

23-26 JANUARY 2018 HYATT REGENCY, MIAMI



DISCOVERY | TRANSLATION & CLINICAL TRIALS | IN THE CLINIC

co-located with



EARLY BIRD
ENDS
DECEMBER 1ST!



450+
Attendees



210+
Organisations



100+
Speakers



30+
Countries

MEET OUR VISIONARY SPEAKERS!



Peter Marks, MD, PhD,
*Director, Center for
Biologics Evaluation and
Research (CBER),
U.S. Food & Drug
Administration*



Anthony Atala, MD,
*Director,
Wake Forest Institute for
Regenerative Medicine*



Hideyuki Okano, MD, PhD,
*Professor & Dean, Keio
University Medical School;
Director of the Japanese
Society for Regenerative
Medicine*



Greg Simon,
*President,
Biden Cancer
Initiative*



Yoji Sato, PhD,
*Head, Division of Cell-Based
Therapeutic Products,
National Institute of
Health Sciences (Japan)*



Arnold Caplan, PhD,
*Director, Skeletal
Research Center,
Case Western Reserve
University*



Shahin Rafii, MD,
*Director, Ansary Stem Cell
Institute Chief,
Regenerative Medicine,
Weill Cornell Medicine*



Dr Joshua M. Hare,
*Director, Interdisciplinary
Stem Cell Institute (ISCI),
Louis Lemberg Professor of
Medicine,
University of Miami
Miller School of Medicine*



Maria T. Millan, MD,
*Interim President & CEO,
California Institute for
Regenerative Medicine
(CIRM)*



Camillo Ricordi, MD,
*Stacy Joy Goodman Professor
of Surgery, Director and Chief
Academic Officer, University
of Miami Diabetes
Research Institute*



Dr Joanne Kurtzberg,
*Director,
Carolinas Cord Blood
Bank At Duke
University; President,
Cord Blood Association*



Richard E. Hayden, MD,
*Professor,
Head and Neck Surgery,
Mayo Clinic*

Brought to you by the



**REGENERATIVE
MEDICINE
FOUNDATION**

Find out more at www.worldstemcellsummit.com



“THE 2018 WORLD STEM CELL SUMMIT IS THE GLOBAL, SUPER-ECOSYSTEM EVENT, TRANS-DISCIPLINARY IN SCOPE. THE SUMMIT IS DESIGNED TO BREAKDOWN SILOS, EXPAND YOUR KNOWLEDGE AND FORGE COLLABORATIONS, WITH THE OVERARCHING COLLECTIVE GOAL TO IMPROVE HEALTH AND DELIVER CURES. LOCATED IN THE GORGEOUS INTERNATIONAL CROSSROADS MIAMI, FLORIDA, WE ARE CREATING A DISTINCTIVE FUTURISTIC EXPERIENCE, WHERE ALL PARTICIPANTS WILL COLLECT OPPORTUNITIES, BECOME INSPIRED AND FLOURISH ”

BERNARD SIEGEL, FOUNDER OF WORLD STEM CELL SUMMIT AND EXECUTIVE DIRECTOR, REGENERATIVE MEDICINE FOUNDATION



“THE WORLD STEM CELL SUMMIT HAS BECOME A MUST-ATTEND EVENT FOR JAPAN'S TOP RESEARCHERS. I AM VERY HONOURED TO SERVE AS A CO-CHAIR OF THE WORLD STEM CELL SUMMIT AGAIN ”

PROFESSOR NORIO NAKATSUJI, FOUNDING DIRECTOR, KYOTO UNIVERSITY'S ICMS



“THE WORLD STEM CELL SUMMIT IS A CRITICAL AND MUST- ATTEND EVENT. WAKE FOREST INSTITUTE FOR REGENERATIVE MEDICINE IS HONORED TO JOIN THE ARRAY OF DISTINGUISHED LEADERS AND INSTITUTIONS THAT ARE ORGANIZING THE MULTIDISCIPLINARY SUMMIT. THE SUMMIT UNITES THE GLOBAL REGENERATIVE MEDICINE COMMUNITY BY BRINGING TOGETHER RESEARCHERS, CLINICIANS, INDUSTRY, FINANCIERS, REGULATORS, PHILANTHROPISTS, MEDIA, PATIENTS AND THEIR ADVOCATES TO UNDERSTAND THE WHAT'S 'HERE AND NOW' WITH AN OVERARCHING GOAL TO POSITIVELY SHAPE THE FUTURE OF THIS PROMISING NEW ERA OF MEDICINE. ”

DR. ANTHONY ATALA, CHAIR OF THE WAKE FOREST INSTITUTE FOR REGENERATIVE MEDICINE

This year the World Stem Cell Summit will be co-located with the industry's premier partnering event; Phacilitate World Leaders Forum, incorporating Cell & Gene Therapy World, Immuno-Oncology Frontiers World, and our shared Cord Blood & Perinatal Stem Cells track.

Together, this will be the world's largest event dedicated to Advanced Therapies and Regenerative Medicine with 1,200+ attendees, 280+ speakers, 150+ exhibitors – it is the one meeting on the global calendar attended by all of the critical decision-makers from both inside and outside of the field.

To find out more about upgrading your pass to gain access to this Phacilitate World Leaders Forum, turn to page 9.

Thank you to our 2018 Co-Organizers



JOIN A GLOBAL COMMUNITY OF PIONEERS

Evren Alici, MD, PhD
Group Leader, Assistant
Professor of Hematology
Karolinska Institutet

Julie G. Allickson, PhD
Director, Regenerative Medicine
Clinical Center
Wake Forest Institute for
Regenerative Medicine

**Graca Almeida-Porada, MD,
PhD**, Professor, Institute for
Regenerative Medicine,
Wake Forest School of
Medicine

Jane C. Andrews, PhD
CEO,
Cell Bridge Consultants

Takashi Asada, PhD
Professor, Field of Stem Cell
Research, Institute for Frontier
Medical Sciences,
Kyoto University

Anthony Atala, MD
Director, Wake Forest Institute
for Regenerative Medicine;
W.H. Boyce Professor and Chair,
Department of Urology,
Wake Forest School of
Medicine

Jakub Baran
CEO,
Polski Bank Komórek
Macierzystych S.A.

Vladimir Beljanski, PhD
Nova Southeastern
University, Florida • Cell
Therapy Institute

Kapil Bharti, PhD
Stadtman Investigator, Unit on
Ocular Stem cell & Translational
Research (OSCTR),
National Eye Institute, NIH

Ed Bosarge, PhD
Founder & CEO,
Capital Technologies, Inc.

Lee Buckler
CEO,
RepliCel Life Sciences, Inc

Bruce Bunnell, PhD
Director,
Tulane Center for Gene
Therapy

Arnold Caplan, PhD
Director, Skeletal Research
Center,
Case Western Reserve
University

Kyle J. Cetrulo
President & Founder
Perinatal Stem Cell Society

Diego Correa, MD, MSc, PhD
Adjunct Assistant Professor,
University of Miami Diabetes
Research Institute

David Courtman, PhD
Director, Biotherapeutics Core
Facilities,
Ottawa Hospital Research
Institute

Dr John E. Davies,
Professor,
University of Toronto;
President,
Tissue Regeneration
Therapeutics, Inc

Dr Colleen Delaney
Founder and Chief Medical
Officer, Nohla Therapeutics

Michael N. Druckman
Partner,
Hogan Lovells

Adil Duru, PhD
Nova Southeastern
University, Florida • NSU Cell
Therapy Institute

Dan Gincel, PhD
Executive Director,
MD Stem Cell Research Fund

Dr. Christine Guenther
CEO,
apceth Biopharma GmbH

Dorit Harati
Vice President, Quality
Assurance, Manufacturing &
Logistics
Gamida Cell

**Joshua M. Hare, MD, FACC,
FAHA**
Louis Lemberg Professor of
Medicine, Molecular and
Pharmacology, and Biomedical
Engineering; Director,
Interdisciplinary Stem Cell
Institute, University of Miami

Richard E. Hayden, MD
Professor, Head and Neck
Surgery,
Mayo Clinic

Outi Hovatta, MD, PhD
Professor, Obstetrics and
Gynaecology,
Karolinska Institutet

Karl-Henrik Grinnemo, MD
Group Leader in Regenerative
Cardiology,
Akademiska University
Hospital (Uppsala University)

Rosario Isasi, JD, MPH
Interdisciplinary Stem Cell
Institute, University of Miami

Akihiko Iwai, PhD, Divisional
Senior Vice President, Astellas
Pharma Inc.; Vice Chairman,
Forum for Innovative
Regenerative Medicine
(FIRM)

John D. Jackson, PhD,
Associate Professor, Institute for
Regenerative Medicine,
Wake Forest School of
Medicine

Alan Jakimo, JD
Senior Public Policy Research
Fellow Regenerative Medicine
Foundation

Karl K. Johe, PhD
Founder & Chief Scientific
Officer,
Neuralstem, Inc

Richard Jove, PhD
Distinguished Research
Professor, Director, Cell Therapies
Institute,
Nova Southeastern
University

Avak Kharvejian, PhD
Partner,
Flagship Pioneering

Karine Kleinhaus
Divisional Vice President, North
America
Pluristem Therapeutics

Wolfgang Knirsch
CEO,
Vita 34 AG

Joanne Kurtzberg, MD
Director,
Carolinas Cord Blood Bank
At Duke University;
President,
Cord Blood Association

Katarina Le Blanc, MD, PhD
Professor, Specialist Physician,
Division of Clinical Immunology,
Karolinska Institutet

Yijia Li
Director, Shunxi Regenerative
Medicine,
Yunnan Province Stem Cell
Bank

**Hans-Gustaf Ljunggren, MD,
PhD**
Professor,
Karolinska Institutet

JOIN A GLOBAL COMMUNITY OF PIONEERS

Jeanne F. Loring, PhD
Professor of Developmental
Neurobiology, Director of the
Center for Regenerative
Medicine,
Scripps Research Institute

S. Peter Ludwig
Principal,
Fish & Richardson P.C.

Janet Marchibroda
Director, Health Innovation
Initiative,
Bipartisan Policy Center

Peter Marks, MD, PhD
Director, Center for Biologics
Evaluation and Research
U.S. Food & Drug
Administration

Todd McAllister, PhD
Executive Director,
Amnion Foundation

Kevin McCormack
Senior Director, Public
Communications & Patient
Advocate Outreach,
California Institute for
Regenerative Medicine

Martin McGlynn
Board Chairman
Regenerative Medicine
Foundation

Maria Millan, MD
CEO & President
California Institute for
Regenerative Medicine

Randy B. Miller, MD
Cosmetic, Reconstruction &
Hand Surgery,
Stem Cell Research &
Therapy

Norio Nakatsuji, DSc
Founding Director,
iCeMS at Kyoto University

Prof. Hideyuki Okano
Professor, Department of
Physiology,
Kio University

Doug Oliver, MSW
Founder-Chair,
Regenerative Outcomes
Foundation

Dr. Biju Parekkadan
Associate Professor,
Bioengineering, Rutgers
University;
co-Founder,
Sentien Biotechnologies, Inc

Graham Parker, PhD
Professor, Department of
Pediatrics,
Wayne State University
School of Medicine

Marc Steven Penn, MD, PhD,
FACC
President and Chief Medical &
Scientific Officer,
Black Beret Life Sciences

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Director of Regenerative Pain
Medicine Practice,
Mayo Clinic

Shahin Rafii, MD
Director, Ansary Stem Cell
Institute Chief, Regenerative
Medicine,
Weill Cornell Medicine

Camillo Ricordi, MD
Stacy Joy Goodman Professor of
Surgery Distinguished Professor
of Medicine, Director and Chief
Academic Officer
University of Miami Diabetes
Research Institute

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Board Certified Plastic Surgeon,
Cosmeticsurg

Shelley Ross
President,
The Cure Alliance

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M.Bioethics
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NYU Langone Medical Center

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Head, Division of Cell-Based
Therapeutic Products,
National Institute of Health
Sciences

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Academic Research Program
Officer,
Wake Forest Institute for
Regenerative Medicine

Marc J. Scheineson, Esq.
Partner,
Alston & Bird

Adrienne Shapiro
Founder/Science Administrator,
AXIS Advocacy

Shane A. Shapiro, MD, RMSK
Assistant Professor, Department
of Orthopedic Surgery,
Mayo Clinic School of
Medicine

Beth Shaz
Chief Medical & Scientific Officer,
New York Blood Center

Elizabeth J. Shpall
Director of the GMP Cell Therapy
Laboratory and Cord Blood Bank,
The University of Texas

Bernard Siegel, JD
Executive Director,
Regenerative Medicine
Foundation

Greg Simon
President,
Biden Cancer Initiative

Susan Solomon
Founder and Chief Executive
Officer,
New York Stem Cell
Foundation

H. Thomas Temple, MD
Senior Vice President of
Translation Research and
Economic
Development, Professor of
Orthopaedics,
Nova Southeastern
University

Nicolas Theys, PhD
CEO,
Novadip Biosciences

Masayo Yumoto, PhD
Regenerative Medicine Research
& Planning Division,
Rohto Pharmaceutical Co.,
Ltd.

Mark Zimmerman, PhD
Vice President, Strategy and
Business Development, Interim
Vice President of Operations,
ViaCyte

Thomas Zwaka, MD, PhD
Interim Director, The Black
Family Stem Cell Institute,
Icahn School of Medicine at
Mt. Sinai

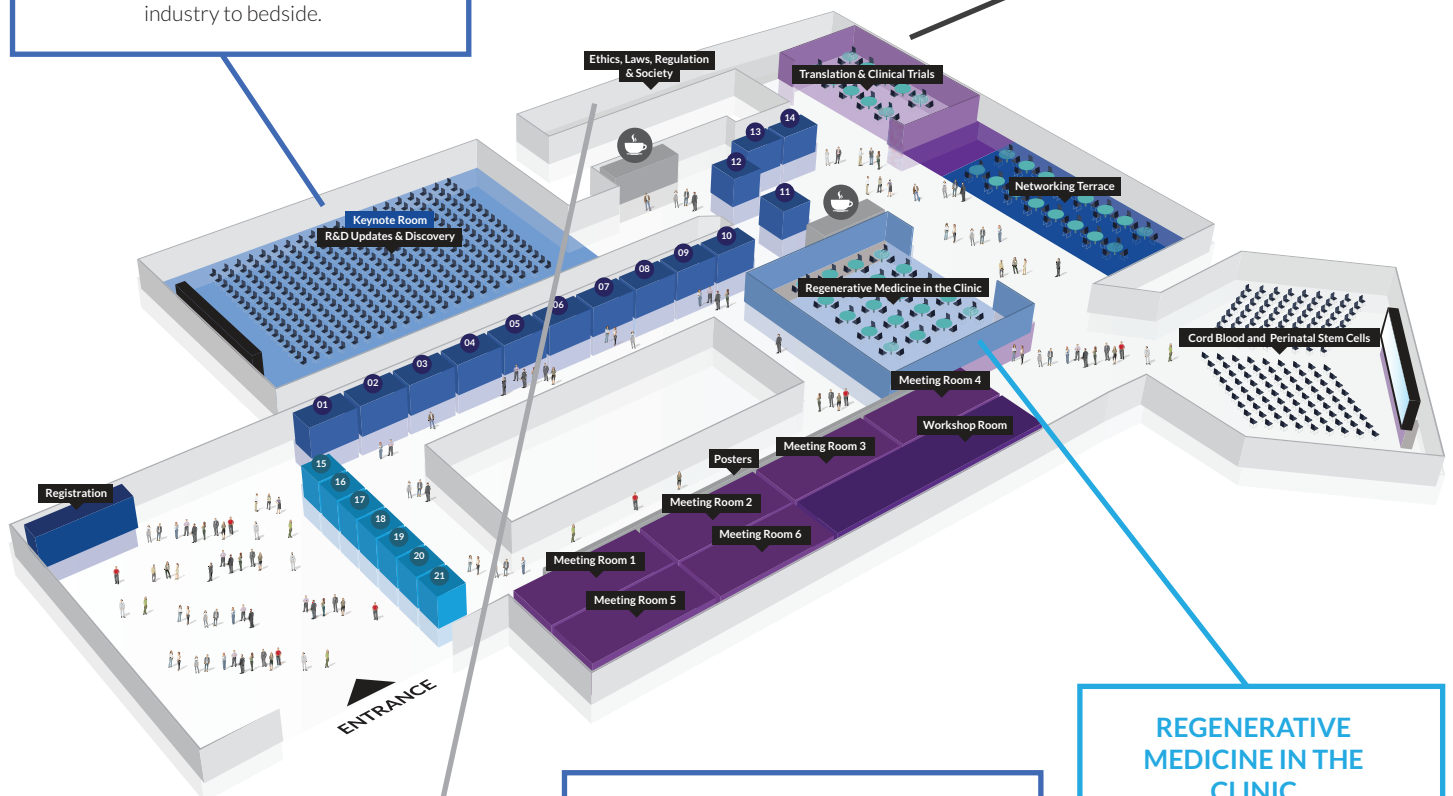
EVENT OVERVIEW

R&D UPDATES & DISCOVERY

presents the latest scientific discoveries and trends coming from laboratories around the world. What are the long-term clinical implications? Consideration will be given to clinical product thinking at early discovery stages, with a focus on the initial product, manufacturing, standardization, safety and regulatory concerns. It is not simply bench to bedside...but bench to industry to bedside.

TRANSLATION AND CLINICAL TRIALS

showcases significant clinical trials from around the world, analyzing the pathways to the clinic and prospects for delivering treatments. The track will include discussions on overcoming regulatory obstacles and the role of patients.



ETHICS AND POLICY WORKSHOP

covers IP, regulatory oversight, registries, RMAT designation, real world evidence, genetic engineering, mini-brains and compliance with FTC, FDA, EMA, and other country-specific regulatory agencies.

EXPERT LUNCHEON ROUNDTABLE DISCUSSIONS

Table discussions focused on all aspects of stem cells and regenerative medicine, including science, business, policy, ethics, education, advocacy and commercialization strategies. This is one of the Summit's most popular and personal networking events.

REGENERATIVE MEDICINE IN THE CLINIC

focuses on the emerging role of regenerative medicine in clinical practice. Presenting the "here and now", panels will include discussions on adipose, SVF, PRP, wound healing, orthopedic treatments, sports medicine and regenerative surgeries.



AGENDA-AT-A-GLANCE

For full conference agenda www.worldstemcellsummit.com

OPENING PLENARY: TUESDAY, JANUARY 23RD

16:00 Registration Opens

18:00

Opening plenary

Alpha Clinic: Near and far horizons for regenerative medicine

Speakers include:

Anthony Atala, MD, Director, **Wake Forest Institute for Regenerative Medicine**

W.H. Boyce Professor and Chair, Department of Urology, **Wake Forest School of Medicine**

Susan L. Solomon, Founder and Chief Executive Officer, **The New York Stem Cell Foundation Research Institute**

Dr Joshua M. Hare, Director, **Interdisciplinary Stem Cell Institute (ISCI)**

Greg Simon, Director, **Biden Cancer Initiative**

19:30

13th Stem Cell & Regenerative Medicine Action Awards Dinner

Since 2005 Regenerative Medicine Foundation has honored the field's top innovators, leaders, and champions at a gala dinner at the World Stem Cell Summit. The awards have recognized dedicated individuals and organizations that have made distinguished contributions to the cause of stem cell research, including advocates, elected officials, philanthropists and scientists.

CONFERENCE DAY 1: WEDNESDAY, JANUARY 24TH

07:30 Registration & Buffet Breakfast in the Exhibition Area

09:00

Plenary Session

6th Annual Japan Symposium Recent Progress of Industry-Academia Open Innovation in Japan for Cell Application

Japan has a fully integrated plan to advance and accelerate regenerative medicine products. Key Japanese leaders from academia, industry and government will present at this must-attend for anyone seeking to gain first-hand knowledge and insight into what is happening in Japan.

Chair's Introduction

Takashi Asada, PhD, Kyoto University

09:10

Keynote Address

Hideyuki Okano, MD, PhD, Professor & Dean, **Keio University Medical School**; Director, **Japanese Society for Regenerative Medicine**

09:35

Keynote Address

Akihiko Iwai, PhD, Vice President, **Astellas Pharma**, Vice Chairman, **Forum for Innovative Regenerative Medicine (FIRM)**

10:00

Regulator's Perspective

Yoji Sato, PhD, Head, Division of Cell-Based Therapeutic Products, **National Institute of Health Sciences (Japan)**

10:25

Roundtable discussion

Featuring speakers of the session, plus:

Prof. Norio Nakatsuji, Professor Emeritus, **Kyoto University**

Masato Ibuki, Regenerative Medicine and Cell Therapy Laboratories, **KANEKA Corporation**

Masayo Yumoto, PhD, Group Leader, Basic Research Group, Regenerative Medicine Research & Planning Division, **Rohto Pharmaceutical, Co., Ltd**

11:00

Morning Coffee in the Exhibition Area



“MAYO CLINIC HAS EMBRACED REGENERATIVE MEDICINE AS A STRATEGIC INVESTMENT IN THE FUTURE OF HEALTHCARE. TO THIS END, THE MAYO CLINIC CENTER FOR REGENERATIVE MEDICINE HAS BEEN ESTABLISHED AS A CATALYST TO ADVANCE NEW KNOWLEDGE ON DISEASE CAUSES AND CURES INTO INFORMED DELIVERY OF QUALITY CARE. THE WORLD STEM CELL SUMMIT BRINGS TOGETHER THE REGENERATIVE MEDICINE COMMUNITY, AND SETS THE STAGE FOR GLOBAL COLLABORATION. OUR TEAM AT MAYO CLINIC IS HONORED TO LEAD IT AS AN ORGANIZER AGAIN THIS YEAR.”

DR. ANDRE TERZIC, CENTER FOR REGENERATIVE MEDICINE, MAYO CLINIC

AGENDA-AT-A-GLANCE

For full conference agenda www.worldstemcellsummit.com

Discovery Track

Star Session

Advancements in pluripotency
Can reprogrammed cells be safely used in cell therapy research?

- Using iPSC's to understand and treat Parkinson's disease and other neurological disorders
- Research advancements utilizing hESC's
- The next wave of research using pluripotent stem cells

Jeanne F. Loring, PhD,
Professor of Developmental Neurobiology
Director of the Center for Regenerative Medicine,
Scripps Research Institute
Thomas Zwaka, MD, PhD,
Icahn School of Medicine at **Mt. Sinai**
Dr Outi Hovatta, Obstetrics and Gynaecology,
Karolinska Institutet, Sweden

Regenerative Medicine in the Clinic

Star Session

Musculo-skeletal Clinical Trials & Clinical Practice in Regenerative Medicine
Includes updates and analysis from the Tulane SVF clinical trial

Bruce Bunnell, PhD,
Director of the
Tulane Center for Gene Therapy
Jaime R. Garza MD, DDS, FACS,
Texas Plastic Surgery, Chair of the Academic Affairs Committee, Immediate Past Chairman, Board of Regents
Texas State University System

Pillars of an Evolving Regenerative Medicine Ecosystem

Star Session

Securing the Regenerative Medicine Advanced Therapy (RMAT) Designation

Chair:
Anthony Atala, MD,
Director, Wake Forest Institute for Regenerative Medicine,
W.H. Boyce Professor and Chair, Department of Urology,
Wake Forest School of Medicine

Speakers:
Dr Julie Allickson, PhD,
Director, Regenerative Medicine Clinical Center,
Wake Forest University School of Medicine
Peter Marks, MD, PhD,
Director, Center for Biologics Evaluation and Research (CBER),
U.S. Food & Drug Administration
Marc J. Scheineson, Esq.,
Partner, Alston & Bird
Janet Marchibroda, Director, Health Innovation Initiative,
Bipartisan Policy Center
Doug Oliver, MSW,
Founder-Chair,
Regenerative Outcomes Foundation

Ethics & Policy Workshops

Star Session

How to capitalize on the future of state funding for stem cell research?

Maria T. Millan, MD,
Interim President & CEO,
California Institute for Regenerative Medicine (CIRM)
Dan Gincel, PhD,
Executive Director,
MD Stem Cell Research Fund

Translational & Clinical Updates: Stem Cell Therapy and Tissue Engineered Products

Star Session

Cardiomyocytes, pancreatic islet cells, MSCs... do the latest data support the recent revival in regenerative medicine?

Case studies & audience Q&A
Chair:
Arnold Caplan, PhD,
Director, Skeletal Research Center,
Case Western Reserve University
Dan Gincel, PhD,
Executive Director,
MD Stem Cell Research Fund
Dr Joshua M. Hare,
Director, Interdisciplinary Stem Cell Institute (ISCI), Louis
Lemberg Professor of Medicine,
University of Miami Miller School of Medicine
Nicolas Theys, PhD,
Chief Operating Officer,
Novadip Biosciences
Dr Biju Parekkadan,
Associate Professor,
Bioengineering, Rutgers
University; co-Founder,
Sentient Biotechnologies, Inc

13.15

Buffet Lunch in the Exhibition Area

OR

Japan Partnering Lunch

This dedicated networking session delivers a unique opportunity to enable new partnerships and discussions with attendees from Japan

2018 World Stem Cell Summit Poster Forum

Attendees are welcome to submit posters in all areas of science, medicine, business, finance, regulation and law, ethics, policy, communications, and other topics related to the societal impact of stem cell research and the regenerative medicine field.

To enter your poster, click here

The topics listed below are suggestions, not a comprehensive list

Basic Research, Medicine and Health

Stem Cell Research

Developmental Biology

Stem Cells for R&D

Translation of Stem Cell Research into the Clinic

Clinical Trials of Cellular Therapies and Drugs/Biologics/Devices derived from Stem Cells

Cell Standardization

Impact of Stem Cell Research and Regenerative Medicine on Public Health

Impact of Stem Cell Research and Regenerative Medicine on Personalized Medicine

Ethics, Law and Society

Patents and Intellectual Property Matters

Licensing and Collaboration Agreements

Stem Cell Ethics

Harmonizing Federal and State Legislation and Regulation within the U.S.

Globally Harmonizing Legislation and Regulation

Chimeras

Research with Neuronal Stem Cells

Stem Cell Banking

Commercial-scale Manufacturing of Stem Cell-based Products

Industry Infrastructure

Sources of Public and Private Capital

Medicare/Medicaid, Private Insurance and Third Party Payment Regimes

Business Models

Collaborative R&D and Commercialization

Public/Private Partnerships

Patient Advocacy and Communications

Stem Cell Advocacy

Applying Social Networking Tools

Stem Cell Science and Regenerative Medicine on the Internet

AGENDA-AT-A-GLANCE

For full conference agenda www.worldstemcellsummit.com



Business Models & Investment: WEDNESDAY, JANUARY 24TH

- **Macro trends in investor, pharma and regulatory environments**
 - Investor and pharma perspectives – how/where will we seek to engage in the cord blood and perinatal stem cell field in future?
 - Global regulatory development updates: will recent evolution of guidelines and legislation (eg, in China) translate to perinatal stem cell banking and application opportunities?
- **Analyzing evolving public and family cord blood and perinatal stem cell banking business models worldwide**
 - What do ongoing public-private convergence and M&A trends, and the continuing development of hybrid business models, mean for the robustness of the banking sector globally?
 - What is the relative health of the sector – and what are the emerging dominant business models – in North America, South America, Europe and Asia?
 - The search for sustainability - weighing up the viability of emerging revenue streams: how are banks, biotechs and tool/service providers innovating to both realize and monetize the potential of cord blood & perinatal stem cells?
 - Beyond the cord – how diversification into the wider biobanking arena is presenting new, sustainable business opportunities.

Clinical Applications & Cell Expansion: THURSDAY, JANUARY 25TH

- **Clinical updates: examining trial designs and the latest data for product candidates based on cord blood and perinatal stem cells**
 - Case studies: what is the latest evidence of therapeutic potential in specific indications? (Cardiovascular diseases, autism, hypoxic ischemic encephalopathy, etc.)
 - What is the regulatory pathway for these candidates to market approval and ultimately, to patients?
 - Perinatal stem cells vs. bone marrow-derived cells – what have been the outcomes from comparative studies to date?
 - What are the future modalities and therapeutic areas/disease applications to target? (Eg. Engineered perinatal cells)
- **What progress in alleviating the cord blood & perinatal cell expansion bottleneck?**
 - Troubleshooting manufacture of perinatal cell and tissue-derived MSCs
 - How to enable closed transitions between cell selection, cell expansion and cell harvesting unit operations?
 - How to address the current shortfalls in testing guidance and available, fit-for-purpose assays?
 - Closing roundtable discussion: How would we approach commercial scale up of a dedicated cord blood & tissue bioprocessing facility? (Where to start: small but scalable? Straight to full scale? Modular?)

SPEAKERS INCLUDE:

- **Jakub Baran**, CEO & COO, Famicord Group, Polski Bank Komórek Macierzystych S.A.
- **Greg Bonfiglio**, Founder & Managing Partner, Proteus, LLC
- **Dr John E. Davies**, Professor, University of Toronto; President, Tissue Regeneration Therapeutics, Inc
- **Dr Colleen Delaney**, Founder and Chief Medical Officer, Nohla Therapeutics
- **Dr Steve Elliman**, CSO, Orbsen Therapeutics, Ltd
- **Dorit Harati**, Vice President, Quality Assurance, Manufacturing & Logistics, Gamida Cell
- **Cade Hildreth**, BS, MS, President & CEO, BioInformant.com
- **Dr Karine Kleinhaus**, Divisional Vice President, North America, Pluristem Therapeutics
- **Dr Wolfgang Knirsch**, CEO, Vita 34 AG
- **Dr Joanne Kurtzberg**, Director, Carolinas Cord Blood Bank At Duke University; President, Cord Blood Association
- **Dr Yijia Li**, Director, Shunxi Regenerative Medicine, Yunnan Province Stem Cell Bank
- **Todd McAllister**, PhD, Executive Director, Amnion Foundation
- **Dr Beth Shaz**, Chief Medical & Scientific Officer, New York Blood Center
- **Elizabeth J. Shpall**, MD, Professor, Howard and Lee Smith Chair in Cancer Research; Director, Cell Therapy Laboratory and Cord Blood Bank; Deputy-Chair, Department Stem Cell Transplantation and Cellular Therapy, University of Texas MD Anderson Cancer Center
- **Frances Verter**, PhD, Founder & Director, Parent's Guide to Cord Blood Foundation & CellTrials.org

“THE WORLD STEM CELL SUMMIT IS A MEETING OF THE STEM CELL MINDS, BRINGING POLICY, SCIENCE, INDUSTRY, ADVOCATES AND CLINICIANS TOGETHER IN A UNIQUE AND POWERFUL FORUM. THE SUMMIT IS OF GREAT VALUE TO RESEARCHERS BY PROVIDING A CONTEXT FOR STEM CELL SCIENCE THAT IS NOT FOUND AT OTHER MEETINGS. BY UNITING THE KEY STAKEHOLDER GROUPS, THE SUMMIT GROUNDS RESEARCH DIRECTION WITH AN UNDERSTANDING OF THE STRATEGIES THAT WILL BE MOST BENEFICIAL FOR DEVELOPING STEM CELL-BASED THERAPEUTICS.”

SALLY TEMPLE, PH.D., SCIENTIFIC DIRECTOR, NEURAL STEM CELL INSTITUTE PRESIDENT, INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH

UPGRADE YOUR PASS FOR ACCESS TO THE PHACILITATE WORLD LEADERS FORUM



PHACILITATE LEADERS FORUM MIAMI

Phacilitate brings together industry leaders to explore trends, opportunities, disruptions and major shifts on the horizon. This year more than 1,200 decision makers and technical experts will unite to collectively shape, experience, and challenge the future of advanced therapies.



3 EVENTS FOR THE PRICE OF 1

The only meeting that connects the ENTIRE ecosystem. Our partnership with World Stem Cells Summit means that you can now meet biopharma leaders as well as KOLs from academia, science and the clinic.



THE LARGEST SHOWCASE OF GROUND-BREAKING SOLUTIONS!

Meet 150+ of the most innovative solution and technology providers who will help you to overcome your business challenges!



DECISION MAKERS & MUCH MORE!

Meet the technical guru's who will help streamline and advance your business processes. Brainstorm with 'super users' and join tailored training sessions.

“ A GREAT WAY TO EXPAND NETWORK WITH GLOBAL EXPERTS IN CELL AND GENE THERAPY WHO ARE FACING SIMILAR CHALLENGES. ”

STEVEN GOODMAN, DIRECTOR, STRATEGY AND ENGAGEMENT, GSK



PREMIUM PARTNERING IN THE WINTER SUN

Meet more decision makers in 4 days than you can in 4 months! 1,200+ attendees, 200+ speakers, 100+ exhibitors – meet your next business partners, suppliers, and competitors.



HANDS-ON TECHNOLOGY DEMONSTRATIONS

Experience hands-on methods for finding creative solutions to business problems. Take a journey through 4 dedicated exhibition features - The Bioprocessing Hub, The Supply Chain Hub, the Immuno-Oncology Hub and The Translation Academy.

FUN, EFFECTIVE NETWORKING

Setting a brand new standard for networking. From themed cocktail receptions on the banks of the Miami Canals, our Japan Partnering Lunch or our already-legendary Phacilitate Miami Yacht Party, Phacilitate Leaders Forum 2018 will support your partnering activities like never before.

GENUINE MUST ATTEND



Independent research from AMR International scored the event 4.5/5 - join 'the world's leading partnering event'

“Rated Excellent”

PRICELESS STRATEGIC & TACTICAL BUSINESS INSIGHT

Stay ahead of the game. Understand successful business and commercialization models. Identify future technologies and trends. Capitalize on opportunities!

Meet the Trainers



Dr Anthony Davies, *President,*
Dark Horse Consulting

After training as a biochemist, chemical engineer and molecular biologist, Anthony Davies has worked in the cell and gene therapy field for some 20 years. Anthony is now Executive Chairman of Dark Horse Consulting, a boutique consulting practice which he founded in 2014, where he focuses on strategic CMC and product development issues in cell and gene therapy.



Jerrod Denham, *Principal & Senior*
Consultant, Dark Horse Consulting, Inc

After training at UCLA in Molecular Biology and Physiological Sciences, Jerrod Denham has worked in the cell therapy industry for 18 years with increasing roles of responsibility. Jerrod is now a Principal and Senior Consultant at Dark Horse Consulting, where he focuses on upstream and downstream process engineering for cell and gene therapy products.



Christopher Bravery, *Director,*
Advanced Biologicals Ltd

Christopher founded Consulting on Advanced Biologicals Ltd at the end of 2009 in order to focus his activities within the Regenerative Medicine sector. Christopher has spent most of his career working in regenerative medicine; starting with a PhD in xenotransplantation immunology. Christopher was involved with national implementation of the new Advanced Therapies Regulation and also involved through his participation in the CHMP's cell products working party (CPWP) in implementation at the EMA level including drafting guidelines.



Mark Metzke, *Associate,* Knobbe Martens

Mark A. Metzke has been an intellectual property attorney at Knobbe Martens since 2011. He has a client practice with a focus on patent prosecution and strategic portfolio management in the pharmaceutical and biotechnological fields. Mark earned his Ph.D. from at the University of California, Irvine, researching synthetic gene delivery vectors and biomaterials. He earned his J.D. from UCLA Law, where he focused on intellectual property law and was the Editor-in-Chief of the Journal of Law and Technology.



Jason Gersting, *Partner,* Knobbe Martens

Jason Gersting is a partner in the Orange County office. He focuses on patent and trademark prosecution and strategic intellectual property portfolio management in the biotechnology and life science industries. Dr. Gersting earned his Ph.D. and J.D. from the University of Florida, where his research focused on role of fetal neuroendocrine signaling and prostaglandins in the initiation of labor and delivery at the conclusion of pregnancy. He also earned his master's degree by developing methods to analyze differential expression of calcium channels in response to disease or injury.



Full Day Comparability Workshop

Christopher Bravery

9:00 – 17:00, Monday 22 January

\$895

Change is inevitable and necessary both in development and over the post-approval product lifecycle. Whenever changes are made it is necessary to confirm they do not adversely impact the quality and therefore safety and efficacy of the product; this requires data beyond meeting current specifications. With any biological product this is challenging, for cell, gene and tissue products that cannot be fully characterised the challenges are greater still. Concerns about comparability undertaken during development are common issues at approval with significant comparability concerns raised during 12 of the 17 ATMP submissions to the EMA. Such questions often delay market approval or contribute to failure to get approval. This course explains what comparability is and how to develop a successful comparability protocol.

Workshop Learning Overview:

- What is comparability?
- Why is meeting existing specifications not comparability?
- How do I apply the principles of comparability to highly variable products?
- Case studies: Common mistakes with comparability and their consequences.
- Interactive exercise: Spot the weaknesses and propose improvements to a worked comparability study

Half Day Quality-by-Design

Anthony Davies & Jerrod Denham

9:00 – 12:30, Monday 22 January

\$495

Quality by Design (QbD) is a science- and risk-based approach to pharmaceutical development. Applied to manufacturing processes, it is intended to ensure a rational and cost-effective approach to product quality. Both the EMA and FDA have systematically assessed QbD elements of regulatory filings and, especially since the FDA's 2011 Process Validation Guidance and the ICH's Q8 through Q11, it has become an intrinsic part of regulatory guidance.

However, understanding and adoption of the principles of QbD has remained relatively limited in the field of cell and gene therapy. We strongly believe that its methodologies are critical to the successful development of ATMPs and that they should be incorporated as early as possible into the science of manufacturing. This workshop will both demystify the fundamentals of QbD and provide concrete examples of its application to this field. You will leave with a crystal-clear understanding of P Diagrams, RAMM matrices, the QTPP and many more tools which you can immediately use to improve your products and processes.

Half Day Authoring the Common Technical Document

Christopher Bravery

11:15 – 15:30, Thursday 25 January

\$495

The ICH Common Technical Document was developed to standardize the way information is shared with regulators, and is accepted or mandatory by agencies following ICH (e.g. EU, US, Japan, Canada etc). The CTD is used for all types of medicinal product but the purpose of each section may not always be clear for ATMP. This workshop aims to clarify:

- What the purpose of each section is
- Whether the section is descriptive or data-driven
- What sorts of data are expected
- Tips and considerations for style, use of figures and tables, etc.

Half Day Intellectual Property 101

Mark Metzke & Jason Gersting

13:30 – 17:00, Monday 22 January

\$495

This session is geared towards providing an overview of intellectual property, including trademarks, design patents and utility patents, geared especially for those new to the process. The course will include a general overview of different types of IP that a company may employ to develop a robust portfolio to build and protect their brand, as well as their contemplated commercial products. The session will emphasize utility patents (their specifications and claims), different types of applications (provisionals, non-provisionals, continuations, divisionals, and continuations-in-part), and what patents do and do not allow patentees to do (enforcement versus the ability to practice patents). The session will cover the nuts and bolts of the patenting process from conception of an invention, to filing/claiming strategies, to prosecution, patenting, and considerations for continued filings, with an aim to touch on domestic and international strategies at a high level. Time permitting, an interactive session will be held where filing strategies are developed for hypothetical inventive entities.

Key Benefits:

- High level overview of different types of IP
- Distilled overview of utility patents and the patenting process
- Overview of patent application types including considerations on when to file
- Interactive session to reinforce the course

CPD Accredited



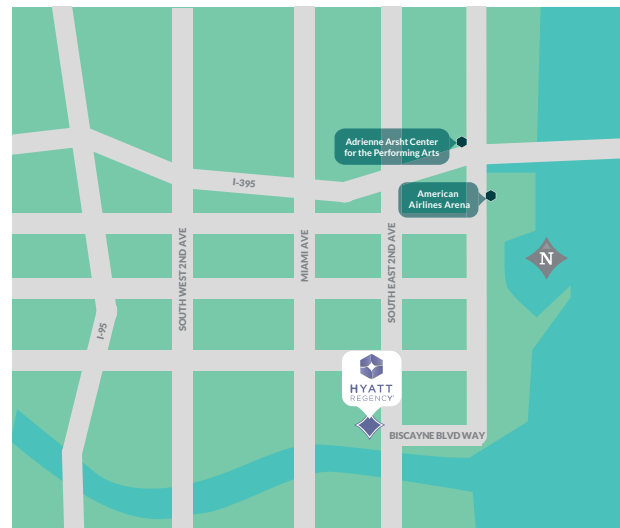
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	Full Rate	\$995	\$1,595
Pharma/Biotech/Clinician	Early Bird	\$1,595	\$2,695
	Full Rate	\$1,795	\$2,895
Service Providers/Consultants/Lawyers	Full Rate	\$2,495	\$3,995
Students	Early Bird	\$445	N/A
	Full Rate	\$545	N/A
Exhibition only	Full Rate	\$545	

OPTIONAL EXTRAS

WSCS Stem Cell & Regenerative Medicine Awards Dinner Ticket, \$150

Yacht Party Ticket, \$300

Phacilitate Training (see pages 10-11)

Comparability Workshop, Monday 22 Jan, 09:00-17:00, \$895

Quality-by-Design, Monday 22 Jan, 09:00-12:30, \$495

Intellectual Property 101, Monday 22 Jan, 13:30-17:00, \$495

Authoring the Common Technical Document, Thursday 25 Jan, 11:15-15:30, \$495

Automation Report: The ROI of Automation in Cell-Based Therapy Bioprocessing and Supply Chains

At the Phacilitate Special Interest Group: Automation held in 2017, the focus was firmly on creating a roadmap towards 'Automation in Cell-based Therapy Manufacturing and Supply Chain'.

Each of the working groups covered a specific theme or question and was tasked with arriving at a specific 'output', conclusions, or better yet, action points for the sector as a whole to take forward and utilize in helping drive progress, whether that be in the realm of regulatory guideline development, standardization, technology development, or defining strategic models for engagement for all stakeholders.

In this exclusive report produced by Phacilitate in partnership with BioLacuna, we explore the role of automation in manufacturing risk management. Add your copy when registering for the exclusive discounted attendee rate of \$1,100!

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