Innovative Technologies, Products & Platforms

Rapid Vaccine & Therapeutic Response Platforms

Mike Angelastro
Acting Director,
BARDA's Division of Manufacturing, Facilities & Engineering

BARDA Industry Day

Vision & Strategy

Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats… *and*

…responsive and nimble programs and capabilities to address novel and emerging threats… *and*

…a ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies.

BARDA Strategic Plan 2011-2016, Goals 3, 4 & 5

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BARDA Strategic Plan 2011-2016, Goals 3, 4 & 5

Rapid...? Platforms…?

- **Rapid Response**
  Days, Weeks, Months, a few Years
- **Vaccine & Therapeutic**
  Primarily biologics
- **Platforms**
  Multi-purpose technology
  Proven vs. Unproven

Innovation Mandate

…reminder…

"**A**dvanced **R**esearch & **D**evelopment"

Innovation Mandate

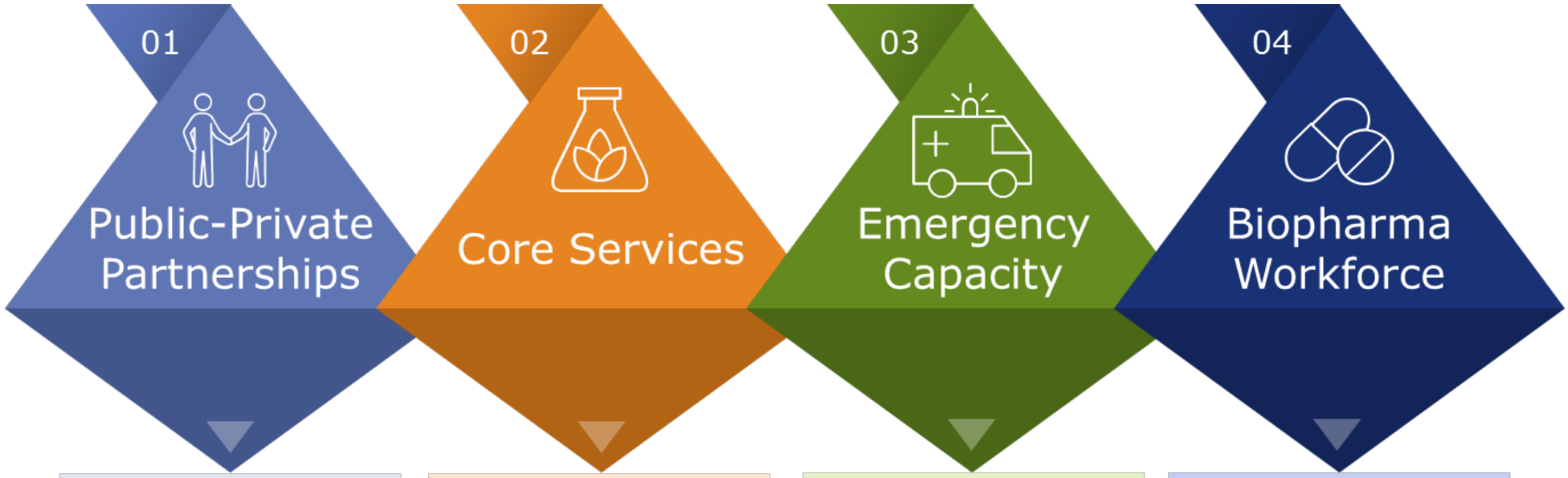
…reminder…

Centers for Innovation in

Advanced **D**evelopment & **M**anufacturing

"**CIADM** Program"

CIADM Program



Establish public-private partnerships to construct or retrofit U.S.-based, commercial-scale, biopharma facilities that support advanced development and manufacturing of MCMs

Provide core services, on a routine basis, for the advanced development and manufacturing of CBRN biopharmaceuticals supported by the U.S. Government

Provide, in an emergency, necessary U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats

Provide biopharma-oriented workforce development through training programs aligned with current regulatory guidelines

Domestic Capacity

Seqirus™
A CSL Company

Holly Springs , NC

1st "cell-based" influenza vaccine manufacturing facility in the U.S.

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Domestic Capacity

emergent biosolutions™

Baltimore, MD

Ribbon Cutting May 2017

Three ~9,000 sq-ft cGMP suites

Domestic Capacity

THE TEXAS A&M CENTER FOR INNOVATION
in Advanced Development & Manufacturing

College Station, TX

National Center for Therapeutics Manufacturing [NCTM]

FUJIFILM Diosynth biotechnologies

Texas Biomanufacturing Facility [TBF]

Flexible Biomanufacturing Facility [FBF]

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Domestic Capacity

Department of Defense's (DoD)
Advanced Development & Manufacturing (ADM) facility
is "Open for Business"
for MCM development & manufacturing

Coordinated Approach

DoD ADMC

- Focused on global threats
- Supports 1.4M service members – 18 to 55 years old
- Works toward a state of good health
- Maintains broad product portfolio to protect service members
- Produces small force to full force scale depending on threat

HHS CIADM

- Focused on threats to the homeland
- Supports U.S. population – pediatrics to geriatric
- Works on the entire health continuum
- Maintains a biological-focused & pandemic influenza
- Produces relatively large scale to support the entire U.S. population.

Capacity & Capability

BARDA has invested to bolster Domestic Infrastructure [Capacity]

+ True Partnership Model
+ Skilled Workforce
+ Proven Technologies/ Platforms
+ Innovative Culture
+ Sustained Funding Commitment

…to get closer to the CIADM Vision!

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Dept of Defense's ADM

Platforms for
Rapid
Integrated
Solutions of
Medical countermeasures

Streamline generation of a *portfolio* of MCM candidates
- Reduce developmental risk
- Shorten timelines
- Reduce costs

Develop a DoD capability to support MCM *rapid response*
- novel threats
- emerging threats

Nicole Kilgore, MS, PMP
Joint Product Director, PRISM
Medical Countermeasure Systems (MCS)
Office: (301) 619-8441
E-mail: nicole.r.kilgore.civ@mail.mil