燃石医学
Burning Rock Dx

Burning Rock Biotech Limited

2Q 2025 results

8 September 2025

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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

MRD[1]

Early-stage oncology patients

Biopharma

Global CDx[2] partners for pivotal trials of targeted drugs. Pharma R&D

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

Late-stage oncology patients

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

Recent progress

Continued efficiency gains, driving towards profitability

Delivering results on

1 Driving sales efficiency

- Increasing sales productivity per head
- Benefiting from more rational industry competition

2 Improving gross margin

- Leveraging our scale
- Delivering on margin improvement projects

3 Reducing G&A expenses

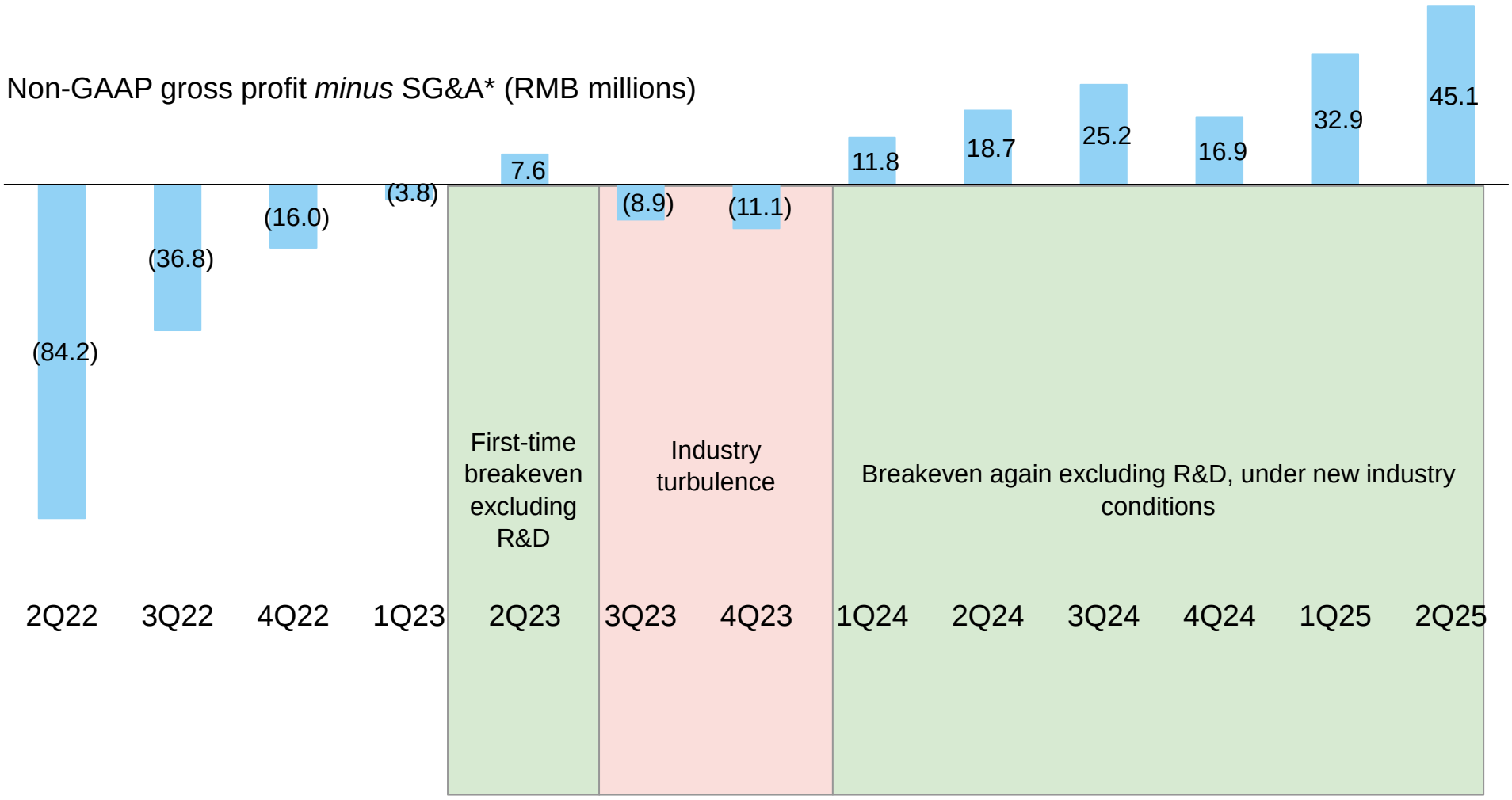
- Cutting overhead and lowering fixed cost-base

4 Reducing R&D expenses

- As clinical programs complete and run down
- Disciplined on new investment

2Q25 continues to get commercial breakeven under new industry conditions

Breakeven defined as Non-GAAP gross profit *minus* SG&A*



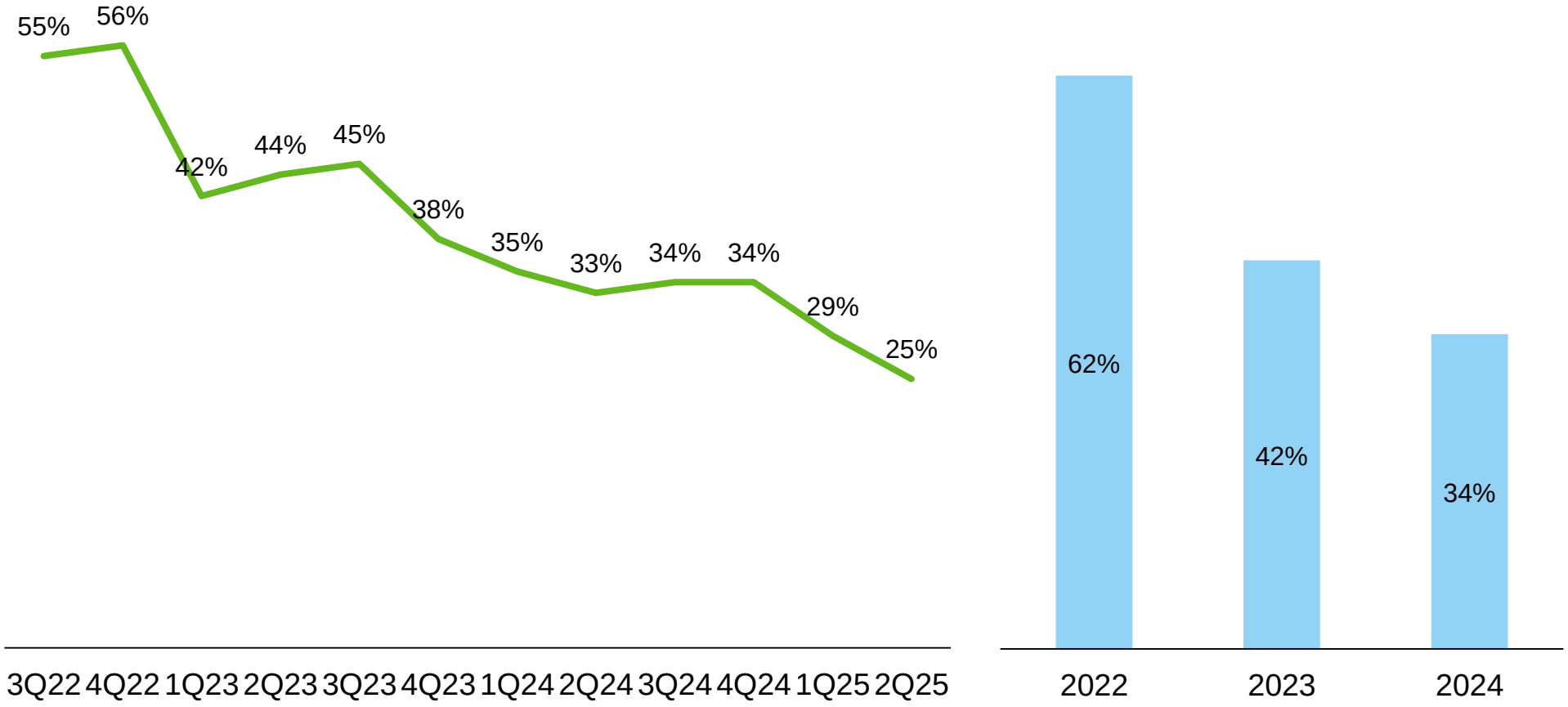
Notes:

* Non-GAAP gross profit, which is defined as gross profit excluding depreciation and amortization. Non-GAAP SG&A refers to selling and marketing expenses and general and administrative expenses, both excluding their respective share-based compensation and depreciation and amortization.

1 Driving sales efficiency

Expect below 40% selling expense going forward

Non-GAAP sales and marketing expenses as % of revenue*

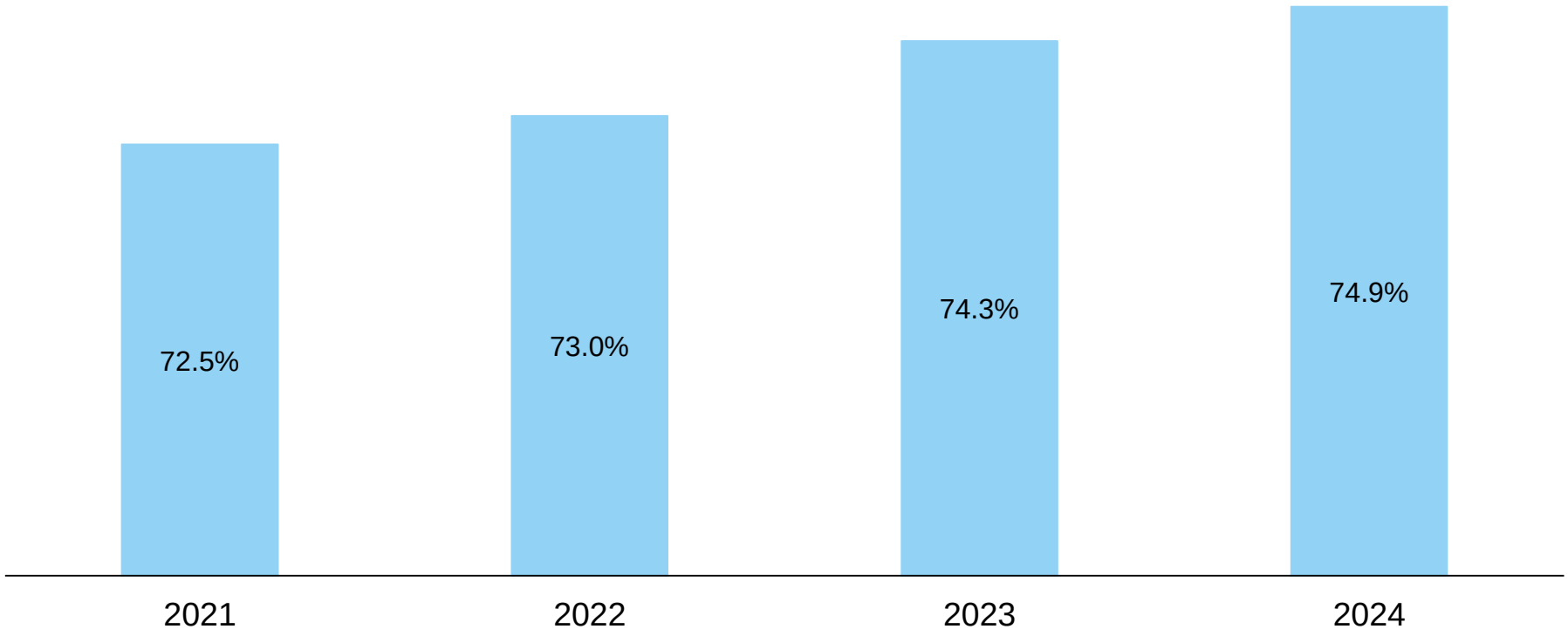


Notes:
* Excluding share based compensation (SBC) and depreciation and amortization (D&A)

2 Improving gross margin

Delivering on margin improvement initiatives

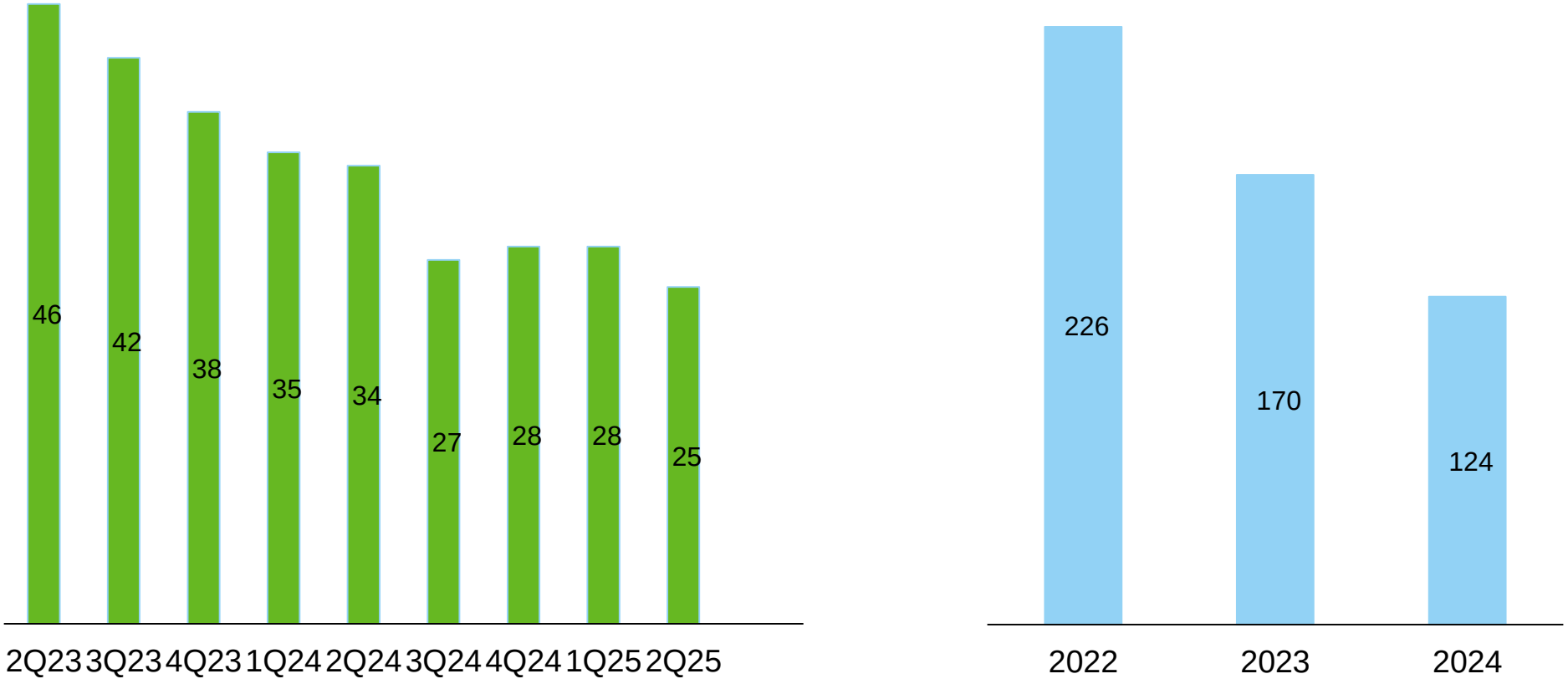
Non-GAAP gross profit as % of revenue*



Notes:
* Non-GAAP gross margin, which is defined as gross margin excluding depreciation and amortization (D&A)

3 Reducing G&A expenses
Cost savings going into 2025

General and admin expenses *minus* noncash items * (RMB millions)



Notes:
* Excluding share based compensation (SBC), depreciation and amortization (D&A) and allowance for doubtful accounts.

Commercial operation (excluding R&D expenses) reached profitability in 1H2025

RMBm	2022	2023	2024	1H2025
Operating cash outflow[1]	457	256	92	68
Capex[2]	75	9	6	1
Sum	532	265	98	69
Cash balance at period-end	925	615	522	455

Notes:
[1] Net cash used in operating activities
[2] Purchase and prepayment of property and equipment and intangible assets, issuance of convertible loan, out of investing cashflows

Financials

Steady progress of improving margins, profitability and reducing cash outflows

RMB millions	2023	2024	YoY	1Q24	2Q24	3Q24	4Q24	1Q25	2Q25	2Q25 YoY	2Q25 QoQ
Revenues	**537.3**	**516.0**	***-4%***	**125.6**	**135.6**	**128.7**	**126.1**	**133.1**	**148.6**	***10%***	***12%***
Central lab	232.8	175.7	*-25%*	47.6	48.8	40.0	39.3	38.3	40.9	*-16%*	*7%*
In-hospital[1]	188.6	224.6	*19%*	57.4	59.9	63.8	43.5	57.7	62.5	*4%*	*8%*
Pharma	115.9	115.7	*0%*	20.6	26.9	24.9	43.3	37.1	45.2	*68%*	*22%*
Non-GAAP gross profit[2]	**399.4**	**386.3**	***-3%***	**93.0**	**101.9**	**97.8**	**93.6**	**100.7**	**110.5**	***8%***	***10%***
Total opex	**1,032.4**	**720.1**	***-30%***	**211.6**	**206.7**	**130.5**	**171.3**	**112.6**	**119.6**	***-42%***	***6%***
R&D[3]	264.8	191.1	*-28%*	49.0	50.8	43.7	47.6	38.0	48.9	*-4%*	*29%*
S&M[3]	227.4	176.4	*-22%*	43.7	45.3	44.2	43.2	38.7	36.8	*-19%*	*-5%*
G&A[3]	188.3	137.3	*-27%*	37.5	37.9	28.4	33.5	29.1	28.6	*-25%*	*-2%*
SBC	258.4	153.7		68.8	67.6	9.8	7.5	4.2	2.1		
D&A	93.5	26.5		12.6	5.1	4.4	4.4	2.6	3.2		
Impairment	-	35.1		-	-	-	35.1	-	-		
Non-GAAP GP – SG&A	**(16.3)**	**72.6**		**11.8**	**18.7**	**25.2**	**16.9**	**32.9**	**45.1**		
Adjusted EBITDA[4]	**(260.4)**	**(101.3)**		**(33.7)**	**(27.3)**	**(16.6)**	**(23.7)**	**(3.1)**	**(0.6)**		
Operating profit	**(669.3)**	**(357.5)**		**(125.8)**	**(111.2)**	**(38.6)**	**(81.9)**	**(15.2)**	**(11.5)**		
Net operating cash flows	**(255.7)**	**(92.2)**		**(40.2)**	**(40.8)**	**(30.3)**	**19.1**	**(23.5)**	**(44.3)**		
Non-GAAP GP margin[2]	74.3%	74.9%		74.0%	75.2%	76.0%	74.3%	75.7%	74.4%		
Opex[3] / revenue	127%	98%		104%	99%	90%	99%	80%	77%		
S&M[3] / revenue	42%	34%		35%	33%	34%	34%	29%	25%		

[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] Non-GAAP gross profit or margin, which is defined as gross profit or margin excluding depreciation and amortization (D&A)
[3] Excluding share based compensation (SBC) and depreciation and amortization (D&A)
[4] 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.

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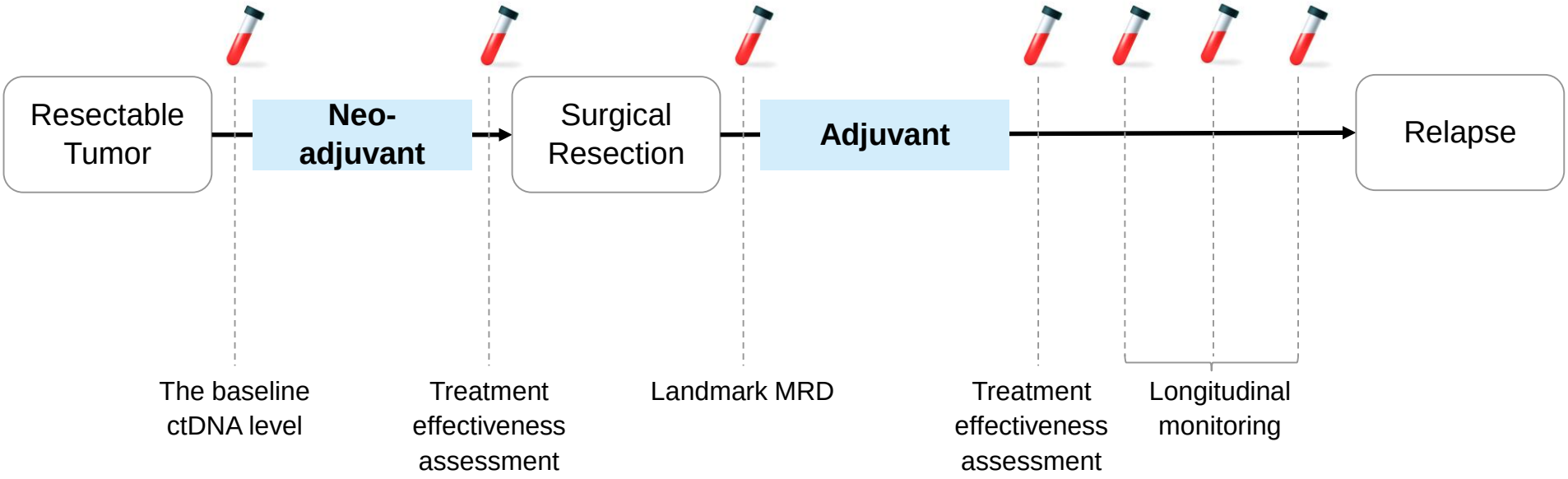
Minimal Residual Disease (MRD)

Burning Rock's MRD clinical publications

Covering adjuvant and relapse settings in lung, colorectal, gastric and other cancers

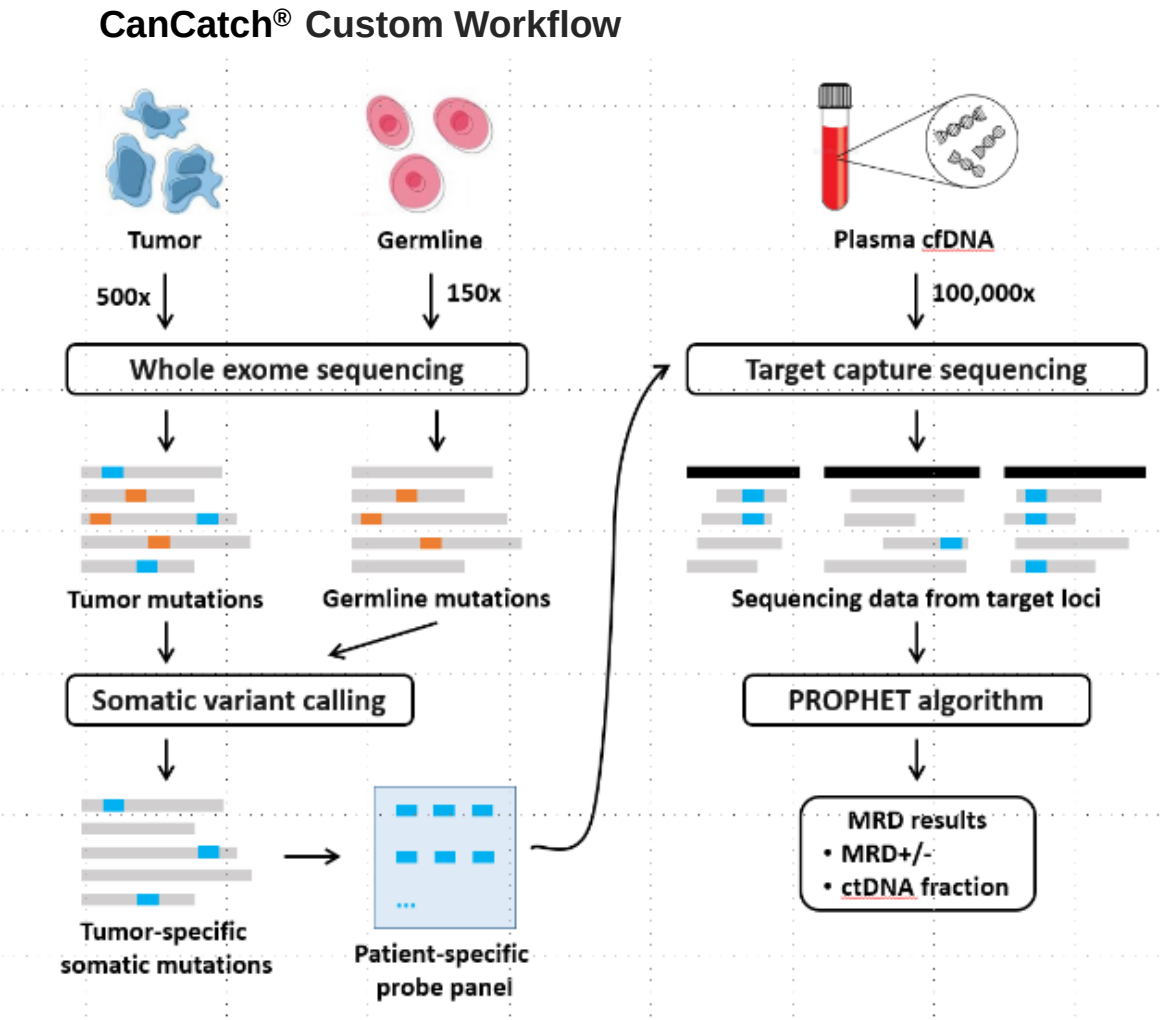


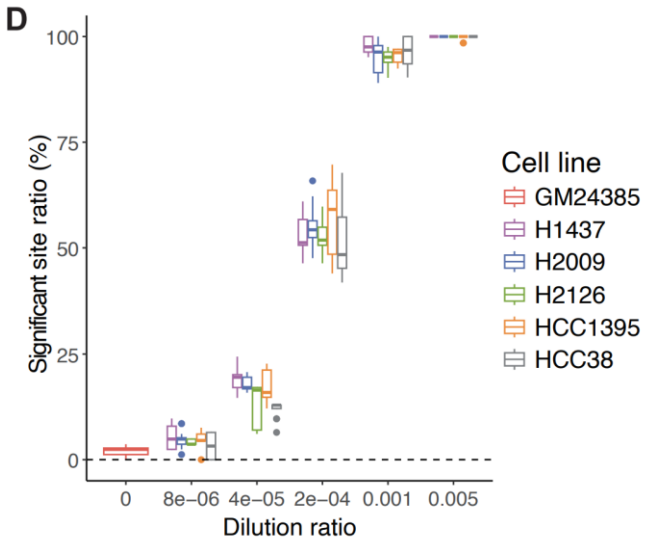
Non-small-cell lung cancer	Baseline, landmark and longitudinal monitoring timepoints completed AACR 2022 Abstract 5916, AACR 2023 Abstract 1039, MEDAL study publication	
Colorectal cancer	Baseline and landmark timepoints AACR 2022 Abstract 5917, ASCO GI 2023 Abstract 213	Longitudinal monitoring ongoing
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	

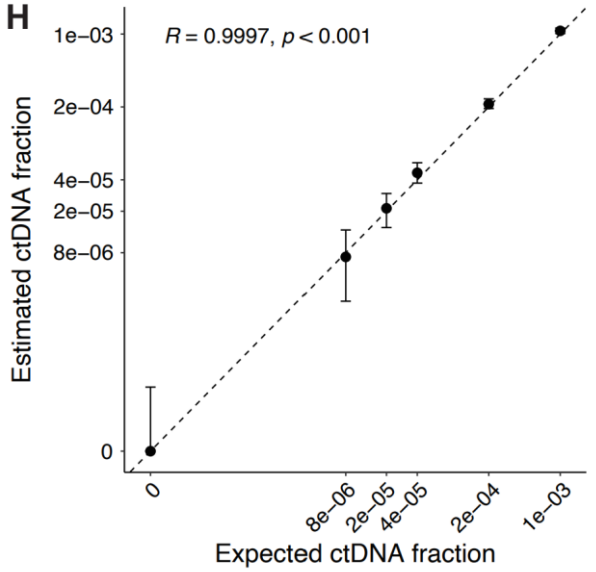
Cancer Cell

Overview of CanCatch® Custom (Previously named brPROPHET)

An ultrasensitive and quantitative MRD assay







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

MEDAL study

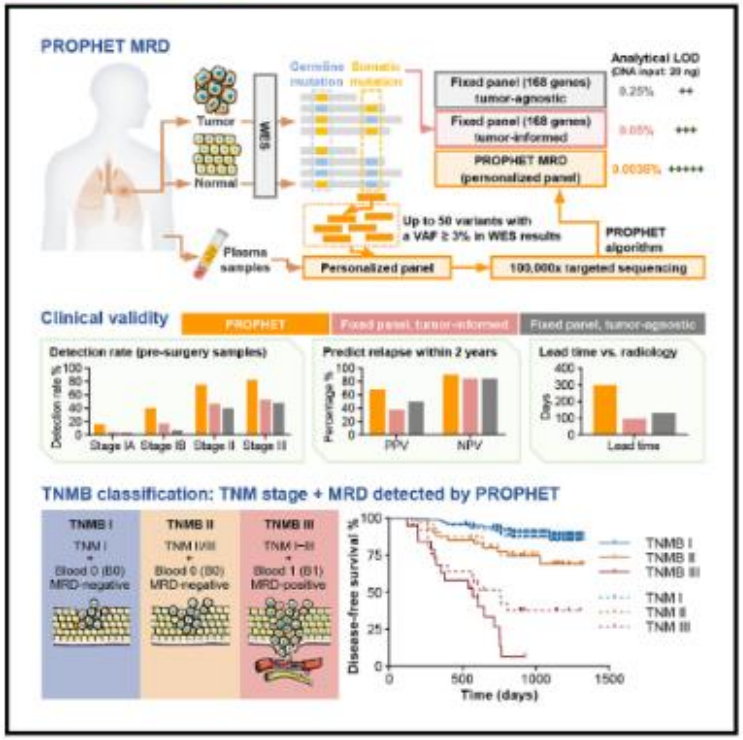
Personalized MRD using CanCatch® Custom on non-small cell lung cancer (NSCLC)

Article

Cancer Cell

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

Graphical abstract



Authors

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Correspondence

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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.

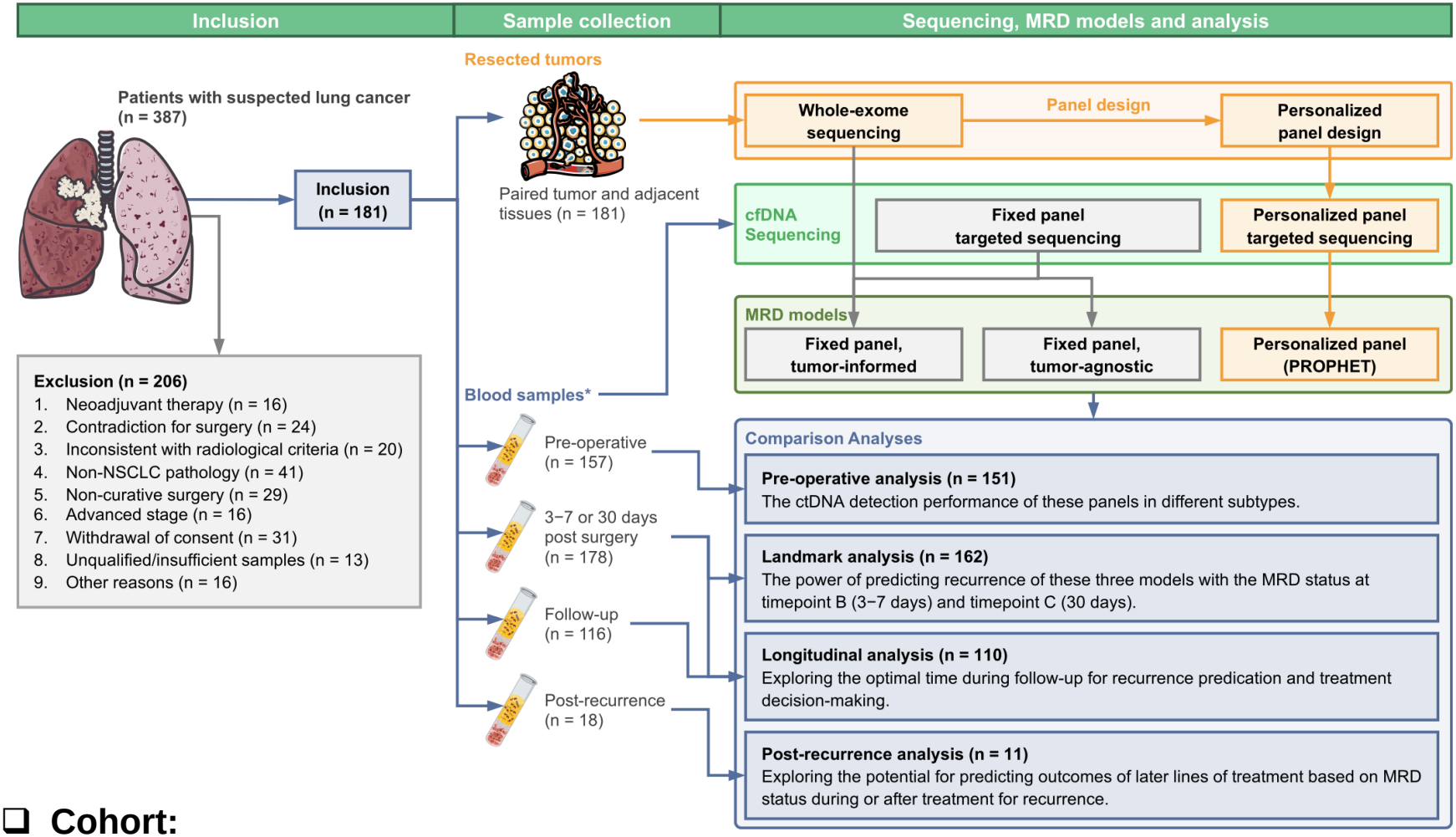
Highlights

- 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

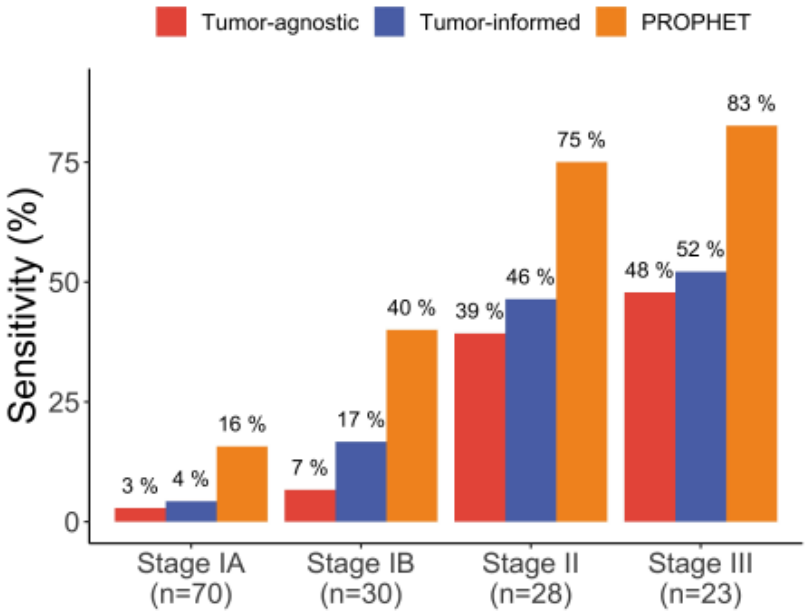
Source: Chen et al., Individualized tumor-informed circulating tumor DNA analysis for postoperative monitoring of non-small cell lung cancer, Cancer Cell, Sep 2023

CanCatch® Custom demonstrates superior sensitivity in ctDNA detection

Clinical validation with pre-operative plasma samples

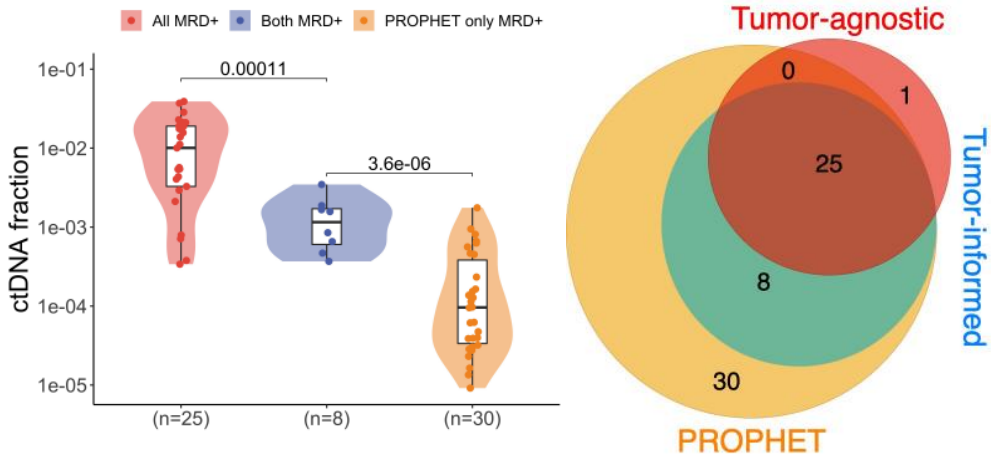
(a)

Sensitivity of pre-operative plasma



(b)

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

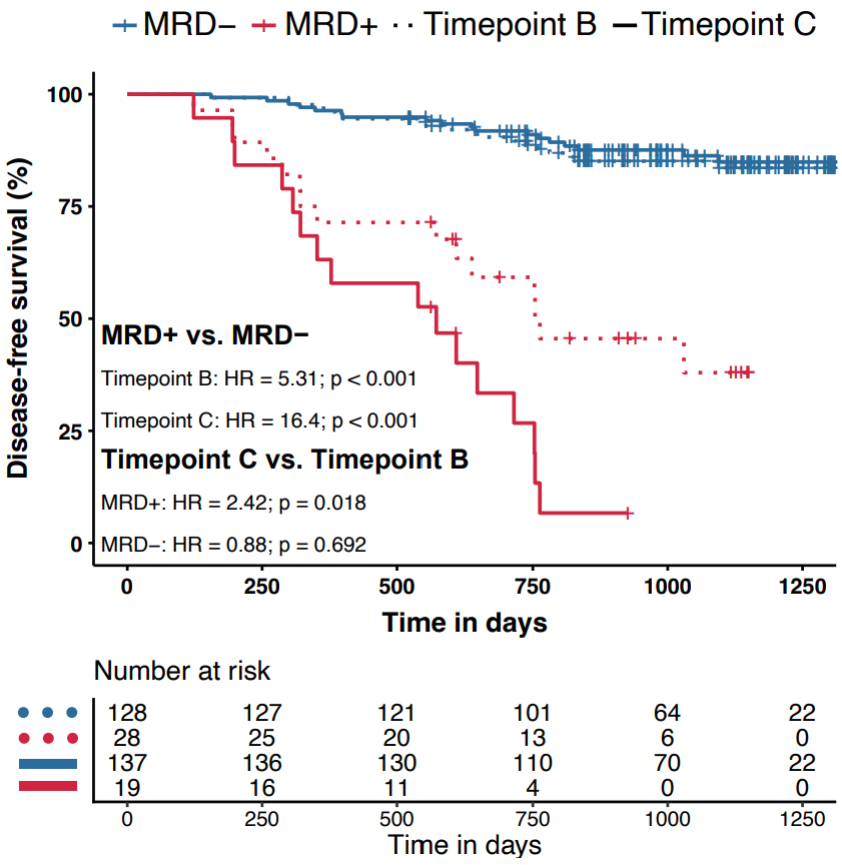


- For pre-operative plasma from patients with different clinical stages, CanCatch® Custom has a higher sensitivity than the other two methods
- The median ctDNA fraction of the 30 patients detected by CanCatch® Custom alone was significantly lower than the 25 patients detected by all three MRD assays

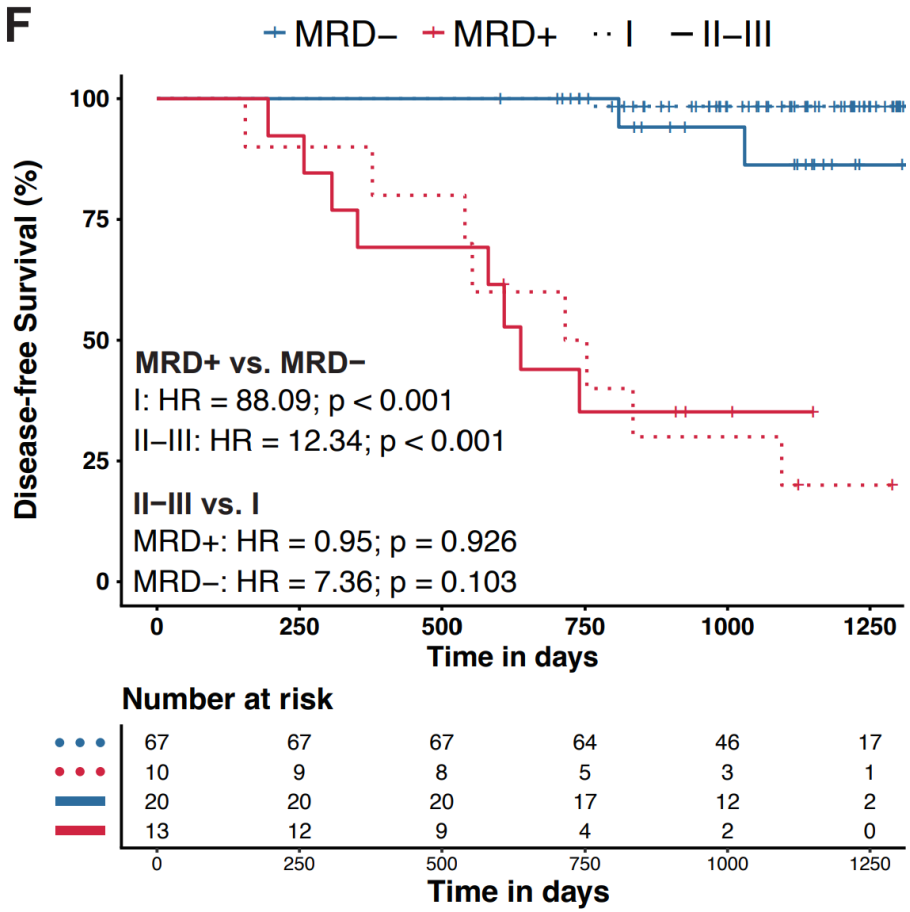
The patient-specific CanCatch® Custom has a higher sensitivity than the two fixed panel detection methods

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

CanCatch® shows strong prognostic value in post-surgery NSCLC patients



Prognostic analysis at Landmark time points



Longitudinal MRD analysis

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

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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

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

Prof. Jie Wang

- Head of the Dept. of Medicine, CHCAMS

PREVENT

Principal Investigator: Prof. Weiming Li

- President of West China Hospital

Notes:
[1] Based on 2018 statistics
[2] http://rank.cn-healthcare.com/rank/general-best
[3] CHCAMS

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Appendix 1

Early detection

Product Development Roadmap

Proof-of-concept
2016 – 2019

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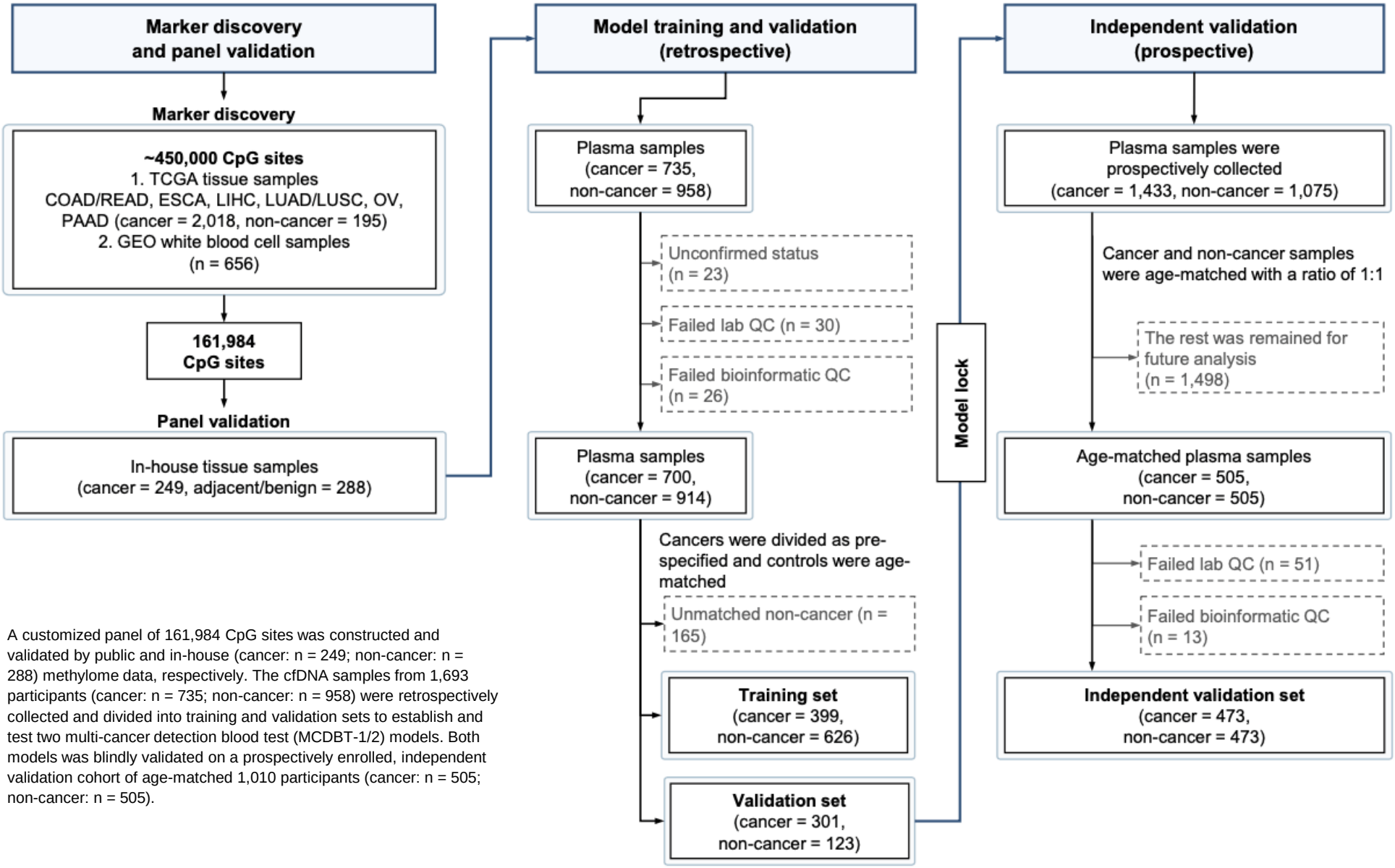
6-cancer test marker discovery and model training

The THUNDER study, 2395 participants



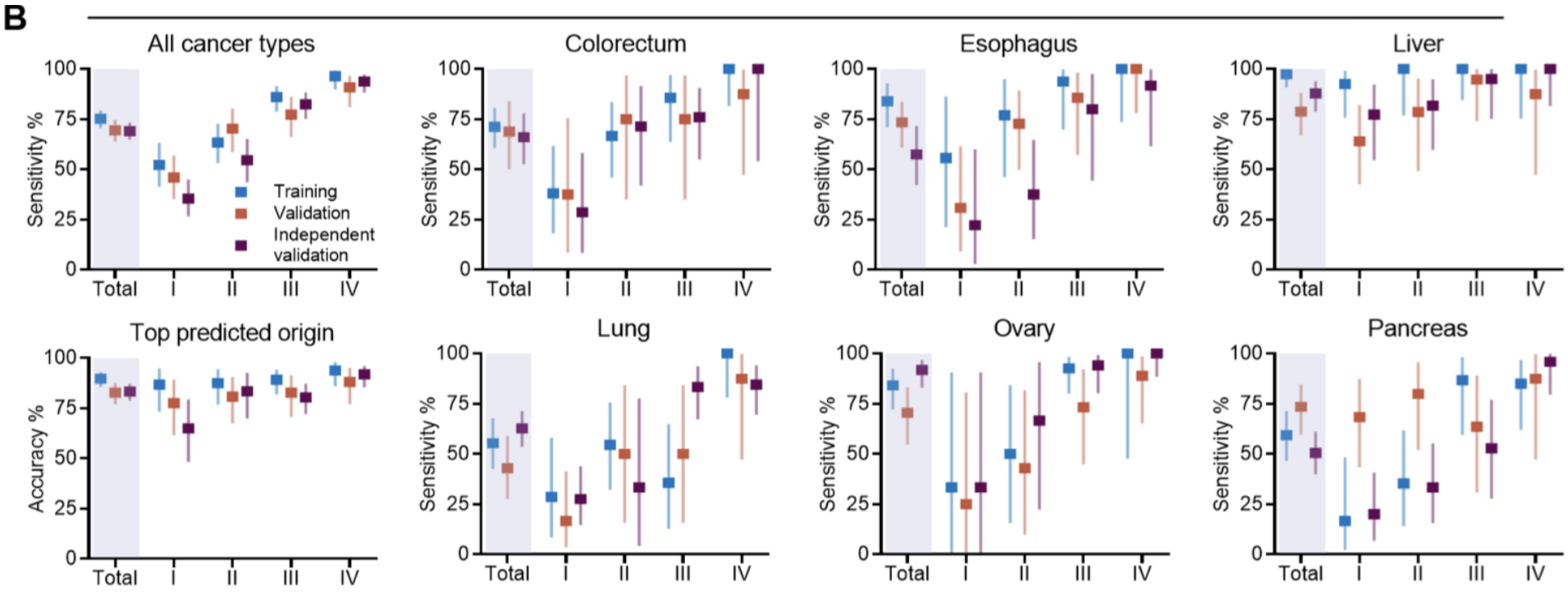
A customized panel of 161,984 CpG sites was constructed and validated by public and in-house (cancer: n = 249; non-cancer: n = 288) methylome data, respectively. The cfDNA samples from 1,693 participants (cancer: n = 735; non-cancer: n = 958) were retrospectively collected and divided into training and 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).

Source: Gao et al., Unintrusive multi-cancer detection by circulating cell-free DNA methylation sequencing (THUNDER): development and independent validation studies, ASCO 2022

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.



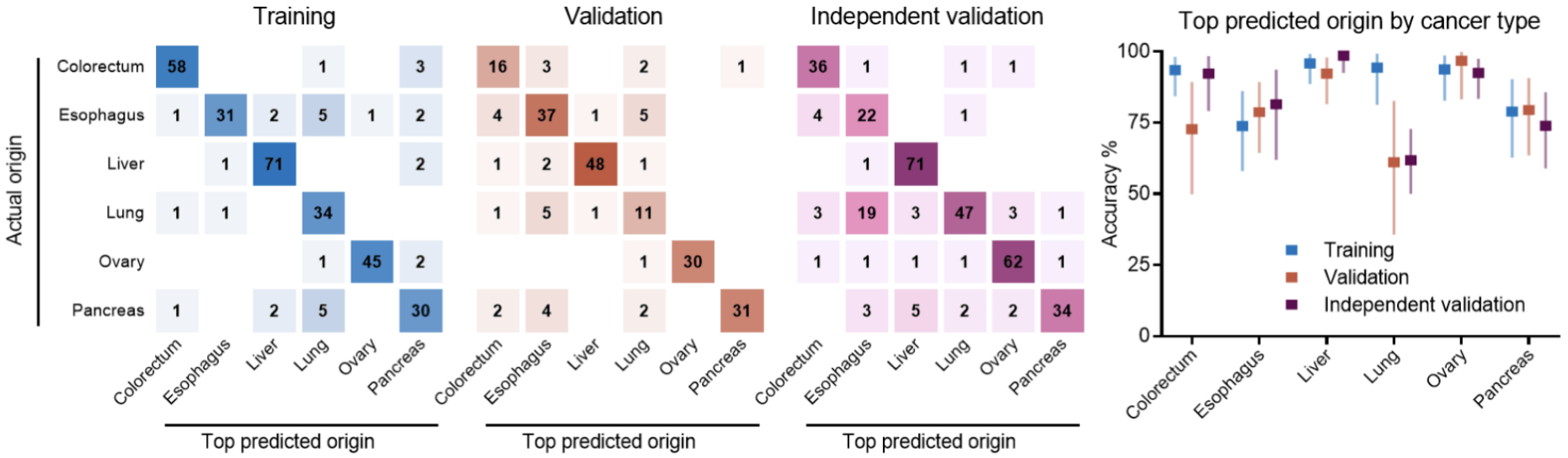
Data set	Specificity (%)	Sensitivity (%)	Accuracy of top predicted origin (%)	Accuracy of top two predicted origins (%)
Training set	99.7 (98.9-100.0)	75.2 (70.6-79.4)	89.7 (85.7-92.9)	94.7 (91.5-96.9)
Validation set	100.0 (97.0-100.0)	69.4 (63.9-74.6)	82.8 (77.0-87.6)	89.4 (84.5-93.3)
Independent validation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

Source: Gao et al., Unintrusive multi-cancer detection by circulating cell-free DNA methylation sequencing (THUNDER): development and independent validation studies, ASCO 2022

6-cancer test, top-predicted-origin performance in case-control cohorts

The THUNDER study

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.



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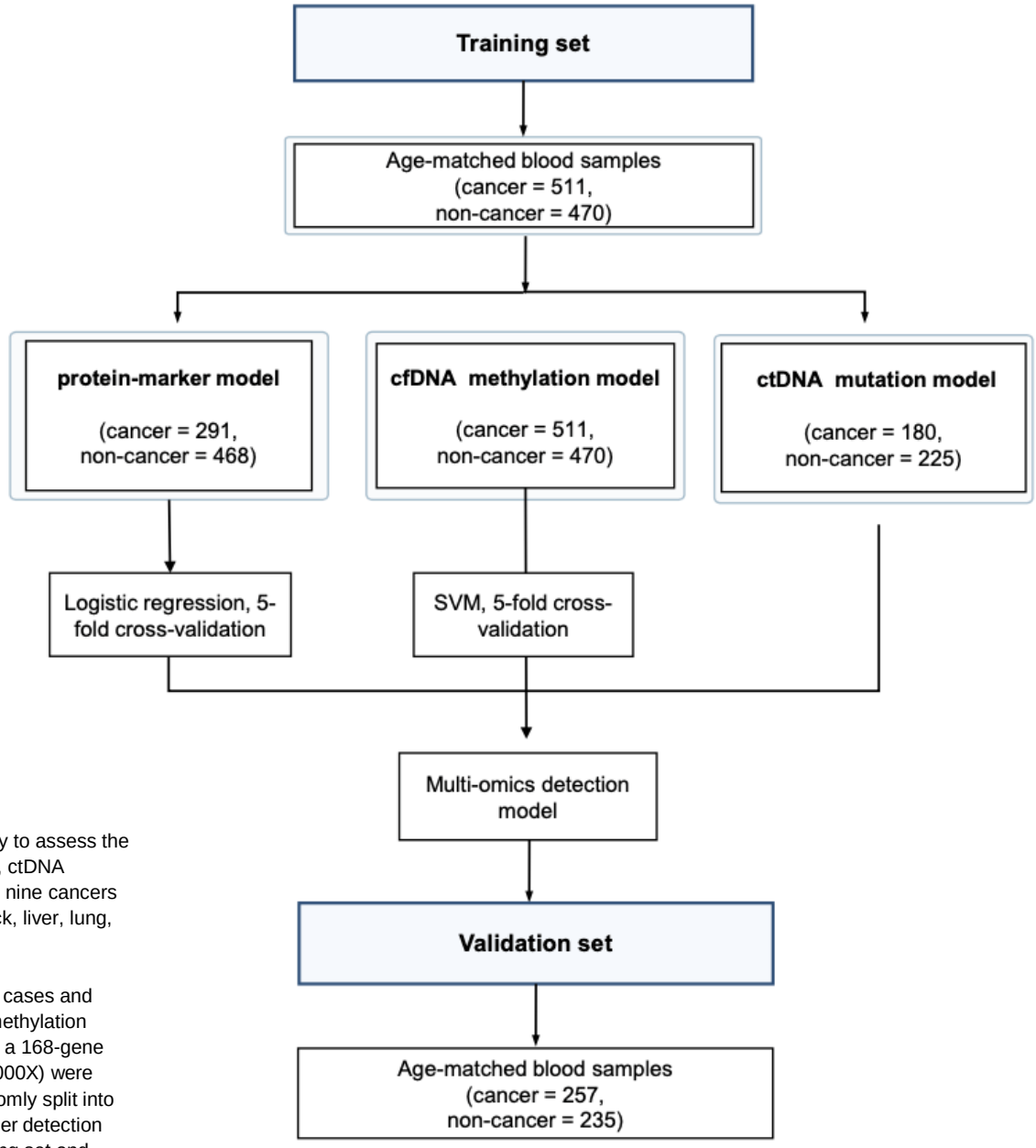
22-cancer
2019 – 2022

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

9-cancer test, multi-omics model

The PROMISE study



PROMISE is a prospective multicenter case-control study to assess the performance of multi-omics including cfDNA methylation, ctDNA mutation and protein biomarkers in the early detection of nine cancers in the biliary tract, colorectum, esophagus, head and neck, liver, lung, ovary, pancreas and stomach.

Blood samples were prospectively collected from cancer cases and non-cancer controls. A targeted cell-free DNA (cfDNA) methylation panel of ~490,000 CpG sites (1,000X) by ELSA-seq and a 168-gene mutation panel (35,000X, matched white blood cells:10,000X) were sequenced. Age-matched cases and controls were randomly split into training (n = 981) and test sets (n = 492). The multi-cancer detection blood test (MCDBT) models were developed in the training set and then validated in the test set.

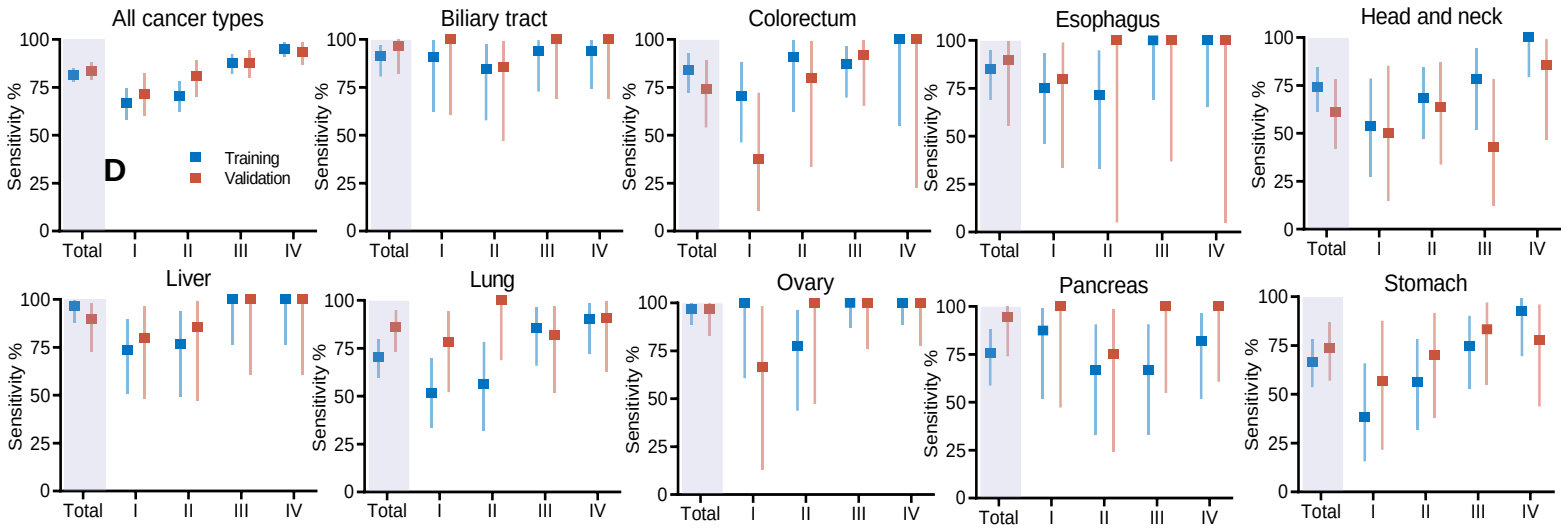
Source: Gao et al., a multi-cancer early detection model based on liquid biopsy of multi-omics biomarkers, ESMO 2022

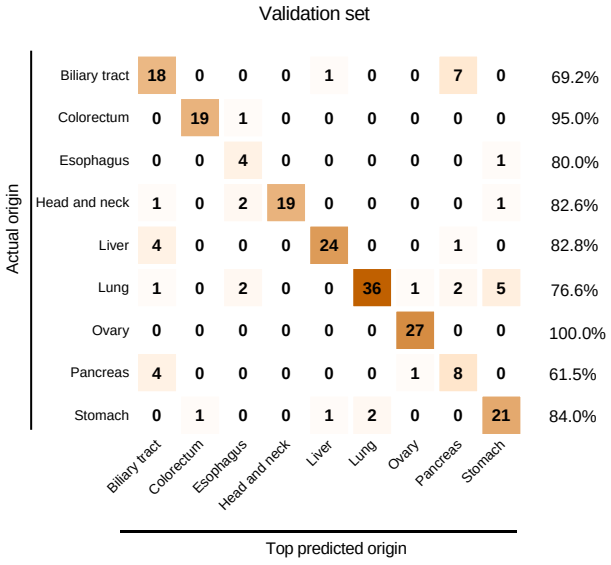
9-cancer test multi-omics model performance

The PROMISE study

	Cancer (n)	Non-cancer (n)	Specificity (%)	Sensitivity (%)	Accuracy of top predicted origin (%)
Training	470	511	97.9% (96.1%-99.0%)	81.7% (78.1%-84.9%)	86.6% (83.0%-90.0%)
Validation	257	235	98.3% (96.6%-99.4%)	83.7% (79.0%-88.0%)	81.9% (76.0%-87.0%)

	Multi-omics	Methylation	Mutation	Protein
Specificity (95% CI)	98.3% (96.6%–99.4%)	99.1% (97.3%–99.8%)	99.6% (97.9%–100.0%)	99.6% (98.7%–100.0%)
Sensitivity (95% CI)	83.7% (78.6%–88.0%)	79.0% (73.5%–83.8%)	49.4% (41.9%–57.0%)	47.8% (40.8%–54.9%)

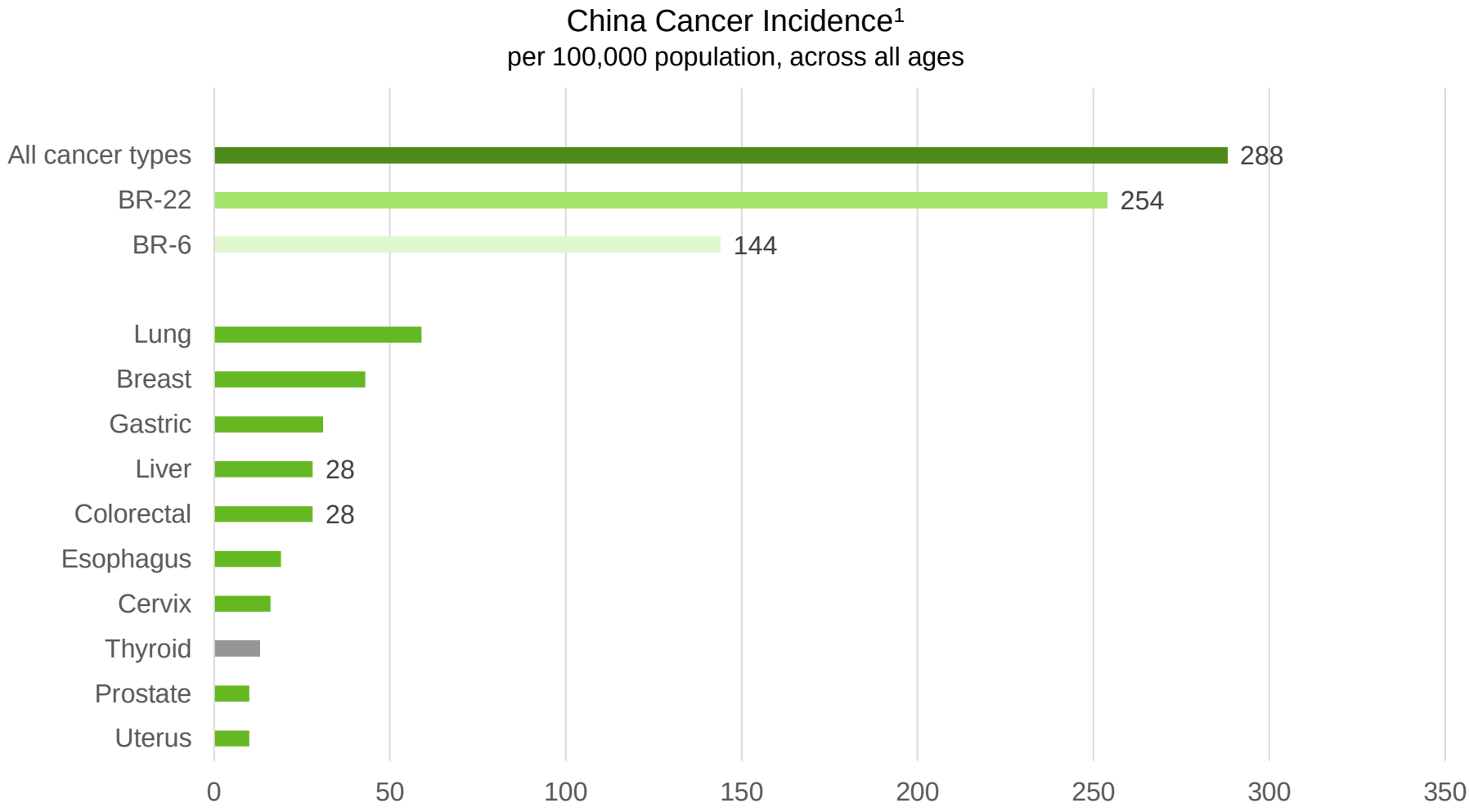




- PROMISE demonstrated 83.7% sensitivity and 98.3% specificity for 9 cancers
- Methylation contributed >90% of the total sensitivity, while protein and mutation collectively provided <10% additional positive detections

Source: Gao et al., a multi-cancer early detection model based on liquid biopsy of multi-omics biomarkers, ESMO 2022

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



Notes:

[1] Incidence data per "2018 China cancer registry annual report ", J He et al., ISBN 978-7-117-28585-8

[2] Final number of cancer types subject to development progress

Leadership in multi-cancer early detection

First-in-class, high entry-barrier, multi-year efforts

	Challenges	BNR position
1 **Technology**	**Low amount of cancer signal** in the circulating bloodstream, much more challenging compared to tissue	**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

燃石医学
Burning Rock Dx

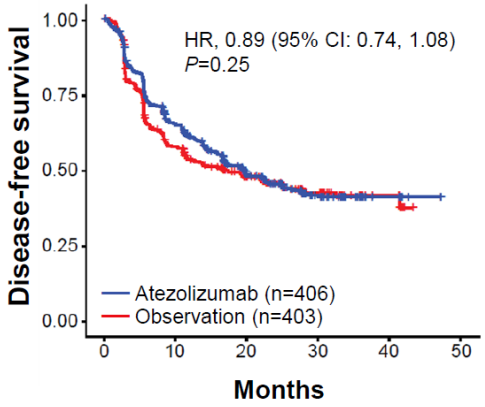
Appendix 2

MRD

How do MRD studies advance utility

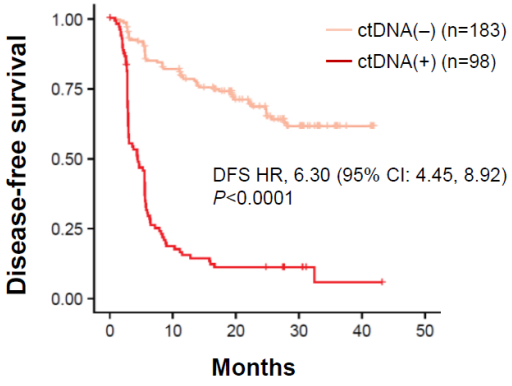
Example 1: IMvigor010, enrich the high-risk group and "tune-up" adjuvant treatment

ITT

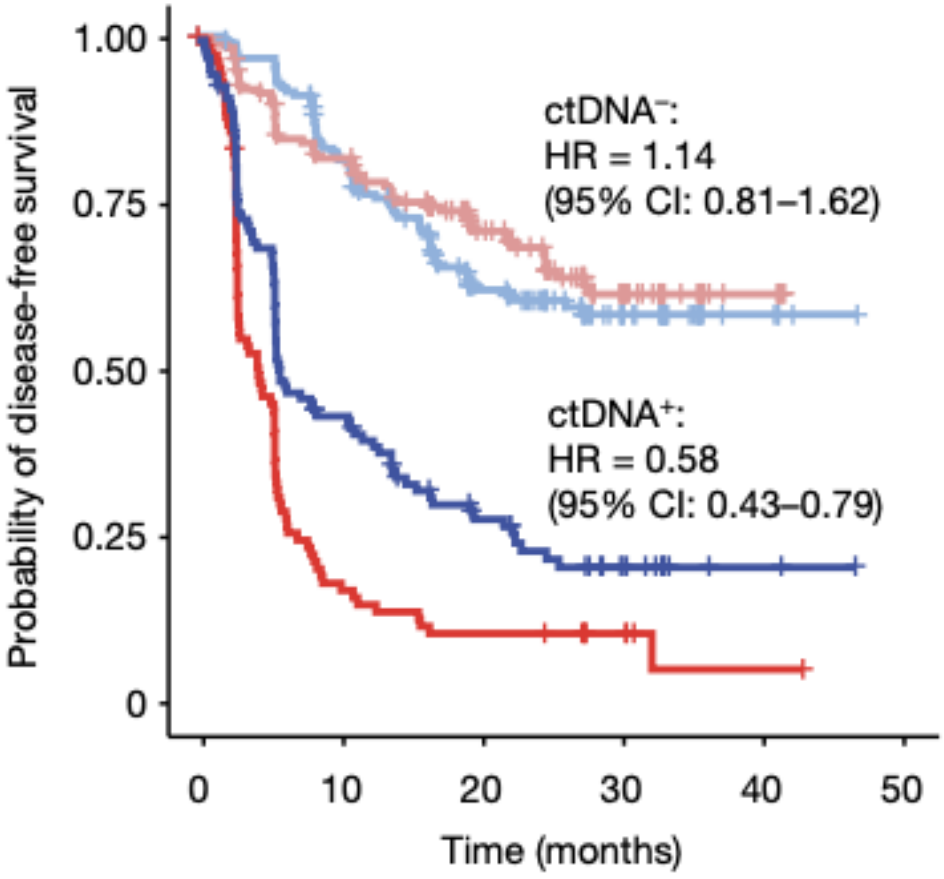


Atezo, MIUC Adjuvant Therapy
"All comers" demonstrated NO efficacy
TMB/PD-L1 showed NO prediction

Observation arm



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

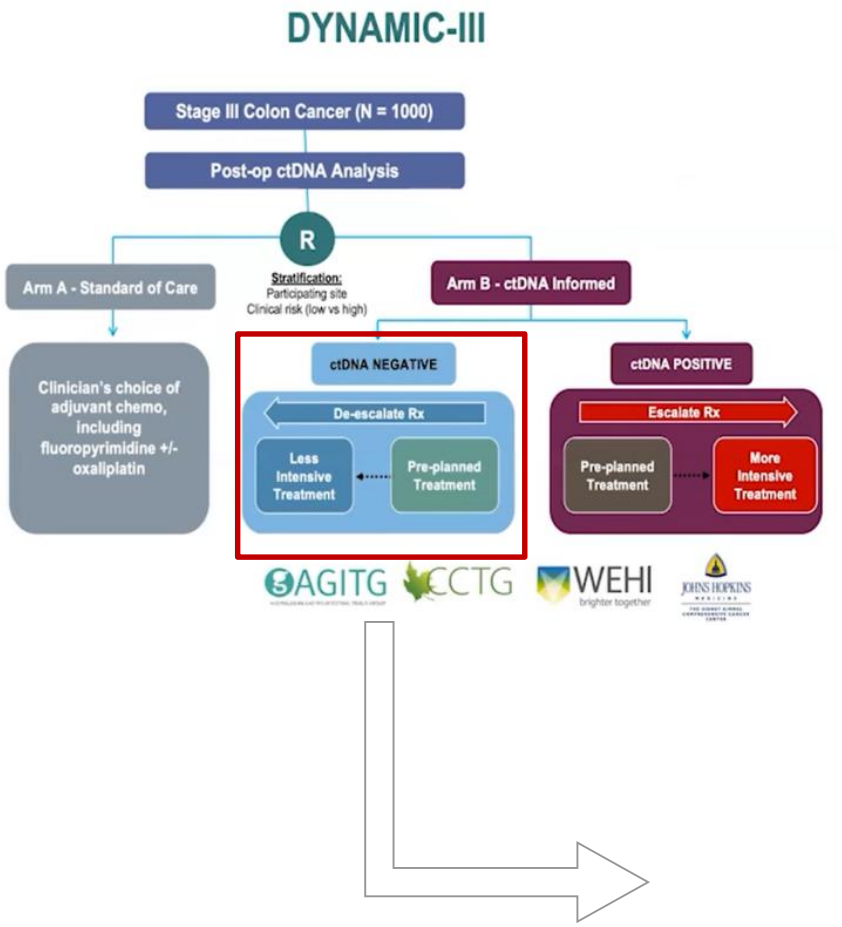


Indeed, only baseline MRD+ pts showed benefit

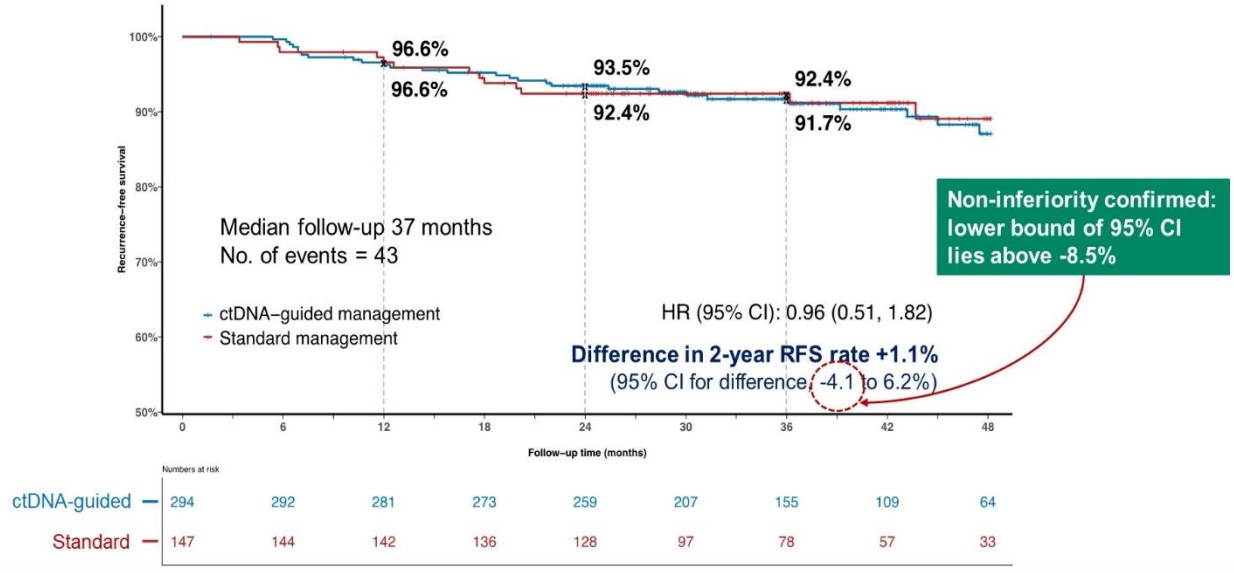
Nature. 2021 Jun 16. doi: 10.1038/s41586-021-03642-9.

How do MRD studies advance utility

Example 2: Dynamic, identify low-risk patients and "tune-down" adjuvant treatment

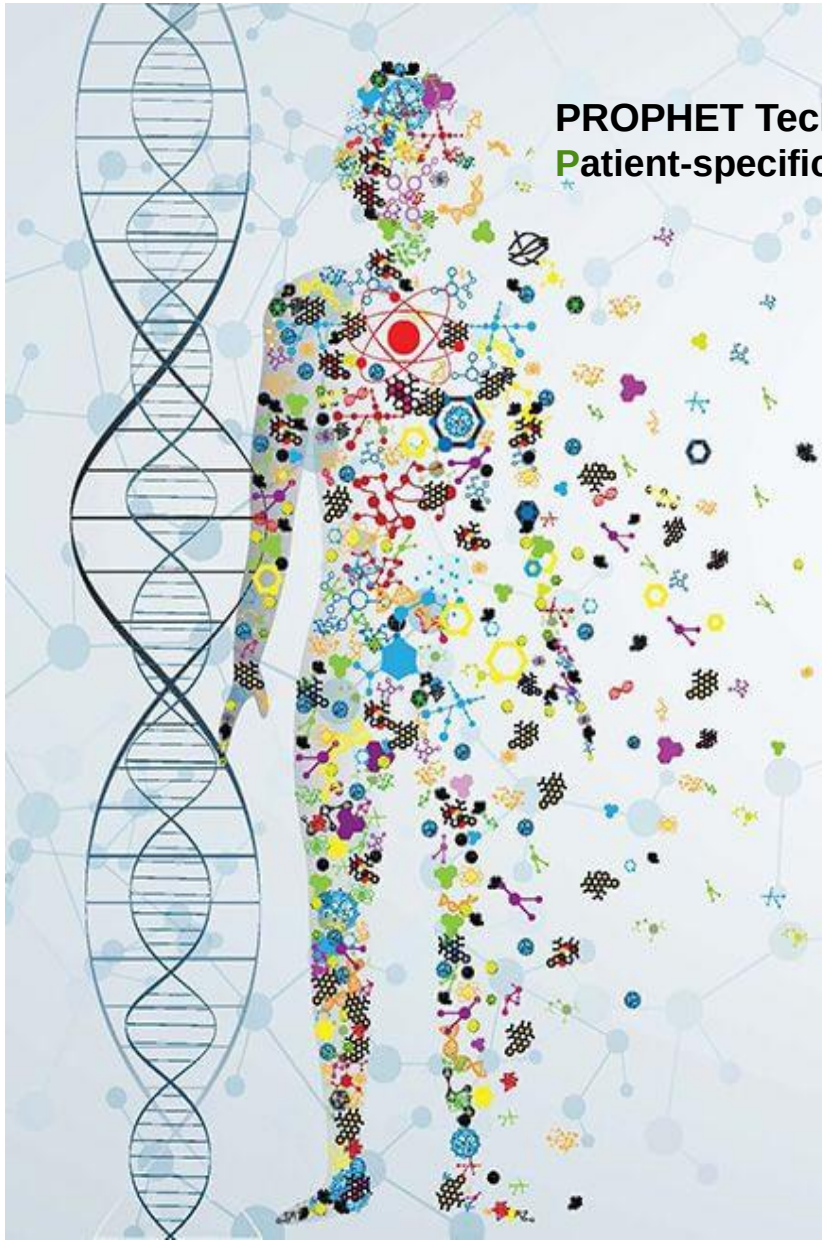


ctDNA-guided vs standard



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 pROgnostic and Potential tHErapeutic marker Tracking

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

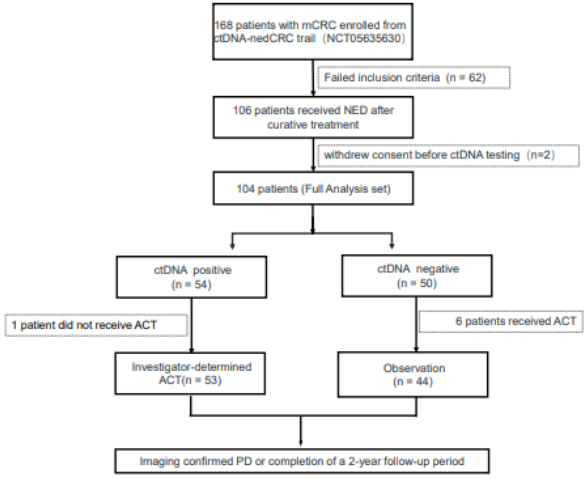
Yaqi Li[1], Xiang Hu[1], Chengcheng Li[2], Peng Cui[2], Xiang Hu[1], Fangqi Liu[1], Wenhua Li[3], Guoqiang Wang[2], Kunli Zhao[2], Qi Pan[4], Jing Wang[2], Bing Li[2], Shangli Cai[2], Junjie Peng[1]

[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.

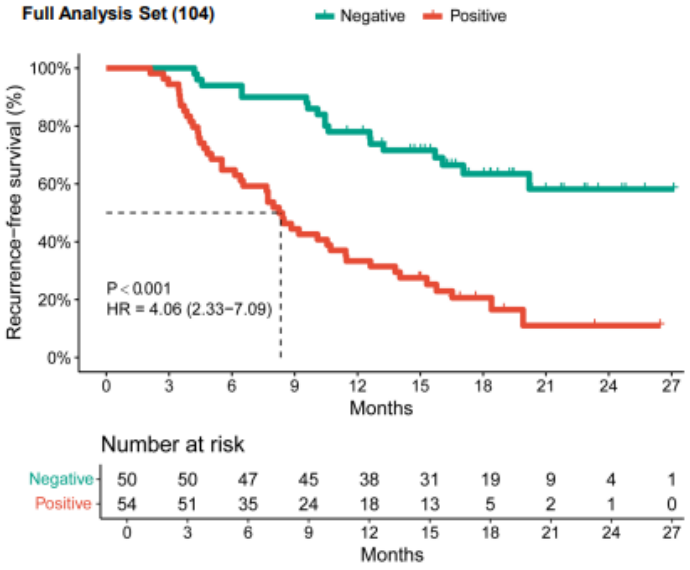
#4567

Flow chart

Figure 1. Flow chart.

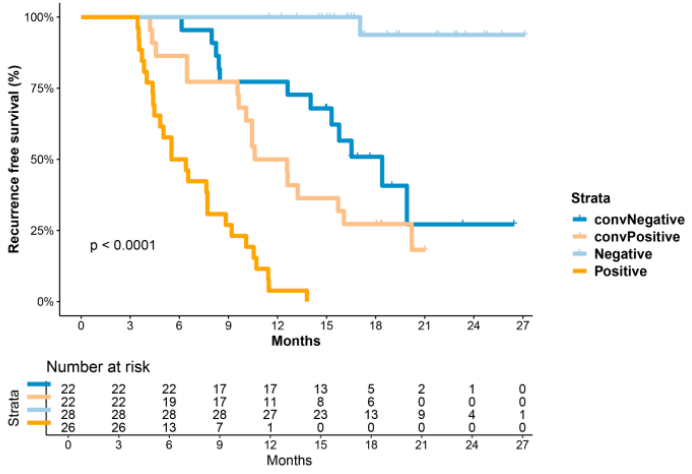


Patients with negative ctDNA results detected by CanCatch® after curative treatment demonstrated superior recurrence-free survival



Longitudinal ctDNA monitoring with CanCatch® demonstrates potential prognostic value

Figure 3. RFS stratified by longitudinal ctDNA status



Source: Li et al. 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 #4567
AACR 2025

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

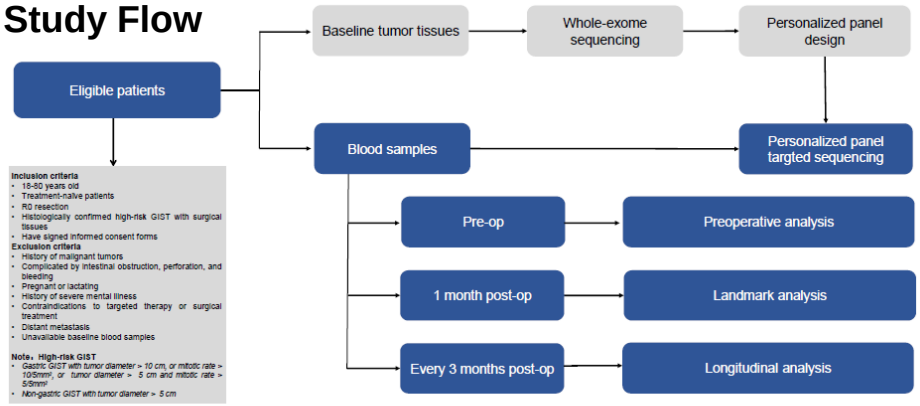
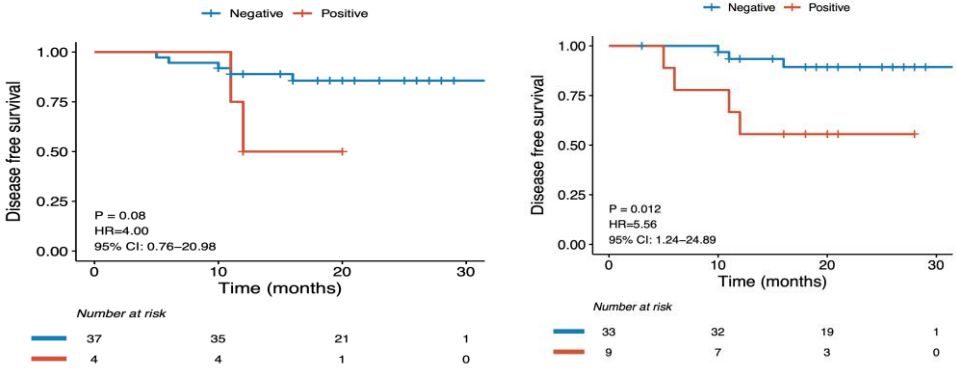
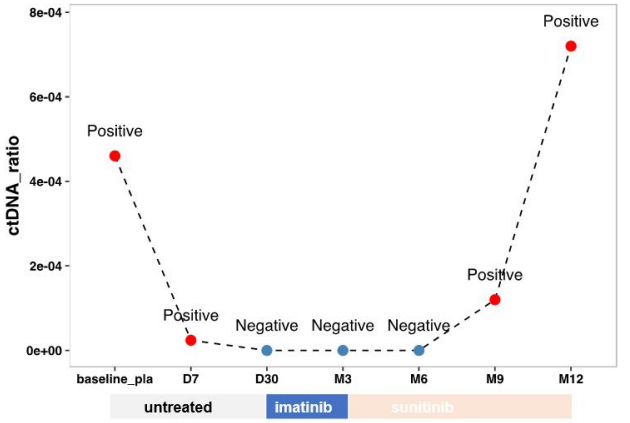


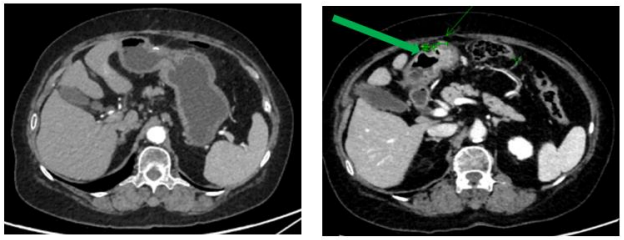
Figure 1: Overview of the study. Flow chart of the study. Pre-op, pre-operatively; post-op, post-operatively; GIST, gastrointestinal stromal tumor.



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.

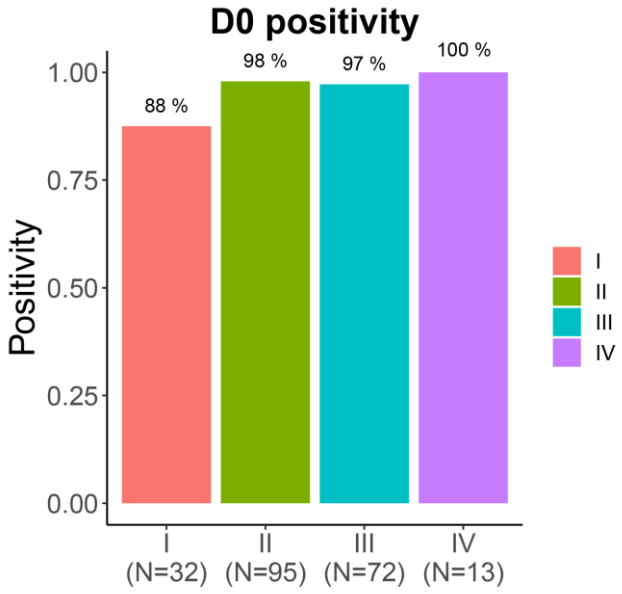
Source: Zhidong Gao et al. Personalized tumour-informed circulating tumor DNA analysis in monitoring recurrence following resection of high-risk locally advanced stage gastrointestinal stromal tumor #11522 ASCO 2025

Colorectal cancer cohort publication at ASCO 2024

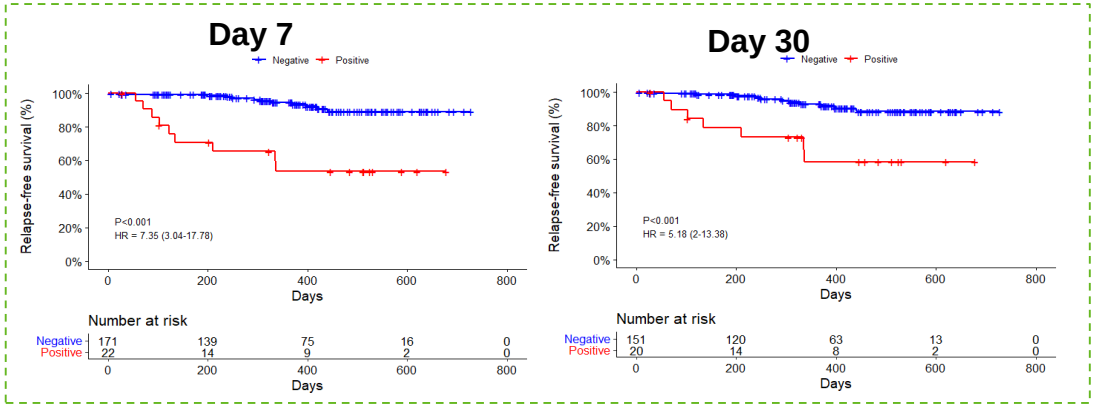
Individualized Tumor-Informed Circulating Tumor DNA Analysis for Molecular Residual Disease Detection in Predicting Recurrence and Efficacy of Adjuvant Chemotherapy in Colorectal Cancer

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



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 na ïve (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.

Source: Di Cao et al. Individualized Tumor-Informed Circulating Tumor DNA Analysis for Molecular Residual Disease Detection in Predicting Recurrence and Efficacy of Adjuvant Chemotherapy in Colorectal Cancer
#3615
ASCO 2024

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Appendix 3

Therapy selection

NMPA approved NGS panels

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

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

Highlights on our second NMPA-approved kit

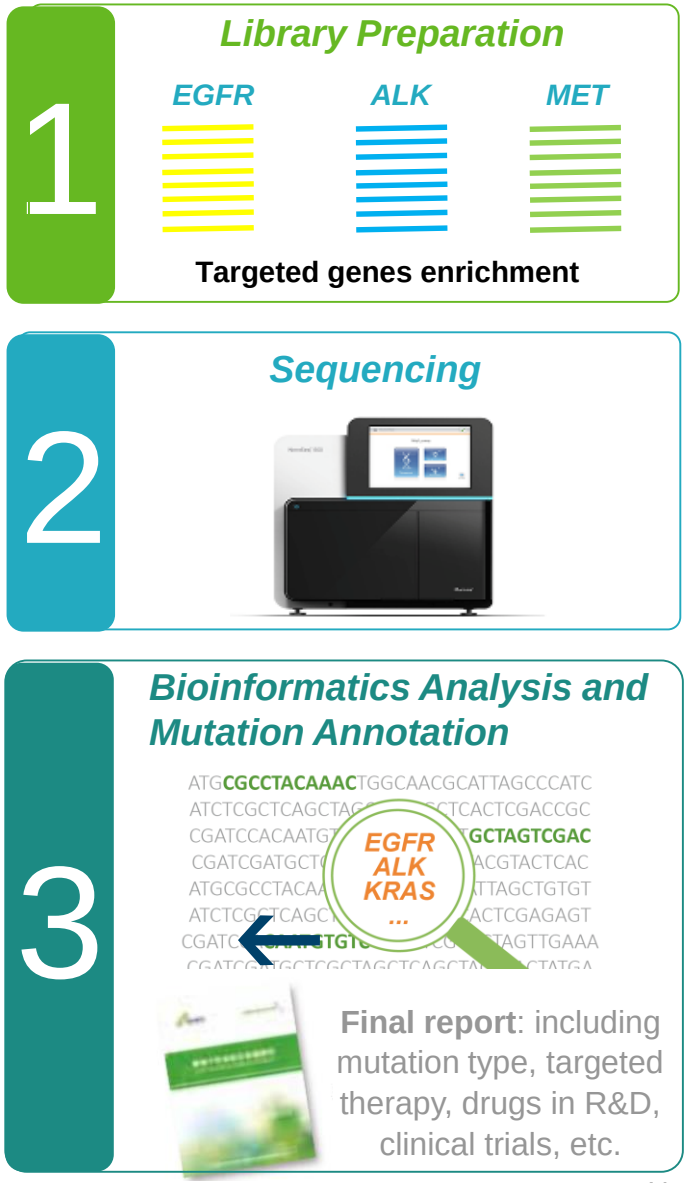
- Only 30ng DNA input required, applicable to small tissue samples
- First NMPA approved NGS kit with CNV[2] mutation type, with MET exon14 skipping

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**



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).

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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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

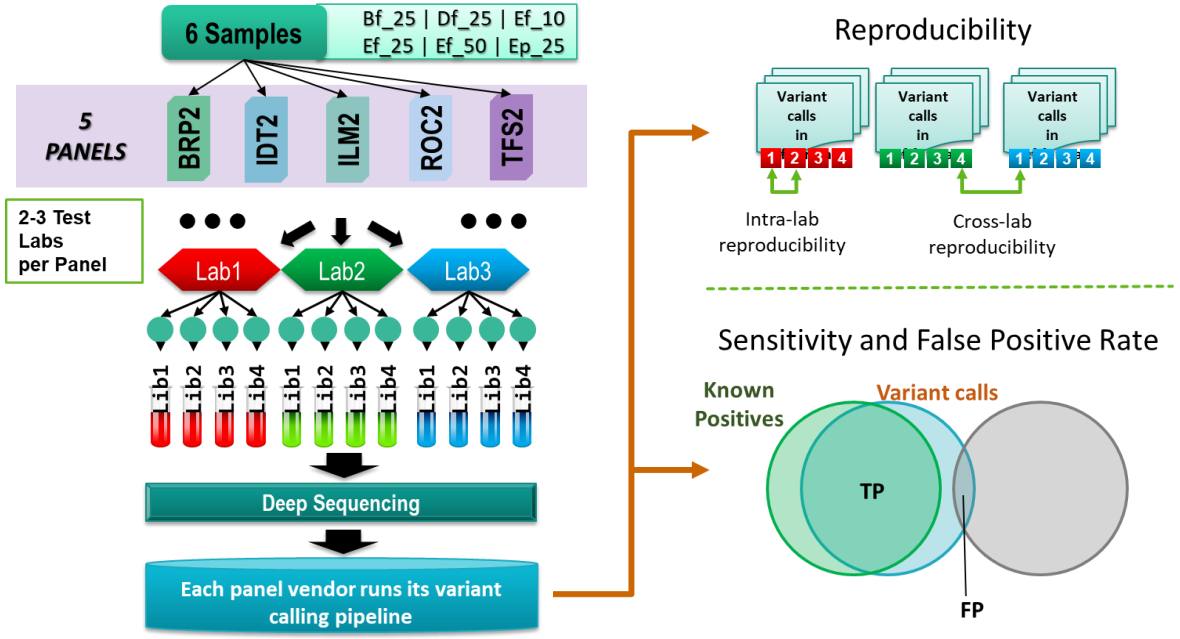
TFS2

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

Source:
Slides from “Establishing the analytical validity of circulating tumor DNA sequencing for precision oncology“, 5th Annual Liquid Biopsy for Precision Oncology Summit, Feb 2021
Further information in Appendix 2

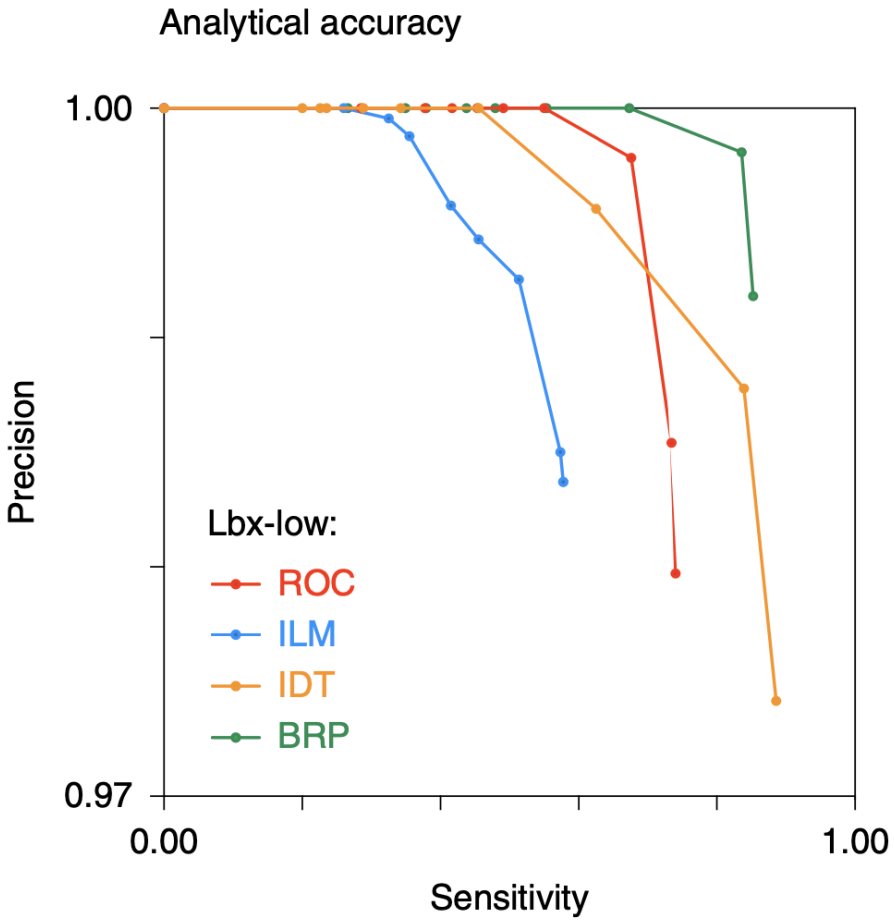
Participating assays and study design

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



Source:
"Evaluating the analytical validity of circulating tumor DNA sequencing assays for precision oncology", Nature Biotechnology, Apr 2021

Overall analytical accuracy and specificity



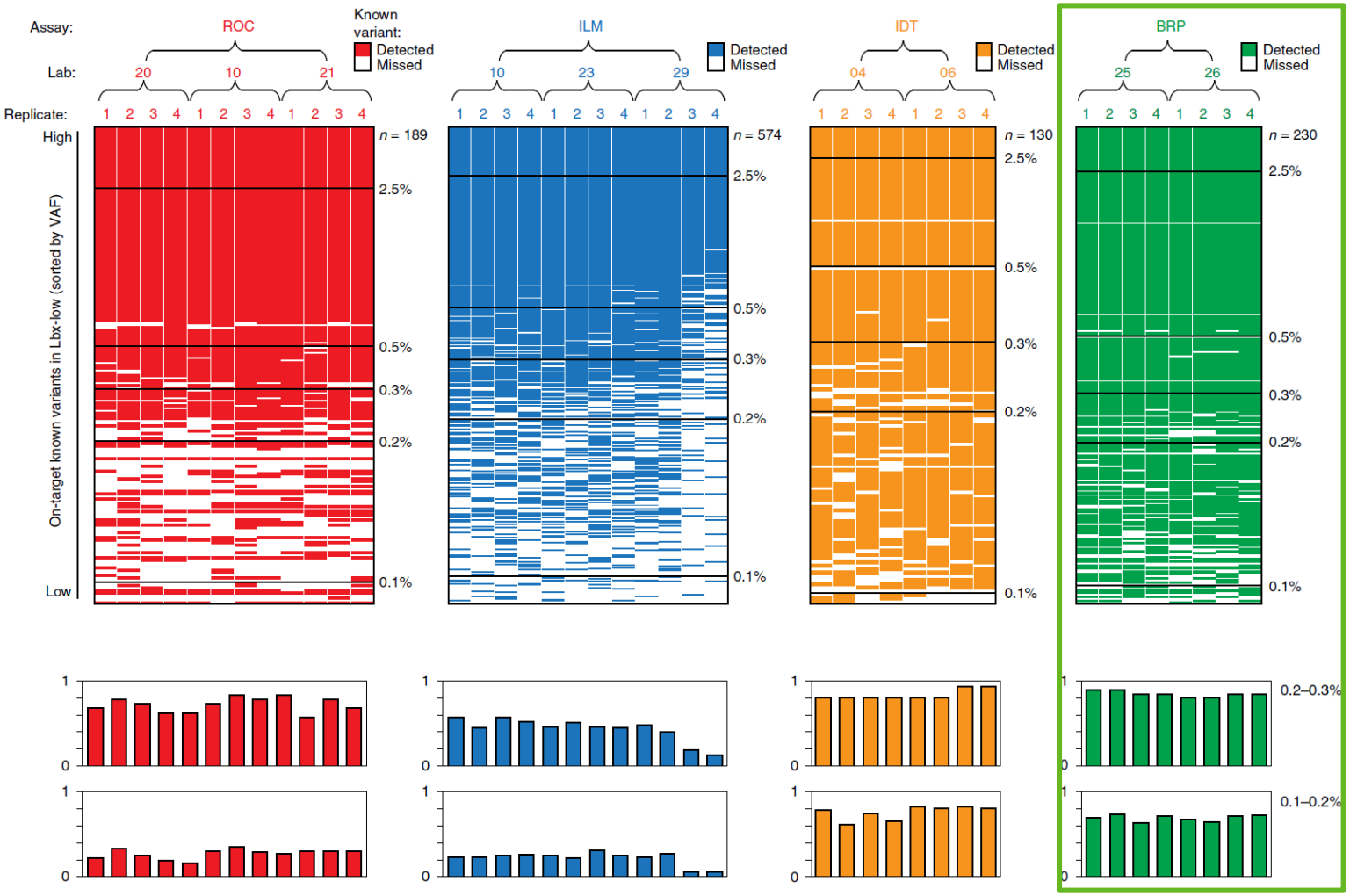
Assay	Known negatives (kb)	FPs per replicate (mean [range])	FP-rate (FP / kb) at specified VAF threshold > 0%	> 0.1%	> 0.5%
ROC	47.1	2.91 [1-6]	0.061	0.044	0.000
ILM	133	5.25 [2-10]	0.039	0.039	0.008
IDT	39.3	2.75 [0-6]	0.070	0.057	0.000
BRP	53.4	1.65 [0-5]	0.030	0.007	0.000

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). "

Source:
"Evaluating the analytical validity of circulating tumor DNA sequencing assays for precision oncology", Nature Biotechnology, Apr 2021

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."

Source:
"Evaluating the analytical validity of circulating tumor DNA sequencing assays for precision oncology", Nature Biotechnology, Apr 2021