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ETHICAL AND LEGAL BOUNDARIES OF DIGITAL INNOVATION IN REHABILITATION: A PERSONALIST FRAMEWORK FOR ASSESSING TECHNOLOGIES, DATA AND ARTIFICIAL INTELLIGENCE

Abstract: Digital technologies are reshaping rehabilitation practice and can increase training intensity and facilitate outcome assessment. Their use also raises questions about legal classification, professional responsibility, data security, algorithmic transparency and clinical oversight. This paper defines the ethical and legal boundaries of digital innovation in rehabilitation and proposes a personalist framework to support implementation decisions. The method combined an interdisciplinary narrative review, doctrinal legal analysis and qualitative analysis of selected writings of John Paul II and professional ethics documents. The synthesis identified three levels of assessment: regulatory, clinical-bioethical and personalist. Neither novelty nor CE marking alone determines whether a use constitutes ordinary care, a non-standard clinical application, a medical experiment or a clinical investigation of a medical device. A nine-domain framework was developed to support implementation decisions. From a personalist perspective, technology is justified when it serves the integral good of the patient, does not reduce the person to a data profile and does not replace the therapeutic relationship.

Keywords: digital rehabilitation, artificial intelligence, spatial accessibility, medical law, personalist bioethics

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Introduction

The digital transformation of rehabilitation has already moved beyond the stage of isolated pilot projects. Hospitals, outpatient clinics and home-based programs now use virtual reality, robotic systems, telerehabilitation, software-controlled neuromodulation and decision-support algorithms. These solutions make it possible to increase the number of repetitions, record the course of movement, adjust exercise difficulty and provide real-time feedback. Their effects, however, are not uniform. They depend on the population, the protocol, the design of the device, the quality of the data and the way the technology is integrated into the team's work. Moreover, an improvement in a parameter measured by the system does not always translate into a change that is noticeable in the patient's everyday life (Dawson et al., 2024; Hsu et al., 2023; Laver et al., 2025; Morone et al., 2025).

The concept of digital innovation covers situations that differ in legal and clinical significance. A technology may be new only for a given facility, while elsewhere it forms part of routine care. A device lawfully placed on the market may be used outside the scope intended by the manufacturer, and a familiar system may be incorporated into a prospective research protocol. Innovation may also concern not the device itself but a new data flow, the automatic adaptation of exercises, or the transfer to an algorithm of tasks previously performed by the therapist. CE marking and market novelty of a solution therefore do not answer the question of whether a particular way of using it is legally correct and clinically justified.

Technology also has persuasive power. A precise graph, a three-dimensional visualization, or the description of a system as “intelligent” can inspire more trust than is warranted by the quality of the evidence. For a person living with chronic disability, pain or loss of independence, access to a new device can easily become a promise of regaining function. The ethical problem therefore arises before consent is signed: in the language of advertising, in the way uncertainty is communicated, in the choice of endpoints, and in the decision as to whether the algorithm's output will be a mere indication or will, in practice, determine the course of therapy.

The basic point of reference is formed by the principles of respect for autonomy, beneficence, non-maleficence and justice (Beauchamp & Childress, 2019). In the case of AI in health care, these are joined by transparency, accountability, protection of privacy, the possibility of contesting a result, and genuine human control (World Health Organization, 2021). Where an activity constitutes research involving human subjects, scientific value, independent ethical review, protection of persons vulnerable to exploitation and reliable reporting also become relevant, and are again emphasized in the revised Declaration of Helsinki (World Medical Association, 2025). In Polish physiotherapy, the professional framework is set by the Act on the Physiotherapist Profession and the principles of professional ethics (Polish National Congress of Physiotherapists, 2022; Act on the Physiotherapist Profession, 2015).

Legal regulations describe individual regimes, and ethical documents formulate general principles for the responsible use of technology. At the level of everyday implementation decisions, however, a model is still lacking that would combine legal

classification, evidence assessment, clinical risk, data protection and the impact of automation with the question of the good of a specific person. The spatial dimension is also too rarely recognized. The same platform may facilitate access to remote care, yet it may equally deepen the gap between a large center and a locality lacking specialists, a stable connection or technical support.

The teaching of John Paul II raises a question that mere compliance with formal requirements does not resolve: what good is being sought for the patient, and whether technology remains a means or begins to define the goal of therapy. Salvifici Doloris presents suffering as an experience of the person, one that cannot be reduced to a physiological signal or a value on a scale. The document describes care for the sick as an active response to a person awaiting help (John Paul II, 1984). Dolentium Hominum frames health care within the perspective of the psychophysical unity of the person (John Paul II, 1985).

This personalist starting point is not simply a restatement of standard biomedical ethics under a different name. Where the four principles of autonomy, beneficence, non-maleficence and justice can each be satisfied item by item, personalism asks a prior question: whether the whole undertaking treats the patient as an embodied subject with their own history and goals, or as a source of measurable states to be optimized. Embodiment matters because rehabilitation acts on and through the body the patient lives, not merely a body that is measured. Agency matters because technology should extend, and never substitute for, the patient's own capacity to set and pursue a goal recognized as their own. These two commitments run through each of the nine domains and distinguish the personalist reading of consent, proportionality or data use from a purely regulatory one.

The aim of this paper is to define the ethical and legal boundaries of digital innovation in rehabilitation and to develop a personalist model of assessment preceding implementation. It is argued that the admissibility of a technology does not follow from its sophistication or from its regulatory status alone. It requires a joint assessment of clinical need, quality of evidence, legal classification, team competence, the proportion of benefits to burdens, the patient's genuine understanding of the information, the way data are used, human oversight, and the effect of the solution on access to health care.

Materials and methods

The article takes the form of an interdisciplinary narrative review and conceptual analysis. The project comprised three complementary layers: a targeted review of clinical evidence on selected digital technologies, doctrinal legal analysis, and qualitative analysis of ethical and personalist documents. This design corresponds to a problem that cannot be resolved on the basis of efficacy research alone. It does not, however, provide the completeness proper to a systematic review.

In the clinical part, the PubMed database was searched, together with other key publications not indexed there. New randomized trials, systematic reviews and studies concerning virtual reality, exoskeletons, neurostimulation, artificial intelligence, telerehabilitation and territorial inequalities were sought. The search used terms

including rehabilitation, virtual reality, exoskeleton, neurostimulation, artificial intelligence, wearable sensors, telerehabilitation, rural rehabilitation, spatial accessibility, systematic review, randomized trial, and adverse events. Searches combined these terms with Boolean operators (e.g., virtual reality AND stroke AND rehabilitation; artificial intelligence AND rehabilitation AND validation) and were run between January and July 2026. English-language systematic reviews, meta-analyses and randomized trials published from 2019 onward were eligible, with earlier or non-English sources included only where they were the primary account of a still-current regulatory or clinical point. Publications were selected purposively to illustrate recurring problems related to the quality of evidence, safety, communication and access. No meta-analysis or formal risk-of-bias assessment was performed.

Legal sources were checked in the official ELI and EUR-Lex databases and in documents of European Union institutions. The analysis covered Polish regulations concerning the physiotherapist profession, patients' rights, medical experiments, medical devices and quality of care, as well as the MDR, the GDPR, the Artificial Intelligence Act and the regulation establishing the European Health Data Space. Particular attention was paid to distinguishing clinical trials of medicinal products from clinical investigations of medical devices. Sources were limited to legislation, official guidance and case law directly bearing on the regimes discussed in this paper; secondary commentary was used only to clarify contested points. The legal cut-off date adopted for this analysis was 31 July 2026, and consolidated texts were re-checked as they stood on that date.

The personalist part was based on Salvifici Doloris, Dolentium Hominum and Redemptor Hominis (John Paul II, 1979, 1984, 1985), as well as the Charter for Health Care Workers and the New Charter for Health Care Workers (Pontifical Council for Pastoral Assistance to Health Care Workers, 1995, 2017). Passages relating to dignity, suffering, professional service and the integral good of the person were juxtaposed with problems identified in the legal and clinical analysis. These documents were selected because they most directly address suffering, the integral good of the person and the responsibilities of health-care workers, rather than through a systematic search of the wider corpus of Catholic social and pastoral teaching. Passages were read in their original context and checked against secondary theological commentary before being related to specific clinical or legal problems.

The model was developed through synthesis. First, the decisions that must be made before implementing a technology were identified. For each of the three source layers, recurring decision points were listed independently by the author most familiar with that layer. The lists were then compared across layers. Overlapping or closely related items (for example, evidence quality and technology status, or consent and information duties) were merged, while items reflecting a distinct legal or clinical consequence were kept separate. This iterative, jointly discussed comparison converged on nine non-redundant domains. They were then assigned a regulatory, clinical-bioethical or personalist basis, and recurring requirements were combined into nine domains. The model is interpretive in nature. It does not replace a legal opinion, the assessment of a bioethics committee, the manufacturer's instructions, or a formal compliance audit.

Results

The analysis organized the problems associated with digital innovation on three levels. The regulatory level concerns the classification of the activity, the status of the technology, professional competence and data management. The clinical-bioethical level covers evidence, safety, proportionality, consent and justice. The personalist level asks whether the adopted goal corresponds to the good of a specific person and whether the technology weakens that person's agency and the therapeutic relationship.

Legal classification of digital innovation

For the purposes of this article, digital innovation in rehabilitation is defined as the use of a device, software, algorithm, sensor, interface or new data flow that is not routine for a given indication, or that substantially changes the mechanism of intervention, the dose, monitoring, or the allocation of responsibility. This is a working definition. Polish law does not create a separate category of "innovative" or "non-standard clinical use", and such a label therefore cannot be used to circumvent the rules proper to health services or research.

The purpose of an activity matters but does not settle the question by itself. Ordinary care is organized primarily around the needs of a specific patient. A therapeutic medical experiment within the meaning of Polish law consists in applying a new or only partially tested method under the conditions set out in the Act on the Professions of Physician and Dentist. A clinical investigation of a medical device follows the separate MDR pathway. These regimes may arise together within a single project, but they are not synonymous (Galewicz, 2023; Regulation (EU) 2017/745; Act on the Professions of Physician and Dentist, 1996).

The greatest difficulty arises when treatment and knowledge generation occur simultaneously. Routine outcome measurement does not automatically turn a service into research, just as an intention to publish does not by itself determine classification. Formal assessment is required, however, for a project in which the protocol imposes an intervention for a scientific purpose, introduces procedures beyond ordinary care, prospectively allocates participants, or serves to establish the safety, performance or clinical benefit of a device. Such an assessment should be carried out before recruitment, not after data have been collected. These distinctions are summarized in Table 1 and are applied when classifying the specific cases discussed throughout Section Legal framework for digital innovation in rehabilitation.

Clinical applications and risk profiles

Virtual reality. Virtual reality can increase the number of repetitions and provide immediate, standardized feedback. The 2025 update of the Cochrane review found evidence of moderate or low certainty for a small improvement in upper-limb function, balance and activity limitations after stroke. Data on participation and quality of life are limited, and results relating to mobility were not conclusive (Laver et al., 2025). A randomized trial conducted by Huang et al. on immersive rehabilitation showed that it supports the possibility of an additional benefit in the subacute phase of stroke, but does

not justify extrapolating the results beyond the study population and protocol (Huang et al., 2024).

Table 1. Practical distinction between ways of applying digital innovation

Category	Main purpose	Typical features	Practical consequences
Standard practice	Direct benefit of a specific patient	Use consistent with competence, current knowledge and intended purpose; ordinary monitoring	Standard information, documentation, quality and professional obligations
Non-standard clinical application (analytical category)	Direct benefit of a specific patient	Rational justification but limited practice, less certain evidence, a new function, or a departure from the typical mode of use	Expanded information about uncertainty, documented justification, stopping criteria and heightened monitoring
Medical experiment	Therapeutic or research purpose within the meaning of the Act on the Professions of Physician and Dentist (1996)	New or partially tested method (therapeutic experiments); formal project design and statutory requirements concerning participants and leadership	Positive opinion of the bioethics committee, special consent, direction by an authorized physician and other statutory safeguards
Clinical investigation of a medical device	Assessment of the safety, performance or clinical benefit of a device	Prospective plan, sponsor and investigator; application of the MDR and national law	Appropriate authorization or notification, ethical review, monitoring, reporting and protection of participants
Other research involving patients	Generation of knowledge without meeting the conditions of the categories above	E.g. an observational study or data analysis; classification depends on the design and data source	Ethical review and data obligations appropriate to the nature of the project

Source: own elaboration based on the regulations analyzed

Nausea, dizziness, eye strain, headache, disorientation and postural instability may lead to shortened sessions or exclude a patient from training. These symptoms are often grouped under the common term cybersickness (Simón-Vicente et al., 2024). Emotional reactions also matter. A program that repeatedly signals failure may heighten frustration, even without a classic adverse event occurring. In pain therapy, VR has been associated with a short-term reduction in symptom intensity, but its attentional or analgesic effect should not be presented as removing the cause of the pain (Mallari et al., 2019).

Exoskeletons and rehabilitation robotics. Exoskeletons and robotic devices that can be fitted to the patient enable intensive, repetitive gait training under controlled conditions. Reviews describe improvement in selected gait or balance parameters. Nevertheless, the size of the effect depends on the phase of recovery, the type of device, the training dose, and the comparator intervention used (Calafiore et al., 2022; Hsu et al., 2023). It is necessary, however, to take into account that a change observed in the laboratory may have limited significance for independent movement at home or in public space.

Risks include falls, skin damage, pain, autonomic symptoms, and overload of both patient and operator. Risk also arises in communication. The image of a person standing

in a powered device may suggest the recovery of independent walking, whereas the realistic goal may be verticalization, limb loading, physiological training, or moving with intensive support.

Neurostimulation and neuromodulation systems. Neurostimulation encompasses many different methods in which electrical impulses are delivered to neural structures via electrodes. Individual techniques differ in invasiveness, site of action, parameters, regulatory status and the amount of evidence supporting their effectiveness. Some are used as an adjunct to rehabilitation in strictly defined indications, while others remain experimental (Dawson et al., 2024).

Before starting therapy, contraindications, the presence of implants, expected adverse effects, emergency procedures and staff competence should be assessed. The patient should know whether the proposed application is well established, constitutes an adjunct of uncertain benefit, or is part of a study.

Software, wearable sensors and artificial intelligence. Software and AI are used to assess movement, make predictions, monitor, classify risk, and adapt exercises. The number of applications is growing rapidly, but the evidence base is uneven. A scoping review conducted by Morone et al. in 2025 found a concentration of studies in neurological and orthopedic rehabilitation, frequent use of small, homogeneous datasets, limited external validation, and rare reporting of explainability (Morone et al., 2025).

Assessment of a system should cover the representativeness of the training data, signal quality, error rate, the ability to reconstruct the basis of a recommendation, and the program's behavior with missing or atypical data. A system may perform well under laboratory conditions and worse in a patient with tremor, an atypical movement pattern, different equipment, or a poor connection. Particular caution is required where an algorithm not only describes a result but automatically changes the dose, difficulty, or order of exercises.

Legal framework for digital innovation in rehabilitation

Professional status and current knowledge. In Poland, a physiotherapist practices a regulated, independent medical profession (Act on the Physiotherapist Profession, 2015). Independence allows decisions to be made within the statutory scope of competence, but does not exempt the practitioner from the obligation to act in accordance with current knowledge, patients' rights, and the limits of their own training. Purchasing a device or completing manufacturer training does not automatically create the competence to safely use every one of its functions. Responsibility also covers patient qualification, team training, and the manner of responding to an incident.

The principles of professional ethics require respect for dignity and autonomy, reliable information, and continuous development of competence (Polish National Congress of Physiotherapists, 2022). With a solution that is new to the team or poorly established, due diligence does not end with starting the program according to the instructions. The therapist should be able to justify the choice, recognize warning signs, and end the intervention when the expected benefit no longer outweighs the burdens.

Patient's right to information and consent. The Act on Patients' Rights protects the right to services meeting the requirements of current knowledge, to information and

consent, and to respect for dignity and privacy (Act on Patients' Rights and the Patient Ombudsman, 2008). With innovation, consent is a process, not a form. The conversation should cover the purpose, the extent of uncertainty, material risks, alternatives, and the consequences of refusal or discontinuation. Information must be adapted to the patient's communicative and cognitive abilities.

Certain circumstances require explicit disclosure, because the patient is unlikely to infer them independently: use outside the intended application, a commercial fee, the use of results for scientific purposes, the transfer of recordings to the cloud, the involvement of an external provider, or the likely end of access after a pilot. Terms such as "breakthrough", "intelligent" or "personalized" do not substitute for information about what is known, what is not known, and what real alternatives exist.

Medical experiment. The medical experiment is governed by the provisions of the Act on the Professions of Physician and Dentist (Act on the Professions of Physician and Dentist, 1996). The Act distinguishes between therapeutic and research experiments and sets out conditions concerning justification, risk assessment, consent, and the positive opinion of a bioethics committee. It also provides that, as a rule, a medical experiment is directed by a physician meeting the statutory requirements. A physiotherapist may play an important role in the team, but their participation does not replace the required leadership or the other safeguards.

Two simplifications should be avoided. The first treats every unfamiliar device as an experiment. The second assumes that a CE-marked device can never be used experimentally. A lawfully available product may become the subject of a research protocol in a new population, configuration, or purpose. Conversely, a solution new to a facility may remain ordinary care if its use is justified, falls within the scope of competence, and corresponds to the intended purpose. What matters is the whole undertaking, not the name given to it by the team.

Medical devices and clinical investigations of devices. The basic EU act on medical devices is Regulation (EU) 2017/745 (MDR), supplemented in Poland by the Act of 7 April 2022 on Medical Devices (Regulation (EU) 2017/745; Act on Medical Devices, 2022). The MDR distinguishes clinical evaluation from clinical investigation of a device. Investigations conducted to establish or confirm safety, performance or clinical benefit are subject, depending on the design, to Articles 62-80 and Annex XV.

Regulation (EU) No 536/2014 concerns clinical trials of medicinal products for human use (Regulation (EU) No 536/2014). It is not a basis for a study of an exoskeleton, a VR system, or a neurostimulator merely because the participants are patients. A combined project may trigger more than one regime, which reinforces the need for classification before the study begins.

CE marking confirms that the appropriate conformity assessment procedure has been passed, but it is not a universal certificate of clinical superiority. The extent of involvement of a notified body and the required data depend on the type and class of the device. For the practitioner, what matters are the intended purpose, the instructions for use, the target group, contraindications, required training, and safety notices. A departure from

the intended purpose requires a particularly clear justification and may change the scope of responsibility.

Health data, geodata, software and AI. Rehabilitation systems may record data more sensitive than their interface suggests: movement trajectories, images, voice, physiological responses, pain ratings, and behavioral patterns. Some telerehabilitation solutions and wearable devices also process the user's location, movement routes, or information about the home environment. Combined with health data, these allow inferences about independence, daily rhythm, and functional barriers. The term “spatial privacy” describes this risk analytically, but it is not a separate legal category under the GDPR.

Beyond compliance, digital instruments do not merely record an already-existing clinical picture and they actively shape what becomes visible to the therapist and what counts as progress. A wearable sensor, a virtual-reality metric or an algorithmic score selects which movements, symptoms or trends are captured and which are not, and this selection then organizes clinical attention. The risk is not data collection as such, but the possibility that a partial, measurable representation of the patient begins to substitute for their lived experience and self-reported goals. Guarding against this requires treating system output as one input among several, routinely checking it against the patient's own account, and keeping the functional goal, not the metric, as the reference point for deciding whether therapy is working.

Before processing begins, a facility should determine the purpose and legal basis, the roles of the facility and the provider, the place of storage, the retention period, access rules, and any use of data to improve the model. Consent to therapy does not amount to consent to every secondary purpose (Regulation (EU) 2016/679). The European Health Data Space establishes a framework for the access, cross-border exchange, and secondary use of electronic health data (Regulation (EU) 2025/327). The regulation entered into force in 2025, but its application will begin in stages from 26 March 2027; at present, it is therefore primarily a point of reference for designing interoperability and future data flows.

Software may be a standalone medical device if it has a medical intended purpose. AI-based functions may additionally be subject to Regulation (EU) 2024/1689. The general provisions and prohibitions apply in stages from 2025. In 2026, the EU legislator adopted Regulation (EU) 2026/1744 (the Digital Omnibus on AI), published in the Official Journal on 24 July 2026 and in force from 27 July 2026, which revised the timetable for high-risk systems: 2 December 2027 for standalone (Annex III) systems and 2 August 2028 for systems embedded in regulated products (Annex I) (European Parliament and Council of the European Union, 2026). From a clinical-governance perspective, prudent safeguards include human oversight, error logging, control of updates, and the ability to reject a recommendation.

Quality, cybersecurity and organization. Digital innovation should enter a facility as the result of a documented decision, not merely the enthusiasm of a single operator. The Polish system of quality and patient safety strengthens the importance of risk management, incident analysis, and corrective action (Act on Quality in Health Care and

Patient Safety, 2023). For digital systems, the assessment should cover access control, updates, backups, business continuity, procedures following loss of connectivity, and the manner of reporting incidents. The scope of legal obligations differs between entities, but the practical rule is common: responsibility must be assigned before first use with a patient.

An implementation plan should indicate who qualifies patients, what the contraindications are, what training the staff require, who approves updates, how outcomes and adverse events are recorded, and when use of the technology will be suspended. A date for re-evaluation is also needed. A recurring lack of meaningful benefit, an unacceptable error rate, or loss of control over the data flow argue for a change of approach, even if the system has already been purchased.

Ethical boundaries of digital innovation

Proportionality of benefits and burdens. Beneficence requires more than a plausible mechanism of action. There must be a reasonable chance of a benefit that matters to the patient, and the anticipated burdens should remain proportionate to that chance (Beauchamp and Childress, 2019). The assessment should take opportunity cost into account. Time, money, and effort devoted to a poorly justified technology may crowd out a better-established therapy or activities important to the patient's life.

It is worth formulating the endpoint functionally. Several additional points on a scale may matter, but need not. For one person the goal will be an independent transfer; for another, the endurance needed to return to work or to caring for a child. A method does not become justified merely because it generates a measurable result; the result must remain connected to a goal the patient recognizes as their own.

Autonomy and therapeutic misconception. Study participants may interpret an invitation to join a project as confirmation of the intervention's effectiveness, or may assume that every element of the procedure was chosen for their individual benefit. This phenomenon is termed therapeutic misconception (Lidz & Appelbaum, 2002). In rehabilitation it may be reinforced by a long-standing relationship with the therapist and the patient's dependence on the team providing ongoing care.

Respect for autonomy requires checking understanding, not merely conveying information. The patient should be able to explain, in their own words, the difference between treatment and research, to identify alternatives, and to know that refusal will not limit ordinary care. Where cognitive or communicative impairments are present, supportive tools and legally appropriate representation are needed, but the ascertainable will of the patient themselves should still be sought.

Spatial justice and access. Cost and place of residence make advanced technologies unevenly accessible. A shortage of specialists, long and costly travel, lower intensity of services, and limited access to specialized competence disproportionately burden residents of rural and remote areas (Mesmar et al., 2025). Justice does not require that every device be available everywhere from the day it reaches the market. It does require criteria that can be clinically justified and that do not turn place of residence, age, or confidence in using technology into a barrier.

Geographic information systems can identify underserved areas, analyze travel time, and juxtapose the distribution of services with residents' needs (Świtała & Sikorski, 2021). Spatial data also help reveal environmental barriers relevant to people with disabilities (Roszewska, 2021). GIS does not determine how to distribute resources fairly, but it makes the grounds for a decision more visible. In research and pilot programs, it is also necessary to establish what will happen after funding ends. Ability to pay alone is not a sufficient qualifying criterion.

Operationalized for rehabilitation planning, this spatial dimension can draw on concrete, mappable indicators: travel time and distance to the nearest qualified facility, formally defined service catchment areas, the ratio of rural to urban provider density, broadband and mobile-connectivity coverage relevant to telerehabilitation, and environmental or infrastructural barriers specific to people with disabilities (Passalent et al., 2013; Ratoza et al., 2025; Wang et al., 2023; Roszewska, 2021; Świtała & Sikorski, 2021). These indicators correspond directly to Domain 1 (clinical need and access context, Table 2), which asks whether service organization reduces the distance barrier, and to Domain 9 (monitoring and access), which requires periodic assessment of travel barriers, digital access and qualifying criteria. In the telerehabilitation case discussed in Section Telerehabilitation with limited access, the same indicators would show whether a hybrid program fills a genuine gap in an underserved catchment area or simply reproduces existing inequities in a different format.

Professional integrity. Polish patients' rights legislation does not establish a general conscience clause for physiotherapists. This must be distinguished from the professional duty not to perform an intervention that exceeds one's competence, is inconsistent with current knowledge, creates disproportionate risk, or is unlawful. A refusal in such a situation is an expression of professional responsibility, not an arbitrary moral veto.
A facility should enable staff to report safety concerns without risk of retaliation. Any objection must, however, be documented and assessed, so that personal disapproval does not deprive the patient of a lawful and clinically indicated service.

Human oversight and responsibility. A digital system can organize data, detect patterns, and propose modifications to therapy, but it does not assume moral or professional responsibility. Human oversight cannot mean merely clicking “accept”. The therapist should understand the tool's intended purpose, know the situations in which its output becomes less reliable, and have a genuine ability to override a recommendation without losing access to the system's other functions.

The risk lies both in uncritical submission to the algorithm and in its arbitrary rejection. Deviations from recommendations, errors, and inconsistencies with clinical observation should be documentable and discussed within quality oversight. The final decision must remain assigned to a person or team with the competence and responsibility for the patient (World Health Organization, 2021).

Personalist foundations of assessment

Suffering is not a therapeutic tool. Salvifici Doloris distinguishes bodily pain from moral suffering and describes suffering as an experience that involves the human being as a person (nos. 5 and 9; John Paul II, 1984). The document does not claim that suffering

improves clinical outcomes. It speaks of the possibility of finding meaning in an experience that has already occurred, not of creating or sustaining pain for a spiritual purpose. In rehabilitation, suffering cannot be presented as a therapeutic mechanism.

This distinction preserves two obligations. The team should treat pain and functional limitations with the best available methods. At the same time, it must remember that regaining range of motion or strength does not always remove fear, grief, dependence, or an altered self-image. Spiritual and existential support may accompany therapy, but it cannot replace it.

The Good Samaritan as a model of relationship. In the final part of Salvifici Doloris, the parable of the Good Samaritan becomes a description of the response to suffering (nos. 28-30; John Paul II, 1984). Its order is concrete: to notice, to stop, and to help. Technology may extend the therapist's range of action, but it will not assume responsibility for attention, presence, and response to what the patient is unable to express directly.

An adaptive system cannot reliably interpret every silence, hesitation, or refusal. An exoskeleton cannot determine whether verticalization is, for a given person, an experience of progress, of pain, or a reminder of loss. A measurement acquires clinical meaning only in conjunction with the patient's own account. Personalism is therefore not a “spiritual module” attached to technology, but a principle determining whose interpretation takes precedence.

The integral good of the person and the subordination of technology. Redemptor Hominis names the human being as the fundamental path of the Church (John Paul II, 1979). Dolentium Hominum applies this orientation to health care and emphasizes the psychophysical unity of the person (John Paul II, 1985). In rehabilitation, this shifts attention from maximizing a device's output toward participation in family, social and professional life, and, where important to the patient, spiritual life as well.

The Charter for Health Care Workers presents the medical professions as a service to life and human dignity (Pontifical Council for Pastoral Assistance to Health Care Workers, 1995). The New Charter updates this framework in light of developments in biomedicine and more recent medico-legal and social problems (Pontifical Council for Pastoral Assistance to Health Care Workers, 2017). For the assessment of contemporary technologies it is the primary point of reference, while the earlier document retains significance for the continuity of the argument.

The criterion drawn from these documents is demanding yet practical. Technology serves the person when it supports a goal established together with the patient, leaves the patient a genuine possibility of refusal, does not reduce them to a data set, and does not weaken solidarity with those who cannot benefit from it or afford it. Progress then becomes part of care, rather than a measure of its quality.

A personalist model for assessing digital innovation

The findings were translated into a nine-domain model of assessment preceding implementation. It is intended for clinicians, research teams, managers, and entities making purchasing decisions. It does not create a new legal test. It is a conceptual synthesis, not an empirically validated instrument, and its predictive or inter-rater properties have not yet been tested. Its purpose is to reveal missing information early

enough that the design of the project, the manner of obtaining consent, the organization of oversight, or the scope of data collected can still be changed.

The model combines three levels. The regulatory level covers the classification of the activity, the status of the technology, competence, and data management. The clinical-bioethical level concerns evidence, proportionality, consent, safety, and justice. The personalist level asks whether the goal genuinely corresponds to the good of the person, preserves their agency, and does not replace the therapeutic relationship with the logic of the system. Responsible implementation requires applying all three perspectives.

Table 2. Nine-domain personalist model for assessing digital innovation

Domain	**Control question**	**Minimum action**
1. Clinical need and access context	What patient problem does the method solve, and does the way the service is organized reduce the distance barrier?	Define an individual functional goal and assess the effect of service organization on access.
2. Evidence	What is the quality and currency of the evidence in the given population?	Separate direct evidence from hypotheses, analogies and marketing materials.
3. Legal classification	Is this a health service, a medical experiment, a clinical investigation of a device, or other research?	Document the classification and establish the required ethical and regulatory pathway.
4. Technology and software status	Are the device, software and functions being used in accordance with their intended purpose?	Check the CE marking, class, intended purpose, version, instructions, contraindications and alerts.
5. Competence	Can staff apply the system and respond to complications?	Ensure training, oversight, an emergency procedure and documentation of competence.
6. Proportionality	Does the expected benefit justify the risk, cost and forgone alternatives?	Establish criteria for continuation, modification and discontinuation of therapy.
7. Consent	Does the patient understand the uncertainty, the alternatives, the funding and any research purpose?	Conduct a conversation, check understanding and separate care from research.
8. Data, geodata and AI	What data are collected, for what purpose, and who makes the final decision?	Establish GDPR roles, minimization, the scope of location data, security, secondary purposes and human oversight.
9. Monitoring and access	How will outcomes, incidents and territorial equity of access be assessed?	Maintain a register of outcomes and events and periodically assess travel barriers, digital access and qualifying criteria.

Source: own elaboration

Table 2 is applied to four illustrative situations in Section Applying the model: four situations The regulatory or clinical-bioethical basis for each domain is set out in the corresponding subsection.

Applying the model: four situations

VR as an adjunct to post-stroke therapy. A facility uses a CE-marked VR system in the population and for the purpose described by the manufacturer. Staff are trained, the intervention supplements ordinary rehabilitation, tolerance is monitored, and no additional data are collected beyond the medical record. Such a situation can remain ordinary clinical practice. It is still necessary, however, to explain that the expected benefit is supplementary and uncertain, and to stop the session when cybersickness or fatigue outweigh the value of the training.

An exoskeleton in a new indication. A team proposes an exoskeleton to patients outside the population intended by the manufacturer. Participants follow a prospective protocol, undergo additional measurements, and receive a predetermined intervention for the purpose of assessing safety and performance. A publication plan is of secondary relevance; it is the research features of the project that determine the need for formal classification. The team must establish whether the provisions on medical experiments and the MDR apply, obtain the required ethical and regulatory decisions, and identify the sponsor, the investigator, and the physician directing any experiment.

An exercise-adapting algorithm and the cloud. A platform records movement, adjusts exercise difficulty, and transmits data to an external cloud provider. Before use, the facility must determine whether the software is a medical device, establish roles and legal bases under the GDPR, check the obligations arising from the AI Act, and ensure the therapist can review and reject recommendations. Ordinary consent to physiotherapy does not remove the obligation to explain remote processing and secondary uses of the data.

Telerehabilitation with limited access. A patient living far from a specialist center receives a hybrid program: an initial in-person qualification visit, home exercises with a motion sensor, and periodic remote consultations. The model may reduce the number of trips, but its fairness depends on internet access, equipment, digital competence, and a safe place to exercise. It is necessary to establish whether the system records location or information about the home, who responds to warning signals, and what happens if connectivity is lost. Spatial analysis can indicate areas where the solution addresses a genuine gap, but it does not replace an individual safety assessment.

Discussion

The boundary that matters legally and ethically does not run between “old” and “new” equipment. It runs between a decision that can be justified by patient need, evidence, and properly organized oversight, and an action whose uncertainty, research purpose, automation, or commercial interest calls for additional safeguards. The same platform may be an ordinary therapeutic tool, a non-standard application, or an element of formal research, depending on the purpose, the population, the protocol, the function of the algorithm, and the data flow.

The current evidence argues for the cautious use of technology in specific indications, not for a general claim of the superiority of digital rehabilitation over conventional care (Dawson et al., 2024; Hsu et al., 2023; Laver et al., 2025; Morone et al., 2025). VR may

bring small additional benefits after stroke, but important areas remain uncertain, which justifies the need for further research in this area (Laver et al., 2025). In AI, the number of applications is growing faster than the quality of external validation and explainability reporting (Morone et al., 2025). Assessment should therefore not end with technical feasibility. It should encompass an outcome that matters to the patient, the frequency of failures, and the conditions of real-world practice.

The proposed model does not replace the MDR, the GDPR, the AI Act, or existing ethical frameworks. It does, however, translate scattered obligations to the level of a specific rehabilitation decision. Compared with general principles of responsible AI (World Health Organization, 2021), it more clearly incorporates the functional goal established with the patient, the physiotherapist's competence, the possibility of discontinuing the intervention, and the risk of weakening the therapeutic relationship. Personalism functions here as an organizing criterion: a technical result matters only insofar as it supports the life and agency of a specific person.

The spatial dimension does not turn the model into a GIS tool. It does, however, protect against assessing technology in isolation from the place where the patient lives and receives care. Data on the distribution of services, travel time, and environmental barriers can support decisions about equipment location, the development of telerehabilitation, and the organization of hybrid models. Such use corresponds to the role of GIS in mapping health needs and accessibility for people with disabilities (Roszewska, 2021; Świtała & Sikorski, 2021; Nsiah et al., 2024).

The legal analysis shows that an outdated or imprecise legal basis is not merely an editorial problem. Trials of medicinal products and investigations of devices are subject to different regimes. A medical experiment carries specific requirements concerning leadership. Software may simultaneously fall under regulations on devices, data, and AI. Each of these classifications affects the body competent to conduct the assessment, the scope of information given to the participant, and the allocation of responsibility.

The personalist contribution does not consist in rejecting technology. It consists in refusing to grant a device the right to define the patient's good. Innovation can be an expression of solidarity when it increases agency, participation, and access to care. It can, however, deepen dependence or exclusion if it is imposed, advertised through unrealistic promises, or available only to those able to pay for it. Salvifici Doloris allows one to speak of the meaning a person seeks in suffering, but it does not turn pain that can be reduced into a moral obligation. In rehabilitation, this leads to an obligation to remain present to the person whose functioning and self-understanding have changed.

Limitations. This paper is a narrative review and conceptual analysis, not a systematic review of effectiveness. The examples serve to identify recurring problems, not to demonstrate the superiority of any single solution. The selection of sources on AI, VR, robotics, neurostimulation and accessibility was purposive and does not cover the entire literature. Although the legal analysis was checked as it stood on 31 July 2026, regulations on devices, data, and AI are changing rapidly. Any actual implementation requires renewed review of the consolidated texts, the manufacturer's documentation, and the practice of the competent authorities.

The personalist interpretation was limited to selected documents concerning suffering, dignity, and service in health care. It does not exhaust moral theology, the philosophy of technology, or data ethics. The nine-domain model is the result of conceptual synthesis. It has not been empirically validated, assessed for inter-rater agreement, or compared with a formal regulatory audit. It should support discussion, not automatically resolve it. Future work should test the model's usability and reliability directly: for example, through an expert Delphi assessment of the domains and control questions, formal inter-rater agreement studies when different teams apply the model to the same case, pilot implementation with structured clinician and patient feedback, and comparison of its conclusions with those of a formal regulatory or bioethical compliance audit.

Conclusions and recommendations

Digital novelty alone does not determine that an intervention is a medical experiment, nor that it is clinically justified. Assessment should jointly cover the purpose, the protocol, the status of the technology, the intended purpose, the degree of automation, additional procedures, and the manner of data use.

The professional independence of a physiotherapist operates within the limits of competence, current knowledge, patients' rights, and professional ethics. The greater the uncertainty surrounding a technology or algorithm, the stronger the justification, monitoring, emergency procedure, and patient information should be.

A medical experiment within the meaning of Polish law and a clinical investigation of a device are separate categories. The former is subject to national provisions on experiments, while the latter is subject to the MDR and national provisions on medical devices. Regulation 536/2014 concerns medicinal products.

Ethically responsible implementation requires a proportion of benefits to burdens, comprehensible consent, data minimization, cybersecurity, genuine human oversight, transparent funding, and access criteria that can be justified both clinically and publicly.

The personalist teaching of John Paul II does not justify limiting pain treatment or forgoing progress. It does, however, require that technology remain a tool serving the person, whose dignity does not depend on functional outcome, digital competence, or the quality of data available to the algorithm.

The nine-domain model helps identify when ordinary clinical management suffices and when a legal opinion, bioethical assessment, a formal regulatory pathway, or the decision to forgo implementation is needed. Its value lies in the simultaneous application of the legal, clinical-bioethical, and personalist perspectives.

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Data Availability

Not applicable. No new dataset was generated or analyzed in this study.

Use of Generative AI and AI-Assisted Technologies

AI-assisted tools were used for language correction, translation support, structural organization, and consistency checking of the manuscript. The authors independently verified the legal sources, the scientific literature, the interpretations, and the final wording of the text, approved the full version of the work, and take responsibility for its content.

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