

[S-2]**New molecular biomarkers at post-genomics era**

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Magic technologies and smart biomarkers at the Omics Age!

This slogan is not only for the pharmaceutical companies as the speedy and cost-reduced development of global drug, but for all of the toxicologists and biologist. Biomarker refers to a variety of physiologic, pathologic, or anatomic measurements that are thought to relate to some aspect of normal or pathological processes (Temple 1995; Lesko and Atkinson 2001). For example, biomarkers of pre-clinical and clinical evaluations are mortality and clinical findings, body weight changes, food consumption, water consumption, ophthalmologic examination, urinalysis, hematology, clinical chemistry, gross pathology, organ weight and histopathology (KIT, Guideline, 2003). Most of these parameters used for pre-clinical and clinical evaluations have been available since the 1950s. Recently, ECG, ERG, MRI, and sonograph were applied as new analytic methods. A surrogate endpoint is a laboratory measurement or physical sign used in therapeutic trials as a substitute for a clinically meaningful endpoint. A well-validated surrogate endpoint will predict the clinically meaningful endpoint (Temple 1999, Lesko and Atkinson 2001). The advent of new technologies (toxicogenomics, proteomics and metabonomics) promises to provide immense opportunity for the discovery and development of new markers, **molecular biomarkers**, of cellular and tissue integrity. Various gene/protein chips will be applied for bridging and predictive biomarkers in soon. Those various candidate methods and biomarkers can be validated and accepted in a scientific and regulatory context. An accurate process map for the validation of these biomarkers and methods will accelerate their scientific and regulatory acceptance (ILSI/HESI, Holsapple, 2003). Even magic technologies and smart biomarkers in hand can not replace the classic methods and parameters completely, but it will be powerful tools for understanding homeostasis and toxic mechanism under standardized and harmonized validation world-widely.