“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

<table>
<thead>
<tr>
<th>Gantt Line #</th>
<th>WBS</th>
<th>Milestone</th>
<th>Deliverable</th>
<th>Success Criteria</th>
<th>Timing</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>1.1.1.3</td>
<td>Complete Project Baseline Schedule</td>
<td>Updated Gantt w/WBS Cross Reference and Identified Deliverables</td>
<td>Includes updates as discussed with PCT at Kickoff meeting, and MS identification for Progress Assessment</td>
<td>Q1,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>8</td>
<td>1.1.1.5</td>
<td>Submission of PMBR MSs and Deliverables to Organization</td>
<td>Updated MS and Deliverables Chart</td>
<td>Includes updated agreed upon MSs and deliverables from the PMBR</td>
<td>Q2,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>11</td>
<td>1.1.2.2</td>
<td>Submit Complete Subcontractor Plan (MS)</td>
<td>Subcontractor management plan</td>
<td>Identifies management and oversight process for subcontractors, MS and deliverable tracking and business terms</td>
<td>Q1,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>13</td>
<td>1.1.2.4</td>
<td>Submit Contractor Agreements</td>
<td>Submission of subcontractor contract agreements to Org</td>
<td>Includes signed agreement</td>
<td>Q1,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>16</td>
<td>1.1.3.2</td>
<td>Submit RMP</td>
<td>Risk Management Plan</td>
<td>Identifies key risks, assessment, mitigations, contingencies and impact as well as update process</td>
<td>Q1,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>22</td>
<td>1.1.4.4</td>
<td>EVMS Live and PMBR Accepted</td>
<td>Submission of updated PDP and EVM Reports</td>
<td>Updated PDP as agreed to by the contractor and PCT, EVM Reports acceptable to PCT EVM Spec</td>
<td>Q2,FY12</td>
<td>Base</td>
</tr>
</tbody>
</table>

#### 1.2 Non-Clinical Toxicology Milestones

<table>
<thead>
<tr>
<th>Line #</th>
<th>WBS</th>
<th>Milestone</th>
<th>Deliverable</th>
<th>Success Criteria</th>
<th>Timing</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>1.2.1.3</td>
<td>Submit PK/PD Study results</td>
<td>Submission of data analysis and study report</td>
<td>Successful study endpoints in accordance with protocol XXXXX</td>
<td>Q2,FY12</td>
<td>Base</td>
</tr>
<tr>
<td>30</td>
<td>1.2.2.2</td>
<td>Submit PK/PD Study results</td>
<td>Submission of data analysis and study report</td>
<td>Successful study endpoints in accordance with protocol XXXXX</td>
<td>Q2,FY12</td>
<td>Base</td>
</tr>
</tbody>
</table>

#### 1.3 Non-Clinical Milestones

<table>
<thead>
<tr>
<th>Line #</th>
<th>WBS</th>
<th>Milestone</th>
<th>Deliverable</th>
<th>Success Criteria</th>
<th>Timing</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>46</td>
<td>1.3.3.7</td>
<td>Completion of Non-Clinical POC activities</td>
<td>Submission of data analysis and study report</td>
<td>Successful study endpoints in accordance with protocols XXXXX, YYYY, ZZZZZ, 11111, and 22222</td>
<td>Q3,FY13</td>
<td>Opt 1</td>
</tr>
</tbody>
</table>
“Company C Mock IPR”

- Presentation
- Q&A Session with Stakeholders
- Contractor Dismissal
- Break
- Government Only Session
  - PCT Presentation
Behind schedule and over budget most months since November 2011.

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
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 immerging infectious disease?

— Remember H1N1?

• Supplemental Funding may not be available
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