SILENT-DS — Study Site Prospectus

A prospective, multi-site, silent-mode evaluation of the DeepSensi Cognitive Medical OS

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The study in one paragraph

SILENT-DS is a prospective, observational, **non-interventional** study. The DeepSensi system runs in parallel with routine care on routinely collected record data, in **silent mode**: its outputs are cryptographically sealed and never shown to treating clinicians, so the study cannot influence — and cannot disturb — clinical work. Outputs are later compared against the final diagnosis established by an independent, blinded adjudication committee. The protocol is written from day one as multi-site with rolling site activation, will be **pre-registered before the first patient**, and will be reported to the STARD-AI standard, whatever the results.

Design at a glance

Design	Prospective, observational, silent-mode (shadow), non-interventional
Population	Consecutive adult admissions to participating internal-medicine / emergency-admission wards
Index system	DeepSensi Cognitive Medical OS — physician-in-the-loop clinical reasoning with explicit deferral when information is insufficient
What is measured	Missed-critical capture · time-to-diagnosis · top-3 concordance with the final diagnosis · deferral discipline
Reference standard	Final diagnosis adjudicated by an independent, blinded committee (with 30-day follow-up)
Sites	Multi-site by design; sites join the same pre-registered protocol on a rolling basis
Registration	ClinicalTrials.gov / OSF, before first patient
Reporting	SPIRIT-AI (protocol) · STARD-AI (results) · DECIDE-AI (early clinical evaluation)

What participation looks like

- A sponsor-funded study node is installed **on your premises**, inside your security perimeter (a fully air-gapped configuration is available). Commodity hardware; installation measured in days.
- **Nothing changes at the bedside.** No new forms, no new clicks, no workflow change; clinicians never see system outputs during the study.
- A part-time study coordinator (supported by the sponsor) maintains the enrollment log and extracts timeline data from records after discharge.
- Reference-standard adjudication is central and independent — your clinicians are not graded; analyses compare the system against adjudicated final diagnoses, and site data is reported in aggregate.
- Sites activate on a rolling basis under the same protocol; early sites are named in the primary publications.

What your hospital gains

- **Co-authorship** (ICMJE) for your site's principal investigator on a registered, multi-site study designed for a top-tier journal.
- **Zero cost:** the sponsor funds the node, coordination support, and adjudication.
- **Aggregate insight into your own diagnostic timelines** — where days are lost between admission and final diagnosis.
- A documented, independent **patient-safety pathway active during the study** (below).

Patient safety during the study

Silent means silent — with one deliberate exception. If the system flags a possibly missed, imminently life-threatening condition, an **independent senior physician (Clinical Safety Reviewer)** examines the medical record and may advise the treating team to consider excluding it. Every such event is logged, independently adjudicated, and reported. During the study window, your patients can only gain.

Data protection

Identifiable data **never leaves your hospital**. De-identification happens at the source, before any study processing; the hospital remains the data controller; study exports are pseudonymized, structured fields only. A complete ethics-submission and data-protection pack (including a DPIA) is prepared by the sponsor for your committee and your DPO.

What we ask of a site

- Acute internal-medicine and/or emergency-admission ward(s) with meaningful admission volume.
- An electronic record from which admissions and discharge documentation can be retrieved (HL7/FHIR interfaces preferred, not required).
- A site principal investigator and a part-time study coordinator.
- A local ethics-committee pathway (submission pack provided by the sponsor).
- Access to 30-day follow-up information (readmissions, mortality, outpatient revisions) for the reference standard.

How to apply

Use the contact form at **www.deepsensi.com/contact** and choose the topic **"Clinical study (site interest)"**, or reach out with your hospital's name, candidate wards, and approximate admission volumes. We respond to every site enquiry.

This document is informational and is not an offer; participation is subject to feasibility review, a site agreement, and local ethics approval. The protocol becomes final upon pre-registration. DeepSensi PBC, Dover, DE, USA. DeepSensi™ — patent-pending. Nothing in this document is medical advice.