Anil S Modak, Transl Med 2012, 2:3
http://dx.doi.org/10.4172/2161-1025.S1.003

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference on
Translational Medicine

September 17-19, 2012 Holiday Inn San Antonio, Texas, USA

Breath tests for personalized medicine and as research tools for selection of patients for clinical trials

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The commercial success of new drugs coming to the healthcare field will depend on utilizing differential diagnostic tests and/or companion biomarker assays to identify patients who may not benefit from the drug prior to enrollment in clinical trials.

Stable isotope-labeled xenobiotics can be used to provide rapid in vivo phenotype assessment of phase I enzymes (CYP P450). The use of suitably labeled stable isotope substrates to induce the generation of biomarker 13CO2 in breath can lead to diagnostic tests to identify non-responders to medications metabolized primarily by specific enzymes.

Rapid, single time-point breath collection, minimally invasive office-based in vivo phenotype assays for CYP1A2, CYP2C19 & CYP2D6 activity could potentially be used as a CDx in clinical trials of new drugs. The integration of diagnostic breath tests during different phases of drug development or targeting existing drugs can result in safer drugs with enhanced therapeutic efficacy and lowered toxicity in a cost-effective way.

The breath tests can potentially help pharmaceutical companies in drug discovery and to design clinical trials in a more effective and efficient way by being able to identify responders and non-responders to the drug. Breath tests can be potentially useful for personalized medicine by early identification of enzyme deficiencies.

Three breath tests to identify P450 enzyme deficiencies will be extensively discussed along with their potential clinical applications.

Biography

Anil Modak, the Associate Director of Medical Products R&D at Cambridge Isotope Laboratories, Andover, MA has been involved in the design, R&D of novel non invasive breath tests for personalized medicine using stable isotope substrates for the diagnosis of disease states and evaluation of enzyme activity. He is the author of several patents, publications and a book chapter. He serves on the Editorial board of the Journal of Breath Research and Journal of Pharmacogenomics & Pharmacoproteomics. His previous experience includes working for Ribozyme Pharmaceutical, Boulder, CO and Monsanto, St Louis, MO. His postdoctoral research was conducted at the University of Iowa and Kings College London.

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