

AdvaMedDx Initiatives

AMDM Fall Focus Meeting
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AdvaMedDx
Vital Insights | Transforming Care

AdvaMedDx 5-Year Strategic Plan: Overview

- ADx Board Approved during October 2023 Meeting
- Purpose, mission and vision statements
- Strategic initiatives and success metrics

Background Information

This AdvaMedDx Strategic Plan:

- Supplements and supports the AdvaMed 2023-2027 Strategic Plan and is a continuation of the AdvaMedDx 2022 Priorities document
- Identifies high-level objectives for AdvaMedDx
- Is not an exhaustive overview of all work undertaken by AdvaMedDx; however, most AdvaMedDx work streams should map to and support these initiatives

Purpose, Mission, Vision Statements

Purpose: Improve patient outcomes, enhance healthcare system efficiency, and advance public health through the development, utilization, and understanding of safe, accurate, and innovative in vitro diagnostics

Mission: Advance domestic and foreign policies that support robust innovation, ensure timely regulatory review, and promote rapid coverage and adoption of reliable and accurate *in vitro* diagnostic tests

Vision: To be a world leader in advocating for the power of in vitro diagnostics to improve health outcomes, enhance quality of life, lower healthcare costs through the addition of clinical value

Strategic Initiatives (Summary)

1. Modernize the Diagnostics Regulatory Environment
2. Optimize International Engagement and Influence Key Market Outcomes
3. Improve Payment Policies and Expand Patient Access to Diagnostic Tests
4. Elevate Industry Perception and Strengthen Alliances through Targeted External Affairs Initiatives
5. Enhance Public Health Policies and Strengthen Disease Response Approaches
6. Strengthen and Grow AdvaMedDx Membership

1. Modernize the Diagnostics Regulatory Environment

- Tier 1**
 - ❑ Drive comprehensive diagnostics regulatory reform, leveraging all possible avenues, including legislation and regulation
 - ❑ Ensure favorable implementation of MDUFA V
 - ❑ Optimize FDA's regulatory policies for diagnostics
- Tier 2**
 - ❑ Integrate and amplify AdvaMed's software/AI, cybersecurity and data stewardship work
 - ❑ Deepen relationships and collaboration with FDA's OHT-7, other relevant CDRH and FDA officials, and CMS

Success: Implementation of favorable FDA policies and regulatory pathways for diagnostics; OHT7 meets MDUFA V total time to decision goals for premarket submissions; OHT7 backlog cleared

Highlighted AdvaMedDx Regulatory Activities/Positions

- » Dx Regulatory Reform
- » Predetermined Change Control Protocols (PCCP)
- » Modernizing POC/Streamlining CLIA Waiver
- » Oncology Companion Diagnostics Pilot Program
- » EMC Expectations for Instruments