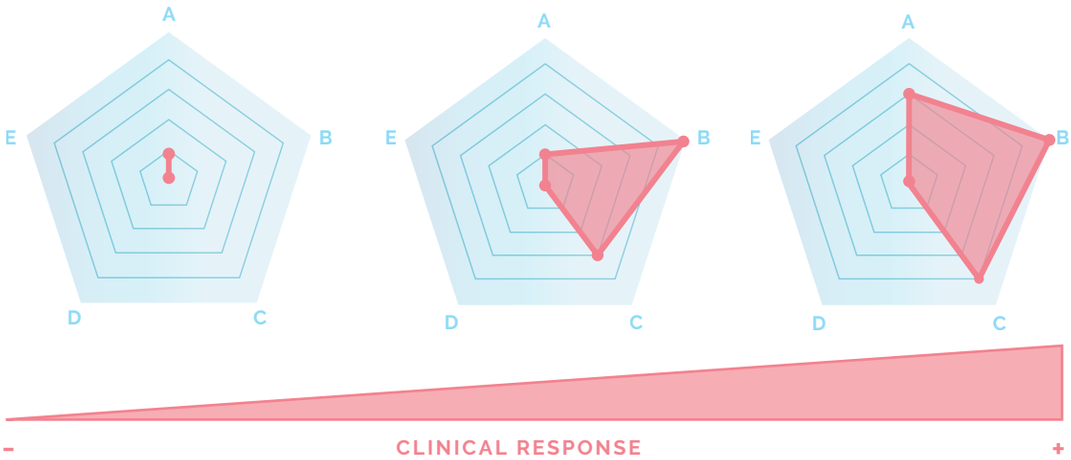
OncoDNA
THE CANCER THERANOSTIC COMPANY

ONCODNA DOCUMENT

Choose the best therapy for Melanoma

PERSONALIZED IMMUNOGRAM



A *PD-L1 (%) (FDA)*

An approved biomarker in NSCLC. But in metastatic melanoma, the predictive value of PD-L1 is still under research, as a definite role has been limited by the expression assays and the cutoffs used in the different studies. And although studies support a predictive role of PD-L1 expression, some melanoma patients with PD-L1 negative have achieved durable response.

APPROVED BIOMARKER IN OTHER CANCERS, BUT SOLO NOT ENOUGH, ITS EXPRESSION LEVEL VERY DYNAMIC AND SENSITIVE TO TUMOR HETEROGENEITY

B *TMB (Tumor Mutational Burden; ASCO 2017) / 15% of TMB are MSI-*

Overall, TMB has been shown to be a predictive biomarker for immunotherapy. High, intermediate, and low TMB were defined as ≥20 mut/Mb, ≥6 and <20 mut/Mb, or <6 mut/Mb, respectively. It has been reported that a minimum of 1.1 Mb of coding genome can accurately assess this TMB compared with sequencing of the whole exome.

NOT ENOUGH SINCE TUMOR MIGHT CARRY SOME MUTATIONS OF RESISTANCE OR MIGHT NOT HAVE THE RIGHT ENVIRONMENT FOR A GOOD IMMUNE RESPONSE

C *CD8 T cell infiltrate (ASCO 2017)*

Studies have shown that in melanoma, increased numbers of tumour-infiltrating CD8+ T-lymphocytes are associated with better clinical outcome.

SOLO NOT ENOUGH SINCE LIKE THE EXPRESSION OF PD-L1, IT IS HIGHLY DYNAMIC AND SENSITIVE TO HETEROGENEITY

D *MSI high (FDA)*

For patients with metastatic melanoma that have progressed following prior treatment and who have no satisfactory alternative treatment options.

APPROVED BUT RARE IN MELANOMA (MOST ARE LOW-FREQUENCY MSI)

E *Resistances (ASCO 2017)*

Mutations in JAK1, JAK2, POLE, STK11, PD-L1, higher number of CNVs, MET-ex14 have been associated with resistance to immunotherapy.

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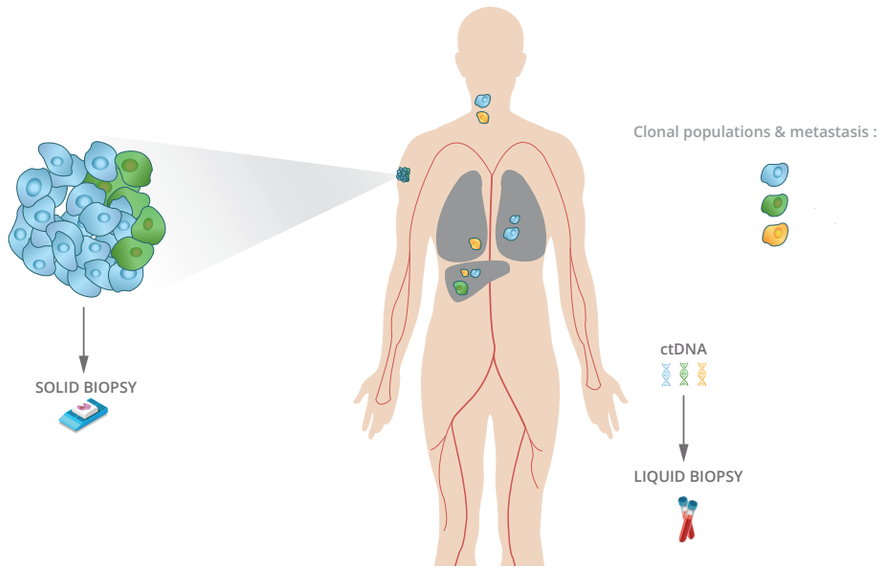
TARGETED THERAPY

	FDA APPROVED	OFF-LABEL (FDA APPROVED FOR OTHER)	IN DEVELOPMENT (ONGOING CLINICAL TRIALS)
BRAF mutations + transloc	✓		✓
NRAS mutations	✓		✓
GNAQ/ GNA11 / NF1 mutations	✓		✓
c-KIT mutations + CNV		✓	✓
ErbBs mutations + CNV		✓	✓
PI3K pathway mutations + CNV		✓	✓
CDK pathway mutations + CNV		✓	✓
NTRKs translocations			✓
CSF1R mutations			✓
AKT1 mutations			✓
TERT expression			✓

BLOOD

Improve the assessment of cancer heterogeneity by combining Solid and Liquid Biopsy



KEY FACT

On June 23rd 2017, the FDA approved the first NGS companion diagnostic that screens for multiple drugs. This test is using the OncoMINE® Dx Target panel and the Ion Torrent technology. Since the beginning we have bet on Ion Torrent technology for our Onco solutions and our **OncoSTRAT&GO®** has been built based on the design of the OncoMINE® comprehensive panel that we improved by adding key regions or genes needed to increase treatment's options for the patients.

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