Role of biomarkers in development of drugs

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Biomarkers serve as indicators of the natural history of a disease process of a known response to a therapeutic intervention, reflecting a clinical outcome.

Clinically, biomarkers are used for patient stratification, selection and description of surrogate endpoints. Protein biomarkers are associated with changes in protein levels of biological samples. Genomic biomarkers are in association with clinical response, selection of dosage, resistance and differential disease diagnosis. Genomic biomarkers are broadly categorized as preventive biomarkers which identify individuals at increased risk of developing mutations, where genetic counseling will be extended to the family. Diagnostic biomarkers may identify the disease at an earlier stage and prognostic biomarkers stratify risk of disease progression in patients undergoing definitive therapy. Other than these there are therapeutic biomarkers which help in quantifying responses in patients undergoing treatment and special biomarkers which help in identifying patients at the risk of developing adverse reactions to specify therapeutics.

Pharmacoimaging is a recent technology that is used for therapies and drug development. The methodology is especially useful in imaging biomarkers with the help of computed tomography, magnetic resonance imaging and position emission tomography.

It is need of the hour for pharmaceutical industries, research institutes and young researchers to intensify their efforts to develop novel molecular biomarkers for therapeutic treatment of several human diseases and generate new diagnostic products. Utility of biomarkers as decision making tools in drug development process is well established, hence there is need to develop better biomarkers.