



SUSTAINABLE PREPAREDNESS FOR CURRENT THREATS:

SUSTAINABILITY

Tyler Merkeley, M.S, MBA
BARDA's CARB-X Program Manager
October 18, 2016
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

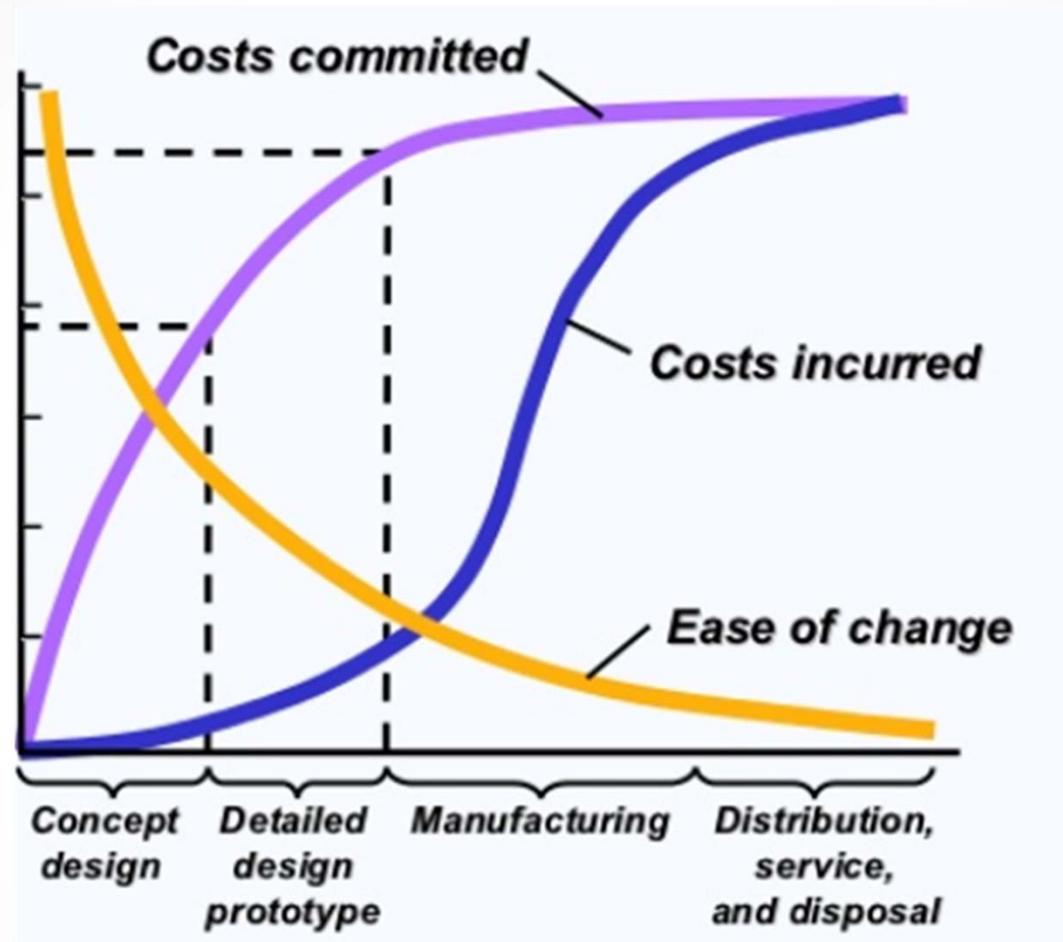


Components of BARDA's TLCC Strategy

- 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



Hit to Optimization	PC to EOP1	Phase II - Marketing
---------------------	------------	----------------------



Where we are in 2016?

TLCC Tool

Total Life Cycle Costs - BARDA 2014 Interim ROM Tool										
Product	Sponsor	Discovery	Preclinical	Phase I	Phase II	Phase III	Approval / License Submission	Phase IV/Post Approval/License Commitment/Post Registration AMD	Procurement & Sustainment (to 2025)	Total Life Cycle Costs (\$ mil)
XXX	XXX	(TRL 1-4)	(TRL 4-6R)	(TRL 6C)	(TRL 7)	(TRL 8)	(TRL 9)	TRL	Cost per Procurement	\$ 74,000,000
Cost		\$ 4,000,000	No Data Provided	No Data Provided	\$ 49,000,000	\$ 21,000,000	\$ -	\$ -	\$ -	\$ -
Source of Data		Estimates by Product Type	Estimates by Product Type	Estimates by Product Type	Estimates by Product Type					
Estimation Sources		Source	No Antisocial	Flu-Advanta Spaving	CBRN Antisocial	CBRN Antisocial	CBRN Antisocial	Flu Antisocial		
Inputs costs (if applicable)										
Add assumptions										

Project Level: TLCC and Cost Avoidance Reporting

Project Name	Sponsor/Company	Compound	Project Lead	Division	Branch	Matrix Team
Text	Drop Down	Text	Text	Drop Down	Drop Down	Drop Down
Technical Approach for TLCC Cost Avoidance		Assumptions:				
Status	Cost Savings Beneficiary	Cost (Original)	Cost (w TLCC Mitigation)	Expense of Cost for Mitigation	Cost Avoidance	When List Cost
Drop Down	Drop Down	\$ XXX,XXX,XXX,XXX	\$ XXX,XXX,XXX,XXX	\$ XXX,XXX,XXX,XXX	\$ XXX,XXX,XXX,XXX	
Schedule Impact		Performance Impact		Included in Register		
Drop Down		Drop Down		Yes/No		

Engaging Sponsors on TLCC

FEDBIZOPPS.GOV Federal Business Opportunities

Home Getting Started General Info Opportunities Agencies

Buyers: [Login](#) | [Register](#) Vendors: [Login](#) | [Register](#)

Broad Agency Announcement (BAA) for the Advanced Research and Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasures for BAR JA
 Solicitation Number: BAA-16-100-SOL-00001
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

BARDA Cost Avoidance Register

By Division: TLCC Cost Avoidance Rollup									
	Tracking	Evaluating	Recommending	Approved/ Funded	Implementing	Cost Avoidance Realized	Total		
	\$ 47,586,000	\$ -	\$ -	\$ 733,920,000	\$ 74,419,625	\$ -	\$ 855,925,625		
DDMD	0	0	0	0	0	0	0		
FLU	0	0	0	0	0	0	0		
MFE	0	0	0	0	0	0	0		
SS&T	0	0	0	0	0	0	0		
RDA	0	0	0	0	0	0	0		
Division Totals	4	0	0	733,920,000	74,419,625	0	855,925,625		

Note 1) If "sponsor" is identified as "Cost Savings Beneficiary," then the costs avoidance will not appear on this rollup.
 Note 2) No costs avoidance will appear on this rollup until the validation step is complete.
 For Official Use Only - Contains Contractor's Confidential and Proprietary Information - FAR 3.104 Procurement Sensitive



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

