**10th Annual** 



20 - 22 May 2015, Business Design Centre, London, UK

Scaling-up, commercialisation and collaboration for market access

50+ EXHIBITORS ...DOUBLED FROM 2014



BRAND NEW INVESTOR FORUM

NEW & IMPROVED BIOTECH ROUNDTABLES



3 DAYS

Created by



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# **Co-located with**



Build deposits, reduce costs, retain quality, decrease volume and increase utilisation



# **Revolutionise Medicine**

The platform where Pharma, Biotech, Academia, Investors, Regulatory and Governmental bodies meet to discuss next steps in commercialisation and collaboration of cell therapies and regenerative medicine globally.

Join discussions on translating the science, optimising the global regulatory landscape and the latest innovations in cell therapy, tissue engineering and organ regeneration as the industry moves closer to commercialisation.



# THE CONFERENCE

**Discover** how best to gain market access for cell therapies

**Understand** how industry leaders view the clinical and commercial futures of stem cells and regenerative medicine and the effect it will have on your business

**Access** investment advice and partnership opportunities through the Investor Forum

**Identify** best practices in technology and latest updates from biotechs, through interactive roundtables

**Hear** pioneering innovations in tissue engineering, organ regeneration and 3D bioprinting



# THE EXHIBITION

**Explore** the best equipment in the market

**Investigate** scalable manufacturing and distribution solutions

**Share** your work and achievements with your industry peers in the Poster Zone

**Network** with other industry leaders to do business and share knowledge as the industry moves towards commercialisation

**Build** new contacts and strengthen your existing relationships



### **Keynote Sessions**



### Mr. Perry Karsen, Chief Executive Officer, Celgene Cellular Therapeutics

Perry will be presenting the opening keynote presentation on translating the science into products that can move into the clinic. He will draw on his experience at Celgene when it comes to being industry leaders across the supply chain.

Perry is currently Chief Executive Officer of Celgene Cellular Therapeutics, Celgene's placental stem cell research and development division. He is also a member of the Board of Directors for the Life Sciences Foundation as well as the Biotechnology Industry Organization, where he is also a member of the Executive Committee.



### Mr. Keith Thompson, Chief Executive Officer, Cell Therapy Catapult

When interviewed by Chris Mason in the opening keynote session, Keith will be looking at how the UK is pioneering cell therapy success.

Keith is the Chief Executive Officer of the Cell Therapy Catapult and serves on its board. Before being named CEO in May 2012, Keith was National Director of the Scottish National Blood Transfusion Service where he led on modernising the blood supply and expanding the service into cell therapy. Keith has also held various senior domestic and international leadership positions where he developed several biomanufacturing businesses to become global players.



### Mr. Brock Reeve, Executive Director, Harvard Stem Cell Institute

In his keynote interview, Brock will be drawing on his professional and personal expertise on how successful translation from the clinical to the commercial is key to enabling market access.

In partnership with the Faculty Directors, Brock has overall responsibility for the operations and strategy of the Institute whose mission is to use stem cells, both as tools and as therapies, to understand and treat the root causes of leading degenerative diseases.



### Prof. Chris Mason, Director, Regenerative Medicine Bioprocessing Unit, University College London

Chris will be chairing this year's World Stem Cells & Regenerative Medicine Congress where he will bring his knowledge to topics such as innovating cell therapy manufacturing, T-cells and tissue engineering.

Chris is internationally recognised to be at the forefront of the emerging field of cell therapy translation and commercialisation. He has a diverse background in academia, surgery and commerce including a clinical sciences degree, a medical degree, a PhD in tissue engineering and a Fellow of the Royal College of Surgeons. Chris is also currently Chair of the BIA Cell Therapy Industry Group; Senior Editor, "Regenerative Medicine"; Director, London Regenerative Medicine Network and a Trustee at the UK Stem Cell Foundation.



### Mr. Greg Bonfiglio, Founder & Managing Partner, Proteus Venture Partners

Greg was an early investor in the field of stem cells & regenerative medicine, and continues to be actively involved in the field. With that knowledge, he will be hosting the workshop on horizon scoping as part of the Investor Forum, giving delegates his views on why to invest in stem cells and regenerative medicine.

Greg is a member of the ISSCR and the ISCT. He also serves on the Boards of StemCyte, Inc. and California Stem Cell, Inc. He is the Chairman of the Board of the Centre for Commercialization of Regenerative Medicine and Co-Founder and Chairman of the Regeneative Medicine Coalition.

# SPETLIGHT ON SPEAKERS

### **Meet the Biotechs**



### Dr. Christian Homsy, Chief Executive Officer, Cardio3 BioSciences

Christian will be hosting a biotech roundtable focusing on new business development strategies to broaden product pipelines within the cell therapy sector.

Christian has been the Chief Executive Officer of Cardio3 BioSciences since its inception. Christian gained his business experience in senior research and development, marketing, business development and sales positions, at Guidant Corporation, a leading medical device company active in the treatment of cardiovascular disease.



### Mr. Geoff MacKay, President & Chief Executive Officer, Organogenesis

Geoff will be presenting in the Tissue Engineering track on Day 3 and directing his talk on innovative use of tissue engineering to heal chronic wounds.

Geoff has served as President and Chief Executive Officer at Organogenesis, a leading regenerative medicine company, since December 2003. In his role, he provides the company with significant global and commercial experience spanning both the pharmaceutical and biotechnology sectors. He also previously served as Chairman of the Board of the Alliance for Regenerative Medicine.



### Mr. Olav Hellebo, Chief Executive Officer, ReNeuron

Olav will be hosting a biotech roundtable concentrating on ReNeuron's stem cell therapy for stroke patients.

Olav was appointed as Chief Executive Officer in September 2014. A highly experienced, international pharmaceutical executive, he has broad commercial experience gained at both major pharmaceutical and small biotechnology companies. He has particular experience of the clinical development, outlicensing, commercialisation and marketing of new therapeutics.



### Mr. Eduardo Bravo, Chief Executive Officer, TiGenix

As a biotech roundtable host, Eduardo will be giving his insights into how best to prepare for market with a specific emphasis on developing a Phase III clinical trial of an allogeneic stem cell compound.

Eduardo has more than 18 years' experience in the pharmaceutical industry. His professional career includes several senior management positions at Sanofi-Aventis.



### Dr. Paul Laikind, President & Chief Executive Officer, Viacyte

In light on the recent achievements at Viacyte, Paul will be hosting a roundtable on "a virtual cure for Type 1 diabetes".

Paul has over 28 years of leadership experience in the biotechnology and life sciences industry in San Diego. A serial entrepreneur, he co-founded and held top executive positions at three San Diego companies that each went public before ultimately being acquired. Just prior to joining ViaCyte, Paul served as Chief Business Officer and Senior Vice President of Business Development at the Sanford-Burnham Medical Research Institute where he established a number of licensing and strategic partnerships with large pharmaceutical organisations.

# SPETLIGHT ON SPEAKERS

### **Meet the Foundations**



### Prof. Trevor Jones CBE, Member, Board of Trustees, UK Stem Cell Foundation

Trevor will be representing the UKSCF who recently funded a project which led to a breakthrough in the treatment of spinal cord injuries.

Trevor was previously a main board director of The Wellcome Foundation and part of the World Health Organisation Commission on Intellectual Property Rights, Innovation and Public Health. He has also been a member of the UK Government regulatory agency, The Medicines Commission; an advisor to the Cabinet Office; a member of the Prime Minister's Task Force on the Competitiveness of the Pharmaceutical Industry and Chair of the UK Government Advisory Group on Genetics Research. Trevor was also Director General of the Association of the British Pharmaceutical Industry.



### Prof. Peter Weissberg, Medical Director, British Heart Foundation

Peter will be representing BHF in the disease foundation panel regarding their role within the stem cells sector. He began his long relationship with the BHF in 1988 when he was awarded a BHF Senior Research Fellowship. In 1994 he was appointed to the first BHF Chair of Cardiovascular Medicine in Cambridge.

Peter's research focused on the cell and molecular biology of atherosclerosis – the narrowing and hardening of the arteries over time – which is the major cause of heart attacks and strokes. In recent years his group developed new clinical imaging techniques to study the cell biology of atherosclerosis in patients with cerebrovascular disease.



### Prof. Alan Silman, Medical Director, Director of Policy & Health Promotion, Arthritis Research UK

Alan has been involved in medical research in the musculoskeletal field for the past 30 years, and he will be focusing his role in the panel on how stem cells and regenerative medicine can help patients affected by arthritis.

Alan has served as Medical Director of Arthritis Research UK since January 2007 and in 2013 he was also appointed to the role of Director of Policy & Health Promotion. He has led the Epidemiology Unit to its award as the European League Against Rheumatism Centre of Excellence in 2006 and is the UK editor of the main leading international textbook 'Rheumatology'. He also chairs the NICE Appeals Panel.



### Mr. Michael Nation, Director of Development, Kidney Research UK

Michael will speak for the renal community in the disease foundation panel on Day 2 which looks at their role in promoting healthcare's uptake of regenerative medicine.

In his role at Kidney Research UK, he is responsible for the initiation, development and implementation of a range of collaborative research projects as well as awareness and education programmes, with a particular focus on tackling health inequalities. His role also involves the development and promotion of patient, carer and public involvement and engagement in research working within the kidney community and the wider NIHR Division and networks.



### Dr. Brian Dickie, Director of Research Development, Motor Neurone Disease Association

Also participating in the disease foundation panel is Brian who will put forward the view on behalf of neurodegenerative disorders such as motor neurone disease and amyotrophic lateral sclerosis.

Brian has worked for the Motor Neurone Disease Association as Director of Research Development for over 16 years. His role includes providing strategic guidance to the Association's research activities, raising the Association's profile within the biomedical and clinical research communities, increasing the quantity and quality of Association-sponsored and collaborative research, amongst other things.

# SPETLIGHT ON SPEAKERS

### **Meet the Innovators**



### Dr. Mike Leek, Chief Executive Officer, TC BioPharm

Described by Chris Mason as a 'pioneer in the field of Regenerative Medicine', Mike will be hosting a biotech roundtable on achieving a successful clinical manufacturing facility.

Mike is currently Chief Executive Officer of TC BioPharm, developing cell-based autologous treatments for cancer. Prior to this, he held the role of founder-manager at Intercytex and spent several years with Smith + Nephew, significantly contributing to their woundcare strategy, playing a large role in S+N's acquisition of the tissue engineered skin replacement - Dermagraft.



### Dr. Steve Bloor, Chief Executive Officer, Videregen

Steve founded Videregen in 2011 as a spin-out from Northwick Park Institute for Medical Research to develop and commercialise the Institute's advanced organ replacement technologies. In his presentation, he will be addressing the need for transplantable organs through the use of patient's own stem cells.

Steve has over 20 years' experience in medical devices and regenerative medicine, with expertise and leadership skills in strategic R&D, clinical compliance and regulation. He has worked in US multinationals (J&J, Covidien) and UK start-up companies. Steve was formerly CSO at Tissue Science Laboratories and was behind the development of TSL's unique tissue replacement technology.



### **Dr. Clive Glover,** Product Leader, Cell Therapy Technologies, **GE Healthcare**

Clive is responsible for driving product development within the group and will be presenting on "a new paradigm of commercial manufacturing for autologous cell therapy".

The Cell Therapy group within GE is focused on developing the infrastructure to support the large scale commercialisation of cell therapies. Previously Clive has held positions in marketing and product management at STEMCELL Technologies.



Dr. Mark Szczypka, Senior Director, Applications and New Product Development, Pall Life Sciences

Highly skilled in the field of cell culture applications, Mark will be presenting on the development of microcarrier-based systems for large-scale expansion of human mesenchymal stem cells.

In addition to his 15 years of experience in cell culture, Mark has been published in numerous scientific journals. Mark was awarded a Howard Hughes Research Scientist fellowship during his tenure at the University of Washington, and his work in gene therapy was published in the journal 'Neuron' and was highlighted on World News Tonight.



# Dr. Stephen Badylak, Deputy Director, McGowan Institute for Regenerative Medicine Researcher, USA Armed Forces Institute of Regenerative Medicine

Stephen will be presenting on in-situ influence of cell fate for functional soft tissue reconstruction within his role at the USA Armed Forces Institute of Regenerative Medicine.

Stephen directs a laboratory focused upon the use of biologic scaffolds composed of extracellular matrix to facilitate functional tissue regeneration. He is also the immediate President-past of the Tissue Engineering and Regenerative Medicine International Society, the author of more than 275 peer reviewed publications, and holds more than 50 issued U.S. patents and 300 patents worldwide. The focus of his work has been the mechanisms by which extracellular matrix signals host tissues to promote and support functional tissue reconstruction and he places high emphasis upon clinical translation of all activities in the laboratory to the patient.



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08:00 Re

Registration opens

08:45

Conference doors opens

08:55

### **Opening remarks**

Miss Hannah Yates, Conference Manager, World Stem Cells & Regenerative Medicine Congress

09:00

### Chairman's opening remarks

Prof. Chris Mason, Director, Regenerative Medicine Bioprocessing Unit, University College London

### STATE OF THE INDUSTRY: NEXT STEPS TOWARDS COMMERCIAL CELL THERAPIES

09:15

### **KEYNOTE:** Translating the science into products that are commercially viable

- Updates on how Celgene have successfully interpreted the science and carried out the right investigations to develop successful commercial cell therapy and tissue engineering divisions
- Hear how fully integrating the supply chain from discovery research through to manufacturing can help you gain market access
- Understand how complementing in-house development alongside industry collaborations can accelerate commercialisation

Mr. Perry Karsen, Chief Executive Officer, Celgene Cellular Therapeutics

09:40

### KEYNOTE INTERVIEWS: Beyond 2015: What's next for stem cells and regenerative medicine?

One-on-one interviews with some of regenerative medicine's principal thought-leaders, discussing how they view the clinical and commercial future for stem cell-based therapies and the challenges and opportunities facing the emerging regenerative medicine sector globally

Interviewer:

Prof. Chris Mason, Director, Regenerative Medicine Bioprocessing Unit, University College London

09:45

### Interviewees:

### INTERVIEW 1: State of the nation, state of the industry: How the UK is pioneering cell therapy success

- What does 2015 promise when it comes to supporting a world-leading cell therapy industry in the UK?
- How can the UK facilitate the growth of the global cell therapy industry?
- What more needs to be done to enable the successful translation of early stage research into commercially viable and investable therapies?

Mr. Keith Thompson, Chief Executive Officer, Cell Therapy Catapult

10:10

### INTERVIEW 2: Translating the clinical to the commercial: The key to successful market access

- What are the lessons learnt through HSCI's experience in founding several stem cell-related start-up companies and serving on leading scientific advisory boards?
- Understanding that HSCI is engaged with several big pharma in joint research projects, what role do
  they need to play moving forward to enable successful market access for stem cells?
- What experiences, both professional and personal, can you draw on to impart knowledge on the industry as we move ever closer to commercialisation of cell therapies globally?

Mr. Brock Reeve, Executive Director, Harvard Stem Cell Institute

10:35

Networking Break

11:35

### PLENARY ROUNDTABLES: HOW TO?

Want to know industry best-practices and 'how-to' guides for solutions that would work best for your cell therapy or regenerative medicine application?

We have 6 senior-level tables hosted by specialists on each type of technology or solution discussed and participants are invited to join in the small-group discussions on a topic of primary importance to them.



### Scalability of autologous immunotherapies

Dr. Clive Glover. Product Leader. Cell Therapy Technologies, GE Healthcare



### Industrialisation of cell-based therapies: Choosing the right platform

Mr. Harvey Brandwein, Vice President, Business Development, Pall Life Sciences



Scalable process solutions



Cost-effective manufacturing



Best practices: Cell therapy logistics



Designing good clinical trials to enable scale

12:35

Networking Lunch

## **NAVIGATING THE GLOBAL**

**REGULATORY LANDSCAPE** 

Chair: Dr. Natalie Mount, Chief Clinical Officer, Cell Therapy Chair: Prof. Chris Mason, Director, Regenerative Medicine

14:00

Catapult

14:10

### Integrating clinical development activities to leverage emerging international regulatory trends

- Lessons learnt when undergoing clinical work on a Phase II stroke trial in the UK
- Opportunities for additional clinical development in Japan and the UK
- Best practices when integrating clinical work taking place concurrently and globally

Dr. Gil van Bokkelen, Chief Executive Officer, Athersys

# **INNOVATING CELL THERAPY MANUFACTURING**

Bioprocessing Unit, University College London

### Developing a scalable process for manufacturing dendritic cells

- How Ocata Therapeutics developed their highly scalable process which involves a readily renewable stem cell source as the starting material
- The importance of a strong IP position around core cell therapy components when scaling up manufacturing processes
- What clinical opportunities become a possibility with a scalable process for manufacturing dendritic cells?

Dr. Paul Wotton, President & Chief Executive Officer, Ocata Therapeutics

14:30

### Regulatory environment for ATMPs in the UK

- Hear scientific advice on market authorisation for ATMPs in the UK
- Practical insights into the role the UK Regenerative Medicine Expert Group plays regarding this regulatory framework
- Lessons learnt and best practices as to what aspects of ATMPs are regulated

Dr Jacqueline Barry, Head of Regulatory, Cell Therapy Catapult

### A new paradigm of commercial manufacturing for autologous cell therapy

- Understand the requirements for a robust and scalable manufacturing setup
- Best practices when maximising efficiency of processing for time and cost while meeting quality and regulatory requirements
- How to prevent contamination, mixing, loss of identity or other events which interfere with the properties and integrity of final product

Dr. Clive Glover, Product Leader, Cell Therapy Technologies, GE Healthcare

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# NAVIGATING THE GLOBAL REGULATORY LANDSCAPE...CONTINUED

# INNOVATING CELL THERAPY MANUFACTURING...CONTINUED

14:50

### Regulatory path to MAA in the EU

- What has been the experience with Holostem navigating the EU regulatory system?
- How does the dynamic of a 'consortium' of countries differ to working elsewhere in the world?
- What are the key requirements to working with the EMA?

**Dr. Andrea Chiesi,** Chief Executive Officer, **Holostem Terapie Avanzate** 

# Bioreactors as adaptable and scalable manufacturing platforms for multiple therapeutic cell types

- Overcome challenges of scaling up manufacturing by transitioning cell cultures into bioreactors
- Practical insights into the best time during clinical development to transition to a bioreactor in order to make it commercially viable
- What more needs to be done with infrastructure to enable this scale-up transition?

**Dr. Thomas Fellner,** Head, Business Development, Custom Development Services, **Lonza** 

15:10

# Experience with clinical trials and navigating the regulatory system in the USA

- Practical experiences when working with the FDA
- What advice can you impart on those looking to launch a clinical trial in the USA?
- How has your experience differed when working in other countries outside of the USA?

Reserved for a supporting partner

# Scale and expertise: Advancing technologies in cell, gene and immunotherapy through long-term strategic partnerships

- Fundamentals to a successful collaboration when improving process scalability through automation
- Gain product confidence with a reproducible process when working with a trusted partner
- Understand the advantages of working with a partner when it comes to the economics of skills, resources and time

Mr. Dave Flaten, Vice President, Cell Processing, Terumo BCT

15:30

### **PANEL: Optimising global regulatory framework**

- What aspects of the global regulatory framework can be optimised to facilitate market access?
- Knowledge transfer: what has worked well that can be rolled out internationally?
- Are there opportunities for a hybrid model combining positive aspects from various frameworks?

Dr. Natalie Mount, Chief Clinical Officer, Cell Therapy Catapult

Dr. Gil van Bokkelen, Chief Executive Officer, Athersys

Dr. Jacqueline Barry, Head of Regulatory, Cell Therapy Catapult

 $\mbox{\bf Dr.}$  Andrea Chiesi, Chief Executive Officer,  $\mbox{\bf Holostem}$   $\mbox{\bf Terapie}$  Avanzate

# Benefits of using a point of care manufacturing process to enable scale with autologous cells

- How does using a point of care manufacturing process differ from traditional methods?
- What business model considerations are there when using autologous cells?
- Successful case studies where a 'black box' process has been used in a hospital

Reserved for a supporting partner

15:50 Networking Break

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### MARKET ACCESS CONSIDERATIONS FOR THE CELL THERAPY INDUSTRY

# BUSINESS MODEL CONSIDERATIONS CELL THERAPIES

16:30

Chair: Mr. Matthew Durdy, Chief Business Officer, Cell Therapy Catapult

Chair: **Prof. Chris Mason,** Director, Regenerative Medicine Bioprocessing Unit, **University College London** 

# Market access considerations for the cell therapy industry

- How do you create value early on to enable product marketing and reimbursement?
- What needs to be considered by biotechs looking to gain market access with their cell therapy?
- Does there need to be better understanding from authorities on cell therapies to facilitate market access?

Mr. Matthew Durdy, Chief Business Officer, Cell Therapy Catapult

# Enabling innovation through the use of national research hubs in the UK

- Overview of the different hubs and their value to the stem cell industry
- Benefits of combining resources, tools and technologies at the hubs to enable commercial development
- Forward facing plans integrating industry communities over disease specific programmes to aid commercialisation

**Dr. David Pan,** Programme Manager, **UK Regenerative Medicine Platform** 

16:45

17:05

17:25

# PANEL: Market access considerations for the cell therapy industry

- How can the economic value differ depending on who does the analysis and what effect does this have on reimbursement?
- Importance of reimbursement when it comes to market access
- What is the feasibility of having one European reimbursement system?

**Ms. Angela Blake,** Head of Outcomes Research, Evidence Based Medicine & HTA Policy, **Pfizer** 

**Dr. Paul Catchpole,** Director of Value & Access, **Association of the British Pharmaceutical Industry** 

Dr. Nick Crabb, Programme Director - Scientific Affairs, NICE

# Adapting your manufacturing business model in line with developing market demands

- Learn how to facilitate market access whilst growing your business through commercialisation
- Ensure you always maintain a long-term perspective when enabling solutions to cell therapy challenges
- Acceleration of the use of automation and integration in anticipation of industrial success

**Progenitor Cell Therapy** 

# How to identify the right technology going forward

- Overcome the challenge of deciding what technology to use for your stem cell therapy
- Best practices when leveraging existing technology to facilitate successful clinical trials
- How can we anticipate what manufacturing process to use in 5 years' time?

Merck Millipore

# Understand the challenge of designing a good clinical trial

- Lessons learnt by The ALS Association when it comes to running clinical trials within the neurodegenerative sector
- Insights into monitoring trials with a focus on frequency and effectiveness
- How have these trials further developed knowledge with regards to advances in iPS cell lines and biomarkers?

Dr. Lucie Bruijn, Chief Scientist, The ALS Association

17:45

Close of Day 1- Evening drinks sponsored by: (see page 26 for details)





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08:00

Registration opens

08:50

Conference doors opens

08:55

### Recap of Day 1 and opening remarks for Day 2

Prof. Chris Mason, Director, Regenerative Medicine Bioprocessing Unit, University College London

### TRANSLATING SCIENCE INTO HEALTHCARE

09:00

### **KEYNOTE PANEL: Using cell therapy to enable spinal cord regeneration**

Hear from those involved in the pioneering therapy that is enabling paralysis reversal and spinal cord regeneration as well as those who would be on the receiving end of future treatments.

- Updates on the use of olfactory ensheathing cells (OECs) in spinal cord regeneration
- What are the next steps for rolling out this cell therapy to more patients suffering from paralysis?
- What more needs to be, and can be, done to treat and cure paralysis and spinal cord injury?

Prof. Geoffrey Raisman, Chair, Neural Regeneration, Institute of Neurology, University College London

Prof. Trevor Jones CBE, Member, Board of Trustees, UK Stem Cell Foundation

Ms. Josie Pearson MBE, Gold medal-winning Paralympian, London 2012

Mr. David Nicholls, Founder, Nicholls Spinal Injury Foundation

09:45

### PANEL: Disease foundations' role in promoting healthcare's uptake of regenerative medicine

- What has the uptake been from healthcare when asked about cell therapy applications within their clinics?
- How is research, conducted through disease foundations, being used to educate medical professionals?
- What more, if anything, can be done to encourage cell therapies to be used in clinics once they have made it market?



Ms. Clare McVicker, Director of Research Advocacy, Juvenile Diabetes Research Foundation



**Prof. Peter Weissberg,** Medical Director, **British Heart Foundation** 



**Prof. Alan Silman,** Medical Director, Director of Policy & Health Promotion, **Arthritis Research UK** 



Mr. Michael Nation, Director of Development, Kidney Research UK



**Dr. Brian Dickie,** Director of Research Development, **Motor Neurone Disease Association** 

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11:30

### PLENARY ROUNDTABLES: BIOTECHS

Are you up to date with the latest biotech advances in cell therapies?

We have 16 senior-level tables hosted by biotechs on various indications and therapy-types and participants are invited to join in the small-group discussions on a topic of primary importance to them.



### "Personalised" cell therapy

Dr. Fred Miesowicz, Chief Operating Officer, Argos Therapeutics



# Human clinical development updates on hESC-derived products

Mr. Pedro Lichtinger, President & Chief Executive Officer, Asterias Biotherapeutics



# Using MultiStem© to treat neurological and cardiopulmonary disease

Dr. Gil van Bokkelen, Chief Executive Officer, Athersys



### Using cell combinations to treat heart failure

Ms. Kristin Comella, Chief Scientific Officer, Bioheart



# Updates on study of allogeneic osteoblastic cell therapy product

Dr. Enrico Bastianelli, Chief Executive Officer, Bone Therapeutics

New business development strategies to broaden product pipelines

Dr. Christian Homsy, Chief Executive Officer, Cardio3 Biosciences



### Understanding the body's own stem cell response

Dr. Rahul Aras, Chief Executive Officer, Juventas Therapeutics



## Updates on Phase I/II studies using Placental eXpanded cells

Mr. Yaky Yanay, Chief Operating Officer & President, Pluristem



# How the Walloon Cell Therapy Platform is enabling development

Mr. Eric Halioua, Co-founder & Chief Executive Officer, Promethera Biosciences



### ReNeuron's stem cell therapy in stroke patients

Mr. Olav Hellebo, Chief Executive Officer, ReNeuron



### Achieving a successful clinical manufacturing facility

Dr. Mike Leek, Chief Executive Officer, TC BioPharm



### Preparing for market: Developing a Phase III clinical trial

Mr. Eduardo Bravo, Chief Executive Officer, TiGenix



### "A virtual cure for Type 1 diabetes"

Dr. Paul Laikind, President & Chief Executive Officer, Viacyte



### Benefits of conducting clinical trials across borders



Production of neural stem cells in commercial quantities



Moving forward from pre-clinical when using mesenchymal cell lineage technology

13:00

**Networking Lunch** 

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### **SPOTLIGHT ON T-CELLS**

14:30

Chair: **Prof. Chris Mason,** Director, Regenerative Medicine Bioprocessing Unit, **University College London** 

# How can working with pharma facilitate commercialisation of novel cell-based therapies?

- Insights based on Adaptimmune's strategic collaboration and licensing agreement with GSK for the development and commercialisation of its lead clinical cancer programme
- What are the benefits of working in collaboration with big pharma when it comes to T-cells?
- Best practices when ensuring a successful balance between what each partner brings to the collaboration

Mr. James Noble, Chief Executive Officer, Adaptimmune

### PATH TO UNDUSTRIALISATION: SCALABILITY

Chair: Mr. David Smith, Head, Business Development, Custom Manufacturing Services, Lonza

# EBiSC: Building a scalable supply chain for banking and distribution of iPS cells

- Best practices in ensuring accessible cell lines whilst not jeopardising quality or variety
- What opportunities are there for more disease representation within iPS cell banks?
- How has the consortium format contributed to the success of EBiSC?

**Dr. Timothy Allsopp,** Head of External Research, Regenerative Medicine, **Neusentis, a Pfizer research unit** & Co-ordinator IMI, **EBISC** 

14:50

# Understand carT-cell therapies' ability to shape the future of oncology

- Is the full potential of this treatment known in its power to turn the patient's immune system against cancer?
- What other opportunities are there for 'personalised medicine' when treating cancer?
- Have we reached a pinnacle moment in finding a cure for cancer?

Reserved for a supporting partner

Understand the overall challenges and role of different technologies to address 'patient scale' production

- What are the benefits of patient scale cell production systems?
- How can automation enable low cost production of these systems at multiple sites?
- Understand how this method allows for different modes of individual clinical delivery whilst using economies of scale and large facilities

Dr. Tim Smith, Chief Executive Officer, Octane

15:10

# Beyond oncology: The use of T-cells to treat major viral infections

- Hear how, alongside all the talk on the use of T-cells in oncology, there is real potential for this therapy to treat major viral infections
- What considerations need to be taken into account when looking beyond cancer for T-cells?
- Updates on clinical trial progress with T-cells to treat HIV and what does the future hold for T-cells and ebola?

**Dr. Keith Gillon,** Director of Clinical & Regulatory Affairs, **TC BioPharm** 

Development of microcarrier-based systems for large-scale expansion of human mesenchymal stem cells

- Understand how these systems increase process control, reproducibility and reduced footprint
- Determine how conditions identified in small scale can be transitioned into environmentally controlled bioreactors demonstrating scalability
- Gain insight into results obtained in recent studies with novel microcarriers for cell expansion in stirred vessels

**Dr. Mark Szczypka,** Senior Director, Applications & New Product Development, **Pall Life Sciences** 

15:30

# What is the pharma perspective on how T-cells could transform cancer treatment

- Gain a better understanding of how big pharma are using T-cells to combat cancer
- What are the clinical advantages of this radiation and chemo alternative that is attracting high levels of investment?
- Lessons learnt juggling therapeutics development and regulatory compliancy for T-cell development

Reserved for a supporting partner

### Lessons learned from two decades of protein therapeutics manufacturing applied to cell therapy

- Developing commercially viable, large-scale manufacturing processes
- How Lonza leverage their manufacturing experience to develop scalable cell therapy manufacturing platforms
- Lonza's vision for the future of cell therapy manufacturing: controlling costs while delivering quality and quantity

Mr. Marc Funk, Chief Operations Officer, Pharma & Biotech, Lonza

15:50 Netw

Networking Break

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**IMPLEMENTING INDUSTRIALISATION THROUGH** 

COST-EFFECTIVE METHODS

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# INTEGRATING THE BUSINESS WITH THE CLINICAL

16:30 Chair: **Prof. Chris Mason,** Director, Regenerative Medicine Bioprocessing Unit, **University College London** 

# Chair: Mr. David Smith, Head, Business Development, Custom Manufacturing Services, Lonza

# Integrating the business with the clinical to enable successful market access

- Realising the economic opportunity early on in regenerative medicine with a shift in perception away from palliative medicine
- Understand how defining the clinical trial more effectively will enable greater commercial gain
- Best practices in integrating the business with the clinical not only throughout research and clinical trials but also from late clinical development to post-marketing

Ms. Kristin Comella, Chief Scientific Officer, Bioheart

# How you can reduce your direct manufacturing cost of goods by up to 40%?

- Insights from a manufacturing research centre working with companies to discover underlying challenges
- Best practices in process intensification and repeatability to ensure stability and efficiency
- Understand how considering your cost of goods ahead of Phase I can save your money

Mr. Mark McCall, Enterprise Fellow, EPSRC Centre for Innovative Manufacturing in Regenerative Medicine

16:50

# How Cambridge scientists are pioneering stem cells' true medical potential

- Hear updates on what late stage research is currently underway at Cambridge
- How has this centre of excellence promoted successful growth within stem cell research?
- Have industrial collaborations influenced Cambridge's success or has it been its educational heritage that has carried it forward?

Prof. Roger Pedersen, Principal Investigator, Wellcome Trust/ Medical Research Council Cambridge Stem Cell Institute

17:10

# Translating scientific findings into commercial applications

- Infrastructure required to successfully translate scientific research into commercially viable therapies
- Lessons learnt in business development and consultancy to contract negotiation and IP management
- How do you successfully identify potential commercial partnerships when it comes to scientific expertise and industry development?

**Dr. Jenny Cusiter,** Business Development Executive, **MRC Centre for Regenerative Medicine** 

17:30

### What are the fundamentals to integrating a startup on the path to industrialisation?

- What do you need to initially consider when spinning out a stem cell project from a research institute in terms of manufacturing?
- How can you mitigate early stage risk to ensure support from investors and industrial partners?
- Do you need to redesign your process to achieve scale or can you successfully optimise existing technology?

Reserved for a supporting partner

# PANEL: Best practices when industrialising the link between equipment and disposables

- Designing equipment and disposables with an eye to large scale production
- Trends in personalised manufacturing logistics
- Understand how industrialisation can mean more than automation and the role that will have on your business

Moderator: **Mr. Richard Grant,** Director, Life Science and Pharmaceutical, **Invetech** 

Dr. Fred Miesowicz, Chief Operating Officer, Argos Therapeutics Dr. Christian Homsy, Chief Executive Officer, Cardio3 Biosciences

17:50

Close of Day 2 & 10th Year Anniversary Party (see page 26 for details)

08:00 | Registration opens

### LATEST INNOVATIONS IN TISSUE ENGINEERING

09:00

Chair: Prof. Chris Mason, Director, Regenerative Medicine Bioprocessing Unit, University College London

09:05

### The innovative use of scaffolding structures to support 3D cell growth

- Understand how applying scaffold technology can enhance cell growth, differentiation and function in vitro
- Best practices when building improved cell-based assays using 3D cell culture technology
- How best to develop models of 3D systems tailored for specific in vitro applications

Prof. Stefan Przyborski, Chief Scientific Officer, Reinnervate

09:25

### Innovative use of tissue engineering to heal chronic wounds

- How is Organogenesis using bio-active wound healing techniques for soft tissue regeneration to treat patients?
- What hurdles have had to be overcome when taking living technology from R&D through scale-up?
- Does more need to be done at healthcare level regarding the adoption of regenerative medicine practices?

Mr. Geoff MacKay, President & Chief Executive Officer, Organogenesis

09:45

### Successful regeneration of tubular and solid organs through the use of tissue engineering

- What has been key to Tengion's success in tubular and solid organ regeneration?
- How successful organ regeneration requires learning aspects of the body not currently being studied
- How has tissue engineering generally presented conditions of the body currently unknown to many?

Dr. Tim Bertram, President, R&D & Chief Scientific Officer, Tengion

10:05

### Addressing the need for transplantable organs through the use of patient's own stem cells

- How Videregen's technology is assisting an imbalance in low organ availability and high patient demand
- Understand their cell-based techniques with scaffolding and autologous cells that has led to their success
- Lessons learnt in spinning out from a research organisation and undergoing regulatory processes and securing funds

Dr. Steve Bloor, Chief Executive Officer, Videregen

10:25

### Streamlining the delivery of cell therapy using smart biomaterials and nanoparticles using robotics

- Hear new methods for testing biomaterials for use in cell therapy
- How to overcome challenges of the development of these systems
- What are the potential outcomes for this new system of delivery

Prof. Daniel Anderson, Associate Professor, Department of Chemical Engineering, Institute for Medical Engineering & Science & Member, Koch Institute for Integrative Cancer Research, MIT

10:45

Networking Break

### **SPOTLIGHT ON 3D BIOPRINTING**

11:20

### Repairing and rebuilding diseased tissues and organs through bioprinting

- How has bioprinting enabled Cytograft to repair diseased cardiovascular tissues and organs?
- Best practices in overcoming the challenges of working with cell-based therapies rather than synthetic biomaterials
- What is next for Cytograft and cardiovascular medicine when it comes to tissue engineering?
- Dr. Todd McAllister, Co-founder & Chief Executive Officer, Cytograft Tissue Engineering

11:45

### How the development of tissue therapies can aid the development of functional organ replacements

- Practical insights into Organovo's tissue engineering technology that has capabilities working with a variety of cell types
- Where are there opportunities to collaborate in order to advance developments in using tissue engineering for organ regeneration?
- Next steps from supplemental tissue therapies towards larger replacement tissues and eventually full
  organ regeneration
- Dr. Eric David, Chief Medical Officer, Organovo

### **SPOTLIGHT ON 3D BIOPRINTING...CONTINUED**

### 12:05

### Pioneering successes in tissue engineering systems: Understanding bioprinting technologies

- What have been the most important considerations when using cells as 'bio-ink' in the development of 3D bioprinting?
- What opportunities, and limitations, does current bioprinting technologies present in the area of tissue engineering and organ regeneration?
- Insights into future trends enabling advances in tissue engineering

Reserved for a supporting partner

12:30

Networking Lunch

### **NEXT GENERATION OF ORGAN REGENERATION**

### 14:00

### In-situ influence of cell fate for functional soft tissue reconstruction

- Updates on the research programme enabling extremity injury treatment to ex-servicemen and women
- What have been the major challenges when working towards restoring the structure and function of the tissue?
- Are there specific considerations with regards to the inclusion of military patients in clinical trials?

Dr. Stephen Badylak, Deputy Director, McGowan Institute for Regenerative Medicine & Researcher, USA Armed Forces Institute of Regenerative Medicine

14:25

# Using ultra-thin nano-membranes and adipose stem cells to create the vascular network necessary in engineering tissue, skin and organs

- Hear from the winner of the 2014 Young Innovator Award in Cellular and Molecular Bioengineering: an award given to talented assistant professors working in the growing bioengineering field
- Brief on developing complex, transparent and permeable membrane "scaffolds" to support cell and tissue growth
- Gain a better understanding of how this method can assist in alleviating some aspects of organ rejection at a time when organ resources are low
- Dr. Thomas Gaborski, Assistant Professor of Biomedical Engineering, Rochester Institute of Technology

### 14:50

### Functional human intestine tissue grown in lab

- Hear an update on how "organoids" of functioning human intestinal tissue grown from pluripotent stem cells in a lab dish have been transplanted into mice
- What does this mean for the study of diseases of the intestine moving forward?
- Could this lead to bioengineering personalised intestinal tissue to treat disease and regenerate organs?
- Dr. Michael Helmrath, Surgical Director, Intestinal Rehabilitation Program, Cincinnati Children's Hospital Medical Center

15:15

### The first in-vitro model of the human stomach

- Bulletin on how scientists have been able to understand how to use stem cells to generate human stomach tissue in a petri dish
- What are the clinical implications of this scientific breakthrough with regards to disease prevention?
- Next steps with applying this development to new drug discovery and replacement tissue therapies
- Dr. James Wells, Stem Cell Biologist, Cincinnati Children's Hospital Medical Center

15:35

### Using multiple combinations of cell populations to grow tissue of the oesophagus

- Lessons learnt from the tissue engineering technique used to grow oesophagus tissue
- What are the clinical implications of this scientific breakthrough with regards to stem cell dynamics and tissue engineering?
- Is this the first step towards fully developed, tissue-engineered oesophagi?

Dr. Tracy Grikscheit, Principal Investigator, Saban Research Institute & Pediatric Surgeon, Children's Hospital Los Angeles

16:00

Close of Conference

Also taking place on Friday 22 May, 2015: Investor Forum (see following page for details)

# **INVESTOR FORUM** - Friday 22nd May, 2015

# Seeking Investment? Looking to Invest? Horizon Scoping?

### **PITCHES**

### **WORKSHOPS**





**Seeking Investment:** You could be one of the 9 companies who will have the chance to pitch to a panel of investors

Increase your chances of securing funds: Sit in on the pitching session to see how others do it and learn from their feedback

**Audience Participation:** Best practices when it comes to successfully pitching your product

See below for more details on how to submit your pitching application

Three workshops aimed at small and medium biotechs and investors not currently active in the regenerative medicine space. Focussing on:

- How to develop the economic arguments for cell therapies
- Understanding the unconventional cell therapy business models in order to get the highest financial return from your investment
- **3.** Horizon scoping: why invest in stem cells and regenerative medicine?

There are nine 20 minute pitching slots available on Friday 22 May 2015. Each pitching slot consists of a 12 minute pitch and 8 minutes for feedback from the investor panel. The panel will be made up of financiers and investors from a variety of financial backgrounds and geographies.

The deadline for applications is **2nd March 2015** and successful companies will be notified 2 weeks later on **16th March 2015**. Successful applicants will also receive a complimentary pass to the World Stem Cells & Regenerative Medicine Congress, taking place 20 - 22 May 2015.

To apply, visit: www.surveymonkey.com/s/stemcells15investorforumpitches or email hannah.yates@terrapinn.com for more information.

# DAY THREE - Friday 22nd May, 2015

08:00 Registration opens

09:00

**Investor Forum - PITCHES** 

Chair's opening remarks

Chair: Mr. Matthew Durdy, Chief Business Officer, Cell

**Therapy Catapult** 

09:05 Introduction to the Investor Panel

**Investor Panel:** 

Ms. Inga Deakin, Healthcare Ventures Associate, Imperial Innovations

Mr. Sinclair Dunlop, Managing Partner, Epidarex Capital

Mr. Marcel Kloosterman, Senior Investment Manager, Chemelot Ventures

09:25

Pitches - Pitching companies to be announced

To apply, visit: www.surveymonkey.com/s/ stemcells15investorforumpitches or email hannah.yates@terrapinn.com for more information.

Submissions close 2nd March 2015.

Investor Forum - WORKSHOPS

Chair's opening remarks

Chair: Hannah Yates, Conference Manager, World Stem

Cells & Regenerative Medicine Congress

Developing the economic arguments for your cell therapies: A guide to how and why

 Understand the importance of looking beyond the clinical trial when developing a cell therapy

 Balancing the considerations around cost of goods and reimbursement early on and in parallel to the clinical development

 Successfully communicate the economic value of your cell therapy where unconventional business models apply

Workshop leaders:

**Dr. Mick Cooper,** Head of Research, Healthcare, **Edison Investment Research** 

**Mr. Christian Glennie,** Analyst, **Edison Investment Research** 

10:45 Networking Break

11:20

Pitching 101: Increase your chances of securing funds

Recap of the morning pitching session: lessons learnt

 Review of the 5 key components of a successful pitch: Need, Product, Defensibility, Management, Plan

 Audience participation: best practices when it comes to successfully pitching a cell therapy

**Workshop leader: Mr. Matthew Durdy,** Chief Business Officer, **Cell Therapy Catapult** 

11:20

Cell therapy business models: Understand the unconventional to get the highest financial return from your investment

 Understand how cell therapy business models are unconventional in comparison to pharma business models

 What are the different types of business model present within the cell therapy sector?

 Best practices for risk mitigation within the stem cell industry

Workshop leader to be announced

12:30 Networking Lunch

14:00

Pitches - Pitching companies to be announced

To apply, visit: www.surveymonkey.com/s/ stemcells15investorforumpitches or email hannah.yates@terrapinn.com for more information.

Submissions close 2nd March 2015.

14:00

Horizon scoping: Why invest in stem cells and regenerative medicine?

 Overview of the key clinical and financial successes within stem cells and regenerative medicine

 Mitigate investment risk by understanding how cell therapies are able to compete with other medicines

 How are the cell therapies organised to compete?

Workshop leader: Mr. Greg Bonfiglio, Founder & Managing Partner, Proteus Venture Partners

15:40 Chair's closing remarks

16:00 Close of Conference

For the Investor Forum registration details, see page 29

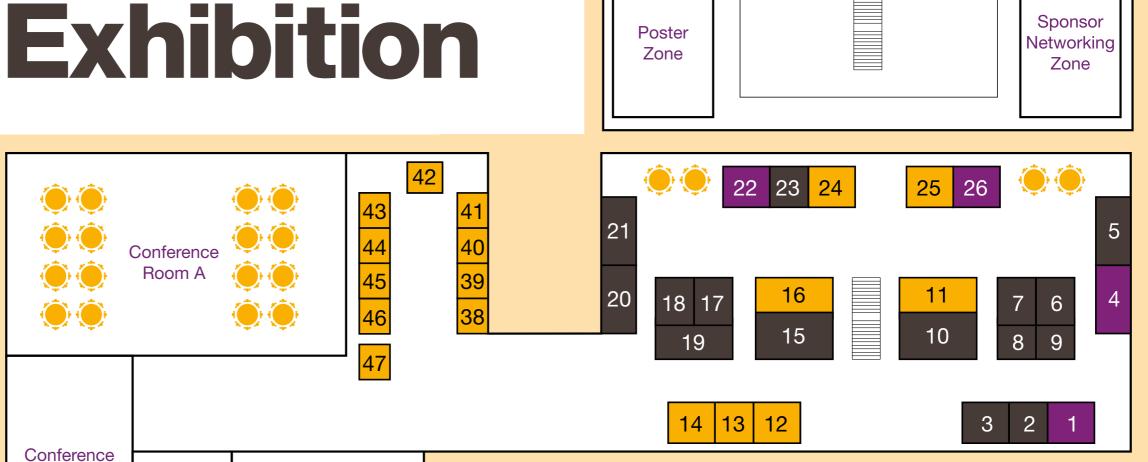
### Who exhibits?

- CMOs
- Upstream and Downstream bioprocessing
- Cell Line
- Cord Blood Banks
- Non governmental Organisations
- Transportation and Logistics Providers
- Investors
- CROs
- Law Firms
- Regulatory and Business Strategy Consultants

### Who attends?

- Heads of Pharma
- Heads of Big Biotech
- Heads of Biotechs
- Heads of Academia
- Investors
- Heads of Regulatory and Governmental Bodies

# The Exhibition



# **Get involved**

- Book a stand
- Join our digital marketing campaign
- Take part in pre-event networking
- Help shape the event plans
- Invite your clients
- Book prospect meetings onsite

| Lounge | Forum |  |
|--------|-------|--|
|        |       |  |
|        |       |  |
|        |       |  |

Investor

Speaker

3 x 4m 3 x 3m

5 x 2m 5 x 2m

3 x 4m

3 x 4m 3 x 3m

3 x 3m

6 x 4m

MedCity

Room B

10

12

| 13 | UPM                   | 25 | GE Healthcare Life Sciences |
|----|-----------------------|----|-----------------------------|
| 14 | PCT                   | 26 | 3 x 4m                      |
| 15 | 6 x 4m                | 27 | 3 x 3m                      |
| 16 | Octane                | 28 | BioSafe                     |
| 17 | 3 x 4m                | 29 | Comecer                     |
| 18 | 3 x 4m                | 30 | Cook Medical                |
| 19 | 6 x 3m                | 31 | TrakCel                     |
| 20 | 5 x 2m                | 32 | Macopharma                  |
| 21 | 5 x 2m                | 33 | Biovault                    |
| 22 | 3 x 3m                | 34 | Sartorius Stedim            |
| 23 | 3 x 3m                | 35 | 3 x 2m                      |
| 24 | Cell Therapy Catapalt | 36 | 3 x 2m                      |
|    |                       |    |                             |

**AVAILABLE** 

SOLD

| 37 | 3 x 3m                   |
|----|--------------------------|
| 38 | Chemometec               |
| 39 | Lonza                    |
| 40 | NHS Blood and Transplant |
| 41 | SCINUS Cell Expansion    |
| 42 | MASTHERCELL              |
| 43 | Cryoport                 |
| 44 | WuXi AppTec              |
| 45 | Theramo BCT              |
| 46 | Miltenyi Biotec          |
| 47 | Merck Millipore          |
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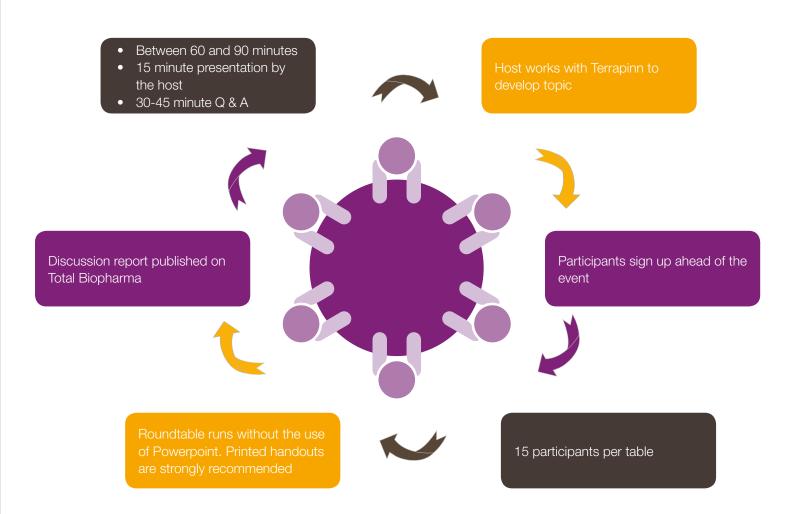
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# **Spotlight on Roundtables**

During these sessions the audience will brainstorm, debate and discuss a series of relevant topics and problems.

# **How Will it Work?**



Confirmed 2015 roundtable hosts include:

Argos Therapeutics, Asterias Biotherapeutics, Athersys, Bioheart, Bone Therapeutics, Cardio3 Biosciences, GE Healthcare, Juventas Therapeutics, Pall Life Sciences, Pluristem, Promethera Biosciences, ReNeuron, TC Biopharm, TiGenix, Viacyte



# WEDNESDAY 20TH MAY











# Shell scheme

£500 per square metre

### Includes:

- Walls on up to three sides of the stand
- Name on the fascia board
- Two chairs and one table
- Power
- Lighting
- Minimum size: 6 square metres

### Includes:

- Raw space
- Inclusion in show guide and event website
- Two chairs and one table
- Power
- Minimum size: 18 square metres

Raw space

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# **Poster Zone**

£50 each

### Includes:

- Space for one A0 poster
- Inclusion in Poster Booklet and event website

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| Benefits  | Diamond           | Platinum          | Gold             | Silver     | Exhibitor                           |
|---|-------------------|-------------------|------------------|------------|-------------------------------------|
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| Keynote Plenary<br>Interview or<br>Presentation | 1                 | 1                 |                  |            |                                     |
| Keynote Plenary Panel                           | 1                 | 1                 | 1                |            |                                     |
| Track Presentation                              | 2                 | 1                 | 1                |            |                                     |
| Roundtable Host                                 | 2                 | 1                 | 1                | 1          |                                     |
| Access to networking<br>Manager                 | Up to 12 meetings | Up to 10 meetings | Up to 8 meetings |            |                                     |
| Lead generation                                 | 3 emails          | 2 emails          | 1 emails         | Newsletter |                                     |
| Delegate pass                                   | 6                 | 4                 | 3                | 2          |                                     |
| Stand   | 24 sqm            | 24 sqm            | 12 sqm           | 9 sqm      | Purchased<br>by sqm - 6<br>up to 24 |

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| Package        | Book before |
|----------------|-------------|-------------|-------------|-------------|-------------|
|                | 27 Feb 2015 | 20 Mar 2015 | 17 Apr 2015 | 08 May 2015 | 20 May 2015 |
| 3 Day Standard | £2510       | £2650       | £2790       | £2930       | £3,070      |
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| Poster         | £50         | £50         | £50         | £50         | £50         |

| Applicable to 20-21 May only   |                  |                 |                 |                 |             |  |  |
|--|------------------|-----------------|-----------------|-----------------|-------------|--|--|
| Package  | Book before      | Book before     | Book before     | Book before     | Book before |  |  |
|  | 27 Feb 2015      | 20 Mar 2015     | 17 Apr 2015     | 08 May 2015     | 20 May 2015 |  |  |
| 2 Day Standard   | £1645            | £1740           | £1830           | £1920           | £2,015      |  |  |
| Package  | <b>SAVE £370</b> | SAVE £275       | SAVE £185       | SAVE £95        |             |  |  |
| 2 Day Academic   | £810             | £905            | £900            | £945            | £990        |  |  |
| Package*   | <b>SAVE £180</b> | <b>SAVE £85</b> | <b>SAVE £90</b> | <b>SAVE £45</b> |             |  |  |
| Poster   | £50              | £50             | £50             | £50             | £50         |  |  |
| * Academic package includes full time clinicians and medical staff. Subject to Terrapinn approval. |                  |                 |                 |                 |             |  |  |

| Applicable to 22 May only |                            |                            |                            |                            |                            |  |
|---------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|--|
| Package                   | Book before<br>27 Feb 2015 | Book before<br>20 Mar 2015 | Book before<br>17 Apr 2015 | Book before<br>08 May 2015 | Book before<br>20 May 2015 |  |
| Investor Forum only       | £855<br><b>SAVE £190</b>   | £905<br>SAVE £140          | £950<br><b>SAVE £95</b>    | £1000<br><b>SAVE £45</b>   | £1,045                     |  |

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