FDA Breakthrough Device Designation (BDD) Case Study

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AMDM Annual Meeting

April 20, 2023

Disclaimer

The views expressed during this presentation are those of the presenter and do not necessarily reflect the policy or position of the US FDA or the current employer.

Outline

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1. Overview of FDA Breakthrough Device Designation (BDD) Program
2. Critical Considerations for Breakthrough Device Designation Request
3. Case Studies

FDA Breakthrough Device Designation Pathway

- More effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- To provide patients and health care providers with timely access to these medical devices
  - Speeding up their development, assessment, and review
  - Preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health

Breakthrough Device Designation – Benefits

- Review Team Support
- Senior Management Engagement
- Interactive and Timely Communication (e.g., Sprint Discussion, Q-sub)
- Pre/Postmarket Balance of Data Collection (e.g., Data Development Plan)
- Efficient and Flexible Clinical Study Design (e.g., Clinical Protocol Agreement)
- Priority Review (e.g., Q-sub, IDE, marketing submissions)
- Manufacturing Considerations for PMA Submissions (e.g., FDA may decide not to conduct an inspection of certain manufacturing sites prior to approval of a Breakthrough Device)
- CMS reimbursement (e.g., IDE study, first 4 years after PMA approval)

Breakthrough Device Designation Request Processes

- Timing: “any time prior to the submission of
  - An application under section 515(c) [21 U.S.C 360e(c)]
  - A notification under section 510(k) [21 U.S.C. 360(k)], or
  - A petition for classification under section 513(f)(2) [21 U.S.C. 360c(f)(2)].”
- Process:
  - Submission of a “Designation Request for Breakthrough Device” Q-Submission
    - FDA guidance: “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”
    - Topics other than designation request in separate Q-Submission
  - FDA grant or denial decision within 60 calendar days of receiving the request

Breakthrough Device Designation Request Contents

- Background Information
  - Device Description
  - Indications for Use
  - Regulatory History
- Designation Criteria
  - Evidence in support of reasonable expectation of more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  - Evidence/justifications for at least one of the second criteria
- Regulatory Pathway
  - PMA, De Novo request or 510(k)
  - Rationale

FDA BDD Program Metrics

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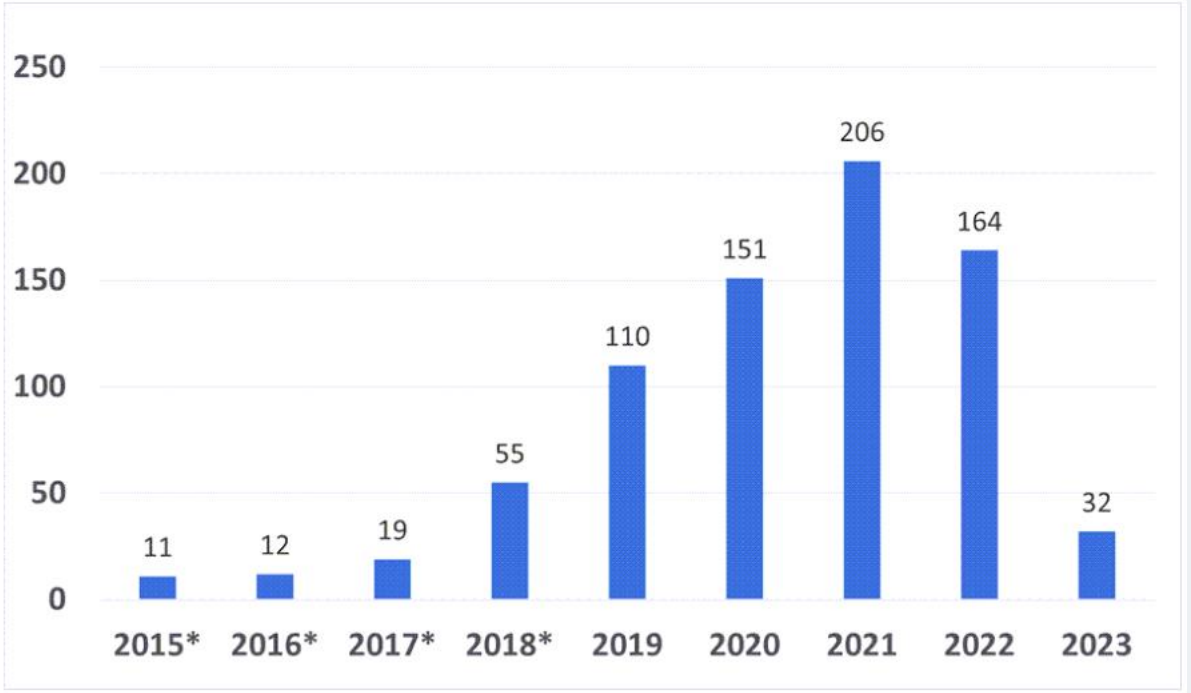
As of March 28, 2023

- CDRH and CBER have granted 760 Breakthrough Device designations
- Total of 62 Marketing Authorizations



Number of Granted Breakthrough Device Designations by Fiscal Year

Outline

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1. Overview of FDA Breakthrough Device Designation (BDD) Program
2. Critical Considerations for Breakthrough Device Designation Request
3. Case Studies

Breakthrough Device Designation Criteria

- Criterion #1: More effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  - More effective:
    - Technical Success – The device could function as intended
    - Clinical success – A functioning device could more effectively treat or diagnose the identified disease or condition
  - Disease:
    - cancer, acute stroke, myocardial infarction, trauma, amyotrophic lateral sclerosis (ALS)
- Criterion #2 (one of the following):
  A. Breakthrough technologies (e.g., liquid biopsy over tissue biopsy)
  B. No approved or cleared alternatives "at the time of the request for Breakthrough Device designation"
  C. Significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies
  D. Available in the best interest of patients (e.g., CDx, MCMs)

Data Development Plan (DDP)

- A high-level document intended to help ensure predictable, efficient, transparent, and timely device assessment and review by outlining data collection expectations for the entire product lifecycle
- Include both clinical (CV-DDP) and non-clinical (AV-DDP) testing approaches, non-clinical testing to be conducted and the timing of such testing relative to planned clinical studies and, as applicable, balance of premarket and postmarket data collection
- Either a complete DDP with all planned clinical and non-clinical testing for pre- and postmarket data collection, if appropriate, or a component or subset of the DDP (e.g., premarket non-clinical testing assessment plan)
- Optimal timeframe for submission varies depending on the device, and is ultimately at the sponsor's discretion, it may be most beneficial to initiate DDP discussions with FDA soon after a Breakthrough Device designation has been granted
- Not subject to an acceptance review

Clinical Protocol Agreement

- An agreement in writing for clinical protocols considered binding on both FDA and the sponsor
- Not subject to an acceptance review
- FDA will work interactively with sponsors on a proposed clinical protocol
- Upon reaching agreement, FDA will issue a letter documenting the agreement
- Reached agreement remain effective unless:
  - Any changes to the previously agreed-upon protocol are agreed upon in writing by both FDA and the sponsor; or
  - Office Director determines that a substantial scientific issue essential to determining the safety or effectiveness of the device exists. In this case, the director's decision must be provided in writing and can be made only after FDA has provided an opportunity to the sponsor to meet and discuss the substantial scientific issue(s). Such a meeting would need to include the Office director and clearly document the substantial scientific issue(s) discussed

Outline

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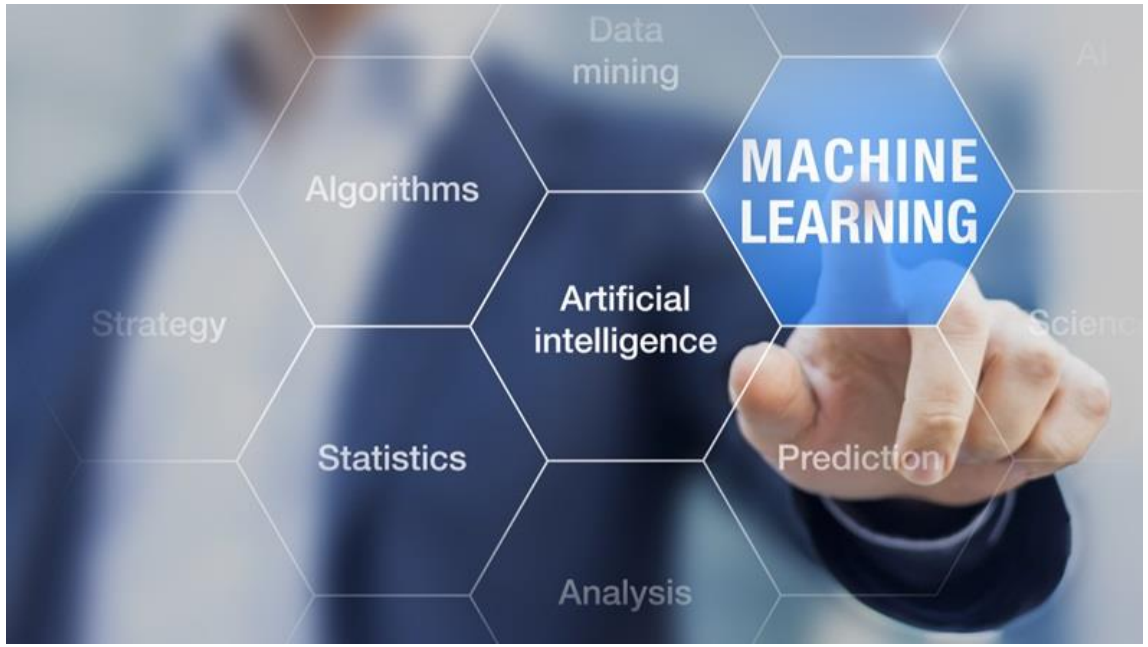
1. Overview of FDA Breakthrough Device Designation (BDD) Program
2. Critical Considerations for Breakthrough Device Designation Request
3. Case Study 1: AI/ML-enabled IVD

Advances in Artificial Intelligence/Machine Learning (AI/ML)

- AI has been incorporated in software in every aspect of healthcare
- Specifically Machine learning (ML), a subset of AI, has become an important part of an increasing number of medical devices
- AI/ML enables creating of new and important insights from vast amount of data generated during the delivery of health care every day



AI/ML-Enabled Medical Devices

Artificial Intelligence (AI):
A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions.

Machine Learning (ML):
A subset of AI that allows computer algorithms to learn through data, without being explicitly programmed, to perform a task.

AI/ML-Enabled Medical Device:
A medical device that uses machine learning to achieve its intended medical purpose.

Descriptions adapted from IMDRF Artificial Intelligence Medical Devices Key Terms & Definitions
Proposed document posted for public consultation Sept 2021 through Nov 29, 2021
http://www.imdrf.org/consultations/cons-aimd-mlmd-ktd.asp

Examples of AI/ML-Enabled Medical Devices

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FDA News Release

FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

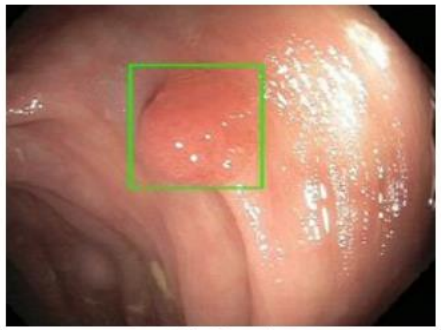
February 7, 2020

Caption Guidance

FDA News Release

FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer

April 9, 2021



GI Genius

Caption Guidance™ (Caption Health, Brisbane AU). Figure from www.captionhealth.com
GI Genius™ (Medtronic Inc., Minneapolis, Minnesota, USA). Figure from Hassan C et al. Gut. 2019.

FDA's Considerations on AI/ML-enabled devices

- Some of the greatest benefits are AI/ML's ability to learn from real - world use and experience, and its capability to improve its performance.
- FDA review medical devices based on a benefit risk model –
  - Ensure the benefits of the device outweigh the risks to patients
- Unique considerations for AI/ML-enabled devices
  - Usability, Trust, Equity, accountability
- FDA emphasizes transparency in AI/ML-enabled devices
  - Transparency is crucial to help providers and patients make informed decisions about their use of a device with AI/ML capabilities

Opportunities and Challenges

Baseline characteristics of FDA approved AI/ML device categories

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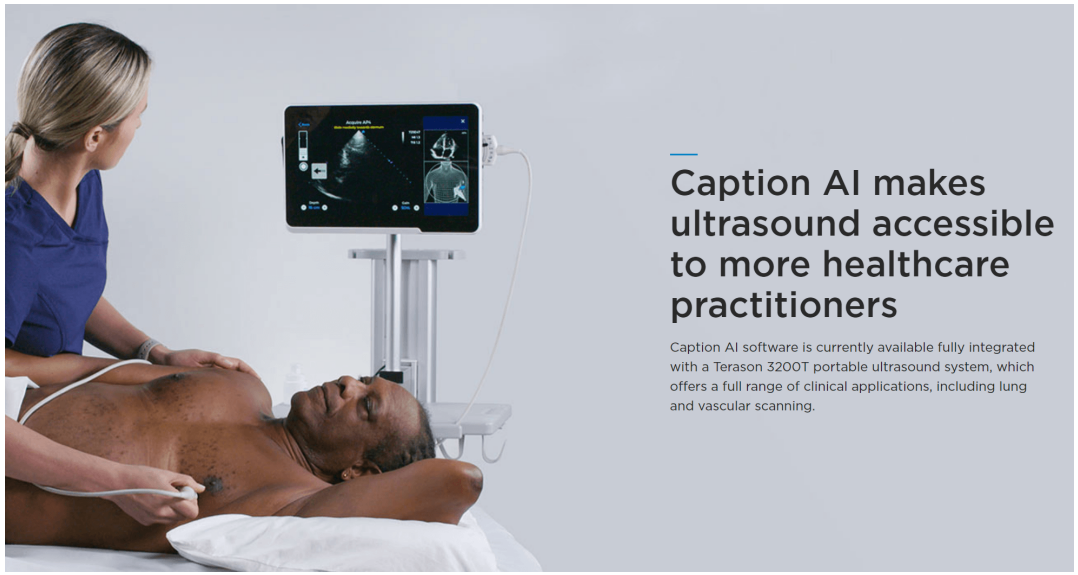
Characteristic	510(k) n = 204	De novo n = 15	PMA n = 3
Country of Origin (n%)			
Australia	3 (1.5)	0 (0)	0 (0)
Austria	3 (1.5)	0 (0)	0 (0)
Belgium	5 (2.5)	0 (0)	0 (0)
Canada	6 (2.9)	0 (0)	0 (0)
China	5 (2.5)	0 (0)	0 (0)
Denmark	1 (0.5)	0 (0)	0 (0)
England	9 (4.4)	0 (0)	0 (0)
Finland	2 (1.0)	0 (0)	0 (0)
France	8 (3.9)	0 (0)	0 (0)
Germany	2 (1.0)	0 (0)	0 (0)
Israel	15 (7.4)	1 (6.7)	0 (0)
Italy	2 (1.0)	0 (0)	0 (0)
Japan	2 (1.0)	0 (0)	0 (0)
Netherlands	4 (2.0)	0 (0)	0 (0)
New Zealand	1 (0.5)	0 (0)	0 (0)
Singapore	2 (1.0)	0 (0)	0 (0)
South Korea	3 (1.5)	0 (0)	0 (0)
Spain	1 (0.5)	0 (0)	0 (0)
Sweden	10 (4.9)	0 (0)	0 (0)
Switzerland	3 (1.5)	1 (6.7)	0 (0)
Taiwan	7 (3.4)	0 (0)	0 (0)
United States	110 (54)	13 (87)	3 (100)
Professional or Patient Use (n%)			
Healthcare Professional	177 (87)	10 (67)	2 (67)
Healthcare Professional and Patient	10 (4.9)	2 (13)	0 (0)
Patient	17 (8.3)	3 (20)	1 (33)

Characteristic	510(k) n = 204	De novo n = 15	PMA n = 3
Medical Specialty (n%)			
Anesthesiology	7 (3.4)	0 (0)	0 (0)
Cardiovascular	35 (17)	5 (33)	0 (0)
Clinical Chemistry	4 (2.0)	1 (6.7)	1 (33)
Clinical Toxicology	1 (0.5)	0 (0)	0 (0)
Dental	1 (0.5)	0 (0)	0 (0)
Gastroenterology/Urology	1 (0.5)	0 (0)	0 (0)
General Hospital	2 (1.0)	0 (0)	0 (0)
Hematology	5 (2.5)	0 (0)	0 (0)
Microbiology	4 (2.0)	0 (0)	0 (0)
Molecular Genetics	0 (0)	1 (6.7)	0 (0)
Neurology	19 (9.3)	2 (13)	0 (0)
Obstetrics/Gynecology	1 (0.5)	1 (6.7)	0 (0)
Ophthalmic	1 (0.5)	1 (6.7)	0 (0)
Radiology	123 (60)	4 (27)	2 (67)
Manufacturer Size (n%)			
Small	158 (77)	12 (80)	2 (67)
Large	46 (23)	3 (20)	1 (33)

Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. Lancet Digit Health 2021;

FDA BDD Case Study -- Caption Guidance

- AI empowers medical professionals without specialized training to perform cardiac ultrasound
- Provide real-time guidance and diagnostic quality assessment of images



Bring the benefits of ultrasound to more patients, help standardize the quality of care, and help institutions realize valuable cost and time savings

Outline

Burning Rock Dx

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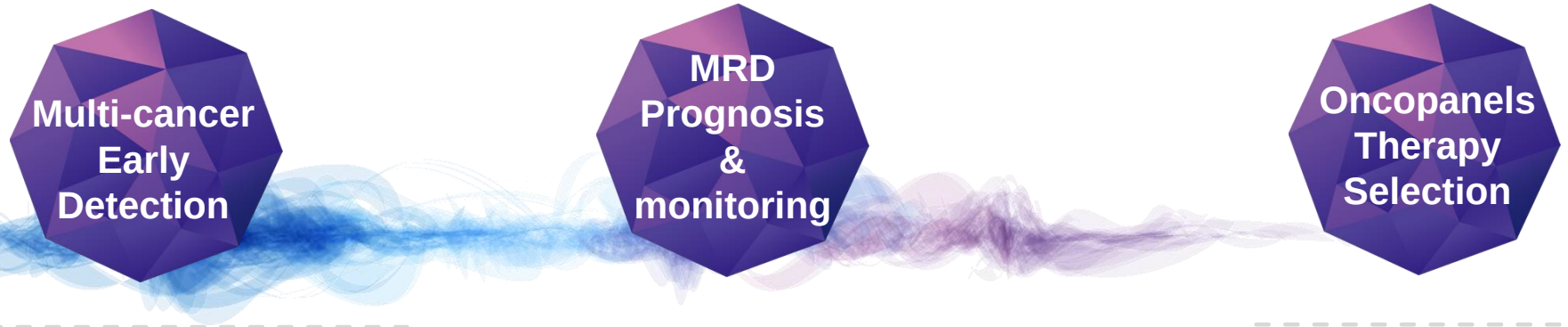
1. Overview of FDA Breakthrough Device Designation (BDD) Program
2. Critical Considerations for Breakthrough Device Designation Request
3. Case Study 2: Burning Rock Dx OverC™ Multi Cancer Early Detection Blood Test

Burning Rock: NGS-based Specialty Oncology Diagnostic Firm Offers Complete Liquid Biopsy Solution

Burning Rock Dx



- **Kit** format
- Commercialized in China (**50+** hospitals)
- **CE**-mark
- **FDA** Breakthrough Designation
- Clinical program forward (n>**33,400**)

- **Tumor-informed, personalized** MRD
- **LOD 4X10^{-5}**
- **100,000X** raw depth

- **Mid-, large-sized** panels (168 genes & 520 genes)
- **C.73000** tested patient samples in China
- **#1** performance in LB tests in FDA-led study

Burning Rock System

1) Mirrored QMS system in both US and China supporting global clinical trials
2) Comprehensive product validation in compliance with multiple regulatory frameworks
3) Regulatory and Quality expertise navigating CN, US, and EU regulatory framework
4) #1 Commercialization infrastructure in China

c.400k Cumulative number of NGS tests
c.**27,000** patients tested in 2022 through central-lab, **44%** ctDNA-based
54,000 distributed IVD kits in 2022
60+ pharma services clients
c.250 R&D staff plus technology, medical, regulatory
24,000+ m^2 laboratories & GMP factories

Burning Rock's OverC™ MCED blood test

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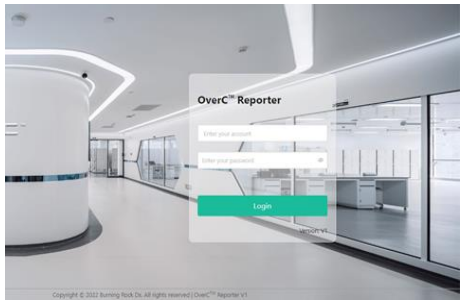
OverC™ is a NGS-based DNA methylation profiling test that detects tumor-derived signals through a simple blood draw. The key elements of its implementation include a **semi-automated liquid biopsy workflow** and a **qualitative data analysis software**.

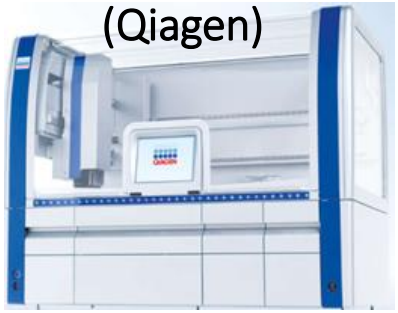
Reagents:

Software:



Instrument:

QIAsymphony SP (Qiagen)



Sciclone G3 workstation (Perkin Elmer)

NovaSeq 6000 (Illumina)

Burning Rock's Early Detection Technology

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Competitive technology

Methylation + machine learning to overcome challenges of low ctDNA abundance, leading to feasibility of multi-cancer early detection

Multi-cancer validation data

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

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

Annals of Oncology 2023

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

AACR 2022

Clinical validation of a multicancer detection blood test by circulating cell-free DNA (cfDNA) methylation sequencing: The THUNDER study.

ASCO 2022

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

ESMO 2022

OverC Breakthrough Device Designation Request

Burning Rock Dx

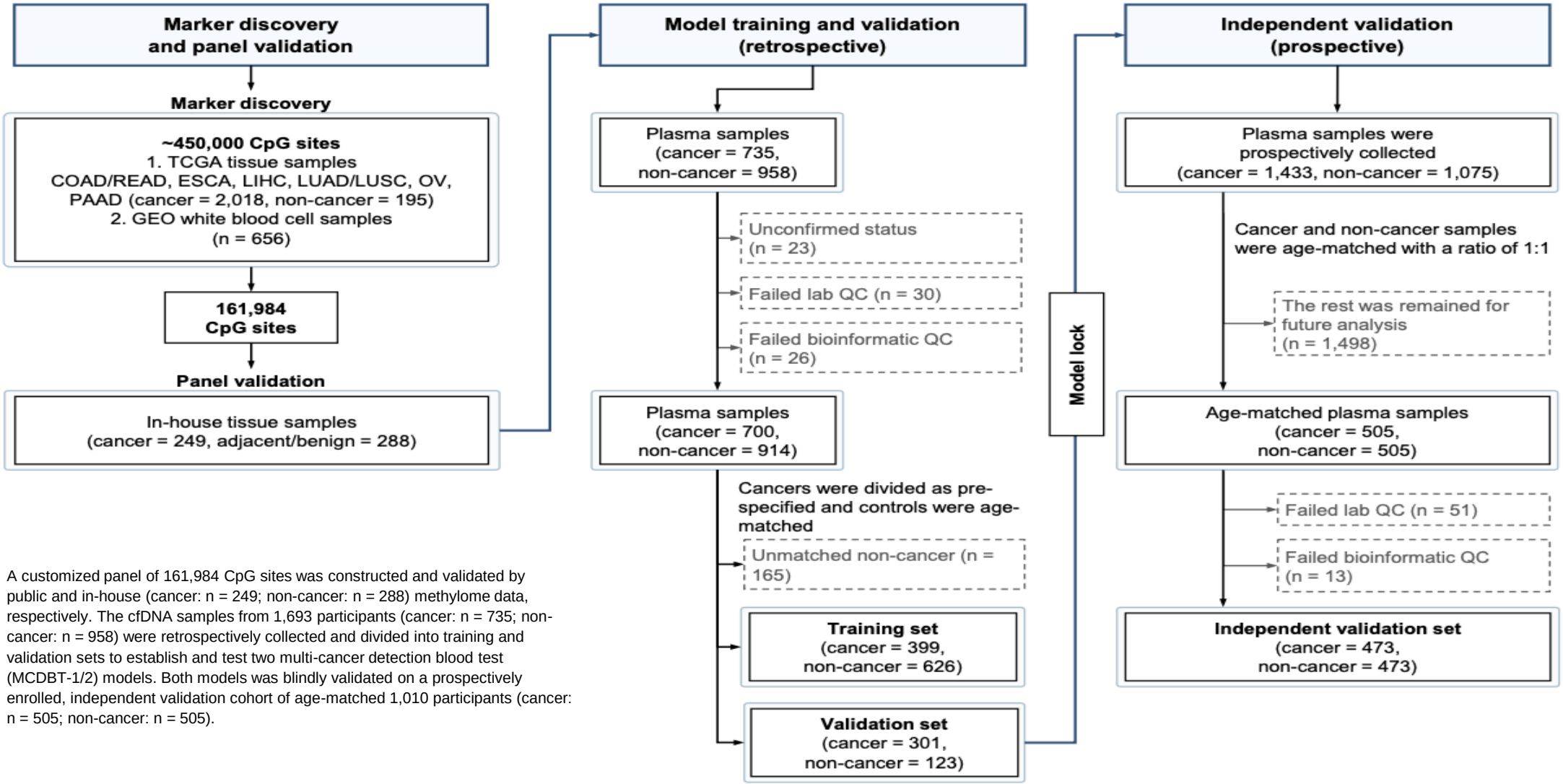
- Device Description:
  - Reagents, software, instruments and procedures for testing plasma cfDNA methylation signature
  - Regions/biomarkers, algorithm, test result and report
- Indications for Use:
  - *OverC ™ Multi-Cancer Detection Blood Test (MCDBT) is a qualitative next-generation sequencing (NGS)-based in vitro diagnostic device intended for the detection of DNA methylation markers using cfDNA isolated from human peripheral whole blood. The test is intended for early detection of multiple cancer types (esophagus, liver, lung, ovary, and pancreatic cancers) in adults of either sex, aged 50-75 years old, at average risk for cancer. Test results of "Detected" with the top one or two predicted origin of cancer-associated signals may indicate the presence of cancer and should be followed up by diagnostic tests suggested by qualified healthcare professionals in accordance with professional guidelines. Test results of "Undetected" do not rule out the presence of cancer, and individuals should continue with guideline-recommended standard of care screening tests. OverC ™test is not a replacement for cancer diagnostic tests or guideline-recommended standard of care screening tests.*
  - *This device is not intended to be used for standalone diagnostic purposes. Assay results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice.*
  - *The OverC ™ Multi-Cancer Detection Blood Test (MCDBT) is a single-site assay performed at Burning Rock Dx, LLC...*
- *Regulatory History*
  - None

OverC Breakthrough Device Designation Request

- Designation Criteria #1: More effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  - Cancer is a life-threatening human disease, especially when diagnosed at later stage
  - Incidence of cancer is high in the U.S. population
  - Limitations of current SoC screening methods in detecting cancers in the U.S. population
  - OverC MCDBT provides more effective early detection of multiple cancer types

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

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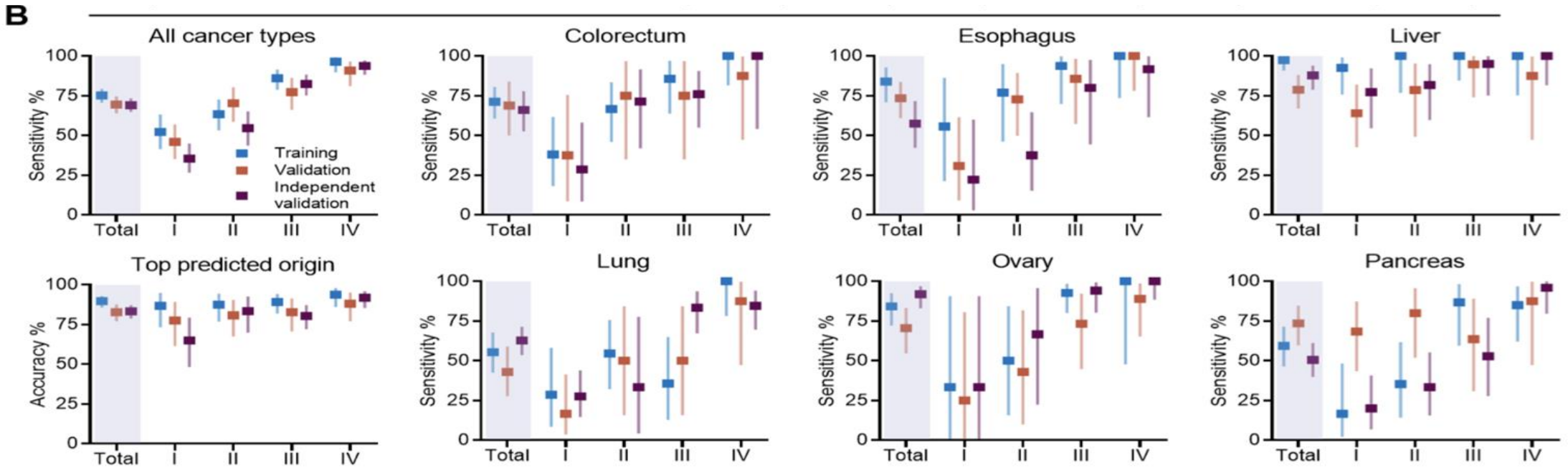
Fig 3. Performance of the MCDBT-1/2 models. A. Sensitivity, specificity, accuracy of top predicted origin, and accuracy of top two predicted origins. **B**. The overall sensitivity, accuracy of top predicted origin, and sensitivity stratified by cancer types reported by tumor stage.



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

OverC Breakthrough Device Designation Request

- Designation Criteria #1: More effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  - Cancer is a life-threatening human disease, especially when diagnosed at later stage
  - Incidence of cancer is high in the U.S. population
  - Limitations of current SoC screening methods in detecting cancers in the U.S. population
  - OverC MCDBT provides more effective early detection of multiple cancer types
- Proposed large population-based prospective study in IU population to demonstrate “More Effective” diagnosis

OverC Breakthrough Device Designation Request

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- Designation Criteria #2:
  A. Represents Breakthrough Technology
     - NGS-based liquid biopsy and ELSA-Seq technology
  B. No Approved or cleared Alternatives Exist
  C. Offers Significant Advantages over Existing Approved or Cleared Alternatives
     - Detect cancers not routinely subject to screening
     - Complement to SoC method with high compliance rate
  D. Device Availability is in the Best Interest of Patients
     - Non-invasive single blood draw increases test availability and adherence to cancer screening, esp. areas with difficulties in accessing screening services
     - Reduce socioeconomic, geographic and racial disparities

Regulatory Milestones Achieved

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CE Mark
(May 2022)

Declaration of Conformity

Manufacturer:	Guangzhou Burning Rock Dx Co., Ltd. Unit 201, 202, Floor 2, No.7 Luoxuan 4th Road Guangzhou International Biotech Island Huangpu District, Guangzhou Guangdong, China 510300
whose single Authorized EU *Representative:*	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany E-mail: info.m@luxuslw.de
Product Name:	OverC™ Multi-Cancer Detection Blood Test

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
Applied standards are listed in the attachment – List of Standards with Compliance

Signature: *Xueying Sharon Liang*

Date: April 20, 2022
Title: Vice President, Global Regulatory and Quality Affairs
Place: Guangzhou, China

FDA Breakthrough Device Designation
(Dec. 2022)

U.S. FOOD & DRUG ADMINISTRATION

December 22, 2022

Burning Rock Dx, LLC
Katrice McLoughlin, Ph.D.
Senior Regulatory Affairs Specialist
121 Innovation Drive, Suite 100
Irvine, CA 92617

Re: Q222374
Trade/Device Name: OverC™ Multi-Cancer Early Detection Test
Received: October 25, 2022

Dear Dr. Katrice McLoughlin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. The proposed indications for use include:

OverC™ Multi-Cancer Detection Blood Test (MCDBT) is a qualitative next-generation sequencing (NGS)-based in vitro diagnostic device intended for the detection of DNA methylation markers using cfDNA isolated from human peripheral whole blood. The test is intended for early detection of multiple cancer types (esophagus, liver, lung, ovary, and pancreatic cancers) in adults of either sex, aged 50-75 years old, at average risk for cancer. Test results of "Detected" with the top one or two predicted origin of cancer-associated signals may indicate the presence of cancer and should be followed up by diagnostic tests suggested by qualified healthcare professionals in accordance with professional guidelines. Test results of "Undetected" do not rule out the presence of cancer, and individuals should continue with guideline-recommended standard of care screening tests. OverC™ test is not a replacement for cancer diagnostic tests or guideline-recommended standard of care screening tests.

This device is not intended to be used for standalone diagnostic purposes. Assay results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice.

The OverC™ Multi-Cancer Detection Blood Test (MCDBT) is a single-site assay performed at Burning Rock Dx, LLC located at 121 Innovation Drive, Suite 100, Irvine, CA 92617.

We are pleased to inform you that your device and proposed indications for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/media/108135/download.

Challenges for Validation Studies

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Analytical Validation

- Specimen handling variability
- Difficulty obtaining clinical samples for rare alleles
- Multiplex assays often require complex validation
- Lack of reproducibility/high analytical variability
- Analytes are not stable
- Lack of comparators, calibrators and standards
- Whole genome technologies present unique challenges to validation strategies

Clinical Validation

- Specimen availability
- Clinical study design and data don't support intended use
- Clinical studies to validate molecular diagnostic test often have unique statistical challenges
- Pre-specified clinical/statistical analysis plan is crucial
- Sensitivity of assay vs. comparator method
- Appropriate determination of clinical cut offs

The validation study should investigate test use in the claimed clinical population in intended setting using the final test configuration!

Take-home Message

- Breakthrough Device Designation offers many benefits to a device manufacturer
  - Interactions with FDA (e.g., Sprint Discussion, Q-subs, Data Development Plan)
  - Priority Review (e.g., Q-sub, IDE, marketing submissions)
  - CMS reimbursement (e.g., IDE study, first 4 years after PMA approval)
- Breakthrough Device Designation request can be submitted any time prior to a marketing submission (e.g., PMA, 510(k), de novo)
- Breakthrough Device Designation request should be submitted as a "Designation Request for Breakthrough Device" Q-Submission with special attentions to:
  - Justification of the Disease or Condition as "Life-Threatening" or "Irreversibly Debilitating"
  - Evidence (and future plans) in support of a reasonable expectation of successes:
    - Technical Success – The device could function as intended
    - Clinical Success – A functioning device could more effectively treat or diagnose the identified disease or condition
- Beneficial to initiate DDP discussions with FDA soon after a BDD has been granted

Thank You!

Burning Rock Dx

Sharon.Liang@brbiotech.com