

# AGENDA

**REGISTRATION, COFFEE, AND LIGHT BREAKFAST** | 7:30 a.m. – 8:30 a.m.  
Ellen H. Yankellow Atrium and Balch Gallery

**MORNING SESSIONS** | 8:30 a.m. – 12:30 p.m.  
1st Floor Auditorium

**SESSION 1: FRAMING THE CHALLENGE** | 8:30 a.m. – 9:45 a.m.  
Room: N103

## Welcome

**NATALIE D. EDDINGTON, PhD, FAAPS, FCP**

*Dean and Professor*

*University of Maryland School of Pharmacy*

*Executive Director, University Regional Partnerships*

## Remarks

**JEFFREY E. SHUREN, MD, JD**

*Director, Center for Devices and Radiological Health*

*Food and Drug Administration*

## Patients and Patient Groups Perspective

**TERRIE COWLEY**

*President and Co-Founder*

*The TMJ Association, Ltd.*

**SESSION 2: KEYNOTE** | 9:45 a.m. – 10:15 a.m.  
Room: N103

## Key Opportunities and Introduction of Keynote Speaker

**FADIA T. SHAYA, PhD, MPH**

*Professor and Vice-Chair, Pharmaceutical Health Services Research Department*

*Associate Director, Center on Drugs and Public Policy*

*Institute for Clinical and Translational Research Bioinformatics*

*University of Maryland School of Pharmacy*

## Keynote Presentation

**ANNE C. BEAL, MD, MPH**

*Associate Director, Center on Drugs and Public Policy*

*Global Head of Patient Solutions*

*Sanofi*

## **MORNING COFFEE BREAK | 10:15 a.m. - 10:30 a.m.**

Balch Gallery

## **SESSION 3: BUILDING THE INFRASTRUCTURE | 10:30 a.m. - 11:30 a.m.**

Room: N103

### **Clinical and Translational Research Infrastructure, ICTR at UMB**

#### **STEPHEN N. DAVIS, MBBS, FRCP, FACE, MACP**

*Dr. Theodore E. Woodward, Chair in Medicine*

*Director, General Clinical Research Center*

*Director, Clinical and Translational Sciences Institute*

University of Maryland School of Medicine

### **Transparency in the Infrastructure**

#### **FRANCIS B. PALUMBO, PhD, JD**

*Professor, Pharmaceutical Health Services Research Department*

*Executive Director, Center on Drugs and Public Policy,*

University of Maryland School of Pharmacy

### **Clinical and Translational Research for Medical Devices: Bioinformatics in the Context of ICTR and Patient Engagement**

#### **FADIA T. SHAYA, PhD, MPH**

*Professor and Vice-Chair, Pharmaceutical Health Services Research Department*

*Associate Director, Center on Drugs and Public Policy*

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University of Maryland School of Pharmacy

### **Overview of NEST**

#### **RACHEL R. RATH, MPH**

*Deputy Director*

NEST Coordinating Center

Medical Device Innovation Consortium

## **SESSION 4: CASE STUDIES | 11:30 a.m. - 12:30 p.m.**

Room: N103

### **Case Study #1: Women's Health Technologies Coordinated Network (CRN) and Beyond: Engaging and Empowering our Patient Partners**

#### **COURTNEY E. BAIRD, MS**

*Research Data Analyst,*

*Division of Comparative Effectiveness and Outcomes Research*

*MDEpiNet, Weill Cornell Medicine*

## Case Study #2: The Vascular Implant Surveillance and Interventional Outcomes Network (VISION): What Do We See Next?

**PHILIP P. GOODNEY, MD, MS**

*Surgeon and Health Services Researcher*

Center for the Evaluation of Surgical Care, Dartmouth

## Case Study #3: The RADCOMP Consortium Experience: Patient Engagement in a Large Pragmatic Randomized Clinical Trial

**JOEY MATTINGLY, PharmD, MBA**

*Assistant Professor and Director of Operations for the PATIENTS Program*

University of Maryland School of Pharmacy

**C. DANIEL MULLINS, PhD**

*Professor and Chair, Pharmaceutical Health Services Research Department*

*Director, PATIENTS Program*

University of Maryland School of Pharmacy

## **BUFFET LUNCH | 12:30 p.m. - 1:30 p.m.**

Balch Gallery

## **AFTERNOON CONCURRENT BREAKOUT SESSIONS | 1:30 p.m. - 2:45 p.m.**

*Small groups will work in parallel to bring together best practices and lessons learned for patient engagement to develop and use real-world evidence.*

### **Breakout Session 1**

**Room: N306**

**Moderator: KATHLEEN M. HEWITT, DNP, RN, CPHQ**

*Associate Vice President*

National Cardiovascular Data Registry

### **Breakout Session 2**

**Room: N310**

**Moderator: KATHRYN (KATIE) M. O'CALLAGHAN**

*Assistant Director for Strategic Programs*

Center for Devices and Radiological Health

Food and Drug Administration

### **Breakout Session 3**

**Room: N314**

**Moderator: DANICA MARINAC-DABIC, MD, PhD, FISPE, MMSc**

*Director, Division of Epidemiology, Office of Surveillance and Biometrics*

Center for Devices and Radiological Health

Food and Drug Administration

**AFTERNOON REFRESHMENTS AND SNACK BREAK** | 2:45 p.m. – 3:15 p.m.  
Balch Gallery

**CLOSING SESSION** | 3:15 p.m. – 4:15 p.m.  
Room: N103

### Panel Discussion

Moderators from breakout sessions will note overlapping points and engage in a panel discussion.

**FADIA T. SHAYA, PhD, MPH**

*Professor and Vice-Chair, Pharmaceutical Health Services Research Department  
Associate Director, Center on Drugs and Public Policy  
Institute for Clinical and Translational Research Bioinformatics  
University of Maryland School of Pharmacy*

**DANICA MARINAC-DABIC, MD, PhD, FISPE, MMSc**

*Director, Division of Epidemiology, Office of Surveillance and Biometrics  
Center for Devices and Radiological Health  
Food and Drug Administration*

### Closing Remarks

**LISA MILLER NOEL, PhD**

*Senior Fellow in the Office of Center Director  
Center for Devices and Radiological Health  
Food and Drug Administration*