



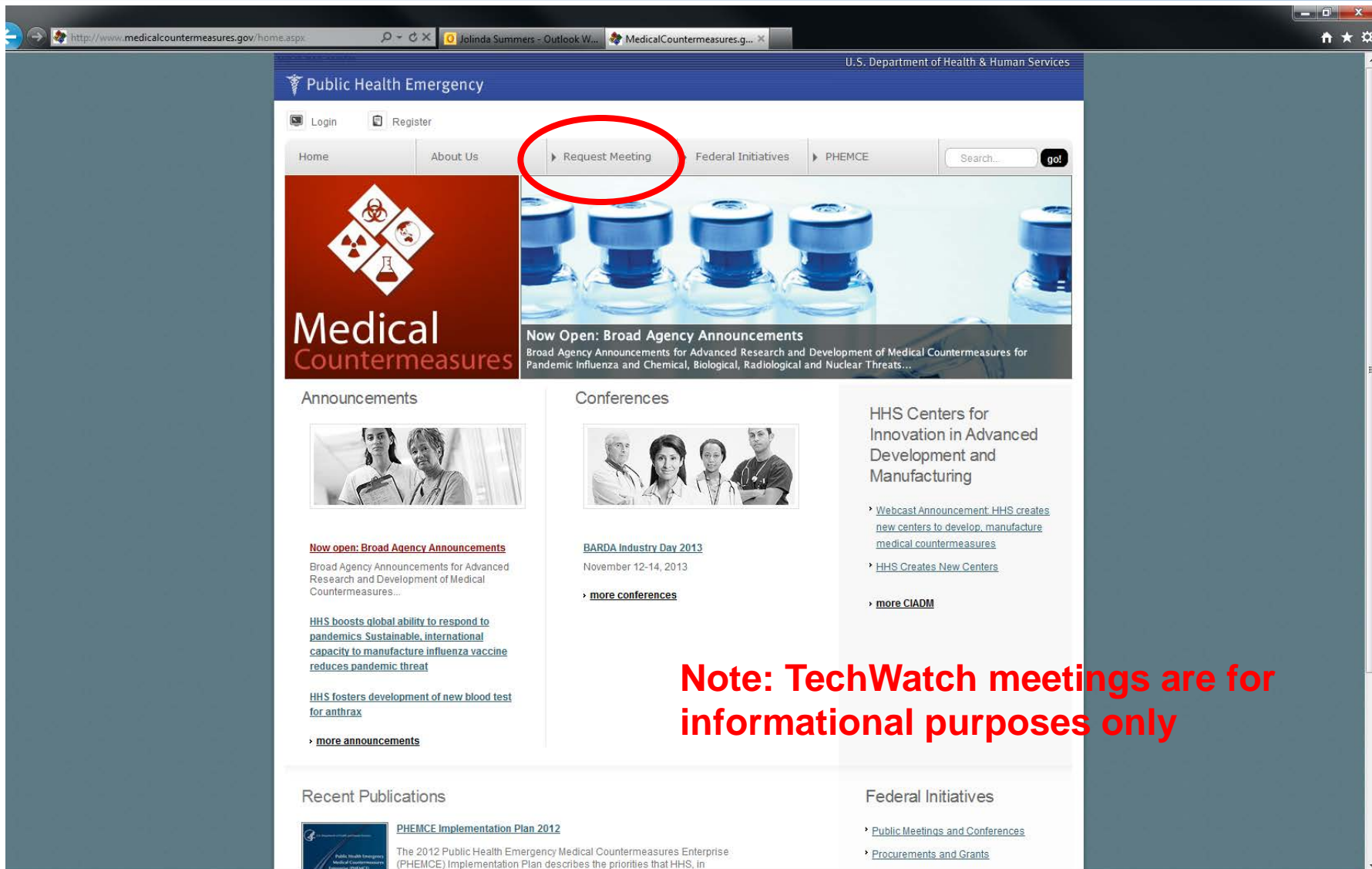
BARDA Industry Day Washington, DC

Online Resources

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Contractor - BRTRC

November 13, 2013



The screenshot shows the homepage of the Medical Countermeasures Enterprise (MCE) website. The browser address bar displays 'http://www.medicalcountermeasures.gov/home.aspx'. The page header includes the U.S. Department of Health & Human Services logo and the text 'Public Health Emergency'. Below the header, there are links for 'Login' and 'Register'. A navigation menu contains 'Home', 'About Us', 'Request Meeting' (highlighted with a red circle), 'Federal Initiatives', and 'PHEMCE'. A search bar is also present. The main content area features a large banner with the text 'Medical Countermeasures' and an image of vials. Below the banner, there are sections for 'Announcements', 'Conferences', and 'Federal Initiatives'. The 'Announcements' section includes a link to 'Now open: Broad Agency Announcements'. The 'Conferences' section includes a link to 'BARDA Industry Day 2013'. The 'Federal Initiatives' section includes a link to 'Public Meetings and Conferences'. A red text overlay on the right side of the page reads: 'Note: TechWatch meetings are for informational purposes only'.

U.S. Department of Health & Human Services

Public Health Emergency

Login Register

Home About Us Request Meeting Federal Initiatives PHEMCE

Search... go!

Medical Countermeasures

Now Open: Broad Agency Announcements
Broad Agency Announcements for Advanced Research and Development of Medical Countermeasures for Pandemic Influenza and Chemical, Biological, Radiological and Nuclear Threats...

Announcements

Conferences

HHS Centers for Innovation in Advanced Development and Manufacturing

Webcast Announcement: HHS creates new centers to develop, manufacture medical countermeasures

HHS Creates New Centers

more CIADM

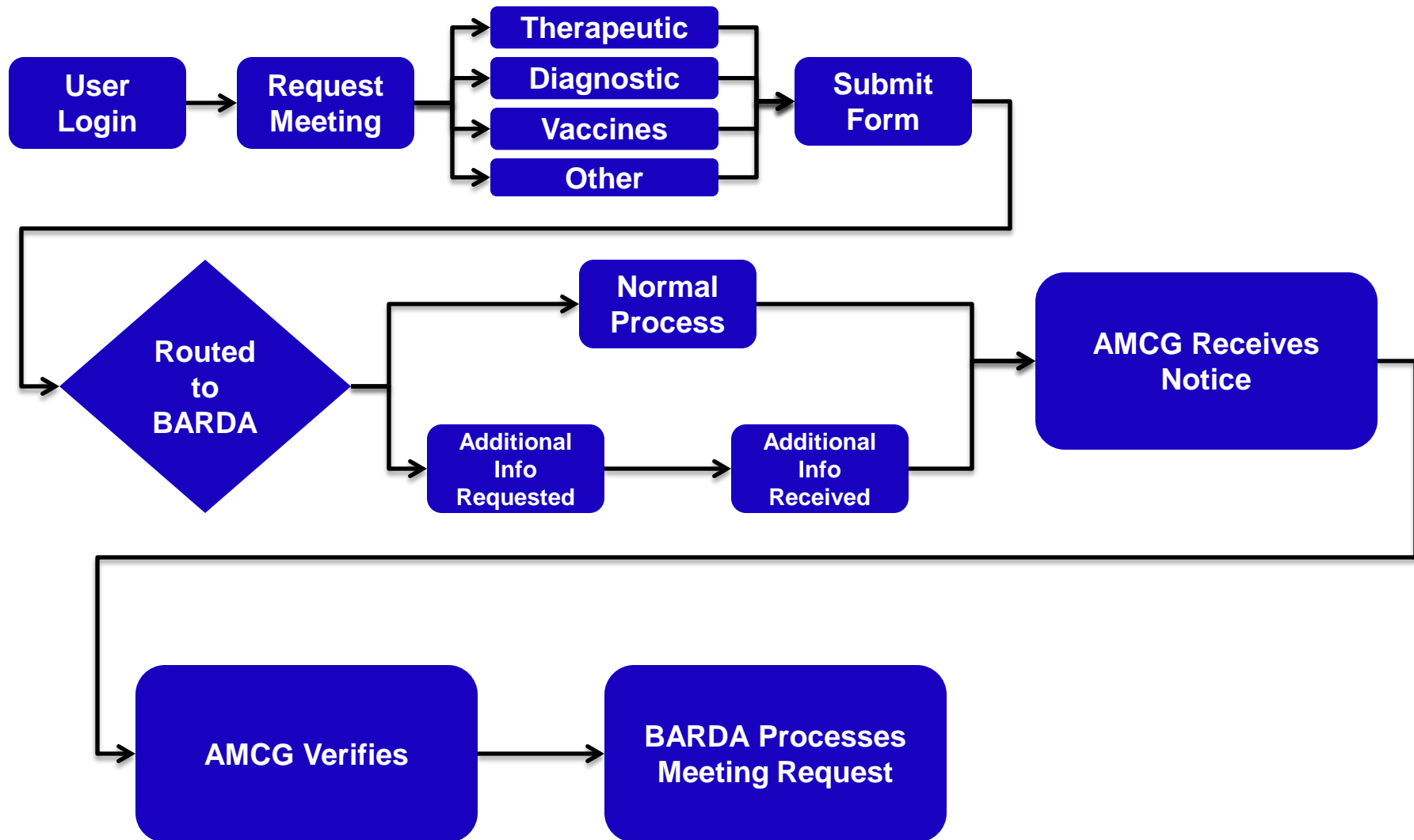
Recent Publications

Federal Initiatives

Public Meetings and Conferences

Procurements and Grants

Note: TechWatch meetings are for informational purposes only





TechWatch Benefits



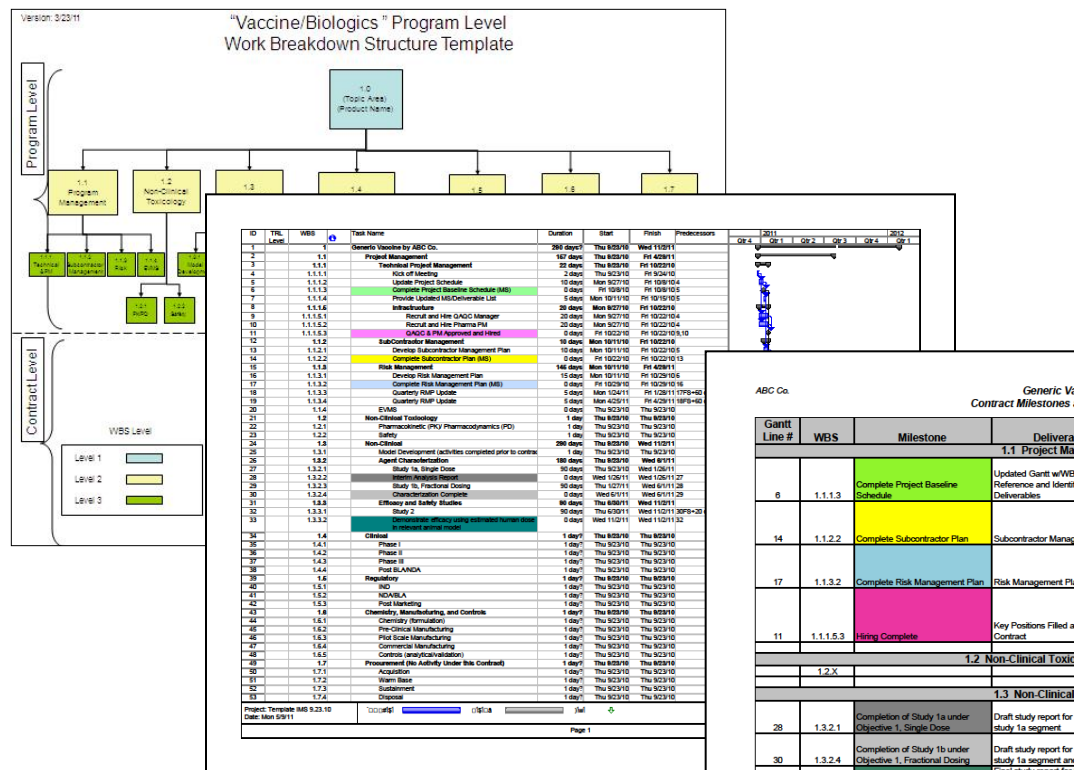
- TechWatch meetings are organized by Strategic Science Technology
- Inform the Government about current countermeasures emerging for preparedness and response
- Companies receive guidance on possible next steps in development of their countermeasure product
- Attendees are Scientific SME's, project management (ASPR, BARDA, NIH, FDA, CDC, DoD) and contracting staff to ensure the procurement integrity guidelines
- Serves as a forum for market research which gather information to help planning the future requirements and solicitation for countermeasure R&D procurement



Business Tool Kit Initiative

Available at

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



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 three 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

The provided example Gantt Chart follows the same structure as the WBS and includes a cross reference to the WBS for the purpose of planning activities in each of the functional areas. The example Gantt Chart includes tasks below the level 3 reporting areas that lead to identified progress* and contract milestones. Expanded example areas within the Gantt include 1.1 Project Management and 1.3 Non-Clinical which are being used to identify flexibilities within these documents beyond the standard level 3 reporting requirements.

1.1 Project Management

Tasks in this section have been planned in accordance with the provided WBS and the associated Milestones / Deliverables have been identified on the Gantt. This is to illustrate planning flexibility; the required categories are included as well as project needs that have been identified through discussions and negotiations.

1.3 Non-Clinical

Tasks in this section have been planned in accordance with the provided WBS and the associated Milestones / Deliverables have been identified on the Gantt. In this example subtopic 1.3.1 Model Development has no tasks as it is noted that activities in that area were completed prior to the award of the contract. This is to illustrate planning flexibility; the required categories are included however do not require activities listed if previously completed or not planned during the contract period of performance.

*Note: Progress Milestones will be used for standardized reporting and assessment and a list/menu of those will be provided upon approval.

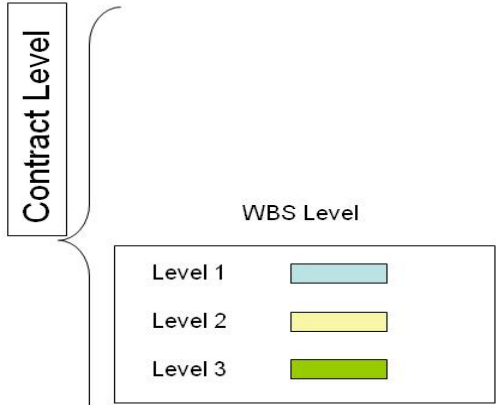
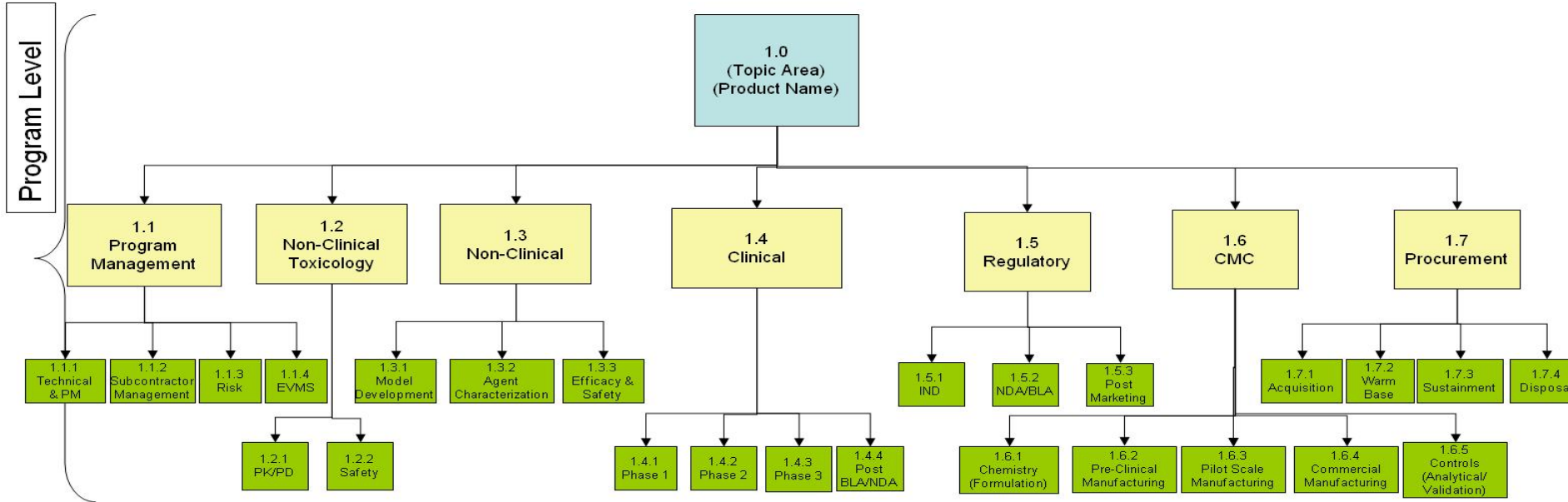


Series of Step by Step Documents for the Development of a Project Development Plan



- **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

“Vaccine/Biologics ” Program Level Work Breakdown Structure Template



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 QA/QC 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	QA/QC & 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

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 Managmeent 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, assesment, 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						
				FDA Concurrentce to proceed with clinical studies and protocol approval by FDA and IRB		



Business Tool Kit



- **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 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 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. 2. Transition financial resources from subcontract to expansion of lab for production. 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 2. Discontinue contract and use lab product 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



Proposal Preparation Resources



- Getting Started located at <http://www.phe.gov/about/amcg/Pages/gettingstarted.aspx>
 - Pre-Proposal Instructions
 - Subcontracting Program
- Cost Proposal
 - Preparation Tips
 - Defined Elements
 - Specific to Periods of Performance
- HHS Office of Small and Disadvantaged Business Utilization



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

