



“Cellular Therapies and Transfusion Medicine in Trauma and Critical Care – Looking Towards the Future”

DAY 1 Transfusion Medicine in Trauma and Critical Care

The goal of sessions 1-4 is to discuss and understand pertinent issues in transfusion medicine related to bleeding and acutely injured trauma patients. Topics of discussion will include hemorrhage control, development and transfusion of novel blood products, whole blood, and blood safety.

7:00am – 5:00pm Registration Area Open: Badge and Materials Pickup
11th Floor Lobby

7:00am Breakfast – *Crystal Lounge – 11th Floor*

7:45am – 7:50am **Welcome**
Shibani Pati, MD, PhD
*Associate Professor and Scientific Director of Cellular Therapies
Blood Systems Research Institute and University of California San Francisco*

SESSION 1: Hemorrhage Control and Transfusion Strategies in Trauma

Moderators:

John Holcomb, MD FACS
*COL US Army (Ret)
Prof. of Surgery at UTHSC-Houston, TX
Center for Translational Injury Research
The University of Texas Medical School
at Houston
Chief Medical Officer Prytime Medical*

Shibani Pati, MD, PhD
*Associate Professor and Scientific
Director of Cellular Therapies
Blood Systems Research Institute and
University of California San Francisco*

7:50am – 8:15am **Introduction**
**Transfusion Medicine and Novel Therapies in Trauma and Critical Care:
Lessons Learned**

John Holcomb, MD FACS
*COL US Army (Ret)
Prof. of Surgery at UTHSC-Houston, TX
Center for Translational Injury Research
The University of Texas Medical School at Houston
Chief Medical Officer Prytime Medical*

8:15am – 8:40am **Current Status & Future Directions of Military-Civilian Efforts in Bleeding
Control for Severe Injury**

COL Todd E. Rasmussen, MD
*Colonel USAF MC Director, US Combat Casualty Care Research Program
Fort Detrick, MD
Professor of Surgery Uniformed Services University Bethesda, Maryland*



- 8:40am – 9:05am** **Blood Products, Looking Forward and Backward**
Paul Ness, MD
Director, Division of Transfusion Medicine
Johns Hopkins School of Medicine
Editor, Transfusion
- 9:05am – 9:30am** **Universal Pathogen Inactivated Freeze Dried Plasma for Early Treatment of Hemorrhagic Shock**
Laurence Corash, MD
Co-Founder, Chief Scientific Officer and Corporate Director
Cerus Corporation
- 9:30am – 9:55am** **Mirasol PRT Pathogen Reduction for Transfusion Safety**
Heather F. Pidcock, MD, PhD
Director, Global Clinical Safety & PRT Scientific Affairs
Terumo BCT
- 9:55am – 10:10am** **COFFEE BREAK - Sponsor Exhibit - Crystal Lounge, 11th Floor**

SESSION 2: Novel Blood Products and Adjuncts to Resuscitation in Trauma

Moderators:

Jeffrey McCullough, MD
Professor Emeritus,
Department of Laboratory
Medicine and Pathology
University of Minnesota

Michael A Dubick PhD, FCCM, FACN
Chief, Damage Control Resuscitation Program
US Army Institute of Surgical Research
San Antonio, Texas

- 10:10am – 10:35am** **Use of Novel Blood Products for Military Casualties in the Netherlands**
LtCol Jon Badloe, MD
Consultant in Transfusion Medicine
Commander, Netherlands Military Blood Bank
- 10:35am – 11:00am** **Frozen RBCs, A Novel Approach to Disaster Scenarios**
Martin Schreiber, MD
COL, MC, USAR
Professor of Surgery & Chief of Trauma, Critical Care & Acute Care Surgery
Oregon Health & Science University
- 11:00am – 11:25am** **The Protective Effect of Tranexamic Acid in Bleeding Trauma Patients: Understanding Molecular Mechanisms**
Joseph F. Rappold, MD FACS
CAPT MC USN (Ret)
Chief, Acute Care Surgery
Trauma Medical Director
Department of Surgery
Tufts University School of Medicine
Maine Medical Center
- 11:25am – 11:40am** **Q&A**
- 11:40am – 12:40pm** **LUNCH- Commandant's Room, 10th Floor**



SESSION 3: Novel Blood Products and Adjuncts to Resuscitation in Trauma *(continued)*

Moderators:

Jaro Vostal, MD, PhD
*Chief, Laboratory of Cellular Hematology
Division of Hematology Research and
Review, OBRR
Center for Biologics Evaluation and
Research, FDA*

Ralph Vassallo, Jr, MD
*EVP / Chief Medical and Scientific Officer
Blood Systems, Inc.*

12:40pm – 1:05pm Potential Impact of a Lyophilized Platelet Derived Hemostatic Agent on Treatment of Hemorrhage and Other Novel Applications

Michael Fitzpatrick, PhD
*COL USA (Ret)
President & Director of Research and Development
Cellphire Inc.*

1:05pm – 1:30pm CRYOPRESERVED PLATELETS (CPP) Properties, Use, and Clinical Trials

Larry Dumont, MBA, PhD
*Senior Investigator and Associate Director
Blood Systems Research Institute-Denver*

1:30pm – 1:55pm Cold Stored Platelets

Heather F. Pidcoke, MD, PhD
*Director, Global Clinical Safety & PRT Scientific Affairs
Terumo BCT*

1:55pm – 2:20pm Whole Blood Transfusion in Trauma

Shawn Nessen, DO
*COL, MC, USA
Commander US Army Institute for Surgical Research
San Antonio, TX*

2:20pm – 2:35pm COFFEE BREAK - Sponsor Exhibit - Crystal Lounge, 11th Floor

SESSION 4: Novel Blood Products and Adjuncts to Resuscitation in Trauma *(continued)*

Moderators:

Paul Ness, MD
*Director, Transfusion Medicine
Johns Hopkins Hospital
Editor, Transfusion*

Shawn Nessen, DO
*COL, MC, USA
Commander US Army Institute for Surgical Research
San Antonio, TX*

2:35pm – 3:00pm French Lyophilized Plasma in Prehospital and in Emergency Unit for Massive Hemorrhage Management

Christophe Martinaud MD, PhD
*Professor in Hematology, Transfusion and Cell Therapy
French Military Blood Institute
Clamart, France*



3:00pm – 3:25pm Plasma and Dried Plasma Products After Trauma: Alternative Mechanisms and Benefits Beyond Bleeding Control

Rosemary Kozar, MD, PhD, FACS
*Professor and Associate Director of Shock Trauma Anesthesia Research (STAR),
University of Maryland*

3:25pm – 3:50pm German Lyoplas

Thomas A. Zeiler, MD
*Medical Director of the Center for Transfusion Medicine of the German Red Cross
Managing Director of the Blood Service West of the German Red Cross
Ratingen, Germany*

3:50pm – 4:15pm Clinical Use of Dried Plasma in Israel

COL Elon Glassberg, MD
*Head, The Trauma and Combat Medicine Branch
Israel Defense Forces Medical Corps*

4:15pm – 4:40 pm FDA Current Considerations on Evaluation of Novel Transfusion Products

Jaro Vostal, MD, PhD
*Chief, Laboratory of Cellular Hematology
Division of Hematology Research and Review, OBRR
Center for Biologics Evaluation and Research, FDA*

4:40pm – 5:40 pm Panel on Production of Dried and Lyophilized Plasma for Use in Trauma Patients

Moderators:

LTC (Ret) Wilbur W. Malloy, MA, MLS (ASCP) SBB
*Health Science Program Manager, Hemorrhage and
Resuscitation, Blood Products, CDMRP
USAMRMC, Ft Detrick MD*

COL (Ret) Richard Gonzales, MS, MT(ASCP)SBB
*Director, Grant Management & Government
Sponsored Research
TerumoBCT*

Panelists for dried plasma:

Lisa Buckley, MPH
*Director of Clinical Trials & Regulatory Affairs
OHSU
Representing Velico Medical*

Christophe Martinaud, MD, PhD
*Professor in Hematology, Transfusion and Cell
Therapy
French Military Blood Institute
Clamart, France*

Chockalingam Palaniappan, PhD
*Executive VP of Innovation and Development
Terumo BCT*

Thomas Zeiler, MD
*Medical Director of the Center for Transfusion
Medicine of the German Red Cross
Managing Director of the Blood Service West of the
German Red Cross, Ratingen, Germany*

Michael Galiger
*Vice President, Operations
Entegriion Inc.*

Adonis Stassinopoulous, PhD
*VP, Global Scientific Affairs and Research
Cerus Inc.*



DAY 2 Cellular Therapies in Trauma and Critical Care Medicine

The goal of Sessions 5-8 is to discuss and understand more about the state of the science of cellular therapies in trauma and critical care. Pre-clinical and clinical studies will be presented in hemorrhagic shock, neurotrauma, acute lung injury, acute kidney injury, wound healing, and tissue regeneration.

7:00am Registration Area Open: Badge and Materials Pickup

7:00am **BREAKFAST – Crystal Lounge – 11th Floor**

7:55am – 8:00am **Welcome and Introduction**

Shibani Pati, MD, PhD

Associate Professor and Scientific Director of Cellular Therapies

Blood Systems Research Institute and University of California San Francisco

SESSION 5: Cellular Therapies for Tissue and Organ Repair in Trauma and Critical Care

Moderators:

Michael Matthay, MD

Professor of Medicine and Anesthesia

Director of the Critical Care Medicine Training

Associate Director of the Intensive Care Unit

University of California at San Francisco

David Livingston, MD

Professor and Chief, Division of Trauma and Surgical

Critical Care

Rutgers-New Jersey Medical School

8:00am – 8:25am **Next-Generation MSCs in Wound Repair and Revascularization**

Jan Nolte, PhD

Professor and Stem Cell Program Director

UC Davis Medical Center University of California Davis

Editor, Stem Cells

8:25am – 8:50am **Identifying a Fibroblast Lineage Responsible for Fibrosis During Wound Healing**

Michael Longaker, MD

Professor and Chair, Surgery - Plastic & Reconstructive Surgery

Stanford University

8:50am – 9:15am **Mesenchymal Stromal Cells: Biology and Potential Therapeutic Value for ARDS**

Michael Matthay, MD

Professor of Medicine and Anesthesia

Director of the Critical Care Medicine Training

Associate Director of the Intensive Care Unit

University of California at San Francisco

9:15am – 9:40am **Stem Cell Extracellular Vesicles in Lung Injury and Repair**

Jae Woo Lee, MD

Associate Professor, University of California San Francisco

Department of Anesthesiology University of California San Francisco



9:40am – 10:05am **Cellular Therapies in AKI and CKD and Reduction of Diabetic Patient Vulnerability and Improved Outcomes by Induction of Durable Glycemic Control with Engineered Neo-Islets**

Christof Westenfelder, MD, PhD

Professor of Medicine at the University of Utah Health Sciences Center

Chief, Section of Nephrology at the George E. Wahlen VA Health Sciences Center

10:05am – 10:20am **COFFEE BREAK - Sponsor Exhibit - Crystal Lounge, 11th Floor**

SESSION 6: Cellular Therapies for Tissue and Organ Repair in Trauma and Critical Care (continued)

Moderator:

Jan Nolta, PhD

Professor and Stem Cell Program Director

UC Davis Medical Center University of California Davis

Editor, Stem Cells

10:20am – 10:45am **Exosomes as an Off-The-Shelf Therapy for Critical Care and Trauma**

Darwin Prockop, MD, PhD

Professor and Director, Institute for Regenerative Medicine

Texas A&M University

10:45am – 11:10am **Mesenchymal Stem Cells Reverse Anemia and Improve Lung Healing Following Trauma, Hemorrhagic Shock and Stress**

David Livingston, MD

Professor and Chief, Division of Trauma and Surgical Critical Care

Rutgers-New Jersey Medical School

11:10am – 11:35am **Cellular Therapies, Gene Editing and Precision Medicine**

Kyle Fink, PhD

Assistant Professor – Department of Neurology Stem Cell and Regenerative Medicine program

UC Davis Medical Center

University of California Davis

11:35am – 12:00pm **California Institute For Regenerative Medicine**

Maria T. Millan, MD

Vice President of Therapeutics

California Institute For Regenerative Medicine (CIRM)

12:00pm – 12:15pm **Q&A**

12:15pm - 1:15pm **LUNCH- Commandant's Room, 10th Floor**



SESSION 7: Cellular Therapies in Neurotrauma

Moderators:

Pramod Dash, PhD
Professor, Dept of Neurobiology and Anatomy
Scientific Director, Mission Connect
UT Houston

Charles Cox Jr., MD
Professor of Pediatric Surgery
Director, Program in Children's Regenerative Medicine
University of Texas- Houston

1:15pm – 1:40pm **MAPCs, Inflammation and Life: Right Place at the Right Time Can Make All the Difference?**

Robert Mays, PhD
Head of Neurosciences and Vice President of Regenerative Medicine
Athersys, Inc.

1:40pm – 2:05pm **Results of a Trial of Autologous Manufactured Schwann Cells in Acute SCI and Update on the Status of CT for SCI in North America**

James Guest, MD, PhD
Clinical Professor of Neurological Surgery
Neurological Surgery and the Miami Project to Cure Paralysis
University of Miami Miller School of Medicine

2:05pm – 2:30 pm **Human Stem Cell-derived Interneurons as a Therapeutic for Spinal Cord Injury**

Alpa Mahuvakar, PhD
Research Associate Professor
Department of Neurosurgery, University of California San Francisco

2:30pm – 2:55pm **Embryonic Stem Cell-derived Oligodendrocyte Progenitors for the Treatment of Spinal Cord Injury**

Casey Case, PhD
Senior Vice President Research and Preclinical Development
Asterias Biotherapeutics

2:55pm – 3:10pm **COFFEE BREAK - Sponsor Exhibit - Crystal Lounge, 11th Floor**

SESSION 8: Cellular Therapies in Neurotrauma continued.

Moderators:

Pramod Dash, PhD
Professor, Dept of Neurobiology and Anatomy
Scientific Director, Mission Connect
UT Houston

Charles Cox Jr., MD
Professor of Pediatric Surgery
Director, Program in Children's Regenerative Medicine- Department of Pediatric Surgery
University of Texas- Houston

3:10pm – 3:35pm **MSC for TBI: Attempting to Relate In Vitro Activity with In Vivo Efficacy**

Scott Olson, PhD
Assistant Professor Dept. of Pediatric Surgery
University of Texas Houston



3:35pm – 4:00pm

Targeting the Endotheliopathy of Trauma with Stem Cell Therapies

Shibani Pati, MD, PhD

Associate Professor and Scientific Director of Cellular Therapies

Blood Systems Research Institute and University of California San Francisco

4:00pm – 4:25pm

Clinical Trials in TBI

Charles Cox Jr., MD

Professor of Pediatric Surgery

Director, Program in Children's Regenerative Medicine- Department of Pediatric Surgery

University of Texas- Houston

4:25pm - 4:50pm

FDA/CBER Regulatory Guidance in Cellular Therapies

Brenton McCright, PhD

Research Biologist

FDA/CBER

Office of Tissues and Advances Therapies

Division of Cellular, and Gene Therapies



4:50pm – 5:50pm Panel Discussion:

The Challenges of Conducting Stem Cell/Novel Blood Product Trials in Trauma and Critical Care Medicine- Academic, Industry, Blood Bank and Regulatory Perspectives

This session is a panel discussion led by Dr. Martin Schreiber MD, Chief of Trauma, Critical Care & Acute Care Surgery at OHSU Portland and Dr. Laura Brosch PhD, Director of the Office of Research Protections, US Army Medical Research and Materiel Command. Both are leaders in the field who have successfully designed and run large clinical trials in trauma and critical care. This panel will discuss critical issues in the design and execution of trials for cellular therapies and novel blood products in trauma and critical care medicine. Topics include regulatory hurdles, timing and dose selection of stem cell therapies, relevant endpoints, inclusion and exclusion criteria, funding, and issues such as exception from informed consent (EFIC).

Moderators:

Martin Schreiber, MD
COL MC USAR
Professor of Surgery & Chief of Trauma, Critical Care & Acute Care Surgery
Oregon Health & Science University

Laura Brosch, PhD RN
COL US Army (Ret)
Director, Office of Research Protections (ORP)
Director, ORP Human Research Protection Office (HRPO)
US Army Medical Research and Materiel Command

Participants in Panel:

Mitchell Jay Cohen, MD, FACS
Chair of Surgery
Denver Health Medical Center
Professor and Vice Chair
Department of Surgery
University of Colorado

Donald Jenkins, MD
COL USAF (Ret)
Professor/Clinical, Division of Trauma and Emergency Surgery
Vice Chair for Quality, Department of Surgery
Associate Deputy Director, Military Health Institute
UT San Antonio, San Antonio, TX

Charles Cox Jr., MD
Professor of Pediatric Surgery
Director, Program in Children's Regenerative Medicine- Department of Pediatric Surgery
University of Texas- Houston

Ralph Vassallo, Jr, MD
EVP / Chief Medical and Scientific Officer
Blood Systems, Inc.

John Holcomb, MD, FACS
COL US Army (Ret)
Prof. of Surgery at UTHSC-Houston, TX
Center for Translational Injury Research
The University of Texas Medical School at Houston
Chief Medical Officer Prytime Medical

Michael Matthay, MD
Professor of Medicine and Anesthesia
Director of the Critical Care Medicine Training
Associate Director of the Intensive Care Unit
University of California at San Francisco



Day 3 Critical Issues in Translation for Cellular and Novel Therapies in Trauma and Critical Care

7:00am Registration Area Open: Badge and Materials Pickup

7:00am **BREAKFAST – Crystal Lounge – 11th Floor**

SESSION 9: Prehospital and Early Care of Trauma Patients

The goal of this session 9 and 10 is to focus upon the issues related to pre-hospital care and interventions in trauma patients. Early and pre-hospital administration of cellular therapies and blood products will be discussed with particular attention to clinical benefits and logistical capabilities in both military and civilian settings.

Moderators:

Joseph F. Rappold, MD, FACS
CAPT MC USN (Ret)
Chief, Acute Care Surgery
Trauma Medical Director
Department of Surgery
Tufts University School of Medicine
Maine Medical Center

Martin Schreiber, MD
COL MC US Army
Professor of Surgery & Chief of Trauma,
Critical Care & Acute Care Surgery
Oregon Health & Science University

8:00am – 8:25am **Introduction to Prehospital Early Care of Trauma Patients**

Martin Schreiber, MD
COL, MC, USAR
Professor of Surgery & Chief of Trauma, Critical Care & Acute Care Surgery
Oregon Health & Science University

8:25am – 8:50am **Blood Safety in Transfusion Medicine in the Context of Pre-hospital and Acute Care**

Steven Kleinman, MD
Clinical Professor of Pathology at U. British Columbia
Senior Medical Advisor to AABB
Vancouver, BC

8:50am – 9:15am **Benefits of Pre-Hospital Administration of Blood Products in Trauma**

Donald Jenkins, MD
COL USAF (Ret)
Professor/Clinical, Division of Trauma and Emergency Surgery
Vice Chair for Quality, Department of Surgery
Associate Deputy Director, Military Health Institute
UT San Antonio, San Antonio, TX

9:15am – 9:40am **Pre-hospital Administration of Novel Therapies in Trauma-PROHS Trial**

John Holcomb, MD
COL US Army (Ret)
Prof. of Surgery at UTHSC-Houston, TX
Center for Translational Injury Research
The University of Texas Medical School at Houston
Chief Medical Officer Prytime Medical



9:40am – 10:05am Adjunctive Therapies for the Early Management of Trauma Patients- VPA
Hasan Alam, MD
Professor and Head of General Surgery
University of Michigan

10:05am – 10:20am COFFEE BREAK - Sponsor Exhibit - *Crystal Lounge, 11th Floor*

SESSION 10: Prehospital and Early Care of Trauma Patients (continued)

Moderators:

Joseph F. Rappold, MD, FACS
CAPT MC USN (Ret)
Chief, Acute Care Surgery
Trauma Medical Director
Department of Surgery
Tufts University School of Medicine
Maine Medical Center

Martin Schreiber, MD
COL US Army
Professor of Surgery & Chief of Trauma,
Critical Care and Acute Care Surgery
Oregon Health and Science University

10:20am – 10:45am Unique Characteristics of Gamma Prime Fibrinogen Amenable to the Prehospital Care of Trauma Patients
David H. Farrell, PhD, FAHA
Professor of Surgery, School of Medicine, Department of Surgery
Oregon Health and Science University

10:45am -11:10am Oxygen Control in RBCs and Whole Blood
Andrew Dunham, PhD
Chief Scientific Officer
New Health Sciences

11:10am-11:35am Cell Based Therapies in the Crosstalk Between Coagulation and Inflammation.
Mitchell Jay Cohen, MD, FACS
Chair of Surgery
Denver Health Medical Center
Professor and Vice Chair
Department of Surgery
University of Colorado

11:35am-12:00pm Stay and Play vs. Scoop and Run, Do Trauma Patients Really Need All of These Interventions
Joseph Rappold, MD
CAPT MC USN (Ret)
Chief, Acute Care Surgery
Trauma Medical Director
Department of Surgery
Tufts University School of Medicine

12:00pm- 12:10pm Q&A Session

12:10pm – 1:10pm LUNCH- *Commandant's Room, 10th Floor*



SESSION 11: Stem Cell Processing, Production Storage and Quality

The goal of this session is to discuss issues that are critical to the production of stem cell therapies to be utilized in clinical trials and for long-term commercialization. Topics to be focused upon include cell production, cell sourcing, cryopreservation, large scale expansion, automated expansion, regulatory issues, standards for cell processing and production, quality and measures of potency.

Moderator:

David McKenna, MD
*Professor, University of Minnesota
Scientific & Medical Director
Molecular & Cellular Therapeutics
Minneapolis/Saint Paul, MN*

1:10pm – 1:20pm

Introduction

David McKenna, MD
*Professor, University of Minnesota
Scientific & Medical Director Molecular & Cellular Therapeutics
Minneapolis/Saint Paul, MN*

1:20pm – 1:45pm

Cell Production and Processing for Early Phase Clinical Trials

David Stroncek, MD
*Chief, Cell Processing Section
Department of Transfusion Medicine
NIH Clinical Center, Bethesda, MD*

1:45pm – 2:10pm

Establishing Platelet Lysate as a Dependable Option for Enabling Cell Production

Brad King, MS, MBA
*Director, Advanced Laboratory Products
Cook Regentec*

2:10pm – 2:35pm

Large Scale Production of MSCs

Jon Rowley, PhD
*Chief Executive & Technology Officer
RoosterBio, Inc.
Frederick, MD*

2:35pm – 3:00 pm

The Current and Future Role of the Blood Center in Cellular Therapy Production

Beth H. Shaz, MD
*Chief Medical and Scientific Officer
New York Blood Center
Adjunct Assistant Professor, Department of Pathology and Cell Biology
Columbia University Medical Center*

3:00pm – 3:15pm

COFFEE BREAK - Sponsor Exhibit - Crystal Lounge, 11th Floor



SESSION 12: Stem Cell Processing, Production Storage and Quality (continued)

Moderator:

David McKenna, MD
*Professor, University of Minnesota
Scientific & Medical Director
Molecular & Cellular Therapeutics
Minneapolis/Saint Paul, MN*

3:15pm – 3:40pm

Standards in Cellular Therapies

Naynesh Kamani, MD
*Vice President, Center for Cellular Therapies & Research
AABB, Bethesda, MD*

3:40pm – 4:05pm

Biopreservation Considerations for GMP Clinical Cell Manufacturing

Aby Mathew, PhD
*Senior Vice President and Chief Technology Officer
Biolife Solutions, Inc.
Bothell, WA*

4:05pm – 4:30pm

Potency Measures in Cell Therapies

Richard Schaefer, MD
*Assistant Professor and Medical Director
Head, Department Cell Therapeutics & Cell Processing, Head QC
German Red Cross Donor Service
Johan-Wolfgang-Goethe-University Hospital-Germany*

4:30pm – 4:55pm

The Role of Professional Organizations in Cell Therapy

Zbigniew “Ziggy” M Szczepiorkowski, MD, PhD
*Associate Professor of Pathology
Dartmouth Geisel School of Medicine
Hanover, New Hampshire
President AABB -2017*

4:55pm – 5:15pm

Discussion Q&A

5:15pm

Closing Remarks