BARDA Industry Day Washington, DC

Medical Countermeasures Development
Decision Process for Acquisition Management

In Process Reviews

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In Process Review

- **Purpose:** To determine the status and management of a development project, intended to improve the potential outcomes through transparent and thorough review, discussion and documentation.

- **Reviews:** Event Driven or 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.

- **Integration/Teaming:** a means to involve all stakeholders with decisions and execution.

Review “Event” Criteria

• Option Execution –
  — Review progress of the current Period of Performance
  — Review development plan next steps
  — Funding Request

• Modification Request –
  — Increases total contract value
  — Alters schedule and achievement of milestones
  — Result of outside factors (FDA as an example)
Review “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 Period of Performance
    • Contractor ability to meet technical requirements / objectives of the contract
    • Based on risk assessment of PCT and SMEs
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)

Major Decision Gates

**Decision Gates Align with FDA Developmental Phases**

- **Discovery**
- **Preclinical**
- **Phase I**
- **Phase II**
- **Phase III**
- **File**
- **Launch**
- **LCM**

**Decision Gate Major Milestones**

- First in Human
- Start of Phase II
- Start of Phase III
- NDA / BLA Approval
- Life Cycle Management

Questions