Exacta®
Integrative Actionable Tumor Investigations

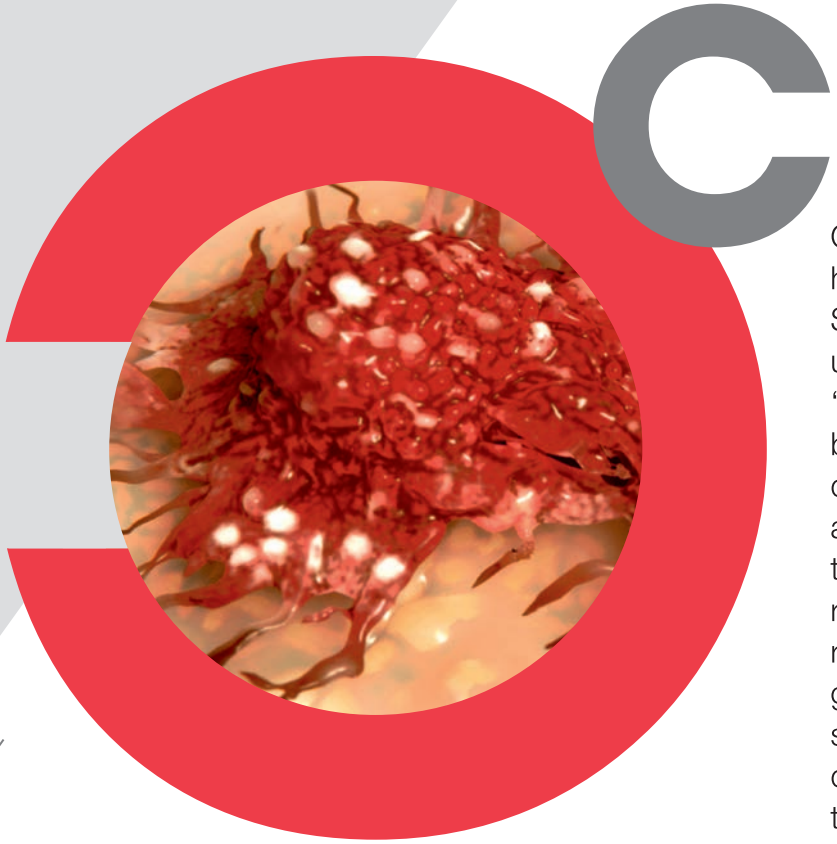
exacta®

ENCYCLOPEDIC TUMOR ANALYSIS

ABSOLUTE IMPACT
ABSOLUTE SCIENCE
ABSOLUTE COMMONSENSE

DATAR CANCER GENETICS

UNITED KINGDOM | GERMANY | INDIA



About Exacta®

Cancer is a genetic disease. Every human being is different and unique, Similarly every person's cancer also is unique. However, conventional 'Standard of Care' approaches are based on limited investigations, which disregard the unique genetic landscape and complex metabolic dynamics of the tumor. As a result, the patients are at a risk of failed therapies or aggressive relapse. It is, thus, imperative that the genetic architecture of the tumor is studied comprehensively before deciding the treatment plan, whichhas to be personalized to individual patient and his or her disease.

Exacta® is a comprehensive, in-depth, integrative, cellular and molecular tumor analysis, which parses millions of data points to present actionable vulnerabilities of the tumor for effective treatment strategies.

Exacta® multi-analyte and multi-coordinate investigations that integrates genomic alterations in 452 genes and perturbation in expressions of 20,800 genes, to unravel actionable mutations and pathways propelling the cancer. Exacta® can identify most-efficacious drugs for every individual cancer and thus enables highly sophisticated treatment strategies beyond conventional perspective, even for difficult cancers.

Exacta® is Particularly Recommended for Cancer Patients Where...

- First-line therapy has failed
- Cancer has relapsed
- Cancer is high-grade / metastatic
- Newly diagnosed patients with difficult cancers such as Sarcoma, Pancreas, Gallbladder. Cancers with limited / no standard options
- Risk of therapy failure is high

Exacta® Methodology

DNA	SNVs, CNVs, Indels, Tumor Mutation Burden, Germline Mutations
RNA	KEGG Pathways (Disease, Actionable, Resistance), Gene Expression, Fusion / Rearrangement
Pharmacogenetics	Genotyping for CYP450 metabolizing enzymes, drug transporters for drug toxicity and efficacy
Chemosensitivity	In-vitro cell based assay for testing cytotoxic drugs and drug combinations

Exacta® Analysis Unravels

Optimal Targeted Therapies:

Exacta® comprehensive molecular analysis includes all relevant biomarkers including mutations, deletions, gene rearrangement, gene amplification and gene expression, to identify tumor vulnerabilities for optimum targeted therapy selection. Exacta® also analyses the confounding impact of concurrent molecular indications for resistance and sensitivity, thus facilitating improved therapy selection as compared to single gene test-based therapies.

Optimal Cytotoxic Therapies:

Exacta® not only evaluates response / resistance to cytotoxic drugs based on genetic analyses, but also includes in vitro chemosensitivity testing on live tumor cells for efficacy prediction of cytotoxic drugs.

Optimal Immunotherapy:

Exacta® includes analysis of clinical biomarkers such as PD-L1, Tumor Mutation Burden (TMB) and Microsatellite Instability (MSI) for selection of optimum Immunotherapy agents.

Drug Toxicity / Adverse Drug Reactions:

Exacta® aids selection of therapies with minimal side effects and best tolerance based on analysis of germline variants in drug metabolizing enzymes (DME) which are linked to drug toxicity and prediction of Adverse Drug Reactions (ADR).

Drug Repurposing:

In case of recurrent or high-grade cancers which have progressed despite prior therapy, Exacta® can explore additional therapeutic options via analysis of the molecular features of the tumors.

Therapy Recommendation:

Proprietary Exacta® analysis also provides the treating physician a curated list of individualized treatment strategies for every individual patient.

Comprehensive Exacta®

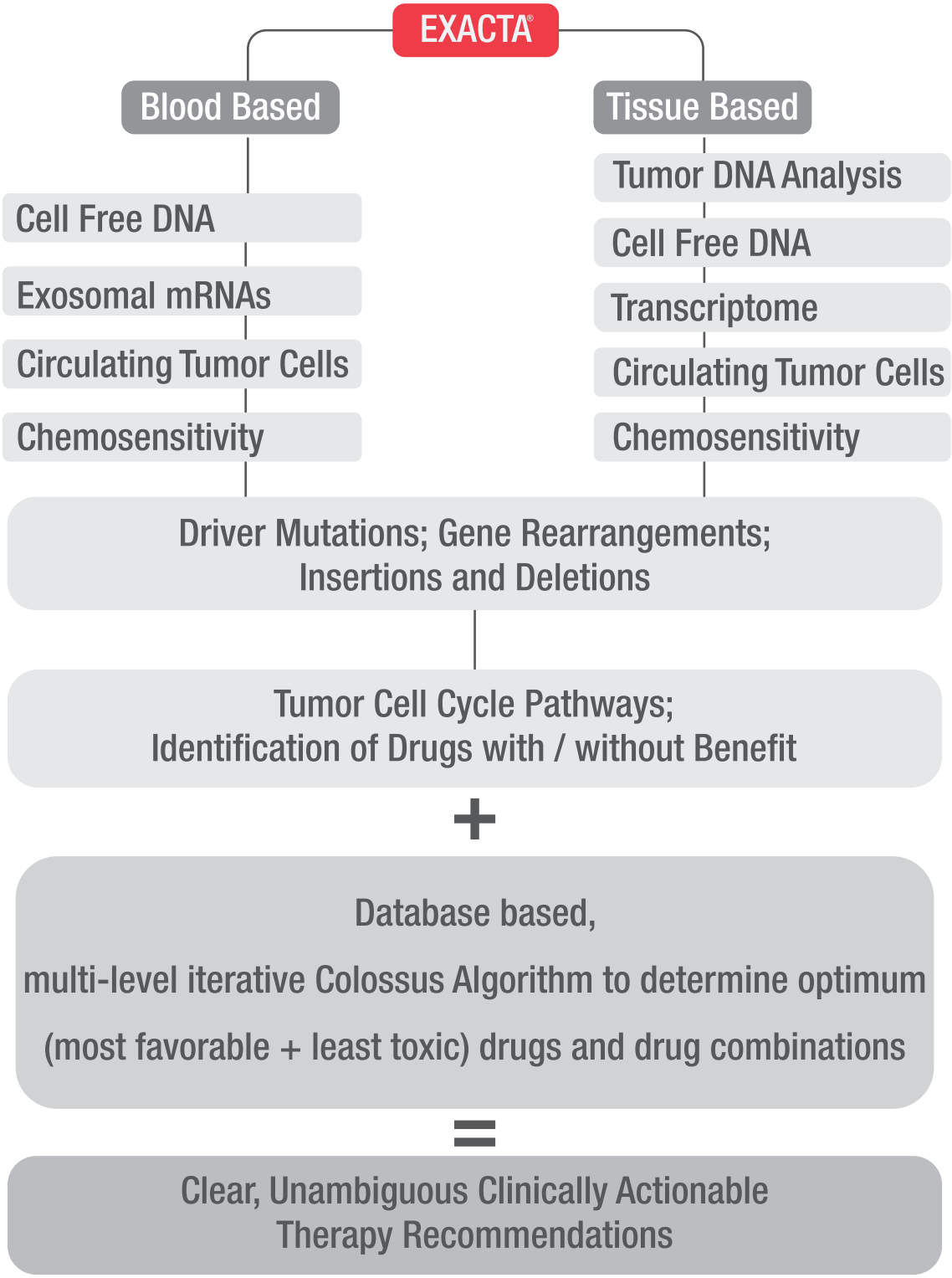
Parameters and Methods of Analysis Exacta® (Tissue Based)	
• Tumor DNA Analysis (452)	• Pharmacogenetics Guidance
• Gene Rearrangements (RNA)	• Microsatellite Instability (MSI)
• Gene Amplification / CNV	• Tissue Tumor Mutational Burden (tTMB)
• KEGG Pathways : Kyoto Encyclopedia of Genes and Genomes	• PD-L1 IHC
• Cell Free DNA (52 Genes)	• Other therapy relevant IHC Markers (ER, PR, AR, HER2)*
• Gene Expression (20,800 Genes)	• Circulating Tumor Cells (CTCs)
• Cytotoxic therapy guidance (in vitro Chemosensitivity on live tumor cells) C-TACs based in case of FFPE Block	• Personalized Comprehensive Therapy Recommendation
* Depending on type of cancer	• Other Therapy Relevant ICC Markers (mTOR, VEGFR1, VEGFR2, EGFR, VEGFA)

Parameters and Methods of Analysis Exacta® (Blood Based)	
• Cell Free DNA (411 Genes)	• Pharmacogenetics Guidance
• Gene Rearrangements (RNA)	• MMR
• Gene Amplification / CNV	• PD-L1 ICC
• KEGG Pathways : Kyoto Encyclopedia of Genes and Genomes	• Blood Tumor Mutational Burden (bTMB)
• Gene Expression (20,800 Genes)#	• Circulating Tumor Cells (CTCs)
• Cytotoxic therapy guidance (in vitro Chemosensitivity on C-TACs)	• Personalized Comprehensive Therapy Recommendation
# Exosomal	• Other Therapy Relevant ICC Markers (mTOR, VEGFR1, VEGFR2, EGFR, VEGFA)

KEGG - Kyoto Encyclopedia of Genes and Genomes
FFPE - Formalin-fixed, Paraffin-embedded
C-TACs - Circulating Tumor Associated Cells
CNV - Copy Number Variation
MMR - Mismatch Repair

100s of Millions of Data Points Analyzed

(from Peripheral Blood and / or Fresh Tissue and / or FFPE Block.)



PROVEN > 90.5%
CLINICAL BENEFIT RATE*

*RESILIENT trial - CTRI No. CTRI/2018/02/011808

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FAQ's

What is Therapy Recommendation?

During Exacta® analysis, the samples submitted by the patient (e.g., fresh tissue, FFPE blocks, blood, fluids) are analysed to identify vulnerabilities of the cancer, for which various drugs may exist. Based on the established efficacy and safety profile, a preference list of these drugs (single drugs or combinations) is assigned for each individual patient. This is the Therapy Recommendation (TR) and is included as an integral part of every Exacta® report.

If two patients have the same histopathological cancer type, and one of them undergoes Exacta® analysis, can the other patient receive the same treatment as indicated in the TR of the first patient?

It is not advisable to do that. Just as each patient is unique, so is each cancer. No two patient's cancers are alike. Even two similar patients (e.g., age, gender, height, lifestyle) with the same type of cancer (e.g., Lung) will have different molecular profile of tumors. Hence, each patient will receive a unique TR. The TR of one patient cannot and should not be used for another patient, no matter how many similarities exist between the patients or their cancers.

How is the TR used?

The TR is not a prescription. It is a patient-specific recommendation of drugs and drug combinations with higher potential for success. Based on the TR, as well as information in the complete Exacta® report, the Treating Oncologist must evaluate the suitability of the therapy choice(s) as well as health and fitness of the patient, and make a final treatment decision. The selected treatment must be administered only under the supervision of the Treating Oncologist.

Why is it important to start treatment immediately?

Cancers can be very aggressive and may evolve rapidly; and the tumor profile can change dramatically over time. Starting the treatment immediately is essential as it is the best strategy to counter the aggressiveness of the cancer. If there is a long enough delay the cancer may gain resistance to treatments and re-analysis may be required.

What kind of drugs will be recommended in the TR?

The TR will include only those drugs which have been approved by the FDA for use in patient's cancer type, or in another cancer type as well as FDA-approved drugs that are used to treat non-cancerous conditions. The TR will never recommend any investigational anticancer drugs or any unapproved drugs.

Are there any follow up molecular tests to assess the result of recommended therapy?

Liquid biopsy permits real time high-frequency monitoring of disease status and response to treatment - it effectively identifies signs of recurrence or emergent chemoresistance, as well as newer vulnerabilities of the tumor. This information empowers the treating clinician to make appropriate therapeutic course corrections in real time to benefit quality of life, overall survival and progression free survival.

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