Governed AI for Cancer Care

An FDA-cleared mammography AI · a governed platform · start small, earn each step.

Most of the science needed to save a life already exists. The hard part is getting the right, current, trustworthy answer to the right clinician at the right moment — **safely, and at scale.** We’d like to start small, with the lowest-risk thing we have: a mammography AI that is already cleared by the FDA.

Presented by **Fatima Boukrim, MBA** — Executive Director, CANONIC Foundation
with Mifta Mohamed, PhD (AI, Madrid) · Junaid Kalia, MD (SaveLife.AI) · Dexter Hadley, MD/PhD (Founder & Chair, CANONIC)

AT A GLANCE

Start with the lowest-risk thing we have: a mammography AI that is already FDA-cleared.

FDA-cleared
The mammography AI we start with is already FDA-cleared — 510(k) K252954

€0
Cost to the health service to evaluate it

4 phases
A staged path — start tiny, grow only if it earns trust

#1
Breast is the most-diagnosed cancer — where screening volume is highest

5
EU rules the platform is built to satisfy (GDPR, AI Act, EHDS, MDR, NIS2)

2 regions
Madrid first, Andalucía in parallel — both already investing in cancer-screening AI

Two regions, one safe starting point: a cleared imaging engine, wrapped in a governed platform, on a path a public health system can actually trust.

WHY THIS CONVERSATION, NOW

A woman with the same tumour can get very different care depending on the city she lives in.

Not because the medicine is unknown — but because the **current** evidence, the right second opinion, and the matching clinical trial don't always reach the room in time. Guidelines change every few weeks; most tumour boards catch up every few months. Radiologists read more mammograms than ever. The knowledge that should compound, instead disappears at the end of each case.

Spain's regions have already decided this is worth solving. **Madrid** announced in 2026 it is deploying AI to help read breast and prostate cancer imaging. **Andalucía** has put €316.5M behind digital health and AI through 2030, cancer screening included. What's missing is a partner who brings something **already proven and safe to start with**, and a way to grow it a public system can trust.

That's why we're here.

WHAT WE BRING

Two things that fit together: a cleared imaging engine, wrapped in a governed platform.

FDA-CLEARED IMAGING

MammoSight · SaveLife.AI

- **FDA-cleared — 510(k) K252954**
- Computer-assisted **lesion prioritization** (product code QFM)
- Flags & prioritises suspicious lesions on the mammogram
- Supports the radiologist — no autonomous diagnosis
- **Proven, not experimental**

GOVERNED CLINICAL INTELLIGENCE

MammoChat · OncoNex

- Patient-navigation layer — **Spanish localization delivered for the pilot**; accessible by design (WCAG-AA)
- Multidisciplinary **tumour-board** assistant
- Staging · biomarkers · matching trials · guideline drift
- **Every statement shows its source**
- Never diagnoses or prescribes on its own

WHAT "GOVERNED" MEANS — IN PLAIN TERMS

The difference between a tool a hospital can defend, and one it can't.

It shows its work. Every clinical statement points to the guideline or evidence it came from. Nothing is a black box.

It refuses what it doesn't know. If the answer isn't in its evidence, it says so. It does not guess.

A clinician is always in charge. It never diagnoses or prescribes on its own. It is a support tool, full stop.

It is built for European rules. Data protection (GDPR), the AI Act, the European Health Data Space, medical-device rules (MDR/CE), and cybersecurity (NIS2) — designed in from the start, demonstrated rather than just declared.

HOW WE'D GROW IT — START TINY, EARN EACH STEP

We don't ask anyone to bet big on day one. Each phase only happens if the one before it earned it.

PHASE	WHAT	WHERE IT LANDS	RISK
0	**MammoSight** (FDA-cleared) reads already-reported mammograms	A screening radiologist's workflow · SERMAS	Lowest — cleared, zero patient risk
1	+ **MammoChat** patient navigation (Spanish) + **OncoNex** tumour board	Oncology services / boards	Low — decision support, clinician in loop
2	+ **OmicsChat** variant interpretation	Madrid genomics centre (CMAG)	Medium — genomics integration
3	European **guideline spine** (ESMO/ESGO/SEOM/SERAM/GEICAM) + published evidence	Society endorsement → procurement; replicate to Andalucía + EU	Scaling

WHO'S BRINGING IT

Two physicians, an AI scientist, and an operator who knows the ground in Spain.

PERSON	ROLE
Fatima Boukrim, MBA	Co-Founder & Executive Director, CANONIC Foundation — leads this conversation; Madrid roots
Junaid Kalia, MD	Founder & CEO, SaveLife.AI — MammoSight (FDA 510(k) K252954) + NeuroICH (FDA 510(k) K241719)
Mifta "Simo" Mohamed, PhD	AI / explainable-AI in healthcare (Carnegie Mellon), Madrid — the local technical voice
Dexter Hadley, MD/PhD	Founder & Chair, CANONIC Foundation; Director of AI, American Board of Precision Medicine

WHAT WE'RE ASKING FOR

One meeting.

A first, no-cost, no-obligation conversation to scope a small pilot — most simply, a clinical-validation study or an innovation **convenio**. We bring the FDA-cleared engine and the governed platform. The health service brings a set of **already-reported cases** and a clinical lead to agree what "good" looks like before we begin.

If it works, we have evidence. If it doesn't, it cost a meeting and a retrospective dataset — and **no patient was ever at risk**.

That's the whole ask: let us show you, safely, on your own data.

We claim exactly what the FDA cleared — and not a word more.

FDA — WHAT IS ACTUALLY CLEARED

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MammoSight = MammoSightAI
510(k) K252954   decided 2026-05-04   "Substantially Equivalent"
applicant        Neurocareai, Inc. (DBA SaveLife.AI)
product code     QFM = Radiological Computer-Assisted PRIORITIZATION
                 Software for Lesions   (21 CFR 892.2080, Class II)
=> cleared for lesion prioritization / triage, NOT autonomous diagnosis.
   Downstream claims must not exceed this cleared category.
Team also holds K241719 (NeuroICH — intracranial-hemorrhage CT triage).
Source: FDA 510(k) database + USERS/JUNAID/VITAE.md (anchored).
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HONESTY GUARDS

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- Pilot / convenio framing only — no EU sub-license before the upstream
  US license; no commercial terms on this deck.
- "Governed": every clinical statement is sourced; refuses outside its
  evidence; never diagnoses or prescribes autonomously; clinician in loop.
- Compliance frame: GDPR + EU AI Act + EHDS + MDR/CE + NIS2 (readiness).
- Spanish UI localization (MammoChat/OncoNex) is a Phase-1 pilot deliverable.
- Guideline spine (Phase 3): localize NCCN/AJCC (US) → European societies
  ESMO · ESGO · SEOM · SERAM · GEICAM.
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CANONIC FOUNDATION · WITH SAVELIFE.AI

An FDA-cleared mammography AI, wrapped in a platform that shows its work.

Start small. No cost to evaluate. No patient at risk.

Pilot → evidence → procurement — Madrid first, Andalucía in parallel, Europe next.

onconex.eu | mammochat.ai | CANONIC.org | savelife.ai

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