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

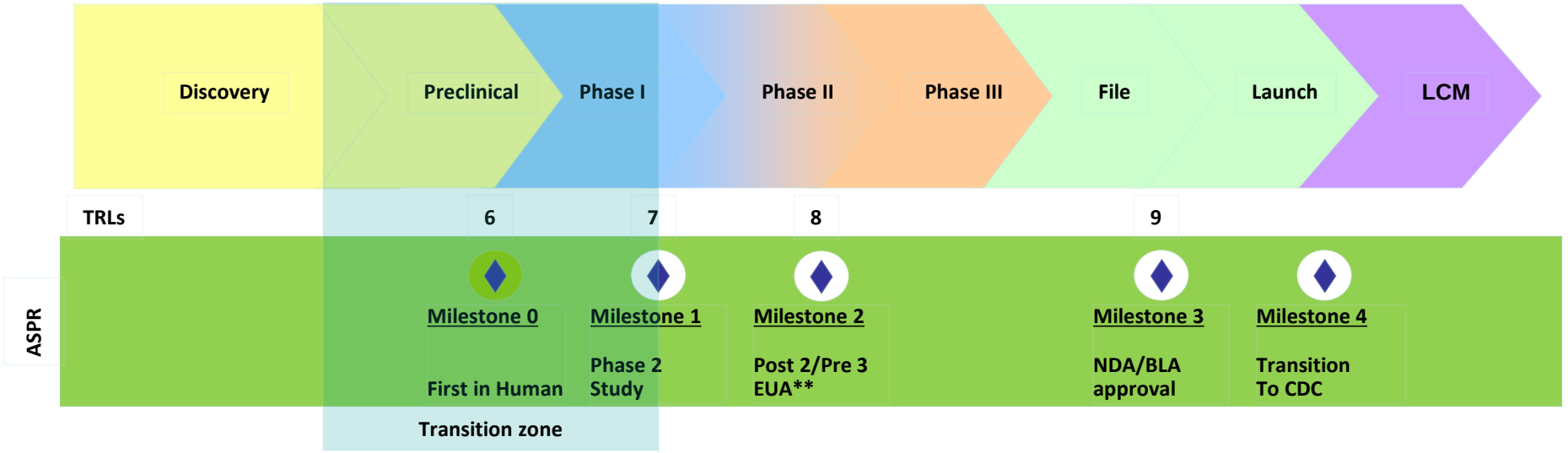
- What if remaining program funding was reallocated due to an immerging infectious disease?
  - Remember H1N1?
  - Supplemental Funding May Not Be Available
- Changes to Strategic Guidance / Priorities
- Portfolio Assessment

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



Decision Gate Major Milestones

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

Questions