

ID	TRL Level	WBS	Task Name	Duration	Start	Finish	Predecessors	2011					2012
								Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1
1		1	<b>Generic Vaccine by ABC Co.</b>	290 days?	Thu 9/23/10	Wed 11/2/11							
2		1.1	<b>Project Management</b>	157 days	Thu 9/23/10	Fri 4/29/11							
3		1.1.1	<b>Technical Project Management</b>	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	4						
6		1.1.1.3	Complete Project Baseline Schedule (MS)	0 days	Fri 10/8/10	Fri 10/8/10	5						
7		1.1.1.4	Provide Updated MS/Deliverable List	5 days	Mon 10/11/10	Fri 10/15/10	5						
8		1.1.1.5	<b>Infrastructure</b>	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	4						
10		1.1.1.5.2	Recruit and Hire Pharma PM	20 days	Mon 9/27/10	Fri 10/22/10	4						
11		1.1.1.5.3	QAQC & PM Approved and Hired	0 days	Fri 10/22/10	Fri 10/22/10	9,10						
12		1.1.2	<b>SubContractor Management</b>	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	5						
14		1.1.2.2	Complete Subcontractor Plan (MS)	0 days	Fri 10/22/10	Fri 10/22/10	13						
15		1.1.3	<b>Risk Management</b>	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	6						
17		1.1.3.2	Complete Risk Management Plan (MS)	0 days	Fri 10/29/10	Fri 10/29/10	16						
18		1.1.3.3	Quarterly RMP Update	5 days	Mon 1/24/11	Fri 1/28/11	17FS+60 days						
19		1.1.3.4	Quarterly RMP Update	5 days	Mon 4/25/11	Fri 4/29/11	18FS+60 days						
20		1.1.4	EVMS	0 days	Thu 9/23/10	Thu 9/23/10							
21		1.2	<b>Non-Clinical Toxicology</b>	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	<b>Non-Clinical</b>	290 days	Thu 9/23/10	Wed 11/2/11							
25		1.3.1	Model Development (activities completed prior to contrac	1 day	Thu 9/23/10	Thu 9/23/10							
26		1.3.2	<b>Agent Characterization</b>	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	27						
29		1.3.2.3	Study 1b, Fractional Dosing	90 days	Thu 1/27/11	Wed 6/1/11	28						
30		1.3.2.4	Characterization Complete	0 days	Wed 6/1/11	Wed 6/1/11	29						
31		1.3.3	<b>Efficacy and Safety Studies</b>	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	30FS+20 days						
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	32						
34		1.4	<b>Clinical</b>	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	<b>Regulatory</b>	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	<b>Chemistry, Manufacturing, and Controls</b>	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	<b>Procurement (No Activity Under this Contract)</b>	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							

Project: Template IMS 9.23.10  
Date: Mon 5/9/11

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