5 Challenges in Precision Medicine

By Dan Peer, Director of Tel Aviv University Cancer Biology Research Center

The great promise of precision medicine for the future of healthcare is finding breakthrough ways to personalize diagnosis and treatment of disease. The idea that medicine can be tailored more precisely to each and every individual is astounding and the benefits are immense. With a wide range of drugs that could be used, doctors and pharmacists have up till now been left to discover through trial and error what works and what doesn’t. Researchers now know that our personal genetic profile plays a crucial role in the interaction between drugs and disease.

There are, however, some clinical, methodological and regulatory challenges that need to be addressed so that we can deliver on this promise. The top 5 are:

1. Lack of disease signature
2. The low predictive power of animal models
3. Lack of appropriate analytical tools
4. The low predictive power of biomarkers
5. Patents and regulation laws

1. Lack of Disease Signatures

The earlier and faster cancer cell signatures are identified, the more effectively patients can be treated. One of the hurdles in identifying these signatures, is the change of genetic signatures over time. This change hinders our ability to provide precise medicine and is one of the reasons that individual medicine is not necessarily precise medicine.

How can we ensure that individual medicine provides the right medication? Is there an opportunity to leverage big data or small data analytics to explore disease signatures and to change the fate of therapeutic intervention?

2. The Low Predictive Power of Animal Models

Preclinical studies in immune deficient animals have low correlation with the corresponding human disease. Without an intact immune system, it is hard to predict potential adverse effects, such as immune suppression or activation.

Can we create a “humanized” immune system within animals, in order to use them as models to predict medicinal effectiveness?

3. Lack of Robust Analytical Tools

It is more than necessary to develop accurate predictable analytical methods. These methods make it possible to perform an accurate determination of drug stability, bio-distribution, immune response etc., under both physiological and pathological conditions in biological fluids, along with a simulated “in vivo-like” blood medium. Simulated biological environment conditions, such as the use of flow chambers for testing drug stability or culture systems, can be used as an analytical tool.
Can a tool be designed to mimic specific tissue micro-environmental conditions, such as the 3D micro-fluidic model in combination with imaging technology?

4. The Low Predictive Power of Biomarkers

No single bio-marker or combination of biomarkers is accurate enough to distinguish between normal, cancer and metastasis cell types. The identification of intra/extracellular biomarkers requires previous knowledge of specific mutations at the genome/ transcriptome/ proteome level, as well as better sensitive detection methods.

**Is there a whole new profession for precision medicine consultants that have vast knowledge of specific mutations?**

5. Patent and Regulations

In order to translate research into successful innovation, a smart research strategy needs to take these two factors under consideration; performing in vitro/ in vivo experiments, and choosing the appropriate formulations and processes. Most therapeutics candidates fail during the regulation stages.

**When developing a personalized, unique drug, how can we ensure a fair and efficient approval process?**

**The Summit on Controversies in Precision Medicine**

The field of precision medicine must cope with these interesting challenges. Raising them and revealing their potential solutions is a crucial step towards a better understanding on how to move precision medicine forward and to become part of the treatment options our national healthcare systems can offer. Our summit will bring together the best minds to tackle these challenges head-on and to discuss key opportunities that will take the field of precision medicine to a higher level.

**Join Us 13-15 November 2017 in Berlin!**

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**About Dan Peer**

Dan Peer is a Professor and the Director of the Laboratory of Precision NanoMedicine at Tel Aviv University (TAU). He is the Director of a national nanomedicine initiative project. He is also the Director of Leona M. and Harry B. Helmsley Nanotechnology Research Fund and the Chair of Tel Aviv University Cancer Biology Research Center that includes 17 affiliated hospitals.

Prof. Peer’s work was among the first to demonstrate systemic delivery of RNAi molecules using targeted nanocarriers to the immune system, and he pioneered the use of RNA interference (RNAi) for in vivo validation of new drug targets within the immune system that has enormous implications in Cancer and inflammation.

Prof. Peer has more than 50 pending and granted patents. Some of them have been licensed to several pharmaceutical companies, and one is currently under registration (as a new drug in inflammatory bowel disease). In addition, based on his work, four spin-off companies were generated Leuko Biosciences, Quiet Therapeutics, SEPL Pharma and ART Bioscience aiming to bring personalised nanomedicine into clinical practice. Prof. Peer a Member of the Israel Young Academy of Sciences.