MDIC-FDA Workshop: Advancing EUA IVD Products Toward Full Marketing Status

February 3, 2020, 8:30 – 5:00 pm

FDA White Oak Campus | Great Room

Summary: The workshop will explore key considerations for using real world data (RWD) to generate real world evidence (RWE) to help support in vitro diagnostic (IVD) products available under FDA's emergency use authorization (EUA) to advance to full marketing status (e.g., De Novo or 510(k)). A roadmap for diagnostic evaluations during emergencies would help enable stakeholders to have templates to use to expedite evaluation of laboratory-based tests and point of care technologies.

Goal: To identify challenges and next steps to the use of RWD/RWE to help support the advancement of EUA IVD products to full marketing status.

Outcome:

- Identify test case(s) of interest to stakeholders
- Discussion to inform development of a roadmap for diagnostic evaluations during emergencies, to include what elements to collect (and how)
- Identify potential projects or next steps for the test case(s) of interest

AGENDA

8:30 AM **Introduction and Objectives**
Danelle Miller, JD, VP, Global Regulatory Policy and Intelligence | Roche Diagnostics
MDIC Clinical Dx Steering Committee Chair

8:35 AM ***Opening remarks*: Pamela Goldberg, MBA**, President & CEO | MDIC

OPENING SESSION: INTRO TO EMERGENCY OUTBREAK SITUATIONS AND DATA COLLECTION

8:40 AM **Keynote: National Preparedness and Response in the 21st Century**
Luciana Borio, MD; Vice President, Technical Staff | In-Q-Tel

9:05 AM **Keynote: Evaluating novel diagnostics in an outbreak setting: lessons learned from Ebola**
Nira Pollock, MD, PhD; Assoc Medical Director of Infectious Diseases Diagnostic Laboratory at Boston Children's Hospital, faculty member of the Division of Infectious Diseases at Beth Israel Deaconess Medical Center, Boston, MA.

9:35 AM **FDA Perspective**
Speakers: **RADM Denise Hinton**, FDA Chief Scientist
Timothy Stenzel, MD, PhD, Director, OHT7: Office of In Vitro Diagnostics and Radiological Health | CDRH
Uwe Scherf, PhD, Director, Division of Microbiology Devices, OHT7: Office of In Vitro Diagnostics and Radiological Health | CDRH
Michael Waters, PhD, SHIELD Team Lead/CDRH RWE Tactical Team OIR Representative | FDA

10:35 AM **BREAK – 15 minutes**

10:50 AM **Industry Perspective on Challenges and Opportunities**

10:55 AM **Case Study: From EUA Through Direct *de novo* Marketing Authorization**
Estela Raychaudhuri, President | InBios International, Inc.

11:10 AM **Industry Panel: Moderator: Danelle Miller, JD** | MDIC Clinical Diagnostics Steering Committee Chair

1. Perceived Barriers in the process
2. Potential Solutions
3. Q&A from audience

Panelists: **Tracy Bush, PhD**, Head of Regulatory Policy - Personalized Healthcare | Roche Diagnostics
Thomas D. Ippolito, VP Quality & Regulatory Affairs | ChemBio Diagnostics Systems, Inc.
Annabel Tsai, PhD, Sr Manager/Scientist, Quality and Regulatory Affairs | InBios International, Inc.
Jeff Zinza, Sr Director, Regulatory Affairs | Hologic, Inc.
Tiffany Miller, RAC, Sr Director Regulatory Affairs | OraSure Technologies, Inc.

11:55-12:30 LUNCH: provided by MDIC

12:30 PM **Data Approaches and Opportunities**

12:35 PM **Surveillance and Data Management in DRC Ebola Response**
CDR James Coburn, MSc, CPH, Senior Advisor for Emerging Technologies | Office of Counterterrorism and Emerging Threats | Office of the Chief Scientist | FDA

12:50 PM **RWE for Diagnostics: Data collection and Quality**
Richard Gliklich, MD, Founder and CEO|OM1

1:10 PM **Applying Standards to Simplify and Streamline Real-World Evidence Data Collection**
Michael Waters, PhD, SHIELD Team Lead/CDRH RWE Tactical Team OIR Representative | FDA

1:20 PM **BARDA Support for Emerging Infections**
Nina El-Badry, MS, RAC (US, EU), Regulatory Branch Chief (Acting) Regulatory & Quality Affairs | Biomedical Advanced Research and Development Authority (BARDA)

1:45 PM **RWE Panel Discussion: Moderator: Richard Gliklich, MD**

Panelists: **Nina El-Badry, MS, RAC**
Michael Waters, PhD,
CDR James Coburn
Nira Pollock, MD, PhD

2:15 – 2:30 BREAK - 15 minutes

2:30 PM **Biorepositories and Reference materials**

2:35 PM **The CDC Preparedness Biorepository**

Jasmine Chaitram, MPH, MT (ASCP), Assoc Director for Laboratory Preparedness; Director, CDC Biorepository; Chief, Informatics and Data Science Branch; Division of Laboratory Systems, Center for Disease Control and Prevention (CDC)

2:50 PM **Are All Assays Equal?**

Mark Page, PhD, Principal Scientist, Head of Emerging Viruses Group, Division of Virology, National Institute for Biological Standards and Control (NIBSC)

3:10 PM **Issues related to providing reference materials during an outbreak scenario**

Mark Page, PhD, Principal Scientist, Head of Emerging Viruses Group, Division of Virology, NIBSC

3:35 PM **WHO EUAL: Past & Future**

Ute Ströher, PhD, Technical Officer, World Health Organization

4:00 PM **Challenges and future steps - Speaker Panel & QA**

- Synthesize information collected during the day and discuss next steps

Moderator: **Sally Hojvat, MSc, PhD**, Independent Consultant, Director of the FDA | CDRH | OIR Microbiology Division 2003-2015

Panelists: **Jasmine Chaitram, MPH, MT (ASCP)**
Richard Gliklich, MD
Mark Page PhD
Nira Pollock, MD, PhD
Estela Raychaudhuri
Ute Ströher, PHD
Jeff Zinza
Uwe Scherf, PhD

- Closing statements

5:00 END

Registration: **https://mdic.org/event/advancing-eua-ivd-products-toward-full-marketing-status/**

Additional Information on visiting the FDA campus can be found here:
https://www.fda.gov/about-fda/white-oak-campus-information/faqs-public-meetings-fda-white-oak-campus