



**Training Workshop to Ensure Diversity, Inclusion and Meaningful Participation in Clinical Trials, the ABC Cardiovascular Study (A CME Program)**

Sponsored by FDA Conference Grant: 1R13FD005981-01

*March 10-11 2017, Atlanta Georgia*

**AGENDA**

***Friday, March 10, 2017***

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| <b>6:00 pm - 6:45 pm</b> | <b>Reception and Meet &amp; Greet</b>   |
| <b>6:45 pm – 7:00 pm</b> | <b>Welcome and Introductions</b><br>Elizabeth Ofili, MD, MPH, Senior Associate Dean, Morehouse School of Medicine and Principal Investigator, RCMI Translational Research Network (RTRN)                      |
| <b>7:00 pm – 7:45 pm</b> | <b>Update on Peripheral Artery Disease</b><br>Wayne Batchelor, MD, MHS, Chair of the Interventional Cardiology Council at Tallahassee Memorial Hospital President of the Tallahassee Research institute (TRI) |
| <b>7:45 pm – 8:00 pm</b> | <b>Questions and Discussion</b>   |
| <b>8:00 pm – 8:15 pm</b> | <b>Closing Remarks</b>  |

***Saturday, March 11, 2017***

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|--------------------------|---|
| <b>7:30 am – 8:30 am</b> | <b>Breakfast and Registration</b>   |
| <b>8:30 am – 8:45 am</b> | <b>Welcome and Introductions</b><br><br>Elizabeth Ofili, MD, MPH, Senior Associate Dean Morehouse School of Medicine and Principal Investigator, RCMI Translational Research Network (RTRN)<br><br>Barbara Hutchinson, MD, President, Association of Black Cardiologists (ABC), President, Chesapeake Cardiac Care<br>Felix Sogade, MD, Chairman of the Board, Association of Black Cardiologists (ABC) CEO Georgia Arrhythmia Consultants & Research Institute |

Cassandra McCullough, Chief Executive Officer, Association of Black Cardiologists(ABC)

Emma Fernandez, PhD, Chair of the RTRN Steering Committee

**8:45 am – 9:00 am**

**US Department of Health and Human Services Action Plan to Reduce Health Disparities and the Role of Minority Serving Institutions**

Jonca C. Bull, MD: FDA Assistant Commissioner for Minority Health

**9:00 am – 9:10 am**

**Discussion, Question & Answer Period**

**9:10 am – 9:25 am**

**The ABC Cardiovascular Study to Improve the Care of Underserved Minority Patients**

Elizabeth Ofili, MD, MPH, Principal Investigator and Chair of the Steering Committee

Ola Akinboboye, MD, MPH, Chair ABC Clinical Trials Committee

**9:25 am – 9:35 am**

**Discussion, Question & Answer Period**

**9: 35 am – 9:50 am**

**The Duke Clinical Research Institute Collaboration and Duke CARRA Registry**

Laura E. Schanberg, MD, Professor of Pediatrics, Co-Chief, Pediatric Rheumatology

**9:35 am – 9:50 am**

**The PLATINUM DIVERSITY Study**

Wayne Batchelor, MD, National co-Principal Investigator

**9:50 am – 10:05 am**

**The ABC Cardiovascular Study: Global Outreach and Collaboration with the Nigerian Cardiac Society and Sickle Cell Foundation of Nigeria**

Janet Ajuluchukwu, MBBS, FNCP, Professor and Head Department of Medicine, University of Lagos, Nigeria

**10: 05 am – 10:20 am**

**Discussion, Question & Answer Period**

**10: 20 am – 10:30 am**

**BREAK**

**10:30 am – 10:45 am**

**The NIH Precision Medicine Initiative (*All of Us*)- Patient Registries and Biological Samples**

Priscilla Pemu, MD, MS, Director, Community Physicians Network (CPN)

Alanna Morris MD, MSc, Assistant Professor of Medicine Emory University Clinical Cardiovascular Research Institute

Lilly Immergluck, MD, MS, Director, Pediatrics CPN

**10:45 am – 11:00 am**

**Discussion, Question & Answer Period**

<b>11:00 am – 11:15 am</b>	<p><b>Ethical Considerations in Research Participation and Informed Consent</b>  Stephen Sodeke, MS, PhD, Bioethicist and Professor; Chair, Institutional Review Board; Tuskegee University National Center for Bioethics in Research and Health Care &amp; College of Veterinary Medicine, Nursing and Allied Health Sciences</p>
<b>11:15 am – 11:25 am</b>	<b>Discussion, Question &amp; Answer Period</b>
<b>11:25 am – 11:40 am</b>	<p><b>Bringing the Patient’s Voice into Clinical Trial Design, Implementation and Dissemination</b>  <b>The Use of Mobile Technologies for Patient and Community Engagement</b>  Priscilla Pemu, MD, MS, Director of Clinical Trials and Community Physicians Network</p>
<b>11:40 am – 11:50 am</b>	<b>Discussion, Question &amp; Answer Period</b>
<b>11:50 am – 12:20 pm</b>	<b>LUNCH</b>
<b>12:20 pm – 1:05pm</b>	<p><b>Community Engagement in Clinical Trials: The Role of Community Advisory Board and Research Navigators</b>  Rev. Dr. Jason E. Owens, D Min., Chair Community Advisory Board, Senior Pastor of Snellville Biblical Deliverance Center in Snellville, GA  Rev. Dr. Leland Jones, Sr. D Min., Greater New Light Missionary Baptist Church, Atlanta  Tabia Akintobi, PhD, Director, Prevention Research Center  Brian Rivers, PhD, Director U 54 Cancer Research Program</p>
<b>1:05 pm – 1:20 pm</b>	<b>Discussion, Question &amp; Answer Period</b>
<b>1:20 pm – 1:45 pm</b>	<p><b>Engaging Community Physicians and Federally Qualified Clinics in Clinical Research</b>  W. Steen James, MD, Co-Chair Community Physicians Network  B. Wayne Kong, PhD, Executive Director, Zoe Pediatrics  Michelle Brown, CEO, Morehouse Choice Accountable Care Organization (ACO)  Deneta Sells, MD, In town Pediatric &amp; Adolescent Medicine  Priscilla Johnson, MSN, PhD, Contracting and Business Associate Agreements</p>
<b>1:45 pm – 2:00 pm</b>	<b>Discussion, Question &amp; Answer Period</b>
<b>2:00 pm – 2:10 pm</b>	<b>BREAK</b>

<b>2:10 pm – 2:25pm</b>	<b>The Business of Clinical Trials:</b> Staffing Model for Conducting Successful Clinical Research Studies in Private Practice Wayne Batchelor, MD President of the Tallahassee Research Institute (TRI)
<b>2:25 pm – 2:40 pm</b>	<b>Discussion, Question &amp; Answer Period</b>
<b>2:40 pm – 3:00 pm</b>	<b>Breakout Sessions</b>
<b>3:00 pm – 3:20 pm</b>	<b>Breakout Sessions</b>
<b>3:20 pm – 4:40 pm</b>	<b>Breakout Sessions</b>
<b>4:40 pm – 5:00 pm</b>	<b>Breakout Sessions</b>
<b>5:00 pm – 5:30 pm</b>	<b>Debrief and Closing Remarks</b> <b>Main Conference Room</b>

### **Breakout Session Topics and Workshop Leaders**

#### **Multi Site Principal Investigators and Co-Investigators: ABC Cardiovascular Study Good Clinical Practice Session**

**Description:** Good clinical practice (GCP) is an international, ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible (FDA).

During this breakout session, a team of experienced clinicians will discuss good clinical practice standards and how these standards should be applied to conducting safe and ethical clinical studies that produce valid and reliable outcomes data. Vanguard Study PIs and coordinators must attend this session

#### **Session Leaders**

Barbara Hutchison, MD, Annapolis, Maryland  
 Felix Sogade, MD, Macon, Georgia  
 Priscilla Pemu, MD, MSCR  
 Lilly Immergluck, MD, MSCR  
 Anne Denny, MSPH, CCRC  
 Clinical Trials Coordinator, CARRA Registry/DCRI Project Leader  
 Duke Clinical Research Institute

#### **Session participants (ABC Cardiovascular Study Vanguard Sites):**

Barbara Hutchison, MD, Annapolis, Maryland  
 Felix Sogade, MD, Macon, Georgia  
 Joe Hargrove, MD, Little Rock, Arkansas  
 Philip Duncan, MD, Richmond, Virginia  
 Osita Onyekwere, MD, Anniston, Alabama  
 Andre Artis, MD, Indianapolis, Indiana  
 Marcus Williams, MD, Newark, New Jersey  
 Malcolm Taylor, MD, Jackson, Mississippi  
 Adefisayo Oduwole, MD, Atlanta, Georgia  
 Rachel Harris, MD, Atlanta, Georgia

## **Investigator and Coordinator Training on ABC Cardiovascular Study Electronic Case Report forms (Medidata RAVE)**

**Description:** This session will review the electronic case report form including data security and privacy, and clinical research data management.

### **Session Leaders:**

Anne Denny, MSPH, CCRC

Clinical Trials Coordinator, CARRA Registry/DCRI Project Leader

Duke Clinical Research Institute

Said Talbi, PhD Director, Information Security and Technology Integration (ISTI) and Interim Director, RTRN Data Coordinating Center

Alnida Ngare, Director, Clinical Data Services, RTRN data Coordinating Center

### **Recruitment and Retention**

## **RCMI Translational Research Network (RTRN) Learning and Action Communities for Research (LACH), to support Community Engagement & Participant Registry**

**Description:** This interactive breakout session will discuss best practices and methods for recruiting and retaining minority participants in clinical studies. Session leaders will discuss outcomes and lessons learned from the recently funded RTRN LACH project that utilized the RTRN and Morehouse School of Medicine community engagement platforms to successfully recruit more than 60 participants. Using a mixed methods approach, the study explored minority perspectives regarding participating in clinical studies.

### **Session Leaders:**

Latrice Rollins, PhD, Evaluation Leader, RTRN

Nicole Crowell, MS, Project Director, RTRN

Pam Cooper, R-CENTER Recruitment Manager R-CENTER

Debra Teague, CPN Program Manager R-CENTER

## **RTRN Session on Regulatory Guidance on Drugs (IND) and Devices (IDE) : Incubator Services**

**Description: TBD**

### **Session Leaders:**

Emma Fernandez, PhD, Principal Investigator, RCMI at University of Puerto Rico Medical Sciences Campus

James Lillard, PhD, Associate Dean for Research and Director, Office of Technology Transfer, Morehouse School of Medicine

Solomon Garner, PhD RTRN Data Coordinating Center

## **RTRN Profiles and eagle-I Demonstration for Clinicians and Research Clusters**

Description: The [RTRN Profiles](#) is the network's collaboration tool for querying expertise and establishing professional connections for team science. Currently, the Profiles system is searchable with more than 1,800 professional profiles representing the diverse spectrum of scientific expertise and skills that exist at the RCMI-funded universities, colleges, and medical schools. [Eagle-I](#) facilitates access to research resources

This session will show participants how to navigate RTRN Profiles database networking tool for

collaborative opportunities and help research professionals connect across institutions. Eagle-I will foster collaborations by providing information on how to access RCMI network research resources

**Demonstration Facilitators:**

Renee Baker, MPH, Research Implementation Manager, RTRN

Traci Hayes, Director Of Communications, RTRN

Cassandra Jackson, Administrative Program Manager, RTRN

Solomon Garner, PhD, Director, Research Resources and Research Networking, RTRN

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*The content of the workshop is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*