

# Physician-as-Pilot: A Regulatory Position Paper

## Intended Audience

This document is written for U.S. FDA reviewers and Software as a Medical Device (SaMD) experts; European Union MDR and UK MHRA regulatory authorities; and clinical AI governance scholars and academic evaluators, including Harvard Medical School capstone tutors and faculty engaged in clinical AI oversight and safety.

## Purpose

This paper proposes a clear regulatory boundary model for non-clinical AI systems in healthcare. The Physician-as-Pilot framework is designed to preserve physician decisional authority, avoid unintended SaMD classification, and enable safe, auditable AI assistance without autonomous clinical action.

## Executive Regulatory Summary

Artificial intelligence is increasingly deployed in unsupervised home care environments, where traditional clinical oversight models are difficult to maintain. Existing regulatory constructs focus primarily on performance and validation but often leave authority, accountability, and escalation pathways underspecified. The Physician-as-Pilot framework addresses this gap by explicitly defining who holds clinical authority, when escalation occurs, and how AI systems are constrained across deployment phases.

## Regulatory Context and Problem Definition

The central regulatory challenge in AI-mediated home care is not model accuracy but governance. As AI systems increasingly influence observation, engagement, and care coordination, the boundary between cognitive assistance and clinical decision-making becomes ambiguous. Without explicit constraints, such systems risk de facto SaMD behavior, erosion of human authority, and post-market oversight complexity.

## The Physician-as-Pilot Governance Model

The Physician-as-Pilot model assigns clear decisional authority to a licensed clinician at all times. AI systems operate only within predefined, protocol-bounded roles and are prohibited from autonomous clinical judgment. Escalation, override, and disengagement pathways are deterministic and auditable.

## Figure 1. Illustrative Governance and Accountability Pathway for AI-Mediated Home Care

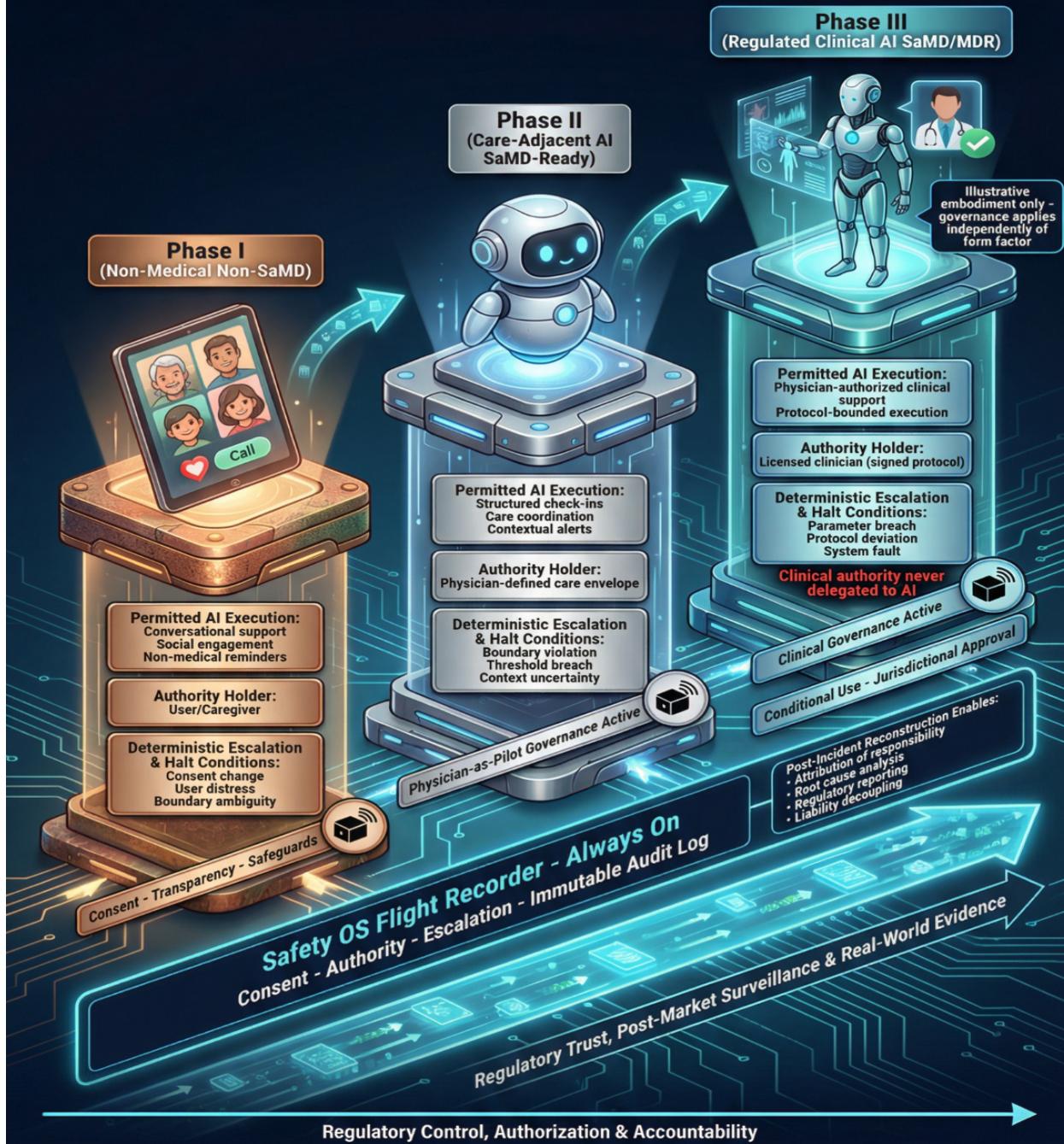
The figure below illustrates governance sequencing, authority boundaries, and escalation thresholds across non-clinical and clinical phases of AI deployment in home care environments. Phase I represents non-medical, non-SaMD functionality governed by explicit consent and caregiver oversight. Phase II introduces clinician-supervised, SaMD-ready AI under physician-retained authority.

Phase III represents regulated clinical AI subject to jurisdictional approval.

The diagram is conceptual and governance-focused and does not imply product capability, commercial readiness, autonomous clinical action, or specific hardware commitments.

# Illustrative Governance & Accountability Pathway for AI-Mediated Home Care

(Illustrates governance sequencing and authorization thresholds  
- not product capability or commercial rollout)



## Why This Is AI-First

By embedding oversight, escalation, and accountability directly into the AI's operational architecture, the system ensures that human authority and regulatory guardrails are active constraints, not afterthoughts. This approach shifts the burden of safety from reactive human intervention to proactive, system-enforced governance, making AI a trusted partner in care rather than a black box.

## The Safety OS Framework

- Enforces consent boundaries and user autonomy
- Monitors risk thresholds and protocol adherence
- Triggers immediate human escalation and system halts
- Maintains an immutable, audit-ready log of all AI actions
- Integrates physician authority as an active, guiding pilot
- Adapts to evolving regulatory requirements and clinical evidence

This diagram illustrates governance sequencing, authority boundaries, and auditability requirements. It does not imply commercial readiness, autonomous clinical action, or specific hardware commitments.

Credit: Andy Squire - Harvard Medical School Executive Education - AI in Healthcare Capstone (2026)

## Explicit Non-SaMD Boundary Conditions

The framework explicitly prohibits diagnostic, prognostic, and treatment recommendation functions in Phase I. AI outputs are non-directive, observational, and informational. All clinical interpretation and action remain human-executed, preserving regulatory clarity and patient safety.

## Safety OS as Governance Infrastructure

The Safety OS functions as a governance layer enforcing consent state management, escalation logic, oversight boundaries, and immutable auditability across the AI lifecycle. It is designed to support regulatory review and post-market surveillance.

## Phased Regulatory Pathway for AI-Mediated Home Care

Phase I validates governance in a non-clinical, non-SaMD context. Phase II introduces clinician-supervised, SaMD-ready functionality. Phase III represents regulated clinical AI subject to jurisdictional approval. Progression between phases is contingent on governance maturity, not technical capability alone.

## Out-of-Scope Clarifications

This framework does not address clinician error, infrastructure outages, cybersecurity threats, or malicious misuse. These domains require complementary safeguards.

## Conclusion

By explicitly defining authority, accountability, and escalation, the Physician-as-Pilot framework offers a regulator-legible pathway for safe AI deployment in unsupervised home care environments.

## Authorship and IP Statement

**Andy Squire** is the sole independent author of the **Physician-as-Pilot (AIITL) governance framework**, including the **Safety OS** architecture, regulatory pathway design, and Phase II / III clinical AI governance model.

The Phase I Home Companion illustrative implementation was developed in collaboration with

**Dr. Cristina Crisan Tran, MD** (Clinical adoption strategy and commercialization pathways) and

**Carla Maldonado, PhD** (Compliance design and operating governance).

The author used AI-based tools for editorial assistance; all ideas, framing, and conclusions are the author's own.