exacta®

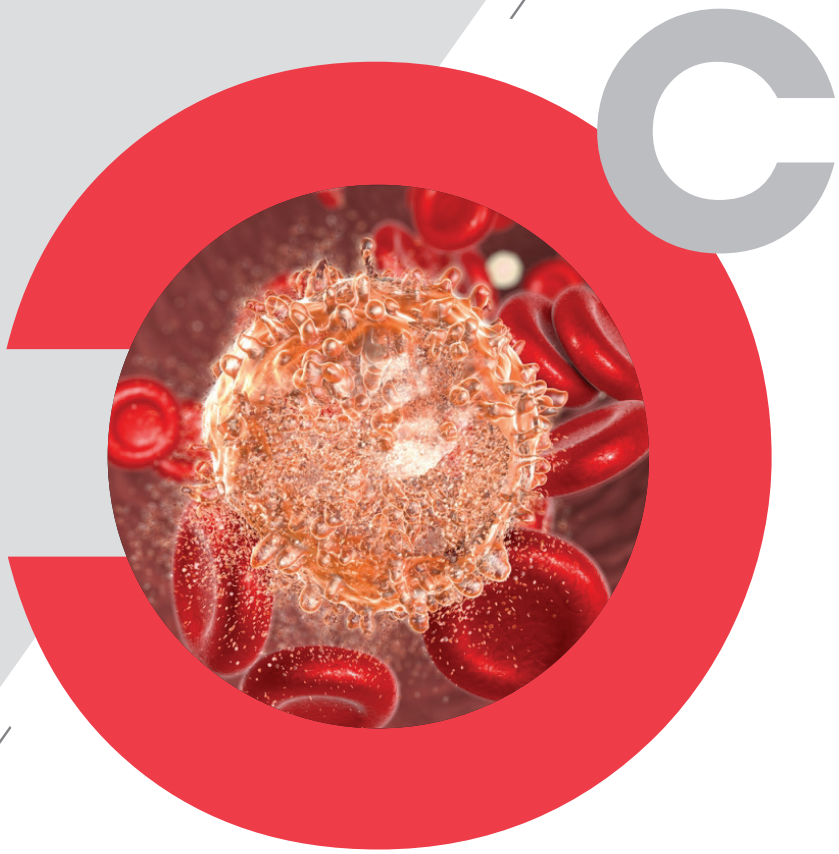
The most comprehensive tumour investigation

exacta®

ENCYCLOPEDIC TUMOUR ANALYSIS

ABSOLUTE IMPACT
ABSOLUTE SCIENCE
ABSOLUTE COMMON SENSE

DATAR CANCER GENETICS
UNITED KINGDOM | GERMANY | INDIA



About exacta®

Every human being is different and unique, similarly ever person's cancer is unique. Conventional 'Standard of Care' approaches do not take into consideration molecular-genetic architecture of a particular patient's tumour. Consequently, patients could suffer due to failed therapies or aggressive relapse. It is, thus, imperative that the molecular architecture of the tumour is studied comprehensively before deciding the treatment plan, which has to be personalised to individual patients and their disease.

exacta® is a comprehensive analysis of molecular-genetic characteristics of solid tumours based on the results of several clinical studies.

exacta® helps unravel driver mutations and pathways that are propelling a person's cancer through multi-analyte and multi-coordinate analysis over 20.805 genes in the cancer genome.
This analysis helps identify drugs that would be most effective for a particular solid tumour. exacta®, thus enables a highly sophisticated treatment strategy beyond conventional perspective, even for difficult to treat or late stage 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 stomach, oesophagus, pancreas, gall bladder, GIST etc.

... risk of therapy failure is high.

exacta® Methodology

Targeted Genes	SNVs, CNVs, Gene amplifications, Mutation burden, Germline mutations
Immunocytochemical markers	mTOR, VEGFR1, VEGFR2, EGFR, VEGFA
RNA Sequencing	KEGG pathways (Disease, Actionable, Resistance)
Pharmacogenetics	Genotyping for CYP450, drug transporters for drug toxicity and efficacy
Chemosensitivity	Patented in vitro cell based assay for testing drugs identified
Liquid Biopsy	Mutation load, Tumour heterogeneity

SNVs: Single Nucleotid Variations CNVs: Copy Number Variations

exacta® Advantages

Most Optimal Targeted Therapy Selection:

- exacta® identifies possible molecular targets and cell cycle pathways to find the most appropriate molecular targets for targeted therapy.
- All relevant biomarkers for targeted therapy selection, including mutations, deletions, gene rearrangement, gene amplification / expression, are analysed.

Most Optimal Cytotoxic Therapy Selection:

- Cytotoxic drug response / resistance of cancer genome, based on DNA and gene expression.
- Comprehensive exacta® includes chemosensitivity testing for cytotoxic drug efficacy prediction.

Assessment of adverse drug reactions:

- Selection of therapy with least side effects based on analysis of germline

Comprehensive exacta®

Parameters and Methods of Analysis	exacta®
Tumour DNA analysis	511 genes (tissue biopsy) 409 genes (liquid biopsy)
Mutations and Gene Amplifications	✓
Fusion / Rearrangements	51 genes (tissue biopsy) 12 genes (liquid biopsy)
Tumour Gene Expression	20.805 genes
Cellular pathways as per KEGG	✓
Chemosensitivity	up to 60 drugs
Liquid Biopsy Cell free DNA (cfDNA)	✓
ICC Immunocytochemistry (mTOR, VEGFR, EGFR, etc.)	✓
Microsatellite Instability (MSI / MMR)	✓ (tissue biopsy / liquid biopsy)
Tumour Mutation Burden (TMB)	✓
Relevant IHC, PD-L1, AR etc.	✓ (tissue biopsy)
Circulating Tumor Cells (CTCs)	✓
Pharmacogenetic Guidance	✓
Immunotherapy Guidance	✓
Limit of Detection (MAF)	2,5% (tissue), 0,1% (cfTNA)
Sensitivity at 0,1% MAF (cfTNA)	97,06%
Sensitivity at 2,5% MAF	96,43%
Positive predictive value	100%

NGS: Next-Generation Sequencing
IHC: Immunohistochemistry
cfDNA: Cell Free DNA

cfTNA: Cell Free Total Nucleic Acid
MAF: Mutant allele frequency
ddPCR: Droplet Digital PCR

KEGG: Kyoto Encyclopedia of Genes and Genomes

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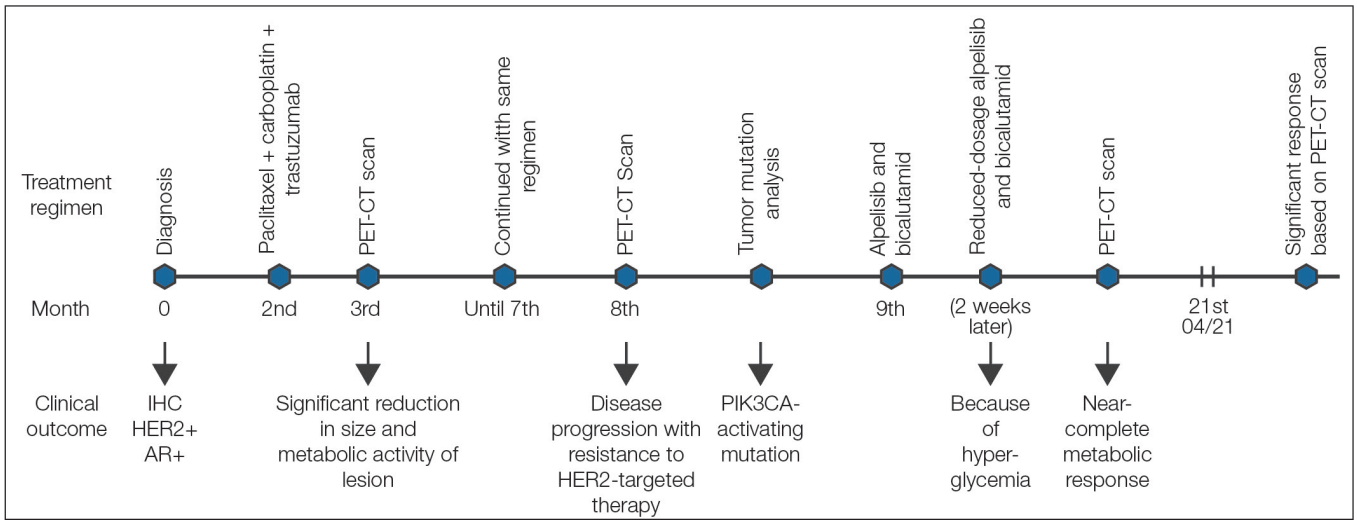
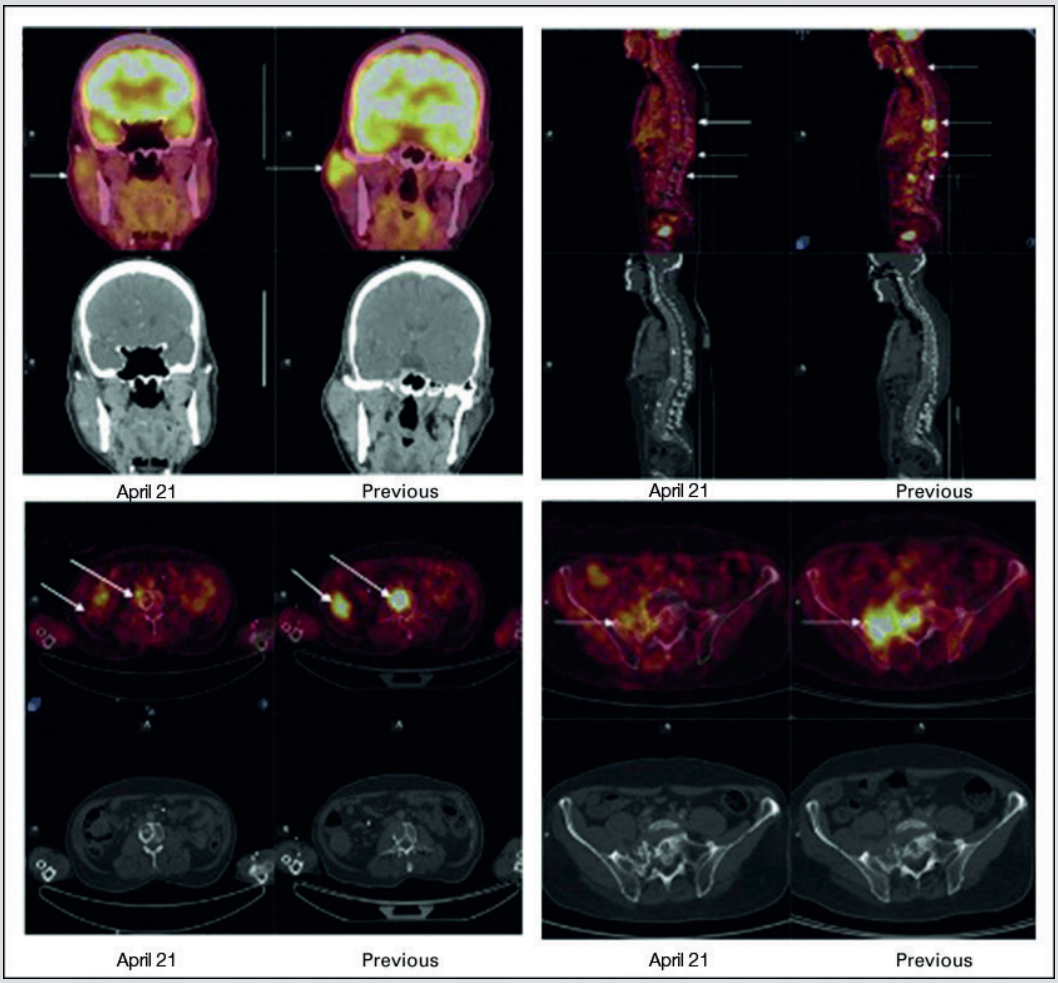
Case Study I

Advanced salivary gland carcinoma, 64-year-old male patient



Result of the recommended therapy



Sheth H. et al. Excellent Response With Alpelisib and Bicalutamide for Advanced Salivary Duct Carcinoma With PIK3CA Mutation and High Androgen Receptor Expression-A Case Report. JCO Precis Oncol. 2021 May 3;5:PO.20.00436. doi: 10.1200/PO.20.00436.

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Case Study – II

Stage IV Triple negative Breast Cancer
22 year old female patient

Clinical History	
Aug ’16	**Diagnosis: Left Breast**
Aug – Jan ’16	Cyclophosphamide + Doxorubicin + Docetaxel
Nov ’16	Left Mastectomy
Feb – Mar ’17	Radiotherapy
May – Jun ’17	Methotrexate + Cyclophosphamide
Jun – Jul ’17	Everolimus
Jul ’17	**PET-CT: Progression**

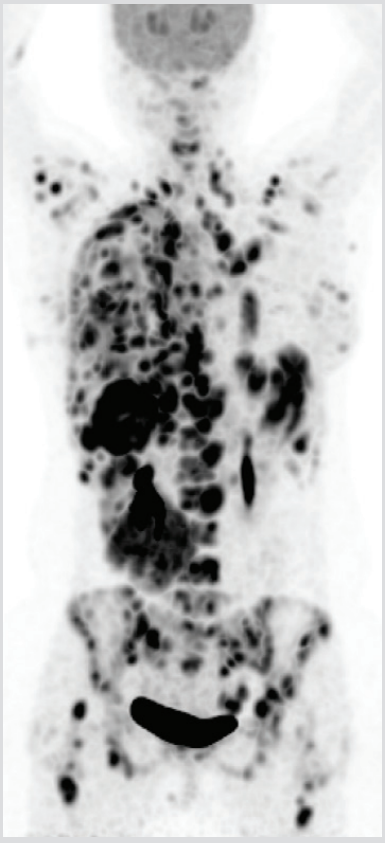
exacta® rationale for therapy selection

Gene / Pathway / Analysis	Feature	Therapeutic Implication
PDGFRA, KIT, KDR	Gain of Copy	Axitinib
Chemosensitivity	Cytotoxicity	Carboplatin Gemcitabine

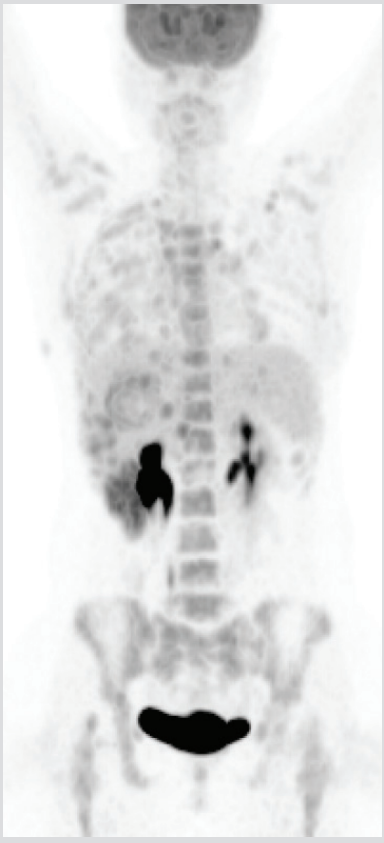
Benefit from exacta® – recommended therapy

before

Cancer had progressed following 5 lines of therapy.



day 0



after

Administration of exacta®: recommended therapy led to regression of cancer.

day 34

Publications

Crook, T., Gaya, A., et al. (2021) 'Clinical utility of circulating tumor-associated cells to predict and monitor chemo-response in solid tumors', Cancer Chemotherapy and Pharmacology, 87(2), pp. 197–205. doi:10.1007/s00280-020-04189-8.

Crook, T., Patil, D., et al. (2021) 'Angiogenesis Inhibitors in Personalized Combination Regimens for the Treatment of Advanced Refractory Cancers', Frontiers in Molecular Medicine, 1, p. 749283. doi:10.3389/fmmed.2021.749283.

Crook, T., Vaid, A., et al. (2019) 'mTOR Inhibitors in Combination Regimens Guided by Encyclopedic Tumour Analysis Show Superior Outcomes Compared to Monotherapy in Refractory Cancers', Annals of Oncology, 30 (Supplement_7):mdz413-115.

Nagarkar, R., Patil, D., et al. (2020) 'Encyclopedic Tumor Analysis for Guiding Treatment of Advanced, Broadly Refractory Cancers: Results from The RESILIENT Trial', Journal of Clinical Oncology 38, no. 15_suppl. published online May 25, 2020, DOI: 10.1200/JCO.2020.38.15_suppl.e15623.

Sheth, H. et al. (2021) 'Excellent Response With Alpelisib and Bicalutamide for Advanced Salivary Duct Carcinoma With PIK3CA Mutation and High Androgen Receptor Expression—A Case Report', JCO Precision Oncology, (5), pp. 744–750. doi:10.1200/PO.20.00436.

Akolkar, D.B., Patil, D., et al. (2021) 'Concordancy of Immunocytochemistry Profiling of Circulating Tumor Cells with Immunohistochemistry for Analysis of Therapeutically Relevant Biomarkers', Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 3047-3047. DOI: 10.1200/JCO.2021.39.15_suppl.3047 Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 3047-3047.

Sample requirement:

- 25 ml blood in DCGL and EDTA tubes
- Optional: 15 ml blood in DCGL and EDTA tubes as well as fresh tissue sample in DCGL transport media (4-6 cm^3 or 5 cores); alternative: FFPE tissue block

Turn Around Time (TAT):

- 10 to 14 days from receipt of the sample

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FAQ's

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 for the first patient?

Just as each patient is unique, so is each cancer. No two patients' cancers are alike. Even two similar patients (e.g. age, gender, height, lifestyle) with the same type of cancer will have different molecular tumour profiles. Hence, each patient should perform an individual exacta® test.

Why is it important to start treatment immediately?

Cancer can be very aggressive and may evolve rapidly; the tumour profile can change dramatically over time. 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 to the patient?

Only drugs that have been approved by the FDA will be recommended. These will include drugs that are FDA approved for use in same cancer / other cancer / other non-cancerous diseases.

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

Molecular tests like our cancertrack™ analysis allow the oncologist to monitor the therapy in real time. In addition, the test provides insights on genetic changes of the original tumour to adapt the therapy.

Publications

1. Crook, T., Gaya, A., et al. (2021) 'Clinical utility of circulating tumor-associated cells to predict and monitor chemo-response in solid tumors', Cancer Chemotherapy and Pharmacology, 87(2), pp. 197–205. doi:10.1007/s00280-020-04189-8.
2. Crook, T., Patil, D., et al. (2021) 'Angiogenesis Inhibitors in Personalized Combination Regimens for the Treatment of Advanced Refractory Cancers', Frontiers in Molecular Medicine, 1, p. 749283. doi:10.3389/fmmed.2021.749283.
3. Crook, T., Vaid, A., et al. (2019) 'mTOR Inhibitors in Combination Regimens Guided by Encyclopedic Tumour Analysis Show Superior Outcomes Compared to Monotherapy in Refractory Cancers', Annals of Oncology, 30 (Supplement_7):mdz413-115.
4. Nagarkar, R., Patil, D., et al. (2020) 'Encyclopedic Tumor Analysis for Guiding Treatment of Advanced, Broadly Refractory Cancers: Results from The RESILIENT Trial', Journal of Clinical Oncology 38, no. 15_suppl. published online May 25, 2020, DOI: 10.1200/JCO.2020.38.15_suppl.e15623.
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6. Akolkar, D.B., Patil, D., et al. (2021) 'Concordancy of Immunocytochemistry Profiling of Circulating Tumor Cells with Immunohistochemistry for Analysis of Therapeutically Relevant Biomarkers', Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 3047-3047. DOI: 10.1200/JCO.2021.39.15_suppl.3047 Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 3047-3047.

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