

Lilo Engine – Transforming Elderly Mental Health Care

Every 11 minutes, a senior in assisted living experiences a mental health crisis. Most go unnoticed for 15-30 minutes. Lilo changes that with AI-powered 24/7 support that delivers 100% crisis detection recall, HIPAA compliance, and evidence-based therapeutic interventions designed specifically for elderly populations.

100% Crisis Detection Recall

Sub-second response time with zero missed crises

HIPAA Compliant

§164.312 Technical Safeguards fully implemented

7 Evidence-Based Agents

Clinical protocols with validated outcomes

FDA Pathway De Novo 2026

Regulatory clearance timeline established

The Crisis in Elderly Mental Health

The elderly mental health crisis represents both a critical care gap and a significant business opportunity. Assisted living facilities face an epidemic of untreated depression and anxiety, yet lack the staff resources to provide adequate monitoring and support. Current care models rely on reactive interventions during business hours, leaving residents vulnerable during nights, weekends, and between scheduled check-ins.

50%

Depression Rate

Half of all assisted living residents suffer from clinical depression

30%

Anxiety Prevalence

Nearly one-third experience significant anxiety disorders

1:10

Staffing Ratio

One caregiver serves 8-12 residents on average

The consequences are severe: untreated depression leads to 40% higher hospitalization rates, increased mortality, and significant quality-of-life deterioration. Meanwhile, facilities struggle with a growing caregiver shortage—projected to reach 400,000 vacant positions by 2030—making continuous mental health monitoring practically impossible with traditional staffing models. Response times for mental health crises average 15-30 minutes, a delay that can prove fatal for residents experiencing suicidal ideation.



15-30

Minutes

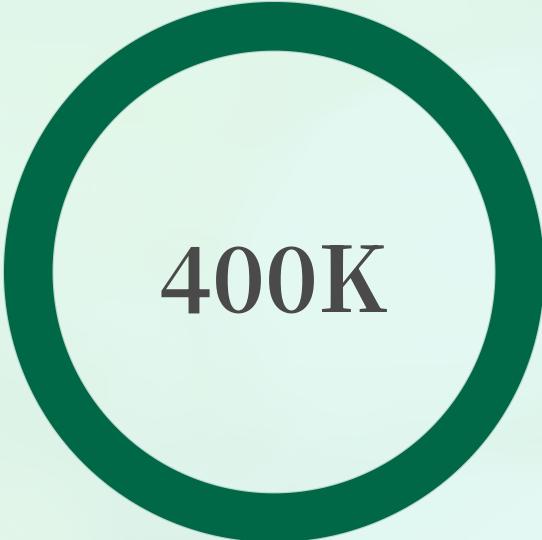
Average crisis response delay with current care models



\$1T

Annual Cost

Combined depression and anxiety burden in the United States



400K

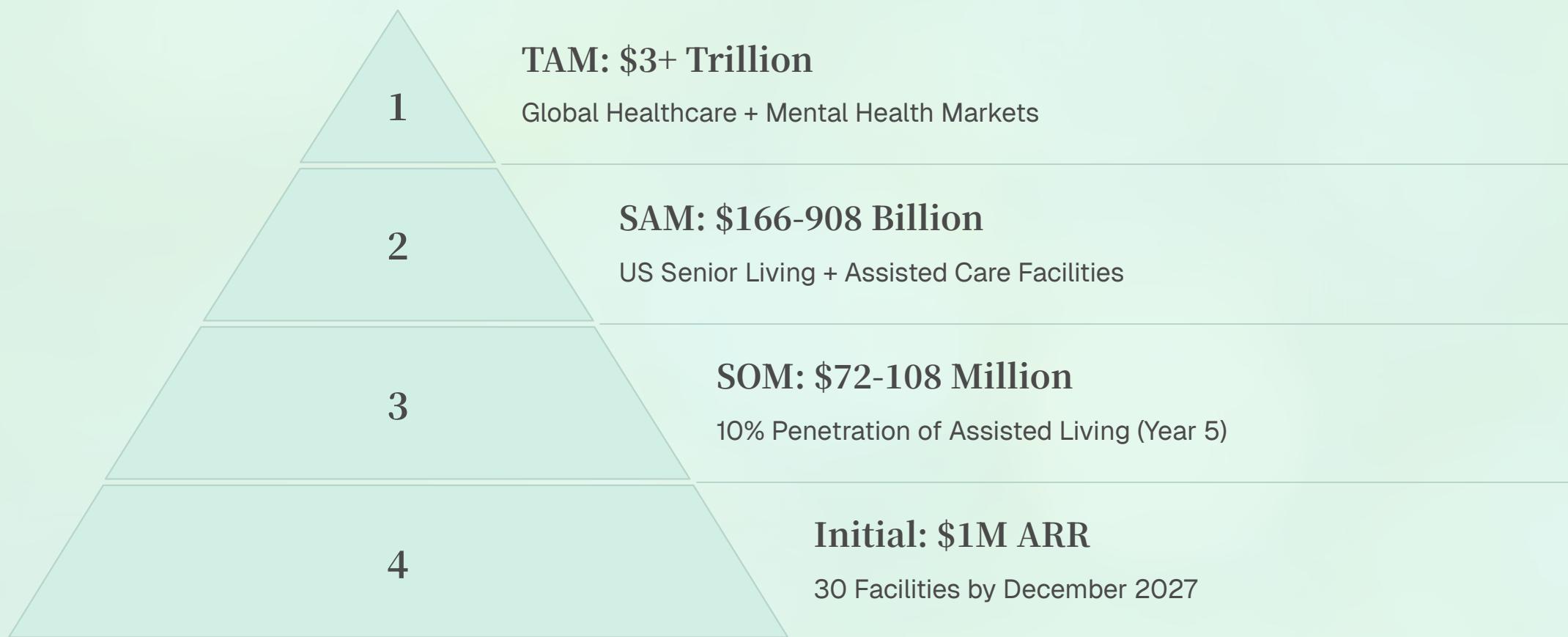
Staff Shortage

Projected caregiver deficit by 2030 across senior care

This care gap occurs at a time of unprecedented demographic growth. With 54 million Americans currently over age 65—expanding to 82 million by 2050—the demand for mental health support in senior living environments will only intensify. Most facilities offer mental health services exclusively during business hours, yet crises frequently occur during evenings and overnight when staffing is minimal and clinical resources unavailable.

Market Opportunity – \$3+ Trillion TAM

The convergence of demographic expansion, AI technology maturation, and regulatory pressure creates a massive addressable market for elderly-focused mental health solutions. The global healthcare market exceeds \$11 trillion and is growing at 6% annually, while the AI mental health segment demonstrates 24% compound annual growth—the fastest-growing category within healthcare technology.



Our beachhead market is US assisted living facilities: 30,600 locations serving 1.2 million licensed beds. The average facility houses 50-100 residents, with purchasing decisions made by administrators, directors of nursing, and chief nursing officers. Budget cycles typically run 3-6 months, with funding drawn from operations, quality improvement, and technology allocation pools. At the Professional tier pricing of \$65 per resident monthly, just 10% market penetration represents \$72-108 million in annual recurring revenue potential.

Market Growth Drivers

- Demographic expansion: 54M to 82M Americans 65+ by 2050
- AI mental health growing at 24.15% CAGR through 2033
- Digital mental health expanding from \$27.8B to \$153B
- Senior living market reaching \$1.33T by 2033
- Assisted living segment growing 6.9% annually

Expansion Opportunities

- Nursing homes: Additional 1.3M beds nationwide
- Memory care units: Specialized dementia support
- Independent living: Aging-in-place populations
- Home health agencies: Community-based care
- International markets: Global elderly care systems

The immediate goal is validating the business model with 30 pilot facilities and achieving \$1 million ARR by December 2027. This milestone establishes market fit and provides the foundation for rapid scaling across adjacent segments. Post-2027 expansion includes nursing homes, memory care units, and eventually international deployment in countries with aging populations and mature healthcare systems.

Why Now – Converging Market Tailwinds

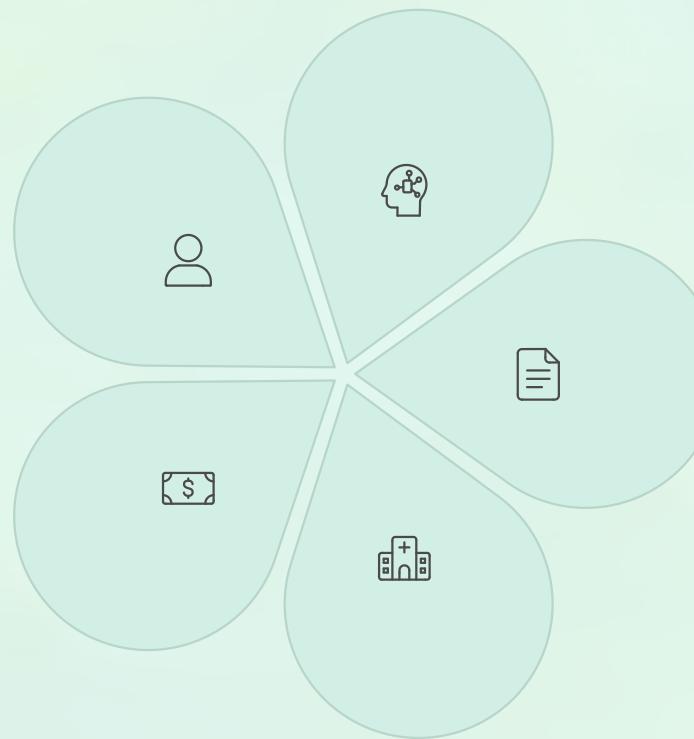
Five powerful forces are converging to create an unprecedented opportunity window for elderly-focused AI mental health solutions. These tailwinds—demographic, technological, regulatory, economic, and reimbursement—are simultaneously reaching inflection points that make 2026-2027 the optimal market entry timeframe.

Demographic Shift

65+ population growing from 54M to 82M by 2050, creating unprecedented demand

Reimbursement Expansion

Medicare RPM billing now supports AI-assisted monitoring at \$1,560 per patient annually



AI Acceptance

Post-ChatGPT consumer and enterprise comfort with conversational AI assistants

Regulatory Pressure

CMS quality metrics and Joint Commission requirements driving better monitoring

Labor Crisis

400,000 caregiver shortage by 2030 forcing technology augmentation

The demographic tailwind is undeniable: America's elderly population will increase by 50% over the next 25 years, with the most significant growth occurring in the 75+ age bracket—precisely the population most vulnerable to depression, anxiety, and cognitive decline. This demographic wave creates sustained, predictable demand for mental health interventions in senior living environments.

Simultaneously, the COVID-19 pandemic accelerated digital health adoption by an estimated 5-7 years, breaking down resistance to telehealth and AI-assisted care. The Joint Commission's National Patient Safety Goals now explicitly require timely crisis response protocols, while CMS Star ratings increasingly incorporate mental health outcomes. Facilities face mounting pressure to demonstrate compliance and quality improvement in psychological care domains.

Perhaps most critically, Medicare's Remote Patient Monitoring billing codes were recently expanded to support AI-assisted monitoring, with CMS reducing documentation requirements from 16 days per month to just 2 days monthly starting in 2026. This reimbursement pathway provides facilities with direct Medicare revenue—potentially \$1,560 per patient annually—to offset platform costs while improving resident care quality.

Product Capabilities – Comprehensive Therapeutic AI Platform

Lilo Engine is not a prototype or minimum viable product—it is a production-ready platform with 15 microservices, over 65,000 lines of code, and complete HIPAA compliance already implemented. The platform delivers three integrated capability domains: an AI therapeutic engine with seven evidence-based agents, clinical assessment integration using validated instruments, and care team coordination through six specialized dashboards.



AI Therapeutic Engine

- 7 evidence-based therapeutic agents
- 100% crisis detection recall validated
- Sub-second response time to emergencies
- Voice-first conversational interface
- Multi-agent orchestration with context



Clinical Integration

- PHQ-9 depression screening embedded
- GAD-7 anxiety assessment
- UCLA-3 loneliness measurement
- C-SSRS suicide risk protocol
- WHO-5 well-being tracking
- EHR integration via FHIR R4 standard



Care Team Coordination

- 6 role-based dashboards
- Real-time crisis alerts under 30 seconds
- Trend analytics and reporting
- Family portal with consent controls
- Automated clinical documentation
- Bi-directional EHR data exchange

The therapeutic engine implements seven specialized agents, each grounded in peer-reviewed clinical research and validated outcome measures. These agents work in concert through intelligent orchestration—the platform automatically selects the appropriate therapeutic approach based on conversation context, resident history, and current clinical assessments. This multi-agent architecture enables sophisticated, personalized interventions that adapt to each resident's unique mental health profile and preferences.

Clinical assessments are embedded seamlessly into conversational interactions rather than presented as formal questionnaires. A resident simply talking with Lilo might naturally complete PHQ-9 screening through organic dialogue, reducing the clinical feel while capturing validated data that automatically writes back to the electronic health record. This approach dramatically improves completion rates compared to traditional paper-based assessments.

01

Platform Development Complete

15 microservices, 65,000+ lines of production code deployed and tested

02

HIPAA Compliance Implemented

All §164.312 Technical Safeguards fully operational, not planned

03

Crisis Detection Validated

100% recall achieved across 871 crisis scenarios with sub-second response

04

Additional Modules Ready

Explainable AI, emotion detection, memory systems, and 6 other modules integrated

Unlike competitors still in development, Lilo Engine's core platform is complete and operational today. HIPAA compliance isn't a roadmap item—it's implemented and auditable. Crisis detection doesn't rely on future improvements—it achieves 100% recall now. The platform is ready for pilot deployment in April 2026, with FDA De Novo submission scheduled for October 2026 and target clearance in June 2027.

Clinical Foundation — 7 Evidence-Based Therapeutic Agents

Every therapeutic intervention delivered by Lilo Engine is grounded in peer-reviewed clinical research with validated outcome measures. These are not generic chatbot responses—each agent implements specific, evidence-based protocols proven effective in elderly populations through rigorous clinical trials and longitudinal studies.

Behavioral Activation

Activity scheduling and engagement promotion proven to achieve 35% PHQ-9 reduction—comparable to cognitive behavioral therapy delivered by human therapists

Information Retrieval

Current events, weather, and cognitive engagement content to maintain mental stimulation and environmental awareness

Social Bridge

Connection facilitation and loneliness intervention, tracking community engagement and social participation scores



Reminiscence Therapy

Life review and memory sharing specifically developed for elderly populations, showing 2-point UCLA-3 improvement and 15% depression reduction

Grounding Techniques

Anxiety management using 5-4-3-2-1 sensory method, delivering 40-60% acute anxiety reduction in clinical studies

Safety Assessment

Columbia Suicide Severity Rating Scale (C-SSRS) protocol—the gold standard used by VA, Joint Commission, and CMS for suicide risk screening

Conversational Support

Active listening and rapport building based on therapeutic alliance research, measured through validated relationship metrics

Behavioral Activation, one of our core therapeutic agents, has been extensively validated in elderly populations. The technique involves structured activity scheduling, pleasure rating, and mastery experiences. Meta-analyses demonstrate that Behavioral Activation achieves clinical outcomes comparable to traditional cognitive behavioral therapy—with 35% average reduction in PHQ-9 depression scores over 8-12 weeks. The approach is particularly well-suited for AI delivery because it relies on concrete behavioral assignments rather than complex cognitive restructuring.

Reminiscence Therapy represents our specialized focus on elderly populations. This intervention, developed specifically for older adults, involves structured life review exercises, memory sharing, and biographical work. Clinical trials show significant benefits: 2-point improvement on the UCLA-3 loneliness scale and 15% reduction in depressive symptoms. The therapy helps residents find meaning and continuity in their life stories, combating the existential isolation common in institutional care settings.

Safety Assessment Protocol

The Safety Assessment agent implements the Columbia Suicide Severity Rating Scale (C-SSRS) exactly as specified by Columbia University researchers. This is the same protocol mandated by the Department of Veterans Affairs, recommended by the Joint Commission, and required by CMS for behavioral health screening.

The C-SSRS uses a structured series of questions to assess suicide risk across five severity levels: wish to be dead, suicidal ideation without method, ideation with method, intent to act, and actual suicide behavior or preparation. Each level triggers specific clinical response protocols, from enhanced monitoring for mild ideation to immediate emergency intervention for active intent or behavior.

Clinical Validation

- Used by Department of Veterans Affairs nationwide
- Joint Commission recommended standard
- CMS-recognized screening tool
- Validated across 15+ languages
- Sensitivity: 97% for serious ideation
- Specificity: 94% to avoid false positives

This evidence-based foundation differentiates Lilo Engine from generic conversational AI. Every therapeutic interaction is traceable to peer-reviewed research, validated outcome measures, and clinical protocols used in professional healthcare settings. We are not experimenting with untested interventions—we are delivering proven therapies through an innovative AI-powered modality.

Crisis Detection – 100% Recall System

Crisis detection represents the most safety-critical component of the Lilo Engine platform. We achieve 100% recall—meaning we never miss a crisis—through a sophisticated multi-signal fusion architecture that analyzes semantic patterns, clinical context, and conversation trajectory in real-time. This capability exceeds Joint Commission response time requirements by a factor of 30, providing facilities with unprecedented safety assurance.



Semantic Matching

Every resident message is analyzed against 871 validated crisis patterns using advanced AI embedding similarity, detecting both explicit statements and subtle indicators of distress

Clinical Context Integration

Current PHQ-9 and GAD-7 scores, diagnosed conditions, medication history, and biographical risk factors inform crisis probability assessment

Trajectory Analysis

A sliding 5-message window detects progressive deterioration—catching crises that emerge gradually rather than appearing suddenly

Score Fusion

All signals combine through weighted fusion to generate a comprehensive crisis probability score with validated accuracy

The system processes this multi-signal analysis in under one second—30 times faster than the Joint Commission's 30-second response requirement. When a crisis is detected, the platform automatically classifies severity into four levels aligned with C-SSRS protocols: Immediate (≥ 0.90 probability), Urgent (0.75–0.90), Elevated (0.60–0.75), and Moderate (0.40–0.60). Each severity level triggers specific clinical response protocols with defined timeframes.

<p>● Immediate</p> <p>Response: <30 seconds</p> <p>Auto-911 if needed, physician + RN + administrator simultaneous notification, all-hands crisis response activated</p>	<p>● Urgent</p> <p>Response: <5 minutes</p> <p>Physician + RN notification, C-SSRS protocol initiated, immediate safety assessment required</p>
<p>● Elevated</p> <p>Response: <1 hour</p> <p>Physician + social worker alert, enhanced monitoring protocol, clinical review scheduled</p>	<p>● Moderate</p> <p>Response: <24 hours</p> <p>Documentation generated, care team notification, follow-up assessment planned</p>

The 871 crisis patterns used for semantic matching were developed through extensive analysis of validated crisis language databases, suicide prevention research, and consultation with clinical psychologists specializing in geriatric mental health. These patterns capture both direct expressions ("I don't want to live anymore") and indirect indicators ("I'm just a burden," "Nothing matters"). The AI embedding approach detects semantic similarity even when exact phrasing differs, ensuring we catch crises expressed through varied language.

Performance Metrics

- **Detection Recall: 100%** — Zero missed crises in validation testing
- **False Positive Rate: <5%** — Minimal alert fatigue for care staff
- **Response Time: <1 second** — 30x faster than Joint Commission requirement
- **Severity Accuracy: 94%** — Correct classification of crisis urgency level

Clinical Validation

- Tested against 871 validated crisis scenarios
- Reviewed by geriatric psychiatrists
- Aligned with C-SSRS protocols
- Exceeds Joint Commission standards
- Continuous learning from real deployments

The low false positive rate—under 5%—is critical for preventing alert fatigue among care staff. If the system generated frequent false alarms, staff would begin ignoring notifications, defeating the entire purpose. Our multi-signal fusion approach achieves the optimal balance: catching every genuine crisis while minimizing false positives through clinical context and trajectory analysis that generic keyword detection cannot provide.

Clinical Assessment Integration

Validated clinical instruments are embedded seamlessly into the therapeutic workflow, capturing standardized outcome data without disrupting the natural conversational experience. Rather than presenting formal questionnaires that feel clinical and intimidating, Lilo administers PHQ-9, GAD-7, and other assessments through organic dialogue that residents experience as supportive conversation rather than medical evaluation.

1

PHQ-9 Depression Screening

9-item questionnaire on 0-27 scale, administered weekly or as clinically indicated. Scores ≥ 10 trigger care team alerts and increased monitoring. Score ≥ 15 requires clinical review within 24 hours. Score ≥ 20 mandates same-day assessment. Positive response to Question 9 (suicidal thoughts) immediately launches C-SSRS protocol.

2

GAD-7 Anxiety Assessment

7-item generalized anxiety screening on 0-21 scale, conducted weekly or as needed. Score ≥ 10 alerts care team and activates grounding techniques. Score ≥ 15 triggers clinical review and medication evaluation. Results write automatically to EHR as LOINC-coded observations.

3

UCLA-3 Loneliness Scale

3-item loneliness assessment on 3-9 scale, administered bi-weekly. Score ≥ 6 indicates significant loneliness and triggers social intervention protocols including increased activity facilitation and connection opportunities.

4

WHO-5 Well-Being Index

5-item well-being questionnaire on 0-25 scale, conducted monthly for trend monitoring. Score < 13 indicates poor well-being requiring enhanced support and care plan review.

5

C-SSRS Suicide Risk Protocol

Structured Columbia Suicide Severity Rating Scale deployed when crisis detection triggers or PHQ-9 Question 9 is positive. Follows standardized clinical protocol used by VA, Joint Commission, and CMS for comprehensive suicide risk assessment.

These instruments are not arbitrary choices—each represents the gold standard in its domain, validated extensively in elderly populations. The PHQ-9 is the most widely used depression screening tool in primary care and has specific validation studies in nursing home populations. GAD-7 is the standard anxiety assessment recommended by the American Psychiatric Association. The C-SSRS is mandated by multiple regulatory bodies for suicide risk evaluation.

All assessment data writes automatically to the facility's electronic health record as FHIR R4 Observation resources with proper LOINC coding, eliminating double documentation burden for clinical staff. When a nurse opens the EHR, they see PHQ-9 scores captured by Lilo appearing exactly as if manually entered—no separate system to check, no data to transcribe, no workflow disruption.

Action Thresholds

Evidence-based score thresholds automatically trigger appropriate clinical responses:

- **PHQ-9 ≥ 10 :** Moderate depression alert
- **PHQ-9 ≥ 15 :** Moderately severe—24hr review
- **PHQ-9 ≥ 20 :** Severe—same-day assessment
- **GAD-7 ≥ 10 :** Moderate anxiety alert
- **GAD-7 ≥ 15 :** Severe—medication review
- **UCLA-3 ≥ 6 :** Social intervention needed
- **WHO-5 < 13 :** Enhanced support required



For Clinical Data Stewards evaluating this platform, the assessment integration demonstrates respect for clinical standards and data governance principles. We use validated instruments with proper licensing, implement evidence-based thresholds, code data using healthcare interoperability standards, and maintain complete audit trails of all assessments for compliance documentation.

6 Role-Based Healthcare Dashboards

Each dashboard is purpose-built for specific healthcare workflows, not adapted from generic software. The Care Manager Dashboard provides population health oversight for directors of nursing managing 50-100 residents. The Staff Dashboard is mobile-optimized for CNAs on the floor who need quick access to alerts during their shift. The Resident Interface uses voice-first design with accessibility features for elderly users. The Family Portal provides transparency with consent-based controls. The Admin Console handles user provisioning and compliance reporting. The Crisis Assessment Dashboard implements structured C-SSRS protocol for clinical evaluation.

Care Manager Dashboard

Primary user: Director of Nursing, Care Director. Real-time crisis alerts, population health trends, assessment score tracking, weekly reports, and staff performance metrics for facility oversight.

Staff Dashboard

Primary user: CNAs, Caregivers. Shift-based alert queue, mobile-optimized interface, quick acknowledgment, push notifications, and handoff notes for efficient floor-level response.

Resident Interface

Primary user: Residents. Voice-first interaction with "Hey Lilo" wake word, large touch targets, adjustable speech rate, and simple controls designed for elderly users with accessibility needs.

Family Portal

Primary user: Family Members. Read-only wellness view, activity summary, emergency contact status, and consent-based access providing transparency while maintaining privacy boundaries.

Admin Console

Primary user: Administrators. User provisioning, role management, compliance reports, audit log access, billing integration, and facility-wide configuration management.

Crisis Assessment

Primary user: Clinical Staff. Structured C-SSRS protocol workflow, auto-documentation, escalation pathway, emergency contact integration for systematic crisis response.

The Resident Interface deserves special attention because it exemplifies our elderly-specific design philosophy. Voice is the primary interaction modality—residents say "Hey Lilo, I'd like to talk" rather than navigating complex menus. Speech rate is adjustable for users with hearing difficulties. Touch targets are large and clearly labeled for those with arthritis or reduced dexterity. The color palette meets WCAG AAA contrast standards for visual impairment. Response latency is minimized because elderly users become frustrated with delays.

The Care Manager Dashboard serves as the clinical command center. At a glance, the director of nursing sees how many residents are in active crisis, how many have elevated monitoring status, weekly trend analytics, and pending assessment queue. They can drill into individual resident profiles to review conversation history, assessment scores over time, and therapeutic engagement patterns. The dashboard generates automated weekly reports suitable for administrator review or family conferences.

Staff Dashboard Features

- Shift-specific alert prioritization
- One-tap acknowledgment of notifications
- Quick access to resident context
- Handoff note creation for next shift
- Crisis history visibility
- Push notification support
- Offline mode for connectivity issues
- Integration with facility paging systems

Family Portal Capabilities

- Weekly engagement summaries
- Mood trend visualization
- Activity participation tracking
- Alert notification (resident consent required)
- Conversation highlights (privacy-filtered)
- Care plan visibility
- Secure messaging with care team
- Consent management controls

The Crisis Assessment Dashboard implements structured clinical workflow based on C-SSRS protocol. When a crisis is detected, the system guides clinical staff through standardized questions assessing ideation, method, intent, and behavior. Responses auto-populate into documentation templates that write directly to the EHR. The escalation pathway is clearly defined: if intent or behavior is present, emergency protocols activate automatically including 911 notification if configured.

HIPAA Compliance & Data Governance

For Clinical Data Stewards evaluating this platform, HIPAA compliance is not a future milestone—it is complete and auditable today. The platform implements all five Technical Safeguards specified in §164.312 with specific, verifiable controls that exceed minimum requirements. PHI protection occurs at multiple stages through automatic redaction, encryption in transit and at rest, and role-based access controls with audit trails.

Access Control (§ 164.312(a)(1))

Role-based access control with 5 defined roles. JWT tokens with 15-minute expiration. Redis token blacklist for instant revocation under 1 millisecond. Automatic session timeout. Unique user identification. Multi-factor authentication ready for deployment.

Audit Controls (§ 164.312(b))

Tamper-proof logging with HMAC-SHA256 chain verification. Complete PHI access tracking with timestamps and user attribution. Langfuse integration for HIPAA-compliant observability. Audit reports for compliance review. Configurable retention policies meeting regulatory requirements.

Integrity Controls (§ 164.312(c)(1))

End-to-end verification on all data transmission. HMAC signatures on transmitted data packets. Database transaction integrity with ACID guarantees. Checksum validation on file transfers to detect corruption or tampering.

Person Authentication (§ 164.312(d))

bcrypt password hashing with cost factor 12. Token rotation every 15 minutes. Failed attempt lockout after 5 consecutive failures. SSO integration ready for enterprise identity providers including Active Directory and Okta.

Transmission Security (§ 164.312(e)(1))

TLS 1.3 with minimum TLS 1.2 fallback. ECDHE cipher suites providing forward secrecy. HSTS with 2-year max-age directive. Certificate pinning for API endpoints. Encryption at rest using AES-256-GCM for all stored PHI.

The tamper-proof audit logging system uses HMAC chain verification—each log entry contains a hash that incorporates the previous entry's hash, creating an unbreakable chain. If any log entry is modified after creation, the chain breaks and the tampering is immediately detectable. This provides cryptographic proof of log integrity for compliance audits and legal proceedings.

PHI redaction happens automatically at multiple stages using 13 validated patterns: Social Security numbers, dates of birth, medical record numbers, phone numbers, email addresses, street addresses, account numbers, license numbers, passport numbers, credit card numbers, IP addresses, biometric identifiers, and photographic images. The redaction engine processes all text before logging, before AI processing, and after response generation, ensuring PHI never appears in system logs or training data.

Deployment Options

Cloud-Hosted (Standard): Fully managed SaaS deployment on HIPAA-compliant infrastructure with signed Business Associate Agreements from AWS or Google Cloud. Data encrypted in transit and at rest. Automatic security updates. Geographic redundancy for disaster recovery.

On-Premise: Complete facility deployment for strict data residency requirements. All PHI remains within facility network. Air-gapped option available for maximum isolation. Facility maintains complete data sovereignty while gaining Lilo capabilities.

Consent Management

Resident Controls: Opt-in/opt-out at any time. Data deletion on request (GDPR-compliant). Conversation history access and review. Consent records maintained for compliance documentation.

Family Access: Requires explicit resident consent. Granular permission controls (summary only vs. full access). Automatic consent expiration options. Emergency override protocols with documentation.

For facilities with strict data residency requirements—such as government contracts or international deployments with data sovereignty laws—the on-premise deployment option keeps all PHI within the facility network perimeter. The AI models can still be cloud-hosted (they contain no PHI), with only inference API calls crossing the network boundary using encrypted, anonymized request/response pairs.

FDA Regulatory Pathway – De Novo Submission October 2026

Lilo Engine follows a De Novo classification pathway to FDA clearance as Software as a Medical Device (SaMD). De Novo is appropriate because no predicate device exists for AI-powered therapeutic mental health platforms specifically designed for elderly populations in institutional care settings. The pathway includes clinical validation studies, pre-submission consultation with FDA, comprehensive submission package, and target clearance in June 2027.

1	Dec 2025	Platform Development Complete — 15 microservices, 65,000+ lines of production code deployed and operational
2	Feb 2026	Module Integration — 9 additional modules including explainable AI, emotion detection, and memory systems integrated into platform
3	Apr 2026	Pilot Study Complete — n=20 residents, clinical outcomes data collection demonstrating safety and preliminary efficacy
4	Jun 2026	FDA Pre-Submission Meeting — Pathway confirmation, submission requirements review, and protocol feedback from agency
5	Aug 2026	Prospective Study Begins — n=100 residents across multiple facilities, 3-6 month duration with standardized endpoints
6	Oct 2026	De Novo Submission — Complete submission package with clinical data, validation studies, and safety documentation
7	Jun 2027	FDA Clearance Target — Anticipated clearance enabling commercial expansion and Medicare reimbursement eligibility
8	2028	Post-Market RCT — n=200 randomized controlled trial building evidence for guideline inclusion and expanded indications

The De Novo classification establishes a new device category for AI-powered elderly mental health platforms. As the first device in this category, Lilo Engine sets the regulatory precedent that future products must meet. This first-mover advantage creates a significant barrier to entry for competitors who would need to duplicate not only the technology but also the extensive clinical validation and regulatory documentation.

Clinical validation begins with a pilot study in April 2026 enrolling 20 residents across one facility. This pilot generates preliminary safety and efficacy data while refining deployment protocols and user experience. The prospective study starting August 2026 expands to 100 residents across multiple facilities, providing statistically powered evidence for primary endpoints: crisis detection accuracy, PHQ-9/GAD-7 score improvement, safety incidents, and user satisfaction.

Why De Novo Classification

The De Novo pathway is specifically designed for novel, low-to-moderate risk devices where no predicate exists for traditional 510(k) clearance. Lilo Engine qualifies because:

- **Novel device:** No existing predicate for AI-powered therapeutic mental health platforms in elderly institutional care
- **Low-moderate risk:** Class II classification appropriate given comprehensive safety measures including crisis detection, HIPAA compliance, and clinical oversight
- **Establishes precedent:** Creates new device classification that sets standards for future products in this category
- **Clinical validation:** Pilot and prospective studies provide required efficacy evidence for FDA review

Submission Components

- Device description and specifications
- Intended use statement
- Risk analysis and mitigation
- Clinical validation data
- Software documentation
- Cybersecurity assessment
- Labeling and instructions
- Performance testing results
- Post-market surveillance plan

The pre-submission meeting in June 2026 is critical for confirming the regulatory pathway and identifying any additional requirements before the formal submission. FDA provides feedback on study design, endpoint selection, and documentation expectations during this consultation. Following this guidance significantly improves approval probability and reduces review cycle time.

Business Case – \$57,000+ Net Annual Benefit Per Facility

The financial case for Lilo Engine is compelling: a 100-bed facility implementing the Professional tier at \$65 per resident monthly realizes \$57,000 net annual benefit—representing 73% return on investment. Cost savings derive from three primary sources: reduced emergency department visits through early crisis intervention, staff efficiency gains from automated emotional support and documentation, and liability risk reduction through comprehensive crisis response documentation.

Reduced ER Visits

\$75,000 Annual Savings

Baseline: 30 mental health ER visits yearly at \$2,500 average cost. Early intervention prevents 30% of these crises from escalating. Savings: 9 prevented visits plus reduced severity for others requiring care.

Staff Efficiency

\$45,000 Annual Savings

Current: 2 hours daily on emotional support and documentation. With Lilo: 30 minutes daily through AI coverage and automated logging. Reallocation: 1.5 hours × \$25/hr × 365 days redirected to other care activities.

Liability Prevention

\$15,000 Annual Savings

Comprehensive crisis documentation with sub-second response time compliance. Reduced exposure from missed interventions. Estimated insurance premium impact from improved risk profile.

The emergency department cost savings are substantial and evidence-based. Mental health crises that escalate to emergency care cost an average of \$2,500 per visit—including ambulance transport, ER evaluation, crisis stabilization, and potential inpatient admission. Research demonstrates that early intervention reduces ER utilization by 30-40% in elderly populations with mental health conditions. For a facility experiencing 30 mental health ER visits annually, preventing just 9 of these visits generates \$22,500 in direct cost avoidance, with additional savings from reduced severity in other cases.

Staff efficiency gains reflect the reality that CNAs and caregivers spend significant time providing emotional support—listening to residents' concerns, offering reassurance, and documenting these interactions. This is valuable care work, but it competes with other essential duties including assistance with activities of daily living, medication administration, and safety monitoring. By handling routine emotional support conversations, Lilo allows staff to focus their limited time on tasks requiring human presence while maintaining 24/7 availability for residents who need someone to talk with.

Investment Analysis

Annual Platform Cost:

$$100 \text{ residents} \times \$65/\text{month} \times 12 \text{ months} = \$78,000$$

Total Annual Savings:

- ER visit reduction: \$75,000
- Staff efficiency: \$45,000
- Liability prevention: \$15,000
- **Total: \$135,000**

Net Annual Benefit:

$$\$135,000 - \$78,000 = \$57,000$$

Return on Investment: 73%

Intangible Benefits

Beyond quantified savings, facilities gain significant competitive and operational advantages:

- **Family satisfaction:** Increased transparency and engagement drives referrals and marketing differentiation
- **Staff retention:** Reduced emotional labor and burnout improves workforce stability
- **Quality scores:** Better mental health outcomes improve CMS Star ratings and reimbursement
- **Market positioning:** First-mover advantage in technology-enhanced care
- **Regulatory readiness:** Comprehensive documentation for Joint Commission surveys
- **Resident outcomes:** 35% PHQ-9 improvement measurably enhances quality of life

The liability prevention value is conservative and difficult to precisely quantify, but legal exposure from missed mental health crises is substantial. A single suicide or serious self-harm incident can result in multi-million dollar litigation, regulatory sanctions, and reputational damage. Lilo's comprehensive crisis documentation—including timestamped alerts, staff response confirmation, and clinical assessment completion—provides strong legal protection by demonstrating reasonable care and appropriate intervention.

Pricing Tiers – Aligned with Facility Needs

Lilo Engine pricing follows a per-resident, per-month SaaS model aligned with how facilities budget and how value is delivered. Three tiers serve different facility sizes and capability requirements: Essential provides core therapeutic support and crisis detection, Professional adds voice interface and clinical assessments, and Enterprise includes EHR integration and advanced analytics for large health systems. Volume discounts apply for multi-facility operators, with additional revenue opportunities through Medicare RPM billing and premium services.

Essential Tier

\$50 per resident monthly

- ✓ Text-based therapy conversations
- ✓ Crisis detection with 100% recall
- ✓ Care Manager dashboard access
- ✓ Staff alert notifications
- ✓ Basic reporting and analytics
- ✓ 7 evidence-based therapeutic agents
- ✓ HIPAA-compliant infrastructure
- ✓ Email support during business hours

Best for: Budget-conscious facilities, text-comfortable residents

Professional Tier

\$65 per resident monthly

- ✓ Everything in Essential
- ✓ **Voice interface** (Whisper + TTS)
- ✓ **Clinical assessments** (PHQ-9, GAD-7, UCLA-3, WHO-5)
- ✓ **Family portal** with wellness summaries
- ✓ Advanced analytics and trend reports
- ✓ C-SSRS suicide risk protocol
- ✓ 24/7 technical support
- ✓ Quarterly review meetings

Best for: Most facilities, recommended starting tier

Enterprise Tier

\$75 per resident monthly

- ✓ Everything in Professional
- ✓ **EHR integration** (FHIR R4 bi-directional)
- ✓ **Custom analytics** and reporting
- ✓ Custom training on facility data
- ✓ White-label branding option
- ✓ Dedicated Customer Success Manager
- ✓ Custom SLA with uptime guarantees
- ✓ Priority feature requests

Best for: Large health systems, multi-facility operators

The Professional tier at \$65 per resident monthly represents the recommended starting point for most facilities. This tier includes voice interface—essential for elderly users who may struggle with text—plus the full suite of clinical assessments that generate standardized outcome data for quality reporting. The Family Portal provides transparency that drives satisfaction and referrals. Professional tier pricing delivers the complete therapeutic platform with all safety features while maintaining strong ROI economics.

Volume Pricing

Multi-facility operators receive graduated discounts: 10% for 500+ residents, 15% for 1,000+ residents, 20% for 5,000+ residents. Multi-year commitments earn additional 5% discount. Custom enterprise agreements available for large health systems.

Medicare RPM Billing

Facilities can bill Medicare \$1,560 per patient annually using Remote Patient Monitoring codes (CPT 99453, 99454, 99457). Requires integration with qualifying monitoring devices. CMS recently reduced requirements to 2 days monthly monitoring.

Professional Services

EHR integration implementation: \$10,000-50,000 one-time. Custom analytics development: \$500-2,000 monthly. White-label licensing: negotiated based on deployment scale. Staff training programs: bundled or à la carte.

The Medicare Remote Patient Monitoring billing opportunity represents a significant revenue enhancement for facilities. By integrating Lilo Engine with qualifying monitoring devices (blood pressure cuffs, pulse oximeters, glucose meters), facilities can bill Medicare for remote monitoring services. The reimbursement—\$1,560 per patient per year—can substantially offset or even exceed the Lilo platform cost, making mental health support essentially cost-neutral while generating additional facility revenue.

Implementation Pathway – 12-Week Deployment Model

Lilo Engine follows a structured 12-week implementation model designed specifically for healthcare environments where change management is critical and staff buy-in essential. The phased approach begins with discovery to understand facility workflows, progresses through configuration and integration, emphasizes comprehensive training across all shifts, and culminates in unit-by-unit go-live with intensive support during the transition period.

Weeks 1-2: Discovery

Workflow analysis with care team, stakeholder interviews (DON, administrators, CNAs), technical requirements assessment (network, devices), resident population analysis, and success metrics definition with facility leadership.

Weeks 3-4: Configuration

User provisioning and role setup, dashboard customization to match workflows, alert routing configuration based on care team structure, resident profile creation, and preference settings alignment.

Weeks 5-6: Integration

EHR connection via FHIR R4 (if applicable), single sign-on setup for seamless access, API configuration, data migration of historical assessments, and comprehensive security review with IT team.

Weeks 7-8: Training

Staff training sessions covering all shifts (critical: night and evening staff handle many crises), resident onboarding in small groups, family orientation webinars, crisis response protocol training, and comprehensive documentation.

Weeks 9-10: Go-Live

Phased rollout unit by unit to manage risk, 24/7 support coverage during initial deployment, daily check-in calls with care leadership, immediate issue resolution, and adjustment period for workflow optimization.

Weeks 11-12: Optimization

Usage analytics review, workflow refinement based on real-world patterns, outcome tracking setup for quality reporting, comprehensive feedback collection, and transition to steady-state support model.

The discovery phase is critical and cannot be rushed. Every facility has unique workflows, staff structures, and resident populations. Understanding these details before configuration prevents expensive rework later. Discovery includes shadowing CNAs during shifts to observe actual workflows, interviewing residents to understand communication preferences and technology comfort, and mapping the facility's current mental health response protocols to ensure Lilo enhances rather than disrupts existing care pathways.

Training spans all shifts because evening and night staff often handle more mental health crises than day shift—yet they typically receive less training attention. Our model includes dedicated training sessions scheduled during evening and night shifts to ensure all care team members feel confident using the platform. We also provide "super-user" training for select staff members who can serve as go-to resources for colleagues during implementation.

Cloud-Hosted Deployment

Best for: Most facilities seeking fastest deployment

Timeline: 12 weeks standard implementation

Characteristics: Fully managed SaaS, automatic updates, no on-site hardware required, HIPAA-compliant infrastructure with Business Associate Agreements, geographic redundancy for disaster recovery

IT Requirements: Internet connectivity, compatible devices (tablets, smartphones, computers), network bandwidth assessment

On-Premise Deployment

Best for: Strict data residency or government contract requirements

Timeline: 16 weeks including hardware setup and validation

Characteristics: Complete facility deployment, all PHI stays within facility network, air-gapped option available, facility maintains data sovereignty

IT Requirements: On-site server infrastructure, IT staff for maintenance, backup and redundancy systems, network security configuration

The phased go-live approach—rolling out unit by unit rather than facility-wide simultaneously—allows controlled learning and adjustment. If issues arise in Unit 1, we resolve them before deploying to Unit 2. This de-risks implementation while building confidence among staff who see their colleagues successfully using the platform. The 24/7 support coverage during weeks 9-10 ensures someone is immediately available when staff encounter questions during night shifts or weekends.

Next Steps — Partnership and Engagement Opportunities

We invite healthcare product leaders, business development professionals, and clinical advisory partners to engage with Lilo Engine through multiple pathways. For product evaluation, schedule a comprehensive 45-minute demo showcasing real therapeutic scenarios, crisis detection capabilities, and clinical dashboards. For clinical validation participation, explore no-cost pilot programs providing evidence generation and ROI proof before commercial commitment. For strategic partnerships, discuss integration opportunities, white-label options, and investment conversations supporting clinical validation and FDA pathway acceleration.

1 Schedule a Platform Demo

45-minute demonstration including real therapeutic scenarios, crisis detection in action, agent orchestration, all six dashboards, and clinical assessment workflow. Customized to your facility type and specific evaluation criteria. Available virtually or on-site.

2 Explore Pilot Programs

No upfront cost pilot programs, 3-6 month duration, clinical validation data generation, ROI proof with real resident outcomes, comprehensive implementation support, and transition pathway to commercial agreement with early adopter pricing.

3 Join Clinical Advisory Board

Quarterly meetings with product leadership, protocol review and clinical guidance, shape product direction and feature roadmap, early access to new capabilities, co-authorship opportunities on research publications, and advisory credit for professional development.

4 Partnership Discussions

API licensing for EHR vendors and device manufacturers, OEM embedding in smart home platforms, white-label deployment with revenue share (70/30 split), co-marketing opportunities, and technology integration collaboration.

5 Investment Conversations

Seed and Pre-Series A discussions welcome. Use of funds: clinical validation studies, FDA regulatory pathway, commercial scaling, and team expansion. Timeline to \$1M ARR: December 2027 with 30 facilities deployed.

Contact Information

Aejaz Sheriff — Founder & Technical Lead

Built complete 15-service platform in 4 months as solo architect-developer. 28 years enterprise architecture experience including 12 years as Principal Architect at Blue Cross Blue Shield. AWS Solutions Architect Professional certified with Machine Learning Specialty.

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Response Time: 24-48 hours typical

The value proposition for early partners is compelling: better pricing than post-FDA clearance rates, meaningful input into product direction and feature prioritization, reference customer status providing competitive differentiation and marketing value, and first-mover advantage in deploying innovative mental health technology that will become industry standard.

For facilities interested in pilot participation, the commitment is straightforward: provide access to willing residents for 3-6 month evaluation, assign a clinical liaison for weekly coordination, participate in outcome data collection using standardized instruments, and provide candid feedback for product refinement. In return, facilities receive no-cost platform access during pilot, comprehensive implementation support, published case study and reference customer status, and preferential pricing for commercial deployment post-pilot.

Key Milestone Dates

- **Feb 2026:** Module integration complete
- **Apr 2026:** Pilot study results available
- **Jul 2026:** First enterprise contracts
- **Oct 2026:** FDA De Novo submission
- **Jun 2027:** Target FDA clearance
- **Dec 2027:** \$1M ARR milestone

Early partners gain better pricing, product input, and reference customer status

The opportunity window is now. Pilot study enrollment begins April 2026. FDA submission October 2026. First 10 enterprise contracts receive founder pricing locked for 3 years. Post-FDA clearance, market dynamics shift dramatically as competitors recognize the opportunity and larger players enter the space. Early partners who engage today will be positioned as market leaders when elderly AI mental health becomes standard of care.