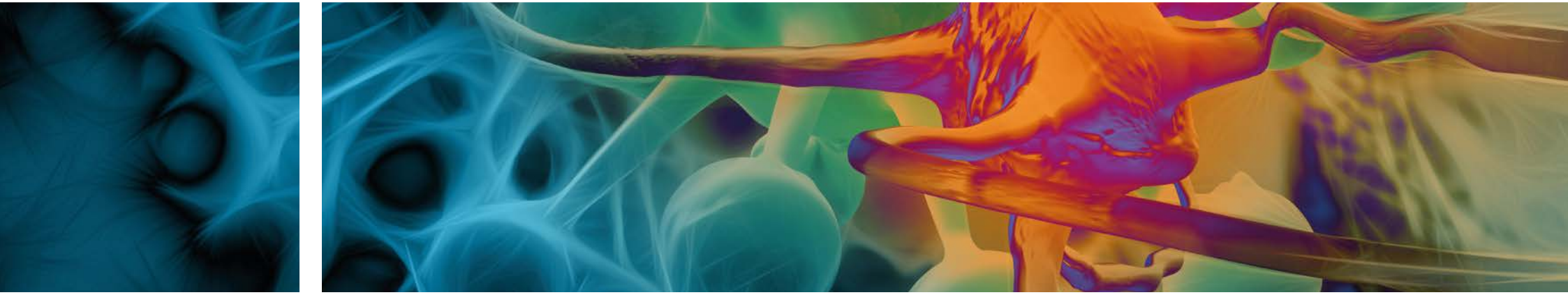
HELIXGYN

BREAST AND OVARIAN CANCER PREVENTION PROGRAM



GENOME INSTABILITY EVALUATION AND MONITORING

BIOSCIENCE GENOMICS

Università di Roma Tor Vergata spin off

HELIXAFE

Cancer is the second leading cause of death worldwide. Aging is the main risk factor. However, it can develop at every age. This is why it is never too soon to start a prevention program. Most genetic tests analyze familial predisposition to cancer. Because of the need of interpreting their results, it is possible to do not have a sure response from them. On the other hand, other screening programs can identify solid cancers only when they already developed and have a significative size. Bioscience Institute's HeliXafe is a tool to prevent cancer before early diagnosis by analyzing the so-called genomic instability by means of the monitoring of germinal and somatic mutations. A positive result makes it possible to reduce cancer risk factors by adopting strategies based on lifestyle changes and food supplements.

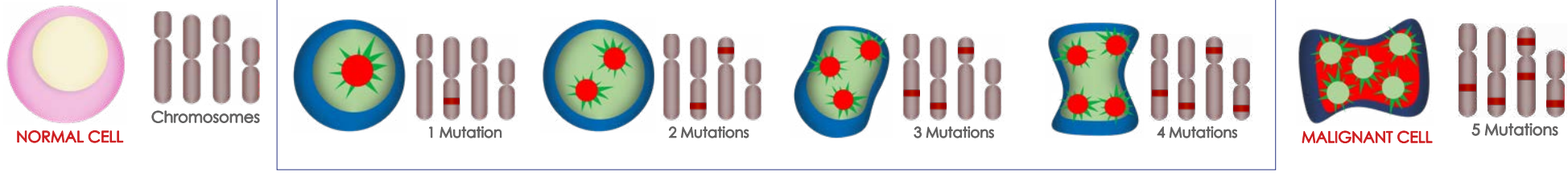
GENOMIC INSTABILITY

Genomic instability depends on the accumulation of genetic and epigenetic mutations in somatic cells. It develops in a time ranging from years to decades, during which cells can acquire both somatic point mutations (SPMs, that is changes in DNA nucleotides) and somatic copy number alterations (SCNAs, that is chromosome loss or gain, chromosome translocation, or gene amplification).

SOMATIC MUTATIONS AND CANCER PRODROMAL STAGE

Genomic instability is not a cancer risk marker, but is associated with the so-called prodromal stage of cancer, that is the phase during which the cells of clinically healthy, asymptomatic people progressively accumulate somatic mutations. This phase can last several years. The relationship between genomic instability and cancer is not based on inherited mutations associated with cancer risk, such as mutations in BRCA 1 and 2 genes, but on acquired, not inherited, mutations in somatic cells. These mutations progressively accumulate in specific tissues, and their accumulation is a marker of the DNA repair capability of the organism.

THE PRODROMAL STAGE



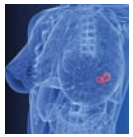
LIQUID BIOPSY and cfDNA

The so-called liquid biopsy is an extremely sensitive method based on a simple blood draw that allows to isolate and analyze cfDNA, ctDNA, Circulating cell-free DNA analyzed by HELIXAFE consists of small fragments in blood plasma. Nowadays it is possible to evaluate individual genome instability by isolating and analyzing these fragments by means of the newest sequencing methods. In the past, gene-based prevention consisted only in the DNA analysis aimed at the individuation of germinal mutations. Today's innovation is the possibility to merge germinal mutations-based prevention with the impartial evaluation of genome instability based on somatic mutations.

HELIXAFE PREVENTION PROGRAM

HeliXafe is nor a screening test nor a tool for risk analysis, early diagnosis or cancer diagnosis. It is a prevention program that allows to study the prodromal, totally asymptomatic, stage of solid cancer (with the exception of brain cancers) by means of the analysis and the annual monitoring of the mutation rate (and hence the genome instability) in cfDNA.
All is needed is to provide each year a small blood sample (10-20 cc). cfDNA will be isolated from this sample and analyzed by Multi Biomarker Next Generation Sequencing (NGS), an innovative DNA sequencing method that allows to contemporaneously sequence an elevated number of DNA fragments with an elevated coverage of interesting regions. In these way it is possible to identify also cancer-associated mutations that are rare in the analyzed sample.

HELIXGYN



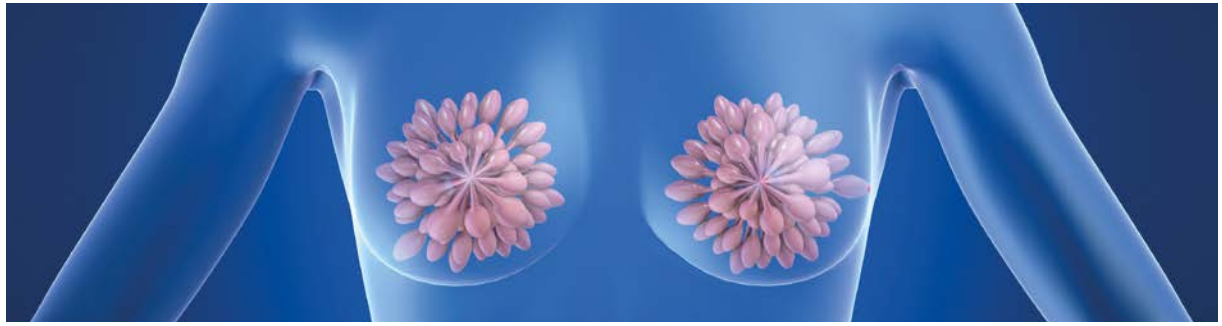
BREAST - OVARIAN CANCER

Breast and ovarian cancer are diagnosed to almost two million women each year worldwide. Risk factors include genetic predisposition, late pregnancy, a history of hormone replacement therapy, contraception or ovarian stimulation.

HELIXGYN is a yearly prevention program for women at risk of developing breast or ovarian cancer.
HELIXGYN monitors the occurrence of specific mutations that arise in the context of breast and ovarian cancer.

10 Genes	
AKT1	FBXW7
EGFR	KRAS
ERBB2	PIK3CA
ERBB3	SF3B1
ESR1	TP53

157 HOTSPOT	
PIK3CA:	E545K and H1047R
AKT1:	E17K
ESR1:	Mutations associated with anti-estrogen resistance
TP53:	Mutations associated with loss of function
ERBB2:	Mutations associated with sensitivity to anti-ERBB2 therapies



CONTRACEPTION Hormonal therapy used as contraceptive contains endocrine hormones, which may stimulate the growth of tumors cells.

HELIXGYN can help to assess the safety of contraceptive hormone treatment or hormone replacement therapy by monitoring the emergence of mutations that are associated to breast and ovarian cancer development.

FIVET growing scientific evidence suggest that some sensitive tissues such as those of breast, uterus, cervix and ovary, may be subject to tumor formation after prolonged hormone stimulation.
Studies have underlined a link between cancer development and treatment against infertility. Also in this case, hormones can accelerate the growth of tumor cells that may be already present in some tissues. HELIXGYN can monitor the occurence of cancer-associated mutations that may arise as a consequence to prolonged hormone stimulation.

TOS the relationship between the hormone replacement therapy during menopause and the risk to develop several tumors has been a debated subject for decades. Hormone replacement therapy taken after menopause increases the risk to develop breast cancer as a function of treatment duration. The risk of endometrial hyperplasia, which could be a precursor for endometrial cancer, has been shown to increase in cases where only estrogens are administered.
HELIXGYN is also designed to assess the safety of hormone replacement therapy.

AZIENDA CERTIFICATA
UNI EN ISO 9001:2015

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