

Pathways for Medical Countermeasure Development and Use

BARDA Industry Day - Contracting for Countermeasures
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U.S. Food and Drug Administration
Medical Countermeasures Initiative

Objective

- Provide the FDA perspective on goal 2 of the 2012 PHEMCE Strategy
- Goal 2 - Establish and communicate clear pathways to facilitate medical countermeasure development and use
 - Objective 2.1 - Identify scientific and regulatory issues that challenge medical countermeasure development or use during public health emergencies and coordinate activities among PHEMCE partners to address those challenges
 - Objective 2.2 - Assist medical countermeasure developers in working interactively with FDA during product development and regulatory review

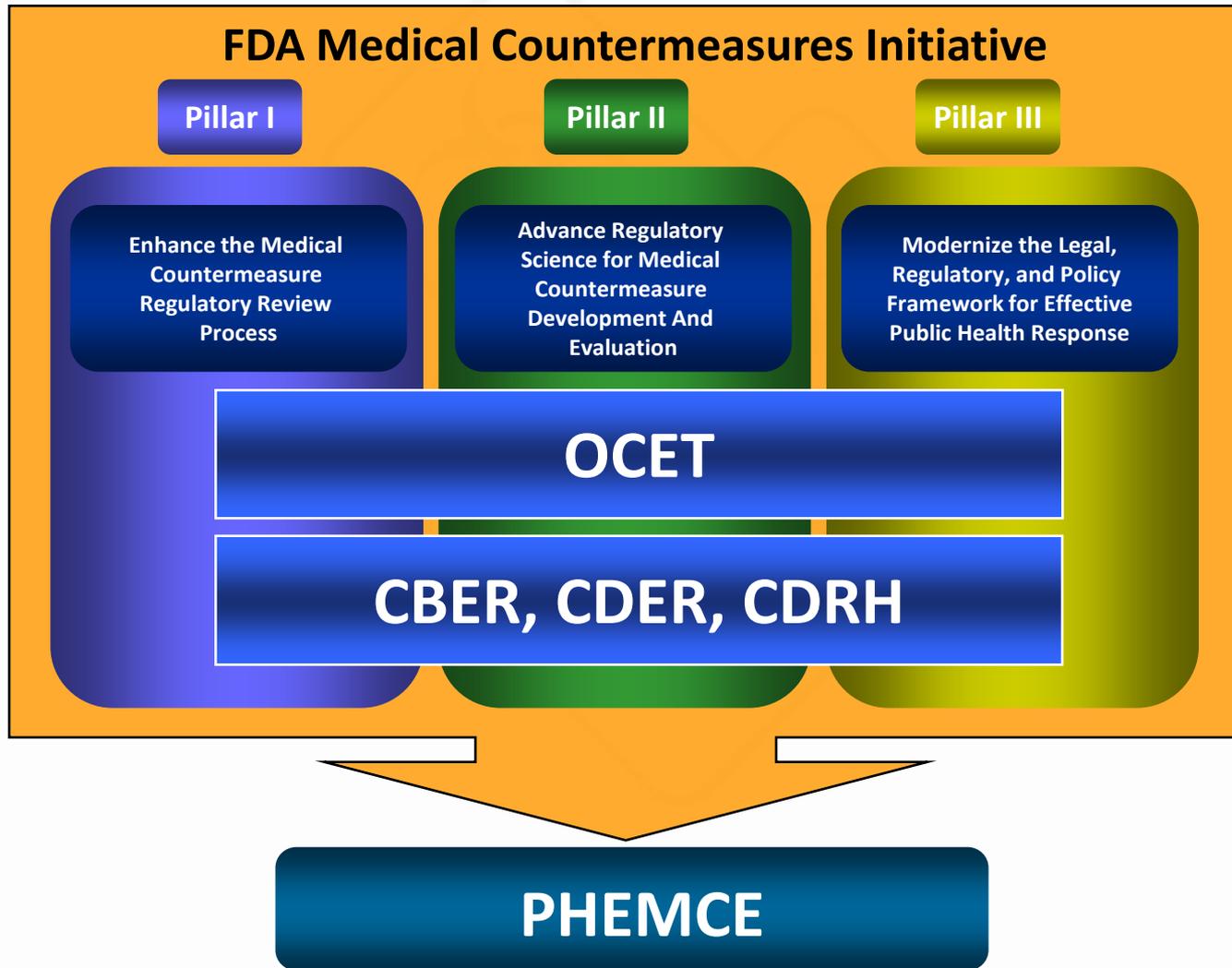
Regulatory Mechanisms for the Development and Use of MCMs

- The goal for MCM development is approval, licensure, or clearance
- In situations where MCMs are available but not yet approved, licensed, or cleared for the particular CBRN indication, FDA has a variety of regulatory mechanisms to facilitate access to MCMs:
 - Investigational Use (e.g., expanded access)
 - Emergency Use Authorization
- All of FDA's regulatory mechanisms for MCMs are based on risk-benefit assessments that are founded on the available scientific evidence

Scientific and Regulatory Issues that Challenge MCM Development or Use

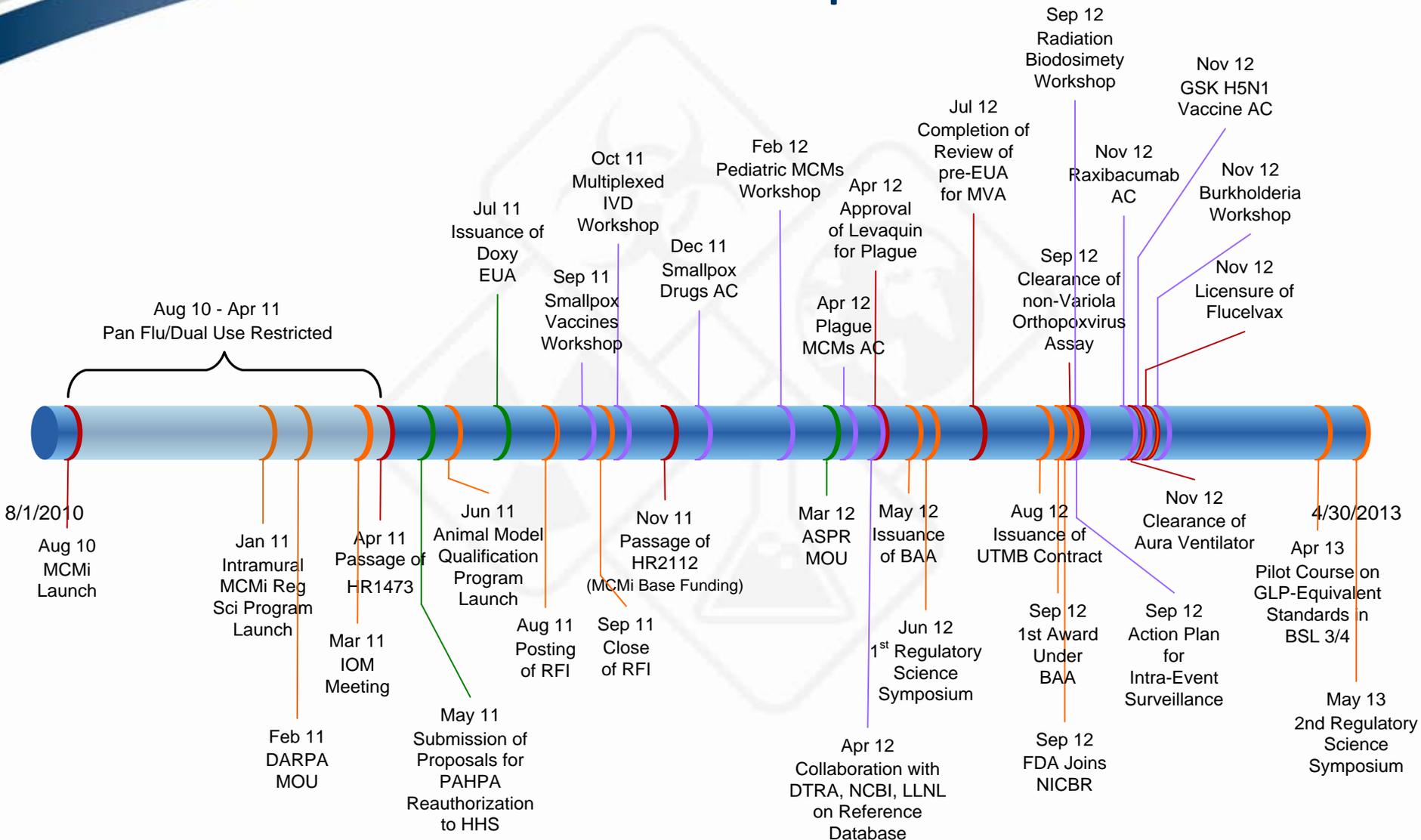
- FDA's regulatory review of MCMs for approval, licensure, clearance or authorization is data-driven
- There are often gaps in scientific knowledge that result in uncertainties that impede or prevent regulatory review
- Gaps in scientific knowledge arise from multiple sources including:
 - Intrinsic uncertainties about the biologic behavior of threat agents
 - Insufficient drug development tools (e.g., animal models) for establishing the necessary data to support regulatory decision-making
- FDA is aggressively working with PHEMCE partners and product developers to identify and narrow these scientific gaps

Resolving Scientific and Regulatory Uncertainties





Selected MCMi Accomplishments



Broad Agency Announcement

- Solicitation for research and development to support regulatory science and innovation including for MCMs (FDA BAA-12-00118)
 - Develop, characterize, and qualify animal models for MCM development
 - Modernize tools to evaluate MCM product safety, efficacy, and quality
 - Develop and qualify biomarkers of diseases or conditions
 - Enhance emergency communication

- Remains open until May 23, 2013



Save the Date! May 29-31, 2013

The Medical Countermeasures initiative (MCMi) Presents:

THE 2013 Regulatory Science Symposium

Silver Spring, MD

For more information, or to submit session suggestions,
please visit www.fda.gov/medicalcountermeasures



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Protecting National Health and Security



Medical Countermeasures Initiative
Strategic Plan 2011 - 2015



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FDA's Medical Countermeasures Initiative
Year-1 Status Report — September 2011



— *Protecting National Health and Security*



MCMi

FDA's Medical Countermeasures Initiative
Year-2 Program Update—November 2012



— *Protecting National Health and Security*



On the MCMi Web site: www.fda.gov/medicalcountermeasures

Assisting MCM Developers During Product Development Regulatory Review

- FDA assists MCM developers via a number of methods including:
 - Formal and informal meetings with product sponsors or applicants seeking technical assistance related to the development, regulatory assessment, and manufacturing of MCMs
 - Enhanced inspection, including pre-approval and compliance activities to support early identification of problems that might impede MCM development /availability
 - Issuance of guidance documents and regulations to guide MCM developers
 - Stakeholder engagements, including meetings, conferences, and workshops, to educate the public on both FDA regulatory processes and its current thinking on regulatory issues and to garner input from interested parties on regulatory issues
 - Advisory Committee meetings to obtain independent expert advice on scientific, technical, and policy matters on specific topics



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Questions? AskMCMi@fda.hhs.gov



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