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Cancer Biomarkers: The Future Challenge of Cancer

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In recent years, spectacular advances in understanding of molecular mechanism of cancer progression have revolutionized the way we see the process of malignant transformation and we are waiting for this knowledge to be translate in better treatments for cancer patients. This progress has attracted the interest towards the development of targeted therapies for cancer and creates the basis for the so called "personalized medicine". However, this advancement has not been paralleled by discoveries in the field of biological indicators, or molecular biomarkers, able to implement the targeted therapies.

Therefore, a future challenge in the cancer research will be the discovery of novel biomarkers. The National Cancer Institute defines a biomarker as "a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process or of a condition or disease." Cancer biomarkers are present in tumour tissues or fluids and encompass a wide variety of molecules, such as DNA, mRNA, transcription factors, cell surface receptors, secreted proteins and small metabolites. We can distinguish different classes of cancer biomarkers based on their functions. For instance, they can be used for screening the general population or individuals at risk (Screening and Predisposition biomarker), or for the detection of the presence of a particular type of cancer (Diagnostic biomarker).

Biomarkers can be used to monitor the progression of the disease, and predict the tumour's outcome (Prognostic biomarker), or help to understand whether a patient will benefit from a specific drug treatment (Predictive biomarker). Finally, a biomarker can be used to evaluate the drug's efficacy and optimize the treatment, providing us the tool to tailor treatment for individual patients (Pharmacodynamic biomarkers).

On this basis, novel aspects of Cancer Biomarkers are the focus of this Special issue of *Journal of Molecular Biomarkers & Diagnosis*. This is a timely topic, as there is tremendous interest in the therapeutic development of cancer biomarkers.

Cooper et al. provide a comprehensive review of the current status of biomarker discovery in human clear cell renal cell carcinoma useful for early detection, stage classification and to estimate the outcome of the disease. This is of particular importance for renal cancer, in which it is crucial to understand the renal cell carcinoma type, the tumour stage and the metastatic potential. Given the peculiar resistance of metastatic clear cell renal cell carcinoma to chemotherapy and radiotherapy, it is imperative to develop novel strategies for early detection of the disease. Similarly important is the development of animal models for identification of potential biomarkers. Urine represents a non-invasive and easy to collect medium for biomarker analysis. In this issue, Chen et al. provide an animal model of urinary metabolomic study of gastric cancer progression. Several differentially expressed metabolites have been identified by using gas chromatography/mass spectrometry in non-metastatic compared to metastatic mice models. Proliferation markers are useful tools for prognosis and tumour staging. A review on cell proliferation markers in oral squamous cell carcinoma is also presented. The development of targeted therapies using specific molecular therapeutics requires the monitoring of pharmacodymanic effects of these agents in cancer patients. The use of biomarkers in preclinical drug discovery is crucial for the optimization of pharmacokinetic and pharmacodynamic properties of therapeutics and the selection of the best molecule candidate to advance to clinical trial. Once an agent reach clinical trials stage, the use of biomarkers is critical for patient's selection and dose and schedule determination. This ultimately assists the clinicians in predicting or explaining clinical outcomes. A novel biomarker for monitoring the activity of the Aurora kinase inhibitor Danusertib is presented in this issue by Carpinelli et al. This biomarker, growth differentiation factor 15, is present in serum, identified by microarray studies and validated by investigation in tissue cell culture, in mice plasma and, more importantly, in plasma of Danusertib treated patients. Finally, the use of β2-microglobulin levels in patients with various solid cancers is also presented, as well as a strategy using peptide phage display for discovery of novel biomarkers for imaging and therapy in ovarian cancer.

In conclusion, I hope the articles of this *Special issue* can represent a useful instrument for readers of *Journal of Molecular Biomarkers & Diagnosis* to understand the current status of molecular markers in the diagnosis and management of cancer.

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