

# RegenBio Summit: Transforming Next-Gen Biotherapeutics 2024

Ponte Vedra Beach, Florida

December 9, 2024 to December 11, 2024

Eastern Standard Time

## Day 1 Monday, December 9, 2024

8:00 AM **Breakfast, Registration & Exhibits**

9:00 AM **Welcome Announcements**  
Julie G. Allickson, Ph.D. and Saranya P. Wyles, M.D., Ph.D.

9:10 AM **Welcome to Mayo Clinic Florida**  
Kent R. Thielen, M.D.

9:15 AM **Keynote: Regulating Regenerative Therapies from IND to BLA**  
Peter Marks, M.D., Ph.D.

10:00 AM **Fireside Chat: Mistakes and Lessons Learned from FDA CBER Director's Desk. An Insight into Accelerated Approval Pathways**  
Moderator: Julie G. Allickson, Ph.D.  
Panelist: Peter Marks, M.D., Ph.D.

10:30 AM **Laryngeal Transplantation and Regeneration: Breaking the Silence**  
David G. Lott, M.D.

11:00 AM **Regenerative Transplantation: A New Paradigm**  
Giuseppe Orlando, M.D., Ph.D.

11:30 AM **Lunch**

12:30 PM **7 advances in CAR-T cell therapy at Mayo Clinic | Inside Mayo Clinic Research**  
Hong Qin, M.D., Ph.D.

1:00 PM **Fireside Chat: Impact of Generative Artificial Intelligence on Cell and Gene Therapy**  
Moderator: Peter A. Noseworthy, M.D., M.B.A.  
Panelist: Rickey E. Carter, Ph.D.

**Regenerative Orthopedics and Musculoskeletal: From Care to Cure**  
Moderator: Daniel B. F. Saris, M.D., Ph.D.

1:30 PM **Hip RECLAIM: A Phase I Safety and Feasibility Trial of REcycled CartiLage Auto/Allo IMplantation for the Treatment and Repair of Focal Hip Cartilage Defects**  
Daniel B. F. Saris, M.D., Ph.D.

1:45 PM **Regenerative Medicine Clinical Trials in Sports Medicine and Orthopedics**  
Brennan J. Boettcher, D.O.

2:00 PM **Clinical Regenerative Medicine at Mayo Clinic**  
Shane A. Shapiro M.D.

2:15 PM **Break and Exhibits**

**Tissue Engineering Session**  
Moderators: David G. Lott, M.D.

2:45 PM **Plenary Highlight: Can We Grow a Personalized Heart**  
Doris Taylor, Ph.D.

3:15 PM            **3D Bioprinting Skin**  
Saranya P. Wyles, M.D., Ph.D.

3:30 PM            **Fireside Chat: Exosomes, Are We There Yet?**  
Moderator: Abba Zubair M.D. Ph.D.  
Panelist: Atta Behfar, M.D., Ph.D., and Jon Rowley Ph.D.

3:45 PM            **Defining the Issues: Approaches to Centralized,  
Decentralized, and Point of Care Manufacturing of  
Regenerative Medicine Products**  
Richard McFarland, Ph.D., M.D.

4:15 PM            **Day 1 Closing Comments**

4:30 PM            **Adjourn**

5:15 PM            **Welcome Reception**  
**Women in Translational Science Award**

**Day 2**                      **Tuesday, December 10, 2024**

8:00 AM                      **Breakfast and Exhibits**

8:00 AM                      **Breakfast with Experts**

**FDA Unveiled: Navigating U.S. Regulations and Regulators**

Drew M. Witter, M.S., RAC

**Harmonizing Excellence: A Global Odyssey to Meet GMP Requirements**

Craig Hasilo

**Precision Engineering of Regenerative Biotherapeutics: A Focus on Process Development and Biomanufacturing**

Cynthia E. Wilkins, Ph.D.

**Precision Engineering of Regenerative Biotherapeutics: A Focus on Process Development and Biomanufacturing**

Snigdha Rai

**Building a Culture of Quality: The Role of QA and QC**

Tony W. DeFusco

**Building a Culture of Quality: The Role of QA and QC**

Cameron E. Jones

9:00 AM                      **From the Desk of Mayo Clinic Center for Regenerative Biotherapeutics Medical Director**

William Faubion, M.D.

9:30 AM                      **Panel: Ethics in Gene Therapy**

Moderators: Michelle McGowan, Ph.D.

Panelist: Megan Allyse, Ph.D., and Scott Wright M.D.

10:00 AM

**Break & Exhibits**

10:30 AM

**Keynote: Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa – First FDA-Approved Topical Gene Therapy**

M. Peter Marinkovich, M.D.

11:00 AM

**Fireside Chat: Mistakes and Lessons Learned From Startups. An Insight into the Success Path of Krystal Biotech, Inc.**

Moderator: Saranya P. Wyles, M.D., Ph.D.

Panelist: M. Peter Marinkovich, M.D.

11:20 AM

**Addressing Challenges in Translation of Cell and Gene Therapy**

Uma Lakshmipathy Ph.D.

11:40 AM

**Mayo MedTech Accelerator: The Future of Cell and Gene Therapy**

Marianne van der Steen, Ph.D.

12:00 PM

**Lunch/Exhibits**

**Cell and Gene Therapy Plenary**

**Moderator:** Sanjay Misra, M.D.

1:00 PM

**Role of Stem Cells in Vascular Injury**

Sanjay Misra, M.D.

1:15 PM

**The Allure of Biomanufacturing Tregs for Inflammatory Bowel Disease**

William Faubion, M.D.

1:30 PM

**CELLTOP: An Update from Autologous Adipose Derived Mesenchymal Stem Cells in the Treatment of Paralysis Due to Traumatic Spinal Cord Injury**

Mohamad Bydon, M.D.

1:45 PM **Tumor-Agnostic Cellular Therapies**  
Michael Gustafson Ph.D.

2:00 PM **An Autologous Dendritic Cell Vaccine Targeting Folate Receptor Alpha in Patients with Ovarian Cancer**  
Matthew S. Block, M.D., Ph.D.

2:15 PM **Panel Discussion**  
Moderators: William Faubion, M.D. and Sanjay Misra, M.D.  
Panelist: Session Presenters

2:30 PM **Fireside Chat: Next Gen Workforce Development**  
Maggie A. DiGuardo, M.D., Saranya P. Wyles, M.D., Ph.D.,  
Elena Maryamchik, M.D., M.B.A.

3:00 PM **Break and Exhibits**

**Showcase: Mayo Clinic Florida**  
Moderators: Wenchun Qu, M.D., Ph.D.

3:30 PM **Beyond the Clinic: The Impact of Mayo Clinic Florida Center for Regenerative Biotherapeutics**  
Alfredo Quinones-Hinojosa, M.D., Brian Hultgren

3:45 PM **Differentiation of Human Induced Pluripotent Stem Cells to Functional Brain Cells**  
Tsuneya Ikezu, M.D., Ph.D.

4:00 PM **Mayo Clinic RNA Discovery and Therapeutics Program: Premise, Promise and Progress**  
Nilufer Taner, M.D., Ph.D.

4:15 PM

**Aptamers: Unlocking the Potential of Immunotherapy and Regenerative Medicine**

Abba Zubair, M.D., Ph.D.

4:30 PM

**Regenerative Clinical Trial Portfolio (Non-engineered Cell Therapy) Moderated Discussion**

Moderators: Abba Zubair, M.D., Ph.D.

Panelist:

Wenchen Qu, M.D., Ph.D.- Regenerative Rehabilitation

LaTonya J Hickson, M.D. – Regenerative Nephrology

Sanjeet S. Grewal, M.D. – Regenerative Neurology

Katherine J. Bodiford, M.D. – Regenerative Dermatology

Sam Farres, M.D. – Regenerative Vascular Surgery

5:00 PM

**Closing and Adjourn**

5:05 PM

**Poster Session & Networking**

6:00 PM

**Adjourn**

**Day 3**      **Wednesday, December 11, 2024**

8:00 AM      **Breakfast and Exhibits**

9:00 AM      **Opening Remarks**  
Saranya P. Wyles, M.D., Ph.D., and Praneetha R. Elugunti,  
M.H.A., M.B.A.

9:05 AM      **Keynote: Exploring the Promise of CRISPR Therapeutics In Vivo and Cell Therapy Applications**  
Birgit Schultes, Ph.D.

9:35 AM      **Fireside Chat: Mistakes and Lessons Learned from Startups. An insight into the success Path of Intellia Therapeutics, Inc.**  
Moderator: Laura J. Lambert, Ph.D.  
Panelist: Birgit Schultes Ph.D.

10:05 AM      **Plenary Highlight: Transforming Lives with Personalized Cancer Therapies**  
Introduction: Alina R. Oancea  
Speaker: Bruce Levine, Ph.D.

10:35 AM      **Mayo Clinic Highlight: New Directions in Engineered Cell Therapy**  
Saad J. Kenderian, M.B., Ch.B.

11:05 AM      **Fireside Chat: Immunotherapy**  
Moderator: Saad J. Kenderian, M.B., Ch.B.  
Panelist: Mohamed A. Kharfan Dabaja, M.D., M.B.A.

11:20 AM      **Fireside Chat: Patient Access for Cell and Gene Therapies – Challenges and Future Solutions**  
Moderator: Julie Allickson, PhD  
Panelist: Miguel Forte, Ph.D., Bruce L. Levine, Ph.D.



11:45 AM **Healthcare Innovation – Discussion**  
Gloria R. Olivier, Ph.D., Rupa Pike, Ph.D., Sarah Creviston

12:10 PM **Lunch & Exhibits**

**iPSC Therapy Plenary**  
Moderator: Zachary Resch, Ph.D.

1:10 PM **A Vision to Grow Stem Cells into Retinal Pigment Epithelium (RPE) for Eyesight**  
Kapil Bharti, Ph.D.

1:25 PM **The Path to a Cure for Type 1 Diabetes: What's Next in Cell Therapy and Beyond?**  
Quinn P. Peterson, Ph.D.

1:40 PM **Closer to Precision Cardiology With iPSCs**  
Max Gnecci M.D. Ph.D.

1:55 PM **iPSC-Derived Cardiac Lineages For Heart Repair in Congenital Heart Disease**  
Timothy Nelson, M.D., Ph.D.

2:10 PM **Panel Discussion: iPSC**  
Moderator: Dennis Wigle, M.D., Ph.D.  
Panelist: Session Presenters

2:25 PM **Closing Remarks**  
Julie G. Allickson, Ph.D., and Saranya P. Wyles, M.D., Ph.D.

2:30 PM **Adjourn**