



# AdvaMedDx Year Ahead: 2012

The world's leading diagnostic manufacturers established AdvaMedDx to advocate for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx has an aggressive public affairs and advocacy agenda planned for 2012 to continue to serve its member companies and advocate for greater patient access to new, innovative diagnostic tests.

## WORKING WITH INDUSTRY

AdvaMedDx will continue to grow its membership in the coming year and provide all of its member companies the opportunity to shape policy and advocacy through participation in a variety of work groups. AdvaMedDx will expand its collaboration with other diagnostics associations around the world, including hosting an inter-association meeting in October with associations from Europe, Japan, Brazil, Australia, and Canada.

## RAISING OUR PROFILE

A new brand and website, as well as social media engagement, will invigorate AdvaMedDx's public affairs activities and create a strong platform for AdvaMedDx to establish itself as an advocacy leader and trusted policy resource. Through conferences, briefings, and a growing resources library, AdvaMedDx will convey the value of diagnostics and demonstrate the need for policy reform.

## ADVANCING OUR AGENDA

AdvaMedDx will continue building relationships with key policymakers and intensify outreach to the wide array of federal agencies working on diagnostics and related issues. Ongoing FDA implementation of a risk-based approach to diagnostics regulation, including regulation of laboratory developed tests; Medicare payment reform; and addressing evidence demands on diagnostic manufacturers all will remain top priorities.

## BUILDING ALLIANCES

Leveraging stakeholder relationships is critical for amplifying AdvaMedDx messages regarding regulatory and payment reform and, in particular, identifying our policy priorities as advancing the interests of patients. AdvaMedDx will build on existing relationships and identify additional key partners from a range of organizations representing patients and health care professionals. (See page 2 for Key Stakeholders list)

## WORKING WITH THE FDA

AdvaMedDx will continue to work directly with the FDA on regulatory issues affecting the diagnostics industry. Further CEO meetings with Dr. Alberto Gutierrez are planned over the course of the year, as are FDA Industry Roundtables, a Vendor Day, and other forums in which to engage FDA senior leadership.

## WORKING WITH CAPITOL HILL

AdvaMedDx will continue to educate Members of Congress and their staff on the value of diagnostics and the impact of specific legislative and regulatory proposals on patient access to safe and effective diagnostic tests. AdvaMedDx will distribute a packet of information on AdvaMedDx to every office on the Hill at the beginning of 2012, and conduct a Congressional briefing series. AdvaMedDx also will work with Representative Leonard Lance (R-NJ) and the National Health Council to help build support for the MODDERN Cures Act.

## KEY STAKEHOLDERS

- » AIDS Institute
- » Alliance for Aging Research
- » Alzheimer's Association
- » American Cancer Society Cancer Action Network
- » American Diabetes Association
- » American Heart Association
- » American Lung Association
- » Bonnie J. Addario Lung Cancer Foundation
- » Breast Cancer Network of Strength
- » C3: Colorectal Cancer Coalition
- » Friends of Cancer Research
- » Juvenile Diabetes Research Foundation
- » Leukemia and Lymphoma Society
- » Lung Cancer Foundation of America
- » Melanoma Research Foundation
- » National Coalition for Cancer Survivorship
- » National Health Council
- » National Organization for Rare Diseases
- » Ovarian Cancer National Alliance
- » Pancreatic Cancer Action Network (PanCAN)
- » Parkinson's Action Network
- » Personalized Medicine Coalition
- » Society for Women's Health Research
- » Susan G. Komen Breast Cancer Foundation
- » American Academy of Emergency Medicine
- » American Academy of Family Physicians
- » American Academy of Home Care Physicians
- » American Academy of Nursing
- » American Association of Clinical Chemistry
- » American Association of Clinical Endocrinologists
- » American Association of Clinical Urologists
- » American College of Cardiology
- » American College of Gastroenterology
- » American College of Physicians
- » American College of Preventive Medicine
- » American College of Surgeons
- » American Congress of Obstetricians and Gynecologists
- » American Medical Association
- » American Society of Clinical Oncology
- » American Society of Clinical Pathology
- » American Society of Hematology
- » College of American Pathologists

## WORKING WITH PAYERS

To respond to growing demands for more clinical evidence supporting the use of diagnostics, AdvaMedDx will be working with member companies to identify and foster appropriate evidence generation and assessment methods for diagnostics. Early in the year, AdvaMedDx will publish a Diagnostics Evidence Glossary defining such key terms as outcomes, causality, study design, and clinical validity vs. clinical utility.

## FEDERAL AGENCY COLLABORATION

In 2012, AdvaMedDx will reach out to the numerous federal agencies working on diagnostics and related topics for introductory meetings and briefings to ensure our industry views are represented in their considerations as well as identify additional opportunities for collaboration. Regular engagement with the Department of Commerce is expected as part of AdvaMedDx work on the implementation of the WHO Pandemic Influenza Preparedness Framework. AdvaMedDx also intends to provide a diagnostics briefing to the Congressional Research Service, the entity that prepares issue reports for Congress.

- » Congress
- » FDA
- » CMS
- » NIH
- » CDC
- » GAO
- » IOM
- » CRS
- » AHRQ
- » BARDA
- » DARPA

## MONTHLY CALENDAR

### January

- » Launch of new AdvaMedDx branding and website
- » Biotech Showcase 2012 – San Francisco, CA (January 9-11)
- » AdvaMedDx Hill Packet

- » Diagnostics Industry Infographic
- » Newsletter
- » Launch U.S. Diagnostics Market Survey

*Cervical Health Awareness Month*

## February

- » EDMA Executive Committee Meeting – Brussels, Belgium (February 7)
- » Molecular Med Tri-Con 2012 – San Francisco, CA (February 19-23)
- » World Consumer Diagnostics Summit – Boston, MA (February 28-March 1)
- » FDA/AdvaMedDx Leadership Meeting
- » Congressional Research Service Briefing
- » Diagnostics Evidence Glossary

*American Heart Month*

## March

- » Diagnostics Congressional Briefing
- » Dx Dinner and Board Meeting – Newport Coast, CA (March 13-14)
- » Congressional Staff Facility Tour
- » Executive Newsletter

*National Colorectal Cancer Awareness Month*

*World Kidney Day – March 11*

*World Tuberculosis Day – March 24*

*American Diabetes Alert Day – March 25*

## April

- » AdvaMedDx, MEDEC, EDMA Meeting – Toronto, Canada (Week of April 2)
- » MTLI Diagnostics Statistics Conference – Washington, DC
- » MTLI Dx Primer Course
- » EDMA Executive Committee Meeting – Brussels, Belgium (April 26)
- » Technology Primer

## May

- » Diagnostics Symposium (Week of May 7)
- » JACRI Annual Meeting – Tokyo, Japan
- » Global Diagnostics Association Meeting – Tokyo, Japan
- » GMTA Meeting – Stockholm, Sweden
- » MTLI Molecular Diagnostics Course
- » Executive Newsletter

*National Colorectal Cancer Awareness Month*

*HIV Vaccine Awareness Day (May 18)*

## June

- » Capitol Hill Fly-In and Board Meeting – Washington, DC (June 14)
- » Briefing for Professional Societies (Week of June 25)

## ONGOING ACTIVITIES THROUGHOUT THE YEAR

- » Educate media, including targeted reporter desk side briefings
- » Conduct introductory meetings with federal agencies working on diagnostics
- » Build a library of information on the industry
- » Expand the new AdvaMedDx website as a resource on diagnostics
- » Collaborate with other diagnostics associations around the world
- » Get out key messages through a variety of communications channels
- » Continue outreach to patient advocacy groups and professional societies
- » Engage in social media through Twitter, Facebook, and LinkedIn
- » Support disease awareness days

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### bioMerieux

Thierry Bernard, Senior Executive Vice President, Commercial Operations and Investor Relations

- » CMS Clinical Lab Open Door Forum
  - » FDA-Industry IVD Roundtable
- National HIV Day (June 27)*

## July

- » AACC Clinical Lab Expo – Los Angeles, CA (July 17-19)
  - » Diagnostics Congressional Briefing
  - » Executive Newsletter
- World Hepatitis Day (July 28)*

## August

- » Regional Event in a Targeted Congressional District
- » Patient Group Briefing
- » Next Generation Dx Summit – Washington, DC (August 21-23)

## September

- » EDMA Executive Committee Meeting (September 25)
  - » Press Event
  - » Executive Newsletter
- Leukemia and Lymphoma Awareness Month*
- Newborn Screening Awareness Month*
- Ovarian Cancer Awareness Month*
- Prostate Cancer Awareness Month*
- National HIV/AIDS & Aging Awareness Day (September 18)*
- World Alzheimer's Day (September 21)*

## October

- » AdvaMed 2012 – Boston, MA (October 1-3)
    - » Board Meeting
    - » Global Diagnostics Industry Association Meeting
  - » EDMA Annual Meeting
- National Breast Cancer Awareness Month*

## November

- » Diagnostics Congressional Briefing
  - » Personalized Medicine Conference – Boston, MA (November 28-29)
  - » Executive Newsletter
- Lung Cancer Awareness Month*
- National Alzheimer's Awareness Month*
- National Stomach Cancer Awareness*

## December

- » Board Meeting – Washington, DC (December 14)
  - » 2012 Year in Review
  - » 2013 Year Ahead
- World AIDS Day (December 1)*

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*continued*

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