



Medical Countermeasures Development Decision Process for Acquisition Management

Decision Gate

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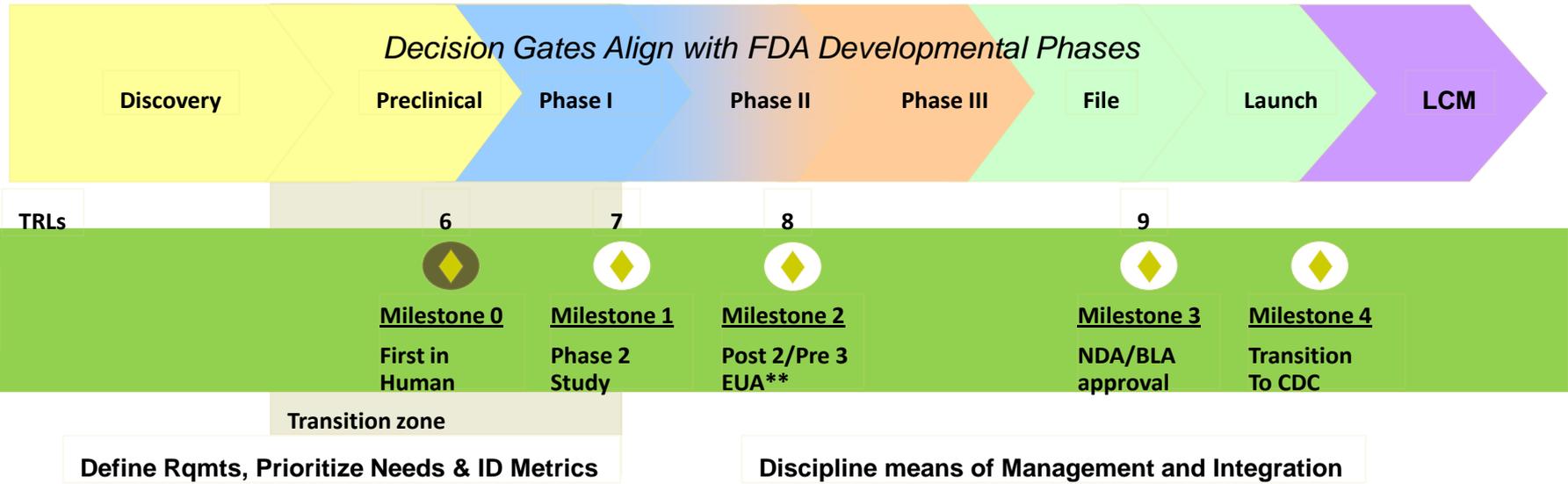
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ASPR Acquisitions Management System Policy

- Policy: Signed February 25, 2011
- Establishes Mandate to use Decision Gate Process
- Decision Points Align BioMedical Product Development Projects to FDA Developmental Phases
- Defines the monetary level for appointment of the Milestone Decision Authority
- Identifies other key roles for the process including the Secretariat and the AMCG Director

ASPR Acquisition Management System - Decision Gate



MDA Determined by Obligated Value		
Category	Dollar Value	MDA
MAC 1	> \$ 300M	ASPR
MAC 2	\$ 200 – 300M	PD ASPR
MAC 3	\$ 50 – 200M	Office Dir
MAC 4	>\$10-50M	Prog Dir

MAC = Major Acquisition Category Level 1, 2, 3, 4
 MDA = Milestone Decision Authority

MDR/IPR Reviews

MDR – Milestone Decision Review
 Based on development life cycle defined time points

IPR – In Process Review
 Event Driven or Annually at a minimum
 Occurs between MDR Reviews

Responsibility of the Project Officer (PO) to inform the MDA in consultation with the Contracting Officer



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 4 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



Business Tool Kit Initiative

Version: 9/23/11

"Vaccine/Biologics" Program Level Work Breakdown Structure Template

Explanation of Examples and How They Can Be Used

The provided WBS is the cornerstone document. The identified categories, to level three, are used for standardized tracking and reporting within the agency for the Vaccines and Biologics programs. There are WBS examples also in development for drugs and devices. Below level three the contractor has the flexibility to develop the project plan in a manner that best suits their organization. It is understood that not all contracts will include activities and tasks within all functional categories. Illustrations of how that can be identified are included in the example documents and will be identified in the descriptions below. These documents are being provided as examples only and not intended to prescribe the use of the specified formats or any software packages.

WBS

includes top level program identification, level two identifies 7 functional categories, and level 3 are the reporting categories used within the agency for progress and tracking. The provided example WBS is being standardized and approved within the agency for vaccines and biologics and will be applied to all vaccine and biologic contracts in the future. Additional standardized WBSs are in development for drugs and devices.

Gantt Chart

includes a cross reference to functional areas. The example Gantt identified progress* and contract Project Management and 1.3 Non-Clinical milestones beyond the standard level 3 with the provided WBS and the identified on the Gantt. This is to illustrate as well as project needs that have with the provided WBS and the identified on the Gantt. In this example noted that activities in that area is to illustrate planning flexibility; require activities listed if previously performance, and assessment and a list/menu of

ABC Co. Generic Vaccine Contract Milestones and Deliverables 10/11/2010

Gantt Line #	WBS	Milestone	Deliverable	Success Criteria	Timing	Option
1.1 Project Management						
6	1.1.1.3	Complete Project Baseline Schedule	Updated Gantt w/WBS Cross Reference and Identified Deliverables	Includes updates as discussed with PCT at Kickoff meeting, and MS identification for Progress Assessment	Q1,FY11	Base
14	1.1.2.2	Complete Subcontractor Plan	Subcontractor Management Plan	Identifies key interaction factors between prime and sub for progress updates and risk management	Q1,FY11	Base
17	1.1.3.2	Complete Risk Management Plan	Risk Management Plan	Identifies key risks, assessment, mitigations, contingencies and impact as well as update process	Q1,FY11	Base
11	1.1.1.5.3	Hiring Complete	Key Positions Filled and added to Contract	Positions identified during negotiations have been filled by qualified personnel for their expected duties associated to the project	Q1,FY11	Base
1.2 Non-Clinical Toxicology Milestones						
1.3 Non-Clinical Milestones						
28	1.3.2.1	Completion of Study 1a under Objective 1, Single Dose	Draft study report for Objective 1 study 1a segment	Characterization of model that achieves protocol end points outlined in protocol XXXXXXXX	Q2,FY11	Base
30	1.3.2.4	Completion of Study 1b under Objective 1, Fractional Dosing	Draft study report for Objective 1 study 1a segment and 1b segment	Characterization of model that achieves protocol end points outlined in protocol XXXXXXXX	Q3,FY11	Base
33	1.3.3.2	Completion of Study 2 under Objective 1, xxxxxx	Final study report for Objective 1 study 1a segment, 1b segment, and study 2 included	Characterization of model that achieves protocol end points outlined in protocol XXXXXXXX	Q1,FY12	Option 1
1.4 Clinical Milestones						

ASPR/BARDA sample template



Business Tool Kit

- Explanation of Examples and Uses
- Work Breakdown Structure
 - Aligned to BARDA Reporting Requirements
- Integrated Management Schedule (IMS)
 - Example includes cross references between documents
- Contract Milestone Chart
 - Used as metrics for progress determination during reviews
- Sample Project Management Plan
- Sample Sub-Contractor Management Plan
- Risk Management Plan
 - Illustrates impact on project if risks are realized



United States Department of

Health & Human Services

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Questions

