From Clinical Requirements to Game Mechanics: A Requirements Engineering Framework for Serious Games for Health

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Abstract. *The development of Serious Games for Health (SGH) requires balancing clinical effectiveness with player engagement. However, the lack of structured development processes often leads teams to adopt ad hoc approaches, resulting in systems that fail to meet clinical objectives or technical quality standards. This methodological gap makes it difficult to translate complex clinical protocols into consistent and executable technical specifications. To address this challenge, this paper proposes a Requirements Engineering framework tailored to SGH development. The framework integrates established software engineering practices and process maturity principles inspired by the Capability Maturity Model Integration (CMMI). It structures a collaborative workflow involving healthcare professionals, software engineers, and end users, and employs a Requirements Traceability Matrix (RTM) to ensure traceability between clinical objectives and game mechanics. To evaluate the framework, we conducted a case study involving the development of a serious game for adults with Autism Spectrum Disorder (ASD). The results provide evidence that the proposed framework improves clinical–technical alignment and establishes a systematic and auditable process for translating clinical needs into implementable game requirements.*

1. Introduction

The discipline of Software Engineering (SE) addresses the inherent complexity of building computational systems, particularly in critical and multidisciplinary domains [Carlier et al. 2023]. At its core, SE seeks to transform abstract ideas into reliable software products through structured and disciplined development processes [Ambros-Antemate et al. 2021]. Despite these advances, determining what a system should do remains a well-known challenge in the software lifecycle [Brooks 1987], especially when system requirements involve complex domain knowledge that extends beyond traditional programming and design concerns [Maxim and Arnedo-Moreno 2025].

The digital games industry traditionally focuses on creating immersive entertainment experiences, often supported by frameworks such as MDA (Mechanics, Dynamics,

and Aesthetics) [Yang et al. 2022]. However, when developers design games for purposes beyond entertainment, such as training, treatment, or education, additional design considerations become necessary [Abdul Aziz et al. 2024]. Serious Games (SGs) aim to achieve these objectives by combining game mechanics with domain-specific goals [Carlier et al. 2023, Honorato et al. 2021].

In the context of Serious Games for Health (SGH), developers face a particularly complex challenge. They must balance player engagement with scientific rigor and clinical effectiveness [Ramalho et al. 2024]. If the system prioritizes clinical rigor alone, the experience may become tedious and lead to patient abandonment. Conversely, if it prioritizes entertainment alone, the clinical purpose may be compromised [Caserman et al. 2020].

The current literature reveals a methodological gap in the engineering of Serious Games for Health. Many SGH systems still rely on empirical and non-standardized approaches [Ambros-Antemate et al. 2021, Maxim and Arnedo-Moreno 2025, Fang et al. 2025]. As a result, teams often struggle to systematically translate clinical protocols and clinical objectives into coherent game mechanics and software requirements. Without structured processes, projects frequently produce solutions that neglect either the user experience or fundamental clinical requirements [Robertson et al. 2021].

To overcome these limitations, Software Engineering practices must provide mechanisms that ensure traceability between clinical objectives and game mechanics. Such mechanisms allow development teams to align clinical needs with ludic elements while progressing toward higher levels of process maturity [Honorato et al. 2021, Piedade et al. 2023]. By adopting systematic methodologies, the development of SGH can evolve from an artisanal and largely intuitive activity into a predictable, auditable, and clinically reliable engineering workflow [Ushaw et al. 2017, Carlier et al. 2023, Santos et al. 2021].

Although previous studies highlight the importance of multidisciplinary collaboration and participatory design in SGH development, the literature still lacks structured Requirements Engineering approaches that ensure traceability among clinical objectives, game mechanics, and software implementation. This limitation makes it difficult to develop SGH systems that simultaneously satisfy clinical validity, technical quality, and player engagement.

To address the limitations observed in the development of Serious Games for Health, which often lack the expected clinical value due to the absence of participatory and structured design processes [Roungas 2021, Ramalho et al. 2024], this paper proposes a Requirements Engineering framework specifically designed for SGH projects. The framework structures collaboration among key stakeholders, including software engineers, healthcare professionals, and end users. It supports the systematic documentation of both clinical and technical aspects of the game and provides mechanisms that allow multidisciplinary teams to maintain a shared understanding of system requirements. In addition, the framework employs artifacts such as the Requirements Traceability Matrix (RTM) to establish explicit links between clinical objectives, game mechanics, and acceptance criteria. Finally, it incorporates practices inspired by the Capability Maturity Model Integration (CMMI) to promote a predictable, auditable, and iterative engineering workflow.

In this context, the main contributions of this work are:

- A Requirements Engineering framework tailored to the development of Serious Games for Health, integrating multidisciplinary stakeholders, practices from CMMI, and structured development artifacts.
- A traceability-driven development approach, linking clinical requirements, gameplay mechanics, and validation metrics through a RTM.
- A practical validation through a case study, demonstrating how the framework can structure the development of a serious game for adults with Autism Spectrum Disorder (ASD).

Ultimately, this work addresses the limitations of empirical development practices by introducing a structured Requirements Engineering framework that preserves clinical objectives while maintaining the engagement expected from digital games.

The remainder of this paper is organized as follows. Section 2 reviews background concepts and related work in Serious Games for Health. Section 3 presents the proposed Requirements Engineering framework and its operational structure. Section 4 evaluates the framework through a case study involving a serious game for adults with ASD. Finally, Section 5 concludes the paper by summarizing the main contributions and outlining directions for future research.

2. Related Work

This section reviews relevant studies on the development of Serious Games for Health (SGH), with a particular focus on Requirements Engineering practices and development methodologies. The literature reveals three main research directions: (i) SGH projects developed for specific clinical domains, (ii) studies investigating requirements elicitation and stakeholder collaboration in SGH development, and (iii) methodological frameworks aimed at structuring the design and implementation of health-related games. By analyzing these contributions, this section identifies key limitations in current approaches and highlights the need for more systematic engineering processes to support SGH development.

A relevant example described in the literature is DiagnosTEA [Barbosa et al. 2024], a digital game developed using the Unity engine to support the diagnosis and treatment of ASD. The available reports indicate that the project followed a largely ad hoc development process. This case illustrates a broader challenge observed in the field of Serious Games for Health (SGH): the lack of standardized development methodologies. Despite its scientific grounding, the absence of a formal Requirements Engineering approach and structured participatory design mechanisms led to a partial disconnect between the implemented game mechanics and the clinical realities of patients. These limitations highlight the need for more systematic engineering approaches in SGH development.

Several studies highlight that the success of SGH systems depends on the adoption of specialized Requirements Engineering approaches. Research focused on ASD, such as the study by [Trindade et al. 2022] on requirements elicitation for exergames using interactive floors, shows that successful requirements elicitation requires close collaboration with domain experts. This collaboration is essential to account for the sensory, cognitive, and motor characteristics of the target audience. These findings support the proposed framework's emphasis on involving healthcare professionals and end users as active

stakeholders during the early stages of development to define clinical requirements and operational constraints.

A recurring theme in the literature concerns the difficulty of translating abstract clinical goals into concrete software functionalities. The work of [Robertson et al. 2021] introduces models such as MECHA (Mechanics, Experiences, Change), which attempt to bridge this gap by mapping intervention objectives to player experiences and software rules. Similarly, the RollAbility project presented by [Ravers et al. 2025] demonstrates that iterative development processes involving domain specialists are essential to ensure that user experience goals do not compromise clinical effectiveness. These studies reinforce the importance of traceability mechanisms that link clinical objectives to implemented game mechanics. In this context, the proposed framework incorporates a RTM to link implemented game mechanics to their corresponding requirements explicitly.

The literature also highlights the absence of standardized development methodologies for SGH systems, with many projects relying on empirical or experience-driven practices. To address this issue, [Souza et al. 2023] proposed CaSEJ (Health Canvas for Game Elaboration), a tool designed to facilitate collaborative brainstorming among multidisciplinary teams during the early design stages. In addition, [Carlier et al. 2023] proposed a framework focused on reusable design components, aiming to facilitate the transfer of domain knowledge across projects. Although these contributions represent important advances, they primarily focus on design support and knowledge reuse rather than on establishing structured engineering processes supported by formal maturity models.

To better position the proposed approach within the current literature, Table 1 summarizes key characteristics of representative studies in the development of Serious Games for Health. The comparison focuses on three aspects: the presence of structured Requirements Engineering (RE) practices, the use of process maturity models, and the main methodological focus of each work.

Tabela 1. Comparison of representative SGH development approaches.

Work	Domain	RE	CMMI	Main Focus
[Trindade et al. 2022]	ASD	Yes	No	Hardware and Software Requirements for interactive floors.
[Ravers et al. 2025]	Motricity	Yes	No	Alignment between clinical protocols and User Experience (UX).
[Souza et al. 2023]	General Health	Yes	No	Collaborative brainstorming via the CaSEJ Canvas.
[Carlier et al. 2023]	General Health	Yes	No	Design reusability and personalization modules.
[Robertson et al. 2021]	Behavior	Partial	No	Behaviour Change Wheel into game design.
[Barbosa et al. 2024]	ASD	No	No	Ad-hoc development focused on theoretical grounding (DiagnosTEA).
Proposed Framework	**General Health**	**Yes**	**Yes**	**Methodological rigor, quality, and repeatability.**

Most existing studies address specific aspects of SGH development, such as requirements elicitation, user experience alignment, or collaborative ideation. While studies such as [Trindade et al. 2022] and [Ravers et al. 2025] provide valuable insights into specific clinical domains, such as ASD and motor rehabilitation, their methodologies remain strongly tied to particular application contexts and are not easily transferable across different healthcare domains. Similarly, frameworks such as those proposed by [Carlier et al. 2023] and [Souza et al. 2023] emphasize design activities and collaborative ideation but do not incorporate formal maturity models to ensure process stability

and governance throughout the development lifecycle.

The proposed framework advances the state of the art by introducing structured engineering practices inspired by process maturity principles from the CMMI. Unlike previous approaches that rely primarily on empirical development, the framework establishes a systematic process that links technical implementations to clinical requirements through bidirectional traceability and auditable development artifacts.

3. Framework Design and Operational Structure

The framework proposed in this study aims to support the development of Serious Games for Health across different clinical contexts. It provides an adaptable methodological structure designed to guide multidisciplinary teams in the systematic engineering of SGH systems.

The framework follows an iterative, Clinic-User Centered (CUC) approach. This specialization moves beyond traditional User-Centered Design by elevating the Healthcare Professional to a 'Domain Authority' who co-designs the technical baseline alongside the IT specialist and the patients. Rather than a strict linear progression, the workflow allows for recursive cycles between elicitation and validation. While these steps align with traditional RE, this framework specializes the process by creating a bidirectional validation. Every requirement must pass a clinical safety gate (defined by the Healthcare Professional) and/or an engagement gate (defined by the End User), preventing games that are either clinically sound but boring or fun but clinically ineffective.

Accordingly, the proposed framework organizes SGH development around three interdependent pillars: People (multidisciplinary stakeholders involved in SGH development), Processes (the Requirements Engineering lifecycle), and Products (documentation artifacts that ensure robustness and traceability). The framework adopts a domain-independent definition of stakeholder roles. Each role emphasizes functional responsibilities rather than specific medical expertise, allowing the methodology to remain stable across diverse clinical scenarios. In this modular architecture, the roles remain constant, whereas the individuals who occupy them may vary by project context. The framework also generates a standardized set of documents to ensure procedural consistency and to institutionalize software quality aligned with process maturity principles at CMMI Level 3. These artifacts establish a documented baseline that supports multidisciplinary collaboration and traceability between clinical objectives and implemented game mechanics.

The framework operates through a decision core centered on stakeholders who orbit a continuous cycle of requirements refinement. As illustrated in Figure 1, this configuration ensures that no game mechanic is implemented without a clear, traceable clinical justification, thereby preventing unstructured development. The following sections describe the operational stages of the framework.

3.1. Stakeholder Roles

The stakeholder architecture is adaptive and modular, allowing the methodology to remain stable across various clinical scenarios. Each role operates within a clearly defined area of responsibility.

- **End User:** Provides feedback on usability, accessibility, and gameplay preferences to ensure engagement and playability. The framework promotes patients' ac-

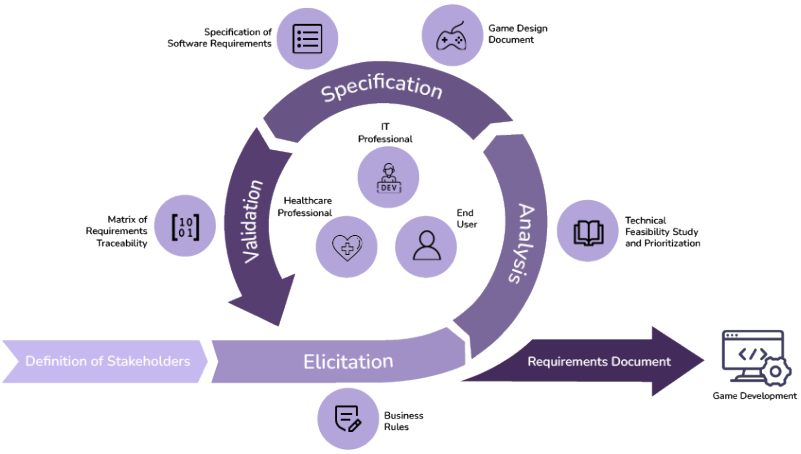

Figura 1. Operational Architecture of the proposed Requirements Engineering framework for SGH development.

tive participation in the requirements process to reduce gaps that may arise when requirements are mediated exclusively by clinical professionals.

- **Healthcare Professional:** Act as the domain authority, responsible for defining clinical objectives, business rules, and non-negotiable safety constraints associated with healthcare protocols.
- **IT Professional:** Responsible for the technical architecture of the system, including the definition of functional requirements, evaluation of technological feasibility, and implementation of game mechanics.

3.2. Requirements Engineering Processes

The framework organizes SGH development into a structured lifecycle comprising four iterative and incremental stages. It builds on the Requirements Engineering model proposed by [Wiegers and Beatty 2013] and adapts it to the multidisciplinary nature of SGH development. In particular, the framework adjusts stakeholder participation and documentation artifacts to integrate clinical rigor with game design and user engagement.

3.2.1. Phase 1: Elicitation

During the elicitation stage, sessions involving the Healthcare Professional and the End User focus on identifying both Business Requirements and Business Rules. Business Requirements define the high-level objectives and expected value of the system, while Business Rules represent non-negotiable clinical constraints derived from healthcare protocols.

The team typically conducts elicitation activities through structured interviews or focus groups. The Healthcare Professional contributes domain expertise in clinical protocols and clinical objectives, while the End User provides insights into usability, accessibility, and engagement. The resulting Business Rules establish the clinical foundation that guides both system behavior and gameplay design.

3.2.2. Phase 2: Analysis

The analysis phase evaluates the feasibility of the requirements collected during elicitation. In this stage, the IT Professional examines the identified requirements to determine

whether they are complete, consistent, and technically viable. A key activity in this phase is translating high-level clinical objectives into technical specifications through a Technical Feasibility Study and requirement prioritization. This process ensures that game mechanics can capture and process relevant health-related information without compromising system performance or patient safety.

Additionally, the development team may create low- or mid-fidelity prototypes to bridge the gap between abstract clinical requirements and concrete gameplay mechanics. These prototypes allow stakeholders to visualize interactions and evaluate potential design alternatives before full-scale implementation.

3.2.3. Phase 3: Specification

During the specification phase, the team formalizes the requirements into a documented development baseline. While traditional software projects typically rely on a Software Requirements Specification (SRS), the proposed framework integrates the SRS with a Serious Game Design Document (Serious-GDD), following the model described in [Vasconcellos and Carvalho 2023].

The team develops these two artifacts in parallel and maintains them in synchronization. The SRS defines the system architecture and technical functionalities that support implementations, whereas the Serious-GDD describes the narrative, mechanics, and aesthetic elements from a gameplay perspective. Bidirectional traceability between these artifacts ensures that each technical functionality has a corresponding gameplay or narrative rationale, thereby preserving the original clinical intent throughout the development process.

3.2.4. Phase 4: Validation

The validation phase confirms whether the implemented increment satisfies the established clinical and technical objectives. In SGH projects, validation requires the joint participation of the Healthcare Professional, the End User, and the IT Professional.

During this stage, the team defines and measures Key Performance Indicators (KPIs) to evaluate both clinical progress and system performance. These metrics allow stakeholders to determine whether the implemented mechanics achieve the intended clinical goals. The validation stage concludes with a formal approval process involving both clinical and technical stakeholders. If a requirement proves clinically valid but technically infeasible or insufficiently engaging, the workflow returns to the Elicitation or Analysis stages to refine the design while preserving clinical objectives.

3.3. Supporting Artifacts and Traceability

Documentation plays a central role in the framework by institutionalizing software quality and aligning development practices with CMMI process principles. The standardized artifacts generated throughout the process establish a stable documentation baseline that supports traceability, repeatability, and auditability. Each artifact emerges during a specific phase of the Requirements Engineering process and contributes to the overall technical and clinical baseline.

- **Stakeholder Profiles (Pre-Phase 1):** At the onset of the project, the framework defines a process to formalize the multidisciplinary triad and document responsibilities and authority levels of the IT Professional, Healthcare Professional, and End User. This artifact prevents responsibility gaps by ensuring that each member clearly understands which requirements they must validate throughout the iterative cycle.
- **Business Rules (Phase 1: Elicitation):** It translates the Healthcare Professional's domain knowledge into formal, logical sentences that define clinical goals and safety limits. Also, it incorporates the End User's input to identify preferred ludic elements and mechanical limitations. This dual focus establishes a clinical foundation while capturing user engagement and accessibility requirements from the outset.
- **Technical Feasibility Study and Prioritization (Phase 2: Analysis):** Generated during the analysis phase, the IT Professional uses this to define the project's real boundaries based on technological viability. It serves as a documentary contract, filtering clinical requirements to ensure that development focuses only on what is technically executable, thereby preventing scope creep.
- **Serious Game Design Document (Serious-GDD) and Software Requirements Specification (SRS) (Phase 3: Specification):** These artifacts work together to formalize the implementation guide. The SRS specifies the system's technical capabilities and functional requirements for the programming team. In contrast, the Serious-GDD describes how players interact with these elements from a gameplay perspective, including narrative, aesthetics, and mechanics.
- **Acceptance Criteria and KPIs (Phase 4: Validation):** Developed in conjunction with the Business Rules but verified in the validation phase, these metrics establish the minimum technical and clinical quality required for success. They translate subjective feedback into quantifiable data to demonstrate that the game meets its intended clinical goals.
- **Requirements Traceability Matrix (RTM) (Continuous):** The RTM is a bidirectional map connecting all four phases. It ensures that a documented clinical justification accompanies each implemented functionality and prevents the loss of requirements during technical translation. To complement the RTM, a system of unique identifiers (e.g., [REQ-01]) is implemented directly within the SRS and GDD. These tags allow developers to immediately identify the source and clinical rationale of a specific mechanic without switching contexts, facilitating automated traceability updates.

These documents aim to provide that each iteration of software development is not a fragmented effort, but a continuous, verifiable process. By linking the Business Rules (clinical logic) to the Serious-GDD/SRS (implementation) and finally to KPIs (validation), the framework creates a closed-loop system.

Because the RTM maps each requirement to a specific KPI, the development team can continuously develop and test the software throughout the iterative process. If a test fails during an iteration, the RTM enables a rapid diagnostic analysis to determine whether the failure lies in the technical specification, the ludic design, or in the original clinical rule itself requiring refinement. This iterative stability ensures that clinical rigor is never sacrificed for recreational objectives, as the team must return to the engineering phases to

update the baseline before any new implementation.

Consequently, integrating these artifacts aligns the framework with the CMMI Level 3 (Defined Process) principles. This maturity emerges through several key factors:

- **Process Institutionalization and Maturity:** The framework transforms SGH development from an individual, experience-driven activity of a developer into a standardized organizational process. By establishing reusable artifacts such as the SRS, Serious-GDD, and RTM, the methodology supports process consistency, organizational learning, and alignment with the CMMI Level 3 (Defined Process) principles.
- **Predictability:** The use of Technical Feasibility Studies and Prioritization ensures that outcomes are foreseeable, minimizing the risks typical of the healthcare sector.
- **Auditability:** By using artifacts like the SRS and RTM, the framework ensures that every line of code is traceable back to a clinical need, creating a transparent and auditable trail for health regulators.

By establishing this documentation baseline, the framework enables different development teams to produce consistent and clinically safe SGH systems. Consequently, the methodology becomes a reusable organizational asset rather than a project-specific practice.

The next section demonstrates the applicability of the proposed framework through a case study involving the development of a serious game designed for adults with ASD[1].

4. Case Study: Development of a Serious Game for Adults with ASD

This section presents the practical application of the proposed framework by developing a serious game for adults with ASD. The case study demonstrates how the development team applied each phase of the Requirements Engineering framework in practice, including stakeholder definition, artifact generation, traceability management, and iterative validation. Furthermore, it illustrates how transitioning from an empirical development approach to a structured engineering process helps preserve both technical consistency and clinical integrity throughout the software lifecycle.

During framework execution, each phase generated specific artifacts that supported the development process and ensured traceability between clinical objectives and gameplay mechanics. The following results illustrate how these artifacts emerged throughout the Requirements Engineering cycle.

1. **Stakeholder Profiles (Pre-Phase 1):** The project formally defined the multidisciplinary team composed of two adult with ASD acting as the End User, three healthcare professionals, and three IT professionals. This definition assigned responsibility for clinical validation, user engagement, and technical implementation from the beginning of the project.

[1]This study was approved by the Ethics Committee of the participating institution. The details of this approval can be found on the Brazil Platform (plataformabrasil.saude.gov.br) under the Certificate of Presentation for Ethical Review (CAAE) number 8442725.6.0000.5083, with approval opinion number 7.615.894.

2. **Business Rules (Phase 1: Elicitation):** Elicitation sessions conducted with healthcare professionals and End User generated several clinical guidelines, including immediate feedback on dialogue consequences and prohibition of high-frequency flashing visual stimuli to avoid sensory overload. These rules constitute the clinical foundation of the system and serve as the origin for subsequent technical and gameplay requirements.
3. **Technical Feasibility Study and Prioritization (Phase 2: Analysis):** During the analysis phase, IT professionals evaluated the clinical requirements against the technical capabilities of the development platform. One example involved the feasibility of implementing indicators representing social-emotional states during gameplay. This analysis established the project's technological boundaries and ensured that development focused on clinically meaningful and technically feasible objectives.
4. **SRS and Serious-GDD (Phase 3: Specification):** The Software Requirements Specification (SRS) and Serious Game Design Document (Serious-GDD) were developed in parallel to synchronize technical implementation and gameplay design. The SRS defined technical capabilities, such as granular volume control across different sound categories. At the same time, the Serious-GDD translated clinical needs into mechanics, such as a relationship thermometer that visualizes affinity toward NPCs.
5. **KPIs and Validation (Phase 4: Validation):** Quantitative indicators were defined to evaluate whether the implemented mechanics achieved the intended clinical objectives. For instance, a key validation metric required that players correctly interpret NPCs' intentions in at least 70% of interaction scenarios. These metrics enabled the team to evaluate the effectiveness of each development increment using real usage data.

As a result, the RTM functions as the primary artifact supporting continuous development and validation. By establishing bidirectional traceability between clinical requirements, software specifications, gameplay mechanics, and evaluation metrics, the RTM directly links each implemented feature to a corresponding clinical objective.

Table 2 illustrates how the RTM connects the ludic experience to clinical goals throughout the development lifecycle. Because each requirement is associated with a specific KPI, the development team can continuously evaluate the system across iterations. For instance, if the validation phase indicates that players do not reach the NPC interpretation accuracy threshold, the RTM allows the team to diagnose the source of the issue. The problem may originate in gameplay design documented in the Serious-GDD, implementation details specified in the SRS, or in the clinical rule defined during elicitation.

Tabela 2. Example of the RTM applied to the ASD Case Study.

ID	Clinical Necessity	Software/Game Design Requirement	Game Mechanic (Implementation)	Validation KPI
REQ-01	Difficulty interpreting social cues and emotional states.	System for representing NPC emotional states.	A visual "Social Thermometer" indicating NPC emotional disposition.	Accuracy rate in NPC intention interpretation greater than 70%.

This traceability mechanism allowed the development team to adjust gameplay without compromising the underlying clinical objectives. Consequently, the team preserved clinical rigor while introducing iterative improvements to enhance user engagement.

The systematic use of these artifacts aligns the development process with the CMMI Level 3 (Defined Process) standard. Instead of relying solely on individual developer expertise, the project followed a structured methodology supported by standardized documentation artifacts. By establishing this documentation baseline, the project addresses gaps in prior empirical development, such as those described in previous SGH projects. It demonstrates how the proposed framework can transform SGH development from an empirical activity into a structured, auditable engineering process.

5. Conclusion

The development of Serious Games for Health involves integrating entertainment design and clinical intervention, requiring a balance that traditional ad hoc development approaches often fail to achieve. This paper presented a Requirements Engineering framework designed to support the systematic development of SGH systems, transforming the process from an empirical activity into a structured, predictable, and auditable engineering workflow.

The proposed framework addresses several gaps identified in the development of SGH solutions. First, it promotes multidisciplinary alignment by institutionalizing the participation of three key stakeholders: IT professionals, healthcare professionals, and end users, so that development teams consider both technical and clinical perspectives throughout the process. Second, it strengthens clinical rigor and traceability by introducing a RTM that explicitly links clinical needs to gameplay mechanics and validation criteria. Finally, the framework advances process maturity by incorporating structured documentation aligned with CMMI Level 3 principles, thereby transforming the development process from an informal practice into a reusable, auditable organizational methodology.

The case study on developing a serious game for adults with ASD demonstrated the practical applicability of the framework. The structured use of Requirements Engineering phases and supporting artifacts enabled the systematic translation of clinical objectives into gameplay mechanics while maintaining traceability and iterative validation throughout the development lifecycle.

Future research may focus on two main directions. First, integrating the RTM into agile development environments could facilitate automated traceability management during iterative development cycles. Second, applying the framework to additional clinical domains, such as neurorehabilitation and physical therapy, may further evaluate its adaptability and scalability. Furthermore, future work may explore the adoption of quantitative process metrics aligned with higher CMMI maturity levels, enabling data-driven evaluation of development performance and continuous process improvement.

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