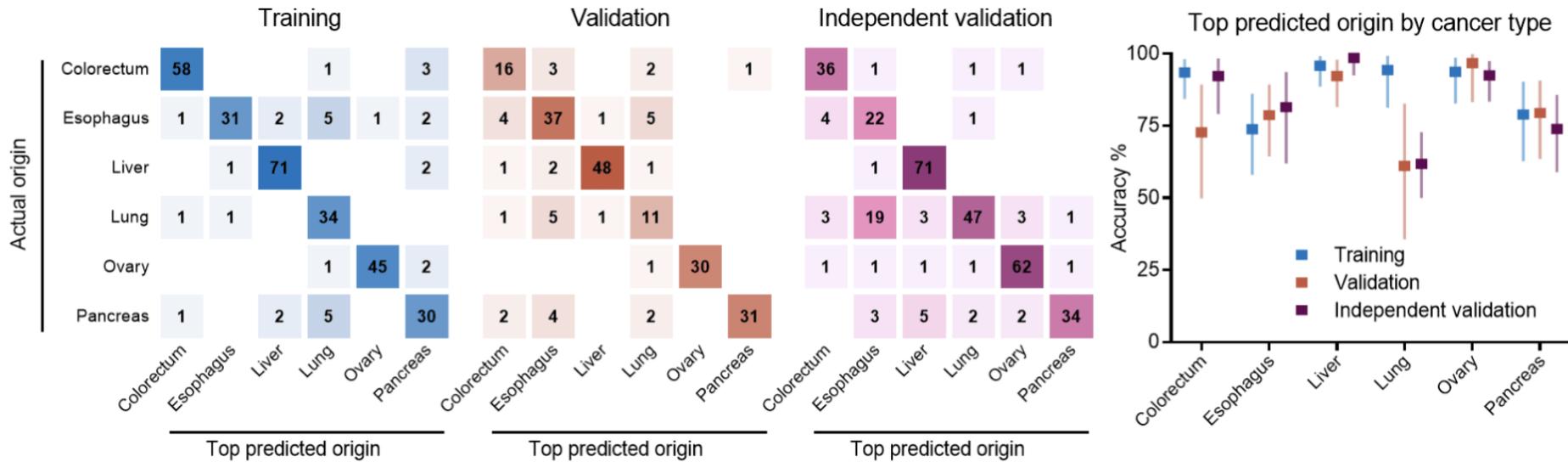

Data set	Specificity (%)	Sensitivity (%)	Accuracy of top predicted origin (%)	Accuracy of top two predicted origins (%)
Training set	99.7 (98.9-100.0)	75.2 (70.6-79.4)	89.7 (85.7-92.9)	94.7 (91.5-96.9)
Validation set	100.0 (97.0-100.0)	69.4 (63.9-74.6)	82.8 (77.0-87.6)	89.4 (84.5-93.3)
Independent validation set	98.9 (97.6-99.7)	69.1 (64.8-73.3)	83.2 (78.7-87.1)	91.7 (88.2-94.5)

Product Development Roadmap

Proof-of-concept
2016 – 2019

- Proof of concept on our methylation based, machine learning aided technology platform
- Results published on *Nature Biomedical Engineering*, "Ultrasensitive detection of circulating tumour DNA via deep methylation sequencing aided by machine learning"

3-cancer
2017 – 2020

- Lung, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC)

6-cancer
2018 – 2020
CE Mark, FDA BDD

- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- THUNDER study (N=2,385) completed, 98.9% specificity and 69.1% sensitivity, top-2 predicted origin accuracy of 91.7% (independent validation cohort)
- PREVENT study (prospective and interventional, IU population) ongoing

22-cancer
2019 – 2022

- Covering 88% of China's cancer incidence
- PROMISE study (N=2,035) completed, improved performance vs. 6-cancer test
- PREDICT/PRESCIENT studies ongoing

The Innovation

ARTICLE

Exploration of multi-omics liquid biopsy approaches for multi-cancer early detection: The PROMISE study

Jianchun Duan,[1,2,21] Qiang Gao,[3,4,5,21] Zhijie Wang,[2,21] Jiachen Xu,[2,21] Yuzi Zhang,[6,21] Yanan Wang,[6] Xi Yang,[7] Lei Zhang,[6] Yu Xu,[6] Qiaoxia Zhou,[6] Bo Yang,[6] Xingyu Yang,[6] Guoqiang Wang,[6] Jing Zhao,[6] Xuefei Wang,[8,9,10] Di Ge,[11] Lijie Tan,[11] Wenju Chang,[12] Jianmin Xu,[12] Pinghong Zhou,[13] Mengjiang He,[13] Yuanlin Song,[14] Jie Hu,[15] Wenhui Lou,[16] Wenchuan Wu,[16] Tingyan Shi,[17] Rongyu Zang,[17] Yuan Ji,[18] Sunfang Jiang,[19,20] Youpei Lin,[3] Liangqing Dong,[3] Shangli Cai,[6,*] Jia Fan,[3,4,*] and Jie Wang[1,2,*]

*Correspondence: shangli.cai@brbiotech.com (S.C.); fan.jia@zs-hospital.sh.cn (J.F.); zlhux

www.the-innovation.org

PUBLIC SUMMARY

- The PROMISE study explored multi-omics liquid biopsy strategy for multi-cancer early detection.
- Proteins showed stronger complementarity to methylation than mutations in cancer detection.
- The multimodal classifier integrating methylation and proteins demonstrated superior performance.
- Annual screening may reduce cancer mortality by shifting cancers from late to early stage.

CellPress Partner Journal   www.

GRAPHICAL ABSTRACT

The PROMISE Study Aimed to Investigate the Feasibility of a Multi-omics Integration Strategy in Multi-cancer Detection Blood Tests (MCDBTs)
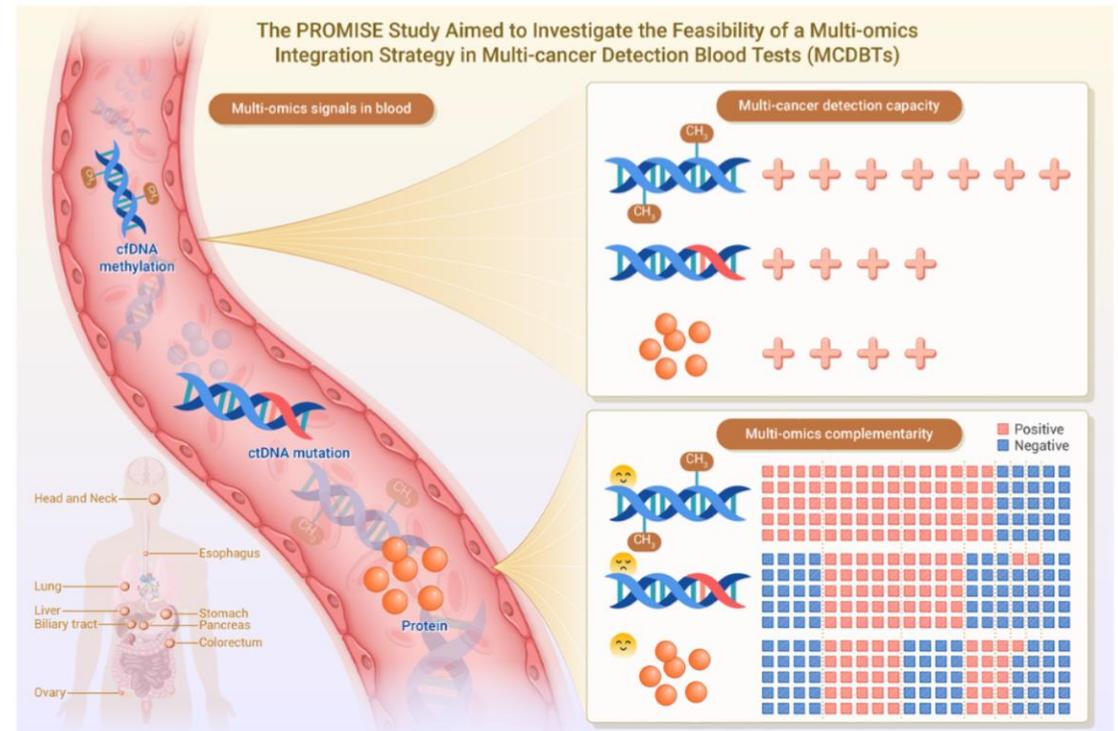
Study design
The PROMISE study, 1,706 participants
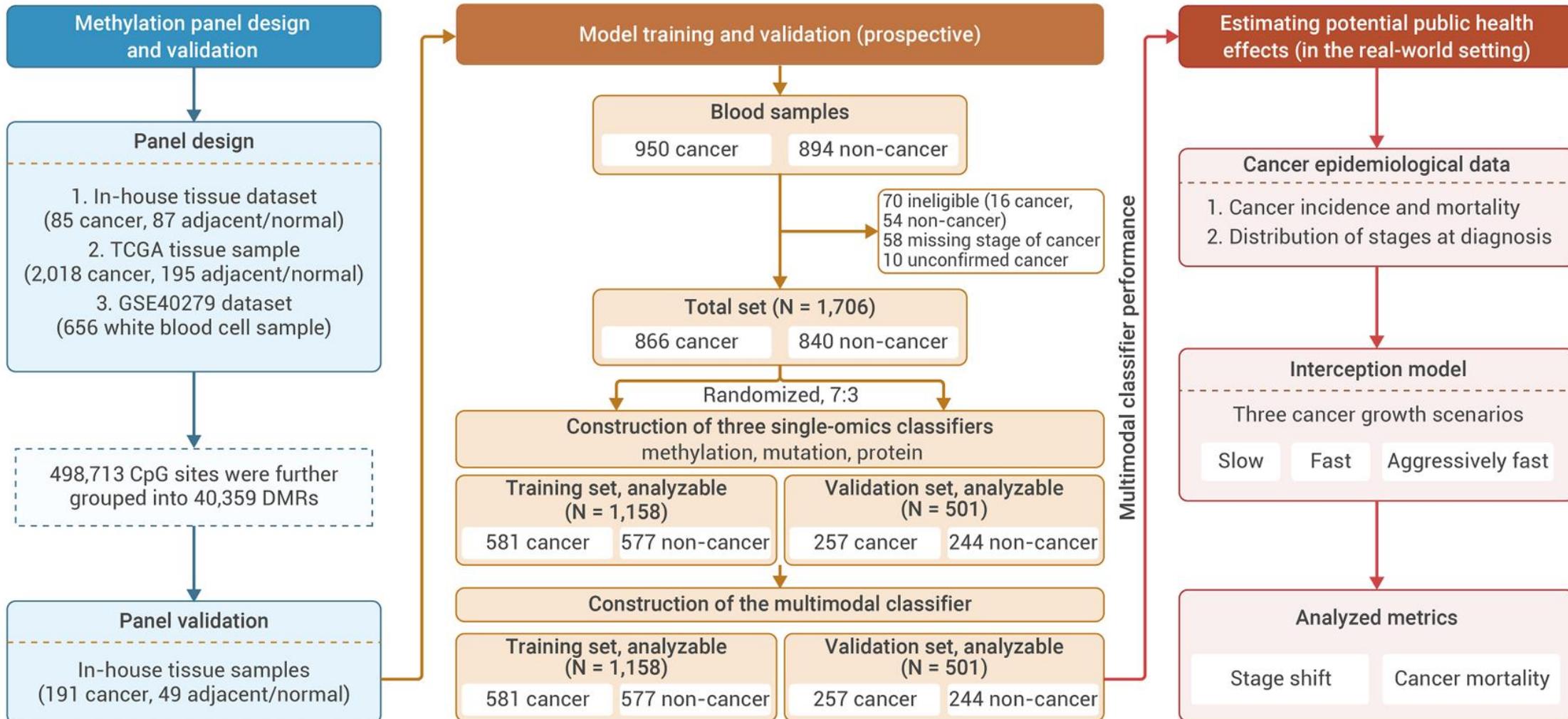
Figure 1. The flow chart of PROMISE study QC, quality control.

Multimodal classifier for 9-cancer, detection-of-cancer performance
The PROMISE study

Performance of the multimodal classifier based on both methylation and protein markers (A) Sensitivity, specificity, and top predicted origin accuracy. (B) Sensitivity reported by cancer stage and cancer type. Error bars represent 95% CI.

(A)	Specificity	Sensitivity	Accuracy of top predicted origin
Training set	97.2% (95% CI, 95.5%−98.4%)	71.6% (95% CI, 67.7%−75.2%)	75.5% (95% CI, 71.1%−79.5%)
Validation set	98.8% (95% CI, 96.4%−99.7%)	75.1% (95% CI, 69.3%−80.3%)	73.1% (95% CI, 66.2%−79.2%)

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Multimodal classifier for 9-cancer, top-predicted-origin performance
The PROMISE study

Performance of the multimodal classifier based on both methylation and protein markers (C)
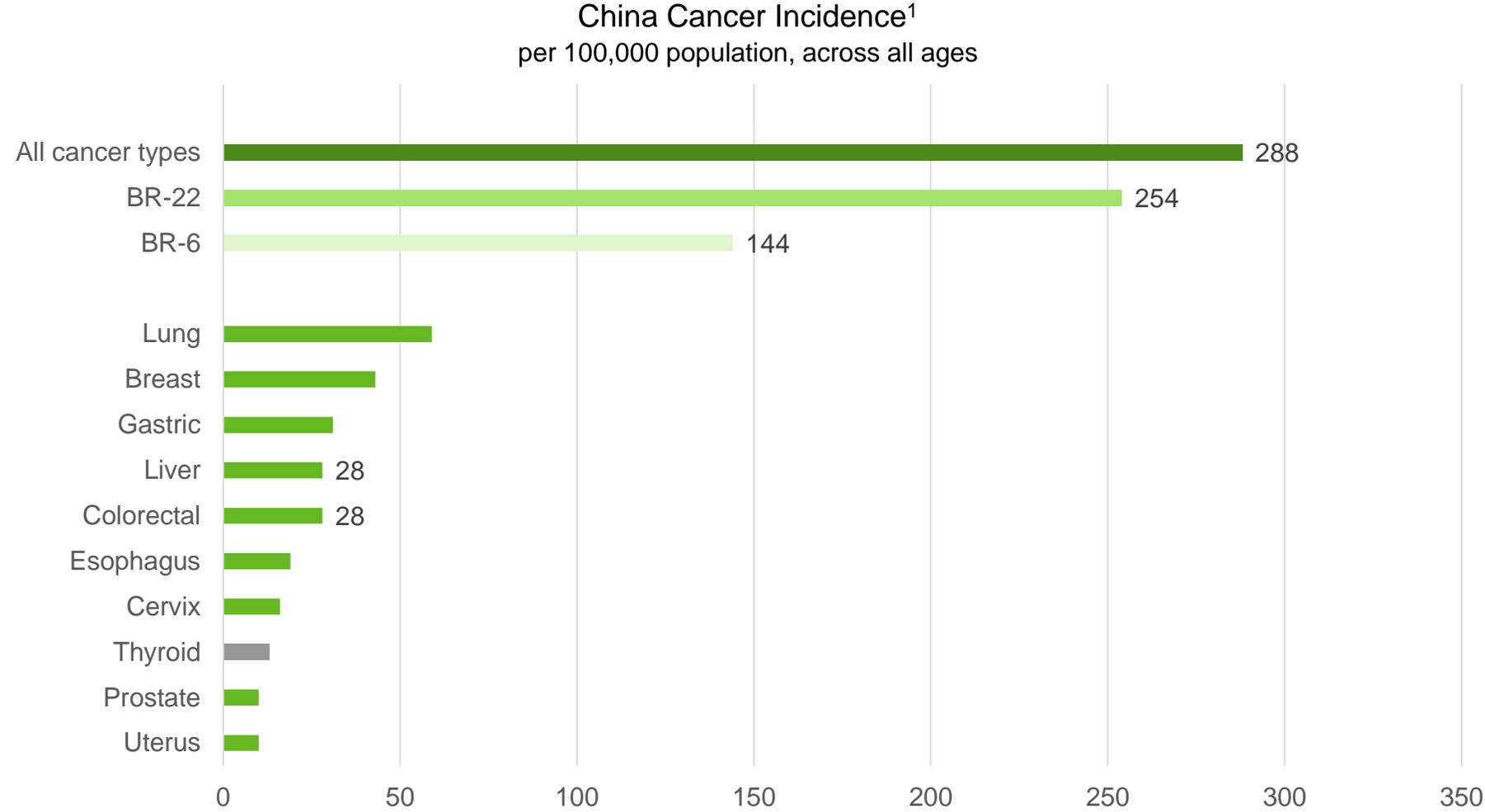Top predicted origin accuracy reported by cancer type.

(C)

Overall accuracy in the training dataset: 75.5% (95%CI: 71.1–79.5%)

Actual origin	Head and neck	Esophagus	Lung	Stomach	Liver	Biliary tract	Pancreas	Colorectum	Ovary
Ovary	n=0 0%	n=0 0%	n=2 3.4%	n=1 1.7%	n=0 0%	n=1 1.7%	n=1 1.7%	n=0 0%	n=53 91.4%
Colorectum	n=0 0%	n=2 3.6%	n=0 0%	n=2 3.6%	n=0 0%	n=2 3.6%	n=0 0%	n=50 89.3%	n=0 0%
Pancreas	n=1 4.3%	n=0 0%	n=1 4.3%	n=1 4.3%	n=0 0%	n=7 30.4%	n=13 56.5%	n=0 0%	n=0 0%
Biliary tract	n=3 5.8%	n=1 1.9%	n=4 7.7%	n=1 1.9%	n=5 9.6%	n=30 57.7%	n=6 11.5%	n=2 3.8%	n=0 0%
Liver	n=0 0%	n=1 2%	n=0 0%	n=0 0%	n=42 85.7%	n=6 12.2%	n=0 0%	n=0 0%	n=0 0%
Stomach	n=3 8.3%	n=1 2.8%	n=2 5.6%	n=21 58.3%	n=0 0%	n=4 11.1%	n=0 0%	n=5 13.9%	n=0 0%
Lung	n=0 0%	n=1 2.1%	n=45 93.8%	n=1 2.1%	n=0 0%	n=1 2.1%	n=0 0%	n=0 0%	n=0 0%
Esophagus	n=12 26.7%	n=23 51.1%	n=4 8.9%	n=2 4.4%	n=0 0%	n=2 4.4%	n=0 0%	n=2 4.4%	n=0 0%
Head and neck	n=37 75.5%	n=4 8.2%	n=4 8.2%	n=0 0%	n=0 0%	n=4 8.2%	n=0 0%	n=0 0%	n=0 0%

Top predicted origin

Overall accuracy in the validation dataset: 73.1% (95%CI: 66.2–79.2%)

Actual origin	Head and neck	Esophagus	Lung	Stomach	Liver	Biliary tract	Pancreas	Colorectum	Ovary
Ovary	n=2 7.4%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=25 92.6%
Colorectum	n=1 4%	n=3 12%	n=2 8%	n=0 0%	n=0 0%	n=2 8%	n=0 0%	n=17 68%	n=0 0%
Pancreas	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=4 30.8%	n=9 69.2%	n=0 0%	n=0 0%
Biliary tract	n=1 4.2%	n=1 4.2%	n=1 4.2%	n=1 4.2%	n=0 0%	n=17 70.8%	n=2 8.3%	n=1 4.2%	n=0 0%
Liver	n=1 5%	n=0 0%	n=1 5%	n=0 0%	n=15 75%	n=2 10%	n=0 0%	n=0 0%	n=1 5%
Stomach	n=4 26.7%	n=0 0%	n=3 20%	n=5 33.3%	n=0 0%	n=1 6.7%	n=0 0%	n=2 13.3%	n=0 0%
Lung	n=1 4.5%	n=1 4.5%	n=18 81.8%	n=2 9.1%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%
Esophagus	n=2 10%	n=11 55%	n=0 0%	n=2 10%	n=0 0%	n=3 15%	n=0 0%	n=2 10%	n=0 0%
Head and neck	n=24 88.9%	n=2 7.4%	n=1 3.7%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%	n=0 0%

Top predicted origin

Burning Rock's 22-cancer test covers 88% of China's cancer incidence

China Cancer Incidence[1]
per 100,000 population, across all ages

Category	Value
All cancer types	288
BR-22	254
BR-6	144
Lung	
Breast	
Gastric	
Liver	28
Colorectal	28
Esophagus	
Cervix	
Thyroid	
Prostate	
Uterus	

Leadership in multi-cancer early detection
First-in-class, high entry-barrier, multi-year efforts

Challenges	BNR position
1 Technology		

1 Technology

Challenges

Low amount of cancer signal

in the circulating bloodstream, much more challenging compared to tissue

BNR position

Proprietary chemistry and algorithm

- On par with global leader, competitive sensitivity in earlier stages for certain cancers
- Multi-year lead vs. China peers (most showing liver-cancer and colon-cancer data only)

2 Clinical

Large, multi-year studies required

from case-control to intend-to-use population, from observational to interventional (e.g. CCGA study: 15,254 participants, 8,584 with cancer, 6,670 without cancer)

Sponsorship from top physicians

- Catching up with global leader, to improve specificity and tissue-of-origin performance through large clinical studies
- Multi-year lead in China as the only company that has launched studies with over 10,000+ subjects

3 Regulatory

First-in-class

with no established regulatory pathway

Leading regulatory capability in China

- Exploring possible pathway, leveraging experience through the country's first NMPA-approved NGS kit

4 Commercial

Unprecedented product

Multi-pronged approach

- Initially working with hospitals' health check-up departments, leveraging synergy from in-hospital therapy selection business
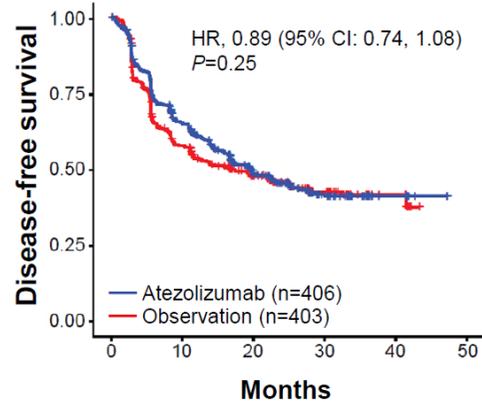
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Appendix 2

MRD

How do MRD studies advance utility
Example 1: IMvigor010, enrich the high-risk group and "tune-up" adjuvant treatment
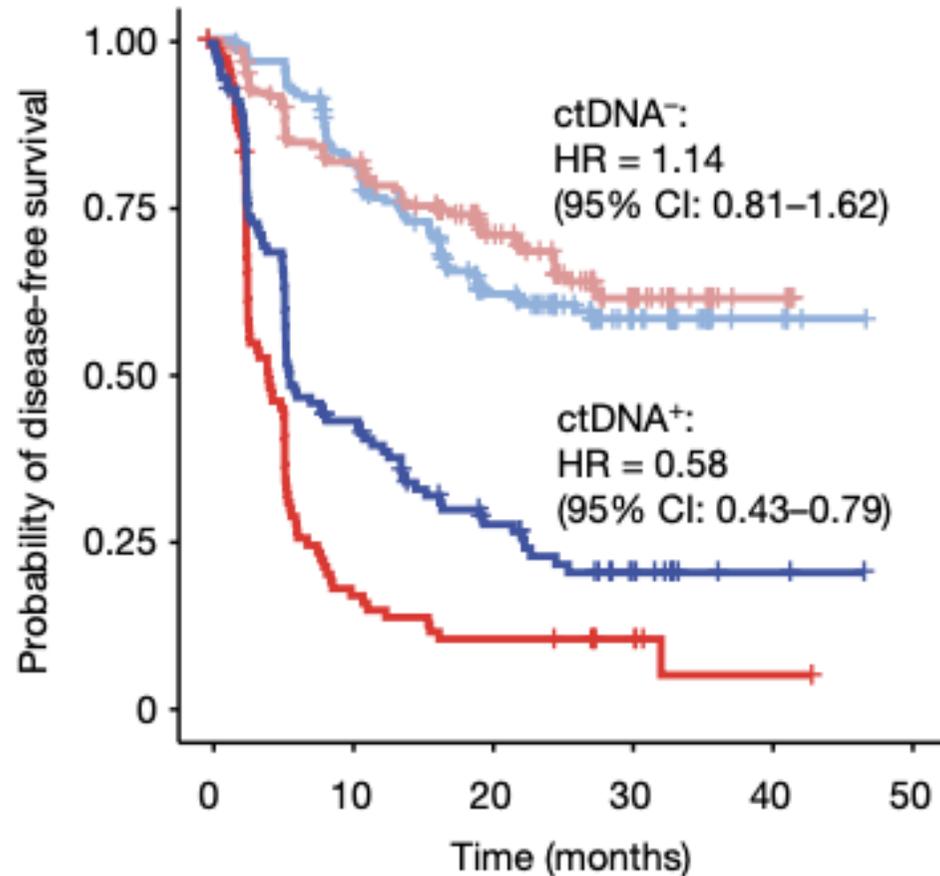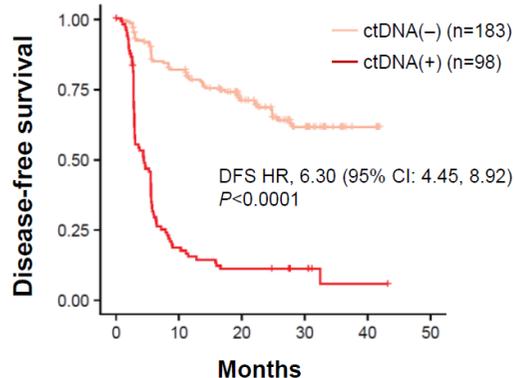

ITT

HR, 0.89 (95% CI: 0.74, 1.08)
$P=0.25$

Atezolizumab (n=406)
Observation (n=403)

Atezo, MIUC Adjuvant Therapy
"All comers" demonstrated NO efficacy
TMB/PD-L1 showed NO prediction

Observation arm

ctDNA(–) (n=183)
ctDNA(+) (n=98)

DFS HR, 6.30 (95% CI: 4.45, 8.92)
$P<0.0001$

Landmark MRD+ pts (39%) had worse prognosis
Maybe only those patients can benefit?

ctDNA⁻:
HR = 1.14
(95% CI: 0.81–1.62)

ctDNA⁺:
HR = 0.58
(95% CI: 0.43–0.79)

Indeed, only baseline MRD+ pts showed benefit
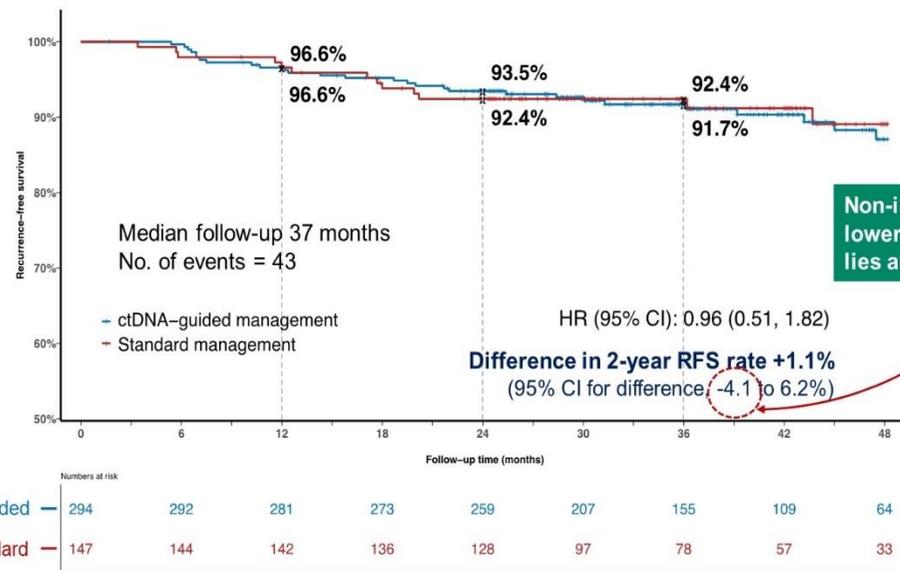
How do MRD studies advance utility
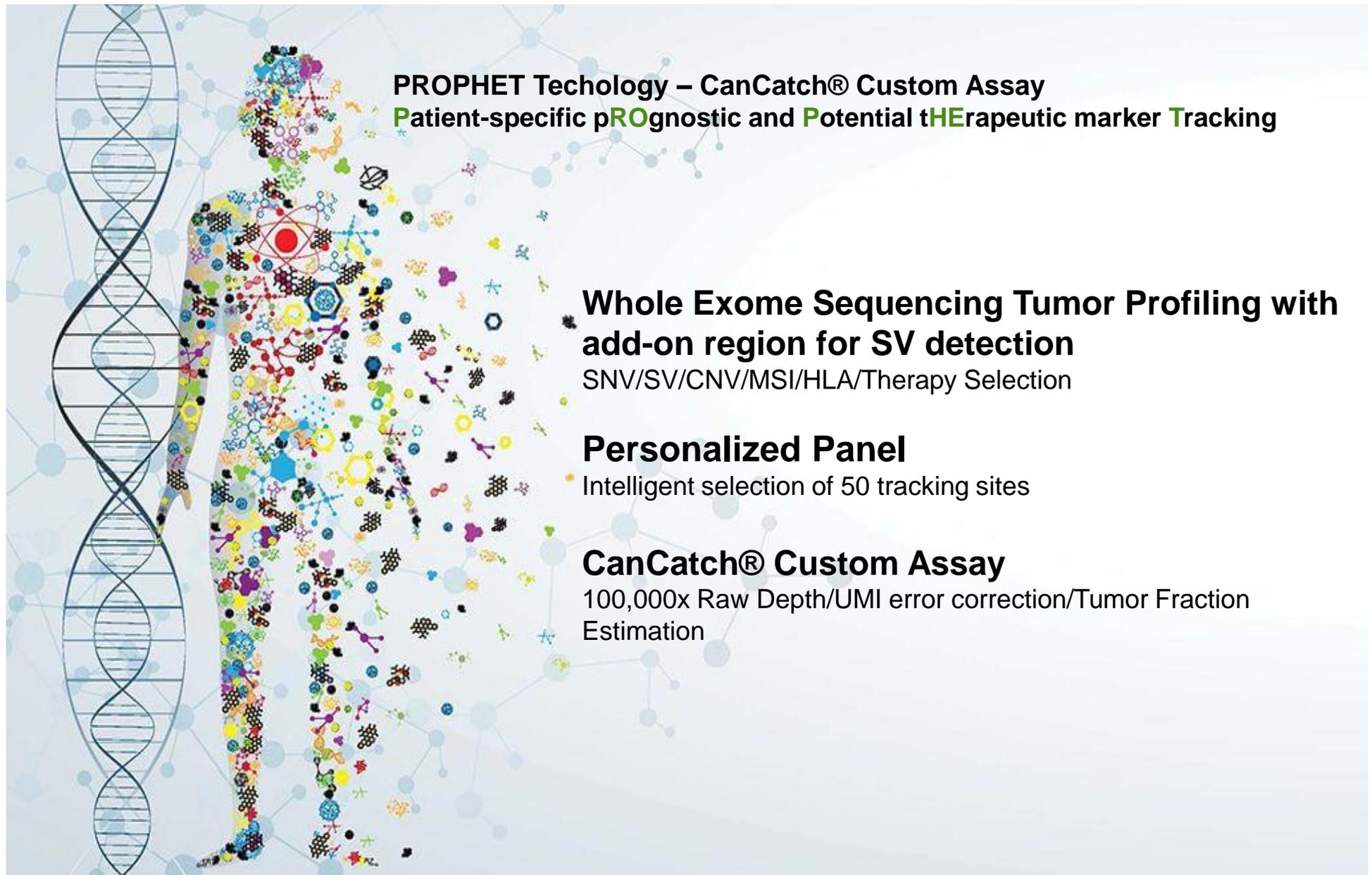*Example 2: Dynamic, identify low-risk patients and "tune-down" adjuvant treatment*
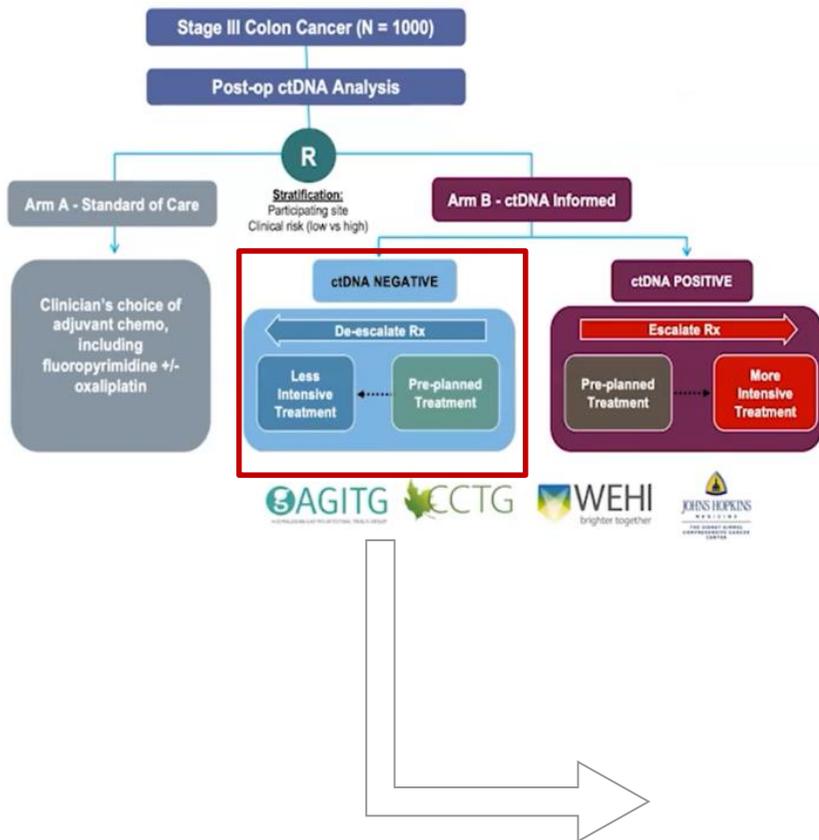
The ctDNA-guided MRD- group had fewer patients with adjuvant chemotherapy than the standard group (15% vs. 29%) with non-inferiority of 3-year RFS (92.4% vs 91.7%)

CanCatch® – Burning Rock's MRD solution

PROPHET Techology – CanCatch® Custom Assay
Patient-specific p**RO**gnostic and **P**otential t**HE**rapeutic marker **T**racking
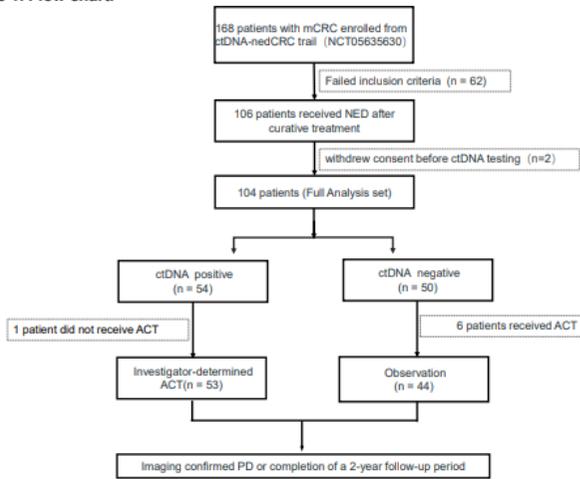
Whole Exome Sequencing Tumor Profiling with add-on region for SV detection
SNV/SV/CNV/MSI/HLA/Therapy Selection

Personalized Panel
Intelligent selection of 50 tracking sites

CanCatch® Custom Assay
100,000x Raw Depth/UMI error correction/Tumor Fraction Estimation

Colorectal cancer cohort publication at AACR 2025

Circulating tumor DNA-based molecular residual disease guides treatment in metastatic colorectal cancer patients with no evidence of disease: An open-label, prospective, phase II study

Yaqi Li[1], Xiang Hu[1], Chengcheng Li[2], Peng Cui[2], Xiang Hu[1], Fangqi Liu[1], Wenhua Li[3], Guoqiang Wang[2], Kunli Zhao[2], Qi Pan[4], Jing Wang[2], Bing Li[2], Shangli Cai[2], Junjie Peng[1]

#4567

[1]Department of Colorectal Surgery, Fudan University Shanghai Cancer Center. [2]Burning Rock Biotech. [3]Department of Medical Oncology, Fudan University Shanghai Cancer Center. [4]Department of Hepatic Surgery, Fudan University Shanghai Cancer Center.
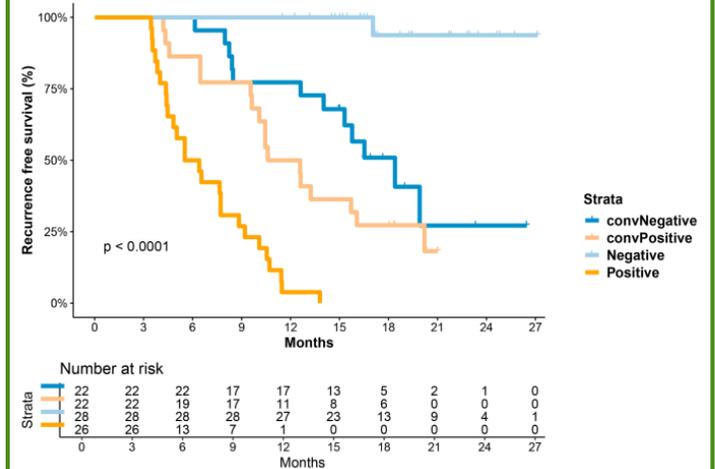
Flow chart

Figure 1. Flow chart.

Patients with negative ctDNA results detected by CanCatch® after curative treatment demonstrated superior recurrence-free survival
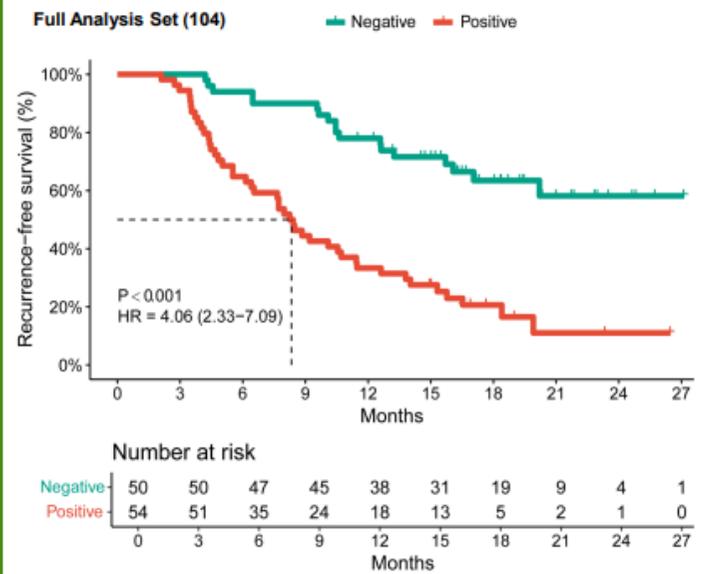
Longitudinal ctDNA monitoring with CanCatch® demonstrates potential prognostic value

Figure 3. RFS stratified by longitudinal ctDNA status

Gastrointestinal stromal tumor publication at ASCO 2025

Personalized tumour-informed circulating tumor DNA analysis in monitoring recurrence following resection of high-risk locally advanced stage gastrointestinal stromal tumor

Zhidong Gao[1], Baosen Cheng[1], Shuya Yang[1], Yudi Bao[1], Peng Cui[2], Chengcheng Li[2], Fujun Qiu[2], Guoqiang Wang[2], Shangli Cai[2], Xin Wu[3], Dongbing Zhao[4], Zhaodong Xing[4], Feng Cao[5], Wei Zhang[5], Yingjiang Ye[1];

1. Department of Gastrointestinal Surgery, Peking University People's Hospital, Beijing, China; 2. Burning Rock Biotech, Guangzhou, China; 3. Department of General Surgery, Chinese People's Liberation Army General Hospital, Beijing, China; 4. National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; 5. Department of General Surgery, Xuanwu Hospital, Capital Medical University, Beijing, China

2025 ASCO #11522

Study Flow
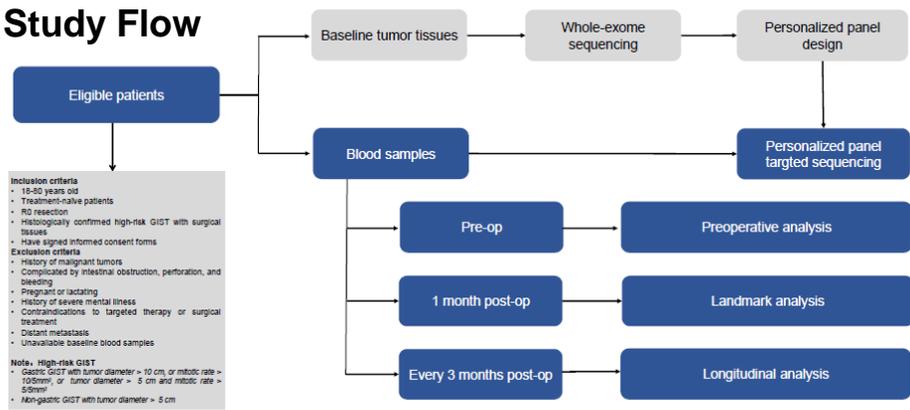
Figure 1: Overview of the study. Flow chart of the study. Pre-op, pre-operatively; post-op, post-operatively; GIST, gastrointestinal stromal tumor.
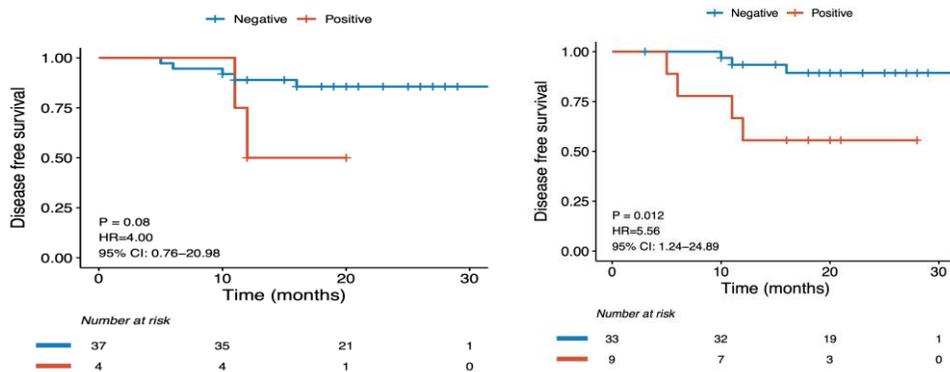
Patients with positive MRD detected by *CanCatch*® at landmark showed marginally worse DFS compared with those with negative MRD (p = 0.08, left). The longitudinal MRD positivity was associated with inferior DFS (p = 0.012, right)

NO.P06 F/71y KIT/PDGFRA WT(NF1 exon54 S2666Cfs*5)
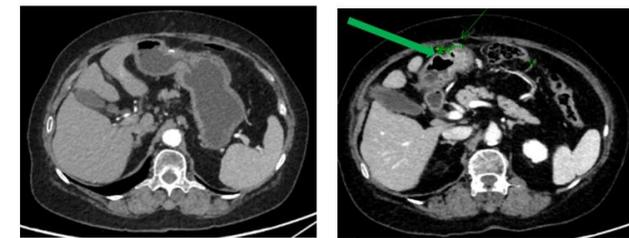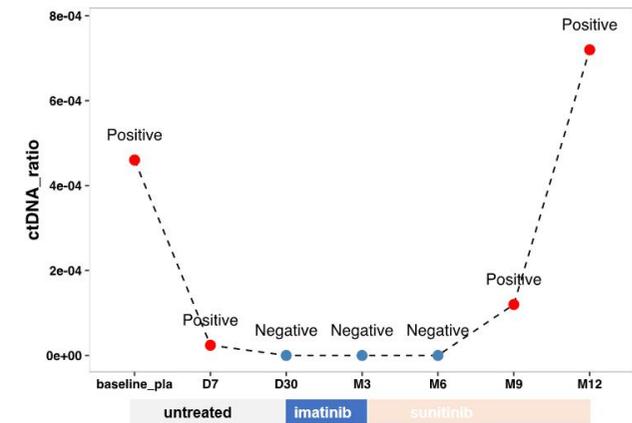
M9 (Negative)   M12 (Positive)

The positive post-operative ctDNA detected by *CanCatch*® informed tumor recurrence prior to radiological evidence with a lead time of 3 months in a 71-year-old patient.

Colorectal cancer cohort publication at ASCO 2024

Individualized Tumor-Informed Circulating Tumor DNA Analysis for Molecular Residual Disease Detection in Predicting Recurrence and Efficacy of Adjuvant Chemotherapy in Colorectal Cancer

Di Cao[1], Qiaoxia Zhou[2], Xuning Fan[2], Jinyu Yang[2], Cong Li[1], Fulong Wang[1], Rongxin Zhang[1], Xiaojun Wu[1], Liren Li[1], Zhenhai Lu[1], Zhizhong Pan[1], Junzhong Lin1, Miaoqing Wu[1], Yifan Liu[1], Guangzhao Lv[1], Fujun Qiu[2], Haoyang Xin[2], Yu Xu[2], Guoqiang Wang[2], Shangli Cai[2], Gong Chen[1]

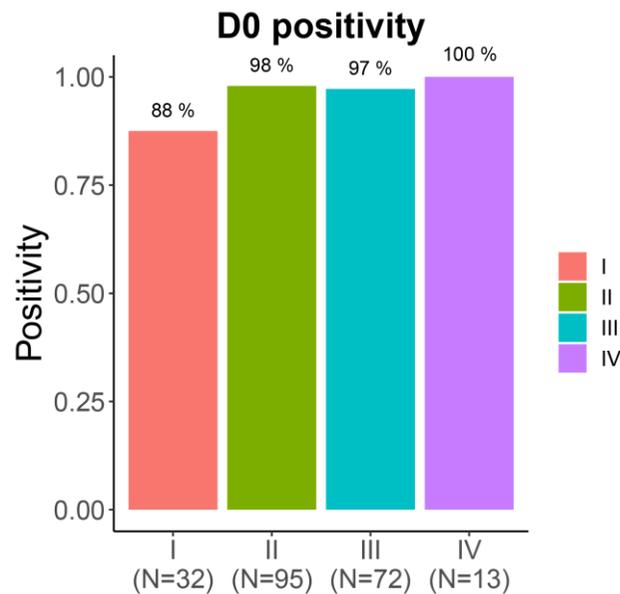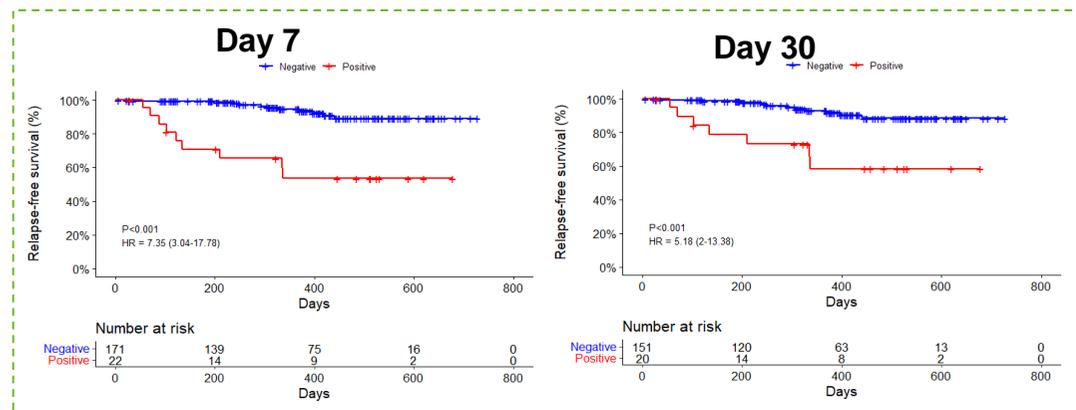1. State Key Laboratory of Oncology in South China, Collaborative Innovation Center of Cancer Medicine, Sun Yat-sen University Cancer Center, Guangzhou 510060, China. 2. Burning Rock Biotech, Guangzhou, 510300, China

D0 positivity

CanCatch® assay showed a positive rate of 96% in preoperative samples.

ctDNA positivity detected by *CanCatch®* at postoperative day 7 and 30 predicted worse RFS

Table 1. Among patients with results from all three approaches (n=168), the CanCatch® assay outperformed TI and TN fixed-panel assays in predicting RFS at POD7.

Time point	Performance	CanCatch®	TI	TN
Baseline	Positivity	97%	72%	64%
POD7	Positivity	11%	8%	7%
	ctDNA+ *vs.* ctDNA-, HR, P	7.52, <0.001	3.43, 0.04	5.60, 0.003
	ACT *vs.* no-ACT in ctDNA+, HR, P	0.13, 0.01	0.15, 0.08	not applicable , 0.008
	ACT *vs.* no-ACT in ctDNA-, HR, P	0.92, 0.91	0.92, 0.90	0.93, 0.91
POD30	Positivity	11%	7%	6%
	ctDNA+ *vs.* ctDNA-, HR, P	4.24, 0.01	8.26, <0.001	9.86, <0.001
	ACT *vs.* no-ACT in ctDNA+, HR, P	0.68, 0.73	0.37, 0.40	0.34, 0.35
	ACT *vs.* no-ACT in ctDNA-, HR, P	0.86, 0.84	0.91, 0.90	0.90, 0.89
Surveillance	ctDNA+ *vs.* ctDNA-, HR, P	7.77, <0.001	5.88, <0.001	9.80, <0.001

Note: TI: fixed panel tumor-informed approach; TN: tumor naïve (TN) approach.

Among patients with results from all three approaches (n=168), the *CanCatch®* assay outperformed TI and TN fixed-panel assays in predicting RFS at postoperative day 7.

Appendix 3

Therapy selection

NMPA approved NGS panels

<table>
<tr><td></td><td></td><th>First NMPA-approved kit</th><th>Second NMPA-approved kit</th></tr>
<tr><td colspan="2">燃石医学 Burning Rock Dx</td><td>EGFR, ALK, BRAF, KRAS
Approved in Jul **2018**
<u>First approved NGS kit in China</u></td><td>EGFR, KRAS, MET, ERBB2, BRAF, PIK3CA, ALK, ROS1, RET
Approved in Mar **2022**</td></tr>
<tr><td colspan="2">Novogene
诺禾</td><td>EGFR, KRAS, BRAF, PIK3CA, ALK, ROS1
Approved in Aug **2018**</td><td></td></tr>
<tr><td colspan="2">Geneseeq
世和</td><td>EGFR, ALK, ROS1, BRAF, KRAS, ERBB2
Approved in Sep **2018**</td><td></td></tr>
<tr><td colspan="2">BGI
华大</td><td>EGFR, KRAS, ALK
Approved in Aug **2019**</td><td></td></tr>
<tr><td colspan="2">Gene+
吉因加</td><td>EGFR, KRAS, ALK
Approved in Dec **2019**</td><td></td></tr>
<tr><td colspan="2">Genetron
泛生子</td><td>EGFR, KRAS, BRAF, ERBB2, PIK3CA, ALK, ROS1, MET
Approved in Feb **2020**</td><td></td></tr>
<tr><td colspan="2">Genecast
臻和</td><td>KRAS, NRAS, BRAF, PIK3CA
Approved in Mar **2021**</td><td></td></tr>
<tr><td colspan="2">3DMed
思路迪</td><td></td><td></td></tr>
</table>

NMPA approved testing kits by major NGS-focused companies[1]

Highlights on our second NMPA-approved kit

- Only 30ng DNA input required, applicable to small tissue samples

- First NMPA approved NGS kit with CNV[2] mutation type, with MET exon14 skipping

Notes:
[1] The list is not exhaustive. A total of 13 kits have been approved by the NMPA as of the date of this presentation
[2] Copy number variation

NGS testing
Diagnostics companies focus on steps 1 and 3

	NGS
Throughput	**High**-throughput
Efficiency	**Parallel** testing
Cost	**Low-cost** per biomarker
Biomarker Profiling	**Comprehensive** profiling & **superior** accuracy
Fit for Liquid Sample	**Liquid availability**

1 *Library Preparation*

EGFR   ALK   MET

Targeted genes enrichment

2 *Sequencing*

3 *Bioinformatics Analysis and Mutation Annotation*

ATG**CGCCTACAAAC**TGGCAACGCATTAGCCCATC
ATCTCGCTCAGCTAG...CTCACTCGACCGC
CGATCCACAATG...**GCTAGTCGAC**
CGATCGATGCTC...ACGTACTCAC
ATGCGCCTACAA...TTAGCTGTGT
ATCTCGCTCAGC...ACTCGAGAGT
CGATC...TGT...TAGTTGAAA
CGATCGATGCTCGCTAGCTCAGCTA...CTATGA

EGFR ALK KRAS ...

Final report: including mutation type, targeted therapy, drugs in R&D, clinical trials, etc.

Leading liquid-biopsy product in China, with globally competitive performance
Demonstrated in high-impact analytical validation study

SEQC2 Study Overview

MAQC/SEQC Consortium Projects – An Overview

- An FDA-led community-wide consortium effort to assess technical performance and application of emerging technologies (e.g., genomics).

Guidance for Industry
Pharmacogenomic Data Submissions —
Companion Guidance

Issues and Study Objectives

- FDA approved several NGS tests with sensitivity for AF ~5%
- Hundreds lab developed tests (LDT): sensitivity ~ 2-10%
- FDA approved ctDNA tests with sensitivity for AF ~0.3%

of ctDNA

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tion !!!

nature biotechnology — ARTICLES
https://doi.org/10.1038/s41587-021-00857-z

Check for updates

Evaluating the analytical validity of circulating tumor DNA sequencing assays for precision oncology

Liquid Biopsy

- False positive rate estimate through Known Negatives
- All of them by VAF ranges:
  - 0.1 - 0.5%, 0.5 - 2.5%, >2.5%
  - Finer VAF ranges for sensitivity: 0.1 - 0.2%, 0.2 - 0.3%, 0.3 - 0.5%
- Evaluate the impact of DNA input amount
  - Three levels of input for Ef: 10ng, 25ng, 50ng
- Evaluate the impact of synthetic plasma (DNA extraction)
  - Qubit HS calibration and quantification
 - Calculate extraction yield

- Enzymatic fragmentation → better ligation efficiency
- Gel-based size selection (160bp-180bp) to mimic cfDNA
- 1ng/ul to mimic concentration after DNA extraction from plasma
- Ep: 40ng/ml Ef in synthetic plasma

25 | Ef_10
50 | Ep_25

TFS2

BRP2: Burning Rock Dx LungPlasma v4
IDT2: IDT xGen Non-Small Cell Lung Cancer
ILM2: Illumina TruSight 170 with UMI
ROC2: Roche AVENIO ctDNA Expanded Kit
**TFS2:** Thermo Fisher Oncomine Lung cfDNA Assay

Participating assays and study design

Name	Vendor	ctDNA assay	Sequencing platform	Target genes	Reportable region (kb)	Coding (kb)	CTR (kb)	Negatives (× 1,000)	Variants
ROC	Roche Sequencing Solutions	AVENIO ctDNA (Expanded Kit)	Illumina NextSeq	77	161.7	140.2	103.8	47.1	189
ILM	Illumina	TruSight Tumor 170 + UMI	Illumina NovaSeq	154	501.0	390.1	338.4	133.0	574
IDT	Integrated DNA Technologies	xGen Non-small Cell Lung Cancer	Illumina NovaSeq	24	110.1	93.2	76.5	39.3	130
BRP	Burning Rock Biotech	Lung Plasma v4	Illumina NovaSeq	168	226.9	148.5	125.1	53.4	229
TFS	Thermo Fisher Scientific	Oncomine Lung cfDNA assay	Ion Torrent S5 XL	11	1.9	1.6	1.3	0.8	5
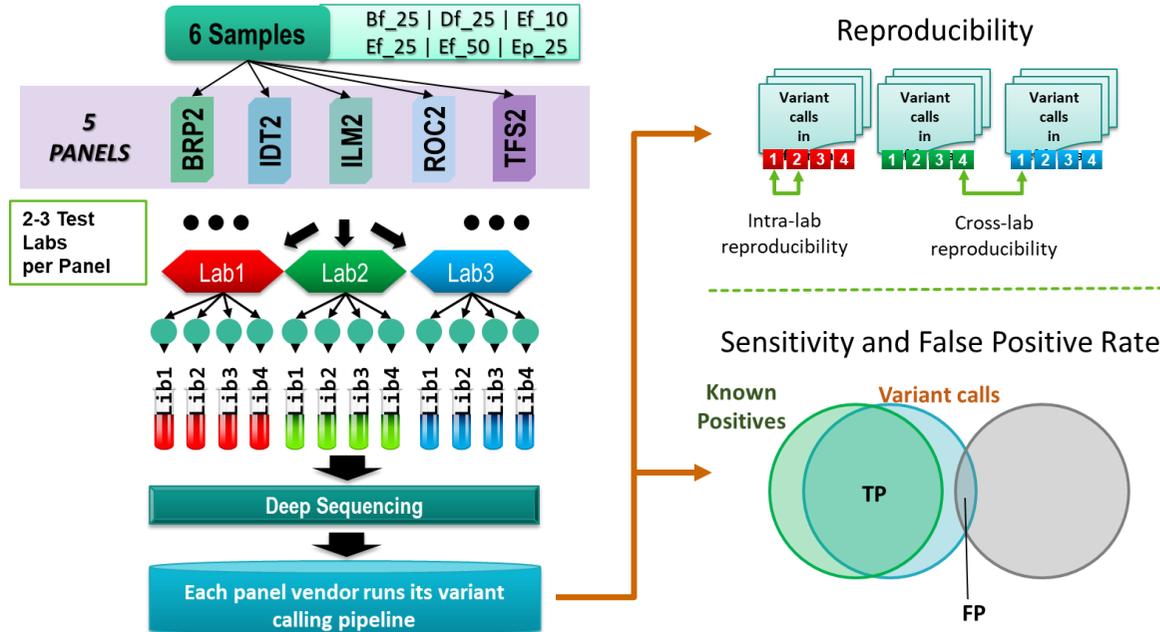
Overall analytical accuracy and specificity

Analytical accuracy

Lbx-low:
- ROC
- ILM
- IDT
- BRP
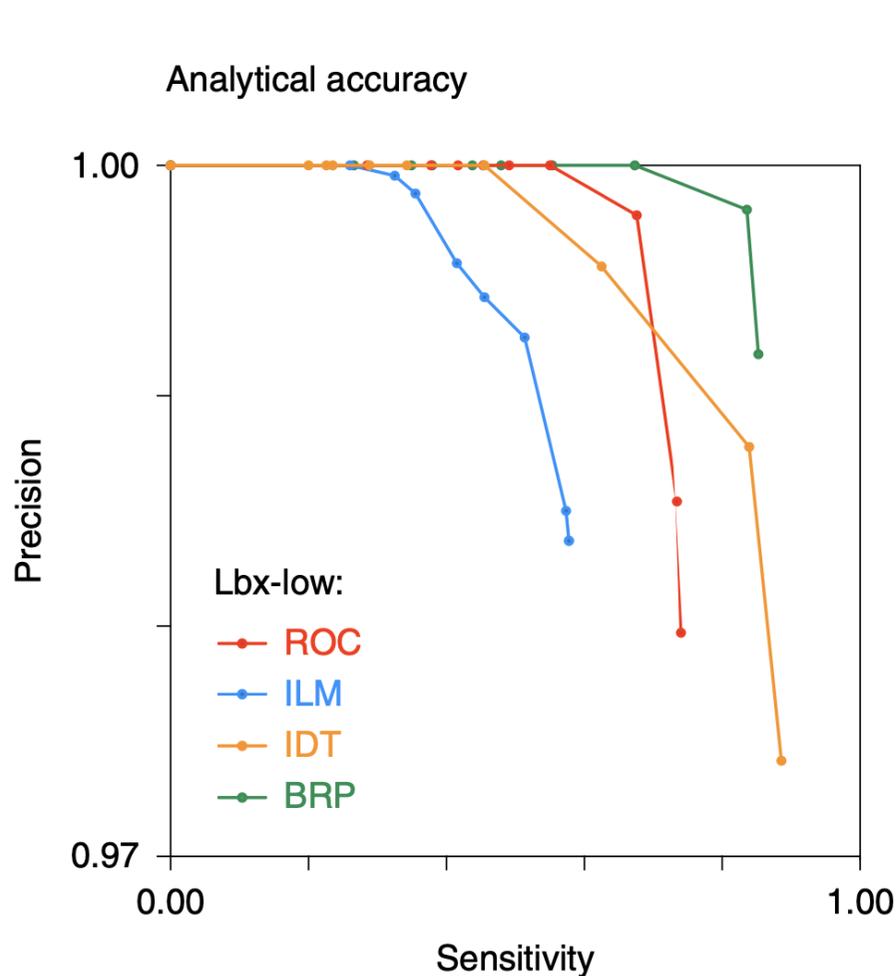
Assay	Known negatives (kb)	FPs per replicate (mean [range])	FP-rate (FP / kb) at specified VAF threshold		
			> 0%	> 0.1%	> 0.5%
ROC	47.1	2.91 [1-6]	0.061	0.044	0.000
ILM	133	5.25 [2-10]	0.039	0.039	0.008
IDT	39.3	2.75 [0-6]	0.070	0.057	0.000
BRP	53.4	1.65 [0-5]	0.030	0.007	0.000

The analytical accuracy was measured by **Precision-Sensitivity** plot (25ng LBx-Low)
The false positive rates were computed by FP/kb region.
Once different VAF threshold increases, FP rates dropped further.

"To compare the accuracy of the participating ctDNA assays, we generated precision recall curves, ranking known variants and FPs according to their observed VAFs. **For Lbx-low samples at 25ng input, BRP was the most accurate assay, with roughly equivalent sensitivity but superior precision to IDT** (Fig. 4b and Supplementary Fig. 4c). "

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Performance – Sensitivity

- LBx-low (25 ng input) replicates in each participating assay in different expected VAF bin.

"**The most sensitive assays (IDT and BRP) achieved sensitivity greater than 0.90 for variants with 0.3–0.5% VAF**; however, no assays reached this mark for variants with 0.2–0.3% or 0.1–0.2% VAF (Fig. 4a)."

"The performance characteristics of the assays evaluated here were broadly similar to what has been reported by several ctDNA sequencing providers (based on internal testing) that did not participate in this study. During validation of the Guardant360 CDx hybrid capture assay, variants were detected with high sensitivity (~94%) at VAF ≥ 0.4%, declining to ~64% among variants with VAF ranging from 0.05% to 0.25%." FoundationACT showed ~99% sensitivity for SNVs with VAF > 0.5%, ~95% for 0.25%–0.5% VAF and ~70% for 0.125–0.25% VAF."

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