## BARDA Industry Day Washington, DC

# Business Tool Kit


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**Contractor - BRTRC**

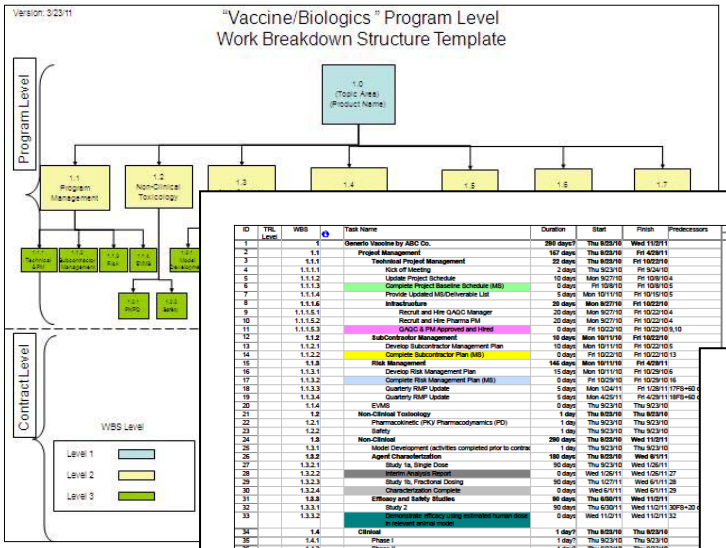

**October 30, 2012**

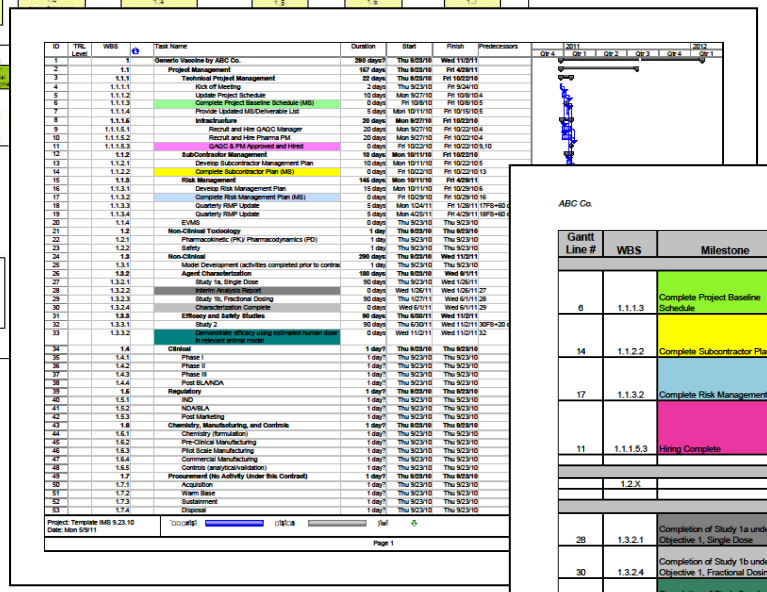
# Business Tool Kit Initiative

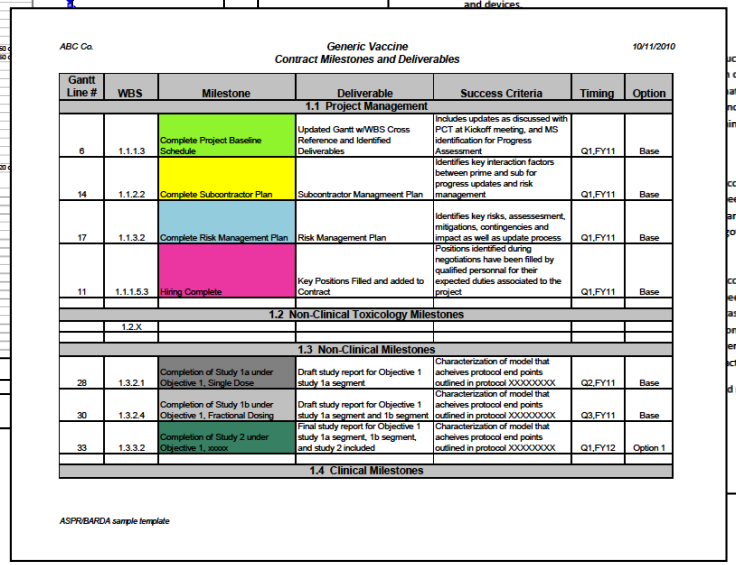
ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Available at

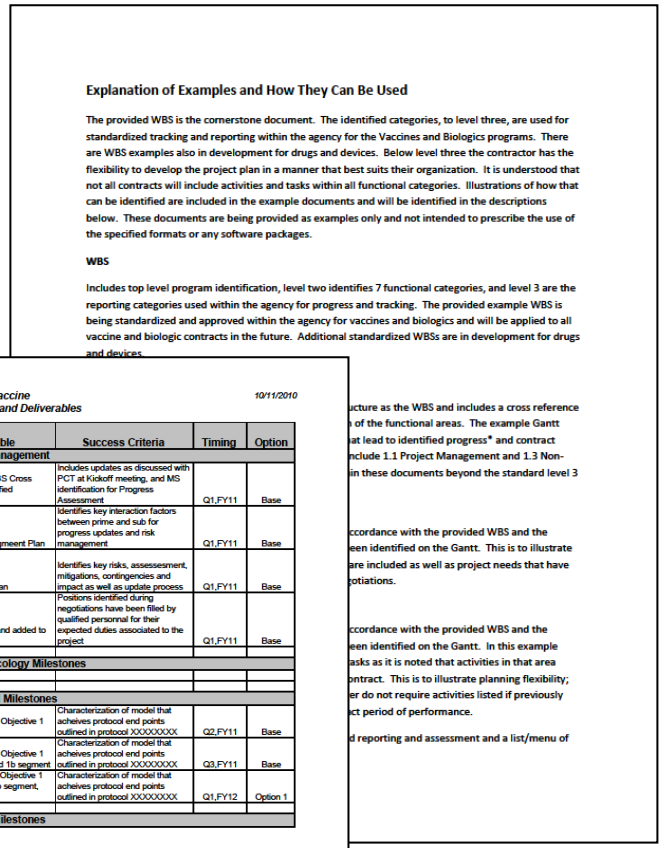
http://www.phe.gov/about/amcg/toolkit/Pages/default.aspx






| 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, assessesment, 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 personnal for their expected duties associated to the project | Q1,FY11 | Base |
| **1.2 Non-Clinical Toxicology Milestones** | | | | | | |
| | 1.2.X | | | | | |
| **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 acheives 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 acheives protocol end points outlined in protocol XXXXXXXX | Q3,FY11 | Base |
| 33 | 1.3.3.2 | Completion of Study 2 under Objective 1, xxxxx | Final study report for Objective 1 study 1a segment, 1b segment, and study 2 included | Characterization of model that acheives protocol end points outlined in protocol XXXXXXXX | Q1,FY12 | Option 1 |
| **1.4 Clinical Milestones** | | | | | | |



**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.

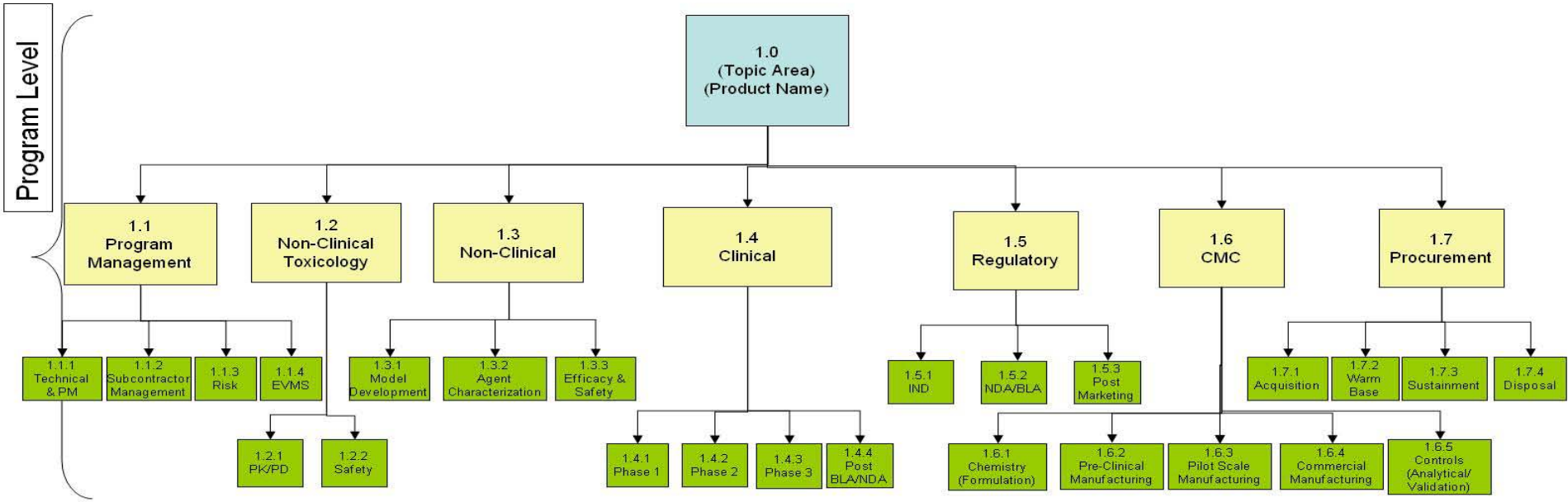
*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*

# Series of Step by Step Documents for the Development of a Project Development Plan

- **Explanation of Examples and Uses**
  - Narrative that walks you through each document and how they are linked
- **Work Breakdown Structure**
  - Aligned to BARDA Reporting Requirements
- **Integrated Management Schedule (IMS) (“Gantt Chart”)**
  - 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
  - Aligns to WBS and IMS

Version: 3/23/11

# "Vaccine/Biologics " Program Level Work Breakdown Structure Template



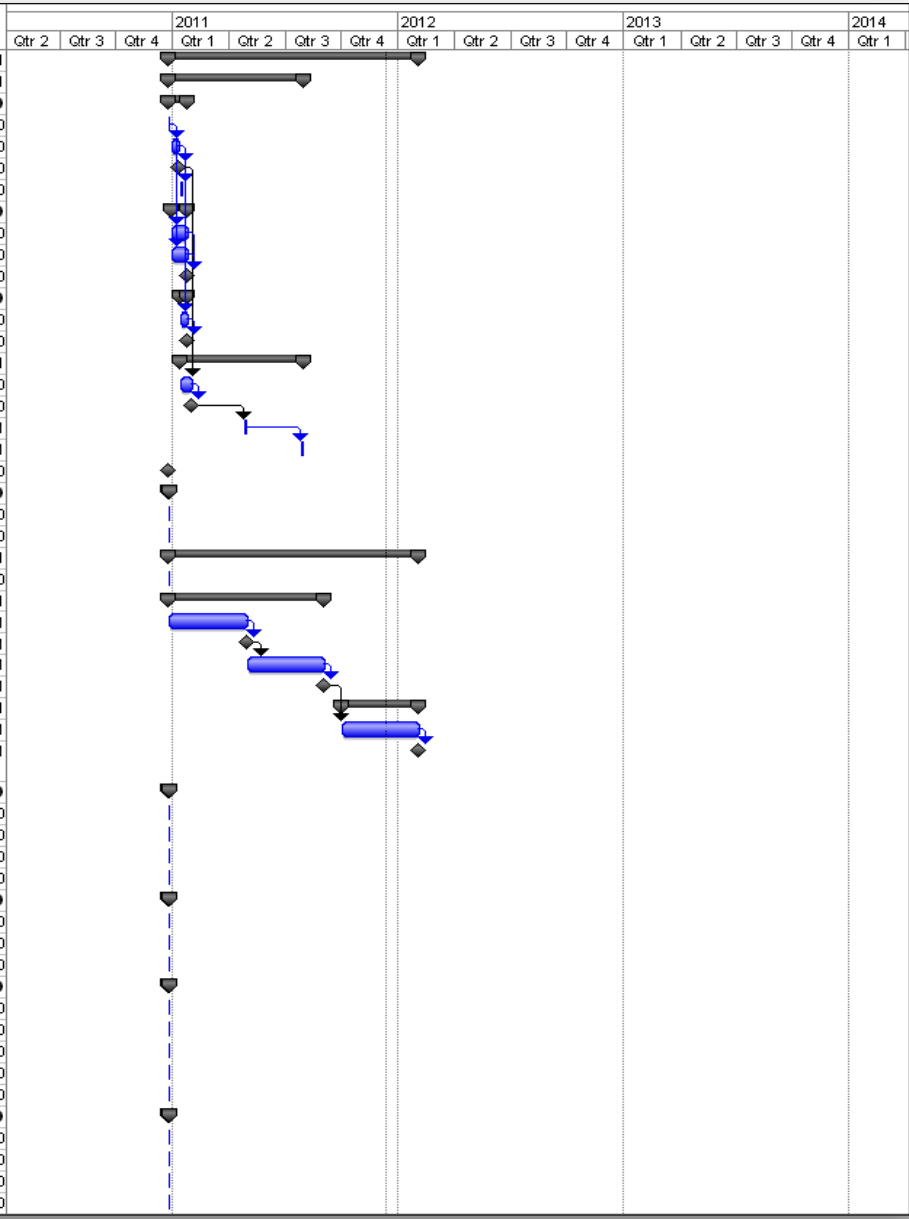

Contract Level

WBS Level

- Level 1
- Level 2
- Level 3

This is a WBS Reporting template. The Program Level WBS structure provides consistency across the program. A contractor should expand their Contractor WBS beyond the top three levels to the appropriate reporting level. Not all contracts will include work that flows into each WBS, please note un-used WBS lines as "reserved."

| ID | TRL Level | WBS | | Task Name | Duration | Start | Finish |
|---|---|---|---|---|---|---|---|
| 1 | | **1** | | **Generic Vaccine by ABC Co.** | **290 days?** | **Thu 9/23/10** | **Wed 11/2/11** |
| 2 | | **1.1** | | **Project Management** | **157 days** | **Thu 9/23/10** | **Fri 4/29/11** |
| 3 | | **1.1.1** | | **Technical Project Management** | **22 days** | **Thu 9/23/10** | **Fri 10/22/10** |
| 4 | | 1.1.1.1 | | Kick off Meeting | 2 days | Thu 9/23/10 | Fri 9/24/10 |
| 5 | | 1.1.1.2 | | Update Project Schedule | 10 days | Mon 9/27/10 | Fri 10/8/10 |
| 6 | | 1.1.1.3 | | Complete Project Baseline Schedule (MS) | 0 days | Fri 10/8/10 | Fri 10/8/10 |
| 7 | | 1.1.1.4 | | Provide Updated MS/Deliverable List | 5 days | Mon 10/11/10 | Fri 10/15/10 |
| 8 | | **1.1.1.5** | | **Infrastructure** | **20 days** | **Mon 9/27/10** | **Fri 10/22/10** |
| 9 | | 1.1.1.5.1 | | Recruit and Hire QAQC Manager | 20 days | Mon 9/27/10 | Fri 10/22/10 |
| 10 | | 1.1.1.5.2 | | Recruit and Hire Pharma PM | 20 days | Mon 9/27/10 | Fri 10/22/10 |
| 11 | | 1.1.1.5.3 | | QAQC & PM Approved and Hired | 0 days | Fri 10/22/10 | Fri 10/22/10 |
| 12 | | **1.1.2** | | **SubContractor Management** | **10 days** | **Mon 10/11/10** | **Fri 10/22/10** |
| 13 | | 1.1.2.1 | | Develop Subcontractor Management Plan | 10 days | Mon 10/11/10 | Fri 10/22/10 |
| 14 | | 1.1.2.2 | | Complete Subcontractor Plan (MS) | 0 days | Fri 10/22/10 | Fri 10/22/10 |
| 15 | | **1.1.3** | | **Risk Management** | **145 days** | **Mon 10/11/10** | **Fri 4/29/11** |
| 16 | | 1.1.3.1 | | Develop Risk Management Plan | 15 days | Mon 10/11/10 | Fri 10/29/10 |
| 17 | | 1.1.3.2 | | Complete Risk Management Plan (MS) | 0 days | Fri 10/29/10 | Fri 10/29/10 |
| 18 | | 1.1.3.3 | | Quarterly RMP Update | 5 days | Mon 1/24/11 | Fri 1/28/11 |
| 19 | | 1.1.3.4 | | Quarterly RMP Update | 5 days | Mon 4/25/11 | Fri 4/29/11 |
| 20 | | 1.1.4 | | EVMS | 0 days | Thu 9/23/10 | Thu 9/23/10 |
| 21 | | **1.2** | | **Non-Clinical Toxicology** | **1 day** | **Thu 9/23/10** | **Thu 9/23/10** |
| 22 | | 1.2.1 | | Pharmacokinetic (PK)/ Pharmacodynamics (PD) | 1 day | Thu 9/23/10 | Thu 9/23/10 |
| 23 | | 1.2.2 | | Safety | 1 day | Thu 9/23/10 | Thu 9/23/10 |
| 24 | | **1.3** | | **Non-Clinical** | **290 days** | **Thu 9/23/10** | **Wed 11/2/11** |
| 25 | | 1.3.1 | | Model Development (activities completed prior to conf | 1 day | Thu 9/23/10 | Thu 9/23/10 |
| 26 | | **1.3.2** | | **Agent Characterization** | **180 days** | **Thu 9/23/10** | **Wed 6/1/11** |
| 27 | | 1.3.2.1 | | Study 1a, Single Dose | 90 days | Thu 9/23/10 | Wed 1/26/11 |
| 28 | | 1.3.2.2 | | Interim Analysis Report | 0 days | Wed 1/26/11 | Wed 1/26/11 |
| 29 | | 1.3.2.3 | | Study 1b, Fractional Dosing | 90 days | Thu 1/27/11 | Wed 6/1/11 |
| 30 | | 1.3.2.4 | | Characterization Complete | 0 days | Wed 6/1/11 | Wed 6/1/11 |
| 31 | | **1.3.3** | | **Efficacy and Safety Studies** | **90 days** | **Thu 6/30/11** | **Wed 11/2/11** |
| 32 | | 1.3.3.1 | | Study 2 | 90 days | Thu 6/30/11 | Wed 11/2/11 |
| 33 | | 1.3.3.2 | | Demonstrate efficacy using estimated human dose in relevant animal model | 0 days | Wed 11/2/11 | Wed 11/2/11 |
| 34 | | **1.4** | | **Clinical** | **1 day?** | **Thu 9/23/10** | **Thu 9/23/10** |
| 35 | | 1.4.1 | | Phase I | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 36 | | 1.4.2 | | Phase II | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 37 | | 1.4.3 | | Phase III | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 38 | | 1.4.4 | | Post BLA/NDA | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 39 | | **1.5** | | **Regulatory** | **1 day?** | **Thu 9/23/10** | **Thu 9/23/10** |
| 40 | | 1.5.1 | | IND | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 41 | | 1.5.2 | | NDA/BLA | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 42 | | 1.5.3 | | Post Marketing | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 43 | | **1.6** | | **Chemistry, Manufacturing, and Controls** | **1 day?** | **Thu 9/23/10** | **Thu 9/23/10** |
| 44 | | 1.6.1 | | Chemistry (formulation) | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 45 | | 1.6.2 | | Pre-Clinical Manufacturing | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 46 | | 1.6.3 | | Pilot Scale Manufacturing | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 47 | | 1.6.4 | | Commercial Manufacturing | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 48 | | 1.6.5 | | Controls (analytical/validation) | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 49 | | **1.7** | | **Procurement (No Activity Under this Contract)** | **1 day?** | **Thu 9/23/10** | **Thu 9/23/10** |
| 50 | | 1.7.1 | | Acquisition | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 51 | | 1.7.2 | | Warm Base | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 52 | | 1.7.3 | | Sustainment | 1 day? | Thu 9/23/10 | Thu 9/23/10 |
| 53 | | 1.7.4 | | Disposal | 1 day? | Thu 9/23/10 | Thu 9/23/10 |



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| | | | | | | |
| **1.4 Clinical Milestones** | | | | | | |
| | | | | FDA Concurrentce to proceed with clinical studies and protocol approval by FDA and IRB | | |

- **Sample Project Management Plan**
  - Generic Example, includes elements and topics for consideration
- **Sample Sub-Contractor Management Plan**
  - Generic Example, includes elements and topics for consideration
- **Risk Management Plan**
  - Generic Example of Management and Oversight Process, includes elements and topics for consideration
  - Example of a 5 by 5 Risk Assessment Matrix with Definitions
  - Risk Registry
    - Illustrates impact on project if risks are realized
    - Aligns to WBS and IMS

| Risk Register for "Generic Vaccine" | | | | | | | |
|---|---|---|---|---|---|---|---|
| Gantt | WBS | Risk | Overall Impact | Mitigation | Contingency | CSP Impact | Timing / Option |
| 30 | 1.3.2.4 | FDA does not agree with the characterization results (non-clinical and clinical studies planned, example if FDA requires NHP instead of used animal model) | Occasional + Moderate = 3C | Early and frequent meetings with the FDA prior to study execution. | Update program design with FDA input, modify SOW, obtain BARDA CO, PO, and Management Approval of new SOW, and provide budget request | Additional $400,000 for NHP Model Study<br><br>Addition of ~9 months | Q3, FY11 - BASE |
| | | Lab unable to produce an adequate amount of product to conduct all studies that are currently scheduled | | Subcontract negotiations with CMO to produce product for use in non-clinical studies. | 1. Slow the pace of the studies to accommodate the production availability<br>2. Use available lab product until CRO cGMP product is available | | |
| | | Contract negotiations failure | | Subcontract negotiations with CMO to produce non-GMP product for use in non-clinical studies. | 1. Use available lab product and schedule studies based on available product.<br>2. Transition financial resources from subcontract to expansion of lab for production.<br>3. Transition financial resources to expedite the execution of the cGMP subcontract. | | |
| | | Manufacturing failure | | Complete technical package and assistance available from lab. | 1. Second manufacturing attempt<br>2. Discontinue contract and use lab product<br>3. Discontinue contract and expedite the cGMP manufacturing contract. | | |
| | | Contract negotiations failure with cGMP facility | | Early RFP for evaluation of multiple CMO facilities | Alternate facility RFP | | |
| | | Tech Transfer failure (lack of detailed information) | | Completion of detailed manufacturing technical transfer package and SME provisions during pilot lot preparations | Manufacturing process development, testing, optimization and validation requirement | | |
| | | Study Task 2 (subtask studies task lines 37 and 38) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |
| | | Study Task 1 (subtask studies task lines 45 and 46) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |
| | | Study Task 3 (subtask studies task lines 52, 53, 54, and 55) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |

# Additional Technical Proposal Elements

- Statement of Work
  - Aligns to Product Development Plan
  - Cross Reference to WBS
- Supporting Research References
  - Prior study results
  - Supporting publications
- Key Personnel Information
  - CVs and Resumes of Key Personnel
  - Hiring Plan

# Cost Proposal

- http://www.phe.gov/about/amcg/Pages/gettingstarted.aspx
- Funding is allocated to specific uses based on the proposal, individual breakouts
  - Labor
  - Subcontractors
  - Consultants
  - Materials
  - ODCs
    - Travel
    - Equipment
- Funding is allocated to specific periods of performance

# Consider…

- Developing your SOW and Cost Proposals based on Work Packages
- Benefits
  - Expedites Proposal Review
  - Changes to the Development Plan during Negotiations
  - Changes to the Development Plan during Execution
  - EVMS Implementation
  - Tracking True Costs

# Questions