



Burning Rock Biotech Limited

BNR US Equity
MSCI China index constituent since May 2021

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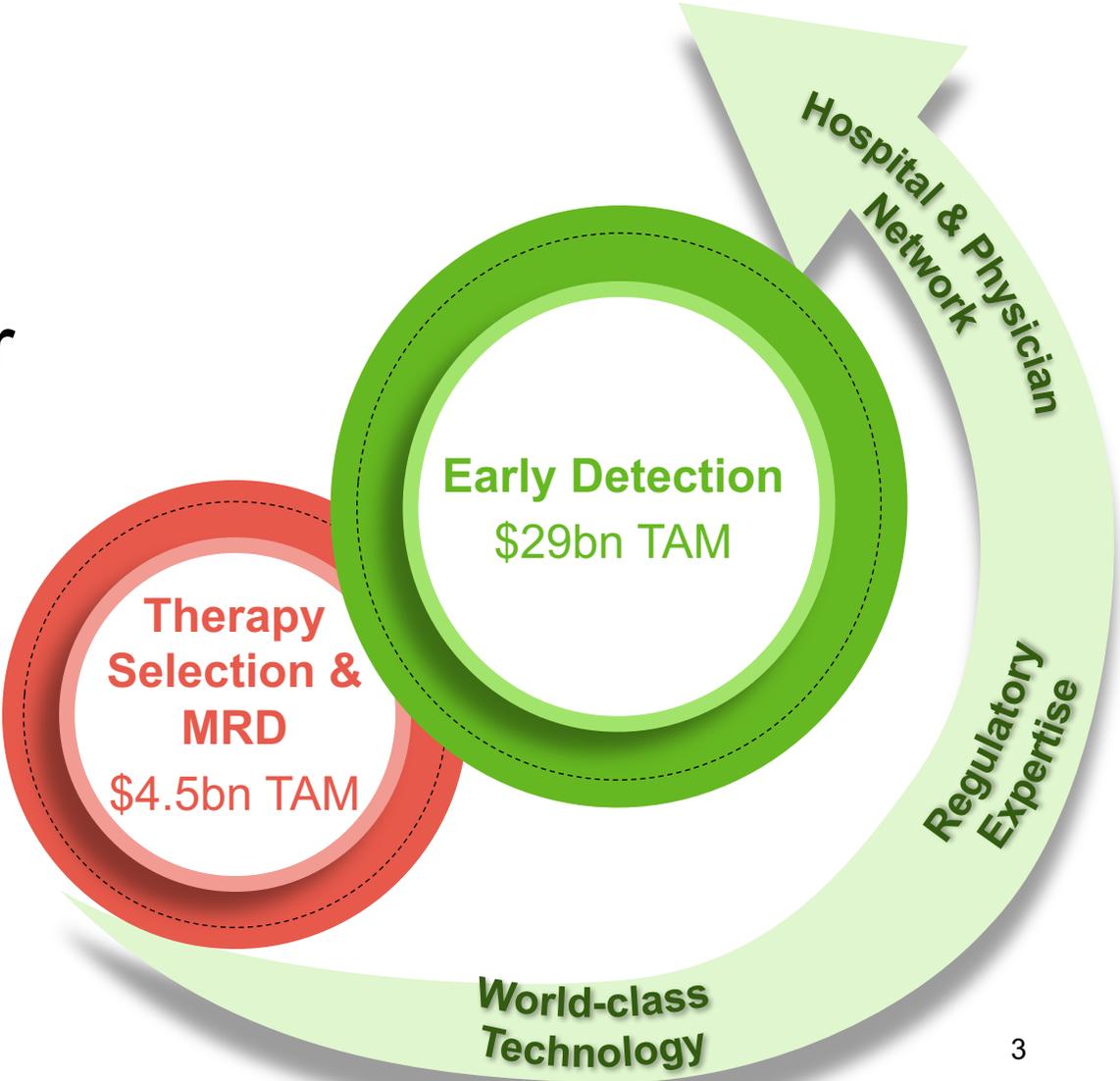
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China's **molecular diagnostics** leader for **precision oncology**



Notes:
Total addressable market size estimated per China Insights Consultancy industry report

Recap of recent progress

Early Detection

- PRESCIENT study launched for the development of our multi-omics 22-cancer test
- Ongoing progress with PREDICT study, for the development of our 9-cancer test
- Ongoing preparation work for commercialization of our 6-cancer test

Therapy Selection

- Full results of the SEQC2 study published. Liquid biopsy section published on Nature Biotechnology



Early detection

Product development roadmap

Multi-year effort, high entry barriers

Proof-of-concept
2016 – 2019

- Proof of concept on our methylation based, machine learning aided technology platform
- Results released at AACR 2019 (lung cancer). Manuscript pending publication



3-cancer
2017 – Jan 2020

- Lung, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC)
- Results released at AACR Special Conference on Liquid Biopsy, Jan 2020
- 95.1% specificity and 80.8% sensitivity¹



Product development completed, capacity ramp-up, prospective interventional study in planning

6-cancer
2018 – Nov 2020

- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- Results released at ESMO Asia, Nov 2020.
- 98.3% specificity and 80.6% sensitivity²
- Tissue-of-origin (TOO) result in 98.6% cases; accuracy 81.0%



Product development in progress

9-cancer
2019 – Ongoing

- Additional cancer types: Gastric, Biliary Tract, Head & Neck
- Ongoing PREDICT study

22-cancer³
Ongoing

- BR-22 covers 88% of China's cancer incidence
- Large clinical development study PRESCIENT kicked off in May 2021

Notes:

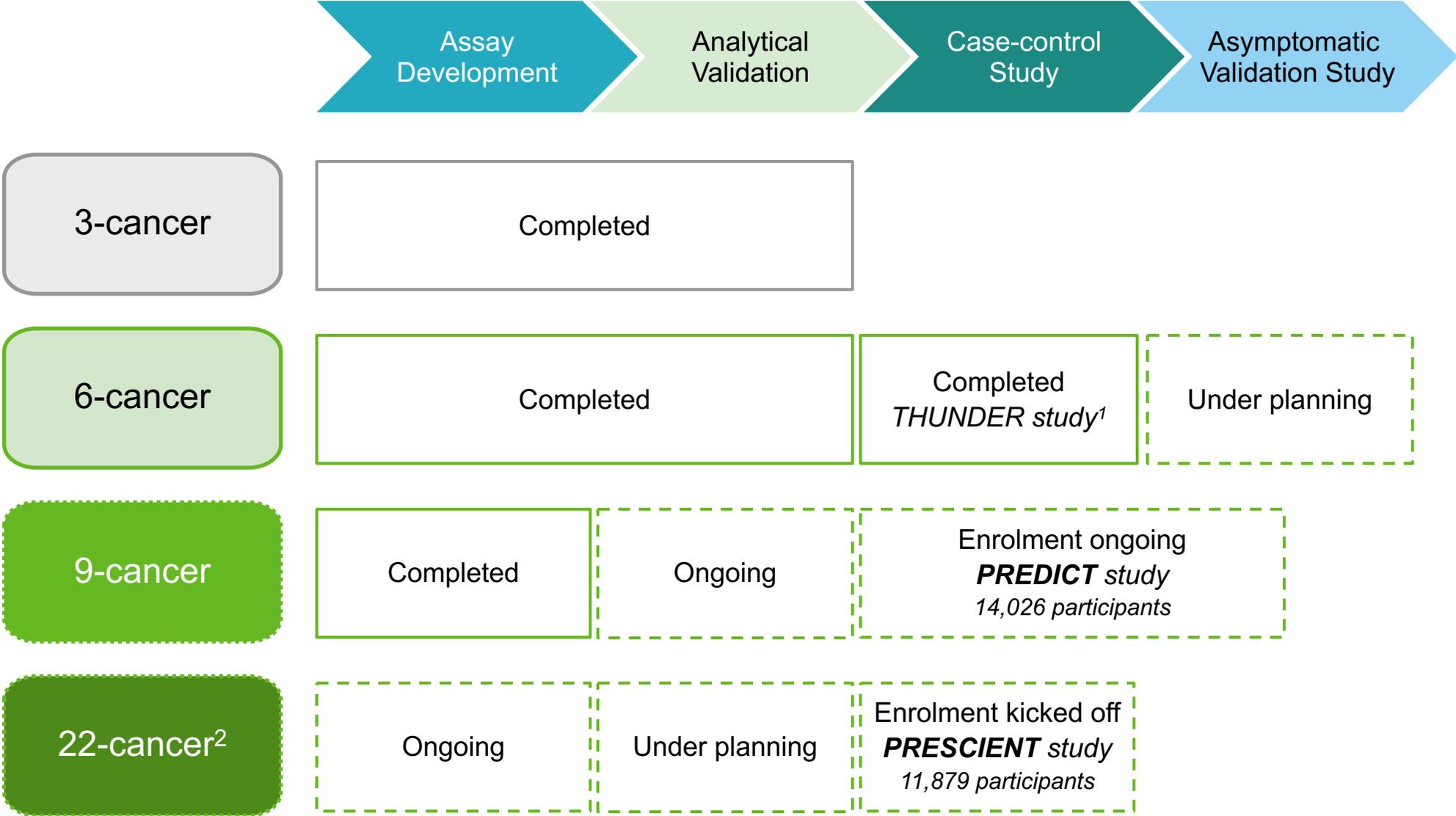
¹ Training and validation cohorts combined, 490 cancer samples, 226 control samples. Sample size is aggregated through a series of case-control studies. 95.1% specificity (95% CI 91.2-97.4) and 80.8% sensitivity (95% CI 77.0-84.1)

² Validation cohort, 351 cancer samples, 288 control samples. Sample size is aggregated through a series of case-control studies. 98.3% specificity (95% CI 95.8-99.4) and 80.6% sensitivity (95% CI 76.0-84.6). Further details in Appendix.

³ Final number of cancer types subject to development progress

Clinical programs

Large-cohort, high-quality clinical execution: key to product development and model training



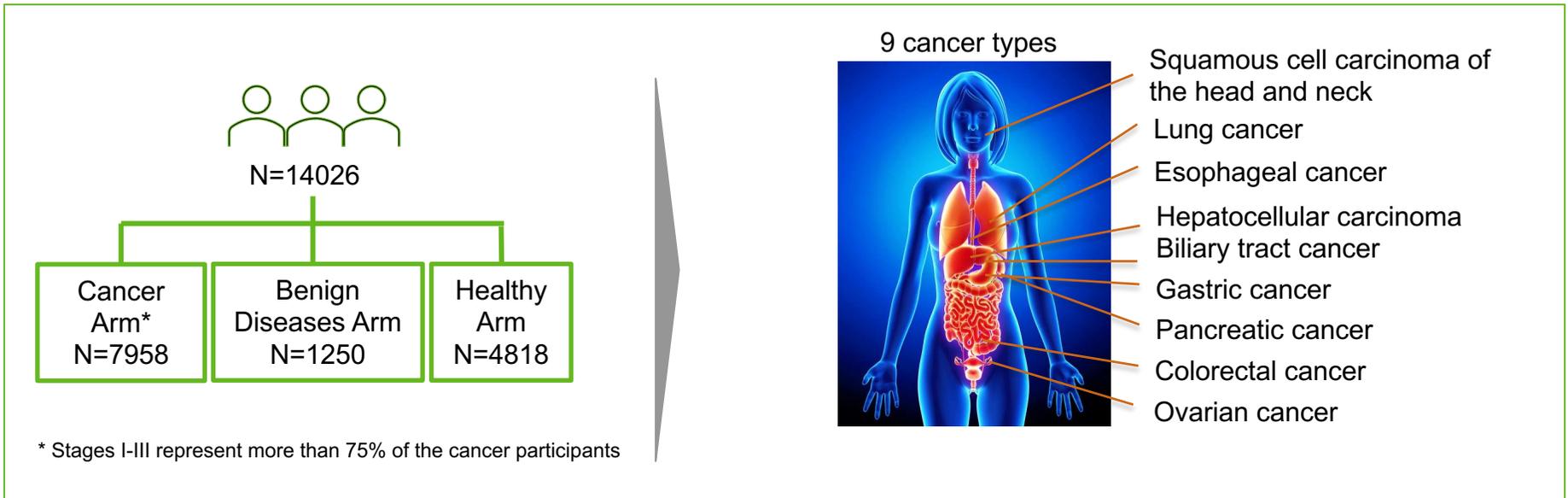
Notes:
¹ THUNDER series of studies. Latest results presented at ESMO Asia, Nov 2020
² Final number of cancer types subject to development progress

The PREDICT study (NCT04817306)

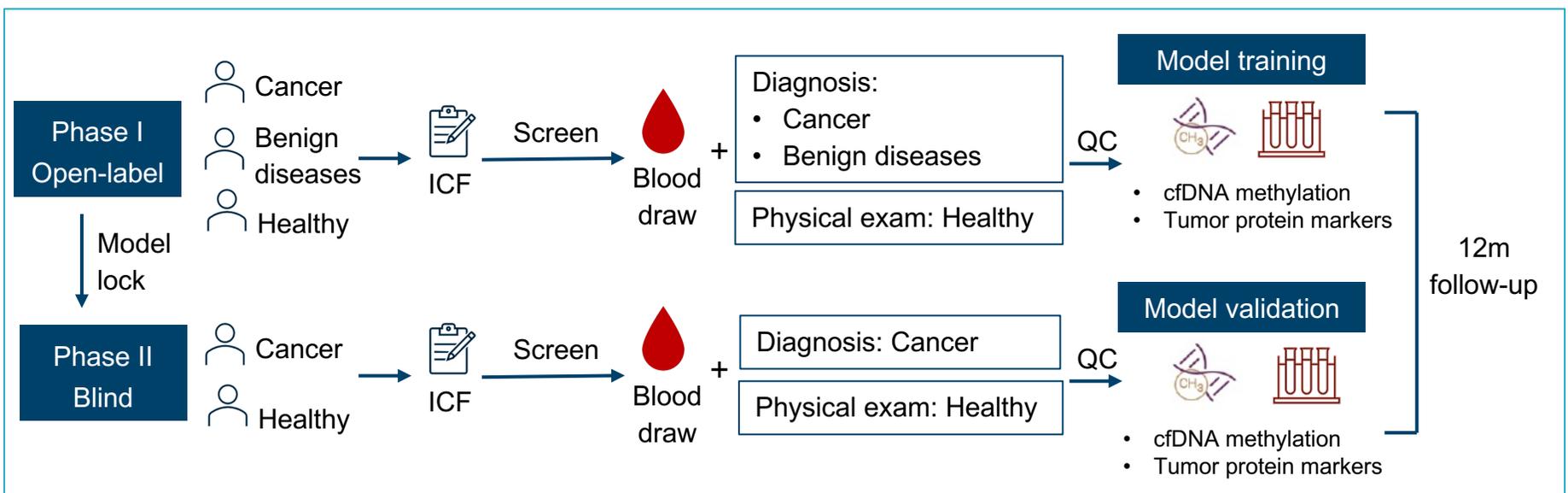
Study design

PREDICT is a *prospective, multi-center, case-control, observational* study for the detection of 9 cancer types through a cell-free DNA (cfDNA) methylation based, machine learning aided model

Participants



Study Design



The PREDICT study (NCT04817306)

Objectives and timeline

Objectives

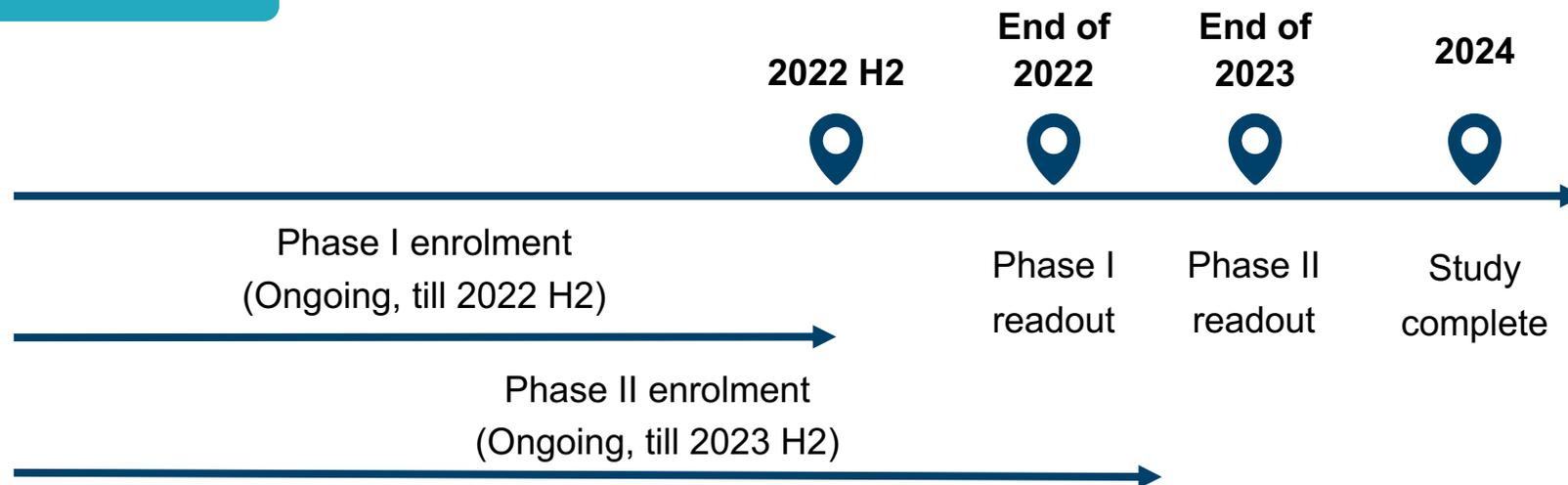
Primary objective:

- To train and validate the *sensitivity, specificity and TOO accuracy* of a cfDNA methylation-based model for early detection of 9 types of cancers

Key secondary objectives:

- To evaluate the sensitivity, specificity and TOO accuracy of a cfDNA methylation-based model in various *types and stages of cancers*
- To evaluate the sensitivity, specificity and TOO accuracy of a cfDNA methylation-based model *combined with other biomarkers*
- To evaluate the *positive predictive value* of a cfDNA methylation-based model among asymptomatic “cancer-free” individuals within a 12-month follow up period

Timeline



The PREDICT study (NCT04817306)

National Oncology Conference on Standardized Diagnosis and Treatment, Beijing, 14th-16th May 2021

国内率先启动“泛癌种”早筛研究

cfDNA甲基化

多癌种

基于cfDNA甲基化检测的早期癌症鉴别诊断模型在多癌种中的探索及验证：一项前瞻性、多中心研究 (Pan-Cancer Early Detection Project, PREDICT)

研究预计纳入癌症、良性病变及健康受试者；
样本量：14026例

NIH U.S. National Library of Medicine
ClinicalTrials.gov
Pan-cancer Early Detection project (PREDICT)
ClinicalTrials.gov Identifier: NCT04817306
Recruitment Status: Not yet recruiting
First Posted: May 12, 2020
Last Update Posted: May 14, 2020
See Contacts and Locations

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The PRESCIENT study (NCT04822792)

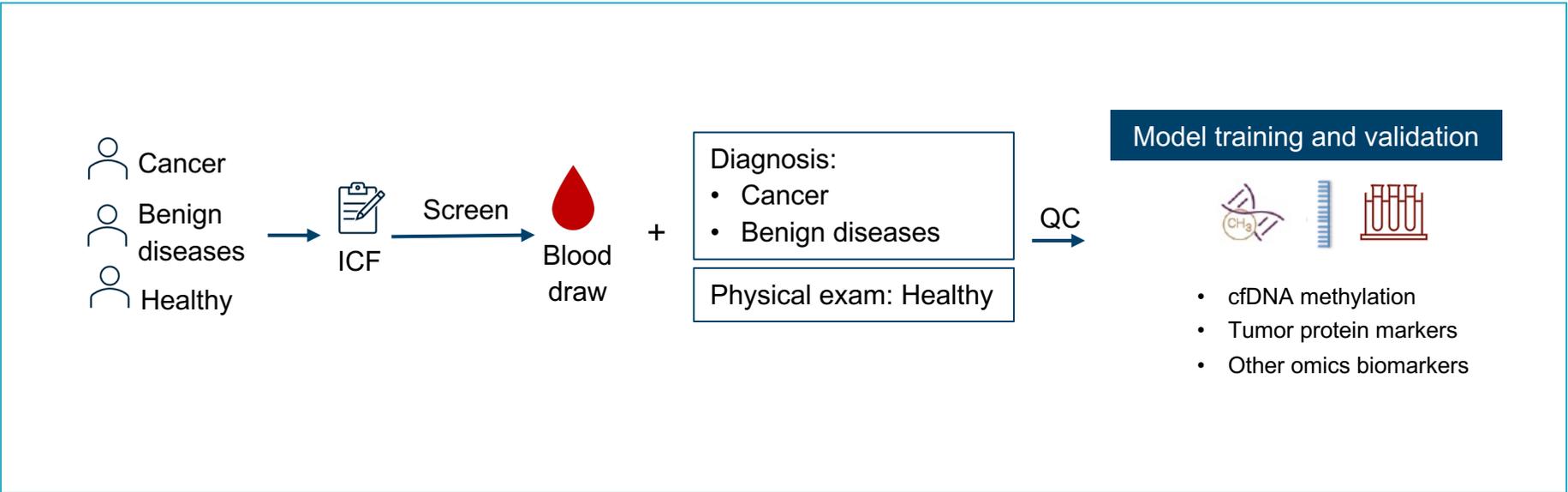
Study design

PRESCIENT is a *prospective, multi-center, case-control, observational* study aimed to train and validate the performance of a multi-omics model in the detection of 22 cancers

Participants



Study Design



The PRESCIENT study (NCT04822792)

Objectives and timeline

Objectives

Primary objective

- To train and validate the *sensitivity, specificity and TOO accuracy* of a cfDNA methylation-based model combined with tumor protein markers for early detection of 22 types of cancers

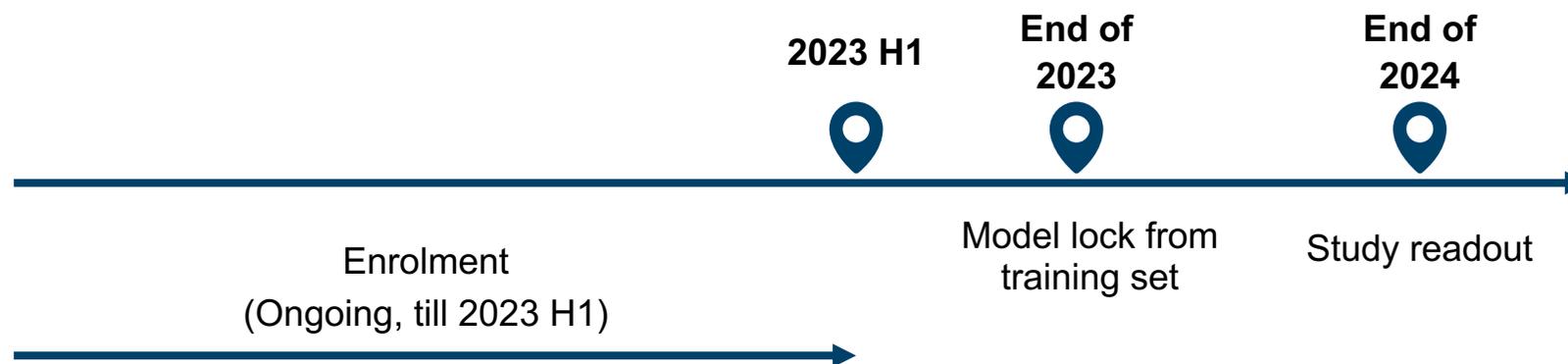
Secondary objective

- To evaluate the sensitivity and specificity of a cfDNA methylation-based model combined with tumor protein markers in early detection of 22 types of cancers *in different stages*

Exploratory objective:

- To evaluate the sensitivity and specificity of *other genetic/epigenetic biomarkers combined with a cfDNA methylation-based model and tumor protein markers* in early detection of cancers

Timeline



Leadership from top-tier principal investigators key to clinical success

PREDICT



- Leading site: Shanghai Zhongshan Hospital
 - One of the 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 basis¹
 - Ranked **top 5** in the 2019 China's general hospital rankings²
- Other sites include but not limited to
 - Ruijin Hospital
 - Shanghai Jiaotong University School of Medicine
 - Fudan University Shanghai Cancer Center

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
 - 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
- Other sites include but not limited to
 - Beijing Cancer Hospital
 - Jilin Cancer Hospital
 - Hubei General Hospital

Principal Investigators

Prof. Jie He



Prof. Jie Wang



Head of the Dept. of Medicine, CHCAMS

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

Notes: ¹Based on 2018 statistics

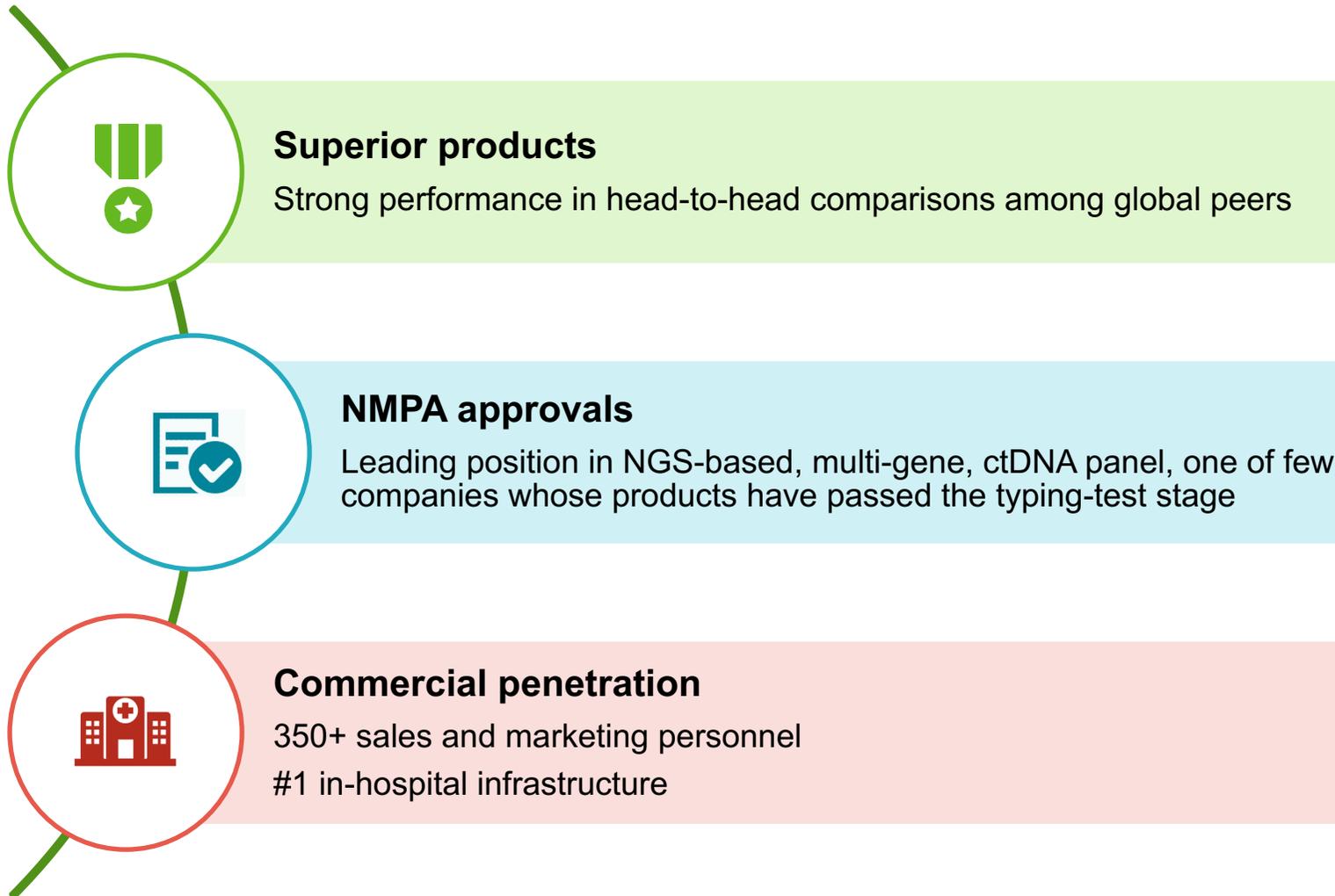
²<http://rank.cn-healthcare.com/rank/general-best>



Therapy selection testing

Factors for long-term success

Strong product performance as the core. NMPA approvals enable competitive differentiation



FDA-led SEQC2 study overview

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%



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

- 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

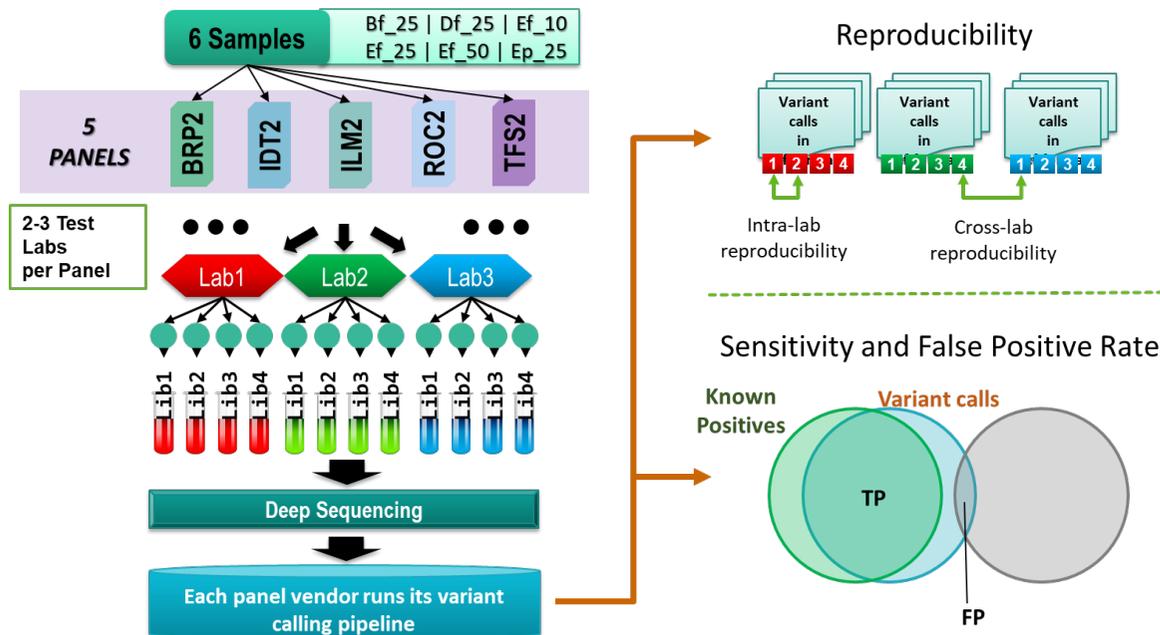
- Enzymatic fragmentation
 - better ligation efficiency
- Gel-based size selection (160bp-180bp) to mimic cfDNA
- 1ng/ul to mimic concentration after DNA extraction from plasma
- Ep: 40ng/ml Ef in synthetic plasma

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

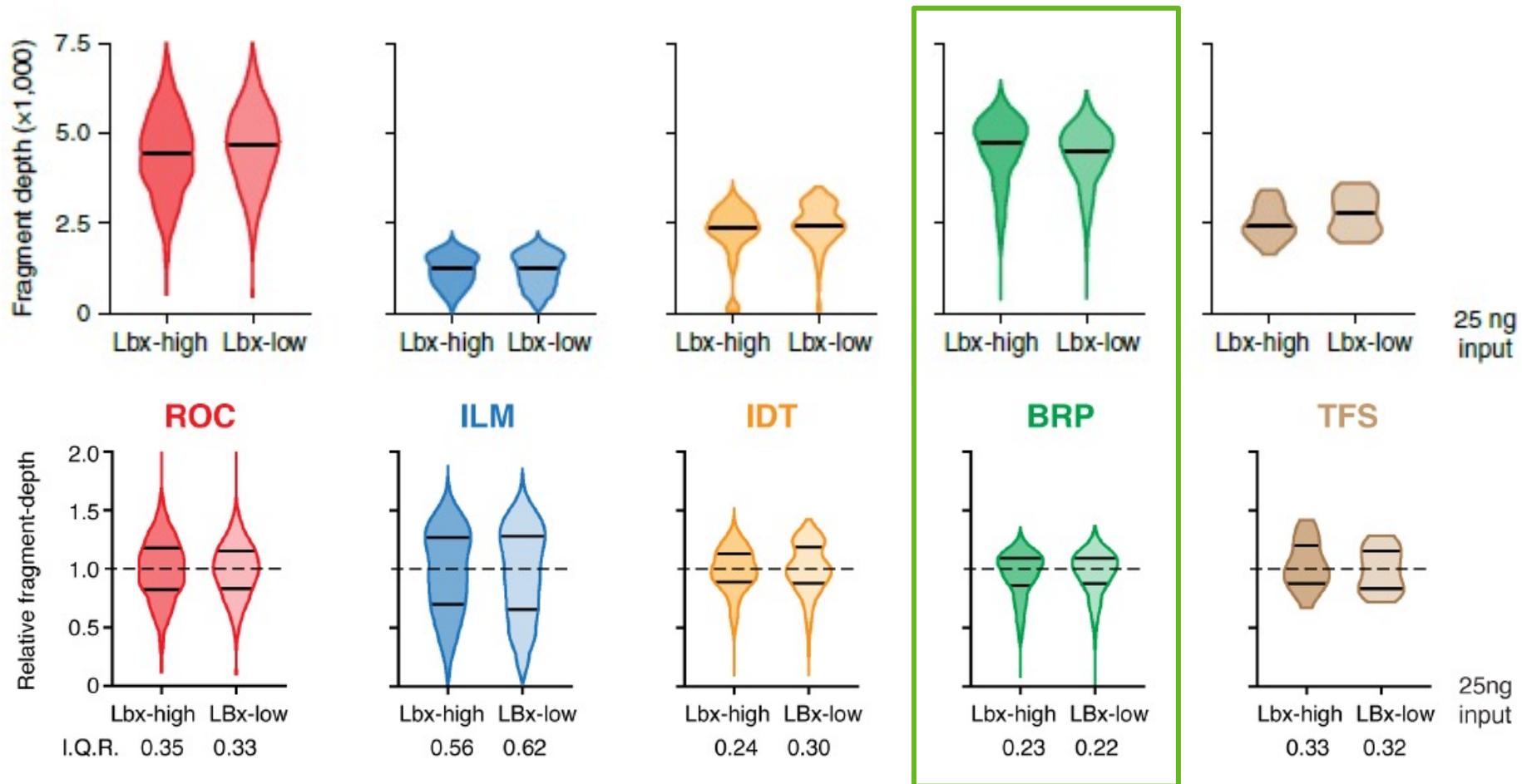
Liquid Biopsy

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

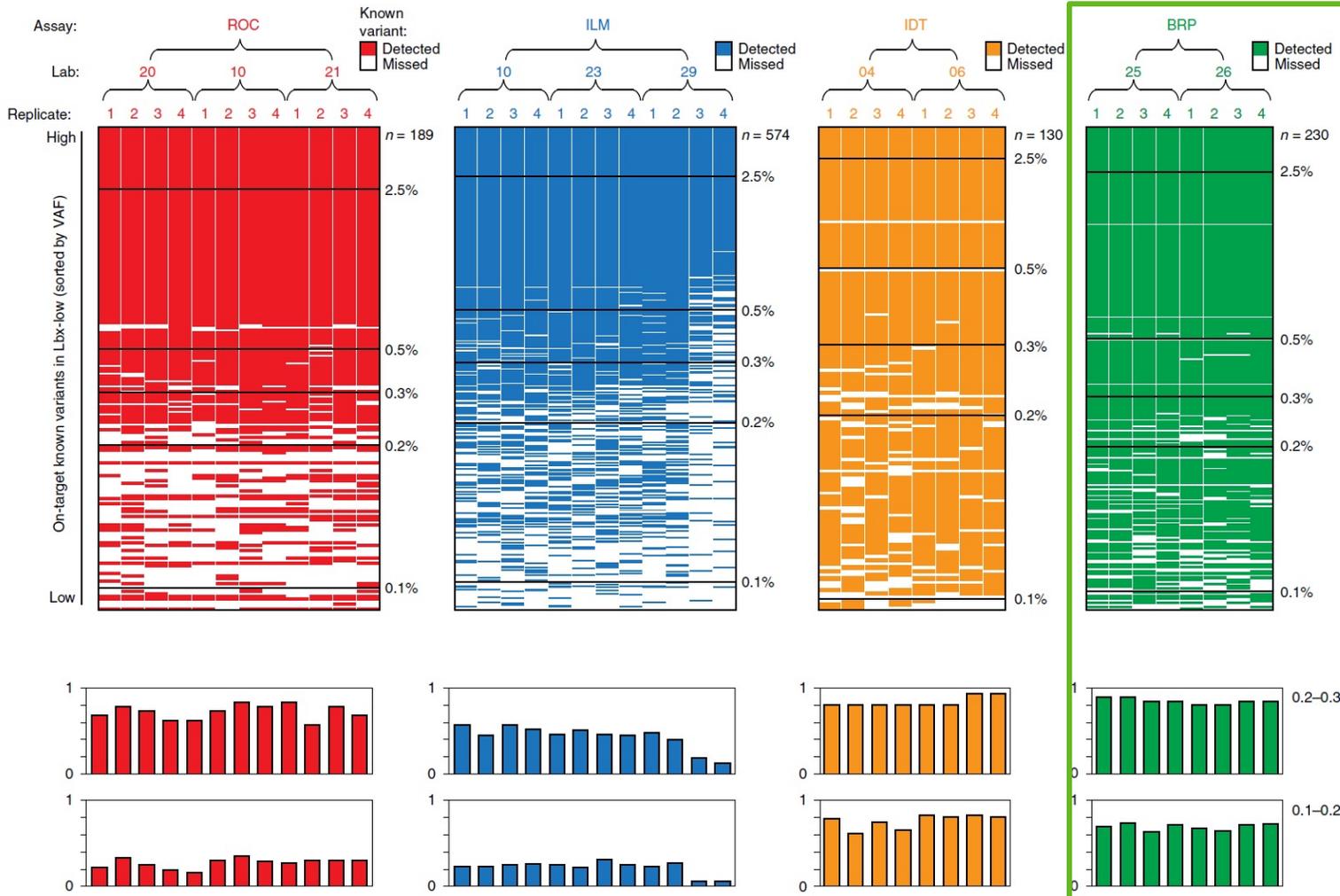


Performance - Molecular recovery capability and coverage uniformity



“We evaluated coverage depth, which is considered a key variable in ctDNA sequencing. **We observed substantial differences in coverage among different assays, with median unique fragment depth ranging from ~4,700-fold (BRP and ROC) to ~1,200-fold (ILM) at 25ng input (Fig. 3c).** Given that DNA input quantities were standardized, these differences reflect the capacity of each assay to exhaustively profile the unique DNA fragments within the input sample and might have a relevant effect on assay performance.”

Performance - Sensitivity

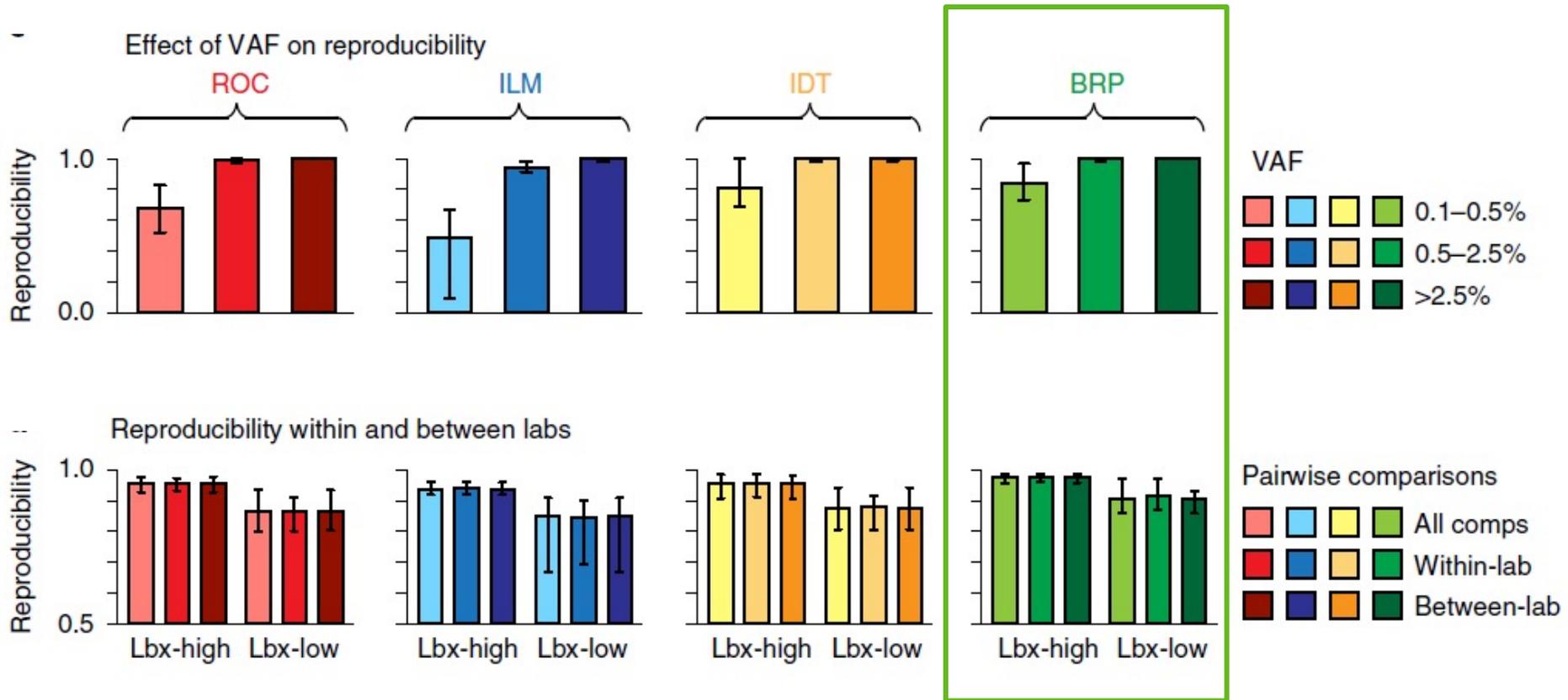


- LBx-low (25 ng input) replicates in each participating assay in different expected VAF bin.

“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).”

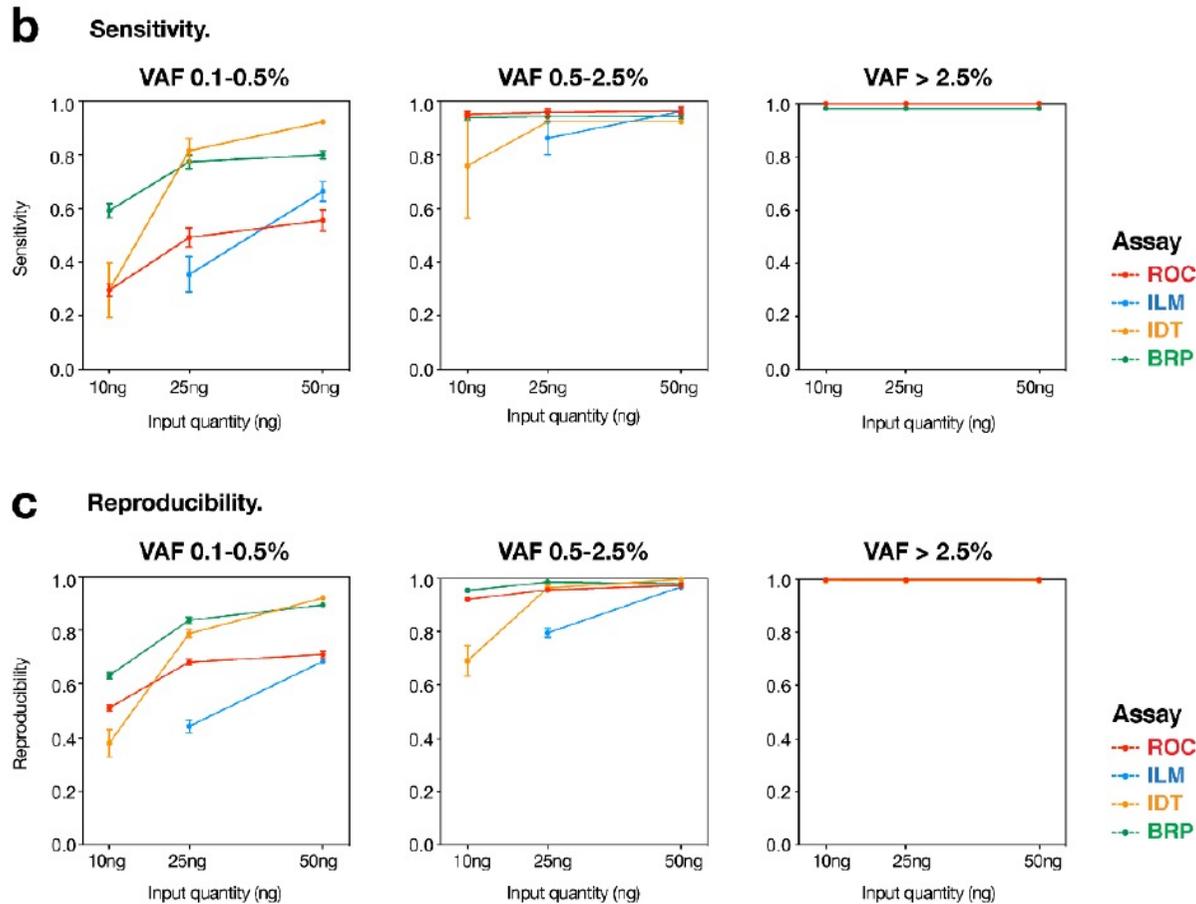
“The performance characteristics of the assays evaluated here were broadly similar to what has been reported by several ctDNA sequencing providers (based on internal testing) that did not participate in this study. **During validation of the Guardant360 CDx hybrid capture assay, variants were detected 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.**”

Performance - Reproducibility



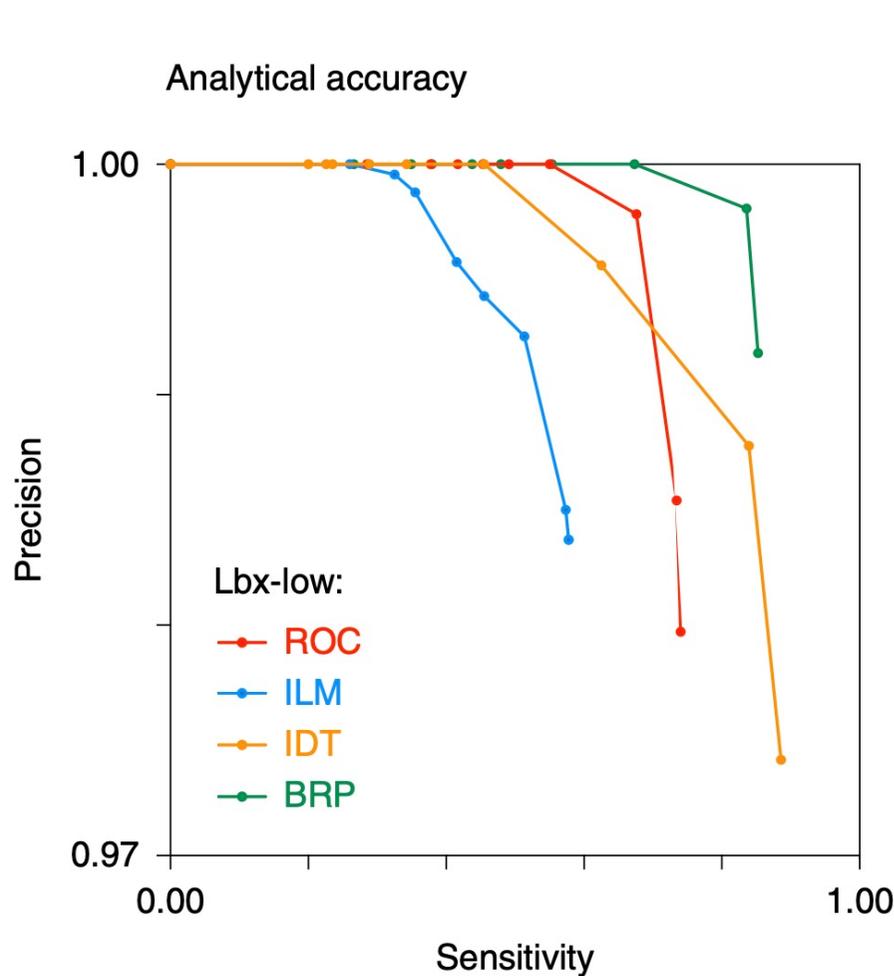
- The reproducibility reduced in lower VAF bin (0.1-0.5%)
- Cross-lab and Within-Lab reproducibility performance is mainly driven by VAF

Performance – Robustness for low-input cfDNA samples



“The increasing fragment-depth afforded by 25 ng input, compared to 10 ng, resulted in substantial improvements in sensitivity, reproducibility and overall diagnostic performance for all assays, particularly for low-frequency variants (Fig. 5b-e; Fig. S5a,b). However, some assays (BRP, ROC) showed minimal further improvement with the addition of 50 ng input (Fig. 5b-e; Fig. S5a,b). **The extent to which performance varied over the range of input quantities tested indicates the robustness of each assay to the variable cell-free DNA input amounts encountered in the clinic.** Overall, the greater fragment-depth achieved by an assay at a given input level, the more robust that assay was to variation in input quantity, **with BRP being the most stable** (Fig. 5b-e).”

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).”



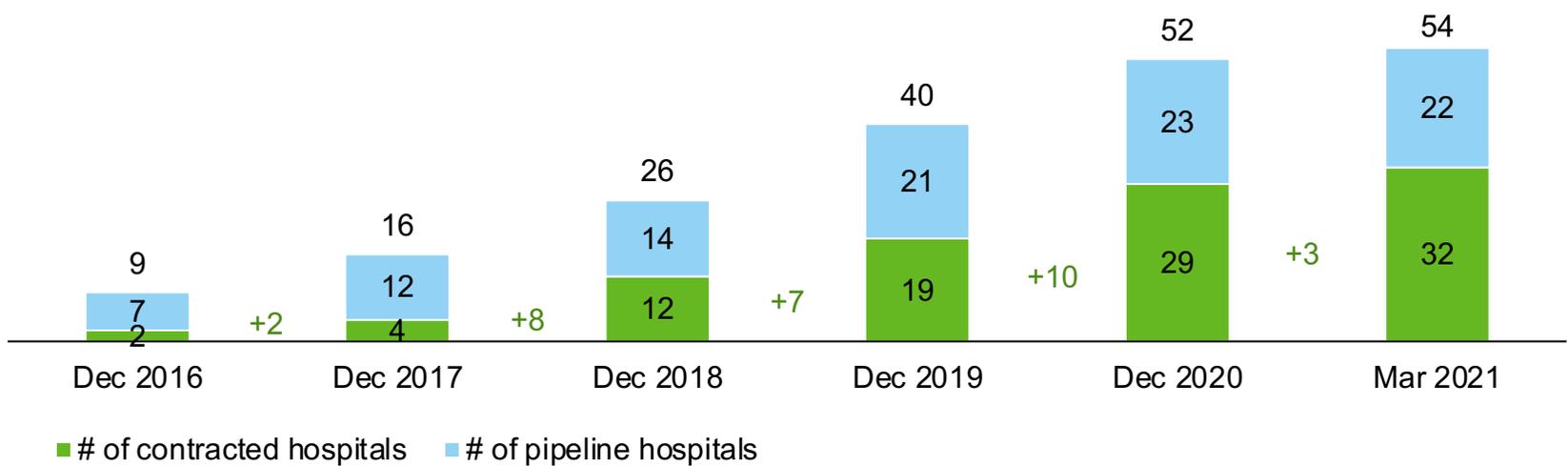
Financials

Operating metrics

Central-lab channel

	2018	2019	2020	1Q19	1Q20	2Q20	3Q20	4Q20	1Q21
# of ordering hospitals	263	335	312	249	232	284	289	294	303
# of ordering physicians	1,135	1,632	1,318	984	810	1,175	1,194	1,114	1,082
# of patients tested ¹	15,821	23,075	25,262	5,336	4,680	7,252	8,644	7,989	7,716
YoY	67%	46%	9%		-12%	20%	28%	5%	65%
QoQ						55%	19%	-8%	-3%

In-hospital channel



Note:

(¹) A patient who took multiple tests in different quarters of a given year is counted only once for that year

Financials

RMB millions	2019	2020	18 YoY	19 YoY	20 YoY	1Q20	2Q20	3Q20	4Q20	1Q21	1Q21 YoY	1Q21 QoQ	2021 Guide
Revenue	381.7	429.9	88%	83%	13%	67.3	107.0	123.9	131.7	106.6	58%	(19%)	610
Central lab	276.3	297.3	83%	71%	8%	46.1	74.6	89.9	86.7	74.6	62%	(14%)	
In-hospital	87.7	117.9	209%	164%	34%	17.1	27.6	31.7	41.5	29.0	70%	(30%)	
Pharma	17.7	14.7	15%	25%	(17%)	4.1	4.8	2.3	3.6	3.1	(25%)	(15%)	
Gross profit	273.3	313.9	88%	102%	15%	44.8	78.4	91.6	99.2	76.9	72%	(22%)	
Total opex	442.4	726.3	54%	49%	64%	104.1	151.4	216.2	254.6	248.8	139%	(2%)	
R&D ¹	147.5	214.1	114%	43%	45%	37.9	45.9	58.7	71.6	55.0	45%	(23%)	
S&M ¹	152.0	165.1	52%	49%	9%	29.6	37.5	43.9	54.2	52.5	77%	(3%)	
G&A ¹	120.8	174.6	18%	40%	44%	32.6	40.6	44.9	56.5	56.9	75%	(1%)	
SBC ²	22.1	172.5				4.0	27.4	68.7	72.3	84.4			
Operating profit	(169.1)	(412.4)				(59.3)	(73.0)	(124.6)	(155.4)	(171.9)			
GP margin	71.6%	73.0%				66.5%	73.3%	73.9%	75.3%	72.2%			
Opex / revenue	116%	169%				155%	142%	175%	193%	233%			
S&M / revenue	40%	39%				44%	36%	36%	43%	52%			

Notes:

1 Excluding share based compensation (SBC)

2 Share based compensation

Appendix 1

Early detection

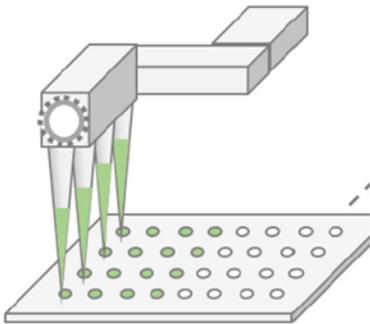
Burning Rock early detection technology – ELSA-seq

R&D started in 2016; combination of targeted deep methylation sequencing and machine learning

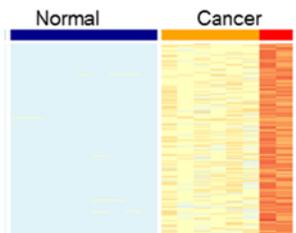
(A) Sample preparation



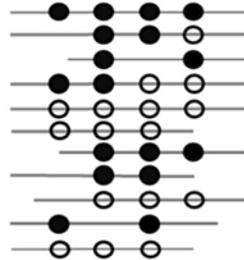
(B) Automated whole-methylome amplification



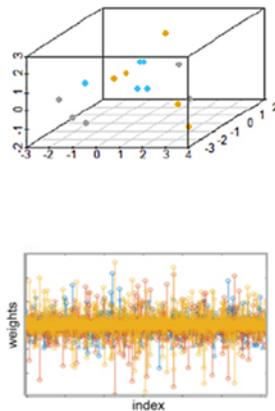
(C) Deep sequencing of cancer-associated markers



(D) Pattern recognition & noise suppression



(E) Machine learning for sparse matrices



Technology Highlights:

- ✓ Single-stranded library prep starts as low as 1ng cfDNA
- ✓ Bisulfite conversion or enzymatic conversion compatible
- ✓ Intelligent probe design to maintain the methylation level fidelity
- ✓ Multiple noise reduction and signal corrections before machine-learning model building

ESMO Asia mini-oral presentation, Nov 2020

Overview of training and validation sets

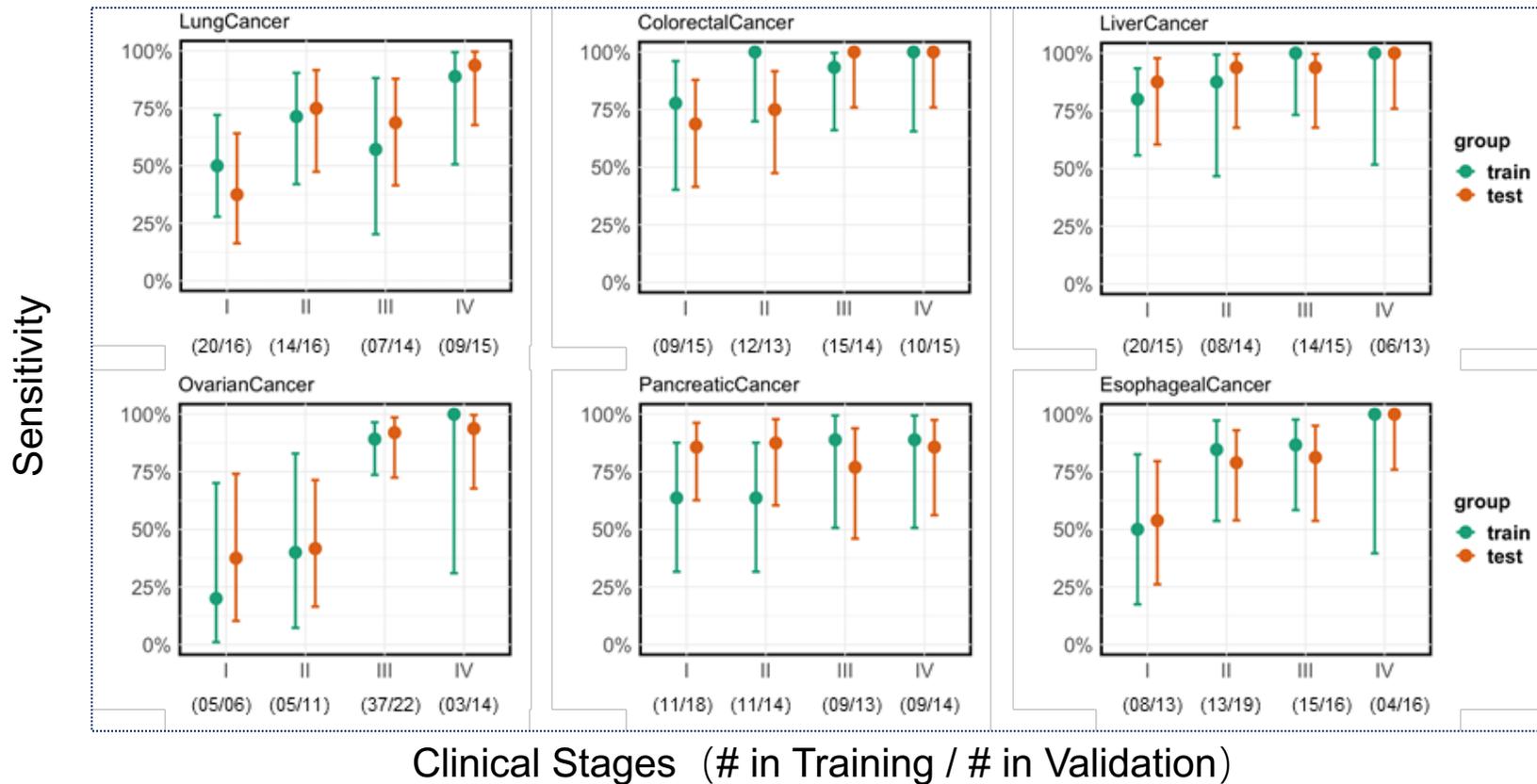
Training	Control	Cancer	LC	CRC	LIHC	OVCA	PAAD	ESCA
total	195	274	50	46	48	50	40	40
age, mean+/-SD	53+/-6	57+/-8	60+/-6	60+/-8	55+/-8	50+/-8	59+/-7	57+/-6
age, min/max	40/72	40/75	47/74	44/75	43/72	40/73	42/71	45/70
sex, female, n (%)	128 (70)	110 (40)	16 (32)	21 (46)	4 (8)	50 (100)	14 (35)	5 (13)
clinical stage, n (%)								
I		73 (27)	20 (40)	9 (20)	20 (41)	5 (10)	11 (27)	8 (20)
II		63 (23)	14 (28)	12 (26)	8 (17)	5 (10)	11 (27)	13 (33)
III		97 (35)	7 (14)	15 (32)	14 (29)	37 (74)	9 (23)	15 (37)
IV		41 (15)	9 (18)	10 (22)	6 (13)	3 (6)	9 (23)	4 (10)

Validation	Control	Cancer	LC	CRC	LIHC	OVCA	PAAD	ESCA
total	288	351	61	57	57	53	59	64
age, mean+/-SD	54+/-6	59+/-8	62+/-7	61+/-9	54+/-8	54+/-7	61+/-9	62+/-6
age, min/max	40/74	40/75	45/74	44/75	40/73	42/68	40/74	46/74
sex, female, n (%)	171 (59)	146 (42)	22 (36)	21 (37)	9 (16)	53 (100)	19 (32)	22 (34)
clinical stage, n (%)								
I		83 (23)	16 (26)	15 (26)	15 (26)	6 (11)	18 (30)	13 (20)
II		87 (25)	16 (26)	13 (23)	14 (25)	11 (21)	14 (24)	19 (30)
III		94 (27)	14 (23)	14 (25)	15 (26)	22 (42)	13 (22)	16 (25)
IV		87 (25)	15 (25)	15 (26)	13 (23)	14 (26)	14 (24)	16 (25)

1. Similar age distribution between cases and controls, and between training set and validation set
2. Balanced sample size among different stages and cancer types

ESMO Asia mini-oral presentation, Nov 2020

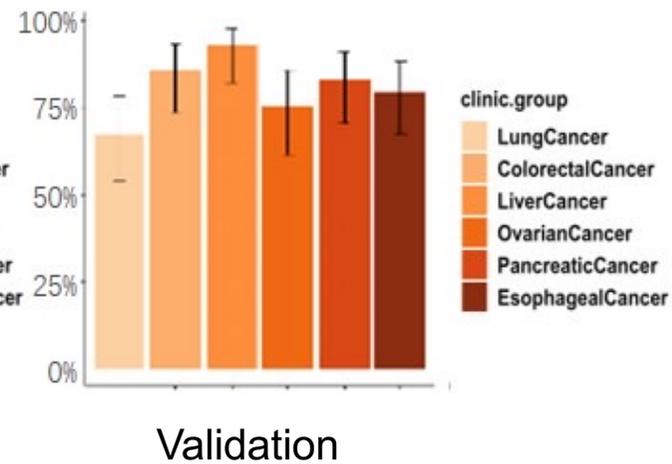
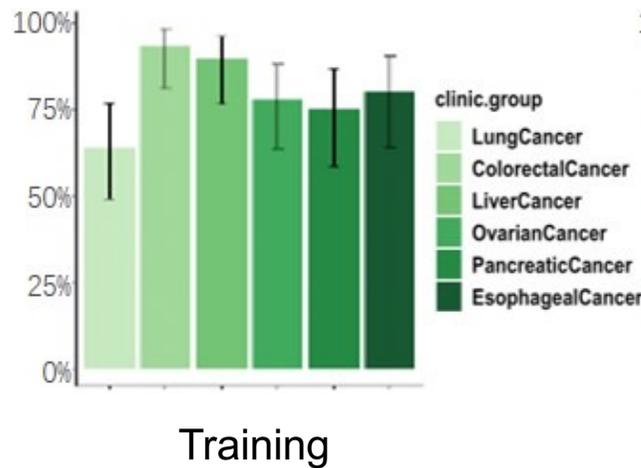
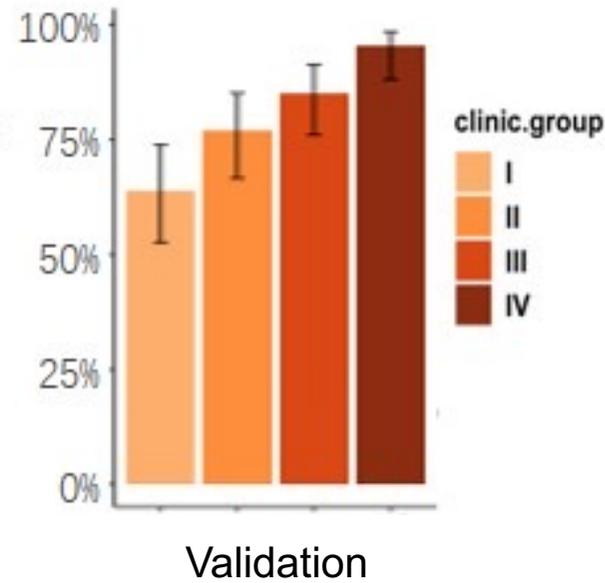
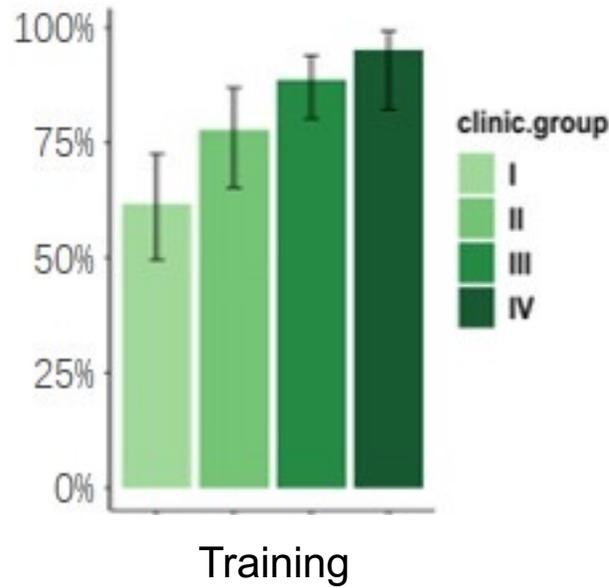
Our test detects cancers at an early stage with high specificity and high sensitivity



- The specificity was **99.5%** (95%CI: 96.7-100%; training) and **98.3%** (95%CI: 95.8-99.4%; validation)
- The sensitivity was **79.9%** (95%CI: 74.6-84.4%; training) and **80.6%** (95%CI: 76.0-84.4%; validation)

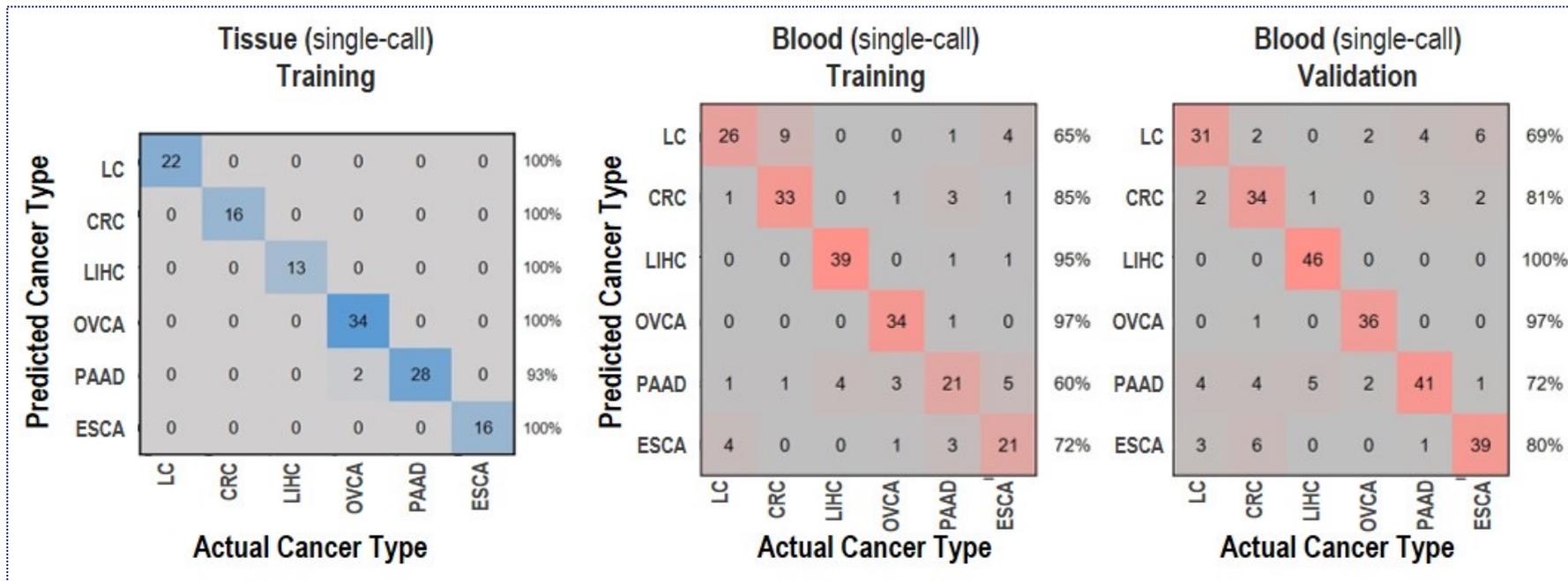
ESMO Asia mini-oral presentation, Nov 2020

Our test detects cancers at an early stage with high specificity and high sensitivity



ESMO Asia mini-oral presentation, Nov 2020

Our test predicts the tissue of origin with high accuracy



- The classifier was able to distinguish different cancer tissue samples with exceptional accuracy (**129/131**).
- **98.6%** of detected cancer blood samples were assigned an organ-source in both training and validation sets:
 - For single organ calls, the predictive accuracy was **79%** (training) and **82%** (validation);
 - For top-two organ calls, the predictive accuracy was **89%** (training) and **87%** (validation).

ESMO Asia mini-oral presentation, Nov 2020

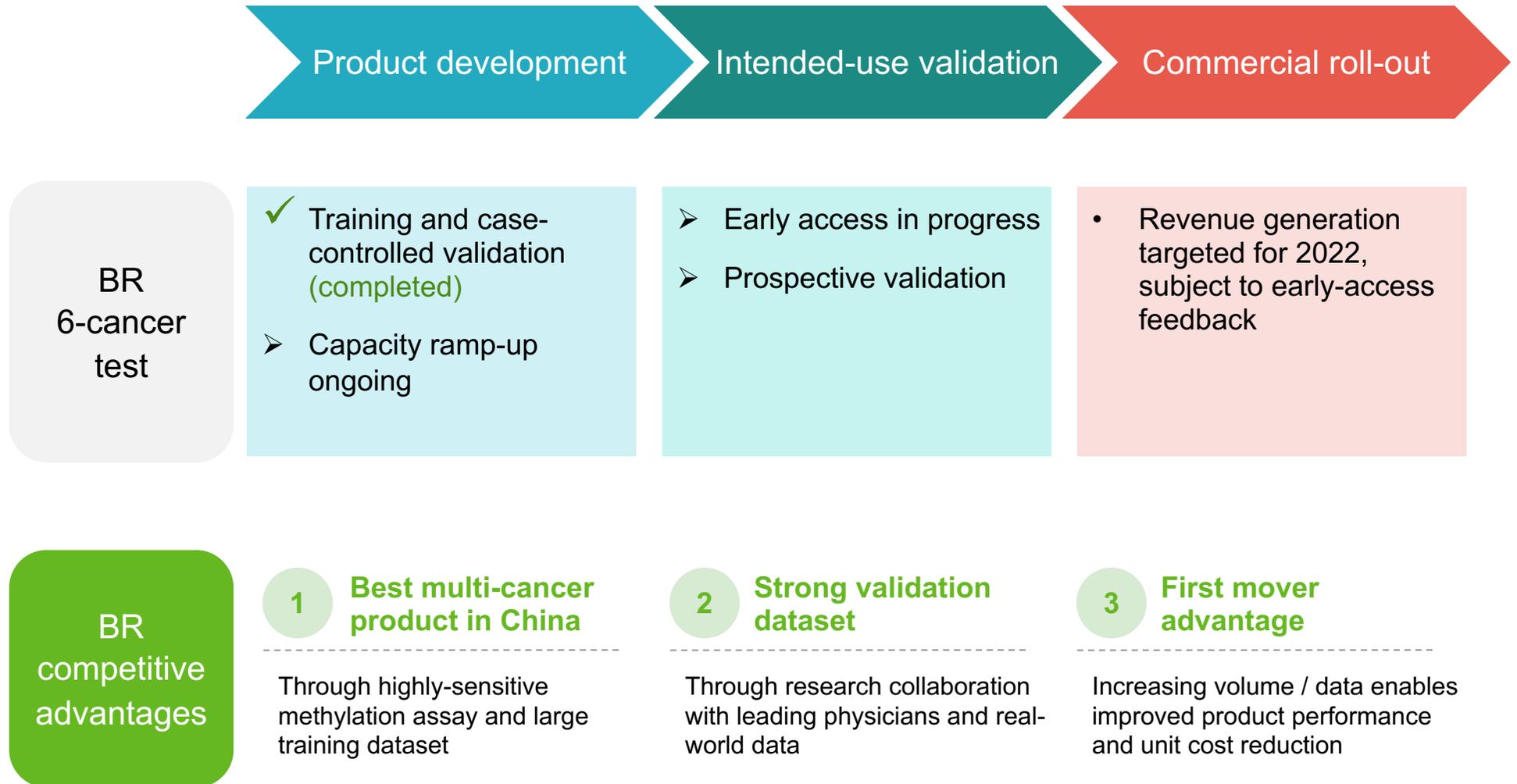
6-cancer test sensitivity by cancer type and stage

Sensitivity and Specificity - Correct#/Total# (%)

Cancer	Group	I	II	III	IV	Overall
Lung	Train	10/20 (50.0)	10/14 (71.4)	4/7 (57.1)	8/9 (88.9)	32/50 (64.0)
	Test	6/16 (37.5)	12/16 (75.0)	9/14 (64.3)	14/15 (93.3)	41/61 (67.2)
Colorectal	Train	7/9 (77.8)	12/12 (100.0)	14/15 (93.3)	10/10 (100.0)	43/46 (93.5)
	Test	10/15 (66.7)	10/13 (76.9)	14/14 (100.0)	15/15 (100.0)	49/57 (86.0)
Liver	Train	16/20 (80.0)	7/8 (87.5)	14/14 (100.0)	6/6 (100.0)	43/48 (89.6)
	Test	13/15 (86.7)	13/14 (92.9)	14/15 (93.3)	13/13 (100.0)	53/57 (93.0)
Ovarian	Train	1/5 (20.0)	2/5 (40.0)	33/37 (89.2)	3/3 (100.0)	39/50 (78.0)
	Test	2/6 (33.3)	5/11 (45.5)	20/22 (90.9)	13/14 (92.9)	40/53 (75.5)
Pancreatic	Train	7/11 (63.6)	7/11 (63.6)	8/9 (88.9)	8/9 (88.9)	30/40 (75.0)
	Test	15/18 (83.3)	12/14 (85.7)	10/13 (76.9)	12/14 (85.7)	49/59 (83.1)
Esophageal	Train	4/8 (50.0)	11/13 (84.6)	13/15 (86.7)	4/4 (100.0)	32/40 (80.0)
	Test	7/13 (53.8)	15/19 (78.9)	13/16 (81.3)	16/16 (100.0)	51/64 (79.7)
Sensitivity	Train					219/274 (79.9)
	Test					283/351 (80.6)
Specificity	Train					194/195 (99.5)
	Test					283/288 (98.3)

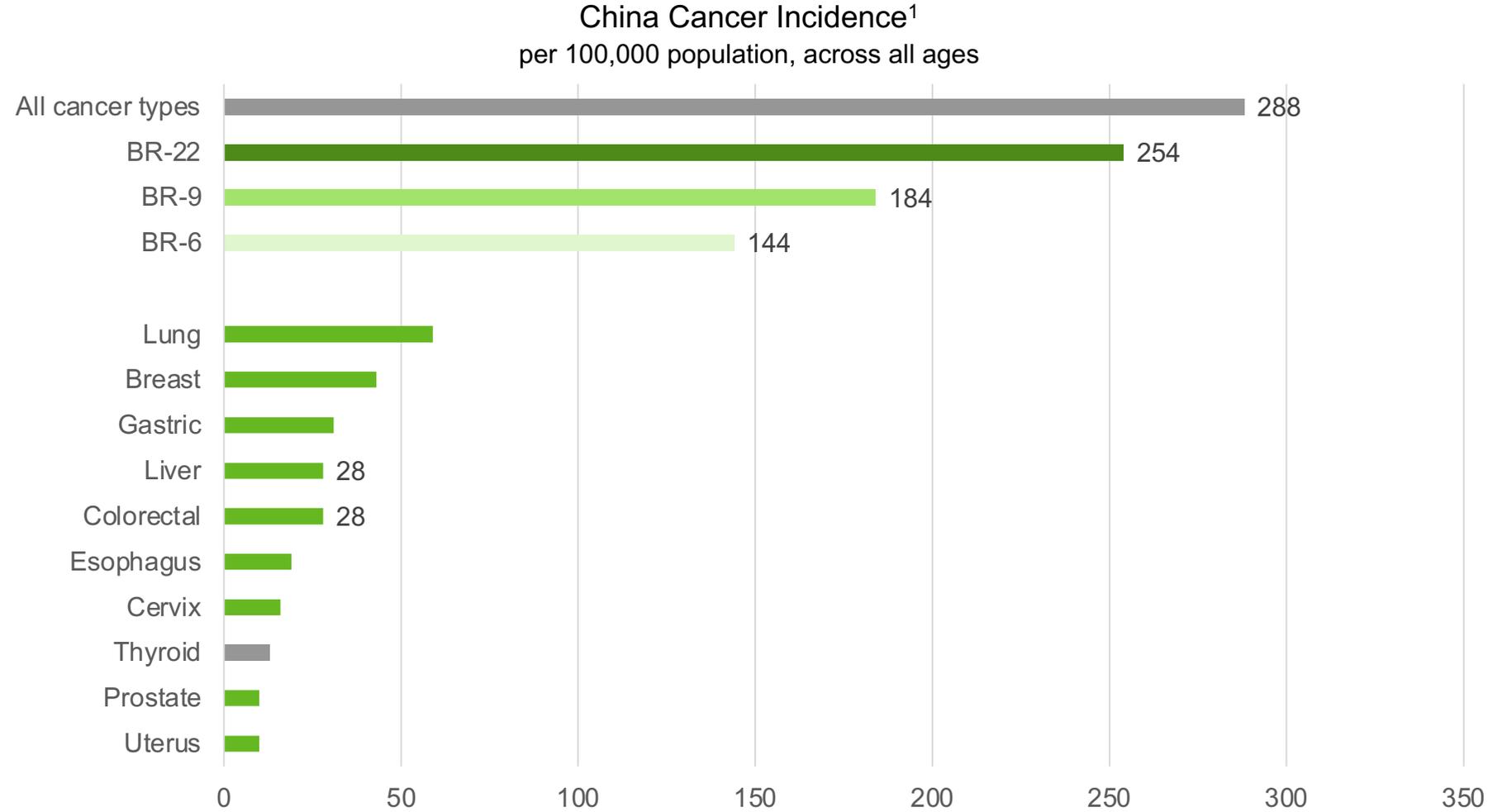
6-cancer test

Product development completed, early access initiated



Multi vs. single cancer early detection

Multiple times larger TAM



BR-22 covers 88% of China's cancer incidence²

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

Multi vs. single cancer early detection in China

Significantly higher technology barrier

Single-cancer test

- Established technology, typically PCR based, with readily available products
 - US – First FDA approved product in 2014 (first submission in 2012)
 - China – NMPA approved products (class-III, including tissue and blood-based) in 2017, 2018, 2019, 2020, 2021, etc
- Small panel, low cost
- Relatively simple genomic data analytics

Multi-cancer test

- Biologically, blood-based tests are multi-cancer in nature
- Highly complex technology with product risk
 - Globally, only a small number of innovators have locked-down products going under intended-use validation
- Data as a key factor for development and validation
 - Evolving dataset leads to continuous product improvement and greater validation
- Unprecedented commercial potential
 - Possibility to fundamentally shift oncology landscape from late-stage therapeutics to earlier stage intervention