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

6:00 pm - 6:45 pm Reception and Meet & Greet

6:45 pm – 7:00 pm Welcome and Introductions
Elizabeth Ofili, MD, MPH, Senior Associate Dean, Morehouse School of Medicine and Principal Investigator, RCMI Translational Research Network (RTRN)

7:00 pm – 7:45 pm Update on Peripheral Artery Disease
Wayne Batchelor, MD, MHS, Chair of the Interventional Cardiology Council at Tallahassee Memorial Hospital President of the Tallahassee Research institute (TRI)

7:45 pm – 8:00 pm Questions and Discussion

8:00 pm – 8:15 pm Closing Remarks

Saturday, March 11, 2017

7:30 am – 8:30 am Breakfast and Registration

8:30 am – 8:45 am Welcome and Introductions
Elizabeth Ofili, MD, MPH, Senior Associate Dean Morehouse School of Medicine and Principal Investigator, RCMI Translational Research Network (RTRN)

Barbara Hutchinson, MD, President, Association of Black Cardiologists (ABC), President, Chesapeake Cardiac Care
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 Akimboboye, 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
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>11:00 am – 11:15 am</td>
<td>Ethical Considerations in Research Participation and Informed Consent</td>
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<td>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</td>
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<td>11:15 am – 11:25 am</td>
<td>Discussion, Question &amp; Answer Period</td>
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<td>11:25 am – 11:40 am</td>
<td>Bringing the Patient’s Voice into Clinical Trial Design, Implementation and Dissemination The Use of Mobile Technologies for Patient and Community Engagement</td>
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<td>Priscilla Pemu, MD, MS, Director of Clinical Trials and Community Physicians Network</td>
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<td>11:40 am – 11:50 am</td>
<td>Discussion, Question &amp; Answer Period</td>
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<td>11:50 am – 12:20 pm</td>
<td>LUNCH</td>
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<td>12:20 pm – 1:05pm</td>
<td>Community Engagement in Clinical Trials: The Role of Community Advisory Board and Research Navigators</td>
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<td>Rev. Dr. Jason E. Owens, D Min., Chair Community Advisory Board, Senior Pastor of Snellville Biblical Deliverance Center in Snellville, GA</td>
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<td>Rev. Dr. Leland Jones, Sr. D Min., Greater New Light Missionary Baptist Church, Atlanta</td>
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<td>Tabia Akintobi, PhD, Director, Prevention Research Center</td>
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<td>Brian Rivers, PhD, Director U 54 Cancer Research Program</td>
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<td>1:05 pm – 1:20 pm</td>
<td>Discussion, Question &amp; Answer Period</td>
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<td>1:20 pm – 1:45 pm</td>
<td>Engaging Community Physicians and Federally Qualified Clinics in Clinical Research</td>
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<td>W. Steen James, MD, Co-Chair Community Physicians Network</td>
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<td>B. Waine Kong, PhD, Executive Director, Zoe Pediatrics</td>
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<td>Michelle Brown, CEO, Morehouse Choice Accountable Care Organization (ACO)</td>
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<td>Deneta Sells, MD, In town Pediatric &amp; Adolescent Medicine</td>
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<td>Priscilla Johnson, MSN, PhD, Contracting and Business Associate Agreements</td>
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<td>1:45 pm – 2:00 pm</td>
<td>Discussion, Question &amp; Answer Period</td>
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<td>2:00 pm – 2:10 pm</td>
<td>BREAK</td>
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The Business of Clinical Trials: Staffing Model for Conducting Successful Clinical Research Studies in Private Practice
Wayne Batchelor, MD
President of the Tallahassee Research Institute (TRI)

Discussion, Question & Answer Period

Breakout Sessions

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 Dennos, 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 Dennos, 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

Co-sponsored by the RCMI Translational Research Network (RTRN) funded by the National Institute on Minority Health and Health Disparities, National Institutes of Health (NIH), through Grant: U54MD008149.

The conference is also supported by the RCMI Clinical and Translational Research Center from the National Institute on Minority Health and Health Disparities (NIMHD) Grant: 8 U54 MD007588, and the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR000454.

*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.*