Healthcare Innovation EXPO 2009, 18-19 June, ExCel, London

Regenerative Medicine: A Forum for Clinical Need

FORUM REPORT

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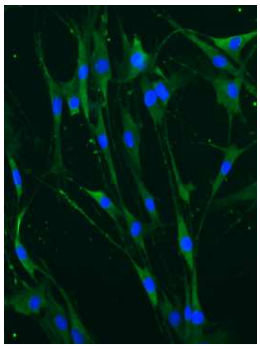

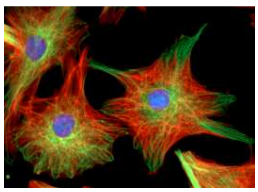

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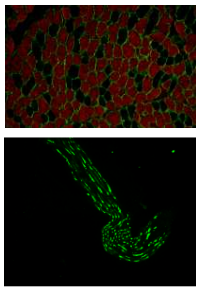
1. Introduction

Dame Julia Polak introduced the meeting and noted that the Regenerative Medicine Forum had brought together a unique mix of participants from academic, clinical, commercial and regulatory backgrounds, all sharing the common goal to translate the huge efforts in UK regenerative medicine into safe and effective healthcare products.

What is regenerative medicine?



A definition for regenerative medicine, taken from Mason & Dunnill, was provided by Martin Birchall in his presentation:

'Regenerative Medicine replaces or regenerates human cells, tissue or organs, to restore or establish normal function'

[Reference: Mason C. and Dunnill P. (2008) A brief definition of regenerative medicine. Regenerative Medicine. 3(1), 1-5]

2. Key Messages

2.1 SUMMARY

The most important strategic question for this meeting was 'How can we get Regenerative Therapies into the NHS - what is needed to get them from the bench and into patients?'

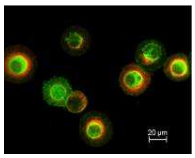
In the inspirational example of the first tissue engineered trachea transplant by Professors Macchiarini and Birchall, the clinical need was the driver for getting the regenerative therapy into the patient.

In this example of a successful cell-based therapy, the technical challenge was high and required the coordinated integration of many critical factors by Professor Macchiarini. However, the infrastructure is not in place to make this routine and so there is the opportunity to replicate this integration of clinical, technology and regulatory requirements within the NHS by developing a **regenerative medicine innovation pathway** – thus bridging the 'translational gap'.

2.2 PARADIGM SHIFT

Living cell therapies require a paradigm shift in therapeutic development and adoption. The aim to physically replace a human tissue through regenerative medicine holds the promise of a cure, not just the management of disease symptoms. This is a step change in disease treatment, as significant as society's transition from the use of candles to light bulbs (Chris Mason).

2.3 LEAP OF FAITH



Laboratory scientists have taken the development of regenerative medicine therapies a long way, but now clinicians need to take on the challenge and apply that learning to clinical situations. Clinicians must have the courage to take a 'leap of faith'. Huge progress will be made in a attempting a few procedures compared to many years of incremental development (Martin Birchall).

2.4 SUCCESS FACTORS

Scientific and clinical excellence

High quality research and considerable clinical experience is required for the successful translation of regenerative medicine products (Paolo Macchiarini, Giorgio Terenghi, Kenny Dalgarno). This is exemplified by Paolo Macchiarini's work on the tissue engineered trachea, which was based on over 16 years of basic research in his laboratory alone (and this would be a great deal more if you also included the considerable research efforts of his collaborators). In addition, the success in treating eye disorders with limbal stem cells is built on an extensive research programme (Julie Daniels).

Collaboration

The complexity of regenerative medicine makes close collaboration and excellent working relationships between all parties (academics, clinicians and industry) a key success factor. The importance of collaboration was highlighted throughout the Forum; Andrew McCaskie and Kenny Dalgarno stated that close collaboration underpins their research and clinical programmes, and good communication at all stages is vital as well as being crucial for successful IP exploitation.

2.5 HEALTH ECONOMICS

- There is a need for an improved understanding of the cost and payment structures related to the adoption of regenerative medicine products (Margaret Parton).
- The cost structure is very different when considering regenerative therapies. They are probably more expensive in the short term but, due to the potential of a cure rather than just management of symptoms, likely to offer cost savings in the longer term (Chris Mason).
- Since approval by NICE has a cost-effectiveness element, regenerative medicine products are not readily taken up (Patrick Ginty).
- We need to get better at identifying the value in early stage products (Mirella Marlow).

2.6 TRANSLATION GAP

A consensus view was that translational research is complicated and composed of multiple steps and interactions. Patrick Ginty stated that one of the major challenges in tissue engineering is to translate the laboratory scale process into a clinically effective, reproducible and economically acceptable manufacturing process. Kenny Dalgarno said that at present there is no single fully

developed translational process. In addition, several speakers mentioned that the development of relevant preclinical models is vital to bridge the gap between bench research and the clinic.

The Cooksey Review was mentioned by the panel members. It identifies two key gaps in the translation of health research:
- translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness; and
- implementing those new products and approaches into clinical practice

[Reference: Cooksey, D. (2006) A review of UK health research funding. HM Treasury]

3. Insights

3.1 This isn't the future, this is now

The use of regenerative medicine is already routine. To date a third of a million patients have received living cell therapies, such as Organogenesis' Apligraf tissue engineered skin product. Soon we can expect regenerative medicine products for the treatment of many conditions and tissue replacement procedures, e.g. bladder, blood vessels, heart failure, stroke, diabetes, etc (Chris Mason).

3.2 Learnings from industry

Product development management techniques, such as Robert Cooper's Stage-Gate process, that are routinely used in the healthcare industry could be adapted for facilitating the translation of regenerative medicine products into the clinic. There is a need to make difficult/hard-nosed decisions to avoid wasting time and resources, with no room for pet projects (Kenny Dalgarno, Patrick Ginty).

3.3 Future research and clinical developments

Andrew McCaskie, Cosimo De Bari and Paolo Macchiarini (in his later talk on the main stage) all said that the future of regenerative medicine lay in using the human body itself to regenerate tissue. For example, by stimulating recruitment of the right factors to target resident stem cells, possibly by pharmacological manipulation. Paolo Macchiarini likened it to using the body as a bioreactor, thereby avoiding the need for in vitro cell culture. Paulo termed his concept "bionic tissue engineering".

4. Opportunities

4.1 Strong platform

The UK is a world leader in regenerative medicine, second only to the US. Of the 687 regenerative medicine firms in the world, 19% (133) are UK based (Chris Bravery).

4.2 Safety

Regenerative medicine appears to be a relatively safe therapeutic approach. Out of a total of 330,000 patients treated with routine regenerative medicine therapies, to date there have been no serious complications (Chris Mason).

4.3 Greater collaboration

Patrick Ginty talked about constructing a community that holds a shared vision. Mirella Marlow suggested that the strong links between academics and clinicians needed to be extended to people carrying out the evaluations at NICE.

4.4 Hospital exemption

Provisions exist in the regulatory legislation to allow the non-routine treatment of exceptional cases. A mechanism to potentially fast track regenerative medicines into the NHS is through use of a Hospital Exemption which facilitates non-routine treatment on a named patient basis (Chris Bravery). Hospital exemption requires the following: named patient, non-routine treatment, a Human Tissue Authority (HTA) licence, manufacturing authorisation from the MHRA (Medicines and Healthcare products Regulatory Agency) and traceability.

5. Areas for Improvement

5.1 Reducing barriers to NHS adoption

There are a number of barriers to the adoption of regenerative medicine products that are both clinically- and system-related. Defining these in more detail could help prepare regenerative therapies for a smoother transition into the NHS (Margaret Parton).

Many small and medium-size UK companies find that the NHS is a barrier to achieving product sales and often turn to the US for initial launch. Whilst the FDA has stringent requirements, there are multiple entry points into the healthcare system which facilitates technology adoption (Patrick Ginty).

5.2 Funding and Staff

There are investment gaps in the translational path for regenerative medicine products in the UK, for example in early technology development and between the late preclinical stage and clinical trials in humans (Kenny Dalgarno, Martin Birchall). The US is directing significant funding to the area, with the state of California recognising the costs involved and earmarking $3 billion to support translation. Martin Birchall noted the importance of specialist staff training in the field of regenerative medicine and hence funding for staff training should be included in any UK investment.

5.3 Cell standardisation

The variable nature of cell-based regenerative therapies has, perhaps rather unsurprisingly, led to large variability in the outcome of regenerative medicine trials. In particular, it is difficult to standardise living cells and this inherent variability can give rise to a range of clinical outcomes. Cosimo de Bari and others have found that the *potency* of stem cells strongly impacts their behaviour and performance. Two major factors are donor variation and the inconsistency of stem cell preparations.

[See also notes from Cosimo's talk below and Reference: Rosenzweig, A. (2006) Cardiac Cell Therapy — Mixed Results from Mixed Cells. New England Journal of Medicine 355:1274-1277]

5.4 More straightforward regulation

Several speakers indicated that they would welcome a more understandable and accessible regulatory process for the translation of regenerative medicine products. Patrick Ginty highlighted that greater support was needed for SMEs. Paolo Macchiarini requested a more straightforward path for the regulation of organ donation between countries; for example the administrative paperwork was the biggest hurdle to overcome in the tissue engineered trachea implant procedure. Receipt and use of the donated organ required lengthy co-ordination between the regulators in UK, Spain and Italy.

5.5 Knowledge sharing

There is a need to make techniques widely available in the developed and developing world. With such high levels of complexity in regenerative medicine, efforts are required to share knowledge to transfer capability to others (Paolo Macchiarini).

6. Appendices:

6.1 Session summaries

Session 1 - The first tissue-engineered airway replacement:

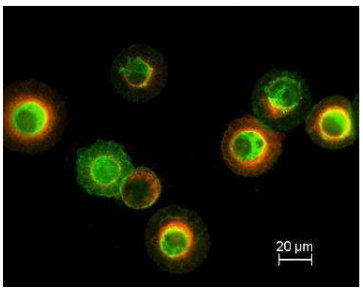
What have we learnt from a stem-cell based, tissue-engineered organ transplant?

Martin Birchall & Paolo Macchiarini

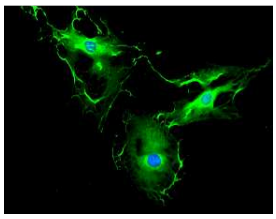
Getting Ready for Regenerative Medicine - New Hope, New Challenges

Martin said that whilst it was impossible to predict the future, we do know that regenerative medicine is going to play a key role in future therapy. He talked about his collaboration with Paolo Macchiarini and said that although it was a great success there was a pressing need to do more and he hoped it would stimulate others. In particular he pointed out that the collaboration and clinical outcome were successful without receiving any additional financial support (a funding application was turned down), so it was important for funders to see the potential in regenerative medicine approaches. Martin also made a number of interesting points about clinical translation.

Paolo described how he, Martin and colleagues came to perform the first tissue-engineered trachea implant. He was approached by a 31 year old woman with end stage disease of the main bronchus, caused by a history of airway TB. The diseased airway needed to be removed and replaced to allow her lung to function. A human donor trachea was received, treated to remove antigens and seeded with a number of cell types including mesenchymal stem cells and cells from the nasal mucosa, giving rise to external chondrocytes and internal respiratory cells. Growth in a bioreactor produced a tissue engineered trachea that was used to surgically replace the diseased portion of the patient's airway in June 2008. After three months the implant was well vascularised and unexpectedly the MSC-derived chondrocytes had moved into the matrix, possibly to areas of higher oxygen concentration. In his main stage talk later that day Paolo speculated that this behavior of the chondrocytes may explain the failure of some other cell therapy treatments, for example treatment of the heart with stem cells may be adversely affected by the low oxygen environment. A year after transplantation the patient is doing well.

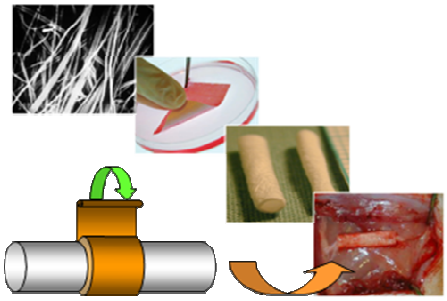


Giorgio Terenghi
How science can take transplant forward?



Giorgio outlined how a greater appreciation of the underlying science will support the clinical translation of regenerative medicine products. His research concerns the bioengineering of nerves from the larynx. An implant designed to bridge the gap between two nerves was prepared and treated with a variety of components, including stem cells and growth factors.

In preclinical studies, nerve regeneration was observed, giving near normal motion of the larynx by 120 days post-procedure. Giorgio's group formerly used bone marrow-derived stem cells but now use adipose-derived stem cells which are more easily accessible, come from the largest source of tissue in the body and proliferate more quickly. Giorgio's future goal is to try and improve the function of a transplanted organ.



[Reference: Kingham, P. et al (2007) Effect of neurotrophin-3 on reinnervation of the larynx using the phrenic nerve transfer technique. European Journal of Neuroscience 25: 2, 331-340]

Session 2 - Can Regenerative Medicine repair the arthritic joint?

Working across the boundaries of engineering and medicine in OA research

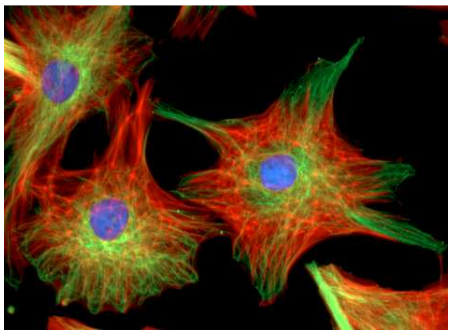
Andrew McCaskie & Kenny Dalgarno
A translational approach to regenerative musculoskeletal bioengineering

Andrew is an orthopaedic surgeon interested in translational research and the process of bi-directional knowledge transfer between scientists and clinicians. The surgery that Andrew performs is at the end stage of disease, such as a hip replacement, but he would like to address surgical points of contact to intervene in disease progression at an earlier stage. He sees a regenerative medicine approach for the treatment of osteoarthritis as the way forward and wants to ensure that as well as regenerating and restoring tissue, it will also work biomechanically. His view is that successful treatments are likely to involve cells as well as biomaterials. He is particularly interested in the interface between an implant and bone and his research is centred on trying to enhance this interaction at the nanoscale. The aim is to generate bespoke nanosurfaces, which have the ability to affect the biological processes involved. Kenny discussed the need to develop translational processes that draw on their resources and capabilities at Newcastle University, but also to complement these where required. They have identified some gaps in translation and are trying to address these, for example through targeted recruitment of candidates with specific skill sets. Kenny identified several success factors and some lessons from industry, such as use of the stage-gate funnel in new product development.

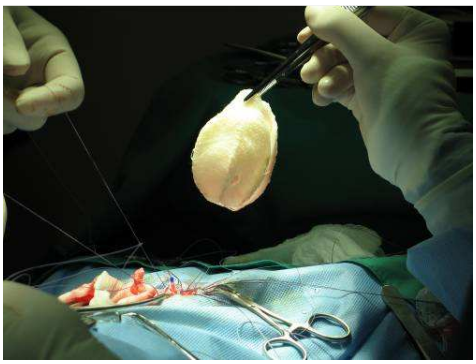
Session 3 - Regenerative Medicine Showcase:

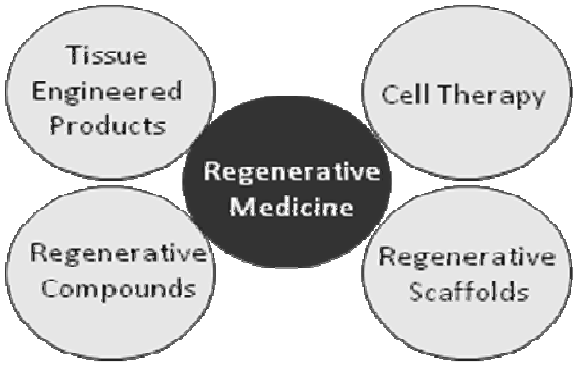
Candidate therapies that have the potential for early entry into the clinic

Chris Mason
Introduction



Chris introduced the session by talking about the regenerative medicine paradigm shift (the promise of a cure rather than simply managing the signs and symptoms). Regenerative medicine comprises tissue engineered products, cell therapies and regenerative compounds and scaffolds. These therapies can be autologous or allogeneic, each with their own pros and cons relating to cost, scalability and speed to clinic. He discussed routine therapies, with which over 330,000 patients have been treated with no serious complications and spoke about the 'tsunami' of new therapies that are on the way.





Christopher Bravery
Policing Regenerative Medicine: Cell or Therapy?

Christopher emphasised the need for a comprehensive legal and regulatory framework to safeguard public health. He outlined the different regulatory pathways and highlighted that there are varying degrees of regulation for medical devices to tissue engineered products. For example, cell therapy and tissue-engineered products are regulated by the HTA, MHRA and EMEA (European Medicines Agency) and need to demonstrate quality, efficacy and safety. Most regenerative medicine products will be considered to be medicines, so making it a long and expensive road before they are available to the NHS. However the first few products are reaching the end of this long road. Christopher mentioned the opportunities of having a strong UK regenerative medicine base and the use of hospital exemption.

Julie Daniels
Treating ocular surface disease of the cornea with adult stem cells

Julie Daniels and her team are using the cornea as a model for adult stem cell research and therapy. They have found evidence for stem cells being located at the limbus of the eye, on the edge of the cornea. If the limbal areas containing stem cells are adversely affected, then the ocular surface changes and neighbouring tissue can grow across causing vascularisation and opacity of the cornea. Limbal cells are expanded for transplantation to patients, both from autologous (through a biopsy) and allogeneic sources (from a cadaveric donor) – termed Limbal epithelial stem cell therapy. It appears that the limbal stem cells are able to give rise to new terminally differentiated corneal cells, thereby improving vision. Using objective measurements, they have demonstrated an improvement in vision in 60% of cases. This work is tightly regulated under HTA and MHRA regulatory guidance.

[Reference: Shortt et al. (2008) Ex Vivo Expansion and Transplantation of Limbal Epithelial Stem Cells Ophthalmology 99:634–638]

Cosimo De Bari
Regenerative Medicine: challenges from a research perspective

Cosimo discussed regenerative medicine approaches such as ACI (autologous chondrocyte implantation) for the treatment of joint surface defects and prevention of osteoarthritis. ACI is an example of a regenerative medicine therapy that NICE has not recommended. The reasoning behind the decision was largely because ACI showed no conclusive evidence of clinical superiority over other techniques such as microfracture. Cosimo puts this lack of evidence down to the difficulty in standardising living cells, with variability that results in a range of clinical outcomes. Cells can show variability between donors, between tissues and even within the same tissue. About 10 years ago, Cosimo and colleagues initiated a programme to develop quality control assays to assess the potency of expanded cell preparations for cartilage and bone repair. The assays centre on the use of biomarkers and related mathematical models that can predict the potency of cells, indicating which cells will produce cartilage/bone and how many cells to use in the treatment.

[Reference: De Bari C et al (2006): Mesenchymal Multipotency of Adult Human Periosteal Cells Demonstrated by Single Cell Lineage Analysis. Arthritis & Rheumatism 2006; 54 (4): 1209-1221]

Session 4 - Adoption of regenerative therapies:

What is needed to enable regenerative therapies to reach the patient?

Margaret Parton

NHS Technology Adoption Centre

Wouldn't it Be Good if……

The NHS had processes in place that would enable it to

- **Horizon Scan**
- **Evaluate**
- **Commission**
- **Procure**

Regenerative medicine products and procedures without all the delays encountered by other transformational technologies?

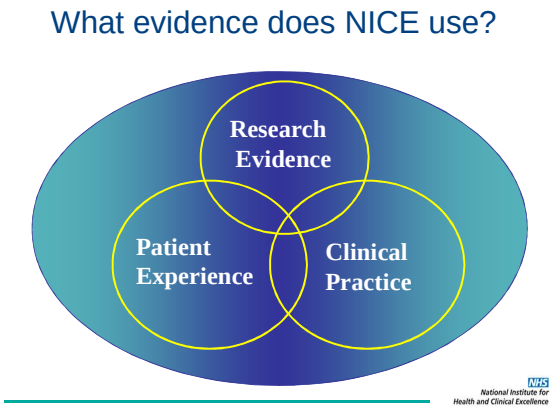
Margaret described the role of the National Technology Adoption Centre in working with NHS management and procurement teams to overcome the barriers to adopting new technologies. The technologies that are considered for support by the centre must already have demonstrated clear benefits to patients and be able to improve system efficacy. There are many issues around new technology adoption, so there are a number of key adoption questions with others still being formulated. Regenerative medicine brings its own challenges and there are a number of elements that needed to be streamlined/developed for regenerative medicine products to be adopted without the delays encountered by other transformational technologies – horizon scanning, evaluation, commissioning, procurement and health economics. In particular Margaret stressed that there was a need for more clinicians to get engaged and to assist in addressing several areas:

- Cost and payment structures
- Specialist centres only to do this type of work?
- Specialist commissioning and which patients should receive certain treatments?
- And is this a new clinical speciality, and if so should there be a new Royal College?

Mirella Marlow

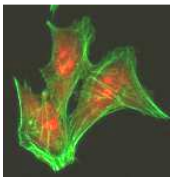
Evaluating innovative medical technologies to support uptake in the NHS

Mirella is leading on the development of a programme to evaluate innovative medical technologies at the National Institute for Health and Clinical Excellence (NICE). NICE assesses the value of healthcare technologies/interventions to the NHS and other public sector organisations. Essentially they try to bridge the gap between research and adoption. The evidence they need to demonstrate value comes from research, clinical practice and patient experience. Current clinical evaluation programmes include:



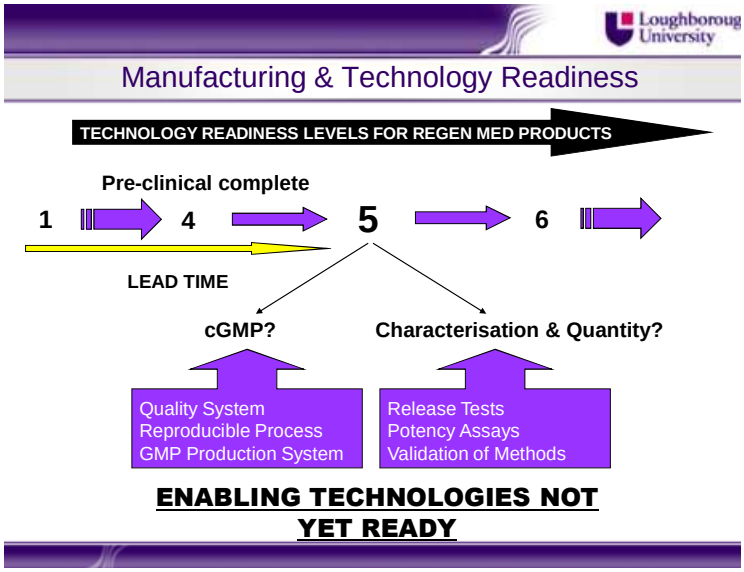
Technology Appraisals – assessments of the clinical and cost-effectiveness of pharmaceutical products and other treatments in high impact disease areas, e.g. cancer, cardiovascular disease, usually where there is an evidence base that includes RCTs.
Interventional Procedures (Mirella's programme) – designed to introduce new surgical procedures safely and in a planned way.
Clinical Guidelines – the clinical and cost-effectiveness of established treatments in the pathway of care.
There are numerous examples of device and diagnostic evaluations in NICE's current programmes. Mirella mentioned that there are suggestions in Lord Darzi's Summer 2008 Next Stage Review to have a common evaluation pathway for medtech products including diagnostics and devices. There would be a single point of entry with defined product selection criteria acting feeding medtech products into evaluation programmes at NICE. Having research evidence will always be key and the types of evidence required are likely to include case reports and safety outcomes in early surgery. See www.nice.org.uk for details of NICE's programmes and developing work on the assessment of medtech products. See www.evidence.nhs.uk for the new NHS Evidence service being provided by NICE, to provide easy access to high quality clinical and non-clinical information about health and social care.

Patrick Ginty
Taking Regenerative Medicine Products to Market – Addressing the Challenges Facing Small UK Businesses



Patrick presented a small business perspective on regenerative medicine, which is an output of research carried out under the remedi project based at Loughborough University (www.remedigc.org). He said that small and medium-sized companies needed to consider a wide range of issues in taking regenerative medicine products to market including science, technology, social, legal and financial issues. He also suggested that the development route taken was strongly influenced by whether the product was device- based or cell-based and that there is a need for a manufacturing-engineering led approach as well as a biocentric one. Some of the other areas Patrick highlighted included:

- The need to validate manufacturing methods.
- The concern that in some cases the enabling technologies lag behind the commercial/ regulatory requirements.
- That support is required to follow regulatory policies and standards/ guidance from MHRA, BSI (British Standards) and EMEA; what is the approval route and what resources are needed?
- The degree of clinical evidence that companies must provide to regulators and payers.
- The importance of considering factors such as regulation and reimbursement at an early stage.



- In the US, the FDA is looking for evidence of safety whilst the healthcare payers require a demonstration of efficacy. These factors need to be built into the product development process.
Lastly Patrick mentioned that as part of the remedi project, Professor Richard Lilford (Professor of Clinical Epidemiology at the University of Birmingham) led a team to assess a cost-effectiveness model for use of tissue engineering in bladder repair but the outcome was not commercially favourable.

[Reference: McAteer Helen et al (2007) Cost-effectiveness analysis at the development phase of a potential health technology: examples based on tissue engineering of bladder and urethra. Journal of tissue engineering and regenerative medicine 2007;1(5):343-9.]
[See also: Cosh et al (2007) Investing in new medical technologies: A decision framework . Journal of Commercial Biotechnology, 13, 4: 263-271(9)]

6.2 Biographies

Chairperson

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 and is now an Emeritus Professor from the Faculty of Medicine and resides in an office in the Department of Chemical Engineering. She is also a member of the Scientific Advisory Board of the Imperial College Institute of Biomedical Engineering and was made a 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 (now MedCell) dealing with Regenerative Medicine Products. She is also the recipient of a heart and lung transplant, in 1995, and into her 14th year post-transplant is one of the longest living survivors in the UK. She has been the recipient of many honours and prizes, too numerous to mention.

Healthcare Panel

Martin Birchall (Professor of Laryngology, UCL)

Martin Birchall is Professor of Laryngology at the Royal National Throat, Nose and Ear Hospital and holds a host of other posts and honours. His special interest is in Head and Neck Surgery and Laryngology. He heads the largest ENT research group in the UK, focused on developing newer and better treatments for throat diseases. A leading innovator in his field he has dedicated his career to finding solutions to the problems faced by people with throat diseases. Martin collaborated with Paolo Macchiarini, who led the project, in the first stem cell-based tissue-engineered trachea transplant.

Paolo Macchiarini (Professor of Surgery, University of Barcelona)

Paolo Macchiarini is, amongst other things, head and chairman of the Hospital Clinic of Barcelona and Professor of Surgery at the University of Barcelona and the Hannover Medical School in Germany. He has worked closely with Martin Birchall in the field of ENT research and his interests include extended surgery for lung, esophageal and mediastinal tumours; lung and heart-lung transplantation; pulmonary endarterectomy; (bio)artificial lung and experimental research, education and training. Similarly to Martin, he has dedicated his career to finding innovative solutions to the problems faced by those with throat diseases of all kinds. This culminated in Paolo leading the pan-European project to tissue-engineer a new windpipe for a Columbian woman.

Andrew McCaskie (Professor of Orthopaedic Surgery, Newcastle University)

Andrew McCaskie is Professor of Trauma and Orthopaedic Surgery at Newcastle University. As a clinician he is interested in lower limb joint replacement and has a related interest in clinical research. From a laboratory research perspective, he is interested in the creation of surfaces that can direct cell behaviour in relation to bone formation, including implant modification at the nanoscale. He was the facilitator for the MRC IDBA (Institutional Discipline. Bridging Award) to Newcastle concerning Medicine and Nanotechnology and other research support has included the arc, MRC, EPSRC, BBSRC and European Commission Framework VI. He is currently Associate Editor for the Journal of Bone and Joint Surgery and a member of the Council of Management. He contributed to the European Science Foundation (ESF) Nanomedicine Forward Look and has been on the faculty committee at ESF nanomedicine conferences 2006 & 2008, as well as summer school 2007.

Julie Daniels (Director, Cells for Sight Tissue Bank/Institute of Ophthalmology UCL)

Julie Daniels obtained her first degree in Microbiology and her PhD in tissue engineering from the University of Leeds. She has worked at the Yorkshire Regional Tissue Bank where she produced cultured keratinocytes for burns victims and leg ulcer patients. She joined the Institute of Ophthalmology, UCL in 1996 as a post-doc with Prof Peng Khaw working on anti-scarring strategies. Julie is now a Lecturer at the Institute and her group is aiming to understand the biology and therapeutic potential of stem cells. She is also the Director of the Cells for Sight Tissue Bank which is delivering stem cell therapy to patients with blinding ocular surface disease.

Margaret Parton (NHS Technology Adoption Centre)

Margaret Parton is the Chief Executive Officer of the NHS Technology Adoption Centre. Since 3 July 2007, Margaret has been spearheading this exciting venture based at Central Manchester & Manchester Children's University Hospitals NHS Trust, establishing the first Technology Adoption Centre for the NHS in England. Formally the UKTI Life Science Sector Champion & Programme Manager for the DTI UK/US Bioscience Collaboration, Margaret is an experienced business developer with an excellent track record in defining technology strategy, establishing partnerships and developing international project proposals. Margaret brings all her enthusiasm and expertise to facilitate successful collaboration with industry, the public sector and national, regional and university groups to ensure cohesive roll out of Technology Adoption Centre projects.

Mirella Marlow (Interventional Procedures Programme, NICE)

Mirella Marlow is the Associate Director of the Interventional Procedures Programme at NICE, having previously spent 15 years in a variety of commissioning roles in the NHS. Since July 2005 she has managed NICE's Interventional Procedures Programme, which assesses evidence on the safety and efficacy of new interventional procedures. From 2007 to 2008 she also managed NICE's Patient Safety Pilot Programme. Mirella is now closely involved in planning new developments at NICE on the evaluation of innovative devices and diagnostics. Mirella's first degree was in mediaeval history and archaeology and she has a Masters in Business Administration. She has recently completed an MA in Medical Ethics and Law at Keele University, where her interests included the ethics of measuring the cost-effectiveness of interventions to improve the safety of healthcare, and legal cases relating to healthcare rationing.

Scientific Panel

Chris Mason (Professor of Regenerative Medicine Bioprocessing, UCL)

Chris Mason holds the Chair of Regenerative Medicine Bioprocessing at University College London. He has a Clinical Sciences degree (Imperial College), a Medical Degree (St. Thomas's Hospital), a PhD in tissue-engineering (UCL) and is a Fellow of the Royal College of Surgeons. He is also Director of the Regenerative Medicine Bioprocessing Unit in the Advanced Centre for Biochemical Engineering at UCL, Senior Editor of "Regenerative Medicine" journal and co-founder and Director of the London Regenerative Medicine Network (LRMN).

Giorgio Terenghi (Professor of Tissue Engineering, University of Manchester)

Giorgio Terenghi holds the Chair of Tissue Engineering in the Nerve Regeneration Group, School of Medicine, University of Manchester. After gaining a Doctor in Biology degree in Milan, Giorgio moved to the UK and attained an MSc degree from the University of Sheffield in 1980, a PhD in Pathology from the University of London in 1985, became a Fellow of The Royal College of Pathology, and in 2001 was awarded an Honorary Degree in Medicine from the University of Umeå in Sweden. The main focus of his present research is tissue engineering of nerve regeneration, developing an alternative clinical approach to nerve reconstruction using nerve conduits and cultured Schwann and adult stem cells. In collaboration with Martin Birchall, Giorgio investigated the application of new nerve repair techniques for the transplantation of the larynx and for the functional recuperation of muscle functions which control breathing and speech.

Kenny Dalgarno (Professor of Manufacturing Engineering, Newcastle University)

Kenny Dalgarno is Sir James Woodeson Professor of Manufacturing Engineering at Newcastle University. For the past decade he has been researching in the area of layer manufacture, with applications in rapid prototyping and manufacturing, polymer engineering and biomedical engineering, with work supported by the EPSRC, the EU, the arc, the Carbon Trust, Yorkshire Forward (the regional development agency), and industry. He is a member of the EU Rapid Manufacturing Platform, and of the Innovative Production Machines and Systems (I*PROMS) Network of Excellence.

Christopher Bravery (Director of Regulatory Affairs, ERA Consulting (UK) Ltd)

Christopher Bravery is currently Director of Regulatory Affairs for Advanced Therapy Medicinal Products at ERA Consulting Ltd, providing process development and regulatory advice to industry covering the entire product lifecycle. Previously Christopher was a Pharmaceutical Assessor in the Biologicals and Biotechnology Unit, Licensing Division at the MHRA where he undertook quality assessment of new biological medicines as well as variations to existing licenses, the majority being via the Centralised procedure administered by the EMEA. This work included assessment of clinical trials applications and both National and EMEA scientific advice procedures. During this time Christopher was involved with National implementation of the new Advanced Therapies Regulation and also involved through his participation in the CHMP's cell products working party in implementation at the EMEA level including drafting guidelines. Previous employment includes over 8 years R & D experience in biotech, including creation of transgenic pigs for xenotransplantation at Imutran Ltd. (owned by Novartis) and a range of cell therapy products at Intercytex Ltd. Christopher has a PhD in transplantation immunology from Imperial College London.

Patrick Ginty (SME & Industry Contact for remedi, University of Loughborough)

Patrick Ginty is currently the SME and Industry Contact for the remedi project and is based at Loughborough University. He completed both his PhD and an 18-month post doctoral fellowship in tissue engineering under the supervision of Professor Kevin Shakesheff. During his time at Nottingham University, Patrick developed novel drug eluting scaffolds for applications in regenerative medicine. He has also spent time in both the future technologies group at the Boots Company plc and RegenTec in Nottingham, where he developed an injectable scaffold for orthopaedic regeneration applications. He is currently working with small businesses involved with the remedi project and training in FDA and EU regulatory affairs.

Cosimo De Bari (Professor of Translational Medicine & Hon Consultant Rheumatologist, University of Aberdeen)

Cosimo De Bari is Professor of Translational Medicine and Hon Consultant Rheumatologist at the University of Aberdeen, heading a unit of stem cell research for skeletal tissue repair in the Bone & Musculoskeletal Research Programme. He graduated in Medicine (maxima cum laude) from the University of Bari (Italy), where he also underwent specialist training in Rheumatology. He then moved to Belgium, where he obtained his PhD from the Catholic University of Leuven. In 2003 Cosimo moved to the UK as a postdoctoral research fellow in the Department of Rheumatology at King's College London. In May 2005 he was awarded an MRC Clinician Scientist Fellowship and in December 2005 was appointed Clinical Senior Lecturer and Hon Consultant in Rheumatology. Cosimo has expertise in the field of stem cell research for musculoskeletal repair, regenerative medicine and tissue engineering.