



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

ASPR: Resilient People. Healthy Communities. A Nation Prepared.



Exercise

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