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Abstract

'Is Regenerative Medicine Ready for Translation into Reliable Clinical Products?'

Regenerative Medicine is a generic and commonly used name to mean the application of the principles and methods of life sciences, medicine and engineering toward the development of biological substitutes to restore, maintain and improve body functions. Cell Therapy and Tissue Engineering are both included within this broad field. The aim is the delivery of safe, effective and consistent therapies for a large number of human disorders.

This field is very new, indicating that the work is breaking new grounds and hence a base line of a set of regulatory issues has not yet been totally sorted. This was amply discussed during the Symposium.

Numerous challenges are still facing us in order to provide safe and reliable therapies for clinical use. These include the clear understanding of which is the best cell source: adult cells, foetal cells or stem cells?

Stem cells are cells which have the capacity for self-renewal and are able to differentiate into specialised cells which make up more than 200 specialised cell types found in the human body. Stem cells are present early in embryo development and continue to exist in adult tissue, albeit in a form less plastic and somewhat less pluripotent. (More limited ability to proliferate or differentiate into the full range of cell types.)

Since the isolation of human stem cells almost a decade ago, the UK Government has taken the lead in establishing a regulatory framework and permissive legislation for research on embryonic stem cells and other stem cells.

CURRENT CHALLENGES THAT NEED TO OVERCOME TO TRANSLATE RESEARCH INTO RELIABLE CLINICAL PRODUCTS

- a) How can we produce industrial scale quantities of cells to treat the huge number of diseases world-wide, whereby stem cell therapy could make a significant difference? This could be achieved by the development of a generic, modular, automated instrument, with no operator involvement, closed looped, computer controlled, clinically compliant. A cell factory.
- b) Which of the diverse stem cell types will be most appropriate in the short, medium and long term of cell therapy? Adult stem cells are most likely to reach the clinic before embryonic stem cells do. Amongst the "adult" stem cell population bone marrow stem cells have been in clinical use for more than 20 years to treat haematological disorders and stem cells taken from umbilical cord are beginning to be used. At least 200 companies are now banking and distributing umbilical cord stem cells.
- c) What is the ideal number of cells needed for successful engraftment and which is the best mode of cell delivery for therapy.
- d) How best to harness the use of bioactive materials for 3D constructs or cell delivery. Rapid advances are taken place on the development of bioactive materials.

Providing technical and scientific solutions to these problems will ensure the robust development of regenerative medicine products into the full range of healthcare markets. Stem cell therapy-related market is likely to reach \$35 billions by 2020.

Illustrations abound as to the immense potential of stem cell therapy to reassess/revise current therapeutic modalities. The healthcare budget that chronic illness costs the NHS or Healthcare Institutions is very large. For instance:

Chronic lung diseases are currently treated by palliative care (e.g. Pfizer, GSK). Regenerative therapies could involve the use of cultured lung cells to aid lung repair in destructive lung diseases. Chronic Obstructive Lung Disease (COPD) or smokers lung

affect 600 million people, 29 millions have disability-adjusted life and 1 million/ annum die due to respiratory failure. (Figures taken from a Report by the World Bank). Palliative treatment costs \$1,522/year/patient.

Current therapies for diabetic patients costs the NHS £ 10 / day and in the Middle East, where the incidence of diabetes is much larger, reaching 26% of the population, stem cell therapy could have a major impact.

The need for clinical grade stem cells is thus incommensurable. Learning how to expand stem cell lineages, in a robust, reproducible and clinically acceptable manner is therefore one of the most pressing priorities we are currently facing if stem cell research is expected to move from the laboratory to clinical practice.

Speaker biography



Professor Dame Julia Polak

Professor Dame Julia Polak graduated from the University of Buenos Aires, Argentina and obtained her postgraduate training in the UK. She is the founder and former Director of the Tissue Engineering and Regenerative Medicine Centre, Imperial College. She is a member of the Scientific Advisory Board of the Imperial College Institute of Biomedical Engineering and has recently been made a new member of the Stem Cell Advisory Board Panel of the joint MRC/UKSCF, Science Advisory Board, (October 2005), Panel of the new EPSRC Peer Review College (2006 – 2009), Panel of the MRC College of Experts (2006 – 2010) and Steering Group of the UK Stem Cell Immunology Programme (March 2006) and UK National Stem Cells Network Committee (October 2006). She

is a council member of the Tissue Engineering Society International and the Academy of Medical Sciences (2002 – 2005) and was also European Editor of Tissue Engineering (up until 2004). She is the author of 992 original papers, 118 review articles and Editor/Author of 27 books and is one of the most Highly Cited Researchers in her field. She is a co-founder and Director of an Imperial Spin Out Company called Novathera dealing with Regenerative Medicine Products. She is also the recipient of a heart and lung transplant, in 1995, and into her 11th year post-transplant is one of the longest living survivors in the UK. She has received a number of honours and won a number of prizes including:-

RECENT HONOURS:

- Dame Commander of the British Empire (DBE) (2003)
- Tea with the Queen and Prince Phillip to celebrate the Pioneers of the country (October 2003)
- Honorary Doctorate from the University of Sheffield (2005)
- Honorary Doctorate from the University of Compostela, Madrid, Spain (1997)
- Honorary Fellowship of the Association of Clinical Pathologists (2003)
- Visiting Professor at The University of Texas Health Science Center at Houston, Texas (2004)
- Life Time Achievement Award for contributions to Endocrine Pathology, March 2006.

RECENT MEDALS:

- Medal, Swedish Society of Pathology (1998)
- The Cable and Wireless Sir Eric-Sharp Prize for Oncology (1986/1987)
- Medal of the Society for Endocrinology (1984)
- Benito de Udaondo Cardiology Prize (for establishing a new way of visualising coronary arteries) (1967)
- The Ellison-Cliffe Medal, Royal Society of Medicine (2004)
- Pathology Society Award for long services to Pathology (2004)
- Feyrter-Oberndorfer Medal and Certificate for ENETS Lifetime Achievement Award, Prague (2006)

RECENT NAMED LECTURES:

- The Israel Doniach Lecture, Pathological Society of Great Britain (2004)
- Oliver-Sharpay Lecturer, Royal College of Physicians (1993)
- Eramus Wilson Distinguished Lecturer, Royal College of Surgeons (1992)
- The Dean's Special Lecture on "Stem Cells and Regenerative Medicine", University of Texas Health Science Center at Houston, 15th November 2004.
- Institutional Lecture at Texas A&M University, College Station, 17th November 2004.
- Institutional Lecture at the Cell and Gene Therapy Center, Baylor College of Medicine, Houston, 15th February 2005.
- Institutional Lecture at the University of Texas at Austin, Austin, 17th February 2005
- Institutional Lecture at the University of Texas Southwestern, Dallas, 22nd February 2005
- Distinguished Guest Lecture and medal in recognition of outstanding contribution to biomedical research, MD Anderson Cancer Center, Houston, 23rd February 2005
- Distinguished Guest Lecture, Rice University, Houston, 2nd March 2005
- Keynote John Clark Memorial Lecture, London, 25th September 2005.