



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

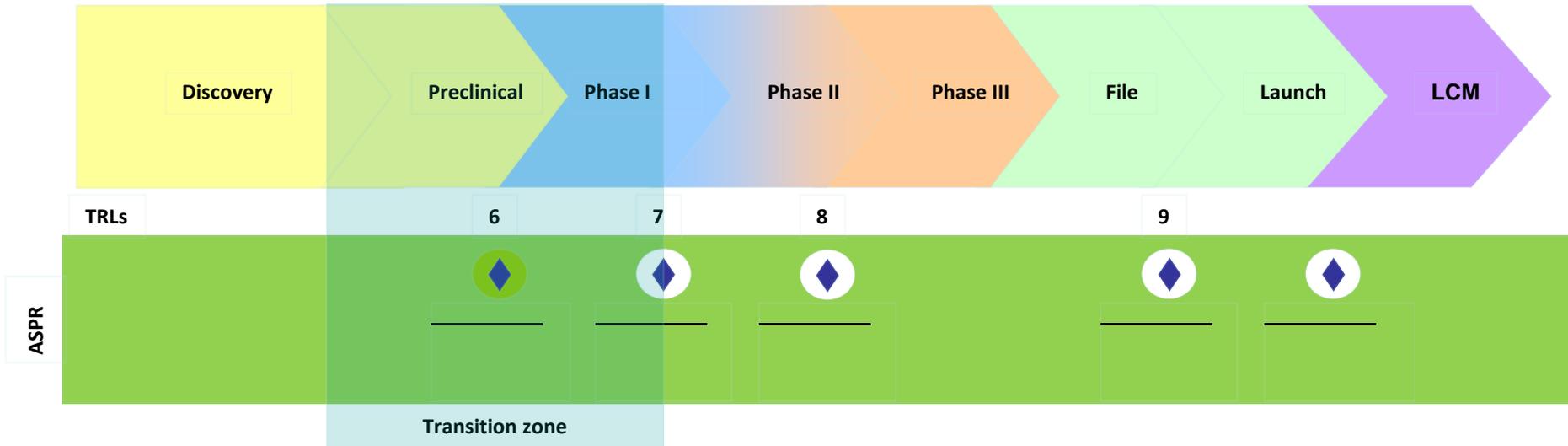


Benefits



- 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)

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

