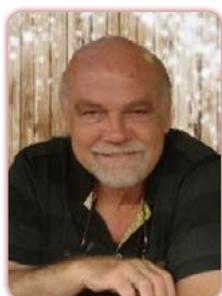


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Cellular therapy, an autologous cellular PoC approach to satisfy patient's needs

Background & Purpose: Cellular treatment and Complementary and Alternative Medicine (CAM) therapy are a potential alternative, disruptive medical treatment especially for an aging population, facing the limitation of evidence base medicine with long termed investigational character and a complex regulatory environment, while globally documented and accepted treatment.

Methods: For cellular treatment, there are two main pathways. First pathway is highly manipulated allogeneic and autologous cellular products, administered oral or via IV, intramuscular, etc., alone or in combination, which need to follow the existing regulatory 12-15 year lasting clinical trial path, or as a new technology, a new clinical trial and review concept as shown in Japan. The second pathway is to administer autologous stem cells in the frame of practice of medicine, the fastest way to personalize medicine with very limited, to no side effects, readily available today but questioned by some scientists and regulators in respect of safety and effectivity, and therefore considered as unproven medical treatment.

Results: Regulatory agencies are trying to find an approach which is beneficial and safe for patients. Unfortunately, by the time this reaches FDA and EMA regulated countries, this may take much time as it is a controversy and is discussed politically by various stakeholders.

Conclusions: Based on current scientific knowledge of risk-benefit of cellular treatment, countries outside the FDA/EMA regulated territory, advanced, approved, respective accepted autologous cellular treatments for patients, even via expansion of own stem cells. In the US, autologous stem cell treatment in the frame of practice of medicine is so far tolerated, but critically reviewed by the FDA with a trial to implement new regulatory limitations of stem cell treatment. The 21st century cure act is a step in the right direction in the US, but does not clarify most controversial issues in cell therapy, PoC treatment is highly debated in a historic FDA public hearing in September 2016. EMA Policy is similar to the US, while other countries are advancing further and faster with disruptive cell, stem cell & CAM technologies, resulting into growing international medical tourism and loss of new applied medical know-how in overregulated countries.

Biography

Falk Heinrichsohn studied Business Administration in Merck, Germany. His main activities include, developing new business, establishing or changing company setups, improving existing business and structures. He has established a foundation called Fundação Século XXI – Saúde e Vida, to promote science and art and bringing them together in exhibitions under the umbrella theme of "Esperança de Vida" to sponsor young artists and patients with unmet medical need. He retired from corporate activity and from the foundation, and since then, he is a Freelance Consultant to various global leading alternative health and wellness companies and developed the first European affiliated Stem Cell Clinic in Malta in 2014 and in 2016, a clinic in Czech Republic, others are under development. Now, he is self-employed, at Aristoloft Lda, Portugal and formerly he worked as a Managing Director of various international subsidiaries of Merck KGaA & Merck Serono, Germany and also a Consultant to Precious Cells International, UK, a European cord blood bank. He is a member of International Consortium for Cell Therapy and Immunotherapy in Europe.

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