BARDA Industry Day Washington, DC

Medical Countermeasures Development Decision Process for Acquisition Management

In Process Reviews

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In Process Review (IPR)

• 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

• Contract 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)

• Breach –
  — Cost, Schedule, Performance (Technical) deviations
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)
IPR Format

• Presentation
  — 30 to 40 minutes

• Q&A Session with Stakeholders
  — 20 to 30 minutes

• Break/Contractor Dismissal

• Government Only Session
  — PCT Presentation
Expected Discussion Topics

• Current Program Status
  ─ Contract Milestone Achievement (progress metrics)
  ─ Ongoing Trials
  ─ FDA Interactions
  ─ Programmatic Confounders (Risks / Mitigations)

• Schedule Overview
  ─ Original
  ─ New

• Budget Overview
  ─ Original
  ─ New

• Business Strategy

• Conclusions and Next Steps
Government Considerations

• What if remaining program funding was reallocated due to an emerging infectious disease?
  — Remember H1N1?
  — Supplemental Funding May Not Be Available

• Changes to Strategic Guidance / Priorities

• Portfolio Assessment
Possible Outcomes

1. Addition of Animal Study SOW Element and Funding
   1. Pro – Keeps Contract on Schedule
   2. Pro – Meets Agency Requirement
   3. Con – Availability of Funds

2. Adjust PDP according to previously programmed funding
   1. Pro – No change to budget
   2. Con – Schedule Slip
   3. Con – Loss of activities currently in the last option of the contract unless additional funding becomes available

3. Terminate – Reprogram Funding
   1. Pro – Cost Savings (including government resources)
   2. Con – Less Robust Portfolio
Major Decision Gates

**Decision Gates Align with FDA Developmental Phases**

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>File</th>
<th>Launch</th>
<th>LCM</th>
</tr>
</thead>
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- Milestone 0: First in Human
- Milestone 1: Phase II Study
- Milestone 2: Post 2/Pre 3 EUA**
- Milestone 3: NDA/BLA approval
- Milestone 4: Transition To CDC

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

Questions