



USAMRMC Decision Gate Process Overview



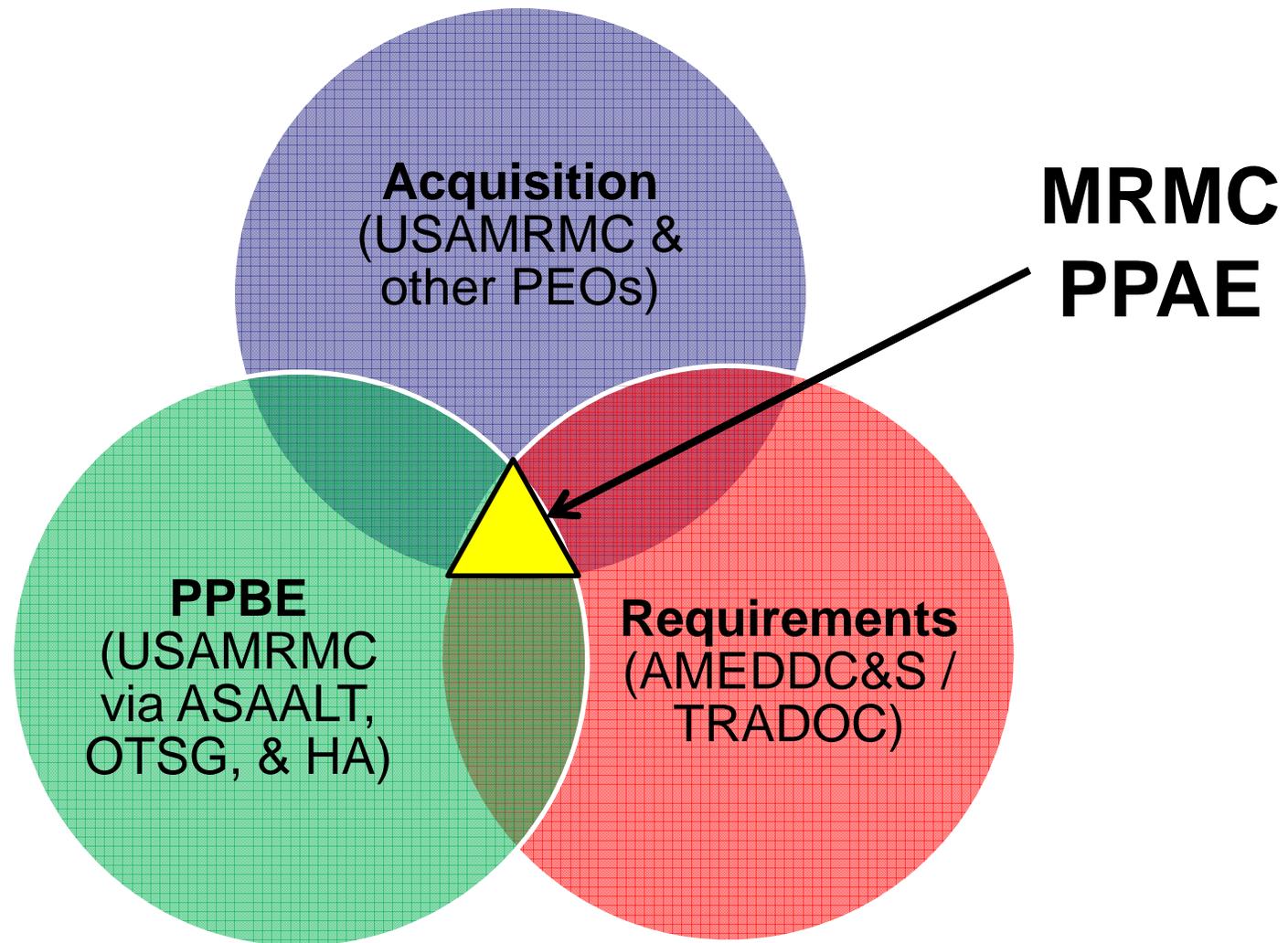
Agenda



- Decision Gate Overview
- Decision Gates
- Advancement Criteria
- Process
- Governance



USAMRMC Integrator of the DOD Major Decision Support Systems





Decision Gate (DG) Process “Product Driven”



- Key components
 - Cradle-to-grave development with clear *Decision Gates*
 - *Advancement criteria* (shared, transparent, uniform)
 - Consistent *decision-making processes*
 - Overarching *governance structure*
- Integrates all disciplines reqd to develop & support products
- Includes multi-disciplined executing and oversight committees with a single final decision authority (MDA)



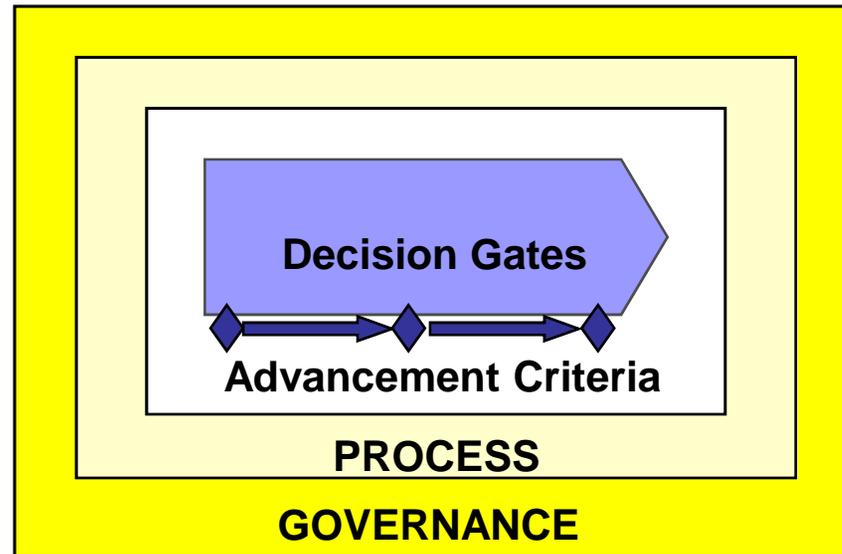
Decision Gate

Decision Gates

Product lifecycle w/ defined decision gates enabling us to work towards a common goal

Advancement Criteria

Defined criteria for advancement thru decision points leading to increased transparency in meeting requirements



Process Consistent, transparent, effectively manage resources & focus efforts to the right products w/ the greatest likelihood to get to the Warfighter

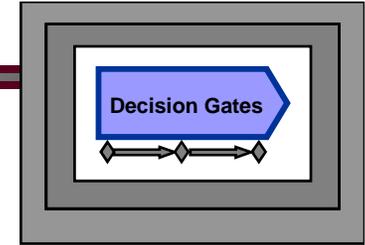
Governance Structure

Committees and IPTs w/ defined roles/ responsibilities for each decision gate enabling timely decision making and problem resolution

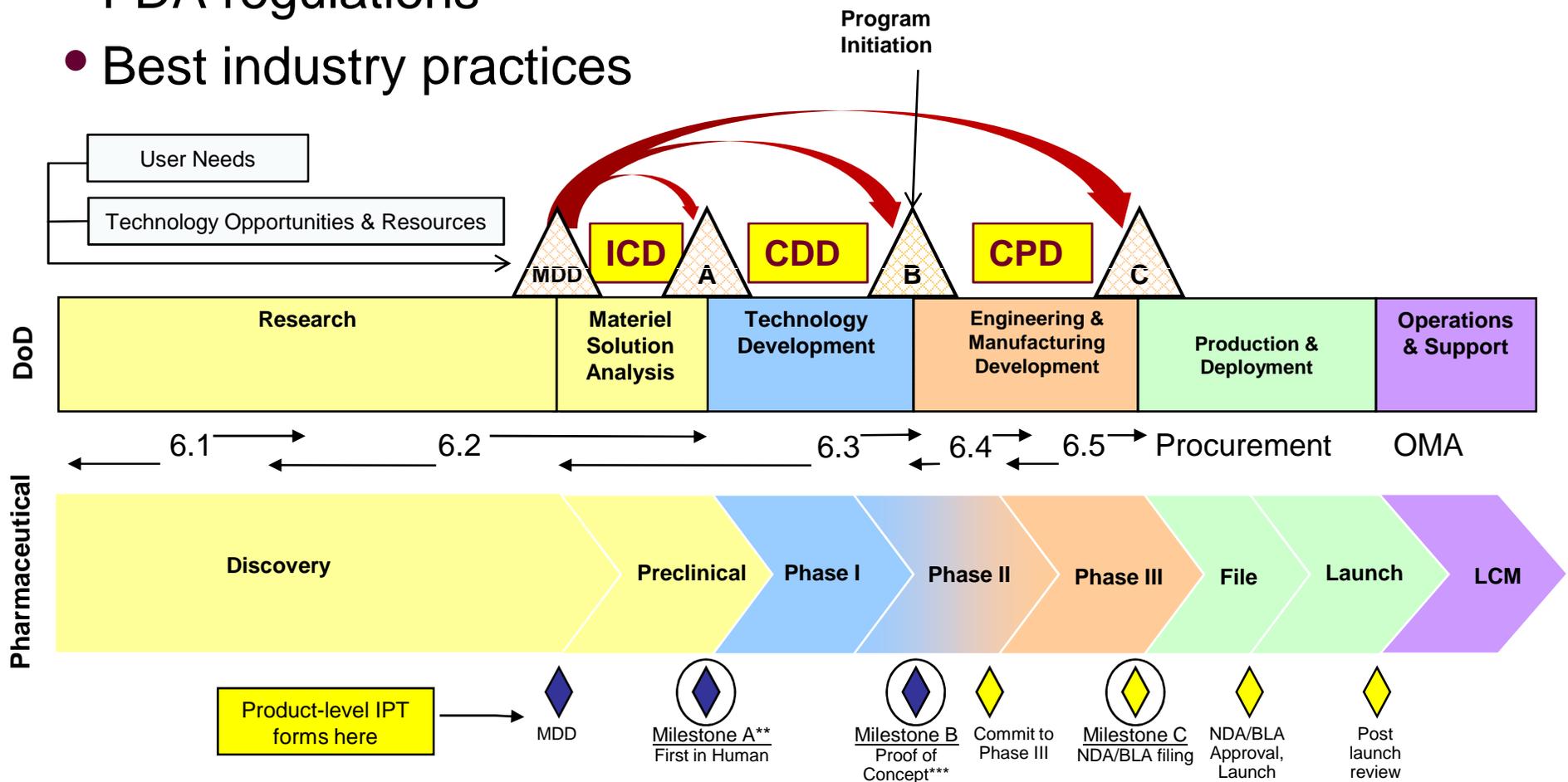
The ability to make the right decisions on time, resource for success, and deliver safe, quality products to the Warfighter



Decision Gates

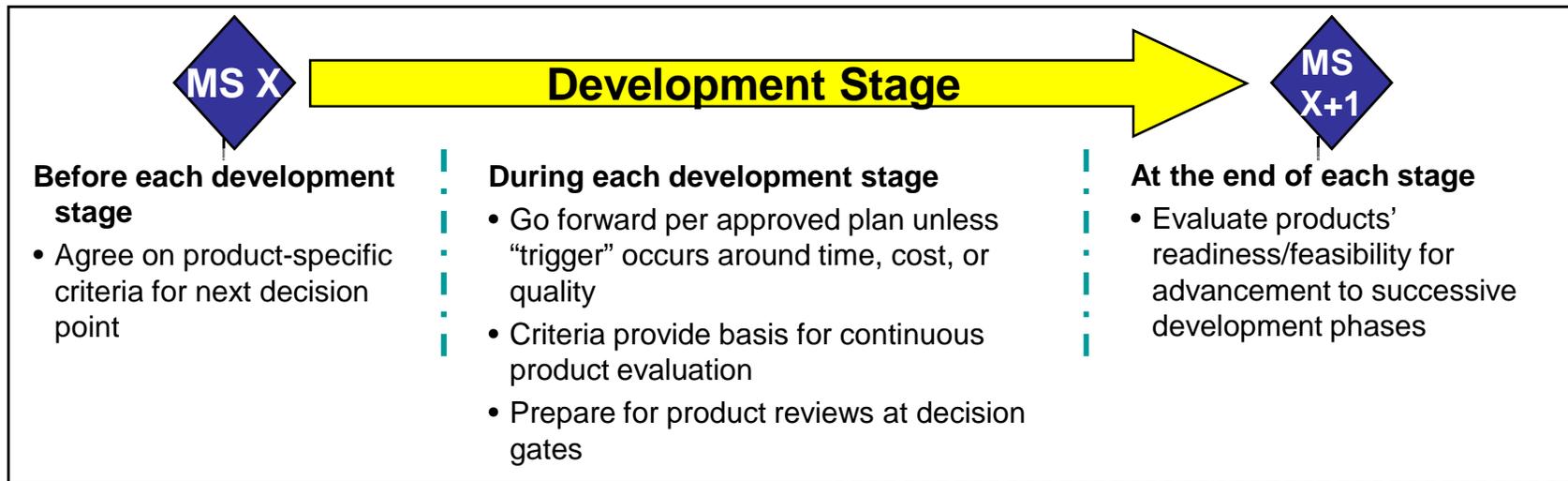
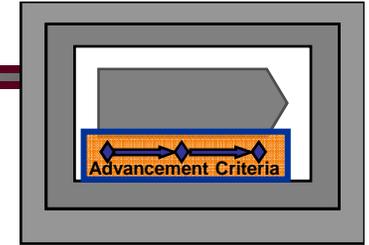


- DoD 5000-series
- FDA regulations
- Best industry practices





Decision Gate Advancement Criteria



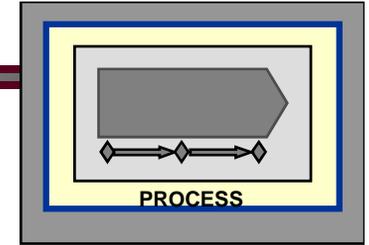
Note:

1. Project-specific criteria is defined for each major decision point.
2. All topics must be considered by MRMC governance committees at each decision point, but collection of information may have been done by alliance partners.
3. Not every product will have a positive answer to each criteria. Criteria serves as a checklist to ensure all appropriate product risks are considered.

	◆ Candidate Selection	◆ First in Human
Corporate Strategy		
• Requirements	✓ Evidence of requirements • Product Target Profile defined	✓ Validated requirements • ICD • Product Target Profile updated
• Intellectual property / patent	✓ Rights for patent understood for pre-clinical	✓ Intellectual Property assessed
• Business assessment	✓ Resources prioritized • Back-up strategy defined	✓ AoA documented • Resources prioritized for Ph I/IIa • Initial cost benefit analysis • Back-up strategy updated
• Competitor research	✓ Initial competitor analysis	✓ Updated competitor analysis
• Alliance strategy		✓ Alliance approach/strategy
• Product development plan	✓ Developed plan formatted	✓ Acquisition Strategy developed
Vaccine Design		
• Antigen construction	✓ In-vitro, in vivo rationale • Feasibility of construction/production	
• Animal models of disease	✓	



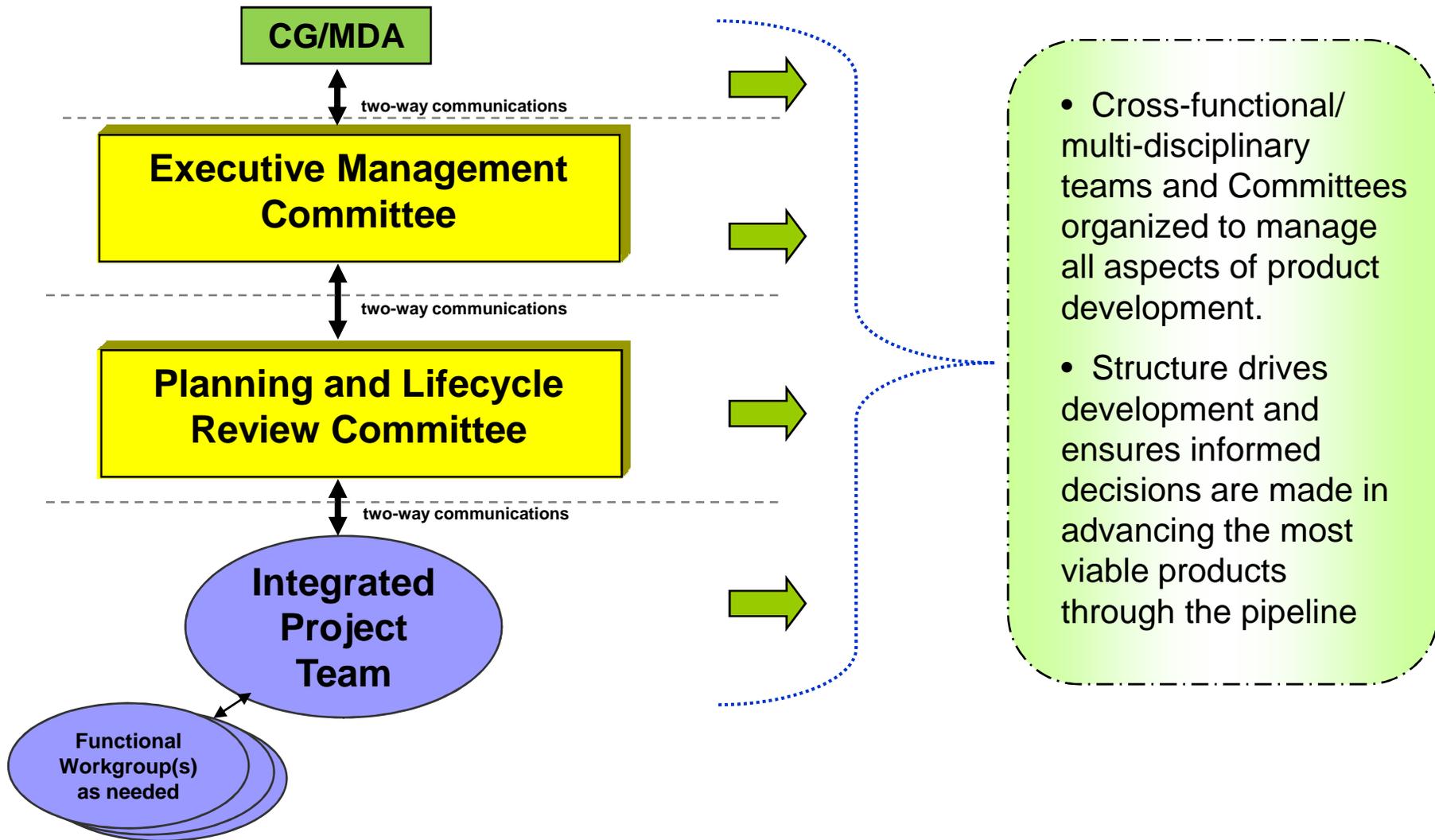
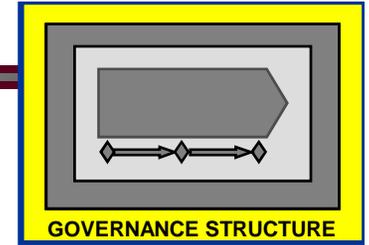
Decision Gate Process



- **Formal decision reviews defined by product development**
 - MDD (Requires ICD)
 - MS A (Requires ICD)
 - MS B (Requires CDD)
 - MS C (Required CPD)
 - Clinical Trial Decisions
- **Annual status reviews (IPR)**
- **Issue Resolution/Triggers**
 - Issues or unforeseen events
 - Requires escalation to higher-level a decision-making committee



DG Committees/Governance





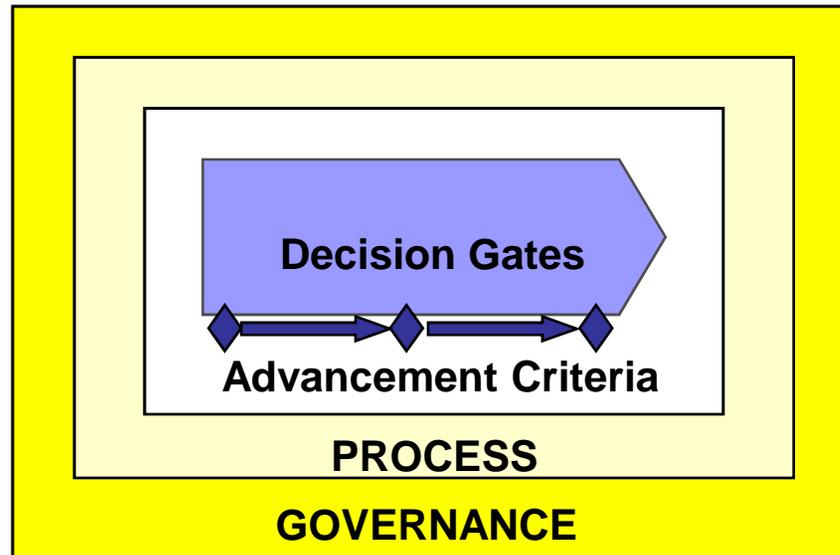
Decision Gate Recap

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