Editorial

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"The Importance of Biomarkers in Research"

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From natural biological processes to pathogenic ones such as Parkinson and Alzheimer disease, cancer detection etc, to be able to assess pharmacological responses of therapeutic interventions how the treatments are doing in particular diseases, biomarkers defined as "any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease", play a key role in many scientific areas.

The World Health Organization (WHO) has uttered a most exhaustive description of biomarkers as "almost any measurement reflecting an interaction between a biological system and a potential hazard, which may be chemical, physical, or biological. The measured response may be functional and physiological, biochemical at the cellular level, or a molecular interaction" [1].

From radioactive isotopes to antibodies, from natural metabolites to specific antigens, biomarkers in their different sense categorized as either prognostic or predictive, are used in medicine and convey relevant information that can be established as parameters.

Biomarkers are used to reflect incidence and outcome of disease, but also effects of treatments and interventions. One of the prominent areas is the early cancer detection; discovery strategies for cancer biomarkers include the customary genomic, proteomic, metabolomic and microRNomic profiling, but also comparative genome hybridization (CGH), single nucleotide polymorphism (SNP) analysis, high throughput screening (HTS) and next generation sequencing (NGS). Amongst novel promising approaches we should highlight assessment of circulating tumour cells (CTC), analysis of cancer stem cells (CSC)-specific markers, or cell-free circulating tumour DNA (ctDNA) [2].

However, despite their potential use in drug development and assessing experimental treatments, there is a substantial risk when clinical designs fail to distinguish biomarkers from clinical endpoints, the most relevant outcome in clinical and biomedical research, which have the ultimate purpose of improving morbidity and mortality. Therefore, we should not forget that a constant reassessment between surrogate endpoints well-known biomarkers with scientific evidence of clinical relevance that act as substitutes for clinical endpoints, and accurately predict a clinical outcome and true clinical endpoints real clinical outcomes is necessary. Studies using biomarkers should always have clinical outcomes, and no numerical parameters, as ultimate measures to avoid endorsing new drugs with no added benefit for patients [3].

Much has been written about the advantages of using biomarkers as surrogate endpoints in clinical trials for some diseases, where survival is uncommon and recurrence may only happen after years of treatment. In these cases, biomarkers can provide for the time being evidence about the safety and efficacy of such treatments until further studies are developed or concluded. Additionally, biomarkers help designing effective studies with small number of patients phase I and phase II clinical trials would be where biomarkers act as most effective endpoints, reducing the exposition to an experimental treatment, and helping to determine if a potential drug is a good candidate for a phase III clinical trial. Some regulatory bodies such as US Food and Drug Administration (FDA) requires phase IV follow-up studies to prove if there is a relevant clinical endpoint correlation [4,5].

In some cases, despite the best biological and statistical evidence, biomarkers that were "validated" even in a series of previous trials have been found to be poor predictors of clinical outcomes. The excess of trust and dependence on biomarkers despite their obvious practicality can be deceptive and lead to erroneous conclusions. Hence, the importance of selecting true clinical endpoints, and continuously reassess the acquired knowledge and validity of biomarkers.

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