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Identifying and Explaining the Components Influencing Artificial Intelligence–Based Patient Relationship Management in Advanced Therapy Medicinal Products (ATMPs)

Mohammad Ali Farzamzadeh [1], Seyed Ahmad Ghasemi [2]*, Asghar Sharifi [3]

1. Department of Management, Ro.C., Islamic Azad University, Roudehen, Iran
2. Faculty Member, Research Institute for Humanities and Social Studies, Jihad Daneshgahi (ACECR), Tehran, Iran
3. Department of Educational Sciences, Ro.C., Islamic Azad University, Roudehen, Iran

*Correspondence: saghasemy@ut.ac.ir

Abstract

This study aimed to identify and explain the components influencing artificial intelligence (AI)-based patient relationship management in the field of Advanced Therapy Medicinal Products (ATMPs) and to develop an integrated conceptual structure appropriate to the specific characteristics of advanced therapies. This applied qualitative exploratory study used a deductive–inductive analytical approach. Initially, a targeted review of the literature was conducted to identify preliminary concepts related to AI capabilities, patient interaction and experience, organizational and infrastructural requirements, governance, and expected outcomes. These concepts informed the development of a semi-structured interview guide. Eleven experts with professional experience in ATMP-related clinical, technical, research and development, cell and gene therapy, quality assurance, management, commercialization, and data-related domains participated in the study. Interview data were analyzed through a deductive–inductive thematic process in which meaning units were coded and progressively organized into concepts, subcategories, and main categories. Analysis of the interviews resulted in ten main categories: AI capabilities across the patient journey; patient interaction and experience; trust and acceptance; governance, ethics, and accountability; infrastructure and organizational readiness; implementation barriers; expected outcomes and value; organizational transformation and digital maturity; model evaluation; and success and sustainability factors. AI capabilities included patient screening, monitoring, adverse-event identification, decision support, data management, and personalized communication. Trust was associated with usefulness, safety, transparency, explainability, and human oversight. Data quality, interoperability, organizational readiness, managerial support, privacy, security, accountability, and regulatory requirements emerged as essential implementation conditions. Expected outcomes included improved clinical performance, service quality, efficiency, patient experience, and continuity of care. AI-based patient relationship management in ATMPs should be understood as a multidimensional, patient-centered, and organizationally embedded system in which technological capabilities create value only when supported by reliable data, interoperable infrastructure, human oversight, organizational readiness, responsible governance, and continuous evaluation.

Keywords: Advanced Therapy Medicinal Products; Artificial Intelligence; ATMPs; Patient Relationship Management; Patient Experience; AI Governance; Digital Health; Organizational Readiness

1. Introduction

Artificial intelligence (AI) has become an increasingly influential component of contemporary health care, with applications extending from diagnostic support and disease prediction to treatment planning, patient monitoring, clinical decision support, resource allocation, and personalized medicine. The increasing availability of large-scale clinical datasets, electronic health records, genomic information, imaging data, and patient-generated health information has created new opportunities for AI-based systems to detect patterns that may not be readily identifiable through conventional analytical approaches. Machine learning, deep learning, natural language processing, and generative AI are therefore being incorporated into a wide range of clinical and organizational processes, creating the potential for health care systems to become more predictive, responsive, and patient-centered (Secinaro et al., 2021). However, the practical value of AI in health care cannot be assessed only through algorithmic accuracy or technical performance. Its contribution depends on whether AI can be meaningfully incorporated into real clinical pathways, organizational structures, professional workflows, patient interactions, and governance arrangements (Jacob et al., 2025; Rahimi et al., 2024).

One of the most important emerging applications of AI concerns the management of interactions and relationships between patients and health care organizations. Traditional approaches to patient relationship management have frequently emphasized the collection of patient information, appointment management, administrative communication, and documentation of encounters. In increasingly digital health systems, however, patient relationship management is becoming more continuous, data-driven, interactive, and individualized. AI can potentially support rapid access to information, personalized communication, prediction of patient needs, automated responses to routine questions, identification of patients requiring additional attention, monitoring of symptoms and outcomes, and coordination of services across multiple points of care. Evidence concerning AI and health service quality indicates that the technology may contribute to responsiveness, efficiency, personalization, and improved service delivery when appropriately designed and implemented (Alghareeb & Aljehani, 2025). Accordingly, AI-based patient relationship management can be conceptualized not simply as the automation of communication but as the intelligent organization of information, interaction, decision support, and continuity throughout the patient journey.

The rapid development of conversational AI and large language models has further expanded the possibilities for direct patient-facing applications. Large language models may support answering health-related questions, summarizing complex medical information, generating patient education materials, assisting clinical documentation, and tailoring information to individual informational needs (Busch et al., 2025). Similarly, AI-supported chatbots have demonstrated potential for medical history-taking, initial information collection, symptom-related communication, and continuous interaction with patients outside conventional face-to-face encounters (Hindelang et al., 2024). These technologies may improve access to information and reduce some routine communication burdens placed on health professionals, particularly when patients repeatedly seek clarification regarding treatment procedures, medications, symptoms, follow-up requirements, or expected outcomes. At the same time, the evaluation of health care chatbots remains methodologically heterogeneous, and their quality cannot be determined solely through response generation capacity. Their usefulness depends on safety, reliability, relevance, usability, transparency, and appropriateness for the clinical and patient context in which they are deployed (Hua et al., 2025).

The growing role of conversational systems also introduces significant concerns. Large language models may produce inaccurate, incomplete, fabricated, or misleading information while presenting responses in a highly persuasive form. Their performance may vary across populations, clinical topics, and contexts, and they may fail to recognize subtle clinical cues that would be meaningful to an experienced health professional (Wang et al., 2024). Consequently, patient-facing AI cannot be considered a simple substitute for professional communication. Instead, it requires appropriate boundaries, validation procedures, escalation mechanisms, and human supervision. The quality of interaction between clinicians and AI systems is itself an important implementation issue because poorly integrated systems may increase workload, disrupt decision-making, or reduce professional confidence rather than improving care (Perivolaris et al., 2024). These challenges illustrate that successful AI-based patient relationship management must preserve meaningful human involvement while using automation selectively to enhance responsiveness, information processing, and coordination.

The importance of these issues becomes even greater in the context of Advanced Therapy Medicinal Products (ATMPs). ATMPs include innovative therapeutic products based on genes, cells, and engineered tissues and have created new possibilities for treating severe, chronic, rare, and previously difficult-to-treat conditions. These therapies represent an important component of regenerative medicine and have substantial potential for restoring, replacing, or modifying biological functions (Goula et al., 2020). Nevertheless, their development and clinical application are characterized by substantial complexity. ATMPs often involve heterogeneous biological materials, highly specialized manufacturing processes, complex quality requirements, individualized or small-batch production, demanding transportation and storage conditions, and extensive preclinical, clinical, regulatory, and post-treatment monitoring requirements. These characteristics distinguish ATMPs from many conventional pharmaceutical products and create substantial challenges for coordinating clinical, manufacturing, regulatory, and patient-related processes.

The regulatory pathway for ATMP development is likewise complex and requires continuous coordination between research institutions, manufacturing organizations, clinical centers, and regulatory authorities. Academic and clinical developers may encounter difficulties associated with product characterization, manufacturing consistency, quality control, documentation, clinical evidence generation, risk assessment, and communication with regulatory bodies (Olesti et al., 2024). Such challenges may affect the speed of development, organizational burden, and ultimately patient access to innovative therapies. The patient pathway is similarly demanding because individuals receiving advanced therapies may require extensive assessment before treatment, precise scheduling and preparation, coordinated product manufacture and delivery, close monitoring during administration, post-treatment surveillance, and long-term follow-up. Patient relationship management in this environment therefore extends far beyond routine appointment or communication functions and requires continuous coordination of information among patients, clinicians, laboratories, manufacturing units, administrative teams, and other stakeholders.

AI offers potentially valuable capabilities for addressing some of these complexities. In regenerative medicine, AI is increasingly being examined for applications such as analysis of cellular and molecular data, prediction of biological behavior, optimization of cell culture conditions, biomaterial design, assessment of treatment responses, and analysis of complex multidimensional datasets (Abuarqoub & Mutahar, 2025). These capabilities suggest that AI may contribute not only to scientific development but also to patient-related processes in advanced therapies. Clinical, laboratory, genetic, behavioral, and longitudinal information could potentially be integrated to support patient identification, risk prediction, individualized communication, monitoring, and decision support. Nevertheless, transferring AI capability from experimental development to routine health care practice is challenging. Implementation requires reliable data, appropriate infrastructure, system integration, professional participation, organizational readiness, and clear governance mechanisms.

Data quality is especially important because AI performance depends fundamentally on the information used for training, validation, and operational decision support. Medical data may be incomplete, inconsistent, fragmented across multiple systems, collected using different standards, or affected by systematic biases. These limitations may reduce reliability and create clinically meaningful errors. The METRIC framework emphasizes the multidimensional nature of data quality for trustworthy medical AI, demonstrating that data suitability should be evaluated beyond simple completeness or volume (Schwabe et al., 2024). This issue is particularly relevant to ATMPs because the relevant patient information may include clinical histories, laboratory measurements, genetic information, manufacturing data, treatment records, adverse events, and long-term follow-up outcomes. Consequently, AI-based patient relationship management requires robust mechanisms for data quality assurance, standardization, integration, and traceability.

Interoperability and organizational integration are also central. Evidence from empirical studies of machine learning implementation in health care organizations indicates that successful adoption is influenced by technological infrastructure, workflow compatibility, organizational resources, user skills, leadership, implementation strategy, and local context (Preti et al., 2024). Similarly, implementation of AI in hospitals requires integration with existing information systems and clinical workflows, access to timely and appropriate data, staff training, multidisciplinary participation, and continuous evaluation (Rahimi et al., 2024). Frameworks developed for procurement, integration, monitoring, and evaluation of clinical AI tools further emphasize that implementation should be treated as a lifecycle process involving assessment before adoption, technical and clinical integration, ongoing monitoring, and periodic evaluation rather than as a one-time technology purchase (Khan et al., 2024). These findings suggest that the effectiveness of AI-based patient relationship management depends not only on the selected algorithm but also on the maturity of the organizational environment in which it is embedded.

Leadership is another essential determinant of organizational transformation through AI. Implementing AI frequently requires changes in professional roles, decision-making processes, data practices, organizational culture, and established workflows. Leadership can influence whether these changes are understood, resourced, coordinated, and accepted by employees. Effective leadership for AI transformation includes strategic direction, stakeholder engagement, workforce development, management of resistance, communication of expectations, and creation of organizational conditions supportive of innovation (Sriharan et al., 2024). In ATMP-related organizations, where clinical, technical, laboratory, production, quality, and managerial functions are closely interconnected, leadership support may be particularly important for ensuring that AI-based patient relationship management is integrated across organizational boundaries rather than implemented as an isolated digital application.

Human acceptance represents another critical dimension. Health professionals may recognize the potential usefulness of AI while remaining concerned about reliability, errors, loss of professional autonomy, unclear accountability, workflow disruption, and inadequate transparency. Trust in AI-based clinical decision-support systems among health care workers depends on factors such as perceived accuracy, reliability, transparency, usefulness, organizational support, and preservation of appropriate human control (Tun et al., 2025). Explainability can contribute to trust by helping clinicians understand the reasoning or information underlying an AI-generated output; however, explainability does not automatically increase confidence and may sometimes reveal limitations that reduce trust (Rosenbacke et al., 2024). Therefore, trustworthy AI requires more than merely presenting explanations. Explanations must be meaningful, contextually appropriate, and connected to validated system performance.

Patient trust is equally important. Patients may evaluate AI according to perceived usefulness, safety, privacy protection, transparency, fairness, and the extent to which human professionals remain involved in care. Reviews of trust factors in AI-health care integration demonstrate that trust is influenced by characteristics of the technology, the health organization, the professional relationship, and individual users (Mertz et al., 2025). Patient perspectives also indicate that attitudes toward AI are not uniformly positive or negative; rather, patients may appreciate increased efficiency and access while remaining concerned about reduced human contact, data privacy, accuracy, and the role of AI in sensitive decisions (Mundzic et al., 2025). These concerns are highly relevant to ATMPs because patients may face serious illnesses, uncertain outcomes, complex treatment information, and long-term follow-up requirements. An AI-based relationship management system must therefore strengthen rather than weaken informed, understandable, and supportive interaction.

Privacy, security, ethics, and governance consequently constitute fundamental requirements. Health AI operates on highly sensitive personal information, and the risks associated with unauthorized access, data leakage, reidentification, algorithmic bias, inappropriate secondary use of information, and insufficient security controls can undermine both patient safety and public trust. Secure and trusted AI requires technical safeguards alongside ethical and organizational mechanisms addressing privacy, fairness, transparency, accountability, and system robustness (Khan et al., 2025). AI governance frameworks similarly emphasize the need to define roles, responsibilities, oversight structures, risk-management procedures, lifecycle monitoring, accountability mechanisms, and ethical requirements for AI systems (Batool et al., 2025). Governance is therefore not an external requirement added after system development but a continuous layer that should shape design, implementation, deployment, monitoring, and revision.

International efforts to define trustworthy and deployable AI in health care reinforce these requirements. The FUTURE-AI consensus guideline emphasizes principles related to fairness, universality, traceability, usability, robustness, and explainability, underscoring that trustworthy health AI must perform reliably across its entire lifecycle and across the populations and settings in which it is used (Lekadir et al., 2025). Regulatory perspectives similarly show that medical AI is challenging traditional regulatory models because adaptive algorithms, changing datasets, lifecycle updates, and complex accountability relationships require approaches that extend beyond conventional premarket evaluation (Zhou & Gattinger, 2024). In ATMP settings, these governance and regulatory issues intersect with already demanding regulatory requirements for advanced therapies, making clear accountability, monitoring, documentation, and human intervention especially important.

A further challenge is how the real-world success of AI should be evaluated. Many AI systems have historically been assessed primarily through technical metrics such as discrimination, accuracy, or predictive performance. However, these indicators do not fully capture implementation quality, usability, clinical integration, patient experience, organizational consequences, fairness, sustainability, or long-term value. The AI for IMPACTS framework emphasizes the need to evaluate the broader and longer-term real-world effects of clinician-facing AI technologies (Jacob et al., 2025). This perspective is particularly relevant for patient relationship management because the ultimate value of an AI system may be reflected in continuity of communication, patient engagement, service coordination, trust, clinical outcomes, workflow efficiency, organizational learning, and equitable access rather than technical performance alone.

Taken together, existing studies provide substantial knowledge regarding AI capabilities, health service quality, conversational systems, clinical implementation, organizational readiness, trust, data quality, explainability, governance, security, regulation, and advanced therapies. Nevertheless, these dimensions have largely been investigated separately or in general health care contexts. The literature provides limited integrated understanding of how technological, human, organizational, infrastructural, ethical, governance, and outcome-related factors should be combined specifically for AI-based patient relationship management in ATMPs. This gap is important because the characteristics of advanced therapies—including personalized treatment pathways, sensitive genetic and clinical information, multiple organizational actors, complex production and care processes, regulatory intensity, and prolonged patient monitoring—make direct transfer of generic AI implementation frameworks potentially insufficient. A context-sensitive framework must therefore account simultaneously for intelligent technological capabilities, patient interaction and experience, professional and patient trust, data and system readiness, organizational conditions, responsible governance, implementation barriers, expected value, and mechanisms for continuous evaluation.

Accordingly, the aim of this study was to identify and explain the components influencing artificial intelligence–based patient relationship management in the field of Advanced Therapy Medicinal Products (ATMPs) and to develop an integrated, context-sensitive conceptual structure based on scientific evidence and expert perspectives.

2. Methods and Materials

This study employed an applied, qualitative, and exploratory research design to identify and explain the components influencing artificial intelligence (AI)-based patient relationship management in the context of Advanced Therapy Medicinal Products (ATMPs). A qualitative approach was considered appropriate because the phenomenon under investigation extends beyond a predetermined set of technological variables and encompasses interrelated technological capabilities, patient-related and human factors, organizational conditions, data and infrastructure requirements, ethical and governance considerations, implementation barriers, and expected clinical and organizational outcomes. This complexity is particularly pronounced in the ATMP context because advanced therapies are characterized by highly individualized treatment pathways, sensitive clinical and genetic information, continuous or long-term patient monitoring, the involvement of multiple clinical and organizational stakeholders, and stringent regulatory requirements. Accordingly, the study was designed to generate a context-sensitive understanding of the phenomenon rather than statistically test predefined relationships among variables. The methodological logic was deductive–inductive. In the deductive component, a targeted review of the relevant scientific literature was initially undertaken to identify concepts previously associated with AI in healthcare, patient relationship management, patient experience and digital interaction, organizational implementation of AI, data and technological requirements, responsible AI governance, and advanced therapies. These literature-derived concepts provided a sensitizing framework for the empirical stage of the study rather than a fixed coding structure. In the inductive component, the actual interview data were examined for concepts and relationships arising from experts' experiences and professional perspectives, thereby allowing the initial framework to be revised, expanded, integrated, or reorganized when warranted by the empirical evidence.

The qualitative participants consisted of 11 experts whose professional knowledge and experience were relevant to ATMPs and associated areas of development, production, clinical application, management, supervision, quality assurance, and commercialization. The selection of experts was intended to provide disciplinary and professional diversity because AI-based patient relationship management in ATMPs represents an inherently interdisciplinary phenomenon that cannot adequately be understood solely from a technological, managerial, or clinical perspective. The participating experts therefore represented different areas of expertise, including immunology and cellular biology, technical management, cell therapy, gene therapy, quality assurance, management and commercialization of advanced therapeutic products, and other professional roles related to the development and delivery of ATMPs. This diversity enabled the study to examine the proposed patient relationship management framework from technological, clinical, organizational, data-related, ethical, regulatory, and managerial perspectives. All 11 interviews constituted the empirical dataset used for qualitative analysis. Because the available study documentation did not contain a formally documented procedure for determining theoretical saturation, such as prospectively monitoring the emergence of new codes and terminating recruitment according to a predefined saturation criterion, theoretical saturation was not claimed. Instead, the adequacy of the qualitative dataset was assessed in terms of the richness of the interview content and the extent to which the interviews collectively covered the major dimensions of the research problem, including AI capabilities, patient interaction and experience, data requirements, organizational readiness, governance, implementation barriers, anticipated outcomes, evaluation criteria, and conditions for successful implementation.

The principal data collection instrument was a semi-structured interview guide developed on the basis of the initial concepts identified through the targeted review of the literature. The literature review addressed the intersection of AI in healthcare, AI-supported patient communication, patient experience, digital interaction, patient relationship management, AI applications in advanced therapies, organizational readiness, data quality and infrastructure, system integration and interoperability, AI ethics and governance, and the expected consequences of AI implementation. The concepts extracted from this review were initially organized into broad conceptual domains concerning technological capabilities, human interaction and patient experience, organization and infrastructure, governance and implementation requirements, and expected outcomes. The technological domain incorporated concepts such as intelligent data analysis, predictive analytics, service personalization, decision support, automation, and intelligent generation or delivery of information. The human and interactional domain included patient experience, digital interaction, patient engagement and empowerment, trust, technology acceptance, communication quality, and continuity of interaction. Organizational and infrastructural considerations included digital maturity, data quality, system integration, organizational culture, managerial support, organizational readiness, training, and change management. Governance-related concepts included transparency, explainability, information security, privacy, ethical considerations, informed consent, algorithmic fairness, accountability, regulatory compliance, and responsible AI governance. These concepts were not treated as definitive dimensions of the final model; rather, they functioned as sensitizing concepts that informed the development of the interview questions while leaving sufficient conceptual openness for participants to introduce new issues or reinterpret concepts derived from the literature.

The semi-structured format was selected to ensure consistency across interviews while retaining sufficient flexibility to explore participants' specialized knowledge and experiences in depth. The interviews addressed the capabilities and functions of AI in managing relationships with patients, the potential application of AI at different stages of the ATMP patient pathway, the quality of patient interaction and experience, responsiveness and continuity of communication, patient and professional trust and technology acceptance, transparency and explainability of AI-generated outputs, ethical requirements, privacy and informed consent, data ownership and control, algorithmic fairness, accountability and allocation of responsibility, data quality and information security, standardization and integration of information systems, interoperability and scalability, organizational and managerial readiness, and technical, human, organizational, ethical, operational, and regulatory barriers to implementation. The discussions also explored the potential clinical, service-related, process-related, organizational, and patient-centered outcomes of AI-based relationship management; its potential contribution to digital maturity and organizational transformation; indicators through which the success of the proposed approach could be evaluated; and the conditions necessary for the successful design, implementation, monitoring, and long-term continuation of such systems. Particular attention was given to the distinctive characteristics of ATMPs, including personalized and multistage treatment pathways, the sensitivity of clinical and genetic data, long-term patient follow-up, coordination among multiple stakeholders, and regulatory complexity. Because the interviews were semi-structured rather than standardized, participants were able to elaborate on issues beyond the preliminary framework, introduce concepts not explicitly represented in the literature-derived domains, clarify relationships among concepts, and identify ATMP-specific requirements that might otherwise have been overlooked.

The interview data were analyzed using a deductive–inductive thematic analysis procedure. The analysis began with systematic examination of the actual interview texts and identification of meaning units relevant to the central research question. Each relevant segment was examined in its original context, and an initial code was assigned as closely as possible to the meaning expressed by the participant. Similar or conceptually related initial codes were subsequently compared and consolidated into more abstract concepts. Related concepts were then organized into subcategories, and conceptually coherent subcategories were integrated into broader main categories. This progressive analytical movement from raw interview material to meaning units, initial codes, concepts, subcategories, and main categories was used to maintain a transparent connection between the empirical data and the higher-order interpretation of the findings. At the final stage of the analysis, the main categories were compared with one another and their conceptual relationships were examined to construct an integrated interpretation of AI-based patient relationship management in the ATMP context.

The deductive and inductive components were integrated throughout the analytical process rather than conducted as completely separate stages. Concepts derived from the literature were used as an initial interpretive reference, but interview data were not forced into these predetermined categories. When empirical data supported a literature-derived concept, that concept was retained; when interview evidence suggested that a concept required greater specificity or a different conceptual boundary, it was modified or expanded; when several concepts reflected substantially overlapping meanings, they were integrated; and when participants introduced substantively relevant issues that were not adequately represented in the preliminary framework, new concepts and categories were incorporated into the developing analytical structure. This procedure allowed the analysis to benefit from the accumulated theoretical and empirical literature while preserving sensitivity to the contextual knowledge of experts working with advanced therapies. Particular care was taken to distinguish among the participants' empirical statements, the codes and categories generated during analysis, and the researchers' higher-order conceptual interpretation. Thus, the final conceptual structure was understood as an analytical synthesis grounded in expert interview data and informed by the literature, rather than as a set of statistically established or causal relationships.

To strengthen the methodological rigor and traceability of the qualitative analysis, a sequential analytical chain was maintained from the original interview material through meaning units, initial codes, concepts, subcategories, main categories, and finally the analysis of relationships among categories. The adequacy of the resulting structure was evaluated through repeated comparison of categories with the interview content and examination of whether the principal areas of the research problem were represented across the dataset. The analysis demonstrated recurrent coverage of issues such as intelligent and predictive AI capabilities, patient interaction and experience, trust and human oversight, data quality and system integration, organizational readiness, privacy and information security, responsible governance, implementation barriers, expected value, model evaluation, and conditions for successful implementation. Consequently, the final conceptual model was developed through the integration of evidence from the targeted literature review and the empirical perspectives of the 11 experts. Given the qualitative and exploratory nature of the study, the identified relationships among categories were interpreted as conceptual relationships emerging from qualitative analysis and were not presented as statistically verified associations or causal pathways.

3. Findings and Results

The qualitative findings were derived from the analysis of 11 semi-structured interviews with experts possessing relevant knowledge and professional experience in Advanced Therapy Medicinal Products (ATMPs) and associated clinical, technical, organizational, and managerial domains. The participants represented heterogeneous professional backgrounds, which was particularly important given the multidisciplinary nature of AI-based patient relationship management in advanced therapies. Their expertise collectively covered the areas of cell, gene, and tissue-based therapies; clinical medicine and treatment-related activities; technical responsibility and technical affairs associated with cellular products; research and development, including gene therapy; production of cellular and advanced therapeutic products; organizational management; management and commercialization of advanced therapeutic products; marketing; information technology and data; and executive experience in organizations and centers involved in ATMP development and delivery. The participant group included, among others, a general practitioner with 23 years of relevant professional experience, professionals responsible for technical affairs related to cellular products, an expert in nanobiotechnology with research and development experience in gene therapy, and managers with experience in the management and commercialization of advanced therapeutic products. Consequently, the findings were not derived from the perspective of a single professional discipline but reflected a combination of clinical, scientific, technological, technical, organizational, commercial, and operational viewpoints. This diversity enabled the phenomenon of AI-based patient relationship management to be examined not merely as an information technology application but as a multidisciplinary system operating within the complex clinical and organizational environment of ATMPs.

Analysis of the interview material proceeded from meaningful units and initial codes toward increasingly abstract concepts, subcategories, and main categories. Expressions closely reflecting the participants' original terminology, including patient identification, monitoring during treatment, recording and evaluation of adverse events, personalization of communication, classification and registration of information, data management, physician decision support, data security, human supervision, resistance to change, data quality, senior management commitment, and continuous monitoring, were initially retained as closely as possible to the interview data. Related codes were subsequently integrated into higher-level concepts and subcategories. Through this analytical process, ten main categories were identified: AI capabilities and functions across the patient journey; patient interaction and experience; trust and acceptance; governance, ethics, and accountability; infrastructure and organizational readiness; implementation barriers and challenges; expected outcomes and value; organizational transformation and digital maturity; model evaluation indicators; and factors contributing to the success and sustainability of the model. Table 1 presents an integrated overview of these main categories and their central dimensions.

Table 1. Main Categories and Core Dimensions of AI-Based Patient Relationship Management in ATMPs

Main category	Core dimensions identified in the interviews	Central meaning within the proposed model
AI capabilities and functions across the patient journey	Patient screening and selection; patient monitoring and follow-up; identification and recording of adverse events; decision support; personalization of communication and care; data management and analysis	Application of AI throughout the ATMP patient journey to identify needs, monitor patients, support clinical decisions, and provide individualized communication and services
Patient interaction and experience	Responsiveness; information provision; service coordination; continuity of communication; patient participation; management of patient touchpoints	Improvement of the quality, continuity, accessibility, and coordination of interactions between patients and the treatment organization
Trust and acceptance	Perceived usefulness; perceived safety; ease of use; personalization; transparency; explainability; human oversight	Establishment of conditions under which patients and professionals can regard AI as useful, understandable, safe, and sufficiently trustworthy for practical use
Governance, ethics, and accountability	Privacy; data security; informed consent; explainability; algorithmic fairness; accountability; determination of responsibility; human oversight; data ownership and control	Ensuring that AI is implemented responsibly, transparently, safely, and with clearly defined human and organizational responsibilities
Infrastructure and organizational readiness	Data quality; standardization; system integration; interoperability; scalability; information technology infrastructure; organizational readiness; staff preparation	Provision of the technical, data, and organizational foundations required for sustainable implementation
Implementation barriers and challenges	Poor data quality; fragmented data; isolated systems; integration difficulties; organizational resistance; insufficient AI skills; ethical challenges; regulatory challenges; ambiguity of responsibility	Factors capable of limiting, delaying, or preventing successful implementation of AI-based patient relationship management
Expected outcomes and value	Improved clinical performance; higher service quality; increased process efficiency; better patient experience; improved treatment outcomes; reduced costs; greater speed and accuracy	Potential patient-level, clinical, process, and organizational benefits resulting from appropriate implementation
Organizational transformation and digital maturity	Data-driven decision-making; data culture; process redesign; interdepartmental collaboration; management dashboards; predictability; technology governance	Transformation of the organization from a predominantly reactive structure toward a data-driven, predictive, coordinated, and patient-centered organization
Model evaluation	Safety; effectiveness; patient experience; acceptance; usability; trustworthiness; fairness; economic value	Multidimensional criteria through which implementation and performance of the model should be evaluated
Success and sustainability factors	AI literacy; continuous training; user support; user readiness; stakeholder participation; data quality and integration; senior management support; continuous monitoring; validation; user-centered design; integration with existing systems	Conditions required not only for initial implementation but also for sustained, safe, and effective operation of the model over time

As shown in Table 1, the findings indicate that AI-based patient relationship management in ATMPs is a multidimensional socio-technical and organizational phenomenon rather than a stand-alone technological intervention. The categories identified through the interviews demonstrate a sequential and interdependent logic. AI capabilities provide the technological functions needed to identify, monitor, communicate with, and support patients, but their value depends on their integration with the actual patient journey. Patient interaction and experience constitute the interface through which these capabilities become meaningful to patients, while trust and acceptance determine whether the technology can be incorporated into routine interactions. At the same time, governance, ethical safeguards, data protection, accountability, infrastructure, interoperability, and organizational readiness constitute foundational conditions for implementation. The interviews further demonstrated that these enabling factors coexist with technical, organizational, human, ethical, and regulatory barriers that may restrict successful adoption. The potential value of the model was identified at clinical, patient, service, and organizational levels; however, participants did not regard these benefits as automatic consequences of introducing AI. Instead, expected outcomes were understood as dependent on appropriate design, organizational preparation, governance, human supervision, and continuous evaluation. The final three categories further extend the model beyond initial implementation by demonstrating that AI-based patient relationship management may contribute to broader organizational digital transformation, requires multidimensional evaluation, and depends on a set of sustainability conditions such as training, stakeholder participation, management commitment, validation, integration, and continuous monitoring.

The first group of findings concerned the direct technological and human-facing components of the model. Experts consistently described AI as potentially relevant throughout the ATMP patient journey rather than only at an isolated communication point. Its proposed applications extended from identifying eligible patients to monitoring patients during treatment, recording adverse events and outcomes, supporting professional decision-making, managing large volumes of patient information, and personalizing communication and care. The interviews simultaneously demonstrated that these technological functions acquire practical value only when translated into improved interaction, responsiveness, and coordination. Trust and acceptance consequently emerged as a distinct but closely connected dimension, while governance and accountability were identified as necessary safeguards surrounding the entire process. These four interconnected categories are presented in greater detail in Table 2.

Table 2. Technological, Interactional, Trust, and Governance Components of AI-Based Patient Relationship Management

Main category	Subcategory/dimension	Components identified from the qualitative analysis	Interpretation within the ATMP patient journey
AI capabilities and functions	Patient screening and selection	Identification of eligible patients; analysis of patient information; use of clinical, laboratory, and genetic information; patient classification	AI can facilitate identification and initial screening of patients whose characteristics may correspond to treatment requirements
AI capabilities and functions	Patient monitoring and follow-up	Monitoring patient status; recording symptoms; monitoring during treatment; recording and evaluating adverse events; reviewing outcomes; post-treatment follow-up	AI can support longitudinal monitoring across treatment and follow-up stages and assist in identifying situations requiring attention
AI capabilities and functions	Decision support	Physician decision support; provision of relevant and up-to-date scientific evidence; organization of information for professional review	AI functions primarily as an augmentative decision-support mechanism rather than a replacement for professional judgment
AI capabilities and functions	Personalization	Personalization of communication; individualized information; personalized education; adaptation of care and communication to patient condition and treatment stage	AI enables movement from uniform communication toward patient-specific communication and support
AI capabilities and functions	Data management and analysis	Classification and registration of information; management of large data volumes; organization of patient information; intelligent analysis	AI may improve the ability of organizations to handle complex and extensive clinical and patient-related information
Patient interaction and experience	Rapid and continuous responsiveness	Responses to recurrent questions; faster access to information; timely communication; continuous availability of appropriate information	AI can reduce delays in access to routine information and complement the limited time available to clinical staff
Patient interaction and experience	Information management	Organization and retrieval of patient information; improved accessibility and quality of information	Better organization of information can improve the quality and consistency of patient communication
Patient interaction and experience	Coordination of patient and treatment team	Coordination of services; connection between patient and treatment team; coordination among organizational units; management of patient touchpoints	AI can serve as an informational and coordination layer across a complex, multistage ATMP pathway
Patient interaction and experience	Continuity and participation	Continuous communication; patient engagement; support across treatment stages; management of repeated points of contact	Patient relationship management extends beyond isolated messages to continuous management of the patient's relationship with the organization
Trust and acceptance	Perceived usefulness	Practical usefulness for patients and the treatment team; meaningful assistance; contribution to information and care	Greater perceived practical benefit can increase willingness to use AI-based services
Trust and acceptance	Perceived safety	Reduction of risk; reliable operation; appropriate safeguards; avoidance of harmful or misleading outputs	Safety is a prerequisite for confidence in AI in clinically sensitive ATMP environments
Trust and acceptance	Ease of use	Simplicity of interaction; accessibility; user-friendliness	Systems perceived as difficult or burdensome are less likely to be incorporated into routine use
Trust and acceptance	Transparency and explainability	Patient awareness that AI is being used; clarification of AI's role; ability to explain outputs or decisions	Patients should understand when and how AI participates in communication and decision-support processes
Trust and acceptance	Human oversight	Presence of a qualified professional; professional verification of AI recommendations; possibility of contacting a human expert	Human supervision reduces concerns and maintains professional responsibility in sensitive decisions

Governance, ethics, and accountability	Privacy	Protection of clinical, personal, and genetic information; confidentiality	Particularly sensitive genetic and clinical information associated with ATMPs requires strong privacy safeguards
Governance, ethics, and accountability	Data security	Secure storage and transmission; access control; protection from unauthorized disclosure	Security mechanisms are essential to maintain confidentiality and confidence in the system
Governance, ethics, and accountability	Informed consent	Patient awareness of AI use; information about data use; consent concerning use of technology and personal information	AI use should occur within an informed and transparent patient relationship
Governance, ethics, and accountability	Algorithmic fairness	Monitoring of bias; assessment of discriminatory performance; equitable application	Performance should be examined across different groups to reduce inequitable outcomes
Governance, ethics, and accountability	Accountability	Identification of responsibility when errors occur; documentation of events; error-reporting pathways; corrective mechanisms	Responsibility should not become ambiguous merely because an automated system contributes to an action or recommendation
Governance, ethics, and accountability	Data ownership and control	Clarity concerning control, access, and use of patient data	Governance should define who may access data and for what purposes
Governance, ethics, and accountability	Human responsibility	Preservation of specialist responsibility; human intervention in sensitive situations; periodic oversight	AI should support rather than displace human professional responsibility

Table 2 demonstrates that technological functionality, patient interaction, trust, and governance were strongly interrelated in the participants' accounts. Regarding AI capabilities, experts did not restrict the technology to automated messaging or chatbot-based communication. Instead, they described applications across the complete patient pathway, including identification of eligible patients, analysis of clinical and genetic information, monitoring during treatment, registration of symptoms and adverse events, assessment of treatment results, long-term follow-up, provision of scientific evidence for professionals, and personalization of communication and care. This led to a broader interpretation of patient relationship management as intelligent management of the patient journey. The interactional findings similarly indicate that AI may contribute to rapid responses to common questions, improved access to information, organization of high-volume patient data, coordination among patients and treatment teams, and continuity of communication across multiple treatment stages. However, improved interaction was not considered to result solely from technical availability. Trust was repeatedly associated with usefulness, safety, simplicity, transparency, and the preservation of human supervision. Participants emphasized that patients should know when they are interacting with AI, understand its role, and retain access to an appropriate human professional. Governance therefore emerged as a cross-cutting requirement rather than a peripheral administrative consideration. Privacy and security were particularly important because ATMP pathways may involve highly sensitive clinical and genetic information. Informed consent, transparency, explainability, algorithmic fairness, responsibility for errors, control over data, and human oversight were consequently identified as integral elements of responsible implementation. Overall, the findings in Table 2 indicate that AI can enhance patient relationship management only when technological capability is embedded within understandable, patient-centered interaction and surrounded by sufficient ethical, governance, and human safeguards.

A second group of findings concerned the conditions that determine whether these capabilities can actually be implemented in organizational practice. Experts repeatedly emphasized that the effectiveness of AI depends fundamentally on the quality and integration of data, technological infrastructure, system interoperability, organizational readiness, staff preparation, and managerial support. The same factors appeared in inverse form as barriers when they were absent or inadequate. In addition to these enabling and constraining conditions, the participants identified a range of potential clinical, service, patient, and organizational outcomes. Table 3 therefore integrates the categories of infrastructure and organizational readiness, implementation barriers, and expected outcomes.

Table 3. Infrastructure, Implementation Barriers, and Expected Outcomes of the Proposed Model

Main category	Dimension	Components identified in the interviews	Implication for implementation
Infrastructure and organizational readiness	Data quality	Accuracy; completeness; consistency; reliability of data	Incomplete, inaccurate, or inconsistent data may directly compromise AI outputs and patient-related decisions
Infrastructure and organizational readiness	Data security	Protection of clinical and genetic data; secure information handling	Sensitive ATMP-related information requires a secure infrastructure throughout the data lifecycle

Infrastructure and organizational readiness	Standardization	Standardized data structures; standardized operational and communication processes	Standardization facilitates consistent data use, system integration, and reproducible organizational processes
Infrastructure and organizational readiness	System integration	Connection between hospital, laboratory, clinical, patient-management, and other organizational systems	Patient relationship management should not operate as an isolated information system
Infrastructure and organizational readiness	Interoperability	Exchange of relevant information among different systems and organizational actors	Interoperability enables an integrated representation of the patient journey across multiple stakeholders
Infrastructure and organizational readiness	Scalability	Capacity to accommodate increasing numbers of patients, services, and therapeutic products	The system should remain functional as ATMP activity and patient volumes increase
Infrastructure and organizational readiness	IT and AI infrastructure	Appropriate technological resources for AI implementation and maintenance	Sufficient technological capacity is required to operationalize AI functions reliably
Infrastructure and organizational readiness	Organizational readiness	Staff readiness; organizational culture; preparedness for technological change	Implementation requires organizational and human preparation, not merely procurement of technology
Infrastructure and organizational readiness	Training	Education and preparation of employees and users	AI literacy and practical competence facilitate appropriate use and reduce resistance
Infrastructure and organizational readiness	Management support	Commitment and support of senior management; resource allocation; leadership	Organizational adoption is more sustainable when AI implementation is supported at the leadership level
Implementation barriers	Technical and data-related barriers	Poor data quality; fragmented data; isolated information systems; difficulties with integration	Weak data foundations may prevent AI from generating reliable or actionable outputs
Implementation barriers	Model and technology barriers	Limited explainability of some models; technological complexity	Lack of explainability can reduce trust and complicate use in clinically sensitive settings
Implementation barriers	Organizational barriers	Resistance to change; inadequate organizational readiness; incompatibility with existing processes	Organizational resistance can prevent incorporation of AI into routine workflows
Implementation barriers	Human barriers	Lack of AI knowledge and skills; insufficient user readiness; alert fatigue	Human factors can reduce adoption and may introduce additional operational burdens
Implementation barriers	Ethical and legal barriers	Privacy concerns; algorithmic bias; uncertainty regarding responsibility for errors	Ethical and legal ambiguity can undermine both adoption and responsible operation
Implementation barriers	Security barriers	Risks associated with disclosure or misuse of sensitive information	Security weaknesses are particularly consequential where genetic information is involved
Implementation barriers	Regulatory barriers	Regulatory uncertainty; unclear requirements for algorithmic systems; uncertainty about responsibility	Complex and evolving regulation may delay implementation or restrict the scope of use
Expected outcomes	Clinical performance	More accurate decision-making; earlier identification of risks; reduced errors; improved monitoring	Appropriate AI use may strengthen the clinical information available during the patient pathway
Expected outcomes	Service quality	Faster responsiveness; improved coordination; personalization; continuity of communication	Patient-facing services may become more timely, coordinated, and individualized
Expected outcomes	Process efficiency	Reduced time; potential cost reduction; automation of selected activities; management of high data volumes	AI may reduce repetitive workload and support more efficient information processing
Expected outcomes	Patient experience	Reduced uncertainty; improved access to information; greater participation; increased trust	Patient-centered AI may improve understanding, involvement, and continuity of support
Expected outcomes	Treatment outcomes	Improved follow-up; reduced adverse consequences; better identification of emerging problems; potential improvement in real-world outcomes	Clinical value is expected to depend on improved monitoring, communication, and timely action

As indicated in Table 3, infrastructure and organizational readiness constitute fundamental prerequisites rather than secondary implementation considerations. Data quality was one of the most prominent issues in the interviews because inaccurate, incomplete, inconsistent, or fragmented information may directly degrade AI performance. This concern becomes particularly consequential in ATMPs, where decisions can involve complex clinical, laboratory, genetic, production, and follow-up information. Experts therefore emphasized not only data quality but also standardization, integration, and interoperability. An AI-based patient relationship management system was not envisioned as a separate technological island; rather, it should be capable of exchanging relevant information with hospital, laboratory, treatment, and other organizational systems so that different stages of the patient pathway can be connected. Scalability was likewise identified as important because systems need to accommodate growth in the number of patients, products, and associated data. Organizational readiness extended these technical requirements into the human and managerial domains through staff preparation, training, organizational culture, and senior management support. The identified barriers represent the converse of these enabling conditions. Poor-quality and fragmented data, isolated systems, difficulties with integration, limited explainability, resistance to change, insufficient AI knowledge, lack of organizational readiness, privacy concerns, algorithmic bias, unclear responsibility, and regulatory uncertainty can substantially constrain implementation. Importantly, participants did not treat the expected benefits of AI as inevitable. Potential improvements in clinical performance, service quality, efficiency, patient experience, and treatment outcomes were considered conditional on adequate data, infrastructure, governance, human competence, and organizational support. When these conditions are met, AI may contribute to earlier risk identification, improved monitoring, more accurate decision support, faster communication, better coordination, personalization, continuity of interaction, more efficient processing of large data volumes, stronger patient engagement, and improved follow-up.

The final group of findings extended beyond implementation itself to the broader organizational consequences, evaluation requirements, and sustainability conditions of the model. Participants described AI as potentially contributing to a transition from reactive and experience-dominated organizational practices toward more data-driven, predictive, standardized, coordinated, and patient-centered modes of operation. At the same time, they emphasized that implementation should be assessed through a broad set of indicators rather than exclusively through technical accuracy, speed, or cost. Safety and clinical effectiveness were particularly prominent, alongside patient experience, acceptance, usability, trust, fairness, and economic value. Finally, a comprehensive set of factors was identified as necessary for long-term success and sustainability. These findings are presented in Table 4.

Table 4. Organizational Transformation, Model Evaluation, and Success and Sustainability Factors

Main category	Dimension	Components/indicators identified in the interviews	Significance for the proposed model
Organizational transformation and digital maturity	Data-driven decision-making	Movement from predominantly experience-based toward evidence- and data-informed decision-making	AI may strengthen systematic use of organizational and patient data in managerial and clinical processes
Organizational transformation and digital maturity	Data culture	Development of a culture in which data are routinely used for monitoring, learning, and improvement	Sustainable AI requires organizational norms supportive of data use
Organizational transformation and digital maturity	Process redesign	Redesign of patient-centered processes; standardization of patient relationship processes	AI implementation may require modification of existing workflows rather than simple addition of a new tool
Organizational transformation and digital maturity	Interdepartmental collaboration	Greater coordination and collaboration among clinical, technical, managerial, laboratory, and other units	Integrated patient management depends on cross-functional collaboration
Organizational transformation and digital maturity	Management capabilities	Development of management dashboards and structured information for organizational monitoring	AI-supported information may improve managerial visibility across the patient pathway
Organizational transformation and digital maturity	Predictive capability	Increased ability of the organization to anticipate needs, risks, and operational requirements	The organization may shift from reactive management toward more predictive activity
Organizational transformation and digital maturity	Technology governance	Establishment of governance structures for intelligent technologies	Digital maturity includes organizational mechanisms for responsible oversight of AI
Model evaluation	Safety	Errors; adverse events; inappropriate or false alerts; safety-related incidents	Safety should be treated as a primary criterion of model performance
Model evaluation	Effectiveness	Clinical outcomes; effectiveness of monitoring and decision support	Technical performance should ultimately translate into meaningful clinical benefit
Model evaluation	Patient experience	Satisfaction; experience; participation; continuity and quality of interaction	Evaluation should capture the patient's experience rather than focus exclusively on system performance
Model evaluation	Acceptance	Degree of actual use; willingness of patients and professionals to use the system	A technically effective system has limited value if users do not adopt it
Model evaluation	Usability	Ease of use; simplicity of interaction; compatibility with user needs	Usability affects sustained engagement and operational integration
Model evaluation	Trustworthiness	Trust; reliability; explainability; confidence in system outputs	Trustworthiness is essential for use in high-sensitivity clinical environments
Model evaluation	Fairness	Differences in system performance across patient groups; potential bias	Performance should be equitable and monitored for discriminatory outcomes

Model evaluation	Economic value	Time; cost; return on investment	Economic indicators are relevant but should not supersede safety and clinical value
Success and sustainability	AI literacy	Knowledge and understanding of AI among users	Users require sufficient knowledge to interpret and appropriately use AI-supported functions
Success and sustainability	Continuous training	Ongoing education rather than one-time instruction	Competence must evolve alongside technologies, workflows, and regulatory requirements
Success and sustainability	User support	Accessible technical and operational support	Continued assistance facilitates sustained use and resolution of implementation problems
Success and sustainability	User readiness	Readiness of patients, professionals, and organizational employees	Adoption requires psychological, practical, and organizational preparedness
Success and sustainability	Stakeholder participation	Participation of relevant clinical, managerial, technical, and patient-related stakeholders	Involvement of users and stakeholders improves contextual fit and acceptance
Success and sustainability	Data quality and integration	Reliable data; integrated data flows; interoperability with existing systems	Sustained performance requires continued access to high-quality and connected data
Success and sustainability	Senior management support	Leadership commitment; organizational support; appropriate resource allocation	Leadership support maintains implementation as an organizational priority
Success and sustainability	Data security	Continuous protection of sensitive information	Security must be maintained throughout system operation rather than addressed only at implementation
Success and sustainability	Validation and continuous monitoring	Ongoing validation; performance monitoring; monitoring of errors and adverse consequences	AI performance should be assessed throughout its operational lifecycle
Success and sustainability	Human oversight	Professional supervision; capacity for human intervention	Human responsibility should remain active throughout system operation
Success and sustainability	User-centered design	Design based on patient and professional needs	Systems should fit the actual needs and capabilities of intended users
Success and sustainability	Integration with existing systems	Technical and workflow integration	Separate or disconnected AI applications are unlikely to create sustainable organizational value
Success and sustainability	Standard operating procedures	Development of clear SOPs, defined processes, responsibilities, and escalation pathways	Formalized processes support consistent and accountable implementation
Success and sustainability	Continuous improvement	Capacity to update, improve, and revise the system	Sustainability requires adaptation as evidence, technology, workflows, and regulatory expectations change

Table 4 shows that the implications of AI-based patient relationship management extend beyond operational automation to organizational transformation and digital maturity. Participants described a potential movement from experience-based and reactive management toward data-driven and predictive decision-making, stronger data culture, redesigned patient-centered processes, enhanced interdepartmental collaboration, development of management dashboards, greater predictability, and formal governance of intelligent technologies. These findings indicate that adoption of AI may require changes in organizational structures and workflows rather than simply installation of a technological application. Evaluation of the model was correspondingly described as multidimensional. Experts proposed safety, clinical effectiveness, patient experience, acceptance, usability, trustworthiness, fairness, and economic value as important assessment domains. Importantly, the qualitative findings suggest a hierarchy of priorities in which safety and clinical outcomes should precede purely economic indicators. Participants specifically emphasized safety, clinical outcomes, patient experience, reliability, trust, acceptance, and completion of follow-up as important indicators, indicating that faster service or reduced cost alone cannot establish the success of the model in the ATMP environment. The identified success and sustainability factors further reinforce this interpretation. AI literacy, continuous education, user support, patient and employee readiness, stakeholder participation, high-quality and integrated data, senior management commitment, information security, continuous validation, human oversight, user-centered design, integration with existing systems, clearly defined standard operating procedures, and continuous system improvement were all identified as necessary conditions. Thus, sustainable implementation was conceptualized as an ongoing organizational capability rather than a one-time technology project.

Taken together, the findings support an integrated conceptual understanding of AI-based patient relationship management in ATMPs. The distinctive characteristics of advanced therapies—including personalized treatment pathways, complex and multistage care processes, sensitive clinical and genetic information, involvement of multiple stakeholders, and the need for prolonged monitoring and follow-up—constitute the contextual foundation of the model. Within this environment, reliable data, interoperable infrastructure, organizational readiness, appropriate technological capacity, trained personnel, and management support provide enabling conditions. AI capabilities can then support patient identification, monitoring, adverse-event detection, decision support, data management, and personalized communication. These capabilities connect with patient-level value through responsiveness, information provision, continuity of interaction, coordination, participation, and management of patient touchpoints. Trust and acceptance influence whether these capabilities are meaningfully used, while governance, privacy, security, informed consent, fairness, accountability, explainability, and human oversight operate across the entire system as safeguards for responsible implementation.

The findings additionally demonstrate that the proposed model should not be interpreted as replacing healthcare professionals or transferring clinical responsibility to an algorithm. Across the interview material, AI was primarily positioned as a supportive capability that can augment professional expertise, improve information management, and strengthen patient coordination while maintaining meaningful human involvement. This point is especially important in ATMPs because treatment decisions and post-treatment monitoring may involve substantial uncertainty, serious clinical consequences, and highly sensitive information. Human oversight therefore performs multiple functions within the emerging model: it contributes to patient trust, supports validation of AI-generated information, provides a mechanism for intervention when automated processes are inadequate, and preserves clear professional responsibility.

Another central finding concerns the movement from isolated communication technology toward intelligent management of the entire patient journey. The experts' accounts indicate that patient relationship management in ATMPs cannot be reduced to chatbots, portals, messaging applications, or automated responses. Although these tools may constitute individual points of interaction, the broader function of the proposed model involves connecting patient information, communication, monitoring, service coordination, professional decision support, organizational processes, and longitudinal follow-up across the treatment trajectory. Under this interpretation, the value of AI is determined less by the existence of individual digital tools and more by whether these tools are integrated into the real clinical and organizational journey of the patient. Intelligent analysis is valuable when it enables timely recognition of patient needs; monitoring is valuable when it facilitates appropriate clinical or communicative action; personalization is valuable when information and services correspond to the patient's condition and stage of treatment; and automation is valuable when it improves responsiveness without eliminating necessary professional interaction.

Finally, the qualitative findings indicate that the successful implementation of AI-based patient relationship management should be understood as a dynamic and continuously governed process. Implementation begins with assessment of data quality, technological infrastructure, interoperability, organizational readiness, workforce capabilities, governance arrangements, and stakeholder needs, but it does not end when the system becomes operational. Continuous monitoring, validation, error reporting, security management, assessment of bias, evaluation of safety and clinical outcomes, user feedback, training, system updating, and organizational learning remain necessary throughout the system lifecycle. Accordingly, the final qualitative structure suggests that the proposed model integrates technological capabilities, patient interaction, trust, organizational infrastructure, responsible governance, implementation conditions, evaluation, and continuous improvement into a single patient-centered architecture. The principal empirical implication of the findings is therefore that AI can contribute meaningfully to patient relationship management in ATMPs when it is embedded within the patient journey, supported by reliable and interoperable data, accepted by patients and professionals, integrated into organizational processes, governed responsibly, and evaluated continuously according to patient-centered, clinical, ethical, operational, and economic criteria.

4. Discussion and Conclusion

The present study aimed to identify and explain the components influencing artificial intelligence–based patient relationship management in the context of Advanced Therapy Medicinal Products (ATMPs). The findings showed that AI-based patient relationship management should not be conceptualized as a single technological application or as the automation of a limited set of communication activities. Instead, the qualitative analysis revealed a multidimensional structure encompassing AI capabilities across the patient journey, patient interaction and experience, trust and acceptance, governance and accountability, infrastructure and organizational readiness, implementation barriers, expected outcomes, organizational transformation, model evaluation, and factors supporting long-term success. Collectively, these findings suggest that meaningful use of AI in ATMP-related patient relationship management requires simultaneous alignment of technological functionality, patient-centered communication, organizational capacity, trustworthy governance, and continuous evaluation.

One of the most prominent findings concerned the role of AI across the entire patient journey. Experts emphasized that AI can contribute to patient screening and selection, monitoring, adverse-event identification, clinical decision support, data management, and personalization of communication and care. This finding is consistent with the broader literature demonstrating that AI applications in health care increasingly extend from diagnosis and prediction to decision support, patient monitoring, personalization, and service management (Secinaro et al., 2021). The relevance of these functions is particularly pronounced in ATMPs, where therapeutic processes may involve complex eligibility assessment, individualized treatment planning, sensitive biological and genetic information, and prolonged monitoring. Research on regenerative medicine has similarly demonstrated that AI may support the analysis of complex biological information, prediction of treatment-related processes, optimization of cellular procedures, and management of multidimensional data (Abuarqoub & Mutahar, 2025). Therefore, the present findings extend existing evidence by showing how these technological capabilities may be integrated specifically into the management of relationships and interactions with patients across the ATMP treatment pathway.

The findings also showed that personalization was a central component linking AI capabilities with patient-centered care. Experts described personalization not merely in terms of treatment selection but also in relation to information, communication, education, follow-up, and service provision. This interpretation is compatible with evidence indicating that AI can improve health service quality by enabling more individualized and responsive services (Alghareeb & Aljehani, 2025). In ATMPs, where therapeutic pathways may differ substantially between patients and where treatment information can be technically complex, standardized communication may not adequately address individual informational and emotional needs. AI-supported personalization may therefore contribute to adapting information to the patient's condition, treatment stage, level of understanding, and follow-up requirements. Nevertheless, the results also indicated that personalization must remain connected to human professional judgment, particularly when decisions involve clinically significant consequences.

A second major finding concerned patient interaction, experience, and responsiveness. Experts identified rapid access to information, continuous communication, coordination of services, organization of patient data, and management of multiple patient touchpoints as important functions of AI-based patient relationship management. These findings are supported by research on conversational AI and medical chatbots, which has shown that such systems can facilitate history-taking, information exchange, patient education, and interaction outside conventional clinical encounters (Hindelang et al., 2024). Large language models may similarly support responses to patient questions, summarization of medical information, and communication-related tasks (Busch et al., 2025). However, the present findings suggest that the value of these tools lies not in replacing communication between patients and professionals but in increasing continuity and responsiveness within a complex patient pathway. This interpretation is also consistent with evidence that health care chatbot evaluation should consider usability, safety, relevance, and contextual appropriateness rather than response generation alone (Hua et al., 2025).

Trust and acceptance emerged as another fundamental category. Participants emphasized perceived usefulness, safety, ease of use, transparency, explainability, and human oversight as major conditions influencing acceptance of AI by patients and health professionals. This finding closely corresponds with previous studies showing that trust in health care AI is shaped by perceived reliability, transparency, safety, organizational context, and the continuing presence of human professional responsibility (Mertz et al., 2025). Patients' perspectives on AI also reveal a combination of perceived benefits and concerns, including expectations of greater efficiency alongside worries regarding privacy, accuracy, and reduction of human contact (Mundzic et al., 2025). Similarly, trust among health care workers in AI-based decision-support systems is influenced by perceived accuracy, usefulness, explainability, and preservation of professional control (Tun et al., 2025). These findings reinforce the conclusion that trust is not a secondary psychological reaction to implementation but a structural condition affecting whether AI systems will actually be used.

Explainability and human oversight were especially important within this category. Participants repeatedly emphasized that patients should know when AI is being used and should retain access to human professionals. Previous research has shown that explainable AI can influence clinicians' trust, although increased explanation does not automatically produce greater trust and may sometimes reveal limitations in system performance (Rosenbacke et al., 2024). Likewise, the quality of clinician-AI interaction can influence whether AI improves or disrupts clinical practice (Perivolaris et al., 2024). The present results therefore support a model in which explainability must be combined with meaningful human oversight rather than treated as an isolated technical feature. In ATMPs, where errors can have significant consequences and where patients may require complex counseling, human supervision appears essential for both safety and acceptance.

Governance, ethics, privacy, security, and accountability constituted another major dimension of the findings. Experts highlighted the importance of informed consent, protection of clinical and genetic information, algorithmic fairness, data ownership, responsibility for errors, and mechanisms for monitoring AI performance. These results align strongly with systematic evidence on AI governance, which emphasizes responsibility allocation, transparency, risk management, lifecycle monitoring, accountability, and ethical oversight (Batool et al., 2025). They are also consistent with research emphasizing the importance of privacy, information security, bias reduction, and ethical safeguards in establishing secure and trusted AI systems in health care (Khan et al., 2025). The sensitivity of these requirements is amplified in ATMPs because patient information may include genomic data and other highly identifiable clinical information. Thus, the current findings indicate that governance should operate across the entire lifecycle of the AI system rather than being treated as a compliance activity added after technical development.

The importance of trustworthy and deployable AI is further supported by international guidance emphasizing fairness, universality, traceability, usability, robustness, and explainability (Lekadir et al., 2025). The findings of the present study are consistent with this multidimensional approach because experts did not regard successful AI-based patient relationship management as dependent on algorithmic accuracy alone. Instead, they emphasized safety, usability, accountability, fairness, human supervision, and organizational integration. Regulatory considerations identified by participants are also supported by the evolving regulatory environment for medical AI, where adaptive systems, continuous updating, and complex responsibility structures challenge traditional regulatory approaches (Zhou & Gattinger, 2024). These concerns are especially relevant in ATMPs, which already operate within complex regulatory frameworks related to development, production, quality control, clinical use, and post-treatment monitoring (Olesti et al., 2024).

Another central finding concerned infrastructure and organizational readiness. Experts identified data quality, standardization, system integration, interoperability, scalability, technological infrastructure, staff readiness, training, and management support as essential implementation conditions. The prominence of data quality is consistent with the METRIC framework, which emphasizes that trustworthy medical AI requires systematic assessment of multiple dimensions of data quality (Schwabe et al., 2024). Poor-quality, incomplete, fragmented, or inconsistent data can directly undermine AI outputs, and this issue is especially important when information originates from multiple clinical, laboratory, and organizational sources. The present findings also support the view that interoperability is critical in ATMP environments because the patient pathway may involve several institutions, specialized laboratories, manufacturing units, and clinical teams.

The organizational findings are likewise consistent with studies of real-world AI implementation. Empirical evidence indicates that successful adoption of machine learning applications in health care organizations depends on technological infrastructure, workflow integration, organizational readiness, implementation strategy, and user capabilities (Preti et al., 2024). Hospital-based implementation studies similarly identify integration with clinical workflows, access to appropriate data, staff training, leadership support, and multidisciplinary collaboration as major enablers (Rahimi et al., 2024). Frameworks for AI procurement and implementation further emphasize that clinical AI should be managed as a lifecycle process involving selection, integration, monitoring, and evaluation (Khan et al., 2024). Accordingly, the current findings suggest that organizations seeking to implement AI-based patient relationship management should first assess their data architecture, interoperability, workforce capabilities, and governance readiness rather than focusing only on software acquisition.

Senior management support and organizational transformation also emerged as important findings. Experts described AI implementation as potentially contributing to greater data-driven decision-making, stronger data culture, redesigned processes, interdepartmental collaboration, management dashboards, predictive capacity, and technology governance. These findings are consistent with evidence highlighting the role of leadership in AI transformation, including strategic direction, workforce development, stakeholder engagement, communication, and management of organizational resistance (Sriharan et al., 2024).

This suggests that AI-based patient relationship management may serve as a catalyst for broader organizational digital maturity, provided that implementation is integrated with strategic and operational change.

The barriers identified in the study were essentially the inverse of the enabling conditions. Poor data quality, fragmented systems, integration difficulties, lack of explainability, organizational resistance, inadequate AI skills, ethical concerns, regulatory uncertainty, and ambiguity regarding responsibility were all identified as potential obstacles. These findings are supported by previous studies showing that health care AI implementation is frequently constrained by technical limitations, data problems, organizational resistance, workflow mismatch, insufficient skills, and governance challenges (Preti et al., 2024; Rahimi et al., 2024). The persistence of these barriers reinforces the conclusion that successful implementation cannot be achieved through technical development alone.

The expected outcomes identified by participants included improved clinical performance, better service quality, greater efficiency, improved patient experience, better monitoring, reduced errors, and potentially improved treatment outcomes. These expected benefits align with the broader literature on AI-supported service quality and clinical decision support (Alghareeb & Aljehani, 2025; Secinaro et al., 2021). However, the present study also showed that experts did not consider these outcomes automatic. Instead, benefits were viewed as contingent on data quality, governance, organizational readiness, human oversight, and integration with actual patient pathways. This interpretation is consistent with frameworks emphasizing the need to evaluate the real-world, long-term effects of AI rather than relying only on technical performance indicators (Jacob et al., 2025).

Finally, the findings concerning model evaluation and sustainability indicate that safety, effectiveness, patient experience, acceptance, usability, trust, fairness, and economic value should be assessed simultaneously. The emphasis placed on safety and clinical outcomes before cost reduction is particularly important in ATMPs, where inappropriate decisions may have serious consequences. The identified sustainability factors—including AI literacy, continuous training, stakeholder participation, management support, validation, continuous monitoring, human supervision, user-centered design, and integration with existing systems—suggest that AI-based patient relationship management should be considered an evolving organizational capability rather than a completed technological project. Overall, the findings support a conceptual model in which AI capabilities create value only when they are embedded within the patient journey, supported by reliable data and organizational infrastructure, accepted by users, governed responsibly, and continuously evaluated.

This study has several limitations that should be considered when interpreting the findings. First, the study was qualitative and based on interviews with 11 experts; therefore, the identified categories and conceptual relationships should not be interpreted as statistically verified associations or causal pathways. Second, although the participants represented diverse clinical, technical, managerial, and organizational backgrounds related to ATMPs, the sample may not capture the full range of perspectives present across all advanced therapy settings, organizations, and regulatory environments. Third, patients were not included as an independent participant group, even though patient experience, trust, acceptance, and communication formed important dimensions of the proposed model. Fourth, because a formal process for documenting theoretical saturation was not available, data adequacy was judged on the basis of the richness and coverage of the interview content rather than a prospectively defined saturation criterion. Finally, AI technologies, regulatory requirements, and ATMP-related clinical and organizational practices are evolving rapidly, and some components of the model may therefore require revision as technologies and implementation contexts change.

Future studies should quantitatively validate the proposed conceptual structure using larger and more diverse samples and appropriate measurement and structural modeling approaches. Research should examine the relationships among AI capabilities, organizational readiness, trust, patient experience, governance, and expected outcomes and determine the relative importance of these dimensions in different ATMP settings. Patients, physicians, nurses, laboratory professionals, managers, technology specialists, quality experts, and regulatory stakeholders should be examined as distinct participant groups to compare their perspectives and identify areas of agreement or divergence. Longitudinal and implementation studies are also needed to evaluate how AI-based patient relationship management influences patient experience, adherence to follow-up, clinical monitoring, organizational performance, workflow efficiency, and treatment outcomes over time. Further research should examine the model across different countries and regulatory systems and investigate whether different types of ATMPs require different configurations of technological, organizational, and governance components. Particular attention should also be given to explainability, algorithmic fairness, human oversight, interoperability, data quality, patient trust, and mechanisms for continuous post-implementation monitoring.

Health care organizations and ATMP providers should approach AI-based patient relationship management as an integrated organizational and patient-care initiative rather than as an isolated information technology project. Before implementation, organizations should assess the complete patient journey, identify critical communication and monitoring points, evaluate data quality and interoperability, determine workforce readiness, and establish clear governance and accountability structures. AI applications should be designed to complement professional expertise, particularly in clinically sensitive decisions, and patients should always have clear information regarding when AI is being used and how they can access human support. Organizations should prioritize security, privacy, informed consent, transparent responsibility, and continuous monitoring from the beginning of system design. Staff and patients should receive appropriate education and support, and implementation should involve clinical, managerial, technical, quality, and patient stakeholders. Finally, organizations should evaluate success through safety, clinical effectiveness, patient experience, usability, trust, fairness, and organizational value rather than relying exclusively on speed, automation, or cost reduction.

Ethical Considerations

All procedures performed in this study were under the ethical standards.

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Conflict of Interest

The authors report no conflict of interest.

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