BARDA Industry Day Boston

Medical Countermeasures Development Decision Process for Acquisition Management

Decision Gate

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Decision Gate

• Purpose: To determine the status and management of a development project with the capability of improving the potential outcomes through transparent and thorough review and documentation.

• Decision Gates: Align with FDA developmental Phases and are Critical “go-no go” points within program.

• Metrics: The means to judge performance between and at decision points (to include organizational transitions).

• Integration/Teaming: A means to involve stakeholders within decisions and execution.

• Development: Tested in BARDA/CBRN since 2008 to begin identification of best practices and lessons learned for greater implementation.

MDR/IPR “Event” Criteria

• Decision Gate Major Milestones
  – First in Human
  – Start of Phase II
  – Start of Phase III
  – NDA / BLA Approval
  – Life Cycle Management

• Review Benefits
  – Entrance / Exit Criteria
  – Promotes Life Cycle Planning
MDR/IPR “Event” Criteria (cont.)

• Breach
  — Cost, Schedule, Performance (Technical) deviations
    • 10% deviation from cost level
    • Projected deviation of 6 months or more
    • Project milestones will not be achieved within the PoP
    • Based on risk assessment of PCT and SMEs
    • Contractor ability to meet technical requirements / objectives of the contract

• Option Execution –
  — Review requirement for exercising a contract option
MDR/IPR “Event” Criteria (cont.)

• Modification Request –
  – Increases total contract value
  – Alters schedule and achievement of milestones
  – Result of outside factors (FDA as an example)

• Guidance –
  – The PCT can request an IPR for the purpose of leadership and stakeholder guidance on issues they are unable to resolve

• Annual –
  – If none of the previously mentioned issues is realized all programs >$10M in obligated funds will be reviewed annually
Decision Gate Benefits

• Consistency of management thru standardization of process
• Accurate assessment of project status
• Involvement of Stakeholders – Uniform Strategic Plan
  — Consideration of End User requirements
  — Consideration of Regulatory landscape
• Thorough consideration of options
• Early identification of issues and resolution
• Assessment of resource requirements (e.g. availability of funds)

Format Options

• Current Practices
  — Four Part Review Session
    • Contractor Presentations
    • Q&A with Contractor
    • PCT Presentation
    • Government Only Q&A
  — Stakeholder Involvement

• Optional Format
  — Two Part Session
    • PCT Presentation
    • Government Only Q&A
  — Stakeholder Involvement

Questions
Exercise