

SILENT-DS: Hospital Site Participation & Expression of Interest

Dossier

A Prospective, Multi-Center, Silent-Mode Diagnostic Accuracy Investigation of the DeepSensi Cognitive Medical OS in Adult Inpatient Internal Medicine

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Study Protocol Reference: DS-CLIN-2026-SILENT-DS (Version 1.3)

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Target Audience: Chief Medical Officers (CMO), Chairs of Internal Medicine, Directors of Hospital Medicine, Chief Information Officers (CIO), Chief Research Officers, and Institutional Review Board (IRB) Leadership.

Section 1. Executive Summary and Institutional Value Proposition

Hospitals across the United States face severe clinical and financial pressures driven by diagnostic delays, cognitive overload, and preventable adverse events. Traditional attempts to deploy artificial intelligence at the bedside frequently fail due to alert fatigue, workflow disruption, clinician skepticism, and legal liability concerns.

SILENT-DS is an institutional, multi-center clinical study evaluating the DeepSensi Cognitive Medical OS across 10,000 inpatient admissions in a non-disruptive, silent-mode framework. The software operates entirely in the background, analyzing existing electronic health records to generate diagnostic predictions that are cryptographically sealed and evaluated only after patient discharge.

Benefits for Participating Medical Centers:

- 1. Zero Clinical Workflow Disruption:** The investigation introduces zero clicks, zero electronic health record alerts, and zero bedside changes. Attending physicians, residents, and nursing staff require no training and maintain complete clinical autonomy.
- 2. Zero Clinical Liability or Patient Harm:** Because software outputs are encrypted and sealed in write-once storage during hospitalization, the software cannot influence acute clinical decision-making or create malpractice exposure.
- 3. Premier Academic Authorship:** Site Principal Investigators and hospital co-investigators receive prominent co-authorship on high-impact multi-center publications reporting diagnostic accuracy against standard hospital care, adhering strictly to STARD 2015 reporting guidelines.
- 4. Priority Access to Next-Generation Clinical Decision Support:** Participating health systems secure preferred enterprise access and grandfathered pricing for DeepSensi enterprise solutions following completion of regulatory clearance.
- 5. Fully Sponsored, Zero-GPU Infrastructure:** DeepSensi PBC provides all high-performance computing via the dedicated DeepSensi Supercluster. The hospital only needs to provide a standard virtual machine (or use a provided lightweight appliance) for the Plug-and-Play Edge Gateway to handle local data anonymization. There is zero capital expenditure for hospital IT.
- 6. Plug-and-Play EHR Integration:** The DeepSensi Edge Gateway features native, turnkey connectors for

all major Electronic Health Record systems (including Epic, Oracle Health, and MEDITECH). It utilizes standard read-only data feeds, eliminating the need for complex custom IT development or disruption of hospital databases.

Section 2. Regulatory and Bioethical Compliance Fortress

SILENT-DS is engineered to provide complete compliance with United States federal regulations, eliminating institutional friction for hospital legal and research compliance offices.

Investigational Device Exemption (IDE) Exemption: The investigation is exempt from federal IDE requirements under 21 CFR Section 812.2(c)(3). The software operates non-invasively, requires no additional biological sampling, introduces zero energy into patients, and is strictly not used for diagnostic purposes during the hospital stay.

Waiver of Informed Consent: Approved under 21 CFR Section 50.22 and 45 CFR Section 46.116(f). The study presents minimal risk to subjects, could not practicably be carried out without a waiver (as seeking prospective consent across 10,000 acute admissions would introduce profound selection bias and exclude emergency admissions), and does not adversely affect subject rights or welfare.

HIPAA Waiver of Authorization: Concurrently approved under 45 CFR Section 164.512(i). Direct identifiers are strictly stripped locally on the hospital network.

Central IRB Support: DeepSensi PBC provides an approved central Institutional Review Board protocol (via WCG IRB / Advarra) for rapid institutional reliance, or supports full local hospital IRB review with a turnkey documentation package.

Section 3. Hospital IT and Cybersecurity Architecture

Hospital Chief Information Officers (CIO) and Chief Information Security Officers (CISO) require ironclad data security. The SILENT-DS architecture is designed around a secure hybrid coded data model.

Hardware Deployment: Deployed as a Plug-and-Play DeepSensi Edge Gateway (a lightweight virtual machine or 1U appliance) within the hospital secure data center. No local GPUs are required.

Data Ingestion Model: Ingestion operates strictly via read-only electronic health record integration using standard HL7 v2 feeds (ADT for admission/discharge/transfer, ORU for laboratory and diagnostic results, MDM for physician notes) or secure local HL7 FHIR APIs.

Inbound and Outbound Security: The Edge Gateway accepts read-only local network feeds. It possesses zero inbound internet access and zero external remote control ports. Outbound traffic is restricted to an encrypted mTLS tunnel to the DeepSensi Supercluster.

Protected Health Information (PHI) Protection and Coded Data: Direct identifiers (names, Social Security numbers, phone numbers, exact addresses) are stripped directly on the local Edge Gateway. The gateway assigns a secure study code, ensuring that only Coded Clinical Data leaves the hospital firewall via mTLS to the DeepSensi Supercluster for inference. The crosswalk linking the study code to the patient identity is held strictly by the hospital and never shared. This operates securely under a Business Associate Agreement (BAA) and a HIPAA Waiver of Authorization (45 CFR Section 164.512(i)).

Section 4. Three-Phase Site Onboarding Roadmap

Phase 1: Governance and Regulatory Execution (Weeks 1 to 4)

1. Institutional execution of standard Data Use Agreement (DUA), Business Associate Agreement (BAA),

and Study Site Agreement.

2. Local Institutional Review Board approval or formal execution of Central IRB Reliance Agreement.
3. Designation of Site Principal Investigator (typically Chair of Internal Medicine, Chief of Hospital Medicine, or Director of Clinical Research).

Phase 2: Technical Integration and Interface Validation (Weeks 5 to 6)

1. IT provisioning of on-premise Edge Gateway virtual machine or hardware appliance.
2. Activation of read-only HL7/FHIR feeds.
3. Automated validation across 200 consecutive test admissions to verify data stream completeness (95 percent completeness benchmark). Test data are permanently discarded from final study analyses.

Phase 3: Silent-Mode Study Execution and Adjudication (Months 2 to 14)

1. Consecutive prospective inclusion of adult internal medicine admissions up to site accrual target (typically 1,500 to 2,500 admissions per site).
2. Post-discharge clinical chart review by designated site clinician adjudicators to verify discharge principal diagnoses.
3. Automated cryptographic matching and aggregate statistical reporting.

Section 5. Official Hospital Site Expression of Interest Application

To participate in the multi-center SILENT-DS clinical investigation, please complete the institutional application below and submit to hospital-partnerships@deepsensi.com.

1. Healthcare Institution Information

Institution / Hospital Name: [Enter Legal Institution Name]

Health System Affiliation (if applicable): [Enter Health System Name]

Hospital Physical Address: [Enter Street Address, City, State, ZIP]

Total Licensed Inpatient Beds: [Enter Number of Beds]

Annual Internal Medicine / Hospitalist Inpatient Admissions: [Enter Annual Volume]

Primary Electronic Health Record (EHR) System: [Epic / Cerner-Oracle / MEDITECH / Other]

2. Institutional Study Leadership

Designated Site Principal Investigator (MD / DO):

Full Name and Degree: [Enter Site PI Name]

Academic Title / Clinical Role: [Enter Title, e.g., Chief of Hospital Medicine]

Medical License State and Number: [Enter State and License #]

Direct Email Address: [Enter Email]

Direct Phone Number: [Enter Phone]

Designated IT / Clinical Informatics Lead:

Full Name and Title: [Enter IT Lead Name]

Department: [e.g., Clinical Informatics / Health System IT]

Direct Email Address: [Enter Email]

Direct Phone Number: [Enter Phone]

Designated Research / Clinical Trials Office Contact:

Full Name and Title: [Enter Research Admin Contact]

Office of Clinical Research Email: [Enter Email]

3. Institutional Research Approvals

Does your institution utilize a local Institutional Review Board, or does it accept central IRB reliance

(such as WCG IRB or Advarra)?

☐ Local Institutional Review Board

☐ Central IRB Reliance Preferred

Anticipated institutional review timeline: [e.g., 30 days / 60 days]

4. Target Implementation Window

Target date for technical Edge Gateway onboarding:

☐ Q4 2026 (November - December 2026)

☐ Q1 2027 (January - March 2027)

5. Institutional Executive Authorization

By submitting this Expression of Interest, the undersigned hospital leadership confirms institutional interest in evaluating participation as a participating site in the SILENT-DS multi-center investigation, subject to final contract and IRB review.

Authorized Institutional Representative:

Name: [Print Name]

Title: [Chief Medical Officer / VP of Research / Chief Executive Officer]

Signature: _____

Date: [DD / MM / YYYY]

Please return the completed form and inquiries to:

DeepSensi Public Benefit Corporation

Division of Clinical Investigations and Health System Partnerships

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