

PATHWAYS TO CLINICAL

XENOTRANSPLANTATION

2019 WORKSHOP

AT UAB

UAB.EDU/XENOCON

THURSDAY & FRIDAY / HILTON BHAM

MARCH 21-22, 2019

808 20TH STREET SOUTH
BIRMINGHAM, ALABAMA

UABXENOCON2019

UAB SPEAKERS

GUEST SPEAKERS

GUERARD BYRNE, PH.D.
HERBERT CHEN, M.D.
DAVID K.C. COOPER, M.D., PH.D.
ZAK DORSEY, FACHE
DEVIN E. ECKHOFF, M.D.
RONALD A. EVANS
ROBERT S. GASTON, M.D.
JAMES KIRKLIN, M.D.
KARL KRAEBBER
JAYME LOCKE, M.D., MPH
CHRISTOPHER MCGREGOR, M.D.
MARTHA TANKERSLEY
JOSEPH TECTOR, M.D., PH.D.
MATTHEW TECTOR, PH.D.

JUDITH ARCIDIACONO
DAVID AYARES, PH.D.
LEO BÜHLER, PH.D.
JAY FISHMAN, M.D.
JON FRIEDMAN, M.D.
STANLEY JORDAN, M.D.
STUART KNECHTLE, M.D.
ROBERT MONTGOMERY, M.D.
JEFFREY PLATT, M.D.
WINSON TANG, M.D.

UAB SCHOOL OF
MEDICINE

The University of Alabama at Birmingham

AGENDA

THURSDAY, MARCH 21

8-8:05 a.m. WELCOME FROM UAB: Dr. Herbert Chen, Dr. Devin Eckhoff

8:05-8:10 a.m. WELCOME FROM IXA: Dr. Leo Bühler, President of the International Xenotransplantation Association

8:10-8:50 a.m. OPENING REMARKS: "Taking Xenotransplantation into the Clinic: A Personal View"
SPEAKER: Dr. Joseph Tector

8:50-9:35 a.m. SESSION 1: Xenotransplantation in Nonhuman Primates: The Present Position
MODERATOR: Dr. Joseph Tector

8:50-9:05 a.m. "Kidney Xenotransplantation"
Dr. David Cooper

9:05-9:20 a.m. "Cardiac Xenotransplantation"
Dr. Christopher McGregor

9:20-9:35 a.m. Discussion

9:35-10 a.m. BREAK

10 a.m. – 12:30 p.m. SESSION 2: Donor Genetic Engineering and Regulatory and Potential Infectious Risk Considerations
MODERATOR: Dr. Joseph Tector

10-10:40 a.m. "Genetic-Engineering Techniques for Donor Pigs and Regulatory Implications"
Dr. David Ayares

10:40-11:20 a.m. "Organ-Source Pig Health Status and Potential Infectious Risks"
Dr. Jay Fishman

11:20 a.m. – Noon "Histocompatibility Testing for Xenotransplantation"
Dr. Matthew Tector

Noon – 12:30 p.m. Round-Table Panel Discussion
Dr. David Ayares, Dr. Leo Bühler, Dr. Jay Fishman, Dr. Matthew Tector

12:30-1:15 p.m. LUNCH

1:15-5 p.m. SESSION 3: Antibody-Mediated Allograft Rejection: Lessons for Xenotransplantation
MODERATOR: Dr. Guerard Byrne

1:15-1:55 p.m. "Antibody-Mediated Allograft Rejection in Nonhuman Primate Models"
Dr. Stuart Knechtle

1:55-2:35 p.m. "Prevention and Treatment of Clinical Antibody-Mediated Allograft Rejection"
Dr. Robert Montgomery

2:35-3:15 p.m. "Chronic Antibody-Mediated Allograft Rejection"
Dr. Stanley Jordan

3:15-3:30 p.m. BREAK

3:30-4:10 p.m. "ABO-Incompatible Pediatric Heart Transplantation"
Dr. Jeffrey Platt

4:10-5 p.m. Round-Table Panel Discussion
Dr. Stanley Jordan, Dr. Stuart Knechtle, Dr. Robert Montgomery, Dr. Jeffrey Platt

5-6:30 p.m. ADJOURN

6:30-8:30 p.m. RECEPTION: Hilton Birmingham at UAB, Montgomery Room

GUEST SPEAKERS

- **Judith Arcidiacono**
 - Regulatory Scientist
 - U.S. Food and Drug Administration
- **David L. Ayares Ph.D.**
 - Chief Executive Officer and Chief Scientific Officer
 - Revivicor, Inc.
- **Leo Bühler, Ph.D.**
 - President, International Xenotransplantation Association
 - Regular Professor of Surgery, University of Geneva
- **Jay Fishman, M.D.**
 - Associate Director, Mass. General Transplant Center
 - Director, Transplant Infectious Diseases and Compromised Host Program
 - Massachusetts General Hospital
- **Jon Friedman, M.D.**
 - Chief Medical Officer
 - Optum Specialty Management
- **Stanley C. Jordan, M.D.**
 - Director, Division of Nephrology
 - Medical Director, Kidney Transplant Program
 - Medical Director, Human Leukocyte Antigen and Transplant Immunology Laboratory
 - Cedars-Sinai
- **Stuart Knechtle, M.D.**
 - Professor, Division of Abdominal Transplant Surgery
 - William R. Kenan Jr. Professor, Department of Surgery
 - Duke University
- **Robert Montgomery, M.D.**
 - Professor, Department of Surgery
 - Director, NYU Langone Transplant Institute
 - NYU Langone Health
- **Jeffrey Platt, M.D.**
 - Professor, Department of Surgery and Department of Microbiology & Immunology
 - Head, Transplantation Biology Program
 - University of Michigan
- **Winson Tang, M.D.**
 - Vice President of Clinical Research
 - Sangamo BioSciences

PROGRAM OVERVIEW

This event, hosted by the UAB xenotransplant team, seeks to provide an opportunity for both national and international experts on xenotransplantation to share their insight and participate in discussions regarding the future of the field.

DESIRED RESULTS

Attendees will understand the potential benefits (and potential risks) of xenotransplantation.

LEARNING OBJECTIVE

To gain a general knowledge of the barriers to successful organ xenotransplantation and how these are being overcome.

The University of Alabama School of Medicine designates this Live Activity for a maximum of 12 *AMA PRA Category 1 Credit(s)*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity. UAB is an Equal Opportunity/Affirmative Action Institute.

UAB SPEAKERS

- **Guerard W. Byrne, Ph.D.**
 - Associate Professor, Department of Surgery
 - University of Alabama at Birmingham
- **Herbert Chen, M.D.**
 - Professor and Chair, Department of Surgery
 - Professor, Department of Biomedical Engineering
 - Fay Fletcher Kerner Endowed Chair
 - Surgeon-in-Chief, UAB Hospital and Health System
 - Senior Advisor, UAB Comprehensive Cancer Center
 - University of Alabama at Birmingham
- **David K.C. Cooper, M.D., Ph.D.**
 - Professor, Department of Surgery
 - Co-Director, UAB Xenotransplant Program
 - University of Alabama at Birmingham
- **Zak Dorsey, FACHE**
 - Director of Business Operations, UAB Comprehensive Transplant Institute
 - University of Alabama at Birmingham
- **Devin E. Eckhoff, M.D.**
 - Professor, Department of Surgery
 - Director, Division of Transplantation
 - Arnold G. Diethelm Chair in Transplantation Surgery
 - University of Alabama at Birmingham
- **Ronald A. Evans**
 - Director, Revenue Integrity
 - University of Alabama at Birmingham
- **Robert S. Gaston, M.D.**
 - Professor Emeritus, Department of Medicine
 - University of Alabama at Birmingham
- **James K. Kirklin, M.D.**
 - Professor and James K. Kirklin Endowed Chair of Cardiothoracic Surgery, Department of Surgery
 - Director, James and John Kirklin Institute for Research in Surgical Outcomes
 - University of Alabama at Birmingham
- **Karl Kraebber**
 - Director, Xenotransplantation Operations
 - University of Alabama at Birmingham
- **Jayme Locke, M.D., MPH**
 - Associate Professor and Vice Chair of Health Services Research, Department of Surgery
 - Director, Incompatible Kidney Transplant Program
 - Director, Transplant Analytics, Informatics & Quality
 - Director, UAB Comprehensive Transplant Institute
 - University of Alabama at Birmingham
- **Christopher G. A. McGregor, M.B., FRCS, M.D. (Hon.)**
 - Professor, Department of Surgery
 - University of Alabama at Birmingham
- **Martha Tankersley**
 - Transplant Administrator
 - University of Alabama at Birmingham
- **Joseph Tector, M.D., Ph.D.**
 - Professor, Department of Surgery
 - Director, Xenotransplantation Program
 - University of Alabama at Birmingham
- **Matthew F. Tector, Ph.D.**
 - Assistant Professor, Department of Surgery
 - University of Alabama at Birmingham

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AGENDA

FRIDAY, MARCH 22

8-10:20 a.m. SESSION 5: Patient Evaluation and Selection for First Clinical Trials

MODERATOR: Dr. David Cooper

8-8:20 a.m. “Evaluation and Selection of the First Kidney Patients”

Dr. Jayme Locke

8:20-8:40 a.m. “Evaluation and Selection of the First Heart Patients”

Dr. Christopher McGregor

8:40-9 a.m. “Evaluation and Selection of the First Pediatric Heart Patients”

Dr. James Kirklin

9-9:20 a.m. “Infection Risks”

Dr. Jay Fishman

9:20-10:20 a.m. Round-Table Panel Discussion

Dr. Leo Bühler, Dr. Jay Fishman, Dr. Robert Gaston, Dr. Stanley Jordan,

Dr. James Kirklin, Dr. Stuart Knechtle, Dr. Jayme Locke, Dr. Christopher McGregor,

Dr. Robert Montgomery, Dr. Jeffrey Platt

10:20-10:40 a.m. BREAK

10:40 a.m. – Noon SESSION 6: Regulatory and Economic Aspects of Clinical Trials of Xenotransplantation

MODERATOR: Dr. Christopher McGregor

10:20-10:40 a.m. “Addressing Regulatory Requirements for the Organ-Source Pig”

Karl Kraebber

10:40-11:00 a.m. “The US FDA Perspective”

Dr. Winson Tang

11-11:20 a.m. “Payer View of Xenotransplantation”

Dr. Jon Friedman

11:20 a.m. – Noon Round-Table Panel Discussion

Judith Arcidiacono, Dr. Jay Fishman, Dr. Jon Friedman, Karl Kraebber,

Zak Dorsey, Ronald Evans, Dr. Winson Tang, Martha Tankersley

Noon – 1 p.m. LUNCH AND DISCUSSION: “What Has This Workshop Achieved?”

MODERATOR: Dr. Joseph Tector

1-1:15 p.m. CLOSING REMARKS: Dr. Herbert Chen, Dr. Devin Eckhoff

1:15 p.m. ADJOURN

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