DATAR CANCER GENETICS

Cancer:

Screening Diagnosis Treatment Guidance Monitoring

DATAR CANCER GENETICS

UNITED KINGDOM | UNITED STATES | GERMANY | INDIA

About Us

- **Internationally accredited IVD, onco-genomic and diagnostics organisation**
- **Unique diagnostics and major lab facilities**
- **Self-funded, profitable, growing and debt-free**
- **Close relationship with leading UK oncologists, surgeons and clinicians – for example at The Cromwell Hospital and at Imperial College**

Office/Lab Locations
UK, India, Germany, USA,

America & Caribbean

Canada
United States
Mexico
Bahamas
Brazil

Europe

Denmark
Germany
Greece
Hungary
Netherlands
Poland
Slovakia
Spain
Sweden
UK

Middle East & Africa

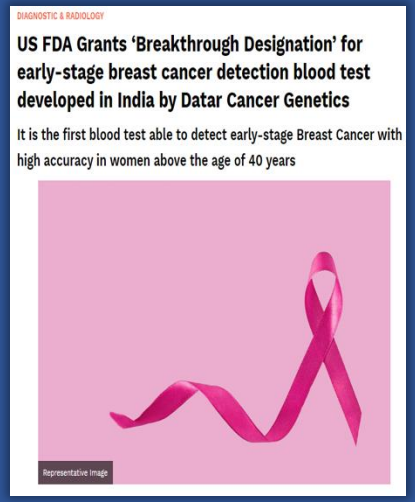
Bahrain
Kingdom of SA
Kuwait
Nigeria
Israel
Qatar
South Africa
Turkey
UAE
Egypt

Asia-Pacific

Australia
Bangladesh
Hong Kong
India
Malaysia
Singapore
Sri Lanka
Uzbekistan
Vietnam
Philippines

3 FDA Breakthrough Device Designations for Early Detection

FDA Grants Breakthrough Designation for Early-Stage Breast Cancer Detection Blood Test Developed by Datar Cancer Genetics



DIAGNOSTIC & RADIOLOGY

US FDA Grants 'Breakthrough Designation' for early-stage breast cancer detection blood test developed in India by Datar Cancer Genetics

It is the first blood test able to detect early-stage Breast Cancer with high accuracy in women above the age of 40 years

Representative Image

US FDA Grants the Coveted Breakthrough Designation for Early-Stage Prostate Cancer Detection Blood Test Developed in India by Datar Cancer Genetics

USFDA grants Breakthrough Designation to Datar Cancer Genetics for blood test detecting prostate cancer

FDA Grants Datar Breakthrough Designation for Blood Test to Help Diagnose Brain Tumors

FDA grants breakthrough designation for blood test to help diagnose inaccessible brain tumours

3 Jan 2023

The US Food and Drug Administration (FDA) has granted 'Breakthrough Device Designation' for 'TriNetra-Glio', a blood test to help in the diagnosis of brain tumours.

Worldwide, brain cancer is the 12th most lethal cancer, and each year, more than 250,000 adults die due to the disease.

Diagnosis of brain tumours is resource-intensive, risk-prone and brain biopsies are impossible to perform in almost 40% of advanced cases.

Presently, no blood test is available for diagnosing brain cancers, and doctors have to rely on complex surgical procedures to obtain tumour tissue for histopathological evaluation.

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DCG Labs and Capabilities

Platforms

- Molecular facility (NGS, ddPCR, q/RT-PCR)
- Cell culture (automated liquid handling, high content imaging and multi-mode imaging scanners, cytology and fluorescent immunocytochemistry)
- Histopathology (immunohistochemistry)
- Full LIMS integration

Bio-informatics

In-house bio-informatics facility with proprietary 'machine learning' and artificial intelligence based capabilities to translate laboratory data into actionable outputs to support cancer management decisions

Accreditations and Certifications

CE IVD Now Marked · CAP ACCREDITED College of American Pathologists · CLIA Accredited Laboratory Reg. No.: 99D2171983 · UKAS Medical · CareQuality Commission · ISO 15189

01 | Molecular Facility

02 | Cell Culture

03 | Histopathology

04 | Full LIMS Integration

05 | Bio-informatics

06 | Artificial Intelligence

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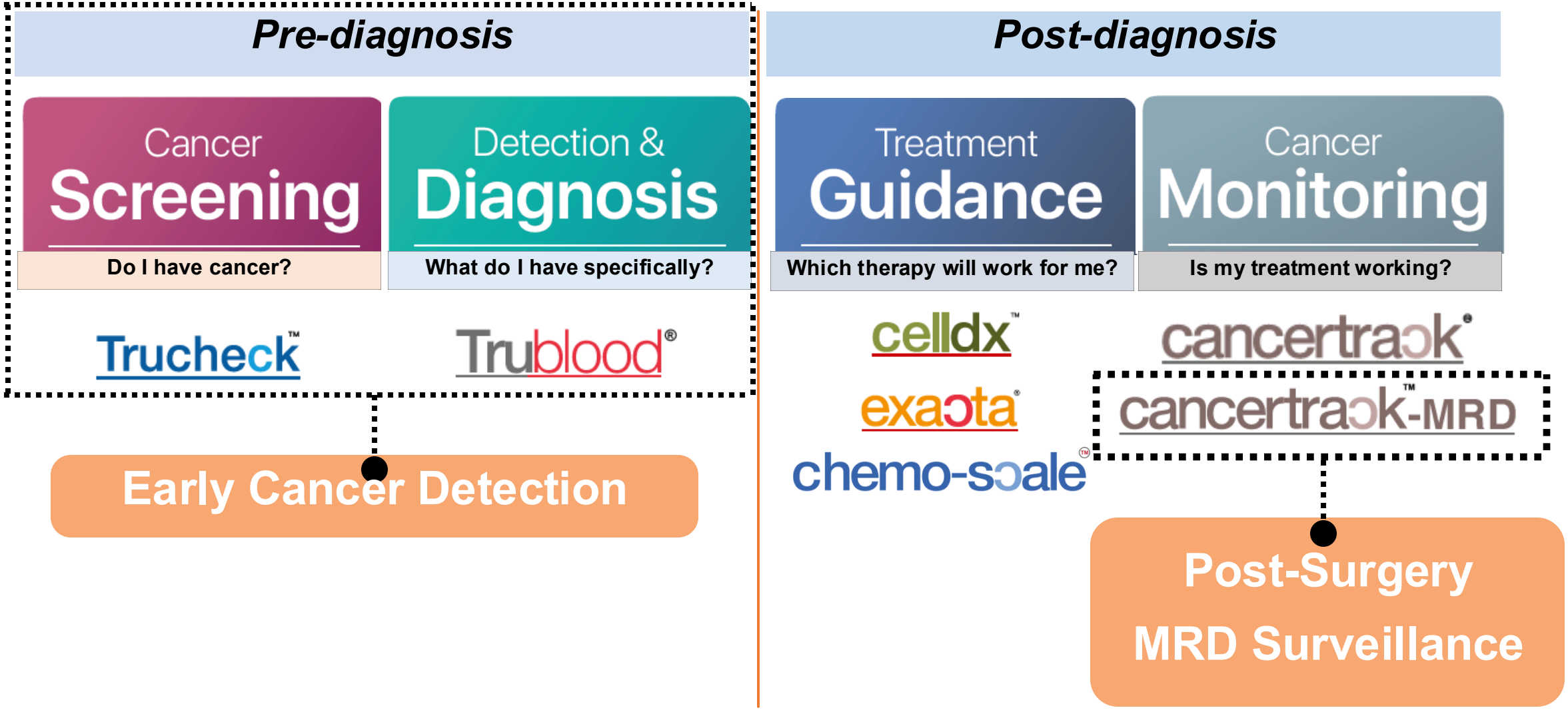
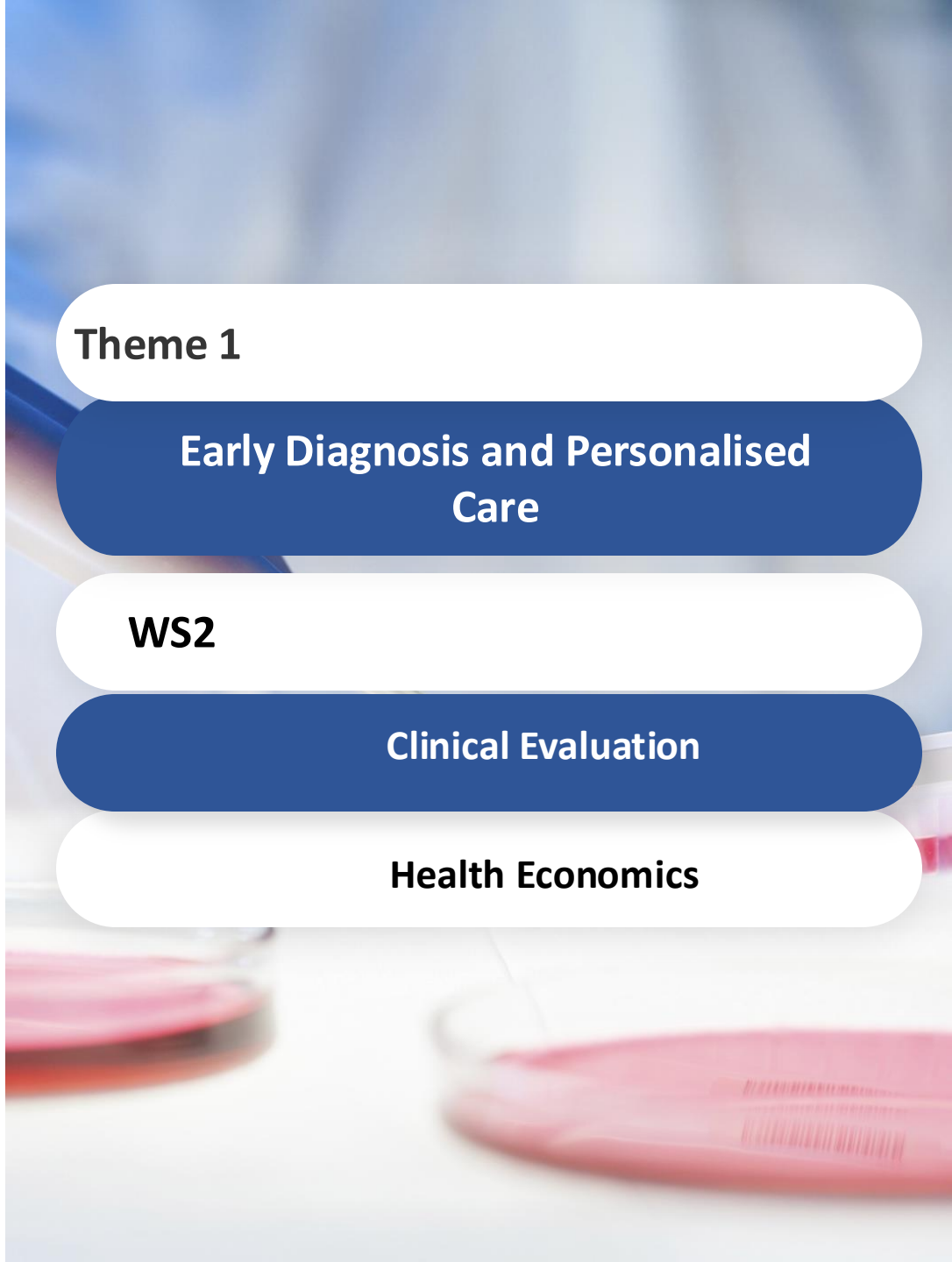
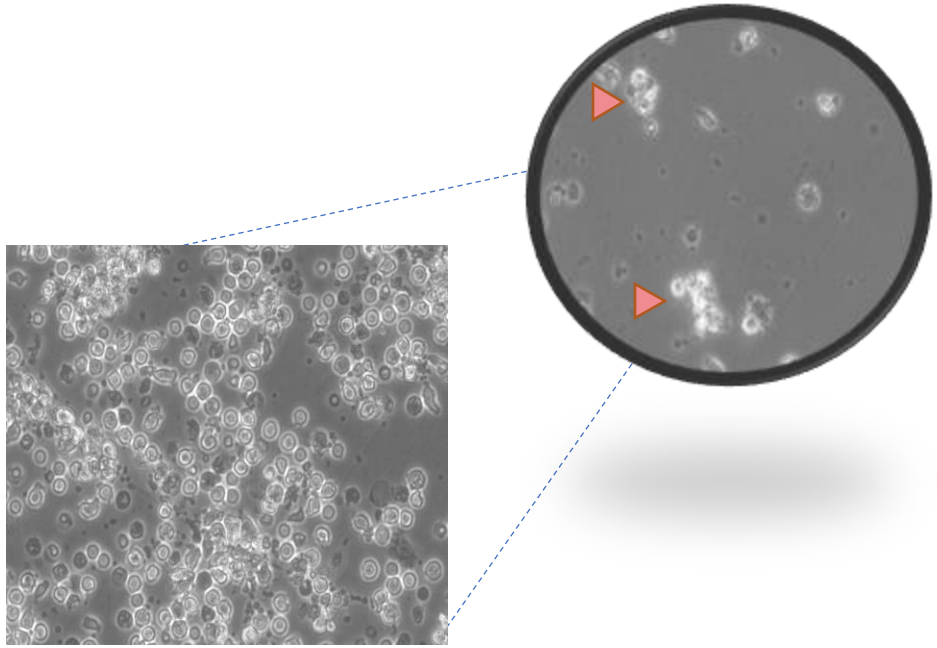
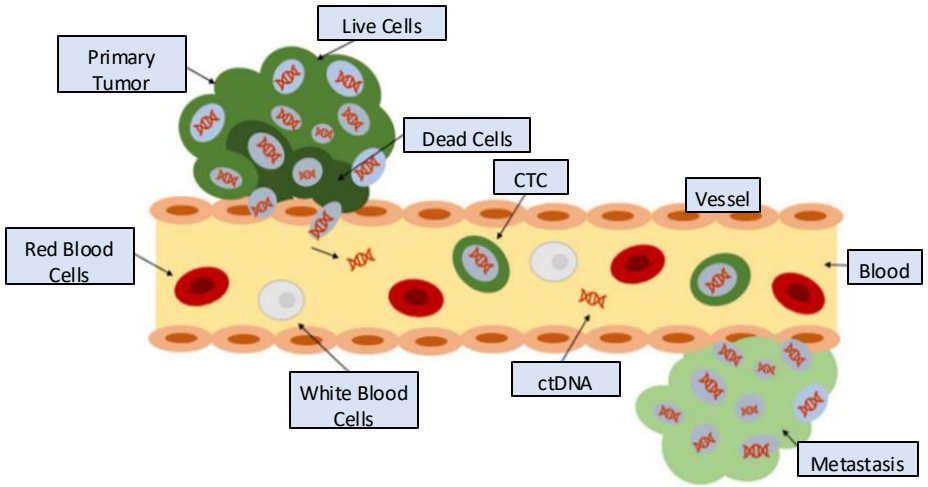
DCG Portfolio in Comprehensive Cancer Management



HRC Goals


Theme 1
Early Diagnosis and Personalised Care
WS2
Clinical Evaluation
Health Economics





Proprietary Technology

CTC Enrichment

Our proprietary technology enables the enrichment of CTCs by selectively killing the non-malignant cells in blood sample

Enriched CTCs are then characterized with EpCAM+, CK+, CD45− and their morphological characteristics

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Evidenced based approach: Key CTC publication

Trucheck™ 2020

[Akolkar et al; 2020 doi.org/10.1002/ijc.32815](https://doi.org/10.1002/ijc.32815)

IJC International Journal of Cancer

Circulating ensembles of tumor-associated cells: A redoubtable new systemic hallmark of cancer

Dadasaheb Akolkar[1], Darshana Patil[1], Timothy Crook[2], Sewanti Limaye[3], Raymond Page[4], Vineet Datta[1], Revati Patil[1], Cynthe Sims[1], Anantbhushan Ranade[5], Pradeep Fulmali[1], Pooja Fulmali[1], Navin Srivastava[1], Pradip Devhare[1], Sachin Apurwa[1], Shoeb Patel[1], Sanket Patil[1], Archana Adhav[1], Sushant Pawar[1], Akshay Ainwale[1], Rohit Chougule[1], Madhavi Apastamb[1], Ajay Srinivasan[1] and Rajan Datar[1]

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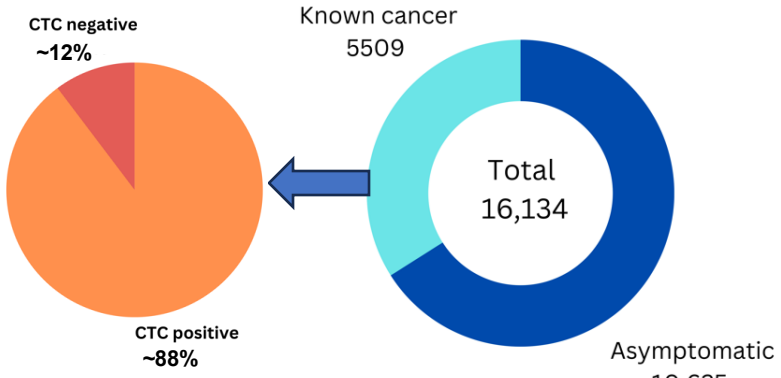
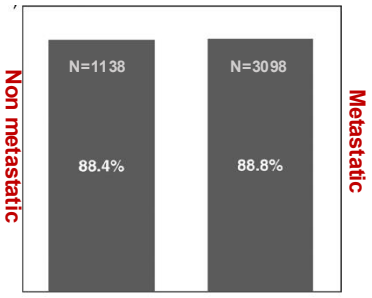
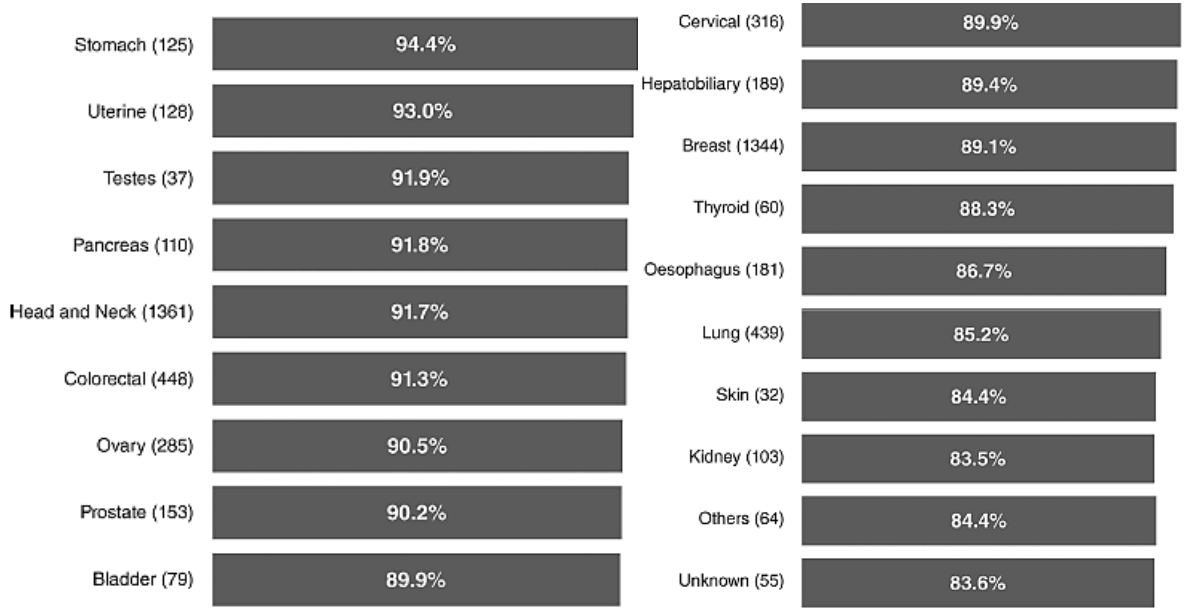
[2]St. Luke's Cancer Centre, Royal Surrey County Hospital, Guildford, United Kingdom
[3]Department of Medical Oncology, Kokilaben Dhirubhai Ambani Hospital, Mumbai, India
[4]Department of Biomedical Engineering, Worcester Polytechnic Institute, Worcester, Massachusetts
[5]Avinash Cancer Clinic, Pune, India





Comparable detection sensitivity in metastatic vs non metastatic patients

1. First report on CTCs
2. Unique enrichment chemistry via depletion
3. Systemic hallmark which is cancer agnostic (solid organ)



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Evidenced based approach: Key CTC publication

Trublood® 2021

[Gaya et al; 2021 doi. org/10.1002/cncy.22366]

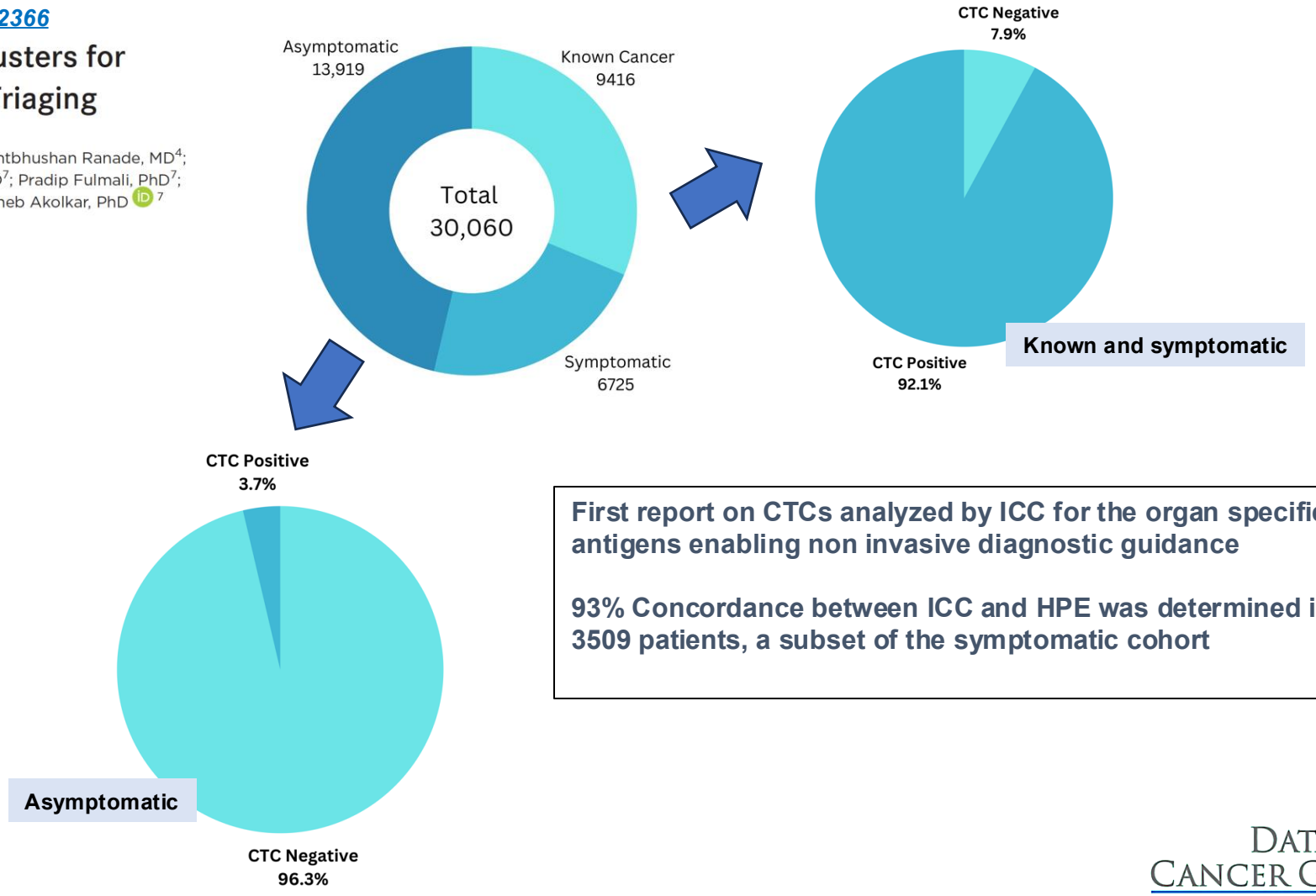
Evaluation of Circulating Tumor Cell Clusters for Pan-Cancer Noninvasive Diagnostic Triaging

Andrew Gaya, MD[1]; Timothy Crook, PhD, MBBS[2]; Nicholas Plowman, MD[3]; Anantbhushan Ranade, MD[4]; Sewanti Limaye, MD[5]; Amit Bhatt, MD[4]; Raymond Page, PhD[6]; Revati Patil, MD[7]; Pradip Fulmali, PhD[7]; Vineet Datta, MD[7]; Prashant Kumar, PhD[7]; Darshana Patil, MD[7]; and Dadasaheb Akolkar, PhD [7]

TABLE 2. Organ-Specific and Subtype-Specific Antibodies[a]

Cancer Type	Marker 1	Marker 2	Marker 3	Marker 4
Bladder	Uroplakin-II	GATA3	CK20	CK7
Breast	GCDFP-15	GATA3	EMA	CK7
CNS	GFAP	S100	Nestin	Olig-2
Cervix	p63	p16	CEA	CK7
Colorectum	CDX2	MUC2	CK20	—
Gallbladder	CEA	Maspin	CK19	CK7
Head and neck	p63	HMWCK	CK5/CK6	—
Kidney	CA-IX	RCC	CD10	Pax-8
Liver	Glypican 3	Hep Par-1	AFP	Arginase
Lung	Napsin-A	TTF-1	p40	CK7
Esophagus	p63	CK5/CK6	MUC2	CK7
Ovary	CA125	WT-1	Pax-8	CK7
Pancreas	CA19.9	CK19	Maspin	CK7
Prostate	AMACR	PSMA	p63	PSCA
Sarcomas	SMA	S100	CSV	—
Stomach	CDX2	CEA	CK7	—
Thyroid	TTF-1	Thyroglobulin	Calcitonin	CK19
Uterine	CK19	Pax-8	CEA	CK7

Abbreviation: CNS, central nervous system.
[a]The listed organ-specific and subtype-specific markers were evaluated by immunocytochemistry profiling for each cancer type.



First report on CTCs analyzed by ICC for the organ specific antigens enabling non invasive diagnostic guidance

93% Concordance between ICC and HPE was determined in 3509 patients, a subset of the symptomatic cohort

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Evidenced based approach: Key CTC publications in 2022, 2023 and 2024

FDA BREAKTHROUGH DEVICE DESIGNATION

TruBlood Breast, 2022

cancers | MDPI

Article

Accurate Screening for Early-Stage Breast Cancer by Detection and Profiling of Circulating Tumor Cells

Timothy Crook [1,*], Robert Leonard [2], Kefah Mokbel [3], Alastair Thompson [4], Michael Michell [5], Raymond Page [6], Ashok Vaid [7], Ravi Mehrotra [8], Anantbhushan Ranade [9], Sewanti Limaye [10], Darshana Patil [11], Dadasaheb Akolkar [11], Vineet Datta [11], Pradip Fulmali [11], Sachin Apurwa [11], Stefan Schuster [12],

Received: 3 August 2023 | Revised: 17 November 2023 | Accepted: 29 November 2023
DOI: 10.1002/ijc.34827

TruBlood Brain, 2023

IJC INTERNATIONAL JOURNAL of CANCER

RESEARCH ARTICLE
Tumor Markers and Signatures

Profiling of circulating glial cells for accurate blood-based diagnosis of glial malignancies

Kevin O'Neill [1] | Nelofer Syed [2] | Timothy Crook [2] | Sudl
Mahadev Potharaju [4] | Sewanti Limaye [5] | Anan
Giulio Anichini [2] | Darshana Patil [7] | Vineet Datta

FDA BREAKTHROUGH DEVICE DESIGNATION

FDA BREAKTHROUGH DEVICE DESIGNATION

TruBlood Prostate, 2023

Cancer Medicine WILEY

RESEARCH ARTICLE

Accurate prostate cancer detection based on enrichment and characterization of prostate cancer specific circulating tumor cells

Sewanti Limaye [1] | Simon Chowdhury [2] | Nitesh Rohatgi [3] | Anantbhushan Ranade [4] | Nelofer Syed [5] | Johann Riedemann [6] | Darshana Patil [7] | Dadasaheb Akolkar [7] | Vineet Datta [7] | Shoeb Patel [7] | Rohit Chougule [7] | Pradyumna Shejwalkar [7] | Kiran Bendale [7] | Sachin Apurwa [7] | Stefan Schuster [8] | Jinumary John [7] | Ajay Srinivasan [7] | Rajan Datar [7]

TruBlood Pancreaticobiliary, 2024

cancers | MDPI

Article

Liquid Biopsy for Detection of Pancreaticobiliary Cancers by Functional Enrichment and Immunofluorescent Profiling of Circulating Tumor Cells and Their Clusters

Andrew Gaya [1,*], Nitesh Rohatgi [2], Sewanti Limaye [3], Aditya Shreenivas [4], Ramin Ajami [5], Dadasaheb Akolkar [6], Vineet Datta [6], Ajay Srinivasan [6] and Darshana Patil [6]

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Unique Combinations of Technologies

CTC Only Liquid Biopsy	**TruCheck** A screening test enabling early detection of multiple cancers in asymptomatic individuals.	**TruBlood** A diagnostic triaging test for suspected patients.	**ChemoScale** An in vitro drug sensitivity test. Chemotherapeutic drugs, repurposed drugs/natural substances.
CTC + Molecular Genomics Liquid Biopsy	**Exacta** A multi-analyte test for comprehensive tumour profiling for relapsed / refractory / metastatic cancer patients.	**CancerTrack** A test to monitor the response to treatment or for disease recurrence.	
Tissue Sequencing: IHC + Molecular Analysis	**CellDx** A deep genomic analysis of tumour tissue.		

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cancertrack™-MRD

Keeping track of cancer post-op

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CancerTrack MRD:

Unique two-pronged approach that combines both tumour-informed and tumour-naïve strategies so as to maximise detection and improve accuracy

CancerTrack MRD Baseline (Tissue + blood)

1. **Tumour profiling at baseline: interrogates pre-selected cancer genes (395 gene panel) and identifies patient-specific somatic mutations**
2. **Tumour-informed approach: ctDNA profiling for patient specific somatic mutations that were identified in baseline tumour profiling by ddPCR assay**
3. **Tumour-naïve approach: ctDNA profiling for 52 preselected cancer genes by NGS**

CancerTrack MRD Follow up (Blood)

- **Performed subsequently (typically every 3-6 months) for disease surveillance**
- **Steps 2 and 3 above**

We are especially seeking clinical evidence and health economics partners in:-

- **Prostate, pancreatic, colo-rectal, brain cancer**
- **Early detection**
- **High sensitivity MRD (minimum residual disease) post-op recurrence and surveillance**
- ***In vitro* chemosensitivity testing**

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Thank You

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