

## Editorial

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# What is a biomarker? It's time for a renewed definition

**Keywords:** biomarker; marker; methodology; terminology.

Usually *Clinical Chemistry and Laboratory Medicine* publishes articles related to the advances in biomarkers. The review on statistics and medical usefulness of biomarkers [1] and an editorial [2] published in this journal are clear examples of this. However, in the mentioned review, as in many other articles, the term “biomarker” is used with two meanings: 1) a biomarker is a component (analyte) of a human biological system (i.e., plasma, urine, etc.); or 2) a biomarker is a biological property (i.e., mass concentration of X in plasma).

The Biomarkers Definitions Working Group gave an international definition of biomarker for the field of pharmacological clinical trials: “a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention” [3]. However, in spite of this definition, the ambiguity described in the preceding paragraph is common in health sciences publications and in the in vitro diagnostics industry literature.

It is terminologically obvious that a scientific term should designate only one concept. Thus, the recommendation of a general and unique definition and the adherence to this recommendation would be very welcomed. It would be reasonable that this definition was written by Nomenclature, Properties, and Units, the joint group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and the International Union of Pure and Applied Chemistry (IUPAC) devoted but not limited to these kind of affairs, but in the meantime the

following definition of biomarker (or simply marker) might be provisionally used: “human or animal biological property whose in vitro measurement or identification is useful for the prevention, diagnosis, prognosis, treatment, and follow-up of human or animal diseases, and for their understanding”.

As a final clarification, it should be kept in mind that in the field of clinical pharmacology (clinical trials) the concept of “biomarker” has a wider meaning than in clinical laboratory sciences: some biomarkers are in vitro measured or identified and others in vivo. In the field of clinical laboratory sciences, as reflected in the proposed definition, the concept of “biomarker” is always related to in vitro measurements or identifications.

## Conflict of interest statement

**Author's conflict of interest disclosure:** The author stated that there are no conflicts of interest regarding the publication of this article.

**Research funding:** None declared.

**Employment or leadership:** None declared.

**Honorarium:** None declared.

**Disclaimer:** The author is a member of the joint group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and the International Union of Pure and Applied Chemistry (IUPAC) on Nomenclature, Properties, and Units, and a member of the Joint Committee on Guides for Metrology (JCGM), Working Group 2 (VIM). The opinions and proposal expressed in this article do not necessarily represent the view of the IFCC-IUPAC or JCGM.

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