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Safety-Governed Development of a Pediatric Robotic Elbow Orthosis for Arthrogryposis Multiplex Congenita: A Multi-Standard Case Study in an Academic Resource-Constrained Setting

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Abstract

Robotic systems for pediatric rehabilitation must provide precise mechanical assistance while ensuring clinically appropriate risk control for vulnerable populations. In low- and middle-income countries (LMICs), academic medical robotics projects frequently fail to progress beyond intermediate Technology Readiness Levels (TRLs 3–5) due to limited translational planning. This study proposes and evaluates an integrated governance framework for academic pediatric rehabilitation robotics in LMIC settings, applied through the development of the AMCOR robotic orthosis for pediatric arthrogryposis multiplex congenita (AMC). The framework combines multiple national and international medical devices development standards and a dual regulatory pathway separating academic development from future translational stages. The framework is structured around four principles—auditability, TRL-proportional documentation, binding decision criteria, and regulatory separation—and is operationalized through a six-gate process. Across the first two gates (G0–G1), 38 traced requirements and 12 failure modes were documented. Five internal audits confirmed operational implementation of the quality management structure. The framework application also shaped core engineering decisions. The low amplitude and poor signal-to-noise ratio of sEMG signals observed in pediatric AMC patients rendered the original single-layer control strategy inadequate, prompting a framework-governed redesign toward a three-layer adaptive architecture based on signal quality thresholds and

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fallback safety logic. These findings demonstrate that a prospective, multi-standard governance model can improve early-stage academic medical robotics in resource-constrained settings. Generalizability beyond the single-center, two-gate application reported here requires further validation; however, the framework provides a replicable foundation for adoption in comparable LMIC contexts.

Keywords: rehabilitation robotics; pediatric robotic orthosis; arthrogryposis multiplex congenita; human–robot interaction; sEMG adaptive control; stage-gate; technology readiness level; ISO 14971; design controls; risk management

1. Introduction

Academic medical robotics has produced a growing number of promising prototypes for rehabilitation, assistance, and clinical support [1], yet the transition from laboratory proof-of-concept to clinically usable and regulatorily defensible systems remains limited. Several systematic reviews across healthcare robotics suggest that many systems remain concentrated in intermediate stages of technological maturity. For example, in a PRISMA-based mapping of upper-limb rehabilitation robots, 57.9% of devices remained at Technology Readiness Levels (TRLs) 4–6, while 40.4% reached high maturity levels (TRLs 7–9) [2]. Among soft robotic wearables, most reported systems (75%) were located at TRL 4–5, with only a minority reaching maturity for end-user testing or market translation [3]. Comparable patterns have been reported in brain–computer interface robotics for hand rehabilitation, where systems rarely progress beyond prototype or preclinical stages [4], and in healthcare collaborative robots, which largely remain at testing and validation levels rather than routine clinical implementation [5].

Together, this evidence points to a persistent translational gap with scientific, economic, and safety implications. Scientifically, prolonged concentration at intermediate TRLs limits the accumulation of clinical evidence and delays validation in real-use settings [3,4]. Economically, regulated medical-device development involves substantial costs related to nonclinical testing, clinical studies, regulatory review, and development failures [6]. From a safety perspective, medical robots are not ordinary engineering prototypes: they may physically interact with patients, including children and other vulnerable populations [7], and must satisfy requirements for software safety [8], usability [9], intended use, documentation traceability, verification, validation [10], and risk control [11]. When these requirements are introduced late, projects may accumulate an incomplete evidentiary record linking clinical needs, design inputs, risks, tests, and acceptance criteria. This condition can lead to prototype persistence and traceability debt: technically feasible but insufficiently justified systems may continue to consume resources without clear evidence for safe clinical progression. Therefore, early governance should not be understood as administrative overhead, but as a mechanism for protecting patients and preserving research resources.

Existing approaches address only part of this challenge [12]. Biodesign [13] structures the identification and validation of clinical needs but does not specify stage-specific engineering evidence, risk thresholds, or documentation requirements. Stage-Gate models [14,15] introduce disciplined decision points but are seldom adapted to academic robotics, where development is iterative, budgets are limited, and teams often lack industrial regulatory infrastructure. TRLs [16] provide a shared language for maturity, yet TRL advancement does not by itself define the quality management, risk management, or software lifecycle evidence required for clinical translation. Conversely, standards such as IEC

62304 [8], IEC 62366 [9], ISO 13485 [10], and ISO 14971 [11] define those expectations but, when applied without adaptation, may be disproportionate for early academic research.

This leaves a methodological gap: the absence of an integrated, proportional, and auditable framework that links clinical need identification, TRL progression, Stage-Gate decisions, risk management, design controls, and software lifecycle requirements from the earliest design stages. The problem is global, but it becomes especially consequential in resource-constrained academic settings, where limited budgets and fragmented regulatory expertise amplify the cost of delayed governance. We therefore treat low- and middle-income country (LMIC) environments not as the sole context for such a framework, but as a stringent implementation context in which methodological weaknesses are especially visible.

To address this gap, we propose an integrated governance framework that combines Biodesign, Stage-Gate logic, TRL mapping, ISO 13485 design control principles, ISO 14971 risk management, and IEC 62304 software lifecycle concepts within a dual academic-to-translational pathway. The framework is organized around four principles: auditability, TRL-proportional documentation, binding decision criteria, and regulatory separation between early academic exploration and future clinical translation. It is intended to support early design decisions, curb uncontrolled prototype persistence, reduce traceability debt, and enforce explicit GO/HOLD/KILL criteria before projects advance toward human-subject testing or patient-facing use. This decision logic is adapted from Stage-Gate models, in which gate reviews function as predefined decision points for continuation, suspension, redirection, or termination of a project [14,15].

We present the AMCOR project (Arthrogryposis Multiplex Congenita Orthosis for Rehabilitation), developed at the Instituto Nacional de Rehabilitación Luis Guillermo Ibarra Ibarra (INR) in Mexico City, as an embedded use case. AMCOR is an active pediatric elbow orthosis for children with arthrogryposis multiplex congenita (AMC), a congenital condition characterized by multiple joint contractures and functional limitations affecting daily activities [17–19]. AMCOR brings together several high-risk features common in medical robotics: pediatric users, physical human–robot interaction, torque delivery to a vulnerable joint, surface electromyographic (sEMG)-based intention detection, and embedded software. These characteristics make it an appropriate test case for evaluating whether early governance can shape real engineering decisions before unsafe or insufficiently justified progression occurs.

Accordingly, this study does not assess clinical efficacy or therapeutic outcomes. Instead, it evaluates the prospective implementation of the framework across the first two development gates. Specifically, we report how the framework structured institutional readiness, requirements traceability, risk analysis, and design decisions, including a governance-driven redesign of the control architecture and a binding HOLD decision triggered by unresolved torque-risk verification. The objective of this study is therefore to demonstrate how a proportional, auditable, and decision-enforcing governance framework can support early-stage academic medical robotics in a way that is globally relevant and particularly applicable to resource-constrained academic settings.

Positioning and Related Work Gap

Passive orthotic systems may provide gravity compensation but lack adaptive active control [20], whereas myoelectric systems generally assume stable electromyographic activity and conventional musculoskeletal mechanics [21]. In practice, many pediatric AMC patients present weak or inconsistent surface electromyographic (sEMG) signals, altered joint mechanics, and reduced force generation, limiting the effectiveness of conventional control strategies [17]. These challenges require development approaches capable

of adapting technical decisions in response to patient-specific biomechanical and electrophysiological constraints while maintaining formal safety governance throughout the design process.

The development of medical devices within academic environments requires navigating a complex intersection of design, engineering, and regulatory compliance [12]. The central premise motivating this work is that the primary barrier to translating AMCOR into clinical practice is not solely an engineering gap, but also a governance gap. Existing frameworks—including Biodesign [13], Stage-Gate methodologies [14], Technology Readiness Levels [15], ISO 13485 design controls [10], ISO 14971 risk management [11], IEC 62304 software lifecycle standards [8], and national regulatory pathways such as NOM-241-SSA1-2025 [22]—each address partial dimensions of this problem, but have not been systematically integrated into a unified framework adapted to LMIC academic environments. While frameworks such as Stanford Biodesign [13] excel at identifying clinical needs, they often lack structured, stage-by-stage engineering execution. To address this, industrial product development employs the Stage-Gate system [14] discipline project milestones. However, these models are rarely integrated or adapted to the resource-constrained workflows of LMIC academia [14,15,23].

A critical gap persists in the medical robotics literature: while research extensively covers technical performance—such as control algorithms, sensor fusion, and haptic feedback—it frequently neglects the systematic integration of safety standards and regulatory traceability during the R&D phase [1]. Existing methodologies present significant limitations: the IDEAL-D framework focuses on clinical evaluation but lacks robust engineering and risk governance [24]; MediGate supports commercialization in emerging markets but lacks the deep electromechanical and software integration criteria (IEC 62304) [8] essential for complex robotic systems [25]. Furthermore, Technology Readiness Levels (TRLs) measure maturity without the Quality Management System (QMS) triggers required for medical translation [26,27], and ISO 13485 remains too industrially scaled for early academic exploration [10,23].

Recent efforts have attempted to bridge these gaps [28]. Recent work by Buist and Ortiz-Catalan [23] regarding ISO 13485 in European academia represents the closest precedent. However, the proposed AMCOR framework differentiates itself by operationalizing safety and compliance across a flexible, six-gate lifecycle: Gate 0 (G0: Identification and Planning), Gate 1 (G1: Concept and Requirements), Gate 2 (G2: Detailed Design), Gate 3 (G3: Verification), Gate 4 (G4: Validation), and Gate 5 (G5: Translational Transfer). Specifying G0 and G1 during initial research is methodologically vital, as these early stages dictate how clinical needs are transformed into traceable requirements before physical manufacturing occurs. To demonstrate how structured governance can resolve these systemic vulnerabilities without causing regulatory paralysis, this paper utilizes Mexico as a rigorous regional case study [22].

In summary, this work advances the field by providing the following:

- A prospective multi-standard governance framework that integrates Stanford Biodesign, Stage-Gate methodology, and TRL mapping with ISO 13485 and ISO 14971 requirements, tailored for LMIC academic medical robotics.
- A multidisciplinary gate-review structure with binding authority (GO/HOLD/KILL), ensuring technical and regulatory compliance is verified before project advancement.
- A dual regulatory pathway (Track A/B) that separates early academic exploration from formal translational compliance, preventing "regulatory paralysis" during initial R&D.
- An empirical case study demonstrating how framework-governed risk analysis [28] directly altered the robotic control architecture of a pediatric device, blocking unsafe progression that traditional academic workflows might have overlooked.

2. Materials and Methods

2.1. Study Design

This is a single-case embedded case study design [29], where the unit of analysis is the AMCOR governance framework, and the gate decisions, audit records, and engineering redesign events generated during prospective implementation are the embedded sub-units. The methodological approach is also consistent with design science research [30], since the framework is the artifact constructed to address the identified problem of governance failure in academic LMIC medical robotics. Therefore, the evaluation derives from prospective operational evidence rather than controlled experimentation.

We do not evaluate clinical outcomes, patient functional improvement, or device therapeutic efficacy. We did not use any device during the period reported. We bounded our analysis to Gates G0 and G1 of the six-gate development plan, covering institutional readiness, biomechanical characterization, concept architecture, requirements tracing, initial risk analysis, and internal quality auditing.

2.2. AMCOR Robotic System—Architecture Overview

The AMCOR robotic orthosis is a single-degree-of-freedom active elbow orthosis designed for children aged 4–14 years with AMC. The system provides active elbow flexion and extension assistance, controlled by patient movement intention estimated from surface electromyography (sEMG), with fallback modes based on inertial measurements. Table 1 summarizes the principal subsystem architecture.

The architecture summarized in Table 1 was derived through the governance pathway applied throughout AMCOR rather than through an isolated selection of technical components. Clinical and biomechanical evidence was first interpreted as a design input and examined in relation to foreseeable hazards and hazardous situations. Applicable risk management, design control, software lifecycle, electrical safety, and usability principles were subsequently used to translate those findings into traceable system requirements, risk control measures, design outputs, and planned verification activities. In this process, the quantitative values associated with range of motion (ROM), torque, sEMG quality, temperature, response time, and other performance limits were derived from clinical, biomechanical, or engineering evidence; the applicable standards governed how those values and the associated requirements were documented, evaluated, traced, implemented, and verified. Accordingly, Table 1 presents the functional decomposition through which these requirements were allocated to the mechanical, electrical/electronic, software, control, and human–machine interface subsystems, while the detailed normative basis and verification logic are described in the subsequent sections.

Mechanical load, fatigue, torque, and ROM constraints were managed as risk control measures under ISO 14971 and maintained as traceable design inputs and verification criteria under ISO 13485. Electrical protection requirements, including the leakage current target and independent shutdown functions, were established with reference to the basic safety and essential performance principles of IEC 60601-1. Software safety functions, including signal quality supervision, fallback behavior, torque control, and emergency stop management, were specified and verified according to the software lifecycle and risk management principles of IEC 62304. Usability-related requirements, including alarm presentation, donning time, and therapist interaction, were addressed according to the usability engineering principles of IEC 62366-1 [9].

Table 1. AMCOR robotic orthosis subsystem architecture and critical interfaces.

Subsystem	Function	Key Components/Specifications	Critical Interfaces	Governing Standards
S01 Mechanical	Structural support, anatomical alignment, torque transmission, and physical interface.	- Single-axis elbow joint - Adjustable cuffs (pediatric anthropometry, 4–14 years) - Total mass $\leq$ 1.5 kg - Structural safety factor $\geq$ 3 - Fatigue resistance $\geq$ 10,000 cycles - Joint encoder - Torque-limiting element	- Actuator/transmission mounting to S02 - Joint encoder feedback to S03 - IMU and force-sensor integration - Anatomical interface via adjustable cuffs	- ISO 13485 [10] - ISO 14971 [11]
S02 Electrical/Electronic	Signals acquisition and conditioning, power management, electrical protection, and actuator drive.	- Shimmer3 sEMG module with integrated 3-axis IMU (Shimmer Research Ltd., Dublin, Ireland) - Battery-management system - PWM motor driver - Current and temperature sensing - Power-disconnection mechanism - Leakage current target < 10 μA	- sEMG signal to S03/S04 - IMU data to S04 (I2C bus) - Motor command from S03 (PWM) - Power distribution to active subsystems - Shutdown/alarm signals to S03	- IEC 60601-1 [31]
S03 Software/Firmware	Real-time control, software safety supervision, subsystem coordination, communication, logging, alarms.	- Real-time control loop - SQI evaluated every 500 ms - Watchdog & emergency stop - BLE data export - AES-256 encrypted session storage - IEC 62304 Class C: torque control, emergency stop; B: sEMG processing, signal quality supervision; A: non-safety-critical HMI	- Sensor data from S02 - SQI/control state between S04 - Torque command to S02 - Alarms and status to S05 - Data export via communication interface	- IEC 62304 [8]

Table 1. *Cont.*

Subsystem	Function	Key Components/Specifications	Critical Interfaces	Governing Standards
S04 Control/ML	Movement-intention estimation, signal quality evaluation, assistance-layer selection, torque command, fallback.	- Three-layer adaptive architecture: - Layer 1—IMU-derived kinematics, postural assistance - Layer 2—RLS filter + sEMG envelope - Layer 3—LDA/LSTM classifiers - SQI-based layer selection - Mahalanobis distance anomaly monitor - Automated fallback logic	- sEMG/IMU inputs from S02 - SQI/control state between S03 - Target torque to S03 to S02 - Calibration, target ROM, patient config from S05	- IEC 62304 [8] - ISO 14971 [11]
S05 HMI/Human Factors	Clinical configuration, calibration, user feedback, alarm presentation, session supervision, controlled export.	- Therapist tablet interface - Patient profile and session configuration - Target ROM selection - Calibration workflow - Visual and auditory alarms; session history - SUS target ≥ 70 - Donning time ≤ 5 min	- Configuration commands to S03/S04 - System status and alarms from S03 - Calibration parameters with S04 - Session data from software subsystem	- IEC 62366-1 [9]

AES: advanced encryption standard; BLE: bluetooth low energy; HMI: human–machine interface; I^2C: inter-integrated circuit; IMU: inertial measurement unit; LDA: Linear Discriminant Analysis; LSTM: Long Short-Term Memory; PWM: pulse-width modulation; ROM: range of motion; sEMG: surface electromyography; RLS: recursive least squares; SQI: Signal Quality Index; SUS: system usability scale.

2.3. The Integrated Governance Framework-Design Principles

The AMCOR framework balances academic flexibility with clinical safety through four foundational design principles:

1. Auditability before agility: All process elements must generate traceable, signed documents. Informal agreements are invalid; every decision is recorded for internal or regulatory audits, in line with the requirements of ISO 13485 and ISO 14971.
2. Proportionality to TRL: The documentation burden scales with the technology readiness level. At low TRL (1–2), minimal but credible evidence is required; at high TRL (4–5), documentation approaches the demands of the standard. Each gate explicitly defines the required evidence, avoiding premature bureaucracy.
3. Binding kill criteria: Go/Kill decisions are mandatory and binding. An external reviewer (not involved in development) participates in each Gate to avoid confirmation bias. Kill criteria are predefined before reviewing the evidence, following the risk management logic of ISO 14971.
4. Regulatory separation: Two parallel pathways are established. Track A (academic) covers TRLs 1–5, with lightweight governance but internal auditing. Track B (commercialization) starts at TRL 6+ and requires full compliance with ISO 13485, ISO 14971, and, for embedded software, IEC 62304. This strategic separation prevents "regulatory paralysis" commonly observed in LMIC institutions during early-stage research.

2.4. Stage-Gate Architecture and Multi-Expert Panel

Academic medical robotics frequently stalls because decision-making is not governed by explicit evidence thresholds and enforceable stop conditions. AMCOR addresses this by adopting a structured Stage-Gate architecture as an evidence-enforcing governance mechanism rather than a schedule-driven tool [14,32]. This concept, originally a disciplined innovation pathway in which each gate is a decision boundary, is adapted to the LMIC context in Mexico to prevent uncontrolled prototype persistence driven by momentum rather than safety, clinical justification, and auditable evidence.

AMCOR utilizes six sequential gates (G0–G5) as formal decision boundaries where continuation is contingent on evidence completeness and risk acceptability. This architecture is reinforced by a multi-expert governance panel designed to operationalize the separation of duties, ensuring no single stakeholder simultaneously defines requirements, implements solutions, and validates safety-critical evidence. Evaluation is distributed across independent roles: technical (engineering feasibility), clinical (need alignment in pediatric AMC context), quality/regulatory (design control consistency), and independent external oversight. The external reviewer provides a structural counterweight to internal optimism and reduces the risk that criteria are relaxed after evidence is presented [10].

The system implements a deterministic GO/HOLD/KILL logic to ensure actionable outcomes. A GO is granted only when the criteria are fully met. A HOLD is triggered by at least one partial failure, requiring closure of non-conformances before progression, preventing the academic pattern of "we will fix it later." A KILL is triggered when requirements are unmet, or failures indicate an unsafe or unjustifiable trajectory, preventing sunk-cost bias. This logic aligns with risk governance: risk control is meaningful only if it can genuinely stop progress when residual risk is unacceptable [11]. In summary, this architecture transforms governance into an evidence-bound decision system designed to sustain safety discipline and auditability in resource-constrained academic environments.

2.5. TRL Mapping and Model Progression

AMCOR integrates Technology Readiness Levels (TRLs) as an evidence-binding construct. TRLs reduce optimism bias by requiring observable evidence for readiness

claims [16,26]. Also, AMCOR integrates multiple international standards through gates (Figure 1).

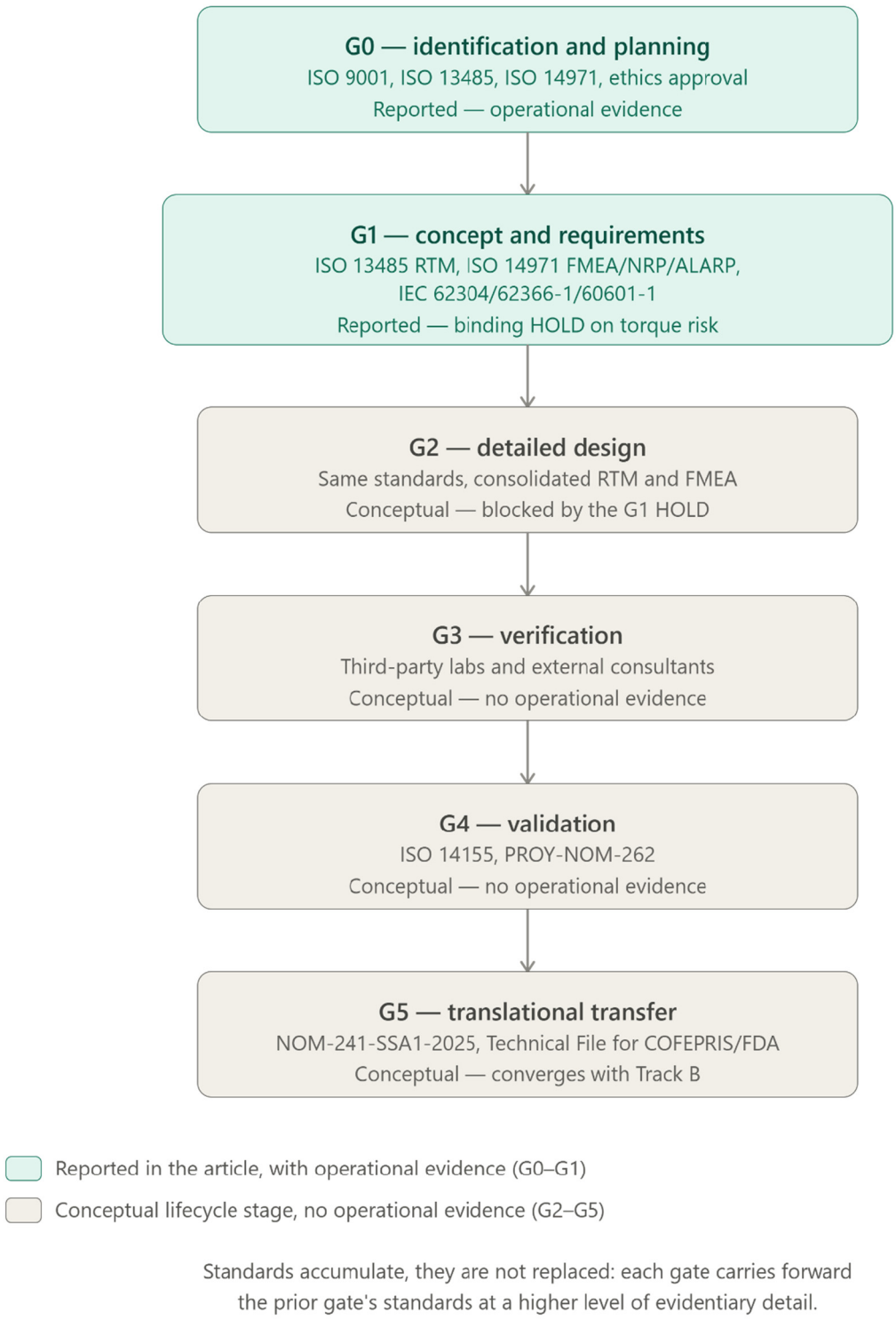

Figure 1. AMCOR gate-to-standard cascade across G0–G5. The figure was generated with Claude Sonnet 4.6 (Anthropic PBC, San Francisco, CA, USA, 2025) from author-developed and verified content.

AMCOR addresses the TRL3 to TRL5 corridor, where clinical evaluation introduces non-negotiable expectations regarding traceability, verification, and risk justification. TRL advancement is strictly prohibited unless the gate evidence package is complete, preventing post hoc justifications.

Methodological proportionality ensures evidence requirements scale with readiness. Early gates emphasize clinical need, governance, ethics, and document control. The Design History File (DHF) serves as a living record of design inputs, outputs, and changes [10]. ISO 14971 frames risk management as a lifecycle process, defining acceptability criteria before design decisions become entrenched [11]. As maturity increases, gates demand quantitative verification, safety, fatigue, and human factors evidence. This avoids common LMIC failure modes like "regulatory paralysis" and "traceability debt," providing a controlled corridor where feasibility work advances without undermining clinical defensibility.

AMCOR reframes readiness as a property of the evidence system, not merely the prototype. This targets structural bottlenecks preventing academic prototypes from moving toward clinical evaluation. This is vital for pediatric AMC orthosis development, where high safety expectations necessitate strong evidence quality.

2.6. ISO 13485 QMS and DHF

A partial QMS was established to support design and development activities. Following approval of the intended use, ISO 13485 design control principles were implemented through a DHF, while administrative processes remained under the institutional ISO 9001:2015 framework [33].

The DHF documented planning, design inputs and outputs, reviews, verification, validation, transfer, and design changes. Early implementation supported traceability and systematic capture of development evidence. Although TRLs measure technological maturity, they do not define the regulatory evidence required for market authorization. Therefore, the DHF was also used to organize evidence supporting future commercialization and clinical validation.

2.7. ISO 14971 Risk Management

Risk management was implemented according to ISO 14971, where risk was defined before hazard identification [11]. A Numerical Risk Priority (NRP) approach was adopted: Acceptable ($\leq$7), Conditional (8–14), and Not Acceptable ($\geq$15). NACC risks require a development hold. For the pediatric application, risks with severity $\geq$ 4 required an ALARP evaluation. During Gate G1, twelve failure modes were identified. Torque overload was classified as a critical risk, leading to a temporary engineering hold. Risk controls and residual risk evaluations will support future usability engineering and clinical investigation planning.

2.8. IEC 62304 Software Classification

IEC 62304 principles were applied from Gate G1. Software was classified as Class C (torque control and emergency stop), Class B (sEMG processing), and Class A (logging and HMI). Class C software required $\geq$80% test coverage, watchdog implementation, and formal code review. Software scenario validation supported early identification of software-related hazards and implementation of risk controls.

2.9. Dual Regulatory Pathway (Track A/Track B)

The AMCOR framework establishes a dual regulatory pathway that decouples the early academic prototyping from the industrial-level system. Track A (TRL 1–5) governs institutional research at the National Rehabilitation Institute (INR), ensuring ethical clearance via protocol Reg. No. 104/22 SP-2 under the MPC-DG-01 manual (ISO 9001:2015). It establishes design controls using international baselines (ISO 14971:2019, IEC 62304, IEC 62366-1) to compile a Design History File (DHF/01–DHF/12) under ISO 13485:2016. Conversely, Track B (TRL 6+) addresses clinical translation and industrial scaling. It states compliance with Mexican NOM-241-SSA1-2025 (GMP) to transform research documen-

tation into a formal Technical File for regulatory submission before COFEPRIS (for its acronym in Spanish) or the FDA, encompassing standardized manufacturing and clinical trials for sanitary registration.

2.10. Gate Evaluation Method and Reproducibility

Gate evaluation was performed by a three-member panel including engineering, clinical, and independent external expertise. Reviewers independently assessed DHF evidence before each gate using predefined MET, PARTIAL, or NOT MET criteria. Disagreements were resolved through discussion. GO/HOLD/KILL decisions were signed and filed in the DHF.

2.11. Biomechanical and sEMG Characterization Protocol

Baseline biomechanical characterization for pediatric elbow-assistive design supported Gate G1 using normative pediatric biomechanics and task-based functional requirements [34,35]. Ethics approval was obtained from the INR Research & Ethics Committee with parental consent and child assent. The evidence package included one reference cohort: an ADL study with eight healthy children aged 6–13 years. AMC was defined as a non-progressive congenital condition involving multi-joint contractures, often fixed elbow extension, and limited flexion, affecting feeding, hygiene, reaching, and play. Elbow angle and sEMG were recorded using Biometrics DataLog hardware, an SG110 electrogoniometer, and SX230FW preamplifiers (Biometrics Ltd., Newport, UK) from the biceps, brachioradialis, and triceps muscles at 1000 Hz. sEMG was filtered, rectified, smoothed, and normalized; kinematics was low-pass filtered and differentiated using MATLAB R2020b (MathWorks Inc., Natick, MA, USA). Six functional tasks defined AMCOR requirements: 0–130° flexion range, maximum velocity 747.66°/s, 4.56 Hz frequency content, and 100°/s controlled assistance speed. These parameters directly informed actuator, sensing, safety, and control specifications for elbow flexion assistance in the intended pediatric AMC population.

2.12. The AMC Three-Layer Adaptive Control

The primary objective of the AMCOR control system is to provide both active elbow flexion and extension assistance, driven by using surface electromyography (sEMG) based on patient intention. However, clinical data gathered during the Gate G1 milestone revealed that pediatric patients with severe Arthrogryposis Multiplex Congenita (AMC) present pronounced muscle atrophy and fibrosis in the biceps brachii. Consequently, the extracted sEMG signals are characterized by low amplitudes and poor signal-to-noise ratios, overlapping significantly with baseline noise (<50 μV root-mean-squared). Implementation of a single intention-driven sEMG model under these physiological conditions might introduce high risks of false positives or command unresponsiveness, violating the safety requirements of the framework. Therefore, a three-layer adaptive control architecture was proposed to overcome such a drawback.

The active control layer is dynamically selected every 500 ms based on a Signal Quality Index (SQI), which continuously monitors the root mean square value (RMS) and the signal-to-noise ratio (SNR) of the acquired sEMG signals. The layer-selection rule was implemented as follows. Layer 1 (Postural Control) is selected when SNR < 3 dB and RMS < 20 μV. Layer 2 (Proportional Assistance) is selected when 3 dB $\leq$ SNR $\leq$ 10 dB or 20 μV $\leq$ RMS $\leq$ 100 μV. Layer 3 (Bio-cooperative Control) is selected when SNR > 10 dB and RMS > 100 μV.

A block diagram of the proposed controller is shown in Figure 2 and Table 2, where the complete control architecture and signals between layers can be appreciated. The aforementioned layers are detailed below:

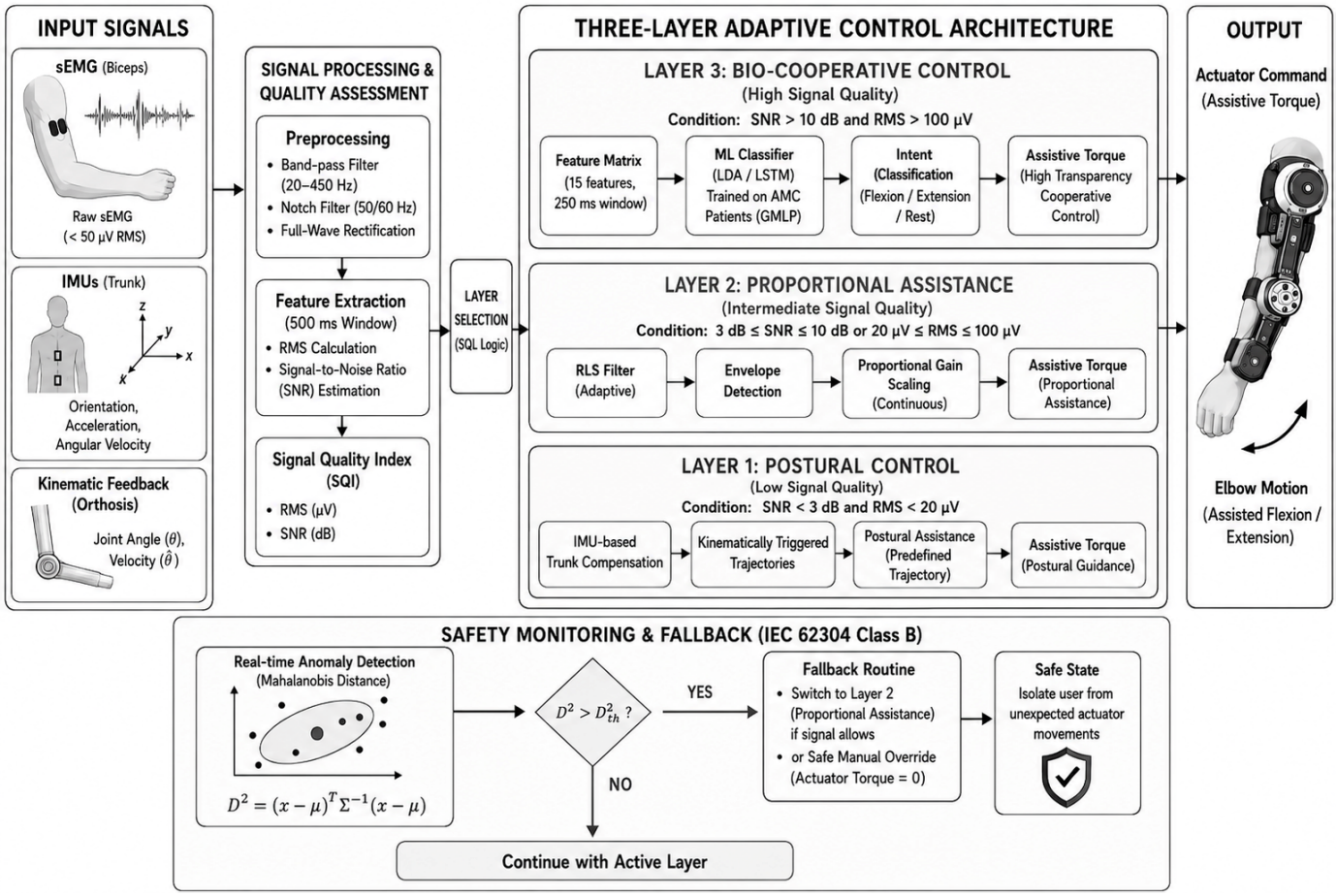

Figure 2. Block diagram of the three-layer controller. Arrows indicate signal and control flow. The figure was generated using ChatGPT Images 2.0 (OpenAI, San Francisco, CA, USA, 2026) from structured textual content developed, reviewed, and verified by the authors.

Table 2. Control performance metrics.

Control Layer	Monitored Variable	Performance Metric	Target Threshold
Postural control	Elbow angular position Noise robustness	RMS error False positive activations	<5.0° 0/20 trials
Proportional assistance	RLS filter output Torque saturation	Convergence time Hardware peak limitation	<100 ms ≤8 N·m
Bio-cooperative control	Intent classification Processing window	Multi-class accuracy Execution latency	≥85% <250 ms
Safety monitor	Feature drift Automated fallback	Mahalanobis distance Routine transition latency	$D^2 \leq D^2_{threshold}$ <500 ms

RMS: root mean squared; RLS: recursive least squares.

2.12.1. Layer 1: Postural Control

When muscle activation is insufficient (SNR < 3 dB and RMS < 20 μV), the system completely bypasses the sEMG inputs to avoid dangerous random triggers. In this state, joint guidance transitions depend entirely on kinematically triggered trajectories. Moreover, trunk compensation mechanisms are measured using inertial measurement units (IMUs) placed on the patient's torso to infer motion initiation so that a structured and predefined postural assistance can be supplied, thereby generating the desired elbow's angular position θ_{desired}. The postural assistance control is given by

$$\tau_a(t) = K_p e_\theta(t) + K_p \dot{e_\theta}(t) + \tau_{grav}(\theta_{elbow}), \quad (1)$$

where $e_\theta = \theta_{\text{desired}} - \theta_{\text{elbow}}$ is the position error of the elbow, $\tau_{\text{grav}}(\theta_{\text{elbow}})$ is the gravity compensation torque for both the patient's arm and the orthosis, and K_p and K_d are positive scalar gains.

2.12.2. Layer 2: Proportional Assistance

In intermediate signal conditions (20–100 μV and SNR, between 3 and 10 dB), a stable proportional assistance law is executed. To handle non-stationary muscular outputs as well as sudden signal drops caused by fibrotic tissue, raw inputs are processed via the recursive least squares (RLS) filter coupled with an envelope detection algorithm. The continuous assistance gain is scaled proportionally to the filtered signal envelope, preventing sudden torque discontinuities, and it is given by

$$\tau_a(t) = \alpha \cdot E(t) \cdot J(\theta_{elbow}), \quad (2)$$

where α is a gain adjusted each session based on the baseline maximum voluntary contraction (MVC) of the patient, $E(t)$ is the envelope obtained from the RLS filter and $J(\theta_{\text{elbow}})$ is the Jacobian that maps forces to torque. It is worth remarking that $\tau_a(t)$ is hardware-constrained to 8 Nm to protect the physical integrity of the patient.

2.12.3. Layer 3: Bio-Cooperative Control

Under optimal signal quality (SNR > 10 dB and RMS > 100 μV), motion intent is classified using machine learning models, namely, Linear Discriminant Analysis (LDA) or Long Short-Term Memory (LSTM) networks. According to Good Machine Learning Practices (GMLP) for medical applications, these models are trained strictly on data obtained from AMC patients, utilizing a 15-feature matrix extracted from sliding windows of 250 ms. System generalizability is validated using a Leave-One-Patient-Out (LOPO) cross-validation protocol.

2.12.4. Safety Monitoring and Fallback Conditions

Following the IEC 62304 Class B medical software requirements, the active control loop integrates a real-time anomaly detection monitor based on Mahalanobis distance (D^2). If biosignal degradation or signal drift is detected, and the distance exceeds a safety threshold ($D^2 > D^2$thr), then the system automatically triggers a fallback routine to Layer 2 or a safe manual override, thereby isolating the user from unexpected actuator movements.

2.12.5. Mechanical and Electrical Safety Constraints

AMCOR operationalizes risk management through a "risk-to-constraint" transformation, converting identified hazards into verifiable quantitative engineering requirements [11]. For pediatric orthoses, safety is expressed as measurable constraints governing mass, structural integrity, and fatigue. The framework incorporates specific state torque limits, including resistive torque characterization (0.3 to 5.0 N·m) and a non-negotiable 8 N·m mechanical limiter threshold. These constraints are falsifiable; violating them allows governance to block progression until compliance is demonstrated.

Electrical and thermal constraints act as layered safety barriers rather than software-dependent behaviors, adhering to IEC 60601-1. Thermal safety and the 8 N·m mechanical threshold utilize independent hardware-enforced mechanisms, ensuring safety regardless of software state [16]. This independence follows software lifecycle thinking where protective barriers must remain effective even if software is degraded [11,31]. AMCOR treats safety constraints as enforceable design controls that allow the governance system to pause advancement when safety verification is incomplete.

3. Results

3.1. Implementation Evidence (Prospective Governance Validation)

AMCOR emphasizes prospective governance over retrospective reconstruction to ensure auditable decisions. The DHF serves as the central backbone, integrating design controls and risk records to prevent prototypes from outstripping justification [10,11]. Governance artifacts must have decision authority; risk policies prevent threshold shifting. Gate G0 establishes institutional readiness via ethics approval and DHF activation. Crucially, the "ability to stop" is a functional requirement, ensuring that technical feasibility alone does not justify clinical use. This enforceable evidence system maintains safety discipline and traceability in resource-constrained environments.

3.2. Gate G0—Identification and Planning

Gate G0 serves as the entry condition for defensible development in AMCOR, ensuring technical work does not outpace ethics readiness, risk governance, and traceability infrastructure. It prevents accumulation of traceability debt by establishing an institutional anchor through clinical need validation, an operational DHF, a risk management plan, and active ethics approval. Sequencing risk governance before detailed hazard identification aligns with ISO 14971, reducing post hoc threshold shifting [11]. Early DHF activation also aligns with ISO 13485 intent, ensuring traceability exists as the design evolves [10].

Methodologically, G0 reframes planning as a verifiable governance state rather than a declarative intention. For pediatric AMC orthosis development in LMIC institutions, G0 ensures subsequent work generates admissible evidence within defined boundaries: design decisions are traced, and risk acceptability remains stable. This foundation allows later gates to evaluate proof-of-concept evidence and risk control adequacy under an auditable governance logic.

3.3. Gate G1—Biomechanical Baseline and Concept Architecture

Gate G1 assessed whether AMCOR had sufficient biomechanical, architectural, risk management, ethical, and traceability evidence to move from early concept definition to Stage 2 engineering. It functioned as a binding governance decision within the integrated Biodesign, Stage-Gate, TRL, and ISO-based framework, rather than as a conventional academic milestone. Its purpose was to determine whether continued development of a pediatric active robotic orthosis for children with arthrogryposis multiplex congenita was justified by auditable evidence and acceptable safety controls.

Seven criteria were evaluated, five critical and two major; see Table 3. The critical criteria addressed pediatric elbow biomechanical characterization, evidence-based safety limits, adaptive control architecture, bidirectional requirements traceability, and initial FMEA-based risk analysis. The major criteria addressed ethics approval and sEMG signal quality characterization. Five criteria were classified as MET and two as PARTIAL, leading to a Conditional GO. Stage 2 engineering could begin, but Gate G2 approval was blocked until the unresolved torque-risk verification nonconformity was closed.

The biomechanical evidence informed assisted ROM, torque limits, control thresholds, and validation planning. The assisted elbow ROM safety envelope was updated to 0–130°, transforming it from an assumption into a design requirement, verification criterion, and FMEA risk control boundary.

Table 3. Gate G1 evaluation record for biomechanical baseline and concept architecture.

Criterion ID	Weight	Criterion	Evidence Reviewed	Result	Gate Decision	DHF Source
G1-C01	CRITICAL	Baseline biomechanical data from pediatric AMC elbows are available.	ROM and sEMG data from pediatric AMC participants.	MET	GO	Biomechanics: elbow biomechanical study
G1-C02	CRITICAL	Evidence-based safety limits defined.	Assisted elbow ROM safety envelope updated to 0–130°.	MET	GO	Biomechanics: elbow biomechanical study
G1-C03	CRITICAL	Concept architecture specified.	Three-layer adaptive control architecture, Signal Quality Index (SQI), five system subsystems, and seven formal interfaces.	MET/PARTIAL for full verification	Conditional GO	Systems engineering; ICD; DDR
G1-C04	CRITICAL	Requirements traceability established.	Bidirectional RTM with verifiable NC → Req → Risk → Test links; URS with 38 items in 10 domains.	MET	GO	Requirements: RTM and URS
G1-C05	CRITICAL	Initial FMEA completed and safety risks identified.	FMEA with ≥5 hazards; torque-overload risk identified; hardware torque limiter not yet experimentally verified.	PARTIAL	HOLD	RMF: risk management plan and FMEA
G1-C06	MAJOR	Ethics protocol approved for human-subject activities.	Institutional ethics approval, informed consent, and assent materials were prepared under applicable human-subject research requirements.	MET	GO	Ethics and privacy file
G1-C07	MAJOR	sEMG signal quality characterized in the AMC population.	sEMG amplitudes are approximately 10–50 μV, and low SNR in more affected patients.	MET	GO	Literature review: biomechanics file

MET/GO: criterion fully satisfied-progression allowed; PARTIAL/Conditional GO: core criterion met, but verification remains open-progression allowed with tracked nonconformity; PARTIAL/HOLD: safety-critical evidence incomplete-progression blocked until resolved; "→" indicates a traceability sequence; AMC, arthrogryposis multiplex congenita; DDR, detailed design review; DHF, Design History File; FMEA, Failure Mode and Effects Analysis; ICD, interface control document; NC, nonconformity; RMF, risk management file; ROM, range of motion; RTM, requirements traceability matrix; sEMG, surface electromyography; SQI, Signal Quality Index; URS, User Requirements Specification.

3.4. Control Architecture Redesign—Governance-Driven Decision

The G1 sEMG finding of low-amplitude, poor-quality signals led to a formal change request. The original single-layer myoelectric controller was deemed unsafe and replaced with a traceable three-layer adaptive architecture, governed by a Signal Quality Index, allowing fallback to safer assistance modes when sEMG quality is poor and showing how clinical evidence directly governed AMCOR design decisions. This was rated PARTIAL because full verification of thresholds, fallback behavior, and safety response remained pending.

This redesign operationalized the evidence-to-requirement pathway described in Section 2.2. The low-amplitude and low-SNR sEMG finding was treated as a risk-related design input and evaluated as a potential source of unintended activation or failure to detect movement intention. Consistent with the risk control principles of ISO 14971, this evidence was translated into requirements for signal quality assessment, controlled mode selection, anomaly detection, and fallback behavior. These requirements were maintained under the design control and traceability principles of ISO 13485 and implemented within the software architecture following the lifecycle and risk management processes of IEC 62304, resulting in the three-layer adaptive control architecture.

3.5. User Requirements Specification Summary

The requirements traceability matrix was accepted as MET. It linked 38 user requirements across 10 domains to clinical needs, technical requirements, risks, tests, populations, and acceptance criteria, demonstrating that AMCOR was progressing as a traceable medical robotics system rather than an informal prototype; see Table 4. However, the FMEA was rated PARTIAL because the hardware torque limiter had not yet been experimentally verified, generating NC-001.

Table 4. User Requirements Specification, linking 38 requirements across 10 domains to measurable acceptance criteria.

Domain	Number of Items	Example Requirement	Key Acceptance Criterion
1. Intended use	2	Assist elbow flexion in children with AMC; supervised clinical/home use	Use consistent with indication; no application in contraindicated conditions
2. Target population	4	Children 4–14 years with AMC; limited ROM; low/absent sEMG	Inclusion per clinical criteria; exclusion of non-intended conditions
3. Use environment	3	Occupational therapy; supervised home use; safe storage	Stable operation at 15–40 °C, 20–80% RH non-condensing
4. Clinical functionality	5	Assist ROM 0–120°; facilitate hand-to-mouth task; compensate low muscle activation	Assisted ROM $\geq$ 115° in $\geq$90% of trials; trajectory error $\leq$ 5°
5. Technical performance	7	Assisted torque $\geq$ 1.5 N·m; operation with sEMG $\geq$ 20 μV; automatic EMG/IMU transition	Accuracy $\geq$ 90%; latency $\leq$ 200–500 ms; SQI layer selection in $\geq$19/20 trials
6. Patient safety	6	Max torque $\leq$ 8 N·m; emergency stop; surface temp $\leq$ 41 °C; leakage current < 10 μA	0 torque exceedances in 20 trials; emergency stop $\leq$ 100 ms in 100% of tests

Table 4. *Cont.*

Domain	Number of Items	Example Requirement	Key Acceptance Criterion
7. Usability/HFE	4	Caregiver donning; simple activation; visual/auditory feedback; intuitive therapist interface	Donning $\leq$ 5 min; 0 critical errors; SUS $\geq$ 70 in formative evaluation
8. Data and cybersecurity	3	CSV export; pseudonymization; access control; session logs	AES-256 encryption; no direct identifiers; restricted access
9. Maintenance and support	2	Guided quarterly recalibration; maintenance by certified technician	Recalibration $\leq$ 10 min; no critical errors; documented technical actions
10. Regulatory compliance	2	Compliance with ISO 13485, NOM-012-SSA3-2012 [36], NOM-241-SSA1-2025, ISO 14971, IEC 62304, IEC 62366-1, human research requirements and biocompatibility	Complete documentary evidence; UR-DS-FMEA-V&V traceability; DHF approval

ROM: range of motion; RH: relative humidity; SUS: System Usability Scale; SQI: Signal Quality Index; V&V: verification and validation.

3.6. Internal Quality Audits

Five internal quality audits were conducted. All resulted in Pass (with AUD-03 and AUD-04 carrying minor observations subsequently closed before the following Gate). Table 5 summarizes key findings.

Table 5. Summary of AMCOR internal quality audits AUD-01 through AUD-05.

Audit	Scope	Gate	Result	Key Finding	Actions
AUD-01	QMS (ISO 13485 §4)	Pre-G0	Pass	QMS-001 v1.0 operational; document control active	1 minor observation: training pending for 1 team member
AUD-02	Risk Management (ISO 14971 §4–6)	Pre-G0	Pass	P $\times$ S policy signed before FMEA initiation; 5 hazards documented	RMF-003 signature confirmed
AUD-03	DHF Completeness (§7.3)	Pre-G1	Pass with observations	12/15 DHF documents effective; 3 pending	NC-001 open; signature collection timeline incorporated in G1 post-gate action plan
AUD-04	Acquisition & Suppliers (§7.4)	Annual Year 1	Pass with observations	Shimmer 3 qualification in progress; supplier matrix configured	Shimmer B qualification target
AUD-05	Ethics & Privacy (NOM-012-SSA3-2012; LFPDPSO)	Annual Year 2	Pass	Study: pseudonymization operational (SHA-256 + AES-256)	Ethics evaluation

QMS: quality management system; DHF: Design History File; P $\times$ S: probability $\times$ severity; FMEA: Failure Mode and Effects Analysis; NC: nonconformity; LFPDPSO: Mexican Federal Law on the Protection of Personal Data Held by Obligated Entities.

3.7. The HOLD Decision as Framework Validation

The strongest validation of the framework is functional rather than documentary: the HOLD condition generated at Gate G1. The NACC designation on MTR-09 was not predetermined; it emerged when the FMEA team calculated that the probability of undetected excessive torque delivery to a pediatric osteopenic joint, in the absence of an experimentally verified hardware limiter, exceeded the COND threshold. The formal HOLD prevented the proof-of-concept build from commencing—engineering work that was technically feasible but not yet demonstrably safe for a pediatric user. This formalized risk criterion with operational authority to pause engineering is precisely what ISO 14971 intends, but is rarely achieved in academic contexts. It demonstrates that the framework has operational, not merely documentary, authority within the AMCOR project. This decision allowed technical progress while preventing unsafe advancement until a critical safety control was verified, supporting the claim that early-stage academic medical robotics can be made safer through predefined, auditable, risk-based decision rules.

3.8. Resource Viability

AMCOR governance costs were estimated from staff time, documentation, gate preparation, audits, software, tools, and DHF infrastructure. Main costs relate to maintaining traceability across decisions, FMEA, RTM, and specifications, concentrated in Stage 1. Annual operation is estimated at USD 3000, feasible for small academic teams.

4. Discussion

Four main novelty contributions were described. First, a prospective integration of five standards into a single operational framework (Biodesign + Stage-Gate + TRL + ISO 13485 + ISO 14971) is proposed, overcoming the usual fragmented approaches. Second, its implementation is feasible in public institutions of LMIC by an expert panel. Third, a hold decision based on the risks identified by the FMEA in an academic robotics context is documented; this is not a common practice reported in the literature. Fourth, the introduction of a dual regulatory model (Path A/Path B) adapted to LMIC contexts represents a flexible strategy for the development of medical devices. Although works combining approaches such as Stage-Gate, TRL, and ISO have been reported previously [8,22], the main contribution of this study is focused on the structural and operative integration of these frameworks with the Biodesign methodology for the development of a pediatric rehabilitation robotic orthosis. The contribution consists of proving the viability, traceability, and complementarity between needs-centered approaches (Biodesign), technological maturity (TRL), design control (Stage-Gate), and the management of quality and risk (ISO 13485 and ISO 14971). This aims to address the lack of integrated frameworks to link clinical innovation, regulation, risk management, and technological advancement in the early stages of medical device development. Additionally, the generalizability of the results is limited because the validation was performed at a single institution and consists only of two gates; therefore, to strengthen the framework's robustness, external replication, which is currently underway, is required. Furthermore, the Path A/Path B model was designed for the Mexican context; consequently, it requires adaptation for regulatory environments such as those of the European Union or the United States (FDA). Moreover, the translational impact is limited because the study was focused on the methodological structure rather than on clinical outcomes assessments. Finally, a relevant methodological gap was identified, i.e., the lack of inter-rater reliability analysis, needed to ensure consistency in the classification of criteria (e.g., PARTIAL vs. MET). However, this represents a clear area of opportunity for future research.

The transition of robotic prototypes from proof-of-concept to clinical validation—TRL 3 to 5 bottleneck—represents a significant methodological challenge, particularly for academic groups in resource-constrained settings, necessitating a shift toward prospective governance models. To effectively mitigate this gap, it is recommended that projects initiate development with a formal Risk Management Plan anchored in institutional mandates, such as mandatory ethics committee approval at Gate G0, while simultaneously establishing explicit GO/HOLD/KILL criteria from the outset to counteract common academic sunk-cost biases. This governance is further strengthened by adopting a dual regulatory pathway that separates academic design controls (Track A) from future commercial manufacturing requirements (Track B), allowing the DHF to function as a living tool that ensures real-time traceability and prevents the accumulation of traceability debt.

The cornerstone of this integrated governance framework is the multidisciplinary review panel, which enforces a rigorous separation of duties frequently absent in academic settings. By including technical, clinical, and quality experts alongside an independent external reviewer, the framework creates a structural counterweight to the internal optimism and developer–evaluator conflation common in research groups. This panel holds genuine GO/HOLD/KILL authority, ensuring that progression to the next TRL depends on completeness and risk acceptability rather than on mere engineering momentum. Such deterministic logic is vital for protecting vulnerable pediatric populations, as it transforms the gate-review process into a binding decision boundary where safety-critical evidence—such as biomechanical baselines—is rigorously challenged before any human interaction occurs. Consequently, the external reviewer ensures that gate criteria are not relaxed to accommodate technical delays, maintaining the project's ethical and regulatory integrity.

Implementing these practices yields substantial benefits, primarily by reducing confirmation bias through established risk limits and acceptability policies that force objective prototype evaluation. This methodology guarantees that all design decisions yield auditable and defensible records, compiled in real time within the DHF to prevent traceability debt that often blocks clinical validation. Furthermore, the framework strengthens safety in clinical translation by converting identified hazards into quantitative engineering constraints. This integrated approach integrates the governance gap in resource-constrained settings, providing a replicable model that facilitates a defensible transition from academic prototyping in Track A to formal manufacturing and regulatory registration in Track B. By treating safety as an enforced design control rather than a post hoc documentation exercise, the framework ensures a reliable path toward clinical efficacy.

The Role of Intellectual Property, Government Support, and Industry Partnerships in Translating Medical Devices from Laboratory to Clinical Practice

For LMICs, such as Mexico, going from the early stages of technological maturity (TRL1–TRL3) to validation in a relevant environment (TRL5) and, subsequently, scaling up to commercialization (TRL9) highly depends on a well-articulated ecosystem among the academy, government, and industry. Moreover, appropriate public policies are fundamental to articulating the innovation ecosystem by defining national priorities, developing strategies for technological risk reduction, and defining mechanisms for early adoption of new technologies. In Mexico, the government can help to catalyze this process by funding mechanisms of the Secretariat of Science, Humanities, Technology, and Innovation (SECIHTI). The most common are calls for proposals focused on developing medical devices and technologies with high potential for reaching clinical application. Ministries of science and technology play a key role by providing funding for translational research and establishing innovation programs to reduce the gap between laboratory developments and their clinical validation, increasing the possibility of product commercialization. In Mexico, the General Law on Humanities, Sciences, Technologies, and Innovation (2023) establishes,

among others, the framework for public funding of research and collaboration between the academy and industry. Moreover, it includes mechanisms that promote private sector participation and consider the protection of intellectual property, an important element of health innovation. Furthermore, spin-offs created by universities or public research centers may qualify for federal tax incentives under specific entrepreneurship programs, which further foster collaboration between academia and industry. In this context, intellectual property is crucial to achieve technology transfer to industry. Protected intellectual property makes it possible to establish clear conditions for commercial exploitation and, most importantly, attract private investment. Additionally, the generation of structured technical documentation (DHF) ensures traceability, design control, and regulatory compliance. All these elements together reflect how the ecosystem can be prepared for the transition to commercialization in stages after TRL6, where commercial viability, regulation, and production scalability are crucial.

The successful transition of the AMCOR robotic orthosis from a research-validated prototype to a clinically available medical device depends on a structured Intellectual Property (IP) strategy that safeguards technical innovations while facilitating institutional technology transfer. Currently, according to the institutional Quality Planning Manual (MPC-DG-01), the project is situated within the results disclosure phase, which encompasses the formal preparation of patent documentation and the internal registration for patent control. This stage ensures that the technical novelty established during TRL 1 to 5 is appropriately protected before wider dissemination or the initiation of commercial-grade development under Track B.

Regarding the international filing timeline, the project follows a tiered strategy initiated by a national filing in Mexico through the Mexican Institute of Industrial Property (IMPI), followed by a Patent Cooperation Treaty (PCT) application within the mandatory 12-month priority window. This international pathway provides a 30-month evaluation period to determine the feasibility of entering the United States (USPTO) and European (EPO) markets, a horizon that aligns with the 5-to-8-year translational trajectory defined for Track B industrial scaling. This phased approach allows the academic team to mature the technology evidence chain within Track A institutional compliance before committing to the full financial and regulatory burden of international patent maintenance.

Finally, the project adopts a Technology Transfer licensing model rather than an institutional manufacturing approach, aiming to maintain device accessibility in resource-constrained LMIC settings. Under this model, the INR-LGII intends to license the DHF to certified industrial partners. For the transition to Track B, these partners must possess NOM-241-SSA1-2025 certification to transform the academic DHF into a formal Technical File for COFEPRIS or FDA registration. This framework ensures that while the core research remains anchored in the public institution, the path toward mass production and clinical distribution is supported by professional manufacturing expertise.

5. Conclusions

The present case study validates an integrated governance framework that systematically integrates Biodesign, Stage-Gate, TRL assessment, ISO 13485, ISO 14971, and IEC 62304 into a unified development workflow. This model, specifically optimized for academic medical robotics in resource-constrained LMIC settings, demonstrates that high-quality design controls are achievable even under limited research budgets. The primary innovation is the multi-standard integration within a single, scalable architecture, which addresses the governance gap that typically stalls academic prototypes at early TRL and frequently prevents them from reaching clinical validation.

This research presents operational evidence from the initial two gates as a proof-of-concept for the governance paradigm rather than clinical efficacy. Gate G0 successfully established a robust governance baseline, ensuring that institutional ethics, risk policies, and regulatory frameworks were operational prior to engineering surpassing safety planning. Subsequently, at Gate G1, the framework's Failure Mode and Effects Analysis (FMEA) identified unverified torque-limiting constraints, triggering a binding HOLD decision that effectively prevented the progression of an unsafe prototype. This event demonstrates that the framework possesses authentic decision-making authority, subordinating technical progress to auditable safety evidence. Moreover, this framework governed a critical design pivot in response to the low sEMG signals (<50 μV RMS) characterized in patients with AMC: the project transitioned toward a three-layer adaptive control architecture based on Signal Quality Index (SQI) thresholds, a choice influenced by the governance process rather than arbitrary technical preference.

The governance architecture of this framework is the multi-member multidisciplinary panel, including an independent external reviewer, which converts technical documentation into binding safety decisions. We recommend this panel model as the minimum standard for academic groups to ensure translational transparency. In conclusion, while clinical efficacy remains to be established in future TRL 5+ stages, this study confirms that auditable and replicable development at early stages (TRL 1–3) is feasible in LMICs. A commitment to future governance, clearly defined organizational responsibilities, and genuine decision authority are necessary to prevent traceability debt and ensure a defensible path toward clinical interaction.

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Data Availability Statement: Gate records, RTM templates, FMEA excerpts, audit checklists, and the governance charter will be shared in a public repository upon acceptance; anonymized biomechanical/sEMG data and code will follow ethics approval and prototype validation.

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Abbreviations

The following abbreviations are used in this manuscript:

ADC	Analog-to-Digital Converter
ADL	Activities of Daily Living
AES	Advanced Encryption Standard
AI	Artificial Intelligence
ALARP	As Low as Reasonably Practicable
AMC	Arthrogryposis Multiplex Congenita
AMCOR	Arthrogryposis Multiplex Congenita Orthosis for Rehabilitation
BLE	Bluetooth Low Energy
BMS	Battery Management System
COFEPRIS	Federal Commission for the Protection against Sanitary Risks
DHF	Design History File
EMG	Electromyography
FDA	United States Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
FSR	Force-Sensitive Resistor
GAI	Generative Artificial Intelligence
GMLP	Good Machine Learning Practice
HFE	Human Factors Engineering
HMI	Human–Machine Interface
I2C	Inter-Integrated Circuit
ICD	Interface Control Document
IEC	International Electrotechnical Commission
IMU	Inertial Measurement Unit
INR	Instituto Nacional de Rehabilitación Luis Guillermo Ibarra Ibarra
ISO	International Organization for Standardization
LDA	Linear Discriminant Analysis
LFPDPSO	Federal Law on the Protection of Personal Data Held by Obligated Entities
LMICs	Low- and Middle-Income Countries
LOPO	Leave-One-Patient-Out
LSTM	Long Short-Term Memory
ML	Machine Learning
MPC	Model Predictive Control
MVC	Maximum Voluntary Contraction
NACC	Not Acceptable
NC	Nonconformity
NOM	Mexican Official Standard
NRP	Numerical Risk Priority
PDR	Preliminary Design Review
PWM	Pulse Width Modulation
QMS	Quality Management System
REST	Representational State Transfer
RH	Relative Humidity
RLS	Recursive Least Squares
RMF	Risk Management File
RMS	Root Mean Square
RMSE	Root Mean Square Error
ROM	Range of Motion
RTM	Requirements Traceability Matrix

sEMG	Surface Electromyography
SNR	Signal-to-Noise Ratio
SPI	Serial Peripheral Interface
SQI	Signal Quality Index
SUS	System Usability Scale
TRL	Technology Readiness Level
UART	Universal Asynchronous Receiver–Transmitter
URS	User Requirements Specification
V&V	Verification and Validation

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