Make a role playing game based on the concepts and rules of Dungeons and Dragons. The game is about a medical device systems engineer who needs to help develop an important medical device. The engineer has to face challenges such as gathering stakeholder needs, defining system architecture, writing requirements, verification and validation.

### **Medical Device Systems Engineer RPG: "The Device of Life"**

**Overview:** In *The Device of Life*, you play as a skilled medical device systems engineer tasked with developing a life-saving device. Your goal is to successfully navigate the complex process of medical device development, from gathering stakeholder needs to ensuring the device meets all regulatory requirements. Throughout your journey, you'll face challenges such as technical dilemmas, stakeholder conflicts, regulatory hurdles, and tight deadlines. Your success will depend on your ability to manage resources, collaborate with team members, and make critical decisions.

### **Character Creation:**

**1. Choose Your Role:**

* **Lead Systems Engineer:** Focuses on big-picture thinking and coordination.
* **Design Engineer:** Specializes in creating detailed designs and prototypes.
* **Verification & Validation Engineer:** Ensures that the device meets all requirements through testing and analysis.
* **Regulatory Specialist:** Manages compliance with medical device regulations.

**2. Attributes:**

* **Technical Expertise:** Your ability to solve technical challenges.
* **Communication:** Your skill in conveying ideas and negotiating with stakeholders.
* **Time Management:** Your ability to prioritize tasks and meet deadlines.
* **Risk Management:** Your skill in identifying and mitigating potential risks.
* **Regulatory Knowledge:** Your understanding of the regulatory environment and standards.

**3. Skills:**

* **Systems Thinking:** How well you can understand and define the system as a whole.
* **Documentation:** Your ability to write clear and comprehensive requirements, protocols, and reports.
* **Collaboration:** Your effectiveness in working with multidisciplinary teams.
* **Stakeholder Management:** Your skill in aligning the needs and expectations of all stakeholders.
* **Problem-Solving:** Your ability to overcome unexpected challenges.

**4. Equipment:**

* **Engineering Tools:** CAD software, simulation tools, etc.
* **Project Management Software:** Tools to keep track of progress and deadlines.
* **Standards Library:** Access to relevant standards like ISO 13485, IEC 60601, etc.
* **Prototyping Kit:** Basic tools and materials for building device prototypes.
* **Verification & Validation Tools:** Equipment needed to perform tests and analyze results.

### **Gameplay Mechanics:**

1. **Task Rolls**:

* For each challenge, roll a d20 and add the relevant attribute and skill modifiers.
* Difficulty Classes (DC) are set by the Game Master (GM) based on the complexity of the task.
  + Easy (DC 10)
  + Moderate (DC 15)
  + Hard (DC 20)

**2. Phases of Development:**

* **Phase 1: Gathering Stakeholder Needs**
  + Tasks: Conduct interviews, prioritize needs, create a stakeholder matrix.
  + Challenges: Conflicting stakeholder interests, unclear requirements.
* **Phase 2: Defining System Architecture**
  + Tasks: Create block diagrams, define interfaces, identify key subsystems.
  + Challenges: Balancing cost, performance, and regulatory requirements.
* **Phase 3: Writing Requirements**
  + Tasks: Write clear, testable requirements; review and iterate with stakeholders.
  + Challenges: Avoiding scope creep, ensuring traceability.
* **Phase 4: Design and Prototyping**
  + Tasks: Develop prototypes, simulate device behavior, iterate designs.
  + Challenges: Technical failures, design trade-offs, resource constraints.
* **Phase 5: Verification and Validation**
  + Tasks: Develop test plans, perform testing, analyze results, document findings.
  + Challenges: Unmet requirements, equipment limitations, unexpected test results.
* **Phase 6: Regulatory Approval**
  + Tasks: Prepare submission documents, conduct audits, manage regulatory communications.
  + Challenges: Navigating changing regulations, addressing nonconformities.

3. **Resource Management**:

* **Budget:** You have a limited budget to allocate towards equipment, testing, and team expansion.
* **Time:** Each phase has a time limit, and you must balance tasks to stay on schedule.
* **Team Morale:** High morale boosts productivity, but poor decisions can lead to burnout.

4. **Conflict Resolution**:

* **Technical Dilemmas:** Use your Technical Expertise and Problem-Solving skills to overcome design challenges.
* **Stakeholder Conflicts:** Use your Communication and Stakeholder Management skills to align competing interests.
* **Regulatory Hurdles:** Use your Regulatory Knowledge to navigate complex regulations and avoid costly delays.

5. **Endgame:**

* After the final phase, your performance is evaluated based on:
  + **Device Efficacy:** How well the device meets its intended purpose.
  + **Regulatory Compliance:** How smoothly the device passed regulatory approval.
  + **Budget Adherence:** How well you managed the project budget.
  + **Time Management:** Whether the device was completed within the project timeline.
* Based on your performance, you may achieve one of the following endings:
  + **Successful Launch:** The device is approved and begins saving lives.
  + **Delayed Approval:** The device is eventually approved but with delays and increased costs.
  + **Project Failure:** The device fails to meet critical requirements or gain regulatory approval.

**Game Master (GM) Tips:**

* Create scenarios that reflect real-world challenges faced by medical device engineers.
* Encourage collaboration and creative problem-solving among players.
* Adjust difficulty based on player experience and choices.

**Example Scenario:** **Phase 1: Gathering Stakeholder Needs**

* **GM:** "You have a meeting with a group of doctors, nurses, and patients to understand their needs for the new cardiac monitor. The doctors are focused on accuracy, while the nurses want ease of use. Patients are concerned about comfort. How do you approach this?"
* **Player (Lead Systems Engineer):** "I'll prioritize Communication and Stakeholder Management. I propose creating a list of requirements ranked by priority and ensure all voices are heard."
* **GM:** "Roll for Communication and Stakeholder Management."
* **Player:** *Rolls d20* "I got a 17, plus my Communication modifier of +3, so 20 total."
* **GM:** "You successfully mediate the discussion, creating a prioritized list that satisfies everyone. However, the doctors push for additional features, potentially increasing costs. How do you address this?"
* **Player:** "I’ll use my Technical Expertise and Cost Management to assess the feasibility of the additional features without exceeding our budget."

In *The Device of Life*, every decision counts, and your ability to navigate the complexities of medical device development will determine the outcome. Good luck, Engineer!

### **Character Sheet: Medical Device Systems Engineer RPG**

#### **Character Overview**

* **Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Role:** Lead Systems Engineer / Design Engineer / Verification & Validation Engineer / Regulatory Specialist
* **Background:** (Describe your character’s experience, education, and relevant background)

#### **Attributes**

*Distribute 25 points across the following attributes (Max of 10 in any one attribute):*

* **Technical Expertise:** \_\_\_\_ / 10
* **Communication:** \_\_\_\_ / 10
* **Time Management:** \_\_\_\_ / 10
* **Risk Management:** \_\_\_\_ / 10
* **Regulatory Knowledge:** \_\_\_\_ / 10

#### **Skills**

*You have 15 points to distribute among the following skills (Max of 5 in any one skill):*

* **Systems Thinking:** \_\_\_\_ / 5
* **Documentation:** \_\_\_\_ / 5
* **Collaboration:** \_\_\_\_ / 5
* **Stakeholder Management:** \_\_\_\_ / 5
* **Problem-Solving:** \_\_\_\_ / 5

#### **Equipment**

*Choose your starting equipment from the list below (Choose 4):*

* **Engineering Tools:** [ ]
* **Project Management Software:** [ ]
* **Standards Library:** [ ]
* **Prototyping Kit:** [ ]
* **Verification & Validation Tools:** [ ]
* **Regulatory Compliance Handbook:** [ ]

#### **Resource Management**

* **Budget:** \_\_\_\_\_\_\_\_\_\_\_ (Set by the GM based on the difficulty level of the campaign)
* **Time:** \_\_\_\_\_\_\_\_\_\_\_ (Days/Weeks until project deadline, managed by the GM)
* **Team Morale:** \_\_\_\_\_\_\_\_\_\_\_ (10-point scale, affects team performance)

#### **Current Project**

* **Device Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Project Phase:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  + Stakeholder Needs
  + System Architecture
  + Requirements Writing
  + Design and Prototyping
  + Verification and Validation
  + Regulatory Approval
* **Current Task:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Challenges:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### **Task Log**

**Task:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Attributes/Skills Used:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Roll Result:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Outcome:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Notes:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### **Conflicts/Challenges Log**

**Conflict:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Attributes/Skills Used:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Roll Result:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Outcome:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Notes:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### **Endgame Evaluation**

* **Device Efficacy:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Regulatory Compliance:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Budget Adherence:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Time Management:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Overall Performance:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Final Outcome:** [ ] Successful Launch / [ ] Delayed Approval / [ ] Project Failure

### **Character Progression**

As your character completes tasks and overcomes challenges, they can earn experience points (XP) that allow them to improve their attributes and skills:

* **XP Earned:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Level:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Start at Level 1, gain a level every 100 XP)
* **Skill Improvements:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **New Equipment:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This character sheet can be used to track your progress through the campaign as you develop the medical device. Every decision, challenge, and task you complete will shape the outcome of the project.

##### **You said:**

Make the game a solo role playing game.

### **Solo Role-Playing Game: The Device of Life**

**Overview:**

*The Device of Life* is a solo RPG where you take on the role of a medical device systems engineer. Your mission is to develop a life-saving device while managing challenges such as stakeholder needs, system architecture, requirements writing, verification, validation, and regulatory approval. You will navigate the project through decision-making, dice rolls, and resource management. The outcome of your journey depends on your choices and luck.

### **Setup**

1. **Choose Your Role:**
   * **Lead Systems Engineer:** Focus on coordination and high-level decision-making.
   * **Design Engineer:** Specialize in detailed design and prototyping.
   * **Verification & Validation Engineer:** Ensure the device meets all requirements.
   * **Regulatory Specialist:** Navigate the regulatory landscape to achieve approval.
2. **Character Creation:**
   * **Attributes:** Distribute 25 points across the five attributes:
     + **Technical Expertise:** \_\_\_\_ / 10
     + **Communication:** \_\_\_\_ / 10
     + **Time Management:** \_\_\_\_ / 10
     + **Risk Management:** \_\_\_\_ / 10
     + **Regulatory Knowledge:** \_\_\_\_ / 10
   * **Skills:** Distribute 15 points across the five skills:
     + **Systems Thinking:** \_\_\_\_ / 5
     + **Documentation:** \_\_\_\_ / 5
     + **Collaboration:** \_\_\_\_ / 5
     + **Stakeholder Management:** \_\_\_\_ / 5
     + **Problem-Solving:** \_\_\_\_ / 5
   * **Equipment:** Choose 4 from the following:
     + Engineering Tools
     + Project Management Software
     + Standards Library
     + Prototyping Kit
     + Verification & Validation Tools
     + Regulatory Compliance Handbook
3. **Set the Project Parameters:**
   * **Device Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   * **Project Deadline:** (Set a specific number of weeks)
   * **Budget:** (Set a budget limit)
   * **Starting Morale:** 10 (on a 10-point scale)

### **Gameplay Phases**

The game is divided into phases, each representing a stage of medical device development. Each phase consists of several tasks you must complete to progress. For each task, you will make decisions, roll dice to determine outcomes, and manage your resources.

#### **Phase 1: Gathering Stakeholder Needs**

* **Task:** Conduct interviews with stakeholders to gather needs and expectations.
  + **Decision:** Choose how to prioritize the needs (e.g., clinical vs. usability).
  + **Roll:** Roll a d20 and add your Communication + Stakeholder Management modifiers.
  + **Outcome:**
    - **20+:** Stakeholders are aligned, and you gain a clear list of requirements. +1 Morale.
    - **15-19:** Some conflicts, but most needs are clear. Proceed with minor adjustments.
    - **10-14:** Conflicting needs lead to unclear requirements. -1 Morale.
    - **<10:** Major conflicts; unclear direction. -2 Morale, spend 1 week resolving.

#### **Phase 2: Defining System Architecture**

* **Task:** Create the system's architecture, balancing performance, cost, and regulations.
  + **Decision:** Choose to prioritize performance, cost, or regulatory requirements.
  + **Roll:** Roll a d20 and add your Technical Expertise + Systems Thinking modifiers.
  + **Outcome:**
    - **20+:** Architecture is robust, meeting all priorities. +1 Morale.
    - **15-19:** Trade-offs made, but the architecture is solid. Proceed with design.
    - **10-14:** The architecture has gaps. -1 Morale, spend 1 week refining.
    - **<10:** Major flaws found; the architecture needs significant rework. -2 Morale, spend 2 weeks revising.

#### **Phase 3: Writing Requirements**

* **Task:** Write detailed, testable requirements for the device.
  + **Decision:** Choose to focus on clarity, traceability, or stakeholder review.
  + **Roll:** Roll a d20 and add your Documentation + Communication modifiers.
  + **Outcome:**
    - **20+:** Requirements are clear, concise, and accepted by all stakeholders. +1 Morale.
    - **15-19:** Requirements are acceptable with minor revisions. Proceed with design.
    - **10-14:** Requirements need multiple revisions. -1 Morale, spend 1 week revising.
    - **<10:** Requirements are unclear; major revisions needed. -2 Morale, spend 2 weeks rewriting.

#### **Phase 4: Design and Prototyping**

* **Task:** Develop and test prototypes of the device.
  + **Decision:** Choose to prioritize speed, cost, or thorough testing.
  + **Roll:** Roll a d20 and add your Technical Expertise + Problem-Solving modifiers.
  + **Outcome:**
    - **20+:** Prototypes are successful; the design is ready for verification. +1 Morale.
    - **15-19:** Prototypes work, but some issues need addressing. Spend 1 week refining.
    - **10-14:** Prototypes have flaws; the design needs significant changes. -1 Morale, spend 2 weeks reworking.
    - **<10:** Prototypes fail; the design needs to be rethought entirely. -2 Morale, spend 3 weeks redesigning.

#### **Phase 5: Verification and Validation**

* **Task:** Test the device against requirements and regulatory standards.
  + **Decision:** Choose to focus on thorough testing, regulatory documentation, or quick completion.
  + **Roll:** Roll a d20 and add your Risk Management + Documentation modifiers.
  + **Outcome:**
    - **20+:** The device passes all tests and meets all requirements. +1 Morale.
    - **15-19:** The device passes most tests; minor issues remain. Spend 1 week fixing.
    - **10-14:** The device fails some tests; significant rework needed. -1 Morale, spend 2 weeks reworking.
    - **<10:** The device fails critical tests; major redesign required. -2 Morale, spend 3 weeks revising and retesting.

#### **Phase 6: Regulatory Approval**

* **Task:** Prepare and submit regulatory documentation for device approval.
  + **Decision:** Choose to prioritize comprehensive documentation, speed, or cost.
  + **Roll:** Roll a d20 and add your Regulatory Knowledge + Documentation modifiers.
  + **Outcome:**
    - **20+:** The device is approved without issues. +1 Morale.
    - **15-19:** The device is approved with minor questions. Proceed with minor updates.
    - **10-14:** The device faces regulatory scrutiny; additional documentation needed. -1 Morale, spend 1 week revising.
    - **<10:** The device fails to gain approval; significant rework needed. -2 Morale, spend 3 weeks resubmitting.

### **Resource Management**

* **Time:** Each phase costs a certain number of weeks, determined by your task outcomes.
* **Budget:** Some decisions or outcomes may require spending additional budget.
* **Morale:** If morale drops to 0, your team becomes unproductive, leading to project failure. Keep morale high through good decisions and successful outcomes.

### **Endgame**

After completing all six phases, assess your project’s success:

* **Device Efficacy:** (Was the device effective and functional?)
* **Regulatory Compliance:** (Did you navigate the regulatory landscape smoothly?)
* **Budget Adherence:** (Did you stay within budget?)
* **Time Management:** (Did you meet the project deadline?)
* **Final Outcome:**
  + **Successful Launch:** The device is approved and begins saving lives.
  + **Delayed Approval:** The device is eventually approved but with delays and increased costs.
  + **Project Failure:** The device fails to meet critical requirements or gain regulatory approval.

### **Example Playthrough:**

**Phase 1: Gathering Stakeholder Needs**

* **Decision:** I prioritize clinical needs over usability.
* **Roll:** I roll a 16. With my Communication + Stakeholder Management modifiers (+4), the total is 20.
* **Outcome:** Stakeholders are aligned, and the needs are clear. +1 Morale.

**Phase 2: Defining System Architecture**

* **Decision:** I focus on performance over cost.
* **Roll:** I roll a 12. With my Technical Expertise + Systems Thinking modifiers (+5), the total is 17.
* **Outcome:** The architecture is solid but needs minor adjustments. I spend 1 week refining it.

This solo RPG allows you to step into the shoes of a medical device systems engineer and experience the challenges of bringing a life-saving device to market. Each phase of the project requires strategic decisions and careful resource management, ultimately determining your success.

##### **You said:**

Give the game a name

**Game Name: "Critical Path: The Systems Engineer’s Quest"**

In **Critical Path**, you take on the role of a medical device systems engineer navigating the complex process of designing and delivering life-saving technology. Balancing technical expertise, stakeholder management, and regulatory hurdles, every decision can affect the project’s success. Will you bring the device to market on time, or will critical failures derail the mission?

##### **You said:**

How about trying to use SysML notation to create the game board. Be creative.

Creating a game board using **SysML (Systems Modeling Language)** notation is an intriguing and creative approach! SysML is typically used for modeling complex systems, but it can certainly serve as an abstract framework for this game. Here’s how we can creatively adapt SysML elements to design a board for **Critical Path: The Systems Engineer’s Quest**.

### **Game Board Structure using SysML:**

#### **1. Phases as Blocks (Block Definition Diagram - BDD)**

Each phase of the game (Stakeholder Needs, System Architecture, Requirements Writing, etc.) can be represented as a **block** with internal properties or tasks. Blocks can show the “inputs” and “outputs” of each phase, along with key attributes (skills, decisions, and resources).

* **Block: Stakeholder Needs**
  + Attributes: Communication, Collaboration, Stakeholder Management
  + Input: Stakeholder Information
  + Output: User Needs List
* **Block: System Architecture**
  + Attributes: Technical Expertise, Systems Thinking
  + Input: User Needs List
  + Output: System Design

This block-based design is connected using **associations** and **dependencies** to show how progress flows from one phase to the next.

#### **2. Action Flows (Activity Diagram)**

We can use **activity diagrams** to represent the paths between phases. These diagrams can include:

* **Initial Node:** Start of the development journey.
* **Decision Points:** Where the player makes critical choices.
* **Action Blocks:** Tasks associated with each phase (e.g., writing requirements, running tests).
* **Final Node:** Completion of the device development.

Players “move” by performing actions associated with each task and rolling dice to determine their outcomes, much like how you’d move along activity flows in SysML.

#### **3. Tokens as SysML Elements**

* **Engineer Tokens:** Represent the player’s character, which could be modeled as an actor in SysML (like in a Use Case Diagram). The token moves through the board as the player progresses through phases.
* **Morale & Time Tokens:** These could be represented as **value properties** inside the blocks. As you go through each phase, you might update your morale and time attributes.

#### **4. Verification/Validation and Requirements (Requirement Diagram)**

Each phase can have **requirements** modeled in SysML that you need to satisfy before moving forward. The **verification and validation** phase could represent a point on the board where these requirements are reviewed, much like how it works in system development. Each requirement could be linked back to a specific task or decision earlier in the game.

### **SysML Notation Visualization for Game Board**

* **Blocks**: Represent each phase of the project as a block, connected by **relationships** (solid lines) and **dependencies** (dashed lines).
* **Activity Flow**: Show actions like “Gather Needs,” “Design Architecture,” “Verify System,” with arrows representing the flow between tasks.
* **Tokens/Actors**: Your player token would represent an actor moving through the system from block to block, with **dashed lines** for optional tasks or decisions.
* **Decision Points**: Use **diamonds** for decision nodes, where the player rolls dice to determine which path to take.

#### **Creative Interpretation:**

* The board itself could resemble a **SysML diagram**, using blocks, flows, and decision nodes in creative ways to depict the development process. Each phase could look like a modular system, with tokens traveling between blocks like "actors" moving in a flow.

##### **You said:**

I need to explain to two systems engineers who are organizing the fundamentals track in systems engineering of the next INCOSE Healthcare conference that I have this game I'm working on and I would like to test it out with some attendees. I would just need maybe 30 min or so.

Here's a concise and professional explanation you can use to propose testing your game at the conference:

**Subject:** Proposal to Test an Interactive Systems Engineering Game at the Fundamentals Track

Dear [Name],

I hope this message finds you well. As part of the upcoming INCOSE Healthcare Conference, I am developing a solo role-playing game called **Critical Path: The Systems Engineer’s Quest**, designed to teach and engage players with the fundamentals of systems engineering. The game immerses players in the process of developing a medical device, navigating challenges like stakeholder analysis, system architecture, requirements development, and verification/validation.

I believe this interactive approach aligns well with the goals of the fundamentals track by providing a unique, hands-on way for attendees to experience key systems engineering principles. I would like to propose a short, 30-minute session during the track to test the game with attendees. This session would serve both as a learning experience and an opportunity to gather feedback on the game for further refinement.

Please let me know if this aligns with the track's objectives and if there are any available slots where this could fit into the agenda. I’d be happy to provide additional details or a demo if helpful.

Thank you for considering this idea. I’m excited about the potential for this game to enhance engagement and understanding of systems engineering at the conference.

Best regards,  
Sandy Weininger  
Senior Electrical/Biomedical Engineer  
FDA, Center for Devices and Radiological Health

##### **You said:**

I plan to submit the game idea to an INCOSE conference. Provide a summary of the game, maximum 1500 characters, be compelling and concise - something that convinces the conference to accept my submission, and convinces the conference audience to attend my session.

**Critical Path: The Systems Engineer’s Quest** is a solo role-playing game designed to immerse players in the complexities of medical device development while showcasing core systems engineering principles. From gathering stakeholder needs to navigating the intricacies of verification and validation, participants step into the role of a systems engineer tasked with bringing a life-saving device to market.

This engaging, gamified experience teaches players how to balance technical challenges, regulatory requirements, and stakeholder expectations under tight deadlines. The game board, inspired by SysML notation, provides a dynamic framework that models real-world systems engineering workflows, encouraging critical thinking, decision-making, and risk assessment.

During the session, attendees will get a hands-on introduction to the game, learning how it bridges education and application in a healthcare context. Whether you're a novice seeking a creative way to grasp the fundamentals of systems engineering or an expert looking for fresh approaches to training and engagement, this session will provide insights into how gamification can transform the way we teach and learn systems engineering.

Join us for an interactive and innovative experience that brings systems engineering to life!

##### **You said:**

I have the following game board materials available, specify with details on how to use these materials for the game: 18 inch blank game board, blank customizable box, 108 x blank poker-size playing cards, 5 x blank dice, 2 x standard dice, 8 x multicolored player tokens, 1 x blank rule sheet, 1 x 60-second sand timer, 8 x blank player boards with multicolored stands, and 1 x game spinner with blank base.

Here’s how you can creatively use the available materials to bring **Critical Path: The Systems Engineer’s Quest** to life:

### **1. Game Board (18-inch blank board)**

* **Design:** Divide the board into six sections, each representing a phase of the systems engineering process:
  + **Stakeholder Needs**
  + **System Architecture**
  + **Requirements Writing**
  + **Prototyping**
  + **Verification & Validation**
  + **Regulatory Approval**
* **Paths:** Use paths between sections with SysML-inspired notations, including decision nodes and flows. Players move along these paths to simulate progress.
* **Icons/Spaces:** Add icons representing challenges, rewards, or tasks (e.g., dice rolls, card draws).

### **2. Customizable Box**

* **Purpose:** Use the box to store all components. Design it to match the game theme, with a title and graphics inspired by medical devices and systems engineering. Include instructions on the box lid or interior.

### **3. Blank Poker-Size Cards (108 cards)**

* **Use as Task and Event Cards:**
  + **Task Cards (60 cards):** Specific challenges tied to game phases (e.g., "Define stakeholder needs," "Identify risk controls"). Include instructions for dice rolls, tokens, or outcomes.
  + **Event Cards (48 cards):** Unexpected situations (e.g., "Regulatory hurdle: Lose 2 turns," "Stakeholder alignment achieved: Gain 3 morale").

### **4. Blank Dice (5 dice)**

* **Custom Labels:**
  + Assign symbols or numbers representing skills (e.g., technical, analytical, communication) or success probabilities for task completion.
  + Example: "1-2 = Fail," "3-4 = Partial Success," "5-6 = Success."

### **5. Standard Dice (2 dice)**

* **General Use:** Roll for decision points or task outcomes. Players can combine results from custom and standard dice for more complex mechanics.

### **6. Multicolored Player Tokens (8 tokens)**

* **Player Representation:** Each token represents the player (engineer) progressing through phases on the board.
* **Team Play Option:** Use additional tokens for cooperative scenarios (e.g., multiple engineers working on the same project).

### **7. Blank Rule Sheet**

* **Game Instructions:** Write concise rules, including how to move, resolve tasks, and win. Include examples for card actions, dice rolls, and special situations.

### **8. Sand Timer (60-second timer)**

* **Time Challenges:** Use the timer for timed tasks (e.g., "You have 60 seconds to brainstorm stakeholder needs"). Adds urgency and excitement.

### **9. Blank Player Boards with Multicolored Stands (8 boards)**

* **Engineer Dashboards:** Use boards to track individual progress, skills, morale, and time.
  + Example Sections: "Skills," "Completed Tasks," "Morale Level," "Pending Tasks."
* **Stands:** Use stands to display active player boards during gameplay.

### **10. Game Spinner with Blank Base**

* **Decision Wheel:** Divide into sections like "Skill Boost," "Morale Drop," "Bonus Turn," and "Project Delay." Use it to introduce random events when players land on special spaces or draw certain cards.

### **Gameplay Example:**

1. Players start on the **Stakeholder Needs** phase with their tokens on the board.
2. Roll the standard dice to determine movement and draw a **Task Card** at each phase.
3. Complete tasks by rolling the custom dice, following outcomes specified on cards.
4. Use **player boards** to track morale, tasks, and progress.
5. The **spinner** or **event cards** introduce randomness, making each game session unique.
6. The first player to complete the **Regulatory Approval** phase wins.

3D printing resources

<https://www.thingiverse.com/thing:4699502>

Notes:

Write the game rule book like it were an entertaining system design specification. Put the rules to use the structure “shall” that and so on.

One rule to include is that a person with ESEP goes first, followed by CSEP, ASEP and then non certified.

Use ChatGPT to create the rule book.

Visit boardgamegeek.com to see what ideas and inspirations I can get from there.

**Comments January 10, 2025:**

Look again into the game mechanics again. Include 2 to 5 players as systems engineers competing against each other to deliver a medical device to the market. Use pawn components to identify the systems engineer. Use some components to identify as resources. The game board should be like a map of the phases of medical device development. There must be some metric per player that indicates progress of the medical device. The game can use playing cards that bring a twist to the game such as events (design freeze, design review), issues (regulatory, audits), bonuses (increase of investment).

Medical Device Maestro: Enhanced Gameplay DetailsEvent Cards (20 Unique Examples)

1. **FDA Fast Track Designation:** Advance to the Regulatory Approval phase immediately.
2. **Cybersecurity Breach:** Lose 2 Morale and 1 Technical Expertise Resource Token.
3. **Unexpected Side Effect:** Return to the Prototyping phase.
4. **Breakthrough Technology:** Gain 2 Morale and 1 Innovation Resource Token.
5. **Supply Chain Disruption:** Lose 1 Funding Resource Token.
6. **Patent Infringement Lawsuit:** Lose 2 Morale and 2 Funding Resource Tokens.
7. **Clinical Trial Success:** Gain 2 Morale and advance to the next phase.
8. **Clinical Trial Failure:** Lose 2 Morale and return to the Prototyping phase.
9. **Key Opinion Leader Endorsement:** Gain 1 Morale and 1 Funding Resource Token.
10. **Competitor Launches Similar Device:** Lose 1 Morale.
11. **Regulatory Changes:** Draw a new Task Card for your current phase.
12. **Patient Advocacy Group Support:** Gain 1 Morale and 1 Public Relations Resource Token.
13. **Ethical Dilemma:** Lose 1 Morale and choose a new Task Card.
14. **Manufacturing Defect:** Return to the Verification & Validation phase.
15. **Unexpected Market Demand:** Gain 2 Funding Resource Tokens.
16. **Product Recall:** Lose 2 Morale and return to the Prototyping phase.
17. **Merger & Acquisition:** Gain 2 Resource Tokens of your choice.
18. **Natural Disaster:** Lose 1 Resource Token of your choice.
19. **Celebrity Endorsement:** Gain 2 Morale and 1 Public Relations Resource Token.
20. **Economic Recession:** Lose 1 Funding Resource Token.

Resources and Their Uses

* **Technical Expertise:** Increases success rate in tasks related to design, engineering, and prototyping.
* **Regulatory Knowledge:** Increases success rate in tasks related to regulatory submissions and compliance.
* **Funding:** Required to complete certain tasks and advance through phases.
* **Innovation:** Increases success rate in tasks related to developing novel solutions and technologies.
* **Public Relations:** Increases success rate in tasks related to stakeholder engagement and public perception.

Game Phases and Order

1. **Stakeholder Needs:** Identify and understand the needs of patients, healthcare providers, and other stakeholders.
2. **System Architecture:** Define the overall system structure and its components.
3. **Requirements Writing:** Translate stakeholder needs into clear and verifiable requirements.
4. **Prototyping:** Develop and test prototypes to refine the design and gather feedback.
5. **Verification & Validation:** Ensure the system meets requirements and user needs.
6. **Clinical Trials:** Conduct trials to evaluate safety and efficacy in human subjects.
7. **Regulatory Approval:** Navigate regulatory processes and submissions to gain market approval.

Winning the Game

The first player to successfully complete all tasks in the Regulatory Approval phase and receive regulatory approval for their medical device wins the game.

**Note:** Players who lose all their Morale are eliminated from the game.

**Critical Path: The Systems Engineer's Quest - Game Rules**

**Introduction**

Critical Path: The Systems Engineer's Quest is a board game that simulates the process of systems engineering in a medical device context. Players take on the role of systems engineers responsible for bringing a medical device from concept to market. The game is designed to be both educational and entertaining, providing players with a deeper understanding of systems engineering principles and practices.

**Game Setup**

1. Place the game board in the center of the table.
2. Each player chooses a player token and places it on the "Stakeholder Needs" phase of the board.
3. Shuffle the Task Cards and place them face down in a stack.
4. Shuffle the Event Cards and place them face down in a stack.
5. Place the dice, sand timer, game spinner, and player boards within reach of all players.

**Gameplay**

1. The player with the highest ESEP (Engineer Systems Engineering Professional) certification level goes first. Play proceeds clockwise around the table.
2. On your turn, you must do the following:
   * Roll the standard dice to determine your movement.
   * Move your token the corresponding number of spaces clockwise around the board.
   * Draw a Task Card from the stack and read it aloud.
   * Resolve the Task Card by rolling the custom dice and following the instructions on the card.
   * If you land on a special space or draw an Event Card, resolve the effect of that space or card.
   * Place the Task Card in the discard pile.
3. Play continues until one player reaches the "Regulatory Approval" phase of the board. That player is declared the winner.

**Special Rules**

* **Skills:** Each player has a set of skills that can be used to resolve Task Cards. The skills are:
  + Technical
  + Analytical
  + Communication
* **Morale:** Players start the game with a morale level of 3. Morale can be increased or decreased by events or Task Cards. A player with a morale level of 0 is eliminated from the game.
* **Time:** Players have a limited amount of time to complete the game. The game timer is the sand timer. If the timer runs out, all players lose.

**Winning the Game**

The first player to reach the "Regulatory Approval" phase of the board is declared the winner.

**Event Cards (30 Unique Examples)**

1. **FDA Fast Track Designation:** Advance to the Regulatory Approval phase immediately.
2. **Cybersecurity Breach:** Lose 2 Morale and 1 Technical Expertise Resource Token.
3. **Unexpected Side Effect:** Return to the Prototyping phase.
4. **Breakthrough Technology:** Gain 2 Morale and 1 Innovation Resource Token.
5. **Supply Chain Disruption:** Lose 1 Funding Resource Token.
6. **Patent Infringement Lawsuit:** Lose 2 Morale and 2 Funding Resource Tokens.
7. **Clinical Trial Success:** Gain 2 Morale and advance to the next phase.
8. **Clinical Trial Failure:** Lose 2 Morale and return to the Prototyping phase.
9. **Key Opinion Leader Endorsement:** Gain 1 Morale and 1 Funding Resource Token.
10. **Competitor Launches Similar Device:** Lose 1 Morale.
11. **Regulatory Changes:** Draw a new Task Card for your current phase.
12. **Patient Advocacy Group Support:** Gain 1 Morale and 1 Public Relations Resource Token.
13. **Ethical Dilemma:** Lose 1 Morale and choose a new Task Card.
14. **Manufacturing Defect:** Return to the Verification & Validation phase.
15. **Unexpected Market Demand:** Gain 2 Funding Resource Tokens.
16. **Product Recall:** Lose 2 Morale and return to the Prototyping phase.
17. **Merger & Acquisition:** Gain 2 Resource Tokens of your choice.
18. **Natural Disaster:** Lose 1 Resource Token of your choice.
19. **Investor Confidence:** Gain 1 Funding Resource Token.
20. **Government Grant:** Gain 2 Funding Resource Tokens.
21. **Trade Show Success:** Gain 1 Morale and 1 Public Relations Resource Token.
22. **Employee Strike:** Lose 1 Morale and 1 Production Resource Token.
23. **Unionization Effort:** Lose 1 Morale and 1 Funding Resource Token.
24. **Workplace Accident:** Lose 1 Morale and 1 Production Resource Token.
25. **Equipment Failure:** Lose 1 Production Resource Token.
26. **Quality Control Issue:** Lose 1 Morale and 1 Production Resource Token.
27. **Environmental Audit:** Lose 1 Funding Resource Token.
28. **Sustainability Initiative:** Gain 1 Morale and 1 Public Relations Resource Token.
29. **Product Launch Event:** Gain 2 Morale and 1 Funding Resource Token.
30. **Market Saturation:** Lose 1 Morale and 1 Funding Resource Token.

**Game board description and overview**

The Critical Path game board is designed to simulate the journey of a medical device from concept to market. It features a winding path that represents the different phases of systems engineering, starting with "Stakeholder Needs" and ending with "Regulatory Approval."

Each phase is divided into several squares, representing specific tasks that players must complete. These tasks include identifying stakeholder needs, writing requirements, developing prototypes, conducting verification and validation testing, running clinical trials, and navigating regulatory processes.

The game board also includes several special spaces, such as "Chance" and "Community Chest," which trigger random events that can help or hinder players' progress.

The board is visually appealing, with colorful illustrations that depict the various stages of medical device development. It also features clear and concise text that makes it easy for players to understand the requirements of each phase.

Overall, the Critical Path game board is a well-designed and engaging visual representation of the systems engineering process. It provides players with a fun and interactive way to learn about the challenges and rewards of bringing a medical device to market.

**Introduction**

Critical Path: The Systems Engineer's Quest is an immersive board game that transports players into the dynamic world of medical device development. As visionary systems engineers, players embark on a thrilling journey, navigating the intricate processes and overcoming challenges to bring their innovative medical device from concept to market. Set against a backdrop of futuristic advancements and pressing healthcare needs, the game offers a captivating blend of strategic decision-making, resource management, and collaborative problem-solving.

**Theme and Lore**

In a world where medical technology is rapidly evolving, the demand for groundbreaking medical devices has never been higher. Players step into the shoes of brilliant medical device systems engineers, each driven by a passion for innovation and a desire to make a lasting impact on healthcare. The game's rich lore unfolds as players progress through the various phases of medical device development, encountering unexpected hurdles, seizing opportunities, and making critical choices that will shape the destiny of their device and the lives of countless patients.

**Objectives**

The ultimate goal of Critical Path: The Systems Engineer's Quest is to successfully navigate the complex regulatory landscape and obtain regulatory approval for your medical device. This requires players to meticulously complete all tasks within the Regulatory Approval phase, ensuring that their device meets stringent safety, efficacy, and quality standards. Along the way, players must also manage resources efficiently, maintain team morale, and adapt to unforeseen challenges to keep their project on track.

**Components**

The game features a variety of components that bring the systems engineering process to life:

* **Game Board:** The game board serves as the visual representation of the medical device development journey, guiding players through the different phases and highlighting key milestones.
* **Player Tokens:** Each player selects a unique token to represent their systems engineer, allowing them to track their progress on the game board.
* **Task Cards:** These cards outline the specific tasks and challenges that players must overcome during each phase of development. They encompass a wide range of activities, from conducting user research and designing prototypes to performing risk assessments and clinical trials.
* **Event Cards:** Event cards introduce unexpected events and scenarios that can either accelerate or hinder progress. These cards add an element of unpredictability and require players to think on their feet and adapt their strategies accordingly.
* **Dice:** Dice are used to determine movement on the game board, simulate the outcomes of certain tasks, and introduce an element of chance.
* **Sand Timer:** The sand timer adds a sense of urgency to the game, enforcing time limits for specific tasks and encouraging players to make timely decisions.
* **Game Spinner:** The game spinner is used to resolve certain events and challenges, adding an element of suspense and excitement.
* **Player Boards:** Each player has a personal player board that tracks their resources, such as time, budget, and team morale. These boards also display the player's progress through the different phases of development.
* **Resource Tokens:** These tokens represent the various resources that players must manage throughout the game, including funding, personnel, and materials.
* **Morale Tracker:** The morale tracker reflects the overall morale of the player's team, which can fluctuate based on the outcomes of events and challenges. High morale can lead to increased productivity and efficiency, while low morale can result in delays and setbacks.

**Gameplay**

Critical Path: The Systems Engineer's Quest is a turn-based game in which players take turns moving their tokens along the game board, completing tasks, and responding to events. The game progresses through the following phases:

1. **Stakeholder Needs:** Players identify and prioritize the needs of various stakeholders, including patients, healthcare providers, and regulatory bodies.
2. **Requirements Definition:** Players translate stakeholder needs into clear and measurable requirements for the medical device.
3. **Design and Development:** Players design and develop the medical device, iterating on prototypes and refining the design based on feedback and testing.
4. **Verification and Validation:** Players conduct rigorous testing to verify that the device meets its requirements and validate that it performs as intended in a real-world setting.
5. **Regulatory Approval:** Players submit their device for regulatory approval, addressing any concerns and demonstrating compliance with all applicable regulations.

Throughout the game, players must make strategic decisions about resource allocation, risk management, and team dynamics. They must also collaborate with other players to overcome challenges and share knowledge and expertise. The player who successfully navigates all phases of development and obtains regulatory approval for their medical device is declared the winner.

Table of Board Game Components & Detailed Descriptions

| **Component** | **Description** |
| --- | --- |
| Game Board | The central playing area, visually representing the stages and phases of medical device development. It may include spaces for different development phases, regulatory hurdles, clinical trials, and market launch. The design should be engaging and informative, reflecting the complex and dynamic nature of the industry. |
| Player Tokens | Unique pieces representing each player's systems engineer. They could be miniature figures, meeples, or custom-designed tokens that reflect the role of a systems engineer. The tokens move around the board according to dice rolls, card draws, and strategic decisions, visually tracking each player's progress through the medical device development journey. |
| Task Cards | Cards that outline specific tasks and challenges encountered during each development phase. These tasks could include conducting research, designing prototypes, obtaining regulatory approval, and managing clinical trials. Each task card may have a difficulty level, resource requirements, and potential rewards or setbacks, adding depth and variety to gameplay. |
| Event Cards | Cards that introduce unexpected events and scenarios that can impact the development process. These events could include technological breakthroughs, regulatory changes, market fluctuations, or unforeseen challenges. Event cards add an element of unpredictability and excitement to the game, forcing players to adapt their strategies and make quick decisions. |
| Dice | Used to determine movement, simulate task outcomes, and introduce an element of chance. The number of dice and the type of dice used (e.g., six-sided, ten-sided) can be customized to fit the desired level of randomness and complexity. Dice rolls can also be used to trigger specific events or determine the severity of challenges. |
| Sand Timer | Used to time certain activities, such as brainstorming sessions or decision-making processes, creating a sense of urgency and simulating the time constraints often faced in medical device development. The sand timer can also be used to limit the amount of time players have to complete certain tasks, adding a competitive element to the game. |
| Resource Tokens | Represent different resources needed to progress through the development process, such as funding, research data, engineering expertise, and regulatory approval. These tokens can be acquired through successful task completion, card draws, or strategic trading. Resource management is a key aspect of the game, as players must balance their resources to achieve their development goals. |
| Chance Cards | Cards that trigger random events, both positive and negative, that can affect a player's progress. These events could include unexpected funding opportunities, unforeseen delays, or changes in market demand. Chance cards add an element of luck and unpredictability to the game, keeping players on their toes and forcing them to adapt to changing circumstances. |
| Community Chest Cards | Similar to Chance cards, these cards trigger random events that can impact a player's resources, progress, or position on the board. The events on Community Chest cards may be more focused on community interactions and collaborations, reflecting the importance of teamwork and partnerships in medical device development. |
| Instruction Manual | A booklet that provides detailed rules and guidelines for gameplay, including setup instructions, turn order, card explanations, and victory conditions. The manual should be clear, concise, and easy to understand, ensuring that players can quickly grasp the game mechanics and start playing. It may also include additional information about the medical device development process, adding an educational component to the game. |
| Game Box & Insert | The physical container for the game components, designed to protect and organize the pieces. The insert may include custom compartments for the board, cards, tokens, and dice, ensuring that everything has its place and is easy to find. The box design should be visually appealing and informative, reflecting the theme of the game and attracting potential players. |
| Rulebook | A comprehensive guide to the game's rules, mechanics, and strategies. It may include detailed explanations of card effects, scenarios, and advanced gameplay options. The rulebook should be well-organized and easy to reference, allowing players to quickly find the information they need. It may also include a glossary of terms and a FAQ section to address common questions. |
| Player Aid Cards | Reference cards that summarize key rules, actions, and information for easy access during gameplay. These cards can be helpful for new players or those who need a quick reminder of specific rules. Player aid cards can also include additional information about the medical device development process, such as regulatory requirements or clinical trial phases. |
| Certificates/Achievements | Additional components that can be awarded to players for reaching certain milestones or completing specific objectives. These could include certificates for completing the development process, reaching market launch, or achieving specific regulatory approvals. Achievements can add a sense of accomplishment and encourage players to strive for excellence. |

**Critical Path: The Systems Engineer's Quest Rulebook**

**Introduction**

Welcome to Critical Path: The Systems Engineer's Quest, an immersive and strategic board game that plunges you into the intricate world of medical device development. Step into the shoes of a medical device systems engineer and navigate the multifaceted challenges of bringing a medical device to market. From understanding stakeholder needs and defining precise requirements to designing, developing, and rigorously testing your device, you'll experience the highs and lows of the product development lifecycle.

Collaborate with your team, manage resources wisely, and mitigate risks as you strive to achieve regulatory approval and ultimately launch your groundbreaking medical device. Critical Path is not just a game; it's a simulation of the dynamic and demanding field of systems engineering, where innovation, problem-solving, and strategic thinking are paramount.

**List of Components**

* **Game Board:** The visual representation of the medical device development journey, featuring distinct phases, action spaces, and a "Market Launch" finish line.
* **Player Tokens (4):** Each player chooses a unique token to represent their progress on the game board.
* **Task Cards (100):** These cards present challenges and tasks related to each phase of development, requiring players to make decisions and utilize resources.
* **Event Cards (50):** These cards introduce unexpected events and scenarios that can impact the development process, forcing players to adapt and strategize.
* **Dice (2 six-sided):** Used to determine movement on the game board and outcomes of certain actions.
* **Sand Timer:** Adds a time constraint to certain tasks and decisions, simulating the pressure of real-world deadlines.
* **Resource Tokens (100):** Represent essential resources like funding, personnel, and materials, which players must manage effectively.
* **Chance Cards (20):** These cards introduce elements of chance and unpredictability, offering opportunities and setbacks.
* **Community Chest Cards (20):** These cards represent collaborative opportunities and shared challenges within the medical device community.
* **Instruction Manual:** Provides detailed instructions on game setup, gameplay, and specific rules.
* **Game Box & Insert:** Stores and organizes all game components.

**Game Setup**

1. **Unfold the Game Board:** Place the game board in the center of the playing area, ensuring all players have easy access.
2. **Prepare the Card Decks:** Shuffle the Task Cards and Event Cards separately and place them face down in their designated areas on the game board.
3. **Resource Pool:** Place the Resource Tokens in a central pool, accessible to all players.
4. **Player Selection:** Each player chooses a Player Token and places it on the "Start" space on the game board.
5. **Starting Player:** Roll the dice. The player with the highest roll goes first. Play then proceeds clockwise.

**Goal of the Game**

The ultimate goal of Critical Path is to be the first player to successfully launch your medical device into the market. This achievement requires you to navigate through all phases of development, secure regulatory approval, and strategically manage your resources along the way.

**General Sequence of Play**

Each player's turn consists of the following actions:

1. **Roll and Move:** Roll the dice and move your Player Token the corresponding number of spaces on the game board.
2. **Space Action:** Perform the action indicated by the space you land on. This could involve drawing a Task Card, resolving an Event Card, collecting resources, paying costs, or making strategic decisions.
3. **Card Resolution:** If you land on a space that requires you to draw a Task or Event Card, follow the instructions on the card and resolve any challenges or opportunities it presents.
4. **Resource Management:** Collect or spend Resource Tokens as required by the space you land on or the cards you draw.
5. **Trading (Optional):** You may choose to trade Resource Tokens with other players if it benefits your strategy.
6. **End Turn:** Once you have completed all actions for your turn, pass the dice to the next player.

**Detailed Sequence of Play**

**1. Stakeholder Needs Phase**

* **Objective:** Identify and prioritize the needs of various stakeholders, including patients, healthcare providers, regulatory bodies, and investors.
* **Actions:** Draw and resolve Stakeholder Needs Task Cards. These cards will present scenarios and challenges related to understanding and balancing the diverse needs of stakeholders. You may need to make decisions, allocate resources, and collaborate with other players to successfully navigate this phase.

**2. Requirements Definition Phase**

* **Objective:** Translate stakeholder needs into clear, measurable, and verifiable requirements for your medical device.
* **Actions:** Draw and resolve Requirements Definition Task Cards. These cards will challenge you to define precise and comprehensive requirements that will guide the design and development of your device. You may need to analyze trade-offs, consider regulatory standards, and ensure that your requirements are feasible and aligned with stakeholder needs.

**3. Design and Development Phase**

* **Objective:** Design and develop your medical device based on the defined requirements.
* **Actions:** Draw and resolve Design and Development Task Cards. These cards will present design challenges, prototyping tasks, and development hurdles that you must overcome. You may need to allocate resources, manage timelines, and make critical decisions to ensure that your device design is safe, effective, and manufacturable.

**4. Verification and Validation Phase**

* **Objective:** Conduct rigorous testing to verify that your device meets its requirements and validate that it performs as intended in a real-world setting.
* **Actions:** Draw and resolve Verification and Validation Task Cards. These cards will guide you through various testing procedures, including bench testing, animal testing, and clinical trials. You may need to analyze test data, address any design flaws, and demonstrate that your device is safe and effective for its intended use.

**5. Regulatory Approval Phase**

* **Objective:** Submit your device for regulatory approval and address any questions or concerns raised by regulatory bodies.
* **Actions:** Draw and resolve Regulatory Approval Task Cards. These cards will simulate the regulatory submission process, including document preparation, agency interactions, and potential delays. You may need to provide additional data, address compliance issues, and demonstrate that your device meets all regulatory requirements.

**End of Game**

The game concludes when the first player successfully reaches the "Market Launch" space on the game board. This signifies that they have completed all phases of development, obtained regulatory approval, and are ready to launch their medical device into the market. The player who achieves this first is declared the winner.

**Credits**

* **Game Design:** [Your Name]
* **Art and Illustration:** [Artist Name]
* **Development:** [Development Team]
* **Testing:** [Testing Team]
* **Special Thanks:** [Anyone who helped with the game]

**Board game contact information:**

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**Stakeholder Needs Task Cards**

| **Stakeholder Needs Task Card** | **Objective** | **Possible Challenges** |
| --- | --- | --- |
| **Patient-Centered Design** | Understand and prioritize the needs and preferences of patients who will use the medical device. | Balancing conflicting patient needs, addressing usability concerns, and incorporating feedback into the design. |
| **Regulatory Compliance** | Ensure that the medical device meets all applicable regulatory requirements and standards. | Keeping up with evolving regulations, managing documentation, and navigating the approval process. |
| **Healthcare Provider Collaboration** | Collaborate with healthcare providers to gather insights and ensure that the medical device meets their clinical needs. | Scheduling meetings, addressing provider concerns, and incorporating feedback into the design. |
| **Investor Expectations** | Align the medical device with the expectations and requirements of investors and shareholders. | Balancing investor demands with patient needs, managing financial risks, and delivering on promised returns. |
| **Market Research** | Analyze market trends, competitive landscapes, and potential customer segments to identify opportunities and threats. | Gathering accurate data, interpreting market dynamics, and making informed decisions based on research findings. |
| **Ethical Considerations** | Address ethical concerns related to the medical device, such as data privacy, patient safety, and equitable access. | Balancing patient rights with commercial interests, navigating legal and regulatory frameworks, and ensuring ethical decision-making. |
| **Environmental Impact** | Assess the environmental impact of the medical device throughout its lifecycle, from manufacturing to disposal. | Identifying sustainable materials, optimizing production processes, and implementing eco-friendly practices. |
| **Cultural Sensitivity** | Consider the cultural and social factors that may influence the acceptance and use of the medical device in different regions or populations. | Understanding cultural norms, addressing language barriers, and adapting the medical device to meet diverse needs. |

**Requirement Definition Task Cards**

| **Requirement Definition Task Card** | **Objective** | **Possible Challenges** |
| --- | --- | --- |
| **Identify Stakeholder Needs** | Elicit and document the needs and expectations of all relevant stakeholders, including patients, healthcare providers, regulators, and investors. | Balancing conflicting stakeholder needs, managing stakeholder expectations, and ensuring inclusivity in the requirements gathering process. |
| **Develop Use Cases** | Create use cases that describe how the medical device will be used in real-world scenarios. | Capturing all relevant use cases, ensuring use cases are specific and measurable, and prioritizing use cases based on stakeholder needs. |
| **Define Functional Requirements** | Specify the functional requirements that the medical device must meet to fulfill its intended purpose. | Balancing completeness and specificity of requirements, ensuring requirements are verifiable and testable, and avoiding over-specification. |
| **Define Non-Functional Requirements** | Specify the non-functional requirements that the medical device must meet, such as performance, reliability, and security. | Balancing competing non-functional requirements, ensuring requirements are measurable and achievable, and considering trade-offs between different requirements. |
| **Allocate Requirements** | Assign requirements to specific components or subsystems of the medical device. | Ensuring requirements are allocated completely and consistently, managing dependencies between requirements, and avoiding duplication of requirements. |
| **Validate Requirements** | Verify that the requirements are complete, consistent, and feasible. | Conducting requirements reviews, soliciting feedback from stakeholders, and testing requirements for completeness and consistency. |
| **Document Requirements** | Create a requirements document that captures all of the requirements for the medical device. | Organizing requirements in a logical and structured manner, ensuring requirements are traceable to stakeholder needs, and maintaining the requirements document throughout the development process. |

**Table of Design and Development Task Cards**

| **Design & Development Task Card** | **Objective** | **Possible Challenges** |
| --- | --- | --- |
| **Concept Generation** | Brainstorm and evaluate different design concepts for the medical device. | Balancing creativity with feasibility, considering user needs and regulatory requirements, and selecting the most promising concept. |
| **Detailed Design** | Create detailed design specifications, including drawings, schematics, and material selections. | Ensuring design for manufacturability and assembly, addressing potential failure modes, and optimizing for cost and performance. |
| **Prototyping** | Build and test prototypes of the medical device to evaluate its functionality and performance. | Selecting appropriate prototyping methods, managing prototyping costs and timelines, and iterating on the design based on test results. |
| **Software Development** | Develop and test the software that controls the medical device. | Writing clean and maintainable code, conducting code reviews, and ensuring software compatibility with hardware and regulatory requirements. |
| **User Interface Design** | Design the user interface of the medical device, ensuring it is intuitive and easy to use. | Conducting user research, creating wireframes and prototypes, and incorporating user feedback into the design. |
| **Design for Manufacturing** | Optimize the design of the medical device for efficient and cost-effective manufacturing. | Selecting appropriate manufacturing processes, minimizing assembly steps, and ensuring quality control. |
| **Design for Reliability** | Design the medical device to be reliable and durable, minimizing the risk of failure. | Conducting reliability analysis, selecting reliable components, and implementing redundancy and fault tolerance measures. |
| **Design for Safety** | Design the medical device to be safe for patients and users, minimizing the risk of harm. | Conducting safety risk assessments, implementing safety features, and complying with safety standards. |
| **Design Verification** | Conduct tests to verify that the design of the medical device meets its specified requirements. | Developing test plans, executing tests, analyzing test results, and documenting findings. |
| **Design Reviews** | Conduct formal design reviews with stakeholders to gather feedback and ensure that the design meets their needs. | Scheduling and facilitating design reviews, addressing stakeholder concerns, and incorporating feedback into the design. |
| **Technical Documentation** | Create technical documentation, such as design history files and device master records. | Ensuring documentation is complete, accurate, and compliant with regulatory requirements. |
| **Intellectual Property** | Identify and protect intellectual property associated with the medical device design. | Conducting patent searches, filing patent applications, and managing intellectual property rights. |

**Table of Verification and Validation Task Cards**

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| **Verification & Validation Task Card** | **Objective** | **Possible Challenges** |
| --- | --- | --- |
| **Test Protocol Development** | Design and document detailed test protocols for specific device functions and requirements. | Ensuring test coverage, selecting appropriate test methods, and defining acceptance criteria. |
| **Design Verification Testing** | Conduct tests to verify that the device's design meets its specified requirements. | Identifying and resolving design flaws, managing test equipment and resources, and documenting test results. |
| **Software Verification** | Verify that the device's software functions correctly and meets its requirements. | Conducting code reviews, unit testing, integration testing, and system testing. |
| **Usability Testing** | Evaluate the device's ease of use and user interface through user testing. | Recruiting representative users, designing realistic test scenarios, and analyzing user feedback. |
| **Biocompatibility Testing** | Assess the device's compatibility with biological systems and tissues. | Selecting appropriate test methods, interpreting test results, and addressing any biocompatibility concerns. |
| **Sterilization Validation** | Validate the effectiveness of the device's sterilization process. | Selecting appropriate sterilization methods, conducting validation studies, and documenting sterilization parameters. |
| **Packaging Validation** | Validate the device's packaging to ensure it maintains sterility and protects the device during shipping and storage. | Designing and conducting packaging tests, evaluating packaging materials, and documenting packaging performance. |
| **Shelf-Life Testing** | Determine the device's shelf life and stability under various storage conditions. | Designing and conducting accelerated aging studies, monitoring product stability, and establishing expiration dates. |
| **Risk Management Review** | Reassess and mitigate any potential risks associated with the device's design, use, or manufacturing. | Identifying new risks, evaluating risk mitigation strategies, and updating the risk management file. |
| **Clinical Trial Support** | Provide technical and regulatory support for clinical trials of the device. | Coordinating with clinical investigators, managing device inventory, and addressing any device-related issues during the trial. |
| **Regulatory Submission Preparation** | Prepare documentation for regulatory submission, including technical files, design dossiers, and clinical data. | Ensuring compliance with regulatory requirements, organizing and formatting documentation, and addressing any deficiencies identified by regulatory bodies. |
| **Post-Market Surveillance** | Monitor the device's performance and safety after it has been released to the market. | Collecting and analyzing post-market data, identifying and addressing any safety issues, and implementing corrective and preventive actions. |

**Table Regulatory Approval Task Cards**

| **Regulatory Approval Task Card** | **Objective** | **Possible Challenges** |
| --- | --- | --- |
| **Prepare Regulatory Submission** | Compile and submit all necessary documentation to the regulatory body for review and approval. | Ensuring completeness and accuracy of documentation, meeting formatting requirements, and addressing any questions or requests for additional information. |
| **Respond to Regulatory Questions** | Address any questions or concerns raised by the regulatory body during the review process. | Interpreting regulatory guidelines, providing clear and concise responses, and gathering additional data or evidence if necessary. |
| **Pre-Approval Inspection** | Prepare for and undergo a pre-approval inspection of your manufacturing facilities and quality systems by the regulatory body. | Ensuring compliance with good manufacturing practices (GMP), addressing any non-conformities, and demonstrating a robust quality management system. |
| **Post-Market Surveillance Plan** | Develop and implement a plan to monitor the device's safety and effectiveness after it has been released to the market. | Defining data collection methods, establishing reporting procedures, and ensuring timely identification and response to any adverse events or safety signals. |
| **Clinical Data Requirements** | Determine and fulfill any clinical data requirements necessary for regulatory approval. | Designing and conducting clinical trials, collecting and analyzing clinical data, and demonstrating the device's safety and effectiveness in a clinical setting. |
| **Labeling and Instructions for Use** | Develop clear and accurate labeling and instructions for use (IFU) for the medical device. | Ensuring compliance with labeling requirements, providing clear and concise instructions, and considering user comprehension and accessibility. |
| **International Regulatory Compliance** | Navigate the regulatory requirements for marketing the device in different countries or regions. | Understanding and complying with varying regulatory standards and requirements, adapting labeling and documentation, and managing international regulatory submissions. |
| **Reimbursement and Coding** | Obtain appropriate reimbursement codes and navigate the reimbursement landscape for the medical device. | Understanding coding systems, working with payers and providers, and demonstrating the device's value proposition. |
| **Ethical and Legal Considerations** | Address any ethical or legal concerns related to the medical device, such as intellectual property, conflicts of interest, or liability. | Ensuring compliance with ethical guidelines, managing intellectual property rights, and mitigating legal risks. |
| **Post-Market Changes and Notifications** | Manage any changes or modifications to the device after it has been approved and released to the market. | Assessing the impact of changes, determining the need for regulatory notification or approval, and implementing change control procedures. |
| **Adverse Event Reporting** | Establish and maintain a system for reporting and investigating adverse events associated with the device. | Complying with adverse event reporting requirements, conducting thorough investigations, and implementing corrective and preventive actions. |

**Table of Resources in Critical Path: The Medical Device Development Board Game**

| **Resource Type** | **Tasks and Events** |
| --- | --- |
| Funding | Developing prototypes, conducting clinical trials, submitting regulatory applications |
| Personnel | Hiring engineers, scientists, and regulatory specialists |
| Materials | Acquiring raw materials, components, and supplies |
| Time | Managing timelines and meeting deadlines |
| Expertise | Consulting with experts in various fields, such as medicine, engineering, and regulatory affairs |
| Collaboration | Working with other players to pool resources and share knowledge |
| Chance | Dealing with unexpected events and opportunities |
| Community | Tapping into the collective wisdom and support of the medical device community |

**Layout board game design**

Here is a potential layout for the "Critical Path" game board, with a description of each space, geared towards systems engineers in the medical device industry, and incorporating the previously mentioned game mechanics:

**Game Board Layout & Space Descriptions**

**1. Stakeholder Needs Phase (Green)**

* **Start:** All players begin here. Receive 5 Funding tokens.
* **Patient Interviews:** Draw a Task Card. Roll for Communication to understand patient needs.
* **Physician Consultation:** Draw a Task Card. Roll for Stakeholder Management to align physician requirements with patient needs.
* **Regulatory Body Meeting:** Draw a Task Card. Roll for Regulatory Knowledge to understand initial regulatory requirements.
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

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

* **Define System Requirements:** Draw a Task Card. Roll for Systems Thinking to translate stakeholder needs into system requirements.
* **Block Diagram Creation:** Draw a Task Card. Roll for Technical Expertise to create a functional block diagram.
* **Interface Definition:** Draw a Task Card. Roll for Documentation to clearly define system interfaces.
* **Risk Analysis:** Draw a Task Card. Roll for Risk Management to identify and mitigate potential risks.
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

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

* **User Needs Specification:** Draw a Task Card. Roll for Documentation to write clear and concise user needs.
* **Design Input Requirements:** Draw a Task Card. Roll for Systems Thinking to translate user needs into design inputs.
* **Traceability Matrix:** Draw a Task Card. Roll for Analytical Skill to establish traceability between requirements and design.
* **Requirements Review:** Draw a Task Card. Roll for Communication to conduct a successful requirements review with stakeholders.
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

**4. Prototyping Phase (Orange)**

* **Prototype Development:** Draw a Task Card. Roll for Technical Expertise and spend Funding tokens to develop a prototype.
* **Design Verification Testing:** Draw a Task Card. Roll for Analytical Skill to verify the prototype meets design inputs.
* **Design Iteration:** Draw a Task Card. Roll for Problem-Solving to address design flaws and improve the prototype.
* **User Feedback:** Draw a Task Card. Roll for Communication to gather and incorporate user feedback on the prototype.
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

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

* **Test Plan Development:** Draw a Task Card. Roll for Documentation to create a comprehensive test plan.
* **Design Validation Testing:** Draw a Task Card. Roll for Analytical Skill to validate the device meets user needs and intended use.
* **Risk Management Review:** Draw a Task Card. Roll for Risk Management to reassess and mitigate risks.
* **Final Design Freeze:** Draw a Task Card. Roll for Time Management to finalize the design before regulatory submission.
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

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

* **Regulatory Submission:** Draw a Task Card. Roll for Regulatory Knowledge and spend Funding tokens to submit documentation.
* **Regulatory Review:** Await the results of the regulatory review (GM determines outcome).
* **Address Regulatory Questions:** Draw a Task Card. Roll for Communication and Regulatory Knowledge to respond to regulatory questions.
* **Approval/Clearance:** Receive regulatory approval or clearance (GM determines outcome based on previous tasks and rolls).
* **Chance:** Draw a Chance card.
* **Community Chest:** Draw a Community Chest card.

**7. Market Launch (Gold)**

* **The first player to land here and has received regulatory approval wins!**

**Board Decoration Ideas for Systems Engineers**

* **Background:** A blueprint-style design with circuit board elements or a human anatomy diagram related to the device's purpose (e.g., circulatory system for a heart device).
* **Phase Colors:** Use colors to differentiate phases (e.g., green for Stakeholder Needs, blue for System Architecture).
* **Icons:** Use medical and engineering symbols (e.g., gears, stethoscopes, microscopes, CAD symbols) to mark spaces.
* **3D Printed Elements:** If available, 3D print miniature models of medical devices or laboratory equipment to place on relevant spaces.
* **Quotes:** Include relevant quotes from famous engineers or scientists around the board.
* **"Easter Eggs":** Hide subtle references to engineering jokes or memes within the board design.
* **Educational Elements:** Add brief explanations of key systems engineering concepts or regulatory terms to certain spaces.

**Additional Considerations:**

* **Resource Tokens:** Use different colored tokens or shapes to represent different resources (e.g., green for Funding, blue for Expertise).
* **Player Boards:** Design player boards with sections to track resources, morale, and progress.
* **Chance and Community Chest Cards:** Make the cards visually distinct and engaging, with clear instructions and outcomes.
* **Task Cards:** Color code task cards to match the phase they belong to.

Note: Use black vinyl wrap for wood

**Resource tokens**

Here are some ideas for Resource Tokens in the "Critical Path" board game, along with suggestions for how to create or source them:

**Resource Token Types and Their Use in Gameplay**

* **Funding:**
  + **Use:** Required to initiate projects, conduct research, run clinical trials, and navigate regulatory processes.
  + **Creation:**
    - Print small paper bills with denominations like $100,000, $500,000, and $1,000,000.
    - Use play money from other board games.
    - Design and 3D print coins with a medical or engineering symbol.
* **Personnel:**
  + **Use:** Represents the team members and experts required for different tasks (e.g., engineers, scientists, regulatory specialists).
  + **Creation:**
    - Use miniature figures representing different professions (e.g., doctor, scientist, engineer).
    - Create custom meeples with different colors or symbols to represent different roles.
    - Print and cut out paper tokens with images or icons of team members.
* **Materials:**
  + **Use:** Represents the raw materials, components, and supplies needed for prototyping and manufacturing.
  + **Creation:**
    - Use small wooden cubes or cylinders in different colors to represent different materials.
    - 3D print miniature models of raw materials or components.
    - Print and cut out paper tokens with images or icons of materials.
* **Time:**
  + **Use:** Represents the time required to complete tasks and phases. Players may gain or lose time based on their actions and events.
  + **Creation:**
    - Use a sand timer or hourglass to track time during the game.
    - Use small hourglasses or tokens with clock symbols to represent increments of time.
* **Expertise:**
  + **Use:** Represents specialized knowledge or skills required for specific tasks (e.g., clinical expertise, regulatory knowledge, engineering expertise).
  + **Creation:**
    - Use tokens with symbols or icons representing different areas of expertise (e.g., brain for clinical, book for regulatory, gear for engineering).
    - Use different colored gems or stones to represent different types of expertise.
* **Innovation:**
  + **Use:** Represents the ability to develop novel solutions and technologies, potentially leading to breakthroughs or faster progress.
  + **Creation:**
    - Use tokens with lightbulb symbols or other icons representing innovation.
    - Use unique or eye-catching tokens, like small puzzle pieces or gears, to represent innovation.
* **Public Relations:**
  + **Use:** Represents the company's reputation and public image, influencing stakeholder relationships and market acceptance.
  + **Creation:**
    - Use tokens with symbols like speech bubbles, microphones, or thumbs-up icons to represent public relations.

**Off-the-Shelf Component Ideas**

* **Poker Chips:** Can represent Funding or other resources with different colors representing different values.
* **Glass Beads or Gems:** Can represent different types of Expertise or Innovation.
* **Wooden Cubes or Meeples:** Can represent Personnel, Materials, or other resources.
* **Play Money:** Can be used directly as Funding tokens.
* **Miniature Figurines:** Can represent Personnel with different professions or roles.

**Tips for Creating Custom Tokens**

* **3D Printing:** If you have access to a 3D printer, you can design and print custom tokens in various shapes and sizes.
* **Laser Cutting:** Laser cutting can be used to create intricate designs on wooden or acrylic tokens.
* **Cardboard or Paper Tokens:** Print and cut out tokens from cardboard or thick paper. Consider laminating them for durability.
* **Craft Supplies:** Use beads, buttons, or other craft supplies to create unique and visually appealing tokens.

**Remember:** The key is to choose tokens that are easy to identify, handle, and differentiate from one another. The visual design of the tokens should also complement the theme of the game and enhance the overall player experience.

**Chance Cards**

| **Card Number** | **Card Description** |
| --- | --- |
| 1 | Advance to the next phase. |
| 2 | Draw an additional Task Card. |
| 3 | Gain 1 Funding token. |
| 4 | Lose 1 Funding token. |
| 5 | Roll again and move forward that many spaces. |
| 6 | Move back 2 spaces. |
| 7 | Skip your next turn. |
| 8 | Draw a Community Chest card. |
| 9 | Gain 1 Expertise token. |
| 10 | Lose 1 Expertise token. |

**Community Chest**

Unfortunately, the text provided does not contain any explicit examples of Community Chest cards. Therefore, I cannot generate a table directly from the given content.

However, based on the context of the game and the provided Chance cards, I can suggest potential themes and examples for Community Chest cards that would align with the medical device development theme:

**Potential Community Chest Card Themes & Examples**

| **Community Chest Card Title** | **Description** | **Resource Impact** | **Morale Impact** | **Movement Impact** | **Additional Actions/Considerations** |
| --- | --- | --- | --- | --- | --- |
| **Industry Collaboration** | A rival company proposes a joint venture. If you accept, gain 1 Innovation and 1 Public Relations token, but lose 1 turn while negotiations take place. | Gain 1 Innovation, 1 Public Relations; Lose 1 Turn | ±0 | Lose 1 turn | Player must decide whether to collaborate, weighing the potential benefits of shared resources and knowledge against the risks of delays and potential conflicts of interest. |
| **Mentorship Program** | You are invited to mentor a promising young engineer. Gain 1 Morale, but lose 1 Time token as you dedicate time to mentorship. | Lose 1 Time | +1 | None | Player may choose to decline the mentorship opportunity, but doing so may result in a loss of potential future benefits (e.g., gaining a skilled team member later in the game). |
| **Research Grant** | Your team secures a research grant. Gain 2 Funding tokens. | Gain 2 Funding | ±0 | None | No additional actions required. |
| **Conference Presentation** | You are invited to present your device at a major conference. Gain 1 Public Relations token and roll for Communication to determine the success of your presentation. | Gain 1 Public Relations | ±0 | None | Roll for Communication: On a success, gain 1 Morale; on a failure, lose 1 Morale. |
| **Community Outreach** | Your company organizes a community outreach program to educate the public about your device. Gain 1 Public Relations token. | Gain 1 Public Relations | ±0 | None | No additional actions required. |
| **Regulatory Compliance Workshop** | Attend a workshop on regulatory compliance. Gain 1 Regulatory Knowledge token. | Gain 1 Regulatory Knowledge | ±0 | None | No additional actions required. |
| **Unexpected Costs** | Unforeseen expenses arise, such as additional testing or material costs. Lose 1 Funding token. | Lose 1 Funding | -1 | None | No additional actions required. |
| **Team Building Retreat** | Your team attends a team-building retreat. Gain 1 Morale. | ±0 | None | No additional actions required. |  |
| **Supply Chain Shortage** | A key component for your device is in short supply. Lose 1 Time token as you search for alternative suppliers. | Lose 1 Time | -1 | None | No additional actions required. |
| **Intellectual Property Dispute** | Another company claims you have infringed on their patent. Lose 1 Morale and roll for Regulatory Knowledge to determine the outcome of the dispute. | Lose 1 Morale | ±0 | None | Roll for Regulatory Knowledge: On a success, no further impact; on a failure, lose 2 Funding tokens and 1 Time token. |
| **Cyberattack** | Your company's computer systems are hacked. Lose 1 Time token and 1 Morale. | Lose 1 Time, 1 Morale | -1 | None | No additional actions required. |
| **Product Liability Claim** | A patient files a lawsuit claiming your device caused them harm. Lose 2 Morale and roll for Risk Management to determine the outcome of the lawsuit. | Lose 2 Morale | ±0 | None | Roll for Risk Management: On a success, no further impact; on a failure, lose 3 Funding tokens and return to the Verification & Validation phase. |
| **Collaboration Opportunity** | A research institution offers to collaborate on your project. Gain 1 Innovation token and 1 Expertise token. | Gain 1 Innovation, 1 Expertise | +1 | None | No additional actions required. |
| **Regulatory Breakthrough** | A new regulatory pathway opens up, potentially accelerating your time to market. Gain 1 Time token and 1 Regulatory Knowledge token. | Gain 1 Time, 1 Regulatory Knowledge | +1 | None | No additional actions required. |
| **Market Disruption** | A new technology emerges that could disrupt the market for your device. Lose 1 Morale and roll for Innovation to determine how you adapt. | Lose 1 Morale | ±0 | None | Roll for Innovation: On a success, gain 1 Innovation token; on a failure, lose 1 Funding token and 1 Time token. |
| **Patient Advocacy** | A patient advocacy group rallies support for your device. Gain 1 Public Relations token and 1 Morale. | Gain 1 Public Relations, 1 Morale | ±0 | None | No additional actions required. |
| **Unforeseen Technical Challenge** | A major technical challenge arises that threatens to delay your project. Lose 1 Time token and roll for Technical Expertise to overcome the challenge. | Lose 1 Time | -1 | None | Roll for Technical Expertise: On a success, no further impact; on a failure, lose 1 Morale and 1 Funding token. |

**Sources of Meeples**

# **Manhattan Project Meeples**

https://www.thingiverse.com/thing:3449847