Translational Medicine
ISSN: 2161-1025

Stephen Suh, Translational Medic 2012, S:1
DOI: 10.4172/2161-1025.S1-e001

Editorial Open Access

Discovery of Novel Biomarkers for the Development of Personalized Medicine

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Since the historic completion of the Human Genome Project in 2003, research and clinical communities have focused on personalized medicine that is largely associated with multiple –omics data [1,2]. However, the road map to personalized therapy is not as simple as we anticipated 10 years ago. We are now challenged with not only the nearly 23,000 genes discovered in 2003, but also with proteins, metabolites, non-coding DNAs, RNAs, and epigenetic, post-transcriptional, and translational modifications that comprise extremely complex systems involved in the development and progression of common diseases [3] such as cancer. The research community now faces new challenges in that the identification of specific genes (i.e., oncogenes and proto-oncogenes) may not readily lead to successful personalized cancer therapy. More advanced technologies are available to test new hypotheses more rapidly, and more comprehensive informatics data are available to dissect accumulated information at lightning speed [4]. To overcome complex challenges and achieve the goal of personalized medicine, additional collaboration is needed among scientific communities from industry, academia, and the public sector, and practical systematic approaches that can address scientific and clinical issues need to be developed. The most crucial component of this task is the discovery of novel biomarkers. Biomarkers can be genes, proteins, metabolites, micro RNAs, and methylation patterns that can help researchers and clinicians detect genetic predispositions for specific medical conditions and metabolic problems and predict toxicities, immune responses, and drug efficacy. For the past decade, the use of nano particles had attracted attention for the delivery of proteins, drugs, and other agents derived from biomarker discoveries [5]. The goal of biomarker discovery is to develop an assay platform that can be clinically applicable in the construction of diagnostic methods with consistency. Obviously, a single volume of a special issue edition cannot address all of the above issues; instead, we have gathered research and review articles that present milestones and novel technologies to facilitate the translation of novel biomarkers to diagnostic applications.

Discovering clinically relevant biomarkers that will allow scientists and clinicians to combine genetic, –omics data, and clinical information will enhance our ability to accurately determine the onset and pathogenic course of cancer and asses the toxicity and efficacy of clinical interventions. Thus, ensuring the quality of biospecimens and collecting a large series of control specimens are important steps in biomarker discovery [6]. Prilutskaya' group in this issue explained the importance of the procurement process and methods to maintain the integrity of biospecimens for biomarker discovery. Biomarkers can be associated with a specific disease or tumor stage. For example, Perrier's group described migration stimulating factor as a biomarker to identify the progression of breast cancer. Additionally, Mann and Tanaka described how E-selection can be used as a biomarker in conjunction with tumor stromal components. These biomarkers are currently undergoing rigorous validation. For all biomarker projects, high-quality biospecimens must be used for validation, and the data should be cross-examined by other independent research groups. This cross-validation step is pivotal because many potential biomarkers do not exhibit efficacy when examined using large and heterogeneous patient cohorts in the clinic. A novel technology in the field of biomarker discovery is the use of aptamers to replace antibodies in diagnostic applications, as described by Somasunderam and Gorenstein. In epigenetic studies of predictive biomarkers for clinical outcomes and drug responses, Thirukonda's group described aberrant methylation signatures as biomarkers for lymphoma and potential biomarkers for similar hematological malignancies. Of interest, this molecular profile of DNA sequences was analyzed by mass spectrometry, and this technology will be used more frequently in the future to quickly reduce the number of potential biomarkers for further validation and study. For decades, tumor biology was studied by two-dimensional cell culture in the *in vitro* setting, and this method often generated artifacts that were not relevant to the tumors in three dimensions *in vivo*. Thus, the central part of *in vitro*-based biomarker discoveries must be performed in a three-dimensional (3D) culture setting. The 3D culture setting must closely mimic the disease *in vivo* by co-culturing stroma cell components and a specific 3D bioreactor set-up. Caicedo-Carvajal's group described multiple 3D cell culture methods that can be uniquely customized for discovering biomarkers for specific diseases and clinical interventions, particularly for personalized cancer therapy. The article focuses on the formulation of a 3D culture set-up that can closely mimic the tumor microenvironment so that the potential biomarkers derived from this setting are highly relevant to clinical phenotypes. Lastly, the community awaits a solid assay platform for quantifying biomarker expression and for use with preexisting equipment set-ups in clinical or scientific laboratories. Lakkis's group described an assay platform based on microfluidics to minimize the use of precious patient-derived biomaterials. This type of technology can be easily adapted in the future to quantify gene and protein expression in tissue and serum samples, as well as to test newly discovered biomarkers. The micro fluidics assays introduced in this issue require less than 5-µl sample volumes. These types of method and similar technologies can be readily adapted for point-of-screening diagnostics in various community events for early cancer detection, during which clinicians or advocacy groups can measure serum protein biomarker levels using finger-prick blood samples.

Biomarker-assisted diagnosis, prognosis, and targeted therapy development comprise the essential foundation of personalized medicine. We now face an unprecedented future of cancer care that will be based largely on the molecular profiles of individuals. Clinical outcome-based research will give rise to a specific set of biomarkers in a multiplex format that can be used to develop a new class of drugs and improve medical practice. Modern oncologic approaches that utilize bioinformatics to manage pertinent information, which is not discussed

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Received February 20, 2012; **Accepted** February 22, 2012; **Published** February 24, 2012

Citation: Stephen Suh K (2012) Discovery of Novel Biomarkers for the Development of Personalized Medicine. Translational Medic S1:e001. doi:10.4172/2161-1025.S1-e001

in this special issue, will particularly enhance medical decision-making. Robust and disease-specific biomarkers will facilitate the discovery of novel molecular targets and drug agents to improve patient pre-selection for clinical trials, in turn changing how the pharmaceutical industry invests in drug development and marketing [7]. Ultimately, we hope that advancements in methods, biotechnology, and biomarker discovery will improve medical decision-making and facilitate the development of targeted therapies to achieve favorable outcomes, reduce toxicity, and improve the prediction of responses.

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This article was originally published in a special issue, **Discovering Novel Biomarkers** handled by Editor(s). Dr. K. StephenSuh, Hackensack University Medical Center, USA; Dr. Takemi Tanaka, Thomas Jefferson University, USA; Dr. Valli De Re, Centro di Riferimento Oncologico, Italy