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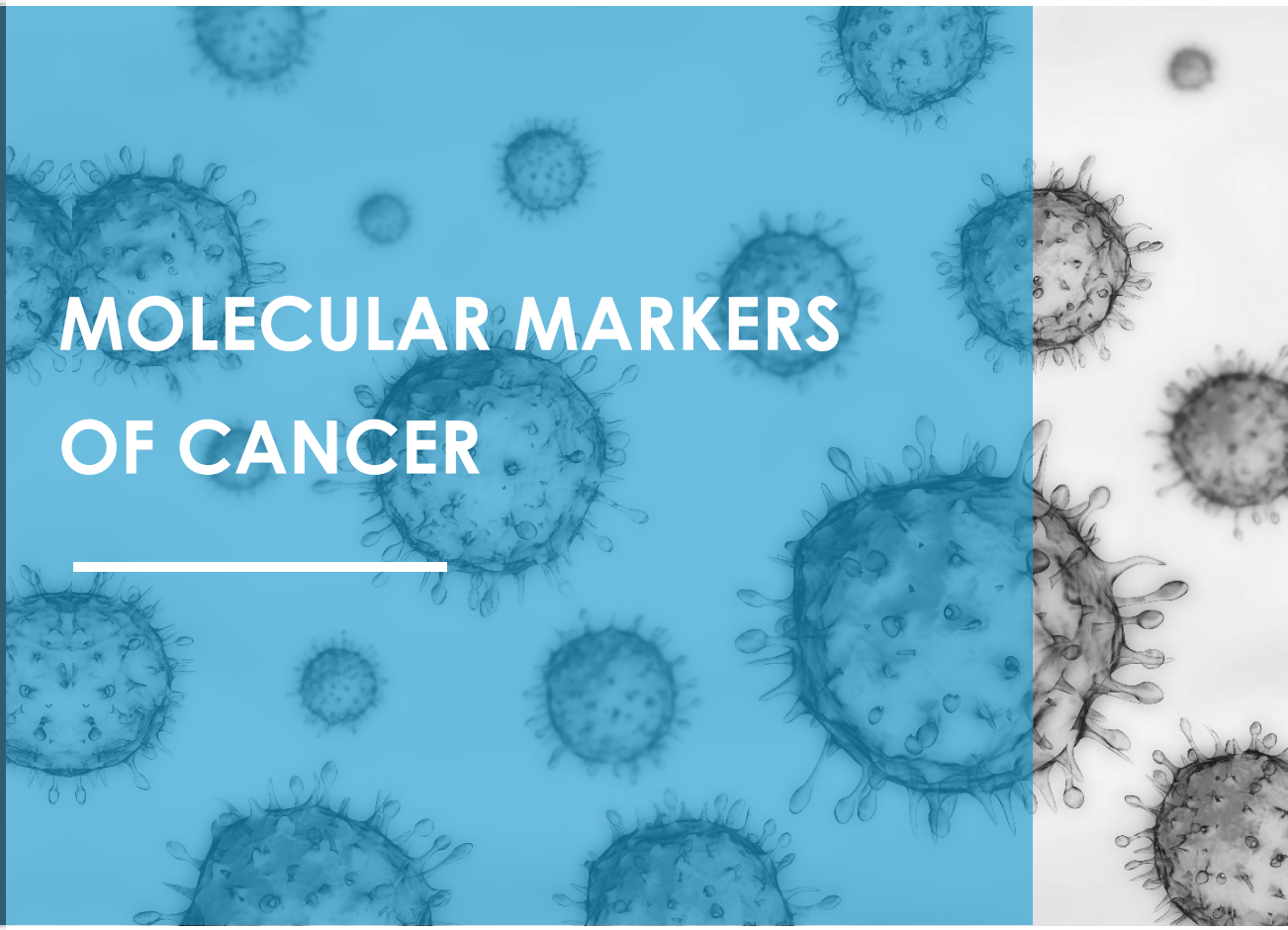

MOLECULAR MARKERS OF CANCER

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Molecular Markers of Cancer

Cancer biomarker (CB) is a biomolecule produced by a tumor cell or other cells of the body in response to a tumor. Each cell type has its own unique molecular and identifiable characteristics, such as the level or activity of a gene, protein or other molecular feature. Biomarkers often distinguish affected patients from those who do not. These changes may be due to a number of factors, including germline or somatic mutations, transcriptional changes, and post-translational modifications. There are a variety of biomarkers that may include proteins (eg, enzymes or receptors), nucleic acids (eg, microRNAs or other non-coding RNAs), antibodies and peptides, metabolites or physiological processes such as apoptosis, angiogenesis or proliferation, and other classes. In addition, biomarkers can also be a collection of alterations, such as gene expression, proteomics, and metabolomics. A marker that responds to cancer is produced by the tumor itself or other tissue. Such biomarkers can be found in a variety of body fluids, tissues and cell lines. Therefore, non-invasive and continuous evaluation can be performed by detecting blood (whole blood, serum or plasma), excretion or secretion (feces, urine, sputum or nipple discharge). In addition, it can also be of tissue origin and can be used for tissue biopsy or special imaging detection.

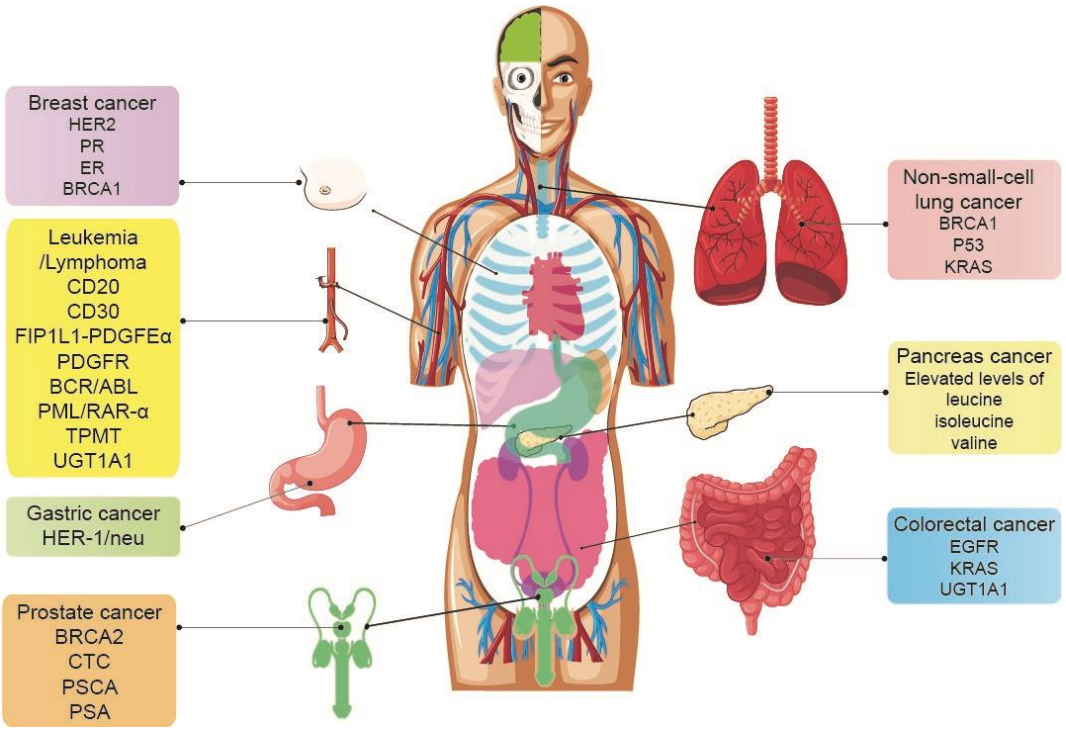

Figure 1. Molecular cancer biomarkers.

Application of Cancer Marker in clinical

The National Cancer Institute (NCI) defines biomarkers as: "Biomolecules found in blood, other body fluids or tissues, are signs of normal or abnormal processes or conditions. Biomarkers can be used to detect treatment Processes, also known as molecular markers and characteristic molecules." Cancer biomarkers are biomarkers that meet the above definition and are only suitable for cancer. Cancer biomarkers can be detected easily, reliably, and economically by using assays with high analytical sensitivity and specificity. According to clinical application classification, tumor biomarkers can be divided into diagnostic (screening) biomarkers, prognostic biomarkers, stratified (predicted) biomarkers and others.

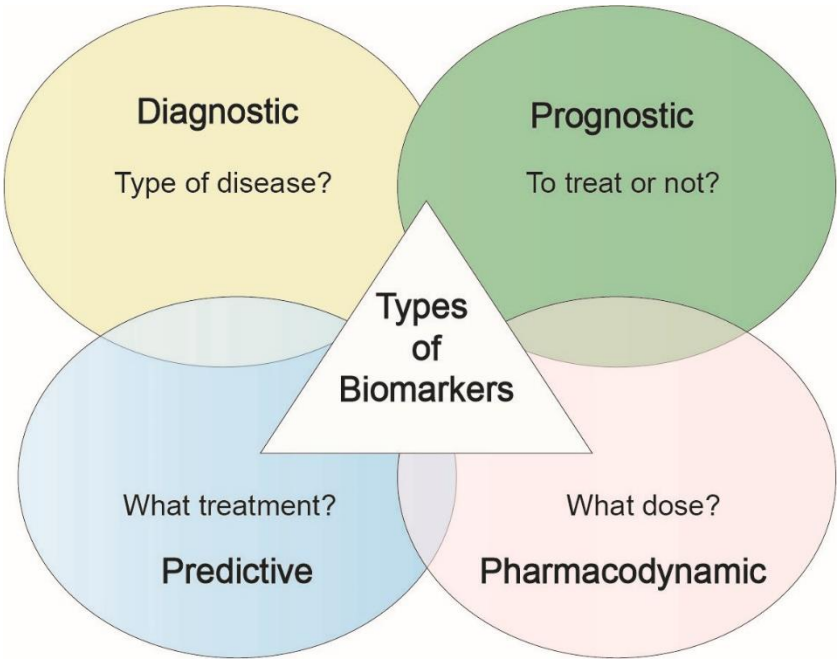

Figure 2. Types of biomarkers.

Diagnosis (screening) biomarker

This type of marker is used to detect and identify markers of a given type of cancer in an individual. These markers are expected to be highly specific and sensitive. For example, the presence of Bence-Jones protein in urine remains one of the important diagnostic targets for multiple myeloma; prostate specific antigen (PSA) is a well-known cancer biomarker Increased PSA levels in men tend to indicate prostate cancer.

Prognostic biomarker

This type of marker is used after the disease state is established. These biomarkers are expected to predict the likely course of the disease, including its recurrence, so they have a major impact on the aggressiveness of the treatment. For example, in testicular teratoma, human chorionic gonadotropin and alpha-fetoprotein levels can distinguish between groups with different survival rates; in breast cancer, many gene expression signatures have been developed that can be estimated for the prognosis of individual patients; in the case of metastatic breast cancer, circulating tumor cells have been shown to be prognostic factors for overall survival.

Stratified (predicted) biomarkers

This type of marker is used to predict the response to a drug prior to the start of treatment and is used to determine which therapy is most likely to be effective. This marker classifies an individual as a possible responder or non-responder to a particular treatment. These biomarkers are primarily derived from array-type experiments, allowing clinical outcomes to be predicted based on the molecular characteristics of the patient's tumor. For example, in colorectal cancer, KRAS is a predictive biomarker because somatic mutations in KRAS are associated with adverse reactions to epidermal growth factor receptor (EGFR) directed therapy; similarly, overexpression or gene amplification of the HER2 gene is predicted in breast cancer and gastric cancer to determine the therapeutic effect of anti-Her2 agents such as trastuzumab on cancer; overexpression of estrogen receptors in breast cancer is predictive of anti-endocrine therapy such as tamoxifen.

Other classification

It has been determined that biomarkers can be used to determine the risk of an individual having cancer. For example, a woman with a strong family history of ovarian cancer can perform a genetic test to determine if she is a carrier of a germline mutation, such as BRCA1, which increases her risk of developing breast and/or ovarian cancer. Biomarkers can also be used to monitor response to treatment in a metastatic environment. Circulating soluble protein tumor markers such as CEA, PSA, CA125, MUC-1 antigens are recommended for the monitoring of metastatic colorectal cancer, prostate cancer, ovarian cancer, breast cancer and pancreatic cancer.

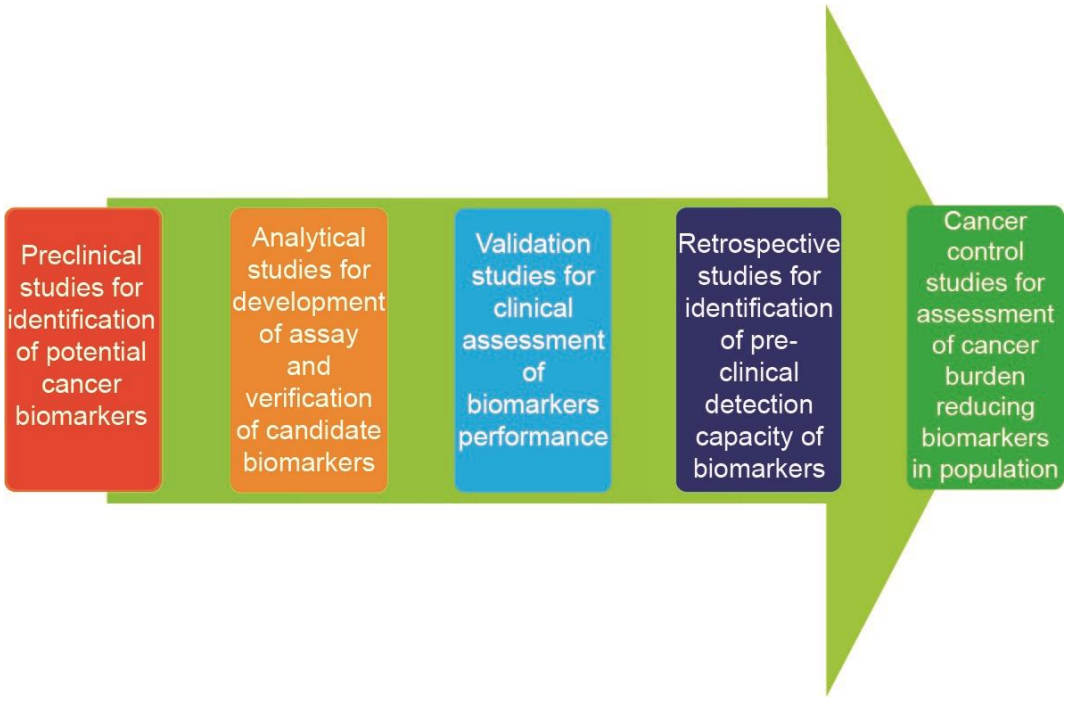

Figure 3. Steps of identification and validation of potential cancer biomarkers for implementation in clinical practice.

Product of Cancer Marker

Cancer Type	Cancer Marker
Breast cancer	
	PR(progesterone receptor)
	ER(estrogen receptor)
	HER2
	BRCA1
Leukemia/Lymphoma	
	CD20
	CD30
	FIP1L1-PDGFEa
	PDGFR
	BCR/ABL
	PML/RAR-a
	TPMT
	UGT1A1
Gastric cancer	
	HER-1/neu
Prostate cancer	
	BRCA2
	PSCA
	PSA
Non-small-cell lung cancer	
	BRCA1
	P53
	KRAS
Colorectal cancer	
	EGFR
	KRAS
	UGT1A1

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