[The Role of Surrogate Endpoint Biomarkers in Oncology Research](http://www.conversantbio.com/blog/the-role-of-surrogate-endpoint-biomarkers-in-oncology-research)

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Biomarkers and surrogate endpoints have an increasingly important role in both cancer research and clinical practice. Biomarkers can be used to assess prognosis and to predict how individual patients will respond to specific treatments, whereas surrogate endpoints potentially enable the effectiveness of new interventions to be assessed more rapidly, and at times with greater accuracy, than classic endpoints (such as survival) in clinical trials. (1)

What is the role of surrogate endpoint biomarkers?

A ‘surrogate’ endpoint, in the cancer clinical trial context, is an endpoint which is used instead of the primary clinical endpoint. The substitution is usually made because the surrogate endpoint can be obtained earlier or more cheaply or with less variability than the clinical endpoint. A surrogate endpoint could be another relevant clinical endpoint but is often an objective biological or biochemical assessment. (2)

Definitions of Surrogates and Biomarkers

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| Term | Definition |
| Biomarker | A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, or pharmacologic responses to therapeutic intervention. |
| Prognostic biomarker | Biomarker that forecasts the likely course of the disease irrespective of treatment |
| Predictive biomarker | Biomarker that forecasts the likely response to a specific treatment |
| Clinical endpoint | Measurement providing information on how a patient feels, functions or survives |
| Surrogate endpoint | Measurement providing early and accurate prediction of both a clinical endpoint, and the effects of treatment on this endpoint |
| Validation | Confirmation by robust statistical methods that a prognostic biomarker, predictive biomarker or surrogate end point fulfills a set of conditions that are necessary and sufficient for its use in the clinic. |

Despite its appealing interpretation, limited research has been conducted to evaluate principal surrogates and existing methods focus on risk models that consider a single biomarker. How to compare principal surrogate value of biomarkers or general risk models that consider multiple biomarkers remains an open research question. (3)

There are many links in the chain of events that lead from the pathogenesis of a disease to its clinical manifestations; biomarkers can be used at any point in the chain, at the molecular, cellular, or organ levels. Likewise, a therapy might be developed to attack any one of these links, in order to try to manipulate the disease, symptomatically or therapeutically. Any measurement short of the actual outcome could be regarded as a surrogate endpoint biomarker. However, although all surrogate endpoints are biomarkers, not all biomarkers are useful surrogate endpoints. (3)

[Ideal characteristics of surrogate biomarkers](http://www.conversantbio.com/blog/bid/383664/5-Core-Characteristics-of-Surrogate-Endpoint-Biomarkers) include:

* Biomarkers should be involved in the process that causes cancer
* Changes in biomarker should be highly related to changes in the disease
* Levels of biomarker should be high enough that they can be measured easily and reliably
* Effective treatment of the cancer should change the level of the biomarker
* Level of the biomarker should not change spontaneously or in response to other factors not related to successful treatment of the cancer

Evaluation of new candidate biomarkers as possible surrogate endpoints for clinical trials requires addressing issues of analytical validation, qualification, and proper utilization. Clinical pharmacologic research plays a vital role in cancer drug development. In recent years, biomarker studies have become integral to this process, specifically the use of pharmacologic biomarkers in the development of targeted therapies and their translation to clinical practice. (4)

How can Conversant Bio help you with your clinical research?

***References***

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