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## Personalized and Precision Medicine (PPM) as a Unique Healthcare Model to Be Set Up through Biodesign, Unique Translational Applications and Upgraded Business Marketing to Secure the Human Healthcare, Wellness and Biosafety

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Traditionally a disease has been defined by its clinical presentation and observable characteristics, not by the underlying molecular mechanisms, pathways and systems biology-related processes specific to a particular patient (ignoring persons-at-risk). A new systems approach to subclinical and/or diseased states and wellness resulted in a new trend in the healthcare services, namely, personalized and precision medicine (PPM).

To achieve the implementation of PPM concept, it is necessary to create a fundamentally new strategy based upon the biomarkers and targets to have a unique impact for the implementation of PPM model into the daily clinical practice and pharma. In this sense, despite breakthroughs in research that have led to an increased understanding of PPM-based human disease, the translation of discoveries into therapies for patients has not kept pace with medical need. It would be extremely useful to integrate data harvesting from different databanks for applications such as prediction and personalization of further treatment to thus provide more tailored measures for the patients and persons-at-risk resulting in improved outcomes and more cost effective use of the latest health care resources including diagnostic (companion ones), preventive and therapeutic (targeted molecular and cellular) etc.

Translational researchers, bio-designers and manufacturers are beginning to realize the promise of PPM, translating to direct benefit to patients or persons-at-risk. For instance, companion diagnostics tools and targeted therapies and biomarkers represent important stakes for the pharma, in terms of market access, of return on investment and of image among the prescribers. At the same time, they probably represent only the generation of products resulting translational research and applications. So, developing medicines and predictive diagnostic tools requires changes to traditional clinical trial designs, as well as the use of innovative (adaptive) testing procedures that result in new types of data. Making the best use of those innovations and being ready to demonstrate results for regulatory bodies requires specialized knowledge that many clinical development teams don't have. The areas where companies are most likely to encounter challenges, are data analysis and workforce expertise, biomarker and diagnostic

test development, and cultural awareness. Navigating those complexities and ever-evolving technologies will pass regulatory muster and provide sufficient data for a successful launch of PPM, is a huge task. So, partnering and forming strategic alliances between researchers, bio-designers, clinicians, business, regulatory bodies and government can help ensure an optimal development program that leverages the Academia and industry experience and FDA's new and evolving toolkit to speed our way to getting new tools into the innovative markets.

Healthcare is undergoing a transformation, and it is imperative to leverage new technologies to support the advent of PPM. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM and TraMed to elicit the content of the new trend. The latter would provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and disease and patient advocacy with an interest in improving the system of healthcare delivery on one hand and drug discovery, development, and translation, on the other one, whilst educating the policy community about issues where biomedical science and policy intersect.

### Biography

**Sergey Suchkov** was born in the City of Astrakhan, Russia, in a family of dynasty medical doctors. In 1980, graduated from **Astrakhan State Medical University** and was awarded with MD. In 1985, Suchkov maintained his PhD as a PhD student of the I.M. Sechenov Moscow Medical Academy and Institute of Medical Enzymology. In 2001, Suchkov maintained his Doctor Degree at the National Institute of Immunology, Russia.

From 1989 through 1995, Dr Suchkov was being a Head of the Lab of **Clinical Immunology**, Helmholtz Eye Research Institute in Moscow. From 1995 through 2004 - a Chair of the Dept for Clinical Immunology, Moscow Clinical Research Institute (MONIKI). In 1993-1996, Dr Suchkov was a Secretary-in-Chief of the Editorial Board, Biomedical Science, an international journal published jointly by the USSR Academy of Sciences and the Royal Society of Chemistry, UK.

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