

HOSPITALAR • POSTMARKET SURVEILLANCE PANEL

Connected Evidence:

Why Patient Safety Lives Between the Records

The systems we need for modern post-market surveillance.



Imagine a *Class III device* maker with a global footprint.

On the same morning, the same device — implanted in two patients — fails. Two call centers. Two handlers. Two languages. One device family. One risk file.

01 · EUROPE

08:42 CET · Barcelona

Surgeon reports unexpected device behavior mid-procedure. Call routed to the European call center.

HANDLER	LANGUAGE	CODED AS
Agent A	Spanish	Malfunction

02 · UNITED STATES

03:42 EST · Cleveland

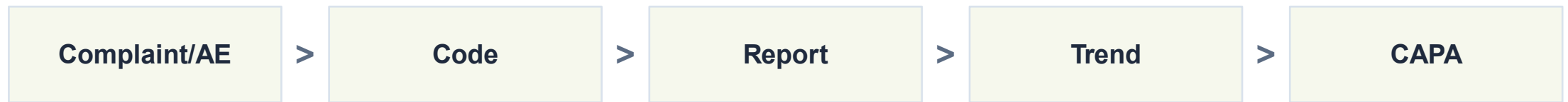
Same moment, half a world away. Same device, different patient. The nurse calls the US support line.

HANDLER	LANGUAGE	CODED AS
Agent B	English	Use error

Will both events be recorded, triaged, investigated, and closed *the same way*?

PM S used to be a *linear workflow*.

THE OLD MODEL



It isn't anymore.

The new reality. *Eight disconnected systems.*

We don't lack data. We lack a way to make data speak the same language. The signal often lives in the relationships between records — not inside any single one.



Complaints

Internal customer feedback



Adverse Events

Reportable clinical outcomes



Service Records

Field engineering signals



Risk Files

Hazards, harms, controls



CAPA

Action history & closure



Public Databases

Regulator, MAUDE, EUDAMED



Literature

Peer-reviewed evidence



Field Voices

Distributors, clinicians, patients

Connected evidence — not isolated workflows.

The burden falls *entirely* on the manufacturer.

Harmonize

across systems and languages

Track

every signal, end to end

Interpret

messy real-world data

Act

at the right moment

Justify

every decision made

Prove

consistency, years later

This is no longer a human-scale task.

Coding is *not data entry*.

It is how a real-world signal becomes a regulatory decision.

ONE EVENT · MANY LENSES

- 1 IMDRF code
- 2 Internal failure code
- 3 Clinical consequence
- 4 Risk-file linkage
- 5 Reportability decision
- 6 Brazil · US · EU view

AND THEN

Why?

Not what we decided. *Why we decided.*

Why this code. Why this report. Why this trend escalated. Why this risk remained acceptable?

Modern PMS must preserve the *reasoning trail*.



Without this trace, automation creates risk. With it, automation creates accountability.

Risk is *interpreted differently.*

BR

Brazil · ANVISA

- Tecnovigilância framework
- Local reporting timelines
- Coding alignment in transition
- Distributor network signals

US

United States · FDA

- MDR reporting thresholds
- MAUDE public visibility
- Periodic / 5-day / 30-day rules
- Trending and CAPA expectations

EU

European Union · MDR

- EUDAMED vigilance modules
- PSUR & trend reporting
- Serious incident definitions
- PMCF integrated with PMS

The challenge is global consistency with local regulatory intelligence.

Similar events. *Similar reasoning.*

REVIEWER A · SÃO PAULO · TUESDAY

"Codes the event as device malfunction. Not reportable."

REVIEWER B · LOS ANGELES · THREE WEEKS LATER

"Codes the same event as use error. Reportable. CAPA opened."

AI MUST GIVE THE EXPERT INSTITUTIONAL MEMORY

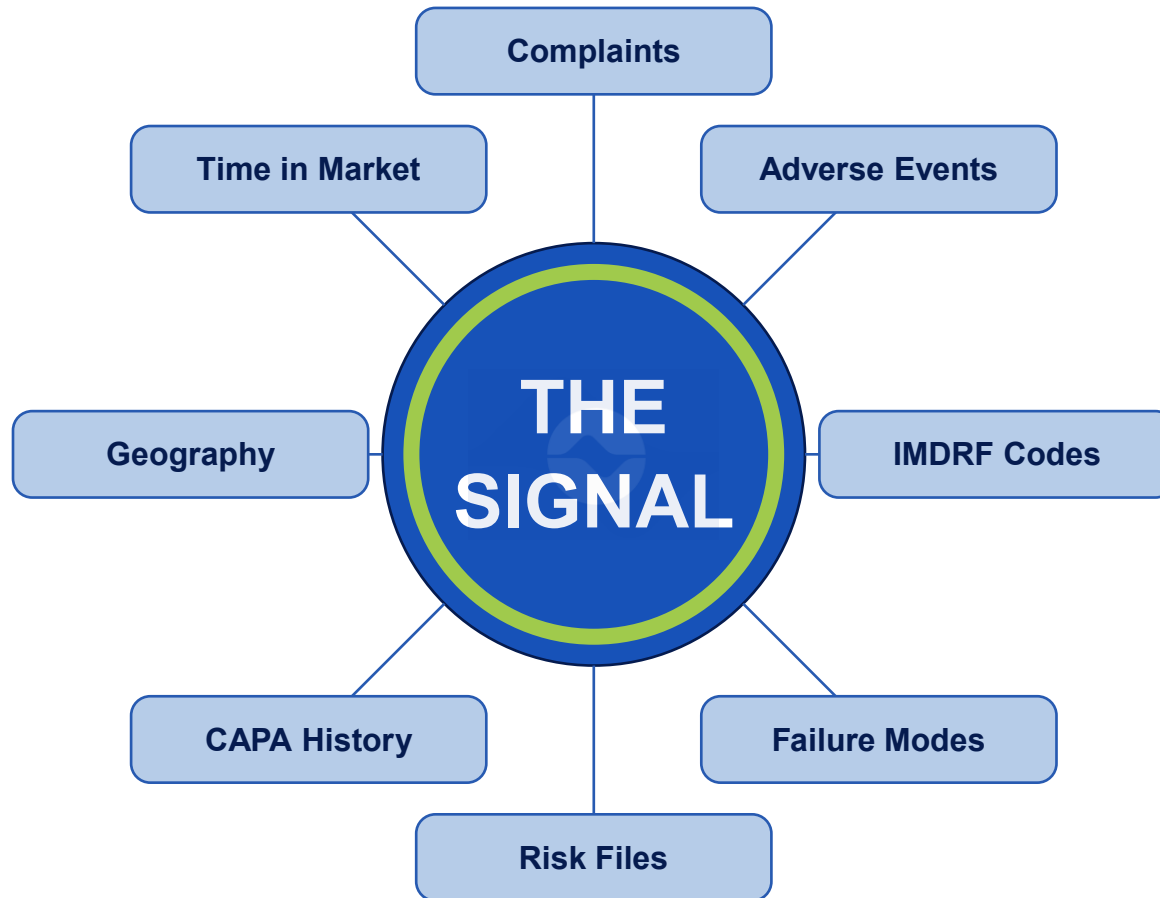
"We have seen events like this before."

"They were coded this way."

"This region treated similar events as reportable."

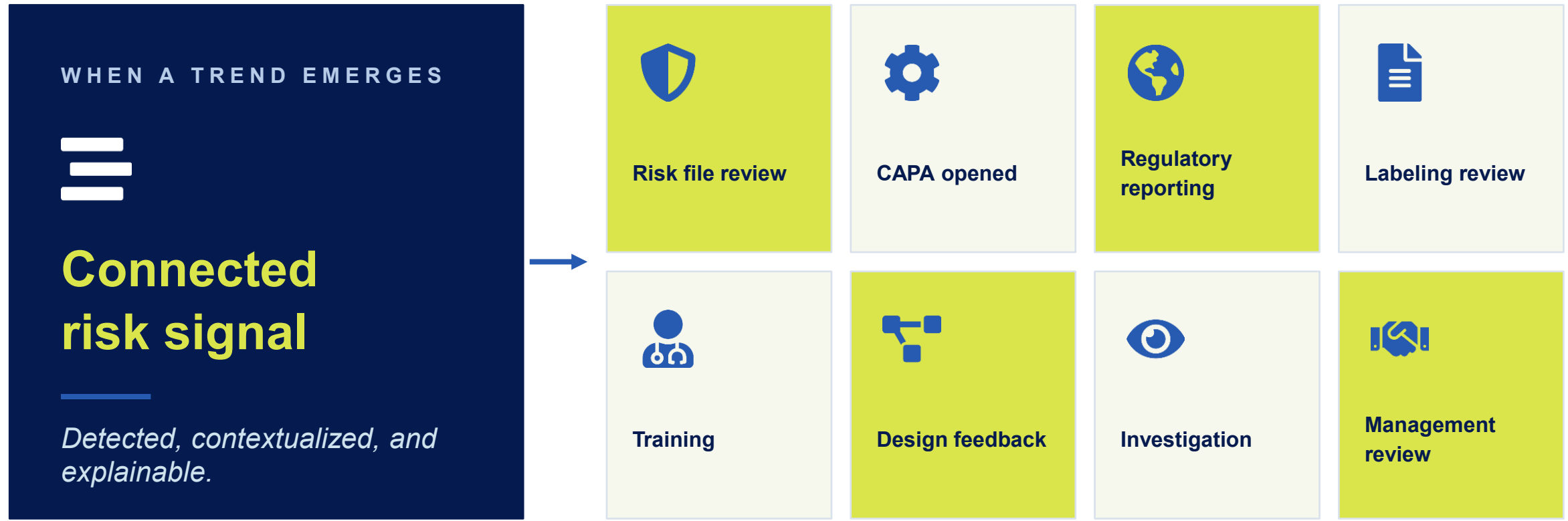
"This decision differs from historical precedent."

Real safety signals live *between systems.*



A small uptick in any one of these may look harmless. Together, they tell a *different* story.

Trend intelligence shouldn't end the process. *It should drive it.*



Human-led. AI-enabled. *Systems-preserved.*

AI

- Listens
- Connects
- Suggests
- Explains

Humans

- Decide
- Provide feedback
- Train the system

Systems

- Preserve the trace
- Maintains consistency

AI is connective tissue, not a chatbot, not a dashboard, not a replacement.

CLOSING

The goal is not to automate
responsibility.

The goal is to strengthen it.



Connect with us to modernize your journey
hello@empowerreg.ai



Turning regulatory
complexity into
competitive advantage

