19th NSW Stem Cell Network Workshop

Innovating the Marketplace with Stem Cells

Convention Centre
Darling Harbour, Sydney
29th November 2013

NSW StemCell NETWORK

Australian Government
Department of Industry

WELCOME

Welcome to the 19th Workshop of the NSW Stem Cell Network.

This workshop is about recognising the strengths and weaknesses of stem cell research in Australia and coming up with solutions on how to build on these strengths and overcome the weaknesses towards a strong and innovative national stem cell industry.

The holy grail of stem cell research is that cells can be produced for any tissue in the laboratory and then used for disease modelling, pharmaceutical discovery and testing or as a transplantation therapy for diseases. Blood stem cells are the gold standard for this and have proven a clinical success for decades. More recently the clinical relevance of other types of stem cells, such as those produced from skin or isolated from the limbus of the eye, are demonstrating therapeutic efficacy. The last 15 years also has seen an explosion of stem cell technologies, with human embryonic stem cells, followed by induced pluripotent stem cells and mesenchymal stem cells with their anti-inflammatory properties. This workshop aims to bring together industry leaders to discuss what the market wants from stem cells, how to strengthen the Australian stem cell industry through building commercial potential and how to keep Australia at the forefront of stem cell innovations.

You will hear from industry leaders in stem cell research who have seen the inception and decay of the Australian Stem Cell Centre and how to use this knowledge towards future successes. You will also hear of products and innovative research from Australian based companies and research institutions that are keeping Australia at the forefront of stem cell technologies.

The goal of the day is solutions. Solutions to move the industry forward. To achieve this we have a panel of speakers from areas as diverse as tax, law, regulation and finance to share their expertise on industry successes and how this can be applied to the stem cell field. It has been said 'The least innovative way of innovating is to discuss innovation'. This meeting is sponsored by the Federal Government demonstrating their support for stem cells. Lets not waste time complaining and asking for more money; lets report back solutions of how we can work together to develop a strong stem cell industry that not only supports basic research but clinical and commercial application and the needs and desires of patients.

The NSW Stem Cell Network aims to bring the community together with a greater understanding of perspectives and desires. We hope that you enjoy the workshop and invite you to expand your network.

Dr. Heather Main
Manager

Prof. Bernie Tuch
Director

NSW Stem Cell Network

PROGRAM

8:00am	Registration opens / Breakfast provided/poster displays mounted
8:30am	Welcome from NSW Stem Cell Network Director **Prof. Bernie Tuch**
8:35am	Opening address – **Prof Alan Trounson – CIRM** (via web from California)
8:45am	***Breakout session:*** *Introductions around table including table leader. Explain Strengths, Restrictions, Solutions daily activity and topic to discuss.*
Session 1	**Where Have We Been and Where are We Going** Chair: A/Prof Megan Munsie – Stem Cells Australia
9:00am	**Prof. Martin Pera – University of Melbourne** Stem Cells and Regenerative Medicine: The Future is Now
9:20am	**Dr Chris Juttner – National Stem Cell Foundation** Learning from the past looking towards the future
9:40am	**Dr Peter Mountford - Principal, Public Systems Innovation** Increase your stake by in the stem cell sector design engineering engagement from an innovation system-wide perspective.
10:00am	Morning tea
Session 2	**Towards Commercial Success in Australia** Chair: Dr Michael Morris – NSW Stem Cell Network
10:30am	**Paul Anderson - Orthocell** Autologous Cell Tendon Repair and Cell Delivery Devices
10:50am	**Dr Phil Kearny – Merck Sharp & Dohme** The Long Road Ahead—Working with Industry to Support Research and Satisfy Market Needs
11:10am	**Dr Uli Schmidt - General Manager, Genea Biocells** From Sydney IVF to Genea Biocells - Linking Science and Commercial Success
11:30am	***Breakout session:*** *10 min to discuss strengths and restrictions of Innovating with Stem Cells in Australia*
Session 3	**What Problems do Commercialisable Australian Research Encounter** Chair: Dr Michael O'Connor – Australasian Society for Stem Cell Research
11:40am	**Prof. Melissa Knothe Tate – University of New South Wales** Next Generation Implant Development - Current Feasibility and Future Directions for Regenerative Medicine
12:00pm	**Clinical Prof. Stephanie Watson – Save SIght Institute, University of Sydney** Transplantating Autologous Stem Cells on a Contact Lens for Blinding Corneal Disease

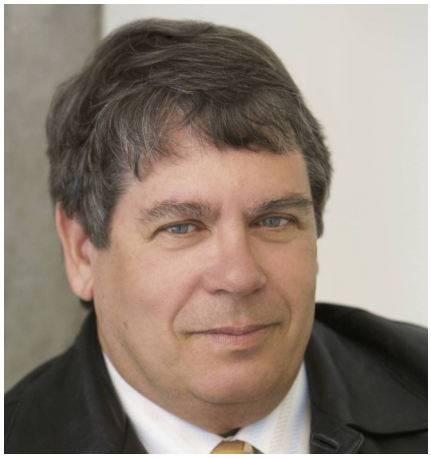
PROGRAM

12:20pm	**Prof. Geoff Symonds – Calimmune** Instating Disease Immunity with Stem Cells
12:40pm	Lunch
Session 4	**Issues in Stem Cell Translation in Australia: Introducing Panel Members** Chair: Dr Robert Nordon – International Society for Cellular Therapy
1:40pm	**Dr Alfredo Martinez-Coll – University of New South Wales** Commercialisation Issues in Academic Institutions
1:50pm	**Dr Gavin Recchia – Partner/Patent attorney, Davies Collison Cave** Maximising Commercial and Clinical Potential Through IP Protection
2:00pm	**A/Prof. Dianne Jackson Matthews – ERA Consulting (Australia) Pty Ltd**. Getting Through the Regulations – Can You Expedite the Process
2:10pm	**Helen Fisher – Deloitte tax** Tax Issues
2:20pm	**Dr Stewart Hay – Therapeutic Innovations Australia** Commercialisation of Cell Manufacture in Australia
2:30pm	**Dr Stephen Thompson – Managing Director - Brandon Capital Partners** Is My Technology Ready for Investment?
2:40pm	**Scott Power – Senior Analyst – Morgans Ltd.** Navigating the Financial Markets
2:50pm	***Breakout session:*** *20 min to discuss solutions*
3:10pm	Afternoon tea
Session 5	**Keeping Australia at the Forefront of Innovation**
3:40pm	**A/Prof Igor Slukvin – University of Wisconsin – sponsored by Cynata Therapeutics Ltd. –** 'Pluripotent Stem Cell-Derived Mesenchymal and Vascular Progenitor: A Novel Technology Platform for Regenerative Medicine'
4:20pm	**PANEL SESSION** – How can we utilise our strengths and develop systems to better support research translation and commercialisation in Australia? Compare: **Prof. David Haylock – CSIRO** Additional Panel Members: **David Oxley** - Vice President, Emerging Markets – Cytori; **John Grew** – Commercialisation Australia; **Dr Paul Brock** - Director of Learning and Development Research - Office of the Director-General, NSW Department of Education and Communities.
6:00-7pm	NETWORKING OPPORTUNITY: Drinks and cocktail food provided

Opening Address

Professor Alan Trounson—California Institute Regenerative Medicine

In Jan. 2008-present, Dr. Alan Trounson was appointed President of the California Institute for Regenerative Medicine, responsible for the management of the $3 billion fund for stem cell research in California (CIRM) <http://www.cirm.ca.gov>. Under his leadership CIRM has constructed 12 new Californian Stem Cell Research Institutes, raising more than $800 Million in donor contributions. These were opened within 2 years of beginning construction. He has developed training programs for new scientists entering stem cell science, drawing a large number of MD-PhD and PhD researchers into the discipline. He established "Bridges" programs that enable students from State Colleges and Universities to train new stem cell courses and to provide 1-2 year fellowships in the major stem cell centers of Californian University and Biotechnology companies. He has also created awards for high school students to spend summer vacations training in stem cell centers in addition to another discipline (e.g. imaging, engineering, music, ballet, physics etc.). He has overseen and extraordinary development of basic science which has led to more than 1000 publications (24% in high impact factor journals) in peer reviewed journals in the 4 years of his tenure as President. These studies are revolutionizing development and clinical applications of stem cell science. Has globalized the stem cell research program and led the translation of basic science discovery into translation and clinical trials that includes: potential new treatments of blood cancers and solid tumors, spinal cord injury, a cure of HIV/AIDS, and treatments for macular degeneration, type I diabetes, ALS – motor neuron disease, stroke, heart disease, genetic diseases and neurodegenerative diseases.

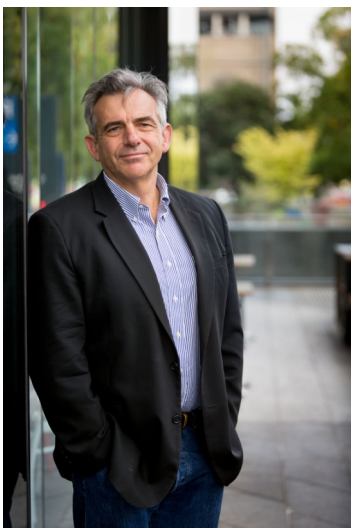


‘Stem Cells and Regenerative Medicine: The Future is Now’

Professor Martin Pera—University of Melbourne

The discovery of human embryonic stem cells in 1998 provided a major stimulus to the exponential growth of the new field of regenerative medicine. Today, clinical trials with embryonic stem cell derived products are underway, and the remarkable technology of induced pluripotency has opened up new horizons in human functional genomics, disease modeling, and drug development, as well as in cell therapy. In this talk we survey current developments in the field, and the challenges that the new paradigms of stem cell science pose to our traditional approaches to funding and managing biomedical research and to health care delivery.

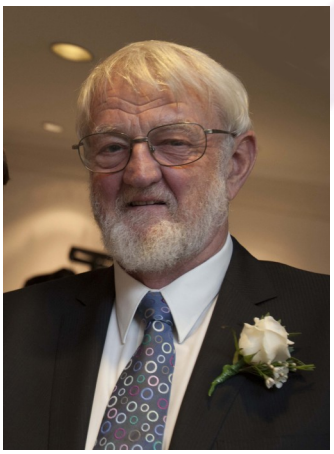
Professor Pera is Professor of Stem Cell Sciences at the University of Melbourne, the Florey Neuroscience Institute, and the Walter and Eliza Hall Institute for Medical Research. He serves as Program Leader for Stem Cells Australia, the Australian Research Council Special Research Initiative in Stem Cell Sciences. His research interests include the cell biology of human pluripotent stem cells, early human development, and germ cell tumours. Pera was among a small number of researchers who pioneered the isolation and characterisation of pluripotent stem cells from human germ cell tumours of the testis, work that provided an important framework for the development of human embryonic stem cells. His laboratory at Monash University was the second in the world to isolate embryonic stem cells from the human blastocyst, and the first to describe their differentiation into somatic cells in vitro. He has provided extensive advice to state, national and international regulatory authorities on the scientific background to human embryonic stem cell research.



'Learning from the Past and Looking Towards the Future'

Dr Chris Juttner – National Stem Cell Foundation of Australia

The success of stem cell therapies is plagued with roadblocks. Over 95% of HSC transplants use techniques that were never patented, proven in rigorous double blind placebo controlled trials or registered. The US biotechnology company SyStemix produced highly purified FACS sorted Autologous HSC transplants for cancer and HIV applications but the business decision to use central cell processing centres led to a cost of US$129,000 per batch, each approaching the complexity of a drug release. Stem Cells Inc developed a promising allogeneic human neural stem and progenitor cell product which showed therapeutic effects in a rat model of spinal cord injury. Clinical trials were stopped in Australia by individuals with moral objections. Success in cell therapy applications requires an initial plan avoiding all xenogeneic exposure, exemplary clinical product planning, management of regulatory burden and proper autologous v allogenic choice. These limitations and the damaging effects of unproven 'stem cell therapies' mean the most prospective stem cell applications lie in disease modelling, disease mechanisms and drug testing.



Dr Juttner has over 40 years experience providing, analysing and developing advanced medical care in haematology, oncology and general medicine. He established the Bone Marrow Transplant (BMT) program for South Australia and was the inaugural Clinical Director of the Hanson Centre for Cancer Research. Chris was recruited by SyStemix and became Vice President of Clinical Development in USA and Europe closely interacting with senior levels of Novartis. Returning to Australia in 1999, Chris's roles included commercial development with Medvet Science, clinical haematologist at the Calvary Cancer Centre and Royal Hobart Hospital as well as leadership and consulting roles at BresaGen Ltd, the Australian Stem Cell Centre, Novartis Australia, Stem Cells Inc, the Australian Stem Cell Centre, Stem Cell Sciences Australia and the National Stem Cell Foundation.

'Increase your stake by in the stem cell sector design engineering engagement from an innovation system-wide perspective'

Dr Peter Mountford—Principal –Public Systems Innovation

The considerable benefit promised by stem cell science, technology and innovation (STI) is attracting diverse investment from a range of stakeholders hoping to secure future benefit. Governments continue to be the major investors in a new and evolving innovation field still devoid of an industry model, large industry leaders and/or large industry investment. By considering the challenges and likely benefits of stem cell innovation as a single, system-wide, global opportunity - one wherein *all* individuals are morally entitled to benefit - some new collaborative models, unusual collaborative partners and prospects for broader collaborative benefits begin to emerge. Individually, these opportunities could help to accelerate development of STI careers, institutions, precincts and even resulting national prosperity. As a suite of complementary co-operative programs and strategies, these and other similar ideas may also provide foundations for development of an alternate stem cell innovation system and industry to that which is likely to emerge from the alternative of market-led development. In the theme of where we have been and where we might go to, this presentation shall provide examples of lessons learnt and possible future directions as evident from an innovation system-wide perspective.

Dr Mountford is a bio-industry entrepreneur specialising innovation systems design for enhanced development and distribution of benefit flowing from publicly sponsored R&D. He has served as a bio-industry advisor to national and international governments and been an invited member/speaker at the World Economic Forum (Davos), the Global Competitiveness Forum (Riyadh) and World Health Summit (Berlin).

'Autologous Cell Tendon Repair and Cell Delivery Devices'

Paul Anderson—Orthocell

Regenerative medicine is one the fastest growing areas of medical research with cell therapies and delivery scaffolds developing as popular therapeutic approaches. The lack of intrinsic capability for the repair of tendon tissue prompted us to develop an Autologous and Homologous cellular approach to the regeneration of recalcitrant tendinopathy. Ortho-ATI™ and the collagen medical device Celgro™ augment repair of tendon and soft tissue, commonly damaged in sporting and occupational injuries, by enabling and supporting tenocyte repopulation. Naturally derived materials such as purified collagen and extracellular matrix are promising as bioscaffolds in tissue engineering with a wide variety of materials available, including Celgro™, their selection depending on their properties and biocompatibility. Phase I/IIa clinical trials provide necessary information in establishing the safety, tolerability and preliminary efficacy, though are not without challenges. Orthocell's recent publication of the Phase I/IIa Ortho-ATI™ study in patients with recalcitrant lateral epicondylitis demonstrates how some of these challenges can be overcome through careful selection of patients and outcome measures.

Paul Anderson is the CEO / MD and founding member of Orthocell Ltd and has over 18 years experience in the medical device and cellular therapeutic fields. His expertise is in the development of emerging medical technologies and bridging the gap between research and clinical practice. Paul has a successful track record in, applying regulatory frameworks to new products, the accompanying 'grey area' interpretation, rebating pathways, marketing and the development of clinical relationships. Paul has a strong track record with his previous board position and has led Orthocell in the development and translation of regenerative medicine approaches to the repair and regeneration of human soft tissue defects and degeneration.

Speaker: Dr Phil Kearny, Merck

'The Long Road Ahead—Working with Industry to Support Research and Satisfy Market Needs'

Dr Phil Kearny—Director – Licensing & External Research, Merck & Co

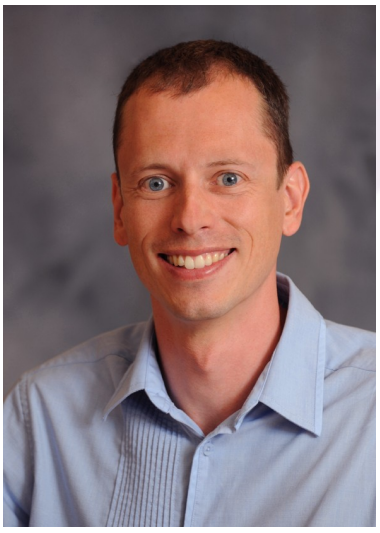
The road to commercialisation is both long and unpredictable. Using Gardasil (Merck & Co.) as an example we will look at some of the issues which emerged along the development path for this vaccine. The lessons around patent wording, partnering and manufacture were just a few which the team lead by Ian Frazer had to overcome. Perhaps the lessons learned there can be applied to the development of another biological product such as stem cells.

Dr Kearney joined Merck Sharp & Dohme Australia in 2007 as the key scout for innovative research and development in Australia, New Zealand and some parts of South East Asia. Prior to joining Merck, Phil spent 7 years in small to medium biotech companies in Scandinavia and held project and executive management positions in Active Biotech Research (Sweden) and Santaris Pharma (Denmark) . He has been the head of the Research Laboratory at St Vincent's Hospital Sydney for over 10 years studying antisense and ribozyme mediated ablation of bcr-abl expression in CML and ran the Molecular Medicine Diagnostic Laboratory for the hospital pathology service, SydPath. Phil holds a Ph.D. from Monash University, has post-doctoral training at the Murdoch Institute in Melbourne and University College London and holds a MBA from the University of Sydney.

'From Sydney IVF to Genea Biocells: Linking Clinical and Commercial Success'

Dr Uli Schmidt—Genea

Genea Biocells is a Sydney-based stem cell company focusing on the development of human disease models for research and drug screening. Genea originated from Sydney IVF who pioneered the in vitro fertilisation (IVF) process and dramatically increased clinical success rates which are now amongst the best in the world. In 2004, Sydney IVF started investing in stem cell research and our scientists derived the first human embryonic stem cell line in Australia. This laid the foundation for what is now the largest bank of human embryonic stem cells with over 100 lines. We also developed a proprietary culture system and set up a cell differentiation platform for the rapid development of efficient cell differentiation protocols. Having the backing of our parent company combined with revenue streams relatively early on allowed us to establish our technology platform and refine our business model which ultimately resulted in the launch of Genea Biocells at the start of the year. We now have a global business development team, and our current products include neurons and skeletal muscle cells which we supply to our customers as ready-to-use frozen stocks to investigate neurodegenerative diseases and muscular dystrophies, respectively. We also partner with industry for custom-developed cell-based assay solutions.



Dr Schmidt has a longstanding interest in the development of novel drug discovery-related technologies with a strong focus on commercialisation and entrepreneurship. His scientific expertise includes molecular and cell biology as well as assay development, high-throughput screening and high-content analysis. He is an inventor on 9 international patents and the author of 16 original research publications. Prior to joining Genea in 2007, Dr Schmidt was the co-founder of 2 other life science companies based on novel GPCR drug screening technologies and an Alzheimer's diagnostic test.

Speaker: Professor Melissa Knothe Tate - University of NSW

'Next Generation Implant Development - Current Feasibility and Future Directions for Regenerative Medicine'

Professor Melissa Knothe Tate—University of New South Wales

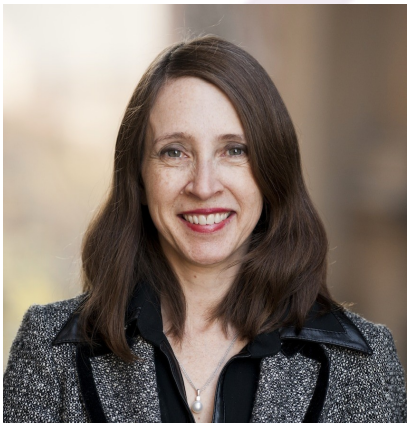
New approaches to treating tissue defects harness the endogenous tissue building and healing capacity of stem cells, nature's own tissue prototypers. A major emphasis of my current R&D program is the development of next generation medical devices and materials that harness biophysical and biochemical cues, using nature's paradigms to promote tissue generation and healing. This talk will outline key findings from my group's research at the interface of biology and mechanics, mechanobiology. I will give examples of how we use tissue engineering to develop new treatment strategies as well as novel materials and therapeutic devices for regenerative medicine. Finally, I will share my experiences regarding the development and commercialization of next generation implants and the necessity for new capabilities in the medical device industry, including training of next generation employees that harness the power of research and education as an engine for innovation in the new economy.

Professor Knothe Tate, newly appointed Paul M. Trainor Chair of Biomedical Engineering at the Graduate School of Biomedical Engineering, University of New South Wales (UNSW), is an internationally recognized leader in the development and clinical translation of next generation implants and materials. As a Fellow of the American Institute for Medical and Biological Engineering as well as the American Society of Mechanical Engineers and Biomedical Engineering Society, Dr. Knothe Tate has received numerous international research and development (R&D) awards. Her R&D program has resulted in several international patents, a spin off company (bioz), over 95 peer-reviewed publications, book chapters and proceedings, 120+ invited presentations including plenary talks, and more than $11M in research, development, training, conference and infrastructure funding. She serves on several editorial boards of journals ranging from *Frontiers in Computational Physiology and Medicine* to *Technology and Health Care.*

'Transplantating Autologous Stem Cells on a Contact Lens for Blinding Corneal Disease'

Clinical Professor Stephanie Watson—The University of Sydney

Limbal stem cells maintain the integrity of the eyes (ocular) surface ensuring clear vision and ocular comfort. Cultured limbal tissue transplants have been increasingly used over the last decade to restore vision in patients with limbal stem cell deficiency (LSCD). The impact on quality of life of LSCD is generally severe and chemical injury, the commonest cause of a LSCD, affects a working age population. In a world first, our research team developed a completely autologous technique to deliver ocular surface progenitors via an FDA approved contact lens for the treatment of LSCD. This technique directly bridged the gap between the 'bench and bedside' in limbal stem cell therapy. Recently we have investigated the long-term outcomes of our translational research and evaluated the issues required to advance the use of cultured limbal transplants. This lecture will address, the need for stem cell therapies to treat LSCD; highlights of our innovative technique; and the current status and future prospects of cultured limbal transplant techniques in Australia and New Zealand.



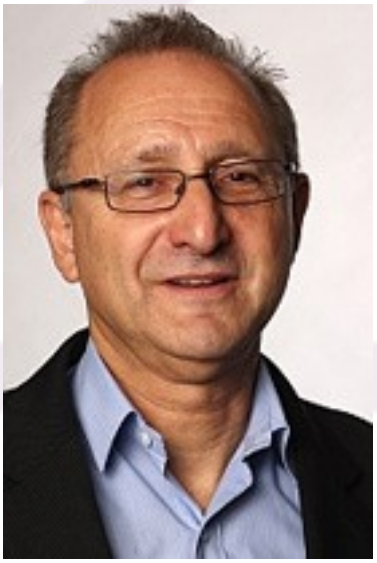
Stephanie Watson is a Clinical Professor and NHMRC Career Development Fellow at the Save Sight Institute, University of Sydney. She is a corneal and cataract specialist with appointments at the Sydney Eye Hospital, Prince of Wales Hospital, and Sydney Children's Hospital. She has published over 70 articles in high-ranked peer reviewed journals and book chapters, and holds international patents. Professor Watson has given close to 100 presentations at national and international meetings. Organisations that have funded her research programme include the NHMRC, ORIA, and Australian Stem Cell Centre. She is a Director of the Ophthalmic Research Institute of Australia and serves on journal editorial boards, She is in private practise in Bondi Junction and Sydney Corneal Clinic, Macquarie Street.

Speaker: Professor Geoff Symonds, Calimmune

‘Using stem cells to instate disease immunity’

Professor Geoff Symonds—Calimmune

HIV/AIDS is a disease not solved. We are testing a different treatment paradigm in which hematopoietic stem cells are transduced with a lentiviral vector containing two expression cassettes – a short hairpin RNA to the HIV co-receptor CCR5 and a C46 fusion inhibitor. The concept is to produce an immune system with cells protected from infection and the pathogenic sequelae thereof. We have shown both in vitro and in vivo that cells containing these two constructs are not compromised phenotypically and are protected from HIV infection. This work is being tested clinically.

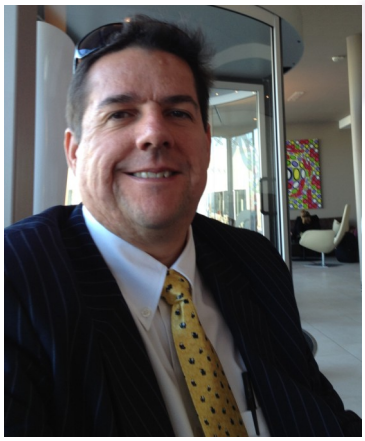


Professor Symonds obtained BSc (1st Class Honours) and MSc degrees from the University of Sydney, PhD from the Weizmann Institute in Israel and Postdoctoral training with Professor J Michael Bishop at the University of California San Francisco (1985). Since that time he has pursued a combined academic and industry career receiving various grant support and NHMRC Senior and Principal Research Fellowships & Johnson work. Inventor on several key patents in the field of cell-delivered gene therapy, author of over 100 peer reviewed publications in the areas of cell transformation, stem cell biology and gene therapy for HIV/AIDS and frequently invited to present at International Scientific Meetings. Appointed Chief Scientific Officer of Calimmune Inc, USA and Director & Secretary of Calimmune Australia Pty Ltd, presently conducting a Phase I clinical trial in the USA and gearing up for clinical trials elsewhere. After leaving Johnson & Johnson in January 2009, re-established Research Group at St Vincent’s Centre for Applied Medical Research with present funding from Calimmune Australia Pty Ltd, RISS, ARC-Linkage Grant plus supervising research group at UCLA with funding from the California Institute of Regenerative Medicine.

'Commercialisation Issues in Academic Institutions'

Dr Alfredo Martinez-Coll—New South Innovations

Academic institutions often grapple with the issue of what to do when faced with the prospect of commercialising stem cell technologies. While materials transfer agreements (MTAs) between institutions is a way to foster research collaborations it is also possible to enter into MTAs for commercial research (drug screening, accelerated drug development, etc..), where specific clauses allow for shared revenues from products or services generated. In the case of generation of new cell lines, iPSCs, etc the patient's genetic information, clinical history, and disease stage are becoming significantly more important for cross-correlation and validation purposes. New methods and processes for using cell lines for regenerative medicine and cell therapies may be suitable for patenting and commercialisation via traditional licensing/spin-off models; however, one must be aware of the existing rights held by WARF and other institutions. It is the role of tech transfer offices within research institutions to align researchers and executive expectations and interests for informed decisions on commercialisation of stem cell technologies given the complex regulatory, ethical, and commercial landscape involved.



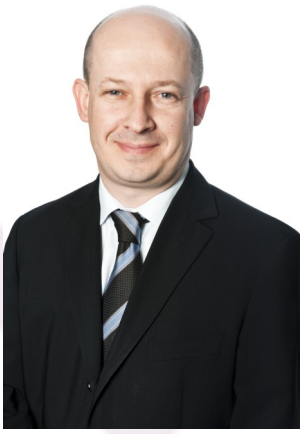
Dr Martinez-Coll graduated with a B.Sc. in Biomedical Engineering from Louisiana Tech University (USA) and completed his PhD and postdoctoral training at the University of Technology, Sydney. Alfredo has more then 16 years experience in biomedical research in Venezuela, the United States, and Australia and has worked in the area of intellectual property and commercialisation across a number of Area Health Services in NSW from 2004-2006. In his current position as Senior Business Development Manager at NSI, his main areas of interest are sustainable funding for science, entrepreneurship, innovation, project management in science and business development with particular expertise in stem cell commercialisation issues from his time at the Diabetes Transplant Unit of POWH.

Speaker: Dr Gavin Recchia, Davies Collison Cave

'Maximising Commercial and Clinical Potential Through IP Protection'

Dr Gavin Recchia—Davies Collison Cave

Recent judicial decisions around the world mean that the IP landscape for stem cells is on constantly shifting ground. Notwithstanding, patents for a wide range of stem cells and stem cell related technologies continue to be granted, with ownership split approximately equally between the public and private sectors. As with most biotechnology and pharmaceutical innovations securing effective IP protection for stem cell technologies remains a crucial plank in most commercialization strategies; commercial returns and most importantly 'technology take up' are more often than not linked to market exclusivity. An understanding of existing intellectual property rights, an awareness of IP requirements, and an openness and willingness to engage with industry are becoming increasingly important for all researchers in the field, including those in academic institutions.



Dr Recchia specialises in the drafting and prosecution of patent applications in the areas of molecular biology, biochemistry, genetics, microbiology, pharmaceuticals and medical and research devices. Having been awarded the University Medal Gavin completed his PhD at the CSIRO Division of Biomolecular Engineering in Sydney before taking up an NHMRC CJ Martin Postdoctoral Fellowship in the UK at the University of Oxford, Department of Biochemistry, working in the field of genetic recombination. After three years in Europe, including short stints at medical research centres in Japan and Norway, Gavin returned to Australia. He is the author of more than 15 refereed research papers in international journals and has been invited to contribute to texts in the fields of antibiotic resistance and molecular microbiology. He continues to lecture widely on biotechnology patenting issues. He has won numerous awards for his research, including the inaugural Australian Society for Microbiology Research Trust Award. Gavin joined Davies Collison Cave as a partner in 2006 having previously been a principal at another Australian IP firm.

'Getting Through the Regulations—Can you Expedite the Process'

A/Professor Dianne Jackson Matthews—ERA Consulting (Australia) Pty Ltd

Regulatory considerations form an inevitable part of any translational strategy for a candidate therapeutic product. In the case of developing a human stem cell-based treatment, this is not only true, but the implications are also likely to be more onerous compared to "conventional" biological products. The regulatory processes and guidelines already established in Europe, the US and Australia must be taken into account where relevant, but should also be examined for opportunities to be leveraged where possible. Numerous product and production requirements exist, whether a potential therapy is based on an autologous or an allogeneic stem cell. Additionally, the challenges in such development programs arise at the very beginning, from product inception onwards, in contrast to the normal evolution of many biological medicines during development. Some options that might allow a clinical translation program for a human stem cell-based treatment to move steadily forward, or even be expedited, will be considered.

A/Prof Jackson-Matthews is Deputy Group Director of Regulatory Affairs for the ERA Consulting Group, and Director of ERA Consulting (Australia) Pty Ltd. Dianne has 25 years experience in pharmaceutical product development in the US, Europe and Australia with experience in developing regulatory and technical strategies, conducting regulatory agency interactions worldwide, performing regulatory and technical due diligence assessments and supporting funding and licensing opportunities for the investment community and industry. Prior to joining ERA in 2001 as the Director of the ERA Washington DC office, Dianne was Director of Regulatory Affairs in a US biotech company and worked in the US *in vitro* diagnostics industry. Dianne received her BSc (Hons) and PhD in Microbiology / Immunology from the University of NSW and carried out post-doctoral research at the University of Pennsylvania. Dianne currently holds an Adjunct Associate Professor position at the University of Queensland.

'Tax Incentives'

Helen Fisher—Deloitte

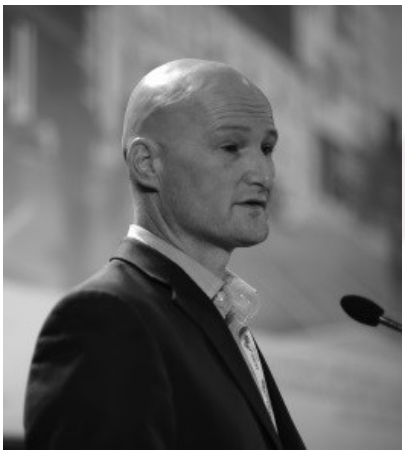
Australia has recently enhanced its R&D Tax Incentive regime to make it more attractive to pre-revenue R&D companies. Companies with an aggregate turnover under AU$20m may be eligible for a cash refund of 45% of their eligible R&D costs. What can companies do to maximise this non-dilutive funding from the Government? Once a company is in late stage clinical trials, close to commercialisation or in the early stages of commercialisation, Australia does not provide on-going incentives and thus risks losing the IP and manufacturing to low-tax jurisdictions or where there are on-going incentives, such as in Singapore, China, Switzerland and Ireland. Introducing a "patent box"-like Australian Innovation and Manufacturing (**AIM**) incentive into our Australian legislative landscape may not only aid in retaining Australia's talent, IP and manufacturing but also attract overseas companies. Further, Australia's tax loss utilisation rules are not designed with high risk Life Sciences/Biotech companies in mind and do not interact seamlessly with the drug development cycle and commercial environment to attract investors. It is important for the Life Sciences/Biotech industry to work with the Government to review and revitalise our tax system to make Australia a better place to invest in the development of novel high risk technologies with great potential, such as stem cells.

Helen Fisher leads Deloitte's Life Sciences industry group in Australia, providing tax consulting and compliance services to publicly listed and large multinational companies. As lead tax partner on a number of clients, Helen has a proven track record of delivering strategic solutions by capitalising on opportunities and managing tax risks. Helen is passionate about the Life Sciences/Biotechnology industry with a deep understanding of the life cycle of Biotechnology and Medical Device companies and the tax issues they face. Helen is a member of the Australian Biotechnology Victorian committee.

'Commercialising Cell Manufacture in Australia'

Dr Stewart Hay—Therapeutic Innovation Australia

To bring a therapeutic product to market the researcher will need to overcome many hurdles including establishing an intellectual property position, capital raising and defining their pre-clinical testing and clinical trial development plans. The cell therapies field also presents unique challenges in comparison to conventional pharmaceuticals such as the determination of potency, assessment of the long term stability and delivery models. Therapeutic Innovation Australia (TIA) has supported manufacturing activities for cell therapy researchers undertaking pre-clinical, Phase I and Phase II clinical trial activity with $3M provided through the Australian Governments National Collaborative Research Infrastructure Research Strategy which enabled 26 clinical trials. In 2011 TIA launched the "Virtual Pharma" initiative which aims to provide access to development expertise and through the broader TIA initiative, access to research infrastructure capabilities.

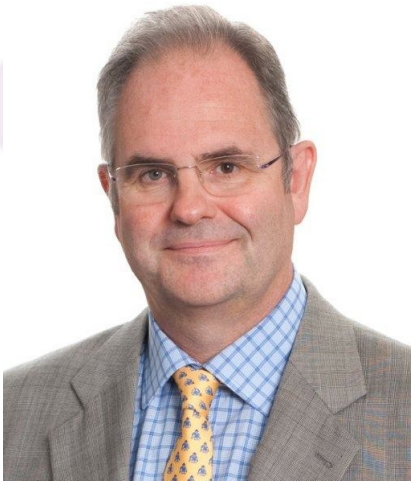


Dr Hay has extensive and broadbased experience in science having worked in medical research and the pharmaceutical, nutraceutical, biofuel and medical device industries. He joined Research Infrastructure Support Services Ltd in 2008 from AusBiotech where he was responsible for implementing and managing a $60M *National Collaborative Research Infrastructure Strategy* project. Prior to this, he worked in research with CSL, the Walter and Eliza Hall Institute of Medical Research and the Fiona Elsey Cancer Research Laboratory. Stewart has conducted research into diabetes, Langerhans Cell Histiocytosis, apoptosis and the characterisation of a novel retrovirus. He has also conducted market feasibility and technical studies as a consultant and has worked with Ventracor and IG Science where he developed new products and a GMP manufacturing facility. Stewart has a PhD in Cancer Cell Biology.

'Is My Technology Ready for Investment?'

Dr Stephen Thompson—Brandon Capital

How do I know if my technology is ready for investment? It is a major undertaking for all involved to take an academic idea (concept) and see it become a registered product on the market. This is especially so when pioneering a new mode of therapy (such as stem cells). Many an enthusiastic inventor/entrepreneur underestimates the time, money and skills required to take something from the academic lab to the clinic and onto the market. It is imperative that the right people, skills and capital are brought to bear on the program. When this occurs it's a thrilling journey (roller-coaster) with the successful outcome being improved healthcare and a reward for investors.



Dr Thompson is a founding partner of Brandon Capital Partners, an Australian life science venture fund manager. Before moving to Australia in 2004 he was a director with Apax Partners based in London and focused on early stage venture investing. Previously he worked with a UK biotechnology company, Cantab Pharmaceuticals, following 10 years of medical research in London and California. Stephen has a BSc and PhD in immunology and an MBA. He is a director of Elastagen Pty Ltd, MiReven Pty Ltd, Vaxxas Pty Ltd and the Cancer Therapeutics CRC.

'Navigating the Financial Market'

Scott Power—Morgans Ltd.

Financing early stage life science companies is a challenging process, most of the time. However there are certain periods when investors are prepared to put money to work in higher risk sectors. In the last 12 months the US market has seen over 35 Initial Public Offerings (IPO) raise over US$3bn for life science companies, a number operating the in stem cells space. Returns achieved over this period are on average above 50% which is attracting more money into the sector. In Australia, investors are quickly warming to the life science sector. Since May the Morgan's Life Science Index has seen a rapid rise, albeit not to the same extent as the US, however the mood is buoyant and we believe the next 12 months in Australia will see a substantial rise in activity in the sector. In this segment we will look at the capital markets and what types of companies are currently attracting investor's attention.

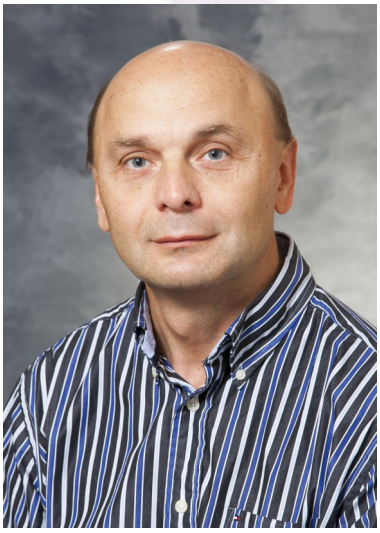
Scott Power is a Senior Analyst with Morgans Ltd covering the following sectors - Healthcare, Life Science, Telecommunications, Technology and Media. He has spent the last twenty years investing in and researching emerging companies. Firstly in his role in the venture capital industry with QIDC and more recently with Morgans which he joined in 1997. He has a Bachelor of Commerce, is a member of FINSIA and is a CPA.

Speaker: A/Professor Igor Slukvin

'Pluripotent Stem Cell-Derived Mesenchymal and Vascular Progenitor: A Novel Technology Platform for Regenerative Medicine'

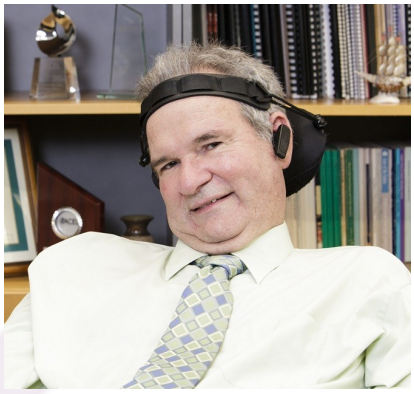
A/Professor Igor Slukvin—University of Wisconsin

Recent advances in stem cell biology and cellular reprogramming have made it possible to generate any type of cell present in the human body in an unlimited number promising innovative solutions for cellular replacement therapies to treat chronic diseases, aging, or congenital defects. We have discovered a novel multipotential progenitor mesenchymoangioblast (MCA) with the capability to differentiate into mesenchymal stem cells (MSCs), pericytes, smooth muscle and endothelial cells. MSCs obtained from MCA can be expanded up to 10^{20}-10^{22} and differentiated into bone, cartilage, and adipocytes. While MSCs have been successfully applied in clinical settings, the limited expansion potential of somatic MSCs, donor-to-donor and intra-population heterogeneity and the difficulties of obtaining pure MSC populations, remain major limitations and contribute to mixed clinical responses. MCA can be derived from iPS cells, to generate an unlimited number of MSCs from a single donor. Preclinical testing revealed the capacity of MCA-MSCs to salvage tissue in the mouse ischemic limb, indicating that these cells have pro-angiogenic properties similar to somatic MSCs. We have also recently developed technology to produce MCA and MSCs from iPSC in completely defined conditions demonstrating several advantages of MCA as a source of MSCs for clinical applications.



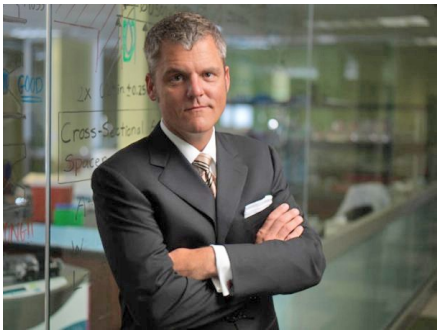
Igor Slukvin is Associate Professor of Pathology and Cell and Regenerative Biology at the University of Wisconsin-Madison, USA. His research interests focus on development of hematopoietic, vascular and mesenchymal lineages from human pluripotent stem cells. He has published more than 70 papers and holds key patents in the area of hematovascular cell production from human pluripotent stem cells. Dr. Slukvin is a scientific founder of CDI in the United States and Cynata in Australia.

PANEL SESSION



Dr Paul Brock is a leader in stem cell patient advocacy in Australia and an inaugural member of the Coalition for the Advancement of Medical Research in Australia (CAMRA). He worked closely with leading scientists and politicians, advocating through media and lobbying for what became the Australian Parliament's ESC and SCNT legislation. With his years of training in moral theology and philosophy, Dr Brock argued against positions maintained by prominent opponents of the Bills, while insisting that rigorous scientific and ethical protocols be an essential component of the Bills. In 2008 the NSW Government established the "Dr Paul Brock Stem Cell Scholarship" to support PhD research in iPS cell research. Dr Brock is a Vice-Patron of the Motor Neurone Disease Association, NSW.

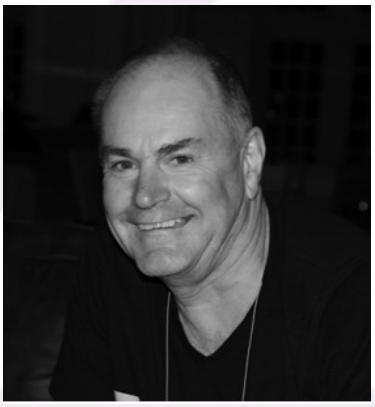
John Grew has over 30 years corporate experience establishing firms, raising capital, investing in, advising for and as Director of numerous life science firms, operationally experienced in biopharmaceuticals, medical devices, regenerative medicine and diagnostics . Since inception, his company the bioadvisory group pty ltd has been retained by Commercialisation Australia; and provide independent due diligence, feasibility studies, market analysis and cGMP operations strategy within the regenerative medicine sector to many firms and government entities. As a Case Manager in NSW /ACT, John is retained to independently assesses grant applications and support successful grant recipients through mentoring, network introduction and independent professional advice for the duration of the grant. John has a Bachelor of Science, Master of Science and a Master of Business Administration.



David Oxley is Vice President of Emerging Markets for Cytori Therapeutics, previously Vice President of Marketing. He was Executive Vice President of World Wide Sales & Marketing (Point-of-Care) and head of U.S. investor relations for Trinity Biotech and has sixteen years IVD market experience, including head of government relations for a medical device company, health care investment banking for a national bank, health care lobbyist for a Washington D.C. law firm and health-care policy work for a member of the United States House of Representatives. Mr Oxley serves on the Board of TB Biosciences and served the not-for profit entities Global Fund to Fight HIV TB & Malaria and Children[1]s AIDS Fund. David is a former member of the National Association of Securities Dealers and holds a Masters from Johns Hopkins University.

Panel Compare

Dr David Haylock is OCE Science Leader within the Biomedical Materials and Devices Theme of the Division of Materials Science and Engineering, CSIRO. In this role he works at the interface of stem cell biology and material science, currently developing technology for large-scale expansion of haemopoietic stem cells and production of mature blood cells for transfusion and transplantation. He is most renowned for conducting Australia's first clinical study with ex vivo expanded haemopoietic stem cells and prior to joining CSIRO in 2009 held positions as Director of the Major National Research Facility of the Australian Stem Cell Centre and Head of Experimental Cell Therapy at the Peter MacCallum Cancer Centre. He has worked closely with the biotech industry and held numerous consultancy positions with international companies including Johnson & Johnson, Dynal, Beckman Coulter, Gambro BCT, Monsanto-Searle and Baxter Healthcare.



'How can we utilise our strengths and develop systems to better support stem cell research translation and commercialisation in Australia?'

PANEL MEMBERS;

Dr Alfredo Martinez-Coll

A/Professor Dianne Jackson Matthews

Dr Stewart Hay

Scott Power

John Grew

Dr Gavin Recchia

Helen Fisher

Dr Stephen Thompson

Dr Paul Brock

David Oxley

Be a Member of the NSW Stem Cell Network

The NSW Stem Cell Network has around 500 members . Our all inclusive, free membership makes this network unique in consisting not only of researchers and practitioners but members of the public, industry and governmental bodies. Our aim is to ensure effective communications between diverse sectors for the advancement of stem cell research. As a member you will receive invitations to upcoming network and external stem cell related events as well as the latest stem cell news. Sign up at;

www.stemcellnetwork.org.au

Careers

To advertise positions related to the field of stem cells, please email;

stemcellinfo@stemcellnetwork.org.au with a full description of the job on offer.

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