



“Company C Mock IPR”



- External Factor – FDA
 - Issue
 - Variances in Data Analysis
 - Not a Safety Concern
 - Addition of Small Animal Study
 - Comparability
 - Mechanism of Action
 - No Hold on Clinical
 - Schedule Concurrently
 - Contract Impact
 - Request Supplement Funding and Contract Modification



“Company C Mock IPR”



- SOW
 - Original SOW outline
 - New / Proposed SOW Outline
- Current Program Status
 - Ongoing Trials
 - FDA Interactions
 - Milestones Met (progress metrics)
 - Programmatic Confounders
- Schedule Overview
 - Original
 - New
- Budget Overview
 - Original
 - New
- Conclusions and Next Steps



Apollo Vaccine - Company C
Contract Milestones and Deliverables



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,FY12	Base
8	1.1.1.5	Submission of PMBR MSs and Deliverables to Organization	Updated MS and Deliverables Chart	Includes updated agreed upon MSs and deliverables from the PMBR	Q2,FY12	Base
11	1.1.2.2	Submit Complete Subcontractor Plan (MS)	Subcontractor management plan	Identifies management and oversight process for subcontractors, MS and deliverable tracking and business terms	Q1,FY12	Base
13	1.1.2.4	Submit Contractor Agreements	Submission of subcontractor contract agreements to Org	Includes signed agreement	Q1,FY12	Base
16	1.1.3.2	Submit RMP	Risk Management Plan	Identifies key risks, assessment, mitigations, contingencies and impact as well as update process	Q1,FY12	Base
22	1.1.4.4	EVMS Live and PMBR Accepted	Submission of updated PDP and EVM Reports	Updated PDP as agreed to by the contractor and PCT, EVM Reports acceptable to PCT EVM Spec	Q2,FY12	Base
1.2 Non-Clinical Toxicology Milestones						
27	1.2.1.3	Submit PK/PD Study results	Submission of data analysis and study report	Successful study endpoints in accordance with protocol XXXXX	Q2,FY12	Base
30	1.2.2.2	Submit PK/PD Study results	Submission of data analysis and study report	Successful study endpoints in accordance with protocol XXXXX	Q2,FY12	Base
1.3 Non-Clinical Milestones						
46	1.3.3.7	Completion of Non-Clinical POC activities	Submission of data analysis and study report	Successful study endpoints in accordance with protocols XXXXX, YYYYY, ZZZZZ, 11111, and 22222	Q3,FY13	Opt 1

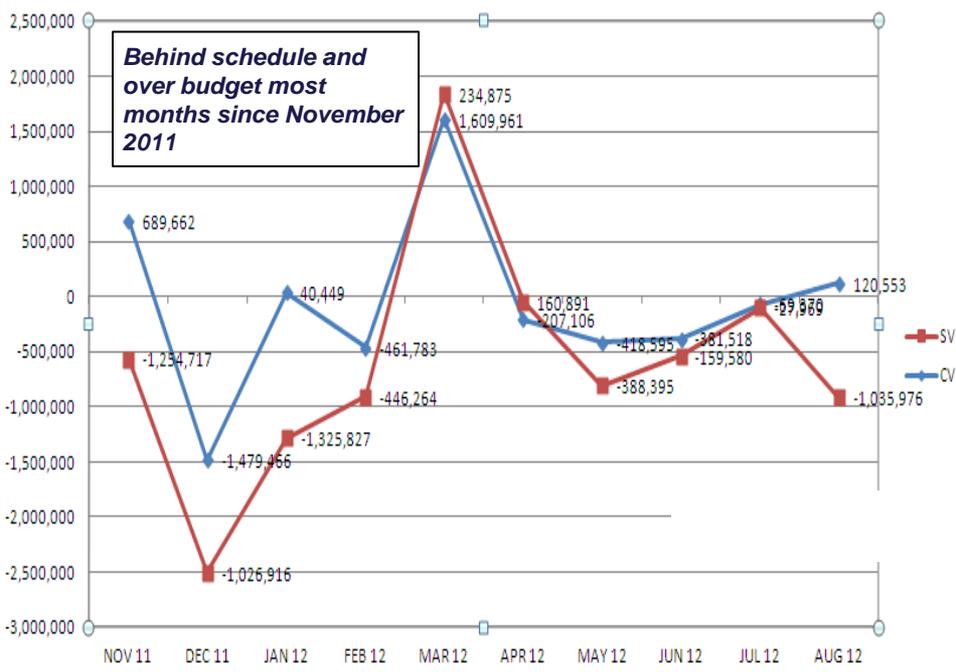


“Company C Mock IPR”



- Presentation
- Q&A Session with Stakeholders
- Contractor Dismissal
- Break
- Government Only Session
 - PCT Presentation

CV/SV Chart thru August 2012



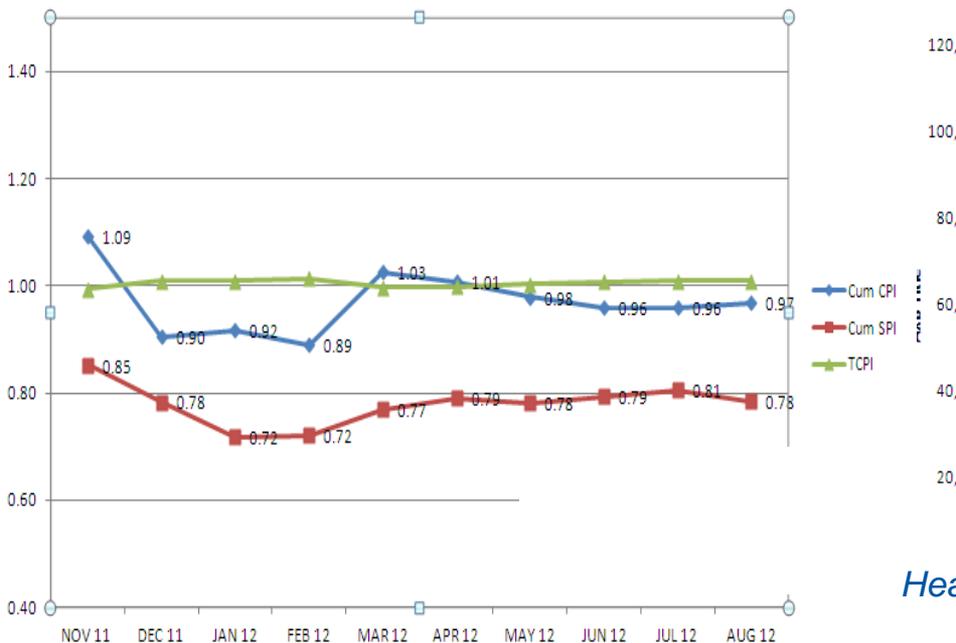
Contractor Dashboard

Earned Value Management Through August 2012

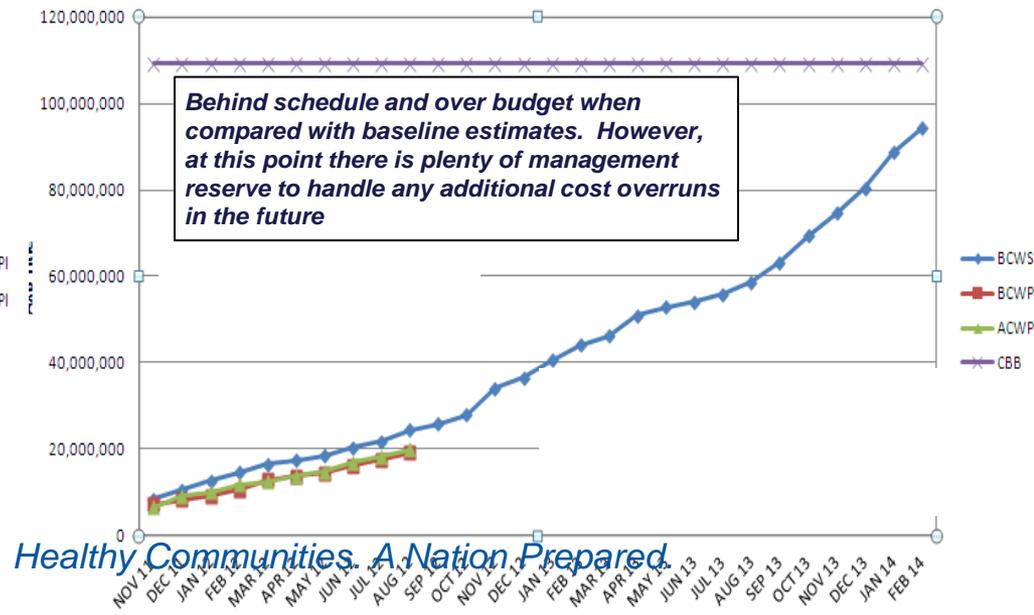
- Through August 2012, Contractor has a negative schedule variance of \$5.65M (negative change of \$1.036M in August) and a \$432K negative cost variance (positive change of \$121K in August).
- 21% (-\$1.016M) of the cumulative negative schedule variance is WBS 1.6.3. The delay in the development impacted the start of the manufacturing campaign by 3-4 months. However, by selecting a single format for the candidates based on previous data, has allowed the Contractor to pull the projected start of the phase 1 clinical study (WBS 1.4.1) forward to offset any delays in the start of manufacturing . .
- 20% (-\$1M) of the cumulative negative schedule variance is in WBS 1.3.1. Variance is due to delays in the development program and team's decision to advance candidate first for manufacturing.

Performance Assessment = Yellow

Cum CPI/SPI Chart thru August 2012



SPA Graph





“Contractor C Mock IPR”



1. Addition of Animal Study SOW Element and Funding
 1. Pro – Keeps Contract on Schedule
 2. Pro – Meets Agency Requirement
 3. Con – Availability of Funds

2. Adjust PDP according to previously programmed funding
 1. Pro – No change to budget
 2. Con – Schedule Slip
 3. Con – Loss of activities currently in the last option of the contract unless additional funding becomes available



Company C IPR Confounders



- What if remaining program funding was reallocated due to an emerging infectious disease?
 - Remember H1N1?
- Supplemental Funding may not be available



“Contractor C Mock IPR”



What does this mean to the contractor?

- MS and Deliverables Chart
- Statement of Work
 - Aligns to Product Development Plan
 - Cross Reference to WBS
- Risk Management Plan
 - Risk Register
- Subcontractor Management Plan
- Cost Proposal
 - 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