



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Decision Gate Review Process

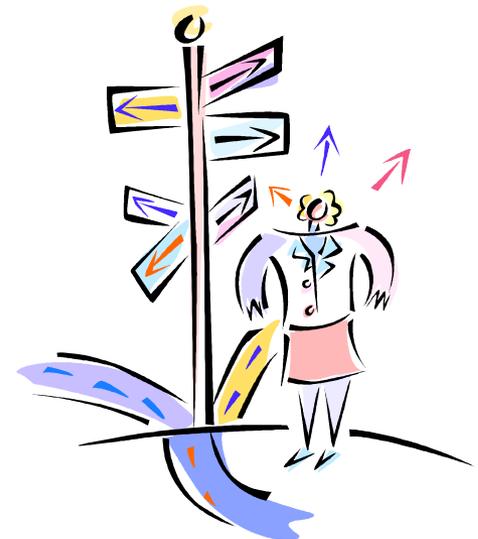
Charmaine Richman, PhD
Decision Gate Review Coordinator
(Contractor in support of AMCG)



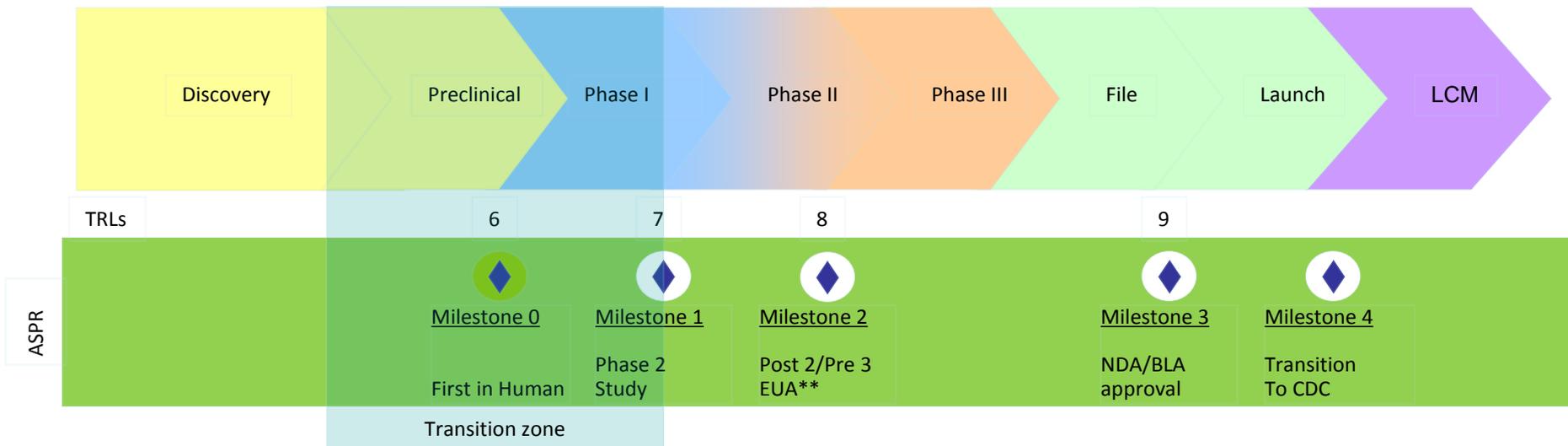
Decision Gate Review Process



- Is a systematic decision management process
- Is transparent, accountable and places paramount importance on the acquisition principles of cost, schedule and performance
- Used to:
 - Identify programmatic risks
 - Make decisions in a timely manner
 - Ensure affordable
 - Appropriate distribution of investments across technologies and programs



- Two types of reviews:
 1. Milestone Decision Reviews occur at specified phases of a program and align with the developmental level of the program

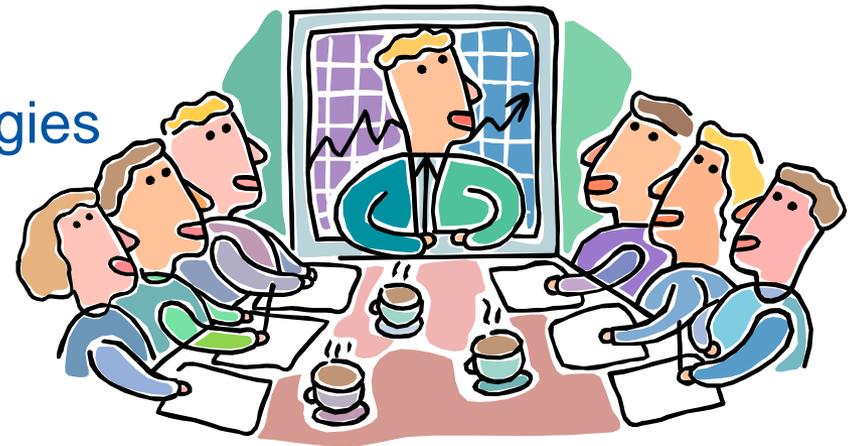


2. In Process Reviews are event driven by:

- Programmatic requirements
- Contractual requirements
 - Option execution
 - Contract modification
- Breach in:
 - cost (>10%),
 - schedule (>6 months) or
 - performance (risk realized) deviations



- Formal meetings
- Evaluate the progress of an entire program toward an acquisition end goal
- Specified format is used that identifies:
 - program progress
 - future business strategy
 - technical and regulatory risks
 - intended future resources
 - plans and/or mitigation strategies

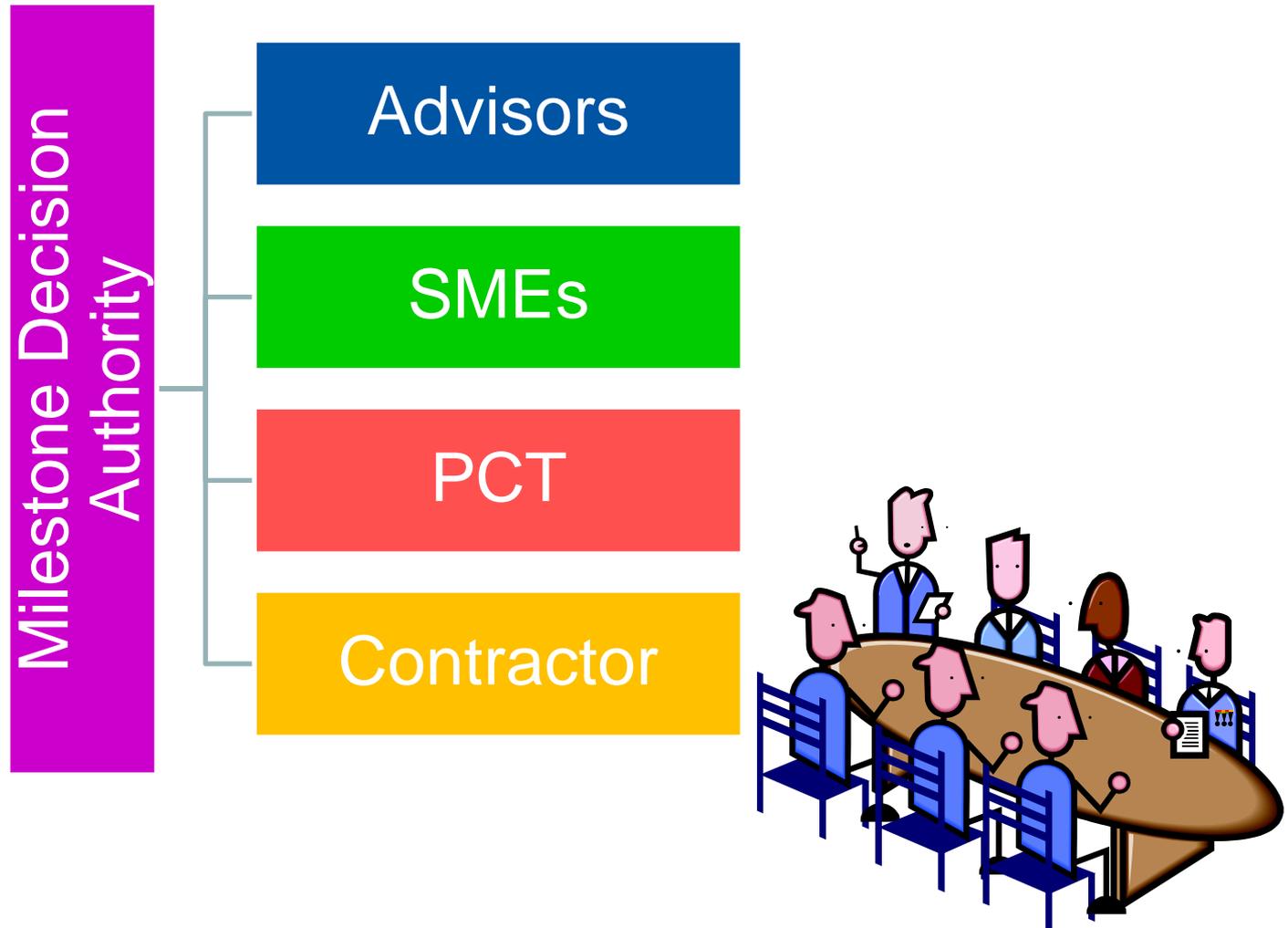


Decision Gate Reviews (continued)

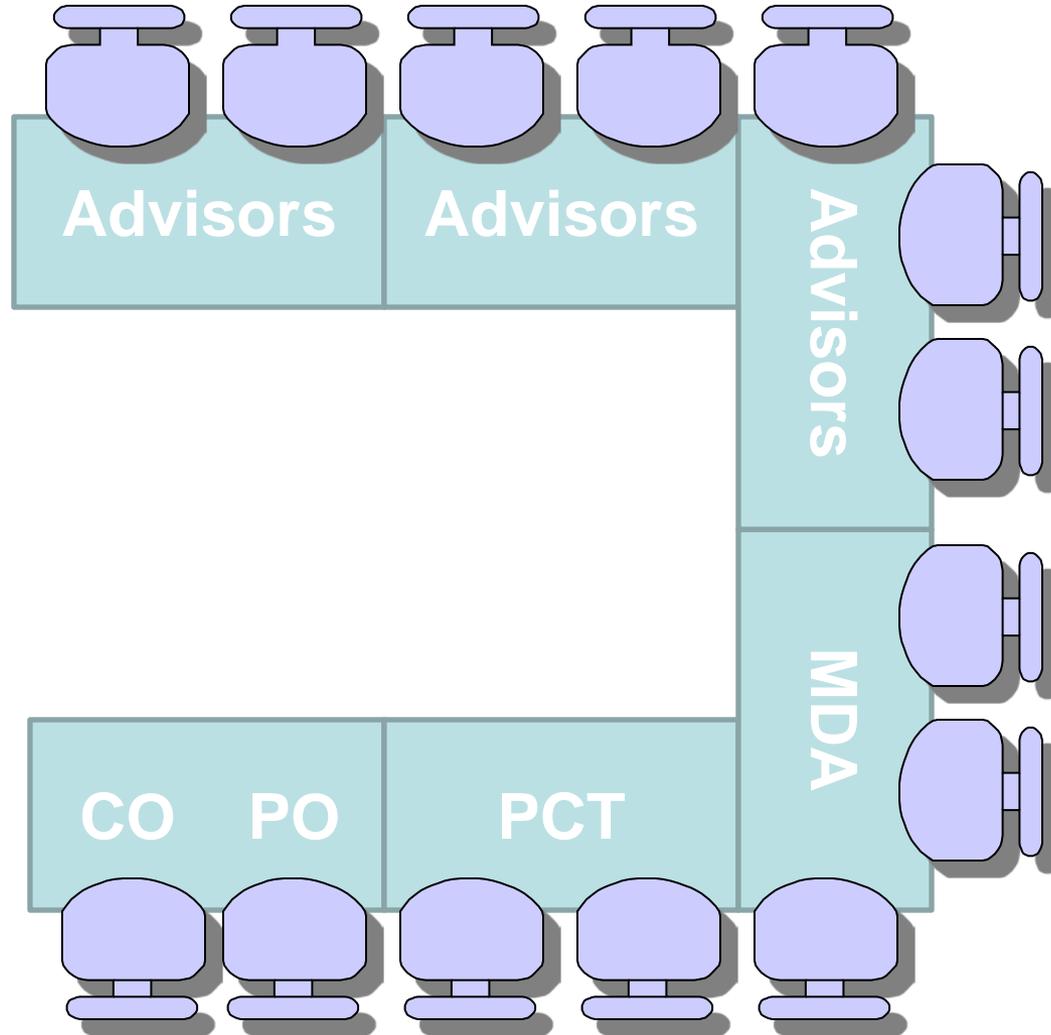
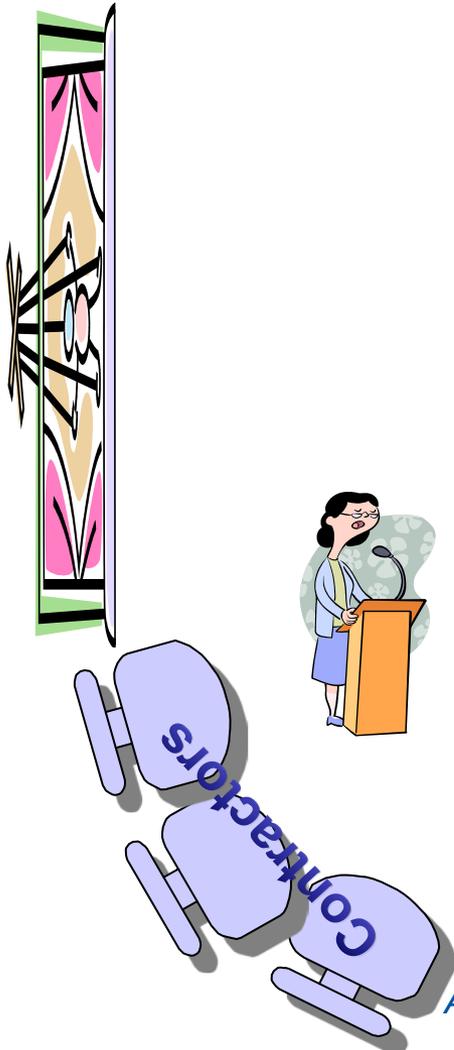
- Typical agenda:
 - Welcome – Milestone Decision Authority
 - Program Overview (10 min) – BARDA Branch Chief
 - Contractor Presentation (30 min) – contractor staff
 - Question and Answer Period (20 min)
- Contractor final presentation
- Both in-person and remote participation available



Cast of Characters



Seating Arrangement



Non-advisory along wall and back of room

- Contractor will provide an oral presentation on the status of the project, including:
 1. Introduction
 2. SOW
 3. Current Program Status
 4. Clinical Trials Update
 5. FDA Interactions
 6. Other Accomplishments and Milestones Met
 7. Programmatic Confounders
 8. Schedule Overview
 9. Critical Path to Licensure
 10. Financial Overview
 11. Conclusion
- Final presentation due 10 days before review date



- Outcome is a decision to:
 - proceed forward to next program phase,
 - approval of a corrective action plan, OR
 - terminate the program
- Contractor notified of the decision by the Contracting Officer





Post Review Survey



- Contracting Officer will send out the survey
- Asked to rate:
 1. Notification process
 2. Quality of information provided in advance of IPR
 3. Time provided to present
 4. Quality of questions asked and/or guidance provided
 5. Feedback following the IPR
- Provide overall comments on the process
- Important to provide feedback on the review process



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