

CareLink- Seizure Alert & Family Escalation

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PROJECT / BUSINESS PROPOSAL

HEALTH CARE PROBLEM

Adolescents with epilepsy may have seizures in away-from-home settings where trained responders or clear protocols are not present, delaying first aid, increasing injury risk, and limiting timely communication to families and clinicians. In more than 70% of cases, first aid is delayed beyond two minutes, raising the likelihood of severe injury or hospitalization. Epilepsy affects over 50 million people worldwide (WHO, 2023), and adolescents in residential environments face a heightened safety gap due to inconsistent Seizure Action Plans (SAPs), poor communication protocols, and limited peer training. In the United States, about 336,000 children and adolescents experience seizures each year, highlighting the scope of this problem at a national level (Zack & Kobau, 2017). The financial burden is significant: in the U.S. alone, direct and indirect costs of epilepsy exceed \$15.5 billion annually (CDC, 2024), with emergency visits and hospitalization representing a large share. This makes the problem urgent and in need of a digital, scalable solution.

SOLUTION PROPOSAL

The proposed solution is CareLink (Seizure Alert & Family Escalation), a cloud-based SaaS platform that integrates wearable technology with real-time escalation workflows. CareLink connects consumer-grade devices, such as the Apple Watch, to a centralized monitoring system that analyzes seizure activity using motion, accelerometer, and heart rate data. When abnormal activity consistent with a convulsive seizure is detected, CareLink triggers automated alerts through secure messaging platforms like Twilio. Notifications follow a role-based chain: family and guardians are contacted first, nearby peers or caregivers second, and clinicians or emergency responders last. For environments with poor connectivity, peer-to-peer fallback ensures alerts still reach designated contacts.

This solution directly addresses the critical gap in seizure management for individuals living in away-from-home or unsupervised care settings, where trained responders or clear protocols may not exist. Delayed intervention is a major safety risk; studies show that living alone increases the risk of SUDEP (Sudden Unexpected Death in Epilepsy) fivefold, and nearly 69% of SUDEP cases could be prevented if patients were not unattended at night (Sveinsson et al., 2020). Furthermore, 43% of people with epilepsy report at least one seizure-related injury in their lifetime, with ~10% injured in just the past year, often due to falls or burns during unwitnessed seizures (Neurology Today, 2021). Without timely care, seizures can escalate to status epilepticus, where delayed treatment of more than one hour cuts good recovery outcomes nearly in half (82% vs. 46%) and increases ICU admissions (Kapur et al., 2019). CareLink mitigates these risks by ensuring rapid detection and escalation, reducing delays in first aid, and enabling data-driven follow-up. By reducing seizure-related hospitalizations and emergency department visits costs that are more than double for uncontrolled epilepsy compared to stable patients (Begley et al., 2021) CareLink directly contributes to lowering avoidable healthcare utilization.

The scope of CareLink extends beyond individual households or institutions. Initially designed for adolescents in unsupervised environments, it can scale across community living facilities, outpatient care, and home-based management. Its SaaS delivery model supports per-patient licensing, EHR/EMS integration, and insurer partnerships, offering both clinical and financial transformation. The financial burden of epilepsy is significant: in the U.S., seizures result in over 1 million ED visits and 280,000 hospitalizations annually, costing an estimated \$2.5 billion per year (CDC, 2020). Uncontrolled epilepsy patients incur more than double the yearly costs of those with stable control, largely due to emergency care (Begley et al., 2021). By enabling faster intervention and reducing hospitalizations, CareLink has the potential to meaningfully lower this economic strain.

Evidence also supports the technical feasibility of CareLink. A multicenter Apple Watch trial demonstrated reliable seizure detection in both monitoring units and real-world ambulatory settings (Shah et al., 2024).

Similarly, the FDA-cleared Embrace2 wearable achieved 98% detection sensitivity for generalized tonic-clonic seizures, with alarm latency of only seconds (Regalia et al., 2019). Importantly, studies show that wearable seizure detection reduced seizure-related injuries in about 30% of patients and improved quality of life by reducing anxiety and caregiver burden (Elger & Hoppe, 2018). CareLink builds on these proven capabilities but goes further by combining wearable detection with multi-party escalation, offline redundancy, and EHR integration. By leveraging real-time monitoring, cloud connectivity, and consent-driven workflows, CareLink offers a comprehensive, scalable, and evidence-based solution that not only reduces harm and costs but also empowers families, clinicians, and patients in unsupervised settings.

VALUE

CareLink delivers measurable value across the Institute for Healthcare Improvement's Triple Aim. First, it improves population health outcomes by reducing seizure-related injuries, hospitalizations, and mortality through faster intervention. Second, it enhances the patient and family experience by providing real-time alerts and peace of mind, lowering stress and anxiety associated with away-from-home seizures. Third, it reduces the per capita cost of care by preventing expensive emergency visits and hospitalizations; uncontrolled epilepsy currently drives costs more than double those of stable patients, with annual U.S. inpatient costs exceeding \$2.5 billion (CDC, 2020). Extending to the Quadruple Aim, CareLink also supports provider well-being, offering clinicians structured, EHR-integrated data rather than fragmented reports. Together, these benefits position CareLink as both a safety innovation and a financially sustainable model for digital health transformation.

COMPETITIVE DIFFERENTIATION

Several seizure monitoring solutions already exist, including the FDA-cleared Embrace2 wristband, Apple Watch based detection apps such as EpiWatch or Inspyre, and the NightWatch nocturnal monitor. While these products demonstrate strong detection capabilities for generalized tonic-clonic seizures, they also reveal critical limitations: reliance on constant smartphone connectivity, lack of multi-party escalation, minimal integration with clinical systems, and limited applicability in unsupervised or away-from-home environments. CareLink builds on these advances but provides distinct advantages. Its consent-based, multi-party escalation model ensures alerts reach both families and on-site peers, while peer-to-peer offline fallback maintains safety even without network coverage. Moreover, its SaaS delivery model allows scalable adoption across organizations and cost-effective licensing, and its FHIR/EHR integration embeds seizure data directly into clinical workflows. These differentiators make CareLink uniquely suited to safeguard adolescents and other vulnerable individuals living away from direct medical supervision.

VISION AND MISSION STATEMENTS

Vision: *Every individual with epilepsy living away from direct supervision is safeguarded by trusted, real-time seizure monitoring and rapid response technology.*

Mission: *To empower families, caregivers, and clinicians with reliable, consent-based monitoring and escalation tools that reduce seizure-related risks, improve care coordination, and provide peace of mind.*

CareLink's mission and vision are grounded in the belief that safety, independence, and connectivity must coexist for vulnerable populations. The mission emphasizes providing a seamless, technology-enabled safety net that engages the right responders at the right time, while respecting patient consent and privacy. By focusing on multi-party, role-based escalation and integration with clinical workflows, CareLink directly fulfills this purpose.

The vision articulates a desired future where seizures, even in unsupervised or away-from-home settings, no longer carry disproportionate risks due to delayed responses or fragmented communication. CareLink enables this future by bridging the gap between patients, families, peers, and clinicians through real-time alerts, offline redundancy, and interoperable data sharing.

Together, the vision and mission align with broader goals of digital transformation in healthcare enhancing patient safety, reducing preventable harm, and integrating technology into care delivery systems. CareLink is not only a monitoring tool but also an enabler of trust and independence, ensuring that adolescents and adults with epilepsy can live more confidently while their families and healthcare teams remain informed and engaged.

SWOT ASSESSMENT

| Name of Organization: | CareLink Health Technologies |
|---|--|
| External Appraisal | Internal Appraisal |
| Opportunities: <ul style="list-style-type: none"> • Growing adoption of wearable health devices and FDA-cleared seizure monitoring technology. • Rising demand for remote patient monitoring and digital health solutions in unsupervised or away-from-home care settings. • Increasing healthcare investment in interoperability (FHIR/EHR integration) and value-based care models. • Potential for insurer partnerships to reduce costly emergency visits and hospitalizations. | Strengths: <ul style="list-style-type: none"> • Consent-based, multi-party escalation model ensures broader and faster response than competitors. • Peer-to-peer offline fallback provides resilience in low-connectivity environments. • SaaS delivery model allows cost-effective scaling across schools, care facilities, and communities. • Integration with FHIR/EHR enables direct value for clinicians and health systems. |
| Threats: <ul style="list-style-type: none"> • Competition from established solutions (e.g., Embrace2, Apple Watch EpiWatch, NightWatch). • Privacy and compliance challenges (HIPAA, GDPR) that could slow adoption. • Risk of regulatory delays in obtaining approvals for new features. • Possible technology fatigue or lack of trust if false alarms occur too frequently. | Weaknesses <ul style="list-style-type: none"> • Dependence on wearable adoption and user compliance (consistent device use). • Potential technical challenges with false positives or negatives. • Need for significant stakeholder training and change management for successful deployment. • Start-up brand recognition is low compared to established players. |

IMPLEMENTATION STRATEGIES (MODULE 6 ASSIGNMENT)

IT GOVERNANCE ALIGNMENT (MODULE 6)

STRATEGIC ALIGNMENT

CareLink directly aligns with institutional priorities around patient safety, timely escalation, and digital care coordination. The solution addresses the suboptimal situation identified in earlier stages—delayed seizure response and lack of consistent communication among caregivers, clinicians, and family members. By integrating wearable data, cloud alerts, and EHR documentation, CareLink supports The Quadruple Aim:

1. Improved patient outcomes (rapid first aid reduces seizure complications).
2. Enhanced patient/family experience (peace of mind through real-time updates).
3. Lower healthcare costs (reduces ED admissions and unplanned visits).
4. Improved clinician well-being (reduces manual monitoring and follow-up calls).

From a business standpoint, CareLink introduces a new SaaS revenue model—per-patient subscription with integrations for EHR and emergency systems. This transforms traditional one-time hardware sales into an ongoing, data-driven service model.

Strategically, the initiative also aligns with public health goals (CDC, 2023) to enhance epilepsy surveillance and digital safety interventions.

BUSINESS AND ORGANIZATIONAL STAKEHOLDERS

| Business Group / Organization | Rationale |
|--|---|
| Clinical Leadership | Oversees clinical validation of seizure-detection protocols and determines alert-response workflows. Holds authority over clinical protocol approval, escalation policies, and integration into patient care processes. |
| Hospital IT & Informatics Department | Ensures the system's technical interoperability, cybersecurity, and compliance with EHR (FHIR/HL7) standards. Has decision authority on data architecture, system security, and infrastructure approvals. |
| Hostel Administration / On-Duty Responders | Manages on-site response coordination for students experiencing seizures. Authorizes operational policies, responder assignments, and training schedules for CareLink use. |
| Families / Guardians | |

| | |
|---------------------------------|---|
| EHR Vendor (e.g., AthenaHealth) | Provides and governs API integration standards between CareLink and electronic health records. Has final authority on interoperability certification and data-exchange protocols. |
| Compliance & Legal Teams | Ensure regulatory alignment with HIPAA, HITECH, and device safety standards. Possess authority to approve Business Associate Agreements (BAAs) and audit reports. |
| CareLink Product & Data Team | Responsible for software development, uptime, and analytics. Holds operational authority for system enhancements, SLA adherence, and release governance. |

IT GOVERNANCE

Since CareLink operates as a healthcare technology startup, it requires a well-defined IT governance framework to ensure data privacy, regulatory compliance, and operational accountability throughout the product lifecycle from project approval to deployment. Because startups typically lack formalized structures, CareLink will establish a lightweight but compliant governance model inspired by the COBIT 2019 framework and integrated with HIPAA Security Rule and NIST Cybersecurity Framework standards.

The governance framework will follow three key pillars: Evaluate, Direct, and Monitor (EDM) to guide decision-making. Under this model, the governance board (consisting of the Product Manager, Chief Compliance Officer, and Chief Information Security Officer) will review proposals, allocate resources, and oversee risk management. All new product releases must pass through three review stages: feasibility approval, compliance validation, and post-deployment evaluation. Each stage ensures that new system features meet safety, privacy, and interoperability requirements before launch.

IT governance processes will include:

1. **Policy and Compliance Oversight:** Development of internal policies aligned with HIPAA, HITECH, and FDA software regulations for medical-grade applications. CareLink will maintain Business Associate Agreements (BAAs) with hospitals, wearable vendors, and EHR partners to manage Protected Health Information (PHI) responsibly.
2. **Security and Access Management:** Implementation of multi-factor authentication, role-based access control (RBAC), and encryption standards (AES-256 for data at rest, TLS 1.3 for data in transit). NIST-aligned risk assessments and quarterly vulnerability scans will ensure continuous security monitoring.
3. **Data Governance and Quality Control:** A dedicated Data Steward will maintain audit logs and ensure interoperability using HL7 FHIR standards for structured data exchange. Data quality checks will validate event timestamps, alert routing, and user consent accuracy.
4. **Change and Incident Management:** A formalized change control process will record all system modifications in Jira, while an incident response plan (IRP) will define escalation pathways for

cybersecurity events or system failures.

- 5. Performance and Accountability: Governance dashboards will track system uptime (target $\geq 99.9\%$), user adoption rates, and incident resolution times. Monthly reports will be reviewed by the governance board to guide continuous improvement.

This governance model ensures CareLink balances innovation with compliance empowering rapid iteration while maintaining the rigorous data protection and oversight required in healthcare environments. By embedding COBIT’s structured accountability and NIST’s continuous monitoring principles, CareLink can scale responsibly while safeguarding trust among users, providers, and regulators.

PERFORMANCE MANAGEMENT

| KPI | Measures (Qualitative & Quantitative) | Goal |
|------------------------------|---|---|
| Seizure Detection Accuracy | Quantitative: Ratio of correctly detected seizures to total confirmed events. Qualitative: Clinician survey on trust and accuracy of AI-generated alerts (“How accurate and clinically useful are the alerts?”). | Achieve $\geq 95\%$ detection accuracy and ≤ 0.1 false alarms per day within the first 6 months of deployment. |
| Average Alert Response Time | Quantitative: Time (in seconds) between seizure event detection and first human acknowledgment. Qualitative: User satisfaction survey asking, “Was the alert timely and easy to act upon?” | Reduce median time-to-first-response to ≤ 2 minutes within 6 months of implementation. |
| User Adoption and Engagement | Quantitative: Percentage of registered users wearing the device daily and acknowledging alerts. Qualitative: Family and clinician feedback on usability, comfort, and perceived value. | Maintain $\geq 85\%$ daily active wearable usage and $\geq 90\%$ satisfaction ratings within 3 months of rollout. |

RISK MANAGEMENT

| IT Risk Area | Mitigation Strategy |
|--------------|---------------------|
|--------------|---------------------|

| | |
|--|--|
| Data Privacy and HIPAA Compliance | Implement encryption for all Protected Health Information (PHI) both in transit (TLS 1.3) and at rest (AES-256). Establish Business Associate Agreements (BAAs) with all data partners. Conduct quarterly HIPAA compliance audits and maintain audit logs for all PHI access, following Jenkins (2021) recommendations for continuous monitoring and accountability. |
| AI Detection Accuracy / False Alarms | Perform continuous model validation with real patient data and clinician feedback. Use diverse datasets to minimize bias and retrain models every quarter. Introduce a human-in-the-loop review for flagged events to prevent alert fatigue and ensure clinical safety. |
| System Downtime or Cloud Outage | Deploy CareLink on multi-region AWS servers with automated failover and 99.9% uptime Service Level Agreement (SLA). Maintain offline fallback communication using Twilio's SMS alerts and Apple's Multipeer Connectivity when the internet is unavailable. |
| Integration / Interoperability Failure | Use HL7 FHIR-based data exchange to ensure compatibility with hospital EHR systems (e.g., AthenaHealth). Test APIs in a sandbox before live deployment, and monitor for latency or version mismatches using automated CI/CD pipelines. |
| User Non-Adherence or Low Adoption | Provide continuous training, user guides, and in-app reminders for students and responders. Track adherence metrics and send periodic family notifications for inactive devices. Conduct monthly feedback surveys to identify barriers and increase engagement. |
| Security Breaches and Cyberattacks | Implement network firewalls, intrusion detection systems, and endpoint protection. Run monthly vulnerability scans and annual penetration tests. Create an incident response plan with defined escalation levels and 24/7 monitoring. |
| Governance Drift Over Time | Hold quarterly governance review meetings including the Product Manager, Compliance Officer, and Clinical Lead to reassess risks and update policies. Maintain a centralized risk register and follow Jenkins' continuous audit model to ensure ongoing vigilance post-deployment. |

STAKEHOLDER / USER READINESS FOR CHANGE ASSESSMENT (MODULE 6)

| Stakeholder | Incentive | Consequence | Risk | Unwilling to Give Up |
|-------------|-----------|-------------------------------|--------------------------------|-----------------------|
| Patients & | Improved | Continued anxiety and delayed | Concern about data privacy and | Control over personal |

| | | | | |
|--|--|--|---|---|
| Families | safety, faster emergency response, and peace of mind knowing caregivers and clinicians are alerted in real time. | response during seizures, leading to higher risk of injury or hospitalization. | possible misuse of health data. | health information and selective sharing rights. |
| Clinicians / Neurologists | Access to real-time seizure data, reduced manual reporting, and better continuity of care. | Missed critical event data and delayed interventions; higher liability for unmonitored episodes. | Alert fatigue, accuracy doubts, and added workload from system notifications. | Clinical autonomy and ability to validate data before documentation |
| Hostel Administration / On-Duty Responders | Clear response protocols, automated alerts, and evidence of rapid response for compliance reporting. | Continued confusion during emergencies and inconsistent first-aid practices. | Fear of system failure or false alerts disrupting operations. | Autonomy to manage emergencies using familiar manual protocols. |
| Hospital IT / Informatics Team | Streamlined integration with EHR systems, automation of documentation, and data accuracy. | Manual entry errors and fragmented health data across systems. | Integration conflicts or data breaches from external APIs. | Control over existing hospital information systems. |
| Compliance & Legal Teams | Demonstrates proactive HIPAA and HITECH compliance; reduces regulatory risk exposure. | Increased vulnerability to audits, penalties, or privacy violations. | Complex audit procedures or resource burden for ongoing oversight. | Current audit workflow simplicity and limited liability exposure. |

Proposal to Overcome Stakeholder Objections

To build readiness and reduce resistance, CareLink will apply the Prosci ADKAR and Kotter's 8-Step Change Management models.

1. **Awareness & Communication:** Conduct informational webinars for clinicians, hostel staff, and families to explain benefits and privacy protections.
2. **Training & Knowledge:** Provide simulation sessions and digital user guides to build confidence in handling alerts and understanding system workflows.
3. **Ability:** Launch a pilot in one hostel and affiliated clinic, allowing hands-on experience with real alerts before scaling.
4. **Reinforcement & Feedback:** Gather feedback via monthly surveys, focus groups, and open forums; adjust features and workflows accordingly.
5. **Transparency:** Publish clear privacy policies, consent controls, and data-sharing dashboards to build trust among users and compliance teams.

This multi-layered readiness plan ensures adoption by addressing both emotional and operational barriers, promoting long-term behavioral change and trust across all stakeholder groups.

COMPANION STRATEGIES

According to Glaser (2021), successful digital health transformations require both *broad leverage strategies* which strengthen the organization's overall capability to manage IT change and *initiative-specific strategies* which focus on the tactical success of a single solution.

For CareLink, broad leverage strategies include establishing a strong foundation of interoperability, governance, and continuous learning. By adopting the HL7 FHIR standard for secure data exchange and maintaining COBIT-aligned governance, CareLink ensures consistent integration with diverse EHR systems while remaining compliant with HIPAA and HITECH regulations. Another broad strategy involves fostering a data-driven culture that encourages clinicians and administrators to use performance dashboards to inform decisions. Finally, building collaborative partnerships with wearable device manufacturers, payers, and regulatory bodies will enhance scalability and sustainability.

Initiative-specific strategies focus on ensuring successful adoption among direct users students, families, and clinicians. CareLink will begin with a pilot implementation in one hostel and affiliated clinic to test usability, technical reliability, and alert response times. Early adopters will be engaged as change champions, providing feedback that shapes subsequent rollouts. A communication and engagement plan, including awareness campaigns ("SAFE Steps") and peer testimonial videos, will reinforce trust and participation. Continuous iteration through agile sprints will allow CareLink to respond rapidly to user feedback and maintain alignment with evolving clinical workflows.

Together, these strategies ensure that CareLink not only succeeds as a pilot but becomes a sustainable, interoperable model for seizure management in distributed care settings.

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