SUSTAINABLE PREPAREDNESS FOR CURRENT THREATS:

SUSTAINABILITY

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HHS/ASPR/BARDA
Total Life Cycle Costs

“The total cost to the United States Government and Sponsor of a product over its full life necessary to achieve and maintain readiness for the desired end state of the product. It may include the costs of discovery, development, acquisition, infrastructure, operations, support, and disposal”
Sustainability and Total Life Cycle Cost

- Total Life Cycle Cost (TLCC) containment is a major component of BARDA’s MCM Sustainability Strategy

- Why is it important?
  - The PHEMCE’s current medical countermeasures (MCM) portfolio faces sustainability challenges. The financial burden could limit resources to respond to new threats and our ability to maintain existing capabilities
  - Opportunities to impact TLCC occur throughout the development life cycle
  - We need your support to contain TLCC and develop enhanced products
Components of BARDA’s TLCC Strategy

- **Legacy Program**
  - Program launched in 2013 with establishment of a standard definition for TLCC
  - Utilizes an internal “BARDA TLCC Tool” to estimate and evaluate the TLCC of product in the BARDA Portfolio
  - Enhanced our understanding of the cost of drug development while improving financial planning and portfolio management

- **New 2016 Initiatives:**
  - Implemented a “TLCC Cost Avoidance Register” to track savings
  - Promoting a culture within BARDA where program teams are considering TLCC in their day to day oversight of their projects
  - BARDA program staff now including TLCC assessments as part of pre-award and at the In-Process Reviews (IPR)
  - Running pilot initiative where Sponsor’s provide TLCC assessment and cost avoidance strategies during pre-award
TLCC are locked in Early
Where we are in 2016?

TLCC Tool

Engaging Sponsors on TLCC

Project Level: TLCC and Cost Avoidance Reporting

BARDA Cost Avoidance Register
Why Sponsor’s estimates are necessary prior to award

- Requires the Sponsor to communicate a technical approach to controlling TLCC

- Allows ASPR to evaluate the Sponsor’s technical approach to decreasing TLCC (e.g. Extended stability, formulation, etc.)

- Provides overview of companies investments (a USG cost savings) and highlights benefits of our public private partnership model

- Provides information on commercial and biodefense market

- Identifies projects where sustainability presents a significant challenge and provides the opportunity to propose cost avoidance mitigation strategies
Why is it important to you?

- Cost containment may increase efficiencies (COGS)
- Value proposition of your product over others product also in development
- Provides cost savings justification for BARDA making investment in replacement products/capabilities