

Critical Path: The Systems Engineer's Quest

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Preface

Welcome to **Critical Path: The Systems Engineer's Quest**, a board game designed to immerse players in the challenges and decision-making processes of medical device development. This game is more than just entertainment—it is a strategic experience that simulates the intricate world of systems engineering in healthcare.

Why This Game?

Medical device development is a complex, high-stakes industry requiring precision, collaboration, and strategic thinking. Engineers, designers, and regulatory specialists must navigate evolving challenges such as stakeholder demands, technical constraints, verification and validation, and regulatory approvals.

By turning these real-world challenges into a **competitive and interactive game**, we provide an engaging way for players to understand and appreciate the intricacies of product development in a highly regulated field.

Who Is This Game For?

This game is designed for:

- **Systems Engineers** – Professionals looking to explore the unique aspects of medical device development.
- **Students & Educators** – Those seeking an engaging, hands-on method to learn about systems engineering principles.
- **Industry Experts** – Engineers, regulatory professionals, and business leaders who want to experience a strategic simulation of their field.
- **Game Enthusiasts** – Players who enjoy deep strategy, resource management, and competitive gameplay.

What to Expect

Throughout the game, players will:

- Balance resources such as funding, innovation, and morale to optimize efficiency.
- Make critical decisions that impact the speed and success of product development.
- Navigate unexpected challenges, from regulatory changes to market disruptions.
- Compete or collaborate with other players to bring their medical device to market.

Acknowledgments

This game was inspired by real-world experiences in systems engineering and medical device development. Special thanks to playtesters, industry professionals, and game design mentors who helped refine the mechanics and make this game both educational and entertaining.

Now, gather your fellow engineers, set up the game board, and prepare to embark on the ultimate systems engineering challenge. **May the best medical device win!**

Ignore this sentence, dummy reference to book Knuth (1984).

1 Critical Path: The Systems Engineer's Quest

1.1 Introduction

Critical Path: The Systems Engineer's Quest is a competitive board game where players take on the role of systems engineers striving to bring an innovative medical device to market. Each player must navigate technical challenges, regulatory hurdles, and stakeholder demands while optimizing resources and time. The game offers a dynamic blend of strategy, risk management, and problem-solving, immersing players in the complexities of medical device development.

1.2 Theme and Setting

In a world where life-saving medical technology is in high demand, players step into the shoes of ambitious engineers working in rival firms. The goal? Successfully navigate the rigorous product development lifecycle and gain regulatory approval before competitors do. Each decision impacts progress, and only the most efficient and strategic engineer will emerge victorious.

1.3 Objectives

Players must:

- Advance through six development phases: Stakeholder Needs, System Architecture, Requirements Writing, Prototyping, Verification & Validation, and Regulatory Approval.
- Manage resources such as funding, innovation, and morale to optimize efficiency.
- Handle unexpected industry events through chance-based draws.
- Balance risk and reward when making critical design and business decisions.
- Be the first to complete all phases and launch their medical device to win!

1.4 Win Conditions

The first player to successfully complete all six phases and gain regulatory approval for their device wins the game. Players who mismanage resources or fail key development milestones may face setbacks, making strategic planning essential for victory.

2 Game Setup

2.1 Components

Before starting, ensure you have the following components:

- **Game Board:** A modular board depicting the six phases of development.
- **Player Tokens:** Representing each systems engineer.
- **Task Cards:** Challenges and tasks tied to each game phase.
- **Event Cards:** Unpredictable industry events that influence gameplay.
- **Dice:** Used for movement, task resolution, and random events.
- **Resource Tokens:** Representing funding, innovation, morale, and time.
- **Player Dashboards:** Used to track progress, resources, and morale.
- **Game Spinner:** Introducing probability-based scenarios.
- **Sand Timer:** Adding real-time pressure for decision-making challenges.

2.2 Player Setup

1. **Choose a Player Token:** Each player selects a color/figure representing their systems engineer.
2. **Distribute Starting Resources:**
 - Each player begins with:
 - 5 Funding Tokens
 - 3 Innovation Tokens
 - 5 Morale Points
 - 2 Time Tokens
3. **Shuffle Cards:**
 - Shuffle Task Cards and place them face down in their designated areas.
 - Task Cards are color-coded and must match the game board task space color during gameplay.
 - Shuffle Event Cards into a separate deck.
4. **Place Player Tokens on the Board:**
 - All players start in the **Stakeholder Needs** phase.
5. **Determine Turn Order:**
 - Players roll a die; highest roll goes first. In case of a tie, the player with the highest engineering certification (ESEP > CSEP > ASEP > Non-certified) goes first.

2.3 Starting the Game

- The first player rolls the dice to begin movement.
- Players follow the board path, drawing **Task Cards** as they enter new phases.
- The first player to complete all six phases and gain regulatory approval wins!

3 Gameplay Mechanics

3.1 Turn Structure

Each turn consists of the following steps:

1. Roll Dice & Move

- Roll a six-sided die and move the corresponding number of spaces along the board.
- If you land on a **Task Space**, draw a **Task Card** and resolve it.
 - Ensure the Task Card’s logo color matches the game board task space color.
 - If the card color does not match, continue drawing cards until a matching card is found.
- If you land on an **Event Space**, draw an **Event Card** and follow its instructions.

2. Resolve Task Cards

- Each Task Card presents a challenge within the current game phase (e.g., “Conduct stakeholder interviews”).
- Roll the required dice (based on skills/resources) to determine success or failure.
- Success advances the player’s project; failure may result in setbacks or lost resources.

3. Manage Resources

- Players may spend **Funding Tokens** to buy additional dice rolls, upgrades, or event mitigations.
- Morale fluctuates based on game events—low morale limits progress.

4. End Turn

- After resolving a Task or Event, the turn passes clockwise.

3.2 Game Phases

Each player must progress through the following six phases to complete their medical device:

1. Stakeholder Needs Phase

- Identify and balance patient, physician, and regulatory requirements.
- Make trade-offs between clinical needs and manufacturability.

2. System Architecture Phase

- Define technical specifications and functional block diagrams.
- Ensure integration of electrical, mechanical, and software components.

3. Requirements Writing Phase

- Translate stakeholder input into clear, testable requirements.
- Align with industry standards (ISO 13485, IEC 60601, etc.).

4. Prototyping Phase

- Build and refine initial device prototypes.
- Conduct design verification tests to identify flaws.

5. Verification & Validation Phase

- Execute preclinical testing, bench testing, and human factors studies.
- Meet all safety and regulatory standards before submission.

6. Regulatory Approval Phase

- Submit documentation to regulatory agencies (FDA, EMA, etc.).
- Address regulatory questions, conduct audits, and finalize

3.3 Advancing to the Next Phase

Once the required Task Cards for the current phase are successfully resolved, players may advance to the next phase. Follow these steps:

1. Declare Phase Completion:

- Announce that you have completed all tasks for the current phase.
- Ensure all required resources and conditions are met.

2. Reset Phase-Specific Resources (if applicable):

- Discard any unused Task Cards from the current phase.
- Draw new Task Cards for the next phase.

3. Start the Next Phase:

- Begin the next phase on your next turn.
- Follow the rules and challenges specific to the new phase.

4. Special Rules for Transition:

- If an Event Card or game mechanic affects phase transitions, resolve it before starting the next phase.

3.4 Winning the Game

The first player to **complete all six phases and gain regulatory approval** successfully launches their device and wins the game!

4 Event Cards

Event Cards introduce unexpected challenges and opportunities that affect player progress. These events reflect real-world hurdles and advantages in medical device development.

4.1 How Event Cards Work

- When a player lands on an **Event Space**, they draw an Event Card and follow its instructions.
- Some cards have **immediate effects**, while others require a dice roll to determine the outcome.
- Players may choose to spend resources to mitigate negative effects.

4.2 Complete List of Event Cards

ID	Event Name	Description	Effect
EV001	FDA Fast Track Designation	Your device qualifies for expedited regulatory review.	Advance directly to the Regulatory Approval phase.
EV002	Cybersecurity Breach	A vulnerability in your device software is exposed.	Lose 2 Morale and 1 Innovation Token .
EV003	Unexpected Side Effect	Clinical trials reveal an unanticipated patient reaction.	Return to the Prototyping Phase to address the issue, losing 1 Time Token .
EV004	Breakthrough Technology	A novel discovery accelerates your development.	Gain 2 Morale and 1 Innovation Token .
EV005	Supply Chain Disruption	A key component is backordered.	Lose 1 Funding Token .
EV006	Patent Infringement Lawsuit	A competitor challenges your IP.	Lose 2 Morale and 2 Funding Tokens .
EV007	Clinical Trial Success	Positive trial results boost your credibility.	Gain 2 Morale and advance to the next phase.
EV008	Clinical Trial Failure	The clinical trial did not meet expected outcomes.	Lose 2 Morale and return to the Prototyping Phase .
EV009	Key Opinion Leader Endorsement	A well-known specialist supports your device.	Gain 1 Morale and 1 Funding Token .
EV010	Competitor Launches Similar Device	Another company beats you to market.	Lose 1 Morale .
EV011	Regulatory Changes	New guidelines require additional documentation.	Draw a new Task Card and spend 1 Time Token .
EV012	Patient Advocacy Group Support	Public support for your device increases.	Gain 1 Morale and 1 Innovation Token .
EV013	Ethical Dilemma	A controversial design decision arises.	Lose 1 Morale and choose a new Task Card .

ID	Event Name	Description	Effect
EV014	Manufacturing Defect	Quality control finds a major flaw.	Return to the Verification & Validation Phase .
EV015	Unexpected Market Demand	Surge in demand for your product.	Gain 2 Funding Tokens .
EV016	Product Recall	A critical failure requires pulling your product from market.	Lose 2 Morale and return to the Prototyping Phase .
EV017	Merger & Acquisition	A larger company offers to acquire your project.	Gain 2 Resource Tokens of your choice.
EV018	Natural Disaster	Supply chain interruptions due to external factors.	Lose 1 Resource Token of your choice (Innovation, Funding, Morale, or Time).
EV019	Celebrity Endorsement	A well-known public figure promotes your device.	Gain 2 Morale and 1 Innovation Token .
EV020	Economic Recession	Funding sources become limited.	Lose 1 Funding Token .
EV021	Investor Confidence	A major investor increases funding.	Gain 1 Funding Token .
EV022	Government Grant	Your device qualifies for federal funding.	Gain 2 Funding Tokens .
EV023	Trade Show Success	Your product receives industry-wide recognition.	Gain 1 Morale and 1 Innovation Token .
EV024	Employee Strike	Workforce disputes slow down development.	Lose 1 Morale and 1 Time Token .
EV025	Unionization Effort	Increased labor negotiations cause delays.	Lose 1 Morale and 1 Funding Token .
EV026	Workplace Accident	A safety issue affects development.	Lose 1 Morale and 1 Time Token .
EV027	Equipment Failure	Critical lab equipment breaks down.	Lose 1 Time Token .
EV028	Quality Control Issue	A design flaw is detected in pre-market testing.	Lose 1 Morale and 1 Time Token .
EV029	Environmental Audit	Your product undergoes scrutiny for environmental impact.	Lose 1 Funding Token .
EV030	Sustainability Initiative	You implement eco-friendly practices.	Gain 1 Morale and 1 Innovation Token .
EV031	Product Launch Event	A marketing push generates excitement.	Gain 2 Morale and 1 Funding Token .
EV032	Market Saturation	Competitors flood the market with similar products.	Lose 1 Morale and 1 Funding Token .

5 Task Cards

Task Cards represent the challenges players must overcome in each phase of medical device development. These tasks require skill checks, resource management, and sometimes dice rolls to progress.

5.1 How Task Cards Work

- When landing on a **Task Space**, the player draws a Task Card.
- Each Task Card specifies a challenge, required skill checks, and possible outcomes.
- Players roll a die and apply skill/resource modifiers to determine the result.
- Some tasks allow players to **spend resources to modify the outcome** if they are unsatisfied with the roll.

5.2 Expanded Task Card Categories

5.2.1 Stakeholder Needs Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
SN001	Conduct Patient Interviews	Communication	4+	Gain 1 Innovation Token	Lose 1 Morale	Spend 1 Innovation Token to re-roll
SN002	Physician Consultation	Stakeholder Management	5+	Define Key Medical Needs	Delay Progress by 1 Turn	Spend 1 Funding Token to skip delay
SN003	Regulatory Body Meeting	Regulatory Knowledge	6+	Identify Early Compliance Needs	Lose 1 Funding Token	Spend 1 Innovation Token to auto-succeed
SN004	Host Public Engagement Session	Communication	5+	Improve Public Trust	Lose 1 Morale	Spend 1 Innovation Token to retry
SN005	Compile Market Research Report	Analytical Skill	4+	Identify Competitive Edge	Lose 1 Time Token	Spend 1 Innovation Token to revise research
SN006	Investigate Competitor Patents	Systems Thinking	5+	Discover Potential Legal Risks	Lose 1 Funding Token	Spend 1 Innovation Token to mitigate
SN007	Conduct Focus Group	Communication	4+	Gain Valuable User Insights	Lose 1 Time Token	Spend 1 Innovation Token to refine survey
SN008	Conduct Market Survey	Analytical Skill	4+	Identify Market Trends	Lose 1 Time Token	Spend 1 Innovation Token to retry

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
SN009	Host Stakeholder Workshop	Communication	5+	Align Stakeholder Expectations	Lose 1 Morale	Spend 1 Funding Token to retry
SN010	Analyze Patient Data	Systems Thinking	6+	Gain Deeper Insights	Lose 1 Funding Token	Spend 1 Innovation Token to mitigate
SN011	Review Clinical Guidelines	Regulatory Knowledge	5+	Ensure Compliance Alignment	Lose 1 Time Token	Spend 1 Innovation Token to retry
SN012	Develop Stakeholder Personas	Documentation	4+	Improve User Understanding	Lose 1 Morale	Spend 1 Innovation Token to refine
SN013	Conduct Competitive Analysis	Analytical Skill	5+	Identify Market Gaps	Lose 1 Funding Token	Spend 1 Innovation Token to retry
SN014	Host Advisory Board Meeting	Communication	6+	Gain Strategic Insights	Lose 1 Morale	Spend 1 Innovation Token to retry
SN015	Draft Initial Project Charter	Documentation	4+	Define Project Scope	Lose 1 Time Token	Spend 1 Innovation Token to revise
SN016	Interview Key Opinion Leaders	Stakeholder Management	5+	Gain Expert Recommendations	Lose 1 Morale	Spend 1 Funding Token to retry
SN017	Validate Stakeholder Requirements	Systems Thinking	6+	Ensure Requirement Accuracy	Lose 1 Time Token	Spend 1 Innovation Token to retry

5.2.2 System Architecture Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
SA001	Define System Requirements	Systems Thinking	5+	Gain 1 Innovation Token	Delay Progress by 1 Turn	Spend 1 Innovation Token to retry
SA002	Interface Definition	Documentation	6+	Improve System Integration	Lose 1 Time Token	Spend 1 Innovation Token to auto-succeed
SA003	Risk Analysis	Risk Management	4+	Mitigate Future Issues	Lose 1 Morale	Spend 1 Funding Token to negate failure
SA004	Map Out Failure Modes	Analytical Skill	5+	Identify Critical Design Issues	Lose 1 Time Token	Spend 1 Innovation Token to find alternative solutions

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
SA005	Develop High-Level System Diagram	Systems Thinking	5+	Improve Component Efficiency	Lose 1 Funding Token	Spend 1 Innovation Token to speed up development
SA006	Select Key Materials	Technical Expertise	5+	Improve Device Longevity	Lose 1 Funding Token	Spend 1 Innovation Token to optimize selection
SA007	Validate Subsystem Interfaces	Documentation	6+	Reduce Future Integration Issues	Lose 1 Morale	Spend 1 Innovation Token to preempt problems
SA008	Develop System Block Diagram	Systems Thinking	5+	Improve System Clarity	Lose 1 Time Token	Spend 1 Innovation Token to retry
SA009	Conduct Feasibility Study	Analytical Skill	6+	Identify Technical Risks	Lose 1 Funding Token	Spend 1 Innovation Token to mitigate
SA010	Define Software Architecture	Technical Expertise	5+	Improve Software Scalability	Lose 1 Morale	Spend 1 Innovation Token to retry
SA011	Select Core Technologies	Systems Thinking	4+	Gain 1 Innovation Token	Lose 1 Time Token	Spend 1 Innovation Token to retry
SA012	Conduct Design Trade-Off Analysis	Analytical Skill	5+	Optimize System Performance	Lose 1 Funding Token	Spend 1 Innovation Token to retry
SA013	Review System Interfaces	Documentation	6+	Reduce Integration Issues	Lose 1 Morale	Spend 1 Innovation Token to revise
SA014	Perform Risk Assessment	Risk Management	5+	Mitigate Potential Failures	Lose 1 Time Token	Spend 1 Funding Token to retry
SA015	Develop System Integration Plan	Documentation	4+	Improve Development Workflow	Lose 1 Morale	Spend 1 Innovation Token to retry
SA016	Validate System Requirements	Systems Thinking	5+	Ensure Requirement Feasibility	Lose 1 Time Token	Spend 1 Innovation Token to retry
SA017	Conduct Technical Review	Stakeholder Management	6+	Gain Stakeholder Approval	Lose 1 Morale	Spend 1 Funding Token to retry

5.2.3 Requirements Writing Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
RW001	Write User Needs Specification	Documentation	5+	Create Clear Guidelines	Rework Required, Lose 1 Turn	Spend 1 Innovation Token to revise immediately
RW002	Conduct Stakeholder Review	Communication	4+	Secure Approval	Lose 1 Morale	Spend 1 Innovation Token to smooth negotiations
RW003	Develop Verification Criteria	Analytical Skill	6+	Improve Requirement Traceability	Lose 1 Time Token	Spend 1 Innovation Token to correct errors
RW004	Define Safety-Critical Features	Risk Management	5+	Improve System Reliability	Lose 1 Morale	Spend 1 Funding Token to increase safety testing
RW005	Standardize Documentation Format	Documentation	4+	Reduce Review Time	Lose 1 Time Token	Spend 1 Innovation Token to streamline process
RW006	Review Regulatory Guidelines	Regulatory Knowledge	5+	Ensure Compliance Alignment	Lose 1 Funding Token	Spend 1 Innovation Token to mitigate regulatory risk
RW007	Evaluate Edge Cases	Systems Thinking	4+	Improve Design Robustness	Lose 1 Time Token	Spend 1 Innovation Token to prevent issues
RW008	Draft Functional Requirements	Documentation	5+	Improve Requirement Clarity	Lose 1 Time Token	Spend 1 Innovation Token to revise
RW009	Conduct Requirements Workshop	Communication	4+	Align Team Understanding	Lose 1 Morale	Spend 1 Funding Token to retry
RW010	Review Industry Standards	Regulatory Knowledge	6+	Ensure Compliance Alignment	Lose 1 Funding Token	Spend 1 Innovation Token to retry
RW011	Define Verification Methods	Analytical Skill	5+	Improve Test Coverage	Lose 1 Time Token	Spend 1 Innovation Token to retry
RW012	Draft Risk Management Plan	Risk Management	4+	Mitigate Future Risks	Lose 1 Morale	Spend 1 Funding Token to retry
RW013	Validate Requirement Traceability	Systems Thinking	5+	Ensure Requirement Accuracy	Lose 1 Time Token	Spend 1 Innovation Token to retry
RW014	Conduct Peer Review	Documentation	6+	Improve Requirement Quality	Lose 1 Morale	Spend 1 Innovation Token to revise
RW015	Define Non-Functional Requirements	Analytical Skill	5+	Improve System Robustness	Lose 1 Time Token	Spend 1 Innovation Token to retry

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
RW016	Review Safety Standards	Regulatory Knowledge	4+	Ensure Safety Compliance	Lose 1 Funding Token	Spend 1 Innovation Token to retry
RW017	Finalize Requirements Document	Documentation	5+	Gain Stakeholder Approval	Lose 1 Morale	Spend 1 Innovation Token to finalize

5.2.4 Prototyping Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
PR001	Build Initial Prototype	Technical Expertise	4+	Gain 1 Innovation Token	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR002	Conduct User Feedback Session	Communication	5+	Improve Prototype Design	Lose 1 Morale	Spend 1 Funding Token to refine design
PR003	Perform Bench Testing	Analytical Skill	6+	Identify Critical Flaws	Lose 1 Funding Token	Spend 1 Innovation Token to mitigate
PR004	Iterate Prototype Design	Systems Thinking	5+	Improve Device Performance	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR005	Source Prototype Materials	Technical Expertise	4+	Reduce Manufacturing Costs	Lose 1 Funding Token	Spend 1 Innovation Token to optimize
PR006	Conduct Design Review	Documentation	5+	Gain Stakeholder Approval	Lose 1 Morale	Spend 1 Innovation Token to retry
PR007	Address Prototype Failures	Risk Management	6+	Mitigate Future Risks	Lose 1 Time Token	Spend 1 Innovation Token to resolve
PR008	Develop 3D Model	Technical Expertise	4+	Improve Prototype Accuracy	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR009	Conduct Material Testing	Analytical Skill	5+	Identify Optimal Materials	Lose 1 Funding Token	Spend 1 Innovation Token to retry
PR010	Perform Stress Testing	Risk Management	6+	Identify Design Weaknesses	Lose 1 Morale	Spend 1 Innovation Token to mitigate
PR011	Build Functional Prototype	Technical Expertise	5+	Gain 1 Innovation Token	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR012	Conduct Usability Testing	Communication	4+	Improve User Experience	Lose 1 Morale	Spend 1 Funding Token to retry

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
PR013	Iterate Prototype Design	Systems Thinking	5+	Improve Device Performance	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR014	Validate Prototype Performance	Analytical Skill	6+	Ensure Design Feasibility	Lose 1 Funding Token	Spend 1 Innovation Token to retry
PR015	Conduct Design Freeze Review	Documentation	5+	Finalize Prototype Design	Lose 1 Morale	Spend 1 Innovation Token to finalize
PR016	Address Prototype Feedback	Communication	4+	Refine Prototype Features	Lose 1 Time Token	Spend 1 Innovation Token to retry
PR017	Source Prototype Components	Technical Expertise	5+	Reduce Manufacturing Costs	Lose 1 Funding Token	Spend 1 Innovation Token to optimize

5.2.5 Verification & Validation Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
VV001	Conduct Preclinical Testing	Regulatory Knowledge	5+	Gain 1 Innovation Token	Lose 1 Funding Token	Spend 1 Innovation Token to retry
VV002	Perform Human Factors Study	Communication	4+	Improve Usability	Lose 1 Morale	Spend 1 Funding Token to retry
VV003	Execute Bench Testing	Analytical Skill	6+	Validate Device Performance	Lose 1 Time Token	Spend 1 Innovation Token to retry
VV004	Address Test Failures	Risk Management	5+	Mitigate Design Risks	Lose 1 Morale	Spend 1 Innovation Token to resolve
VV005	Finalize Validation Protocols	Documentation	4+	Ensure Compliance Alignment	Lose 1 Time Token	Spend 1 Innovation Token to revise
VV006	Conduct Risk Mitigation Review	Systems Thinking	5+	Reduce Future Compliance Issues	Lose 1 Funding Token	Spend 1 Innovation Token to retry
VV007	Prepare Validation Report	Documentation	6+	Gain Regulatory Confidence	Lose 1 Morale	Spend 1 Innovation Token to finalize
VV008	Conduct Clinical Simulation	Regulatory Knowledge	5+	Gain 1 Innovation Token	Lose 1 Funding Token	Spend 1 Innovation Token to retry
VV009	Perform Environmental Testing	Analytical Skill	6+	Validate Device Durability	Lose 1 Time Token	Spend 1 Innovation Token to retry

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
VV010	Execute Software Validation	Technical Expertise	5+	Ensure Software Reliability	Lose 1 Morale	Spend 1 Innovation Token to retry
VV011	Conduct Failure Analysis	Risk Management	4+	Mitigate Design Risks	Lose 1 Time Token	Spend 1 Funding Token to retry
VV012	Validate Human Factors	Communication	5+	Improve Usability	Lose 1 Morale	Spend 1 Funding Token to retry
VV013	Review Validation Protocols	Documentation	6+	Ensure Test Accuracy	Lose 1 Time Token	Spend 1 Innovation Token to revise
VV014	Conduct Preclinical Study	Regulatory Knowledge	5+	Gain Regulatory Confidence	Lose 1 Funding Token	Spend 1 Innovation Token to retry
VV015	Address Validation Failures	Risk Management	4+	Resolve Design Issues	Lose 1 Morale	Spend 1 Innovation Token to resolve
VV016	Finalize Validation Report	Documentation	5+	Gain Stakeholder Approval	Lose 1 Time Token	Spend 1 Innovation Token to finalize
VV017	Conduct System Integration Testing	Systems Thinking	6+	Ensure System Compatibility	Lose 1 Funding Token	Spend 1 Innovation Token to retry

5.2.6 Regulatory Approval Phase

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
RA001	Submit Regulatory Documents	Documentation	5+	Advance to Regulatory Review	Lose 1 Time Token	Spend 1 Innovation Token to retry
RA002	Address Regulatory Questions	Regulatory Knowledge	6+	Resolve Compliance Issues	Lose 1 Funding Token	Spend 1 Innovation Token to resolve
RA003	Conduct Internal Audit	Risk Management	4+	Improve Submission Quality	Lose 1 Morale	Spend 1 Innovation Token to retry
RA004	Respond to Inspection Findings	Communication	5+	Satisfy Regulatory Inspectors	Lose 1 Time Token	Spend 1 Funding Token to expedite
RA005	Finalize Submission Package	Documentation	6+	Gain Regulatory Approval	Lose 1 Morale	Spend 1 Innovation Token to finalize
RA006	Address Market Feedback	Systems Thinking	5+	Improve Market Readiness	Lose 1 Funding Token	Spend 1 Innovation Token to retry

ID	Task	Required Check	Dice Roll	Success Outcome	Failure Outcome	Alternative Action
RA007	Secure Final Approval	Regulatory Knowledge	6+	Launch Product Successfully	Lose 1 Time Token	Spend 1 Innovation Token to retry
RA008	Prepare Risk Management Report	Documentation	5+	Ensure Compliance Alignment	Lose 1 Time Token	Spend 1 Innovation Token to revise
RA009	Conduct Regulatory Gap Analysis	Regulatory Knowledge	6+	Identify Compliance Issues	Lose 1 Funding Token	Spend 1 Innovation Token to resolve
RA010	Address Regulatory Feedback	Communication	5+	Satisfy Regulatory Inspectors	Lose 1 Morale	Spend 1 Funding Token to expedite
RA011	Conduct Final Submission Review	Documentation	4+	Ensure Submission Accuracy	Lose 1 Time Token	Spend 1 Innovation Token to finalize
RA012	Respond to Market Feedback	Systems Thinking	5+	Improve Market Readiness	Lose 1 Funding Token	Spend 1 Innovation Token to retry
RA013	Conduct Post-Market Surveillance	Risk Management	6+	Identify Market Risks	Lose 1 Morale	Spend 1 Innovation Token to mitigate
RA014	Finalize Regulatory Submission	Documentation	5+	Gain Regulatory Approval	Lose 1 Time Token	Spend 1 Innovation Token to finalize
RA015	Conduct Internal Compliance Audit	Regulatory Knowledge	4+	Improve Submission Quality	Lose 1 Morale	Spend 1 Innovation Token to retry
RA016	Secure International Approvals	Communication	5+	Expand Market Reach	Lose 1 Funding Token	Spend 1 Innovation Token to retry
RA017	Address Post-Approval Changes	Systems Thinking	6+	Maintain Compliance	Lose 1 Time Token	Spend 1 Innovation Token to resolve

6 Board Layout

The **Critical Path** game board visually represents the journey of bringing a medical device to market. It consists of six primary phases, each containing various task spaces and event spaces. Players progress through these phases in sequence, overcoming challenges along the way.

6.1 Board Structure

The game board is divided into: 1. **Stakeholder Needs Phase (Green Section)** - Focuses on gathering user requirements and stakeholder alignment. - Includes spaces for patient interviews, physician consultations, and regulatory meetings.

2. **System Architecture Phase (Blue Section)**

- Players define system components, interfaces, and risk analysis.
- Spaces for requirement definition, technical analysis, and subsystem integration.

3. **Requirements Writing Phase (Yellow Section)**

- Writing clear, verifiable, and regulatory-compliant requirements.
- Spaces for drafting user needs, system requirements, and validation plans.

4. **Prototyping Phase (Orange Section)**

- Developing and refining a prototype based on defined requirements.
- Spaces for prototyping, iteration, and user feedback collection.

5. **Verification & Validation Phase (Purple Section)**

- Players conduct testing, analyze results, and finalize product design.
- Spaces for test execution, risk mitigation, and final design approval.

6. **Regulatory Approval Phase (Red Section)**

- Players prepare regulatory submissions and address compliance issues.
- Spaces for documentation submission, regulatory review, and inspection.

6.2 Special Spaces

- **Chance Spaces:** Players draw from the Chance Deck, introducing random industry events.
- **Community Spaces:** Players draw from the Community Deck, representing external collaboration and business opportunities.
- **Fast Track Lane:** A shortcut available only if players meet specific requirements (e.g., FDA Fast Track approval).

6.3 Movement Rules

- Players move by rolling a **six-sided die (D6)**.
- Some paths have decision nodes where players can take alternate routes, introducing strategic choices.
- Landing on **Event Spaces** forces players to draw an **Event Card** and resolve it immediately.

6.3.1 Example Layout (Conceptual)

Start → Stakeholder Needs → System Architecture → Requirements Writing → Prototyping → Verification & Validation → Regulatory Approval → Market Launch

Players progress along this path, completing challenges in each phase until they reach the final goal: **Market Launch**.

7 Terminology

This section defines key terms used throughout **Critical Path: The Systems Engineer's Quest** to ensure clarity and consistency in gameplay.

7.1 General Game Terms

- **Player Token:** A game piece representing a player's progress through the phases.
- **Task Card:** A card drawn when a player lands on a task space, requiring them to complete a specific challenge.
- **Event Card:** A card that introduces unexpected challenges or opportunities.
- **Chance Space:** A space where players draw a random **Chance Card**, leading to unpredictable consequences.
- **Community Space:** A space where players draw a **Community Card**, representing industry collaborations and opportunities.
- **Dice Roll:** Players roll a six-sided die (D6) to determine movement or resolve task outcomes.

7.2 Resource Terms

- **Funding Token:** Represents financial resources required for research, development, and regulatory approvals.
- **Expertise Token:** Symbolizes technical knowledge and proficiency in medical device development.
- **Innovation Token:** A resource that enables players to develop breakthrough technologies or expedite project phases.
- **Morale Points:** Measures team motivation; losing morale affects progress and task success rates.
- **Time Token:** Represents available time to complete tasks before facing penalties or project failure.

7.3 Game Phase Terms

- **Stakeholder Needs Phase:** The initial phase where players identify user needs and regulatory expectations.
- **System Architecture Phase:** The phase where players define technical specifications and system design.
- **Requirements Writing Phase:** The phase where players document clear, testable, and regulatory-compliant requirements.
- **Prototyping Phase:** The stage where players develop, test, and refine early device models.
- **Verification & Validation Phase:** The process of testing the device against requirements to ensure it meets safety and performance standards.
- **Regulatory Approval Phase:** The final phase where players submit documentation and seek market approval.

8 Strategy Tips

To succeed in **Critical Path: The Systems Engineer's Quest**, players must balance risk, resource management, and strategic decision-making. Here are some essential strategies to help you win the game.

8.1 Prioritize Key Resources

- **Funding Tokens:** Allocate funds wisely to avoid financial setbacks in later phases.
- **Innovation Tokens:** Use these sparingly but effectively—breakthroughs can accelerate your progress.
- **Morale Points:** Keep morale high; low morale impacts dice rolls and task outcomes.

8.2 Plan Your Path Efficiently

- **Use Alternate Routes:** Some board spaces allow for different paths—take advantage of shorter or less risky routes.
- **Fast Track Lane:** If possible, qualify for the Fast Track to bypass difficult phases.
- **Avoid Delays:** Losing time tokens can prevent you from keeping up with competitors.

8.3 Manage Risk and Adapt to Events

- **Mitigate Negative Event Cards:** Keep extra resources handy to counteract setbacks.
- **Leverage Positive Events:** Certain cards offer bonuses—be ready to maximize their effects.
- **Balance High-Risk Decisions:** Some challenges offer big rewards but come with high failure rates—assess your chances before taking the risk.

8.4 Master Task Resolution

- **Optimize Dice Rolls:** Certain skills improve success rates; investing in expertise early can pay off.
- **Look for Bonus Rewards:** Some tasks provide additional benefits if completed successfully—choose them wisely.
- **Don't Rush Prototyping:** A well-tested prototype can prevent costly rework later.

8.5 Consider Player Interactions

- **Trade Strategically:** Exchange expertise and resources with competitors when beneficial.
- **Block Opponents:** Delay others by securing patents, outbidding funding, or leveraging event outcomes.
- **Negotiate Alliances:** Temporary alliances can help overcome shared obstacles, but be ready to compete in the final stretch.

8.6 Stay Flexible

- **Monitor Competitor Progress:** Adjust your strategy based on what other players are doing.
- **Adapt to Changing Conditions:** Regulatory updates and market shifts can affect your approach—stay nimble.
- **Don't Hoard Resources:** Spend wisely, but avoid over-saving—unused resources don't win games!

9 Design Notes

This section outlines the key design principles behind **Critical Path: The Systems Engineer's Quest**, integrating best practices from *Your Turn!: The Guide to Great Tabletop Game Design* by Scott Rogers.

9.1 Core Design Philosophy

The game is built upon three fundamental design principles:

1. **Engagement Through Realism** – The game accurately reflects the challenges of medical device development.
2. **Decision-Driven Gameplay** – Players must make strategic choices at every stage.
3. **Dynamic Interaction** – The combination of competitive and cooperative elements fosters an engaging experience.

9.2 Applying *Your Turn!* Principles

9.2.1 Player Agency & Meaningful Decisions

- Players are not just rolling dice but making crucial trade-offs (e.g., speed vs. quality in prototyping).
- Choices affect future outcomes—bad risk management early on can lead to major setbacks later.

9.2.2 Risk vs. Reward Mechanics

- High-risk strategies (e.g., pushing a product to market early) can yield fast wins but also potential failures.
- Players must balance resources wisely, mirroring real-world engineering constraints.

9.2.3 Thematic Integration

- The game board is structured as a development timeline, reinforcing the process-based nature of medical device engineering.
- Task Cards and Event Cards are modeled after real-world scenarios, ensuring authenticity.

9.2.4 Player Interaction & Competition

- Players can trade, form temporary alliances, or sabotage competitors (e.g., patent disputes, regulatory hurdles).
- Limited resources encourage strategic conflict—who secures funding first?

9.2.5 Accessible but Deep Mechanics

- Simple dice rolls determine movement and task outcomes.
- Advanced players can develop strategic depth through resource planning and negotiation.

9.3 Playtesting Insights & Iterations

- **First Iteration:** Too much complexity—simplified task resolution mechanics.
- **Second Iteration:** Players enjoyed competition, so we added more interaction points (e.g., blocking regulatory approval).
- **Third Iteration:** Adjusted balance for resource tokens to prevent runaway leaders.

9.4 Next Steps

- Finalize graphic design and board layout.
- Expand playtesting to refine balance.
- Develop digital companion tools (e.g., online score tracker, virtual task cards).

10 Resource Management Rules

To ensure a balanced gameplay experience, **Critical Path: The Systems Engineer's Quest** limits how players acquire, use, and trade resources. This section outlines the rules governing **Innovation Tokens**, **Funding Tokens**, **Morale**, and **Time Tokens**.

10.1 How Players Gain Tokens

Method	Token Type	Limitations
Completing Key Tasks	Innovation Tokens, Morale	Players can earn a maximum of 2 tokens per phase .
Certain Event Cards	Funding Tokens, Morale	Capped at 1 token per event effect to prevent overflow.
Successful Phase Transitions	Innovation Tokens, Funding Tokens	Players receive 1 predefined token per major phase transition .
Trading with Other Players	Any Resource Token	Players may trade, but each exchange must be 2:1 (e.g., 2 Innovation Tokens for 1 Funding Token) .

10.2 Spending Tokens

- **Innovation Tokens** – Used to re-roll task failures or unlock special shortcuts (e.g., bypassing verification delays).
- **Funding Tokens** – Required for high-cost actions (e.g., regulatory submissions, phase transitions).
- **Morale** – Boosts efficiency; if morale drops to 0, the player **loses a turn until morale is restored**.
- **Time Tokens** – Used to reduce delays or extend deadlines in project development.

10.3 Limits on Token Accumulation

- Players may hold a **maximum of 3 of any token type at a time**.
- Excess tokens must be **spent or exchanged before acquiring new ones**.
- Some high-value actions **require specific token types**, ensuring steady use of resources.

10.4 Phase-Based Token Refresh

- At the start of each new phase, **all players receive 1 free token** (type depends on the phase):
 - **System Architecture Phase** → 1 Innovation Token
 - **Prototyping Phase** → 1 Innovation Token
 - **Verification & Validation Phase** → 1 Morale Token
 - **Regulatory Approval Phase** → 1 Funding Token

10.5 Trading and Negotiation Rules

- Players may **exchange tokens** during their turn.
- Trades must follow a **minimum 2:1 ratio** (e.g., trading 2 Innovation Tokens to gain 1 Funding Token).
- Players **cannot gift tokens**—every trade must be a fair exchange.

References

Knuth, Donald E. 1984. “Literate Programming.” *Comput. J.* 27 (2): 97–111. <https://doi.org/10.1093/comjnl/27.2.97>.

A Appendices

This section contains supplementary materials to support gameplay, including card templates, optional mechanics, and additional clarifications.

A.1 Playing Card Templates

A.1.1 Task Card Template

- Task Name: Task Title
- Phase: Game Phase
- Challenge: Brief Description
- Success Roll: Dice + Skill Modifier
- Failure Penalty: Lose Resource (Innovation, Funding, Morale, or Time), Delay Turn, etc.

A.1.2 Event Card Template

- Event Name: Event Title
- Effect: Positive or Negative Outcome (affecting Innovation, Funding, Morale, or Time)
- Resolution: Immediate or Requires a Roll

A.2 Optional Mechanics

A.2.1 Solo Mode

- Players take turns simulating competitors by rolling dice to create random AI-driven decisions.
- AI players can disrupt funding rounds, regulatory approval, or cause unexpected setbacks.

A.2.2 Cooperative Mode

- Players form a team, each specializing in a different engineering discipline.
- Collective resource pool and shared goal of bringing one device to market together.

A.2.3 Advanced Regulations Expansion

- Adds stricter compliance rules requiring more strategic planning.
- Players must monitor evolving regulations and adapt submissions accordingly.

A.3 Extra Rule Clarifications

- **Who Goes First?** Players with higher engineering certifications (ESEP > CSEP > ASEP > Non-certified) go first.
- **Tie Breaker:** In the event of a tie, the player with the most remaining funding wins.
- **Fast Track Lane Eligibility:** Players must complete specific milestone tasks to unlock this shortcut, which may require spending Innovation or Time tokens.

A.4 Printable Game Aids

- Reference sheet summarizing key rules.
- Quick start guide for new players.
- Player tracking sheet for resources and morale.

B Instructions for Modifying a 20" x 20" Board for Critical Path: The Systems Engineer's Quest

To effectively design a **game board**, you should divide it into **six key development phases**, integrate **paths for movement**, and ensure **clear sections for events and actions**. Below is a **detailed step-by-step guide** to modifying the blank board.

B.1 Define the Game Board Layout

The board should be structured **like a Monopoly-style layout**, with **all spaces on the outer edge** and players moving **clockwise** around the board.

B.1.1 Board Sections and Spaces (Clockwise Path)

Position	Phase	Space Type	Description
1	Stakeholder Needs	Start Space	Players begin their journey.
2	Stakeholder Needs	Task Space	Conduct Stakeholder Interviews.
3	Stakeholder Needs	Event Space	Draw an Event Card.
4	Stakeholder Needs	Task Space	Meet with Key Opinion Leaders.
5	Stakeholder Needs	Collaboration Space	Players may trade tokens.
6	Stakeholder Needs	Task Space	Perform Market Research.
7	Stakeholder Needs	Fast Track Space	Spend an Innovation Token to advance two spaces.
8	System Architecture	Task Space	Define System Requirements.
9	System Architecture	Event Space	Draw an Event Card.
10	System Architecture	Task Space	Conduct Risk Analysis.
11	System Architecture	Reinvestment Space	Spend Funding Tokens to improve technology.
12	System Architecture	Task Space	Review Technical Specifications.
13	System Architecture	Task Space	Identify Subsystem Requirements.
14	Requirements Writing	Task Space	Draft Initial Requirements.
15	Requirements Writing	Market Challenge Space	A competitor introduces a rival product.
16	Requirements Writing	Task Space	Conduct Stakeholder Review.
17	Requirements Writing	Event Space	Draw an Event Card.
18	Requirements Writing	Task Space	Ensure Regulatory Compliance.
19	Prototyping	Task Space	Develop First Prototype.
20	Prototyping	Event Space	Draw an Event Card.
21	Prototyping	Task Space	Test Prototype for Usability.
22	Prototyping	Collaboration Space	Players can trade resources.
23	Prototyping	Task Space	Conduct Design Iteration.

Position	Phase	Space Type	Description
24	Prototyping	Fast Track Space	Spend an Innovation Token to advance.
25	Verification & Validation	Task Space	Execute Test Plan.
26	Verification & Validation	Event Space	Draw an Event Card.
27	Verification & Validation	Task Space	Conduct Risk Management Review.
28	Verification & Validation	Task Space	Perform Biocompatibility Testing.
29	Verification & Validation	Market Challenge Space	A new regulation changes testing requirements.
30	Regulatory Approval	Task Space	Submit Regulatory Documentation.
31	Regulatory Approval	Event Space	Draw an Event Card.
32	Regulatory Approval	Task Space	Respond to Regulatory Questions.
33	Regulatory Approval	Audit Space	Players must pass a compliance check.
34	Regulatory Approval	Final Task Space	Obtain Market Approval.
35	Market Launch	Victory Space	Players complete their product launch!

B.2 Preparing the Board Surface

B.2.1 Materials Needed

- Permanent markers or **vinyl stickers** for labeling.
- **Painter’s tape** for layout adjustments.
- **Acrylic paint or printable decals** for coloring sections.
- **Clear sealant spray (optional)** for durability.

B.2.2 Step-by-Step Board Modification

1. **Mark the Outer Border** – Use a **ruler and marker** to **outline 35 spaces** along the board’s edges.
2. **Divide the Board into Sections:**
 - Assign each space based on the list above.
 - Use **painter’s tape** to ensure correct alignment before finalizing.
3. **Add Visual Elements:**
 - **Arrows and direction markers** to show clockwise movement.
 - **Icons and colors** to differentiate each phase.

B.3 Special Spaces and Gameplay Enhancements

B.3.1 Fast Track Spaces:

- Players who land here can **spend an Innovation Token** to **skip ahead** by two spaces.

B.3.2 Collaboration Spaces:

- Players may **trade tokens and strategies** when landing here.

B.3.3 Market Challenge Spaces:

- A competitor event occurs, requiring a **dice roll to determine impact**.

B.3.4 Regulatory Audit Space:

- Players must **roll a die** to pass compliance. Failure results in losing a turn.

B.4 Coloring and Design Enhancements

- **Green** → Stakeholder Needs
- **Blue** → System Architecture
- **Yellow** → Requirements Writing
- **Orange** → Prototyping
- **Purple** → Verification & Validation
- **Red** → Regulatory Approval
- **Gold** → Market Launch (Final Victory Space)

Use **paint, colored markers, or printed decals** to define these zones clearly.

B.5 Final Touches

- Test the board with prototype gameplay before finalizing.
- Ensure all spaces are readable and visually distinct.
- Laminate the board for added durability.

C Player Feedback Form

This **Player Feedback Form** is designed based on the **Failure Reporting, Analysis, and Corrective Action System (FRACAS)** methodology. The goal is to systematically collect, analyze, and implement improvements based on player experiences to enhance **Critical Path: The Systems Engineer's Quest**.

C.1 Instructions

Please complete this form after playing the game. Your feedback will help refine gameplay mechanics, balance, and overall enjoyment.

C.2 General Information

Field	Response
Player Name (Optional)	_____
Game Session Date	_____
Number of Players	_____
Role Played (if applicable)	_____
Overall Satisfaction (1-10)	_____

C.3 Game Experience

Question	Response
How engaging was the gameplay? (1-10)	_____
How clear were the rules and instructions? (1-10)	_____
Were there any points where you felt stuck or confused?	Yes No
If yes, please describe:	_____
Did you feel the game was too easy, too hard, or well-balanced?	Too Easy Too Hard Well-Balanced
Which aspect of the game did you enjoy the most?	_____
Which aspect of the game needs improvement?	_____

C.4 Mechanics and Balance

Question	Response
Did any game mechanics feel overpowered or underpowered?	Yes No
If yes, which ones and why?	_____
Were tokens and resources well-distributed throughout the game?	Yes No
If no, what adjustments would you recommend?	_____
Did you find the dice roll mechanics fair and balanced?	Yes No

Question	Response
Would you recommend more ways to earn or spend tokens?	Yes No

C.5 FRACAS: Issue Tracking & Corrective Actions

Failure / Issue Observed	Impact on Gameplay	Suggested Fix
	Minor Major Critical	
	Minor Major Critical	
	Minor Major Critical	

C.6 Additional Comments

C.7 Would You Play Again?

Question	Response
Would you play this game again?	Yes No Maybe
Would you recommend this game to others?	Yes No Maybe

Thank you for your feedback! Your input will help make **Critical Path: The Systems Engineer's Quest** a better experience for all players.